Exploring Integrity in Medicine

The Bander Center for Medical Business Ethics

Casebook

Edited By

Rebecca L. Volpe, PhD
Erin Bakanas, MD, MA
Kelly K. Dineen, JD, PhD, RN
James DuBois, DSc, PhD

Revised Version. August 2016

Contents

Volpe RL, Bakanas E, Dineen K, DuBois J (eds). *Exploring Integrity in Medicine: The Bander Center for Medical Business Ethics Casebook*. St. Louis: Saint Louis University. 2014.

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possible, find a new space because each learner needs the opportunity to engage actively in discussion.

- **Duration**. If facilitators take time to explore the relevant stakeholders, facts, norms and options in each case—allowing time for discussion, debate, and summary of key points—then one or at most two cases might be covered in a 50-minute learning period.

Teaching using case discussion can be interesting and educationally fruitful. It can also be a poor use of time with little learning occurring. The difference between a fruitful session and one that is not often is determined by the amount of preparation the facilitator invests into the session and whether best practices are followed. The Facilitation Guide published below distills best practices from several educational resources developed by ethicists and moral psychologists.[5-7]

Facilitation Guide

1. Educate yourself about the relevant ethical norms, facts, and laws prior to presenting the case. Most information you will need is contained in the Case Analysis section of each chapter.
    - We recommend that you study the case and case analysis and make note key learning points.
    - If you lack the expertise to facilitate discussion of the complex ethical, leg and medical issues, we recommend that you seek a qualified facilitator.
    - Alternately, you may want to assign some individual or subgroups of participants the task of mastering a portion of the case analysis informatio such as the relevant facts, the ethical principles, or the legal norms.
2. Start by asking the open-ended action question that follows each case.
    - Doing so requires learners to identify the salient issues and to engage in problem-solving by considering stakeholders, facts, norms, laws, diverse options, the consequences of different options, who they might ask for hel or information, and so forth.

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Ms. Brigsby, because her health and financial outcomes are intertwined. She is also an economic agent in a fee-for-service arrangement with the radiology group and the hospital. For example, if Ms. Brigsby exhausts her available financial resources to pay down the MRI bills, she impairs her ability to pay for continued health insurance, routine care, and medications.
- Dr. Jones, because his employing organization (LHS) benefits financially from the fee-for-service arrangement.
- LHS, because of the financial benefit of referrals and the risks of financial loss from patients' inability to pay non-negotiated rates. LHS has an interest in making sure prior authorizations or payment arrangements are made before tests are performed. LHS also has an interest in patients who wish to return for future services.
- Third-party payers, including Ms. Brigsby's insurance company because they share some financial risk with Ms. Brigsby. They have an interest in making sure that preventive and routine care is accessible for Ms. Brigsby to reduce long-term costs.
- Society, because unpaid medical bills, exorbitantly priced health care services, and conflicts of interest drive up the cost of health care for everyone.

Facts

- The Accreditation Council for Graduate Medical Education (ACGME) includes as one of its 'global' physician competenci

- The primary responsibility for making an informed decision about which physicians and facilities to visit for tests is the patient's. However, patient autonomy is a two-way street: health care providers are ethically obligated to provide information that facilitates their patient's autonomy. In this case, Dr. Jones could have facilitated Ms. Brigsby's autonomy by reminding her to double check if LHS Hospital was in-network, or by employing someone at his office who could help with insurance questions.

- Beneficence: obligations to provide benefits and to balance benefits against risks.
  - Dr. Jones' primary responsibility is to maximize Ms. Brigsby's health and wellbeing. Although physicians are not obligated to know in-depth information about patients' insurance plans, an awareness of cost and the associated patient burdens is critical. A basic understanding of insurance procedures and processes by Dr. Jones or his employees is a reasonable expectation. If Dr. Jones consistently refers his patients to particular providers without advising patients on insurance matters (either checking in office or telling patients to check), Dr. Jones is failing to maximize beneficence for his patients.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
  - Referring patients for services based on referral agreements or even convenience can cause harm. In the case at hand, Ms. Brigsby's financial harm may negatively impact her ability to afford routine care and prescriptions.
- Justice: obligations of fairness in the distribution of benefits and risks.
  - The high costs of Ms. Brigsby's tests were not only avoidable, but they also require her to take on higher health care costs than a similarly situated peer.

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Case 2

Pennywise State University gets Aggressive about Health Insurance

By Rebecca Volpe

Lisa Archer has been an employee at the Pennywise State College of Medicine for 12 years. Her present role is as an administrative assistant in the Department of Family and Community Medicine. Ms. Archer has just established a new therapeutic relationship with Dr. Bruce, and on her first visit, Ms. Archer has several questions about the new health insurance program that Pennywise State is rolling out for all its employees.

