

INTERVIEW WITH

Dr. MARIA JULIA MARINISSEN

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

January 28th, 2010

November 2010, National Library of Medicine Archives

Interview with Dr. Maria Julia Marinissen
Interviewed at Dr. Marinissen's Office
Washington, DC, U.S.A.
Interviewed on January 28, 2010
H1N1 Oral History Project
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Dr. Maria Julia Marinissen: MJM
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr. Maria Julia Marinissen. It was conducted on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on January 28th, 2010, at Dr. Marinissen's office in Washington, DC. The interviewer is Sheena Morrison.

I'd like to begin with a question about you. What is your position here at the Office of Medicine, Science, and Public Health, and how long have you held this position?

Maria Julia Marinissen: Right. Fantastic. I am currently the team leader for the International Partnerships and Initiatives Team. We are a group of people who are doing international public health emergency preparedness and response. So our team is the one that deals with all

international issues around what we do here. We take our mission, which is a nation prepared to respond and to recover from public health emergencies, but we take it to the international arena. So, we work with international partners, other countries, international organizations like the World Health Organization, the International Atomic Energy Agency, to make sure that we share information and that we coordinate preparedness plans. And that's our role. We work with Mexico, with Canada to enhance preparedness in North America.

SM: Is this a specific unit within-?

MJM: It is, it is, it is. It's called the International Partnerships and Initiatives Team.

SM: Okay.

MJM: And actually now, there is also another team that is under my team that was International Response Policy Coordination. So we help a lot in the international response coordination. And we develop policy for international response. We're not the responders, but we help a lot.

SM: And how long have you held this position?

MJM: I started to be acting team leader in September, but I've been in the office for more three years. I was in the Biomedical Advanced Research and Development Authority before, in BARDA, and I've been in this office in the international team for two years and a half now.

SM: Are you an epidemiologist by training?

MJM: No, I'm a scientist by training. I have a PhD in Molecular Biology and I've been working on basic cancer research. I spent 7 years at NIH, and then I had my own laboratory, and then I started to work on the policy field more than three years ago.

SM: So how did you happen to become part of this?

MJM: I wanted to do this for a long time. You know, I really love science, but I wanted to take it one level up to the point at which you can really impact society. And I wanted to do policy, use my science knowledge and the skills you develop doing scientific work in terms of

method, the scientific approach. I've come to the government to sort of help a little bit to make decisions based on science, on scientific evidence and data.

So, I applied to the Science and Technology Fellowship from the American Association for the Advancement of Science, the triple AS (AAAS). They bring PhDs and engineers that are successful somehow in their field to work for the government for a year. There's a selection process, and after the selection process, you go through a placement process. You pick a placement in the government, the place picks you, and then you do a year fellowship. Then you're on your own. If you succeed, you find a job. And I came to ASPR.

I had the opportunity to stay at NCI, the National Cancer Institute, or come here. And I said, "Well, you know this is something of direct--". At that point, cancer is what I was doing, so I said, "Let me learn something new." This was a very new field and very exciting, with a lot of opportunities to the develop new policies based on science. So, I went in BARDA. You know, it's all medical countermeasures development, so you need a strong

scientific background to do that, to do policy and program. And so, that was sort of a way of getting into ASPR.

Then, I started to see all the gaps in international preparedness and how we were not necessarily collaborating with other countries, or the need to do that. We're in a global period. I mean, the world is flat, the book says. And I was always convinced that there was a need to start talking to other countries about how to do this, like, "If we do this together, it can be easier because there's no way that a single country can be prepared for everything that could happen." Especially working on medical countermeasures, which is what I was doing in BARDA.

We're spending tons of money to prepare for a variety of threats. It's almost impossible to prepare for every single biological or radiological or chemical threat that could be out there. And you know, thinking of when I was there, we were all thinking, like, "How can we do? Maybe if we collaborate with other countries we could do this in a better way: We can pull more resources; we can share research and development agendas, rather than reinventing the wheel." So, that's where I started really thinking about international collaborations.

And this office had international team. They had a couple of multilateral initiatives, so I said, "That's the place. Let me bring together what I learned in BARDA about our mission: the medical countermeasures, what we're doing--the planning, the operations. And then, let me do the international work, plus a little bit of my own background." I always care about international collaboration, so I came to this office, and then I started to work right away on this, on these issues.

SM: Alright.

MJM: That's the story. [Laugh.]

SM: It's a good story. [Both laugh.]

