Institute of Medicine
Elder Abuse and its Prevention

ETHICAL CONSIDERATIONS IN RESEARCH AND PRACTICE

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Agenda

- Ethical goals and ethical principles in practice and in research
- Elder Justice Concept Map Project: Source of key issues concerning elder justice
- Ethical issues in decisional capacity
- Ethical issues in informed consent using the example of antipsychotic drug use
- Ethical issues in reporting elder abuse
- HIPAA and perceived barriers to reporting elder abuse
- Health care fraud prosecutions, and remedies

Ethical Goals in Elder Abuse Research and Practice

- Prevent unnecessary suffering
- Maintain autonomy and dignity (autonomy involves questions of decisional capacity)
- Maintain quality of life

Ethical Principles in Elder Abuse

- Four major Ethical Principles that have an impact on elder abuse situations:
  1. **Autonomy** is the right to self-determination, independence, and freedom. **Autonomy** expresses the concept that professionals have a duty to treat the person according to the person's desires, within the bounds of accepted treatment, and to protect the individual's confidentiality.
  2. **Justice** is the obligation to be fair to all people.
  3. **Beneficence** requires that health-care providers do good for individuals under their care by understanding the individual from a holistic perspective that includes the individual's beliefs, feelings, and wishes as well as those of the individual's family and significant others.
  4. **Nonmaleficence** is the requirement that health-care providers do no harm to their patients and that they protect their patients from harm.

Elder Justice "Concept Map Project"

- Concept Map Project
  - DOJ with financial support from HHS contracted with Concept Systems Inc. (CSI) to develop a concept map of the elder justice field
- CSI began the concept map process by inviting 750 professionals from the field to respond to the following prompt:
  - "To understand, prevent, identify, or respond to elder abuse, neglect, or exploitation, we need…"

Elder Justice "Concept Map Project"

- This brainstorming phase generated ideas which were consolidated into categories and rated for feasibility and importance

- The concept map identified some of the key ethical issues addressed here:
  - Brain health and function
  - Elder abuse reporting
  - HIPAA
  - Long-term care quality and abuse prevention

Ethical Issues and Decisional Capacity Key Terms: Decision-making Capacity vs. Competency

- **Decision-making capacity** implies the ability to understand the nature and consequences of different options, to make a choice among those options, and to communicate that choice.
- Decision-making capacity is required in order to give informed consent.
- Decision-making capacity may fluctuate over time, as a result of transient changes in a person's ability to comprehend and communicate.
- Decision-specific capacity depends on a person's ability to make a specific decision in question. Capacity is not totally absent or totally present.

Ethical Issues and Decisional Capacity: Decision-making Capacity vs. Competency

- **Competency** is a legal determination as to mental disability or incapacity; whether a person is legally fit and qualified to give testimony or execute legal documents.
- The law presumes that all adults are competent and have the decision-making capacity to make health decisions.
- To be considered competent, an individual must be able to comprehend the nature of the particular action in question and be able to understand its significance.

Decisional Capacity: Research Study and the Legal System

- Research Study
  - Capacity to consent to participate in a research study
    - Does the older adult have the decision-making capacity to understand the nature and consequences of participation in this study at this time?
- Legal System
  - Capacity of vulnerable adult to testify in an elder abuse case
  - Could be used as a defense litigation strategy to preclude testimony
  - Will be based on whether the witness understands the oath and is capable of giving a correct account of what he or she has seen and heard
  - Individuals with dementia can perceive and be witness for "emotional events" such as psychological abuse

Ethical Issues in Informed Consent

- Informed consent is required before participating in a study or consenting to a proposed treatment
- After being given information, a person gives informed consent if they:
  - can make a choice,
  - understand and appreciate the issues,
  - rationally manipulate information, and
  - make a stable and coherent decision.
- The following age-related changes influence or may impede the process of informed consent for older adults:
  - Sensory deficits in hearing and vision
  - Impaired ability to ask a question
  - Values and beliefs about making health-care choices or participating in a study to help the research community (i.e., “let the doctor decide”)

Ethical Issues in Informed Consent: Antipsychotic Drug Use in Practice

- Informed Consent is important in the area of "medication" abuse or overuse of antipsychotics
  - CMS Initiative
  - Bill introduced in Congress and in some states

CMS' National Partnership to Reduce Antipsychotic Drug Use

- CMS Developed a National Partnership to improve dementia care and optimize behavioral health
- CMS hopes to reduce unnecessary antipsychotic medication use in nursing homes and eventually other care settings
- In December 2011, the national rate in long-stay residents was 23.9% (based on MDS data)

Antipsychotic Medication in Nursing Homes

- High Prevalence rates of antipsychotic medication use in nursing home residents has been reported in residents with a diagnosis of dementia
- According to the CMS Quality Measures/Quality Indicator reports between July and September 2010, 39% of nursing home residents nation-wide who had cognitive impairment and behavioral issues but no diagnosis of psychosis received anti-psychotic medication

