Exploring Integrity in Medicine

The Bander Center for Medical Business Ethics

Casebook

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The cases published in this Casebook were written by the research assistants, faculty, and associates of the Bander Center: Erin Bakanas, Joshua Crites, Kamal Gursahani, Elena Kraus, Heidi Pieroni, and Rebecca Volpe. In some instances, the cases were directly based upon previously published accounts of business challenges in medicine: The original sources for the storylines are cited in a footnote following the case narrative.

The editors played a variety of roles: Rebecca Volpe edited all cases, and in some instances drafted the Mid-Level Principles of Biomedical Ethics and the AMA Principles of Medical Ethics sections; Erin Bakanas reviewed cases to ensure that the medical aspects were accurate and realistic; Kelly Dineen wrote the legal analysis section for each case; and James DuBois provided a framework for the Casebook and wrote the Acknowledgements and Introduction.

Cynthia McKenna produced the artwork for the cover.

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Introduction

Nearly every dimension of medical practice and research includes a significant business component. Decisions about prescriptions, ordering tests, and providing clinical services, as well as dedicating effort to research all involve the exchange of money and financially affect a variety of parties—patients, insurers and government payers, physicians, and healthcare and research institutions. Exploring these dimensions through case discussion provides the opportunity to increase sensitivity to the ethical issues, to foster professional problem-solving skills, and to gain knowledge of relevant facts, principles, and laws.

Addressing matters of medical business ethics also provides the opportunity to engage at least two of the general competencies for graduate medical education established by the Accreditation Council for Graduate Medical Education (ACGME): *professionalism*, which includes recognizing "the importance and priority of patient care" and being "able to identify ethical issues in clinical situations"; and *systems-based practice*, which includes being "knowledgeable about the health care system, including principles of economics, public health management, quality assurance and patient safety."[1]

The Casebook was developed with several assumptions in mind:

- The learners are adults—medical students, residents, and faculty—who learn best through interactive sessions that require problem solving. Therefore, a case-based approach is appropriate because it requires learners to ask questions, engage different viewpoints, and apply general knowledge to specific situations.
- Learning time is at a premium and many educational sessions are limited to 1 hour—or 50 minutes of actual learning time. Therefore, we designed all cases in this Casebook to be discussed within a 50-minute block of time.
- The facilitators may not have a lot of expertise in ethics, and particularly in medical business ethics. Therefore, in writing analyses of cases, we made sure to include relevant facts and to identify relevant ethical norms and laws with references that allow for further reading.

At first glance, not every case in this Casebook may appear to address a matter of "business ethics." However, every case includes a business dimension at least indirectly; identifying this dimension and exploring how it affects medical practice or research is valuable insofar as it enables reflection on the incentives and values that influence physician behaviors.

The Structure of the Casebook

Each chapter of the Casebook has the same structure:

- A Case Presentation followed by a question that asks what the involved clinician should do. In each instance, we ask specifically what the clinician in the case should do—even when it's clear that others should also take action, in fact, even when others are in the best position to fix the situation. The rationale for this is simple: We intend this book for use in clinician training and want always to return to the question, "What can you as a professional do in such a situation?"
- A Case Analysis framework that examines the relevant stakeholders, facts, norms, and options—dimensions to the case that should be considered as participants seek to answer the basic action question following each case.*
- Reflection questions that assist facilitators in identifying salient ethical issues that might be discussed.
    - Often the problem in the case involves not merely knowing the right thing to do but figuring out how to do it amidst financial and professional pressures. SMART problem-solving strategies can be helpful in these instances, and so SMART reflection questions are included in each case and the full SMART approach is outlined in Appendix C.
- References to works cited in the case analysis.

Engaging Norms—Both Ethical and Legal

When presenting norms, the editors adopted a standard strategy for each case. We first identify how the mid-level principles of biomedical ethics—popularized by the principlist framework of Beauchamp and Childress—apply to the case.[2] Second, we identify relevant sections of the AMA Principles of Medical Ethics.[3] Finally, we identify relevant laws—focusing on federal law and common principles governing Tort and State laws. **Disclaimer: This book is not meant to offer legal advice. We encourage users of the Casebook to consult with legal counsel or risk management if they have specific questions about legal matters raised in the cases.** At the same time, since the business dimension of medical practice and research is addressed in many laws, regulations, and court cases, it would be foolish to ignore the legal dimension; good ethical deliberation therefore takes into account a broad range of factual and contextual information, including the societal norms expressed in law and the legal risk posed by going against these norms—knowingly or unknowingly. We do not want identification of legal issues to shut down ethical discussion. Rather, we present legal material in the spirit of the twofold obligation presented in the AMA Principles of Medical Ethics: "A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient."[3] On the one hand, there is a prima facie obligation to respect the law. On the other hand, there is an

* The case analysis framework presented here, which focuses on stakeholders, facts, norms, and options (SFNO) is based on the framework developed in James M. DuBois, *Ethics in Mental Health Research* (New York: Oxford, 2008). The relevant chapter from this book is available for free at http://emhr.net. explains more fully the significance of each component to the ethical analysis of a complex case.

obligation to advocate for changes in laws that do not serve patients well. We encourage frank discussion of laws in the arena of medical business ethics with the aim of identifying what serves patients well and what thwarts the aims of medicine.

How Were Topics Identified?

Business ethics in medicine is a relatively young field of inquiry, and there exists no canonical list of topics that should be addressed in medical education. Accordingly, several of the Casebook authors (James DuBois, Elena Kraus, Kamal Gursahani, and Erin Bakanas) conducted a Delphi survey with experts and stakeholders in medical practice and medical research with the aim of establishing a consensus on what topics should be addressed in the undergraduate and graduate medical curriculum.[4] The indices at the end of the Casebook present the highest-ranked topics that were identified by the Delphi panelists, and identifies which cases address the topic. We wrote cases to address each topic. Most cases directly or indirectly address more than one topic.

All cases are based on real events that occurred in medicine. Our sources of case material included personal experiences of some physician authors, published case studies, and reports in the medical news.

How to Use the Casebook

We offer two forms of guidance on using the cases in the educational setting: Logistical suggestions and guidance on the process of facilitating case discussion. Because we believe instructors may want the Facilitation Guide handy while leading sessions, we present it below as a table that can be printed and consulted during sessions.

Logistics of Case Discussion

We recommend the following:

- **Handouts**. As a facilitator, you will want a copy of the Facilitation Guide, the case, case analysis, and reflection questions. Learners only need a copy of the case. Ideally, each small group will have at least one hard copy of the case that they can consult throughout discussion. (Cases do not fit onto 1 slide, so it is generally not feasible to avoid printing copies.)
- **Group Size**. Even if you have a large group (say, 150 medical students) try to form groups of 4–6 people at least for the initial discussion of cases. If you do not have a sufficient number of trained group facilitators (who have studied the case analysis and the Facilitation Guide), then ask groups to appoint a note taker who will summarize the plenary discussion. After individual groups have completed discussion, ask note takers to share their summary, and engage the larger group in discussion using the guidelines presented in the Facilitation Guide.
- **Space**. We recommend facilitating case discussion in a space that allows people to form small groups by forming a circle of chairs or by sitting around a table. If this is not possible, ask learners to turn in their seats to form groups. If this is not

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]

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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 notes on key learning points.
   - If you lack the expertise to facilitate discussion of the complex ethical, legal, and medical issues, we recommend that you seek a qualified co-facilitator.
   - Alternately, you may want to assign some individual or subgroups of participants the task of mastering a portion of the case analysis information 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 help or information, and so forth.
3. **Teach by asking questions**. Reflection questions prompt students to explore issues and options when they seem to be reaching a conclusion prematurely or are having difficulty identifying key issues.
   - Introduce new factual information only if the group fails to mention it in the course of discussion.
   - When new information is presented, ask how it influences learner's deliberations.
4. **Encourage exploration of multiple options**.
   - Even if you feel the group has quickly reached a recommendation that is best or at least ethically defensible, ask them to consider alternatives and to explore the values behind the alternatives.
   - Cognitive dissonance and perspective taking foster ethical and professional development.
5. **Explore not only decisions, but also the processes used to arrive at good decisions.**
   - In many cases, it is not difficult to recognize what is the right thing to do—but it is very difficult to figure out how the individual in the case can do the right thing in the midst of financial or professional pressures.
   - Such cases provide an excellent opportunity to explore the use of good decision-making strategies.
     Appendix C includes SMART professional decision-making strategies, which involve: Seeking help, Managing emotions, Anticipating consequences, Recognizing rules and power dynamics, and Testing assumptions. Following each case analysis, we have included a series of SMART decision-making strategy questions to guide case discussion when the interpersonal, psychological, or political issues seem more salient than the policy/ethics issues. With some cases, you may wish to use only these questions to guide discussion; in other cases, you may wish to use just 1 or 2 such questions; and in other cases (e.g., those with a policy focus) these questions may not be relevant.

6. **Do not dominate but do manage discussion**. Find courteous ways to prevent one person from dominating discussion.
    - Recognize tangents and redirect toward salient issues.
    - Consult your Case Analysis notes and return to key teaching points.
7. **Do not allow people to be passive**.
    - If the group is small enough, call on those who are silent.
    - If you are overseeing multiple small groups, circulate and encourage everyone to be active.
    - If the group is large or you fear that some people will not participate actively in discussion, then ask individuals to write their own response to the case prior to engaging in discussion. Brief writing exercises are an excellent way of ensuring that every individual actively engages the material.
8. **Provide a conclusion.** Conclude group discussion with a summary of the key learning points and by identifying those options that are ethically defensible.
    - In the Case Analysis, we do not defend a particular course of action; rather, we present relevant facts, ethical principles, and laws that enable individuals to rule out certain options, narrowing the field of defensible options.
    - We do not assume that there is one right option for each case, but neither do we think all options are equally good. We would prioritize options that are consistent with the law, balance ethical principles in a reasonable manner, and are consistent with the goals of medicine and fiduciary obligations generated by a patient-physician relationship.

Case 1

Pricing for Health Care Services

By Heidi Pieroni

Dr. Jones is an internal medicine physician at Luke Health Systems (LHS) in a large American city. During an office visit about a sinus infection, Sue Brigsby, a 55-year-old female patient with Type 1 diabetes, complains to Dr. Jones about a bill she received from LHS.

The bill was for magnetic resonance imaging (MRI) that Dr. Jones ordered as part of a kidney function study six months ago. Dr. Jones ordered the study at the LHS Hospital located across the street from his office. The MRI was for the purpose of assessing the underlying cause of her hypertension that was not adequately controlled with the current medication regimen.

Ms. Brigsby told Dr. Jones that the MRI bill from LHS Hospital was $4,000, plus a $4,500 interpretation bill from the LHS radiology group. Ms. Brigsby indicated that her insurance company was refusing to cover any of the costs because both the hospital and radiology group are out-of-network providers. Even if the services were covered in-network, Ms. Brigsby's health insurance benefits require a $3,000 deductible; therefore, she has to pay $3,000 out-of-pocket before any scheduled benefit can take effect.

Ms. Brigsby is unable to pay because she recently lost her job and pays $1,000 per month for Consolidated Omnibus Budget Reconciliation Act (COBRA) continuation coverage. Ms. Brigsby's son, a college student, contacted LHS and the hospital was willing to offer a 10% discount if the bill was paid in cash or by credit card within 30 days. He also contacted two other MRI service providers in the area and learned that the same study was available elsewhere for as low as $900 for both the MRI and a radiologist's interpretation.

Angry and frustrated, Ms. Brigsby broke down and cried at the visit. She wondered aloud how she was going to afford her overdue health care bills as well as her medications, rent, and other living expenses. Ms. Brigsby was certain that the LHS Hospital and radiologist's charges were excessive, but she didn't know what do to about it.

***How should Dr. Jones respond to Ms. Brigsby's concerns*?**

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 competencies being "knowledgeable about the health care system, including principles of economics, public health management, quality assurance and patient safety."[1]
- "Future health care professionals, in order to be more attuned to the needs of those they serve, will need to have a greater understanding of the factors and parties that influence wellness, the delivery of healthcare, and public health." [2]
- Dr. Jones' employment with LHS hospital raises ethical and legal questions about his referral and whether it was sufficiently transparent. The self-referral may constitute a legal issue or a conflict of interest, with the interests of the hospital and Dr. Jones misaligned with those of Ms. Brigsby. The arrangement between Dr. Jones and the hospital may not be known by Ms. Brigsby.

Norms

Mid-Level Principles of Biomedical Ethics[3]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.

    - 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.

AMA Principles of Medical Ethics[4]

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
    - Delivery of competent medical care requires more than clinical competence; many other skills and competencies are required, including a basic understanding of health insurance and health billing.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
    - Partnerships, tie-in agreements, and conflicts of interest can take advantage of patients in an already-vulnerable position who rely upon their physicians to look out for their best interests.
- IX. A physician shall support access to medical care for all people.
    - The challenges of navigating complex health care plans can lead to increased costs for patients. Physicians should strive to help patients find affordable options to meet their needs and empower patients to consider alternatives.

- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - If Dr. Jones ordered the study at the LHS Hospital because of affiliation and convenience, he has sacrificed the interests of his patient to his personal convenience or other secondary interests, such as financial benefit.
- 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.
    - It is not clear that Dr. Jones made relevant information available to Ms. Brigsby. Arguably, whether the provider was in-network or out-of-network is a basic piece of information that ought to have been considered—and communicated—before almost everything else.

Legal

Referral to LHS for MRI

- There are five major federal laws that address fraud and abuse in health care: 1) the False Claims Act; 2) Anti-Kickback Statute; 3) Physician Self-Referral Law; 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, the Centers for Medicare and Medicaid Services, and the Department of Justice.[5]
- The Physician Self-Referral Law (commonly known as the Stark law) prohibits physicians from referring patients for designated health services to entities with whom they (or the physician's immediate family members) have a financial relationship.[5] No intent or knowledge is required for liability to apply under the Stark law. However, there are multiple exceptions to the Stark law based upon the circumstances of either the referral or of the type of financial relationship.[6]
    - Dr. Jones has a financial relationship with LHS, and MRIs are designated health services under Stark, but Dr. Jones' referral may fall into one of two of the Stark exceptions: 1) the bona fide employment relationship exception (if Dr. Jones is an employee and is paid a salary that is not based on or conditioned on referrals) or 2) the in-office ancillary services exception (designated health services provided in the same office by practice physicians or those supervised by practice physicians).
    - Dr. Jones may also be required to provide patients with written notice of alternate providers when referring patients for certain imaging services.[7]
- The Anti-Kickback Statute (AKS) prohibits physicians from engaging in any arrangements with other individuals (including patients and providers) or entities that would induce or reward referrals for services through money or the transfer of *anything of value* (directly or indirectly).[5] There are serious criminal and administrative sanctions as well as monetary penalties for a violation of the AKS.
    - Dr. Jones cannot be required by LHS to refer to them.

