# Biosafety & Infection Prevention: Bridging the Gap

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# EMERGENCY MANAGEMENT

**First Circle Responders**

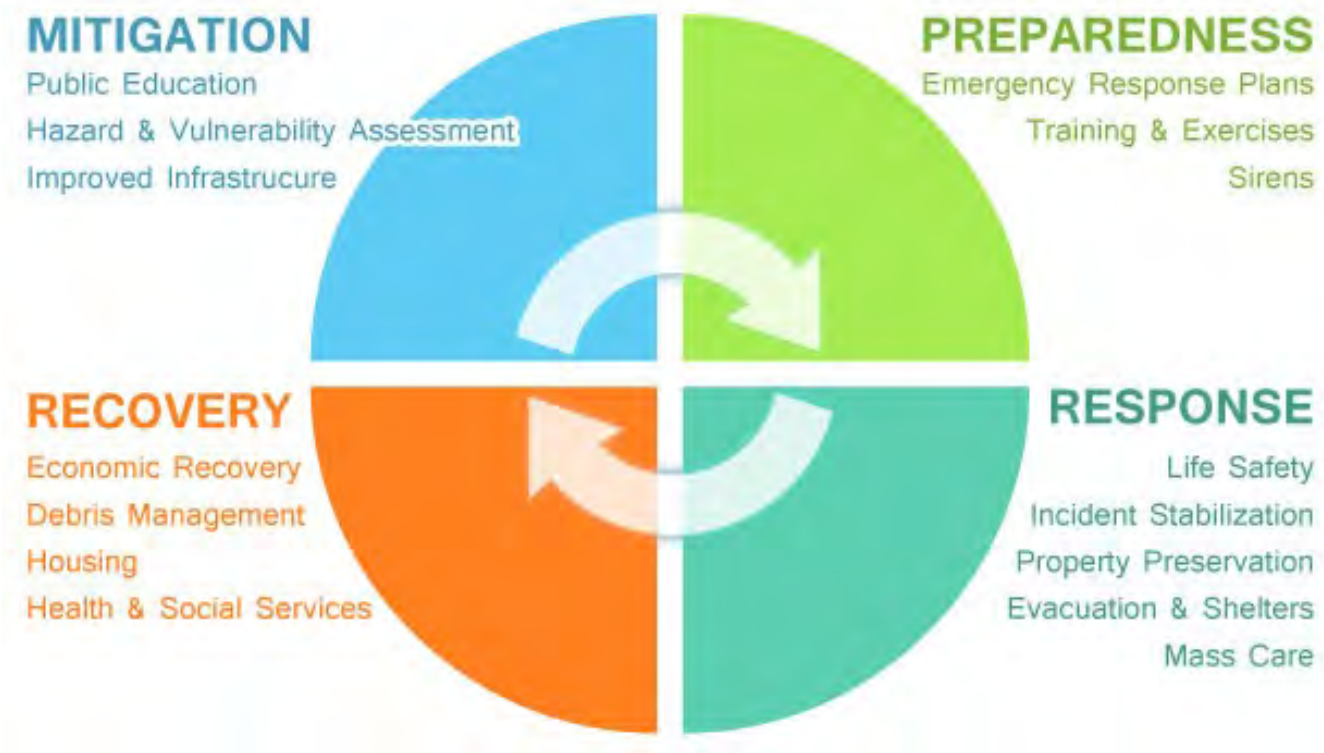
- Fire
- Police
- Emergency Medical
- Emergency Management

**Second Circle Responders**

- Hospitals
- Public Works
- Utilities
- Transportation
- Public Health

**Third Circle Responders**

- Private Business
- Charities
- Community Groups
- Religious Institutions
- Schools



# ACADEMIC HEALTH CENTERS

An academic health center encompasses all the health-related components of universities, including their health professions schools, **patient care operations**, and **research enterprise**. Thus, an academic health center consists of an allopathic or osteopathic **medical school**; one or more other health profession schools or programs such as

- Allied Health
- Dentistry
- Graduate Studies
- Nursing
- Pharmacy
- Public Health
- Veterinary Medicine
- **and one or more owned or affiliated teaching hospitals or health systems.**

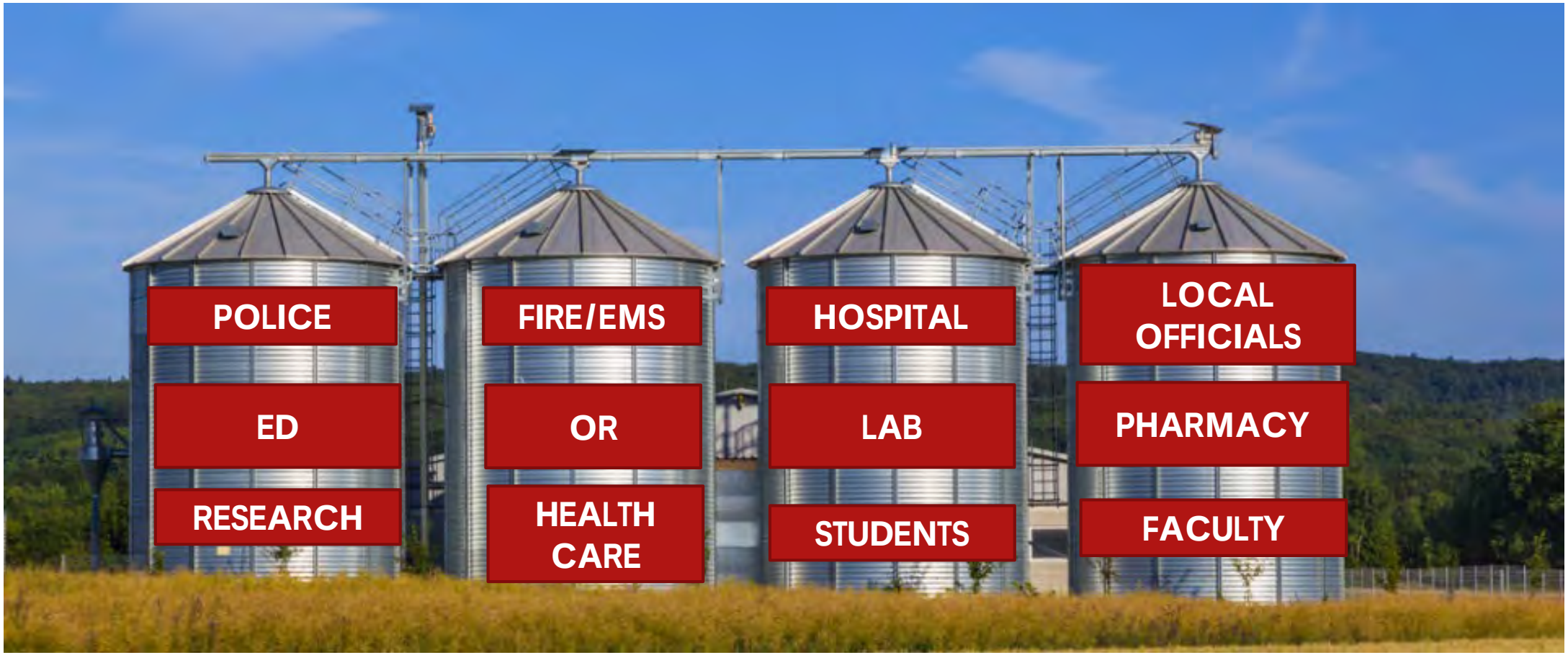
Association of Academic Health Centers

www.aahcdc.org

# ACADEMIC HEALTH CENTERS: IMPACT

AAHC member institutions are deeply imbedded in their communities, **often serving as safety-net providers and standing on the country's frontline of defense in response to public health outbreaks, natural disasters, local crises, and potential terrorist attacks**. In addition, academic health centers **provide tertiary and quaternary healthcare services**, specializing in the most complex and difficult diagnoses and treatments while **educating the next generation of health professionals**. Their research provides important new knowledge leading to advances in understanding and treatment of diseases. Academic health centers also have a significant economic impact both locally and globally; they employ thousands of professionals and staff, while often producing original products and technologies that benefit millions of people worldwide.

- AAHC lists 90 members in the United States and 49 International members.


