INTERVIEW WITH

DR. NICOLE LURIE

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Nicole Lurie
Interviewed at La Madeline's Restaurant
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Interviewed on October 12, 2009
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Dr. Nicole Lurie: NL
Sheena Morrison: SM

Sheena Morrison: October 12th. And this interview is with Nicole Lurie. So, we're going to go back to some of the things you spoke about in our last interview.

Nicole Lurie: Okay. That sounds fine.

SM: One of the things that kept coming up in your conversation was that you were concerned primarily with what systems were working well and what wasn't, and you mentioned two: distribution systems and monitoring the vaccine. And then you talked about active surveillance. And what I'd like you to do is tie that in for me in a little bit more detail the relationship between the active surveillance and the monitoring of vaccine safety.

NL: Got it. So previously, we had a couple of systems to monitor vaccine safety. The one that's more well-known is called VAERS and run by CDC and FDA, and it's a passive system, i.e., it requires people to report in potential vaccine adverse events. And then somebody takes these reports, tries to figure out if there's anything to them, validates them. And then after that we try to figure out, are they occurring at a greater rate than normal either in the population or above what would have been expected?

There's also something called the vaccine safety data link, which is a more automated "active" system now. And what that does is, it takes claims data from a bunch of HMOs. It covers about 9 million people: 6 million are in Kaiser. And it links receipt of vaccination to a whole bunch of potential adverse events, and automatically runs some preset programs that help you look for anything that you hadn't anticipated looking for, as well as things of potential concern. So now, the group has run a whole bunch of computer programs that they run every week. They run a cohort of how many people got what vaccine this week, and then how many people showed up with x,y,z events after that to look for any thing that's unusual. So, is that clear now?

SM: Yes.

NL: So the thing about that is, it only covered nine million people, and they were pretty concentrated in one state. It was sort of set up to deal with childhood vaccines. And it just isn't going to be robust enough to give us an answer quickly enough if people start feeling like there might be things going on with this year's flu vaccine.

So, what we tried to do is use that model and build on it, and then rapidly expand it by getting a number of other health insurers' claims linked with claims data from immunization registry. Now, you know, one thing about that is, you don't like to start up something brand new in an emergency. So we're using the same computer programs and algorithms and all that stuff that VSD does.

But the business about linking the registries to health plan data are a little bit new, however. It rapidly expands your denominator to about 40 million people. And it's not going to work perfectly, but it puts us on a pathway to

something that may be a much more robust solution for the long haul.

SM: Okay. You mentioned that one of the things you started out doing early on was reaching out to private health care systems.

NL: Yeah.

SM: And working with them to get to their willingness to pay for vaccine administration. Can you tell me a little bit more about the process?

NL: Well, I guess what I would say just from my prior work, it was really clear to me that health insurers had a lot of capabilities that could be very useful in dealing with this. Some of it was obviously about payment, but some of it really had to do with reaching target populations, and reaching health care providers in ways that seemed like they could be constructive. So, I called a couple of chief medical officers who I knew from my prior life, and we sort of talked broadly about what kinds of capabilities did they have that could be helpful. And they offered some that I hadn't thought about. I asked about also their willingness

to pay for vaccine administration. They said, "Yeah, this is kind of a no-brainer, but we're going to to have to work it through." But they identified first--and I can't remember if we talked about this last time, that any time they recognize a pregnant woman--did we go through that stuff?

SM: Yes.

NL: Okay. So then on the vaccine payment side, you know, the Federal Government is buying vaccine for free. It gives it to people who want to be vaccinators. So what we're looking for are insurers to cover an administration fee. And one of the challenges is that, particularly in adults, vaccines are often not a covered benefit. So one of the things that I really wanted to explore were whether there were ways that health insurers would be willing to pay for H1N1 vaccine, and whether they would be willing to pay for two flu shots, one seasonal and one H1N1.