MJM: And then, working on these international issues is when flu happened. I was the project officer--I am the project officer--for a program that have with Mexico. It's called the Early Warning Infectious Disease Surveillance System, EWIDS; we call it EWIDS. So, I do have a very strong relationship with my Mexican colleagues because we are helping them to build a BSL3 Laboratory--Bio Security

Level 3 Laboratory--so they can do diagnostics of biological threat agents, including pandemic influenza, which is something that they didn't have. And we're also helping them to build an early warning notification system, so when they start to have outbreaks in places in the country, they can detect it in an easy way, can be notified in an easy way to the Federal Government to take action, which is something that they didn't have.

So, I happen to be in Mexico on April, the week before the outbreak was announced. And I was talking to my Mexican colleagues. We were having dinner after working the whole day--the Director of INRE, the National Institute of Epidemiological Reference and Diagnostics, Dr. Selio Buche, and then Dr. [Undecipherable 8:21] who is the Director of Epidemiology in Mexico. I was having dinner with them, and they were telling me, "We're a little worried because we're seeing these cases of people with flu complicated with pneumonia. And it's weird because they are young adults, and it's a little late in the flu season. That's weird. We're a little concerned; we have a few cases."

Interestingly enough, we had emergency communications test with a series of countries that worked together on

something called the Global Health Security Initiative. So, Mexico had to initiate the test that day I was there. So I said, "Let's do the test." So, in the video conference, we asked Canada, "We're seeing these cases a little late in the flu season. Do you have something similar? Are you seeing something similar in Canada?" And the Canadians said, "Not that we know of. We're not, not now." They called CDC to say, "Are you seeing something similar?" There was no real information. I believe that that was like a Thursday.

On Tuesday, I remember coming here talking to the senior leadership, and said, "Well, there's something coming up. The Mexicans are worried." Obviously, I didn't even imagine the dimensions of what was coming at all, you know. But my concern is that they're having these issues, and they have no way to identify what it is, or how bad it is. And that was a Tuesday.

On Thursday, my husband traveled to Mexico. That same Thursday night, I go home and I said, "Well, you know, I'm going to have a quiet night all by myself." And all of sudden, the phone rang. It was Mexico, and they told me, "We need to talk to Admiral Vanderwagen"--who was our

Assistant Secretary at that time. Then I said, "Okay, it is urgent?" "Yeah, and it's related to what we mentioned to you last week." And that was the first call. I guess it was on April the 23rd, if I believe correctly, around those days, or the 17th. I believe the 27th, around those days. And they talked to Admiral Vanderwagen and said, "We want to let you know that we're having these very bad cases, and that we're sending samples to Canada because we don't know what it is. We're suspicious that this is something not normal." From that point on, I didn't sleep anymore until now. It's been really tough because all the communications started.

That weekend, we got a call from Canada. They wanted to talk to us because they finalized the diagnostics. They discovered a new type of influenza. And before going public, they wanted us to know about it. But that time, CDC was already working on samples that Mexico sent. It was the same diagnostic: that it was a new virus. And that's when the panic started. We didn't know what it was, and the communications were not very senior level of, "what do we do here?" Mexico was totally unprepared because they didn't have a stockpile of antivirals. We knew it was a new virus.

Then we started quickly to see cases here in the United States.

The cases in Mexico started to expand, and it was a little bit of a panic because, again, nobody knew what could happen, you know.

Their response here was amazing. That same week, we had that call on Thursday night with Admiral Vanderwagen. Then they called from CDC on the weekend. Everyone gathered here on the weekend and said, "What do we do? We need to trigger the response." We immediately thought about Canada.

Canada called us that same week. We were happening to be here in the ASPR conference room when Canada called me, and said, "Our Minister of Health wants to talk to your Minister." At that time, we had the Acting Secretary, Charles, um, oh my gosh, I can't think of his name now. Well, Secretary Sibelius was not designated at that point. And he happened to be in the room when he asked me, "Can we put Canada on the phone." And the Canadians started to take cases. The first cases they take, they wanna hear how we're going to go about communication with the public and all that.

And it was really challenging. One of the aspects that was very challenging in terms of communications was the language issue. When we wanted to call Mexico, the operators there don't speak English. So I became a little bit, for the first three weeks, like the communication hub with Mexico at the senior level. Because, as I said, even if the senior leadership speaks English, just going through the operators was a little bit of a nightmare. Not everyone could pick the phone and call. So really, thanks to the personal relationships developed by working together with the Mexicans in some of the programs, we were able to do this quick communications. It was a matter of even speaking. Mexico does not have an operation center like we have here. So, all the communications were basically for a while, via my phone. It was challenging, and at the same time, it was a real opportunity to see how things evolved so quickly. And the lack of knowledge that everyone had at the beginning, how everyone immediately started to talk to their peers, to see, "How do we do this? How do we go about this?"

