Public Health Law 101

A CDC Foundational Course for Public Health Practitioners

Public Health Law Program

http://www.cdc.gov/phlp

PUBLIC HEALTH LAW 101
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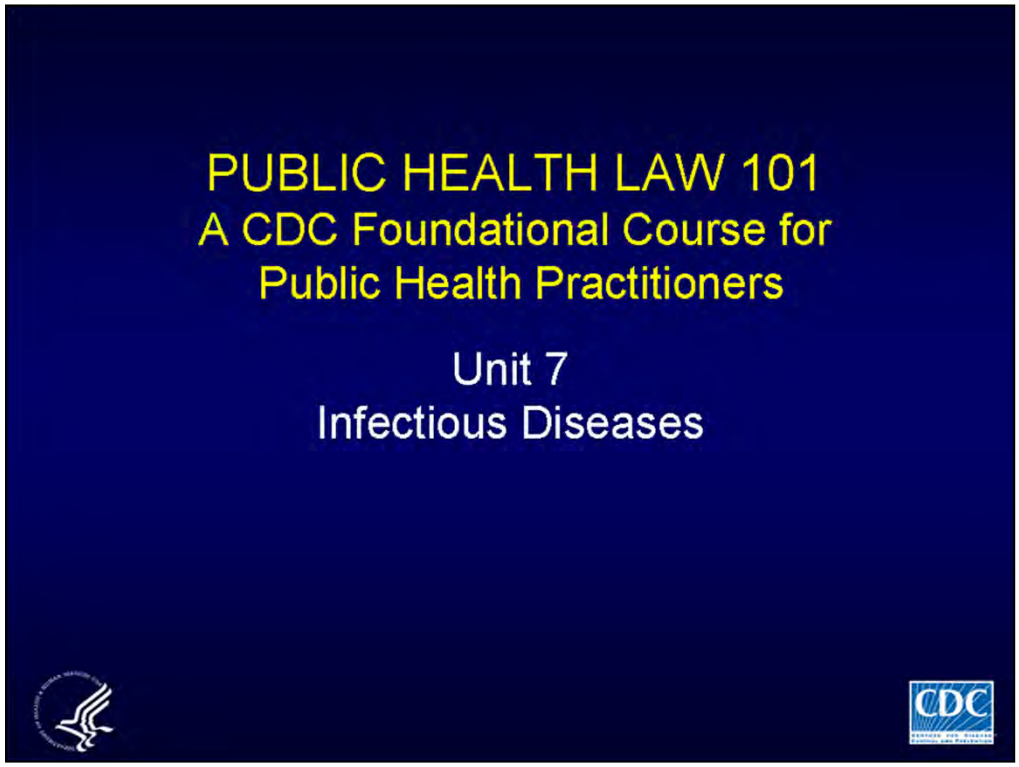
- Unit 1: Key Concepts of U.S. Law in Public Health Practice
- Unit 2: Ethics and the Law
- Unit 3: Administrative Law
- Unit 4: Role of the Legal Counsel
- Unit 5: Law of Public Health Surveillance, Investigations, and Emergencies
- Unit 6: Privacy and Confidentiality
- Unit 7: Infectious Diseases
- Unit 8: Environmental Public Health, Occupational Health, and Injury
- Unit 9: Chronic Diseases and Birth Defects


PUBLIC HEALTH LAW 101
A CDC Foundational Course for
Public Health Practitioners
Unit 7
Infectious Diseases
CDC

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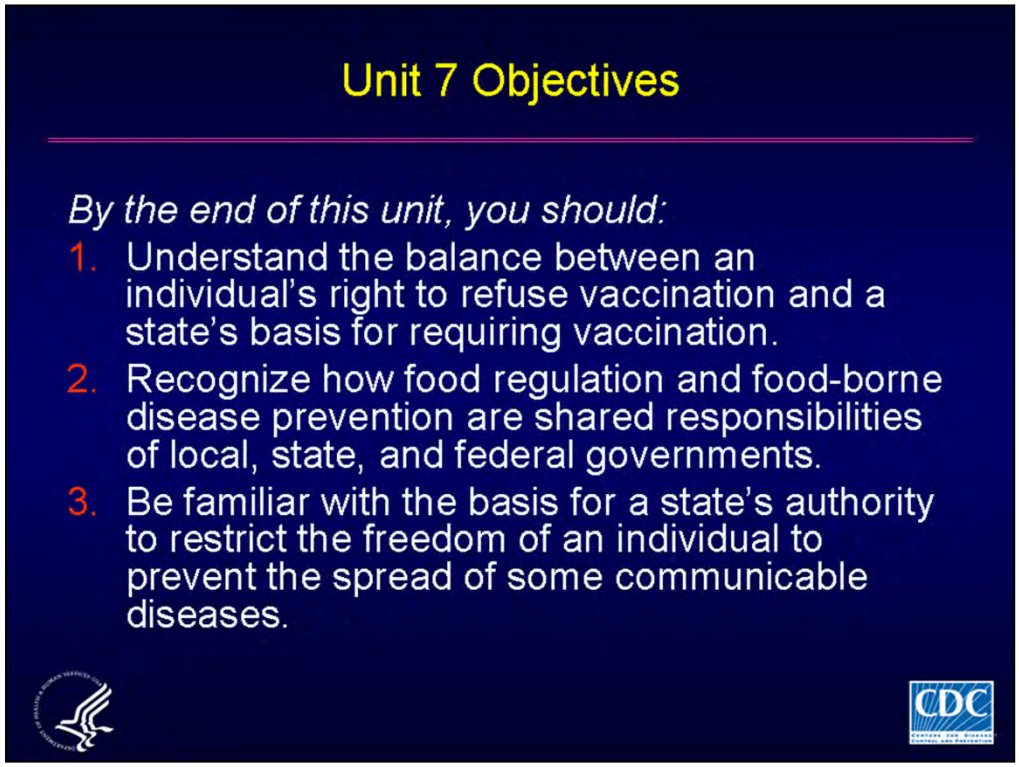
Infectious Diseases: Public Health Law Issues