POLICE
FIRE/EMS
HOSPITAL
LOCAL OFFICIALS
ED
OR
LAB
PHARMACY
RESEARCH
HEALTH CARE
STUDENTS
FACULTY

# Healthcare setting can affect the players

# UTHEALTH & UTPHYSICIANS

UTHealth™
The University of Texas
Health Science Center at Houston

UT★Physicians
A Part of UTHealth

## RESEARCH

Biomedical Informatics

Biomedical Sciences

Dentistry *

Nursing *

Public Health *

McGovern Medical School

## HEALTHCARE

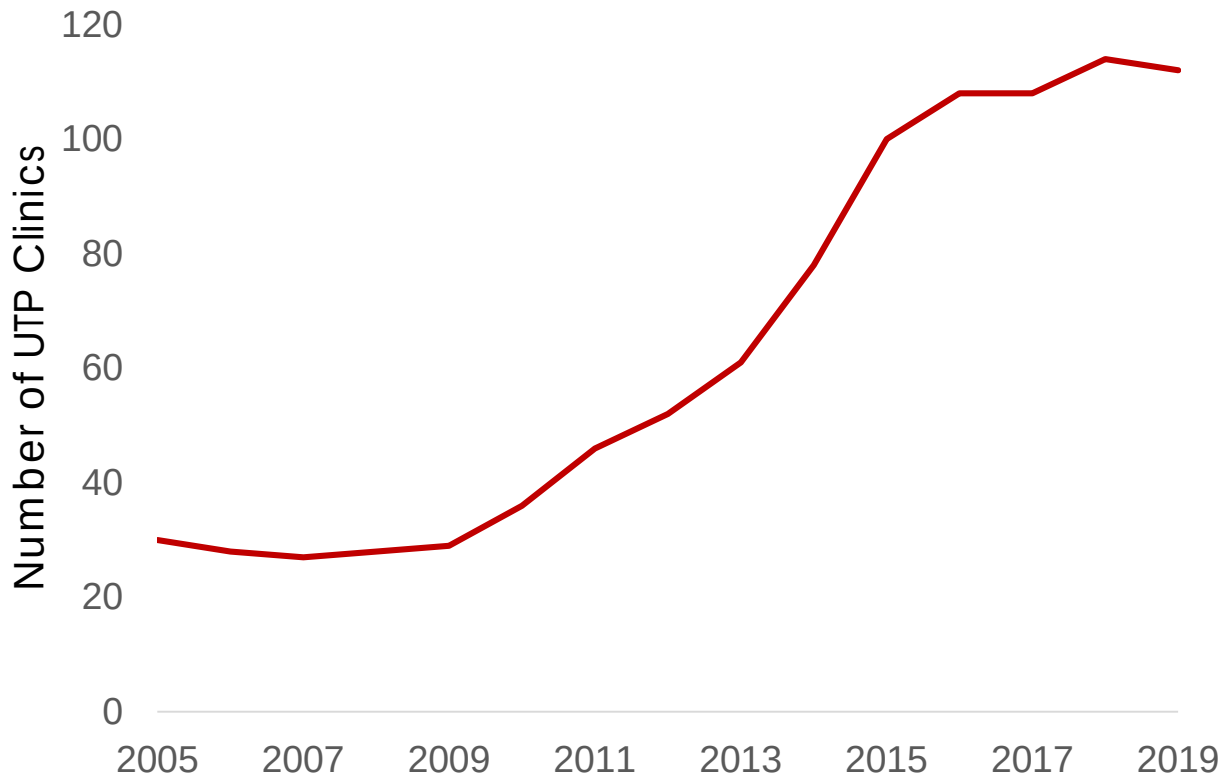
Medical Practice Group
(Outpatient Physician)

2,000+ Clinicians

80+ Specialties

150 Physician Office Clinics
(Some shared with other institutions)

# UTHEALTH & UTPHYSICIANS




2012 - 2013

- RAPID EXPANSION
- UTH EMPLOYEES
- NEED FOR INFECTION PREVENTION
- WHO?
- WHICH DEPARTMENT?
- STRUCTURE?

# ARE BIOSAFETY & INFECTION PREVENTION PROFESSIONALS INTERCHANGABLE?

# INTRODUCTION

## BIOSAFETY

Laboratories

Protects Workers from Disease

Microbiological Practices & Procedures

Containment facilities

Research

Healthcare

## INFECTION PREVENTION

Hospitals
Ambulatory
Behavioral
Home Care
Nursing Home

Protects Patients &Workers from Disease

Clinical Application of Microbiology

Epidemiology

# WHAT ARE COMPETENECIES?

- Standards of the knowledge, skills and abilities of a competent practitioner
- The ability to do something well or to do a job properly
- Set of defined knowledge and behaviors that provide a structured guide for enabling the identification, evaluation and development of a competent individual
- Core competencies are capabilities and/or technical expertise unique to a particular organization or profession

# COMPARING COMPETENCIES

- Credentialing is a tangible demonstration of the highest level of competency within a field.

- Biological Safety – Certified Biological Safety Professional (CBSP)
  - American Biological Safety Association International

- Infection Prevention – Certified in Infection Prevention and Control (CIC)
  - Certification Board of Infection Control and Epidemiology, Inc. and Association for Professionals in Infection Control and Epidemiology

# COMPETENCY CATEGORIES

65 Competencies

- Disinfection, Decontamination and Sterilization
- Safe Work Practices and Procedures
- Risk Assessment and Hazard Identification
- Regulatory Aspects, Standards and Guidelines
- Program Management and Development
- Equipment Operation and Certification
- Facility Design

48 Competencies

- Identification of Infectious Disease Process
- Surveillance and Epidemiological Investigations
- Prevention/Controlling the Transmission of Infectious Agents
- Employee/Occupational Health
- Management and Communication
- Education and Research
- Environment of Care
- Cleaning, Sterilization, Disinfection and Asepsis

**Stated Competency Categories Primarily Applicable to Biosafety**

Prevention of laboratory associated infections
Recombinant/synthetic nucleic acid molecules
Animal work
Compliance with profession-specific regulations
Institutional Biosafety Committees (IBCs)
Laboratory facility design issues
Biosafety-specific equipment (BSC)

**Stated Competency Categories Applicable to *Both* Professions (with some differences)**

Disease history, transmission, prevention
Risk assessment and management
Exposure controls for infectious agents
Patient/Community/Workers
Personal Protective Equipment
Sterile techniques
Hand hygiene
Containment issues
Education & Training
Project management & communication
Guidelines / Regulations (BBP)
Decontamination/Disinfection/Sterilization
Biohazardous and sharps waste management & disposal

**Stated Competency Categories Primary Applicable to Infection Prevention**

Environment of care
Patient safety
Surveillance and Epidemiology
Clinical facility design issues
Community – patients/families

# ORGANISMS OF CONCERN

## Research (LAI)

- *Mycobacterium tuberculosis*
- Arboviruses
- *C. burnetii* (Q Fever)
- Hantavirus
- *Brucella* sp.
- Hepatitis B virus
- Shigella
- Salmonella
- Hepatitis C virus
- *Neisseria meningitidis*

## Healthcare (HAI)

- *Clostridium difficile*
- Enterobacteriaceae (carbapenem-resistance)
- Hepatitis
- Human Immunodeficiency Virus (HIV)
- Influenza
- Methicillin-resistant *Staphylococcus aureus*
- Norovirus
- Pseudomonas aeruginosa
- *Staphylococcus aureus*
- Tuberculosis

# BSL-2 LAB VS HEATHCARE EXAM ROOM

## BSL -2 Lab

- BSC, centrifuge, etc
- Lab door self closing
- Sink for hand washing
- No carpet or rugs
- Space between furniture/equipment accessible
- Benchtops impervious to water/heat/chemical
- Non-porous chairs
- Windows not recommended
- Eye wash
- Inward flow of air to space outside lab
- HEPA filtered exhaust from Class II BSC
- Method for decontaminating waste

## Healthcare Exam Room

- Exam table
- Vital sign and diagnostic equipment
- Sink for hand washing
- No carpet or rugs
- Space between furniture/equipment to move patients
- Non-porous surfaces for disinfection
- Eye wash
- Separate spaces for sample collection, laboratory, equipment sterilization and hazardous waste storage
- Secured storage of medications/supplies
- ASHAE air change rates vary by room type

