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. Schuchat'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 March 12th, 2010 at the CDC's office in Washington, DC. The interviewer is Sheena Morrison.

Hi Anne, so, let's pick up from our last point which was the public/private policy decisions.

Anne Schuchat: Sure. I think there were a couple of things that happened in the May/June timeline that I sort of skipped over as we talked last time. Of course, in the Spring, we were responding to the disease, but we also relatively quickly began the preparations to be able to make a vaccine should we want to use one. And as you worked with ASPR you know there was a whole set of decision-making about off-ramps--if we might use a vaccine and so forth.

And by July 9th, the Secretary announced that we were going to have a voluntary national vaccination effort assuming we could produce a safe and effective vaccine. Basically the issue was, was there enough disease to bother with using a vaccine? We crossed that threshold compared to 1976. Maybe they shouldn't have actually used a vaccine.

SM: Uh huh.

AS: Okay. So, in mid-May, we were notified by HHS that we needed to come up with a budget for a vaccination program, and linked with that was what kind of vaccination program would we have. I think it was May 17th. That weekend, Saturday, I came in and got one other guy, and we were calling all these different people to put the pieces together with what a program would look like. The issue of vaccine procurement was being handled by BARDA, but everything else was going to be our deal: the distribution; the delivery system; the safety monitoring; the effectiveness evaluation; the communication effort; the logistics; the tracking of doses that would feed into the safety assessment. So we started to think that through really for the purposes of the request for emergency funds. How much is this piece of everything that we might need

going to look like? And together with that we had to think through: what is the way that this vaccine would be given?

Before the pandemic, there was a lot of planning around a very severe pandemic: very scarce vaccine; vaccine will be a security issue; it will go from manufacturers to what they were calling ship-to sites, and each state gets a certain number of them. And essentially, the number was about the same as the number of local health departments. And the vaccine will be given out at these points of distribution, and those health departments would, either break it up beyond there, further distribute it, or just do these mass distribution things.

And what had happened between when this plan was made and 2009 was we had really changed our vaccine distribution system in the U.S. for the Vaccines for Children or the childhood program that's publicly supported. And instead of every state having a storage facility for vaccines and providing vaccines to providers, we got rid of all of that. We transitioned to a central distribution mechanism where government buys vaccine and it goes to a central distributor, and they ship it out to actual doctor's offices, sometimes to health departments, sometimes to

other places. But it doesn't go physically through the health department; it goes virtually because they have to say where to send it. But it doesn't go to them, and they don't have inventories left and people left to break up boxes and further divide.

We also were dealing with a situation that wasn't exactly like a 1918 kind of pandemic where we would have the kind of demand or need to very tightly control vaccine the way we would in a scenario like 1918. And we had a lot of uncertainties in terms of what things would be like by the fall: would there be no demand and a lot of vaccine? No vaccine and a lot of demand, or both at the same time in different places?

We also started to cost out if this was a purely public program. How much would it cost to administer vaccine where for every dose that's administered the cost of the administration is borne by the public sector or the government? And pretty quickly, it became clear that if we really were going to vaccinate a whole lot of people, the cost could be substantial, and the delivery could be challenging.

And so, we developed a decision memo that eventually was signed off by the Secretary, which proposed a publicly directed mixed delivery model--a public or private delivery model for vaccination that would have the state or local health departments allocate vaccine to different places up to a whole lot of providers. And there would be flexibility jurisdiction to jurisdiction, and over time, maybe the first month, the public sector would be doing it all, and then maybe it would shift to the private offices.

We had to develop this policy in the space of a whole lot of uncertainty. Would doctor's offices be swamped with sick people and not be able to vaccinate even if they wanted to? Would nobody want the vaccine whether it's in a public or private place? Would people who want the vaccine not be comfortable going to a public place? Could the health departments that had been so decimated by the economic recession even pull off these public programs, even if we gave them money? Would they be able to do it even with money because there wasn't a whole lot of time? And so, this public/private policy was a mix of a strategy, and it had an accompanying budget.

So for the month of May 17th till about June 18th or 19th when the Secretary signed off on the strategy we were dealing with, this was a very stressful time of thinking though policies, trying to get cost estimates, having people question them. Almost everything in them was questioned, because we really didn't know if 100% of the vaccine was given in the private sector, the administration costs would be quite low. We didn't think that would happen. If 100% was given in the public sector, it was going to cost a lot to administer it, even more than what we guesstimated because of how expensive it really is, depending on flow. And some place in between would be truth but not in every state. Were we going to allocate proportionate to the state, the money, even though they didn't up front know how much was going to be public or private?