- As a public health official, what can you do under the law …
  - … if a group of parents refuses to have their elementary school children vaccinated because of fears of unsubstantiated severe side-effects?
  - … if cases of listeriosis are diagnosed in emergency rooms in four cities around your state?
  - … if a TB patient, after 5 days of treatment, leaves the hospital in your jurisdiction and disappears?



•Instructor: this is an essential slide, as the objectives frame the order of content included in this unit.

Federalism and Allocation of Public Health Powers

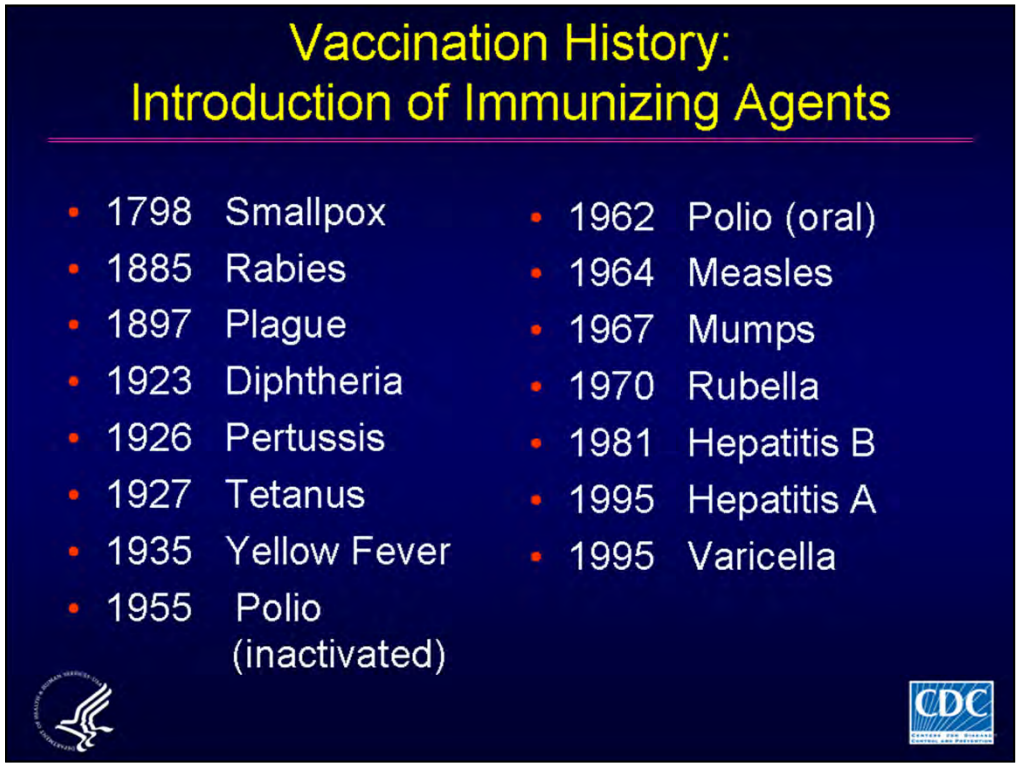
- The Constitution divides powers between the states and the federal government
- Federal Powers in public health
  - Interstate commerce
  - Foreign trade and travel
  - National security
- State Powers
  - All powers not given to the federal government
  - "Police powers" – Powers exercised by the states to enact legislation and promulgate regulations to protect public health, welfare, and morals, and to promote the common good

Federalism and Disease Control Authority

- State and local governments carry out most communicable disease control under the police power
- Federal government provides lead role in controlling diseases related to goods in interstate commerce, such as food
- Federal and state governments cooperate when:
  - Communicable disease threats cross state lines
  - Federal and state authority overlap, as in food safety

Objective 7.1

Understand the balance between an individual's right to refuse vaccination and a state's basis for requiring vaccination.


