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Ethics in Healthcare: Current Ethics, Ethical vs Unethical Research through 1970

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Modern Ethics in Current Use

- Today, the principles and values of medical ethics have achieved a great deal of acceptance within the medical community
- The field can be roughly divided into four areas:
  - Hospital ethics
  - Ethics at private practices
  - Clinical research ethics
  - Ethics in public health

Hospital Ethics

- Much of modern ethics concerns itself with inpatient matters
- Many of the most pressing ethical issues, such as withdrawal of treatment for dying patients and informed consent for procedures, primarily take place in the hospital
- This is why almost every large hospital today has an ethics committee, but hospital ethics committees are a relatively new phenomenon

Hospital Ethics Committees

- One of the first hospital ethics committees was mandated in a decision by the New Jersey Supreme Court on the right-to-die case of Karen Ann Quinlan in 1976
- In a situation that made headlines across the country, the hospital had a very important ethics decision to make, but did not have the expertise to do so
- The hospital needed to have a panel of physicians and others who would be dedicated to such questions

Hospital Ethics Committees

- At first, the number of hospital ethics committees was quite small, but it took off in the next decade
- Growth was accelerated by a new requirement by The Joint Commission, the hospital accreditor, that all hospitals had to have some mechanism for ethics review
- In 1983, only 1% of US hospitals had an ethics committee, but by 2001 more than 90% had one

Hospital Ethics Committee Functions

- Hospital ethics committees bring together professionals from a variety of disciplines, including doctors, nurses, chaplains, social workers, ethicists, and lawyers
- Their work is mainly advisory
- Functions include:
  - Developing hospital policies on key issues, such as end-of-life care
  - Educating staff on ethical issues
  - Retrospective review of cases and overseeing clinical ethical consults in the hospital

Ethical Consultants

- Ethics committees often defer to ethical consultants, usually known as “medical ethicists” to help doctors resolve problems with patients or their families, as well as many other ethical issues in the hospital
- Medical ethicists often are healthcare providers with training in bioethics

Ethical Consultants

- Their work requires one-on-one communications, tactful negotiation, and a firm grasp of the issues
- A recent survey found that 100% of hospitals with more than 400 beds had ethical consultants, and 81% of the smaller hospitals had them

Ethics in Private Practices

- Although most hospitals provide medical ethicists for doctors to consult, relatively few practices have them on staff
- Physicians in small practices must fend for themselves in terms of ethics, even though they too have many ethical issues
- Whereas physicians in hospitals face high-profile issues, such as end-of-life decisions or the use of novel experimental treatments, private practices face such issues as cultural sensitivity, professional responsibility, distribution of resources, and time constraints on appointments

Clinical Research Ethics

- Obtaining informed consent from research participants is the single greatest ethical issue in medical research
- Investigators are asking participants to take a risk, primarily to benefit someone else
- Potential participants sign up often because they think they're going to get a new cure — even though they will often see little or no benefit, at least in early trials

Clinical Research Ethics

- Clinical research is a closely monitored activity
- Under federal law, the organization doing the research is required to set up an institutional review board (IRB), a group of peers who are not supposed to benefit financially if the study is successful
- The IRB sets criteria for the study's deliberations and decisions, such as weighing risks and benefits of a particular experiment, making sure potential participants know their options, and overseeing the informed consent process
- Owing in large part to IRBs, research institutions take their ethical obligations very seriously

Informed Consent in Research

- Informed consent documents must thoroughly describe the risks and benefits, but they can't be so long that research participants can't easily read through them, and they can't use terms that the participants don't understand
- Increasingly, visual and electronic aids are used to supplement written consent and improve comprehension by research participants

Ethics in Public Health

- A great deal of medical ethics has to do with public health
- This is territory riven with ethical pitfalls, involving such issues as preventing disease, prolonging life, and promoting health through organized efforts
- Public health authorities deal with such problems as flu epidemics, drug abuse, providing mental health services, monitoring children for health issues at birth, and the cost of healthcare
- All of these areas have to do with resource allocation, which is a seminal issue in modern medical ethics

