Physicians and Society
Chapter 3

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Physicians and Society

Objectives:

After working through this chapter you should be able to:

1. **Recognize conflicts between the physician's obligations to patients and to society and identify the reasons for the conflicts**
2. **Identify and deal with the ethical issues involved in allocating scarce medical resources**
3. **Recognize physician responsibilities for public and global health.**

Physicians and Society

Case # 2:

Dr. S is becoming increasingly frustrated with patients who come to her either before or after consulting another health practitioner for the same ailment. She considers this to be a waste of health resources as well as counter productive for the health of the patients. She decides to tell these patients that she will no longer treat them if they continue to see other practitioners for the same ailment. She intends to approach her national medical association to lobby the government to prevent this form of misallocation of healthcare resources.

What is special About Physicians-Society Relationship?

- **Medicine is a profession. The term ‘profession’ has two distinct, although closely related, meanings:**

1. **An occupation that is characterized by dedication to the well-being of others, high moral standards, a body of knowledge and skills, and a high level of autonomy.**
2. **All the individuals who practice that occupation.**

- **‘The medical profession’ can mean either the practice of medicine or physicians in general.**

What is special About Physicians-Society Relationship?

- **Medical professionalism involves the relationship between a physician and a patient, relationships with colleagues and other health professionals, as well as a relationship with society.**
- **Medicine is today, more than ever before, a social rather than a strictly individual activity.**
- **It takes place in a context of government, and corporate organization funding.**
- **It relies on public and corporate medical research and product development for its knowledge base and treatments.**

What is special About Physicians-Society Relationship?

- It requires complex healthcare institutions for many of its procedures.
- It treats diseases and illnesses that are as much social as biological in origin.
- The Hippocratic tradition of medical ethics has little guidance to offer with regard to relationships with society.
- Present-day medical ethics addresses the issues that arise beyond the individual patient-physician relationship.

What is special About Physicians-Society Relationship?

- **Because society, and its physical environment, are important factors in the health of patients, both the medical profession in general and individual physicians have significant roles to play in public health, health education, environmental protection, laws affecting the health or well-being of the community, and testimony at judicial proceedings.**

What is special About Physicians-Society Relationship?

- **As the WMA Declaration on the Rights of the Patient puts it: "Whenever legislation, government action or any other administration or institution denies patients [their] rights, physicians should pursue appropriate means to assure or to restore them."**

Dual Loyalty

- **Physicians are called upon to play a major role in the allocation of society's scarce healthcare resources, and sometimes they have a duty to prevent patients from accessing services to which they are not entitled.**
- **Implementing these responsibilities can raise ethical conflicts, especially when the interests of society seem to conflict with those of individual patients.**

Dual Loyalty

- **When physicians have responsibilities and are accountable both to their patients and to a third party and when these responsibilities and accountabilities are incompatible, they find themselves in a situation of 'dual loyalty'.**
- **Third parties that demand physician loyalty include governments, employers (hospitals and managed healthcare organizations), insurers, military officers, police, prison officials and family members.**

Dual Loyalty

- **Although the WMA International Code of Medical Ethics states that "A physician shall owe his/her patients complete loyalty," it is generally accepted that physicians may in exceptional situations have to place the interests of others above those of the patient.**
- **The ethical challenge is to decide when and how to protect the patient in the face of pressures from third parties.**
- **Dual loyalty situations comprise a spectrum ranging from those where society's interests should take precedence to those where the patient's interests are clearly paramount.**

Dual Loyalty

- In between is a large grey area where the right course of action requires considerable discernment.
- At one end of the spectrum are requirements for mandatory reporting of patients who suffer from designated diseases, those deemed not fit to drive or those suspected of child abuse.
- Physicians should fulfil these requirements without hesitation, although patients should be informed that such reporting will take place.

Dual Loyalty

- **At the other end of the spectrum are requests or orders by certain authorities to take part in practices that violate fundamental human rights, such as torture.**
- **The WMA provides specific guidance to physicians who are in this situation.**
- **In particular, physicians should guard their professional independence to determine the best interests of the patient and should observe, as far as possible, the normal ethical requirements of informed consent and confidentiality.**

Dual Loyalty

- **Any breach of these requirements must be justified and must be disclosed to the patient.**
- **Physicians should report to the appropriate authorities any unjustified interference in the care of their patients, especially if fundamental human rights are being denied.**
- **If the authorities are unresponsive, help may be available from a national medical association, the WMA and human rights organizations.**

Dual Loyalty

- Closer to the middle of the spectrum are the practices of some managed healthcare programs that limit the clinical autonomy of physicians to determine how their patients should be treated.
- Although such practices are not necessarily contrary to the best interests of patients, they can be, and physicians need to consider carefully whether they should participate in such programs.

Dual Loyalty

- **If they have no choice in the matter, for example, where there are no alternative programs, they should advocate vigorously for their own patients and, through their medical associations, for the needs of all the patients affected by such restrictive policies.**

Dual Loyalty

- **A particular form of a dual loyalty issue faced by physicians is the potential or actual conflict of interest between a commercial organization on the one hand and patients and/or society on the other.**
- **Pharmaceutical companies, medical device manufacturers and other commercial organizations frequently offer physicians gifts and other benefits that range from free samples to travel and accommodation at educational events to excessive remuneration for research activities.**

Dual Loyalty

- **A common underlying motive for such company generosity is to convince the physician to prescribe or use the company's products, which may not be the best ones for the physician's patients and/or may add unnecessarily to a society's health costs.**
- **The primary ethical principle of WMA's guideline in this situation is: physicians should resolve any conflict between their own interests and those of their patients in their patients' favor.**

Resource Allocation

- **In every country in the world, there is an already wide and a steadily increasing gap between the needs and desires for healthcare services and the availability of resources to provide these services.**
- **Healthcare rationing, or ‘resource allocation’, takes place at three levels:**

Resource Allocation

1. **At the highest ('macro') level, governments decide how much of the overall budget should be allocated to health; which healthcare expenses will be provided at no charge and which will require payment either directly from patients or from their medical insurance plans; within the health budget, how much will go to salaries for physicians, nurses and other heath care workers, to capital and operating expenses for hospitals and other institutions, to research, to education of health professionals, to treatment of specific conditions such as tuberculosis or AIDS, and so on.**

Resource Allocation

2. At the institutional ('meso') level, which includes hospitals, clinics, healthcare agencies, etc., authorities decide which services to provide; how much to spend on staff, equipment, security, other operating expenses, renovations, expansion, etc.
3. At the individual patient ('micro') level, healthcare providers, especially physicians, decide what tests should be ordered, whether a referral to another physician is needed, whether the patient should be hospitalized, whether a brand-name drug is required rather than a generic one, etc.

Resource Allocation

- **It has been estimated that physicians are responsible for initiating 80% of healthcare expenditures, and despite the growing encroachment of managed care, they still have considerable discretion as to which resources their patients will have access.**
- **The choices that are made at each level have a major ethical component, since they are based on values and have significant consequences for the health and well-being of individuals and communities.**

Resource Allocation

- The individualistic approach to medical ethics survived the transition from physician paternalism to patient autonomy, where the will of the individual patient became the main criterion for deciding what resources he or she should receive.
- More recently, another value has emerged and has become an important factor in medical decision-making, that is justice.
- It entails a more social approach to the distribution of resources, one that considers the needs of other patients.
- According to this approach, physicians are responsible not just for their own patients but, to a certain extent, for others as well.

Resource Allocation

- **This new understanding of the physician's role in allocating resources is expressed in many national medical association codes of ethics and in the WMA Declaration on the Rights of the Patient, which states:**
- **"In circumstances where a choice must be made between potential patients for a particular treatment that is in limited supply, all such patients are entitled to a fair selection procedure for that treatment. That choice must be based on medical criteria and made without discrimination."**

Resource Allocation

- **One way that physicians can exercise their responsibility for the allocation of resources is by avoiding wasteful and inefficient practices, even when patients request them.**
- **The overuse of antibiotics is just one example of a practice that is both wasteful and harmful.**

Resource Allocation

- **A type of allocation decision that many physicians must make is the choice between two or more patients who are in need of a scarce resource such as emergency staff attention, the one remaining intensive care bed, organs for transplantation, high-tech radiological tests, and certain very expensive drugs.**

Resource Allocation

- **Some physicians face an additional conflict in allocating resources, in that they play a role in formulating general policies that affect their own patients, among others.**
- **This conflict occurs in hospitals and other institutions where physicians hold administrative positions or serve on committees where policies are recommended or determined.**
- **Although many physicians attempt to detach themselves from their preoccupation with their own patients, others may try to use their position to advance the cause of their patients over others with greater needs.**

Resource Allocation

There are several approaches to justice in dealing with these allocation issues by physicians:

1. **Libertarian: resources should be distributed according to market principles (individual choice conditioned by ability and willingness to pay, with limited charity care for the destitute). (??!!)**
2. **Utilitarian: resources should be distributed according to the principle of maximum benefit for all**
3. **Egalitarian: resources should be distributed strictly according to need.**
4. **Restorative: resources should be distributed so as to favor the historically disadvantaged.**

Resource Allocation

- **The WMA Statement on Access to Health Care says that "No one who needs care should be denied it because of inability to pay. Society has an obligation to provide a reasonable subsidy for care of the needy, and physicians have an obligation to participate to a reasonable degree in such subsidized care."**
- **Even if the libertarian approach is generally rejected, however, medical ethicists have reached no consensus on which of the other three approaches is superior.**

Resource Allocation

- **Some countries, such as the U.S.A., favor the libertarian approach; others, such as Sweden are known for their egalitarianism; while still others such as South Africa, are attempting a restorative approach.**
- **Many health planners promote utilitarianism.**

Public Health

- **The 20th century medicine witnessed the emergence of an unfortunate division between ‘public health’ and other healthcare.**
- **It is unfortunate because the public is made up of individuals, and measures designed to protect and enhance the health of the public result in health benefits for individuals.**
- **The term ‘public health’ refers both to the health of the public and also to the medical specialty that deals with health from a population perspective rather than on an individual basis.**

Public Health

- **There is a great need for specialists in this field in every country to advise on and advocate for public policies that promote good health as well as to engage in activities to protect the public from communicable diseases and other health hazards.**
- **The practice of public health (sometimes called ‘public health medicine’ or ‘community medicine’) relies heavily for its scientific basis on epidemiology, which is the study of the distribution and determinants of health and disease in populations.**

Public Health

The WMA Statement on Health Promotion notes:

- **“Medical practitioners and their professional associations have an ethical duty and professional responsibility to act in the best interests of their patients at all times and to integrate this responsibility with a broader concern for and involvement in promoting and assuring the health of the public.”**

Public Health

- **Public health measures such as vaccination campaigns and emergency responses to outbreaks of contagious diseases are important factors in the health of individuals, but social factors such as housing, nutrition and employment are equally significant.**
- **Physicians are advised to participate in public health and health education activities, monitoring and reporting environmental hazards, identifying and publicizing adverse health effects from social problems such as abuse and violence, and advocating for improvements in public health services.**

Public Health

- **Sometimes the interests of public health may conflict with those of individual patients, for example, when a vaccination that carries a risk of an adverse reaction will prevent an individual from transmitting a disease but not from contracting it, or when notification is required for certain contagious diseases, for cases of child or elder abuse, or for conditions that may render certain activities, such as driving a car or piloting an aircraft, dangerous to the individual and to others.**
- **These are examples of dual-loyalty situations.**

Public Health

- **In general, physicians should attempt to find ways to minimize any harm that individual patients might suffer as a result of meeting public health requirements.**
- **For example, when reporting is required, the patient's confidentiality should be protected to the greatest extent possible while fulfilling the legal requirements.**

Public Health

- **A different type of conflict between the interests of individual patients and those of society arises when physicians are asked to assist patients to receive benefits to which they are not entitled, for example, insurance payments or sick-leave.**
- **They should rather help their patients find other means of support that do not require unethical behavior.**

Global Health

- **The recognition that physicians have responsibilities to the society in which they live has been expanded to include a responsibility for global health.**
- **This term has been defined as health problems, issues and concerns that transcend national boundaries, that may be influenced by circumstances or experiences in other countries, and that are best addressed by cooperative actions and solutions.**

Global Health

- **Global health is part of the much larger movement of globalization that encompasses information exchange, commerce, politics, tourism and many other human activities.**
- **The basis of globalization is the recognition that individuals and societies are increasingly interdependent.**
- **This is clearly evident with regard to human health, as the rapid spread of diseases such as influenza, SARS and Corona has shown.**

Global Health

- **Such epidemics require international action for their control.**
- **The failure to recognize and treat highly contagious diseases by a physician in one country can have devastating effects on patients in other countries.**
- **For this reason, the ethical obligations of physicians extend far beyond their individual patients and even their communities and nations.**

Global Health

- **The development of a global view of health has resulted in an increasing awareness of health disparities throughout the world.**
- **The gap in health status between high and low-income countries continues to widen.**
- **This is partly due to HIV/AIDS, which has had its worst effects in poor countries, but it is also due to the failure of many low-income countries to benefit from the increase in wealth that the world as a whole has experienced during the past decades.**

Global Health

- **Even in middle- and high-income countries, physicians encounter patients who are directly affected by globalization, such as refugees, and who sometimes do not have access to the medical coverage that citizens of those countries enjoy.**
- **Another feature of globalization is the international mobility of health professionals, including physicians.**
- **The outflow of physicians from developing to highly industrialized countries has been advantageous for both the physicians and the receiving countries but not so for the exporting countries.**

Global Health

- **The WMA, in its Ethical Guidelines for the International Migration of Health Workers, states that: physicians should not be prevented from leaving their home or adopted country to pursue career opportunities in another country. It does, however, call on every country to do its utmost to educate an adequate number of physicians, taking into account its needs and resources, and not to rely on immigration from other countries to meet its need for physicians.**

Physicians and the Environment

- **A major threat to both public health and global health is the deterioration of the environment.**
- **The 2006 WMA Statement on the Role of Physicians in Environmental Issues states that "The effective practice of medicine increasingly requires that physicians and their professional associations turn their attention to environmental issues that have a bearing on the health of individuals and population."**
- **These issues include air, water and soil pollution, unsustainable deforestation and fishing, and the proliferation of hazardous chemicals in consumer products.**

Back to the Case Study

- **According to the analysis of the physician society relationship presented in this chapter, Dr. S is right to consider the impact on society of her patient's behavior.**
- **Even if the consultations with the other health practitioner occur outside of the health system in which Dr. S works and therefore do not entail any financial cost to society, the patient is taking up Dr. S's time that could be devoted to other patients in need of her services.**

Back to the Case Study

- However, physicians such as Dr. S must be cautious in dealing with situations such as this.
- Patients are often unable to make fully rational decisions for a variety of reasons and may need considerable time and health education to come to an understanding of what is in the best interests of themselves and of others.
- Dr. S is also right to approach her medical association to seek a societal solution to this problem, since it affects not just herself and this one patient but other physicians and patients as well.

Medical Ethics In The Arab-Islamic Civilization

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Medical Ethics In The Arab-Islamic Civilization

- **Many famous Moslem Physicians during that time (100 years ago) were interested very much in the Ethics of Practicing Medicine.**
- **The published several books on the subject of medical ethics.**
- **Abu Al-Hasan Ali Al-Tabery described "the Islamic Law of Medical Ethics" in the 9th century BC in a book named "Firdaws Al-Hikma" as follows:**

Medical Ethics In The Arab-Islamic Civilization

1. The physician should be humble, noble, compassionate.
2. The physician should wear clean clothes, and to be reverent (وقورا), and combs the hair of his head and beard very well.
3. The physician should choose his friends from those who are reputable.
4. The physician should be accurate with what he says, and not to hesitate asking for forgiveness if he comets a mistake.
5. The physician should be tolerant and and not to intend revenge.

Medical Ethics In The Arab-Islamic Civilization

6. The physician should be affectionate and peace maker.
7. The physician should avoid prediction whether a patient is going to live or die because Allah only know that.
8. The physician should not loose control (يفقد صوابه).
9. If the patient continues to ask question, the physician should answer gently and with compassion.
10. The physician should treat the rich and the poor, the master and the slave by the same way. Allah will reward him if helps the needy.

Medical Ethics In The Arab-Islamic Civilization

11. The physician must keep time and appointments and to be trustworthy.
12. The physician should not argue about his fees if the patient is severely ill, or came as an emergency, and he should thank him regardless how much money he pays.
13. The physician should not prescribe drugs to pregnant ladies to help them get aborted, except when necessary to the mother health.

