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Guide to Professionalism and Ethics in the Practice of Orthopaedic Surgery

2016

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AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

GUIDE TO PROFESSIONALISM AND ETHICS IN THE PRACTICE OF ORTHOPAEDIC SURGERY
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Foreword

The ethical practice of orthopaedic surgery is a matter of utmost importance to all orthopaedic surgeons. The American Academy of Orthopaedic Surgeons (AAOS) first adopted its *Code of Ethics for Orthopaedic Surgeons (Code of Medical Ethics and Professionalism)* in 1988 and its *Principles of Medical Ethics in Orthopaedic Surgery (Principles)* in 1991. These have been revised several times, based upon comments from the Fellowship and other orthopaedic organizations. The Board of Directors, upon the recommendation of the Ethics Committee, adopted *Medical Professionalism in the New Millennium: A Physician Charter (Physician Charter)* in 2002.

This booklet, the 2016 edition of the *Guide to Professionalism and Ethics in the Practice of Orthopaedic Surgery*, deals with these documents and how they can and should be used. The *Code of Medical Ethics and Professionalism, Principles,* and *Physician Charter* provide aspirational standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon and promote the highest quality of care for our patients.

In addition, this booklet deals with Standards of Professionalism (SOPs). Adopted beginning in 2005, Standards of Professionalism draw from the **aspirational** *Code of Medical Ethics and Professionalism, Principles,* and *Physician Charter* to establish the **mandatory** minimum levels of acceptable conduct for orthopaedic surgeons. The AAOS Fellowship has adopted Standards of Professionalism in the areas of:

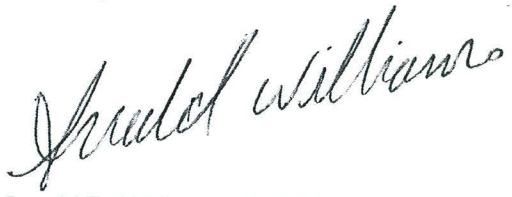
- Providing Musculoskeletal Services to Patients;
- Professional Relationships;
- Orthopaedic Expert Opinion and Testimony;
- Research and Academic Responsibilities;
- Advertising by Orthopaedic Surgeons; and
- Orthopaedic Surgeon-Industry Relationships.

Violations of the Standards of Professionalism may serve as grounds for formal complaints to and action by the AAOS as outlined in the Bylaws.

Developed by the AAOS Ethics Committee, this booklet includes these documents as well as the AAOS official Opinions on Ethics and Professionalism and various Position and Information Statements that involve ethical issues.

I urge each of you to take an opportunity to review and understand this *Guide to Professionalism and Ethics in the Practice of Orthopaedic Surgery – 2016.* Please use this book, discuss it with your colleagues, and retain it in your personal files for future reference.

Sincerely,



Gerald R. Williams, Jr., MD
President
AAOS Board of Directors

Introduction

Ethics is the discipline dealing with principles or moral values that govern relationships between and among individuals. It defines what one physician ought to do.

The Principles of Medical Ethics and Professionalism in Orthopaedic Surgery (*Principles*), *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* (*Code of Medical Ethics and Professionalism*) of the American Academy of Orthopaedic Surgeons (AAOS) and *Medical Professionalism in the Millennium: A Physician Charter (Physician Charter)* provide standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon. They are **aspirational**. The basic tenet of these documents is that, within orthopaedic surgery, the orthopaedic surgeon must develop and maintain a deeply ingrained moral commitment to the patient's best interests. This basic tenet is articulated in several ways within the *Principles, Code of Medical Ethics and Professionalism* and *Physician Charter.*

The Standards of Professionalism play a different role in guiding behavior for orthopaedic surgeons. While drawing from the aspirational documents identified above, the Standards of Professionalism establish **mandatory** levels of professional conduct. Alleged violations of the Standards of Professionalism may lead to professional compliance actions, such as censure, suspension, or expulsion from the AAOS.

Orthopaedic surgeons may be obliged to comply with several standards of conduct. *The Principles,* the *Code of Medical Ethics and Professionalism*, and *Medical Professionalism in the New Millennium: A Physician Charter* specifically recognize several:

- Legal standards and constraints;
- Personal standards relating to the care of orthopaedic patients as viewed by most orthopaedic surgeons; and
- Societal standards of conduct.

At times, these standards appear to be in conflict, and when there is a conflict between these aspirational ethical standards and the law, the legal standards and constraints will by necessity prevail. For example, physician advertising is legal, though distasteful to some. Nevertheless, professional ethical codes must conform to the standards within the law. Thus, the AAOS' *Principles* and the *Code of Medical Ethics and Professionalism* permit truthful advertising but prohibit an orthopaedic surgeon from publicizing him or herself "through any medium or form of public communication in an untruthful, misleading or deceptive manner." These concepts are explored in greater detail in the Standards of Professionalism on Advertising by Orthopaedic Surgeons and the Opinions on Ethics and Professionalism on Advertising by Orthopaedic Surgeons.

The Fellowship-adopted Standards of Professionalism establish standards that may be higher than those included in state or federal law; they are requirements for admission to and continuing membership in the AAOS, a voluntary membership organization. Membership in the AAOS is not a requirement to practice medicine or to function as a physician in any state, but is an indication that the orthopaedic surgeon-member agrees to adhere to the "AAOS Standards of Professionalism, maintain a

good reputation and standing within his or her community, and [is] of high ethical character and professional repute." [Bylaws of the American Association of Orthopaedic Surgeons, Paragraph 5.1.f.]

Underlying the AAOS' *Principles, Code of Medical Ethics and Professionalism, Medical Professionalism in the New Millennium: A Physician Charter,* and the AAOS Standards of Professionalism are critical professional values (e.g., compassion, respect for the patient, and honesty) and the integrity to commit one's professional life to them. These values and integrity form the foundation for an ethical career in orthopaedic surgery.

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General Information

A. Genesis

In 1988, the American Academy of Orthopaedic Surgeons (AAOS) adopted its first *Code of Ethics for Orthopaedic Surgeons* (now *Code of Medical Ethics and Professionalism*) in response to numerous requests from its members. The AAOS' first *Code of Ethics* was developed by a task force through an exhaustive two year review process.

When the Board of Directors adopted the *Code of Ethics*, it also established a permanent AAOS Ethics Committee. This Committee, which reports directly to the Board of Directors, is charged with reviewing and suggesting revisions of the *Code* when appropriate and with offering general interpretations of the *Code*. The Board of Directors amended the *Code of Medical Ethics* in 1991, 1995, 2001, 2002, 2004, 2005, 2009, and 2011, based upon recommendations made by the Ethics Committee.

In 1991, the Board of Directors adopted *The Principles of Medical Ethics in Orthopaedic Surgery* (the *Principles)*. Created upon recommendation of several Academy committees and developed by the Ethics Committee, these ten Principles represent a distillation of the most important aspects of the *Code* in a simple one-page document. The *Principles* were amended in 1995 and 2002.

In 2002, the Board of Directors, upon the recommendation of the Ethics Committee, adopted *Medical Professionalism in the New Millennium: A Physician Charter (Physician Charter).* It also revised the name of the *Principles* and the *Code of Medical Ethics* to include the already-in-existence concept of professionalism which they embrace.

In 2005, the AAOS established a Professional Compliance Program and the Fellowship adopted the first three Standards of Professionalism (SOPs), which represent a significant departure from the previous AAOS ethical statements. (Additional information about the Standards of Professionalism begins on Page viii.) All other ethical statements from the AAOS are **aspirational**, that is, above the standards established by the law. The Standards of Professionalism, however, identify **mandatory** standards of conduct for all Fellows and Members. Alleged violations of the Standards of Professionalism may serve as the basis for a formal grievance to and professional compliance action by the AAOS Board of Directors. Professional compliance actions may include reprimand, censure, suspension, or expulsion from the AAOS.

While violations of the *Principles*, the *Code of Medical Ethics and Professionalism,* or the *Physician Charter* reflect poorly on the profession, only violations of the Standards of Professionalism may lead to professional compliance action by the AAOS.

B. Purpose

The AAOS believes that the education of orthopaedic surgeons regarding ethics is one of the most important mechanisms to promote the needs and concerns of individual orthopaedic patients. The goal of all of the AAOS' ethical documents is to ensure that patients receive the highest quality orthopaedic care available. The development of these ethical documents has provided the AAOS, its committees, and many orthopaedic surgeons and orthopaedists-in-training with an opportunity for thought and inquiry concerning ethics and professionalism in orthopaedic surgery.

C. Opinions on Ethics and Professionalism

As part of the AAOS' educational efforts regarding ethics, the Board of Directors has charged the Ethics Committee with developing Opinions on Ethics and Professionalism, amplifying the *Principles,* the *Code of Medical Ethics and Professionalism*, and the *Physician Charter* and applying them to practical situations. These Opinions are available to orthopaedic surgeons and the public through the AAOS website (www.aaos.org), and generally are published in *AAOS Now* or other AAOS publications upon adoption.

D. Complaints by Patients Regarding Orthopaedic Surgeons

The AAOS occasionally has received complaints from patients regarding orthopaedic surgeons and their office staffs. These complaints often deal with poor treatment in the surgeon's waiting room, rudeness on the part of the orthopaedic surgeon or the staff, and billing issues. Some deal with quality of orthopaedic care provided.

The AAOS does not directly handle complaints by orthopaedic patients. It communicates with the patient, urging the patient to discuss the situation with his or her physician, the county or metropolitan medical society where the alleged matter occurred, and sometimes the state medical board. In addition, when appropriate, and unless specifically prohibited by the patient, the complaint will be shared with the orthopaedic surgeon about whom the complaint has been filed. The AAOS will encourage him or her to contact the patient about the concern.

E. Standards of Professionalism (SOPs)

In 2004, the AAOS launched the Expert Witness Program in response to the Fellowship's desire that the AAOS take proactive steps regarding fraudulent or misleading orthopaedic expert witness testimony. During the development of this program, the Board of Directors approved expanding the scope of the Expert Witness Program to include a broader range of ethical and professionalism issues. The Board also renamed the broader program the AAOS Professional Compliance Program.

In 2005, the Fellowship overwhelmingly adopted Bylaws amendments that established the Professional Compliance Program. Also in 2005, the Fellowship adopted the first three Standards of Professionalism (SOPs) that set mandatory minimum levels of acceptable conduct for all Fellows and Members. Alleged violations of the SOPs may serve as the basis for a formal grievance to and adjudication by the AAOS. AAOS processes all grievances following a set of Board-approved Professional Compliance Program Grievance Procedures.

Since 2005, the Fellowship has adopted SOPs on a variety of ethical topics that touch the working lives of orthopaedic surgeons. To date, the Fellowship has adopted SOPs on:

- Providing Musculoskeletal Services to Patients (2005, revised 2008);
- Professional Relationships (2005);
- Orthopaedic Expert Opinion and Testimony (2005, revised 2010);
- Research and Academic Responsibilities (2006);
- Advertising by Orthopaedic Surgeons (2007); and
- Orthopaedic Surgeon-Industry Relationships (2007, revised 2012).

To date (September 2016), the Board of Directors has taken professional compliance action against 50 Fellows based on violations of the SOPs.

F. Applying and Interpreting the SOPs

Two committees, each with specific responsibilities under the Professional Compliance Program, apply the mandatory standards of the SOPs:

- The **Committee on Professionalism (COP)** conducts grievance hearings based on alleged violations of the SOPs and may make a recommendation to the AAOS Board of Directors for appropriate professional compliance action. In addition, the COP has responsibility for reviewing and considering all proposed SOPs.

- The **Judiciary Committee**, which functions as an appellate body, conducts appeals hearings. Following the appeals hearing, the Judiciary Committee will uphold the findings and recommendations of the COP unless it finds that due process has been violated or that such report and findings and recommendations are contrary to the clear weight of the evidence. The Judiciary Committee makes its recommendations on professional compliance actions to the AAOS Board of Directors.

When making its final determinations of appropriate professional compliance action, the AAOS Board of Directors ultimately interprets the mandatory standards contained in the SOPs. Its decisions are final and not appealable.

G. Grievances for Alleged Violations of the SOPs

During the development of the Professional Compliance Program and the SOPs, the AAOS Board of Directors carefully considered appropriate sources of grievances. Discussions ensued regarding whether patients, other health care providers, insurance companies, or hospitals would be allowed to file grievances with the AAOS. Among issues considered, the AAOS Board reviewed other medical associations' procedures and their number of grievances processed annually. Ultimately, the AAOS Board reached consensus that the Professional Compliance Program grievance procedure would be limited to AAOS Fellows and Members.

All grievances filed by Fellows and Members must be signed and conform to an approved format. The AAOS Office of General Counsel completes an administrative review of grievance material prior to submitting the documents to the Committee on Professionalism (COP) for its consideration. Grievances follow time limitations detailed in the Professional Compliance Program Grievance Procedures. Information submitted by either the Grievant or the Respondent is shared with the opposing party.

By design, the AAOS Professional Compliance Program is not considered a peer review program, nor do its participants fall under the protections of the federal Health Care Quality Improvement Act. Under the AAOS Professional Compliance Program, all material provided by the Grievant, Respondent, or AAOS may be discovered upon appropriate request.

H. Notification of Professional Compliance Action for Violations of the SOPs

Professional compliance action taken by the Board of Directors for violations of the SOPs will be reported to the following entities:

- AAOS Fellowship at least annually;
- National Practitioner Data Bank, for matters that relate to patient health and welfare;
- State medical licensing boards;
- State orthopaedic societies;
- American Board of Orthopaedic Surgery (ABOS); and
- Other medical boards or associations as appropriate.

I. Other Avenues to Redress Complaints

1. Obligation to Report Unethical or Illegal Conduct

One of the more frustrating experiences for dedicated orthopaedic surgeons is to observe what they believe is clearly unethical or illegal conduct by colleagues, without a clear method for resolving the issue. The *Principles* provides that "the orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception." In addition, the AAOS *Code of Medical Ethics and Professionalism* provides that

> "Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that another orthopaedic surgeon or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to the duly-constituted peer review authorities or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct."

A distinguishing feature of orthopaedic surgery is that most orthopaedic surgeons have committed themselves to standards of conduct that are higher than the legal minimum and more demanding than the morals of the marketplace. Naturally, when other orthopaedic surgeons appear to violate these norms, it is distressing to those who do not. More importantly, when patients may have been deceived or harmed or when laws may have been violated, orthopaedic surgeons have an obligation to take some sort of action. This is particularly true in situations in which the orthopaedic surgeon has information unavailable to the patient or others, so that if he or she takes no action, it is likely that no one will. Yet, the orthopaedic surgeon wishing to act faces limitations of the process.

2. Role of the AAOS

As discussed previously, for several reasons and except as it relates to the AAOS Professional Compliance Program regarding alleged violations of Fellowship-adopted SOPs, the AAOS has a limited role in complaints brought by orthopaedic surgeons against other orthopaedic surgeons:

- If an orthopaedic surgeon is concerned about the conduct of an orthopaedic surgeon who is not a member of the AAOS, the AAOS will have no jurisdiction over the matter. The AAOS SOPs and ethical guidelines officially cover only AAOS Fellows and Members.

- The AAOS *Principles,* the *Code of Medical Ethics and Professionalism*, and the *Physician Charter* are directed primarily to ensuring that orthopaedic patients receive the highest quality care available; they do not deal with all possible subjects or professional activities or misconduct. When the conduct of an orthopaedic surgeon lies outside of the subjects dealt with in the *Principles* or the *Code of Medical Ethics and Professionalism*, these documents may or may not have provisions that apply. In addition, the SOPs establish minimum mandatory standards of behavior only for those topics ultimately approved by the Fellowship. By necessity, there will be many activities that are not governed by specific SOPs.

- Because of the AAOS' limited resources, it cannot "police" all orthopaedic conduct. Thus, if criminal activity (e.g., the diversion of controlled substances) is involved, the criminal justice authorities are better able to deal with the matter. If billing fraud is involved, a federal agency is authorized to act far more effectively than the AAOS. Although these cases have ethical dimensions, they are not primarily ethical, but rather legal and institutional management problems.

- While the AAOS has interest in such issues as corporate conduct affecting orthopaedic surgery and disagreements among orthopaedic surgeons, the SOPs, *Principles, Code of Medical Ethics and Professionalism,* and *Physician Charter* provide little guidance on how best to address these Issues.

In cases that do not raise issues that are primarily ethical, the AAOS encourages those who wish to file a complaint to seek assistance either from other competent organizations with jurisdiction over the matter or from the appropriate government agency or agencies.

3. Possible Legal Risks to the Orthopaedic Surgeon Who Brings a Complaint

A practical question many orthopaedic surgeons ask is: "Can I get myself in legal trouble for reporting misconduct?" Unfortunately, the answer is yes. However, one must distinguish the legal risk of being found liable from the risk of being sued unsuccessfully. Even if an orthopaedic surgeon has an unassailable legal position, the reality is that in some instances he or she may be sued for reporting misconduct. Laws vary from jurisdiction to jurisdiction. A reporting physician should be familiar with the applicable laws of the state in which the alleged misconduct occurred and when as appropriate and possible, seek local counsel before reporting suspected misconduct.

4. Other Avenues for Specific Issues

The following offers alternative avenues that physicians might consider when particular, fairly frequently occurring issues arise.

- **False or Deceptive Advertising**

  At the federal level, the Federal Trade Commission (FTC) is the federal agency best able to investigate charges of false and deceptive advertising. The principal statute enforced by the FTC forbids all deceptive acts or practices in interstate commerce, including misleading advertisements. If one believes in good faith that an advertisement substantially misrepresents credentials or fees or the success or nature of the procedures performed by an orthopaedic surgeon or by other health professionals, a letter may be submitted to the FTC requesting that it investigate. The FTC will review the material submitted and then determine whether a full investigation is warranted.

  If the false advertisement was disseminated through the U.S. mail, then the U.S. Postal Service may also be contacted. The Postal Service has the power to halt the use of the U.S. mail for fraudulent purposes. Generally, the Postal Service will handle cases involving physicians only if the advertised product or service seems fraudulent. In such a situation, the Postal Service has very powerful enforcement tools. Should one believe that an orthopaedic surgeon is using the mail as part of a scheme to defraud consumers, the nearest postal inspector may also be called.

  Finally, if the false statements relate to a drug or device, the U.S. Food and Drug Administration (FDA) may have jurisdiction. However, the FDA's authority over physician conduct is limited because of a provision of the law stipulating that the FDA may not regulate the "practice of medicine." The FDA generally does not act against physicians who make false claims concerning drugs or devices manufactured by others.

  Several states have enacted laws specifically directed at false or misleading advertisements by physicians. In these states, the State Attorney General may have authority to regulate deceptive advertisements.

- **Fraudulent Billing**

  Medicare The U.S. Department of Health and Human Services (DHHS) routinely investigates allegations of Medicare fraud and abuse. If an orthopaedic surgeon learns of cases where a physician or other health professional is fraudulently billing patients covered by Medicare, he or she can notify the Inspector General of DHHS by calling 800-447-8477 (800-HHS-TIPS). DHHS also maintains ten regional offices for investigating allegations of Medicare fraud; the nearest local office can also be contacted. In addition, because Medicare fraud is a criminal offense, the United States Attorney for the district is empowered to investigate allegations of Medicare fraud. If an orthopaedic surgeon feels he or she has been unjustly accused of fraud and wishes to dispute the allegations, the Academy recommends contacting his or her state medical society for attorney referrals.

  Medicaid Sometimes the complaint concerns patients covered by Medicaid rather than Medicare. In that situation, one can contact the State Attorney General of the state where the fraud occurred. Most states have established special Medicaid fraud control units, usually in the State Attorney General's office.

Fraud on Third-Party Payers State and local law enforcement officials also investigate fraud. If an orthopaedic surgeon believes that a health professional has committed fraud, regardless of whether Medicare or Medicaid funds are involved, he or she may notify the State Attorney General, the county prosecutor or the district attorney. In addition, state insurance commissioners also investigate complaints.

False Claims or Services State medical licensure boards may have jurisdiction over false claims or services. Many state statutes provide that a physician's license can be suspended or revoked for submitting bills for services not actually provided.

- **Unfair Commercial Practices**

Federal law prohibits fraud and abuse associated with Medicare coverage or payments. This statute is very broad and prohibits the solicitation or receipt—or the offer of payment—of any remuneration in return for purchasing, leasing or ordering any Medicare-covered good or service. The courts have determined that those payments may be illegal even if the physician actually provides some services, if just one of the purposes of the arrangement is to stimulate additional referrals. An almost identical statue applies to Medicaid. Information that a health professional is receiving fees simply for referrals can be forwarded to the Office of the Inspector General of DHHS or to the local U.S. Attorney.

The states also have statutes regulating commercial relations. For example, states uniformly treat "kickbacks" and bribery as criminal offenses. Information regarding the seemingly unlawful exchange of money or services may be forwarded to the State Attorney General, the district attorney or county attorney, or other appropriate law enforcement body—or to a state board of medicine or licensure, some of which have authority over commercial relationships.

Approaching an Ethical Dilemma

Ethics is the discipline dealing with the principles and moral values that govern the behavior of individuals. Medical ethics defines what the physician ought to do and how he or she should behave. Ethical principles are aspirational.

As physicians, we are permitted to do things to individuals that no one else in society is permitted to do. Complete strangers come to our offices and we routinely invade their private lives, touch them, manipulate their bodies, cause them pain, cut into their flesh, expose them to radiation and give them poisons to ingest. Because of the relationship we have with our patients, as well as the privileges granted to us by our training and society, any decisions we make, any actions we take, can have a serious impact on a patient's life. Consequently, as physicians, all of our actions fall under the domain of medical ethics.

With these privileges, however, come specific and demanding **moral obligations**, namely to:

1. Use of knowledge of science and medicine;
2. Work together with others; and
3. Act for the good of the patient.

It is this last obligation, *to act for the good of the patient* that has become the central tenet of medical ethics. Acting for the good of the patient defines the foundation of all of our behavior with respect to the **goals of medicine**, namely to:

1. Preserve life;
2. Cure disease;
3. Restore function; and
4. Alleviate pain and suffering.

The majority of ethical dilemmas that physicians face are not egregious acts of unethical behavior, but rather conflicts among these goals of medicine. The dilemma often arises in deciding which goal has priority and who is entitled to make that decision. As physicians we quickly realize that there are times when we need to ignore one goal in order to satisfy another. For example, many of us have and continue to cause pain in order to cure disease. Likewise, any tumor surgeon will attest to the fact that function may actually be destroyed in an attempt to preserve life.

The ethical conflict arises in deciding which of these goals has priority. The order may differ among individuals and even with the same individual under varying circumstances. The importance of any one goal may change over time or with the medical situation at hand. An ethical conflict may also arise in determining who has the right to decide which goals take precedence: the patient, the physician, family members, or the courts?

Approaching an Ethical Dilemma

Although the particular situation at hand may be significantly complex, there are three basic steps in approaching any ethical dilemma:

1. Gather the information;
2. Clarify the ethical issues; and
3. Resolve the dilemma.

Gather Information

The key to assessing any ethical dilemma is to gather as much information as possible. What are the medical facts of the situation? Does the patient have the capacity to make an informed decision? Are there any existing advanced directives, living wills or documented surrogates? What are the views and opinions of the treating healthcare team members?

Clarify the Ethical Issues

In the midst of a significant ethical crisis, it is easy to become trapped in a quagmire of issues, including medical decisions, treatment plans, family disputes, personality conflicts, and power struggles among and between hospital and family members. The important goal here is to clarify and address only the pertinent ethical issues at hand. For example, with which issues is one dealing?

- Patient autonomy
- Patient refusing treatment
- Decision-making capacity
- Surrogate decision-making
- Informed consent
- Paternalism
- Confidentiality
- Disclosing complications
- End of life decisions
- Conflicts of interest
- Impaired physicians
- Relationship issues: patient, family, peer, subordinates, professional, industry.

It is important to define, as clearly as possible, the explicit ethical issue involved and to address that specific situation.

Resolve the Ethical Dilemma

It is often necessary to gather all of the involved parties seeking a resolution to any ethical dilemma. This should be done only after all of the available information has been gathered and the specific ethical issues identified. The physician or ethics team leader may need to meet with the patient, family, surrogate, health care team, colleagues, or any involved parties. It may be helpful to consult with the hospital's bioethics committee. All available alternatives should be explored and evaluated. Finally, every attempt should be made to come to a mutually acceptable position.

Sample Case Scenario

Let us take the situation of an elderly female patient with a displaced hip fracture whose children disagree over the appropriate treatment for their mother. It is very easy to become embroiled in a family dispute in this type of setting. Family members may disagree among themselves about what is best for their parent. They may often attempt to enlist the physician as an ally to support their position.

An approach to this type of situation is, first and foremost, to gather information and identify the ethical issues at hand. What is the nature of the patient's fracture, medical condition, living arrangements, and ambulation status? Does this patient have the capacity to make his or her own decisions? If so, then patient autonomy becomes the default position. If not, then issues of surrogacy, living wills and advanced directives may come into play. If the patient has clearly expressed a desire or there is documentation of a previous decision, plan or health care proxy, the issue is made much easier.

It is important to keep in mind that our primary goal as physicians is to act for the good of the patient. If it is determined that a patient has the capacity to make a decision regarding his or her healthcare, then that decision must be respected. Very often support from social workers, nursing staff and the hospitals bioethics team can assist the physician in dealing with these very complex issues.

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Principles of Medical Ethics and Professionalism in Orthopaedic Surgery

The following *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery* have been adopted by the Board of Directors of the American Academy of Orthopaedic Surgeons. They are not laws, but rather standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon.

I. **Physician-Patient Relationship.** The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns. The orthopaedic surgeon should be dedicated to providing competent medical service with compassion and respect.

II. **Integrity.** The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception.

III. **Legalities and Honor.** The orthopaedic surgeon must obey the law, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. The orthopaedic surgeon also has a responsibility to seek changes in legal requirements that are contrary to the best interest of the patient.

IV. **Conflicts of Interest.** The practice of medicine inherently presents potential conflicts of interest. Wherever a conflict of interest arises, it must be resolved in the best interest of the patient. The orthopaedic surgeon should exercise all reasonable alternatives to ensure that the most appropriate care is provided to the patient. If a conflict of interest cannot be resolved, the orthopaedic surgeon should notify the patient of his or her intention to withdraw from the care of the patient.

V. **Confidentiality.** The orthopaedic surgeon should respect the rights of patients, of colleagues, and of other health professionals and must safeguard patient confidences within the constraints of the law.

VI. **Medical Knowledge.** The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public.

VII. **Cooperation.** Good relationships among physicians, nurses, and health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development of an expert health care team that will work together harmoniously to provide optimal patient care.

VIII. **Remuneration.** Remuneration for orthopaedic services should be commensurate with the services rendered. Orthopaedic surgeons should deliver high quality, cost-effective care without discrimination.

IX. **Publicity.** The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner.

X. **Societal Responsibility.** The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon.

Adopted October 1991. Revised December 1995, May 2002.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Code of Medical Ethics and Professionalism for Orthopaedic Surgeons

Preamble

Concerns for patient welfare and the appropriate behavior of the physician are a part of the heritage of medicine originating with the Code of Hammurabi, a code of ethics dating from 2000 B.C. Although the themes remain similar throughout history, guidelines for ethical behavior must address the demands of contemporary orthopaedic practice. The American Academy of Orthopaedic Surgeons (AAOS) developed *The Principles of Medical Ethics for the Orthopaedic Surgeon* and the *Code of Ethics for Orthopaedic Surgeons* primarily for the benefit of our patients. They serve as guides for conduct of the physician in the physician-patient relationship. These documents are, in part, derived from the *Current Opinions of the Council on Ethical and Judicial Affairs* of the American Medical Association (AMA). Since the AMA document is necessarily broad, the Academy documents are directed to concerns of specific interest to orthopaedic surgeons. Orthopaedic surgeons are encouraged to refer to the *Current Opinions of the Council on Ethical and Judicial Affairs* of the AMA for guidance if the particular ethical matter at issue is not addressed in the AAOS's *Principles of Medical Ethics for the Orthopaedic Surgeon* or *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons.*

The Academy's *Principles of Medical Ethics for the Orthopaedic Surgeon* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provide standards of conduct that define the essentials of honorable behavior for the orthopaedic surgeon. *The Principles of Medical Ethics for the Orthopaedic Surgeon* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, while taking into account the legal requirements of medical practice, call for and espouse a standard of behavior that is often higher than that required by the law.

Orthopaedic surgeons should recognize that they are role models for orthopaedic surgeons-in-training and other health care professionals and should by their deeds and actions comply with the AAOS's *Principles of Medical Ethics for the Orthopaedic Surgeon* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons.*

I. The Physician-Patient Relationship

I. A. The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns.

I. B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedist has an obligation to render care only for those conditions that he or she is competent to treat.

I. C The orthopaedist shall not decline to accept patients solely on the basis of race, color, gender, sexual orientation, religion, or national origin or on any basis that would constitute illegal discrimination.

I. D. The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care. Both orthopaedic surgeons and patients may have contracts with managed care organizations, and these agreements may contain provisions which alter the method by which patients are discharged. If the enrollment of a physician or patient is discontinued in a managed care plan, the physician will have an ethical responsibility to assist the patient in obtaining follow-up care. In this instance, the orthopaedic surgeon will be responsible to provide medically necessary care for the patient until appropriate referrals can be arranged.

I. E. It is not ethical for an orthopaedic surgeon to sever his or her relationship with a patient because of failure of a treatment or because no further operative treatment is indicated. The orthopaedic surgeon is ethically obligated to assist the patient in transferring care to a specialist appropriate to treat the problem.

I. F. When obtaining informed consent for treatment, the orthopaedic surgeon is obligated to present to the patient or to the person responsible for the patient, in understandable terms, pertinent medical facts and recommendations consistent with good medical practice. Such information should include alternative modes of treatment, the objectives, risks and possible complications of such treatment, and the complications and consequences of no treatment.

II. Personal Conduct

II. A. The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount.

II. B. The orthopaedic surgeon should conduct himself or herself morally and ethically, so as to merit the confidence of patients entrusted to the orthopaedic surgeon's care, rendering to each a full measure of service and devotion.

II. C. The orthopaedic surgeon should obey all laws, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that a physician or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly-constituted peer review authority or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct.

II. D. Because of the orthopaedic surgeon's responsibility for the patient's life and future welfare, substance abuse is a special threat that must be recognized and stopped. The orthopaedic surgeon must avoid substance abuse and, when necessary, seek rehabilitation. It is ethical for an orthopaedic surgeon to take actions to encourage colleagues who are chemically dependent to seek rehabilitation.

II.E Orthopaedic surgeons should promote their own physical and mental well being by maintaining healthy lifestyles. They should be attuned to evolving mental or physical impairment, both in themselves and in their colleagues, and take or encourage necessary measures to ensure patient safety. These measures might include medical intervention, professional counseling, or, in situations where reasonable offers of assistance are declined, reporting the impairment to appropriate authorities.

III. Conflicts of Interest

III. A. The practice of medicine inherently presents potential conflicts of interest. When a conflict of interest arises, it must be resolved in the best interest of the patient. The orthopaedic surgeon should exercise all reasonable alternatives to ensure that the most appropriate care is provided to the patient. If the conflict of interest cannot be resolved, the orthopaedic surgeon should notify the patient of his or her intention to withdraw from the relationship.

III. B. If the orthopaedic surgeon has a financial or ownership interest in a durable medical goods provider, imaging center, surgery center or other health care facility where the orthopaedic surgeon's financial interest is not immediately obvious, the orthopaedic surgeon must disclose that financial interest to the patient. The orthopaedic surgeon has an obligation to know the applicable laws regarding physician ownership, compensation and control of these services and facilities.

III. C. When an orthopaedic surgeon receives anything of value, including royalties, from a manufacturer, the orthopaedic surgeon must disclose this fact to the patient. It is unethical for an orthopaedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular product. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable.

III. D. An orthopaedic surgeon reporting on clinical research or experience with a given procedure or product must disclose any financial interest in that procedure or product if the orthopaedic surgeon or any institution with which that orthopaedic surgeon is connected has received anything of value from its inventor or manufacturer.

III. E. Except when inconsistent with applicable law, orthopaedic surgeons have a right to dispense medication, products, assistive devices, orthopaedic appliances, and similar related patient-care items, and to provide facilities and render services as long as their doing so provides a convenience or an accommodation to the patient without taking financial advantage of the patient. Ultimately, the patient must have the choice of accepting the dispensed medication, products or patient-care items or obtaining them outside the physician's office.

IV. Maintenance of Competence

IV. A. The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill, and should make available to patients and colleagues the benefits of his or her professional attainments. Each orthopaedic surgeon should participate in relevant continuing medical educational activities.

V. Professional Relationships

V. A. Good relationships among physicians, nurses, and other health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development and utilization of an expert health care team that will work together harmoniously to provide optimal patient care.

V. B. The professional conduct of the orthopaedic surgeon may be scrutinized by local professional associations, hospitals, managed care organizations, peer review committees, and state medical and/or licensing boards. These groups merit the participation and cooperation of orthopaedic surgeons.

V. C. Orthopaedic surgeons are frequently called upon to provide expert medical opinions or testimony. In providing opinions, the orthopaedic surgeon should ensure that the opinion provided is non-partisan, scientifically correct, and clinically accurate. The orthopaedic surgeon should not offer opinions concerning matters about which the orthopaedic surgeon is not knowledgeable. It is unethical for an orthopaedic surgeon to accept compensation that is contingent upon the outcome of litigation.

VI. Relationship to the Public

VI. A. The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner. Competition between and among surgeons and other health care practitioners is ethical and acceptable.

VI. B. Professional fees should be commensurate with the services provided. It is unethical for orthopaedic surgeons to bill individually for services that are properly considered a part of the "global service" package where defined, i.e., services that are a necessary part of the surgical procedure. It is unethical for orthopaedic surgeons to submit billing codes that reflect higher levels of service or complexity than those that were actually required. It is unethical for orthopaedic surgeons to charge for services not provided.

VI. C. Physicians should be encouraged to devote some time and work to provide care for individuals who have no means of paying.

VI. D. The orthopaedic surgeon may enter into a contractual relationship with a group, a prepaid practice plan, or a hospital. The physician has an obligation to serve as the patient's advocate and to ensure that the patient's welfare remains the paramount concern.

VII. **General Principles of Care**

VII. A. The orthopaedic surgeon should practice only within the scope of his or her personal education, training, and experience. If an orthopaedic surgeon contracts to provide comprehensive musculoskeletal care, then he or she has the obligation to ensure that appropriate care is provided in areas outside of his or her personal expertise.

VII. B. It is unethical to prescribe, provide, or seek compensation for unnecessary services. It is unethical not to provide services that are medically necessary. It is unethical to prescribe controlled substances when they are not medically indicated. It is also unethical to prescribe substances for the sole purpose of enhancing athletic performance.

VII. C. The orthopaedic surgeon should not perform a surgical operation under circumstances in which the responsibility for diagnosis, care, or decision-making is delegated to another who is not qualified to undertake it.

VII. D. When a patient submits a proper request for records, the patient is entitled to a copy of such records as they pertain to that individual. Charges should be commensurate with the services provided to reproduce the medical records. Certain correspondence from insurance carriers or attorneys may call for conclusions on the part of the orthopaedic surgeon. As such, a reasonable fee for professional services is permissible.

VIII. **Research and Academic Responsibilities**

VIII. A. All research and academic activities must be conducted under conditions of full compliance with ethical, institutional, and government guidelines. Patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time.

VIII. B. Orthopaedic surgeons should not claim as their own intellectual property that which is not theirs. Plagiarism or the use of others' work without attribution is unethical.

VIII. C. The principal investigator of a scientific research project or clinical research project is responsible for all aspects of the research, including reporting. The principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of the responsibility for work conducted by the other individuals.

VIII. D. The principal investigator or senior author of a scientific report is responsible for ensuring that appropriate credit is given for contributions to the research described.

IX. **Community Responsibility**

IX. A. The honored ideals of the medical profession imply that the responsibility of the orthopaedic surgeon extends not only to the individual but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon.

Adopted October 1988. Revised 1991, 1995, 2001, 2002, 2004, 2005, 2009, 2011.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Medical Professionalism in the New Millennium: A Physician Charter

[Note: The Board of Directors of the American Academy of Orthopaedic Surgeons adopted this statement on "Medical Professionalism in the New Millennium: A Physician Charter" as AAOS policy during its meeting on May 17, 2002.]

Physicians today are experiencing frustration as changes in the health care delivery systems in virtually all industrialized countries threaten the very nature and values of medical professionalism. Meetings among the European Federation of Internal Medicine, The American College of Physician-American Society of Internal Medicine (ACP-ASIM), and the American Board of Internal Medicine (ABIM) have confirmed that physician views on professionalism are similar in quite diverse systems of health care delivery. We share the view that medicine's commitment to the patient is being challenged by external forces of change within our societies.

Recently, voices from many countries have begun calling for a renewed sense of professionalism, one that is activist in reforming health care systems. Responding to this challenge, the European Federation of Internal Medicine, the ACP-ASIM Foundation, and the ABIM Foundation combined efforts to launch the Medical Professionalism Project in late 1999. These three organizations designated members to develop a "charter" to encompass a set of principles to which all medical professionals can and should aspire. The charter supports physicians' efforts to ensure that the health care systems and the physicians working within them remain committed both to patient welfare and to the basic tenets to be applicable to different cultures and political systems.

Preamble

Professionalism is the basis of medicine's contract with society. It demands placing the interests of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health. The principles and responsibilities of medical professionalism must be clearly understood by both the profession and society. Essential to this contract is public trust in physicians, which depends on the integrity of both individual physicians and the whole profession.

At present, the medical profession is confronted by an explosion of technology, changing market forces, problems in health care delivery, bioterrorism, and globalization. As a result, physicians find it increasingly difficult to meet their responsibilities to patients and society. In these circumstances, reaffirming the fundamental and universal principles and values of medical professionalism, which remain ideals to be pursued by all physicians, becomes all the more important.

The medical profession everywhere is embedded in diverse cultures and national traditions, but its members share the role of healer, which has roots extending back to Hippocrates. Indeed, the medical profession must contend with complicated political, legal, and market forces. Moreover, there are wide variations in medical delivery and practice through which any general principles may be expressed in

both complex and subtle ways. Despite these differences, common themes emerge and form the basis of this charter in the form of three fundamental principles and as a set of definitive professional responsibilities.

Fundamental Principles

Principle of primacy of patient welfare. The principle is based on a dedication to serving the interest of the patient. Altruism contributes to the trust that is central to the physician-patient relationship. Market forces, societal pressures, and administrative exigencies must not compromise this principle.

Principle of patient autonomy. Physicians must have respect for patient autonomy. Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care.

Principle of social justice. The medical profession must promote justice in the health care system, including the fair distribution of health care resources. Physicians should work actively to eliminate discrimination in health care, whether based on race, gender, socioeconomic status, ethnicity, religion, or any other social category.

A Set of Professional Responsibilities

Commitment to professional competence. Physicians must be committed to lifelong learning and be responsible for maintaining the medical knowledge and clinical and team skills necessary for the provision of quality care. More broadly, the profession as a whole must strive to see that all of its members are competent and must ensure that appropriate mechanisms are available for physicians to accomplish this goal.

Commitment to honesty with patients. Physicians must ensure that patients are completely and honesty informed before the patient has consented to treatment and after treatment has occurred. This expectation does not mean that patients should be involved in every minute decision about medical care; rather, they must be empowered to decide on the course of therapy. Physicians should also acknowledge that in health care, medical errors that injure patients do sometime occur. Whenever patients are injured as a consequence of medical care, patient should be informed promptly because failure to do so seriously compromises patient and societal trust. Reporting and analyzing medical mistakes provide the basis for appropriate prevention and improvement strategies and for appropriate compensation to injured parties.

Commitment to patient confidentiality. Earning the trust and confidence of patients requires that appropriate confidentiality safeguards be applied to disclosure of patient information. This commitment extends to discussions with persons acting on a patient's behalf when obtaining the patient's own consent is not feasible. Fulfilling the commitment to confidentiality is more pressing now than ever before, given the widespread use of electronic information systems for compiling patient data and an increasing availability of genetic information. Physicians recognize, however, that their commitment to patient confidentiality must occasionally yield to overriding considerations in the public interest (for example, when patients endanger others).

Commitment to maintaining appropriate relations with patients. Given the inherent vulnerability and dependency of patients, certain relationships between physicians and patients must be avoided. In particular, physicians should never exploit patients for any sexual advantage, personal financial gain, or other private purpose.

Commitment to improving quality of care. Physicians must be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also working collaboratively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care. Physicians must actively participate in the development of better measures of quality of care and the application of quality measures to assess routinely the performance of all individuals, institutions, and systems responsible for health care delivery. Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.

Commitment to improving access to care. Medical professionalism demands that the objective of all health care systems be the availability of a uniform and adequate standard care. Physicians must individually and collectively strive to reduce barriers to equitable health care. Within each system, the physician should work to eliminate barriers to access based on education, laws, finances, geography, and social discrimination. A commitment to equity entails the promotion of public health and preventive medicine, as well as public advocacy on the part of each physician, without concern for the self-interest of the physician or the profession.

Commitment to a just distribution of finite resources. While meeting the needs of individual patients, physicians are required to provide health care that is based on the wise and cost-effective management of limited clinical resources. They should be committed to working with other physicians, hospitals, and payers to develop guidelines for cost-effective care. The physician's professional responsibility for appropriate allocation of resources requires scrupulous avoidance of superfluous tests and procedures. The provision of unnecessary services not only exposes one's patients to avoidable harm and expense but also diminishes the resources available for others.

Commitment to scientific knowledge. Much of medicine's contract with society is based on the integrity and appropriate use of scientific knowledge and technology. Physicians have a duty to uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use. The profession is responsible for the integrity of this knowledge, which is based on scientific evidence and physician experience.

Commitment to maintaining trust by managing conflicts of interest. Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including medical equipment manufacturers, insurance companies, and pharmaceutical firms. Physicians have an obligation to recognize, disclose to the general public, and deal with conflicts of interest that arise in the course of their professional duties and activities. Relationships between industry and opinion leaders should be disclosed, especially when the latter determine the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

Commitment to professional responsibilities. As members of a profession, physicians are expected to work collaboratively to maximize patient care, be respectful of one another, and participate in the processes of self-regulation, including remediation and discipline of members who have failed to meet professional standards. The profession should also define and organize the educational and standard-setting process for current and future members. Physicians have both individual and collective obligations to participate in these processes. These obligations include engaging in internal assessment and accepting external scrutiny of all aspects of their professional performance.

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Ann Inter Med. 2002;136:243-246

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AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

ADVERTISING

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Standards of Professionalism

Advertising by Orthopaedic Surgeons

Adopted April 18, 2007

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

At the core of the patient-physician relationship is a sense of trust. A patient trusts that the physician is knowledgeable and provides appropriate representations of his or her abilities. An orthopaedic surgeon who misrepresents his or her abilities or advertises musculoskeletal services in a false or misleading fashion damages the patient-physician relationship of trust. In addition, the orthopaedic surgeon who misleads through advertising may prevent a patient from making informed decisions about important health care matters.

For purposes of these Standards of Professionalism, advertising to the public includes, but is not limited to, information appearing on behalf of an orthopaedic surgeon and/or his or her professional entity (e.g., partnership, limited liability partnership or corporation) on the Internet or e-mails and in phonebooks, magazines, newspapers, direct mail, flyers, billboards, video presentations, and directories available to the public. In addition, advertising includes printed material typically used in the practice setting: letterhead, mailing envelopes, business cards, referral forms, office forms, appointment cards, brochures, pamphlets, office mailings, and signage inside or outside of the office. Advertising includes radio and television advertisements, including interviews, and telephone voice messages. Advertising includes any activity in which an orthopaedic surgeon pays in any way, including providing services in exchange for advertising, to communicate with the public.

Advertising of services, as well as competition between and among orthopaedic surgeons and other health care practitioners, is ethical and acceptable. It is the obligation of the orthopaedic surgeon to present a fair and honest representation of services and the goals, alternatives, expectations and risks associated with these services. In advertising as in all communications with patients and the public, orthopaedic surgeons have an ethical obligation to present themselves and the services they provide to patients in a clear and accurate manner. This principle of ethical conduct, when it is applied to advertising, is buttressed by its enforcement in law.

