

CDC Ebola Response Oral History Project

The Reminiscences of

Anne Schuchat

David J. Sencer CDC Museum

Centers for Disease Control and Prevention

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Anne Schuchat

Interviewed by Sam Robson
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Interview 1 of 1

CDC Ebola Response Oral History Project

Q: This is Sam Robson here with Rear Admiral Anne Schuchat. Today's date is May 6th, 2016, and we're here in the audio recording studio at CDC's [Center for Disease Control and Prevention] Roybal Campus in Atlanta, Georgia. I'm interviewing Anne as part of the CDC Ebola [Response] Oral History Project.

Anne, thank you so much for being here with me today. For the record, could you please state your full name and your current position with CDC?

Schuchat: Yeah. I'm Dr. Anne Schuchat. It's A-N-N-E, S-C-H-U-C-H-A-T, and I'm the principal deputy director for the Centers for Disease Control and Prevention.

Q: Thank you. Can you tell me when and where you were born?

Schuchat: Washington, DC, in 1959.

Q: Just tell me a bit about growing up.

Schuchat: I come from a big family. I'm the fourth of five kids and very close to my siblings. I grew up in Washington, DC, and in Maryland, and was a very nerdy student. I had a pretty close family and a lot of social life [centered] around the family and the extended family and friends. My school identity was "the good student." The joke in the family amongst my siblings was, Anne doesn't have to do dishes because Anne is a wonderful student. I was basically very focused on school and was very happy in moving on to my academic studies. My siblings are really different from me. Wonderful people and oriented in other areas.

Q: What did your parents do?

Schuchat: My dad was a lawyer and my mom went back to school after my little brother was born and became an anthropologist, got a PhD in anthropology.

Q: Was there a specific area he focused in with anthro?

Schuchat: My mom.

Q: Oh, your mom. I'm sorry. Dad was a lawyer and mom was an anthropologist.

Schuchat: Dad was a lawyer and mom went back to school, yes. My dad continued to be a lawyer. My mom did cultural anthropology. An interesting part of growing up was her friends and classmates, and so forth, that she had—and my dad's clients, and so forth. We

actually had a pretty international set of family friends through my mom's school and just her social and professional network. Her thesis was on Hungarian food habits. She went to Hungary in the sixties. I guess it was '69 when we landed on the moon, and my mom was in Hungary which was very communist, and everyone was congratulating her [for landing on the moon] because she was the only American in Hungary that week, I think. She studied food habits in Hungary and then studied food habits among Hungarians in the Washington, DC, area who had immigrated. My parents actually housed a family who were refugees from Hungary in 1956 and they'd become real close with them and helped them get settled and so forth. My mom knew a lot of Hungarians because of the family friends that we had. She studied "what do you keep and what do you change" when you move to a new kind of context. That was one area, but she did a lot of different areas over her time.

Q: What kinds of things were you interested in up through high school?

Schuchat: I was quiet, introverted, took piano lessons. Summers I went to sleepaway camp and I loved the outdoors, hiking and swimming and those sorts of things. I would say, I read all the time. I was a pretty nerdy kid, but that's good, right?

Q: No doubt. What did you think you were going to do upon graduation?

Schuchat: Right, sorry. Like you're probably trying to—forget about my life here. Early on I think when I was eight or nine I decided I wanted to be a doctor. The plan was I was

going to be a small town family doctor. I liked to write and I thought, even at that young age, maybe a little bit older, that medicine would be a chance to learn a lot about the world. I think I was introverted enough to think that I would need to experience life through others, through my patients. That would be the human condition and then I'd have something to write about, but I would never write about my patients because that's not ethical, but I would learn about life through my patients. In any case, the early plan was to become a doctor and move to a small town and be a doctor in a small town.

I went to college, was pre-med, but I ended up studying philosophy as my major, the last blast of liberal arts. I just loved that, but still went on to medical school from college. Then in medical school, which I did in a small town, I realized that that wasn't for me and went to New York City for my internship and residency. And so, big city, incredible experience. A lot of my medical training was in the mid-eighties during the AIDS [acquired immunodeficiency syndrome] epidemic, so that was a huge experience for me and everybody of my generation who was learning medicine at that time. [About] one out of three patients on the wards had AIDS, and [many were] dying, and confronting family and friends, and not having a whole lot of time to plan [with each other]. I think the medical education [I got] was extraordinary. The social, emotional, societal education was extraordinary. I really loved being an intern and resident. I [experienced] the intensity, wonderful friends, great patients and grew a lot probably. And had the whole, "oh my God, what am I going to do now," because you can't do that forever. So somebody at the hospital that I worked at told me about the Epidemic Intelligence Service, or EIS program, and from that [conversation] I remembered I'd heard of it

before back in med school. I applied and then I came here as an EIS officer. My was— [coming] not to do public health, not to do epidemiology. Just coming out of this extremely intense and rich but challenging experience. I thought, okay, I'll go off and learn that and then do clinical work afterwards. That's my journey to the CDC.

Q: I believe you're EIS class 1988?

Schuchat: Right.

Q: Okay. Got you. Can you tell me some of the responses or the projects that you were involved in that were really impactful for you?

Schuchat: I had a couple really important projects assigned to me as an EIS officer that [I worked on for] multiple years. Either [they] grew into many other projects or had a big impact. One of them was, I was asked to work on setting up surveillance for group B streptococcal disease. That's a bacterial infection that women can spread to their babies during delivery. It turns out it was the leading cause of newborn infections in the US in the first week of life and quite severe, often fatal or life-[threatening]. I was asked to take that on. That grew into many, many projects that I did or that I supervised, and eventually into guidelines to prevent group B strep in pregnancy—or to prevent the newborns from getting it and essentially has led to the prevention of ninety thousand infections since we issued guidelines. That was a pretty meaningful project to get assigned as an EIS officer. The guidelines came in '96, but the family of studies we did building up to them helped

provide an evidence base. Working with the community group, working with professional groups, we got everybody on the same page to issue guidelines that everybody signed off on and really changed the standard of care for every baby born in America. That was pretty incredible to be part of.

The other project that's quite remarkable from my EIS experience—the other one was with the other EIS officer, Bob [Robert W.] Pinner, the two of us were first-years. We both were assigned listeriosis projects. The branch was doing a ton of projects around foodborne listeriosis which had been recognized as a cause of outbreaks, but we didn't know if [foodborne transmission] caused sporadic disease—the one at a time kind of cases. We were studying sporadic listeriosis and I led the case control study of risk factors, dietary risk factors, and Bob led the refrigerator study. I interviewed one hundred or two hundred, I forget, people who had had *Listeria* or controls because I was blinded to who was who. I just called them on the phone and did all these interviews about what they'd eaten six weeks before a certain date. Our collaborators in the states went to their homes and got the stuff from their refrigerator and sent it in for testing. It was an incredible project with a lot of [CDC] lab people testing new methods. Our study early on found a match, like a fingerprint match, between a patient who had listeriosis—severe disease—[and *Listeria* from] the food from her refrigerator, the turkey franks in the unopened package at the store and the factory that processed the turkey to make the turkey franks. We basically were able to have that smoking gun of, this individual with sporadic listeriosis had eaten this turkey frank from a plant that was producing turkey franks with the [same strain of *Listeria monocytogenes*] in it. That led the USDA [United

States Department of Agriculture] to make a new policy to have zero tolerance of *Listeria monocytogenes* in ready-to-eat meats. Before that, you couldn't have *Listeria monocytogenes* in [dairy products], but there was this sense that meat is different. Nobody really believed that, but there were strong interests that were saying [*Listeria* in meat] wasn't a problem. Our study really—we [reported in] the MMWR [Morbidity and Mortality Weekly Report], and it really changed national policy. The rest of the study was good, too, but that was an early finding.