    - Regularly waiving co-payments and other charges can be an AKS violation under certain circumstances. However, it is NOT a violation of the AKS to waive fees for a particular patient after an *individual* determination of inability to pay. If Dr. Jones is satisfied that the charges are not an error, it is legally permissible for Dr. Jones to waive some fees if he has the power to do so.
- Many states also have laws that prohibit self-referrals and kickbacks, as well as licensure statutes that consider such arrangements as a basis for discipline or revocation.[8]

Insurance Coverage

- COBRA plans are governed by the Employee Retirement Income Security Act of 1974 (ERISA). ERISA sets minimum standards and appeals processes for coverage decisions.[9]
    - COBRA coverage is an extension of *existing* insurance and therefore it is legally required that Ms. Brigsby receive the same benefits that everyone still on the employer's group plan receives. Ms. Brigsby must be notified in writing of any changes to the plan. It is illegal for plan benefits to be decreased or changed for just the individuals on COBRA coverage.[10]
    - The plan must also have an appeals process for coverage determinations.
- There may be lower cost options for Ms. Brigsby, such as a health plan created under the Affordable Care Act or a state Medicaid plan, if she qualifies.[11]

Options

1. Dr. Jones could apologize to Ms. Brigsby and tell her that he will look into the MRI and radiology bill on his end. Dr. Jones or someone from his office could follow up with LHS to see if they have a charity care policy that would benefit Ms. Brigsby and potentially cover some or all of her bill.
2. Dr. Jones could refer Ms. Brigsby to her insurance company, indicating that every insurance plan is different, and she needs to work through the details with her insurer.
3. Dr. Jones could refer Ms. Brigsby to a local legal clinic (local legal services offices or law school legal clinics are often excellent resources) for assistance and advocacy with her COBRA plan or negotiating with LHS.
4. Dr. Jones could refer Ms. Brigsby to an LHS social worker for assistance with locating and qualifying for benefit programs, charity care services, appealing previous coverage decisions, or other sources of financial assistance with health care expenses.
5. Dr. Jones could waive the physician's fees or co-pays. Dr. Jones could also ask LHS to waive or more substantially lower Ms. Brigsby's charges.
6. Dr. Jones could personally help Ms. Brigsby pay the bills.
7. Dr. Jones could consider a referral to an in-network psychologist or counselor to assist Ms. Brigsby with the stress of job loss and financial difficulties.
8. To prevent similar future situations, Dr. Jones' office could modify its procedures and also urge LHS to amend scheduling procedures to include insurance review,

pre-authorization, and patient prompts to determine whether ordered tests are covered and at what level (e.g., in-network v. out-of-network). Both entities could provide patients with a list of other local MRI service suppliers as well as remind patients to check with their insurance companies about coverage of the ordered tests.

Reflection Questions

1. Is Ms. Brigsby's complaint justified? If so, on what basis?
2. Is Dr. Jones at fault? Does he have a professional obligation to Ms. Brigsby with respect to her role as a consumer or payer of medical expenses?
3. Is Dr. Jones obligated to provide any advice or counsel on the matter of prices for services and products that he prescribes? If so, to what extent?
4. What, if anything, should Dr. Jones do for Ms. Brigsby?
5. What, if any, changes should Dr. Jones make in handling orders for similar tests or diagnostic procedures for other patients in the future?
6. How much, if any, expertise should health care providers have of their patients' medical insurance plans?
7. Is it possible to practice competent medicine without any understanding of insurance structures?
8. As the patient, what if anything should Ms. Brigsby have done differently?
9. How much of the responsibility for the present situation falls on Ms. Brigsby? How much on Dr. Jones?

SMART Decision-Making Strategy Questions

1. Seeking help: What kind of assistance might Dr. Jones need in a situation such as this? Who might Dr. Jones turn to for help?
2. Managing emotions: If you were in Dr. Jones' position, what emotions might you experience? How might you effectively manage them?
3. Anticipating consequences: What sorts of consequences should Dr. Jones anticipate for each of the options she might consider in this case? This includes both short-term and long-term consequences, and consequences to different stakeholders including her patient, LHS, and herself.
4. Recognizing rules and power dynamics: What rules or norms are salient in this case? To what extent is Dr. Jones in a position to resolve this problem, and to what extent do other stakeholders have the authority to address it?
5. Testing assumptions: What assumptions might Dr. Jones make about LHS or about Ms. Brigsby? Might some of these assumptions be mistaken? How might she go about testing her assumptions?

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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 results of the biometric screening get uploaded onto the online wellness profile. *And*, I'm pretty sure that they're going to transfer my personal health record—so this visit, for example—and upload *that* onto my profile too."

Dr. Bruce injects, "Really? I didn't know that."

"Yes, it's true!" Ms. Archer continues, "and if I fail to do any of those three things, I have to pay an extra $100/month—that's $1,200 a year! Of course, Pennywise State says that they're doing this whole Take Care Initiative because they are projecting double-digit increases in the cost of employee health care, and they can't just maintain the status quo."

"So, I really have a number of questions and concerns," Ms. Archer goes on. "First of all, I think this type of program—where they charge you extra—is called a penalty program, right? And the alternative is an incentive program? So, is there any evidence that a penalty program is better than an incentive program? Also, I really don't want all my information online! I'm worried about confidentiality—who knows what the wellness profile company will do with my information?

"Well," Dr. Bruce says, "I understand your concern, but I think it's safe to assume that the online wellness profile is HIPAA compliant."

"But even if they don't give it away or sell it on purpose, don't we hear all the time about breaches to the firewalls of major online companies? Plus, there's one last thing" Ms. Archer continues, "employees who smoke will be charged an extra $75/month. But what if a patient does not report their smoking and then has a positive screening test for nicotine---would their doctor be told? Couldn't that affect the therapeutic relationship?"

Dr. Bruce reflects that she really hasn't paid much attention to the new insurance program and wonders what she should tell Ms. Archer.

How should Dr. Bruce respond to this situation?

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Ms. Archer and other Pennywise State employees, because they are concerned about privacy, confidentiality, the primacy of the physician-patient relationship, and keeping health insurance affordable.
- Dr. Bruce, because in her role as a physician she should understand the insurance and advocate for any needed improvements.
- Pennywise State University, because the organization needs to be able to afford health insurance for its 44,000 employees.

Facts

- Some studies show modest savings from wellness programs[1] and others do not. Harvard School of Public Health professor Katherine Baicker—who authored one of the studies showing a cost-savings from wellness programs—recently said that it is "too early to tell" whether workplace wellness programs save money.[2]
- There is no evidence indicating that penalty programs (i.e., 'the stick') are more effective than incentive programs (i.e., 'the carrot'); in fact, if anything, incentive programs seem to be more effective than penalty programs.[3]
- While clinical intuition indicates that patients sometimes lie to providers, this is not well documented in the medical literature. However, some empirical literature does indicate that patients lie to physicians (often about behaviors such as drinking or smoking, or to obtain pain medications or exemptions).[4]

Norms

Mid-Level Principles of Biomedical Ethics[5]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - The financial penalties Ms. Archer will face could be perceived as coercive and may therefore negatively impact her right to be free from controlling influences when making decisions that impact her wellbeing. If Ms. Archer cannot afford to pay the $100/month penalty, she really has no choice but to comply with the wellness program, making the 'option' to participate in the wellness program not only farcical, but also coercive.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - One justification for penalty programs is that they reduce the overall cost of health care, thereby financially benefiting patients like Ms. Archer. If the programs are not effective in achieving this aim, on what basis are patients' rights infringed upon? If they are effective, does financial benefit justify the potential harms associated with the program?

    - Another justification for penalty programs is that they improve the health of individual patients like Ms. Archer by encouraging preventive health measures.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - There is the potential for harm if Ms. Archer loses trust in her caregivers or if her personal health information is inadequately protected on the online wellness profile, or if her insurance rates increase without providing additional benefits.
- Justice: obligations of fairness in the distribution of benefits and risks.
    - Health insurance works by sharing and pooling risks associated with illness. The theoretical purpose of wellness programs is to bring down the cost of health care, thereby benefiting the entire organization by maximizing savings and minimizing costs.
    - Wellness programs allocate individual costs based on health behavior and to a lesser extent, on health status.
    - Fixed financial penalty programs disproportionally affect those with lower incomes.
    - Wellness programs based on health status are potentially discriminatory by disproportionately burdening those with underlying conditions and disabilities.

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.
    - If Dr. Bruce concludes that the Take Care Initiative is contrary to the best interests of her patients, she may have a professional responsibility to try to change it.
- IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
    - The documentation Dr. Bruce makes in Ms. Archer's health records may be included on the online wellness profile. If true, this raises privacy concerns related to inappropriate access and disclosure.
- 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.
    - Perhaps Dr. Bruce should systematically educate her other patients about the Take Care of Your Health Initiative.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
    - The Pennywise wellness program could contribute to the betterment of public health, to the extent that it reduces health care costs and makes

employees more aware of their health status.

Legal

- Multiple federal laws are implicated by this situation, with complex and overlapping applicability. Particularly relevant here are the Health Insurance Portability and Accountability Act (HIPAA), the Americans with Disabilities Act (ADA), and the Genetic Information Non-discrimination Act (GINA). These all apply to wellness plans and insurer practices in the context of employment, and the Employee Retirement Income Security Act (ERISA) applies to most employer-based health plans. HIPAA also applies to the protection of patients' personal health information.
- The major legal concerns are whether the wellness program is 1) lawful and non-discriminatory and 2) protective of personal health information (privacy), especially through the online wellness profile.

Non-discrimination

- HIPAA and ERISA prohibit health plans from discriminating against individuals based on a health factor, including through the use of wellness programs, with some exceptions.[5] All group health plans, even those not subject to ERISA, must comply with the non-discrimination provisions of HIPAA.
- Federal law divides wellness programs into two categories: 1) participatory wellness programs (participatory programs) and 2) health-contingent wellness programs (contingent programs).
    - *Participatory programs* do not require individuals to meet specific health measures to realize a reward; examples include reimbursement of gym memberships or rewards for simply participating in a health fair. They are presumed lawful if they are available to all plan members without regard to health status. There is no legal limit to a financial reward for participatory programs.[7,8]
    - *Contingent programs* require individuals to satisfy some health-related standard for a reward, such as a certain weight or smoking cessation. Contingent programs are at greater risk of violating the non-discrimination provisions of ERISA and HIPAA and must meet five specific requirements, including notice to participants, reasonable alternative to individualized health standards, and limited financial rewards.[7]
    - The first three requirements of the Take Care Initiative are probably part of a participatory program if the reward is realized by simply *participating* in an annual exam, the biometric screening, and the online wellness profile (but not requiring disclosure of any particular type or amount of information).
    - The smoking cessation part of the program is a health-contingent wellness program because it is contingent on actual smoking cessation. The program must obtain that information directly from the participant rather than through their health care provider.

- There is no federal legal distinction between penalties and incentives in wellness plans; both are included in the definition of reward.[7,9]
- 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, under HIPAA the plan may not use or disclose genetic information for underwriting (premiums and coverage cannot be based on genetic information).[11]
    - To comply with GINA and the ADA, the wellness program and each of its components must be voluntary, not be connected with financial inducement for information disclosure, provide written information, and obtain consent or refusal in writing.
    - The Take Care Initiative Wellness Profile component must be optional in order to comply with the law. Any requirement to provide health information tied to a financial reward is impermissible. The plan should not ask employees questions about their family medical history, which is genetic information under GINA. The information in the Wellness Profile can only be available to the individual and their health care providers, with their consent.

Privacy

- HIPAA's privacy rule applies to any information collected as part of the wellness plan because her employer is also a health care provider and therefore is a covered entity under HIPAA's privacy rule.[11,12]
- The online wellness profile company is almost certainly a business associate under HIPAA's enhanced final rule and now subject to *direct liability* for noncompliance.[11]
    - Ms. Archer cannot be required to participate in the wellness plan or the online wellness profile. If she does so voluntarily, the information is probably protected in compliance with HIPAA *in this particular circumstance*. In any event, the information should be structured to flow into the medical record, rather than the medical record flowing into the online wellness profile.
- A variety of state laws also impact health insurance regulation and health privacy and confidentiality.[13]

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 patients be balanced against promoting the public health and good of society?
4. Would you want your health record posted on an online wellness profile? Why or why not?
5. Would you find a penalty or incentive program more motivating? Why? Do you agree with the federal government's approach of characterizing all penalties or incentives as simply rewards?
6. Do you agree that contingent wellness program rewards should be limited to a percentage of the total cost of individual coverage and is that percentage appropriate (generally 30% but an additional 20% reward from smoking cessation is now permissible)? Is the distinction between smoking and other health behavior justified?

SMART Decision-Making Strategy Questions

1. Seeking help: What kind of assistance might Dr. Bruce need in a situation such as this? Who might Dr. Bruce turn to for help?
2. Managing emotions: If you were in Dr. Bruce's position, what emotions might you experience? How might you effectively manage them?
3. Anticipating consequences: What sorts of consequences should Dr. Bruce anticipate for each of the options she might consider in this case? This includes both short-term and long-term consequences, and consequences to different stakeholders including her patient, Pennywise State University, and herself.
4. Recognizing rules and power dynamics: What rules or norms are salient in this case? To what extent is Dr. Bruce in a position to resolve this problem, and to what extent do other stakeholders have the authority to address it?

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?

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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. on hospital day two, Mr. Henderson pushes his call light when he needs to urinate. A nursing assistant had emptied his urinal two hours prior but forgot to put it back within the patient's reach. After 10 minutes of waiting, the patient gets up from his bed unassisted, attempts to get to the bathroom, and falls, hitting his head against the baseboard of the wall. He is found unconscious on the floor bleeding from a scalp laceration on the left side of his head. He awakens to verbal stimuli, but remains confused, and does not follow any commands. He has no recollection of what happened. Hospital administration is notified of the incident.

Dr. Williams orders a CT scan of the brain, which reveals a small acute left subdural hematoma and Mr. Henderson is transferred to the ICU in the care of a neurosurgeon.

Mr. Henderson is on a routine dose of a blood thinner following stent placement for coronary artery disease and in the ICU, he receives a platelet transfusion. His repeat CT brain scan at 24 hours is unchanged. He does well and is transferred out of the ICU on hospital day five.

The patient's daughter and son in law are furious about the fall and resulting injury, prolonged hospital stay, and cost of the treatment. They ask Dr. Williams, "How can this have happened in a hospital? It seems like he would have been safer at home. Isn't bleeding in the brain really dangerous? He could have died, couldn't he? What about the bill? And what about the follow up visits with the neurosurgeon… who is going to pay for all of this?"

How should Dr. Williams and hospital administration approach this situation?

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Mr. Henderson and his family, because the fall was avoidable, and caused significant physical harm to the patient as well as financial burden to the patient and family.
- Health care providers, because the model of care delivery can impact a group's approach to patient safety. Patient safety errors are often systems errors, in that they have multifactorial influences, ranging from group behavior to economic incentives. For example, some argue that in a fee for service (FFS) system, there is no incentive to improve patient safety, as injuries result in more testing, treatment, and opportunities to bill for services. Alternatively, some argue that using pay for performance (PFP) will improve patient safety by creating monetary incentives to keep patients safe and healthy. In fact, The Centers for Medicare and Medicaid Services (CMS) will not reimburse fees associated with preventable hospital injuries.
- The hospital system, because it bears the cost of care related to the fall as well as the costs associated with threatened or actual litigation.
- Payors, because they have an interest in spending judiciously, and expenditures related to preventable patient injuries are not the best use of limited funds.

Facts

- Falls are the most common inpatient adverse event. Up to one-third of falls result in injuries including fractures, subdural hematomas, bleeding, and, in some cases, death. Patient falls can increase hospital bills dramatically: one study estimated that costs increased 60% following a fall, and another study found that patients who fell had bills that were $4,200 more than those who do not fall.[1,2]
- There are quality improvement initiatives across the nation to reduce hospital falls.[3]
- There are financial implications for patient safety errors: CMS has limited reimbursement for hospital-fall related treatment.[4] If a fall results in an injury and a diagnosis that was not present on admission, no reimbursement is provided.
- Factors that increase fall risk include confusion upon admission, treatment with central nervous system affecting drugs that can impair cognition (e.g., sedative/hypnotics, antipsychotics, anticonvulsants, narcotics, etc.), and frequent need to urinate or defecate, especially in the evening and during the night.[1,5] Urinary tract infections can result in mental status changes, especially in the elderly, as well as frequent urination.
- An interdisciplinary model of care delivery and fall prevention is required to effectively implement a fall prevention program.[6,7]
- The Swiss cheese model of systems errors is a metaphor for understanding medical error. According to the model, every step in a process has the potential for error, to varying degrees, and often a subsequent step will stop the error from

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 focusing 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 their promise to do no harm. Yet many health care environments and systems interfere with this maxim, including the FFS model.

