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MEDICAL ETHICS

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What is a disease?

JOSEPH H. FRIEDMAN, MD
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In preparing for a debate on the question of whether dementia with Lewy bodies (DLB) is the same or a different disease than Parkinson’s disease with dementia, I thought I’d first address the question, what is a disease? Although this is a longstanding and obvious question, I found very little written about the topic.

The concept of what defines a disease is more complicated than it might first appear. It was not until the sixth version of the International Classification of Diseases (ICD 6) was published in 1949 that mental disorders were included. While not defining what a disease is, the World Health Organization (WHO) defined “health” as a “state of complete physical, mental and social well-being not merely the absence of infirmity,” in 1948, and has not revised it. I doubt anyone would consider that failure to meet this definition would constitute a disease.

A 2015 paper suggested that ICD 11, the next edition of disease classification and codes, should classify aging itself as a disease, an oxymoronic concept. The justification for such a classification is based largely on the idea that there are “stakeholders” who might profit from this notion, leading to greater investments by industry in developing interventions to retard or reverse various aspects of aging.

I suspect that most of us, those in medical fields and those outside it, feel that they have a good grasp of what a disease is, like Potter Stewart’s observation on recognizing pornography, “you know it when you see it.” However, a 2012 study in Finland that surveyed a large population of physicians, health professionals and the general population, found that there was a large divergence of opinion (Tikkinen KAO 2012) about what constituted a disease, at least when one focused on addictive and other self-destructive behaviors.

The problems arise when different syndromes are caused by the same pathology, or when the same syndrome is caused by different pathologies. Malaria may cause the common febrile painful illness, but may also cause a disorder that targets the kidneys, or the brain. The disorders are all “malaria,” but different “variants.” Even autosomal dominant inherited disorders, like Huntington’s disease, may cause disparate although overlapping neurological syndromes, yet we consider the diseases the same. Parkinson’s disease may be caused by a recessive inherited disorder in which different family members, although bearing the same phenomenology, have different pathologies. Does the gene or the pathology classify the disease?

Psychiatrists have been dealing with this in a very organized fashion since the first Diagnostic and Statistical Manual. Since psychiatric diagnoses are not based on pathology or laboratory tests, their conceptualization is more fluid and subject to change based on scientific advances as well as social moirés and politics.

The classification of neurological disorders, as with all of clinical medicine, is always in flux, with diseases, previously defined by their phenomenology or laboratory biomarker profiles, are increasingly classified by their genetics, or other objectively measured markers. This is undoubtedly useful for disorders that are caused by a single gene abnormality, but not all disorders have known genetic substrates, and some have very variable genetic contributions, often confounded by different abnormalities in the same gene. In the case of dementia with Lewy bodies, all experts agree that DLB and PD are closely related to each other, for reasons I will mention below, but it is startling to realize that we’re not very sure about how to define Parkinson’s disease, itself. One colleague suggested, probably with universal agreement, that “Parkinson’s disease” is really a group of diseases, based on the observation that certain genetic changes cause people to develop all the clinical criteria required for the diagnosis, but for some members of the same family to have the classic pathological changes.
required for the diagnosis of PD, whereas others, equally afflicted, to lack the Lewy body itself, an absolute requirement for the diagnosis of PD. This undermines the current “gold standard” of PD identification, histopathology. It is obvious that sibs in a family with the same clinical disease have the “same” disease, suggesting that the Lewy body requirement is, perhaps, useful but not an absolute requirement. On the other hand, there are cases, not rare, where people who had been closely monitored with neuropsychological testing were found to have moderate Alzheimer’s disease pathologically at death who had no clinical evidence of dementia.

It used to be thought that once we find the genes or the toxic agent we would identify the disease, but the more we learn, the more difficult these problems become.

What are the controversial issues concerning PDD and DLB? Both have identical dementia findings on neuropsychological exams; both feature the same types of hallucinations and delusions; both have the same or closely similar motor dysfunction; both have the same clinical fluctuations in dementia; both progress in the same manner; both have the same response to medications; both share genetic risk factors; neuropathologists cannot distinguish the two. Currently they are distinguished only by the onset time of dementia with respect to onset of parkinsonism. So, you might ask, why should it matter what we call the disorder?

I’m unsure what the answer to that is. Classification may affect research funding. Will it affect which type of physician cares for the patient, whether treatments will be more or less likely to be funded? Will a dementing illness be funded through the NINCDS or the NIMH? Are the “stakeholders” different? Does DLB benefit from being linked with Alzheimer’s disease, clearly the greatest threat to the elderly population?

Rationality calls for diseases to be classified by whatever markers seem to be likely to group together the most salient aspects of the disease, knowing that single genes may be causal but that other genes may modify phenotype, just as heredity modifies how infectious and toxic agents cause disease. We have “syndromes” until we have causality. We can then hone down the varieties of clinical and laboratory pathology as we learn more, from order, family, genus, to species, just as we’ve classified animals over the last three hundred years, in an ongoing and ever exacting process. There are different advantages to lumping and splitting.

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A music vigil’s healing power at the end of life

HERBERT RAKATANSKY, MD

Every day for several months I went to see Gregg (not his real name) in a nursing facility with music in my hand.

My friend was dying from an untreatable cancer. There was little pain or physical discomfort and thus he required little medication. He suffered from a para-neoplastic syndrome, cancer cachexia, a condition in which appetite is depressed and the body’s energy use is increased. There is no effective treatment and it inevitably leads to death. Gregg was fully aware of the situation. He had little pain and his doctors from Hospice, while readily available, were not frequently needed.

Gregg was a man whose satisfactions in life derived primarily from intellectual pursuits. He was a retired university professor and appeared to have derived little satisfaction from his personal emotional life. Years of unresolved personal and family issues had ignited flames of familial resentment and there was little if any emotional succor from his family. His “best friend” lived far away.

I knew him socially through several discussion groups and as a wine, food and music lover. Our conversations occasionally had ventured into his areas of emotional discontent but never to the extent that we could explore critical issues and facilitate helpful insight. We both enjoyed classical music and, over the years, attended a number of symphony concerts.

Gregg and I became friends later in life and initially I was not aware of most of his and his family’s underlying feelings. I wondered, and I suspect he also wondered, whether sharing these feelings and getting help in dealing with them years earlier might have enabled him to live a more satisfying life and ultimately enabled more emotional support in his final journey.

What does one say to a friend in this situation? His terminal illness was not an appropriate subject for intellectual discussions and, due to the nature of his illness, food and wine were “off the table.”

It may not be possible for persons intimately caught in the web of intense negative emotions to forgive, if not to forget, past behaviors, even when a person is dying. The emotions of friends and relatives do not disappear as death approaches, in fact they may play out in an exaggerated fashion, as they did with Gregg. These persons might say that the patient does not deserve comfort and that, even if he did deserve emotional sustenance, they, personally, would be unable to provide such support. “Deathbed forgiveness” may not be an option.

Most of us have a basic core of “humanity” though it may be more accessible in some than in others. Sociopaths and psychopaths do not make emotional connections with others and likely are the exceptions to this rule. It is difficult to conceive of having empathy for a Nazi doctor, for example.

Reams have been written about caring for the dying. We try very hard to encourage patients to express their feelings and connect emotionally with friends and families about their lives (life review) and continue activities they love for as long as possible. But, as with Gregg, long-standing emotional conflicts may interfere and occasionally make this approach impossible.

In these end-of-life and other difficult situations we should seek that core of humanity that most of us possess. The...
path to this may be conversation or it may be non-verbal.

Music is a separate portal to the brain. It may be a source of pleasure and solace for all but is especially important when it is the major or sole pathway to comfort.

Last year an article in the New York Times described some famous (and not so famous) people who specified the music they wished to hear on their deathbed. Live music has been a part of this approach as well. Palliative care specialists have suggested that terminally ill persons may hear speech and music even when they are unable to respond.

For some persons conversation is impossible. A close relative of mine, minimally verbally responsive due to advanced Alzheimer’s, responds with apparent pleasure to the music she loved, played through headphones. Music therapy for dying patients [music thanatology] is a recognized specialty and music has been incorporated in hospice care in some areas. Music is therapeutic in many medical conditions, such as autism. Children who attend schools that have active music programs do better in their academic subjects.

There was nothing I could discuss with Gregg that could in any way alter his despair and gloom. He did not want many words and we did not have deep conversations. But every day I brought a CD of the music he and I both loved: one day a Brahms symphony, another day a Beethoven concerto, etc. We would talk about past performances we had heard and then we would just listen. As the disease progressed inexorably, Gregg would increasingly doze during the music and toward the end of his illness it seemed that he heard little, at least consciously. But I am sure that the effects of the music as he passed repeatedly from consciousness to drowsiness and then finally to eternal sleep were emotionally meaningful and brought him comfort. Certainly he was happy when I arrived for our daily “concert.”

In anticipation of their final step, many people plan their own funeral and determine the music attendees will hear. And in some cases the music is an integral component. Think about the New Orleans funerals with jazz, a musical Requiem in church, bagpipes at Scottish funerals, etc. There are a number of classical music selections traditionally played in memory of the deceased.

If an ending like Gregg’s comes to befall me or if I become unable to converse during a terminal illness, I anticipate loving family members and friends sharing those sad moments. But putting some Mozart and Beethoven in the mix wouldn’t hurt. And at my funeral please, some Bach fugues on the organ at full volume rather than the usual dirge.

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Holding Hands
ANANYA ANAND, ScB, MSc

Walking from room to room at Rhode Island Hospital, getting horrendously lost in the labyrinths of adjoining buildings, it finally dawned on me that I was now fully immersed in the medical profession. As part of my medical school’s Doctoring course, I had to spend several sessions shadowing a physician and working with patients in a nearby hospital. My first doctoring session was a flurry of struggling to communicate with patients who were experiencing tremendous pain and discomfort and trying to recall all the elements of taking a patient history as my mentor looked on. Now, for my second session, I was on my own, a 24-year-old first-year medical student set loose with a pen, notepaper, white coat and stethoscope upon a group of unsuspecting patients.

My first patient was Ms. F, a 90-year-old woman who had fallen a few days prior and felt like she “was taking her last breath in this world,” but had survived and ended up in the hospital, now presenting with lower-extremity edema, cardiac arrhythmia, and worsening shortness of breath. I walked into the room, excited but highly anxious to be on my own, and was greeted by a beautiful smile and sparkling blue eyes that calmed my nerves immediately. Doctors (and perhaps even medical students) are expected to appear in control and to provide comfort for patients, but it was Ms. F who immediately eased my anxiety with her demeanor. She was lying in bed, and as I started to introduce myself, I realized that there was nowhere for me to sit in the room. Immediately, I felt a slight sense of panic – it would have been terribly awkward to conduct Ms. F’s patient interview looming over her in the small, confined space. She smiled at me, noticing my sudden-onset diaphoresis, and patted the space on the bed next to her. “Come sit here next to me, sweetie!”

For the next hour, she patiently gave me her medical history and allowed me to take her vitals and conduct a brief, bumbling cardiopulmonary exam. But even more amazingly, she opened up to me in a way I could not have foreseen. Ms. F recounted how she fell in love at 17 and had been with her husband until he passed away in 1999 from colon cancer. She still resided in her childhood home and loved to cook Italian meals with her sister, particularly eggplant parmesan. She told me about her five children and cried when she recalled how her youngest son, studying to be a physician assistant, was killed outside a hospital in a hit-and-run. In the short time we spent together, Ms. F and I truly connected. I was astounded that she felt comfortable with me, so comfortable in fact that she revealed to a complete stranger her deeply personal experiences. I wondered whether it stemmed from the power of my white coat – that somehow patients are more inclined to trust their medical providers. Before I left Ms. F’s room, she asked if I would come back to see her before I left that evening since she would be discharged the next day. I told her I absolutely would.

I wonder if my ability and desire to connect with people on a deeply personal level, which I consider a strength, is a weakness in the context of the medical profession. I recall reading an article in preparation for the Doctoring course about how, in the primary care setting, sharing personal information and experiences, referred to as self-disclosure, with patients is not beneficial and can be detrimental to the physician-patient relationship. I was incredulous at reading that article – understandably, there is a limit to the sharing of personal stories and information, but when patients are expected to provide extremely intimate details about their lives to doctors, is it not understandable that they feel some comfort when doctors appear human too?

Patients may have complicated medical histories but it is crucial to view them as much more than their diseases and disorders. I strongly believe that doctors are far more than alleviators of pain and curers of disease. Ours is a deeply personal profession, where
patients are at their most vulnerable and are looking for their doctors to provide care but also to be caring. Being at the hospital can be very emotional, and I think that emotion is important. It is what will keep me human and what will remind me that my patients are human too. This is probably the reason I enjoy writing about my patient encounters so much – because it gives me an avenue through which I can share my experiences and formulate my thoughts about the kind of doctor I want to be. Hopefully, years from now, I can look back on these musings and feel like I have stayed true to myself.

After I finished the rest of my duties at the hospital that day, I went back to see Ms. F. We sat opposite one another, and she reached for my hands. She held them as we looked at each other. She told me about her acceptance of her impending mortality and how she hopes for a better world where people are not judged or discriminated for who they are. She felt blessed to have had so many wonderful memories, and she prayed that I have wonderful ones in my life as well. When I got up to leave, I was deeply saddened, knowing that I would likely never see Ms. F again, but I also felt like I could not have had a more perfect first patient. She reminded me of the reasons I decided to become a doctor.

It has been almost two years since that encounter, but I know I will never forget Ms. F, who touched my life in ways she probably never anticipated. It was difficult to tear myself away from her bedside that evening, but I know that I will always remember our time together whenever I think about the kind of doctor I want to be.

Reference

Disclaimer
The view expressed herein are those of the author and do not necessarily reflect the views of the Warren Alpert Medical School.

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Alison Migliori, PA-S, a student in the Bryant University Physician Assistant Program, and Zoe Weiss, MD, a second-year resident in internal medicine at Rhode Island Hospital, viewed the September issue from their phones during RIMS’ Annual Convivium at the Save The Bay Center in Field’s Point. [see page 60]

The journal reaches a worldwide audience. This summer, readers from 69 countries accessed our articles from their computers and mobile devices. Wherever you may be, or wherever your travels take you, be sure to check the journal on your mobile device and send a photo to us: mkorr@rimed.org.
Medical Students Analyze Complex Ethical Issues Observed in Clinical Rotations

THOMAS A. BLEDSOE, MD, FACP
GUEST EDITOR

This issue of the Rhode Island Medical Journal features ethically complicated cases identified and analyzed by medical students at Brown University during their third-year clinical clerkships. These cases were selected by a core group of students from over 120 papers submitted by their classmates and provide a unique view into the process of professionalization of medical students. In medical situations that practitioners see every day, the medical students identify issues that are ethically complicated (and sometimes deeply morally troubling). What can we learn from their ethics analyses of these situations?

All medical students at Brown participate in six semi-structured small-group ethics seminars during their clinical rotations with the twin goals of learning to recognize the ethical tensions in all medical encounters and to develop the skills to critically analyze those tensions and find solutions that work for both the members of the health-care team and the patient and family. These medical students, being incompletely professionalized, have a tremendous ability to call out injustices and to identify approaches that do not adequately respect patient autonomy. They see “solutions” that may result in harm to patients while attending to others’ goals and motivations, issues that might well be “swept under the rug” by busy practitioners. With medicine increasingly being delivered by teams in a hierarchical environment, it is likely that ethical concerns of some members of the team are left unaddressed. Learning to identify and address those concerns is a third goal.

Each of the cases presented in this issue was originally identified and analyzed by a student. Each presentation and formal analysis presented here was written collaboratively by the original submitting student and other students in the core group. Practical ethics in the real world requires an action plan that is ethically defensible. Even choosing to do nothing is a choice that requires justification. As such, the formal analysis that follows [by these student authors] is intended to both identify a “best” path forward and to present an ethical justification for it. Members of the Rhode Island Hospital Ethics Committee were then asked to provide additional commentary on the cases as submitted. Some of these Ethics Committee commentaries were provided by 4th year students who had spent the previous 2 years as invited committee members.

In reviewing these cases, the reader will be challenged to decide whether to allow a psychiatrically ill patient to refuse major surgery, how to account for cultural issues in a patient who may (or may not) have paranoia, what to do about a patient with widely metastatic peritoneal cancer who sells the opiates she gets from the hospice doctor but certainly suffers from severe pain, or whether to continue a surgery when a patient clearly asks the surgeon to stop. If you are conflicted about the “best” path forward after reading these cases, don’t despair, as the conclusions of various consultants are also more often than not conflicting as well.

We hope that these cases stimulate the readers’ interest in and attention to the ethical tensions in their day-to-day clinical work, and that the students’ approach to these situations will be helpful in both addressing and mitigating the ethical tensions in the readers’ clinical work.

Author

Thomas A. Bledsoe, MD, FACP, Clinical Associate Professor of Medicine, Alpert Medical School of Brown University.
There are as many methods of teaching medical ethics as there are of doing medical ethics. Despite some degree of standardization across other disciplines within the science of medicine both in the material to be taught and the methods of teaching (pedagogy), clinical ethics education is largely a “home-grown” product in most medical schools. National organizations like the American Society of Bioethics and Humanities have ethics education interest groups but have not developed formal curricula in these areas. Within the house of Medicine, similarly, professional organizations have published ethics guidelines and manuals but these are usually specialty or sub-specialty specific with little attempt or success in identifying and publishing common standards or methods of imparting these professional ethics to students.

Often, medical ethics education is attached to or incorporated into courses that teach general professionalism in the context of teaching the skills of medical interviewing or physical examination. For example, some boundary issues and standards of professional behavior might be appended to teaching about taking a sexual history or specific physical exam maneuvers. In these schools, ethics education is seen as part of the process of professionalization with the hope that professional ethics will be absorbed and then adopted by the students before they get to their more comprehensive clinical training. (Of course, once their clinical rotations get started, they are at risk of being more forcefully swayed into other approaches by the “hidden” curriculum1 that they pick up informally from colleagues, more senior medical students, house officers, faculty and others who work in health care.)

