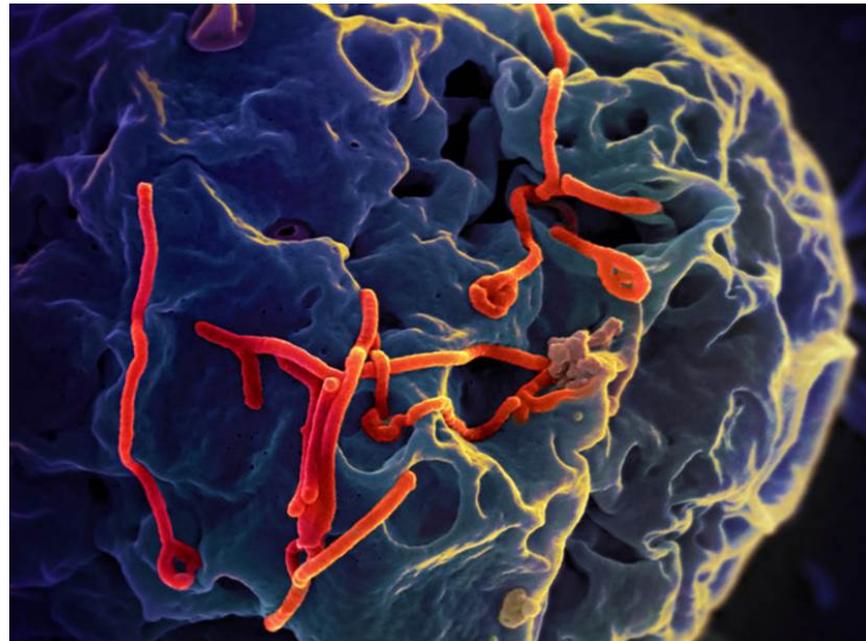




# **BARDA's Response to the Ebola Epidemic in West Africa**

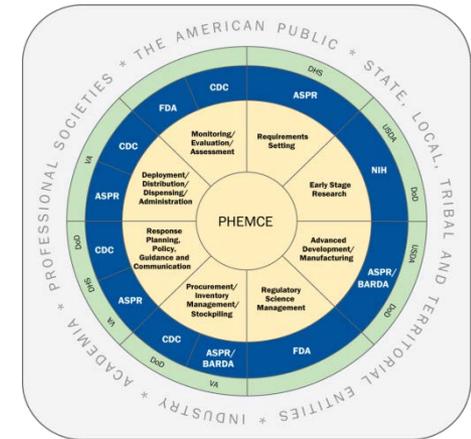


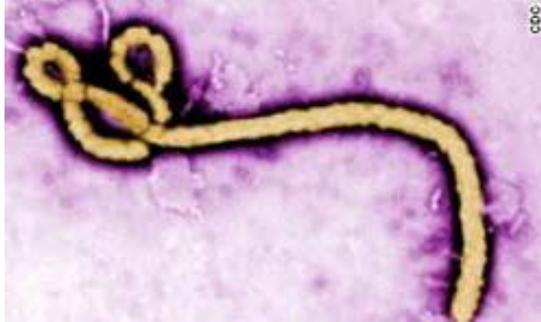


# This is a PHEMCE and USG Response

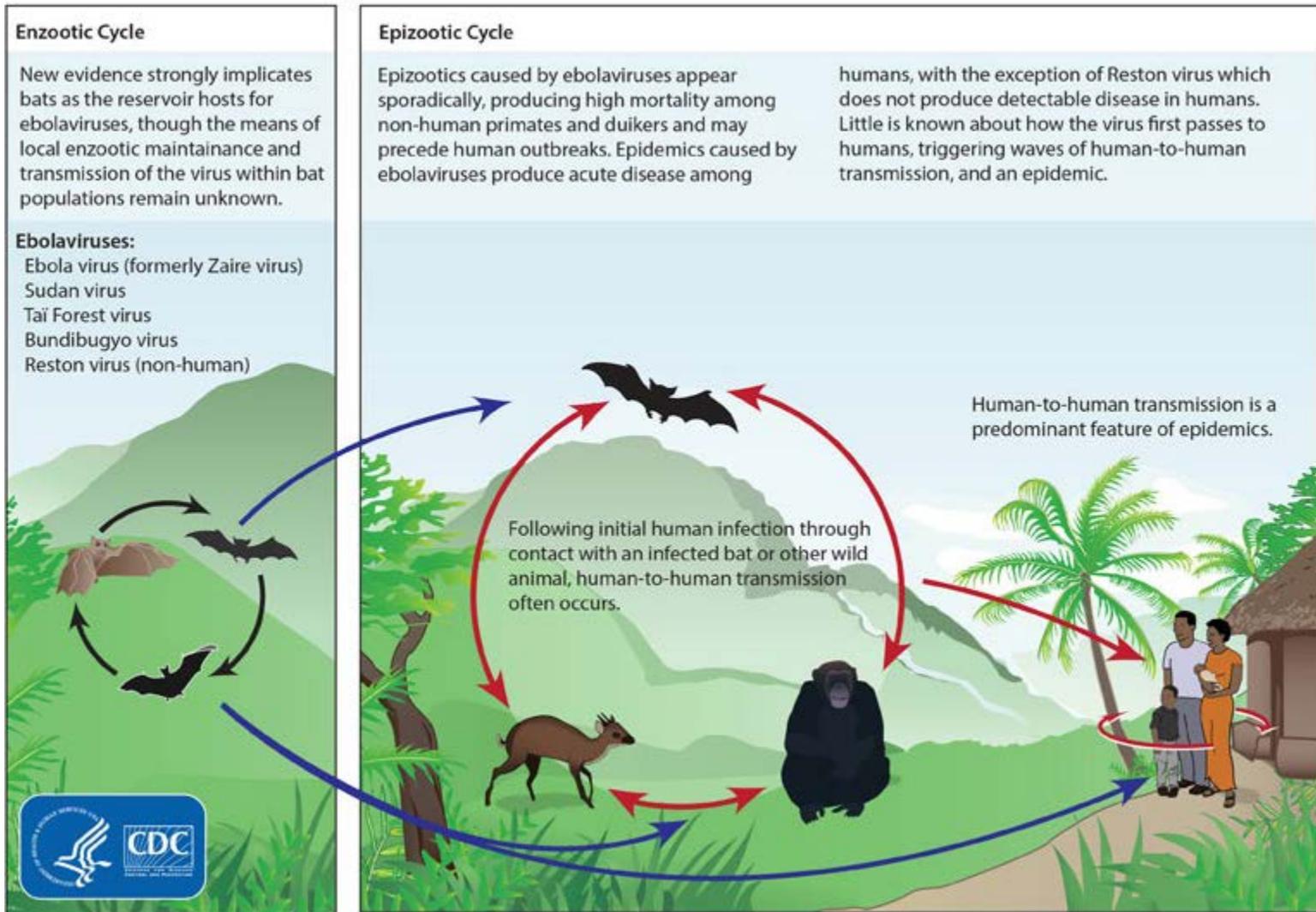


- ASPR – Lead for PHEMCE activities and interactions with International Organizations
  - OEM – Lead for SOC activities
- CDC – Providing support for epidemiology, surveillance, and infection control
- FDA – Expediting review of INDs
- USAID – Supplies and medical personnel
- OPP – Coordinating activities with international partners
- NIH – Development of vaccines and therapeutics and clinical trials
- DoD – Development of vaccines and therapeutics, clinical trials, deploying mobile field hospitals
- BARDA – Development of therapeutics and vaccines
  - Programs will potentially transition to BARDA
  - Support activities for Phase 2 studies and other uses of candidate products (expanded access)
  - Coordinate use of CIADMs and Fill/Finish Network to assist developers