Medical Ethics In The Arab-Islamic Civilization

14. The physician should be polite with women, and not breech the confidentiality of his patients.

15. The physician should not talk with an evil way about any descent person in the society, and should not criticize the religious believes of any body, and should talk in a good manner about his colleagues.

16. The physician should not glorify himself and criticize others.

Medical Ethics In The Arab-Islamic Civilization

- **Isaac Bin Ali Alrahawi wrote in his book " Adab Al-Tabib" in the 10th Century BC about the following:**

1. **Loyalty and Sincerity that the physician should believe in.**
2. **The care of medical professionals.**
3. **Things the physicians should avoid and be cautious about.**
4. **The Physician's instructions to patients.**
5. **The behavior of patient's visitors.**

Medical Ethics In The Arab-Islamic Civilization

6. The physician should no simple and complex drugs.
7. The type of questions that physicians should ask patients about.
8. The need that patients must trust physicians.
9. The need that patients follow physician instructions.
10. Patient’s behavior towards who serves him.
11. Patient’s behavior towards his visitors.
12. Honor of the medical profession.

Medical Ethics In The Arab-Islamic Civilization

13. The general public respect to the physician according to his skills.
14. Distinctive incidents of interest to physicians.
15. Individuals with the right temperament and high moral qualities only should practice the medical profession.
16. Physicians should be examined before authorizing them to practice medicine.
17. Corruption among physicians should be corrected.

Medical Ethics In The Arab-Islamic Civilization

18. Beware of charlatans who call themselves physicians.
19. Bad habits that hurt people were also addressed.

- In addition to that the book contains valuable information about conditions conducive to personal health, physician-patient relationships, and some notes on the relationship between the medical profession and government.

Medical Ethics In The Arab-Islamic Civilization

Abu Baker Mohammad Bin Zakaryya Al Razi in his book "Akhlaq Al-Tabeeb":

- **He pointed out that the physician should be expert in meicie and should serve as a role model.**
- **This book represents the first model of medical ethics in The Arab-Islamic Civilization.**
- **He divided his vision to medical ethics to:**

Medical Ethics In The Arab-Islamic Civilization

1. **The physician's responsibility towards the patient.**
2. **The physician's responsibility towards himself.**
3. **The patient's responsibility towards the physician.**

- **According to his opinion:**

1. **The physician should continue educating himself in medicine, and continue his commitment to medical education to others.**
2. **The physician must be effective and honorable, and holds back from vanity, and be devoted to his patient and gives him love.**

Medical Ethics In The Arab-Islamic Civilization

3. **Physicians should be concerned about their look, an their clothes and hair should be clean and tidy.**
4. **Among the duties of physicians toward patients are: treating them with compassion, not to be rude or hostile, and must be tender-hearted and humble.**
5. **The physician must keep the secretes that he gets to know during treatment of the patient as stated in the Hippocratic oath.**

Medical Ethics In The Arab-Islamic Civilization

6. The physician should psychologically encourage the patients, even those with no hope to live, and to instill hope in them.
7. The physician should treat all patients in the same way regardless of their wealth.
8. The primary aim of the physician should be the cure of the patient, and not the fees that he gets.
9. Caution should be exercised when treating women, and not looking at their private parts.

Medical Ethics In The Arab-Islamic Civilization

10. The patient duty toward the physician is respect and to speak to him in a kind way.

- Al-Razi attacked the charlatans and those who claimed knowledge in medical practice, who roam the country and distant districts, to sell their drugs that cure every disease.
- He also pointed out that the most skilled physicians have no answers to all medical problems, and can not cure all diseases.
- Physicians should rely on Allah alone, and to expect recovery from him alone, Almighty (جل وعلا).

Some Medical Ethics Issues
Chapter 4

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Reporting Unsafe or Unethical Practices

- **Medicine, with pride, is a self regulating profession.**
- **In return for the privileges accorded to it by society and the trust given to its members by their patients, the medical profession has established high standards of behavior for its members.**
- **In addition, disciplinary procedures were established to investigate accusations of misbehavior and, if necessary, to punish the wrongdoers.**
- **This system of self-regulation has often failed.**

Reporting Unsafe or Unethical Practices

- In recent years steps have been taken to make the profession more accountable, for example, by appointing lay members to regulatory authorities.
- The main requirement for self-regulation, however, is wholehearted support by physicians for its principles and their willingness to recognize and deal with unsafe and unethical practices.
- This obligation to report incompetence, impairment or misconduct of one's colleagues is emphasized in codes of medical ethics:

Reporting Unsafe or Unethical Practices

- **The WMA International Code of Medical Ethics states that "A physician shall…report to the appropriate authorities those physicians who practice unethically or incompetently or who engage in fraud or deception."**
- **The application of this principle is seldom easy.**
- **On the one hand, a physician may be tempted to attack the reputation of a colleague for unworthy personal motives, such as jealousy, or in retaliation for a perceived insult by the colleague.**

Reporting Unsafe or Unethical Practices

- A physician may also be reluctant to report a colleague's misbehavior because of friendship or sympathy.
- The consequences of reporting can be very detrimental to the one who reports, including almost certain hostility on the part of the accused and possibly other colleagues as well.
- Despite these drawbacks to reporting wrongdoing, it is a professional duty of physicians.

Reporting Unsafe or Unethical Practices

- **Not only are they responsible for maintaining the good reputation of the profession, but they are often the only ones who recognize incompetence, impairment or misconduct.**
- **However, reporting colleagues to the disciplinary authority should normally be a last resort after other alternatives have been tried and found deficient:**

1. **The first step might be to approach the colleague and say that you consider his or her behavior unsafe or unethical.**

Reporting Unsafe or Unethical Practices

- If the matter can be resolved at that level, there may be no need to go farther.

2. If not, the next step might be to discuss the matter with your and/or the offender's supervisor and leave the decision about further action to that person.
3. If this tactic is not practical or does not succeed, then it may be necessary to take the final step of informing the disciplinary authority.

Relationships with Other Health Professionals

- There is a great importance of respect and equal treatment in the physician-co-worker relationship.
- In particular, the prohibition against discrimination on grounds such as “age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor” (WMA Declaration of Geneva) is applicable in dealings with all those with whom physicians interact in caring for patients and other professional activities.
- Non-discrimination is a passive characteristic of a relationship.

Relationships with Other Health Professionals

- **Respect is something more active and positive.**
- **With regard to other healthcare providers, whether physicians, nurses, auxiliary health workers, etc., it entails an appreciation of their skills and experience insofar as these can contribute to the care of patients.**
- **All healthcare providers are not equal in terms of their education and training, but they do share a basic human equality as well as similar concern for the well-being of patients.**

Relationships with Other Health Professionals

- **Sometimes there are legitimate grounds for refusing to enter or for terminating a relationship with another healthcare provider.**
- **These include lack of confidence in the ability or integrity of the other person and serious personality clashes.**
- **Distinguishing these from less worthy motives can require considerable ethical sensitivity on the physician's part.**

Cooperation

- **Medicine is, at the same time, a highly individualistic and a highly cooperative profession.**
- **On the one hand, physicians are quite possessive of ‘their’ patients.**
- **It is claimed, with good reason, that the individual physician-patient relationship is the best means of attaining the knowledge of the patient and continuity of care that are optimal for the prevention and treatment of illness.**
- **The retention of patients also benefits the physician, at least financially.**

Cooperation

- **At the same time, medicine is highly complex and specialized, thus requiring close cooperation among practitioners with different but complementary knowledge and skills.**
- **This tension between individualism and cooperation has been a recurrent theme in medical ethics.**
- **The weakening of medical paternalism has been accompanied by the disappearance of the belief that physicians ‘own’ their patients.**

Cooperation

- **The traditional right of patients to ask for a second opinion has been expanded to include access to other healthcare providers who may be better able to meet their needs.**
- **According to the WMA Declaration on the Rights of the Patient, "The physician has an obligation to cooperate in the coordination of medically indicated care with other healthcare providers treating the patient."**
- **However, physicians are not to profit from this cooperation by fee-splitting.**

Cooperation

- These restrictions on the physician's 'ownership' of patients need to be counterbalanced by other measures that are intended to safeguard the primacy of the patient-physician relationship.
- For example, a patient who is being treated by more than one physician, which is usually the case in a hospital, should, wherever possible, have one physician coordinating the care who can keep the patient informed about his or her overall progress and help the patient make decisions.

Cooperation

- **Whereas relationships among physicians are governed by generally well-formulated and understood rules, relationships between physicians and other healthcare professionals are in a state of flux and there is considerable disagreement about what their respective roles should be.**
- **Many nurses, pharmacists, physiotherapists and other professionals consider themselves to be more competent in their areas of patient care than are physicians and see no reason why they should not be treated as equals to physicians.**

Cooperation

- **They favor a team approach to patient care in which the views of all caregivers are given equal consideration, and they consider themselves accountable to the patient, not to the physician.**
- **Many physicians, on the other hand, feel that even if the team approach is adopted, there has to be one person in charge, and physicians are best suited for that role given their education and experience.**

Cooperation

- **Although some physicians may resist challenges to their traditional, almost absolute, authority, it seems certain that their role will change in response to claims by both patients and other healthcare providers for greater participation in medical decision-making.**
- **Physicians will have to be able to justify their recommendations to others and persuade them to accept these recommendations.**
- **In addition to these communication skills, physicians will need to be able to resolve conflicts that arise among the different participants in the care of the patient.**

Cooperation

- **A particular challenge to cooperation in the best interests of patients results from their recourse to traditional or alternative health providers (‘healers’).**
- **Although some would consider the two approaches as complementary, in many situations they may be in conflict.**
- **Since at least some of the traditional and alternative interventions have therapeutic effects and are sought out by patients, physicians should explore ways of cooperation with their practitioners. In all such interactions the well-being of patients should be the primary consideration.**

Conflict Resolution

- Although physicians can experience many different types of conflicts with other physicians and healthcare providers, the focus here will be on conflicts about patient care.
- Ideally, healthcare decisions will reflect agreement among the patient, physicians and all others involved in the patient's care.
- However, uncertainty and diverse viewpoints can give rise to disagreement about the goals of care or the means of achieving those goals.
- Limited healthcare resources and organizational policies may also make it difficult to achieve consensus.

Conflict Resolution

- **Disagreements among healthcare providers about the goals of care and treatment or the means of achieving those goals should be clarified and resolved by the members of the healthcare team so as not to compromise their relationships with the patient.**
- **Disagreements between healthcare providers and administrators with regard to the allocation of resources should be resolved within the facility or agency and not be debated in the presence of the patient.**

Conflict Resolution

- **Since both types of conflicts are ethical in nature, their resolution can benefit from the advice of a clinical ethics committee or an ethics consultant where such resources are available.**

Conflict Resolution

The following guidelines can be useful for resolving such conflicts:

1. **Conflicts should be resolved as informally as possible, for example, through direct negotiation between the persons who disagree, moving to more formal procedures only when informal measures have been unsuccessful.**
2. **The opinions of all those directly involved should be elicited and given respectful consideration.**
3. **The informed choice of the patient, or authorized substitute decision-maker, regarding treatment should be the primary consideration in resolving disputes.**

Conflict Resolution

4. If the dispute is about which options the patient should be offered, a broader rather than a narrower range of options is usually preferable. If a preferred treatment is not available because of resource limitations, the patient should normally be informed of this.
5. If, after reasonable effort, agreement or compromise cannot be reached through dialogue, the decision of the person with the right or responsibility for making the decision should be accepted. If it is unclear or disputed who has the right or responsibility to make the decision, mediation, arbitration or adjudication should be sought.

Conflict Resolution

- **If healthcare providers cannot support the decision that prevails as a matter of professional judgement or personal morality, they should be allowed to withdraw from participation in carrying out the decision, after ensuring that the person receiving care is not at risk of harm or abandonment.**

مقدمة حول السرية الطبية

- السرية الطبية: تمثل حجر الزاوية في العلاقة بين الطبيب والمريض.
- السرية الطبية: التزام أخلاقي وقانوني يحفظ خصوصية المريض ويصون معلوماته.

الخصوصية والسرية

- الخصوصية :حق الإنسان في عدم التدخل في شؤونه أو المراقبة. من قبل الآخرين
- السرية :حق الفرد في الحفاظ على معلوماته الطبية بعيدًا عن الآخرين.
- الخصوصية تتعلق بمكان الفحص، والسرية تتعلق بالمعلومات.

مفهوم السرية والخصوصية

- **الخصوصية:** حق الفرد في عدم التدخل في شؤونه الجسدية أو المعلوماتية.
- **السرية:** التزام بعدم مشاركة المعلومات الطبية مع أي طرف دون إذن صريح.

أهمية الحفاظ على السرية

- تعزز ثقة المريض بالطبيب.
- تحمي المريض من الوصمة الاجتماعية أو الأذى القانوني.
- تستند إلى قسم الأطباء والتشريعات الأخلاقية الدولية.

إجراءات الحفاظ على خصوصية المريض أثناء الفحص في المنشآت الصحية

- التأكد من إجراء الفحوصات الجسدية في أماكن منفصلة بعيدًا عن المرضى الآخرين أو الزوار غير المصرح لهم أو أفراد الطاقم غير المعنيين.
- توفير غرف انتظار وفحص تراعي الفروقات بين الجنسين.
- توفير ملابس ملائمة للمرضى المقيمين في المستشفى.
- ضمان تغطية المرضى جيدًا عند نقلهم من مكان إلى آخر داخل المستشفى.
- التأكد من كشف جزء الجسم المطلوب فقط بما يتناسب مع ضرورة الفحص أو الإجراء الطبي.

إجراءات الحفاظ على خصوصية المريض أثناء الفحص في المنشآت الصحية

- الحرص على وجود شخص آخر (ممرضة) من نفس جنس المريض أثناء أي فحص طبي.
- الحصول دائمًا على إذن المريض قبل البدء بأي فحص.
- ضمان توفير الخصوصية التامة عند جمع المعلومات من المرضى.

ممارسات إضافية لحماية خصوصية المرضى أثناء الفحص

- تجنّب إبقاء المريض في غرفة الفحص مدة أطول من المطلوب للإجراء.
- يُمنع فحص المرضى في الممرات أو مناطق الانتظار.
- لا يجوز السماح لأي شخص غير معني من خارج الكادر الطبي بالتواجد أثناء الفحص.
- يجب إعطاء المريض وقتًا كافيًا لكشف موضع الألم بنفسه.
- لا يُسمح بدخول غرفة الفحص إلا للأشخاص المعنيين مباشرة بالإجراء الطبي.

Hippocratic oath

"What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about".

قسم ابوقراط :

" أقسم بالله العظيم أن أكون أمينا على الشرف والبر والصلاح في مزاولة صناعة الطب وأن أسعف الفقراء مجانا ولا أطلب أجرا يزيد على أجر عملى ، وأنى إذا دخلت بيتا لا أتعرض لما لا يعنينى من أموره ولا أفشي سرا، ولا أستعمل صناعتى في إفساد الخصال الحميدة و إرتكاب الآثام ، ولا أعطى سما البته ولا أدل عليه ولا أشير به ولا أعطى دواء يضر الحوامل أو يسقط أجنتهن، وأن أكون موقرا للذين علمونى معترفا بفضلهم مسديا أوولادمم ما فى إستطاعتى من معروف وإحسان".

قسم الطبيب : مادة (1) من لائحة مزاولة المهنة:

" أقسم بالله العظيم أن أراقب الله في مهنتي ، وأن أصون حياة الإنسان في كافة أدوارما في كل الظروف وأوحوال باذلاً وسعي في استنقاذما من الهلاك والمرض وأولم والقلق، وأن أحفظ للناس كرامتهم ، وأستر عورتهم، وأكتم سرهم ، وأن أكون على الدوام من

وسائل رحمة الله باذلاً رعايتي الطبية للقريب والبعيد ، للصالح والخاطئ ، والصديق والعدو وأن أثابر على طلب العلم أسخره لنفع الإنسان لا أوذاه ، وأن أوقر من علمني ،وأعلم من يصغرني ، وأكون أخا لكل زميل في المهنة الطبية متعاونين على البر والتقوى، وأن تكون حياتي مصداق إيماني في سري وعلانيتي ، نقيةً مما يشينها تجاه الله ورسوله والمؤمنين، والله على ما أقول شهيد".

المادة٨- يحظر على مقدم الخدمة ما يلي:-

هـ- إفشاء أسرار متلقي الخدمة التي يطلع عليها أثناء مزاولة المهنة أو بسببها سواء أكان متلقي الخدمة قد عهد إليه بهذا السر وأتمنه عليه أم كان مقدم الخدمة قد أطلع عليه بنفسه، ولا يسري هذا الحظر في أي من الحالات التالية:-

١- إذا كان إفشاء السر بناء على طلب متلقي الخدمة وبموافقته الخطية.

