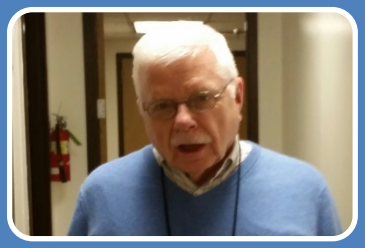
Ebola in Dallas County 2014

Disclaimer

- The intent is to provide the perspective of DCHHS's response to the Ebola cases in Dallas County.
- The steps taken where deemed essential at the time based upon the input of stakeholders involved
- Attempting to recreate the guidance provided should involve a fair risk assessment to assess the appropriate support needed by internal and external stakeholders
- Any omissions or misrepresentation of those involved is not meant to personally discredit or belittle one's efforts.

The DCHHS Players

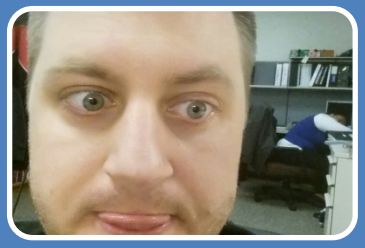


Dr. Bannister

- Laboratory Director / RO
- “I’ll smile when I’m retired”

Joey Stringer

- General Laboratory Manager / ARO
- “This presentation is dumb and longwinded”



Derek Orbach

- Microbiologist
- Maybe you could make a slide so that people stop calling me Blake with something that proves Samira actually exists…

Samira Peyrovi

Do I even exist?

In the Beginning

- Dallas County had forwarded CDC guidance and composed several emails to the community recognizing the need for Sentinel Laboratories to prepare for a possible Ebola case.
- Health Alerts for EV-D68 and Legionella were disseminated on 9/25/2014.
- Chikungunya was considered the pending emerging disease threat.
- The were no available funds to be drawn from until Oct. 6th when the general laboratory budget would be dispensed.

The First Call

- On Sunday, 9/27/2014 the Chief Epidemiologist contacted the laboratory in the evening asking us to ship a specimen
- On Monday the two specimens were packaged at the Presby laboratory and dropped off at DCHHS
- They were sent Category A in a STP 310 insulated box.

Stages of Response

- Provide Support and Guidance to Presby
- Expedite the testing of Specimens
- Provide guidance and consultations to Dallas County Sentinels as a whole
- Acquire PPE, assay and guidance for DCHHS testing development
- Implement a testing workflow among internal staff
- Communicate with an extensive network of internal and external stakeholders

Follow up visits to Presby

- They had a negative air pressure room with a BSC, autoclave and PPE procedures that were reviewed and appeared suitable.
- Explained in the long run what DSAT would like to see reported on a form 4
- Since they were relatively un-initiated in this process and the cultural confirmation was pending we destroyed or shipped all suspected Category A agents to CDC
- We then suggested they keep records of all specimens and a COC.

Information Exchange

- Lots of Emails, Phone Calls and questions from Sentinels
- Seemed random at first but hospitals began to standardize their approach to being prepared
- With the many correspondence within the first week a better conceptualized framework arose
- We then tried to consolidate all generally asked questions to provide information to our sentinels

Pathogenesis of Ebola

- Ebola virus spreads from the initial site of infection via monocytes and dendritic cells to lymph nodes (likely via the lymphatics) and to the liver and spleen (via blood). At these sites, the virus infects tissue macrophages, dendritic cells, and fibroblastic reticular cells.
- A series of events then occur that lead to virus-induced immunosuppression and apoptosis of T lymphocytes. As the disease progresses, apoptosis of natural killer cells also occurs, which limits the innate immune response.
- Unchecked viral replication then leads to increased levels of additional pro-inflammatory cytokines, chemokines, and possibly other mediators, which cause vascular impairment and trigger the coagulation cascade, ultimately leading to DIC.
- DIC then results in hemorrhagic shock, failure of multiple organs, and death.

Risk Assessment for EVD

Within 21 days before symptom onset:

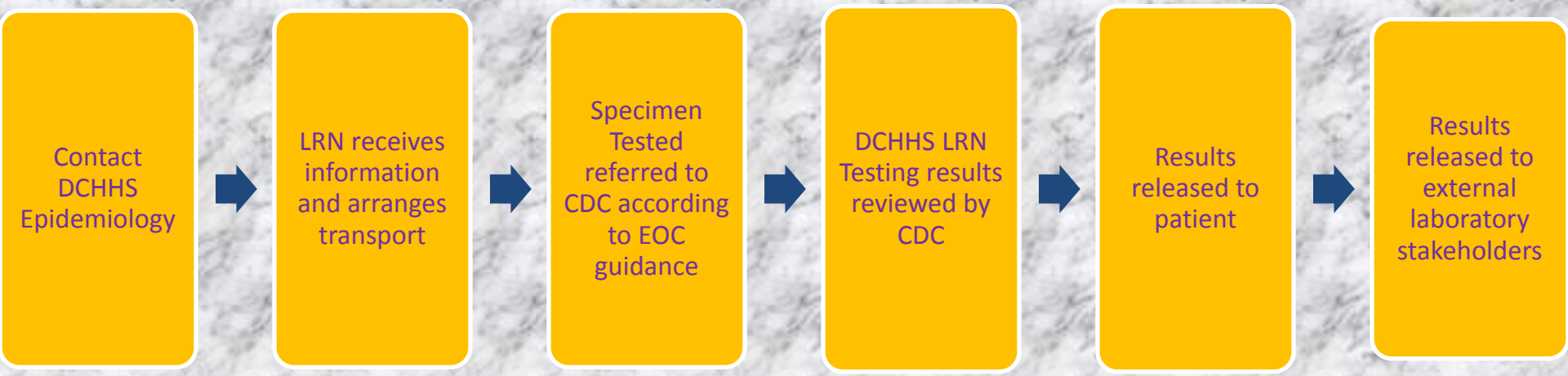
High Risk Exposure	Low Risk Exposure	No Known Exposure
Percutaneous or mucous membrane exposure or direct skin contact with body fluids of an EVD patient without appropriate personal protective equipment (PPE) **OR**	Patient care or other close contact (without high-risk exposure) with EVD patients in healthcare facilities or community settings of outbreak affected countries **OR**	Persons who had residence in (or travel to) an EVD outbreak-affected area in the last 21 days **WITHOUT** high- or low-risk exposures
Processing body fluids of confirmed EVD cases without appropriate PPE or standard biosafety precautions **OR**	Household contact with an EVD patient **OR**	
Contact with a dead body without appropriate PPE in a country where an EVD outbreak is occurring	Direct handling of bats, rodents, or primates or raw bushmeat from disease-endemic areas	

Clinical Presentation

Immediately report/consult DCHHS if High Risk or Low Risk exposures are identified, regardless of symptoms: 214-819-2004 or 877-605-2660.

High Risk Exposure	Low Risk Exposure	No Known Exposure
With or Without Fever (≥101.5°F (38.6°C)	Fever (≥101.5°F (38.6°C)	Fever (≥101.5°F (38.6°C)
Compatible symptoms: severe headache, muscle pain, vomiting, diarrhea, abdominal pain, **or** unexplained hemorrhage **AND**	Compatible symptoms: severe headache, muscle pain, vomiting, diarrhea, abdominal pain, **or** unexplained hemorrhage **AND**	Compatible symptoms: severe headache, muscle pain, vomiting, diarrhea, abdominal pain, **or** unexplained hemorrhage **AND**
Unknown or abnormal blood work including: thrombocytopenia <150,000 cells/µL **AND/OR** elevated hepatic transaminases	Unknown or abnormal blood work including: thrombocytopenia <150,000 cells/µL **AND/OR** elevated hepatic transaminases	Unknown or abnormal blood work including: thrombocytopenia <150,000 cells/µL **AND/OR** elevated hepatic transaminases
		And No Alternate Diagnosis

Referral Testing



- PUI meets testing criteria Epi contacts CDC EOC 770 488 7100
- Epidemiology refers sample to LRN – Transport is arranged
- Perform test and confer with CDC for results submission, ship specimen overnight
- Release results to patient
- Release results to external stakeholders
- Autoclave wastes