Especially when we knew that the disease was started to spread outside North America, how immediately we connected

with our partner countries under the Global Health Security Initiative, the GHSI. We started to talk immediately: "What do we do? Are you detecting cases? How many? What's the mortality? What's the severity of the disease?" We started to share information right away through these international mechanisms.

And of course, when all this started the first week, the Director of the WHO, Dr. Margaret Chan, was in town. She happened to be here, and she came and met with us. And I couldn't believe I was in the room with the Director of WHO. She conveyed the message of how much she relied on the U.S. opinion, the U.S. expertise, in order to move ahead with how to go about this worldwide. She was in touch with our senior leadership all the time, and the communication worked in a way that I couldn't even imagine that it could be done. All the players were connected, especially in the countries in which we started to detect this right away. So it was good.

Then the main point was the uncertainty. Okay, it's a new virus. It's spreading so quickly. People are getting infected so quickly, and young people are dying. Pregnant women showed to be a target right way. So the social

implications were serious. I know that right now, we're going through countries accusing WHO of overreacting. We have a little bit of that here, but, you know, being within the government, inside, I cannot even imagine doing it in a different way because we didn't know anything about the virus. We knew it was spreading in no time, all over the world. We were, at those days, doing three international situational reports a day, and every time we would go to the WHO webpage, we would see the number multiplying, multiplying, and all these young people dying, which was not the usual target of the seasonal flu. So, we're so uncertain about what could happen.

And the main fear is--the main fear was--that the virus could mutate at any time and become a very severe disease. So, there were many decisions to make about deploying the stockpile of antivirals and start the manufacturing of the vaccine. Of course, it was tough, because you couldn't predict how many more people would get infected; you couldn't predict what would be the peak of the disease. We couldn't predict if people wanted to get vaccinated or not.

But what do you do when you have a disease that is spreading so badly, and you don't know what's going to

happen to the virus? Especially when it's a virus that has been reassorted, and it has already sequences from three species? And you say, "Oh my gosh, this may be jumping from species to species really quickly and become a new virus at any time." So everyone mobilized in order to say, "Okay, let's do what we had to do." It's better to be accused of overreacting rather than suffering the consequences of not being prepared, and all this time having a disease that is horribly severe and you're not prepared. You have no vaccines, no drugs. But it was tough.

And then when people say, "Well, why things are so slow? Why the vaccine wasn't ready earlier?" It is not easy. This is the manufacturing of a new vaccine, and there were complications with the yield of the vaccine that we did not anticipate. And there was a normal manufacturing process for a new product and all the rules to get approval. So, it was complicated.

And also, there was a lot of confusion with the declaration by WHO of the pandemic, Phase 6, the maximum level of pandemic. People got really scared. Perhaps it wasn't clear, that pandemic phase 6 means spread around the world, and not necessarily severity.

SM: I see.

MJM: So people started to panic a little bit at the beginning. And I think WHO was trying to be clear and say, "This is not related to the severity; it's related to the global spread." And still, when you have something that is spreading all over, you don't know what's going to happen.

MJM: And that has been a little bit the story.

It's been challenging, especially working on the international side of this story because communications are always a challenge in different languages, different cultures, different perceptions, different ideas.

And then, the most challenging thing for me, particularly for the work I do, had been to work on the vaccine donation to WHO, the World Health Organization, because that's been really the most difficult part of my particular work within this whole response to H1N1.

Initially, there was a lot of demand. Because we didn't know how severe the disease would be, many countries wanted the vaccine. There's no manufacturing capacity enough in the world to produce vaccine quickly for everyone that needed it, or thought that would need the vaccine at the beginning. So it was a struggle. Because obviously, we do have all these contracts to get vaccine for the American people right away, and it took a while. There were a lot of problems with the manufacturing, with the regulatory issues, so it took time.

At the same time, we have all these countries saying we need vaccine, and WHO saying vaccine needs to be distributed equally to the world, especially the less developed countries. And then for us, it was really hard because we did not have the vaccine for the American people, and at the same time we need to be global citizens and help the less developed countries. And I saw the policy makers, the decision makers here, struggling because our role is to look first for the American people and, at the same time, to know that there is a need out there. So, making the decision of what resources you will send abroad because you understand the need versus how you protect your

own country was really challenging. It was really challenging. It was a tough decision.

Based on policy recommendations from an interagency policy group, President Obama took the leadership and said, "We're going to donate 10% of our vaccine to the developing world through WHO, and we're going to do it through an international organization that can decide who's going to get the vaccine based on public health needs." And it's been very challenging because when we were in the process of doing all that, then we started to have more data about the disease: it was not as severe as we thought it would be. So now, countries don't necessarily want the vaccine, and it's been challenging.

