

# Ethical, Legal and Organizational Aspects of Medicine

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<b>Legal Framework</b> . . . . .	<b>2</b>	<b>Organization of Health Care in Canada</b> . . . . .	<b>15</b>
Sources of Law		Legal Foundation	
		History	
<b>Ethical Framework</b> . . . . .	<b>2</b>	Key Principles of the <i>Canada Health Act</i>	
Principles of Ethics		Health Care Expenditure and Delivery in Canada	
Code of Ethics		Ethical Considerations in Resource Allocation and Physicians' Role	
		Role of the Provincial Licensing Authorities	
<b>Specific Issues in Private Health</b>		Licensure and Certification	
<b>Law and Ethics</b> . . . . .	<b>4</b>	Role of Professional Associations	
Doctor-Patient Relationship			
Consent and Capacity		<b>The US Health Care System</b> . . . . .	<b>19</b>
Consent		History	
Capacity		Health Care Expenditure and Delivery in the US	
Confidentiality and Reporting Requirements		Access to Health Services	
Privacy of Medical Records		Health Care Reform	
Physician Competence and Professional Conduct			
Truth Telling		<b>References</b> . . . . .	<b>22</b>
Research Ethics			
Physician-Industry Relations			
Physician Responsibilities Regarding Death			
Role of the Coroner			
Palliative and End-of-Life Care			
Reproductive and Sexual Health Law and Ethics			

Further information on these topics can be found in the *Objectives of the Considerations of the Legal, Ethical and Organizational Aspects of the Practice of Medicine (CLEO)* – which can be downloaded free of charge from the Medical Council of Canada website at <http://mcc.ca/wp-content/uploads/CLEO.pdf>

Canadian law applicable to medical practice varies between jurisdictions and changes over time. Criminal law is nationwide, but non-criminal (civil) law varies between provinces. This section is meant to serve only as a guide. Students and physicians should ensure that their practices conform to local and current laws.

## Acronyms

AE	adverse event	CPSO	College of Physicians and Surgeons of Ontario	PIPEDA	Personal Information Protection and Electronic Documents Act
AMA	American Medical Association	HCCA	Health Care Consent Act	POA	power of attorney
ART	advanced reproductive technologies	LMCC	Licentiate of the Medical Council of Canada	SDM	substitute decision maker
CCB	Consent and Capacity Board	MCC	Medical Council of Canada		
CMA	Canadian Medical Association	OECD	Organization for Economic Co-operation and Development		
CMPA	Canadian Medical Protective Association				

# Legal Framework

## Sources of Law

Source of Law	Definition	Example
<b>Common Law</b>	Legal rules and principles that define private rights and obligations	Tort Law: defines breaches of civil duty owed to someone else Contract Law: define mutually agreed upon rights and obligations that may result in award of damages if breached
<b>Statutes</b>	Laws passed by provincial legislatures and the federal parliament Basis of province/territory specific health care acts Used to establish the provincial/territorial Licensing and Regulatory Authority for health care professionals	In Ontario: <i>Health Care Consent Act, Personal Information Protection Act</i> Criminal Code of Canada which defines breaches of duty owed to society in general
<b>Constitution</b>	Supreme law of Canada All other laws must be consistent with constitution	Canadian Charter of Rights and Freedoms is part of the constitution and guarantees the rights of life, liberty, security of the person, and equality under the law



### Categories of Health Law and Policy

- **Private:** regulates the relationship between "private" actors, such as Doctor and Patient
- **Public:** regulates the actions of "public" actors such as the provincial and federal governments

# Ethical Framework

## Principles of Ethics

- ethics addresses:
  - 1) the principles and values that help define what is morally right and wrong
  - 2) the rights, duties and obligations of individuals and groups
- the practice of medicine assumes there is one code of *professional* ethics for all doctors and that they will be held accountable by that code and its implications



**Table 1. The Four Principles Approach to Medical Ethics**

Principle	Definition	In Practice Do's	In Practice Don'ts
<b>Autonomy</b>	<ul style="list-style-type: none"> <li>• Recognizes an individual's right and ability to decide for themselves according to his/her beliefs and values</li> <li>• Not applicable to newborns, young children, or in situations where informed consent and choice are not possible or may not be appropriate</li> </ul>	<ul style="list-style-type: none"> <li>• Respect and promote an individual patient's values and preferences in decision making to empower him or her</li> <li>• Understand, appreciate, and respect a patient's decision even if it may differ from the recommendation of the physician</li> <li>• Show fidelity to incapable patient's prior capable views if known, and treat them with worth and dignity</li> </ul>	<ul style="list-style-type: none"> <li>• Doctors are not obliged, and indeed ought not, to comply with patients wishes that are illegal or might be considered to be 'conduct unbecoming a doctor' (unprofessional conduct, falling below the standard of care)</li> <li>• A patient's autonomy may be compromised by illness; the principle of autonomy is not a trump card and must be balanced by the rest of the listed principles</li> <li>• Patients are not expected to act in ways considered 'reasonable' or rational by others as long as they do not harm others</li> </ul>



### Autonomy vs. Competence

**Autonomy:** the right that patients have to make decisions according to their beliefs and preferences.

**Competence:** the ability or capacity to make a specific decision for oneself.

**Table 1. The Four Principles Approach to Medical Ethics** (continued)

Principle	Definition	In Practice Do's	In Practice Don'ts
<b>Beneficence</b>	<ul style="list-style-type: none"> <li>The patient-based 'best interests' standard that combines doing good, avoiding harm, taking into account the patient's values, beliefs, and preferences, so far as these are known</li> <li>Autonomy should be integrated with the physician's conception of a patient's medically-defined best interests</li> <li>The aim is to minimize harmful outcomes and maximize beneficial ones</li> <li>Paramount in situations where consent/choice is not possible or may not be appropriate</li> </ul>	<ul style="list-style-type: none"> <li>Try to ensure that a treatment's benefits outweigh its burdens</li> <li>Recommend treatment based on evidence and professional experience to patients and help them weigh the risks and benefits of various options</li> <li>Where a patient's capacity is compromised, physicians have more authority to act purely in the patient's best interests as defined by the therapeutic relationship but they still ought to do so in ways informed by the patient's known wishes and with the involvement, where possible, of the patient's substitute decision-maker</li> </ul>	<ul style="list-style-type: none"> <li>Do not make a decision without a patient's input (direct or indirect)</li> </ul>
<b>Non-Maleficence</b>	<ul style="list-style-type: none"> <li>Obligation to avoid causing harm; <i>primum non nocere</i> ("First, do no harm")</li> <li>A limit condition of the Beneficence principle</li> </ul>	<ul style="list-style-type: none"> <li>Efforts should be made to reduce error and adverse events and ensure patient safety</li> <li>A key guide for all management plans</li> </ul>	<ul style="list-style-type: none"> <li>Do not recommend a treatment because it will have some harm associated with it</li> </ul>
<b>Justice</b>	<ul style="list-style-type: none"> <li>Fair distribution of benefits and harms within a community, regardless of geography or privilege</li> <li>Concept of fairness: Is the patient receiving what he/she deserves – his/her fair share? Is he/she treated the same as equally situated patients? How do one set of treatment decisions impact on others?</li> <li>Respects rules of fair play and basic human rights, such as freedom from persecution and the right to have one's interests considered and respected</li> </ul>	<ul style="list-style-type: none"> <li>Scarce resources are distributed based on the needs of patients and the benefit they would receive from obtaining a specific resource e.g. organs for transplantation are fairly distributed if they go to those who are the most unwell, who are the most likely to survive the longest with the transplant, and who have waited the longest to receive a transplant</li> </ul>	<ul style="list-style-type: none"> <li>Physicians ought to be 'door openers', not 'gate-closers', for their patients</li> </ul>



**The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada**

*CMAJ* 2004;170:1678-1686

**Study:** Hospital charts randomly selected and reviewed in four randomly selected Canadian hospitals for the fiscal year 2000.

**Patients:** 4174 patient charts sampled, 3745 eligible charts (>18 yr of age; nonpsychiatric, nonobstetric, minimum 24 h admission).

**Results:** AE rate was 7.5% per 100 hospital admissions (95% CI 5.7-9.3). Highly preventable AEs occurred in 36.9% of patients with AEs (95% CI 32.0-41.8%) and death occurred in 20.8% (95% CI 17.8%-23.8%). An estimated 1521 additional hospital days were associated with AEs. Patients with AEs were significantly older than those without (mean age [and standard deviation] 64.9 [16.7] v. 62.0 [18.4] yr;  $p=0.016$ ). Men and women experienced equal rates of AEs.

**Conclusions:** The overall incidence rate of AEs of 7.5% suggests that, of the almost 2.5 million annual hospital admissions in Canada similar to the type studied, about 185 000 are associated with an AE and close to 70 000 of these are potentially preventable.



**Adverse Event (AE)**

An unintended injury or complication from health care management resulting in disability, death or prolonged hospital stay.

## Code of Ethics

- CMA developed a Code of Ethics that acts as a common ethical framework for Canadian physicians
  - prepared by physicians for physicians and applies to physicians, residents, and medical students
  - based on the fundamental ethical principles of medicine
  - sources include the Hippocratic Oath, developments in human rights, recent bioethical discussion
  - statements are general in nature
  - CMA policy statements address specific ethical issues not mentioned by the code (e.g. abortion, transplantation, and euthanasia)
- the American Medical Association (AMA) has a Code of Medical Ethics
  - articulates the values of medicine as a profession and defines medicine's integrity
  - source of the profession's authority to self-regulate
  - evolving document that changes as new questions arise; AMA policy positions ("AMA Policy") address current health care issues, the health care system, internal organizational structure, decision-making processes, and medical science and technology



The CMA Code of Ethics is a quasi-legal standard for physicians. If the law sets a minimal moral standard for doctors, the Code ratchets up these standards.