Vaccination History:
Introduction of Immunizing Agents
1798 Smallpox
1885 Rabies
1897 Plague
1923 Diphtheria
1926 Pertussis
1927 Tetanus
1935 Yellow Fever
1955 Polio (inactivated)
1962 Polio (oral)
1964 Measles
1967 Mumps
1970 Rubella
1981 Hepatitis B
1995 Hepatitis A
1995 Varicella
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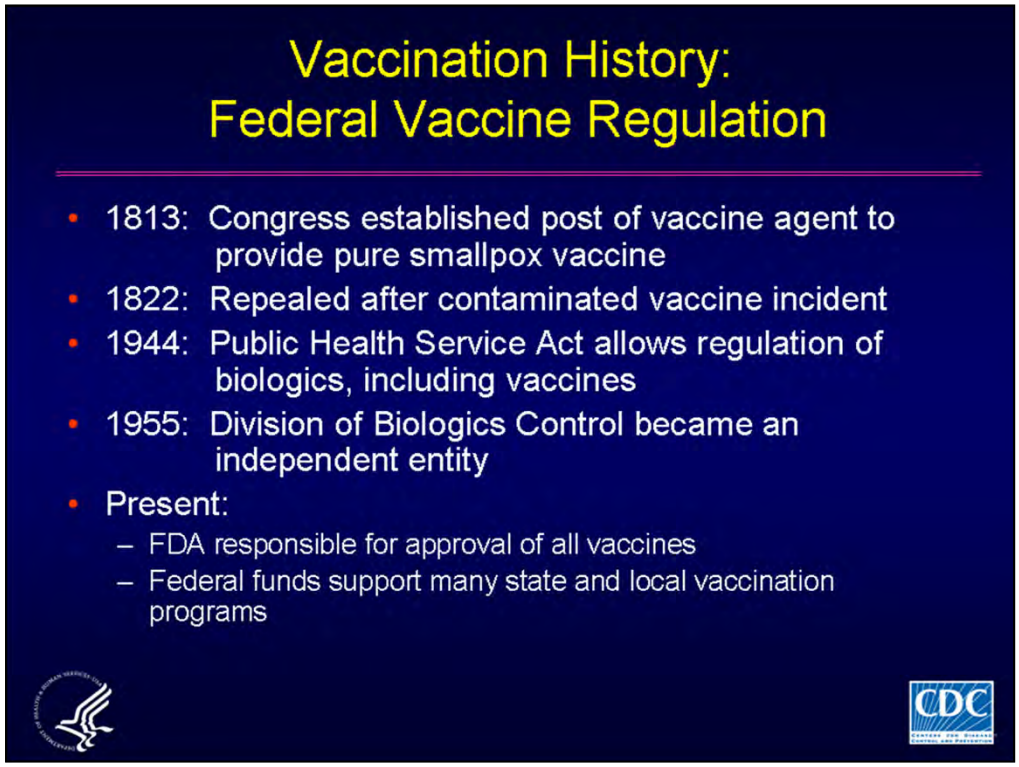


Federal Vaccination Laws

Milestones in U.S. Food and Drug Law History
http://www.fda.gov/opacom/backgrounders/miles.html

Vaccination History: State Vaccination Laws

- States began requiring smallpox vaccinations in the 1800s
- These laws were upheld in an opinion written by Justice Harlan in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)
- The Supreme Court held that submitting to public health measures is a duty of those living in society

Justice Harlan

The Legal-Scientific Basis for Mandatory Vaccination Laws

- Herd Immunity
  - A primary purpose of mandatory vaccination laws is to slow or prevent spread of disease in the community
  - The proportion of vaccinated persons is inversely related to the likelihood that an infected person will transmit disease
  - Vaccines that do not provide complete protection for individuals can still reduce the spread of disease in the community
- It is community (not individual) protection that justifies mandatory vaccinations

Contemporary Vaccination Laws

- Most vaccine laws are state and local laws
  - With few exceptions, there are no federal vaccination requirement laws
    - Exceptions include: foreign travel restrictions and OSHA laboratory worker requirements
  - Federal guidelines encourage vaccination
- Target populations
  - Children
  - Special populations and settings

Childhood Immunization Laws

- Enforcement is through school exclusion
  - Children must be vaccinated to attend school
  - Requirements monitored and enforced by schools
- Many states have extended these requirements to related settings
  - Private pre-school and day-care settings
  - Colleges
  - Home schools

Example of School Vaccination Requirements: New York Education Law Sec. 914

- Effect of this law:
  - Each school must require of every child entering or attending proof of immunization against poliomyelitis, mumps, measles, diphtheria, rubella and varicella.

Requirements for Special Populations: Adult Health-Care Workers

Code of Massachusetts Regulations, Title 105, Chapter 130.00 (Hospital Licensure)

- "(F) Personnel assigned to maternal and newborn areas shall have:
  - (1) Demonstrated immunity to rubella either via rubella titer or physician-documented rubella vaccine received on or after 12 months of age.
  - (2) Demonstrated immunity to measles (rubeola) either via measles titer, physician-diagnosed disease or physician-documented live measles vaccine received on or after 12 months of age."

