Bioethics Q&A

1. **What is an informed consent? Give a brief definition?**
   A. **Informed consent** is a process for getting permission before conducting a healthcare intervention on a person, or for disclosing personal information. Can be a consent to receive therapy/ participate in a research/ disclose personal information/ have a procedure.
   B. An informed consent is given based upon a clear appreciation and understanding of the facts, implications, and consequences of an action.
   C. Adequate informed consent is rooted in respecting a person’s dignity.
   D. To give informed consent, the patient must have adequate reasoning and be in possession of all relevant facts. Impairments to reasoning and judgment that may prevent informed consent include basic intellectual or emotional immaturity, high levels of stress such as (PTSD) or a severe intellectual disability, mental disorder, intoxication, Alzheimer’s /dementia, coma.

2. **What is the declaration of Helsinki?**
   A. The Declaration of Helsinki is a set of ethical principles regarding human experimentation.
   B. Developed for the medical community by the World Medical Association (WMA) in June 1964.

3. **Who established the Declaration of Helsinki? When? For what?**
   A. WMA (world medical association).
   B. June 1964.
   C. To establish a set of ethical guidelines in the research done on human beings for the medical society.

4. **What does the Declaration of Helsinki states regarding research conducted on children? Is it ethically acceptable according to his document?**
   A. It should be done just under exceptional circumstances.
   B. Only if the research is responsive to health needs and priorities of children.
   C. Where there is a reasonable likelihood for major beneficial outcome for children/ those who the research results aim to benefit.

5. **What are the major criteria of informed consent validity?**
   A. Disclosure: all necessary information is given to the patient in order for them to make autonomic choice. Make sure the patient understands all information given.
   B. Capacity: the ability of the patient to understand all information and capability to conclude an autonomic decision.
   C. Voluntariness: the right to freely exercise their decision making without being subjected to external pressure such as manipulation, or undue influence.

6. **Case: A GP receptionist sees that a neighbor has had an appointment with the GP. Suspecting the neighbor is pregnant in intent to congratulate her she takes a look in her notes. Is that a breach of confidentiality? How serious? Justify with ethical analysis. [(0) no breach. (1) Trivial. (2) Significant. (3) Serious breach.].**
   A. It is a breach of confidentiality.
   B. (3) serious.
   C. Although the receptionist is not a doctor she is under the responsibility of the physician to keep patient info confidential. By breaching confidentiality, she undermines the physician-patient trust and relationship. This may have an immediate affect on the patient health, a delayed affect for future medical treatment (impaired trust of the patient, impaired compliance) and maybe even disturb with the future treatment of other patients.
   D. The ethical issue discussed here is that the patient information must not be disclosed and the patient has the right for privacy- the right to decide who receives what information regarding themselves.

7. **Case: Doctor discuss his patients with identifiers. Is that a breach of confidentiality? How serious? Justify with ethical analysis. [(0) no breach. (1) trivial breach. (2) significant breach. (3) serious breach.].**
   A. It is a breach of confidentiality.
   B. (2) significant-(3) serious depending on how important were the identifiers to the medical discussion and how disclosing they where
   C. A physician has to keep patient info confidential. By breaching confidentiality, they undermines the physician-patient trust and relationship. This may have an immediate affect on the patient health, a delayed affect for future medical treatment (impaired trust of the patient, impaired compliance) and maybe even disturb with the treatment of other patients.

8. **What are the main roles of IRB’s or REC’s in medical research?**
   A. Review the purpose, ethical considerations, standards.
9. What are the 4 principles of medical ethics? (same + Beauchamp and Childress)?
   A. Respect for autonomy
   B. Non-maleficence
   C. Beneficence
   D. Justice

10. What are the differences between traditional and modern medical ethics?
    A. Point of clinical care: TME - lab, clinic. MB - patient.
    B. Based on: TME - population. MB - individual.
    C. Method: TME - hierarchy - orders to the patient. MB - partnership, collaboration.
    D. Data owned by: TME - institution only (where expert experience dominates). MB - owned and shared by the patient, data is limitless and accessible.
    E. Physician status: TME - authority, orders. MB - guide.