# Specific Issues in Private Health Law and Ethics

## Doctor-Patient Relationship

Ethical Basis	Legal Basis
<ul style="list-style-type: none"> <li>• A partnership based on the physician providing expert opinion, information, options, and interventions that allows the patient to make informed choices about his/her health care</li> <li>• Within this relationship, the doctor and patient share the goals of positive health outcomes, good communication, honesty, flexibility, sensitivity, informed consent, and respect</li> <li>• This relationship has the potential to be unequal due to a power difference <ul style="list-style-type: none"> <li>• Patients are ill and lack medical expertise</li> <li>• Physicians possess specialized medical knowledge and skills</li> <li>• Physicians are in a fiduciary relationship with their patients</li> </ul> </li> <li>• Due to the nature of the doctor-patient relationship, the physician will: <ul style="list-style-type: none"> <li>• Place the best interests of the patient first</li> <li>• Establish a relationship of trust with the patient</li> <li>• Follow through on undertakings made to the patient in good faith</li> </ul> </li> <li>• The physician will accept or refuse patients requesting care: <ul style="list-style-type: none"> <li>• Without consideration of race, gender, age, sexual orientation, financial means, religion or nationality</li> <li>• Without arbitrary exclusion of any particular group of patients, such as those known to be difficult or afflicted with serious disease</li> <li>• Except in emergency situations, in which case care must be rendered</li> </ul> </li> <li>• Once having accepted a patient into care, the physician may terminate the relationship provided: <ul style="list-style-type: none"> <li>• It is not an emergency</li> <li>• After a reasonable period of time (usually a month) for the patient to find alternate care</li> <li>• Adequate notice (usually an explanatory letter by registered mail) has been given to the patient</li> <li>• There are other options to find 'medically necessary care' (in other words, in smaller communities with fewer options for care, there may need to be some flexibility in cessation of care)</li> </ul> </li> <li>• The reason for termination ought to be 'failure of trust'</li> <li>• The physician will not exploit the doctor-patient relationship for personal advantage – for sexual, financial, academic or other purposes</li> <li>• The physician will disclose limitations to the patient where personal beliefs or inclinations limit the treatment the physician is able to offer</li> <li>• The physician will maintain and respect professional boundaries at all times <ul style="list-style-type: none"> <li>• Including physical, emotional, and sexual boundaries</li> <li>• Regarding treatment of themselves, their families, and friends</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Duties and rights defined partly by: <ul style="list-style-type: none"> <li>• Tort law that allows patients to recover damages for wrongful acts committed against them; the most important are: <ol style="list-style-type: none"> <li>A. Negligence: breach of a legal duty of care (in tort) which results in damage <ul style="list-style-type: none"> <li>• Legal finding, not a medical one</li> <li>• Physicians may be found negligent when the following four conditions are met: <ol style="list-style-type: none"> <li>1. The physician owed a duty of care to the patient (the existence of a doctor-patient relationship generally suffices)</li> <li>2. The duty of care was breached (e.g. by failure to provide the standard of care) <ul style="list-style-type: none"> <li>• The standard of care is one that would reasonably be expected under similar circumstances of an ordinary, prudent physician of the same training, experience, and specialization</li> </ul> </li> <li>3. The patient was injured or harmed</li> <li>4. The harm or injury was caused by the breach of the duty of care</li> </ol> </li> </ul></li></ol> </li> </ul> </li> <li>• Errors of judgment are not necessarily negligent</li> <li>• Making the wrong diagnosis is not negligent if a reasonable doctor might have made the same mistake in the same circumstances</li> <li>• Failure to reconsider the diagnosis if the patient does not respond to treatment may be negligent</li> <li>• Physicians can be held liable for the negligent actions of their employees or other individuals they are supervising</li> </ul> <li>B. Battery: the application of force to a person's body without their consent <ul style="list-style-type: none"> <li>• Contractual rights and obligations that if breached may result in the award of damages</li> <li>• Fiduciary duty of physicians to their patients (i.e. to act in their best interest)</li> </ul> </li>



In situations in which it would be more difficult for a patient to find alternate "medically necessary care", the physician may need to exhibit some flexibility in cessation of care.



"Failure of trust" situations include "double-doctoring" on the part of the patient and patient threats of violence.



### CPSO Policy: Treating Self and Family Members

Physicians will not diagnose or treat themselves or family members except for minor conditions or in emergencies and then only if no other physician is readily available.



### CPSO Policy: Ending the Physician-Patient Relationship

Discontinuing services that are needed is an act of professional misconduct unless done by patient request, alternative services are arranged, or adequate notice has been given.



### Dealing with Controversial and Ethical Issues in Practice

- Discuss in a non-judgmental manner
- Ensure patients have full access to relevant and necessary information
- Identify if certain options lie outside of your moral boundaries and refer to another physician if appropriate
- Consult with appropriate ethics committees or boards
- Protect freedom of moral choice for students or trainees

Source: *MCC-CLEO Objectives* 1998

## Consent and Capacity



- the autonomous authorization of a medical intervention by a patient
- applies to acceptance and refusal of treatment

### Ethical Principles Underlying Consent and Capacity

- usually the principle of respect for patient autonomy overrides the principle of beneficence
- where a patient cannot make an autonomous decision (i.e. incapable), it is the duty of the SDM (or the physician in an emergency) to act on the patient's known prior wishes or, failing that, to act in the patient's best interests
- there is a duty to discover, if possible, what the patient would have wanted when capable
- central to determining best interests is understanding the patient's values, beliefs, and cultural or religious background
- more recently expressed wishes take priority over remote ones
- patient wishes may be verbal or written
- patients found incapable to make a specific decision should still be involved in that decision as much as possible
- agreement or disagreement with medical advice does not determine findings of capacity/incapacity
- however, patients opting for care that puts them at risk of serious harm that most people would want to avoid should have their capacity carefully assessed



#### CPSO Policy Consent

Obtaining valid consent before carrying out medical, therapeutic and diagnostic procedures has long been recognized as an elementary step in fulfilling the doctor's obligations to the patient.

## Consent

### Obtaining Legal Consent

- consent of the patient must be obtained before any medical intervention is provided; consent can be:
  - verbal or written, although written is usually preferred
    - ♦ a signed consent form is only evidence of consent – it does not replace the process for obtaining valid consent (see Figure 1)
    - ♦ what matters is what the patient understands and appreciates, not what the signed consent form states
  - implied (e.g. a patient holding out their arm for an immunization) or expressed
- consent is an ongoing process and can be withdrawn or changed after it is given, unless stopping a procedure would put the patient at risk of serious harm
- *Health Care Consent Act* (of Ontario) covers consent to treatment, admission to a facility, and personal assistance services (e.g. home care)

### Four Basic Requirements of Valid Consent

#### 1. Voluntary

- consent must be given free of coercion or pressure (e.g. from parents or other family members who might exert 'undue influence')
- the physician must not deliberately mislead the patient about the proposed treatment

#### 2. Capable

- the patient must be able to understand and appreciate the nature and effect of the proposed treatment

#### 3. Specific

- the consent provided is specific to the procedure being proposed and to the provider who will carry out the procedure (i.e. the patient must be informed if students will be involved in providing the treatment)

#### 4. Informed

- sufficient information and time must be provided to allow the patient to make choices in accordance with their wishes. This information should include:
  - ♦ the nature of the treatment or investigation proposed and its expected effects
  - ♦ all significant risks and special or unusual risks
  - ♦ alternative treatments or investigations and their anticipated effects and significant risks
  - ♦ the consequences of declining treatment
  - ♦ risks that are common sense need not be disclosed (i.e. bruising after venipuncture)
  - ♦ answers to any questions the patient may have
- the reasonable person test – the physician must provide all information that would be needed "by a reasonable person in the patient's position" to be able to make a decision
- disclose common adverse events (>1/200 chance of occurrence) and serious risks (e.g. death) even if remote
- it is the physician's responsibility to make reasonable attempts to ensure that the patient understands the information
- physicians should not withhold information about a legitimate therapeutic option based on personal conscience (e.g. not discussing the option of emergency contraception)



#### 4 Basic Elements of Consent

- Voluntary
- Capable
- Specific
- Informed



The Supreme Court of Canada expects physicians to disclose the risks that a "reasonable" person would want to know. In practice, this means disclosing minor risks that are common as well as serious risks that happen infrequently, especially those risks that are particularly relevant to a particular patient (e.g. hearing loss for a musician).