Ethics in Public Health

- Public health issues traditionally exist at the government level, but they are increasingly arising at the practice level
- A few examples in practices involve countering the opioid epidemic, counseling on safe use of guns, urging the use of bike helmets, and making sure patients are vaccinated

Current Ethical Issues: Vaccination

- In the case of vaccinations, some parents refuse the measles vaccine for their children, citing baseless claims that it causes autism
- At first blush, these parents appear to be merely exercising their individual rights, a sacred issue for Americans, but the overriding concern is a societal problem
- Unvaccinated children can spread the disease to others
- Requiring vaccinations thus becomes a matter of "protecting the herd"

Vaccine-Autism Myth Started 20 Years Ago

- The vaccine-autism myth is an example of fraudulent science
- February 28, 2018 marked the 20th anniversary of an infamous article published in the prestigious medical journal, *The Lancet*
- Andrew Wakefield, a British doctor, falsely linked the MMR (measles, mumps, and rubella) vaccine to autism

Vaccine-Autism Myth Started 20 Years Ago

- The paper eventually was retracted by the co-authors and the journal. Wakefield lost his license to practice medicine for his deceit and "callous disregard" for children
- It took nearly two decades for the United Kingdom (UK) immunization rates to recover
- UK families experienced more than 12,000 cases of measles, hundreds of hospitalizations, — many with serious complications — and at least three deaths

Vaccine-Autism Myth Persists

- Amplified by the British media, celebrity endorsement, and social media
- Wakefield has moved beyond the initial vaccine-autism claim to attacking the Centers for Disease Control and Prevention (CDC) in his controversial film Vaxxed
- The film was pulled before screening at the Tribeca Film Festival but found its way into independent theaters in the U.S. and Europe
- Europe's four-fold increase in measles cases and 35 measles-related deaths in 2017 — due largely to people not getting vaccinated — also reflects how Wakefield's vaccine-autism scare can spark vaccine refusals that lead to debilitating and fatal cases of measles

Vaccine-Autism Myth Persists

- In the U.S., measles was declared eliminated in 2000; however, there has been a resurgence of measles with more than 2,216 reported cases since 2001
- Wakefield's anti-vaccine fanaticism contributed to the 2015 outbreak in Disneyland in California, which eventually infected more than 130 people, and to the 2017 measles outbreaks in Minnesota, where his message persuaded many parents not to vaccinate their children

Vaccine-Autism Myth Persists

- The vaccine-autism myth has also prompted an alarming number of millennials — the generation that came of age in the era of Wakefield's misinformation — in the U.S. not to vaccinate their children
- Vaccine reluctance does not apply just to measles; flu kills 100 to 300 children under age 5 each year in the U.S., and up to 85% of them were not vaccinated when they died

Current Ethical Issues: Vaccination

- The medical community must ensure the integrity of research evidence and move rapidly to address suspected scientific fraud
  - An investigation published by the British Medical Journal (BMJ) concludes Dr. Andrew Wakefield misrepresented or altered the medical histories of all 12 of the patients whose cases formed the basis of the 1998 study

Current Ethical Issues: Vaccination

- Health policy has moved to requiring vaccination of children to enter school in states who were more lax, like California
- Wakefield was not disciplined by the UK medical authorities, nor was the article retracted by *The Lancet* until 2010, despite serious concerns raised by experts at the time of publication and the 2004 exposé on Wakefield's fabricated data and retraction by co-authors

Current Ethical Issues: Politicization of Firearms

- In 2011, Florida enacted a law that barred doctors from discussing the dangers of gun ownership with their patients
- Doctors who disobeyed the law could be censured, fined, or lose their licenses
- Besides Florida, 14 other states considered similar bills

Current Ethical Issues: Politicization of Firearms

- But none of them were passed, and an appeals court overturned the Florida law in 2017, ruling that it violated doctors' right to free speech
- Now that doctors are free to talk about gun safety, how should they handle this issue?
- Studies show they will be more effective if they refrain from a disapproving tone and instead focus on the risks of suicide prevention, keeping guns in homes, and other storage practices