Ms. Archer says to Dr. Bruce, "Well as you know they're doing this, 'Take Care of Your Health Initiative' (Take Care Initiative), which requires that I do three things in order to avoid an additional $100 a month charge. First, I have to certify that I'll have a preventive physical exam, which is easy enough, because I just have to check a box. But then, I have to make an appointment with a health screener and get a 'biometric screening' where they measure my cholesterol, height, weight, and all that jazz. Finally, I have to complete an online 'wellness profile,' through a separate company. And then the

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- There is no federal legal distinction between penalties and incentives in wellness plans; both are included in the definition of reward.[7,8]
- Wellness plans must also comply with the ADA and GINA. An ADA compliant plan may request medical history *only if* 1) the participant can choose to provide it voluntarily, and the information is 2) kept confidential, and 3) kept separated from personnel records. Voluntary means the employer *neither requires* participation *nor penalizes* employees who do not participate.[8] In 2016, the Equal Employment Opportunity Commission (EEOC) issued proposed rules under the ADA and GINA that limit the financial reward or penalty to employees for wellness plans and health risk assessments.[9]
- Under GINA, a wellness plan may inquire about the participant's genetic information (including family and medical history) only if the program is 1) voluntary, 2) program information is provided, 3) written authorization is obtained, 4) no financial inducements are provided to the employee for providing the information, and 5) no individual genetic information is provided to the employer.[10] Even if an individual voluntarily discloses genetic information,

Options

1. Dr. Bruce could listen empathetically to Ms. Archer but take no further action.
2. Dr. Bruce could investigate the specifics of the Take Care Initiative, including the online wellness profile.
3. Dr. Bruce could correct Ms. Archer's misinformation or misunderstandings about the Take Care Initiative.
4. Dr. Bruce could make sure the Take Care Initiative was reviewed by the University for legal compliance.
5. Dr. Bruce could advocate for change in the Take Care Initiative
6. Dr. Bruce could support the Take Care Initiative because the University predicts cost-savings.
7. Dr. Bruce could work with the University to develop or revise educational materials for plan participants that include all legally required disclosures and other important information. If Ms. Archer has questions, other patients do too.

Reflection Questions

1. What ought to be the individual physician's role in institutional health policy?
2. Should physicians be advocates? If so, for whom/what? If not, why not?
3. How should the rights of individual patientsm 0 t?

5. Testing assumptions: What assumptions might Dr Bruce make about Pennywise State University or about Ms Archer? Might some of these assumptions be mistaken? How might she go about testing her assumptions?

References

1. Baicker K, Cutler D, Song Z. Workplace wellness programs can generate savings. *Health Affairs*. 2010;29(2):304-311.
2. National Public Radio. Can your boss fine you for not disclosing your weight? August 7, 2013.
3.

Case 3

An Avoidable Patient Fall and the Model of Care Delivery

By Kamal Gursahani

Mr. Henderson, an 86-year-old male with multiple medical problems presents to the hospital for confusion. Although he answers questions and follows commands, he is not oriented to place or year. His daughter, with whom the patient lives, reports that he is fully oriented under normal circumstances.

In the emergency department, the patient is diagnosed with a urinary tract infection and treatment with antibiotics is initiated. The doctors believe the infection is likely the reason he is confused. Mr. Henderson is admitted to the general floor under the care of Dr. Williams.

At 2 a.m. he

cascading. The model is analogous to a stack of Swiss cheese slices. The holes are opportunities for error, and when the holes line up, an error occurs. Functional systems would create processes and checks in subsequent steps to avoid the holes from lining up.[8]

- Professional competencies in medical residencies include rigorous focus on patient safety, analyzing and improving practice, working effectively in interprofessional teams, and understanding and improving systems.[9]

Norms

Mid-Level Principles of Biomedical Ethics[10]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
  - Health care providers cannot chemically or physically restrain all high-fall risk patients; restraints are not effective in preventing falls[11] and would rob them of their right to control their own bodies. The central challenge is identifying strategies that respect patient autonomy while keeping patients safe.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
  - Physicians must be leaders in the area of patient safety in order to uphold the standards of the profession.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
  - Physicians should above all keep 1 0 0H0 0H0 0H0 0H0 0H0 0Hr1m02 792 Q q pdo

- The amount of reimbursement the physician receives should not influence the type of or quality of care that is delivered