The U.S. Federal Trade Commission also has rules governing physician advertising. It is the responsibility of AAOS Fellows and Members to be familiar with and comply with these regulations as well as applicable State and local laws. Regulations make advertisements that are false or misleading illegal and subject to prosecution. Parties are encouraged that before

filing a complaint with AAOS they attempt to resolve their disputes through other alternatives including state or federal resources.

The Standards of Professionalism draw from the aspirational *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* that appears in bold italics. The statements that follow the **aspirational** *Code* establish the baseline standard of acceptable conduct for orthopaedic surgeons who advertise their services. Violations of these **mandatory** standards may serve as grounds for a formal complaint to and action by the AAOS as outlined in the AAOS Bylaws Article VIII.

These Standards of Professionalism apply to all AAOS Fellows and Members and all forms of advertising. Only an AAOS Fellow or Member may file a complaint of an alleged violation of these Standards of Professionalism regarding another AAOS Fellow or Member.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I. F.:
When obtaining informed consent for treatment, the orthopaedic surgeon is obligated to present to the patient or to the person responsible for the patient, in understandable terms, pertinent medical facts and recommendations consistent with good medical practice. Such information should include alternative modes of treatment, the objectives, risks and possible complications of such treatment, and the complications and consequences of no treatment.

Mandatory Standards:

1. An orthopaedic surgeon shall not advertise information in a manner that misleads patients to believe that a diagnosis can be made without consultation or that one method of treatment is suitable for all patients. Advertising shall not be false, misleading, or lead patients to believe that any given procedure is without risk.

2. An orthopaedic surgeon shall preserve and maintain the integrity of the profession by not advertising false or misleading statements to a patient or the person responsible for the patient.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, II. A.:
The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount.

Mandatory Standards:

3. An orthopaedic surgeon shall not, when advertising his or her services to the public, make false or misleading representations of his or her ability to provide medical treatment.

4. An orthopaedic surgeon shall not use false or misleading photographs or other images in advertising.

5. An orthopaedic surgeon shall not use photographs, images, endorsements, and/or statements in a false or misleading manner that communicate a degree of relief, safety, effectiveness, or benefits from orthopaedic care that are not representative of results attained by that orthopaedic surgeon.

6. An orthopaedic surgeon shall prevent false or misleading advertising by approving all advertisements regarding his or her practice before dissemination. An orthopaedic surgeon shall be held responsible for any violations of this Standard of Professionalism incurred by a public relations, advertising, or similar firm which he or she retains.

7. An orthopaedic surgeon shall make a reasonable effort to ensure that statements made by an academic institution, hospital or private entity on his or her behalf are not false or misleading.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, VI. A.:
The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner. Competition between and among surgeons and other health care practitioners is ethical and acceptable."

Mandatory Standards:

8. An orthopaedic surgeon shall abide by all state and federal laws and regulations related to the advertising of degrees(s) and credentials, not advertising them in a false or misleading manner.

9. An orthopaedic surgeon, when advertising his or her services to the public, shall not advertise false or misleading certification levels.

10. An orthopaedic surgeon, when advertising his or her services to the public, shall not make false or misleading claims or personal representations, including volume of procedures performed and the nature and level of academic appointments and affiliations.

11. An orthopaedic surgeon, when advertising, shall not misrepresent or falsely state his or her role in the development or study of a particular surgical procedure.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

Advertising by Orthopaedic Surgeons

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

What parameters exist to guide orthopaedic surgeons regarding advertising?

Legal analysis

Federal and state antitrust laws prohibit medical associations like the Academy from impeding physicians who use truthful advertising. The reason for this prohibition is to preserve and promote a free and open market by enabling physicians to disseminate information about their services to patients. Policy makers at the federal and state level believe that truthful advertising may assist patients in making better informed judgments and choices.

Although truthful advertising has substantial legal protections, physician advertising that is not truthful is not protected by federal or state antitrust laws nor is it protected from state regulation by the First Amendment. In fact, physician advertising that is false, deceptive, or misleading within the meaning of Section 5 of the Federal Trade Commission (FTC) Act is illegal. [15 U.S.C. Sect. 45]. The FTC has the authority to sue physicians who disseminate false or deceptive advertising. In addition, the FTC may enjoin them from further dissemination of misleading advertisements, and under some circumstances, may levy fines. Furthermore, physicians who violate an FTC order which prohibits the dissemination of false or deceptive advertising are subject to substantial fines.

In addition, many state consumer protection laws and medical practice acts prohibit false or deceptive physician advertising. These laws generally empower state attorneys general to sue physicians who engage in false advertising for fines or to enjoin further illegal activity. State medical licensure boards often have the authority to discipline physicians who engage in false advertising. In addition, patients who have been injured by false or misleading physician advertising may be able to sue the physician involved for damages under consumer protection statutes or common law fraud claims.

Ethical analysis

Orthopaedic surgeons, like all physicians, have an ethical obligation to present themselves and the services they provide to patients in a clear and accurate manner. This principle of ethical conduct is buttressed by its enforcement in law.

A successful physician-patient relationship is based on trust. The patient trusts that the physician has the appropriate training and skills, will listen to the patient's complaints and symptoms, and will advise the patient accurately and objectively about the alternative courses of treatment. It is essential to this relationship that the patient has confidence that the physician is honest and is not manipulating the information presented for any purpose. Because the patient is often in a relatively uninformed position, patients usually assume that the physician is telling them all they need to know and that what they are told is accurate. Consequently, patients are especially at risk for untruthful, misleading or deceptive advertising.

For this reason, false and deceptive advertising by physicians destroys the trust relationship between the physician and patient which is essential to quality medical care. A physician's misrepresentation may harm patients by making them less likely to seek out treatments they need or vulnerable to accepting treatments that are not essential.

The FTC has developed four general rules to determine whether physician advertisements are truthful and not false, deceptive or misleading. The four rules are:

1. Advertisements should be accurate and not contain explicit false claims or misrepresentations of material fact. Generally, a false claim or a misrepresentation of fact would be material if it would be likely to affect the behavior or actions of an ordinary and prudent person regarding a physician or physician service.

2. Advertisements should not contain material implied false claims or implied misrepresentations of material fact. An advertisement that does not contain direct false claims or misrepresentations should not by implication create false or unjustified expectations about the physician or physician services being publicized. An implied false claim or misrepresentation would be material if it would be likely to affect the behavior of an ordinary and prudent person towards a physician or physician service.

3. There should be no omissions of material fact from advertisements. In advertisements, disclosures of information are necessary where omission would make the advertisement as a whole misleading to an ordinary and prudent person or an average member of the audience to whom it is directed.

4. Physicians should be able to substantiate material claims and personal representations made in an advertisement.

The ultimate question of whether an advertisement is truthful can be determined by addressing whether all four of these rules of truthful advertising have been followed in the development and dissemination of the advertisement.

Specific issues

Advertising by Employers or Third Parties

With the increase in employed physicians and practice partnerships with other healthcare entities, advertising for physicians and their services is increasingly organized and paid for by entities other than the physician themselves. Industry publications describe how hospitals can leverage physicians as "brand advocates." While marketers may see patients more as 'customers' or 'consumers,' the orthopaedic surgeon has a professional and ethical duty to care for patients that transcends transactional terminology.

Though the physician may not directly control this advertising by proxy, they still maintain an obligation to "make a reasonable effort to ensure that statements made by an academic institution, hospital or private entity on his or her behalf are not false nor misleading." Thus, the orthopaedic surgeon should be cognizant of how their services are being advertised or 'branded' by their employer or affiliates and apply the considerations below to such marketing as well.

New Media and Public Content

Traditional advertising has focused on paid advertising content in print, radio, mailings, billboard, and television. Increasingly, physicians and healthcare entities are utilizing newer media (e.g. social media sites, blogs, online videos, practice websites, etc.) to advertise and brand their services and expertise. The orthopaedic surgeon should apply high standards for professional, truthful communication to all these forms of public communication and advertising, traditional or non-traditional.

Endorsements and Pictures

Endorsements and pictures are sometimes used to represent the benefits of specific orthopaedic services, such as the degree of relief, recovery, or other benefits that may be attained if the services are used. The primary concern raised by endorsements and pictures is whether they communicate benefits of orthopaedic services that are representative of the benefits ordinarily attained by the average patient. If they communicate a degree of relief or recovery that is exceptional or otherwise not representative of the average patient, they may mislead patients into having unjustified medical expectations about the orthopaedic services advertised. Images should not be materially altered or enhanced to misrepresent the magnitude of benefits or to mislead patients.

Claims: "Painless," "Painfree," or "Ouchless"

The degree of comfort, ease, or pain involved in the provision of an orthopaedic service is difficult to measure by objective standards. How these factors are experienced by an individual is subjective and varies from patient to patient. Therefore, claims or representations about the degree of comfort, care or lack of pain involved in an orthopaedic service and where they are provided (e.g. ER) may be difficult to substantiate and may be misleading if not used with care.

Statements that an orthopaedic procedure does not cause pain or is painless raise concerns if the services advertised are invasive. It is highly unlikely that an invasive orthopaedic procedure will not cause some degree of pain.

Claims: "Safe" or "Effective"

General representations about the safety or effectiveness of specific orthopaedic services should not be misleading. Such representations may cause a layperson to lack appreciation for the nature of any risks or adverse effects associated with the orthopaedic procedure, even if the likelihood that adverse effects may occur is low. More specific representations can also cause concerns. For example, a statement that an orthopaedic surgeon has cured or successfully treated a large number of cases involving a particular serious ailment is deceptive if it implies a certainty of result and creates unjustified and misleading expectations in prospective patients.

Representations about the safety or effectiveness of orthopaedic services should be substantiated with sound scientific support, such as peer reviewed publications in medical literature or other authoritative sources of scientific information. Such claims should not contradict or be inconsistent with conclusions reached by authoritative federal agencies, such as the National Institutes of Health, the Centers for Medicare and Medicaid Services, the Food and Drug Administration or others, unless such a contradiction or inconsistency can be substantiated with sound scientific evidence.

Simply using a phrase such as "safe" is likely to deceive prospective patients by implying an absolute or binary ("safe" versus "unsafe") standard, when in fact the "safety" of an orthopaedic procedure is necessarily a qualified concept. The failure to qualify the claim is particularly objectionable since a variety of phrases could easily be employed to communicate the safety/risk relationship (e.g. "relatively safe," "safe for most patients," or "among the safer types of orthopaedic surgery").

Claims: "Cure"

Use of the term "cure" with reference to a problem is often deceptive. To "cure" a condition means to alter the circumstances so that the condition no longer exists and will not recur. In order not to be misleading, the term "cure" should almost always be further explained and qualified to give the patient an accurate understanding of his/her prospects for improvement.

Claims: Physician Qualifications

Orthopaedic surgeon qualifications include education, training, and other indicators of status or achievement within the profession. The lay public does not have a good understanding about what various qualifications represent. Most patients will assume that physician qualifications in an advertisement indicate training, knowledge, expertise, and competence with respect to the services being advertised. That assumption is likely because patients will conclude that qualifications are listed in an advertisement to substantiate the orthopaedic surgeon's ability to perform the services being advertised. It is possible for patients to be misled if the qualifications listed imply a level of education or training which the orthopaedic surgeon did not receive; if they imply a degree of scrutiny of the orthopaedic surgeon's knowledge, training and competence that did not in fact occur; if they imply a qualification which the orthopaedic surgeon does not have; if the qualifications are inaccurately listed; or if the qualifications do not indicate education, training, knowledge, expertise, or competence with respect to the services being advertised. For example, a brief, observership with a prominent surgeon should not be misrepresented as the equivalent to operative training received via a formal fellowship.

Claims: "World Famous," "Top Surgeon," "Pioneer"

Only a small fraction of all orthopaedic surgeons can justifiably claim to be "world-famous." These may include some orthopaedic surgeons who are editors of major journals, who have authored widely used texts, or who have made major, original contributions to medical techniques. However, it is the very elusiveness of measures of "fame" which makes invoking them in trying to lure patients misleading. Merely traveling extensively, presenting addresses at professional meetings or treating patients from abroad does not mean that an orthopaedic surgeon is "world-famous." To so indicate is to use the inherent imprecision of the concept of fame to mislead patients. There can be little question that such claims are employed in order to give patients the impression that the orthopaedic surgeon meets some objective, high level of competence, skill or recognition - which probably does not exist with respect to the advertiser. Use of superlative language in advertising (e.g. "Top orthopaedic surgeon," "Exceptional," "Top doctor," "Best doctor") raises the same issue and is on the rise as competition intensifies among some healthcare institutions and providers. If such claims are made, they should be properly substantiated or qualified.

Saying that one has "pioneered advances in orthopaedic surgery" is also deceptive. Such a phrase connotes a major breakthrough, not a minor alteration or refinement of conventional procedures. Simply being one of many "investigators" for a type of orthopaedic prosthesis, using one piece of equipment, or using a slightly refined surgical procedure does not justify use of the term "pioneer." Since all orthopaedic surgery requires some degree of innovation, an orthopaedic surgeon cannot meaningfully claim to be an originator or developer of a technique or product simply because he or she has modified what existed before in some minor way.

Claims: Fees and Costs

Orthopaedic surgeons may advertise truthful information about fees and costs. However, statements about fee information can be misleading if they do not fairly inform the public about the costs likely to be incurred when patronizing the advertised physician. For example, the description of any service for which a fee or a range of fees is advertised must not be deceptive or misleading, and the statement should also indicate whether there may be additional fees for related services that are commonly required when the advertised service is obtained.

Claims: "Minimally Invasive"

Since patients are obviously interested in having surgical procedures that do as little harm as possible to their bodies, there has been great public interest in "minimally invasive" surgical approaches. Unfortunately, the term is often abused, misunderstood and misapplied, and physicians have inappropriately used the term in advertisement and marketing programs as well.

Patients may mistakenly assume that "minimally invasive" equates with minimal tissue damage, faster recovery, lower risk, and better clinical results. In some clinical studies those facts do not bear out, and numerous reports elucidate the complications of so-called minimally invasive procedures. Thus, the concept that minimally invasive procedures are safer, less damaging, demonstrate clinically superior results or are better for the patient must not be inferred, stated or implied in physician advertising.

Claims: "Bloodless"

There is no such thing as bloodless surgery. Statements that surgical procedures are "bloodless" convey a false impression to the patient. Qualifying terms such as "relatively little blood lost" or "little blood lost in most patients" are preferable.

It is rare, even in arthroscopy, that a surgical procedure will result in no loss of blood. There may be relatively little blood lost at the time of the procedure but almost all surgical cases will result in some blood loss either at the time of surgery or during the post-operative period.

Some institutions have established "bloodless surgery centers" developed for patients with religious objection to transfusions. Physicians at these centers should make every effort to explain that the term "bloodless center" does not imply that no blood is lost but rather that a transfusion may not be required.

References:

AAOS Standards of Professionalism on Advertising by Orthopaedic Surgeons, adopted April 18, 2007. The entire document is relevant.

Applicable provision of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

"IX. The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner."

Applicable provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

"I. F. When obtaining informed consent for treatment, the orthopaedic surgeon is obligated to present to the patient or to the person responsible for the patient, in understandable terms, pertinent medical facts and recommendations consistent with good medical practice. Such information should include alternative modes of treatment, the objectives, risks and possible complications of such treatment, and the complications and consequences of no treatment."

"II. A. The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount."

"VI. A. The orthopaedic surgeon should not publicize himself or herself through any medium or form of public communication in an untruthful, misleading, or deceptive manner. Competition between and among surgeons and other health care practitioners is ethical and acceptable."

Other references

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics.* Chicago, IL, 2014-1015 edition.

Opinion 5.01 ("Advertising and Managed Care Organizations") [Issued prior to April 1977. Updated June 1996.]
Opinion 5.02 ("Advertising and Publicity") [Issued prior to April 1977. Updated June 1996.]

Opinion 1205

For additional information, contact Richard N. Peterson at (847) 384-4048 or email peterson@aaos.org

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Position Statement

Pharmaceutical and Device Company Direct to Consumer Advertising

This Position Statement was developed as an educational tool based on the consensus opinion of the authors. It is not a product of a systematic review process. Readers are encouraged to consider the information presented and reach their own conclusions.

Since the late 1990's, Direct to Consumer (DTC) advertising has become a multi-billion dollar enterprise. Understandably, drug and device companies want to be sure that patients recognize the availability of their products.

Although more high quality research is needed to determine its benefits and problems, DTC advertising may well:

- Create more informed patients,
- Foster shared decision making between patients and physicians,
- Increase physician-patient communication,
- Improve patient compliance, and
- De-stigmatize diseases.

However, DTC advertising also has the potential for negative consequences. For example, advertising may confuse patients by implying that minor differences among competing products represent major therapeutic advances.

The American Academy of Orthopaedic Surgeons (AAOS) believes Direct to Consumer advertising that is presented in a responsible and ethical manner may be of some value to patients. Such information should be scientifically substantiated, accurately presented, and free of false or misleading claims. Direct to Consumer advertising and marketing of pharmaceuticals, devices, or surgical procedures may create patient safety concerns if it leads patients to seek health care solutions without consulting with a physician.

Problems with DTC advertising of pharmaceuticals include patients that seek medications from pharmacies on the Internet and outside the United States without a physician's prescription or without physician monitoring of medications. Patients may not be aware of the entire spectrum of other more appropriate and less expensive therapeutic options than the advertised drug. Side effects are often not communicated in a comprehensive manner in advertising or marketing communications. Furthermore, patients are often unaware of drug-drug, drug-herb, drug-supplement, or drug-food

interactions. Physician monitoring ensures pharmaceuticals are appropriate for a patient's particular health condition.

DTC advertising of orthopaedic devices may not inform patients about differences in product design, composition of materials, and strength of the devices. Patients may not have access to data on post-marketing surveillance issues relating to device performance and patient safety. When surgeons choose devices tailored to an individual patient's needs, wear of orthopaedic implants is a significant consideration, but consumers may not be aware of such issues.

Companies recently began marketing surgical procedures directly to potential patients. Consumers may be confused about all of the treatment options for their particular medical condition, and it may prove challenging for them to compare one surgical procedure to another.

Because of the highly individual nature of surgery and other musculoskeletal treatments, the AAOS believes that great care should be taken in advertising orthopaedic devices, drugs, and procedures directly to consumers. Advertising should be truthful, useful to patients, and not misleading or ambiguous. Advertising that an individual surgeon has received training to perform a procedure does not imply the same standards as certification by the American Board of Orthopaedic Surgery (ABOS). The AAOS supports continued research efforts on the effects of Direct to Consumer advertising on public health.

Position Statement 1162

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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COMMUNICATIONS

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Information Statement

Communicating Adverse Events or Poor Outcomes

This Information Statement was developed as an educational tool based on the consensus opinion of the authors. It is not a product of a systematic review process. Readers are encouraged to consider the information presented and reach their own conclusions.

Adverse events or poor outcomes are inevitable in the practice of medicine. Frank discussion and honest communication about the event between the physician and the patient/family are imperative. An adverse or poor outcome does not necessarily result from an error or negligent care, but may be from a combination of factors, including complications, diverse biological interactions, or unrealistic expectations regarding treatment benefits versus potential risks.

Consistent with Joint Commission standards and the American Academy of Orthopaedic Surgeon's Principles of Medical Ethics and Professionalism, the AAOS believes that an orthopaedic surgeon should put the interests of the patient first and communicate directly with a patient/family member in an honest, compassionate manner as soon as possible after an adverse event or poor outcome occurs.

As stated in the AAOS Information Statement on The Importance of Good Communication in the Physician-Patient Relationship, good communication with patients has always been essential in orthopaedic practice and is the cornerstone of the physician – patient relationship. Open, honest communication favorably affects patient behavior, health outcomes, patient satisfaction, and often reduces the incidence of medical professional liability actions.

When an adverse event or poor outcome occurs, the orthopaedic surgeon should first address the patient's immediate health care needs and then institute an investigation to collect all pertinent information. The orthopaedic surgeon should discuss the event honestly and empathetically with the patient and/or family with disclosure of known facts and an explanation offered as to the likely cause. This disclosure conversation should also include a discussion of ongoing treatment, follow up care, and prognosis.

If the adverse outcome or poor outcome is the result of a medical error, the orthopaedic surgeon has an ethical and professional obligation to disclose the error to the patient and/or family. This disclosure conversation should include what happened, why it happened, health implications for the patient, and what measures are being instituted to prevent recurrences. Many patients have expressed that an apology is important. The physician should support the patient and family, show compassion and concern, and acknowledge their emotional response and needs during this difficult time. This will help to set clear goals for the future patient-physician interaction.

The physician-patient relationship is built upon trust and honesty. The AAOS Code of Medical Ethics and Professionalism reinforces these principles in section II.A. which states: "The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount." Consistent with these principles, the AAOS urges orthopaedic surgeons to behave in a manner consistent with these recommendations when communicating about adverse events or poor outcomes with their patients and their family members.

Information Statement 1028

For additional information, contact Public Education and Media Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Information Statement

Patient-Physician Communication

This Information Statement was developed as an educational tool based on the consensus opinion of the authors. It is not a product of a systematic review process. Readers are encouraged to consider the information presented and reach their own conclusions.

Successful medical encounters require effective communication between the patient and the physician. "Success" implies that the patient and physician have developed a "partnership" and the patient has been fully educated in the nature of his or her condition and the different methods to address the problem. This allows the patient to be actively involved in the decision-making process and establishes agreed upon expectations and goals.[1] Many models have been developed to assist healthcare providers in developing approaches to improve their ability to communicate with their patients. These models focus on improvement in the quality of the encounter and do not necessarily require any significant increased investment in the length of the encounter. These approaches have been demonstrated to improve patient satisfaction and also allow the provider to demonstrate empathy, concern and humanism.[2,3,4] Learning communication skills allows the orthopaedist to build trust, promote healing, and ultimately improve outcomes. Interestingly, not only do successful encounters improve patient outcomes, they have also been shown to improve professional satisfaction. These skills lead to professional respect among the physician's peers and result in patients seeking care from these providers. Finally, interviews with patients who have filed malpractice suits against their physicians often site poor communication and lack of empathy as a factor in pursuing legal action.[5,6]

The American Academy of Orthopaedic Surgeons (AAOS) urges orthopaedic surgeons to use patient-focused communication skills during their direct patient encounters. These include:

- ***Sitting down during patient encounters***
- ***Developing an understanding of the patient as an individual, not as a disease or a musculoskeletal condition***
- ***Showing empathy and respect***
- ***Listening attentively and creating a partnership***
- ***Eliciting concerns and calming fears***
- ***Answering questions honestly***
- ***Informing and educating patients about treatment options and the course of care***
- ***Involving patients in decisions concerning their medical care***
- ***Demonstrating sensitivity to patients' cultural and ethnic diversity***

When time counts, it is the quality and not necessarily the quantity of physician-patient communication that is vital. To the patient, quality is often measured by how well the physician listens, validates their musculoskeletal complaint, and acknowledges the patient's concerns. It is measured by how thoroughly the physician explains the diagnosis and treatment options, and how

well the physician involves the patient in decisions concerning his or her care. These factors play an important part in the way patients perceive, recall, and evaluate their visits with the physician.[2,3,4]

AAOS believes that orthopaedic surgeons must place an emphasis on good communication with patients and the quality of the interaction, especially when time is limited.

Informed Consent

Components of Informed Consent

Obtaining consent to perform a medical intervention is a mainstay in the current practice of medicine. It allows the physician to subscribe to and follow the three basic tenants of medical ethics: respecting patient autonomy, beneficence (doing good), and non-maleficence (not causing harm). The process needs to be "informed" and the physician should spend time with each patient to insure that the patient (or legal guardian) understands the proposed treatment and has had an opportunity to have any questions addressed. Even if the patient is given written materials to explain the proposed treatment, the physician should review the explanation with the patient. It is important that the discussion utilize words which the patient is able to understand. Specifically, the consent process should include the following elements:

- Nature of the problem
- Proposed treatment to address the condition (if the surgeon has a specific recommendation)
- Alternative treatments
- Anticipated benefits of each treatment option
- Risks and side effects of each treatment option
- Consequences of no treatment
- Assessment of the patient's understanding of the proposed treatment

The surgeon is bound to disclose any information which the patient needs to know to make an informed decision about a recommended course of treatment. Generally, this would include the framework listed above and include the commonly reported complications of a procedure and less frequent complications which have significant long term implications for the individual. Any adult patient with decision-making capacity has the legal right to refuse care, even if this refusal may ultimately result in the loss of a limb or death.

Documentation

Documentation of the consent process is critically important. Institutional consent forms are designed to allow patients to verify with their witnessed signature that they have been fully informed and agree to the proposed procedure. These forms are very general in their wording and do not include the specifics of each informed consent discussion. The surgeon should document the complete informed consent process with a comprehensive note in the patient's medical record. This entry should report the nature of the discussion and include all of the specific information outlined above. It is recommended that this note document that the patient or guardian understands the explanation and has had an opportunity to have any questions answered. Finally, the note should report that the patient (guardian) wishes to proceed with the recommended treatment.

The World Health Organization (WHO) and the AAOS recommend that the surgeon verify the correct surgical site with the patient. This site should be "signed" (usually with the surgeon's initials) and witnessed by the patient prior to the patient being brought into the operating room.

In some states and institutions, the physician is required to obtain pre-operative consent from the patient for the operating room attendance of people who are not members of the health care team.

This may include representatives of biomaterial or implant device manufacturers or other observers. The surgeon should be familiar with state and institutional regulations requiring permission for observers in the operating room. Surgeons should also obtain specific consent for intra-operative medical photography for the purpose of documenting the patient's condition.

Minors

Minors (ages 18-21, state dependant) are not legally permitted to consent to surgery. Despite this, it is well recognized that children should actively participate in the discussions related to their health care. The degree of involvement will depend on the age of the child and his or her individual capacity to understand the discussion. In 1994 the American Academy of Pediatrics, Committee on Bioethics, released a position statement entitled "Informed Consent, Parental Permission and Assent in Pediatric Practice. (This position was reaffirmed in October 2006).[7,8]

The position statement outlines the benefits and limitations in the participation of a minor in health care decisions. By obtaining "assent" we allow the child to "achieve a developmentally appropriate awareness of his or her condition". Care must be taken to insure that the discussion is age and capacity appropriate and not deceiving. A nine-year-old child with an open fracture needs to be treated in the operating room. This process should include an explanation to the child as to what happened and what has to be done to help. Seeking permission (assent) and receiving a refusal would lead the child to mistrust the healthcare providers. A sixteen-year-old with normal capacity scheduled for surgery for idiopathic scoliosis should actively participate in the discussion and assent to the procedure. Many physicians actually have the adolescent child and the guardian both sign the informed consent form.

One of the additional protections provided by the law to minors is their right to receive limb- or life-saving treatment even when this treatment is refused by the guardian. Thus the surgeon may provide, for example, a blood transfusion to the child of parents who refuse this treatment, if he/she believes that the child's life is at risk without the transfusion. The surgeon should be familiar with the institutional and legal processes to be followed when providing limb- or life-saving treatment to a child against the wishes of the child's parent.

Under certain circumstances, minors are legally allowed to provide informed consent for their own treatment. The most common circumstance encountered by physicians is when minors have a condition for which they might fail to seek treatment if parental consent was required, such as pregnancy, sexually transmitted disease, substance or alcohol abuse, or a psychiatric condition. Minors with these conditions may have concomitant orthopaedic problems, complicating the issue of their capacity to provide consent. Because the conditions for which minors are emancipated vary from state to state, orthopaedic surgeons should familiarize themselves with the specific requirements of the states and institutions in which they practice.

AAOS urges orthopaedic surgeons to provide information and education to their patients about treatment alternatives and the course of care, especially expectations for surgical outcomes. Discussing the risks of surgery and possible complications, in a kind and compassionate manner, can create realistic expectations on the part of the patient, increase patient satisfaction, and minimize the risk of malpractice claims.[5,6]

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Information Statement 1017

For additional information, contact the Public Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Position Statement

Public Reporting of Provider Performance

This Position Statement has been developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Background

Performance measurement is a growing phenomenon in which providers of health care are required to report the results of clinical measures of quality. There has been increasing demand to accelerate quality improvement and promote transparency through public reporting of this performance data.[10] This trend was accelerated by the passage of the Patient Protection and Affordable Care Act (PPACA), which includes provisions to support public reporting. Public reporting has been accompanied by efforts to reduce rising healthcare costs, create accountable and high performing health systems, and improve the overall quality of patient care.[10] Public reporting is viewed as a necessary building block in the pursuit of value-based healthcare, but there remain significant challenges to the accurate collection and reporting of information on the cost, quality, and value of healthcare. These challenges include accurate collection of data, appropriate risk adjustment for patient comorbidities, adequate sample size, validity, reliability, and clinical relevance.[11]

Public reporting would ideally be the public dissemination of statistically valid, reliable, and useful information[1, 17] of performance data that can be used by consumers, providers, purchasers, health plans, and policymakers.[7] A number of metrics, including process measures, volume measures, outcome measures, structural measures, and patient experience, have been used to measure and report healthcare physician and hospital performance.

The American Association of Orthopaedic Surgeons (AAOS) supports public reporting as a means to empower patients and increase transparency and accountability of providers. It is critical that the measures reported be reliable, actionable, meaningful, and appropriately risk adjusted.

Development of Public Reporting Programs

Performance profiling did not figure prominently in U.S. health care policy until 1986, when the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services, or CMS) began to publicly report hospital specific mortality rates.[16] More recently, efforts have been made to use administrative billing data to create public reporting programs. Most notably, CMS developed a large public reporting program known as Hospital Compare (http://www.hospitalcompare.hhs.gov), measuring and reporting process measures of high-quality care for acute myocardial infarction, heart failure, pneumonia, and general surgery.[16]

CMS, through its Physician Quality Reporting System (PQRS), and hospital reporting of the Surgical Care Improvement Project (SCIP) measures, has also expanded its quality reporting and public reporting initiatives. To date, these are primarily measures of process (such as a patient receiving a treatment within the right time). Several of these CMS initiatives have specific financial incentives for participation and penalties for non-participation.[15] Other organizations such as the National Committee for Quality Assurance (NCQA), Healthgrades, Inc., Leapfrog, and Blue Cross Blue Shield use public reporting as a window into health outcomes.

The AAOS believes that systems for measuring and reporting quality in health care should continue to evolve and expand. The current generation of quality measures, which primarily rely on process measures and administrative data, have not yet been proven to accurately correlate with improved functional outcomes, which are the primary outcomes of interest to patients who undergo orthopaedic procedures. The AAOS strongly supports development of patient centered outcome measures and patient centered outcomes reporting with a goal of increasing public awareness of the relative risks, benefits, and costs associated with operative and non-operative care of musculoskeletal conditions. The AAOS also believes public reports of provider performance should be thoroughly vetted for accuracy and have a reliable and rapid mechanism for challenging and removing inaccurate information from provider profiles.

Effects of Public Reporting on Quality Improvement and Physician Performance

The effect of public reporting on health care outcomes is a subject of much debate. While public reporting can improve accountability and transparency, there is some risk that publication of complication rates will cause physicians to avoid taking on more difficult patients (e.g. "cherry-picking") in an attempt to decrease their risks of complications and thereby improve their quality ranking and achieve "target rates" for health care interventions. This may result in decreased access to care for certain vulnerable populations of patients who are at higher risk for peri-operative morbidity.

In the past, public reporting and risk adjustment have been largely based on administrative or claims data. Administrative data are routinely collected, relatively inexpensive to analyze, and allow for easy identification of geographical and ethnic subgroups with particular access problems.[1] However, they do not address the nuances of comorbidities, severity, conditions that were present on admission, complications, patient satisfaction, patient education, and provide inadequate risk adjustment. Clinical data is accurate and comprehensive, but it is very expensive and often difficult to obtain as there are variations in how hospitals and physicians document and collect data. With the substantial differences in the cost of obtaining various types of clinical data, enhancement of administrative data sets appear to be both practical and desirable.[14] It is important to collect and publicly report meaningful information; however, there is a need for harmonization between administrative and clinical data because both have pluses and minuses. Administrative data is accessible, but is a blunt tool. Harvesting clinical data gives more accurate information, but places a significant work burden on physicians.

As physicians, we recognize there can be vast differences between groups of patients with the same diagnoses. Diabetes can be mild, controlled, brittle, or uncontrolled. The variations are difficult to measure and have significant implications on surgical decision making. Other conditions, such as a history of previous fracture in a patient undergoing knee replacement can make the surgery markedly more complicated, yet are difficult to accurately convey to public reporting systems. Further, there is growing evidence that patients' socioeconomic status has a profound influence on outcomes.[5]

The AAOS reinforces the need for balance in implementing public reporting systems between the increasingly urgent need to improve the quality and efficiency of care and the importance of developing clinically valid and appropriately risk-adjustment performance measures that will ensure ongoing access for patients who are at higher risk of complications and poor outcomes. The AAOS supports ongoing research into performance measure development and proper risk adjustment of all publically reported outcome measures. Risk adjustment for age, sex, comorbidities, disease severity, and socioeconomic status allows measures to be believable and comparable across providers and delivery systems.

Summary

Public reporting of provider performance is rapidly expanding. The AAOS supports the judicious use of public reporting that is clinically relevant, timely, valid, reliable, appropriately risk adjusted, and actionable, and that minimizes the burden of data collection on patient, physicians, and hospitals. In order to achieve these goals, the AAOS believes it is essential for physicians and public reporting agencies to work collaboratively to:

- Develop clinically valid and appropriately risk-adjusted performance measures in order to ensure ongoing access for patients who are at higher risk of complications and poor outcomes
- Continue research into performance measure development and proper risk adjustment of all publicly reported outcome measures
- Create comparable measures that take into account age, sex, comorbidities, disease severity and socioeconomic status
- Fully vet all public information to ensure it is accurate, clinically relevant, timely, valid, reliable and actionable by the public and care providers

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Position Statement 1183

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Position Statement

Shared Physician-Patient Responsibilities

This Position Statement was developed as an educational tool based on the consensus opinion of the authors. It is not a product of a systematic review process. Readers are encouraged to consider the information presented and reach their own conclusions.

In furtherance of its mission to champion the interests of all patients and advance the highest quality musculoskeletal health, the AAOS believes that appropriately shared physician-patient responsibility in medical care is an essential ingredient for a successful outcome and patient satisfaction.

Introduction

Successful medical care requires active collaboration between the patient (and family as appropriate) and the physician.[1] An informed and engaged patient is key to a successful outcome and patient satisfaction. The patient physician partnership is central to this and is based upon mutual respect, honesty and trust.[2] It "does not imply that both partners have identical responsibilities or equal power. While physicians have the responsibility to provide health care services to patients to the best of their ability, patients have the responsibility to communicate openly, to participate in decisions about the diagnostic and treatment recommendations, and to comply with the agreed-upon treatment program."[1,3]

The Benefits, Patient Autonomy and Safeguards

1. A physician places the patient's safety and wellbeing above all other considerations, keeps the patient informed about her/his condition and treatment, and advocates for the patient's best interests resolving any conflicts of interest in favor of the patient.[4,5,6]

2. Through years of education and training, the orthopaedic surgeon acquires extensive knowledge and demanding technical and professional skills, and then maintains competency through lifelong learning in the field that is constantly being advanced, all in order to most effectively serve the patients.[7,8,9]

3. "Like patients' rights, patients' responsibilities are derived from the principle of autonomy" which "holds that an individual's physical, emotional and psychological integrity should be respected and upheld."[1]

4. Each party is mutually dependent on the other for the effective discharge of its responsibility in order for the patient to realize the above benefits and safeguards (1 and 2 above).

Informed, Shared Decision Making

1. "When obtaining informed consent for treatment, the orthopaedic surgeon is obligated to present to the patient or to the person responsible for the patient, in understandable terms, pertinent medical facts and recommendations consistent with good medical practice. Such information should include alternative modes of treatment, the objectives, risks and possible complications of such treatment, and the complications and consequences of no treatment."[10,11] Discussion should include what the patient may expect in the course of treatment and in the outcome. A similar approach should be followed in planning tests, consultation or referrals.

2. Each patient is unique in culture, value system, decision making and response to treatment. Alternatives and choices are available for many orthopaedic conditions. The patient autonomy "principle also recognizes the human capacity to self-govern and choose a course of action from among different alternative options. Autonomous, competent patients assert some control over the decisions which direct their health care." The orthopaedic surgeon should engage in informed shared decision making with the patient using the patient's values and respect the patient's decision even if it is in disagreement with the physician's recommendation.[12,13]

3. "The goal of shared decision making is a well-informed patient acting on well-considered preferences."[13]

Decision making: Patient's Rights and Responsibilities

1. For the patient, with the "exercise of self-governance and free choice comes a number of responsibilities."[1]

2. The patient should provide complete and truthful information, express any concerns, request information or clarification in the discussion, and engage actively in understanding and decision making.[1,14]

3. The patient should ask the necessary questions to be well informed in the details and choices and what to expect in the course of treatment and outcome as well as what is expected of her/him in the treatment plan. Patients who actively participate in medical interviews influence physicians to adopt a more patient-centered style of communication.[15]

4. After reaching a mutually agreed evaluation or treatment plan the patient should cooperate and carry out her/his role in faithful and timely fashion.[1,16,17] The patient must communicate regarding completion of tests/consultations etc., difficulties encountered, if any, and any desire to reconsider the agreed upon plan.[14]

5. The patient has an inherent right to not follow the recommended test, consultation or treatment.[18] The patient should communicate this decision to the physician for a mutually productive relationship.[1]

Patient Compliance: Physician Role and Patient Autonomy

1. In recommending tests, consultations and treatments etc., the physician should engage in informed, shared decision making.

2. The physician should arrange for or instruct the patient on how to arrange for the test/consultation and for any return visit to see the physician and regarding timelines and any urgency.

3. The physician should interpret the test/consultation results and, as appropriate, engage the patient in informed, shared decision making for further evaluation/treatment.

4. The physician should have a system to act on the results of tests and consultations. However, it is not the duty of the physician to remind patients of or ensure patient compliance with recommended return visits, tests, consultations or treatments.[16] Physician attempts to ensure compliance would create undue pressure on the patient beyond informed, shared decision making and may thus compromise patient autonomy by involuntarily substituting the physician's values for the patient's.[14]

5. In a case where the physician determines that patient non-compliance materially interferes with the physician's ability to provide appropriate care, the physician would have the option of terminating the patient-physician relationship following appropriate legal and ethical standards and procedures that facilitate future continued care of the patient by another physician.[19,20,21]

The AAOS believes that the orthopaedic surgeon should inform the patient of the medical condition and treatment, respect the patient's autonomy and values, and encourage the patient to actively engage in her/his treatment and in shared decision making. The AAOS also believes that for successful treatment and patient satisfaction the patient must exercise her/his rights of being informed and autonomy to make choices by being engaged, asking the necessary questions and assuming responsibility for carrying out his/her part in following through with agreed upon recommendations.

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Position Statement 1182

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Information Statement

Use of Structured Communication Tools to Improve Surgical Patient Safety

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Communication in surgical settings is the process by which important clinical and non-clinical information is sent and received among surgical patients, their families, members of surgical teams, departments and organizations necessary to provide optimal surgical care.[1]

Communication between surgeons and their patients is the critical factor in safety (accurate/timely diagnosis), quality (patient-centered care, shared decision making) and value. Surgeons' communication "styles" are critical in patients' perceptions of their treatment as reflected in CAHPS scores[2] as well as their willingness to adhere to recommended treatments. Surgeons' communication style, when abrupt or disrespectful, inhibits open communication and impairs competent teamwork.

Communication is both verbal and nonverbal; surgeons must be "mindful" that their nonverbal communication (posture, facial expression, vocal tone) is concordant with their words. For true patient centered care and shared decision making, surgeons must be willing to demonstrate empathy (recognizing and acknowledging patient's emotions) as well as adequately discussing patient concerns.[3]

Effective, structured communication is the lifeline of the surgical team's performance and is a crucial component in optimizing surgical patients' outcomes. For communication to be effective, the shared information must be accurate, complete, clear, brief, timely and verifiable/validated.[1] Communication in medicine and surgery is the key to the accurate "shared mental models" that define effective, safe surgical teams.

An analysis of Sentinel Event categories from The Joint Commission - unintended retention of a foreign body, wrong-patient, wrong-site or procedure surgery, operative/postoperative complications, delays in treatments- from 2010 through 2014 found that the most common root causes were communication, leadership, and human factors (staffing issues, fatigue, training, etc.).[4]

The American Academy of Orthopaedic Surgeons (AAOS) believes that regular use of structured communication systems, tools and techniques by surgeons and surgical teams is essential for safe surgical care.

The Agency for Healthcare Research and Quality has developed TeamSTEPPS (Strategies and Tools to Enhance Performance and Patient Safety) to increase surgical team competencies and improve surgical safety.[1] TeamSTEPPS is based on the aviation industry's crew resource management program and identifies four key skills - leadership, communication, situation monitoring, and mutual support – needed to improve team performance, knowledge and attitudes.

Structured information exchange tools and techniques from TeamSTEPPS have demonstrated value with a reduction of errors and improved surgical outcomes. These tools are incorporated into the "Safe Surgery Checklist".[5] Although recent literature casts some doubt on the efficacy of the checklist,[6] even more recent studies suggest that incomplete or inconsistent checklist usage may reduce efficacy.[7]

These tools and techniques should be used in all surgical settings and include:

- Surgical Team '**Brief**' – focused team discussion prior to surgery to assign roles, establish expectations and climate, and anticipate outcomes and likely contingencies

- Surgical Team '**Huddle**' – ad hoc team discussion to re-establish situation awareness, reinforce surgical plan, assess or adjust the surgical plan

- Surgical '**Time-out**' – focused, structured team confirmation of critical intended surgical plan, including identification of the patient, planned surgical site and procedure; and if appropriate, planned implant and spine level

- Surgical Team '**De-Brief**' – review of team performance following an episode of care designed to improve next/future episodes of care

- '**SBAR**' - **S**ituation-**B**ackground-**A**ssessment-**R**ecommendation – a technique used to relay critical patient-condition information requiring immediate attention and treatment recommendation
    - Situation—Brief and to-the-point explanation of what is happening with the patient
    - Background—Clinical background pertinent to the current situation
    - Assessment—Clinical impression of the patient
    - Recommendation—Suggestions of what action is to be taken

- '**Call-Out**' –surgical team member empowered to communicate important and timely information

- '**Check-Back**'or '**Read-Back**' – a closed-loop team information verification process – receiver and sender verifying message understood – confirmed by individuals or team

- **Hand-Off'** – team members transferring patients accurately across transitions of care, including questions for clarification and confirmation while transferring authority and responsibility. Lack of clarity about responsibility for care and decision-making is a major contributor to medical error. The Joint Commission National Patient Safety Goals require facilities to have a standardized approach to hand-offs, including the opportunity to ask and respond to questions.

    - 'I-PASS the BATON' – a structured communication tool to enhance exchange of information during transitions of care

        - **I**ntroduction – personal introduction and role
        - **P**atient information – name, age, sex, location
        - **A**ssessment – chief complaint, vital signs, symptoms, diagnosis
        - **S**ituation – current condition, code status, recent changes and response to treatments
        - **S**afety Concerns –critical labs, allergies, socio-economic factors
        - **B**ackground – comorbidities, current medications, family history
        - **A**ctions – required actions and rationale
        - **T**iming – urgency and prioritization of actions
        - **O**wnership – responsible team members and family
        - **N**ext – plan, anticipated changes, contingencies

    Other validated 'Hand-Off' tools include:

    - **ANTIC**ipate (**A**dministrative data, **N**ew clinical information, **T**asks to be performed, **I**llness severity and **C**ontingency plans for changes)
    - ****IPASS** (**I**llness severity, **P**atient summary, **A**ction list for the new team, **S**ituation awareness contingency plans and **S**ynthesis and 'read-back' of the information)[8]
    - **SHARQ** (**S**ituation, **H**istory, **A**ssessment, **R**ecommendations/Result and **Q**uestions).

All these communication tools, when understood and used regularly by the surgical team, allow team members to collaborate, mutually support each other, and share a 'mental model' of care that improves both the safety and quality of the care provided.

The AAOS believes that effective surgical team communication and behaviors require surgeon leadership supported by surgical team education and training. Surgical team communication is an important learned, non-technical surgical skill that is essential for optimized surgical team performance in all surgical settings and helps provide safe surgical care.

