26. Physicians role for family planning. Prophylaxis of congenital diseases. Physician's role in problem families (single parents, cohabitation, families with chronic patients).

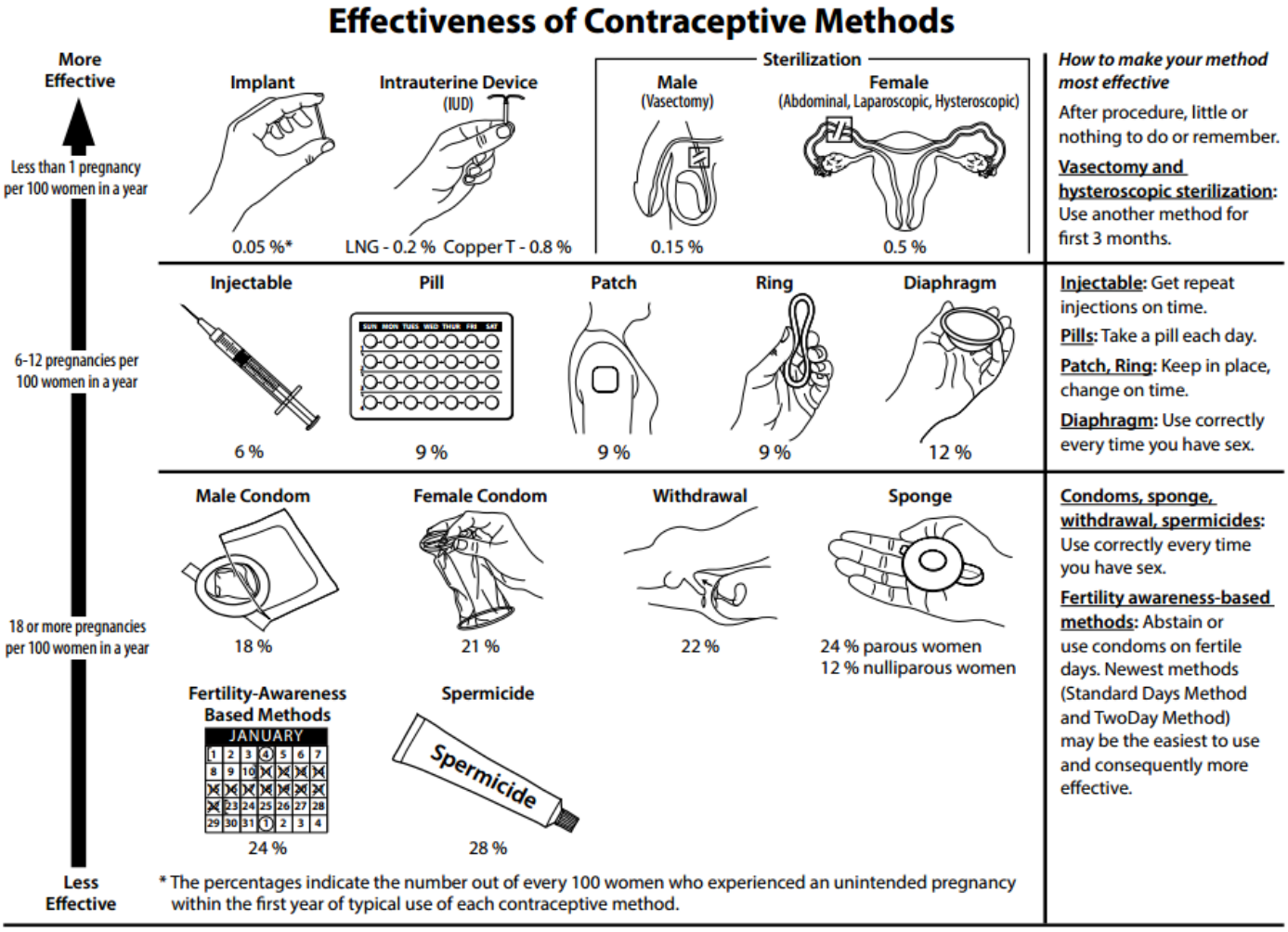
Family Planning
Family planning refers to the factors that may be considered by a couple in a committed relationship and each individual involved in it, deciding if and when to have children.

It may involve consideration of the number of children a couple wish to have as well as the age at which they wish to have them. These matters are obviously influenced by external factors such as marital situation, career considerations, financial position, any disabilities that may affect their ability to have children and raise them, besides many other considerations.

Physicians role for family planning

Physicians can provide family planning services which are defined as "*educational, comprehensive medical or social activities which enable individuals, including minors, to determine freely the number and spacing of their children and to select the means by which this may be achieved.*"

If sexually active, family planning may involve the use of contraception and other techniques to control the timing of reproduction. Physician can administer and advise about different types of contraception, give pre-conception counselling and management, and provide sex education regarding prevention and management of STIs.



Contraception recommendations for:

- Adolescents → condoms as pills may affect their hormones
- Someone who has never been pregnant → Not IUD as there are complications to uterus, recommend pill, condom etc instead.
- Someone who has been pregnant before → IUD or Implant. The combined pill, contraceptive patch and vaginal ring should not be used in the first 3 weeks after having a baby. This is because the risk of blood clots is higher after giving birth.
- For someone who has just had a baby → The contraceptive implant, injection, progestogen-only pill and condoms can be started immediately after having a baby. The IUD and IUS (coils) can be fitted at the time of a caesarean section or immediately after a vaginal birth. If they are not fitted within the first 48 hours, fitting should be at least four weeks after giving birth.

Physician can support couples regarding infertility management.

- Women
  - Lifestyle modifications → cessation of alcohol, nicotine, and recreational drug use as they contribute to subfertility.
  - Treatment of underlying causes (e.g., levothyroxine for hypothyroidism, bromocriptine for hyperprolactinemia, metformin for PCOS)
  - Ovulation induction
  - Assisted reproductive technology
    - In vitro fertilization
    - Intracytoplasmic sperm injection
  - Intrauterine insemination (IUI): a procedure in which washed and concentrated sperm are introduced directly into the uterine cavity
  - Oocyte donation
  - Surgery: removal of tubal, cervical, or uterine adhesions, myomas, and/or scar tissue
- Men
  - Modification of lifestyle factors such as alcohol, nicotine, and recreational drug use
  - Assisted reproductive technology
    - Intrauterine insemination
    - In vitro fertilization
    - Intracytoplasmic sperm injection
  - Surgical treatment of testicular anomalies and/or defects

References

- https://www.contraceptionchoices.org/
- https://next.amboss.com/us/article/RM0log?q=infertility#Ya748d2770e5a3489fb0eb2036b199b4d

Prophylaxis of congenital diseases

Primary prevention

- Before conception
  - Health information
  - Sexual and reproductive education
  - Folic acid (supplementation or fortification)
  - Genetic counselling
- After conception
  - Health information and education for avoiding known risk factors during pregnancy

Secondary prevention

- Before birth
  - Regular prophylactic exams and tests
  - Prenatal screening of the pregnant woman
  - Prenatal selective screening in at-risk pregnancies (amniocentesis, CVS)
- After birth
  - New-born screening
  - Selective screening of new-borns
  - Regular prophylactic exams and test

Physician's role in problem families - single parents

- Children may not have guidance, may have psychological problems
- Families who have become separated from one of the parents by death or divorce face much stress and adjustment. In addition to carrying the extra burdens of parenting and running a household alone, the single parent may feel isolated from friends and family. Loneliness, depression, and confusion can manifest themselves in various physical and emotional ways. At the beginning of an office visit, the physician should try to ascertain whether any important changes have occurred in the patient's life and should record this information in the patient's chart. Once single parenthood is determined, the importance to the patient and the circumstances of the separation should be obtained.
- For example, *a woman needs to work and has no money for childcare so the GP should recommend/advise other services such as childcare services, free food for children, services that provide clothes for kids; inform her of different social policies that can help her.*

Physician's role in problem families - cohabitation

- Problems in cohabiting families
  - Cohabitation is often a marker of family instability, and family instability is strongly associated with poorer outcomes for children. Children born to cohabiting parents see their parents break up more often than do children born to married parents. In this way, being born into a cohabiting family sets the stage for later instability, and children who are born to cohabiting parents appear to experience enduring deficits of psychosocial wellbeing (aggression, anxiety, and depression).
  - At birth, children born into cohabiting parent families are more likely to have low birth weight than are their counterparts born to married parents.
  - Health disadvantage extends to age five; children born to cohabiting parents more often experience asthma, obesity, and poor health than do children born to married parents.
- Physician can refer children to a therapist, treat asthma, educate on obesity and the problems that may arise in these families

Physician's role in problem families - families with chronic patients

- What kind of advice should the doctor give?
- How can they educate?
- What kind of diet?
- How to organise home?
- Is there a regular examination?

Physicians can provide:

- Comprehensive Care: curative care, prevention, health education and promotion
- Continuous Care: they take in account patient's history and episodes of illness
- Personal Care: individual patient centred care
- Integral Care: consider non-medical factors such as social and family characteristics.
- General Care: care to all age groups and sexes with a family

References

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27. Occupational medicine – definition, principles, organisation in Bulgaria

Occupational medicine – definition

Is a branch of clinical medicine concerned with the maintenance of health in the workplace, including prevention and treatment of diseases and injuries, with secondary objectives of maintaining and increasing productivity and social adjustment in the work environment.

Law on Health and Safety At Work (2014)
Regulates the right and obligations of the:

- Government
- Employers
- Employees
- Representatives of health and safety at work of those who work in private or in partnership
- Other organizations and entities who ensure health and safety

Occupational medicine – principles

The law establishes principles of prevention and tries to stimulate improvements for the safety and health of employee:

- Prevention of occupational risks
- Protection of human's health and safety
- Eliminate the risks and causes of work accidents and occupational diseases
- Informing, consulting, training
- Balanced participation

Obligations of the employer
The employer is obliged to provide health and safety of workers through:

1. Avoiding risks
2. Assessment of the risks that cannot be avoided
3. Risk reduction at the source of error
4. The adaptation of work to the worker, especially in regard to the design of workplaces, the choice of work equipment, working and production methods to alleviate or eliminate monotonous work, work at a predetermined rate, and reduce their impact on workers' health
5. Adapting to technical progress
6. Replacing the dangerous by the non-dangerous or the less dangerous
7. Designate existing hazards and sources of adverse health and safety factors
8. Implementing a coherent overall prevention policy that covers technology, organization of work, working conditions, social relationships, and the influence of the elements of the work environment and work process
9. Use of collective protective methods in preference to personal protective equipment
10. Giving appropriate instructions to the workers.

Occupational medicine – organisation in Bulgaria

Occupational Medicine Services

- Occupational health service units have predominantly preventative functions.
- They advise and assist employers on working conditions in the planning, organization, and implementation of their obligations under:
  - Providing and maintaining safe and healthy working conditions
  - Strengthen the health and performance of employees when carrying out their work
- Occupational Medicine Services are registered with the Ministry of Health

National Council on Labour Conditions

- Chairman → Minister of Labour and Social policy
- Representatives of:

- Council of Ministers.
- National Insurance Institute.
- National representative organizations of employers
- National representative organizations of employees

Minimum requirements for staff of the Occupational Health services

- A person with a master's degree in medicine and specialisation in occupational medicine
- A person with a higher education degree in specialities included in the professional areas in the field of technical sciences pursuant to the Classification of Higher Education Areas and Professional
- Areas and three years of professional experience in the sphere of safety and health at work
- A technical assistant with no less than secondary education

Main activities of Occupational Health Services

- Helping employers to create an organization for health and safety at work
- Evaluation of occupational risk and analysis of the health status of workers
- Proposing measures for removal and reduction of the risk
- Monitoring the health status of workers
- Train employees and officials on the rules for health and safety at work

28. Expert evaluation of temporary incapacity for work. Indicators.

Definition of Working Capacity: Working capacity is state of the organism that allows the person to accomplish his working obligations.

Definition of Working Incapacity: Working incapacity is the state of not being able to work because of illness, traumas or the working conditions increase the chance of worsening health status.

Types of Working Incapacity

- **According to the duration**
  - **Temporary incapacity**
    - It is the state in which the person is not able to work for certain period and is expected to be fully recovered and work normally in a time.
  - **Permanent incapacity**
    - It is the state in which the pathological changes done by the disease have progressive and irreversible character and the person is not able to work for long time or forever. This type of incapacity is determined in comparison with ability of a healthy person, if there is a need for other person's help, the period of invalidity, negative working conditions etc.
- **According to degree of losing the capacity of working**
  - **Complete**
    - The person cannot work at all and needs a special regimen
  - **Partial**
    - The person cannot work as usually and needs alleviating working conditions.
    - Such state we do have when a person is healthy but needs a treatment in home, because of pregnancy, looking after an ill member of the family, quarantine etc.

The medical expertise of ability for work is organized and directed by the Ministry of Health and is included in the minimal package of health services, provided by the National Health Insurance Fund.

Temporary inability for work (sick leave) is present in the occasions of

- General illness
- Accident
- Injury
- Professional disease
- Health resort treatment
- Quarantine
- Looking after a diseased or quarantined member of the family
- Urgent accompany of a sick family member for medical examination, pregnancy, and childbirth
- Looking after a healthy child, because of a quarantine in the kindergarten
- When a person who depends on the employee for care (such as a child or elderly parent) is sick or injured, etc.

Documentation for Temporary Incapacity

The document "medical sickness certificate" for temporary inability for work. Medical sickness certificate for temporary inability for work are issued only by health- provided and working people. Medical sickness certificate is issued for calendar days, not in working days. The medical sickness certificate has financial, legal, medical, and statistical function.

The shortest duration of the medical sickness certificate is 1 day. Getting medical sickness certificate for previous days before the examination is not allowed.

Two types of medical sickness certificate

- Primary medical sickness certificate (issued for every new illness with temporary inability for work)
- Extension of the medical sickness certificate (issued for repeated visit to the doctor on the occasion of the same illness).

Expert evaluation of temporary incapacity for work

- GP and dentists
  - They have the right to give till 14 sick - leave days at once, generally till 40 days per year.

- The Medical Consulting Commission (LKK)
  - Medical consulting commission includes no less than 2 permanent members, and they are approved by the Director of RHI.
  - They have the right to give till 30 sick – leave days at once, generally till 180 sick – leave days per year.
- Territorial Expert Medical Commission
  - Have the right to give more than 180 sick – leave days.
  - The commission takes part in the expertise of temporary inability for work, but they issue Expert Evaluation.
  - The GP must prepare the patient for her/his TEMC-examination.
- National Expert Medical Commission decides over controversial points of the expertise of inability for work.

Temporary Incapacity – Pregnancy

- **135 days with 3 medical certificates:**
  - 45 days before the term → medical certificate from GP/OG
  - 42 days after birth → document of maternity given when being discharged from hospital
  - 48 days → medical certificate from the child's paediatrician
- In case of delivery of a dead child → First and second medical sickness certificates are issued
- In case of premature birth when the 45-day sick leave has not expired → the women is entitled to use the days left or the unused days for leave, due to pregnancy, which are included in the third medical sickness certificate.
- After pregnancy due date → the medical certificate is issued by the doctor who observed the pregnant woman until the birth delivery

Indicators of Incapacity

- **Prevalence of cases with temporary disability** = number of cases with temporary inability for work (number of only primary list)/number of health provided.

- **Prevalence of days with temporary disability** = number of days with temporary inability for work (sum of all hospital lists)/ number of health provided people * 10

29. Expert evaluation of permanent incapacity for work. Territorial expert medical commission.

Definition of Working Capacity: Working capacity is state of the organism that allows the person to accomplish his working obligations.

Definition of Working Incapacity: Working incapacity is the state of not being able to work because of illness, traumas or the working conditions increase the chance of worsening health status.

Types of Working Incapacity

- **According to the duration**
  - **Temporary incapacity**
    - It is the state in which the person is not able to work for certain period and is expected to be fully recovered and work normally in a time.
  - **Permanent incapacity**
    - It is the state in which the pathological changes done by the disease have progressive and irreversible character and the person is not able to work for long time or forever.
    - This type of incapacity is determined in comparison with ability of a healthy person, if there is a need for other person's help, the period of invalidity, negative working conditions etc.
- **According to degree of losing the capacity of working**
  - **Complete**
    - The person cannot work at all and needs a special regimen
  - **Partial**
    - The person cannot work as usually and needs alleviating working conditions.
    - Such state we do have when a person is healthy but needs a treatment in home, because of pregnancy, looking after an ill member of the family, quarantine etc.

The medical expertise of ability for work is organized and directed by the Ministry of Health and is included in the minimal package of health services, provided by the National Health Insurance Fund.

Expert evaluation of permanent incapacity for work

The expertise of the permanent disability in Bulgaria is carried out by:

- Territorial Expert Medical Commission
- National Expert Medical Commission

The permanent disability is defined as a percentage lost ability for work compared to the abilities of the healthy person.

The expertise includes defining of:

- the extent of the permanent inability for work in percentage compared to the healthy person
- the need for somebody else's assistance
- the initial date of becoming disabled
- the duration of the permanent inability for work and the final date of it
- the contra-indicated work conditions and the necessity for a transfer to more appropriate job.

Territorial Expert Medical Commission

Territorial Expert Medical Commission issue "Expert Evaluation for permanent incapacity of work" for a period of 1- 3 years or lifelong.

The GP must prepare the patient for her/his TEMC-examination.

Groups of permanent incapacity

- The loss of working capacity is over 90% (rreceives an assistant to care for them [who gets paid on that document])
- Loss of working capacity is between 71% - 90%.
- Loss of working capacity is between 50% - 70%.
- Loss of working capacity is under 50%

30. Preventative medicine – definition and objectives. Primary, secondary, and tertiary prophylaxis. Health promotion.

Preventative medicine – definition

Preventative medicine aims to prevent, interrupt, and reverse the disease processes by intervention of the disease precursors and risk factors. It focuses on the health of the individuals, communities, and defined populations.

Preventative medicine – objectives

Its goal is to protect and maintain health and wellbeing, and to prevent disease, disability, and death.

Primary prophylaxis

Definition of Primary prophylaxis: Is an intervention at the stage of susceptibility and reducing the exposure, thus preventing the occurrence of the disease.

Aims to prolong their healthy period during phase of disease that may have underlying economic, social, and environmental conditions leading to disease. It targets the total population, selected groups, and individuals at high risk.

Primary Non-specific Prophylaxis (Health Promotion)

- By enhancing awareness, changing behaviour, and creating environments that support good health practices
- Legislation and enforcement to:
  - ban or control the use of hazardous products, *(e.g., asbestos)*
  - to mandate safe and healthy practices *(e.g., use of seatbelts and bike helmets)*
  - radiology clinic workers have a radiation exposure device (dosimeter) to alarm them
- Health education about healthy and safe habits *(e.g., eating well, exercising regularly, not smoking)*

Primary Specific Prophylaxis

- Immunisation/vaccination
- B12, Folic acid (before conception)
- Barrier contraception for STD
- Iodine tablets in case of irradiation/nuclear fallout
- Fortification of foods

Secondary prophylaxis

Definition of Secondary prophylaxis: Early detection and treatment of diseases at the pre-clinical and clinical stages to prevent progression and complications.

Examples of Secondary Prophylaxis

- Biochemical screening of pregnant women
- Pre-natal selective screening at risk pregnancies
- Neonatal mass screening
- Selective screening of new-born
- Mammography
- Colorectal screening
- Cervical Pap smear
- Prostate screening

Requirements of a screening program

- The Disorder must be
  - Severe condition
  - Well-known natural history
  - Long period between first signs and overt disease
- The Diagnostic test must be
  - Highly sensitive
  - Simple and safe

  - Acceptable
- The Treatment must be
  - Effective
  - Acceptable
  - Safe

Tertiary prophylaxis

Definition of Tertiary prophylaxis: Limitation of disability and rehabilitation.

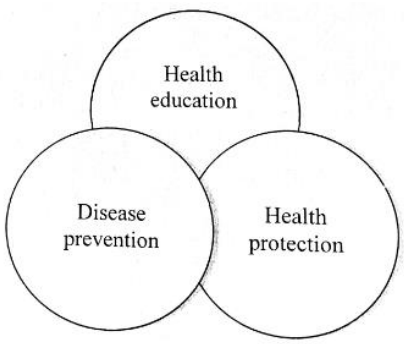
Examples of Tertiary prophylaxis

- Cardiac or stroke rehabilitation programs
- Chronic disease management programs (e.g., for diabetes, arthritis, depression, etc.)
- Support groups that allow members to share strategies for living well,
- Vocational rehabilitation programs to re-train workers for new jobs when they have recovered as much as possible.

Health promotion

Definition of Health Promotion: It is the process of enabling people to increase control over and to improve their health.
It is the science and art of helping people change their lifestyle to achieve a state of optimal physical, emotional, social, spiritual and intellectual health.

Tannahill's Model of Health Promotion



Principles of Health Promotion

- Build healthy public policy
  - Combines legislation, fiscal measures, taxation, and organizational change
  - It is coordinated action that leads to health, income and social policies that foster greater equity
- Create supportive environments for health
  - Includes tobacco control legislation for workplace
  - Banning junk food advertising to children
- Strengthen community action for health
  - Community development draws on existing human and material resources in the community to enhance self-help and social support, and to develop flexible systems for strengthening public participation in the direction of health matters.
- Develop personal skills
  - Health promotion supports personal and social development through providing information, education for health and enhancing life skills. By doing so, it increases options available to people to exercise more control over their health and environments
- Re-orient health services
  - The role of the health sector must move increasingly in a health promotion direction by:
    - Expanding mandate of public health units and community health centres to focus on strengthening protective factors, reducing risk factors, and facilitating access to the social determinants of health
    - Invest in initiatives to increase the access that people have to protective factors and the social determinants of health
    - Create bridges between partners from health, social and education sectors, and community
    - Work across levels of government.