Legal

- CMS sets payment policies for all federal health care programs. Falls are considered hospital acquired conditions for which reimbursement *is not* provided.[13,14] Hospitals are also prohibited by federal law from passing on the costs of hospital acquired conditions to the patient.[13,15]
- State tort law governs professional malpractice and hospital liability for preventable falls. In many states, the hospital as well as the caregivers may be liable for a patient's injuries. For liability to attach in malpractice cases, the following conditions must be met: 1) a professional *duty* to the patient (provider patient relationship), 2) a *breach* of that duty, 3) that is the *cause* of 4) *harm* to the patient with 5) *damage* that can be monetized.[16]
  - Falls with injuries during a hospitalization are among the most straightforward malpractice cases.
  - The providers here all have a professional duty to the patient under their care in the hospital. They failed to implement appropriate fall prevention strategies and the patient was injured as direct a result. His injuries resulted in more advanced care and possible long-term care needs, all of which are damages.
- State laws vary on whether apologies by providers or expressions of sympathy can be used later as evidence in a malpractice trial.[17] Some states prohibit the use of expressions of sympathy but still allow the use of actual statements of fault.[18]
- Prompt disclosure of mistakes can improve the process for all involved and minimize the overall costs involved in malpractice cases.[19] Some sta7.432 re W* n Bre
- The hospital probably has an adverse event and error disclosure protocol that the doctors should follow in answering the family's questions and concerns. Following the disclosure protocol as early as possible may have 0.00000912 2jr7( )-Tm 0 g

evaluation program. Patient sitters are generally more affordable than skilled consequences? Which stakeholders will be affected and how? How can risks be minimized? How might this decision impact Dr. William's career?

4. Recognizing rules and power dynamics: What rules or norms are salient in this case?

Case 4

Observing Questionable Medical Business Practices

By Elena Kraus

Dr. Amy Aucel works as an orthopedic surgeon specializing in back pain in a private clinic with two other physicians. They all have privileges at a nearby hospital. The practice distributes salaries to their physicians depending on how the group does as a whole. The practice has historically been very busy and lucrative. Because of their

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Case Analysis

Stakeholders

The following are stakeholders in the case:

- Dr. Aucel, because she benefits financially when the practice orders more MRIs and performs more surgeries. She is also affected (positively or negatively) by the reputation of the practice. Because she is part of the practice, Dr. Aucel has at least some ethical and legal responsibility for the quality and nature of care delivered by the practice.
- Dr. Fraxure (similar to Dr. Aucel), because he benefits financially when he and others in the practice order more MRIs and perform more surgeries. He is also affected by the reputation of the practice and of the care provided for the patients of the practice. He has a direct legal and ethical responsibility for the care he provides.
- Dr. Aucel, Dr. Fraxure, and all of the providers in their practice because they face the possibilities of substantial civil, criminal, and administrative penalties for violations of fraud and abuse laws (directly or through conspiracy charges). These include allegations of criminal behavior, license revocation, and exclusion from the practice of medicine.
- Other practice colleagues, because they too have their reputations and finances at stake.
- Patients, because their health is at stake; unnecessary surgeries are harmful and financially burdensome. Unnecessary MRI scans are also harmful and financially burdensome, although less so than unnecessary surgeries.
- Insurance companies and Centers for Medicare and Medicaid Services, because they are paying for unnecessary procedures and tests, and this, in turn, drives up costs to patients and taxpayers.
- Numerous federal and state agencies, because they are responsible for implementing and enforcing health care fraud and abuse laws.
- Other physicians, because unnecessary care hurts their collective reputation as well as damages public trust in the profession.
- State medical boards, because they are responsible for the protection of the public through licensure and regulation of physician practice.

Facts

- Empirical studies have shown that financial incentives inherent in physician self referral arrangements result in increased use of services and higher payments from third-party payers.[1]
- Regardless of MRI service ownership, there is evidence of significant overuse of MRIs (and many other health care services). One study of lumbar spine MRIs indicated less than half of requests for this procedure were considered appropriate, and an additional 27.2% were of uncertain value.[2]

Legal

- Various fraud, abuse, and waste laws could apply; many of the laws require no specific intent to defraud, and cases often involve physicians who do not understand the difference between medical practices and other businesses.
- These cases also frequently involve physicians who are simply ignorant, negligent or sloppy with business practices, relationships, and billing. The federal government places tremendous trust in physicians to provide appropriate care and guard federal resources allocated through Medicare, Medicaid and other federal programs.[6]
- There are five major federal laws that address fraud and abuse in healthcare: 1) the False Claims Act (FCA), 2) Anti-Kickback Statute (AKS), 3) Physician Self-Referral Law (Stark), 4) Exclusion Statute, and 5) Civil Monetary Penalties Law. Multiple federal agencies are involved in their enforcement, including, but not limited to, Health and Human Services Office of Inspector General (OIG), the Centers for Medicare and Medicaid Services (CMS), and the Department of Justice (DOJ).[6]
- Violation of fraud and abuse laws can lead to civil and criminal penalties, substantial fines, exclusion from federal programs (including exclusion from employment by any organization or person that participates in federal programs) and revocation of medical licensure.[6]
- The False Claims Act (FCA) dates back to the late 1800s and criminalizes any knowing (including "should have known") presentation of a false claim for payment to the federal government.[7] No specific intent to defraud the government is required. The FCA has been widely applied to health care to enforce claims for health care services that are false as defined as 1) fictitious (billing for non-existent patients), 2) exaggerated (billing for services in excess of what was provided or upcoding), and 3) excessive or medically unnecessary. Violations of Stark and the AKS are also a basis for FCA prosecutions (e.g., one arrangement that violates Stark or the AKS gives rise to the additional FCA prosecution).[6,7]
- The FCA allows the government to bring suit against the provider(s) th 0 g 0 G [( )] TJ ET