11. Give the examples of medical paternalism (at least 3). Medical paternalism is a set of attitudes and practices in medicine in which a physician determines that a patient’s wishes or choices should not be honored. These practices were current through the early to mid 20th century, and were characterized by a paternalistic attitude, surrogate decision-making, and a lack of respect for patient autonomy.
    A. Activity-passivity refers to the traditional version of paternalism, in which the doctor treats the patient as one who cannot or should not make decisions. This relationship is similar to that of a parent and child. Treatment is performed “irrespective of the patient’s contribution and regardless of outcome.” This model is considered justified in emergency situations in which there is no time to consider the patient’s preferences or contributions.
    B. Guidance-co-operation is a relationship used in more long-term situations. The doctor provides instructions to the patient, to which patient - expected to comply. Comes from the expectation that the physician will guide the patient, who will co-operate, but who retains their individuality.
    C. Mutual Participation involves the physicians making it clear that they do not always know what is best. This model is more of a partnership, in which the doctor helps the patient to help him or herself. This model is often employed in cases of chronic disease or pain, in which the patient can have a higher degree of freedom and be more independent of the doctor.

12. What ethical issues can arise from the phase 1 trials?
    A. In case of Patient volunteers:
       1. The risk to benefit ratio is unfavourable for research subjects.
       2. May take advantage of or be manipulated by hopeless vulnerable patients.
    B. In case of healthy volunteers:
       1. Can not personally benefit from it.
       2. Moreover, can impair volunteers’ health.

13. What is the etymology (original meaning) of euthanasia?
    A. Eu = Good. Thanasis = Death.
    B. The “Good death”. Peaceful, lucid, painless death surrounded by loved ones.

14. What is the moral difference (if there is such a thing) between active-passive euthanasia in your opinion?
    A. Although some laws or voices may advocate for a moral difference between active and passive euthanasia due to the fact in passive you do not prevent death and in active you actively inducing it I find the result to be the same and therefore I do not believe there is a significant moral difference between the two.

15. Why so people ask for euthanasia? List their reasons.
    A. Seek control of their on inevitable death.
    B. Long term sever depression.
    C. Long term untreatable chronic pain.
    D. Disease consuming quality of life irreversibly.
    E. Loss of independence/ clear mind/ control of own life/dignity.

16. What ethical problems could arise with regard to the usage of placebo in RCT’s? How could those possibly be avoided in your opinion?
    A. Issues:
       1. Lack of treatment up to serious harm (even death).
       2. Helsinki declaration: use standard treatment as control.
       3. Used where minimal risk.
       4. Patients may not enroll/ withdraw.
B. Way to avoid: (?)

17. What does the Hippocrates oath states about euthanasia and abortion?
A. Euthanasia: forbids it. "I will never give a deadly drug to anybody who asks for it nor will I make a suggestion to this effect".
B. Abortion: forbids it. "I will not give to a woman an abortive remedy".

18. What are the legitimate reasons for breaching the confidential-relationship?
A. Contagious diseases (HCV, HBV, AIDS).
B. Population social risk in case of sever mental disease.
C. Minor (under aged patient).
D. Other physicians to include them in the medical team handling the case.

19. What the general rule of confidentiality states?
A. Patient information must not be disclosed (can be discussed without identifiers for medical purpose).
B. Patients have the right for privacy- the right to decide who receives what information regarding themselves.

20. Major criteria to assess patient's competence to give consent to treatment.
A. Clinical assessment of decision-making capacity should include the patient ability to:
   1. Understand the risks, benefits and alternatives.
   2. Evaluate the information provided by he physician.
   3. Voluntarily reach a conclusive decision regarding their plan without influence of third party.

21. Definition between voluntary and non-voluntary euthanasia.
A. Voluntary euthanasia (refers to mercy killing that takes place with the clear and voluntary consent of the patient, either verbally or in a written document such as a living will).
B. Non-voluntary euthanasia (refers to the mercy killing of a patient who is unconscious, comatose, or otherwise unable to explicitly make his intentions known).
C. Involuntary euthanasia (done against the wishes of the patient and would clearly count as murder).

22. What statements are formulated in the original version of the Hippocrates oath?
A. I swear by Apollo Physician and Asclepius and Hygieia and Panacea and all the gods and goddesses, making them my witnesses, that I will fulfil according to my ability and judgment this oath and this covenant:
B. To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art- if they desire to learn it- without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else.
C. I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.
D. I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly, I will not give to a woman an abortive remedy. In purity and holiness, I will guard my life and my art.
E. I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.
F. Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.
G. 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.
H. If I fulfil this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.