٢- إذا كان إفشاء السر لمصلحة الزوج أو الزوجة وتم إبلاغه شخصيا.

٣- إذا كان الغرض من إفشاء السر منع وقوع جريمة أو الإبلاغ عنها ويكون الإفشاء في هذه الحالة للجهة الرسمية المختصة.

٤- إذا كان مقدم الخدمة مكلفاً بذلك قانونا.

٥- اذا كان إفشاء السر أمام اللجنة الفنية العليا.

المادة ٢٠- مع عدم الإخلال بأي عقوبة أشد ورد النص عليها في أي تشريع آخر:-

أ- يعاقب كل من يخالف أحكام المادة (٧) والفقرات (أ)، (ج)، (د)، (هـ)، (و)، (ز) من المادة (٨) من هذا القانون بغرامة لا تقل عن (٣٠٠٠) ثلاثة آلاف دينار ولا تزيد على (٥٠٠٠) خمسة آلاف دينار.

المعلومات التي تشملها السرية الطبية؟

تشمل السرية الطبية جميع المعلومات التي يمكن من خلالها التعرف على المريض، مثل:

- الحالة الصحية الجسدية أو النفسية للمريض في الماضي أو الحاضر أو المستقبل.
- أي معلومات سريرية تتعلق بالتشخيص أو العلاج الطبي.
- الصور الفوتوغرافية، مقاطع الفيديو، التسجيلات الصوتية، أو أي مواد مرئية أو صوتية تخص المريض.
- اسم الطبيب المعالج، والمواعيد أو العيادات التي يراجعها المريض.
- أي معلومات قد تُستخدم للتعرف على المريض بشكل مباشر أو غير مباشر.
- تفاصيل المدفوعات المتعلقة بالرعاية الصحية: السابقة أو الحالية أو المتوقعة.

متى يمكن خرق السرية؟

- بموافقة المريض الصريحة أو الضمنية.
- في حالات يوجب فيها القانون الإبلاغ (مثل الأمراض المعدية، العنف، الحوادث).
- عند وجود خطر على الآخرين أو على الصحة العامة.

تطبيقات عملية

- لا يجوز مناقشة حالة مريض في مكان عام.
- لا يُسمح بالإفصاح عن معلومات مريض عبر الهاتف دون إذن منه.
- لا يجوز إبلاغ العائلة عن وجود المريض دون موافقته.
- جميع الأفراد لهم نفس الحق في السرية الطبية، بما في ذلك الأطفال وكبار السن وذوي الإعاقة الذهنية والمتوفون.

دور الطبيب في حماية السرية

- توفير بيئة آمنة أثناء الفحص.
- التأكد من وجود طاقم طبي فقط أثناء مناقشة الحالة.
- التوعية بحقوق المريض في الخصوصية.

متى يُسمح بكشف السرية الطبية؟

يمكن كشف السرية الطبية في ثلاث حالات رئيسية:

1. **بموافقة صريحة من المريض**
   (مثل التوقيع على نموذج يسمح بالإفصاح).
2. **بموافقة ضمنية من المريض**
   (مثل التحويل إلى طبيب مختص أو مشاركة المعلومات داخل الفريق الطبي).
3. **دون موافقة المريض**
   (في حالات محددة ينص عليها القانون أو تقتضيها مصلحة عامة).

1. الإفصاح بموافقة صريحة من المريض:

- **لأغراض البحث أو الوبائيات أو السجلات الطبية**، بشرط:
  - الحصول على موافقة لجنة أخلاقيات البحث.
  - ضمان عدم الإضرار بالمريض.
  - إزالة أي بيانات يمكن أن تكشف هوية المريض.
- **للشركات التأمينية** عند طلب تعويضات أو إصدار بوليصات تأمين.
- **في الفحوصات الطبية ما قبل التوظيف**، عند الحاجة إلى تقييم الحالة الصحية للمتقدم للعمل.

2. الإفصاح بموافقة ضمنية من المريض

- **طلب استشارة أو رأي طبي ثانٍ:**
يتم مشاركة المعلومات الضرورية فقط داخل الفريق الطبي أو مع مختصين آخرين من أجل تحسين رعاية المريض.
- **تحويل المريض إلى طبيب مختص آخر:**
مثل تحويل حالة ألم مزمن في البطن لإجراء تصوير بالموجات فوق الصوتية (سونار) مع إرسال التشخيص الأولي أو الشكوى الأساسية.

الافصاح دون موافقة المريض – وفقًا للقانون

1. **الإفصاح المطلوب بموجب القانون**

- التبليغ عن: الولادات، الوفيات، الإجهاض، الحوادث، حالات التسمم.
- تنفيذ أوامر قضائية أو التعامل مع قضايا سوء الممارسة، القضايا الجنائية (العنف)، والتعويضات.
- في حال وجود تهديد جدي بإلحاق الأذى بالآخرين (لمنع الجريمة).
- حالات إساءة معاملة الأطفال (جسدية أو جنسية).
- الحوادث المرتبطة بتعاطي المخدرات أو الكحول.
- المخاطر الصحية العامة: الأمراض المعدية الواجب الإبلاغ عنها، مثل: السل، التهاب الكبد، الإيدز، التيفوئيد، الكزاز، التهاب السحايا، الدفتيريا، الجمرة الخبيثة، الملاريا، شلل الأطفال، الجدري، البروسيلا، الجذام وغيرها من الامراض السارية او المعدية.

الإفصاح دون موافقة المريض –

- **لحمايتة المريض وصالحه:**

- في حالات الطوارئ الطبية.
- إذا كان المريض قاصرًا أو غير مؤهل عقليًا لاتخاذ القرار.
- لتجنّب ضرر مباشر للمريض (مثل مرضى الصرع أو الاضطرابات النفسية).
- عند الاشتباه بتعرض المريض للإهمال أو سوء المعاملة.

- **لحماية الآخرين من أذى محتمل**

- مثل مرضى الذهان العدوانيين.
- للوقاية من ارتكاب جرائم أو أذى جسيم.
- في حال الإصابة بأمراض معدية تهدد الصحة العامة (مثل الإيدز، التهاب الكبد).

- **للحفاظ على الأمن القومي:** (مثل حالات الإرهاب أو التهديدات الأمنية)

اتخاذ قرار

تعمل طبيبًا في قسم الطوارئ:

- حضر مريض مصاب بفيروس معدٍ ((HIV) وطلب منك عدم إبلاغ زوجته بحالته والزوجة تتردد في زياراته وتطلب منك الاطمئنان على حالته الصحية وسبب مرضه.

- كيف توازن بين الحفاظ على سرية المريض وحماية الآخرين وهل يمكنك كسر السرية في هذه الحالة؟ ولماذا؟

مواقف واقعية

- اتصل بك صحفي يطلب معلومات عن حالة مريض شهير تُعالج في المستشفى، كيف تتصرف؟
- أحد زملائك يناقش حالة مريض في مقهى عام بصوت مرتفع، هل تتدخل؟ وكيف؟
- مريض شاب مصاب بمرض معدٍ يرفض إبلاغ أسرته، كيف تتعامل مع هذا الموقف؟

خاتمة وتوصيات

- السرية الطبية ليست خيارًا بل واجب.
- يجب التوازن بين حق الفرد وسلامة المجتمع.
- التزام الطبيب بالسرية يعكس احترامه للمهنة والإنسان.

The end

Good luck to you all

بسم الله الرحمن الرحيم

آداب الطب

Medical Ethics

مساق آداب الطب لطلبة الطب

- MEDICAL ETHICS COURSE
- FOR MEDICAL STUDENTS

الاهداف العامة

- **General Objectives:**
- **1 . تطبيق مبادئ آداب الطب أثناء الدراسة والتدريب على العلوم السريرية**
- **1 . Apply the principles of Medical Ethics, through training in clinical years.**
- **2 . تطبيق آداب الطب قديما وحديثا في ضوء آداب الطب الأردنية**
- **2 . Apply the Codes of Medical Ethics (the old and recent ones at the international level), taking in to consideration the national code.**
- **3 . التفريق بين الإلتزام بمتطلبات آداب الطب ومتطلبات القوانين**
- **3 . Differentiate Ethical from Legal obligations.**
- **4 . توظيف المعارف والخبرات الطبية بما يحقق أهداف القوانين**
- 4 . Apply Medical knowledge and experience to the administration of Law.

- 5 .تحديد الاولويات في حال تعارض تنفيذ الواجب الطبي والواجب القانوني
- 5 . Determine priorities when medical obligations are in contradiction with legal obligations.

6 . إدراك النتائج المترتبة على الملاحقة التأديبية والملاحقة القضائية في

- حال مخالفة مبادئ آداب الطب والقوانين

- 6 . Identify legal and disciplinary implications of ignorance or violation of Law or Medical Ethics.
- 7 . يتابع بشكل دوري التعديلات التي تطرأ على آداب الطب والقوانين ذات العلاقة.
- 7 . follow periodically changes in Ethical and legal issues.
- 8 . Practice communication skills. 8 . يمارس مهارات الاتصال

تحكم الآداب جميع المهن ولكنها أشمل وأوضح في المهن الطبية

All professions are guided and controlled by Ethics, but more emphasis was put on Medical Ethics.

- فرض التقدم المطّرد في الطب والعلوم ذات العلاقة اهتماما
- كبيرا لتطويرها على الدوام
- Due to rapid advancements in Medicine and allied sciences,
- Health Professionals paid much of their attention and concern to develop Medical Ethics.

من المتعارف عليه عالميا، ضرورة تعليم آداب الطب لطلبة الطب، إلا أن عدد قليلا من كليات الطب أخذ بالاعتبار ضرورة وضعها في مناهجها

Ethics education is well recognized world wide as so essential to medical students, but few Medical Schools responded positively to this matter in their curricula.

وهنا نسأل، هل من الضروري تعليم آداب
الطب للطلبة؟

Is there a need to teach
our students Medical Ethics?

وللإجابة على ذلك،
دعونا نرى مدى معرفتنا بواجباتنا تجاه أي من الممارسات
والوقائع التالية، وذلك على سبيل المثال لا الحصر، ومدى اتفاقها والقوانين الطبية
وآداب الطب أو مخالفتها لها؟

Let us go through the following exercise:
Which of the following practices is Ethical?

تصوير مريض أو تصوير الآفة المرضية أو الجروح والإصابات دون إذن المريض

Taking photographs of the patient, (even pathological lesions, wounds and injuries), without his/her consent?

الإبلاغ عن الأخطاء الطبية التي لم ينجم عنها أي ضرر إلى إدارة المستشفى أو الجهات المسؤولة من صحية أو قضائية

Notifying/ Reporting Medical Errors (without damages) to hospital administrator, Health or Legal Authorities?

الإبلاغ عن الأخطاء الطبية التي ألحقت أضرارا بالمرضى إلى إدارة المستشفى أو الجهات المسؤولة من صحية وقضائية

Notifying/ Reporting Damages due to Medical Errors to hospital administrator, Health or Legal Authorities?

الإبلاغ عن الحالات الطبية القضائية للشرطة أو الجهة القضائية المختصة

Notifying/ Reporting Medico-Legal to Police Or Legal Authorities.

إفشاء أسرار المرضى بقرار قضائي

Disclosure Upon Court Order

إفشاء أسرار المرضى المصابين بالأمراض الخمجية المعدية والسارية إلى:

Disclosure of Infectious Diseases to:

الجهات الصحية المسؤولة ,Health Authorities

الزوجة أو الزوج ,Wife or Husband

أصحاب العمل ,Work Authorities

غيرهم ..... Others

إخفاء خطورة المرض أو الترجيح المميت عن المريض

Hiding Serious Complications and Fatal Prognoses From the patient?

هل هنالك استثناء لهذه القاعدة؟

Is there an exception to the rule:

مثل واجب إبلاغ الأهل بذلك إذا لم يبلغ المريض

the right to know or disclosure to the family?

مناقشة الحالة المرضية مع المريض أو ذويه على الهاتف

Discussing patient’s condition, with the patient or his/her relative, on the phone?

مناقشة الحالة المرضية مع المريض عن طريق البريد الإلكتروني

Discussing patient’s condition with the patient bye mail?

إخبار الزوج بمرض زوجته دون موافقتها، وبالعكس

Telling the husband about the condition of his Wife without her consent, and vice versa?

معاينة أنثى قاصر بناء على طلب الشرطة أو بقرار قضائي دون موافقة وليها

Examining a Junior Female upon police or legal order without her Fathers’ consent?

تجاوز الحد الأعلى للأجور المهنية للطبيب، المقررة والمعلنة في الجريدة الرسمية؟

القيام بإجراء تشخيصي أو علاجي أو جراحي لغير ضرورة طبيّة تُبرّرُه؟

اشتراك الطبيب مع زميله الطبيب المعالج في استشارة طبية، أو القيام بإجراء علاجي أو جراحي دون أخذ رضا المريض مسبقا؟

..... إلخ.

علينا النظر إلى المستجدات ذات العلاقة بآداب الطب وتطبيقاتها من خلال استخدام البحث العلمي لاتخاذ القرار اللازم قبل الأخذ أو عدم الأخذ بها، آخذين بالاعتبار القيم والتقاليد والمعتقدات الاجتماعية

We have to look in to Ethical issues arising from recent developments and their applications through research, in order to work out Ethical guidelines.

Values, traditions and background of the community must be taken into consideration.

تعريف آداب الطب: ما تعارف عليه الأطباء منذ القدم، بما لا يتعارض مع الدساتير الطبية والقوانين المحلية.

Definition of Medical Ethics:

A code of behavior accepted voluntarily within the profession or imposed by official legislation.

"Oldest Code of Medical Ethics "Hippocratic Oath" and its restatements".

الحالات الطبية القضائية وواجبات الأطباء نحوها

Medico-legal cases and the role of Physicians towards these cases

تعرف الحالات الطبية القضائية بأنها كل حالة طبية يستعان فيها بالأطباء لغايات التقاضي

Medico-legal cases (Medical cases referred to physicians for legal purposes):

تشمل الحالات الطبية كل حالة ادعاء أو اشتباه بأي مما يلي:

الإيذاء من قبل الغير قصدا أو من غير قصد. والإيذاء هو كل ما نجم عن الضرب أو الجرح أو بإعطاء مواد ضارة أو بأي فعل مؤثر من وسائل العنف أو الاعتداء

1. Homicides: wounds, injuries, intoxication (poisoning), or any other injury by the wrongdoing of another person

جرائم السكر)السكر المقرون بالشغب وإزعاج الناس، قيادة مركبة تحت تأثير الكحول، تقديم المسكر لمن لم يتم الثامنة عشرة من عمره، وتقديمه لمن يدل ظاهر حاله أنه بحالة سكر

2. Crimes under the influence of alcohol.

3. Illegal dealing with narcotics. التعامل غير المشروع مع المخدرات

4. Illegal sexual acts. الجرائم الجنسية) الاغتصاب، الزنا، السفاح وهتك العرض

5. Criminal abortion. الإجهاض غير المشروع)كل إجهاض غير علاجي

الوفيات القضائية)الموت قتلا أو بأسباب مجهولة باعثة على الشبهة

6. Death due to any of the above causes

انتفاء المسؤولية والمسؤولية الناقصة) العمر، الجنون، والسكر والمخدرات

7. Criminal responsibility (Age, insanity, Alcohol and Narcotics).

أي حالة أخرى يستعان فيها بالأطباء لغايات التقاضي)الأهلية في الوصية والهبة

8. Any other case referred to a physician for legal purposes (i.e. for litigation, e.g Testamentary Capacity – validity of a will).

ما يحتاجه الطب من قوانين

Legal aspects of Medicine:

قانون الصحة العامة، قانون المجلس الطبي الأردني، قانون نقابة الأطباء الأردنيين، قانون الانتفاع بأعضاء جسم الإنسان .....إلخ

Public Health Act, Jordan Medical Council, Jordan Medical Association, Tissue Transplantation Act,…etc.

الجهات المسؤولة عن المهنة

Health authorities responsible for the profession and the professionals.

المجلس الصحي العالي / قانون المجلس الصحي العالي

Higher health council.

وزارة الصحة / قانون الصحة العامة

Ministry of health/Public health act.

المجلس الطبي الأردني / قانون المجلس الطبي الأردني

Jordan medical council.

نقابة الأطباء الأردنيين / قانون نقابة الأطباء الأردنيين

Jordan medical association.

