Review Article

DYSHORMONIA IATROGENICA: CROSSROADS OF MEDICINE, MALPRACTICE LAW, AND PROFESSIONAL ETHICS IN CLINICAL ENDOCRINOLOGY

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ABSTRACT

**Objective:** To present 2 challenging cases of patients who request endocrine therapies that their physician considers to be outside of the standard of care.

**Methods:** With these complex cases as a backdrop, we explore the constructs of medicine, malpractice law, and professional ethics that guide physicians’ medical decision-making processes.

**Results:** These cases illustrate a common conundrum for clinical endocrinologists, who often find themselves struggling to balance patient satisfaction and well-being with generally accepted standards of medical care. From the perspective of a malpractice lawyer, we review the keys to limiting medicolegal liability, with emphasis on thorough documentation, informed consent, and effective doctor-patient communication. We then review the constructs of professional ethics that guide patient care, with emphasis on virtues of the “good physician,” patients’ right to self-determination, and paternalism. Finally, we explore some justifications for a compassionate physician to refuse a patient’s desired treatment plan.

**Conclusion:** In the end, we hope that this manuscript helps to facilitate best medical, legal, professional, and ethical practices of clinical endocrinology. (Endocr Pract. 2012;18:731-736)

CASE STUDIES

**Patient 1**

A 37-year-old woman presents to you for ongoing clinical management of her “hormonal imbalances.” In 2004, she presented to her previous (out-of-state) physician with concerns of chronic fatigue, weight gain, and excessive hair growth on her upper lip. Despite a lean body frame (height, 165 cm; weight, 54 kg); normal physical examination findings; and normal thyrotropin, cortisol, and glucose levels, the patient was diagnosed with both “hypothyroidism” and “cortisol excess.” During the next several months, she was prescribed a multidrug regimen including levothyroxine, 125 mcg daily; liothyronine, 5 mcg twice daily; spironolactone, 50 mg twice daily; metformin, 1000 mg twice daily; pioglitazone, 30 mg daily; orlistat, 120 mg 3 times daily; ketoconazole, 200 mg daily; and 6 additional proprietary vitamin supplements. On this complex regimen, she feels very well, and she requests that you refill her many prescriptions.

During the medical history, you strongly suspect a body dysmorphic disorder. On physical examination, you note a slim, attractive, and energetic woman, with a pulse rate of 88 beats/min and a blood pressure of 120/76 mm Hg. The thyroid gland is normal to palpation, and she exhibits no cushingoid features. Fasting laboratory studies reveal a normal glucose concentration of 80 mg/dL, a normal hemoglobin A\(_{1c}\) level of 4.9%, normal chemistries, normal liver function, and a fully suppressed thyrotropin concentration of less than 0.01 mIU/L.

**What is your plan?**

**Patient 2**

A 56-year-old registered nurse presents to your office for “specialty management” of her longstanding
hypothyroidism. In 1994, she was diagnosed with symptomatic Graves hyperthyroidism after unintentionally losing 18 kg. After several months of medical therapy with propylthiouracil, she was treated with radioactive iodine therapy in 1995. Following her radioactive iodine therapy, she was prescribed Armour Thyroid tablets. Because she felt sluggish and quickly regained her lost body weight, she was “allowed to titrate her dose” of Armour Thyroid to clinical effect. (By history, you note that she used her professional status to “influence” this dose titration.) Under the supervision of another local endocrinologist, the patient has taken 9 grains (540 mg) of Armour Thyroid once daily for the past decade. Despite these astronomically high thyroid hormone doses, she felt clinically well, and she reported no tremors, palpitations, insomnia, or anxiety.

In December 2009, at the height of the national Armour Thyroid shortage, the patient presented to her primary care physician for a replacement thyroid prescription. She was prescribed levothyroxine, 150 mcg daily. Within just 3 weeks, she developed severe fatigue, cold intolerance, constipation, and dry skin, and she also reported severe cognitive impairment that affected her work performance. After a documented total thyroxine concentration of 12.7 µg/dL (with a suppressed thyrotropin concentration <0.01 mIU/L), the patient then negotiated a prescription for levothyroxine, 300 mcg daily, which she has taken for the last 8 weeks. At her initial visit, she reports a 14-kg weight gain over the past 3 months. She also reports severe fatigue, major depression, and ongoing cognitive difficulties. In her words, “I just can’t live like this. You have to help me.”