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Information 1046

For additional information, contact the Public Relations Department at 847-384-4036.

AAOS American Academy of Orthopaedic Surgeons
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EDUCATION

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

Continuing Medical Education

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

What are the standards of continuing medical education to which orthopaedic surgeons should subscribe?

Background

Every orthopaedic surgeon has an ethical and professional obligation to stay abreast of the developing knowledge in the musculoskeletal sciences. The contract that exists between surgeon and patient, and between the profession and society, requires the acceptance of this obligation. The rate of growth of scientific knowledge and clinical experience in our specialty places an extraordinary responsibility on each orthopaedic surgeon to maintain his or her knowledge base.

The American Academy of Orthopaedic Surgeons believes that a lifelong commitment to continuing medical education is essential for orthopaedic surgeons. This commitment is necessary if orthopaedic surgeons, as professionals, are to fulfill their obligation to provide high quality health care. The choice of educational methods or experience is the responsibility of individual orthopaedic surgeons. The Academy places no specific requirements on its Fellows in terms of areas or types of instruction, minimum number of hours of education during a particular time period, or preferred providers of educational programs. However, there are specific requirements from the American Board of Orthopaedic Surgery related to the Maintenance of Certification (MOC) program. In addition, some states and jurisdictions have specific requirements for licensure. The AAOS does expect practicing orthopaedic surgeons to fulfill the requirements of the MOC program and to meet the requirements for licensure in their state, including the necessary CME hours in culturally competent care where appropriate.

The AAOS believes the goal of CME should be improved patient safety and practice improvement. Methods by which CME may achieve these goals include improved physician performance and competency leading to better outcomes. To achieve these goals ethically, CME must be independent of commercial interests. Furthermore, CME activities need to follow the guidelines of the Accreditation Council for Continuing Medical Education (ACCME), the U.S.

Food and Drug Administration (FDA), and the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG).

The AAOS has created mandatory Standards of Professionalism on Orthopaedic Surgeon – Industry Relationships. The AAOS expects all AAOS members to follow those standards as they pertain to CME activities and courses.

Recommendations

The Academy believes that each orthopaedic surgeon must develop his or her own approach to knowledge maintenance in an organized and explicit manner to assure that it addresses content in all areas in which care is provided. To do this requires:

- A self-generated practice audit to determine the types of conditions, procedures, complications, etc. which comprise one's practice experience, and to assess the results of treatment provided.

- A periodic self-assessment evaluation which addresses the knowledge and content areas relevant to the individual's practice.

- The development of a personal education plan, to include study in identified areas of deficiency, and the subsequent scheduling of educational activities to fulfill the goals developed in the education plan.

As an organization devoted to the education of orthopaedic surgeons and others, the Academy makes available current authoritative and evaluative educational materials to enhance orthopaedic knowledge and to facilitate the provision of improved patient care. The Academy's commitment to education is enduring and substantive. Every orthopaedist should make a similar commitment to excellence.

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References:

Applicable provisions of *AAOS Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships*

Mandatory Standard 12: An orthopaedic surgeon shall accept no financial support from industry to attend industry-related social functions where there is no educational element.

Mandatory Standard 13: An orthopaedic surgeon who is attending a CME event shall accept no industry financial support for attendance at a CME event. Residents and orthopaedists-in-training may accept an industry grant to attend a CME event if they are selected by their training institution or CME sponsor and the payment is made by the training program or CME sponsor. *Bona fide* faculty members at a CME event may accept industry-supported reasonable honoraria, travel expenses, lodging and meals from the conference sponsors.

Mandatory Standard 14: An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept only tuition, travel and modest hospitality, including meals and receptions; the time and focus of the event must be for education or training.

Mandatory Standard 15: An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept no financial support for meals, hospitality, travel, or other expenses for his or her guests or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Applicable provisions of *AAOS Standards of Professionalism on Providing Musculoskeletal Services to Patients*

> Mandatory Standard 9: An orthopaedic surgeon shall commit to life-long medical and scientific learning.
>
> Mandatory Standard 10: An orthopaedic surgeon shall provide only those services and use only those techniques for which he or she is qualified by personal education, training, or experience.

Applicable provision of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

> "VI. The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."

Applicable provision of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

> "IV. A. The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill, and should make available to patients and colleagues the benefits of his or her professional attainments. Each orthopaedic surgeon should participate in relevant continuing medical educational activities."

Other references:

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics.* Chicago, IL, 2014-1015 edition.

> Opinion 8.061 – Gifts to Physicians from Industry. Issued June 2014 based on the report *Amendment to E-8.061, Gifts to Physicians from Industry,* adopted November 2013.

American Medical Association, *Principles of Medical Ethics*, Article V. "A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated." Adopted June 1957; revised 1980 and 2001.

Opinion 1203

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

HEALTH CARE REFORM

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Position Statement

Medicaid and State Children's Health Insurance Program (SCHIP)

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

With the introduction of Medicare in 1965, the United States virtually eliminated the number of uninsured individuals over the age of 65. While the AAOS believes the Medicare program is in need of significant reform, it also recognizes that Medicare is likely to play a significant role in ensuring that the older and disabled population in the United States maintains health insurance. Further, with the 2015 Medicare Access and CHIP Reauthorization Act, State Children's Health Insurance Program (SCHIP) will continue to play an important role. With introduction of subsidized insurance plans and Medicaid expansion under the Accountable Care Act, the current estimate of the number of Americans without insurance is 25.5 million adults and 3.4 million children.[1] To the extent that these programs provide health care coverage for individuals in the United States, the AAOS believes that there are principles that should apply to these programs and that structural changes that outlined below must be made in order for patients to have access to high quality, safe, cost effective medical care in general and specifically to be able to obtain necessary musculoskeletal care.

Universal Coverage

The American Association of Orthopaedic Surgeons (AAOS) believes that in any consideration of changes to the health care financing and delivery system in the United States, the well-being of the patient singularly must be the highest priority.

The AAOS strongly supports providing individuals consistent access to patient centered, timely, unencumbered, affordable, and appropriate health care and universal coverage while maintaining that physicians are an integral component to providing the highest quality treatment.

The AAOS supports prioritizing the coverage of children under the SCHIP program.

Universal Access

The ability of eligible beneficiaries to access care via Medicaid and SCHIP programs is negatively impacted by the number of physicians that choose not to participate in those programs. Current Medicaid and SCHIP payment rates often fail to cover the cost of providing care, limiting the number of these patients who can be treated in a solvent practice. Regrettably, with these insurance programs, coverage does not always equate to access

The AAOS supports equity in Medicaid and SCHIP payments with Medicare payment rates; this should be structured as a payment floor under which states could not reimburse providers at levels lower than payment under Medicare. Medicare payment to physicians must be structured so that it remains economically viable for physicians to participate.[2]

This type of provision would assist in stopping the well-documented flight of physicians from the Medicaid program and help relieve the financial burden placed on the increasingly few providers (physicians and hospitals) that treat Medicaid and CHIP patients.

In addition, the AAOS believes that patients must be guaranteed their choice of physicians in Medicaid and SCHIP managed care plans.

Accountability

The American Association of Orthopaedic Surgeons believes that physicians, hospitals, patients, and the federal and state governments have a shared responsibility to ensure stability of Medicaid and CHIPS programs. By participating in these programs, physicians can help to secure access to needed health care services for the most vulnerable populations.

Benefit Package

The AAOS believes that rules governing Medicaid and SCHIP provide a "defined benefit" rather than a "defined contribution."

Continuity of Care

The ability of orthopaedic surgeons to provide the care that Medicaid and SCHIP beneficiaries need is dependent on those individuals being covered by those programs for a reasonable and foreseeable period of time. The manner in which many Medicaid and CHIP programs are structured can leave patients falling in and out of eligibility several times throughout the course of a single year. This unpredictability can have a serious effect on patient health and the ability of orthopaedic surgeons to carry out a course of treatment.

The AAOS believes that all Medicaid and SCHIP programs should be required to provide "continuous coverage" defined as coverage for one year from the date of eligibility.

In addition, in several states there is a 3-month uninsured period in order to be eligible for SCHIP coverage. The AAOS is concerned that this could serve as a significant barrier to care.

The AAOS believes that uninsured waiting periods should be eliminated as an eligibility requirement from SCHIP programs.

Cost Containment

The Medicaid program is severely underfinanced. This must be addressed at both the federal and state level to ensure that beneficiaries are able to access care, and this can be partially accomplished by bringing a focus in the Medicaid program back to medical services.

The AAOS believes that the primary cost containment focus in the Medicaid program should focus on the increased spending associated with long-term care services and not on reducing coverage or eligibility associated with Medicaid acute care benefits.

In addition, the inequity between the state/federal matching rates for SCHIP and Medicaid programs should be addressed. When CHIP was first created in 1997 and states needed an incentive to dedicate the resources to the creation of the program, a higher matching rate was reasonable. However, CHIP programs currently exist in every state.

The AAOS believes that the rationale for a higher state/federal matching rate for CHIP no longer exists, and the inequity between Medicaid and CHIP matching rates should be eliminated.

External Reforms

The AAOS believes that SCHIP beneficiaries should be allowed to purchase private insurance with their SCHIP dollars if there are minimum benefit guarantees; and that there is a SCHIP option available for those that do not chose private programs.

Infrastructure and Administration

The AAOS supports Medicaid and CHIP provisions that make it clear that physician should not be required to act as immigration agents by restricting care only to citizens and that they should be appropriately reimbursed for all medically necessary care that they deliver to all individuals.

Quality of Care

The AAOS believes that educational standards are important and that patients are best served when their care is overseen by physicians. We support a requirement that Medicaid and CHIP programs and care be directed by physicians.

The AAOS supports the creation of Medicaid and SCHIP initiatives that:

- ***Establish state reporting requirements on access information indicators;***
- ***Create a national database that would collect utilization information;***
- ***Include access measures as an indicator of quality;***
- ***Align Medicaid and SCHIP quality initiatives with Medicare quality initiatives; and***
- ***Create an advisory council similar to the Medicare Payment Advisory Commission (MedPAC) that would focus on SCHIP and Medicaid quality and access issues.***

References:

1. Pear, R: Number of Uninsured Has Declined by 15 Million Since 2013, Administration Says. *NY Times,* August 12, 2015.
2. Skaggs, DL: Access to Orthopedic Care for Children with Medicaid Versus Private Insurance, *JPO* 2006 May-June 26(3) 400-4.

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For additional information, contact the Public Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Position Statement

Principles of Health Care Reform and Specialty Care

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Overview

Health care spending in the United States has increased from $75 billion (7% of Gross Domestic Product [GDP]) in 1970 to more than $2 trillion (16% of GDP). This is twice the rate of spending of other developed countries, yet for a number of health outcomes Americans trail behind other nations. In spite of this level of spending, tens of millions of Americans lack insurance. Uncompensated and under-compensated care are persistent problems and remain among the greatest concerns to physicians who consistently put patients first in our health care system.

Among the factors leading to increased and inefficient health care spending are:

- High administrative costs
- A broken liability system
- An increase prevalence of chronic disease
- A shift in cost from the uninsured to the insured
- A predominant third-party payer system
- Unnecessary patient care

The existing employer-based system of health care coverage poses unique problems with regard to portability and the availability of health care for all. The current health insurance and health care delivery system is not sustainable. The demand is infinite and must be checked through a variety of means (i.e., a defined basic benefit package and structured co-payments determined by an individual's ability to pay). Any health care reform must address these systemic problems.

Americans receive their health care coverage through a variety of public and private arrangements. As the Congress considers various initiatives to reform the existing health care system, it is important that policy makers avoid creating new unaffordable programs that repeat past mistakes. Existing government programs – Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) – face long-term sustainability challenges due to trillions of dollars in unfunded liabilities. The financial restraints of these programs lead policy makers to erect bureaucratic impediments to care and reimbursement rates that make it difficult for providers to cover the cost of care.

The demands upon physicians, providers, and payers is infinite but can be contained through incremental changes to the system. For example, altering the allocation of federal and state resources or increasing the portability and availability of health care coverage can increase the number of individuals with health insurance. However, significant changes to the system are necessary to overcome current challenges and to ensure tens of millions of uninsured Americans without health insurance are able to enroll in affordable insurance that provides access to high quality medical care, including unencumbered access to needed specialty care.

The American Association of Orthopaedic Surgeons (AAOS) believes that in any consideration of changes to the health care financing and delivery system in the United States, the well-being of the patient must be the highest priority. The AAOS strongly supports the reform measures and principles set forth in this statement as providing individuals consistent access to patient centered, timely, unencumbered, affordable and appropriate health care and universal coverage while maintaining physicians as an integral component to providing the highest quality treatment.

The AAOS believes that as policymakers consider health care reforms they should:

- ***Make certain that patients are empowered to control and decide how their own health care dollars are spent***
- ***Ensure unencumbered access to specialty care***
- ***Make health care coverage more affordable***
- ***Improve the quality of care***
- ***Extend both coverage and access for the uninsured and under-insured***
- ***Avoid establishing new unsustainable programs***

While the AAOS believes that expanding health care coverage and access should be implemented through a public-private partnership, we strongly oppose proposals that create a federal health care authority or move health care further in the direction of a single-payer health care system.

Improving Access to Medical Care and Affordable Coverage

While states can provide innovative initiatives to expand health care access and coverage, the federal government must take the lead to ensure access to health care for all. The individual has the right to select the health care coverage of his or her choice and the responsibility to enroll in coverage. At a minimum, individuals and families must have access to basic health care coverage, including catastrophic coverage, in order to avert not only personal financial ruin but also to avoid shifting the costs of their care to those who are insured.

The AAOS believes that everyone within the United States should receive access to health care coverage – including specialty care - without financial barriers or undue burdens placed on the patient or physician. The responsibility of financing appropriate health care services must be a shared public-private cooperative effort that advances a patient-centered model for choosing affordable health care options.

Benefit options for individually purchased coverage must align with employer-based coverage options. While individuals and families must have access to ample financing for the sole purchase of catastrophic health care coverage, a newly reformed health care system should allow individuals or employers to assert social responsibility when purchasing additional services or insurance as part of a structured or packaged offer. Open market approaches similar to the Federal Employees Health Benefits Program (FEHBP) can ensure portability and continuity of care.

The Uninsured

A large and growing number of uninsured and under-insured Americans constitute a major burden on the health care system. Among the factors contributing to the growing ranks of the uninsured are:

- Lack of access to affordable coverage
- Loss of employment and consequently insurance coverage
- Individuals simply choosing to go without insurance coverage
- Failure of eligible individuals to enroll in Medicaid or SCHIP
- Immigration status

In some states the cost of providing medical care to non-citizens has placed the local health care delivery system at risk.

As policy makers consider legislation to expand health care coverage access, it is important that they bear in mind that the demographics of the 45 million uninsured people in the United States vary widely. Among the facts to consider:

- 12 million are currently eligible to enroll in an existing government program
- 12 million are uninsured for less than one year
- 18 million earn more than $50,000/year- including 5 million single adults earning more than $80,000/year
- 10 million uninsured are non-citizens
- 25 million are childless adults
- 14 million have incomes below 200% of the poverty level ($41,000/family of four) but are not eligible for a public program
- 70% are in families where there is at least one full-time worker

Physicians and health care facilities provide care to all, but they alone cannot and should not bear the burden and assume the costs of providing care to those who are uninsured or who have inadequate coverage. The problem of the uninsured demands a federal solution that recognizes that there are a variety of factors contributing to the lack of insurance and that a multifaceted approach is needed to expand both health care coverage and access for the uninsured.

Existing Health Care Programs

The federal government established, in conjunction with the states, both Medicaid and SCHIP to provide lower income Americans and children with health care coverage. Yet, millions of Americans that are eligible for these programs are not currently enrolled and are among the ranks of the uninsured. Additionally, some policy makers have proposed expanding Medicare enrollment eligibility to those under age 65 to help address the problem of the uninsured.

The AAOS believes that the states should make it a priority to enroll in Medicaid and SCHIP those who are currently eligible but who are not already enrolled. In addition, states should make it a priority to provide physician payments in Medicaid and SCHIP at parity to Medicare rates. Given Medicare's short-term and long-term insolvency, the AAOS is opposed to proposals that would expand eligibility for enrollment in Medicare.
(See AAOS Position Statement 1174 on Medicaid and State Children's Health Insurance Program (SCHIP) and Position Statement 1175 on Principles of Medicare Reform for a more thorough discussion.)

Financing Issues in Health Care

Health care financing reform should engage all stakeholders:

- Patients
- Insurers
- Hospitals
- Health care professionals
- Employers
- Governments
-

Consistent with the concept of patient-centered care, the patient's basic medical needs must be the first priority in any payment/financing system.

The AAOS supports efforts to ensure that physicians are adequately compensated for providing medical care to the uninsured. In the absence of universal coverage and adequate reimbursement, the AAOS supports providing physicians with tax initiatives to defray the cost of uncompensated care. The AAOS believes it should be a priority for the federal and state governments to provide adequate long-term sustainable funding for existing government health care programs to ensure that these programs are sustainable and enrollees retain access to medical care. The AAOS opposes the use of any tax on health care professionals to finance changes to the health care delivery system. The AAOS also believes that administrative expenses in private health care plans should more closely mirror those of public programs, ensuring that a more significant portion of spending is dedicated to medical care.

Empowering Individuals to Access Affordable Coverage

Individuals should be able to choose the type of health care coverage that they want and that best fits their needs. Today's tax laws disadvantage individuals and those employed by small businesses. Employees who do not have access to health insurance through their employers are not able to benefit from the more than $125 billion in tax subsidies the federal government provides through employer-provided health benefits.

The AAOS supports a number of tax initiatives as components of health care reform that will level the playing field and help make health care coverage more affordable. The health care marketplace, which has suffered from the lack of competition, should be strengthened by adoption of policies that restore equity and enhance market competition. Among the reforms that policy makers should consider are:

- ***Tax credits, vouchers and tax deductions for individuals and families for the purchase health care coverage, including refundable tax credits and vouchers to assist lower-income Americans in purchasing health insurance***
- ***Additional subsidies for those with higher than average health care costs will help keep overall premium costs lower***
- ***Extension of tax-favorable Health Savings Accounts (HSAs)***
- ***Open markets that permit individuals and families to purchase health insurance across state lines***

Patient Empowerment and Personal Responsibilities

Individuals have a personal responsibility and a right to choose and select the health care plan and benefits of their choice. There are significant existing federal and state structural barriers that make the current marketplace less competitive and impede the current market resulting in limited choices and higher costs. Individual choices should be expanded beyond those developed by government bureaucracies or employers. Individuals who make healthy life-style choices should be able to benefit from those choices by paying lower premiums or receiving other financial rewards.

The AAOS strongly believes that patient empowerment and individual responsibility are necessary components of health care reform. Healthy choices should be recognized and preventive care should be promoted.

Health Care Marketplace, Administrative, and Structural Reforms

Ensuring Continuity of Care and Coverage

Employer-based health care poses unique problems, since large group purchasers are favored under the current health care insurance delivery system. The current system must be changed so that individuals no longer lose their access to health insurance because they lose or change jobs. By linking health care to the individual rather than the place of employment, individuals will have more choices. Those who wish to remain in an employer-based insurance plan should be permitted to retain that choice.

The AAOS believes that all health care options should be linked to the patient (not the employer). All insurance coverage options must be portable and affordable to provide optimal access and continuity of quality health care.

Finding Alternatives to the "Medical Home" Concept

Formal legislative proposals and suggestions that outline the importance of a physician coordinator or overseer of all patient care may be appropriate in some circumstances when it is in the best interest of the patient. However, policy makers must avoid the creation of new health care delivery models that impede, delay, withhold, or deny access to necessary specialty care. As the practice of medicine has become increasingly specialized, it is important to ensure that patients have access to timely, high quality, affordable specialty care, including the physician of their choice.

The AAOS supports timely, unencumbered, affordable access to appropriate specialty care as it is paramount to achieving quality health care for all patients. Patients must have access to the right treatment, by the right health care professional, at the right time. For some conditions, the most efficient and effective entry point into the health care system is through appropriate specialty access. More specifically, the AAOS believes that access to essential musculoskeletal services must not be impeded – including access to preventive care, pediatric musculoskeletal care, trauma treatment, emergency room care, and disaster preparedness. In certain situations, an orthopaedic practice could serve as the medical home.

Ensuring Patient Access to Specialty Services

While the initial passage of laws banning physician self-referral was well-intentioned, unintended consequences have placed continuity of patient care at risk. Responsible physician ownership of services and facilities has been demonstrated to improve patient safety, access, quality, efficiency and the delivery of cost-effective services, and it should not be prohibited.

Integral to patient care, continuity of care, patient convenience, patient choice, and patient safety is the provision of in-office ancillary services as well as ensuring that patients continue to have the choice of receiving care in a specialty hospital setting. It is in this patient-centered context that physician owned services and physician self-referral must be examined and permitted. The AAOS believes that the well-being of the informed patient is paramount in any health care policy.

Guaranteeing Individuals the Right to Enroll in a Health Care Plan of Their Choice

Individuals should to be able to choose a health plan with the benefits, providers, and patient cost-sharing arrangements of their choice. It is important that policy makers ensure that health plans cover basic health care benefits, including access to specialty care, while avoiding the temptation to impose excessive mandates that drive up the cost of medical insurance. This will ensure that basic health care needs are met, while giving health plan enrollees greater choices and flexibility.

Some policy makers have proposed the creation of governmental agencies (i.e., a National Health Board) that may limit, directly or indirectly, the types of benefits and services that could be offered in private health care plans. Such objectionable limits could include:

- An outright ban on plans that provide additional services
- Excluding plans that provide such services from participating in health care exchanges
- Denying these plans the same tax treatment as the plans that meet the government's mandates

The AAOS believes that it is appropriate to establish a minimum benefit package for private health care plans - at the federal and/or state level – but would caution policy makers to ensure that such mandated benefits are basic to ensure that essential health care needs are met, including access to specialty care, and that the cost of a basic health care plan remains affordable.

The AAOS believes strongly that patients should be empowered to control and decide how their health care dollars are spent and thus opposes the establishment or use of a federal regulatory body that would impose on private insurance plans any limitations on benefits and services offered or provided under such plans. Furthermore, the AAOS opposes any policy that would impose such limitations directly or indirectly through tax policy, regulations, regulatory bodies, or other means.

Emergency Room Care

Throughout the nation, patients are finding it difficult and sometimes impossible to obtain emergency care services in a timely manner because of:

- An ever-increasing patient population seeking emergency care
- A decrease in the number of hospital emergency departments
- A shortage of specialists available to take call
- Shortages of other hospital resources to support emergency care services
- An increasing volume of uninsured or underinsured patients
- A challenging liability environment

The AAOS believes that all stakeholders must work together to address emergency department coverage issues. A solution to this problem must include solutions to the unfunded mandate of EMTALA in order to ensure the success of any health care reform proposal. Participation by a patient in a particular health care plan should not restrict access or reimbursement to any and all emergency rooms and necessary providers. (Please see the AAOS Position Statement 1172 on Emergency Orthopaedic Care for more information.)

ERISA Reform

While states are able to pass strong patient protection legislation, the laws apply to few health plans since most insurers are exempt from state law by the Employee Retirement Income Security Act (ERISA). ERISA currently impedes the ability of states to improve the quality of medical care provided in their states.

The AAOS believes that ERISA should be amended to allow states to enact laws that affect all insurance plans when consistent with federal policy objectives of improving patient care.

Antitrust Relief Must Level the Playing Field

Under existing law, insurance companies, health plans, and hospitals have an unfair advantage in setting prices. The playing field should be leveled, and physicians should be allowed to share information and negotiate collectively with health plans. The current "third party messenger" model has proven an ineffective, cumbersome and costly attempt at addressing this situation. Moreover, the McCarran-Ferguson Act effectively exempts insurance companies from the very antitrust laws which physicians are required to follow.

The AAOS believes that the antitrust laws should be changed to allow physicians to collectively negotiate with health plans and insurers without the necessity of joining a labor union. The McCarran-Ferguson Act needs to be amended to change the anti-competitive practices of insurance companies and establish equity among health plans, insurers, and physicians.

Providing Efficient Care and Coverage (Cost/Efficiency vs. Quality/Value/Safety)

In recent years, several initiatives have been introduced to either control costs or improve quality:

- "Pay-for-performance"
- Gainsharing
- Value-based purchasing

Patients deserve the highest quality treatment and any cost-control mechanism must be implemented in a manner that is in the best interest of the patient. Patient safety and the well-being of the patient must always be the first consideration.

The AAOS supports efforts by stakeholders to control costs to attain a workable, affordable, and sustainable health care system that is based upon high levels of evidence-based medical research. However, any cost-containment mechanism must be balanced with quality in order to provide patients with the most valuable care.

Medical Liability Reform

Patients who suffer an injury because of the negligence of a health care professional should be justly compensated. Yet the high cost of defensive medicine in today's punitive and adversarial environment has a detrimental effect on affordability and access for all patients.

The AAOS strongly maintains that meaningful medical liability reform at the federal level and/or constitutionally sustainable state medical liability reforms are a necessary component of any viable health care reform proposal. Absent liability reforms, billions of dollars will continue to be wasted on defensive medicine, driving up the cost of health insurance. (See the AAOS Position Statement 1118 on Professional Liability: Tort Reform for greater detail.)

Reduction of Administrative Costs in the Health Care System

In the United States, the proportion of total health care expenditures diverted to administrative expenses is far too high. In some plans, administrative costs can be as high as 50 percent. In addition, individual physician practices continue to face undue regulatory and administrative burdens.

The AAOS believes that the burden of administrative cost of private health care plans should mirror the costs in the public sector and that the great preponderance of all health care expenditures should be spent on actual delivery of health care.

Health Information Technology (HIT)

Efficient administrative systems, including comprehensive HIT infrastructure and implementation, are essential to maximize funding available for actual patient care. Adoption of HIT may reduce costly inefficiencies by enhancing physicians' access to medical tests and reducing the need for duplicative services. It is critical that interoperable standards be established in a timely manner to ensure more rapid adoption of HIT. Given the failure of Medicare reimbursements to keep pace with inflation, the growing cost of providing care to the uninsured and underinsured and other financial pressures on physician practices, it is unreasonable to expect the physician community to bear the cost of HIT implementation.

The AAOS believes that health information technology has the potential to enhance the quality of care for musculoskeletal patients. Adequate funding for interoperable HIT must be allocated by the federal government, subsidized by cooperation-based state grants, or supported by other private insurer financing mechanisms. The cost of implementing HIT must not be borne by the physician community. AAOS also believes that HIT must accord with preset standards as long as the highest quality patient care is delivered.

Professionalism

Recently, there has been a focus of attention in the public arena on conflicts-of-interest with industry, direct-to-consumer marketing, and advertising by physicians. The AAOS has addressed these issues in other documents which can be accessed at www.aaos.org/profcomp.

AAOS maintains among the highest standards of professionalism and has developed a *Code of Ethics and Professionalism for Orthopaedic Surgeons.* The best interest of the patient is the cornerstone of physician conduct and should direct all physician activities.

Workforce and Graduate Medical Education

The federal government, through Medicare, is the largest financial supporter of graduate medical education. The private sector contributes to graduate medical education by paying the higher charges of teaching hospitals. In recent years, however, the private sector has become less willing to pay these higher charges. If the Medicare program involves more managed care and/or privatizes, support for graduate medical education may decrease significantly, threatening quality and access to care for all Americans. In addition, Medicare's current funding formulas for graduate medical education have led to increases in the number of trainees in fields which may not be consistent with the nation's current and anticipated needs.

The AAOS believes that all payers should contribute equitably to graduate medical education funding. A mechanism should be developed to ensure that the number of residency positions funded through Medicare and other payers actually reflects the nation's health care needs. More specifically, policy makers must ensure that additional resources and residency slots are provided for orthopaedic surgeons and other specialists involved in providing trauma care. In addition, loan repayment programs should be expanded and loan deferment programs should be extended to the full length of residency.

Medical Care and Non-Citizens

Over the past several years, policy makers have debated the impact of immigration on the Medicaid and SCHIP programs. One focal point of the immigration debate has been citizenship documentation. In this and other areas, federal policy makers should delegate immigration issues to those who are best-situated to deal with those issues: immigration and homeland security experts.

The AAOS believes that physicians should not be required to act as immigration agents by restricting care only to citizens and that they should be appropriately reimbursed for all medically necessary care that they deliver to all individuals.

Conclusion

As we approach the great public debate on health care reform in America, the AAOS believes preservation of the autonomy of the physician-patient relationship to be of the highest priority. Though challenges and opportunities are many, each part of the solution must ensure patient-directed physician empowerment to deliver individual value, overall quality and systemic efficiency. All Americans are or will become patients. Implementing a reformed public-private partnership health care system that reflects the principles addressed will serve this and future generations with meaningful universal coverage and real access for all.

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For additional information, contact the Public Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Position Statement

Principles of Medicare Reform and Access to Specialty Care

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Medicare is the Federal health insurance program for the nation's elderly. Part A of the program covers inpatient hospital services, inpatient care in skilled nursing facilities after hospitalization, home healthcare, and hospice care among other services. Part B of the program covers physician services, outpatient hospital care, diagnostic services, durable medical equipment, and ambulance services among other services. Part D provides coverage for prescription drugs.

Medicare continues to face both short-term and long-term fiscal challenges that impact both patients and providers. Factors causing the growth in Medicare costs include but are not limited to:

- a 50 percent increase in the number of beneficiaries since the start of the program;
- an increase in the life span of beneficiaries which increases the number of years that they use medical services;
- advances in medical science and technology that prolong and enhance the quality of life but may be costly;
- the addition of the part D prescription drug benefit;
- the increased prevalence of obese patients which is a significant factor in the growth of Medicare expenses associated with treating chronic diseases among seniors;[1]
- increased beneficiary demand for services due to many factors - first dollar coverage among Medigap plans, direct-to-consumer advertising, lower beneficiary cost-sharing requirements, the growth of chronic disease among seniors and a medical liability system that encourages inefficiencies including the practice of defensive medicine; and fraud and abuse.

The American Academy of Orthopaedic Surgeons (AA0S) believes that the Medicare program needs fundamental reform because of its impending financial crisis which threatens patient access to medical care. To achieve Medicare solvency, the AAOS believes that policymakers must undertake a thorough review of all program components, including health care delivery and benefits, payments to providers, and initiatives to contain costs.

I. Health Care Delivery and Benefits

Quality Initiatives

The AAOS has been engaged in quality initiatives to improve patient care and outcomes for several decades and maintains this as a top priority. The AAOS is actively involved in developing the quality measures for orthopaedic care. Through the Orthopaedic Quality Institute, the AAOS works with government and private stakeholders to define needs and expectations of quality measures. Using this input, orthopaedic surgeons and staff are producing metrics which better define and measure value in musculoskeletal health. These measures are anticipated to improve systems such as the Physician Quality Reporting System (PQRS) and evaluations by private payers.

To further enhance quality care in orthopaedics, the AAOS produces Evidence-Based Clinical Practice Guidelines, Systematic Reviews, Appropriate Use Criteria (AUC), and Clinical Performance Measures for the most common musculoskeletal conditions (e.g., management of hip fractures, anterior cruciate ligament injuries, etc.) These evidence-based quality products help drive care algorithms, supplement patient-clinician discussions and decision-making, improve efficiency, and add value to specialty care delivery and can be viewed via the OrthoGuidelines webpage (www.orthoguidelines.org). The AAOS believes it is important that orthopaedic surgeons have direct input into the development of quality standards and supports quality initiatives that demonstrate effectiveness in improving patient outcomes. It is important that quality and reporting initiatives are regularly re-evaluated to ensure that they continue to improve the quality of orthopaedic care.

II. Ensuring Patient Access to Specialty Services

While the initial passage of laws banning physician self-referral was well-intentioned, unintended consequences have placed continuity of patient care at risk. Responsible physician ownership of services and facilities has been demonstrated to improve patient safety, access, quality, efficiency and the delivery of cost-effective services and should not be prohibited.[2]

Integral to patient care, continuity of care, patient convenience, patient choice, and patient safety is the provision of in-office ancillary services as well as ensuring that patients continue to have the choice of receiving care in a specialty hospital setting. It is in this patient-centered context that physician owned services and physician self-referral must be examined and permitted. The AAOS believes that the well-being of the informed patient is paramount in any health care policy.

Guaranteeing Individuals the Right to Enroll in a Health Care Plan of Their Choice

Individuals should to be able to choose a health plan with the benefits, providers, and patient cost-sharing arrangements of their choice. It is important that policy makers ensure that health plans cover basic health care benefits, including access to specialty care, while avoiding the temptation to impose excessive mandates that drive up the cost of medical insurance. This will ensure that basic health care needs are met, while giving health plan enrollees greater choices and flexibility.

Some policy makers have proposed the creation of governmental agencies (i.e., a National Health Board) that may limit, directly or indirectly, the types of benefits and services that could be offered in private health care plans. Such objectionable limits could include:

- An outright ban on plans that provide additional services
- Excluding plans that provide such services from participating in health care exchanges
- Denying these plans the same tax treatment as the plans that meet the government's mandates

The AAOS believes that it is appropriate to establish a minimum benefit package for private health care plans - at the federal and/or state level - but would caution policy makers to ensure that such mandated benefits are basic to ensure that essential health care needs are met, including access to specialty care, and that the cost of a basic health care plan remains affordable.

The AAOS believes strongly that patients should be empowered to control and decide how their health care dollars are spent and thus opposes the establishment or use of a federal regulatory body that would impose on private insurance plans any limitations on benefits and services offered or provided under such plans. Furthermore, the AAOS opposes any policy that would impose such limitations directly or indirectly through tax policy, regulations, regulatory bodies, or other means.

III. Cost Containment and Solvency

In order to ensure the long-term sustainability of Medicare, policy makers must adopt new models of providing health care coverage for seniors and ensure that seniors have access to a wider range of choices that best meet their health care needs.

Enhanced Beneficiary Cost-Sharing

The way in which Medicare is financed will also have serious consequences for patient access to quality care. Currently, Medicare Part A is supported by a 2.9 percent payroll tax on annual wages. Part B is financed through general revenues. Both parts are also funded through contributions from beneficiaries in the form of premiums (Part B), deductibles (Parts A and B) and co-payments (Parts A and B).

When Medicare began in 1966, Part B premiums paid 50 percent of program costs and Part B deductibles paid about 45 percent of the average charges for medical services. Today, Part B premiums pay only 25 percent of program costs and deductibles pay less than 5 percent of average charges. In 2003 Congress acted to increase Part B premiums for higher income seniors, in 2015, individual seniors with income under 85,000 paid $104.90 per month while individuals with incomes between $85,000 and $107,000 paid $146.90 and those with income between 107,000 and $160,000 paid $209.80. The highest premium was paid by individuals with incomes over $214,000 who paid $335.70 per month.

While this step was taken to decrease the subsidy to higher income seniors, other Medicare cost-sharing provisions have failed to keep pace with inflation. Consumer prices increased more than seven-fold between 1966 and 2008, but the Part B deductible has only increased from $50 to $147 per year as of 2015 - less than one third the increase in the consumer price index. Yet growth in Part B costs averaged 9.6% annually from 2002 through 2007. Furthermore, there is no premium for Medicare Part A, and there is no co-payment required for home health, clinical laboratory, pathology or skilled nursing facility services.

As contributions from beneficiaries have decreased in relation to costs, the financial burden of Medicare has been covered, increasingly, by working people under age 65 through higher general revenue taxes. This financial burden on younger working people is compounded by the fact that the number of workers is shrinking in proportion to the growing number of Medicare beneficiaries. Moreover, many young workers are not able to afford their own health insurance yet must contribute their taxes to Medicare coverage for seniors.

The AAOS believes that most beneficiaries should assume greater cost-sharing responsibility for the Medicare program, with protections for low income beneficiaries, in order to preserve their access to quality care. There are a broad range of options that policy makers could consider for enhancing beneficiary cost-sharing, among them are:

- Indexing Part B premiums to gradually raise the overall beneficiary proportion of Part B expenditures above 25%.
- Further reducing the subsidy for Medicare Part B premiums for high-income beneficiaries so that they assume a greater share of program costs.
- Increasing Part B deductibles and indexing them to better reflect the cost growth in the program.
- Replacing the complex set of cost-sharing arrangements with a single standardized coinsurance rate.
- Restructuring Part A financing, including establishing a Part A premium.
- Establishing a co-payment for home health, clinical laboratory, pathology and skilled nursing facility services.
- Raising the eligibility age for Medicare beneficiaries to be consistent with the Social Security program.
- Eliminating the costs generated by the increased utilization of services due to Medigap first dollar coverage.
- Enacting liability reform to lower the costs of liability insurance and the practice of defensive medicine.
- Establishing a basic benefit package for every Medicare patient; the projected cost of which, is within the budget and would be expected to cover all basic health care needs. Then allowing supplemental insurance to be offered by private companies to enhance an individual's coverage if they choose.

IV. Access to Specialty Care

As Alternative Payment Models (APMs) evolve under Medicare payment reform, creative solutions are expanding for patient care. Some of these models such as such as Accountable Care Organizations or Patient Centered Medical Homes offer ways for primary care and specialists to work together. However, the models can also place primary care providers in a gate-keeper role, limiting the access of their patients to direct specialty care.

The AAOS encourages and supports Alternative Payment Models (APMs) which allow creative delivery and reimbursement models. However, access to specialty care must remain an option for our patients.

V. Payments to Providers

Limiting access to services and cuts in payments to providers have been the traditional means by which government policy makers have sought to curb Medicare spending. For more than two decades Medicare payments to physicians and hospitals have been cut by tens of billions of dollars. Payment to physicians, which account for 23% of Medicare expenditures, have been cut due to a number of factors including reimbursement freezes, fee reductions, limits on balance billing, implementation of the "resource-based" payment system, and a flawed Medicare reimbursement formula. If allowed to continue this will result in significant access and quality problems as providers struggle to deliver care below their actual costs.

Balance Billing

The ban on balance billing under the Medicare program has further impacted the ability of providers to cover the widening gap between inadequate Medicare payments and the cost of providing services. The AAOS believes that, in the absence of reimbursement that reflects the full costs of care for Medicare beneficiaries, the federal rules prohibiting balance billing should be repealed and insurers should be forbidden from including balance billing prohibitions in physician-insurer contracts.

The AAOS believes that repeal of the ban on balance billing will help providers close the gap between inadequate Medicare payments and the cost of providing services to seniors.

References:

Footnotes

1. Finkelstein EA, Fiebelkorn IC, Wang G: National medical spending attributable to overweight and obesity: How much, and who's paying. *Health Affairs,* May 13, 2003.
2. Medicare's Financial Condition: Beyond Actuarial Balance. Issue Brief American Academy of Actuaries, March 2008.

General

3. Physical Therapy: Self-Referring Providers Generally Referred More Beneficiaries but Fewer Services per Beneficiary. GAO-14-270: Published: Apr 30, 2014. Publicly Released: Jun 2, 2014 http://www.gao.gov/products/GAO-14-270
   Status of the Social Security and Medicare Programs, 2008 Annual Report.

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For additional information, contact the Public Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

INDUSTRY RELATIONSHIPS

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Standards of Professionalism

Orthopaedic Surgeon-Industry Relationships

Adopted April 18, 2007; Amended April 23, 2012

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

The primary focus of the orthopaedic profession is care of the patient. As part of their lifetime commitment to patients, orthopaedic surgeons must maintain specialized knowledge and skills through participation in continuing medical education (CME) programs, seminars, and professional meetings. Often, these professional functions are sponsored by the manufacturers of medical devices, biologics, drugs and other items use in the care of the patient (Product). These businesses play an important role in the support of CME events and the development of new technologies. This collaborative effort ensures that patients have the best outcomes through the invention and testing of new technology, research and evaluation of existing technology, and continued education of orthopaedic surgeons.

Cooperative relationships between orthopaedic surgeons and industry benefit patients. Orthopaedic surgeons are best qualified to provide innovative ideas and feedback, conduct research trials, serve on scientific advisory boards, and serve as faculty to teach the use of new technology. Orthopaedic surgeons, in an effort to improve patient care, rely on industry to bring their creative ideas to fruition. A collaborative relationship between orthopaedic surgeons and industry is necessary to improve patient care, but must be carefully scrutinized to avoid pitfalls of improper inducements, whether real or perceived.

A potential conflict of interest exists when professional judgment concerning the well being of the patient has a reasonable chance of being influenced by other interests of the physician. Disclosure of a conflict of interest is required in communications to patients, the public and colleagues. Orthopaedic surgeons, like all physicians, have an ethical obligation to present themselves and the services they provide to patients in a clear and accurate manner.

When faced with a potential conflict of interest that cannot be resolved, an orthopaedic surgeon should consult with colleagues or an institutional ethics committee to determine whether there is an actual or potential conflict of interest and how to address it.

These Standards of Professionalism draw from the aspirational *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* that appears in bold italics. The statements that follow the **aspirational** *Code* establish the **mandatory** minimum standards of acceptable conduct for orthopaedic surgeons when engaged in relationships with industry. Violations of these minimum standards may serve as grounds for a formal complaint to and action by the AAOS as outlined in the AAOS Bylaws Article VIII.

The Standards of Professionalism on Orthopaedic Surgeon - Industry Relationships apply to all AAOS Fellows and Members. Only an AAOS Fellow or Member may file complaints of an alleged violation of these Standards of Professionalism regarding another AAOS Fellow or Member.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I.A.:
The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns.

Mandatory Standards:

1. An orthopaedic surgeon shall, while caring for and treating a patient, regard his or her responsibility to the patient as paramount.

2. An orthopaedic surgeon shall prescribe products or other treatments primarily on the basis of medical considerations and patient needs, regardless of any direct or indirect interests in or benefit from industry.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, II. C.:
The orthopaedic surgeon should obey all laws, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that a physician or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly-constituted peer review authority or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct.

Mandatory Standard:

3. An orthopaedic surgeon shall comply with all relevant federal and state conflict of interest and fraud and abuse laws.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.A.:
The practice of medicine inherently presents potential conflicts of interest. When a conflict of interest arises, it must be resolved in the best interest of the patient. The orthopaedic surgeon should exercise all reasonable alternatives to ensure that the most appropriate care is provided to the patient. If the conflict of interest cannot be resolved, the orthopaedic surgeon should notify the patient of his or her intention to withdraw from the relationship.

Mandatory Standards:

4. An orthopaedic surgeon shall, when treating a patient, resolve conflicts of interest in accordance with the best interest of the patient, respecting a patient's autonomy to make health care decisions.

5. An orthopaedic surgeon shall notify the patient of his or her intention to withdraw from the patient-physician relationship, in a manner consistent with state law, if a conflict of interest cannot be resolved in the best interest of the patient.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.C.:
When an orthopaedic surgeon receives anything of significant value from industry, a potential conflict exists which should be disclosed to the patient. When an orthopaedic surgeon receives inventor royalties from industry, the orthopaedic surgeon should disclose this fact to the patient if such royalties relate to the patient's treatment. It is unethical for an orthopaedic surgeon to receive compensation of any kind from industry for using a particular product. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable.

Mandatory Standards:

6. An orthopaedic surgeon shall decline subsidies or other financial support from industry, except that an orthopaedic surgeon may accept non-monetary items which benefit patients or serve an educational function and which have a fair market value of less than $100.

7. An orthopaedic surgeon who has influence in selecting a particular product or service for an entity shall disclose any relationship with industry to colleagues, the institution and other affected entities.

8. An orthopaedic surgeon shall disclose to the patient any financial arrangements with industry that relate to the patient's treatment, including the receipt of inventor royalties, stock options or paid consulting arrangements with industry.

9. An orthopaedic surgeon shall accept no direct financial inducements from industry for utilizing a particular product or for switching from one manufacturer's product to another.

10. An orthopaedic surgeon shall enter into consulting agreements with industry only when such arrangements are established in advance and in writing to include evidence:

    - That there is an actual need for the service;
    - That the provision of the service will be verified;
    - That the compensation for services provided by the orthopaedic surgeon is based on fair market value;
    - That the compensation for services provided by the orthopaedic surgeon is not based on the volume or value of business he or she generates; and
    - That reimbursement for reasonable and actual expenses, such as modest meals, travel and lodging, incurred by the orthopaedic surgeon is based on appropriate need and accurate documentation.

11. An orthopaedic surgeon shall consult at only those meetings that are conducted in clinical, educational, or conference settings conducive to the effective exchange of basic science and/or clinical information.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, IV.A.:
The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill and should make available to patients and colleagues the benefits of his or her professional attainments. Each orthopaedic surgeon should participate in continuing medical educational activities.

