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 October 13, 2009
H1N1 Oral History Project
Interviewed by Sheena Morrison

Dr. Nicole Lurie: NL
Sheena Morrison: SM

Sheena Morrison: My name is Sheena Morrison, and today's October 13th, and I am interviewing Dr. Nicole Lurie. And the question that I posed was, first, we started off with something that you spoke about the last time--

Nicole Lurie: The goals of the program--

SM: Right.

NL: Clearly, the overall goal of the program is to, if you want to put it that way, keep people from getting terribly sick or dying from H1N1, as well as be prepared if things get worse, which is a part of keeping people from being sick.

SM: And you also mentioned that one of the major challenges is to help people make informed, appropriate choices for themselves.

NL: Right. And so we had to get to a vaccine that's safe and effective. We had to get to appropriate use of antivirals. We have to help people understand; most people don't think of themselves as at risk. Are they in a group of people that are at a special risk for this, et cetera? And ultimately, to give people as much information as we possibly can to make choices for themselves about getting vaccinated, getting early treatment, and all of that. My hope is that we'll give people enough information so that a lot of people will make a choice to get vaccinated with the H1N1 vaccine, but there's, as you know from reading the paper everyday and watching television, deep and profound skepticism about that.

SM: I especially liked your story yesterday.

NL: Yesterday? (Laugh) But you know, that's life and that's reality, and that's the challenge that we have, to be honest.

SM: Thank you. Can you tell me what were some of the major issues that you immediately had to contend with?

NL: Sure. On the one hand, a really immediate issue communicated to me was significant concern and dissatisfaction by the Secretary and the immediate staff about policy coordination of the entire effort and all of its various parts. On the other hand, I jumped in right as companies were starting getting seed strains and starting to make vaccines. But in the initial contracts, there were all kinds of issues, logistics issues involved in vaccine, in antivirals, in communication, in still some of the research issues, in the logistics issues, in the international issues. Every aspect of this thing had unresolved issues. So there needed to be, in part, a way to organize the thinking in our organization, assure that things were moving along. We tried to identify and understand what ASPR's role was, and put together a team to do this.

And then for me, having to come in with some thoughts whether they were on target or not about what systems were working well and what wasn't. And who do we really think we're going to count on to do all the things that had to be

done, was sort of a whole other question. A lot of time, energy, and effort has been spent on the process of making vaccine projections about how much vaccine is going to be available, when it's going to be available, what formulation it is, all these kinds of things.

And getting back to the earlier experience that I had with a plan, I just keep thinking, one of the things that we kept identifying and harping on early was actually the research area. And every time you talk about the research and science, you talk about the science of making a vaccine and making it faster, and all the science of safety, and all that stuff. And in my earlier life we kept identifying, you know, that there's a lot of research that needs to be done about communicating to the public more effectively, and dealing with misperceptions. There's a huge amount of research that has to be done on operations and logistics, because there's a whole science of how to do this, and those were messages that just were not really heeded. And now I feel like they're just coming home to roost. (Laugh) That's how it is.

And a bunch of these issues, whether it was about the distribution systems or the systems for monitoring vaccine

safety, et cetera, were ones that were very much on my mind from my prior work, where I had, for better or worse, reasonably formed thoughts about how well and not well these things would work. And I identified some things early on.

One of the lessons that I took from 1976 was the whole set of issues about public confidence in vaccine, and responding to vaccine efforts. So one of the things I took on very quickly was trying to look at the systems we have in place for how we were going to monitor safety once we got a vaccine. And had very strong feelings that the systems in place to do that were not going to serve us effectively. And so, I went about trying to help put some other components in place.

SM: What was the first thing that you tackled from that perspective?

NL: One of the first things I tackled was looking again at the systems, talking with some of the folks who were involved in vaccine safety, and really working through and thinking through, first, trying to get a sense if any of my assumptions were on target or not. Had any thing changed

since I last looked at it? It seemed like things hadn't really changed a lot. There was a lot of awareness of the need to address safety issues, but I think like with many of these things, when you're really close to the systems you think they work really well. And they may, on the one hand, be scientifically really pure, and on the other hand, they may not serve all the needs we have. So we have these dual needs for scientific accuracy and speed. And speed wasn't an attribute of a lot of these things (laugh). So, there's one of the things that I took on.