So, in talking with them, a couple of them--and the person who stands out the most for me is Reed Tuckson at United Health Care, who I think has just played an incredibly important role in all this--he and a guy named Wayne

Rawlins at AETNA, Sam Nussbaum at Wellpoint felt like this was a good thing to do. Reed just went ahead and said "United is going to pay for H1N1 vaccine for any beneficiary." At which point he started hearing from large employers that said, "What are you talking about, we don't cover vaccines in adults?" And so he really sort of had to start to do some negotiation around all this, which was a very interesting dynamic. We ended up having the Secretary write a letter to all the health plans asking for their cooperation asking all hands on deck. And we ended up writing letters to the large employer groups saying, "We recognize it's not a covered benefit, but we'd like you to have insurers go ahead and do it anyway." And insurers were very willing to do it, and they understood this was kind of in their interest.

But it's emblematic of how chaotic our health care system is. Just as the fact that if you get triaged in a tent outside the emergency room, it's out of network care and so you have a higher co-pay? I mean the whole thing is completely crazy. And so we've been trying to work through a number of those things.

So, anyway, we had a number of meetings with ASTHO, Health Plan representatives, including their professional organization, AHIP, pharmacists, because pharmacies are going to be a big vaccination site, and typically health plans don't reimburse pharmacies. We worked through a whole bunch of mechanisms for health plans agreeing to pay administration fees, health plans being able to reimburse pharmacies, if pharmacists want to do that.

We've worked out this idea of a statewide universal claim form where people can check off the box about what insurance they have and submit it to a claims processor, and the health plan could pay. Then, health plans were willing to waive the co pays, and it's up to doctors then not to balance-bill if they choose not to. But in order for the health plans to waive the co-pays--can you turn it off for a second? Hello…

NL: So, it turns out that for the health plans to be able to wave their co-pay, they need to, some of them need to re-engineer their internal claims processing programming which is a pretty hard thing to do. So what they wanted was a unique CPT code for vaccine, and vaccine administration.

Well the AMA only issues this once a year. We had to go to the AMA, ask them to issue a CPT code. There's a huge amount of controversy then about whether there's a separate one for mass vaccinators like public health clinics, and a separate one for doctors. And I think some argued that it's more work for a doctor to give a shot than it is in a mass vaccination clinic. I think, ultimately, our feeling was regardless of where you vaccinate people, they have to be counseled about the vaccine and told about the vaccine side effects. So no matter what, it's work.

So we went through this whole controversy about two codes versus one code, because some people wanted to be able to be paid different rates, and others didn't. So we ended up with AMA doing a number of back flips to issue a code, and then they issued a code that said 'Immunization With Counseling When Appropriate'. So anyway, now there's a health code so health plans can program their systems not to reject claims for H1N1 vaccine.

Having said that, the pediatricians particularly are upset because they feel like they're underpaid for vaccinations in Medicaid, in general. And they're wanting to use this as a way to call attention to their plight and yell that

they're not getting paid enough for vaccine administration. So it's controversial, no matter what you do.

But the health care system--I mean AMA, the health plans, the pharmacists--they all came together with public health to get this done, and that's pretty unusual, and I feel pretty good about it.

SM: It is a good thing.

NL: What?

SM: I said it is a good thing.

NL: It is a good thing. And then, you know, as recently as yesterday morning, we're still having a bunch of questions that AMA and the pediatricians were raising about how they enter the CPT codes, and is it fraud to do what is most expedient? The health plans wanted to enter a charge of one penny to make their system work better, and some providers are saying they're worried that it's fraud. And it's sort of the whole thing again about making the point again about

how little they get paid. CMS has also been fabulous about paying for this. They put out how they were going to pay for this, what the rules are. Yesterday morning, we had somebody from CMS call the chief medical officer of a health plan to explain something about policies and clarify the billing. They've been fabulous.

SM: You spoke about a self triage tool a group at Emory and their association--I'm assuming your communication outreach group--and your efforts supporting your staff in health literacy. Can you tell me a little bit more about your involvement with that?

NL: Sure. Actually before I got to HHS, ASPR had engaged this group at Emory to try to put together a self-triage tool. And I think the much broader view is that whenever there's a public health emergency, we ought to be able to get something out there for people to be able to use quickly to make decisions about their care. So this was kind of a test case, and frankly, it could be used every flu season. It turned out that I knew the folks from Emory pretty well who were doing this, we all trained together in the Clinical Scholars Program.

