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Partner Practice Question #1

You are a practicing clinician and have become aware that your colleague, Dr. Smith, has been recommending homeopathic medicines to his patients. There is no scientific evidence to suggest that homeopathic medicines work; moreover, you have heard Dr. Smith say that he doesn't believe them to work. He has been recommending homeopathic medicine to people with mild and non-specific symptoms such as fatigue, headaches, and muscle aches because he believes that they will do no harm, but his patients may benefit from the placebo effect. You are becoming increasingly concerned about Dr. Smith’s approach. How might you handle this situation?

CROSS-CULTURAL ISSUES AND DIVERSE BELIEFS

UW Medicine Department of Bioethics and Humanities
https://depts.washington.edu/bhdept/ethics-medicine/bioethics-topics/detail/59

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Topics addressed:

- Why is it important to respect what appear to me to be idiosyncratic beliefs?
- What are some ways to discover well known sets of beliefs?
- What is my responsibility when a patient endangers her health by refusing a treatment?
- Can parents refuse to provide their children with necessary medical treatment on the basis of their beliefs?
- What kinds of treatment can parents choose not to provide to their children?
- Can a patient demand that I provide them with a form of treatment that I am uncomfortable providing?

Patients may bring cultural, religious and ideological beliefs with them as they enter into a relationship with the physician. Occasionally, these beliefs may challenge or conflict with what the physician believes to be good medical care. Understanding and respecting the beliefs of the patient represents an important part of establishing and maintaining a therapeutic relationship. While the principle of respect for autonomy requires that a physician respect the medical decisions of a competent adult patient, in cases of surrogate decision-making, the physician has an independent duty to guard the interests of the patient.

Why is it important to respect what appear to me to be idiosyncratic beliefs?

Respecting the beliefs and values of your patient is an important part of establishing an effective therapeutic relationship. Failure to take those beliefs seriously can undermine the patient's ability to trust you as her physician. It may also encourage persons with non-mainstream cultural or religious beliefs to avoid seeking medical care when they need it.

What are some ways to discover well known sets of beliefs?

There are many groups that share common sets of beliefs. These belief systems may be based on shared religion, ethnicity, or ideology. Knowledge of these beliefs and the reasonable range of interpretation of doctrine can be very helpful in deciding if unusual beliefs should be respected. Good resources for guidance in this area include patients and family members themselves, staff members with personal knowledge or experience, hospital chaplains, social workers, and interpreters. Unusual beliefs that fall outside known belief systems should prompt more in-depth discussions to insure they are reasonable.

It is important to explore each individual's beliefs, as shared membership in a particular religious or cultural group does not necessarily entail identical belief systems.

What is my responsibility when a patient endangers her health by refusing a treatment?

Adults have a moral and legal right to make decisions about their own health care, including the right to refuse treatments that may be life-saving. The physician has a responsibility to make sure that the patient understands the possible and probable outcomes of refusing the proposed treatment. The physician should attempt to understand the basis for the patient's refusal and address those concerns and any misperceptions the patient may have. In some cases, enlisting the aid of a leader in the patient's cultural or religious community may be helpful.

Can parents refuse to provide their children with necessary medical treatment on the basis of their beliefs?

Parents have legal and moral authority to make health care decisions for their children, as long as those decisions do not pose a significant risk of serious harm to the child's health. Parents should not be permitted to deny their children medical care when that medical care is likely to prevent substantial harm or suffering. If necessary, the physician may need to pursue a court order or seek the involvement of child protective services in order to provide treatment against the wishes of the parents. Nevertheless, the physician must always take care to show respect for the family's beliefs and a willingness to discuss reasonable alternatives with the family.

What kinds of treatment can parents choose not to provide to their children?

Parents have the right to refuse medical treatments when doing so does not place the child at significant risk of substantial harm or suffering. For example, parents have the right to refuse routine immunizations for their children on religious or cultural grounds.

Can a patient demand that I provide them with a form of treatment that I am uncomfortable providing?

A physician is not morally obligated to provide treatment modalities that they do not believe offer a benefit to the patient or which may harm the patient. Physicians should also not offer treatments that they do not feel competent to provide or prescribe. However, it is important to take the patient's request seriously, consider accommodating requests that will not harm the patient or others, and attempt to formulate a plan that would be acceptable to both the physician and patient.

Partner Practice Question #2

You are a physician. You approach a patient's hospital room in order to provide anxiously awaited results of an important biopsy. You are intercepted by the patient's son, who asks you for the results. When you reply that would like to discuss the findings directly with the patient and that the son should accompany you into the room, the son responds that you should disclose the results to him and he will then transmit the information to his father. The son adds that he and other family members have always played a significant role in helping to transmit information and make decisions for his father; this biopsy result should certainly be handled in that same fashion. You firmly respond that the information belongs to the patient, that the biopsy result will lead to important clinical decisions, and that you must present the information directly to the patient. Blocking the hospital room doorway, the son threatens that you must talk to him or he'll move his father to another hospital. How might you handle this situation?

CASE REPORT

Medical Futility and Psychiatry: Palliative Care and Hospice Care as a Last Resort in the Treatment of Refractory Anorexia Nervosa

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ABSTRACT

Objective: The concept of medical futility is accepted in general medicine, yet little attention has been paid to its application in psychiatry. We explore how medical futility and principles of palliation may contribute to the management of treatment refractory anorexia nervosa.

Method: We review the case of a 30-year-old woman with chronic anorexia nervosa, treated unsuccessfully for several years.

Results: Ongoing assessment, including ethical consultation, determined that further active treatment was unlikely to resolve her condition. The patient was referred for palliative care and hospice care, and ultimately died.

Discussion: Although circumstances requiring its use are rare, palliative care may play a role in the treatment of long suffering, treatment refractory patients. For poor prognosis patients who are unresponsive to competent treatment, continue to decline physiologically and psychologically, and appear to face an inexorably terminal course, palliative care and hospice may be a humane alternative. © 2009 by Wiley Periodicals, Inc.

Keywords: anorexia nervosa; palliative care; hospice; medical futility; eating disorders

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Introduction

Anorexia nervosa continues to have one of the highest mortality rates of any psychiatric illness.[1] Clearly, cases of anorexia nervosa exist that are refractory to all available treatments.[2] Despite the fact that approximately 20% of patients develop a chronic course of the disorder[2] no specific definitions exist for determining that a patient demonstrates treatment refractory anorexia nervosa,[3] and few guidelines consider what courses of action are suitable for patients who show unrelenting, treatment refractory deterioration.[4] Although shifts from aggressive treatment to palliative care related to concepts of medical futility are well recognized and accepted in general medicine, except for patients with advanced Alzheimer's disease[5] and one brief opinion piece regarding anorexia nervosa[6] such issues have received little discussion in the psychiatric literature.[7]

We describe a patient, Ms. A, who reached a clinical point at which neither forcing her into involuntary treatment nor waiting for her to voluntarily engage in treatment appeared likely to resolve her illness, return her to a state of life-sustaining clinical stability or provide her a decent quality of life. When the treating professionals found themselves faced with a patient unwilling and unable to engage in further care, lack of appropriate resources, and no treatment options likely to meaningfully impact her downward spiraling course, Ms. A's management was shifted to palliation and ultimately hospice care. On the basis of our experiences with this patient, we consider circumstances under which issues of medical futility, palliation and referrals to hospice care might have a place in psychiatry, specifically in the management of some end-stage patients with treatment refractory anorexia nervosa.

Case Review

Ms. A was a 30-year-old white female who contacted the clinic upon request of her primary care physician (PCP) for "help managing my psych meds." She would not consent to a weight check, but medical records from her PCP showed a height

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of 5′4″ and a weight of 64 pounds; a body mass index (BMI) of 10.9. Ms. A reported that she was suffering from a long history of anorexia nervosa, binge-purge subtype, and obsessive compulsive disorder (OCD). She was first diagnosed with anorexia nervosa at age 19, and described multiple episodes of prior treatment, including two attempts at residential eating disorder programs, a two-year inpatient certification, and several more years of participation in an eating disorders day hospital program. She reported her primary current method of weight control to be calorie restriction, limiting herself to no more 300 calories daily. She ran up to 2 hours every day and had multiple exercise rituals for managing her weight and as manifestations of her OCD. Upon intake into the psychiatric clinic, she was offered medication management, supportive therapy by a Licensed Clinical Social Worker and case management in an effort to help her access appropriate eating disorders treatment. Her weight remained in the 60–65 pound range and she subsequently incurred several injuries due to passing out and hitting her head, requiring suturing for scalp lacerations. She also sustained several falls while exercising. After several months of ongoing ambivalence about residential treatment and suffering increasingly dangerous falls, she was involuntarily hospitalized.

Hospital Course

Once in the general psychiatric hospital, after initial medical stabilization, the staff's focus turned to discharge planning. The team first recommended that Ms. A go to a long-term residential eating disorders program, but Ms. A refused to go voluntarily and the eating disorder programs that were potentially available to her refused to accept her on an involuntary status. The state hospital refused to accept her on a long-term certification, stating their facility was not equipped to handle her significant medical problems related to the eating disorder. Nursing homes that would normally accept patients on certifications and that might have been able to manage the medical complications of her illness declined to accept her on the basis that they did not have the ability to manage her behaviorally. The team located an out-of-state eating disorders treatment program willing to take her on an involuntarily basis, and even found a psychiatrist licensed in both states who was willing to accept legal responsibility for her transfer and care. But the cost of the program was several thousands dollars per month, and no funds were available to pay these expenses. All of the local, highly experienced eating disorder experts who had worked with Ms. A extensively over the past 10 years were consulted. They all considered her anorexia nervosa to be refractory to treatment with any currently available method. Because no viable treatment options existed, the medical center's ethics committee was consulted. The committee's members struggled to understand how one could die from a psychiatric illness (other than by suicide or unintentional overdose) and were not sure how to proceed. Although they could delineate the differences between acute mental health risks such as suicide, drug overdoses, psychosis or self-neglect, they had no points of reference regarding how to manage a patient who was chronically a danger to herself, unwilling to engage in further treatments, and unresponsive to all prior attempts to treat her involuntarily. The only examples the committee raised for comparison concerned drug users who received heart valve replacements, yet continued to use, knowing that such ongoing use would kill them. In such cases, if a high risk of ongoing subsequent IV drug use was suspected ahead of time, the decision was often made not to provide valve replacements, but there was no forced treatment. The committee and treatment team discussed the option of attempting to have Ms. A declared legally incompetent and appointing a guardian for medical decisions, but hospital attorneys who reviewed her case opined that Ms. A would most likely not meet criteria for court ordered guardianship. The patient's family clearly stated that they would not assume guardianship and were overwhelmed and burned out by the years of Ms. A's frustrating and untenable behaviors.

Based on an interdisciplinary review of history, past medical records, the diagnostic and prognostic assessments offered by several eating disorder experts, and the evidence that there had been almost no change in the course of her illness despite repeated exposures to numerous biological, psychotherapeutic and psychosocial treatments, the treatment team determined that Ms. A suffered from a treatment refractory type of anorexia nervosa. Given her history, resource limitations, and in the opinion of hospital attorneys, no legal grounds for prolonged forced intervention, the treatment team and the ethics committee determined that her physical and psychiatric impairments were likely to lead to her death, despite any plausible attempts at aggressive intervention.

At the request of the staff and with the patient's consent, the palliative care team met with the patient, the patient's family and the outpatient treatment team, including psychiatry and internal medicine, to discuss shifting Ms. A's care from an

active to a palliative treatment stance. The clinicians explained that Ms. A would receive no further involuntary treatment for her eating disorder. If she chose to pursue treatment she would be assisted, but the staff would not force her into any involuntary placements or impose any treatment she did not want. There would be no weigh-ins, no calorie or exercise monitoring, no IM medications and no required therapy sessions. She would be offered outpatient therapy only as she felt desirable and necessary. Psychiatric medications would be prescribed as the patient deemed necessary to help manage depression, anxiety and insomnia. The patient would receive weekly visits from a palliative care nurse, who would work with her to manage her symptoms and keep her comfortable. The patient agreed to no further hospitalizations, but did not fully agree with the plan for "palliative care" since she did not believe she was going to die. In fact, she refused to sign the Do Not Resuscitate order (DNR), which presented a difficult dilemma for the ethics team. How do you provide end of life comfort and support for someone who does not believe she is at the end of her life? However, the family and the treatment team clearly understood that no other options existed and were supportive of the plan. Consequently the palliative care team eventually agreed to work with Ms. A without an explicit DNR order and agreed to provide her with support regardless of her belief that she was not likely to die from her condition. The patient was discharged from the hospital weighing 85 pounds (BMI of 14.6).

Post-Hospital Course

Immediately upon discharge Ms. A resumed her strict caloric restriction and began running once again, leading to new stress fractures, as well as bruising and abrasions from numerous falls. She resumed a pattern of binge/purge behaviors, including both vomiting and significant laxative use. Within 6 weeks, she lost all the weight she had gained in the hospital. Despite her weight loss and behavioral dyscontrol Ms. A continued to refuse residential treatment for her eating disorder. She came regularly to outpatient therapy sessions, during which life stressors were discussed, but the eating disorder per se was not directly addressed. She was reluctant to discuss end of life issues, continuing to state that she did not believe she would die, nor did she want to die. She made several emergency room visits for dehydration and injuries from over-exercising. During one emergency room visit, staff recorded a weight of 55 pounds (BMI 9.4), blood pressure of 40/30, and marked abnormalities in serum electrolytes. Because of her palliative care status, the staff only administered fluids, provided comfort medications, treated her wounds, and then discharged her. Given her precarious weight and ongoing self-destructive behaviors, the treatment team prognosticated that her life expectancy would be short, so home hospice services were offered.

Surprisingly, Ms. A lived for several additional months and briefly even appeared to be doing better. However, she eventually resumed her self-injurious exercise behaviors accompanied by further exacerbations of binging, purging and restricting behaviors. Once again, she lost weight rapidly, yet she continued to deny the need for treatment and turned down offers of long-term treatment options. Her family, overwhelmed by years of this same pattern, requested help, at which point the team once again reviewed the option of involuntarily hospitalization. But, after due consideration, the team determined that with the illness in this terminal stage another hospitalization would make no difference in the course of her illness. With a burned out family system, no meaningful treatments available, and worsening medical symptoms, Ms. A was referred back to the palliative care team, who continued to monitor her condition and provide comfort care. After several weeks of palliative care and further emergency room visits for medical complications, Ms. A eventually became so weak that she was moved to an inpatient hospice. Ms. A died at the hospice 3 weeks later.