Federal Role in Vaccine Guidelines

- CDC-sponsored Advisory Committee on Immunization Practices (ACIP) develops recommendations for vaccinations
  - States typically consider these recommendations in their decisions about vaccination mandates
  - Recommendations may be incorporated into administrative regulations
  - Private employers and health care providers also rely on these recommendations

Medical Exemptions

- Contraindications to vaccinations
  - Persons with immunocompromised conditions may be at risk for serious complications from live virus vaccines
  - Persons with hypersensitivity to certain vaccine components
- All states allow medical exemptions
  - Generally must be certified by a physician
  - Some states have tried to limit improper physician certifications through actions such as allowing hearings

Constitutional Issues and Vaccination: Religious Exemptions

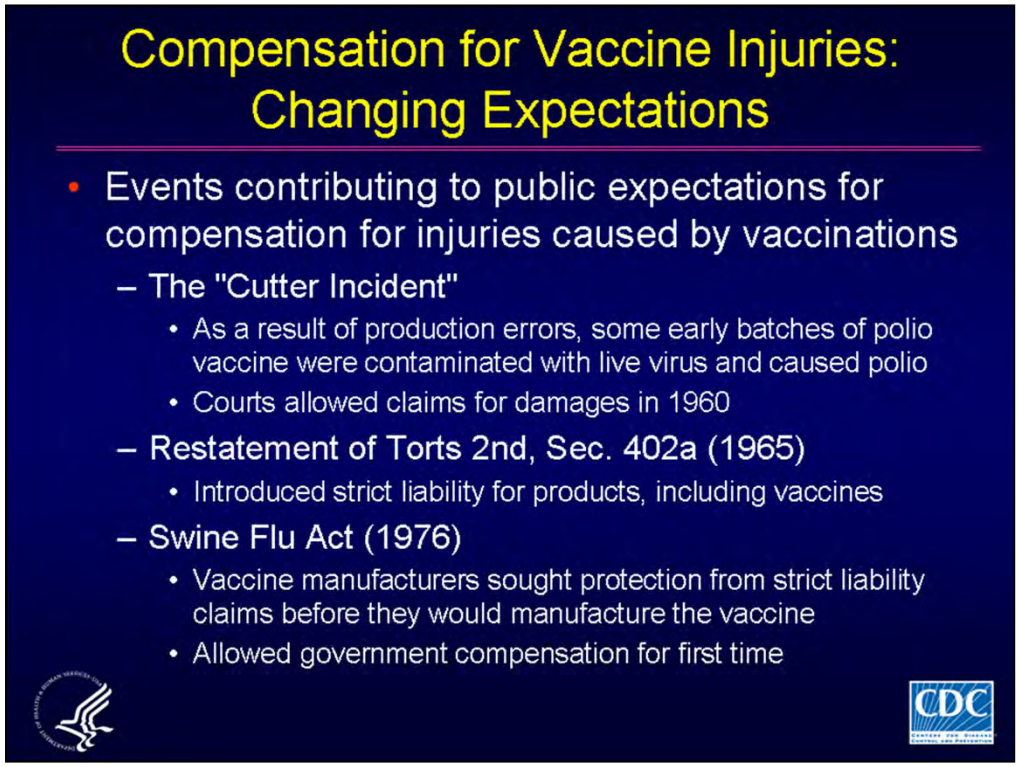
- Exemptions to vaccination requirements based on religious grounds are not required by the U.S. Constitution
- Constitutional Issues
  - States cannot choose which religions qualify
  - State laws that only allowed exemptions for organized and recognized churches have been held unconstitutional
  - Many states now allow exemptions for both philosophical and religious reasons

Impact of Vaccination Exemptions

- Reduces herd immunity
  - Increases spread of disease within community
  - Increases risk to individuals with medical contraindications to vaccination
- Issue:
  - Some states allow suspension of exemptions during an emergency to allow for faster mass immunizations
  - Should exemptions apply in emergencies (e.g., during a smallpox outbreak)?

Compensation for Vaccine Injuries: History

- Smallpox vaccine was the first effective human vaccine
  - Historically, the vaccine was often contaminated and dangerous
  - The Supreme Court recognized this risk in *Jacobson v. Massachusetts*
- Risks of smallpox vaccination were considered part of life and there was no compensation for injuries



•Polio - Gottsdanker v. Cutter Laboratories, 182 Cal.App.2d 602, 6 Cal.Rptr. 320, 79 A.L.R.2d 290 (Cal.App. 1 Dist. Jul 12, 1960) (http://biotech.law.lsu.edu/cases/vaccines/gottsdanker.htm)

•Swine Flu - *Unthank v. United States*, 732 F.2d 1517 (10th Cir. 1984) (http://biotech.law.lsu.edu/cases/vaccines/Unthank.htm)

