INTERVIEW WITH

DR. ANNE SCHUCHAT

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Anne Schuchat
Interviewed at Dr. Shuchat's Office
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H1N1 Oral History Project
Interviewed by Sheena Morrison

Dr. Anne Schuchat: AS
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr. Anne Schuchat on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on February 1st, 2010, at Dr. Schuchat's office in Atlanta. The interviewer is Sheena Morrison.

SM: May I call you Anne?

AS: Sure.

SM: Okay. Can you tell me what your position here is at CDC, and how long have you held this position?

AS: Sure, can I give you a complicated answer?

SM: Absolutely.

AS: I'm the director of the National Center for Immunization and Respiratory Diseases, and since December 2005, I've been in either this position or its predecessor. There was a reorganization.

At the time that the pandemic began, I was on the detail that began in February to be the Acting Deputy Director for Science and Programming for CDC. I was reporting to the Acting Director, Rich Besser, and that was supposed to be about a three month detail before I went back to my regular job.

So, the other position is that pretty much since June, instead of returning to my Center, I was really full time on the response. I've considered my position more to be the chief health officer for the H1N1 response. And then hopefully, relatively soon, I'll be able to go back and be the actual director of my Center. My deputy is serving as the acting director right now. So, it's not a short answer.

SM: Alright. So you've been wearing multiple hats then.

AS: Right. My long term hat is Center Director for the Center that contains the entire influenza division and the

whole domestic immunization program, and that has lots of international immunization responsibilities as well. So, many aspects of the pandemic would have been in my long term responsibilities. But then right at the beginning, I was in a different leadership post above that, not as day to day involved.

SM: So you got, in essence, an on-the-job training at the highest possible point.

AS: Yes. And so probably, as you're talking to folks you're learning that you need to talk to many people to piece things together, because the pandemic--really the U.S. recognition of the pandemic--began in April, and we did not yet have a Secretary of HHS. We did not have a permanent CDC Director; we didn't have a permanent ASPR; we didn't have a permanent ASH. There were lots of political positions that weren't yet established. So much of the leadership was either temporary or the career people.

SM: Okay. So at what point did you actually become involved in the response efforts?

AS: For me, it was Friday, April 17th, when I came home that evening and walked in the door and my cell phone rang and it was my--it's complicated--but the person who was then serving as the Acting Center Director in my old job called me in my new job as Deputy to notify me that they had found two children in Southern California who had a new influenza virus. They had gotten sick earlier--I think March or so was their illness dates. One of them was recognized through this diagnostic test we were funding to have developed, and the other was recognized through a border infectious disease system.

Essentially, the strains had come in and turned out to be different from what we knew about of swine origin. And every time we had one of these (we'd been having swine origin influenza cases,) they become reportable nationally. And we also were reporting them to WHO as unusual things. Since there were two with the same strain from two different counties in Southern California, it was even more urgent than just one. I was being notified, and I immediately called Rich Besser who was acting director to let him know.

And they let me know that the team was working that weekend to put together alerts so that we would find more cases, and to try to do an MMWR article. And I think they were doing an EPI-X, some of the notification things that we do.

I then learned a little more on Sunday when I was at my every Sunday meeting with my acting director to find out what was going on at the Center, and she called me up about some of the additional work that was being done. So essentially, we didn't know if it was going to be something, but it seemed like they were working on it the right way. A lot of the focus at that point was to get the word out, so we could find out if there's anybody else with this kind of thing and also to work with California to try to do a more intensive investigation--to get an invitation to be able to help them or encourage them to really look and figure out whether there were more cases.

SM: So what mechanisms were in place once you determined that this was actually a highly transmissible virus? What mechanisms were put in place to communicate with the different states?

AS: Right. So the first week, there are a couple of different things. And I'll probably have to check, but one thing was this MMWR article that was an early release. It actually came out at about 2:00 in the morning on Tuesday, April 21st.

I think they also did some other things, like, there's this health alert network thing you can do, the EPI-X posting, which is a secure network that goes around to the Health Departments to basically ask people to look at their specimens and if they had un-typed influenza to send it in so people could check and see what it is. With the MMWR on Tuesday, there was some media availability, so the subject matter experts answered questions of the key reporters.

And then by Thursday, we knew of 5 more cases, and that was when we held our first press conference. So the 23rd, I did that press conference with Nancy Cox, who is the Flu Division Chief. And there we were. The MMWR on Tuesday was already out. We were going to be updating more information, I think, in the MMWR on the following day, but we just on Thursday let people know, "Okay, now there are 7 cases. Everybody's recovered. One of the people was hospitalized. They include 2 kids in Texas who went to the same school.

