INTERVIEW WITH

Dr. JOSE FERNANDEZ

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Jose Fernandez
Interviewed at Dr. Fernandez's Office
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H1N1 Oral History Project
Interviewed by Sheena Morrison

Dr. Jose Fernandez: JF
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr. Jose Fernandez. It was conducted on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on January 22nd, 2010, in Dr. Fernandez's office in Washington D.C. The interviewer is Sheena Morrison.

So let's begin first with a question about you, and what your position is here at the Office of Medicine, Science, and Public Health.

Jose Fernandez: Okay. My! Thanks to H1N1, my position has changed a bit, not much, not my title or anything else.

Let's put it this way: my official title is senior science adviser.

SM: Okay.

JF: And prior H1N1--so, prior to April of 2009--I had multiple responsibilities. One was to focus on some discrete areas of science and security related to the National Science Advisory Board for Bio-security and some of their reports, and the interagency processes surrounding that. That's one part of what I had as a portfolio.

The other part was the International Health Regulations. Since January of 2007, and even a little bit before that, I became involved with the U.S. Government's process for implementing the International Health Regulations [Phone rings.] I'll leave that ring.

SM: Okay.

JF: You have my time.

SM: Thank you.

JF: Beginning January 2007, the U.S., with 193 other countries, looked at how they were going to implement the World Health Organization's International Health Regulations, a new and revised version of these, essentially, global health security regulations. And so, I went through an implementation process with the U.S. Government and essentially led that process, coordinated that process for the White House. As part of that process, we stood up an International Health Regulations program within the Office of Medicine, Science, and Public Health within HHS/ASPR. And that officially came into being essentially when the initial implementation ended for the U.S.G. and that was July of 2007. And so, I had essentially two roles: One is to focus on some discrete areas of the science of security issues and policy making implementation around that, and then the International Health Regulations program responsibilities.

SM: Okay. And how long have you been in those two positions?

JF: Since I've been in the federal government, I've always been in ASPR, or the Office of Public Health and Emergency Preparedness which predated ASPR--same office, different name. I came as a triple A, as an American Association for the Advancement of Science and Technology fellow in mid-September of 2006. And so, what is that roughly? three plus years now, three and a half years.

SM: It is a little warm.

JF: It is, in here. I could get a fan in here, but it might play havoc with the tape recorder. So, let me know if we need to take a break though.

SM: No, no, I've got it. This is fine. But thank you for being so considerate. So, you started off saying that after H1N1, you took on another role.

JF: I was literally still involved in leading a part of the U.S.G. policy process for the science and security issues right up to the time that the U.S. Government made

its first notification of WHO that we had in fact identified two cases of what would become 2009 H1N1. At the time, it was the swine flu--two separate cases in California, what we consider the two first cases in the U.S. At that point, and a few days after that, it became very apparent that we were not facing just another sort of oddity in public health, and that we were actually looking down the barrel of a real pandemic, potentially.

And that's when the need for international expertise up here in the office of the secretary became very clear. And I had the IRTR expertise, essentially. We had a number of folks engaged in international activities in ASPR--in OMSPH--focusing on various bilateral/multilateral activities. And there wasn't much beyond that within the office of the secretary, except for the Office of Global Health Affairs, and specifically, the International Influenza Unit, which resides within OGHA.

We decided very quickly, and I mean quickly--within days--that we were going to be individually overwhelmed if we did not join forces and become efficient quickly at how we were

going to process the information needs that everyone seemed to have. When I say everyone, I mean senior leadership needed situational awareness about what was going on internationally. They needed people who knew the international public health piece of this, including the IHRs (but not exclusively); people who had contacts; people who could explain the process; essentially, people that could reach out.

In addition, our Operations Center--the Secretary's Operations Center here in the department--needed support because they do not (still do not) have an international expertise. And that works fine when you have a domestic event, which information's flowing through. You're sending out teams to a state to assist in a public health event or some other event. It does not work when you are dealing with an international event. So there were those needs.

And there was an enormous amount of information. It actually wasn't as bad in the early days as it became probably within a week of the beginning of the outbreak, as it were. The volume of information! I'll say this up front,

and we'll likely get to it later, but I want to say it up front: The sheer volume of information that was moving within the federal government was enormous. I've never seen that much information moving that frequently for any event. It was astounding, and it was overwhelming.

There was so much information moving from CDC alone. They stood up multiple task forces, it seemed: they had some public affairs people; the influenza division was moving information; they had other people in CDC moving information. We were trying to provide updates to folks up here, including leadership.

The State Department at some point--not immediately--but at some point reasonably early in the outbreaks, stood up their task force, and they were moving a ton of information as well. So there was a point at which there was enormous amounts of information floating around.