So it was very, very complicated: both a lot of education for people at HHS and OMB about, well, how does seasonal flu vaccine work? About, how does the Vaccine for Children program work? What are we saying? It's not really either; it's in the middle there. When will we have vaccine and how much? And depending on the flow of vaccine, your demand supply situation changes, and your efficiency and the cost

of the program changes. Will we have a safety problem right up front, and nobody will want the vaccine?

So, we were pretty confident about the piece of this which was safety monitoring, effectiveness monitoring, communication as a major component, tracking doses--we had not planned for that--and so forth, coverage assessment.

But the issue of just exactly proposing something that was public/private mixed with local flexibility meant a huge uncertainty: on the costs needed, which meant we had to ask for a lot of money just in case, but we didn't think we'd need all of that; and also on effectiveness, because we really didn't know how much the states could do given their erosion of capacity. And we didn't know what the public would do. And if you look around the world now, I would say that our uncertainty is borne out country by country, how different it looked. Most countries had less demand than we had, and many countries that have essentially a single payer type or universal health care could have a single approach everywhere, and still they had challenges. So, we were going with flexibility everywhere from the beginning, and that was tricky.

So, for me personally, the response--the stress and pressure and personal challenges of the response--were very different from what you could measure by media attention, which the spring was worse than the fall, or by disease burden, which the fall was worse than the spring, and were very much related to what I personally had to do.

And then just for the historians, there was a period of time in May and early June which was particularly challenging for me. Probably when you talk to Steve Redd, it might have been challenging for him because Rich Besser really had moved on. He was still Acting Director before Tom Frieden got there. But he had, once it wasn't on TV every second--Steve and I were running the response--he wasn't really making these policy decisions or communicating with Washington where he had been *the* communicator with leadership during the late April, early May period. And this was before Dr. Frieden got here. It was also before he really checked in, in terms of, once he got here in June, the first couple of weeks he was just getting his feet on the ground and not day to day leading the flu response. So there was a few week period where some pretty big decisions were being made, or HHS was looking to

CDC for strong direction, where I had a different role than I had earlier or later. (Phone rings.)

SM: Is that my phone or your phone?

AS: I don't think it's mine.

SM: Okay.

AS: It's not mine.

SM: That must be mine.

AS: Then also, because it was hard--it's pretty hard to exaggerate how much uncertainty there was about the vaccination program's implementation when we had to plan it, and uncertainty that's inevitable because, will we get a vaccine? Will it work? Will we need two doses? Will it be safe? Will anybody want it? Will doctors that think they want to give it be able to give it? Will the doctors that ought to give it be convinced to do it--the obstetricians for instance? Will these big mass clinics that people had planned for be a total turn-off to the public? Is it fair to say poor people have to go to the public clinics and

rich people go somewhere else? How can we design a system that's equitable, that's dealing with the contingency of a very scarce supply or an ample supply and variable demand at any one point? So we had this fairly large, big, $1.8 billion program that you had to plan with a lot of questions marks.

So I think that I felt the weight of history when I had to come up with--I was not the only person, but I was leading the work.

Then the other thing was, at CDC (I think I told you this last time,) we had this huge surge of help in the spring, thousands of people working on the response. Everybody. Of course, this is our agency's highest priority. We have to be there in late April or in May.

By June, everyone was back to their job and this core of us was still on the response. And I was both having my old role with media and HHS and congressional staff and strategy and science, but suddenly in charge of this whole vaccine planning thing. So, in June, I also could see that this was not going to be a part time job--this was a really

big thing--and I was very grateful to be able to recruit Jay Butler. I'm not sure if you've spoken with him.

SM: Not yet.

AS: So Jay was working as the health officer in Alaska and resigned (which is a whole story he can tell you), and was essentially looking for a next position and talking to several people at CDC, and I recruited him to come. And he really came June 22nd, I think, and stayed till today. I think his last week is next week. So, he came to take on this really big job of running what became the Vaccine Task Force and reporting up through the response. But I was sort of doing health officer, vaccine planning, policy—everything--which was very difficult.

SM: Wow.

AS: So I forgot to tell you that because it's blocked out of my mind.

SM: [Laugh.]

AS: You also remember we didn't have--since you've been working in ASPR, you have seen that there have been lots of changes, but in, of course, the first week or so of the response, we didn't have a permanent secretary. We didn't have the new ASPR, Nicki Lurie, until July. She wasn't sworn in until sometime in July. So all of this planning was with--Dr. Freidan actually signed the memos that went up to the Secretary recommending a vaccination program: "Let it be this way, mixed public/private." And certainly, he began to focus on the response in time to ask us a lot of questions about, "Is this the right way?" "What about this?" So he did assume ownership, but we had to do the beginning part of it before he really was on the ground.