# BSL-2 VS STANDARD PRECAUTIONS

## BSL -2 Procedures

- Applicable to clinical, diagnostic, teaching, research
- Standard Microbiological Practices
  - Hand Hygiene
  - No Food/Drink/Smoking/Cosmetics
  - Mouth pipetting prohibited
  - Safe handling of sharps
  - Reduction of splashes/aerosols
  - Decontaminate work surfaces, materials, & cultures
  - Waste Management
- Safety Equipment – Containment & PPE
- Laboratory Facilities

## Standard Precautions

- Minimum infection prevention measures
- Apply to all patients
- In any healthcare setting
- Aim to protect HCW and spread of infections among patients
- 5 Principals
  - Hand Hygiene
  - Use of PPE (gowns, gloves, facemask)
  - Respiratory hygiene and cough etiquette
  - Safe injection practices
  - Safe handling of potentially contaminated equipment or surfaces in patient environment

# BIOSAFETY & INFECTION PREVENTION PROFESSIONALS ARE NOT INTERCHANGABLE


# BACKBONE FOR ESTABLISHING IP POLICIES

Emergency Response

Exposure Control Procedures

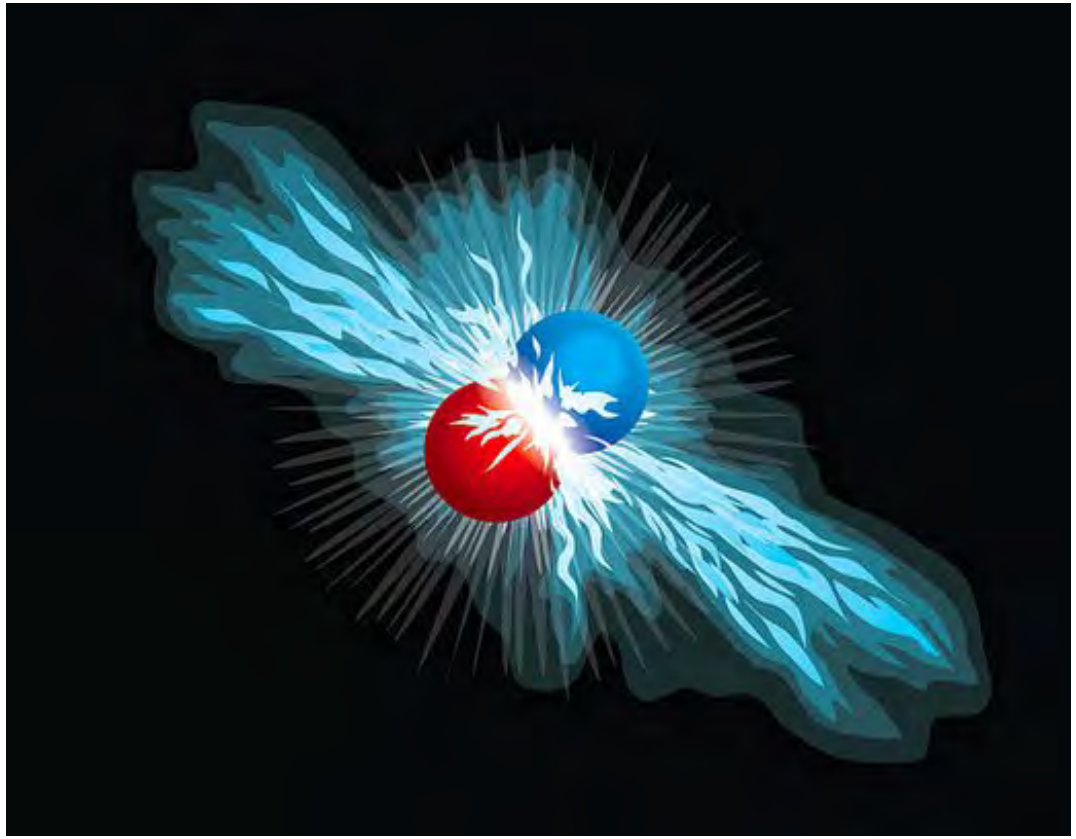
Biohazard Waste Management

Biohazardous Exposure to Workers

Proper Handling of Biological Material

Decontamination, Sterilization and Disinfection

# COLLISION EVENTS OR COOPERATIVE OPPORTUNITES



# CURRENT TRENDS

Patients and Workers from Natural and Engineered Biological Hazards

Coordinating Research Institutions with Healthcare

Need to Protect Basic Research and Clinical Application (Gene and Cell Therapies)

# NATURAL AND ENGINEERED BIOLOGICAL HAZARDS

# GLOBAL SURVIELLANCE

Infection Prevention

Contact/ Droplet/ Airborne Precautions

Medications

Biosafety

Impending research

New techniques

# HIGH CONSEQUENCE INFECTIOUS DISEASES

Highly lethal viral, bacterial, prion and related infections and diseases of unknown origin

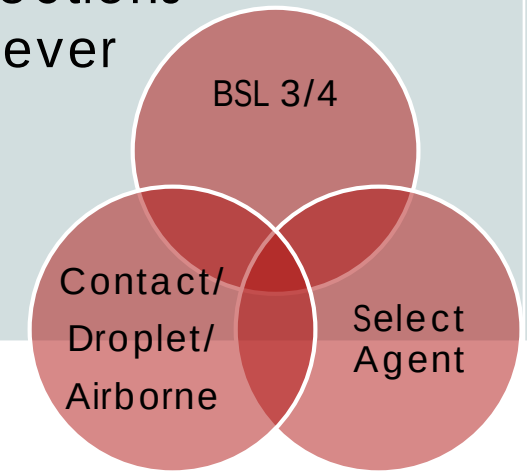
High-consequence pathogens have one or more of the following features:

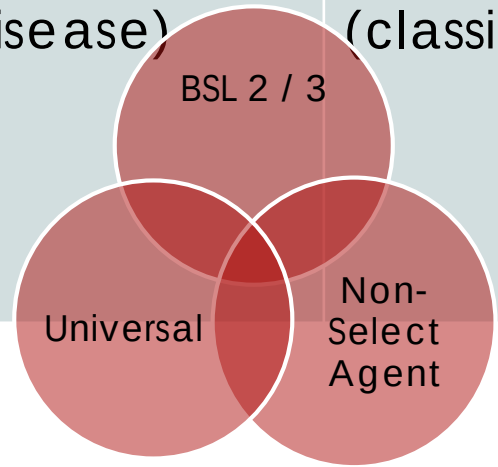
- potential to cause epidemics or pandemics
- infect/affect many people
- spread rapidly in a short time
- infection results in high cost to society (loss of worker productivity)
- infection results in high cost to the healthcare system

CDC – Division of High Consequence Pathogens and Pathology (CHCPP)

# DISEASES OF HIGH CONSEQUENCE

| Viral | Bacterial | Prion |
|---|---|---|
| Ebola virus disease<br>Hantavirus pulmonary syndrome<br>Marburg hemorrhagic fever<br>Poxvirus infections<br>Rift Valley fever<br>Smallpox*<br>Rabies<br>Zika | Actinomycoses & nocardiosis<br>Anthrax<br>Brucellosis<br>Buruli ulcer<br>Glanders<br>Leprosy (Hansen disease)<br>Leptospirosis<br>Melioidosis | Bovine spongiform encephalopathy (mad cow disease)<br>Chronic wasting disease<br>Creutzfeldt-Jakob disease (classic and variant) |