## Exceptions to Consent

### 1. Emergencies

- treatment can be provided without consent where a patient is experiencing severe suffering, or where a delay in treatment would lead to serious harm or death and consent cannot be obtained from the patient or their substitute decision maker (SDM)
- emergency treatment should not violate a prior expressed wish of the patient (e.g. a signed Jehovah's Witness card)
- if patient is incapable, MD must document reasons for incapacity and why situation is emergent
- patients have a right to challenge a finding of incapacity as it removes their decision-making ability
- if a SDM is not available, MD can treat without consent until the SDM is available or the situation is no longer emergent

### 2. Legislation

- Mental Health legislation allows for:
  - ◆ the detention of patients without their consent
  - ◆ psychiatric outpatients may be required to adhere to a care plan in accordance with Community Treatment Orders (see [Psychiatry, PS7](#))
- Public Health legislation allows medical officers of health to detain, examine, and treat patients without their consent (e.g. a patient with TB refusing to take medication) to prevent transmission of communicable diseases (see [Population Health and Epidemiology, PH19](#))

### 3. Special Situations

- public health emergencies (e.g. an epidemic or communicable disease treatment)
- warrant for information by police

## Consequences of Failure to Obtain Valid Consent

- treatment without consent is battery (an offense in tort), even if the treatment is life-saving (excluding situations outlined in exceptions section above)
- treatment of a patient on the basis of poorly informed consent may constitute negligence, also an offense in tort
- the onus of proof that valid consent was not obtained rests with the plaintiff (usually the patient)

## Capacity

- capacity is the ability to:
  - understand information relevant to a treatment decision
  - appreciate the reasonably foreseeable consequences of a decision or lack of a decision
- capacity is specific for each decision (e.g. a person may be capable to consent to having a chest x-ray, but not for a bronchoscopy)
- capacity can change over time (e.g. temporary incapacity secondary to delirium)
- most Canadian jurisdictions distinguish capacity to make health care decisions from capacity to make financial decisions; a patient may be deemed capable of one, but not the other
- a person is presumed capable unless there is good evidence to the contrary
- capable patients are entitled to make their own decisions
- capable patients can refuse treatment even if it leads to serious harm or death; however, decisions that put patients at risk of serious harm or death require careful scrutiny
- capacity assessments must be conducted by a physician and, if appropriate, in consultation with other health care professionals (e.g. another physician, a mental health nurse)
- clinical capacity assessment may include:
  - specific capacity assessment (i.e. capacity specific to the decision at hand)
    1. effective disclosure of information and evaluation of patient's reason for decision
    2. understanding of:
      - his/her condition
      - the nature of the proposed treatment
      - alternatives to the treatment
      - the consequences of accepting and rejecting the treatment
      - the risks and benefits of the various options (test: can the patient recite back what you have disclosed?)
    3. for the appreciation needed for decision making capacity, a person must:
      - acknowledge the condition that affects him/herself
      - be able to assess how the various options would affect him or her
      - be able to reach a decision and adhere to it, and make a choice, not based primarily upon delusional belief (test: are their beliefs responsive to evidence?)
  - general impressions
  - input from psychiatrists, neurologists, etc.
- employ "Aid to Capacity Evaluation" (see Table 2)



### Major Exceptions to Consent

- Emergencies
- Communicable diseases
- Mental Health legislation



Administration of treatment for an incapable patient in an emergency situation is applicable if the patient is:

- Experiencing extreme suffering
- At risk of sustaining serious bodily harm if treatment is not administered promptly



Patients may also ask to waive the right to choice (e.g. "You know what's best for me, doctor") or delegate their right to choose to someone else (e.g. a family member).



### Consent

- Treatment without consent = battery, including if NO consent or if WRONG procedure
- Treatment with poor or invalid consent = negligence



### CPSO Policy on Capacity

Capacity is an essential component of valid consent, and obtaining valid consent is a policy of the CMA and other professional bodies.



**Table 2. Aid to Capacity Evaluation**

Ability to understand the medical problem
Ability to understand the proposed treatment
Ability to understand the alternatives (if any) to the proposed treatment
Ability to understand the option of refusing treatment or of it being withheld or withdrawn
Ability to appreciate the reasonably foreseeable consequences of accepting the proposed treatment
Ability to appreciate the reasonably foreseeable consequences of refusing the proposed treatment
Ability to make a decision that is not substantially based on delusions or depression

Adapted from Etchells, et al. 1996

- a decision of incapacity may warrant further assessment by psychiatrist(s), legal review boards (e.g. in Ontario, the Consent and Capacity Review Board), or the courts
- judicial review is open to patients if found incapable

**Treatment of the Incapable Patient in a Non-Emergent Situation**

- obtain informed consent from SDM
- an incapable patient can only be detained against his/her will to receive treatment if he/she meets criteria for certification under the *Mental Health Act*. In such a situation:
  - document assessment in chart
  - notify patient of assessment using appropriate Mental Health Form(s) (Form 42 in Ontario)
  - notify Rights Advisor

**SUBSTITUTE DECISION MAKERS (SDMs)**

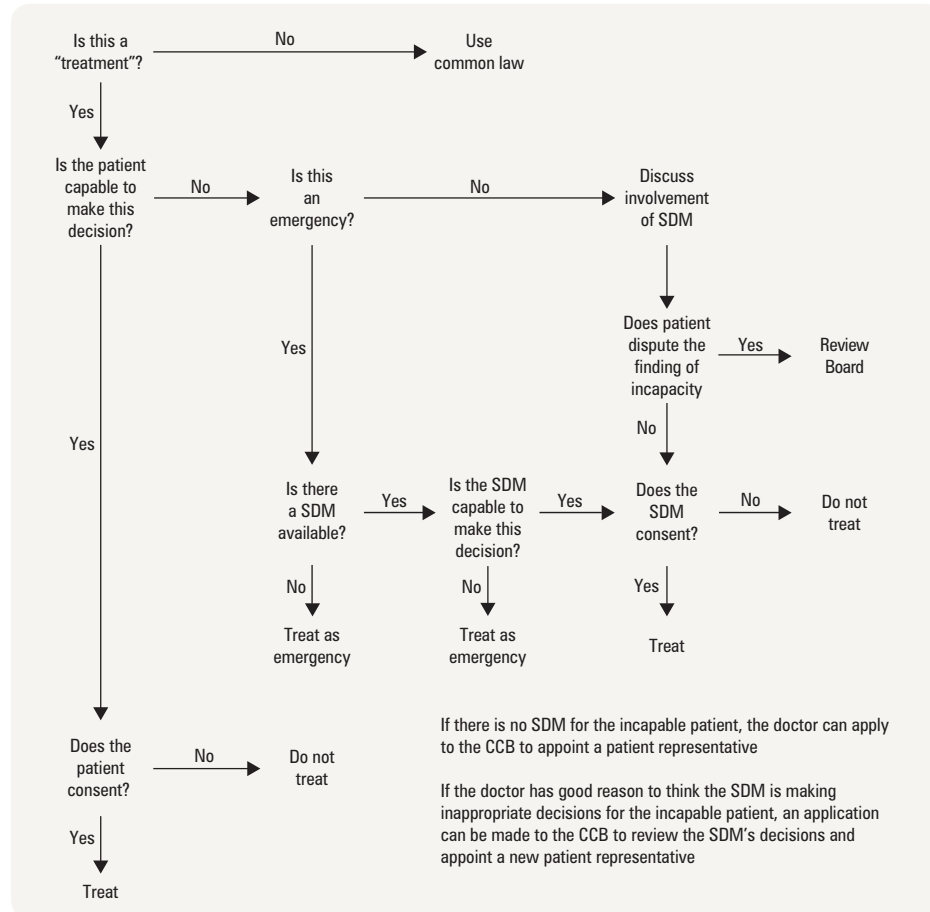
- SDM must follow the following principles when giving informed consent:
  - act in accordance with wishes previously expressed by the patient while capable
  - if wishes unknown, act in the patient's best interest, taking the following into account:
    1. values and beliefs held by the patient while capable
    2. whether well-being is likely to improve with vs. without treatment
    3. whether the expected benefit outweighs the risk of harm
    4. whether a less intrusive treatment would be as beneficial as the one proposed
  - the final decision of the SDM may and should be challenged by the MD if the MD believes the SDM is not abiding by the above principles



Most provinces have legislated hierarchies for SDMs; the hierarchy in Ontario is:

- Legally appointed guardian
- Appointed attorney for personal care, if a power of attorney confers authority for treatment consent (see *Powers of Attorney, ELOAM8*)
- Representative appointed by the Consent and Capacity Board
- Spouse or partner
- Child (age 16 or older) or parent (unless the parent has only a right of access)
- Parent with only a right of access
- Sibling
- Other relative(s)
- Public guardian and trustee

**Figure 1. Ontario consent flowchart**



SDM = substitute decision maker

Adapted by Hébert P from Sunnybrook Health Sciences Centre Consent Guidelines

## INSTRUCTIONAL ADVANCE DIRECTIVES

- allow patients to exert control over their care once they are no longer capable
- the patient sets out their decisions about future health care, including who they would allow to make treatment decisions on their behalf and what types of interventions they would want
- takes effect once the patient is incapable with respect to treatment decisions
- in Ontario, a person can appoint a power of attorney for personal care to carry out his/her advance directives
- patients should be encouraged to review these documents with their family and physicians and to reevaluate them often to ensure they are current with their wishes

## POWERS OF ATTORNEY

- all Guardians and Attorneys have fiduciary duties for the dependent person

### Definitions

- **Power of Attorney for Personal Care**
  - a legal document in which one person gives another the authority to make personal care decisions (health care, nutrition, shelter, clothing, hygiene, safety) on their behalf if they become mentally incapable
- **Guardian of the Person**
  - someone who is appointed by the Court to make decisions on behalf of an incapable person in some or all areas of personal care, in the absence of a POA for personal care
- **Continuing Power of Attorney for Property**
  - a legal document in which a person gives another the legal authority to make decisions about their finances if they become unable to make those decisions
- **Guardian of Property**
  - someone who is appointed by the Public Guardian and Trustee or the Courts to look after an incapable person's property or finances
- **Public Guardian and Trustee**
  - acts as a SDM of last resort on behalf of mentally incapable people who do not have another individual to act on their behalf
- **Pediatric Aspects of Capacity Covered by the HCCA, Ontario**
  - no age of consent; consent depends on patient's decision-making capacity
  - QC has a specific age of consent, but common law and case law deem underage legal minors capable, allowing them to make their own choices; all other provinces and territories do not have an age of consent
  - infants and children are assumed to lack mature decision-making capacity for consent but they should still be involved (i.e. be provided with information appropriate to their comprehension level)
  - adolescents are usually treated as adults
  - preferably, assent should still be obtained from patient, even if not capable of giving consent
  - in the event that the physician believes the SDM is not acting in the child's best interest, an appeal must be made to the local child welfare authorities
  - under normal circumstances, parents have right of access to the child's medical record

## Confidentiality and Reporting Requirements

- a full and open exchange of information between patient and physician is central to a therapeutic relationship
- privacy is a right of patients (which they may forego), while confidentiality is a duty of doctors (which they must respect barring patient consent or the requirements of the law)
- if inappropriately breached by a doctor, he/she can be sanctioned by the hospital, by the court or by his or her regulatory authority
- based on the ethical principal of patient autonomy, patients have the right to:
  - control their own information
  - expect information concerning them will receive proper protection from unauthorized access by others (see *Privacy of Medical Records*, ELOAM9)
- confidentiality may be ethically and legally breached in certain circumstances, e.g. the threat of harm to others
- unlike the solicitor-client privilege, there is no 'physician-patient privilege' by which a physician, even a psychiatrist, can promise the patient absolute confidentiality
- physicians should seek advice from their local health authority or the Canadian Medical Protective Association (CMPA) before disclosing HIV status of a patient to someone else
  - many jurisdictions make mandatory not only the reporting of serious communicable diseases (e.g. HIV), but also the reporting of those who harbour the agent of the communicable disease
  - physicians failing to abide by such regulations could be subject to professional or civil actions
- the legal duty to maintain patient confidentiality is imposed by provincial health information legislation and precedent-setting cases in the common law



There is no age of consent in Ontario.