The EIS experience for me was both a beginning of a focus of my first ten years at CDC with group B strep, and then a really interesting, multiple discipline, multi-state project I was part of that changed national policy. Then of course when the policy changed we had a 35% reduction in [listeriosis] disease. Both projects led to huge impact in health.

Q: That's fascinating that you go to EIS and you're almost immediately participating in these projects that have such wide-ranging effects, ultimately.

Schuchat: Yeah. But I think that you've probably heard this from others, the day-to-day of EIS is not that way. [laughter] The day-to-day, I actually had back problems for a couple years at CDC with EIS because you're sitting there. You're on the phone, you're on your computer. In the hospital you're on your feet all day running around. The beginning of the day in the hospital in the residency program, you're admitting patients, you're discharging patients. Somebody comes in with something terrible. You help diagnose it, you help them get better or sometimes they get worse. It's very, very fast-

paced. Whatever they say about EIS, except in the era of Ebola, these projects take a long time. But I've been here so long that I can see the extraordinary impact some of our projects have. For me at the time, it was just this wonderful learning experience. I did surveillance projects. I did analyses. I did a really interesting project on pneumococcal disease and HIV [human immunodeficiency virus] which now, there have been four permutations of it since then. Really at that time, pneumococcal disease [increased rates were] a sentinel that there was a lot of HIV in the community before we were even [HIV] testing on any kind of population level because [pneumococcal disease] was an early sign of immunosuppression. Then as we got antiretroviral medications, you could actually see that elevated rate in certain communities coming down. In any case, I was able to do an interesting project with a New Jersey surveillance system and then got to later do pretty much the same thing in South Africa after they had the big transformation of offering care and antiretrovirals to HIV there. Again, EIS reverberates later on.

Q: Okay.

Schuchat: You probably want to focus on Ebola, because the Ebola stuff is pretty extraordinary.

Q: I do, but I have this vision of you coming out of—and tell me if this is wrong—of you in New York with these patients who have HIV and just the horror of that. And the desire coming from that, seeing such a widespread epidemic, to want to help people on a larger scale.

Schuchat: I would say that wasn't my story. I think that's a good story which a lot of people have. But as I mentioned, I was kind of a nerdy person. I loved my residency because I learned so much and the human interaction was incredible. I grew personally, I grew professionally. I just learned a lot of skills and I really felt like I was in the middle of this incredible horror. It was really terrible, but there was a lot of humor. There were really amazing people. Some of the patients you knew really well because you [admitted] them multiple times, and some of the folks, you just saw someone go from working on Wall Street to on a respirator in a very short period of time. Others, you saw the end of their life and the network that they had or didn't have. It was pretty—it wasn't like I was trying to get away from that or that I was trying to have more impact. I think a lot of people in public health and epidemiology want to have impact. I thought it sounded interesting. It sounded like it would be a fun thing to do and it would be a break in terms of learning something new, but that of course I was going to take care of patients because I loved taking care of patients, and I loved the diagnostics, and I loved the patient interaction, and both the intellectual and the emotional work that is being a physician. I was not expecting to stay here for my whole career. The impact was like gravy. [laughter] You've got to have—but for me, the epidemiology was just so interesting. It was intellectually, using my brain, playing with data, figuring out what it meant. That, I really liked. So I don't have an altruistic "why I was here." I have a, this was going to be something that challenged me and would be interesting.

Q: I love that story, too, actually. Thanks for telling it.

Schuchat: Now I think it's incredible that what we do does save so many lives. It's really, it is very gratifying but my entry here wasn't for that purpose.

Q: Okay. Thank you for that.

Schuchat: You will edit the tape so that I don't sound like a terrible person.

Q: You don't. Actually, you sound like a real person and that's great. So, you continue in CDC throughout the nineties. I guess you'd been in CDC since EIS?

Schuchat: Since 1988, yeah.

Q: Since '88.

Schuchat: Longer than most of your oral history here.

Q: Can you tell me about—and this is probably skipping ahead a bit, but becoming director of NCIRD [National Center for Immunization and Respiratory Diseases]?

Schuchat: Okay. My journey to becoming director of NCIRD. I had been a branch chief for some time and was asked to do a detail two levels above where I was. I was chief of a branch and the center director was going to be retiring and there was some reorganization

happening. I was asked to act as the director of the National Center for Infectious Diseases and I didn't really want to do that. I was in the middle of a big project in South Africa that needed money. My staff were the leads and I was the branch chief. I told my staff, you worry about the science, and the collaboration, and making this a really good study and I will find us money. So when I was asked to do this position, the acting position, I said, you know, if you can help me find money for this study, of course I'll help. I really need to make sure this study works. The rand had devalued and the funds we had for the study were suddenly worth half of what they were supposed to be, so we didn't have enough money to get the study finished. It was a really important—it was actually trying to prevent newborn sepsis like the group B strep stuff we did here, but using a chlorhexidine wipe. It was essentially testing a method that had been looked at before with conflicting results. We wanted to do a pivotal trial. It's really important for a big health problem and we were doing this eight-thousand-person trial and we didn't have enough money to keep it going, and that was a problem.

So I agreed to [be] acting director. It was very unpleasant, very stressful. The agency was changing, reorganization. I was asked to lead this center reorganization process at a time when there was no trust. There was a lot of distrust of the change. People were really not ready to change, but we had to change and I was in the middle of all the conflict. I wasn't really particularly happy about that, but I was happy to help the agency which I love, but I had to see that. I was put in a position of a lot of conflict.

When the position to be a permanent center director opened up that was going to be the result of this reorganization, I was actually in South Africa when I had to decide, did I want to apply or not. Made my lists of why I should do it and why I shouldn't do it. My lists of why I should do it is that everybody thinks I should do it. They want me to do it, they trust me, who else is going to do it? That kind of list, as opposed to what a great job. Ironically, I took the job out of a sense of duty and it ended up being an awesome job. I had the best job at CDC. I really ended up with—there were all these fun things that come with the job which I had no idea about. There was this incredible set of people that I had never worked with, programs I didn't know anything about that I got to learn about, and this wonderful set of partners and community outreach. So while the immediacy of patient care, you don't really have at CDC—although I was doing a clinic a month, basically, to keep that up—the job as center director involved visiting states and their programs, talking with communities. Just a lot of outreach that I liked. Then leadership that I really enjoyed—different kind of leadership than branch chief. I was backed into something that turned out to be just a wonderful ten years.

Q: I appreciate that. Thank you. I know that Ebola is not your first encounter with West Africa, right?

Schuchat: Right, right. Yeah.

Q: Can you tell us about the work that you had done relating to West Africa before Ebola?

Schuchat: Yeah. Sure. It's actually twenty-five years since my first trip to West Africa, which I just realized it's been twenty-five years. In any case, I was helping try to find sites to study meningitis vaccines. I went to a couple different countries in 1991 and then we selected Niger to work in. I helped local collaborators with a series of studies of meningococcal conjugate vaccine and *Haemophilus influenzae* b conjugate vaccine testing. The Hib [*H. influenza* type b] study was just to sort of get the site some experience with doing immunogenicity studies and then the meningococcal conjugate study was to test a lot of different schedules—one, two, three, or four doses in babies. That was multiple [visits] in the same country, and then I was on the steering committee for this extraordinary trial in The Gambia testing the pneumococcal conjugate vaccine in babies. That trial, oh my God. That's a whole oral history for that trial. It had every problem you could imagine. The site was flooded out. The people were in a canoe with the data, computers and stuff. In any case, the study had to be half as large as it was planned to be because the control vaccine was no longer available, so it was underpowered. We had to change the [study] outcome. Then it ended up showing an impact on mortality. It was underpowered for what we were trying to do, but then we got this extraordinary effect because it was such a great vaccine. It was a real—that was a winner to be involved in that one. It was also, it's been transformative for Africa to have pneumococcal conjugate vaccine. So it was really exciting to be part of a study that could show that in a very high-burden, high-mortality location, this vaccine could save lives. The meningitis stuff took forever for my part of it, but later other people really got that field moving and now we've had over two hundred million people vaccinated against

meningitis and the really horrible epidemics for group A are gone. My West Africa experience was not living there, but the trials that I was involved with were quite—they were long in planning, long in implementation, but it ended up with a lot of impact.