And then for safety, I mean it was clear that you have to have a huge denominator under something that looked like active surveillance. And from a lot of my work with the National Health Plan Disparities Collaborative, I really came to understand a lot of the capabilities that health plans have, and was able to at least conceptualize a way forward where we could take advantage of health plan/health insurance collaboration, knowing that they'd cover a hundred and something million people. And to think about whether we could use their claims data to really get a large part of the population under active surveillance. We now have a system that's launching which is very exciting, and I actually feel really good about that. Obviously,

every step of it has been a slog, and a lot of it again has to do with openness to look at one's own systems, and decide whether they're going to do the job or not.

One of the things I came into this job with was a perception, based on several years of interviewing staff at a number of the agencies, that there had sort of got to be this culture of telling people that everything was okay. And telling people what it was that they wanted to hear about certain programs, because otherwise there'd be retribution. I think people started to believe that stuff. And so it was really hard. There were some desires on the part of previous leadership to change the directions of some of the program. People who didn't feel like that was a good direction felt as though they couldn't really express their views. Others were enthusiastic, but since I'd interviewed all these people, I kinda understood what their views were, and got to see both sides of this. And so, again, it just made me feel like what we needed to do was just ask a lot of questions about how these systems were working. And help people potentially see when we could or couldn't rely on them to work. That was the case, I think, with the vaccine safety stuff.

I was very, very frustrated about the stuff about distribution, because for me it was kind of an issue from the get-go. And every time you try to talk about it early on, it was just this enormous pushback, almost anger, "What do you mean its not working? Of course it's working. Leave us alone"--kind of thing. But you know, we're working through a number of these things. So, I guess that was one of the things early on, the safety issues, and the distribution issues that I wanted to delve into early.

And then other issues about how we're going to identify some risk populations differences to see if we could end up with a program that had fewer disparities in it than our programs historically have. But I think it's really hard for people to change what they're doing.

I'd also say that an overall philosophy for me in this has been, there are a whole lot of systems that are involved in a vaccination program, the seasonal flu, and all of this stuff, that just have never worked as well as they could and now they need to work in a pandemic. And this crisis was really an opportunity to figure out how we could fix them for the long term. So I've tried as much as I can to focus energies not only on what we need to do, but if we're

going to invest in systems, to think about what are we building for the long run of the program.

So to that end, the other thing I spend a huge amount of time, energy and effort on has been thinking about how do we engage the private health care system on this. I think partly because its not something public health does terribly well. I think that in planning, the major model is about 'medical surge capacity', especially getting hospitals to be creative about hos to care for a lot more people. And then, "Gee, when things get bad, the feds are going to fly in stuff," and I didn't think we could really fly our way...fly enough stuff if this was a really bad pandemic, number one. And, we really needed broad buy-in and support from the mainstream health care system.

So just for starters, I called a couple of health plan Chief Medical Officers who I'd come to know well from working on the Disparities Collaborative. And I just said, "Could I brain storm with you?"--I know the plans, together they've got a hundred and something million enrollees--"I know you guys take care of 8 or 10 million people. What do you think you could you do to help?" And they had enormously creative ideas. Some of them, I sort of knew

that they had, and others I didn't. And so, for example, I sort of vaguely knew that they had this high risk pregnancy program. Three in a row said, "You know, we call every pregnant woman when we recognize pregnancy in claims, and we try to assess whether she is in a high risk pregnancy group, and if she is, we enroll her in a high risk pregnancy program. So we could reach to these people and remind them to get vaccine." Or, "We've got these disease management programs, and we know who all our asthmatics and diabetics are, and we could use disease management to help people understand the need for vaccine and early treatment." Those were a number of things that I got engaged in, and then really working with them to get to their willingness to pay for vaccine administration. And that's been a really interesting adventure.

But back to this. So those were some things I really engaged in early on, jumping in with both feet. And then, before I came, I also became aware of this group at Emory that was trying to put together this self-triage tool, was actually being developed by a guy who years ago was in the Clinical Scholars Program with me. And so, before I came, I connected him to folks that did a lot of communications outreach for health plans, because I figured out that would

be a good connecting way to embed that program again into the day to day operations of the health insurance industry. And in addition, I suggested--it was the part I was really pleased about--he work with the health literacy experts so that whatever they came up with it would be readable at 6th grade level. And so, I've been, in the back of my mind, following that, and supporting our staff doing that. And that's been another whole contentious thing (undecipherable). So basically, engaged on a lot of these really complex issues.