On physical examination, you note a pleasant but clearly anxious woman (height, 165 cm; weight, 76 kg), with a pulse rate of 80 beats/min and a blood pressure of 132/82 mm Hg. Scalp examination reveals fine, brittle hair without focal alopecia. Skin feels cool and dry. Neck examination reveals a nonpalpable thyroid gland. The patient exhibits no overt signs of Graves’ ophthalmopathy. There is no resting tremor, and deep tendon reflexes are normal. Recent laboratory studies reveal an elevated total thyroxine concentration of 17.2 µg/dL and a suppressed thyrotropin concentration of less than 0.01 mIU/L.

What is your plan?

DISCUSSION

These real patient cases illustrate a common conundrum for clinical endocrinologists, who often find themselves struggling to balance patient satisfaction and well-being with accepted standards of medical care. The compassionate physician’s dilemma is similar in both presented cases: both patients are clearly quite content with their current medical plan, and both are blissfully unaware that their plan blatantly violates usual standards of care. Understandably, neither patient wants to alter what she perceives as effective medical therapy.

On a medical board exam, most physicians would agree that most (if not all) of Patient 1’s medications should be discontinued, while Patient 2 should simply be treated with lower doses of thyroid hormone. Of course, the real-world challenge is to recruit these patients as allies in the effort to wean them from their unnecessary (and potentially harmful) medications. A major barrier exists here: patients chronically overtreated with thyroid hormone clearly become “accustomed” to higher serum thyroxine levels, partly through down-regulation of their thyroid hormone receptors. (Similar phenomena occur in patients on chronic glucocorticoid therapy; this topic deserves another manuscript all its own.) As a result, patients can experience true “hypothyroid” symptoms even with elevated thyroxine levels, which are simply lower than the levels to which they have adapted. In such patients, the abrupt cessation of hormone therapy—or even simple dose reductions—can generate undesirable clinical symptoms. In addition, psychosocial issues, such as body dysmorphic disorder, the social desire for low body weight, and professional access issues, can further complicate these already difficult cases.

From the medicolegal perspective, physicians treating these patients are clearly facing a difficult conundrum. If physicians simply agree to renew a patient’s unnecessary (or clearly overdosed) medication, they clearly risk legal liability. Plaintiff lawyers can interpret such actions as willfully contributing to adverse clinical sequelae. For example, patients overtreated with thyroid hormone may experience an osteoporotic fracture or a stroke secondary to atrial fibrillation. However, if patients perceive that their physicians are purposely contributing to unpleasant clinical symptoms, they are far more likely to leave that physician’s practice, and/or to become uncooperative or even litigious. The unfortunate reality is that in these cases, even a thoughtful “middle-of-the-road” approach (such as a slow and careful dosage taper to limit patient discomfort) leaves the physician open to potential malpractice litigation.

From a professional ethics perspective, these cases illustrate the concepts of patients’ right to self-determination and physician paternalism. As a rule, patients want to feel well, and they are generally less concerned (and/or less certain) about chronic medication-related complications. In their quest for wellness, “difficult” or “demanding” patients can generate complex ethical issues, discussed below. Physicians, however, want to practice sound medicine by adhering to national standards of care and avoiding iatrogenic injury. Since these challenging cases can generate dissatisfied patients, unhealthy doctor-patient relationships, and even malpractice litigation, what is an honest and compassionate physician to do?
MEDICOLEGAL PERSPECTIVE

When providing care to challenging patients, physicians must consider whether their actions (or inactions) could result in adverse clinical consequences, and also whether they could be considered legally liable for those consequences. Legal responsibility for poor clinical outcomes depends on a large number of variables, including the specifics of the patient, the disease state, the treatment plan, and untapped therapeutic alternatives. In medical malpractice litigation, a physician’s assessment and plan are expected to fall within an accepted standard of care. This standard—which applies to all aspects of the physician-patient relationship—can be loosely defined as the degree of care generally considered adequate by other physicians within a medical specialty. So, the standard of care examines what a “typical” or “reasonable” endocrinologist would recommend under similar clinical circumstances (1,2).