SM: So you and Steve were essentially a two person team?

AS: No, it was more than that. For me, Beth Bell, who was the other Chief Health Officer (my deputy really,) was part of the core group. And when we went to the White House, the Homeland Security Staff, the National Security staff wanted to hear, what's this proposal for? How this vaccination thing is going to work? Beth and I went up. Beth did the presentation for that.

And it was quite interesting there too that leadership was there in terms of, it was convened by Heidi Avery in the NSS group. But Tony Fauci was there, as well as Laura, Petrou. (I don't really believe Nicki was in yet. I think it was before her time.) But in any case, we had invited a couple state and local health folks: the state health officer from Alabama; the head of the National Vaccine Advisory Committee who works in New York State Health Department; the city of New York's immunization lead. So we had a handful of local or state experts.

And really, the assembled folks from White House and HHS were saying, "Well, you know..." This was this chicken and egg thing of, what's the program going to look like? Will there be money for it? Are we even going to have a program? And there were some decisions there that it would be much easier for the states and locals to plan concretely if there was a decision that we're going to have a vaccination effort even before we have a vaccine, because they wouldn't be able to have folks take them seriously in their planning until it seemed more concrete. So at that meeting, there was discussion that said, "Well, you know, would it be better for us to craft this as we're going to have a program, unless x, y, and z, happens?" As opposed to,

"We're waiting for some unspecified point in August to decide if we're going to have a program." And there were plenty of reasons that it was appropriate to say, "We're going to have one assuming we had vaccine" and so forth. So that was kind of a big day. So the short answer is, it wasn't just me and Steve. There were a couple of other people that were very key, and Beth Bell was, for sure, big. And one of the things that was funny about it was I was sort of running writing the memos and revising, and she was also on the conference calls.

And then I would turn 50 on June 15th, and I was planning this big party. Back before the pandemic started, my mom had had a big 80th birthday party, and I was like, "I wanna have some friends. I wanna do a big party." In January or February I'm thinking, oh, you know, I'm into this, I'm going to have a fun party. And then it dawned on me that I can't have a party while we're having a pandemic. And then closer, maybe May, I said, "Oh, I could still have my party!" I didn't really send out invitations till pretty late, but I said, "I'm going to have my party and I need a day off and, you know, whatever."

So, I remember the timing quite clearly because we had lots of the stuff from May 17th on till June 12th or so. But I was taking the weekend of the 13th and 14th off. My parents were coming to town, and I was taking the 15th. And then I was going to Geneva on the 16th for another thing that I'd long delayed.

So Beth was sort of, "Okay, the memo's here." And she had to do from Saturday through when I got back from Geneva. That's why she presented at the White House, because she had to deal with all the comments from all the other departments. And all the headaches of the policy is 97% done, but now we have to nickel and dime it. And so she did the last mile of it and got to present at the White House because she'd done the last mile.

SM: So what determined how you chose the public/private?

AS: So, the issues here was--I'm sure for history's purpose, there's a whole decision memo that went through options, and you should get that because I probably can't reproduce it all--the critical factor was the most likely to succeed. If the goal is to have a program that is robust, that will meet all of these uncertainties, that

will be likely to be able to give out a whole lot of vaccine quickly, that will be acceptable, that will be reasonably economic (at least incorporating, using capacity that the government wouldn't have to pay for in the event that that capacity is available), that would deal with the fact that some state and local health departments would just not be able to manage this at all--this was going to be the most likely to succeed, knowing that even with all of this, it was going to be really hard.

So, we went through lots of factors there about, should we have a strictly private program? Should we have a strictly public program? Should we have two programs: private sector does this, and poor people get it this way? What's the best way for this to actually achieve the goal of protecting the American public and incorporating the values of the policy makers?

SM: Well I guess it's just--

AS: I can't believe I didn't tell you about this last time. Well, I kind of directed you to the distribution.

SM: But that was way after the fact.

AS: We also in June had the meeting with BARDA about, should we use our central distribution system? And that was pretty important because it meant a different role for the states, who would be allocating but not breaking down boxes.

SM: Okay.

AS: And then we could centralize that part, because with five companies and all these different formulations, you couldn't just send one company to this state and another company to that state. If we'd done that, the states that were going to get GSKs wouldn't have ever gotten vaccine. So there were plenty of reasons that we needed a way to coordinate it, and we had a system to do that were used to doing the vaccine for children central distribution program.

SM: And you had used McKesson?