And then, at the same time, we have the world supply of antigen, and we've had to do a lot of discussions about what is our global commitment, and how are we going to share vaccine with the world? Especially early on when we might not have enough for ourselves, et cetera.

And I guess the other thing I engaged in earlier on was thinking about what are the sets of decisions that we might need to make down the road, and what information would we need to make those decisions. And what are the triggers for making those decisions. Again, it built on some work I did just before I came, which was putting together a set of decisions maps and algorithms for a new administration

should there be a pandemic. And what I found is that the identification of overall decisions were right, and probably the sub decisions we thought about weren't granular enough, but it was a good frame for thinking about them. It was clear that what we had to do was identify the branch points on the decision tree, and what would drive us to make them. So what I really wanted to have by the time this thing launched was the equivalent of an FAA pilot's check list that before you launched the plane you've done all of these things, and I've really tried to live by that in my own mind. And, you know, George has sort of taken the lead in putting together decision memos, decision trees and collaboration.

SM: George?

NL: George Korch in collaboration with everyone. So I really felt, feel like, as we're launching this thing we have checked off the boxes on the pilot's check list as well as we can. And whenever we've come to a decision point, we've been able to fall back on: here's what we said, here's what the trigger was. In my mind any time we get remotely close to a trigger, or a date, we got to say, "Okay, were the assumptions that we had two weeks ago still

the same? Were the facts that we looked at two weeks ago the same? What's changed that would make us make a different decision than we are now?" Again, it's a guiding principle of how I use this.

SM: Well, yesterday in a meeting, the group was focusing on triggers for Stafford versus Emergency, and I watched the process that you just spoke of. And it seems that that's a really difficult place to enumerate triggers.

NL: It's a really interesting thing, because I've been working on this thing since 2005. And certainly, as we put together the overarching..."What are the big decisions that have to be made by a new administration if there is a pandemic early on?" One of them was, "When do you declare a public health emergency?" And the other was, "When do you issue a Stafford Act declaration?" And it's been one that nobody's been willing to say, here's how we define the triggers.

SM: I heard you mention that too.

NL: It's really interesting. And so, on the one hand, there's been this whole discussion that's gone on with

Homeland Security, and the White House, and the Domestic Readiness Group. All of this about, what are the triggers, and when do you declare the Stafford Act, and what happens if you do? And here, this model is when you declare the Stafford Act, it lets you access other funds and have other flexibilities to help States. But what is it that we do if we're going to help states? Well, you know, it basically releases money. But we still have this mental model about flying stuff in. So then you say, well, how bad does stuff have to get before you're going to declare a Stafford Act? And what are the ways that we know? And this is the thing about every aspect of this. What are the ways that we know that things are getting bad enough to have to do it? What are the ways that we know that the disease is getting bad enough that we would need to use an adjuvant? And that was a huge set of decisions.

What would push us to use an adjuvanted vaccine in this country given the public's confidence? And it was the same thing. The disease would have to be more severe, more people would have to be dying, and whatever vaccine we made wouldn't be effective, blah, blah, blah. And all these things we had in place. But even our surveillance systems that we all think are so great, they're good, but they

don't provide us, in a really timely way, the information that we need. And they are really getting better, especially through this, as people are seeking to make it work.

So, you've got to make decisions under conditions of uncertainty. And there is a whole science about how to do that. And there are people who've put together these little frameworks for how to do that. Again, part of my team at RAND developed such a guide over the last year. And again, I've been able to have this mental model of, 'here's how you do that.'

The military does this all the time. You take all of the information you have--now, there's this plans decision unit that is working with CDC--and they take all the information, and they go into a room where a bunch of people can't bug 'em, and they kinda think it all through, and you lay out all the pros and cons. You're sure that all the parties have been heard from. There's a whole thing you go through that at the end of the day, you come up with a set of options and your best judgement. That's what we have to do. That's what we have to do about adjuvants, that's what we have to do about the Stafford Act. But you can

define a set of triggers for doing it, just like the triggers for when you declare a pandemic.