We were doing, one stretch of time within the first wave, what they call sit-reps (situation reports); just HHS, three sit-reps a day. And other departments were also doing

multiple sit-reps because the information was being updated so frequently. New information was always coming in: on the virus, on the case counts, on the mortality, and everything else. The problem is that now, you not only had so much information flowing, but there were multiple versions of it. So if you were reading the 7 AM sit-rep, that was a lot different than the 11 AM sit-rep. Then we had version control problems where, if you report something, someone says, "That's not the information that we had." This other sit-rep says, "Ah, but that was 4 hours ago." And so, it was a sheer volume of information, and it was how rapidly the situation evolved. It was, even joining forces, a serious challenge. And from my perspective, especially early on, it was a serious challenge for everyone involved to simply be able to manage the volume of information.

SM: So when did you first hear? Where were you, when you first realized that this was actually something that was highly transmissible, and what were you doing?

JF: [Laugh.] Here's where the specific dates escape me, but this is in the very beginning here. And this ties

nicely with another interview you've done with Dr. Maria Julia. At the time, Maria Julia was the Project Officer for Capacity Building, a project program in Mexico. And as part of that activity, she'd gone down to do some assessments and meet with folks down there at the ministry of health.

When she came back (and this was several weeks before we even notified), she did a report out with senior staff--at the time, Admiral Vanderwagen and his principle deputy, Dr. Parker, among others. And she said there was something odd. They had had an unusual end of their flu season. Essentially, it was going on a lot longer, but they weren't sure what was going on. And she said it gave her an odd feeling. And so I knew about this.

One night, I got a call from her on my blackberry, and she said, "I just got a call from"--I think the equivalent of their Deputy Secretary in Mexico's Ministry of Health. She said, "I just got a call from Mexico." And she told me, "They have unusual symptoms; it's more severe. They've talked to Canada already, and they've confirmed that Canada hasn't experienced this. And they've talked to CDC, and CDC

says, "We're not experiencing this either with our flu season.'" And my immediate reaction was, "Oh my God, we've actually got a pandemic starting." I mean, no, we didn't have all that information. It was just this eerie feeling that this is the beginning. I mean, we've been planning for this, and we've been talking that this could happen anytime. We've been saying this for years. It was eerie to have that conversation and to realize, "Oh crap, I think this really is the start of it."

And then obviously, as it played out over the coming days and weeks, it turned out that, yeah, in fact, this wasn't just a little blip that was abnormal in Mexico. It's one of the things that, as I said, I've sort of refreshed my memory a little bit looking at some of the old paper work and timelines. But there are some things that are burnt in my head: I know I was standing in my kitchen when I got the phone call from her on my blackberry. It was just bizarre.

SM: So what was the first thing that you had to contend with in your role?

JF: One of my responsibilities was, and continues to be, in terms of the International Health Regulations for HHS specifically, to oversee the process of notifying the WHO whenever there's an event under the regulations we need to report to them. And there's no need for any details, but essentially, the regulations have a little flow chart algorithm. You assess the event at hand and determine whether, in fact, you're required to notify.

The Secretary's Operation Center in our case serves as what they term a National Focal Point: It's that single point of contact on all [undecipherable.] Any messages to the WHO go through--the SOC is the bottom line. So this is part of my role: if there is an event, I look at the traffic that comes in to the SOC, or they send me things, and we determine if it's something that needs to be formally assessed.

Periodically, CDC will proactively assess something to determine whether it's notifiable and send up a finished report. When they do these things, there's actually a method to my madness for this. During the implementation

process in 2007, we actually developed [indistinct] with CDC. We took the information out of the regulation, the flow charts and the accompanying text that went with it, and created a form, a standardized form that the U.S. government always used to formally assess and then notify events. It provides all the information that WHO wants. It provides some free text boxes so we can notify them of some clinical data, test results, and that sort of thing, if appropriate. And to give them more information on it so they can do their own risk assessments.

We've had a lot of conversations with Mexico and Canada. We've done a lot of trilateral work over the years under various fora. I kid you not, April 1st, April Fools Day, I had a phone conversation with the Director General for Epidemiology at the Ministry of Health in Mexico, and his Senior Advisor for International Affairs, Maria Julia in our office. And we were just talking about IHR implementation and some of the challenges and the process the U.S. government went through. And I sent them slides, and so we're both looking at slides in two different countries. And when I got to the slide on our notification

process, it showed a screen shot basically of our reporting form. And he (his name is Hugo,) asked me if they could have a copy of that for them to use. Sure! I sent it to them; they translated it into Spanish--identical form translated into Spanish.