AS: Yes, we had used McKesson, but the issue there is it's about 80 million doses a year of publicly procured childhood vaccines or any vaccines that we buy and go

through us to the states for a whole year. And we've shipped 120 million doses of H1N1 vaccine. Really, within the first three months, we'd shipped 120 million doses on top of the regular childhood program. So this was a huge jump, and we were doing it with 4 depots instead of, I think we have 2. We were doing overnight shipments, and everyday people were putting in orders. And they were allocating ultimately 120,000 providers that were signing agreements instead of 45,000 vaccines for children providers. So, it was a much bigger program, much quicker, and done with very short term planning without a pilot and multiple years of rolling it out. So it was a very, very big undertaking.

SM: And the funding, how did you determine what you would need? We know that the states were already hurting because of their budgets, but--

AS: So that weekend, that May 17th weekend, it wasn't actually just for vaccine; we had to put the budget for everything together. I was just doing the vaccine, and there, the biggest component was the per dose administration costs. And we took available data from the literature, data from calling a lot of health departments

during that weekend. There was actually a meeting going on that one of our key staff was at, with about six or seven health officers. So he just, "Okay, we're meeting in the lobby. We're figuring this out. You're calling the people."

And so there are models of how many people per hour we could vaccinate: what's the staffing that goes behind that if it's a commercial cost or a public cost? If it's a public health nurse working for the state, it's one rate. If you have to contract through a community vaccinator then it's a commercial rate, it's a bit more. Schools would be a certain through-put; nasal spray would be a certain through-put, quicker than injections. What percent might be private sector versus public? We sort of said, "Well, the under 2 year olds would be in private offices. And what if the high risk adults are in private offices, but the children and general adults would be in this public venue? So we had a lot of base cases estimates and the OMB made us run it 400 times with different permutations to get to some costs.

SM: I recall that.

AS: You do?

SM: Yes. Okay, so let's see. The next questions are really to help me clarify some things that you said during the last interview. You mentioned that your official role in the H1N1 response has been as chief health officer, which among other things involves strategy in science. Where have you had to employ strategies in science as the chief health officer for H1N1? In what areas?

AS: Right. So obviously, the strategy of vaccine use would be one thing. A lot of this is my directing others to do things; it's not my doing it all.

But it was fairly clear in the spring that the planned way that we were going to assess the severity of the pandemic was not something that could be implemented with this pandemic; the idea that the case fatality ratio over 1% or 2% was really bad, and that the percents involved would be really quite difficult to determine in populations like what we were seeing, and that it would be hard to differentiate things. So the spring experience was such that we pretty much said, "Well, this is of moderate severity. It's not a 1918 kind of severity situation. It's on the order of - there's a shift of the age downward so

we're seeing severe disease in younger people than we usually do, but it's not a devastating 1918 type of scenario."

But it was clear that the interventions that we were introducing were a balance of what would be too disruptive to be acceptable given this level of severity and what's got an evidence base that's worth doing, and what is just a waste of everyone's time--you know, to keep schools closed permanently or something. But it was also clear that influenza disease can change and that influenza virus can mutate or become different, and that we were going to have to continue to monitor the situation. So, we dealt with what was the spring like and tried to learn about that.

We monitored the southern hemisphere and what was going on there. But we know that--we expect the disease to increase in the fall because it never went away in the summer. And in fact, we thought it would come, increase early as soon as schools opened, and that's what it did.

And we had a charge to really be able to figure out whether there are any changes. And during the summer, part of the strategy was pushing the tasks forces very hard, to say,

"Epi guys, we need you to tell us how you're going to track severity really, now that we know how hard it is to track, because you need to be able to tell us that something has changed." And the community mitigation task force: "We need you to develop guidance for schools and for work places and for daycares, and we need it to incorporate what we'll do if it's like it was, and what will we do if it's worse. And we need it to be evidence based wherever there is - So get your act together. Go look at the data from the spring." And this is why we needed all these people in the summer.

So, part of the strategy was to be sort of ahead of things on that, to say, "We can't just in the fall be surprised that it's hard to measure severity. We need you guys to figure out how we're going to do that." So that was tasking people to go look at data a lot of different ways and coming up with something that we would be tracking at the time. And you know we got something that at least we were tracking. I don't think it's going to be the ultimate.

And we're going to have this severity summit this summer to, in retrospect, think, well, what shall we do next time? What's a way that would work in the spring as well as longer term? So that's sort of that sense of, what

information needs to be critically looked at in order for us to have policy that is going to meet the needs that we have?

Other issues were strategy related to communication: how important it was to be preparing the media and the community for the acceptability of the vaccine in terms of messaging, and how to do that in a way that was mindful of the current attitudes in a lot of parts of the country. So there was a strategy about what needed to be done for a second or third wave. Who should be out there talking about these things? What data needed to be put together in ways that would address the questions and concerns people had?

