

# Step 2 CK – Important Ethics Concepts

## Health Care System

7 questions

### Summary

The US health care system consists of a multitude of subsystems and is subject to different regulations in different states. There is no universal health care coverage, and a significant number of individuals do not have health insurance. Health insurance may be funded by the state (e.g., Medicare), employers, individuals, or a combination thereof. There are two widely used health insurance payment models, which are used by both public and private health insurance systems: fee-for-service and value-based performance models.

### Epidemiology

- According to the US Census Bureau reports published in September 2020:
  - 8% (26.1 million) of Americans did not have health insurance during 2019.
  - 92% of Americans had health insurance coverage during 2019.
    - 68% via private insurance
    - 34.1% via public insurance

### Health insurance funding

#### A. Government-funded health insurance

- **Definition:** any of the federal social health care programs enacted with the revisions to the Social Security Act aimed at providing health insurance to specific groups

#### Medicare

- Eligibility
  - Individuals  $\geq 65$  years old
  - Patients with end-stage renal failure or amyotrophic lateral sclerosis
  - Individuals with permanent disabilities **irrespective** of age
- **Parts:** The two main coverage options are Original Medicare (part A and part B) and Medicare Advantage (part C). Individuals also have the option of adding part D to their main coverage.
  - Part A: hospital care, hospice care for terminal patients, skilled nursing facility care (if services are needed daily after a minimum 3-day stay in a hospital)
  - Part B: doctors' fees, emergency department visits, diagnostic tests, rehabilitation
  - Part C (Medicare Advantage Plan): all services covered by parts A and B, plus a private insurance plan
    - "All in one" plan that allows people to enroll in a private health insurance plan approved by Medicare
    - Medicare pays other organizations, e.g., insurance companies, hospital systems, and managed care organizations, to provide care.
  - Part D: prescription drugs

#### Medicaid

- **Funds:** jointly funded by the state and federal government
- Eligibility
  - Nonfinancial
    - Beneficiaries must be American citizens or lawful permanent residents.
    - Individuals must live in the state in which they receive their coverage.
  - Financial: households with an income at or below 133% of the federal poverty level (which includes individuals, families, and pregnant women)
    - All low-income Americans < 65 years of age
    - Children at 133% of the federal poverty level are covered in every state.
    - Coverage for adults with an income at or below 133% of the federal poverty level is decided by each state.
- **Coverage:** hospital care, laboratory tests, diagnostic tests (such as x-rays), doctors' visits, skilled nursing care, vaccinations, home health care

#### Children's health insurance program (CHIP)

- **Eligibility:** uninsured children of families with low income, but not low enough to qualify for Medicaid

#### B. Private health insurance

- Used by more than half of the American population
- May be employer-sponsored (most common), college-sponsored, or purchased individually

#### C. Self-pay patient

- Individuals who pay out-of-pocket for a health care service and do not have any third-party coverage from a government entity (e.g., Medicare, Medicaid), private health care insurer, or plan
- Typically includes patients who:
  - Cannot or do not want to pay a fixed monthly premium
  - Have chronic or preexisting conditions not covered by an insurance company

### Health insurance basics

#### A. Health insurance premium

- **Definition:** a payment made to the health insurance provider, typically monthly. Premiums usually depend on the policy type and individual risk.
- Characteristics
  - The premium depends on the type of policy and individual factors (e.g., individual or family plan).
  - The deductible, copayments, and coinsurance are paid separately.
  - It can be paid by individuals (monthly), an employer, or both.
  - If individuals receive insurance through an employer, they pay the premium through payroll deductions.
  - Generally, plans with a higher premium will have lower out-of-pocket expenses (i.e., a lower deductible and copayments).

#### B. Out-of-pocket expenses

- **Definition:** payments made by individuals to their insurance company, including deductibles, coinsurance, and copayments
- Out-of-pocket maximum
  - An annual limit on the amount of money that an individual has to pay for covered health care services in a year (not including premiums)
  - After this amount is reached, all covered health services are paid in full by the health plan for the rest of that plan year.
  - Payments that apply to the deductible, copays, and coinsurance also apply to the out-of-pocket maximum.

#### C. Deductible

- **Definition:** a predetermined amount paid out of pocket by the patient before the insurance company begins to pay
- Types of deductible
  - Comprehensive deductible: applies to and includes all areas of coverage of the health insurance policy
  - Noncomprehensive deductible
    - Applies to specific areas of coverage or medical expenses in a health insurance policy
    - Not all medical areas of coverage in the plan have a deductible.
  - Individual deductible: a deductible that each individual in the plan pays
  - Family deductible: a deductible that usually applies to two or more individuals
    - Embedded deductible

- Two deductible amounts within one insurance plan (individual and family)
      - Each member contributes the same amount towards meeting the deductible.
      - Once a member of the plan meets the deductible, the individual becomes eligible for copayment and coinsurance (out-of-pocket expenses).
    - True family deductible
      - Members can meet the deductible by pooling expenses.
      - Can be met by all members or just one member of the family
      - There is no limit to the amount each member can pay towards meeting the family deductible.
      - Once the deductible is met, the entire family is eligible for copayment and coinsurance.
  - Characteristics
    - Typically annual
    - After the deductible is paid, the individual usually only pays for copayment or coinsurance for covered services.
    - Generally, plans with lower monthly premiums have higher deductibles and vice versa.
      - If the individual is healthy and does not expect costly medical services: higher deductible and lower premium
      - If the individual has a medical condition and expects costly medical services: lower deductible and higher premium
  - Example:** A \$2,000 deductible means the individual needs to pay \$2,000 in medical expenses. After reaching that amount, the insurance provider covers the remainder.
- D. Copayment
- Definition:** a **fixed amount** paid by the patient to a health service provider at the time of the service (e.g., doctor's appointment, filling of a prescription)
  - Characteristics
    - Typically defined in the insurance policy
    - Paid each time the patient receives medical services
    - The amount can vary by the type of service (e.g., prescription drugs, lab tests).
    - Meant to discourage individuals from seeking unnecessary medical care
    - Sometimes counts towards meeting the deductible
    - Generally, plans with lower monthly premiums have higher copayments and vice versa.
  - Example:** a health insurance plan that allows a doctor's appointment cost of \$100 and sets the copayment for this service at \$20
    - If the individual has not reached the deductible, they will pay the full amount for the visit (\$100).
    - If the individual has reached the deductible, they will pay \$20 at the time of the visit.
- E. Coinsurance
- Definition:** a payment of a predetermined **percentage** made to the insurance provider after the individual has met the deductible
  - Characteristics
    - Refers to the individual's share of the costs of a health care service
    - Must be paid before any policy benefit is paid by the insurance company
    - This applies to covered services and is paid in addition to the copayment.
    - Typically paid after the individual meets the deductible
    - Billed by the provider directly to the individual
    - Generally, plans with low monthly premiums have higher coinsurance and vice versa.
  - Example:** If an insurance plan covers 85% of the costs, the individual is responsible for the remaining 15% (this 15% is the coinsurance).
- F. Health insurance network (preferred providers)
- Definition:** a group of health care providers, suppliers, and facilities that have a contract to provide services to members of health insurance plans at a discounted rate
  - In-network
    - A health care professional, hospital, and/or service provider who has a contract with the insurance company to provide services at a discounted price
    - In-network copayment and coinsurance usually cost less than out-of-network copayment and coinsurance.
    - Exclusive provider organization (EPO) and health maintenance organization (HMO) plans only cover in-network care, except in the case of a medical emergency.
  - Out-of-network
    - A health care professional, hospital, and/or service provider who does not have a contract with the insurance company to provide services at a discounted price
    - Out-of-network copayment and coinsurance usually cost more than in-network copayment and coinsurance.
    - Preferred provider organization (PPO) plans may have out-of-network care coverage. However, the out-of-pocket cost for out-of-network care may be significantly higher than for in-network care.

## Health care payment models and health insurance plans

### Health care payment models

- Fee-for-service
  - Health care providers are compensated by the insurer and/or patient for **each individual service** provided (e.g., individual laboratory tests, imaging studies, procedures).
  - Dominant payment model in the US
  - Incentivizes health care providers to overtreat patients because compensation is based on the number of services provided
  - Associated with high overall health care costs
  - Discounted fee-for-service
    - A fixed payment schedule with discounted prices negotiated between health care providers and payers for each individual service
    - Often used by PPOs
  - Per diem payment (per day payment)
    - A fixed amount per patient per day paid to the health care provider for a specific care service provided, regardless of the actual costs involved in providing services for a particular patient.
    - Often used for reimbursement of inpatient services
    - The rates are typically stratified. A hospital can be paid different rates depending on the service provided (e.g., a hospital is paid a rate for a surgical day and a higher rate for a critical care unit day).
- Capitation
  - Health care **practitioners** are compensated a **fixed amount** by the insurer during each payment period, regardless of the actual amount of health care services utilized by the patient.
  - Often used by HMOs
  - The payment period is usually monthly.
  - Incentivizes health care providers to deliver efficient care (e.g., cost-effective preventive health care to avoid larger downstream costs)
  - Carries the risk that patients will be undertreated because compensation is not based on the quantity or quality of services provided
- Global payment
  - The insurer makes a **single, fixed payment** to a health care organization for the needs of a **population of patients** (i.e., enrollees in a health plan) during a specified time period (e.g., monthly or yearly) for expenses associated with an incident of care.
  - Usually paid to a single health care organization
  - Covers a wide range of services: typically includes physician fees, hospital services, tests, prescription drugs, and other services, such as follow-up visits
  - Often used for nonurgent surgery, with the coverage extending to all costs associated with the pre- and postoperative visits
  - Incentivizes health care providers to coordinate, deliver efficient care, and keep expenses low

- Holds providers fully accountable for compensated services
- Bundled payment
  - The insurer makes a **fixed payment** to a health care organization for **all** services provided for a **clinically-defined episode** of care (e.g., hip replacement, cholecystectomy).
  - The compensation is distributed among all health care providers involved in the care of the patient during that defined episode.
  - Incentivizes health care providers to deliver coordinated and efficient care (e.g., health care providers avoid unnecessary procedures, duplicate tests)
  - Typically based on the estimated cost of all of the services a patient would require during a single medical treatment episode or procedure
  - Example: a payment beginning 2 days prior to a knee replacement surgery and extending 30 days past a patient's discharge from the hospital for this procedure
- Pay for performance (P4P)
  - A payment model in which compensation depends on health care providers meeting certain metrics for the quality and efficiency of care provided
  - Calculated using specific measures of quality and by determining the overall health of populations
    - Providers are required to report specific metrics (e.g., safety, clinical care, efficiency and cost reduction, and patient and caregiver-centered experience) to payers and demonstrate improvement.
    - Providers typically track and report data on hospital readmissions, adverse events, population health, and patient engagement.
  - Improves value and quality of care by encouraging adherence to clinical guidelines and proven best practices (move from volume to value and better outcomes) through financial incentives
  - Motivates health care providers to protect and improve their reputation; improves accountability and transparency
  - Disadvantages
    - Reimbursement issues: Medicare penalizes hospitals with poor performance.
      - Payments are reduced by 2% and the funds are redistributed if the provider's performance or quality of care measures are unsatisfactory.
      - Hospitals with high readmission rates for specific episodes of care (i.e., myocardial infarction, heart failure, COPD, pneumonia) have their payments reduced by up to 3%.
      - Hospitals in the bottom quartile of performance based on nosocomial conditions with high readmission rates (e.g., CLABSI, CAUTI, surgical site infections, MRSA, C. difficile infections) have their payments reduced by 1%.
    - High administrative costs to gather data
    - Reduces access for socioeconomically disadvantaged patients: Health practitioners may not be incentivized to treat these patients, as they may have difficulty attending follow-ups and paying for treatment, which may lower performance on P4P measures.

#### Common types of health insurance plans

Health insurance plans				
Common <u>health insurance plans</u>	Health care delivered through	Coverage	Specialist care	Member costs
Health maintenance organization (HMO)	<ul style="list-style-type: none"> <li>• Network of doctors, specialists, and hospitals</li> <li>• The primary care physician is the first contact person.</li> </ul>	<ul style="list-style-type: none"> <li>• No coverage for <u>out-of-network</u> providers, except emergency visits that are covered at <u>in-network</u> rates</li> <li>• Low out-of-pocket payments</li> </ul>	<ul style="list-style-type: none"> <li>• <u>Referral</u> needed from primary care physician to see a specialist</li> <li>• Women have direct access to obstetric and gynecological care.</li> </ul>	<ul style="list-style-type: none"> <li>• Low (most affordable)</li> </ul>
Point-of-service (POS)		<ul style="list-style-type: none"> <li>• Coverage for <u>out-of-network</u> providers</li> <li>• High out-of-pocket payments</li> </ul>	<ul style="list-style-type: none"> <li>• <u>Referral</u> needed from primary care physician to see a specialist</li> </ul>	<ul style="list-style-type: none"> <li>• Moderate</li> </ul>
Preferred provider organization (PPO)	<ul style="list-style-type: none"> <li>• Network of doctors, specialists, and hospitals</li> <li>• No primary care physician needed</li> </ul>	<ul style="list-style-type: none"> <li>• Coverage for <u>out-of-network</u> providers</li> <li>• High out-of-pocket payments</li> </ul>	<ul style="list-style-type: none"> <li>• Specialists can be seen without a <u>referral</u> from a primary care physician.</li> </ul>	<ul style="list-style-type: none"> <li>• High</li> </ul>
Exclusive provider organization (EPO)		<ul style="list-style-type: none"> <li>• No coverage for <u>out-of-network</u> providers</li> </ul>		<ul style="list-style-type: none"> <li>• Low</li> </ul>
Accountable care organization (ACO)	<ul style="list-style-type: none"> <li>• Coordinated network of doctors, specialists, and hospitals that are voluntarily enrolled</li> </ul>	<ul style="list-style-type: none"> <li>• <u>Medicare</u> patients</li> </ul>	<ul style="list-style-type: none"> <li>• Enrollment of specialists on a voluntary basis</li> </ul>	<ul style="list-style-type: none"> <li>• Varies</li> </ul>

#### Social aspects of health care

Just and equitable health care benefits a society as a whole by ensuring certain standards of public health that, in turn, reduce the burden of disease on the entire population. Accordingly, a health care system should strive to provide access and treatment to all population groups regardless of identity and socioeconomic status, while ensuring that underprivileged groups are not ignored.

Recognizing and addressing inequalities due to social health determinants can improve the health of the most vulnerable and at-risk groups.

##### A. Social justice in health care

- **Definition:** delivery of high-quality and fair treatment, regardless of an individual's age, race, ethnicity, economic status, disability, or sexual orientation
- Types of social injustice in health care
  - Distributive injustice: allocation of health care resources to the disadvantage of certain individuals or groups who require said resources to the same degree as those to whom they are made available (e.g., coverage of disease-modifying multiple sclerosis therapies for uninsured women but not uninsured men, who less commonly develop the disease but benefit equally from the treatment)

- Relational injustice (identity devaluation): allocation of health care resources to the disadvantage of certain individuals or groups due to prejudice (e.g., refusing health care to individuals with limited proficiency in English)
  - Measures to improve social justice in health care
    - Measures to improve distributive justice
      - Allocate resources in ways that benefit more people (e.g., set up a budget inclusive of underserved populations).
      - Further develop distributive justice indices.
      - Foster patient relationships (e.g., involve patients in the decision-making process and emphasize their involvement in determining outcomes).
    - Measures to improve relational justice
      - Provide training to ensure health care providers are culturally competent and advocate for patient rights.
      - Create diverse care delivery models (e.g., by increasing diversity in recruiting of health care providers, on-site interpreter services, hiring staff members that speak multiple languages pertinent to the community it serves).
      - Provide virtual clinical services to enhance access to the most vulnerable groups and to facilitate scheduling (e.g., telemedicine, remote patient monitoring).
      - Allocate funds to ensure equitable care is provided to underserved populations.
- B. Health care disparity
- **Definition:** differences in health care quality and/or outcomes among specific populations due to economic, social, and/or environmental factors
  - Measured by:
    - Access to health care
    - Quality of care received
  - Consequences
    - Earlier onset of illness
    - Severe disease
    - Poorer quality of care
    - Reduced lifespan
- C. Social determinants of health
- **Definition:** the political, cultural, and socioeconomic conditions into which individuals are born and with which they live that have an impact on health, e.g., education, the environment, nutrition, wealth distribution, gender, race, and/or access to health care
  - Race or ethnicity
    - On average, minorities, particularly black, Asian, and Latino Americans, have more limited access to health care and other community health resources.
    - These individuals are often more acutely ill when they do find a source of care and incur higher medical costs.
    - Studies have shown that physicians tend to have unconscious racial bias, leading to poorer communication and lower quality of care.
  - Gender roles, identity, and sexual orientation
    - Members of the LGBTQ community may experience discomfort with genital, breast, or rectal exams, or when discussing sexual issues.
    - Judgemental attitudes toward patients compromise the doctor-patient relationship and physician's ability to provide good health care. They also discourage patients from seeking medical attention
  - Education and literacy
    - Considered the strongest social determinant of health
    - An individual's level of education influences their type of employment and potential income, which in turn influence an individual's socioeconomic status
    - Low literacy can negatively impact an individual's health outcome
      - Without the appropriate literacy skills, patients may not be able to obtain and understand basic health information and services needed to make appropriate health decisions for themselves.
      - Results in barriers to health care and insurance access
      - Associated with adverse health outcomes due to underutilization of preventive services, increased rates of hospitalization, nonadherence to treatments, and higher mortality rates
  - Socioeconomic status
    - Mostly determined by race/ethnicity in the US
    - Low socioeconomic status often involves reduced access to job opportunities and higher education.
    - Income determines access to social and health resources (e.g., timely health care, preventive health care, healthy habits, food security).
    - Low-income populations are more likely to be targeted by the fast food and tobacco industries, which encourage unhealthy habits.
  - Housing
    - Access to and/or affordability housing (e.g., unaffordability increases the risk of homelessness)
    - Environmental hazards are associated with poor housing conditions (e.g., presence of mold, water leaks, lead paint)
    - Neighborhood conditions
      - Access to nutritious food, transportation, parks, clean water, unpolluted air, low crime rates, safe streets, and sidewalks
      - Individuals living in disadvantaged neighborhoods are more likely to have poor health outcomes and chronic conditions.
  - Mental health and disabilities
    - Interpersonal safety: Individuals who live in households in which family members are abusers, have committed crimes, and/or have drug and alcohol use disorders are more likely to have mental health and/or substance use disorders later in life.
    - Individuals with disabilities have more challenges accessing economic opportunities and resources (e.g., technology, fitness facilities).
      - Negatively affects socioeconomic status and social environment
      - Leads to decreased access to health care
- D. Approach towards social determinants of health
1. Learn about how social factors influence health.
  2. Acknowledge and address implicit bias.
    - Look for behaviors that signal mistrust in the patient.
    - Inquire about past experiences of racism in a health care setting and acknowledge the possible harm done.
    - Treat patients with dignity and respect.
  3. Inquire about and seek to understand the patient's community.
    - Create a safe space for disclosure of information.
    - Evaluate a patient's mental health and social support systems.
    - Inquire about cultural preferences/norms (e.g., culturally-imposed beliefs, awareness and acceptance of cultural differences, procedures and tests that go against a patient's culture).
    - Determine how the patient wants to address their health problem.
    - Inform the patient that members of the community can be present at consults.
  4. Establish a rapport with the local health departments and county and city health officials.
  5. Encourage health care teams to ask patients about their social challenges and connect patients with resources within their communities (e.g., organizations that provide financial assistance, food assistance, job placement, and training).
  6. Develop processes that promote health literacy by presenting information clearly and adapting to the patient.
    - In the case of a language barrier, document the language preference and assess the need for medical interpretation.
    - Maintain eye contact and avoid speaking too quickly.
    - Break down information by repeating instructions in an understandable manner (i.e., use plain language instead of medical jargon or technical language).
    - Use visual aids to illustrate a procedure or condition.
    - Assess the patient's understanding of the information provided without shaming them or causing embarrassment.
    - Have the patient explain the instructions themselves and/or demonstrate the relevant procedures.
    - Provide the patient with forms and educational resources in their own language.

- Schedule follow-up appointments with a family member present.

## Health care access

US Congress and state legislatures have implemented a number of policies in attempts to extend and guarantee access to health care.

### A. Emergency medical treatment and labor act (EMTALA)

- **Definition:** an act passed by Congress in 1986 that requires emergency departments to evaluate, treat, and stabilize patients presenting with emergency medical conditions (including labor) regardless of the patient's ability to pay for the treatment provided
- Aims
  - Ensure public access to emergency services
  - Reduce the incidence of patient dumping and inappropriate discharging
  - Prevent refusal to treat indigent patients
- Characteristics
  - Hospitals cannot refuse emergency treatment for any reason, including age, sex, religious affiliation, or other characteristics.
  - Hospitals should not obtain prior authorization from the insurance company before screening or stabilizing a patient.
  - Hospitals can be held liable for injuries or deaths that result from refusing to admit or treat a patient.
- Disadvantages
  - EMTALA has led to inappropriate use of the emergency department by uninsured patients and subsequent overcrowding.
  - Negatively affects the efficiency and type of services provided (e.g., prolonged waiting times, stressful therapeutic environments, poor clinical outcomes)
  - Reimbursement issues
    - Health plans deny or reduce payments, claiming:
      - Treatment was not medically necessary.
      - The individual did not have an emergency condition.
      - Treatment was provided at an out-of-network hospital.
    - The number of physicians willing to serve in emergency departments has declined due to uncompensated care.
    - Hospitals are closing emergency departments and are under increasing financial strain: Hospitals made up for uncompensated care by charging more for services for the insured. However, due to changes in the payment system, this is no longer possible.

### B. Critical access hospital

- **Definition:** a designation created by Congress in 1997, through the Balanced Budget Act, that is assigned to small hospitals in rural areas by the Centers for Medicare and Medicaid Services in order to ensure and improve access to health care services
- Aims
  - Improve access to health care services in rural areas
  - Reduce the financial vulnerability of hospitals in rural areas
- Characteristics
  - Specific requirements must be met (e.g.,  $\leq 25$  inpatient beds, located  $\geq 35$  mi or  $\geq 56$  km from another hospital, continuous emergency care services).
  - Each state decides how Medicaid reimbursements will be paid (e.g., pay-for-performance, fee-for-service).
  - Critical access hospitals need to maintain quality assurance and improvement with organizations or hospitals that are part of the network.
- Disadvantages
  - Negatively affects the efficiency and type of services provided due to challenges in recruitment and retention of health care professionals
  - Reimbursement issues lead to financial insecurity for some hospitals.

### C. Affordable care act (Obamacare)

- **Definition:** a comprehensive health care reform law made by the US Congress in 2010 to ensure and expand affordable health care
- Aims
  - Make health insurance affordable for more people, especially individuals who cannot afford it
  - Expansion of eligibility for Medicare
  - Support health care delivery models that lower the costs of health care
- Characteristics
  - Individuals are required to have health insurance for a minimum of 9 months out of every year.
  - Dependent children are covered until they reach the age of 26.
  - It subsidizes the cost of health insurance for people who have income below the federal poverty level.
  - Individuals pay reduced copayments and deductibles.
  - Services such as preventive screenings, prescription drugs, laboratory tests, hospitalization, and outpatient, maternity, mental health, and rehabilitative services are included.
- Disadvantages
  - Increased costs for insurance companies
  - Beneficiaries need to show proof of employment before being eligible for Medicaid.

### D. Patient-centered medical home (PCMH)

- **Definition:** a health care delivery model that provides comprehensive advanced primary care coordinated through the individual's primary care physician
- Aims
  - Facilitate patient and physician partnership
  - Patients receive necessary treatment at the time and place they need it
  - Improve quality and experience for patients and health care providers
  - Lower medical costs
- Characteristics
  - Patient-centered approach
  - The primary care physician is the first point of contact.
  - A multidisciplinary health care team is assembled according to the patient's need
  - Based on five core functions
    - Accessibility and continuity of services
    - Comprehensive and coordinated care
    - Patient and caregiver satisfaction
    - High-quality care and patient safety
    - Planned care and population health management
- Disadvantages
  - Not enough data to assess effectiveness
  - Not enough payers currently adopting this model
  - Evidence on cost is mixed.

### E. Health care fragmentation

- **Definition:** a lack of integration and coordination between the services of health care providers and/or organizations
- Causes
  - Reimbursement models that disincentivize care coordination (e.g., fee-for-service)
  - Prioritization of individual over shared accountability among health care providers in both medical training and practice
  - Lack of accessibility for health care providers or organizations to health care information generated by other providers or organizations
  - Breakdown in communication

- Window-shopping for services by patients and overutilization of specialist services
  - Variation among the practices and preferences of health care providers
  - Complexity of care required for patients with multiple comorbidities
- Consequences
  - Increased incidence of medical errors
  - High costs for health care
  - Gaps and discontinuities during transitions of care
  - High workload for health care providers
  - Increased risk of provider burnout
  - Unnecessary repetition of diagnostic and therapeutic interventions
- Prevention
  - Integrated delivery systems (IDS)
    - Organized networks that contractually require health care providers in the network to coordinate care across settings for a particular patient population
    - IDS are accountable as a whole for both economic and clinical outcomes of the services they provide.
    - Principles of prevention of IDS include:
      - Team-based care and multidisciplinary care models
      - Require all providers in the network to use the same practice guidelines.
      - Utilization of reimbursement models and insurance plans that incentivize care coordination (e.g., pay-for-performance, global payment, health maintenance organizations, accountable care organizations)
      - Ensure the correct proportion of personnel to demand in general and of physicians to specialists in particular
      - Provision of care according to the least invasive and most efficient option within the network
  - Electronic health record (EHR) systems with a high degree of interoperability
    - EHR interoperability enables authorized individuals to generate and share protected health information within and across the boundaries of an organization.
    - The 2009 HITECH Act was passed to encourage the adoption of EHR systems, but a lack of interoperability remains a major impediment to the integration of health care services.
    - Under the 21st Century Cures Act, the Department of Health and Human Services and Centers for Medicare & Medicaid Services have set up programs to incentivize the use of certified, interoperable EHR systems.
  - Handoffs among providers between shifts, following inpatient transfers, and before patient discharge
  - Introduction of systems-based practice curricula in medical education

## Infection Prevention and Control

11 questions

### Summary

Health care-based infection prevention and control programs aim to reduce the spread of infections between patients and health care personnel (HCP). The most commonly used methods include standard precautions, which are a universal set of precautions that should be taken with all patients, and isolation precautions, which are designed to break the chain of infection for specific infectious diseases. Standard precautions include hand hygiene and routine cleaning and disinfection of devices and surfaces. Community-based precautions are utilized for notifiable diseases and during epidemic and pandemic disease outbreaks. HCP may be exposed to infectious pathogens, either through insufficient use of isolation precautions or a breach of personal protective equipment (e.g., a needlestick injury). Any HCP who have been exposed to an infectious pathogen should seek immediate advice from their occupational health department to prevent the development of infection and/or reduce the risk of further transmission. Specific protocols exist to reduce the risk of health care-associated infections (HAIs), which are often associated with the use of indwelling devices such as urinary catheters. Some of the recommendations outlined in this article to prevent specific HAIs may differ depending on local infection patterns and between institutions, therefore, always consult hospital-specific protocols.

### Standard precautions

- Definition: standard practices that should be used for all patients to minimize the spread of infectious material, whether an infection is suspected or not
- Includes the following:
  - Hand and respiratory hygiene
  - Personal protective equipment (PPE): use of gloves, gowns, masks, and eye protection as needed
  - Aseptic and safe injection techniques
  - Routine cleaning, disinfection, and/or sterilization of devices, instruments, and surfaces

### Health care hygiene

#### A. Hand hygiene

- **Definition:** practices used to minimize pathogens on the hands of HCP
- Options
  - Antiseptic (most often alcohol based) hand rub: preferred method for unsoiled hands
  - Handwashing with soap and water: preferred method for soiled hands
- Basic precautions
  - Nails: cut short, no artificial nails
  - No jewelry on the hands or forearms
  - Avoid touching the face.
- General indications
  - If hands are not soiled, use alcohol-based hand rub before and after the following:
    - Work shifts and breaks
    - Contact with each patient and/or their immediate environment
    - Moving from contaminated to clean body sites on the same patient
    - Handling medication, syringes, invasive equipment, and infusions
    - Putting on and removing gloves
  - Wash hands with plain soap and water:
    - If hands are visibly soiled
    - Following exposure to spore-forming bacteria
    - Before eating and after using the restroom
    - If hand rub is not available
- Barriers to hand hygiene compliance
  - Work overload and time constraints
  - Poor situational awareness of the instances when hand hygiene should be performed
  - Intolerance or aversion to certain disinfectant formulations
  - Lack of a safety culture at the workplace
- **Measures to increase hand hygiene compliance:** The most effective measures to increase hand hygiene compliance are based on human factors engineering strategies.



- Implement **real-time feedback loops**, in which designated **hand hygiene** observers or **electronic hand hygiene systems** monitor compliance and provide immediate feedback (e.g., verbal feedback on improper technique, real-time data visualization of each hospital floor's **hand hygiene process measures**).
  - Repeat training sessions on **hand hygiene** frequently to increase **situational awareness**.
  - Increase the number of **hand hygiene** stations and visual reminders (e.g., posters) and provide them at easily accessible locations.
  - Provide alcohol-based hand rubs at **hand hygiene** stations.
- **Hand care:** to prevent occupational **irritant contact dermatitis**
  - Use **alcohol**-based rubs when possible to minimize handwashing.
  - Avoid using hot water.
  - Use **skin** care products (e.g., moisturizers, emollients) regularly.

Hand antisepsis and handwashing			
	Hygienic hand rub ( <b>antiseptic</b> hand rub)	Hygienic hand wash ( <b>antiseptic</b> handwashing)	Handwashing
Mechanism	<ul style="list-style-type: none"> <li>• Reduces the number of live bacteria and inhibits further growth on the hands</li> </ul>	<ul style="list-style-type: none"> <li>• Reduces the number of <b>transient flora</b> and inhibits further growth on the hands [2]</li> <li>• Physically removes contaminants from the hands</li> </ul>	<ul style="list-style-type: none"> <li>• Physically removes contaminants from hands</li> </ul>
Efficacy [3]	<ul style="list-style-type: none"> <li>• Most effective</li> </ul>	<ul style="list-style-type: none"> <li>• Second most effective</li> </ul>	<ul style="list-style-type: none"> <li>• Least effective</li> </ul>
Cleaning agent used	<ul style="list-style-type: none"> <li>• Hand rubs containing 60–95% <b>alcohol</b> [3]</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Antiseptic</b> soap or hand wash</li> </ul>	<ul style="list-style-type: none"> <li>• Plain soap (nonantiseptic and nonantimicrobial)</li> </ul>
Technique	<ul style="list-style-type: none"> <li>• Apply a palmful of alcohol-based hand rub onto dry <b>skin</b>.</li> <li>• Cover all surfaces of the hands and rub them together for at least 20–30 seconds until dry.</li> </ul>	<ul style="list-style-type: none"> <li>• Wet hands with water.</li> <li>• Apply enough soap or hand wash to cover all surfaces of the hands.</li> <li>• Rub the hands together vigorously for at least 15–20 seconds before rinsing.</li> <li>• Dry the hands completely with a disposable towel.</li> <li>• Use the towel or <b>elbows</b> to turn off the sink faucets.</li> </ul>	

When using any **hand hygiene** method, pay particular **attention** to the fingertips, thumbs, and the spaces between the fingers.

**Alcohol-based hand rubs** are preferred unless hands are visibly soiled or if there has been contact with **spore-forming** pathogens. Hand rubs are quicker to use, more effective, and less irritating to the **skin** than handwashing.

#### B. Respiratory hygiene

- **Definition:** practices used to control the transmission of respiratory infections (e.g., **influenza**, **COVID-19**)
- Methods
  - Place a mask on **coughing** patients.
  - Cover the mouth when **coughing** or sneezing.
  - Maintain a distance of 3–6 feet from others while **coughing** or sneezing.
  - Dispose of tissues after use.
  - Perform **hand hygiene** after **coughing** or sneezing or coming into contact with respiratory secretions.
  - See also “**COVID-19**: Infection control.”

#### C. Personal protective equipment (PPE)

##### Overview

- **Definition:** a collection of physical barriers to protect against and/or prevent the transmission of microbiological, chemical, and/or radiological hazards
  - Prevents the spread of infection between patients and **HCP**
  - Examples include gloves, gowns, masks, face shields, and **respirators**
- General principles
  - Work from clean to dirty areas.
  - Change gloves and gowns:
    - When heavily soiled
    - Before using shared or portable equipment
    - Upon leaving a patient's room
  - Perform **hand hygiene** before and after **PPE** use.

Ensure all staff who enter a patient's rooms (including students and nonmedical staff, e.g., housekeeping) receive adequate training on how to use **PPE** properly.

#### Types of PPE and proper use

**Standard precautions** and **isolation precautions** require **HCP** to use **PPE** in the following situations.

Types of PPE and proper use [6]	
PPE	Indications

Gloves	<ul style="list-style-type: none"> <li>Anticipated exposure to: <ul style="list-style-type: none"> <li>Body fluids or infectious material</li> <li>Mucous membranes</li> <li>Nonintact skin</li> <li>Chemicals</li> </ul> </li> <li>Aerosol-generating procedures</li> <li>Working with or around patients on <u>contact precautions</u></li> </ul>
Gowns	<ul style="list-style-type: none"> <li>Anticipated clothing and/or body exposure to blood or body fluids</li> <li>Aerosol-generating procedures</li> <li>Working with or around patients on <u>contact precautions</u></li> </ul>
Masks	<ul style="list-style-type: none"> <li>Anticipated exposure to: <ul style="list-style-type: none"> <li>Respiratory secretions</li> <li>Sprays or splashes of blood or body fluids</li> </ul> </li> <li>Should also be worn by <u>coughing</u> patients</li> <li>Aerosol-generating procedures</li> <li>When performing procedures requiring <u>sterile technique</u></li> <li>Working with or around patients on <u>droplet precautions</u></li> </ul>
<u>Respirators</u> (N95, elastomeric, <u>PAPR</u> )	<ul style="list-style-type: none"> <li>Aerosol-generating procedures with certain pathogens</li> <li>Working with or around patients on <u>airborne precautions</u></li> </ul>
Face protection (face shield, goggles)	<ul style="list-style-type: none"> <li>Anticipated exposure to: <ul style="list-style-type: none"> <li>Respiratory secretions</li> <li>Sprays or splashes of blood or body fluids</li> </ul> </li> <li>Aerosol-generating procedures</li> </ul>

#### Procedure-based PPE considerations

Some procedures, such as aerosol-generating procedures, clean technique procedures, and sterile technique procedures, require additional PPE.