AMA Principles of Medical Ethics[12]

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
    - The providers in the present case should deliver the highest quality patient care they can, regardless of their reimbursement structure. "Providers" encompasses physicians, nurses, ancillary staff, and members of the hospital administration.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
    - Physicians have an ethical obligation to be advocates for better health systems. In the present case, it is worth asking the question, "Do physicians have a professional obligation to publicly advocate for a health care system that thrives economically from keeping patients healthy as opposed to sick?"
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

- 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]
- 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 minimized some of the family's distress and deescalated the situation.[19]

Options

1. Dr. Williams could disclose the error to the patient's family in compliance with any existing hospital protocol. In the absence of a protocol, Dr. Williams could disclose the error anyway and apologize.
2. Dr. Williams could listen empathetically but refrain from taking responsibility or apologizing.
3. Dr. Williams could tell the family they need to speak with hospital administration.
4. The hospital could further encourage physicians, nurses, and other providers to uphold professionalism standards by mandating basic patient safety training and outcomes as part of employment requirements.
5. As part of an overall evaluation, Dr. Williams could encourage the hospital to consider increasing use of patient sitters along with a formalized training and

evaluation program. Patient sitters are generally more affordable than skilled nursing staff and can monitor patients for their safety.

6. Dr. Williams and the hospital administration could explore educational campaigns to engage the community to improve patient safety and foster interdisciplinary cooperation.
7. The hospital and Dr. Williams could consider an interdisciplinary review of this event, overall hospital fall rates, and existing fall protocols. They could revise or replace those protocols as needed, using established sources such as the evidenced-based, interdisciplinary protocols available from the Agency for Healthcare Research and Quality.[6] If the hospital does not have an error disclosure protocol, the administration could consider working with or encouraging the general counsel's office to develop one.
8. Dr. Williams and the hospital administration could support expansion of current changes in the health care financing system, such as pay for reporting or pay for performance, which discourage increased utilization of resources resulting from hospital-acquired conditions.

Reflection Questions

1. When patient safety errors occur, where does the responsibility lie? Where do the solutions lie? How much responsibility rests with the institution and how much rests with physicians, nurses, and other providers?
2. What are the barriers to implementing safe environments?
3. What could the providers have done differently to prevent the fall? What factors contributed? Are all falls preventable?
4. What is the Swiss cheese model of systems errors and how might it apply to this case?
5. Do you agree with the federal government's approach of non-reimbursement for hospital acquired falls? For whom do you think this economic disincentive is most effective in changing behavior?
6. What, if any, are the obligations of physicians to advocate for improved health systems structures?
7. Should providers promptly disclose when a patient safety error occurs? Should they apologize? Why or why not? If yes, to whom should they be speaking?

SMART Decision-Making Strategy Questions

1. Seeking help: What kind of additional information does Dr. Williams need in a situation such as this? Who might Dr. Williams turn to for assistance? Have Dr. Williams and the other healthcare providers involved welcomed correction and owned to mistakes?
2. Managing emotions: If you were Dr. Williams, 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. Williams anticipate for each of the options in this case? What are the short- and long-term

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? To what extent is Dr. Williams in a position to address this problem, and to what extent do other stakeholders have the authority to address it?
5. Testing assumptions: What are Dr. Williams' assumptions in this case? Might Dr. Williams be making faulty assumptions about the causes of the situation or alternatives?

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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 success, the practice was able to add a fourth physician, Dr. Fraxure, about two years ago.

Unfortunately, Dr. Aucel is increasingly concerned about some patterns of care she is observing from Dr. Fraxure. First, Dr. Fraxure sees significantly more patients than the other physicians in the practice see on a daily basis. Dr. Aucel believes this is because in lieu of a complete history and physical, Dr. Fraxure tends to depend more on MRIs, which he orders for virtually all his patients. This does not completely surprise Dr. Aucel, since Dr. Fraxure convinced the practice to invest in its own MRI center, and she knows this arrangement incentivizes the overuse of this expensive imaging.

What is most troubling, however, are the patients who come to her for a second opinion after seeing Dr. Fraxure. Often, they are looking for an alternative to surgery. After a thorough physical exam and a re-examination of their MRIs, Dr. Aucel finds most of the MRIs results are inconclusive and therefore do not necessarily indicate surgery. On a number of occasions, she has seen elderly patients with significant comorbidities scheduled for surgery; patients who would not expect to appreciate significant benefits from surgery.

Dr. Aucel's colleagues do not share her concerns about Dr. Fraxure. They attribute Dr. Fraxure's practice patterns to differences in medical judgment and believe that a few more MRI scans will not hurt patients because they are offering a convenient and discounted MRI service. After all, the clinic has never done better financially, and they are all seeing increases in their salaries.

***How should Dr. Aucel respond to this situation*?**

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]

- Addressing bad behavior can improve staff satisfaction and retention, improve practice reputation, improve patient safety and risk-management, and create more productive work environments.[3]
- Unprofessional behaviors are associated with poor adherence to practice guidelines, loss of patients, low staff morale and turnover, medical errors and adverse outcomes, and malpractice suits.[3]

Norms

Mid-Level Principles of Biomedical Ethics[4]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - If Dr. Fraxure is not doing an appropriate history and physical, his treatment recommendations are based on incomplete knowledge of his patient. The patient then does not have sufficient information about his medical needs to make an informed decision about his medical care.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - Dr. Fraxure is causing physical harm to patients by performing unnecessary medical procedures, emotional harm due to the stress incurred, and financial harm insofar as unnecessary procedures are an unnecessary expense.
- Justice: obligations of fairness in the distribution of benefits and risks.
    - Dr. Fraxure's fraudulent tests place an unfair burden on patients and the healthcare system.

AMA Principles of Medical Ethics[5]

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
    - Dr. Fraxure's practice may be in violation of this principle if he is prioritizing his own financial wellbeing at the expense of providing competent medical care.
- 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. Aucel believes that Dr. Fraxure is potentially incompetent or engaging in fraud or deception. It appears that Dr. Fraxure is ordering unnecessary and costly tests and performing unnecessary surgeries. Dr. Aucel has an obligation to address the situation.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - These responsibilities extend to all the practice's patients. The patients' wellbeing ought to take precedence over financial gains.

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) through the DOJ or a private party with knowledge of the conduct (whistleblower) may bring suit on behalf of the government through its *qui tam* provision.[7]
    - Even though Dr. Fraxure is seeing more patients than his colleagues, he should not be billing significantly more overall because he is providing a lower level of care. If he is generating more revenue than his colleagues while performing minimal examinations on patients, there may be fraudulent billing occurring, such as upcoding.
    - Dr. Fraxure is probably violating the FCA by ordering medically unnecessary MRIs and performing unnecessary surgeries.
    - The pattern of second opinion patients with no clear-cut indications for surgery, including those who are at very high risk due to underlying health issues, probably triggers the knowledge component of the FCA and places Dr. Aucel and colleagues outside the law and at risk of liability if the government does take action.

- The Stark law prohibits physicians from referring patients to entities with whom they (or immediate family members) have a financial relationship for designated health services.[6] Nearly half of states have similar laws that apply to private insurance.[8] No intent or knowledge is required for liability to apply under the Stark law. However, there are multiple exceptions to the Stark law based upon the circumstances of either the referral or the type of financial relationship.[9]
- Physician group practices are exempt from the Stark law prohibition for 1) referrals for patients to be examined by physicians in the same group practice and 2) in-office ancillary services (including imaging services) if the services are a) personally provided by the referring physician or b) directly supervised by a practice physician and c) are conducted in a building in which the group's designated health services are provided. However, any profits or bonuses the group practice members enjoy must be structured in a manner that is not directly related to the volume or value of referrals by the group practice physicians.[9]
    - The doctors may refer to each other within the same group practice under the group practice exception and the imaging services may be lawful under the in-office ancillary services exception (depending on additional unknown facts).
    - Nonetheless, their profits cannot be related to the volume or value of referrals. Therefore, the fact that some of the physicians noted that Dr. Fraxure's excessive MRIs are increasing their salaries is of serious concern.
- The Office of the Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) have created processes for voluntary self-disclosure of suspected violations of Stark, AKS, FCA and other fraud and abuse laws.[10,11]
- The federal government has increased its scrutiny on even lawful self-referrals to imaging centers recently.[12]
    - The group's referrals to their own MRI center are self-referrals under Stark. The group has a financial relationship with the MRI center. It can only be permissible under the law if it meets the Stark in-office ancillary services exception.
    - In any event, effective January 2011, *the practice is required to provide patients with written notice* of at least five local, alternative providers of MRI services.[13]
- The Anti-Kickback Statute (AKS) prohibits physicians from engaging in any arrangements with other individuals (including patients and providers) or entities that would induce or reward referrals for services through money or the transfer of *anything of value* (directly or indirectly).[6,14] There are serious criminal and administrative sanctions as well as monetary penalties for a violation of the AKS.
    - For example, if the group requires their physicians to refer to their own MRI center, it would be an AKS violation.
- Many states also have laws that prohibit self-referrals and kickbacks, as well as licensure statutes that consider such arrangements as a basis for discipline or revocation.[8,15]
- The practice group may have ways to terminate or sanction Dr. Fraxure for unethical behavior based on their business organization documents or

employment agreements. However, this does not relieve the individual physicians from potential fraud and abuse liability.

Options

1. Dr. Aucel could continue working at the clinic under threat of legal liability.
2. Dr. Aucel could confront Dr. Fraxure directly with her suspicions that he is not acting in the best interest of patients.
3. Dr. Aucel could follow up with her colleagues regarding her concerns with more information and attempt to persuade them that Dr. Fraxure's practices put them all at risk. This could include advocating for measures ranging from sanction to termination of Dr. Fraxure.
4. Dr. Aucel could urge the practice to hire a lawyer with expertise in health care law and ask for a formal opinion and an internal audit including chart reviews and billing practices of the group's physicians.
5. Dr. Aucel could urge the group practice to work with a health care lawyer to explore self-disclosure of fraud and abuse via the federal process.
6. Dr. Aucel could urge the practice to develop a compliance program going forward. Mandatory compliance programs are often a condition of fraud and abuse settlements with the federal government.
7. Dr. Aucel could approach the problem using graduated interventions:[3]
    a. Have an informal talk with Dr. Fraxure indicating her concern about one or a handful of specific incidents.
    b. Schedule a meeting with her colleagues and Dr. Fraxure to provide non-punitive awareness of Dr. Fraxure's patterns using information on patient and procedure volume from the practice.
    c. Restrict Dr. Fraxure's privileges or terminate his employment, and/or report his behavior to appropriate authorities.
8. Dr. Aucel could approach a health care lawyer individually to self-disclose fraud and abuse or to bring a qui tam action as a whistleblower.
9. Dr. Aucel could leave the practice.

Reflection Questions

1. What is the best approach for confronting colleagues suspected of unprofessional, unethical, or illegal acts?
2. How can physicians keep up-to-date on legal requirements that impact their practice?
3. How can physicians stay aware of patterns of ethically or legally questionable practices by others in their own practice? Are physicians responsible for this knowledge? Are there systems or processes that might help?
4. How can physicians create a culture of compliance to prevent fraud and abuse violations before they occur?
5. How has the implementation of third-party payment challenged the responsibility of physicians and patients to be good stewards of health resources?

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 each of the options she might consider in this case? Which stakeholders will be affected and how? How can risks be minimized?
4. Recognizing rules and power dynamics: What rules or norms are salient in this case? To what extent is Dr. Aucel in a position to address this problem, and to what extent do other stakeholders have the authority to address it?
5. Testing assumptions: What are Dr. Aucel's motives in this case? What assumptions might Dr. Aucel make about Dr. Fraxure and the other partners in the practice? How can Dr. Aucel determine if her assumptions are mistaken? How might she test these assumptions? How will others view her choices?

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Case 5

Interventional Cardiology and a Potential Referral

By Heidi Pieroni

Dr. Taylor began medical school only a few years after Dr. Andreas Gruentzig performed the first coronary angioplasty on a human in 1977. The result of Gruentzig's research spurred the development of a new subspecialty: interventional cardiology. Dr. Taylor soon found himself fascinated with the field of cardiology and gravitated toward this subspecialty in residency. Dr. Taylor now works in a large group practice that recently adopted minimum volume criteria to continue performance of interventional procedures. Dr. Taylor supports this policy because high-volume interventional centers and high-volume interventional clinicians tend to have better patient outcomes. However, Dr. Taylor took some time off last year for health reasons, and he will likely fall short of the caseload requirement (150 cases in the preceding two years).

Carol Irwin enters his office shortly after Dr. Taylor comes to this realization. Ms. Irwin was referred to him for evaluation of a heart murmur. After a careful history and physical exam, Dr. Taylor orders an echocardiogram, which reveals an atrial septal defect (ASD). Ms. Irwin's condition requires ASD closure, which would help Dr. Taylor make up his falling numbers. However, due to the complexity of this case, he wonders if he ought to refer the case to Dr. Loft, a young partner in the practice who sub-specializes in the particular technique that may be appropriate for Ms. Irwin. As Dr. Taylor deliberates over his options he considers that keeping Ms. Irwin would not only be beneficial to him per the new volume criteria but performing this procedure would be a valuable experience and, as an experienced interventional cardiologist, Dr. Taylor is confident in his ability to achieve a successful outcome.[†]

What variables should Dr. Taylor take into account in deciding what to do?

[†] Case adapted from: Zientek D. The evolution of conflicts of interest in a new subspecialty: A case study of the development of interventional cardiology. *Narrative Inquiry in Bioethics.* 2011; 1(2): 88-90.

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Drs. Taylor and Loft, because the more procedures they do, the more they bill. Additionally, better outcomes may increase reimbursement with the initiation of value-based reimbursement (e.g., pay for performance). They also benefit from the experience of performing the procedure. Finally, Dr. Taylor benefits from the increase in his numbers, bringing him closer to meeting the caseload requirement.
- The group practice, because it benefits from enforcing the new volume criteria, which will lead to better patient outcomes and, theoretically, more financial gain. However, the practice could also suffer by limiting Dr. Taylor's privileges and thus increasing the workload of other practice cardiologists.
- Ms. Irwin, because it is in her best interests for the most experienced and specialized cardiologist to perform her procedure.
- Future patients (society), because they benefit from having access to trained physicians. However, society also benefits from an environment that emphasizes trust in the physician-patient relationship, where the physician is expected to recommend the best possible treatment course for the patient. This requires adequate physician self-assessment of knowledge and skills.

Facts

- Some individual studies have shown that that high–volume interventional centers and high-volume interventional clinicians tend to have better patient outcomes.[1] More recent review articles and consensus statements have qualified the role of high-volume centers and clinicians in patient outcomes.[2,3]
- The current consensus statement from the American College of Cardiology, the American Heart Foundation, and the American College of Physicians Task Force on Clinical Competence and Training now recommends only 50 procedures per year (averaged over two years) to maintain competency and avoid adverse outcomes related to inexperience.[2] Dr. Taylor is well within that recommendation.
- To acquire skills or expertise in an area, physicians need practice with patients and cannot always refer to the most experienced physician.[4]
- After proficiency has been obtained, achievement in a given domain is limited by factors unaffected by experience and training, such as basic abilities, mental capacities, and innate talents.[5] Thus, Dr. Taylor may be as qualified as Dr. Loft, or his innate talent may be greater, despite his lack of extensive experience in this procedure.

Norms

Mid-Level Principles of Biomedical Ethics[6]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - To make an autonomous, fully informed decision about her medical care, Ms. Irwin needs to know Dr. Taylor's past experience and competence in performing the required procedure.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - Dr. Taylor needs to base his decision on the best interest of his individual patient.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - By not referring Ms. Irwin to a potentially more qualified physician, Dr. Taylor exposes her to increased risk.
- Justice: Obligations of fairness in the distribution of benefits and risks.
    - If society wants to enjoy the benefits of competent physicians, then they must assume some risks by allowing procedures to be performed in a responsible manner by physicians who are developing skills.