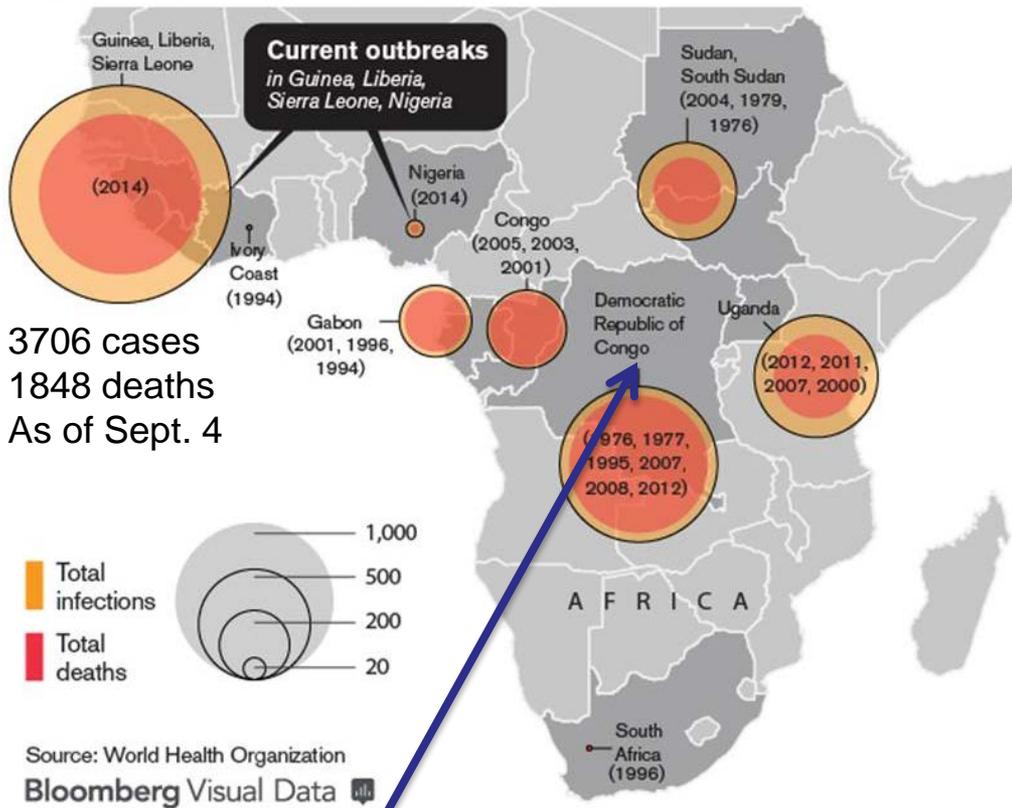


- Ebola virus belongs to the family *Filoviridae*
  - Five identified subspecies
    - Ebola virus (formally Zaire)
    - Sudan
    - Tai Forest
    - Bundibugyo
    - Reston
- Known to cause disease in humans
- 
- Enveloped virus containing non-segmented, negative strand, RNA genome
  - Symptoms appear 2 – 21 days after exposure, 8 – 10 days most common
    - Fever, severe headache, muscle pain, weakness, diarrhea, vomiting
  - Advanced disease includes gastrointestinal bleeding, rash, and coagulation abnormalities
  - Death attributed to diffuse internal bleeding and hypotensive shock
  - There currently are no licensed/approved vaccines or treatments for Ebola

# Ebola Virus Ecology



# Ebola Virus Outbreaks in Africa Historic and Current



Unrelated Outbreak  
 In DRC  
 62 cases as of Sept 10



# Providing Care Under Extreme Conditions





# Vaccines Under Development



- Due to the urgency, the FDA is expediting review of INDs to allow for evaluation in Phase 1 studies
- Vaccine Research Center (NIH) and GSK – ChimpAd3 vector vaccine
  - Currently in Phase 1 – bivalent vaccine (Zaire and Sudan) NIH
  - Currently in Phase 1 – monovalent (Zaire) UK
  - Additional monovalent vaccine being manufactured (Zaire)
- Newlink Genetics and Public Health Agency Canada – rVSV vector vaccine
  - Phase 1 to start in September – WRAIR (18-50yrs of age)
  - Phase 1 being planned at NIH – include patients above the age of 50
  - Phase 1 being discussed at NIH – HIV+ individuals
  - PHAC has pledged 800 doses to WHO
- Programs will potentially transition to BARDA to support scale-up of manufacturing to support Phase 2 studies and other uses such as expanded access
  - BARDA is also working with manufacturers to offer assistance under the Fill/Finish Network



# ZMapp™ – The “Secret Serum”



- ASPR/BARDA awarded a contract to Mapp Biopharmaceutical (San Diego, CA) on September 2 for manufacturing new lots of product
- ZMapp is a combination of 3 monoclonal antibodies that bind to the glycoprotein of Ebola virus (100% Survival NHP 5 dpi)
- ZMapp is manufactured in tobacco plants
- ZMapp has been administered to 6 individuals
  - 2 US Citizens evacuated to US
  - 1 Spanish citizen – 1 dose of 3
  - 3 individuals in Liberia
- BARDA is collaborating with DTRA and NIAID
  - BARDA will perform all manufacturing
  - DTRA – non-clinical study evaluating dose
  - NIAID – IND enabling tox and TXR and potential Phase 1
- BARDA is evaluating alternatives to increase manufacturing capacity, both short- and long-term
  - Additional tobacco plant CMOs
  - Large scale production using cell culture





# Additional Therapeutics Under Development



- FDA has, or is, meeting with sponsors to discuss IND enabling studies and potential use of their products
- BioCryst – BCX4430 – adenosine analog
  - Has been evaluated for efficacy in NHP for Marburg
  - Evaluation in NHP for Ebola at USAMRIID
- Tekmira – TKM-Ebola – siRNA
  - Completed Phase 1 SAD, was placed on Clinical hold, revised to partial clinical hold to allow for administration to individuals infected with Ebola
  - Treatment courses sent to Emory, UK, Germany and France
- Medivector – T-705 – RNA polymerase inhibitor
  - Currently in 2, Phase 3 studies for Influenza
  - Being evaluated in NHP for Ebola at USAMRIID
  - Japan has donated 20,000 treatment courses to WHO
- BARDA is currently working with our PHEMCE partners to determine how BARDA can assist in manufacturing and/or development of candidate products

# Thank You

- ASPR Leadership
- PHEMCE partners
- BARDA Leadership
- AMCG
- BARDA Team
  - CBRN
  - MFE
  - Regulatory
  - Clinical
  - Influenza
  - DMD
  - SST
  - ADS – Lead for modeling efforts across the USG and with International partners