6. Despite an emphasis on professionalism in medical practice, what experiences in your medical training or practice have exposed you to unprofessional behavior? What have these experiences taught you about the implications and consequences of unprofessional behavior? What have they taught you about approaches for addressing such behavior?

SMART Decision-Making Strategy Questions

1. Seeking help: What kind of additional information does Dr. Aucel need in a situation such as this? Who might Dr. Aucel turn to for assistance? Would it help to involve a mentor or consultant?
2. Managing emotions: If you were Dr. Aucel, what kind of emotions do you think you would be experiencing? How could these emotions influence your decision making? How can you effectively manage these emotions?
3. Anticipating consequences: What consequences should Dr. Aucel anticipate for

8. Mitchell JM. The prevalence of physician self-referral arrangements after Stark II:

Legal

- Dr. Taylor must disclose all material information to Ms. Irwin in order for her to make an informed decision about the procedure. At a minimum, this includes the diagnosis, the nature and purpose of the treatment, risks of treatment, and alternatives (including doing nothing).[8] There is also some limited legal support for the duty to disclose physician-specific risks such as level of experience and past outcomes.
- Courts judge whether informed consent is sufficient based on one of two

- Mr. Engle did not suffer any long-term complications. Therefore, the economic harm or damages to Mr. Engle are not likely substantial enough to justify a lawsuit absent ongoing complications, such as incontinence and impotence.

Options

1. Dr. Kruger could continue practicing as he currently does.
2. Dr. Kruger could limit his financial conflict of interests by outsourcing his laboratory and pathology testing or transferring his interest in the laboratory, thus eliminating the potential financial incentive for unnecessary screenings.
3. Dr. Kruger could consider the ways in which he communicates with patients with marginal PSA elevations. Could Dr. Kruger have framed the options in a more objective manner? If so, how?
4. Dr. Kruger could set practice guidelines based on the current literature for screening and treatment approaches, including factors such as the percent rise in PSA that justifies a biopsy.
5. Dr. Kruger could examine the extent to which his ability to perform procedures coupled with his desire to please patients may unduly influence what approaches he offers patients.

SMART Decision-Making Strategy Questions

1. Seeking help: What further information does Dr. Kruger need to evaluate his practice? Where can he find this information? Who might Dr. Kruger turn to for assistance?

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9. U.S. Department of Justice. *A primer on the False Claims Act*. 2014. http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Primer.pdf
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¶ A physician must not abandon a patient. Abandonment has been defined as the physician's unilateral withdrawal from the relationship without formal transfer of care to another qualified physician.[4,5]

¶ Physicians have a professional obligation of self-management, including acknowledging and accepting their own emotional responses to patients and attempting to ensure personal wellbeing.[1]

¶ The ethical obligation of the physician to maintain a therapeutic relationship with a patient is not without limits.[6] Experts have argued that a physician may refuse to continue caring for a patient, e.g., when continuing that relationship may harm other patients or the physician, as in the case of a patient who threatens physical violence.[7] Likewise, physicians are not required to violate their own fundamental personal values, standards of medical care, ethical practice, or the law.

- Some physicians may exhibit a tendency to discriminate against patients with mental health and substance abuse disorders, which may contribute to behaviors labeled "noncompliant." Mr. Green's behaviors suggest he may require treatment for underlying problems, whether they are mental health issues, chronic pain, or substance dependency.

AMA Principles of Medical Ethics[10]

¶ I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

- The abandonment of a patient for economic reasons violates the physician's duty to show respect for human dignity and human rights. Mr. Green's condition and perhaps his economic status make him vulnerable, and his expulsion from the practice would potentially leave him untreated and suffering. Physicians must carefully assess patients in chronic pain for underlying issues, exacerbating factors, and comorbidities. Patients on long-term opioid therapy should be carefully assessed for tolerance and the other overall effectiveness of the therapy. This includes a clear delineation of expectations and follow-through on those expectations.

¶ VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.

- A physician is not required to violate his or her own personal values or standards of medical care in providing patient care. The reasons for discharging a patient must be justifiable and ethical.[5,6] Discharging a patient because of economic concerns is ethically objectionable.