Q: Okay. Thank you. Just to get a sense of the chronology. Getting involved in 1991 is what you said?

Schuchat: Well, yeah. My first trip was '91. Our first study was '94. Compared to this Ebola thing, it was like, let's go find a site, let's find collaborators, let's find money, let's write protocols. But in those days, of course, there weren't even—there was not email when we started those things. You didn't have instant communication with your collaborators in West Africa. It was pretty—and traveling and working there, it was really—it wasn't as quick as things can be now.

Q: Okay. Well, I suppose we should get to it at some point.

Schuchat: Probably. [laughter] We're going to be finished before we get to Ebola. I have been here a long time.

Q: I appreciate that and I appreciate that little bit of background because I think that will be helpful to the people looking back. Just tell me about learning about the Ebola epidemic and then becoming involved in the response here at CDC.

Schuchat: Sure, okay. As one of the center directors, I would be in meetings learning about updates on “it’s worse than we think” and so forth. There was a meeting of what’s called the Global Health Leadership Council or something like that, I forget what it’s called, where someone had presented an update of what’s going on and mentioned, we’re going to ask for EIS officers to help. That happened a couple days before I was going to be talking to the EIS officers, the new ones. I usually—not usually. A couple of times, I had done a lecture in the orientation for new EIS officers, which is about EIS officers in emergency responses. I was giving my usual lecture later that week and I said the famous last words, I said a couple things. I said, “Some years are really defined by a big problem.” I gave the example of 2001 and anthrax or the SARS [severe acute respiratory syndrome] epidemic [in 2003]. And “I understand people are probably going to be asked as EIS officers to be part of the Ebola response because it’s really getting difficult.” This was July 2014. I remember one of them asked the question of, well do you have restrictions or is it people who have experience? I said, “Look. We never make people do things that they’re not comfortable with. It’s really important that we’re safe. Of course some of the new officers will have international experience or they’ll have conflict experience, so we’re really, we want people to be safe. This is about your training, it’s about your learning.” Of course every single EIS officer was part of the Ebola response. That was probably the last time they thought they were going to the position that they were matched to. And they didn’t ask me back to do the lecture the next year. I think there’s a strong correlation.

So I was basically following [the epidemic] and then as a center director, would be offering our staff. Many of my staff have done lots of emergency responses and activations, so just making sure that we were providing really good individuals to help with it. I was not too involved, as opposed to just being aware, until September [2014] when Dr. [Thomas R.] Frieden contacted me because the leadership of Health and Human Services were looking at the exponential growth, and NIH [National Institute of Health] was planning this trial in Liberia of a gold standard, randomized controlled [vaccine] trial. He was wondering whether there were other ways that we could look at vaccines or any other approach we could use, what kind of sample [size was needed]—could I get some ideas to him? Actually I was, for your oral history purposes, I was—I want to say Saturday morning in September when I was at my thirtieth year medical school reunion renting a house with a batch of old friends, got up early, checked my stupid BlackBerry, saw this thing. The next three hours [I] was e-mailing and calling people to see who could help me get some sample size calculations done, and who was available that weekend to get [planning] going on this. Obviously, everything about Ebola had a fast turnaround.

From that weekend on was an evolution or a journey of thinking about how to try to test a future Ebola vaccine in the middle of an epidemic in a place that had never—that had not got a vaccine field site going. The next several months were—we can go into however much detail as you want, but developing, recruiting a couple people to work on this fulltime, to develop it out. Then many changes in our design and plans.

Q: What are some of the most important of those changes of those decisions?

Schuchat: We initially proposed a stepped wedge approach. You may, you probably heard. There was a lot of discussion about, can you test—a randomized controlled trial is a pretty hard thing to pull off. Double-blind, large numbers, everybody involved needs to—you have to follow incredible protocol, details, of course. But also the idea of placebo and blinding is pretty complicated when you're—even just an investigational vaccine is pretty complicated. We thought, well maybe we could do a stepped wedge design which would be a way that everybody's eventually going to get it, but they don't all get it on the same day. You use the observation time before you get it of what's going on, but it takes a huge population and you actually have to get everything ready to go in terms of enrolling the whole population and tracking disease in them before you start giving vaccine, or there's problems.

We started off with that plan and we started developing sample size calculations doing the paper version of the protocol. Then October 23rd, 2014, there was a meeting at WHO [World Health Organization in Geneva] about vaccine trials. I went for CDC and there were folks there from NIH and there were folks there from a number of academic institutions. Then there were people from the [affected] countries, as well as a number of donors. We were talking about what could be done. There were manufacturers there about their candidate vaccines. Where are we? Because frankly, we were talking about stuff but [products] hadn't really gone into people very much at all at that point. That

usually takes—it takes multiple years [to go] from animal [trials] to people for the small studies in people, and we were talking about doing a big field trial.

October 23rd was the first time that we offered. [CDC] had folks in West Africa already for the emergency response, but at that [Geneva] meeting we started to talk about this idea and if Sierra Leone was interested, or others were interested, we would be interested in working with somebody on this. Then the next week, or the last week in October or first week in November, we sent three people from CDC Atlanta to Sierra Leone to start meeting with counterparts and start talking about possible studies. Initially the possible study was this stepped wedge design. The folks—you'll probably talk to different people. People who went to the field in November and December—I'd made my first trip early December and by then we had a lead from the Sierra Leone College of Medicine and Allied Health Sciences, our principal investigator. We had a lead from the Ministry. They had been doing a lot of outreach to try to understand what was important to people. If we were going to do a study, what needed to be considered? They were looking for possible sites, trying to figure out where would we do it, trying to match what was going on with the epidemiology with the logistic needs that we have.

December, early December, it was still quite hypothetical, but it was still quite urgent. I think the week I was there was actually, looking back, the peak week of disease in terms of the number of cases per week and so forth. An overarching principle for us was not to distract from the response. CDC's staffing really had to go for emergency response. Staffing for our trial team couldn't take people who were going to be working on the

response. We needed a lot of different kinds of people, but we had to make sure. It was kind of exciting to work on a vaccine trial, but [we couldn't reassign people], no, no. You've got to fill the spots in the response [first] and then we can get people, although we needed people with certain skills.

In any case. In December, we were having leads here in Atlanta for the design, or for the trial which at that time was a planning [activity], and leads in the field who were figuring out [logistics like] who were the counterparts, where might we do it, what's all involved in this? Just to jump ahead. I think we've had over three hundred CDC staff involved in this trial, because people were rotating through both in the field and in Atlanta. I may be the only person who's been involved since September [2014]. We changed the design, we had to select a vaccine, we had to identify who would be eligible, we had to develop a cold chain. We had to do this in a way that would be acceptable and that would be, have both short-term and long-term acceptability. Our leads in the field from Sierra Leone, as they went out talking about this project, learned that when you talk about an Ebola vaccine people think you're talking about a vaccine that gives you Ebola. We learned that CDC didn't necessarily have a good reputation in Sierra Leone before the Ebola outbreak and that there were concerns that that field station CDC had in the eighties might have been where Ebola came from. It was really important to us that there be country ownership and a country voice and face for the trial, and that CDC work on this in a collaboration. My first trip in December, our lead from the university, we had a really good discussion and he said that the most important things from his perspective were

transparency and mutual respect. I said, perfect, because those are really important to me, too.

