

## Day 1

### A Survivor's Story: Dual Citizenship at the Ebola

- Q. I was struck by the number of infected laboratory workers. Were these persons who did blood draws in units?
- A. In this particular space these were more typically phlebotomists who were drawing blood outside the ETU (early on, before red flags were raised and before there was a formal ETU) or in the triage process. There also were lab workers infected in the handling and processing of blood specimens in the lab (especially early on before alarm bells went off). During my time there, we were not doing much phlebotomy in the ETU other than in convalescent patients (who were asymptomatic for some days by then, and quite likely to have (-) PCR or very high CT values)) as the capacity to do other "hot" blood work (creatinine, potassium, etc) had been limited by equipment issues.
- Q. Where can public health professionals and IPC professionals offer the greatest value in preparedness, care, and outbreak management in the resource poor setting such as the Kenema hospital?
- A. 1. First, prepare well where you are!
2. If interested, begin to engage similar settings (there are multiple ways to get there) in the INTER-OUTBREAK period in endeavors focusing on good on-ground training or development of material for that kind of training. Often, IPC training and standards (given the LONG list of unresourced priorities) traditionally receive little priority in hospitals (from MOHs) at all levels (primary health centers, secondary/district hospitals, even tertiary referral hospitals) until something like this outbreak exposes how crucial they are. The IPC needs and gaps, not just related to high threat pathogens but increasingly to all the other things we're attending to in capacitated centers in more developed settings. There certainly are academic/NGO actors who are paying this more attention especially after the last few years, and several ways you could go.
3. If interested in being part of teams for primary deployments in outbreaks, I would recommend getting in contact with WHO GOARN (global outbreak alert response network) for criteria to become part of "available" personnel who could potentially be deployed when needed.
- Q. The ongoing needs of the survivors struck me. Could you please provide additional guidance on how to support the ongoing psychosocial needs of the survivors?
- A. Thanks for this question, it is of great interest to me as well. The psychosocial needs are immense, though there is a great need not just to name them but to understand them and the expertise needed to address them. Efforts to understand and address them are ongoing, but expose some much longer-term health system inadequacies. For example, there might be only one trained psychiatrist per country (and sometimes none) that are available to deal with psychiatric consequences, basic first-line antidepressants are often unavailable, trained psychotherapists also sparse. In the setting of LIKELY psychiatric sequelae (PTSD, depression/anxiety, grief reactions) after severe personal/family losses, the need for well-trained psychologists and community health workers who have (even a little!) counseling expertise, cognitive-behavioral expertise, ability to triage and recognize those who need URGENT psychiatric help is very much needed. WHO/Ministries of Health are (trying to) address these issues in survivors, but much more is needed. This is a pitch perfect example for how meeting an immediate care need in survivors (training/resource capacity in meeting mental health needs) could also more broadly help rebuild (or build for the first time!) the health care

system in a broader sense. Efforts over the past few years have been focused on training mid-level providers in basic triage and diagnosis, treatment, etc using the WHO MHGAP material (**the MHGAP guide is attached**) as well as one recently published study of Guinean survivors from the Postebogui cohort. Having pointed out the gaps/needs, I also think there is a great need for survivors to be able to tell their stories (to each other, to others) in safe and well-curated spaces as part of the healing process—this isn't rocket science, and having a few good folks able to conduct groups like this would go a long way to addressing some of these needs. The truth is that people/families/communities/churches/mosques/etc often will naturally be doing this anyway, unfortunately even these natural "in-situ" responses can be hijacked by the fear and stigmatization that surround survivors in some places.

Q. Can you think back to a time or event where in retrospect you may have become infected? Would you change the type of PPE used while working in Kenema if you could?

A. I've racked my brain, of course, to try to answer this question. Three places you get infected; (1) inside PPE in the ETU, (2) outside PPE (in the hospital or outside community), or (3) during the transition from 1 to 2.

For each: (1) We had 60-80 or more patients on any given day; we were very under-staffed, and we were treating very sick patients. So, we were exposed to high amounts of virus (diarrhea/stool is teeming with virus for example). But, there were no high risk exposure incidents for me—no one vomited on my mask, for example—and there were not in-unit breaches (2) Outside PPE (unlikely, we never touched other human beings while there - i.e. no physical greetings, no other contact, etc. (3) Doffing: there were no (apparent) breaches of protocol, that I can remember. So the short answer is: I don't know (like many of the HCW infections).