So this is much more widespread." And the press conference was basically to let people know we need to look for this. It might be serious, it might not be. We don't know. And that was sort of one level of alert.

At the same time really during the same weeks, there had been notification of serious respiratory disease in Mexico, and it was on Pro Med. It was in our various rumor reports and such, and there was back and forth trying to figure out what's going on there. They tested for flu and said it was flu negative. Was it SARS? No, it wasn't. So there was a lot of back and forth going on there.

And I didn't know about it, but our flu folks were involved with the back and forth with the Mexicans in terms of getting specimens. I'd sent an email about, I don't know, the week before, something like, "We better get specimens. I'll feel more comfortable that what's happening in Mexico is not flu when we have specimens in our own lab." But I think that that same Thursday, April 23rd, when we had the press conference that evening, the Canadians called Rich Besser to let him know about the lab results, and Mexicans called Nancy, and basically, CDC was officially-unofficially informed. We also had the specimens and were

able to test them ourselves. And so, by Thursday afternoon or evening, there was awareness that serious disease in Mexico and the mild disease in the U.S. were caused by the same virus.

So that led to all kinds of notifications of leadership within the U.S. Government and dialogue with Canada and Mexico. Also Friday, the second press conference we had, which Rich Besser did--basically my press conference was, "Something we were watching. We don't know if it's important or not." Rich's press conference was, "This is important. This is a new virus that's causing fatalities, and we all need to work together on this urgently." And then it was pretty much non-stop communication from then on.

SM: So can you tell me a little bit more about your role within the scope of the response efforts?

AS: Right. I think because I both have the long term Center responsibilities for this area, and because I was the Acting Deputy, I had a fairly senior role from the beginning. They asked me to do the first press conference. Rich could only do so many things at the same time for

leadership duties. Fairly quickly, he was being pulled in multiple directions and asked by Monday of the following week. He said there were all these hearings that were being scheduled. They wanted him to come to DC, but he was leading the response. He basically said, "I need you to go to Washington and do these things that the CDC Director is supposed to do. You be me up there. I will run the response down here." We joke that I had to go talk about this thing; I actually got sent to Siberia.

They allowed him to do one congressional hearing by video conference from here. He did one in the morning. In the afternoon, I did one. That following week I did three congressional hearings, and then the week after that I did two more. And you know, one of them I did with Secretary Napolitano, which was really unusual. You think a Secretary of another Department would usually be at a hearing with a Secretary of HHS, but we didn't yet have our Secretary of HHS. Then maybe, she'd be doing it with a CDC Director, but we didn't have a CDC Director. Or maybe, she'd be doing it with CDC's Acting Director. Well, he said, "I have to be running a response."

I shouldn't say this on tape but the funny thing from my perspective was, there was this email from our CDC Washington office saying, "They've okayed the Schuchat option", which is basically a total breach of protocol, to have someone who's not even the acting director--I'm not even the Acting Deputy Director, I'm the permanent Center Director. I think that's how they listed me on the hearing. So, I did that hearing with Secretary Napolitano, and then we both went to address this lunch with this joint bipartisan Congress thing--Congress people from both parties, hundreds of them. Secretary Sebelius had just been sworn in; she met us there. And so I got to meet the Secretary on her first day in office after testifying with the other Secretary.

So my role initially was partly to be--I mean, I didn't move to Washington, but I was up there practically every week--to partly be a senior leader with science credibility for Washington duties, either supporting our Secretary once she got there or representing the agency for Congress.

And then I split some of the media work with Rich. He did lots of the press conferences, I did other ones. We were not turning down anything because that was the policy. So

we both were pretty much nonstop doing work, and he would do usually the Morning Show big stuff, and I would do a lot of the other stuff.

But also, my official role in the response is called the Chief Health Officer and that involves the strategy in science. And so, for the key leadership updates the teams would pull together information and brief the response leadership. We would have director's updates. We would have them twice a day, I think, at the beginning, but then we moved to once a day. But now, they're basically a couple times a week. But at those meetings, I would ask questions but also advise on directions and priorities and strategy. So, I view it as, I had a lot of media responsibilities and congressional representation and also strategy in science input into how we were responding.

SM: May I ask what was the nature of the congressional hearings? I mean, you spent a lot of time there. I'm assuming that it was at the direction of Congress.