We had multiple objectives. Our overarching objective was to accelerate use of a vaccine while simultaneously evaluating its safety and efficacy. We didn't want to [roll out] vaccine that was unsafe. We wanted to find out if it worked quickly, because if it worked quickly it would be important to scale it up. We didn't want to just answer a study question and then stop. In Liberia, their goal was really good science of randomized, controlled, placebo-controlled safety and immunogenicity of two different vaccines against placebo. They didn't really have the phased introduction idea. In our study, we didn't stop when we realized we're not going to be able to measure efficacy because part of [our purpose] was accelerating availability and we were targeting high-risk healthcare workers and frontline workers. We ended up pretty much vaccinating anybody in the five districts we targeted who met the criteria, who could be enrolled. Essentially, [health workers in] those districts pretty much were eligible. We got over eight thousand people vaccinated with what I think is probably a very effective vaccine. The vaccine's [still] not licensed. It's 2016. As there are new cases and we do outbreak response, [vaccine] still [has to be used] under a research protocol [in order for] people to get vaccinated in the rings. We had from the beginning that goal of quickly figuring out if [the vaccine] works or if it's harmful while [if it's not harmful] making it available as quickly as possible.

The second overarching goal was to strengthen the capacity of Sierra Leone. We wanted to do this trial in a way that not only was safe, ethical, scientifically rigorous, but that had a long-term benefit for the country even if the vaccine didn't work, or even if the vaccine was harmful.

I think it's really hard in 2016 to fully remember or understand that this was a pretty scary enterprise. In December of 2014, a little study in Switzerland found unexpected side effects of one of the two vaccines. We had to decide which of these two vaccines are we going to use. We said, one of them has a better [chance]—we think theoretically it might be more effective. We didn't know. Just based on the nonhuman primate [results] and the immunogenicity, you couldn't really tell. We think the one that might be more effective is the one that might have unexpected side effects. We're talking about a community that has—is dealing with an epidemic, has very limited healthcare, all those things. We had to go through all this expert review to figure out which of the two vaccines to propose. Then we needed the country to decide, what do they think? They agreed with us and we went with the one vaccine [vesicular stomatitis virus, VSV]. The first doses [were given] when Jane [Seward] was there—that was intense. In January of 2015, we got the first dose response results from the human immunogenicity studies done elsewhere and instead of this dose [that we had expected], we needed a higher dose. Instead of a dose we were expecting, we needed an even higher dose and that meant that the bottled formulations had to be diluted in the field in a different way. It's a live replicating vaccine. Just the quality control of dilution. The vaccine had to be kept at minus eighty degrees. We had to get that to happen in a place with a very—where the

power—just to have power and a backup generator and everything was really complicated. We had to transport [vaccine doses] to all these different sites that we were going to be using. The logistics [reality] and the rigor [needed] were always in tension, just to make sure that we could do this carefully and well.

Then we had an extraordinary communication plan, because it was really important to us that people voluntarily participate, that they understand we didn't know if this [product] worked or not, that they didn't put themselves at extra risk because they thought they were protected with the vaccine. One of the reasons we didn't use a placebo—we changed our design, but we didn't ever use a placebo—was our principal investigator felt like people won't believe if you just give them a shot, they're not going to believe it's not real. Whatever you tell them, they're not going to believe it. We counseled everybody on continuing to use protective equipment and so forth. Anyway. We had to pick the vaccine, we had to change the formulation plans and really try to do everything as safely as possible.

Our communication program, the folks in Sierra Leone and our team from CDC really worked hard on stakeholder engagement, visiting the chiefs in the districts, visiting the health leaders in the districts, meeting with all the healthcare workers before they could enroll to really understand how we should design this in a way that was going to be acceptable. Then had to do the training, very short notice because it was a race against time to get the trial going. Both because we wanted it to be useful and because the cases were starting to go away, which was good.

My role was—there was many funny things about this trial, but my role was cheerleader because almost every day additional problems emerged. The two leads in Atlanta would meet with me every day, tell me what they were hearing from the field, what was the latest catastrophe, and I would reflect what we ought to do or help give them feedback. Then I had these pom-poms and I would bring out my pom-poms to say, we're going to get through this. It looks like there's no way out of this, but we've gotten through worse before and we'll keep getting through it. I think nobody believed it was going to happen until it started and then when it started, of course, there were so many other additional challenges. Whenever we thought it was about to slow down, something else happened. It's been a big journey. Very, very meaningful to be part of, but not easy.

Q: I have a question. Reflecting back on something you said way back a few minutes ago.

Schuchat: I told you, you weren't going to have any trouble getting me talking.

Q: It's good. It's good. This is whether you looked into why CDC had a scary reputation from their field office that was in the eighties.

Schuchat: Yeah. No, there was—I don't know that much. Remember, Sierra Leone has had a civil war. There was a field station that closed up and left. People presumably lost their jobs. The field station was a hemorrhagic virus field station. It wasn't an Ebola field station, it was a Lassa fever field station, but I think that it sort of makes sense that people

are there, then they're not there and it was one of those scary viruses. The rumors all around were challenging.

I would say that it was important to us that this wasn't a CDC trial, this was a Sierra Leone trial, and that we work really closely to assist and support and empower the Sierra Leoneans. They were dealing with an epidemic. The medical school was closed, the pharmacy school was closed, the nursing school was closed. All those people who were faculty or students worked for our trial because their school was closed. I think that we didn't want this to be the West swooping in because that wouldn't help them long term and that would only reduce trust. I think that the way the Ebola response worked, I think CDC was really well—very, very valued by the Sierra Leoneans. The emergency response was done with good partnership and care and putting the country's needs first. We wanted to be in the backdrop of that, so I do think CDC has a good reputation in the region now. But yeah, there was this sort of mystery about why were they there, and then they were gone. I would just say that we were sensitive to not getting off on the wrong foot there and doing it in a careful way.

Q: Right. Okay. I appreciate that explanation.

Schuchat: The other thing is just—because we probably [will] run out of time. We were designing a large trial to measure efficacy. You can study reactions, you can study immune response in the US. You can study that in Europe, but you can't measure efficacy when there's no disease. You have to do, if you're going to try to measure

efficacy it needs to be where there is disease. But we said from the beginning, in my cheerleader role, the best thing that could happen is the disease is controlled and we can't measure efficacy. That's the best outcome. Not that we'd get an answer and there's a [protective efficacy] number associated with this vaccine. That's the best thing.

The second best thing, that the partnership is strong and that we don't do things that will threaten the relationship long term. If we can contribute to licensure of an effective vaccine, amazing. If we can protect a lot of people who were putting their lives on the line by doing healthcare, that's fantastic. If we put as few [people as] possible at risk, because maybe it's a risky vaccine, we have to find [that out] really fast, so we don't give it to a lot of [other] people. Those things put a lot of pressure on us, but the issue of disease control was the highest priority for this epidemic, so we didn't want [our trial] to threaten that [disease control] and if it meant we weren't going to answer our question, that's okay.

Q: Let's come back to that a little bit, in a little bit. One question I had. Among the things that you were having to decide like among choosing the vaccine, you mentioned deciding who would be a part of the trial.

Schuchat: Yeah. We had intended from the beginning that we wanted to target healthcare workers. That was both practical and ethical. The idea was, the healthcare workers were at greater risk. They had about a hundred times higher risk than others early in the epidemic and if there's not enough doses for everybody in West Africa to get vaccine,

you would want to be directing the doses that are available to a trial where you could figure out if it works or is risky to highest risk people.