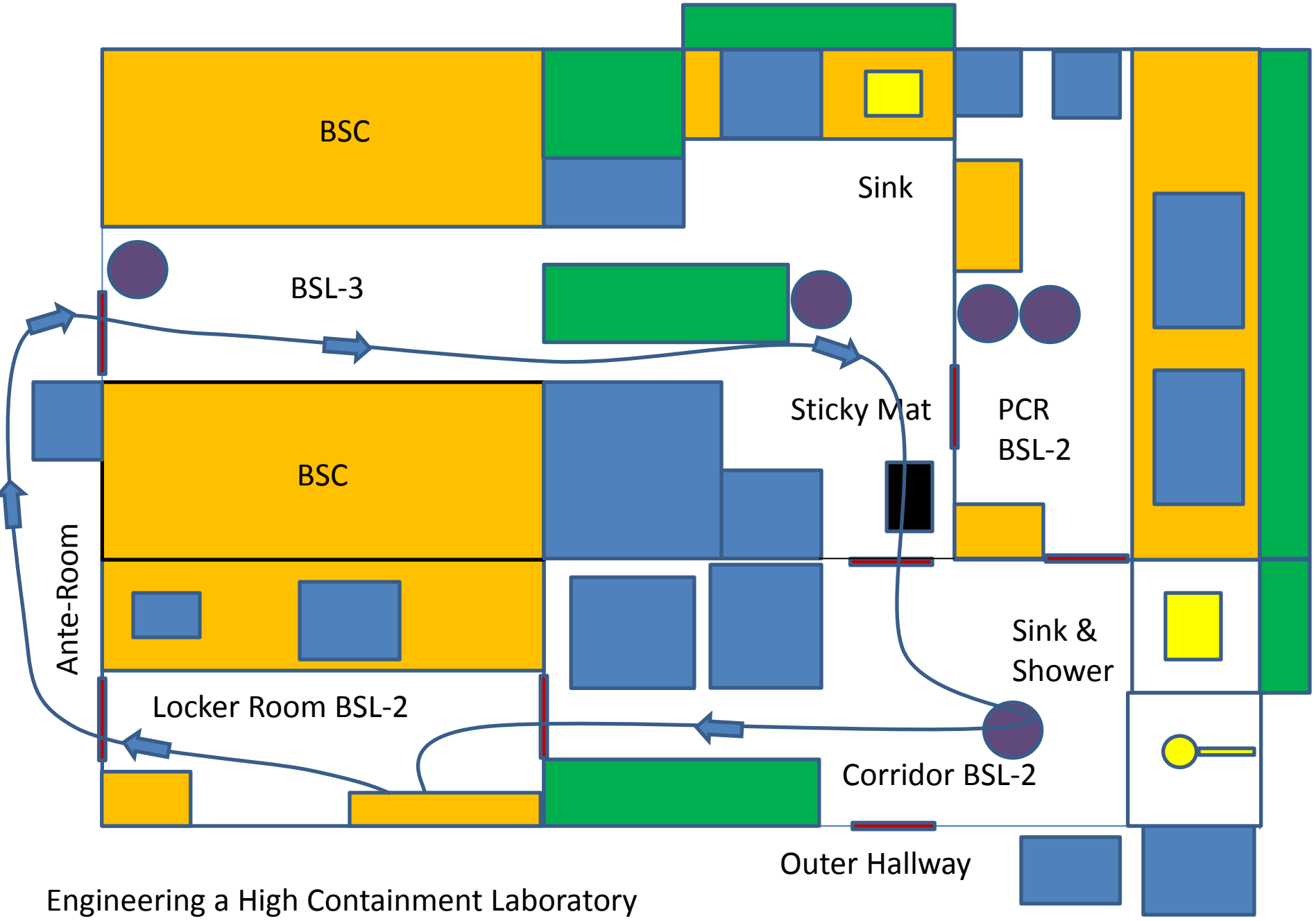
Select Agent Laboratory Safety

- **Engineering Controls** – Isolated Laboratory, Locker room, at least two levels of bio-containment, External Exhaust BSC, Covered Bucket Rotors, Limited Use of Glassware, Scissors, Scalpels and automated aerosol producing equipment

- **Management Controls** – Specific operation programs, train, outfit and provide acceptable Safety Controls in the execution of Ebola diagnostics utilizing dedicated resources when possible.