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.
    - Dr. Taylor is confident that he could provide competent, compassionate, and respectful care for Ms. Irwin. However, he suspects that Dr. Loft may have more technical expertise.
- 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.
    - Dr. Taylor has an obligation to continue his medical education and enhance his skills: in order to do so he needs to do more procedures and take on more complicated cases even when cardiologists with greater expertise work in the practice.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - Ms. Irwin's wellbeing and safety ought to take precedence over Dr. Taylor's educational and career aspirations. Though his ability to continue performing certain types of procedures is at risk, the patient's health is ultimately more important.

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 standards, depending upon the state law. The first standard is the reasonable patient standard, meaning the information that a reasonable patient, in Ms. Irwin's situation, would find material. The second is the reasonable provider standard, meaning the information that a reasonable provider would consider material to disclose to the patient.[8]
- Dr. Taylor is not prohibited from referring to a doctor within his own group practice, nor is the volume requirement of 150 procedures *expressly* prohibited by federal law, *so long as* the quota is *purely* based on quality *and* the physicians' compensation does not reflect the volume of those referrals or procedures. Otherwise, federal fraud and abuse laws may be implicated. Nonetheless, it may be prudent for the practice to develop written guidelines that consider a variety of experiential factors, rather than just quantity. The volume requirement could create an incentive for unnecessary procedures.

Options

1. Dr. Taylor could inform Ms. Irwin of the diagnosis and the recommended procedure without providing information about Dr. Loft's expertise in the relevant sub-specialty or Dr. Taylor's need for additional procedures of this type to maintain his standing.
2. Dr. Taylor could inform Ms. Irwin of the diagnosis and the recommended procedure and include information about his 30 years of experience and impressive patient outcomes balanced against his recent lower procedure volume. Dr. Taylor could add assurances that he can perform the procedure and that she is in good hands.
3. Dr. Taylor could inform Ms. Irwin of the diagnosis and the recommended procedure and include information about his confidence in his abilities balanced against his recent lower procedure volume but give Ms. Irwin Dr. Loft's information as an alternative choice or for a second opinion.
4. Dr. Taylor could inform Ms. Irwin of the diagnosis and the recommended procedure but recommend that she make an appointment with Dr. Loft for the procedure.
5. If Dr. Loft is going to perform the procedure, Dr. Taylor could ask to assist with the procedure.
6. Dr. Taylor could ask Dr. Loft about the possibility of her consultation or stand by assistance during surgery to build Dr. Taylor's expertise. Dr. Taylor could then

inform Ms. Irwin as per number 2 above but include the information about Dr. Loft's assistance during the procedure.
7. Dr. Taylor could present the recent consensus guidelines to the group practice and encourage them to revise their volume requirements and other measures of quality accordingly.

Reflection Questions

1. How can physicians balance their responsibility to continue their education and develop their skills with prioritizing patient welfare?
2. If a physician is confident they can provide competent care, to what extent do they need to disclose information such as competing obligations, individual past patient outcomes, or level of experience?
3. Throughout your medical training or practice, when have you felt comfortable learning by doing and when have you felt obligated to rely on other more experienced physicians? What have these experiences taught you about honesty in patient communication and the necessity of skill acquisition?
4. Society benefits from having well-trained physicians, but some patients must agree to care by physicians who are in training. How does the good of society factor into whether Dr. Taylor should perform the procedure?
5. Do you think volume alone is a sufficient indicator of physician procedural competence? What are the benefits and harms of volume requirements?
6. Should physicians disclose their individual level of experience and previous outcomes? Should experience and outcomes be considered part of the material information required for informed consent? Why or why not?

SMART Decision-Making Strategy Questions

1. Seeking help: What further information does Dr. Taylor need to make a decision in a situation such as this? Who might Dr. Taylor turn to for help? Would it help to involve a mentor or consultant?
2. Managing emotions: If you were in Dr. Taylor's situation, what kind of emotions do you think you would be experiencing? How could these emotions influence your decision-making? How could you effectively manage these emotions?
3. Anticipating consequences: What consequences should Dr. Taylor anticipate for each of the options he might consider in this case? This includes short- and long-term consequences as well as positive and negative consequences. Which stakeholders will be affected and how? How might Dr. Taylor's decision impact his career?
4. Recognizing rules and power dynamics: What laws or policies are salient in this case? What are the causes of the problem in this situation, and what causes might Dr. Taylor be able to change?
5. Testing assumptions: What are Dr. Taylor's motives in this case? What assumptions might Dr. Taylor make about Ms. Irwin, Dr. Loft, and the procedure? How can Dr. Taylor determine if his assumptions are mistaken? How might he test these assumptions?

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Case 6

The Business of Prostate Cancer Screening

By Kamal Gursahani

A 65-year-old male, Mr. Engle, visits his longtime private urologist, Dr. Kruger, for his annual exam. Mr. Engle has no new complaints, just baseline occasional difficulty initiating a urinary stream. He has a history of lithotripsy for an obstructing ureteral stone 15 years ago and hypertension controlled on medication.

During the annual exam, Dr. Kruger performs a digital rectal examination and finds a mildly enlarged prostate with normal texture. Dr. Kruger orders a prostate-specific antigen (PSA) test as he does every year. Mr. Engle is transferred to the in-office laboratory (a different room in the same office) where his blood is drawn and analyzed by an in-house lab tech.

A few days later, Dr. Kruger calls Mr. Engle to report a PSA level of 4.1 ng/mL, which is a little higher than his level from last year of 3.8 ng/mL. Dr. Kruger relates the slight possibility that this increase signifies cancer, but more likely represents benign enlargement. When Mr. Engle reacts with obvious concern, the doctor offers to do a biopsy to make sure Mr. Engle does not have cancer, to which Mr. Engle agrees.

Mr. Engle undergoes an uncomplicated ultrasound guided prostate biopsy in Dr. Kruger's office. He is sent home on an antibiotic as prophylaxis against infection. Dr. Kruger sends the tissue samples to his in-house pathologist for analysis.

Mr. Engle presents to the emergency department the next day with fever, vomiting, and hematuria. After an exam and blood work, he is diagnosed with acute prostatitis and admitted by Dr. Kruger for IV antibiotics to treat the infection. During that time, Mr. Engle is informed that his biopsy was negative for cancer, but the infection had been caused by a common strain of bacteria, E Coli, that turned out to be resistant to the prophylactic antibiotic.

Two weeks later, Mr. Engle stops by Dr. Kruger's office with a plate of cookies made by his wife. He gives Dr. Kruger a high five and thanks him, saying "See ya next year, doc!"

How might Dr. Kruger reevaluate the way he practices medicine?

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Mr. Engle and other patients, because unnecessary tests and other interventions place them at risk with little expectation of benefit. Patients may also lose the opportunity to make informed decisions, if information is presented to them in a biased manor. Finally, patients incur additional costs associated with potentially unnecessary evaluations and interventions.
- Dr. Kruger and other urologists, because prostate cancer positives and false positives lead to more physician services (more business), regardless of the reimbursement scheme. Urologists are also likely to have industry relationships in the business of prostate cancer management.[1]
- Other physicians, including primary care physicians (PCPs), because it may be safer and more cost effective for PCPs to make decisions about the management of cancer screenings. PCPs may have industry relationships, but those relationships are unlikely to be specific to prostate cancer screening.
- Hospitals and hospital providers, because prostate cancer positives and false positives lead to more physician services (more business), and in the current reimbursement schema, hospitals and physicians still make money off many preventable complications of treatment.
- The pharmaceutical industry, because greater diagnosis of disease leads to greater use of pharmaceutical therapy and more business in general for drug companies, as well as any drugs used to treat the complications of diagnostic procedures or therapies related to prostate cancer (e.g., prostatitis).
- Society, because medically inappropriate tests and procedures drive up the cost of health care for everyone.
- Taxpayers and the federal government, because unnecessary testing is likely leading to unnecessary Medicare spending and the federal government is responsible for enforcement of fraud, waste, and abuse.

Facts

- There is strong evidence against use of PSA: one systematic review pooled six randomized controlled trials (n=387,286) and divided patients into screening with PSA versus no screening. The authors found that all-cause mortality and prostate cancer mortality were *unaffected* by screening with PSA. The authors also report that one of the six studies reported up to 76% of PSA positives were false positives, and another study reported a complication rate of 0.7% for biopsies.[2]
- The U.S. Preventive Services Task Force recommends against the use of PSA screening for prostate cancer; however, they also acknowledge that decisions about whether to offer the screening should be guided by shared decision making and a careful explanation of the benefits and harms of screening.[3]

- There is no difference in prostate cancer mortality when comparing patients who received PSA test and those who received a digital rectal exam, although the incidence of cancer diagnosis was 12% higher for PSA patients.[4]
- A recent study found that urologists who self-refer billed for 72% more specimens per biopsy than urologists who refer out for pathology services, and also that cancer detection rates were 12% higher for men treated by urologists who referred out for services.[1]
- A conflict of interest exists in clinical care when the physician's primary interest (the wellbeing of the patient) is threatened by a secondary interest, such as financial gain. Self-referrals for pathology services create a financial secondary interest that can jeopardize the physician's primary interest.

Norms

Mid-Level Principles of Biomedical Ethics[5]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - Mr. Engle needs to be provided with the information necessary to make an informed decision about whether he should have a PSA level drawn or a prostate biopsy. Dr. Kruger may make recommendations based on best evidence and his own experience, but his advice must be free from coercion.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - Dr. Kruger is obliged to weigh the risk associated with tests and treatments against the potential benefit to his patient. It would be unethical for Dr. Kruger to include his own potential financial benefit in the risk-benefit analysis.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - If Dr. Kruger administered the ultrasound guided prostate biopsy without medical justification, he unnecessarily placed Mr. Engle at risk for infection (which occurred) and other potentially harmful side effects.
- Justice: obligations of fairness in the distribution of benefits and risks.
    - Unnecessary testing places an unjust burden on patients and the health care system; resource stewardship is a professional obligation.

AMA Principles of Medical Ethics[6]

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
    - If Dr. Kruger is ordering unnecessary tests and procedures, he is not providing competent medical care and is failing to respect his patient's rights to avoid discomfort that has no reasonable possibility of benefit.
- 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.
    - If Dr. Kruger is not disclosing his financial conflict of interest, he is deceiving his patients by withholding information and depriving them of their right to make fully informed decisions.
- 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.
    - Dr. Kruger should investigate whether he is in violation of federal law regarding kickbacks.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - Dr. Kruger needs to revisit the U.S. Preventive Services Task Force recommendations and consider whether his practice pattern is justifiable or leaves him at risk of appearing to either promote his own self-interest or being ignorant of current best evidence.

Legal

- Under federal law, physicians may not refer patients for designated health services to other providers or institutions with whom they have a financial relationship. Many states have similar laws that apply to private insurance.[7,8] There are several exceptions to the federal law.
- Under the in-office ancillary services exception, physician group practices may refer for certain designated health services, including laboratory and pathology services, if those services are personally performed or supervised by them or another physician in the same group practice.[8] Nonetheless, even legally permissible arrangements may incentivize overtreatment.
- The False Claims Act (FCA) criminalizes any knowing presentation of a false claim for payment to the federal government.[7] 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]
    - The federal government has displayed willingness in recent years to pursue physicians for excessive treatment. Dr. Kruger's decision to conduct a biopsy after a very slightly elevated PSA may be considered excessive or medically unnecessary, especially if this is a pattern of practice.
- State law requires physicians to practice within the standard of care. Dr. Kruger could be subject to a malpractice case for failing to follow the standard of care of watchful waiting of a PSA level of 4.1.
- 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.[10]
    - Physicians are rarely liable in malpractice for overtreatment as long as it does not result in more injury to the patient.

- 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.
6. Dr. Kruger could participate in the development of best practices for urologists in communications with patients about testing and treatment choices.
7. Dr. Kruger could institute a procedure requiring disclosures of conflicting interests and possible bias to patients who go to his lab for testing and offer a list of alternate labs to patients.
8. Dr. Kruger could stop ordering routine PSA screening tests, because evidence-based medicine does not support the practice.
9. Dr. Kruger could stop offering biopsies in patients with no significant elevations in PSA.

Reflection Questions

1. Should physicians who have financial relationships with labs be reimbursed for the screening of their patients for prostate cancer? What are the pros and cons of this approach?
2. How can physicians keep up-to-date on common pitfalls in particular medical tests, diagnoses, and treatments? Are physicians responsible for this knowledge? Are repercussions appropriate for physicians who fail to practice evidence-based medicine?
3. Should there be a Stark law exception for in-office lab services if the medical group meets specific criteria? Why or why not? If yes, what criteria should be met?
4. Can conflicts of interest be eliminated? If not, why not? If so, how should they be managed? Does disclosure eliminate conflicts of interest?
5. How has the implementation of third-party payment challenged the responsibility of physicians and patients to be good stewards of health resources?

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?
2. Managing emotions: If you were in Dr. Kruger's situation, what kind of emotions might you experience? How could these emotions influence your decision?
3. Anticipating consequences: What short- and long-term consequences should Dr. Kruger anticipate for each of the available options? How might each of the various options impact Dr. Kruger's career? Which stakeholders will be affected and how? How can Dr. Kruger maximize benefit and minimize risk for all stakeholders involved?
4. Recognizing rules and power dynamics: What laws, policies, or norms are salient in this case? To what extent does Dr. Kruger have the ability to resolve this issue? What factors might limit his ability to resolve the issue?
5. Testing assumptions: What are Dr. Kruger's motives in this case? What assumptions might Dr. Kruger make about his practice and patients like Mr. Engle? How can Dr. Kruger determine if his assumptions are correct? How will others view Dr. Kruger's choices?

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Case 7

Value Based Pay for Performance

By Heidi Pieroni

Pay for performance (PFP) is an umbrella term for initiatives aimed at improving the quality, efficiency, and overall value of healthcare. These payment systems provide financial incentives to hospitals and physicians who meet various metrics or measures of quality in their care of patients. In theory, paying providers for achieving better outcomes for patients should improve care, but in practice studies have yielded mixed results—there is limited evidence that PFP is an effective tool for improving quality of care or containing healthcare costs. Furthermore, serious concerns have been raised about the impact of PFP on poorer and disadvantaged populations: there are fears that PFP programs may increase avoidance of complex patients and exacerbate health disparities if those patients negatively impact the quality metrics.[*]

Dr. Smith is a busy internist in Boston who treats a large population of diabetic patients. One patient, John Green, has recently been weighing on his mind. Mr. Green has been a patient of Dr. Smith's for many years, and only recently has Mr. Green become difficult. Mr. Green suffers from a number of complications of poorly controlled diabetes, including painful peripheral neuropathy. Recently, despite the advice, information, and encouragement from Dr. Smith, Mr. Green gained significant weight and resumed smoking. Furthermore, Mr. Green does not follow his diabetes care plan: he does not consistently measure his blood sugar or take medications other than for pain.

Mr. Green also has recently made it a habit to stop by the clinic without an appointment; at these visits he claims to have lost his prescription for pain medication and requests another prescription. In the last unexpected visit several weeks ago, Dr. Smith reviewed a pain contract with Mr. Green, and Mr. Green agreed to abide by the terms. Dr. Smith now suspects the Mr. Green is either abusing the medication or selling it. Furthermore, Mr. Green missed his scheduled appointments for hemoglobin A_{1c} testing and blood pressure checks. Although Mr. Green's last lipid profile was cause for concern, he did not appear to take his discussion with Dr. Smith seriously.

Dr. Smith is frustrated by Mr. Green's behavior, and he is considering ending the therapeutic relationship. But Dr. Smith is not sure how to go about doing so in a way that is both legal and ethical. He is aware that the PFP model his medical group uses could be swaying his decision; because Mr. Green is failing to comply with diabetes measures, Dr. Smith's performance profile would undoubtedly improve were he to drop Mr. Green.[**]

What should Dr. Smith do?

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[*] James, J. Health Policy Brief: Pay-for-Performance. *Health Affairs*, October 11, 2012.