Physicians often fail to recognize that a critical component of meeting the standard of care involves communicating the proposed treatment plan, as well as explaining the potential risks, benefits, and alternatives. While these concepts have become second nature to physicians performing hospital-based procedures, they are often overlooked in office-based, cognitive medical practice. During malpractice trials, plaintiff’s attorneys seek to exploit sparse documentation, which can suggest that a physician did not execute a thoughtful treatment plan. A poorly documented medical record also implies (often incorrectly) that the medical plan was not properly communicated to the patient, and that informed consent did not occur. Physicians entering trial with inadequate documentation are clearly facing an uphill battle.

Simply stated, proper documentation is the key to limiting medicolegal liability. We propose the following 6 underused documentation tips to help physicians to defend against potential malpractice litigation:

a) Where possible, dictate your notes and/or type them into an electronic medical record. All handwritten notes must be neat and legible. Sloppy or illegible notes are often exploited during malpractice trials, since they are more subject to interpretation by plaintiff’s expert witnesses. (Cases in which physicians cannot read their own notes are particularly damaging.)

b) Do not write in the margins of the chart, or in different colored inks. Do not add subsequent text to an original chart note. These practices give the appearance of an altered medical record. Physicians should clearly label, date, and time all chart addendums. Document each note chronologically.

c) Clearly distinguish between objective and subjective findings: that is, do not speculate about a patient’s state of mind or medical complaints. It is best to record subjective complaints exactly as they are reported by the patient.

d) Chart entries should be comprehensive. They should include specific details regarding patient complaints, diagnostic information, and the proposed treatment plan. Ideally, they should also acknowledge discussions of informed consent, including risks, benefits, and therapeutic alternatives.

e) Where possible, document the reason(s) why the medical plan is proceeding in a certain manner. This is especially important when choosing between acceptable medical alternatives. Properly documented thought processes are of great help in defending malpractice litigation.

f) Obtain informed consent before initiating a medical treatment plan. Informed consent requires that a patient understands the material risks and benefits of a proposed therapy, along with reasonable alternatives (3). Specific legal criteria for informed consent vary from state to state, so physicians should know their local standards. While documentation is critical to this process, a signed consent form does not guarantee protection from legal liability.

Finally, of course, physicians should seek to cultivate warm and positive relationships with their patients. Patients who like their physicians are less likely to initiate lawsuits against them. To this end, physicians should routinely engage their patients in interactive discussions that generate mutual agreement. In medicolegal cases surrounding a poor clinical outcome, patients who felt pressured into a specific course of action often claim that they were not fully informed about the risks, benefits, and alternatives.

PROFESSIONAL ETHICS CONSiderATIONS

Before focusing specifically on challenging patient cases, it is worth briefly reviewing how physicians decide what to do—in a general sense—for all of their patients. In a thoughtful review of the virtues and professional responsibilities of the “good physician,” medical ethicist Edmund Pellegrino notes that in any patient encounter, the physician is implicitly (or explicitly) “professing” 2 central claims: (a) that she is competent to help the patient, and (b) that she is operating with the patient’s best interests in mind (4). Moreover, the “good physician” is characterized by several key virtues, including benevolence (acting for the good of the patient), intellectual honesty (knowing the limits of one’s knowledge and abilities), and truthfulness (4). Specific professional obligations of the physician include an obligation to “remedy the patient’s information deficit” (5) as completely as possible, and also to obtain the patient’s informed consent. These basic concepts are critical for physicians to consider when navigating difficult patient encounters. For adult patients of sound mind, it is
here suggested that medical actions should be guided by some combination of the following 5 factors:

a) What the physician perceives to be in the patient’s best interest, on the basis of available scientific data, and on the basis of the expected physical, psychological, social, and economic impact of the proposed treatment plan on the patient.
b) The patient’s wishes.
c) The feasibility of the proposed treatment plan (including the likelihood of adherence, as well as social and financial considerations).
d) Accepted standards of care.
e) The physician’s conscience.

In each of the 2 cases presented, an endocrinologist may determine that the patient’s desired treatment plan is not in her best interest (ie, that the risks exceed the benefits), or that the patient’s preferred plan is clearly less appropriate than another available option. In such cases, the physician may choose to recommend a treatment plan that she feels is more consistent with the patient’s best long-term interests. While this common-sense approach seems appropriate from a scientific standpoint, and while it seems like “good medicine,” it also raises the specter of paternalism.

Paternalism generally refers to acting “like a parent” by choosing for another (here the patient) what is perceived by the presumably more knowledgeable individual to be in her best interests. In the past, this model was widely accepted within the medical profession, on the basis of the central virtue of benevolence. Pellegrino and others have rightly concluded that the patient’s welfare remains central to an appropriate professional ethic (4). However, the paternalistic approach may be inadequately respectful of patients’ right to choose for themselves.