AS: It was very interesting because we had these round of hearings in April and May, and then others this fall. And they were really different, as you can imagine. So the

first hearing, there was no testimony. They basically asked one day and the next day we were up there. And so it was just answering their questions about what's going on, and basically, trying to keep them informed. Are we ready? What's going to happen?--lots of questions out of concern. They were concerned because their constituents were concerned.

At the five hearings--two Senate, three House (then some briefings, one of them with the Homeland Security Committee)--some of the senators were like, "Why aren't we closing the border? We should close the border." Very much about, are we being aggressive enough? Then lots of the congressmen wanted to know, "What's going to happen? Is this going to be the end of the world? Are we ready? What more should we have done?" Initially, they were much more, very, very respectful. Whoever was testifying was pretty much, we had the scientists here to tell you what's going on. And they were doing more policy stuff. Later, some of the policies would get questioned more. And so, certainly in the spring, they were, I would say, more informational, like, "What are the right approaches here?" And then in the fall, they became a little bit more accusatory--not always, often not--but if you ever look (I mean there's transcripts

of all these things), they really, in the spring, were reacting to what was an enormous amount of public concern and media interest. And in the fall, started to get into, "Who can we blame for everything?"

SM: Right, right. One of the themes in the interviews has been about funding, and how to get money to move forward.

AS: Okay. Yes.

SM: Was that also a topic that was discussed?

AS: Right. Well, I think at the hearings in the spring, there was, like, "Do you have everything you need?" And pretty much, at some point, it was clear that the President was going to ask for the emergency funds, and there was just a lot of support. Basically, Congress was saying, "You need to do everything you need to do to respond. The health of the American people is really important." Same thing from the President--"We'll worry about the money later." So, there were (I forget), there were so many rounds of funding issues. But from the Congressional side, the ones I was involved in were less about--I don't recall that as being a big deal. Certainly, one of them, we were able to

announce (I forget which hearing): "The President's putting in this request for a billion dollars or two billion dollars." I can't remember the details. It was sort of this jockeying, like, Congress wanted to offer money, but the President was going to ask. Everybody was so supportive that this is an emergency--we must take it seriously; money should not be the problem here.

There were lots of other aspects of the response where money issues were very challenging. Not because there wasn't a willingness to support this emergency, but the cogs of government funding and procurement for a response like this where you needed local health departments to be capable of doing big things, you needed to get money from Washington to CDC to states to counties. And there are lots of ways that that took forever, which in terms of the fall response, we need to be able to do that better in the future. It was not the great way to assure effective planning, to have so much time elapse between when you knew you were going to need to do big things, and when the locals really had resources to hire or contract.

SM: So there was really no other precedent to test the cogs of government, so to speak?

AS: Yes. This was an unusual thing, because usually, you have something like a hurricane or earthquake where there's an immediate emergency and money pours in and all the rules are off the table.

This was a mix because there was an immediate emergency, but much of the resources were going to be needed for something in the future: we were going to need to make a vaccine. And the other was money right away. That was some of the early contingency funds to get money for the companies to start producing vaccine. And then, NIH basically used their money to do the clinical trials. And we got emergency money for our response to help with call centers, and emergency this, that, and the other, that the states were doing.

But a lot of the other money was going to go for implementing this vaccine program in the fall. And well, it's not till the fall, there's plenty of time. So, it took applications and three rounds. I mean, there's been four rounds of applications that the states have had to apply for, which is not necessarily...when they're understaffed because their budgets have been so bad, and they don't have

core infrastructure. It's just this balance between effective planning, paperwork that is important for micro planning, or that's just checking the boxes.

And then when we finally get the money, it wasn't as efficient as it needed to be. And I think in many emergencies you just... The Presidential emergency wasn't declared till the fall. The spring, we had the HHS emergency equivalent which gives some things but not actual--the ways. The government procurement stuff, we probably needed a better approach for that, in retrospect. And it took a lot of people's time and effort away from what would have been more productive, I think. Steve could probably share more about that when you talk with him.

SM: Okay. Can you tell me about some of the issues that you immediately had to contend with even before it was decided to launch a campaign?

AS: Okay, sure. You mean in the spring?

SM: Right.

AS: The first days there were decisions based on planning that we had done. We knew that the emergence of a new strain would mean options to consider about trying to slow the spread of it. We were way beyond quenching it or containing it, but slowing the spread, which is where some of the border strategies come in. Should we have been doing anything with Mexico? Should we have been doing things with U.S. travelers leaving the U.S. - screening before they depart, keep them from spreading infection elsewhere? So, we had a whole border travel strategies that had to be worked out, including, should we change policies for travel to Mexico? We temporarily had deferring non-essential travel, and then we downgraded that.