Characteristics of Health Promotion

- Empowers families and communities to improve their quality of life and achieve and maintain health and wellness.
- Emphasises promotion of positive good health
- Emphasises personal, social, political, and institutional resources as well as physical capacities
- Is directed towards action on the determinants of health
- Health promotion requires a close co-operation of sectors beyond health services, reflecting the diversity of conditions which influence health
- Government, local and national level has a responsibility to act appropriately and timely to ensure environment which is beyond control of individuals and groups is conducive to health
- Is a process enabling individually and collectively increased control over determinants of health and improved health status
- It does not mean only responsibility of the health care system, but also individual responsibility

Extra

- **Primary prevention → population (mass) strategy**
  - *Population strategy is directed at the whole population irrespective of individual risk levels*
  - *For example, studies have shown that even a small reduction in average blood pressure or serum cholesterol of a population would produce a large reduction in the incidence of cardiovascular disease*
  - *Population approach is directed towards socio-economic, behavioural and lifestyle changes*
  - ***Advantages of Population Strategy***
    - *Radical*
    - *Behaviourally appropriate*
    - *Large potential for whole population*
  - ***Disadvantages of Population Strategy***
    - *Small benefit to individuals*
    - *Poor motivation of subject*
    - *Poor motivation of physicians*
    - *Benefit to risk ratio may be low*
- **Primary prevention → high risk strategy**
  - *Aims to bring preventative are to individuals at special risk*
  - *Requires detection of individuals at high risk by optimum use of clinical methods*
  - ***Advantages of High-risk Strategy***
    - *Appropriate for individuals*
    - *Subject motivation*
    - *Physical motivation*
    - *Favourable benefit to risk ratio*
  - ***Disadvantages of High-risk Strategy***
    - *Difficulties in identifying high risk individuals*
    - *Behaviourally inappropriate*
    - *Temporary effect*
    - *Limited effect*

31. Dispensary method – types and patient groups. Indicators.

Definition of Dispensary: Dispensary is a specialized medical institution which executes the dispensary method and has a region for observation.

Definition of Dispensary Method: The dispensary method is an active method for observation of the health status of different groups of the population.

Definition of Dispensarisation: The dispensarisation is a complex of medical, social and public actions for active search, active observation and active recovery.

Dispensary method – types and patient groups

1. Prophylactic – healthy people are observed and the aim of it is health promotion and health protection:
    a. Children till 7 years
        i. Child development (Growth)
        ii. Hearing tests
        iii. Visual acuity testing
    b. Pregnant women
    c. Sporting people
        i. Assessment of vital signs, vision, hearing, CVS, Musculoskeletal system
        ii. ECG
        iii. Exercise stress testing
        iv. Routine lab tests
2. Dispensarisation after medical treatment - observation of people that were ill, working in condition that is bad for their health. They must be checked one time per year.
    a. For example, people after COVID may have complications so it would be good to observe them. Also, patients with TB, pneumonia, occupational medicine diseases.
3. Dispensarisation of people with chronic diseases with stable condition. They must be checked one time per year.
4. Dispensarisation of people with chronic diseases with serious condition. They must be checked 4 times per year.
5. Dispensarisation of people with chronic diseases with critical condition. They need to have additional care.

Stages of the Dispensary method

1. Active and early searching, discovering and registration of the ill people as well of some healthy people during prophylactic examination (screenings).
2. Active treatment and observation – certain dispensaries are built that cure people with similar diseases. The grouping of the people could be done upon the type of their illness or upon the stage of their disease.
3. Rehabilitation – it starts during the medical treatment and could be physiotherapy, remedial gymnastic, working therapy, staying in a health resort.
4. Active individual and public prophylaxis for the living and working conditions of the dispensarised people. The doctor should observe the condition at home and work.

Who does the dispensarisation?

- GPs
- Medical specialist in outpatient care
- Doctors in inpatient care
- Some specific departments – oncology, pulmonology
- Some specific centers
    - Mental Health Centre
    - Skin and Venereal disease Centre
    - Complex Oncology Centre

Mental Health Centre

Mental health center means a medical establishment where physicians, assisted by other personnel, carry out the following activities:

1. Emergency psychiatry aid.
2. Diagnosis and treatment of persons with mental disorders.

3. Periodical monitoring and consultation of persons with mental disorders and home patronage.
4. Psychotherapy and psycho-social rehabilitation.
5. Psychiatric and psychological expert activity.
6. Clinical testing of medicinal products.
7. Establishment and maintenance of regional information system of persons with mental disorders
8. Promotion, prevention, and improvement of the mental health of the population.
9. Public information in the sphere of the mental health.
10. Research activities in the sphere of mental health.

The medical activity in a mental health center shall be headed by a physician holding an acknowledged specialisation in psychiatry and qualification in health management.

The mental health center shall include the following units and departments:

- reception-diagnostic
- for emergency and mobile psychiatric aid
- for active treatment of persons with severe mental disorders, which may be specialised according to sex, age, disease profile or other features
- rehabilitation and re-socialization, including for labour therapy.

Skin and Venereal disease Centre

Skin and venereal disease center means a medical establishment where physicians, assisted by other personnel, carry out the following activities:

1. Diagnosis, treatment, and rehabilitation of persons with acute and chronic dermatological diseases.
2. Periodical monitoring and consultation of persons with skin and venereal diseases, including life-threatening bullosa dermatological diseases (pemphigus forms)
3. Diagnosis, treatment, and prophylactics of persons with sexually transmissible diseases.
4. Clinical testing of medicinal products
5. Periodical analysis of epidemiological indices for sexually transmissible infections and assessment of the quality and efficiency of the undertaken diagnostic, treatment, prophylactic and rehabilitation activities.
6. Expert activities in the sphere of sexual health and skin and venereal diseases.
7. Promotion, prevention and improvement of the sexual health of the population and of the skin and venereal diseases.
8. Public information regarding the problems of the sexual health and the skin and venereal diseases.
9. Research activities in the sphere of sexual health and skin and venereal diseases.

Other requirements of Skin and venereal disease Centre

- The medical activity in a skin and venereal disease centre shall be headed by a physician holding an acknowledged specialisation in skin and venereal diseases and qualification in health management.
- The skin and venereal disease centre shall include specialised diagnosis and consultation offices and assistance units.
- Up to 10 accommodation places for diagnosis and treatment stay may be opened within the skin and venereal disease centre.
- The structure, activity and internal order of the skin and venereal disease centre shall be set out in regulations.

Complex Oncology Centre

Complex oncology centre means a medical establishment where physicians, assisted by other personnel, carry out the following activities:

1. Active search, diagnosis, and treatment of persons with oncological diseases.
2. Periodical monitoring, consultation and supervision of oncologically diseased and precanceroses
3. Registration and dispenserisation of oncologically diseased and precanceroses.
4. Establishment and maintenance of cancer registry for the relevant territory, of the serviced region and for the needs of the national cancer registry.
5. Promotion and prevention of the oncological diseases.
6. Public information regarding the problems of the oncological diseases.
7. Expert and consultation activities in the sphere of oncology and medical oncology.
8. Research activities in the sphere of oncology.
9. Performance of clinical and therapeutic trial in the sphere of medical oncology.
10. Clinical testing of medicinal products.

11. Realisation of complex educational and specialisation programmes in oncology, medical oncology and x-ray treatment and healthcare.
12. Consultation on the problems of oncology diseases within the serviced region.
13. Prophylactics and screening programmes of the oncology diseases.

The medical activity in a complex oncology centre shall be headed by a physician holding acknowledged specialisation in oncology or medical oncology and qualification in health management.

The Complex Oncology Centre shall have the following structure:

1. Diagnosis and consultation block, including specialised diagnosis and consultation offices, laboratories, and departments without beds in image diagnosis, pathoanatomy and nuclear medicine.
2. Stationary block, including departments corresponding to the primary methods of the complex treatment – medical oncology, ray treatment, oncological surgery.
3. Unit for registration and prophylactic of oncological diseases.
4. A pharmacy for internal purposes.
    a. Accommodation places for final treatment, continuous treatment, rehabilitation, and palliative care may be opened within the complex oncology centre.
    b. The complex oncology centre may provide social services as set out in the Law on the Social Support.

Indicators of Dispensarisation

- **Relative part of early discovered ill people** = (number of these people/number of all new ill people) * 100
- **Relative part of regularly observed ill people** = (number of these people/number of all dispensarisated people)*100
- **Relative part of regularly treated people** = (number of these people/ number of all dispensarisated people) *100
- **Timeliness of dispensary method** = (number of dispensarisated for the first-time people/number of discovered for the first-time ill people) *100
- **Relative part of people with improvement** = (number of these people/number of all dispensarisated people) *100
- **Relative part of people without improvement** = (number of these people/number of all dispensarisated people) *100
- **Relative part of people with change for worse** = (number of these people/number of all dispensarisated people)*100
- **Relative part of people who died** = (number of these people/number of all dispensarisated people)*100
- **Medium temporary incapacity for work** = (general number of sick leave days/number of all dispensarisated people) *100

32. Hospital care. Functions, structure, and organisation. Indicators. Hospitalisation: reasons and types of hospitalisations. Rights and obligations of hospitalised patients. [!] Indicators.

Definition of Hospital Care: it is one of the branches of medical establishment in which doctors with the assistance of other specialists and auxiliary personnel carry out all or some of the following activities:

1. Diagnostics and treatment of diseases when the purpose of the treatment cannot be achieved in the conditions of non-stationary care.
2. Natal care.
3. Rehabilitation.
4. Diagnostics and consultations requested by a doctor or a dental doctor or by other medical establishments.
5. Transplantation of organs, tissues, and cells.
6. Taking, storing, supply of blood and blood components, transfusion supervision.
7. Medical cosmetic services.
8. Clinical tests of medicines and medical equipment according to the legislation acting in the country.
9. Educational and scientific activity.

Hospital care - functions

- Clinical help – diagnostic, treatment, rehabilitation
- Consultative help
- Health promotion
- Prophylaxis
- Social
- Qualification
- Economic

Hospital care - structure

The medical treatment facility for hospital care shall consist of:

- Clinic and/or departments with beds
- Consulting rooms, medical diagnostic and medical technical laboratories, departments without beds
- Hospital pharmacy
- Units for administrative, economic and servicing activities.

Hospital care – organisation (types of medical establishments)

- **According to treatment duration:**
  - 1) Hospital for active treatment - Treated in the hospital for active treatment shall be patients with acute diseases, traumas, aggravated chronic diseases, conditions requiring operative treatment in hospital conditions, as well as natal care and medical cosmetic services.
  - 2) Hospital for further treatment and continuous treatment - shall admit persons needing long recovery of health and persons with chronic diseases requiring care and sustenance of satisfactory corporal and psychological condition.
  - 3) Rehabilitation hospital - shall admit persons needing physical therapy, motor, and psychic rehabilitation, balneological, climatological and thalassotherapy
  - 4) Hospital for final treatment, continuous treatment, and rehabilitation – mix of two and three
- **According to profile:**
  - Multi-profiled → means a medical establishment containing departments and clinics for at least two medical specialities.
  - Specialized → is a medical establishment containing departments or clinics for one medical or dental speciality. In the specialised hospital may be opened also structures of prevailing surgery, therapeutic, clinic and diagnostic or other direction and for anaesthesiology and intense treatment, providing for the performance in the speciality, in which the hospital has specialised.
- **Determined by Council Ministers, University Hospitals are for:**
  - Clinical training of students and doctors in medicine, stomatology

- Pharmacy
- Clinical training for health care and medical colleges
- Post graduate training

- **According to location (area served):**
  - National hospitals (university hospitals, national centres) - National hospitals deliver highly specialized care (usually tertiary care) for cases that cannot be treated at local or district level.
  - District hospitals - District hospitals are located in the district centres, include almost all medical specialties and ensure services for cases that cannot be solved at the local level. They are required to have 24-hour emergency wards, clinical pathology and transfusion haematology wards and units for forensic medicine.
  - Local (municipality) hospitals. Local hospitals are multi-profile or specialized and are located in smaller towns, usually consisting of several wards in the basic specialties (paediatrics, obstetrics and gynaecology, internal medicine, neurology, general surgery, and physiotherapy).
- **According to type of ownership:**
  - State owned
  - Private hospitals are enterprises (including Ltd, PLC, etc.).
  - Some university hospitals and other national hospitals are still owned by the state
  - District hospitals are owned by the state (51%) and the municipalities of the district (49%)
  - Local (municipal) hospitals are owned entirely by the municipalities

Changes in ownership

- This change in ownership meant a reconstitution and registration of all health care establishments in accordance with the requirements of Commercial Law.
- Ownership rights of state-owned hospitals are exercised by the Minister of Health, and of municipal hospitals, by the respective municipal council.
- Hospitals under other administrations (the ministries of defence, internal affairs, transport, and justice) are entirely state-owned and the rights are exercised by the respective minister. Thus, hospital care is currently provided by public and private health care establishments.

The Management of Hospitals

- Is organized by the owner of the respective unit, depending on the form of registration (as Ltd, PLC, etc.).
- Hospitals are led by a manager with executive power.
- Managerial positions in public hospitals are obtained through a competitive selection process organized by the respective owners (the Ministry of Health, other ministries, or the municipal councils).
- Hospital managers sign a three-year managerial contract with the hospital owner and are usually physicians with additional qualification in health care management.
- All hospitals must have a nursing manager (a head nurse).
- Other managerial positions (medical director, financing director, administrative director, heads of departments and wards) depend on the structure of each hospital and are recruited for by competitions organized by the hospital manager.
- Collective organisations with advisory functions (Medical Council, Nursing Council, and commissions) are typically involved in the management.

Clinical pathways

- Under the health law, insured patients are entitled to hospital care pathways.
- When treatment is planned, patients choose the hospital for their treatment. It is enough to have referral from GP, and hospitals to have free capacity.
- If treatment is urgent, patients are taken to the nearest multi-profile hospital or in existing regional hospital with 24 hours of service.
- Hospitals receive funding mostly through case-based payments (clinical pathways).

Indicators of Hospital Care ???

1. **Quantitative indicators** – they describe how the hospital beds are utilized.
   a. Data necessary to calculate statistical indicators of hospital activities
      i. Total number of beds
      ii. Total number of patients passed through the facility (calculated as sum of patients admitted and discharged divided by 2, at particular clinic from other clinics also are taken into account.)

iii. Total number of patient days.

b. **Average length of stay** is the total number of patient days per year counting the day of admission but not the day of discharge, divided by the total number of patients who passed through the facility.
c. **Bed turnover rate** is total number of patients who passed through the facility divided by the total number of beds.
d. **Average bed occupancy rate** is total number of patient days divided by the number of beds.

2. **Qualitative indicators** – such as hospital case-fatality rate, post-operative complications, etc.
   a. **Case-fatality rate** is calculated as the number of deaths in a hospital divided by the number of admitted patients multiplied by 100.
   b. **Post-operative complications** - basic quality indicator for measuring outcomes at surgical units.
   c. Accessibility of hospital care is assessed by no. of beds per population (1000):
      i. Low = under 4 beds per 1000
      ii. Average = 4-7 beds per 1000
      iii. High = 7-10 beds per 1000
      iv. Very high = over 10 beds per 1000

Hospitalisation

Definition of Hospitalisation: the act of taking someone to hospital and keeping them there for treatment when the purpose of the treatment cannot be achieved in the conditions of non-stationary care.

Hospitalisation - reasons

- Medical
- Social
- Medical-social *(e.g., child on street, no money during winter for food or heating)*

Hospitalisation - types of hospitalisations

- Emergency
- Planning *(e.g., doctor sends patient with a specific document to hospitalise them, referral. Maybe the hospital is full at the time, so they have a planned referral for another time, not emergent cases)*

Rights and obligations of hospitalised patients

- Comply with applicable laws and regulations of the Hospital.
- Hand the clothes and shoes to the hospital store at admission to the hospital.
- Comply with the daily schedule of the department where the patient is hospitalized.
- Observe recommendations of the physician, nurses, and other medical staff of the hospital.
- Not taking any medications nor undergoing any medical procedures without the prescription from attending physician or doctor on duty. Attending physician as well as the head physician of the department are responsible for the regular treatment process of the patients in a department.
- Keep a diet determined by patient's attending physician and not serving food and beverages brought from the outside to other patients.
- Observe the hygiene/personal cleanliness in accordance with the degree of patient's dexterity.
- Stay in designated areas at the time of the rounds, medical treatments and dressing and at mealtimes.
- Visiting hours – 2 times per day
- The patient can stay outside the hospital only with the permission of the attending physician or the doctor on duty.
- Respect the rights of other patients, in particular the right to privacy and peace indispensable during treatment and rehabilitation.
- Adhere to the absolute prohibition of smoking, drinking alcohol and using intoxicants in the hospital area, where non-compliance can result in patient's discharge from the hospital, provided that there is no risk that the discontinuance of the health services may result in direct threat to patient's life or health.

Criteria of organization of a patient in hospital

- Sex
  - Examples: ob/gyn department
  - Exceptions: anaesthesiology
- Severity of diseases

- Examples: ICU, NICU vs normal ward
- Infectious diseases/non-infectious diseases
  - Examples: TB

Indicators related to Hospitalisation ***???***

1. **Average length of stay** is the total number of patient days per year counting the day of admission but not the day of discharge, divided by the total number of patients who passed through the facility.

2. **Average bed occupancy rate** is total number of patient days divided by the number of beds.

3. **Bed turnover rate** is total number of patients who passed through the facility divided by the total number of beds.

4. **Case-fatality rate** is calculated as the number of deaths in a hospital divided by the number of admitted patients multiplied by 100.

33. Medico-social issues of women and maternal care. Maternal Health Programme of National Health Insurance Fund. [!]

Maternal health refers to the health of women during pregnancy, childbirth, and the postpartum period. Perinatal health refers to health from 22 completed weeks of gestation until 7 completed days after birth. New-born health refers to babies' first month of life. A healthy start during the perinatal period influences infancy, childhood, and adulthood.

Medico-social issues of women and maternal care

Laws in Bulgaria

Constitution of the Republic of Bulgaria

- Article 47.
  - (2) Mothers shall be the object of special protection on the part of the State and shall be guaranteed prenatal and postnatal leave, free obstetric care, alleviated working conditions and other social assistance.

Labour Code of Bulgaria

Chapter 15. SPECIAL PROTECTION FOR SOME CATEGORIES OF WORKERS AND EMPLOYEES

- Section II. SPECIAL PROTECTION FOR WOMEN
  - Protecting Pregnant Women and Nursing Women
  - Women's Rooms
  - Job Reassignment for Pregnant Women and Nursing Mothers
  - Commissioning of Pregnant Women and Mothers
  - Work to be done at Home

Health Act

- Article 2.
  - The preservation of the health of the citizens as a state of a complete physical, psychic, and social welfare is a national priority and shall be guaranteed by the state through applying the following principles:
    - 1. Equality in using health services
    - 2. Providing accessible and qualitative health care, with priority for children, pregnant women, and mothers of children up to 1 year
    - 3. Priority of the health promotion and the integrated prophylactics of diseases
    - 4. Prevention and reduction of the risk for the health of the citizens from the unfavourable effect of the factors of the living environment
    - 5. Special health protection of children, pregnant women, and mothers of children up to one year of age and disabled and mentally disordered persons
    - 6. State participation in financing activities aimed at preservation of the health of the citizens.
- Article 127.
  - For ensuring risk free motherhood each woman shall have right to access to health activities, directed to ensuring optimal health status of the woman and the foetus from occurrence of the pregnancy till rounding of 42 days age of the child.
    - 1. Promotion, directed to preservation of the health of the woman and the foetus
    - 2. Prophylactics of the danger from abortion and premature birth
    - 3. Training in feeding and care of the newly born
    - 4. Active medical observation of the pregnancy, implemented on dispensary principle by the medical establishments for primary and specialised off hospital care
    - 5. The prenatal diagnostics and prophylactics of genetic and other diseases under conditions and by order, determined with ordinance of the minister of health
    - 6. Ensuring of optimal living environment for the women in childbed and the newly born
    - 7. Dispensary observation and health cares for the woman in childbed and the child
    - 8. Free access of the pregnant woman or the woman in childbed to medical establishments for specialised off hospital care

- 9. Free access of the pregnant woman to medical establishments for specialised off hospital and hospital care upon statuses, threatening the pregnancy
- 10. Right to choice for the pregnant woman of medical establishment for hospital care for childbirth.

Nursing care for health for uninsured women

Ministry of health (state budget) provides 1 prophylactic exam during the pregnancy for each uninsured woman.

The prophylactic exam includes:

- Consultation = medical history, risk factors assessment, calculation of the expected date of delivery, blood pressure measurement, anthropometry, gynaecological exam, ultrasound, child heart tones (if applicable)
- Lab tests = blood count, glucose, urine test, syphilis test, HbSAg test

Free medical services for childbirth (reimbursed by the state budget).

Main principles

- Family planning = a human right to decide if/when to have children
  - Ideal, desired, and planned number of children
  - Time intervals before/between births
- Role of medical professionals = who, when, how
  - Health promotion, information, and education for sexual/reproductive issues
  - Target groups
  - Responsibilities
- Best age for childbirth = between 20 and 30 years

Maternal Health Programme of National Health Insurance Fund

The Maternal Health Programme of the NHIF regulates the activities of the general practitioner for the follow-up normal pregnancies as well activities of the obstetrics and gynaecology specialist for the follow-up normal pregnancy and pregnancy at risk. This program covers the minimum required for pregnancy monitoring.