### Other Types of Capacity Not Covered by the HCCA

- Testamentary (ability to make a will)
- Fitness (ability to stand trial)
- Financial (ability to manage property – Form 21 of the *Mental Health Act*)
- Personal (ability to care for oneself on a daily basis)



### Legal Aspects of Confidentiality

Advice should always be sought from provincial licensing authorities and/or legal counsel when in doubt.



### CMA Code of Ethics

"Disclose your patients' personal health information to third parties only with their consent, or as provided for by law, such as when the maintenance of confidentiality would result in a significant risk of substantial harm to others or, in the case of incompetent patients, to the patients themselves. In such cases take all reasonable steps to inform the patients that the usual requirements for confidentiality will be breached."



### Statutory Reporting Obligations

- legislation has defined specific instances where public interest overrides the patient right to confidentiality; varies by province, but may include:
  1. suspected child abuse or neglect – report to local child welfare authorities (e.g. Children's Aid Society)
  2. fitness to drive a vehicle or fly an airplane – report to provincial Ministry of Transportation (see [Geriatric Medicine](#), GM10)
  3. communicable diseases – report to local public health authority (see [Population and Epidemiology](#), PH25)
  4. improper conduct of other physicians or health professionals – report to college or regulatory body of the health professional (sexual impropriety by physicians is required reporting in some provinces)
  5. vital statistics must be reported; reporting varies by province (in Ontario, births are required to be reported within 30 d to Office of Registrar General or local municipality; death certificates must be completed by a MD then forwarded to municipal authorities)
  6. reporting to coroners (see *Physician Responsibilities Regarding Death*, ELOAM13)
- physicians who fail to report in these situations are subject to prosecution and penalty, and may be liable if a third party has been harmed

### Duty to Protect/Warn

- the physician has a duty to protect the public from a known dangerous patient; this may involve taking appropriate clinical action (e.g. involuntary detention of violent patients for clinical assessment), informing the police, or warning the potential victim(s) if a patient expresses an intent to harm
- first established by a Supreme Court of California decision in 1976; supported by Canadian courts
- obliged by the CMA Code of Ethics and recognized by some provincial/territorial regulatory authorities
- concerns of breaching confidentiality should not prevent the MD from exercising the duty to protect; however, the disclosed information should not exceed that required to protect others
- applies in a situation where:
  1. there is a clear risk to identifiable person(s);
  2. there is a risk of serious bodily harm or death; and
  3. the danger is imminent (i.e. more likely to occur than not)

### Disclosure for Legal Proceedings

- disclosure of health records can be compelled by a court order, warrant, or subpoena

## Privacy of Medical Records

- privacy of health information is protected by professional codes of ethics, provincial and federal legislation, the *Canadian Charter of Rights and Freedoms*, and the fiduciary duty
- the federal government created the *Personal Information Protection and Electronic Documents Act* (PIPEDA), which established principles for the collection, use, and disclosure of information that is part of commercial activity (e.g. physician practices, pharmacies, private labs)
- PIPEDA has been superseded by provincial legislation in many provinces, such as the *Ontario Personal Health Information Protection Act*, which applies more specifically to health information

### Duties of Physicians with Regards to the Privacy of Health Information

- inform patients of information-handling practices through various means (e.g. posting notices, brochures and pamphlets, and/or through discussions with patients)
- obtain the patient's expressed consent to disclose information to third parties
  - under Ontario privacy legislation, the patient's expressed consent need not be obtained to share information between health care team members involved in the "circle of care." However, the patient may withdraw consent for this sharing of information and may put parts of the chart in a "lock box"
- provide the patient with access to their entire medical record; exceptions include instances where there is potential for serious harm to the patient or a third party
- provide secure storage of information and implement measures to limit access to patient records
- ensure proper destruction of information that is no longer necessary



#### Reasons to Breach Confidentiality

- Child abuse
- Fitness to drive
- Communicable disease
- Coroner report
- Duty to inform/warn



#### Ontario's Medical Expert Panel on Duty to Warn

*Ferris et al., 1998*

- There should be a duty to inform when a patient reveals that he/she intends to do serious harm to another person(s) and it is more likely than not that the threat will be carried out
- Where a threat is directed at a person or group and there is a specific plan that is concrete and capable of commission and the method for carrying it out is available to the threatener, the physician should immediately notify the police and, in appropriate circumstances, the potential victim. The report should include the threat, the situation, the physician's opinion and the information upon which it is based



#### CMA Code of Ethics

- Protect the health information of your patients
- Provide information reasonable in the circumstances to patients about the reasons for the collection, use and disclosure of their health information
- Be aware of your patient's rights with respect to the collection, use, disclosure and access to their health information; ensure that such information is recorded accurately



#### Lock Boxes

The term "lock boxes" applies to situations where the patient has expressly restricted his or her physician from disclosing specific aspects of their health information to others, even those involved in the patient's circle of care.

## Physician Competence and Professional Conduct



### CanMEDS Competencies (Ethical/Policy Statement)

- a framework of professional competencies established by the Medical Council of Canada (MCC) as objectives for the Medical Council of Canada Qualifying Exam (MCCQE)
- further information on MCC objectives can be found at [www.mcc.ca](http://www.mcc.ca)

#### 1. Communicator

- display sensitivity to people of all ages, races, cultures, religions, sexual orientations, and genders
- accept or refuse patients without consideration of age, race, culture, religion, sexual orientation, and gender
- understand the variation in values and morals and their impact on approaches to care and decision-making
- elicit patients' beliefs, concerns, and expectations about their illness
- conduct patient-centered interviews, ensure patient comprehension

#### 2. Collaborator

- respect all members of the health care team
- identify the roles and competencies of each member, and delegate tasks appropriately
- consult other physicians and health care professionals effectively and appropriately
- consult with patients and families regarding continuing care plans
- be able to outline co-ordination of services (e.g. Public Health, Home Care, Social Services, Workers' Compensation, Children's Aid Society, etc.)

#### 3. Health Advocate

- identify determinants of health:
  - biological (e.g. genes, impact of lifestyle)
  - physical (e.g. food, shelter, working conditions)
  - social (education, employment, culture, access to care)
- influence public health and health policy to protect, maintain, and promote the health of individuals and the community

#### 4. Manager

- meet regulatory requirements in an office practice (e.g. medical record-keeping, narcotic control, infection control, etc.)
- be prudent in utilization of health care resources, based on anticipated cost-benefit balance
- regulate work schedule such that time is available for continuing education

#### 5. Professional

- maintain standards of excellence in clinical care and ethical conduct
- exhibit appropriate personal and interpersonal behaviour
- enhance clinical competence through lifelong learning
- accept responsibility for personal actions
- do not exploit the physician-patient relationship for personal advantage (e.g. financial, academic)

#### 6. Scholar

- commitment to critical appraisal, constructive skepticism
- participate in the learning of peers and others (e.g. students, health care professionals, patients)

#### 7. Medical Expert

- integration of all CanMEDS competencies to provide patient centred care
- combination of knowledge, clinical skills and judgment, procedural skills and professional behaviour for effective patient care

### Legal Considerations

- the competence and conduct of physicians is legally regulated in certain respects to protect patients and society
- physicians are legally required to maintain a license with the appropriate authority
- physicians must ensure that patients have access to continuous on-call coverage and are never abandoned
- sexual conduct with patients, even when consented to by the patient, is a serious matter that can lead to criminal, civil, and disciplinary action
  - sexual conduct includes intercourse, undue touching, inappropriate reference to sexual matters, sexual jokes, and physician presence when capable patients undress or dress
  - in some situations physicians may have a personal relationship with a patient provided a year has passed since the last therapeutic contact



### Professional Considerations

#### Elderly Patient

- Identify their resuscitation options (CPR or DNR), if applicable
- Check for documentation of advance directives and POA where applicable
- For further details, see [Geriatric Medicine, GM12](#)

#### Pediatric Patient

- Identify the primary decision-maker (parents, guardian, wards-of-state, emancipated)
- Regarding capacity assessment see Pediatric Aspects of Capacity Covered by the HCCA (ELOAM8)
- Be wary of custody issues if applicable

#### Terminally Ill or Palliative Patient

- Consider the SPIKES approach to breaking bad news
- What are their goals of care, i.e. disease vs. symptom management?
- Identify advance directives, POA, or SDM, if applicable (see ELOAM7)
- Check for documentation of resuscitation options (CPR or DNR) and likelihood of success
- For further details, see [Geriatric Medicine, GM12](#)

#### Incapable Patient

- If not already present, perform a formal capacity assessment
- Identify if the patient has a SDM or who has their POA
- Check the patient's chart for any Mental Health Forms (e.g. Form 1) or any forms they may have on their person (e.g. Form 42)



### CanMEDS Competencies

- Communicator
- Collaborator
- Health Advocate
- Manager
- Professional
- Scholar
- Medical Expert



### CMA Code of Ethics

Report any unprofessional conduct by colleagues to the appropriate authority.