There were decisions about deploying antiviral medicines. We had the stockpile. Should we send antiviral medicines to the states? Should we send them just to the states that have cases, or should we send them to all the states? How much should we send? Should we send only for requests or to everybody? And we had formal decision briefs about that kind of thing to say, "Well, by the time we know, it will be better to get the medicines out there than just have them waiting for requests." So we basically sent a 25% portion of the stockpile medicines and other material to

all of the areas, whether they already detected cases or not.

We had to get this emergency use authorization for many things: to be able to use drugs differently; to be able to treat infants because there weren't any antiviral medicines for infants; to be able to use diagnostic tests that we made, everywhere. So we shipped these tests out to all the states and to other countries and needed the FDA to go through this EUA thing.

So we had decisions right away about our response which, generally, CDC would have to initiate these things: either make a decision on the stockpile and get it okayed by the Secretary or request these emergency use authorizations; work with the Department of State on travel recommendations. So that was happening.

There were also decisions about surveillance, and how to assure that we had very frequent information about what was going on everywhere.

And then we had a lot of technical decisions about the best ways to treat or prevent: should we use these antiviral

medicines just for treatment? Should we also use them for prevention of contacts? In some countries, they were treating everybody in a school when a person had the disease. We had to make decisions about school policy: if you found a case in a school, a group of cases in a school, should you recommend it be closed or not? How long should it be closed for? So the first two weeks, there were just huge numbers of policy decisions and then management decisions. Some of them were updated within that first two weeks.

There were lots of outreach also in terms of the communication about what people could do while this was all going on.

Actually, other decisions about testing--how could we make sure we know what's going on without overwhelming the docs that everybody who's worried is in an emergency department waiting for, to figure out if they have this or not? So many decisions before we got to the vaccination.

SM: Was CDC the lead agency in the response efforts?

AS: Yes. Absolutely. Yes.

SM: Is that something that would normally have been because, as you said, we were in a transition period for a lot of the heads, the leaders? And so, had everything been the ideal situation, would CDC have been the lead agency, because of the nature...? Or, is it something that happened?

AS: Yes. I think that the nature of that phase of pandemic, CDC has a natural leadership role. Whether our director would have been the face the way he was the first 10 days or so versus a Secretary is hard to say. It could be. There were definitely policy decisions later, when there was permanent leadership, about wanting the scientists to be the spokespeople and not having this be a political thing--not having the President do all the talking--but either the Secretary or one of the leadership technical people from CDC, NIH, or FDA, or whatever.

Because this was detection of infectious disease that affected local health departments and clinical labs were doing this, this is our bread and butter. If you think about outbreaks of infectious disease, usually CDC is in the lead for explaining what's going on and responding. If

there had been, initially, overwhelming devastating inter-sectoral impact then, officially, the Secretary of Homeland Security has this lead role for coordination. But in terms of response, given the nature of what was going on, it was clearly in the...HHS always has the lead for the health aspects, and then CDC would have that information-detection-response capacity.

SM: You mentioned a new diagnostic test. Was this something that was developed in the process of responding to the virus, or was it already something?

AS: Yes. There were two different tests that are worth talking about: (1) you know that HHS and BARDA had received funds to promote advanced development of diagnostic test for influenza, and there were a variety of strategies that were used. CDC actually developed a PCR diagnostic test to detect the H5N1 influenza, other influenzas—influenza A or B, the regular seasonal H1N1s, the regular seasonal H3N2s, and then influenza A that cannot be typed. It's not one of those known human influenza viruses. That test was developed by our scientists.

FDA helped get the company that makes the platform that the test is used on; it's called ABI. There's sort of a machine that you do the test on. We developed the test, but for FDA's approval you actually have to get the platform and the test to be approved. And so pretty much, FDA encouraged the company that worked with us on this submit the full application. So CDC applied for this five target PCR test which was really designed so that state and local health departments could find H5N1. That was actually approved by September 2008.

So this wasn't like, let's get a company out there to make a big test. We made the test with our scientists. But FDA helped nudge the company that makes the machine to go in on it so that states would be able to use it without an emergency. So, September 2008, that test was approved, and we were in the process of getting machines out to all the state health departments, getting them trained. CDC was paying for their maintenance agreements on the machines. So we basically had infrastructure to do PCR tests for un-typeable influenza.

Initially, the states already could get the flu strains and said, "Hey it's influenza A, and it cannot be typed. That's probably this."