Discussion

Psychiatry commonly deals with patients who are not able to fully participate in treatment. Depending on diagnoses and clinical signs and symptoms, patients may be considered "incompetent" and treated involuntarily, with forced hospitalizations and medical treatments. Precipitating factors may entail presenting as danger to self or others or inability to care for oneself.[8] Alternatively, if the clinical condition is viewed as volitional, treatment refusal may be thought to signify a pre-contemplative state, in which case clinicians may use motivational interviewing techniques to attempt to move patients toward increasing readiness to engage in treatment voluntarily.[9] In practice, the spectrum of patients' displays of denial, minimization, treatment refusal and ambivalence about treatment is often more complex. In the case of patients with serious anorexia nervosa, the degree of personal volition reflected in treatment refusal often varies from patient to patient, with the stage and severity

of the illness, and with the personal perspectives of different clinician observers.[4]

In treating Ms. A, the team pondered all of these issues and the treatment options each implied. One option was for the clinicians treating Ms. A to continue to allow her to make treatment decisions while attempting to motivate her, to see if she might eventually agree to voluntary treatment. This option did not appear feasible, since without strict monitoring and supervision Ms. A had clearly demonstrated a strong tendency to starve, purge and over-exercise.

With respect to general medical illnesses, patients who are deemed legally competent have the right to refuse treatment and risk dying.[10] Patients who have suffered a long duration of illness, multiple treatment failures, poor quality of life, and possibly irreversible medical complications and who are deemed competent to refuse further treatments often do so, especially if the outcomes of those treatments are likely to be unsuccessful and if they impose burdens. Patients on chronic hemodialysis without hope for renal transplant, for example, sometimes opt to stop coming for dialysis treatments and, as a result, die after a brief span of time. Some patients with end-stage cancer or amyotrophic lateral sclerosis exhibit food refusal in their terminal stages.[4]

It has been argued that patients with anorexia nervosa should have similar rights to discontinue treatment, despite the fact that in their case food refusal may seem irrational.[11] Although patients with anorexia nervosa may irrationally choose not to eat, they are often competent to make decisions in all other areas of their lives.[10,11] Patients who have experienced repeated treatment failures, as had Ms. A, are likely to become discouraged and may realistically assess that further treatment efforts are as likely to fail as previous ones. Thus, they may "judiciously" refuse treatment. Yet Ms. A did not turn down treatment believing that it would fail or that death was her likely outcome. Although her family and the medical profession were able to see that she was slowly dying, she herself never acknowledged a belief that her life may end.

Another option was to continue to treat her involuntarily. Patients with anorexia nervosa often abhor and refuse treatment.[3] The literature contains numerous case examples of patients with chronic, refractory anorexia nervosa who have been forced into involuntary treatment, continually hospitalized and re-fed.[1,10,11] In younger patients, involuntary treatment has been shown to serve as a protective factor and result in short term outcomes similar to those of voluntarily treated patients.[1] Many patients who are initially treated involuntarily subsequently express gratitude for these interventions.[12,13] The use of involuntary treatment in these instances has been justified by the fact that patients with unrelenting anorexia nervosa clearly represent a danger to themselves and that ensuring their safety is an ethical responsibility.[10] In many cases, involuntary treatment is often the only way to keep these patients alive long enough to engage them in the therapeutic work.[11]

To treat Ms. A involuntarily would have required legal intervention. Ms. A was never taken to court for a determination of legal competence because the hospital attorneys believed that they would not win a case declaring her incompetent. Legal rulings about competence in patients with anorexia nervosa have been mixed and remain areas of ongoing debate. In several cases, patients with chronic treatment refractory anorexia nervosa have repeatedly met legal criteria for competence and have had requests to withdraw treatment granted.[10,11] However, in these cases, the patients were able to express clearly their understanding that their withdrawal of treatment and refusal of food would ultimately lead to their deaths.[10] Ms. A never believed she was going to die, nor did she believe she needed or deserved hospice services. Although her thoughts about food, eating, and her weight manifested a fatal denial, these thought patterns per se did not mean that she would meet legal criteria for incompetence. But even had she been declared legally incompetent regarding her ability to make food related decisions for herself, then what? Unlike the other legal cases reviewed, withdrawal of treatment and hospice care were neither Ms. A's choice nor her preferred way to alleviate suffering through the end of her life.

In Ms. A's case, and in psychiatric practice in general, two broad options for consideration in such situations are (1) either subjecting the patient to involuntary treatment or (2) attempting to motivate the patient until such time as she may be ready to engage willingly in treatment. In Ms. A's case, involuntary interventions resulted in brief periods of weight restoration on several occasions, but they never adequately treated her illness well enough to return her to an acceptable, sustained quality of life. Despite the ineffectiveness of legal recourse and lack of resources, had she been hospitalized indefinitely and subjected to involuntary treatment, IM medications and forced feedings, she might have remained alive, but these treatments seemed to be unlikely to reverse the underlying processes of her disorder. Ms. A was continually offered alternative care options including voluntary

residential treatment, intensive day programs and skilled nursing facilities, but she consistently turned these down. After more than a decade of failed treatments, her refusal to make use of any option offered, and her downward spiraling course, what more could be done for this patient?

General medical care offers an additional option. The concept of medical futility has long been applied in medical settings in response to circumstances where it is clearly understood that further treatment will have no impact on the illness. Medical futility is defined as "a clinical action serving no useful purpose in attaining a specified goal for a given patient."[14] A treatment is defined as "futile" if it "cannot result in the physiological effect as intended by the physician"[15] or when "recovery is impossible or virtually impossible."[16] Quantitative futility can be defined when there is less than a 2–5% chance of recovery.[14] Futility is not the withdrawal of all care, only the withdrawal of aggressive treatments; a shift of care from active treatment to palliative or comfort care.[14]

Although many psychiatric disorders are deemed chronic and refractory to treatment, the acute life threatening behaviors that accompany them can often be managed through aggressive treatments, such as hospitalization, involuntary medications and legal actions.[8] Once these acute issues are managed, death may be a less likely outcome. The lack of consideration of futility in psychiatry may result from a commonly held view that, except for suicide or accidental overdose, people cannot die from psychiatric disorder. This notion is refuted by the fact that suicides and unintentional drug overdoses claim their share of lives. For an unfortunate minority, anorexia nervosa is a chronic terminal, treatment refractory illness, following a decline that often takes years and ends with starvation, physiological collapse, or with suicide.[4]

Clinical Guidelines for treatment of Anorexia Nervosa support weight restoration as the primary goal.[17] However, this goal is often not achieved, particularly with patients who have chronic courses. For these patients, achieving the secondary goal of sufficiently motivating them to cooperate with the restoration of healthy eating patterns is even less attainable.[17] Even after weight restoration, relapse is common. One study showed that 50% of patients had relapsed within a year, whereas 20% continued all along to meet criteria for the illness.[18] In another study, 70% of the participants either dropped out of treatment or made "little to no gains" regardless of how much weight had been gained.[19]

In the case of Ms. A's case, after a thorough and careful case review, the treatment team ultimately made the very difficult decision that ongoing aggressive treatments would most likely be futile. An interdisciplinary review of history, tests, records, diagnosis and prognosis was compiled leading to the decision that Ms. A likely had a refractory type of anorexia nervosa, as there had been almost no change in her course of the illness despite repeated exposures to therapies and treatments.[13] Mortality rates increase with having compulsory treatments, having more than one hospital admission, having a co-morbid illness, such as OCD, having a long duration of the illness and having low psychosocial functioning.[1] In addition, duration of the illness beyond 10–15 years and vomiting with laxative use are associated with a poorer prognosis.[2] APA Clinical Guidelines propose that patients who weigh less than 85% of ideal body weight often have difficulty gaining weight outside a structured treatment program[17] but Ms. A refused residential placements. As for outpatient therapies, the odds were also against her based on statistics. APA Guidelines state "attempts at formal therapy with starving patients who are negativistic and obsessional or cognitively impaired by their weight may be ineffective."[17] In one study of therapies with anorexic patients with, a BMI under 14.5 were deemed "unsuitable for psychotherapy treatment."[19] Based on her history and the literature surrounding mortality in anorexia nervosa, it seemed likely that Ms. A was going to die regardless of any feasible treatment efforts. Palliative and hospice care were the only humane choices the treatment team and the family could identify under the circumstances.

Once the treatment team determined that forced treatment and strict caloric monitoring was medically futile, such treatments were discontinued and she was no longer psychiatrically hospitalized. But this did not mean she was cut off from all care.[14] Throughout the course of her illness, she was offered ongoing non-specific supportive therapy by a licensed clinical social worker, which is often as effective as other types of treatment for anorexia nervosa.[19] She was offered medication to manage her psychiatric symptoms as well medications to help with sleep and pain. The option to go to a residential program was frequently presented and would have been available to her as a voluntary patient at any point. She and her family received visits from an RN to monitor pain and medications, chaplain services, art therapy services, and massage therapy services from the palliative care team, and she eventually used both inpatient and outpatient hospice services. She received care through the end of her life, but it was not the forceful, intrusive, autonomy-depriving, yet physical-life

sustaining types of medical interventions that she experienced as so personally unacceptable. Although she never believed she was going to die, she found great support and comfort in the treatment team that was with her when her life ended.

Conclusion

Decisions to use palliative care and hospice care are undoubtedly rare in cases of anorexia nervosa and in our view, constitute only a last resort. From the perspectives of the clinicians and ethicist who pondered these issues in the case of Ms A, palliative care approaches may have a place in the management of care for patients who suffer from deteriorating, treatment refractory psychiatric conditions in which no known or available interventions are likely to return them to a reasonable quality of life. While we strongly support research to improve the treatment of anorexia nervosa, we recognize that the limits of current approaches mean that little other help exists for the small but, certain percentage of patients that anorexia nervosa grips in a death spiral. In such instances, following ethical consultation and full discussion about options and alternatives with the patient and family, palliative care may be the most humane available approach that the healing professions can offer.

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Case study: An ethical dilemma involving a dying patient

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Abstract

Nursing often deals with ethical dilemmas in the clinical arena. A case study demonstrates an ethical dilemma faced by healthcare providers who care for and treat Jehovah's Witnesses who are placed in a critical situation due to medical life-threatening situations. A 20-year-old, pregnant, Black Hispanic female presented to the Emergency Department (ED) in critical condition following a single-vehicle car accident. She exhibited signs and symptoms of internal bleeding and was advised to have a blood transfusion and emergency surgery in an attempt to save her and the fetus. She refused to accept blood or blood products and rejected the surgery as well. Her refusal was based on a fear of blood transfusion due to her belief in Bible scripture. The ethical dilemma presented is whether to respect the patient's autonomy and compromise standards of care or ignore the patient's wishes in an attempt to save her life. This paper presents the clinical case, identifies the ethical dilemma, and discusses virtue ethical theory and principles that apply to this situation.

"Juana" (fictitious name) a 20-year-old, Black Hispanic female, 32 weeks pregnant, was brought to the emergency department (ED) in an ambulance by the paramedics. She arrived in the ED immobilized on a flat board with a hard cervical collar in place. Juana was the driver of a sedan involved in a single-vehicle collision. She stated she was driving at approximately 60 miles per hour on the highway and suddenly lost control of the vehicle and crashed into a light pole. She also stated her head hit the windshield and shattered the glass. She denied loss of consciousness. Upon her arrival in the ED, Juana was alert and oriented to person, place, and time and had a Glasgow Coma Scale of 15/15. Her initial complaints were lightheadedness, weakness, left shoulder pain, and severe abdominal cramping that started immediately following the car accident. She had a past medical history of sickle cell disease and no previous pregnancies. Her lungs were clear bilaterally. Juana's heart rate was 90 beats per minute (bpm), her respiratory rate was 28, and her initial blood pressure (BP) was 130/80, and fetal pulse rate was 90. Once the cervical spine films were taken and the flat board was removed, her BP reflected orthostatic changes of 100/60 and pulse of 120 bpm.

Diagnosis and interventions

Juana was placed on a 100% nonrebreather mask. Peripheral intravenous lines were started bilaterally to replace fluid loss that was indicated by the change in vital signs. It was suspected that she was bleeding internally into her thoracic or abdominal

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cavity. Blood specimens were drawn and sent to the laboratory. A hemoglobin of 6 g/dl and hematocrit of 21% indicated internal bleeding. Ultrasound showed blood in the amniotic cavity and Doppler confirmed a fetal heart rate of 90 bpm indicating fetal distress. The patient was informed by the medical team of the critical nature of her condition.

The plan of care for her was an immediate blood transfusion and an emergency cesarean section. Matters became complicated when Juana informed the medical team that she was a Jehovah's Witness and refused the proposed plan of care. The physician then recommended the use of alternative blood products. Juana insisted that this was also against her religion and she refused the alternative treatments being offered. The medical team advised her that Jehovah's Witnesses could choose certain blood byproducts, such as albumin, cryoprecipitate, and globulin (Watchtower Bible and Tract Society, 2004).

According to Juana and her husband, both believed that if she accepted the blood transfusion or blood products she would no longer be a Jehovah's Witness and would be condemned to hell. The husband then presented the physician with Juana's blood card, created by the Watchtower Bible and Tract Society, the governing organization of Jehovah's Witnesses. The card stated her advance directives, including the prohibition of blood and blood products.

The beliefs of Jehovah's Witnesses stem from their interpretation of passages from the old testament of the Bible, which they believe is the inspired word of God (Watchtower, 2004). For example, according to the New World Translation of the Bible, blood symbolizes the life of the person or animal (Gen.9.36). Revelations (1.5) states, "The only appropriate use of blood is the sacrificial blood of Jesus." Another passage that Jehovah's Witnesses emphasize declares, "And whatsoever man there is among you, that eateth any manner of blood, I will even set my face against that soul that eats blood, and will cut him off from among his people" (Lev.7.10-14).

Juana's condition worsened within 2 hours of admission to the ED. She went into labor and delivered a stillborn baby boy. She was immediately transferred to the intensive care unit where, despite continued aggressive attempts to stabilize her, she went into cardiac arrest and died.

The ethical dilemma

This case presents an ethical dilemma, a situation which arises when one must choose between mutually exclusive alternatives (Beauchamp & Walters, 2003). Decisions may have results that are desirable in some respects and undesirable in others. In Juana's case, her decision to refuse the blood transfusion had the desired outcome of allowing her to remain true to her religious beliefs. However, her choice also resulted in her death. If she had followed the recommendation of the physicians and the team, the desirable outcome would have been possible survival but would have had the undesired effect of violating her religious principles. The major ethical dilemma was that by honoring the patient's autonomy and religious beliefs, the physicians and interdisciplinary team were faced with compromising their moral duty to administer professional care in accordance with established standards (Chua & Tham, 2006). A brief review of the literature of Nursing Collection II: Lippincott Nursing Journals (from Ovid) and CINAHL databases for the past 5 years found no evidence to support best practice for a Jehovah's Witness who is pregnant and has experienced blunt trauma.

Healthcare providers faced with this situation have sometimes attempted to obtain court orders that would overrule the patient's decision and result in her submitting to recommended medical treatment. For example, the Illinois Supreme Court (*Illinois v. Brown*, 1996) upheld a mother's decision to refuse blood transfusions even though they were vital for both the mother's and fetus' survival. The Patient's Bill of Rights states that the healthcare providers' responsibility is to give patients accurate information and that patients must consent to treatment (New York State Department of Health, 2008). This is consistent with the Federal government's recommendations to create guidelines that assure healthcare quality and to reaffirm the critical role consumers play in safeguarding their own health, (United States Department of Health and Human Services, 1999).