- physicians are permanently prohibited from personal relationships with patients whom they saw for psychotherapy
- in Ontario, physicians must report any colleagues of whom they have information regarding sexual impropriety
- physicians must maintain adequate records for each patient, including:
  - showing that care has been continuous and comprehensive
  - minimal standards for record-keeping include diagnosis, differential diagnosis, appropriate tests and referrals, coherent patient record (full standards available at www.cpso.on.ca)
  - keeping records for 10 yr in most jurisdictions
  - although the medical record is the property of the physician or an institution, the patient or the patient's delegate must be allowed full access to information in the medical record upon (usually written) request
- in the hospital, physicians must ensure their own competence, respect hospital by-laws and regulations, practice only within the limits of granted privileges, cooperate with other hospital personnel, and maintain adequate hospital records

## Truth Telling

### Ethical Basis

- helps to promote and maintain a trusting physician-patient relationship
- patients have a right to be told important information that physicians have regarding their care
- enables patients to make informed decisions about health care and their lives

### Legal Basis

- required for valid patient consent (see *Consent and Capacity*, ELOAM5)
  - goal is to disclose information that a reasonable person in the patient's position would need in order to make an informed decision ("standard of disclosure")
- withholding information can be a breach of fiduciary duty and duty of care
- obtaining consent on the basis of misleading information can be seen as negligent

### Evidence about Truth Telling

- most patients want to know what is wrong with them
- although many patients want to protect family members from bad news, they themselves would want to be informed in the same situation
- truth telling improves compliance and health outcomes
- informed patients are more satisfied with their care
- negative consequences of truth telling can include decreased emotional well-being, anxiety, worry, social stigmatization, and loss of insurability

### Challenges in Truth Telling

#### Medical Error

- medical error may be defined as 'preventable adverse events' caused by the patient's medical care and not the patient's underlying illness. Some errors may be identified before they harm the patient, so not all error is truly 'adverse'
- many jurisdictions and professional associations expect and require physicians to disclose medical error; that is, any event that harms or threatens to harm patients must be disclosed to the patient or the patient's family and reported to the appropriate health authorities
- physicians should disclose to patients the occurrence of adverse events or errors caused by medical management, but should not suggest that they resulted from negligence because:
  - a) negligence is a legal determination
  - b) error is not equal to negligence (see *Negligence*, ELOAM4)
- disclosure allows the injured patient to seek appropriate corrective treatment promptly
  - physicians should avoid simple attributions as to cause and sole responsibility of others or oneself
  - physicians should offer apologies or empathic expressions of regret ("I wish things had turned out differently") as these can increase trust and are not admissions of guilt or liability
  - *Apology Acts* across Canada protect apologies, both as expressions of regret and admissions of responsibility, from being used as evidence of liability and negligence

#### Breaking Bad News

- 'bad news' may be any information that reveals conditions or illnesses threatening the patient's sense of well-being
- caution patients in advance of serious tests about possible bad findings
- give warnings of impending bad news (see sidebar for example) and make sure you provide time for the patient
- poorly done disclosure may be as harmful as non-disclosure
- truth-telling may be a process requiring multiple visits
- adequate support should be provided along with the disclosure of difficult news
- SPIKES protocol was developed to facilitate "breaking bad news"



#### CPSO Policy on Truth Telling

Physicians should provide patients with whatever information that will, from the patient's perspective, have a bearing on medical decision-making and communicate that information in a way that is comprehensible to the patient.



#### Examples of warning of impending bad news:

"I have something difficult to tell you...";  
 "This may come as a shock to you, but the tests indicate..."; and  
 "There is no easy way for me to tell you this, so I will tell you straight away that you have a serious problem..."



#### Protocol to Break Bad News: SPIKES

**S** Setting the scene and listening skills  
**P** Patient's **p**erception of condition and seriousness  
**I** Invitation from patient to give information  
**K** Knowledge – giving medical facts  
**E** Explore emotions and empathize  
**S** Strategy and summary

Baile WF and Buckman R 2000

### Arguments Against Truth Telling

- may go against certain cultural norms and expectations
- may lead to patient harm and increased anxiety
- 10-20% of patients prefer not to be informed
- medical uncertainty may result in the disclosure of uncertain or inaccurate information

### Exceptions to Truth Telling

- patients may 'waive' the right to know: patient declines information that would normally be disclosed
- a patient may waive their right to know the truth about their situation when
  - the patient clearly declines to be informed
  - a strong cultural component exists that should be respected and acknowledged
  - the patient may wish others to be informed and make the medical decisions for him/her
- the more weighty the consequences for the patient from non-disclosure, the more carefully one must consider the right to ignorance
- 'Emergencies': an urgent need to treat may legitimately delay full disclosure; the presumption is that most people would want such treatment and the appropriate SDM cannot be found
- 'Therapeutic privilege'
  - withholding information by the clinician in the belief that disclosure of the information would itself lead to severe anxiety, psychological distress or physical harm to the patient
  - clinicians should avoid invoking therapeutic privilege due to its paternalistic overtones and is a defense of non-disclosure that is rarely accepted anymore. It is often not the truth that is unpalatable; it is how it is conveyed that can harm the patient

## Research Ethics



- involves the systematic analysis of ethical dilemmas arising during research involving human subjects to ensure that:
  - study participants are protected
  - clinical research is conducted to serve the interests of the participants and/or society as a whole
- major ethical dilemmas arise when a physician's obligation to the patient comes into conflict with other obligations and incentives
- any exceptions to disclosure for therapeutic consent do not apply in an experimental situation

**Table 3. Ethical Principles for Research Involving Human Subjects**

- Patient's participation in research should not put him/her at a known or probable disadvantage with respect to medical care (i.e. cannot deny participants in research 'known effective care', for example, unethical to randomize some patients who are depressed to a placebo arm)
- Participant's voluntary and informed choice is usually required
  - Consent may not be required in special circumstances: chart reviews without patient contact; emergency situations for which there is no accepted or helpful standard of care and the proposed intervention is not likely to cause more harm than such patients already face
- Access to the treatment that is considered standard
  - Placebo-controlled trials are generally acceptable where patients still receive the standard of care and are informed about the placebo arm and what that entails
- Must employ a scientifically valid design to answer the research question
  - Scientific rigour ensured via peer review, expert opinion
- Must demonstrate sufficient value to justify the risk posed to participants
- Must be conducted honestly (i.e. carried out as stated in the approved protocol)
- Findings must be reported promptly and accurately without exaggeration, to allow practicing clinicians to draw reasonable conclusions
- Patients must not be enticed into risky research by the lure of money and investigators must not trade the interests of patients for disproportionate recompense by a sponsor; both participants and investigators are due fair recompense for their time and efforts
- Any significant interventional trial ought to have a data safety monitoring board that is independent of the sponsor and can ensure safety of the ongoing trial

Laid out in the Declaration of Helsinki, the Belmont Report, etc.

## Physician-Industry Relations

- health care delivery in Canada involves collaboration between physicians and the pharmaceutical and health supply industries in the areas of research, education, and clinical evaluation packages (e.g. product samples)
- physicians have a responsibility to ensure that their participation in such collaborative efforts is in keeping with their duties to their patients and society
- gifts or free products from the pharmaceutical industry are inappropriate
  - sponsorship for travel and fees for conference attendance may be accepted only where the physician is a conference presenter and not just in attendance
  - physicians receiving such sponsorship must disclose this at presentations or in written articles



### Guiding Principles for Research Ethics

- Respect for persons: informed consent
- Beneficence: harm vs. benefit
- Justice: avoid exploitation/unjustified exclusion



### Informed Consent for Research

- Inform about**
- Purpose of study
  - Sum of funding
  - Name and probability of harm and benefits
  - Nature of physician's participation including compensation
- Proposals for research must be submitted to a research ethics board.



### CMA and CPSO Guidelines for Ethically Appropriate Physician-Industry Relations:

- The primary goal should be the advancement of the health of Canadians
- Relationships should be guided by the *CMA Code of Ethics*
- The physician's primary obligation is to the patient
- Physicians should avoid any self-interest in their prescribing and referral practices
- Physicians should always maintain professional autonomy, independence, and commitment to the scientific method



The *AMA Code of Medical Ethics* has a number of opinions on "Practice Matters" including "Industry representatives in clinical settings," "Financial incentives and the practice of medicine," and "Gifts to physicians from industry," (see <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.shtml>).