Mandatory Standards:

12. An orthopaedic surgeon shall accept no financial support from industry to attend industry-related social functions where there is no educational element.

13. An orthopaedic surgeon who is attending a CME event shall accept no industry financial support for attendance at a CME event. Residents and orthopaedists-in-training may accept an industry grant to attend a CME event if they are selected by their training institution or CME sponsor and the payment is made by the training program or CME sponsor. The industry entity funding the grant shall have no influence in the selection of the individual recipients. *Bona fide* faculty members at a CME event may accept industry-supported reasonable honoraria, travel expenses, lodging and modest meals from the conference sponsors.

14. An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept only tuition, travel and modest hospitality, including meals and receptions. The time and focus of the event must be for the presentation of *bona fide* scientific, educational or business information or training.

15. An orthopaedic surgeon, when attending an industry-sponsored non-CME educational event, shall accept no financial support for meals, hospitality, travel, or other expenses for his or her guests or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III.D.:
An orthopaedic surgeon reporting on clinical research or experience with a given procedure or product must disclose any financial interest in that procedure or product if the orthopaedic surgeon or any institution with which that orthopaedic surgeon is connected has received anything of value from its inventor or manufacturer.

Mandatory Standards:

16. An orthopaedic surgeon, when reporting on clinical research or experience with a given procedure or product, shall disclose any financial interest in that procedure or product if he or she or any institution with which he or she is connected has received anything of value from its inventor, manufacturer, or distributor.

17. An orthopaedic surgeon who is an investigator shall make his or her best efforts to ensure at the completion of an industry-sponsored study that relevant research results are reported and reported truthfully and honestly with no bias or influence from funding sources, regardless of positive or negative findings.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

The Orthopaedic Surgeon's Relationship with Industry

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

Under what, if any, circumstances is it appropriate for orthopaedic surgeons to accept gifts or other financial support from industry, including pharmaceutical, biomaterial or device manufacturers, laboratories, durable medical equipment suppliers, or other vendors?

Discussion

Orthopaedic surgeons have long recognized the importance of continuing medical education in maintaining their professional skills. Both orthopaedists-in-training and practicing orthopaedic surgeons attend and participate in numerous continuing medical educational programs and seminars. Industry, including pharmaceutical, biomaterial and device manufacturers, has generously supported many of these beneficial programs.

For several years, there has been concern about industry making gifts to physicians. Some of these gifts that reflect customary marketing practices of industry may not be consistent with basic principles of medical ethics. The line is sometimes blurred between industry's providing funds for an actual continuing medical educational experience and providing funds to promote the use or purchase of a particular pharmaceutical, biomaterial or piece of orthopaedic equipment.

Generally, the American Academy of Orthopaedic Surgeons (AAOS) believes that it is acceptable for industry to provide financial and other support to orthopaedic surgeons if such support has significant educational value and has the purpose of improving patient care. All dealings between orthopaedic surgeons and industry should benefit the patient, be able to withstand public scrutiny, and comply with applicable laws.

Guidelines

To avoid acceptance of inappropriate gifts or other financial support, the AAOS recommends that orthopaedic surgeons observe the following guidelines:

1. **Benefit to Patients.**

   The patient's best interest is paramount. Therefore, it is of utmost importance that any gift or other financial support accepted by an orthopaedic surgeon should primarily entail a benefit to his or her patient. A gift of any kind from industry should in no way influence the orthopaedic surgeon in determining the most appropriate treatment for his or her patient. It is only by strict adherence to this principle that the orthopaedic surgeon may maintain the patient's trust.

2. **Gifts With Conditions Attached.**

   Orthopaedic surgeons should not accept gifts or other financial support with conditions attached. No gifts (including goods, meals, accommodations, meeting registrations, travel, etc. to attend educational meetings or learning new skills under the tutelage of an expert) should be accepted with the explicit or implicit requirement or expectation that the orthopaedic surgeon use the products or services provided by that particular industry.

3. **Social Functions.**

   Although the AAOS is generally opposed to orthopaedics surgeons participating in social events sponsored by industry, social functions supported by industry in combination with significant continuing medical education events are sometimes acceptable. However, social functions supported by industry (e.g. dinners, tickets to sporting events or theater, golf outings, etc.) where there is no educational element should not be offered to nor accepted by orthopaedic surgeons

4. **Cash Gifts.**

   Cash gifts from industry to orthopaedic surgeons must not be offered nor accepted.

5. **Continuing Medical Education (CME) Events.**

   a. Subsidies

      Subsidies by industry to underwrite the costs of educational events where CME credits are provided can contribute to the improvement of patient care and are acceptable. A corporate subsidy received by the conference's sponsor is appropriate and acceptable so long as such support is publicly acknowledged and the location, curriculum, faculty, and educational methods of the conference or meeting are determined solely by the organization sponsoring the educational course, not industry. Direct industry reimbursement for an orthopaedic surgeon to attend an educational event is not appropriate.

   b. Faculty Expenses and Honoraria for Continuing Medical Education Activities. It is appropriate for faculty at educational events where CME credits are provided to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging and meal expenses from the conference's sponsor.

6. **Other Educational Events.**

Educational events sponsored by industry may be of educational value and improve patient care. Orthopaedic surgeons are responsible for ensuring that decisions to accept subsidies from industry are in the best interest of their patients. The AAOS believes a potential conflict of interest exists when an orthopaedic surgeon receives such subsidies.

Special circumstances may arise in which orthopaedic surgeons may be required to learn new surgical techniques demonstrated by an expert in the field in his/her institution or to review new implants or other devices on-site. On-site education provides the added benefit of educating a larger number of attendees per session and offers important insights into the function of ancillary staff and institutional protocols. In these circumstances, reimbursement for expenses may be appropriate.

Reimbursement should be limited to expenses that are strictly necessary and able to withstand public scrutiny. In no case should honoraria or reimbursement for time off to attend the course be offered or accepted. In addition, attending the course and learning the technique must not require or imply that the orthopaedic surgeon must subsequently use that technique.

7. **Scholarships for Orthopaedic Surgeons-in-Training.**

Scholarships or other special funds from industry to permit orthopaedic surgeons-in-training to attend continuing medical education conferences are appropriate as long as the selection of students, residents or fellows who will receive the funds is made by the orthopaedist-in-training's program director.

8. **Consultant Expenses and Honoraria.**

It is appropriate for consultants to industry who provide genuine services as faculty in educational events to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token or sham consulting or advisory arrangements, such as passive attendance at a meeting or being named to an advisory board for simply discussing a device without making any real contribution to product development or analysis, cannot be used to justify compensating orthopaedic surgeons for their time, travel, lodging or other out-of-pocket expenses.

9. **Other Consulting Arrangements.**

A symbiotic relationship exists between orthopaedic surgeons and industry. Orthopaedic surgeons are best qualified to provide innovative ideas and feedback, conduct research trials, serve on scientific advisory boards, and to serve as faculty to teach the use of new technology. Orthopaedic surgeons, in an effort to improve patient care, rely on industry to bring their creative ideas to fruition. A collaborative relationship between orthopaedic surgeons and industry is necessary to improve patient care, but must be carefully scrutinized to avoid pitfalls of improper inducements, whether real or perceived.

It is appropriate for consultants to industry who provide genuine services to receive reasonable compensation for their services. Such arrangements should be established in advance and in writing to include evidence of the following: 1.) Documentation of an actual need for the service. 2.) Proof that the service was provided; and 3.) Evidence that physician reimbursement for consulting services does not exceed fair market value.

Examples of inappropriate relationships between orthopaedic surgeons and industry include, but are not limited to: 1.) Receiving a consultant fee for simply attending a meeting; 2.) Receiving remuneration (i.e., anything of value, such as monetary payment, stock or other ownership interests, or investment opportunity) for using a particular implant; and 3.) Receiving consultant fees or other financial inducement for switching om one manufacturer's product to another.

10. Disclosure

a. Fellows of the AAOS are encouraged to participate in the AAOS disclosure program. The AAOS Orthopaedic Disclosure Program serves as a central repository of all relevant commercial relationships for orthopaedic surgeons and other healthcare professionals involved in organizational governance, clinical practice guidelines (CPG) and appropriate use criteria (AUC) development, CME faculty or authors of enduring materials, editors-in-chief and editorial boards.

b. Physicians should be honest, transparent and complete in reporting relationships with industry to their patients as appropriate, and to colleagues and learners in presentations and publications.

c. Government regulations regarding reporting continually evolve. It behooves practitioners to stay current of prevailing rules and practices. For example, Physician Payment Sunshine Act, calls for increased reporting by drug and device manufacturers of certain gifts and payments they make to physicians. It is in the best interest of the physician to be aware of what is being reported under his/ her name as related to the Sunshine Act and other similar channels.

Proper collaborative relationships between orthopaedic surgeons and industry are critical for advancement and improvement in patient care. Such relationships allow industry to fulfill their goals to improve patient care and increase patient access to new products and also are beneficial to orthopaedic surgeons and their patients. Orthopaedic surgeons must continually strive to improve patient care through the development of new advances and methodology.

Orthopaedic surgeons should never lose sight of their primary ethical responsibility to provide competent, compassionate patient care, maintaining professionalism and objectivity at all times.

References:

Applicable provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

"I. **Physician-Patient Relationship**. The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns. The orthopaedic surgeon should be dedicated to providing competent medical service with compassion and respect."

Applicable provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

"I. A. The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns."

"III. C. When an orthopaedic surgeon receives anything of significant value from industry, a potential conflict exists which should be disclosed to the patient. When an orthopaedic surgeon receives inventor royalties from industry, the orthopaedic surgeon should disclose this fact to the patient if such royalties relate to the patient's treatment. It is unethical for an orthopaedic surgeon to receive compensation of any kind from industry for using a particular device or medication. Reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable."

"IV. A. The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill and should make available to patients and colleagues the benefits of his or her professional attainments. Each orthopaedic surgeon should participate in continuing medical educational activities."

Other references:

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics.* Chicago, IL, 2014-1015 edition.

Opinion 8.061 – Gifts to Physicians from Industry. Issued June 2014 based on the report *Amendment to E-8.061, Gifts to Physicians from Industry,* adopted November 2013.

Australian Orthopaedic Association, "Orthopaedic Surgeons and Their Relationship with Industry," *Australian Orthopaedic Association Bulletin*, December 1997.

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Position Statement

Alignment of Physician and Facility Payment and Incentives

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The United States healthcare system continually faces numerous challenges. Current methods of physician reimbursement by government programs and private insurance have changed in recent years, but continue to offer little incentive to help control the cost of delivering care. Increasingly complex regulation, high patient cost responsibility, variation in practice patterns and eroding public confidence in the quality of healthcare delivery in the U.S. have become recognized as major threats to our healthcare system. Faced with these daunting challenges, alignment of physician and facility payment incentives has caught the interest of federal policymakers and many other stakeholders, who are searching for ways to stimulate savings and improve operational and financial performance. "Episode of care" bundled payment initiatives and gainsharing arrangements with physicians, when led by physicians, are common examples of ways to align facility and provider incentives.

The American Association of Orthopaedic Surgeons (AAOS) supports efforts of all stakeholders to develop and evaluate payment methodologies that will incentivize coordination of care among providers (including physicians and hospitals) and help reduce healthcare inflation. As the demand for musculoskeletal care increases with a more active society and an aging population, it is incumbent on orthopaedic surgeons to take a lead role in the development and deployment of such programs.

Currently, hospitals are paid under a Diagnosis Related Groups (DRG)-based prospective payment system which adjusts for severity and resource use in the discharge diagnosis. Physicians have traditionally been separately paid under a fee-for-service schedule without incentives to control volume or cost. The Centers for Medicare and Medicaid Services (CMS), along with multiple other stakeholders, believe that there are savings to be realized if the hospital and the physicians are paid and incentivized by the same methodology. With a single payment issued for the entire episode of care, interested parties hope to align the incentives of the facility and all involved providers, resulting in more efficient delivery of care and better compliance with standards and reporting requirements.

As traditionally defined, an "episode of care" bundled payment is a single payment covering all care, facilities, laboratories, implants, physician fees and all other health care professionals – for the entire episode of care provided to the patient. Episode of care payment programs may include a physician incentive or gainsharing component. Gainsharing refers to an arrangement between a physician and a hospital to share in the cost savings that result from specific actions to improve the efficiency of care delivery. Gainsharing programs may also be established with or without bundled payment programs.

Bundled, payment methodologies and gainsharing arrangements may carry unintended consequences. One possible consequence is "cherry picking," the deliberate avoidance of complex or risky patients. The patient must remain the focal point of any initiative; payment mechanisms must not create incentives to treat healthier patients and limit access for sicker patients. Additionally, because a bundled payment covers a specific time period defining the episode of care, a workable and reasonable re-admission policy would be an essential piece to such initiatives. The system should not create incentives for patient diversion when a discharged patient in need of re-admission is sent to a different facility or provider. Developing a coherent risk adjustment policy is the most essential method for preventing the practice of deselecting patients and addressing the readmission issues with this method of payment.

To prevent limiting patient access to care, the AAOS believes risk adjustment is an indispensable component of any successful episode of care or bundled payment initiative and policy. Risk adjustment is important because unpredictable and unavoidable outcomes can occur even in the presence of evidence-based practice. Episodes of care must be risk-adjusted for patient demographics, socio-economic status, co-morbidities, and severity of illness and procedure-specific characteristics that account for the differences that contribute to outcome and costs of treatment.

Protecting Patient Access to Quality Care

The AAOS embraces change that improves quality and lowers cost, but the patient must be the primary focus of all initiatives. Orthopaedic surgeons should continuously work to provide high-value musculoskeletal care reflecting the needs and desires of their patients. Orthopaedic surgeons should be empowered to provide appropriate, evidence-based care to patients while recognizing how their medical decisions affect costs, A facility's attempt to control costs and maintain clinical programs should not interfere with the surgeon's goal of providing the highest quality care and serving the patient's best interest. As part of a collaborative effort, orthopaedic surgeons should collaborate with hospitals and health care systems in the development of cost-containment strategies which protect patient safety, choice, and where quality of care is never compromised and the proper safeguards are in place.

Necessary Safeguards for Patient Centered Care:

- The patient must be the primary focus of all initiatives.
- The patient should be empowered to be a fully participating stakeholder in their healthcare process.
- The patient's access to quality care must be a priority The physician must be the primary advocate
- All stakeholders must disclose potential conflicts of interest when providing patient care.
- No stakeholders should be incentivized to limit care or provide unnecessary care.
- Patients must maintain access to a variety of necessary providers and facilities.

Protecting and Facilitating Provider Alignment

The AAOS believes safeguards must be in place to protect the practice of medicine and the financial interests of all parties. The AAOS believes patient access to quality care requires trust, collaboration, and alignment of all involved providers and systems. The incentives and influence should facilitate an environment in which all stakeholders can efficiently improve quality.

Necessary Safeguards to Ensure Provider Equity:

- The burden to affect cost savings must be on all providers and stakeholders.
- The process must be transparent so that all financial incentives and any revisions are known by all stakeholders.
- The initiative must incentivize all stakeholders to collaborate. An appropriate time scale should be allowed to foster this collaboration.
- All stakeholders must be represented when developing initiatives to align payment and incentives.
- The payment must be agreed upon prior to delivering care.
- All stakeholders must be represented when creating a method of distribution for payment.
- The compensation for work must be fair and reasonable for all providers.
- Payment must be risk adjusted for patient and procedure specific characteristics.
- Competition must be maintained in the health care system.
- A physician must retain the autonomy to provide care that addresses each patient's unique medical needs.

References:

1. National Health Expenditure Accounts (NHEA), by the Office of the Actuary, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services. See https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html.
2. National Coalition on Healthcare: The American Health Systems Big Problem: Cost. http://www.nchcbeta.org/wp-content/uploads/2012/09/The-American-Health-Systems-Big-Problem-Cost-2.pdf

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For additional information, contact the Public Relations Department at 847-384-4036.

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

MEDICAL EXPERT OPINION, TESTIMONY, AND PEER REVIEW

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Standards of Professionalism

Orthopaedic Expert Opinion and Testimony

Adopted April 18, 2005; Amended May 12, 2010 (effective for expert opinions offered on or after May 12, 2010 expert witness opinions rendered prior to May 12, 2010, are governed by the original Standards of Professionalism for Orthopaedic Expert Witness Testimony, adopted April 18, 2005)

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

Orthopaedic surgeons are frequently called upon to provide oral or written medical testimony or expert medical opinions in legal or administrative proceedings. It is in the public interest for orthopaedic testimony and medical opinions to be readily available, knowledgeable and objective. As a member of the orthopaedic profession, an orthopaedic surgeon must recognize a responsibility to provide testimony and expert medical opinions that are truthful, scientifically correct and appropriate for the context of the issues being considered. All Fellows and Members of the American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons ("AAOS") are required to accept this responsibility. For purposes of these SOPs, all Fellows and Members of the AAOS are considered to be "orthopaedic surgeons," regardless of whether they perform surgery. In recognition to this responsibility, the AAOS has adopted these Standards of Professionalism.

These Standards of Professionalism draw from the aspirational Code of Medical Ethics and Professionalism that appears in bold Italics. The statements that follow the aspirational Code establish the minimum standard of acceptable conduct for AAOS Fellows and Members. Violations of these minimum standards may serve as grounds for formal complaint to and action by the AAOS as outlined in the AAOS Bylaws Article VIII.

These Standards of Professionalism apply to all AAOS Fellows and Members who provide oral or written expert opinions, testimony and other services to attorneys, litigants, administrative agencies or the judiciary in the context of administrative, civil or criminal matters and include but are not limited to writing expert opinions, signing certificates or affidavits of merit, reviewing medical records, and providing sworn testimony. Only an AAOS Fellow or Member may file a grievance about alleged violation of these Standards of Professionalism against another AAOS Fellow or Member.

A. IMPARTIAL TESTIMONY

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, V. C.:
Orthopaedic surgeons are frequently called upon to provide expert medical opinions or testimony. In providing opinions, the orthopaedic surgeon should ensure that the opinion provided is non-partisan, scientifically correct, and clinically accurate.

Mandatory Standards:

1. An orthopaedic surgeon shall not knowingly provide oral or written medical testimony or expert medical opinions that are false.

2. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall provide these statements in a fair and impartial manner.

3. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall have knowledge and experience regarding the standard of care and shall evaluate the medical condition and care in light of generally accepted practice standards at the time, place and in the context of care delivered.

4. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall neither condemn performance that falls within generally accepted practice standards nor endorse or condone performance that falls outside these standards.

5. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall be prepared to explain the basis of his or her statements. If these statements vary from generally accepted practice standards, he or she shall indicate how and why they vary and whether they are supported by personal experience, specific clinical and/or scientific evidence.

6. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall seek and review all pertinent medical records and applicable legal documents, including relevant prior depositions, before rendering any statement or opinion on the medical or surgical management of the patient.

B. SUBJECT MATTER KNOWLEDGE

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, V. C.:
Orthopaedic surgeons are frequently called upon to provide expert medical opinions or testimony. In providing opinions, the orthopaedic surgeon should ensure that the opinion provided is non-partisan, scientifically correct, and clinically accurate.

Mandatory Standard:

7. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall provide statements only about subject matters in which he or she has relevant clinical experience and specific orthopaedic knowledge in the areas of medicine that are the subject of the proceeding.

C. QUALIFICATIONS

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, V. C.:
The orthopaedic surgeon should not offer opinions concerning matters about which the orthopaedic surgeon is not knowledgeable.

Mandatory Standards:

8. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall have a current, valid, and unrestricted license to practice medicine in one or more U.S. states or territories.

9. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall maintain a current certificate from the American Board of Orthopaedic Surgery (ABOS), the American Osteopathic Board of Orthopaedic Surgery (AOBOS), or the certifying body, if any, in the country in which the orthopaedic surgeon took his or her training.

10. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall be engaged in the active practice of orthopaedic surgery or demonstrate enough familiarity with present practices to warrant designation as an expert on the subject matter of the inquiry.

11. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall accurately represent his or her credentials, qualifications, experience or background.

D. COMPENSATION

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, V. C.:
It is unethical for an orthopaedic surgeon to accept compensation that is contingent upon the outcome of litigation.

Mandatory Standards:

12. An orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall not agree to or accept a fee that is contingent upon the outcome of the matter.

13. Compensation for an orthopaedic surgeon who provides oral or written medical testimony or expert medical opinions shall be reasonable and commensurate with expertise and the time and effort necessary to address the issues raised.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Information Statement

Orthopaedic Surgeon's Role in Medical Peer Review

This Information Statement has been developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Medical peer review is a process by which a professional review body considers whether a practitioner's clinical privileges or membership in a professional organization will be adversely affected by the physician's competence or professional conduct.[1] Peer review is also used as a risk management tool, with the primary goal of promoting high quality medical care and ensuring patient safety.[2]

The Health Care Quality Improvement Act of 1996 (HCQIA)[3] set standards for medical peer review activities. If the review process complies with HCQIA standards, the review body and its members and participants are generally shielded from liability in damages under most federal and state laws. Peer review information would be considered confidential and privileged and inadmissible in court.

The American Academy of Orthopaedic Surgeons (AAOS) believes that medical peer review is an important part of physician licensing and regulation, evaluation of clinical privileges, and physician performance improvement measures. AAOS strongly supports the peer review process as a beneficial means of improving the quality of medical care and ensuring patient safety.

Orthopaedic surgeons have an obligation to actively work towards improving patient safety by complying with federal and state laws and regulations, the requirements for maintaining clinical privileges, continuing education requirements, and any board imposed maintenance of certification. These responsibilities include voluntary service as a peer reviewer for state medical and licensing boards, hospitals and professional societies.

The Federation of State Medical Boards has recommended that state medical and licensing boards use qualified physicians to serve on peer review panels, adding that the "voluntary participation of licensees as reviewers" should be encouraged.[4]

In the musculoskeletal context, the AAOS encourages orthopaedic surgeons to participate in the peer review process. The Personal Conduct section of the AAOS *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*[5] provides:

II.C. The orthopaedic surgeon should obey all laws, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that a physician or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly-constituted peer review authority or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct.

II.E. Orthopaedic surgeons should promote their own physical and mental well-being by maintaining healthy lifestyles. They should be attuned to evolving mental or physical impairment, both in themselves and in their colleagues, and take or encourage necessary measures to ensure patient safety. These measures might include medical intervention, professional counseling, or, in situations where reasonable offers of assistance are declined, reporting the impairment to appropriate authorities.

More specifically, the Professional Relationships section of the code provides:

V.B. The professional conduct of the orthopaedic surgeon may be scrutinized by local professional associations, hospitals, managed care organizations, peer review committees, and state medical and/or licensing boards. These groups merit the participation and cooperation of orthopaedic surgeons.

Similarly, the Preamble of the AAOS Standards of Professionalism (SOPs) on Orthopaedic Expert Opinion and Testimony[6] outlines the obligation of orthopaedic surgeons to provide expert services in many formats. While acting as an expert in a peer review proceeding, an orthopaedic surgeon must provide truthful, scientifically correct and appropriate testimony consistent with the SOPs.

Orthopaedic surgeons are frequently called upon to provide oral or written medical testimony or expert medical opinions in legal or administrative proceedings. It is in the public interest for orthopaedic testimony and medical opinions to be readily available, knowledgeable and objective. As a member of the orthopaedic profession, an orthopaedic surgeon must recognize a responsibility to provide testimony and expert medical opinions that are truthful, scientifically correct and appropriate for the context of the issues being considered. All Fellows and Members of the American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons ("AAOS") are required to accept this responsibility.

These Standards of Professionalism apply to all AAOS Fellows and Members who provide oral or written expert opinions, testimony and other services to attorneys, litigants, administrative agencies or the judiciary in the context of administrative, civil or criminal matters and include but are not limited to writing expert opinions, signing certificates or affidavits of merit, reviewing medical records, and providing sworn testimony.

The AAOS encourages orthopaedic surgeons to actively participate in peer review programs, including those processes established by hospitals, state medical or licensing boards, insurance companies, and professional associations. When serving as expert reviewers, orthopaedic surgeons must adhere to the Mandatory Standards of the most current version of the SOPs on Orthopaedic Expert Opinion and Testimony and the SOPs on Professional Relationships.

The role of peer review in maintaining the quality of care and ensuring patient safety remains critically important. Orthopaedic surgeons serving in peer review capacities may find the process to be time consuming. While HCQIA and state laws generally provide protection from legal liability for such service, some orthopaedic surgeons may have concerns about potential legal or professional ramifications of such service. In general, however, regulation of the medical profession remains a function that is best performed by peers with familiarity in the medical issues raised. It is only by having qualified, fair and impartial reviewers can the actions of orthopaedic surgeons be appropriately evaluated.

The AAOS supports participation of orthopaedic surgeons in the peer review process, both as members of any oversight board and as peer reviewers. In order to achieve these goals, the AAOS believes it is important for orthopaedic surgeons to:

- ***Actively participate in the peer review process, including service on review boards and panels;***
- ***Maintain educational competency to ensure the application of the appropriate standard of care in the review of individual cases;***
- ***Educate themselves on the peer review processes within their practices, hospitals, state medical and licensing boards, insurance companies, and professional associations; and***
- ***When serving as a peer reviewer, comply with the AAOS Mandatory Standards of Professionalism on Orthopaedic Expert Opinion and Testimony and the Mandatory Standards of Professionalism on Professional Relationships.***

References:

1. Council on Ethical and Judicial Affairs: *Code of Medical Ethics,* Opinions 9.05 and 9.10. Chicago, IL, American Medical Association, ed. 2012-2013.
2. SJ Jayasankar: Medical Peer Review and Risk Management. AAOS Now, October 2008.
3. Health Care Quality Improvement Act of 1996, 42 USC §1101 et seq
4. MJ Martin: Report of the Special Committee on Evaluation of Quality of Care and Maintenance of Competence. *FSMB Journal* 1998; 85(1): 35-43.
5. American Academy of Orthopaedic Surgeons: *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*. Adopted 1988, revised 2011.
6. American Academy of Orthopaedic Surgeons: *Standards of Professionalism on Orthopaedic Expert Opinion and Testimony*. Adopted 2005, amended 2010.

Information Statement 1037

For additional information, contact the Public Relations Department at 847-384-4036.

AAOS American Academy of Orthopaedic Surgeons
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PRACTICE ISSUES

AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Opinion on Ethics and Professionalism

The Orthopaedic Surgeon in the Managed Care Setting

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

What ethical parameters exist for orthopaedic surgeons treating patients in a managed care setting?

Applicable provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

"I. A. The orthopaedic profession exists for the purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns."

"I. B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedist has an obligation to render care only for those conditions that he or she is competent to treat..."

"I. D. The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care. Both orthopaedic surgeons and patients may have contracts with managed care organizations, and these agreements may contain provisions which alter the method by which patients are discharged. If the enrollment of a physician or patient is discontinued in a managed care plan, the physician will have an ethical responsibility to assist the patient in obtaining follow-up care. In this instance, the orthopaedic surgeon will be responsible to provide medically necessary care for the patient until appropriate referrals can be arranged."

"II. C. ...Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that a physician or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly-constituted peer review organization or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct."

"VI. D. The orthopaedic surgeon may enter into a contractual relationship with a group, a prepaid practice plan, or a hospital. The orthopaedic surgeon has an obligation to serve as the patient's advocate and to ensure that the patient's welfare remains the paramount concern."

Other references

Principles of Medical Ethics and Professionalism in Orthopaedic Surgery, Article I, "The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns. The orthopaedic surgeon should be dedicated to providing competent medical service with compassion and respect."

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs,

Opinion 4.04	("Economic Incentives and Levels of Care") [Issued June 1986.]
Opinion 8.021	("Ethical Obligations of Medical Directors") [Issued December 1999.]
Opinion 8.051	("Conflict of Interest Under Capitation") [Issued December 1997. Updated June 2002.]
Opinion 8.052	("Negotiating Discounts for Specialty Care") [Issued December 1997.]
Opinion 8.053	("Restrictions on Disclosure in Managed Care Contracts") [Issued June 1998. Updated June 2002.]
Opinion 8.054	("Financial Incentives and the Practice of Medicine") [Issued June1998. Updated June 2002.]
Opinion 8.11	("Neglect of Patient") [Issued prior to April 1977. Updated June 1996.]
Opinion 8.115	("Termination of the Physician-Patient Relationship") [Issued June 1996.]
Opinion 8.13	("Managed Care") [Issued June 1996. Updated June 2002.]
Opinion 8.132	("Referral of Patients: Disclosure of Limitations") [Issued June 1986. Updated June 2002.]
Opinion 8.135	("Managed Care Cost Containment Involving Prescription Drugs") [Issued June 1986. Updated June 2002.]
Opinion 9.031	("Reporting Impaired, Incompetent or Unethical Colleagues") [Issued March 1992. Updated June 1994, June 1996, and June 2004.]

Definitions and Background

Managed care is a system for delivering health care that was designed with the goal of providing efficient, cost-effective, quality care through a variety of managed care organizations ("MCOs"). In this Opinion on Ethics and Professionalism, MCOs are defined as organizations that provide specified medical services to an enrolled population. MCOs employ or contract with a limited number of approved physicians. Patients covered by MCOs must use one of these approved physicians unless there is an "opt-out" or point of service option. Similarly, MCOs may enter into agreements with particular hospitals and other facilities. Patients enrolled in MCOs must go to an approved facility for inpatient or outpatient care for their services to be covered.

MCOs typically establish certain guidelines and procedures to prevent unnecessary expenditures and to ensure quality care. These measures may include pre-admission certification, concurrent review, discharge planning, independent peer review, case management and expanded quality assurance and utilization review.

By participating in managed care arrangements, both the physician and the patient typically sign written contracts with the MCO that may place constraints on both the physician and the patient's choices. Hence the implied "contract" of the traditional physician-patient relationship is altered by the constraints of the MCO. Established physician-patient relationships may be interrupted. This may place a strain on established ethical principles such as the physician's freedom to accept or reject a patient, refer the patient to a colleague of one's choice, provide the treatment he or she prefers, discuss some alternative treatments that may not be provided

in the MCO, etc. The withholding of information from patients based on the requirements of the MCO (i.e., a "gag rule") is unethical and has been ruled illegal in many states. Withholding information impacts the physicians' ability to act effectively as a patient advocate, and could potentially erode individual and public trust in medicine. Additionally, the efficiency of prompt treatment may be hampered by additional utilization review, mandatory second opinion and peer review processes.

Not every specific instance can be addressed in this Opinion on Ethics and Professionalism, but the following guidelines may be of assistance in resolving ethical dilemmas.

Ethical considerations

1. **Prior to joining a managed care organization (MCO), the orthopaedic surgeon should be fully familiar with the MCO's utilization guidelines and reimbursement policies to ultimately ensure that the patient's welfare remains the paramount concern. *(Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, Paragraph VI. D).***

   By understanding all of the guidelines and policies prior to joining the MCO, the orthopaedic surgeon will be able to provide care for patients and should not be surprised by any unknown aspects of the MCO. Specifically, the orthopaedic surgeon should not be disappointed by the MCO's use of utilization guidelines to evaluate his/her diagnosis and treatment of patients. If a capitation plan exists, the physician should evaluate it prior to joining to ensure that the quality of patient care is not threatened. In addition, the orthopaedic surgeon will receive remuneration for his/her services in an amount he/she has knowledge of prior to providing those services. By understanding all of these aspects of the MCO, the orthopaedic surgeon can concentrate on patient care and work in a constructive manner within the MCO.

2. **In a managed care setting, as in all medical situations, the orthopaedic surgeon has a legal and ethical obligation to "ensure that the patient's welfare remains the paramount concern." (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VI. D.)**

   In all that physicians do, they should act in the best interests of their patients. The orthopaedic surgeon should advocate for medically necessary patient care. As managed care plans proliferate, it is possible that orthopaedic surgeons who contract with MCOs may encounter subtle or direct incentives to reduce the level of medically necessary care provided to enrolled patients.

   It is possible that health insurance enrollment agreements between the patient and the MCO may limit the services that an orthopaedic surgeon may provide without additional cost to that patient. The MCO has the obligation to inform its enrollees regarding the terms and conditions of their coverage; if the MCO limits medical services which the physician may provide, the MCO has the obligation to inform the enrolled patient of these limitations. The enrolled patient has the obligation to understand what is covered by his or her managed care plan. However, the orthopaedic surgeon should be aware that some patients do not understand the terms and conditions of their health insurance enrollment agreements. The physician has the obligation to inform the patient of the diagnosis and the patient's treatment options and, if required by the physician's service agreement with the MCO, to certify that the medical services proposed are medically necessary.

A situation may occur in which an orthopaedic surgeon believes care is medically necessary for an enrolled patient and the MCO does not authorize it. The orthopaedic surgeon should inform the enrolled patient of this circumstance so that he or she might appeal through the MCO's appellate process. The orthopaedic surgeon has an obligation to provide medical information to assist in the enrolled patient's appeal and to participate in a more active role, if necessary. If the MCO's appeal mechanism has been used and the MCO's utilization review committee, upon review, does not determine that the proposed care is medically necessary, the orthopaedic surgeon should document this decision in the medical record.

It is ethical for the orthopaedic surgeon to "enter into a contractual relationship with a group, a prepaid practice plan, or a hospital." (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VI. D.) The service agreement between the physician and the MCO must allow the orthopaedic surgeon to act in a manner which is ethical and which is in the best interest of the enrolled patient.

The orthopaedic surgeon should understand the services he or she will be required to provide under his or her service agreement with the MCO. It is unethical for the physician to enter into an agreement with the MCO that prohibits the provision of medically necessary care.

3. **Having joined the managed care organization, the orthopaedic surgeon should interact in a professional manner, so that the patient's psychological and physical welfare continues to remain of paramount concern (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VI. D).**

The orthopaedic surgeon should remember that patients who are being treated for a medical illness are physically and psychologically susceptible to unprofessional comments from their physician. While it is reasonable for the orthopaedic surgeon to explain to his/her patients the diagnostic and treatment limitations of the MCO, criticizing the MCO in front of the patient does not help the patient feel comfortable in a time of stress. Furthermore, such open criticism may weaken the doctor-patient relationship. While physicians are tempted to use patients as allies to improve managed care scenarios, in reality, when physicians attempt to do so in the physician-patient treating relationship, it is usually unsuccessful and frustrating to the patient.

A more appropriate way for the orthopaedic surgeon to deal with utilization or treatment issues regarding a particular patient is to go directly to the MCO's Medical Director or Administrator and voice concerns that a particular aspect of the utilization process is not providing adequate care for this patient.

More effective changes in MCO policies can occur if the orthopaedic surgeon works within the system. If such change is not likely to occur, the orthopaedic surgeon should rise above the conflict and maintain a professional approach to the problem. The orthopaedic surgeon has an ethical obligation to educate the MCO and its employees about musculoskeletal patient care. If done in a professional way, this is often very beneficial to the MCO and the care that its physicians provide patients. Such general education should include educating other health care professionals and include an appreciation for research projects related to outcome and other topics.

Ultimately, if negotiations with the MCO do not affect reasonable changes, then it is reasonable for the orthopaedic surgeon to consider resigning from the MCO rather than continuing to be in a state of conflict.

If a conflict does exist between the physician's opinion and the MCO's opinion, the physician should remember that the patient's welfare is of paramount importance.

4. **It is ethical for the orthopaedic surgeon to consider cost as one factor in determining appropriateness of care (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph IX. A).**

   The orthopaedic surgeon has the ethical responsibility to consider the health of the public, particularly with regard to allocation of medical resources in society. Therefore, it is ethically appropriate for the orthopaedic surgeon to consider cost as one factor in choosing between equivalent but alternative forms of treatment, particularly in those cases with multiple treatment options.

   When health care plans establish contracts for orthopaedic devices, the orthopaedic surgeon is obligated to advocate for devices/implants that meet the medical needs of his or her patients. The orthopaedic surgeon should:

   - Be knowledgeable about implant and device selection;
   - Be involved in the decision making process;
   - Establish mechanisms for ongoing peer review;
   - Notify proper authorities if inappropriate influences on implant selection are perceived;
   - Advocate for changes to the device/implant list that would benefit the patient;
   - Keep abreast of evidence-based medicine; and
   - Choose quality improvement rather than cost containment as the determinant if exclusions to the device/implant list must be made.

   Receiving a financial return for services can encourage some physicians to overtreat. Conversely, a system that uses a capitated reimbursement plan may encourage physicians to undertreat. The orthopaedic surgeon's personal economic consideration should not influence his/her decision-making in patient care. Patients should be informed of financial incentives that could impact the level or type of care they receive. Physicians should avoid reimbursement systems that, if disclosed to patients, could negatively affect the patient-physician relationship.

5. **The orthopaedic surgeon has the legal and ethical responsibility to practice only within the scope of his or her personal education, training and experience (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph VII. A).**

   The MCO should allow the orthopaedic surgeon to practice within the scope of his or her education, training and experience. If the physician enters into an agreement with an MCO to provide a broad spectrum of care that he/she is not adequately trained to provide, the physician should look elsewhere for appropriate alternate care within the MCO or elsewhere to treat the patient. The orthopaedic surgeon's service agreement with the MCO should include a mechanism to allow appropriate referrals to other physicians.

6. **Having undertaken the care of the patient, the orthopaedic surgeon has a legal and ethical responsibility to continue providing appropriate patient care within limits established by the MCO (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph, I. D).**

The relationship between the orthopaedic surgeon and the patient is the central focus of all ethical concerns. Consequently, a difficult situation is created when care for a patient in a MCO is interrupted either by the patient's change in insurance or by a change in the physician's service agreement with the MCO. If the patient is no longer qualified to be treated in the MCO, there should be provisions regarding transferring of care such that the orthopaedic surgeon can complete the patient's current treatment program with the least interruption.

Prior to the lapsing of the physician's service agreement with the MCO, the orthopaedic surgeon should give adequate written notice to the patient regarding the termination of the relationship and attempt to minimize disruption in the transfer of the care of the patient to another physician. The orthopaedic surgeon should make available the patient's medical records upon request.

7. **The orthopaedic surgeon has the ethical obligation to report recognized unethical activities of gatekeepers, specialists and other health care professionals (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph II. C).**

   If the MCO utilizes a gatekeeper who declines to refer and enroll patients for medically appropriate care or who refers and enrolls patients inappropriately, substandard care may result. Although the primary responsibility for monitoring the performance of the physicians within the MCO rests with the MCO itself, the orthopaedic surgeon, as part of the MCO, should report unethical and/or substandard patient care. It is important for the orthopaedic surgeon to carefully weigh the advantages and disadvantages of involving the patient in discussions of the activities of other physicians that the orthopaedic surgeon feels are unethical.

8. **The orthopaedic surgeon has the ethical obligation to educate managed care organizations and their employees and agents about musculoskeletal concerns. (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph IX. A.)**

   The Code of Medical Ethics and Professionalism for Orthopaedic Surgeons provides that "the honored ideals of the medical professional imply that the responsibility of the orthopaedic surgeon extends not only to the individual but also to society as a whole." (*Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*, Paragraph IX.) Individuals and society will both benefit when orthopaedic surgeons discuss with MCOs, their employees, affiliated physicians and other health care professionals their unique concerns about the musculoskeletal system and its care. This may enhance the quality of care being provided by MCOs. This discussion might also emphasize the need for managed care systems to support the education of health care professionals and the conduct of research, for without either the quality of musculoskeletal care, and indeed all medical care, will be diminished over the long term.

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Opinion on Ethics and Professionalism

Second or Additional Medical Opinions in Orthopaedic Surgery

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issues raised

What are the ethical obligations involved in relationships between orthopaedic surgeons with respect to providing second or additional medical opinions? What different types of second or additional medical opinions exist?

Background

People ultimately control their own personal health care decisions, although their choices may be severely limited by circumstance. Many people have their choice limited because of their insurance coverage or costs. The physician also has a contractual obligation in undertaking the care of a patient, while the patient is the ultimate owner of the contract and has a right to participate in all decisions affecting his or her care.

Many people find medical decision-making difficult, particularly in regard to advanced technologies and new drugs and treatments. There has also been increased publicity in recent years in regard to medical errors and "malpractice". For these reasons, and also the pressures to contain costs, there has been increasing interest on the part of patients and insurers alike in obtaining a "second opinion" from a different physician.

Patients have sought independent second or additional opinions in the past, but the frequency of doing so has increased greatly in the past decade. There has been an exponential increase in the amount of medical information of varying quality readily available to the lay community. This contributes to an undercurrent of skepticism and distrust and encourages the seeking of additional medical opinions. Compounding this is confusion about the medical decision-making process in the lay and health care communities. One result is that both patients and physicians have on occasion experienced anxiety, frustration, anger, and intimidation.

There are many questions about the ethics of seeking and providing second or additional medical opinions. Some actions have resulted in accusations of impropriety and unethical behavior. While unethical behavior has occasionally occurred, many times the conflict has arisen from a lack of proper communication and mutual respect between the treating physician

and the physician from whom the patient has sought additional information. This conflict raises the specter of "turf," greed, and dishonesty and, if visible in the public forum, does much to discredit the profession.

Definitions

Distinct types of interactions exist involving the gathering of additional medical opinions to which different ethical rules apply. They include:

- Consultations with a colleague, initiated by the treating physician, on behalf of and with the implicit consent of the patient, to gain additional diagnostic insight or confirmation in order to continue providing a comprehensive treatment plan for the patient;

- Referrals to a colleague, initiated by the treating physician, on behalf of and with the consent of the patient, to share the care of the patient in the performance of a specified service. A referral might be temporary or permanent; this decision should be made between the two physicians at the time of the referral.

- Transfers, initiated by the treating physician, to transfer all care of the patient to another physician. There are legal requirements for the treating physician in transferring a patient. The consent of the patient is required.

- Withdrawals, initiated by the treating physician, to discharge a patient from his or her care. There are legal requirements for the treating physician who is withdrawing services from a patient. In addition, the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care."

- Second opinions, initiated by the patient, with or without the knowledge of the treating physician, seeking additional information and opinions regarding treatment options.

- Second opinions, initiated by a third party payer or the insurance company of the insured prior to giving authorization to the physician to perform the procedure. In most health insurance contracts, patients must comply with this requirement to receive the full benefit of their contract. The choice of which provider will provide the additional opinion is the sole decision of the insurer.

- Independent medical examinations, which are consultative examinations requested and utilized by third-party payers or insurers such as workers' compensation, disability determination, automobile insurance carriers, and self-insured employers, for determination of benefits. These may be used to establish causation, compensability, extent of injury, or other issues affecting the determination or issuance of benefits.

The patient has complete freedom to seek additional medical opinions by initiating a consultation with another physician concerning his or her care plan or by dismissing the treating physician and transferring all care to another health care professional. The patient's course of action is entirely within the patient's prerogative.

Ethical considerations

The patient has the ultimate decision-making authority in seeking second or additional medical opinions and referrals. Although a patient may have surrendered a certain degree of free choice by accepting insurance coverage with certain limitations, the choice ultimately remains with the patient.

The physician has an ethical obligation to honor and support this free exercise of choice. If a patient indicates a desire to obtain an additional opinion, *for any reason,* the physician must provide upon request copies of all records, including x-rays, under his or her control at reasonable cost because this is in the patient's best interest. There can be no ethical justification for harming a patient's interest by increasing stress by withholding, distorting, or concealing pertinent information.

The American Academy of Orthopaedic Surgeons recommends that orthopaedic surgeons observe the following guidelines regarding second or additional medical opinions and referrals:

1. Any illegal action is unethical. For example, it would be illegal as well as unethical for the orthopaedic surgeon providing the second or additional medical opinion to slander the referring physician if the slanderous information is known or can be proven to be false.

2. In accepting a patient for consultation, it is ethical for the consulting orthopaedic surgeon to render an opinion and return the patient to the treating physician for continuing care. The consulting orthopaedic surgeon should communicate with the patient as well as the referring physician about the opinion.

   It is unethical for the consulting orthopaedic surgeon to solicit care of the patient. However, at the *sole* discretion of the patient, the patient ethically may choose to terminate his or her relationship with his or her treating physician and then enter into another treatment relationship with the consulting orthopaedic surgeon. It is ethical for the consulting orthopaedic surgeon to accept the patient under these circumstances, although some orthopaedic surgeons choose not to accept the patient because of their personal view that a conflict of interest situation might be created.