So before I came, I actually hooked them up with the company that does all the outbound phone calls for the health plans that I'd also met through the Disparities Collaborative to see if actually you could build this into scripts, and health plans could make their hotlines available, and do all this kind of stuff. So they started working together. And then, because health literacy has been an interest and focus of mine for a while, I said, "You know, if you are going to do this, I really want it to be at a 6th grade reading level, or something really basic. Can you work with the health literacy folks to be sure that the interface of this is something that is unbelievably easily readable?" And, actually, the person I term 'the queen of health literacy' is also at Emory and also a colleague. So she started working with these guys on this interactive tool.

SM: Who is she?

NL: Her name is Ruth Parker. And the guy who has led the development of the tool is a guy named Kellerman.

So, anyway, they've got a good chunk of this thing together. Then what happened is all kinds of issues got raised about, what's the legal liability if this thing is up on flu.gov? CDC says it doesn't give medical advice, they didn't want it on the CDC website.

Then there were a whole set of issues and controversies about whether this was a device that needed to be regulated by the FDA because supposedly it gave diagnostic information. So, weeks of machinations with lawyers ensued. I mean, there's algorithms out there all over the web. There's clinical guidelines all over the web. What makes one a tool that needs to get regulated by the FDA and what makes one that doesn't? And so we ended up in a lot, a lot, a lot of discussion about this. I think, in the long run they want to exert authority over people who do irresponsible programming or have irresponsible algorithms. But they sort of agreed to, for now, that we ought to just go forward. Then it turned out, the only way that you could do this would be--the suggestion was that they provide for us under Emergency Use Authorization. But that would be really ridiculous.

And then, to be given under an EUA the tool would have to be termed a counter measure. And while some people were real proponents of this being a counter measure, this notion that you could go on line and then try to figure if your fever or cough meant that you had flu or not was a counter measure that should be protected under the PREP ACT [undecipherable] didn't seem to pass the laugh test. So the long and short of this was, after many, many weeks worrying about the liability and all of that, we then had to renegotiate this with CDC. CDC says that it doesn't want to give advice to patients. It didn't really want to have an algorithm. And finally they agreed to put together an algorithm for clinicians, which is a pretty simple flow chart based on all their guidance, which is what the original thing had been based on anyway. It was this whole thing about not necessarily wanting to accept somebody's outside work that had taken two years to research. But to do their own two years of research to come up with an algorithm would have taken too long--the whole thing would be OBE anyway.

But now, finally, there's this algorithm on the CDC website, and finally, this self-made triage tool on flu.gov. We made a lot of efforts also to make the

algorithm available to the private sector. Microsoft launched a version, as well. A group at Harvard Medical School did the same. I mean it's not rocket science to take the CDC guidances and turn them into advice for patients. I mean, what's it for anyway? So, we ultimately got there. And it's now being translated into Spanish, so that's also a good thing.

SM: Who did you have to bring to the table to make this happen?

NL: Well, it was a variety of folks, at a variety of times: sometimes it was FDA and lawyers, sometimes the CDC, and the subject matter experts and their lawyers, ASPR's lawyers and the Department lawyers. There are a couple of meetings with outside groups, you know, Microsoft and a number of others - VOXIVA, ELIZA and a bunch of IT companies. Actually, there ended up having to be a special IOM meeting on triage algorithms to get expert advice. The controversy seemed a bit ridiculous, though I understood why it came to be that way. And ultimately there was a bunch of pressure from the White House too, saying they wanted people to be able to have a triage algorithm like this. Whether it's going to keep people out of emergency

rooms, I have no idea, but I guess we'll have to find out. By the way, the VA just quietly went and put one up there on their website for their own patients, which is just basically the same thing developed by the same guys.

SM: I wonder if they had the same kind of issues.

NL: Well, they are different. They are a health care system so they can make this available to their patients as opposed to the public, but they were much less concerned about the issues.

