INTERVIEW WITH

Dr. ROBIN ROBINSON

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Robin Robinson
Interviewed at Dr. Robinson's Office.
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H1N1 Oral History Project
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Dr. Robin Robinson: RR
Sheena Morrison: SM

SM: The following interview was conducted with Dr. Robin Robinson, Director of the Biomedical Advanced Research Development Authority, on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on December 9th, 2009, at the Indian Museum in Washington, DC.

RR: It's December the 14th.

SM: Right. We were supposed to do it December 9th. Okay, December 14th, at the American Indian Museum in Washington, DC. The interviewer is Sheena Morrison.

Okay. So, Dr. Robinson how long have you been in your current position as the Director of BARDA?

RR: Since April, 2008. Before that, I was head of the influenza program within the predecessor to BARDA, and that was when I came to the Government, in May of 2004. Before that, I was in industry, and Director of Vaccines at a vaccine company called, Novelvax. I came originally in 2004 because I was arm twisted by General Russell to set up a pandemic program. I thought I would come in and set up the program and leave after a year or so. I felt that public service was not only a worthwhile endeavor, but it was also a way that could make a bigger difference than my entire career would in industry or even in academia.

SM: Can you give me an overview of BARDA's role in the Federal Government's planning and response efforts to the H1N1 pandemic?

RR: Our mission at BARDA is to provide countermeasures, medical and non-medical, for pandemic influenza, emerging infectious diseases, and chemical, biological, and radiological threats.

So, in those medical consequences for these threats: we can provide vaccines, antibiotics or antiviral drugs, diagnostics, and also non pharmaceutical products, such as

ventilators or personal protective masks, and respirators. We do it through development of the products, and we did that this year with the H1N1 with our colleagues at NIH, and also with our partners in industry through contract support for clinical trials, and the material that people use in those clinical trials, the H1N1 vaccines, through acquisition of products, having contracts with the manufacturers to make the H1N1 vaccine. We started off in May and are still making right now.

Antiviral drugs: buying those, providing those through the strategic national stockpile. And then, also a product that we had developed with a company called BioCryst called Paramavir that's now being used as a life saving drug for individuals that are very ill in the hospital with influenza H1N1. And then, we provided for HHS, antiviral drugs, and personal protective equipment such as masks and respirators.

And we developed the first product that was used to detect H1N1 back in April - we and the CDC had funded a company called Mesoscale - with a product that was actually in clinical testing, and actually detected the very first case

of H1N1 within 30 minutes of actually...So, it was field tested before it was actually approved by the FDA.

SM: And when was this?

RR: That was in April, third week of April of this year.

SM: Amazing!

RR: So, a large...a different area. So, this represents the first time that BARDA has been asked to play a response role. We are primarily a preparedness organization within HHS of developmental products and stockpiling products, or building facilities, which we were fortunately able to...One of our contractors opened a facility in North Carolina for cell based influenza vaccine. No, it couldn't be used this year, but it will be used in the future and will have a substantial effect.

But response efforts are very different from preparedness efforts. And so you have day to day, hour to hour, minute to minute responsibilities. And since May of this year, we have been, our staff have been, in operation mode in this response acquiring the vaccine (to some extent the

antivirals, which haven't been as big of a project.) The vaccine project has been overwhelming in that it's very large. We interface with CDC on a day by day, hour by hour, minute by minute basis with what's going on -

SM: Right.

RR: ...to get the vaccine there, if there are problems, to understand those problems to be able to litigate those if we can. And then, to communicate those within the department, and then the state and local health officials, and then also with the public. So that's what we've been doing in this pandemic.

SM: Well, what makes this pandemic so different that BARDA has been called on to undertake a response role?

RR: Because we had a preparedness function to provide the pandemic vaccines, and we had contracts to provide those vaccines - such as H5N1 Avian Flu Vaccine, if we needed that. We actually had the underpinnings of what you actually needed to have in place to go forward with the vaccine, with the manufacturing portion of it. And we're the Department's eyes and ears, and the acquisition mode of

that, and the scientific mode of that, too. Because we have a large staff of people that were from industry that have actually made influenza vaccines before that know what's involved.