In some schools, ethics education is taught by philosophers who are more observers of the medical profession than practitioners of it. A particularly complicated or challenging situation that is originally based in an actual case is presented, and then the details of the case are twisted like a Rubik’s cube with a series of “what-if” questions in an attempt to glean the underlying ethical principle in the case. Many but not all medical schools do teach medical ethics using the approach of “principlism” developed by Beauchamp and Childress and first presented in their book Principles of Biomedical Ethics originally published in 1979.2 Most clinical medical students are able to recite “the big 4” principles of Autonomy, Beneficence, Non-maleficence and Justice while making the mistake of thinking these 4 are presented as a hierarchy [with autonomy at the top], that this approach can help one decide what to do and that there are only four principles to remember.

**METHODS OF MEDICAL ETHICS**

There are actually many different ways of “doing” medical ethics.3 A relatively simple approach is to use virtue ethics and simply ask, “What would a good doctor do?” when faced with an ethically complicated situation. While running the risk of circularity and begging the question of “what makes a good doctor,” this approach is often surprisingly useful. We all have had or have heard about physicians who behave in exemplary [or less than exemplary] ways and some model of ideal behavior is usually close at hand. Another approach is to use casuistry or cased-based ethics. Like the philosophers mentioned above, this approach starts with the presentation of a case and proceeds with a discussion intending to identify the “best” approach to the situation. Cases that are similar or different in ethically relevant ways are then examined in an effort to identify the aspects of the case that are most ethically relevant while also looking for underlying ethics tenets that are strong enough to stand up in different but similar situations. The hope is that by deciding the best course in this case, the practitioner will have also identified a strategy that will be a useful guide in other ethically similar cases in the future.

The tools of feminist ethics can be used to attend to those whose interests are often discounted. Communitarian ethics seeks the approach that results in the best outcome for the community [which contrasts with the [mistaken?] approach often taken which allows individual autonomy to assume a dominant role in directing behavior].4 While many approaches to medical ethics ask the question from the physician’s or practitioner’s perspective, at Brown we tend to lean more heavily on a technique called deliberative bioethics.

**DELIBERATIVE BIOETHICS**

Now more than ever, the practice of medicine has become a “team sport,” so the question for the physician is less “what should I do?” and more “What should we do?” and that “we” entails the involvement of others.
In a paternalistic model of care delivery, the “we” is the patient and the physician: Using paternalism the physician decides what is best for the patient. As such, the question “What should we do?” is actually “What should I do to [and for] you, the patient?” In a hierarchical practice environment, the physician may consider and then decide on the best approach and inform the rest of the team what has been decided. In this way, akin to medical paternalism, “What should we do?” becomes simply “What will we do?” as the physician uses authority to direct the team’s actions.

Using a model of shared decision-making, this “What should we do?” seeks to incorporate the values of the patient as understood by the patient in an effort to attain a philosophically rich, autonomy-respecting model of shared decision-making by incorporating medical facts, medical science and practical wisdom and both patient’s and physician’s goals and values.

Similarly, the approach of deliberative bioethics rests on the premise that the “best” approach from an ethics standard is the one that seeks to maximize the goals and values of all of those involved. Included would be conversation about the worthiness and prioritization of conflicting motivations which may be intrapersonal or interpersonal. This approach mirrors shared decision-making between physician and patient.

Ethics is about theories of right action and deliberative bioethics requires the participants to present defensible reasons for one action or another. Gutman and Thompson, in discussing deliberative democracy, have stated that “citizens and officials must justify any demands for collective action by giving reasons that can be accepted by those who are bound by the action.” Similarly, in deliberative bioethics, other members of the medical team and members of the patient’s social circle have a right to the same types of reasons.

Gutman and Thompson have presented four characteristics of ethical reasons that must be present for this approach to succeed. First the reason must be accessible or comprehensible. Second the reason must be moral, i.e., general and therefore applicable to all in similar situations. Third, the reason must be reversible. The very process of entering into ethical deliberation requires that one is willing to revise one’s position, if presented with an adequately compelling argument. Finally, the reason must be respectful. As Gutman and Thompson state, “much moral disagreement will persist even among good-willed and intelligent people” so entering into deliberative bioethics one accepts the possibility that consensus may not be possible. That said, deliberative bioethics seeks to understand and then balance these types of reasons with the goal of a shared decision about the best path forward together.

**CLINICAL MEDICAL ETHICS EDUCATION AT BROWN**

At Brown, clinical ethics education is based on a balance between acquiring the ethics of the profession and the humility required to deliberate ethically with others, whether those others are classmates, patients and their families or other members of a healthcare team. This often requires doing extra work to better understand the perspectives and priorities of others with a goal of shared decision-making. As such, students are given an assignment in two of their clinical clerkships to identify and then formally analyze an ethically complex medical situation using assigned templates that encourage use of deliberative ethics.

In our experience with clinical ethics consultations, those involved are often at loggerheads over an intervention with both “sides” pretty sure they are making the right choice and that the others are mistaken. Surprisingly, the facts of the case are often not mutually agreed upon and this lack of a common understanding of the situation may have led to the divergent views on what should or should not happen. Even when the facts are clear to all, goals and values of the participants are often assumed and not adequately explored. Sometimes there is open hostility or disdain for the (assumed) goals of the other side. We have found that stepping back from questions about interventions and doing a more formal analysis of goals often yields an understanding and appreciation of the other and will frequently allow for respectful shared decision-making moving forward.

In the students’ medicine clerkship, they are asked to complete a 6-step ethics consultation template that mirrors what we use in clinical ethics consultation. In the first step, the facts of the case are presented including biologic, social and psychologic factors. As noted, in actual ethics consultations, what feels like a very complicated ethics dilemma is sometimes simply the result of a failure to communicate. The goal of step 1 is to have a common understanding of the situation before delving into more complicated issues of ethics. In subsequent steps, the student is asked to clarify the pending medical decision and then attempt to crystallize the ethics question. As ethics is often about obligation or permissibility, this may take the form of a “should” or “may” question.

Once the ethics question is posed, there is a conscious attempt to list out those involved in the pending medical decision and subsequent ethics question and then to delineate the needs, preferences, values and obligations related to the decision at hand of each of those involved. Some of these motivations will be readily apparent and some will require some background work. With an eye toward the actual medical decision and knowledge of the motivations of the various “players,” the student is then asked to balance the motivations against each other while also looking for commonalities. This balancing exercise is the crux of the ethics analysis. The final step in the analysis is a “preventive
ethics review” which seeks to learn from the very existence of this ethical dilemma: What could have been done differently in this or a similar case that would have mitigated the ethical tensions?

A slightly different tack is taken in the students’ obstetrics and gynecology rotation. In this assignment, the students are also tasked with identifying an ethically complicated medical situation. The obstetrics environment is rich with conflicting motivations and interests and, with minimal prompting, the students present a fascinating array of cases to analyze. Once the case is chosen and presented, the students are asked to simply outline the competing considerations in the case and to put themselves into the role of attending physician and decide what their chosen path would be with supporting reasons for that action. Recognizing that others may well choose differently, they are then asked for the most compelling reasons why one might choose differently. Finally, as James Dwyer has written, there is a great danger in medical ethics in remaining silent7 and the students are specifically asked to discuss what harms might ensue if they choose to keep their ethics concerns to themselves in the medical situations they have chosen to analyze.

It is our contention that there are ethical tensions inherently present in every medical encounter8 and that physicians (and especially trainees) disregard those tensions at their own and their patients’ peril. Attending to their own personal and professional ethics and also actively seeking to understand and incorporate the goals and values of their patients and colleagues into a model of shared decision-making is presented as an important element in their professional development.

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Risk-Benefit Evaluation for Surgery in a Patient with Psychiatric Complications

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THE CASE
Our patient was a 56-year-old woman with bipolar disorder and chronic obstructive pulmonary disease who continued to smoke, and who presented to the ER with intermittent substernal chest pain. In the last year, she had had several similar episodes, with multiple presentations to the ED. Each time, she refused further evaluation and left the hospital against medical advice, reportedly “to smoke cigarettes.” At this visit an electrocardiogram revealed an inferior non-ST elevation myocardial infarction. She was admitted to the CCU for cardiac angiography, which revealed multi-vessel coronary artery disease. The cardiologists recommended coronary artery bypass graft (CABG) surgery.

During medical rounds, the cardiology team presented the results of the angiogram and treatment recommendations to the patient and her boyfriend. The team also discussed the risks and benefits of the CABG procedure, including medications the patient would start and continue daily, such as dual antiplatelet therapy and other important medications. She also declined nicotine replacement therapy, while becoming aggressive towards medical staff because she was not allowed to leave the hospital to smoke.

As she became increasingly agitated, she stated she was not reliable enough to take the daily medications after surgery and refused the surgery until she could go outside to smoke. Her agitation escalated into violent behavior towards staff and she began pulling out her intravenous lines. In response, the cardiac team called hospital security as well as a psychiatric consult to evaluate her capacity. The psychiatric team determined that she lacked capacity to make medical decisions due to her agitation, inability to make rational decisions, and behaviors that necessitated sedation. While she was sedated, discussions with her family revealed their anxiety about her prognosis and their strong desire for her to undergo CABG.

THE ETHICS DILEMMA
Should the physicians perform CABG or pursue optimizing medical treatment of the patient’s heart disease and psychiatric disease?

STUDENT ANALYSIS: (TT, AT, JM, YS)
In this case our patient has stated her clear refusal of CABG surgery. It may be argued that the care team should heed both her aversion to surgery and her refusal to adhere to the post-operative therapy prescribed. Although surgery may be indicated for this medical condition in an ideal candidate, the ethical principle of physician non-maleficence might prevent the physicians from taking this patient to surgery. She is a poor candidate for surgery due to her many risk factors, history of medical non-adherence, and significantly, her expressed intent to stop post-operative medications. In this instance, the anticipated harm of surgery, including significant morbidity or death, could outweigh the potential benefit of improved life expectancy, and surgery could easily be construed as causing harm.

The ethical principle of justice further supports not operating on this patient. Operating on this patient may well deprive others of needed care. Surgical supplies, operating room time, and support personnel required to pursue this operation are expensive. The current healthcare landscape demonstrates that the number of patients with surgical needs will continue to rise while the pool of surgeons trained to treat them will fail to keep pace.

There are, however, many arguments in favor of performing the surgery. It is the nature of medicine that some patients will respond to treatment more poorly than others. This is not, and has never been, a justifiable reason to withhold treatment from patients who do not or potentially will not respond as well. Researchers have rigorously studied the short- and long-term risks of CABG, resulting in many models to predict a patient’s risk based on individual characteristics. That the surgery was offered at all indicates this patient could benefit from CABG even with her mental health comorbidities.

To respect patient choice, physicians have a duty to offer care that may reasonably improve patient health, even in the context of risk. A patient with decision-making capacity may decline the intervention. However, in this patient without decision-making capacity, the physician must work with a surrogate decision-maker when one is available.

The American Medical Association’s Principles of Medical Ethics states that physicians are responsible for helping surrogate decision makers use the “standard of substituted judgment” in medical decision-making. The standard obligates
the surrogate to mirror the patient’s desires, including “the patient’s views about life and how it should be lived,” as well as “the patient’s attitudes towards sickness, suffering, and certain medical procedures.” When our patient was previously thought to have capacity, she had explicitly stated that she was incapable of adhering to complicated treatment plans. Her surrogate decision makers have an obligation to adhere to these “attitudes towards sickness,” despite their trepidation with the prognosis.

While the patient’s family desires surgery to potentially prolong her life, she has proven time and time again to be non-compliant with physicians for evaluation and treatment of her heart disease. Again, many of these scenarios occurred when the patient was felt to have capacity for medical decision-making. The family argues that the patient’s non-compliance is founded on her anxiety and that she would comply with treatments if given the opportunity. The patient, however, has not demonstrated this in past interactions with the healthcare system, specifically in her numerous departures from the Emergency Department against medical advice.

While physicians often determine optimum treatments based on risk-benefit modeling in complicated patients, these determinations are neither static nor permanent. Over time, physicians may get to know their patients and form different opinions of prognosis based on personal expertise with prior cases. In no way does a physician’s past offer of a procedure remain open out of principle, especially if new information comes to light that negates the prior risk-benefit assessment. In this case, it behooves the treatment team to focus on optimizing medical and psychiatric treatment of the patient’s heart disease and psychiatric comorbidities, before any attempt at surgical intervention.

**ETHICS COMMITTEE ANALYSIS #1 (SM)**

Analyses of these difficult cases benefit greatly from discussions among diverse members of the Hospital Ethics Committee. As Director of Risk Management, I tend to view ethical dilemmas in terms of risks and benefits.

It is not uncommon for patients to be noncompliant with care; patients have the right to make testing and treatment choices, even if these choices appear poorly considered to the medical team. In this case, the team has determined that the patient does not possess the capacity to make her own medical decisions at the moment of crisis. While the psychiatric diagnosis of bipolar disorder may be clouding her ability to do so, at that moment it is the sedatives that are impeding her most. When a patient is deemed to lack capacity, a surrogate decision maker is needed. One of the health care team’s jobs is to look for someone who is best positioned to know what the patient would have wanted if she could choose for herself. In cases involving chronic diagnoses, we would first inquire about an advance directive created during previous periods of lucidity. Absent that, in Rhode Island, there is no law determining who can make decisions for the patient and function as a surrogate. In this case, it may be helpful to follow the guidance of the Rhode Island General Laws Uniform Anatomical Gift Act in determining who may act as the surrogate decision maker. Not infrequently, there are situations in which a friend or clergy member may know the patient’s wishes better than family. The surrogate decision maker must be informed that treatment should conform to what the patient would want based on written or oral advance care planning if available. If these preferences are not known, care preferences should be founded on evidence of what the patient would have chosen based on the patient’s values, previous choices, and beliefs (substituted judgment) or, failing that, the best interests of the patient.

Patients with psychiatric disorders that directly affect cognition may benefit from both a period of treatment and more intensive efforts at education, in order to optimize understanding of relevant information. Introducing a known and trusted confidante may also help the patient to make decisions consistent with his or her best interest[s].

In this case, the “evidence” known thus far includes the fact that the patient chooses to live her life without pills. These have been seen as decisions on her part worthy of respect [did anyone try to compel her to take her outpatient medications?] and may represent her true wishes. At the same time, she has not expressed suicidal ideation. Other critical questions to ask include: “What is the bigger risk for the patient, not proceeding with the surgery or having it and taking anticoagulant medications inconsistently?” “Is there time to delay the surgery to allow her psychiatric medications to help her gain a more solid capacity?” The health care team’s short-term solution of sedating her to avoid her leaving against medical advice is only that. Taking advantage of these chemical restraints to allow family to override a consistently expressed desire to forego surgery by the patient would be similarly difficult to defend from an ethical perspective. [Our Risk Management opinion in such a case would also suggest that such an approach carries significant legal risk.]

If there is time to delay the surgery, the clinical team should continue to work with the patient, the trusted patient confidante and the patient’s outpatient providers, while continuing to educate her about the risks of avoiding surgery and the benefits of having it, seeking her consent.

**ETHICS COMMITTEE ANALYSIS #2 (CR)**

The patient in question is having an NSTEMI and CABG surgery is indicated. Without this surgery, she has a very high risk of severe morbidity and death. It has been determined that she lacks capacity for medical decision-making and her family would like her to undergo CABG. However, all parties are concerned that she will be noncompliant with
her anticoagulant medication and continue to smoke. The question of whether to move forward with surgery will be based on the team’s concern for noncompliance, essentially their assessment of her ability to care for herself. They must decide whether her noncompliance is of greater risk than forgoing the surgery altogether.

To perform a surgery and put her at risk for clotting raises the specter of violating the principle of non-maleficence even though serious clotting is not an inevitability. We don’t know if or how often she will neglect to take her pills.

We have many other patients who end up in the cath lab after decades of artery hardening smoking, neglected diabetes, etc., yet we continue to provide treatments from of our duty of beneficence. It would be neglectful to deny her the standard of care that we would provide to another patient who simply didn’t declare as stubbornly and honestly about the likelihood of noncompliance. Doing so violates our obligation to beneficence as well as the principle of justice. Unlike transplant recipients, our patient does not have to prove herself to be capable of compliance. Though cardiac surgery is expensive, her receiving a CABG does not mean someone else will not. She has been declared to lack capacity to decline care and CABG is the standard of care.

It is also quite possible that her mental health will improve and that she will become more capable of keeping up with daily medication. Perhaps an unjust distribution of resources left her incapacitated by psychiatric illness, and now facing denial of lifesaving surgery because she doesn’t have the coping skills to take a daily medication. We can attempt to address the broader psychosocial context at play and mitigate her noncompliance with wrap-around services at discharge. It is our ethical obligation to serve and not abandon our patients, to perform the standard of care when possible, and to provide the opportunity for patients to recover from ailments of the body as well as the mind. For these reasons, the most ethically defensible course is to perform the CABG with the valid informed consent of her surrogate decision-makers, and to then work with the patient upon discharge to give her the best chance for health through her surgical recovery and beyond.