Pregnancy monitoring by a specialist in obstetrics and gynaecology is carried out with a "Medical referral" issued by the general practitioner (GP), once for the duration of the pregnancy and the first 42 days after delivery.

- Women have the right to choose who to follow pregnancy through a GP or obstetrician
  - Option A: Follow up by a GP
  - Option B: Gynaecologist
- Initial examination and tests. If necessary, the father of the baby has been tested
- In case of a woman over 35 years OR partner is older than 50 years OR having a child with congenital anomalies of the previous pregnancy → genetic counselling.
- Every month → visit the doctor
- In the last 45 days of the pregnancy → 2+ times

The First Visit for the pregnant women

- During the first visit, consultative review with obstetrician, which includes:
  - Ultrasound
  - Preventive PAP test
  - Taking vaginal fluid for microbiological examination.

- During the first visit, the doctor is entitled to the following medical diagnostic activities:
  - Determination of blood group and Rh factor
  - Screening for syphilis
  - Screening for hepatitis B (HbSAg)
  - Testing for HIV (only with consent)
  - Hemoglobin, erythrocytes, leukocytes, Ht, MSV, MCH

- ESR
- Urine: sediment
- A free check-up by a dentist

Consultations and ultrasonography of pregnant women
2 free ultrasound examinations by a specialist obstetrician

- Once in the first trimester of pregnancy
- Once at the 5th month of pregnancy

During the consultation the GP determines the probable date of birth and monitors:

- Weight of the pregnant woman
- Blood pressure
- Abdomen
- Movements and fetal heart rate patterns
- Position of the baby

Option B – Gynaecologist

- Pregnancy with complications
- Poor general health condition
- Long-time infertility
- Miscarriage
- Stillbirth age of under 20 or over 35 years
- Multiple pregnancy
- Previous birth by surgery
- Blood type incompatibility with the biological father of the child
- A family history of diabetes

Pregnancy at risk

- Age over 35:
  - Two additional ultrasound examinations
  - Serum screening for:
    - Alpha-fetoprotein
    - Free Beta hCG to assess the risk of Down syndrome and neural tube defects.
- Age under 20 years:
  - Test for Chlamydia.
- In case of blood type incompatibility with biological father → blood test for antibodies against own Erys and an additional ultrasound.

Women whose pregnancy is not risky are entitled to 12 health insurance-paid check-ups:

- once per month in the first 7 months of pregnancy
- two in the last two months and two after the birth

Indications for hospitalisation of pregnant women

- Bleeding and pain
- Swelling of face and hands
- Vomiting - five, 10 or more times a day
- Bleeding and pain and low blood pressure
- Premature ruptured membranes
- Delayed pregnancy
- Narrow pelvis
- Difficult childbirth per vias naturalis
- Previous caesarean birth

- Breech fetus
- Multiple pregnancy
- Long-term infertility
- Other diseases - diabetes, cardiovascular, neurological, ocular and others.

Primary prevention for pregnant women

Folic Acid

- All women who are planning pregnancy are advised to take 400 micrograms (0.4 mg) of folic acid (vit. B9) daily for at least 2 months before the conception
- Vit. B9 reduces the risk of birth defects in the baby up to 70% by contributing to the proper development of the spinal cord, the brain, the formation of DNA and the proper development of the cells
- At-risk pregnancies - 4 mg/day
- Prevents neural tube defects that are serious birth defects of the spine (e.g., spina bifida) and he brain (e.g., anencephaly) that occur during early pregnancy, often before a woman knows she is pregnant
    - 50-70% of these defects can be prevented if a woman consumes sufficient folic acid daily before conception and throughout the first trimester of her pregnancy.

Other forms of primary prevention:

- Proper diet
- Genetic counselling
- Preconception education
- Smoking cessation
- Nutritional supplements (pre-natal vitamins)

Prenatal screening of pregnant women

Maternal serum screening

- 11-13 weeks (early)
    - Ultrasound
    - Biochemical screening (free beta-HCG and RARP-A)
- 15-20 weeks (late)
    - Ultrasound
- Measures the amount of free beta-human chorionic gonadotropin (93-hCG) and APP-A in serum and ultrasound measurement of specific markers o Using a specialized software to estimate the risk for:
    - Trisomy 21 (Down's syndrome)
    - Trisomy 13 (Patau)
    - Trisomy 18 (Edwards)
    - Triploidy
    - Monosomy X (45, X) (Turner)
- Risk:
    - Risk >1:100 → Amniocentesis in 16-20 g.w **or** chorionic villus sampling (CVS) in 11-13 g.w
    - Risk between 1:100 and 1:1000 → Repeat ultrasound diagnostics and screening in 15-19 g.w
    - Risk <1:1000 → regular follow up
- Chorionic biopsy after 11 g.w
- Amniocentesis between 16-20 g.w

Non-invasive prenatal testing (NIPT)

After 9 g.w for trisomies 21, 18, and 13 in the average-risk or general population.

Social protection of pregnant women

- 410 days → paid 90% of the average daily insurable income for the last 24 months before pregnancy
    - 135 days with 3 notes for sick leave:
        - 45 days before the term → from the GP / OG
        - 42 days after birth → from the OG at the hospital

        - 48 days → from the child's GP
    - 275 days - paid by the National Insurance Institute (NII)
- Optional - cash compensation for raising a child until the age of 2 years (minimal salary)
- Single compensation for the birth of a child – 250 levs

34. Medico-social issues of women and maternal care. Child Health Programme of National Health Insurance Fund [!]

Medico-social issues of women and maternal care

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  - Health promotion, information, and education for sexual/reproductive issues
  - Target groups
  - Responsibilities
- Best age for childbirth = between 20 and 30 years

Child Health Programme of National Health Insurance Fund

Child Healthcare

National Health Insurance Fund (NHIF) has developed a program for children from age 0 to 18 called "Child health". This program is implemented by the child's GP or paediatrician.

It defines all preventive activities (examinations, tests, immunisations) that are required to monitor the growth and development of the child.

The program is aimed at both healthy children and children with increased medical and social risk as well as at children with chronic diseases.

At birth:

- In the hospital all necessary medical care requires performing examinations, tests, treatments.
- After first 12 hours → the infant should be vaccinated for hepatitis B
- 24 hours after birth → vaccine for tuberculosis.
- Children born outside hospital → mandatory vaccination for tetanus.

After discharge:

- Home visit by the GP → up to 7 days after birth and after 30th day

New-born screening (NBS)

NBS is considered to be the longest running and most successful population screening activity worldwide. Also know has heel prick test.

All new-borns in the OG ward in Bulgaria (2-5 days after birth) for:

- Phenylketonuria
- Congenital hypothyroidism
- Congenital adrenal hyperplasia

Procedure for carrying out the examination is as follows: during the first days of the baby's life, usually on the 3rd to 5th day, a few drops of blood are taken for a sample on a special filter form (Guthrie card). It is immediately sent to the National Genetic Laboratory.

Wilson JMG, Jungner JJ. Principles and practice of screening for disease. Public Health Paper 34. Geneva: World Health Organization; 1968
Opportunity to increase the number of studied diseases through new methods (MS / MS)
Ethical and economic problems

Future → Whole-genome sequencing (WGS)

Prevention of congenital diseases

Primary prevention

- Before conception
  - Health information
  - Sexual and reproductive education
  - Folic acid (supplementation or fortification)
  - Genetic counselling
- After conception
  - Health information and education for avoiding known risk factors during pregnancy

Secondary prevention

- Before birth
  - Regular prophylactic exams and tests
  - Prenatal screening of the pregnant woman
  - Prenatal selective screening in at-risk pregnancies (amniocentesis, CVS)
- After birth
  - New-born screening
  - Selective screening of new-borns
  - Regular prophylactic exams and test

Age periods and prevention in each period

0-1 years (infants)

- ***Risk factors:*** Infections, malnutrition, dehydration, poor socio-living conditions
- ***Primary prevention***
  - ***Non-specific:*** Healthy eating, breastfeeding, parenting advice (clothing, position)
  - ***Specific:*** Immunization for hepatitis B, diphtheria, tetanus, pertussis, polio, BCG
- ***Secondary prevention:***
  - Examinations every month:
    - Measurement of height and weight
    - Assessment of mental development
    - Measurement of head and chest circumference
  - Hip luxation exam (1 and 4 month)
  - General vision and hearing evaluation (6 month)
  - 3 times laboratory tests (at birth, 6m and 12m)

1-3 years (toddler)

- ***Risk factors:*** Infections, trauma, late passage, urinary infections.
- ***Primary prevention***
  - ***Non-specific:*** Healthy eating, breastfeeding, hygiene recommendations
  - ***Specific:*** Vaccines for measles mumps rubella polio, diphtheria, tetanus, pertussis
- ***Secondary prevention*** = Check-ups every 4 months

3-7 years (pre-school)

- ***Risk factors:*** Risk of trauma, poisoning, infection, parasitosis.
- ***Primary prevention***
  - ***Non-specific:*** Health information, health education, socialization, hygiene and primary education habits
  - ***Specific:*** Diphtheria, Tetanus, Pertussis, Polio, BCG vaccinations
- ***Secondary prevention:***
  - Health check - twice a year (at every 6 months)
  - Measurement of height, weight, and chest circumference - twice a year
  - (every 6 months).
  - Assessment of mental development - once a year.
  - Physical development assessment - once a year
  - Parasite screening - once a year
  - Lab - blood count and BH at 3yrs.

7-14 years (school)

- ***Risk factors:*** educational needs, risk of visual abnormalities, spinal deformation, Infections, reduced physical activity.
- ***Primary prevention***
  - ***Non-specific:*** Health information, physical activity promotion, work posture advice. Sex education.
  - ***Specific:*** Measles, Mumps, Rubella, Diphtheria, Tetanus, Pertussis, Polio, BCG vaccinations
- ***Secondary prevention***:
  - Measurement of height, weight and chest circumference - one time annually
  - Blood pressure measurement - once a year
  - Physical development assessment - once a year
  - Vision test for visual acuity and colour perception - once annually
  - Examination for deviations in musculoskeletal development system - once a year

14-18 years (teens)

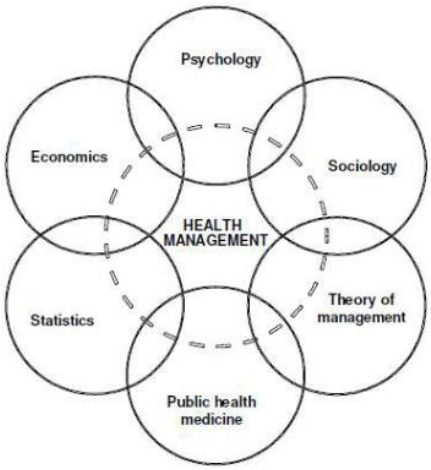
- ***Risk factors:*** risk of sexually transmitted infections, health information, addictions (alcohol, drugs)
- ***Primary prevention***
  - ***Non-specific:*** Health information, physical activity promotion, work posture advice. Sex education.
  - ***Specific:*** Measles, Mumps, Rubella, Diphtheria, Tetanus, Pertussis, Polio, BCG vaccinations
- ***Secondary prevention*:**
  - Measurement of height, weight, and chest circumference - one time annually
  - Blood pressure measurement - once a year
  - Physical development assessment - once a year
  - Vision test for visual acuity and colour perception - once annually
  - Examination for deviations in musculoskeletal development system - once a year

35. Health management – basic principles. Management of human resources.

Health management – basic principles

Definition of Health Management: Regulation of a system by decreasing its entropy (chaos, uncertainty).
A methodical and systematic control and improvement of business processes to achieve predetermined objectives.

Integrative nature of Health Management



Healthcare is complex to manage due to many stakeholders. These include the country/government, patients (want cheap/free treatment), medical professionals (want to be paid well), pharmaceutical industries (want to make most profit). So, there are many disciplines involved and good health management includes all of these.

Health Manager

The Health manager is officially given the power to impact purposefully on the health organisation by him. The Health Manager guides the activities of the Health Personnel.

Responsibilities of Health Manager

- Responsible for adequate utilisation of the resources of the health care organisation
- Responsible for the results of the activities of the organisation
- Is competent and trained to direct the health resources (organisational, personal, and financial).

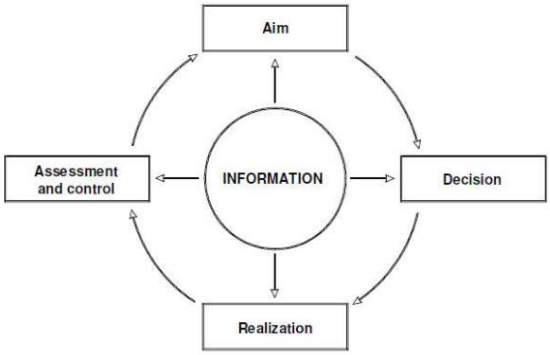
Levels of Management

1. High management = political level → Ministry Of Health
2. Coordinating management = middle level → Regional Health Care Centres (offices)
3. Operating management = management of the "straight line" → Director of a Hospital, Department etc.

The Managing Cycle of Health Management

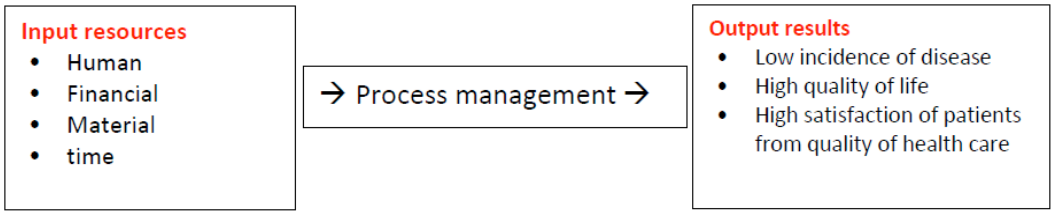
- Determine the aims *(e.g., improve outcome of patients with cardiac arrest)*
- Take decisions
- Planning
- Organisation and coordination
- Management, control, assessment

Information



Vital for aim, decision, assessment control and monitoring costs including resources such as time, money, people, and material.

Resources and results
To solve the task, we have given resources as input, this must be transformed by process of management in order to obtain a desired result (output):



Management of human resources

The process of effective utilization of the personnel in order to realize the aims of an organization at one hand and satisfaction of the needs and expectations of people at the other.

Target groups of the medical HR management:

- Personnel
- Patients

Main aspects to consider:

- Planning the personnel - attraction, selection & assessment
- Providing high quality occupational health & security
- Continuous education & training
- Motivation & stimulation of personnel

Extra

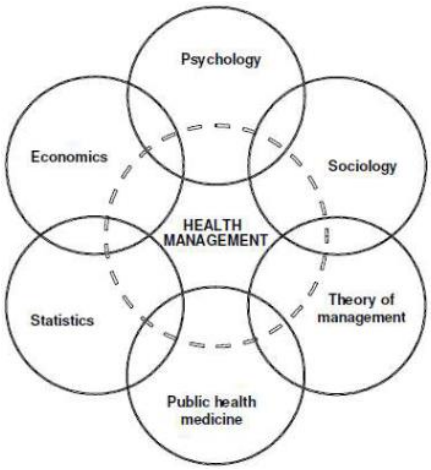
- **What are the basic principles of health management?**
  - *Health management supposes the existence of MANAGING and MANAGED systems, e.g., SUBJECT and OBJECT of the management,*
  - *The managing system is the country (state) with its legislative power (parliament).*
  - *Managed system type "A" is a state, public, monopolistic health care (e.g., UK, ex- communist countries from Eastern Europe. etc)*
  - *Managed system type "B" is a public health care that is pluralistic and determined by equal in rights state, health insured, charity, private and other elements. It includes aspects of psychology, sociology, economics, theory of management, public health medicine, and statistics in an integrative nature*

36. Health management. Governance. Management of financial resources. Management of the organisational change.

Health management – basic principles

Definition of Health Management: Regulation of a system by decreasing its entropy (chaos, uncertainty).
A methodical and systematic control and improvement of business processes to achieve predetermined objectives.

Integrative nature of Health Management



Healthcare is complex to manage due to many stakeholders. These include the country/government, patients (want cheap/free treatment), medical professionals (want to be paid well), pharmaceutical industries (want to make most profit). So, there are many disciplines involved and good health management includes all of these.

Health Manager

The Health manager is officially given the power to impact purposefully on the health organisation by him. The Health Manager guides the activities of the Health Personnel.

Responsibilities of Health Manager

- Responsible for adequate utilisation of the resources of the health care organisation
- Responsible for the results of the activities of the organisation
- Is competent and trained to direct the health resources (organisational, personal, and financial).

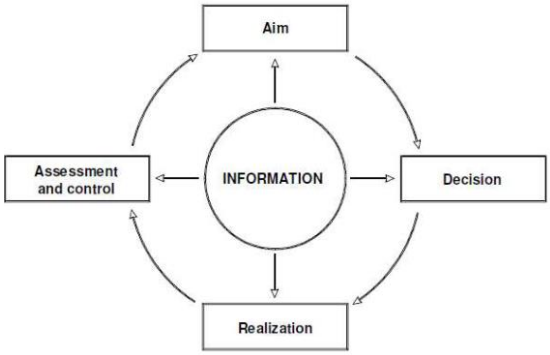
Levels of Management

1. High management = political level → Ministry Of Health
2. Coordinating management = middle level → Regional Health Care Centres (offices)
3. Operating management = management of the "straight line" → Director of a Hospital, Department etc.

The Managing Cycle of Health Management

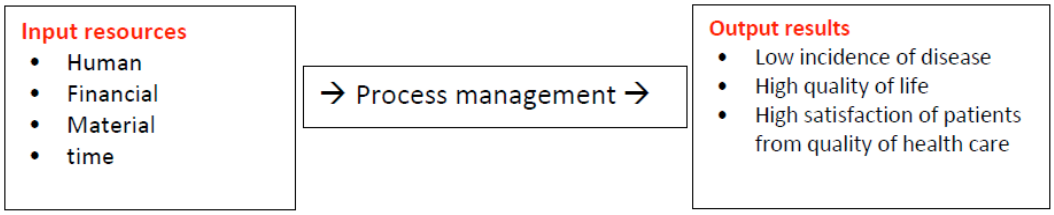
- Determine the aims *(e.g., improve outcome of patients with cardiac arrest)*
- Take decisions
- Planning
- Organisation and coordination
- Management, control, assessment

Information



Vital for aim, decision, assessment control and monitoring costs including resources such as time, money, people, and material.

Resources and results
To solve the task, we have given resources as input, this must be transformed by process of management in order to obtain a desired result (output):



Governance

The style of management reflects the typical behaviour and attitude of the manager towards his personnel during the process of taking decisions:

- Autocratic style → The manager takes a decision and announces it like an incontestable fact.
- Advisory style → The manager presents his opinion and expects comments and different points of view from his subordinates in order to take a better decision.
- Concerned style → The manager presents a project for a decision and asks for suggestions for the final decision.
- Democratic style → The manager gives an outline of the task and invites the working groups to reason their decisions.
- Self-regulating style → The manager allows his sub-ordinates to act freely in order to achieve a common aim.

The Leader
Is the central person in the informal structure. He is not appointed and doesn't have an official position in power. His managerial functions are based off mutual attraction, agreement, and consensus with the members of the informal structure.

Team Members
The instrument that will assure the success of the management. The manager must select members for his team with the necessary characteristics and styles of behaviour.

- Leader
  - Stable, dominating, consistent, purposeful.
  - Coordinates the efforts of the other team members.
  - Can arrange the tasks according to their priority.
- Initiator - constructor
  - Restless, vigorous, dominating.
  - Guides the execution of particular tasks.
- Innovator
  - Dominating, intelligent, generator of ideas.
  - He has the greatest power of imagination and intelligence among all team members.
- Appraiser (controller)
  - Intelligent, stable, "cold" observer & interpreter of the reality.
  - Objective and unprejudiced.
- Company worker
  - Stable and can be under control.
  - Works systematically and methodically.
  - The organizer of the practical realization of the taken decisions.
- Resources discoverer
  - He is the team member, who becomes most quickly pleasant and attractive during business meetings.
  - Works mainly outside the team by gathering useful information about the necessary resources – financial, material, human.
- Team worker
  - Plays the role of internal social communicator in the team.
  - Tries to maintain the balance between the formal and informal structure of the organization.
- Performer "to the end"
  - Targets the details of each task and their final completion.

Team evolution – stages of team growth

- Undeveloped team
  - Close relationships are avoided. Unclear aims.
  - The leader takes most of the decisions.
- Experimenting team
  - Problems are discussed more freely.
  - Personal opinion is considered by the members.
  - The team becomes temporarily self-analytical.
- Self-controlling team
  - Personal relations are built on the basis of collaboration.
  - Tasks are clear + aims are agreed and test procedures for a teamwork are experimented.
- Mature team
  - Personal relations are open.
  - A wide spectrum of alternatives is discussed.
  - The team members are flexible + can take the responsibility of the team.