23. The Four principles of bioethics. Describe one of them briefly.
A. Respect for autonomy.
B. Non-maleficence- "given an existing problem, it may be better not to do something, or even to do nothing, than to risk causing more harm than good".
C. Beneficence- researchers should have the welfare of the research participant as a goal of any clinical trial or other research study.
24. Which of the four principles of bioethics is the “youngest” or the most recent among them? Why?
   B. Why?

   A. Autonomous decision made by the patient.
   B. The patient knows all the necessary information that the decision requires.
   C. The patient decides freely without any form of force/pressure.
   D. The patient understands the provided information!

26. What are the legitimate reasons for breaching the confidential-relationship?
   A. Patient has the right to decide who can have information about his case.
   B. Medical information could be given (without patient’s consent) just to those persons that take part in the care of the patient.
   C. Consent of the patient is not necessary if:
      1. It is ordered by the law.
      2. It can be overruled in the name of a third party, when it is required by the defense of a third party's life or health.

27. What are legitimate reasons for not seeking the consent of the patient before medical intervention, treatment or diagnosis?
   A. (3.3) When a patient is unable to express his or her will and a medical intervention is urgently needed, the consent of the patient may be presumed, unless it is obvious from a previous declared expression of will that consent would be refused in the situation.
   B. (3.4) When the consent of a legal representative is required and the proposed intervention is urgently needed, that intervention may be made if it is not possible to obtain, in time, the representative's consent.

28. List some ethical guidelines regarding experimentation on human being.
   B. Belmont:
      1. Respect for persons: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.
      2. Beneficence: making efforts to secure their well-being, do not harm and maximize possible benefits and minimize possible harms.
      3. Justice: Who ought to receive the benefits of research and bear its burdens.

29. Major ethical problems with the usage of placebo control groups in clinical trials:
   A. Lack of treatment up to serious harm (even death).
   B. Helsinki declaration: use standard treatment as control.
   C. Used where minimal risk.
   D. Patients may not enroll/ withdraw.

30. What groups of people are problematic in informed consent?
   A. Not all patients are capable of making rational decisions: mental illnesses, dementia, cognitive impairment of all types. This undermines the principle of informed consent and makes research with and treatment of mentally demented patients difficult as it is based on the model of autonomous, fully competent individual.

31. Major criteria to assess patient's competence to give consent to treatment:
   A. There are certain principles that govern the competency to accept or refuse treatment. The patient should understand information given to him or her and manipulate it in a rational manner, as well as appreciate the situation and its likely consequences + be able to express a choice.
   B. The factual understanding includes the understanding of the diagnosis, the proposed treatment with its risks and benefits, the alternative treatments, and the outcome without treatment.
   C. The factual understanding can be impaired in cases of: low IQ, mental retardation, dementia, poor education, poor attention span, or aphasia.
   D. The appreciation is altered when there is denial, delusions, suicidality, or confabulation. Ambivalent patients or the ones that have communication difficulties may not be able to express a choice or preference for a certain treatment.
32. As a doctor, you are obligated to seek the consent of your patient before treatment. The provided information should include the following:
   Medical information should contain:
   A. The diagnosis of the patient's medical condition and its prognosis.
   B. A description of the essence, course, goal, anticipated benefit, and likelihood of success of the treatment proposed.
   C. The risks entailed in the proposed treatment, including side effects, pain, and discomfort.
   E. Where the treatment is innovatory, the patient shall be so informed.

33. Which principles are explicitly present in the original Hippocrates oath?
   A. The prohibition of abortion.
   B. The importance of privacy.

34. What does paternalism mean in medicine and bioethics?
   A. The doctor does everything for the best medical interest of their patient regardless of their interest.
   B. The proper relationship between doctors and patients is similar to that of parents and children because of doctors' expertise in medicine.

35. Slippery Slope in argument:
   A. Long term consequences of ethical decisions.
   B. The argument tries to take the changing attitude of people into consideration.

36. The biological basis of the whole brain death conception:
   A. The cessation of the functioning of the body as an integrated entity.
   B. The irreversible loss of bodily regulations such as homeostasis.

37. Which bioethical topics are in close relations with the whole brain death conception?
   A. Transplant.
   B. End of life decisions.

38. Distinctions about the various forms of euthanasia used in bioethics:
   A. Active-Passive.
   B. Voluntary- Non voluntary.