[**] Case adapted from: Farber N, Snyder L. The Difficult Patient: Should You End the Relationship? What Now? An Ethics Case Study. *American College of Physicians Ethics Case Studies* 2009; http://www.medscape.org/viewarticle/706978. Accessed December 11, 2013.

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Dr. Smith, because there is a financial disincentive (i.e., the PFP model) for Dr. Smith to maintain a therapeutic relationship with Mr. Green. In addition, Dr. Smith will likely experience other benefits if he no longer treats Mr. Green; treatment of difficult, non-cooperative patients can be extremely frustrating and time/energy-consuming. Yet this raises the question: does a physician's professional obligation to a patient change if the patient is difficult?
- Mr. Green, because his medical treatment will be disrupted, and he may well suffer both physically and emotionally due to being discharged from Dr. Smith's practice.
- Other physicians in Dr. Smith's medical practice and their patients, because competing with other PFP practices may encourage the physicians in Dr. Smith's practice to act, perhaps unethically, to improve their performance profiles.
- The Drug Enforcement Agency and other state agencies, because they are involved in licensure and authorization of prescriptive privileges, prescription monitoring program enforcement and compliance.

Facts

- In lieu of discharging Mr. Green, who is a long-term patient, alternate approaches may be effective in improving his health status.
- So-called difficult patients are not rare: the prevalence is estimated to be 15% of patients.[1] Patients in chronic pain, such as those like Mr. Green with peripheral neuropathy, are commonly considered among the most difficult patients.[2]
- Mr. Green's behavior related to his pain medication may or may not be evidence of substance abuse. Patients in chronic pain may display "drug-seeking" behavior because of uncontrolled pain that will resolve once pain is treated appropriately. The incidence of substance abuse in the chronic pain population is no more than that in the general population. [2]
- Chronic pain can lead to a multitude of related comorbidities, including depression, apathy, withdrawal, feelings of hopelessness, etc. It is possible that Mr. Green's more recent behavior is related to these issues.[2]
- Patients may not follow treatment recommendations for many reasons, and there are a variety of models for maintaining relationships while improving compliance. For example, case management models in which a nurse or other health professional maintains regular communication with the patient can be helpful in increasing compliance. Referrals to a mental health provider or interdisciplinary pain treatment center, if available, may be useful in managing health problems.[2]
- Contracts with patients, such as the pain contract reviewed with Mr. Green, are increasingly common in medicine as an approach to dealing with "difficult" patients. Some have called for the addition of provisions that emphasize that the provider will not completely abandon the patient.[3]

- 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 in providing patient care.[4]
- Ignoring the difficult patient or exporting (referring or dropping) the patient to another physician does not make the difficulty disappear.[1] Either of these extremes is not an appropriate option without more thoughtful exploration of underlying issues with Mr. Green.
- Pay for performance initiatives' quantification of quality is arguably insufficient as it is based on pre-determined measures of quality.[8]

Norms

Mid-Level Principles of Biomedical Ethics[9]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - Interactions with Mr. Green should ensure that he is empowered to make good choices, e.g., by providing adequate information and fair warning about conditions under which the patient-physician relationship might be terminated.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - Discharging Mr. Green from Dr. Smith's practice might violate the principal of beneficence. Dr. Green has a lengthy relationship with the patient that will not easily be replaced, if it is replaced at all.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - Discharging Mr. Green could cause physical and mental harm. Mr. Green could also lose trust in physicians in general. If Mr. Green does not find or chooses not to see another physician, his physical condition will likely rapidly decline.
- Justice: obligations of fairness in the distribution of benefits and risks.
    - The PFP model may incentivize providers to exclude certain types of patients from their practice: patients who are non-compliant, have language barriers, or limited access to transportation may lower a providers' PFP score.

- 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 co-morbidities. 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. Smith may be putting his own interests above Mr. Green's due to his own frustration and the financial incentive to discharge him.

Legal

- Patient abandonment is a legal and ethical issue. Physicians have an obligation to treat patients with whom they have a relationship unless the relationship is terminated by 1) mutual consent, 2) explicit dismissal by the patient, 3) patient needs that are outside the provider's competence and training, 4) patient need for services outside the scope of the original agreement, or 5) the patient's failure to cooperate.[11,12]
- "Failure to cooperate" cases require patient actions sufficient to show an implied termination of the relationship by the patient.[11]
  - Even though Mr. Green has missed appointments, he has returned several times to the office unexpectedly: This is evidence that he does not intend to terminate the relationship.

    - 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-patient relationship between Dr. Smith and Mr. Green.
    - Physicians are not legally obligated to continue a *particular type* of treatment, including any medication that is not medically indicated. In fact, physicians are legally obligated to follow the standard of care, including discontinuing non-therapeutic and harmful treatment. Cessation of unnecessary or harmful treatment, such as tapering off non-therapeutic opioids, is not abandonment.
- Most states have prescription monitoring programs (PMP), although participation is voluntary in at least half of the states.[15] Massachusetts has a PMP, and in 2013, the state began automatically enrolling all prescribers of controlled substances. The PMP allows prescribers to search the database for a patient's recent history of filled prescriptions for controlled substances.[16]
    - If available, Dr. Smith should use the PMP to see if there is any evidence that Mr. Green filled prescriptions he claimed to have lost or is using multiple prescribers to obtain pain medication.

Options

1. Dr. Smith could discharge Mr. Green from the practice with a formal letter and 30 days advance notice and assist Mr. Green with finding another physician.
2. Dr. Smith could increase communication with Mr. Green to explore the reasons he is not following treatment recommendations, including an open discussion of his concerns about pain control, substance misuse, and mental health issues. Dr. Smith could help Mr. Green identify his own values, beliefs and goals to inform the plan of care.
3. Dr. Smith could draft a formal agreement with Mr. Green that includes commitments to increased communication, regular blood tests, urine opioid screenings, and conditions for discontinuation of prescription pain medications. Dr. Smith should decide if this agreement will include conditions for discontinuation of the relationship, in which case he will provide Mr. Green with notice and assistance with finding a new physician, or if it will include a provision that Dr. Smith will not abandon Mr. Green (although treatment may change).
4. Dr. Smith could recommend interdisciplinary supports for Mr. Green's increased pain and assist him with a referral.
5. Dr. Smith could keep Mr. Green as a patient and increase communication with Mr. Green but reconcile himself to the fact that patients have the right to make decisions in keeping with their own values, despite the risks.[17] Even if Mr. Green

is not complying with his physician's recommendations, he is probably getting more out of seeing Dr. Smith than a doctor with whom he does not have a long-standing therapeutic relationship.

Reflection Questions

1. What obligations does Dr. Smith have to Mr. Green considering Mr. Green's resistance to treatment and lack of cooperation?
2. What are the legal requirements of notifying Mr. Green of discharge from Dr. Smith's practice? How are the ethics considerations different from the legal requirements in this case? What is the relationship between law and ethics?
3. Is Dr. Smith making assumptions about his patient regarding pain and compliance rather than providing compassionate care with increased communication and support?
4. How much does the stigma of drug abuse and non-compliance impact our attitude toward patients? How can or should physicians manage those issues?
3. What potential questionable business practices are associated with pay for performance incentives?

SMART Decision-Making Strategy Questions

1. Seeking help: Where might Dr. Smith seek additional information or an unbiased, objective opinion? Who could Dr. Smith turn to for advice and assistance for this case?
2. Managing emotions: If you were in Dr. Smith's situation, what kind of emotions would you be experiencing? How could these emotions affect your decision-making? How would you effectively manage these emotions?
3. Anticipating consequences: What consequences should Dr. Smith anticipate if he drops or keeps Mr. Green? Which stakeholders will be affected and how? What consequences does Dr. Smith have some control over? How can risks be minimized and benefits maximized?
4. Recognizing rules and power dynamics: What rules or social norms are salient in this case? What factors place limitations on Dr. Smiths' choices?
5. Testing assumptions: What are Dr. Smith's motives in this case? What assumptions is Dr. Smith making about Mr. Green? How can Dr. Smith determine if his assumptions are correct? How might he test these assumptions?

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Case 8

SellCells

By Erin Bakanas

Mary Smith is a patient with secondary progressive multiple sclerosis. Diagnosed two decades ago, she has tried every available Food and Drug Administration (FDA) approved drug and has participated in two clinical trials, but unfortunately the disease progressed. She is now wheelchair bound and unable to work.

Through her own research, Mrs. Smith learned about adult stem cell replacement as a possible treatment. Initially available only abroad, adult stem cell replacement recently became available in the U.S. Mrs. Smith contacts the company, SaveYourCells, and is given the name of a local doctor who can evaluate her as a potential recipient of the adult stem cell therapy. After the evaluation, she is deemed an appropriate candidate. Mrs. Smith pays $28,000 for stem cell replacement, which will involve the removal of some of her own stem cells, manipulation by SaveYourCells to make more, and then reinfusion of the cells.

Mrs. Smith is referred to a neurologist, Dr. Walker, who is reimbursed $500 by SaveYourCells to supervise the first stem cell infusion treatment in his office. After Mrs. Smith's first series of infusions, she reports improvement or resolution of a number of her multiple sclerosis symptoms. She and her husband plan to finance a second round of infusions, but before this can happen the FDA shuts down SaveYourCells.

The FDA indicates that the stem cell therapy involves changing patients' cells in a way that constitutes the production of a product or drug, and thus requires FDA approval and regulation. SaveYourCells argues that it is simply a laboratory service provider and that it only provides treatment to independent doctors who request it for their patients.

Critics note that SaveYourCells was cofounded by Dr. Strongback, an orthopedic surgeon who himself is a recipient of the therapy and was instrumental in bringing adult stem cell therapy to the U.S. Dr. Strongback is an investor in the company and a member of its board of directors. He is also the physician who evaluated Mrs. Smith for treatment.

SaveYourCells closes its lab in the U.S. and informs patients they will now be working with doctors outside U.S. jurisdiction. In the meantime, the company also announces it will work with the FDA to set up a research arm.

Mrs. Smith is devastated by this news. She schedules an appointment with the neurologist, Dr. Walker, and expresses her great frustration and disappointment. She asks him what she should do.[*]

What advice should Dr. Walker give to Mrs. Smith?

[*] Case adapted from: FDA Challenges Stem Cell Companies As Patients Run Out Of Time, by NPR Staff, February 02, 2013, 4:42 PM ET.

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Mary Smith, because she is experiencing the progression of multiple sclerosis, and had hoped to continue her stem cell treatments only to discover it was no longer available and that the FDA was questioning whether appropriate safety evaluations had been conducted. Mrs. Smith also has made a significant personal financial investment in her treatments from SaveYourCells.
- Dr. Strongback, because of his financial interest as a founder, investor, and board member of SaveYourCells. His professional reputation as a physician, especially because he continues to see patients, will also be impacted by the outcome of the FDA evaluation.
- Dr. Walker, because his professional reputation as a practicing neurologist will be impacted by the ongoing FDA evaluation. He also has a financial interest because he is reimbursed directly from SaveYourCells for treating patients in his office.
- Other patients who have turned to SaveYourCells for treatment for a variety of medical problems, who may have failed multiple other treatment options and are likely highly invested in the success of the treatment from SaveYourCells.
- The medical research community, because they have an interest in maintaining the integrity of scientific inquiry.
- The FDA, because they have an obligation to protect patients from unproven and unsafe products.

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. […] Primary interests include promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education."[1]
- The American Medical Association offers the following definition of informed consent: "It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention. This communication should include the following elements: diagnosis, the nature of the proposed treatment, risks and benefits of the treatment, and risks and benefits of alternative treatment including no treatment."[2]
- The International Study for Stem Cell Research (ISSCR) has issued Guidelines for the Clinical Translation of Stem Cells, stating that it is responding to "an urgent need to address the problem of unproven stem cell interventions being marketed directly to patients. Numerous clinics around the world are exploiting patients' hopes by purporting to offer new and effective stem cell therapies for seriously ill patients, typically for large sums of money and without credible scientific rationale, transparency, oversight, or patient protections. The ISSCR is deeply concerned about the potential physical, psychological, and financial harm

to patients who pursue unproven stem cell-based therapies and the general lack of scientific transparency and professional accountability of those engaged in these activities."[3]

Norms

Mid-Level Principles of Biomedical Ethics[4]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - Patients who pursue treatment, especially under the referral and guidance of physicians, need to have complete and accurate information in order to make a reasoned decision about their treatment options.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - Patients assume unknown burdens because the stem cell infusion program has not been evaluated for safety. Patients may experience physical benefits, but the nature of those benefits is unknown.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - The safety of the SaveYourCells infusions has not met FDA standards; the potential harms of the stem cell modification and reinfusion are not established.

AMA Principles of Medical Ethics[2]

- 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.
    - By offering the SaveYourCells technology to Mrs. Smith, Dr. Strongback and Dr. Walker have not adhered to FDA requirements.
- 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.
    - Treatment innovations are necessary but cannot be fast tracked. The SaveYourCells treatment was not scientifically evaluated prior to being administered to patients.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - Drs. Strongback and Walker have financially profited from SaveYourCells; it is unclear whether their primary focus is the safety and wellbeing of patients or their own self-interests.

Legal

- The FDA is a 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."[5] The FDA acts pursuant to the Federal Food, Drug & Cosmetic Act (FDCA) to regulate drug safety and the Public Health Service Act (PHSA) to regulate biological products (biologics) safety.[6]

- The FDCA and PHSA have detailed regulations for the development, manufacture, and labeling of all drugs and biologics to ensure quality, efficacy, and safety. Drugs and biologics that do not comply are deemed adulterated and misbranded in violation of federal law.[6,7] The FDA is empowered to stop their manufacture and distribution.[6,8]
- The FDA's Center for Biologics Evaluation and Research (CBER) also regulates human cells, tissues, and cellular or tissue-based products (HCT/Ps) intended for implantation, transplantation, infusion, or transfer into a human recipient. Stem cells are HCT/Ps.[9]
- HCT/Ps are classified by the FDA as drugs, biologics, or combined drug/biologics. Most HCT/Ps are subject to the FDA's strict regulatory requirements for drugs.[6]
- Investigators wishing to study a new drug or biologic in humans must first submit an application for an Investigational New Drug (IND). There are also procedures for emergency INDs when a practitioner or investigator wishes to use the product for a particular patient because of an urgent medical need.[10]
- 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, biologics, HCT/Ps). The FDA will deny a new drug or biologic application for omitted, incomplete, or false information.[11]
- Organizations who accept federal research funding are required to have processes for reviewing and managing conflicts of interest.[12]

Options

1. Dr. Walker could encourage Mrs. Smith to travel abroad to undergo a second round of infusions.
2. Dr. Walker could discuss the concerns of the ISSC and the FDA with Mrs. Smith, including the conflicts of interest involved in this case so that she has information about the possible risks associated with the treatment itself as well as the risks of the treatment without FDA oversight for safety.
3. Dr. Walker could offer to treat Ms. Smith as her neurologist. He could disclose his conflict of interest to Mrs. Smith and explain the lack of evidence for the treatment. He could also do further research and share the information with her.
4. Dr. Walker could offer to assist Mrs. Smith in participating in the FDA study once it is set up.
5. Dr. Walker could advise Mrs. Smith to wait for the FDA evaluation and (possible) approval to be completed and promise to continue to work with her as her neurologist in the interim.
6. Dr. Walker could work with SaveYourCells to apply for an emergency IND for Mrs. Smith.

Reflection Questions

1. What are the conflicting interests in this case?
2. What are Dr. Walker's responsibilities to SaveYourCells? To Mrs. Smith? To other patients? To maintaining the integrity of scientific inquiry?
3. Should patients be told about their doctor's investment ties? Why or why not?
4. Patients who have failed multiple conventional therapies and experience progressive health decline represent an especially vulnerable treatment population. In the arena of treatment innovation, what safeguards would you propose to help physicians uphold the principle of beneficence in treating such patients?
5. Should HCT/Ps such as the SaveYourCells infusion be regulated as stringently as drugs or biologics by the FDA? Why or why not?