It could be argued that during the past half-century, medical ethics in the United States (and other developed countries) has witnessed a gradual shift from an emphasis on benevolence to the obligation to respect patients’ right to self-determination. As a result, overly paternalistic approaches to medical practice have largely fallen from favor. Mentally competent adult patients are now generally perceived as having the right to refuse any recommended medical treatment plan, with the possible exception of situations wherein such refusal puts others at risk of harm (eg, isolation and mandatory therapy for multidrug-resistant tuberculosis).

This respect for patient choice, while critically important to the ethical practice of medicine, must not be overinterpreted or misconstrued. Specifically, while a patient has the right to refuse any medical intervention, even a potentially lifesaving one, this does not imply that the same patient has a right to demand a specific treatment. In a landmark publication in 1983, the President’s Commission for the Study of Ethical Problems in Medicine very specifically addressed this concern: “Although competent patients… have the legal and ethical authority to forego some or all care, this does not mean that patients may insist on particular treatments. The care available from healthcare professionals is generally limited to what is consistent with professional standards and conscientiously held beliefs” (6).

Professional standards, commonly known as “standards of care,” rightly influence which medical therapies should be made available to patients. However, it is here suggested that the obligation to practice within a perceived standard of care should be proportional to the weight of scientific evidence supporting that standard, and also to the clinical experience upon which that standard is based (7). In other words, this obligation is strongest if that standard is based on sound physiologic rationale, randomized controlled clinical trials, and extensive clinical experience. However, if that standard is based solely upon common medical practice, the obligation is weaker, and weaker still if that standard lacks either medical evidence or physiologic rationale. For example, if most physicians prescribe antibiotics for a viral respiratory infection, and on this basis alone these actions are proposed as the standard of care, there should be no ethical obligation to adhere to that standard. In summary, physicians must carefully consider not only the standard of care, but also the strength of the foundation upon which that standard stands.

At first glance, the importance of “conscientiously held beliefs” may seem less relevant to the practice of medical endocrinology than, for example, to the practice of reproductive medicine or critical care. However, this is not necessarily the case. At any time, a physician may struggle with what she feels is right in the face of competing pressures, such as when a patient demands therapy that the physician does not endorse. As discussed above, physicians should always respect patients’ right to self-determination. Clearly, however, thresholds do exist beyond which a physician need not (or should not) cross. Stated another way, physicians also have a right to self-determination; like the competent patient, the physician must preserve the right to say no. This conclusion may surprise some patients, who live in the modern era of medical consumerism, in which patients often claim the right to select the medical “products” that they purchase. At a sandwich shop, a paying customer simply selects his desired sandwich from the menu. In some patients’ minds, a physician is not so different from the man who makes their sandwich.

Indeed, it has become commonplace for physicians to justify questionable medical decisions (to others and/or to themselves) by noting that the patient or their family member(s) insisted upon it. This unhealthy shortcut can make medical practice easier, and certainly less stressful, by helping a physician to avoid difficult conversations. This approach, however, fails to acknowledge the essential
moral agency of the physician, who remains fully responsible for her actions. In other words, physicians cannot justify their actions by claiming that they were just following orders, even if those orders come directly from the patient. In clinical practice, physicians may refuse patient requests, and in some instances they may be morally obligated to do so. The hard work lies in determining when such refusals are ethically justified. In complex medical cases, reasonable individuals may draw different conclusions about a physician’s right to refusal; the physician must also wade through this thoughtful deliberative process.

We suggest here at least 3 reasonable justifications for refusing patients’ demands: (a) the proposed treatment plan cannot accomplish the patient’s desired goals, (b) the proposed treatment plan is not feasible, and (c) the proposed treatment plan is clearly opposed to the patient’s best interests.

Regarding the first justification, professional ethics articles often refer to the concept of medical “futility.” An exact definition of futility remains controversial within the field of medical ethics, yet one still commonly hears clinicians invoke this term as a justification for refusing patients’ (or surrogates’) requests. Indeed, the term futile may be invoked by physicians who wish to avoid difficult conversations; in many cases, these physicians possess insufficient clarity about the scientific data supporting their conclusion. Recently, the term futility has fallen out of favor with some medical ethicists (8). Nevertheless, physicians are generally not obligated to initiate or continue medical therapies that clearly cannot accomplish their intended goals.