39. The concept of living will:
   A. An advanced directive of end-of-life medical decisions.
   B. It is made by competent individuals in case they are no longer able to make decisions.

40. The basic principals of surrogate decisions:
   A. It has to represent the best interest of the patient.
   B. It has to recognize the doctors’ opinion.

41. Nuremberg Code:
   A. Ethics Principles for human experiments.
   B. 1947 International of the ethical requirements of human experiments.
   C. Importance of informed consent & autonomy.
   D. Voluntary consent.
   E. Results for good of society.
   F. Based on animal exp.
   G. Avoid suffering, no Death, degree of risk, proper preparations, qualified people, patient/doctor can end.

42. How to strengthen autonomy?
   A. Patients’ rights.
   B. Partnership, doctor-patient relationship model.

43. Aim of patient rights:
   A. Humanisation of patient.
   B. Patient equal partner.
   C. Decrease defencelessness/ increase compliance.

44. Patient law principle (2 examples):
   A. Right to autonomy.
   B. Right to medical information.
45. Patients’ rights:
   A. Health care.
   B. Dignity.
   C. Self determination.
   D. Medical information- Diagnosis + prognosis 2. description of treatment 3. risks 4. likelihood of success
   E. Privacy- Decides who can have the info, can be given to those taking part in the care. Limitation- by law, third party, death, birth, infectious disease.

46. Informed consent:
   A. Autonomous decision made by the patient.
   B. All info known
   C. Patient understands the information.
   D. Decides freely.

47. Problems with informed consent:
   A. Myth.
   B. Legal requirements are harmful (psychological effect).

48. Avoid Scandals- autonomy, individual interest-social interest, informed consent, ethical guidelines.

49. Ethical guidelines:
   A. Nuremberg code 1947
   B. Helsinki 1964
   C. Belmont report 1979. Principles:
      1. Respect for person.
      2. Beneficence (secure well being).

50. Practice: intervention solely to enhance the well being of the patient that have reasonable expectations of success. Provide diagnosis or treatment.

51. Research: Test a hypothesis, contribute to general knowledge.
   B. Ethical checks- study have informational value, risks, controls for risk, informed consent, feedback, take responsibility, approved by IRB.
   C. Fabrication: making up results.
   D. Falsification: changing data.
   E. Plagiarism: not giving credit.
   F. Authorship: made a significant scientific contribution & will share responsibility of results. Function:
      1. Responsibility.
      2. Credit.
   G. ICMJE- international committee of medical journal editors.

52. Abortion reasons (the conflict: Right of the fetus to live vs. right of women for abortion).
   A. Dangerous life/health of mother.
   B. Genetic problem.
   C. Result of crime (rape)/abuse.
   D. Mother in social/financial crisis.
   E. Under-aged/ minor mother.

53. Personhood:
   A. Conservative- Immediate, Moderate - Delayed, Liberal- after birth.
      • Personhood is the status of being a person. Defining personhood is a controversial topic in philosophy and law and is closely tied with legal and political concepts of citizenship, equality and liberty. According to law, only a natural person or legal personality has rights, protections, privileges, responsibilities, and legal ability.

54. Preformation.
55. Euthanasia:
   A. Originally: "Good death".
   B. Definition: Intentional termination of life by another at the request of the person who dies. End of life medical decision.
   C. **Active vs. Passive:** (Rachel- no diff).
      1. **Active:** active means to bring about someone's death.
      2. **Passive:** refusing to intervene in order to prevent death.
   D. Reasons: Depressed, pain, quality of life, independence, dignity, control of the dying process.
   E. Who?
      1. Terminally ill.
      2. Suffering intense pain.
      3. Choses to die to escape suffering.
   F. Possibility regarding request:
      1. Ignore.
      3. Take active measures- end life.
   G. Who decides?
      1. Voluntary.
      2. Non-voluntary (coma).
      3. Involuntary (against will).
   H. **Legalization** reasons for and against.
      1. For:
         • Dignity
         • Pain
         • Not forced to stay alive
         • Right to suicide
      2. Against:
         • Not just for terminally ill.
         • Health care cost containment.
         • Become non voluntary.
         • Rejection of the importance of human life.

56. Medical futility (non treatment decisions):
   A. Withholding treatment.
   B. Withdrawing treatment (preform an act).
   C. Pain management (pills).
   D. Physician assisted suicide.
   E. Voluntary active euthanasia.