INTERVIEW WITH

DR. NICOLE LURIE

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Nicole Lurie
Interviewed at Dr. Lurie's Office
Washington D.C., U.S.A.
Interviewed on April 2nd, 2010
H1N1 Oral History Project
Interviewed by Sheena Morrison

Dr. Nicole Lurie: NL
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr. Nicole Lurie on behalf of the National Library of Medicine for the Making History: H1N1 Oral History project. It took place on April 2nd, 2010, at Dr. Lurie's Office in Washington, DC. And the interviewer is Sheena Morrison.

Nicole Lurie: So formal!

SM: Well, you know, you learn as you go.

NL: There you go.

SM: So, can we first start with are there any pressing issues that you're currently dealing with related to H1N1?

NL: Pressing? Well there's a couple of issues and they're in very different spheres. One is, and I don't know if you

were here last week when we talked about this uptick of disease in the Southeast, and what it means. And on Monday, Anne and others really did a nice job. Anne and Regina Benjamin, at this press conference, talked about the uptick of disease and really encouraged people to be getting vaccinated. Kinda working on that. So, that's an issue, and you know, I think we'll just keep our eye on it.

We heard today about two of the systems that are being used to track hospitalizations that are supposed to go offline after another week. And you heard, I guess, my discomfort with that and wondering whether, in some areas, we ought to revisit that or whatever that looks like. So, I think we'll think about that. So, that's issue number one.

This issue about what we do with all of the vaccine that's not gonna get used and how to dispose of it properly is issue number two, which is it's own complicated mess. Because, turns out, the rules for shipping expired vaccine interstate are different from the rules for shipping unexpired vaccine interstate. You name it, it's like you can continue to not make this stuff up. There's a team at CDC and BARDA that have been working together. It seems that every time a team at FDA, I mean at CDC and BARDA need

to work together, it takes them all a really long time to be comfortable with one another. And so, we're seeing that again. But mindful of that, at least, we can prevent it from going off the rails.

SM: Well, and they have prior experience working with each—

NL: Well, so, it's different people involved in this set of issues, in part, so that's issue number two. And then I think issue number three really has to do with budget issues, going forward in terms of what has to be in the budget for continuing flu activities. Not only to build on lessons learned, but to be sure that we get the manufacturing capacity that we need in the future. That we're sure we can develop the products that we need in the future. To see if to the extent possible, we can bring the flu stuff and the focus on all the other medical countermeasures we need to make together, and be really forward looking in our strategy. And so we owe the Secretary a report pretty soon. So, that's that. And then, there's emerging this issue about continuing to be on the lookout for safety signals.

SM: And that's going to be discussed this afternoon.

NL: So, we have eight different systems going. And so, chances are good, at one point or other, one of them is gonna find something that might be real. And it might just be on the basis of chance alone. And so, I think that what we've seen is a concern that maybe there's something going on. We don't know if it's real or not. We don't know if it's on the basis of chance alone or not. We don't know anything, but it's risen to the level where we need to talk about it.

SM: Okay. Well, you mentioned that you're still following the uptick in Georgia. Have you had any conversations with your counterparts in the Southern hemisphere that would indicate that there is anything to be concerned about?

NL: Well, the Southern Hemisphere and Georgia are pretty different in terms of their flu patterns. I think the thing for me is that a lot of disease started in the Southeast, and it spread north and west before, and so just wondering about patterns per se. But it's hard to know at this point what's going on. I mean, it was nice to see that hospitalizations for flu fell in Georgia, but who knows

what that means, yet. And I think we'll just see if it was just a small epidemic of sporadic disease, and now it's over. I think that would be the best. I just don't want us to take our eyes off the ball.

SM: Absolutely. Having played an outside role in shaping the conceptual framework for the national strategy for pandemic influenza implementation plan, how did it serve you, and how is it serving you in your effort to coordinate policy support?

NL: That's a really fun question. I guess for me what it did most of all is it really helped me hit the ground running familiar with what the issues are, having a framework to think about them, to organize them into. To have my own sense, which was then informed and molded by all of the other people working on this when I got here in this situation, of what were important things, and where we need to focus or not.

It also gave me a sense of where I thought maybe we're in pretty good shape to start with, and where I thought we might have some gaps. And so, I think it was really helpful from that perspective. It was also helpful, I think,

because in the process of doing that other work, I got to know a lot of the people that I've been working with, and so it made it, I think, easier to just kinda get started, because we all know each other.