- See “Isolation precautions” for PPE required during isolation precautions (e.g., contact, droplet, airborne).
- See “Presurgical infection prevention measures” for PPE required during surgical procedures.

<u>PPE</u> for procedures [6]			
	Purpose	Recommended <u>PPE</u>	Example procedures
Aerosol-generating procedures	<ul style="list-style-type: none"> <li>Reduces the transmission of infectious aerosolized particles</li> <li>Prevents patient to provider and patient to patient transmission</li> </ul>	<ul style="list-style-type: none"> <li>Gloves</li> <li>Gown</li> <li>Face protection: mask and <u>eye</u> protection (i.e., face shield or goggles)</li> <li><u>Respirator</u> if <u>M. tuberculosis</u>, <u>SARS-CoV-2</u>, <u>avian flu</u>, or <u>pandemic flu</u> are present or suspected</li> </ul>	<ul style="list-style-type: none"> <li>Bronchoscopy</li> <li><u>Endotracheal intubation</u></li> <li>Suctioning of respiratory secretions</li> </ul>
Clean technique procedures	<ul style="list-style-type: none"> <li><b>Reduces</b> the number of microorganisms that are present</li> <li>Prevents patient to provider transmission</li> </ul>	<ul style="list-style-type: none"> <li>Sterile equipment</li> <li>Nonsterile gloves</li> <li>Nonsterile gown, if splashes are expected</li> </ul>	<ul style="list-style-type: none"> <li>Peripheral venous blood draws</li> <li>Uncomplicated wound dressing changes</li> <li>Uncomplicated simple <u>laceration</u> repair [7]</li> </ul>
Sterile (aseptic) technique procedures	<ul style="list-style-type: none"> <li><b>Eliminates</b> any microorganisms that are present</li> <li>Prevents provider to patient transmission</li> </ul>	<ul style="list-style-type: none"> <li>Sterile equipment</li> <li>Sterile gloves</li> <li>Sterile gown (for some procedures)</li> <li><u>Surgical mask</u> for <u>surgery</u> and certain procedures</li> </ul>	<ul style="list-style-type: none"> <li>Urinary catheter insertion</li> <li><u>Central line</u> insertion</li> <li>Complicated or severe <u>laceration</u> repair</li> <li><u>Lumbar puncture</u></li> <li>Complicated wound dressing changes</li> <li><u>Surgery</u> (see “<u>Presurgical infection prevention measures</u>”)</li> </ul>

#### Putting on PPE (donning)

- Gather the required equipment, ensuring the correct size has been selected.
- Put on equipment in the following order:
  - Long-sleeved isolation gown: Fully cover the torso, extending from the neck to knees and ends of the wrists, then close the back.
  - N95 respirator or facemask: Secure and fit.
  - Eye protection (e.g., goggles or disposable full face shield): Place and adjust.
  - Clean, nonsterile gloves: Cover the cuffs of the isolation gown.



Example of donning PPE	
Order of PPE	Proper technique
Hygiene	<ul style="list-style-type: none"> <li>• Tie back hair.</li> <li>• Remove any jewelry, watch, and jacket.</li> <li>• Remove eyeglasses and clean them.</li> <li>• Check all PPE for damage.</li> <li>• Perform hand hygiene with hand rub.</li> </ul>
Gown	<ul style="list-style-type: none"> <li>• Put on the isolation gown and tie all closures.</li> </ul>
Mask or respirator	<ul style="list-style-type: none"> <li>• Mask <ul style="list-style-type: none"> <li>○ Put on the mask.</li> <li>○ Use both index fingers to gently mold the nosepiece for a proper fit.</li> <li>○ Ensure the mask covers the nose, mouth, and chin.</li> </ul> </li> <li>• Respirator <ul style="list-style-type: none"> <li>○ Hold the mask firmly to the face while placing the straps over the head.</li> <li>○ The top strap goes above the ears and rests on the crown of the head.</li> <li>○ The bottom strap goes below the ears and rests near the nape of the neck.</li> <li>○ Ensure the mask covers the nose, mouth, and chin.</li> <li>○ Use both index fingers to gently mold the nosepiece for a proper fit.</li> <li>○ Perform a “user seal check” by placing both hands gently over the mask while forcefully exhaling and inhaling, feeling for any air leaks.</li> </ul> </li> </ul>
Goggles or face shield	<ul style="list-style-type: none"> <li>• Place eyeglasses back on.</li> <li>• Place the goggles or face shield over any personal eyeglasses.</li> </ul>
Gloves	<ul style="list-style-type: none"> <li>• Put on disposable gloves of the correct size.</li> <li>• Ensure the gloves cover the cuffs of the gown and are tight enough to stay in place.</li> </ul>

Do not touch the front of the mask after entering the patient's room.

#### Safely removing PPE (doffing)

- There are a variety of ways to remove PPE without contaminating the user; see examples.
- Do not touch any contaminated part of the PPE with ungloved hands during removal.
- Remove all PPE (except for a respirator) before leaving the contaminated space (e.g., the patient's room).
- Wash your hands or use an alcohol-based hand rub between steps any time they are contaminated.

#### Examples

Examples of <u>doffing</u> PPE		
Order of <u>PPE</u> removal		
	Proper technique (example 1)	Proper technique (example 2)
Gloves	<ul style="list-style-type: none"><li>• Using a gloved hand, grasp the wrist area of the other gloved hand and peel it off so that it is inside out.</li><li>• Hold the removed glove in the other gloved hand.</li><li>• Slide the fingers of the ungloved hand under the wrist of the remaining glove (do not touch the gown) and slide it off, inside out, over the first glove.</li><li>• Discard the gloves in a waste container.</li></ul>	<ul style="list-style-type: none"><li>• Grasp the front of the gown and pull away from the body until the ties break (only touch the outside of the gown with gloved hands).</li><li>• Pull the gown away from the neck and shoulders from the outside and allow it to fall away from the body.</li><li>• Before the gown is removed from the wrists, use a gloved hand to hold the opposite glove and sleeve together before removing the arm and hand; the removed arm and hand should only touch the inside of the gown.</li><li>• Using the ungloved hand, grab the inside of the gown to remove the remaining arm and hand from the gown.</li><li>• Roll up the gown so that it is inside out, only touching the inside surface.</li><li>• Place the gown and gloves into a waste container.</li></ul>
Gown	<ul style="list-style-type: none"><li>• Unfasten the ties without touching the body with the sleeves.</li><li>• Grab the inside of the gown above the shoulders and pull it away from the body.</li><li>• Turn it inside out over the arms.</li><li>• Roll up the gown and discard in a waste container.</li></ul>	
Goggles or face shield	<ul style="list-style-type: none"><li>• Grab the back of the headband or earpieces and lift them up and over while avoiding the face.</li><li>• If reusable, place in a designated receptacle; otherwise, discard in a waste container.</li></ul>	

Mask or respirator	<ul style="list-style-type: none"> <li>Grasp the bottom ties or elastics and lift them upwards without touching the front.</li> <li>Repeat the preceding step for the top ties or elastics.</li> <li>Place the mask or <u>respirator</u> in a designated area.</li> </ul>
Hygiene	<ul style="list-style-type: none"> <li>Immediately wash hands or use an <u>alcohol-based hand rub</u>.</li> </ul>

### Disinfectants, antiseptics, and sterilization

Common disinfectants and antiseptics

Disinfectants and antiseptics equally destroy microorganisms or inhibit their growth and the terms are often used interchangeably. The difference is that disinfectants are used on nonliving surfaces, whereas antiseptics are used on living tissue.

Most common <u>disinfectants</u> and <u>antiseptics</u> [10][11]				
Agent		Mechanism of action	Active against	Sporicidal
Alcohol-based disinfectants (e.g., <u>isopropyl alcohol</u> and ethyl <u>alcohol</u> )		<ul style="list-style-type: none"> <li>Causes membrane damage and <b>denaturation</b> of <u>proteins</u></li> </ul>	<ul style="list-style-type: none"> <li>Bacteria</li> <li><u>Enveloped viruses</u></li> <li>Fungi</li> </ul>	<ul style="list-style-type: none"> <li>No</li> </ul>
Bisbiguanides (e.g., chlorhexidine)		<ul style="list-style-type: none"> <li>At low concentrations: leakage of intracellular components due to <u>cell membrane</u> disruption</li> <li>At high concentrations: cause precipitation of intracellular <u>proteins</u> and <u>nucleic acids</u></li> </ul>		
Phenol (e.g., orthophenylphenol and ortho-benzyl-para-chlorophenol)		<ul style="list-style-type: none"> <li>At low concentrations: inactivates essential enzymes and induces leakage of metabolites</li> <li>At high concentrations: disrupts <u>cell wall</u> and precipitates cell <u>proteins</u></li> </ul>		
Halogen-releasing agents	Iodine and iodophors (e.g., povidone-iodine and poloxamer- <u>iodine</u> )	<ul style="list-style-type: none"> <li><b>Halogenation</b> of <u>RNA</u>, <u>DNA</u>, and <u>proteins</u></li> </ul>	<ul style="list-style-type: none"> <li>Bacteria</li> <li><u>Viruses</u></li> <li>Fungi</li> </ul>	<ul style="list-style-type: none"> <li>Yes (with prolonged contact time)</li> </ul>
	Chlorine-releasing agents (e.g., <u>sodium hypochlorite</u> and <u>chlorine dioxide</u> )	<ul style="list-style-type: none"> <li>Highly active <b>oxidizing agents that denature proteins</b> and <u>nucleic acids</u> and disrupt <u>oxidative phosphorylation</u></li> </ul>		<ul style="list-style-type: none"> <li>Yes (e.g., effective against highly resistant spores of <i>Clostridium</i> species)</li> </ul>
Hydrogen peroxide		<ul style="list-style-type: none"> <li>An oxidant that produces hydroxyl <b>free radicals</b> (<math>\cdot\text{OH}</math>), which damage essential cell components, including lipids, <u>proteins</u>, and <u>DNA</u></li> </ul>		<ul style="list-style-type: none"> <li>Yes (only at higher concentrations and longer contact times)</li> </ul>
Aldehydes (e.g., glutaraldehyde)		<ul style="list-style-type: none"> <li>Microbicidal effect is mediated by <b>alkylation</b> of <u>sulphydryl</u>, <u>hydroxyl</u>, <u>carboxyl</u>, and <u>amino groups</u> of <u>RNA</u>, <u>DNA</u>, and <u>proteins</u>.</li> </ul>		<ul style="list-style-type: none"> <li>Yes</li> </ul>
Quaternary ammonium compounds (e.g., <u>benzalkonium chloride</u> )		<ul style="list-style-type: none"> <li>Induces inactivation of energy-producing enzymes, <u>denaturation</u> of essential cell <u>proteins</u>, and disruption of the <u>cell membrane</u></li> </ul>		<ul style="list-style-type: none"> <li>No</li> </ul>

Skin and/or mucous membrane disinfection

- Commonly used agents:** alcohols (e.g., ethanol), biguanides, phenols [3]
- Mechanism of action:** protein denaturation

- **Advantage:** rapid onset of action and generally well-tolerated
- Disadvantages
  - Ineffective against bacterial spores and nonenveloped viruses
  - Antiseptic efficacy is reduced after it comes into contact with protein (e.g., blood).
- **Alternative:** iodine preparations

#### Surface disinfection

- **Commonly used agents:** aldehyde, halogens, ammonium compounds, oxidants (e.g., hydrogen peroxide)
- **Mechanism of action:** denaturation of various structures (proteins, nucleic acids, cell nuclei)
- **Advantage:** high efficacy also against spores and nonenveloped viruses, minimal decrease in antiseptic/disinfecting efficacy after contact with proteins (e.g., blood)
- **Disadvantage:** poorly tolerated
- Alternative
  - Quaternary ammonium compounds
  - Disadvantage
    - Ineffective against gram-negative bacteria, mycobacteria, and mycoplasma
    - Decreased efficacy after contact with proteins

#### Sterilization (microbiology)

- **Definition:** the process of destroying all microbial life, including spores, on a surface or in a fluid.
- Aim
  - Medical equipment that has come into contact with sterile tissue or fluids must also be sterilized.
  - Heat-stable equipment is sterilized mainly using steam (autoclave).
  - Heat- and moisture-sensitive equipment (plastics, electrical devices, and corrosion-susceptible metal alloys) require low-temperature sterilization using, e.g., ethylene oxide, hydrogen peroxide gas plasma, peracetic acid.

#### Sterilization techniques for heat-stable equipment

- Steam sterilization (autoclave)
  - Exposing equipment to **direct steam** at a certain temperature and pressure for a specified period of time
  - Mechanism of action: irreversible coagulation and denaturation of enzymes and structural proteins
  - Active against bacteria, fungi, viruses, and **spores**
  - Treated at > 121°C: typically uses 134°C for 3 minutes or 121°C for 15 min
  - Prions are not destroyed by standard autoclaving. They must be sterilized at 121–132°C for 60 min (not a standardized method).
- Dry air sterilization
  - Exposing equipment to dry heat, which gets absorbed by the external layer and transferred inward to the interior layer by a process called conduction
  - Denatures and oxidizes proteins and other cell components
  - Commonly uses 170°C (340°F) for 60 min, 160°C (320°F) for 120 min, and 150°C (300°F) for 150 min

#### Sterilization techniques for heat- and moisture-sensitive equipment

- Ethylene oxide gas sterilization
  - Ethylene oxide: flammable and explosive gas
  - The sterilization process includes preconditioning and humidification, gas introduction, exposure, evacuation, and air washes.
  - Mechanism of action: **alkylation** of protein, DNA, and RNA
  - Microbicidal against all microorganisms, with limited sporicidal effect due to spores resistance.
  - Disadvantages: lengthy cycle time, costly, and hazardous
- Hydrogen peroxide gas plasma sterilization
  - Hydrogen peroxide diffusion and gas plasma generation → formation of **free radicals** → damage enzymes, nucleic acid, and disrupt cellular metabolism
  - Active against bacteria (including mycobacteria), yeasts, fungi, viruses, and bacterial spores

#### Pasteurization

- **Aim:** pathogen destruction through brief heating, especially of milk and other protein-containing products
- **Procedure:** treated with mild heat (< 100°C)
- **Efficacy spectrum:** destruction of a broad spectrum of bacteria but not heat-resistant spores

#### Isolation precautions

Isolation precautions (also known as transmission-based precautions) provide additional protection against the spread of suspected or confirmed highly contagious infections, and are used in addition to standard precautions.

##### A. General principles

- Minimize interactions with the patient.
  - Coordinate tasks to minimize the number of patient encounters.
  - Perform tasks (e.g., imaging, procedures) inside the patient's room, if possible.
- Place patients in single-patient rooms, if possible.
  - Absolute indications: patients on airborne precautions and/or in protective environments
  - Consider for patients on droplet precautions and those with infectious gastrointestinal disorders.
- Utilize cohorts
  - Patient cohorts: grouping patients (e.g., by room or floor) with the same or similar medical condition
  - Provider cohorts: a single provider cares for patients with the same medical condition

##### B. Types of isolation precautions

- Contact precautions
  - Transmission method: direct contact with body fluids or fomites.
  - Commonly used in hospitals to prevent the transmission of:
    - Drug-resistant pathogens (e.g., MRSA, VRE)
    - Enteric infections (including *Clostridioides difficile*, *Escherichia coli* O157:H7)
    - Skin conditions, including scabies, impetigo, varicella, and draining abscesses
  - Required HCP PPE: gloves and gowns, even when direct contact with the patient or infected material is not expected
  - Medical equipment should be dedicated to a single patient; if this is not possible, disinfect before reuse.
- Droplet precautions
  - Transmission method: large respiratory droplet spread (typically droplets > 5 micrometers in size) via coughing, sneezing, or talking
    - E.g., *Neisseria meningitidis*, *Bordetella pertussis*, Influenza, Parainfluenza, Adenovirus, *Haemophilus influenzae* type B, *Mycoplasma pneumoniae*, and Rubella
  - Required HCP PPE: a mask when within 6 feet of the patient. The patient should also wear a mask during transport.
- Airborne precautions
  - Transmission method: aerosolized particles (particulates and aerosols < 5 micrometers in size) that remain suspended in the air (e.g., tuberculosis, varicella)

- Goal: Prevent contaminated air from escaping the patient's room.
- Airborne infection isolation rooms (AAIRs) can provide the following:
  - Constant negative air pressure compared to the hallway
  - Frequent air changes (6–12 air cycles/hour)
  - HEPA filtration of outgoing air
- Required HCP PPE: a fitted N95 respirator or PAPR when entering the patient's room
- If patient transport is necessary, the patient should wear a surgical mask.

Isolation precautions, when indicated, are used in addition to standard precautions. A combination of isolation precautions may be indicated for patients with particular infections (e.g., varicella) and those with certain conditions.

#### Protective environment for immunosuppressed patients

- **Indication:** allogeneic hematopoietic stem cell transplantation (HSCT) recipients
- **Goals:** Keep potentially infectious air out of the patient's room and prevent exposure to fungal spores (reverse isolation).
- Precautions
  - Positive pressure rooms
    - Constant positive air pressure compared to the hallway
    - Frequent air changes
    - HEPA filtration of incoming air
  - Keep no carpet or upholstery, flowers, or potted plants in the patient's room.
  - Special room cleaning
    - Daily surface disinfection
    - Avoid dispersal of dust (e.g., damp dusting cloth, HEPA filtered vacuum).
  - Patients should only leave their room for diagnostic and therapeutic procedures.
  - Required HCP PPE: Only wear PPE as indicated by standard precautions or isolation precautions.
  - During periods of hospital construction work, patients should wear N95 respirators when outside their room.

#### Prevention of community spread

##### A. General measures

Certain communicable diseases have the potential to spread in the local community and must be reported to the local health department (notifiable diseases). Controlling local outbreaks may involve the following methods.

- **Isolation:** separation of a person or group of people with a confirmed or suspected infection caused by a highly infectious pathogen, e.g., SARS-CoV-2
- **Quarantine:** separation of asymptomatic individuals who have been exposed to a virus
- **Contact tracing:** Trained health workers contact patients who test positive for certain infections in order to identify the source of infection and prevent further spread.
  - They identify and notify individuals who came into close contact with the patient while they were infectious.
  - This allows the application of quarantine and isolation to prevent further spread.
- **Postexposure prophylaxis (PEP):** a form of secondary prevention in which treatment is administered following exposure to a highly infectious pathogen
  - Types of PEP include immunizations, antibiotics, antivirals, and immunoglobulins.
  - Conditions that may require PEP include HIV, bacterial meningitis, tuberculosis, hepatitis B, tetanus, rabies, varicella, measles, and anthrax.

##### B. Epidemic control

During widespread epidemics and pandemics, government-mandated public health measures may be enacted.

- Social distancing :
  - Maintain a distance of ~ 6 feet (2 meters) from others.
  - Avoid congregate settings (e.g., shopping centers) and mass gatherings (e.g., concerts, rallies).
- **Lockdown:** Local or national governments encourage and/or mandate individuals not to leave their homes unless absolutely necessary.

#### Prevention of common health care-associated infections

Healthcare-associated infections (HAIs) or nosocomial infections are avoidable infections acquired within a medical setting. A number of health care quality improvement initiatives focus on reducing the number of HAIs.

##### A. General infection control measures

- Follow standard precautions.
- Ensure patients are screened for common causes of HAIs, e.g., MRSA, and isolated appropriately.
- Use antibiotics judiciously to prevent the spread of antimicrobial resistance and antibiotic-associated infections, e.g., C. difficile.
- Ensure health care staff do not work if they are ill and that they are up to date on their vaccinations (see “Preventing health care personnel infections”).

##### B. General precautions for indwelling devices

- Only insert medical devices and perform medical procedures when clearly indicated.
- Consider alternative, less invasive options.
- Inspect devices daily and provide proper care.
- Assess daily whether the device is still needed and remove it as soon as it is no longer required.
- Consider using hospital bundles to automate prevention steps.
- Do not routinely use systemic prophylactic antibiotics.

##### C. Prevention of common healthcare-associated infections

- The following prevention steps should be used in addition to the general precautions listed above.
- For further information on definitions, risk factors, and management steps for each condition, see “Overview of nosocomial infections” in “Nosocomial infections.”

##### D. Prevention of catheter-associated urinary tract infections (CAUTIs)

- Procedural
  - Consider whether routine catheterization is necessary.
  - Consider alternative options
    - Clean intermittent catheterization (CIC)
    - Condom catheters
  - Select the smallest catheter necessary.
  - Use sterile technique during insertion.
  - The use of antimicrobial catheters is not routinely recommended.
- Postprocedural
  - Perform daily maintenance for indwelling catheters.
    - Clean the genital area, including the meatal area, with soap and water.
  - Systemic prophylactic antibiotics are not recommended.

##### E. Prevention of intravascular catheter-related infections (CLABSIs and CRBSIs)

- Procedural
  - Consider a peripherally inserted central line (PICC).
  - Avoid femoral lines in adults if possible.
  - For the procedure:

- Perform skin preparation with chlorhexidine and alcohol.
  - Follow hand hygiene and strict aseptic technique.
  - Place the line under ultrasound guidance.
- Postprocedural
  - Replace lines that were inserted emergently within 2 days.
  - Perform regular maintenance.

#### Prevention of ventilator-associated infections

- Procedural
  - Consider alternatives, e.g., NIPPV
  - Oral rather than nasal intubation, if possible
- Postprocedural
  - Oral care with sterile water
  - Use a ventilator bundle protocol that includes:
    - The lowest level of sedation possible
    - Early exercise and mobilization
    - Minimizing secretion pooling
    - Elevation of the head of the bed to 30–45°
  - Maintain the ventilator circuit.
  - Further measures may be utilized in high-risk groups.

#### Prevention of surgical site infections (SSIs)

- Procedural
  - Use alcohol-based surgical skin preparation.
  - Follow local or national guidelines for IV antimicrobial prophylaxis.
  - Prior to elective operations:
    - Advise smoking cessation one month prior to surgery.
    - Treat all infections.
    - Advise patients to bathe or shower the night before surgery.
  - Perioperatively, maintain:
    - Blood glucose levels < 200 mg/dL
    - Normothermia
    - ↑ FiO2 when under general anesthesia and immediately post extubation
- Postprocedural
  - Do not apply antimicrobial agents to the incision.
  - Inspect dressings regularly and change as needed.
  - Minimize blood loss to avoid the need for transfusion, however, do not withhold necessary blood transfusions to prevent SSIs.

#### Preventing health care personnel infections

HCP have an increased risk of acquiring infections from work, including those caused by multidrug-resistant organisms and highly communicable diseases, compared with the general population. HCP can also potentially transfer infectious pathogens to vulnerable patients.

##### General principles

- Follow standard precautions and isolation precautions.
- Advise HCP not to attend work if they are unwell.
- Ensure HCP are up to date on their vaccinations.
- Consider preexisting health conditions.
- Ensure protocols are in place to deal with exposures in the workplace.

##### Vaccines

Vaccinations for staff without preexisting immunity help prevent the contraction and spread of infectious diseases. However, vaccinated individuals should still use the recommended standard precautions and isolation precautions when caring for patients.

- All staff:** Administer routine vaccinations for their age group.
  - The occupational health department may require proof of immunity for the following conditions:
    - Hepatitis B
    - Influenza (annual vaccination is typically required)
    - Measles, mumps, and rubella
    - Pertussis
    - Tetanus
    - Varicella
    - COVID-19
  - For further information on routine vaccinations, see “Vaccination” and “Immunization schedule.”
- High-risk groups
  - Conditions that may require additional vaccinations and/or boosters include:
    - Asplenia
    - Chronic liver disease
    - Immunosuppression
  - Laboratory and/or research workers handling certain infectious pathogens
  - Staff members traveling abroad should be advised to have the recommended immunizations for travel for their destination.

#### Health care personnel exposures

Exposures occur when potentially infectious body fluids penetrate protective barriers.

##### Types of exposure

- Percutaneous injuries, e.g., needlestick and sharps injuries: piercing of the skin by an object (e.g., scalpel, wires, pins, needles, glass shards) contaminated with body fluids
- Bites
- Through nonintact skin
- Splashes onto mucous membranes

##### Prevention

- General: Follow standard and isolation precautions and use PPE.
- Percutaneous injury prevention
  - Avoid using needles if possible (e.g., needle-free IV systems).
  - Use medical devices with built-in safety features (e.g., blunt-tip suture needles, safety syringes, safety scalpels).
  - Do not remove a contaminated needle from the syringe.
  - Do not recap or bend needles.
  - Use a neutral zone rather than directly handing sharps to other members of staff.
  - Dispose of used needles and sharps in appropriate sharps disposal containers.
  - Consider double gloving. [28]

Percutaneous injuries pose the highest risk for transmission of bloodborne viruses. Despite precautions, ~ 385,000 exposures occur every year in the US, resulting in significant health care costs and anxiety.

#### Approach

The following steps may help prevent an infection from developing.

- Exposed HCP
  - Perform first aid.
  - Notify the supervisor and occupational health department.
  - Immediately seek medical care (e.g., through occupational health or the emergency department).
- Treating clinician
  - Obtain further history about the exposure.
  - Order laboratory studies for both the exposed HCP and source patient, if possible.
  - Arrange follow-up and provide PEP, if indicated.
  - Counsel on additional recommended precautions to take during the follow-up period.

#### First aid

- Percutaneous injuries
  - Wash gently with soap and water.
  - Allow the wound to bleed for > 1 minute under running water.
- Nonintact skin exposures: Rinse under running water.
- Splashes to the eyes, nose, or mouth: Flush or irrigate with water or normal saline.
- Eye exposures: Irrigate the eyes with clean water, saline, or sterile irrigants.

#### History

- Verify that an exposure occurred.
- Document how the injury occurred.
- Confirm if the source patient is known.
- Determine if the exposure was high risk for transmission of bloodborne viruses, e.g.:
  - Percutaneous injuries
  - Source patient with a high viral load
- Confirm that the HCP is up to date with hepatitis B and tetanus vaccinations.

#### Baseline laboratory studies

Health care exposures require laboratory studies for both the source patient, if identified, and the exposed HCP. These studies focus on bloodborne pathogens, e.g., HIV, hepatitis B, and hepatitis C.

<u>Laboratory studies for HCP exposures</u> [31][32][33]		
<u>Baseline laboratory studies</u>	Source patient	Exposed <u>HCP</u>
<u>HIV</u>	<ul style="list-style-type: none"> <li>• <u>HIV</u> Ag/Ab or anti-<u>HIV</u> 1 and 2</li> <li>• AND a rapid <u>HIV</u> test, if available</li> </ul>	<ul style="list-style-type: none"> <li>• <u>HIV</u> Ag/Ab or anti-<u>HIV</u> 1 and 2</li> </ul>
<u>HBV</u> (only if <u>HCP</u> is nonimmune/ <u>immunity</u> status unknown)	<ul style="list-style-type: none"> <li>• <u>HBsAg</u></li> </ul>	<ul style="list-style-type: none"> <li>• <u>anti-HBs</u></li> </ul>
<u>HCV</u>	<ul style="list-style-type: none"> <li>• <u>HCV RNA</u> (preferred)</li> <li>• OR anti-<u>HCV</u> AND, if positive, <u>HCV RNA</u></li> </ul>	<ul style="list-style-type: none"> <li>• <u>Anti-HCV</u> AND, if positive, <u>HCV RNA</u></li> </ul>

#### Postexposure prophylaxis (PEP)

- Indications
  - Source patient is positive or high risk for a bloodborne pathogen
  - Source patient unknown
- Depending on risk factors, exposed HCP may require:
  - HIV postexposure prophylaxis (e.g., PEP antiretroviral therapy)
  - Hepatitis B postexposure prophylaxis (e.g., HBIG and/or hepatitis B vaccine): only in HCP without documented immunity
  - Tetanus prophylaxis (e.g., tetanus booster and/or immunoglobulin)
- There is no postexposure prophylaxis for hepatitis C.
- Additional precautions during the follow-up period depend on the suspected pathogen
  - Any bloodborne pathogen: Avoid donations of blood, plasma, organs, tissue, and semen.
  - HIV
    - Use barrier contraception (e.g., condoms).
    - Avoid breastfeeding and becoming pregnant.

In the United States, the Clinician's Post-Exposure Prophylaxis Hotline (1-888-448-4911) and website (<https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis>) are available to provide further assistance regarding the initiation and management of PEP therapy after a workplace exposure.

#### Pre-surgical infection prevention measures

##### General

- **Aim:** reduce the risk of an intraoperative surgical site infection through contamination with bacteria from the skin
- **Who:** all sterile staff members of a surgical team in the operating room (e.g., surgeons, scrub technicians, medical students assisting in a procedure)

##### Preparation

- Appropriate surgical attire
  - The fingernails should be short. No artificial nails and/or nail polish should be worn.
  - All jewelry (e.g., bracelets, rings, watches) should be taken off.
  - The surgical staff member should wear:
    - Surgical scrubs
    - Surgical footwear (e.g., closed rubber clogs, shoe covers)
    - Surgical cap
    - Surgical mask
    - Protective eyewear
- **Material:** Gowns and gloves have to be prepared before scrubbing.



- Gowns: Place the gown package on a clean surface. Pull on the outer edges of the wrapping to expose the gown without touching the sterile content that is inside.
- Gloves: Open the plastic packaging and let the inner sterile glove packet drop onto the gown.

#### Prescrub wash

- **Indication:** only required before the first case of the day or when the hands are visibly soiled
- Instructions
  1. Adjust the water temperature to a comfortable, lukewarm level.
  2. Open the scrub sponge package and set it on the side. The sponge is not used during the prescrub wash.
  3. Wet the hands and arms and apply antimicrobial soap.
  4. Start by washing the hands, followed by the arms, and lastly the elbows.
  5. Use the nail pick from the scrub sponge package to clean the subungual spaces under running water.
  6. Thoroughly rinse off the soap from the hands and arms.

### Surgical hand disinfection

#### A. Scrubbing in (surgical scrub)

- **Indication:** before each operation, before gowning and gloving
- **Methods:** Every institution has its own protocol for scrubbing in. The two most common are the brush stroke method and the timed method.
  - Brush-stroke method: A specific number of brush strokes is applied to each surface of the fingers, hands, and forearms. (see instructions below)
  - Timed method: The scrub is performed for a specific amount of time (typically 3–5 minutes).
- Substances
  - The most common scrub solutions contain one of the following agents:
    - Chlorhexidine gluconate
    - Povidone-iodine
  - Mechanism of antimicrobial action
    - Elimination of transient bacterial flora, reduction of resident bacterial flora
    - Inhibition of bacterial growth under the glove
- General rules
  - Always hold the hands at a higher level than the elbows.
  - Start with the fingertips and work towards the elbows.
  - Every area is only scrubbed once. Do not return to a previously scrubbed area.
  - To ensure thorough cleaning, the fingers, hands, and arms should be seen as having four sides, each of which has to be brushed individually.
  - Completely finish one side (left/right) before moving to the other hand and arm.
  - The abrasive side of the scrub sponge (nail brush) is only used to clean the fingernails. [2]
  - Neither the hands nor forearms should come in contact with any nonsterile object or surface (e.g., scrubs, tap). Otherwise, the entire scrubbing procedure needs to be repeated.
  - After scrubbing, the hands should stay at a level between the waist and the neck at all times.
- Instructions for the brush-stroke method [37]
  - Remove the scrub sponge from the wrapper and moisten it under running water until you work up a sufficient lather.
  - Put the fingertips of one hand together and brush the fingernails with the abrasive side of the scrub sponge for 30 strokes.
  - Use the nonabrasive side of the scrub sponge to apply 10 strokes to all four sides of each finger, starting with the thumb. Do not forget the interdigital folds.
  - Apply 30 strokes to the palm and 30 strokes to the back of the hand.
  - Move on to the forearm. Mentally divide the arm into three equal increments, the most proximal of which ends two inches above the elbow. Scrub all four sides of each increment with 10 strokes, moving from distal to proximal.
  - Switch sides and repeat steps 2–6.
  - Discard the scrub sponge into the bin.
  - Rinse off the foam.
    - Start at the fingertips and move forward under the water in a single fluid motion.
    - Do not move back and forth under the water.
    - Completely rinse off one side before moving to the other.
  - Wait and let the water drip from the elbows. Do not shake the arms.
  - Dry off the hands with the sterile towel from the already opened gown package. (See “Preparation” above.)
    - Take the towel without touching anything else.
    - Dry off one side completely (hand before arm), then continue with the opposite side.
    - Dab with the towel, rather than rub.

#### B. Alcohol-based disinfection (hand rub)

- **Indication:** This method is an alternative to scrubbing with a sponge.
- **Substances:** disinfectants containing alcohol and phenol mixtures
- Instructions
  1. Wash hands and forearms with nonantimicrobial soap. Thoroughly rinse off all foam.
  2. Completely dry off the hands and forearms with disposable paper towels.
  3. Use the elbow to dispense the disinfectant into the opposite hand.
  4. Set a timer and use the hands to thoroughly rub disinfectant on the hands and forearms for ≥ 3 minutes.
  5. During the set time, reapply disinfectant if necessary. All areas should have constant contact with the disinfectant.

Do not touch nonsterile objects and/or surfaces during the disinfection process. Otherwise, the entire routine needs to be repeated.

The hands should always be held at a higher level than the elbows.

