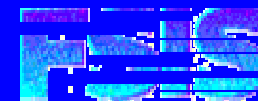


# The Physical Hazards of Foreign Materials

Presentation for the Public Meeting on Foreign Material  
Contamination  
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# Objectives

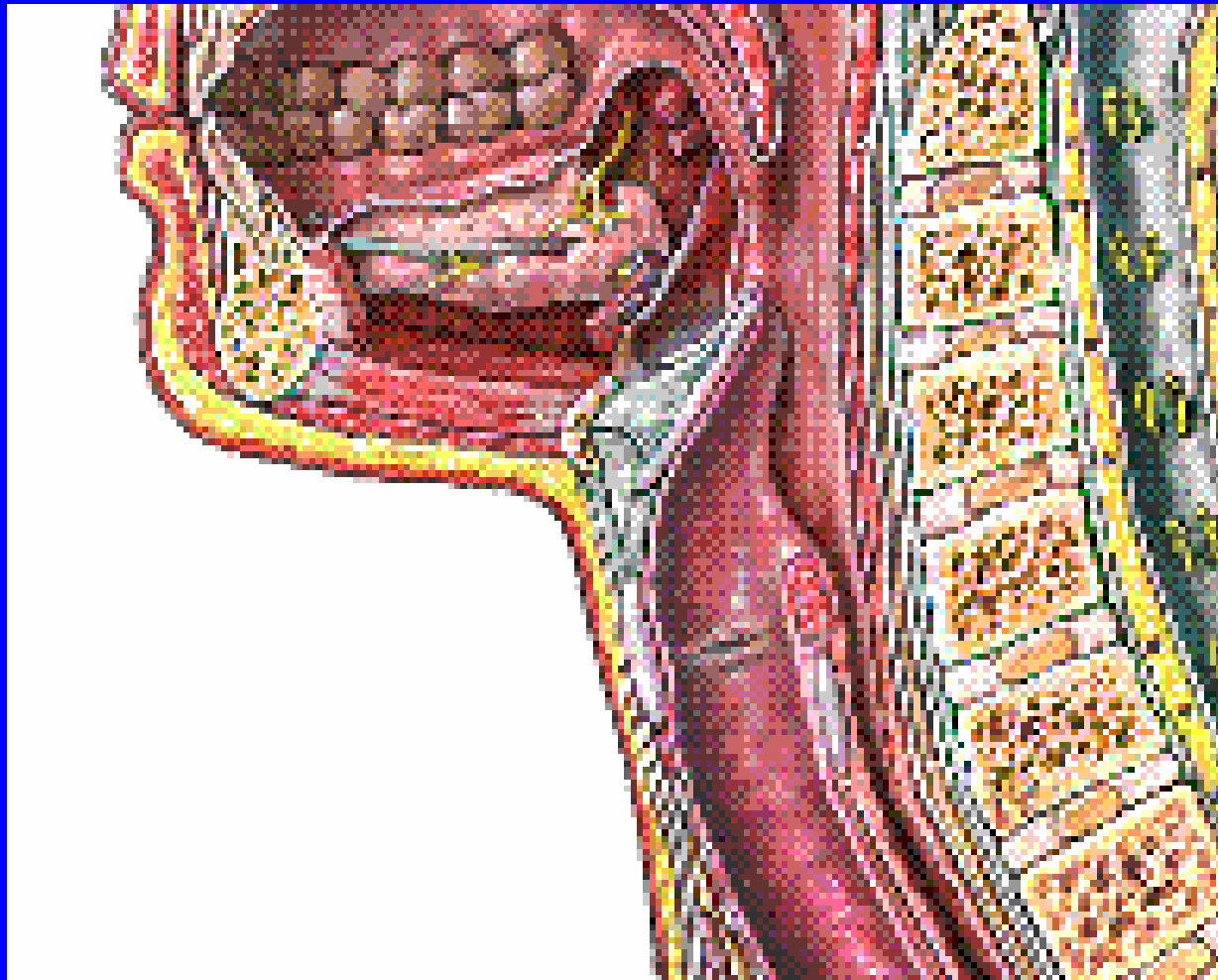
- Describe generally the physical hazards of ingested foreign bodies
- Review epidemiologic and clinical data on foreign body ingestion
- Describe Federal efforts, based on the characteristics of the foreign material, to minimize risks to human health