SM: Tell me more about Team B. I've heard you mention Team B.

NL: Team B is a group of outside experts that aren't part of government that hopefully aren't as in the fog of war as many inside government are with this, and can provide outside advice. So it's kind of an interesting thing. One of the things that I took from (and I wouldn't for a moment claim credit for Team B starting) the swine flu episode was that everybody on the government team got so immersed in this, that some couldn't easily express a divergent

opinion. It was kind of this groupthink, and there's a lot of groupthink around this now, which is pretty challenging.

And over the last couple of years when I was setting up these decision making algorithms for the new administration, and all this stuff, one of the things that was really clear to me was, a number of points along the way you either need to go to an advisory committee, or you need to have a pre-designated group of experts who you can just call on who will be brutally honest with you and tell you if your thinking is warped. So, when all of this stuff started in the spring, and Rich and I were talking, I said that one of the things that I took from this was the need for outside experts. And we built this into algorithms, and all that. Next thing I know, whether from that or whether he just realized it was a good idea, he had put together very quietly a team of experts. To his credit, they actually also included some of our worst critics so that, very carefully and confidentially, they could provide advice. And they met everyday as necessary, every week as necessary. They reviewed the epi-, they'd take up issues, they'd say "Have you thought about this or that?" I think they've been really helpful overall.

SM: So you used them at your different-

NL: So, CDC used them, especially in the spring, pretty extensively. They used them some in the fall. I mean, now. They meet almost every week. And you know, partway through this, I was saying to myself, "I need a reality check here. I almost feel like I need my own Team B." And then I just joined the calls to take advantage of what Team B has to offer. And that has been very helpful.

For vaccine safety, NVAC made a recommendation, which I also feel very strongly and positively about, that there needs to be a tight group of experts looking over the vaccine safety data, if for no other reason than to be transparent with the public, that the government isn't hiding stuff from people. And so there's going to be a set of outside experts that just review vaccine safety data every week or every other week, and let us know if we need to be concerned for that same set of reasons. I mean, that's about also creating transparency. Team B is really just so that we can have advice.

SM: Can you tell me who is on Team B?

NL: At some point I probably can send you a list. Yeah. It's chaired by David Senser who was the key figure in the swine flu episode.

SM: [Undecipherable] and now to get back to groupthink, which you mentioned. In your last interview you said that every phase of the campaign, this groupthink has been-

NL: So, at every phase of this, two things have been an issue. One has been this groupthink. And the other is multiple layers of government being involved in ways that are sometimes helpful, but usually more often than not, counter productive. So, just in terms of groupthink, whether it's about how severe this is, whether it's about how great we are in terms of our surveillance systems of one kind or another, or our ability to have a distribution system or all that, it's kind of like everybody comes to this shared perspective, and its becomes very challenging to offer, and have heard, alternative perspectives. And so, you know, whether it's about, this is a horrible epidemic and we need to have a vaccination campaign, or whether it's about surveillance, or whether it's about safety, you know, is the vaccine safe or whatever, this sort of groupthink can make things really, really difficult. I felt like I

always need to be on my guard and force myself to consider the counterfactual.

You know, that's one of the things that Team B is very helpful for--as has been one of the advisory committees that I think has been the most helpful, the NBSB. Early on, they shunned conventional wisdom about a bunch of the linear processes that we usually go through when we do flu vaccines. They said, early on, "You know, this is looking pretty serious. We suggest that you fill and finish the vaccine before you know the right doses, and just base it on our experience of the seasonal flu vaccine." That would mean that we could have vaccine several months earlier than we would otherwise. You know, we listened to it; we thought about it, and we said, "Yeah, that's right." But otherwise, groupthink could have just had us plodding through these processes.

You know, I do think, still, has been a lot of groupthink until pretty recently about how severe this thing is--although now it's looking more severe again--whether we should be doing a vaccination campaign at all.

SM: Do you think there is a difference between developing triggers for yourself and developing them specifically for the White House to address some of the difficult choices that you have to make?

NL: What do you mean developing them from the White House?