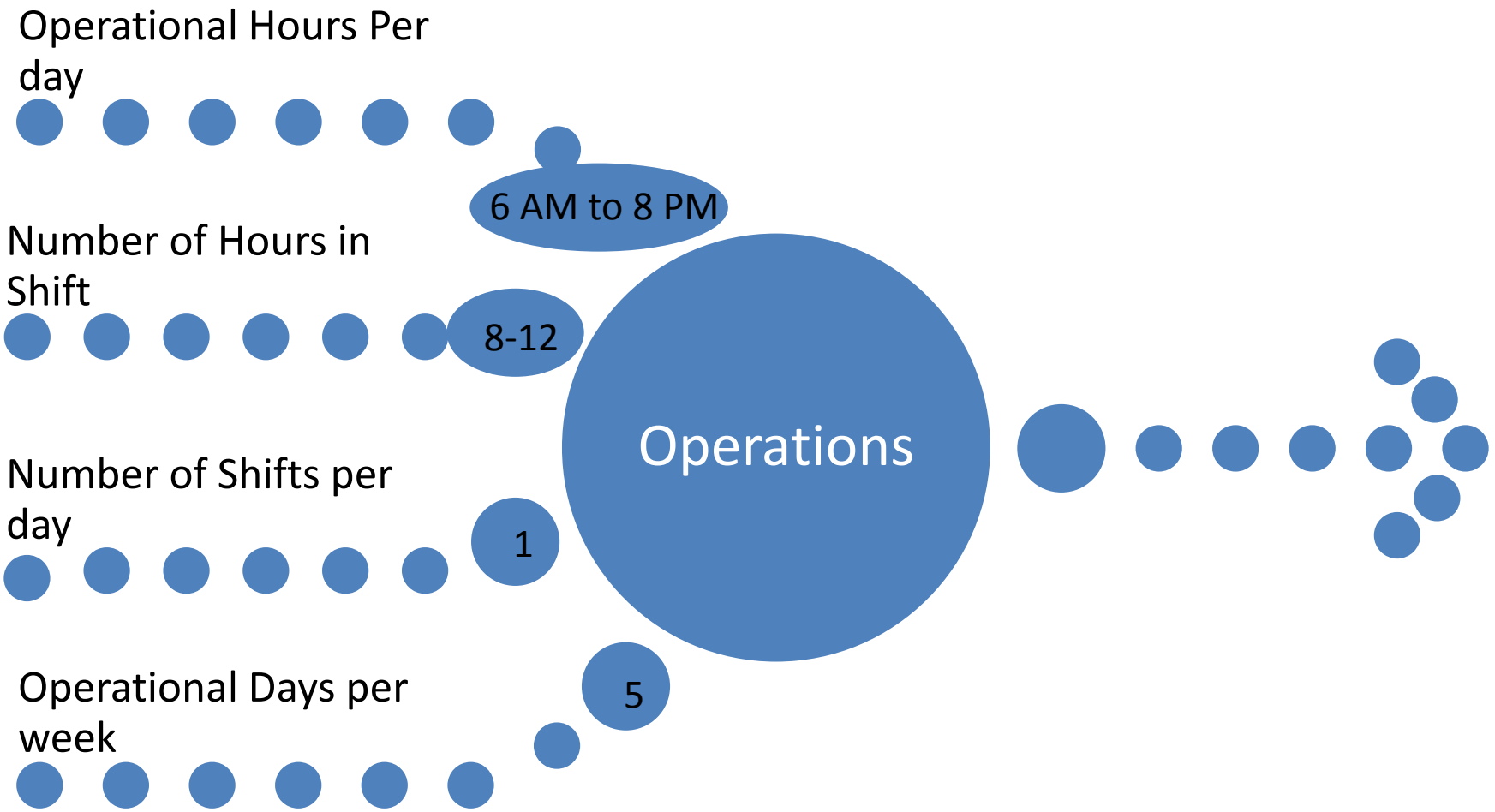
- **PPE** – Wrap around gowns, double gloves, N-95 respirators, face shields, Laboratory Goggles, Booties / leggings, Tyvek suits, PAPRS etc…

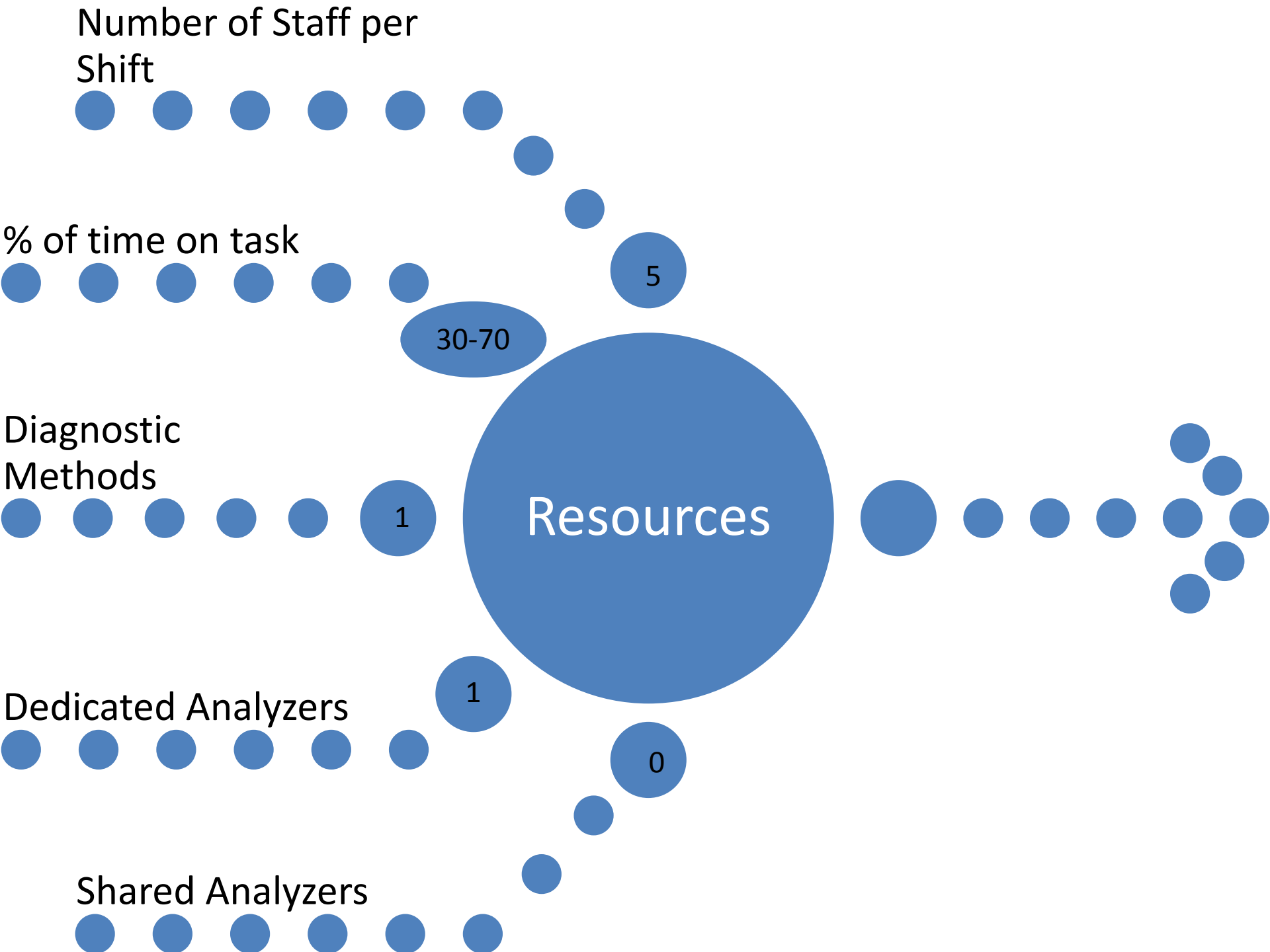
- **Standard Operating Procedures** – Don Doff procedures, Specimen Transport procedures, Log-in procedures, BSC procedures, Retain procedures, Biosecurity procedures, Documentation, Referral Packing and Shipping procedures, Results Submission