SM: Okay. And in June when everyone was sort of scattering and going back to their regular jobs, was that a function of the fact that you were waiting for the next wave, or there was still so much uncertainty that people had to go back to doing what they?

AS: Well the roles changed. The issue of everyday having hundreds of calls from health officers or media requests or lots of data that was coming in everyday and clusters that needed to be investigated, those kinds of things changed.

What we knew was, this is a planning mode. This is an absolute everyday-is-precious because we have to worry, counting how many weeks until schools open. We have to have guidance for schools by the first week in August and it's June 10th. This is not a whole lot of time. And people are barely finished with coming back from the field. Investigations that were carried out in the spring, someone needs to go look at that data, and we need to review it. We need to think about it and then come up with what makes sense. So there was, from the leadership of the response, this was our highest priority.

I was leaving that operations center later than ever in June and July, but there were not masses in there with us, it was a very small group that was there. And people were exhausted. And people who were on loan from other groups were like, "Okay, I get to go back to my regular job now." And for many of them it was appropriate because their skills weren't the ones that we needed. You know, we didn't need a whole lot of people answering phones or triaging. We needed people who could analyze a situation and prepare guidance and that required different recruiting.

And so, the problem really in July and August was getting a staffing and rotation recruitment system that worked - getting the requests for people to come help to be taken seriously and be filled. It took the agency leadership saying, "Oh, okay, this is a priority. You guys need help, let me help you get that." It wasn't that we dismissed them. We didn't actually dismiss, some just left.

SM: [Laugh.] They had to go.

AS: Steve might say, "Yes, we shouldn't have demobilized." I'm like, "I didn't demobilize. I recruited Jay!" The vaccine team, it was growing. As soon as Jay got there I had this skeleton of what it should look like, and it just kept growing everyday. I was very mindful of how hard this was going to be and that you can't turn it on tomorrow. To turn it on in two months is really hard. And the daily issues of what's going on in the companies, and what's going on with the states, and what they need to know.

And then a huge set of issues around getting money out there: having the grant applications written; having the guidance for applications, and then the states apply. I think I told you all through the 4th of July weekend, we

made people review the draft proposals so that we could get it posted by the summit on July 9th, and then the applications in by the 22nd or something, and then money out by the 31st, which didn't really happen. But you, that was just for the first phase of funding. We were really...everyday was very precious.

SM: Once Steve goes back, does he go back to Alaska? Will I be able to contact him?

AS: Jay would be the one.

SM: I mean, Jay, right.

AS: Yes. He'll be back in Alaska, and I'm sure you can contact him there. But he's apparently officially working through March 19th. I'm not sure if he's got trips coming back. Probably, there'd be some reasons that he'd be on the east coast again.

SM: I should contact him. I don't particularly want to take a trip to Alaska.

AS: Yes.

SM: So let's see.

SM: Can you explain to me more what your portfolio for the Acting Deputy Director for Science and Program is?

AS: So, that's not my permanent job. That was just what I was doing at the beginning of the response. I was, from February 1st officially through June 1st, the Acting Deputy Director for Science and Program. But really, that was from February 1st until the response took off in May when the only things I was doing for CDC's Office of the Director was H1N1. I had negotiated to go back to my Center job June 1st, and as it turns out, I went back to my Center last week. So what do you wanna know?

SM: I really want to know about your (that was my next question) responsibilities and your permanent position.

AS: So, before February, and then since last week, I am the Director of the Center for Immunization and Respiratory Diseases. And this Center has about 800 people and maybe more than that because of our reorganization I guess. And we have a budget right now of about $4.5 billion, most of

which is the Vaccine for Children program (VFC), which includes about $4 billion or so or more than $3.5 billion to buy vaccines that are an entitlement for children without insurance, native American, Alaskan native, uninsured Medicaid eligible folks.

The Center runs the domestic U.S. immunization program, which funds state health departments and some of the big city health departments or county health departments to do immunization activities together with the vaccine that we procure. And it also includes the global immunization division, which runs our global polio eradication program and our international--we have something called The Measles Initiative, which is trying to reduce childhood mortality from measles by 90% worldwide by 2010. We're close: we're at 78% as of 2008. The three other divisions are the influenza division, which of course has the laboratory, epidemiologic, and international staff that are doing influenza for CDC. And then we have the division of bacterial diseases and the division of viral diseases, which have both laboratory and epidemiologic capacity for both vaccine preventable diseases in the U.S.: measles, mumps, rubella, pneumonia from pneumococcus, and also Haemophilus influenzae B, rotavirus. And also, they have

the acute respiratory infectious disease programs--also for pneumonia--in the U.S. and abroad, and for a few other things that are not pneumonia, RSV and so forth. So it's a pretty big job within.