SM: Well, I'll go back to Stafford again. When you're developing them for yourself you--

NL: Got it. Okay. So, the triggers that I think, for me, that have been the most important are the triggers about vaccine manufacturing--whether we use adjuvant, when we switch to an adjuvant, when do we start the campaign, what's on that checklist? Setting triggers about Stafford is also really important. But I think the development of the triggers about Stafford, it's not like you develop them for the White House. But, you know, somebody has to take the lead in the analytic work to put something out there for a point of discussion. I think there's a big difference, and I see that that's a big responsibility that we have, if that helps.

SM: Yeah, well, it seems that no one really has posed the question. You posed it at the beginning of a meeting, and you then rephrased it at the end, and it seemed that no one's willing to ask, or respond, so you keep coming back to it.

NL: Technically, it's the responsibility of DHS to make the recommendation to trigger the Stafford Act. So, the question is, DHS isn't a public health organization. Typically, the Stafford Act gets triggered after a hurricane, or a flood, or when a place is really hit. And triggering a Stafford Act for a public health emergency, as opposed to something left or right of 'boom', is a very different kettle of fish. And so, it's our responsibility to start to think about what that looks like. At the same token, you know, ASPR's sense of what the Stafford Act is good for i.e. fly in people and stuff, and pop-up hospitals and all that, I just don't really think it's very practical to fly stuff in. We can't get our way out of the pandemic that way. And so, under what circumstance you would do that is an open question. What the Stafford act does is it lets money flow, and that's pretty important. When money flows, you can send people, you can send technical assistance. Yeah we could send pop-up hospitals, if we needed to. We

could transport people, if we needed to, et cetera. But we could also get money to states.

SM: What would you like to do, I mean you--

NL: So, a lot of people seem to feel like they could get more support to states and get it faster if there were a Stafford Act declaration. I think the issue really has to do with how much money do states need? What do they need the money for? How quickly do they need it? If they had more money, could they actually hire people?--all of those kinds of things. Could it help them handle this? When can you know? When do we, as the Feds, need to provide additional assets of any kind to help them out? Certainly, it would be better if every time you wanted to spend some money to respond, you didn't have to turn around and get permission everywhere, or go to congress, or do whatever. But I actually personally think, as Feds, we have the resources and the authorities under the current situation. I think if places got so hard hit that part of their infrastructure, or part of their health care infrastructure really started to suffer, yes, then I'd really want there to be a declaration that let us provide additional assets,

if we really thought they could help, and if we really thought we could do them, and if it were more focal.

I think the other thing that's pretty clear, is that there were a lot of misconceptions about what you really needed a Stafford Act for. And it turns out, one of the things that people really wanted them for was additional flexibilities under Medicare and Medicaid. (I need to get this for a second). We also need to support states, but you can do that, I think without Stafford.

SM: [Undecipherable.] And what kind of assistance do states actually need. You can use--

NL: Right. Yeah, ok. I guess in my mind that's the biggest issue. It turns out what you really need is flexibility in Medicare and Medicaid. And Stafford Act doesn't get you this. Something else called The National Emergencies Declaration or Act gets you there. I don't think anybody, including myself, really appreciated this at all before. So peeling it all back, what is it that we're really seeking to get here? Yes, we want to give the health care system as much flexibility as possible, which we would do under a

National Emergencies Declaration, as opposed to the Stafford act.

SM: And that would sort of--

NL: It would let CMS grant 1135 waivers that gave you more flexibility about alternative care facilities, and all that kind of stuff. It's been an interesting process.

SM: Well, if you do it this way, giving the Medicaid and Medicare system more flexibility, would that counter or address your concerns about the current model which is having the feds fly in--

NL: Not particularly. I mean, it seems to me that they need these flexibilities to be resilient and to be able to handle things on their own. And if all of our focus on the long run needs to be, how do you have communities be resilient, how do you have health care systems be resilient? Then part of it is relaxing some federal policies that inhibit their ability to be responsive when they need to be. Yet, still, to provide equity and fairness, and not dump patients and all that kind of stuff. So, that's kind of what the back and forth is about. There

may be some circumstance where we either want to fly stuff in or be able to transport people out that we would need Stafford Act Declaration to pay for. That happens, it happens, you know? But this whole issue is separate from supporting the public health response.