¶ VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

- Dr. SmithŜ r" r.א ט " cian! ble,

  - It may be that Mr. Green's case is sufficiently complicated to warrant referral to a specialist (and thus outside the scope of this doctor-patient relationship).
- A physician who terminates a relationship must follow and document procedural safeguards to avoid abandonment and harm to the patient. Some state medical boards have specific requirements, but general safeguards include appropriate written notice to the patient and assistance with continuity of care, such as providing referrals to appropriate alternate providers.[13,14]
  - There is a long-standing doctor

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Case Analysis

to patients who pursue unproven stem-cell

Case 9

The Business of Knee Injuries

By Kamal Gursahani

A 44-year-old male, Mr. Davis, twists his left knee while skiing at Vail. Despite the pain, he takes anti-inflammatories and continues to ski for the next three days, unwilling to cut his vacation short.

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Case Analysis

Stakeholders

The following are stakeholders in the case:

- Drs. Adams, Baker, Carter, and other sports orthopedists, because surgical repair of knee injuries leads to more referrals and business. Medically inappropriate interventions, however, might lead to increased patient complications and potential physician liability.
- Radiologists and imaging centers, because they provide the imaging services for knee injuries.
- Outpatient surgical centers, because surgical repair of knee injuries leads to more business.
- Patients, because imaging and surgery exposes them to potential harm as well as potential prolonged recovery time, lost work and wages, and decreased quality of life.
- Patients also have an interest in knowing that their physicians are not unduly influenced by conflicts of interest.
- Society and third-party payers, because medically inappropriate tests and procedures drives up the cost of health care for everyone.
- The state medical boards, because they license physicians for the safety of the public.

Facts

-

literature does not support the idea that outcomes are significantly different between operative and conservative treatment.[4,5]

Norms

Mid-Level Principles of Biomedical Ethics[6]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
  - If Drs. Adams and Baker have financial conflict of interest that impact their medical recommendations, this infringes on Mr. Davis' ability to make decisions based on accurate, objective medical information.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
  - Physicians ought not recommend interventions that are known to risk unnecessary harms to patients (e.g., surgical complications absent countervailing benefits).
  - The treatment recommendation should be based solely on professional judgment about what is most likely to benefit the patient.
- Justice: obligations of fairness in the distribution of benefits and risks.
  - Drs. Adams and Baker must consider if they are acting as good stewards of scarce health care resources.

AMA Principles of Medical Ethics[7]

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
  - If Drs. Adams and Baker are recommending unnecessary knee surgeries, they are not providing competent medical care and are failing to respect their patients' rights to avoid unnecessary discomfort and expense.
- II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
  - Dr. Carter should consider whether she has a professional responsibility to report what she may perceive to be the incompetent medical practices of Drs. Adams and Baker.
- V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
  - Drs. Adams and Baker may simply need a refresher on the peer-reviewed literature around ACL tears. They have a professional obligation to stay up-to-date on the standard of care in their field.
  - The literature appears to be inconclusive with regard to evidence for or against surgery. As with many decisions in medicine, this choice is physician-dependent, leaving the decision to the discretion of Drs. Adams

and Baker.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

- Even if fee-for-service medicine is not categorized as a financial conflict of interest, Drs. Adams and Baker should establish processes to minimize the influence of pay-for-service on their medical decision-making.

Legal

- The Ohio state medical board may take disciplinary action against a physician for several behaviors relevant to Drs. Adams and Baker. These include 1) "failure to employ acceptable scientific methods in the selection of…modalities for treatment of disease," 2) [m]aking a false, fraudulent, deceptive, or misleading statement…in relation to the practice of medicine and surgery," and 3) "obtaining of, or attempting to obtain, money or anything of value by fraudulent misrepresentations in the course of practice."[8]
  - Unnecessary surgeries fueled by incompetence, error, or financial gain jeopardize a physician's medical license. State boards are more likely to institute disciplinary proceedings when there is a pattern of practice.
- Unnecessary procedures that are billed to the federal government are a violation of the False Claims Act (FCA). Violation of the FCA is a criminal offense and can lead to substantial fines and other criminal penalties, exclusion from federal programs (including exclusion from employment by any organization or person that participates in federal programs), and revocation of medical licensure.[9,10]
- The FCA criminalizes any knowing (including "should have known") presentation of a false claim for payment to the federal government.[10] No specific intent to defraud the government is required. The FCA has been widely applied to health care to enforce claims for health care services that are false as defined as 1) fictitious (billing for non-existent patients), 2) exaggerated (billing for services in excess of what was provided or upcoding), and 3) excessive or medically unnecessary.[9,10]

Case 10

Defensive Medicine

By Kamal Gursahani

A 36-year-old man, Mr. George, presents to his private insurance assigned primary care provider (PCP) for the first time for low back pain. The pain started after he helped a friend move, three weeks prior to the visit. Mr. George has been taking anti-inflammatories with some relief, but the pain keeps coming back. He has not modified any 85 68 Tm9/6(a)4(in kee)6(p)-9(s c) q 0.14 c 0 1 106.7 589.18 Tm 0 g0- W* n BT /F4 9not 0