We also had, in advance, developed a contract with this organization called ATCC, the American Type something Collection (I forget what the other C is), Clinical Collection or something, but we had developed a relationship with them—contractual--so that they could do the surge production of kits for us. So instead of us having to make kits they could make the kits, and this was both for seasonal flu and for researchers. And at the time of the pandemic, they could really scale up. So our scientists developed the primers and probes and such and basically had the company make a lot of reagent kits for this specific test--not just un-typeable, but this new H1N1.

And so we applied for an EUA with FDA for the new kits and FDA approved that. And then this company, what we call the Influenza Reagent Resource, shipped these kits out to hundreds of labs in the U.S. and hundreds of labs—four hundred some labs--overseas so that everybody could detect this new virus. So that was one sense where preparedness

was really good, and the CDC labs deserve a ton of credit and I think FDA as well.

Second thing is also interesting that the HHS had gotten money for new diagnostic development tests. And one of the priorities was point of care testing; something you could do at the bedside that would be quick. And CDC was the project officer on this thing, and Dan Jernigan (you should probably talk to him), he oversaw this contract. It was one of those survival things where a number of companies get funded, and then some of them do or don't make the milestones, and in the end, we only had two left that were surviving. But one of them was this company, Meso-Scale. They were doing a little study out in San Diego of this kit, and within, I think, the first 25 specimens or something of their testing, they found one that was, "Hmm, it's not typeable. That's weird."

And so the protocol was, you send it on to another place and then they send it on to CDC. And that specimen came from a child that was one of the first cases, actually, was the first case. So the idea of, it wasn't like that test was ready to go, but that test that was just in a research phase found, confirmed the first case. And you think, well,

that's pretty pathetic if we're relying on a little clinical trial. So we think that we found the U.S. disease very early. We didn't have lots of severe disease when we found it, and we found it because we were incredibly aggressively looking, doing these research projects, making unusual flu reportable. So the two first cases we knew about, whereas in Mexico, they had lots of disease and they couldn't figure out what it was and finally got specimens to Canada and then to us also, who could tell them what it was.

SM: So am I to understand that this was something going on prior to any notification, but because it was in the process, we were able to implement its use?

AS: Yes. Right. So the PCR tests that the states used, we had an approval for the general one that could tell us it's an un-typeable strain. And then we quickly could tell you specifically with the reagents that were produced against this new strain. We could quickly tell you that. So that was a great preparedness success. The Meso-Scale thing that alerted us to that first one was the fact that we were doing research, wasn't just to develop a new test. It actually found this first case for us, which was really

helpful because even then, we didn't get vaccine as quickly as we wanted. Had we just two or three weeks earlier gotten confirmation for what was going on in Mexico, it would have made a world of difference for the vaccine production, because you couldn't start making the vaccine till you had a new strain.

SM: CDC had a role in the beginning for vaccine development, and CDC plays also a role in distribution. Can you tell me about the first days during the development?

AS: Yes. Even at the first press conference when Nancy Cox talked, I did the little situation update then she answered some questions about influenza virus.

The CDC is one of four international WHO collaborating centers. So we have a big role globally as well as here in the U.S with influenza virus characterization and vaccine development, because we'll help select the strains that go into the vaccine formulation for seasonal flu. And when there's a new strain, CDC is able to prepare it for handoff to manufacturers. There's also the lab at the New York Medical College that does the same thing--so the two, CDC and New York Medical College.

When the new strain was identified, you have to prepare it in a way that's basically safe and clean and pure to be made into a candidate vaccine strain. You play around growing it in eggs and finding some strains that grow well, or trying to find strains that grow well. So yes, even at that first one when we only had seven cases and nobody knew whether this was going to just fizzle out, Nancy said, "We're taking the steps to prepare a vaccine strain." And there's a standard procedure whenever a new influenza virus is identified, whether it's an animal or a human one. Somebody starts to purify, and so forth. So, we basically have that kind of role with the strain surveillance and then preparation for industry.

Another part--my Center really oversees the Vaccine for Children Program and the Public Health Service, Section 317 Program. Those two programs support the state and local health departments, and buy vaccines and help private providers be able to deliver vaccines. And so for children under 18 who are uninsured, or meet a couple other criteria, they're eligible for free vaccines bought by CDC and directed by the states to the private offices.

Now, influenza vaccination is generally much more influenza vaccines used in adults than in children, and influenza vaccination of children is relatively new. It's been only since 2004 that kids between the ages of 6 months and 23 months were even getting annual influenza vaccine and more recently, older children as well. So we haven't been buying a lot of free vaccine for kids.