I say this because [laugh] 4 or 5 days after we made our formal notification of the two cases in California of H1N1 in children, Mexico did the same. And we had an ongoing trilateral agreement where, if one of the trilateral partners notifies WHO of what they call Potential Public Health Emergency of International Concern, we simultaneously notify our trilateral partners. So, when we notified, we automatically notified Canada and Mexico as well, and they did the same for us. I was very amused because when we got that, I opened it up and realized the first time they had notified (they've notified the WHO of a few other things), with this one, it was the first time they'd used the form. And they were notifying of what would later become a pandemic. Our meeting--our phone call and exchange of information--was very timely, because they ended up using it three weeks later to notify the impending

pandemic. (You're going to love listening to the tape after this; I tend to go circular.)

SM: No, no, no, you're fine, it's fine.

JF: [Laugh.] So, part of my role is that overseeing.

The U.S. has notified under the IHRs. There are always four notifiable conditions that don't have to go through the algorithm. They don't do the risk assessments. You look at them, if you've got one of these, if it meets the case definition, you notify. And one of them is human influenza caused by a novel sub-type, in other words, something that doesn't normally circulate within humans. And swine origin influenzas happen in the U.S. every year. We've got probably 6, 8, 10 cases of those that are confirmed. They resolve themselves, typically. They're not typically transmitted human to human: usually associated with exposure to swine somehow. But they meet the case definition, therefore we should--we always--notify. And we've notified several cases.

And when we got these cases, these were just two more cases of something that we had notified before--swine origin influenza. Okay. In the context of what we knew about some weird things in Mexico, it was concerning.

And I remember part of the process is that the assistant secretary always sees the notification prior to it going out. This is the final green light essentially to send something out. And I can assure you at that point, we've probably notified a dozen things since mid-July of 2007, and Admiral Vanderwagen had probably commented on one thing in that time. But he'd already heard about some weird things going on in Mexico, and when he saw the notification, he emailed me. We gave him a couple of hours to look at these things, and he emailed me back and said, "You know, those things are damn close to the border. I wonder if this has anything to do with what's happening in Mexico right now." I said "Damn it. Okay." So yeah, we had little bits of information that made everyone uneasy, you know.

So, my role was to get our notification out initially. And then the onslaught after that, my role evolved into IHR expert. I found it somewhat amusing because the IHR is all theoretical up to the point of H1N1 for a lot of people. Yes, we had agreed to them like 193 other countries. Yes, we were supposed to fully implement. Yes, we were supposed to notify. But honestly, almost everyone slept through everything. We did notifications of various events. Nothing that would have been catastrophic necessarily, but they met the criteria. And most people probably didn't care, besides the people who had to push the button at SOC to get it out to WHO, and because the Admiral had to review it before it went out. But for most people, it was nice and it was, you know, "We did IHRs."

All of a sudden, everyone wanted to--in the space of about a day--everyone wanted to know, "What does this mean under IHRs?" The WHO can make recommendations for health measures: "What kind of health measures can they recommend?" All of a sudden, leadership all through the OS was all spun up about IHRs. I had to actually have our colleagues at the Pan American Health Organization (PAHO),

which is the WHO regional office, I had to have them send over a packet of (it's actually very nice, it's a small booklet basically) the regulations. And I had them send over like a dozen of them so I could distribute them, because everyone all of a sudden needed to know about them.

SM: And what were their concerns?

JF: They were concerned about what this meant in terms of what WHO might do. One of the big concerns--within the IHRs, these regulations give the WHO (based a lot on the SARS experience,) a lot of latitude in terms of being able to make recommendations for health measures, whether it's recommendations to a particular country or broad recommendations for the global community as to what kind of health measure countries should implement in regard to a particular public health event. And there was the unknown. It was really the unknown. Folks were very spun up about what WHO might do, and it was primarily because people didn't know anything about the IHRs. They knew the basics, but they hadn't read them, and they didn't really have any reason to.

I think it first started off when we did the notification (and I'd have to look back at the calendar to see what day of the week it was). But within like a day or two, Margaret Chan, the director general of WHO, was actually going to be in the States anyway. I think she was going to be at CDC for something. When she saw this, when she looked at the reports from the U.S. and, at that point, Mexico (yeah, that's right, Mexico had just notified; we'd notified first, Mexico had notified about 4 days after us,) she looked at both of those reports and said that oh, this is a Public Health Emergency of International Concern. So she changed her travel plans a little bit.

She met with the acting. This all happens in a transition time for the government, so we have an acting CDC director; we have an acting secretary; we have a lame duck Assistant Secretary--profoundly bad time to have a pandemic. She'd met with Rich Besser who was at the time the acting CDC Director and then flew up here and asked for a meeting with seniors in the department: That was the secretary's counselors, meaning the incoming administration's two

lawyers who were sort of handling a lot of the transition stuff up here; the Office of Global Health Affairs, and ASPR, the office of the Assistant Secretary for Preparedness and Response. Actually, Admiral Vanderwagen, I think, was on the phone because he was traveling at the time.