I wore both general types of PPE—always dealing with the tension between the need to increase our ability to stay at the bedside and provide care (especially when so undermanned) and our own safety. Safety is always paramount, of course. I preferred PPE strategies that allowed longer time at the bedside—the debate about this is ongoing. While I would love the luxury of a PAPR (!) that wasn't relevant at the time. I would not change PPE type. There are good resources easily available from CDC and WHO.

Q. After your experiences what career steps would you recommend IPC & public health professional's take who are interested in working toward improving the emergency preparedness, IPC, clinical care and outbreak response in African resource poor hospitals/health care system's? Thank you for your presentation!

A. thanks for your question, similar to another asked. Quick answer:

1. First, prepare well where you are!

2. If interested, begin to engage similar settings (there are multiple ways to get there) in the INTER-OUTBREAK period in endeavors focusing on good on-ground training or development of material for that kind of training. Often, IPC training and standards (given the LONG list of unresourced priorities) traditionally receive little priority in hospitals (from MOHs) at all levels (primary health centers, secondary/district hospitals, even tertiary referral hospitals) until something like this outbreak exposes how crucial they are. The IPC needs and gaps are not just related to high threat pathogens but increasingly to all the other pathogens/HAIs/etc we're attending to in capacitated centers in more developed settings. There certainly are

academic/NGO actors who are paying this more attention (especially after the last few years) and several ways you could go. In that regard, I would take steps to get on ground with these groups or at least to connect to leadership. IPC expertise in Africa (and elsewhere) is much needed, especially experts who are willing to get on ground and so the longer non-sexy work to mentor and train local talent. This is the most effective way to change the game, however!

3. If interested in being part of teams for primary deployments in outbreaks, I would recommend getting in contact with WHO GOARN (global outbreak alert response network) for criteria to become part of “available” personnel who could potentially be deployed when needed. There are of course multiple other avenues, and CDC, MSF, others would be good to explore if the acute outbreak response interests you.

Q. Beyond the infrastructural disparities, what impact do you feel the social/cultural elements played in the WA outbreak? Is preparedness in these countries addressing these issues?

A: Great question, and a broad one. Socio-cultural elements of many stripes had significant impact and influence in all phases of the outbreak, including impact on transmission (specific cultural and social practices around burials, for eg.), attitudes toward and resistance to educational messaging on infection prevention and control, perceptions of “harm” and resistance to contact tracing, quarantining, Ebola Treatment Units, research studies, and even to HCWs. These have also been important in thinking about and addressing residual risk in survivors in ways that also minimize their stigmatization. Addressing these and a number of other sociocultural issues require expertise that is not always considered part of an outbreak response (anthropologists, social scientists, for e.g.) and most importantly working in ongoing hand-in-hand relationships with community social/civic/religious leaders; this type of community engagement was a central crucial theme of outbreak response and control. Preparedness for future outbreaks is in some ways addressing these issues in addition to the “classic” elements (surveillance, IPC, case detection, clinical management, etc), but much still needs to be understood about these themes; in reality, they often get less attention than the “harder” preparedness issues. I've attached a recent paper summarizing some of those issues/insights from this outbreak (reference below, PDF attached).

Wilkinson, A., Parker, M., Martineau, F. & Leach, M. Engaging ‘communities’: anthropological insights from the West African Ebola epidemic. *Philos. Trans. R. Soc. Lond., B, Biol. Sci.* **372**, 20160305 (2017).