So, since we had the contracts in place, we knew the budgetary portion of it, the contracting portion of it, how that interdigitates with the vaccine development portion of it with the NIH, and actually, how that was to go forward with the CDC in the actual release of the product to go into distribution for the states to order.

Now, the scale that we were working on is very much different from previously. We prepared to have a capacity of anywhere from 600 million doses, if everyone in the country needed two doses. Fortunately, the vaccine cooperated with us; it was very immunogenic and still is, so we needed less than that. One dose for most people, and for those who are 10 years and younger, 2 doses. There's a licensed vaccine, standard dosage, and all of that came out in the clinical studies in the development of the vaccine over the summer and this fall. So that was very good.

The manufacturing portion, we had contracts in place: 5 licensed influenza manufacturers that could actually...And we worked with them. What happened in May, though, is that we were not the only ones that wanted vaccine; there were many other countries. And so we had to make the contracts become as advantageous as possible for us in a competing market. So we were, we actually had letters of intent to buy 600 million if we needed it, and the timelines and milestones for a quarter of that.

Then we actually started making...the manufacturers started making the vaccine in July - late June, early July. Then about August, we started seeing the first problems, and by late August, we knew that there was a real problem, that the vaccine production was not going to deliver us the number of vaccines we anticipated in October/November. And certainly then, it was not a few percent, or even 10 or 15, but several fold. When we expected anywhere from over a hundred million, a hundred and twenty million, and it goes down to 20 million, that's big change. And so, we had to communicate that, and sometimes, I have a saying that "Don't confuse poor communication with bad news."

SM: Okay. (Laughs).

RR: Bad news is bad news. There's no other way you can get around it other than, just say it. And then, in our era of news transparency, with the new administration, one of the things you see is that you're going to get all the news, including all the warts, and all the things that are surprising. And so, I think when we look through September, mainly late September, October, and early November, deservedly so, the projections that we had were much less than the reality of what we were receiving. And so, it had big impacts upon the state and local health officials, and the communities, and how they administered the scarcity of vaccine at that time.

Since then, we're now in a position where we have a large amount of vaccine. Hopefully, we'll have 100 million doses for the states to order this week. This is the 11th week, so that's...What we did anticipate is that we really would be playing the dispatcher role. We say, "This is how much vaccine you're gonna have this day." They tell us, "Okay, we needed an order from the states for this amount." We tell the manufacturers, "Have the trucks to ship it to the different central distribution sites" - which are four

across the country. And then it moves on through that part of the system.

And so, everyday we have a roll call of how much vaccine we have, and how much actually can be delivered to the different places. And it's delivered in very customized vehicles that regulate the temperature and the humidity of the product. So, we actually have field representatives at those sites.

In addition, we planned something many of the other countries didn't do, and certainly they didn't go to this extent. All they did was, other countries just, "Here is an order, tell us when its coming." We not only had orders, but we actually knew when they actually made it, as it was being processed, when it was being tested, if FDA was going to approve it, and it was getting out the door and be able to ship.

Also, we thought that it would be best that the providers, whether they be mass, clinics in school, or some other place, or just an individual physician providing, that they needed to have the ancillary supplies: syringes and needles, alcohol swabs, and so on, that they wouldn't have

to wait, that it's all there. Fortunately, that has exceeded my expectations, because we thought it would be some problems with coordinating that, but it actually has turned out, we have not had a single case where we didn't have those products already there. So when the vaccines arrived, everything was there. That's actually worked out very well, and I think that's a tribute to the CDC and our group, and the manufacturers of those products, and the people that actually do the packaging. We've been able to coordinate that very well. So, we're very, very pleased with the central distribution. That was a wrinkle that we had not anticipated doing, but we did it, and I think that's turned out well.

SM: Well, I mean, you have been in the business of preparing the country for a pandemic for a number of years. Would you say that this is something that you think should continue, or do you think that the preparedness and response efforts should be separate?

