Ethics of Pain Management and Research

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Introduction

Medical ethics involve the consideration of numerous principles and values that collectively guide how patients should be cared for and how research should be conducted around them. In modern Western medicine, many of these values are first expressed through a famous vow of ethics known as the Hippocratic Oath and evolved while practicing throughout one's career. This is a complex undertaking that involves situations that are uncertain and difficult, but decisions need to be made considering the patient preferences, medical indications and moral deliberation. There are four cornerstone principles that guide modern discussions of medical ethics: autonomy, beneficence, justice and non-maleficence.

Autonomy

Autonomy is derived from the two Greek roots *autos* meaning "self" and *nomos* meaning "law". In current day practice, autonomy centers around a patient's understanding of medical/procedural risks and benefits, independent assessment of this medical decision and their right to accept or refuse treatment; informed consent. A fully informed patient must be mentally competent to make decisions and not coerced into choosing one way or the other. As long as the decision is informed, the patient can proceed in a manner that is not in their best medical interest [1].

Beneficence

Beneficence involves actions that are taken to improve or benefit the situation of others. Therefore, the provider should "do good" for their patients in every situation. Providers may enter into contracts that dictate the care of a group but this does not excuse them from their ethical duty to put the patient's welfare first.

Justice

Justice begins with its global application to deliver access to healthcare for all. At the heart of the principle, every provider should be fair with every patient giving them their due without prejudice [2]. The simplicity of justice is often skewed with consideration of the patient's legal rights versus what local, state and national laws may dictate. In addition, insurance companies now compromise this moral with pre-authorization and limitation of vehicles of care available to patients based upon their provider.

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Non-maleficence

Non-maleficence originates from the Latin phrase *primum non nocere,* meaning "above all, do no harm". Its presence is also clear in the Hippocratic Oath with the statement "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrongdoing." [2] The application of this principle comes through directly not causing harm when a moral dilemma or crossroad in care occurs, but also applies to the physician maintaining his knowledge and skillsets, staying up to date on modern evidence based medicine and knowing one's limitation so referral and outside consult can be made when needed.

Even with these core principles to guide ethical care, weighing some morals heavier than others may keep you ethically sound but change your resolution of a moral dilemma. One of the most complex ethical dilemmas encountered by pain management physicians involve the prescription of opioids for chronic pain. This is especially true since the Center for Disease Control (CDC) passed guidelines for reduction of opioid prescription for chronic pain. Many patients will present with an expectation of narcotics being the only source for resolution of their pain or with large doses of opioids being prescribed by an alternative provider. Helping these patients when they have become fixated on one specific modality of care becomes difficult and leads to a patient perception of nonadherence to the principles autonomy and beneficence. Additionally, if these patients are turned away there is the consideration of justice and nonmaleficence. This is simply a single incident incurred daily by pain management physician that taxes all these pillars of medical ethics.

Ethics of Research in Pain Management

The goal of clinical research is to improve our knowledge of the mechanisms, progression, diagnosis and treatment of human disease, but it is the responsibility of the researcher to ensure patient safety throughout the process. The underlying principles of medical ethics above also guide the practice of research ethics. When this research is performed on a human subject, pain could be stimulated and treatment can be delayed which may cause harm to this single subject in the short term with the goal being long term benefit to the population at large [1]. With these acute harms in mind, some considerations need to be taken by the investigator to protect these subjects.

1. Prior to initiating the study, the experimental process should be approved by an independent committee on human research consisting of researchers, healthcare practitioners and lay persons. The patient population studied, selection process, underlying negative effects, need for review and early cessation should all be addressed [3].
2. Informed consent should be obtained from all participating subjects. They should be informed of all goals, procedures, and risks, allowed to make an independent decision and be aware they can withdraw from experimentation without risk or penalty at any time throughout the process [4].
3. Patient selection should exclude those that are incapable of giving informed or voluntary consent. These populations would include the mentally handicapped, prisoners, children, and the elderly, unless it is essential to the goals of the study. For subjects unable to provide informed consent, a legal parent, guardian or power of attorney must provide informed consent on their behalf [5].
4. During experimentation, when painful stimuli need to be generated, the minimal stimulus needed to accomplish the desired effect should be used. The stimulus should never exceed the individual's tolerance and the subject should have the ability to end the simulation as desired. When a new treatment is being compared against a placebo or sham treatment, the subject has the right to request a known effective pain relief method. The subject should be informed of this available alternative prior to the initiation of the experiment [3].

High Yield Points

- The four principles that guide modern ethical discussions are autonomy, beneficence, justice and nonmaleficence.
- Autonomy allows the patient to make or refuse medical decisions as long as they are informed of risk, benefits and alternatives even if the decision is not in their best interest.
- Beneficence involves the provider always acting in the patient's best interest.
- Justice entails every provider being fair to each patient and giving each of them equal access to treatment.
- Non-maleficence originates from the Hippocratic Oath and means never do harm.
- Prior to research being initiated on a group of patients, the study should be approved by an independent committee, patient's selected based on study aims and informed consent obtained from all involved.
- During a research study, the minimal stimulus needed to elicit pain should be used, patients should be aware that they can withdraw from the study free of penalty and alternative treatments must be available to the patient.

Questions

1. A 45 year old female is found to have L3-4 disc herniation on MRI with concordant physical exam findings. The provider decides the best course of action is a lumbar epidural steroid injection and coerces the patient into agreeing to proceed with the procedure. Which ethical principle did the provider violate?
   A. Justice
   B. Nonmaleficence
   C. Autonomy
   D. Beneficence
   Answer: C
2. Which of the following is not a consideration that an experimenter should take when implementing a research study on pain?
   A. Prior to initiation of the study, it should be approved by an independent committee.
   B. Subject's can be selected from any population regardless of the goal of the study.
   C. When testing against a sham treatment, an effective alternative pain method must be available to the subject.
   D. If a subject is unhappy with how the study is progressing, they have the right to withdraw at any time.
   Answer: B
3. Which of the following must be discussed with the patient in order to obtain informed consent?
   A. Goals of the study
   B. Risks and benefits
   C. Alternative treatment options
   D. Ability to withdraw without risk or penalty
   E. All of the above
   Answer: E

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