## A Hospital Epidemiologist's Guide to the Galaxy

- Q. How many rooms do you have in your AIIR unit? Are there any areas you created by retrofit?
- A. I don't recall the exact number but the 'isolation unit/floor' that was designed into our newer hospital pavilion has probably 30 rooms or so. Overall the institution has about 150 AIIRs; one older unit has one hallway of all AIIRs (I think it is about 20 rooms) and the other hallway the rooms can be easily retrofitted to be all AIIRs. That was the unit we were going to use as our 'isolation unit/floor' prior to the construction of the new pavilion. The hallways are dead end hallways which minimizes traffic through the unit. Additionally there is a large conference room just outside the unit that could be used for staff changing to PPE before entering the unit (this was done for SARS in Toronto - additional PPE was donned prior to entering patient rooms).
- Q. For the work quarantine grocery store, where did the funds for that come from? Did local public health provide? Donations?
- A. This was done in Toronto hospitals. The staff would shop and pay for the food as in a grocery store - the food was not free. The hospital ordered some different food/food types (eg, boxes of cereal, milk in gallon jugs, fresh fruit/vegetables, frozen foods, etc) to stock the staff grocery store that was created adjacent to the cafeteria. There was not a lot of choice but it was adequate.
- Q. Is your hospital unionized? How did you handle training nursing personnel? Volunteers? All comers?
- A. No, my hospital is not unionized except for food/nutrition staff. Anyone needing to be trained on Ebola PPE was trained the same and together. We felt it was important that they be comfortable working as a team - looking out for each other and being comfortable correcting donning/doffing before errors were made. There was an initial didactic session followed by an intense in person session donning/doffing PPE. They had to be signed off on donning/doffing PPE and the results were recorded in their electronic personnel file so they could be identified as passed PPE training (and ongoing refresher training is performed and recorded the same way). We had a group of 'master' trainers who were also available for just in time training to reinforce training when staff needed to use PPE (eg evaluation/care of a PUI). Eventually, it was decided that ICU staff (adult and pediatric) nurses/physicians, and some hospitalists, would be the core team as our Ebola care rooms were in 2 ICUs and we needed to be ready to care for critically ill patients. In the ED, all staff had to be trained and ready to care for a patient at any time (basic PPE training was provided to front desk/triage staff; patient care staff received training on Ebola PPE). We set up our plan to minimize need for anyone to enter the patient care room and be able to care for the patient as much as possible with telemedicine. The plan and rationale was presented to ED and ICU staff, for the most part they were receptive.
- Q. For the PPE cache you have created, about how many respirators does that include? How do you manage expiration dates?
- A. We started out by making some assumptions: we wanted PPE to be able to care for 200 patients/day for 8 weeks. We used the estimated number of healthcare personnel contacts/24 hour period we had from past observations and studies we had done at our hospital. We routinely use respirators so our stockpile is always being rotated (first in-first out) thus expiration dates is not a problem. During 2009 H1N1, we realized that the proportion of medium to small size respirators was not correct - we ran out of small size. Since then, we tried to change the respiratory model to one that is one size. Storage of larger amounts of PPE (not just respirators) was a major challenge; we tend to function with just in time delivery of supplies.

## Newbie's Guide to Policy Development

Q. While discussing travel screening, I thought of potential screening for MDROs. We have thought about screening questions related to recent healthcare exposure variables (i.e. coming from a LTAC etc.). What are your thoughts on this? Emerging MDROs!!

A. The idea of screening for MDRO's may be difficult as patients may not be able to answer questions. We have instituted presumptive contact isolation for patients coming into the hospital with stage 3 or 4 pressure ulcers, or other large chronic ulcers, or tracheostomies. We are doing this based on the fact that these are the individuals in our hospital most likely to be colonized with MDRO Acinetobacter. It is important to balance the potential benefits of isolation vs. potential harm, and each healthcare facility should decide the best approach depending on their patient population

Q. For travel screening can you provide sample questions?

A. It was a stepped screening for Ebola, now just travel

Travel screening questions:

Do you have cough and fever or rash and fever? If yes, have you traveled in the last 21 days outside of the country?

Q. General comment: as a health department representative, we have set up a general email addresses that contact multiple people instead of providing specific contact information for individual people. This way contact information remains current even with staff turnover. This has been very useful for situations that warrant a rapid response. Some of our healthcare facilities have adopted this method and think this would be a good suggestion for those who have not yet done the same.

A. This is a great suggestion. Thank you

Q. Are their guidance documents available for developing robust HR plans surrounding HCW safety and compensation (i.e. what is reasonable for hazard pay or call pay or something else)?

A. I'm not aware of specific HR guidelines that address compensation. Healthcare worker safety is addressed on multiple sites through recommendations for PPE. The NETEC site (<https://netec.org>) also has guidance on occupational health. Since each healthcare facility is different, compensation and hazard pay is something that needs to be individualized for specific facilities.