إباحة ممارسة المهنة

Legal reference for practicing medicine

1 . نص المادة 62 من قانون العقوبات

(Section 26, Penalty Law)

لا يعتبر الفعل الذي أجازه القانون جريمة

Any action allowed by law is not Considered as a crime.

أجاز القانون:

Physicians must abide with Section 26, of the Penalty Law which permits:

الإجراءات العلاجية والمداخلات الجراحية المنطبقة على أصول الفن

Medical and surgical treatment which is reliable and agreeable by the profession.

بشرط رضى العليل أو رضى ممثليه الشرعيين

After getting Informed Consent

أو في حالات الضرورة الماسة

Or In Emergency Situations

2. الترخيص لمزاولة المهنة من وزارة الصحة

To be Licensed by the Ministry of Health

شروط مزاولة المهنة

1. شهادة المجلس الطبي الاردني (بموجب قانون المجلس الاردني)

Getting the Jordan Medical Council Certificate

2 . الانتساب إلى النقابة (بموجب قانون نقابة الأطباء الأردنيين.)

Registration by the Jordan Medical Association

3 . الترخيص من وزارة الصحة (بموجب قانون الصحة العامة)

Licensed by the Ministry of Health

الالتزامات الأدبية والقانونية للأطباء

Legal and Ethical obligations.

المدلولات الطبية والقانونية للرضا المبني على معرفة المريض المسبقة بطبيعة مرضه ومستقبله، الإجراءات التشخيصية والعلاجية اللازمة ومدى السرعة اللازمة لإجرائها، والنتائج والمضاعفات المترتبة عليها

Medico-legal concepts of "Consent" to Medical examination and treatment, (Informed Consent).

Privileged communications

جواز إخفاء خطورة المرض أو الترجيح المميت عن المريض

Right to be well informed; and the ability to decide when it is morally justified to withhold information from a patient.

تداول الطبيب مع مريضه بالهاتف أو بالبريد الإلكتروني أو بالفاكس

Discussing patient's on the phone, by fax or e mail.

الأشخاص أو الجهات المخولون بالمعرفة عن أو الاطلاع على تقارير أو ملفات المرضى

Persons, party/parties who have the privilege to gain access to information, medical records and reports

Disclosure of medical records

السر المهني أو أسرار المرضى

Professional secrecy

السر المهني: هو كل ما اطلع عليه الطبيب من أحوال مريضه المهنية بحكم العلاقة بينهما (الدستور الطبي).

All what the physician know about any aspect of the patient's life through their professional relationship.

المادة 355 من قانون العقوبات الأردني:

(كل من كان بحكم مهنته على علم بسرّ فأفشاه دون سبب مشروع يعاقب بالحبس حتى ثلاث سنوات).

Punishment for illegal disclosure is up to five years imprisonment.

الأحوال التي يسمح به بإفشاء أسرار المرضى :

Conditions under which physicians are obliged to notify / disclose information, medical records and reports about their patients:

بموافقة المريض أو بناء على طلبه أو بموافقة وليه

Patient's consent or his guardian

تبليغ وزارة الصحة عن الأمراض السارية والمعدية

Notification of infectious diseases to health authorities.

تبليغ الشرطة أو المدعي العام المختص عن الجرائم التي تلاحق بالحق العام

Notification of medico-legal cases to the police and legal authorities

تبليغ الأحوال المدنية عن الولادات والوفيات

Notification of births and deaths to the Registrar General of births and deaths

الأبحاث العلمية بشرط عدم إتاحة فرصة التعرف على هوية المريض

Scientific research (consent and identity of patients)

مراعاة القواعد أو الشروط الطبية والأدبية والقانونية في إجراء الأبحاث على الإنسان أو الحيوان

Medical, ethical and legal issues must be strictly followed on humans and animals (Clinical trials and Research)

الرعاية التلطيفية

Attitude towards the terminally ill (Palliative care)

التعامل مع حالات الوفاة، وكيفية إبلاغ الأهل، وتسليمهم نموذج تبليغ الوفاة معبأ حسب الأصول

Attitudes towards the dead, including breaking bad news, and death certification

واجبات الأطباء وحقوق المرضى
Patients' Rights
And
Duties of medical practitioners

حرية المريض في اختيار الطبيب (التأمين الطبي)

Patients' right to choose physician (medical insurance?)

وحرية الطبيب في اختيار المريض (الطبيب المتعاقد)

Right to accept the patient (Physician as an employee).

حق الطبيب في التوقف عن متابعة علاج مريضه، شريطة:

أ . أن لا يضر ذلك بمصلحة المريض الصحية،

ب. وأن يزود المريض بكافة البيانات اللازمة عنه حتى يتمكن من متابعة علاجه لدى طبيب آخر.

Physician's right to discontinue medical treatment. In this case two conditions must be fulfilled:

A . It will not cause any harm to the patient's health, and

B . The patient will be provided with all necessary documents, that will help other colleague to take over.

اقتراح إجراء أو عقد استشارة طبية حق للمريض وواجب على الطبيب

Suggestion of Medical consultation

Patient's right and Physician's duty to suggest

كتابة التقرير الطبية (دون محاباة)

Writing medical reports physician's Duty upon patient's request (It must not be biased)

تقتضي ممارسة الطب في بعض الأحيان إعطاء وثائق أو تقارير أو مصدقات يحددها القانون وكل وثيقة من هذا النوع يجب أن تحمل توقيع الطبيب الذي يعطيها ممهورا بخط يده

Signature must be hand written.

مراعاة سر المهنة

Professional secrecy must be considered

التأكد من الهوية الشخصية للمريض

Make sure of the identity of the patient

توخي الموضوعية والدقة

Objectivity and accuracy

الأسباب التي أوجبت كتابة التقرير

Preferably, the purpose for which the report is written to be mentioned

أن تكون المعلومات الواردة في التقرير موافقة للهدف المطلوب

Make sure that the purpose of the report is achieved

تدوين تاريخ ووقت المعاينة الطبية في التقرير، وتاريخ كتابته ووقتها

Date and time of both the exam and the report

أن يفرق بين المعلومات التي حصل عليها الطبيب نتيجة الفحص السريري وبين المعلومات التي يعطيها المريض أو أي شخص آخر مع تحديد هوية الشخص الآخر

Differentiate between complaint, history, physical signs, … source of information…. etc.

إعطاء تقرير طبي مغرض أو بقصد المجاملة يعتبر خطأ يحاسب عليه

Biased reports are held negligence and impose punishment.

لا يجوز للطبيب إعطاء تقرير عن متوفى لم يشهد نزعه أو لم يطلع على مرض موته السابق لوفاته إلا بعد أن يقتنع بسبب الوفاة حسب خبرته القضائية الطبية. وفي الحوادث المشتبه بكونها جنائية عليه إعلام السلطات التي تكون حينئذ صاحبة الحق في إجازة الدفن بعد الفحص من قبل الطبيب الشرعي فحصاً ظاهرياً أو تشريحياً، وعلى الطبيب المعالج في الوقائع الجنائية التي تنتهي بالموت أن يمتنع عن إعطاء شهادة وفاة وأن يخبر السلطات التي يعود إليها حق التصرف بالواقعة.

Notification of death to the registrar of births and deaths (knowing the cause of death of his patient, and that it is due to natural causes, and not due to homicide. If homicide is suspected, notify police or legal authorities.

قد تقع حوادث موت فجائي في العيادات الخاصة وتكون موضوع مسئولية الطبيب المهنية ولا سيما منها أثر إجراءات طبية فعلى الطبيب في مثل هذه الوقائع أن يمتنع عن إعطاء شهادة وفاة وأن يخبر أقرب سلطة مختصة ويحاول إخبار العائلة بدون تأخير أن أمكن

Suspicious death in a physician's clinic.

يحظر على الطبيب الذي يشغل منصبا ما أن يستغل هذا المنصب سواء كان إداريا أو سياسيا أو اجتماعيا لغايات مهنية تستهدف زيادة مرضاه، كما يحظر عليه استغلال وظيفته للحصول على كسب مادي من المرضى.

Exploitation of his position, whether political, social, professional, etc.

الدعاية والإعلان
Advertisement

تحظر الكتابة في الصحف والمجلات واستعمال أية وسيلة أخرى للنشر بأسلوب يفهم منه الدعاية الشخصية أو بشكل يسيء إلى المهنة وإلى حقوق الزمالة الطبية والمهن الطبية الأخرى.

Writing to the press for personal advertisement, or in a way that it may harm the profession or the relationship with other health professionals.

يحظر على الطبيب القيام بأي عمل أو تقديم نصيحة من شأنها إضعاف مقاومة الأشخاص الجسدية أو العقلية إلا في الحالات التي يقتضيها العلاج الطبي كالتخدير مثلا.

A physician must not act or give a medical advice to render the physical or mental condition of any person, unless indicated for medical purposes, such as giving an anesthetic for surgical treatment.

يحظر اللجوء إلى أساليب الغش والتدجيل والادعاء باكتشاف طريقة للتشخيص أو العلاج غير مثبتة علميا.

All diagnostic procedure and treatment must be scientifically recognized and approved.

يحظر على الطبيب إقامة أي نوع من العلاقات تقوم على السمسرة أو المكافأة الطبية مع أي من زملائه أو مع المؤسسات الطبية أو مؤسسات المهن الطبية الأخرى وأفرادها، أو استخدام من يقوم بهذا العمل.

Brokerage relations with a colleague, health institutions, or through any of their personnel directly or indirectly.

يحظر على الطبيب بيع العينات الطبية سواء كان لمريض أو لأي شخص أو مؤسسة.

Selling medical samples to a patient, person or an institution is prohibited.

يحظر على الطبيب ممارسة أي عمل يتنافى مع كرامة المهنة وعدم إتيان أي عمل من الأعمال التالية:

Doing any act that disagrees with dignity of the profession, or any of the following acts is prohibited:

السماح باستعمال اسمه في ترويج الأدوية والعقاقير ومختلف أنواع لعلاج

Allowing his name to be used for advertisement and circulation of any drug or any way of treatment.

إعارة أسمه لأغراض تجارية بأية صورة من الصور

Loaning his name for any commercial purposes.

طلب أو قبول مكافأة أو أجر مهما يكن لقاء التعهد بوصف أدوية أو أجهزة معينة للمرض، أو لقاء إرسالهم إلى مستشفى أو مصح علاجي أو دور للتمريض أو صيدلية أو مختبر محدد في داخل الأردن أو خارجه.

Asking for or accepting a reward or a lease for meeting the commitment to prescribe any drug or the circulation of certain equipment, or sending them to a certain health institution.

إجراء الاستشارات في محال تجارية أو في ملحقاتها مما هو معد لبيع الأدوية أو الأجهزة بقصد النصح باستعمالها سواء أكان ذلك بالمجان أو نظير مرتب أو مكافأة.

Offering medical consultations, whether for free, salary or a reward, in business places used for selling drugs or equipment's in order to advice people to use them,

لا يجوز للطبيب أن يتقاسم أجره مع أي من زملائه إلا من يشترك معه في العلاج فعلاً، كما لا يجوز له أن يعمل وسيطاً بأجر لطبيب آخر أو مستشفى أو مخبر بأية صورة من الصور.

Sharing his fees with a colleague, unless he has actually participated in the treatment, or acting as an intermediary for another colleague, hospital or laboratory.

أتعاب وأجور الأطباء

Professional fees and wages

للنقابة الحق في وضع حد أدنى وحد أعلى للأجور الطبية ويحظر على الطبيب تقاضي أجور أقل أو أعلى من الأجور المقررة من النقابة، ولكن الطبيب حر في أن يقدم خدمات مجانية عندما يدفعه ضميره إلى ذلك ويحظر على الطبيب استيفاء أية أتعاب من زملائه الأطباء كما جرت العادة أن يعالج الأطباء مجاناً عائلات زملائهم وطلاب الطب على أن المطالبة بأتعاب هؤلاء لا يشكل مخالفة مسلكية.

It is the right of the Jordan Medical Association to put the minimal and maximum range of professional fees and wages. But physicians are free to treat for free. They must not get any wages from their colleagues, although it is usually the case to treat their family members or medical students for free.

لا يجوز الإعلان عن أوقات محددة للمعالجة المجانية وللطبيب الحق في أداء واجبه مجاناً لأسباب وجدانية وإنسانية في جميع الأوقات.

Treatment for free must not be adjusted in certain times or days.

إن المعالجة بطريق المقاولة محظورة سواء أكان ذلك على أساس مدة المعالجة أو نتيجتها يستثنى من ذلك العمليات الجراحية والولادة والعلاج الطبيعي والاستطباب في مصحات الاستشفاء.

Treatment mortgaged upon cure or for a certain period is prohibited, except for cases of surgical treatment, physiotherapy, …etc.

إذا قام طبيب آخر بمساعدة الجراح لظروف اقتضتها طبيعة العملية فان له الحق في تقاضي أتعابه من أجر العملية مباشرة.

Any physician involved in surgical treatment have the right to get his own fees.

اجتماع الطبيب المعالج مع زميل آخر في استشارة طبية يبرر حصوله على أتعاب خاصة.

Any physician involved in a consultation have the right to get his own fees.

يحظر على الطبيب إعطاء أي مصدقة أو تقرير طبي دون أن يسبق ذلك فحص طبي.

No Medical report shall be given unless the patient is examined first.

على الطبيب أن يتجنب المزاحمة غير المشروعة في المهنة، وحماية الدجالين الذين يأتون أعمالاً مخالفة للقانون في أي من فروع الطب.

Illegal competition must be avoided, and the charlatans must not be protected.

يجب أن تسود علاقات الأطباء ببعضهم صلات الزمالة الحسنة التي تضمن توفر الاحترام والثقة المتبادلة فيما بينهم وتيسر سبل تعاونهم في كل ما يخدم المرضى ويحفظ مكانة المهنة.

Good relationship between physicians must be in good terms, and trustworthy to help serve the patient and the profession.

على الأطباء تحاشي وقوع ما يسيء إلى علاقات الزمالة وأن يسعوا إلى حل ما قد يحصل بينهم من خلافات بطريق التفاهم الودي، وإذا استعصى ذلك رفع الأمر إلى النقابة.

Any issue that may lead to bad relations must be avoided, and all disagreements must solved through friendly understanding. Other wise disagreements must be referred to the Jordan Medical association.

يحظر على الطبيب بشكل مطلق أن يطعن بأحد زملائه أو أن يردد الإشاعات التي تسيء إليه أو تؤذيه في ممارسته لمهنته.

Spreading doubts and rumors about colleagues is prohibited.

يمنع الطبيب من السعي لاستدراج مرضى آخرين إليه أكان ذلك مباشرة أو بالواسطة كما لأي يقبل منه السكوت عمن يقوم بذلك لمصلحته وبعلمه.

Persuasion of patients of other colleagues, directly or indirectly, is prohibited.

من حق الطبيب أن يستقبل في عيادته كل المرضى دون التزام نحو أي طبيب آخر سبق له أن عالجهم.

It is the physician’s right to receive any patient in his clinic.

ينظم الطبيب سجلاً لمرضاه يدوّن فيه التشخيص والعلاج وعليه الاحتفاظ بمثل هذا السجل مدة لا تقل عن خمس سنوات.

A registry for patients must be made containing the diagnoses and treatment, which must be kept for at least five years.

واجبات الأطباء العامة تجاه كل من:

General Duties of Medical Practitioners towards:

1. المريض, The Patient

تقوم العلاقة بين الطبيب والمريض على أساس تقديم رعاية وليس الشفاء، وعدم الإهمال. (تقديم رعاية، وليس تحقيق نتيجة)

Physician's duty is to offer best care but not cure.

2. الحالات الطارئة والمستعجلة, Emergency situations

الإسعاف مرتبط بالإمكانات المتاحة للطبيب.

Emergency treatment is dependent upon available medical services.

إدخال الحالات الطارئة إلى المستشفى بغض النظر عن القدرة المالية للمريض. على الطبيب أن يكتب أمر الدخول والفحوصات المخبرية والشعاعية في الحالات الطارئة وغيرها بغض النظر عن القدرة المالية للمرضى

Admission order and investigations must be ordered regardless of the financial abilities of the patient.

إذا كانت حالة المريض غير قابلة لتحويله إلى مستشفى آخر، فيجب كتابة ذلك على أمر الدخول وإبلاغ إدارة المستشفى بذلك.

In non transferable cases, a note of that must be shown on the admission order, and the administration must be notified.