RR: No, I think we probably should be the right ones. I think since it was our first response effort, clearly there's much improvement that can be made, and we can

certainly do that internally, and bring in some outside people to help us do that. And we will do that.

There are certainly things that we had in our plans for preparedness and response that we didn't use, because they were not just applicable. But we were able to provide contingency plans in case we moved from a mild or moderate pandemic to a very severe one. And so we were, which is what all our planning assumptions really went around, those very severe pandemic.

For us, huge number of lessons, and being able to train and to exercise those plans and the staff to understand what they should do, and to cross train individuals. We ended up doing that, being able to use, not just the influenza division which I ran but also, the entire BARDA. So that people out in the field actually accepting vaccines come from all over BARDA, not just the influenza group, which is one of my main objectives when I became the first BARDA director. And that was, I wanted it to be one organization, not just a flu group, or Bioshield group, or the emerging infectious diseases, but all of it together. Clearly, there is expertise needed for each of those areas, but as we get into a response that is exactly what we had hoped - that

everyone would be able to play a role. And that part of it's turned out really well too.

So, I would say two big things that went wrong. One is that on very good scientific basis, we made projections. However, that's what they were in the summer. There was capacity: how much capacity do we have? And it was detailed and very meticulous. But when and how to communicate that we can do a better job on. Because we set expectations that the public and health officials, other health officials, certainly were disappointed when the manufacturers weren't able to meet those. So, I think, tempering that and being a little more wise about that is certainly one thing. And I think that would assuage much of the early problems that we had. No matter the...I mean, these things happen.

And the other thing is to have the necessary resources of people, a much larger group, so that we don't get tired and burned out, 'cause we have been going 24/7 since late April and fatigue sets in. We weren't large enough to be able to accommodate that. So we have to be able to expand on that with the interface of the distribution of the vaccine, from the manufacturing to the distribution. So, those were the

things, the two big things that we have to improve on and that are specifically our responsibilities.

There are other things that are other people's responsibility in how we interface with those. On the one side, the vaccine development has been great. It went as well as possible as it could go. The distribution side - we changed from what we had planned the last several years in June, to a new...Everything had not been tested, and we weren't trained on that. So, the month of October we really were playing around with the system, trying to work out the bugs, and unfortunately, that was real time. That was when we had real vaccine for real people to get out. We don't want to have to go through that again. We have to be able to train and exercise our plans.

SM: Well, I've seen you (you didn't see me however,) eating on the run with your coat tails flying behind you. I said, "Oh, there's Dr. Robinson over there." But the other thing that I would like you to talk about - you said you switched, that there was a new process for you. Can you tell me a little bit about why you switched, and what it was?

RR: Yes, we were at the National Vaccine Advisory Committee meeting in June 6th, of this year. And NIH and CDC and BARDA were each presenting our different portions of the pandemic preparedness and response. So, we talked about manufacturing. CDC then talked about the distribution plan for the vaccine, which at that time was to go from the manufacturers to about 750 to 800 points of distribution within the states. That was the plan; that's what has been used for other types of events, and had similarly been exercised the last several years. State and local health officials were at the meeting and they said, "We don't have the infrastructure to do that. We can't just take it and then start giving it out. And as another level of distribution, we actually need to have it go out to many more providers" because of the layoffs that had occurred at the state and local level with the health department and with the recession.

That caused us to have to change. We had to go to a system in which there you could account for the vaccine, have the states be able to order what they need and to get it to many more sites. When we came up with plans, the CDC's plan that's used now for the Vaccine for the Children's Program was adapted, which usually handles about 40 million doses

of children's vaccine over an entire year. So we're now saying, "We want you to do, now, upwards." At that time, it could be 600 million doses, but it just turned out much less than that, but in three or four months. So we want you to do more and to do it in less time.

And so, it meant that we had to really engineer a different type of process, and it was. We worked on it through the summer, but we were never able to exercise that program, I think, because of limited resources of just people more than anything else, and time. So, from there, that was a big change for all of us.