Q. Should minimum air exchange rate be mandated for new construction and renovations given the protective effect for patients and staff?

A. Minimum air exchanges are recommended in the ASHRAE guidelines, but there is no specific guidance regarding the number of negative pressure rooms that must be available.

Q. Nurses tend to do a good job of competency-based training at annual skills fairs. Physicians often not trained at all. Are there examples of good ways to get physicians trained and retrained with return demonstration?

A. We retrain every few months for Ebola, none for general PPE use. Physician education certainly follows different models than nursing education

How often do you do PPE competency?

A. Annual training may not be sufficient for PPE training, and it is important to have physicians and anyone who interacts with patients trained as well. PPE training should ideally be done in

person with an observer. We require quarterly training for individuals that would work in our special disease care unit. We also use simulation for training.

Q. Do you have a software program that does data mining for risks? Which do you use? Right now we have an electronic triage system but has to be checked manually (usually by me!)

A. There are data-mining programs, but we are currently not using one. For potential high-risk infectious diseases, we are contacted directly.

We are developing epic icon reports for some risk factors and working on more sophisticated models. It is certainly an important emerging area!

### Case Study 1: MERS-CoV

Q. What do we know about “super-spreaders” with respect to host, viral, environmental risk factors?

A. Unfortunately, I am unaware of data that has looked at risk for being a “super-spreader” beyond the early work in TB. We recognize that there are individuals with respiratory illnesses that have spread to more people and hypothesize that it is related to increased viral shedding in late stage infection and the increased need for procedures that will aerosolize particles etc.

Q. In your intervention slides, is "hand washing" strictly washing with soap and water or EtOH-based too? Impacts separately?

A. This reflects a mixture of hand hygiene strategies including Alcohol Hand Rubs and traditional soap and water. I am not aware that the impact of soap and water versus alcohol based hand rubs have been looked at separately in this context. In other settings Alcohol has been compared to soap and water and is considered as good if not superior. There is no reason not to think this holds true for prevention of respiratory virus infections.

Q. What’s your take on respiratory protection for visitors? Should they be given N95s or surgical masks? If they’re provided N95s is this a double standard?

A. This is a complicated issue and depends on the setting. During respiratory virus season, I believe visitors should be at least screened and I think you can make a compelling argument for the use of medical masks in the height of respiratory virus season especially among high risk groups such as neonates, the elderly and immunocompromised. Even in the setting of respiratory viral outbreaks there is not data to suggest that the use of N95 masks is superior to MM in visitors who are not performing aerosol generating procedures. So at this point MM are considered adequate. That being said in the setting of MERS CoV units and SARS where transmission has not been totally understood and where there is not treatments one can argue that an N95 should be used. However, visitors are not fit tested and there are data to suggest that without fit testing the benefit of the seal is lost.

Q. Can you explain the transmission graphs? How were these graphs generated? Are the length of the lines significant, or are they just linking cases of transmission?

A. Transmission graphs are generating by working with statisticians and epidemiologists who specialize in modeling and use equations to estimate the point of when the person was exposed and developed disease. They look at multiple points to estimate the true incubation period and serial intervals. The transmission graphs are not drawn to scale and just show the links. The length of the line has no significance.