#### C. Gowning

- **Indication:** A sterile gown has to be donned for all surgical procedures. Often, surgeons are being gowned by an assistant that is already wearing sterile attire. However, every sterile member of the surgical team should be able to perform self-gowning.
- **Instructions:** The gown needs to be prepared before scrubbing (see “Preparation” above).
  1. Pick up the folded gown, only touching the inner side.
  2. Identify the sleeve openings and slide the hands into it on both sides.
  3. Take a step back to ensure that the gown can not touch any nonsterile objects while unfolding.
  4. Let the gown unfold while simultaneously sliding the arms into the sleeves. At no point should the hands exit the sleeve cuffs. Keep the hands above waist level.
  5. An assistant will fasten the gown and secure it with a velcro tab at the neck and upper back.
  6. Proceed with gloving (see “Closed glove method” below).
  7. Pull only the left (shorter) tie out of the gown pass card.
  8. Pass the card to an assistant without letting the remaining tie slip from the card.
  9. Make a 360° turn so that the tie that is held by the assistant wraps around your waist.
  10. Pull the tie out of the card and secure both ties with a bow at your waist.

The gown is not considered sterile on the back, below the waist, or above the neck, because these areas are more likely to come in contact with unsterile objects.

## Gloving

### A. Closed glove method

- **Indication:** preferred method when preparing for a surgical procedure
- **Instructions:** Before starting closed gloving, a sterile gown must be donned.
  1. Open the sterile wrapper containing the gloves while the hands remain in the gown sleeves.
  2. Pick up the right glove by grabbing the folded cuff edge with the left sleeve-covered hand.
  3. Make sure the palm of the right hand faces the ceiling in the gown sleeve.
  4. Place the right glove on the right hand with the fingers of the glove pointing towards the shoulder. The palm of the glove should face the palm of the hand.
  5. Grab the palm-facing side of the folded cuff of the glove with the right sleeve-covered hand and hold onto it.
  6. Pull the ceiling-facing side of the folded cuff with the left sleeve-covered hand.
  7. Pull the glove up with the left hand and over the right hand.
  8. Pull the gown and glove up the arm to position your fingers inside the glove.
  9. Remove excessive gown sleeve from underneath the glove by pulling only on the gown. Make sure that the gown cuff stays fully covered by the glove cuff.
  10. Using the gloved hand, repeat the procedure for the other glove.

The gown cuff has to be fully covered by the glove cuff.

### B. Open glove method

- **Indication:** predominantly used for smaller procedures that only require the hands to be sterile
  - Placing a urinary catheter
  - Performing a bone marrow biopsy or lumbar puncture
  - When gloves have to be changed during an operation
- Instructions
  - Ask an assistant to help you in retrieving the sterile wrapper containing the gloves from the plastic packaging.
  - Place the sterile wrapper on a clean surface.
  - Unfold the wrapper by grabbing the outer edges without touching the inner surface. The gloves should now be exposed.
  - Take the folded edge of the right glove with the left hand and hold onto it. Insert the right hand into the glove and pull the cuff over the hand.
  - Slide the fingers of the gloved hand underneath the rolled cuff of the left glove.
  - Lift the glove so that the opening is facing upwards.
  - Widen the opening with the fingers of the gloved hand that are underneath the cuff.
  - Insert the fingers of the left hand and pull the cuff over the hand.

# Palliative Medicine

7 questions

Palliative medicine is a comprehensive, interdisciplinary approach to medical care that aims to relieve suffering and provide optimal quality of life in patients with serious or life-threatening illnesses. It is often provided in conjunction with life-prolonging therapy. Crucial components of palliative medicine include symptom relief, assistance in the organization of nursing and social services, and psychological support of patients and their families. As a consequence, palliative care teams are typically multidisciplinary: Palliative care specialists identify needs and coordinate care, oncologists (or other specialists) manage the underlying disease, primary care providers address symptom relief, pain specialists treat advanced pain, and mental health providers and chaplains administer psychological and spiritual support. The palliative care team addresses symptoms including pain, breathlessness, nausea, constipation, and delirium, and provides end-of-life comfort care. Palliative care has been shown to decrease symptom intensity, improve quality of life, decrease hospital admissions, and help bereaved family members adapt to their loss. If a patient desires or meets the criteria for palliative care referral, it should be initiated as quickly as possible.

## Basics

- Key elements of palliative care
  - Symptom relief, particularly sufficient analgesia
  - Assistance in the organization of adequate, needs-based care
  - Support regarding social services
  - Psychological support of patients and their families
- Members of a palliative care team
  - Physicians (including palliative care specialists)
  - Nurses
  - Social workers
  - Psychologists
  - Chaplains
  - Pharmacists

**Note: Palliative medicine is not synonymous with end-of-life care. It is often used to improve a patient's quality of life even as life-prolonging therapy continues.**

## General Approach

- Consider enrolling patients with cancer or other high-morbidity illness in a palliative care program.
- Frequently reassess the patient's symptoms.
- If new symptoms arise or current symptoms change, consider investigating the etiology of the change in addition to managing symptoms.
  - Discuss the risk-benefit profile and confirm goals of care with patients and caregivers prior to initiating management of a new or newly exacerbated complication.
  - Adjust approach to eliminate diagnostic and therapeutic procedures that are too invasive, painful, or have other side effects that are not aligned with the patient's preferences or wishes.

Overview of symptom management in palliative patients	
Symptoms	Symptomatic therapy
Pain	<ul style="list-style-type: none"><li>• Optimize nonpharmacological therapy for all patients.</li><li>• Consider early escalation to opioids to provide sufficient pain relief and titrate to effect.</li><li>• Combine fixed-schedule slow-release opioids with short-acting opioids as needed.</li><li>• Consider specific therapy for neuropathic pain and bone pain.</li></ul>
Gastrointestinal	<ul style="list-style-type: none"><li>• Nausea and vomiting: antiemetics (e.g., metoclopramide), fluid therapy</li><li>• Constipation<ul style="list-style-type: none"><li>• Optimize fluid and fiber intake.</li><li>• Consider treatment with stimulant laxatives with or without osmotic laxatives.</li></ul></li><li>• Others<ul style="list-style-type: none"><li>• Loss of appetite: dexamethasone or prednisolone [19]</li><li>• Thirst: oral care</li><li>• Diarrhea: fluid and electrolyte replacement [20]</li></ul></li></ul>
Pulmonary	<ul style="list-style-type: none"><li>• Dyspnea<ul style="list-style-type: none"><li>• Consider treatment of reversible causes (e.g., pleural effusion).</li><li>• Low-dose opioids, e.g., morphine; breathing and relaxation techniques</li><li>• Cough: Consider expectorant drugs or antitussive drugs depending on the type of cough (e.g., productive or nonproductive). [21]</li></ul></li></ul>
CNS	<ul style="list-style-type: none"><li>• Anxiety and depression: benzodiazepines, antidepressants, psychotherapy [22]</li><li>• Delirium: antipsychotics, benzodiazepines<ul style="list-style-type: none"><li>• Optimize nonpharmacological and preventative measures (see "Delirium prevention").</li><li>• Consider pharmacotherapy with antipsychotics.</li><li>• Add benzodiazepines for refractory symptoms.</li></ul></li></ul>
Terminal phase	<ul style="list-style-type: none"><li>• Discontinue unnecessary investigations, monitoring, and treatments not required for comfort care.</li><li>• Optimize mouth care and patient positioning.</li><li>• Optimize route of medication delivery for symptomatic treatment. [23]</li><li>• Manage noisy terminal respiratory secretions.<ul style="list-style-type: none"><li>• Respiratory physiotherapy [24]</li><li>• Repositioning</li><li>• Consider anticholinergic drugs to reduce secretions: e.g., glycopyrrolate, atropine. [25]</li></ul></li><li>• Consider palliative sedation in select patients in consultation with a specialist for refractory distress or agitation.</li></ul>

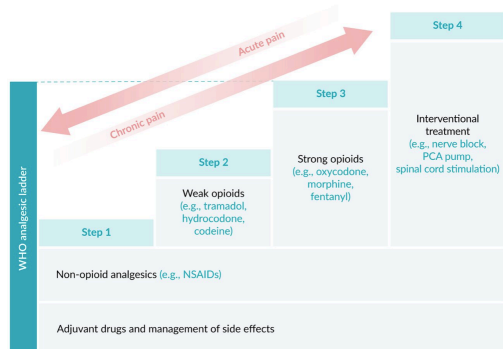
- Involve associated healthcare professionals (e.g., dietitians, physical therapists, and occupational therapists) to help anticipate and prevent complications.
- See also “[Principles of cancer care](#).”

## Pain

**Pain** is an unpleasant experience with sensory and emotional components that may occur with or without actual or potential tissue damage.

## Approach

- Address multifactorial components of **pain**.
  - **Nociceptive pain**: caused by damage or potential damage to tissue (excluding neural tissue)
  - **Neuropathic pain**: caused by damage to a somatosensory nerve
  - **Nociplastic pain**: caused by altered **nociception** despite there being no underlying tissue damage
  - **Mixed pain**: the simultaneous or concurrent presence of **nociceptive**, **neuropathic**, and/or **nociplastic pain** in one area of the body
  - **Emotional pain**: a term used to describe both mental suffering and the impact of emotions on the experience of **pain**
  - **Total pain**: the combination of physical, social, spiritual, and psychological/**emotional pain** components
- Maximize nonpharmacological therapy to either complement or replace pharmacotherapy.
- Use the **WHO analgesic ladder** to structure treatment.
- Consider the following causes of **pain** in patients with cancer:
  - Disorders associated with the **tumor** (e.g., **thrombosis**, **paraneoplastic syndrome**)
  - Therapy: postoperative **pain**, side effects of **radiotherapy** or **chemotherapy** (e.g., **mucositis**, **polyneuropathies**, **stomach ulcer** associated with **NSAIDs**)
  - **Tumor** effects: infiltration of **soft tissue** and bones; compression of nerves, lymphatic vessels, or **blood vessels**; **cerebral edema**



## Nonpharmacological therapy

- **Spiritual and social services**: e.g., chaplains, spiritual advisors, and social workers
- **Physical interventions**: e.g., **physical therapy**, acupuncture, massage, **transcutaneous electrical nerve stimulation**
- **Mental health interventions**: e.g., depression and **anxiety** treatment, relaxation therapy, **cognitive behavioral therapy**

## Nonopioid pharmacotherapy

- **First-line agents**: **acetaminophen** and **NSAIDs**
- **Neuropathic pain**: Consider adding **gabapentinoids** and **antidepressants**.
- **Metastatic bone pain**
  - Consider adding **bisphosphonates** and **denosumab**.
  - Consult radiation oncology for **external beam radiotherapy**.

## Opioid therapy

Most patients require a combination of regularly scheduled slow-release **opioids** and fast-acting doses as needed for breakthrough **pain**.

- Treat severe **pain** first with parenteral therapy.
- Transition to oral medications once the **pain** is controlled.
- Consider administering preemptive doses before painful procedures, e.g., dressing changes, bed baths.
- Consider continuous opioid infusions to provide sufficient **pain** relief in terminally ill patients (see “[Management of imminently dying patients](#)”).
- Consider extended-release formulations in patients whose **pain** is not controlled with as-needed dosing or those requiring  $\geq 4$  as-needed doses per day.

## Other Symptoms

Many medications are used **off-label** or with **off-label** dosage regimens in palliative care. The recommendations in the following section are consistent with those of palliative care experts.

## Breathlessness (dyspnea)

- **Background**
  - Breathlessness/**dyspnea** is common in palliative care patients.
  - This symptom manifests uniquely in these patients, as it often:
    - Is not easily attributable to an organic disease process
    - Responds poorly to standard medical therapies, e.g., **bronchodilators**, **diuretics**
- **Approach**: Tailor to the individual's palliative care plan.
  - Identify and treat reversible causes and provide respiratory support in accordance with the patient's wishes.
  - Optimize nonpharmacological therapy.
  - Offer palliative pharmacotherapy as a symptomatic treatment for patients with irreversible breathlessness.
- Palliative pharmacotherapy for breathlessness
  - Low-dose **opioids**
  - **Benzodiazepines** (second line)

## Nausea and vomiting (N/V)

- **Approach**
  - Symptoms related to cancer treatment (e.g., **chemotherapy**, **radiotherapy**): Consult oncology and consider treatment for **CINV**.
  - Symptoms unrelated to cancer: See “[Nausea and vomiting](#)” for broad differential diagnosis.
  - Identify and treat underlying causes in accordance with the patient's wishes and care plan.
  - Begin immediate symptomatic treatment of **nausea and vomiting** while working up underlying causes.
- **Pharmacological therapy**:
  - Start with a **dopamine receptor antagonist**, e.g., **metoclopramide**, and titrate to maximum tolerance.
  - Add an additional drug class if needed.
    - **Serotonin (5HT<sub>3</sub>) antagonist** (e.g., **ondansetron**): for postoperative N/V
    - **Antihistamine** (e.g., **meclizine**) or **anticholinergic** (e.g., **scopolamine** patch): for vestibular N/V
    - **Corticosteroid** (e.g., **dexamethasone**): for meningeal irritation,  $\uparrow$  ICP-related N/V, or malignant **bowel obstruction**
  - Consider **benzodiazepines** for N/V triggered by **anxiety** (see “[Palliative anxiolysis](#)”).
  - See “[Antiemetics](#)”.

## Constipation

- Background
  - Occurs in up to 90% of palliative care patients.
  - Consequences include:
    - Pain
    - Nausea and vomiting
    - Bowel obstruction
    - Urinary retention
    - Delirium
- **Assessment:** Consider standardizing the severity of subjective symptoms with patient reporting tools.
- Management
  - Address common underlying causes in palliative care, e.g.:
    - Reduce or replace offending medication, e.g., anticholinergics, opioids.
    - Manage bowel obstruction.
    - Address electrolyte abnormalities (e.g., hypercalcemia and hypokalemia).
    - Optimize diet and fluid intake.
  - Provide symptomatic treatment of constipation: See “Overview of laxatives”.

## Delirium

- **Background:** Occurs in up to 90% of patients receiving palliative care.
- Etiologies in palliative medicine include:
  - Medications (e.g., opioids, steroids, antiemetics, benzodiazepines)
  - Pain
  - Distended bowel or bladder
  - Metabolic causes (e.g., hypercalcemia, hyponatremia, hypomagnesemia, dehydration)
  - Disruption of the sleep-wake cycle
  - CNS pathology (e.g., brain metastases)
- **Assessment:** See “Confusion assessment method” and “Symptom-based diagnostic workup of delirium.”

## Management of delirium in palliative care

See also “Delirium management” for a general approach to therapy in nonpalliative patients.

- All patients
  - Address underlying causes in accordance with the patient's care plan, especially pain and constipation (see also “Delirium etiology”).
  - Initiate nonpharmacological supportive measures to prevent and reduce symptoms of delirium (see “Delirium prevention”).
  - Perform medication reconciliation and minimize polypharmacy.
  - Discontinue offending agents commonly encountered in palliative care: e.g., glucocorticoids, anticholinergic medications, benzodiazepines.
- **Consider pharmacotherapy** depending on symptoms severity.
  - Mild symptoms: Begin with oral antipsychotics.
  - Severe symptoms: Consider switching to parenteral antipsychotics.
  - Refractory symptoms: Add a benzodiazepine to antipsychotics.

## Anxiety

- Anxiety and depression are very common in palliative care and inadequate treatment can worsen nausea, pain, and depression and decrease the patient's quality of life.
- Consider early treatment with antidepressants or anxiolytics.
- Palliative anxiolysis: Benzodiazepines are first-line in most patients.
  - Short-acting “L-A-zy”
    - Lorazepam
    - Alprazolam
  - Long-acting
    - Clonazepam
    - Diazepam

## Outcome measurement in Palliative Medicine

The health care system measures the outcome (quality of results) of medical treatment and its influence on the current and future health of patients and their quality of life.

- Features of outcome measurement in palliative medicine
  - General outcome measurements assess, for instance, the physical and psychological aspects of an illness.
  - Specific outcome measurements focus on the evaluation of symptoms, clinical situations, or patient populations.
- Common outcome measurements in palliative medicine
  - Numeric rating scale (NRS) and visual analog scale (VAS)
    - One-dimensional scales that are based on self-reported data: NRS scale 0–10, VAS scale 0–100
    - E.g., report of pain level, level of respiratory distress, nausea, quality of life, satisfaction, stress
  - Tools to assess functional performance of individuals receiving palliative care: Karnofsky performance status scale, palliative performance status (PPS), Eastern Cooperative Oncology Group (ECOG) performance status

## Hospice

### Definition

- **Type of palliative care specifically given to patients at the end of life**

### Principles

- Preserve the dignity of patients during the final stages of life.
- Provide maximum comfort to the patient.
- Ensure pain relief (including administration of opioids, anxiolytics, or sedatives).
- Prioritize positive effects over potential negative effects (e.g., pain relief over the risk of respiratory depression), according to the ethical principle of double effect.

### Who is eligible for hospice care?

- Estimated life expectancy < 6 months
- Patients are usually on Medicare, Medicaid, or private insurance plans.
- The patient (and family) has made the decision to stop curative or life-preserving treatment in order to maximize quality of life.

**Note:** Not all treatment should be withdrawn. Antibiotics, for example, can still be given if the patient develops an infection.

### Facilities

- Patients can receive hospice care at home, in a skilled nursing facility, or at a hospital.
  - Home hospice services may consist of regular nursing visits, assistance with activities of daily living (e.g., cooking, cleaning, bathing, etc.), or support for home medical equipment (e.g., hospital beds, walkers, bedside commodes, etc.).
  - Hospice care in a hospital or nursing facility may be indicated if the patient's pain or symptoms require more specialized care.
- Services are available 24 hours a day, 7 days a week.

## Pediatric palliative care

- Communication
  - Full information for the parents/legal guardians regarding the diagnosis, treatment options and goals, and prognosis with and without therapy
  - Disclosure to the child: should be adapted according to the age and developmental level

- **Preschoolers** (< 6 years): often cannot conceptualize death; provide a clear explanation of their situation with parental presence
  - **Elementary schoolers**: often begin understanding death and their own situation; allow participation in medical decisions when appropriate
  - **Adolescents**: often have a full understanding of death; allow participation in decision-making, respect privacy and autonomy
- Consider the values and preferences of the family.
- **Decision making and ethics**
  - Parents/legal guardians are the legal medical decision-makers.
  - **Parental consent must be obtained in the pediatric setting** (see “**Informed consent**” in “**Principles of medical law and ethics**”).
  - Assent from the minor with an appropriate developmental level should also be obtained
  - Consider previously agreed upon **DNR orders** or **advance directives**.
  - Encourage exchange with parents in similar situations and facilitate contact with support groups.
  - Ethics committees can aid parental decision making.
- **Psychosocial support**
  - Facilitate psychosocial and/or spiritual support for the child patient and his/her family.
  - Address implications of the condition (e.g., disability and death).
  - Consider the personal wishes of the child (e.g., make-a-wish grants, family activities).
  - Facilitate contact to **grief** and **bereavement** support for family, e.g., counseling services, support groups.
- **Symptom management**
  - Pharmacological management of symptoms (see “Symptoms and symptom control” above)
  - Nonpharmacological measures include massages, **physical therapy**, acupuncture, behavioral/cognitive techniques (e.g., play therapy, music therapy, art therapy, guided meditations).

## Patient Communication and Counseling

13 questions

### **Summary**

**Patient counseling** is the process of providing information, advice, and assistance to patients to improve their health, treatment adherence, and quality of life. A **patient-centered approach** facilitates and improves the patient-physician relationship and communication. This approach is based on open communication and shared decision-making. Health care decisions should be discussed using understandable terms and straightforward **language**. If there is a **language** barrier, medical interpretation services should be provided to the patient. For counseling and communication in specific circumstances, see the individual sections below.

### **General concepts of patient counseling**

#### A. Key principles of communication and counseling

- **Patient counseling**: the process of providing information, advice, and assistance to patients to improve their health, treatment adherence, and quality of life
- Establishing the patient-physician relationship
  - Patients may feel vulnerable and have a fear of rejection/apathy from caregivers.
  - A patient's first visit is critical to the patient-physician relationship (e.g., establishing trust).
  - Empathy, interest, and continuity of care are valued by patients.

#### Patient-centered approach

- Objectives
  - Open communication between the patient and the provider, **shared decision-making**, and a shared goal of alleviating discomfort for the patient (see also “**Decision-making capacity and legal competence**” in “**Principles of medical law and ethics**”)
  - Takes into account the patient's individual preferences, concerns, and emotions
  - Outcomes are measured and monitored (e.g. pain level, functional status)
  - Used to optimize care of chronic conditions that include multiple management strategies (e.g., **pain management**, cancer therapy). The patient can select those treatments which are best aligned with the patient's priorities.
- Interviewing communication techniques
  - Introduction and building rapport
    - Begin by introducing yourself to the patient and any accompanying person; address the patient by their preferred name or, if unknown, inquire about their preferences; seat yourself at eye level with the patient.
    - Introduce any further health care workers present at the visit.
    - Family, friends, and caregivers commonly accompany patients to health care visits. This can have benefits (e.g., emotional support for the patient, providing additional information about the patient's health, facilitating communication between the patient and physician), but may also present challenges (e.g., the accompanying person interfering with the course of the interview).
    - In patients with **decision-making capacity** who are accompanied by another person, verbally confirm that the patient understands that you will be discussing personal health matters and that they agree to this confidential information being shared with the accompanying person.
    - Request that any accompanying persons leave the room if the patient indicates they would prefer them to.
  - Avoid interrupting the patient during the interview and **listen actively**. Be polite if you have to interrupt the patient, e.g., due to time constraints.
  - Identify the purpose(s) of the visit early in the interview and structure the interview in collaboration with the patient.
    - Use **open-ended questions** to determine the purpose of the visit (e.g., “How may I help you?”, “What can I do for you today?”).
    - Give the patient space to freely express their concerns.
    - Ask **close-ended questions** to collect specific information about the **chief concern** (e.g., “Where does it hurt”, “Is it a sharp **pain**?”).
    - Ask the patient if they have any additional concerns until you feel all concerns have been addressed (e.g., “Is there anything else you would like to discuss?”).
    - Prioritize the patient's concerns based on preference and/or medical urgency.
    - Negotiate the agenda for the visit with the patient if there are many concerns to address within the scheduled timeframe. Offer to discuss remaining concerns at a follow-up visit (e.g., “Since our time is limited, let us quickly discuss which of these concerns to prioritize,” “You have expressed concern about your **cholesterol** levels and **high blood pressure**; if it's okay with you, I would prefer we looked at the rash on your leg first and perhaps schedule a follow-up appointment to discuss your other concerns?”).
  - Make an effort to elicit, understand, and relate to the patient's concerns and expectations (e.g., “Do you have any thoughts on what might be the cause for your high **cholesterol** levels?” “Does your condition cause you any particular difficulties?” “What is currently your main health concern?”).
  - Show interest, compassion, and empathy for the patient's concerns to affirm the legitimacy of the patient's point of view (e.g., “I can see how this might make you feel anxious,” “I'm here to help you any way I can”).
  - Summarize information provided by the patient to ensure it has been understood correctly.
  - Show that you respect and value the patient's questions and that you consider them valid throughout the interview.
  - Provide information on the (working) diagnosis and treatment options.
    - Assess the patient's knowledge and understanding of the illness.
    - Assess the patient's preference for information (e.g., “How much information would you like to receive at this time?”, “Do you prefer to receive the information in stages or all at once?”)
    - Provide reassurance to reduce and address fear or **anxiety** regarding a diagnosis or treatment.
    - Assess the patient's hopes, fears, and expectations regarding a proposed treatment to ensure that there are no misunderstandings and to help provide the appropriate emotional support.

#### PEARLS model

- **Definition:** a psychosocial model that aims to help caregivers express empathy and support emotions in order to build a trusting relationship with patients
- Components
  - Partnership: Reassure the patient of your commitment to the collaborative goals, offer resources.
  - Empathy: Acknowledge and validate the patient's emotions.
  - Apology: Take responsibility if appropriate (e.g., for a long waiting time).
  - Respect: Commend constructive patient behavior (e.g., attending a doctor's appointment, remaining optimistic).
  - Legitimization: Validate and acknowledge the patient's emotions (e.g., frustration, anger).
  - Support: Offer and ensure support.

#### Language

- General considerations
  - Avoid judgemental or defensive **language** or behavior.
  - Discuss health care decisions with patients in relatable terms (e.g., avoid medical jargon, tailor **language** to the patient).
- **Language barriers**
  - Ask the patient questions to assess **language** proficiency before starting an interview.
  - If there is a **language** barrier between the patient and caregiver, establish the patient's preferred **language** and use a **professionally trained medical interpreter**.
  - Spoken interpretation services are available in person, via video call, or telephone.
  - Deaf patients or patients with **hearing** impairment should be offered a medical interpreter trained in **American Sign Language**. Other communication options include computer-assisted real-time **transcription** and assistive listening devices.
  - Having a family member interpret should be avoided unless it is the patient's wish (in which case, this should be recorded in the patient's chart).
  - A professionally trained medical interpreter should be present even if the appointment is limited to a **physical examination**.
  - Interpretation by nonqualified individuals (e.g., family members, medical staff) may be necessary in certain (e.g., emergency) situations in which delaying care in order to access interpreter services might result in patient harm.
- Interviewing techniques when an interpreter is present
  - Introduce the interpreter to the patient.
  - Position of the interpreter
    - Spoken **language**: slightly behind or next to the patient
    - Sign **language**: behind the physician
  - Address the patient, not the interpreter, and maintain **eye** contact.
  - Avoid third-person statements, keep phrases short, and ask one question at a time.
  - Allow extra time for the interview.

#### B. Psychosocial counseling

- **Definition:** care related to the emotional and psychological well-being of the patient and their family members.
- Principles
  - Aims to reduce both psychological distress and physical symptoms by increasing quality of life and enhancing coping (e.g., identify and treat **anxiety** and depression)
  - Based on good communication, assessment, and interactional skills (e.g., compassion, empathy) to build a rapport with the patient and their family.
  - Encourages patients to express their feelings about the disease (e.g., consequences, relationships, self-esteem issues)
  - Provides psychological and emotional well-being tools for patients and their caregivers

#### C. Enabling behavioral change

- Patients should be encouraged to participate in treatment and therapy decisions.
- **Shared decision-making** enables patients to make informed choices.
- **Motivational interviewing** can be a helpful tool to strengthen a patient's motivation to change behavior (e.g., **substance use disorders**, lifestyle changes).
  - Aims to explore and resolve ambivalence about changing behaviors by eliciting the patient's reasons for change
  - Helps to assess the barriers that make behavioral change difficult for the patient

#### Transtheoretical model of behavioral change

- **Definition:** a biopsychosocial model that focuses on an individual's intentional change of behavior
- Objectives
  - To assess an individual's readiness to modify a certain behavior
  - To provide strategies to guide the individual, e.g., in overcoming **substance use disorder**, managing weight, adhering to medication

Stages of behavioral change		
	Patient behavior	Interviewing techniques
Precontemplation stage	<ul style="list-style-type: none"> <li>• Denies or is unaware of the problem and its consequences</li> </ul>	<ul style="list-style-type: none"> <li>• Encourage introspection by asking open, probing, and nonjudgmental questions that explore the patient's perception of the situation.</li> <li>• Emphasize your availability and the importance of follow-up visits.</li> <li>• Demonstrate the discrepancy between the patient's personal goals and values and current behavior.</li> </ul>
Contemplation stage	<ul style="list-style-type: none"> <li>• Aware of the problem but unwilling to change it</li> </ul>	<ul style="list-style-type: none"> <li>• Discuss the benefits and disadvantages of the patient's current behavior.</li> <li>• Use a readiness-to-change scale to determine the patient's motivation to change (e.g., "On a scale of 1 to 5, how ready are you to lose weight?") [3]</li> <li>• After the patient states a number, ask the patient why they picked this number rather than a lower one.               <ul style="list-style-type: none"> <li>◦ This approach applies the <b>framing effect</b> to an individual's <b>decision matrix</b>.</li> <li>◦ It encourages the patient to reflect and focus on the disadvantages of the current state and the benefits of change (instead of the benefits of the current state and disadvantages of change), thereby enabling further discussion on the reasons to embrace change.</li> </ul> </li> <li>• Suggest possible ways to support behavior changes.</li> </ul>
Preparation stage	<ul style="list-style-type: none"> <li>• Preparing to make a change</li> </ul>	<ul style="list-style-type: none"> <li>• Help to set achievable goals and provide resources.</li> <li>• Encourage changes and adjust expectations as necessary.</li> </ul>



Action stage	<ul style="list-style-type: none"> <li>Demonstrates a change in behavior</li> </ul>	<ul style="list-style-type: none"> <li>Help to maintain change by collaboratively developing <u>coping strategies</u> (e.g., identifying/avoiding triggers) and self-help strategies.</li> <li>Emphasize positive changes that have been made.</li> <li>Acknowledge difficulties.</li> </ul>
Maintenance stage	<ul style="list-style-type: none"> <li>Maintains behavioral changes and integrates them into lifestyle</li> </ul>	<ul style="list-style-type: none"> <li>Support and praise ongoing positive changes.</li> <li>Assess the risk for relapse.</li> <li>Provide support, encouragement, and reinforcement.</li> </ul>
Relapse stage	<ul style="list-style-type: none"> <li>Behavioral changes are reversed.</li> </ul>	<ul style="list-style-type: none"> <li>Reassure the patient of ongoing support, availability, and the possibility of change.</li> <li>Encourage a return to prior behavioral changes.</li> <li>Help the patient to learn from the relapse.</li> </ul>

#### 5 As model of behavior change

- Definition:** an evidence-based behavioral intervention strategy originally developed for smoking cessation that can be adapted for multiple behaviors and health conditions to help individuals with intentional behavior change
- Components
  - Assess the patient's behavior, beliefs, knowledge, and level of motivation.
  - Advise the patient on personal health risks and the benefits of change.
  - Agree on appropriate treatment goals and methods (shared decision-making).
  - Assist the patient to identify personal barriers, create self-help strategies, access social or environmental support for behavioral change, and supplement with adjunctive medical treatments if appropriate.
  - Arrange specific plans for follow-up support to provide ongoing support and adjust the treatment if necessary.

#### Directive counseling (prescriptive counseling)

- Definition:** an approach to counseling in which the physician assumes an active role in guiding the therapeutic process along lines that they consider relevant and in the best health interests of the patient
- Principles
  - While providing directive counseling, the physician should:
    - Provide information objectively and ensure that there is no element of duress, coercion, or manipulation in guiding the therapy.
    - Keep in mind that patient autonomy always takes precedence and that patients with decision-making capacity can refuse to follow the physician's recommendations.
  - Examples of situations in which directive counseling is applicable include:
    - The patient is making a decision (e.g., due to knowledge deficit or wrong beliefs) that is detrimental to their own well-being (e.g., opting for a home birth when it is contraindicated, opting for home remedies to treat early-stage cancer, continuing to drive despite being unfit to do so)
    - The patient requests a test or treatment that is inappropriate or ineffective.

#### D. Counseling on substance use disorders

- Screening for substance use disorder
  - Should be routinely performed in a primary care setting
  - Use initial screening questions.
    - For alcohol use: "How many times in the past year have you had four or more drinks in a day?"
    - For drug use: "How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?"
  - If a patient screens positive in the initial screening question, assess the severity of misuse.
  - SBIRT approach: screening, brief intervention, referral to treatment
    - Aims to enable early intervention for patients with, or at risk of developing, substance use disorders
    - Used in primary care centers, emergency rooms, or trauma centers
    - Brief intervention is used to increase insight and awareness regarding substance use and to motivate behavioral change.
    - Referral to specialty care ensures more extensive treatment.
- Techniques for counseling on substance use disorder
  - Motivational interviewing
  - Transtheoretical model of behavioral change
  - 5 As model of behavior change
- General principles of addiction counseling
  - Can be individual or group counseling (e.g., Alcoholics Anonymous)
  - Includes patient education
  - Aims to help patients avoid people or situations that might trigger substance use
  - May also incorporate cognitive, behavioral, and/or supportive psychotherapies (see "Psychotherapy and defense mechanisms")

#### Counseling on smoking cessation

- Using the 5 As model of behavior change, the clinician should:
- Ask: Inquire about and document the use of tobacco.
  - Advise: Urge quitting with clear and personalized language.
  - Assess: Assess the patient's willingness to quit.
  - Assist: Provide resources to help the patient quit.
  - Arrange: Schedule regular follow-ups.

Smoking is the single greatest preventable cause of death in the US, regardless of age at the time of quitting or the number of previous pack years.

#### Counseling on alcohol use disorder

- Provide feedback to the patient regarding their level of alcohol consumption and engage the patient in a conversation using reflective or motivational listening (a technique in which the topic is broached by repeating or rephrasing the patient's own words and using open-ended questions).
- Inform the patient about psychosocial support groups (e.g., Alcoholics Anonymous).
- Inform the patient about pharmacological treatment options (e.g., naltrexone, disulfiram).
- Assess the patient's readiness to change by using the transtheoretical model, and schedule regular follow-ups.

#### Counseling on illicit drugs

- Engage the patient in a conversation using reflective or motivational listening.
- Provide feedback to the patient regarding their level of drug consumption.
- Assess the patient's readiness to change by using the transtheoretical model and schedule regular follow-ups.

#### Counseling on lifestyle modifications

- Lifestyle modifications involve altering long-term habits, and adopting and maintaining healthier behaviors.
- Lifestyle modifications can be used to treat a wide range of conditions (e.g., cardiovascular diseases, obesity).
- Cardiovascular diseases are the leading cause of death in the US for both men and women.
  - In one hour, approx. 83 people in the US die from heart disease and stroke.
  - More than 25% of these deaths could have been prevented or delayed by lifestyle modifications that help control modifiable risk factors and promote healthier behaviors (e.g., smoking cessation, regular exercise).
  - See “Etiology” and “Primary and secondary prevention of atherosclerosis” in “Atherosclerosis” for more information.
- Many people in the US are affected by sleep disorders (e.g., insomnia) or insufficient sleep.
  - Insufficient sleep has been linked to the development of chronic diseases (e.g., type 2 diabetes, cardiovascular disease, obesity, depression).
  - Sleep hygiene interventions target behavioral habits that negatively impact sleep.
  - See “Sleep and sleep disorders” for more information.
- The prevalence of obesity in the US is approx. 42% and has been increasing substantially in the past decades, and behavior modification is a cornerstone of therapy.