صلات الأطباء بزملائهم وبأعضاء المهن الطبية والصحية الأخرى

Relationships with colleagues and other health professionals

يجب أن تسود علاقات الأطباء ببعضهم وبأعضاء المهن الطبية الأخرى روابط التعاون والاحترام ومراعاة استقلال مصالح الجميع والحرص على عدم الإساءة إليهم مادياً ومعنوياً وتجنب كل تدخل لا تتطلبه مصلحة المريض أو المهنة وكل خلل يصيب هذه العلاقات يرفع إلى النقابات المهنية ذات العلاقة.

Mutual respect. Any disagreements must be referred to the association concerned.

لا يجوز للطبيب الممارس أن يشارك في أي مؤسسة دوائية أو مخبريه باستثناء الشركات المساهمة العامة كما لا يجوز أن يتقاضى أي راتب أو عمولة أو هبه باستثناء العينات والهدايا التي يجري توزيعها بشكل عام من أية مؤسسة متصلة بالعمل الطبي.

Physicians must not own or have shares in any private drug or lab company. They must not get any salary, commission or gifts except medical samples.

على الطبيب أن يمتنع عن إعطاء أي شهادة خطية بشأن مستحضر طبي إلا لغايات علمية وبأسلوب علمي دون ذكر للاسم التجاري أو اسم المصنع المنتج.

No written certificate shall be given about any medical preparation, except for scientific purposes and without mentioning the commercial and factory name.

Consent
(Informed consent)
الرضى المبني على المعرفة المسبقة

يكون الرضى معتبرا أدبيا وقانونيا إذ كان مبنيا على معرفة المريض المسبقة بطبيعة مرضه ومستقبل مرضه، ومعرفة طرق التشخيص والعلاج ومدى السرعة في إجرائها، والنتائج والمضاعفات المتوقعة عادة لكل منها في.

Consent is accepted ethically and legally, If taken after the patient is well informed about his illness, investigations and type of treatment required, and the usually expected complications.

The right to know.

الرضى في حالات:

Consent and the:

الأطفال دون السن القانونية

Minor

المرض المصابون بمرض عقلي أو نفسي

Mentally Disordered

المرضى الغائبون عن الوعي

Unconscious

على الطبيب عدم تجاوز الرضا الذي سمح به المريض

Limitations of Consent

Medical Ethics

الإنسان
(الحي والميّت)
Tissue Transplantation Act
(The living and the dead)

نقل العضو : نزعه أو إزالته من جسم إنسان حي أو ميت حسب مقتضى الحال وتصنيعه أو غرسه في جسم إنسان حي آخر

Taking out an organ from a human body to transplanted in another human body.

أ- يشترط في اجراء عمليات نقل الاعضاء وزراعتها ما يلي

Conditions for taking out an organ for transplantation:

1. الالتزام بالفتاوى الصادرة عن مجلس الافتاء الاردني بهذا الشأن وبخاصة ما يتعلق منها بالموت الدماغي .

Fetwa regarding Brain death must be followed.

2. ان يتم النقل في مستشفى تتوافر فيه الشروط والمتطلبات الفنية اللازمة لنقل الاعضاء وزراعتها من قبل فريق من الاطباء والفنيين المختصين.

Specialized physicians, technicians and technical facilities must be available at a recognized hospital to take out and transplant an organ.

3. اجراء جميع الفحوصات والتحاليل المخبرية اللازمة لهذه العمليات لمعرفة الحالة الصحية لكل من المتبرع والمريض الذي سينقل له العضو للتأكد من ان حالة المتبرع تسمح بذلك كما ان حالة المريض تستدعي ذلك

All necessary investigations for both the donor and the recipient to make sure that the donor's condition allows donation, and recipient's condition indicates this donation

ب- يصدر مجلس الوزراء بناء على تنسيب الوزير التعليمات المتعلقة بالأمور التالية ويتم نشرها في الجريدة الرسمية:

Upon the suggestion of the Minister of Health, the Council of Ministers shall issue regulations to be published in the official journal of the government.

1. الشروط والمتطلبات الفنية اللازم توافرها في المستشفى الذي تجري فيه عملية نقل الاعضاء وزراعتها

2. مستوى الخبرة الواجب توافرها في اعضاء الفريق من اطباء وفنيين الذين يقومون بإجراء عملية نقل الاعضاء وزراعتها والإشراف عليها

The level of capabilities required in the medical team (physicians and technicians) involved.

3 . الفحوصات والتحاليل المخبرية اللازمة

Necessary medical and laboratory investigations

4. المواصفات الفنية الواجب توافرها في الاماكن المخصصة لحفظ الاعضاء وتنظيم الافادة منها.

Technical conditions to be available to preserve The organs and how to get use of them.

المادة رقم (4)

أ- للأطباء الاختصاصيين في المستشفيات المعتمدة من الوزير نقل العضو من انسان حي الى آخر بحاجة اليه وفقا للشروط التالية:-

According to the following conditions, specialists

Can take out an organ from living person to another.

1. ان لا يقع النقل على عضو اساسي للحياة اذا كان هذا النقل قد يؤدي لوفاة المتبرع ولو كان ذلك بموافقته.

Taking out an organ must not threaten the life of the donor even with his consent.

2. ان تقوم لجنة مؤلفة من ثلاثة اطباء اختصاصيين بفحص المتبرع للتأكد من ان نقل العضو من جسمه لا يشكل خطرا على حياته، وتقديم تقرير بذلك.

Three specialists must examine and certify in writing that donation does not threaten the life of the donor.

3. ان يوافق المتبرع خطيا - وهو بكامل ارادته واهليته على نقل العضو من جسمه وذلك قبل اجراء عملية النقل.

Donor must be legally fit, and give a written consent before donation.

ب- اذا قرر الطبيب الشرعي تشريح جثة المتوفى لأغراض قانونية لمعرفة سبب الوفاة او لاكتشاف جريمة فانه يسمح له بنزع القرنية منها ، وذلك وفقا للشروط التالية:

1 . أن لا يؤثر نزعها على معرفة سبب الوفاة ، ولو بعد حين

2 . أن تؤخذ موافقة ولي امر المتوفى خطيا ودون اكراه.

If a forensic autopsy is to be performed, just the cornea may be taken out under two conditions:

It will not affect determination of the cause of death, even later,

Consent of the guardian given, without being enforced upon him.

ج - لا يجوز ان يتم التبرع بالعضو مقابل بدل مادي او بقصد الربح.

Donation must be for free.

المادة رقم (5)

للأطباء الاختصاصيين في المستشفيات التي يوافق عليها وزير الصحة نقل العضو من جسم إنسان ميت الى جسم إنسان آخر حي يكون بحاجة لذلك العضو في أي من الحالات التالية :-

Specialists can take out a donated organ from a dead body, under any the following conditions:

أ. إذا كان المتوفى قد أوصى قبل وفاته بالنقل بإقرار خطي ثابت التوقيع والتاريخ بصورة قانونية.

deceased will officially documented

ب. إذا وافق أحد أبوي المتوفى في حالة وجودهما على النقل أو وافق عليه الولي الشرعي في حالة عدم وجود الأبوين.

Consent of any one of the parents, or the official guardian if they were not available.

.

ج. إذا كان المتوفى مجهول الهوية ولم يطالب أحد بجثته خلال (24) ساعة بعد الوفاة على أن يتم نقل في هذه الحالة بموافقة المدعي العام.

By the approval of the public prosecutor, if the body was unclaimed for 24 hours after death.

المادة رقم (6)

للأطباء الاختصاصيين في المستشفيات التي يوافق عليها وزير الصحة فتح جثة المتوفى ونزع أي من أعضائها إذا تبين أن هناك ضرورة علمية لذلك على أن يكون المتوفى قد وافق على ذلك خطياً بصورة قانونية صحيحة قبل وفاته، أو بموافقة وليه الشرعي بعد الوفاة.

Specialist physicians in recognized hospitals can open a body and take out an organ for scientific purposes, upon official consent of the deceased before death or the guardian.

المادة رقم (7)

لا يجوز ان يؤدي نقل العضو في اية حالة من الحالات الى احداث تشويه ظاهر في الجثة يكون فيها امتهان لحرمة المتوفى.

Taking out an organ should not leave any apparent disfigurement that may insult the

المادة رقم (8)

لا يجوز فتح الجثة لأي غرض من الأغراض المنصوص عليها في هذا القانون إلا بعد التأكد من الوفاة بتقرير طبي، و يشترط في ذلك أن يكون الطبيب الذي يقرر الوفاة هو غير الطبيب الاختصاصي الذي يقوم بعملية النقل.

No organ should be taken out of a dead `body before diagnoses of death being confirmed by a physician who is not involved in taking out the Organ from the body.

المادة رقم (9)

أ . يتم التحقق من حالة الموت الدماغي، لغاية نقل الاعضاء وزراعتها من قبل لجنة تشكل في المستشفى الذي يتم فيه نقل الاعضاء او زراعتها من ثلاثة اطباء في التخصصات التالية على الاقل على ان لا يكون من بينهم الطبيب المنفذ للعملية :

1 . اختصاصي امراض الاعصاب والدماغ.

2 . اختصاصي جراحة الاعصاب.

3 . اختصاصي تخدير.

Brain death must be confirmed by a committee of three specialist physicians namely: neurologist, neurosurgeon, and anesthesiologist.

ب- تعد اللجنة تقريرا مفصلا بهذه الحالة وفق الاصول ويكون قرارها بالإجماع ومعللا وتعتبر ساعة وفاة الشخص هي ساعة توقيع الاعضاء على التقرير.

Detailed report must be prepared by the committee regarding the diagnosis of brain death, signed and agreed upon unanimously by the committee. The time by which the report is signed is regarded as the time of death.

ج - يشارك في اللجنة المذكورة في الفقرة (أ) من هذه المادة طبيب شرعي ينتدبه الوزير.

A forensic pathologist nominated by the Minister of Health shall participate in this committee

د - تدعو اللجنة المدعي العام المختص للمشاركة في اجتماعاتها في الحالات التي تستوجب ذلك وعليه ان يضع تقريرا مفصلا بما تتوصل اليه اللجنة.

In certain cases, a public prosecutor shall join the committee and write a detailed report regarding the conclusions of the committee.

المادة رقم (10)

دون الاخلال بأي عقوبة ورد النص عليها في اي تشريع آخر يعاقب كل من ارتكب مخالفة لأحكام هذا القانون بالحبس مدة لا تقل عن سنة أو بغرامة لا تقل عن عشرة آلاف دينار او بكلتا هاتين العقوبتين.

Regardless of any other punishment stated in any other law, any breach of this law is punishable by a minimum of one year imprisonment or a fine not less than ten thousands JD, or both.

المادة 13

لمجلس الوزراء إصدار الأنظمة اللازمة لتنفيذ أحكام هذا القانون.

Council of Ministers shall issue the necessary regulations to help apply this law.

التلقيح الصناعي

Artificial Insemination (IVF)

التعقيم

Sterilization

البنوّة المتنازع عليها

Disputed Paternity

الإجهاض (الإجهاض المشروع والاجهاض غير المشروع)

Abortion (Legal and Illegal Abortion)

الإجهاض العلاجي
Therapeutic Abortion

1 . أ . مع مراعاة القوانين المرعية يحظر على الطبيب إجراء الإجهاض الاختياري بأية وسيلة إلاّ إذا كان استمرار الحمل خطراً على حياة الحامل ويشترط حينئذ:-

Conditions for therapeutic abortion (to save the life of the pregnant woman):

1 . أن يتم الإجهاض من قبل طبيب مختص وبموافقة طبيب - مختص آخر في مستشفى مرخص.

Written statement made by two licensed specialists physicians one of whom shall do the operation.

2 . أن يحرر محضر بتقرير الحاجة الملحة للإجهاض قبل - إجراء العملية.

A statements must be issued before abortion being done.

3 . أن تنظم منه أربع نسخ أو أكثر حسب اللزوم يوقعها الأطباء

والمريضة وزوجها أو وليها وتحفظ نسخة في ملف المريضة.

Four copies of the statement or more are signed by the physicians, the patient, her husband or guardian. A copy is kept in her own file at the hospital.

ب . إذا رفضت الحامل إجراء العملية رغم توضيح الطبيب لها خطورة وضعها فعليه الامتثال لإرادتها بعد تثبيت معارضتها.

Rejection of abortion by the pregnant woman must be respected. Her rejection must be documented.

2 . أ . يحظر على أي طبيب وصف أي شيء بقصد إجهاض امرأة حامل أو إجراء عمليه إجهاض لها، إلا إذا كانت عملية الإجهاض ضرورية لحمايتها من خطر يهدد صحتها أو يعرضها للموت وعلى أن يتم ذلك في مستشفى عام أو مستشفى للتوليد شريطة توافر ما يلي :-

Prescribing any thing to abort a pregnant woman is prohibited, unless it is made in a hospital to save her life or health, under the following conditions:

1 . موافقة خطية مسبقة من الحامل بإجراء العملية وفي حالة عدم مقدرتها على الكتابة أو عجزها عن النطق تؤخذ هذه الموافقة من زوجها أو ولي أمرها.

Patient’s written consent shall be taken before carrying out the operation, but if she is un able to do so, consent may be given by the husband or her guardian.

2 . شهادة من طبيبين مرخصين ومن ذوي الخبرة تؤكد وجوب إجراء العملية للمحافظة على حياة الحامل وصحتها.

Two expert licensed physicians shall certify the necessity of the operation to save the life and health of the pregnant woman.

3 . تضمين قيود المستشفى اسم الحامل وتاريخ إجراء العملية - ونوعها والاحتفاظ بالموافقة الخطية وبشهادة الطبيبين لمدة عشر سنوات على أن تزود الحامل بشهادة مصدقة من مدير المستشفى بإجراء هذه العملية.

Hospital records should include the patient's name, date and type of the operation, her written consent and the two written medical statements for at least 10 years. A report is issued and countersigned by the hospital director about the operation.

ب. على الرغم مما ورد في قانون العقوبات، لا تلاحق الحامل والشخص أو لأشخاص الذين أجروا أو اشتركوا في إجراء عملية الإجهاض لها وفقا لأحكام الفقرة (أ) من هذه المادة بتهمة اقتراف جريمة الإجهاض.

Regardless of the penalty law, no one involved in therapeutic abortion shall be sued for committing criminal abortion.

وبموجب الدستور الطبي الصادر بموجب قانون نقابة الأطباء الأردنيين.

All of the above issues about therapeutic abortion are in accordance with the medical ethics code in Jordan.

Physician Assisted Suicide.

الانتحار بمساعدة الأطباء محظور بموجب قانون العقوبات الأردني،

مادة 339 من قانون العقوبات:

It is considered a crime according the penalty law.

أ . من حمل إنسانا على الانتحار أو ساعده بطريقة من الطرق المذكورة في المادة 80 عوقب بالاعتقال المؤقت.

Instigating or helping a person to commit suicide is punishable by temporary detention.

ب . وإذا بقي الانتحار في حالة الشروع عوقب ذلك الشخص بالحبس من ثلاثة أشهر إلى سنتين، وتكون العقوبة حتى ثلاث سنوات إذا نجم إيذاء أو عجز دائمين.

If death does not occur, punishment will be 3 month to two years imprisonment.

If the result is doing permanent harm or disability, punishment will be up to 3 years imprisonment.

الاستنساخ
Cloning

واجبات الأطباء في أيام السلم والحرب

Ethical responsibilities In peace and war

Protecting prisoners and detainees against torture, and other cruel, inhumane or degrading treatment or punishment (whether by passive or active acts or advice).

مبادئ آداب الطب

في الثامن عشر من كانون الأول / ديسمبر 1982 أقرت الجمعية العامة للأمم المتحدة بصفة رسمية في دورتها السابعة والثلاثين مبادئ آداب الطب الخاصة بدور العاملين الصحيين، خصوصا الأطباء، في حماية السجناء من التعذيب

المبدأ 1 . من واجب الموظفين الصحيين، وخاصة الأطباء، المكلفين بالرعاية الطبية للمسجونين والمحتجزين أن يوفروا لهم حماية صحتهم البدنية والنفسية وأن يعالجوا المرض معالجة من نفس النوعية والمستوى المتاحين لغير المسجونين أو المحتجزين

المبدأ 2 . إن مما يشكل انتهاكا جسيما لآداب مهنة الطب، وجريمة بموجب الصكوك الدولية المنطبقة، أن يقوم الموظفون الصحيون، ولا سيما الأطباء، بطريقة إيجابية أو سلبية، بأعمال تشكل مشاركة في التعذيب وغيره من ضروب المعاملة أو العقوبة القاسية أو اللاإنسانية أو المهينة أو تواطؤا أو تحريضا على هذه الأفعال أو محاولات لارتكابها.