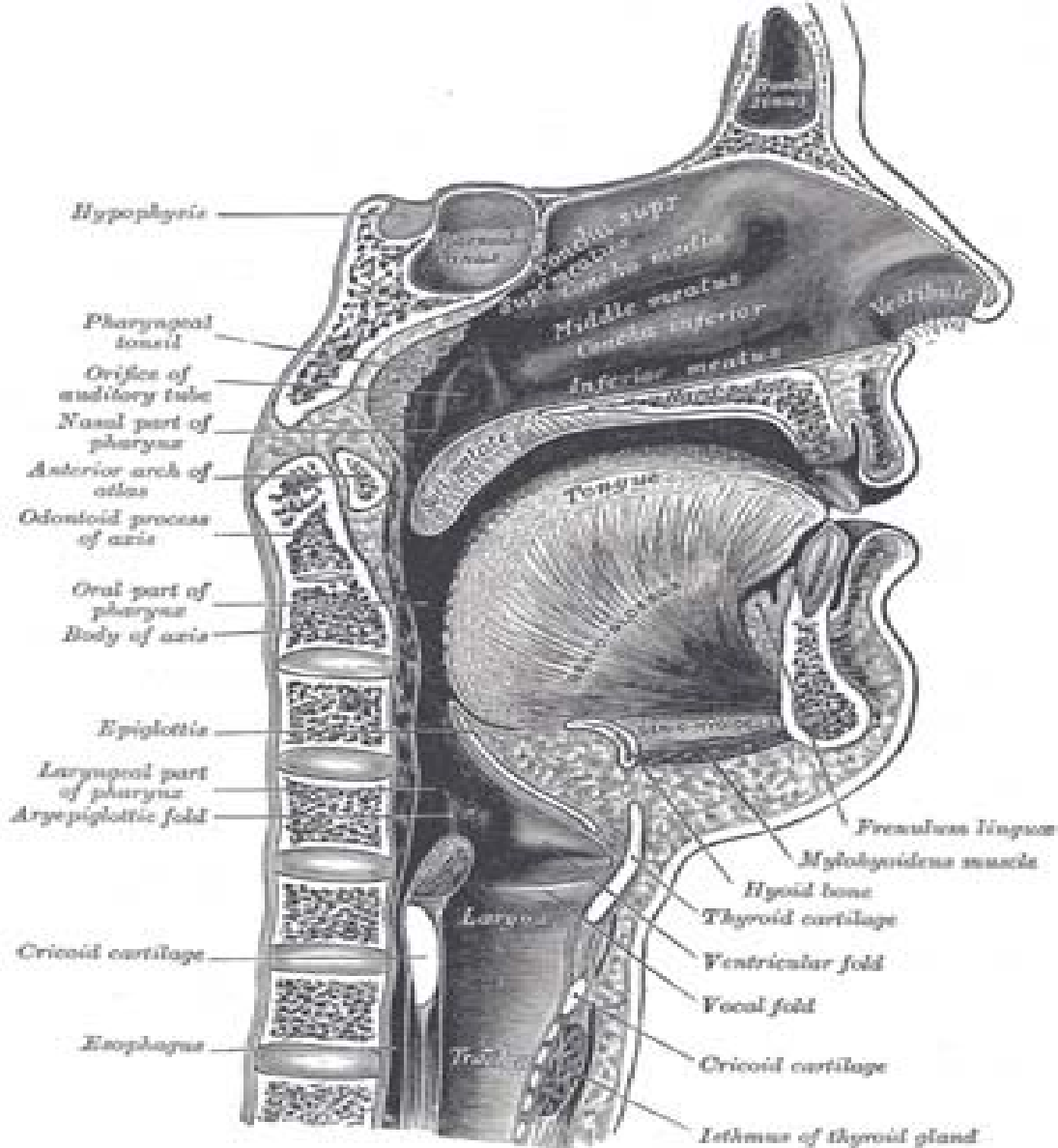
# What Parts of the Human Anatomy are at Risk?