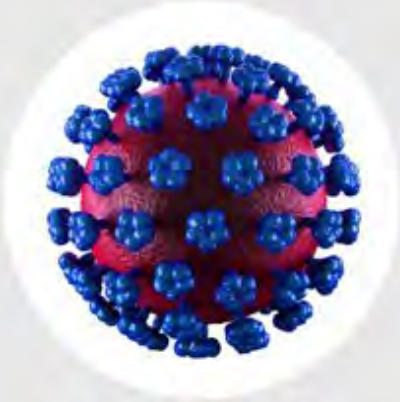


# Recent HCID Outbreaks Around the World

**Ebola**

Democratic Republic of Congo, 2018



**Lassa Fever**

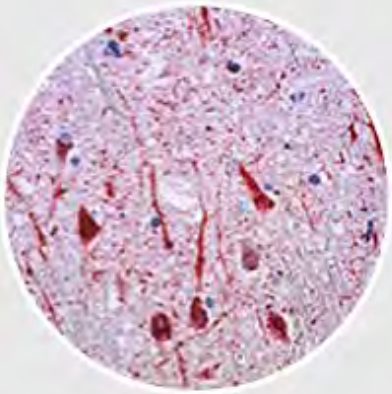
Nigeria, 2018

**Middle East Respiratory Syndrome**

Middle East, ongoing activity

&

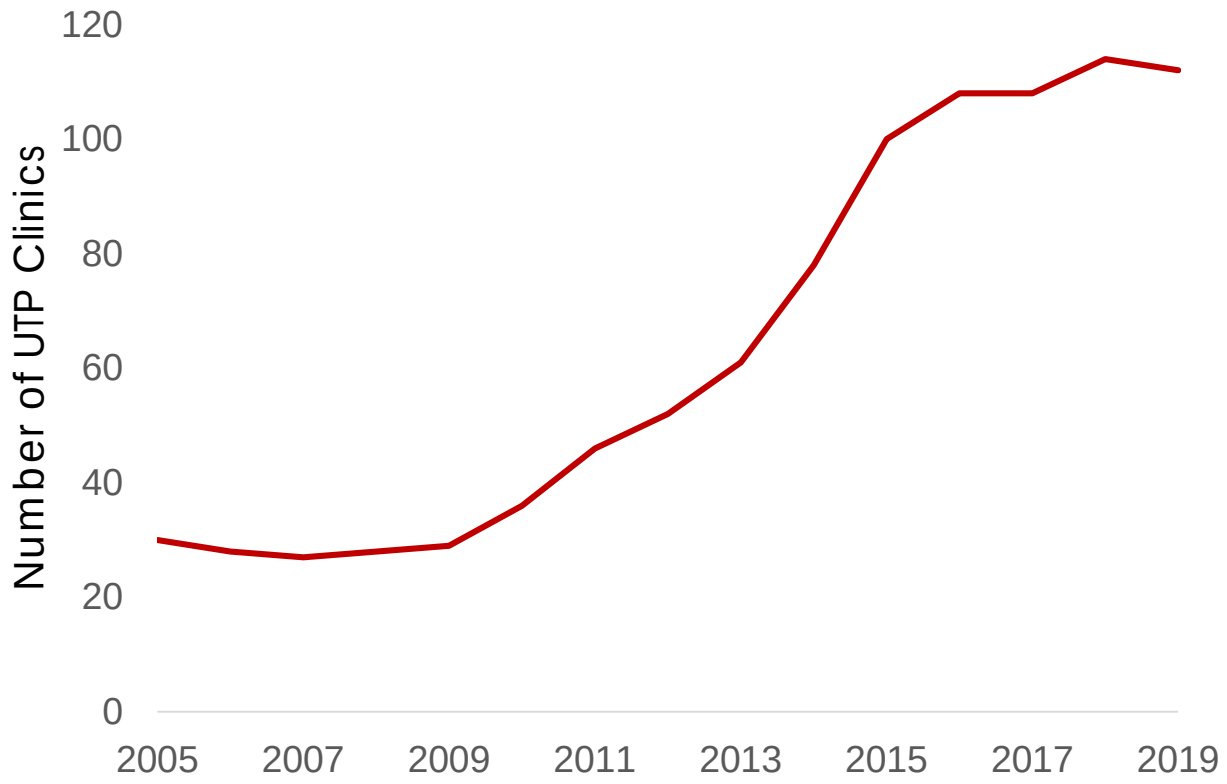
South Korea, 2015



**Nipah Virus**

India, 2018

# UTHEALTH & UTPHYSICIANS

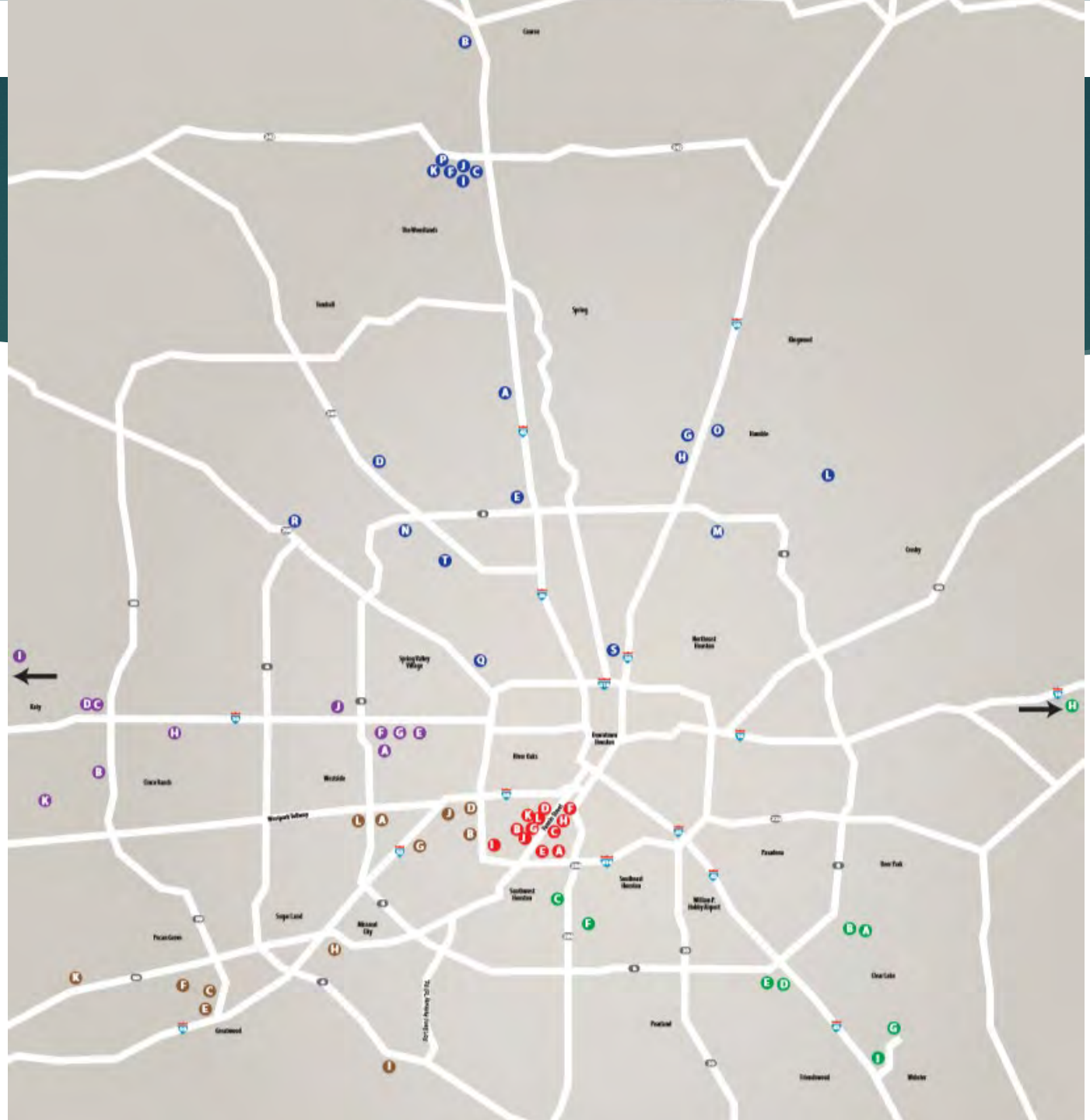



2013

- INFECTION PREVENTION

2014

- EBOLA OUTBREAK



**156 Clinics**

**~1/4 Walk-ins**

## Ebola Algorithm

START

Does patient have any of the following:
fever (>38.6 °C or 101.5 °F)
AND
severe headache, muscle pain, vomiting, diarrhea, abdominal pain, or hemorrhage?

YES

NO

Patient does not meet case definition for Ebola. Proceed with routine triage questions.