We also thought initially, the healthcare workers are probably more likely to be literate, knowledgeable, whatever—to be able to understand the idea of an investigational vaccine which is [a] pretty foreign [concept] to everybody [in] America [or] Sierra Leone. What? You're giving me a vaccine and you don't [even] know if it works or not? We sort of thought they might be [open], it might be more acceptable [to healthcare workers] to be part of a study. Healthcare workers is a big category. The epidemiology was saying healthcare workers and frontline workers, so our counterparts were actually discussing with the stakeholders who should be [included] and who should be out. Healthcare workers, we ended up saying, whatever your job—if you were in an Ebola treatment unit or a healthcare facility, if you were there cleaning up, doing sanitation, if you [worked in] administration but your workplace was one of the healthcare facilities—you were in.

Frontline workers. We kept going around and around. Ambulance drivers, burial workers, the people that swab, the surveillance. Who's a frontline worker and who isn't? It was this mix of their risk, their literacy, what their groups thought about being in a study, was it a fluid group that was only formed because of the epidemic where they could be identified? That was a process that the field team and the Sierra Leone leads really worked out with the nursing association, and the medical association, the district health officers. Really that sense of—it was both I would say, probably week to week it varied whether being in a trial was a good thing or being in a trial was a bad thing in terms of

which groups should be in or not. That was one of the many details that had to get worked out.

Q: I imagine also in the early stages that funding, you might have had to figure that out. Was that part of your role at all?

Schuchat: That was, yes, but that I would say, compared to [addressing challenges in] Sierra Leone, the original phase of this the funding wasn't a worry. That was, it was more, it was a worry for the agency, but that part, that got worked out fairly quickly in terms of, there were discussions about should the US government do more than one trial because the government was supporting the NIH trial. There were a series of senior discussions across the government to decide, yeah. It's a good idea to do more than one trial, more than one place, more than one design to mitigate the risk that one or the other—there was a third trial in [Guinea] that WHO and a consortium supported. Three different big trials helped make sure each country had the opportunity to be part of a big trial and also help mitigate the risk that one or more [trials] wouldn't achieve its objectives—or if there was a catastrophe in one of [the areas], there would be a way to keep going elsewhere. Yeah, there were some discussions [about funding but] compared to the usual, money wasn't the big headache for this one initially.

Q: Got you. Okay, thank you. You also mentioned hiring fulltime staff for the project. Can you talk about some of those people and those processes?

Schuchat: Yeah. I think that for the response we knew that we needed to have long-term staff and that it wasn't any way to do a field trial to have people rotating in for six or eight weeks. Initially we had people rotating in for six or eight weeks, so we did work to try to identify people who wanted to go move to West Africa and do this trial for what we thought would be six months. Surprise, surprise. We found—I would say all those processes took a lot longer than we wanted. We started working on that in probably November, December, and it was not until March, I think, when we got folks, the first of [the long-term staff] there and maybe others not until August. It was a pretty long process, but it was really good to get people who could stay for a long period of time.

What we didn't know initially was that some of the people we recruited for the fall and winter really became so committed that they were able to negotiate with their supervisors to go back later. We had a couple people, I think, who did three deployments [total] during different seasons. That was helpful, because honestly, when I went there in December [2014] the first thing anyone from Sierra Leone asked an American was, "How long are you here for?" It was usually, "I [am not here] for very long at all," but it was usually not the right answer of, "Until this is over." Which is—so that was difficult.

The Atlanta part was difficult, also. The people I recruited as team leads—in December I got two folks to be co-leads who were kind of committed to go the duration, but the duration was a lot longer than we thought [it would be] and one of them has moved to Kenya since then. The other of them, I thought after five or six months her role could be less, but it was still more than fulltime. We ended up when we were able to get—it took a

long time before we got folks who could liberate themselves from their permanent jobs and commit for longer. But it's been great to have the people that we've gotten for the long term.

Q: Can you describe some of those people?

Schuchat: There's so many people.

Q: Some of the ones you've worked most closely with.

Schuchat: Okay. Well, I can talk a little bit about Marc-Alain Widdowson. I don't know if you interviewed him or not, but he's in Kenya now. He joined us in November [2014] as our second Atlanta co-lead. A wonderful guy from, had been working in the [National Center for Immunization and Respiratory Diseases] Influenza Division doing a lot of international projects, had a very upbeat, light personality. Has a couple kids. I was not familiar with *The Lego Movie*, but he introduced me to the song "Everything is Awesome," so that became the little theme song for the trial because no matter how horrible things were, "everything is awesome."

Marc-Alain went back and forth several times. He identified some great NGOs [non-governmental organizations] in-country that could help with certain gaps. We had this whole thing with the cold chain, and the backup generators, and the backup-backup generators, and the electrical wiring. He found, he used to call them "his Germans," but

he found a German NGO that was really good at that who helped with filling some gaps in our central cold chain to make sure that we could safely wire and reinforce the cold chain where the vaccine was being stored.

He also—WHO had actually had found this very innovative approach to cold storage, so Marc-Alain was kind of the poster boy for that. Really helping us see what a really exciting innovation we had. These sort of big thermos things that had phase change material that could keep the vaccine cold for a long time. Marc-Alain was able to bridge the field-Atlanta divide in a nice way, but it was pretty—I totally underestimated how much work and detail and staffing we needed. He, and everybody else, was way overworked on this. In August, he moved off to Kenya where he's doing great things. Let's see. That's a person you may or may not be able to talk with.

Q: Sure.

Schuchat: Okay?

Q: Anyone else?

Schuchat: Is your goal—I mean, there's hundreds of people. Is your goal for me to talk about somebody that you've interviewed, or just notable people?

Q: No. My goal is really to talk about the people who are within your experience. The ones who you spent the most time with.

Schuchat: Sure, okay.

Q: Yeah, and we can talk about Sierra Leoneans, the professor. The—yeah.

Schuchat: Yeah, okay. Dr. [Mohamed] Samai, the principal investigator—you've got to see this from his perspective. He is the acting provost for this university system that's been closed because of the epidemic. The government asks him to be our lead on this because the Ministry is so busy dealing with the emergency response. We keep sending different people to work with him as the lead, he's very patient, very smart, a very wise person. You could sort of see in him as we were underestimating how huge this was, what a huge responsibility it was for him because he really was the face of the trial and the voice of the trial with the media, with the leadership, with the parliament, with the regional folks.

We were so lucky that he was asked to do this. He really—there's not a job description for what we were asking him to do. To be thoughtful, strategic, calm, insightful. He really [was] just tireless. We got way more than—he really did a beautiful job. This was not easy. When I went in December 2014, I got to go to this faculty meeting where he was presenting to the senior faculty, or whatever they call the faculty, the leadership of the university system. The registrar, and the deans, the department chairs. He's presenting

this idea of a trial and he's kind of doing his roadshow which he'd been doing out with the district health officers, with the medical association. He's presenting to this [academic] group. It was interesting because it was an African group, but sort of half British-African, half West African-African. They were just like faculty meetings anywhere. Just the—everybody had their opinion and their two cents and wanted to talk about odd things. He just answered every question and was—the questions would come and I would think of the answer because I thought, maybe I'm going to have to answer this. He always had a better answer than I would have. He just always knew who was asking and knew how to absorb it and listen to it and then give a thoughtful response.

Everybody had an agenda and everybody—but the university was really excited at that meeting, anyway, maybe because I was there, but they were very excited that the university was taking this on. They said, we really need to step up and as an institution in the middle of this epidemic, we need to do more and this is the perfect thing for us to do. It was also very—in that month, early December, the meetings would start with a moment of silence. The halls where you're waiting to have your meetings had the photos of the physicians that had died or the nurses that had died. While we there another close friend of our colleagues had just died. Dr. Samai said something at that meeting about, in these days, we wake up not knowing which of us isn't going to be there at the end of the day. Essentially, the discussion of the faculty after all the academic methods was, we have to do this trial. We have to do this. What choice do we have? It's just so important for us to control this epidemic and to find a longer term solution.