SM: Were there any surprises?

NL: I think for me that there were a couple of surprises. I think in my outside work, there were a number of people that had expressed concerns about a set of issues: that they didn't feel that it was safe, or that they had permission, or that I don't know what, to express those concerns inside of their organization. And I didn't know from the outside necessarily how to think about that, and whether these were really significant concerns to pay attention, or they were concerns of a disgruntled minority, or what it might be. But it did make me sort of pay special attention to some of those issues.

I think the other thing that was surprising to me was that some of the very same people who expressed a lot of frustrations about, or concerns, I would say, about gaps in the system (or a piece of the system that they might have been working in when I was on the outside) had a pretty

hard time as we were trying to then use some of those systems to make them work--wouldn't say a hard time, but expressed the perspective that those gaps did not exist.

And so it was really hard to, having looked at things, you said, "Here are some things that have gaps." You got to say, "We got to handle this thing with what we have right now. You got to use the systems you have right now, gaps or none. But knowing the gaps ought to help you figure out how to use them better, or if there's anything you can do in the short term to plug." And I think we did a really good job being able to use the systems that we had, even if they were a little creaky, or had gaps in them. But I think that we might have done even better if we could have confronted those more openly at the outset.

SM: Is that something that you can share? Is there anything in particular that was more significant for you, as the person who was orchestrating things?

NL: Well, I think that there's a strong sense all along, and I think it continues to be a real strong sense, that we do better with the systems that we have day to day than ones that we have to stand and take out the moth balls in

an emergency. That the systems that we use for seasonal flu ought to work pretty well. Or, that we ought to be able to use them and are counting on using them if we had a pandemic. And so, some of those surveillance systems, I think when you had gaps or challenges, some had been really scaled back, and they had to get scaled up again, kind of, to deal with this. So, I think I would say, some was in the surveillance domain, some of it was in the health care--how to get data out of health care systems domain? Some of it had to do with tracking mortality reporting. A lot of it was in the surveillance domain. And then some parts of it were in the vaccine ordering and distribution system. So, certainly, we knew that they were in year-I-don't-know-what of a multiyear plan to get to a really robust distribution system, and it wasn't ready yet. And we knew that there were challenges with the ordering system and the distribution system and needed to work through those.

SM: So when you first came on, how were you briefed? I mean, I know that you were actually working on many of the things prior to coming on. I'm trying to get a sense of how you--

NL: Like I just dropped in here day one.

SM: How you felt, because there was a lot of uncertainty. What were some of the things that were going through your mind, that you put in place in order to address those things?

NL: Well, you know, I talked with my predecessor. I talked with--

SM: Who I have an interview with, by the way.

NL: Good. Tell him, hi. He's just a lovely person. I talked with my predecessor. And then there was another guy named John Monahan, who was more recently running the Office of Global Health Affairs, but he was one of the counselors. He came over and sort of helped with some of this. And that's partly, I guess, why Laura got so involved too, because we were in that transition period. But John and I met when I was waiting for this position. He came and said, "How do I even think about this? Give me a framework. Tell me what the big buckets and the big issues are. Help me think about getting organized around this." And we had a whole bunch of meetings around this.

SM: And the people who became your lead people, so to speak, how did you choose them? Or did you choose them?

NL: Here?

SM: Uh huh.

NL: Really, a huge part of this, as you know, has been organized at CDC. And Steve Redd had been the head of the Influenza Coordination Unit before, in charge of all the planning. So it was logical that he was the incident commander. And then Rich Besser was the Acting Director at CDC.

SM: I have an appointment with him as well.

NL: Oh, good. Say hi there too. And was functioning as his deputy, and they had been in place as the CDC team. Peggy and Josh asked Jesse to be the FDA lead on this. So, I didn't choose him, in that sense. (Laugh.)

SM: Peggy?

NL: Peggy Hamburg, who's FDA commissioner.

SM: Oh, okay. Is she someone I should speak to?

NL: Depends on how wide a net you're casting or not. But asked Jesse to do that. And Tony has always been the lead for this at NIH. Within ASPR, I mostly needed to figure out who's gonna help me on this internal team and had some advice from Jerry Parker, who's my deputy, about who to involve in this. And I actually had met Claire in my previous work when she'd been detailed over to the Coast Guard, because the Coast Guard admiral there was the principal federal official for pandemic planning and preparedness. Claire was over there, and I'd met her here and had been really impressed. And so, when I had the opportunity to figure out who should help lead the effort here, I said, "Well, gosh, it really needs to be somebody with good command of what the issues are as well, and organized and blah, blah, blah." And so, she became the task force lead.