Management of financial resources

Management of the organisational change

Organisational iceberg

- Formal structure
  - Is mandatory
  - It's built in a top-down direction
  - Leading position is the manager who is given the power
- Informal structure
  - Appears spontaneously on the basis of the psycho-social demands of people.
  - It cannot be "created" and is not mandatory
  - It is built in a bottom-up direction
  - It is characterized by a strong emotional component, providing mutual attraction or repulsion of the members

Types of organisation change

- Partial
- Fundamental:
  - Change in the mission (general aim)
  - Change in the methods, means and structure

Barriers of the change

- According to the source:
  - Inner resistance = It is determined by elements of the organization – structure, qualification of personnel, motivation, style of management
  - Outer resistance = It is determined by the environment outside the organization political, economic, legislative, cultural, and other factors
- According to the reasons
  - Individual resistance
    - The most important barrier of changes, because of:
      - Acquired habits
      - Conflict of interests
      - Fear from losing freedom or power
      - Possible social losses
      - Possible economic losses
      - Fear from the unknown
      - No information about the reasons for the change.
  - Organizational resistance
    - Due to the pursuit of the organization to keep the balance. The main reasons are:
      - Striving to maintain stability

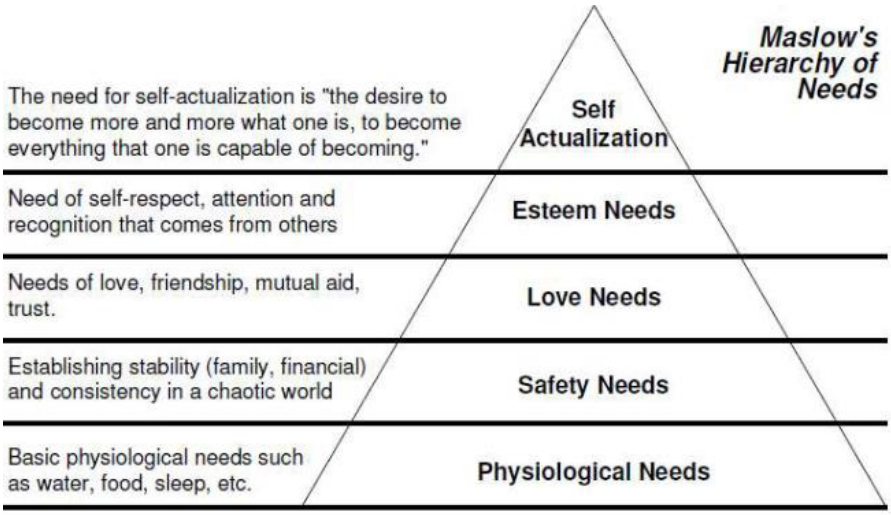
- Bureaucracy
- Already invested resources
- Fear from losing power

Approaches to overcome the barriers of change

- Partnership → Involving more persons in the planning and realization of the changes.
- Education → Usage of dedicated educational programs for augmentation of the management culture and knowledge inside the organization.
- External influence → The intervention of a factor outside the organization (politician, journalist, expert) may naturally reduce the resistance toward the forthcoming change.
- Compulsion → Should be used carefully since may result in more negative attitude and reaction to the changes.
- Stimuli → Mandatory for every change. The most important issue is justice of the way of giving and amount of the rewards.
- Gradualness → Sharp and fast changes always cause resistance, in contrast to the gradual changes "step by step", that are accepted more naturally.

Extra

- **Motivation**
  - Effective HR management requires the manager is aware in each moment not only how and what his sub-ordinates work, but also what sense and satisfaction they get from their labour.
  - Motivation is a result of the needs of people and is characterizes by a certain level of autonomy



37. Stages of biomedical research. Research plan and programme. Data collection and information processing.

3 Stages of biomedical research

1. Planning and organization
2. Conduction and investigation
3. Data processing and analyses of results

Research programme

- Aim of the study → The aim of the investigation is trying to summarize and clearly formulate the research hypothesis.
  - **General idea of hypothesis testing involves:**
    - Making an initial assumption
    - Collecting evidence (data)
    - Based on the available evidence (data), deciding whether to reject or not reject the initial assumption.
  - In the practice of statistics, **we make our initial assumption when we state our two competing hypotheses:**
    - the null hypothesis (H_0)
      - The null hypothesis is usually stated as the absence of a difference or an effect.
      - The null hypothesis says there is no effect.
      - The null hypothesis is rejected if the significance test shows the data are inconsistent with the null hypothesis.
    - the alternative hypothesis (H_A)
      - It is usually the complement of the null hypothesis.
      - If, for example, the null hypothesis says two population means are equal, the alternative says the means are unequal
  - In statistics, we always assume the null hypothesis is true. That is, the null hypothesis is always our initial assumption.
- Object → Object of the investigation is the event, that is going to be studied.
  - **Population** includes all objects of interest whereas sample is only a portion of the population. Parameters are associated with populations and statistics with samples. We compute statistics, and use them to estimate
  - parameters.
    - **Descriptive Statistics** → The procedure used to organize and summarize masses of data
    - **Inferential Statistics** → The methods used to find out something about a population, based on a sample.
  - **Sampling**
    - **Types of sampling**
      - Random = Each element in the population has an equal chance of occuring.
      - Systematic = The list of elements is "counted off". This is similar to lining everyone up and numbering off "1,2,3,4; 1,2,3,4; etc". When done numbering, all people numbered 4 would be used.
      - Convenience = readily available data is used. That is, the first people the surveyor runs into.
      - Cluster = accomplished by dividing the population into groups (clusters), usually geographically. The clusters are randomly selected, and each element in the selected clusters are used.
      - Stratified = divides the population into groups called strata. However, this time it is by some characteristic, not geographically.
    - **Properties of a good sample**
      - Random selection
      - Representativeness by structure
      - Representativeness by number of cases
      - Law of Large Numbers = Bigger sample size, smaller margin of error.
    - **The sample size for any study depends on the:**
      - Acceptable level of confidence
      - Power of the study
      - Expected effect size

- Underlying event rate in the population
- Standard deviation in the population

- Units of observation
  - Logical unit – each studied case
  - Technical unit – the environment, where the logical
- Indices of observation → not too many, but important; measurable; additive and self-controlling.
  - Factorial
  - Resultative
- Place
- Time
  - Single = events are studied in a single moment of time, the so called "critical moment".
  - Continuous = used to characterize a long-term tendency of the events
- Statistical analyses
  - **Choice of a statistical test depends on:**
    - Level of measurement for the dependent and independent variables
      - Four levels of measurement: Nominal, Ordinal, Interval, and Ratio. These go from lowest level to highest level.
        - Nominal is the lowest level. Only names are meaningful here. e.g., genotype
        - Ordinal adds an order to the names. e.g., pain score from 1 to 10
        - Interval adds meaningful differences. e.g., temperature in C
        - Ratio adds a zero so that ratios are meaningful. e.g., height
    - Number of groups or dependent measures
    - Number of units of observation
    - Type of distribution
    - The population parameter of interest (mean, variance, differences between means and/or variances)
  - **Statistical significance**
    - The statistical significance (p-value) of a result is an estimated measure of the degree to which it is "true".
    - P-values are the probability of obtaining an effect at least as extreme as the one in your sample data, assuming the truth of the null hypothesis.
- Methodology

Research plan

1. Definition of the team, responsible for the study and preliminary training.
2. Administration and management of the study.

Data collection and Information processing

- Check data and correct
- Data coding (MS Excel, IBM SPSS® Statistics)
- Data aggregation
  - According to the data usage
    - Primary - get the data yourself
    - Secondary - get data from library or internet
  - According to the number of indices
    - Simple
    - Complex
- Describe data (mean, media, SD, SEM, range) and summarise it
  - You become familiar with the data and the characteristics of the sample that you are studying
  - You can also identify problems with data collection or errors in the data (data management issues)
  - Range checks for illogical values
  - Visual ways = tables, bar charts, histograms, box plots
- Compare data (look for difference or association, perform parametric or non-parametric tests)
- Modelling and forecasting (regression analysis, survival analysis)

38. Descriptive statistics. Measure of central tendency. Confidence interval for population mean.

Descriptive statistics

We compute statistics and use them to estimate parameters. Computation is the first part of the statistical analysis i.e., Descriptive statistics.

Definition of Descriptive statistics: is used to organise and summarise masses of data, and reporting measures (observations).

Descriptive Statistics - Organizing data

- Tables
  - **Frequency distributions** (records how often data occurs) → classes of values
    - This is a report in the form of a table of the number of times each score of a variable occurred.
    - The categories of the frequency distribution must be stated in a way that permits each case to be counted in one and only one category. Categories must not overlap (they should be "mutually exclusive")
    - Table should have a title and clearly labelled categories and columns
    - Why construct frequency distributions?
      - To facilitate computational procedures for measures of average and spread
      - To enable the reader to determine the nature or shape of the distribution
      - To enable the reader to make comparisons among different data sets
      - To organise the data in a meaningful, intelligible way to enable the researcher to draw charts and graphs for the presentation of data.
    - Steps to define classes for a frequency distribution with quantitative data
      - Determine number of non-overlapping classes
        - Use between 5 and 20 classes
        - Data sets with a larger number of elements require a larger number od classes and smaller sets, fewer
        - The goal is to use enough classes to show the variation in the data, but not so many classes that some contain only a few data items
      - Determine width of each class
        - Use classes of equal width
        - Approximate class with = R/number of classes
        - Making the classes the same width reduces the chance of inappropriate interpretations
      - Determine the class limits
        - Class limits must be chosen so that each data item belongs to one and only one class
        - The lower-class limit identifies the smallest possible data value assigned to this class
        - The upper-class limit identifies the largest possible data value assigned to the class
        - The appropriate values for the class depend on the level of accuracy of the data
        - An open-end class requires only a lower-class limit or an upper-class limit
    - **Example:** A frequency distribution table shows how often something happens, e.g., in this particular table, the counts are how many people use certain types of contraception.

Method	Number
Abstinence	14
Condoms	47
Injectables	1
Norplant	1
Pill	35
None	307
Total	405

  - **Relative frequency distributions** → classes of intervals
    - With a relative frequency distribution, we don't want to know the counts. We want to know the percentages. In other words, what percentage of people used a particular form of contraception?

- **Example**: This relative frequency distribution table shows how people's heights are distributed.

Height	Frequency	Rel. Freq.
57 or less	1	0.025
57.1 to 58.6	1	0.025
58.6 to 60.1	3	0.075
60.1 to 61.7	6	0.15
61.7 to 63.3	8	0.2
63.3 to 64.8	11	0.275
64.8 to 66.4	3	0.075
66.4 to 68.0	7	0.175
Total	40	1

- Note that in the right column, the frequencies (counts) have been turned into relative frequencies (percents). **How you do this:**
  - Count the total number of items. In this chart the total is 40.
  - Divide the count (the frequency) by the total number. For example, 1/40 = .025 or 3/40 = .075.

- ***References***
  - https://www.statisticshowto.com/probability-and-statistics/statistics-definitions/relative-frequency-distribution/

Graphs

- **Bar chart**
- **Histogram**
  - Use: graph of a frequency distribution
  - For: Continuous variables
  - Rules:
    - No space between bars
    - Equal areas must represent equal percentages or numbers
    - Percentages often preferred to numbers for vertical axis
- **Box plot**
  - Shows the distribution (shape, center, range, variation) of continuous variables
- **Others:**
  - **Dot plot**
    - In a dot plot, each case is represented by a dot and dots are stacked. Easy way to see each case.
  - **Stem and leaf plot**
    - A chart that displays a frequency distribution similar to a histogram.
    - Shows:
      - Spread of the data
      - Mode
      - Whether the distribution is skewed
      - Whether there are any gaps in the data
      - Whether there are any unusual data points

Descriptive Statistics - Summarising data

- **Central tendency** (looks at location/sample's middle value)
  - Mean
  - Median
  - Mode
- **Variation** (looks at spread/summary of differences within groups)
  - Range
  - Interquartile range
  - Variance
  - Standard deviation

Measure of central tendency

Measures of central tendency focus on the average or middle values of data.

Mean

- Most commonly called average. Mean is the balance point.

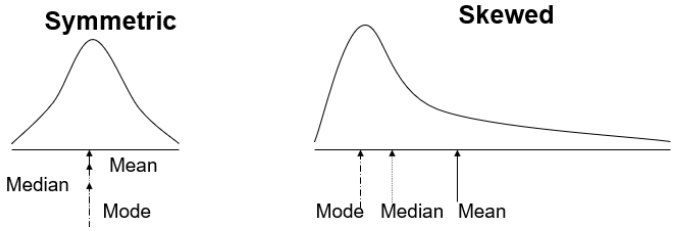
- Means can be heavily affected by outliers (data points with extreme values unlike the rest).
  - Outliers can make the mean a bad measure of central tendency or common experience.
- The mean is equal to the sum of all the values in the data set divided by the number of values in the data set.
- **Advantages of looking at the mean:**
  - Very sensitive measures
  - Considers all the available information
  - Can be combined with means of other groups to give the overall mean
- **Disadvantages of looking at the mean:**
  - Very sensitive measure (outliers)
  - Can only be used on interval or ratio data
  - Can only be used when scores are symmetrical above and below the arithmetic mean (normal distribution)

Median

- The middle value when a variable's values are ranked in order.
- The point that divides a distribution into two equal halves.
- When data are listed in order, the median is the point at which 50% of the cases are above and 50% below it.
  - The 50th percentile.
- The median is unaffected by outliers, making it a better measure of central tendency, better describing the "typical person" than the mean when data are skewed.
  - If the recorded values for a variable form a symmetric distribution, the median and mean are identical.
  - In skewed data, the mean lies further toward the skew than the median.
- **Advantages of looking at the median:**
  - Unaffected by extreme scores
  - Can be used at all levels above nominal
  - More informative measure of centrality in case data lacks normal distribution
- **Disadvantages of looking at the median:**
  - Only considers order – value ignored

Mode

- The most common data point is called the mode.
  - It is possible to have more than one mode.
  - If all values are unique, there is no mode.
- Mode may not be at the center of a distribution.
  - It may give you the most likely experience rather than the typical or central experience.



- In symmetric distributions, the mean, median and mode are the same.
- In skewed data, the mean and median lie further toward the skew than the mode.
- **Advantages of looking at the mode:**
  - Quick and easy to locate
  - Unaffected by extreme scores
  - Can be used at any level of measurement
- **Disadvantages of looking at the mode:**
  - Terminal statistics
  - A given sub-group could make this measure unrepresentative

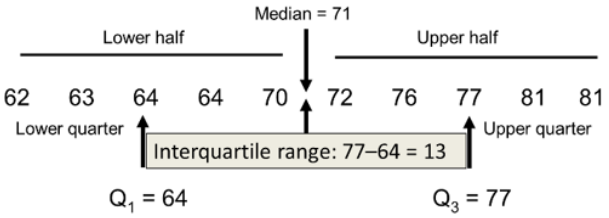
Variation

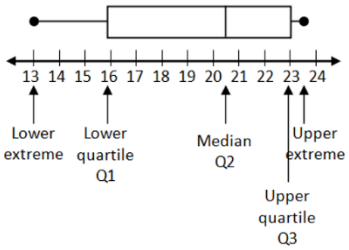
Range

- The spread, or the distance, between the lowest and highest values of a variable.
- To get the range for a variable, you subtract its lowest value from its highest value.

Interquartile range

- The interquartile range (IQR) is a measure of variability, based on dividing a data set into quartiles.
- Quartiles divide a rank-ordered data set into 4 equal parts. The values that divide each part are called first, second, and third quartiles. They are denoted by Q1, Q2, and Q3, respectively.
- IQR is equal to Q3 minus Q1.





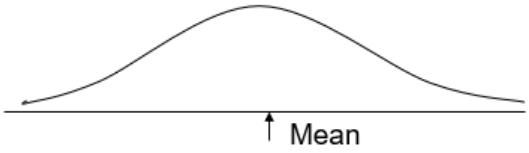
Variance (spread)

A measure of the spread of the recorded values on a variable or a measure of dispersion. Average (roughly) of squared deviations of values from the mean.

Why squared deviations?

- Adding deviations will yield a sum of 0
- Absolute values are tricky
- Squares eliminate the negatives
- Result → increasing contribution to the variance as you for farther from the mean

The larger the variance, the further the individual cases are from the mean.



The smaller the variance, the closer the individual scores are to the mean.

Central tendency and spread

- Central tendency: Mean, mode and median
- Spread: Range, interquartile range, standard deviation
- Mistakes:
  - Focusing on only the mean and ignoring the variability
  - Standard deviation and standard error of the mean
  - Variation and variance.
- What is best to use in different scenarios?
  - Symmetrical data: mean and standard deviation
  - Skewed data: median and interquartile range.

Standard deviation

- Most commonly used measure of variation and has the same units as the original data.
- Standard deviation considers all individual deviations. A deviation is the distance away from the mean of a case's score.
- **Definition of SD:** degree of dispersion or the scatter of the data points relative to its mean. Also written as S_x. **Formula for grouped data SD (class values):**

$$SD = \sqrt{\frac{(X - \overline{X})^2 \times f}{\sum f}}$$

x = *individual values in sample*
$\overline{x}$ = *sample mean*
- $\overline{x}$ = ($\Sigma x * f/\Sigma x$) *for grouped data (class values)*

f = frequency
Σf = *total frequency*

- The larger standard deviation, the greater amounts of variation around the mean.
- Standard deviation is equal to 0, only when all values are the same.
- Like the mean, the standard deviation will be inflated by an outlier case value.

Confidence interval for population mean

The confidence interval for the mean gives us a range of values around the mean, where we expect the "true" population mean is located.
Population mean: point estimate vs interval estimate

Standard Error Of The Mean is how close the sample mean is likely to be to the population mean (also written as $S_{\overline{x}}$)
- The sample mean estimates individual values. The uncertainty, with which this mean, estimates individual values, is given by the standard deviation.
- The sample mean estimates the population mean. The uncertainty with which this mean estimates the population mean is given by the standard error of the mean.

$$S_{\bar{x}} = \frac{S_x}{\sqrt{n}}$$ also written as $$SEM = \frac{SD}{\sqrt{n}}$$

$S_{\overline{x}}$ = *standard error of the mean (SEM)*
S_x = *standard deviation (SD)*
n = sample *size*

Assumptions: a random representative sample, independent observations, the population is normally distributed (at least approximately).
Confidence interval (CI) depends on: sample mean, standard deviation, sample size, degree of confidence.
Mistakes:
- 95% of the values lie within the 95% CI.
- A 95% CI covers the mean ± 2 SD.

95% Confidence Interval for The Population Mean

$$\bar{X} \pm (Z \times S_{\bar{x}})$$ also written as $$\mu = \overline{X} \pm (1{,}96 \times SEM)$$

$\overline{x}$ = *sample mean*
$S_{\overline{x}}$ = *standard error of the mean (SEM)*
Z = degree of confidence

Example of how to calculate the 95% CI for the population mean
The duration of time from first exposure to HIV infection to AIDS diagnosis is called the incubation period. The incubation periods (in years) of a random sample of 30 HIV infected individuals are: 12.0, 10.5, 9.5, 6.3, 13.5, 12.5, 7.2, 12.0, 10.5, 5.2, 9.5, 6.3, 13.1, 13.5, 12.5, 10.7, 7.2, 14.9, 6.5, 8.1, 7.9, 12.0, 6.3, 7.8, 6.3, 12.5, 5.2, 13.1, 10.7, 7.2. Calculate the 95% CI for the population mean incubation period in HIV.
Answer:

- *X = 9.5 years; SD = 2.8 years*
- *SEM = 0.5 years (SEM = 2.8/√30 = 0.5)*
- *95% level of confidence → Z = 1.96*
- *μ = 9.5 ± (1.96 x 0.5) = 9.5 ± 1 years*
- *95% CI for μ is (8.5; 10.5 years)*

If you want to calculate 99% level of confidence, then Z is 2.58:

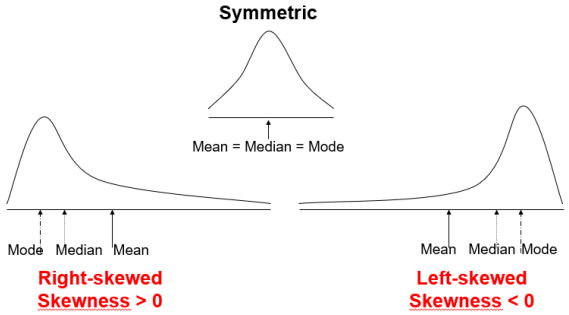
- *μ = 9.5 ± (2.58 x 0.5) = 9.5 ± 1.3 years*
- *99% CI for μ is (8.2; 10.8 years)*

Extra

- **Characteristics of normal distribution**
  - *Bell-shaped, single peak at exact center of distribution*
  - *Arithmetic mean, median and mode of the distribution are equal and located at the peak*
  - *Half the area under the curve is above the peak and the other half is below it*
  - *Normal distribution is asymptotic = the curve gets closer and closer to the x-ais but never actually touches it.*
  - *Area under curve = 1*
- **Why is distribution important?**
  - *Determines which measure of central tendency to use*
  - *Determines which measure of variability to use*
  - *Provides Z-score for standardised comparisons*
  - *Determines further statistical analysis*
- **Outliers**
  - *Values that lie very far away from the other values in the data set.*
  - *Outliers can occur for several reasons:*
    - *Invalid data entry*
    - *Biological diversity*
    - *Random chance*
    - *Experimental error*
    - *Skewed distribution*
  - **Mistakes:**
    - Not realizing that outliers are common in data sampled from skewed distribution
    - Eliminating outliers only when you do not get the results you want
    - Truly removing outliers from your records
  - **Outlier test:**
    - If values are sampled from a normal distribution, what is the chance one value will be as far from the others as the extreme value observed?
    - Examples: Chauvenet criterion, Grubbs test, Peirce criterion
  - Nevertheless, deletion of outlier data is generally a controversial practice!
- **Rule of 3-sigma**
  - *When data are normally distributed:*
    - *approximately 68% of the data lie within one SD of the mean*
    - *approximately 95% of the data lie within two SDs of the mean*
    - *approximately 99% of the data lie within three SDs of the mean*
- **Skewness**
  - *The degree of distortion from the symmetrical bell curve or the normal distribution. Skewness measures the lack of symmetry in data distribution. It differentiates extreme values in one versus the other tail.*

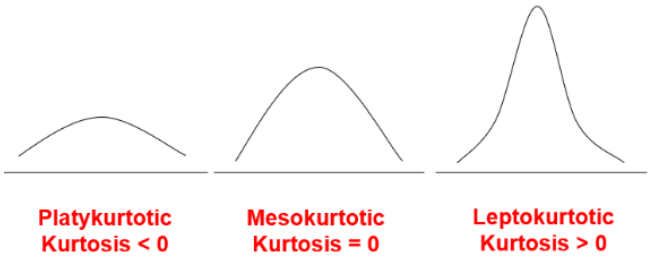
$$Skewness = \frac{\sum(X - \bar{X})^3}{(n-1) \times {S_x}^3}$$

  - ***Examples of distributions with finite skewness include the following:***
    - *A normal distribution has a skewness of 0*
    - *A half-normal distribution has a skewness just below 1*
    - *An exponential distribution has a skewness of 2*



- **Kurtosis**
  - *Kurtosis gives an idea of the central concentration of a distribution, defining how acute the central area is, or the reverse – how distributed the tail is. It is defined as a measure of 'peakedness'*
  - *It is a measure of whether the data are heavy-tailed or light-tailed relative to a normal distribution.*

$$Kurtosis = \frac{\sum(X - \bar{X})^4}{(n-1) \times {S_x}^4} - 3$$



  - *Platykurtotic → has a flatter peak (negative kurtosis)*
  - *Mesokurtotic →Normal distribution*
  - *Leptokurtotic → more acute peak (positive kurtosis)*

Further reading

- https://www.investopedia.com/terms/d/descriptive_statistics.asp

39. Descriptive statistics. Confidence interval for population proportion. Comparing proportions.

Descriptive statistics

We compute statistics and use them to estimate parameters. Computation is the first part of the statistical analysis i.e., Descriptive statistics.