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To Continue or to Withhold Opioid Analgesics? An Ethical Dilemma Involving a 63-year-old Cancer Patient Who ‘Broke the Pain Contract’

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THE CASE
We present a 63-year-old woman with a history of poly-substance abuse, end-stage pancreatic adenocarcinoma and ten recent admissions for pain control. She re-presented with severe epigastric pain and anorexia. Prior to presentation, the patient’s pain was controlled with opiates prescribed by a palliative care physician. This physician was no longer prescribing opiates because of a breach in the patient’s pain contract: the patient was believed to be selling her opiates to support her methamphetamine addiction. At the time of previous discharges, she would be given a short course of opiates to last until the follow-up appointment. Despite this, the patient would return days after discharge complaining of severe pain and asking for or even demanding more pain medication. Upon each re-admission, even though the patient’s toxicology screen was positive for methamphetamines, opiates were restarted. Per the chart, the patient had admitted that she was selling her pills to obtain illicit drugs. Consequently, during the patient’s final admission, the patient’s treatment team encountered an ethical dilemma.

THE DILEMMA
Should the team again prescribe this patient opiate pain medication on discharge to treat her pain until outpatient care could be established or should treatment be withheld due to the knowledge of the patient’s continued illicit drug use and selling of her prescription medications?

STUDENT ANALYSIS (BL, NL, RO, YS)
The ethical dimensions of this case are complex, especially when one considers the fact that Rhode Island (RI) ranks first in the country in opioid-related deaths. Deaths from overdose have occurred from illicit drugs, prescription medication, and combinations of both. In 2016, there were 1,567 overdose case reports in RI, 336 of which resulted in death. This represents a 16 percent increase in drug-related overdose deaths since 2015. Although the rate of deaths caused by prescription drugs has leveled since 2009, deaths from illicit drugs are increasing. In addition, overdose deaths caused by dual use of illicit drugs and prescription medication are up nearly a third since 2011.

Like many other states, the overdose crisis in RI began with prescription drugs. Health-care providers, who are part of the reason for the opioid epidemic, have an obligation to help prevent opioid-related deaths by ensuring that those who are prescribed opioids are using them responsibly. Model “pain contracts” typically include terms of treatment including risks and benefits of treatment, prohibited behaviors and points of termination, patient responsibilities, and rules for interacting with caregivers. Typically, contracts include statements that explicitly prohibit patients from giving (or selling) their prescription medications to anyone else, and discourage them from using any mind or mood-altering or illicit drugs while receiving treatment unless authorized by a physician. Willfully prescribing opioids to this patient in the context of her untreated methamphetamine addiction carries risks beyond those of the opiates themselves. For example, providers run the risk of supporting the patient and others’ illicit drug addiction, and thereby contributing to the state’s opioid crisis. Since the patient is not complying with her end of the pain contract, this provider team may be well supported, under the ethical principle of non-maleficence, to terminate the contract and withhold treatment.

It is important, however, to remember that controlled substance agreements exist not to punish patients who do not act in accordance with physician goals, but rather to allow personalized patient counseling and promote shared decision-making about the risks and benefits of opioid use. The use of these agreements as an enforcement tool only serves to further stigmatize patients with chronic pain and erodes their access to healthcare. Moreover, such usage is frequently ineffective, as patients with legitimate needs for pain medication (as in this case of a patient with pancreatic cancer) can often easily acquire pain medication from other physicians. In this view, it is the role of the physician to build a therapeutic alliance with the patient, instead of effectively forcing her to switch providers to obtain the same outcome of receiving her required pain medications or being left without treatment of either her pain or her methamphetamine addiction. Such handoffs of patients only cause discontinuities in care, leading to suboptimal management and poor patient-doctor relationships.

Physicians should have a goal of respecting patient autonomy while seeking to optimize outcomes. This means allowing the patient to define what the best goals are, even if they may be at odds with medical opinion. This is especially true...
in the realm of oncology and palliative care, where patients are faced with a deeply intimate choice and can make a wide variety of decisions about their goals of care. While physicians should not endorse or become complicit in decisions that harm a patient’s health, such as abusing methamphetamine, they must also respect the patient’s freedom to decide to continue such actions. It would be more productive to establish a trusting relationship with the patient and explore the patient’s motivations for using methamphetamine and encourage treatment, rather than attempting to forcibly reduce her access to methamphetamine by withholding important and indicated medical therapies.

Additionally, this case was noteworthy because it illustrated the competing demands under which physicians are often placed—specifically, balancing the physician’s obligation to the patient with the obligation to society. Clearly, the sobering facts surrounding the explosive rise of prescription and illicit opioid abuse epidemic illustrate that physicians and other public health professionals have an ethical obligation to ensure that any opiates provided are in the smallest dose possible and used appropriately. However, in patients with legitimate and ever-changing needs such as this patient, it is very difficult to advocate for cessation of opiate prescriptions even with the suggestion that this patient may be using these prescriptions inappropriately. Ultimately, we recommend a compromise solution such as a discharge with appropriate home follow-up in which a visiting provider could provide medication in small amounts frequently, while continuing to monitor the patient’s pain needs. This would minimize the risk that the opioids are sold or exchanged. This setup would give the patient, suffering from a devastating illness, the opportunity to have more of a focus on quality of life at the end of her life.

There is concern that discharging patients from a pain practice serves to further stigmatize them and deny care to those most in need. Pain contracts are an important tool to establish a physician-patient relationship but can become ethically fraught if a patient violates the terms of the agreement and the physician then feels bound to remove them from their practice. This situation may be further complicated if a patient’s objectionable actions may have been influenced by their disease itself. A team-based approach that is mindful of community and outpatient resources may prove to be helpful to find creative solutions to continue to ensure appropriate treatment for patients who may struggle to have access to care. This case illustrates the degree to which decisions to continue care or discharge a patient from a practice are individualized and heavily influenced by the details of each patient’s case. The specter of the opioid crisis suggests that more attention needs to be given to any possible instance of opioid abuse, but particularly in end-of-life cases, individual physician judgment should take precedence to ensure compassionate and ethical care.

**ETHICS COMMITTEE ANALYSIS #1 (JB)**

This case study illustrates a healthcare provider’s ethical conflict of wanting to minimize the potential harm of prescribing opioids to a patient who acknowledges active drug diversion while addressing her legitimate need for pain management due to underlying abdominal cancer. The patient was described as seeking recurrent acute care hospitalizations for pain control but, upon discharge, would sell her prescribed opioids to purchase methamphetamines. The patient has a diagnosis of cancer and presumed methamphetamine use disorder. Compton’s reports that there is a lack of evidenced-based guidelines for the management of chronic pain in patients with a history of addiction.

Although the patient has the autonomy (right) to make her own decisions about the use of prescribed opioids, this right can be overruled by a provider’s concern that a requested treatment is ineffective, can cause harm to the patient or others, or is contrary to existing laws. The provider’s intent is to provide pain relief for the patient. To continue to prescribe opioids knowing that they are being diverted for illicit drugs is neither minimizing harm nor providing therapeutic benefit for the patient. In fact, the patients’ diverting of opioids places others at risk and is illegal behavior. Kotak believes the opioid prescriber shares with the patient an ongoing ethical responsibility for the proper use of the drug.

From an ethical standpoint, the prescribing physician should stop prescribing opioids and refer the patient for substance use treatment. Ideally, the patient would be seen by a hospital-based substance use team and referral for treatment could be arranged in coordination with on-going medical follow-up. Use of methadone or suboxone would not be indicated as the primary drug being abused is methamphetamines. Chang and Compton strongly believe that untreated addiction results in poor functionality and subsequent poor pain outcomes. Once the methamphetamine use is controlled then use of opioids could be reconsidered in conjunction with continued substance use treatment. For patients with a short-life expectancy, deferral of opiate prescribing may not be an option. The question then becomes how to safely manage acute/chronic pain needs. Realistically, there are only two viable options. First, that patient could be admitted to an inpatient hospice unit where the focus of care would be on comfort. Alternately, the patient could have home hospice based services with a designated caregiver who would dispense opiate medication.

**ETHICS COMMITTEE ANALYSIS #2 (MM)**

This complicated patient case identifies several ethical challenges. Do drug users deserve to be treated autonomously? Does someone with a personality disorder have that right? Can a provider ethically refuse to provide narcotic treatment for someone with cancer pain? The two principles of
autonomy and beneficence can be applied as helpful lenses with which to consider all aspects of the case.

Caring for this woman respectfully necessitates considering her wishes. However, her history of cocaine and methamphetamine abuse is important. She has an increased risk of opioid abuse due to this history and has now explicitly told providers that she is not taking prescribed pain medication. It is in her best interest – the physician is guided by beneficence – to refuse to prescribe opioids and to offer alternative pain management strategies. While at first pass it may seem rash (i.e., to make treatment decisions based on a patient’s addiction, not to mention her non-adherence), this is widely considered a “best practice” when considering opioid prescribing.

When considering the patient-provider relationship, both parties ostensibly want a trusting one. The patient has been truthful in admitting sale of her medication. The provider is bound to use that information to guide her care. Further, the provider should be similarly honest with the patient. At this point, his or her role can focus on clear and open communication: review of the risks of illicit drug use, explain treatment options, review the risks of undertreated pain and discuss non-opioid alternatives. Previous providers terminated the relationship due to poor adherence, doing so again would not be for her own good (previous terminations did not improve her course). Considering the patient autonomous – truly autonomous and capable of engaging in treatment discussions rather than seeing her as a meth addict – could lead providers to in-depth care planning discussions suggested above. While she has been honest about what she did with previous prescriptions, she has not been clear or transparent regarding her motives. The physician can present him or herself as honest and forthright and attempt to elicit a reciprocal response from the patient.

Much of this assumes the provider is motivated to expect more from the patient, a difficult task after a frustrating treatment course. She has not followed recommendations and has potentially put one’s medical license at risk by selling her medication. She may be emotionally labile and dramatic. She has terminal cancer and cancer-related pain and is using methamphetamines – ultimately disheartening! The provider should seek peer consultation and acknowledge disappointment about the patient’s decisions thus far. It is imperative to do so in order that non-medical judgments about the patient’s psychosocial background do not influence the physician’s medical recommendations. Maintaining compassion and respect for non-compliant patients is a challenge and in this case doing so involves withholding of opioids.14

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Does Doctor Know Best? Cultural competence is patient-centered care

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THE CASE
Ms. M is a 77-year-old American Indian woman with a history of multiple myeloma who presents with severe back pain. Imaging reveals five new, in addition to four known, spinal compression fractures. She is otherwise healthy. Her physical exam is notable for tenderness to palpation along the lumbar and thoracic vertebrae.

She is being treated in the hospital only for her pain. She has declined orthopedic consultation and chemotherapy. Ms. M is appropriately alert and conversant. The primary care team deems her capable of medical decision-making. Nevertheless, she repeatedly voices concerns that the government and the hospital are conspiring against her and her people, intentionally poisoning them and trying to kill them. She insists that no one in any hospital ever has her interests at heart and see her as a vehicle for scientific experimentation, her current care team included. She is not even convinced that she either has multiple myeloma, or that if she does, that it will prove fatal. She states, “Doctors would never tell white people it’s fatal for them.”

At the time of her diagnosis months ago, she declined any intervention, and she continues to deny the severity of her disease. Presented again with evidence supporting treatment for symptomatic improvement as well as disease modification, she remains strongly opposed to any such treatment.

THE ETHICS DILEMMA
Ms. M carries a deadly diagnosis. However, she distrusts the findings and suggestions offered by those caring for her. Ms. M’s situation puts in tension her well-established right to autonomous decision-making about her health and the obligation of beneficence on the part of the team. Her physicians must determine what is “best” for this patient – or if such a decision is even theirs to make.

STUDENT ANALYSIS (KN, NAN)
The central issue of Ms. M’s dilemma is a pervasive current of institutional and historical racism, discrimination and maleficence towards Native Americans and communities of color. At first mention, this woman’s claims could be written off as the ideas of a conspiracy theorist. However, Ms. M’s resistance to allopathic treatment is justified based on historical context. A review of medical history reveals a sordid past of forced sterilization, coerced experimentation, and intentional infection with incurable diseases. Beginning in the 15th century, smallpox was spread throughout American Indian tribes as a form of ethnic genocide. Later, physicians with the Indian Health Service (IHS) performed non-consensual total hysterectomies and tubal ligations on women without their consent. The IHS also tested new drugs on American Indians in the name of research. The hepatitis trial vaccine program in South Dakota involved giving experimental hepatitis A vaccines to American Indian children. As incentives to participate in the program, they offered free diapers to families and candy to children.

This history seeded a distrust that contributes to worse health outcomes. American Indians/Alaskan Natives are more likely than non-Hispanic whites to experience a delay between cancer diagnosis and cancer treatment. American Indians who perceive discrimination in the clinic are less likely to complete treatment for chronic disease. This cultural dissonance can undermine even the best intentions. In order to alleviate this distrust – and subsequent substandard care – we must acknowledge and educate ourselves about the systemic and historical racism that continues to alienate many patients.

Critics will suggest this places an undue burden on physicians but ignoring Ms. M’s concerns is disrespectful and has not worked. Recent literature suggests that medical curricula can and should confront the systemic inequities perpetuated by generations of oppression. With such training, doctors will develop a more nuanced understanding of patients’ values and concerns, enabling equitable decision-making that honors both autonomy and beneficence allowing future generations of physicians to feel confident in the practice of anti-racist cultural competence, delivering improved outcomes for all patients.

ETHICS COMMITTEE COMMENTARY #1 (NW)
This case describes a patient who is making decisions that the medical team feels are wrong and not in her best interest. Worse still, these decisions will prevent her from getting life-saving care and the reasoning seems unsound (and perhaps insane). The question is what to do next. The principle of autonomy dictates that we respect her decisions and the
principle of beneficence dictates that we not allow her to harm herself because of a possible mental illness affecting her ability to make these decisions.

Determining when a patient has capacity to make decisions can be complex and unrecognized “incapacity” may be common in adult medical patients. In general, patients tend to fall roughly into three categories. The first category [no capacity], is patients who have a definable, clear-cut, major mental illness and we deem them unable to make medical decisions. The second group is comprised of patients who are clearly of sound mind, fully grasp the consequences of their decisions and choose an approach that goes against conventional medical wisdom or societal norms (i.e. Jehovah’s Witnesses). The third group is more difficult [capacity unclear]. There are occasionally patients who seem to pass the test for mental health using our usual, often cursory bedside tests [do you hallucinate? What day is it? Do you understand what will happen if you don’t do this? etc.] but seem to lack insight into the consequences of their actions or present such an unusual set of reasons that suggest to the team that they may have some low-grade [or masked] psychiatric condition or cognitive deficit. What happens next in this case depends on the category to which our patient belongs.

Because of this, a lot hinges on the student’s sentence, “The primary care team deems her capable of medical decision-making.” Given the import of these decisions, the radical nature of the patient’s stance, and almost paranoid beliefs [suggestive of schizophrenia] it is important that this be delved into in much detail, perhaps with more psychiatric consultation. For the purposes of this discussion however, we will take as given that the patient does not have a major psychiatric illness. If this is the case, there is actually not much that the team can do. The team should make every effort to engage the patient and her family in discussions about her reasons. While there is a chance that short-term emotions, misconceptions, or poor advisors are influencing her and a different decision may be made, this patient’s decision may stand after such engagement.

Ultimately then, there are not many options in a case like this. Were the team to decide that the best decision was to pursue therapy against her will, what would happen next? If she held to her decision, they would have to force therapy on her. This may require physical and or chemical restraint. How successful would weeks of intense therapy be with a patient who does not cooperate? Practically, this would be very difficult. By causing harms and violating her autonomy [capacity having been established], such a course would have two ethical “strikes” against it, and would be hard to defend.

ETHICS COMMITTEE COMMENTARY #2 (BO’C)

“I have lived a long time with the white people and I know what they do. They are people who are very kind to anyone who is ready to do whatever they wish.” Sarah Winnemucca (1844–1891), Northern Paiute educator, activist, and author.

This case demonstrates the critical importance of cultural and historical issues to possible resolution of an ethical dilemma, and to accurate diagnosis of a patient’s state of mind.

Ms. M will know of the several-hundred-year history of abusive practices on the part of Anglo-European “officialdom” with respect to American Indian tribes and Nations.

Health care for Native Americans has since 1955 been the responsibility of the Indian Health Service (IHS), an agency of the federal government. The IHS has been rife with inadequate care and abuses of patients. Our patient or her daughters might well have been at risk or even been victims of this malafeasance.

In light of these facts, declarations of intentions “to help you” may be received with skepticism if not outright disbelief and mistrust. This history puts Ms. M’s mistrust of medical advice in a light of rationality and self-protection.

Is Ms. M perseverating, or is she being vigilant in guarding her own safety? Is she engaging in “conspiracy theories” [implying some irrationality], or is she responding reasonably to a well-documented history of threats from “officials” and healthcare professionals to Native American patients, especially women? Is she ignorant of her diagnosis/prognosis, or is she taking precautions against allowing others who may have their own agendas to define her likely outcome and her treatment options? Should we work to redirect this patient’s concerns, or to redirect our own understanding of where she is coming from?

We cannot accurately diagnose Ms. M’s mental status or accurately interpret her rationales without some non-medical, but clinically relevant knowledge. Without this information, we cannot confidently defend as ethical any decisions regarding whether to attempt to override her autonomy [always ethically dicey, for any adult patient with decisional capacity] in refusing medical treatment for her diagnosis of multiple myeloma.

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Disclosure

The views expressed in this article are the opinions of the authors and do not necessarily reflect the views of the Warren Alpert Medical School of Brown University.

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CASE SUMMARY
Ms. Smith, a 64-year-old woman, presented to her PCP with diffuse abdominal pain, nausea, and constipation. She had a history of chronic lower back pain and multiple back surgeries for which she had an implanted intrathecal morphine pump. She was referred to the hospital for an esophagogastroduodenoscopy and colonoscopy, both of which were unrevealing. After the procedures, Ms. Smith felt “miserable” and lethargic and was subsequently admitted to the hospital for observation. The admitting physicians verbally confirmed her code status as DNr/DNI.