Nursing practice is governed by the patient's right to autonomy rather than her religious beliefs (Levy, 1999). The first item in the American Nurses Association (ANA) Code for Nurses with Interpretative Statements (2001) addresses respect for human dignity:

> "Truth telling and the process of reaching informed choice underlie the exercise of self-determination, which is basic to respect for person ... Clients have the moral right to determine what will be done with their own person; to be given accurate information, and all the information necessary for making informed judgments; to be assisted with weighing the benefits and burdens of options in their treatment; to accept, refuse, or terminate treatment without coercion; and to be given necessary emotional support" (p. 1).

However, it is difficult to witness death based on a person's decision to forgo care when medical options to sustain life are available. Treating this type of patient becomes particularly challenging when it involves two lives.

Virtue ethics

To analyze this ethical dilemma, the principles of Western medicine and the religious beliefs of Jehovah's Witnesses were examined. The questions that surfaced were (a) how would the application of virtue ethics provide insight into Juana's situation, (b) what were the ethical principles in conflict, and (c) why was it an issue to administer a blood transfusion to Juana in an emergency situation.

Volbrecht's framework for ethical analysis was utilized to address the clinical dilemma and the questions listed above. Virtue ethics was the primary theory employed prior to the 17th century. This theory centers on shared familial and cultural histories and religious traditions and acknowledges the community's ability to identify, interpret, prioritize, and adjust to moral considerations within a particular context (Volbrecht, 2002). The following is an exposition of this case according to virtue ethics.

Virtue ethics focuses on what is morally correct from the patient's viewpoint and

"The caregivers focused on Juana's autonomy and her right to choose what she perceived best in spite of the possible outcomes."

centers on the patient's autonomy. Actions and character are intertwined, and the ability to act morally is contingent on one's moral character and integrity. Virtue ethics focuses on the context of the situation (Volbrecht, 2002). Ethical analysis of virtue ethics entails (a) identifying the problem, (b) analyzing context, (c) exploring options, (d) applying the decision process, and (e) implementing the plan and evaluating results (Volbrecht, 2002).

Identifying the problem

Juana, a 20-year-old Hispanic woman, 32 weeks pregnant, was involved in a car accident. Internal bleeding to the thoracic or abdominal cavity was suspected. The stakeholders were the woman, her husband, the fetus, and the interdisciplinary healthcare team. The team thought the best method of treatment for this patient was to administer a blood transfusion and perform an emergency cesarean section. Both the patient and her husband refused this option because of their religious beliefs and provided written documentation indicating that the patient would not accept blood or blood products. The value issues were the physical survival of the woman and her fetus versus the woman's religious integrity.

Analyzing context

To understand the decision-making process in this case, one must consider the ethical principles of autonomy, beneficence, nonmaleficence, justice, compassion, and respect. The patient's religious beliefs and how they influenced her decision must also be taken into consideration. Gardiner (2003) confirms that the ethical principles mentioned above influence one's choices. In Juana's case, the healthcare team suspected she was experiencing internal bleeding and that she and the fetus were in physiological distress. Juana's decision to reject the proposed treatment was based on her stated religious beliefs.

The contextual factors of this case centered on the patient's religious beliefs. The patient stated she would "rather be embraced in the hollow bosom of Jehovah than to be condemned for all eternity," if she should receive a blood transfusion. Nurses draw from the code of ethics to reflect upon and understand the person's perspective, and to honor her wishes. "The nurse provides services with respect for human dignity and the uniqueness of the client, unrestricted by considerations of social or economic status, personal attributes or the nature of the health problem" (ANA, 2001, p.1). To respect the patient's decision and honor her dignity, supportive care was provided to the patient in an effort to save her life, while at the same time respecting her wishes. The ANA Code of Ethics supports the point of view that healthcare providers should respect patients' wishes and decisions despite their own personal beliefs (ANA, 2001).

Applying an ethical decision process

Looking through the lens of virtue ethics, the caregivers focused on Juana's autonomy and her right to choose what she perceived best in spite of the possible outcomes. Juana was a competent, pregnant woman who made informed decisions not to receive blood transfusions or a caesarean section. Based on virtue ethics, the healthcare providers respected the patient's autonomy by reflecting on and honoring the decision of the patient and her husband based on her religious values and beliefs. The healthcare providers also drew on the principle of beneficence, which centers on promoting the well-being of others. In this case, the well-being was not physiological but spiritually oriented. The principle of nonmaleficence was also employed by not intentionally inflicting harm on the patient and honoring her wishes. Violation of a client's deeply held beliefs is a form of doing harm. (Leonard & Plotnikoff, 2000). They also drew from the principles of veracity and respect, which entail being truthful to the patient and allowing her to make an informed decision (Volbrecht, 2002). The nursing virtues of compassion, moral courage, and self-reliance also contribute to an understanding of this situation.

Evaluating results

At the time this clinical situation presented itself there were no specific guidelines in the institution for dealing with the dilemma presented by this case. However, there are guidelines for Jehovah's Witnesses specifically geared to early identification and management of gynecological patients. For example, in Australasia, there are specific guidelines for treating pregnant women that focus on stabilizing the patient by using traditional and new treatment modalities to meet patient needs, particularly for Jehovah's Witnesses or other patients who decline blood transfusions (Women's Hospitals Australasia, 2005). For antepartum patients, the guidelines focus on early identification of Jehovah's Witnesses during prenatal visits, as well as placing these patients on a high risk protocol, including maintenance of high hemoglobin and hematocrit levels, having advance directives completed, and establishing affiliations with other hospitals that are well-equipped and staffed to meet these patients' needs (Women's Hospitals Australasia, 2005). The Hartford Hospital in Connecticut has a similar program and also performs bloodless procedures on patients who are Jehovah's Witnesses (Miller, 1996).

As a result of Juana's case being reviewed by the ethics committee post-mortem, a risk-management protocol was developed requiring patients who refuse blood transfusions to sign a waiver that removes the legal responsibility for the decision from the hospital and caregivers. To support this type of protocol, the Society for the Advancement of Blood Management maintains a database of hospitals that provide blood-conserving services in the United States as well as in Canada, Chile, Korea, and South Africa (Society for the Advancement of Blood Management, 2008).

The problem, however, in an emergency situation is that it may not be possible to get the patient to a participating hospital. The Watchtower Bible and Tract Society (2004) recommends that advance directives and other legal papers be in place should an emergency arise. These documents should be easily accessible so that healthcare providers can honor the patient's directives. In so doing, they will be applying the theory of virtue ethics and, therefore, respect the patient's wishes (Macklin, 2003). Healthcare providers should practice beneficence and non-maleficence without imposing their beliefs as to the right thing to do. More explicit and universal guidelines would benefit both patients and providers when faced with similar ethical dilemmas.

Conclusion

In nursing practice, cases of patients refusing blood transfusions or other interventions are becoming more common. Therefore, content regarding ethical issues, such as Juana's case, needs to be integrated into nursing curricula and the clinical arena. Nursing educators who incorporate bioethics into critical thinking in clinical decision making situations can prepare novice and experienced nurses to handle complex ethical dilemmas, such as described in this paper. The learning process may be facilitated through integrating lectures with case studies and utilizing patient simulators to further enhance the learning process (Larew et al., 2006). These teaching approaches would provide the opportunity to expose nurses to scenarios of acute patients where they can intervene in a safe environment, which in turn would decrease their anxiety and promote learning. Nurse educators can further facilitate the learning process by providing clinical experiences with diverse patient populations in a variety of settings followed by discussion of actual clinical experiences, ethical issues, and debriefing (Larew et al., 2006).

Nursing faculty have an ethical responsibility to prepare competent nurses and facilitate continuing education that will help nurses recognize ethical dilemmas in practice and apply ethical principles in trying to resolve them. The focus in practice, education, and research must be on providing care that respects patients' cultural beliefs and autonomy. Nursing educators should place equal emphasis on ethics in order to provide the best holistic care possible. To do anything else is a disservice both to the profession and to our patients.

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Placebos Without Deception: Outcomes, Mechanisms, and Ethics

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Abstract

Scientific research indicates that open-label and dose-extending placebos (that patients know are placebos) can elicit behavioral, biological, and clinical outcome changes. In this chapter, we present the state-of-the-art evidence and ethical considerations about open-label and dose-extending placebos, discussing the perspective of giving placebos with a rational, as dose extension of active drugs, or expectancy boosters. Previous comprehensive reviews of placebo use have considered how to harness placebo effects in medicine and the need to focus on elements of the clinical encounter as well as patient–clinician relations. Here, we illustrate the similarities and differences between standard (deceptive) placebos, open-label placebos and dose-extending placebos. We conclude that placebos without deception would override ethical barriers to their clinical use. This paves the way to future large-scale, pragmatic randomized trials that investigate the potential of ethical open-label and dose-extending placebos to improve patients' outcomes, and reduce side effects.

Keywords

Expectancy; Conditioning; Verbal suggestions; Learning; Dose-extending placebo

1. INTRODUCTION

> Three factors are of major importance in the suffering of badly wounded men [during the Second World War]: pain; mental distress; and thirst. Therapy has been almost entirely directed to pain, and this usually limited to the administration of morphine in large dosage.
>
> Henry Knowles Beecher, American anesthetist and medical ethicist

Surveys from around the world consistently find that healthcare practitioners prescribe placebos quite often (Colloca, Enck, & DeGrazia, 2016; Fassler, Meissner, Schneider, &

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Linde, 2010; Howick et al., 2013). Placebo use, however, is criticized as being unethical for two reasons. First, placebos are supposedly ineffective (or less effective than "real" treatments), so the ethical requirement of beneficence (and "relative" nonmaleficence) renders their use unethical. Second, they allegedly require deception for their use, violating patient autonomy. Here, we take it as given that at least for some conditions, placebos have effects (see Howick, 2017; Howick et al., 2013 for discussion). The recent research on open-label placebos suggests that the second objection—namely the claim that placebos require unethical deception—is also invalid. If placebos can have effects even when patients are told they are placebos, then placebos do *not* require deception and ethical objections to placebo use lose their force.

2. DO PLACEBOS REQUIRE DECEPTION? THE MYSTERIOUS CASE OF OPEN-LABEL PLACEBOS

A handful of studies have shown that long-term placebo effects can also be elicited under open-label conditions, in which patients are *explicitly* informed that they will receive a placebo (Blease, Colloca, & Kaptchuk, 2016; Charlesworth et al., 2017). This is counterintuitive since placebos supposedly work because people believe they do, but (presumably) *knowing* a treatment is a mere sugar pill makes it difficult to believe they will work. In spite of the lack of intuitive appeal, numerous studies have demonstrated that deception may not be needed to elicit placebo effects and have also demonstrated potential effectiveness at improving significant clinical outcomes in patients with irritable bowel syndrome (IBS) (Kaptchuk et al., 2010), chronic low back pain (Carvalho et al., 2016), depression (Park & Covi, 1965), attention-deficit hyperactivity disorder (ADHD) (Sandler, Glesne, & Geller, 2008), rhinitis (Schaefer, Harke, & Denke, 2016), and cancer-related fatigue (Hoenemeyer, Kaptchuk, Mehta, & Fontaine, 2018).

3. CLINICAL OPEN-LABEL PLACEBO TRIALS

Park and Covi (1965) were the first to attempt we are aware of to test the apparent paradoxical effect of open-label placebos in patients suffering from a range of anxiety symptoms (Park & Covi, 1965). The patients were told that they would have received sugar pills but that they would have perceived benefits in terms of symptom relief. Despite the small number of enrolled patients (14), significant symptom improvement was reported at 1 week of taking open-labeled placebos. In pain medicine, other studies have recently shed light on the potential efficacy of open-labeled placebos without deception in patients suffering from IBS (Kaptchuk et al., 2010) and low back pain (Carvalho et al., 2016).

In a more recent trial conducted by Kaptchuk et al., 80 patients diagnosed with IBS were randomized to receive either open-label placebo pills or no treatment (Kaptchuk et al., 2010). The open-label placebo was presented as follows:

> The provider clearly explained that the placebo pill was an inactive (i.e., "inert") substance like a sugar pill that contained no medication and then explained in an approximately 15 minute a priori script the following "four discussion points:" 1) the placebo effect is powerful, 2) the body can automatically respond to taking

placebo pills like Pavlov's dogs who salivated when they heard a bell, 3) a positive attitude helps but is not necessary, and 4) taking the pills faithfully is critical (Kaptchuk et al., 2010).

Investigators then measured the effect of the treatment on the IBS Global Improvement Scale (IBS-GIS, stated primary outcome). Open-label placebo produced significantly higher mean global improvement scores (IBS-GIS) at both 11-day midpoint and 21-day endpoint.

In Carvalho et al.'s (2016) study, 83 patients with at least 3 months of chronic lower back pain were randomized to receive two open-label placebo tablets, taken twice daily, or treatment as usual, for 3 weeks (Carvalho et al., 2016). Patients were told that the placebo pill was an inactive substance, like a flour pill, that contained no active medication in it. Patients were also taught about placebo effects using four "discussion points." These were: (1) the placebo effect can be powerful, (2) the body automatically can respond to taking placebo pills like Pavlov dogs that salivated when they heard a bell, (3) a positive attitude can be helpful but is not necessary, and (4) taking the pills faithfully for 21 days is critical. All participants were also shown a video clip (1 min and 25 s) of a television news report, in which participants in an OLP trial of IBS were interviewed (excerpted from http://www.nbcnews.com/video/nightly-news/40787382#40787382). Primary outcomes were mean weekly retrospective pain assessments (0–10) and the Roland–Morris Disability Questionnaire (RMDQ) assessed at 3 weeks. The open-label placebo demonstrated a statistically significant benefit over treatment as usual (TAU).

Gathering all these studies together, a recent meta-analysis found that open-label placebos can lead to positive therapeutic effects when compared to no-treatment. The clinical conditions were IBS, depression, allergic rhinitis, back pain, and ADHD (Charlesworth et al., 2017). However, the meta-analysis involves only five trials that were small, had different control groups (TAU vs waiting-list group), often included positive suggestions alongside the open-label placebos, one involved elements of partial conditioning (ADHD amphetamine treatment and placebos) and were rated as having a moderate risk of bias. Importantly, all these trials are characterized by the lack of blinding that can be achieved by comparing open placebos vs hidden placebos and the comparison with the best available treatment to estimate the relevance of open placebo potential effectiveness. Recently, open label placebos have been tested in 74 cancer survivors in a 21-day assessor blinded, randomized-controlled trial that compared an open-label placebo to TAU for fatigue (Hoenemeyer et al., 2018). Two placebo pills taken twice induced a 29% improvement in fatigue severity, and a 39% improvement in fatigue-disrupted quality of life. Open label placebos were tested in 74 cancer survivors (N=74) in a 21-day assessor blinded, randomized-controlled trial that compared an open-label placebo to TAU for fatigue (Hoenemeyer et al., 2018). Two placebo pills taken twice induced a 29% improvement in fatigue severity, and a 39% improvement in fatigue-disrupted quality of life (Table 1). These and the provocative studies on dose-extending placebos (see Section 6) may open up new research avenues with a focus on translational and mechanistic approaches.