Engineering a High Containment Laboratory

Managerial Controls




Number of Staff per Shift
5
% of time on task
30-70
Diagnostic Methods
1
Resources
Dedicated Analyzers
1
0
Shared Analyzers

Preparing High Containment Infrastructures

- Three Hospitals were designated as Ebola treatment hospitals in Dallas
- Site visits were conducted to consult on high containment strategies
- Both patient rooms, wards and laboratory space were assessed
- In most cases general laboratory was overlooked as an essential engineered aspect

First Responders & Medical Examiner

- Ambulance and the pre-screening process
- Environmental or Laboratory PPE for PD
- Law Enforcement and terrorist acts
- The ME's office was less than thrilled in being asked to perform an Autopsy on a body within there 21 days

Moving into a diagnostic Role

- Initial email in first week
- Directors request
- Forwarding of email to Director and request sent to CDC Director
- CDC contacts laboratory and tentatively schedules validation
- Notified the Community of our intent
- Risk assessment and resource grab
- Testing Controls and SOP presented to LRN personnel

Specimen Receiving

- Specimen arrives, a risk assessment is performed concerning the package
- The receiving technician requires courier to sign chain of custody and signs themselves
- Specimen is carried back to laboratory according to risk assessment
- Technicians places specimen outside BSL-3 on cart
- Technician sends email confirming receipt of specimen

Specimen Log-in

- Dissemination of an Updated LRN Submission Form
- Name, Birthdate, Date of Collection, Ordering Physician, Fax Number, Date of Onset, Symptoms
- CDC form 50-34
- CDC Viral Special Pathogens Bench Form (VSPB)
- CDC 50-34 and VSPB will be placed in the Shipper and faxed/emailed to CDC

BSL-3 Entry Order

- BSC Technician will be supervised while donning and enter BSL-3 first
- BSC technician will set up extraction procedures
- The BSC technician will assure laboratory is free of clutter, trash is removed, equipment is turned on, attain sample passed through from outside the BSL-3.
- BSC assistant will DON second
- Once under the hood:

Documenter

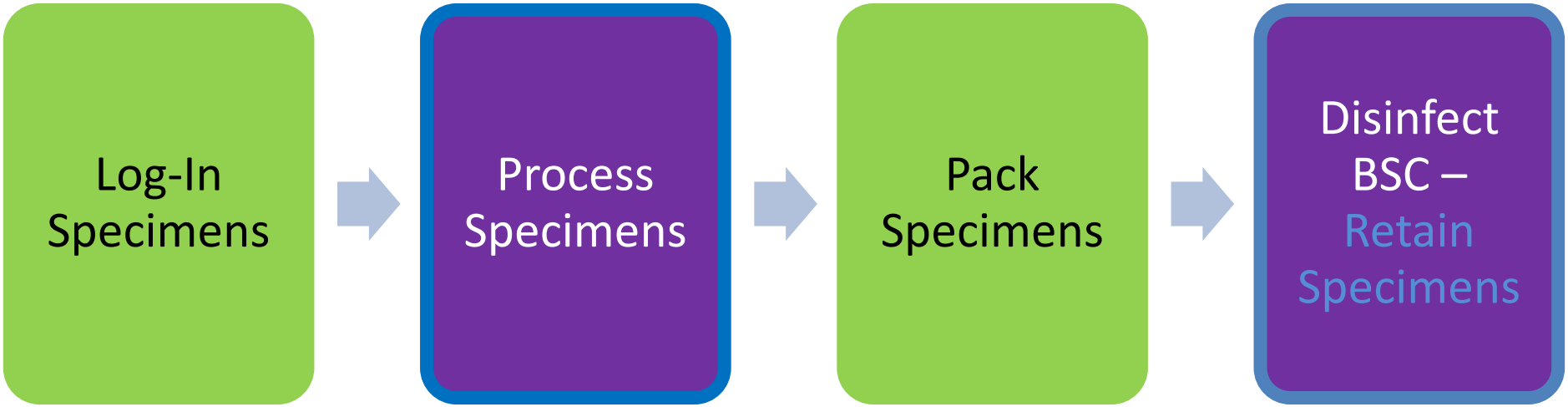
- Assist in Donning & Doffing
- Manage paperwork
- Prepare package for shipment

BSC Technician

- Set Up Hood
- Process & Split Specimens in BSC
- Bag up Trash and Specimen in BSC

BSC Assistant

- Communicate & Lend Assistance
- Transport Specimens outside the BSC
- Monitor safety of BSC Technician



- Specimens will be removed and acceptability assessed
- Specimen Canisters shall be Decontaminated and passed out of hood, the assistant will receive it with another Dispatch wipe to be placed in shipper or retain fridge

PCR Procedures

- Make labels for reagents
- Stick labels on tubes for reagents
- Aliquot Reagents
- Store Reagents in PCR room
- Prepare Calculations
- Monitor available inventory for testing
- Prepare master mix, change gloves and coat, load template, run test
- Decontaminate hoods 10% bleach for 15 min followed by alcohol
- Communicate end time and assure Results Approval
- Contact Luis Lowe or CDC EOC when results are approved

Waste Disposal

- A two person team will be prepared to destroy laboratory wastes upon the acceptability of test results
- Two teams consisting of both a supervisor and junior personnel will oversee and be responsible for either waste disposal or results review
- Waste Disposal will DON wrap arounds, Booties, Face Shields, N-95 masks, and double gloves
- Wastes will be autoclaved
- Doffing procedures will be performed in the BT BSL-3
- Another autoclave run will be performed to sterilize PPE used for waste removal
- General BSL-3 PPE may be worn on second run based upon a risk assessment

Points of Interest

- Error-Proofing
- Limit Specimens
- Limit Excess Motion in isolation
- Limit Excess Movement of Materials in isolation
- Assure Efficiency of Time
- Assure availability of Inventory and equipment
- Prevent Excess Processing and Testing

Personal Protective Equipment

- For Laboratorians in High Containment Situations

  Disposable Scrubs

  Laboratory Shoes

  Impermeable wrap around gowns

  Or Tyvek Suits (1-2 sizes larger than coats)

  Thick Nitrile Gloves at least 12” length and tape

  Fit tested and approved N-95 Mask

  Or PAPR with hood

  Goggles

  Faceshield

  Booties or Leggings and tape

  Plastic Aprons

Documenter

- [ ] Disposable Scrubs
- [ ] Impermeable Wrap Around Gown
- [ ] 12” Gloves
- [ ] Fit Tested and Approved N-95 Mask
- [ ] Face Shield / Goggles
- [ ] Booties / Leggings

BSC Technician

- [ ] Disposable Scrubs
- [ ] Laboratory Shoes
- [ ] Tyvek Suit
- [ ] 12”Taped and Triple Gloved
- [ ] Plastic Apron
- [ ] PAPR, Hood, and Belted Charged Battery Pack
- [ ] Booties

BSC Assistant

- [ ] Disposable Scrubs
- [ ] Laboratory Shoes
- [ ] Tyvek Suit
- [ ] 12”Taped and Triple Gloved
- [ ] Plastic Apron
- [ ] PAPR, Hood, and Belted Charged Battery Pack
- [ ] Booties

Standard Operating Procedures

- Donning & Doffing
- Spill Clean Up
- Needle Stick
- Procedural Notes
- Packing and Shipping