The next morning, a nurse reported that Ms. Smith had been complaining of severe headache and leg shaking. Around 7 a.m., Ms. Smith was discovered unresponsive in her bed. She responded to naloxone and sat bolt upright, confused and agitated, swinging her arms and attempting to escape the bed. Given this vigorous response to naloxone, the team considered opiate overdose from a malfunctioning morphine pump as a potential etiology for the event. However, given the possibility of an intracranial hemorrhage or stroke, an urgent head CT was deemed necessary. It was clear that having the patient remain still for the scan would be a difficult task, especially as her combativeness persisted after receiving 2 mg of lorazepam. The team was hesitant to give more benzodiazepines in the setting of potential opiate overdose, especially since the patient’s code status was DNR/DNI and she could not be intubated if needed.

After reviewing the chart, the attending physician found it unusual that such a relatively healthy, young woman was not Full Code and explored this with Ms. Smith’s husband, her medical power of attorney. Mr. Smith explained that his wife had filled out an advanced directive with her PCP, delineating her wishes to be DNr/DNI, but that the document was at home. After a discussion of the implications of the DNR/DNI status, the husband clarified that Ms. Smith would want life-saving measures if there were a reasonable chance of recovery.

After the husband’s explanation of his wife’s wishes and despite the presence of an advanced directive, the team decided to change the patient’s code status to Full Code to allow more leeway in administering additional medications with the potential to cause respiratory suppression in the workup of this unresponsive episode. In this case, giving additional lorazepam could potentially be life-saving if the CT showed a brain hemorrhage. On the other hand, the patient was clear in her DNR/DNI status prior to admission and had written documents expressing these wishes.

Medical Students’ Ethics Analysis (EW, SR, NM)
As Ms. Smith’s case demonstrates, despite tools such as advanced directives and powers of attorney, it remains difficult for patients to achieve prospective autonomy in regards to future care. This results in myriad ethical dilemmas. Many patients with DNR/DNI orders have conflicting wishes when queried with hypothetical scenarios. Additionally, medical details are impossible to predict which makes directives misleading and difficult to adapt. Therefore, would it have been ethical to carry out Ms. Smith’s advanced directive since it was inflexible and presupposed unrealistic understanding on the patient’s part? Surrogate decision makers offer a plausible alternative since they can adapt to new details and information while keeping the patient’s values and wishes in mind. However, surrogate decision makers frequently make choices that do not align with what the patient would have decided in the same situation. Given this, was it ethical for Ms. Smith’s husband to change her code status in the face of her acute condition and the need for potentially life-saving sedation? How should the balance between patient autonomy and physician non-maleficence be approached? To explore this dilemma, we consider the history and evolution of ethical issues related to DNR/DNI orders.

CPR orders were originally intended to restrict use of CPR for patients who had decided that the potential harms of resuscitation outweighed the potential benefits. Primarily, these patients were nearing the ends of their lives, due to age or irreversible illness. As DNR orders became more common, many patients who did not wish to undergo CPR still chose to undergo procedures, including those requiring anesthesia or sedation, often for palliative purposes. This created undeniable discomfort, particularly for anesthesiologists tasked with balancing the goal of achieving analgesia/amnesia against the potential for cardiovascular collapse inherent in administering anesthesia/sedation. Subsequently, many anesthesiologists assumed the DNR order to be suspended during surgery, and this assumption was often made without the patient’s knowledge or input.
Despite being employed by many organizations, the policy of automatically suspending DNR orders poses many ethical (and legal) issues, and certainly violates the principle of a patient’s right to autonomy. Of course, that is not to say that DNR orders should never be suspended.

On the role of DNR orders in surgery, Truog offered several reasons that may ethically justify suspending a DNR order in cases requiring anesthesia/sedation. First, administering anesthesia/sedatives by nature involves the purposeful depression of vital functions followed by a skillfully planned “resuscitation”; therefore, any consent for anesthesia implies consent for the necessary resuscitation. Second, spontaneous cardiac arrest is notably different from an arrest that occurs “as the result of a therapeutic intervention” (i.e., respiratory depression from a drug overdose), as the latter is significantly more likely to be reversible. We posit that these conditions applied to the administration of sedatives in the case of Ms. Smith, making it ethically defensible to suspend her code status for sedating her to obtain emergent diagnostic imaging.

Since the inception of DNR orders, conventions for physicians around respecting these orders have undergone substantial change. One approach towards a more ethical use of DNR orders has been for physicians to adopt a “procedural approach” to determining patients’ preferences, perhaps recording specifically that a patient does not want ICU care or endotracheal intubation, for example. An alternative “goal-directed approach” has been suggested, in which discussions of the patient’s goals, values, and fears are used to inform the physician’s decision of which procedures should be performed under which circumstances in real time. This approach is accompanied by several challenges, perhaps the most significant of which is that it requires the clinicians making the decisions to have a nuanced knowledge of the patient’s wishes. However, a goal-direct approach recognizes that it is impossible to represent the full range of scenarios that may arise over the course of care, particularly when anesthesia and sedation are involved, and offers the best opportunity for the patient to experience their desired outcome.

**ETHICS COMMITTEE ANALYSIS (AN, KDEC)**

There are multiple options in this scenario: (1) treat the patient for suspected morphine overdose and do not obtain head CT, (2) administer medications needed to obtain head CT; if this results in respiratory compromise, proceed to intubation, (3) administer medications needed to obtain head CT; if this results in respiratory compromise, do not proceed to intubation.

If this patient’s code status is an accurate reflection of her wishes, then it is not appropriate for the care team to place her in a position that risks need for intubation [option #3]. Options #1 and #2 are both ethically consistent; the challenge lies in clarifying her wishes. The medical team’s bias towards a Full Code status for this relatively young and healthy patient has no bearing on her autonomy to refuse intubation. However, there is compelling information to suggest the patient’s code status is not consistent with her actual wishes. Because she is unable to convey her wishes, we must rely on prior documentation, reach out to her PCP, and seek interpretation from her surrogate decision-maker.

The literature sets precedent that code status should not dictate care, but rather inform exploration with the health care proxy of specific medical situations. The spouse’s willingness for this patient to be intubated should be taken into account because “research suggests that many patients do not expect surrogates to rigidly follow their traditional advance directives, but rather intend for surrogates to exercise judgment to determine the course of care when there is insufficient information available or for extenuating circumstances.”

Silveira et al. suggest we must “accept surrogate decisions as valid expressions of the patient’s autonomy, even when those decisions conflict with the patient’s written preferences.”

The PCP should play an important role in advanced care planning. Resources such as The Conversation Project offer tools to achieve the widely called for goal “to transform advance care planning from the act of signing a form to a process.” However, plan as we may, “no prior discussion or documentation can anticipate all scenarios.” It is unreasonable to assume that this patient thought through the present case when she made her wishes known— but it is still possible she may have considered similar circumstances. If her spouse feels confident that she would accept possible intubation in this instance, it is reasonable for the medical team to move forward with CT scan, even if anesthesia is needed, and proceed to intubation should that become necessary.

**References**


Disclaimer

The views expressed herein are those of the authors and do not necessarily reflect the views of the Alpert Medical School and the Department of Medicine, Brown University.

Acknowledgment

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Counseling Women on Long Acting Reversible Contraceptive (LARC) Use While Maintaining Reproductive Justice

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THE CASE
A 32-year-old G7P5115 (seventh pregnancy, 5 live births) mother at 30-weeks of gestation was admitted with preterm labor for a trial of labor after cesarean section. Her first five deliveries were uncomplicated vaginal births that resulted in healthy babies; however, her sixth was an emergency C-section for preterm premature rupture of membranes and fetal distress. The infant was born premature, and did not survive. For this pregnancy, the patient was not adherent to prenatal care, only attending some prenatal appointments.

The Department of Children, Youth, and Families (DCYF) removed her first child due to concerns of neglect. She elected to give each of her subsequent children to DCYF for placement and planned on giving this child to DCYF as well. The medical student assisted the patient in her labor and delivery room, discussing her current concerns about the delivery and her experience with birth control. She hadn’t had “good experiences” with birth control in the past and had no plans for postpartum contraception. When asked if she was interested in preventing future pregnancies, the patient said, “No, I’m not.” The student verified that the patient had correct information about birth control options. The patient acknowledged the information, saying that having a baby at this point was “no big deal.” Other providers had explained the dangers of multiple pregnancies on her health, the potential negative outcomes for future unborn babies, the hardship of living in the DCYF system, and the ease of various birth control options. The medical student felt a professional obligation to address birth control options with the patient even though the patient was consistent in her lack of interest in starting a birth control method.

THE ETHICS DILEMMA
Should reproductive health practitioners continue to discuss LARC use to women who repeatedly decline?

STUDENT ANALYSIS (CG, NN, NN)
This provider-patient interaction highlights the tension between patient autonomy and medical beneficence. The reversibility, widespread access, and insurance coverage of long acting reversible contraceptives (LARCs) make these an attractive solution to prevent unintended pregnancies for women. The American College of Obstetricians and Gynecologists states that women have the “right to safe childbearing with resources available to reduce maternal and infant morbidity and mortality” in their statement of policy for LARC use. Although some may argue that this stance is paternalistic, the Hippocratic oath gives clinicians the responsibility to offer treatment to patients whenever possible. Multiparity is a well-studied risk that has been linked to increased complications like placenta previa and low Apgar scores.

Most would agree that unfettered access to reproductive choices is a worthy goal, perhaps especially for those caring for patients living in poverty. LARCs offer a solution to help break the vicious cycle of poverty by allowing women to exercise sexual autonomy without the financial implications of raising a child. The percentage of children born into low-income families has gradually been increasing in recent years. Children in low-income families are more likely to be premature, have failure to thrive, and to later develop illnesses. This increases psychological, financial, and emotional stress on the family and poses a financial burden for the healthcare and social systems.

Physicians have a responsibility to care for their patients in ways that will benefit those patients long-term and also to consider the effects that those patients have on the healthcare system. Practitioners should help protect the system to ensure optimal care for all. Advocacy for contraceptive use is rooted in the passion to improve patient sexual freedom and healthcare costs. LARCs are safe, reversible options that should be presented to patients, especially those at higher social risk for unplanned pregnancies. Encouraging LARC use has significant benefits for both the patient and society as a whole.

However, concerns have been raised about whether efforts to expand access to long-term birth control methods limit the ability of marginalized women to exercise their right to reproduce. It has been well documented that disenfranchised women have been forcibly sterilized. The Eugenics Board of North Carolina, established in 1933, oversaw the practice of involuntary sterilization of prison inmates and hospitalized psychiatric patients as a tool to combat poverty and welfare costs. Welfare officials petitioned for sterilization of welfare recipients to control rising expenditures. Well-meaning contraceptive advocates during the Progressive era suggested promotion of contraception to control growing immigrant and poor populations.

In the 1990s, a levonorgestrel-releasing implant was
aggressively marketed to poor women and women of color, especially in urban neighborhoods. Several bills were proposed that provided financial incentives to female welfare recipients who agreed to use this method. Judges have offered it as an alternative to jail time for women convicted of drug abuse during pregnancy.

Such coercive approaches are hard to justify. However, due to the convenient reversibility of LARCs, is it permissible to aggressively encourage LARC use for low socioeconomic and young women? A reproductive justice approach would involve the perfect balance between reducing barriers to LARC access, especially amongst those who have poor access to healthcare, while respecting a decision to not use these methods. In the patient scenario presented, healthcare providers have a strong obligation to counsel the patient to adopt the use of LARCs because of her pregnancy history and social history, despite the patient repeatedly declining. Health providers should work to improve access to LARCs while respecting patient autonomy. This approach is tested in this case, in which the physician has a hard time convincing a patient that her reproductive choices are, in fact, “a big deal.”

ETHICS COMMITTEE ANALYSIS #1 (NA)

This patient has the right to decide whether or not she wants to use birth control. In this scenario, respecting her autonomy has a direct impact on others, namely her children who are now wards of the state. Yet, pushing a conversation on someone who is not willing or ready to listen is fruitless at best and paternalistic at worst. The medical team’s primary responsibility is the patient. There is a conflict between the student’s sense of responsibility to an unborn baby and desire to keep a patient happy through labor and delivery. While medical professionals try to act in the best interest of their patients, many decisions focus on what the doctor thinks is best, with less concern for a patient’s individual circumstances. When the patient’s conception of “best” does not match the medical team’s, the resulting paternalism can be frustrating for all. Respect for autonomy requires that physicians remember that the patient willingly sought care and has the right to make her own decisions. Despite the concerns about the patient’s children, her autonomy with regards to birth control should be respected.

A conversation earlier in the pregnancy might have been tremendously helpful to understanding the patient’s choices, if possible. Contraceptive counseling in clinics has been associated with increased hormonal contraceptive use, and counseling regarding specific types of contraception has been associated with an increase use of those methods. In a more relaxed setting, further questioning into the patient’s circumstances and motivations and a better understanding of her barriers and hesitations might have helped alleviate the frustrations of the medical student.

However, the medical student’s reach is limited to what she can do in the hospital. This much-needed conversation was not going to take place during the patient’s labor and delivery, which the student likely realized. Similarly, the physicians on the team can only provide help to patients who want it. The best that an inpatient team can do is to meet the patient’s needs at the point of care and send her with as many tools as she can and is willing to carry.

ETHICS COMMITTEE ANALYSIS #2 (EM)

Ethical considerations for the medical student include the precarious position as a student observer and the potential to anger the birthing woman to the point of expulsion from the case. There may be a personal agenda from the medical student to prevent future pregnancies, based on sympathy for children who are adopted or living in the foster care system. Each of these factors present ethical dilemmas and may be adding to moral fatigue for the medical student.

Should the student insist on having a conversation about birth control with the laboring mother? The ethic of respect for persons includes a commitment to the duty-based ethical principle of autonomy. A birthing mother, with capacity, has a negative ethical right to be free of the pressure of listening to education that she does not want, and the health care team should respect this.

However, the mother also has the positive right to competent care from the health care team, which includes education. The principle of fidelity establishes the responsibility of loyalty and trust between the patient and the providers. In this case, there is conflict between the ethical duties to respect autonomy and maintain fidelity. Ranking and balancing the duty-based principles of autonomy and fidelity are best understood within the American cultural context of placing high value on autonomy. Autonomy therefore becomes the prevailing or *prima facie* principle. Additionally, it is unlikely that health promotion or birth control education efforts, during labor, would produce the hoped-for results.

Perhaps another health care team member at another time may be able to build a trusting relationship to advance optimal patient-centered options while providing respectful treatment of birthing mothers, particularly in cases of infant relinquishment.

Finally, the medical student should consider the reexamination of her personal agenda in this case, in which she would like to prevent future pregnancies based on sympathy for children who are adopted or living in the foster care system and the assumption that future children will also be relinquished. The primary obligation must be to the birthing mother and the impact of multiple pregnancies on her physical and emotional health. Perceived prejudice by healthcare providers could negatively impact the health of the birthing mother. There is no definite information here that her previously relinquished children remain in foster care or that they have had difficult life courses. Additionally, there are legal and ethical limits to the scope of interference that can be unilaterally imposed on the birthing mother.
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Putting the “No” in Non Nocere: Surgery, Anesthesia, and a Patient’s Right to Withdraw Consent

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THE CASE
Ms. K is a 53-year-old G2P1 with Stage IIIA endometrial cancer who presented to the Women & Infants ambulatory surgical unit for a bilateral salpingo-oopherectomy and lymph node dissection. In the pre-operative unit, a resident reviewed the standard informed consent protocol with the patient, outlining the reasons for the procedure, the risks and benefits of proceeding, and the risks and benefits of doing nothing. The resident emphasized the necessity of surgery to stage the cancer and prevent further spread. Ms. K appeared anxious, but signed the consent form. The anesthesia team then proceeded with their evaluation, determining that she had hypertension, type 2 diabetes, an anxiety disorder, a BMI of 58.2 kg/m² and a Mallampati Class IV airway that she had hypertension, type 2 diabetes, an anxiety disorder, a BMI of 58.2 kg/m² and a Mallampati Class IV airway difficult for intubation. The team thus decided to proceed with an awake intubation, using video laryngoscopy to visualize the larynx with minimal sedation to reduce the risk of airway collapse. Ms. K agreed to the plan.

The nursing staff then began preparing her for surgery, including inserting a peripheral IV for fluid and medication delivery. On the first failed attempt, Ms. K cringed. After the fourth unsuccessful needle stick, she became agitated and said, “I don’t want to do this anymore” multiple times. The crowd of IV nurses now assembled at her bedside reassured her and finally established access. The first medication through her IV was midazolam for mild sedation. She was then given pre-operative antacid but regurgitated half the solution. She was instructed to drink another cup, which she eventually swallowed through a steady stream of tears.

In the operating room (OR), the anesthesiologist began intubation. Despite the video camera attachment, the first few attempts were unsuccessful. She gagged multiple times and regurgitated fluid that obscured view of her airway. Over and over, she cried, “I don’t want to do this – I want to go home,” to which the anesthesiologist and nurses replied, “It’s ok, we’re almost there.” Finally, with a collective sigh of relief, the endotracheal tube was properly inserted. Medications for full sedation were administered and when the patient was fully sedated, the operation proceeded.