4. LABORATORY (OPEN-LABEL) PLACEBO STUDIES

Placebo (conditioned) hypoalgesic effects persisted after revealing that the cream used to reduce the experimental heat pain was merely Vaseline (Schafer, Colloca, & Wager, 2015). Participants were told that the study aimed "to compare the analgesic effects of a topical cream with an active analgesic component (placebo cream) to a topical cream with no active ingredients (control cream)." An initial calibration phase, either long or short conditioning, and a test phase were performed. Placebo analgesia was tested before and after participants were told the treatment was a vaseline cream. Placebo analgesia was defined as the difference in pain reports between placebo and control stimulations at identical heat temperatures. Schafer and colleagues demonstrated that experiencing multiple conditioning sessions leads to robust placebo analgesia that persist even when the true nature of the placebo treatment is convincingly revealed to study participants (Schafer et al., 2015). Additionally, this study provided evidence that experienced placebo analgesia can be uncorrelated with expected analgesia. Conditioned placebo analgesia can be mediated by processes not accessible by reportable expectancy, and that there is a transition from expectancy-mediated processes to more involuntary analgesic processes as those initial expectancies are reinforced through repeated experience. These results parallel emerging evidence from other studies, suggesting that placebo analgesia might sometimes occur in the absence of belief (Charlesworth et al., 2017). Therefore, informing study participants about the realm of the placebo phenomenon and its mechanisms presents no negative reactions or negative consequences and may help engage potential factors that favor outcome improvements.

Open-label placebos have also been explored in healthy participants in a standardized experimental heat pain modulation paradigm and research has shown that they are as effective as deceptive placebos when accompanied by a rationale (Locher et al., 2017). Locher et al. (2017) explored the effectiveness of open-label placebo given with a rationale (Locher et al., 2017) as compared to open-label placebo without a rationale, deceptive placebo, and no-intervention in 160 participants who were randomly assigned to the experimental groups. All groups received an application of a placebo cream except the no-intervention group. Baseline and posttreatment measurements of pain tolerance, pain intensity, and pain unpleasantness ratings were assessed as primary outcomes. Those who received the placebo given with a rationale and the deceptive placebo compared with those who received the placebo treatment without a rationale reported significantly less pain intensity and unpleasantness ratings. These changes in pain experience were independent from the individual level of pain tolerance. A rationale given along with the placebo was as efficacious as the deceptive placebo (Locher et al., 2017) in an experimental setting.

Locher et al. findings are in contrast with other results obtained in a clinical context. Placebo analgesic effects appeared to be larger when full deceptive disclosures are given to patients with postoperative pain (Colloca, 2017; Pollo et al., 2001). The authors compared clinical pain outcomes in acute pain patients who received saline solution and were told nothing about the analgesic effect (natural history) of a basal infusion in the postoperative setting; were told that the treatment could have been either a potent pain-killer or a placebo (similar to a double-blind clinical trial); or were told that the basal infusion was a potent painkiller

(full-deceptive administration) (Pollo et al., 2001). Operationally, the placebo effect was defined as the change in the amount of requested doses of buprenorphine over the 3-day postoperative pain treatment when a continuous saline infusion was added to the active buprenorphine treatment. Overall the buprenorphine requests decreased by 20.8% in the double-blind group, and by 33.8% in the deceptive group in comparison to the natural history, respectively, leading to a significant reduction of the buprenorphine opioid intake (Pollo et al., 2001). A genuine placebo-induced analgesic effect was observed with the more transparent disclosures although the deceptive group elicited the larger reduction of buprenorphine requests.

5. DOSE-EXTENDING (OPEN-LABEL) PLACEBOS

Placebos have been given as “dose extenders” to prone the brain–body systems to create conditioned responses (CR) that are similar to the effects of the treatments (US) when deliberate conditioning stimuli (CSs) are paired with the US.

For example, Goebel et al. administered cyclosporine A (2.5 mg/kg, US) along with a green-colored, strawberry-flavored milk drink (CS) in healthy participants to test the hypothesis that cyclosporine-like effects can be detected when placebos are given with the CS in place of the cyclosporine (Goebel et al., 2002). Placebos administered with the flavored drink significantly suppressed immune functions in terms of interleukin-2 (IL-2) and interferon gamma (IFN-gamma) mRNA expression, in vitro release of IL-2 and IFN-gamma, as well as lymphocyte proliferation, suggesting that placebos can act as “dose extenders” of the cyclosporine action (Goebel et al., 2002). The duration of such a conditioned effect (e.g., suppression of T-cell function) extinguished after 14 unreinforced exposures to the CS drink. However, administering subtherapeutic dosages of cyclosporine A (0.25 mg/kg) along with the CS drink prevented the extinction of the conditioned immunosuppression (Albring et al., 2014). The intrinsic action of dose-extending placebos is illustrated in human research that demonstrated that pharmacological conditioning is effective in extending the response to morphine (Amanzio & Benedetti, 1999; Benedetti, Pollo, & Colloca, 2007; Guo, Wang, & Luo, 2010). Robust analgesic responses were documented when the administration of morphine for two consecutive days was replaced by a placebo on the third day (Amanzio & Benedetti, 1999). Importantly, different schedules of pharmacological conditioning worked in eliciting morphine-mimic effects, at least in the range of days and weeks (Benedetti et al., 2007). These observations suggest that a pharmacological conditioning procedure creates a learned response that can be reevoked. Similar results have been found in mice using pharmacological opioid and nonopioid conditioning (Guo et al., 2010).

Clinically speaking, a recent study demonstrated the effectiveness of dose-extending placebo in patients with psoriasis treated with corticoste-roids (Ader et al., 2010). Patients were treated under a partial schedule of pharmacological (corticosteroid) reinforcement in which a full dose was given 25%–50% of the time and substituted by placebos the other times as compared to a dose control group, in which patients received the full dose 25%–50% of the time but not placebos, and a group receiving the full dose of active corticosteroids (100%). The frequency of relapse under partial reinforcement was lower (26.7%) than in the control group (61.5%) and clinically comparable to the reduction in symptoms induced by a full

dose of corticosteroids (22.2%). Thus, dose-extending placebos given with the partial schedule of pharmacotherapeutic reinforcement (Ader et al., 2010) with corticosteroids given one quarter or half as frequently as currently prescribed along with dose-extending placebos were sufficient to mitigate psoriasis relapses.

Importantly, a study in children with ADHD (Sandler & Bodfish, 2008) used a methodological twist in which open placebos and partial reinforcement were merged. In fact, placebo use was described to both parents and children transparently. Following a model for preauthorized placebo use, patients and parents were explicitly informed that placebos (e.g., lactose or talc pills) will be given to extend medication effects (amphetamines). Children were assigned to three arms. Those in arm 1 received a placebo pill paired with a 50%-reduced dose of amphetamine. The same reduction of treatment was performed in arm 2 but without a controlled conditioned cue (control group). Children in arm 3 received a full dose of amphetamine treatment. Pairing a conditioned stimulus (CS) with amphetamines produced placebo-conditioned responses that allowed children with ADHD to be treated effectively with a lower dose of stimulant medication. Moreover, Per-lis and colleagues randomized patients with chronic insomnia to distinct regimes of 10mg zolpidem including nightly treatment with 10 or 5mg, intermittent treatment with 10mg, or partial reinforcement treatment with placebos and 10mg for 12 weeks (Perlis et al., 2015). The partial reinforcement group maintained treatment response that were similar to the full treatment groups and better than the outcomes observed in those patients assigned to the intermittent treatment who exhibited poorer sleep quality. These pioneering clinical trials could potentially merge open-label placebos, authorized deception, and (evidence-based) rationale for using placebos, clinically.

6. POTENTIAL MECHANISMS

6.1 Pharmacological Memory

The mechanisms by which open-label placebos given without a formal conditioning are complex and remain to be confirmed (see Fig. 1 and 2). It is possible that sugar pills labeled as placebos work because they retrieve a pharmacological memory, therefore acting as a conditioned cue that elicits previously learned responses in line with the learning theories including classical and nonclassical forms of conditioning (Colloca & Miller, 2011a, 2011c).

In addition to (subconscious) conditioning, conscious expectancy could play a role in how open-label placebos work. Often, the open-label placebos were delivered in addition to the TAUs and importantly with explicit positive suggestions (Carvalho et al., 2016; Hoenemeyer et al., 2018; Kaptchuk et al., 2010; Schaefer et al., 2016) proving a rationale (e.g., “Pavlovian conditioning”) and instilling some hope of improvement. The only study that lacked any positive framing and instruction sets had the smallest effect size (Kelley et al., 2012). It is known that the expectation of pain relief has been found to modulate the central regulation of pain through, in particular, the dopamine reward system and the endogenous opioid system (Price, Finniss, & Benedetti, 2008). There is also a growing body of evidence that in addition to what practitioners say, the way in which they deliver these messages (for example, with more or less empathy) can also affect health outcomes (Annoni & Miller, 2016; Caspi & Bootzin, 2002; Friedman, Sedler, Myers, & Benson, 1997).

6.2 Partial Reinforcement and Classical Conditioning

Dose-extending placebos rely on the ability of a nonhuman and human being to acquire a physiological reflex via associative learning processes (e.g., classical conditioning and partial reinforcement learning paradigms) (Ader, 1989, 1990; Colloca & Miller, 2011a). Classical conditioning experiments demonstrated that dogs would salivate (CR) in response to a bell (CS) that had previously been paired with the administration of food (unconditioned stimulus, US), Fig. 1. For dogs conditioned in this way, a ringing bell implied food, causing such automatic physiological responses as salivation (Pavlov, 1927). Similarly, visual, tactile, and gustatory cues can be associated with the US of active medication, through repeated pairing, to elicit responses (Colloca & Miller, 2011a; Enck, Bingel, Schedlowski, & Rief, 2013). As described earlier, these learning mechanisms can account for responses elicited using dose-extending placebos. Although the CS–US pairing mechanisms can explain most of the conditioned responses described in Section 5, further studies are needed to understand how adaptive responses that compensate for the primary drug effect can develop. Opposite conditioned responses (e.g., tachycardia) can occur when tolerance, a decreased response to a drug within the course of administrations, develops (Siegel, Baptista, Kim, McDonald, & Weise-Kelly, 2000). Dogs treated with epinephrine every few days presented *tachycardic* responses but when epinephrine was replaced by placebo, *bradycardic* response was observed (Subkov & Zilov, 1937). Despite potential limitations, dose-extending placebos work by means of learning effects and can enhance treatment outcomes with transparent use of placebos give as adjunct treatments Fig. 2A. In the real-world setting of health care, these putative placebo mechanisms are likely to operate in unison. Therefore, it is reasonable to assume that these proposed mechanisms are combined, to differing degrees depending on the individual and their disease, to demonstrate effectiveness.

6.3 Embodied Cognition

“Embodied cognition” is a relatively new theory that beginning to help explain how open-label placebos might work but is currently at the speculative stage. According to this theory (Shapiro, 2014) our physical interaction with the world influences or even determines our cognitions (Kemmerer, Miller, Macpherson, Huber, & Tranel, 2013). For example, the sound of the dentist’s drill might trigger a specific bodily sensation (Thompson, Ritenbaugh, & Nichter, 2009). Hence, sensory signals could evoke different reactions including those involved in positive and negative healing experiences (Fuchs & Schlimme, 2009). Embodied cognition is related to conditioning because it operates at a subconscious level and is automatic. However, it also differs in important respects. For one, it does not require a specific conditioning procedure (such as the learned pairing of a bell ringing with food). Relatedly, the cognitions arise directly from bodily experiences that are not mediated by the brain Fig. 2A. Some healthcare settings in which open-label placebos are delivered could induce the body to react in a way that subsequently leads to cognitions, which, in turn, induce the brain to produce endogenous substances such as analgesic endorphins. Further work is warranted to investigate the role of embodied condition in explaining how open-label placebos work.

In the real-world setting of health care, these putative placebo mechanisms are likely to operate in unison. Therefore, it is reasonable to assume that these proposed mechanisms are combined, to differing degrees depending on the individual and their disease, to demonstrate efficacy.

7. CLINICAL IMPLICATIONS

Whether placebos can be prescribed to achieve similar or better outcomes compared with usual medical care, whether and how physicians may recommend treatments that lack any specific efficacy remains controversial (Colloca, 2014; Comaroff, 1976; Henriksen & Hansen, 2004).

A number of studies reported that placebos are indeed used by clinicians across different countries (Fassler, Meissner, Schneider, & Linde, 2010; Kermen, Hickner, Brody, & Hasham, 2010; Louhiala, 2012; Meissner, Hofner, Fassler, & Linde, 2012; Nizan, Barash, Valinsky, Lichter, & Manulis, 1997; Tilburt, Emanuel, Kaptchuk, Curlin, & Miller, 2008) including United States (Kermen et al., 2010; Sherman & Hickner, 2008; Tilburt et al., 2008), Canada (Harris & Raz, 2012; Raz et al., 2011), Germany (Linde et al., 2013; Meissner, 2005), Switzerland (Fassler, Gnadinger, Rosemann, & Biller-Andorno, 2009), Denmark (Hrobjartsson & Norup, 2003), United Kingdom (Howick et al., 2013), Israel (Nitzan & Lichtenberg, 2004), India (Shah, Panchal, Vyas, & Patel, 2009), Saudi Arabia (Hassan, Fauzi, & Hasan, 2011), and New Zealand (Holt & Gilbey, 2009). A systematic review of 22 studies from 12 different countries reported that between 17% and 80% of interviewed clinicians administered sugar pills or saline injections during their careers (Fassler et al., 2010). Still physicians feel that there is a lack of harm and even a potential benefit associated with placebo use but that deception is essential to elicit placebo effects (Bishop et al., 2014). Interestingly, patients feel that potential benefit outweighs the importance of transparency in use. In the United States patients viewed deceptive placebo use acceptable (70%), and approximately 79% would prefer transparency over deception (Hull et al., 2013).

Other factors are also likely to play a role, including biopsychosocial forces arising from contact with a healthcare practitioner (Holt-Lunstad, Smith, & Layton, 2010), and lowered patient anxiety due to a positive expectation of recovery (Benedetti, Carlino, & Pollo, 2011; Darragh et al., 2016).

7.1 Patients' Perspective

Information regarding the views of patients, especially surrounding the concept of deception, would help inform the clinical use of placebos (Bishop et al., 2014; Cohen & Shapiro, 2013; Gold & Lichtenberg, 2014; Hull et al., 2013; Justman, 2013). Ortiz and colleagues performed a qualitative analysis of part of a US national survey to uncover underlying patient attitudes about the use of placebo in the face of deception or transparency. A total of 853 participants participated in a telephone survey (Hull et al., 2013). Adults seen in an outpatient clinic for a chronic health problem at least once in the prior 6 months were invited to participate in the survey. Respondents were women (61%) and men (39%), with an average age of 45 years. 58% were white and 42% were nonwhite. 44% had at least an

undergraduate college education. Given the large size of this survey, relative frequencies of patients' attitudes and how demographic characteristics (e.-g., sex, age, race, and level education) influence such attitudes were explored. Lack of harm and potential benefit are the most common themes to justify acceptability of placebo use. Of the minority of respondents who judged it never acceptable for doctors to recommend placebo treatments, the majority referred to the doctors' obligation to do further clinical tests. The demographic characteristics that emerged as relevant were the level of education and age. Those participants with higher education mentioned potential benefit as a reason for using placebos clinically. Older age was associated with likelihood to identify overall physician–patient relationships, as opposed to treatments as relevant factors for optimal care.