## Physician Responsibilities Regarding Death

- physicians are required by law to complete a medical certificate of death unless the coroner needs notification; failure to report death is a criminal offence

## Role of the Coroner

- *Coroner's Act* (specific to Ontario, similar in other provinces) requires physicians to notify a coroner or police officer if death occurs:
  - due to violence, negligence, misconduct, misadventure, or malpractice
  - during pregnancy or is attributable to pregnancy
  - suddenly and unexpectedly
  - from disease which was not treated by a legally qualified medical practitioner
  - from any cause other than disease
  - under suspicious circumstances
- coroner investigates these deaths, as well as deaths that occur in psychiatric institutions, jails, foster homes, nursing homes, hospitals to which a person was transferred from a facility, institution or home, etc.
- in consultation with forensic pathologists and other specialists, the coroner establishes:
  - the identity of the deceased
  - where and when the death occurred
  - the medical cause of death
  - the means of death (i.e. natural, accidental, suicide, homicide or undetermined)
- coroners do not make decisions regarding criminality or legal responsibility

## Palliative and End-of-Life Care

- focus of care is comfort and respect for person nearing death and maximizing quality of life for patient, family, loved ones
- appropriate for any patient at any stage of a life-threatening illness
- may occur in a hospital, hospice, in the community or at home
- often an interdisciplinary team of caregivers
- addresses the medical, psychosocial, and spiritual dimensions of care

### Euthanasia and Physician-Assisted Suicide

- euthanasia: a deliberate act undertaken by one person with the intention of ending the life of another person to relieve that person's suffering where the act is the cause of death
- physician-assisted suicide: the act of intentionally killing oneself with the assistance of a physician who deliberately provides the knowledge and/or the means
- ethical issues and arguments:
  - right to make autonomous choices about the time and manner of own death
  - belief that there is no ethical difference between the acts of euthanasia/assisted suicide and foregoing life-sustaining treatments
  - belief that these acts benefit terminally ill patients by relieving suffering
  - patient autonomy has limits
  - death should be the consequence of the morally justified withdrawal of life-sustaining treatments only in cases where there is a fatal underlying condition, and it is the condition (not the withdrawal of treatment) that causes death
- the use of palliative sedation with opioids in end-of-life care, knowing that death may occur as an unintended consequence (principle of double effect) is distinguished from euthanasia and assisted suicide where death is the primary intent
- the appropriate withdrawal of life-support is distinguished from euthanasia and assisted suicide as it is seen as allowing the underlying disease to take its 'natural course'
- despite all this, refusals of care by the patient that may lead to death ought to be carefully explored by the physician to rule out any 'reversible factors' (poor palliation, depression, poverty, ill-education, isolation) that may be hindering authentic choice
- law
  - Canada: euthanasia and physician-assisted suicide are punishable offences under the Criminal Code of Canada
  - United States: euthanasia is punishable under general homicide laws; Oregon, Washington, and Montana are the only states to have enacted legislation allowing physicians to actively assist patients who wish to end their lives



#### Notify Coroner if Death Occurs due to:

- Violence, negligence, misconduct
- Pregnancy
- Sudden or unexpected causes
- Disease not treated
- Cause other than disease
- Suspicious circumstances



#### Know the Difference

Palliative care assists patients who are dying, but unlike euthanasia or physician-assisted suicide, it does not aim directly at or intend to end the person's life.



#### Euthanasia: Ethically Appropriate Actions

- Respect competent decisions to forgo treatment
- Provide appropriate palliative measures
- Decline requests for euthanasia and assisted suicide
- Try to assess reasons for such requests from patients to see if there are 'reversible factors' (such as depression, pain, loneliness, anxiety) that can be treated



## Reproductive and Sexual Health Law and Ethics

### Maternal-Fetal Relationship

- in general, maternal and fetal interests align
- in some situations a conflict between maternal autonomy and the best interests of the fetus may arise

### Ethical Issues and Arguments

- principle of reproductive freedom: women have the right to make their own reproductive choices
- coercion of a woman to accept efforts to promote fetal well-being is an unacceptable infringement of her personal autonomy

### Legal Issues and Arguments

- law: upholds a woman's right to life, liberty, and security of person and does not recognize fetal rights
  - if a woman is competent and refuses medical advice, her decision must be respected even if the fetus will suffer
  - the fetus does not have legal rights until it is born alive and with complete delivery from the body of the woman
- *Royal Commission on New Reproductive Technologies* recommendations:
  - medical treatment must never be imposed upon a competent pregnant woman against her wishes
  - no law should be used to confine a pregnant woman in the interest of her fetus
  - the conduct of a pregnant woman in relation to her fetus should not be criminalized
  - child welfare should never be used to control a woman's behaviour during pregnancy
  - civil liability should never be imposed upon a woman for harm done to her fetus during pregnancy
- examples of implications
  - a woman is permitted to refuse HIV testing during pregnancy, even if vertical transmission to fetus results
  - a woman is permitted to refuse Caesarean section in labour that is not progressing, despite evidence of fetal distress

### Advanced Reproductive Technologies (ART)

- includes non-coital insemination, hormonal ovarian stimulation, and in vitro fertilization (IVF)
- ethical issues and arguments
  - donor anonymity vs. child-centred reproduction (i.e. knowledge about genetic medical history)
  - preimplantation genetic testing for diagnosis before pregnancy
  - lack of sufficient data regarding efficacy and complications to provide the full disclosure needed for truly informed consent
  - use of new techniques without patients appreciating their experimental nature
  - embryo status – the Supreme Court of Canada maintains that fetuses are “unique” but not persons under law; this view would likely apply to embryos as well
  - access to ART
    - ♦ private vs. public funding
    - ♦ social factors limiting access to ART (e.g. same-sex couples)
  - against the ‘commercialization’ of reproduction; e.g. payment of gamete donors is currently illegal in Canada
  - however, no regulations as yet means the ART Act is not being enforced; caught in the legal web as to whether such regulations are a provincial or federal responsibility

### Fetal Tissue

- pluripotent stem cells have been derived from human embryonic and fetal tissue
- potential uses of stem cells in research:
  - studying human development and factors that direct cell specialization
  - evaluating drugs for efficacy and safety in human models
  - cell therapy: using stem cells grown *in vitro* to repair or replace degenerated/destroyed/malignant tissues (e.g. Parkinson's disease)
  - genetic treatment aimed at altering somatic cells (i.e. myocardial or immunological cells) is acceptable and ongoing
  - genetic treatment aimed at altering germ cells is prohibited in Canada and elsewhere
    - ♦ *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Government of Canada, 2010)
    - ♦ see TCPS 2 at: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
  - embryo research is permitted up to 14 d post-fertilization
  - embryos created for reproductive purposes that are no longer required may be used
  - gamete providers must give free and informed consent for research use
  - no commercial transactions in the creation and use of the embryos is permitted



The fetus does not have legal rights until it is born alive and with complete delivery from the body of the woman.



Once outside the mother's body, the neonate becomes a member of society with all the rights and protections other vulnerable persons receive.

- Non-treatment of a neonate born alive is only acceptable if <22 wk gestational age (GA)
- 23-25 wk GA: treatment should be a consensual decision between physician and parents
- 25 wk GA and more: neonate should receive full treatment unless major anomalies or conditions incompatible with life are present

Source: *Paed Child Health* 2012:443



### Advanced Reproductive Technologies: Ethically Appropriate Actions

- Educate patients and address contributors to infertility (e.g. stress, alcohol, medications, etc.)
- Investigate and treat underlying health problems causing infertility
- Wait at least 1 yr before initiating treatment with ART (exceptions – advanced age or specific indicators of infertility)
- Educate and prepare patients for potential negative outcomes of ART



Surrogate mothers cannot be paid or offered compensation beyond a reimbursement of their expenses.  
Source: Assisted Human Reproduction Act



No one under age 18 can donate sperm or eggs, except for the purpose of creating a child that the donor plans to raise themselves (example: young patients receiving radiation therapy for cancer that may cause infertility).

Source: *Semen Regulations of the Food and Drug Act*



The CMA remains neutral on the issue of embryonic stem cell research.



- creation of embryos solely for research purposes is prohibited
- human cloning is strictly prohibited
- risks of coercion must be minimized:
  - may not pressure fertility treatment team to generate more embryos than necessary
  - only discuss option of using fetal tissue for research after free and informed choice to have a therapeutic abortion has been made
  - physicians responsible for fertility treatment may not be part of a stem cell research team

### Induced Abortion

- CMA definition of induced abortion: the active termination of a pregnancy before fetal viability
  - fetal viability: fetus >500 g, or >20 wk gestational age
- CMA policy on induced abortion:
  - induced abortion should not be used as an alternative to contraception
  - counselling on contraception must be readily available
  - full and immediate counselling services must be provided in the event of unwanted pregnancy
  - there should be no delay in the provision of abortion services
  - no patient should be compelled to have a pregnancy terminated
  - physicians should not be compelled to participate in abortion – if morally opposed, the physician should inform the patient so she may consult another physician
  - no discrimination should be directed towards either physicians who do not perform or assist at induced abortions or physicians who do
  - induced abortion should be uniformly available to all women in Canada and health care insurance should cover all the costs (N.B. the upper limit of gestational age for which coverage is provided varies between provinces)
  - elective termination of pregnancy after fetal viability may be indicated under exceptional circumstances
- ethical and legal issues and arguments:
  - according to common law, the rights of a fetus are not equal to those of a human being
  - no law currently regulates abortion in Canada – it is a woman's medical decision to be made in consultation with whom she wishes; no mandatory role for spouse/family
  - 2nd and even 3rd trimester abortions are not illegal in Canada, but are usually only carried out when there are serious risks to the woman's health or if the fetus has died in utero or has major malformations (e.g. anencephaly)

### Prenatal/Antenatal Genetic Testing

- uses:
  - confirm a clinical diagnosis
  - detect genetic predisposition to a disease
    - ♦ allows preventative steps to be taken and helps patient prepare for the future
  - give parents the option to terminate a pregnancy or begin early treatment
- ethical dilemmas arise because of the nature of genetic information:
  - it has individual and familial implications
  - it pertains to future disease
  - it often identifies disorders for which there are no effective treatments or preventive steps
  - also can be used to identify the sex of the fetus leading to termination of pregnancy if the fetus is of the unwanted sex; this is considered inappropriate by some but is entirely legal as a woman can request an abortion for any reason
- ethical issues and arguments:
  - obtaining informed consent is difficult due to the complexity of genetic information
  - doctor's duty to maintain confidentiality vs. duty to warn family members
  - risk of social discrimination (e.g. insurance) and psychological harm
- law:
  - no current specific legislation exists
  - testing requires informed consent
  - no standard of care exists for clinical genetics but physicians are legally obligated to inform patients that prenatal testing exists and is available
  - breach of confidentiality – duty to warn family members
    - ♦ only acceptable if can likely prevent serious harm, such as if treatment or prevention is available (e.g. familial adenomatous polyposis)



#### Genetic Testing: Ethically Appropriate Actions

- Thorough discussion and realistic planning with patient before testing is done
- Genetic counselling for delivery of complex information, supportive discussion

## Organization of Health Care in Canada

- one federal, three territorial, and ten provincial systems
- federal system provides care to Aboriginal groups, the RCMP, and the armed forces
- financed by both the public (70%) and private (30%) sectors
- each provincial plan must cover all medically necessary health services delivered in hospitals and by physicians; may choose to cover services such as home care and prescription drugs
- non-insured health services and fees are either covered by private insurance or by the individual
- workers' compensation funds cover treatment for work-related injuries and diseases

## Legal Foundation

The legal foundation of the Canadian health system is based on two constitutional documents:

1. *Constitution Act* (1867): deals primarily with the jurisdictional power between federal and provincial governments
2. *The Canadian Charter of Rights and Freedoms* (1982): does not guarantee a right to health care but, given government's decision to finance health care, they are constitutionally obliged to do so consistently with the rights and freedoms outlined in the Charter (including the right to equality, physician's mobility rights, etc.)