#### Counseling on support options for regular exercise and diet changes

- Counseling on regular exercise
  - Patients should have 150 minutes of moderate aerobic activity or 75 minutes of vigorous aerobic activity per week.
  - The specific activity or sport should be tailored to patient preferences to increase the likelihood of adherence.
- Counseling on weight and diet changes
  - Suggest including family members or friends in diet and exercise plans to enhance social support.
  - Encourage patients to increase physical activity.
  - Encourage regular weighing.
  - Encourage patients to monitor what they eat and develop stimulus control (e.g., buying fewer calorie-rich foods).
  - Provide education on nutrition.
  - Set realistic goals in collaboration with the patient.

Selfmonitoring of daily weight, food intake, and exercise is associated with increased success rates and greater long-term maintenance of weight loss.

#### Counseling on sleep hygiene and lifestyle modifications to improve mood

- Counseling on sleep hygiene
  - Recommended amount of sleep per night
    - Older adults (> 65 years): 7–8 hours
    - Adults (18–65 years): 7–9 hours
    - Teenagers (14–17 years): 8–10 hours
    - School-aged children (6–13 years): 9–11 hours
    - Preschool children (3–5 years): 10–13 hours
    - Toddlers (1–2 years): 11–14 hours
    - Infants (< 1 year): 12–15 hours
    - Newborns (< 4 weeks): 14–17 hours
  - Encourage patients to maintain a regular sleep schedule.
  - Advise patients to avoid the following:
    - Stimulants (e.g., caffeine, nicotine) in the evening
    - Exposure to electronic screens before bedtime
    - Naps
  - Encourage regular exercise.
- Counseling on lifestyle modifications to improve mood
  - Educate patients on relaxation techniques.
  - Encourage regular exercise.
  - Educate patients on mindfulness and meditation.

#### Counseling on the use of prescription opioids

- Inform patients about the possibility of opioid intoxication, addiction, adverse effects, and opioid withdrawal (see “Opioid intoxication and withdrawal”).
- Educate patients on buying opioids only from licensed pharmacists and stores.
- Stress that patients should take opioids exactly as prescribed and that they should not use opioids prescribed for someone else.
- Patients should avoid mixing opioids with any other drugs, especially alcohol or sedatives (e.g., benzodiazepines).
- Establish specific SMART goals for opioid therapy.
- Opioids should be stored in their original containers, out of sight/reach of children.
- Physicians should address suspected opioid misuse in a nonjudgmental, collaborative discussion with the patient that aims to understand the reasons for misuse.

#### Counseling on sexual health and contraception

- Taking a sexual history
  - Routinely incorporate sexual history into primary care.
  - Adolescents > 12 years of age should be interviewed alone and confidentiality should be ensured.
  - To take a baseline sexual history, the 5 Ps can be used to determine a patient’s sexual health needs.
    - Partners: Ask the patient about the number and gender(s) of sexual partners.
    - Pregnancy: Ask the patient whether they want to avoid pregnancy or are planning a pregnancy.
    - Practices: Ask which types of sex are practiced (e.g., oral, vaginal, anal).
    - Protection against STIs: Ask about the protective measures against STIs currently used by the patient or their partner(s).
    - Past history of STIs: Ask the patient if they have a previous history of STIs.
  - See also “Communicating with transgender and gender-diverse patients” below.
- Counseling on safe sex practices
  - Inform patients about factors that increase the risk of contracting STIs (e.g., not using condoms, multiple sex partners).
  - Discuss testing (e.g., HIV testing) and the benefits, risks, and limitations of different contraceptive methods.
- Counseling on contraceptive options
  - Discuss the patient’s priorities regarding whether, when, and how to have children.
  - If the patient wishes to know about contraceptive options, discuss their effectiveness and adverse effects.
  - Hormonal contraceptive options (reversible)
    - Most effective: contraceptive implants and intrauterine devices with progestin
    - Other options include injectable contraceptives, oral contraceptives, and transdermal patches.
  - Nonhormonal contraceptive options
    - Most effective: vasectomy (may be irreversible), female sterilization (irreversible), and intrauterine devices (reversible)
    - Less effective, reversible options include diaphragms and condoms.
  - For more information on contraceptive methods, see “Hormonal contraceptives” and “Nonhormonal contraceptives.”

#### Counseling on support options for domestic violence

- Screening for intimate partner violence (IPV)
  - At initial visits or routinely
  - If a patient mentions a new intimate relationship
  - At prenatal and immediate postpartum visits
  - If a patient presents with concerning trauma or symptoms consistent with IPV
  - Screening should be conducted using standardized questioning tools (e.g., abuse assessment screen).
- Counseling on IPV
  - Encourage disclosure by asking direct questions and ensuring confidentiality.
  - Express empathy, validation, acknowledgment, and nonjudgmental support following disclosure of IPV.
  - Thoroughly document the details of abuse.
  - Assess the patient's willingness to take action and evaluate whether the patient is currently safe.
  - The patient should be referred to a social worker or domestic violence advocate/hotline for advice on preparing a safety plan.
  - Do not encourage patients to leave the relationship.
  - Counsel and evaluate for psychological comorbidities.
  - For more information on IPV, see "Domestic violence" and "Ethically challenging situations" in "Principles of medical law and ethics."

Clinicians should not encourage patients to leave an abusive relationship but should support them if they come to that decision on their own.

#### Counseling for patients with memory loss and/or cognitive impairment

- General considerations
  - Evaluate emotional stability (e.g., suicidality), safety risks, adequacy of supervision, and whether there is evidence of neglect.
  - Clinicians should have contact information for the patient's caregiver or next of kin, who should be advised to determine whether the patient is adequately handling finances, medications, and other responsibilities.
- Interviewing techniques
  - Use concrete, direct, and specific language.
  - Provide a quiet, nondistracting space for the interview.
  - Adjust questions to the patient's level of comprehension.
  - Do not make assumptions about a patient's abilities (e.g., literacy).
  - See "Communicating with patients with disabilities" below.

#### Counseling for patients with chronic diseases and/or terminal illness

Patients with chronic/terminal diseases can feel isolated, frustrated, and/or hopeless. These patients should be counseled on learning how to handle difficult emotions and develop an understanding of their disease. See "Grief and end-of-life counseling" for more information on counseling patients with terminal illness.

- Counseling for chronically ill patients
  - Emphasize that the patient is not alone and offer referral to support groups.
  - Listen to the patient's frustrations and challenges and empathize with them; do not dismiss their concerns.
  - Avoid platitudes such as "Everything will be OK" or "I'm sure you'll feel better soon."
  - Discuss why treatment adherence is important for slowing or reversing disease progression.
  - Counsel the patient on lifestyle modifications to improve mood.
  - Educate patients on mindfulness and meditation.
  - Spiritual counseling: See "End-of-life counseling for patients."
  - See also "Psychosocial models" in "Overview of palliative medicine" and "Psychosocial counseling."

#### Counseling for patients following disfiguring injuries or surgeries

- Following disfiguring injuries or surgeries (e.g., amputations, facial injuries), patients frequently experience psychiatric distress and are at an increased risk for psychiatric disorders (e.g., major depressive disorder, posttraumatic stress disorder, social phobia).
- If a patient feels unattractive:
  - Explore the patient's reaction to their condition with an open question.
  - Do not give false reassurance.
  - Use a patient-centered approach to listen actively to the unique concerns expressed by the patient.
  - Discuss further treatment options if necessary.

#### Counseling on sudden infant death syndrome (SIDS)

To prevent SIDS, physicians should educate parents on the following measures:

- Babies should be placed to sleep on their backs and on a firm surface.
- Encourage mothers to breastfeed for as long as possible.
- Avoid exposing the baby to cigarette smoke.
- There should be no pillows, loose bedding, or blankets in the crib where the baby sleeps.
- Avoid overheating the baby.
- The baby should sleep in the same room as the parents but not in the same bed.
- The use of a pacifier can also reduce the risk of SIDS.

#### Communicating with transgender and gender-diverse patients

##### Principles

Affirmative care is a model of health care that takes a respectful, validating, and supportive approach to topics of gender identity, sexuality, and sexual relationships. The foundation of affirmative care is awareness for the special needs of and respect for patients with identities beyond the cisgender, heterosexual spectrum. This involves creating an inclusive clinical environment in which patients feel welcome and safe to discuss their health. A respectful and identity-affirming doctor-patient relationship is key to ensuring that all patients, but especially individuals belonging to potentially marginalized minorities who have often experienced discrimination, receive the health care they require.

##### Inclusive environments

- Try to ensure that registration systems and intake forms allow for including information on "gender identity," "sex assigned at birth," "preferred name," "preferred pronouns," and "preferred form of address" (e.g., Mr., Mrs., Ms, first name only, other)
- Provide separate all-gender bathrooms, if possible.
- Familiarize yourself with the preferred terminology used in the LGBT+ community.
- Provide training for staff to ensure behavior and language that promotes inclusivity.

##### Communication

- Use gender-neutral language (a style of language that avoids attribution of individuals to binary gender categories) until a setting can be established to ask the patient what name and pronoun they prefer.
- Consider that individuals may be nonbinary, bigender, not identify with any gender, or be uncertain of their gender identity.
- Avoid making assumptions regarding gender identity and sexual orientation and refer to the information provided in the intake form when addressing questions of gender and sexuality.
- Only address questions of gender identity and sexual orientation if it is relevant to the patient's visit.

- Offer open communication about gender identity; Expressing empathy and acknowledging an individual's nonbinary or transgender identity establishes trust with positive effects for an individual's self-affirmation and quality of life.
- Be honest about mistakes made in gendered language and show a willingness to learn and improve.
- Provide information and resources about transgender care and facilitate access to health care services (e.g., gender-affirming therapy) if the patient expresses interest.
- Offer counseling and referral to mental health services if patients show signs of gender dysphoria, major depressive disorder, anxiety, social isolation, and suicidal ideation.
- Reiterate that a nonbinary or transgender identity is not a disorder and that medical attention is unnecessary unless the identity causes physical or mental health issues.
- Reassure patients of confidentiality.
- Only discuss a patient's gender identity with team members or colleagues involved in the patient's care if it is relevant, i.e., the information is needed to address the patient respectfully.

#### Reporting

- Summarize information provided by the patient to ensure it has been understood correctly.
- Report the patient's gender identity, chosen name, and pronouns used in order to ensure that this information is accessible to all health care professionals involved in the care of the patient.
- If the chosen name does not match the name on medical records or insurance, these documents may be updated to avoid confusion and clerical errors.

#### Special considerations in youth

- Adolescents > 12 years of age should be interviewed alone and confidentiality should be ensured.
- Establish a setting that offers the opportunity to openly communicate about gender identity and sexuality.
- Provide the opportunity for children and adolescents to speak openly about gender and sexuality and do not assume gender binarity.
- Provide information and resources to educate parents, family members, school teachers about transgender and nonbinary identities, transition options, and creating a safe, inclusive environment at home and in one's social surroundings.
- Social transition measures (e.g., changes in clothing, hairstyles, names, and pronoun use) are an option for young individuals to reduce identity-related distress.
- Provide information and resources about medical interventions
  - See puberty suppression
  - See gender-affirming hormone therapy
  - See gender-affirming surgery
- For safety reasons, do not disclose a child's gender identity to their parents without receiving consent/permission.

#### Gender-inclusive language in clinical practice

- Use the patient's preferred name.
- Use the patient's preferred pronoun (e.g., "they," "ze," "xe," "hir," "per," "ve," "he," "she") or, if preferences are unknown, the gender-neutral singular "they."
- Use gender-neutral language and avoid language that implies that gender is binary. For example:
  - Avoid "a physician should care for his patients" and rather say "physicians should care for their patients."
  - Avoid gendered terms such as "mankind," "chairman," and "policeman" and use "humankind," "chairperson," "police officer" instead.
  - Avoid phrases such as "he or she," "male or female," or "opposite sex" and use open or inclusive terms such as the singular "they," "gender," and "another sex"/"other sex."
- Use gender-neutral age-specific nouns (e.g., infant, child, adolescent, adult) and/or nouns corresponding with the patient's identity (e.g., boy, girl, woman, man, transgender woman, transgender man) instead of "male" or "female" in the noun sense (e.g., "the patient is a 23-year-old woman" rather than "the patient is a 23-year-old female"). "Male" and "female" may, however, be used in the adjectival sense to specify gender-neutral terms (e.g., "male infant").
- Do not confuse the terms "sex" and "gender" or the concepts underlying them.
- Avoid assumptions about the patient's environment or lifestyle relating to gender identification and sexual orientation (e.g., "do you live in a partnership" rather than "are you married?" or "do you have a husband?").

#### Communicating with patients with disabilities

- General considerations
  - Use a normal tone of voice and talk directly to the patient.
  - Caregivers accompanying the patient may provide additional information if necessary.
  - Ask the patient if they need assistance, do not assume help is needed.
  - When communicating with family members or caregivers, apply people-first language, e.g., "a person with a disability" instead of "the disabled (person)."
  - Make eye contact.
  - If a physical examination is necessary, do not miss out any relevant components.
  - Only address the patient's disability if it is relevant to the visit.
- Communicating with patients who have hearing loss
  - Ask the patient about their preferred means of communication (e.g., sign language, lip reading).
  - Allow extra time for the interview.
  - Make use of visual/tactile signals to maintain the patient's attention.
  - Offer a medical interpreter trained in American Sign Language. Other communication options include computer-assisted real-time transcription and assistive listening devices.
  - Ensure that your lips are visible to the patient; if droplet precaution measures are necessary, a transparent surgical mask should be worn.
  - See "Interviewing techniques when an interpreter is present" in "General concepts of patient counseling" above.
- Communicating with patients who have speech difficulties
  - If you have difficulties understanding a patient, ask them to write down the information.
  - Repeat information provided by the patient to ensure correct interpretation and/or understanding.
  - Eliminate background noise and distractions.

#### Trauma-informed communication

- Behavioral health screenings for patients with a history of trauma
  - Substance use
  - Social support
  - Suicide risk
  - Trauma-related symptoms interfering with social/occupational function
- Interviewing techniques
  - Avoid asking the patient to repeat their trauma history (review the patient's chart instead)
  - Emphasize confidentiality.
  - Inform the patient about what to expect during the history taking and, if relevant, during a physical examination.
  - If the patient requires a physical examination, inform them beforehand that they determine the pace and/or continuation of the examination and can signal at any time if there is emotional or physical discomfort.
  - Ask the patient for permission before conducting each part of the physical examination.
  - Let the patient know that they can have one or more friend or family member present in the room for support.

#### Culture in the health care setting

##### Culture as an aspect of health and medicine

- Culture is the set of ideas, social behaviors, and customs shared by a group of people as a defining factor of their social cohesion. Manifestations such as religion, ethnicity, language, and nationality can be regarded as elements of culture as well as cultures in their own right.
- Culture shapes people's perceptions of and views on health, disease, and medicine.

- Accordingly, culture also shapes the way people experience and manifest symptoms as well as how they express the experience of symptoms.
- Cultural concepts of distress
- The interaction between health and medicine in a specific cultural context can give rise to **cultural concepts of distress**, which refers to cultural idioms, explanations, or conditions that individuals from the corresponding culture use to describe and contextualize symptoms (see below for details).
  - Such descriptions may have no correspondence to concepts of evidence-based medicine, making diagnosis and treatment difficult.
  - To avoid misdiagnosis and provide the best possible care, physicians should be aware of the patient's cultural background. This is best done with the help of a **cultural formulation interview**.
- Types of **cultural concepts of distress**
- **Cultural explanations/perceived causes of distress:** culture-specific etiological models for symptoms, illness, or distress. Such models may be founded on traditional medicine as well as cultural manifestations such as folklore, religion, and diet.
  - **Cultural idioms of distress:** culture-specific expressions for symptoms or states of distress
  - **Cultural syndromes:** clusters of psychiatric and/or somatic symptoms that occur exclusively in a specific culture or context and are generally recognized as medical conditions in the respective communities
- Examples of **cultural syndromes**
- **Ataque de nervios ("attack of nerves")**
    - An acute syndrome among individuals of Iberian origin or descended cultures (e.g., Hispanic, Caribbean) characterized by intense emotional distress (typically **anxiety**, anger, or **grief**) and a sense of losing control
    - Symptoms include uncontrollable screaming and crying, trembling, verbally and/or physically aggressive behavior, **palpitations**, chest tightness, breathlessness, a sensation of heat rising up to the head, sweating, fainting, dissociative experiences (e.g., **amnesia**, **depersonalization**), and seizure-like episodes.
    - Typically precipitated by stressful events in the family (e.g., **death**, divorce, accidents, conflict) or, less commonly, the accumulated experience of suffering
    - Manifestations may resemble **panic attacks**, specific or unspecific **dissociative disorders**, and **conversion disorder**.
  - **Khyal cap ("wind attack")**
    - An acute syndrome among Cambodian individuals and those of Cambodian descent characterized by symptoms of **panic attacks** (e.g., **palpitations**, **tachycardia**, **anxiety**) and autonomic arousal (e.g., neck soreness, **tinnitus**)
    - Attributed to disruptions of the flow of khyal (a form of inner "wind" comparable to air and pneuma in classical **humoral** theory) in the body.
    - Often meets the criteria of **panic attacks** and may be associated with **PTSD** [22]
  - **Taijin kyofusho ("disorder of fear of interpersonal relations")**
    - A syndrome among Japanese individuals and those of Japanese descent characterized by social **anxiety** about and the avoidance of interpersonal relations due to a sense of inadequacy or feeling that one's actions or appearance may be offensive to others
    - Social situations or their anticipation may trigger **panic attacks**.
    - Manifestations may meet the criteria of **social anxiety disorder**, **body dysmorphic disorder**, and **delusional disorder**.
  - **Dhat syndrome ("semen loss")**
    - A broad range of symptoms seen in South Asian male individuals and those of South Asian descent characterized by fear attributed to the loss of "dhatu," one of the seven essential bodily humors in Ayurvedic medicine (generally equated with semen).
    - Common manifestations include fatigue, **anxiety**, **erectile dysfunction**, weight loss, and depressive **mood** in absence of any physiological dysfunction.
- Cultural considerations in clinical care
- A patient's cultural background may influence their views on health and health care and affect their preferences and decisions regarding treatment.
    - Such preferences and decisions may conflict with standard clinical practice and/or physician values. [23][24]
    - Physicians should make an effort to understand and accommodate cultural differences with their patients' best health interests in mind.
    - Physicians should not provide treatments that they believe are unethical or harmful, regardless of any cultural concerns.
    - Physicians should respect the cultural values and precepts of their patients and tailor the clinical approach accordingly. [25]
  - A direct conversation with the patient about their cultural background can help to improve mutual understanding. [23][25]
    - An interpreter should be involved if there is a **language** barrier between a physician and a patient (see "**General concepts of patient counseling**" in "Patient communication and counseling" for more information about the use of interpreters).
    - If needed, social workers, chaplains, or team members with the same cultural background may be involved in the conversation.
    - Physicians may not override a capable patient's wish to refuse treatment, even if the wish is motivated by cultural precepts that conflict with standard clinical practice. However, physicians may offer education to convince patients to reconsider refusing treatment, recommend against treatments they believe are ineffective, and refuse treatments that they believe are harmful or unethical.
  - **Cultural formulation interview**
    - A set of questions asked during a mental health examination in order to assess a patient's perception and experience of psychiatric symptoms within their cultural context, including **cultural factors** that influence the way the patient perceives the manifestation and cause of the distress as well as the actions they take to resolve distress
    - Promotes physician-patient communication, helps avoid linguistic and/or cultural misunderstandings, enhances the patient's cooperation during the mental health examination, increases the **accuracy** of diagnosis and therapeutic planning, and helps bridge any cultural differences between the physician and the patient that may hinder treatment
- Genetic counseling
- **General considerations**
    - In the US, **genetic counseling** is provided by specially trained professionals called "genetic counselors." [26]
    - All the principles of **medical ethics** apply also in **genetic counseling**.
  - **Purposes**
    - Providing families information about the nature of a genetic disease and/or predisposition to a **multifactorial disease** with a strong genetic influence (e.g., **type 2 diabetes mellitus**, certain types of cancer)
    - Discussing possible risks and benefits of **genetic testing**
    - Performing and interpreting genetic tests
    - Counseling on treatment of genetic diseases
    - Helping individuals and their families cope with the psychological burden of a genetic disorder
  - **Responsibilities of genetic counselors** [27]
    - Discussing the risks and benefits of **genetic testing** with patients
    - Screening for genetic conditions in certain populations (e.g., for **Tay-Sachs disease** in **Ashkenazi** Jewish individuals)
    - Genetic risk assessment (e.g., for certain types of cancer)
    - Diagnostic testing in individuals suspected of having a genetic disorder
    - Preimplantation testing (possibly in the setting of assisted reproduction)
    - Interpretation of test results
    - Educating individuals and families with a genetic disease and/or a predisposition to a **multifactorial disease** with a strong genetic influence (e.g., **type 2 diabetes mellitus**, certain types of cancer) about the nature of the disease
    - Counseling on the management of a genetic disease
    - Helping individuals and families cope with the psychological burden of a genetic disorder
  - **Types**
    - **Pre-test counseling:** focuses on evaluating the need for a test and informing the patient about the purpose of testing, details of the test (e.g., its strengths and limitations), possible consequences of testing, and obtaining **informed consent**
    - **Post-test counseling:** focuses on delivering the test results, providing education about the disease, discussing management options, providing psychological support



- Elements of a **genetic counseling** session
  - Taking a history of the disorder and **family history**
  - **Pedigree analysis** (if applicable)
  - Discussing the appropriate genetic test (see “**Genetic testing**” for indications for individual genetic tests)
  - Obtaining **informed consent** for **genetic testing**: A patient should be informed about the benefits and risks of **genetic testing**, possible findings **genetic testing** can reveal, and the ways the obtained information may influence disease or risk management.
  - Result disclosure and discussion
  - Psychological support

#### Counseling on complementary and alternative medicine

- Explore the patient’s reasons for requesting complementary and alternative treatment.
- Discuss the risks and benefits of these treatments.
- Be open to integrating modalities with proven safety and **efficacy**.

#### Counseling on clinical uncertainty

- Patient is uncertain about a certain treatment/diagnostic step
  - Acknowledge the degree of uncertainty.
  - Convey the potential seriousness of the situation.
  - Include an individualized discussion of differential diagnosis based on known facts of the case.
  - Explain the need for further evaluation.
  - Include a clear plan for follow-up.
  - Allow the patient an opportunity to ask questions.
- Patient declines a recommended treatment/diagnostic step
  - Provide accurate and complete information on the procedure.
  - Provide a balanced assessment of the recommended intervention, including benefits, risks, and limitations.
  - A thorough explanation of further medical steps and plans can reinforce patient **autonomy** and improve decision-making.

## Quality and Safety

#### 29 questions

Quality in health care is the measure of the best possible outcomes in **patient-centered** care considering the circumstances and the resources available. Safety is a central dimension of quality in health care. It is the measure of standards in place to mitigate the risk of hazards and keep patients and health care workers free from harm due to error, patient management, and environmental factors. Hazards can result from **human factors** (e.g., poor communication), system factors (e.g., a mismatch between resources and workload), and external factors (e.g., weather). System errors (e.g., using outdated guidelines, untrained staff) generate potential hazards that pose the greatest risk to the quality and safety of an organization. The greatest **risk factor** in patient safety is **medical error**, which can result from acts of commission (e.g., **amputation** of the wrong limb) or omission (e.g., failure to amputate a **necrotic limb**). The deliberate deviation from standards, laws, or rules constitutes a violation. If an error or violation has occurred, health care workers must inform the patient immediately, disclose the nature of the error, and implement corrective measures to minimize harm to the patient. Although individuals must be held accountable for the errors they commit, error mitigation is most effective when it relies less on disciplining error and focusing more on eliminating hazards on a systemic level while fostering a **safety culture** that encourages individuals to openly express safety concerns, admit error.

Continuous **quality improvement** in health care is based on **improvement science** and employs tools such as **variation management** and the Plan-Do-Study-Act cycle (**PDSA cycle**) to identify areas of improvement and establish standards of quality. **Error prevention** relies on **safety culture**, error analysis, and **human factors design** to identify and address risks in actionable ways. **Teamwork** and communication are essential in high-risk organizations, such as hospitals, where collaborating and sharing information are vital in maintaining high standards of quality and safety.

#### Health care quality

Health care quality refers to the degree to which health services generate the desired outcomes efficiently and in line with current standards of care.

##### A. Key aims of health care (STEEEP)

- **Safety**: Avoid or minimize risks and hazards that may lead to harm (e.g., **iatrogenic injuries/conditions**).
- **Timeliness**: Reduce delays that may lead to harm.
- **Effectiveness**: Provide evidence-based health care and avoid services or treatments of doubtful benefit.
- **Efficiency**: Provide the highest quality care at the least investment of resources (e.g., avoid overutilization of medical resources, unnecessary diagnostics, overmedication).
- **Equitable care principles**: Provide equal care to all patients regardless of **gender**, ethnicity, **sexuality**, and socioeconomic status.
- **Focus on patient needs**: Individualize treatment with respect for patient preferences, values, and needs (see also “**Patient-centered approach**” in “**Patient communication and counseling**”).

##### B. Integrated care

- **Definition**: a multidisciplinary approach aimed at coordinating health care across levels, services, and settings to ensure the continuous improvement and delivery of health promotion and prevention, diagnosis and treatment, **rehabilitation**, and **palliative care**
- Principles
  - Education, shared decision-making, and local services to empower individuals and communities to share in health care responsibilities
  - Services tailored to the needs of individuals, communities, and the population as a whole
  - Continuous improvement of health care access, quality, user satisfaction, and efficiency to ensure the best possible outcomes with the resources available (e.g., shared guidelines and protocols)
  - Performance improvement through with feedback loops

##### C. Attributes of high-quality health care

###### Cost-conscious care

- **Definition**: a focus on controlling the costs of health care with the aim of providing affordable and accessible high-value care to the population at large
- Overview
  - Health care providers have an obligation to manage resources responsibly and promote the accessibility as well as affordability of health care.
  - Health care providers should be constantly aware of the cost of illness
- Principles
  - Treatment recommendations and decisions should be individualized to foster adherence and prevent unnecessary treatment (see also “**Shared decision-making**”).
  - Decisions should be made in accordance with evidence-based recommendations and guidelines to ensure effective and efficient treatment.
    - Avoid overutilization of resources
      - Overutilization can cause financial, physical, and psychological harm to patients.
      - Health care providers should collaborate with patients on defining health care goals and provide realistic recommendations to achieve those goals.
      - Health care providers should be transparent regarding treatment alternatives but recommend the course of action that provides the greatest benefit at the least expense of resources (e.g., prescribing a generic drug over the brand-name alternative)



- Unnecessary diagnostic tests or procedures should be avoided (e.g., unnecessary consultations, **imaging studies, antibiotic or opioid prescriptions**, maternity care interventions)
      - Only truly necessary interventions or treatments should be recommended (e.g., ineffective nonpalliative services at end of life such as routine **screening tests** for cancer patients, Pap smears for patients with limited life expectancy and no relevant clinical features)
      - Antibiotic stewardship programs (ASPs)
        - Key elements to optimizing **antibiotic** use in hospitals are hospital leadership commitment, accountability, pharmacy expertise, action, tracking, reporting, and education
        - Initiatives with the goal to measure, critically review, and improve the way **antibiotics** are recommended by physicians and used by patients in order to guarantee effective treatment, prevent adverse effects to unnecessary **antibiotic** use (e.g., *C. difficile* infection), and reduce **antibiotic** resistance
    - Organizations should assess the benefits, harms, and costs of diagnostic tests and interventions to determine whether they provide value in the treatment of specific diseases.
      - Promotion of cost data transparency
      - Facilitation of training regarding health care costs and health care spending for health care providers
      - Collaboration between health care providers and government agencies to reduce financial and other obstacles to health care access
      - Develop patient-friendly summaries to facilitate patient understanding of commonly used tests and procedures
  - Goals
    - Improvement of health care outcomes and **patient-centered care** that avoids unnecessary and even harmful interventions
    - Reduction of the rapidly expanding costs of the **health care system**
- Benefit-cost analysis
- Overview
    - An economic method used to compare the costs and benefits of an intervention or program
    - Evaluates the impact of a program or intervention in quantifiable, monetary terms
    - Assesses costs in the immediate (intervention) as well as the more distant future (intervention benefits)
    - Allows ranking interventions and programs in order of decreasing net benefits in order to budget priorities accordingly (i.e., improves resource stewardship)
  - Measures
    - Benefit-cost ratio
      - Provides **insight** into the amount of money saved for the amount spent on a program or intervention
      - Benefits are divided by the net costs.
      - Programs or interventions are generally implemented if the **benefit-cost ratio** is > 1.
    - Net benefit (preferred measure)
      - The costs are subtracted from the benefits.
      - Programs or interventions are generally implemented if the **net benefit** is > 0.
  - Costs
    - Staff, facilities, and medical supplies
    - Psychological costs of disease increase long-term financial costs.
  - Benefits
    - Decreased medical expenditures due to a prevention initiative or treatment of a disease
    - Increased productivity and satisfaction for health care employees due to improved outcomes
    - Positive outcomes for patients have secondary, psychological benefits for health care workers
- Equitable care
- Overview
    - The provision of high-quality, affordable, and prompt care to all individuals regardless of age, **gender**, race, ethnicity, or socioeconomic status (see also “**Health care disparity**” in “**Health care system**”).
    - Stakeholders in health care (i.e., health care organizations, health insurance companies, physicians, medical societies public policy makers) should collectively ensure access to appropriate health care for all people.
- Patient-centered care
- **Overview:** a collaborative approach to the decision-making process between physicians, patients, and patient families that focuses on patient needs, requests, and desired outcomes
    - Health care providers should keep the emotional, social, and financial effects of health care in perspective for each individual patient.
    - Family members should be encouraged to participate if the patient desires. Their views and values should be discussed, respected, and taken into account.
  - Pillars of **patient-centered care**
    - Respect the patient's values, preferences, and needs.
    - Provide adequate information and education (e.g., information for patients on condition, treatment plan, assistance with behavioral changes).
    - Ensure access to care (e.g., facilitate making an appointment, short waiting time in office, timely response to telephone calls, efficient use of consultation time, electronic prescription refills).
    - Provide emotional support.
    - Involve family and friends, if the patient so desires.
    - Ensure a safe and appropriate transition between health care settings (e.g., posthospital follow-up and support, proper information transfer between physicians and care providers)
    - Provide a psychologically and physically comfortable setting for the patient.
    - Guarantee proper coordination of care (e.g., coordination of specialist care, filling prescriptions to monitor patient adherence).
- Timely care
- Overview
    - Waiting times and operational hours that ensure patients receive the care they require in the event of an emergency.
    - Timely delivery of care can help reduce mortality and **morbidity** also for chronic conditions.
  - Principles to improve care timeliness
    - Convenient operational hours
      - Staggered shifts to extend operational hours
      - Integrated services to provide appointment flexibility
      - Appropriate number of staff and service hours
      - Remote consultation or telemedicine services
    - Low waiting times
      - Easy-access appointment system for patients
      - Enable making appointments via homepage, email, and **SMS** as well as telephone.
      - Specific days or times for walk-ins or same-day appointments

#### D. High-Reliability Organizations (HROs)

- **Definition:** organizations that consistently experience fewer accidents or harmful events than anticipated and manage to avoid these despite operating in complex, high-risk environments

#### Principles of HROs (principles of reliability)

Reliability in health care refers to the maintenance of a system's capability of performing its intended functions consistently according to the given standards of quality and safety. HROs operate under the principles of **patient-centered**, timely, and effective care to promote consistency and quality.