STUDENT ANALYSIS (CY, RH, WK)
This case involves a patient originally deemed to have full capacity who has consented to potentially life-extending surgery. In the process of preparing her for the operation, she expresses reluctance with continuing, to the point of specifically asking that the procedure be aborted. Many ethics analyses center on the presence or absence of proper informed consent; fewer discuss withdrawal of consent. However, the right to withdraw consent remains a standard component of every informed consent protocol. The UK Department of Health offers a useful paradigm for such situations: “A person with capacity is entitled to withdraw consent at any time, including during performance of a procedure. Where a person does object during treatment, it is good practice for the practitioner, if at all possible, to stop the procedure, establish the person’s concerns and explain the consequences of not completing the procedure.” It has in fact been deemed more than just “good practice” for the practitioners to stop the procedure – in a 2012 case, Pallacovitch v. Waterbury Hospital, the plaintiff sued on grounds of battery after her request to stop a blood draw was ignored. In this case, the patient’s initial refusal occurred before medications which might interfere with her capacity had been administered. At that moment, pausing preparations for the procedure would have been safe and possible from a medical standpoint. Presuming that this patient was indeed attempting to withdraw her consent, the team would have been violating her basic rights to autonomy and self-determination as well as opening themselves to medicolegal culpability.

The argument could be made that the patient did not have capacity to withdraw consent. Evidence that decision-making capacity is intact includes the ability to understand the current situation, use relevant information, and communicate preferences supported by reasons. The American Society of Anesthesiologists identifies groups of patients with “limited” decision-making capacity, including patients who can usually make decisions but whose decision-making capacity is temporarily altered. In these cases, physicians must use clinical judgment to determine a patient’s capacity, taking into account altering agents such as preoperative sedation and pain medication, as well as non-pharmacologic factors such as pain, panic, and shock. As previously mentioned, this patient’s initial refusal occurred before the administration of any medication. Perhaps, then, the clinical judgment of the team deemed that panic or pain diminished her decision-making capacity. However, should her mental state have been called into question, the team should have attempted to re-evaluate her capacity at that moment. This would involve a complete stop in the procedure to allow thorough reassessment of the patient’s understanding of her current situation and rationale regarding her desire to
withdraw consent. Without such an evaluation, a determination that she lacked capacity would be hard to defend.

In this case, all members of the health care team ignored the patient’s requests to stop the procedure in favor of continuing as originally planned. That choice could have been made for a myriad of reasons: not wanting to waste time and resources spent on preparing the operation, reluctance to delay a busy OR schedule, or interpretation of her statements as an expression of pain rather than withdrawal of consent. However, continuing a procedure in light of such statements is in direct opposition to basic ethical principles of autonomy and decision-making capacity.

ETHICS COMMITTEE ANALYSIS #1 (TS)
This case presents an interesting, though unfortunately common, situation of a patient who consents for a procedure but then has second thoughts when she is experiencing physical discomfort. Considering usual practices and for the purposes of this analysis, we will assume that the patient was given a description of the operative plan and potential complications before signing the consent form. That said, no patient can ever be fully informed about what they may experience. Hearing a laundry list of possible complications and difficulties that “may” arise is a lot more palatable than actually experiencing the pain of multiple failed IV sticks, the nauseating taste of medication solutions, and the visceral discomfort of medical instruments being stuck down one’s airway. The reality may end up being more than patients had initially thought they were agreeing to endure. Accordingly, while the pre-operative consent conversation is an important step in ensuring that we are respecting patient autonomy, we must also consider that a patient’s wishes may change at any time and we must address their concerns as they arise. 

In this situation, when the patient verbalized “I don’t want to do this anymore,” taking the time to pause and address the patient’s concerns would have been the best way to ensure respect of the patient’s wishes if this could be done safely. This patient likely retained decision-making capacity at that point in time. Though the healthcare team was surely doing what they thought was in her best interest by continuing their attempts at starting an IV and later intubating the patient, ignoring her protests denied her the opportunity to be involved in decisions about her own care.

As the team may have assumed, it is very likely that the patient was just scared in those moments of discomfort and would have chosen to continue with the procedure if given the chance to have a discussion, but making this assumption without her input may risk a paternalism that undermines the patient’s autonomy and ultimately her trust. Breaching autonomy could severely damage the doctor-patient relationship, discouraging her from seeking medical attention in the future and doing more harm than good in the long term. While the argument could be made that continuing the procedure was an act of beneficence by the healthcare team, as the surgery was a vital component of her cancer treatment, it is not our place as healthcare providers to unilaterally make decisions on behalf of the patient, but rather to try to incorporate their values and ideals in shared decision making which is the basis for a strong doctor-patient relationship and improved healthcare outcomes.3,4

Taking the time to address patient anxieties when trying to make progress with a procedure can be very frustrating, especially when facing a busy day’s schedule and considering the expense of OR time. But if a patient of sound mind clearly and repeatedly states that she would like to stop, I think we are ethically obligated to at least hit pause.

ETHICS COMMITTEE ANALYSIS #2 (GB)
The vignette raises questions about autonomy, beneficence, non-maleficence. Was the patient’s autonomy violated? The patient gave informed consent to both the surgical procedure and anesthesia. Informed consent involves providing the patient with information about the nature of the surgery, the expected benefits, possible risks and adverse events, alternative treatments to the surgery and consequences of not having the surgery.5 It has become standard practice for anesthesiologists to consent patients for anesthesia with a separate consent process.

Autonomy was preserved up until pre-operative discomfort made the patient cry out that she did not want to go through with surgery. The team may have assumed that this represented anxiety that would be overcome once the IV and endotracheal tube were in place and not an informed withdrawal of consent. But they did not assess that.

The principle of beneficence was upheld since the patient’s chances of survival with the surgery seem greater than her chances without the surgery. Some authors have argued that beneficence should be seen as balancing the benefits against the risks.6 We do not know whether the surgical consent as outlined above described the risks and the consequences of not doing the surgery.

The need to do no harm was observed in this case. While some might see continuing despite her cries as causing transient distress, the overall harm of cancelling the surgery would far outweigh the harm caused by continuing despite her anxieties. Admittedly, an effort to assess the patient’s fear ahead of surgery and the risk of surgery in the morbidly obese7 might have helped her understand and reduce her distress at the time of surgery.

In summary, assessing the patient’s anxiety as she was prepared for surgery may have allowed her more autonomy and reassured the team that it was justified in continuing with the procedure despite her initial protestations.

Acknowledgments
The authors thank Dr. Thomas Bledsoe for kickstarting this ambitious endeavor and lending his tireless support to every step of the process.
References


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Treating Pain in an Established Patient: Sifting Through the Guidelines

ALAN L. GORDON, MD; SEAMUS L. CONNOLLY, DO

ABSTRACT
The CDC Guideline for Prescribing Opioids for Chronic Pain, published last March, provided major steps toward bringing the medical community together to address the opioid epidemic in the U.S. However, the Guideline focuses primarily on treatment of new inductions into opioid therapy for pain. Physicians may have difficulty figuring out how to apply the CDC’s recommendations to patients who are already receiving opioid maintenance therapy for chronic pain. Patients already maintained on opioids for chronic pain should not be subjected to abrupt cessation or rapid tapers, and the CDC’s Guideline confirms this. Physicians should not balk from treating opioid-dependent patients with chronic pain, and the CDC’s recommendations do contain helpful information if one reads through them carefully. This article attempts to distill the major points from the Guideline for the treatment of chronic-pain patients already on long-term opioid therapy.

KEYWORDS: Centers for Disease Control and Prevention (U.S.), chronic pain, analgesics, opioid, practice guidelines as topic

INTRODUCTION
The CDC Guideline for Prescribing Opioids for Chronic Pain,1 published March 2016, provided major steps toward bringing the medical community together to address the opioid analgesic abuse, addiction, and overdose epidemic that has gotten exponentially worse in the last 15 years. There was reason to focus on prescribing practices, and there is reason to believe that these new guidelines will be broadly implemented with a positive effect. However, readers may note that the guidelines focus primarily on treatment of new inductions into opioid therapy for acute pain. There may be cause for concern that patients already receiving opioid maintenance therapy (i.e., “established patients”) may not gain optimal benefit from the CDC guideline.2

This is not to say that the CDC did not include optimal practice suggestions for patients already taking opioids. At earliest opportunity, the provider is urged to outline treatment goals with opioid-maintained established patients, emphasizing functional improvement; this is similar to standard practice in initial encounters with opioid-naïve patients.1, p.19 The visit should culminate in an agreement on objective outcomes that will govern opioid therapy being continued, changed, or terminated.1, p.19 Established patients taking in excess of 90 MME per day should be seen at an encounter separate from a regular prescribing visit to offer opportunity to reconsider treatment.1, p.21 Guidelines suggest that all relevant decisions should be made with the patient’s active involvement. Should tapering be sought by the patient, the clinician may cautiously implement a taper, as suggested.1, p.24 This unique taper is the longest of those utilized in standard practice and may include repeated pauses.1, p.24 The optimal target dose may or may not be complete opioid discontinuation, as decided by the patient who has been educated by the treatment provider.1, p.24 These are reasonable medical suggestions that, if broadly implemented, would likely provide substantial benefit.

PROBLEMS WITH THE GUIDELINE
Unfortunately, the CDC’s recommendations for established patients appear within a lengthy, cumbersome document in incongruent patches. Pertinent passages for these patients appear near the middle of the recommendations, and there are no shortcuts, hints, or hyperlinks in the document that would afford efficient reference. If one skims headlines and summaries to find specific information, the document seems to imply that treatment of established patients is similar and auxiliary to the treatment of patients who have not been on opioid medication. In fact, however, treating established patients differs strongly from therapies afforded to opioid-naïve patients but is equally important. Not one of the several clinical tools created to ease guideline implementation outlines unique details of treating established patients. Any reasonable physician might invest several hours studying the guideline and still lack clarity regarding standards of practice.

Significant numbers of patients are already taking over 90 MMEs a day by prescription, and the CDC’s guideline says little about how the physician is expected to treat such patients.3 Abruptly switching a patient to a significantly lower dose or rapidly tapering a patient who is already dependent on opioids would arguably represent a deviation
from the standard of care, not to mention a violation of medical ethics (“first, do no harm”). A potential contributor to the current opioid epidemic is the unwillingness of some prescribers to help patients who have a substance abuse history or who are having difficulty tapering down from long-term opioid prescriptions. Abandoning such patients can precipitate crises and increase psychosocial risk factors that contribute to worse outcomes.

There is a possible unintended consequence of the guideline as currently available. A new prescribing pattern may arise as providers – motivated by their misreading or their institution’s misreading of the guideline, or by payer restrictions on reimbursement – discontinue or alter medical treatment in a manner contrary to the new practice standards and contrary to the humane treatment of patients experiencing chronic pain. As the AMA notes:

“[T]he recommendations on dosage and duration limits conflict with the approved product labeling for opioids and with the U.S. Food and Drug Administration’s own conclusions about the wisdom of establishing a maximum dose based on daily morphine milligram equivalents. We [the AMA] are concerned that insurers and other payers will use the recommendations to deny or impose new hurdles to coverage of any dose that exceeds the CDC’s recommended thresholds. We are concerned that pharmacies will be under pressure to deny prescriptions that exceed those thresholds, and that patients who require more than 50 morphine milligram equivalents per day could face additional prejudice and stigma.”

It is likely to benefit the entire medical community if the CDC were to update its recent guideline and clinical tools, such that tailored recommendations for treating opioid-established patients could be obvious and easy to obtain.

Several commentators have criticized the CDC’s reliance on very limited empirical evidence, including low-quality study data, in its development of the recommendations in the 2016 guideline.

Applying the Guideline to Established Patients

The CDC’s guideline presents 12 recommendations, most of which are worded in such a way as to apply primarily to novel opioid induction patients. Table 1 (next page) presents suggested applications of these recommendations to treating established patients who are already on long-term opioid medication for chronic pain.

SUGGESTIONS FOR CHANGE

Just as the opioid epidemic has resulted from a complex interaction of factors, its resolution will need to come from multiple sources, not just the issuance of additional clinical practice guidelines and restrictive policies that further discourage physicians from helping patients with chronic pain and/or a history of substance abuse.

Research

The FDA and other scholars have called attention to the dearth of high-quality scientific research evidence on the treatment of chronic pain, underscoring the importance of funding for programs and studies to find safe, effective treatments for chronic pain. Long-term follow-up data are particularly lacking, which contributes to the poor quality of studies. High-quality research, however, is expensive, and improving the empirical data available to help inform treatment decisions for patients with chronic non-cancer pain will likely require increased funding to support longitudinal studies.

Education

Education will also play an important role in reversing the opioid epidemic. There is evidence that continuing education through the use of clinical vignettes can help to improve prescribing behaviors in primary care physicians, for whom the new CDC guideline is intended. The hectic pace of modern medicine places extreme demands on the physician’s time; it is unrealistic and unreasonable to expect most physicians to wade through a lengthy set of cumbersome guidelines repeatedly whenever decisions must be made about treating patients with chronic pain. For clinical education to be effective, priority should be given to materials that simplify the application of guidelines like the CDC’s.

Additionally, there is room for improvement in the education that patients receive about treatments for chronic pain. For example, many patients have never heard of opioid-induced hyperalgesia. Similarly, more patients and members of the public are familiar with opioid analogics than with non-opioid treatments like Duloxetine or Pregabalin. The CDC’s guideline places a high emphasis on improving communication between the physician and the patient and allowing the patient to take a more active role in treatment decisions regarding the use of opioids. Physician assistants and other medical practice staff (e.g., nurses, secretaries) may be able to assist in locating useful patient- and family-education resources.

Policy Changes

Individual physicians should be expected to make a very important contribution reversing the opioid epidemic, however effective strategy will require, a systematic approach that includes public education, policy changes and access to care. As Kay and Bernstein argue, “[i]nterventions beyond
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Application to Established Patients</th>
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<tr>
<td>1. “Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.”</td>
<td>Discuss with the patient various nonpharmacological treatments and nonopioid medications that may help to lessen risk. Patients may not be aware of existing non-opioid treatments.</td>
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<td>2. “Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.”</td>
<td>Re-evaluate with the patient the goals of treatment, and consider renewing or reformulating the treatment plan as the patient’s goals may change. Provide the patient with educational materials to help inform their treatment-planning decisions.</td>
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<td>3. “Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.”</td>
<td>Periodically reevaluate the treatment plan, and reaffirm the responsibilities of the clinician and the patient in the treatment process.</td>
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<td>4. “When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.”</td>
<td>If the patient is currently taking ER/LA opioids, consider transitioning to an opioid with a shorter half-life.</td>
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<td>5. “When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.”</td>
<td>If dose escalation presents, consider the likelihood of tolerance or opioid-induced hyperalgesia, and discuss with the patient the pros and cons of different treatment options, such as transitioning to a different opioid or trying a slight decrease in dose if hyperalgesia is suspected. For patients already taking ≥ 90 MME/day, re-assess treatment goals with the patient, and discuss the risks and benefits of different treatment options. Monitor for factors that may increase risk, such as concurrent use of other medications such as tricyclic antidepressants.</td>
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<td>6. “Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.”</td>
<td>In the event of new-onset acute pain in an established patient, consider the likelihood of tolerance or opioid-induced hyperalgesia, and discuss with the patient the pros and cons of different treatment options, such as transitioning to a different opioid or trying a slight decrease in dose if hyperalgesia is suspected.</td>
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<td>7. “Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.”</td>
<td>Schedule treatment-planning appointments every three months with established patients.</td>
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<td>8. “Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.”</td>
<td>During the treatment-planning appointment, discuss existing risk factors and steps the patient can take to reduce these risks.</td>
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<td>9. “Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.”</td>
<td>Shortly before each treatment-planning appointment, check the PDMP to monitor any new prescriptions of controlled substances for the patient.</td>
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<td>10. “When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”</td>
<td>In established patients, consider adding a urine tox screen as a component of the annual physical exam.</td>
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<td>11. “Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.”</td>
<td>Shortly before each treatment-planning appointment, review the patient’s current medications. If benzodiazepines or other medications that may increase risk (e.g., tricyclic antidepressants) are present, plan to devote some of the treatment-plan discussion time to educating the patient about these risks and strategies for harm prevention.</td>
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<tr>
<td>12. “Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.”</td>
<td>Keep contact information for methadone clinics, pain specialists, and buprenorphine waiver clinicians handy, and review the common warning signs of opioid misuse. In the event of suspected misuse, consider screening for opioid use disorder, and consider consultation and/or referral for specialist care if warning signs of opioid misuse are present and do not resolve. Do not abruptly discontinue patients with opioid use disorder from your practice.</td>
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* Quotations from the CDC Guideline’s Box 1, p. 16
the provider level, such as policy change and increasing access to care, are likely necessary to adequately address the opioid situation.9 The AMA has noted that the current situation in the U.S. with payment models and insurance coverage may result in undesirable uses of the CDC’s guideline by insurers and other payers to deny coverage to patients with legitimate treatment needs.5 Although radical change in payment models for medical care in the U.S. is unlikely to happen overnight, some existing problems might be addressed through advocacy on the part of patient groups and professional organizations such as the AMA, AAAP, ASAM and others. Target legislative changes, for example, might include requiring insurance reimbursement for medication-assisted treatment for opioid use disorder. Patients and their families will likely have an important role to play in driving policy changes.

CONCLUDING THOUGHTS

The CDC has noted that improved physician-patient communication about opioids is one of the key objectives of the guideline.11 The guideline’s individual recommendations, at first glance, may intimidate prescribers whose patients are already taking over 90 MMEs per day, but physicians should not discharge these patients from care or initiate rapid tapers. The guideline itself recommends against rapid tapers. Instead, patients should be given an active role in treatment planning.6 The physician’s practice as a whole, including other staff, may be able to assist in providing educational materials to patients and their families to facilitate this process.

There are numerous resources freely available from the CDC and other agencies, including decision checklists, informational handouts and posters for patients, and training materials.10,11,12 Lembke, Humphreys, and Newmark provide excellent risk-management suggestions, including a set of easy-reference tables, one for each stage of treatment (before beginning opioids, during opioid treatment, and during a taper to discontinue).10 These materials may be helpful starting points for discussions with patients about realistic expectations and treatment goals.