SMART Decision-Making Strategy Questions

1. Seeking help: What further information does Dr. Walker need before offering advice to Mrs. Smith? Who might he turn to for help?
2. Managing emotions: If you were in Dr. Walker's situation, what emotions would you likely experience? How might these emotions affect your decision-making? How would you manage your emotions effectively?
3. Anticipating consequences: What consequences should Dr. Walker consider before giving Mrs. Smith advice? These include short- and long-term consequences as well as positive and negative consequences. What consequences would Dr. Walker have control over?
4. Recognizing rules and power dynamics: What laws, policies, and/or norms are salient in this case? What factors limit Dr. Walker's options in this case? Which factors are creating problems in this case? Which stakeholders have the ability to resolve these problems?
5. Testing assumptions: What are Dr. Walker's motives in this case? What assumptions is Dr. Walker making about Mrs. Smith, the SaveYourCells company, the FDA, and the other stakeholders? How can Dr. Walker determine the accuracy of his assumptions?

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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.

When he returns home, Mr. Davis sees an orthopedist, Dr. Adams, for continued knee pain. Dr. Adams orders a MRI, which reveals a torn anterior cruciate ligament (ACL). Dr. Adams recommends surgery. Mr. Davis does his own research and finds that in many cases, it may take months to recover from knee surgery. He decides to get a second opinion and sees a sports orthopedist, Dr. Baker. Dr. Baker's opinion is no different from Dr. Adams. Mr. Davis schedules the surgery, but while waiting, decides to do some more research. He discovers an orthopedic surgeon, Dr. Carter, who published an article describing a new technique for torn ACLs that results in shorter recovery time. Mr. Davis decides to pay Dr. Carter a visit.

Mr. Davis flies to Pittsburgh from his home in Ohio for the third opinion. Dr. Carter reviews the MRI and concludes that the diagnosis made by Dr. Adams and Dr. Baker was ambiguous based on the imaging provided. Dr. Carter orders another MRI at the University of Pittsburgh, which shows that Mr. Davis's ACL is completely intact and that his pain is actually due to an avulsion fracture of the fibula. Dr. Carter recommends physical therapy, not surgery.

Mr. Davis is shocked at how different Dr. Carter's conclusion is from Drs. Adams and Baker. When he asks Dr. Carter how the diagnoses and treatment options could differ so much, Dr. Carter says, "I'm not sure. If your ACL really was torn, there is no way you could have skied the next day. But with an avulsion fracture, which is really small, you might have been able to get by because it doesn't affect the stability of the joint." Basically, Dr. Carter says that the first MRI was inconclusive because there was no definitive injury to the ACL. Only the avulsion fracture was apparent, and that was seen on both MRIs. Therefore, Dr. Carter concludes that Mr. Davis did not need the surgery that was recommended by Drs. Adams and Baker.

Mr. Davis does physical therapy for two months and then continues the recommended at-home therapies on his own. He sees significant improvement and starts running again. He plans to go skiing again next winter.[*]

How should Dr. Carter handle this situation? Should Drs. Adams and Baker make changes to the way they practice medicine? Why or why not?

[*] Case adapted from: Kolata G. Sports Medicine Said to Overuse M.R.I.'s. *The New York Times.* October 28, 2011;Health.

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

- The typical clinical presentation of an ACL injury is a classic 'popping' followed by immediate pain and swelling with a feeling of instability and 'giving way' episodes that prevents further activities. ACL injury is much more common in women versus men and usually occurs from a non-contact injury during skiing, soccer, or basketball.[1]
- ACL tears are diagnosed in three ways.[1]
    - Good history and properly performed knee exam can be 80%+ sensitive for ACL injury. This option is low risk for the patient and also generally low-cost for the health care system (doctors' office fees).
    - MRI is also commonly used and has a sensitivity of 90-98% for ACL tears. Bone bruising is also visible on MRI and is present in approximately 90% of ACL injuries. MRI is minimally risky for properly screened patients; however, it is more costly than exam alone at approximately $800 to several thousand dollars per scan depending on facility and location, exclusive of interpretation fees.[2]
    - Diagnostic arthroscopy is expensive and invasive. Its use has decreased while the use of MRI has increased in the past decade. This option has a 2.5% complication rate (e.g., infection, blood clots, hemarthrosis).[3]
- ACL injuries are managed either operatively or non-operatively. Surgical reconstruction is typically used if the patient wants to return to a high level of athletics or if the injury is affecting everyday activities. However, existing

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 conflicts 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]
  - Accepting reimbursement from the federal government for treatment and repair of ACL injuries in patients with no such injury violates the FCA.
- The state of Ohio has criminal fraud laws that apply to both Medicaid related claims and private insurance fraud.[11]
  - If. Drs. Adams and Baker are knowingly recommending unnecessary treatment, they could face state felony charges.
  - Conviction of a felony is also a basis for disciplinary action by the state medical board.[8]
- Private insurance companies with whom Drs. Adams and Baker contract almost certainly have provisions that allow them to audit provider records and rescind payment. Private insurance companies can also bring civil law suits against providers who conduct unnecessary procedures or upcharge for breach of contract, fraud, and misrepresentation.

Options

1. Dr. Carter could call Drs. Adams and Baker and explore why they arrived at different diagnoses and recommendations.
2. Mr. Davis could follow up with Drs. Adams and Baker and tell them about Dr. Carter's diagnosis and the success of his treatment plan.
3. Dr. Carter could call the medical director to whom Drs. Adams and Baker report and relay their misdiagnosis.
4. Dr. Carter could contact the Ohio state medical board about Drs. Adams and Baker.
5. Dr. Carter or Mr. Davis could report suspected fraud to the Office of the Inspectors General; anonymous submissions are accepted.
6. Mr. Davis could contact his insurance company about his concerns.
7. Dr. Carter or Mr. Davis could contact the Ohio Department of Insurance Fraud Unit.
8. Insurance companies could stop reimbursing for most surgical repairs to ACL tears or develop more specific criteria for reimbursement.

Reflection questions

1. Who takes on the financial risk of a false positive MRI? How do physicians mitigate this financial risk?
2. Are there ways to redesign systems to prevent the potential for fraud in this scenario?
3. What are the potential patient safety concerns with regard to the case?
4. How might the reimbursement criteria for physicians in this scenario impact their medical decision-making?
5. How is medical decision-making affected by a fee-for-service system?
6. What are a surgeon's billing options if he or she opens the knee to find there is no ACL injury to repair?
7. What are the challenges to the physician and patient if reimbursement is affected by outcome? For instance, an outcome might be the patient's ability to work and to participate in activities, rated as inadequate, adequate, back to baseline or above.

SMART Decision-Making Strategy Questions

1. Seeking help: What additional information does Dr. Carter need before addressing the situation? How might he obtain this information? Who could Dr. Carter ask for advice? How should Dr. Carter evaluate the two different diagnoses to minimize bias?
2. Managing emotions: If you were in Dr. Carter's situation, what kind of emotions would you experience? How could these emotions affect your decision-making? How would you effectively manage these emotions?

3. Anticipating consequences: What consequences should Dr. Carter expect when addressing this situation? Which consequences are under Dr. Carter's control? Who will be affected and how?
4. Recognizing rules and power dynamics: What rules or norms are salient in this case? To what extent does Dr. Carter have the ability to resolve this issue of medical practice? To what extent do other stakeholders have the ability to address this situation?
5. Testing assumptions: What are Dr. Carter's motives in this case? What were Drs. Adams and Baker's motives? What assumptions is Dr. Carter making about Drs. Adams and Baker? How can Dr. Carter determine if her assumptions are correct? How might she test these assumptions?

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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 of his activities. He has not missed any work, and he continues to be able to run long distances despite the symptoms. Mr. George finds that the pain is worse when he gets home from work, where he sits at his desk for long periods of time.

Mr. George decides to see a doctor because he is tired of the pain. He wants surgery, but his insurance requires a referral. Mr. George believes surgery will help because his friend, who happens to be a lawyer, had an operation six months ago for similar symptoms and feels 100% better.

Mr. George can urinate and have bowel movements normally. He has no numbness or weakness, and his physical exam is normal.

The PCP diagnoses Mr. George with acute low back pain, explains that an MRI would not be useful at this time and surgery is risky, and there is little proven scientific evidence of any long-term benefit. The PCP prescribes muscle relaxants to add to Mr. George's use of anti-inflammatories and advises minimizing strenuous activity for the next two weeks and walking around more during work hours to prevent spasms. The PCP also gives Mr. George a set of strengthening exercises to start once the pain improves and asks him to follow up in 4-6 weeks if necessary.

Mr. George is not satisfied with this plan. He says, "Why did I even come here today? Are you absolutely sure I don't need surgery? Shouldn't you do an MRI or refer me to a spine surgeon? I know a lot of people who have sued doctors for just this type of treatment."

How should the PCP respond to Mr. George's questions? How should the PCP respond to the insinuation that Mr. George will sue?

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. non-operative intensive physical therapy and education have shown little difference in outcomes in terms of quality of life, use of health care resources, and symptom improvement.[3,4] Similarly, the long-term differences in patient outcomes between surgical and non-surgical treatment of herniated lumbar discs are not significant, particularly in the absence of neurologic deficits.[5]

    - Given surgical costs and the risk of complications relative to modest benefit, surgery is not justified for most patients with low back pain unless they have neurologic compromise and correlated MRI findings.
- It is estimated that the number of lumbar fusion procedures increased by 134% from 1993 to 2003,[4] and more than doubled between 2000 and 2011.[6] This increase may reflect the powerful financial incentives that accompany fusion procedures, which often include complex instrumentation produced by major device manufacturers. These procedures also have generous reimbursement rates for both the facility and the physician, even when compared to other types of surgery.[6]

Norms

Mid-Level Principles of Biomedical Ethics[7]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - Patients have the right to ask for treatments they believe will be of benefit to them, but not the right to demand unnecessary treatment.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - Unnecessary interventions cause harm to the patient.
- Justice: obligations of fairness in the distribution of benefits and risks.
    - Referring patients for costly imaging and/or surgical procedures that do not benefit the patient drives up the cost of health care for other patients.

AMA Principles of Medical Ethics[8]

- 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.
    - The PCP is obliged to refer Mr. George to other health professionals *when medically indicated*; the PCP ought not refer to other health professionals for the sole reason of appeasing a litigious patient.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - Despite the fact that Mr. George has threatened to sue, the PCPs primary obligation is unchanged: to provide competent medical care.
- IX. A physician shall support access to medical care for all people.
    - If the PCP routinely refers patients for unnecessary tests and procedures, the PCP is increasing the cost of care and therefore impeding access to medical care for all people.

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.
    - There is no malpractice cause of the action in this case.

Options

1. The PCP can attempt to educate Mr. George by sitting down and addressing each and every concern and informing him of the limitations of an MRI and surgery.
2. The PCP can acknowledge that Mr. George may be feeling powerless because of the pain and fears about its duration. Reassuring Mr. George that the pain will most likely improve with time may reduce his anxiety and aggression and foster better communication. The PCP could discuss the practice guidelines and tell Mr. George that if the pain remains or worsens over time, additional testing may be warranted.
3. The PCP can refer Mr. George to another primary care physician to get a second opinion.
4. The PCP can refer Mr. George to his local imaging center to get a MRI, just to be sure.
5. The PCP can refer Mr. George to a local spine surgeon.
6. The PCP can permanently refer Mr. George to another primary care physician.

Reflection Questions

1. What is defensive medicine? What are its effects? How can providers try to minimize the negative effects of litigation threats?
2. How might the threat of legal action change a physician's medical decision-making?
3. What are some of the ways health care professionals have tried to combat defensive medicine?

SMART Decision-Making Strategy Questions

1. Seeking help: What further information does the PCP need before responding to Mr. George and his threat to sue? Who should the PCP turn to for advice?
2. Managing emotions: If you were in the PCP's position, what emotions would you likely experience when confronted by a threat to sue? How might these emotions affect your decision-making? How might you effectively manage these emotions?
3. Anticipating consequences: What are the main options open to the PCP, and the consequences of each of those options? This includes short- and long-term consequences as well as positive and negative consequences. Which stakeholders will be affected and how? What consequences does the PCP have control over?
4. Recognizing rules and power dynamics: What rules or norms are salient in this case? To what extent does the PCP have the ability to resolve the issue, and to what extent do other stakeholders have the ability to resolve the issue?
5. Testing assumptions: What are the PCP's motives in this case? What assumptions might the PCP be making about Mr. George in this case? How could the PCP determine if his assumptions were correct?

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Case 11

Stock Option Ownership

By Heidi Pieroni

Dr. Sara Pierson, a Professor of Pediatrics at Large University, is the Principal Investigator (PI) for a large NIH-funded R01 grant focused on respiratory syncytial virus (RSV). RSV is the leading cause of bronchiolitis and pneumonia in children and infants under the age of one and can also affect the elderly. The NIH study focuses on the basic immunologic properties of RSV.

Dr. Pierson has also recently been invited to be the PI for a multi-site, Phase II clinical trial of a RSV vaccine. The trial will test a pediatric population for the safety and immunogenicity of an inactivated vaccine for RSV. A publicly traded small biotech company, VacSponsor, which makes the vaccine, is sponsoring the study.

Dr. Pierson believes that the VacSponsor study is important work, and also thinks that the results from the VacSponsor project could be fruitfully incorporated into the R01 project.

Dr. Pierson has stock options in VacSponsor, which she must disclose to her institutional conflict of interest committee so that her role and a conflict of interest plan can be reviewed. Values above $5,000 are considered significant financial interests by her institution. Her 'put' in the company's stock has declined past the exercise prices (meaning her equity interest cannot be easily valued), so she is not sure how to estimate the value of her interests and is not convinced that her stock with VacSponsor will affect her work on the proposed project.

How should Dr. Pierson proceed?

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: the obligation to respect the decision-making capacity of autonomous persons.

    - Dr. Pierson's conflict of interest could lead her to overstate the potential benefits of the drug while obtaining consent, which would undermine the subject's ability to give informed consent.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - Researchers are obligated to "do no harm," and to "maximize possible benefits and minimize possible harms."[4] This includes designing protocols to maximize benefits to both individual research subjects as well as to society. Thus, it is necessary to determine if the PI has conflicts of interest that may lead to an increased risk to safety. Dr. Pierson's financial interest in VacSponsor could knowingly or unknowingly influence the way she conducts this research. It could affect her enrollment of patients into control versus experimental groups; and bias her assessment of the vaccine safety and efficacy.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - If VacSponsor licenses the vaccine to other larger companies before conducting all the necessary research, it could lead to financial benefits before the long-term effects of the vaccine are properly understood. Society could therefore potentially be harmed.

AMA Principles of Medical Ethics[5]

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
    - Dr. Pierson ought not allow her financial interests to influence the recruitment of patients into this study or the interpretation of study results. She must not compromise the patients' rights to make voluntary and informed decisions to participate.
- 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.
    - Conflicts of interest can lead to unconscious or even blatant dishonesty and deception.
- 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.
    - It is appropriate and admirable that Dr. Pierson wants to work on developing a vaccine for this vulnerable population, and to advance scientific knowledge. However, she needs to do so in such a way that the knowledge she produces as a result of her study is reliable and valid.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - Dr. Pierson would not have a doctor-patient relationship with the individuals enrolled in her research study; she would have a researcher-

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, disprove, 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 conflicts of interest, including disclosure to research participants.[16]
- Some authors have advocated for mandatory ongoing review of research by the institution when significant conflicts of interest exist in specialized research.[17]

Options

1. Dr. Pierson could work with her institutional conflict of interest committee in a proactive manner to develop a management plan that complies with federal law.
2. Dr. Pierson could divest ownership interests in VacSponsor.