3. When treating a patient referred by a colleague, the accepting orthopaedic surgeon ethically should return the patient to the referring physician after the index care has been rendered unless prior arrangements have been made with consent of both the referring physician and the patient to transfer the patient's care permanently. In a referral, professional courtesy dictates that some type of direct communication be given to the referring physician.

4. In the specific case where orthopaedic surgeons agree to render "second" medical opinions for a third party who then directs patients to them, the assumption of that patient's care may be prohibited expressly by the terms of the physician's arrangement with the insurance company. If the patient independently is seeking an additional medical opinion, the orthopaedic surgeons may render an opinion and advise the patient of a proposed treatment plan, provided the contract permits such action. The physician must be aware of the provisions of his/her agreement with the third party.

5. As an extension of patient autonomy, patients have an ethical right to prompt and complete access to their medical record information unless the physician is bound by a contract with the patient's third party payer. As a corollary, orthopaedic surgeons who proffer second or additional medical opinions at the treating physician's or patient's request also have the right to complete access to this information. In general, the physician (or the physician's clinic or group practice) legally "owns" the patient's medical records that he or she maintains. However, this ownership is subject to the patient's right of privacy and, in legal proceedings, the physician-patient privilege. It is also subject to the patients' right in most states to obtain copies of those records or to have copies transferred to another person.

   It is in the patient's best medical interests for orthopaedic surgeons to cooperate fully, consistent with HIPAA guidelines, in providing upon request copies of a patient's medical records, including physician notes, prescriptions, charts, reports, laboratory results, technical information used to assess the patient's health condition, letters, photographs, x-rays, and diagnostic imaging. This is true whether the patient is referred by one orthopaedic surgeon to another for a consultation or if the patient elects to see another orthopaedic surgeon for continuing treatment.

6. The orthopaedic surgeon is bound legally and ethically to give his or her best medical opinion, regardless of whether the orthopaedist is the treating physician or the physician who is asked to render a second or additional medical opinion. The best interest of the patient should clearly remain the guiding principal.

Ultimately, patients independently may choose their treating physicians, request transfers of their care, and dismiss their physician at their own discretion.

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References:

Applicable provisions of the *AAOS Standards of Professionalism on Professional Relationships*

Mandatory Standard 2: "An orthopaedic surgeon shall maintain fairness, respect, and appropriate confidentiality in relationships with colleagues and other health care professionals. An orthopaedic surgeon shall communicate in a manner that enhances the profession."

Mandatory Standard 3: "An orthopaedic surgeon shall conduct himself or herself in a professional manner in interactions with colleagues or other health care professionals."

Mandatory Standard 4: "An orthopaedic surgeon shall work collaboratively with colleagues and other health care providers to reduce medical errors, increase patient safety, and optimize the outcomes of patient care."

Mandatory Standard 5: "An orthopaedic surgeon who transfers care of a patient to another physician or other health care provider shall facilitate the transfer of care for the welfare of the patient and cooperate with those receiving the patient."

Applicable provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

"I. The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns. The orthopaedic surgeon should be dedicated to providing competent medical service with compassion and respect."

Applicable provisions of the *Code of Medical Ethics and Professionalism for the Orthopaedic Surgeon*

"I. B The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party."

"I. D. The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care."

"VII. A. An orthopaedic surgeon should practice only within the scope of his or her education, training and experience."

"VII. D. When a patient submits a proper request for records, the patient is entitled to a copy of such records as they pertain to that individual. Charges should be commensurate with the services provided to reproduce the medical records."

Other references:

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics.* Chicago, IL, 2014-2015 edition.

Opinion 3.04 Referral of Patients. Issued prior to April 1977. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion304.page

Opinion 7.01 Records of Physicians: Availability of Information to Other Physicians. Issued prior to April 1977. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion701.page

Opinion 7.02 Record of Physicians: Information and Patients. Issued prior to April 1977; updated June 1994. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion702.page

Opinion 8.12 Patient Information. Issued March 1981; updated June 1994. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion702.page

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Information Statement

Child Abuse or Maltreatment, Elder Maltreatment, and Intimate Partner Violence (IPV): The Orthopaedic Surgeon's Responsibilities in Domestic and Family Violence

This Information Statement was developed as an educational tool based on the consensus opinion of the authors. It is not a product of a systematic review process. Readers are encouraged to consider the information presented and reach their own conclusions.

Child Abuse or Maltreatment, Elder Maltreatment, and Intimate Partner Violence (IPV) are major societal and medical concerns in both the United States and the world. Victims are of all ages, from newborn children to the elderly and include both males and females. Perpetrators are from all walks of life and may knowingly or unknowingly be harming their loved ones. The public health impact in terms of lives lost or lives harmed is immeasurable and likely underestimated by statistics. These problems present in a variety of settings in our health care system, including school health offices, clinics, private offices and hospital emergency departments.

Identifying victims of abuse, maltreatment and violence may be challenging. Sometimes the abuse is obvious, but often the maltreatment is "hidden." Maintaining a perspective of cultural context and cultural sensitivity is important and may have implications on the understanding of the observed behaviors. American society is multicultural and different cultures have acceptable, but differing norms for familial relationships and interactions.

This Information Statement is intended to give the orthopaedic surgeon a current overview of the problem of child abuse and maltreatment, elder maltreatment, and intimate partner violence (IPV). Understanding the magnitude of the problem and its different presentations allows the orthopaedic surgeon to have a heightened awareness of these problems and assists the orthopaedic surgeon in identifying victims and seeking help.

DOMESTIC OR FAMILY VIOLENCE: CHILD ABUSE OR MALTREATMENT, ELDER MALTREATMENT, AND INTIMATE PARTNER VIOLENCE (IPV)

Domestic or family violence, abuse and maltreatment include all circumstances in which an individual with a personal relationship harms another individual for whom he or she has some form of current or prior relationship. This includes legal relatives living together, relatives or extremely close personal friends (often considered "relatives"), cohabitating individuals and close personal friends left with the responsibility of caring for another's family member. The most common forms include child abuse and maltreatment, elder maltreatment and intimate partner violence (spouses and domestic partners). Violence and maltreatment include any physical, psychological, sexual or economic control over another individual which compromises the victims' quality of life and his or her ability to maintain a healthy lifestyle.

Child Abuse or Maltreatment

Definition

The U.S. Centers for Disease Control and Prevention (CDC) defines child abuse or maltreatment as including acts of commission and acts of omission. Acts of commission are conscious and overt and include physical and sexual violence and psychological abuse. Acts of omission exist when the parent or guardian fails to create a healthy environment for a growing child. These are often more insidious, but equally as harmful as acts of commission. They can include an absence of emotional and physical support, lack of appropriate supervision of a child's activities and exposing the child to inappropriate social situations, failure to seek preventative and emergency medical care and failure to maintain a child's education.

Statistics

Child protective services statistics (2008) estimate that 10.3 children per thousand were victims of abuse or maltreatment. Children under the age of one are most vulnerable. They are defenseless, non-verbal, require a large time commitment to be cared for and as a result are "demanding". The estimated rates of abuse or maltreatment for children are:

21.7	per 1,000 for infants less than 1 year old
12.9	per 1,000 for 1 year-olds
12.4	per 1,000 for 2 year-olds
11.7	per 1,000 for 3 year-olds
11.0	per 1,000 for 4 to 7 year-olds
9.2	per 1,000 for 8 to 11 year-olds
8.4	per 1,000 for 12 to 15 year-olds
5.5	per 1,000 for 16 to 17 year-olds

The statistics demonstrate a decreasing incidence of abuse or maltreatment as children become older, with an approximately 11-12/1000 from ages one to seven. Abuse or maltreatment can be fatal and it was estimated that there were 1770 deaths from maltreatment in 2008. Eighty percent (80%) of the deaths occurred in children under the age of four.[1]

Those responsible for fatal child abuse or maltreatment are:

81%	One parent acting alone or with someone else
37%	Mother acting alone
19%	Father acting alone
13%	Non-parent[2]

In addition, those responsible are often young adults without a high school diploma who themselves have been victims of abuse or maltreatment.

In reviewing fatalities, there is often find a pattern of neglect or abuse leading up to the death of a child. Recognition and management of victims are vital skills for all health care providers to prevent continued maltreatment and possibly death.

In addition to the devastating personal toll, child abuse or maltreatment creates a huge economic burden on our health care system and society. A recent CDC study "found the total lifetime estimated financial costs associated with just one year of confirmed cases of child maltreatment (physical abuse, sexual abuse, psychological abuse and neglect) is approximately $124 billion."[3]

Elder Maltreatment

It is expected that elder maltreatment will become more common as the population ages and we face continued economic stresses in the United States. Orthopaedic surgeons may be the first health provider with an opportunity to identify an elderly individual being maltreated. It is important that orthopaedic surgeons be aware of and recognize the common presentations of victims of elder abuse (Recognizing and documenting abuse, see below).

Definitions

The CDC has established definitions of elder maltreatment in an attempt to standardize behaviors which are felt to be harmful to the elderly. Common definitions are necessary for developing strategies for recognizing and preventing maltreatment as well as to treat, assist and protect the victims of maltreatment. The CDC definition of elder maltreatment is "...any abuse or neglect of persons age 60 and older by a caregiver or another person in a relationship involving an expectation of trust". The following behaviors are identified by the CDC as forms of elder abuse:

Psychological abuse: Any behavior which is degrading to a person or creates fear, humiliation or coercion. In addition, socially isolating an individual and preventing interaction with other friends or family members compromises the quality of life for the elderly victim.

Physical abuse: Activities which cause injury or threat of injury with a weapon.

Sexual abuse and abusive sexual contact: Any unwanted sexual contact or sexual contact with an individual who lacks capacity to give consent.

Neglect: Failure to provide a healthy and safe environment by a caretaker. This includes nutrition, shelter, access to health care, protection from others and maintaining an environment of emotional support.

Abandonment: Leaving an elderly individual under the care of a health care provider without arranging for alternative care. A common form of abandonment is to bring an elderly individual to a hospital emergency department and to leave without advising the staff.

Financial abuse or exploitation: Using an individual's financial recourses for personal gain without authorization. Care givers who attempt to limit the use of elderly person's resources for their own future gain are abusing their relationship.[4]

Statistics

The incidence of fractures and musculoskeletal injuries secondary to physical maltreatment of the elderly is unknown. Undoubtedly, orthopaedic surgeons will care for injuries which are the result of physical maltreatment. The suffering of elders is often silent. Orthopaedic surgeons must be alert to the problem and aware of changes in a patient's behavior or circumstances as well as strained relationships with caregivers.

A 2004 Survey of State Adult Protective Services provides an insight into the problem of elder maltreatment. For the year 2003:

Reports of suspected maltreatment: 565,747
Investigated reports of suspected maltreatment: 192,243
Investigated reports substantiated: 46.7%
Maltreatment occurring in a domestic setting: 89%
Maltreatment occurring in an institutional setting: 11%[5]

Prevention
The aging population will place significant stresses on their caregivers. Programs to educate caregivers and developing adequate public support services will be necessary. Identifying victims of maltreatment is vital to prevent further abuse and to assist providers in strategies to improve their skills in the challenging task of caring for the elderly.

Intimate Partner Violence (IPV)

Definition
Intimate partner violence (IPV) occurs between any two individuals with either a current or former "close" relationship. It can occur between both heterosexual couples and homosexual couples. It includes acts of rape, physical and psychological violence and stalking. A large proportion of the perpetrators have been victims of physical and emotional abuse.

Statistics
Intimate partner violence has reached epidemic proportions in the United States. Approximately one in three women and one in four men report some form of IPV. 9.4% of woman report being raped by a partner. Nearly 17% of woman and 8% of men report experiencing other forms of sexual violence, and 24.3% of women and 13.8% of men report severe physical violence. The majority of victims report IPV before the age of 25 (69% of females and 53% of males).[6]

In 2005, the Bureau of Justice statistics reported 1510 deaths from IPV (1181 female and 329 males). An intimate partner committed 11% of all homicides and nearly half of the women victims had visited a hospital emergency department with an injury in the previous year.[7] Repeated violence over time seems to carry more serious consequences. The importance of recognition and intervention is clear in preventing the progressive effects of such violence.

Consequences
Victims of IPV are at risk for a variety of physical and psychological illnesses and significant economic losses. Chronic headaches, musculoskeletal pain, sleep disturbances, sexually transmitted diseases and post traumatic stress disorders (PTSD) are widely reported. Women are at risk for asthma, gynecological problems, irritable bowel syndrome and diabetes. Victims frequently miss days of work and as a result are at risk for losing their jobs. Substance abuse is common. Frighteningly, when women leave an abusive relationship, they are at increased risk for being murdered by the perpetrator.

The economic costs of IPV are staggering and include direct medical costs, loss of productivity, mental healthcare and judicial expenses. Extrapolation of 1995 cost estimates in 2003 dollars estimates a cost of 8.3 billion dollars not including the costs associated with judicial process including investigation, prosecution and incarceration.[8] Chan and Cho published a review of the economic costs associated with IPV.[9] Worldwide costs analyses have varied widely and depend on which associated costs are included in the analysis.

Among the costs of IPV are direct medical costs, mental health care, property damage and loss, productivity losses, loss of consumption efficiency, governmental loses, use of services and pain, suffering and lost quality of life.[6]

RECOGNIZING AND DOCUMENTING ABUSE AND VIOLENCE

The cumulative psychological, economic, social and personal costs of child abuse or maltreatment, elder maltreatment, or IPV are enormous and not well accounted for anywhere. Depression, anxiety, suicide, fear of intimacy and distrust of the opposite sex are among them. Victims are also more likely to engage in high-risk behavior with sex, drugs, alcohol, smoking, and eating. Chronic pain is common. This clearly constitutes a major public health problem that orthopaedic surgeons should be aware as they encounter patients who seek care of injuries which are the result of these actions.

Orthopaedic surgeons need to be aware of the common presentations of victims of child abuse or maltreatment, elder maltreatment, or IPV. Musculoskeletal injuries that should raise a suspicion of a problem include:

- Multiple injuries/fractures
- Bilateral injuries/fractures
- Unusual patterns of injury/fracture
- Injuries/fractures of varying ages
- Injuries/fractures inconsistent with or disproportional to the history
- Multiple injuries treated in different hospital emergency departments or by different providers

Non-musculoskeletal aspects that should alert health care providers to child abuse or maltreatment, elder maltreatment or IPV include:

- A central pattern of injury
- Defensive pattern of injury
- Substantial delay between injury and treatment
- Differing recollections of the cause of the injury
- Injuries during pregnancy
- Repeated injuries
- Frequent utilization of health care services for seemingly inconsequential problems
- Inappropriate/strained relationship with patient's partner
- Excessive anxiety demonstrated by the patient or family member/partner/caregiver
- Body language transmitting fear
- A caregiver insisting that they explain the events leading to the injury
- The failure of a patient with capacity to discuss the events leading to the events of the injury

Appropriate medical records are vital to assist victims. Records can be utilized to obtain legal protection and to obtain other social services such as public housing and welfare benefits. The following suggestions for medical record documentation should be considered to benefit the victim both medically and in any social service or legal proceedings:

- Take photographs to document injuries
- Use body maps or drawings to document injuries
- Write legibly or use electronic medical records
- Utilize exact quotes of what the patient is describing
- Include the name/ names of the individual(s) who harmed the patient
- Fully describe the management of the injuries prior to your evaluation
- Describe the patient's demeanor and psychological state
- Request that you be allowed to interview the patient alone after initially performing an evaluation with the caregiver/ guardian present (Adult with capacity, adolescent child)

THE ROLE OF THE ORTHOPAEDIC SURGEON

In the context of domestic and family violence, the American Academy of Orthopaedic Surgeons (AAOS) believes that an orthopaedic surgeon should:

- ***Be knowledgeable about the prevalence and presentation of child abuse and maltreatment, elder maltreatment, or intimate partner violence***
- ***Be aware that he or she may be the first physician to be caring for the victims***
- ***Maintain a heightened awareness of the problem and develop skills to identify the victims***
- ***Ensure that they maintain comprehensive and accurate medical records documenting the events and examinations***
- ***Assess and assure the safety of the victim***
- ***Appropriately treat victims***
- ***Take steps to prevent further harm***
- ***Be familiar with the applicable laws and resources for reporting and referring suspected cases of violence and abuse***
- ***Transfer an elderly victim who is in immediate danger to a hospital emergency department and notify the emergency department physician of the transfer and the reasons for your concern***
- ***Help educate the public and other health care professionals about the problems of child abuse or maltreatment, elder maltreatment, or intimate partner violence***
- ***Encourage and participate in research on domestic violence and abuse***
- ***Advocate for appropriate legislation and public policy***

The AAOS also believes that in addition to his or her primary responsibility to care for the patient, an orthopaedic surgeon has the legal obligation to report any known incident or suspicion to the appropriate authorities. Reporting of suspected child abuse is required in all states while the reporting requirements for elder maltreatment and IPV are not uniform among states. The orthopaedic surgeon is obligated to understand the laws applicable to his or her practice location.

Resources:

The following resources are current as of this update. Since laws and phone numbers change with time, orthopaedic surgeons should check the current status of the information.

CDC Centers for Disease Control and Prevention Injury Center: Violence Prevention
Link to all CDC sites related to family and domestic violence
http://www.cdc.gov/ViolencePrevention/intimatepartnerviolence

Child Abuse or Maltreatment

CDC link to all CDC related links and many non-CDC related links
http://www.cdc.gov/ViolencePrevention/childmaltreatment/index.html

[1]U.S. Department of Health and Human Services, Administration on Children, Youth and Families. *Child Maltreatment 2008* [Washington, DC: U.S. Government Printing Office, 2010] available at: http://www.acf.hhs.gov. and at:
http://www.cdc.gov/ViolencePrevention/childmaltreatment/datasources.html

[2]CDC Children's Bureau: Child Maltreatment 2010.
http://www.acf.hhs.gov/programs/cb/pubs/cm10/cm10.pdf

[3]Fang X, Brown D, Florence C, Mercy J: The economic burden of child maltreatment in the United States and implications for prevention. *Child Abuse and Neglect,* February 2012.

Child Abuse Prevention & Treatment Act as amended by the Keeping Children Safe Act of 2003. URL links to the full text of the federal law.
https://www.congress.gov/bill/108th-congress/house-bill/14

Child Welfare Information Gateway. URL links to an information reporting hotline (800-422-4453) and to state specific numbers for reporting child abuse.
https://www.childwelfare.gov/topics/responding/reporting/

Child Welfare Information Gateway. URL links to state specific laws related to child abuse.
https://www.childwelfare.gov/topics/systemwide/sgm/

Elder Maltreatment

[4]CDC: Elder Maltreatment
Link to all CDC and many non-CDC sites related to elder maltreatment
http://www.cdc.gov/ViolencePrevention/eldermaltreatment

[5]U.S. Department of Health and Human Services, Administration on Aging. The 2004 Survey of State Adult Protective Services: Abuse of Adults 60 Years of Age and Older. Available at:
http://www.ncea.aoa.gov/Resources/Publication/docs/2-14-06_FINAL_60_REPORT.pdf

National Center on Elder Abuse. This is funded by the U.S. Administration on Aging and is the most comprehensive resource on elder abuse. It includes links to state hotlines and resources.
http://www.ncea.aoa.gov/

Intimate Partner Violence

CDC website with links to all CDC and many non-CDC sites
http://www.cdc.gov/ViolencePrevention/intimatepartnerviolence

[6]CDC National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention: National Intimate Partner and Sexual Violence Survey 2010 Summary Report.

[7]Bureau of Justice: Intimate Partner Violence, 2005 report.
http://bjs.ojp.usdoj.gov/content/intimate/ipv.cfm

[8]Max W, Rice DP, Finkelstein E, Bardwell RA, Leadbetter S. 2004. The economic toll of intimate partner violence against women in the United States. *Violence Vict* 19(3):259–72.

[9]Chan, KL and Cho, EY. (2010) A Review of Cost Measures for the Economic Impact of Domestic Violence; *Trauma, Violence and Abuse*. 11(3): 129-143.

National Coalition Against Domestic Violence Hotline. 800-799- SAFE (7233)
URL links to the NCADV and also to each state's coalition against domestic violence.
http://www.ncadv.org/

McCord-Duncan EC, Floyd M, et.al (2006) Detecting Potential Intimate Partner Violence: Which Approach Do Women Want? *Fam Med*; 36(6): 416-22.

American Prosecutors Research Institute.
This is a good source of information and issues about reporting domestic violence related to competent adult victims. It summarizes the relevant state statutes for medical professionals.
http://www.ndaa.org/apri/

National Resource Center on Domestic Violence. 800-537-2238
This is a good resource for information on and help with domestic violence in adults.
http://www.nrcdv.org/

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For additional information, contact the Public Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Information Statement

Consistency for Safety in Orthopaedic Surgery

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Patients, physicians, surgical team members, providers, and healthcare regulators increasingly recognize that patient safety is an essential element of the evolving U.S. health care system. Six "Cs of Surgical Safety" have been identified as critical,[1] including Consistency in surgical processes and practice. Consistency in surgery is enabled through the regular use of standardized, validated evidence- or consensus-based processes, often summarized as surgical checklists. Consistency and use of well-designed checklists can enhance the ability of surgical teams to provide and document safe, efficient, high quality patient care.

Checklists have long been utilized in other industries, such as aviation and building construction, to enhance safety and streamline processes. They have also been widely applied outside of the operating room - for example, in the form of standardized order sets, clinical care pathways, and discharge planning tools. Over time, health care providers and administrators have increasingly recognized that evidence-based, standardized, systematic care plans - in contrast to physician-unique care plans - can help reduce error rates and costs, thereby improving patient outcomes.

The rationale for routine use of checklists in surgery was widely introduced in the United States in 2008-2009.[2] With the contributions of practicing U.S. surgeons, the World Health Organization (WHO) developed the 'Safe Surgery Checklist' consisting of nineteen 'checks' to be performed by the surgical team-including the surgeon, anesthesiologist, circulating nurse, and other OR team members. These 'checks' were developed as a series of linked surgical steps, used regularly, to support timely communication and summarize important surgical information. Improvements in care have been validated through the use of this checklist and through peri-operative safety and quality data collection and analysis.

The WHO checklist[3] is divided into three sections:

1. **" Brief "** - Performed by surgical team members to confirm important safety information prior to anesthesia: confirming proper patient identification, surgical site marking, surgical consent, a functioning pulse oximeter connected to the patient, patient's medication allergies, potential airway problems, and availability of blood products, if needed.

2. **" Time-Out "** - Performed by the surgical team immediately prior to the surgical incision: confirming correct patient, procedure/s, surgical site/s or level/s, appropriate antibiotic administration, availability of appropriate radiographic images and planned surgical implants, anticipated length of surgery and blood loss, and any critical or special surgical concerns during the surgery.

3. " **De-Brief** " - Completed at the end of the case, but prior to leaving the OR: confirming and recording the accurate name of the procedure, labeling of pathology tissue specimens, correct needle, sponge and instrument counts, and identifying surgical equipment problems during the case to be resolved prior to the next case and any special post-operative care required.

Since 2008, use of surgical checklists - either unmodified WHO checklists or, more commonly, site-modified WHO checklists - has been widely adopted by hospitals and surgi-centers as a central component to their surgical patient safety programs in the U.S. and worldwide. Following implementation of operating room checklists several institutions have documented significant reductions in 30-day surgical complications, including wound infection, blood loss, and death in a range of hospitals in both developed and developing countries.[4-7] The performance of the surgical "Brief", "Time-Out" and "De-Brief" checklists enhances operative team cohesion, reduces communication failures,[8-10] and promotes a perception of improved safety among hospital staff[11] and patients alike.[12] It has also been suggested that the use of checklists may reduce the potential for medical liability claims from surgical patients.[13]

In spite of widespread documentation regarding effectiveness in improving patient safety and reducing surgical complications, regular use of checklists has not yet been universally implemented. A few studies cast doubt on the association between use of mandated checklists and improved surgical outcomes.[14-15] Even among institutions that have adopted operating room checklists, there is wide variation in compliance and implementation, both within and among hospitals.[16-19] Several challenges and potential pitfalls have been identified including: inadequate physician leadership, inadequate surgical team support, and irregular or incomplete utilization.

Effective implementation of standardized safety processes in surgery involves more than the introduction of simple item lists to be 'ticked' by the surgeon and operating room personnel. Traditional surgical hierarchical power structures need to be leveled, so that all team members can communicate in standardized formats without distractions, and data evaluating performance needs to be collected and analyzed regularly. It is important that all members, including nursing and other surgical team members, feel that they can openly share any safety concerns. Throughout this process, surgeon leadership and endorsement are critical to both developing and maintaining successful surgical safety programs.

The AAOS recognizes that mandated use of 'one-size-fits all' surgical checklists often do not achieve the intended result of improved patient safety and outcomes. Checklists are most effective when they are modified locally and developed to best suit specific surgical settings and/or location needs. Such checklists are more likely to be endorsed by local surgeons and surgical team members, leading to regular use and improved protection for the patient populations they are designed to serve.

Initiation of effective surgical safety checklists requires the endorsement of surgical providers with surgeon leadership of a multi-disciplinary checklist team-often including anesthesia, nursing, pharmacy, operating room, and administration representatives. This team should review available evidence and/or expert consensus regarding "best" safety practices and tailor the checklist to the needs of the patient population it intends to serve. The team should regularly monitor checklist compliance and effectiveness, making adaptations when appropriate.

Not every element of standardized surgical checklist will apply to every orthopedic procedure or patient, but consistent use of the entire peri-operative routine supports best care. Surgical checklists do not substitute for sound clinical judgment and technical skill; nor do they guide surgical teams through the steps of a complex operation. Rather, they serve as evidence-based tools to help avoid preventable harm to patients, promote a culture of safety, and maximize communication and teamwork in the operating room. Surgeon leadership is enhanced-not diminished-when all members of the OR team are engaged in the surgical timeout process. Regularly performed checklists enable all surgical team members- typically within one or two minutes - to ensure that important safety

concerns are addressed, so the surgical team can be confident that the team has identified important patient care concerns to reduce complications and provide the best quality care possible.

The AAOS is dedicated to providing safe care in all orthopedic surgical settings and supports the consistent use of evidence-based processes, including checklists by surgeons and their surgical teams, as a tool to help improve the safety and outcomes of orthopaedic patients.

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For additional information, contact Public Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Information Statement

Disruptive Behavior and Orthopaedic Patient Safety

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The American Academy of Orthopaedic Surgeons (AAOS) believes that the development of high quality information that defines which diagnostic, treatment, and prevention services are most effective for specific patients and populations will improve informed patient choice and shared decision-making. Such efforts will maximize the improvement of health status of individuals and populations.

Orthopaedic surgeons depend on effective surgical and clinical teams to support optimal outcomes for their patients. The surgical and clinical team includes orthopaedic surgeons, nurses, anestheologists, and others with responsibilities in the operating suite. For these health care teams to function safely and effectively, cooperation, clear communication, and collegiality is required. Hostile, aggressive, and passive-aggressive behaviors undermine team cohesiveness. The American Medical Association (AMA) defines such behaviors as "Disruptive Behavior" including any abusive personal conduct, verbal or physical, that potentially or negatively affects patient care.[1, 2, 3]

Medical practice inherently requires complex human interactions and critical decision making with resultant stress and frustrations for health care providers. Isolated events resulting from these stresses and frustrations generally do not constitute disruptive behavior. Disruptive behaviors are displayed most commonly as a pattern of behaviors by individuals with personality traits interfering with clinical judgment and performance.[4]

The AAOS supports adherence to a code of conduct for all surgeons and surgical team members, including nurses and anesthesiologists, that fosters a cooperative, collegial working environment and that identifies and addresses 'disruptive behaviors' within the health care team. Isolated egregious disruptive events or patterns of disruptive behavior should not be tolerated. Controversial ideas or well-intended criticisms of the medical systems or situations by surgeons or team members, however, should not be labeled disruptive.

State Medical Boards have traditionally borne the primary responsibility for delineating and enforcing standards of competence and ethical behavior for physicians. In recent decades, attention was focused primarily on the "impaired physician" as a physician unable to safely perform his or her duties due to substance abuse and/or psychiatric conditions.[5] During the 1990s, increased awareness of the deleterious effects of a hostile work environment prompted a broadening of the scope of 'unprofessional conduct' to include disruptive physician behavior.

The Federation of State Medical Boards, in its 2000 Report to the Special Committee on Professional Conduct and Ethics, raised concerns about disruptive physician behavior. They recommended that State Medical Boards be "empowered to take disciplinary action against physicians whose behaviors or practices are not in the interest of patient safety and welfare and are outside the bounds of professional practice".[6] In 2000, the AMA also promulgated its opinion that "verbal or physical behavior that, actually or potentially, negatively affects patient care constitutes disruptive physician behavior "[7] The AMA went on to caution that "criticism that is offered in good faith with the aim of improving patient care should not be construed as disruptive behavior"[7].

In 2004, the American College of Physician Executives reported that more than 95% of surveyed members "encountered disturbing, disruptive and potentially dangerous [physician behaviors] on a regular basis".[8] In a 2005 survey of Critical-Care Nurses, more than three-fourths of the respondents reported regularly working with doctors and nurses who are condescending, insulting or rude.[9] Furthermore, they found that the frequency and duration of such behaviors correlated with the worker's intent to quit his/her job.[9] Concerns have been raised that disruptive physician behavior can contribute to healthcare work place turnover and even nursing shortages.[10,11]

The Joint Commission (JC) has mandated that, "to assure quality and promote a culture of safety, health care organizations must address the problem of behaviors that threaten the performance of the health care team. "[12] Citing evidence that intimidating and disruptive behaviors can contribute to medical errors, adverse outcomes, physician and administrator turnover, and increase the cost of care, on January 1, 2009, the JC issued a Leadership Standard, LD.03.01.01, for all accreditation programs.[12] This required hospitals and medical organizations to establish and enforce a code of conduct that defines acceptable, disruptive, and inappropriate behaviors.[12] The JC recommends education of all team members regarding these behaviors and standards, and recommends that all be held accountable for modeling desirable behaviors.[12]

The AMA currently defines disruptive behavior as conduct, including sexual and other forms of harassment, or other forms of verbal and non-verbal conduct that harms or intimidates others to the extent that quality of care or patient safety could be compromised.[4] Openly aggressive behaviors, such as yelling, insults, and throwing things, are easily identified. Passive aggressive behaviors, such as hostile avoidance, condescension, and sarcasm, are more difficult to identify and are more subjective to evaluate and document. Such subjectivity must be carefully considered by disruptive event investigations.[7, 13, 14] An orthopaedic surgeon should work collaboratively with colleagues and other healthcare providers to reduce medical errors, increase patient safety, and optimize the outcomes of patient care.[18]

Orthopaedic surgeons, as the leaders of the patient care team, must foster work environments that are collegial and cooperative. Patients are best served by healthcare teams that function harmoniously in which all team members feel respected for their contributions and empowered to speak freely regarding any patient safety concerns.

Orthopaedic surgeons, surgical team members, nurses and anesthesiologists, should recognize that a determination that their behaviors are disruptive will have adverse professional and work place consequences. Surgeons, team members, nurses and anesthesiologists should be educated and knowledgeable about the rules, regulations, policies, or protocols of their practice settings.[15] All complaints of 'disruptive behavior' should be carefully considered by surgeons, surgical team members, nurses and anesthesiologists. Accused surgeons, surgical team members, nurses and anesthesiologists should be aware and respectful of their rights within the investigation and may benefit from legal consultation[16, 17]

The AAOS believes that 'disruptive behavior' harms surgeons, surgical team members, nurses and anesthesiologists and that such behavior undermines cohesiveness and effectiveness of healthcare teams, impairs sound medical decision-making and increases medical errors. All such behavior is 'unsafe', should be reported, investigated and appropriately corrected.

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Position Statement

Electronic Health Records (EHRs)

This position statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Access to and correct usage of patient Electronic Health Records (EHRs)/Electronic Medical Records (EMRs) provide major benefits to patients and physicians alike. When properly designed and utilized, Electronic Health Records can improve patient safety, increase clinical efficiency, reduce costs,[1] allow seamless transfer of vital patient information,[2] and allow physicians to better use their time and expertise treating patients.

The AAOS believes:

1. ***Health Information Technology (HIT) should strive to improve quality care, and not detract time and attention from the care of patients.***
2. ***An electronic medical record in a physician's office offers great potential to be beneficial for patient care, patient safety, quality care, and measurement of outcomes.***

The American Academy of Orthopaedic Surgeons (AAOS) encourages all members to adopt Electronic Health Records that are affordable, well designed, and widely available. The AAOS strongly supports the development of interoperability standards for all EHRs. The AAOS also supports the development of appropriate standards for meaningful use of electronic health records by Government agencies and private carriers which balance the needs of patients and their families, physicians and their staffs, and regulators. Finally, the AAOS believes these standards should be collaboratively developed by physicians through their professional organizations in cooperation with government agencies. The process should emphasize the requirements for the highest level of quality patient care while recognizing the limits and clinical specialty focus of physicians who use the systems.

Overview and History

Electronic Health Records refers to the storage of patient information and records in computer systems rather than on paper forms. When EHR systems are affordable, well designed, and widely available, their use has several advantages, including the ability of physicians to instantly access a patient's complete medical history. The use of EHRs can also reduce medical errors[3] and unnecessary testing[4] and thus, potentially save lives. EHR systems also greatly facilitate the search for specific information within the patient's stored information. Correctly implemented, it can save the health care team time and money, which in turn frees physicians and their staffs to treat patients more effectively. However, challenges in implementation are great. A poorly designed and implemented EHR system will be of far less utility than a system that is functional and adaptable.

Widespread adoption of EHRs has the potential to facilitate advances in medical research. Researchers could have access to incredibly rich sources of data across practitioners and patient populations, and our profession may be able to harness this information into valuable discoveries of the relationships between patient care modalities and patient outcomes.

EHR System Concerns and Goals

In recent years, the development of EHR systems has exploded, with dozens of vendors offering variations on "turnkey" systems. In practice, however, many systems have turned out to be unwieldy and require a large, in some cases excessive, investment of time and resources to implement and operate. Poorly designed systems can affect access to care as a reduction in the number of patient appointments occurs. Many systems are geared toward primary care medical practice which can limit the utility of EHRs for specialty surgical practice.

The AAOS believes vendors should consider the specific practice workflows and needs of orthopaedic surgeons in developing, implementing and maintaining EHR systems.

Regulatory Concerns and Goals

In 2011, Federal agencies such as the Centers for Medicare and Medicaid Services (CMS) began to pay incentives to physicians for the adoption and meaningful use of EHR systems. Grants totaling up to $44,000 will be made over five years to any physician that can demonstrate adoption and "meaningful use" of EHRs. Beginning in 2015, CMS is imposing payment penalties on Medicare participants who have not adopted EHRs for their practices.

The AAOS believes the following standards are essential for the successful development of meaningful use standards and EHR systems certification:

- ***Establish EHR standards by the collective wisdom of physicians actively caring for patients***
- ***Establish a comprehensive set of certification standards, including data and interoperability standards for all EHR systems***
- ***Establish implementation thresholds rather than requiring implementation of all meaningful use criteria as an all-or-nothing requirement that will serve to discourage, not encourage, adoption of EHRs.***
- ***Recognize the different needs and uses of EHRs by disparate medical specialties, especially the differences between surgical specialties and primary care specialties***
- ***Create meaningful use criteria that are HIPAA compliant, protect patients' privacy, and provide safe harbors so as not to expose physicians and other health care professionals to penalties for unintended HIPAA violations.***
- ***Recognize that many aspects of EHRs such as interaction with government, private payers, labs, patients, pharmacies and physicians are still in development and therefore, criteria requiring interoperability for the sharing of data may not be attainable for reasons beyond the control of physicians***
- ***Recognize the cost burden of adoption of EHRs, particularly for small private practitioners, and for practitioners in rural areas.***

The AAOS endorses efforts to encourage the adoption of Electronic Health Records by physicians and patients. However, the AAOS believes that unless the standards are appropriate and realistic, CMS will end up imposing an untenable and counterproductive burden on physicians that may

disrupt the patient-physician relationship and access to care. Therefore, it is essential that physicians from many specialties and clinical practices be involved in the discussions and deliberations; otherwise, the appropriate and laudable goal of universal EHR adoption will be thwarted.

Summary

The AAOS believes the potential benefits of EHR adoption are vast, and we believe widespread usage of well-designed EHRs will benefit our patients and the practice of medicine. We recognize, however, the cost of implementation may appear prohibitive to many practices. We encourage physicians to weigh the benefits versus the risks and costs and also take into account the fact that, in the near future, payers will likely make EHRs a requirement in order to participate in their networks. The AAOS recommends the adoption of well-designed EHRs; however, physicians should take the time to find the system most appropriate in terms of functionality and cost for their own practice. The AAOS also recommends that payers and government agencies recognize variations in system capabilities in setting standards, incentives, and penalties.

References:

1. One of the most common cost savings tool in EHRs is the ability to check for a drug's formulary status, drug-drug interactions, and allergy checks. Each of these checks improves the reliability of prescription writing, eliminates wastage of medications, and improves patient safety.
2. For example, patient information can be transferred via secure connection from a patient's primary care physician to a surgical specialist seeing the patient for a specific condition or injury. This can occur not just within the same hospital but across providers in different cities all together.
3. Most EHRs put in place a system of careful medicine reconciliation. This process reduces medication errors significantly, and improves the ability of physicians to be sure that patients are kept on important medications they were on prior to admission.
4. For example, you can easily review the patient's previous charts and see when the patient has had a recent CT that answers the question you are trying to answer and thus you are not required to conduct a second CT scan. Time and money is saved, and quality is improved.

EHRs are allowing instant translation of ICD9 to ICD10 codes

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Position Statement

Emergency Orthopaedic Care

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Emergency orthopaedic care includes acute trauma care and urgent general orthopaedic care delivered in hospital emergency rooms. Access to emergency orthopaedic care in the United States is problematic and may get worse. At present, there is variable access to orthopaedic emergency care in many communities in the United States.

Since this access problem varies from community to community, one solution which is applicable to all locales remains elusive.

Factors contributing to the emergency orthopaedic care access problem include:

- An increasing patient population seeking emergency orthopaedic care[1]
- A shortage of physicians available to take emergency orthopaedic call in certain parts of the country[2]
- Unique difficulties in pediatric orthopaedic coverage[3]
- Government health care programs that do not provide adequate coverage for emergency care
- Inadequate hospital facilities and insufficient resources to support emergency care services[4]
- A decrease in the number of hospital emergency departments[5]
- Decreasing professional reimbursement and increasing professional practice costs[6]
- An increasing volume of uninsured patients, uncompensated care, underinsured patients[7]
- A challenging medical liability environment[8]
- Changing practice patterns with increased orthopaedic subspecialization
- An anticipated orthopaedic manpower shortage[9]

Recognizing thisevolving crisis in emergency orthopaedic care, the American Academy of Orthopaedic Surgeons (AAOS) believes that orthopaedists, working in conjunction with all stakeholders, including other physicians, hospitals, and government policymakers, have a responsibility to address the problems in access to emergency orthopaedic care. Accomplishing this objective is in the best interests of patient care.

Local Emergency Care

Most injuries occur near a patient's home. It is inconvenient and costly to transfer injured patients out of their local community for emergency orthopaedic care; however, polytrauma patients should be transferred to specialized trauma centers, which provide specialized, multidisciplinary emergency care for trauma patients. At present, from time to time, trauma centers become overburdened with transfers of patients for routine urgent orthopaedic care which can lead to impairment of the trauma center's ability to care for legitimate acute trauma victims.

The AAOS believes emergency orthopaedic care should be provided in the patient's local community whenever possible, recognizing that acute trauma care may necessitate transfers to polytrauma centers.

The Responsibility of the Orthopaedic Community

Orthopaedic surgeons are the most qualified physicians to provide acute musculoskeletal trauma care and urgent general orthopaedic care. Access to these services is a critical factor in the emergency orthopaedic care issue. Reasons for variability in access to acute trauma care and urgent general orthopaedic care include:

- The availability of orthopaedic surgeons for emergency room call
- The willingness of hospitals to provide facilities and resources for emergency orthopaedic care
- The development of hospital business models to negotiate call arrangements with on-call physicians
- Public policies and health plan coverage to pay for the costs of treating uninsured and underinsured patients in the emergency room.

The AAOS believes board-eligible and board-certified orthopaedic surgeons possess comprehensive orthopaedic clinical competency and are qualified to provide emergency orthopaedic care.

The AAOS believes orthopaedic surgeons have a responsibility to take a leadership role in working with their hospitals to ensure that emergency patients with musculoskeletal problems receive timely and appropriate care in their local communities.

Leadership responsibility for emergency orthopaedic care requires collaboration with hospitals, communities, health plans, other physicians, and patients to develop an emergency orthopaedic care system that addresses the needs of the patients, the community, the hospitals, and the physicians.

The AAOS believes orthopaedic surgeons in a local community have a responsibility, utilizing mutually agreed upon incentives with their hospitals, to provide a call system for emergency orthopaedic care in their local community.

The Role of Other Stakeholders

<u>The Responsibilities of Hospitals</u>

Hospitals must provide facilities and resources to allow orthopaedic surgeons to provide safe, high quality emergency orthopaedic care. Specifically, hospitals should provide adequate facilities, equipment, devices, and well-trained ancillary personnel, as well as guaranteed operating room time to manage emergency cases the night of admission or the following day. Of paramount importance is that these provisions are made regardless of patients' insurance status or ability to pay.

Hospitals should also share the financial burdens that orthopaedists and other physicians now bear alone when they take call and provide emergency services. These financial burdens include:

- Opportunity costs associated with not being able to provide care for elective patients on the day of call and the day after call because of obligations associated with providing emergency orthopaedic care;
- Extra costs that physicians absorb when they treat uninsured and underinsured emergency patients, including additional liability risks, and
- Loss of sleep and other disruptions to personal and professional routines from being on-call and providing emergency orthopaedic care.

Hospitals are obligated to assume an appropriate portion of these costs given the federally mandated responsibility for provision of emergency services. Given decreases in physician reimbursement, from both federal and private payers, assumption of the costs for provision of emergency services by physicians is not reasonable or sustainable.

The Joint Responsibilities of Orthopaedists and Hospitals

Hospitals have a federally mandated responsibility to provide care to emergency patients. Hospitals and orthopaedic surgeons have a joint responsibility to ensure that orthopaedic patients receive timely and appropriate emergency orthopaedic care. Hospitals and orthopaedic surgeons have a joint responsibility to: develop call schedules based on the local community's emergency care needs and local orthopaedic workforce issues (age of orthopaedists, years of emergency service, on-call frequency, and sub-specialization); developing protocols for transferring patients to other facilities based on objective clinical criteria and the ability of the orthopaedist to provide high quality care; and executing defined agreements with receiving centers for acceptance of the transfer of patients for whom musculoskeletal emergency services cannot be provided at the initial receiving center.

Coverage for the emergency room should be based on mutually agreed incentives and not mandates to take call.

The Responsibilities of Government

Government must take greater responsibility for helping physicians and hospitals meet society's expectations for delivering emergency orthopaedic care regardless of ability to pay.

- Medicaid reimbursement should be facilitated for the uninsured who require emergent care, and must be sufficient to ensure adequate emergency orthopaedic access to care for Medicaid beneficiaries.
- Federal, state, and local governments must support fair and reasonable compensation for trauma and emergency services and create new sources to finance emergency orthopaedic care for underinsured patients.
- Best practice models for delivering emergency orthopaedic care should be identified and promoted.
- Impediments to access to emergency orthopaedic care, including an actual or perceived increase in liability exposure must be addressed. Federal and state medical liability reform must be enacted to restore and preserve access to care for patients who require emergency orthopaedic care throughout the U.S.
- Continue to promote safety measures and educate our citizens with regard to behaviors such as helmet wearing for motorcycles, seatbelts, DUI programs, etc.

Relationships between Health Care Plans and Trauma Systems

Physical trauma from accidents and violence is a leading medical problem in young Americans. Each year, 57 million citizens are injured, resulting in 155,000 deaths and 2.3 million hospitalizations. Providing high quality, expedient, and cost-effective care to trauma victims is a societal goal, and a challenge to the United States health care system.