This has been really interesting, because the U.S. never had a definition of when you could declare a pandemic, and so we're going with the WHO one, which is fine, because we're a part of the world. But every time you get close to when those triggers should be activated you don't necessarily activate it, but you go back and say, "Okay this trigger is really there to make me decide if I need to take action or not. So, in order to decide whether to take action, first, I have to revisit whether the facts are still as I thought they were based on the best available information I have at the time," which admittedly isn't going to be perfect, right? "So, based on the best available information I have available at the time, is it a pandemic?" "Yes," "no." "Should I use adjuvants?" "Yes," "no."

You know, when we came to understand that we were going to have far less vaccine early on than we thought, one of our triggers for moving to adjuvant was not having enough vaccine. And we still did not have a good handle on how severe this disease was going to be. So, we looked at the

potential shortage, and we said, "Gosh, one of our triggers for revisiting this decision about adjuvant was this." We pulled everybody together, we reviewed the epidemiology, we reviewed the science, we reminded each other that this was a trigger. "Did we want to move to using adjuvanted vaccine now?" The answer was, "No," given the facts on the ground. But to be prepared, we decided that we needed to go and fill/finish some adjuvant that could be mixed at the bedside to generate the response if we needed it. And that was an example of, "Okay, we hit a trigger," in my mind. We didn't make a decision to go ahead and develop fully adjuvanted vaccine and decidethat we were going to go on a track of using it. But, gee, it's an insurance policy, and very much in line with the President being very clear, saying, "I want us to be over prepared, not underprepared. I want us to be prepared for the worst case scenario."

SM: There was a comment that you made yesterday in the meeting. It had to do with, again, triggers. And the challenge was how to articulate medical impact in non-medical terms, and that seems to be a constant struggle with each phase of the program. Can you tell me a little bit more about how that's being done in terms of messaging it to the public?

NL: Oh, gosh. Communications is just such a huge part of this, and communications about all different kinds of things are a huge part of it. And different people get information in different ways through different channels, and all those sorts of things. So there is a communications team at CDC that has a long history, and a track record doing a lot of things; they are very active. There's a communications team here that's very active. There's a communications team at the White House that has a huge amount of emphasis on (new media? indistinct), a lot of message testing.

SM: We could go another ten minutes?

NL: Yes. But it's a continued struggle. And it's a continued struggle when you know you've got people who are really deep subject matter experts trying to communicate to the lay person. So to go back to the story I told yesterday.

SM: Can you tell it for me?

NL: (Laugh) Sure I'll tell it for you. I had two really interesting experiences yesterday. The first thing was that I talked to a very prominent physician, nationally prominent thought-leader, sort of opinion-setter.

SM: This was at the clinic where you-

NL: This was before clinic. I talked to him on the phone because I heard through the grapevine that he was advising people not to get vaccine. For somebody whose thinking I really respect, I was thinking, "Holy yikes, if this person really doesn't think we should be using vaccine I really need to understand what that's about. And I need to be sure that we are not being, all of us, lulled into a false sense of security about the safety of the vaccine." And that's sort of an issue all along for me. Just as (people working really hard on this—undecipherable) can really get into this groupthink. And it's really hard. So if I go back to the decision to vaccinate, I really think, ultimately people got to the right decision. But, there's also been groupthink to guard against every step of the way. Team B has been pretty helpful in posing questions from the outside along the way, challenging the traditional way we did things, and some of their efforts are really the

reason, frankly, that there is vaccine there, et cetera. And we should get back to this discussion about groupthink, because I think it's pretty important.

But anyway, the story was, I called up this guy to talk with him, and when I first talked to him, obviously, I really caught him by surprise when I called him. But then ultimately, he agreed to talk. We actually had a good conversation, but it was sort of a conversation about safety, risk and all those things. You know, he knows quite a lot about how people perceive risk, and all the science about that, which is very helpful. We had a good conversation. So, it's also pretty clear to me that some of the messages we'd thought we'd been putting out very effectively, even for somebody as well informed as this person was, had not been necessarily heard. And you know, I think that's pretty important because we're all just working so incredibly hard. And somehow, people think that every time there's an event, it's a message that the whole public can use, which I think is nonsense. We just cannot repeat enough, in as many ways and by many channels as we can, this message.