- Digestive Tract
- Respiratory Tract
- Mouth and Teeth
- Extremities (Hands)

# Hazards to the Digestive Tract

- Esophageal laceration
- Esophageal perforation
- Fistula formation
- Laceration or perforation of other portions of the digestive tract
  - Pharynx
  - Stomach
  - Intestine





# Hazards to the Respiratory Tract

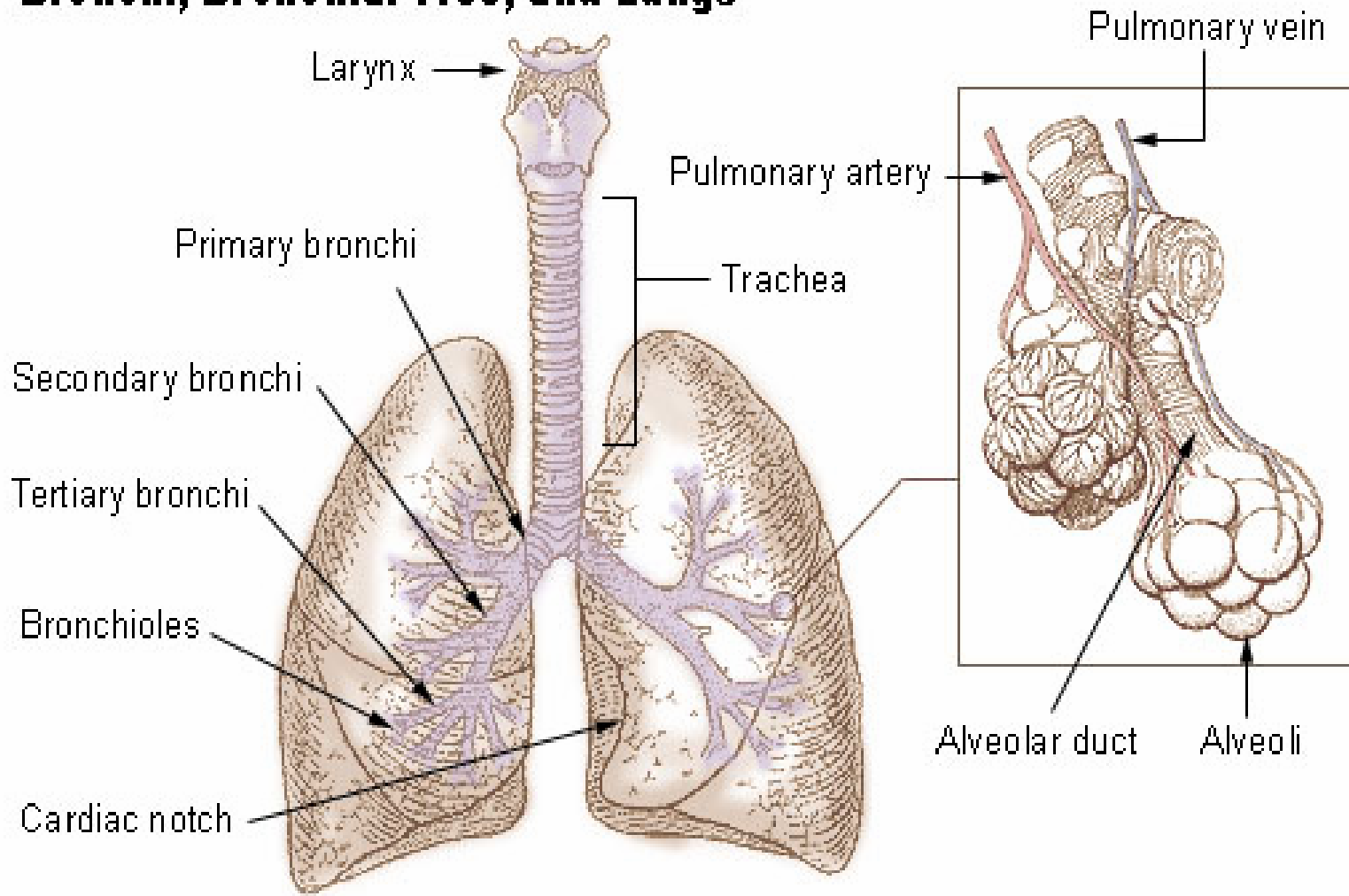
- Choking--occlusion of the airway
  - Children under age 3 at greatest risk
  - Common hazards are foreign objects (coins or toys) or food, *though not foreign objects in food*
  - Objects may become lodged in the upper esophagus and cause choking/asphyxiation by compression of the trachea