•The National Influenza Immunization Program of 1976 (commonly called the "Swine Flu Act"), Pub. L. No. 94-380,. 90 Stat. 1113 (codified at 42 U.S.C. § 247(b) (1976) (repealed 1978)

•The Swine Flu Affair: Decision-Making on a Slippery Disease, Richard E. Neustadt and Harvey V Fineberg, DHEW, 1978 (http://biotech.law.lsu.edu/cphl/history/books/sw/index.htm)

Compensation for Vaccine Injuries: National Childhood Vaccine Injury Act

- By 1980s, vaccination litigation claims were driving manufacturers from the market
- National Childhood Vaccine Injury Act of 1986
  - Established National Vaccine Injury Compensation Program (VICP)
  - Provides no-fault, government compensation for injuries associated with routinely administered childhood vaccines
  - Shifts monetary costs of vaccine injuries away from vaccine recipients and manufacturers
  - Specifies compensation process and gives HHS Secretary discretion to revise list of compensable injuries

Issues in Vaccine Compensation and Emergency Preparedness

- Smallpox vaccination campaign of 2002
  - Targeted health care workers and first responders
  - Some people indicated that absence of an injury compensation program affected their decision not to participate
- There are no provisions for compensating adults who are vaccinated during public health emergencies
  - Claims against manufacturers have been limited by new laws
  - Will this affect public participation?
  - What is government's role in providing compensation?

Objective 7.2

Recognize how food regulation and food-borne disease prevention are shared responsibilities of local, state, and federal governments.

The International Food Network

- Where does your food come from?
  - Eggs from a local farm
  - Beef from the Midwest
  - Shrimp from Louisiana
  - Apples from New Zealand
  - Raspberries from Central America
  - Grapes from Chile
  - Fish from Vietnam
- Ensuring safety of the food supply involves local, state, and federal agencies


Federal Authority to Regulate Food Safety
• Domestic food supply
– Interstate commerce clause
– National security powers for bioterrorist threats to food
• International food imports
– Federal government has exclusive authority over international trade
– Federal government may enter into treaties with other counties over trade
CDC

Federal Enforcement Agencies: Agriculture

- U.S. Department of Agriculture (USDA) is a dual role agency:
  - Helps farmers produce and sell more food
  - Has primary role in assuring that food is produced and processed safely
- USDA inspectors work with food processing facilities, including direct oversight of meat packing and enforcement of standards
- USDA plays important role in protecting food supply from plant and animal disease outbreaks

Federal Enforcement Agencies: FDA

- FDA regulates type and amount of drugs used in farm / food animal production
- FDA regulates food labeling
  - Nutritional content
  - Safe handling information (e.g., cooking eggs)
  - Deceptive labeling (as to content or health value)
- FDA regulates food additives and ingredients

Federal Non-enforcement Agency: CDC

- Activities
  - Publishes guidelines and best practices for food sanitation and food-borne illness prevention
  - Provides epidemiologic assistance to states during large or novel outbreaks

State Authority to Regulate Food Safety

- The Police Powers
  - Broad powers
  - Allow the state to license, inspect, and close businesses that do not meet the food sanitation codes
- Limitations
  - May not conflict with federal laws
  - May not be used as a barrier to interstate commerce by favoring local businesses over out-of-state businesses

State Agencies

- State and local health departments
  - Establish food safety standards through regulations
  - Conduct restaurant inspections
  - License local food processors
- State agriculture departments
  - Regulate grocery stores in some states
  - Regulate food production

Routine Inspections

- Cornerstone of food safety is routine inspection of businesses involved in producing, shipping, and serving of food
- Federal, state, and local agencies issue licenses and permits to regulated businesses that require:
  - Compliance with applicable regulations as a condition of operation
  - Allow warrantless, surprise inspections during regular business hours
- Businesses that do not comply can be closed

Surveillance for Food-borne Outbreaks

- State and local laws require reporting of potential food-borne illnesses
  - Starting point for investigations
  - Reporting sources: physicians, emergency rooms, laboratories
- Voluntary reporting
  - Persons not required to report an illness may make a voluntary report
  - Individuals may report their own illness

Issue:
Overlapping Authority and Jurisdiction

- Federal Jurisdiction and Authority
  - Federal government has not preempted state and local regulation in many areas of food safety
  - Federal government depends on state and local regulation in some areas of food safety (e.g., restaurant inspections)
- State governments cannot act across state lines
- Local governments cannot act outside their jurisdiction

Federal, State, and Local Cooperation

- Multi-jurisdictional outbreaks
  - Food-borne outbreaks can involve more than one locality or even several states
  - State and local officials will work together and with federal agencies to assure cooperation
- Overlapping authority
  - FDA may regulate food processing in a factory, and may generally inspect without a warrant or consent

Legal Actions to Protect the Public

- Emergency closure orders for suspected businesses
- Halting local and interstate shipments of the affected food
- Barring imports of suspect food
- Seizure of potentially contaminated inventory
- Recall of packaged food
- National consumer warnings