I remember sitting in that conference room, and on the other side of the room is Margaret Chan, and she is a very practical person. She was the public health director in Hong Kong during SARS, so she has a pretty good perspective on these events. And she was trying to explain why she was there, what she was doing there, and what this all meant. And people were scrambling making photocopies of the IHRs into everyone's hands so people could, you know, "What does this mean? What does this mean?" No one seemed to actually get it even after the explanation. Poor Margaret. She'd really tried hard to explain. The explanation was simple: "I'm here as a courtesy call. I've made the preliminary decision that this in fact does meet the criteria for a Public Health Emergency of International Concern, the first PHEIC declared under the IHR. I need to convene an

Emergency Committee to make the formal recommendation and therefore my final determination. But this is a courtesy call."

There were concerns about whether this meant that the WHO director general would declare a PHEIC for Canada, for Mexico, and for the U.S. And so then, you could imagine the kinds of implications this had if you single out a country. There's a Public Health Emergency of International Concern for the U.S., and it's like, "Oh God, what does this mean for public perception and for travel and trade and all?" So, there were a lot of concerns about what a formal announcement would make for the WHO. And there was a lot of wrangling at the meeting about, frankly, "We need to consult and we'll let you know if we agree or not with your initial determination." At some point, she stopped trying to explain it because they didn't get that she'd already made the initial determination. She wasn't asking for their opinion.

SM: [Laugh.]

JF: But it was sweet that they were going to give it to her anyway. But there were those concerns. It was palpable in the room. There were a lot of concerns about what does this mean for the U.S? What is this going to do to us? What is WHO going to do? Trying to figure this out on the fly without enough information--always good! But it turns out that Public Health Emergency of International Concern is just that, and that was declared for everyone. But there was at least a few days of serious angst about what the declaration would mean.

SM: So, what kinds of mechanisms were in place to communicate with the international community as well as the lead agencies here in the United States?

JF: Well, thankfully, this doesn't happen in 2006. So, we the global community had a couple of years, along with the WHO, to establish communication systems--essentially the processes, I should say--for National Focal Points for IHR communication. It turns out that the system of National Focal Points--each country has one, they 're supposed to be 24/7/365--was absolutely positively invaluable to the

information sharing that happened--that needed to happen--especially in the first month or two of the event. So we had those in place.

There are a number of streams of communication that are going on: the communication with WHO, both with Geneva, principally with our regional office PAHO. There was a lot of email exchange, a lot of information exchange going on. In fact, we were giving PAHO 2 or 3 updates a day on our case counts, when those had meaning. That was going through the IHR channels.

In addition, because we have a lot of trilateral activities in North America, CDC established a trilateral call. In the beginning, it was at least 3 times week. It seemed like it was every day, actually, for the first few weeks, and then I think it tapered off a little bit. But these were all the relevant players from Canada, Mexico, and the U.S. talking about the latest epi- information: the clinical presentations, the latest case counts and mortality, any trends, messaging, public affairs.

And PAHO was part of that, and WHO was plugged into that. That was key. At least, in the North American context that was key, and frankly globally, because we were sharing with PAHO. PAHO was feeding information to Geneva, and the amount of information sharing that was going on between Canada, Mexico, and the U.S. really made a difference. Not just for North America. It made a big difference for the rest of the world because the rest of the world had to know what was going on in the U.S. because we were (I hate using the term) exporting, essentially, the pandemic.

And so, knowing a lot of what was going on at the epicenter--not just the numbers because those just kept going up like crazy--but any of the virus characteristics, the genetics of the virus, were important: Any changes in the virus--the sensitivities to antivirals, the clinical presentation, and the age groups targeted--all the things that a little later on will become obvious to general public that this was a different virus, that it attacked different age groups, et cetera. All that information was very key, very critical. And it was all being shared trilaterally and then more broadly than that as well.

In addition, this is essentially part of an investment. Each global partner had invested essentially in at least doing something with IHRs, at least setting up the communications process at the national level. The six regional offices of WHO had invested in standing up an IHR contact point, which was the WHO regional office equivalent of the National Focal Point, and having these communication processes within WHO to share information. We had invested a lot in sharing communication systems within the U.S. government--processes, not actual hardware--to share information.

In addition, we had been involved in the Global Health Security Initiative, the G7 + Mexico's health ministers, since Tommy Thompson had the idea back in 2001/2002 (if my memory serves me right. You should fact check that one.) But so you know, this is something that Admiral Vanderwagen had been a part of, developed relationships with these people over a fairly long period of time. These are the same players that were, quite a number of years, sharing

information. They had developed close relationships and a lot of trust, which was the key.