And we had a much more direct role in the day to day of [indistinct] because it went to a central distribution system, so that in one way, it was very good, because it went from 750 to 800 sites for the manufacturers, to only 4. So that was good. The bad part about that is that there were only 4 sites. (Both laugh) And we were having to use 5 manufacturers that were all going to be contributing to that.

And then the logistics of accounting for that. And that's turned out to be cumbersome, because we never understood

what our real needs were relative to states, and the department and the Federal government's needs, to give information out. So, we ended up going from a biweekly, now we go to weekly update, which are every Friday. And so, Thursdays, we talk to all the manufacturers to understand exactly what they're gonna have that coming week, two weeks, and at least eight weeks in advance. And those are what we call projections, and those have been somewhat of a heated storm in many cases, because things don't always go the way that you've planned, or even the way that they've planned. That would be another area that we...certainly, that's part of the role of communications that we can improve on.

SM: But it was a new system.

RR: Yes, that is absolutely true. But you'll probably see that the distribution system will be revised, certainly, after-action lessons are learned. But we'll probably look as a department at ways that industry does this better than what we do. This is truly a public system, really, done in a very, very short period of time. So, I guess if we had a couple of years to do it, we would probably come up with a better system than we have. But this is what we had to work

with, and I'm sure we'll improve on this. And again, not only take lessons that we've learned from ourselves, but also get templates from others that actually do this on a day to day basis, like the Fedex's, like the Walmarts that actually contract things from the time it actually leaves the factory, to the time it actually gets to your house, and you unfold it, and they know that you have it, and they send you an email, or a telephone call, and say, "Hey would you like another?" (Both laugh).

SM: Okay. Let's see. So in essence, you wear multiple hats in this role as the director; you're actually out there in the front, interacting in a much more hands on way than you would have in previous.

RR: The other part of that is that I do have other responsibilities than just the flu: all the bio threats, chem. threats, those programs are still going on. We have issues and problems and challenges and successes there too. I always worry that they feel like they're being left out, or not getting the amount of attention that...and there's probably some days that's actually true. Fortunately, we do have other people that are strong that can be involved, but this is part of building our own resources, that I can be

at a level that doesn't require me to be so operational. Especially in this kind of event, 'cause this is not a hurricane where it's two weeks and its over; this has been six months, seven months, eight months, going forward. So this is a little bit different type of response than you would have for an immediate event.

SM: Yeah, Bruce, he made a reference to that too. He called it his day job, and then the H1N1 response is his other job. Can you recall where you were and what you were doing when it became clear that this novel H1N1 virus was highly transmittable?

RR: Yes, because we were getting the results back from the clinical trials with the products that we had been supporting. So we knew very early on that something strange and different was happening, and kept getting reports and reports. I guess the thing that we didn't realize until probably in early May was that it was more than just us and Mexico, that it was going to spread from there, that these weren't just isolated outbreaks, which then prompted us to have to move to the next step and prepare for, not prepare, but actually start responding to an oncoming pandemic. And the virus was different than we all anticipated. It was not

the avian influenza, H5N1, and it wasn't on foreign soil; it was here in the U.S. And it was a related virus, H1N1, but it was not related enough that our previous vaccines would protect you. That changed the dynamics, so that stockpile of vaccine that we had, we had to use for the critical workforce and more people than that. It wasn't applicable. And so, one of our big weapons in our armory couldn't be used.

SM: How did this affect the...So at that point, you had to switch, you switched modes.

RR: So, we just said, "That's not going to be available." We immediately knew that we would have to contract for vaccine, and we immediately did that. Fortunately, we already had 3 of the 5 contracts in place, so we didn't have to renegotiate those. The other 2, we quickly did those the same way we had done the others. But there was some heavy negotiation going on in May in order to get the U.S. supply.

SM: Were you there alone, or did you have some support?