المبدأ 3 . إن مما يشكل انتهاكا جسيما لآداب مهنة الطب، أن يقيم الموظفون الصحيون، ولا سيما الأطباء، أية علاقة مهنية مع السجناء أو المحتجزين، لا يكون القصد الوحيد منها هو تقييم أو حماية أو تحسين الصحة البدنية أو النفسية للسجين أو المحتجز

المبدأ 4 . إن مما يشكل انتهاكا لآداب مهنة الطب، أن يقوم الموظفون الصحيون ولا سيما الأطباء بما يلي:

أ . استخدام معارفهم ومهاراتهم للمساعدة في أساليب استجواب السجناء والمحتجزين على نحو قد يضر بالصحة أو الحالة البدنية أو العقلية لهؤلاء المسجونين أو المحتجزين، أو يتنافى مع الصكوك الدولية ذات الصلة.

ب . الشهادة، أو الاشتراك في الشهادة، بأن السجناء أو المحتجزين لائقون لأي شكل من أشكال المعاملة أو العقوبة التي قد تضر بصحتهم البدنية أو النفسية والتي تتنافى مع الصكوك الدولية ذات الصلة،أو الاشتراك بأية كيفية في تلك المعاملة أو في إنزال تلك العقوبة التي تتنافى مع الصكوك الدولية ذات الصلة.

المبدأ 5 . إن مما يشكل انتهاكا لآداب مهنة الطب، أن يشترك الموظفون الصحيون، ولا سيما الأطباء، في أي إجراء لتقييد سجين أو محتجز إلا إذا تقرر بمعايير طبية محضة أن هذا الإجراء ضروري لحماية الصحة البدنية أو النفسية أو السلامة للسجين أو المحتجز ذاته، أو زملائه السجناء أو المحتجزين' أو حراسه ولا يشكل خطرا على صحته البدنية أو النفسية

المبدأ 6 . لا يجوز تقييد المبادئ السابقة الذكر لأي سبب من الأسباب، بما في ذلك حالة الطوارئ العامة.

الجوانب الأدبيه والقانونيه للإهمال الطبي

Ethical and Legal issues on Medical Negligence.

الإجراءات التأديبية والقضائية المتخذة عند اتهام أو إدانة الأطباء بالمخالفات المهنية والمسلكية.

Legal and disciplinary Procedures, and actions taken against medical practitioners if accused and/or convicted of unethical or serious professional misconduct.

1. الملاحقة التأديبية

Disciplinary actions

2 . الملاحقة الجزائية

Criminal actions

3 . الملاحقة الحقوقية

Civil actions

مخالفة نص المادة 62 من قانون العقوبات الأردني،

A physician is ethically and legally sued if he does not abide with section 62 of the penalty law.

أجاز القانون:

ج . العمليات الجراحية والعلاجات الطبية المنطبقة على أصول الفن، شرط أن تجرى برضى العليل أو رضى ممثليه الشرعيين أو في حالات الضرورة الماسة

تعريف الخطأ: إهمال أو قلة احتراز أو عدم مراعاة القوانين والأنظمة.

Negligence is defined as causing harm to a patient by an act of commission or omission, or by not abiding with rules and regulations.

أركان مساءلة الأطباء:

1 . وقوع ضرر للمريض

2 . وقوع خطأ من جانب الطبيب

3 . وجود علاقة بين الضرر والخطأ

For a physician to sued for negligence, three conditions must be fulfilled:

a . Harm to the patient (damages), and

b . Wrongful act by the physician, and

c . That damages are caused partially or totally by the wrongful act of the physician.

السلطة التأديبية
(الملاحقة التأديبية)
Disciplinary procedures

موجبات الملاحقة التأديبية

Bases for disciplinary actions

الإخلال بالواجبات المهنية

Professional misconduct

ارتكاب خطأ مهني

Medical negligence

إذا تجاوز حقوقه أو قصر بالتزاماته

If he did not abide with his rights and duties.

إذا رفض التقيد بقرارات مجلس النقابة

Refusal of the decisions of the association.

إذا أقدم على عمل يمس شرف المهنة

Acting in a way that it may harm the honor of the profession.

أو تصرف في حياته الخاصة تصرفا يحط من قدرها

If he acts in his private life in a way that it may harm the profession.

الإجراءات التأديبية المتعلقة بأطباء القطاع الخاص

Disciplinary procedures against physician in the private sector

يتم النظر في قضايا المخالفات بناء على: طلب من وزير الصحة أو النيابة العامة

Upon a request from the Minister of health or public attorney.

صدور حكم قطعي بعقوبة السجن أو الحق الشخصي المهنة أو كفاءته لأمور تمس استقامة الطبيب أو شرف

If he is punished by imprisonment according to a final court of law verdict due to matters regarding the standard of his practice, or matters that did harm his honor or the profession.

إذا وصل إلى علم المجلس ارتكاب الطبيب للمخالفات رغم عدم ورود شكوى

If the association knew of any wrong doing made by a physician, whether there was a complaint or not.

إذا تقدم أحد الأطباء أو المواطنين بشكوى خطية

If a complaint is made by a physician or a citizen.

إذا طلب الطبيب نفسه خطيا، إذا رأى نفسه موضع تهمة غير محقة

Upon physician’s request to defend him self against unfair accusation.

إذا اقتنع المجلس بوجود أساس للشكوى

التحقيق الأولي الإحالة إلى مجلس التأديب استئناف حكم مجلس التأديب مجلس التأديب الأعلى الطعن لدى المحكمة الإدارية

If a case is found against the physician, the council of the association will start a preliminary inquest.

If a case still exist, it will be referred to the disciplinary council.

Upon the verdict of this council, the physician, the patient and the council of the association may resume the verdict to the higher disciplinary council.

The verdict of the higher council may also be finally resumed to the higher court of justice at the Ministry of justice.

إيقاف الطبيب عن العمل

Disciplinary councils may decide that the physician stop practicing until decided other wise.

العقوبات
Disciplinary Punishments

Warning

التنبيه

Reproach

التوبيخ

الغرامة لا تقل عن 100 ولا تزيد عن 1000 دينار

100-1000 JD fine

الحرمان من الترشح لمنصب النقيب أو عضوية المجلس لمدة دورتين

To be deprived from being a member of the council for 2 sessions.

المنع النهائي من ممارسة المهنة وشطب اسمه من السجل بعد إدانته بحكم قضائي اكتسب الدرجة القطعية

The final prevention from practicing medicine for life, and his name to be erased, after being charged by a court of law.

تنفذ الوزارة أو المجلس أو النيابة العامة أو دائرة الإجراء كل حسب اختصاصه القرارات والأحكام الصادرة عن مجلس التأديب بعد اكتسابها الدرجة القطعية

It is the responsibility of the Ministry of Health, the council of the association, Public attorney …etc to execute the verdicts and decisions of the disciplinary councils.

على النيابة أن تخطر مجلس النقابة قبل الشروع في التحقيق في أي شكوى او اتخاذ أي إجراء ضد الطبيب وللنقيب او من ينتدبه أن يحضر جميع مراحل التحقيق مع الطبيب قبل استجوابه من النيابة العامة وفي حالة الجرم المشهود يبلغ النقيب او المجلس بالسرعة الممكنة بما تم من إجراءات.

يشكل الوزير لجنة فنية أو أكثر برئاسة من يسميه الوزير وعضوية أربعة أطباء يمثلون الوزارة والخدمات الطبية الملكية والنقابة وكلية الطب في الجامعات الأردنية الرسمية وبالتناوب فيما بينها تتم تسميتهم من الجهة المختصة في كل منها وذلك خلال ثلاثين يوما من تاريخ نفاذ أحكام هذا القانون .

تكون مدة العضوية في اللجنة المشكلة وفقا لأحكام الفقرة (أ) من هذه المادة لمدة سنتين قابلة للتجديد لمرة واحدة.

تتولى اللجنة تقديم الخبرة الفنية بناء على طلب النيابة العامة أو المحاكم أو النقابة أو الوزارة فيما يتعلق بالأخطاء الطبية المنسوبة للأطباء.

تحدد المسؤولية الطبية بناء على مدى الالتزام بالقواعد المهنية وتدخل في تحديدها البينة الطبية والمعايير الخاصة بها والعوامل والظروف التي تسبق أو تتزامن أو تتبع عمل مقدم الخدمة.

على الرغم مما ورد في قانون أصول المحاكمات الجزائية، لا يجوز توقيف أي طبيب مشتكى عليه بجرم ارتكاب خطأ طبي أدى إلى وفاة أحد المرضى أو إصابته أو عجزه إلا بعد صدور قرار الحكم واكتسابه الدرجة القطعية.

The public attorney (Public Prosecutor) must inform the Jordan Medical Council before interrogating any physician, except in cases where there is a witnessed crime, where he is obliged to inform the Council about all his investigation And procedures.

Introduction to Clinical Research

GCP Lecture I

Dr. Laila Tutunji

Nov 2024

Good Clinical Practice (GCP)

What is GCP

Acquiring a GCP Certification

GCP Certification

This is an introduction to our medial students on the **WHO** designed global principles and regulations governing research on human subjects

GCP Certification is part of the Graduation Research Project Requirements

GCP Certification

It builds upon previous courses including Quantitative and Qualitative Research.

Each student should obtain official GCP certification by the Beginning of Feb 2024

GCP Certification

Session 1:

Introduction/ Ethics/

Session 2:

Global Regulatory Framework

Session 3:

GCP Training/ IRBs.

Session 4:

GCP Training/ Research Protocol Basics.

GCP Course

The chosen course certificate by our Medical School is issued by the US NIH because it is recognized globally.

The NIH GCP Certificate will be recognized in the USA and worldwide and valid for three years

Link to the Course

- Link to the course:
- https://gcp.nidatraining.org/
- Create an account to sign in:
- https://gcp.nidatraining.org/register
- Under organization kindly write:
  The University of Jordan

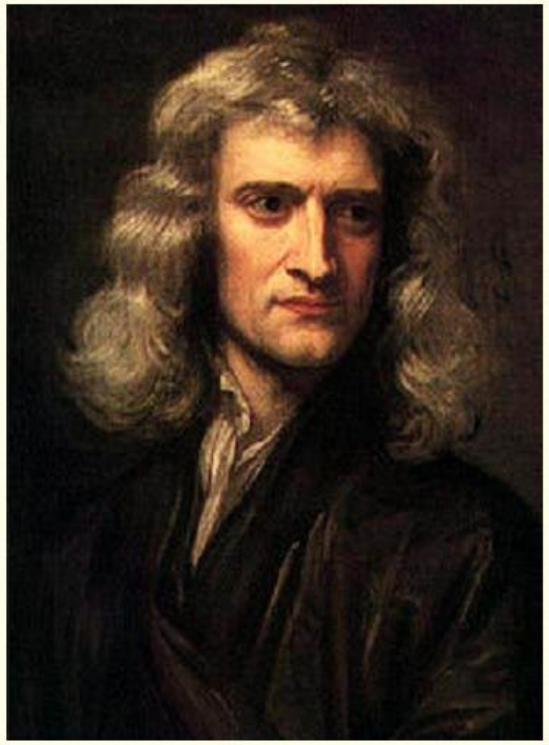
GCP Course Information

Enter your Name

Enter your Institution as the University of Jordan

Our IRB requires 80% of answers correct

Why Clinical Research ?



Sir Isaac Newton

(1642-1727)

Born in Lincolnshire, England

"If I have seen a little further, it is by standing on the shoulders of giants"

- Sir Isaac Newton, 1676

- *“If I have seen a little further, it is by standing on the shoulders of giants”*

Isaac Newton

Definition of Clinical Research

- **Patient-Oriented Research**

  Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects…includes:

  - Development of new technologies
  - Mechanisms of human disease
  - Therapeutic interventions
  - Clinical Trials

- **Epidemiologic and Behavioral Studies**
- **Outcomes Research and Health Services Research**

*From NIH Director's Panel on Clinical Research, 1996


History of Clinical Research
- A Merging of Diverse Cultures -

History of Clinical Research

- A Merging of Diverse Cultures -

John I. Gallin, M.D.

Director, NIH Clinical Center

October 13, 2015

National Institutes of Health
Clinical Center

Ethics
The Soul of Medicine

Hippocrates, Principles of Medical Ethics

1. Non-Maleficence
2. Beneficence
3. Justice
4. Respect for Autonomy
5. Confidentiality

The First Principle

Non-Maleficence

“Primum, Non Nocere”

First, DO NO HARM

The Second Principle

Beneficence

The Third Principle

Justice

The Forth Principle

Respect for Autonomy

The Fifth Principle

Confidentiality

To see and See Again

- Shoulder of giants
- The spirit of inquiry, our responsibility ?
- Al Rhazi
- Ibn Sena
- Ibn Al Haitham
- Where do We Stand?

To See and See Again

You Can Make A Difference

GCP

IRBs

Institutional Review Board (IRB)

Contents

Clinical Quest

Part 1: What is an Institutional Review Board?

Part 1: What is an Institutional Review Board?

An Institutional Review Board (IRB) is an independent body established to protect the rights and welfare of human research participants.

Individual institutions or sponsors may require that all research, no matter how it is funded, be reviewed and approved by an IRB.

An IRB has specific authority over the conduct of research under its jurisdiction. No clinical study may begin enrolling participants until it has received IRB approval.

Part 1: What is an Institutional Review Board?

The IRB has the authority to:

- Approve, disapprove, or terminate all research activities that fall within its jurisdiction under federal regulations and institutional policy.

- Require modifications in protocols, including protocols of previously approved research.

Part 1: What is an Institutional Review Board?

- Require that participants be given any additional information that will assist them in making an informed decision to take part in research.

- Require documentation of informed consent or allow a waiver of documentation.

Part 1: What is an Institutional Review Board?

- Every institution that participates in research studies must identify an IRB to review and approve those studies.

- Some research sites are under the jurisdiction of two or more IRBs. In these cases, the IRBs may perform joint review, separate review or agree to abide by the review of one of the involved IRBs.

Part 2: Purpose of an IRB?

Part 2: Purpose of an IRB?

The purpose of an IRB is to safeguard the rights, safety, and well–being of all human research

Participants primarily

And

Ensuring that there is a scientific validity to the research and weighing risks vs benefits.

Part 2: Purpose of an IRB?

The IRB fulfills this purpose by:

- Reviewing the full study plan (IRB responsibilities for the documents which comprise a full protocol) for a research study.

- Confirming that the research plans do not expose participants to unreasonable risks.

- Reviewing and approving proposed payments or other compensation to study participants.

Part 2: Purpose of an IRB?

- Ensuring that human participant protections remain in force throughout the research by conducting continuing review of approved research. This continuing review is conducted at intervals appropriate to the degree of risk posed by each study, but not less frequently than once a year.

- Considering adverse events, interim findings, and any recent literature that may be relevant to the research.

- Assessing suspected or alleged protocol violations, complaints expressed by research participants, or violations of institutional policies.

- Reviewing proposed changes to previously approved studies.

Clinical Quest

Part 2: Purpose of an IRB?

The IRB may suspend or terminate ongoing research that:

- Is not being conducted in accordance with IRB requirements, or
- Is associated with unexpected or serious harm to participants.

The IRB may also suspend or terminate research when additional information results in a change to the study's likely risks or benefits.

Part 3: Membership of an IRB

Part 3: Membership of an IRB

- An IRB must have a diverse membership that includes both scientists and non-scientists.
- Scientist members may include researchers, physicians, psychologists, nurses, and other mental health professionals.
- Nonscientist members of an IRB may have special knowledge of a certain population (pregnant women, children, or prisoners).
- Collectively, IRB members must have the qualifications and experience to review and evaluate the scientific, medical, behavioral, social, legal, and ethical aspects of a proposed study.

Part 3: Membership of an IRB

- An IRB must have at least five members. However, it may have as many members as necessary to perform a complete and adequate review of research activities.

Diversity of Membership

- IRB membership must be diverse in terms of race, gender, and cultural heritage.
- Members must be sensitive to issues such as community attitudes.

Part 3: Membership of an IRB

- Every effort must be made to ensure that no IRB consists entirely of men or entirely of women. However, no one can be appointed to an IRB solely on the basis of gender.
- No IRB may consist entirely of members of one profession.
- Each IRB should include at least one member whose primary concerns are in scientific areas and one member whose primary concerns are in non-scientific areas.
- Each IRB should include at least one member who is not affiliated with the institution or study site

Part 3: Membership of an IRB

ICH	FDA
Minimum 5 members	Minimum 5 members
Minimum 1 member with scientific background	At least 1 scientific & 1 non-scientific
1 member not affiliated with any institution	1 member not affiliated with any institution
Independent of sponsor to provide opinion	Diverse (race, gender, culture, vulnerable population representative)
	No conflict of interest

Clinical Quest

Part 3: Membership of an IRB

Knowledge of Vulnerable Populations

- If the IRB reviews research that involves vulnerable populations — such as children, prisoners, pregnant women, or disabled or cognitively impaired persons — its membership should include one or more persons who are knowledgeable about and/or experienced in working with these populations.