NO

Did patient have close contact to a person with history of travel to West Africa (Guinea, Liberia, or Sierra Leone) within the past 21 days?

NO

Does patient have a history of travel to West Africa (Guinea, Liberia, or Sierra Leone) within the past 21 days?

YES

YES

**PATIENT MEETS CASE DEFINITION FOR EBOLA.**

1. Place surgical mask on patient and yourself
2. Immediately call nurse or medical assistant to front desk to escort patient to a private room and notify physician
3. All personnel in contact with patient MUST wear Ebola appropriate PPE
4. Refer the patient immediately to Memorial Hermann Hospital Emergency Room for diagnosis and management
5. Call MHH to advice them that a suspect case is coming
6. Notify MHH Infection Control: pager #: 281-278-0923
7. Enter patient info and contacts on a log sheet and file
6. Call for ambulance and inform ambulance driver of suspect Ebola case.
7. Notify UT Police Dispatch 713-792-2890
8. Notuify UT Physicians Administration
9. Notify Environmental Health and Safety for Waste Removal
10. Page Dr. Karen Vigil (713-608-0031) or Dr. Luis Ostrosky (713-608-0398) if you have any questions

# ATTENTION ALL PATIENTS


**Please inform the front desk and your nurse/medical assistant if you are sick and have recently been out of the country, or if you have been in contact with a person who recently travelled and is now sick.**

UT Physicians
A Part of UTHealth

# LESSONS LEARNED FROM DISEASES OF HIGH CONSEQUENCE

## Selection of Personal Protective Equipment

- Infection prevention is familiar with basic PPE and isolation precaution routinely used in healthcare

- Biosafety is familiar with options for higher levels of protection such as powered air purifying respirators or ensembles commonly used in high containment laboratories

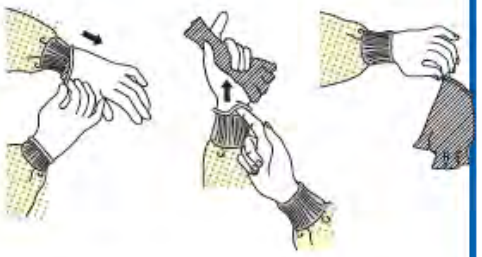
Courtesy of The University of Nebraska Medical Center Biocontainment Unit

# SEQUENCE FOR REMOVING PERSONAL PROTECTIVE EQUIPMENT (PPE)

Except for respirator, remove PPE at doorway or in anteroom. Remove respirator after leaving patient room and closing door.

## 1. GLOVES

- Outside of gloves is contaminated!
- Grasp outside of glove with opposite gloved hand; peel off
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist
- Peel glove off over first glovet
- Discard gloves in waste container



## 2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield is contaminated!
- To remove, handle by head band or ear pieces
- Place in designated receptacle for reprocessing or in waste container

## 3. GOWN

- Gown front and sleeves are contaminated!
- Unfasten ties
- Pull away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard

## 4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- Grasp bottom, then top ties or elastics and remove
- Discard in waste container

**PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE**

UT★Physicians
A Part of UTHealth

## PERSONAL PROTECTIVE EQUIPMENT (PPE) FOR HEALTHCARE PERSONNEL EVALUATING A PATIENT WITH SUSPECTED EBOLA DISEASE

The minimum recommended PPE that should be worn by HCP upon entry into patient rooms or care areas with a patient with a suspected case of EVD include:

- Gloves
- Impermeable gown
- Eye protection (goggles or face shield)
- Facemask

Additional PPE might be required in certain situations (e.g., copious amounts of blood, other body fluids, vomit, or feces present in the environment), including but not limited to:

- Double gloving
- Fit-tested N 95 respirator
- Disposable shoe covers
- Leg coverings

HOW TO DON PERSONAL PROTECTIVE EQUIPMENT:

1. Perform hand hygiene
2. Put on a disposable gown
3. Put on a facemask
4. Put on a face shield or disposable googles
5. Put on gloves

PPE REMOVAL

PPE should be removed in the following order, and immediately placed in a biohazard bag:

1. Carefully remove gloves – Remember that the outside part of the gloves is contaminated.
2. Remove gown
3. Perform hand hygiene
4. Remove face shield or goggles
5. Remove mask
6. Perform hand hygiene

# LESSONS LEARNED FROM DISEASES OF HIGH CONSEQUENCE

## Biohazardous and Sharps Waste Management and Disposal

- Requires robust handling, packaging and shipping procedures commonly implemented by biological safety professionals
- Now must be implemented in less controlled patient care environments with the capacity to process significant quantities of waste
- Infection prevention required to consider these waste management issues