SM: I didn't realize that we only had 30 minutes, and it's actually over, but I--

MJM: We can cancel with Jose, if you wanna keep talking or we can-

SM: Would that be okay? Let me stop this.

MJM: I mean it's been a very challenging issue to work on because as I say, the vaccine was acquired originally for the American people, paid by the American people, by the taxpayers. All of a sudden, when at the beginning we had these lines of people waiting to get the vaccine here, and we were trying to donate part of the vaccine abroad, it was a very awkward situation.

SM: I would like to get a sense of the kinds of mechanisms that were in place early on to coordinate response efforts within the United States, and also with our global partners?

MJM: Outside, other countries? Right.

SM: Yes. Can you tell me a little bit in detail what it was like, and what actually took place in the effort to do so?

MJM: Well, I never worked in flu before this. I was working more on chemical, biological, radiological, and nuclear threats.

But still, from working in ASPR, I knew what the program was, and for me, one of the most amazing things was that when this happened, we did have a stockpile of antivirals ready. And the decision was made right away, and the stockpile was deployed to the states. And immediately we said, "Here." The government was prepared and had the drugs. The plans were in place for distribution, and that happened really quick, and all the information was there.

Immediately, there were a declaration of public health emergency, so all the legal protections were implemented right away. So, as soon as there was enough evidence to say this may become something really serious, the declaration was in place to allow for all the legal protections and all the funding that's needed to respond.

There was a lot of work done previously; there was a national plan for response to pandemic influenza. So obviously, there are always challenges because we were always thinking of the diseases starting somewhere else. We never imagined that it could be first detected in Mexico, and a week later, we have it here. And we will be one of the first countries with the disease. We were always thinking a little bit more on the disease starting

somewhere else, and to contain the disease somewhere else before it would hit the United States. And all of a sudden, we were in a situation in which the disease started almost here, or in our border at least with Mexico, and then Canada. It was an interesting shift, you know, from thinking of containment somewhere else to dealing with the disease right here. But I think that we were prepared.

SM: What were some of the lead agencies that you were in contact early on?

MJM: Right. Well, you know, immediately, we started to have daily meetings even before Dr. Lurie came on board. Admiral Vanderwagen was here.

Obviously, within HHS, HHS has the lead under the National Response Framework (NRF)--Emergency Support Function Number 8--which is public health emergencies. HHS becomes the lead. The Secretary is the lead to respond to those emergencies, and essentially, the secretary delegates to the Assistant Secretary. We didn't have a Secretary at the time, so everything was being decided basically here.

Immediately, ASPR obviously had the coordinating role across the interagency. And within ASPR, the offices-- BARDA, of course, has to make a contribution; the two policy offices, OPSP and OMSPH; OPEO--the Office of Preparedness and Emergency Operations obviously played a key role because they handled the operations center. So, all the response in terms of deployments and all that was coordinated from here.

CDC had a definitely key role. Especially under CDC, you have all the epidemiological surveillance, all the diagnostics, and all the stockpile deployment. They had the stockpile, so the collaboration with ASPR and CDC was important.

FDA was another key player because of all the regulatory issues and emergency use authorizations to use use medical countermeasures, like for example, antivirals in kids younger than one year old.

The Office of General Counselor, because all the legal issues associated were critical, so they were important players. (I'm talking about the meetings here internally in HHS.)

Then ASRT--at the time the Assistant Secretary for, I think, it's Technology and Resources: all the money basically.

Then people from ASPA, the Assistant Secretary for Public Affairs, because all the public communication. That was one of the most critical aspects of all this response. I mean, how do you keep the public informed? How you avoid creating panic? How you give clear messages when you don't have all the science, all the evidence, all the data? So, how do you convey that sense of leadership when you don't have all the information that you had to make some decisions as you go. So, that was critical, and I believe have done a tremendous job here in this country compared to what I've seen in other countries. That's been great.

Let me think. NIH--obviously, they play a critical role--especially when we go into the vaccine development and manufacturing because, obviously, they did all the critical trials for vaccine safety. So they played an amazing role.

And then outside of HHS it was very important to be plugged into the White House structure. They immediately created

these sub-IPC to deal with the response to the pandemic. There were meetings, I believe for a while, daily, and then twice a week where all the agencies will come to the table and deal with everything that had to do with borders, security, communications.

OMB--obviously, it was very important to have them because they have the overall funding for the flu response.

DOD also was very important, was a very important player.

State Department became a player immediately because of the word *pandemic*: This is an international event; USAID, the Agency for International Development, also. And again, from the international perspective, the White House created a sub-IPC on H1N1 International Request and Engagement because, obviously, we started to have requests for assistance very early on, very early on. The first one was from Mexico: We had a request for antivirals. Then we had a request from Chile. Then we started having requests from all over the world for antivirals, basically, and for diagnostics.

