BARDA at the Intersection of AMR and Pandemic Preparedness

Mark Albrecht, PhD
Chief, Antibacterials Branch
Biomedical Advanced Research and Development Authority

PACCARB

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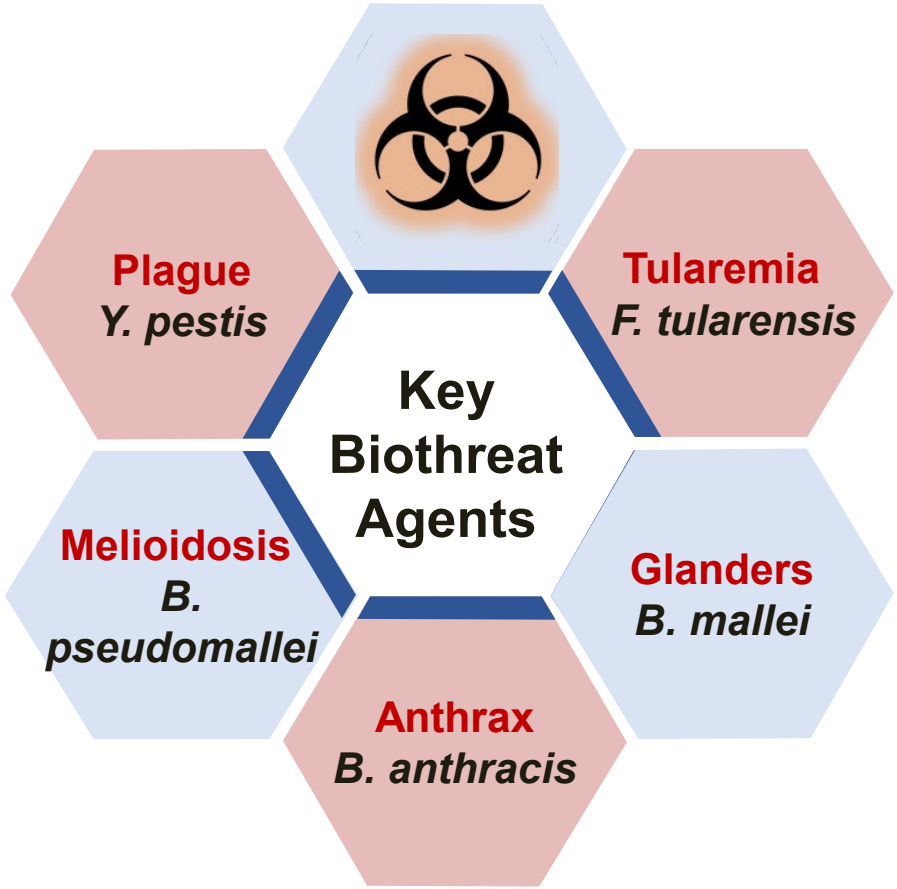
ASPR Mission

Save Lives and Protect Americans from 21st Century Health Security Threats

Bacterial Threats in Multiple Dimensions

Biothreat agents



Opportunistic and Secondary infections

Chlorine	Dyspnea	Lung injury	Opportunistic infection	Persistent infection + sepsis
Sulfur Mustard	Blistering	Cellulitis	Opportunistic infection	Systemic infection + sepsis
Burns	Blistering	Skin sloughing	Opportunistic infection	Systemic infection + sepsis
Acute Radiation	Neutropenia	Immune ablation	Poor wound healing	Systemic infection + sepsis
Anthrax	Pneumonia	Disruption of gut flora	Opportunistic infection	Persistent infection + sepsis
Influenza	Fever	Congestion	Opportunistic infection	Systemic infection + sepsis
Ebola	Fever	Vomiting / diarrhea	Bleeding	Systemic infection + sepsis
Smallpox	Fever	Extensive rash / pustules	Opportunistic infection	Systemic infection + sepsis

Co-/Secondary Bacterial Infections During Pandemics

A common complication of respiratory viral disease can be secondary bacterial infection

11%-35%

of laboratory confirmed cases of influenza exhibit bacterial co-/secondary infection (Klein 2016 Influenza Other Respir. Viruses 10, 394–403.)