RR: There were other people, but sometimes you had to have the CEO of the company and myself talk out the terms in the big scheme of things, which sometimes could be very heated. And then they'd let our staff work out the details, once we had agreed on the principles of what we'd go forward with. And that's basically how it played out. Looking back on it, I don't think that we could have changed the way our contracts were...in the relative way that things worked out, because other countries had priorities over our vaccines delivery. Simply because, the manufacturers were not just in the United States; only one of them is totally located in the United States. So, for example, Canada had orders with one manufacturer that took precedence over us. At the time, we made a contract with another manufacturer that was in Australia who, we were the only contract they had. As time wore on, they finally were able to consummate a contract with Australia, and our contract then went behind the Australia Government contract. Actually, it hurt us very much in the beginning, because that was the manufacturer that was going to provide a large amount of the early vaccine that we were gonna use, but instead, it went to Australia.

What that points out, though, is something that we already knew (that we're still preparing), is that we have to have domestic manufacturing infrastructure here that can provide all the U.S. needs. And fortunately, that supply can be used for others too, which we're involved in providing the international donation for the U.S. government. But that's where we want to be. That was a very specific objective and goal of our preparedness plans. We just weren't, we weren't in year 5, we were in year 3. (Both laugh) So, it really did test us, 'cause we weren't ready with the new things that we had been doing. They just weren't ready as a facility. Or, they were not ready as being licensed that we thought the U.S. public would be willing to use at this time.

SM: So is your office involved in the plan to donate to the international community?

RR: Uh huh.

SM: In what way?

RR: The vaccines that are being donated were manufactured off the contracts that we negotiated, administrated, and

managed. So that's part of the domestic supply. So we are the principals in knowing how much there's there, where is it, how do we get it where it needs to go. So, we will provide that, and then, turn it over as it turns out to USAID and the State Department for them to work out moving it to the country or WHO designate. Or, the countries where it was going, which I wont say. So.

SM: Okay (laugh). I've heard.

RR: This is clearly the President's policy, for us to take the leadership role as a country in international vaccine donation, and that we would work in a multilateral manner with the World Health Organization. That's clear public policy, and the total amount is also public. And it will, again, we'll be providing that probably in the coming weeks and months.

SM: You mentioned that you're close to having a hundred million now for the States, and that's not too far from the original projected amount.

RR: Well our original projection would be that we would be close to 300, if we had needed it by now. And our

projections (as we moved into September) it's getting close to what we had thought, once we knew that the manufacturers were having problems manufacturing the vaccine because the virus (you'll hear the term) 'doesn't grow very well' or 'it grows slowly'.

SM: Is that something that they notified you of, or you had to discover?

RR: Both. Both. We sometimes had to ask the question and revisit it on a daily basis. Because they really were trying to catch up by making changes in their manufacturing process with new strains of virus, and that sometimes didn't work. And so, some of them were able to do it, but they had other issues, production line that was new, that didn't quite come on line the way they thought it would initially. So, a series of issues, but the biggest one was that the virus didn't grow as well. And so that put us, multifold, less than that.

However, once we actually started putting people into plants there everyday with one manufacturer, it made a huge difference. They became completely transparent, and it actually changed; the quality of their production improved

immensely. So, right now, what we're seeing (probably the last four weeks,) is that we're producing at full capacity now, and that is similar to even the initial projections that we had.

SM: Do you think the fact that the virus appeared in between the seasonal flu period had anything to do with the way they were able to begin their process?

RR: Well, they were at the end of their normal manufacturing for seasonal influenza, which is late summer. The problem is that similar to H1N1, the manufacturers specifically wasn't able to produce one of the strains of the three strains you have in seasonal flu vaccine. That delayed their shut down time to change over to H1N1. And what was variable there, they said, "Oh, we'll be through by September. Oh we'll be through by the 15th of September. Oh, we'll be through by the end." By then, it was then the middle of October, when they could have been making H1N1 vaccine 45 days sooner.

Our expectation (we made our decision not to interfere with seasonal influenza vaccine manufacturing) was, it would only be the 15th of September. Well it didn't turn out that

way. And so, it did have an impact, both on the seasonal flu vaccine in that they were able to finally finish it (it was late), but also, it had an impact on how much H1N1, and not just for us but for other countries, including Mexico. So that had a very big role.