The seasonal flu vaccine--about 15% of seasonal flu vaccine is bought by the public sector and 85% is private docs or hospitals, or distributors will buy it from the companies. So we have a big role in surveillance for flu, and in health communication for flu, and in support of state and locals and private providers with their use of influenza vaccine. But we don't own seasonal influenza vaccine the way that we're pretty much very central in the pediatric vaccinations that are much more common: measles, mumps, rubella, rotavirus, pneumococcal. Those we'll buy half the vaccine for the country, but for adult vaccines, it's much more of a private sector enterprise.

SM: So initially, when CDC received the virus strain (you kind of touched on it,) you hope that the eggs grow as fast. Is that an area that you can elaborate on?

AS: Right. So, there were different roles and responsibilities. So CDC's lab--Nancy Cox is the Division Director--they were preparing these strains, injecting lots of eggs and trying to get good strains. They make these reassortant things, which are a mixture of viruses that grow really well and the genetic components of the new strain: the antigen from the new strain and the other parts from a safe strain that you can grow easily. And so, they were playing around, doing their work trying to develop vaccine strains, as was the New York Medical College. And it is always finicky with influenza viruses; the ones that grow well in the eggs are not necessarily the ones that you want. You're trying to get the ones that express the antigen of the new strain, not ones that are just good growers. And so I don't have the details of all they found, but I know they would typically grow lots of different ones and pick the best ones to send off to industry. There were some glitches that probably Nancy or FDA could describe.

Once they got the stuff, they couldn't send to companies unless they had the right bio-safety level capacity. It wasn't safe to put these things in animals unless such and such was being done. And so, there were some companies who

had the right bio-safety level got the strains right away, others had to wait until more testing had been done, or they had a different capacity certified. But basically, by I think it was May 23rd or 25th, we'd gotten these strains shipped out, and it was really industry's story.

But the influenza pandemic vaccine production was quite unusual because instead of manufacturers making vaccines for the private market or making vaccines for CDC to buy, they were making vaccine under contract to BARDA. And so, the communication between the companies and the government was all through BARDA. It wouldn't necessarily have been through our flu division--we're having this strain or that strain. It was all through BARDA, which was contractually their project officers.

So I think that historically (for history), over the course of the year, there are lots of lessons learned about five different companies and all that they were going through. The BARDA team that was supporting the companies, but also supporting the rest of government, the HHS leadership, all of us trying to connect and understand what was going on. I think there's probably lots of times where we--different parts of the system--were worrying about the wrong thing.

You know, if the right thing was being worried about, we might have been able to fix it sooner. (Both laugh.)

I just personally say there was a point where there was an enormous amount of focus on our central distributor, which was a big thing. We decided in June we're not going to be able to do this by each company shipping directly to states. That's going to be a big mess--with 5 companies and 10 products and 50 states and several cities, and we were going to need something that would be better able to distribute daily according to what's coming off the pipeline.

So I would say people in Washington were really concerned about our shipment plans: you know, can we speed this up or that up? Or, why is this going to take two days? Can't it be one day? When really, the big, big, big rate limiting step was the vaccine production: whether enough people were worried at an intense enough level early enough and could have fixed things up, or whether, no matter what, it couldn't have gone any better. There are lots of things with proprietary information and who can share what with whom. Whereas when you're having an emergency, wouldn't you want to say, "Whatever's going the best, everybody's gotta

do the same thing"? So I think there were policy and, probably, legal and regulatory reasons that information sharing wasn't excellent. But in having vaccine--lots of vaccine--three weeks before we had it would have made a big difference. But you know, we did the best we could.

SM: So, traditionally then, when the government purchases vaccine, it's through CDC and not BARDA?

AS: Right. Well, first, the childhood vaccines. We have contracts directly with the manufacturers. With seasonal flu, we buy vaccine directly from the manufacturers. We don't buy a lot, but we buy directly from the manufacturers. The VA would buy vaccine directly from the manufacturers. So BARDA is an entity that exists for this kind of thing. They all buy vaccine for emergencies like anthrax, perhaps.

My Immunization Services Division has a Vaccine Supply and Assurance branch. And our procurement grants officers have annual contracts with the industry for 17 different vaccines against 17 different diseases, and multiple products for some of those diseases. So we have a lot of vaccine contracts. And the states can buy off of our

contracts too. They get vaccine through us, but they can also put their own money into these negotiated contracts that we have. But this was not investigational, because the FDA ended up licensing it. But this was government bought vaccine at that central level of BARDA.