So very early on, the Admiral was talking to his counterparts in France and Germany, et cetera, his GHSI senior official colleagues, the people at his level. They were sharing information that they would never have shared normally outside of their own country or outside of the European context, for the most part. So that was another mechanism for sharing information and getting a feel for what was going on in the EU, for example, very quickly--and Japan, because Japan is another member.

So, it was an opportunity to also share information about what was happening here in a different context. There were a number of investments, multilateral investments I guess, that paid off when we needed them so that we could share information internationally and get information internationally, fairly rapidly. And that was a big deal.

And it turns out, as it progressed, we were receiving (and this is in the first couple of months, when people even

thought about this,) direct communications to our Secretary's Operation Center from other National Focal Points in other countries, offering contact tracing information saying that one of our citizens was on a Swiss Air flight: "We noticed from the manifest that you had three U.S. citizens on the same flight near the index patient. Would you be interested in having the contact racing information so that you can follow up with your own citizens?" We had a number of those kinds of contacts at the National Focal Points, which means that (and that's the idea of the IHR and the National Focal Points,) you're not just supposed to be contacting WHO, you're supposed to contact each other directly. And the system worked.

I have to say that for all of the bad press that the initial response got, it was just darned impressive from my perspective. You're always going to have some level of chaos. It's going to be organized chaos, but it's still going to be chaos. I think it worked out really well given what we had to deal with especially.

SM: The fact that the entire government was in transition at the time, what kind of an impact did that have on actually moving forward?

JF: So, yeah, it was a little awkward because the Acting Secretary was a holdover from the previous administration. And let's just say that no one wanted to put him on stage in front of cameras because he was one of the previous administration's guys, not one of ours. That's just the political reality of it.

Did that affect the way that the response played out in the early days? No, surprisingly enough. It changed the players who were up in front of the cameras. We had Rich Besser, the acting CDC director up there. Now Rich went on to work for ABC. He is tall, he has great hair for TV and all, but had we had a secretary, that secretary would have been up there. And Rich would have been beside he or she.

That was not the case. DHS had a Secretary, and Janet Napolitano was up there with Rich Besser, and we didn't have a Secretary. So the Department as a whole--it was a

little embarrassing, but the decisions were made--I don't think that that actually hindered the decisions because we still had the key players in place.

The incoming administration was hanging on to Admiral Vanderwagen for an indeterminate amount of time because I think they realized the importance of the position before H1N1. They realized the importance of the position. They didn't wanna change horses midstream, as it were. What the reality was, who knows, but I think that was important.

The Admiral was an operations oriented guy, boots on the ground kind of guy, and so this was in his wheel house. It was good to have him on board. Had we not had an assistant secretary, or had we had a brand spanking new political who wasn't familiar with response ops, I'm not sure how well it would've played out. Might have, but it seemed to work well. The new administration's counselors to the secretary essentially had a lot of authority.

SM: Who were they?

JF: John Moynihan, who is now acting as the Interim Director of the Office of Global Health Affairs, and Dora Hughes--she's still functioning as a counselor. They have various portfolios. But they were it, in terms of Secretary. They were the authority right now. They were representing the administration's interest, and they were sitting right there. And so, they were people who were authorized to make the decisions in the room, and the right person was at the helm. So, it went well. I think the after-action reports would probably show that we could have done better, always does. But I don't think the transition made a functional difference, at least a significant one.

SM: Who was the lead agency then? I mean, because ASPR didn't have a Secretary at the time, right?

JF: Right. So, ASPR had an assistant secretary. Admiral Vanderwagen just happened to be (if I can use this term with him), God love him, but lame duck. He was a holdover from the previous administration, but the Admiral was the Assistant Secretary for Preparedness and Response.

The issue having Charlie (and his last name escapes me) who was the Acting Secretary, that was nearly immaterial. Charlie was brought in for meetings he had to be at, but in terms of the amount of power that he had, it was almost a courtesy to have Charlie in the room. He would sign on the dotted line when he had to sign on the dotted line. I don't mean to be disrespectful of Charlie or the politicals or others that were in the room at the time, but my perspective is that they would wheel Charlie in when they needed him and wheel Charlie out when they didn't need him. He wasn't making the decisions. That was up to the new administration's people, Admiral Vanderwagen, and the civil service staff, essentially. We had the people that could make the decisions, basically, and the acting secretary wasn't one of them.

SM: So then what agencies--?