It's quite related to the response because the immunization services division that runs the program for children typically works closely with state and local health departments: on giving out vaccines or working with the private sector to give out vaccines; to do the quality oversight of that; to track coverage, and to do communication around that, or education around that. And then the influenza division, which of course is doing the surveillance and picking the strains that are going to vaccine formulation, and looking at resistance and mutation. So there are parts of pandemic work that are not in our center, but the majority of the influenza seasonal and pandemic work is out of our center.

SM: Okay. So I'm assuming they were recruited full time into the response?

AS: Well, about half of the people in the center were part of the response, but a whole lot of the people that worked

on the response on activities that would have been our center's role came from elsewhere. So our vaccine taskforce was a mixture. The head of our taskforce, Jay Butler, we recruited him from Alaska. The people who lead our regular immunization program were busy doing that. The person, Jeanne Santoli, who runs our vaccine supply assurance branch which handles the central distribution, she was doing both. She was dealing with this new issue, how H1N1 vaccine will go through our system, and continuing to run the other, but she got a lot of additional staff to help. So, the Center staff was involved. The whole flu division was involved. But we had lots of epidemiology and other lab people come to the rescue to help them. Our whole group that does anthrax vaccine lab work went and joined the flu lab because they had good capacity and methods that are quite similar for vaccine evaluation, and they just got right plugged into this virologic serology evaluation. So we had to shift priorities and put some things on the back burner.

SM: Okay. Did you attend the meeting in April when Margaret Chan came to--?

AS: To D.C.?

SM: No, to CDC and then she also went to--

AS: I think when she went to CDC, I was in D.C. because I think I told you (it was either April 27th or April 28th,) I was sent to Washington to do these hearings. And so the first two weeks, a whole ton of the April/May/June, I was up here a lot. So I wasn't...the meeting with Margaret Chan. During that beginning part, during the World Health Assembly, the U.S. sent a delegation: the Secretary and Rich Besser went with her, and John Monahan, and a few others. They had a video conference from the emergency operations center in Geneva back to Atlanta, and also included Washington, Steve Redd and I--the CDC presence--waving to Margaret and others. So I did not attend that meeting.

SM: You did not attend.

AS: Yes.

SM: Okay. And you touched on this a little the last time. My notes from the 12:30 meetings first indicate there would be vaccine delays on October 16th, that's when it was

discussed in the ASPR meetings. So I wanted to know, when did CDC know? When did you know, and how did that impact your ability to move forward once you realized that there was going to be shortage?

AS: October 16th?

SM: That's what I have.

AS: I think that there were several different permutations of things that people found out about. So probably, as you talk to people, you wanna clarify going from x to y projection. There was something that happened in August: I finally had a week off in August, and while I was away, I guess people found out about some problem. I think they found out about the potency results and that once the potency reagents were available and people measured the vaccine, the bulk antigen wasn't as much as they thought it was. So that was one drop.

And then I think there was something in September, which I don't know what that was.

And then in October (I'm just vaguely remembering October 12th or something; Nicky had calls with a million people) Tom Frieden was asked to be on some kind of phone call, and he asked me to be on it, with Nancy Cox and Steve Redd as well. And that might have been around after they found out about I think it was Novartis, I believe. So that might have been a mid October kind of thing. There was a call that wasn't the regularly scheduled Chief of Staff thing. It was a special discussion, so that date sounds a little bit late.

Because what I recall was (maybe that was right) there was a press...My recollection is fuzzy because I wasn't actually very close to the numbers part of this. What I know was (our July 29th ACIP meeting where we came up with the scenarios of maybe we'll have a lot of vaccine, maybe we won't, and here's what we do if we don't have a lot of vaccine,) most of the press discussions that I did were not providing any numbers. And so, I think there's one transcript where my line is, "I don't know if we'll get a vaccine. Even if we get it, I don't know if it'll work. Will it be enough?" [Both laugh] There's a lot of uncertainties here. So, hold your horses because with

seasonal flu, it's unpredictable; anything could happen here."

So my first concrete time that I actually know that I was talking about vaccine was around then, in October. Or maybe it was earlier, when I did a press conference and told the public and the media, "Well you may have heard..." Part of my answers, I guess, were that we're not expecting to get as much vaccine this month as we had thought. And on further pushing, I said it might be, I think, people before me had been saying, maybe 40 million doses by the end of the month, that at this point, it looks more like 10 or 12 million less than that. And so, that that was my first time talking about numbers because I didn't usually either have them or talk about them.