## Hope Is Not a Plan

- Q. Can you share your staffing schedule planning grid (nursing and physician)? You stated that if someone was in PPE for 2 hours and had to get out that they were relieved of duty. What is a good guide for staffing?
- A. We have at least 3 nurses on each shift, along with several other staff members (RT, Tech) depending on the acuity of the patient. We use a 4 hour rotating schedule, however if a nurse is unable to complete the 4 hour shift in the patient room for any reason, one of the other nurses would take over. Other nursing roles in our unit include donning/doffing partner, tasker (phones, med delivery, etc), and they rotate on break as well. The physicians have an on-call schedule that provides 24 hour coverage. These schedules are made in advance (for instance, we have an on-call schedule currently even though we are not activated) to account for other clinical duties, vacations, etc. More information is available in one of our publications: <http://www.sciencedirect.com/science/article/pii/S0196655315000371>
- Q. In our hospital's emerging ID plan (more extensively expanded with Ebola planning), while patient is in the ED awaiting final readying of the inpatient room, we place a triple lumen PICC with one lumen saved for TPN at that time. If there is suggestion of failure of renal function, we have our IR physicians also place a permacath. Our room is already fitted to handle ventilation and dialysis needs so the patient doesn't need to move. Fellows and residents are not allowed in the red zone (by definition to me if they need supervision they are not critical). Can you comment on these decisions? What other pre-emptive maneuvers do you utilize. We also have two way visual and audible communication. We can take clinical photos that can be loaded into the electronic medical record so specialists need not enter the room. Your thoughts?
- A. All of these things are very good and definitely indicate a great level of preparedness, so kudos to you and your team. Triple lumen PICCs or CVCs are needed for fluids, meds, TPN, etc while a dialysis catheter may indeed be needed as well, and it sounds like you have that covered. Providing a dedicated space without the need for patient movement is optimal. We did not allow residents, students, etc at the bedside, however we did have them inside our unit to participate in the care of the patient via our telemed system, which provided an educational component without all of the associated risks. It is important to have the ability to take photos at the bedside, and we found this useful for documenting consent for experimental products.
- Q. Are there trainings available that get into the details about developing systems that can effectively and efficiently assess staffing availability for both care of an EVD patient as well as backfilling those positions that are left open by staff who are pulled to care for an EVD patient? Many healthcare facilities seem to overestimate their staffing capabilities for caring for an EVD patient for more than 96 hours.
- A. Staffing models will vary facility to facility, but it is important to involve the nurse managers from the home units to ensure the ability to backfill positions during activation. They have been very helpful to us when recruiting potential team members and making on-call schedules for activation.
- Q. In your experience, in the categories discussed do you think there is any one of these particular areas (transport, staffing, clinical care, communication, etc) that healthcare facilities are currently the least prepared in for these kinds of outbreaks? In your opinion, where are we the weakest and need to make the greatest improvements?

- A. In my experience, facilities seem to be the least prepared in the area of clinical care of Pedi and OB patients with highly infectious diseases, and there are many areas for improvement when dealing with the issues surrounding the care of these special populations.
- Q. How do you manage the wastewater from your bio containment unit?
- A. We place a disinfectant into the toilet and allow it to dwell for 10 minutes prior to flushing.
- Q. Can you speak more about blood bank challenges? Considerations not just for giving blood products but patient as future donor.
- A. We used a slide agglutination method for blood typing due to challenges with traditional type and cross. More information on this can be found in one of the publications from our lab group: <https://academic.oup.com/ajcp/article/143/1/4/1760657/Safety-Considerations-in-the-Laboratory-Testing-of>
- Q. About CP-CRE screening--special hospitals with frequent international patients are doing this now at their own expense. Remember that all states now have access to CP-CRE screening of roommates or perhaps unit patients in response to a known CP-CRE with novel mechanisms (NMD, OXA-48, VIM or even KPC if you are in an area where it is still rare) through their state health department HAI coordinator and the 7 CDC funded Antimicrobial Resistance Laboratory Network labs. This kind of screening is free and Fedex transport is covered by regional labs. Request through state health department HAI coordinator.
- A. Thank you for the information. This is helpful.
- Q. You discussed the importance of internal and external communications while caring for Ebola Virus patients. What did collaboration of internal communications and PR look like? Were there any concerns for staff "leaking" internal communications? How were these concerns handled?
- A. Both internal and external communications were handled by the same PR team. We were always sent internal communications prior to release of information to the media on topics like patient arrival, etc. However, there was not a large time period in between the release of info to employees vs external communications, so 'leaking' was not much of a concern, as we knew this would occur.
- Q. Could you share information about how samples were tested in the blood bank for the patient in the biocontainment unit? Was T&C offered?
- A. Blood typing was performed using slide agglutination. More information on this can be found in one of our publications: <https://academic.oup.com/ajcp/article/143/1/4/1760657/Safety-Considerations-in-the-Laboratory-Testing-of>

## **Location, Location, Location**

### **Ambulatory Setting**

- Q. In your very last slide you showed a woman in PPE. She had on a headset. What kind of headset was that?
- A. This is actually what we used to use to communicate with staff inside of the room. It is a closed circuit Bluetooth headset which links to a "buddy" role headset and a "facilitator" role headset. We actually no longer use that method because it was very easy to accidentally shut off the device while in PPE, making your lines of communication limited.