Definition of Descriptive statistics: is the procedure used to organise and summarise masses of data, and reporting measures (observations).

Descriptive Statistics - Organizing data

- Tables
  - **Frequency distributions** (records how often data occurs) → classes of values
    - This is a report in the form of a table of the number of times each score of a variable occurred.
    - The categories of the frequency distribution must be stated in a way that permits each case to be counted in one and only one category. Categories must not overlap (they should be "mutually exclusive")
    - Table should have a title and clearly labelled categories and columns
    - Why construct frequency distributions?
      - To facilitate computational procedures for measures of average and spread
      - To enable the reader to determine the nature or shape of the distribution
      - To enable the reader to make comparisons among different data sets
      - To organise the data in a meaningful, intelligible way to enable the researcher to draw charts and graphs for the presentation of data.
    - Steps to define classes for a frequency distribution with quantitative data
      - Determine number of non-overlapping classes
        - Use between 5 and 20 classes
        - Data sets with a larger number of elements require a larger number od classes and smaller sets, fewer
        - The goal is to use enough classes to show the variation in the data, but not so many classes that some contain only a few data items
      - Determine width of each class
        - Use classes of equal width
        - Approximate class with = R/number of classes
        - Making the classes the same width reduces the chance of inappropriate interpretations
      - Determine the class limits
        - Class limits must be chosen so that each data item belongs to one and only one class
        - The lower-class limit identifies the smallest possible data value assigned to this class
        - The upper-class limit identifies the largest possible data value assigned to the class
        - The appropriate values for the class depend on the level of accuracy of the data
        - An open-end class requires only a lower-class limit or an upper-class limit
    - **Example:** A frequency distribution table shows how often something happens, e.g., in this particular table, the counts are how many people use certain types of contraception.

Method	Number
Abstinence	14
Condoms	47
Injectables	1
Norplant	1
Pill	35
None	307
Total	405

  - **Relative frequency distributions** → classes of intervals

- With a relative frequency distribution, we don't want to know the counts. We want to know the percentages. In other words, what percentage of people used a particular form of contraception?
- **Example**: This relative frequency distribution table shows how people's heights are distributed.

Height	*Frequency*	*Rel. Freq.*
57 or less	1	0.025
57.1 to 58.6	1	0.025
58.6 to 60.1	3	0.075
60.1 to 61.7	6	0.15
61.7 to 63.3	8	0.2
63.3 to 64.8	11	0.275
64.8 to 66.4	3	0.075
66.4 to 68.0	7	0.175
Total	*40*	*1*

- Note that in the right column, the frequencies (counts) have been turned into relative frequencies (percents). **How you do this:**
  - Count the total number of items. In this chart the total is 40.
  - Divide the count (the frequency) by the total number. For example, 1/40 = .025 or 3/40 = .075.
- ***References***
  - https://www.statisticshowto.com/probability-and-statistics/statistics-definitions/relative-frequency-distribution/

Graphs

- **Bar chart**
- **Histogram**
  - Use: graph of a frequency distribution
  - For: Continuous variables
  - Rules:
    - No space between bars
    - Equal areas must represent equal percentages or numbers
    - Percentages often preferred to numbers for vertical axis
- **Box plot**
  - Shows the distribution (shape, center, range, variation) of continuous variables
- **Others:**
  - **Dot plot**
    - In a dot plot, each case is represented by a dot and dots are stacked. Easy way to see each case.
  - **Stem and leaf plot**
    - A chart that displays a frequency distribution similar to a histogram.
    - Shows:
      - Spread of the data
      - Mode
      - Whether the distribution is skewed
      - Whether there are any gaps in the data
      - Whether there are any unusual data points

Descriptive Statistics - Summarising data

Central tendency (looks at location/sample's middle value). Measures of central tendency focus on the average or middle values of data.

Mean

- Most commonly called average. Mean is the balance point.
- Means can be heavily affected by outliers (data points with extreme values unlike the rest).
  - Outliers can make the mean a bad measure of central tendency or common experience.
- The mean is equal to the sum of all the values in the data set divided by the number of values in the data set.
- **Advantages of looking at the mean:**
  - Very sensitive measures
  - Considers all the available information
  - Can be combined with means of other groups to give the overall mean
- **Disadvantages of looking at the mean:**
  - Very sensitive measure (outliers)

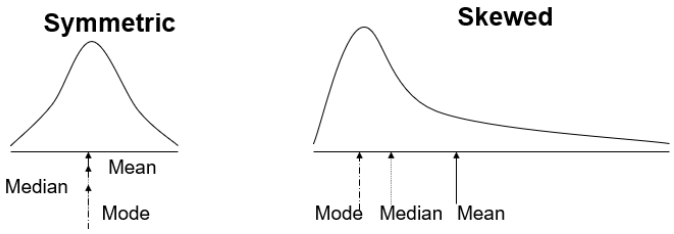
- Can only be used on interval or ratio data
- Can only be used when scores are symmetrical above and below the arithmetic mean (normal distribution)

Median

- The middle value when a variable's values are ranked in order.
- The point that divides a distribution into two equal halves.
- When data are listed in order, the median is the point at which 50% of the cases are above and 50% below it.
  - The 50th percentile.
- The median is unaffected by outliers, making it a better measure of central tendency, better describing the "typical person" than the mean when data are skewed.
  - If the recorded values for a variable form a symmetric distribution, the median and mean are identical.
  - In skewed data, the mean lies further toward the skew than the median.
- **Advantages of looking at the median:**
  - Unaffected by extreme scores
  - Can be used at all levels above nominal
  - More informative measure of centrality in case data lacks normal distribution
- **Disadvantages of looking at the median:**
  - Only considers order – value ignored

Mode

- The most common data point is called the mode.
  - It is possible to have more than one mode.
  - If all values are unique, there is no mode.
- Mode may not be at the center of a distribution.
  - It may give you the most likely experience rather than the typical or central experience.



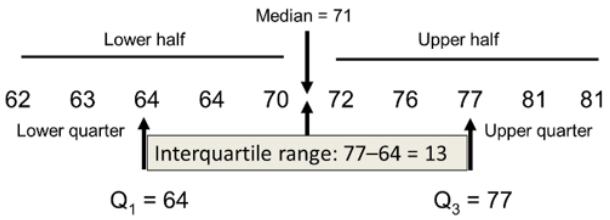
- In symmetric distributions, the mean, median and mode are the same.
- In skewed data, the mean and median lie further toward the skew than the mode.
- **Advantages of looking at the mode:**
  - Quick and easy to locate
  - Unaffected by extreme scores
  - Can be used at any level of measurement
- **Disadvantages of looking at the mode:**
  - Terminal statistics
  - A given sub-group could make this measure unrepresentative

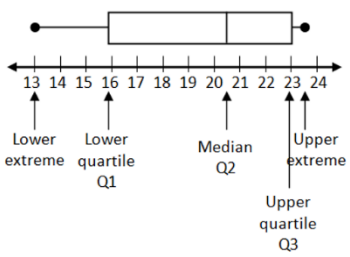
Range

- The spread, or the distance, between the lowest and highest values of a variable.
- To get the range for a variable, you subtract its lowest value from its highest value.

Interquartile range

- The interquartile range (IQR) is a measure of variability, based on dividing a data set into quartiles.
- Quartiles divide a rank-ordered data set into 4 equal parts. The values that divide each part are called first, second, and third quartiles. They are denoted by Q1, Q2, and Q3, respectively.
- IQR is equal to Q3 minus Q1.





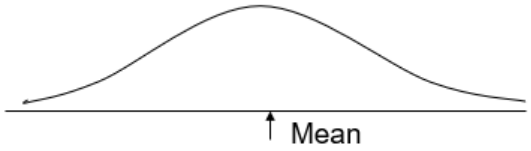
Variance (spread)

A measure of the spread of the recorded values on a variable or a measure of dispersion. Average (roughly) of squared deviations of values from the mean.

Why squared deviations?

- Adding deviations will yield a sum of 0
- Absolute values are tricky
- Squares eliminate the negatives
- Result → increasing contribution to the variance as you for farther from the mean

The larger the variance, the further the individual cases are from the mean.



The smaller the variance, the closer the individual scores are to the mean.

Central tendency and spread

- Central tendency: Mean, mode and median
- Spread: Range, interquartile range, standard deviation
- Mistakes:
  - Focusing on only the mean and ignoring the variability
  - Standard deviation and standard error of the mean
  - Variation and variance.
- What is best to use in different scenarios?
  - Symmetrical data: mean and standard deviation
  - Skewed data: median and interquartile range.

Comparing proportions

Comparing proportions is a qualitative variable in descriptive statistics.

Used to report relative size by comparing the number of cases in a specific category to the number of cases in all categories.
Can also compare a part (specific category) to a whole (all categories)

- The part is the numerator (*f*)
- The whole is the denominator (*n*)

$$\text{Proportion} = \hat{p} = \frac{f}{n}$$

$$\text{Percentage} = \% = \left(\frac{f}{n}\right) \times 100$$

f = frequency or the number of cases in any category
n = the number of cases in all categories

In the real world, you usually don't know facts about the entire population and so you use sample data to estimate p. This sample proportion is written as p̂, pronounced p-hat. It's calculated in the same way, except you use data from a sample: just divide the total number of items in the sample by the number of items you're interested in.

For example

In a survey of 3121 people, 412 are under-vaccinated. What is the proportion of under-vaccinated people in the local population?

You don't know population data for the local area, so use the sample data:

$\hat{p} = f/n$

= 412/3121

= 0.132

Confidence interval for population proportion

Estimation theory

Is a branch of statistics that deals with estimating the values of parameters based on measured/empirical data that has a random component. An estimate is a single value that is calculated based on samples and used to estimate a population value. An estimator is a function that maps the sample space to a set of estimates.

Confidence intervals can be used to estimate several population parameters. One type of parameter that can be estimated is a population proportion. You can find the confidence interval (CI) for a population proportion to show the statistical probability that a characteristic is likely to occur within the population.

When a characteristic being measured is categorical — for example, opinion on an issue (support, oppose, or are neutral), gender, political party, or type of behaviour (do/don't wear a seatbelt while driving) — most people want to estimate the proportion (or percentage) of people in the population that fall into a certain category of interest.

Standard Error of Proportion (S_p)

It is a statistic indicating how greatly a particular sample proportion is likely to differ from the proportion in the population proportion, p.

$$S_p = \sqrt{\frac{p \times (100 - p)}{n}}$$

p = population proportion

Formula for Confidence Interval For Population Proportion

$$\rho \pm (Z \times S_p)$$

Extra theory to understand above

For example

In a recent poll of 200 households, it was found that 15 households had at least one computer. Estimate the proportion of households in the population that have at least one computer.

$$\hat{p} = x/n$$

$\hat{p}$ = *probability*

x = *the number of occurrences of the event*

n = *sample size*

$$\hat{p} = 152/200 = 0.76$$

Which means that in our sample, 76% of households have one computer. This is just a single estimate, we took one sample from the entire population, so it's probably off from the actual value of the population proportion. Because of this, we're going to create a confidence interval to give a more realistic impression of what the actual population proportion value may be.

Two requirements for constructing meaningful confidence intervals about the population proportion:

1. ***The size of your sample is no more than 5% of the size of the population it was drawn from.***
2. np(1-p) ≥10
    a. ***If the sample meets this requirement, it means that it has an approximately normal distribution***

So, for the example above, construct a 95% confidence interval to estimate the population proportion. Does it meet the requirements?

1. ***The size of your sample is no more than 5% of the size of the population it was drawn from.***
    a. YES. 200 households is less than 5% of all existing households in the world
2. np(1-p) ≥10
    a. 200*0.76 (1-0.76) ≥10
    b. 36.48 ≥10
    c. *Therefore, YES, there is approximately a normal distribution.*

Formula to calculate the confidence interval for population proportion:

$$\hat{p} \pm z\sqrt{\frac{\hat{p}(1-\hat{p})}{n}}$$

p̂ = *sample proportion*
n = *sample size*
z = standardised normal distribution (obtained from table)

The part in square rot is the Standard Error of Proportion (margin of error for our estimation of the population proportion)

$$0.76 - 1.96\sqrt{\frac{0.76(1-0.76)}{200}} = 0.701 = lower\ bound$$

$$0.76 + 1.96\sqrt{\frac{0.76(1-0.76)}{200}} = 0.819 = upper\ bound$$

We are 95% confident that the proportion of households in the population with at least one computer is between 0.701 and 0.819.

Estimating population parameters
There are a number of population parameters of potential interest when one is estimate health outcomes or "endpoints"

Parameter → a statistical constant that describes a feature about a phenomenon, population etc. Examples of parameters include:

- Binomial probability of "success" p ("the population proportion")
- Expected value μ ("population mean")
- Standard deviation σ ("population standard deviation")

Two types of estimates for each population parameter

- Point estimate

  - A single numerical value that describes sample data used as an estimate of the value of a population parameter. So, they are points used to infer parameters directly, for example:
    - Sample proportion, $\hat{p}$ ("p hat") is the point estimator of p
    - Sample mean, $\bar{x}$ ("x bar") is the point estimator of μ
    - Sample standard deviation, s, is the point estimator of σ
  - Point estimates are calculated from data and vary from study to study, unlike parameters. Point estimates are random variables, but parameters are constant.
- Interval estimate
  - The process of estimation of a parameter in terms of an interval that contains the actual value of the parameter with a given probability.
  - The method for calculating an interval estimate from the sample data, known as an interval estimator

Assessing point estimator

Point estimator can be evaluated based on:

- Unbiasedness (mean) = whether the mean of this estimator is close to the actual parameter
- Efficiency (variance) = whether the standard deviation of this estimator is close to the actual parameter
- Consistency (size) = whether the probability of distribution of the estimator becomes concentrated on the parameter as the size increases

For both continuous variables (e.g., population mean) and dichotomous variables (e.g., population proportion):

- One first computes the point estimate from a sample
- The confidence interval estimate (CI) is a range of likely values for the population parameter based on:
  - The point estimate e.g., the sample mean or sample proportion
  - Investigators desired level of confidence (most commonly 95%)
  - The sampling variability or the standard error of the point estimate
  - https://www.youtube.com/watch?v=3ReWri_jh3M&ab_channel=statslectures

Confidence interval

- In order to calculate a confidence interval, we must first decide on our confidence level (C')
- The confidence interval is the range of values that (we hope) contains the true value.
- The size of the interval is determined by the size of the confidence level that we choose. If we choose a higher C, we end p with a larger interval and vice versa.

We need to quantify our degree of certainty that the confidence interval contains the true population mean. We quantify our degree of certainty by the confidence level. We first decide on our desired confidence level, and then we calculate the confidence interval. We get to choose any confidence level we want from 99, 95, 90%. The penalty we pay for choosing a higher confidence level, is a wider confidence interval.

Confidence Level	z*-value
80%	1.28
90%	1.645 (by convention)
95%	1.96
98%	2.33
99%	2.58

The formula shown in the above example for a CI for population proportion is used under the condition that the sample size is large enough for the Central Limit Theorem (CLT) to be applied and allow you to use a z*-value, which happens in cases when you are estimating proportions based on large scale surveys.

Central Limit Theorem

- CLT theorem states that if you have a population with mean μ, and standard deviation σ, and take sufficiently large random samples from the population, then the distribution of the sample means will be approximately normally distributed. The larger the value of n, the better the approximation.

- Provides insight into why many random variables have probability distributions that are approximately normal
- For example, the measurement error in a scientific experiment can be thought of as the sum of a number of underlying perturbation and errors of small magnitude.
- A practical difficult in applying the CLT is in knowing when n is sufficiently large. The problem is that the accuracy of the approximation for a particular n depends on the shape of the original underlying distribution being sampled.
- If the underlying distribution is close to a normal density curve, then the approximation will be good, even for a small n, whereas it is far from being normal, then a large n will be required.
- Rule of thumb:
    - If n > 30, the CLT can be used.

References

- https://www.statisticshowto.com/population-proportion/

40. Non-parametric tests. Chi-square test. Hypothesis testing.

Non-parametric tests

- Samples with small number of observations are treated with non-parametric statistics because of the absence of normal distribution (N≤30)
- Based on model that specfies only very general conditions and none regarding the specific form of the distribution from which the sample was drawn.
- **Definition of Non-parametric test:** test with distribution free methods with no assumptions that the data have been drawn from a normally distributed population.
- Certain assumptions are associated with most non-parametric statistical tests:
  - Observation are independent
  - Variable under study had underlying continuity

Type of test	Non-parametric	
Scale	**Nominal**	**Ordinal**
1 group	X^2 goodness of fit test	Wilcoxon signed rank test
2 unrelated groups	X^2 test	Mann–Whitney U test
2 related groups	McNemar test	Wilcoxon signed rank test
K unrelated groups	X^2 test	Kruskal–Wallis H test
K related groups		Friedman matched samples test

McNemar Test (qualitative test)

- The McNemar test is a non-parametric test for paired nominal data. It's used when you are interested in finding a change in proportion for the paired data.
  - For example, you could use this test to analyse retrospective case-control studies, where each treatment is paired with a control.
- The three main assumptions for the test are:
  1. You must have one nominal variable with two categories (i.e. dichotomous variables) and one independent variable with two connected groups.
  2. The two groups in your the dependent variable must be mutually exclusive. In other words, participants cannot appear in more than one group.
  3. Your sample must be a random sample.
- In order to run a McNemar test, your data should be placed into a 2×2 contingency table

Reference

- https://www.statisticshowto.com/mcnemar-test/

Wilcoxon signed rank test (quantitative test)

- Ordinal data two related samples.
- The Wilcoxon signed rank test compares your sample median against a hypothetical median.
- The null hypothesis for this test is that the medians of two samples are equal.
  - **H_0:** Two sampled populations are equivalent in location (they have the same mean ranks).
- Considers information about the magnitude of differences within pairs and gives more weight to pairs that show large differences than to pairs that show small differences.
- Based on the ranks of the absolute values of the differences between the two variables.

Reference

- https://www.statisticshowto.com/probability-and-statistics/statistics-definitions/wilcoxon-signed-rank-test/

Mann-Whitney U test (quantitative test)

- Ordinal data independent samples.
- **H_0:** Two sampled populations are equivalent in location (they have the same mean ranks or medians).
  - The observations from both groups are combined and ranked, with the average rank assigned in the case of ties.
  - If the populations are identical in location, the ranks should be randomly mixed between the two samples.
- **Aim:** Compare the average ranks or medians of two unrelated groups.
  - For example, *comparing pain relief score of patients undergoing two different physiotherapy programmes*.
- **Effect size:** Difference between the two medians (mean ranks).
- **Null hypothesis:** The two population medians (mean ranks) are identical.
- **Meaning of P value:** If the two population medians (mean ranks) are identical, what is the chance of observing such a difference (or a bigger one) between medians (mean ranks) by chance alone?

Kruska-Wallis H test (quantitative test)

- Ordinal data independent samples.
- **H_0:** K sampled populations are equivalent in location (they have the same mean ranks).
- The observations from all groups are combined and ranked, with the average rank assigned in the case of ties.
- If the populations are identical in location, the ranks should be randomly mixed between the K samples.
- The Kruskal Wallis test will tell you if there is a significant difference between groups. However, it won't tell you which groups are different.