Courtesy of The University of Nebraska Medical Center Biocontainment Unit

# LESSONS LEARNED FROM DISEASES OF HIGH CONSEQUENCE

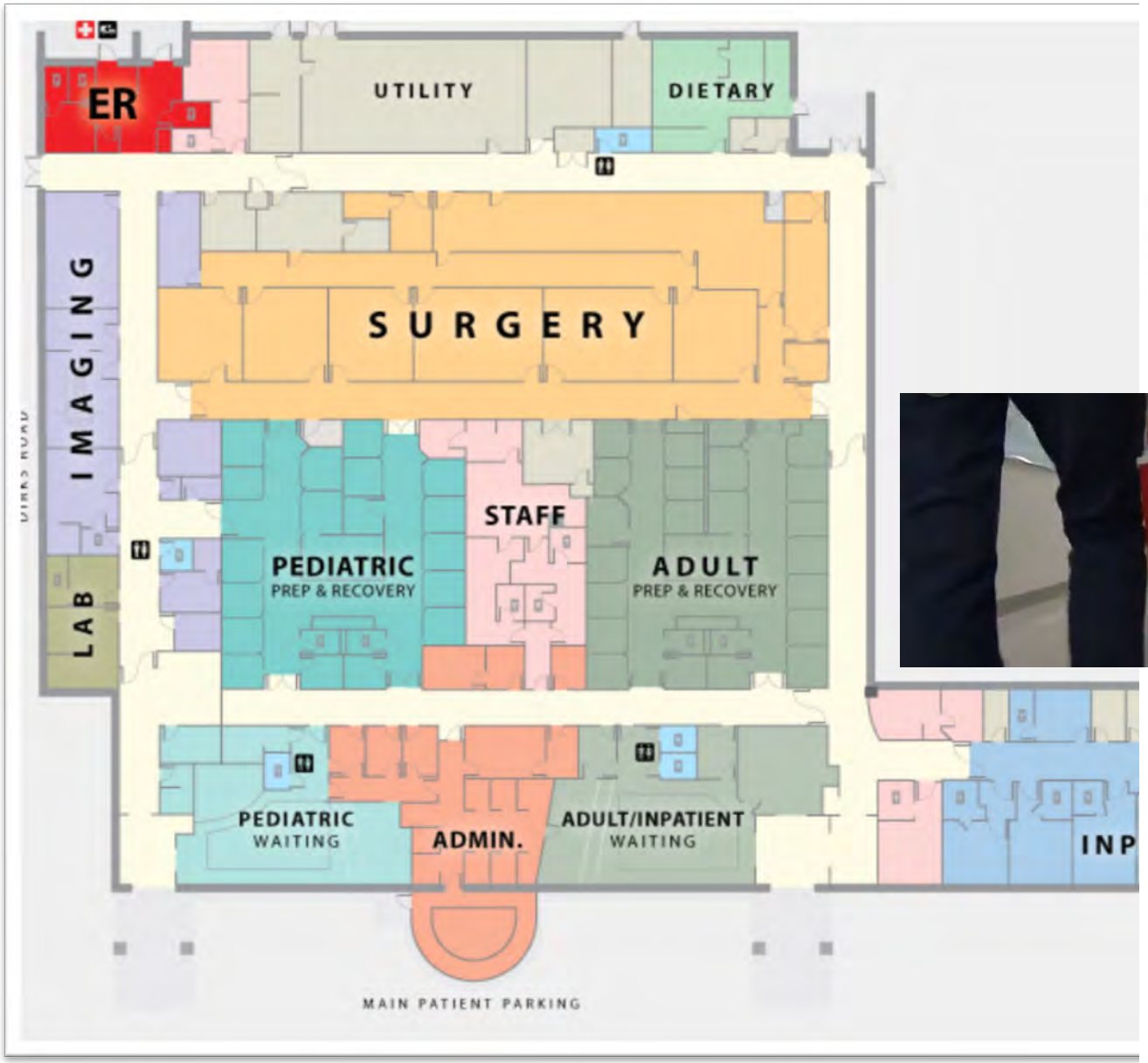
## Clinical Laboratory

- Infection prevention oversees biosafety in clinical diagnostic laboratories

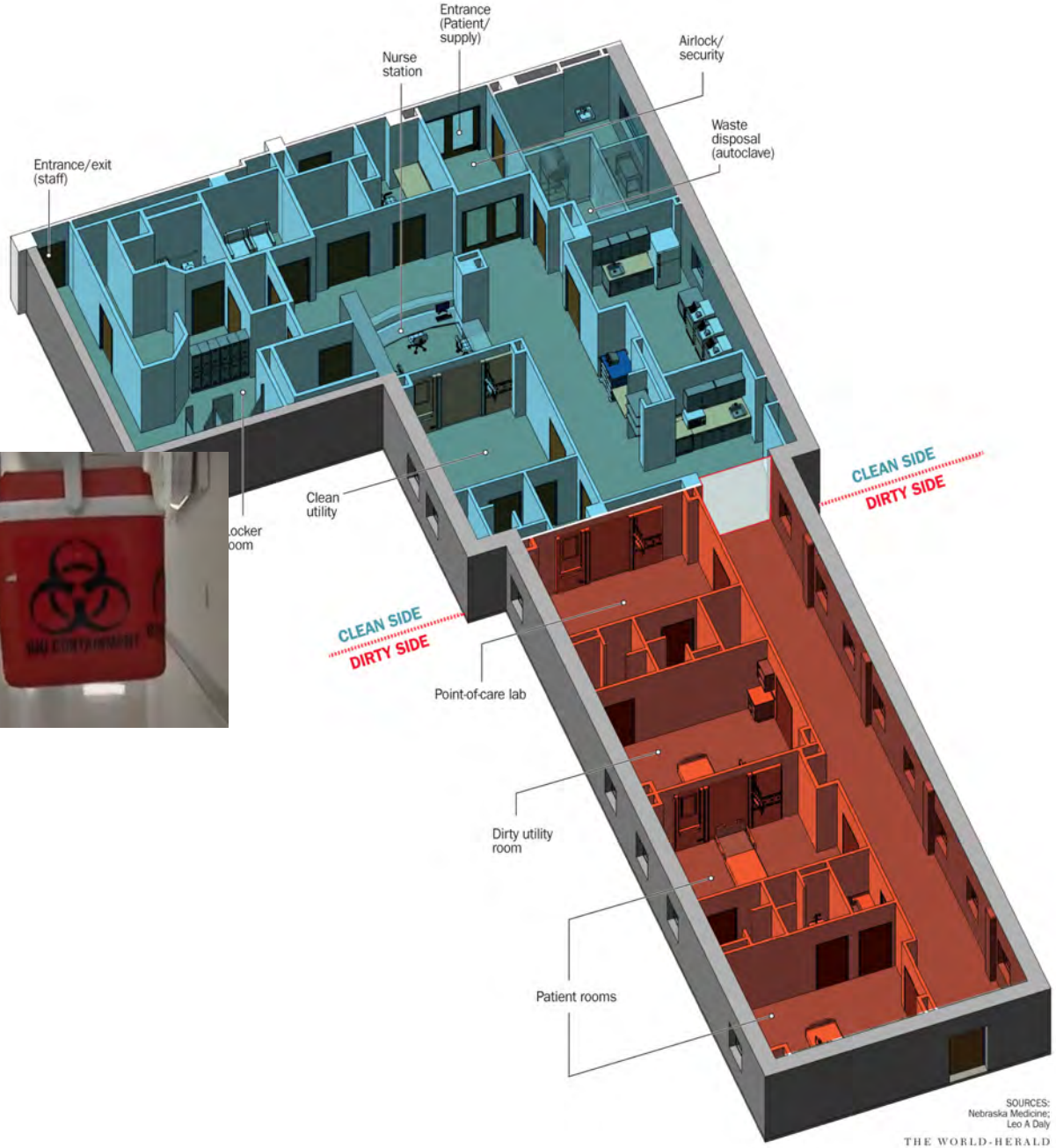
- Risk assessments with Biosafety and Infection Prevention for each piece of diagnostic equipment and identifying potential strategies to optimize BSCs

BSL-2 Like

Courtesy of The University of Nebraska Medical Center Biocontainment Unit


ER
UTILITY
DIETARY
IMAGING
SURGERY
LAB
STAFF
PEDIATRIC
PREP & RECOVERY
ADULT
PREP & RECOVERY
PEDIATRIC
WAITING
ADMIN.
ADULT/INPATIENT
WAITING
INP
MAIN PATIENT PARKING




Entrance (Patient/ supply)
Nurse station
Airlock/ security
Waste disposal (autoclave)
Entrance/exit (staff)
Clean utility
CLEAN SIDE
DIRTY SIDE
CLEAN SIDE
DIRTY SIDE
Point-of-care lab
Dirty utility room
Patient rooms
SOURCES: Nebraska Medicine; Leo A Daly
THE WORLD-HERALD

# LESSONS LEARNED FROM DISEASES OF HIGH CONSEQUENCE

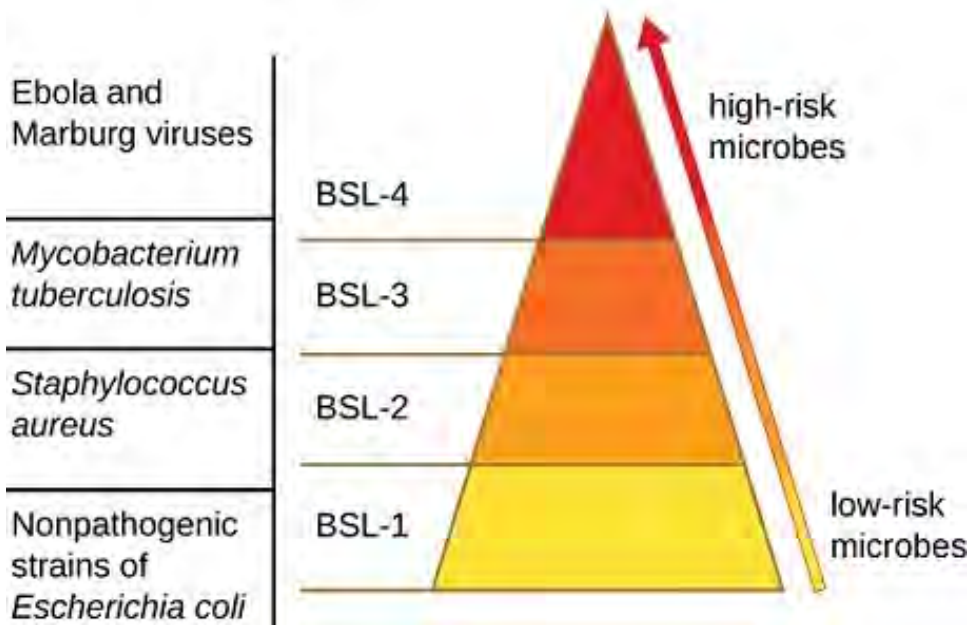
## Environmental Cleaning

- Biosafety developed comprehensive cleaning protocols for the clinical environment

- Infection Prevention implemented the protocols into cleaning checklists for nurses and medical technicians


Courtesy of The University of Nebraska Medical Center Biocontainment Unit

# CLINICAL CONTAINMENT LEVELS




| Clinical Containment Levels | |
|---|---|
| 4 | Exotic/HCID |
| 3 | Aerosol transmission |
| 2 | BBP, fecal/oral diseases |
| 1 | “Don’t make healthy people sick” |