We now have a washable closed circuit telecommunication system which we have worked with our simulation center to set up in our unit.

### **EMS/Emergency Department**

- Q. Where does Grady EMS don their PPE if picking up a patient at a private residence? How many crews respond to this call?
- A. The answer varies based on the circumstances of the transport and the condition of the patient. For a planned patient transport, PPE is partially applied in some discrete location in advance of arrival at the residence, with final application of PPE (respiratory protection) completed in the back of the ambulance prior to making patient contact. Depending on patient condition and if they are ambulatory, the patient may simply be asked to walk to the back of the ambulance and enter it to avoid a spectacle in front of the home. If the patient needs assistance, the paramedic will enter the residence after fully applying the PPE. For a low-risk PUI, the transport would be completed by an ambulance staffed with two paramedics. Only one would make patient contact if the patient could safely be managed that way. If both paramedics need to make patient contact to manage the patient safely, a third person will serve as the vehicle operator. For a high risk PUI or a confirmed case, the Grady EMS response team includes two paramedics, a supervisor and an EMS physician. A webinar hosted by ASPR/TRACIE today will describe a new EMS Infectious Disease Playbook, and may answer more of your questions. [Registration for the webinar is available here.](https://register.gotowebinar.com/register/4196593274079113217)
- Q. Please address urgent care centers, including stand-alone ones, as they have limited equipment
- A. Ambulatory care centers, and other outpatient care facilities, should be able to implement the “identify, isolate and inform” strategy for the safety of their staff, patients and visitors. This link to the CDC website navigates to guidance that was in place during the 2014 Ebola outbreak. <https://www.cdc.gov/vhf/ebola/healthcare-us/outpatient-settings/index.html>
- Q. Reminder that most state health departments still offering free ICAR assessments for Ebola assessment hospitals and most frontline facilities as well until March 2018.
- A. The National Ebola Training and Education Center also provides resources for health systems preparing for management of patients with serious communicable diseases, offering education and training, technical assistance and site assessments. The website can be found here <https://netec.org>

### **Transporting Infectious Patients Within Your Facility**

- Q. Describe any differences in approaching a patient with possible Mers-CoV vs Ebola in terms of PPE, transport etc.
- A. The CDC recommendations for transferring SARS recommends masking Patient on transporting.
- Q. Why a PAPR for Ebola but N95 for Mers-CoV?
- A. It is not necessary to wear a PAPR to transport Ebola patient, some facilities use N95 with face shield.

### **Pediatrics**

- Q. From which SARS affected countries did the Koller study pull its data and did all five pediatric patients recover?

- A. This study included patients in Toronto, Canada. All of the included children recovered from SARS and were discharged.

### **Environmental Services/Labs/Pathology/Mortuary**

- Q. Where was the autoclave that you used for the waste decon located? What issues/challenges did that create?
  - A. In our case it was located within 200 feet of the patient unit; so, for us distance was not a challenge.  
If someone has an autoclave farther away, as in a different floor or building, it still can be used. However, a detailed SOP has to be worked out on the route of waste bag transportation to the autoclave location.
- Q. Can blood from Mers patients be processed by lab in normal fashion? Or POC testing only? How about VHF?
  - A. If it is confirmed, MERS appropriate PPE should be worn before testing. Respiratory protection, mucous membrane protection, gloves, coveralls  
For VHF? This is an entire family including Ebola virus fever. So it all depends on specific agents
- Q. What kind of material should the PPE be made of? In a laboratory we are required to use fluid resistant gowns for handling any type of patient specimen. The blue or yellow disposable gowns we use with direct patient contact are not fluid resistant and can absorb liquids. Seems like this is a concern in that a HCW with direct patient contact could be exposed to more body fluids than a 3-5mL tube of blood.
  - A. We use only fluid resistant gowns on top of tyvek
- Q. Do you have procedures for after death care for patients with a pacemaker? My understanding is a pacemaker cannot go into a crematorium.
  - A. Cremation with the pacemaker. I suppose there could be an explosion risk depending on the type of battery, but I don't think pacemakers use Li ion batteries.  
Removing the pacemaker poses a high risk for healthcare worker exposure because it requires surgery with a scalpel and the leads can require a fairly forceful pull to dislodge them. This could lead to blood spray.