Regarding the second justification, if a given treatment plan could work in theory, but cannot feasibly be carried out, there should be no obligation to initiate that plan. This justification for refusal is deeply rooted in common sense, and is also rightly held in the ethical dictum (sometimes attributed to Kant) that “ought implies can.” That is, to suggest that someone is obligated to complete a task implies that they are capable of doing so; if one is incapable of completing a task, then it follows that one cannot be obligated to do so.

Ultimately, a physician’s right to decline a patient’s desired therapy should most often be rooted in promoting the patient’s best interest. The “good physician,” by most understandings of virtue-based medical ethics, is motivated by benevolence to act in the patient’s best interest. As a moral agent, the physician bears responsibility for her actions, and therefore bears responsibility for any harm that results from those actions. Indeed, depending on the severity of the anticipated harm, the physician may be not only justified in her refusal, she may in fact be ethically (and legally) obligated to do so.

To be complete, this discussion must include another important aspect of the physician’s obligation that cannot be overlooked: the obligation to teach. In other words, it is not enough to simply refuse a patient’s request based on her best interests. The patient, too, is a moral agent, albeit usually with far less medical knowledge than the treating physician. To aid patients with their own ability to make decisions, it is incumbent upon the physician to “remedy the patient’s information deficit as completely as possible” (5). After fulfilling this obligation, the physician can then reasonably refuse to provide treatment, provided that this refusal is accompanied by a good-faith effort to help the patient to understand the grounds for that refusal. The final goal, after all, is to treat the patient most appropriately.

As a final note, it should be considered here whether the risk of harm to the physician (rather than to the patient) stands as legitimate justification for physician refusal. One can easily imagine clinical scenarios wherein the risk to the physician (eg, personal, professional, economic, and/or legal) may outweigh the potential benefit to the patient. In the 2 cases presented here, real patient harm (liver injury on ketoconazole therapy, osteoporotic fracture induced by iatrogenic hyperthyroidism) could result if the physician simply yields to her patients’ desires. In such cases, physicians are best guided by an appreciation of their fiduciary obligation to place their patients’ best interests ahead of their own. Indeed, in justifying treatment refusal, physicians must always focus on the patient’s best interests, rather than the need to limit their own professional or legal liability.

EPILOGUE

For each patient case presented, the endocrinologist must determine for herself if the risk of the patient’s desired treatment regimen is high enough to justify physician refusal. If the physician refuses to prescribe a given therapy, she must communicate openly with the patient, and she must comprehensively document the reasons for this refusal in the medical record. Indeed, it is the physician’s moral obligation not to avoid these difficult conversations. While it would be far easier to refuse the patient’s request and walk away without explanation (which may involve considerable time and stress), these actions clearly fall short of the physician’s moral obligation to educate. In the end, the best medical plan may involve some degree of compromise, to minimize medical risks while maximizing the likelihood of patient compliance and satisfaction. Of course, such a compromise must fall within the bounds of what the physician (and the medical community) perceives to be medically sound and ethically acceptable.

Patient 1

At the first visit, the patient was engaged in an open conversation about the excessive risks imparted by her extensive medical regimen. To avoid “shock,” and to facilitate patient adherence and satisfaction, the plan was to slowly and deliberately wean the patient off of her many
unnecessary medications. Because of their toxicity or adverse effects, ketoconazole and pioglitazone were discontinued at her first visit, without event. At the patient’s follow-up visit, it was then suggested that she stop metformin and spironolactone therapies. The following day, the patient requested that her medical records be transferred to another endocrine practice. A typed letter was sent by registered mail to formalize the doctor-patient separation.

**Patient 2**

At the first visit, the patient was provided another short-term prescription for levothyroxine, 300 mcg daily. She was educated about the risks of iatrogenic hyperthyroidism (this discussion was extensively documented in the chart), and she agreed to enter into a long-term “contract” that involved purposefully slow and gradual reductions in her levothyroxine dosage. At the time of writing this article, the patient feels reasonably well on levothyroxine, 250 mcg daily. Although her thyrotropin level remains fully suppressed, her total and free thyroxine levels are slowly approaching the reference range. Further dosage reductions are planned.

In the end, physicians are legally and ethically responsible for their actions and the consequences of those actions. **Physicians don’t just make sandwiches.**

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**REFERENCES**