And two statutes:

1. *Canada Health Act* (1984): outlines the national terms and conditions that provincial health systems must meet in order to receive federal transfer payments
2. *Canada Health and Social Transfer Act* (1996): federal government gives provinces a single grant for health care, social programs, and post-secondary education; division of resources at provinces' discretion

## History

- 1867 *British North America Act* (now *Constitution Act*) establishes Canada as a confederacy
- government has minimal role in health care at this time
  - "establishment, maintenance, and management of hospitals" under provincial jurisdiction
- 1947 Saskatchewan introduces universal hospital insurance
- based on taxes and premiums
  - other provinces follow
- 1957 Federal government passes *Hospital Insurance and Diagnostic Services Act*
- provinces with universal hospital insurance receives federal funds
  - federal government pays for approximately 50% of insured services
- 1962 Saskatchewan implements universal medical care insurance
- physician services included
- 1965 *Royal Commission on Health Services (Hall Commission)* recommends federal leadership and financial support with provincial government operation
- 1966 *Medical Care Act* passed by federal government
- federal government contribution maintained at 50% on average, with poorer provinces receiving more funds
  - medical insurance must be comprehensive, portable, universal, and publicly administered'
- 1977 *Established Programs Financing Act* passed by federal government
- federal government gives "tax points" to provinces by reducing federal taxes and allowing provinces to collect more
  - funding no longer tied to direct services → federal influence wanes
  - provinces bear greater costs and impose restrictions on physicians
  - physicians respond with "extra-billing"; patients pay a supplementary fee
- 1984 *Canada Health Act* passed by federal government
- replaced *Medical Care Act* and *Hospital Insurance and Diagnostic Services Act*
  - extra-billing banned by new fifth criterion: Accessibility
- 1996 *Canada Health and Social Transfer Act* passed by federal government
- federal government gives provinces a single grant for health care, social programs, and post-secondary education; division of resources at provinces' discretion
- 1999 *Social Union Framework Agreement* signed by the Prime Minister and all Premiers and territorial leaders except Quebec
- federal and provincial/territorial governments vow to concentrate their efforts to modernize Canadian social policy
- 2001 *Kirby and Romanow Commissions* appointed
- Kirby Commission* (final report, October 2002)
- one-member committee of the Senate: examined history of health care system in Canada, pressures and constraints of current health care system, role of federal government, and health care systems in foreign jurisdictions
- Romanow Commission* (final report, November 2002)
- one-member royal commission (former Saskatchewan Premier Roy Romanow) appointed by the Prime Minister to inquire into and undertake dialogue with Canadians on the future of Canada's public health care system

- 2003 *First Ministers' Accord on Health Care Renewal* signed
- First Ministers agreed on an action plan to improve access to quality care for all Canadians and to prepare an annual public report on primary and home care
  - First Health Council (composed of government and expert/public representatives) appointed to improve accountability in the health care system
- 2004 *First Ministers' Meeting on the Future of Health Care* produces a 10-yr plan
- priorities include reductions in waiting times, development of a national pharmacare plan, and primary care reform
- 2005 *Chaoulli v. Quebec*, Supreme Court of Canada Decision
- ruled that Quebec's banning of private insurance would be unconstitutional under the Quebec Charter of Rights, given that patients do not have access to those services under the public system in a timely way
  - Quebec government was given one year to respond
- 2011 First progress report by the Health Council reviews progress towards 2004 First Ministers' 10 yr plan
- significant reductions in wait times for specific areas (such as cancer, joint replacement and sight restoration) while these reductions may have inadvertently caused increases in wait times of other services
  - despite large investments into electronic medical records (EMRs), Canada continues to have very low uptake, ranking last in the Commonwealth Fund International Health Policy survey, with use of only 37% use by primary care physicians
  - little progress in creating a national strategy for equitable access to pharmaceuticals; however, there has been some success in increasing pharmacists' scope of practice, reducing generic drugs costs and implementing drug info systems
- Federal Government announces that it will not renew 2004 *First Ministers' Accord on Health Care Renewal*
- increases in funding to provinces at 6% per annum until the 2016-2017 fiscal year, from then onwards, increases tied to nominal GDP at a minimum of 3% per annum
- 2012 Second progress report by the Health Council reviews progress towards 2004 First Ministers' 10 yr plan
- funding is sufficient; however, more innovation is needed including incentivizing through models of remuneration
  - 46 recommendations were made to address the lack of progress in prevention, access to primary-care physicians, long-term, respite and palliative care services, wait-time benchmarks, accountability, IT, Aboriginal health and more
- 2013 Federal Government announces that it will stop funding the Health Council of Canada in 2014
- the council (born in 2004) will close in 2014 leaving no other independent national body to assess the performance of the Canadian health care system
- 2014 Expiry of current *10 Year Health Care Funding Agreement* between Federal and Provincial governments

## Key Principles of the *Canada Health Act*

1. Public Administration
  - provincial health insurance programs must be administered by public authorities
2. Comprehensiveness
  - provincial health insurance programs must cover all necessary diagnostic, physician, and hospital services
3. Universality
  - all eligible residents must be entitled to health care services
4. Portability
  - emergency health services must be available to Canadians who are outside their home province, paid for by the home province
5. Accessibility
  - user fees, charges, or other obstructions to insured health care services are not permitted



The federal government can reduce its contributions to provinces that violate the key principles of the *Canada Health Act*.



### Principles of Canada Health Act

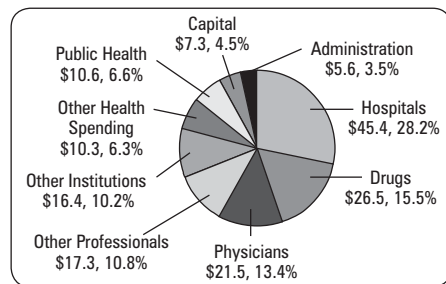
- Public Administration
- Comprehensiveness
- Universality
- Portability
- Accessibility

## Health Care Expenditure and Delivery in Canada

- projected total health care expenditure in 2009 was \$182.1 billion, 11.9% of the GDP, approx. \$4,363 USD per capita (*Canadian Institute of Health Information*)
- 2009 Canadian health care expenditure as a percentage of GDP ranked 6 out of 29 for Organization for Economic Cooperation and Development (OECD) member nations (*Canadian Institute of Health Information*)
- 70.9% of health care spending came from public sector sources in 2009 as compared to 47.7% in the US
- in 2006 there were 2.1 physicians per 1000 population, ranking 26th out of OECD member countries

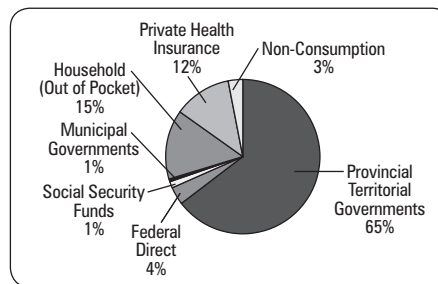
### Delivery of Health Care

- hospital services in Canada are publicly funded but delivered through private, not-for-profit institutions owned and operated by communities, religious organizations, and regional health authorities
- this differs from other countries, such as the US (a mix of public and private funding, as well as private-for-profit and private not-for-profit delivery) and the UK (primarily public funding and delivery)



**Figure 2. Health expenditure in Canada by use of funds (billions of dollars), 2009**

Source: Canadian Institute for Health Information. National Health Expenditure Trends. 1975 to 2011



**Figure 3. Canadian health care dollars by source of funds, 2007**

Source: Canadian Institute for Health Information. National Health Expenditure Trends. 1975 to 2009

## Ethical Considerations in Resource Allocation and Physicians' Role

- the distribution of goods and services to programs and people
- physicians have the duty to inform patients about therapeutic options even if they are not available
- consider justice: physicians must make health care resources available to patients in a manner which is fair and equitable, without bias or discrimination
  - need and benefit are morally relevant criteria for resource allocation
  - gender, sexual orientation, religion, level of education or age alone are morally irrelevant criteria
- ethical dilemmas that arise when deciding how best to allocate resources
  - fair chances versus best outcome: favouring best outcome vs. giving all patients fair access to limited resources (e.g. transplant list prioritization)
  - priorities problem: how much priority should the sickest patients receive?
  - aggregation problem: modest benefits to many vs. significant benefits to few
  - democracy problem: when to rely on a fair democratic process to arrive at a decision
- guidelines for appropriately allocating resources
  - the physician's primary obligation is to protect and promote the welfare and best interests of his or her patients
  - choose interventions known to be beneficial on the basis of evidence of effectiveness
  - seek the tests or treatments that will accomplish the diagnostic or therapeutic goal for the least cost
  - advocate for one's patients but avoid manipulating the system to gain unfair advantage for them
  - resolve conflicting claims for scarce resources justly, on the basis of morally relevant criteria such as need and benefit, using fair and publicly defensible procedures
  - inform patients of the impact of cost constraints on care, but in a sensitive way
  - seek resolution of unacceptable shortages at the level of hospital management or government



### Payments for Care at Private For-Profit and Private Not-for-Profit Hospitals: A Systematic Review and Meta-analysis

*CMAJ* 2004;170:1817-1824

Meta-analysis of 8 US observational studies involving more than 350 000 patients. Concluded that care provided by private for-profit hospitals was more expensive (Relative payments for care=1.19; 95% CI=1.07-1.33; p=0.001). If half of Canadian hospitals were converted to private for-profit institutions, an extra \$3.6 billion would be paid annually.