Special Regulatory Issues

- Exemptions from the permitting process
  - Some states exempt non-profit groups such as churches
  - Large family gatherings do not need permits
- Investigation of exempt businesses and individuals
  - No right of warrantless entry and search

Punishment and Compensation

- Administrative actions
  - Fines
  - Quality control requirements
- Lawsuits in tort
  - Private lawsuits for damages
  - Public health inspectors may be called to testify
  - Public health records and laboratory information may be used for evidence
- Criminal prosecution
  - Rarely used, usually for repeat offenders
  - Corporate executives may be held liable

Objective 7.3

Be familiar with the basis for a state's authority to restrict the freedom of an individual to prevent the spread of some communicable diseases.

Communicable Disease Control: Example of Tuberculosis (TB)

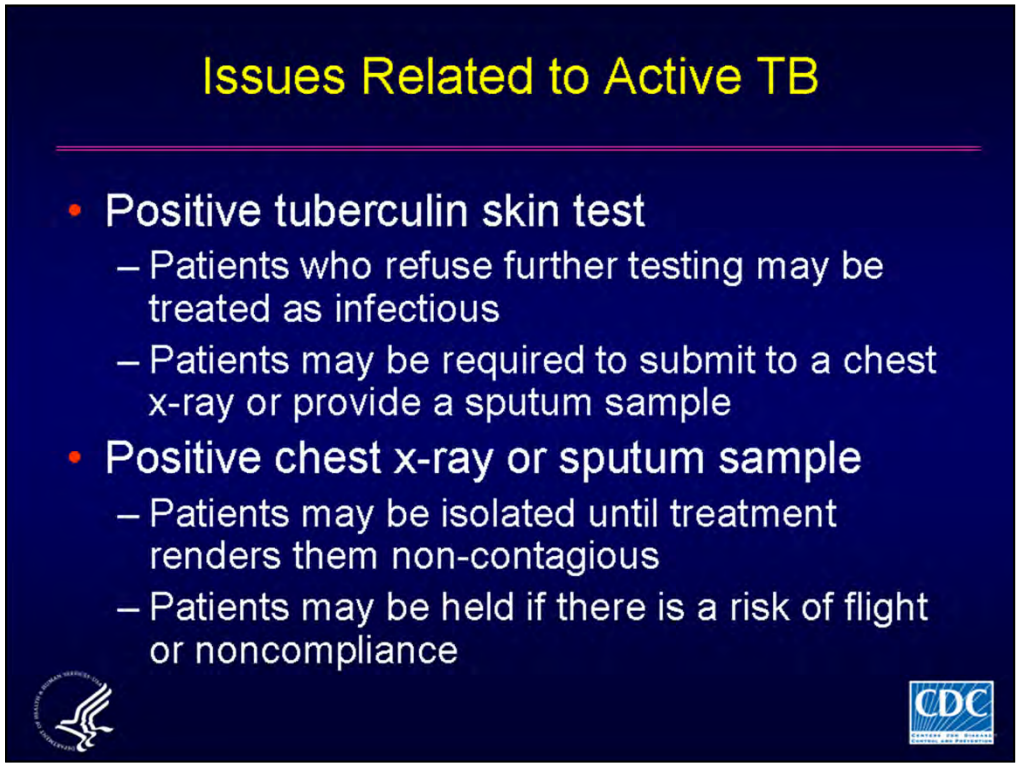
- Why TB is a good model for exploring legal issues in communicable disease control:
  - A well-understood disease that still poses risks in the U.S.
  - A serious and potentially fatal disease spread by person-to-person contact
  - Control is through individual restrictions and treatment, rather than vaccination
    - Control sometimes requires use of isolation
  - Provides a useful model for some other non-vaccine preventable diseases, such as SARS
  - Most TB control law is state-level law with considerable variation in legal regimens by state

Legal Issues in TB Control

- Who can the health department screen?
  - Is screening voluntary?
  - What if someone refuses?
- Refusing treatment
  - Can a patient be detained to compel compliance?
  - Can a patient be physically compelled to accept medication?
- Isolation
  - What are the patient's rights?
  - Can patients be isolated indefinitely if they remain contagious?