Current Ethical Issues: Cost and Utilization of Healthcare Resources

- Cost issues are another topic that is increasingly turning up in physician practices
- With the emergence of accountable care organizations and other modes of value-based payments, physicians are under greater pressure to keep costs in check without harming quality

Current Ethical Issues: Cost and Utilization of Healthcare Resources

- Some physicians are adopting the concept of stewardship as an ethical way to balance cost-savings with quality of care
- Although patient advocacy comes first, doctors can also consider whether it is worthwhile to provide services that are only marginally beneficial to their patients

Current Ethical Issues: Cost and Utilization of Healthcare Resources

- Stewardship also is a growing need for patients
- As patients increasingly pay for services out-of-pocket, the high costs of marginally beneficial services can threaten their livelihood
- Physicians can get help in deciding when to reject marginal services by consulting Choosing Wisely, a list of over-utilized services selected mainly by medical associations
- Doctors and their patients can discuss the list and hold conversations about the costs and benefits of medical services

Current Ethical Issues: Discussions of Political Views

- With physicians under pressure to take a stand on various issues, how much should they voice their views on these issues to their patients?
- Physicians have a great deal of influence over patients' views on healthcare issues, such as advocating the use of health savings accounts, defending the Affordable Care Act, or calling for a single-payer healthcare system
- Doctors may even bring up issues that directly affect the medical profession rather than patients; such issues include tort reform, opposition to maintenance of certification, or the need to reduce physician burnout

Current Ethical Issues: Discussions of Political Views

- Physicians do have a right to raise these issues
- Political action is the only way they can deal with issues such as inadequate healthcare
- Be prepared to lose some patients owing to your views
- However, physicians need to exercise discretion about their causes
- If the patient does not appear to be interested in the pitch or actually disagrees with it, the doctor should drop it
- Maintaining a good patient/doctor relationship is more important than scoring political points

Current Ethical Issues: Medical Marijuana Use

- Ethical issues involving the medical use of marijuana include whether it is possible for the benefits to exceed its known risks

Current Ethical Issues: Medical Marijuana Use

- Evidence base for marijuana benefits remains quite limited since published trials are compromised by their small sample sizes, heterogeneous populations, lack of active comparators, differing exclusion criteria, differing concentration, and subjective outcomes, in contrast to the published studies of marijuana's risks, which are larger, longer-lasting, better-controlled for confounders, and have clearer outcomes
- No compelling ethical grounds exist for physicians recommending the medical use of marijuana outside of current federal regulations

Current Ethical Issues: Medical Marijuana Use

- Do physicians put profit above proper medical practice when staffing medical marijuana clinics?
- State laws can be very generous in what conditions medical marijuana can be prescribed
- For example, in California [Proposition 215] the list of indications includes "other chronic or persistent medical symptoms"
- Should physicians recommend referrals to pain team specialists, palliative care specialists, and integrative medicine specialists for patients with refractory symptoms such as pain, nausea, muscle spasms, and wasting?

Current Ethical Issues: Medical Marijuana Use

- The available evidence suggests most recommendations occur in a physician-patient relationship focused on the prescription for marijuana, narrowing the physician-patient relationship to the provision of an otherwise illicit substance
- Medicines are purified chemicals that are approved in specific doses, based on scientifically-determined efficacy, safety, and purity by the food and drug administration (FDA)

Current Ethical Issues: Medical Marijuana Use

- Medications are dispensed to patients on legal physicians' orders to be used for specific periods of time, for specific reasons, and in specific amounts
- The American Society of Addiction Medicine recently issued a white paper opposing medical marijuana because it fails to meet this standard
- Nonmaleficence imposes an obligation on clinicians to refrain from doing harm, and there are several potential harms associated with cannabis and additional harms associated specifically with the smoked form of the drug