Moreover, participants were asked their opinions about disclosing the use of a placebo. The majority of participants thought that physicians should not lie to patients when actively asked by the patient, a view that was based on the *patient's right to know*, the value of *honesty*, and the chance to harness the *power of the mind*. Only a minority of participants felt the patient should not be informed of the use of placebos for reasons related to *potential harm*, *obligation to do more*, and potential *lack of benefit* in being told about the use of a placebo.

8. ETHICAL IMPLICATIONS

8.1 Authorized Deception and Placebo Use

Despite the common belief that placebo research has to involve elements of deception consisting of deliberately communicating misleading information about the goal of the research study and the nature of experimental procedures, theoretical and experimental research is advocating the possibility of obtaining authorization to use placebos (Miller & Kaptchuk, 2008; Miller, Wendler, & Swartzman, 2005; O'Neil & Miller, 2009). Importantly several authors have created elegant normative work as well as empirical results on the use of deception in placebo research and pain. For example, Martin and Katz (2010) tested the inclusion of authorized deception in the informed consent process by randomly assigning participants to an authorized deception group or a deception group without authorized deception. Interestingly, the authors found that authorized deception did not influence the size of placebo-induced placebo analgesia, recruitment, and retention of participants. Martin and Katz found that informing participants about the nature of the placebo manipulation does not cause distress and lack of trust in research (Martin & Katz, 2010). More recently, Corsi and Colloca (2017) and Colloca, Pine, Ernst, Miller, and Grillon (2016) published findings that have been obtained with a preauthorization to use deceptive information. Namely the study participants were told that the research would have involved deception during the informed consent process with a verbal and written section that describes deception in the consent form as follows:

> "Use of Deception - At some point during the study, we will provide you with misleading information. After the study is completed we will give you a written explanation on how the information was not true and why. We will also answer any questions that you have about the procedure and the use of any misleading information."

Participants had been informed about the deceptive component of this study (why and when the reduced dose was used) and had the opportunity to withdraw the data after they are done participating. The so-called authorized deception approach did not impact the possibility to observe robust placebo and nocebo effects in behavioral and pharmacological research with healthy participants. Importantly, the same approach had been recently used in fibromyalgic pain patients. Perceptions about participation in an authorized deception study were examined in fibromyalgia patients and healthy controls. The majority of participants expressed little or no concern about the deception, still trusted the scientific process, and found the debriefing procedure helpful and worthwhile (personal communication).

8.2 Ethics of Open Label Placebos

Since open-label placebos do *not* require deception, their existence and effectiveness undermine the ethical objections to placebo use. The blooming research in this area warrants an investigation and perhaps revision of ethical standards surrounding placebo use. There are, however, a few notes of caution that must be issued about the ethics of open-label placebos.

First, the arguments that placebos can be ethical since they do not require deception apply to *open-label* placebos and not deceptive placebos. (Recall that deceptive placebos may be ethical but the objection that they violate autonomy is hard to eradicate altogether.) Second, up to half of patients in clinical trials do not recall or understand what they consented to (Tam et al., 2015). If not, then perhaps patients who consent to taking an “open-label placebo” might actually believe it is a real treatment. In two open-label placebo trials investigating this possibility, patients did indeed appear to understand that they were taking placebos (Carvalho et al., 2016; Kaptchuk et al., 2010). Third, the positive suggestions often delivered alongside open-label placebos could involve an element of deception, depending on their wording. This is, strictly speaking, a distinct issue and we leave a discussion of the ethics of therapeutic communication to another study (Annoni & Miller, 2016). In short, the research demonstrating the effects and mechanisms of open-label placebos demands a reanalysis of ethical strictures on placebo use, and further discussion on how open-label placebos might be implemented is warranted.

8.3 Ethics of Dose-Extending Placebos

An area where dose-extending placebo use could be particularly interesting and ethical is in comparison with standard full regimens of medication. Dose-extending placebos—wherever effective—have several benefits. First, extending the effects of a medication through the use of dose-extending placebos—rather than using only medication for a treatment of equal duration—may reduce the side effects associated with the medicine, a speculation that has been confirmed in some studies in which side effects were monitored (Sandler & Bodfish, 2008; Sandler et al., 2008). However, side effects (nocebo effects) may respond to conditioning and learning mechanisms (Colloca & Miller, 2011b), so there is a risk of conditioned side effects instead of conditioning drug efficacy when dose-extending placebos are paired with active treatments. Second, dose-extending placebos may decrease physiological or psychological dependence to medication and habit-forming behaviors toward medication. Third, using dose-extending placebos for part of the therapeutic strategy

rather than using medication for the entire treatment will lower costs by reducing the total intake of the required medication. Last but not least, dose-extending use of placebos provided with patients' education will raise awareness about the body's capacity for self-healing. Finally, by including the primary therapy alongside the dose-extending placebo, the benefits of conditioning could boost the placebo effect.

An obvious area where placebo use could improve patient outcomes is the treatment of pain, where opioid overuse has become a crisis (Belcher, Ferré, Martinez, & Colloca, 2017; Colloca, 2017). Using open-label placebos, perhaps as dose extenders, could reduce the harms caused by the opioid epidemics (Colloca, Enck, & DeGrazia, 2016). Although animal studies can be used to inform clinical studies, further human studies are needed to determine in which diseases and conditions the use of dose-extending placebos can be effective and safe. Methodologically, the ideal study protocol should include three arms: (1) an arm with a partial schedule of pharmacological reinforcement in which the full dose is given 25%–50% of the time and substituted by placebos at other times; (2) a control arm in which the full dose is given 25%–50% of the time and no placebos are administrated; and (3) a comparator arm in which full dose of medication. Whenever feasible, this study design would help circumscribe changes in the efficacy outcome measures due to spontaneous remission, regression to the mean, and natural history of the disease.

Some factors stand in the way of using dose-extending placebos. These include the irreversibility of a disease, clinical contraindication to introduce treatment reductions, and the pharmacokinetic properties of the agent (e.g., US–CS pairings). Safety, optimization, and feasibility studies will help obtain a meaningful investigation of dose-extending placebos.

9. CONCLUSIONS

In conclusion, the recent flourishing of open-label and dose-extending placebo research shows that placebo effects do not necessarily require deception to produce their effects bypassing at least some of the conventional ethical barriers to their clinical use. Future large scale, pragmatic randomized trials should investigate the potential of open-label and dose-extending placebos to improve outcomes and reduce side effects. A parallel body of evidence is needed to inform us about the mechanisms underpinning how open-label and dose-extending open placebos work. Open label placebo research demands a reanalysis of ethical barriers to clinical placebo use.

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Case 8

Medical Decision-making and Cross-cultural Issues

Overview

A physician approaches a patient's hospital room in order to provide anxiously awaited results of an important biopsy. He is intercepted by the patient's son who asks him for the results. When the physician replies that he would like to discuss the findings directly with the patient and that the son should accompany him into the room, the son responds that the physician should disclose the results to him and he will then transmit the information to his father. The son adds that he and other family members have always played a significant role in helping to transmit information and make decisions for his father; this biopsy result should certainly be handled in that same fashion. The physician firmly responds that the information belongs to the patient, that the biopsy result will lead to important clinical decisions, and that he must present the information directly to the patient. Blocking the hospital room doorway, the son threatens that the physician must talk to him or he'll move his father to another hospital.

Objectives

- Recognize variation in decision-making models, particularly among different cultures, and the potential role of family in making decisions for patients.
- Understand the ethical implications of alternative decision-making models.
- Develop an approach to patients and families who might desire an alternative decision-making model
- Become familiar with the use of a translator in communicating with patients.

Questions to Stimulate Discussion

Why does the son want his father's biopsy information?

Within a family, individuals inherently attempt to protect more vulnerable members of the group. This is true of parents for children and applies to adults with ill spouses and siblings or aging parents. Such protection extends to medical information. The healthier and younger members of the family unit often feel a need to protect vulnerable individuals from bad news.

This perspective is dominant throughout the world; the United States and other Western European countries preserve the value of family protectivity to a lesser extent. Many Asian cultures have a clear hierarchical decision-making model in which information is transferred to familial groups and then filtered before it is communicated to patients. The amount and tenor of information transmitted is related to the diagnosis and the prognostic importance.[1,2] Similar decision-making models and familial control of information has been demonstrated in other communities. Deviation from a familial-based model to one with a greater focus on patient autonomy occurs almost exclusively in countries with a Western bioethics focus.

Why is shielding the patient from information ethically problematic?

In the Western bioethical model, patient autonomy is the central value guiding medical care. Patients can make autonomous decisions only if they are informed of the clinical circumstances and of their

treatment options. Interrupted information flow to the patient prevents informed decision-making. Under such situations, patients may receive medical care that they do not want or be hindered from receiving care that would have been desirable to achieve their goals.

However, under most circumstances, a patient may waive the right to some or most elements of clinical information. The patient may even cede some or all decision-making to others. Yet, in an autonomy-based model, this is a course that must be actively pursued by the patient. In other words, family members cannot decide that a patient should not receive information, but the patient can express preference for a familial-based decision-making model.

Another concern is that family members who protect patients from information do so for their own good rather than the patient's. Many family members fear that transmitting bad news will harm their loved ones, particularly in certain cultural groups.[3] It is not unusual to hear a family member say something like "Oh, we can't tell mother that she has cancer. It will kill her!" Yet interviews with patients who have malignancies and other serious medical conditions suggest that patients want at least some information about their clinical condition.[4] In addition, many patients know or strongly suspect a serious or fatal undisclosed diagnosis. Lack of communication may isolate the patient. Discussions with family members who want information withheld should focus on helping them identify their difficulties with the information exchange and recognize the benefits of having the patient participate in decision-making, at least about whether information should be withheld or provided.

How does recognizing and respecting cultural variation improve medical care?

Physicians provide medical care within a cultural context. Culture affects the way that people understand their illness and its meaning. Thus communications about illness and medical care must consider the cultural context. Although culture is commonly related to ethnicity, there are a range of views and values within ethnic groups. Characterizing any ethnic group as having specific cultural values is tantamount to stereotyping or profiling.

In the context of decision-making, failure to consider a patient's cultural perspective can be destructive to the physician-patient relationship and also may harm the patient. On the other hand, accepting a stereotypical view without evaluating its applicability discounts the values of the medical care system and American society. Disregard for either cultural perspective or individual variation may slight the preferences of the patient.[5] The essential elements of cultural competency require that physicians assess cultural differences, value diversity, and consider cultural differences in communication and behavior.[6]

"Cultural competence" requires that a physician recognize that variation in decision-making models exists among different groups. Such recognition calls on the physician to exhibit restraint in demanding a purely autonomy-based model. The approach to the patient and family members must account for cultural variation in decision-making.

How should a physician approach a family that wishes to block information transferred to a patient?

This dilemma is easily solved prospectively, but extremely difficult to unravel when the test results have just come in and the family is blocking access to the patient. Recognizing cases in which the decision-making model might not fit the Western paradigm is not always easy. In the context of an ongoing patient relationship, one might suspect such a model when family members are always present and particularly when the family members make medical decisions with the patient present. For consultants meeting a patient for the first time, however, it is much more difficult to identify an alternate decision-making model unless it is openly queried. An orthopaedic consultant might question whether nonAnglo patients accompanied by family members could adhere to a familial-based decision-making model.[1-3,5] Many Anglo families also will wish to protect their older loved ones from information they perceive to be adverse.

The preventive approach is to anticipate circum-

stances in which bad news might be encountered. For example, prior to a biopsy or excision of a mass, the physician might ask the patient about how the results should be communicated. This should be couched in permissive phrasing, such as: "Some people would prefer that physicians talk with their family members rather than the patient about certain types of important information. Is that how you feel?" Such a question must be posed directly to the patient and cannot be communicated through family translation. The question should be asked when family members are not present. If posed in a nonthreatening fashion, many patients will indicate that it would be best if the doctor relate specific news, such as results of a biopsy, directly to designated family members. Other patients will tell the physician directly that they prefer to be informed. It is much more difficult to have this discussion after the biopsy results are back. Occasionally family members will not allow clinician contact with the patient if they believe bad news might be conveyed.

How should a translator be used in medical interactions?

It is not uncommon for physicians to encounter patients with whom they do not share a common language. Although it is always optimal to use a translator for communication, this is frequently impractical. A translator may not be available in a timely fashion, and oftentimes a family member who can translate is present. However, the physician should recognize that there are special situations in which family members are inappropriate translators, particularly when physicians are attempting to understand the decision model that patients would like to follow. When a sensitive discussion of this sort must take place and no translator is available, the physician should use a telephonic translation service.

When communicating through a translator, physicians should speak directly to the patient as if both were speaking the same language. This allows for nonverbal and empathetic elements to be communicated directly, even though the words are spoken in a different language. The physician should present information in small chunks to facilitate translation and permit an interactive check that information is being understood. This is likely to improve the accuracy of information being relayed by the physician. The patient must also have an opportunity to ask questions of the physician while the translator is present.

Practicum

Students should form groups of three for the roles of physician, patient, and family member. In the first situation, the patient has a mass in his femur and will be admitted to the hospital for an open biopsy. The physician has described the procedure, but the family member did most of the talking and provided the informed consent. The patient assented to the procedure and signed the consent form. In this exercise, the physician is to make arrangements to provide the results to the patient after the procedure. The physician should excuse the family member from the room and then use permissive phrasing to determine the decision-making model and ask to whom information should be transmitted.

The students then switch roles for a second exercise. One student plays the role of physician, and the other two are both family members. The family members have detained the physician as she was about to provide biopsy results to the patient. The family members want to know the results and do not want the physician to provide the information directly to the patient. The physician must construct a plan with the family members about how to proceed.

Conclusion

Families may play a prominent role in decision-making, even for patients with decision-making capacity. But it is the patient who should direct the decision model. Delineating to whom test results should be provided is easily done in advance, but very difficult to accomplish once the results are in.

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A Practitioner's Guide to Ethical Decision Making

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Introduction
Counselors are often faced with situations which require sound ethical decision making ability. Determining the appropriate course to take when faced with a difficult ethical dilemma can be a challenge. To assist ACA members in meeting this challenge, the ACA Ethics Committee has developed A Practitioner's Guide to Ethical Decision Making. The intent of this document is to offer professional counselors a framework for sound ethical decision making. The following will address both guiding principles that are globally valuable in ethical decision making, and a model that professionals can utilize as they address ethical questions in their work.

Moral Principles
Kitchener (1984) has identified five moral principles that are viewed as the cornerstone of our ethical guidelines. Ethical guidelines can not address all situations that a counselor is forced to confront. Reviewing these ethical principles which are at the foundation of the guidelines often helps to clarify the issues involved in a given situation. The five principles, autonomy, justice, beneficence, nonmaleficence, and fidelity are each absolute truths in and of themselves. By exploring the dilemma in regards to these principles one may come to a better understanding of the conflicting issues.