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Case Analysis

Stakeholders

The following are stakeholders in the case:

- Primary care providers (PCPs), because of the culture of litigation and the pressure to satisfy the patient. As the first line of access to patients, PCPs are often also faced with being the "gatekeepers" of medicine; they can choose to refer or deny access to further testing and treatment.
- Mr. George and other patients, because unnecessary imaging exposes them to harm.
- Physicians (e.g., spine surgeons, radiologists) and imaging centers, because receiving more referrals, rather than less, from their PCP colleagues results in financial benefit.
- Spinal device manufacturers, because they benefit financially from surgical procedures with their products.
- Society, because medically inappropriate tests and procedures drive up the cost of health care for everyone.

Facts

- Low back pain is very common. It accounts for 2.3% of physician visits in the US, and more than 20% of Americans report experiencing significant back pain in the last three months. Low back pain is also the leading cause of disability in Americans <45 years of age. Most people with acute low back pain report complete recovery after several months, but up to a quarter may still have pain at 12 months.[1]
- The cost associated with the management of low back pain exceeds $100 billion annually, inclusive of opportunity cost due to lost wages, missed work, and decreased productivity.[1]
- Evidence-based recommendations from the American College of Physicians regarding the diagnosis and treatment of low back pain call for imaging only for patients who have severe or progressive neurologic deficits or signs or symptoms that suggest a serious or specific underlying condition.[2,3]
- Clinical practice guidelines for back pain that lasts less than four weeks state that medication, recommendations to patients to remain active, and information about back pain are appropriate.[2]
- Depending upon the MRI and physical exam findings, back pain due to disc disease is surgically managed with either a lumbar discectomy or a more extensive decompression and lumbar fusion procedure.[3-5]
- Studies that compared the benefits of lumbar fusion vs. nonoperative intensive

- Given surgical costs and the risk of

Legal

- Physicians have no legal obligation to provide and patients have no legal right to receive care that is not medically necessary and is outside the standard of care.
- In fact, the physician is practicing within the standard of care. Compliance with clinical practice guidelines is an indication of this, although courts are divided on their treatment of guidelines.[9]
- To succeed in a medical malpractice case, a patient must establish the following: 1) the physician's professional *duty* to the patient (provider-patient relationship); 2) *breach* of that duty; 3) that is the *cause* of; 4) *harm* to the patient; 5) with *damage* that can be monetized.[9]
  - The physician does have a duty to the patient because of an existing physician-patient relationship but no breach or harm has occurred. The patient is still working and active with no signs of neurologic compromise and care is consistent with clinical practice guidelines m 0 g 0 G [( )] TJ ET Q gT6 r

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Case Analysis

Stakeholders

The following are stakeholders in the case:

- Dr. Pierson, because if the vaccine is determined to be safe and effective it may be subsequently licensed to a larger company for marketing, which will directly benefit Dr. Pierson financially as well as advance her career.
- VacSponsor, because the company could see enormous profits if the vaccine is found to be safe and effective.
- The children and infants in the VacSponsor trial, because they are exposed to risk as subjects of research. The subjects could also potentially benefit from the vaccine received, although the benefits of the trial vaccine are unknown at this time. It is also possible that the information generated via the study will benefit the study subjects at a later date, if they develop bronchiolitis or pneumonia.
- Society, because both studies could provide valuable information and lead to a safe and effective vaccine if they are conducted with integrity

Facts

- According to the Institute of Medicine, "A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[1] A PI's primary interest in research is the integrity of the research study. A financial interest in the vaccine manufacturer could unduly influence Dr. Pierson's actions to compromise the integrity of the study.
- Ownership of equity in a drug or device manufacturer developing the study component constitutes a significant financial conflict of interest.[1]
- The AAMC guidelines—and the policies of many institutions of higher education—prohibit individuals with a financial conflict of interest from serving in the role of PI.[2]
- Industry funding and relationships in biomedical research have led to biased reporting in clinical research and a general reduction of openness in science.[1]
- Phase I research studies involve administering a new drug to a small group of people for the first time to evaluate its safety, to determine a safe dosage range, and to identify side effects. Phase II clinical research studies involve giving the drug to a larger group of people to see if it is effective and to further evaluate its safety.[3]

Norms

Mid-Level Principles of Biomedical Ethics[4]

- Autonomy

subject relationship with them. Nevertheless, as a physician-researcher, Dr. Pierson is obliged to treat her subjects ethically and responsibly.

Legal

¶ The Food and Drug Administration (FDA) is the federal agency responsible for "protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products, and medical devices."[7] The FDA requires robust investigation of new products for safety and efficacy through clinical research.