- The individuals specializing in vulnerable populations may be fulltime voting members or alternates to fulltime voting members.

Part 3: Membership of an IRB

Conflicts of Interest

- No IRB member may participate in the review of any project in which he or she has a conflicting interest, except to provide information requested by the IRB.
- An investigator may be a member of an IRB. However, the investigator (or any other IRB member) cannot participate in the review or approval of any research in which he or she has a current or potential conflict of interest.
- The investigator should be absent from the meeting room while the IRB discusses and votes on the research in which he or she has an interest.

Part 3: Membership of an IRB

Non-Voting Members

- The IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that of the IRB members.
- These consultants are not voting members of the IRB. However, when research involves vulnerable populations, individuals specializing in these areas must be voting members of an IRB and maintained on the IRB roster accordingly.

Interactive: Assemble Your IRB

A multisite clinical study package (including the protocol, informed consent forms, recruitment materials, and other related documentation) is being submitted for IRB approval. This US-based study is to assess the efficacy of BioMedXYZ's drug for Attention Deficit Hyperactivity Disorder in children ages 7 to 15.

Clinical Quest

Interactive: Assemble Your IRB

From a list of eight, choose the most appropriate candidates as members of the IRB and ensure that the composition of the IRB meets the minimum criteria outlined for clinical research in the U.S.

- Each candidate has a bio or biography to review. After reviewing the candidates' bios determine if they are right for this clinical study.
- Choose a total of five voting members and one non-voting expert for consultation
- ‘must have’ criteria : (1) diversity, (2) a non-scientific member, and (3) a non-affiliated member.
- Be careful to avoid any conflict of interest with the chosen candidates.

Interactive: Assemble Your IRB

Listed below are the candidates for the IRB, including names, credentials, current title, and a brief bio on the candidate's background and expertise.

Candidate 1: Juan Telmo, PhD - Statistical Scientist
Juan has an MS degree in Data Analytics, with a concentration in Statistics, and PhD degree in Statistical Science. He has been a statistical scientist working for the past 5 years at BioMedXYZ firm that develops medical devices. He has expertise in statistical theory, methods, analyses, device development, and clinical research.

Interactive: Assemble Your IRB

Candidate 2: Tomer Teivel, RN - Social Worker
Tomer had a rough start in life, his mother was an alcoholic when he was a child. He found his passion helping people dealing with addiction. He earned his MS degree in social work and obtained his social worker license (LCSW). He has worked for the past 12 years in schools, hospitals, and other agencies and also in community drug treatment programs. Previously, Tome had participated in numerous research studies involving participant drug use. He has expertise in mental health treatment, research, families, and community.

Interactive: Assemble Your IRB

Candidate 3: Lilith O'Conner, BS - Teacher
For the past 3 years, Lilith has worked as a Teacher at the local Elementary School. She serves as the
Youth Committee Secretary for the local Community Center and is a teacher representative for the local
Board of Education. Lilith has expertise in children, education, and community. She earned her BS degree
in Psychology and Early Childhood Education.

Candidate 4: Carla Fox, JD, MHA - Ethicist
Carla earned her JD and MHA degrees in Health Care Law. She serves as Chairperson on the local chapter for the Board of Bioethics in Hospital Administration. She also works as a lawyer for healthcare organizations. Carla has expertise in health policy, bioethics law, and community engagement.

Interactive: Assemble Your IRB

Candidate 5: Brian Bradford, MD - Pediatrician
Brian attended medical school, completed residency in a children's hospital, and obtained his medical licensure. He is a partner pediatrician in general practice for 20 years. He has expertise in pediatrics and clinical care.

Candidate 6: Dorian Picard, MD - Therapist
Dr. Picard earned a PhD in behavioral therapy and has been working in both the hospital and private sector for the last 15 years, specializing in children and adolescent behaviors with a special interest in ADHD. Due to his schedule he has limited availability.

Interactive: Assemble Your IRB

Candidate 7: Dung Nguyen, MPH - Policy Analyst
Ms. Nguyen obtained a Master's degree of Public Health and Policy and now works as a management policy analyst at a firm that advises hospital and legislative administrators on health care policies. She has expertise in public health policies, epidemiology research, and biostatistics.

Candidate 8: Manfred Howard - Minister
Manfred was formerly incarcerated in the state criminal justice system. He is now a minister at the local church. He's worked for 6 years as an advocate for adults leaving the prison system and transitioning-to work programs. He has expertise in prisoners and community.

Interactive: Assemble Your IRB

Let's consider the feedback for the Non-Voting Member.

- One candidate has a conflict of interest – he works for BioMedXYZ. He would not be an appropriate choice for the IRB. That candidate is Juan Telmo, PhD.
- Additionally, while Manfred Howard may be an expert in his field, he is not a good choice in this case because his area of expertise is adults and prisoners.

Interactive: Assemble Your IRB

Several candidates would serve the IRB best as a voting member instead of a non-voting member for consultation.

For example, Tomer Teivel, RN, works in environments that cater to the age group targeted for the study. He would serve the IRB better as a voting member as well as Lilith O'Conner, BS, because she has experience in early childhood education and expertise working with the target study population.

Carla Brown, PhD, has legal experience and serves on a board of bioethics and Dr. Brian Bradford has a pediatric medical practice. Dung Nguyen, MPH, has expertise in epidemiology research and biostats. These candidates will be a good fit for the IRB as voting members.

That leaves one candidate who is a good choice to be added to the IRB as an advisor and a non-voting member, Dorian Picard, MD. His expertise is in children and adolescents with ADHD. However, his busy schedule only allows for limited availability. So, he has agreed to be available for expert advice only.

Interactive: Assemble Your IRB

Now, consider the feedback for the ideal candidates to serve as voting members of the IRB for this clinical trial.

Several candidates have experience working directly with the age group targeted for the study – Tomer Teivel has additional experience in drug treatment and research, Lilith O'Conner has experience in early childhood education, and Dr. Brian Bradford has a pediatric medical practice.
Another candidate has legal experience and serves on a board of bioethics, Carla Brown.
Having regulations and ethics covered, the final ideal voting member has expertise on epidemiology research and biostatistics, Dung Nguyen.
Each of these candidates would serve the IRB well as voting members.

Interactive: Assemble Your IRB

Conversely, there a few candidates that are not ideal to serve on the IRB as voting members.

- Dr. Telmo has a conflict of interest. He works for BioMedXYZ, the pharmaceutical company supplying the drug for the study.
- While Manfred Howard may be an expert in his field, he is not a good choice in this case because his area of expertise is adults and prisoners.
- Dr. Picard would be a great addition to the IRB; however, his schedule does not allow him to commit to being a voting member of the team.

Part 4: Responsibilities of an IRB

Part 4: Responsibilities of an IRB

The principal responsibilities of an IRB include the following:

1. **Provision of an Infrastructure to Support the Ethical Review of Proposed and Ongoing Research**

This infrastructure includes the following IRB processes:

- Perform its functions according to written operating procedures.
- Maintain written records of its activities and minutes of its meetings.
- Comply with all applicable federal and state regulatory requirement(s).
- Should review a proposed clinical trial within a reasonable timeframe.

Part 4: Responsibilities of an IRB

- Make its decisions at announced meetings at which a quorum is present.

- Retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least 3 years after completion of a study and make them available upon request from any regulatory authority.

- Notify investigators promptly in writing of its decisions, stating the reasons for those decisions and noting the procedures for appeal

Part 4: Responsibilities of an IRB

2. Reviewing and Understanding the Full Plan of Study

To provide a full review, the IRB should obtain the following documents (examples of information included in a full plan of study):

- Study protocol(s) and protocol amendment(s).
- Written Informed Consent Form(s) and consent form updates that the investigator proposes to use.
- Documents and other media relating to participant recruitment procedures (e.g., advertisements).
- Written information to be provided to participants including questionnaires and explanatory materials.

Part 4: Responsibilities of an IRB

- Information about payments and compensation available to participants.
- Investigator's Brochure.
- Available safety information, including references to relevant literature.
- Investigator's current curriculum vitae and/or other documentation that provides evidence of the investigator's qualifications.
- Any other documents needed to fulfill the IRB's responsibilities

Part 4: Responsibilities of an IRB

3. Keeping a Written Record of IRB Decisions

The following written records should be kept pertaining to an IRB's review of a proposed study:

- Identification of the study.
- List of documents reviewed.
- Decision reached:
  - Approval.
  - Disapproval.
  - Rationale for disapproval.
- Termination or suspension of prior approval.
- Date decision was reached.
- Correspondence with the investigator.

Part 4: Responsibilities of an IRB

4. Considering the Investigator's Qualifications

The IRB should consider the qualifications of the investigator for the proposed study, as documented by a current curriculum vitae or other relevant documentation.

5. Conducting Continuing Review of Ongoing Studies

The IRB conducts continuing review of each ongoing study at intervals appropriate to the degree of risk to human participants. By regulation, this interval must be at least once per year.

6. Requesting More Information When Necessary

The IRB may request more information to assist in their review. One of the reasons for such a request would be when the IRB judges that the additional information would add meaningfully to the protection of the rights, safety, or well-being of participants.

Part 4: Responsibilities of an IRB

7. Reviewing Incentives for Participation

Payment to participants for their participation in a research study must never be coercive in either amount or method of distribution.

The IRB should review both the amount and method of payment to participants to assure that neither exerts undue influence on study participants.

Payments to participants should be prorated (divided in a proportional manner) and not entirely contingent on a participant's completion of the study (no large, consolidated payment at the end).

Part 4: Responsibilities of an IRB

The IRB should confirm that information regarding payment to participants, including the methods, amounts, and schedule of payments to study participants, is justified by the protocol and set forth in the written Informed Consent Form and any other written information provided to participants. The way payment will be prorated should be specified.

Some IRBs have written requirements concerning what is adequate compensation for study participants. Investigators should be familiar with these requirements before submitting a protocol to the IRB for approval.

Part 5: Criteria for IRB Approval of Research

Part 5: Criteria for IRB Approval of Research

The **Belmont Report**, the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research established three key principles that underlie the current system of human research protections:
Respect for persons,
Beneficence (do no harm/maximize possible benefits and minimize possible harms), and
Justice.
These principles are the basis for the criteria for Institutional Review Board (IRB) approval of research (Reference: The Belmont Report).

Select from the three principles as they relate to the given criteria and descriptions:

A. Respect
B. Beneficence
C. Justice

Part 5: Criteria for IRB Approval of Research

Criteria 1: Risks to Participants are Minimized
The IRB should ensure that procedures used in the proposed research are consistent with sound research design, that they do not expose participants to risk unnecessarily, and, when appropriate, involve diagnostic or treatment procedures that pose no further risk.

Feedback: Which of the three principles relates to this criterion: Respect, Beneficence, or Justice?

This criterion relates to the principle of beneficence in the Belmont Report.

Part 5: Criteria for IRB Approval of Research

Criteria 2: Risks to Participants are Reasonable in Relation to Anticipated Benefits

The IRB should consider only risks and benefits that may result from the research, as distinct from risks and benefits of therapies participants would receive even if they were not participating in the research.

The IRB should not consider the possible long-range effects of applying the knowledge gained in the research.

Feedback: Which of the three principles relates to this criterion: Respect, Beneficence, or Justice?

This criterion relates to the principle of beneficence in the Belmont Report.

Part 5: Criteria for IRB Approval of Research

Criteria 3: Selection of Participants is Equitable

No single gender or racial, ethnic, or socioeconomic group should disproportionately carry the burden or reap the benefits of the research. The IRB should ensure that the gender and racial, ethnic, and socioeconomic status of the participants of a research study match as closely as possible to that of the persons expected to benefit from the research.

The IRB should also be mindful of the special challenges of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

Feedback: Which of the three principles relates to this criterion: Respect, Beneficence, or Justice?

This criterion relates to the principle of justice in the Belmont Report.

Clinical Quest

Part 5: Criteria for IRB Approval of Research

Criteria 4: Informed Consent is Properly Obtained and Documented

The IRB must review the informed consent form and ensure that Informed Consent is sought from each prospective participant or from the participant's legally authorized representative.

The IRB must also ensure that the process of obtaining Informed Consent is properly documented.

Adequate provision is made for monitoring the data collected to ensure the safety of participants.

The IRB must review the plans for data collection, storage and analysis and for ensuring participant safety. This includes the plan for capturing and reporting information about adverse events.

Part 5: Criteria for IRB Approval of Research

Criteria 4 (cont)

Complex or high-risk studies may be required to have a data and safety monitoring plan.

Some sponsors may require all studies to have a data safety monitoring plan. For example, in the Clinical Trials Network, all studies must have a data and safety monitoring plan and be monitored by a Data and Safety Monitoring Board.

Feedback: Which of the three principles relates to this criterion: Respect, Beneficence, or Justice?

This criterion relates to the principle of respect for persons in the Belmont Report.

Part 5: Criteria for IRB Approval of Research

Criteria 5: Adequate Provision is Made to Protect Participants' Privacy and Maintain the Confidentiality of Data
Protection of participants' privacy.

The IRB must consider whether the research involves an invasion of privacy.

Factors to be considered include:

- The private or sensitive nature of the information sought.
- The likelihood that participants will regard the study as an invasion of privacy.
- The importance of the research.
- The availability of alternative ways to conduct the study.

Part 5: Criteria for IRB Approval of Research

Confidentiality of data.

IRBs must evaluate whether adequate provisions exist to safeguard the confidentiality of information that is collected.

Feedback: Which of the three principles relates to this criterion: Respect, Beneficence, or Justice?

This criterion relates to the principle of respect for persons in the Belmont Report.

Part 5: Criteria for IRB Approval of Research

Criteria 6: Additional Safeguards are Included for Vulnerable Populations

Some individuals' willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or by actual or perceived coercion by persons in positions of authority. Examples of such vulnerable populations include:

- Children.
- Prisoners.
- Pregnant women.
- Mentally disabled persons.
- Economically or educationally disadvantaged persons.
- Patients with incurable diseases.
- Patients in emergency situations.

Part 5: Criteria for IRB Approval of Research

- Medical, nursing, dental, and pharmacy students.
- Subordinate hospital personnel.
- Members of the armed forces.

When some or all of a study's participants are likely to be drawn from a vulnerable population, the IRB must ensure that appropriate additional safeguards are included in the study to protect the rights and welfare of these participants

Part 5: Criteria for IRB Approval of Research

. Such additional safeguards may include:

- Heightened monitoring of the informed consent process. In some cases, the IRB may wish to approve the enrollment of each participant in the study.
- Changes to the composition of the IRB. For example, when research involving prisoners is being reviewed, at least one voting member (or Alternate) of the IRB must be a prisoner or a prisoners' representative with appropriate background and experience to serve in that capacity.
- If a particular research project is under the jurisdiction of more than one IRB, each IRB of record needs to satisfy this requirement.

Feedback: Which of the three principles relates to this criterion: Respect, Beneficence, or Justice?

This criterion relates to the principle of Beneficence and Respect for persons in the Belmont Report.

Clinical Quest

Part 6: Expedited Review

Part 6: Expedited Review

An IRB may use an expedited review procedure for research that:

- Involves no more than minimal risk and
- Falls into a category that appears on an approved list of categories of research eligible for expedited review.

An IRB may also use expedited review to approve minor changes in previously approved research that are made during the period (1 year or less) for which the approval is authorized.

The IRB must have written procedures that specify how an expedited review will be conducted.

Part 6: Expedited Review

An expedited review (which may involve less waiting time for IRB approval) may be carried out by the IRB chairperson or by one or more experienced IRB members designated by the chairperson.

The reviewers may exercise all of the authorities of the IRB except that of disapproving the research.

A proposal submitted for expedited review may be disapproved only by the full IRB.