It wasn't the AIDS epidemic, but it was an acute [crisis]—everybody knew people who were affected in a country with, I think, only about two hundred physicians [total]; they had eleven or twelve die from Ebola. You just think of what it means to become a physician in a country like Sierra Leone and stay there. It's really, really extraordinary and for that many [to die], as well as all. It was hundreds of health workers. I think as we're not going chronologically, I can tell you, just about a year after that first trip that I made I was invited to speak at the graduation for the medical school, nursing school, pharmacy school as their guest speaker. It was incredible.

That school, those kids, their classes were cancelled. They really didn't know if they were going to get to graduate. About fifty of them worked on our trial. The young person who was awarded the best physician award, a young woman and a man who was awarded the best pharmacy student were both [staff] from our trial. Getting to speak to them you just realize their whole training was interrupted by the worst epidemic you could imagine, but they were getting their graduation, getting their diplomas. It was just really meaningful to get to be there and to see life come back in the families, and so forth. It was about a five-hour ceremony and about 900 degrees temperature. [laughs] Everybody was—they were all wearing the gowns. I didn't have to wear a gown, but it was really incredible to get to be part of that and talk to them.

Q: How many trips did you make?

Schuchat: I did three trips.¹ We also, we had—I went there in early December then in February [2015] we had this meeting in Brussels. We had a meeting in Brussels where Dr. Samai came and a couple other people from Sierra Leone came, but we had our first meeting of the Data and Safety Monitoring Board [DSMB] and the international scientific steering committee. This was before we launched, but we had our protocol under review at FDA [Food and Drug Administration], and all the institutional review boards, and in Sierra Leone. We wanted the [DSMB] to give us input about the safety [evaluation] and whether [the plans] were okay. We wanted the scientific steering committee to give us advice about implementation.

We met at [a hotel at] the Brussels Airport. It was less than twenty-four hours or something that we were actually there, I guess, practically. The hotel at the airport which, of course, went through such a horrible [terrorist attack] last year. Anyway, that same airport. We met there because the West Africans and the Europeans on our trial and Americans—it was sort of equidistant for everybody, or one flight for some people. It was five flights for the poor guys from Sierra Leone because all the [routine] flights were cancelled, so they got rerouted. That was a pretty intense meeting because we hadn't quite started, but we'd been in this [planning stage] for a while now. We were still waiting for the money to get there so they could hire the people who could then get trained. We were waiting on the contract research organization to get funded, and so forth.

¹ Note from A. Schuchat, January 2017: I had made three trips at the time of this interview. I returned again in August 2016 for a fourth trip.

In any case, that was really pretty intense because we'd been talking about this since September [2014]. Now, a lot of the people on the committees had done a zillion vaccine trials. They were like, "Oh my God. You're trying to go from here to there overnight, practically". For us it was like, "we've changed the design twice already. Please don't make us change the design again." Really thoughtful input, really intense because the circumstances had changed a lot since the fall. By February the rates were much lower. Are we thinking of everything?

The Data and Safety Monitoring Board said no. We're worried about this safety [plan]. So few people—like, forty people in the world had gotten the dose of vaccine that we were [going to be] giving. They said, we need to see the safety data much more often. We want you to do the sub-study on the safety at the beginning. We said, look. Can we do that later after we've got all the kinks worked out? When we're very—when we've got [a smooth] enrollment [process] going. They said, no, no. You need to do that sub-study on safety right at the beginning because if there's a problem, we don't want to wait two months to find it out, which just doubled the amount of work we had to do at the beginning. They had a lot of influence at that meeting. That was sort of the first convergence of a higher-level West with the international experts with a couple of the folks from the field.

Then I went back in April [2015]. In April, a couple weeks after the vaccine trial had started, and it was pretty incredible. This was so hypothetical for a long time. Getting to go to—I got to go to the Connaught site and they were—I basically got to walk through.

Had the sisters do the enrollment with me and they were hilarious, just sharing some of their [stories]—a couple women who had worked together as midwives, basically, were now in charge of the enrollment or the consent phase. Tell me their war stories but also what it meant to be part of the trial. I got to walk through the whole thing where they did screening, and enrollment, and consent, and then walk across the street to where they did the vaccinating. You walk into the room where they're doing the vaccinating, we're really doing this. It's incredible. To talk to some of the participants. We had to observe people for some time after they got the shot to see if there were short-term reactions, so I chatted with the folks that were in it. I think they were—the folks that I talked to were [mainly] the frontline workers, not the healthcare workers. They were, "I saw a friend get it. It seemed okay, so I thought I would, too." That sense of, sure I'll be part of this. It was pretty interesting.

Then again, going back in November [2015] when we had finished enrollment, but were continuing with the follow up. To go—oh, my God. I didn't tell you about this. The first visit in December [2014], Dr. Samai shows—Rana Hajjeh was the field team lead then. Dr. Samai takes Rana and me into a—we were talking about where we can do the central [trial management], where's the trial [data center] going to be based. He said, I think we have a place where we could do it. He walks us down this hill near his office. They call it the conference room. He said, I think we could kind of fix this place up and it could be where the trial staff are based. We thought, this is great, because it's right by him so he'll really be close. It will be easy. It's not across town. We go in there and, honestly, Marc-Alain had the great line. He goes, he thinks people were living in it. There were definitely

animals living in it. It was just like your ultimate attic [filled with] papers from the [ages]—they had to clean it out and we were going to renovate it. That was the joke because they were going to renovate it and then they found out it was totally not structurally sound, so it had to be leveled and then built. We have photos of the before [and after stages].

When I got to go back in November [2015] to see it filled. I went in April and they were still—the files were all over the place, it wasn't really set up yet. When I went back in November and it's just abuzz with all these Sierra Leoneans. The nurses, the data people, the monitors, the supervisors. You could just see that this was a well-oiled machine. We got to dedicate the building while I was there. It was just really beautiful to see what was really a horrible storage/bird spot turned into a really nice place that they can use for other research monitoring.

Then all these people that had gained so many skills. I know Dr. Samai was saying, a lot of the students were coming in like, I thought I wanted to do clinical work but I really want to do public health. The trial really changed their trajectories. That was pretty meaningful.

Q: To whom or to what did you dedicate the building?

Schuchat: Oh, okay. Basically the dedication. Yes, their—there was a plaque that was placed because the building itself was actually paid for by a generous donation from the

CDC Foundation which was actually from the Mark Zuckerberg and [Priscilla] Chan Foundation. There's just a tiny, little sign that says that because they were low key [about their donation] and whatever. There's a tiny sign. We got to do that, but it was essentially like a party. The Minister of Health, Dr. Samai, the "head of the [university] court" I think is what they call the university [senior authority]. The CDC [office] country director and I got to speak at the dedication and they invited all the partners and the staff, and so forth. It was kind of an official dedication or opening, I guess, of the [site]. It was one of the many ceremonies.

Then we got to have a closing ceremony for one of the sites, which was awesome. Where the head nurse, they all spoke about what it had been like to be [part of the trial]—we were shutting down that site because it had finished enrollment and follow-up. A lot of people were losing their jobs, but it was a really fun event. The people, I think they were just so proud of what they'd done. The stories that the staff were telling about that, everybody had to have a selfie. In this era. I had to be in everybody's selfie which was very fun. It was pretty special.

Then [one] trip was also [over] Thanksgiving. So I got to see all the CDC staff in the country for Thanksgiving—this was 2015—who were spending their month [or more] over there. It was just nice. Our workforce was just awesome. Really, really special people who went far away to do difficult stuff and threw everything at it.