Most countries did not have diagnostic capacity so they were asking CDC for diagnostics. And then they were asking for Personal Protective Equipment, PPE, from all over the world. So we at HHS got the antivirals; CDC had the diagnostic kits (also are part of HHS). And the PPE, the main sources were USAID and DOD.

So, we immediately started to work together: HHS; Homeland Security also, because these things were affecting homeland security; DOD; State Department; AID; OMB (um, I'm thinking about who else was at that table at the White House); SHIRE, the name of the sub-IPC was SHIRE; IPC on H1N1 International Response and Engagement. So, we've been meeting bi-weekly at the beginning to figure out how to go through mechanisms of providing assistance to other countries. It was really challenging.

SM: Well, acknowledging that the United States was most concerned about getting vaccine for the American people, what was the next challenge?

MJM: So, this sub-IPC was dealing, as I say, with mostly these issues of assistance in terms of antivirals, diagnostics, and PPE.

When the vaccine came into play, then the White House created another working group called International H1N1 Vaccine Assistance, because vaccine was a little more particular. You know, we did have a supply of antivirals, diagnostics, and PPE already in place, so it was a matter of deciding how much will we share; how much we could share, and how to do it, and determine the principles and criteria to do that. With the vaccine, it was a little more complicated because we didn't know when the vaccine will be here; we didn't know how much we will have; we didn't know how much to buy. Obviously, we didn't know how much to share, we didn't know when. So that was a very hard political decision to make--to the point that, as I say, even the President got involved and made the final executive decision of doing it in terms of 10%.

SM: How did they come up with the figure, 10%?

MJM: A good question. For the antivirals, there was a decision to use--we originally had some amount of antivirals set aside for containment in other countries, for containment operations. So when this happened, and we saw the disease was spread all over, containment didn't

make any sense. So we said, "Well, let's use that 5% that we have allocated for international containment for international assistance." And we thought it was a reasonable number. In the ideal world you'd have time to do modeling and figure out how this will deplete the United States population, what the impact that that 5% will have abroad.

As I say, this was happening very quickly, and at the beginning, we didn't know how many people would die or not. We had to make decisions right away. So pretty much, that 5% in the planning that was allocated for containment then was assigned for international assistance, thinking there was, a number that in some countries could make a difference but it wouldn't affect or put at risk the health security of the United States' people. It was a number perhaps large enough to help some countries, and small enough not to affect people in the United States.

Obviously, it was very complicated to determine the principles under which we would provide assistance, because our number one principle is that in some way, providing assistance has to protect the United States health security. And when we shipped the antivirus to Mexico,

again before knowing what happened with the disease, we say, "If we can help people fight the disease there, we will make sure that we delay more infected people coming to the United States," just to give you an example.

Obviously, the second criteria was to provide humanitarian assistance to countries that have a public health emergency because we started to have a lot of requests from countries that did not have any cases. They just wanted to be prepared. So in that case, when you have very limited resources, what do you say? We'll say now, "Well, if you don't have any cases, sorry, you have to wait. We're going to help the ones that are really having cases." And also, one of our principles was to take into account foreign relationships with other countries, the diplomatic consequences, and the DOD presence in the world in those places. [Phone rings.] I'm sorry, I can stop that.

SM: Do you want--?

MJM: No. In those places where the United States has a relationship or there's a war, there's a military presence; we will have, obviously, some special considerations. Or, there are other countries that are embargo countries. Then

those countries, we don't necessarily help them, depending a little bit on the circumstances.

And the other principle is that we wanted to coordinate to the extent possible with multilateral organizations, because it's totally unrealistic to think that we can help every single country in the world and every single person in the world.

SM: And how did that work, who were the players involved in--?

MJM: Making the decisions?

SM: Right.

MJM: The same interagency players that I mentioned within this SHIRE group, this sub-IPC.

So, we put together the principles, and under each principle, there are a series of criteria; for example, we're going to help this country because it has a public health emergency.

One of the criterion was do they have the logistics in place to distribute antiviral once it gets there? Not to waste it? Because again, we are preventing our people from getting it to give it to a country that's asking for it, but don't have the resources to give it to their people.

Or, we wanted to make sure that the drugs were distributed according more or less with our policies; we initially say, health care providers, at-risk populations. And that it will get there, and it will get into the hands of the politicians, for example--we were taking into account all those things.

We have a decision tree, and this is an interagency decision: HHS, DOD, Homeland Security, State Department, USAID, OMB--there was budget implication, obviously.

SM: Did you attend the meetings?