1. Autonomy is the principle that addresses the concept of independence. The essence of this principle is allowing an individual the freedom of choice and action. It addresses the responsibility of the counselor to encourage clients, when appropriate, to make their own decisions and to act on their own values. There are two important considerations in encouraging clients to be autonomous. First, helping the client to understand how their decisions and their values may or may not be received within the context of the society in which they live, and how they may impinge on the rights of others. The second consideration is related to the client's ability to make sound and rational decisions. Persons not capable of making competent choices, such as children, and some individuals with mental handicaps, should not be allowed to act on decisions that could harm themselves or others.

2. Nonmaleficence is the concept of not causing harm to others. Often explained as "above all do no harm", this principle is considered by some to be the most critical of all the principles, even though theoretically they are all of equal weight (Kitchener, 1984; Rosenbaum, 1982; Stadler, 1986). This principle reflects both the idea of not inflicting intentional harm, and not engaging in actions that risk harming others (Forester-Miller & Rubenstein, 1992).
3. Beneficence reflects the counselor's responsibility to contribute to the welfare of the client. Simply stated it means to do good, to be proactive and also to prevent harm when possible (Forester-Miller & Rubenstein, 1992).
4. Justice does not mean treating all individuals the same. Kitchener (1984) points out that the formal meaning of justice is "treating equals equally and unequals unequally but in proportion to their relevant differences" (p.49). If an individual is to be treated differently, the counselor needs to be able to offer a rationale that explains the necessity and appropriateness of treating this individual differently.
5. Fidelity involves the notions of loyalty, faithfulness, and honoring commitments. Clients must be able to trust the counselor and have faith in the therapeutic relationship if growth is to occur. Therefore, the counselor must take care not to threaten the therapeutic relationship nor to leave obligations unfulfilled.

When exploring an ethical dilemma, you need to examine the situation and see how each of the above principles may relate to that particular case. At times this alone will clarify the issues enough that the means for resolving the dilemma will become obvious to you. In more complicated cases it is helpful to be able to work through the steps of an ethical decision making model, and to assess which of these moral principles may be in conflict.

Ethical Decision Making Model

We have incorporated the work of Van Hoose and Paradise (1979), Kitchener (1984), Stadler (1986), Haas and Malouf (1989), Forester-Miller and Rubenstein (1992), and Sileo and Kopala (1993) into a practical, sequential, seven step, ethical decision making model. A description and discussion of the steps follows.

1. Identify the Problem.
   Gather as much information as you can that will illuminate the situation. In doing so, it is important to be as specific and objective as possible. Writing ideas on paper may help you gain clarity. Outline the facts, separating out innuendos, assumptions, hypotheses, or suspicions. There are several questions you can ask yourself: Is it an ethical, legal, professional, or clinical problem? Is it a combination of more than one of these? If a legal question exists, seek legal advice.

   Other questions that it may be useful to ask yourself are: Is the issue related to me and what I am or am not doing? Is it related to a client and/or the client's significant others and what they are or are not doing? Is it related to the institution or agency and their policies and procedures? If the problem can be resolved by implementing a policy of an institution or agency, you can look to the agency's guidelines. It is good to remember that dilemmas you face are often complex, so a

useful guideline is to examine the problem from several perspectives and avoid searching for a simplistic solution.

2. Apply the ACA Code of Ethics.
   After you have clarified the problem, refer to the Code of Ethics (ACA, 2005) to see if the issue is addressed there. If there is an applicable standard or several standards and they are specific and clear, following the course of action indicated should lead to a resolution of the problem. To be able to apply the ethical standards, it is essential that you have read them carefully and that you understand their implications.

   If the problem is more complex and a resolution does not seem apparent, then you probably have a true ethical dilemma and need to proceed with further steps in the ethical decision making process.

3. Determine the nature and dimensions of the dilemma.
   There are several avenues to follow in order to ensure that you have examined the problem in all its various dimensions.
   - Consider the moral principles of autonomy, nonmaleficence, beneficence, justice, and fidelity. Decide which principles apply to the specific situation, and determine which principle takes priority for you in this case. In theory, each principle is of equal value, which means that it is your challenge to determine the priorities when two or more of them are in conflict.
   - Review the relevant professional literature to ensure that you are using the most current professional thinking in reaching a decision.
   - Consult with experienced professional colleagues and/or supervisors. As they review with you the information you have gathered, they may see other issues that are relevant or provide a perspective you have not considered. They may also be able to identify aspects of the dilemma that you are not viewing objectively.
   - Consult your state or national professional associations to see if they can provide help with the dilemma.

4. Generate potential courses of action.
   Brainstorm as many possible courses of action as possible. Be creative and consider all options. If possible, enlist the assistance of at least one colleague to help you generate options.

5. Consider the potential consequences of all options and determine a course of action.
   Considering the information you have gathered and the priorities you have set, evaluate each option and assess the potential consequences for all the parties involved. Ponder the implications of each course of action for the client, for others who will be effected, and for yourself as a counselor. Eliminate the options that clearly do not give the desired results or cause even more problematic consequences. Review the remaining options to determine which option or

combination of options best fits the situation and addresses the priorities you have identified.

6. Evaluate the selected course of action.
   Review the selected course of action to see if it presents any new ethical considerations. Stadler (1986) suggests applying three simple tests to the selected course of action to ensure that it is appropriate. In applying the test of justice, assess your own sense of fairness by determining whether you would treat others the same in this situation. For the test of publicity, ask yourself whether you would want your behavior reported in the press. The test of universality asks you to assess whether you could recommend the same course of action to another counselor in the same situation.

   If the course of action you have selected seems to present new ethical issues, then you'll need to go back to the beginning and reevaluate each step of the process. Perhaps you have chosen the wrong option or you might have identified the problem incorrectly.

   If you can answer in the affirmative to each of the questions suggested by Stadler (thus passing the tests of justice, publicity, and universality) and you are satisfied that you have selected an appropriate course of action, then you are ready to move on to implementation.

7. Implement the course of action.
   Taking the appropriate action in an ethical dilemma is often difficult. The final step involves strengthening your ego to allow you to carry out your plan. After implementing your course of action, it is good practice to follow up on the situation to assess whether your actions had the anticipated effect and consequences.

The Ethical Decision Making Model at a Glance

1. Identify the problem.
2. Apply the ACA Code of Ethics.
3. Determine the nature and dimensions of the dilemma.
4. Generate potential courses of action.
5. Consider the potential consequences of all options, choose a course of action.
6. Evaluate the selected course of action.
7. Implement the course of action.

It is important to realize that different professionals may implement different courses of action in the same situation. There is rarely one right answer to a complex ethical dilemma. However, if you follow a systematic model, you can be assured that you will be able to give a professional explanation for the course of action you chose. Van Hoose and Paradise (1979) suggest that a counselor "is probably acting in an ethically responsible way concerning a client if (1) he or she has maintained personal and professional honesty, coupled with (2) the best interests of the client, (3) without malice or personal

gain, and (4) can justify his or her actions as the best judgment of what should be done based upon the current state of the profession" (p.58). Following this model will help to ensure that all four of these conditions have been met.

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Principles of Clinical Ethics and Their Application to Practice

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Highlights of the Study

- Main principles of ethics, that is beneficence, nonmaleficence, autonomy, and justice, are discussed.
- Autonomy is the basis for informed consent, truth-telling, and confidentiality.
- A model to resolve conflicts when ethical principles collide is presented.
- Cases that highlight ethical issues and their resolution are presented.
- A patient care model that integrates ethics, professionalism, and cognitive and technical expertise is shown.

Keywords
Ethics · Confidentiality · Autonomy · Informed consent · Professionalism · Integrated patient care model

Abstract
An overview of ethics and clinical ethics is presented in this review. The 4 main ethical principles, that is beneficence, nonmaleficence, autonomy, and justice, are defined and explained. Informed consent, truth-telling, and confidentiality spring from the principle of autonomy, and each of them is discussed. In patient care situations, not infrequently, there are conflicts between ethical principles (especially between beneficence and autonomy). A four-pronged systematic approach to ethical problem-solving and several illustrative cases of conflicts are presented. Comments following the cases highlight the ethical principles involved and clarify the resolution of these conflicts. A model for patient care, with caring as its central element, that integrates ethical aspects (intertwined with professionalism) with clinical and technical expertise desired of a physician is illustrated.

Introduction

A defining responsibility of a practicing physician is to make decisions on patient care in different settings. These decisions involve more than selecting the appropriate treatment or intervention.

Ethics is an inherent and inseparable part of clinical medicine [1] as the physician has an ethical obligation (i) to benefit the patient, (ii) to avoid or minimize harm, and to (iii) respect the values and preferences of the patient. Are physicians equipped to fulfill this ethical obligation and can their ethical skills be improved? A goal-oriented educational program [2] (Table 1) has been shown to improve learner awareness, attitudes, knowledge, moral reasoning, and confidence [3, 4].

Ethics, Morality, and Professional Standards

Ethics is a broad term that covers the study of the nature of morals and the specific moral choices to be made. Normative ethics attempts to answer the question, "Which general moral norms for the guidance and evalu-

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Table 1. Goals of ethics education

• To appreciate the ethical dimensions of patient care
• To understand ethical principles of medical profession
• To have competence in core ethical behavioral skills *(Obtaining informed consent, assessing decision-making capacity, discussing resuscitation status and use of life-sustaining treatments, advanced care planning, breaking bad news and effective communication)*
• To know the commonly encountered ethical issues in general and in one's specialty
• To have competence in analyzing and resolving ethical problems
• To appreciate cultural diversity and its impact on ethics

ation of conduct should we accept, and why?" [5]. Some moral norms for right conduct are common to human kind as they transcend cultures, regions, religions, and other group identities and constitute *common morality* (e.g., not to kill, or harm, or cause suffering to others, not to steal, not to punish the innocent, to be truthful, to obey the law, to nurture the young and dependent, to help the suffering, and rescue those in danger). *Particular morality* refers to norms that bind groups because of their culture, religion, profession and include responsibilities, ideals, professional standards, and so on. A pertinent example of particular morality is the physician's "accepted role" to provide competent and trustworthy service to their patients. To reduce the vagueness of "accepted role," physician organizations (local, state, and national) have codified their standards. However, complying with these standards, it should be understood, may not always fulfill the moral norms as the codes have "often appeared to protect the profession's interests more than to offer a broad and impartial moral viewpoint or to address issues of importance to patients and society" [6].

Bioethics and Clinical (Medical) Ethics

A number of deplorable abuses of human subjects in research, medical interventions without informed consent, experimentation in concentration camps in World War II, along with salutary advances in medicine and medical technology and societal changes, led to the rapid evolution of bioethics from one concerned about professional conduct and codes to its present status with an extensive scope that includes research ethics, public health ethics, organizational ethics, and clinical ethics.

Hereafter, the abbreviated term, ethics, will be used as I discuss the principles of clinical ethics and their application to clinical practice.

The Fundamental Principles of Ethics

Beneficence, nonmaleficence, autonomy, and justice constitute the 4 principles of ethics. The first 2 can be traced back to the time of Hippocrates "to help and do no harm," while the latter 2 evolved later. Thus, in Percival's book on ethics in early 1800s, the importance of keeping the patient's best interest as a goal is stressed, while autonomy and justice were not discussed. However, with the passage of time, both autonomy and justice gained acceptance as important principles of ethics. In modern times, Beauchamp and Childress' book on Principles of Biomedical Ethics is a classic for its exposition of these 4 principles [5] and their application, while also discussing alternative approaches.

Beneficence

The principle of beneficence is the obligation of physician to act for the benefit of the patient and supports a number of moral rules to protect and defend the right of others, prevent harm, remove conditions that will cause harm, help persons with disabilities, and rescue persons in danger. It is worth emphasizing that, in distinction to nonmaleficence, the language here is one of positive requirements. The principle calls for not just avoiding harm, but also to benefit patients and to promote their welfare. While physicians' beneficence conforms to moral rules, and is altruistic, it is also true that in many instances it can be considered a payback for the debt to society for education (often subsidized by governments), ranks and privileges, and to the patients themselves (learning and research).

Nonmaleficence

Nonmaleficence is the obligation of a physician not to harm the patient. This simply stated principle supports several moral rules – do not kill, do not cause pain or suffering, do not incapacitate, do not cause offense, and do not deprive others of the goods of life. The practical application of nonmaleficence is for the physician to weigh the benefits against burdens of all interventions and treatments, to eschew those that are inappropriately burdensome, and to choose the best course of action for the patient. This is particularly important and pertinent in difficult end-of-life care decisions on withholding and

withdrawing life-sustaining treatment, medically administered nutrition and hydration, and in pain and other symptom control. A physician's obligation and intention to relieve the suffering (e.g., refractory pain or dyspnea) of a patient by the use of appropriate drugs including opioids override the foreseen but unintended harmful effects or outcome (doctrine of double effect) [7, 8].

Autonomy

The philosophical underpinning for autonomy, as interpreted by philosophers Immanuel Kant (1724–1804) and John Stuart Mill (1806–1873), and accepted as an ethical principle, is that all persons have intrinsic and unconditional worth, and therefore, should have the power to make rational decisions and moral choices, and each should be allowed to exercise his or her capacity for self-determination [9]. This ethical principle was affirmed in a court decision by Justice Cardozo in 1914 with the epigrammatic dictum, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body" [10].

Autonomy, as is true for all 4 principles, needs to be weighed against competing moral principles, and in some instances may be overridden; an obvious example would be if the autonomous action of a patient causes harm to another person(s). The principle of autonomy does not extend to persons who lack the capacity (competence) to act autonomously; examples include infants and children and incompetence due to developmental, mental or physical disorder. Health-care institutions and state governments in the US have policies and procedures to assess incompetence. However, a rigid distinction between incapacity to make health-care decisions (assessed by health professionals) and incompetence (determined by court of law) is not of practical use, as a clinician's determination of a patient's lack of decision-making capacity based on physical or mental disorder has the same practical consequences as a legal determination of incompetence [11].

Detractors of the principle of autonomy question the focus on the individual and propose a broader concept of relational autonomy (shaped by social relationships and complex determinants such as gender, ethnicity and culture) [12]. Even in an advanced western country such as United States, the culture being inhomogeneous, some minority populations hold views different from that of the majority white population in need for full disclosure, and in decisions about life support (preferring a family-centered approach) [13].

Resistance to the principle of patient autonomy and its derivatives (informed consent, truth-telling) in non-western cultures is not unexpected. In countries with ancient civilizations, rooted beliefs and traditions, the practice of paternalism (*this term will be used in this article, as it is well-entrenched in ethics literature, although parentalism is the proper term*) by physicians emanates mostly from beneficence. However, culture (a composite of the customary beliefs, social forms, and material traits of a racial, religious or social group) is not static and autonomous, and changes with other trends over passing years. It is presumptuous to assume that the patterns and roles in physician-patient relationships that have been in place for a half a century and more still hold true. Therefore, a critical examination of paternalistic medical practice is needed for reasons that include technological and economic progress, improved educational and socioeconomic status of the populace, globalization, and societal movement towards emphasis on the patient as an individual, than as a member of a group. This needed examination can be accomplished by research that includes well-structured surveys on demographics, patient preferences on informed consent, truth-telling, and role in decision-making.