Q: Right. I think we have—you're good until 5:30?

Schuchat: Yeah.

Q: Okay, so we have about twenty minutes. That's good. Can you tell me a bit about becoming principal deputy director in 2015 in the midst of all of this?

Schuchat: Oh, really? Okay.

Q: You don't have to.

Schuchat: No, no. What I can say is, when I was asked to do this I negotiated to keep STRIVE [Sierra Leone Trial to Introduce a Vaccine against Ebola]. I just did not feel that it was appropriate with so much turnover to hand over my role, which was not fulltime the way a lot of people were. The continuity and the, you know, I feel, I guess officially I'm the executive sponsor so we had a number of people in key [leadership] roles. Marc-Alain, and Stephanie [J.] Schrag, and Jane Seward and now Barbara Mahon. As somebody who saw it from the beginning, I did feel that [responsibility]. I was able to negotiate. Initially it was like, well, how much time is it going to be? That's the irony, because whenever you say it's this much time it's like, ten times as much time.

I think everyone who was part of STRIVE feels very specially about it. I had been working in infectious diseases and vaccines, as well, for almost my whole time at CDC. Infectious diseases for twenty-eight years, vaccines for almost that whole time and I have

done other vaccine trials and I've done outbreaks, and I've done a lot of emergency responses. This really brought a lot together. For me, I think this is probably the most difficult project that I've been involved with. The pandemic was pretty hard. The pandemic [was a] big team effort. SARS was pretty hard, but I think as a project, a research study, this was definitely the hardest thing I've ever been involved in.

Obviously, doing a research study in the middle of an epidemic with a temporary workforce, and counterparts that have never done this kind of thing, and a lot of us who have never done this kind of thing in the middle of an Ebola epidemic. It's pretty tough.

To do it where people feel better about the partnership now than before, and stronger now. I think it was really important to me to do it in a way that we could all be proud of.

There was so many—it could have been a risky vaccine. It could have been a vaccine that didn't work. We think it probably worked, but to do this in a way that a long time from now we can look back proudly was important to me.

Changing jobs. I was really glad I could keep this. My job's really different than my old job. My time with the team which is no longer daily, but weekly, and then a lot of emails, is really special.

Q: Great. Thank you. I'm wondering if we can take a minute and evaluate. One of the goals of the program you said was to build capacity. For it not just to be this flash in the pan thing that then leaves. Can you talk about to the extent that you feel that, that has been done and continues to improve?

Schuchat: Well, we trained about four hundred staff in what's called good clinical practices, you know, the way you're supposed to do research trials. They have skills that they didn't have. Many of them may use them in future research projects, many may not, but they got that additional training. There were physical investments in terms of the data center or the cold chain minus 80 freezers that will stay and be useful to the country. There were a lot of collaborations that were launched. One of the things I was trying to do in finding people to be field team leads was inviting people from a number of different programs who had leadership skills, field skills, but who also might find a spark, or an idea, or a collaboration that they would want to follow up on. We're hopeful that [there will] be follow-on research that CDC's involved in and that others are involved in to take advantage of the individuals and some of the capacity [that was built].

It's, unfortunately, a lot of research is done in places with a lot of capacity. Sierra Leone is a very high-mortality place. A lot of disease burden, a lot of need and I hope after the Ebola epidemic that it's a huge opportunity for them to grow in their skills and their impact. Research in that context, there's so many things that could be addressed that they really need. We hope their public health capacity will improve. I know we helped their research capacity. You know, it's very important that it be what they want to do. What's important, what's a priority for them. We've tried to help with contacts, and with ideas, and with support, but it really needs to be based on their priorities, I think.

Q: What are those priorities?

Schuchat: Well, their health—there's twofold, you know. This is a context where, what are the big causes of death? Even malaria's huge, maternal mortality is important. I think sometimes at the university they'll be research interests that people have based on the training that they got, which might have been in Europe. One of the interests of one of the folks that we—with one of our investigators was cardiovascular disease, you know, stroke. A neurologist. Just where the rates of hypertension are extraordinary in West Africa and the preventable disease burden is high. You could say, what's the research versus the public health program? There's just a lot of potential program growth that could save a lot of lives, but then also I think for the university folks, they're trying to marry what their passions are with what the need is. They don't have a lot of resources.

Q: Right. Of course I asked that knowing that there are so many priorities and a diversity of opinions.

Schuchat: Yeah. I think that, we think that the priority from our perspective as an agency is really to strengthen their public health capacity. STRIVE was this research thing, but the public health capacity is all about early detection, response, and prevention. That they don't have an outbreak that gets this out of control. They had really bad outbreaks of measles because they couldn't vaccinate because [of the] Ebola [epidemic]. The malaria mortality went way up because the health services were pretty much shut down [during the Ebola epidemic]. There's rebuilding from the interrupted services and then there's

really getting a much better public health capacity that can be sustained without the West there.

Q: Right. Can you tell me about what's left to do for STRIVE?

Schuchat: Yeah. Part of the protocol was that after vaccination you get followed for six months for any serious event—hospitalization or seeking medical care. We still have folks that are in that phase and they'll be finished in June [2016]. We have been doing a study of the immune response, and so we'll be—we've finished collecting bloods at six months after vaccination, but we are also going to collect bloods around twelve months. That will be wrapping up in June or July [2016].

Then we excluded people who were pregnant in terms of enrollment. Honestly, that was another thing. We had to get pregnancy tests and water so people—we really had to get facilities for people so that we could check urine pregnancy tests. Although we wouldn't enroll anyone who was pregnant, if a woman became pregnant within two months of getting the vaccine our protocol requires that we follow her through pregnancy and through the baby's delivery, so [there will] be some pregnancies that [began] within two months of vaccination that we'll still be following up probably through next fall. That's a little bit of a tail.

There's a huge amount involved with closing up of this kind of trial because you want to archive the records in case something strange happens in another study. You need to do

all the quality control of the records. Then the data analysis, the lab testing, the papers.

This summer the program's doing a writing workshop that's meant to link up a Sierra Leonean lead with a US counterpart and then kind of a didactic, and then hands-on session so folks can get more experience with writing up the results of the study.

Then a number of presentations in the fall that we hope our West African colleagues will be giving. I think this is part of the skills transfer. There's the, what do we have to do as a study? What do we have to do as a partnership? We had to find a storage place. I don't know if Jane mentioned. We had to find how to store the papers where they were saying, we have to get a room and then air conditioning. I'm like, I don't want to air condition a room that people are not in. This is wrong. We're getting some container or something that will keep the papers from the trial, the original records, okay for five years. There's logistics in everything and that's another thing they're looking into, and costing out, and figuring out how we're going to do. There's plenty of details left.

Even like shipping the specimens. Honestly, the specimens are their own oral history, though. We had to do fake specimen shipments to make sure it was going to work, because you had to keep them frozen. The first fake shipment didn't work. Even getting the vaccines shipped there, the first time the doses were stuck in Casablanca, then they were stuck in New York. The sagas in this trial were incredible. We do have six-month specimens, I think almost all of them here. We split. We kept half there, but we have aliquots here. We have to get it to the special lab that the company is using so the results

will be submitted to FDA. There's a lot of science left to do and logistics, but in terms of the huge field staff, it's downsized already.

Q: Right. One thing that Jane emphasized that she really cares about is that, these vaccines don't just fade into nothing and go nowhere.