SM: In your opinion, do you think that it facilitated the process in a more expedient way, or would it have been more expedient to go through the CDC channels? And I know that this is counterfactual, but--

AS: I think it's hard to say. I don't think that BARDA doing the contracting is a bad thing, but I think that this is really different than business as usual. You're making a vaccine as you go, and somebody with product experience needs to be...The type of experience needed to oversee these sorts of contracts isn't necessarily what CDC has. Typically, we buy vaccine all the time, but we're buying licensed vaccine that's pretty routinely produced. It's not being produced in an emergency. You know, this vaccine turned out to be vaccine that's just like the licensed except that it's monovalent. But BARDA was also buying adjuvants, which aren't licensed. They're buying all kinds of other stuff, so I don't think that's necessarily the

problem, because we would need to have different expertise in order to take on that role.

But I think that there probably are (and I wasn't as close to it as others), I think there are probably aspects of doing this that they took on that were neither familiar nor overseen as well as they needed to be. And it just may be the difference between being a big group that's funding research, and actually funding response. So, the kind of thing that would be...We had to totally change, to be doing things in a very, very urgent--daily contact with the states, daily contact with BARDA, the central distributor. We had to really scale up to handle this amount of product going this quickly through our system. But I think that negotiation with industry, and then the oversight of it, it's almost more of an FDA thing than certainly a CDC thing. And you run into these issues where FDA is always in the face of manufacturers, but they can't tell anyone what's happening. So BARDA's doing it, BARDA is talking to FDA, and there's just a lot of room for confusion up there. So I don't think we want that role. (Both laugh). But I think BARDA wants it to work better. Nobody thinks it worked as well as it should have.

SM: Right. Right now, we're in the distribution phase of the campaign. Can you tell me some of the initial plans that CDC put into place to prepare for this phase, the distribution phase?

AS: I think that there may be two things worth noting. One is that before the pandemic, there had been planning about how vaccine would be distributed, and much of that planning needed massive update because of the circumstances. One aspect was the idea that there would be about 3500 places that the companies would ship vaccine to, essentially every local health department--these ship-to sites. There was an idea: one or more companies would make product and it would go to these 3500 sites. The sites would administer vaccine--Points of Dispensing, or PODs--in a mass dispensing approach, and under security. Everything would be done in a certain kind of way. That approach relied on the states being able to further distribute from those PODs to other places. And we have been going through a multiyear transition away from the states having their own inventories and depots, and distributing vaccine to their thousands of providers.

Over the past several years, we transitioned to--for our routine childhood program--a central distribution mechanism called VMBIP (Vaccine Management Business Improvement Project.) We basically saved a lot of money by dismantling these state depots and the people who used to ship vaccine and break up the boxes. We got public health out of being shippers and receivers, and back into being public health. But that meant that these 3400 sites were not going to be enough. And also, our states were really familiar with the central distributors. So we basically had to, in June, say, "We better really use this central distributor even though this is a much bigger scale." Usually, we handle 80 million doses of vaccine a whole year for kids, with about 45,000 providers that the vaccine gets shipped to. And this was going to mean, theoretically it could mean, hundreds of millions of doses. Now it's like 150 million doses that's going to go out, and the 3400 sites is not enough. So we had to quickly modify distribution plans: get a new contract in place so that the central distributor, instead of 2 depots would have 4 depots, and would have all kinds of specs that were for very quick shipping, not once a month kind of stuff or once a week kind of stuff, but daily in and out because it was expected to be very dynamic.

We also had an emergency meeting in July of the Advisory Committee on Immunization Practices so that they could make recommendations on who ought to get vaccinated in the context of what we knew as of the summer. We pretty much knew that disease wasn't going to fizzle out because it was still spreading, and the southern hemisphere was having a lot. But we didn't know exactly what the fall would be, but we knew that we needed to have recommendations for vaccination that the state, locals, and providers could implement. So, July 29th they met and came up with recommendations that really formed the basis, in a very good way, for target populations for vaccination.

We had asked the states to do planning. In June, we were telling them to plan, and on July 9th, we had a kickoff with this flu summit in Washington. All the states participated, basically saying, "Time is precious here, and we have to be ready to go as soon as vaccine's available. We don't know when disease is going to happen, but as soon as we get vaccine, we want to use it." It's hard to plan in a vacuum, so getting these concrete, "Here are the groups you should vaccinate" made it much more tangible for them to plan.

And having pregnant women be a priority group, you realize: okay we don't usually vaccinate a lot of pregnant women, we better figure out how we're going to do that. Children up to the age of 18, really 24, that's a group that hardly ever gets flu vaccine. What's our plan for that? Oh well, we wanna do school vaccination. Now, that takes a lot of planning. So the July 9th meeting was really a line in the sand for states and locals to say, "Okay, we don't have our money yet, but we've got to get our act together because everyday is precious to be able to implement."