Now before that of course, Tom Freiden had done press conferences in September talking about, we could wait until we have a lot; or we could just give it out as soon as we get it, and we think the right thing to do is to give it out knowing that there'll be some bumps in the road. So, we're sort of preparing people for the idea that we think we just have to have a bumpy start, because we can't hold on to this stuff when there's so much disease around. That

mid October might be around when (16th sounds a little bit late to me, but sometime in October) we did this messaging that we're not going to get what we thought or what we had communicated.

SM: But did it have any impact on the relationship between CDC and the states?

AS: All the way along, I mean, the issue with the numbers was very, very difficult. I think that one of the challenges here was that BARDA was primarily dealing with the manufacturers and CDC was primarily dealing with the states, and the CDC/BARDA communication wasn't ideal. You know, it's gotten better over time, but this was just a lot of people working hard under difficult circumstances. From the state perspective, they can't possibly plan logistically activities without some parameters, and it's fine to say the parameters may change, but they needed something.

We had a little period where people were giving numbers and dates and not meaning the same thing: if BARDA would say, "We'll have so many doses by such and such a date," that might mean, leaving the manufacturer. And we might mean,

either you have to go from the manufacturer to McKesson, which includes depots on the west coast and the east coast, and from the central depots to the states.

And we spent a lot of time actually trying to snip off hours and days in this McKesson transfer: when it gets there what can we do with it, and how quickly can we get it out? Whereas the big problem was production, not the 24 hours or 48 hours of checking it in, making sure it's okay, getting it into the data system and then reallocating it out. You know, that was nothing compared to the slow trickle. So there were jokes about, there's only so much you can do with a trickle.

For us, the issue was credibility with the states; their total frustration that (everyone was frustrated) there wasn't enough vaccine at the beginning. But also that when we've arranged all the school things, now we have to reschedule them all. We're losing the confidence of our partners. Everybody's dying to get vaccine. We can't tell them where to get it because we don't know where it'll be because it'll depend on when we get it. And they didn't wanna advertise it anywhere until they were sure it was going to be there. So, I think it was a bad situation all

around. And one where over time, obviously, there was more vaccine, but those early weeks were really quite difficult all around. And you know, sharing the challenge with the public, sharing it with the health department, sharing it with BARDA; I think nobody was in an enviable position there.

SM: Right. And there were the things that were happening publicly that everyone had to deal with. But then there were the things behind the scenes that were being resolved that never reached the public. For things to have moved forward, a lot of work was being done behind the scenes. And so, I was interested in what was happening at that point. What was happening for everyone in order (1) to move forward and (2) to stave off panic or distrust or mistrust in the public, and so on?

AS: I think that we had been messaging, since June really, that there was a lot of uncertainty and that we were going to be open and transparent. There was some breakdown in the Washington/Atlanta relationships when there was a period where there'd been so many, you know, the spreadsheets weren't right and information had been shared. There was a brief period where BARDA was not sharing with us what they

thought was going to happen, and maybe they'd been told, don't share until we get this corrected. But from our perspective, nothing's going to happen unless it moves out. You know, it's not enough to produce it, it has to get beyond that. So we had some testy few days there where Steve and I were managing people below us and above us in terms of, "hey, we got to work this out because it's not in any of our interests to shut down between parts of the government. We have to work together on this." There was a shared frustration that we couldn't, that we didn't have more, but we had to cope with not having more and figuring out what to do about it.

But I think that Glen Nowack is a big hero about this, because he's the head of our media affairs and he really strategically set up our communication and messaging to prepare people for uncertainty, to prepare people for variability; that it might look one way in one place and another way in another place and that's okay, and that's just to be expected. And the demand may be high in one place and not elsewhere. He was right on in terms of the issues that came forward and helped us try to foreshadow them, and try to get people to be ready for them.

But I think some of the kinks of working out within government that's part of the lessons learned: that we need to really be a team, and that the definitions are important. And that everyone was working hard under hugely difficult circumstances, but if internal communication wasn't good, how the heck were we going to get the external communication right? So, there was a little bit of a disconnect between the few of us that were the public faces and voices not having information. Well, it's not like we're going to share it, but we don't even know what it is. So, trying not to have the Secretary embarrass herself, trying not to have Nicki and Tom say different numbers, you know. And I never said numbers until I was told to say this number. But it was sometimes challenging because the response was, "We'll ask Washington", and Washington didn't wanna tell people. So, nobody had an easy job at that point.

SM: Okay.

AS: I've been talking forever here, so.

SM: You aren't, but I have 10 minutes?

AS: Okay.

SM: Okay. Let's see. Well you've been in the role of readying-- This may be a long one though [laugh].