MJM: Yeah. I did have a leading role in developing the document because I was previously working on the policy and operational framework to share medical countermeasures from our stockpile with other countries. So, when this happened--thanks to that work that we did, that we had in process--

we were sort of able to apply the concepts to that and draft the framework really quick.

SM: Was there resistance early on from other-?

MJM: Yes.

SM: Can you tell me a little bit?

MJM: Yeah, it was really challenging. And I had to say that I've been in meetings with even the White House present in which I was accused not caring enough about the health security of the American people. And, you know, I was quite shocked. I couldn't believe it because I didn't understand what part of the word *pandemic* people didn't understand. I mean, a pandemic, that is across the world by definition.

So, this was not just a domestic problem. And we did have a domestic problem, but you needed to tackle the problem in a much more wider way because people were traveling. When we knew the disease, at the beginning, we didn't know the severity. The disease is contagious for god's sake. People are traveling in and out all the time. So, even if you have vaccine and antivirals for the people here, you still have

people coming in and out from other countries. So you need to figure out what to do with all that.

And there were decisions about closing borders. We made the decision not to do so, but it was a very tough political decision to make because some other countries did it. And that created all sort of diplomatic problems, and trade problems. You close the borders, and all of a sudden, you stop everything: you stop trade, you stop the economy, and then, you may have consequences that are worse than the disease itself, or the social disruption that you create.

So, it was a very complicated problem. And some people that had been all their life working on domestic preparedness that don't have a world vision did not understand that there was a problem beyond our borders.

And that you needed to work with partners; just to make the decision of closing your borders, you need to work with the country that was on the other side of the border. Now, this was truly an international problem. So yeah, there was resistance.

When we donated antivirals to Mexico and the decision was made, I was really accused of not caring about the health

security of the United States because we donated antivirals to Mexico. And I said, "Well, we've been working on the security and prosperity partnership of North America that was an initiative from the previous government. And that continues with this government." We've been working for years with Mexico and Canada talking about secure North America, more prepared North America. We do have something that is called NAPAPI, the North American Plan for Avian and Pandemic Influenza. It was a plan agreed upon by the three countries. And all of a sudden, we had a country right next to us where the disease was spreading and killing people here and there during the first two weeks saying, "Can you please help?" And we're going to say no?

And there are three very important things there. Okay. You need to help a country that is next to you because you don't know the implications that that can have in your country right away. So, that's protecting the health security of the United States. Then, humanitarian assistance--you've been talking for years about collaboration, and when they need it, you're not there to help. And then you know, all the diplomatic implications that could have had to say "No" to Mexico in terms of everything else that we do with them, like, in every

aspect: economic, social, political. So there were tough decisions to make, and some people could not take into account the whole picture. They were only thinking about doses of antivirals, for example. And when we started to deal with the vaccine, it was the exact same issue.

SM: Well then who were allies of the plan? It was a difficult decision, but--

MJM: It was a difficult decision, but I think we worked it out here, obviously, within HHS.

A player that I forgot to mention, and I apologize, is the Office of Global Health Affairs here in HHS. Immediately, my team, the international team in ASPR, and the international influenza unit directed by Dr. Miller in HHA, we team up. We created something that we called the "super team". And we started to work on all the international response and all the international policy. We team up the two teams and we've been working together. That people had the global perspective--international perspective. And they were very good allies here (internally in HHS) to explain to people the global implications of say "yes" or say "no". So internally, that was critical.

Outside of HHS, and when we went to the White House, it was very important to have USAID and the State Department and DOD, the Department of Defense, with all the international engagement that they have because they could provide that other side of the coin. Then we have Homeland Security (and HHS, we really have a more domestic focus). We have these departments with international mission, so we were able to come to consensus on, again, what we can do to help others.

SM: Right.

MJM: So, you have a responsibility as a global citizen because you are affecting the rest of the world. So, you do have a responsibility to do something. And at the same time, again, as the U.S. government, your primary role is to protect the people in your country. So, we were able to come to the table together; say, "Okay, these are the assets. This is what we think we're going to get. These are all the complications about getting the assets for the American people. How much could we realistically give to help internationally without putting our people at risk?" And again, it was a tough decision, but the President and his people were saying, "This is going to happen because we

have a moral obligation to help the world. Find a way to do it.”

SM: Who was the contact person at the White House at the meetings?

MJM: Well, there are a series of persons, the staff level person that we've been working with, Dr. Richard Hatchet. He was the one that led the International H1N1 Vaccine Assistance Working Group. And on the SHIRE, the committee that we worked with on international assistance before we had the vaccine, it was Dr. Ben Pietro. Those were the liaises of the working group. Of course, there were people above them: Heidi Avery and the same, John Brennan from the White House, the Homeland Security Advisor. So those were the high level people. Ben Pietro and Richard Hatchet were the interface at the most working level. But it was challenging.