Marijuana's Known Impact on Health

- The movement toward legalization of marijuana for medical purposes is based in part on the belief that the substance has beneficial medical effects
- The debate over legalizing medical marijuana centers squarely on the definition of a Schedule I drug and whether cannabis should still be considered as such
- According to the Controlled Substances Act, passed by Congress and signed into law by President Nixon in 1970, a Schedule I drug has a high potential for abuse, has no currently-accepted medical use in treatment in the United States, and lacks acceptable safety for use under medical supervision

Marijuana's Known Impact on Health

- Marijuana was included in the "Hallucinogenic Substances" category as a Schedule I substance, so the sale, purchase, or consumption of marijuana became illegal
- Thus the legal status of medical marijuana is determined by whether or not it has an "accepted medical use in treatment in the United States"

Marijuana's Known Impact on Health

- In 2011, pursuant to California law, a doctor may prescribe marijuana for patients suffering from AIDS, anorexia, arthritis, cancer, migraine headaches, seizures, severe nausea, glaucoma, and chronic pain
- While the California Medical Association declares the evidence supporting the medical value of marijuana is inconclusive, they assert that marijuana use has led to plenty of anecdotal evidence
- The California Medical Association also cautions that there is a absence of research in this field and that more conclusive evidence will require more data

Marijuana's Known Impact on Health

- Though the California Medical Association (CMA) issued recommendations for the use of medical marijuana, the CMA references multiple health risks associated with marijuana use:
  - Addiction
  - Short-term cognitive effects
  - Long-term cognitive effects
  - Psychiatric conditions
  - Chronic obstructive lung disease (COPD)
  - Reproductive risks

Marijuana's Known Impact on Health

- Many of the negative side effects of marijuana – including increased risk of cancer, lung damage, bacterial pneumonia, poor pregnancy, among others – can be removed if marijuana is administered via methods other than smoking
- The American Cancer Society (ACS) concludes in a position paper on the medical use of marijuana, that marijuana delivers harmful substances to the body, similar to many of the cancer-causing substances found in tobacco smoke

American Cancer Society Position

- The ACS states that marijuana has potential to treat those suffering from pain, nausea, vomiting, poor appetite, and AIDS
- According to their position paper on marijuana:
  - "the ACS is supportive of more research into the benefits of cannabinoids. Better and more effective treatments are needed to overcome the side effects of cancer and its treatment. [However], the ACS does not advocate the use of inhaled marijuana or the legalization of marijuana"

Unintended Consequences of Medical Marijuana Use

- Because of the classification of marijuana as a Schedule I drug, little research has been done to prove definitively that the use of marijuana for medical purposes has no value

Unintended Consequences of Medical Marijuana Use

- Whatever the medical benefits or harms of marijuana, there is also discussion of unintended consequences – both good and bad – of legalizing marijuana for medical use
  - In Colorado, more than a dozen young children have been unintentionally poisoned with marijuana as a result of children consuming marijuana-laced cookies, brownies, sodas, and candy, according to researcher Dr. George Sam Wang of the Rocky Mountain Poison and Drug Center in Denver
  - According to a report published by the Yale Medical School, frequent marijuana use among young adults significantly increases the risk of greater involvement with other illegal drugs

In Conclusion

- Do no harm, nonmaleficence, imposes an obligation on clinicians to refrain from doing harm, and there are several potential harms associated with cannabis and additional harms associated specifically with the smoked form of the drug
- Informed consent requires caregivers the mandate to inform patients of potential benefits of marijuana, but also ensure they are well-informed of known and potential health risks
- One key ethical challenge to caregivers is agreement to patient demands for marijuana based on changing social and political realities, rather than scientific evidence or meaningful empirical data

Ethical vs. Unethical Research

- Ethical studies protect subjects and are carried out using scientific principles
- Unethical research includes:
  - Scientific misconduct
  - Fraud, research protocol violations
  - Fabrication, falsification, forging of data
  - Plagiarism
  - Putting subjects at risk without consent

Elements of Ethical Research

- Protecting human rights
- Understanding informed consent
- Understanding institutional review of research
- Balancing benefits and risks in a study