Legislative Issues: Informed Consent and Antipsychotic Drug Use

- In 2012 Senators Kohl, Grassley, and Blumenthal introduced a bill which would require federal regulators to issue standardized rules for nursing homes to follow in seeking permission from residents or their designated health care agents before administering antipsychotics for “off-label” use
- Off-label use in this context refers to the use of medications for dementia residents without a diagnosis of serious mental illness
- The proposal would require nursing homes to provide information about the possible risks and side effects associated with these drugs, as well as alternative treatment options

Ethical Issues in Reporting Elder Abuse

- In practice with providers reporting abuse
- Research Study

Mandatory Reporting Requirements

- Reporting Requirements of most states address abuse and neglect
  - Medical professionals
  - Health care providers
  - Mental health counselors
  - Service providers
  - All government agents who come in contact with the elderly

Ethical and Practical Issues for a Provider in Reporting Suspected Elder Abuse

- Need a working definition of abuse
  - Psychological
  - Physical
  - Sexual
  - Neglect
  - Financial
- Awareness of laws regarding abuse reporting in the relevant state
- Knowledge and understanding of the next steps after abuse is reported (e.g., placement, prosecution)
- Case: ER doctor – psychiatric home healthcare nurse

Ethical Issues and Legal Obligations in Reporting Elder Abuse Found in a Research Study

- In the Research Study
  - There is a societal interest in knowledge gained from a study
  - There is a key interest in protecting an older adult from harm
  - Professional law and duty to take reasonable measures to protect potential victims
  - Build provisions for protection of potential victims into research protocols
  - If the older person is at risk of serious and imminent harm, a report to protective services may be justified even if the older person refuses assistance

HIPAA and Perceived Barriers to Reporting and Prosecuting Elder Abuse

- HIPAA has been identified as a barrier to
  - Information sharing between EMS and local and state prosecutors
  - Information sharing between hospitals and local and state prosecutors
  - Information sharing between EMS and Hospitals and APS

HIPAA and the Law Enforcement Exception

- HIPAA was created to provide extensive, nationwide protection to medical information by regulating how "covered entities" use and disclose protected health information
- DHHS enacted a number of exceptions that allow covered entities to provide protected health information to law enforcement officials and social service agencies

HIPAA and the Law Enforcement Exception

- There are a number of exceptions that permit law enforcement officials to access protected health information. These exceptions bypass the requirement that the individual consent or be given an opportunity to decide whether his or her protected health information will be disclosed.
- Required by law/mandatory reporting laws: A covered entity may disclose protected health information to law enforcement officials if it is required to do so by law. An example would be a state law mandating the reporting of certain wounds or other physical injuries.
- As permitted by a judicial officer.
- Restricted access for administrative requests.
- Restricted access for the purpose of identifying or locating a suspect.

HIPAA and the Law Enforcement Exception

- Victims of a crime: Health care entities may also provide law enforcement officials with an individual's protected health information if the individual is a suspected victim of a crime. In such cases, covered entities can only disclose information if 1) the individual agrees to disclosure, or 2) the covered entity cannot obtain the individual's agreement because of incapacity or an emergency.
- Victims of abuse, neglect or domestic violence: A covered entity that believes an individual has been the victim of abuse may disclose the individual's protected health information to a government agency that is authorized by law to receive reports of abuse, neglect or domestic violence.

Health Care Fraud Prosecutions and Remedies

- Under the False Claims Act (FCA) 31 U.S.C. § 3729:
- Any person who:
  - Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or
  - Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim
- Is liable for treble damages and penalties of $5,500 to $11,000 per false claim.

Billing for Worthless Services = Fraud

- Providers who…
  - knowingly render grossly substandard care or no care at all,
  - that harms or kills frail patients, (not a required element, but usually present), and
  - bill Medicare or Medicaid for the alleged care,

- … can be pursued under the False Claims Act.

The United States has Brought Cases against the following Providers:

- Nursing Facilities
- Assisted Living Facilities (ALFs)
- Board and care or adult care homes
- Psychiatric and Acute Care Hospitals
- Group homes for people with intellectual or mental disabilities

The United States' Prosecution of Failure of Care Cases

- Systemic Facility or Chain Problems
- Clear Failures of Care and Violations of Law that have Led to Egregious Outcomes
- Serious Injury or Death
  - Not a Necessary Element for Criminal or Civil Liability

Failure of Care Examples

- Wound care - maggots in wounds
- Excessive falls and fractures
- Impacted feces
- Residents lying in their own waste
- Dehydration and malnutrition
- Excessive medication errors
- Chronic staff shortages

Remedies in FCA cases

- Money damages
- Monitoring and other injunctive relief
- HHS-OIG remedies (Corporate Integrity Agreements (CIA), exclusion)

HHS-OIG Corporate Integrity Agreements

- Do not replace CMS or state survey
- Focus on systemic issues, internal quality assurance and improvement mechanisms
- Chain-wide (often multi-state) approach
- Facility, corporate and regional visits
- Meetings with corporate boards
- Periodic reports to OIG and provider

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