And it continues to be challenging because as I say, now that we do have the vaccine finally to donate, the disease is not as severe as we thought it would be. So, the demand changed and countries that will get the vaccine now are rethinking if they really want it because obviously, even

if the vaccine is donated, if it's for free, they still need to implement their vaccination campaigns and the deployment strategy, and that costs money. Distributing the vaccine in the country costs a lot of money. So, now that they are seeing that this is not as severe as we anticipated, they're saying, "Well, do I really wanna spend this money knowing this is not that severe? Maybe I buy antivirals for the few people that get sick, or I invest in health care facilities to treat the people that get sick, rather than spend lot of monies implementing a vaccination campaign."

Now, it's very challenging because there is an excess vaccine in Europe. Many countries bought two doses per person before the efficacy was studied. Today, being prepared they bought two doses per person, by the time the result of the studies, one dose proved to be effective. So now they have large excess of vaccine.

Some companies also donated product. At the beginning, we donated. It was a group of more than 13 or 14, by now probably 16 countries that donated vaccine or money or ancillary supplies like syringes and needles--everything that's needed. Now, there's an excess of vaccine that

nobody seems to want. And so, it's very challenging to figure out. You don't want to waste all this vaccine when the disease is still around. Again, it's not severe, but the virus can mutate at any time, and it will be horrible to start disposing vaccine when a lot of people can use it.

We're trying to focus a little bit on the Southern Hemisphere. Now, it's summer down there, but they had the first wave in our summer here--July, August. But now they're in the summer, and their flu season is going to start in March, April. They may have their second wave. So, we're focusing in trying to see if we can assist the Southern Hemisphere, but this is still in the works.

SM: Besides countries reconsidering whether or not they want it, what other kinds of challenges are present?

MJM: One big challenge is--past the decision of donating, the political decision, all the public health decisions--you get into the logistical challenges. As I said, the target countries for WHO were the less developed countries, and as such these countries have no infrastructure to put plans in place. So, the main challenge that has been delaying all these donations has been the lack of

preparedness in these countries. It's taken forever for them to put deployment plans in place. And that's one of the main requirements by WHO. They wanna see a deployment plan to make sure that the vaccine is not wasted: that all this vaccine gets there and there's no way to distribute it. And it's taken forever for these countries to get their plans finalized.

Another main challenge around that is the lack of resources in WHO. They have very few people working on this, and they are totally overwhelmed. There are 95 target countries. I think 86 indicated that they were interested in getting the vaccine. And WHO has a very small of 3, 4 people doing all the logistics. So you can imagine--3, 4, people dealing with almost ninety countries (the less developed countries), which means they have no infrastructure, no organization, no nothing. So, things are very slow. They're dealing with their own bureaucracy. Plus, the bottleneck is in terms of the personnel.

Now, we're working with WHO to try to send them personnel from here, from the United States, to help them deal with all these countries. And it's been very challenging to explain to people here. People here are very frustrated:

"Why this is not going faster?" "Why these countries are not ready?" And for me, coming from a developing country, it's very hard to explain to these people how things work in the rest of the world. We take things for granted here. We get organized. We have structures in place; they don't.

I have a person that works with me that makes a joke that is sad, but a reality: "They have one computer and it's broken" in many of these countries. So, it's a slow process, and WHO doesn't have the resources.

And that has been very challenging because, once we got the vaccine, everything slowed down a little bit because of the demand, and because of the lack of put the mechanisms in place right away.

And then the very logistics, the things that are very tied to the logistics, like, who's paying for the transportation of all this? We at HHS have the product. Who's going to pay for transporting the vaccine? This is very expensive, especially when you start to send to 90 different countries. How you do that? The logistics are enormous.

And then one big barrier that has slowed down the entire process are the legal issues. We have the vaccine licensed in the United States for use in the United States, and we have a declaration of emergency here. So, we have PREP ACT; the vaccine is licensed. There are sort of legal protections around all these things, for all the decisions that we're making: for the U.S. Government, for the companies, for the health care workers. But the vaccine is donated to another country, then we're not protected.

SM: Right.

MJM: If something happened, if there are secondary effects, anyone can come and sue us for giving them a product that has secondary effects, just to put it in a very simple language. It's a little more complicated than that. So it has taken forever for us to develop an agreement with WHO, for WHO to develop an agreement with the companies, and for us to develop an agreement with the companies. So, it's WHO and the companies, the companies and us and WHO, and WHO with the recipient countries. They also have legal agreements--not just for the deployment plans, for the logistics--but for the legal agreements with the recipient

countries and WHO, releasing the donor from the liability, in case there are problems.