Respecting the principle of autonomy obliges the physician to disclose medical information and treatment options that are necessary for the patient to exercise self-determination and supports informed consent, truth-telling, and confidentiality.

Informed Consent

The requirements of an informed consent for a medical or surgical procedure, or for research, are that the patient or subject (i) must be competent to understand and decide, (ii) receives a full disclosure, (iii) comprehends the disclosure, (iv) acts voluntarily, and (v) consents to the proposed action.

The universal applicability of these requirements, rooted and developed in western culture, has met with some resistance and a suggestion to craft a set of requirements that accommodate the cultural mores of other countries [14]. In response and in vigorous defense of the 5 requirements of informed consent, Angell wrote, "There must be a core of human rights that we would wish to see honored universally, despite variations in their superficial aspects …The forces of local custom or local law cannot justify abuses of certain fundamental rights, and the right of self-determination on which the doctrine of informed consent is based, is one of them" [15].

As competence is the first of the requirements for informed consent, one should know how to detect incompetence. Standards (used singly or in combination) that

are generally accepted for determining incompetence are based on the patient's inability to state a preference or choice, inability to understand one's situation and its consequences, and inability to reason through a consequential life decision [16].

In a previously autonomous, but presently incompetent patient, his/her previously expressed preferences (i.e., prior autonomous judgments) are to be respected [17]. Incompetent (non-autonomous) patients and previously competent (autonomous), but presently incompetent patients would need a surrogate decision-maker. In a non-autonomous patient, the surrogate can use either a substituted judgment standard (i.e., what the patient would wish in this circumstance and not what the surrogate would wish), or a best interests standard (i.e., what would bring the highest net benefit to the patient by weighing risks and benefits). Snyder and Sulmasy [18], in their thoughtful article, provide a practical and useful option when the surrogate is uncertain of the patient's preference(s), or when patient's preferences have not kept abreast of scientific advances. They suggest the surrogate use "substituted interests," that is, the patient's authentic values and interests, to base the decision.

Truth-Telling

Truth-telling is a vital component in a physician-patient relationship; without this component, the physician loses the trust of the patient. An autonomous patient has not only the right to know (disclosure) of his/her diagnosis and prognosis, but also has the option to forgo this disclosure. However, the physician must know which of these 2 options the patient prefers.

In the United States, full disclosure to the patient, however grave the disease is, is the norm now, but was not so in the past. Significant resistance to full disclosure was highly prevalent in the US, but a marked shift has occurred in physicians' attitudes on this. In 1961, 88% of physicians surveyed indicated their preference to avoid disclosing a diagnosis [19]; in 1979, however, 98% of surveyed physicians favored it [20]. This marked shift is attributable to many factors that include – with no order of importance implied – educational and socioeconomic progress, increased accountability to society, and awareness of previous clinical and research transgressions by the profession.

Importantly, surveys in the US show that patients with cancer and other diseases wish to have been fully informed of their diagnoses and prognoses. Providing full information, with tact and sensitivity, to patients who want to know should be the standard. The sad consequences of not telling the truth regarding a cancer include depriving the patient of an opportunity for completion of important life-tasks: giving advice to, and taking leave of loved ones, putting financial affairs in order, including division of assets, reconciling with estranged family members and friends, attaining spiritual order by reflection, prayer, rituals, and religious sacraments [21, 22].

In contrast to the US, full disclosure to the patient is highly variable in other countries [23]. A continuing pattern in non-western societies is for the physician to disclose the information to the family and not to the patient. The likely reasons for resistance of physicians to convey bad news are concern that it may cause anxiety and loss of hope, some uncertainty on the outcome, or belief that the patient would not be able to understand the information or may not want to know. However, this does not have to be a binary choice, as careful understanding of the principle of autonomy reveals that autonomous choice is a right of a patient, and the patient, in exercising this right, may authorize a family member or members to make decisions for him/her.

Confidentiality

Physicians are obligated not to disclose confidential information given by a patient to another party without the patient's authorization. An obvious exception (with implied patient authorization) is the sharing necessary of medical information for the care of the patient from the primary physician to consultants and other health-care teams. In the present-day modern hospitals with multiple points of tests and consultants, and the use of electronic medical records, there has been an erosion of confidentiality. However, individual physicians must exercise discipline in not discussing patient specifics with their family members or in social gatherings [24] and social media. There are some noteworthy exceptions to patient confidentiality. These include, among others, legally required reporting of gunshot wounds and sexually transmitted diseases and exceptional situations that may cause major harm to another (e.g., epidemics of infectious diseases, partner notification in HIV disease, relative notification of certain genetic risks, etc.).

Justice

Justice is generally interpreted as fair, equitable, and appropriate treatment of persons. Of the several categories of justice, the one that is most pertinent to clinical ethics is *distributive justice*. Distributive justice refers to the fair, equitable, and appropriate distribution of health-care resources determined by justified norms that struc-

ture the terms of social cooperation [25]. How can this be accomplished? There are different valid principles of distributive justice. These are distribution to each person (i) an equal share, (ii) according to need, (iii) according to effort, (iv) according to contribution, (v) according to merit, and (vi) according to free-market exchanges. Each principle is not exclusive, and can be, and are often combined in application. It is easy to see the difficulty in choosing, balancing, and refining these principles to form a coherent and workable solution to distribute medical resources.

Although this weighty health-care policy discussion exceeds the scope of this review, a few examples on issues of distributive justice encountered in hospital and office practice need to be mentioned. These include allotment of scarce resources (equipment, tests, medications, organ transplants), care of uninsured patients, and allotment of time for outpatient visits (equal time for every patient? based on need or complexity? based on social and or economic status?). Difficult as it may be, and despite the many constraining forces, physicians must accept the requirement of fairness contained in this principle [26]. Fairness to the patient assumes a role of primary importance when there are conflicts of interests. A flagrant example of violation of this principle would be when a particular option of treatment is chosen over others, or an expensive drug is chosen over an equally effective but less expensive one because it benefits the physician, financially, or otherwise.

Conflicts between Principles

Each one of the 4 principles of ethics is to be taken as a *prima facie* obligation that must be fulfilled, unless it conflicts, in a specific instance, with another principle. When faced with such a conflict, the physician has to determine the actual obligation to the patient by examining the respective weights of the competing *prima facie* obligations based on both content and context. Consider an example of a conflict that has an easy resolution: a patient in shock treated with urgent fluid-resuscitation and the placement of an indwelling intravenous catheter caused pain and swelling. Here the principle of beneficence overrides that of nonmaleficence. Many of the conflicts that physicians face, however, are much more complex and difficult. Consider a competent patient's refusal of a potentially life-saving intervention (e.g., *instituting* mechanical ventilation) or request for a potentially life-ending action (e.g., *withdrawing* mechanical ventilation). Nowhere in the arena of ethical decision-making is conflict as pronounced as when the principles of beneficence and autonomy collide.

Beneficence has enjoyed a historical role in the traditional practice of medicine. However, giving it primacy over patient autonomy is paternalism that makes a physician-patient relationship analogous to that of a father/mother to a child. A father/mother may refuse a child's wishes, may influence a child by a variety of ways – nondisclosure, manipulation, deception, coercion etc., consistent with his/her thinking of what is best for the child. Paternalism can be further divided into *soft* and *hard*.

In *soft* paternalism, the physician acts on grounds of beneficence (and, at times, nonmaleficence) when the patient is nonautonomous or substantially nonautonomous (e.g., cognitive dysfunction due to severe illness, depression, or drug addiction) [27]. Soft paternalism is complicated because of the difficulty in determining whether the patient was nonautonomous at the time of decision-making but is ethically defensible as long as the action is in concordance with what the physician believes to be the patient's values. *Hard* paternalism is action by a physician, intended to benefit a patient, but contrary to the voluntary decision of an autonomous patient who is fully informed and competent, and is ethically indefensible.

On the other end of the scale of hard paternalism is consumerism, a rare and extreme form of patient autonomy, that holds the view that the physician's role is limited to providing all the medical information and the available choices for interventions and treatments while the fully informed patient selects from the available choices. In this model, the physician's role is constrained, and does not permit the full use of his/her knowledge and skills to benefit the patient, and is tantamount to a form of patient abandonment and therefore is ethically indefensible.

Faced with the contrasting paradigms of beneficence and respect for autonomy and the need to reconcile these to find a common ground, Pellegrino and Thomasma [28] argue that beneficence can be inclusive of patient autonomy as "the best interests of the patients are intimately linked with their preferences" from which "are derived our primary duties to them."

One of the basic and not infrequent reasons for disagreement between physician and patient on treatment issues is their divergent views on goals of treatment. As goals change in the course of disease (e.g., a chronic neurologic condition worsens to the point of needing ventilator support, or a cancer that has become refractory to treatment), it is imperative that the physician communi-

Table 2. Application of principles of ethics in patient care

Beneficence, nonmaleficence	*Clinical assessment* Nature of illness (acute, chronic, reversible, terminal)? Goals of treatment? Treatment options and probability of success for each option? Adverse effects of treatment and does benefit outweigh harm? Effects of no medical/surgical treatment? If treated, plans for limiting treatment? Stopping treatment?
Respect for autonomy	*Patient rights and preferences* Information given to patient on benefits and risks of treatment? Patient understood the information and gave consent? Patent mentally competent? If competent, what are his/her preferences? If patient mentally incompetent, are patient's prior preferences known? If preferences unknown, who is the appropriate surrogate?
Beneficence, nonmaleficence, respect for autonomy	*Quality of life (QOL)* Expected QOL with and without treatment? Deficits – physical, mental, social – may have after treatment? Judging QOL of patient who cannot express himself/herself? Who is the judge? Recognition of possible physician bias in judging QOL? Rationale to forgo life-sustaining treatment(s)?
Distributive justice	*External forces and context* Conflicts of interests – does physician benefit financially, professionally by ordering tests, prescribing medications, seeking consultations? Research or educational considerations that affect clinical decisions, physician orders? Conflicts of interests based on religious beliefs? Legal issues? Conflicts of interests between organizations (clinics, hospitals), 3rd party payers? Public health and safety issues? Problems in allocation of scarce resources?

cates with the patient in clear and straightforward language, without the use of medical jargon, and with the aim of defining the goal(s) of treatment under the changed circumstance. In doing so, the physician should be cognizant of patient factors that compromise decisional capacity, such as anxiety, fear, pain, lack of trust, and different beliefs and values that impair effective communication [29].

The foregoing theoretical discussion on principles of ethics has practical application in clinical practice in all settings. In the resource book for clinicians, Jonsen et al. [30] have elucidated a logical and well accepted model (Table 2), along the lines of the systematic format that practicing physicians have been taught and have practiced for a long time (Chief Complaint, History of Present Illness, Past History, pertinent Family and Social History, Review of Systems, Physical Examination and Laboratory and Imaging studies). This practical approach to problem-solving in ethics involves:

- Clinical assessment (identifying medical problems, treatment options, goals of care)
- Patient (finding and clarifying patient preferences on treatment options and goals of care)
- Quality of life (QOL) (effects of medical problems, interventions and treatments on patient's QOL with awareness of individual biases on what constitutes an acceptable QOL)
- Context (many factors that include family, cultural, spiritual, religious, economic and legal).

Using this model, the physician can identify the principles that are in conflict, ascertain by weighing and balancing what should prevail, and when in doubt, turn to ethics literature and expert opinion.

Illustrative Cases

There is a wide gamut of clinical patient encounters with ethical issues, and some, especially those involving end-of-life care decisions, are complex. A few cases (Case 1 is modified from resource book [30]) are presented below as they highlight the importance of understanding

and weighing the ethical principles involved to arrive at an ethically right solution. Case 6 was added during the revision phase of this article as it coincided with the outbreak of Coronavirus Infectious Disease-2019 (COVID-19) that became a pandemic rendering a discussion of its ethical challenges necessary and important.

Case 1

A 20-year old college student living in the college hostel is brought by a friend to the Emergency Department (ED) because of unrelenting headache and fever. He appeared drowsy but was responsive and had fever (40 °C), and neck rigidity on examination. Lumbar puncture was done, and spinal fluid appeared cloudy and showed increased white cells; Gram stain showed Gram-positive diplococci. Based on the diagnosis of bacterial meningitis, appropriate antibiotics were begun, and hospitalization was instituted. Although initial consent for diagnosis was implicit, and consent for lumbar puncture was explicit, at this point, the patient refuses treatment without giving any reason, and insists to return to his hostel. Even after explanation by the physician as to the seriousness of his diagnosis, and the absolute need for prompt treatment (i.e., danger to life without treatment), the patient is adamant in his refusal.

Comment. Because of this refusal, the medical indications and patient preferences (see Table 2) are at odds. Is it ethically right to treat against his will a patient who is making a choice that has dire consequences (disability, death) who gives no reason for this decision, and in whom a clear determination of mental incapacity cannot be made (although altered mental status may be presumed)? Here the principle of beneficence and principle of autonomy are in conflict. The weighing of factors: (1) patient may not be making a reasoned decision in his best interest because of temporary mental incapacity; and (2) the severity of life-threatening illness and the urgency to treat to save his life supports the decision in favor of beneficence (i.e., to treat).

Case 2

A 56-year old male lawyer and current cigarette smoker with a pack-a-day habit for more than 30 years, is found to have a solitary right upper lobe pulmonary mass 5 cm in size on a chest radiograph done as part of an insurance application. The mass has no calcification, and there are no other pulmonary abnormalities. He has no symptoms, and his examination is normal. Tuberculosis skin test is negative, and he has no history of travel to an endemic area of fungal infection. As lung cancer is the most probable and significant diagnosis to consider, and early surgical resection provides the best prospects for cure, the physician, in consultation with the thoracic surgeon, recommends bronchoscopic biopsy and subsequent resection. The patient understands the treatment plan, and the significance of not delaying the treatment. However, he refuses, and states that he does not think he has cancer; and is fearful that the surgery would kill him. Even after further explanations on the low mortality of surgery and the importance of removing the mass before it spreads, he continues to refuse treatment.

Comment. Even though the physician's prescribed treatment, that is, removal of the mass that is probably cancer, affords the best chance of cure, and delay in its removal increases its chance of metastases and reaching an incurable stage – the choice by this well informed and mentally competent patient should be respected. Here, autonomy prevails over beneficence. The physician, however, may not abandon the patient and is obligated to offer continued outpatient visits with advice against making decision based on fear, examinations, periodic tests, and encouragement to seek a second opinion.