- Preoccupation with failure
  - High sensitivity to the potential consequences of failure and error maintains vigilance for hazards and risks high even as rates of failure and error decrease

- Accordingly, near misses are regarded as potential failures that provide opportunities to test and improve the system rather than the confirmation of safety.
- Reluctance to simplify
  - The appreciation of a system's necessary degree of complexity prevents individuals from cutting corners in the endeavor for efficiency in areas where safety is a concern.
  - At the same time, there is an awareness of how unnecessary or excessive complexity also poses a hazard and that efficiency can be an important aspect of safety (as reflected, e.g., by standardization, streamlining processes, and reducing variation).
- Sensitivity to operations:** situational awareness of how individual processes and actions affect the operations of a system as a whole
- Commitment to resilience
  - Recognition of the fact that failure can be unpredictable and that a completely error-free environment cannot be created.
  - Individual members are trained to continuously analyze challenging situations efficiently and minimize harm effectively.
- Defence to expertise:** an organizational culture that encourages collaboration with and seeking advice from individuals with the experience and expertise necessary for the task at hand rather than relying on the authority of senior rank in challenging situations

#### E. Measures of health care quality

- Definition:** indicators used to assess and compare the quality of health care systems, based on the model developed by physician and health care services researcher Avedis Donabedian
- Donabedian model
  - A framework for evaluating the quality of health care based on the assessment of structural, process, outcome, and balancing measures
  - Based on the assumption that the structural context of health care (i.e., facilities, equipment, staff), the processes that take place within that context, the outcomes generated by the processes, and the interaction (balancing) of systems affect one another and determine the overall quality of health care

<u>Donabedian model</u>		
	Definition	Examples
Structural measures	<ul style="list-style-type: none"> <li>Measures of the resources available to a health care facility (e.g., equipment, facilities, staff)</li> </ul>	<ul style="list-style-type: none"> <li>Number of nutritionists available for patients with <u>diabetes</u></li> <li>Physician-patient <u>ratio</u></li> <li>Number of beds</li> </ul>
Process measures	<ul style="list-style-type: none"> <li>Measures of <u>health care system</u> performance as planned</li> </ul>	<ul style="list-style-type: none"> <li>Percentage of individuals who receive a particular preventive service (e.g., immunizations, cancer screening, <u>HbA1c</u> measurement) over a period of time</li> </ul>
Outcome measures	<ul style="list-style-type: none"> <li>Measures of the final impact of service provided by a health care facility, including mortality and <u>morbidity</u></li> </ul>	<ul style="list-style-type: none"> <li>Average <u>HbA1c</u> measurement of patients over a period of time</li> <li>Rates of <u>nosocomial infections</u></li> <li><u>Maternal mortality rates</u></li> </ul>
Balancing measures	<ul style="list-style-type: none"> <li>Measures of the impact of one system on another</li> </ul>	<ul style="list-style-type: none"> <li>Cost-benefit analysis (e.g., using <u>number needed to treat</u>) of hiring more nutritionists to educate patients with <u>diabetes</u></li> <li>Evaluating readmission rates after an initiative to reduce the average length of stay</li> </ul>
Composite measures [15][16]	<ul style="list-style-type: none"> <li>Measures that aggregate structural, process, and/or <u>outcome measures</u> into a single score</li> </ul>	<ul style="list-style-type: none"> <li>Assessing the management of a condition aggregates the following three categories of measures:               <ul style="list-style-type: none"> <li><u>Structural measures</u>: a health care facility's professional and organizational resources (e.g., staff expertise, electronic health records, facility capacity)</li> <li><u>Process measures</u> <ul style="list-style-type: none"> <li>The methods by which health care is provided (e.g., procedures, tests, surgeries)</li> <li>Reflect the ability of a facility to screen, diagnose, and manage diseases (e.g., diagnostic <u>accuracy</u>, adequate treatment)</li> </ul> </li> <li><u>Outcome measures</u>: the consequences of a patient's interaction with the <u>health care system</u> or the desired result (e.g., reducing patient death)</li> </ul> </li> <li>Example: A <u>composite measure</u> for assessing the <u>management of atrial fibrillation</u> (AF), may, e.g., aggregate the following measures:               <ul style="list-style-type: none"> <li>Are potential triggers of AF (e.g., infection) being controlled?</li> <li>Has the indication for <u>rhythm control</u> been assessed? If appropriate, are <u>rhythm control</u> measures provided?</li> <li>In <u>permanent AF</u>: are <u>rate control</u> measures provided?</li> <li>Is anticoagulation being prescribed, if necessary?</li> </ul> </li> </ul>

#### Physician Quality Reporting System (PQRS)

- Definition:** a reporting program created by the Centers for Medicare and Medicaid Services (CMS) and in place until 2017, which gave health care professionals the opportunity to assess the quality of care they were providing to their patients in order to ensure patients were receiving timely and appropriate care.
- General principles
  - Eligible health care providers: Medicare physicians providing covered professional services based on the Medicare Physician Fee Schedule (MPFS) (e.g., physicians, practitioners, therapists) could submit data about the quality of their care.
  - Quality measures (based on STEEP)
    - The types of measures reported changed from year to year.
    - Generally varied by specialty and focused on areas such as public health, care coordination, patient safety, clinical processes, and effectiveness
    - 254 quality measures and outcome measures were defined, for which health care providers could submit data, including:
      - Effective clinical care
      - Efficiency
      - Cost reduction

- Patient safety
    - Communication and care coordination
  - Goal: collecting data on quality of care across health care systems
- Prior to 2015
  - Providers enrolled on a voluntary basis
  - Participants were paid an incentive for reporting on selected quality measures based on their Medicare fee for service claims (i.e., participants were financially compensated for providing data)
- Between 2015 and 2017
  - Shift to a mandatory program
  - Health care professionals who did not satisfactorily submit data on quality measures, for their covered professional services, for the quality reporting period for the year would be subjected to payment adjustments for noncompliance.
  - Based on a P4P system
  - In 2017, PQRS was integrated into the Merit-based Incentive Payment System (MIPS).

#### Merit-based Incentive Payment System (MIPS)

- **Definition:** a performance-based incentive program implemented by the Centers for Medicare and Medicaid Services (CMS) in place since 2017 that offers payments to eligible health care providers for high-quality and cost-effective care; aimed at improving overall health care quality, reducing costs, and increasing the use of appropriate health care information
- General principles
  - Integrates various Medicare incentive and payment programs into a single system (e.g., PQRS, Value-based Payment Modifier Program, Medicare Electronic Health Record Incentive Program)
  - Participation is mandatory for all eligible clinicians and practices (e.g., part of Medicare Part B program, previously involved in Medicare).
    - Those who fail to report are penalized financially.
    - Eligible participants can report as individuals or groups.
  - Performance measures: reporting requirements vary for each category
    - Quality measures
      - Providers and groups can select their own quality measures.
      - Physicians and groups must report six quality measures.
    - Improvement activities: measure of patient engagement and improvements in health care and process management
    - Promoting interoperability: an effort to make health information more available for patients, providers, and payers in order to facilitate information exchange and reduce administrative burdens across the health care system
    - Cost
      - Participants who meet the specified minimum case volume required are scored using different performance measures (e.g., total per capita cost, medicare spending per beneficiary).
      - CMS collects this data directly from the Medicare claims data.
      - Aimed at making health care more cost-efficient and affordable
  - Participants are financially incentivized to submit data and scored according to the amount of data provided.
    - In order to achieve maximum points, participants must report sufficient data for every performance category as well as demonstrate improvements in the quality of health care and a reduction in its costs.
    - The overall score is compared to a performance threshold to determine payment adjustments.
      - Scores above the threshold: receive a payment incentive
      - Scores below the threshold: receive a negative payment adjustment
      - Scores equal the threshold: receive a neutral payment adjustment

#### Continuous quality improvement in health care

Quality improvement is a continuous process of prospectively and retrospectively reviewing measures of quality control and maintenance to progressively improve the standard of health care and prevent medical error.

#### A. Improvement science

- Multidisciplinary approach
- Applied science field based on researching and determining which improvement strategies work in the health care system and policies in order to ensure quality, safety, and value
- Focuses mainly on three areas of health care: interventions to improve or change existing processes, the implementation and systematic study of changes implemented, and the context or conditions in which the changes are applied.

#### Variation management

Variation in health care refers to the difference between the expected outcome of an intervention or process and the actual outcome. Some variation is expected and even necessary (e.g., new guidelines, new treatments, changes to processes) since every patient is different and should receive personalized care. However, the frequent occurrence of unexpected events due to unpredictable processes can also pose a risk to health care workers and patients. Proper variation management involving patients, health care managers, clinicians, and researchers increases the predictability of a health care system and the understanding of how care is being delivered, thereby improving the overall quality of care (i.e., stable and safe processes, care effectiveness and generalizability, clinical outcome).

- Types of variation
  - Common cause variation
    - A natural variation that is **inherent** to processes in a health care system
    - Generally occurs at **stable** and **predictable** intervals, but may be unpredictable
    - Typically cannot be traced back to a root cause
    - Examples: patients with different manifestations for the same disease, demographic or socioeconomic differences between patients, hospital staff skills
  - Special cause variation
    - A variation attributable to a **specific cause** that is not inherent to processes in a health care system
    - Occurs sporadically and unpredictably
    - Typically, can be traced to a root cause that can then be identified and addressed
    - May occur due to system or process management
    - Examples: patient information is missing due to human error (file misplacement or wrong patient coding), the order in which patients are seen and treated (i.e., patients being seen out of turn), how hospital services are scheduled, the staff's workload during a shift, ordering different tests for the same clinical presentation
- **Goals of managing variation:** reducing special cause variation and properly managing common cause variation
  - Understanding the type of variation before using internal data to positively impact systematic improvement strategies and, subsequently, improve quality and reduce potentially costly variations
  - Improving patient safety and satisfaction
  - Introducing instruments to assess and control variation in order to facilitate the detection of flaws in the system and establish consistency based on best practices

#### Instruments of variation management

- Variation analysis

- Identify the sources and types of variation.
  - Determine how variations affect the system across time, place, and staff within the system.
- **Variation management:** implement measures to control variation
  - **Standardization** of care and implementation of guidelines: protocols, checklists, clinical pathways (see “**Human factors and ergonomics**”)
    - **Standardization of processes**, technology, and equipment reduces variation, costs, and the risk of error to improve health care quality and patient safety
    - Typically used to improve processes that exhibit **common cause variation**
  - Quality improvement interventions or models: a systematic framework for establishing change processes in **health care systems**, services, or suppliers for the purpose of increasing the likelihood of optimal quality of care
    - The components of **quality improvement interventions** can be applied to organizations, **health care systems**, the behavior of health professionals, and the patients cared for
    - These interventions aim to identify inefficiencies and implement standardized processes to reduce costs and improve overall productivity.
    - Typically measured by positive health outcomes in individuals and populations
    - **Examples:** **Plan-do-study-act cycle**, Six Sigma, LEAN, physician education, physician reminder systems, facilitated clinical data to providers, feedback, benchmarking, practice guidelines, critical pathways, patient education, patient reminder systems, and promotion of self-management.
  - Providing feedback of performance data to the health care provider
    - Establish a data monitoring system to review physician performance and appropriate use of standardized criteria
    - Implement peer review programs to identify problems in performance and conduct focused professional practice evaluations
  - Identifying the areas within the system that have the most variation utilization potential (e.g., hospital readmissions, CU utilization, emergency room utilization, surgical procedures, imaging tests)
  - Creating a work culture based on improvement, transparency, safety, and excellence: Systems should strive for continuous performance improvement by implementing benchmarks, being open to collaboration, and providing external or internal leadership examples.
- **Variation monitoring:** Routinely collect, analyze, and report variation in clinical outcomes and **outliers**, in order to measure the impact of applying certain clinical practices and processes on clinical outcomes.

### Conceptual models of improvement

Continuous process control and improvement are fundamental aspects of quality management in any **health care system**. The models most commonly used today are the plan-do-study-act cycle (**PDSA**) and the plan-do-check-act cycle (**PDCA**), iterative four-step cycles that ideally culminate in the consolidation of the lessons learned through **process standardization**. The cycles are repeated until the problem is resolved or the process is perfected. However, due to the effects of variation in **complex systems**, process improvement is rarely finalized, and the **PDSA/PDCA** typically begins anew based on the standards set in the previous cycle.

- **Plan:** assessing the need for improvement and planning the actions required to achieve the desired outcomes
- **Do:** carrying out the actions determined necessary for improvement and testing their applicability
- **Study/Check:** evaluating the data collected in the previous steps/inspecting compliance
- **Act:** implementing the measures of process improvement based on the data collected

While the individual steps of the **PDSA** and **PDCA** are very similar, there are key differences between the **PDCA** and the **PDSA**.

- **PDCA**
  - The precursor to the **PDSA** model, but still preferred in some business settings
  - Focus on testing currently running processes to ensure compliance
  - Check-stage
    - Process inspection to ensure compliance
    - Comparison of expected results and actual results
    - Measurement of the improvement necessary for progressing to the Act-stage
- **PDSA**
  - Often preferred in health care organizations
  - Focus on the development and testing of process changes
  - Focus on continuous learning as a basis for continuous improvement
  - Study-stage
    - Analysis of data collected in previous stages
    - Reflection of metrics being analyzed

### Steps in the cycles

- **Plan**
  - In this phase, an area that needs improvement is defined, followed by the planning of potential changes or actions to bring about a corrective change.
  - SMART criteria can be applied to accurately define and develop the objectives of change
    - **Specific:** objectives are clear and specific with regard to actions required, expected impact, target population, and responsibilities
    - **Measurable:** determine indicators that allow quantification of an objective's impact and the progress made towards achieving it
    - **Assignable:** determine responsibilities in the team and set objectives that can realistically be achieved with the resources available.
    - **Realistic:** set objectives that align with the intended goal and mission
    - **Timely:** set objectives that can be achieved within a specific time frame and establish realistic timelines
- **Do**
  - In this phase, the new action is tested.
  - Attempt to solve the defined problem by mapping out possible hypotheses and trying new methodologies.
  - Problems and unexpected observations should be documented.
- **Study**
  - This phase completes the analysis of the data **before and after** the action took place and assesses its impact on the quality of health care.
    - Outcomes are measured and monitored
    - Outcomes are compared with the predictions and hypothesis
  - One of the following improvement measurement tools may be used:
    - **Pareto chart:** a type of graph that combines bars and a line, in which the bars represent a total for each category (arranged from highest to lowest) and an overlaid line represents the cumulative percentage of the total.
      - Typically used to identify defects and prioritize improvement processes for the most significant categories (frequency or cost of problems).
      - Example: identifying the highest ranked reason for inadequate patient transfers and what percentage of the total this reason represents.
    - **Shewhart chart (control chart):** a graphic representation of data plotted over time by comparing the degrees of variation in a measure to determine if a perceived improvement in quality is **statistically significant** in the long term.
      - Typically uses lines determined by previous data: a **central line** (shows the average), an upper line (shows the upper control limit), and a lower line (shows the lower control limit)
      - Helps to identify variation (common cause vs. special cause) within the process by comparing current data to the aforementioned lines.
    - **Run chart (time plot):** a line graph that plots data over time to **analyze trends**
      - The data displayed visualizes process performance over time
      - Vertical axis: represents the process (currently being measured)
      - **Horizontal axis:** represents time
      - Center line: represents the mean or average

- **Run charts** do not use control limits; accordingly, they cannot provide information on whether a process is stable or not.
  - Example: analysis of the impact of an intervention over time to help determine whether the improvement is a random occurrence or a true trend
- Check
  - Review the effects of the implemented change (i.e., what was intended to be achieved actually happened)
  - Analyze the results and identify learnings.
- Act
  - This phase revolves around taking action
  - Will result in either of the two options:
    - **Implementation** of new processes according to the data collected in the “do” and “study” phases, if these showed a positive impact on health care quality
    - Determine what modifications should be made to the tested action and **prepare a new change plan** (i.e., begin the cycle again)

### Patient safety

Patient safety is concerned with maintaining health care systems that keep patients free during management and reducing the risk of harmful incidents to an acceptable minimum.

### Medical error

A medical error is a preventable adverse effect of medical care, regardless of whether or not it causes the patient harm or becomes evident. As the 3rd leading cause of death in the US, responsible for ~ 250,000 deaths per year, it represents the greatest threat to quality and patient safety. Medical error is distinct from iatrogenesis, which describes harm to the patient caused by medical care. Iatrogenesis may be due to unforeseeable events (e.g., previously undocumented allergic reactions or drug interactions, calculated risks of treatment) as well as medical error. For the legal consequences of medical error, see “Medical malpractice.”

#### A. Classification of medical errors

The classes of medical error listed below are not mutually exclusive but rather tend to occur in conjunction or complement each other. For example, the administration of the wrong drug due to medications with similar packaging being stored together is a latent systems error and a potential never event (a flaw in the storage system precipitated the administration of the wrong drug) as well as an active and individual error of commission (the person who gave the drug is responsible).

Overview of medical error types		
Type of <u>medical error</u>	Definition	Examples
Active error	<ul style="list-style-type: none"> <li>• Error at the <b>direct level of contact</b> between health care personnel and patients</li> <li>• Has an immediate impact on the patient</li> </ul>	<ul style="list-style-type: none"> <li>• Surgery on the incorrect site</li> <li>• Wrong route of drug administration</li> </ul>
Latent error	<ul style="list-style-type: none"> <li>• Error inherent to a system that may cause patient harm under specific circumstances</li> <li>• <u>Latent error(s)</u> in conjunction with <u>active error(s)</u> can cause <u>adverse events</u>.</li> </ul>	<ul style="list-style-type: none"> <li>• Medications with similar packaging that are stored directly next to each other</li> <li>• Flaws in hospital organization</li> <li>• Implementation of new equipment without adequate staff training</li> </ul>
Individual error	<ul style="list-style-type: none"> <li>• <u>Medical error</u> resulting from the failure of a single health care professional</li> </ul>	<ul style="list-style-type: none"> <li>• A physician administering the wrong dose of a drug</li> </ul>
Systems error	<ul style="list-style-type: none"> <li>• <u>Medical error</u> resulting from a series of actions and/or factors in treatment or diagnosis, from flaws in technical and organizational design and/or decision-making, or from failure to recognize and mitigate hazards and risks in the health care setting</li> </ul>	<ul style="list-style-type: none"> <li>• Lack of trained staff leads to bottlenecks in emergencies</li> </ul>
Error of execution	<ul style="list-style-type: none"> <li>• Preventable failure to perform an act of medical care as intended</li> </ul>	<ul style="list-style-type: none"> <li>• Misdosing the appropriate drug</li> </ul>
Error of planning	<ul style="list-style-type: none"> <li>• Performing an incorrect act of medical care to achieve an appropriate aim</li> </ul>	<ul style="list-style-type: none"> <li>• Prescribing the wrong drug</li> </ul>
Error of omission	<ul style="list-style-type: none"> <li>• Failure to execute the appropriate action when required</li> </ul>	<ul style="list-style-type: none"> <li>• Failure to note a history of allergies leading to the administration of a drug against which the patient has a known <u>allergy</u></li> </ul>
Error of commission	<ul style="list-style-type: none"> <li>• Inappropriate execution of an action or execution of an inappropriate or unnecessary action</li> </ul>	<ul style="list-style-type: none"> <li>• Administering a subcutaneous drug intravenously</li> <li>• Performing unnecessary surgery</li> </ul>

Never event/ sentinel event [27]	<ul style="list-style-type: none"> <li>A serious <u>adverse event</u> that is clearly identifiable, causes serious injury or <u>death</u>, and is considered sufficiently preventable that it should never occur</li> </ul>	<ul style="list-style-type: none"> <li>Includes injury, disability, or <u>death</u> due to the following: <ul style="list-style-type: none"> <li>Wrong-site <u>surgery</u></li> <li>Wrong-patient <u>surgery</u></li> <li>Post-procedure retention of a foreign object in a patient</li> <li><u>Suicide, suicide attempt</u>, or self-harm within a health care facility</li> <li>Using contaminated devices or medications</li> <li>Using medical devices for purposes other than their intended function</li> <li>Administering the wrong medication</li> </ul> </li> </ul>
Near miss ( <u>close call</u> ) [28]	<ul style="list-style-type: none"> <li>A <u>medical error</u> that could have resulted in an <u>adverse event</u> but did not, either incidentally or due to a timely intervention</li> </ul>	<ul style="list-style-type: none"> <li>An incorrect order that is identified by a nurse before being filled</li> </ul>

#### B. Specific medical errors

Overview of specific <u>medical errors</u>			
Type of error	Definition		Examples
Communication error	<ul style="list-style-type: none"> <li>Error in communication between health care personnel and patients as well as among health care personnel</li> </ul>		<ul style="list-style-type: none"> <li>Errors in: <ul style="list-style-type: none"> <li><u>History taking</u></li> <li>Giving directions</li> <li>Explaining planned medical procedures to the patient</li> <li>Written communication (e.g., poor handwriting on order sheets or prescription pads)</li> <li>Verbal communication (e.g., lack of standardized terminology, use of jargon, lack of personnel skilled in foreign <u>languages</u>)</li> </ul> </li> </ul>
Diagnostic error	<ul style="list-style-type: none"> <li>Errors or delays in diagnosis</li> </ul>		<ul style="list-style-type: none"> <li>Not ordering the required investigations</li> <li>Use of outdated tests; errors in diagnostic studies</li> <li>Failure to adequately monitor clinical signs or <u>laboratory studies</u></li> <li>Misinterpretation</li> </ul>
Laboratory error [29][30]	<ul style="list-style-type: none"> <li>An error that occurs at any stage from the ordering of the test to the reporting and interpretation of the test result</li> <li>An important cause of <u>diagnostic errors</u></li> <li>For more information, see “<u>Basics of laboratory analysis</u>” in “<u>Laboratory methods</u>”</li> </ul>	<ul style="list-style-type: none"> <li>Preanalytical phase errors <ul style="list-style-type: none"> <li>Occur before the specimen arrives in the laboratory</li> <li>Account for 60–70% of <u>laboratory errors</u></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Misplaced or incomplete test orders</li> <li>Ordering an inappropriate test</li> <li>Improper specimen collection, storage, and/or transport (e.g., <u>hemolysis</u> in a blood sample, insufficient blood volume, postprandial blood sample for a lipid profile test)</li> <li>Specimen contamination</li> <li>Incorrect identification of the patient and/or labeling of the specimen (misidentification error) [31]</li> </ul>
		<ul style="list-style-type: none"> <li>Analytical phase errors: occur during the processing and analysis of the specimen</li> </ul>	<ul style="list-style-type: none"> <li>Malfunction or improper calibration of laboratory equipment (<u>device error</u>)</li> <li>Reagent or specimen contamination</li> </ul>
		<ul style="list-style-type: none"> <li>Postanalytical phase errors: occur during the reporting and/or interpretation of the test results</li> </ul>	<ul style="list-style-type: none"> <li>Transcribing error (<u>documentation error</u>)</li> <li>Prolonged turnaround time</li> <li>Misinterpretation of the results</li> </ul>
Treatment error	<ul style="list-style-type: none"> <li>Errors or delays in treatment</li> </ul>		<ul style="list-style-type: none"> <li>Unnecessary medical procedures</li> <li>Incorrect administration of treatment</li> <li>Incorrect drug dosage</li> <li>Incorrect route of administration</li> <li>Failure to provide treatment or respond to diagnoses in a timely manner</li> </ul>



Preventive error	<ul style="list-style-type: none"> <li>Errors in prophylaxis</li> </ul>	<ul style="list-style-type: none"> <li>Failure to implement appropriate prophylaxis</li> <li>Failure to provide adequate monitoring or follow-up treatment</li> <li>Failure in equipment and system maintenance</li> </ul>
Medication error	<ul style="list-style-type: none"> <li>Errors in prescription</li> <li>Errors in transcription</li> <li>Errors in dispensation</li> <li>Errors in administration</li> </ul>	<ul style="list-style-type: none"> <li>Failure to correctly transcribe drug names, dosages, routes of administration (e.g. mistranscription of a trailing zero)</li> <li>Incorrect drug dispensation due to errors related to medications with similar name or appearance</li> <li>Errors in <u>medication reconciliation</u></li> <li>Administering the wrong drug, dosage or using the wrong route of administration</li> <li>Mathematical errors</li> </ul>
Patient identification errors	<ul style="list-style-type: none"> <li>Misidentification of the patient</li> </ul>	<ul style="list-style-type: none"> <li>Mislabeling (e.g., <u>wrong patient</u> identification wristband) that can lead to further errors (e.g., <u>transfusion</u> errors)</li> <li>Lack of dual validation (e.g., verbal verification of administered medication)</li> </ul>
Device errors	<ul style="list-style-type: none"> <li>User-associated <u>device errors</u></li> </ul>	<ul style="list-style-type: none"> <li>Incorrect use of equipment due to improper training</li> <li>Unergonomic equipment</li> </ul>
	<ul style="list-style-type: none"> <li>Device-associated <u>device errors</u></li> </ul>	<ul style="list-style-type: none"> <li>Outdated or malfunctioning equipment</li> </ul>
Monitoring errors	<ul style="list-style-type: none"> <li>Errors associated with monitoring equipment or medication</li> </ul>	<ul style="list-style-type: none"> <li>Errors in cardiac monitoring/telemetry, such as: <ul style="list-style-type: none"> <li>Most often due to failure at the level of the device-patient interface (e.g., disconnected wires, improper connection)</li> <li>Other <u>medical errors</u> that can result in cardiac monitoring errors include <u>communication errors</u> e.g., resulting in incorrect settings, <u>device errors</u> in form of equipment malfunction, and <u>alert fatigue</u></li> </ul> </li> <li>Errors in drug monitoring (e.g., no <u>INR</u> monitoring when using <u>warfarin</u>; no measurement of <u>vancomycin</u> trough levels)</li> </ul>
Documentation errors	<ul style="list-style-type: none"> <li>Errors in documentation of patient-associated information</li> </ul>	<ul style="list-style-type: none"> <li>Incomplete or inaccurate documentation</li> <li>Misinterpretation of information due to indecipherable handwriting or the use of nonstandard abbreviations</li> <li>Entry of medical information into the <u>wrong patient's</u> medical record (misidentification error)</li> <li>In electronic health records, improper use of copy-paste or copy-forward functionality can lead to: <ul style="list-style-type: none"> <li>Note bloat: creation of lengthy record notes that make it difficult to identify key aspects relevant to the patient's current care</li> <li>Propagation of incorrect or outdated information (e.g., previous <u>vital signs</u>, old drug doses)</li> <li>Ordering tests or treatment unnecessarily or for the <u>wrong patient</u></li> </ul> </li> </ul>
Procedural errors	<ul style="list-style-type: none"> <li>Errors associated with procedures</li> </ul>	<ul style="list-style-type: none"> <li>Errors associated with universal protocol, including: <ul style="list-style-type: none"> <li><u>Wrong patient</u></li> <li>Wrong site</li> <li>Wrong procedure</li> </ul> </li> <li>Retained foreign bodies</li> <li>Iatrogenic harm <ul style="list-style-type: none"> <li><u>Paracentesis</u>: <u>bowel perforation</u></li> <li>Central venous/arterial line injuries: arterial puncture, bleeding, venous thrombosis</li> <li><u>Thoracentesis</u>: <u>pneumothorax</u></li> <li><u>Lumbar puncture</u>: bleeding, paralysis</li> </ul> </li> <li>Anesthesia-related errors (e.g., calculating the wrong dosage)</li> </ul>
Transition of care errors	<ul style="list-style-type: none"> <li>Error during patient transfer/<u>hand-off</u> (e.g., from HCP to HCP, in between shifts, transfer between units, at discharge)</li> </ul>	<ul style="list-style-type: none"> <li>Vital information (e.g., lab results) is lost during <u>hand-off</u></li> <li>Patient is discharged without booking of a necessary follow-up appointment</li> </ul>

#### Prescription cascade

- **Definition:** a cycle of prescription triggered by the physician failing to identify adverse effects of a preexisting prescription as such and consequently treating the symptoms with additional prescriptions rather than by adjusting the preexisting prescription
- Stages of the prescription cascade
  1. Prescribed medication (e.g., NSAIDs for musculoskeletal pain) causes an adverse effect (e.g., hypertension)
  2. The adverse effect is misinterpreted as a new condition by the physician, which leads to:
    - Prescription of a new drug (e.g., an ACE inhibitor) and/or
    - Patient self-medicating with over-the-counter drugs
  3. The newly prescribed medication/over-the-counter drug, in turn, causes new adverse effects (e.g., dry cough), triggering another cycle of the prescription cascade
- Prevention
  1. Periodic medication reviews (of over-the-counter as well as prescription drugs) to identify potential medication errors
  2. Informing and educating patients on the potential adverse effects of their current medication and newly prescribed drugs
  3. Asking patients about new symptoms after the prescription of any new medication

#### Hazards, risk, and risk factors

##### A. Definition

- **Hazard:** a source of potential harm
- **Risk:** the probability that the hazard will actually cause harm and the degree of harm it might cause, depending on the circumstances
- **Risk factor:** a variable or attribute that increases the probability of developing a disease or injury
- **Example:** A wet floor represents a hazard that can lead to falls and subsequent injury. The degree of risk depends on the circumstances of the floor, e.g., it will represent a greater risk in a busy emergency department than in a storage closet that is rarely opened. Additional factors that could influence the risk of slippery floor causing harm could be the spill of soapy water, a lack of personnel to quickly address the hazard, or a lack of "Caution: wet floor"-signs.

##### B. System-associated risk factors

- Complex systems
  - Complex systems (e.g., hospitals) consist of innumerable interacting elements (e.g., machines, staff, facilities).
  - The interaction of many individual elements introduces a certain degree of unpredictability (e.g., malfunction, illness) that makes these systems susceptible to failure (e.g., incorrect results, interruption of processes).
  - Complex systems are characterized by:
    - Nonlinear processes
    - Multiple/circular causality
    - Multilevel cooperation
    - Open systems
    - Self-organization
    - Synergy
- **Environmental factors** (e.g., high noise level, poor lighting, inadequate room temperature, weather)
- Workspace design
  - Floor plan of wards (e.g., location of nursing station for optimal proximity to all patient rooms)
  - Ergonomics of facilities (e.g., a designated place with fresh gloves, bandages, syringes in every patient room), furniture, and equipment
  - Communication technology (e.g., ineffective nurse call systems)
- Human resources
  - Staffing (e.g., understaffing)
  - Scheduling

##### Health care personnel-associated risk factors

- **Excessive workload** (e.g., due to mismatched ratio of medical personnel to a number of patients)
  - Burnout: overall exhaustion due to an excess of stress over an extended period of time
    - Lack of motivation and interest
    - Feelings of failure and helplessness
    - Cynical and detached work attitude
    - Impaired immune function
    - Decreased concern
  - Fatigue
    - Chronic sleep deprivation
    - Decreased energy and motivation
    - Impaired cognitive function
    - Impairment in intellectual function
- **Alert fatigue:** the tendency to become desensitized to and subsequently ignoring alerts prompted by clinical decision support systems due to the excessive number or limited clinical relevance of the alerts in the past
- **Inexperience:** deficiency of practical skills and/or knowledge, predisposing for judgment and/or diagnostic errors
- **Overcommitment:** associated with burnout (especially exhaustion and cynicism)
- Cognitive biases
  - **Confirmation bias (psychology):** the tendency to favor evidence that supports preconceived notions, ignoring other results
  - **Anchoring bias:** the tendency to inappropriately rely on initial perception or information, which hinders later judgment when new information becomes available (e.g., favoring a diagnosis proposed earlier despite new evidence)
  - **Availability bias:** the tendency to make judgments based on the availability of information from memory (e.g., when a physician makes a premature diagnosis that comes to mind easily and quickly due to having seen several patients with a similar clinical presentation)
  - **Framing bias:** the tendency to be influenced by how information is presented (e.g., the order of symptoms and/or emphasis placed on specific findings)
  - **Visceral bias:** the tendency for clinical decisions to be influenced by positive or negative feelings towards the patient (e.g., doubts regarding symptoms when described by a patient with substance use disorder)
  - **Ascertainment bias (psychology):** the tendency to base decisions on preset assumptions (e.g., gender bias, stereotyping bias)
  - **Gender bias:** the tendency to base decisions on false assumptions about an individual's real or perceived gender
  - **Information bias (psychology):** the tendency to collect more information than necessary for a decision
  - **Aggregate bias (psychology):** the tendency to assume that aggregated data (e.g., clinical guidelines) does not apply to the individual patient
  - **Commission bias:** the tendency to prefer action over inaction
  - **Omission bias:** the tendency to prefer inaction over action

##### B. Patient-associated risk factors

Patient behavior can contribute to the occurrence of system failure, adverse events, and error. Risk factors include:

- Poor adherence to the treatment regimen (e.g., failure to make lifestyle changes, take medication as prescribed, or make follow-up appointments)
- Low level of health literacy and awareness, often associated with low socioeconomic status
- Cultural factors (e.g., religious rules that do not permit men to examine women or vice versa)
- Extremes of age
- Non-white race \*this is the case in some, but not all, adverse safety events
- Low English proficiency

- Medicaid insurance
- Multiple comorbidities
- Prolonged hospital stay

Assume that all patients have limited health literacy (i.e., use universal health literacy precautions).

## Adverse events

### A. Definitions

An adverse event is any untoward reaction following medical treatment that may or may not be the result of a medical error.

- **Preventable adverse event:** any adverse event that could have been prevented by observing the rules of safety and error prevention
- **Ameliorable adverse event:** unpreventable adverse event whose severity could have been reduced through the application of specific strategies

### B. Responding to adverse events

#### General principles

- Implement corrective measures immediately to minimize patient harm.
- Health care providers who have reason to believe a colleague has committed an error should urge that colleague to report the error to the patient and their supervisor.
- If a colleague refuses to report an error when urged, the individual suspecting the error should report the event via the **standard protocol in place**.
- If the cause of an adverse event is not immediately known, the physician should inform the patient and maintain contact while investigations are being carried out.
- A just culture that holds individuals accountable for their actions but discourages blame and focuses on addressing system errors rather than punishing individual errors encourages error reporting.
- Use of an incident reporting system

#### Disclosing the error

- Disclose error to the patient and, if necessary, a supervisor and administration
- The following points should be considered for optimal error disclosure:
  - Clearly **admit** an error has occurred.
  - State the course of events leading up to the error.
  - Explain the consequences of the error, both immediate and long-term (if applicable).
  - Express personal regret and **apologize**.
  - Describe corrective steps.
  - Allow ample time for questions and **continued dialogue**.

Regardless of the outcome of a treatment, a physician must inform the patient immediately if an error has occurred and disclose the nature of that error.

Don't say: "I'm sorry you feel like that," "I'm sorry you took it that way," "I'm sorry, BUT...". Instead say: "I'm sorry this happened," "I'm truly sorry for the distress caused," "I'm sorry, we have learned that..."

### C. Incident reporting systems (IRS)

- Overview
  - IRS provide a means of reporting errors and expressing concerns (e.g., aggregation of near misses).
  - Analysis of the reports collected facilitates the identification of risks within the organization.
- **Goal:** developing and implementing strategies to address identified risks and prevent further errors
- Advantages
  - Useful in identifying commonly occurring and local systemic errors (e.g., medication errors due to trailing zeros on labels), for which substantial data can be collected
  - Aggregation of data with the help IRS facilitates the analysis of more severe adverse events (e.g., never events) for which only limited data exists.
  - Conclusions drawn from IRS data can be shared within and/or across organizations, which is also generally recommendable as this helps identify risks and prevent future error on a larger scale.
- Limitations
  - IRS cannot be used to measure safety in general and/or changes over time.
  - Comparing organizations with one another based on data from IRS is impossible.
  - Organizations might not have enough resources to thoroughly review the large number of reports that IRS generate.