# Hazards to the Respiratory Tract

- Aspiration--inhalation of foreign matter into the bronchial tree--may result in:
  - partial lung collapse
  - secondary infection
  - destruction of lung tissue from retained material



# Bronchi, Bronchial Tree, and Lungs



# Hazards to the Mouth and Teeth

- Lacerations of the mouth
- Lacerations of the tongue
- Chipped teeth
- Broken fillings
- Damage to prosthetics

# Other Hazards

- Lacerations on the hands occurring during food preparation
- Illness complaints
  - Nausea and vomiting
  - Diarrhea
  - Headache, fever and dizziness
  - Chest pain

# Clinical Observations about Foreign Body Ingestion

- About 80% of foreign body (FB) ingestions occur in the pediatric age group
- 80-90% of FBs ingested will pass spontaneously over 4-7 days
- Estimated that 1-5% of FBs ingested will result in injury

# Clinical Observations about Foreign Body Ingestion

- Sharp objects account for about 10% of FB ingestions, but a disproportionate number of injuries
- In a case series of foreign bodies removed surgically, 37% were in the airway and 63% were in the upper digestive tract

# Clinical Observations about Foreign Body Ingestion

- In a review of FDA consumer complaints of foreign materials in food, the most frequently reported injury was mouth or throat laceration
- In the FDA review glass was the foreign material most frequently reported as causing illness or injury

# Characteristics of Foreign Materials that May be Hazardous

## Size of the Object

- FSIS in its 1995 Public Health Hazard Analysis Board on bone particles concluded:
  - bone particles  $< 1$  cm not a safety hazard;
  - particles 1-2 cm are a low risk;
  - particles  $> 2$  cm have the potential to be a safety hazard and may cause injury

# Characteristics of Foreign Materials that May be Hazardous

## Size of the Object

- FSIS (1995): The presence of foreign material other than bone may pose a potential hazard, and each instance should be considered on a case-by-case basis, irrespective of size



# Characteristics of Foreign Materials that May be Hazardous

## Size of the Object

- Consumer Product Safety Commission (1995): spherical objects  $< 1.75$  inches in diameter are dangerous to children under 3 years (choking, ingestion or aspiration)
- CPSC uses a Small Parts Test Fixture (a cylinder) to judge other non-spherical objects for choking hazard

# Characteristics of Foreign Materials that May be Hazardous

## Size of the Object

- FDA Health Hazard Evaluation Board conclusions in cases of foreign materials (1972-1997) found that 56% of objects 1-6 mm might pose a limited acute hazard
- For objects  $> 6$  mm, only 2.9% were judged to present no hazard

# Characteristics of Foreign Materials that May be Hazardous

## Size of the Object

- FDA/ORA Compliance Policy Guide
  - Criteria for direct reference seizure: Hard or sharp objects 7-25 mm and RTE
  - Criteria for recommending legal action :
    - 7-25 mm and requires additional preparation
    - < 7 mm and intended for special-risk group
    - > 25 mm in length

# Characteristics of Foreign Materials that May be Hazardous

## Shape of the Object

- Spherical or cylindrical shaped objects present a greater risk for choking
- Slender and sharp or pointed objects present a greater risk for laceration or perforation

# Characteristics of Foreign Materials that May be Hazardous

## Consistency of the Object

- rigid objects (e.g., coins) caused most choking deaths in children 3 years and older
- conforming objects (e.g., balloons) caused more choking deaths in children under age 3 years

# Conclusions

- Foreign material contamination does occur in food items
- Injuries have resulted from foreign materials in foods
- Size matters: particles in food that are small are more likely to escape detection, but less likely to cause injury

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