References


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**ABSTRACT**

New Rhode Island regulations require physicians and other licensed practitioners to make significant adjustments to comply with new requirements for prescribing narcotics for chronic pain. Responding to the opioid epidemic, the new rules are intended to improve patient safety by changing physicians’ prescribing patterns. However, the new rules may overlook the importance of treatment-access problems and the importance of buprenorphine products for treating pain and opioid dependence. Empirical data have demonstrated the safety and efficacy of buprenorphine in treating opioid-dependent patients with chronic pain, including those with and without substance abuse histories, but access to buprenorphine treatment remains limited throughout the state. The new regulations call upon physicians to make use of consultation services, which are also of limited availability. Although well intentioned, the new rules may contribute to treatment-access problems, and patients with chronic pain may resort to higher-risk “street” drugs when they are unable to access safe but effective medical treatment.

**KEYWORDS:** analgesics, opioid, buprenorphine, social control, formal, chronic pain, referral and consultation

**BACKGROUND: UNDERSTANDING THE OPIOID EPIDEMIC**

The national epidemic of deaths related to opioid abuse and dependence is recognized as a crisis of historic proportions, and Rhode Island has not escaped its effects. Drug overdose death rates are roughly five times greater than they were in the early 1980s, and the percentage of fatal overdoses involving opioids roughly doubled within the first 10 years of the 21st Century. In 2009, deaths from drug overdoses exceeded those from motor vehicle accidents in the U.S. for the first time, with a significant portion of these deaths involving opioids. Because many of the overdose deaths occurred in patients who had originally obtained opioid prescriptions, many states have been developing new or revised legislation to control physician prescribing practices.

The opioids that have been associated with the highest morbidity and mortality include oxycodone, hydrocodone, and methadone, which are all full opioid agonists. These are often taken in combination with alcohol or other drugs, frequently benzodiazepines. Concurrent use of opioids with benzodiazepines increases the risk of overdose.

The Centers for Disease Control and Prevention (CDC) issued a new Guideline for Prescribing Opioids for Chronic Pain in March 2016, intended to help curb the rate of opioid overdose deaths and the rising tide of opioid dependence in the U.S. The Guideline provided recommendations aimed mainly towards primary care physicians treating adult patients with chronic non-cancer pain. The recommendations were also targeted primarily for new prescriptions.
rather than toward the treatment of patients who are already on long-term opioid treatment.

Legislation like that of the new Rhode Island rules represents a well-intentioned effort among regulatory bodies to improve patient safety and to reverse some of the worrying trends seen in recent years with opioid use and abuse. However, new and additional regulations carry the risk of unintended and undesirable consequences for patients and healthcare providers. The new regulations may contribute to existing problems with treatment access among patients with opioid dependence.

THE ROLE OF BUPRENORPHINE IN MANAGING THE OPIOID CRISIS

There are safer ways to help patients with chronic pain, but access problems are significant. Empirical data support the safety and efficacy of buprenorphine in treating patients with chronic pain, including those with a history of substance abuse, but access to buprenorphine treatment is limited. In contrast to full opioid agonists, buprenorphine products, which are potent partial opioid agonists, have not been implicated in life-threatening overdoses. In fact, buprenorphine products have a significant protective mechanism through their stronger binding to opioid receptors. This results in less sedation and respiratory depression compared to full opioid agonists.

Several open studies have observed that buprenorphine products are highly effective for treating chronic pain. This effectiveness has been demonstrated both in opioid-dependent and non-dependent patients. Malinoff and colleagues evaluated the treatment of 95 patients with chronic pain who were referred for detoxification from opioid analgesics. Buprenorphine treatment was successful in 86% of patients, including measured improvements in mood, functioning, and subjective difficulty with pain. In a study of 143 veterans with chronic pain and opioid dependence treated with buprenorphine/naloxone, Pade and colleagues observed high treatment retention and “modest but statistically significant improvement” in pain scores on buprenorphine/naloxone.

Streltzer et al. studied the treatment of comorbid opioid dependence and pain in primary care, exploring whether treatment response differs between patients with and without a history of substance abuse. Patients in the sample had chronic pain that was difficult to manage, were taking morphine equivalent doses of at least 120 mg (except for three patients), and most had been diagnosed with opioid dependence. Following treatment with buprenorphine, patients reported high levels of treatment satisfaction and “much less preoccupation with pain.” There was no significant difference in treatment outcome between patients with and without substance abuse history.

THE ROLE OF CONSULTATION SERVICES

The above findings are consistent with the experience of this author, who has been providing consultation to Rhode Island community physicians who have become uncomfortable managing difficult chronic pain with opioid treatment. In the current climate of prescription narcotic abuse, physicians are increasingly uncomfortable prescribing opioid analgesics. In light of this, the new regulations recommend utilizing consultation services.

RESOURCES AND OBSTACLES TO OBTAINING TREATMENT

Consultation and treatment services are of limited availability. There are several pain management clinics identified in the community, as well as other physicians with the qualifications to provide consultation. Unfortunately, these resources generally do not appear to manage patients identified as needing to be tapered or discontinued from high-dose opioid analgesics, even when they are clinically indicated. Regulations should be revised or clarified to allow for treatment and reimbursement in a substance abuse treatment setting if there are no other available treatment settings.

This author has been providing consultation primarily in the context of hospital-based dual-diagnosis programs at Butler Hospital. Patients have been primarily evaluated for their potential to either detox completely from opioids or transition from high-dose full-agonist opioids with induction to buprenorphine products. Many of these patients meet the criteria for opioid dependence and substance use disorder, past or present. Because of the medical complexity and high morphine equivalent dosing, buprenorphine induction takes place in a dual-diagnosis outpatient [and, on occasion, inpatient] hospital-based setting. Clinical outcomes in Butler Hospital’s dual-diagnosis program have generally been remarkably positive, with patient reports of pain reduction and increased functioning and quality of life.

Dual-diagnosis hospital-based detox clinics are one of the only available settings for discontinuing narcotic analgesics and/or transitioning with induction to buprenorphine products. This raises the question as to what settings are available for a patient without an Opioid Use Disorder (OUD), but still requiring the protocol for buprenorphine induction to transition to the safer product. In order to access treatment in a substance abuse treatment center, a diagnostic code of OUD is required for meeting criteria and therefore reimbursement. In many cases, a comorbid diagnosis of OUD is appropriate, but there are times that there is no apparent comorbid OUD. These patients find themselves without an available setting for this important treatment option. Buprenorphine induction may be clinically indicated for patients without a history of opioid abuse and raises questions as to whether an OUD diagnostic code should be required.
CONCLUSION

Just as the CDC Guideline provided a major step toward bringing the medical community together in order to address the opioid abuse and overdose epidemic, the new Rhode Island regulations represent another effort to improve patient safety. However, the guidelines do not differentiate between different types of prescription opioids, which may lead more physicians to avoid the use of safer products like buprenorphine, even when they are clinically indicated. There needs to be physician education to increase awareness that the use of buprenorphine products is approved when clinically indicated. Prescriptions only require the stipulation that the prescription is for pain. No special waiver is required. New regulations should aim to increase the availability of Medication-Assisted Treatment (MAT) for OUD and buprenorphine products for chronic pain. When MAT and safer opioids (like buprenorphine) are unavailable to mitigate withdrawal, patients may resort to street drugs with a higher potential for abuse and fatal overdose. New regulations should make it easier for physicians to utilize safe and effective treatment for patients with chronic pain. Regulations should be revised or clarified to allow for treatment in a substance abuse treatment setting, even if there is no diagnosis of an opioid use disorder, if there are no other available treatment site options.
Garcinia Cambogia, Diabetic Ketoacidosis, and Pancreatitis

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KEYWORDS: garcinia cambogia, hydroxycitric acid, pancreatitis, diabetic ketoacidosis

INTRODUCTION

Obesity affects 36.5% of all American adults,¹ and many people struggle to achieve sustained weight loss. Lifestyle modifications like dieting and exercising are effective, but difficult, so patients often try dietary supplements to more quickly and easily lose weight. However, supplement intake is not without its risks. Dietary supplement products are portrayed as treatment of a disease, despite insufficient evidence to support their use. Furthermore, a recent report analyzing emergency room visits due to supplement intake showed that 25.5% of cases implicated a weight-loss product.²

Garcinia cambogia (GC) is a dietary supplement marketed primarily for weight loss, as well as for appetite suppression, cholesterol reduction, and blood sugar control. Hydroxycitric acid (HCA) is the active ingredient in GC products. The primary mechanism of action of HCA for weight loss is via inhibition of adenosine triphosphatase (ATP) citrate-lyase, preventing the conversion of citrate to oxaloacetate and acetyl coenzyme A (ACA). Inhibiting the formation of oxaloacetate and ACA reduces fatty acid synthesis in the cell cytosol.³ There have been several reports of adverse effects associated with consumption of GC including hepatotoxicity,⁴ rhabdomyolysis,⁵ nephropathy,⁶ serotonin toxicity⁷ and cardiovascular toxicity.⁸ We report the case of a 56-year-old woman who presented with diabetic ketoacidosis (DKA), pancreatitis, and stress cardiomyopathy after several weeks of GC consumption.

CASE REPORT

A 56-year-old woman with a history significant for insulin-dependent diabetes mellitus, hypertension, hepatitis C infection, and opioid abuse, abstinent for more than 18 years, presented to the emergency room with altered mental status. On the day of admission, she had been found by her son in the bathroom, lethargic and confused. Earlier that day, she had reported mild abdominal pain and vomiting. Her outpatient medications had not been significantly adjusted in the last three years (Table 1). On admission, her pulse was 103 beats/min and regular, respiratory rate 24 breaths/min, blood pressure 115/70 mmHg, and temperature 95.8 degrees Fahrenheit. Her Glasgow Coma Scale was 13. There were no focal neurological deficits, and her mucous membranes were dry. Initial laboratory data was significant for a plasma glucose of 1,150 mg/dL, arterial pH of 7.33, serum bicarbonate of 7 mmol/L, serum beta hydroxybutyrate of 5.4 mmol/L, serum anion gap of 35, troponin I of 5.12 ng/mL, and serum lipase of 861 u/L. A computed tomography of the abdomen without contrast showed peripancreatic stranding, as well as possible pancreatic atrophy. Initial electrocardiogram revealed normal sinus tachycardia without acute ST-segment changes.

The patient was admitted to the intensive care unit for management of DKA, pancreatitis and elevated troponin. She was treated with aggressive hydration, insulin drip, and electrolyte repletion. Her DKA and pancreatitis resolved within three days. Her mental status improved in three days and she reported excellent adherence to all of her medications and no dietary transgressions. In fact, she had been trying and had successfully lost approximately 40 pounds in the last month. When the medical team inquired further, the patient admitted to taking GC for the last month. She had been taking two tablets of GC by mouth three times a day with meals (1,400–1,440 mg HCA per day depending on the brand) in addition to taking an unknown quantity of another dietary supplement, Irvingia gabonensis or African Mango. Her hospital course was complicated by atrial fibrillation with rapid ventricular response, which was treated with amiodarone.

Table 1. Outpatient Medications on Admission

<table>
<thead>
<tr>
<th>Drug, Dose, Route, Frequency</th>
<th>Indication</th>
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<tr>
<td>Diazepam, 10 mg, PO, daily</td>
<td>Anxiety</td>
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<tr>
<td>Methadone, 125 mg, PO, daily</td>
<td>Opioid abuse</td>
</tr>
<tr>
<td>Aspirin, 81mg, PO, daily</td>
<td>Primary prevention</td>
</tr>
<tr>
<td>Metoprolol tartrate, 25 mg, PO, twice daily</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Metformin, 1,000 mg, PO, twice daily</td>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Hydrochlorothiazide, 12.5 mg, PO, daily</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Lisinopril, 5 mg, PO, daily</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Atorvastatin, 20 mg, PO, daily</td>
<td>Hyperlipidemia</td>
</tr>
<tr>
<td>Insulin glargine, 75 U, SubQ, daily</td>
<td>Diabetes mellitus</td>
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NOTE – PO: by mouth, SubQ: subcutaneous.
A transthoracic echocardiogram revealed significantly depressed left ventricular function. The mid to distal anterolateral, anteroseptal, inferior, and entire apical wall appeared severely hypokinetic, consistent with stress cardiomyopathy. The patient was discharged after seven days, fully recovered.

DISCUSSION

Pancreatitis is caused by inflammation, leading to inappropriate activation of amylase and lipase and autodigestion of the gland. Pancreatitis can be idiopathic or caused by gallstones, alcohol, illicit drugs, infections, diabetic ketoacidosis, or medications. Typical cases of medication-induced pancreatitis involve antimicrobials, valproic acid, furosemide, thiazide diuretics, immunosuppressants, NSAIDs, tamoxifen, L-asparaginase, and estrogen. Of these agents, the patient had only reported taking her prescription aspirin and hydrochlorothiazide. Case reports have suggested that a few other medications on her list may rarely cause pancreatitis: statins, angiotensin converting enzyme (ACE) inhibitors, and metformin.

Diabetic ketoacidosis is a physiological adaptation to starvation. Common causes of DKA are insulin non-adherence, starvation, infection, acute stress, pancreatitis, or medications including antipsychotics, cocaine, alcohol, corticosteroids, glucagon, interferon, sympathomimetics, and thiazide diuretics. DKA is more common in Type I diabetes than Type II diabetes. When cells lack sufficient intracellular glucose to function, the body begins breaking down fat. ACA is then metabolized to acetone, acetoacetate, and beta hydroxybutyrate [ketone bodies] rather than entering the citric acid cycle. The accumulation of ketone bodies lowers pH and patients often experience nausea, vomiting, abdominal pain, confusion, hyperglycemia, and ketonuria. By losing 40 pounds in one month, the patient was essentially in starvation mode.

Based on the mechanism of action, it is possible that GC caused her weight loss, in addition to the unwanted side effects of DKA and pancreatitis. GC works to reduce weight by altering the availability of oxaloacetate and ACA, but this may also alter glucose and fatty acid metabolism. Low levels of oxaloacetate shunt ACA from the citric acid cycle to the ketogenic pathway. This patient was already at risk for ketosis due to her sudden weight loss. Therefore, GC could have caused ketosis both indirectly through weight loss, and directly by inhibiting the production of oxaloacetate and shunting ACA into the ketogenic pathway.

Since being featured on television and endorsed by celebrities, GC has been widely used by women for weight loss, despite lack of evidence to support efficacy or safety. Various products recommend different daily doses of GC and contain different percentages of HCA. There is no standardized dosing for GC, and clinical trial doses vary from 1g to 2.8g of HCA daily. A meta-analysis of twelve small, randomized, double-blinded placebo controlled trials demonstrated a statistically significant difference in weight loss versus placebo, with an average of -1% body weight loss in the HCA group versus placebo. Of note, all twelve studies had at least one methodological weakness and provided little or no information regarding blinding procedure, allocation, or randomization. A sub-analysis of the two highest quality GC trials from the meta-analysis showed no statistical difference between groups.

Since the passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994, dietary supplements have been recognized as a distinct class of products that contain a vitamin, mineral, herb/botanical, or amino acid, intended for ingestion for the purpose of supplementing the diet. While medications in the US must be approved by the FDA before marketing, dietary supplements are not held to these standards of safety and efficacy. The FDA only regulates dietary supplements to ensure that good manufacturing practices and minimum labeling requirements are met. Therefore, the primary method of identifying potential dietary supplement toxicity is through post-market patient reports. Manufacturers are required to report serious adverse events to the FDA. Health care professionals, public health officials, researchers, and citizens are also encouraged to report dietary supplement adverse events to the FDA.

Hepatic toxicity associated with the use of GC has been reported for over a decade, but pancreatitis may be an under-recognized adverse effect. There is only one other published case of pancreatitis associated with GC. In 2016, a middle-aged woman with a history of type 2 diabetes mellitus, hypertension, and chronic hepatitis C developed acute pancreatitis after using GC for weight loss. While a home medication list was not included in this case report, it seems reasonable to assume that the patient case from 2016 and our patient would be taking similar drugs due to overlapping comorbidities of diabetes, hypertension, and opioid use disorder. As previously stated, thiazide diuretics, ACE inhibitors, statins, aspirin, and metformin have all been associated with acute pancreatitis. However, our patient had been receiving these medications chronically, with no recent dose changes and no previous episodes of pancreatitis. The
supplements may have had an additive effect in these two patients with high baseline risk.

While no definitive cause was determined, the use of GC may have contributed to her DKA and pancreatitis based on the Naranjo algorithm for estimating adverse drug reaction causality. Each of the ten questions in the algorithm is scored, and the total is summed. The likelihood of an adverse drug-event is categorized as definite, probable, possible, or doubtful based on high to low total score. The patient’s total score was five, which coincides with a probable adverse drug reaction.

**CONCLUSION**

Garcinia cambogia supplements may have serious adverse effects, especially in patients with pre-existing metabolic disorders. Patients may not always mention their dietary supplement use during medication reconciliation and may be surprised to learn that dietary supplements can potentially be deleterious to their health. Our patient assumed that GC must be safe because it was endorsed by a trusted TV figure.

Providers must be sure to identify patients that use dietary supplements, counsel these patients on their risks, and report any possible adverse effects to the FDA. (FDA Safety Reporting Portal at US Department of Health and Human Services: https://www.safetyreporting.hhs.gov)

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**References**


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More Rhode Island Adults Have Dental Coverage After the Medicaid Expansion: Did More Adults Receive Dental Services? Did More Dentists Provide Services?

SAMUEL ZWETCHKENBAUM, DDS, MPH; JUNHIE OH, BDS, MPH

ABSTRACT

OBJECTIVE: Under the Affordable Care Act (ACA) Medicaid expansion since 2014, 68,000 more adults under age 65 years were enrolled in Rhode Island Medicaid as of December 2015, a 78% increase from 2013 enrollment. This report assesses changes in dental utilization associated with this expansion.