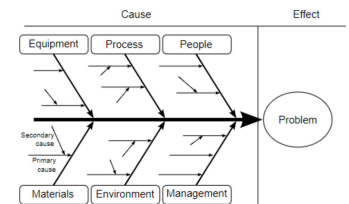
## Medical error analysis

### Introduction

- Medical error analysis investigates the existing and potential causes of error in order to mitigate the occurrence of new errors and prevent the recurrence of past errors.
- Goal: to minimize the number of medical errors by implementing safety measures and checkpoints; focus on systemic errors
- There are 2 types of medical error analyses:
  - Retrospective: an analysis of past errors done to gain knowledge of the types and causes of error
  - Prospective: an analysis of potential errors done to assess risks and hazards that may lead to errors in the future

### A. Root cause analysis

- **Definition:** a **retrospective** analysis used to identify the (root) causes of an error and develop measures to **prevent its recurrence**
- Procedure
  1. Identify the medical error ("What happened?")
    - Retrospective analysis of all possible factors that could have led to the error considering patient documentation, the equipment/drugs used, and the environment the patient was in
    - Examples include: slippery floor, infectious ward, nonquarantined patient, incorrect management protocol
  2. Determine what could have prevented the error from occurring ("Why did it happen?").
    - Tool used: Fishbone diagram
      - Also called Ishikawa diagram or cause-and-effect diagram
      - Used to break down and visualize all potential events that led to the error
  3. Develop preventive measures ("What can be done to prevent recurrence?"): e.g., updating technology, employing double checks, using checklists, staff education on new policies



Root cause

### B. Failure mode and effects analysis (FMEA)

- **Definition:** a **prospective** analysis used to identify potential risks and hazards by assessing the failure modes (i.e., the manner in which failure occurs) of a system's components, determining the effects such failures may have, and developing measures to prevent these failures from occurring
- Procedure
  1. Choose a specific system component.
  2. Select a specific potential failure (failure mode).
  3. Identify why it could go wrong (failure causes).
  4. Identify the consequences of potential failures (failure effects).
  5. Prioritize the hypothetical failures by their probability of occurring and the severity of their effects.
  6. Proactive implementation of corrective measures.

- Example
  1. Component: medication error
  2. Failure mode: dispensing error (in this case: wrong medication given to the correct patient)
  3. Failure causes
    - Nurse confused medication due to similar appearance or name
    - Wrong medication in the packaging
    - Medication accidentally got swapped during dispensing
  4. Failure effects: ranging from no effect to severe patient harm/death
  5. Prioritization
    - Nurse confused medication due to similar appearance or name
    - Medication accidentally got swapped during dispensing
    - Wrong medication in the packaging
  6. Implementation of corrective measures
    - Introduce measures to reduce the probability of medication getting swapped, e.g., changes in storage, tall man lettering.
    - Implement measures to prevent medication getting swapped during dispensing, e.g., physical barriers between the single medications, not dispensing the medications for all patients on the ward in one run.
    - Educate staff to double-check packaging before removing medication from wrapper.

#### C. Morbidity and mortality review (M&M)

- **Definition:** a **retrospective** analysis performed in a clinical peer review activity format
- Procedure
  - Meetings are held at regular intervals to confidentially present, review, and discuss selected cases among peers.
  - The goal of the meeting is to identify medical errors, determine steps for improvement, and increase situational awareness among team members.
  - Traditionally, the meetings were held within a single department and focused on individual actions that led to an adverse event. Today, meetings more often include health care providers from different departments and focus on systemic causes for medical errors rather than the errors of individuals.
  - The meeting's proceedings, findings, and recommendations (as well as any documentation thereof) are protected from legal discovery and inadmissible in malpractice lawsuits.

#### Error prevention

##### Introduction

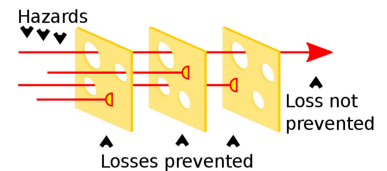
- Error prevention is a core aspect of quality and patient safety that begins with identifying and mitigating the risks and hazards that can result in medical error.
- No environment can be maintained completely free of risks, hazards, or errors.
- Accordingly, the goal of error prevention is to reduce medical error to an acceptable minimum.
- Error prevention is most effective when its focus lies on systemic errors, rather than individual errors.
- Safety culture should, therefore, incentivize openness in error reporting rather than focusing on disciplinary action against individuals who have made an error.

##### A. Fundamentals of error prevention

- Safety culture
- Hazard and risk awareness
- Error reporting
- System error monitoring
- Ongoing personnel training: keep up-to-date with current guidelines, standards, and procedures
- Ongoing equipment maintenance: sorting out of outdated or malfunctioning equipment

##### Safety culture

- **Definition:** a workplace culture that promotes safety awareness, develops and implements measures for the maintenance of a safe work environment, and ensures that individuals can openly express safety concerns and so improves prevention as well as identification of errors.
- Key features
  - Create awareness for risks and consequences of errors
  - Foster a sense of responsibility in maintaining a safe work environment
  - Create an environment in which employees are not afraid to report errors
  - Flattening steep hierarchies in order to:
    - Promote collaboration between different ranks and disciplines
    - Reduce the reluctance to speak up to superiors



##### B. Swiss cheese model of error causation

- Every safety system is imperfect and will, therefore, have flaws that allow hazards to provoke errors and, potentially, harm.
- The Swiss cheese model illustrates how a **multilayered safety system** (multiple slices of cheese) can help prevent flaws (holes in each slice) from allowing hazards to pass through the entire system, i.e., if a hazard manages to pass one layer, the next will likely block it.
- Alignment of flaws in the individual layers will allow a hazard to pass through and allow the error to occur.

#### B. Human factors and ergonomics (HFE)

##### Overview

- Human factors and ergonomics deals with the design and engineering of equipment, systems, processes, methods, and environments to fit the individuals who interact with them.
  - Incompatibilities between health care personnel and the equipment they use, constitute a safety risk/hazard (e.g., surgical scissors designed with loops that are too small to handle comfortably and precisely).
  - Poor design generates obstacles in the workflow, forcing staff to adopt temporary solutions that will increase the risk of errors.
- Key HFE measures include:
  - Forcing functions
  - Standardization
  - Simplification
  - Effective communication
- Goal: reducing error while improving efficiency, productivity, safety, and comfort

##### Forcing functions

- Equipment, process, method, or system design features that prevent error by forcing the best option by default
- The most effective technique for minimizing adverse events because it inhibits a chain of action that causes or perpetuates error
- Examples include:
  - Anesthesia gas cylinders with gas-specific nozzles for different gases
  - Software that prevents incorrect dosages of drugs and warns the user of potential adverse reactions or interactions
  - A software design that requires the physician to log out of one patient's electronic medical record before opening a second one
  - Electronic medical record that requires the user to enter a password and a reason for accessing confidential psychiatric records

##### Standardization

- Principles
  - The development and implementation of standards that apply to various aspects of a process or system in order to improve reliability, efficiency, communication, and safety
  - Examples of standardization:
    - Protocols and guidelines: help ensure a consistent level of quality and increase efficiency (e.g., a standard protocol for antepartum hemorrhage reduces the variation in response time and increases the likelihood that the physician takes the correct action)
    - Equipment: facilitates use across a system (e.g., the same model of patient monitors across the hospital reduces the risk of improper use)

- Checklists: help prevent common errors (e.g., instrument and mop count before abdominal closure following laparotomy ensures no material is accidentally left inside the patient)
  - Handoff
    - The exchange of predefined items of information between health care providers when passing on responsibility for the care of patients (e.g., at the end of a shift) to reduce the risk of **medical errors**
    - Standardization** of verbal and written **handoffs** to reduce transition errors
      - I-PASS method: A comprehensive **handoff** program that trains clinicians to exchange patient information concisely covering the following points:
        - I: illness severity
        - P: patient summary
        - A: action list
        - S: situational awareness and contingency plans
        - S: synthesis by the receiver
      - SBAR tool**: See “**Strategies for effective communication**” below.
      - Clearly written instructions
        - Use standardized formats to highlight the most pertinent information.
        - A complete **handoff** should include: relevant diagnoses, **code status**, summary of the hospital course, current medications, recent changes to management, explicit suggestions for anticipated concerns, tasks to complete.
      - Appropriate environment
        - Determine a specific location and time.
        - Choose a setting in which interruptions are unlikely.
      - Ensure continuity-enhanced **handoffs**
        - Healthcare providers from the same team should work in serial shifts rather than in parallel.
        - A team of physicians rather than a single physician should be responsible for patient care.
        - At least one member from the sender (provides the information about the patient) and receiver (receives the information to later assume care of the patient) team should know each other.
        - Both sender and receiver should be invested in learning and advancing the patient’s care.
        - Double **handoffs** should be avoided: Members of the primary team should have first-hand knowledge of patients.
      - Handoffs** for high-risk or critical patients should be customized.
  - Medication reconciliation
    - Performed during transitions of care (e.g., admission, transfer, discharge) in which new medication orders are compared to past medication orders
    - Comparing a patient’s medication orders to the medications they have been taking
    - Used to avoid **medication errors** such as duplication, omission, dosing errors, and **drug interactions**
  - Terminology**: helps prevent **communication errors** (e.g., use of the chemical name of a drug rather than its generic name or brand name)
  - Abbreviations and writing styles
    - Help prevent communication and **transcription** errors
    - Tall man lettering: a strategy used to prevent dispensing errors related to medications that look or sound alike (e.g., buPROPion vs. busPIRone)
    - Standardized prescription order writing
      - Use precise, simple **language**.
      - Name the drug, dosage, route, frequency, and duration of administration.
      - Indicate the reason for the medication on the prescription as an additional safety checkpoint.
      - Avoid Latin, abbreviations, and acronyms that may be misinterpreted.
      - Example: nitrofurantoin, 100 mg, orally, twice a day, for 5 days; prescribed for an **uncomplicated lower urinary tract infection**
  - Clear discharge instructions
    - Explain instructions to the patient and caregiver (e.g., using the teach-back method, asking the caregiver if they need training for special tasks).
    - Should include the complete list of the patient’s medications with dosages and usage information
    - Detailed explanations should also be provided to the next care setting (e.g., nursing home).
    - Arrange a follow-up appointment or phone call prior to discharge.
      - Identify and/or confirm that the patient has a primary care provider.
      - Book a post-discharge follow-up appointment for the patient with their primary care provider.
  - Time out**: a preoperative pause conducted by the surgical team to confirm the patient’s identity, surgical site, and planned procedure to prevent harm from a **wrong procedure** at the **wrong site** or patient
- Simplification**
- Reduction of complexity of equipment, systems, and processes to increase efficiency and reduce the risk of error
  - Examples include:
    - Ordering laboratory tests electronically
    - Streamlining administration
    - Readily available standard equipment (e.g., **tongue** depressors, latex gloves, scissors)
    - Clinical decision support system (CDSS): a computer-based system designed to analyze data within electronic health records to assist health care professionals in clinical decision-making tasks (e.g., by reporting drug-drug interactions).
    - Multicompartment medication device
- Effective communication**
- Closed-loop communication**
  - Patient involvement: prior to administering **drugs** or inducing anesthesia, the patient is asked for verification of identity and any further relevant information (e.g., site of **surgery**, planned procedure, consent)
  - Computerized order entry (CPOE): a system in which electronically placed orders for medications, tests, procedures, and consults are directly transferred to the recipient (used to prevent errors due to poor handwriting or ambiguous abbreviations)
- Collaboration and teamwork**
- Significance
    - The basis of health care quality and safety
    - Teamwork** and a collaborative work environment improve employee morale and, subsequently, the quality of health care.
    - Collaboration and **teamwork** are professional expectations that every physician will be evaluated on.
  - General domains
    - Communication
    - Teamwork** and mutual support
    - Leadership
    - Situation monitoring
    - Conflict resolution
- Workplace communication**
- A. General principles
- Objective**: communicating effectively and avoiding **communication errors**, e.g., by sharing incomplete, wrong, or ambiguous information
  - Nonviolent communication
    - Communication approach developed by Marshall Rosenberg designed to improve communication through empathy and awareness for the violence inherent to coercive and manipulative communication strategies



- According to Rosenberg, the source of conflict often lies in miscommunication about human needs, and violent language further fuels the conflict. Understanding the needs of others empathetically and expressing one's own needs honestly can prevent and help resolve conflict.
- Involves 4 components (i.e., observation, needs, feelings, and requests) and 3 modes (i.e., self-empathy, honest expression, and empathetic reception)
- **Cultural humility:** open-minded and respectful attitude towards aspects of other persons' cultural identity that may be particularly important to them
- **Active listening:** technique that involves listening closely, employing verbal (e.g., "I understand," "Ok") and nonverbal cues (body language, e.g., nodding), and paraphrasing back to the speaker to signal that one is positively engaged in the conversation
- **Information sharing:** making sure to provide all the information team members need to fulfill a task

#### B. Strategies for effective communication

##### SBAR tool

- **Definition:** a framework used in health care to avoid errors in the communication of a patient's condition
- **Example scenario:** A physician communicates the patient's condition to a colleague.
  - **Situation:** assess what is happening at the moment (e.g., patient shows signs of arousal, discomfort, chest pain)
  - **Background:** provide patient history (e.g., the patient was jogging when she began to feel chest pain)
  - **Assessment:** express what the issue is (e.g., chest pain, discomfort, and/or arousal are potential signs of myocardial infarction)
  - **Recommendation and Request:** develop a solution for the issue and take the appropriate steps to implement the solution (e.g., getting help from senior residents, ordering the nurse to take an ECG, preparing the patient for cardiac catheterization)

##### Check-back

- **Definition:** a form of closed-loop communication used in health care to avoid communication errors in which the listener repeats the information received back to the speaker and the speaker confirms that the information has been received as intended
- **Example scenario:** During surgery, a patient loses a significant amount of blood and requires blood transfusions.
  - The anesthesiologist (sender) calls out: "The patient is losing a lot of blood, we need two bags of A+ blood as soon as possible."
  - The nurse responsible (receiver) for taking care of this request responds: "Got it, we need two bags of A+ blood. I will order those right away."
  - The anesthesiologist (sender) confirms that the information has been received as intended by saying: "Correct!"

#### C. Strategies for escalating concerns/making assertions

##### DESC

- **Definition:** a technique in four steps employed to give concise, constructive feedback
  - **Describe:** Describe the situation or behavior in question as objectively as possible.
  - **Express:** Express your thoughts and feelings associated with the situation (using first-person statements, e.g., "I feel my concerns are not being considered," and avoiding blame, e.g., "you never listen").
  - **Specify:** Specify your wishes and preferred outcome.
  - **Consequences:** Outline the consequences, i.e., the positive payoff for you and others, of your preferred outcome.
- **Example scenario:** A nurse pages a resident in the middle of the night with a nonurgent question.
  - **Description:** "Nurse Roberts, you paged me in the middle of the night with a question that didn't need answering right away."
  - **Expression:** "I woke up thinking there was an emergency, only to realize that you had a question that, in my opinion, could have waited until tomorrow."
  - **Specification:** "I encourage you to closely evaluate the urgency of your requests before paging me outside work hours and, especially, at night."
  - **Consequences:** "I have to perform brain surgery tomorrow morning and without proper rest, I might not be able to perform to the height of my abilities."

##### Two-challenge rule

- **Definition:** a technique for avoiding conflict while escalating a situation that involves voicing concern, e.g., regarding unsafe conduct, at least twice to the person responsible, before initiating a more assertive approach (e.g., intervening) or alerting a person in a higher position if the concerns are not addressed.

##### CUS

- **Definition:** technique that involves voicing that you feel Concerned, Uncomfortable, and that the situation is not Safe.

##### PACE model for graded assertiveness

- **Definition:** a strategy to escalate concerns effectively and appropriately in situations of potential crisis
  - Probe the situation by voicing your concerns and assessing the reaction of others.
  - Alert the persons involved if unsatisfied with the response, reiterating your concerns more emphatically.
  - Challenge the situation openly if still unsatisfied with the response, formally stating your concerns and pointing out the consequences.
  - Emergency action should be taken if all previous efforts to avert the crisis have been unsuccessful.
- **Example scenario:** A patient needs an antibiotic. An inexperienced resident is about to give penicillin to the patient. He appears to have missed the documented penicillin allergy in the patient's file. An attentive nurse intervenes:
  - **P:** "Doesn't this patient have a severe penicillin allergy?"
  - **A:** "The antibiotic you're about to give to the patient is penicillin and the patient has a documented penicillin allergy!"
  - **C:** "If you administer penicillin, the patient may have an anaphylactic shock. You should not give penicillin to this patient and change the antibiotic regimen immediately."
  - **E:** "Step away from the patient! I am taking over and contacting your supervisor!"

#### Teamwork and mutual support

Teams are composed of various individuals and in health care, the individuals working together often come from different medical specialties (e.g., cardiologists, surgeons, anesthesiologists) and professional backgrounds (e.g., nurses, physicians, physiotherapists, psychiatrists). The foundations of good teamwork are efficient, clear, and open communication; mutual respect and support; and **psychological safety** (i.e., a work environment that permits and encourages voicing ideas, concerns, mistakes, and questions without fear of negative consequences).

##### Definitions

- **Interprofessional team:** a team composed of individuals with different professional backgrounds or specialties (e.g., a nurse, a physical therapist, and a physician; a surgeon, an anesthesiologist, and a radiologist) collaborating towards a common goal
- **Intraprofessional team:** a team composed of individuals with the same professional background (e.g., a team of physical therapists) collaborating towards a common goal

#### A. Fundamentals of teamwork

- **Adaptability:** the ability to react adequately to changes in a team's circumstances (team reflections, debriefing)
- **Collective intelligence in medical decision-making:** pooling insights and skills of a team to generate more effective decisions
- **Cooperation:** defining shared goals, consulting with one another, and working together to achieve goals efficiently
  - Being aware of other team members' skills and roles
  - Staying open to suggestions from others, even when they concern one's own area of expertise
- **Coordination:** structuring the different individual levels of skill, knowledge, and behavior
  - Clearly defined shared goals, norms, expectations
  - Role clarification
- **Effective Communication:** clear, proactive communication aimed at facilitating cooperation and minimizing communication errors
- **Mutual respect and support**
  - Cooperation founded on trust, decision-making based on collective intelligence, and positive attitudes towards conflict resolution, ensuring that contributions from all members are equally recognized and respected
  - A positive attitude towards conflict resolution
  - A culture that fosters individuals feeling comfortable admitting mistakes and knowledge gaps
- **Synergy:** The benefits of teamwork are greater than the sum of what individuals can achieve working separately.

A team will complete a task more efficiently than the same number of individuals working on the same task separately.



## B. Goals of teamwork

- Team members
  - More job satisfaction
  - Greater role clarity
  - Improved sense of well-being
- Team
  - Improved coordination of care
  - Efficient use of resources
  - Enhance communication efficiency and professional synergy
- Organization
  - Reduce time/costs of hospitalization
  - Better accessibility for patients
- Patient
  - Better care
  - Greater satisfaction
  - Lower cost

## C. Challenges in teamwork

- Changing roles
- Changing settings
- Hierarchies
- Individualistic approaches of different team members (e.g., bedside manner, treatment choices) that may cause inconsistencies within the team
- Frequent changes in team composition (emergency teams, chronic care)

## Leadership

Leadership is a central factor in determining the culture of a health care organization and developing strategies for effective and efficient delivery to patients. Health care leaders should lead by example and shape their team through collaboration from within. Accordingly, successful leadership requires interpersonal (soft) skills as well as organizational (hard) skills.

### A. Organizational skills

- Coordination
  - Clarify roles
  - Set clear goals
  - Assign tasks
  - Structure team
  - Manage resources
- Monitoring
  - Modify plans as necessary and communicate changes
  - Evaluate team performance
  - Provide necessary feedback

### B. Interpersonal skills

- Lead by example
- Encourage teamwork through engagement in the team
- Foster positive team culture and atmosphere
- Provide team members with the necessary information and facilitate information sharing
- Encourage and mediate conflict resolution

### C. Situation monitoring

- **Goal:** ensuring a common understanding of the situation to reach common goals efficiently and safely
- **STEP** components of situation monitoring
  - **Status** of patient
  - **Team** members (skills, performance, stress, and fatigue)
  - **Environment** (resources and equipment)
  - **Progress** towards goal
- **Cross-monitoring:** Team members monitor each other to ensure that procedures are followed appropriately and safely.

# Principles of Medical law and Ethics

73 questions

## Summary

Best medical practice is founded upon legal and ethical principles that guide the choices physicians and health care providers make when caring for patients or performing research. The core ethical principles of medicine are autonomy, beneficence, nonmaleficence, and justice. For a patient to be considered able to make choices about their health care, they must demonstrate mental capacity and competence; when these are lacking, the patient may have a surrogate make choices in their place.

Unemancipated minors are unable to make medical decisions on their own and so must have a parent or caretaker act make decisions for them. The patient has the right to full disclosure about their health, medical status, medical records, and involvement in research protocols.

End-of-life issues include medical aid-in-dying, organ donation, and the pronouncement of death. The physician is legally and ethically obligated to keep patients' medical information confidential, and may only break this confidentiality in particular settings. Social factors that may need to be considered include driving restrictions, elder abuse, and torture.

Patients must be briefed on all of their treatment options, including potential risks and benefits, prior to treatment or medical intervention.

Conflicts of interest occur when an external factor (e.g., payment from a pharmaceutical company) influences the physician's ability to make an objective medical decision.

Medical research must be conducted according to ethical principles as well, and there is a specific set of guidelines for research on vulnerable populations (e.g., pregnant women, children, prisoners).

## Medical ethics

### A. Core ethical principles

#### Overview

- Medical ethics is founded on a set of core principles that are based on respect to patients as individuals.
- Ethical dilemmas arise when respecting one of these principles becomes impossible without compromising another.

- Ethical responsibilities usually align with legal precedence, but the two systems remain distinct.

#### Principles

- **Autonomy**
  - Provide sufficient information for the patient to be able to make their own decisions regarding their care (i.e., **informed consent**).
  - Honor the patient's choices to accept or decline care.
- **Beneficence**
  - Advocate for the patient and act in their **best interest** (fiduciary relationship).
  - May conflict with autonomy
- **Nonmaleficence**
  - Avoid causing injury or suffering to the patient.
  - May conflict with beneficence: The balance of risks and benefits must be favorable to the patient.
  - Frequently discussed in reference to drugs and surgical procedures
- **Justice**
  - Treat patients fairly and equitably.
  - Equity is not the same as equality.

#### B. Obligation to treat

- A physician is legally obligated to treat a patient when failing to provide treatment would immediately endanger the patient's life.
  - This law was established in the Emergency Medical Treatment and Labor Act (**EMTALA**).
  - Any hospital with an emergency department is required to screen for emergency medical conditions if requested and, if such a condition exists, provide treatment until that condition is stabilized.
- Physicians are not obliged to treat a patient longitudinally and may end a doctor-patient relationship if they wish.
  - The patient or their surrogate must be notified and have the ability (e.g., time, money) to establish care with another physician.
  - The physician is also obligated to facilitate the transfer of care.

### Decision-making capacity and legal competence

#### A. Decision-making capacity

- **Definition:** the psychological and/or legal ability to process information, make decisions, communicate a choice, and understand the consequences of a decision
- **Components:** The patient must have all of the following to demonstrate decision-making capacity.
  - **Choice:** the patient's ability to clearly and consistently communicate their choice of treatment
    - E.g., patients with severe stroke or advanced dementia may not be able to construct comprehensible sentences
    - Choice can be assessed by asking the patient what treatment they have decided to receive and then asking them to restate their choice later in their hospital stay.
  - **Understanding**
    - The patient's ability to comprehend the information provided by the physician, including therapeutic options and alternatives
    - Understanding can be assessed by asking the patient, "Please describe to me in your own words your understanding of what your physician told you regarding the status of your health, your treatment options, and the risks and benefits of treatment."
  - **Appreciation of relevant facts**
    - The patient's ability to recognize and evaluate the facts that are relevant to their situation
    - Appreciation can be assessed by asking the patient, "What do you understand about what is good or bad about your health at this moment?" or, "Do you believe that you require some form of medical treatment?"
  - **Reasoning in medical decision making**
    - The patient's ability to describe the thought process behind the decisions they make about their own care
    - Reasoning can be assessed by asking the patient, "How did you decide to accept or refuse treatment?"
- **Caveats**
  - **Capacity** is assessed and determined by the **treating physician**.
  - The patient must be ≥ 18 years of age or legally emancipated to have capacity (see "Medical decision-making in pediatrics" below).
  - The patient's decision must not be secondary to manifestations of a mood disorder or change in mental status (e.g., intoxication).
  - An individual's decision to refuse treatment may be disregarded if that decision endangers others (e.g., refusing treatment for active tuberculosis infection).
  - If a patient with capacity makes a decision, it cannot be reversed if the patient becomes incapacitated.
  - Intellectual disability (e.g., trisomy 21) or low literacy level does not exclude an individual from having capacity.
  - A pregnant individual has the right to refuse certain treatments even if their decision poses a risk to the unborn fetus (e.g., refusal of cesarean section).
    - This principle upholds the right to patient autonomy.
    - For pregnant patients with severe mental health disorders, a psychiatric professional should be integrated into the care team to make sure the core ethical principles and decision-making capacity are upheld.

#### B. Medical decision-making in pediatrics

- **Pediatric definitions**
  - **Minor:** any person < 18 years of age (in most states)
  - **Emancipated minor:** a minor who fulfills at least one of the following criteria
    - Lives separately from parents and is financially self-reliant
    - Is married
    - Is on duty in the armed forces
  - **Mature minor**
    - An unemancipated minor who is deemed to have capacity
    - The status of a mature minor is decided by individual state courts.
    - The exact definition of a mature minor varies state-by-state.
- **General**
  - Unemancipated minors do not possess decision-making capacity.
    - The consent for medical procedures or treatments of unemancipated minors is given by the patient's surrogates (i.e., parents or caretakers).
    - See "Informed consent" below for exceptions and more information.
  - Emancipated minors are considered to be capable of medical decision-making.
  - **Mature minor doctrine:** a common-law rule that allows mature minors to consent to treatment under certain conditions
    - The minor is an older adolescent (the age varies by state law).
    - The minor is capable of understanding the information regarding the medical procedure.
    - The benefits of the procedure clearly outweigh the risks, and the risks are not high.

#### C. Legal competence

- **Definition:** the legal assessment of a patient's ability to freely make conscious decisions (including those regarding their care)
- **General**
  - Assessed by a **court of law** (with input from the patient's family and physicians as needed): Physicians do not have the power to pronounce individuals legally incompetent.
  - If an individual is determined legally incompetent, the court will assign a guardian to make decisions on their behalf.
    - The court may waive the appointment of a guardian or grant a limited guardianship if there is a durable power of attorney.
    - Generally, a guardian cannot issue the commitment of their ward to a mental health facility.
    - The directives of a guardian override the directives of family members.

- Questions of legal competence arise in the presence of reduced mental capacity (e.g., severe mental illness, intoxication, impulsive/constantly changing decisions, decisions that are inconsistent with the patient's values)

#### D. Shared decision-making

- **Definition:** a model in which patients and physicians decide on the best treatment option together
- General
  - Empowers the patient, as it is based on the patient's personal values, cultural beliefs, and preferences
  - Aimed at producing better health outcomes and increasing patient satisfaction
  - Is a key component of the patient-centered approach in patient-physician communication
- Three-step model for shared decision-making
  - Choice talk: an introductory discussion in which the patient is informed that there are choices available and that they will be able to participate in determining their treatment
  - Option talk: a description of all the available options, including the pros and cons of each option
    - The discussion may include the use of decision aids (e.g., videos, brochures)
    - Should be concluded by checking the patient's understanding of all the options
  - Decision talk: A discussion in which the patient either decides on their preferred treatment or defers the decision. When the patient is ready to make the decision, their understanding of the treatment should be checked again, and the decision talk should be repeated.

#### E. Surrogate decision-making

- **Definition:** a model in which another person makes treatment decisions for the patient because they lack decision-making capacity and/or competence
- General
  1. Advance directives (ADs) or surrogates are only used if the patient has lost the ability to make their own decisions.
  2. ADs may be **revoked** by the patient at any time if they retain decision-making competence.
  3. Surrogate decisions should be based on what the patient would have wanted.
- **Hierarchy of decision-making:** The surrogate may be appointed by the patient (e.g., medical power of attorney), legally appointed (e.g., court-ordered guardian), or next of kin (if no AD exists).
  1. A **mentally competent** patient capable of making their own decisions
  2. **Advance healthcare directive:** prespecified legal instructions from the patient used to guide medical decision-making
    - **Living will:** a legal document in which individuals describe their wishes regarding their healthcare (e.g., to maintain, withhold, or withdraw life-sustaining care) should they become incapacitated
    - **Durable medical power of attorney (health care proxy):** a legal document through which an individual designates a surrogate to make specific health care decisions
    - **Oral advance directive:** an incapacitated patient's prior oral statements regarding their preferences
  3. Next of kin
    - Spouse
    - Adult child
    - Parent
    - Adult sibling
    - A close friend (in approx. 50% of U.S. states)
  4. Ethics committee or legal consult
- **Caveats:** if the patient's preferences cannot be determined and there is a disagreement regarding the course of action (e.g., the wishes of a designated surrogate who is not a family member conflict with the wishes of family members)
  1. The physician should facilitate a meeting between the disagreeing parties with the aim of reaching an agreement about what the patient would have desired.
  2. No matter what the outcome of the conflict, the wishes of the designated surrogate should be followed.

Oral ADs may pose problems of interpretation, because oral statements are not as specific or easy to confirm as written statements. The validity of an oral AD increases when the patient has made an informed choice, the instructions were specific, and the directive was confirmed by multiple people.

Patients with decision-making capacity and competence have the right to provide or withdraw informed consent at any time (even during a procedure).

### Informed consent

#### A. Overview

- **Definition:** the process of briefing a patient (or surrogate) about their medical condition and treatment options, then obtaining consent to pursue a selected course of treatment
- Necessary components of informed consent
  - **Voluntariness:** The patient must not be forced into a decision.
  - **Capacity:** The patient (or surrogate) must demonstrate decision-making capacity before they can consent to treatment.
  - **Comprehension:** The patient must understand the ramifications of the proposed intervention.
  - **Disclosure:** Relevant medical information regarding the intervention must be discussed with the patient.
- **Timing:** The patient must be informed far enough in advance of the procedure that they have adequate time to make a thoroughly considered decision.
- **Patient briefing:** The patient should be educated about the **benefits, risks, alternatives**, and **indications** of treatment as well as the **nature** of their illness.
  - Known complications, including estimated risks of **death** and **morbidity**
  - Types and risks of anesthesia, if relevant
  - Alternative treatments
  - The diagnosis and natural course of the disease without any treatment
- Unexpected findings during surgery
  - The patient should be informed about the possibility of intraoperative findings that may require more intervention than originally planned.
  - If consent was not obtained
    - If a finding requires immediate action (e.g., appendicitis is found during surgery for ectopic pregnancy), the procedure can be performed without obtaining the patient's consent.
    - If a finding does not require immediate action (e.g., findings concerning for pulmonary malignancy during surgery for tension pneumothorax), the patient should give informed consent before any other procedures are performed.
- Expressing a decision
  - The patient with decision-making capacity is **free to provide or revoke** their decision at any time and without the need for a written document.
  - The decision must be free from any coercive pressure.
  - The patient (or their surrogate) must clearly communicate their decision.

Use your **BRAIN: Benefits, Risks, Alternatives, Indications, Nature** (to brief patients about informed consent).

Obtaining patient consent is crucial because without it, any medical procedure can represent an attempt to initiate harmful or offensive contact with the patient.

#### B. Language and use of an interpreter

- Discuss health care decisions with patients in terms they can relate to.
- Communicate in a language that the patient **understands**.
- Request an interpreter if you are unable to communicate with the patient in a language in which you can have a comprehensive discussion and assess the patient's understanding of the relevant information.

- Both in-person and remote (e.g., phone, video) interpreter services are appropriate.
  - Communicating without an interpreter can result in patients accidentally consenting to unwanted procedures, misunderstanding their diagnosis, and poorly complying with medical advice.
- For more information about particular instances of the use of medical interpretation, see “General concepts of patient counseling” in the “Patient communication and counseling” article.

Multilingual relatives are not acceptable alternatives to professional interpreters in the nonemergency medical setting.

#### C. Exceptions to standard informed consent

- **Life-threatening emergencies** (e.g., an unconscious **trauma patient** without a surrogate present)
- The patient lacks **decision-making capacity**, but their surrogate has authorized intervention.
- The patient decided to **waive** the legal right of **informed consent**.
- Disclosing may pose a **threat** to the patient or affect their decision-making capacity (i.e., **therapeutic privilege**—more information in disclosure).

Difficulties in obtaining consent should not delay life-saving procedures.

#### D. Parental consent for minors

- Overview
  - Minors are considered legally incompetent to make medical decisions.
  - Parental consent is generally required before a minor receives medical care; exceptions are listed below.
  - Although not legally mandatory, it is recommendable that physicians obtain the minor's approval for medical care.
  - For children to participate in medical research, documented consent must be obtained from parents or guardians and assent must be obtained from minors.
  - If the parents of the patient are themselves minors, grandparents may give consent for their grandchildren.
  - For minors who have been removed from their parental care and whose parent's right to consent has been revoked by a juvenile court, the court must assign a guardian (e.g., grandparent) who can provide consent.
  - In the absence of another guardian, child protective services authorize all health care services for children whose parents have had their parental rights terminated.
- Exceptions to the requirement of parental consent
  - **Emergency** and/or **life-saving interventions** (e.g., severe trauma, suicidal ideation, blood transfusion for life-threatening hemorrhage).
  - The minor is legally emancipated.
  - Care regarding sex (e.g., **contraception**, **STIs**, **pregnancy** care except for abortion in most states)
  - **Addiction** care (e.g., health services to treat drug and/or alcohol dependency)
  - Minors who are parents themselves or who are married
  - Minors should be encouraged to discuss medical issues with their parents regardless of the exceptions that apply.
- Refusal to consent
  - Generally, parents and legal guardians may refuse any treatment for a minor under their care.
    - A parent cannot refuse an emergency **life-saving intervention** for a minor for any reason (e.g., religious refusal).
    - This refusal is only acceptable if that decision does not pose a risk of serious harm to the minor. Legal intervention (e.g., **court order**) may be necessary to mandate treatment for a non-emergency but fatal medical condition against the parent's or legal guardian's refusal to consent.
    - Physicians should always attempt to address concerns motivating the refusal of treatment (e.g., misunderstanding of the procedure, fear of potential side effects).
    - Physicians should respect religious beliefs and/or cultural values of patients that may affect treatment and make therapeutic decisions accordingly within the legal scope of what treatment may be refused.
  - Parents are legally permitted to refuse **vaccinations** for their children.
    - In rare cases, it may be appropriate to overrule a parental decision to decline **immunization** (e.g., in emergencies such as a child with a contaminated puncture wound and signs of life-threatening **tetanus** infection).
    - Efforts should be made to understand the parents' refusal to vaccinate their children and, where possible, to help them understand the advantages of **vaccination**.