SM: Let's see. Can you tell me what are some of the global issues that you have to contend with early on? You began by talking about antigen supply--

NL: Before we do that, you know, one of the things that I hope you'll be able to capture somehow in a number of your interviews has been these multiple layers that involve the National Security Council, National Security Staff, and then, the White House. And in the context of lessons learned from 1976 that there shouldn't be direct political involvement. There hasn't been any political involvement in science, but you know, very much, the White House sees that this is the President's very first test as to whether he can protect the country. And so they've been very hands on. Sometimes their perspectives are really helpful, sometimes it just creates more work and demands. And we should come back and talk about that. And I'm sure you'll hear that from other people, because I think, particularly the folks

at CDC have never had this experience of having so much really senior White House or cabinet level involvement in what they do.

Alright, having said that, the global stuff. The short version of this is that we've been preparing for a long time. When all this started, we went ahead and put contracts in place with five manufacturers to produce H1N1 vaccine. We bought between a quarter and a third of the world's manufacturing capacity for antigen. Clearly if you use an adjuvanted vaccine, you'd get a two to one, three to one, four to one, whatever increment increase in the number of doses of vaccine available. And especially before we knew if we needed one dose or two, it was going to make it impossible for the world to have vaccine.

So, there's been a lot of pressure on us to use adjuvant as a way to make vaccine go further. Because of the very fragile confidence in our vaccine system, and because these adjuvants have never been tested or licensed in the U.S., and because the disease wasn't that severe yet, we all felt really strongly that we shouldn't be using adjuvant. And that was not group think. There were a lot of different perspectives about that early on. And as things became

clear about how severe the disease was that we're dealing with, people came more and more to the perspective that, particularly for children and pregnant women, we weren't using adjuvants. And for anybody, we weren't using adjuvants, unless we're really pushed to. And at the same time we had to contract for, and purchase, adjuvant in case we needed it. Fortunately, that can be used for the stockpile for H5N1 vaccine, or whatever the next pandemic is. Hopefully by then, it will be tested and we'll have decided if it's safe or not.

So, we then embarked on a process of trying to figure out how should we be sharing vaccine? What should we do about making vaccine available to the world? Some of the manufacturers have pledged 10 percent of their manufacturing capacity. Then it was pretty clear that the world wasn't going to get any vaccine until the western countries had gotten their supply. And then after that developing countries can get theirs. Well, that sort of didn't fly so well. So, there's been pressure from outside. There's been pressure from WHO, and frankly, there was a lot of pressure internally by our whole team that wants to do diplomacy differently, to think about this differently. So there have been a whole set of meetings that have

already been called that have involved the State Department, that have involved the U.N. ambassador, that have involved the Security Council, and the USAID, the HHS, all these different parties, to try and figure out what we should do. And there have been a couple of parts to it. The long and short of it is that everybody felt that we ought to be making vaccines available somehow to the world.

Then the question was, when? How can the American public tolerate giving vaccine away when we know we don't have enough for our own people? That's one huge chunk of it. We don't want to continue to say to people, we're going to take care of ourselves, then take care of you. So, how do we, how could we walk some fine line being able to do that? Well, we'll make vaccine available on a proportionate basis as it becomes available to us. We were helped a little bit by a number of things: One was this one dose versus two business. But the other thing we were really helped by is that by the time we decided how best to do this, it was clear that WHO was a month away, or six weeks away from being able to use the vaccine. So we bought ourselves some time that way.

Then it kind of turned out that some other people were thinking about how can they organize these countries to make these pledges. They were going to have this meeting, and they were going to try to get it done beforehand so that everybody could meet at the G20 and hammer out some details. And it was also really clear that it would take a little more leadership than that. And so we're of the belief that the U.S. ought to play a leadership role here, that we ought try to do it well before the G20. And the State Department and the National Security Advisor called all these donor countries, got them all--this was a great idea--got them all on the line. And there was this big announcement that the President made that they've got all of these countries to pledge vaccine or money, which has been pretty cool. And now, apparently, a lot of the world is referring to this as 'The Obama Initiative', and his vaccine initiative. And actually, it's kind of cool from that perspective.