Unethical Studies

- Nazi medical experiments
- Tuskegee syphilis study
- Willowbrook study
- Jewish chronic disease hospital study

Nazi Human Experimentation

- Over the course of the Third Reich and the Holocaust, Nazi Germany conducted a series of medical experiments on Jews, prisoners of war, Romani, and other persecuted groups
- The experiments were conducted in concentration camps, and in most cases resulted in death, disfigurement, or permanent disability

Nazi Human Experimentation

- Especially disturbing experiments included attempts to genetically manipulate twins; bone, muscle, and nerve transplantation; exposure to diseases and chemical gasses; sterilization, and anything else the infamous Nazi doctors could think up
- After the war, these crimes were tried as part of the Nuremberg Trials and ultimately led to the development of the Nuremberg Code of medical ethics

Ethical Codes and Regulations

- Nuremberg Code (1949)
- Declaration of Helsinki (1964)
- Department of Health, Education, and Welfare (DHEW) regulations (1973)
- National Research Act (1974)
  - National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978)
  - The Belmont Report (1976)

Nuremberg Code (1949)

1. The voluntary consent of the human subject is absolutely essential
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature

(Levine 1986, pp. 425-426)

Nuremberg Code (1949)

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment

(Levine 1986, pp. 425-426)

Nuremberg Code (1949)

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
5. No experiment should be conducted where there is a reason to believe that death or disabling injury will occur, except, perhaps, in those experiments where the experimental physicians also serve as subjects

(Levine 1986, pp. 425-426)

Nuremberg Code (1949)

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death

(Levine 1986, pp. 425-426)

Nuremberg Code (1949)

8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible

(Levine 1986, pp. 425-426)

Nuremberg Code (1949)

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject

(Levine 1986, pp. 425-426)

Willowbrook Study (1956 to 1970)

- Mentally handicapped children housed at the Willowbrook State School in Staten Island, New York, were intentionally given hepatitis in an attempt to track the development of the viral infection
- The study began in 1956 and lasted for 14 years
- The researcher also wanted to determine the effectiveness of gamma globulin injections as protection against hepatitis

Willowbrook Study (1956 to 1970)

- They justified their deliberate infections and exposures by claiming that given that there was a high rate of infection in the institution, it was practically inevitable that the children would become infected
- In a series of letters published in a journal there was a discussion of the moral nature of the experiment
- The issues include: the vulnerability of the test subjects, interference with informed consent, and the non-therapeutic nature of their experiment for their subjects

Goldby's Criticisms (April 1971)

- It is morally wrong to perform an experiment on either a normal or a mentally handicapped child when no benefit can result for that child
- The institutionalized should not be used for human experimentation
- A healthcare professional on the staff of a substandard institution has a duty first and foremost to improve the institution: It is morally wrong for the healthcare professional to turn the institution's failings to experimental advantage

Krugman's Defense (May 1971)

- There was no additional risk for the subjects. Under the normal conditions at the institution the subjects would have been exposed to the same strains of hepatitis
- Experimental subjects had a lowered risk of complications since they were housed in a special unit where there was little danger of exposure to other diseases
- Experimental subjects had the chance of benefiting from immunization
- Experimental subjects were obtained only with informed consent from parents

Pappworth's Criticisms (June 1971)

- Experimentation on children, even with parental informed consent, is illegal unless it is in the interests of the child
- According to one report, parents were told that the only way their child could be admitted to Willowbrook is through the hepatitis unit
- The intention of the experiment was never the immunization of the children. That was merely an expected consequence. A moral purpose is required to justify an experiment
- Every patient has a right to be treated decently by physicians – i.e., every physician has an obligation first and foremost to the patient. The patient's right supersedes every consideration about what would benefit humanity

In conclusion

- Through 1970, many more unethical research practices were uncovered
- The Nazi medical experiments and Willowbrook Study just happened to be highly publicized
- Researchers around the world and scholars began to establish rules to govern biomedical research
- These rules would be further developed in the 1970s to govern all research, whether biomedical in nature or not

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