### CPSO Policy on Resource Allocation

Physicians should "recognize [their] responsibility to promote fair access to health care resources" and should "use health care resources prudently."

## Role of the Provincial Licensing Authorities

- the medical profession in Canada self-regulates under the authority of provincial legislation;
- physicians in each province are self-regulated by a licensing authority (e.g. College of Physicians and Surgeons of Ontario, the CPSO); membership is mandatory to practice in that province
- self-regulation is based on the premise that the licensing authority must act first and foremost in the interest of the public
- licensing authority functions include:
  - provincial licensing authorities provide non-transferable licensure to physicians
  - issuing non-transferable licenses allow doctors to practice only in that province
  - maintaining ethical, legal, and competency standards and developing policies to guide doctors
  - investigating complaints against doctors
  - disciplining doctors guilty of professional misconduct or incompetence
  - at times of license investiture and renewal, physicians must disclose if they have a condition (such as HIV positivity or drug addiction or other illness that may impact their ability to practice safely)
- in an evolving area of responsibility, physicians may be required to report colleagues who may be a hazard to patients (e.g. the inebriated colleague)

## Licensure and Certification

- the Medical Council of Canada (MCC) certifies physicians
  - certification is known as the Licentiate of the MCC (LMCC)
  - LMCC is acquired by passing the MCC Qualifying Examination Parts I and II
- the Royal College of Physicians and Surgeons of Canada (RCPSC) certifies specialists who complete an accredited residency program and pass the appropriate exam
  - voluntary membership of RCPSC is designated FRCPC or FRCSC (Fellow of the Royal College of Physicians/Surgeons of Canada)
- the College of Family Physicians of Canada (CFPC) certifies family physicians who complete an accredited residency program and pass the Certification Examination in Family Medicine
- the RCPSC and CFPC are responsible for monitoring ongoing continuing medical education (CME) and professional development



Certification by the LMCC plus either the RCPSC or CFPC is a minimum requirement for licensure by most provincial licensing authorities.

## Role of Professional Associations

- membership in a provincial or national association is voluntary
- provincial medical associations represent the economic and professional interests of doctors
- the Canadian Medical Association (CMA) is a national association that provides leadership to doctors and advocates for access to high quality health care in Canada
- the CMA represents physician and population concerns at the national level, while the provincial medical associations negotiate fee and benefit schedules with provincial governments
- medical residents are represented nationally by the Canadian Association of Interns and Residents, and provincially by Provincial Housestaff Organizations, which uphold the economic and professional interests of residents
- medical students are represented at their universities by student societies; these bodies collectively form the Canadian Federation of Medical Students; francophone medical schools participate in the Federation of Quebec Medical Student Societies
- the Canadian Medical Protective Association (CMPA), a physician-run organization, is a voluntary insurance association that protects the integrity of member physicians by providing legal defense against allegations of malpractice or negligence and by providing risk management and educational programs, and general advice

## The US Health Care System

- the United States health care system is more market-based than the Canadian system
- it is funded and delivered by a mixture of the public, private, and voluntary sectors; private-for-profit is the prevailing method of delivery
- public funding is derived from taxes raised at both the federal and state government levels

## History

- 1850 Franklin Health Insurance Company of Massachusetts
- offers accident insurance to cover injuries acquired during railroad or steamboat travel
  - informal “sickness insurance” evolved from this to cover different injuries or diseases
- 1901 American Medical Association established as the national organization of state and local medical groups
- 1929 Baylor Plan developed
- created by Dr. Justin Ford Kimball to ensure that teachers could pay their medical bills
  - teachers pay 50 cents/month in exchange for guarantee of medical services for 21 d
- 1930s More hospitals adopt medical insurance plans as per the Baylor Plan
- emergence of private, commercial, health insurance as a service of life insurance companies
- 1939 Community hospitals work together to create health care plans
- American Hospital Association (AHA) uses the term “Blue Cross” to describe health care plans that meet their standards
  - emergence of prepaid plans covering physician and surgeon services
- 1940s and 1950s
- employee benefit plans increase in number with more comprehensive health care insurance packages
  - companies compete for employees using the proposed health care plan
  - reason why workplace is currently main source of health care insurance
- 1946 Blue Shield created and represents physician sponsored health care plans
- 1954 Social Security coverage begins to include disability benefits
- 1960 Blue Cross becomes the official designation for AHA health care plans
- 1965 Medicare and Medicaid programs introduced government funded health care plans
- 1971 Blue Cross and Blue Shield merge into one company
- 1970s and 1980s
- emergence of Health Maintenance Organizations (HMOs)
  - HMOs offer managed care plans: health care packages that are provided by an HMO approved network of health care providers
- 1993 Universal health care system proposed but rejected by congress
- 1996 *Mental Health Parity Act* passed
- invoked to decrease discrimination in health care coverage for mental health illnesses
  - aggregate annual and lifetime limits for mental health services must match aggregate annual and lifetime limits for medical and surgical services
- 1996 *Health Insurance Portability and Accountability Act* passed
- Title 1: Health Care Access, Portability, and Renewability
    - provides protection of health care coverage to employees and their families if they change or lose their job
  - Title 2: Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform
    - addresses and establishes national standards for electronic health care transactions and security and privacy of health data
- 1997 State Children’s Health Insurance Program (SCHIP) created
- states extend health coverage to uninsured children
- 1999 *Ticket to Work and Work Incentives Improvement Act*
- enables people with disabilities to be employed without affecting their Medicaid or Medicare coverage
- 2010 *Affordable Care Act*
- reform to health care to improve access to affordable health coverage and creates regulations on activities of private health insurance providers



## Health Care Expenditure and Delivery in the US

- health care spending in the US represents a large economic sector
  - health care comprises over 17.4% of the gross domestic product (GDP) (highest in the OECD), amounting to \$7960 USD per capita in 2009
  - one advantage is the widespread availability of technology – the US has 4 times as many MRI machines per capita than Canada
- the US scores poorly on some indicators of population health, with a life expectancy below the OECD average and infant mortality above the OECD average. Possible factors that account for this discrepancy are:
  - poor health of large uninsured population
  - high cost of health care administration
  - the provision of inefficient high-cost, high-intensity care
    - ♦ the higher-spending regions in the US do not provide any better quality of care, access to care, health outcomes or satisfaction with care when compared to the lower-spending regions
- the US has the highest level of obesity of all OECD nations at 34.3%; this has major implications for future health care spending



### Cost of Health Care Administration in the United States and Canada

*NEJM* 2003;349:768-775

Administrative costs were estimated from data on insurance overhead, employers' costs to manage benefits, and the administrative costs of hospitals, practitioners' offices, nursing homes, and home care. In 1999, the cost of U.S. health administration was \$1,059 per capita, more than three times greater than the cost in Canada (\$307 per capita).

## Access to Health Services

- 70% of Americans under the age of 65 have private health insurance, either employer-sponsored or individually purchased; 12% receive health care through public health insurance; 18%, mainly the poor, have no health insurance
- access to publicly funded health services occurs primarily through two programs, Medicare and Medicaid, which were created by the 1965 *Social Security Act*
- other federal government-funded health programs include the Military Health Services System, the Veterans Affairs Health Services System, the Indian Health Service, and the Prison Health Service

**Table 4. Medicare and Medicaid Program Information**

	Medicare	Medicaid
<b>Eligibility</b>	People over the age of 65 People with end stage renal disease People of any age meeting the Medicare definition of disability	People who receive funds through social assistance programs Pregnant women People with developmental disabilities Low-income children through the 1997 State Children's Health Insurance Program
<b>Coverage</b>	Basic "Part A" providing inpatient hospital care, home care, limited skilled nursing facility care, and hospice care Supplemental "Part B" covers outpatient physician and clinic services, and requires payment of a further monthly fee	Basic coverage involves inpatient and outpatient hospital care, laboratory and x-ray services, skilled nursing care, home care, physician services, dental services, and family planning Financing for Medicaid is provided jointly by the federal and state governments, and program details vary greatly between states
<b>Co-payment</b>	To help pay for out-of-pocket expenditures, and to cover many of the services not insured by Medicare, the majority of Medicare beneficiaries buy supplemental private health insurance	States may impose deductibles, coinsurance, or co-payments on some Medicaid recipients for certain services Medicaid is not health insurance – coverage is unreliable as improvement in an individual's financial status can lead to a loss of Medicaid eligibility

Source: Centers for Medicare and Medicaid Services. <http://www.cms.gov>

## Health Care Reform

- *Patient Protection and Affordable Care Act* and the *Health Care and Education Reconciliation Act of 2010* are federal statutes signed into law in March 2010 that include a number of new health care provisions to be implemented over 8 yr
  - expand Medicaid eligibility, provide subsidies for insurance premiums and incentives for businesses to provide health care benefits, prohibit denial of coverage/claims for pre-existing conditions, and establish health-insurance exchanges
  - costs are offset by a number of health care related taxes, including a tax penalty for citizens with no health insurance (low income persons are exempt)

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