Schuchat: Right, yeah. I think that there's a big work plan around that and it takes a lot of pushing, because the world's focused on Zika now and these same companies are focused on Zika. We're hammering them that we've been working with Merck and I think Merck's committed, but we don't want you to move on to the next one just because you think you're done. Because the vaccine's still under its IND [investigational new drug authorization], it can only be [used] under a research protocol if it's approved by the country and so forth. Right now when there's been flare-ups in Liberia, Sierra Leone, or Guinea, the vaccine's been given through one or another protocol and STRIVE has helped in terms of cold chain or vaccinators, or something. That's been done with one or another partner so we are still working out how to do that. In the period before vaccine's licensed, but where there's still these outbreaks or clusters, how do we get this ring protocol implemented anywhere that needs it? It's been pretty ad hoc so far.

Jane's working on that and some others across CDC are working on that, as well. Yeah, there's a lot to do. Working with the FDA, working with the company, working with the contract lab, working with our lab. Yes, so we're not—this is a journey and we're not finished with the journey yet. Yeah.

Q: Okay. Do you have any other, anything else that you'd want to make sure that we have on record that's about STRIVE or about your experience with the response?

Schuchat: It's easy to talk about building capacity in Sierra Leone, but I actually think STRIVE built capacity at CDC. We do epidemiology, we work on vaccines, we deal with research in Africa, but this was a really big undertaking. The number of CDC staff that were trained, that gained new skills, that grew as a part of this I think is a really nice legacy, as well.

Q: What has it meant for you?

Schuchat: When you move from being frontline staff or the hands-on part of the agency to a leadership or management role, you gain and you lose. I think that this project has let me be a supervisor, again, of people who were awesome, who were doing great work. Let me feel connected with the Ebola epidemic. I would say before STRIVE or before I was asked to help with vaccines, I was feeling odd because it's the first of the huge CDC responses that I wasn't in the middle of, or didn't have a role in since I'd been here. With the anthrax, and hantavirus, and the pandemic—my role might have been a little like being on phone duty for hantavirus. But I was pretty much watching the situation with Ebola and not really having a concrete role. It gave me a really meaningful role. I think whenever there's a global emergency or a US emergency and you're at CDC, you want to be part of it. You want to help. As a leader, how was I going to help? This was a very

meaningful way to be involved. I met a lot of great people. A wonderful contrast to the rest of my duties. I think it helped with reminding me, as well as me reminding everybody else that, there wasn't a problem that we couldn't handle. We just had to break it down and take it apart, be patient, be persistent and we would get through it. Almost everything that went wrong we can find a way to get through this and fix it, and make it right, and keep our principles of transparency, mutual respect, leaving the country stronger, and ideally accelerating vaccine availability.

Q: Okay. That's all I have.

Schuchat: Okay. You probably got a little bit about STRIVE in there.

Q: I did. I did.

Schuchat: I told you that it was going to be focus, was going to be my problems.

Q: No. This has been brilliant and it's been a privilege hearing about it from you. Thank you.

Schuchat: Yeah. I'm sure you're hearing all kinds of things from the folks that you're—it is. Everybody has their little slice.

Q: Yeah. I really liked that dual metaphor that you were using. It's an elephant, but it's also a river.

Schuchat: Totally. Yeah. I think the thing is, Jane's been involved probably since February or March [2015]. She's been involved. That's a pretty long time, but we had months before that. Jane and I have totally different experiences, because Jane—they love her in Sierra Leone. She was such a great leader in terms of the challenges. Her watch was when we started [the trial itself] and if Jane had not been there then, we wouldn't have started. We needed her skillset to get to that push, push, push. Address, adjust. There was nothing she wasn't going to tackle. This was so complicated, so detailed, that we kind of all needed to play our role.

Q: Right. I felt a little anxiety that I should have been asking you more about the first few months and that whole theoretical stage, but I think we got some good stuff about how the model changed.

Schuchat: Yeah. There's a person you could talk to if you wanted to hear more about it, because she was awesome. I was going to, depending on time. Stephanie Schrag came in as the co-lead with Marc-Alain. She's really smart and she's really analytical. She looked at it—I don't know if you talked to her.

Q: Not yet.

Schuchat: You might have talked to her. She was in the field at Dallas. Poor Stephanie.

The things Stephanie was—Stephanie will probably kill me, but Stephanie was one of my EIS officers and she's really smart and she's really great. Anyway, I needed somebody to join the team as co-lead with Marc-Alain and I wanted a really smart, detail-oriented person because Marc-Alain is great, but he's more like the make-things-happen [guy] than the go-deep. And you needed both. Stephanie, I reached out to her. "Could I get you to help with this?" She goes, "oh my God. I just came back from Dallas. I'd love to be part of this vaccine trial, but I just came back from Dallas. I was going to take two weeks [off]." I said, "Well could you make it one week because we really need you?" She agreed. "I need to be out by May because I'm doing this international [study] that they really need me and the whole study." I said, "Okay. Could you make it one week and yeah you can be out by May."

Then I get all the letters from her counterpart in Bangladesh, who's depending on her for May. How could I take her away from him? She came and looked at the situation, and looked at the epi, and just really—then started to reach out about the methods and said, "I don't think we should go with this design." We'd been talking about this design for a couple months now. She said, "What's on the table here?" I said, "What do you want?" She goes, "Well, I think we should change designs." I said "well, you make a compelling case and say what you think we should do and let's talk about it." She called some of the experts, got the statisticians, came up with some stuff. December was like this. She came up, what can we change? What can't we change? We had a whole give and take there, because of course Stephanie would have rather done a randomized controlled double-

blinded placebo clinical trial. She came up with this change so then we had to say, “What do we think? Should we do it? Then what do the partners think, because they’ve been telling everybody, too, in country.”

Which is so good at CDC. A smart person looks at the same thing and says, I don’t know. I think we should go this other direction. She was terrific, really, with a lot of the details with the protocol, with the FDA, with the DSMB. She also has her Dallas stories, so she was—and this is where, we had people who were brilliant at the science, and the people who were really good at the implementation, people from all these parts of the agency who had done trials under INDs which are really complicated. None of us had all of the skills, myself for sure, but we cobbled together what we could and we had some great partners outside the agency, too.

[break]

Q: Yeah. My interview with Jane was one of my favorites, definitely. We spent three hours.

Schuchat: Yeah. She’s been back several times. Yeah, no. It was—I went three times when there were three different field leads each time. The third time, I don’t know if you talked to Amanda, but Amanda [C.] Cohn was like the point of the spear, I tell her. She’s a very petite woman. She was our explorer who went to talk about the trial as the first lead. She went back a year later. When I went the second time she was there. She had

worked on it at the beginning when it was just pitching. Then she got to go see it as a very mature.

Q: That's nice. Full circle.

Schuchat: Anyway. Jane went for three months or something. I think she went March, April, May or something like that. Then she went back in July. I think it might be her fourth trip now or longer, but she would go for quite a while each time and then when she came back, she was able to stay with it. She was awesome.

Q: Yeah. So really funny. She was one of the funniest.

Schuchat: I'm just unsure. There's some—I'm sure there's some stuff she shouldn't have told you, but there is definitely some stuff. Did she tell you about the rats?

Q: No.

Schuchat: There was this one point where we had to go through conditions of the beginning. She and this senior person from the ministry were assigned to negotiate. To go through the list of [requests] and figure out what should and shouldn't be addressed. She describes it. The two of them sat under this tree at Connaught Hospital for a couple hours in the dark reviewing the list and watching the rats run around. I was in that site. She

goes, “oh, yeah that’s where we sat right under there, but we were watching the rats, but we got it done.” It was very memorable.

Q: That’s so funny. She talked about sitting under the tree, but no rats.

Schuchat: Yeah, the sitting under the tree. You heard about sitting under the tree. That was the turning point, really. It was a very important day when she sat under that tree, but there were rats running around while she sat.

Q: She didn’t mention that.

Schuchat: It could be. I saw a rat in a New York City hospital, so I’m not going to say anything about them.

Q: I saw one last night walking to Chipotle.

END