Courtesy of Behavioral-Based Improvement Solutions

# CURRENT TRENDS

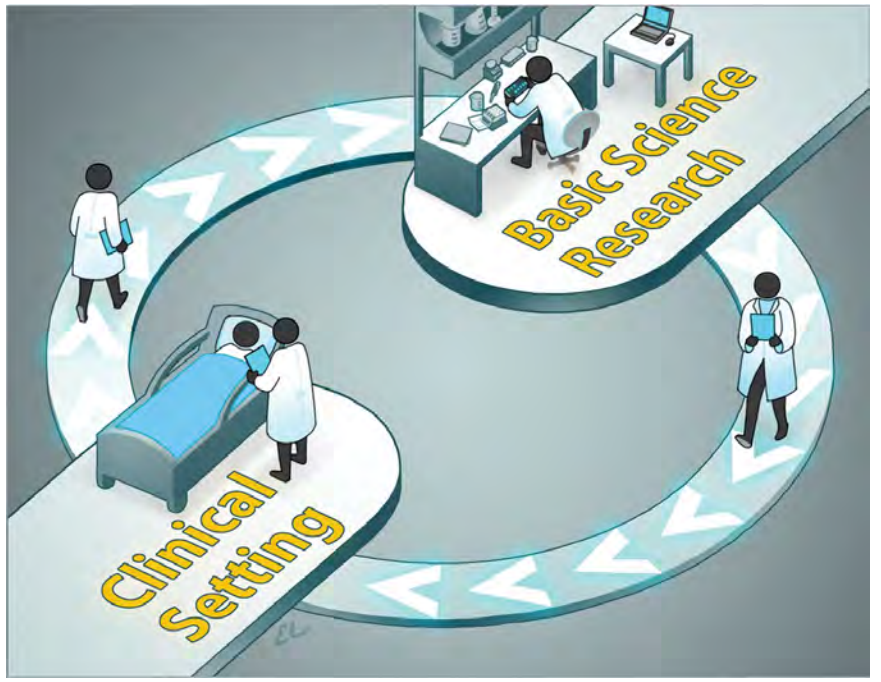
Patients and Workers from Natural and Engineered Biological Hazards

Coordinating Research Institutions with Healthcare

Need to Protect Basic Research and Clinical Application (Gene and Cell Therapies)

# BENCH TOP TO BEDSIDE

- Translational Medicine "branch of medicine that uses knowledge gained from basic scientific research to develop practical applications"
- "Repeating loop of research-base medical care, in which clinical observations stimulate research (bench), which leads back to the bedside for implementation"
  - Drug development / therapy
  - Genome sequencing technologies for accelerated diagnosis and development of new treatments
- To the community



# SAFETY ISSUES WITH CLINICAL STUDIES

<u>Infection Prevention</u>

Hand Hygiene
PPE
Sample storage
Occupational exposures
Decontamination
Waste Disposal/Spill

Injection Safety
Equipment Sterilization
HAI Surveillance

<u>Biosafety</u>

Hand Hygiene
PPE
Sample transport and preparation
Occupation exposures
Decontamination
Waste Disposal/Spill

Use of Equipment

# CLINICAL STUDIES WITH GENE THERAPY

**Human Gene Therapy**

Treatment of human genetic disorders

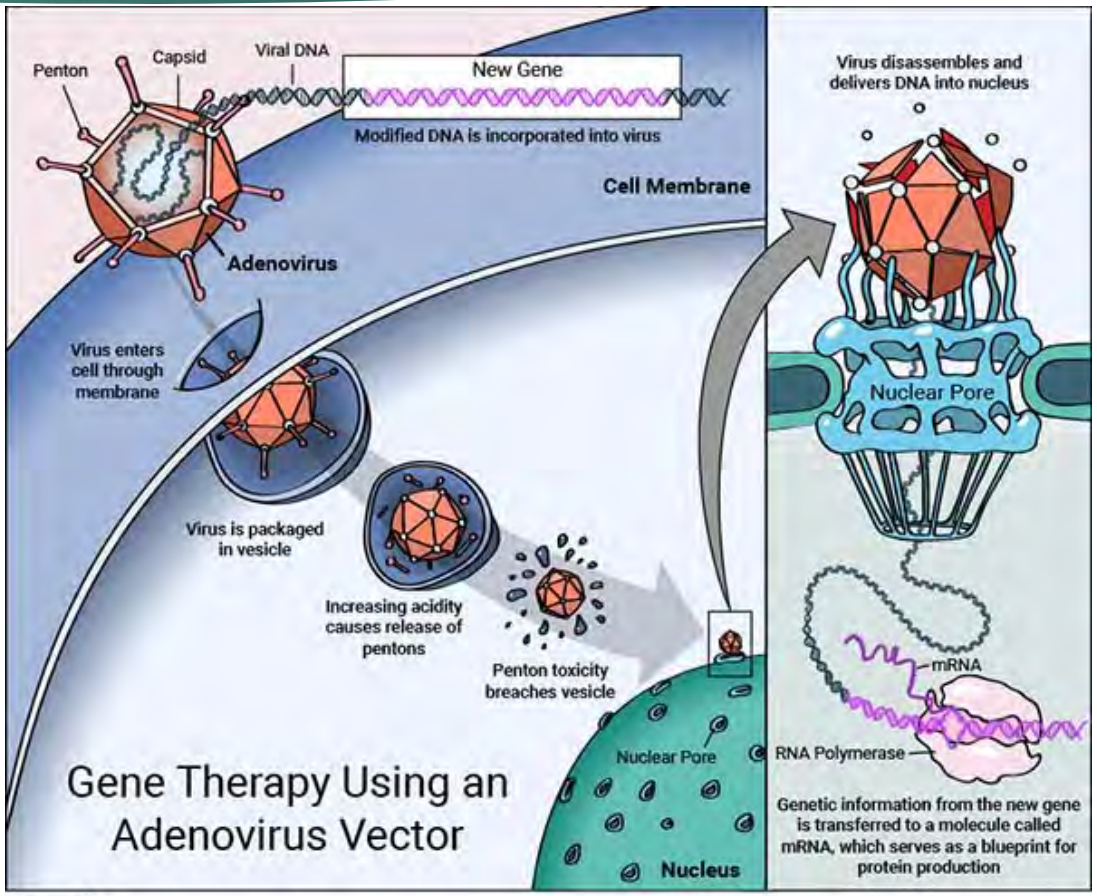
Functioning gene is inserted into a human cell to correct a genetic error or introduce a new function to the cell

Use viral vectors to transfer genes

IRB and IBC review

NIH rDNA Guidelines

FDA



# CLINICAL STUDIES WITH CELL THERAPY

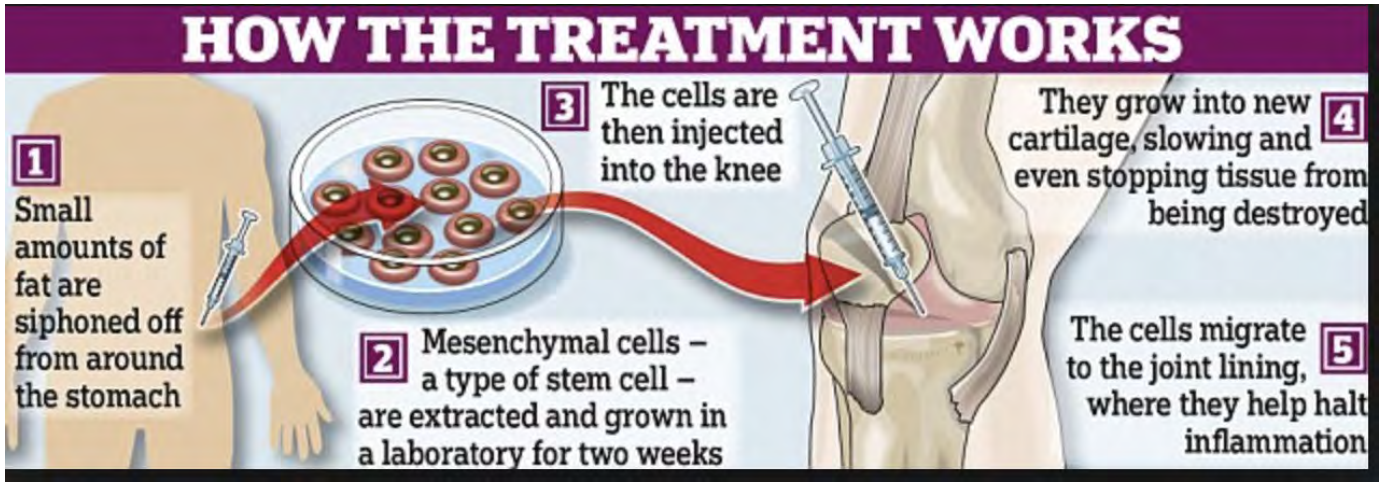
**Cellular Therapy**

Transplantation of human cells to replace or repair damaged tissue and/or cells

Stem cells

Lymphocytes

Dendritic cells




IRB and IBC review

NIH rDNA Guidelines

FDA

# CLINICAL STUDIES WITH GENE THERAPY

**Biological material used in treatment**

- Risk Group 1 – not known to cause disease in adult humans
- Risk Group 2 – cause disease which is rarely serious, treatment available
- Risk Group 3 – cause disease which is serious or lethal, treatment available