SM: So, as planned as the response is, you have very little control over a lot of things, right?

RR: That's right. So there are ways in which one can learn to work with activities where you don't have complete control, or you don't have a lot of control. I think we have to be able to learn from others that do that for a living on a day to day basis. How you actually can (a) do it operationally, (b) understand it and comprehend and train for it, and then actually be able to communicate it effectively beyond that. And I think we'll certainly do that. That's very straightforward, and we actually look forward to learning that. How do you manage the unknown?

SM: Right. Well it can be an exciting journey.

RR: Yes.

SM: How much time have we got?

RR: About 15 minutes.

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

RR: Early May. The same time CDC was making the announcements that we had multiple outbreaks, we moved into a response mode looking at the contracts that we had, and also the manufacturers that we had working with us, not just for making the product but also developing the product, doing the clinical studies. Because they were already doing it for H5N1, and we just had to redirect them to now, to move from that to doing it for H1N1 and then coordinating with CDC and NIH.

SM: If you had to name 6 principal players early on in making policy as part of the response, who would they be?

RR: Certainly CDC and the director at the time. The first one was the Secretary, and the Secretary arrived end of April and walked right into it. (Both laugh). So that would be the...And she had been there everyday and on it. I think

the next person would be at ASPR, the former ASPR, Craig Vanderwagen, and then, Nicky Lurie. Initially, there was a transition there so both of them had major roles, and Nicky made it even a bigger role for ASPR in coordinating what goes on in the department. The chief of staff, which usually doesn't play a big role in many things, but this chief of staff of the Secretary did. So, I think that's how the secretary knows what's going on day to day. CDC, NIH and FDA, all three agencies and their seniors, not just one person but the senior level people in all of those. And outside of the Department, we would say we had a role with the Department of Defense. Not as big, some role with the Department of Homeland Security, because they have the overarching role of coordinating everything across all the departments and vertically down to the federal and state, from federal down to state and local levels. But the medical point of it is certainly our Department.

SM: Why do you think the chief of staff played such an intimate role?

RR: I think it was the eyes and ears for the Secretary. I think that was by design. And I think she felt that that was her responsibility.

SM: She has a huge one.

RR: That's right. And I should also say that early on, probably the people in our budget department played a huge role, because that was a role we thought that would be very straightforward; it was not. It played a huge part in the work that I did early on of (a) setting up the contract, but then actually setting up the budget so that we could then finish executing our contract, and convincing the Office of Management and Budget that we needed this amount of funds to go forward with. It was much more difficult than any of us anticipated, and certainly, it was not on any implementation plan at all. It was like, you'd have to do this. And it should have been, because it was a major endeavor, and certainly took up a large part of my time.

SM: Was there a spokesperson or a team in the budget?

RR: Certainly a team, but the different functional areas such as development of vaccine, the NIH and we were together. The manufacturing, that was BARDA. And then, the distribution and administration, that was CDC. So we interfaced with them.

SM: Wow.

RR: And it still goes on today. We set up a very different model. It wasn't one where you said: okay, I'm going to give you an order, and this is when we expect it. It was: we ordered so much, and as we learned more, we ordered more and more. Then as we forward them, we'll start thinking about either not buying any more but, actually, trying to exit of off of the existing orders that we have so that we don't over buy.

SM: So where are you now in the process?

RR: We are in the very first stages of what we called 'off ramping' or 'down loading' some of the contracts. But we're still keeping a very close eye. If we need extra, we have a contingency plan or reserve or cushion there, in case we have a spring wave.

SM: Well that was going to be my next question. In your opinion do you think that - like, this is the second wave - it's basically died out?

RR: It's close, it's close; there's still some areas where there's still outbreaks. But widespread outbreaks? I think by the end of the year, we'd probably have seen the, at least in this country, not be in very few areas where it's widespread.

SM: How will it be determined? Like, the seasonal flu is upon us, right?