Laboratory Donning W/O Tyvek

- Donning
  - Check Gauges & Sign In
  - Enter Locker Room
  - Stow all personals
  - Get undressed
  - Don Disposable Scrubs
  - Enter Ante-Room
  - Don Wrap Around Gown
  - Don first pair of Gloves inside out and over cuff of Gown
  - Tape Gloves to Gown
  - Don second Pair of gloves
  - Don N-95 Mask
  - Don goggles or face shield
  - Don booties or leggings
  - Check Gauges
  - Enter Laboratory

Laboratory Doffing W/O Tyvek

- Doffing
  - Doff outer pair of glove at the completion of tasks
  - Position one's self in the Dirty exit area
  - Doff one booty while stepping onto a clean sticky mat
  - Doff the second booty now positioning oneself entirely in the clean exit area
  - Spray disinfectant over inner glove and Doff tape
  - Untie, peel away from the inside, roll down, and dispose of the wrap around gown
  - Spray disinfectant over gloves
  - Exit laboratory into corridor
  - Remove goggles / face shield, do not touch the front, dispose of or bag up for autoclave
  - Remove and dispose of mask, do not touch front of mask
  - Doff inner gloves
  - Wash hands
  - Enter Locker Room
  - Dispose of Scrubs
  - Get dressed
  - Collect personal belongings
  - Sign out

Laboratory Donning with Tyvek & PAPR

- Donning
  - Check Gauges, Sign In
  - Enter Locker Room
  - Stow all personals
  - Get undressed
  - Don Disposable Scrubs
  - Don laboratory socks & shoes
  - Tape socks to scrubs
  - Don first set of gloves
  - Enter Ante-Room
  - Plug battery in to assure charge
  - Don belt and battery
  - Assemble PAPR and hood
  - Inspect Tyvek for tears
  - Don Tyvek
  - Don 2nd pair of Gloves inside out and over cuff of Gown
  - Tape Gloves to Tyvek
  - Don 3rd Pair of gloves
  - Plug PAPR into battery
  - Don PAPR
  - Zip up Tyvek
  - Tie PAPR under neck
  - Don booties
  - Don Apron
  - Check Gauges
  - Enter BSL-3 Laboratory

Laboratory Doffing with Tyvek & PAPR

- Doffing
  - Doff outer pair of glove whenever exiting the BSC
  - Don Pair of gloves
  - Doff apron
  - Disinfect gloves
  - Doff gloves
  - Move to the doffing area
  - Position one's self in the Dirty exit area
  - Doff one booty while stepping onto a clean sticky mat
  - Doff the second booty, now positioning oneself entirely in the clean exit area
  - Disinfect 2nd pair of gloves and Doff tape/glove
  - Untie, peel away from the inside, roll down, and dispose of the Tyvek
  - Disinfect gloves
  - (last pair)
  - Exit laboratory into corridor
  - Disinfect gloves
  - Doff PAPR, do not touch the front, dispose of hood, bag up PAPR for autoclave if possible
  - Disinfect gloves
  - Doff tape from socks
  - Doff last pair of gloves
  - Wash hands
  - Enter Locker Room
  - Dispose of Scrubs
  - Get dressed
  - Collect personal belongings
  - Sign out

Spill Outside the BSC

- Upon the release of Agent
  - Notify those working around you & Supervisor (if possible)
  - Assess the Span of the affected area
  - Hang signs restricting entrance
  - Doff booties & Don new ones
  - Doff outer gloves & Don new ones
  - Gather Spill Kit
  - Spread absorbent material from the outside of the spill inwards
  - Soak area with general hospital disinfectant
  - Doff booties & Don new ones
  - Doff outer gloves & Don new ones
  - Wait required amount of time according to disinfectant label
  - Collect absorbent material and any other disinfected wastes using tongs
  - Dispose of absorbent material and wastes in biohazard Tub
  - Bag up tongs for autoclave
  - Thoroughly mop area
  - Bag up mop or mop head for autoclave
  - Doff booties & Don new ones
  - Doff outer gloves & Don new ones
  - Log incident