Reference

- https://www.statisticshowto.com/probability-and-statistics/statistics-definitions/kruskal-wallis/

Friedman test (quantitative test)

- Friedman's test is a non-parametric test for finding differences in treatments across multiple attempts.
- Your data should meet the following requirements:
  - Data should be ordinal (e.g. the Likert scale) or continuous,
  - Data comes from a single group, measured on at least three different occasions,
  - The sample was created with a random sampling method,
  - Blocks are mutually independent (i.e. all of the pairs are independent — one doesn't affect the other),
  - Observations are ranked within blocks with no ties.
- The **null hypothesis** for the test is that the treatments all have identical effects, or that the samples differ in some way. For example, they have different centers, spreads, or shapes. The alternate hypothesis is that the treatments do have different effects.

Reference

- https://www.statisticshowto.com/friedmans-test/

Advantages of Non-parametric tests

- If the sample size is very small, there may be no alternative except to use a non-parametric statistical test.
- Non-parametric tests typically make fewer assumptions about the data and may be relevant to a particular situation.
- The hypothesis tested by the non-parametric test may be more appropriate for research investigation.
- Non-parametric statistical tests are available to analyse data which are inherently in ranks as well as data whose seemingly numerical scores have the strength of ranks
  - Example: var anxiety; statement - subject A is more anxious than subject B without knowing at all exactly how much more anxious A is. Thus, if the data are inherently in ranks, or even if they can be categorised only as plus or minus (more or less, better, or worse), they can be treated by non-parametric methods)
- Available to treat data which are simply classificatory and categorical, i.e., are measured in nominal scale.
- Samples made up of observations from several different populations at times cannot be handled by Parametric tests.
- Non-parametric statistical tests typically are much easier to learn and to apply than are parametric tests. In addition, their interpretation often is more direct than the interpretation of parametric tests.

Disadvantages of Non-parametric tests

- Wasteful if all the assumptions of a parametric statistical model are in fact met in the data and the research hypothesis could be tested with a parametric test
- The degree of wastefulness is expressed by the power-efficiency of the non-parametric test:

- if a non-parametric statistical test has power efficiency of 90%, this means that when all conditions of parametric statistical test are satisfied the appropriate parametric test would be just as effective with a sample which is 10 percent smaller than that used in non-parametric analysis.

- Another objection to non-parametric statistical test has to do with convenience: tables necessary to implement non-parametric tests are scattered widely and appear in different formats (the same is applicable of many parametric tests too).

Chi-square test

A χ^2 (chi-square test) is a statistical test used to compare observed results with expected results (which is checking if there is any association between two categorical variables). The purpose of this test is to determine if a difference between observed data and expected data is due to chance, or if it is due to a relationship between the variables you are studying.

- H_0: There is no association between the variables.
- H_A: There is an association between the variables.

Association is not causation! The observed association between two variables might be due to the action of a third, unobserved variable.

If two categorical variables are associated, it means the chance that an individual falls into a particular category for one variable depends upon the particular category they fall into for the other variable.

A chi-square test is used to help determine if observed results are in line with expected results, and to rule out that observations are due to chance. A chi-square test is appropriate for this when the data being analysed is from a random sample, and when the variable in question is a categorical variable.

Two main kinds of Chi-square tests

- Test of Independence, which asks a question of relationship, such as, "*Is there a relationship between student sex and course choice?*"
  - A χ2 test for independence can tell us how likely it is that random chance can explain any observed difference between the actual frequencies in the data and these theoretical expectations.
- Goodness-of-fit test, which asks something like "*How well does the coin in my hand match a theoretically fair coin?*"
  - χ2 provides a way to test how well a sample of data matches the (known or assumed) characteristics of the larger population that the sample is intended to represent. This is known as goodness of fit. If the sample data do not fit the expected properties of the population that we are interested in, then we would not want to use this sample to draw conclusions about the larger population.
  - **Overview:**
    - Uses frequency data from a sample to tests hypotheses about the shape or proportions of a population
    - Each individual in the sample is classified into one category on the scale of measurement
    - The data, called observed frequencies, simply count how many individuals from the sample are in each category
    - H_0 specifies the proportion of the population that should be in each category
    - The proportions from the H0 are used to compute expected frequencies that describe how the sample would appear if it were in perfect agreement with the null hypothesis

Test of Independence

The chi-square test for independence, also called Pearson's chi-square test or the chi-square test of association, is used to discover if there is a relationship between two categorical variables.

Can be used and interpreted in two different ways:

a. Testing hypotheses about the relationship between two variables in a population
   i. Views the data as one sample in which each individual is classified on two different variables
   ii. The data are usually presented in a matrix with the categories for one variable defining the rows and the categories of the second variable defining the columns
   iii. The data, called observed frequencies, simply show how many individuals from the sample are in each cell of the matrix

iv. The null hypothesis for this test states that there is no relationship between the two variables; that is, the two variables are independent

b. Testing hypotheses about differences between proportions for two or more populations.
   i. Views the data as two (or more) separate samples representing the different populations being compared
   ii. The same variable is measured for each sample by classifying individual subjects into categories of the variable
   iii. The data are presented in a matrix with the different samples defining the rows and the categories of the variable defining the columns
   iv. The data, again called observed frequencies, show how many individuals are in each cell of the matrix
   v. The null hypothesis for this test states that the proportions (the distribution across categories) are the same for all of the populations

Although the two versions of the test for independence appear to be different, they are equivalent, and they are interchangeable. The first version of the test emphasizes the relationship between chi-square and a correlation, because both procedures examine the relationship between two variables.

Goodness-of-fit Test Assumptions

1. Assumption #1 → One categorical variable (i.e., the variable can be dichotomous, nominal, or ordinal (considered as nominal)).
   - Examples of dichotomous variables include gender (2 groups: male or female), treatment type (2 groups: medication or no medication), educational level (2 groups: undergraduate or postgraduate) and religious (2 groups: yes or no).
   - Examples of nominal variables include ethnicity (e.g., 3 groups: Caucasian, African American and Hispanic), and profession (e.g., 5 groups: surgeon, doctor, nurse, dentist, therapist).
   - Examples of ordinal variables include Likert scales (e.g., a (-point scale from "strongly agree" through to "strongly disagree"), amongst other ways of ranking categories (e.g., a S-point scale for measuring job satisfaction, ranging from "most satisfied" to "least satisfied"; a 4.-point scale determining how easy it was to navigate a new website, ranging from "very easy" to "very difficult; or a 3point scale explaining how much a customer liked a product, ranging from "Not very much", to "It is OK", to "Yes, a lot"), and physical activity level (e.g., 4 groups: sedentary, low, moderate and high).
2. Assumption #2 → Independence of observations, which means that there is no relationship between any of the cases (e.g., participants).
3. Assumption #3 → Your two variables should consist of two or more categorical, independent groups.
   - Example independent variables that meet this criterion include gender (2 groups: Males and Females), ethnicity (e.g., 3 groups: Caucasian, African American and Hispanic), physical activity level (e.g., 4 groups: sedentary, low, moderate, and high), profession (e.g., S groups: surgeon, doctor, nurse, dentist, therapist), and so forth.
4. Assumption #4 →The groups/values of the categorical variable must be mutually exclusive.
   - Example: if the four groups of a categorical variable, Physical Activity Level, were "Sedentary", "Low", "Moderate" and "High", a case (e.g., a participant in an exercise study) could only be in one of these four groups (e.g., a participant could not be classified as having a "High" activity level and a "Low" activity level, but only one or the other).
5. Assumption #5 → There must be at least 5 expected frequencies (or greater in at least 80%) of cells in each group of your categorical variable.
6. Assumption #6 → The total number observed must exceed 20. The data must be in the form of frequencies counted in each of a set of categories. Percentages cannot be used.

Calculation of the test statistic

Both chi-square tests use the same statistic. The calculation of the chi-square statistic requires two steps:

1. A large discrepancy results in a large value for chi-square and indicates that the data do not fit the null hypothesis and the hypothesis should be rejected
   a. For the goodness of fit test, the expected frequency for each category is obtained by:
      i. **Expected frequency = f_e = pn** *(p = proportion from the null hypothesis, n = sample size)*
   b. For the test for independence, the expected frequency for each cell in the matrix is obtained by:
      i. Expected frequency = f_e = (row total) (column total)/n
2. The null hypothesis is used to construct an idealized sample distribution of expected frequencies that describes how the sample would look if the data were in perfect agreement with the null hypothesis. A chi-square statistic is

computed to measure the amount of discrepancy between the ideal sample (fe from H_0) and the actual sample data (the observed frequencies = f_0).

Formula for χ^2

$$\chi^2 = \sum \frac{f_0 - f\mathrm{e}^2}{f\mathrm{e}}$$

f_0 = *the observed frequencies*
f_e = *the expected (theoretical) frequencies*

A large discrepancy results in a large value for Chi-square and indicates that the data do not fit the null hypothesis and the hypothesis should be rejected.

The fact that the Chi-square tests do not require scores from an interval or ratio scale makes these tests a valuable alternative to the t tests, ANOVA, or correlation, because they can be used with data measured on a nominal or an ordinal scale.

The Chi-square test for a two-way table with r (rows) and c (columns), uses critical values from the Chi-square distribution with degrees of freedom.

Formula for degrees of freedom

$$df = (R - 1) \times (C - 1)$$

Relationship between χ^2 test and 2-sample t-test for comparing proportions

When do we use χ^2 test and when do we use 2-sample t-test?

- **Situation 1:** Both categorical variables of interest have exactly 2 levels.
  - **Question: Is there a relationship between the variables, or is there a difference in the proportions?**
    - **Answer:** Either χ2 test or two sided 2-sample t-test will lead to the same conclusion!
      - ❖ In this case, the χ2 statistic = (t-statistic)2, and the p-values of the two tests are equal.

- **Situation 2:** Both categorical variables of interest have exactly 2 levels.
  - **Question: Is one proportion greater/smaller than the other?**
    - **Answer:** This is a one-sided test and you must use a 2-sample t-test

- **Situation 3:** At least one of the two categorical variables of interest has more than 2 levels.
  - **Question: Is there a relationship between the variables?**
    - **Answer:** You must use a χ2 test.

References

- https://www.investopedia.com/terms/c/chi-square-statistic.asp

Hypothesis testing

A hypothesis is tentative statement that proposes a possible explanation to some phenomenon. A useful hypothesis s a testable statement which may include a prediction.

A hypothesis (plural hypotheses) is a precise, testable statement of what the researcher(s) predict(s) will be the outcome of the study. It is stated at the start of the study.
This usually involves proposing a possible difference/relationship between two variables.

In research, there is a convention that the hypothesis is written in two forms, the null hypothesis (called working hypothesis), and the alternative hypothesis (called the experimental hypothesis when the method of investigation is an experiment).

Overview of Hypothesis testing

- A procedure leading to a decision about a particular hypothesis
- Hypothesis-testing procedures rely on using the information in a random sample from the population of interest.
- If this information is consistent with the hypothesis, then we will conclude that the hypothesis is true; if this information is inconsistent with the hypothesis, we will conclude that the hypothesis is false.

Essentials of Hypothesis testing

- Formulation
- Data collection
- Rejection/failure of rejection (acceptance)

Types of Hypothesis testing

- The parametric tests assume that the data have come from a Type of probability distribution and makes inferences about the parameters of the distribution
- The non-parametric tests refer to tests that do not assume the data or population have any characteristic structure or parameters.

Decision criterion of Hypothesis testing

- Traditional method
  - Reject H0 if the test statistic falls within the critical region.
  - Fail to reject H0 if the test statistic does not fall within the critical region.
- P-value method
  - Reject H0 if the p-value<a (where a is the significance level, such as 0.05).
  - Fail to reject H0 if the p-value≥a
- Another option
  - Instead of using a significance level such as 0.05, simply identify the p-value and leave the decision to the reader

Hypothesis testing objectives

- Identify → Given a claim, identify the null hypothesis and the alternative hypothesis, and express them both in symbolic form.
- Calculate → Given a claim and sample data, calculate the value of the test statistic.
- Identify → Given a significance level, identify the critical value(s).
- Identify → Given a value of the test statistic, identify the P-value.
- State → State the conclusion of a hypothesis test in simple, nontechnical terms

Components of a formal Hypothesis test

- Null Hypothesis (H_0)
- Alternative Hypothesis (H_1)

Extra theory

Choice of a statistical test depends on:

- Level of measurement for the dependent and independent variables
- Number of groups or dependent measures
- Number of units of observation
- Type of distribution
- The population parameter of interest (mean, variance, differences between means and/or variances)

Levels of measurement

These go from lowest level to highest level.

- Nominal scale – e.g., genotype (only names are meaningful here)
  - You can code it with numbers, but the order is arbitrary, and any calculations would be meaningless.
- Ordinal scale – e.g., pain score from 1 to 10 (adds an order to the names)
  - The order matters but not the difference between values.
- Interval scale – e.g., temperature in C
  - The difference between two values is meaningful.
- Ratio scale – e.g., height

- It has a clear definition of 0. When the variable equals 0, there is none of that variable. When working with ratio variables, but not interval variables, you can look at the ratio of two measurements.

41. Moral aspects of physician-patient relationship. Models of physician – patient relationship. Informed consent. Conflicts in the physician-patient relationship. The physician as a patient.

Moral aspects of physician-patient relationship

Physicians have many different roles in the provision of healthcare, including individual patient care, public health delivery, health services management and policy development. The relationship with individual patient forms the professional and ethical core of their work.

Three key concepts define this relationship – consent, confidentiality and truth telling.

What is a fiduciary relationship?

A relationship in which one party (the fiduciary) is placed in a position of trust and confidence in relation to another party and acts on their behalf or in their interests in some respect.

Medical encounter

- Most of the medical encounter is spent in discussion between practitioner and patient
- The medical interview is the major medium of health care
- The interview has three functions and 14 structural elements
    - Functions
        - Determine and monitor the nature of the problem
        - Develop, maintain, and conclude he therapeutic relationship
        - Carry out patient education and implementation of treatment plans
    - Structural elements
        - Prepare the environment
        - Prepare oneself
        - Observe the patient
        - Greet the patient
        - Begin the interview
        - Detect and overcome barriers to communication
        - Survey problems
        - Negotiate priorities
        - Establish the life context of the patient
        - Establish a safety net
        - Present findings and options
        - Negotiate plans
        - Close the interview

Psychodynamic explanation of physician-patient interaction

There are three aspects of the psychodynamic model:

- Real relationship
    - This relationship is an equal and unique relationship between two adults. The physician will have been chosen by the patient because of his clinical attributes and skills
- Treatment alliance
    - Is an equal relationship between two adults but this relationship can be affected by the patients anxieties and concerns
- Transference
    - This is not an interaction between two adults. In this interaction the patient is the child, and the physician is the father. Represents the past.

Aspects of the patient-physician relationship

- Eliciting patient's own explanations of their illness
- Giving patients information
- Involving patients in developing a treatment plan
- Obtaining patient's informed consent

- Applying the basic moral principles

Basic moral principles in medical ethics

Principle for autonomy

Autonomy is capacity for self-determination, independent decisions, actions, evaluations
Respect for autonomy means to acknowledge person's right to hold views, make choices and to take actions based on personal values and beliefs
Autonomy may be compromised or lost (partially or completely) on person's life and it develops over time (in case of children)

This principle is described in the Lisbon Declaration and includes the following patient rights:

- Every patient has the right to choose his own doctor
- Every patient has the right to accept or refuse treatment after having received information
- Every patient has the right to accept or refuse participation in the study
- Every patient has the right to die with dignity
- Every patient has the right to receive further information from the doctor about the disease
- The physician must respect the patients right to choose a doctor and treatment

Specific moral rules derived from the principle respect for autonomy:

- Tell the truth
- Respect the privacy of the others
- Protect confidential information
- Obtain consent for intervention
- Physician performs the intervention after obtaining the patient's consent, this means that the patient is involved in the choice of treatment
- The patient has the right to receive information about the disease, examination, diagnostic methods, treatment, prognosis, potential risks of treatment and cost of treatment.

Principle of Beneficence

The obligation to do good, to make efforts to secure the patients well-being

Applying this principle in medical practice often poses difficult problems for the physician. The mayor problem in applying the principle of beneficence is whether the respect for autonomy has to take priority over professional obligation to provide benefit.

Principle of Non-Maleficence

The obligation to protect the patients from harm, to avoid doing harm, reduce risk of harm.

Risk can be imposed by careless or unreasonable action of professionals. Medical competence is a must for professional practice
Some ethicists claim that the duty to avoid harm is actually a stronger obligation in health care relationships than the obligation to benefit.

"*Primum non nocere*" is the Hippocratic tradition in medical practice.

Principle of Justice

The principle of formal justice states the equals should be treated equally and that those who are unequal should be treated differently according to their needs.

The patient should receive optimal treatment according to his own needs. Social status, factors such as race, gender, ethnicity should not affect the quality of treatment.

This principle involves fairness, equity, and equality.

Models of physician – patient relationship

Paternalistic model

The physician-patient interaction ensures that patients receive the interventions that best promote their health and well-being.

Strong paternalism

- The patient is competent to give his consent, but the doctor does not provide him with sufficient information. Accepted only in few cases:
  - obligatory treatment of infectious diseases
  - obligatory tests in specific professions

Weak paternalism
- The patient cannot give his informed consent due to age, incompetence. Accepted in:
  - emergency situations
  - small children, very old patients
  - mentally ill patients in emergency situations with no time for surrogate decision-making
  - when the patient cannot make decision because of temporal incompetence due to pain, shock etc.

Active paternalism = the patient himself prefers the doctor to make decisions for him
Passive paternalism = the doctor refuses to cooperate with the execution of the patients choices because these are not compatible with medicos standards or are against the doctors conscience.

Autonomous model
The patient takes the decision and the responsibility for its consequences. Doctor is responsible for the execution of the medical part of the decision.

Based on the principle of respect for autonomy → informed consent
Disadvantages are that the autonomy of the physician is not respected; the patient can choose even medically irrational course of action.

Partnership model
Patient and the doctor decide together what is the best in the context of patient's life and interests.
The doctor brings his knowledge and the patient share his values.
Based on the balance of beneficence and respect for autonomy.
Best applied to cases of chronic diseases.

What model to apply?
Acute diseases = paternalistic model might be appropriate
Chronic diseases = partnership model might be appropriate
Always try the partnership model and if this model is not applicable, try with autonomous model.

Emmanuel's models of physician-patient relationship
Informative Model
The objective of the physician-patient interaction is for the physician to provide the patient with all relevant information about:
- the disease states
- the nature of possible diagnostic and therapeutic interventions
- the probability of risks and benefits of interventions and the cost

At the end patients could come to know all the medical information and select the intervention, that best realizes their values. Then the patients can give the informed consent.

Interpretative Model
The aim of the physician-patient interaction is to elucidate the patient's values and what he actually wants and to help the patient select the available medical interventions that realize these values.

Deliberative Model
The physician's objectives include suggesting why certain health-related values are more worthy and should be aspired

The patient is empowered to consider through dialogue, alternative health related values, their worthiness, and their implications on the treatment.

Three basic models proposed by Szasz and Hollender (1956)
Model of Activity-Passivity

Entirely paternalistic in nature; this is analogous to the parent-infant relationship described previously. This model is not an interaction, as the person being acted upon is unable to actively contribute. The treatment session – an example of the model.

Model of Guidance-Co-operation

Employed in situations which are less acute. They argued that despite the fact that the patient is ill, they are conscious and thus have feelings and aspirations of their own. During this time the patient may suffer from anxiety and pain and in light of this he may seek help. The patient is, therefore, ready, and willing to "cooperate" and in doing so he places the doctor in a position of power.
Therefore, the doctor will speak of guidance and thus expect the patient to cooperate and obey without question. They described this model as a prototype in the relationship between a parent and a child (adolescent). The dental check-up visit – an example of the model.

Model of Mutual Participation

Based on the belief that equality amongst human beings is mutually advantageous. In this model the doctor does not confess to know exactly what is best for the patient. The management of chronic disease provides a good example (caries, periodontal diseases).
This model therefore provides the patient with a greater degree of responsibility and is characterised by a high degree of empathy and has elements often associated with friendship and partnership, as well as the imparting of expert medical advice.

Model	Physician's Role	Patient's Role	Clinical application of model	Prototype model
Activity-Passivity	Does something to the patient	Recipient (unable to respond to inert)	Anaesthesia, acute trauma, coma, delirium	Parent-Infant
Guidance-Cooperation	Tells patient what to do	Co-operator (obeys)	Acute infectious processes	Parent-Child (adolescent)
Mutual participation	Helps patient to help himself	Participant in "partnership" (uses expert help)	Chronic illnesses, psychoanalysis	Adult-Adult

Communication skills
Developing strong communication skills is integral to becoming and effective health provider. In recent years, good doctor-patient communication has been linked to improved patient satisfaction, better patient care and a decrease in malpractice lawsuits.

Creating trust between a doctor and a patient plays a major role in the success of a therapy. To build this trust, before starting treatment, the doctor should inform his patient about: diagnosis and prognosis of the disease; upcoming tests; potential risks of those and the subsequent therapy; treatment options.

The quality of the health service depends on how well it meets the individual needs of the patient. In the complex system of modern health insurance, the best way to achieve high-quality care is to use a patient-centred approach. This includes respect for the dignity of the individual, based on the ethical and moral standards.

A major role in understanding the presented information by the patient is the way in which communication is carried out. According to some authors, 65% of information is transmitted nonverbally and only 35% verbally. These two methods of communication complement each other, the information given can be accepted as a complete message.
To be successful, the physician should be familiar with the various methods and techniques of communication, because it is a part of good medical practice.