RR: Well we haven't seen that much H3N2 yet, so we'll have to wait to see. Usually, we'll see it start to come by this time of the year and usually peaks in February. But what we're concerned about is if we were to see H1N1 die down, and then in the spring it would come back again, similar to what happened in 1957.

SM: Well you also have the Southern Hemisphere as a model.

RR: It's true that that should be a good barometer for us, but one of the things that you have to say is constant about influenza, it's unpredictable. (Both laugh). That's the one predictable thing about it that it's unpredictable. So, we have to be in a position that we're prepared if it does happen and that we're, I mean, that's just part of the

preparedness. We thought that would be a pandemic at some point so we prepared. And as we go forward, there's always a possibility of a third wave; we should be prepared for that, and that's what we're going towards right now.

SM: So even though its on the decline, you're poised to prepare for the next possible-

RR: If there's a third wave?

SM: Right.

RR: And then the next big efforts will be for the next pandemic, for a different strain of influenza.

SM: Which, again, is unpredictable.

RR: That's right. There's just...1968 was the last one

SM: Well this is a major thing, even though it's been, I think, handled really well. But this is a major thing in our era.

RR: I mean, this is what I always said, "This is how our generation will be measured", as how we handled and met the challenge of this, the way it was different and the resources that we have available to us. I think history will probably judge us much better than we're judged right now.

Because if you look at the amount of vaccine that was in 1976, that was provided, that was 40 million. They had to stop that. We have a much more robust monitoring program for any type of adverse event that might occur, especially severe adverse events, and those that might be similar to the 1976 virus. Can we improve on that? Absolutely. And that's one of the things that we will do. We want to be able to say that when that vaccine leaves the factory, we want to be able to know exactly who got it, and to know what happened to them, one week, two months, a year down the road. And that really builds into the reforming or restructuring of health care, and that reform, if we do it right, will then afford us an opportunity to do that.

SM: Okay I'll ask you this last question. What kind of mechanisms were in place to help coordinate and communicate your response efforts with other agencies?

RR: I think several fold. We had a working relationship with each of the other agencies: NIH, CDC, and FDA. Because of that, we quickly built on those we already had in place and then made new ones.

With other departments, the same thing. With the Department of Defense, they needed a vaccine. They don't go directly and get a vaccine from manufacturers; they go through us. And so, we worked with them. Again, a preexisting relationship, and a preexisting program that we had used. And that's part of a bigger program, that's much more influenza and pandemic influenzas, for all countermeasures. So we built on that.

I think our communication with FDA has been stellar - our communication and our interaction with them, both. With NIH, its been great.

I think we're in the day to day trenches with CDC. I think we had to learn how to operate with one another on a day to day basis and what our expectations and our levels of trust were. I think because we had not, in the response and the preparedness, we were fine and we still are. We're

developing products. We have worked with them very well, but we had not worked with them in response, like OPEO has from ASPR, Kevin Yesky's group. They had worked with them; we hadn't. I think it was a learning curve there, and a level of, or a timeline to build trust with one another. At the same time, we had some bad news that had to be given, and so that affected a lot of that trust, and it probably has taken longer than it should have, but that's just the way it is. I think coming out of this, similar to what I saw in 2004/5 when we had a shortage of influenza vaccine that year for seasonal, when we lost one of our major manufacturers, in that event, we worked very, very well together. And I think overall, we built off of that, in fact. I think we'll see the same thing. It will help us if we do it properly, and we say these are all challenges that we can do better, and we trust each other to work to do better. But I think we'll be fine. If we start blaming each other, then I think our cause is lost.

SM: Well I didn't see much of that in the meetings. I told you it was an admirable process, because everyone seemed to bring the important issues to the table, and there didn't seem to be any hesitancy if someone thought that there...if

someone believed counter to what was being put on the table.

RR: Well, in the that regard, I think that that's exactly right. Everyone is very open to other's thoughts. You may not agree with them, but they have the...it's important for them, if they want, to have the opportunity to say what's on their mind. And we all believe in that. I think that's part of the respect that we all had with one another coming into this, and that part has stayed intact. Again, operationally, when you're on a day to day basis, then you learn a different kind of respect for one another. Are you gonna cover my back? Are you gonna be there when we need you? And that just comes in the day to day of how you interact with one another. I think, overall, we went through the hard times together, and I think it will build very strong bonds as we go forward, and that we're not turning on each other.