TB Testing and Screening Issues

- Routine TB Screening
  - Once conducted at population level
  - Now limited to persons at risk, such as:
    - Persons in contact with others sick with TB
    - Health care workers
    - Refugees and other immigrants
- What if someone refuses screening?
  - Potentially infectious workers can be excluded from employment
  - Persons can be required to submit to screening
  - Involuntary screening *generally* requires a court order



Active (Infectious) TB Cases

Mandatory public health testing does not violate freedom of religion - Washington v. Armstrong, 39 Wash. 2d 860, 239 P.2d 545 (Wa. 1952)

http://biotech.law.lsu.edu/cases/reporting/wa-armstrong.htm

Issues Related to Treatment

- What if a patient who is infectious, or is presumed infectious, refuses treatment?
  - While court orders for testing are routine, there is limited precedent for physically compelling treatment outside of selected special populations such as prison inmates
  - Most state laws allow for involuntary hold only after less restrictive measures are exhausted
  - Persons may be isolated until they are proven non-contagious
  - Some states require patients to be released when they are non-contagious, even if treatment is not complete

Issues Related to Compliance with Treatment

- It is recommended that all persons with active TB undergo directly observed therapy (DOT)
  - Whether DOT must be used depends on state law
  - Some laws require that all persons undergo DOT to ensure uniform enforcement
- For patients who refuse or do not cooperate with DOT:
  - Isolation may be imposed until they adhere
  - A court may be asked to order adherence

Louisiana Tuberculosis Control Law: LA RS 40:4

(c) Control the spread of tuberculosis by:

...

(vii)(aa) Requiring the isolation and/or quarantine for directly observed therapy (medication taken in the presence of a health care provider) of any person with tuberculosis in a communicable state who has failed to comply with a daily self-administered course of chemotherapy for tuberculosis prescribed by a Louisiana licensed physician.

(bb) Requiring a more restrictive isolation and/or quarantine environment specified by the state health officer or by court order for any person who fails to comply with directly observed therapy under isolation and/or quarantine as provided in Subitem (aa) of this Item.

Hearing Requirements for Isolation Orders

- U.S. Constitution allows for "post-deprivation" hearing in emergencies
  - Many states have adopted pre-hearing requirements
  - Persons who are isolated or otherwise held by the state are generally entitled to a hearing after detention
- Right to appointed counsel
  - Some states provide appointed counsel

Habeas Corpus

- The U.S. Constitution gives every detained person the right to a *habeas corpus* hearing
- Habeas corpus requires:
  - The person to be brought before a judge
  - The government to show the legal authority for the detention
  - The government to show the factual basis for the detention
- If state's isolation law does not provide due process, *habeas corpus* may be available if the state's isolation law does not provide adequate due process

Is There A Right to the Least Restrictive Alternative for Isolation?

- "Least restrictive alternative" relates to government's use of the least restrictive means that will accomplish a legitimate government objective
- Possible examples:
  - Home isolation using electronic monitoring bracelets
  - Isolation in a private hospital with full services rather than a state hospital with limited facilities
- Constitutional requirements
  - Some state laws explicitly require least restrictive alternative

Paying for and Implementing Public Health Restrictions

- TB isolation and treatment is expensive
  - Covered by private health insurance?
  - What if the person is homeless?
  - Usually is an obligation of the jurisdiction that orders the restriction
- Costs may cause smaller health departments to be reluctant in ordering restrictions
- Isolation facilities are limited
  - Large outbreak could overwhelm facilities
  - Home isolation orders are difficult to enforce

Cooperation with Other Institutions

- Hospitals
  - OSHA requires hospitals to follow infection control practices, including patient isolation of persons with infectious TB
  - Hospitals have no legal authority to keep patients in their rooms
  - Health department must order and oversee enforcement of restrictions on hospital patients
- Jails and prisons
  - Jails and prisons can impose restrictions
  - Public health departments may assist in managing and investigating cases
  - Infectious prisoners can spread disease into community when released

Immigration-Related Issues

- TB is common worldwide
  - Refugee camps facilitate spread of TB
  - Immigrants may be infected
- Legal issues
  - Should new immigrants be screened?
  - How are cases investigated in the undocumented immigrant community?
  - What agencies should be involved?

Airline Travel: Multi-Jurisdictional Considerations

- A passenger with active TB poses risk to other passengers
- Airlines are regulated by Federal Aviation Administration
- Airport safety is regulated by the Transportation Safety Administration
- Both agencies may be involved in investigation of airline- and airport-associated transmission
- Notification and screening of exposed passengers may involve the airline, CDC, and state and local health departments