METHODS: Medicaid enrollment and dental claims for calendar years 2012–2015 were extracted from the RI Medicaid Management Information System. Among adults aged 18–64 years, annual numbers and percentages of Medicaid enrollees who received any dental service were summarized. Additionally, dental service claims were assessed by provider type (private practice or health center).

RESULTS: Although 15,000 more adults utilized dental services by the end of 2015, the annual percentage of Medicaid enrollees who received any dental services decreased over the reporting periods, compared to pre-ACA years (2012–13: 39%, 2014: 35%, 2015: 32%). From 2012 to 2015, dental patient increases in community health centers were larger than in private dental offices (78% vs. 34%). Contrary to the Medicaid population increase, the number of dentists that submitted Medicaid claims decreased, particularly among dentists in private dental offices; the percentage of RI private dentists who provided any dental service to adult Medicaid enrollees decreased from 29% in 2012 to 21% in 2015.

CONCLUSION: Implementation of Medicaid expansion has played a critical role in increasing the number of Rhode Islanders with dental coverage, particularly among low-income adults under age 65. However, policymakers must address the persistent and worsening shortage of dental providers that accept Medicaid to provide a more accessible source of oral healthcare for all Rhode Islanders.

INTRODUCTION

According to statewide health behavior surveys in 2012, more than one quarter of Rhode Island adults younger than 65 years were estimated to be without dental insurance coverage, and they were more likely not to have received preventive or treatment dental care than insured adults.1 Beginning in January 2014, all Rhode Island adults with incomes at or below 138% of the federal poverty level became eligible through the ACA for Medicaid that includes a comprehensive adult dental benefit, with diagnostic, preventive, restorative, periodontal, surgical, prosthetic, and limited endodontic services. Unlike commercial dental insurance, there are no patient deductibles or co-pays. Before this expansion, Rhode Island Medicaid eligibility for adults was limited to adults with disabilities, pregnant women, and parents of Medicaid-enrolled children. Attributed mostly to the Medicaid expansion, approximately 68,000 more adults, aged 18–64 years, were enrolled in Medicaid in 2015, compared to 2013 enrollment. This number represents 8% of Rhode Island adults who were most likely medically and dentally uninsured before the ACA.

Expectations of the impact of ACA coverage expansion on dental care usage were tempered nationally with the understanding that the capacity to treat patients with Medicaid coverage is low.2 With the goals of addressing barriers in obtaining dental care among Rhode Island Medicaid enrollees, this report assesses: [1] to what extent Medicaid expansion improved utilization of Medicaid-covered dental services; [2] where these services were received, in private or public dental care settings; and [3] if Medicaid participating dentists increased in the post-expansion era, in parallel with the enrollment change.

METHODS

For calendar years 2012–2015, Medicaid enrollment, among adults aged 18–64 years, and dental claims were extracted from the Rhode Island Medicaid Management Information System. Annual unduplicated numbers and percentages of Medicaid enrollees who received any dental service were summarized by calendar year. Additionally, dental services claims were assessed by provider type (private practice or health center). The Rhode Island Dental Safety Net Survey3 and Health Resources and Services Administration [HRSA] Health Center Report4 were used to determine FTE dentists at federally qualified health centers [FQHCs]. The Rhode Island Licensure Database5 was used to determine the total number of licensed dentists in private offices, for the corresponding study period. Based on these data, the ratios were calculated of Medicaid enrollees who received dental services to dentists who provided dental services.
RESULTS

The number of adult Medicaid enrollees increased from 86,742 in 2013 to 136,753 in 2014, and to 154,434 in 2015, a total increase of 78% (Figure 1). However, between 2013 and 2015, the change in the number of enrollees who received any dental service at least once in a year was a 46% increase [33,800 to 49,312], not parallel with that of the enrollment change (Figure 1). Accordingly, the percentage of enrollees who received dental care dropped from 39% in 2013 to 32% in 2015 (Figure 1).

In the post-expansion years, the volume of patients with Medicaid increased both in private dental offices and the FQHCs. While more patients received dental treatment from private dental providers across the study period, the extent of increase in patient numbers at the FQHCs was far greater (78% increase from 2012 to 2015) than at private practices (34% increase) (Figure 2).

FQHCs typically see three times more Medicaid enrollees per dentist than private practice dental offices. Rhode Island FQHCs increased their number of dentists from 29 FTEs in 2012 to 35 FTEs in 2015 (Figure 3, graph in left). Compared to 2013, the year before the expansion, 250 and 170 more Medicaid-enrollees were treated per dentist in FQHCs in 2014 and 2015, respectively (Figure 4, graph in left).

Meanwhile, the number of dentists in dental offices who submitted any Medicaid claim dropped from 163 (29% of all RI licensed dentists) to 121 (21%) (Figure 3, graph in right). Consequently, the Medicaid-enrolled patient allocation to each Medicaid participating dentist increased from 132 enrollees per dentist in 2012 to 238 in 2015 (Figure 4, graph in right).

Figure 1. Rhode Island Adults’ (age 18–64 years) Medicaid Enrollment* and Number & Percentage of Enrollees Who Received Any Dental Service, 2012–2015

Figure 2. Rhode Island Adult Medicaid Enrollees Age 18–64 Years Who Received Any Dental Service by Provider Type, 2012–2015

Figure 3. Number of Dentist FTEs in FQHCs (left) and Number of Dentists Practicing in Private Office Who Submitted Any Medicaid Claim (right)

Figure 4. Ratios of [Medicaid enrollees who received any dental service] to [Dentists who submitted any claim] by Provider Type

* calendar year monthly enrollments averaged
DISCUSSION
As anticipated, the number of Medicaid enrollees increased after expansion, and so did the number of enrollees receiving dental services. Unfortunately, even with a comprehensive dental benefit, Medicaid enrollees’ low dental service utilization has been a persistent issue in the post-expansion years. The fact that the percentage of enrollees receiving dental services decreased could be due to a combination of several factors: enrollees’ insufficient knowledge of their dental benefits, including information on how and where dental services are obtained, and dental providers’ reduced participation in Medicaid program.

Dentists in private practice have not observed an increase in reimbursement rates since 1992. With current reimbursement at roughly 25% of dental fees,6 dentists have little incentive to accept Medicaid in their dental offices. Fortunately, a network of Rhode Island FQHCs have taken on an important dental safety net role.3 FQHCs’ dental providers perform a disproportionately large volume of services to Medicaid enrollees. This, again, is likely due to economics, as the reimbursement rate for dentists in private practice via fee-for-service tends to be lower than the FQHC’s encounter rate.

When dentists have little financial incentive to participate in Medicaid, as reflected by the decreasing number of Medicaid participating dentists in this report, those remaining will see more requests for care. Without a balanced supply of dentists in Medicaid to meet the increasing demand of care, it is likely that many dentists have reached their capacity and have little motivation to bring in new patients. Dentists participating in Medicaid strive for a patient mix in their schedule which allows them to maintain financial viability. They may choose to provide care for as few or as many patients with Medicaid as they wish, largely dictated by appointment availability.

The FQHC situation is dissimilar in that they receive rates that allow them to survive financially, and are incentivized to provide care and hire additional staff to meet rising needs. The increase in the number of dentists at FQHCs does not give the full picture, as recent safety net data also show increases in dental hygienists and dental assistants at these sites.7 All of these efforts improve capacity to address the needs of the growing population of Medicaid enrollees seeking care. FQHCs may also have incentives to focus their payor mix on certain populations based on their mission and their grant funder requirements. Some have focused more on children, some have sought to increase access to infants and pregnant women, while others conform to the needs and demographics of their community or agency. This targeted-population approach may be a barrier to improved access for some adult Medicaid beneficiaries.

Finally, limitations of this study should be acknowledged. Reasons for dental visit, types of dental service provided (such as preventive vs. treatment, simple vs. complicated, or routine vs. emergent), and frequency of visits were not weighted in differentiation. Therefore, further studies to understand the true driving forces in dental utilization change that followed the Medicaid expansion are warranted. In addition, the extent of charity care, or unreimbursed care that is known anecdotally to contribute to bridging the dental service gap for low-income underserved population is not quantifiable.

CONCLUSIONS
While the ACA did increase the number of adult enrollees, the dental system did not see as great an upturn as may have been expected. This is likely a reflection of capacity and reimbursement, with dentists in private offices reducing their participation and having little incentive to take on more patients due to low reimbursement. While it is anticipated that the FQHCs will continue to attempt to meet demand, their ability to do so may be more difficult due to challenges in growth, primarily related to dentist and dental auxiliary recruitment and retention. Ideally, the private practices would respond to increased demand, but this will likely only come with increased reimbursement rates. The patient awareness of dental benefits is still unknown, and likely increased medical-dental integration will encourage non-dental providers to refer in greater numbers for dental care. If that happens, the overarching question of concern is whether the dental community will be able to meet that demand.

References
5. RI Department of Health [RIDOH]. License Database (License 20009).

Authors
Samuel Zwetchkenbaum, DDS, MPH, is the Dental Director for the Oral Health Program at the Rhode Island Department of Health, and for the Medicaid Program at the Rhode Island Department of Human Services. Junhie Oh, BDS, MPH, is a Senior Public Health Epidemiologist in the Division of Community Health and Equity at the Rhode Island Department of Health.
**Rhode Island Monthly Vital Statistics Report**

**Provisional Occurrence Data from the Division of Vital Records**

<table>
<thead>
<tr>
<th>VITAL EVENTS</th>
<th>APRIL 2017</th>
<th>12 MONTHS ENDING WITH APRIL 2017</th>
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<tr>
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<td>Number</td>
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<tr>
<td>Live Births</td>
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<td>11,576</td>
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<tr>
<td>Deaths</td>
<td>883</td>
<td>10,212</td>
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<td>Infant Deaths</td>
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<td>Neonatal Deaths</td>
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<td>53</td>
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<tr>
<td>Marriages</td>
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<td>Divorces</td>
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<td>Induced Terminations</td>
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<tr>
<td>Spontaneous Fetal Deaths</td>
<td>68</td>
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<tr>
<td>Under 20 weeks gestation</td>
<td>63</td>
<td>546</td>
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<tr>
<td>20+ weeks gestation</td>
<td>5</td>
<td>69</td>
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* Rates per 1,000 estimated population  
# Rates per 1,000 live births

<table>
<thead>
<tr>
<th>Underlying Cause of Death Category</th>
<th>OCTOBER 2016</th>
<th>12 MONTHS ENDING WITH OCTOBER 2016</th>
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<tr>
<td></td>
<td>Number (a)</td>
<td>Number (a)</td>
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<tr>
<td>Diseases of the Heart</td>
<td>207</td>
<td>2,338</td>
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<tr>
<td>Malignant Neoplasms</td>
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<td>2,179</td>
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<tr>
<td>Cerebrovascular Disease</td>
<td>36</td>
<td>430</td>
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<tr>
<td>Injuries (Accident/Suicide/Homicide)</td>
<td>72</td>
<td>872</td>
</tr>
<tr>
<td>COPD</td>
<td>41</td>
<td>450</td>
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</tbody>
</table>

(a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.  
(b) Rates per 100,000 estimated population of 1,056,298 (www.census.gov)  
(c) Years of Potential Life Lost (YPLL).  

**Note:** Totals represent vital events, which occurred in Rhode Island for the reporting periods listed above. Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.
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Contact Sarah if you’ve missed an issue, sstevens@rimed.org.
Working for You: RIMS advocacy activities

September 1, Friday
Conference Call with Anchor Medical Associates and the Department of Health regard Diabetes Prevention Program Grant
Governor Raimondo Fundraiser,
President-elect Bradley Collins, MD, attending

September 5, Tuesday
RIMS Physician Health Committee:
Herbert Rakatansky, MD, Chair
AMA Advocacy Resource Center call regarding Economic Impact Study of Physician Practices

September 11, Monday
Meeting with WAMS Students regarding legislation
Board of Directors Meeting:
Sarah J. Fessler, MD, President

September 12, Tuesday
AMA Advocacy Resource Center call regarding national opioid crisis
AMA conference call, Washington DC Staff, regarding MACRA update

September 13, Wednesday
Board of Licensure and Discipline (BMLD) presentation by Herbert Rakatansky, MD, and Kathi Boyd, LICSW, on Physician Health Program
Meeting with Opioid Treatment Association regarding potential legislation
Governor’s Opioid Overdose and Prevention Task Force meeting

September 14, Thursday
Meeting with Megan Ranney, MD, regarding gun violence project for primary care providers
SIM Meeting: Peter A. Hollmann, MD, Vice President

September 15, Friday
Chairman Craven Fundraiser:
Michael E. Migliori, MD, and Steven R. DeToy
RIMS Convivium, Awards Ceremony and Installation of New Officers (right, and page 60)

September 19, Tuesday
Legislative Hearings, final day of 2017 legislative session

September 20, Wednesday
Primary Care Physicians Advisory Committee
Meeting with Department of Health and RI Health Centers Association regarding the Health Professionals Loan Repayment Program, “Health Policy in America” by Michael E. Migliori, MD, and Steven R. DeToy, at the Warren Alpert Medical School.

September 21, Thursday
Meeting with Diabetes Prevention Program CME Planning Committee
Meeting with RI Quality Institute

September 22, Friday
Meeting with RI Dermatology Society

September 23, Saturday
Meeting of the New England Delegation to the AMA and Council of New England State Medical Societies, Waltham, Massachusetts: Peter A. Hollmann, MD; Alyn Adrain, MD, Newell Warde

September 26, Tuesday
Improving End of Life Care Coalition

September 28, Thursday
Rhode Island HIT Data Sharing meeting

OFFICE SPACE AVAILABLE
RIMS has 442 square feet of newly renovated office space (3 contiguous offices of 200 sf, 121 sf and 121 sf), complete with convenient sheltered parking and the opportunity for tenants to share three well-equipped meeting spaces, break room, office machinery, etc. on the western edge of downtown Providence. Suitable for a small non-profit organization, boutique law firm, CPA firm or other office-based small business.

Inquiries to Newell Warde, nwarde@rimed.org
It’s a new day.

The Rhode Island Medical Society now endorses Coverys.

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401-331-3207
The Rhode Island Medical Society continues to drive forward into the future with the implementation of various new programs. As such, RIMS is expanded its Affinity Program to allow for more of our colleagues in healthcare and related business to work with our membership. RIMS thanks these participants for their support of our membership.

Contact Marc Bialek for more information: 401-331-3207 or mbialek@rimed.org

Neighborhood Health Plan of Rhode Island is a non-profit HMO founded in 1993 in partnership with Rhode Island’s Community Health Centers. Serving over 185,000 members, Neighborhood has doubled in membership, revenue and staff since November 2013. In January 2014, Neighborhood extended its service, benefits and value through the HealthSource RI health insurance exchange, serving 49% the RI exchange market. Neighborhood has been rated by National Committee for Quality Assurance (NCQA) as one of the Top 10 Medicaid health plans in America, every year since ratings began twelve years ago.

RIPCPC is an independent practice association (IPA) of primary care physicians located throughout the state of Rhode Island. The IPA, originally formed in 1994, represent 150 physicians from Family Practice, Internal Medicine and Pediatrics. RIPCPC also has an affiliation with over 200 specialty-care member physicians. Our PCP’s act as primary care providers for over 340,000 patients throughout the state of Rhode Island. The IPA was formed to provide a venue for the smaller independent practices to work together with the ultimate goal of improving quality of care for our patients.
The Bebop Docs performed at RIMS’ 4th Annual Convivium at the Save the Bay Center in Field’s Point in Providence on September 15.

RIMS 2017–2018 leadership: President-Elect Peter A. Hollmann, MD; President Bradley J. Collins, MD; Secretary Christine Brousseau, MD; Vice President Norman A. Gordon, MD; and (seated) Immediate Past President Sarah J. Fessler, MD. Not present: Treasurer Catherine A. Cummings, MD.

RIMS Executive Director Newell E. Warde, PhD (second from left) and students in the Bryant University Physician Assistant Program, Dan Leary Alison Migliori, and Ida Apel.

RIMS members, guests, staff, and sponsors enjoyed the opportunity to get acquainted or chat with old friends while enjoying appetizers, beverages, and dessert, in an informal setting.

RIMS President Bradley J. Collins, MD, addresses the attendees.

Dr. Charles L. Hill Award recipient Jerry Fingerut, MD; Dr. John Clarke Award recipient Kathleen C. Hittner, MD; Dr. Herbert Rakatansky Award recipient Michael E. Migliori, MD.

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David Washington, MD, shares his stormy start to new position in Houston

MARY KORR
RIMJ MANAGING EDITOR

David Washington, MD, MSc, a Brown University ’07 and Alpert Medical School ’11 alum, moved from Providence to Houston this July, in the month before Hurricane Harvey hit.

It was not the welcome he and his wife, Emma, and their young daughter could have anticipated when they made the decision to move to Houston after Dave completed his MSc from the Boston University School of Public Health, and where Emma had secured a position at NASA, in Mission Control as part of the EVA team (the “Space Walk” division).

The Rhode Island Medical Journal reached out to Dave in the aftermath of the hurricane and asked him to share his thoughts and experiences.

What type of patient issues have you come across?
Patients have come in with all sorts of issues. We commonly saw traumatic injuries such as broken bones and ankle sprains due to mechanical falls, but also saw issues due to patients losing their chronic medications as a result of the flooding. This was then compounded by many of the pharmacies also being damaged/losing their medications, so patients had no place to fill scripts or obtain medications. Subsequently, patients would present to the emergency room needing these medications, or in congestive heart failure, or having seizures.

What was the disruption for practices such as yours? How has this affected physicians’ offices - were they closed and for how long?
Many physicians’ offices were closed for 3–4 days, forcing patients with dire needs to present to the ER. Even if offices were physically able to be open, it was difficult to staff them as so many health care workers were personally...