Physicians should:
1. Sit down
2. Attend to patient comfort
3. Establish eye contact
4. Listen without interrupting
5. Show attention with nonverbal cues, such as nodding allow silences while patients search for words
6. Acknowledge and legitimize feelings
7. Explain and reassure during examinations
8. Ask explicitly if there are other areas of concern

Informed consent

Informed consent is the process by which a fully informed patient can participate in choices about his health care. Goal is to give the patient the opportunity to be informed so that they are capable of taking the right decision.

Informed consent is based on the principle of respect for autonomy. The law relating to consent is founded upon the patient's autonomy and there are clear legal consequences if the physician acts in its absence.

The complete informed consent includes a discussion of:

- The nature of the procedure
- Reasonable alternatives to the proposed intervention
- The relevant risks
- Assessment of patient understanding
- The acceptance of the intervention by the patient

Basic consent entails letting the patient know what the doctor would like to do and asking him if that is alright. The consent must be voluntary. To encourage the voluntariness, the doctor can make it clear to the patient that he is participating in a decision, not just signing a form.

Standard for deciding whether you have given the patient enough information

- Reasonable physician standard → what would a typical physician say about the intervention?
- Reasonable patient standard → what would the average patient need to know in order to be an informed participant in the decision
- Subjective standard → what would this patient need to exactly know, in order to make an informed decision.

Most used standard is the second one. The best approach to the question of how much information is enough is one that meets both your professional obligation to provide your best care and the respect to the patient as a person who has the right to participate in taking the decision.

Interventions that require informed consent

- Surgery
- Anaesthesia
- Invasive procedures

For many decisions, written consent is neither required, nor needed but a meaningful discussion is needed

Criteria for capacity to consent

1. The ability to understand given information
2. The ability to appreciate the nature of the situation
3. The ability to assess the relevant facts
4. The ability to exercise choice
5. The ability to use understood information for realistic and reasonable decisions
6. The ability to appreciate the consequences of giving or refuting consent

When it is not clear, a psychiatric consultation should be done. Refusing treatment does not mean they are incompetent. Other situations where patient's ability to take decisions is questionable include:

- Premedicated patient
- Patient is in labour
- Patient is in stress
- Patient is with well-known mental disease
- Patient is with an organic brain disease
- Immature patient

If the patient is determined to be incompetent, a surrogate decision maker must speak and take the decision for him.

Groups of people without the capacity to consent

- The patient with learning difficulties
- The mentally ill patients
- The children

- Confused elderly
- Unconscious people

Doctor influencing a patient during the informed consent process
The influence can be divided into three categories
- Coercion = application of a credible threat to the patient. Always unethical and unacceptable
- Manipulation = incomplete or non-truthful presentation of information. Ethically suspected
- Persuasion = involves presentation of an argument for a certain choice and is permissible, even desirable in the consent process

Conflicts in the Physician - Patient relationship
Some common physician-patient relationship problems that can arise include
- A doctor ignoring patient input in their decision making.
- Disorganization at a doctor's office.
- A doctor withholding relevant information.
- A doctor giving off the impression of not respecting a patient.
- Poor communication between a doctor and patient.
- A doctor discouraging second opinion.

Problems with a doctor-patient relationship can be very damaging. They can seriously erode the relationship between a patient and their doctor, which can have major negative implications. It could lead to a patient not fully trusting a doctor and their recommendations. It could also result in a doctor not being as engaged in a patient's care as they should be. A doctor not being properly engaged in a patient's care could increase the chances of mistakes occurring in connection to the care. Thus, doctor-patient relationship problems could have serious patient safety ramifications.

References
- https://www.defranciscolaw.com/blog/what-problems-can-arise-in-a-doctor-patient-relationship/

The physician as a patient
Several factors may influence doctor-patients' perceptions of illness and ultimately influence their care. These factors can range from anxiety, denial of illness, need to feel omnipotent, and loss of self-esteem to fear that illness equates to weakness and an inability to reverse roles and become a patient. Some doctor-patients may fall victim to very-important-person syndrome.

Nurses and other healthcare professionals may find it challenging to deal with a doctor-patient, and the situation can be compounded by their circumvention of administrative and medical regimens. Such issues can affect a doctor-patient's care and may result in confusion, hostility, and poor outcome.

Altering the decision-making process and providing a different treatment to a doctor-patient can potentially augment such hostility and be counterproductive. Professional payments can become an awkward issue and a cause for embarrassment. Intense economic and social fears may follow, accompanied by the undue anxiety of worst possible outcome of a particular clinical condition. Such factors may explain the view that doctors make the worst patients.

Dos as the physician
- Take history and perform examination thoroughly (as for any other patient).
- Deal with the patient's anxiety directly.
- Clarify the doctor-patient relationship as early as possible.
- Avoid overly close identification because of empathy or sympathy.
- Discuss the management plan in detail to allay anxiety.
- Leave plenty of time for a clear discussion of opinions and recommendations.
- Speak to the patient directly, or if desired, along with the relatives. If relatives need to be spoken to separately, this should be done with the patient's consent.
- Discuss issues of privacy, confidentiality, insurance, and payment early.
- Maintain professional courtesy; the relationship should be more than a financial arrangement.

Don'ts as the physician
- Accept the responsibility if you feel an excessive degree of anxiety.
- Walk away until you find someone who is willing to undertake the responsibility.

A doctor should not treat a doctor-patient differently from a lay patient. Alterations of treatment do not necessarily lead to a better outcome and could even be counterproductive. The focus of treatment should strictly be on the nature of the ailment, rather than the profile of the patient. Being a doctor's doctor can be a challenging prospect for some, and relevant issues should be considered before taking on such a role.

Extra theory

- **Truth-telling and withholding information**
  - Should physicians not tell the truth to patients in order to relieve their fears and anxieties? Not telling the truth may take many forms, has many purposes, and leads to many different consequences.
  - Questions about truth and untruth in fact pervade all human communication. In each context, the questions are somewhat differently configured.
  - Not telling the truth in the doctor-patient relationship requires special attention because patients today, more than ever, experience serious harm if they are lied to. Besides harming a patient's autonomy, patients themselves are harmed, and so are the doctors, the medical profession, and the whole society which depends on humane and trustworthy medicine.

- **Kant's categorial imperative doctrine**
  - Kant argued for truth and the strict rejection of all lying - truth telling is a duty (imperative) which binds unconditionally (categorical).
  - A lie is always evil because it harms human discourse and the dignity of every human person.
  - Truth telling is always a duty, whether the other has the right to know or whether innocent persons will be severly harmed.
  - Truth obviously is an essential moral good.

- **"Truth-dumping"**
  - Violation of beneficence - usually perceived by patient as cruel and uncaring
  - Violation of autonomy?
    - Does cruel disclosure make patient a better (freer) decision-maker?
    - Does patient get a voice in *how* truth is told?

- **Truthful disclosure vs lying in a clinical context**
  - Lying in a clinical context is wrong for many reasons (patient is depressed and irrational and suicidal, is overly pessimistic).
  - Doctors can do as much harm by cold and crude truth-telling as they can by cold and cruel withholding of the truth.
  - To tell the truth in the clinical context requires compassion, intelligence, sensitivity, and a commitment to staying with the patient after the truth has been revealed.

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- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4482553/

42. Medical mistakes. Confidentiality.

Medical mistakes

How do mistakes occur?

All physicians make mistakes, and most mistakes are not the result of negligence. A physician may make a mistake because of an incomplete knowledge base, an error in perception or judgment, or a lapse in attention. Making decisions on the basis of inaccurate or incomplete data may lead to a mistake. The environment in which physicians practice may also contribute to errors. Lack of sleep, pressures to see patients in short periods of time, and distractions may all impair an individual's ability to avoid mistakes.

What if I see someone else make a mistake?

A physician may witness another health care provider making a major error. This places the physician in an awkward and difficult position. Nonetheless, the observing physician has some obligation to see that the truth is revealed to the patient. This should be done in the least intrusive way. If the other health care provider does not reveal the error to the patient, the physician should encourage her to disclose her mistake to the patient. Should the health care provider refuse to disclose the error to the patient, the physician will need to decide whether the error was serious enough to justify taking the case to a supervisor or the medical staff office, or directly telling the patient. The observing physician also has an obligation to clarify the facts of the case and be absolutely certain that a serious mistake has been made before taking the case beyond the health care worker involved.

Malpractice is a preventable effect of medical care, whether or not it is evident or harmful to the patient. This might include an inaccurate or incomplete diagnosis or treatment of a disease, injury, syndrome, behaviour, infection, or other disease.

Types of malpractice

- Due to objective reasons
  - Imperfection of the medical science and technology, lack of time, bad working conditions. These errors cannot be imputed to the physician
- Due to subjective reasons
  - Lack of knowledge, negligent performance of duties, failure to provide medical equipment. These errors are categorised as inexcusable, intent, crime.
- Medical mistakes unit with the diagnosis, treatment, technical mistakes, medication errors

Avoiding malpractice

Each stage of the treatment of patients must be thoroughly checked, registered, and documented
Any procedures that have to be undertaken should be done after obtaining voluntary, informed consent of the patient.

Medical error statistics

- Medical errors
  - 98,000 Americans die every year from a preventable medical error
  - Cost of medical error is about $29 billion annually
- Medication errors (most common medical error)
  - 1.5 million people harmed annually
  - 7000 deaths annually
  - Costs more than $3.5 billion annually (hospitals

Do physicians have an ethical duty to disclose information about medical mistakes to their patients?

Physicians have an obligation to be truthful with their patients. That duty includes situations in which a patient suffers serious consequences because of a physician's mistake or erroneous judgement. The fiduciary nature of the relationship between a physician and patient requires that a physician deal honestly with his patient and act in her best interest.

In general, even trivial medical errors should be disclosed to patients. Any decision to withhold information about mistakes requires ethical justification.

Won't disclosing mistakes to patients undermine their trust in physicians and the medical system?

Some patients may experience a loss of trust in the medical system when informed that a mistake has been made. Many patients experience a loss of trust in the physician involved in the mistake. However, nearly all patients desire some acknowledgment of even minor errors. Loss of trust will be more serious when a patient feels that something is being hidden from them.

Physician's responsibility

- Disciplinary responsibility in cases of breath of the employment, professional and academic discipline
- Administrative and criminal responsibility, the punishment for which is a fine or revocation of licenses for practice
- Civil liability
- Criminal liability
- Iatrogenesis is the occurrence or progression of disease caused by medical personnel can be:
  - Direct = caused by careless and negligent performance of duties
  - Indirect = caused by adverse psychological impact of speech, when the doctor does not communicate adequately and carefully with the patient

Confidentiality

Confidentiality is one of the core and fundamental tenets at medical practice. It requires health care providers to maintain a patient's personal health information *private* unless consent to release the information is provided by the patient.
It was established in Hippocratic Oath (5th BC).

Confidentiality provides a foundation for trust in the physician-patient relationship. Physicians are obliged to keep all of the information about their patients confidential.

Core of the Confidentiality is based on

- Respect the patient privacy – the patient expects doctors to maintain confidentiality
- Confidentiality promotes trust in physician-patient relationship
- Confidentiality heartens patients to seek medical attention
- Confidentiality encourages patients to share information that can be important for the decision on the treatment
- Prevention of harmful consequences to patients – discrimination based on ill health

What information is Confidential?

All identifiable patient information, whether written, computerised, visually or audio recorded is subject to the duty of confidentiality. It covers:

- Any clinical information about an individual's diagnosis or treatment
- A picture, photograph, video, audiotape, or other images
- Who the patient's doctor is and what clinics patients attend and when
- Shared medical information at conferences
- All facts that have been found out during the consultation and investigations
- All the information about the patient that the physician has learned while practicing his profession

What does the duty of confidentiality require?

Electronic medical records can pose new and unique challenges to confidentiality. In accordance with the **Health Information Portability and Accountability Act of 1997 (HIPAA)**, institutions are required to have policies to protect the privacy of patients' electronic information, including procedures for computer access and security.

Violation of confidentiality levels

- Zero degree → no breach of confidentiality
  - In the case of sharing patient information between members of the medical team
- First degree → trivial breach of confidentiality
  - When the doctor said information without identifying the patient (the medical cases described in medical textbooks)
- Second degree → significant breach of confidentiality
  - Sharing patient's information with his identification with external persons
- Third degree → severe breach of confidentiality
  - When revealing information about the patient causes heavy moral and material damage to the patient

When can confidential information be disclosed?

- Exception 1 = Concern for the safety of other specific persons.

    - Physicians have a duty to protect other individuals from any serious threat of harm if they have information that could prevent the harm (when the patient shares a specific plan with a physician to harm a particular individual)
- Exception 2 = Concern for public welfare
    - The duty to protect public health outweighs the duty to maintain a patient's confidentiality (physician must report certain communicable/infectious diseases to the public health authorities
- Exception 3 = In the cases of suspicion of child abuse and some criminal proceedings (criminal abortion, murder)

What if a family member asks how the patient is doing?
If there is not explicit permission from the patient to share information with family member, it is generally not ethically justifiable to do so. Except in cases where the spouse is at specific risk of harm directly related to the diagnosis, it remains the patient's rather than the physician's, obligation to inform the spouse.

43. Role of physicians and patients in dealing with chronic diseases. Breaking bad news. Euthanasia.

Role of physicians and patients in dealing with chronic diseases

Role includes improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care. A strong primary care infrastructure shown to be a patient-centered, high quality, cost-effective way is a way to achieve these aims. Patients with access to a regular primary care physician have lower overall health care costs than those without one, and health outcomes improve. Primary care based health systems are associated with lower hospitalizations, less duplication in treatment, more appropriate use of technology, lower Medicare spending, higher quality of care and lower rates of healthcare disparities.

A chronic disease as a medical condition lasting 3 months or more. They remain permanently, can be managed once they are present but cannot typically be prevented by vaccines, cured by medication, nor do they spontaneously disappear. The standard list of chronic medical conditions typically includes arthritis, current asthma, cancer, cardiovascular disease, chronic obstructive pulmonary disease, and diabetes.

Chronic disease management involves managing the symptoms of a long-term disease, thereby allowing patients to enjoy life. It includes an integrated care approach to managing illness which includes screenings, check-ups, monitoring and coordinating treatment, and patient education. Through managing chronic disease, doctors can help slow down the progression of disease and help control the symptoms – so you patients can take back control of their life.

Doctor should examine lifestyle to understand what other factors are possibly contributing to the chronic condition. For example, if you have diabetes, an unhealthy diet can make it worse; if you have asthma, living in an environment with airborne irritants can cause more asthma attacks.

Managing the disease involves understanding not only the disease, but also the environment and lifestyle – and their impacts on your condition. Managing all of the various factors can help to slow down the progression of chronic diseases.

Doctor can help patient by connecting clinical services to community programs that help people prevent and manage their chronic diseases and conditions

- Linking public health services, such as tobacco cessation services, to health care systems.
- Using health care workers like pharmacists, patient navigators, and community health workers to help people manage their own health
- Educating people to become more involved in their own health care

Breaking bad news

Robert Buckman's Six Step Protocol for Breaking Bad News - SPIKES

1. **S** = SETTING UP the Interview
    a. Arrange for some privacy.
    b. Involve significant others.
    c. Sit down.
    d. Make connection with the patient.
    e. Manage time constraints and interruptions.
2. **P** = assessing the patient's PERCEPTION
    a. With the implementation of the axiom "before you tell, ask" - the clinician uses open-ended questions to create a reasonably accurate picture of how the patient perceives the medical situation—what it is and whether it is serious or not (e.g., "What have you been told about your medical situation so far?)
3. **I** = obtaining the patient's INVITATION
    a. While a majority of patients express a desire for full information about their diagnosis, prognosis, and details of their illness, some patients do not.
4. **K** = giving KNOWLEDGE and Information to the patient
    a. Start at the level of comprehension and vocabulary of the patient
        i. Try to use nontechnical words
        ii. Give information in small chunks and check periodically as to the patient's understanding
        iii. When the prognosis is poor, avoid using phrases such as "There is nothing more we can do for you."
5. **E** = addressing the patient's EMOTIONS with emphatic responses

a. Patients' emotional reactions may vary from silence to disbelief, crying, denial, or anger.
b. When patients get bad news, their emotional reaction is often an expression of shock, isolation, and grief.
c. In this situation the physician can offer support and solidarity to the patient *by making an empathic response*.

6. **S** = STRATEGY and SUMMARY
   a. Patients who have a clear plan are less likely to feel anxious and uncertain.
   b. Before discussing a treatment plan, it is important to ask patients if they are ready at that time for such a discussion.

Truth Protocol (RB) Conclusions

- Pick a good time and setting and assemble right people
- Find out how much the patient already knows
- Find out how much the patient wants to know
- Share the information the patient seeks
  - in sensitive manner
  - in appropriate "chunks"
- Respond to patient's feelings
- Planning and follow-through

What if the patient starts to cry while I am talking?
In general, it is better simply to wait for the person to stop crying. If it seems appropriate, you can acknowledge it ("Let's just take a break now until you're ready to start again") but do not assume you know the reason for the tears (you may want to explore the reasons now or later). Most patients are somewhat embarrassed if they begin to cry and will not continue for long. It is nice to offer tissues if they are readily available (something to plan ahead); but try not to act as if tears are an emergency that must be stopped, and don't run out of the room--you want to show that you're willing to deal with anything that comes up.

I had a long talk with the patient yesterday, and today the nurse took me aside to say that the patient doesn't understand what's going on! What's the problem?
Sometimes patients ask the same question of different caregivers, sometimes they just didn't remember it all, and sometimes they need to go over something more than once because of their emotional distress, the technical nature of the medical interventions involved, or their concerns were not recognized and addressed.

I just saw another caregiver tell something to my patient in a really insensitive way. What should I do?
First, examine what happened and ask yourself why the encounter went badly. If you see the patient later, you might consider acknowledging it to the patient in a way that doesn't slander the insensitive caregiver ("I thought you looked upset when we were talking earlier, and I just thought I should follow up on that--was something bothering you?").

Euthanasia

From Greek "Eu" – good and "thanatos" – death, death without suffering. In clinical practice, is considered gentle death.

Definition of Euthanasia: It is an act where a third party, usually implied to be a physician, terminates the life of a person, either passively or actively.

Euthanasia by consent

- Voluntary euthanasia
  - Intentional ending of life of a competent patient on his voluntary request.
  - According to some ethicists euthanasia can be only voluntary. The other types are considered murder.
- Non-voluntary euthanasia
  - In case of unconscious or otherwise unable to make a reasonable choice between living and dying person; someone else takes the decision on their behalf. In children considered underage to take end of life decision
- Involuntary euthanasia
  - When the person's life is taken away against his will to live (murder)

Euthanasia by means

- Active euthanasia = death is brought about by an act
  - Not legal in the United States
  - Legal in Netherlands and Australia
  - Examples: Drugs are administered at lethal levels.

- Passive euthanasia = death is brought about by an act of omission. Examples: Turning off respirator, refusing chemotherapy.
    - Withdrawing treatment → to stop a treatment that has been initiated, e.g., withholding ventilator support for breathing may be considered an act of passive euthanasia because the person would die on his or her own without the ventilator
    - Withhold treatment → not perform a treatment or procedure because it will extend life for a short time, e.g., not operating because this will expand patient's life only shortly.

Types of Euthanasia

- Euthanasia by a certain action, such as lethal injection substance.
- Euthanasia by ending the life support procedures, such as termination of human nutrition.

Reasons for the termination of human life

- Unbearable pain that cannot be copied with known medical methods
- Limited life expectancy
- Clear desire to terminate the life of the man himself or dependent individual (person has his life and has the right to decide how to die)
- Derogatory to the dignity of the human physical form and mental state of terminally ill
- Emotionally engaging nearby
- Financial burden on relatives
- Financial burden on the health system
- Lack of moral and / or spiritual support from family and / or religious community

Ethical issues of Euthanasia

- Responsibility of physician is to preserve life, not end it
- Physicians' codes of professional behaviour demand application of all methods to preserve life
- Death is final: life is lost
- Death should be a natural process
- Always the possibility of future discovery of cures that could preserve life. Assisted suicide restricts the usefulness/opportunity of such a cure

Arguments in favour of Euthanasia

- Respect for autonomy – right to self-determination has to be respected always in spite of all technology advances pain and suffering cannot be fully alleviated and, in some cases, patients have the right to request their suffering to be relieved by the act of euthanasia. It is the duty of the doctor to relieve the pain and suffering at all times and he has to act according to the wishes of the patients (the most merciful action).
- If the pain is unbearable the patient will benefit most from death rather than from life
- Legalizing euthanasia is in favour of only few who suffer uncontrollable pain. It is a wrong response of the profession to create precedent of difficult–to–treat cases and allow killing to doctors
- Medical power for ending life
- "Personally controlled death" - Euthanasia started to be regarded as a personal right, doctor performs euthanasia on the basis of agreement with the patient, usually at his home and without other people knowing about it
- Assault on the integrity and ethics of the medical profession – the involvement of the doctor in the death of the patient will undermine the physician-patient relationship based on trust, confidence, and mutual respect

Arguments not in favour of Euthanasia

- Motives for asking for euthanasia could not be related to the terminal phase of the disease but to other personal circumstances, and his actual wish is to end suffering or being burden for the family, not to end life
- Self-determination can never be absolute; we have obligations to the others, and they limit our freedom in certain limits
- Autonomy cannot be self-defeating. The act of giving to someone the right to kill us is a radical form of relinquishment of autonomy
- Assisted suicide is more appropriate form to be supported if one wants to end his life in case of terminal illness
- Judgment of patient's best interest is difficult
- Third party judgment – by legal representative or substitute
- Whose interest is defended – the patient's or the interest of others?