SM: Has here been any resolution?

MJM: Yeah, yeah. At least with the companies that we are donating our product from, we do have the agreements in place with the companies. And we do have the agreements in place with WHO. There is one more company that we're thinking of donating some product because we may have additional product we may not use here, we may not end up needing here. And WHO is working with the company to make sure that that product is, the word is called, "pre-qualified." Apart from the product being licensed in the country who's buying it, WHO has an extra step of pre-qualification--they look at the product being licensed by some regulatory authority, but also look at how that product can be deployed to certain countries, the product specifications. It's very complex.

SM: And what about the cost of shipping?

MJM: That's still a challenge. That's still a challenge. USAID offered to pay for the first deployment. The way we

organized our plan was to donate 10% of what we originally thought we would buy. That was 250 million doses. We're going to end up buying a little less because we need less now. But we're still going to give 25 million doses. So we split the vaccine in 5 million doses, 10 million, and 10 million to allow for WHO to work with these countries to take the vaccine. So, AID offered to pay for the first 5 million doses that are going abroad, and now we're trying to figure how to pay for the deployment of the other 20 million doses. It's pretty expensive.

SM: Do you know how other countries are doing it?

MJM: It has taken a while to figure out all the things because again, these are new. Shipping this enormous amount of vaccines in between countries and things like that is not the norm, and especially, in a short time. So yeah, we explore several mechanisms.

Some other countries are doing it through UNOPS--the United Nation's Operative Branch, and they ship. They're working with WHO, and they're in charge in shipping the vaccine. We're considering our options: whether to use private carriers here in the United States--request for proposals,

get bids, and choose the best offer; try to have the company shipping directly to the country that is going to be the recipient, or do it through this UNOPS mechanism. Right now, we're finding that that could be potentially the cheapest one. But we're still exploring what the final mechanism. We're obviously trying to protect the taxpayer money, use the cheapest one.

SM: I know we have like 10 minutes left. Are there any documents that would help researchers in the future understand the series of events?

MJM: I will be more than happy to share the policy documents that we develop and talking points and everything. You need to give me a little bit of time. I have them pretty organized, but I wanna pick some that could be critical: This SHIRE framework that I spoke to you about with the principles and the criterias will be very important for you; the policy papers on vaccine donation and how that was decided here internally first before it went to the White House; how we worked through the options of donating finished product, or releasing manufacturing capacity so someone else could buy it at a lower price; or how we negotiated with UNICEF, this international agency,

to see if they could pull all these countries and buy it from the companies at a lower price, lower than we were paying.

The final decision of donating product took forever because people were trying to explore many options to make the most product available at the lower price to the American taxpayers. So, it took a long time. And I'm more than happy to share these documents with you.

SM: Okay. So I'm going to free you.

MJM: Thank you so much.

SM: Thank you.

END OF INTERVIEW

Broad Themes

- International Partnerships and Initiatives Team
- International Response Policy Coordination

- Science-based policy decision making
- International preparedness
- International collaborations
 - Collaborations with Mexico
 - Early Warning Infectious Disease Surveillance-EWIDS
 - BSL3 Laboratory–Bio Security Level 3 Laboratory
- Mexico-Initial flu cases, expansion of cases
- Global Health Security Initiative
- CDC, Canada-diagnostics of H1N1
- Communications
 - With Mexico
 - With the public
- Uncertainty
- Challenges
 - International vaccine donation
 - Manufacturing capacity
 - Political/public health decisions
 - Logistical challenges of international donations
 - Infrastructure of developing countries
 - Licensure of vaccine
 - shipping

- o Lack of resources in WHO
- Mechanisms in place to coordinate response efforts in U.S., and with global partners
- Lead Agencies
 - o National Response Framework—Emergency Support Function-8: ESF-8
- International H1N1 Vaccine Assistance
- Containment operations
- Principles for vaccine donation
- Decision tree-interagency decision7038349800
- Domestic preparedness and world vision
- NAPAPI—the North American Plan for Avian and Pandemic influenza
- Office of Global Health Affairs—OGHA
- Severity of Disease
 - o Demand and supply
- Southern Hemisphere

Names

- Dr. Selio Buche - Director of INRE, the National Institute of Epidemiological Reference and Diagnostics, Mexico
- ... Director of Epidemiology, Mexico

- Margaret Chan
- Dr. Miller-Director, International Influenza Unit, HHA
- Dr. Richard Hatchet-Head of International H1N1 Vaccine Assistance Working group
- Dr. Ben Pietro-SHIRE
- Heidi Avery
- John Brennan-Homeland Security Advisor, White House

Documents

- SHIRE framework
- Policy papers on vaccine donation