JF: CDC had the lead. There was no doubt about that. And that was made very clear that CDC had the lead early on in this response. This was clearly a public health response: This was about the surveillance of virology. They were the

lead agency on this. That was communicated very clearly. Not by them, but by us. And this is a big deal politically, because the previous administration had some reasonable level of mistrust of--what Lavinder referred to as the OPDIVS, the operating divisions--the agencies within HHS: CDC, FDA, and NIH. And so, there was not a complete level of trust up here in terms of CDC. They always had to know what CDC was doing, needed to have situational awareness, couldn't let them go too far, blah, blah, blah, whatever.

It was a significant deal that CDC was identified as the lead agency. And I think as a result (this is getting beyond what you're looking for potentially), H1N1 had a significant impact on how the new administration and how new leadership here approached the CDC, especially, because they had all of the expertise. We might be able to do response ops up here, but they had the expertise for everything that was going on with this from the public health aspect. And they were given a lot of autonomy over running with this, which was a good thing because they were the experts.

I think that in the end, folks saw the value of letting the OPDIVS, at least the CDC, do their thing and not interfere. And it has paid off for CDC. CDC was the lead, and we had a coordinating role. The SOC, as the Secretary's Operations Center, convenes the Emergency Support Function 8, the ESF-8 calls--these public health and medical interagency calls. We had the convening and coordinating role, but CDC was the doer.

SM: Okay. And did you meet daily with the CDC? What kind of communication was in place?

JF: In addition to ESF-8 calls which happened--if I look back, I'd probably be frightened if I had to--they probably had them multiple times a day. But in addition to multiple calls with CDC on the line, there were a lot of meetings happening on a number of levels every day. There were large interagency calls; there was a variety of people on them. There were senior leadership calls; CDC was always on those calls. Any ad hoc decision making calls, CDC was always on those calls.

So, in terms of the connection that ASPR was having with CDC daily--three, four, five times a day--lots of information coming in, lots of decisions being made, and a need to have someone who could explain what the information meant, because information without an explanation is just information to people. What does it mean that we've suddenly doubled our case counts? Does that mean it's getting worse? Does that mean we're getting better at detecting it? So, one of the big roles of the CDC was to actually be able, not only to provide the information, to interpret the information in a way that leadership could understand; a thing that it took them a little while to get good at, but that was very important because the volume of information overwhelms anyone, especially someone in a senior leadership position.

And we got to see it. MJ and I were sitting in a lot of these meetings, Maria Julia and I, and we got to see just the sheer volume of information. I said, "Well, what does this mean?" And CDC trying to explain--sometimes successfully, sometimes not--what the data actually meant, and what implications it had. But yeah.

So, from a personal perspective, since we did the implementations of two years--nearly two years at the time of H1N1--I've had a lot of contact with CDC (not with the influenza division). But I can assure you that now, I'm very familiar with them and they're very familiar with me, and we had lots of conversations. I'd say probably at all levels: both at the senior leadership level as well as the more working level. There was daily contact and probably three, four, times a day easily on that. And then there was international calls as well, which we were all on together.

SM: Okay. So, the first few months of the event (we'll call it an event), there was a lot of communication with the international community. At what point did it solely become the U.S. focusing on its epi-, and [knock on the door] at which point did it just become each country focusing on their own epidemiology?

JF: I can't speak for other countries, but for us (and I could probably speak for most countries), it never devolved into... Even in the first few months--three months later,

four months later--there were still reporting requirements for the WHO. There was still a value in information sharing, even when WHO recommended that countries stop testing every suspected case. And so, when case counts essentially became meaningless, there were still a lot of information sharing going on.

And even now, I mean now that we have Haiti, no one's actually thinking about H1N1. But we are still reporting on a few qualitative indicators and our current status on flu and a whole variety of data points to PAHO every week. So are all 34 other countries, theoretically at least, in the region. And PAHO is publishing that information.

We never stopped reporting. You know, some countries don't have the capacity. They report some weeks and not others. They may not report at all. Speaking specifically for the U.S., we never stopped reporting information.

The amount of, the type of information we are asked to report, the frequency with which we were asked to report it changed as the event evolved. But this always had both

domestic and international aspects. The hard part for us at times was making sure that the international piece didn't get lost in the domestic piece.

ASPR is primarily a domestically focused staff division within HHS. Our operations people are essentially exclusively domestically focused, and so we certainly had those discussions where people were getting cranky at times in meetings about why the hell are we dealing with the international stuff? And it continued to come up even when we started talking about vaccine donations and donations of antivirals. I think that's where we probably reached a head, but we continued to support the international aspects of this, and even to this day.

SM: And right now, with the U.S. commitment to donate vaccine for the international community, do you have a role in that?

JF: Thankfully Dr. [indistinct] gets to have that pleasure. She's essentially one of ASPR's leads in this. She is the brain child of the concept and the process that

has been laid out. I don't have to deal with that, and I'm very thankful for that.