Secondary bacterial pneumonia identified in

29-55%

cases of H1N1 in 2009 (CDC 2009)

1/3 to 1/2

of all deaths resulting from the 2009 H1N1 pandemic in the U.S. were caused by secondary bacterial pneumonia that was contracted by hospitalized patients

During the 1918-1919 Spanish Flu pandemic, bacterial pneumonia is estimated to have occurred in

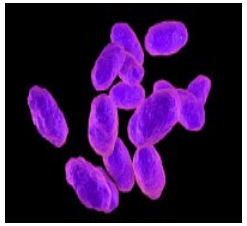
95%

of all fatal cases with many of these deaths directly attributable to a bacterial infection (Morens 2008 J. Infect. Dis. 198, 962–970)

The leading etiologic pathogens of bacterial pneumonia are:

Streptococcus pneumoniae

Staphylococcus aureus (including MRSA)



Haemophilus influenzae

The pace of drug development has not kept pace with the rate at which antimicrobial resistance is developing.

Antibiotic Resistance (AMR) causes

700,000

global deaths each year.

Common medical procedures are becoming too dangerous to undertake

May rise to

10M

deaths annually by 2050

costing

$100

trillion

THE LACK OF EFFECTIVE ANTIBACTERIALS CAN IMPEDE OUR ABILITY TO RESPOND TO ANY PUBLIC HEALTH EMERGENCY

Impact of bacterial infections on COVID-19

Emerging Infections Network (EIN)

Managed by the Infectious Diseases Society of America out of University of Iowa; funded by the CDC

IDSA Infectious Diseases Society of America

CDC Centers for Disease Control and Prevention

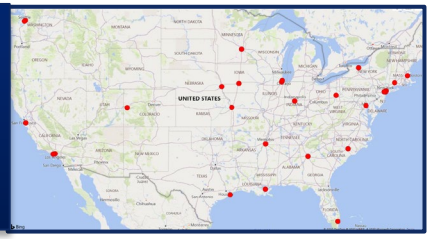
~2600 infectious disease specialists

Primarily in North America, but also global

EIN Surveys

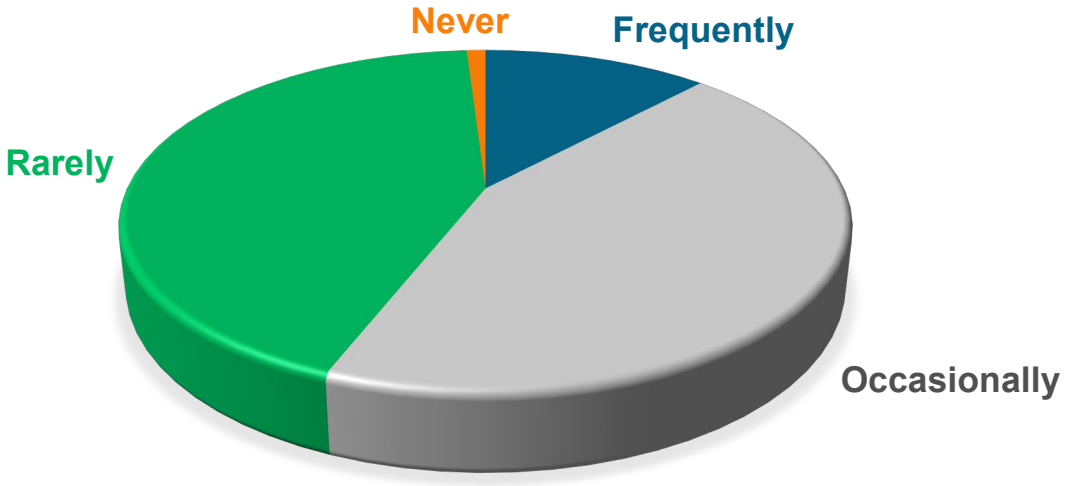
- ❑ How often are you seeing suspected superinfections in COVID-19 patients?
- ❑ Number of infections?
- ❑ Types of infections?
- ❑ Infecting pathogen?
- ❑ Use of empiric antibiotics?