¶ Federal law protects human subjects in clinical research through the Common Rule, a set of regulations issued by the U.S. Department of Health and Human Services.[8] Fifteen other federal agencies have adopted the Common Rule, including the Food and Drug Administration (FDA).[9]

¶ Institutional Review Boards (IRBs) are responsible for protecting the wellbeing of human subjects (i.e., participants) in research at their institutions.[8] Conflicts of interest impact the wellbeing of human subjects.

¶ The Common Rule specifies the following requirements for research that are relevant to conflicts of interest: 1) risks must be minimized; 2) risks must be reasonable in relation to anticipated benefits; 3) subject selection is equitable; and 4) informed consent is obtained from subjects or their legal representatives (e.g., parents).[10] In addition, the possibility of coercion must be minimized.[11]

¶ IRBs are empowered by law to approve, disapprove, conditionally approve, suspend or terminate research activities for the protection of subjects.[12] IRBs may also require additional information be provided to participants that would meaningfully enhance their rights and welfare.[13]

¶ The FDA has stringent requirements for disclosures of financial conflicts of interest by investigators and others involved in research of products under their jurisdiction (e.g., drugs, vaccines). The FDA will deny a new product application for omitted, incomplete, or false information.[14]

¶ There are also stringent regulations for disclosures of financial conflicts of interest when research is supported by the government.[15]

¶ Organizations involved in research have conflict of interest review and disclosure processes to protect the welfare of human subjects, which is required if they accept federal funding. The Department of Health and Human Services has issued guidance for institutions, IRBs, and investigators involved in even privately sponsored research that recommends policies and procedures for management of financial confli

3. Dr. Pierson could ask Large University to appoint an independent faculty investigator as the PI of the VacSponsor trial and restrict Dr. Pierson's role to that of co-investigator or collaborator. The PI could not have a financial relationship of any kind with Dr. Pierson nor could the PI be a close friend or relative. The PI also should not be subject to Dr. Pierson's approval authority or report to her directly or indirectly.
4. Dr. Pierson could recuse herself from participant selection, recruitment, consent, and unblinded data analysis.
5. Dr. Pierson and Large University could require all members of the research team to fully disclose their financial relationships to all study subjects.
6. Dr. Pierson or Large University could assign responsibility for the clinical assessment of the progress of subjects to a new PI or other designee. The role of Dr. Pierson or her laboratory staff in this trial could be restricted to the analysis of blinded data.
7. The Large University IRB could require mandatory ongoing review of the research.
8. If Large University holds equity in VacSponsor it could explore ways to address the institutional conflict of interest.

Reflection Questions

1. What is the specific conflict of interest that [(W) 0 td5.23 Tm(or)] TJ ET Q q2363.oq9009

5. Testing assumptions: What are Dr. Pierson's motives in this case? Would bias affect her decision-making? What assumptions could Dr. Pierson be making in regard to the VacSponser company and the other stakeholders? How could she test her assumptions?

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1. Lo B, Field MJ, Institute of Medicine (U.S.). Committee on Conflict of Interest in Medical Research Education and Practice. *Conflict of interest in medical research, education, and practice*. Washington, D.C.: National Academies Press; 2009.
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8. 45 CFR § 46, Subparts A-E.
9. 21 CFR §§ 50, 56, 312 and 812.
10. 45 CFR § 46.111(a); 21 CFR § 56.111(a).
11. 45 CFR § 46.116; 21 CFR § 50.20.
12. 45 CFR § 46.109(a); 45 CFR § 46.113.
13. 45 CFR § 46.109(b), 21 CFR § 56.109(b).
14. U.S. Departmen 12 T.3 Q q 0.00000912 0 oh912 0 612 792 re W* n BT /F9 12 Tf 1 0 0 1

Case Analysis

Stakeholders

6. Should the FDA have the legal authority to exclude all research conducted pursuant to an application to market a new drug because of a conflict of interest? Why or why not? What are the consequences of exclusion?
7. Does it matter if investigators and sponsors comply with conflict of interest disclosures just to get a drug to market rather than because it is the ethically appropriate action?

SMART Decision-Making Strategy Questions

1. Seeking help: What additional information does Dr. Gold need before making a decision? Who could Dr. Gold turn to for help? Would it help to involve a mentor or consultant?
2. Managing emotions: If you were in Dr. Gold's situation, what emotions might you be experiencing? How might these emotions affect your decision-making?
3. Anticipating consequences: What consequences should Dr. Gold anticipate if she choose to be the PI on the Antibody Therapeutics study? What consequences if she chooses against it?
4. Recognizing rules and power dynamics: What laws or norms are salient in this case? Which factors would be problematic if Dr. Gold took or did not take the PI position? To what extent does she have control over these issues?
5. Testing assumptions: What are Dr. Gold's motivations in this case? What biases could affect her decision-making? What assumptions might Dr. Gold be making about the situation?