SM: Okay. Also could I get a copy of the IHR regulations?

JF: You bet.

SM: Okay. Let's see. Well, we have 10 minutes. Are you good or would you like to reschedule?

JF: I have a 4.30 call that I need to be on, so we can go for a while yet if you'd like.

SM: Let's see. What were some of the underlying assumptions that guided the decision making process in the spring, like, how to proceed?

JF: One of our planning assumptions was that this would happen someplace else. I bet you've heard that in every interview you've done, and it's true. You will also hear a lot of people say, "That didn't make a difference." That's not entirely true. Actually, it's not true. We did

anticipate that this would happen somewhere else, maybe Southeast Asia. It didn't; it happened in Mexico. It happened here quickly, and we were stuck with something happening in North America. So, planning especially, number 1, went out the window: it's not going to happen someplace else. It's going to happen in our own backyard.

There was quite a bit of angst (I think that's a good descriptor for it actually) over what the meaning of the stages was. Since these kinds of things were predicated on it happening someplace else and moving towards the U.S., these took up a little bit of time to have these discussions.

So, did it have an impact on the overall discussions? Yeah. Not sure that it actually negatively affected our response. But that caught people off guard, though I'm not sure that it should have. The response dealt with the reality, which is, it's here. It's here now, and it's leaving and going other places.

Luckily, we'd had a lot of discussions (and some of these predate my time in ASPR) about--what are we going to do about screening incoming travelers? What are we going to do about exit screening? We had a lot of these discussions already so that regardless of where it started (and we had to deal with the reality), we already had a lot of those key discussions. So, we knew that there was not a lot of value in doing exit screening. It was an enormous burden, resource wise, for not a lot of-- You don't get a lot of bang for your buck, let's put it that way, for something like influenza.

And so, based on the kinds of discussions we'd already had, the kinds of decisions we'd already made, if we could look at an unusual situation starting here, the decisions could be made as to, what do we wanna do? Okay, we're not going to do exit screening. What do we need to do? Okay, we need to ramp up our surveillance. What do we need to think about? Hmm, we also need to think about what's in the Strategic National Stockpile. So does that get at what you're looking for?

SM: Yes. So, well (and this is related also), whose increase in its influenza pandemic alert level changed your planning?

JF: By the time they actually got to Phase 6, it was such a moot point that it was funny. So, as they increased the phases, I think it created more angst probably in the general public than it did in folks here. But then they waited around to go to Phase 6, and it's like, [whispering] "I think we're in a pandemic now." [Louder] "I think we've made it there", and delay, delay, delay because at some point, they got cautious. You don't wanna say. You don't wanna push the button, although Margaret Chan was happy to push the button very early to declare a PHEIC, which was a good thing. But then, the phase declaration thing, that was a comedy. It didn't do a lot for us.

I think it probably did, more the fact that we had to deal with the messaging surrounding that. And Public Affairs had a big role in this from the beginning, both up here in the department and down at CDC as well in how to craft messages: How to get our messages aligned so that we're all

saying the same thing across the federal family as well. So that when DHS puts something out, it's actually the same thing that we're saying and that CDC is saying. That probably affected the messaging more than anything else.

SM: Has there ever been any other event that has brought the agencies together in such an intimate way? For me, sitting in the meetings, everyone is there, and a consensus is reached for every phase, every action. So, I'm just curious.

JF: Though I wasn't involved in it, Katrina, probably, is another example of something that got a lot of people together. I mean, that involved a number of departments and agencies' response at the federal level. Surprisingly, the federal government can actually do a pretty decent job of getting the right people around the table when it has to. Because of the magnitude of this event, this is, in my experience, singular. This is a unique event. Haiti, for example, is a major catastrophe, and we have [indistinct] throughout the federal government, dozens of departments and agencies on the phone or on email traffic.

But it still doesn't reach the--even though the magnitude is large, and it's what we do with responses to natural disasters. The magnitude is large, but the focus is discrete: It's there; it's New York; it's Haiti; it's some place. Pandemics are unique, or any large communicable disease outbreaks. They're unique because they spread. So, your focus isn't one place where it's a contained thing. There's no containment with a pandemic. I think that made it very different.

Pandemics go in waves, and what we see with wave 1 may be radically different than what we see with wave 2. And the uncertainty involved kept everyone working very closely together: lots of concerns about how this would affect our own domestic security. Whether, if we had a severe second wave that could seriously impact critical infrastructure, what that would do to the first responder community; if our services would be overwhelmed for public health and medical. [Both laugh.] It's a little different, but it's true.