AS: Well, you know me, so it's okay.

SM: You've been in the role of readying the country for influenza pandemics prior to this current outbreak. Has there been much difference in the degree of senior level and White House involvement in the response efforts when compared to previous administrations or previous efforts?

AS: Well, I would qualify what I say by saying that my role before the pandemic was certainly--the content of what my Center does is quite connected with pandemic flu. I did some Washington events, like a couple hearings that I testified in, and supporting Secretary Leavitt in the flu summit.

But Julie Gerbarding, really, she did a huge amount at the senior level for CDC related to pandemic flu. She didn't delegate the highest level stuff. She was actually

educating across the Department. Before the pandemic, the administration at very high levels was pretty interested in flu and got emergency funding. Secretary Leavitt really made this a big piece of his focus, and Julie Gerberding made it a big piece of her leadership of CDC.

Before this pandemic, I didn't have any contact with the White House.

My contact with the Secretary of HHS was when he visited Atlanta a couple times, or when I went to Idaho for one of the-- He went and visited every state, did a summit in every single state, so they needed a CDC counterpart. Dr. Gerbarding did a lot of them, and I did the Idaho one. She had two or three of us that were acceptable surrogates to be the big person who did the talks. So I did one of those big talks for her. I did other big talks for her occasionally, because she couldn't do everything. So I was among the three of us that were on that list--the short list of Rich Besser and Mitch Cohen and I were her alternates.

And then for outreach kind of stuff, I did some exercises with the intelligence community or the Department of

Defense, those types of meetings. But my role was different from Steve Redd. Or before him, Jim LeDuc was doing more with BARDA and ASPR than I was. I wasn't really doing much at all with that. And then my flu division was directly working with Ambassador Lange around Indonesia or some of these big issues. So I was aware and informed but not personally spending a huge amount of my time on it, although I was doing some stuff with congress with the appropriation staff and everything. So this for me--both because I was Acting Deputy when it began, and then because it was a pandemic, and because I ended up being one of the few people that survived being a spokesperson [both laugh], we joked about how many more people can they fire for this-- but I managed to be a spokesperson who everybody was comfortable with. And sometimes it needed to be a different person. But for the most part, the powers that be were quite comfortable with me being a voice on this, and also because you couldn't have the agency director. The Secretary was so great about doing a zillion events and wanted a senior scientist with her that it would not have been feasible for the CDC director to do all of those, and Steve Redd was running the response. So I became the person that was doing a lot of that. So this was a big change in my role.

You're right, it was a long answer. Sorry.

SM: You've been talking for an hour straight, so I think I'll stop here.

END OF INTERVIEW

Broad Themes

- Vaccination program – planning for request for emergency funds
  - Severe pandemic
  - Scarce vaccine as security issue
  - POD's to control distribution
- Distribution systems - changed in U.S.
  - Change to central distribution
  - Virtual distribution
- Public vs. private cost of vaccine admin
- HHS policy
  - Memo proposing publicly directed mixed delivery model
  - Public/private mix of strategy
- Seasonal flu vaccine/children's vaccine
- Cost effectiveness of public/private model
- Uncertainty re: vaccine program implementation
- Surge of personnel on response

- Vaccine task force
- White House presentation
    - Meeting with HHS, NSS, DHS, Fauci, Petrou – planning for vaccine program
- Local and state health officers
- Decision memo on public/private model
- McKesson
- Shipments: 4 depots, overnight shipments, H1N1 plus children's vaccine
- Strategies in science
    - Vaccine use
    - Assessing severity of pandemic
    - Intervention based on evidence
    - Virus mutation and increase of disease
    - Epidemiology and tracking of disease severity
    - Evidence-based guidance for institutions
    - Use of data
    - Strategy related to communication
    - Strategy for 2nd or 3rd wave
- Staffing and rotation recruitment system and demobilization, preparation for 3rd wave
- Acting Deputy Director for Science and programing
- Center for immigration and respiratory diseases
- CDC divisions – Domestic U.S. Immunization program, Global Immunization division, The Measles Initiative, Influenza Division, Division of Viral Diseases, Acute Respiratory Infectious Disease Program

Timeline

- July 9th – Secretary announces Voluntary National Vaccine Effort
- May 17th – Notification by HHS for budget for vaccination program
    - Calls to put together vaccination program
- May 17th – June 18th or 19th – Policies, cost estimates, overall budget
- June – End of personnel surge
- June – meeting with BARDA about central distribution systems

Names

- Jay Butler
- Dr. Freiden – Memo recommending mixed public/private program
- Beth Bell – Chief Health Officer
- Avery of NSS

Documents

- Decision memo on public/private model