Now, we had been talking about a mid-October beginning of vaccination from the companies saying, "This is when vaccine will be ready. Or we think we can have vaccine by such and such." And we got advice from different advisory groups about ways to cut corners that were not safety corners, like: you could wait until you see the results of dose testing to decide 15 micrograms is the right amount of stuff to put in the vial. Or, you could say: 15 micrograms is probably going to be right if we don't have to wait. Then if we don't have to wait, then we could tell the companies to fill the vials a month sooner and then save time. And worse case, you throw out the vaccine; best case, you have an extra month of product. So we gave an

early go ahead and that type of stuff. (Okay, I think it's almost time.)

But there was a lot happening in the summer to get stuff ready. And the next big thing that happened, there wasn't as much vaccine as people expected. And that just kept getting whittled away. You're probably talking to other people about who knew what at different points, but the other thing that was happening for us was that during the month of September, there was a decision that we shouldn't wait till the middle of October to begin our program. We should try to begin it as soon as there's product, and that meant the soonest we could get everything ready with a little bit of product was September. The states could start ordering September 30th, and that would mean vaccination begins October 5th. And so that was a whole big thing (September to get states and locals ready), which was, "Oh my God, we have to begin two weeks before we thought." And okay, now, it's only going to be the flu mist. And okay, now, it was really complicated. And it's hardly anything. So it took a lot to get the system ready for that.

The question is distribution. There was the timing. And for whom, and how much? Then the states had to figure out:

well, do we wanna go with the regular ACIP recommendations, or with their subset, this smaller group that would be...? And the smaller group was not necessarily well matched to the product that we had available at the beginning. So the summer was really, really busy getting ready for all that.

SM: Can you tell me what was...Well, why don't we end here?

AS: You're organized with the rest of the...? I see why you need multiple times. Okay.

Broad Themes

- Diagnostic test
- Border infectious disease system
- Reportable influenza – nationally and internationally
- Notifications – MMWR, IBX
- Communication mechanisms
- Disease in Mexico
- Congressional hearings – April, May, Fall
    - Two Senate
    - Three House
    - Briefings
        - Homeland Security Council
- Funding – moving money forward
    - Nature of emergency – immediate and non-immediate funding
    - Vaccine production
    - Clinical trials
    - Call centers
    - Implementation of Fall vaccine program
        - Rounds of applications

- Pre-campaign issues and decisions
  - Containment of disease spread
  - Border travel strategies
  - Decisions about deploying stockpile of antiviral medicine to states
  - Emergency Use Authorization for drug use, infants, diagnostic tests
- Surveillance decisions
  - Technical decision on prevention and treatment
  - School closure policy
  - Policy and management decisions
  - Communication outreach – content of,
- CDC as lead agency for response
  - Scientists not politicians as spokespeople
  - Emergency outbreaks of disease
  - Information, detection, response capacity
- New diagnostic tests for influenza
  - PCR test for H5N1, five types of flu, untypeable influenza A
    - ATCC – American Type Culture Collection
    - Influenza reagent resource
  - Point of care testing
    - Mesoscale
    - Influenza virus characterization and vaccine development for manufacturing
    - Strain surveillance
    - Preparation for industry
    - New York Medical College
- Vaccine for Children/Public Health Service Section 317 Programs
- Vaccine production
  - Reassortant strains
- Biosafety level capacity
- Manufacturers under contract to BARDA – as project officers for manufacturers
- 5 manufacturing companies
- Vaccine distribution policy
  - Focus on central distributor
  - Vaccine contracts for 17 vaccine for 17 diseases
  - Immunization Services Division – CDC
  - Vaccine Supply and Assurance Branch – CDC
- Vaccine Distribution Phase
  - Initial plans of CDC for
  - Ship-to sites as Point of Dispensing – PODs
  - Central Distribution Mechanism

- Emergency Meeting of Advisory Committee for Immunization Practices
  - Recommendations for target populations – July 29th, 2009
- Flu Summit – Washington D.C. July 9th, 2009
- October 2009 – Beginning of vaccination campaign

Timeline

- April 17th – Call about flu cases in California
- April 21st – MMWR article released
- April 23rd – Press conference
- April 24th – First/second press conference
- July 9th – National Flu Summit, Washington D.C.
- July 29th – Emergency Meeting of Advisory Committee for Immunization Practices

Names

- Nancy Cox – Flu Division Chief
- Dan Jernigan

Documents

None