Needle Stick

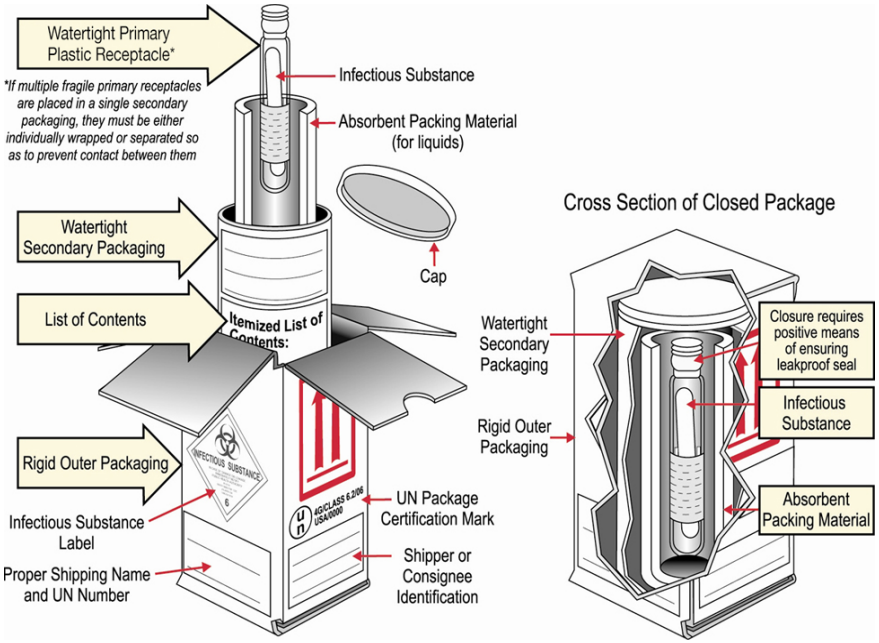
- Technician must immediately alert those around them
- If necessary secondary technicians may assist but first Doff gloves and Don new ones
  - Remove object that has caused injury in BSC
  - Carefully remove glove and dispose of in bio-hazardous waste bin
  - Express wound under running water for 15 minutes
  - Wash wound with antiviral soap
  - Apply first aid
  - Report incident
  - Self-monitor twice daily for fever and other symptoms for 21 days from exposure or until Ebola is ruled out
  - Seek medical evaluation at first sign of illness
  - Expedite Ebola testing by contacting CDC & LRN
  - Follow internal protocols for Needle Stick evaluation

Procedural Notes

- Specimens must always be transported outside the BSC in a secondary container
- Do not work under the BSC without external assistance
- Do disinfect the BSC before and after every use and provide a bucket of 50% bleach for all wastes
- Do not allow TRIsol LS to mix with Bleach
- Documenting Patient name, birthdate, Collection Date, size / additive of collection tube, and final volume in ml on the appropriate retain form
- When finished autoclaving do copy the autoclave log and keep copy as proof of destruction for positive samples

Packing and Shipping

- Permission must be granted through CDC
- CDC Form 50-34 VSPB must be completed
- Paperwork must be submitted in the shipper
- Saf-T-Pak STP 300
- Saf-T-PAK STP 310
- 4ml Whole Blood in Plastic tube
- On dry ice or Cold Packs
- Always in a Hard Canister



A moving Scenario

- Initial specimen was sent as a suspected category A agent – No problem
- Lost in the crowd was challenged by shipping agencies
- Diagnostic specimens were sent Category B
- DSHS requested all specimens be shipped Category A
- Specimens were driven in Category A, IATA labeled STP 300's
- After referring the community to the utility of these boxes – STP ran out of inventory
- Took up the STP 310 with the STP 100 overpack
- CDC requested only positive specimens be shipped
- Dallas County rewrote our protocol
- CDC would have to handle there shipping

Result Submission

- Done by a Supervisor
- Do not put names of patients in emails
- Do notify Patient first
- Do report Presumptive Positive
- Email reporting
  - DCHHS, Lab, epi, Medical Authority, Director, Assistant Directors
  - DSHS Lab, epi
  - CDC, lab

Additional Sites

http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

http://www.cdc.gov/vhf/ebola/pdf/ebola-lab-guidance.pdf

http://www.cdc.gov/vhf/ebola/hcp/guidance-safe-handling-human-remains-ebola-patients-us-hospitals-mortuaries.html

http://www.cdc.gov/vhf/ebola/hcp/select-agent-regulations.html

CDC Ebola Case Definition

http://www.cdc.gov/vhf/ebola/hcp/case-definition.html

Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Patients with Suspected Infection with Ebola Virus Disease

http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html

Monitoring and Movement recommendations

http://www.cdc.gov/vhf/ebola/hcp/monitoring-and-movement-of-persons-with-exposure.html

Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Hemorrhagic Fever in U.S. Hospitals

http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html

Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus

http://www.cdc.gov/vhf/ebola/hcp/environmental-infection-control-in-hospitals.html

Sequence for Removing Personal Protective Equipment (PPE)

http://www.cdc.gov/vhf/ebola/pdf/ppe-poster.pdf

Ebola Virus Disease Information for Clinicians in U.S. Healthcare Settings

http://www.cdc.gov/vhf/ebola/hcp/clinician-information-us-healthcare-settings.html

Guidance on Air Medical Transport for Patients with Ebola Virus Disease

http://www.cdc.gov/vhf/ebola/hcp/guidance-air-medical-transport-patients.html

VHF CIDRAP

http://www.cidrap.umn.edu/infectious-disease-topics/vhf