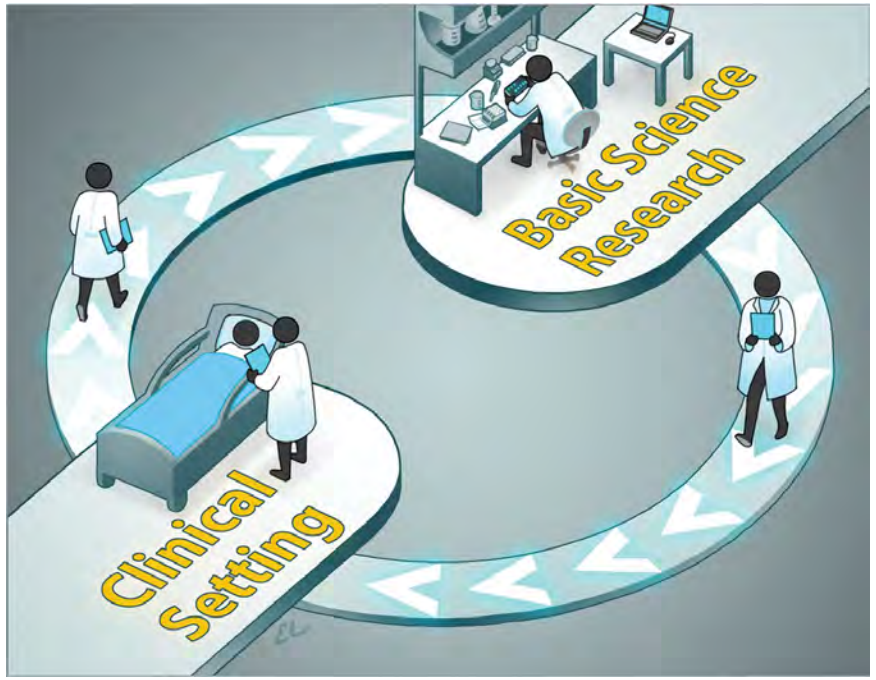
- BSL 1 – minimal potential hazard to personnel/environment
- BSL 2 – moderate hazard to personnel/environment
- BSL 3 – serious or potentially lethal

- RNA/DNA, Bacteria with rDNA
- Viral vectors
  - Adenovirus
  - Retrovirus
  - Vaccinia virus

# CLINICAL STUDIES WITH GENE THERAPY

**More risks to workers and patients**

- SOPs for healthcare staff
- Transporting from pharmacy to subject
- Risk of Shedding after treatment
- Occupational exposures

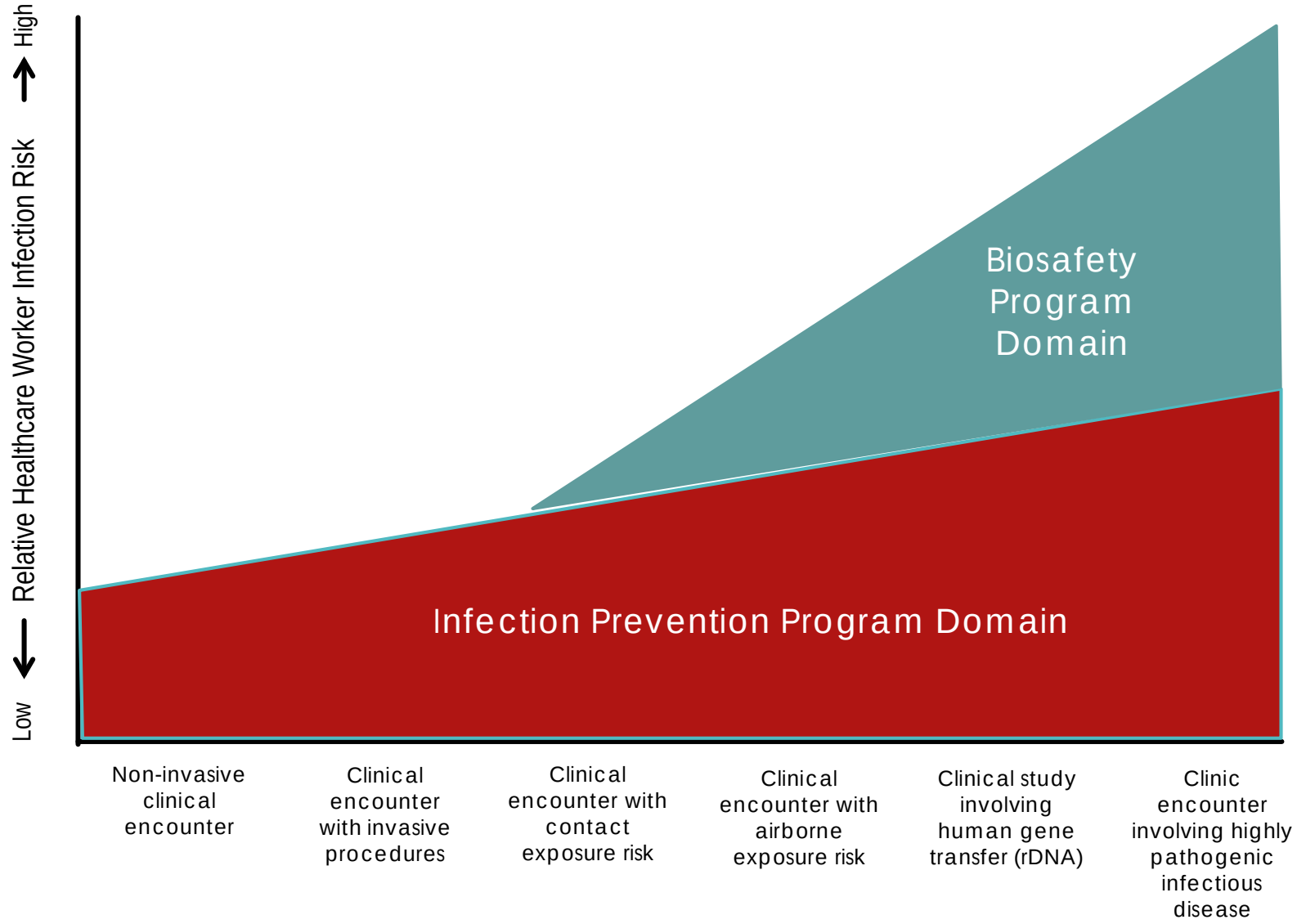



- BSL 2 facilities and training
  - Safe preparation, storage, transport, disposal
- Occupational exposures
- NIH rDNA regulations

- SOPs for pharmacy
- Sterility of product
- Cleanroom requirement
- Validation of equipment

**Joint Risk Assessment and Education**

# Relative Involvement of Infection Prevention and Biosafety Programs by Complexity of Clinical Encounter




Added issues: Additional regulations (Select Agents, rDNA) IBC review, Enhanced PPE selection and use, proper donning and doffing, specimen handling and transport, waste disposal, water releases, worker training, reporting, advanced decontamination

Typical infection prevention activities include hand hygiene, patient and medication safety, injection & sharps safety, blood / transplant safety, vaccine safety, monitoring for Healthcare Associated Infections (HAIs)

# SUMMARY

- Biological Safety ≠ Infection Prevention
- Sharing collective skills will enhance job performance & quality
- Preparedness for next outbreak of infectious disease of public health significance

# THANK YOU


UTHealth™
The University of Texas
Health Science Center at Houston