And I think the U.S. leadership in this also was a good wake up call to WHO to get them to say, "Whoa, we've got to get ready sooner than in October or January. We better get our act together." So I think that's all been pretty productive.

There's now a long series of discussions going on about, well, what do all these pledges really mean? How do we get them to materialize? How can we give up a space in the manufacturing queue so that we can start putting out a certain amount of vaccine available doses at the end of October? So, that active discussion is going on as we speak. And it may involve a bunch of Secretaries getting on the phone with manufacturing CEO's, and seeing if we can all get into some partnership to do this. Technically, we want to give up some of our manufacturing capacity, and then what we want them to do is sell that vaccine, not at the price per dose that the U.S. pays, but at a reduced, tiered pricing. And, you know, that cuts into manufacturer's profits. They don't necessarily want to do that. So we're trying to negotiate all that stuff right now.

At the same time, all these western countries have suddenly been approaching us for access to unadjuvanted vaccine. They're all getting really cold feet about using adjuvanted vaccine in pregnant women and children, and some of them are taking late delivery. So Canada wants unadjuvanted vaccine, Mexico just wants vaccine. This is very awkward

cause the disease started in Mexico. They're not going to get vaccine from Sanofi till December. They want us to give them some vaccine now. We don't have vaccine for ourselves yet, let alone to give it to anybody else. Sanofi is now blaming us for not having seasonal vaccine. They're blaming the Federal Government for our country not having enough seasonal vaccine, which is nonsense. It's a very complicated diplomatic thing. Long and short, you've got eight or twelve countries all wanting unadjuvanted vaccine from us and wanting these bilateral deals, which we don't want to do. We'd rather work multilaterally. So it's really, really interesting to figure out how to do this, and how to see it play it all out.

SM: I know that you only have a few minutes. What I wanted to ask you is, what are some of the things that you are dealing with right now, some of the pressing things? If we could get started, and then I'll pick up on the next--

NL: Sure. The most pressing things in my mind are fixing this distribution system so that we can get vaccine out to states really quickly and being sure that we have the rest of the safety components in place and can communicate to the public. So, helping the public understand what we know

about the safety of vaccine and helping them make choices is pretty pressing in my mind. And I think some of the new data makes me wonder if we need to be revisiting what our priority groups are for vaccine. But I think the most pressing thing is getting this whole system of being able to estimate the number of doses of vaccine and then getting vaccine out to states, should be really important. In my mind, that, right now, and this whole global discussion, are the most pressing things.

SM: Thank you.

END OF INTERVIEW

Broad Themes

- Relationship between active surveillance and monitoring of vaccine safety
- VAERS – Vaccine Adverse Event Reporting System
- VSD – Vaccine Safety Data link
- Health plan data and registries – linkages between
- Private health care systems

  - CPT codes
  - Vaccine administration
  - Statewide Universal Claim Form
- U.S. health care system – Chaos in
- Self-triage tool
  - On www.flu.gov
  - EUA - Emergency Use Authorization
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  - INVAC Recommendation
  - Severity of disease
- Groupthink
- Multiple layers of government involvement
  - National Security Council
  - National Security staff

    - White House
- NBSB Advisory Committee on fill and finish
- Triggers – ASPR versus Stafford
- Stafford Act
    - DHS responsibility
    - Money – states needs
        - Flexibilities under Medicaid and Medicare
- National Emergencies Declaration Act
    - Flexibilities under Medicaid and Medicare
    - 1135 Waivers
    - Federal policies and flexibility
- Global issues
    - Sharing vaccine supply
    - Antigen supply
    - Adjuvanted vaccine
        - Use of
        - Request from Western countries
    - The Obama Initiative
        - WHO preparedness
        - Vaccine pledged

Names

- Ruth Parker

- Kellerman
- Team B members