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 the 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 exists in this case study?
2. Could the outcome of the study significantly benefit the public? Why does this matter?
3. Should Dr. Pierson be allowed to pursue this research as PI in view of her conflict of interest? If so, should any conditions be put in place for Dr. Pierson as PI? If not, can someone else serve in the role of PI? Is society harmed if no one else is qualified to serve as PI?
4. Assuming Dr. Pierson has a conflict of interest, would disclosure of the conflict to the study subjects and the government resolve the problem?

SMART Decision-Making Strategy Questions

1. Seeking help: What kind of assistance does Dr. Pierson need before making a decision in this case? What resources could she turn to for help?
2. Managing emotions: If you were in Dr. Pierson's position, what kind of emotions would you likely experience? How would these emotions affect your decision-making? How could you effectively manage your emotions?
3. Anticipating consequences: What positive and negative consequences should Dr. Pierson anticipate for the options available? How can the benefits be maximized and the risks/harms be minimized?
4. Recognizing rules and power dynamics: What laws, rules or norms are salient in this case? To what extent is Dr. Pierson in a position to resolve the issue and to what extent do the other stakeholders have the authority to address the issue? What factors are limiting her choices?

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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Case 12

Start Up Company Conflict of Interest

By Heidi Pieroni

Dr. Gold is an Assistant Professor of Medicine in the Hematology-Oncology Division at a respected university. In her research on ovarian cancer, Dr. Gold discovered a monoclonal antibody (MAB) to a protein in ovarian cancer cells that slows cancer progression in a mouse xenograft model. Dr. Gold applied for but did not receive NIH funding for a Phase I study of the MAB in humans.

After successfully raising local venture capital money and gaining approval from the university, Dr. Gold starts a small biotech company called Antibody Therapeutics, so she can develop the antibody and further study its effects. Because she developed the antibody at the university, the university must license the MAB technology to Antibody Therapeutics. Dr. Gold has very little involvement in the license negotiations between Antibody Therapeutics and the university. Though she is neither an officer nor a member of the Board of Directors, Dr. Gold is a member of Antibody Therapeutics' Scientific Advisory Board, for which she receives $30,000 annually. She also owns 100,000 shares of founders' stock.

Antibody Therapeutics chooses to sponsor a Phase I trial of MAB in humans with ovarian cancer, and requests that Dr. Gold serve in the role of PI because she is the leading expert on the subject.

Should Dr. Gold serve as PI for the Antibody Therapeutics study?

Case Analysis

Stakeholders

The following are stakeholders in the case:

- Dr. Gold, because as founder of Antibody Therapeutics—which uses technology generated in her university laboratory under a license from the University—the outcome of the MAB study holds significant financial and intellectual interest.
- Antibody Therapeutics, because the company could profit from the outcome of the study.
- The women who would serve as subjects in the clinical trial, because they undergo risk as research subjects. They could also potentially benefit from the study (if the antibody turns out to be safe and effective).
- Society, because this research could provide valuable information and lead to more effective treatment for ovarian cancer. However, if Dr. Gold is not collecting and reporting her data with integrity (e.g., if she is falsifying or fabricating her data) it could cause harm to future patients and future researchers.

Facts

- Ownership of equity in a company that manufactures the study drug or device is recognized to be a 'significant' financial interest.[1]
- As a general rule, absent compelling reasons to the contrary, the AAMC guidelines and the policies of many institutions of higher education would discourage or prohibit participation in a clinical trial as PI if an individual has significant ownership of the sponsoring corporation.[2]
- Some evidence suggests that industry funding and relationships in biomedical research have led to biased reporting in clinical research and a general reduction of openness in science.[3]

Norms

Mid-Level Principles of Biomedical Ethics[4]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - Dr. Gold ought not allow her financial interests to influence the recruitment of patients into this study or the interpretation of study results. She must not compromise the patients' rights to make voluntary and informed decisions to participate.
- Beneficence: obligations to provide benefits and to balance benefits against risks.
    - It is necessary to determine if the PI has conflicts of interest that may compromise scientific integrity. Dr. Gold could knowingly or unknowingly influence her enrollment of patients into control versus experimental groups, and that could in turn influence her clinical

assessment, which might lead to an unwarranted positive assessment of MAB.
    - The prior decision by the NIH not to fund the study is worrisome; it could indicate that there are methodological problems in the study design, that there is a lack of peer or institutional support, or that preliminary results have not provided strong enough evidence to warrant a Phase I study. On the other hand, given limited NIH funding, many strong proposals are not funded, and industry funding might move a promising idea from bench to bedside.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - The participants of the study could be harmed by the use of MAB if it is too early to safely conduct a Phase I study. Society too could be harmed if Dr. Gold's conflict of interest leads to biased reporting of findings, which could lead to unnecessary expenditures on future research based on compromised data or the use of a drug that has not been thoroughly studied.

AMA Principles of Medical Ethics[5]

- 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.
    - Even if Dr. Gold fully discloses her conflict of interest, participants might be unknowingly misled through their interactions with her, particularly concerning recruitment and informed consent.
- 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.
    - A conflict of interest might influence Dr. Gold's recruitment of subjects for the study as well as interpretation of study results.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - Pushing the study to Phase I without sufficient evidence could potentially result in harm to the participants. Dr. Gold's conflict might lead her to prioritize study outcomes over the welfare of the subjects.

Legal

- The Food and Drug Administration (FDA) is the federal agency responsible for enforcing federal law in protecting the public health by assuring that new drug and biologic products are safe and effective.[6] Within the FDA, monoclonal antibody products are studied by the Center for Drug Evaluation and Research to "ensure that safe, efficacious and high quality monoclonal antibody products are available for the diagnosis, prevention and treatment of illnesses."[7] The FDA also

oversees safe and consistent manufacturing of products, including those used in Phase I studies.[8]
    - Regardless of funding source, FDA requirements apply to all products under study for possible introduction into the market for patient treatment.
    - Antibody Therapeutics must demonstrate safe and consistent manufacturing of the MAB product (even for Phase I use).
    - Dr. Gold and Antibody Therapeutics must demonstrate satisfactory research procedures and design if they hope to eventually gain FDA approval to market the MAB product for cancer treatment.
- Phase I studies cannot begin until the FDA approves an Investigational New Drug (IND) application. The FDA also allows for early exploratory IND studies (before Phase I studies) that are very short in duration and limit exposure to human research subjects; these allow drug manufacturers to test new chemical entities or compounds before fully investing in the IND process.[10]
    - Even in this early stage, Antibody Therapeutics and Dr. Gold must comply with federal regulations and seek approval through an IND application to begin Phase 1 trials. The FDA will review the data provided in making the determination to issue an IND number.
- The FDA has stringent requirements for disclosures of financial conflicts of interest by investigators and sponsors of products under their jurisdiction (e.g., drugs, biologics, etc.). Investigators must disclose all conflicts of interest in all phases of application (e.g., IND applications and premarket approval applications). The FDA will deny a new product application for research biased by conflicts of interest or for omitted, incomplete, or false disclosures.[11]
- Federal law expressly identifies the following financial conflicts of interest: 1) compensation affected by the outcome of the clinical trial (e.g., equity interest in sponsor or royalties tied to product sales); 2) significant equity interest in the sponsor (e.g., any ownership interest in a private company); 3) proprietary interest in tested product (e.g., patent, trademark, licensing, etc.); 4) significant payment of other sorts (e.g., payments to investigator or institution exceeding $25,000).[12]
    - Dr. Gold has significant equity interest in Antibody Therapeutics (100,000 shares of stock) and has received significant payments of other sorts ($30,000 per year as advisor). The proprietary interest is unclear but should be addressed.
- The "FDA may consider clinical studies inadequate and the data inadequate if…appropriate steps have not been taken…to minimize bias."[12] When evaluating whether conflicts of interest biased a study, the FDA considers "designs that utilize such approaches as multiple investigators… blinding, objective endpoints, or measurement of endpoints by someone other than the investigator may adequately protect against any bias."[12]
    - It is in Dr. Gold's and Antibody Therapeutics' interest to take careful steps in the study design and procedures to minimize bias if they hope to successfully bring the MAB product to market.
- If the FDA has serious questions about the integrity of data because of a conflict of interest, it can initiate audits of the data, require further analysis or additional independent studies, or exclude the data altogether.[12]

    - Failure to minimize the effects of bias could lead to increased scrutiny, expense or even exclusion of completed research data by the FDA.
- The Department of Health and Human Services' regulatory guidance directs institutions involved in research to have formal processes for managing financial conflicts of interest (e.g., conflicts review committees, disclosure to research participants, and the use of independent organizations to hold or administer the institution's financial interests).[14] Some authors have advocated for mandatory ongoing monitoring of research when significant conflicts of interest exist.[15]
    - The University should consider measures to minimize the impact of its financial interest in Antibody Therapeutics.
    - The University could require ongoing independent monitoring of the study to minimize the adverse impact of its conflict of interest.

Options

1. Dr. Gold could divest her interest in the company if she wants to serve as PI.
2. Dr. Gold could serve as PI with a proper conflict of interest management plan in place. (Explore if a proper plan is possible, and if so, what it requires)
3. Dr. Gold or the University could identify a faculty investigator to serve as the PI and limit Dr. Gold's role to co-investigator or collaborator. The FDA's guidance should be followed in selecting the individual. The faculty investigator should not be a close friend or relative or have a subordinate relationship to Dr. Gold. Furthermore, Dr. Gold's interaction with human subjects would then be limited, especially in the recruitment, selection, or consent process.
4. The university could require all members of the research team to fully disclose their financial relationships to all human research participants before allowing Dr. Gold to proceed as PI.
5. If the university holds equity in Antibody Therapeutics it could find a way to address the institutional conflict of interest, such as through engagement of an independent entity. Ideally, the university would eliminate its holdings in the company before the clinical trial takes place.
6. The University or Dr. Gold could require independent monitoring of the research in light of the multiple conflicts of interest.

Reflection Questions

1. What conflicts of interest exist? What, if any, is the specific financial conflict of interest? Is there more than one conflict of interest?
2. How could the outcome of the study benefit the public? Why does this matter?
3. Should Dr. Gold be allowed to pursue this research as PI in view of her conflict of interest? If so, should any conditions be put in place for Dr. Gold as PI?
4. Is there a risk to data integrity? If so, why does this matter?
5. Assuming Dr. Gold has a conflict of interest, would disclosure of the conflicts to the study subjects resolve the problem?

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 should 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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Case 13

Balancing the Roles of Researcher and Physician

By Joshua Crites

Dr. Blackstone, a primary care physician who has been in private practice for eight years, was recently recruited by an academic medical center for her expertise in treating obesity related diseases. Eager to dive into more academic endeavors, she designs a study to examine the effects of peer support groups for patients who are trying to make lifestyle changes to lose weight. Subjects are randomized either to a control group (lifestyle changes only) or an intervention group (lifestyle changes and weekly "check-ins" with a support group). Each subject in the intervention group is asked to meet regularly with other members of the peer support group for one year and to complete quarterly progress reports. She recruits patients from her outpatient clinic—both her own patients and those seeing colleagues.

Five months into the peer support study, Dr. Blackstone learns about a new drug, Theniva, for weight loss that has been tested in Phase I clinical trials. The drug manufacturer contacts her to participate in a multi-center, Phase II clinical trial they are sponsoring. Theniva works by mimicking neurologically active hormones related to satiety, effectively "tricking" a person's brain into believing that the person is full. Dr. Blackstone reviews the Phase I study results, which reveal only minimal risk, and agrees to help recruit study subjects to the Phase II study. To be eligible for participation in this study, subjects must be under age 45, not currently pregnant, and agree not to attempt to manage their weight through other means, including diet and exercise, during the study. This means that subjects could *not* participate in the peer support study and the Theniva study simultaneously. The Theniva protocol requires Dr. Blackstone to enroll 10 patients locally in order achieve statistical power for the study.

Dr. Blackstone has enjoyed a solid recruitment rate for her peer support group study, partly the result of her close professional relationship with many of her patients. She has enrolled more than enough participants to ensure adequate statistical power of that study. However, this recruitment success means that the number of patients eligible for the Theniva trial is limited. After two months of recruiting, Dr. Blackstone has been able to enroll only eight participants. She is acutely aware that the most likely way to reach recruitment goals for Theniva study would be to pull participants away from her peer support study.

During a review of her schedule for the next week, Dr. Blackstone sees that Darlene is scheduled for a follow-up visit. Dr. Blackstone recruited Darlene, a 28-year-old woman who has struggled with obesity since early childhood, into the peer support group study during her initial visit three months prior. On the day of Darlene's scheduled appointment, Dr. Blackstone sees on Darlene's intake vitals that she lost 11 pounds since her last visit. This is positive news, though Dr. Blackstone would still like Darlene to lose another 50 pounds to reach a recommended healthy weight for a woman of her age and build.

When Dr. Blackstone enters the exam room, Darlene is noticeably slimmer and exhibits a much more positive demeanor than in the past. She thanks Dr. Blackstone effusively for suggesting the peer support study, and excitedly tells Dr. Blackstone that in

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 her responsibilities as Darlene's physician?

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 understanding that they are entering into research and that any benefits they might receive are secondary to the goal of acquiring information intended to extend the body of scientific knowledge.
- Colleagues in the practice, because if they are only wearing the "doctor hat," they have an obligation to protect the interests and wellbeing of their patients. Patients of these physicians may suffer a loss of trust if they do not benefit from research participation but believed that it was being recommended because of an expectation of direct benefit; this loss of trust could hamper the physician-patient relationship.
- Future patients who have struggled to maintain or reduce weight, because the findings from both studies may present a better alternative to other interventions they have tried in the past.
- The drug manufacturer, because a drug such as Theniva could be quite profitable but they cannot market the drug until appropriate clinical trials have been completed.
- Society, because there could be a reduction in physician trust should members of society come to believe that physician-researchers are abusing their standing as physicians to enroll patients into research studies. Alternatively, successful strategies to manage weight could be an incredible boon to society and help control skyrocketing health care costs.

Facts

- Despite increased attention from health care providers and pharmaceutical companies, obesity continues to rise at an alarming rate, contributing to a range of preventable diseases.[1]
    - Research into novel behavioral and pharmacologic treatments is scientifically valuable and may result in a reduction of obesity and obesity related disease.
- There is an inherent, sometimes unavoidable—but perhaps manageable—conflict of interest for the physician-investigator created by the competing obligations of the roles.[2]
- Individuals recruited by their physicians to participate in research, especially when that physician is also an investigator on the proposed study, are more likely to experience the therapeutic misconception, that is, to confuse enrolling in a research study with receiving individualized therapy.[3,4]
- A phase I research study involves 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.A Phase II clinical research study involves giving the drug to a larger group of people to see whether it is effective and to further evaluate its safety.[5]
- 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."[6] The primary interest of physicians is the welfare of their patients while the primary interest of researchers is protecting the integrity of research. Secondary interests can include financial gain, prestige, and personal obligations. In a dual role, the integrity of research can constitute a secondary interest that interferes with the primary obligation to the patient's welfare.[6]

Norms

Mid-Level Principles of Biomedical Ethics[7]

- Autonomy: the obligation to respect the decision-making capacity of autonomous persons.
    - Dr. Blackstone's patients may (consciously or unconsciously) believe that Dr. Blackstone's offer of study participation is a clinical recommendation. This could contribute to the therapeutic misconception and threaten the understanding of informed consent, thereby undermining autonomy.[2]
    - Given that Darlene is currently eligible for the Theniva study, respecting her autonomy may mean that Dr. Blackstone should at least inform her of the opportunity to participate. If Darlene is actively trying to become pregnant or becomes pregnant she would not be eligible for the Theniva study.
- Beneficence: the obligation to provide benefit to others and to balance benefits against risks.