It's also been the case that I've been talking to my patients about vaccinations. It's also the case that every year I talk to my patients about flu vaccine. And it's always really hard. I always say that it's harder for me to talk my patients into a flu vaccine than an HIV test, which I think, in and of itself, is a pretty profound statement about the state of the people's skepticism about vaccine, at least in the patient population that I deal with.

So, last week I had an interesting conversation with one of my patients who wanted to know about this big T1 shot and what did I think of it. Yesterday, one of the residents came and got me and told me she had just seen a nursing assistant, and had talked to her about getting a flu shot, and said, well, she wasn't going to get an H1N1. She had been reading all this stuff on the internet, and she thought it wasn't safe. So I said, "That's really interesting."

And I had a little bit of time, and I went in the room, and I said, "So, I heard you've been looking at stuff on the internet, and I'm curious about what you've seen." And she said, "The internet! I don't know how to use the internet!" I said "That's really interesting because this other doctor

had told me that." And she said "Well, I really wanted to find a way to get her to tell me if the vaccine was safe or not, because I've been hearing stuff on the radio. So I told her that I read this about stuff on the internet because the internet has the truth, and I figured she would just tell me. That would make her admit if there was anything really bad about the vaccine".

It was kind of testing, you know. Patients test all the time, and have all different ways of testing. So I sort of took that, and so we said, "So, what have you been hearing on the radio?" "I've been hearing that a lot of people don't want it, and I've been hearing all this stuff. And if it's safe, why are people protesting that they don't want to take it?" Good question, et cetera. I heard a lot of questions about being around swine, and eating pork meat, and a bunch of questions about safety. Was I going to get the vaccine? Yes. Why hadn't I had it already? Well, 'cause it's not here yet. That was a really hard concept for her, that, we're all talking about it, but I haven't had it because there's no vaccine yet. But we sort of went a good part of the way through that. And I also said I felt that she and I both were health professionals, and as health professionals we have a really profound responsibility to

our patients not to make them sick because we're sick, and part of that, in my mind, involved getting a flu shot. She was able to see that, and putting us in this together was obviously helpful.

She thought for a while and she asked if I was a Christian, and when I asked why she asked if I believed in the will of God. (Laugh) And I said, "Well, a lot of people who aren't Christian believe in the will of God." I said "There's Jews, and Muslims, and Buddhists, and lots of people who believe in the will of God." She said "So how would you feel about mixing in a little bit of that will of God into that vaccine?" and I said "Well, that works for me. What do you mean?" And she said, "Well, I guess I have to do my part, but God has to do God's part, and if it's the will of God that I get this vaccine, then I'll do it." And, um, (both laugh) it was a, frankly, it's not a very unusual conversation to have with people. We have it a lot about breast cancer screening and about breast cancer treatment with people who have cancer because there are a lot of patients who I see who believe that God's going to save them, and they don't need to get treatment for their breast cancer, or they don't need a mammogram because it's just up

to faith. And I'm sure it's something that you're quite familiar with.

SM: Uh huh.

NL: So it wasn't all that surprising. Again, it just sort of hit home to me the challenges that we have of communicating, and the deep skepticism. And that we have to push our ways of thinking well beyond, maybe, what we traditionally come up with, with our risk communicators, to help reach people like this. And I thought, well, the will of God is the perfect adjuvant here, since we've made this decision not to use adjuvant, so maybe this is a safe adjuvant. I don't know, but (laugh) it was a good conversation. That said, the conversation probably took about twenty minutes, and she's willing to come back as soon as there's vaccine available and get her H1 vaccine. But most primary care doctors don't have twenty minutes to talk to a patient at a time into getting a shot, and that's really hard. And that's a place where our system just does not work at all. So, part of it is about how we do public messages and mass communication, how we create a message environment around people that addresses their issues and concerns and helps them do this, how we work with the faith

community around this, which there are active efforts in, et cetera. But it was quite interesting.

SM: Yes?

NL: Yeah. Good.

END OF INTERVIEW

Broad Themes

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