### Disclosure

#### A. Full disclosure

- Patients have the right to full medical disclosure.
- Family members do not have the right to ask a physician to withhold information from a patient with decision-making capacity and competence without good reason
- Exceptions
  - The patient requests that the physician withhold information from them.
  - **Therapeutic privilege**: The physician determines that full disclosure would cause **severe psychological harm** to the patient (e.g., it may be reasonable to postpone disclosure of full diagnosis to a patient who is discovered to have multiple sclerosis who is having a concurrent major depressive episode with suicidal ideation due to divorce).

#### B. Medical errors

- A **medical error** is a preventable adverse effect of medical care (e.g., due to the improper choice of medical care methods or failure to perform the proper method correctly), regardless of whether or not it causes the patient harm or becomes evident.
- **Health care providers** must inform patients about any errors that occur under their management.
- It is unethical to blame other providers for **medical errors** or to downplay errors to patients.
- If a **health care provider** suspects another **health care provider** of being responsible for a **medical error**:
  - If the individual suspecting the error is not involved in the patient's treatment, they must seek the patient's permission to look into the matter (e.g., look at medical records, discuss details with the treating physician).
  - Once an error has been confirmed, its cause has been determined, and the person(s) responsible (if any) have been identified, the physician currently responsible for the patient's care should inform the patient about the error. The implications of the error and further course of action should be discussed with the patient in a separate meeting including all persons involved in the patient's care at the time of the error.
- The individual suspecting an error to have occurred should try to establish whether and why an error has occurred by speaking to the person they believe is responsible privately and in a nonjudgmental manner.
  - Consider the circumstances and whether the root cause may be a systems error or patient factor (e.g., failure to follow dosage instructions or keep appointments) rather than an individual error.
  - Follow the chain of events that led to the **adverse event** (e.g., incomplete medical records being responsible for providing the wrong treatment).
  - Communication in a supportive setting helps both providers to learn and prevent similar incidents from recurring.
- For more information, see “Medical error” in “Quality and safety.”

### Confidentiality

#### A. Overview

- The physician is ethically and legally obligated to keep the patient's medical information (including information disclosed by the patient to the physician) confidential.
- **Confidentiality** upholds patient **autonomy** and **privacy**.
- The patient may waive the right to **confidentiality** (e.g., if an insurance company requests patient information or the patient allows the physician to disclose information to a family member).

- o Verbal or written consent is needed before releasing medical information.
  - o Individual hospitals or physician practices may have additional policies to verify the identity of the receiver (e.g., via phone call) before sharing information.
- If the patient loses capacity, health information should be disclosed according to the patient's best interest (e.g., the physician will disclose relevant health information to friends, family, or the health care proxy to help guide medical decisions).
- Healthcare providers should make their best efforts to ensure the safety of patient information (e.g., patient information should not be discussed in public areas, even within the hospital setting).
- B. Special exceptions to confidentiality
  - The patient has suffered penetrating **wounds** from an assault (e.g., a stab or gunshot wound).
  - The patient may endanger the public (e.g., driving while **impaired** or with epilepsy).
  - The patient has a transmissible **infectious disease** (see "Notification of diseases" below).
    - o The physician may be legally obliged to notify a public health official.
    - o The patient should be encouraged to inform any third parties that may have been infected (e.g., sexual partners).
    - o In most states, the physician does not have the right to inform third parties without the patient's consent.
  - The patient intends to cause harm to others or commit violence (e.g., planned homicide or assault).
    - o **Tarasoff decision**: California Supreme Court ruling that established that healthcare providers have the duty to protect the intended victim of a violent crime.
    - o Duty to protect laws require the healthcare provider to evaluate aspects such as the identity of the victim, imminence and certainty of the harm, and type of harm (e.g., physical harm, **death**) before breaching patient confidentiality.
    - o Law enforcement authorities should be notified and/or the victim should be warned.
  - The patient poses a threat to themselves (e.g., **suicidal intent**).
  - Elder abuse
  - Child maltreatment
  - The patient is a minor and care does not involve sexual or addiction treatment (see "Parental consent for minors" above).
- C. Health Insurance Portability and Accountability Act (HIPAA)
  - The HIPAA was created by the U.S. Congress to protect the privacy of electronic health information.
  - The HIPAA establishes rules for the protection of individually identifiable health information, including information about the individual's physical and mental condition at any point in time, provision of health care, and related payments.
  - HIPAA rules apply to all instances of the use of patient information for medical education.
- D. Minimum necessary standard
  - The HIPAA Privacy Rule establishes the standard policy for the disclosure of health information.
  - Accessibility and disclosure of protected health information to outside parties must be limited to the minimum necessary to accomplish a particular task.
- E. Patient privacy and permitted information disclosures
  - The information can be fully disclosed to the patient themselves.
  - It is not necessary to gain the patient's consent for disclosure to the following parties:
    - o Health care workers and service providers that are immediately involved in the patient's care (e.g., as required for a referral to another healthcare provider or requesting a consultation)
      - Any other requests by health care workers to share information should be denied.
    - o Parties that process health care payments
    - o Health care operations providers (e.g., audits, legal services, administrative activities)
  - The patient should give informal permission for the disclosure of their health information for the following unless the patient is incapacitated, in an emergency situation, or unavailable:
    - o Information about the patient's health status and location in the health care facility for anyone who asks for them by name
    - o If a patient doesn't want their family/friends to know their health status or that they are in the hospital, the physician should not disclose any information or attempt to contact them.
    - o Notification of authorities in case of disaster if doing so would aid relief efforts
  - Health information may be shared without the patient's consent if it is in the public interest (see examples in "Special exceptions to confidentiality" above).

**WAIT a SEC: Wounds, Automobile-driving impairment, Infections, Tarasoff decision, Suicidal intention, Elder abuse, Child abuse** (cases that override confidentiality).

- F. Access to patient health records
  - According to HIPAA, health care providers must provide individuals with a copy of their protected health information upon request, with the following exceptions:
    - o Information gathered in expectation of a probable civil, criminal, or administrative claim or process
    - o Notes documented by a mental health care provider during psychotherapeutic counseling
  - Once requested, the medical record must be received within 30 days.
  - Outstanding medical bills do not affect an individual's right to access their medical records.

Under HIPAA, patients have a legal right to obtain copies of their medical records within 30 days of submitting the request.

#### G. Electronic information safety

- All healthcare personnel authorized to use electronic medical records should receive proper training on data safety.
- Health information on electronic devices must be secured by technical safety measures such as firewalls, passwords, and anti-virus protection.

### End-of-life issues

#### A. Overview

- A number of ethically challenging scenarios may arise in the context of end-of-life care.
- At the end of life (as throughout life), the core ethical principles of medicine should be upheld and the physician should act in the best interest of the patient.
- Proper knowledge of the legal and ethical aspects of end-of-life care allows the physician to practice efficient and evidence-based medicine while respecting the patient's wishes.
- In disputes over end-of-life issues, the physician plays a key role in facilitating communication and emphasizing the importance of focusing on what patients themselves would have preferred.

#### B. Life support to end-of-life issues

##### Orders and legal considerations in end-of-life care

- Code status
  - o A term used to describe a patient's expressed preferences regarding cardiopulmonary resuscitation and endotracheal intubation; there are three possible codes:
    - "Full code" (make all efforts to resuscitate),
    - "DNR" (do not resuscitate order)
      - A legal AD to withhold cardiopulmonary resuscitation or advanced cardiac life support in the setting of circulatory and respiratory cessation
      - Typically, DNR orders include avoidance of other resuscitative measures as well (e.g., feeding tubes).
      - DNR orders may be accompanied by do not intubate (DNI) orders.
    - "DNI" (do not intubate order)
  - o The term is unlikely to be familiar to a layperson; therefore it should not be used in discussion with patients or their family members.
  - o A patient's code status should be confirmed verbally with the patient or their appropriate surrogate at each hospital admission, regardless of the previous status, and documented.



- Withdrawal of care
  - Patients with decision-making capacity (or their surrogate) have the right to refuse any form of treatment at any time, even if doing so would result in the patient's **death**.
  - There is **no ethical distinction** between withholding care and withdrawing care at a later time.
  - The physician should make an effort to understand the reasons behind the patient's decision for refusing treatment.
  - Patients who opt to withdraw from treatment and have limited life expectancy may be approved for hospice care.
- Futile treatment
  - Medical treatment or intervention for a terminally ill patient that is deemed nonbeneficial by the healthcare team or family
    - The concept of **medical futility** is vague and there are many interpretations of the practice; there is no universally accepted definition.
    - Some believe that futility only applies to end-of-life care, while others apply the term to any medical intervention that appears to lack a significant medical benefit.
  - The physician is not ethically obligated to provide treatment if it is considered medically futile.
  - Treatment can be considered medically inappropriate or futile if:
    - There is no evidence for the **effectiveness** of treatment.
    - The intervention has previously failed.
    - Last-line therapy is failing.
    - Treatment will not fulfill the **goals of care**.
- **Persistent vegetative state (PVS)**: The decision to maintain a patient in PVS depends on their advance directive or surrogate decision-maker and should be made with the patient's best interests in mind.

#### Standardized forms for end-of-life care directives

- Individuals with life-limiting conditions, multiple chronic conditions, or conditions that cause frailty can begin planning end-of-life care with their health care providers.
- Standardized advance directive forms such as the Medical Orders for Life-Sustaining Treatment and the Physician Orders for Life-Sustaining Treatment forms allow for documentation of the patient's preferences regarding end-of-life medical care, including the following:
  - Medical treatment (e.g., use of **antibiotics** or **analgesics**)
  - Hospitalizations
  - Artificial feeding and fluid administration
  - Resuscitation
  - Intubation
- The advance directive form can be completed and signed either by the patient or, if the patient lacks capacity, a surrogate.
- The form is completed after a series of conversations between the patient and health care providers about the patient's medical condition, prognosis, and values and personal goals for end-of-life care.
- In contrast to a living will or healthcare proxy, which act only if the patient loses decision-making capacity, advance care directive forms apply independent of the decision-making capacity of the patient at the time of application.

#### Medical aid in dying

- Physician-assisted dying
  - Physician provision of medication, intervention, or information to a patient to enable or accelerate their **death**
  - **Illegal** in most states
  - The U.S. Supreme Court has ruled three times that the laws of physician-assisted **death** are to be decided on a state-by-state basis.
- Euthanasia
  - Active and intentional termination of a patient's life, usually by sedative or paralytic, performed by the physician at the explicit request of the patient
  - Requires the full process of informed consent before initiation
  - Currently **illegal** in the U.S.
- Terminal sedation
  - The administration of sedative medication to a terminally ill patient to relieve intractable end-of-life pain
  - Legal and distinct from euthanasia
  - The intent must be to relieve pain rather than bring about **death**, even though doing so may hasten the dying process.
  - Not an appropriate means of addressing suffering that is primarily existential (e.g., death anxiety).
  - Relies on the principle of double effect
    - An ethical principle that legitimizes an act of good intent despite causing serious harm
    - An act may be justified when the positive effects outweigh the negative ones (e.g., administering large amounts of opioids to relieve pain despite causing respiratory depression).

#### Training healthcare providers on deceased patients

- Performing procedures on newly deceased patients can provide valuable hands-on training for inexperienced health care providers.
- Training procedures may be performed if the deceased patient has consented through advanced directives.
  - In the absence of an advanced directive, consent may be obtained from the next-of-kin.
- If the deceased patient's identity is unknown, health care providers may search through the patient's belongings and share the patient's personal information (e.g., social security number) with authorities to determine their identity and contact next-of-kin.
- Performing any kind of unnecessary procedure on a deceased person's body without written consent from the patient or the next-of-kin is unethical, regardless of the procedure's degree of invasiveness.
- If consent is obtained, the patient's body should be treated with respect, and the educational/research procedures should be conducted according to a plan and under direct supervision of an expert.
- All procedures undertaken on the cadaver should be documented in the patient's medical record.

#### Death

See the article "Death" for more information about definitions, signs, pronouncing, addressing loved ones, documentation, investigation, and autopsy.

- **Criteria: Death** can be diagnosed if a patient meets the criteria for **brain death** or **cardiopulmonary death**.
- **Brain death**
  - Irreversible, complete loss of function of the entire brain (including the brainstem), even if cardiopulmonary functions can be upheld by artificial life support
  - Two physicians are required to make the legal diagnosis of **brain death**.
  - See "Requirements for the diagnosis of **brain death**" for more information.
- **Cardiopulmonary death**: the absence of a spontaneous heartbeat in an asystolic patient
- Ethical issues concerning brain death
  - If a patient has been declared to have **brain death**, **no consent** is needed to withdraw life-sustaining therapy.
  - The patient's family should be informed that the patient is being assessed for **brain death** as soon as the evaluation has started.
  - The patient's family should be given a reasonable amount of time to visit the patient and accept the diagnosis before discontinuation of life-sustaining treatment.
  - If the patient's family disagree with a diagnosis of **brain death**:
    - Discuss the family members' concerns with them; express empathy and respect for their position and provide additional information to eliminate any misunderstandings regarding the diagnosis.
    - Involving a hospital ethical committee may be helpful in resolving disagreements.
    - If the disagreement stems from religious or cultural beliefs, consider involving chaplains and/or local cultural leaders in the discussion.

#### **Reporting**

##### A. Notification of diseases

- General



- Many infectious diseases must be reported to **public health** officials (e.g., **CDC**) when diagnosed.
  - The patient must be informed that their disease is reportable, and they should be encouraged to inform any recent contacts at risk of infection.
  - **Public health** officials are typically responsible for notifying third parties if the patient refuses to inform them.
- **Reportable diseases**
  - **HIV/AIDS**
    - All **HIV** cases must be reported to the local health department and the **CDC**.
    - Many states have partner notification laws (i.e., if the patient tests positive, either they or the physician are legally obligated to inform their partner).
    - Specific laws vary state-by-state.
    - If the patient refuses to disclose their **HIV** status to their partner, the physician should employ **confidential partner notification procedures**.
    - The physician's right to disclose a patient's **HIV** status is dependent on the state in which they practice.

Overview of common reportable diseases	
	Pathogen/disease
<u>Sexually transmitted diseases</u>	<ul style="list-style-type: none"> <li>• <u>Treponema pallidum</u> (syphilis)</li> <li>• <u>Neisseria gonorrhoeae</u> (gonorrhea)</li> <li>• <u>Chlamydia trachomatis</u> serotypes D–K (chlamydial genitourinary infections)</li> <li>• <u>Haemophilus ducreyi</u> (chancroid)</li> <li>• <u>Hepatitis C virus</u></li> </ul>
Diseases affecting unvaccinated patients	<ul style="list-style-type: none"> <li>• <u>Measles virus</u></li> <li>• <u>Rubella virus</u></li> <li>• <u>Varizella zoster virus</u> (chickenpox)</li> <li>• <u>Mumps virus</u></li> <li>• <u>Poliovirus</u> (poliomyelitis)</li> <li>• <u>Hepatitis A virus</u></li> <li>• <u>Hepatitis B virus</u></li> <li>• <u>Corynebacterium diphtheriae</u> (diphtheria)</li> <li>• <u>Haemophilus influenzae type b</u> (epiglottitis, meningitis)</li> <li>• <u>Neisseria meningitidis</u> (meningitis)</li> <li>• <u>Clostridium tetani</u> (tetanus)</li> <li>• <u>Bordetella pertussis</u> (pertussis)</li> </ul>
<u>Zoonotic diseases</u>	<ul style="list-style-type: none"> <li>• <u>Brucella</u> spp. (brucellosis)</li> <li>• <u>Rhabdoviruses</u> (rabies)</li> <li>• <u>Chlamydophila psittaci</u> (psittacosis)</li> </ul>
Water/foodborne diseases	<ul style="list-style-type: none"> <li>• <u>Vibrio cholerae</u> (cholera)</li> <li>• <u>Salmonella enterica</u> (typhoid, salmonellosis)</li> <li>• <u>Shigella</u> (shigellosis)</li> <li>• Shiga-toxin-producing <u>E. coli</u> (bloody <u>diarrhea</u>, <u>HUS</u>)</li> <li>• <u>Clostridium botulinum</u> (botulism)</li> <li>• <u>Listeria monocytogenes</u> (listeriosis)</li> <li>• <u>Legionella pneumophila</u> (legionellosis)</li> <li>• <u>Giardia lamblia</u> (giardiasis)</li> <li>• <u>Trichinella</u> spp, mostly <u>T. spiralis</u> (trichinellosis)</li> </ul>
<u>Tick borne diseases</u>	<ul style="list-style-type: none"> <li>• <u>Borrelia burgdorferi</u> (Lyme disease)</li> <li>• <u>Rickettsia rickettsii</u> (RMSF)</li> <li>• <u>Ehrlichia</u> spp. (ehrlichiosis)</li> <li>• <u>Francisella tularensis</u> (tularemia)</li> </ul>
Mosquito borne diseases	<ul style="list-style-type: none"> <li>• <u>West Nile virus</u> (West Nile fever)</li> </ul>
Potential biological weapons	<ul style="list-style-type: none"> <li>• <u>Bacillus anthracis</u> (anthrax)</li> <li>• <u>Yersinia pestis</u> (plague)</li> <li>• <u>Poxviridae</u> (smallpox)</li> </ul>
Other	<ul style="list-style-type: none"> <li>• <u>Mycobacterium tuberculosis</u> (tuberculosis)</li> <li>• <u>M. leprae</u> (leprosy)</li> <li>• <u>Staphylococcus aureus</u> (toxic shock syndrome) <ul style="list-style-type: none"> <li>○ <u>Vancomycin-resistant S. aureus</u> (VRSA)</li> <li>○ <u>Methicillin-resistant S. aureus</u> (MRSA)</li> </ul> </li> <li>• <u>Coronavirus</u> (SARS)</li> <li>• <u>Coccidioides immitis</u> (coccidiomycosis)</li> <li>• <u>Cryptosporidium parvum</u> (cryptosporidiosis)</li> </ul>

#### B. Elder abuse

- **Definition:** any form of physical, sexual, psychological, financial mistreatment or neglect of an elderly person (> 60 years of age) at the hands of a caregiver or someone the individual trusts
- General

- Physicians are legally and ethically obligated to report suspected elder abuse.
- See “Elder abuse” in the article “Sexual violence, domestic violence, elder abuse” for more details.

#### C. Child abuse

- **Definition:** any act (or failure to act) that produces an imminent risk of serious harm to an individual < 18 years old
- General
  - The precise legal definition of child abuse varies state-by-state.
  - Physicians are legally and ethically obliged to report suspected child abuse.
  - In most US states, child care providers, social service providers, and educators are also required to report suspected child maltreatment.
  - Which authority (e.g., child protective services, local police department) the report should be made to varies between jurisdictions.
  - See also “Child maltreatment” for risk factors and clinical manifestations.
  - See also “Abuse” in “Ethically challenging situations” below.

#### D. Child protective services (CPS)

- A government agency responsible for protecting children who have experienced abuse and/or neglect. In the United States, child protective services are organized at state level.
- Once a report has been filed, CPS reviews the claims and determines whether a formal investigation is warranted. This involves speaking to anyone potentially involved in the case, including the child, family, and caregivers.
- Measures taken by CPS if an investigation concludes that intervention is necessary:
  - Once the safety and risk assessment is done, CPS develops plans, provides services (e.g., parenting education), sets goals, and identifies possible resources (e.g., mental health services, income support services, child care support)
  - Family preservation is paramount if the child can remain safely at home, to which end CPS may provide family preservation and support services (typically for about 1 year; for a maximum of 18 months).
  - A foster placement is arranged if CPS determines that a child cannot remain at home.
    - Family reunification and preservation should be the ultimate goal for children placed in foster care. Up to 18 months of family preservation and support services may be provided to families in which CPS determines that reunification is a realistic prospect.
    - Children who cannot be returned to a safe home must be placed in foster care that provides a familial structure.

#### Foster care

- A **temporary service** provided by the state that organizes the placement of children who cannot live with their families in the care of relatives, foster families, residential care facilities, designated group facilities, emergency shelters, or supervised independent living until a permanent living arrangement can be found.
- The first choice for temporary and, subsequently, permanent placement is usually kinship care.
- The next preferred arrangement is adoption by foster parents or by someone close to the child.
- Permanent and, in some cases, temporary caregivers become legal guardians with the corresponding rights and responsibilities (e.g., providing consent for minors; see “Parental consent for minors” in “Informed consent,” above for details).

#### E. Domestic violence

- Definition
  - Any form of actual or threatened physical or emotional harm committed by one member of a household against another, frequently used as an extension power by the perpetrator against the person experiencing the violence
  - Intimate partner violence (IPV): any form of physical, emotional, or sexual violence that is carried out by a cohabitating or noncohabitating intimate partner against the other
- General
  - Physicians may not report domestic violence without patient consent.
  - When a physician suspects domestic violence, they should speak privately with the patient, inquire further, and offer assistance.
  - If the patient refuses assistance, the physician should reiterate that they support the patient and are available to provide aid at any time.
  - See “Abuse” in “Ethically challenging situations” below.
  - See “Domestic violence” in the article “Sexual violence, domestic abuse, and elder abuse” for more details.

#### F. Driving restriction

- General
  - The physician may be required to report patients who are considered unsafe to drive to the licensing authority (e.g., Department of Motor Vehicles).
  - Before reporting, the physician should share their concerns with the patient and encourage further treatment (e.g., occupational therapy, substance rehabilitation).
  - The physician should always suggest another means of transportation.
- Common conditions that may impair driving
  - Severe visual defects
  - Dementia
  - Epilepsy
    - Frequent, poorly-controlled seizures
    - Recent history of seizures
  - Cardiac arrhythmias
  - Substance dependency

### Malpractice, misconduct, and physician impairment

#### A. Medical malpractice

For more information about different types of errors leading to negligence, see “Medical error” in the article “Quality and safety.”

- **Definition:** Negligent conduct on the part of a healthcare provider or performance of a medical task with unreasonable lack of skill.
- Elements of malpractice
  - The physician-patient relationship has been established.
  - This obligation to provide care has been neglected.
  - There is damage to the patient.
  - The medical negligence is directly responsible for the damage to the patient.
- Reporting malpractice
  - Physicians are ethically obliged to report any violations resulting from their colleagues' incompetence, negligence, and/or unethical conduct.
  - Contact the hospital authorities at the first instance; if the consequences of the malpractice pose a threat to patients' health, contact the state licensing board.
- **Defensive medicine:** testing and treatment that is not medically necessary but is performed by the physician to avoid legal liability
  - Is unethical and should be avoided because it increases risk of patient harm and does not add significant benefits (e.g., an unnecessary CT scan causes radiation exposure)
  - Physicians should openly communicate with patients about the risks and benefits of tests or treatments that they believe are not medically necessary.

The **4 D's of malpractice:** Duty (obligation to deliver proper medical care to the patient), Dereliction of duty, Damage to the patient, Direct cause of damage.

#### B. Physician misconduct

- Physician misconduct is any physician behavior that goes against the ethical principles of medical practice.
- Physician misconduct can occur outside the established physician-patient relationships and thus does not always constitute malpractice.
- Examples of misconduct
  - Bullying
  - Inappropriate comments towards colleagues or patients

- Sexual harassment of colleagues or patients
    - Billing fraud
    - Receiving expensive gifts from patients or industry
  - Colleagues who suspect a physician of **misconduct** should report their concerns to the **state medical board** and, if the **misconduct** implies any legal liability, to the proper federal authorities.
- C. Physician impairment
- **Definition:** the inability of a physician to provide adequate medical care due to mental health disorder, substance-related disorder, or physical condition that limits the use of motor, cognitive, or perceptive skills
  - Potential signs of impairment
    - Disruptive behavior (e.g., increased conflicts with colleagues or patients, irritability, **anxiety**, aggression)
    - Physical signs of **substance use disorder** (e.g., needle marks, alcohol **smell**)
    - Nonadherence with working schedule (e.g., being late or absent at work for no reason) or sudden changes in schedule (e.g., unusually early or late appointments)
    - Decreased quality of care (e.g., increased rate of **medical errors**, incorrect charting)
    - Personal life problems (e.g., divorce, withdrawal from family, debts)
  - **Physician Health Program:** a program that is supervised by a **state medical board** and is aimed to prevent, detect, and manage disorders that cause impairment in physicians
    - Colleagues of a physician should contact the PHP if they suspect impairment.
    - The PHP performs a thorough assessment of the potentially **impaired physician** and arranges management if impairment is confirmed.
    - If an **impaired physician** accepts the treatment voluntarily, the PHP is not obliged to notify the **state medical board** about the physician's condition.
    - If the physician refuses treatment, the PHP will report the physician's condition to the **state medical board**, which may lead to an involuntary **referral** for treatment and disciplinary actions.
    - After treatment, the PHP monitors the physician with regular assessments and/or laboratory tests for 1–5 years depending on the condition underlying the impairment.
- D. Physician-patient romantic relationships
- Romantic relationships with current patients are always unethical and inappropriate.
    - A romantic physician-patient relationship compromises the objectivity of the physician's decisions in regard to the care of that patient.
    - Such relationships make patients more vulnerable to exploitation.
  - Romantic relationships with former patients are also inappropriate if:
    - Less than one year has passed since the end of the patient-physician relationship.
    - The physician has a position of influence or influence from their previous experience with the former patient (e.g., knowledge of trauma expressed during therapy).
    - The former relationship was a patient-**psychiatrist** relationship
  - Should a physician feel that their actions may be perceived as sexual and/or lead to a romantic relationship with a current patient, the physician should take active measures to avoid unnecessary contact with the patient.
    - Use direct, close-ended questions.
    - Conduct interviews with a chaperone present.
  - Romantic relationships with patient-accompanying third parties (e.g., their children, friends, surrogates) may also be inappropriate in case the third party plays a considerable role in physician-patient interaction and may be emotionally dependent on the physician.

## Conflicts of interest

### A. Overview

- **Definition:** A **conflict of interest** (COI) occurs when a physician's objectivity regarding their primary interest (i.e., patient welfare) is potentially affected by a secondary interest (e.g., personal financial gain).
- Minimizing COIs
  - Physicians should always disclose COIs to patients, employing institutions, and when presenting medical results (e.g., at a medical **conference** or in a peer-reviewed journal).
  - Gifts of significant value from the medical industry should be declined.
    - Gifts may only be accepted if they directly benefit patients and do not have substantial monetary value (e.g., pens, notepads, medical textbooks).
    - Cash should never be accepted.
    - Gifts that have “strings attached” should not be accepted (e.g., a gift that affects the physician's prescribing practices).
  - Physicians should not allow pharmaceutical industry-funded advertisements in their practice.
  - Industry subsidies for physician travel, lodging, or personal expenses should be declined.
- Acceptable gifts and donations
  - Gifts from patients that are small and do not have substantial monetary value (e.g., home-cooked meals, flowers, knitted quilts).
    - The gift should not influence the patient's care.
    - Gifts that may represent a financial sacrifice for the patient should be declined.
    - No amount of direct cash exchange (e.g., checks, deposits) is acceptable.
    - The physician may suggest that the patient donate to a charitable organization in lieu of a personal gift.
  - Medical industry honoraria to attend medical education **conferences**
  - Industry-funded simple meals or social events
  - Remuneration for medical consultation for a pharmaceutical or medical device company
  - Industry-funded scholarships for travel to academic **conferences** by medical students or residents.

The physician must disclose all COIs to all affected parties and, in the event of a COI, refer patients to an unbiased colleague whenever possible.

### B. Referral of patients

- The physician may refer a patient to another physician or diagnostic or therapeutic service if they consider the **referral** beneficial to the patient.
  - The **referral** may involve nonphysician **health care providers**.
  - It is never ethical to refer a patient to illegal medical treatment.
  - **Referrals to complementary and alternative medicine** providers may be ethical if the use of such practices is grounded in scientific knowledge (e.g., chiropractic interventions or acupuncture for **lower back pain**).
- Stark law prohibits the physician from **self-referrals** (i.e. referring patients to entities with which the physician or one of their immediate family members has a financial relationship). There are a number of exceptions to this law.
- Physicians who perform **self-referrals** should ensure that the **referral** is indeed required, disclose all the potential COIs to the patient, and provide them with information about alternative care providers.

## Research in vulnerable populations

### A. Overview

In addition to the requirement of obtaining **informed consent** from study participants, special protections exist for **vulnerable populations** in research.

- The policy on the protection of **vulnerable populations** is regulated by the Office for Human Research Protection (**OHRP**).
- Regulatory and ethical checks are enforced to ensure the protection of populations that are at increased risk of harm in clinical trials.
- Applications and proposals must fulfill **OHRP** requirements in order to receive federal department or agency support.

### B. Pregnant individuals and fetuses

- **Permitted research:** only clinical trials or research studies that fulfill the following requirements

- Preclinical studies involving pregnant animals and clinical studies involving nonpregnant individuals have been conducted.
  - Adequate data regarding the potential risks to pregnant individuals and fetuses are available.
  - The clinical trial has the potential to directly benefit the pregnant individual and/or their fetus.
  - There are no other means of answering the research question and the research poses minimal risk for the pregnant individual or fetus.
- Requirements
  - The investigators should not have any role in determining the viability of the fetus.
  - No incentive may be offered to terminate a **pregnancy**.
  - If the research is only of benefit to the fetus, paternal consent should also be obtained unless the father is unavailable, temporarily incapacitated, or the **pregnancy** resulted from **rape** or incest.

#### C. Neonates

- **Permitted research:** only clinical trials with the purpose of obtaining crucial biomedical knowledge that cannot be obtained by other means or that has the potential to provide direct benefit to the **neonate** without posing any additional risk
- Requirements
  - For **neonates** of uncertain viability, the research must increase the **probability** of their survival.
  - Nonviable **neonates** may only be involved in research if:
    - Vital functions of the **neonate** are not artificially maintained.
    - The heartbeat and respiration of the **neonate** will not be terminated by the research.
    - The research poses no additional risk to the **neonate**.
  - Legally effective **informed consent** must be obtained from the parents, guardians, or legally authorized representatives.

#### D. Children

- **Permitted research:** clinical trials that pose no greater risk of harm to children than to adults and pose no other ethical reasons for the exclusion of children
- Requirements
  - If the intervention being tested poses a greater risk of harm to children than adults, the trial should only be conducted if the research question cannot be answered by any other means and the research has the potential to directly benefit the individual subjects or is likely to provide generalizable knowledge about the condition being studied.
  - It is necessary to obtain **informed consent** from the parents as well as assent from the child.

#### E. Prisoners

- **Permitted research:** clinical trials or behavioral research that investigate health issues directly related to the prison population
- Requirements
  - The risks associated with the research should not:
    - Be greater for prisoners than for nonprison volunteers
    - Pose more than minimal risk
    - Be an inconvenience to the subjects
  - At least one member of the **institutional review board (IRB)** that reviews the ethical **validity** of the study should be a prisoner or a prisoner representative.
  - None of the nonprisoner members of the **IRB** should have any affiliation with the prison.
  - Any potential advantages offered to the prisoners through participation in the research may not be so great that they affect the prisoner's ability to weigh the risks of participation against the benefits.

#### Involuntary commitment

- **Definition:** a legal intervention through which an individual who experiences symptoms of a severe mental disorder can be detained in a mental health facility for involuntary treatment or receive such treatment in outpatient settings
- Regulations
  - The criteria differ state-by-state, but generally include the following components:
    - Grave disability (e.g., inability to self-feed or shelter)
    - Danger to self or others
    - Need for treatment
  - The commitment settings should be the least restrictive that is possible.
  - Proceedings for commitment are usually initiated by a family member or **health care provider**.
  - Individuals can typically be held for some period of time specified by the state law without a court order given that the admission is medically certified.

#### Use of social media by physicians

Physicians increasingly use social media and other internet resources for learning, networking, interacting with patients, and disseminating health care related knowledge. The following considerations can help ensure that their online presence aligns with professional ethics.

- Identifiable patient information should not be posted online (unless documented consent has been obtained from the patient).
- Appropriate boundaries should be maintained when communicating with patients online.
- Proper personal conduct should be maintained (e.g., in comments on social media posts), even in the context unrelated to medicine.
- If a colleague posts professionally inappropriate content online, the colleague should be alerted to the fact that their behavior is inappropriate and be encouraged to remove the content and avoid inappropriate posts in the future. If personal communication fails to resolve the issue, appropriate authorities (e.g., **state licensing board**) should be notified.
- Physicians should follow cybersecurity measures to ensure that their personal information is safeguarded.

#### Abortion and stillbirth laws

- **Stillbirth:** An **autopsy** of the fetus and **placenta** should be performed (with permission from the grandparents if the parent is a minor) after a confirmed unexplained stillbirth.
- **Abortion:** Abortion laws vary greatly state-by-state.
  - Most states require that parents of minors undergoing an abortion procedure are notified and/or sufficiently informed to provide consent.
  - **Patient counseling** prior to **abortion procedures** is mandatory in some states.
  - Most states allow physicians to refuse to perform abortions under the condition that patients are referred to another physician who is skilled and willing to perform abortions.
  - Many states only permit abortions under certain conditions:
    - The mother's life or health is at risk because of the **pregnancy**.
    - The procedure is performed by a licensed physician.
    - The fetus is below a certain **gestational age**.

#### Examples of ethically challenging situations

##### Autonomy

- An adult patient refuses treatment based on religious beliefs.
  - Explain the treatment options and available alternatives.
  - Make sure that the patient understands the consequences.
  - Respect the patient's choice.
- A patient wants to try alternative medicine.
  - Identify the underlying reason.
  - Do not negate or devalue the patient's decision.
  - Evaluate for possible **drug interactions**, adverse effects, and safety.
  - Allow treatment integration if it poses no risk of harm to the patient.