    - In her role as a researcher, Dr. Blackstone has only a secondary obligation to provide benefit directly to research participants; her primary obligation as the researcher is to ensure the integrity of the research study.[6] Darlene seems to be benefiting from the peer support group study, which has minimal risks; the balance of benefit and burden is less clear were she to enroll in the Theniva study. It may burden Darlene to delay a second pregnancy as well.
    - Dr. Blackstone's obligations as Darlene's physician are distinct from her obligations as an investigator, and arguably Dr. Blackstone should prioritize her physician-obligations rather than her researcher-obligations. Prioritizing her physician-obligations over her researcher-obligations would likely mean keeping Darlene in the peer support study, since it seems to benefit her with little risk of harm.
- Nonmaleficence: the obligation to avoid intentionally causing harm without proportional benefit.
    - Both physicians and researchers have an obligation not to harm their patients and/or research participants without the prospect of benefit. The difference lies in how risk of harm is justified. In clinical settings, risk of harm to a patient is ethically justified by the physician's intent to benefit that person directly; sometimes physicians prescribe medications that may have side effects or recommend lifestyle changes that may be uncomfortable, but the prospect (and intent) of direct benefit "outweighs" those risks. Concerning research, exposing participants to risk is balanced by their informed consent to participate and by the prospect of benefit to future individuals.
    - The Theniva study likely represents increased (and perhaps unforeseen) risk of harm with an unknown likelihood of direct benefit. If Dr. Blackstone was not Darlene's physician, it may be justifiable to recruit her to the Theniva study on the grounds that Darlene would provide her consent and that the study is likely to benefit others in the future. However, because Dr. Blackstone is obligated not only to avoid harm but also to seek direct benefit for Darlene, she should not recruit Darlene to the Theniva study.
- Justice: obligations of fairness in the distribution of benefits and risks.
    - Dr. Blackstone must balance her researcher-obligation to be maximally inclusive when selecting research participants (i.e., giving everyone a fair chance to participate) with her physician-obligation to protect her patients and promote their individual wellbeing.
    - Dr. Blackstone must also manage her multiple researcher conflicts because pulling some patients out of the peer group study to place them in the Theniva study may create a bias in the data from the peer group study. It also may create a bias in the Theniva study because those participants have been involved in a weight loss activity prior to enrollment. Asking patients to participate in unsound research is not an appropriate distribution of risks and benefits.

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.
    - 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.
    - 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.
    - 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.
    - 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.
    - 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 harm to the patient.[10]
- 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.[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. In light of Darlene's success in losing weight from her participation in the peer support group study, Dr. Blackstone could choose not to tell Darlene about the Theniva study.
4. Dr. Blackstone could work to add another researcher as co-PI and they each could agree not to seek consent from their own patients.
5. Dr. Blackstone could consult with the pharmaceutical company sponsoring the Theniva study to determine whether recruitment could begin after a sufficient number of individuals have *completed* the peer support study. Dr. Blackstone could also decide to stop enrollment in the peer support study now that she has sufficient numbers and move to recruiting for Theniva.
6. To avoid potential complications related to therapeutic misconception, Dr. Blackstone could remove her own patients from those studies for which she is an investigator and recruit additional subjects from other physicians and clinics.
7. Dr. Blackstone could exclude from the Theniva study those patients that are enrolled in her peer support group and instead only enroll new patients or those who did not join or stay in the peer support group study.
8. Dr. Blackstone could refuse to act as an investigator on the Theniva study as doing so creates competition between studies for subject recruitment.

Reflection Questions

1. In what ways are the roles of physician and researcher similar? How are they different?
2. How might physician-researchers best manage the inherent conflict of interest represented by these two roles? Can (or should) this conflict be avoided altogether?
3. When is it permissible for physicians to recruit research participants from their own patient pool? When is it impermissible? What situations might create a stronger moral obligation either to include or exclude their own patients from research participation on studies for which they are investigators?
4. When should the primary obligations of a physician override the primary obligations of a researcher? When might the converse be true?

5. What obligations, if any, do physicians in an academic medical center have to conduct their own research or act as a co-investigator on other studies (whether local or multi-center)?

SMART Decision-Making Strategy Questions

1. Seeking help: What additional information does Dr. Blackstone need to properly address this situation? Who might be able to help? Would it help to involve a mentor or consultant?
2. Managing emotions: If you were in this situation, what emotions would you likely experience? How might these emotions affect your decision-making? How would you manage these emotions effectively?
3. Anticipating consequences: What consequences should Dr. Blackstone consider before deciding what to do? These include short- and long-term consequences as well as positive and negative consequences. How can risk and benefit be balanced in this case?
4. Recognizing rules and power dynamics: What rules or norms are salient in this situation? What factors limit Dr. Blackstone's options in this case? Which factors are creating problems here?
5. Testing assumptions: What are Dr. Blackstone's motives in this case and how do they compare with the motives of other stakeholders? What assumptions might Dr. Blackstone be making? How might these assumptions be tested?

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13. 45 CFR § 46.111.

Case 14

Unforeseen Consequences: The Bayh-Dole Act

By Erin Bakanas

The Bayh-Dole Act of 1980 allows recipients of government funding who develop a patentable invention to retain the patent rights. Prior to the passage of the Act, the government retained ownership of the inventions produced by government-funded research. As a result, multiple discoveries did not move forward in marketing and development because private companies could not obtain an exclusive license and were forced to compete with many other companies, reducing profit significantly. Many important discoveries did not make it to the marketplace.

While the Bayh-Dole Act is seen as promoting the dissemination and utilization of scientific information, there are potential conflicts that result from its provisions as well. For example, consider a physician-researcher at Big University who received federal funding to study treatments for Fabry disease. Patients with Fabry disease lack an enzyme necessary for the metabolism of a glycolipid, which then accumulates in various tissues. The abnormal accumulation of the glycolipid can result in a range of symptoms and system failures including abdominal pain, fatigue, heart failure, renal failure, and malabsorption and weight loss. Patients with Fabry disease have a shortened life expectancy and usually die from advanced cardiovascular or renal disease.

The Big University team developed an enzyme replacement therapy (ERT) that alleviated pain and slowed organ damage in patients with Fabry disease. The ERT was patented by Big University, and subsequently developed and marketed by ERT Incorporated. The ERT product was the only available treatment for Fabry disease in the U.S.

Recently, the FDA forced ERT Incorporated to close one of its manufacturing sites for ERT because of contamination in the product. As a result, there is a national shortage of the drug. ERT Incorporated rationed the drug and patients are being given one third of the recommended dose. Patients are noticing a return of symptoms with the dose reduction, and there is additional concern that end organ damage is also accelerating. Patients with Fabry disease are now petitioning the NIH to require Big University to grant a license for the ERT patent to other drug companies so national production can increase.

How should the physician- researcher who led the team in developing ERT for Fabry disease respond to this situation?

Case Analysis

Stakeholders

The following are stakeholders in the case:

- The physician-researcher, because his ability to conduct research depends on his ability to secure grant funding. He financially benefits from the successful patenting and marketing of his innovation because grantee institutions must share profits with the inventor. He also has a relationship with his patients that could be negatively impacted if he is perceived as contributing to obstructing their access to ERT.
- The research institution, because the ability to attract funding and patients depends on having a solid reputation for responsible business and patient care conduct, and the institution might profit significantly if it chooses to bring the product to market.
- The pharmaceutical company, ERT Incorporated, because its stockholders expect the company to make money.
- Government regulatory bodies (in this case the FDA and NIH), because of their obligation to both protect and promote the public interest.
- The greater scientific research community, because of their obligation to balance promoting scientific inquiry, making profits, and benefitting while not harming patients.
- The community of patients with Fabry disease, because their wellbeing and survival are dependent upon their access to necessary medication.

Facts

- Fabry disease is estimated to affect 1 in 117,000 persons. In the US, the estimated number of persons affected varies, from a low of about 2,000 to a high of about 50,000.[1]
- A patent is an "intellectual property right granted by the Government of the United States of America to an inventor to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States for a limited time in exchange for public disclosure of the invention when the patent is granted."[2] The owner of the patent can grant limited or exclusive use to other companies through a license.
- The Orphan Drug Act of 1983 created a profitable market for drug and biotech companies. The Act created additional financial incentives and extended ownership rights for companies that invest in research and manufacturing of drugs for rare diseases, defined as conditions that impact less than 200,000 people in the United States.[3] Treatments for Fabry disease are included under the Orphan Drug Act.
- The cost of care for people with Fabry disease is extremely high, with therapies costing several hundred thousand dollars per year.[4]

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-Dole Act. However, he now faces another provision of the Act in deciding whether to support expansion of ERT production by companies other than ERT Incorporated.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
    - The physician-researcher takes care of patients with Fabry disease and will have to manage the physical consequences of the ERT shortage in their clinical care, as well as respond to their petition to get enzyme replacement production expanded.

Legal

- The Bayh-Dole Act (1980) allows institutions that use government funding to retain the patent rights for innovations that result from research conducted by their scientists. While institution retain the patent rights, they often grant limited or exclusive licenses (or permission for use) to a small number of companies for production—such as for the manufacturing of a drug. However, under a set of specific criteria, including health and safety concerns of the public, the government does retain the right to "march-in" and force the patent holder to grant licenses to other users.[7]
- The patent holder usually resists the government "marching in" because of future economic losses. Once the government forces the patent holder to share their intellectual property to more groups, the patent holder will have great difficulty

defending its patent in the future and will suffer economically from the increased competition.

- There are strict procedural requirements involved in march-in rights and include notice and comment periods, as well as appeal processes. The government may terminate the process at any time.[7]
    - If the government elects to march-in, the process will take time. It is possible that ERT Incorporated may correct its manufacturing deficiencies in time to prevent other companies from acquiring a license.
    - A march-in can cause financial harm to the institution and the manufacturer by limiting their ability to enforce their patent in the future and driving down prices through competition, making it more difficult for private companies to realize a return on their investments.
- By law, institutions are required to have agreements in place with researchers by which invention rights are transferred from the researcher to the institution. The researcher continues to receive a portion of any royalties.[7]
    - The physician-researcher will continue to earn royalties from the invention, even if other companies are granted a non-exclusive license.
    - The FDA, through federal law, incentivizes development of drug therapies for rare diseases. The Orphan Drug Act aids development of drugs for diseases affecting less than 200,000 or more than 200,000 but the cost of development cannot be recovered.[8] The incentives include extended market exclusivity and modified approval requirements. The FDA can withdraw the drug manufacturer's rights to market exclusivity if there are insufficient quantities of the drug.[9]

Options

1. The Big University physician-researcher could advocate for an exploration of all options to expedite the restoration of an adequate supply of ERT, including the option of allowing another company to produce the enzyme.
2. The physician-researcher could choose to not get involved and instead let the NIH resolve the problem.
3. The physician-researcher could gather support and advocate for the government to exercise its march-in rights.
4. The physician-researcher could support ERT Incorporated retaining the exclusive right to manufacture ERT.
5. The physician-researcher could encourage the University and ERT Incorporated to challenge the FDA's findings and actions in closing the plant to get ERT Incorporated manufacturing ERT again.
6. The physician-researcher could disclose his conflict to his patients with Fabry disease.

Reflection Questions

1. Physician-researchers often care for patients with limited treatment options for their conditions, such as Fabry disease. They also research and develop new or

novel treatments for those same diseases and may profit from the sales of their discoveries if they make it to market. How can these physician-researchers best manage these conflicts?
2. Do large research institutions have any obligations beyond promoting research with the goal of getting innovations to market?
3. Should the NIH step in and grant other companies licenses to produce drugs or treatments in the event of severe shortages?

SMART Decision-Making Strategy Questions

1. Seeking help: What additional information does the physician-researcher need to properly address this situation? Who might be able to help? Where might the physician-research find an unbiased, objective opinion?
2. Managing emotions: If you were in this situation, what emotions would you likely experience? How might these emotions affect your decision-making? How would you manage these emotions effectively?
3. Anticipating consequences: What consequences should the physician-researcher consider before addressing the situation? These include short- and long-term consequences as well as positive and negative consequences. What consequences does the physician-researcher have control over? How can risk and benefit be balanced in this case?
4. Recognizing rules and power dynamics: What laws or norms are salient in this situation? What factors limit the physician-researcher's options in this case? Which stakeholders have the ability to address these problems and how can this be done?
5. Testing assumptions: What are the physician-researcher's motives in this case and how do they compare with the motives of other stakeholders? What assumptions might the physician-researcher be making of Big University and industry? How might these assumptions be tested?

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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 from COI	✓			✓	✓		✓	✓	✓	
General health care organization and systems	✓	✓	✓				✓		✓	✓
Fostering patient care quality and safety		✓	✓		✓	✓				✓
Medical professionalism, the goals of medicine, and their relationship to medical ethics				✓	✓	✓	✓	✓		
The structure and ethical issues surrounding reimbursement systems for physicians	✓			✓		✓	✓		✓	✓
COI arising from physician relationships with pharmaceutical and device industries								✓	✓	✓
The legal framework for the business of medicine	✓		✓	✓	✓	✓		✓	✓	✓

Appendix B. Index of Business Ethics in Medical *Research* Cases

Case	#11	#12	#13	#14
Topic				
The ideals of the medical research profession	✓		✓	
Potential problems that conflicts of interest cause	✓	✓	✓	
Strategies for managing conflicts of interest in research	✓	✓	✓	
Challenges of playing the roles of both physician and researcher			✓	✓
Legal and policy issues surrounding conflicts of interest in research	✓	✓	✓	✓

Appendix C. SMART Decision-Making Strategies*

STRATEGIES FOR PROFESSIONAL DECISION MAKING: THE SMART APPROACH²

Professionalism & Integrity IN RESEARCH

STRATEGY	DIMENSIONS	SAMPLE REFLECTION QUESTIONS
SEEK HELP	▪ Seeking information ▪ Requesting mediation ▪ Welcoming correction	▪ Where might I seek additional information or an unbiased, objective opinion? ▪ Would it help to involve a mediator or consultant? ▪ Do I welcome correction or input from others, including subordinates? ▪ Have I owned up to mistakes and apologized as necessary to move forward with all involved?
MANAGE YOUR EMOTIONS	▪ Identifying emotions ▪ Managing emotions ▪ Both positive (excitement) and negative (depression, anxiety, anger) emotions	▪ What are my emotional reactions to this situation? Am I anxious, frustrated, or depressed? Feeling pressure or urgency? ▪ How might my emotions influence my decision-making? ▪ Would taking a "time out" or deep breath help? Using "Freeze Frame" technique? ▪ Am I managing stress each day?
ANTICIPATE CONSEQUENCES	▪ Consequences to others and to self ▪ Long-term and short-term consequences ▪ Positive and negative consequences ▪ Risk management	▪ What are the likely short-term and long-term outcomes of various choices? ▪ Who will be affected by my decisions and how? ▪ How might this decision impact my career and me? ▪ Which outcomes in this situation are controllable? Which cannot be changed? ▪ How can risks be minimized? ▪ How can benefits be maximized?
RECOGNIZE RULES AND CONTEXT	▪ Recognize rules—formal (e.g., laws & policies) and informal (prevailing social norms) ▪ Recognize the power dynamics (e.g., social hierarchies, decision-makers)	▪ What are the causes of the problems in this situation? Which causes can I change? ▪ What ethical principles, laws, or regulations apply in this situation? ▪ What factors place limitations on my choices? ▪ Who are the decision-makers in this situation? ▪ Does anyone have the power to control outcomes? If so, who and how?
TEST YOUR ASSUMPTIONS AND MOTIVES	▪ Test your assumptions and unspoken rules ▪ Examine your motives ▪ Empathically compare your assumptions and motives to those of others	▪ Might I be making faulty assumptions about the causes of the situation, alternatives, or other's intentions? How can I find out? ▪ What are my motives? Are they the same or different as those I serve? ▪ Could self-serving biases be distorting my perception of the situation? ▪ How will others view my choices?
Notes:	The strategies are related and overlapping, but they have distinct elements. E.g., testing assumptions is sometimes a good way to manage emotions and it can lead to seeking help. Want to be SMARTER? Add "Evaluate" outcomes of your actions, and "Revise" your approach based on outcomes.	

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