The American Academy of Orthopaedic Surgeons (AAOS) believes that major trauma victims have the best chance for survival and optimal recovery in American College of Surgeons-verified and/or state-designated trauma centers that work in conjunction with Emergency Medical Systems.

The AAOS encourages all health care delivery systems to participate in regional trauma system planning and to integrate their approach to trauma care into trauma centers.

Collaborative relationships between established trauma centers and health care plans can ensure immediate access of all major trauma patients to trauma centers, high quality patient care and timely transfer of patients, equitable reimbursement for the care of trauma patients in trauma centers, and creation of a partnership between health care plans and trauma centers for cost-effective trauma management.

The AAOS believes that representatives of regional trauma planning systems and health care plans should agree on trauma care policies that foster optimal patient care, cost-effectiveness, and effective communication among providers.

Other Considerations

Reimbursement and medical liability are significant contributing factors in the emergency orthopaedic care access problem, and they should be addressed by hospitals, communities, health plans, other physicians, and patients.

In return for developing emergency orthopaedic care services, the AAOS believes orthopaedic surgeons should be fairly compensated for the knowledge, skills, work, expertise, and management of risks which they deliver to their community.

Support for orthopaedic surgeons who provide emergency coverage may include, but not be limited to, access to the hospital emergency room, utilization of hospital operating rooms and staff, assistance from hospital mid-level professionals, payment for specific professional services (clinical and administrative), and payment for time.

General Principles to Address the Emergency Care Crisis

The AAOS believes orthopaedic surgeons can stimulate change to improve the emergency orthopaedic care access problem. However, orthopaedic surgeons cannot accomplish this alone. The AAOS believes all stakeholders including orthopaedic surgeons, the government, hospitals, policymakers and payers must work together to improve access to emergency orthopaedic care in the United States.

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Position Statement

Medical Error/Patient Safety Reporting Systems

This Position Statement was developed as an educational tool based on the consensus opinion of the authors. It is not a product of a systematic review process. Readers are encouraged to consider the information presented in this Position Statement and reach their own conclusions.

In the years since the release of the Institute of Medicine report and subsequent Congressional hearings, public attention has focused on the need to improve patient safety and minimize medical errors. Proposals to achieve this objective include nationwide patient safety reporting systems.

The American Academy of Orthopaedic Surgeons (AAOS) is committed to ensuring patient safety and to decreasing medical errors.

Programs and initiatives of the AAOS directed towards reducing medical errors and improving patient safety to date include:

- A series of closed-claim professional liability insurance studies by the AAOS Committee on Professional Liability carried out since 1990 to determine common causes of orthopaedic error and resulting in the publication of the first and second editions of Managing Orthopaedic Malpractice Risk.
- The "Sign Your Site" initiative, which was developed as a result of a September 1997 AAOS task force study of preventable errors occurring in the operating room including surgery on the wrong site. The task force advised that surgery on the wrong site would rarely if ever occur when an awake and alert pre-operative patient and the surgeon mark the operative site immediately prior to surgery.
- A system of Continuous Quality Improvement, including clinical practice guidelines and performance measures, developed to improve quality and efficiency of care and focus on patient safety, which can be used to assist physicians in diagnosis and treatment decisions.
- Ongoing educational opportunities designed to educate orthopaedic surgeons in the best practice of orthopaedic care, including online education modules.

Medical error reporting should lead to improvements in patient safety. The AAOS believes the following principles are essential to ensure the success of a nationwide effort to reduce the number of medical errors:

- Public and private initiatives to ensure patient safety and reduce the number of medical errors.
- Ensuring patient confidentiality and appropriate legal protection of all information involved in patient safety reporting systems is critical.
- Patient access to their medical records should not be jeopardized by new initiatives.
- Before instituting new reporting systems, federal and state governments should first determine, through supporting research, whether and how existing reporting programs as well as public and private initiatives have led to a reduction in medical errors.

The AAOS urges that the goal should be to prevent patient harm and minimize health systems errors. An important goal of any reporting system should be to foster open dialogue and reporting. Systems with punitive undertones would defeat an open dialogue.

To encourage maximum reporting, all information developed in connection with reporting systems, at all phases of reporting activity, should be privileged for purposes of federal and state judicial proceedings, both in civil matters and in administrative proceedings including discovery, subpoenas, testimony, and other forms of disclosure. The submission of information to reporting systems, or the sharing of information with third parties for the purpose of improving patient safety should not be construed as waiving any privilege of confidentiality recognized under state or federal law or established as part of a reporting system. All such information should be exempt from the Freedom of Information Act.

The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) provides for the creation of Patient Safety Organizations (PSOs) to protect information gathered in the pursuit of improved patient safety. The Academy anticipates the implementation of this Act will facilitate prospective data collection and encourage the reporting of medical errors in a non-punitive environment. The AAOS encourages initial, scientifically sound research into reporting programs, including those mandated in approximately 25 states, to determine whether and how they have led to a reduction in medical errors. Funding should be available to redesign systems based on research findings to prevent further errors. The costs to hospitals and other providers for implementing these systems should be considered. Research should not be disproportionately skewed to hospital-based errors but should target a broad range of practice settings.

Policies should encourage a constructive partnership between the federal government, hospitals, physicians, and other medical providers and personnel to initiate policies that can effectively decrease medical error in the United States. Federal government patient safety initiatives should involve a broad range of public and private organizations, including medical specialty societies, to continually advance efforts to improve patient safety.

The AAOS stands ready to work with a broad range of public and private agencies, including hospitals, medical professionals and others, to ensure safe patient practices. The AAOS has designated this initiative as a high priority in its policies and advocacy.

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Information Statement

Opioid Use, Misuse, and Abuse in Orthopaedic Practice

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The United States is in the midst of an epidemic of opioid drug (narcotic drug) use, misuse, and abuse.[1] To address this critical public health issue, all physicians and orthopaedic surgeons must be accountable for their direct or indirect contributions to the epidemic and should responsibly develop solutions to effectively treat this epidemic.

It is estimated that the United States consumes 80 percent of the global opioid supply.[2] According to the U.S. Food and Drug Administration (FDA), more than 50 million Americans were prescribed some type of narcotic pain medication in 2011, which represents a nearly 100 percent increase in narcotic pain medication prescriptions since 2008.[2] This increase in opioid prescription medication corresponds to an increase in opioid diversion to nonmedical users as well as a resurgence in heroin use.[3-5] Opioid overdose is now the leading cause of accidental death in young adults.[6] Opioids are associated with a higher risk of postoperative death.[7] Opioids also increase the risk of fall and fracture in the elderly.[8, 9]

The AAOS believes that a comprehensive opioid program is necessary to decrease opioid use, misuse, and abuse in the United States. New, effective education programs for physicians, caregivers, and patients; improvements in physician monitoring of opioid prescription use; increased research funding for effective alternative pain management and coping strategies; and support for more effective opioid abuse treatment programs are needed.

The American Academy of Orthopaedic Surgeons supports the following strategies for safer and more effective pain management and treatment:

Standardized Opioid Prescription Protocols/Policies: Orthopaedic surgeons and their team members can more effectively depersonalize discussions about opioids by using standardized opioid protocols in all settings (inpatient, outpatient, office) to control opioid use. Orthopaedic practices should establish protocols/policies to better control and limit opioid prescription dosages as well as appropriate/inappropriate opioid uses for acute musculoskeletal injuries, postsurgical pain, and chronic pain. Surgeons and team members should explain to patients that opioid protocols/policies benefit patients and extended families and cannot be violated. Such opioid protocols/policies should include:

- **Practice-based Opioid Use Consensus:** Each practice should set ranges for acceptable amounts and durations of opioids for various musculoskeletal conditions treated, both surgically and nonsurgically.

- **Strict Limit on Opioid Prescription Size:** A prescription should only include the amount of pain medication that is expected to be used/appropriate, based on the protocol established. For patients who live longer distances from their surgeons, two prescriptions for smaller amounts of opioids with specific refill dates should be considered rather than a single large prescription. Most patients do not fill the second prescription, so this strategy limits potential opioid misuse.

- **Limit Extended-Release Opioids**: Orthopaedic surgeons most often treat acute pain following injury or surgery. Such acute pain typically improves over hours to days, rather than days to weeks. With one exception, extended-release opioids are not FDA-approved for the treatment of acute pain.

- Extended release opioid medications have the following characteristics:

    - They are intended for severe, long-lasting pain from cancer.[10] The effectiveness, risks, and role of long-term opioids for nonmalignant pain are unclear. Orthopaedic surgeons should consider using alternative non-opioid treatments or referring patients to multidisciplinary pain centers for treatment of chronic nonmalignant pain.

    - They do not allow for the titration and decrease of opioids, which makes it more difficult to limit opioid intake.

    - They are a popular class of opioid medications among opioid misusers and abusers.

    - They should be restricted to approved research protocols until the risks and benefits for the treatment of acute orthopaedic pain are better understood.

- **Restriction of Opioid Use for Preoperative and Nonsurgical Patients**: Pain from acute trauma or chronic degenerative diseases can usually be managed without opioids prior to surgery. Surgical patients using opioids preoperatively have higher complications rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery.[11] The effectiveness of opioid use for the treatment of chronic pain other than cancer is debatable. Policies/protocols that limit use of opioids in patients with non-acute conditions can help limit patients' soliciting opioid prescriptions from more than one physician. Policies/protocols that restrict opioids for preoperative, nonsurgical, and chronic pain patients should be considered.

Predictive Opioid Use/Misuse/Abuse Tools: Patients at risk for greater opioid use should be identified (eg, using the opioid risk tool http://www.mdcalc.com/opioid-risk-tool-ort-for-narcotic-abuse/). Patients with symptomatic depression and ineffective coping strategies should be identified and treated prior to elective surgery. Physicians, the public, and policy makers should value interventions to lessen stress, improve coping strategies, and enhance support for patients recovering from injury or surgery.

Communication Strategies: Surgeons should script and practice empathetic and effective communication strategies, appropriate for all levels of health literacy. Patients are more comfortable and use fewer opioids when they know their doctor cares about them as individuals.

Professional, Interpersonal, and Organizational Collaborations: Partnerships need to be established among hospitals, employers, patient groups, state medical and pharmacy boards, law enforcement, pharmacy benefit managers, insurers, and others. Patients need to understand that opioid medications should be used only as directed and to practice safe storage and disposal. The patient's family and friends should also be educated to help with physical activities that are difficult and to provide emotional support for recovery. Prior to elective surgeries, physicians should encourage (or should work with) patients to establish a social network—including visiting nurses and home health aides, as well as neighborhood volunteers—to provide emotional and physical support during recovery.

Improved Care Coordination and Opioid Use Tracking: It should be possible for a surgeon and pharmacist to see all prescriptions filled in all states by a single patient. Opioid use is best coordinated through a single prescribing physician/surgeon/practice, especially when dealing patients have ongoing/chronic pain issues. Doctors in emergency departments or other consulting physicians can then contact that prescribing physician/surgeon/practice to determine if an exception is warranted. Referral for alternative pain management strategies should be considered for atraumatic musculoskeletal pain. Evidence is available that ongoing pain after injury or surgery is most often associated with symptoms of depression, posttraumatic stress disorder, and ineffective coping strategies—all of which are responsive to cognitive behavioral therapy.

Continuing Medical Education (CME) for Physicians: Physician and caregiver awareness of the risks and appropriate uses of opioid medications is important. Requiring periodic CME on opioid safety and optimal pain management strategies will help physicians reduce opioid use and misuse.

Quality Improvement: Physicians and caregivers should integrate performance improvement in pain management, stricter opioid prescribing, and screening and treatment for substance use disorders into new delivery model quality metrics. Questions about satisfaction with pain relief and pain medication may not be optimal quality measures.

Maintenance of Proper Opioid Access: Even as healthcare providers and regulators take steps to address the problem of opioid abuse, they must recognize that, in certain settings and for certain conditions, patients with terminal conditions and other appropriate indications should have access to opioid analgesics to manage their pain.

Opioid Culture Change: Making opioids the focus of pain management has created many unintended consequences that often put both patients and their families at increased risk of addiction and death. A new approach to pain management is needed to effectively change the cultural expectations of patients with pain. Patients with similar injuries and surgeries experience varying amounts of pain. The differences in pain for a given injury or surgery are largely explained by individual patient circumstances, characteristics, and mindset. Stress, distress, and ineffective coping strategies create greater pain. Peace of mind is the strongest pain reliever. Studies have found that opioids are associated with more pain and lower satisfaction with pain relief. Opioids are potentially dangerous medications for all patients; they are highly addictive and can cause death.

In the United States, the current cultural expectation of opioid use as the primary treatment for acute and chronic pain has created an opioid epidemic. Only a culture change led by physicians dedicated to limiting inappropriate opioid use will solve this epidemic.[12] Physicians, patients, and caregivers in the United States need to learn how to treat pain with less dependency on opioid medications.[11]

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Information Statement

Orthopaedic Surgical Consent

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The American Academy of Orthopaedic Surgeons (AAOS) believes that the development of high quality information that defines which diagnostic, treatment, and prevention services are most effective for specific patients and populations will improve informed patient choice and shared decision-making. Such efforts will maximize the improvement of health status of individuals and populations.

Surgical consent in elective surgery is a critical surgical safety process. Surgical consent provides proper:

- Legal documentation as mandated by state laws,
- Surgical facility documentation as regulated by surgical facility certification organizations such as the Joint Commission,[1]
- Surgical site, side, level, implant, procedure and patient confirmation for surgeons and surgical team members.

Despite the many legal and regulatory consent requirements, consent inconsistencies and errors remain one of six most frequent causes of 'preventable surgical harm' as identified in the Joint Commission Sentinel Events database.[2]

Surgical consent in elective surgery is not a discrete event or document rather a sequential surgical safety process. To provide safest and best quality surgical care, surgical consent should be:

- **Timely** - if possible prior to the day of surgery (for elective surgery) and prior to pre-op holding area for emergency surgery (if possible)
- **Accurate** - proper clearly identified surgical site, side, level, implant, procedure and patient
- **Understandable** - legible, without complex medical terminology or jargon, in a language understandable for the patient (with a translator if needed), in a quiet well lit room with family/friend/s for support
- **Complete** - providing legal documentation in the facility-based format including time, date, patient name, clear procedure description and both patient and witness signature,
- **Surgeon-led** with a full/adequate discussion with time for questions to test understanding and retention.

Inaccuracy, deficiency or absence of any of these surgical consent components increases risk of surgical harm.

Orthopaedic surgeons and surgical teams recognize the importance of a surgeon-led timely, accurate, understandable and complete surgical consent process in elective surgery as a key component of surgical safety.

Surgical consent is also recognized as key element of patient-surgeon communication and patient-centered care. Proper surgical consent can increase both surgical patient understanding and satisfaction. Active engagement of the patient and family in surgical consent discussions facilitates patient-surgeon shared surgical decision-making. Placing and maintaining the patient in the center of the consent process maintains safety and best surgical outcomes in clear focus for the entire surgical team. Use of some complimentary consent programs such as multi-media or classroom presentations can increase understanding, retention and satisfaction. Older or culturally diverse patients have been shown to both understand and retain less surgical consent information. Surgeon directed questions, "say-backs" and "read-backs" to confirm understanding can increase retention and improve surgical patient satisfaction.

The AAOS recommends routine utilization of patient-centered surgical consent processes in elective surgery to minimize - with a goal of eliminating - preventable surgical harm.

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Position Statement

Physician Directed Use of Medical Products

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Definitions

Off-label is a term describing the physician directed use of prescription drugs, biologics, and approved medical devices in a manner that is not specified in the labeling approved by the U.S. Food and Drug Administration (FDA). For cleared medical devices, off-label means any use that is not included in the cleared indications for use." Labeling is considered any written material which accompanies, supplements, or explains the product.

Background - Practice of Medicine

Currently, the practice of medicine presents difficult challenges for the orthopaedic surgical community to stay abreast of new and innovative medical developments that may advance patient care in an era when technological developments may rapidly outpace traditional educational opportunities for discussion and the regulatory review framework. It is not uncommon for some uses of medical products to become standard of care in the practice of medicine before there is approval or clearance of the labeled indications for use for a particular product.

Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics, and devices according to their best knowledge and judgment.[1] The government has long recognized that physicians may prescribe or administer any legally marketed product for an off-label use within the practice of medicine. If physicians use a product for an indication not in the approved or cleared labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, to maintain awareness of the product's use and effects, and to discuss alternative treatments. The practice of medicine is regulated by state laws, and surgeons should adhere to all applicable state and federal laws and regulations.

FDA Regulatory Principles

The FDA regulates the marketing approval or clearance, labeling, and promotion of pharmaceutical, medical device, and biologic products in the United States. These products may only be labeled, promoted, and advertised for the uses that the FDA has approved or cleared.

Promotion means all proactive activities (written, oral or otherwise) that directly or indirectly market, sell or support product sales and use, or that contribute to the sales growth of a company's products. For example, the FDA views promotion as including written labeling and advertising materials, interactions with sales representatives, company websites, dissemination of journal articles, and, in some cases, trade show presentations, physician training, and

reimbursement advice. Certain medical education activities also can stray into promotional conduct if undertaken for the purpose of inducing commercial sales.

FDA released updated guidance in 2014, intended to clarify their current thinking on the exchange of information related to unapproved new uses of drugs, biologics, devices, and combination products. FDA regulations do allow the exchange and dissemination of scientific information on a product's unapproved uses in certain circumstances. Types of scientific exchange include:

1. scientific or medical journal articles;
2. scientific or medical reference texts;
3. clinical practice guidelines.

Labeling

The FDA and the manufacturer must negotiate the labeling claims of a medical product to ensure that the labeling accurately reflects the safety and effectiveness data presented in the manufacturer's marketing application. If surgeons are unsure of the labeled indication of the medical product, the FDA website[3] contains information for medical products on approved labeling and indications for use.

Restrictions on Distribution and Use

In some circumstances, the FDA authorizes the use of risk, evaluation, and mitigation strategies (REMS) to limit the distribution of medical products to certain physicians or to restrict the distribution to particular patients. These products must be used according to their labeled indications. Another example of restricted distribution is humanitarian use devices that have been authorized for marketing for a rare disease or condition and which requires IRB approval for the use of the device for the FDA approved indication.

Special Populations

In certain patient populations, off-label use of medical products is extensive where appropriate therapies are not available. Two of those populations include oncology and pediatric patients. Oncology patients depending on the type and severity of the disease are frequent recipients of off-label therapies. The FDA has recently recognized the need for accelerating the approval of cancer drugs. Pediatric surgeons are likely to use off-label therapies on neonates, infants, children, and adolescents due to the lack of medical products on the market labeled for use in these populations. Surgeons find a lack of approved pediatric devices for many reasons including a historical exclusion of children in medical trials, and liability concerns among other issues. In 2007, the Congress recognized significant issues with pediatric device development and signed the Pediatric Medical Device Safety Act into law as part of the Food and Drug Administration Act Amendments of 2007.

Best Practices and Professional Standards

There are instances when the off-label use of medical products has evolved to be recognized as a generally accepted medical standard within the physician community. Public health agencies, such as CMS, have authorized reimbursement of off-label use of approved products in specially defined circumstances where such use is recognized under generally accepted medical standards. Standard of care changes over time and new literature may continually alter the legal landscape. Surgeons should adhere to best medical practices in the off-label use of legally marketed products. Surgeons should appropriately counsel patients about the benefits and risks of the proposed treatment, and alternative treatments that might be available. Surgeons are

encouraged to report adverse events occurring with the off-label usage of medical products to manufacturers and/or appropriate federal authorities.

Orthopaedic surgeons should be aware of company sales and marketing tactics that may undermine the free and credible exchange of scientific information on new products and technologies, including inappropriate product comparisons between FDA approved and cleared products, misleading claims regarding product safety, efficacy and outcomes, the dissemination of biased clinical data, and the omission of adverse clinical data.

Orthopaedic surgeons should be aware of the potential that certain interactions may create an actual or potential conflict of interest in advancing new scientific and clinical information to the orthopaedic surgeon community and avoid compromising situations that may call independent medical judgment into question. The orthopaedic surgical community should rely for guidance on the *AAOS Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships* in evaluating industry interactions that directly or indirectly involve communications relating to the use or recommended use of unapproved products.

Orthopaedic surgeons with compensated arrangements with industry should undertake appropriate precautions and financial disclosures in CME, grand rounds and other medical education and professional activities that may involve communications and interactions regarding the off-label use of products and avoid scenarios in which the surgeon is used in white coat marketing activities that are promotional in nature.

Enforcement Actions and Trends

Physicians and surgeons are not insulated from the law if they are engaging in sales and marketing activities on behalf of or in conjunction with manufacturers. The off-label promotion of medical devices is expected to have increased scrutiny from federal authorities. Violations of the federal False Claims Act are cited in *qui tam* suits which may or may not also allege conflicts of interest with certain manufacturers.

The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons may prescribe or administer any legally marketed product for an off-label use within the authorized practice of medicine in the exercise of appropriate medical judgment for the best interest of the patient. If surgeons use a product for an indication not in the approved or cleared labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain awareness of the product's use and effects. Surgeons should appropriately counsel patients about the benefits and risks of the proposed treatment, and alternative treatments that might be available. In the case of an adverse event with an off-label use, surgeons can submit a report to the manufacturer and/or the FDA. Orthopaedic surgeons should disclose all conflicts of interest to patients, institutions, and medical associations and adhere to all state and federal laws and regulations.

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For additional information, contact the Public Relations Department at 847-384-4036.

Frequently Asked Questions About Physician Directed Use

Q. What is off-label use?

A. "Off-label" or physician directed use for prescription drugs, biologics, and approved medical devices means any use that is not specified in the labeling approved by the U.S. Food and Drug Administration (FDA). For cleared medical devices, "off-label" means any use that is not included in the cleared "indications for use." Labeling is considered any written material which accompanies, supplements, or explains the use, purpose, and indications of the product.

Q. The term "off-label use" seems pejorative. What other terms are used to describe off-label use?

A. The phrase "physician-directed application" is used by some physicians and surgeons.

Q. Where do I find out the specific labeled indications for use on a product that I'm using?

A. Labeling information is available on material accompanying the medical product. For the most current device labeling information, orthopaedic surgeons should contact the product manufacturer's representative. The FDA website will not contain the most up-to-date labeling information for Class III or pre-market approval (PMA) devices, due to frequent supplemental approval applications. The FDA's 510k data base does not contain labeling information on 510k cleared devices.

Q. Does the FDA regulate the practice of medicine?

A. No. The FDA by law does not regulate or assert legal jurisdiction over the practice of medicine. State law provides the authority and legal standards for the practice of medicine.

Q. How does FDA regulate manufacturers in connection with the promotion of company products?

A. The FDA regulates manufacturers in the advertising and promotion of approved and cleared company products. FDA regulations prohibit the advertising and promotion of the off-label use of medical products. An off-label use of a medical product cannot be described by the company as safe and effective for a particular use.

Q. Are surgeons entitled to receive scientific information relating to unapproved products and technologies?

A. Yes. Companies may provide unbiased, non-misleading scientific and clinical information regarding their products in response to an unsolicited request for information from a surgeon.

Q. Can company representatives provide technical support in the operating or procedure room when the procedure or product involves an off-label use?

A. No, company representatives are not allowed to provide technical or verbal guidance for an off-label use.

Q. How is standard of care determined?

A. Standard of care changes over time due to the available literature, use of medical products, and outcomes of medical and product liability legal cases. It is not uncommon for some technologies to become standard of care in the practice of medicine before there is formal regulatory approval or clearance of a particular product.

Q. In practical terms, what happens when a manufacturer attempts to run a clinical trial on a marketed product in order to claim another indication on their labeling?

A. Identifying and enrolling patients in such trials is often difficult since the product is available on the market and is often used in an off-label manner. Patients are increasingly unwilling to be randomized in these trials when they can acquire the marketed product for the off-labeled indication from a physician or surgeon.

Q. Since the FDA does not regulate the practice of medicine, can I use a product in any manner in which I choose?

A. A physician may use a medical product for an indication not in the approved or cleared labeling. Physicians and surgeons should be well informed about the product and base the use on firm scientific rationale and sound medical evidence. Surgeons should counsel patients about the benefits and risks of the proposed treatment and alternative therapies that may be appropriate.

Q. Is the consent process sufficient for the off-label use of a medical product?

A. Institutions/facilities have different practices for issuing informed consent and the documentation of off-label use. Additionally, some physicians may not be aware of the labeled indication of the medical product and may unknowingly use a product in an off-label manner. Surgeons may want to explain to patients that within the practice of medicine, physicians may choose a treatment option that is off-label if it is in the best interest of the patient. Surgeons may want to document the planned use of off-label products in the medical chart.

Q. Should I document the use of off-label medical products in the patient's medical chart?

A. Documentation in medical charts may vary according to the standard of care of the product and the availability of "on-label" products to treat the medical condition.

Q. What should I do if I find that a patient has experienced an adverse event with the off-label use of a medical product?

A. Physician reporting of adverse events is voluntary. Adverse events can be reported to the FDA's Medwatch system at:
http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085568.htm

Physicians and surgeons may want to alert the hospital and contact the company to ensure that it is aware of the problem.

User-facilities, such as hospitals and nursing homes, are legally required to report suspected medical device-related deaths to both FDA and the manufacturer, if known, and to report medical device-related serious injuries to the manufacturer or to FDA, if the manufacturer is unknown.

Q. What are the latest enforcement trends regarding off-label use?

A. Recently, there have been several significant government enforcement actions against pharmaceutical and other companies for off-label advertising and promotion of FDA approved or cleared products to physician communities. These enforcement actions reveal industry tactics that may manipulate, distort and undermine the natural and essential collaboration and exchange of scientific and medical information between academia, physicians and industry.

Physicians and surgeons are not insulated from the law if they are engaging in sales and marketing activities on behalf of or in conjunction with manufacturers. The off-label promotion of medical devices is expected to have increased scrutiny from federal authorities. Violations of the federal False Claims Act are cited in *qui tam* suits which may or may not also allege conflicts of interest with certain manufacturers.

Q. What do conflicts-of-interest have to do with off-label use?

A. Federal government agencies and Members of Congress have increased their scrutiny of conflicts-of-interest in response to the filing of *qui tam* suits. These suits allege that employees or consultants of medical device, biologic, or device manufacturers engage in illegal marketing schemes to promote the use of a medical product for unapproved, cleared, or licensed indications.

In July 2007, Jazz Pharmaceuticals agreed to pay the government $20 million to settle criminal and civil allegations in an off-label marketing investigation. A psychiatrist was charged with violating criminal misbranding provisions of the Food, Drug and Cosmetic Act after he gave talks around the country promoting a drug for off-label uses. The psychiatrist was a consultant of Jazz Pharmaceuticals and also advised physicians how to conceal off-label uses from insurers to maximize reimbursements.

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Information Statement

Surgeon and Surgical Team Concentration

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Maintaining concentration among all team members in high intensity/high risk work environments has been demonstrated to be critical for effective performance. Maintaining concentration among all surgical team members in operating rooms (ORs) and peri-operative areas is a critical component of surgical patient safety.[1] Loss of concentration and distraction among surgical team members has been identified as a frequent contributor to surgical errors. Anything that diverts attention from critical tasks (i.e. distraction) runs a significant risk to undermine safe task completion.[2] Effective surgical team concentration supports shared team focus and elevates team intelligence optimizing safety and improving surgical outcomes.

The AAOS believes that identification and removal of distractions that undermine concentration is a responsibility of all surgical team members.

Common specific identifiable impediments to surgical team concentration:

1. Noise: Many orthopaedic OR environments are filled with noise. The combined effect of noise created by surgical power instruments, patient monitoring devices, heating/cooling/ventilation fans, and surgical team conversation can create distraction, and impair surgical team communication.[3] To minimize OR noise distractions and maximize effective surgical team communication, all surgical team members, including surgeons, nurses, and other operating team members, should minimize noises that are disruptive or noises that create distraction. Silence and focus is particularly important during critical portions of surgical cases, including timeouts, briefings, debriefings and implant selection/confirmation. Every OR team member is responsible for situational monitoring that effectively limits distractive noises and facilitates surgical team members attention on all the important elements of the surgical procedure itself.
2. Fatigue: Fatigue among surgeons and surgical team members can impair concentration. Limitations on resident work hours are the result of studies identifying fatigue as a cause of medical errors.[4] Fatigue can result from lack of sleep, inadequate recovery from long distance travel, illness or cumulative overwork and/or cumulative sleep deprivation. Regardless of its cause, fatigue can limit effective focus on task and concentration.[5] Self-regulation among team members is important to promote safety. If fatigued, surgeons or surgical team members must always ask themselves, 'In my current state of fatigue, can I concentrate effectively enough to perform this procedure in a safe manner?' If not, safe alternatives such as replacement of fatigued team members or re-scheduling of non-emergent procedures should be considered to optimize safety.

3. Task Saturation: According to Gordon[6], there are two causes of task saturation; information overload and inadequate prioritization of inputs. Surgeons and team members must remain effectively focused on single tasks. Multi-tasking may, in a surgical setting, impair concentration and can contribute to surgical errors. Effective concentration among team members is focus upon single task completion in a standardized sequence. The ability to manage task saturation requires concentration to 'triage' information input in order of importance and develop techniques for analysis and action on those inputs. Increased task saturation is unavoidable and may be necessary in certain orthopaedic situations such as assessment and management of the poly trauma patient. In this setting, team organization and situational leadership can mitigate some of the negative effects of task saturation and thereby maintain safe processes.

4. Continuation Bias: Surgeons and surgical team members are task and goal oriented. Task completion focus, however, can impair team sensitivity for clues that may require deviation from normal protocols or techniques. Continuation bias is the complete and intense focus on finishing familiar tasks that limits awareness of evidence suggesting needed attention to evolving problems. Continuation bias can impair team performance and surgical decision making. This is most often seen in OR settings when unusual or unexpected events necessitate consideration of deviations from normal procedural steps. Effective surgical teams maintain concentration on the completion of standardized sequential steps of a procedure but allow measured adaptability for unexpected surgical events.[7]

5. Task Repetition: Consistency and standard procedures are recognized as important surgical safety principles to assure optimal surgical outcomes. However, the performance of tasks in a repetitive fashion has the potential to undermine concentration and create complacency. Repetitive tasks not directly related to clinical care, such as completion of the surgical record or EMR documentation have the potential to distract the OR team from more critical elements of the surgical procedure.[8] It is important for surgeons and team members to maintain vigilance and the same degree of caution and focused concentration even during the more the repetitive components that exist in any surgical procedure. Active team member situation monitoring allows for concentration on details in familiar or common procedures, just as in less common procedures.

6. Communication Devices: Personal cell phones, computers, tablets and other communication devices have become indispensable and critical tools for timely communication and acquisition of important information. Effective use of these devices is important to fulfill clinical responsibilities. Removal of these devices is impractical and may be dangerous in some critical care environments. However, inappropriate and unnecessary use in OR settings may introduce distractions and prevent focus on the important clinical task at hand. It is important for OR policies and procedures to assure appropriate use of such devices in the OR setting to promote optimal surgical and emergency care.

7. Team Member Impairment: The side effects of medication or substance abuse impair surgeon and team performance. It is the responsibility of all surgical team members to be aware of and report behaviors that may indicate impairment or substance abuse.

8. Disruptive Behavior: Concentration of the surgical team is undermined by disruptive behavior of any surgical team member, including surgeons. Abusive personal conduct, whether verbal, emotional or physical, can have a serious impact on patient safety.[9] These impacts include increased stress levels within a team, frustration, inhibition of team collaboration, inhibition of information transfer and impaired communication. All of these behaviors inhibit concentration and are not conducive to effective team function. It is the ongoing obligation of the surgeon to continually assess behaviors that he or she, or any member of the team may exhibit that inhibits effective team function.

The AAOS supports creating and maintaining OR environments that promote optimal concentration and minimize distraction among all surgical team members: surgeons, nurses, surgical team members and surgical facility administrators. The AAOS supports team centered strategies focused on a shared monitoring model to manage distraction and facilitate concentration, with the goal of improved surgical safety and team performance.

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For additional information, contact the Public Relations Department at 847-384-4036.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Information Statement

Surgical Site and Procedure Confirmation

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Orthopaedic surgical patients are at risk of surgical errors based upon procedures requiring accurate confirmation of proper limb(s), digit(s), spinal level(s), and surgical procedure(s). A recent survey study revealed that 21 percent of hand surgeons reported performing at least one wrong-site surgery.[5] Errors in surgical confirmation contribute to wrong- patient, surgical site, side, procedure, spinal level, and implant surgery.

The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons, surgical teams, and patients are responsible for reliably confirming all surgical information needed to properly identify and perform any planned preventive, diagnostic, and therapeutic services. Proper confirmation is essential for the improvement of both the individual patient and general population and is supported through effective communication, informed patient choice, and shared decision making.

Accurate, timely and effective confirmation is supported through:

- **Surgical Team Engagement:** The operating room is similar to an airplane cockpit, where improvements in communication through 'Crew Resource Management' have demonstrated improved safety. All members of the surgical team should feel valued and are emboldened to 'speak up' and actively participate. It is the responsibility of all surgical team members to monitor and report potentially harmful situations before patient harm is caused. As with pilots and their crews' use of standardized flight procedures, use of standardized surgical systems, including the use checklists, is critically important to keep patients safe.

- **Patient Confirmation:** According to data from the Joint Commission (2006), 17 percent of wrong-site surgeries were performed on the wrong patient. Effective communication including 'Read-Backs' that use two identifiers (e.g., name and birth date or medical record number), patient/family involvement, and accurate surgical 'Time-Out' improve proper patient confirmation. According to the World Health Organization's Surgical Safety Checklist, patient identification is the first part of both the sign-in and the time-out after team introductions. The use of identification bands that cannot be removed and are worn throughout the hospitalization reduces errors.

- **Surgical Site and Procedure Confirmation:** The Canadian Orthopaedic Association introduced the "Operate through Your Initials" initiative in 1994, instructing orthopaedic surgeons to mark the incision site with their initials so that they would know the precise location through which they would make the incision. In this way the ink acts as a bull's-eye

drawing the surgeon's attention to the correct surgical site. The AAOS introduced the "Sign Your Site" safety program in 1998 designed to reduce wrong site surgeries through improved site identification. Permanent ink should be used to mark the site(s) with the patient's assistance prior to surgery and confirmed by the surgical team during the 'Time-Out' immediately prior to starting the surgical procedure. To ensure the correct spine level, the North American Spine Society recommends its "Sign, Mark, and X-ray" program (SMaX), as spinal levels are not always visually identifiable and should be confirmed with imaging.

- **Multiple Procedures and Surgical Sites Confirmation:** Many surgeries in orthopaedics contain multiple procedures and surgical sites. Confirmation of the intended multiple procedures and sites is essential to provide the safest surgical care. A separate 'Time-Out' for each separate procedure and site, with confirmation from the entire surgical team, is recommended.

- **Surgical Implant/s Confirmation:** The proper implant, including the correct side, size, and implant type, should be confirmed before being surgically implanted. Implants to be opened individually during the procedure should be confirmed by the entire surgical team prior to opening the package by reading directly from the implant package label. Use of a separate implant 'Time-Out' supports focused team communication and reduces surgical errors. Proper type, side, and/or size of individual implants, as part of a set of implants (often opened at the beginning of orthopaedic cases e.g., plates and screws) should be confirmed individually by the surgical team as each part is requested by the surgeon.

  Many orthopaedic procedures include temporary implants that need to be removed before closing the incision, such as guide wires, pins, or screws inserted as guides for fracture fixation and/or drill/saw guides. These temporary implants should be counted and confirmed with a 'Read-Back' list by the surgical team. Intra-operative imaging may be useful for some procedures to confirm temporary hardware fixation removal.

- **Biopsy/Specimen Confirmation:** Surgical specimens, such as fluid/tissue for culture, analysis, or pathologic evaluation, should be identified and confirmed using the patient name and intended testing, by the entire surgical team at the time the specimen is obtained. During the 'De-Brief' as the surgery is completed, the surgical team should confirm aloud with a 'Read-Back' the specimen including the patients name and type of testing to be performed. The confirmation of the surgical specimen should be recorded in the patient record.

The Joint Commission Universal Protocol recommends accurate and timely surgical site and procedure confirmation.[7] Confirmation processes should be organized, customized, implemented and supported based upon individual facility/organization needs to best optimize surgical safety.

The AAOS believes that immediately prior to incision the surgeon and entire operative team should confirm the identity the patient, read aloud and confirm the informed surgical consent, and confirm proper surgical site marking. The surgeon should lead the process of procedure confirmation. If the planned surgery involves multiple surgical sites, procedures and implants, each should be individually identified during the initial surgical 'Brief', the surgical 'Time-Out', and the final 'De-Brief', as well as confirmed individually with a 'Time-Out' before each planned separate site, procedure, and implant.

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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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Information Statement

Unified Information Statement on Orthopaedic Surgical Safety

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

In 1997 the American Academy of Orthopaedic Surgeons (AAOS) introduced surgical site identification through the '*Sign Your Site*' program designed to reduce Wrong Site Surgery (WSS).[1] In 2002 the Joint Commission (JC) incorporated surgical site marking into an expanded surgical safety program - Universal Protocol (UP).[2] Despite the introduction and adoption of many surgical safety initiatives including UP, improvements in surgical care and reduction of preventable harm remains an important shared safety goal for surgical patients, surgeons, healthcare organizations and payers. [3,4] A recent survey of orthopaedic surgeons reveals that most orthopaedic surgeons use safety processes in hospital settings, but use safety processes much less frequently for procedures performed in surgicenters and office settings.[5]

All orthopaedic surgeons support minimizing - with a goal of eliminating - all types of preventable surgical harms including wrong site/side/level/procedure/patient/implant surgeries.

Safest surgical care can be provided through highly organized surgical systems of care designed to minimize preventable harms by effectively managing the interfaces among patients, families, physicians, surgical staffs, suppliers, equipment, and surgical environments. Several important components of safe surgical care have been identified as deficient or absent in adverse surgical events reported to the JC including:[6]

- **Surgical Consent – accurate, timely and understandable**
- **Surgical Team and Patient Communication – effective, team-based, and transparent**
- **Surgical Site/Side/Level/Procedure/Patient Identification/Implant – clearly marked, identified and confirmed as accurate surgical site, side, level, procedure, and patient**
- **Surgical Checklists – standardized evidence-based and/or consensus-based 'best' surgical practices used consistently for key elements of surgical procedure(s)**
- **OR Environment Supportive of Concentration – Focused surgical team effort without distraction**
- **Surgical Safety Data Collection – regular collection and analysis of surgical safety and quality data supporting surgical performance improvement**

Orthopaedic surgeons and organizations recognize the national safety goals of the JC, National Quality Forum (NQF) and Agency for Healthcare Research and Quality (AHRQ) designed to minimize preventable harms and improve surgical outcomes.
Orthopaedic surgeons also recognize the important role of leadership and collaboration with hospital administration, anesthesia, nursing and other surgical support services to insure that these surgical safety practices are supported and regularly used at the 'unit level' of care for all orthopaedic surgical patients.[7] Regular use of these safe surgical care processes has been shown to improve the safety, quality, and value of surgical care.[8]

All orthopaedic surgeons and organizations support routine utilization of appropriate and effective surgical safety practices and processes in all orthopaedic settings – hospital ORs, ambulatory surgery centers and office procedure rooms – providing the best possible surgical care and outcomes for all orthopaedic patients.

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3. JC, NQF and AHRQ National Patient Safety Goals, 2012
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5. AAOS Surgical Safety Survey, 2011
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7. AHRQ SUSP Program, 2012
8. WHO *Safe Surgery Saves Lives* Program, 2009

For additional information, contact the Public Relations Department at 847-384-4036.

AAOS American Academy of Orthopaedic Surgeons
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PROFESSIONALISM

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Standards of Professionalism

Professional Relationships

Adopted April 18, 2005

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

As healers and professionals with specialized knowledge, orthopaedic surgeons hold a unique position of trust with patients, fellow physicians and health care providers. The professional relationships established between orthopaedic surgeons, fellow physicians and health care professionals are powerful tools that aid in caring for patients. To this end, the American Academy of Orthopaedic Surgeons and the American Association of Orthopaedic Surgeons ("AAOS") have adopted these Standards of Professionalism.

The medical profession requires physicians to subordinate their own interests in favor of the patient's best interests and hold themselves to high ethical and moral standards. Patients who entrust their medical care to orthopaedic surgeons have an expectation that they will be treated with compassion, empathy, honesty and integrity. It is incumbent on orthopaedic surgeons to develop professional relationships with colleagues and other health care professionals that satisfy the patient's expectations.

The Standards of Professionalism draw from the aspirational Code of Medical Ethics and Professionalism that appears in bold italics. The statements that follow the aspirational Code establish the minimum standard of acceptable conduct for orthopaedic surgeons in their professional relationships. Violations of these minimum standards may serve as grounds for a formal complaint to and action by the AAOS as outlined in the AAOS Bylaws Article VIII.

These Standards of Professionalism apply to all AAOS Fellows and Members in their interactions as healers and as professionals valued for their knowledge and expertise. Only an AAOS Fellow or Member may file complaints of an alleged violation of these Standards of Professionalism regarding another AAOS Fellow or Member.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I. A.:
The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns.

Mandatory Standard:

1. An orthopaedic surgeon shall, while caring for and treating a patient, regard his or her responsibility to the patient as paramount.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, V. A.:
Good relationships among physicians, nurses, and other health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development and utilization of an expert health care team that will work together harmoniously to provide optimal patient care.

Mandatory Standards:

2. An orthopaedic surgeon shall maintain fairness, respect, and appropriate confidentiality in relationships with colleagues and other health care professionals. An orthopaedic surgeon shall communicate in a manner that enhances the profession.

3. An orthopaedic surgeon shall conduct himself or herself in a professional manner in interactions with colleagues or other health care professionals.

4. An orthopaedic surgeon shall work collaboratively with colleagues and other health care providers to reduce medical errors, increase patient safety, and optimize the outcomes of patient care.

5. An orthopaedic surgeon who transfers care of a patient to another physician or other health care provider shall facilitate the transfer of care for the welfare of the patient and cooperate with those receiving the patient.

Adopted April 18, 2005

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Standards of Professionalism

Providing Musculoskeletal Services to Patients

Adopted April 18, 2005. Amended April 24, 2008

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

The orthopaedic profession exists for the primary purpose of caring for the patient. As a member of this profession, an orthopaedic surgeon should be dedicated to providing competent musculoskeletal service with compassion and respect.

The Standards of Professionalism draw from the **aspirational** *Code of Medical Ethics and Professionalism* that appears in bold italics. The statements that follow the aspirational *Code* establish the minimum standard of acceptable conduct for orthopaedic surgeons when providing musculoskeletal services to patients. Violations of these **mandatory** standards may serve as grounds for a formal complaint to and action by the AAOS as outlined in the AAOS Bylaws Article VIII.

These Standards of Professionalism apply to all AAOS Fellows and Members in their interactions as healers and as professionals valued for their knowledge and expertise. Only an AAOS Fellow or Member may file complaints of an alleged violation of these Standards of Professionalism regarding another AAOS Fellow or Member.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I. A.:
The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns.

Mandatory Standard:

1. An orthopaedic surgeon shall, while caring for and treating a patient, regard his or her responsibility to the patient as paramount.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I. C.:
The orthopaedic surgeon shall not decline to accept patients solely on the basis of race, color, gender, sexual orientation, religion, or national origin or any basis that would constitute illegal discrimination.

Mandatory Standard:

2. An orthopaedic surgeon shall treat patients equally and shall not decline to accept patients solely on the basis of race, color, ethnicity, gender, sexual orientation, religion or national origin.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I. D.:
The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue service only after giving adequate notice to the patient so that the patient can secure alternative care. Both orthopaedic surgeons and patients may have contracts with managed care organizations, and these agreements may contain provisions which alter the method by which patients are discharged. If the enrollment of a physician or patient is discontinued in a managed care plan, the physician will have an ethical responsibility to assist the patient in obtaining follow-up care.

Mandatory Standard:

3. An orthopaedic surgeon, or his or her qualified designee, shall be available to provide needed and appropriate care of a patient.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, I. F.:
When obtaining informed consent for treatment, the orthopaedic surgeon is obligated to present to the patient or to the person responsible for the patient, in understandable terms, pertinent medical facts and recommendations consistent with good medical practice. Such information should include alternative modes of treatment, the objectives, risk and possible complications of such treatment, and the complications and consequences of no treatment.