In retrospect, would I have set up the task force? Don't know. Would I have done it like I did it? Um, maybe, maybe not. Probably would have tried to integrate some of the other things maybe more into some of the more response

operations thing. But what I've learned from both this and Haiti is that in our concept of how we do response (and I think that was one of the problems early, and I'd be interested in my predecessor's take on this) this organization was always very much in this response culture. And so, it's all about how you're gonna get your teams and your stuff to where…and what are you gonna do.

But along with that operational response, there's sort of a policy response. And when I got here, like on day one, it was clear that the Secretary was needing to make a lot of policy decisions advised by this leadership team, but that the structure and apparatus for doing it just needed to be strengthened some. And that largely, this office, ASPR, hadn't really been well organized to support that role for her. So, day one of the earthquake, we set up a policy response team. We had a daily noon call. The whole Department, everybody involved, came. And people who wanted to learn about it came. Again, I think it was something I just really learned from this--that having a regular, daily, everybody touch base, share what they got, task out the problems that need to be resolved by smaller teams, et cetera, and come back to work on them--worked really well. So, yeah.

SM: Okay.

NL: Then it was sort of frustrating. The first two weeks or so I was here as a consultant, and so, I couldn't take part in a number of things I would have liked to do. There was another briefing from Harvey on lessons learned from swine flu, for example. There were a couple of other things that I just couldn't participate in. But it was in the context of everybody inhaling his every word that I said, "Gosh, we have to think about doing this in a way that makes it easier for whoever comes after us to do this better." And so, that was the genesis of this project. And then, obviously, we're working hard on that with the after-action thing and others. So, I think that's fine. Then I went to Harvey and said, "How should I do this?"

SM: He was really easy to talk to and very helpful.

NL: Good.

SM: I mentioned this earlier, but I wasn't so specific. One of the things that comes across in the interviews that I've been doing so far is the enormous amount of

uncertainty that people experienced as they went about their task. Were there things that you were able to immediately put into place to mitigate some of this uncertainty in coordinating the response, once you came on board?

NL: Well, I mean, I think that uncertainty existed at a lot of different levels. But the primary uncertainty, it's like none of us had any idea what was gonna happen. This started off really bad in Mexico. Everybody was set for something that was gonna be a lot worse in their own mindset, and was reacting that way. But we had no idea what was gonna happen.

We didn't know how long it was gonna take to make vaccine, and those timetables kept falling further and further behind. We didn't know how much was a dose. We didn't know if you needed one dose or two. We didn't know whether the vaccine was gonna work. So all of that kind of uncertainty, there's nothing you can do to mitigate that. But what you can do is set up processes and structures for making decisions that will help you make the best decision you can make in the face of uncertainty. And that's really, I think, what that was geared to. And I think some of that

was underway before I came, but I think for me that was a big focus.

And actually, I had been involved in this very interesting project in decision making under uncertain conditions in my prior life. So, tried to think through some of those kind of principles as well. George was just great about this. We laid out a whole array of decisions that we might have to make. We didn't know if we were gonna need to use adjuvants. Adjuvants weren't licensed here. I mean all of these things that were going on. So we sort of laid out all these decision trees, and what would be the triggers for these. And every time we got close to one of those triggers or decision points, we would sort of convene the group and say, "We laid this out before. We're getting close to this point. So that we're not backed up against having to make an urgent decision, can we talk through where we are and see it?" So that was, I think, one of the major ways to mitigate that.

SM: Okay.

NL: So. Good. It seems like we're going have to do our call.

END OF INTERVIEW

Broad Themes

- Uptick of disease in the South East
- Systems being used to track hospitalizations.
- Vaccine disposal.
- Budget issues.
- Safety signals.
- Disease spread patterns
- Gaps in the response system
    - Surveillance system gaps
- Data from health care systems
    - Surveillance domain
    - Vaccine ordering and distribution
    - Tracking mortality reporting
- Addressing uncertainty
- Task force/Internal Team
- Operational Response
- Policy response
- Genesis of the project
- Uncertainty

- Decision making under uncertain conditions

Names

- Peggy Hamburg, FDA Commissioner

Documents

None