## Abuse

- A patient discloses abuse by a close partner.
  - Evaluate safety and the presence of an emergency plan for the victim.
  - Show empathy and willingness to provide continuous support.
  - Counsel and evaluate for psychological comorbidities.
  - Perform thorough documentation of abuse (the patient may want to take legal measures against their abuser).
  - Do not force the patient to leave their partner.
- A pediatric patient has an injury inconsistent with the caregiver's report.
  - Physicians are obliged by law to report cases of child abuse.
  - Inform the authorities and keep the child in a safe place.

## Confidentiality

- **Family members request information about the patient's health condition:** Do not discuss issues with relatives without the consent of the patient.
- Family members request that the physician withhold diagnostic information from a patient.
  - Explore why the family members want to withhold this information.
  - Evaluate the extent of the information that the patient wants to receive.
  - Deliver the patient information according to their preferences.
  - According to **therapeutic privilege**, the physician may withhold information from the patient if disclosure increases their likelihood of causing self-harm.
- A patient with HIV refuses to inform their partner.
  - Encourage the patient to disclose the information to individuals they may have transmitted HIV to.
  - All cases of HIV must be reported to the local and state health departments.
  - If the patient refuses to inform their partner, the use of confidential partner notification procedures via the health department is encouraged.
  - For a more in-depth explanation of the legal nuances surrounding this issue, see "HIV" in "notification of diseases," above.

## Competence and decision making

- Parents refuse life-saving treatment for their child.
  - Emergency treatment: Provide life-saving treatment.
  - Non-emergency essential treatment: Get a court order.
- A pregnant 16-year-old wants to have an abortion.
  - Many states require parental consent for abortion in minors.
  - If there are no medical risks associated with the pregnancy, the physician should respect the legally accepted decision for or against abortion in any case of maternal age or fetal condition.
- A 15-year-old wants to keep her baby against her parents' will.
  - Pregnant individuals have the right to decide to carry their infants to term, and to choose to keep the baby or put it up for adoption.
  - Provide practical information about all options.
  - Accept and support the patient's decision.
  - Encourage good communication between the patient and her parents to evaluate the options and arrive at an agreement.
- A 14-year-old girl requests contraceptives.
  - Offer advice on safe sex practices and prescribe contraceptives.
  - There is no need to notify parents to get consent.
- A patient's family insists on maintaining life support indefinitely despite evidence of brain death because the patient still moves when touched.
  - Carefully explain to the family that brain death is equivalent to death and it excludes any chance of recovery.
  - Clarify that the movements are only an involuntary result of spinal arc reflex.
  - Refer the case to the ethics committee regarding futile treatment and withdrawal of life-sustaining therapy.
- A father and 13-year-old son are found unconscious with internal bleeding after a car accident; the father is found to have a religious preferences card, which states that he declines blood transfusions because of religious beliefs.
  - Ensure transfusion to the son but not to the father.
  - Adults may refuse emergency treatment based on **advance healthcare directive** if explicitly stated or reliably arguable.
- A patient asks for a non-emergency treatment or procedure that is in opposition to the physician's personal or religious beliefs.
  - Impartially inform the patient about all the options, in order to help them make an informed decision.
  - Respectfully explain that you do not perform the requested intervention.
  - It is mandatory to facilitate the transfer of care to another qualified physician.
- A patient is suicidal or homicidal.
  - The patient is considered to have impaired decision-making.
  - Assess the threat (organized plan, access to weapons).
  - Admit the patient voluntarily; admit involuntarily if the patient refuses.
  - If the patient produces homicidal threats, inform authorities and the threatened individual (**Tarasoff decision**).
- A patient with terminal disease asks for assistance in ending their own life.
  - Physician-assisted death is not supported by the majority of U.S. states.
  - Appropriate analgesics can be prescribed regardless of their eventual effect in shortening the patient's life.

## Malpractice

- **A patient receives wrong treatment/test:** Inform the patient, even if no harm has been inflicted, and apologize.

## Emotional support

- A patient complains that she feels "ugly" after a mastectomy.
  - Support the patient in identifying and breaking down the reasons why she feels this way.
  - Avoid comments that give false comfort (e.g., "You look good anyway").
- A 6-year-old child experiences the death of a sibling and feels responsible.
  - Describe with simple and honest words what happened, avoiding euphemisms and clichés.
  - Offer reassurance, explaining to the child with clear and logical arguments that they cannot be responsible in any way.
  - Help the child to label feelings and fears, and normalize them.
  - Encourage healthy coping behaviors (e.g., making time for playing, creating a special way to remember their sibling).

## Miscellaneous cases

- **Angry patient (e.g., waiting at the office for a long time):** Apologize, acknowledge anger, refrain from justifying or explaining the delay.
- A patient complains about the treatment received from another physician.
  - Suggest that the patient contacts that physician directly to speak about their concerns.
  - If the issue regards a member of your staff, let the patient know you will address the issue with the staff member personally.
- A patient requests an unnecessary intervention (e.g., diagnostic or therapeutic procedure, unnecessary medication).
  - Find out why the patient wants the intervention and address any underlying concerns.
  - Avoid performing unnecessary medical or surgical interventions.
  - Do not refuse to see the patient or refer the patient to another physician.
- A patient has poor adherence to or difficulty taking medications.
  - Identify the underlying causes of nonadherence.
  - Take a nonjudgmental stance and use **motivational interviewing** if possible.
  - Evaluate the patient's willingness to change.
  - Describe the treatment plan in easily understandable language, give written instructions, use the teach-back method, and involve close friends and relatives (with the permission of the patient).



- Do not refer the patient to another physician.
  - A pharmaceutical company offers a physician a sponsorship to advertise a new drug.
    - Physicians should decline the offer of any gifts that can potentially create a COI.
    - The **AMA** Code of Ethics identifies the following as acceptable gifts that do not create a COI:
      - Gifts directly entailing a benefit to patients
      - Gifts with no substantial value
      - Scholarships or other special funds for the medical education of students, residents, or fellows
      - Grants that identify beneficiaries based on independent qualification criteria
      - For more information, see "Conflicts of Interest," above.
  - A physician is impaired in the work environment (e.g., due to substance use).
    - Impaired physicians are a threat to the safety of patients and should be reported to a supervisory entity.
    - The **Physician Health Program** (PHP) is the supervisory entity that handles suspected **physician impairment**.
    - If PHP measures fail, the **state licensing board** needs to be informed.
  - A patient shows attraction to a physician.
    - Romantic relationships between patients and physicians are never appropriate.
    - Ask specific, close-ended questions.
    - Use a chaperone if needed.
    - Consider transitioning care to another physician.
  - A patient asks a medical student to disclose treatment, diagnostic, or prognostic information.
    - Medical students usually lack the experience and knowledge to disclose complex diagnostic, treatment, or prognostic information.
    - Hence, they should ensure the following:
      - Act in the best interest of the patient at all times.
      - Maintain honesty (if the information is available, explain why disclosure has been postponed).
      - Inform the patient that complex treatment plans or diagnostic information will be disclosed by senior members of the team.
      - Disclosure should take place in an appropriate environment and at a suitable time to ensure that the patient's privacy and emotional needs are met.
  - A patient needs medical therapy that is not covered by their insurance.
    - Always guarantee the necessary care regardless of its costs.
    - Evaluate all the therapeutic options with the patient, including those not covered by their insurance.
  - Parents refuse to vaccinate their child.
    - Respect the parents' decision and address their concerns regarding **vaccination**.
    - Provide the parents with reliable information regarding the risks and benefits of **vaccination**, and attempt to address/adjust misconceptions to ensure that an informed decision can be made.
    - Revisit the topic in subsequent visits.
  - Self-treatment and treatment of relatives
    - Physicians should generally avoid treating or prescribing **drugs** for themselves or their immediate relatives. Exceptions:
      - Emergency cases when no other qualified physicians are available
      - Minor events (e.g., a bloody nose, small minor burn)
    - Rationale:
      - A physician's personal feelings may affect their professional **judgment** and result in inadequate or improper care.
      - Treatment of a close relative may interfere with the patient's **autonomy**.
  - A patient requests that a physician intervenes in a conflict with one of their family members
    - Encourage the patient to voice their concern directly to the family member.
    - Avoid a **triangulated relationship**: A **triangulated relationship** occurs when two individuals that are in conflict both try to align with a third individual for support and/or mediation.
    - If both the family members are the physician's patients and one of the family members has difficulty voicing their concern to the other, the physician can:
      - Offer a space for communication between the two individuals during a family consult (family interview).
      - Refer the patients to a family therapist.
    - In the case of suspected abuse or neglect, the physician should intervene on the patient's behalf.
- Prisoner execution**
- There is debate over whether physicians should be involved in prisoner executions.
  - Most medical resources agree it is not ethical for physicians to participate in any executions.
  - Some proponents of physician involvement in **prisoner execution** argue that physicians should be involved to make sure the procedure occurs without additional unnecessary harm to the prisoner.
- Torture**: Physicians should oppose and refuse to participate in **torture**; Physicians must not be present if **torture** is used or threatened.
- Physicians may treat prisoners undergoing **torture**, but may not evaluate a prisoner's health so that **torture** may begin.

## Death

5 questions

### **Summary**

Death is the cessation of life, but where life ends and death begins is not always clear. In medical contexts, a distinction is drawn between **cardiopulmonary death** (irreversible cessation of heartbeat and respiration) and **brain death** (irreversible cessation of all brain and **brainstem** function). Considering that **pronouncing death** is usually a physician's responsibility, it is important to know the **signs of death** and the differences between reversible and irreversible **clinical death**. If there is a delay before death has been pronounced or the events leading up to death are unclear, knowing irreversible **postmortem changes** also helps in determining both the manner and time of death. These changes may be of medical and/or legal interest and include **rigor mortis**, **livor mortis**, **Tardieu spots**, and **decomposition**. When **pronouncing death**, it is important to understand the events leading up to death, if it was expected or not, and to conduct a careful examination before declaring the death and its time. Since **addressing family and friends after death** is a very emotional and vital responsibility, clinicians should be prepared by having a clear approach for dealing with this situation. In addition, special documentation must be handled, including writing a **death note**, **death summary**, and **death certificate**. Important steps should also be considered if the patient is a potential donor candidate or if a medical examiner/coroner should be notified for further investigation and possibly an **autopsy**. **Clinical autopsies** are performed for the purpose of medical diagnosis and research, while forensic (i.e., medicolegal) **autopsies** are performed for the purpose of establishing the cause and **manner of death**, especially if there is evidence of foul play.

### **Definitions**

- **Death**: An ambiguous term referring to the cessation of life.
- Apparent death
  - Reduction of vital function to a minimum, creating the appearance of death without signs of certain death
  - Misdiagnosing **apparent death** as **clinical death** can have grave consequences such as postponing vital care, false alarms for **organ donation**, and unnecessary emotional stress for family members.
- **Clinical death** (somatic/systemic death): a term for the cessation of respiration and circulation
  - May be reversible
  - Some descriptions may also consider the loss of brain activity as a component of **clinical death**.
- **Cardiopulmonary death**: **irreversible** cessation of circulatory and respiratory functions



- **Brain death:** irreversible, complete loss of function of the entire brain (including the brainstem), even if cardiopulmonary functions can be upheld by artificial life support
- **Intermediary life:** the period of time between irreversible cardiopulmonary death and biological death
- **Biological death** (molecular/cellular death)
  - Permanent and irreversible cellular damage with complete cessation of metabolic cell function
  - Tissue that has undergone biological death is unsuitable for transplantation.
- Legal death
  - Recognition of a person's death under the law
  - Legal death comprises medically determined death (e.g., via a doctor's declaration of death) as well as the presumption under the law that a person is dead after a prolonged and unexplained absence with no signs of life (declaration of death in absentia).
- Uniform determination of death act
  - In the US, legal provisions regarding death and the clinical examinations or legal investigations it may entail vary from state to state.
  - However, all states have adopted the "Uniform determination of death act" (1981), which specifies that the determination of death must be made in accordance with accepted medical standards and depends on either cardiopulmonary death or brain death.

### Signs of death

- Understanding the signs of clinical death is important for correctly declaring death.
- Prematurely pronouncing death can have grave consequences, including neglecting potentially vital care, giving false alarms for organ donation, and unnecessary emotional stress for family members.
- **Uncertain signs** of death must be considered in relation to **certain and irreversible signs** of death, such as cardiopulmonary and brain death.
- If there is a delay before death has been pronounced or the events leading up to death are unclear, irreversible postmortem changes can help also in determining both the manner and time of death.

#### A. Uncertain signs of death

- Certain changes that necessarily occur after death may also occur in individuals who are still alive. They, therefore, cannot provide certainty of death. Such unreliable signs of death include:
  - Cardiac and respiratory arrest
  - Unconsciousness
  - Pale, dry, tight skin
  - Areflexia
- These signs must be considered in the context of determining cardiopulmonary death or brain death.

#### B. Cardiopulmonary death

Cardiopulmonary death is the irreversible cessation of circulatory and respiratory functions. The following factors must be considered before making this determination:

- Monitoring of the patient for a specific period of time to confirm continuous apnea, unconsciousness, and lack of circulation
- Exclusion of factors that may be the cause of the cardiorespiratory arrest, such as:
  - Hypothermia
  - Endocrine dysfunction
  - Metabolic causes
  - Biochemical imbalances (e.g., hyperkalemia)
- No intention of beginning or continuing cardiopulmonary resuscitation (CPR); prohibition of any intervention that might restore cerebral blood flow
- Often synonymous with clinical death, but it is important to understand that clinical death is usually considered to be reversible

#### C. Brain death

- **Definition:** the irreversible, complete loss of function of the entire brain (including the brainstem), even if cardiopulmonary functions can be upheld by artificial life support
- **Practical steps for determination of brain death:** The American Academy of Neurology has published a practical guide that consists of four steps. It cites specific measures and interpretations (e.g., limits of body temperature) that can be used to determine brain death, although not all of them are evidence-based.
- Management
  - If brain death is proven, no consent is required to remove life support or other forms of treatment (e.g., antibiotic therapy).
  - If the surrogate decision-maker disagrees with the physician's decision, it is judicious to consult a hospital's ethical committee.
  - For further ethical and legal topics concerning brain death, see "Ethical issues concerning brain death" in the "Principles of medical law and ethics" article.

#### C.1. Clinical setting

- Loss of brain function must be attributable to a specific cause (e.g., clinical or radiologic evidence of acute, severe damage to the CNS that is consistent with brain death).
- **Irreversible** loss of brain function
- Factors that may impede proper clinical judgment must be absent.
  - Complicating or mimicking conditions (e.g., electrolyte imbalances, locked-in syndrome)
  - Abnormal core temperature
  - Abnormal systolic blood pressure
  - Intoxication or effects of CNS-depressing drugs/neuromuscular blockade

#### C.2. Neurological examination

Neurological examination should confirm coma, brainstem areflexia, and apnea.

- **Coma:** no sign of arousal or awareness
- Brainstem areflexia
  - Absence of pupillary light reflex: nonreactive pupils that are either mid-sized or dilated
  - Absence of vestibuloocular reflex (VOR): normally, eye movement can be elicited by activating the semicircular canals of the vestibular system and mediated by the afferent sensory pathway of CN VIII and the efferent motor pathway of the contralateral CN VI and the ipsilateral CN III; can be tested via:
    - **Oculocephalic maneuver:** used to test VOR by observing the patient's eye movement while stimulating the vestibular system
      - Rapid rotation of the head to one side normally elicits eye movement in the opposite direction to stabilize the image in the center of the visual field.
      - This test should not be performed in patients with injuries to the cervical spine, since it may cause further damage
    - **Caloric test:** used to test VOR by stimulating the vestibular system
  - Absence of corneal reflex, gag reflex, and cough reflex
  - No motor reaction to noxious stimulation of limbs or face
- Apnea testing
  - An essential part of the evaluation of brain death, as it measures brainstem activity.
  - After preoxygenation with 100% oxygen, the patient is disconnected from the ventilator and observed for evidence of respiratory drive (such as gasps or chest movement).
  - After 8–10 minutes, an arterial blood gas reading is obtained.
  - $pCO_2 > 60$  mm H and/or decreased pH  $< 7.30$  when mechanical ventilation assistance is removed signifies an absence of respiratory drive, and the apnea test is considered positive.

If spontaneous breathing is present, the medulla is intact. If the corneal reflex is present, the pons is intact. If the pupillary light reflex is present, the midbrain is intact.

Factors that falsely suggest cerebral function

- Spontaneous or reflexive complex motor activity (e.g., repetitive leg movements)
- False triggering of ventilator detection system for spontaneous breathing drive

### C. 3. Ancillary brain death tests

- Only to be performed if clinical examination and/or apnea testing are inconclusive, or if patient is < 1 year
- One ancillary test is sufficient; suitable ancillary brain death tests are:
  - Electroencephalography (EEG)
  - Cerebral angiography
  - Transcranial Doppler ultrasonography
  - Cerebral scintigraphy

### Postmortem changes

With the onset of death, all organisms undergo changes, mainly as a result of decomposition from putrefaction and autolysis, although external factors such as climate and location can also affect the state of a cadaver. Postmortem changes are signs of certain death that can provide information regarding the time, cause, mode, mechanism, and manner of death, as well as whether the location of the body corresponds to the place of death. These changes may be of medical and/or legal interest.

#### A. Early postmortem changes

- Rigor mortis
  - The stiffening of the muscles after death, potentially with muscle shortening
  - Usually occurs within 1–2 hours of death
  - Starts to reside after about 24 hours
  - Caused by persistent attachment of actin to myosin due to lack of ATP
- Livor mortis
  - Definition: purple-red discoloration of dependent areas of skin not exposed to pressure that begins 20–30 minutes after circulation stops due to blood settling under the force of gravity (hypostasis)
  - Occurrence
    - At least 30 minutes to 2 hours after onset of death
    - Maximum observed at 6–12 hours
  - Location: blood pools in areas of dependency under the force of gravity
    - Person died lying face-up: back of the corpse
    - Hanging death: feet, fingertips and ear lobes
    - Drowning: face, upper chest, hands, lower arms, feet, and calves
    - Lividity is evident on the ear lobes and the nail beds
    - Also occurs in visceral organs (e.g., lungs)
  - Features
    - Redistribution: lividity can be altered up to 6 hours after onset of death
    - Blanching: skin will turn white when applying pressure within the first ~ 12 hours
  - Color: the intensity of color depends on the amount of hemoglobin in the blood
    - Bluish-purple: normal lividity
    - Greenish-red: hydrogen sulfide (produced in decaying organic matter)
    - Dark brown: phosphorus poisoning
    - Brownish-red: poisoning with methemoglobin-forming substances (such as nitrite or aniline)
    - Pale pink (barely pronounced): blood loss, severe anemia, severe hemorrhage
    - Cherry red: carbon monoxide poisoning
    - Bright red: cyanide poisoning
- Injuries incompatible with life (e.g., incineration, decapitation)
- Post mortem clots: separation of red blood cells and plasma creates clots of plasma that resemble “chicken fat” and blackish-red erythrocyte clots that resemble “currant jelly”

Livor mortis occurs approx. 30 minutes to 2 hours after the onset of death and is the first definite sign of death.

#### B. Late postmortem changes

- **Decomposition**: breakdown of bone and tissue through aerobic and anaerobic processes
  - Insect and other animal activity can further advance decomposition; entomological investigations of larval development can help determine the time of death.
  - **Casper's rule**: a body will show similar marks of decomposition after one week of exposure to air, two weeks submerged underwater, and eight weeks of interment.
  - Autolysis: aerobic decomposition through endogenous acids and enzymes in the stomach, pancreas, etc.
  - Putrefaction
    - Anaerobic decomposition from colonization of tissue by endogenous and exogenous bacteria and fungi
    - Signs of putrefaction: marbling outlining vasculature, green discoloration, increase in temperature due to bacterial activity
  - Mummification: Warm environments with extremely low humidity can cause bodies to mummify and resist decomposition.
  - Adipocere: Wet anaerobic environments (e.g., moors, bodies of water) may induce bacterial hydrolysis of fatty tissue (saponification), transforming tissue into a waxy substance called adipocere.
  - Venous patterning (marbling): prominent purple discoloration of subdermal vessels
  - Degloving: Thermal exposure, immersions, or advanced decomposition of skin and tissues result in degloving of skin (common in hands and feet).
- **Vibices**: pale marks caused by pressure (e.g. from a rope in hanging death or generally from tight clothing, e.g., socks, belt, and bra)
- **Tardieu spots**: dark pinpoint spots develop in dependent areas (e.g., in the legs of a hanged person due to increased gravitational pressure)

### Pronouncing death

- Laws regarding who is authorized to pronounce a person clinically and/or legally dead as well as who is authorized to order an investigation into the circumstances of death vary from state to state.
- If a patient dies while under care, it is generally the physician's responsibility to examine the body to pronounce the death and record the time. Clinicians may also be called to the bedside for declaration of death.
- In some states, registered nurses (especially in hospice settings) are authorized to pronounce death.
- If no physician or registered nurse is readily available, a medical examiner or coroner is called to the scene to declare death.
- Emergency response teams may pronounce a person “Dead on Arrival” (DOA) if certain criteria are met (e.g., obvious postmortem changes or injuries that are incompatible with life such as decapitation or evisceration of thoracic contents).
- The specific procedures vary depending on the clinical scenario (e.g., cardiac death vs. brain death). Signs of death aid in diagnosing certain death and determining the time of death.

#### A. Approach

- If called to declare death, determine:
  - If it was expected or not
    - If it was unexpected, efforts should be made to go immediately to the patient for assessment.

- Who has already been informed
  - If family members are present
- Assess the patient
  - Confirm the patient ID
  - Generally, evaluation should last at least 2–10 minutes.
  - Check for responses to tactile stimuli
  - Look for signs of cessation of circulatory function with subsequent cessation of neurological function.
    - Clinical
      - Circulatory: e.g., absence of pulse, heart or breath sounds, chest movement or respiratory effort, and arterial blood pressure
      - Neurological: e.g., coma, fixed dilated pupils
    - Monitoring: e.g., PEA or asystole on ECG tracing
  - Consult a specialist if:
    - There is any doubt surrounding death determination
    - Formal determination of brain death (without circulatory death) is required, e.g.:
      - Complete brainstem reflex evaluation: e.g., corneal reflex, gag reflex, vestibuloocular reflex, cough reflex, oculocephalic reflex
      - Ancillary testing: e.g., apnea testing, EEG
- Pronounce the time of death
  - The official time of death is the time at which the examination confirms death.
  - If family or friends are present, determining the time of death via phone should be avoided. Instead, a watch or wall clock should be used.
- Determine further information
  - The circumstances surrounding the patient's death
  - Whether organ donation is planned (if known). If a deceased individual is a potential donor candidate and had not refused to donate organs or tissue (e.g., in a living will), the proper organ donation organization/team should be notified immediately.
    - See "Organ donation considerations after death" for more details.
  - Whether an autopsy is planned or if a medical examiner/coroner should be notified to determine if an autopsy is necessary. Indications for notifying a medical examiner/coroner vary but may include any death associated with:
    - An unknown cause
    - Occurring within 24 hours of admission
    - Suspected homicide, suicide, poisoning, or drug overdose
    - Any indications of trauma
    - Any procedures or potential malpractice
    - SIDS
    - Any unusual circumstances
  - If there is reason to notify a medical examiner/coroner, he or she will determine if an autopsy is necessary. Neither the body nor medical equipment should be removed until the medical examiner/coroner has confirmed it is acceptable to do so.
- Address family and friends: see below
- Complete documentation: see below

### Addressing family and friends after death

If family or friends are present:

- Introduce yourself (e.g., "I am Dr. X. I am one of the doctors on the team taking care of "Mr. Y" or "I am covering for the doctors taking care of Mr. Y") and explain why you are there (e.g., "I regret to inform you that Mr. Y has died").
- If possible, sit with the caregivers or family members.
- Be direct in disclosing the death and avoid any euphemisms that may be ambiguous.
- Offer condolences (e.g., "I'm so sorry for your loss").
- Offer them the opportunity to step out of the room for a few minutes while you pronounce the death.
- Solicit extra help and information for families that are interested, including assisting in finding psychosocial counseling.
- Helpful resources include:
  - Hospital chaplains
  - Case managers and social workers
  - Grief counselors and bereavement support groups
  - Organ donation teams

### Coping and processing death

- Take some time to process the patient's death.
- Your response to a patient's death will depend on the specific circumstances, e.g., whether the death was expected or unexpected and your relationship with the patient.
- It is okay (and healthy) to express emotions.
- Find a coping mechanism that works well for you.
  - Speak with family, friends, and other members of your support system.
  - Reflect on the care provided to the patient, particularly considering any positive contributions you have made to their care.
  - Depending on your relationship with the patient, sending condolences to a patient's family may help them to process the death.
  - If the death occurs in the middle of a busy shift and you do not have a lot of time to cope in the moment:
    - Make sure to take even a few minutes before seeing your next patient to process your emotions, while taking additional time after your shift.
    - Taking time to provide support to the patient's family can be helpful, if appropriate.
    - Consider checking in with a peer, senior resident, or attending.
    - Think about the ways you will be working to help your next patient(s).
- Use this opportunity to reflect on end-of-life care in general (see "End-of-life issues" in "Principles of medical law and ethics").

### Documentation of death

Physicians should follow local institutional protocols. They generally include:

- Death note: a brief note of the patient's death in the medical record
- Death summary: detailed documentation of the hospital course (similar to a discharge summary)
- Completing the death certificate (see below)
- Adhering to criteria for notifying the medical examiner/coroner (see "Reportable types of death")

### Death certificate

- In the US, the authority to sign death certificates varies from state to state. Generally, physicians are authorized to sign death certificates when the manner of death is natural, whereas in, e.g., violent or suspicious deaths, the authority lies with a coroner or medical examiner.
- The U.S. Standard Certificate of Death provided by the CDC's National Center for Health Statistics (NCHS) records the following information:
  - To be provided/verified by the funeral director
    - Decedent's personal information (name, address, relations, race, education, occupation, etc.)
    - Place of death
    - Method and place of disposition
    - Funeral facility information
  - To be provided by the medical certifier

- Date and time of death (actual or presumed and when pronounced)
- Whether coroner/medical examiner was contacted
- Cause of death (immediate cause and conditions leading/contributing to the cause)
- Whether autopsy was performed
- Tobacco use
- Pregnancy or history of pregnancy
- Manner of death
- Date, time, place, and circumstances of injury
- Certifier information

## Investigation of death

### A. Reportable types of death

The initial postmortem examination may not provide conclusive information regarding the manner, cause, mechanism, or mode of death. In certain types of death, an investigation is required by law. The specific characteristics of death that require an investigation vary from state to state. Below is a selection of the types of death that most commonly require reporting:

- Undetermined death
- Suspicious/unusual/unnatural circumstances
- Accident/casualty
- Suicide
- Violence
- Homicide
- Fetal/infant death
- Sudden death when in apparent good health
- Abortion/criminal abortion (maternal or fetal)
- Death from injury
- Therapeutic death or circumstances suggesting gross negligence in a healthcare setting
- Death that may constitute threat to public health
- Death in jail/police custody
- Drug and/or chemical overdose or poisoning

### B. Professionals involved in the investigation of death

- Physician
  - Conducts postmortem examination
  - Determines the cause, time, and manner of deaths that occurred under natural circumstances; declares death; issues death certificates
  - Notifies local death investigation office if the type of death requires reporting (e.g., if it occurs under unnatural circumstances)
- Coroner
  - Elected government official tasked with running the investigation to determine the cause, time, and manner of deaths that occurred under unexpected, violent, and suspicious circumstances or in the absence of a physician
  - Declares death; issues death certificates; initiates inquests; requests autopsies; qualifications, functions, and authority vary from state to state; does not require medical training
- **Medical examiner:** medically trained government official qualified to perform autopsies; otherwise similar functions and authority as coroner
- **Forensic pathologist:** establishes cause of death and performs autopsy upon the request of the medical examiner or coroner
- **Death investigator:** assists the medical examiner/coroner in investigating deaths, focusing on the collection of information on the decedent and guiding the investigation process.

### C. Inquest

- A legal inquiry before a coroner or medical examiner to establish the identity of the decedent and the time, place, cause, and manner of death.
- Often involves a jury; inquiries are conducted almost exclusively in the event of deaths taking place under unexpected, violent, or mysterious circumstances.

## Manner of death

The first step in investigating a death is determining the manner by which a person died. If the manner of death is determined to be natural, a further investigation is not legally obligatory, while unnatural manners of death elicit an inquiry into the precise circumstances. The manner of death is distinct from the mode, cause, and mechanism of death in so far as the manner is the root cause of how the death occurred (e.g., “homicide” involving an axe attack), while the cause is the disease or injury that causes death (e.g., an “axe wound”), the mechanism is the physiological derangement that causes death (e.g., “exsanguination” due to an axe wound), and mode is the abnormal physiological state in an individual at the time of death (coma = failure of brain function, syncope = failure of heart function, asphyxia = failure of respiratory system; e.g., “coma” from axe wound). The manner of death is of particular importance because of the legal consequences that inevitably follow any unnatural manner of death.

- Natural manner of death
  - Due (nearly) exclusively to disease and/or age
  - Patient history characteristic of a specific cause of death
  - Clear and objectifiable findings characteristic of underlying disease
  - No evidence of third-party interference in the course of the disease
- **Unnatural manners of death:** death caused by external events or a third party
  - Accident: death from injury or poisoning without evidence of third party intent to kill or cause harm
  - Suicide: death from intentional, self-inflicted injury or poisoning for the purpose of causing self-harm or death
  - Homicide: death from intentional injury or poisoning committed by another person for the purpose of causing fear, harm, or death. Intent is a common element, but it is not required for classification.
- **Could not be determined:** applied to deaths in which the manner could not be determined even after consideration of all information available
- **Pending investigation:** if determination of the manner of death depends on further information

## Types of autopsy

### Overview

- Close examination of a body to determine the cause of death; typically involves dissection of the body
- Many states require that a pathologist performs the autopsy.
- However, in some states, autopsies may also be performed by medical examiners without a degree in pathology.

### A. Clinical autopsy

- Purposes
  - Medical investigation into the cause of a natural death (i.e. does not consider the manner of death) and any pre-existing illnesses
  - Diagnosis of diseases that can only be confirmed postmortem (e.g., Parkinson's disease) or where antemortem efforts failed
  - Confirmation that the diagnosis made before death was correct and that the treatments administered were reasonable
  - Requested by next of kin
  - Research
- Authorization
  - In life: patient or healthcare surrogate

- Postmortem: next of kin
- B. Forensic autopsy
  - Purposes
    - Medicolegal investigation into the circumstances of unexplained or (possibly) unnatural deaths
    - Establishing the identity of the decedent and the time, place, and manner of death
    - Collect forensic evidence
    - Reconstruct a crime or accident
  - Authorization
    - Does not require authorization from the next of kin
    - Ordered by a court, a coroner, or a medical examiner who deems it necessary or in the public interest
  - Characteristics of death that may require a forensic autopsy
    - Deemed necessary or in the public interest by a coroner/medical examiner
    - Request by the police, by the district attorney, or a court
    - If circumstances of death are suspicious, unusual, unnatural, esp. homicide and suicide
    - If cause of death poses a potential threat to public health
    - Sudden fetus/infant deaths that appear natural and occur when in good health
    - Suspected sudden infant death syndrome (SIDS)

## Autopsy findings

### A. Signs of vitality (vital reactions)

Signs of vitality (not to be confused with vital signs) are signs that a body was still alive at the time of having sustained damage as opposed to the damage having occurred postmortem.

- Circulation
  - Signs of exsanguination
  - Signs of venous obstruction: congestive hemorrhage, Perthes pressure congestion
  - Embolisms
    - Fat embolism from injury to bone and subcutaneous fatty tissue
      - Findings: capillary microthrombi that fan out like antlers
      - Staining method: Sudan stain to visualize triglycerides
    - Air embolisms
    - Tissue embolisms
- **Metabolism:** metabolism of toxins (metabolites of toxins detectable in urine)
- Respiration
  - Aspiration: soot, blood, water, gastric contents
  - Evidence of toxic gasses such as carbon monoxide in the lungs
  - Subcutaneous emphysema in deep thoracic injuries
  - Collapsed lung in pneumothorax from external application of force
- Central nervous system
  - Soot-free radial bands beside the eyes (crow's feet) in fire victims
  - Evidence of a functioning autonomic nervous system at the time of injury: blood that has been swallowed or coughed up

Signs of vitality provide clues that damage to an organism occurred before the onset of death.

### B. Supravital reactions

Supravital reactions are certain physical functions that persist for some time after the onset of death. They provide specific clues regarding the time of death.

- Up to 8 hours after onset of death: skeletal musculature
  - Up to 8 hours postmortem: Mechanical stimulation causes slight idiomuscular bulging that may persist for up to 24 hours.
  - 3–5 hours postmortem: Mechanical stimulation causes pronounced reversible idiomuscular bulging.
  - 1.5–2.5 hours postmortem: **Zsako's muscle phenomenon**, i.e., mechanical stimulation causes propagated excitation
- **Up to 17 hours:** pupillary response
- **Up to 80 hours:** motile sperm cells

## Special circumstances

### Evidence of live birth

The condition of the lungs and the gastrointestinal tract can provide evidence of whether an infant was alive at birth or stillborn.

- **Lung float test:** Lungs that are lighter than water suggest that respiration occurred and that the infant was, therefore, alive at birth. The test is, however, unreliable as a variety of factors can lead to false-negative or false-positive results.
  - False-positive : ventilation of lungs from resuscitation attempts or the buildup of gas during putrefaction
  - False-negative : aspiration of liquid or asphyxiation from smothering
- **Breslau's second life test:** Air in the gastrointestinal tract provides clues as to how long an infant lived before dying. The further down there is air in the gastrointestinal tract, the higher the probability an infant survived birth.
  - Air in stomach and duodenum: onset of death a few minutes after birth
  - Air in the entire small intestine: onset of death up to six hours after birth
  - Air in the entire large intestine: onset of death up to twelve hours after birth