Mandatory Standard:

4. An orthopaedic surgeon, or his or her qualified designee, shall present pertinent medical facts and recommendations to and obtain informed consent from the patient or the person responsible for the patient.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, II. B.:
The orthopaedic surgeon should conduct himself or herself morally and ethically, so as to merit the confidence of patients entrusted to the orthopaedic surgeon's care, rendering to each a full measure of service and devotion.

Mandatory Standards:

5. An orthopaedic surgeon shall serve as the patient's advocate for treatment needs and exercise all reasonable means to ensure that the most appropriate care is provided to the patient.

6. An orthopaedic surgeon shall safeguard patient confidentiality and privacy within the constraints of the law.

7. An orthopaedic surgeon shall maintain appropriate relations with patients.

8. An orthopaedic surgeon shall respect a patient's request for additional opinions.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, IV. A.:
The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill, and should make available to patients and colleagues the benefits of his or her professional attainments. Each orthopaedic surgeon should participate in relevant continuing medical educational activities.

Mandatory Standards:

9. An orthopaedic surgeon shall commit to life-long medical and scientific learning.

10. An orthopaedic surgeon shall provide only those services and use only those techniques for which he or she is qualified by personal education, training, or experience.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, II. D.:
Because of the orthopaedic surgeon's responsibility for the patient's life and future welfare, substance abuse is a special threat that must be recognized and stopped. The orthopaedic surgeon must avoid substance abuse and, when necessary, seek rehabilitation. It is ethical for an orthopaedic surgeon to take actions to encourage colleagues who are chemically dependent to seek rehabilitation.

Mandatory Standards:

11. An orthopaedic surgeon with a temporary or permanent impairment due to substance abuse (alcohol and/or drugs) shall seek professional evaluation and treatment in order not to jeopardize patient care and safety. He or she shall limit or cease his or her practice as recommended by his or her physician(s) or health care professional(s).

12. An orthopaedic surgeon with a temporary or permanent physical or mental disability shall seek professional evaluation and treatment in order not to jeopardize patient care and safety. He or she shall limit or cease his or her practice as recommended by his or her physician(s) or health care professional(s).

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III. A.:
The practice of medicine inherently presents potential conflicts of interest. When a conflict of interest arises, it must be resolved in the best interest of the patient. The orthopaedic surgeon should exercise all reasonable alternatives to ensure that the most appropriate care is provided to the patient. If the conflict of interest cannot be resolved, the orthopaedic surgeon should notify the patient of his or her intention to withdraw from the relationship.

Mandatory Standard:

13. An orthopaedic surgeon shall disclose to the patient any conflict of interest, financial or otherwise, that may influence his or her ability to provide appropriate care.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, III. B.:
If the orthopaedic surgeon has a financial or ownership interest in a durable medical goods provider, imaging center, surgery center or other health care facility where the orthopaedic surgeon's financial interest is not immediately obvious, the orthopaedic surgeon must disclose this interest to the patient.

Mandatory Standards:

14. An orthopaedic surgeon shall not enter into any contractual relationship whereby the orthopaedic surgeon pays for the right to care for patients with musculoskeletal conditions.

15. An orthopaedic surgeon shall make a reasonable effort to ensure that his or her academic institution, hospital or employer shall not enter into any contractual relationship whereby such institution pays for the right to care for patients with musculoskeletal conditions.

16. An orthopaedic surgeon or his or her professional corporation shall not couple a marketing agreement or the provision of medical services, supplies, equipment or personnel with required referrals to that orthopaedic surgeon or his or her professional corporation.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

Care and Treatment of the Medically Underserved

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

What are the orthopaedic surgeon's obligations to care and/or treat the medically underserved, i.e., patients who do not have insurance and who are unable to pay for such services?

Applicable provision of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

"X. **Societal Responsibility.** The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support and participation of the orthopaedic surgeon."

Applicable provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

"I. B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedist has an obligation to render care only for those conditions that he or she is competent to treat.

"I. D. The orthopaedic surgeon may choose whom he or she will serve. An orthopaedic surgeon should render services to the best of his or her ability. Having undertaken the care of a patient, the orthopaedic surgeon may not neglect that person. Unless discharged by the patient, the orthopaedic surgeon may discontinue services only after giving adequate notice to the patient so that the patient can secure alternative care. Both orthopaedic surgeons and patients may have contracts with managed care organizations, and these agreements may contain provisions which alter the method by which patients are discharged. If the enrollment of a physician or patient is discontinued in a managed care plan, the physician will have an ethical responsibility to assist the patient in obtaining follow-up care. In this instance, the orthopaedic surgeon will be responsible to provide medically necessary care for the patient until appropriate referrals can be arranged."

"VI. C. Physicians should be encouraged to devote some time and work to provide care for individuals who have no means of paying."

"IX. A. The honored ideals of the medical profession imply that the responsibility of the orthopaedic surgeon extends not only to the individual but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon."

Other references

American Academy of Orthopaedic Surgeons, Position Statement on Health Care Coverage for Children at Risk, September, 1997.

American Medical Association, *Current Opinions* of the Council on Ethical and Judicial Affairs,

Section 2.095 ("The Provision of Adequate Health Care")
Section 9.065 ("Caring for the Poor")

American Medical Association Council on Ethical and Judicial Affairs, "Caring for the Poor," JAMA, 269: 2533-2537 (1992).

Background

A significant portion of the citizens in the United States have inadequate access to medical care.[1] According to a 1992 study, 17 percent of Americans had inadequate access to physicians, reflected in such factors as premature death and disability caused by controllable illnesses and high rates of infant and child mortality.[2] A 1996 study by researchers in the Harvard School of Public Health found that 37 million Americans (31 percent) were without health insurance or had difficulty getting or paying for medical care at some time during 1995.

Since 1988, the number of *uninsured* persons in the United States has increased steadily each year. The non-elderly uninsured population grew from 33.5 million in 1988 to nearly 40 million in 1994, the year of the most recent national estimate.[4]

The number of American under age 65 with private insurance who are *underinsured* is estimated to be between 25 to 48 million, or ten to twenty percent of the population. These figures are 50% larger than analogous figures for 1987 and may be growing, since employers are offering less generous health insurance policies than in the past.[5] In addition, the percentage of Americans with employer-sponsored health insurance is decreasing; nearly 6% fewer American under age 65 had such insurance in 1995 than in 1988.[5]

While a lack of insurance or underinsurance do not necessarily result in reduced access to medical care, it clearly has an impact. People who are uninsured report up to 47% fewer visits to physicians and fewer hospitalizations than those who have insurance, even though they are in worse health.[6]

The lack of access to health care in the United States is disproportionately distributed throughout the population. Well over half of U.S. population living under the poverty level are women and children. One in seven children in the United States is without health insurance. This is nearly one-fourth of the total uninsured population. When compared to the insured, they are four times more likely to report needing, but not receiving health care.[7] In addition, strong differences in access to and utilization of health care persist for various racial and ethnic groups.[8] The lack of access to health care, particularly primary and preventative health care, has pronounced consequences both for the health care system and for society in general.

In addition, as the health care environment changes, there has been tendency by many Managed Care Organization (MCOs) not to cover those without insurance or those who are underinsured.

Ethical Considerations

I. Obligation of Individual Physicians To Treat the Medically Underserved

Organized medicine has long recognized that the individual physician has an ethical obligation to treat the medically underserved. For example, the first *Code of Ethics* of the American Medical Association (AMA) in 1847 provided that "to individuals in indigent circumstances, professional services should be cheerfully and freely accorded."[9] More recently, in 1993, the AMA Council on Ethical and Judicial Affairs stated that medical professionals should reaffirm their responsibility for making health care available to the needy.[6]

Each physician has a moral and ethical obligation to care for the medically underserved. The objective of the medical professional is to care for the sick, to treat the ill without regard for who they may be, what their diseases are or whether they can pay. While reimbursement may follow, the pursuit of material gain is not the primary end of the medical profession.

The obligation of individual physicians to help care for the medically underserved is based in the concept of professionalism, including its pursuit of moral ideals such as justice and beneficence. By drawing on the physician's mercy, compassion and empathy, charity care strengthens the bond between physician and patient that have often been weakened by increased commercialization of medicine. Providing care to patients without expectation of payment reaffirms the primacy of medicine as a helping profession.

Although physicians provide considerable charity care, improvements can and should occur. For example, in 1996, the AMA House of Delegates recognized a growing need for voluntary physician efforts to care for the uninsured in an era of increased fiscal constraint in both public and private sector programs.[10] While most physicians provide free or reduced fee care within their practices, in 1993 as many as one-quarter to one-third failed to provide services to the medically underserved.[6]

What Care Individual Physicians and Orthopaedic Surgeons Are Providing

In 1994, the AMA reported that 68% of all practicing physicians provided some free or reduced fee care, and devoted an average of 12% of their work time, 7.2 hours per week, to caring for the medically underserved, up from 6.5 hours per week in 1990.[10]

According to *Orthopaedic Practice in the United States: 1996/7,* approximately ten percent of the care provided by orthopaedic surgeons is uncompensated or is paid by the Medicaid program. Four percent of the care is entirely uncompensated.[11] In the most recent Orthopaedic Census Survey that specifically dealt with the issue of orthopaedic surgeon's providing uncompensated care, the Academy found:

- Eighty-one percent of orthopaedic surgeons regularly provide care for patient from whom they neither expect nor receive compensation (including charity care clinics);

- Orthopaedic surgeons provide, on average, 37 professional hours per month on uncompensated care or where compensation is Medicaid or other reduced payment. This includes 9.1 hours where compensation is neither expected nor received; 13.3

hours where compensation is expected but not received; and 14.8 hours where compensation is Medicaid or similar reduced payment; and

- Sixty percent of orthopaedic surgeons indicate they are providing more uncompensated or reduced compensated care than they were five years ago. The average increase in hours per month indicated was 31 percent.[12]

Recommendation of the AMA Council on Ethical and Judicial Affairs

In 1993, the Council on Ethical and Judicial Affairs of the AMA adopted a guideline regarding the individual physician's obligation to treat the medically underserved. The Academy generally endorses this guideline and has revised it as appears below:

Caring for the medically underserved should be a normal part of each physician's overall service to patients. Although the measure of what constitutes an appropriate contribution may vary with circumstances such as community characteristics and geographical location, orthopaedic surgeons should work to ensure that the needs of the medically underserved in their communities are met. Since a large number of the medically underserved are children, the orthopaedic surgeon has a special obligation to treat them without discrimination based on the ability to pay.

Orthopaedic surgeons should devote their energy, knowledge, and prestige to designing and lobbying at all levels to better programs to provide care for the medically underserved.

II. Obligation of Society and the Medical Profession To Treat the Medically Underserved

The duty to care for the medically underserved rests not only with individual physicians, but also with society and the medical profession as a whole. The policies of the Academy make improved access to medical care a clear priority. Since 1992, the Academy has publicly supported universal, affordable health care available to all. In its response to health care reform, the Academy stated that this country "must provide an essential and universally accepted health package for all Americans, regardless of ability to pay. This health care package must include a basic level of high quality health services, including musculoskeletal services.[5] In 1992, the Academy also stated that the medically underserved should be covered through "an expansion of the federal-state health care financing system.[13]

What Services the AMA and Medical Societies Are Providing?

A survey conducted by the AMA in 1997 found that 29 state or metropolitan medical societies conducted programs to arrange for the provision of free care by participating physicians in the state or area. In addition, 36 state or metropolitan medical societies sponsored or participated in free clinics to serve the medically underserved.[10]

Recommendation of the AMA Council on Ethical and Judicial Affairs

In 1993, the Council of Ethical and Judicial Affairs of the AMA adopted a guideline regarding the obligation of society and the medical profession to treat the medically underserved. The Academy generally endorses the guideline and has revised it as appears below:

The American Academy of Orthopaedic Surgeons and state and local medical societies should help society meet its obligations to provide health care services to the medically underserved. By working together in providing care for little or no compensation, by volunteering at local free

clinics and/or by participating in active professional organizations and their affiliated alliances, orthopaedic surgeons and other physicians can be directly involved in and can encourage the provision of coordinated quality care for the medically underserved.

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Opinion 1210

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

Sexual Harassment and Exploitation

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

What is sexual harassment? What should an orthopaedic surgeon do to help eliminate sexual harassment and exploitation?

Applicable provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

"II. **Integrity**. The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception."

"III. **Legalities and Honor**. The orthopaedic surgeon must obey the law, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. The orthopaedic Surgeon also has a responsibility to seek changes in legal requirements that are contrary to the best interest of the patient.

"V. **Confidentiality**. The orthopaedic surgeon should respect the rights of patients, of colleagues, and of other health professionals and must safeguard patient confidences within the constraints of the law."

"VII. **Cooperation**. Good relationships among physicians, nurses, and health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development of an expert health care team that will work together harmoniously to provide optimal patient care."

"X. **Societal Responsibility**. The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving both the health and well-being of the individual and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon."

Applicable provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

"II. A. The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount."

"II. C. The orthopaedic surgeon should obey all laws, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that another orthopaedic surgeon or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly-constituted peer review authority or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct."

"V. A. Good relationships among physicians, nurses and other health care professionals are essential for good patient care. The orthopaedic surgeon should promote the development and utilization of an expert health care team that will work together harmoniously to provide optimal patient care."

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American Medical Association Council on Ethical and Judicial Affairs *Current Opinions:*

Opinion 3.08 Sexual Harassment and Exploitation Between Medical Supervisors and Trainees. Issued March 1992. Updated June, 1994.
Opinion 9.031 Reporting Impaired, Incompetent, or Unethical Colleagues. Issued March 1992. Updated June 2004.

U. S. Equal Employment Opportunity Commission (EEOC): *Facts About Sexual Harassment.* http://www.eeoc.gov/facts/fs-sex.html

Background

Unwelcome sexual advances, requests for sexual favors, and other verbal or physician conduct of a sexual nature constitute sexual harassment when submission to or rejection of this conduct explicitly or implicitly affects an individual's employment, unreasonably interferes with an individual's work performance or creates an intimidating, hostile or offensive work environment.

Sexual harassment can occur in a variety of circumstances, including but not limited to the following:

- The victim as well as the harasser may be a woman or a man. The victim does not have to be of the opposite sex.
- The harasser can be the victim's supervisor, an agent of the employer, a supervisor in another area, a co-worker, or a non-employee.
- The victim does not have to be the person harassed but could be anyone affected by the offensive conduct.
- Unlawful sexual harassment may occur without economic injury to or discharge of the victim.
- The harasser's conduct must be unwelcome.

Despite years of media coverage of this topic, surveys of women in medical school, post graduate programs, and in academic medicine show the incidence of perceived gender discrimination and harassment to be unchanged. Recent articles indicate that nearly half the women experience some form of gender-based harassment, especially early in their medical careers.[1 & 2]

Legal considerations

In recent years, the number of complaints of sexual harassment in the workplace has increased substantially as has the number of lawsuits alleging violations of state or federal law based on incidents of sexual harassment.

Legal claims of sexual harassment fall into two categories: "quid pro quo harassment," whereby submission to or rejection of the sexual conduct is used as the basis for employment decisions; and "hostile environment harassment," in which conduct is so pervasive that it unreasonably interferes with an individual's job performance or creates an intimidating, hostile or offensive working environment.

Perceptions of what constitutes offensive behavior sometimes differ between men and women. Men generally are less inclined than women to view sexual teasing as harassment. Recently, some courts have begun to adopt the "reasonable woman" test for sexual harassment, ruling that behavior was sexual harassment if a "reasonable woman" would view it as such.

In a case of alleged hostile environment sexual harassment, a plaintiff must prove that "the employer did not respond promptly and effectively when it was apprised of (or should have discovered) the harassment." An internal investigation followed by appropriate disciplinary action, when warranted, has been held to constitute a proper response in a number of cases.

Employees, such as nurses and support staff, who are sexually harassed may also seek redress from the federal Equal Employment Opportunity Commission (EEOC) and its state counterparts. In the educational context, medical schools and medical trainees are often perceived as sharing an educational rather than an employment relationship. However, the EEOC has determined that interns and residents are sometimes considered to be employees of the medical schools that provide them with clinical training. As such, interns and residents may have the same legal standing as employees to file charges of sexual harassment and discrimination under Title VII of the Civil Rights Act of 1964. In addition, the Civil Rights Act of 1991 gives victims of sexual harassment, whether employees or physicians-in-training, the right to receive punitive damages of up to $300,000. Sexual harassment is also widely prohibited under state law.

Ethical considerations

By definition, conduct that would constitute sexual harassment is unethical. Patient care may be jeopardized in this circumstance by the creation of a sexually hostile or offensive work environment.

Orthopaedic surgeons should ensure that their actions cannot be considered sexual harassment even by the most critical observer. They should strive to stop sexually harassing behavior by others in the work environment whether they are witness to or the recipient of such activity. The orthopaedic surgeon should promptly inform the harasser that his or her behavior is inappropriate and report continuation of said behavior to the appropriate authority. The orthopaedic surgeon must ensure that the nurturing and caring health care environment does not become sexually hostile or offensive by inappropriate communications, touching or sexual favoritism.

Consensual sexual relationships between medical supervisors and trainees are generally considered unethical because of inherent inequalities in the status and power that medical supervisors wield in relation to medical trainees. Whenever a sexual relationship exists between a medical trainee and a supervisor who has professional responsibility for the trainee, the supervisory role must be eliminated if they wish to pursue their relationship.

Policies dealing with sexual harassment and exploitation

The American Academy of Orthopaedic Surgeons urges orthopaedic surgeons to comply with institutional sexual harassment policies and to develop and enforce such policies (or the concepts underlying these policies) in their own offices. These policies should acknowledge that both men and women are subject to sexual harassment or exploitation from members of the same or opposite gender and that mechanisms for resolving inappropriate sexual conduct must be equally stringent in all cases. Sexual harassment policies should also assure the rights of both the accuser and the accused and, to the extent possible, should protect the confidentiality of all involved. Generally, an effective sexual harassment policy will include:

- A description of the types of conduct that constitute sexual harassment;
- A strong statement that sexual harassment is unethical and unlawful and that the institution/orthopaedic surgeon will not tolerate such behavior;
- A statement of an employee's right to complain about harassment without fear of retaliation;
- A requirement that supervisors and employees promptly report any sexually harassing conduct;
- A procedure for prompt, full and objective investigation of sexual harassment charges; and
- A statement that offenders will face disciplinary action and possible discharge.

Recommendations

The American Academy of Orthopaedic Surgeons urges orthopaedic surgeons to be aware of and sensitive to issues of sexual harassment and exploitation. Orthopaedic surgeons should conduct their activities professionally and should not jeopardize patient care through inappropriate sexual actions or comments. Policies should be implemented and followed to ensure that all members of the health care team may perform their professional duties without fear of sexual harassment or exploitation.

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Opinion 1201

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

Sexual Misconduct in the Physician-Patient Relationship

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue Raised

What obligations does an orthopaedic surgeon have regarding sexual misconduct in the physician-patient relationship?

Background

Sexual misconduct exploits the physician-patient relationship. The burden of recognizing this and avoiding this exploitation is always on the physician. The prohibition of sexual contact between a patient and his or her physician extends back to the Hippocratic Oath: "In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasure of love with women or men, be they free or slaves." Such prohibitions were intended to improve the poor image of the physicians of the time. Physician sexual misconduct is harmful to the patient and detrimental to providing care.

The American Medical Association (AMA), the American Academy of Orthopaedic Surgeons (AAOS), and state licensing and disciplinary authorities uniformly condemn sexual contact between physicians and their patients. Publicized cases of physician assault of incompetent, unconscious or otherwise compromised patients have led states to elaborate and strengthen their rules of sexual misconduct. There has been an increasing awareness and public reaction to the existence of this problem and its harmful effects.

State medical licensure and disciplinary boards are charged with protecting public welfare, and in 2006 the Federation of State Medical Boards (FSMB) issued guidelines for state boards to use in dealing with physician sexual misconduct. These policies reflect a strict intolerance of sexual misconduct on the part of physicians and allow the state medical licensure and disciplinary board to take prompt and decisive action against any physician who commits sexual misconduct.

It is estimated that 5-10% of all physicians have had sexual contact with patients.[1] Physicians from all specialties and backgrounds are involved. Nearly all violators are males and most victims are females. It is also felt that the true extent of the problem may be underreported. Reporting systems by states do not categorize complaints or actions by type or specialty, and data is limited.

Definitions

Many states have generated detailed lists of various behaviors in order to leave little doubt about what may be considered a sexual misconduct violation. Others have very brief definitions of physician sexual misconduct.

From a legal and ethical perspective, sexual misconduct may include a spectrum of behavior. Sexual misconduct is the exploitation of the physician-patient relationship in a sexual way. It is the use of the physician's power and dominance to satisfy his or her sexual desires at the expense of the patient. Verbal or physical behavior of a sexual nature including conversation, gestures, and inappropriate touching may constitute sexual misconduct.

According to the FSMB guidelines, sexual misconduct may be categorized in two ways:

- Sexual impropriety – behavior, gestures or expressions that are sexually suggestive, seductive or disrespectful of a patient's privacy or sexually demeaning to a patient.

- Sexual violation – physical sexual contact between a physician and a patient, whether or not it was consensual and/or initiated by the patient. This would include any kind of sexual intercourse or genital contact or masturbation, and touching of any sexualized body parts for purposes other than appropriate medical related examination or treatment. Exchange of prescriptions or other professional services for sexual favors would be another example of such a violation.

Legal and Disciplinary Considerations

State licensing or disciplinary boards have a range of sanctions that may be applied to physician sexual misconduct. In cases of forced sexual contact, it is likely that the physician will lose his or her medical license. Current national tracking systems of licensing actions may lead to similar action by other states where a physician may have a license or prevent a license from being acquired elsewhere. In other situations, a physician found guilty of sexual misconduct may be allowed to retain his or her medical license on probation and be monitored by the state medical licensure or disciplinary board. Many state boards require a special evaluation of the physician and attendance at specific courses on ethics and boundary violations.

There is limited information about the incidence of state licensing actions regarding physician sexual misconduct. There is also little known about recidivism for physicians who have committed sexual misconduct and continue to practice.

In 2005, the AAOS Fellowship adopted Standards of Professionalism (SOPs) on Providing Musculoskeletal Services to Patients. Mandatory Standard 7 explicitly provides that "an orthopaedic surgeon shall maintain appropriate relations with patients." Thus, if evidence is found of physician sexual misconduct with patients which has not otherwise been acted upon by the state licensure or disciplinary body, the AAOS (through its Professional Compliance Program) may take appropriate action regarding their AAOS membership, such as reprimand, censure, suspension or expulsion from the AAOS.

Physicians found guilty of sexual misconduct may also face a variety of professional liability claims and possibly criminal charges, depending on the circumstances. There is heightened awareness and intolerance on the part of the public and professional organizations in dealing with this problem.

Reporting of Sexual Misconduct

Anyone, including physician colleagues, may report instances of suspected physician sexual misconduct to the state licensure or disciplinary boards. State boards are obligated to investigate such complaints. Often patients do not report sexual misconduct to the authorities because of feelings of shame, humiliation degradation and self-blame.

Physicians have an ethical and in most jurisdictions a legal obligation to report sexual misconduct by physician colleagues. Reporting of sexual misconduct is a required ethical standard by the AMA, AAOS and by many state licensing or disciplinary boards. Failure to report may be considered professional misconduct and subject to disciplinary action as well. However, studies reflect a significant discrepancy between awareness of misconduct and reporting.

Ethical Consideration: Patient Consent and the Physician-Patient Relationship

Ethical concerns related to physician sexual misconduct exist, even if the patient consents to the relationship or terminates the physician-patient relationship in order to then enter into a sexual relationship with his or her physician.

A patient cannot give meaningful consent to sexual contact with his or her physician due to the position of trust and the disparity of power in the patient-physician relationship. Sexual or romantic attraction between physicians and patients is common, and most physicians will acknowledge having such feelings. This may be a problem especially when the attraction may have come before or after the physician-patient relationship. While such attractions may seem natural and normal, they do not override the concerns of unequal power, vulnerability and potential for exploitation that come with a sexual relationship between the physician and the patient.

The patient must be able to trust that the physician will work only for the patient's welfare. The needs or interests of the physician must not become a consideration in decisions about the patient's medical care. Sexual involvement with a patient affects or obscures the physician's medical judgment and is inevitably harmful to the patient. Accordingly, sexual relationships between patients and physicians are uniformly considered unethical and a form of professional misconduct. A consenting sexual relationship does not relieve the physician of the ethical and legal prohibition against such relationships.

Termination of a physician-patient relationship so that a sexual relationship may then be entered into may not always resolve this problem. If a physician finds there is a sexual or romantic attraction to a patient, there is an obligation to discontinue the patient relationship if the attraction cannot be appropriately controlled. However, [~~great~~] care must be taken when ending a physician-patient professional relationship and continuing with a romantic or sexual one. These latter cases may be unduly influenced by the previous trust, knowledge, influence, or emotions derived from the professional relationship. One is open then to the same considerations of sexual misconduct.

Some professional groups and state licensing or disciplinary boards provide designated time limits following the termination of the physician-patient relationship before the treating physician may ethically enter into a sexual relationship with a former patient. There is not agreement on such standards. Some feel that such relationships with former patients are always unethical. The relevant consideration is the potential for the misuse of physician power and exploitation of patient emotions derived from the former relationship. The ethical propriety of a sexual relationship between a physician and a former patient depends substantially on the nature and context of the former relationship.

Recommendations

The American Academy of Orthopaedic Surgeons condemns sexual misconduct by orthopaedic surgeons and other physicians. AAOS believes orthopaedic surgeons should educate themselves about the issues of sexual misconduct in patient care and that orthopaedic surgeons who become aware of alleged sexual misconduct by colleague physicians should report it timely and appropriately. By doing so, orthopaedic surgeons will foster professional interactions with patients that are free of inappropriate sexual actions and comments.

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References:

Applicable provisions of the *AAOS Standards of Professionalism on Providing Musculoskeletal Services to Patients*

Mandatory Standard 1: "An orthopaedic surgeon shall, while caring for and treating a patient, regard his or her responsibility to the patient as paramount."

Mandatory Standard 3: "An orthopaedic surgeon shall serve as the patient's advocate for treatment needs and exercise all reasonable means to ensure that the most appropriate care is provided to the patient."

Mandatory Standard 5: "An orthopaedic surgeon shall maintain appropriate relations with patients."

Applicable Provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

"I. Physician-Patient Relationship. The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns. The orthopaedic surgeon should be dedicated to providing competent medical service with compassion and respect."

"II. Integrity. The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception."

"III. Legalities and Honor. The orthopaedic surgeon must obey the law, uphold the dignity and honor of the profession, and accept the profession's self- imposed discipline."

"V. Confidentiality. The orthopaedic surgeon should respect the rights of patients, of colleagues, and of other health professionals and must safeguard patient confidences within the constraints of the law."

Applicable Provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

"I. A. The orthopaedic profession exists for the primary purpose of caring for the patient. The physician-patient relationship is the central focus of all ethical concerns."

"I. B. The physician-patient relationship has a contractual basis and is based on confidentiality, trust, and honesty. Both the patient and the orthopaedic surgeon are free to enter or discontinue the relationship within any existing constraints of a contract with a third party. An orthopaedist has an obligation to render care only for those conditions that he or she is competent to treat."

"II. A. The orthopaedic surgeon should maintain a reputation for truth and honesty. In all professional conduct, the orthopaedic surgeon is expected to provide competent and compassionate patient care, exercise appropriate respect for other health care professionals, and maintain the patient's best interests as paramount."

"II. B. The orthopaedic surgeon should conduct himself or herself morally and ethically, so as to merit the confidence of patients entrusted to the orthopaedic surgeon's care, rendering to each a full measure of service and devotion."

"II. C. The orthopaedic surgeon should obey all laws, uphold the dignity and honor of the profession, and accept the profession's self-imposed discipline. Within legal and other constraints, if the orthopaedic surgeon has a reasonable basis for believing that a physician or other health care provider has been involved in any unethical or illegal activity, he or she should attempt to prevent the continuation of this activity by communicating with that person and/or identifying that person to a duly constituted peer review authority or the appropriate regulatory agency. In addition, the orthopaedic surgeon should cooperate with peer review and other authorities in their professional and legal efforts to prevent the continuation of unethical or illegal conduct."

Other references:

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics.* Chicago, IL, 2014-2015 edition.

Opinion 8.14 Sexual Misconduct in the Practice of Medicine. Issued December 1989; Updated March 1992 based on the report *Sexual Misconduct in the Practice of Medicine,* adopted December 1990 (*JAMA*. 1991;266:2741-2745). http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion814.page

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Washington State Medical Quality Assurance Commission, "Sexual Misconduct and Abuse Rules." 2005.
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Sansone RA, Sansone LA: Crossing the line: Sexual boundary violations by physicians. *Psychiatry (Edgmont),* 2009 Jun: 6(6):45-8. (This study suggests that physician sexual misconduct, as measured in confidential surveys, may be more common than data from disciplinary boards suggest.)

Footnote:

[1]American Medical Association: CEJA Report A-I-90 *Sexual Misconduct in the Practice of Medicine,* adopted December 1990 (*JAMA*. 1991;266:2741-2745).

Opinion 1208

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

RESEARCH

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Standards of Professionalism

Research and Academic Responsibilities

Adopted May 12, 2006

AAOS Standards of Professionalism (SOPs) establish the minimum standards of acceptable conduct for orthopaedic surgeons. Violations of any SOP may result in professional compliance actions against an AAOS Fellow or Member found in violation. Not prepared using a systematic review, SOPs are developed through a consensus process and are ultimately adopted as official AAOS statements by the two-thirds vote of the AAOS Fellowship casting ballots.

The orthopaedic profession exists for the primary purpose of caring for the patient. As a member of this profession, an orthopaedic surgeon may often conduct or participate in research and academic endeavors that may lead to improvements in musculoskeletal services provided to patients.

Under the AAOS Professional Compliance Program as adopted in April 2005, the Fellowship votes on all Standards of Professionalism. A Standard of Professionalism establishes the minimum standard of acceptable conduct for orthopaedic surgeons in a particular area. A Standard of Professionalism is mandatory and applies to all Fellows and Members of the AAOS.

The Standards of Professionalism draw from the aspirational *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* that appears in bold italics. The statements that follow the aspirational Code establish the baseline standard of acceptable conduct for orthopaedic surgeons who engage in research or who author or present information to other orthopaedic surgeons or the public. Violations of these standards may serve as grounds for a formal complaint to and action by the AAOS as outlined in the Article VIII of the Bylaws of the American Association of Orthopaedic Surgeons.

These Standards of Professionalism apply to all AAOS Fellows and Members in their capacity as researchers or authors and presenters valued for their knowledge and expertise. Only an AAOS Fellow or Member may file complaints of an alleged violation of these Standards of Professionalism regarding another AAOS Fellow or Member.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, VIII. A.:
All research and academic activities must be conducted under conditions of full compliance with ethical, institutional, and government guidelines. Patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time.

Mandatory Standards:

1. An orthopaedic surgeon shall, while caring for and treating a patient participating in research program or protocol, regard his or her responsibility to the patient as paramount.

2. An orthopaedic surgeon, or his or her qualified designee, shall present pertinent information to and obtain informed consent from the patient participating in research program or protocol, or from the person responsible for the patient.

3. An orthopaedic surgeon shall honor a request from the patient, or from the person responsible for the patient, to withdraw from a research program or protocol.

4. An orthopaedic surgeon shall, while conducting research and academic activities, seek appropriate peer review and comply with appropriate institutional and governmental regulations.

5. An orthopaedic surgeon shall, while conducting research and academic activities, be truthful and honest with patients and colleagues. An orthopaedic surgeon shall communicate in a manner that enhances the profession.

6. An orthopaedic surgeon shall report those who engage in fraudulent or deceptive research to the appropriate authorities.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, VIII. B.:
Orthopaedic surgeons should not claim as their own intellectual property that which is not theirs. Plagiarism or the use of others' work without attribution is unethical.

Mandatory Standards:

7. An orthopaedic surgeon shall claim as his or her own intellectual property only research and academic articles for which he or she made substantial contributions to the design, collection of and interpretation of data, and final version of the report.

8. An orthopaedic surgeon shall not present ideas, language, data, graphics, or scientific protocols created by another person without giving appropriate credit to that person.

9. An orthopaedic surgeon shall, while conducting research or academic activities, maintain the integrity of the profession by exposing through the appropriate review process those physicians who engage in fraud or deception.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, VIII. C.:
The principal investigator of a scientific research project or clinical research project is responsible for all aspects of the research, including reporting. The principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of the responsibility for work conducted by the other individuals.

Mandatory Standards:

10. An orthopaedic surgeon shall warrant that he or she has made significant contributions to the conception and design or analysis and interpretation of the data, drafting the manuscript or revising it critically for important intellectual content, and approving the version of the manuscript to be published.

11. An orthopaedic surgeon shall disclose the existence of duplicate articles, manuscripts, or other materials that report his or her scientific or clinical research.

Aspirational: AAOS Code of Medical Ethics and Professionalism for Orthopaedic Surgeons, VIII. D.:
The principal investigator or senior author of a scientific report is responsible for ensuring that appropriate credit is given for contributions to the research described.

Mandatory Standards:

12. An orthopaedic surgeon shall credit with authorship or acknowledge and not exclude those individuals who substantially contributed to the proposed research, the analysis and interpretation of the data, and the drafting and revising of the final article or report.

13. An orthopaedic surgeon shall, in reporting on research, publicly acknowledge the source of all relevant funding or consulting arrangements.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

Ethics in Health Research in Orthopaedic Surgery

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issues raised

What are the general ethical issues involved in the conduct of health research in orthopaedic surgery?

Definitions

Orthopaedic surgeons conduct basic science, translational and clinical research. "Health research" is a broad term encompassing all research designed to contribute to our understanding of how best to care for our patients. Health research covers various types of research, including clinical research (defined by the AMA as "a part of a systematic program competently designed, under accepted standards of scientific research, to produce data that are scientifically valid and significant"), basic science research, research on animals as precursor to human research, outcome studies research, psychosocial research, and demographic and economic studies. In this Opinion on Ethics and Professionalism, unless otherwise noted, the broad term "health research" will be used.

Ethical considerations

According to the Academy's *Opinion on Ethics and Professionalism on Continuing Medical Education*, upon completion of orthopaedic residencies or fellowships, orthopaedic surgeons assume an ethical and professional obligation to stay abreast of developing knowledge in the musculoskeletal sciences. Many orthopaedic surgeons have chosen to go beyond this basic obligation to assist in the advancement of musculoskeletal knowledge and its dissemination.

Orthopaedic surgeons who conduct health research have an ethical responsibility to ensure that any research performed meets all of the standards which have been developed to protect their research subjects while furthering our medical knowledge. Failing to ~~do so~~ follow internationally accepted practices related to human and animal research is unethical and may also be illegal. Results obtained from unethical practices will not become part of the body of scientific

knowledge nor will it be accepted for presentation or publication. In addition, failure to perform well designed studies without appropriate ethical considerations may impede or delay progress in learning about the musculoskeletal sciences and will damage the credibility of all health researchers, thereby harming not only the research community, but also the greater orthopaedic community and the patients whose care depends on the results of research.

The Academy believes the ethical tenets described below constitute reasonable guidelines to assist health researchers in orthopaedics. These guidelines include the following:

The purpose of health research: Health research should be designed and conducted to develop new or confirmatory knowledge that promotes health, prevents diseases and injuries, and improves diagnosis and treatment of diseases and injuries. Research involving human subjects is only appropriate when the potential risks to the research participant are reasonable in relation to the potential benefits to the participant or to future patients and are sensible because of the importance of the knowledge which might be gained.

Examples of unethical conduct:

- Designing and conducting research with the primary purpose of discerning methods of causing injury, illness or suffering;
- Designing or conducting research that is repetitious or redundant with the primary intent of advancing individuals or specific groups financially or professionally;
- Designing or conducting research that is not intended to produce new or confirmatory information that is valid or significant; and
- Purposefully stating, reporting or misinterpreting (by omission or commission) data to arrive at a pre-determined theory or opinion.

Support of sponsorship of research: Most financial support for health research comes from the federal government, industry, philanthropic organizations, or is self-funded. Each source of funding presents a potential conflict of interest.

Three primary parties have distinct interests when corporations fund health research:

1. the researcher;
2. the research institution;
3. the corporation funding the research.

The relationships among these groups may vary substantially, and the goals of the research projects are not necessarily aligned.

In the most frequent type of relationship, the funding corporation develops a Request for Proposal (RFP) or presents a research protocol to the researcher and funds the researcher for carrying out the protocol. This essentially creates a fee-for-service arrangement.

Reimbursement for additional resources and the time devoted to complete the investigation are appropriate. Many research institutions have created structures that allow for funded research to be negotiated in a manner that attempts to eliminate any potential conflicts in the negotiations between the research and the sponsoring industry. Generally, the Office of the Vice-President for Research or the Dean for Research understands the ethical guidelines to minimize conflicts of interest and will be a valuable source in the development of an ethical and legal contract.

A second type of relationship involves the researcher submitting an unsolicited research proposal directly to the funding corporation.[1] The researcher would benefit by obtaining funds for needed equipment and supplies and the funding corporation would benefit by the possibility of expanding its market potential for a given product. This arrangement also may be viewed as ethically appropriate and mutually beneficial, assuming the proper conduct of science ensues and full disclosure is maintained.

A third type of relationship involves truly cooperative projects.[1] Often, these types of relationships are enacted in the setting of a clinical trial. Numerous advantages exist for the researcher, the research institution, and the funding corporation for the development of cooperative programs between medicine and industry. Full disclosure is essential to the success of this type of venture.

Ethical problems may arise when the researcher or the research institution have a direct financial interest in the research program. For example, researchers may hold stock or stock options in the funding corporation that manufactures the product or they may have other profit-sharing arrangements with the company. These financial interests may compromise (or give the impression of compromising) the objectivity of the researchers and cause them to downplay or suppress negative data while exaggerating favorable data. Such economic incentives may also introduce subtle biases into the way research is conducted, analyzed or reported.

The Academy believes that guidelines for circumstances in which researchers face economic conflicts of interest may be determined in reference to two ethical principles:

- A researcher ethically may share the economic rewards of his or her efforts. If a drug, device, or other product becomes financially remunerative, the researcher may receive profits that reasonably resulted from his or her contribution. The Academy's *Standards of Professionalism on Orthopaedic Surgeon-Industry Relationships* and the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* explicitly permit an orthopaedic surgeon to receive royalties. However, ethically the researcher may not reap profits that are not justified by the value of his or her actual efforts.
- Potential sources of bias in research should be eliminated, particularly where there is a direct relationship between a researcher's personal interests and potential outcomes of the research.

Several conclusions result by applying these two ethical principles. Once the researcher becomes involved in a research project for the funding corporation or knows that he or she might become involved in the research, he or she should not buy or sell the funding corporation's stock until the involvement ends and the results of the research are publicly disseminated. As long as the researcher is involved in investigating the funding corporation's product, he or she has the potential to derive profits that stem from inside information, rather than from individual effort.

Researchers may serve as consultants or may be retained to lecture on behalf of the funding corporation. However, the researcher's remuneration ethically must be commensurate with his or her actual efforts on behalf of the funding corporation.

Safeguards may be necessary to protect against the appearance of impropriety, even when ethically permissible relationships among the researcher, research institution and the funding corporation exist. Full disclosure presents the best mechanism to address doubts about the propriety of a research arrangement. Researchers should disclose all ties to corporations whose products they are investigating. For example, the researcher's participation in educational

activities supported by the corporation; participation in other research projects funded by the corporation; and consulting arrangements with the corporation must be disclosed to the research institution, to the funding corporation, to audiences who hear the research results and to journals that publish the results of the research.

Example of unethical conduct:

- Knowingly negotiating for more funding than is appropriate to support the project and related institutional and departmental overhead costs;
- A researcher's selling or purchasing stock in a company whose orthopaedic device is being tested by that orthopaedic surgeon-researcher;
- A researcher's accepting financial incentives to alter data;
- A researcher's accepting excessive remuneration by the funding corporation for evaluating or interpreting data about that corporation's products;
- A failure to disclose research or consulting arrangements with the funding corporation when reporting about research on devices manufactured by that corporation.

Use of research resources: Resources allocated by governmental agencies (federal, state or local), industry, or philanthropic organizations for the performance of specific research should be used only for that purpose unless the granting agency gives specific permission for reallocation of the resources.

Use of animals in research: The Academy believes that the appropriate and humane use of animals in research is justified to enhance the quality of life of both humans and animals. Animals should be used in research only when there are no suitable alternatives. Research projects should be designed to use the minimal number of animals possible in a manner that avoids abuse of the animals and maintains appropriate standards of animal care. Researchers should conduct animal research only with the approval of the institution's Animal Care and Use Committee and in compliance with all applicable regulations and standards. [See also AAOS Position Statement 1103 on *Animals in Biomedical Research and Education*.]

Examples of unethical conduct:

- Using methods that cause animals unnecessary discomfort;
- Failing to maintain appropriate standards of animal care;
- Using excessive numbers of animals to perform experiments;
- Using inadequate numbers of animals to allow for an appropriately powered study;
- Using inappropriate animal models; and
- Using animals when other methods of conducting the research would be scientifically valid, e.g., computer simulations, tissue culture or mathematical models.

Use of human subjects in research: The *Statement of Principles* of the American College of Surgeons provides "[t]he progress in medical care through research depends on informed partnership between patients and physicians in the development of new drugs and treatment methods. It is recognized that certain advances in the knowledge of treatment of disease can only be learned by properly conducted clinical trials during which the results of varying treatments recommended by individual doctors are carefully compared." [5,6,7]

Human subjects should be used in health research only when there is no reasonable alternative. Human subjects should never be exposed to unnecessary risk, embarrassment or expense and should fully understand the purpose of the research and if their participation may

benefit them (a therapeutic experiment) or is intended primarily to benefit future patients (a nontherapeutic experiment). The selection criteria of human subjects must be objective and reasonable.

Human subjects should provide **voluntary informed consent** before being included in a prospective study and should be allowed to decline to continue participation in a research program at any time without compromising their medical care. Mandatory Standards 2 and 3 of the AAOS *Standards of Professionalism on Research and Academic Responsibilities* provide:

2. An orthopaedic surgeon, or his or her qualified designee, shall present pertinent information to and obtain informed consent from the patient participating in research program or protocol, or from the person responsible for the patient.

3. An orthopaedic surgeon shall honor a request from the patient, or from the person responsible for the patient, to withdraw from a research program or protocol.

In addition, Paragraph VIII. A. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time." To ensure full informed consent, three elements must exist:

1. The orthopaedic surgeon must explain to the patient in terms the patient can understand the proposed treatment, its likely effect on the patient, and purpose of the research. Orthopaedic surgeons must provide at least the degree of information that is required by applicable state and federal law, which will include at a minimum information on the purpose of the research, its potential side effects, alternatives and risks of the proposed treatment as well as the method, purpose, conditions of participation and the opportunity to withdraw from the research protocol without penalty.

2. The patient must understand for what they are providing consent. The orthopaedic surgeon must ensure that the patient has understood the basic information and has engaged in rational decision-making in deciding to participate in the research; and

3. The patient's consent must be voluntary. Voluntary consent requires that the patient agreeing to participate in the project has a full understanding of all alternative treatments beyond the research protocol. The orthopaedic surgeon must believe that the patient's consent is free from undue or overbearing influences, e.g., fear of the loss of care or medical benefits if the patient declines to participate.

Human subjects participating in clinical research programs should receive the care and treatment that is in their best interest and be assured that the potential benefit of the research outweighs the risks. Researchers should conduct human subject research only with the approval of the research institution's Institutional Review Board (IRB) and any other review committees required by the institution, and in compliance with all applicable regulations and standards, including the Health Information Portability and Accountability Act (HIPAA) Privacy Rule (see below). This review and approval mechanism ensures that there is informed consent, that the rights of patients are respected, and that patients participating in the research protocol are treated with the same concern and devotion as other patients.

Sham surgery in research can be acceptable only if done for investigation of an appropriate procedure and if performed in a manner that minimizes risk to human subjects. Research protocols that utilize sham surgery should adhere to the following guidelines.[2]

1. There is skepticism regarding the therapeutic merits of a particular treatment.
2. There are disagreements about the perceived benefits of a particular procedure compared with the placebo.
3. Benefits might be due to the "experience of surgery" and the postoperative care regimen.
4. Risks are reduced as far as possible in the sham surgery arm without compromising trial design.
5. There is a lack of a superior therapy.