- Slippery slope – if euthanasia of terminally ill patients is acceptable who is going to prevent society from accepting euthanasia of "defective, imperfect" people
- Nazi ideology accepted initially that there is a life not worthy to be lived (severely and chronically ill) and expanded the category to all non-Germans
- The legalization of euthanasia will condition the society to its presence. This may affect the society's perception and understanding of value of life and finally the process of dying may be substituted by the act of euthanasia
- Euthanasia is an easy way to prevent future development of medicine

Physician assisted suicide (PAS)

A doctor intentionally helping a patient's death by providing the necessary information or means that a patient could use to commit suicide.
The main distinction between physician assisted suicide and active euthanasia is that the doctor is not the person performing the act.
Assisted suicide is an active choice by and the act of a person to end his or her own life.

Prior to the passage of the Oregon Death with Dignity Act in 1996, the term most often used was "physician-assisted suicide" (PAS). Those who use this term feel that it is an accurate reflection of the relationship between doctor and patient and refer to the etymological roots of suicide as "auto-killing" or "self-killing." The use of this term ties the role of the physician to one that aids the patient in killing him or herself.

Physician aid-in-dying (PAD) refers to a practice in which a physician provides a competent, terminally ill patient with a prescription for a lethal dose of medication, upon the patient's request, which the patient intends to use to end his or her own life.

Patients request PAD for a variety of reasons

- People with life-threatening disease think often about suicide
- Due to physical, psychological, social, spiritual suffering or practical concerns
- As a first expression of unrelieved suffering
- An intent of thinking out loud about the response to their present and anticipated future
- On the base of life-long values
- As a plea for help, signalling a crisis where unmet needs have built up over time

Arguments for PAD

- Respect for autonomy
  - Decisions about time and circumstances of death are personal. Competent people should have right to choose the timing and manner of death.
- Justice
  - Justice requires that we "treat like cases alike." Competent, terminally ill patients have the legal right to refuse treatment that will prolong their deaths. For patients who are suffering but who are not dependent on life support, such as respirators or dialysis, refusing treatment will not suffice to hasten death. Thus, to treat these patients equitably, we should allow assisted death as it is their only option to hasten death.
- Compassion
  - Suffering means more than pain; there are other physical, existential, social, and psychological burdens such as the loss of independence, loss of sense of self, and functional capacities that some patients feel jeopardize their dignity. It is not always possible to relieve suffering. Thus, PAD may be a compassionate response to unremitting suffering.
- Individual liberty vs. state interest
  - Though society has strong interest in preserving life, that interest lessens when a person is terminally ill and has strong desire to end life. A complete prohibition against PAD excessively limits personal liberty. Therefore, PAD should be allowed in certain cases.
- Honesty & transparency
  - Some acknowledge that assisted death already occurs, albeit in secret. The fact that PAD is illegal in most states prevents open discussion between patients and physicians and in public discourse. Legalization of PAD would promote open discussion and may promote better end-of-life care as patients and physicians could more directly address concerns and options.

Arguments against PAD

- Sanctity of life
  - Religious and secular traditions upholding the sanctity of human life have historically prohibited suicide or assistance in dying. PAD is morally wrong because it is viewed as diminishing the sanctity of life.
- Passive vs. Active distinction
  - There is an important difference between passively "letting die" and actively "killing." Treatment refusal or withholding treatment equates to letting die (passive) and is justifiable, whereas PAD equates to killing (active) and is not justifiable.
- Potential for abuse
  - Vulnerable populations, lacking access to quality care and support, may be pushed into assisted death. Furthermore, assisted death may become a cost-containment strategy. Burdened family members and health care providers may encourage loved ones to opt for assisted death and the protections in legislation can never catch all instances of such coercion or exploitation. To protect against these abuses, PAD should remain illegal.
- Professional integrity
  - Historical ethical traditions in medicine are strongly opposed to taking life. For instance, the Hippocratic oath states, "I will not administer poison to anyone where asked," and I will "be of benefit, or at least do no harm." Furthermore, some major professional groups such as the American Medical Association and the American Geriatrics Society oppose assisted death. The overall concern is that linking PAD to the practice of medicine could harm both the integrity and the public's image of the profession.
- Fallibility of the profession
  - The concern here is that physicians will make mistakes. For instance, there may be uncertainty in diagnosis and prognosis. There may be errors in diagnosis and treatment of depression, or inadequate treatment of pain. Thus, the State has an obligation to protect lives from these inevitable mistakes and to improve the quality of pain and symptom management at the end of life.

Is physician aid-in-dying (PAD) the same as euthanasia?
No. While both physician aid-in-dying and euthanasia involve the use of lethal medications to deliberately end a patient's life, the key difference is in who acts to end the patient's life.

Legal issues of Euthanasia

Countries that perform euthanasia is permitted by law

- Belgium → the law is adopted in September 2002. (The number of cases of illegal euthanasia in Belgium are around a few thousand per year).
- Australia, Northern Territory → in 1995 the law adopted the so-called rights of terminally ill patients. Very soon after this, the law was repealed, but 3 people were euthanized.
- Colombia → May 1997, the euthanasia is legalized for terminally ill when they give their consent. Forthcoming precise specifications and algorithm for obtaining consent and accurate assessment of the cases.
- Oregon, USA → since 1994 with amendment in 1997 the euthanasia is permitted under following conditions:
  - 18-year-olds
  - Resident of oregon
  - Person is informed and individually been agreed. Man can digest the information given to him and was able to express an opinion.
  - Diagnosis shows 6 months of life and the decision is not taken in a state of depression or other mental disorder.
  - The decision of the patient is given to 2 people witnesses and the condition of the patient is assessed by at least 2 independent doctors.
- Netherlands → theoretically euthanasia is criminal acts, but since 1993 (completed in July 1999) doctors complied with the following conditions are not prosecuted:
  - The patient suffers from unbearable pain, is not necessarily to be terminally ill
  - The patient repeatedly and insistently wanted to die, and the desire is completely voluntary and well-considered
  - There is no alternative for the copying of the pain
  - Two doctors agree to conduct with the procedure
  - The appropriate medical care must be taken of the patient
  - Death has been reported
- Japan → by March 1995, euthanasia is applicable if the patient meets the following criteria:
  - Unbearable pain which cannot be coped in any way
  - Death is inevitable, and recent (terminally ill)

- The patient has clearly expressed his decision to terminate the life of her / his.

In Europe some forms of euthanasia are legalised in:

- Belgium (2002), euthanasia for children (2014)
- Luxembourg (2008)
- Andalusia in Spain (passive euthanasia)
- France (passive euthanasia) – 2005
- Sweden (passive euthanasia)

Assisted suicide for terminally ill patients is allowed in Germany and Switzerland only if the lethal drug is taken without any help

- In Italy – patients can refuse care
- In US - assisted suicide is legalised in 5 states – Oregon (1997), Washington, Vermont, Montana and New Mexico. In 2013 about 300 terminally ill Americans were prescribed lethal medication and around 230 died as a result of taking them

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44. Moral aspects of transplantation. Bulgarian Law on Transplantation of Organs, Tissues, and Cells.

Moral aspects of transplantation

Transplantation includes medical and other activities of obtaining organs, tissues and cells from human cadaver or living person and their implantation to other person for treatment.

Donor is a person from whom grafting material has been taken. Recipient is a person who receives a transplant.

Organs that can be transplanted

- Heart
- Kidneys
- Thymus
- Liver
- Lungs
- Pancreas
- Intestine

Basic definitions in transplantation

- Heterotransplantation/Xenotransplantation = from animal to human
- Homotransplantation/Allotransplantation = from human to genetically non-identical human
- Isotransplantation = between twins
- Autotransplantation = from and to the same person
- Biotransplantation = non-organic transplants to humans

Brain death

Brain death is the absence of all brain functions and all brain-stem reflexes.

Social formulation, describing irreversibly lost personhood → loss of consciousness and capacity to relate to other people and the world.
Persistent vegetative state → total loss of cerebral cortical function with a functioning brain stem (spontaneous respiration and stable cardiac function).

Common causes of brain death

- Trauma
- Intracranial haemorrhage
- Hypoxia due to resuscitation after cardiac arrest
- Drug overdose
- Near drowning
- Primary brain tumour
- Meningitis
- Homicide
- Suicide

Diagnosis is uncertain unless the patient is observed for several months.

Criteria for brain death

1. Identifiable cause of death
2. Exclusion of all potential reversible conditions for loss of consciousness/hypothermia, CNS depressants and muscle relaxants
3. Cerebral unresponsiveness
4. Absence of pupillary reflexes = fixed pupils
5. Absence of response to pain stimuli applied to cranial nerve innervation regions
6. Absence of brain stem reflexes
    a. Corneal

   b. Oculovestibular
   c. Oculocephalic
7. Muscle atonia
8. Straight line of EEG for 30 minutes (not less than 12 hours or 6 hours when EEG used)

Ethical problems or organ donation and transplantation

Major ethical values

- Donation is a voluntary altruistic act
- Informed and voluntary consent for donation
- Privacy and dignity of the patient guaranteed
- Distributive justice

Examples of donations

- Living organ donation
- Relatives
- Unrelated donors
- Cadaveric donation
    - Full protection of potential donors' rights – establishment of brain death from an independent team of 3 physicians
    - Providing informed consent for donation before death or from a relative after death
    - Removal of the organ – time and team
- Brain dead donors
- Non-heart beating cadaver donors
    - Dead patients brought into hospital, sometimes after unsuccessful resuscitation. They can be donors of skin, bones, cornea, or heart valves
    - Patients on intensive care units with heart failure, who for reasons of futility of treatment, will not be or are unsuccessfully resuscitated and who have agreed (or would not presumably not object) to become organ donors, can be a source of any type of organ or tissue
    - Informed consent is obtained from the prospective donors or from the relatives after death
    - Information provided for an informed decision should include data about the risks of transplantation, organ compatibility tests, measures of organ protection till the moment of removal, what will be donated, what will happen in case of refusal to donate
    - Declared living consent → USA, Canada, England, the Netherlands, Germany, Ireland; final decision – by the relatives
    - Presumed consent → Wells, Belgium, Bulgaria, Nordic countries – the consent is presumed in absence of proofs for refusal
    - No legal regulation of donor's consent

There may be an ethical conflict between the principle of beneficence and the principle of non-maleficence.
Risk from a procedure without a direct medical benefit for the donor.

Health risks for the donor

- Only paired organs or parts of self-regenerating tissues or organs or organs that will still function without them (a portion of the liver, lobe of the lung)
- Age of donor – over 18 years
- Donors aged under 18 – only for self-regenerating tissues and cells
    - Can be used as donors for their relatives only in case of:
        - Absence of suitable donor aged over 18
        - Transplantation is a life-saving procedure for the recipient
        - Close genetic relation
        - Informed consent of the parents or legal guardian
        - If the child has the capacity to express consent, it should be taken into account
- Informed consent is always needed
- Family/emotional relationship put external or internal coercion on the decision process
- Organs from anencephalic infants – parent's consent is needed
- No health risks to be transmitted to the recipient (HIV, Hepatitis B/C, genetic diseases)
- Expert examination of physical and mental health of the donor

- Advertisements, payment, and trade of organs is prohibited
- Incompetent people cannot be donors

Informed consent

- It has to guarantee personal autonomy of potential donors
- "Opt-in" systems: explicit informed consent by the deceased person before death is required (by carrying an organ donor card, a written statement, a notice in the driver license etc)
- A combination of individual consent and proxy consent as a substitute and guardian of the deceased person's will
- "Opt-out" system is based on presumed consent and people who reject the donation option have to explicitly state their will (e.g., by registering in a data bank, or by personal communication)
- Dead bodies are no longer subject to personal rights, and thus, implies a right of society to dispose of organs
- In Scotland potential donors have declared their will to become donors in advance
- Bulgaria – Law for transplantation, 2003
- Declared living refusal for donation
- In case of not expressing any will, after the death a consent is obtained from the relatives

Distribution of transplantable organs

The shortage of organs brings the potential recipients in a situation of competition

Criteria for selection of organ recipients:

- Medical = diagnosis, extent of the disease, probability of success, time on waiting list, best immunological match
- Other = marital status, social status, unhealthy habits, mental problems

Some specific problems:

- Neurotransplantation of embryo and fetal tissues obtained from aborted embryos for treatment of some neurological diseases after obtaining consent of the woman
- Amniotic cells and blood stem cells from the umbilical cord of the new-borns after obtaining consent of the mother
- Transplantation of animal organs to humans
    - Intrusion into natural laws
    - Higher risks as compared to homotransplantation
    - Risks of transferring new diseases to human
    - Harm to the animals

WMA Statement on Organ and Tissue Donation (adopted by the 63rd World Medical Association General Assembly, Bangkok, Thailand, October 2012)

Based on the principles of altruism, autonomy, beneficence, equity, and justice

- Raising public awareness
    - It is important that individuals are aware of the option of donation and have the opportunity to choose whether or not to donate organs and/or tissue after their death
- Key principles to be included in the national protocols for organ and tissue donation from deceased donors
    - Decisions to withhold or withdraw life-prolonging treatment should be completely separate from any decisions about organ donation
    - The diagnosis of death should be made according to national guidelines and as outlined in the WMA's Declaration of Sydney on the Determination of Death and Recovery of Organs
    - There should be a clear separation between the treating team and the transplant team. The physician who declares or certifies the death of a potential donor should not be involved in the transplantation procedure or in the care of the organ recipient
    - Potential donor's wishes are paramount. Relatives and those close to the patient should be strongly encouraged to support a deceased person's previously expressed wish to donate organs and/or tissues
    - Donation should be unconditional. In exceptional cases, requests by potential donors, or their substitute decision makers, for the organ or tissue to be given to a particular recipient may be considered if permitted by national law
- Allocation of organs from deceased donors
    - Policies governing the management of waiting lists should ensure efficiency and fairness
    - Criteria that should be considered in allocating organs or tissue include:
        - Severity and urgency of medical need
        - Length of time on the waiting list

- Medical probability of success measured by such factors as age, type of disease, likely improvements in quality of life, other complications, and histocompatibility
- There should be no discrimination based on social status, lifestyle, or behaviour. Non-medical criteria should not be considered

WMA advocates informed donor choice

Countries that have adopted or are considering a policy of "presumed consent" (or opt-out), or "mandated choice", should make every effort to ensure that these policies do not diminish informed donor choice. National donor registries to be established in order to collect and maintain a list of citizens who have chosen either to donate or not to donate their organs and/or tissue. Detailed information, proper controls and safeguards are essential for the protection of living donors.

Prospective donors or their substitute health care decision makers should have access to accurate and relevant information about:

1. The procedures and definitions involved in the determination of death
2. The testing that is undertaken to determine the suitability of the organs and/or tissue for transplantation and that this may reveal previously unsuspected health risks in prospective donors and their families
3. Measures that may be required to preserve organ function until death is determined and transplantation can occur
4. What will happen to the body once death has been declared
5. What organs and tissues can be donated
6. The protocol that will be followed in the event that the family objects to donation
7. The possibility of withdrawing consent

Bulgarian Law on Transplantation of Organs, Tissues, and Cells (in force from 01.01.2004)

History of transplantation in Bulgaria

- 1968 – the first kidney transplantation was performed
- 1986 – was made the first successful heart transplantation
- 1996 – begins the transplantation of hematopoietic stem cells and bone marrow cells

Chapter One - General Provisions

This law shall regulate the conditions and order of commitment of transplantation of organs, tissues, and cells in human medicine.

- Article 3 Transplantation shall be conducted under conditions which guarantee equal rights of patients, in necessity of transplantation, as well as protection of human rights and freedoms of actual and potential donors and recipients
- Article 4
  - (1) Transplantation shall be conducted in accordance with medical standards and selection criteria, approved in a regulation of the Minister of Health
  - (2) Transplantation shall be performed only when other therapeutic methods shall be less effective, or not applicable.
- Article 5 Human organs shall not be a subject to retribution deal.

Chapter Two - National Transplantation System

- Article 10 (amended - State Gazette, 36/2009)
  - (1) The Minister of Health shall administer the government policy in the field of transplantation.
- Article 11 The Executive Agency Medical Supervision shall be the competent authority to manage, coordinate and control transplantation in the Republic of Bulgaria.
- Article 12
  - (1) Under Council of Ministers shall be established and Ethical Commission on Transplantation.
  - (2) Commission under paragraph 1 shall consist of nine members and shall include mandatory physicians, psychologists, theologians, and lawyers. The staff of the Commission shall be determined by a decision of the Councils of Ministers on proposal of the Minister of Health, for a period of five years. Ethical Commission on Transplantation shall give opinions on deontological and ethical issues in the field of transplantation and shall permit collecting of organs and tissues from persons in cases under this law.

Chapter three - Collecting of Organs, Tissues, and Cells

Section I - Collecting of Organs, Tissues, and Cells from Deceased Human Bodies

- Article 18
  - (1) Collecting of organs, tissues and cells might be done from human cadaver, after detection of death, in accordance with the medical criteria and order, determined by regulation of the Minister of Health.
  - (2) When all functions of the brain have stopped irreversibly and active heart function, death shall be detected, by a permanent commission, composed of three physicians.
- Article 19 In case, the person had been declared written refusal to collecting organs, tissues, and cells, it shall not be allowed.
  - (2) Collecting of organs, tissues and cells shall not be allowed from cadaver of a person under 18 years of age, as well as persons under judicial disability, unless with the written consent of his/her parent, guardian, or trustee. The refusal to collecting organs, tissues and cells shall be expressed to the general practitioner by signing declaration, approved by the Minister of Health on proposal of the Executive Agency Medical Supervision.

Section II - Collection of Organs, Tissues and Cells from a Living Donor

- Article 24
  - (1) Collecting of organs, tissues and cells from donor shall be conducted only under the condition, that it shall not harm his/her life and his/her notarized written consent had been received, after preliminarily in a comprehensive language the undertaken risks had been explained to him/her.
  - Donor might withdraw the given consent any time prior to collecting of organs, tissues, and cells.
  - Collecting of organs for transplantation from a person under the age of 18 shall not be allowed. Collecting of organs for transplantation from person under 18 years of age, shall be allowed only in cases specified in this law.
  - The physical and psychological health of the donor shall be established by a commission, assigned by the director of the medical institution, conducting the collecting of organs, tissues, and cells, consisting of at least three physicians, who shall not participate in the collecting, or transplanting team, under protocol, signed by all members of the commission.
- Article 25 Only one from even organs, or a part of self-reconstructive organs might be collected for transplantation from a living donor.
- Article 26 Donor of organs and tissues might be only a person, who shall be a spouse, or a relative of direct descent, or collateral relative to fourth degree, including relationship, based on adoption, but not earlier than three years after the adoption, in case, when the donor shall be adoptive parent, which shall be verified by an official document.
- Article 27 Collecting of self-reconstructive tissues from persons under 18 years of age shall be conducted only when the transplantation shall be intended for parent, spouse, brother, or sister, son, or daughter, under the following conditions:
  - non availability of suitable donor over 18 years of age.
  - transplantation shall be a lifesaving treatment

Section III - Collecting of Embryonic organs, Tissues and Somatic, Cells from Placenta and Amniotic Cell

- Article 30
  - (1) Embryonic organs, tissues and somatic cells, placenta cells, and amniotic cells intended for transplantation might be collected from fetus after miscarriage, after receiving informed consent from the woman, who had aborted the fetus.

Section IV - Collecting of Organs, Tissues, and Cells from Animals

- Article 31 Animal organs, tissues and cells might be used for transplantation under conditions and order, determined by regulation of the Minister of Health.

Chapter Four - Transplanting of Organs, Tissues and Cells

- Article 32 Transplanting of organs, tissues and cells shall be conducted only under the condition that:
  - the recipient and his/her legal representatives had given informed consent for the future transplanting procedure.
  - the recipient had been included in the official registry of the Executive Agency Medical Supervision.

Previous oral exam questions

- **WHO says that the central unit of national health system is:**
  - *Primary care*
- **What medications does NHIF not pay for?**
  - *As stated in the National Frame Contract → narcotics and intoxicating agents*
- **How much of monthly wage is for insurance and what is the ratio that employer: employee pays for**
  - *8% of monthly wage*
  - *60:40*
- **Main Bradford Hill criteria**
  - *Temporality*
- **Activities of the WHO**
  - *Management and coordination of international health activities*
  - *Assisting governments to develop national health services*
  - *Development of agreements, conventions, and more concerning international and national health issues*
  - *Cooperation with the specialized agencies of the UN system - UNICEF, FAO, UNESCO*
  - *Stimulating scientific research*
  - *Specialization and training of medical staff*
  - *Development of international standards for food, biological and pharmaceutical products*
  - *Publishing activity etc.*
- **Definition of patient**
- **Definition of the law**
- **What's an example of a cohort study?**
  - *Framingham Heart Study*
- **Equation for chi squared**
- **Transplantation laws**
- **Difference between parametric and non-parametric?**
  - *Parametric assumes that the variable measured in the sample is normally distributed in the population whereas non-parametric tests make no assumption.*
- **Difference between public fund and private system**
- **Theories of acceleration**
- **Childcare-new-born screening**
- **Definition of standard error**
- **Definition of standard deviation**
- **Types of questionnaires**
- **Define euthanasia**