Case 3

A 71-year-old man with very severe chronic obstructive pulmonary disease (COPD) is admitted to the intensive care unit (ICU) with pneumonia, sepsis, and respiratory failure. He is intubated and mechanically ventilated. For the past 2 years, he has been on continuous oxygen treatment and was short of breath on minimal exertion. In the past 1 year, he had 2 admissions to the ICU; on both occasions he required intubation and mechanical ventilation. Presently, even with multiple antibiotics, intravenous fluid hydration, and vasopressors, his systolic blood pressure remains below 60 mm Hg, and with high flow oxygen supplementation, his oxygen saturation stays below 80%; his arterial blood pH is 7.0. His liver enzymes are elevated. He is anuric, and over next 8 h his creatinine has risen to 5 mg/dL and continues to rise. He has drifted into a comatose state. The intensivist suggests discontinuation of vasopressors and mechanical ventilation as their continued use is futile. The patient has no advance care directives or a designated health-care proxy.

Comment. The term "futility" is open to different definitions [31] and is often controversial, and therefore, some experts suggest the alternate term, "clinically nonbeneficial interventions" [32]. However, in this case the term futility is appropriate to indicate that there is evidence of physiological futility (multisystem organ failure in the setting of preexisting end stage COPD, and medical

interventions would not reverse the decline). It is appropriate then to discuss the patient's condition with his family with the goal of discontinuing life-sustaining interventions. These discussions should be done with sensitivity, compassion and empathy. Palliative care should be provided to alleviate his symptoms and to support the family until his death and beyond in their bereavement.

Case 4

A 67-year old widow, an immigrant from southern India, is living with her son and his family in Wisconsin, USA. She was experiencing nausea, lack of appetite and weight loss for a few months. During the past week, she also had dark yellow urine, and yellow coloration of her skin. She has basic knowledge of English. She was brought to a multi-specialty teaching hospital by her son, who informed the doctor that his mother has "jaundice," and instructed that, if any serious life-threatening disease was found, not to inform her. He asked that all information should come to him, and if there is any cancer not to treat it, since she is older and frail. Investigations in the hospital reveals that she has pancreatic cancer, and chemotherapy, while not likely to cure, would prolong her life.

Comment. In some ancient cultures, authority is given to members of the family (especially senior men) to make decisions that involve other members on marriage, job, and health care. The woman in this case is a dependent of her son, and given this cultural perspective, the son can rightfully claim to have the authority to make health-care decisions for her. Thus, the physician is faced with multiple tasks that may not be consonant. To respect cultural values [33], to directly learn the patient's preferences, to comply with the American norm of full disclosure to the patient, and to refuse the son's demands.

The principle of autonomy provides the patient the option to delegate decision-making authority to another person. Therefore, the appropriate course would be to take the tactful approach of directly informing the patient (with a translator if needed), that the diagnosed disease would require decisions for appropriate treatment. The physician should ascertain whether she would prefer to make these decisions herself, or whether she would prefer all information to be given to her son, and all decisions to be made by him.

Case 5

A 45-year-old woman had laparotomy and cholecystectomy for abdominal pain and multiple gall stones. Three weeks after discharge from the hospital, she returned with fever, abdominal pain, and tenderness. She was given antibiotics, and as her fever continued, laparotomy and exploration were undertaken; a sponge left behind during the recent cholecystectomy was found. It was removed, the area cleansed, and incision closed. Antibiotics were continued, and she recovered without further incident and was discharged. Should the surgeon inform the patient of his error?

Comment. Truth-telling, a part of patient autonomy is very much applicable in this situation and disclosure to patient is required [34–36]. The mistake caused harm to the patient (morbidity and readmission, and a second surgery and monetary loss). Although the end result remedied the harm, the surgeon is obligated to inform the patient of the error and its consequences and offer an apology. Such errors are always reported to the Operating Room Committees and Surgical Quality Improvement Committees of US Hospitals. Hospital-based risk reduction mechanisms (e.g., Risk Management Department) present in most US hospitals would investigate the incident and come up with specific recommendations to mitigate the error and eliminate them in the future. Many institutions usually make financial settlements to obviate liability litigation (fees and hospital charges waived, and/or monetary compensation made to the patient). Elsewhere, if such mechanisms do not exist, it should be reported to the hospital. Acknowledgment from the hospital, apologies from the institution and compensation for the patient are called for. Whether in US or elsewhere, a malpractice suit is very possible in this situation, but a climate of honesty substantially reduces the threat of legal claims as most patients trust their physicians and are not vindictive.

Case(s) 6

The following scenario is at a city hospital during the peak of the COVID-19 pandemic: A 74-year-old woman, residing in an assisted living facility, is brought to the ED with shortness of breath and malaise. Over the past 4 days she had been experiencing dry cough, lack of appetite, and tiredness; 2 days earlier, she stopped eating and started having a low-grade fever. A test for COVID-19 undertaken by the assisted living facility was returned positive on the morning of the ED visit.

She, a retired nurse, is a widow; both of her grown children live out-of-state. She has had hypertension for many years, controlled with daily medications. Following 2 strokes, she was moved to an assisted living facility 3 years ago. She recovered most of her functions after the strokes and required help only for bathing and dressing. She is able to answer questions appropriately but haltingly, because of respiratory distress. She has tachypnea (34/min),

tachycardia (120/min), temperature of 101°F, BP 100/60 and 90% O_2 saturation (on supplemental O_2 of 4 L/min). She has dry mouth and tongue and rhonchi on lung auscultation. Her respiratory rate is increasing on observation and she is visibly tiring.

Another patient is now brought in by ambulance; this is a 22-year-old man living in an apartment and has had symptoms of "flu" for a week. Because of the pandemic, he was observing the recommended self-distancing, and had no known exposure to coronavirus. He used saline gargles, acetaminophen, and cough syrup to alleviate his sore throat, cough, and fever. In the past 2 days, his symptoms worsened, and he drove himself to a virus testing station and got tested for COVID-19; he was told that he would be notified of the results. He returned to his apartment and after a sleepless night with fever, sweats, and persistent cough, he woke up and felt drained of all strength. The test result confirmed COVID-19. He then called for an ambulance.

He has been previously healthy. He is a non-smoker and uses alcohol rarely. He is a second-year medical student. He is single, and his parents and sibling live hundreds of miles away.

On examination, he has marked tachypnea (>40/min), shallow breathing, heart rate of 128/min, temperature of 103°F and O_2 saturation of 88 on pulse oximetry. He appears drowsy and is slow to respond to questions. He is propped up to a sitting position as it is uncomfortable for him to be supine. Accessory muscles of neck and intercostals are contracting with each breath, and on auscultation, he has basilar crackles and scattered rhonchi. His O_2 saturation drops to 85 and he is in respiratory distress despite nebulized bronchodilator treatment.

Both of these patients are in respiratory failure, clinically and confirmed by arterial blood gases, and are in urgent need of intubation and mechanical ventilation. However, only one ventilator is available; who gets it?

Comment. The decision to allocate a scarce and potentially life-saving equipment (ventilator) is very difficult as it directly addresses the question "Who shall live when not everyone can live? [5]. This decision cannot be emotion-driven or arbitrary; nor should it be based on a person's wealth or social standing. Priorities need to be established ethically and must be applied consistently in the same institution and ideally throughout the state and the country. The general social norm to treat all equally or to treat on a first come, first saved basis is not the appropriate choice here. There is a consensus among clinical ethics scholars, that in this situation, maximizing benefits is the dominant value in making a decision [37]. Maximizing benefits can be viewed in 2 different ways; in lives saved or in life-years saved; they differ in that the first is non-utilitarian while the second is utilitarian. A subordinate consideration is giving priority to patients who have a better chance of survival and a reasonable life expectancy. The other 2 considerations are promoting and rewarding instrumental value (benefit to others) and the acuity of illness. Health-care workers (physicians, nurses, therapists etc.) and research participants have instrumental value as their work benefits others; among them those actively contributing are of more value than those who have made their contributions. The need to prioritize the sickest and the youngest is also a recognized value when these are aligned with the dominant value of maximizing benefits. In the context of COVID-19 pandemic, Emanuel et al. [37] weighed and analyzed these values and offered some recommendations. Some ethics scholars opine that in times of a pandemic, the burden of making a decision as to who gets a ventilator and who does not (often a life or death choice) should not be on the front-line physicians, as it may cause a severe and life-long emotional toll on them [35, 36]. The toll can be severe for nurses and other front-line health-care providers as well. As a safeguard, they propose that the decision should rest on a select committee that excludes doctors, nurses and others who are caring for the patient(s) under consideration [38].

Both patients described in the case summaries have comparable acuity of illness and both are in need of mechanical ventilator support. However, in the dominant value of maximizing benefits the two patients differ; in terms of life-years saved, the second patient (22-year-old man) is ahead as his life expectancy is longer. Additionally, he is more likely than the older woman, to survive mechanical ventilation, infection, and possible complications. Another supporting factor in favor of the second patient is his potential instrumental value (benefit to others) as a future physician.

Unlike the other illustrative cases, the scenario of these 2 cases, does not lend itself to a peaceful and fully satisfactory resolution. The fairness of allocating a scarce and potentially life-saving resource based on maximizing benefits and preference to instrumental value (benefit to others) is open to question. The American College of Physicians has stated that allocation decisions during resource scarcity should be made "based on patient need, prognosis (determined by objective scientific measure and informed clinical judgment) and effectiveness (i.e., likelihood that the therapy will help the patient to recover), … to maximize the number of patients who will recover" [39].

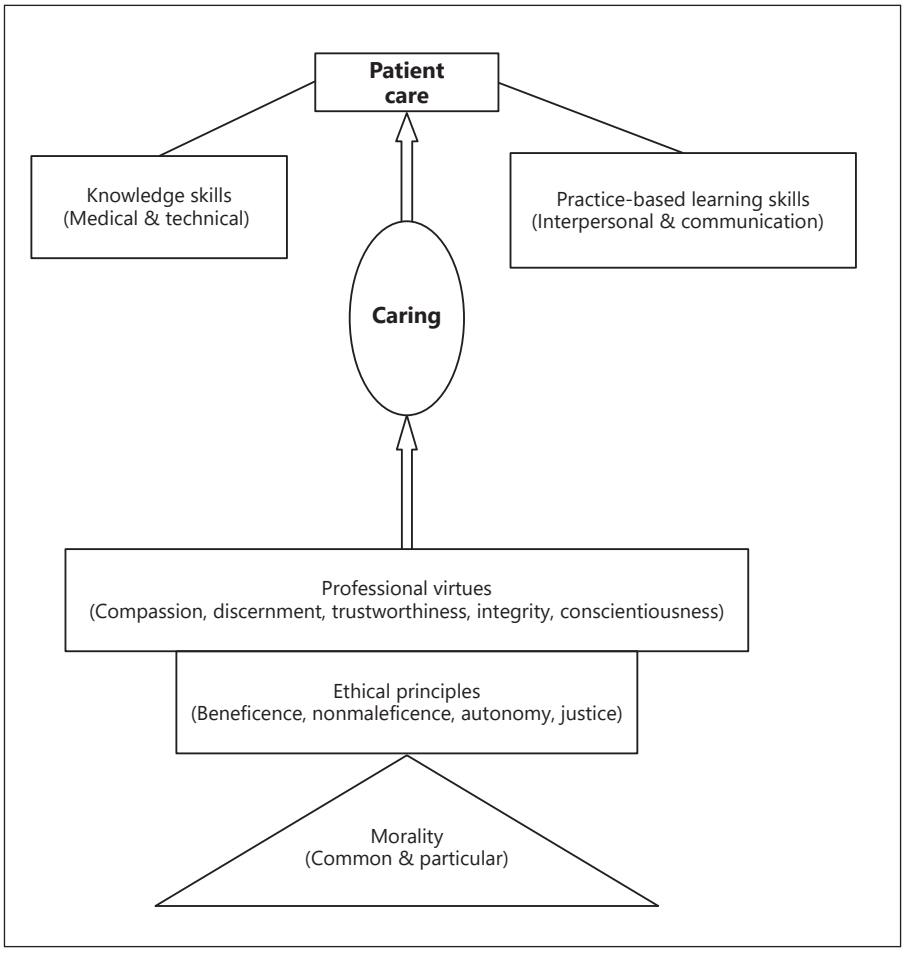

Fig. 1. Integrated model of patient care.

Conclusion

This review has covered basics of ethics founded on morality and ethical principles with illustrative examples. In the following segment, professionalism is defined, its alignment with ethics depicted, and virtues desired of a physician (inclusive term for medical doctor regardless of type of practice) are elucidated. It concludes with my vision of an integrated model for patient care.

The core of professionalism is a therapeutic relationship built on competent and compassionate care by a physician that meets the expectation and benefits a patient. In this relationship, which is rooted in the ethical principles of beneficence and nonmaleficence, the physician fulfills the elements shown in Table 3. Professionalism "demands placing the interest of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health" [26, 40].

Table 3. Physicians obligations

• Cure of disease when possible
• Maintenance or improvement of functional status and quality of life (relief of symptoms and suffering)
• Promotion of health and prevention of disease
• Prevention of untimely death
• Education and counseling of patients (condition and prognosis)
• Avoidance of harm to the patient in the course of care
• Providing relief and support near time of death (end-of-life care)

Drawing on several decades of experience in teaching and mentoring, I envisage physicians with qualities of both "heart" and "head." Ethical and humanistic values shape the former, while knowledge (e.g., by study, research, practice) and technical skills (e.g., medical and

surgical procedures) form the latter. Figure 1 is a representation of this model. Morality that forms the base of the model and ethical principles that rest on it were previously explained. Virtues are linked, some more tightly than others, to the principles of ethics. Compassion, a prelude to caring, presupposes sympathy, is expressed in beneficence. Discernment is especially valuable in decision-making when principles of ethics collide. Trustworthiness leads to trust, and is a needed virtue when patients, at their most vulnerable time, place themselves in the hands of physicians. Integrity involves the coherent integration of emotions, knowledge and aspirations while maintaining moral values. Physicians need both professional integrity and personal integrity, as the former may not cover all scenarios (e.g., prescribing ineffective drugs or expensive drugs when effective inexpensive drugs are available, performing invasive treatments or experimental research modalities without fully informed consent, any situation where personal monetary gain is placed over patient's welfare). Conscientiousness is required to determine what is right by critical reflection on good versus bad, better versus good, logical versus emotional, and right versus wrong.

In my conceptualized model of patient care (Fig. 1), medical knowledge, skills to apply that knowledge, technical skills, practice-based learning, and communication skills are partnered with ethical principles and professional virtues. The virtues of compassion, discernment, trustworthiness, integrity, and conscientiousness are the necessary building blocks for the virtue of caring. Caring is the defining virtue for all healthcare professions. In all interactions with patients, besides the technical expertise of a physician, the human element of caring (one human to another) is needed. In different situations, caring can be expressed verbally and non-verbally (e.g., the manner of communication with both physician and patient closely seated, and with unhurried, softly spoken words); a gentle touch especially when conveying "bad news"; a firmer touch or grip to convey reassurance to a patient facing a difficult treatment choice; to hold the hand of a patient dying alone). Thus, "caring" is in the center of the depicted integrated model, and as Peabody succinctly expressed it nearly a hundred years ago, "The secret of the care of the patient is caring for the patient" [41].

Conflict of Interest Statement

The author declares that he has no conflicts of interest.

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