Research on populations designated by the federal government as vulnerable (including children and pregnant women) is scrutinized with special care by the IRB. Research should only be performed on these patient groups if the result of this research is directed towards the care of that vulnerable population. The vulnerable population should only be used if the study cannot feasibly be carried out on a non-vulnerable population with the same effect.[3] For research involving minors, assent (by the minor) may be required in addition to parental or guardian consent. In addition, any review of any patient information, including retrospective chart and x-ray review, for any purpose other than care of an individual patient or quality improvement, must be approved by the IRB. In many cases, the IRB will grant a "chart review exemption," but this must be obtained before initiating chart and x-ray review. Further information can be obtained from the National Institutes of Health website.

All individuals should be given access to research trials and be able to participate. Efforts should be made to prevent any specific populations from being significantly underrepresented in research.

Examples of unethical conduct:

- Failing to disclose risks (synonomous with a non-voluntary consent);
- Exposing patients who are participating in the research protocol to unnecessary risks;
- Failing to obtain voluntary, fully informed consent of adult patients or to obtain the substituted consent of the patient's legally authorized representative when the patient lacks the legal capacity to consent (e.g., is a minor);
- Causing human subjects unnecessary embarrassment;
- Causing human subjects unnecessary expense;
- Manipulating human subject cohorts with selected medical problems or results of treatment with the intent of proving the investigator's bias or to promote a given treatment or medical device; and
- Directly or indirectly coercing human subjects to participate in the research protocol.
- Failing to follow any IRB requirements regarding subject recruitment or research participation.

Responsibility of the research institution: The ultimate responsibility for the ethical conduct of research resides within the institution in which the health research is conducted and/or with the Primary Investigator (PI). Research institutions should assure that rigorous scientific standards are upheld by each of their faculty, staff, and students and should extend these standards to all reports, publications, and databases produced by the institution. All medical schools and research institutions should implement guidelines for a review process for dealing with allegations of scientific misconduct, which include appropriate due process protections for

those alleged to have committed scientific misconduct. In addition, the research institution must be capable of and committed to implementing effective procedures for examining allegations of scientific misconduct.

Examples of unethical conduct:

- The research institution's failing to maintain guidelines for dealing with allegations of scientific misconduct or fraud;
- The research institution's failing to inform and educate staff and students of institutional guidelines for dealing with allegations of scientific misconduct or fraud; and
- The research institution's failing to implement and enforce institutional guidelines for dealing with allegations of scientific misconduct or fraud.

Responsibilities of the Principal Investigator: The Principal Investigator of a health research project is responsible for proposing, designing and reporting the research. In addition, the Principal Investigator is usually accountable for dispensing project funds. In designing trials, it is incumbent upon the Principal Investigator to identify clinical questions for which there exists equipoise. The Principal Investigator may have a preference or opinion regarding the clinical condition being investigated, but a clinical trial should only be pursued to answer the clinical question if there is debate in the medical community as to the optimal approach.

Paragraph VIII. C. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that "the principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of responsibility for work conducted by other individuals." In addition, Mandatory Standard 12 of the *Standards of Professionalism on Research and Academic Responsibilities* provides "An orthopaedic surgeon shall credit with authorship or acknowledge and not exclude those individuals who substantially contributed to the proposed research, the analysis and interpretation of the data, and the drafting and revising of the final article or report."

Federal regulations under the HIPAA Privacy Rule also affect the storage and dissemination of research information. The Privacy Rule requires that personally-identifiable information designed as Protected Health Information (PHI) must be kept private. PHI includes any information which might identify an individual (social security number, address, photographs, etc.) as well as any information in a medical record, including diagnosis, treatment, and health status and test results. The Principal Investigator is responsible for following the Privacy Rule, and the IRB requires the researcher to determine the minimum amount of PHI necessary to perform the research; to obtain consent from all subjects for obtaining PHI for research, and to document how PHI for research will be stored, who will have access to PHI, and how reports including PHI will be disseminated. Additional limitations on the use of PHI for research may be imposed by the institutional IRB. Failure to adhere to the requirements of the HIPAA Privacy Rule of HIPAA may result in civil and criminal penalties.

Examples of unethical conduct:

- The Principal Investigator's failing to participate in and supervise the design or conduct or a research project;
- The Principal Investigator's failing to adequately supervise those conducting the project;
- Failure to maintain confidentiality of PHI obtained for the purposes of research by the Principal Investigator or anyone else assisting with the project; and
- The Principal Investigator's failing to critically review the results and verify the accuracy of reports.

Reporting results of research: The results of research should be reported in a timely, objective, accurate, complete manuscript. Any potential conflicts of interest should be fully reported and explained. Mandatory Standard 13 of the *Standards of Professionalism on Research and Academic Responsibilities* states: "An orthopaedic surgeon shall, in reporting on research, publicly acknowledge the source of all relevant funding or consulting arrangements." Paragraph III. D. of the Academy's *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons* provides that when reporting on clinical research or experience with a given device or procedure, orthopaedic researchers have an ethical obligation to "disclose any financial interest in that procedure or device if the researcher or any institution with which that researcher is connected has received anything of value from its inventor or manufacturer." In accordance with the HIPAA Privacy Rule, reports may not disclose individual PHI without the express permission of the subject. Objectives, outcome measures, and levels of significance of research should be established prior to the initiation of trials. Randomized control trials should also be registered prior to initiation of trials in order to ensure this.

Examples of unethical conduct:

- Failing to provide timely, accurate reports;
- Failing to report unfavorable results;
- Providing reports that do not contain a sufficient and accurate methodology to replicate the experiments or references to where such information might be obtained;
- Falsifying reports;
- Fabricating results;
- Reporting results of uncertain or minimal significance unless clearly stated as such;
- Preparing multiple partial reports or duplicate reports of the same work to increase apparent productivity of the investigators; and
- Failing to identify potential conflicts of interest including possible financial benefits to the investigators from research reports.

Authorship and credit for scientific work: The Principal Investigator of a research study is responsible for ensuring that articles describing the research include appropriate credit for individuals contributing importantly to the research. Mandatory Standards 12 and 10 of the *Standards of Professionalism on Research and Academic Responsibilities* are relevant:

12. An orthopaedic surgeon shall credit with authorship or acknowledge and not exclude those individuals who substantially contributed to the proposed research, the analysis and interpretation of the data, and the drafting and revising of the final article or report.

10. An orthopaedic surgeon shall warrant that he or she has made significant contributions to the conception and design or analysis and interpretation of the data, drafting the manuscript or revising it critically for important intellectual content, and approving the version of the manuscript to be published."

In addition, the authorship policy of *The Journal of the American Academy of Orthopaedic Surgeons*, states that each author must have contributed significantly to one or more aspects of the study; its design, data acquisition, analysis and interpretation of data, drafting of the manuscript; critical revision of the manuscript; statistical analysis; and/or supervision. In addition, each author should be able to defend and assume full responsibility for the content of the manuscript, regardless of the specific contributions. The sources of financial and technical support and individuals who provide important materials and information should also be acknowledged.

Examples of unethical conduct:

- Failing to credit co-workers; individuals who have designed the project or who have interpreted the data; individuals or agencies that have provided resources to fund the project; or individuals or groups that have previously performed similar research, if such research is valid and appropriate;
- Failing to credit sources of quotations;
- Plagiarizing or using others' work without attribution;
- Failing to review and credit relevant previous publications; and
- Including as authors individuals who did not make substantial contributions to the work.

Copyrights and royalties: Most research institutions maintain an intellectual property policy which encourages controlled entrepreneurial activity by research faculty. A typical structure for managing these matters involves the research institution's Committee on Intellectual Property (or similarly named group), which serves in a capacity advisory to the administrative officer overseeing the policy. These intellectual property policies have many variations peculiar to the particular institution, but in general determine distribution of rewards for researchers for developing new products and authors for writing and publishing articles and books.

Typically, the patent to devices created and the copyright to articles written belong to the Principal Investigator or his or her research institution or funding corporations. The ownership of patents, the allocation of revenues, copyright and other intellectual property interests among Principal Investigators, the research institution and the funding corporations and other important issues should be made clear either in standing policies of the research institution or in clear contracts executed before the commercial support is received. The rewards of commercialization should be fairly allocated.

It is ethically acceptable for a Principal Investigator to receive royalties from a funding corporation for using a particular device or medication the researcher has developed. However, it is unethical for an orthopaedic surgeon/Principal Investigator to be involved in an investigation of a device or medication in which he/she receives a royalty, has a financial interest in the manufacture of the device, or could have any other potential monetary payment or reward. An orthopaedic surgeon who has developed a new implant or device should delegate scientific investigation of the benefit of the new device to a disinterested third party who has no potential financial benefit from the utilization of the device. The patient should be informed of the interests of the orthopaedic surgeon/Principal Investigator; however, disclosure to the patient does not fully remove the conflict of interest of the inventor, and the results of the study would clearly be open to concerns of conflict of interest compromising the applicability of the study.

Examples of unethical conduct:

- The Principal Investigator's agreeing to always use a device he or she developed.

Research records: Accurate and complete records of research data should be maintained until there has been sufficient time for critical review. The time will vary with the type of research, but five years after publication is sufficient for most work. Most IRBs interpret the HIPAA Privacy Rule to require that the Principal Investigator specify the length of time that records will be stored and who will have access to them, the location of the records and precautions to prevent misuse.

Example of unethical conduct:

- Failing to maintain accurate complete records of research activity so that replication of the work or verification of the results is difficult or impossible.

Scientific errors; contradictory results and inability to replicate results: If errors in the proposal, conduct or reporting of research are identified, the Principal Investigator has an ethical obligation to report such errors. If the Principal Investigator or other investigators repeat an experiment and obtain results that contradict the initial report or they are unable to replicate the experiment, the contradictions or inability to replicate an experiment should be reported. If the long-term results of a health research project differ from the initial reported results, the differences should be reported. Scientific publications have a responsibility to publish reports of scientific errors, contradictory results, and failures to replicate previously reported research.

Examples of unethical conduct:

- Failing to report any significant scientific error;
- Failing to report work that contradicts previously reported data or conclusions;
- Failing to report late adverse outcomes for techniques or devices which were introduced with favorable initial experience;
- Failing to report difficulties in replicating or verifying previous findings; and
- A scientific publication's failing to publish reports of scientific errors, contradictory results, and failure to replicate previously reported research.

Obligation to report scientific misconduct (versus differences in methods, interpretation and judgment): Orthopaedic surgeons have an ethical obligation to report scientific misconduct in research if they become aware of it. Mandatory Standard 6 of the *Standards of Professionalism on Research and Academic Responsibilities* states: "An orthopaedic surgeon shall report those who engage in fraudulent or deceptive research to the appropriate authorities." A spectrum of activities constitutes scientific misconduct, ranging from duplicate publication at the lower end to fraud and plagiarism at the upper end. The U.S. Public Health Service (PHS) and the National Science Foundation (NSF) broadly define "scientific misconduct" to include research fraud (including plagiarism, deception, falsification and/or fabrication of scientific data) as well as "other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research."

However, while it is clear that unequivocal scientific misconduct must be reported, members of the health research community have a concurrent responsibility to attempt to distinguish between honest error and scientific misconduct. Orthopaedic surgeons must also respect differences in scientific methods and analysis, interpretation and judgment about data.

Examples of unethical conduct:

- Failing to identify and report unequivocal instances of scientific misconduct;
- Personally attacking, verbally or in writing, other investigators, based upon differences in methods, analysis, interpretation, judgment or opinion;
- Attempting to discredit or intimidate other investigators because of differences in methods, investigation or interpretation of data;
- Attempting to restrict funding or research, publication or presentation of data because of differences in interpretation; and
- Making accusations of scientific misconduct when honest error may be as likely.

Recommendations

The American Academy of Orthopaedic Surgeons urges orthopaedic surgeons who participate in health research to review and adopt these ethical tenets, which have been developed by the Academy's Ethics Committee and Council on Research and Scientific Affairs. These tenets provide a flexible, ethical framework for the conduct and the publication of research results.

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References:

AAOS Standards of Professionalism on Research and Academic Responsibilities, adopted May 12, 2006. The entire document is relevant

Applicable provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

> "II. **Integrity**. The orthopaedic surgeon should maintain a reputation for truth and honesty with patients and colleagues, and should strive to expose through the appropriate review process those physicians who are deficient in character or competence or who engage in fraud or deception."
>
> "VI. **Medical Knowledge**. The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."

Applicable provisions of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

> "III. C. When an orthopaedic surgeon receives anything of value, including royalties, from a manufacturer, the orthopaedic surgeon must disclose this fact to the patient. It is unethical for an orthopaedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular product. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable."
>
> "III. D. An orthopaedic surgeon reporting on clinical research or experience with a given procedure or product must disclose any financial interest in that procedure or product if the orthopaedic surgeon or any institution with which that orthopaedic surgeon is connected has received anything of value from its inventor or manufacturer."
>
> "IV. A. The orthopaedic surgeon continually should strive to maintain and improve medical knowledge and skill, and should make available to patients and colleagues the benefits of his or her professional attainments."
>
> "VIII. A. All research and academic activities must be conducted under the conditions of full compliance with ethical, institutional, and government guidelines. Patients participating in research programs must have given full informed consent and retain the right to withdraw from the research protocol at any time."
>
> "VIII. B. Orthopaedic surgeons should not claim as their own intellectual property that which is not theirs. Plagiarism or the use of others' work without attribution is unethical."

"VIII. C. The principal investigator of a scientific research project or clinical research project is responsible for all aspects of the research, including reporting. The principal investigator may delegate portions of the work to other individuals, but this does not relieve the principal investigator of the responsibility for work conducted by other individuals."

"VIII. D. The principal investigator or senior author of a scientific report is responsible for ensuring that appropriate credit is given for contributions to the research described."

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Footnotes:

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2. Mehta, S., et al., The Ethics of Sham Surgery in Clinical Orthopaedic Research. *J Bone Joint Surg AM,* Vol. 89. 2007. 1650-1653.
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AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Opinion on Ethics and Professionalism

Medical and Surgical Procedure Patents

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

Is it unethical for an orthopaedic surgeon to patent a medical and/or surgical procedure?

Background

For more than a century, medical and surgical methods and processes for diagnosing and treating disease were not considered patentable. In 1952, Congress amended the patent law, adding to the list of subject matter that could be patented "new and useful processes." At the time, the clear legislative intent was to codify existing policy, not change it. Regardless of this intent, since 1952, the U.S. Patent and Trademark Office ("PTO") has routinely issued method or process patents for purely medical and surgical procedures not associated with any drug or medical device (hereinafter referred to as "Medical Procedure Patents"). In fact, the PTO has estimated that as many as 100 medical procedure patents are issued every month. Until recently, such patents were rarely enforced. However, over the past few years, the holders of some of these Medical Procedure Patents actively have sought to enforce them, and consequently the number of Medical Procedure Patents has continued to increase

In October 1996, President Clinton signed into law legislation involving Medical Procedure Patents. The legislation permanently precludes the filing of infringement suits against physicians and other medical practitioners for the performance of "medical activities" that would otherwise violate patents on medical or surgical procedures. A "medical activity" is broadly defined to include the performance of a medical or surgical procedure on a human body, organ or cadaver or on an animal used in medical research. The Act does not apply to patents issued before October, 1996 and it does not affect enforcement of biotechnology patents, patents on drugs or devices or patents on new uses of drugs or other compositions of matter.

Ethical Issues

The patients who we serve are assured a higher quality of care if innovations in medicine and surgery are openly discussed and disseminated by physicians and other health care professionals. Medical Procedure Patents may inhibit these discussions on both legal and financial grounds. In addition, with costs of health care rising, orthopaedic surgeons have an

obligation to support and participate in cost-effective musculoskeletal care. Medical Procedure Patents potentially may increase the costs of new procedures and devices, as the "inventor" would be entitled to compensation over and above the on-going accepted cost of the new procedure or device. They may also limit the access of providers to technology that is more cost effective than the procedures currently used.

The training of future orthopaedic surgeons and continuing medical education for practicing orthopaedic surgeons are based on the free sharing and passing on of knowledge, methods, and procedures. Since it would be in the patent holder's interest to keep an "invention" a secret until the patent is granted, Medical Procedure Patents may discourage orthopaedic surgeons from openly sharing developing medical information. In addition, the enforcement of Medical Procedure Patents is a strong disincentive for orthopaedic surgeons to share the results of their professional experiences and/or independent discoveries of similar existing methods with their colleagues, since this sharing may identify themselves as a potential target for infringement suits. Thus, the granting of Medical Procedure Patents may undermine the process of peer review, evaluation, and critical appraisal of medical innovation within orthopaedics.

If the PTO continues to grant Medical Procedure Patents, medical education similarly may be compromised. Medical schools, medical societies (including the Academy) and other entities providing medical education might either be prohibited from teaching certain patented procedures or would be required to pay a licensing fee to the inventor before teaching a course that includes the patented method. The cost of medical education would also increase if medical schools were required to pay royalties to patent holders to teach patented surgical and medical techniques.

In addition, Medical Procedure Patents may unreasonably interfere with the practice of medicine and the physician-patient relationship. Orthopaedic surgeons have a fiduciary duty to patients to provide the best possible care without outside influence. With Medical Procedure Patents, patients may be denied access to certain procedures, or their choice of physicians may be restricted to only those doctors who are paying royalties to the original "inventor" of the process. Moreover, enforcing such Medical Procedure Patents may compromise patient confidentiality since all procedures will have to be recorded. Thus, granting Medical Procedure Patents may adversely affect the quality of care, jeopardize patient confidentiality, and contribute to the increasing cost of health care.

Medical Procedure Patents may impede the advancement of medicine, curtail academic access, compromise peer review, place unreasonable limits on the research community, directly interfere with the education of new physicians, and interfere with the physician-patient relationship and the quality of medical care provided to the patient. Under these circumstances, the patenting of "pure" medical procedures or techniques would be unethical.

Legal and Other Issues

The consensus in the medical community is that no medical process is really new. Other professional organizations, including the American Medical Association (AMA), have opposed Medical Procedure Patents as unethical. Every procedural innovation is largely based on "prior art." Every advancement in medicine builds on existing knowledge. Sufficient "prior art" exists in almost every instance where the PTO has granted a Medical Procedure Patent. Seen in this light, the PTO should not grant these patents. Also, a real possibility exists of expensive litigation over whether a Medical Procedure Patent should have been granted in the first place. Such litigation has already occurred in this country and further increases the cost of health care.

The PTO has neither the staff nor the expertise to identify "prior art." Moreover, most medical methods and procedures have not been patented, and consequently, the PTO is ill-equipped to determine whether a process is new. In most instances, these medical and surgical processes have existed for years, and have been transferred from teacher to student through practice seminars, actual "hands-on" training, and through the medical literature.

Recommendations

Consistent with the *Principles* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons,* the American Academy of Orthopaedic Surgeons believes that it is unethical for orthopaedic surgeons to seek, secure, or enforce patents on medical or surgical procedures.

The granting of Medical Procedure Patents may pose a serious threat to medical advancement, medical education, and patient care, as well as contribute to the spiraling costs of health care. Furthermore, the Academy believes that the granting of Medical Procedure Patents conflicts with the Academy's mission of fostering and assuring the highest quality and most cost-effective musculoskeletal health care.

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References:

Applicable provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

> **"VI. Medical Knowledge.** The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."
>
> **"X. Societal Responsibility.** The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon."

Applicable provision of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

> **"IV. A.** The orthopaedic surgeon must continually strive to maintain and improve medical knowledge and skill, and should make available to patients and colleagues the benefits of his or her professional attainments."

Other references:

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics.* Chicago, IL, 2014-2015 edition.

Opinion 9.095 - The Use of Patents and Other Means to Limit Availability of Medical Procedures. Issued June 1996 based on the report *Ethical Issues in the Patenting of Medical Procedures*, adopted June 1995 (*Food & Drug Law J.* 1998;53:341-57); updated June 2008 based on the report *Trademarks, Patents, Copyrights, and Other Legal Restrictions on Medical Procedures*, adopted November 2007. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9095.page

U.S. Constitution, Art. 1, Section 8, cl. 8. Congress has the power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

Opinion 1209

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Position Statement

Animals in Biomedical Research and Education

This Position Statement was developed as an educational tool based on the consensus opinion of the authors. It is not a product of a systematic review process. Readers are encouraged to consider the information presented and reach their own conclusions.

The American Academy of Orthopaedic Surgeons (AAOS) is committed to ensuring humane treatment of animals used for laboratory research or surgical education. Government agencies, accrediting agencies, and research institutions must monitor activities within the current laws and guidelines, and individual investigators must increase their sensitivity and discrimination in the use of animals for these purposes.

This position statement asserts that the appropriate use of animals in conducting biomedical and veterinary research and education is justified to enhance the quality of life for both humans and animals. Numerous medical advances, many of which today are taken for granted, were the results of research that required the use of animals. The development of insulin, for example, was critically dependent upon animal experimentation. The development of novel chemotherapeutics routinely requires such experimentation to establish efficacy and safety for use in humans and animals. Improvements in internal fixation of fractures, often life-threatening in animals, have also relied upon animal models of fracture repair.

The AAOS believes federal, state, accrediting agency, and local institutional guarantees and protections provide an appropriate framework for current animal research.

The Animal Welfare Act of 1966 as amended by the Food Security Act of 1985 (PL 99-198), the Health Research Extension Act of 1985 (PL 99-158), the National Institute of Health Guide for the Care and Use of Laboratory Animals (revised 2011), and the Public Education Health Service Policy on Humane Care and the use of Laboratory Animals by Awardee Institutions (revised 2002) provide excellent protections against the misuse or abuse of animals for research purposes. Additionally, the American Association for Accreditation of Laboratory Animal Care ensures that accredited care facilities meet reasonable and appropriate guidelines for the care of animals. Federal law requires each institution to have a local committee that reviews and assesses the appropriateness of all projects requiring animal experimentation. Peer review groups at granting institutions also provide another level of review of appropriate animal use and further protections. Appropriate use of these laws and guidelines will ensure that alternatives to animal experimentation have been first explored, that minimal numbers of animals and appropriate species have been chosen, that the experiments will answer meaningful questions, and that the animals are being treated in a caring and humane way.

The AAOS believes and encourages investigators employing experimental protocols involving laboratory animals to carefully consider the appropriateness and sensitivity of the protocols prior to choosing and using live animals.

The "3Rs" should be considered before investigators adopt an animal-based experimental protocol. **Replace** animal subjects with nonsentient organisms such cell or tissue cultures, or with an inanimate model such as a bench or computer simulation; **reduce** the number of sentient animal subjects by carefully designing and conducting experiments in a manner that produces reliable and statistically significant results, eliminating the need for repetitive confirmatory tests; or refine clinical protocols to reduce the incidence or severity of distress experienced by laboratory animals.

The above approaches, however, do and will continue to have common and particular inherent limitations. It is clear that cells and tissues in culture do not behave entirely like cells in the intact organism. It is also clear that bench and computer simulations do not always serve as sufficient proxies for "live" surgical intervention and that they must always be validated through some sort of animal or human behavior before they can achieve wide use.

Examples can be cited in which research studies depend on animal models because they permit in vivo study of the interaction of many tissue and organ systems:

- *The study of skeletal infection and pharmacokinetics - the interaction between antibiotics and infectious organisms can be quite different in a living animal and in a laboratory environment.*
- *Fractures of long bone and soft tissue injury and repair - the repair process involves many tissues and our current knowledge of these interactions is incomplete. Laboratory or experimental models do not provide the complex interactions required to adequately observe the repair process.*

The AAOS believes research funds should be allocated within governmental and private research agencies to support the development of alternative approaches to animal research.

Current funding policies tend to favor biomedical research that addresses specific clinical problems, rather than research that develops and explores alternative experimental methods. Additional funding specifically aimed at developing alternative approaches to animal experimentation is warranted at this time. The AAOS has provided resources and continues to be supportive of these ongoing efforts.

The AAOS believes that animal models, in specific circumstances, can be used for surgical education and refinement of new surgical techniques.

Coronary bypass surgery and organ transplantation are two examples of numerous instances in which surgical techniques were developed and perfected in animals and later adopted as standard of care in humans. More recently, endoscopic technologies that have minimized the invasiveness and morbidity associated with open surgery were initially tested and refined using carefully selected animal models. The decision to use live animals for the development and improvement of surgical techniques should be done with caution and only after the proof of concept and feasibility of the procedures have been clearly established. Live animal models should be used for surgical education only when no other means for practical training are sufficient.

The AAOS believes current regulations, restrictions, and guidelines will need periodic review as alternative approaches evolve.

Alternative approaches to animal usage in research and education have changed significantly as they have become more refined and sophisticated, as their limitations have become known, and as new methods have become available. Additionally, increasingly refined, safe, and sophisticated human research has reduced the need for some animal experimentation. In fact, humans continue to be the most common species used for biomedical experimentation and medical education. Thus, current guidelines will need to be periodically updated in light of new methods and alternatives.

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Position Statement

Comparative Effectiveness Research

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The American Academy of Orthopaedic Surgeons (AAOS) believes that the development of high quality information that defines which diagnostic, treatment, and prevention services are most effective for specific patients and populations will improve informed patient choice and shared decision-making. Such efforts will maximize the improvement of health status of individuals and populations.

Overview and history:

Comparative effectiveness research (CER) seeks to determine what works in real life situations such as those encountered in an individual practitioners practice setting for their particular patients. This differs significantly from randomized controlled studies (RCT) that seek to identify the maximal effect of an intervention under carefully controlled clinical and research circumstances. CER is defined by the Institute of Medicine (IOM) as the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care[1]. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels. There has been a long history of efforts to assess new biomedical research by the Federal government culminating in the Patient Protection and Affordable Care Act (PPACA) of 2010 [1-8]. These efforts have been accompanied by concerns that CER could lead to rationing of health care.

The marked expansion of federal governmental support for biomedical research led to the development of academic medical institutions after WWII. With the introduction of the Drug Amendment of 1962, the Social Security Amendments of 1965, and the Medical Device amendments of 1976 modern safety and efficacy regulations were first established.[9-11] Largely due to advances in biomedical technology, the costs of Medicare rose at unexpected levels leading to concerns about the federal government's ability to make good decisions about paying for new technology. Through the 1970's and 80's, the Technology Assessment Act created the Office of Technology Assessment (OTA), congress established the National Center for Health Care Technology (CHCT) and the National Center for Health Services Research and Development (NCHSR) within the Department of Health Education and Welfare which was the predecessor of the Department of Health and Human Services (DHHS). All had the purpose of determining whether Medicare should pay for new biotechnology and along with the Health Care Financing Administration (HCFA) predecessor of the Centers for Medicare and Medicaid Services (CMS) funded research on the efficacy of medical treatments and delivery. Controversy and political opposition led to the elimination of the OTA and defunding of the CHCT with replacement of the NCHSR by the Agency for Health Care Policy and Research (AHCPR) in 1989. The AHCPR had

broad responsibilities in determining whether Medicare should pay for medical technologies and in doing so was charged to consider the "safety, efficacy, and effectiveness, and as appropriate, the cost-effectiveness and appropriate uses of such technologies." A series of controversial decisions culminating with the development of guidelines for the treatment of low back pain led to the replacement of the AHCPR by the Agency for Healthcare Research and Quality (AHRQ) through the Health Care Research and Quality Act of 1999. The AHRQ was broadly charged to improve health care quality without setting national standards for care in an effort to avoid the political challenges faced by the AHCPR [5, 6, 9 - 11].

In 2003, the Medicare Modernization Act expanded the AHRQ's role in generating and disseminating evidence about the comparative effectiveness of medications, devices, diagnostic tools, and other interventions. A series of administrative and legislative actions, demonstration programs, and the economic recession of 2008 culminated in the American Recovery and Reinvestment Act of 2009 (ARRA). This act called for coordination of comparative effectiveness research across the federal government with the establishment of the Federal Coordinating Council for Comparative Effectiveness Research, a large expansion in funding for the AHRQ and research dollars for the NIH to fund CER ($1.1 billion), creation of a list of national CER research priorities by the institutes of medicine (IOM), and funding to the FDA to improve methodologies for CER [1,5,6,13]

The passage of the PPACA in 2010 established the Patient-Centered Outcomes Research Trust Fund (PCORTF) and the Patient-Centered Outcomes Research Institute (PCORI)[2, 3, 7, 12, 14]. The stated purpose of this publicly supported, independent, non-profit institute is: "to assist patients, clinicians, purchasers, and policy makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which disease, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described". In contrast to the British National Institute for Health Care and Excellence (NICE), PCORI is specifically restricted to "not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII."[14 - 18].

Comparative Effectiveness Research:

Tools

Despite the focus of the federal government to separate the use of CER from the actions of defining public policy, investigators have viewed CER as combining elements of clinical effectiveness (CE), cost effectiveness analysis (CEA), and pragmatic trials in which benefits of treatments in routine clinical practice are assessed [19 – 22]. Clinical effectiveness has been the focus of most traditional clinical research over time and has typically been highly controlled with the randomized controlled clinical trial being the gold standard research design to evaluate clinical efficacy.

The tools used to assess the comparative effectiveness are similar to those used in conventional evidence based medicine (EBM), but the methodology of this research is unfamiliar to many researchers and training programs [3, 23]. Systematic reviews, randomized clinical trials, and analyses of observational databases are widely used in EBM as explanatory studies to determine

clinical efficacy. By controlling for confounding variables, they maximize our understanding of intervention's singular effect, thus facilitating an understanding of if and how an intervention may work. In CER these tools can also be utilized, but the focus is on application of methods under routine practice situations without variable factors control (internal validity) using tools like the PRECIS [24] to determine how pragmatic or explanatory their trial is under non-ideal situations. By using more heterogeneous populations and clinical conditions, the impact upon priority populations is believed to be more definable and the resulting information potentially more useful to decision makers such as health care providers, patients, and policy makers. In essence, CER can be construed as a natural endpoint of EBM.

The AAOS believes that comparative effectiveness research using pragmatic study designs will be beneficial to the development of knowledge of which specific treatment interventions are most effective for patients under specific circumstances taking into account the specific medical, cultural, social, and unique needs of differing subpopulations.

The AAOS supports continued EBM research and explanatory studies that will continue to bring forth new technological developments in areas related to musculoskeletal health and care, increase our understanding of how specific interventions work and the conditions necessary to optimize improvements in health status.
The AAOS further believes that CER and more traditional EBM research are not mutually exclusive efforts and that rather than defunding one over the other, both should be highly supported as initiatives to enhance the value of health care.

Cost Effectiveness

The laws governing PCORI do not allow for the application of cost analysis that would discount the value of a life because of an individual's disability and because of fears of health care rationing. The rising cost of health care, however has created a need for better value within our health care system. CEA is a methodology utilized to help decision-makers allocate scarce resources. Incremental cost-effectiveness ratio (ICER) is an analytical tool used to do this. It divides the difference in costs between two treatments by the difference in outcomes. When both cost and health outcomes are portrayed in monetary amounts the same analysis becomes a Cost Benefit Analysis (CBA).

One of the outcomes measures widely used in CEA is the Quality-Adjusted Life Year (QALY) as a unit for measuring the health gain of an intervention. It assumes that health is a function of quantity of life and quality of life and that a year lived in perfect health is worth 1 QALY. If health status is less than perfect (utility value), then the QALY is adjusted accordingly based upon the degree of health status loss and/or the length of the year at a given health status. QALY's can then be incorporated with medical costs as cost/QALY to develop a CEA for any treatment or diagnostic tool [19, 21].

The AAOS supports comparative cost effective analyses of interventions done to prevent, diagnose, monitor, and manage the musculoskeletal health of diverse populations. The AAOS however, strongly believes that cost should not be the primary driver of policy decisions related to the comparative effectiveness of treatments of patients, and that strong consideration of efficacy, potential harms, and the unique circumstances of health status for each sub-population should be given.

Harms

Incorporation of harms into calculations of comparative effectiveness has not been widely used. These assessments have often been developed by FDA, FTC, and CMS evidentiary standards [25] or derived from observational studies. As harms are patient specific events, future research initiatives by PCORI are expected to incorporate more of this into comparative effectiveness assessments.

The AAOS believes that there should be ongoing research to identify potential harms of interventions or the withholding of interventions that takes into account the heterogeneity of patient populations and "real world" issues of health care delivery. The AAOS supports the development of CER methods that take into account these potential harms in the comparison of effect.

Implants and Medical Devices:

Implants and medical devices have FDA regulated approval processes and FTC regulated marketing oversight that significantly impacts usage, litigation, and limits availability of measurement tools and outcomes data. CER for implants and medical devices has added complexities due to the large variation in pricing, complex methods for setting pricing, lack of unifying standards governing the industry of devices due to the broad scope of types of devices, and learning curves associated with the use of implants and devices that impact safety and efficacy in differing ways over time [16, 23, 26]. Lack of agreement about how to conduct such assessments, lack of knowledge and expertise in how to construct and perform outcomes and effectiveness research, and limited access to measurement tools and outcomes data have been identified as needs in this area going forward [23, 27, 28].

The AAOS is committed to working with a broad range of stakeholders to develop methods for CER related to musculoskeletal care and specifically for procedures that involve implants. These methods should include increased use and transparency of outcome data through shared databases and should seek to eliminate outcome variations due to training and use.

Structure and Knowledge:

In the United States, passage of the PPACA has stimulated much funding and interest in CER. Establishment of the federally supported, but independent PCORI has created a vehicle for these efforts in close collaboration with the NIH and AHCRQ who continue to fund efficacy studies while supporting efforts to develop and implement tools to support CER.

The methodology being used by PCORI has been to [16]:

- Prioritize research questions
- Develop and use appropriate study designs and analysis for CER
- Incorporate patient and stakeholder perspectives throughout the research continuum

To implement this, PCORI has created patient focused questions to frame research efforts:

- Given my personal characteristics, conditions, and preference, what should I expect will happen to me?
- What are my options and what are the benefits and harms of those options?
- What can I do to improve the outcomes that are most important to me?
- How can the health care system improve my chances of achieving the outcomes I prefer?

The AAOS supports the role of an independent public-private entity that prioritizes, funds, conducts, and coordinates comparative effectiveness research. The AAOS supports the existing principles of CER as articulated in the charter for PCORI. These include:

- Having a single entity coordinate CER initiatives to avoid redundant efforts
- Maintaining stand-alone governance with federal and political independence
- Maintaining stable dedicated public and private financing of CER
- The use of rigorous research methods with transparency of methods, decision-making, and findings.
- Broad public and stakeholder involvement and representation in the development and dissemination phases of a CER
- Production of timely and objective research
- Development of accessible centralized repositories of CER activities
- Wide dissemination of information on a regular, recurring basis
- Maintaining a separation between research and policy setting

Unresolved are issues related to the transparency of process and information generation and the dissemination of information [29]. A prior IOM study has shown an average 17 years for the broad adoption of more effective treatment that has been linked to failure to trust new information, physician engagement to abandon less effective treatments, and acceptance of new treatments by the public and policy makers [2, 30, 31]. Adoption of CER by policy makers and patients and consumer groups is believed to require continued independence of process, expanded education of consumers, and the creation of an increasing array of real time tools [31, 32].

Coincident with the focus on CER and patient centered outcomes has been the push towards expansion of electronic health records, integrated health care systems, and greater detail in documentation. Much of this is driven by the PPACA, but realization of enhancements in patient care and safety is still limited with an increasing recognition of the need for accuracy in documentation and incorporation of patient centered outcomes into these processes [33 - 35].

The AAOS believes that expanded use of electronic health records to capture patient related outcomes is of benefit in CER in real world settings and should be encouraged and supported by CER initiatives.

The AAOS strongly supports widespread dissemination of the findings of CER and believes that this should be done through partnerships with professional medical specialty organizations such as the AAOS and it's specialty societies.

Gaps in the knowledge to execute CER have been increasingly identified [36]. It's application to diagnostic and population health issues is uncertain given the need to not only assess technology, but it's application and interface between disciplines[36]. Concerns also about the opportunity cost of shifting resources to this work and its impact upon technological advancement and innovation have been raised [12, 36 - 38].

The AAOS believes that support of education and training in the methodology of CER by a broad range of public and private entities is needed to optimize the ability of CER to positively impact health status and health care spending in a meaningful way.

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Position Statement 1178

AAOS AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
AMERICAN ASSOCIATION OF ORTHOPAEDIC SURGEONS

Information Statement

Orthopaedic Data Collection

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

Collection of reported events and analyzing safety data is necessary to drive continuous quality improvement and innovation. The Institute of Medicine (IOM) released *To Err Is Human: Building a Safer Health System* in 1999, stimulating a drive for healthcare workers and health care institutions to work toward a safer environment for patients and employees.

The American Academy of Orthopaedic Surgeons (AAOS) is committed to improving patient safety and to decreasing medical errors through promoting the use of reporting systems that, first and foremost, benefit patients, while also protecting the information and health care personnel involved with the event.

Event reporting and data collection should not be limited to sentinel events only, such as wrong-site surgery or accidental death, but should also be focused on improving patient outcomes through the collection and analysis of 'near miss' events. Data collection should include all common adverse events such as pulmonary complications, cardiac complications, surgical-site infections, readmissions and others.

Several reporting systems have been established to gather patient safety data:

Organization/Facility: Each health care organization/facility should have a system in place to routinely and systematically collect safety data with the goal of improving patient safety and minimizing surgical harm. Fostering a non-punitive environment will encourage safety reporting.

Voluntary national: Several voluntary national reporting systems are in place that gather and analyze safety data and publish safety recommendations.

Mandatory state: Currently, at least 27 states have mandatory reporting systems where a list of certain medical errors and events are required to be reported as they occur. The intention of these reporting systems is to bolster national reporting systems in preventing patient harm.

Mandatory national: Congress has enlisted the Centers for Medicare and Medicaid Services to form agencies that collect and analyze data from patient safety events. CMS reports the results from its analysis in an attempt to prevent medical errors and patient harm through a national network.

Improvements that have resulted from data reporting range from system-wide changes that have an immediate impact to subtle cultural changes that may not be evident immediately. Orthopaedic surgery can greatly benefit from these reporting systems.

Within local healthcare organizations/facilities data should be collected routinely concerning the essential elements of surgical safety that will help detect and reduce medical errors contributing to:

- Adverse drug reactions and medication errors
- Incorrect surgical site or procedure confirmation including wrong site surgery
- Communication failures including hand-off errors during transitions of care
- Proper use of surgical /Briefs/, 'Time-Outs' and 'De-Briefs'
- Adverse surgical outcomes, including surgical-site infections and re-admissions

The AAOS believes the following principles are essential to ensure the success of a nationwide effort to reduce the number of medical errors:

- Public and private initiatives to ensure patient safety and reduce the number of medical errors.
- Ensuring patient confidentiality and appropriate legal protection of all information involved in patient safety reporting systems is critical.
- Patient access to their medical records should not be jeopardized by new initiatives.
- Hospitals and medical organizations should foster an attitude of valid feedback and appreciation for error reporting and minimize punitive and adversarial approaches to error reporting. This attitude towards error reporting will foster an environment of safety and comfort in reporting, not one of fear and unwillingness to report errors.
- Before instituting new reporting systems, federal and state governments should first determine, through supporting research, whether and how existing reporting programs as well as public and private initiatives have led to a reduction in medical errors.

To enhance reporting, systems should foster an environment of non-punitive reporting with regard to medical error and adverse event reporting. Congress has led the movement on this matter, establishing the Patient Safety and Quality Improvement Act of 2005, which protects safety event information from being used in medical liability cases.

Orthopaedic surgeons and their organizations/facilities should support and participate in orthopaedic devise registries, such as the American Joint Replacement Registry (AJRR). Through voluntary reporting of key patient and orthopaedic device information to local, state and national device registries both patient care and safety can be improved.

The AAOS strongly recommends orthopaedic surgeons to foster a safety culture through data collection and reporting. Furthermore, the AAOS recommends physicians have an open and honest dialogue with their patients and appropriate health care providers when adverse events occur to promote improvement and reduce future errors.

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Information Statement

Principles of Patient Reported Outcome Measures (PROMs) Reporting

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There has been much written in recent years on the need to improve value in health care, where value is defined as outcomes achieved per dollar spent.[1] In health care, *outcomes* include both the *quality* of care delivered as well as the *service* as experienced by the patient. This has led to great debate over how *quality* should be defined in healthcare. As Teisberg and Porter[1] have noted in their work, value in any field is defined by the customer, not the supplier. Therefore, it is important to measure outcomes from the patient's perspective using patient reported outcomes measures (PROMs). Although PROMs have long been used in clinical outcomes research in orthopaedic surgery, efforts to incorporate PRO measurement into routine clinical practice have been more challenging.[2] However, significant progress has been made in developing and validating PROMs for specific musculoskeletal disorders or treatments and those that give a broader picture of general health status. Furthermore, technological advances have made PRO measurement less burdensome for patients and providers.

At the Fall 2014 Council on Research and Quality (CORQ) meeting, significant time was spent investigating this topic, including presentations by a variety of experts in the development, implementation, and use of these measures. Certain key informational items and principles for future development of these measures became clear:

1. **Patient Reported Outcomes are important to patients and providers.** Change in patient reported outcome is arguably the best measure of the "success" of an orthopaedic procedure. Various public reporting and value-based payment programs are beginning to use PROMs as tools for defining value and provider reimbursements to hospitals, and physicians in the coming years are likely to be impacted by these measures. Functional assessment of total hip and total knee patients are already reporting options in the Physician Quality Reporting System (PQRS) program, and the Centers for Medicare and Medicaid (CMS) is developing a plan for hospital level total joint cost and outcomes measures. In addition, there are plans to include these data at the Hospital Compare and Physician Compare websites.

2. **This is not a research effort, but one aimed at practice improvement.** Validated PROMs presented to the surgeon and the patient can be very helpful in the course of preoperative shared decision making and in tracking progress post-operatively. These provide another tool for surgeons to continue to improve the care that they provide to their patients.

3. **Patients and orthopaedic surgeons should work together to make patient-reported outcomes data as complete and accurate as possible.** If only a few patients respond, or respond at time points that are not comparable, then the results will not be representative, reliable, or relevant.

4. **The orthopedic community, through the AAOS, should look to develop agreement on a common set of metrics.** This is to be distinguished from developing or endorsing specific tools or survey instruments. Examples of the former might be Overall Quality of Life, Physical Function, or Pain Interference. Examples of the latter might be the Short Form 36 Health Survey (SF-36) or the Oxford Hip or Knee Scores. There is emerging research technology to allow the score on one instrument for a specific metric to be translated into a score on a different tool measuring the same metric. This eliminates the need for the AAOS to pick winners and losers amongst the various survey instruments, and to instead focus on the underlying metrics that best reflect the impact that orthopedic surgery provides to our patients.

5. **Both generic and condition-specific measures of health-related quality of life should be used.** It is important that providers capture both generic (e.g., SF-12 [12-Item Short-Form Health Survey], EQ-5D [EuroQol-5D]) and condition-specific (e.g., HOOS [Hip disability and Osteoarthritis Outcome Score], KOOS [Knee injury and Osteroarthritis Outcome Score], ODI [Oswestry Disability Index]) measures of health related quality of life, in order to understand the impact of an intervention on both the patient's overall health as well as the specific condition (e.g., arthritis) the intervention attempts to address.

6. **Members selecting survey tools for PROM acquisition should be sure that those instruments are easily administered, validated, and free to use** (e.g., no licensing fees for use). In this regard, the AAOS will be working with the specialty societies to identify appropriate generic and disease specific measures of health related quality of life. There are a number of providers of these services, ranging from the National Institute of Health (NIH)-sponsored PROMIS (Patient Reported Outcomes Measurement Information System)platform, to foundations (AO [Arbeitsgemeinschaft für Osteosynthesefragen]), to various commercial entities delivering PROM acquisition alone or as part of a larger practice analytics program.

7. **Every effort should be made to make the gathering of PROM data as easy and reliable as possible for patients and providers.** Every effort should be made to provide a means to gather, calculate, and present the results at the time of the office visit. Many technologies are available to facilitate these goals, including the use of digital acquisition over the web, the use of tablet computers in waiting or exam rooms, and the adoption of computerized adaptive testing (CAT) which can decrease the respondent burden by up to 70-80%.

References:

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