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light of her increased energy she and her husband are considering trying to conceive their second child. Dr. Blackstone congratulates Darlene on her weight loss success, and, in the course of the visit, clears her of any additional follow-up for what brought her in three months ago. Before sending Darlene to the checkout nurse, Dr. Blackstone congratulates Darlene again, and considers approaching her about the Theniva trial.

How should Dr. Blackstone balance her responsibilities as a principal investigator with ?

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Darlene, because she is likely to believe that any recommendation (or suggestion) Dr. Blackstone offers is intended to benefit her directly. Such a belief may prevent Darlene from making an accurate risk-benefit assessment and may lead Darlene to make decisions about research participation that she would not make were the study not being presented by her own primary care physician. This mindset is created by her physician-patient relationship with Dr. Blackstone and likely reinforced by the benefits she has enjoyed by participating in the peer support group study.
- Dr. Blackstone, because as a physician-researcher she has obligations to her patients and research subjects that may conflict. Dr. Blackstone must make treatment recommendations based on the specific needs of an individual patient when acting as a physician. On the other hand, as a researcher, Dr. Blackstone must recruit enough patients to achieve significant statistical power and make decisions (such as whether a participant is randomized into the intervention or control arm) based on the study protocol.
- Patients recruited from other physicians into Dr. Blackstone's peer support study, because they may have an impression similar to Darlene's that proposed research participation is intended to benefit them directly (though this attitude may be tempered by the fact that Dr. Blackstone is not their personal physician). They, like Darlene, should make a decision about participating based on the

AMA Principles of Medical Ethics[8]

¶ II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
  - o Dr. Blackstone should be clear about, and reinforce at regular intervals, her dual-role as physician and investigator—especially amongst those research participants recruited from her own practice.
  - o This principle may also obligate Dr. Blackstone to remind her own patients that the primary purpose of research (whether the peer support study or the Theniva study) is to advance scientific knowledge and that any benefits they may experience personally are secondary to that goal.

¶ V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
  - o In caring for patients who are at risk for obesity related diseases, Dr. Blackstone is obligated to seek treatments that will improve the health and wellbeing of those patients. This obligates her not only to recommend treatments guided by the particular needs of individual patients but also to engage in research to develop better interventions for future patients.

¶ VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
  - o Social determinants of health contribute significantly to obesity. Dr. Blackstone's peer support study may contribute to the improvement of the community and the betterment of public health.

¶ VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
  - o Particularly salient in this case, Dr. Blackstone can never fully step out of her role as the physician for her patients who are participants in research studies for which she is an investigator. This may mean that she chooses to exclude patients for whom she believes participation may not to be in their best medical interest.

Legal

¶ Physicians are obligated to act within the standard of care for the welfare of their patients.

¶ Physicians have a legal duty to disclose their competing interests; some courts have declared such information as material to the informed consent process for treatment.[9]

¶ Malpractice actions can be based on failure to obtain appropriate informed consent within the standard of care when it causes rticipanhe rents.

Services.[11] Fifteen other federal agencies have adopted the Common Rule, including the Food and Drug Administration (FDA).[12] The Common Rule requires that an Institutional Review Board review and approve the recruitment plan for a clinical trial such that subject selection is equitable.[13]

Options

1. Dr. Blackstone could have a study coordinator or other study staff member not associated with Darlene's clinical care inform Darlene of the Theniva study, give her all the relevant information, explain options, and engage in an informed consent process with Darlene if she is interested in participating.
2. Dr. Blackstone could tell Darlene about the Theniva study and let Darlene make up her own mind about what to do.
3.

Case Analysis

Norms

Mid-Level Principles of Biomedical Ethics[5]

- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - Fabry patients benefit from a system that supports the production and distribution of the ERT that counteracts the multisystem decline caused by the disease.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - The Fabry patients who received reduced (possibly sub-therapeutic) ERT will be harmed by both symptom increase and disease advancement if the situation is not resolved in a timely manner.
- Justice: obligations of fairness in the distribution of benefits and risks.
    - The treatment population in this case is being asked to bear the full burden of the plant shutdown and ensuing drug shortage.

AMA Principles of Medical Ethics[6]

- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements that are contrary to the best interests of the patient.
    - The physician-researcher has successfully brought his research product to commercial availability, in keeping with the provisions of the Bayh-

7. The University and Small Business Patent Procedures (Bayh-Dole) Act of 1980.

Appendix A. Index of Business Ethics in Medical Practice Cases

Case	#1	#2	#3	#4	#5	#6	#7	#8	#9	#10
Topic										
Problems that can arise fro[illegible] COI										

Appendix B. Index of Business Ethics in Medical Research Cases

Case	#11	#12	#13	#14