Part 6: Expedited Review

Research Eligible for Expedited Review

- Collection of hair or baby teeth.
- Collection of external secretions, including sweat and saliva.
- Recording of data from adults using noninvasive procedures that are routinely employed in clinical practice (not including exposure to electromagnetic radiation outside the visible range, for example, x-rays or microwaves.)
- Collection of blood samples by venipuncture.
- Voice recordings made for research purposes, such as investigations of speech defects.
- Moderate exercise by healthy volunteers.
- **Study of existing data, documents, records, pathological specimens, or diagnostic specimens.**

Part 7: Investigators' Responsibilities to the IRB

Part 7: Investigators' Responsibilities to the IRB

The investigator must:

- Ensure that the IRB receives all the documents it requires to review the proposed research.
- Admit no participant to a study before the IRB has issued its written approval of the study.
- Make no changes to or deviations from the study protocol without prior written approval from the IRB, except when necessary to eliminate immediate hazards to participants.
- Report promptly to the IRB:
  - Changes to or deviations from the protocol, including changes made to eliminate immediate hazards to study participants.
  - Changes that increase the risk to participants or significantly affect the conduct of the study.
  - All adverse drug reactions that are both serious and unexpected.
  - New information that may adversely affect the safety of participants or the conduct of the study.

Part 7: Investigators' Responsibilities to the IRB

Reporting requirements may vary, and it is the investigator's responsibility to know the individual reporting requirements of each IRB involved with the research study.

For example, an IRB may require that every serious adverse drug reaction be promptly reported, whether it was unexpected or not.

Responsibilities (cont.)

- Respond in a timely fashion to all requests from the IRB for additional information about a research study.
- Submit progress reports to the IRB annually, or more frequently, if requested by the IRB, and submit a final report to the IRB when the study is completed or terminated.

Part 8: IRBs and Multi-Site Research

Part 8: IRBs and Multi-Site Research

Multi-site trials are characterized by the involvement of multiple institutions and study sites engaged in a single research study.

When a research study involves more than one institution, each institution is responsible for safeguarding the rights and well-being of research participants at that institution.

With the implementation of the NIH policy on Use of a Single Institutional Review Board for Multi-Site Research (effective May 25, 2017), multi-institutional research in the U.S. involving non-exempt human participants will use a single IRB. Based on 45 CFR 46.114, the use of a single IRB allows for a more streamlined IRB review and increases efficiencies while maintaining the protection of human study participants (NIH Office of Extramural Research, 2016).

Part 9: Summary of Key Points

- The purpose of an Institutional Review Board (IRB) is to safeguard the rights, safety, and wellbeing of all human research participants.
- Any research involving human participants must be reviewed and approved by an IRB.
- Any clinical investigation involving a product regulated by the FDA must be reviewed and approved by an IRB.
- An IRB has the authority to approve or disapprove all research activities that fall within its jurisdiction. It may disapprove a research project with a request for modification. It also has the authority to suspend a research study that it previously approved.
- All previously approved ongoing research must be reviewed by an IRB at least once a year to determine whether approval should be continued.
- .

Clinical Quest

Part 9: Summary of Key Points

- Every institution, that participates in a clinical study must identify all IRBs that have jurisdiction to review and approve the protocol.
- To approve a research protocol, the IRB must ensure that:
  - Risks to participants are minimized.
  - Risks to participants are reasonable in relation to anticipated benefits.
  - Selection of participants is equitable.
  - Informed consent is properly obtained and documented.
  - Adequate provision is made for monitoring the data collected to ensure the safety of participants.
  - Adequate provision is made to protect participants and maintain confidentiality of data.
  - Additional safeguards are included for vulnerable populations

Introduction to Clinical Research

GCP Lecture II

Dr. Laila Tutunji

Nov 2024

GCP Certification

This is an introduction to our medial students on the **WHO** designed global principles and regulations governing research on human subjects

GCP Certification is part of the Graduation Research Project Requirements

GCP Certification

Session 1:

Introduction/ Ethics/

Session 2:

Global Regulatory Framework

Session 3:

GCP Training/ IRBs.

Session 4:

GCP Training/ Research Protocol Basics.

Link to the Course

- Link to the course:
- https://gcp.nidatraining.org/
- Create an account to sign in:
- https://gcp.nidatraining.org/register
- Under organization kindly write:
  The University of Jordan

GCP Course Information

Enter your Name

Enter your Institution as the University of Jordan

Our IRB requires 80% of answers correct

What Went Wrong in Medical Research ?

Germany The Nuremberg Trials

- Starting in the mid-1920s, German physicians, usually proponents of racial hygiene, were accused by the public and the medical society of unethical medical practices.
- In response to the criticism of unethical human experimentation, the Reich government issued "Guidelines for New Therapy and Human Experimentation" in Weimar, Germany.
- The guidelines were based on beneficence and non-maleficence, but also stressed the legal doctrine of informed consent

Germany The Nuremberg Trials

- The guidelines from Weimar were negated by Adolf Hitler.
- By 1942, the Nazi party included more than 38,000 German physicians, who helped carry out medical programs such as the Sterilization Law, as well as trials conducted in concentration camps.
- German physicians responsible for conducting unethical medical procedures on humans during the war were tried.

Germany The Nuremberg Trials

- After World War II, a series of trials were held to hold members of the Nazi party responsible for a multitude of war crimes. The trials were approved by President Harry Truman in January 1946 and were led exclusively by the United States.

- They began on December 9, 1946 in Nuremberg, Germany, in what became known as the Nuremberg trials.

- The 10 points constituted the "Nuremberg Code", which includes such principles as informed consent and absence of coercion; properly formulated scientific experimentation; and beneficence towards experiment participants. It is thought to have been mainly based on the Hippocratic Oath and the basic ethics governing Medicine.

Milestones in Clinical Trial Regulations
1947
The Nuremberg Code

1947 **Nuremberg Code**

Thalidomide Tragedy

- Thalidomide was one of the greatest cases in history of a drug disaster tragedy
- Thalidomide had been tested on animals extensively prior to its marketing
- The first drug recognized to cause birth defect in humans.
- Around 20,000 children were born with physical disability

Thalidomide Tragedy *(cont…)*

- Thalidomide was first marketed in 1957 in West Germany under the trade name **Contergan**.
- The German drug company Chemie Grünenthal developed and sold the drug. Primarily prescribed as a sedative or hypnotic, thalidomide also claimed to cure "anxiety, insomnia, gastritis, and tension". Afterwards, it was used against nausea and to alleviate morning sickness in pregnant women.
- Thalidomide became an over-the-counter drug in West Germany on October 1, 1957.
- Shortly after the drug was sold in West Germany, between 5,000 and 7,000 infants were born with phocomelia (malformation of the limbs). Only 40% of these children survived

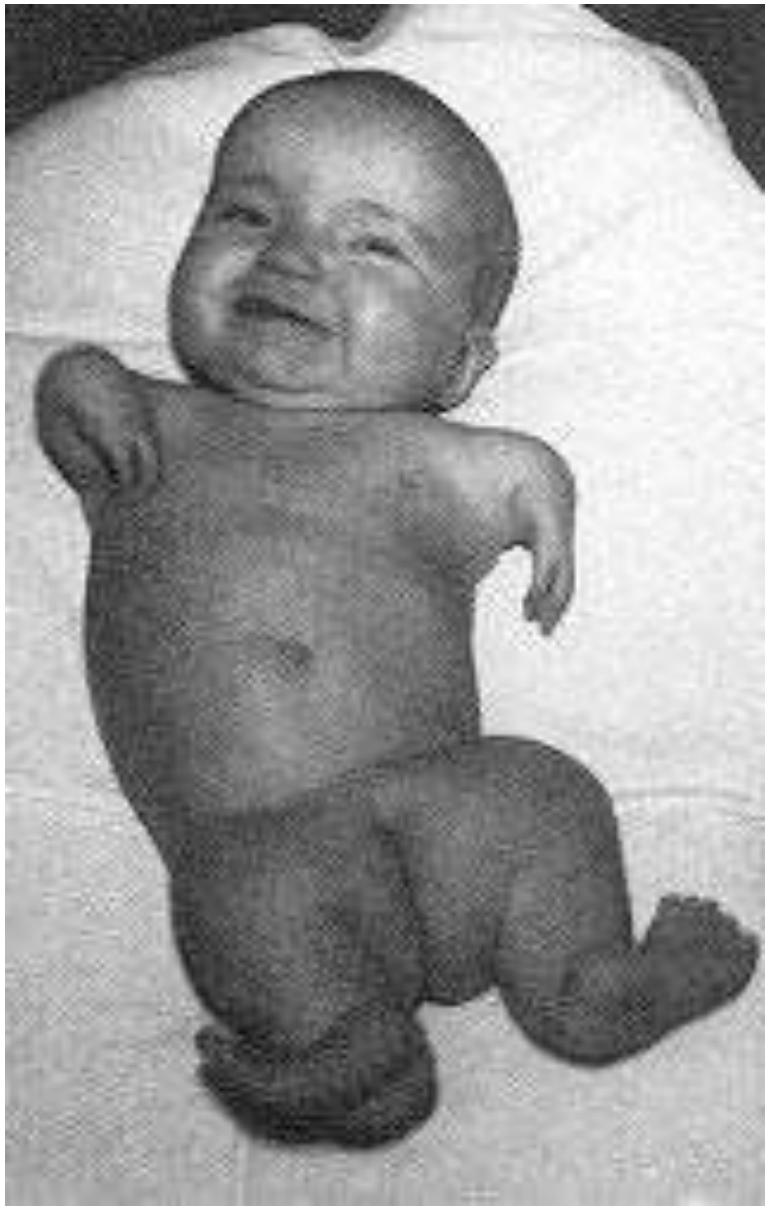
Thalidomide Tragedy *(cont…)*

- Throughout the world, about 10,000 cases were reported of infants with phocomelia due to thalidomide; only 50% of the 10,000 survived.

- Those subjected to thalidomide while in the womb experienced limb deficiencies in a way that the long limbs either were not developed or presented themselves as stumps.
- Other effects included deformed eyes and hearts, deformed alimentary and urinary tracts, blindness and deafness

Thalidomide Tragedy *(cont…)*

- The Medical Research Council maintained that the vast bulk of evidence from laboratory and animal tests is against thalidomide having any genetic effects



- **Researchers tried to reproduce the same effect in dozens of species of lab animals without success.**

Thalidomide Tragedy *(cont…)*

- **The negative effects of thalidomide led to the development of more structured drug regulations and control over drug use and development.**

Milestones in Clinical Trial Regulations
1964 – Declaration of Helsinki

1947 Nuremberg Code

1964 **Declaration of Helsinki**

The Declaration of Helsinki

- **Is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA).[1]**

- **It is widely regarded as the cornerstone document on human research ethics.**

- **The Declaration was originally adopted in June 1964 in Helsinki, Finland, and has since undergone seven revisions (the most recent *by the 75th WMA General Assembly, Helsinki, Finland, October 2024***

The Tuskegee Experiment

- An unethical clinical study conducted between 1932 and 1972 by the U.S. Public Health Service.
- Investigators enrolled in the study a total of 600 impoverished, African-American sharecroppers from Macon County, Alabama.
- Of these men, 399 had previously contracted syphilis before the study began, and 201 did not have the disease and were purposely infected.

The Tuskegee Experiment

- The participants were primarily sharecroppers, and many had never before visited a doctor.

- Doctors from the U.S. Public Health Service (PHS), which was running the study, informed the participants—399 men with latent syphilis and a control group of 201 others who were free of the disease—they were being treated for bad blood, a term commonly used in the area at the time to refer to a variety of ailments

The Tuskegee Experiment

- The men were monitored by health workers but only given placebos such as aspirin and mineral supplements, despite the fact that penicillin became the recommended treatment for syphilis in 1947, some 15 years into the study.
- PHS researchers convinced local physicians in Macon County not to treat the participants, and instead, research was done at the Tuskegee Institute. (Now called Tuskegee University, the school was founded in 1881 with Booker T. Washington as its first teacher.)
- In order to track the disease's full progression, researchers provided no effective care as the men died, went blind or insane or experienced other severe health problems due to their untreated syphilis.

The Tuskegee Experiment

- In the mid-1960s, a PHS venereal disease investigator in San Francisco named Peter Buxton found out about the Tuskegee study and expressed his concerns to his superiors that it was unethical.
- In response, PHS officials formed a committee to review the study but ultimately opted to continue it—with the goal of tracking the participants until all had died, autopsies were performed, and the project data could be analyzed.

The Tuskegee Experiment- The Whistleblower

- **Buxton then leaked the story to a reporter friend, who passed it on to a fellow reporter, Jean Heller of the Associated Press.**
- **Heller broke the story in July 1972, prompting public outrage and forcing the study to finally shut down.**

- **By that time, 28 participants had perished from syphilis, 100 more had passed away from related complications, at least 40 spouses had been diagnosed with it and the disease had been passed to 19 children at birth.**

- **In 1973, Congress held hearings on the Tuskegee experiments, and the following year the study's surviving participants, along with the heirs of those who died, received a $10 million out-of-court settlement. Additionally, new guidelines were issued to protect human subjects in U.S. government-funded research projects.**

The Tuskegee Experiment

- The Tuskegee Syphilis Study, cited as "arguably the most infamous biomedical research study in U.S. history",[8] led to the **1979 Belmont Report** and to the establishment of the **Office for Human Research Protection (OHRP).**[9]
- It also led to federal laws and regulations requiring **Institutional Review Boards for the protection of human subjects in studies involving them.**

The Belmont Report 1978/1979

The *Belmont Report* summarizes ethical principles and guidelines for research involving human subjects.

Three core principles are identified: respect for persons, beneficence, and justice.

Three primary areas of application are also stated: informed consent, assessment of risks and benefits, and selection of subjects.

The Tuskegee Experiment

On May 16, 1997, President Bill Clinton formally apologized on behalf of the United States to victims of the experiment.

During his apology, Clinton announced plans for the establishment of Tuskegee University's National Center for Bioethics in Research and Health Care.

The final study participant passed away in 2004.

Hippocrates, Principles of Medical Ethics

1. Non-Maleficence
2. Beneficence
3. Justice
4. Respect for Autonomy
5. Confidentiality

Milestones in Clinical Trial Regulations
1989 – US French and Japanese GCP Laws

1947 Nuremberg Code

1964 Declaration of Helsinki

1989 **US French and Japanese GCP Laws**

Milestones in Clinical Trial Regulations
1991 – European Union – GCP Guidelines

1947 Nuremberg Code

1964 Declaration of Helsinki

1989 US French and Japanese GCP Laws

1991 European Union – GCP Guidelines

Milestones in Clinical Trial Regulations
1994 – WHO – GCP Guidelines

1947 Nuremberg Code

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1989 US French and Japanese GCP Laws

1991 European Union – GCP Guidelines

1994 **WHO - GCP Guidelines**

Milestones in Clinical Trial Regulations
1997 – ICH – GCP Guidelines

1947 Nuremberg Code

1964 Declaration of Helsinki

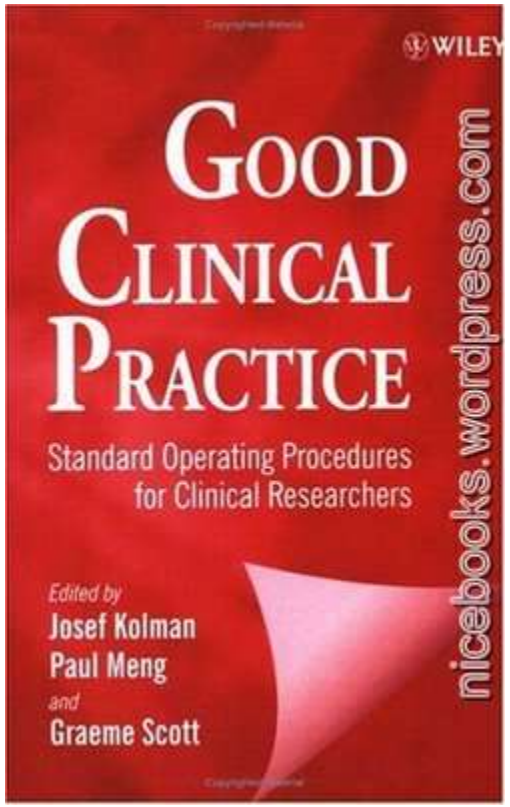
1989 US French and Japanese GCP Laws

1991 European Union – GCP Guidelines

1994 WHO - GCP Guidelines

1997 **International Conference on Harmonisation ICH – GCP Guidelines**

What is GCP



- Good Clinical Practice (GCP):

"Standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected"

Ethics
The Soul of Medicine

The First Principle

Non-Maleficence

“Primum, Non Nocere”

First, DO NO HARM

The Second Principle

Beneficence

The Third Principle

Justice

The Forth Principle

Respect for Autonomy

The Fifth Principle

Confidentiality

To see and See Again

- Shoulder of giants
- The spirit of inquiry, our responsibility ?
- Al Rhazi
- Ibn Sena
- Ibn Al Haitham
- Where do We Stand?

To See and See Again

You Can Make A Difference