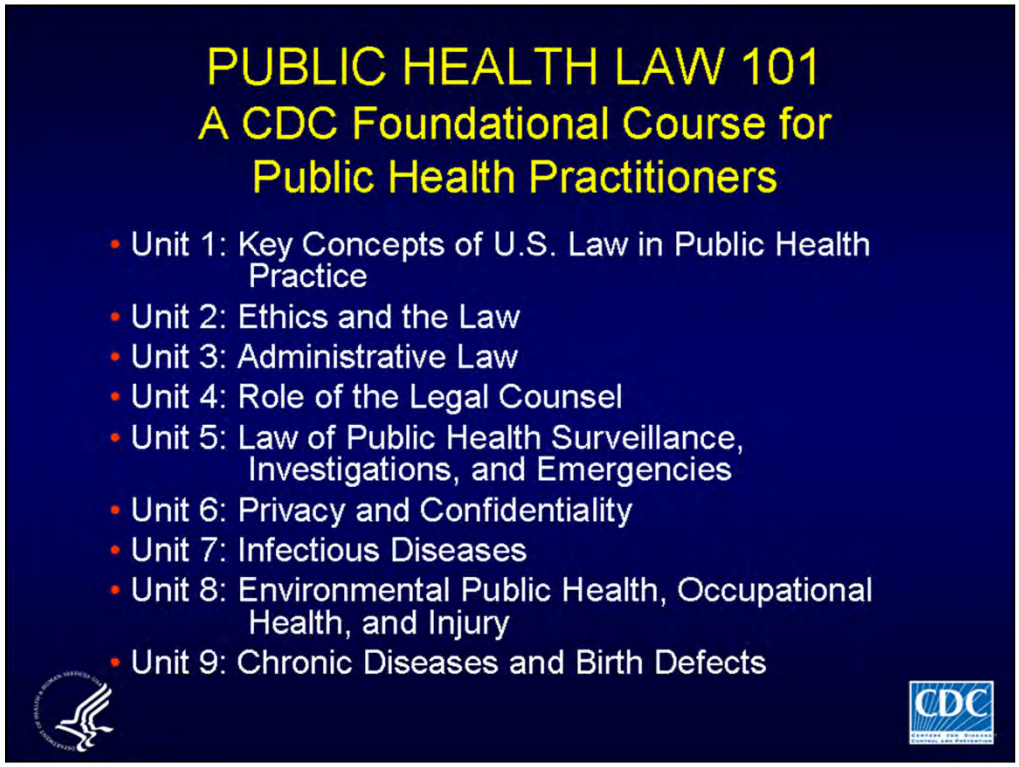
Interstate Disease Investigation and Management

- Persons with infectious TB who travel interstate may be subject to federal isolation
- State departments also can assist each other in tracking disease carriers who leave the state
- Law enforcement may be asked to help find individuals who have left treatment while still infectious
- CDC, through DHS, may prevent persons with infectious TB from boarding commercial flights via a "Do Not Board" order

Conclusion:
Unit 7

Summary: Unit 7

- Vaccination policy depends on a delicate balance between individual rights and the state's power to require vaccination to protect the public's health
- Food sanitation and outbreak investigation is one of the most legally complex public health activities, crossing local, state, and national boundaries
- States have broad powers to investigate communicable diseases and to restrict infected, potentially infected, and exposed individuals who do not cooperate with necessary public health measures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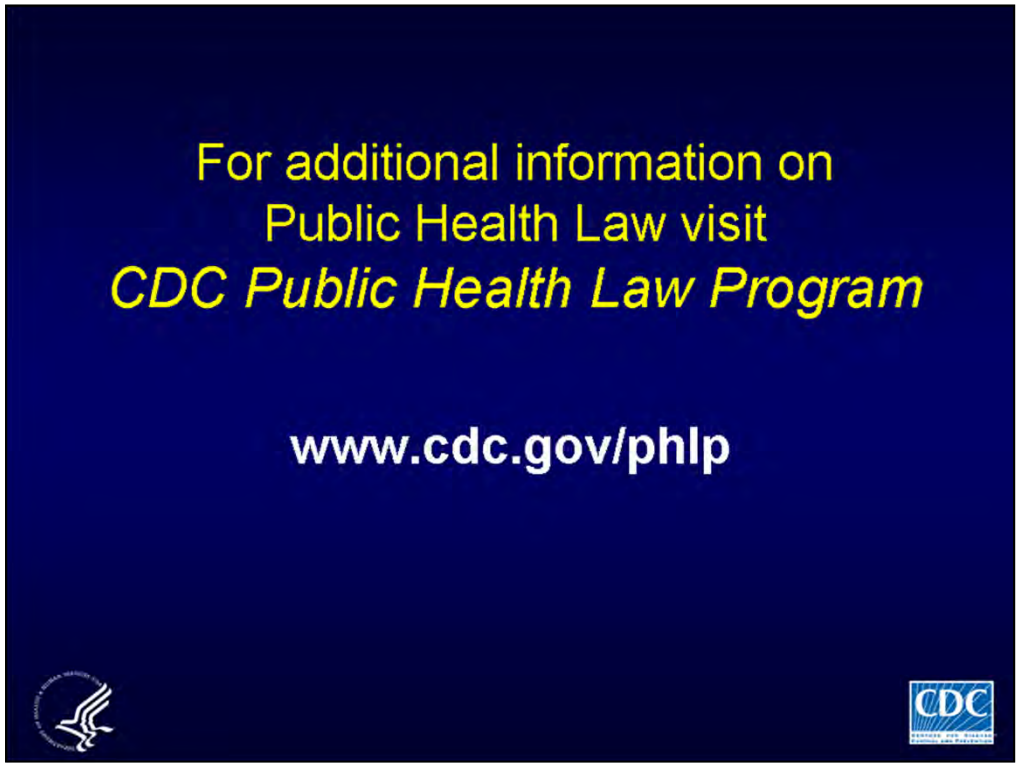
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