What kind of personal and professional impact did this national disaster have on you?
Personally, I was blessed as our home and family were safe. My home only experienced minor electrical damage. However, just around the corner from us, many neighbors lost nearly everything. The contrast between my street and neighborhoods several blocks away is astounding, with large piles of debris still present by the curbs of affected homes and businesses.

Professionally, I was just settling into my new role as an Internal Medicine and Pediatrics physician with the Texas Gulf Coast Medical Group and Bay Area Regional Medical Center when the storm hit. I had been working just 4 weeks.

Hurricane Harvey image captured by NOAA’s GOES-16 satellite August 25, 2017.
affected by the storm. This led to those that could get to the office/hospital to work 24–72 hours.

What sort of emergency volunteer services did you and physicians you work with provide?

My hospital’s ER, Bay Area Regional Medical Center, did stay open through the storm. I worked several 12–14 hours shifts in the ER. I saw adults and children in an attempt to help take the pressure of the overworked and understaffed ER doctor (there was only one that could get in for several days).

I also set up and ran a “Fast Track” of sorts, taking care of patients triaged as levels 3, 4, and 5. It was very difficult to prescribe medications as there were limited medications in the hospital pharmacy that could be dispensed, and there were not many pharmacies open for several days. Even if pharmacies were open, they did not have a fully-stocked formulary, so we had to make due with what was available.

One of the hardest hit patient groups were those with end-stage renal disease on dialysis. Many came in having missed their dialysis for anywhere from 3–5 days. They were feeling nauseous, weak, and were quite frightened. Many had to sleep overnight in the hospital ER or in the waiting room, until they were at least able to set up a makeshift dialysis center in the ICU. This was for 1–2 days until other dialysis centers opened and patients could be redirected.

Another problem we had was that our ER was seeing double the usual volume with half the staff, and we did not have enough staff to operate many medical floors, which meant patients that would normally have been quickly admitted to the floor had to stay in the ER. This also occurred for 1–2 days until enough staff could get in to work. So many health care workers were affected by the storm and could not get in that our CEO had to fly staff from his home state New Jersey, to help the hospital function.

How would you describe the aftermath of the storm on the city and the patients you have come into contact with?

What is interesting to me is this storm was unique and hit everyone, rich and poor, old and young. I get the sense from Houstonians that have lived through other storms and floods that this was particularly unique about Hurricane Harvey. Places that don’t usually flood, did this time. This took many people and businesses off guard, making the clean-up now much worse. Many did not have flood insurance because they were not in a certified flood plain. The shock alone was crippling to many.

Almost two weeks after Hurricane Harvey, its effects are still ever present. Many of my patients have lost everything, and are dealing with scrapes and coughs related to trying to clear out what is left of their homes (and those are the lucky ones).

Depression and anxiety underscore many chief complaints. I have been trying to be more mindful during this time in my visits with patients, keeping quiet to allow them to say what is on their minds. Patients are extremely grateful for this. I think it affords them some modicum of control over what is, otherwise, a particularly chaotic time.

I do feel sad for this city I was just getting to know. My wife and I do, however, feel uniquely bonded to the Houston area now, and, while still very much Rhode Islanders at heart, are proud to be a part of this community. There are many incredible individuals that have donated countless hours and resources for neighbors and strangers alike. I have heard many people down here say in response to being asked why they put their own safety in jeopardy to help another: “Because that’s what we do here!”

I’ll leave with one of my favorite encounters over the past two weeks. I was seeing a mother and her 13-year-old and 6-year-old sons. They had lost all their possessions and home due to flooding and were living in a shelter. When I entered the room, the young one ran up to me and said with complete sincerity, “Hey doctor, I don’t know if you know this, but, like the WHOLE world flooded and now I get to wear my pajamas all day!!” Leave it to children to find a silver lining amidst the aftermath of turbid flood waters.
Brookdale Overview

Independent Living *An ideal retirement living experience*
- Spacious apartments with minimal maintenance
- Restaurant-style dining
- Plenty of planned activities every day

Assisted Living *The right choice for people who need extra help with daily activities*
- Qualified staff assists with taking medication, dressing, bathing, etc.
- Floor plans, from studio to two-bedroom apartments
- Activities and events for various levels of acuity

Alzheimer’s & Dementia Care *Person-centered care for people at various stages*
- Programs that leverage the latest dementia care research
- A care philosophy defined by more than the symptoms of Alzheimer’s & dementia
- An experienced staff who help residents thrive

Rehabilitation & Skilled Nursing *For short-term surgerical recovery or long-term rehabilitation*
- Around-the-clock, licensed nursing care
- Providing clinical resources in a comfortable setting that feels like home
- A mission and focus to helping residents get well and then get home as quickly as possible

Personalized Living *For people who just need a little help with things*
- One-on-one non-medical services for home care needs
- Additional personal needs for those in assisted living or home such as escorts to doctor appointments and more

Home Health *For qualified people in need of therapy or rehabilitation — all in the comfort of home*
- Get Medicare-certified assistance from experienced professionals
- Many healthcare services such as wound care and stroke therapy

Therapy *Specialized programming personalized to encourage recovery*
- An emphasis on education, fitness and rehabilitation that helps seniors retain or enhance their independence
- Most insurances accepted

Hospice *Promoting comfort by addressing the full range of needs of patients and families*
- Primary focus of quality of life
- Specially trained staff help families and patients cope with overwhelming feelings accompanying end-of-life care

The Rhode Island Network

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- Brookdale Cumberland
- Brookdale Smithfield
- Brookdale Greenwich Bay
- Brookdale Pocasset Bay
- Brookdale Sakonnet Bay
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Brown launches mindfulness center to improve, disseminate evidence

PROVIDENCE — As mindfulness-based health interventions increase in popularity, Brown University is set to launch a new center for research and public service focused on increasing the quality of the evidence base and promoting adoption of well-proven mindfulness practices.

The Mindfulness Center at Brown University aims to help scientists, health care providers and consumers alike better understand whether particular mindfulness interventions work, for which health concerns, and for whom, said ERIC LOUCKS, PhD, director of the center and associate professor of epidemiology in the Brown University School of Public Health.

“There are early research findings that mindfulness may positively impact mental health and physical health outcomes,” Loucks said. “As a result, there is an increased market for interventions based in these practices. All around Rhode Island, the country and the world, there are people looking to learn more. We are bridging across Brown’s fields of study, with an emphasis in epidemiology, to focus on methodological rigor in the field.”

Brown Provost Richard Locke and School of Public Health Dean Terrie Fox Wetle joined Loucks at a September 13 event to launch the center. The kickoff also included faculty members from fields as diverse as biostatistics, religious studies and psychiatry at Brown and at partner universities along with providers of evidence-based mindfulness interventions, including from the Miriam Hospital and Rhode Island Hospital, who have affiliated with the center.

The wide range of disciplines coming together through the center will be a key to its ability to make an impact, Locke said.

In addition to Loucks, other Brown faculty members who will be integral to the Mindfulness Center’s work include Willoughby Britton, assistant professor of psychiatry and human behavior, Jared Lindahl, visiting assistant professor of religious studies, Elena Salmoirago-Blotcher, assistant professor of medicine, and Brandon Gaudiano, associate professor of psychiatry and human behavior.

Rigorous research

Loucks has studied the relationship between mindfulness and cardiovascular health for years. In 2015, for example he, Lindahl and Britton received a $4.7 million grant from the National Institutes of Health to study whether and how different mindfulness-based interventions change people’s ability to “self-regulate” their attention and behavior and whether that can help people better follow medically recommended lifestyle alterations, such as changes in diet.

Since then he’s been working with colleagues at Brown, Harvard University and the University of Massachusetts. In all, the teams are running five randomized, controlled trials of mindfulness interventions looking at outcomes including medication adherence, mood, blood pressure and other key health indicators. The coordination among those teams, Loucks said, provides a perfect example of how a center can enhance mindfulness research across the board.

Launched with a $50,000 award from Brown’s Office of the Vice President for Research, the Mindfulness Center has the resources to launch pilot studies as it pursues further grants and other funds.

Another key capability of the new center, Loucks said, will be to share best practices and advice on evidence and study design with others planning research studies. Collaborations could include partnering on multisite trials of mindfulness interventions.

Already the center is convening like-minded researchers, Loucks said. In January, for example, faculty will convene the first-ever worldwide meeting of scholars studying mindfulness and cardiovascular health.

The center will not only study mindfulness benefits but also its potential to produce challenging experiences for practitioners as well, Loucks said.

“We are going in with open eyes, investigating impacts of mindfulness on health effects and reporting what we find, whatever it is,” he said.

In the coming weeks, the center will launch a website listing local mindfulness providers who offer evidence-based interventions. Information will include the intended health effect of the intervention, the target population and a description of how the provider evaluates and maintains treatment quality.

The center will also work with community providers who aren’t conducting their own research services, including offering the ability to perform systematic program evaluations, Loucks said.

“I hope that we will provide a clear, simple pipeline for consumers to know who is offering evidence-based mindfulness interventions that can help them,” he said. “We want to build the quantity and the quality of such interventions.”

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CNE President & CEO Dennis Keefe announces retirement

James E. Fanale, MD, will become interim president, CEO

 PROVIDENCE – DENNIS D. KEEFE, president and CEO, Care New England Health System (CNE), will be retiring effective December 31, 2017 after serving in the leadership role since August 2011. Effective January 1, 2018, James E. Fanale, MD, who currently serves as executive vice president, chief clinical officer, and chief operating officer of CNE, will become the interim president and CEO of CNE. Following his retirement, Mr. Keefe will serve as a consultant to CNE for up to one year to assist in a smooth transition of leadership and to provide continued assistance on major pending transactions including partnership opportunities with Partners HealthCare and the acquisition of Memorial Hospital by Prime Healthcare Foundation.

“Since my arrival at Care New England, I have been impressed with the dedication and commitment displayed by everyone at this institution focusing on our mission of caring and healing. I am extremely proud and honored to be a member of this organization for that reason,” said Mr. Keefe. “Despite our challenges and recent difficulties, I remain confident in a future of sustained financial stability for Care New England. That is a testament to the work we have done together, and that you will continue to do going forward. It represents the best and necessary path to ensure a strong Care New England regardless of the outcome of our important and current business opportunities.”

JAMES FANALE, MD, currently serves as executive vice president, chief operating officer, and chief clinical officer for Care New England. Prior to arriving at Care New England, Dr. Fanale served as senior vice president for system development and chief operating officer at Jordan Hospital, where he was responsible for the development of one of the nation’s first Medicare Shared Savings Programs – Accountable Care Organizations (ACO). In this capacity, he created and implemented programs involving population health management, was responsible for the overall operations of the system, and assisted in the merger of Jordan Hospital into Beth Israel Medical Center. He also advanced key relationships with health plans and the physician networks to pioneer both the clinical and management aspects of health care in the accountable care environment. He has been instrumental in the continuing development of Care New England’s ACO, Integra, including the establishment of Integra as a Medicaid Accountable Entity. In addition, he serves as the prime investigator of the recently awarded, $3.9 million CMS Accountable Communities Grant.

Dr. Fanale earned his medical degree from Chicago Medical School and completed his residency at UMass Memorial Medical Center. He is an associate professor of medicine at the University of Massachusetts Medical School. Dr. Fanale is a fellow in the American College of Physicians and the American Geriatrics Society, and is a past president and chair of the board of the American Geriatrics Society. He is a member of numerous professional organizations, and has served as an advisor or consultant to numerous public and private organizations.

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Rhode Island a national leader in immunizations for adolescents

Immunization rates for teenagers in Rhode Island are among the highest in the country, according to new data released by the Centers for Disease Control and Prevention (CDC).

The data were gathered through a version of the National Immunization Survey that focuses on children from 13- to 17-years-old (NIS-Teen). Surveyors made randomized telephone calls to parents and guardians. The information they provided was confirmed with the child’s healthcare provider. The study revealed that:

- 90% of Rhode Island girls and 88% of Rhode Island boys received at least one dose of Human papillomavirus (HPV) vaccine, the highest rates in the country, and much higher than the national averages for the first dose of HPV vaccine: 65% for girls and 56% for boys.
- 95.4% of Rhode Island teens received the combined vaccine called Tdap, which protects against tetanus, diphtheria, and acellular pertussis. This was the second highest rate in the nation.
- 96.4% of Rhode Island teens received at least one dose of Meningococcal Conjugate vaccine, the highest rate in the country.

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**Recognition**

**CharterCARE, South County Health recognized for standardizing care to treat addiction and overdose**

Governor Gina Raimondo’s Overdose Prevention and Intervention Task Force has recognized South County Health and CharterCARE Health Partners for their leadership in providing consistent, comprehensive care for opioid-use disorder in hospitals and emergency departments in Rhode Island.

This recognition was based on treatment criteria met at Roger Williams Medical Center and Our Lady of Fatima Hospital (both CharterCARE facilities), and South County Hospital. These criteria were established in March by the Rhode Island Department of Behavioral Healthcare Developmental Disabilities and Hospitals (BHDDH) and Rhode Island Department of Health (RIDOH) in a document titled Levels of Care for Rhode Island Emergency Departments and Hospitals for Treating Overdose and Opioid Use Disorder. The aim of these first-in-the-nation standards is to ensure that best practices in the treatment of opioid-use disorder are in place at emergency departments (EDs) and hospitals throughout the state.

The Levels of Care document established a three-tiered system. Designations are made through an application process submitted to RIDOH and BHDDH. All hospitals must qualify for at least a level three, with the expectation that many will attain higher designations, which involve expanded capacity to provide care for opioid-use disorder (i.e., medication-assisted treatment), recovery services, and more.

Roger Williams Medical Center and Our Lady of Fatima Hospital earned a level-one distinction, the highest distinction. This means that these hospitals are, among other steps, providing comprehensive discharge planning to all overdose patients, screening all patients for substance-use disorder, offering peer recovery support services, and maintaining the equivalent to a Center of Excellence where patients can receive treatment for opioid-use disorder.

South County Hospital was recognized for achieving a level-three designation. This means that the hospital is fulfilling the requirements of the 2016 Alexander C. Perry and Brandon Goldner Act, sponsored by Chairman Joshua Miller and Representative David Bennett. The hospital is also submitting the required reports of overdoses to RIDOH within 48 hours and testing routinely for fentanyl.

Work to build South County Hospital’s levels of care infrastructure was led by William Sabina, MD, Chief of Emergency Medicine, and Steven Juchnik, BSN, RN, CEN, Emergency Services Director.

On September 26, 2017, RIDOH’s regulations will be updated to require all Rhode Island emergency departments to meet almost all level three requirements. This regulations update reinforces the 2016 Alexander C. Perry and Brandon Goldner Act that specifies discharge planning procedures in emergency departments and hospitals for patients with opioid-use disorder. This will include standardized screening evaluations, laboratory drug screenings to determine the cause of overdose; education on the risks and benefits of prescribed opioids, as well as safe storage and disposal; written policies that outline when a prescriber should dispense or prescribe naloxone to patients; education on the administration of dispensed or prescribed naloxone; opportunities to speak with peer recovery support specialists; information about treatment options; and, notification of a patient’s emergency contacts and peer recovery support specialist. ❖
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Appointments

Women & Infants adds four new providers to Ob/Gyn

Four new providers have joined the Department of Obstetrics and Gynecology at Women & Infants Hospital of Rhode Island, a Care New England hospital.

**ERIN M. CLEARY, MD**, of Warwick, has joined the Division of Emergency Obstetrics and Gynecology. A graduate of Tulane University School of Medicine, Dr. Cleary completed her internship and residency at TriHealth [Good Samaritan and Bethesda North hospitals] in Cincinnati, Ohio, where she was involved in many quality improvement projects during her training. Her interests are in high-risk obstetrics and medical education.

**DENNIS GOULET, MD, MPH**, of Cranston, has joined the Division of Emergency Obstetrics and Gynecology. A graduate of Boston College, Dr. Goulet received his master of public health at Dartmouth College. He graduated from medical school at the University of Washington and completed a residency at Brown University/ Women & Infants Hospital. Dr. Goulet has a special interest in minimally invasive gynecologic surgery as well as advocating for policies that support and improve the health of his patients.

**ELIZABETH KETTLE, CNM, MSN, MPH**, of Dover, MA, has joined the Midwifery Division. Elizabeth received a bachelor of arts degree in women’s studies and biology from Dartmouth College, and a master’s of science in nurse midwifery and masters of public health from Yale University. She has a broad scope of experience as a nurse midwife including working for Harvard Vanguard Medical Associates in several Boston hospitals, where she taught medical, nurse practitioner, and nurse midwifery students. She served as the director for Harvard Vanguard’s Midwifery Service at the Brigham and Women’s Hospital and the director of the Ob/Gyn Department at the East Boston Neighborhood Health Center. Among many initiatives, she developed an orientation program for new graduate RNs and NPs, and created a Zika screening and surveillance system. She has a long-standing interest in enhancing quality of care through optimization of electronic medical records.

**MELISSA RUSSO, MD**, of Barrington, has joined the Division of Maternal-Fetal Medicine. A magna cum laude graduate of Colgate University, Dr. Russo earned her medical degree from Georgetown University School of Medicine. She completed her residency in obstetrics and gynecology and fellowship in maternal-fetal medicine and clinical genetics at Johns Hopkins University. Dr. Russo is board certified in obstetrics and gynecology, maternal-fetal medicine, and genetics. She comes to Women & Infants from Texas Children’s/Baylor University in Houston, Texas, where she was an assistant professor of maternal-fetal medicine and human and molecular genetics. Her research interests include prenatal genetics, reproductive and pregnancy outcomes in women with connective tissue disorders such as Marfan syndrome and Loey-Dietz syndrome. ❖