SM: And you guys do a lot of work outside of the office, over the weekends, and late nights.

RR: Oh yeah, its really 24/7, which is an issue I have personally with our people on BARDA, them being able to,

what I call 'heal' after this. That they've worked many, many long hours, have been under a tremendous amount of stress and pressure, and they need time to heal. Not just to get away, they actually need time to heal. And I use this sports analogy in that when athletes are put into very stressful long periods of activity that their bodies and their minds and their spirits really take a toll, and that they have to have time to actually decompress and then actually heal up. And I think that's true for us too. I'm sure other agencies have something similar, and different words, but that's the way I look at it.

SM: Have you anything in mind how that might happen?

RR: One of the things that we're gonna do is we're gonna have a confirmation that in one of our all-hands meeting that people basically have to sign on to say: I'm taking this period of time off, and this is how I think I'm gonna decompress and heal up and recuperate.

SM: Okay.

RR: And that we actually then publicly to one another in our meetings actually say: this is what we're going to do,

and acknowledge that. And that the others will, if they don't do it, the other's will put peer pressure and say: you've got to do that; you said you were going to do it, and we need for you to do that so that you can be a full member and contribute, because we'll be back into a different role and preparedness, but then also, we'll have to do our action.

SM: Well, thank you.

RR: Thank you.

Broad Themes

- BARDA's role in response effort
    - Preparedness versus response – the difference between
- Medical and non-medical countermeasures
- H1N1 Vaccine development
    - NIH partnership
    - Industry partnership
    - Biocryst – Paramavir

- Personal Protective Equipment – masks versus respirators
- Equipment for H1N1 detection
    - Mesoscale
- Vaccine Manufacturing Preparedness
- Vaccine Acquisition and preparedness
    - Scientific preparedness for vaccine manufacturing
    - Contracts and budgets
    - Interdependence of NIH, BARDA, CDC, FDA
- Scale of response
- Immunogenicity of vaccine
- Global demand for vaccine in May
- Timeline of delivery – projections versus reality
- Field representatives
- Monitoring of vaccine production and distribution
- Provision of ancillary supplies
- Central distribution coordination
- Internal and external review of response effort
- Integrating different aspects in BARDA
- Correction of BARDA's role in response effort
    - Faulty projections
    - Small human resource pool
    - Improve interface of vaccine distribution

- Vaccine distribution – training, exercising of plan
- National Vaccine Advisory Committee meeting, June 6th, 2010
- Adoption of CDC distribution plan of children's vaccine
- Logistics of accounting
- Manufacturer projections
- Review of distribution system
    - Lessons from industry – FEDED, Walmart
- Robinson's responsibilities
- Initial spread of outbreak – North America
- H1N1 versus H5N1
- Stockpile
- Contracts for vaccine supply – 5 companies
    - Dynamics of negotiations in May
- Specific goal and objectives of preparation plan – domestic manufacturing information
- Vaccine donations from domestic supply
- President's policy – U.S. leadership role in international donations
- Production shortfalls – poor virus growth
- BARDA's presence in plants – manufacturing process improvements

- Manufacturers shutdown time – seasonal flu to H1N1
- Delivery systems – using day to day models
- Principal players in response efforts
- Offloading or downloading contracts
- Contingency plans – reserve vaccines
- H3N2
- Spring uptick of disease
- Southern Hemisphere as model
- Unpredictability of influenza
    - Preparedness
    - Third wave
- H1N1 as challenge of a generation
- Robust monitoring program for adverse events
- Health care reform
- Mechanisms to coordinate response efforts with other agencies
    - Preexisting programs and relationships – CDC, NIH, DOD, FDA
    - CDC response interface with BARDA
        - Learning curve
        - Building trust
- Openness to others in meetings
- Working 24/7

- Time to ‘heal’
- Sports analogy