## **Day 2**

### **PCR Is Not Always the Answer**

- Q. What is the process to pull FDA approved CIDTs off market when they prove to be useless after FDA approval and adoption? I.e. Rapid campy assays?
  - A. Recall of an FDA approval is a serious process. This can occur in one of two ways: 1) voluntary withdraw of a medical device (all laboratory tests submitted and approved by the FDA are considered medical devices), or 2) an involuntary withdraw of a medical device ordered by the FDA. Recalls of approved devices are due to some serious risk to health.  
I am by no means an expert in FDA device recalls, but I would suggest visiting the FDA site: <https://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/recalls corrections and removals/default.htm>.

It provides a lot of information, and refers you to the specific sections in the CFR related to device recalls.

What you may be asking is how do manufacturers handle previously approved devices that prove to be clinically less effective? This can happen when the assay is more widely adopted, allowing experience using tests in the real world and outside of the clinical trials of devices. In some instances, manufacturer's may go back and revise their assay or device to try and improve it. Significant changes or modifications require additional FDA review and approval. In some instances, the manufacturer may phase out those older assays all together.

Q. Do you have any recommendations for *C.difficile* testing/algorithms?

A. There is a lot of debate about which test to use for *C. difficile* testing. Laboratories moved to molecular assays because they are more sensitive compared to EIAs. The drawback of only PCR testing is that we are calling positives on patients who may not have clinical disease, those who are asymptotically colonized.

Some laboratories have adopted a two-step screening method using a EIA for glutamine dehydrogenase, which is a common antigen present in toxigenic and non-toxigenic strains of *Clostridium*. If it is negative, then labs report the result as such and no further testing is needed. If it is positive, labs are reflexing to a molecular assay to detect the toxin gene. I think this is a good approach, but if labs are only going to perform one test for *C. difficile* they should be performing a molecular assay due to the increased sensitivity (less risk of false negatives in patients with true disease).

Whatever test strategy you recommend or adopt in your laboratory, it is important that the laboratory only test samples that are appropriate (i.e., liquid stools), and samples submitted for *C. difficile* testing that are formed should be rejected. The only exception to this rule would be if there was suspicion that an ileus was due to *C. difficile*.

### Preparing for the Zombie Apocalypse

Q. What lessons do you think can be learned from hospitals' experiences in Hurricane Katrina and Super Storm Sandy?

A. Prepare and drill evacuation processes

Go to pediatric disaster coalition website for detailed information

Plan how records can be made available for evacuation if IT goes down

Harden the essential and expensive basement content against flooding

Help your community plan to support the elderly and disabled before, during, and after the event

There is an entire report on our website: [www.pediatricdisastercoalition.org](http://www.pediatricdisastercoalition.org)

### #LightsCameraAction

Q. What are effective tactics for communicating to people who may think something does not pertain/affect them, when in fact it does, or you need them to take action?

A. First you acknowledge the validity of their feelings, ie. "I can understand why you may believe this is something that can't happen here or won't happen to you, but let me tell you a story about someone else who thought it couldn't happen (and then deliver that short story)." Go on to say something like: "Even if you think this isn't relevant to you right now, the possibility exists and that's why I want to give you the tools to take actions that will help prevent a worst

case scenario sometime down the road.” If someone is quite stubborn, first ask them why they don’t think something is going to affect them, and then use their answer to present some facts to make them question their own assumptions.

- Q. Could you please share the name of the book you referenced early on in your presentation regarding effective communication?
- A. [“If I Understood You, Would I Have This Look on My Face?”](#) by Alan Alda
- Q. What is your opinion of moving waste, products, etc into or out of the hospital in the middle of the night when less likely to be caught on camera while caring for a patient with Ebola or other high consequence pathogen versus during middle of the day as a form of transparency?
- A. In the spirit of transparency, providing information and boosting public confidence in the process, I would proceed with operations as you normally would. You might even invite select and trusted media to report on the process, so the reader/viewer acquires a spirit of confidence in the organization/team knowing how to handle this material and following protocol and why. If you change the normal process to avoid media, it’s likely to leak out somehow (perhaps through a nervous or disgruntled employee).