38 responses from U.S. (red dots), Mexico and India



COVID-19: An Ongoing Case-Study

OCCURRENCE OF SUPERINFECTIONS

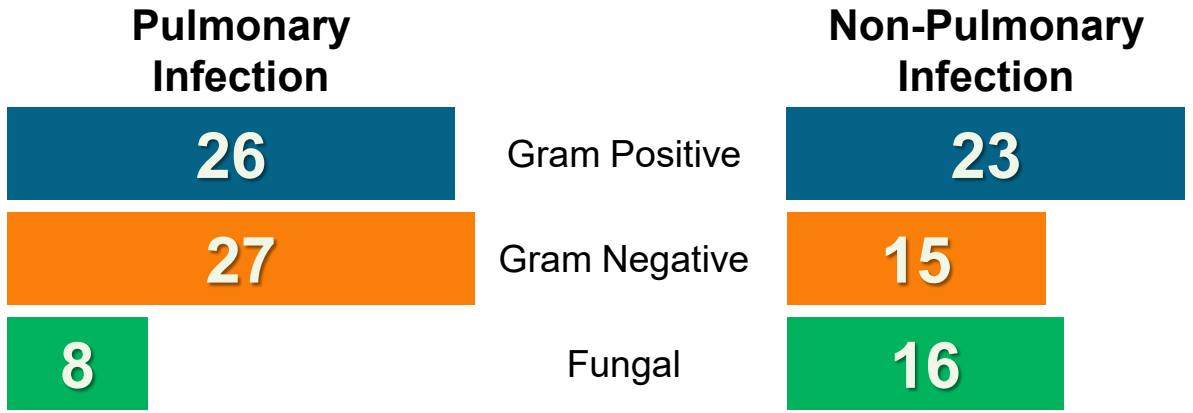


Survey Responses = 212

50%
of responses stated ICU admission was the trigger for empiric antibiotics

76%
of responses stated superinfections were diagnosed when patients were receiving mechanical ventilation

INFECTING PATHOGEN



Types of Infections	Major Pathogens (*Pulmonary & Non-pulmonary infections*)		
VAP CLABSI CAUTI	*P. aeruginosa* *S. aureus* - MRSA	*Klebsiella* *Candida*	*E. coli* *Aspergillus*

Challenges Caused by the COVID-19 Pandemic

Most of our funded Phase 3 studies are paused and/or sites are temporarily closed

Manufacturing facilities are closed

Resources for manufacturing and supplies for clinical trial conduct are limited due to clinical demand

Study and manufacturing costs are increasing

Bacterial MCM Program

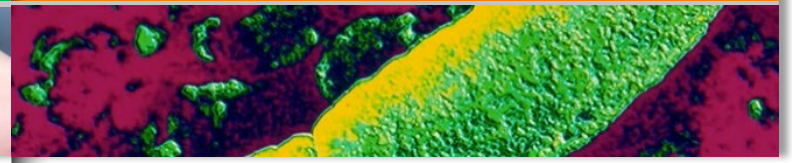
MISSION

Reduce the morbidity and mortality caused by a biothreat or antimicrobial resistant (AMR) infection following a mass casualty event or a disease outbreak

STRATEGY

Revitalize and incentivize the antimicrobial pipeline through innovative public-private partnerships

PRIORITIES



Invest in new types of antimicrobials and products that target both MDR pathogens and bioterrorism infections

Incentivizing and Catalyzing Antibiotic Development

BARDA will continue to leverage its unique authorities to provide innovative business tools that support end-to-end product development, from the earliest stages under CARB-X to commercial procurement via PBS, while at the same time exploring technical solutions to the challenges facing the commercial market.

How to Contact BARDA

medicalcountermeasures.gov

Portal to BARDA: ***Register to request a TechWatch meeting!***

beta.sam.gov/

Official announcements and info for all government contract solicitations

phe.gov/BARDA

Program description, information, news, announcements

drive.hhs.gov

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