I think that the take home message (and you've had a chance to see this,) for this decision making process has been, you get the right people on the table. When there's not an emergency, people in the interagency discussions can go on and on. And they can take forever to get anything cleared through anyone. But I saw the same thing that you've had a chance to see, which is people get the urgency, and they can make the decisions when they have to. And even if they don't have all of the data in front of them, they have to make a decision, and they have to make a decision with the best available data and adjust later. And that's what I've seen, by and large, from these meetings.

SM: Okay. This is really interesting. Well what are some of the international issues you're dealing with right now related to influenza, H1N1 influenza?

JF: I think that the primary one--now that the cases are essentially decreasing, and we don't know if we're going to get another wave or not, but assuming that we don't get another wave and then it's not a severe change in the virus

or something--the principle issue has been this long process of donating vaccine.

It all surrounds vaccine, actually. There was the production of vaccine: The U.S. had contracted with 5 companies, I think, to produce vaccine, and these are the same companies that produce our seasonal influenza vaccine as well. A couple of other countries had locked in contracts for vaccine. That didn't leave anything for the rest of the world, especially the developing world. And the back and forth about whether we should donate vaccine or not has been confusing to me. I don't understand why there was ever a question. But the amount of time it's taken is a disaster, really, from my diplomatic point of view. Not only do we lock in all the damn vaccine, but then we spent months going back and forth about whether we should, and how we would do it.

And then, additionally, lots of time with WHO trying to figure out how we would do it. Turns out, the *how* is very difficult, honestly. It's not just bureaucratically.

There's a lot of issues. That's the principle thing that we are dealing with now.

Yeah, we're still reporting out on all of our influenza information for the domestic piece. But by and large, all of our issues are right around medical countermeasure sharing, specifically with the vaccine. And how, at this late date, will we now get it out to the WHO and get it to countries when this thing is transitioning to a seasonal strain? Wow. I'm happy to report that that's, at least from where I sit, our principle issue right now, barring any changes in the virus.

SM: Okay. Well then. So you responded to my email saying some of us are having flashbacks to April 2009. Can you tell me a little bit more about that?

JF: [Laugh.] I have to say there is something else. We seemed to have learned a little bit from H1N1 in the early days, at least. As I mentioned, this International Coordination Team that was stood up was a combination of the OGHA influenza unit and the international group within

ASPR. And so it took us a while. We quickly realized that we had to do that kind of thing for our own sanity and for efficiency's sake.

But as soon as the earthquake happened, we quickly realized that we were going to be doing this all over again. There were going to be more ESF-8 calls. We were going to have reports out just like last time, and it seemed eerily familiar. Except this time, we had already gone through this before, and so we knew the processes. We knew we were going to have to do report outs. We knew there were going to be situation reports coming out of the Operation Center here. We knew that we would have to contribute to those.

It turns out that Haiti has not been nearly the complete spun up huge beast that H1N1 was, thankfully. But yeah, we're going back to ESF-8 calls, and the latest on the ground, and what's the international aspect of this, and how do we connect with PAHO? Eerily in some ways, there are similarities, at least in the needs.

And just like with H1N1, the response people don't have international expertise. And once again, it's an international response, or response to an international event. And we policy shop, need to step in and support the response operations folks. But now, we are much more, I think by and large, much more comfortable. We really understand our role a lot better, and it's proceeded much more smoothly.

I was kidding people in the office last week that by the fifth or sixth event, we are going to have this down cold. What I really would like for the record here, for the archive is can we please not have events overlapping? But yeah, especially with the events happening reasonably close together, we did learn a lot. So, it's a flashback, but it's a useful flashback, I guess.

SM: Well, perhaps something else will come out of this in terms of having more international--

JF: I can guarantee that. Something that's been worked on for a while now is an international emergency response

framework for the U.S.G. And in conversations with leadership, that is something that is going to happen. It's absolutely necessary. If we didn't learn from H1N1, it's going to be reinforced with the Haiti response. We need a very clear, well-articulated framework for responding to international events. I think after this one, we might actually get there.

SM: We really are a global community.

JF: Yeah. You know, when we keep saying things like, "We're a global community" and "Diseases do not respect borders", that all sounded really interesting and kinda cute--until H1N1. And then people started realizing it was really true.

SM: Right. Thank you.

JF: Thank you.

Broad Themes

- Responsibilities: International Health Regulations and Science of security and policy making implementation
- First two cases
- Volume of information moving within federal government
- Situational reports
- Disease outbreak in Mexico – call from Deputy Secretary of Mexico's Ministry of Health to Marinissen
- Secretary's Operations Center – SOC
    - National Focal Point
- International Health Regulations
    - Notification requirements
        - Four notifiable conditions
    - Risk assessments
    - Public Health Emergency of International Concern-PHEIC
- Pan American Health Organization-PAHO, WHO regional office
- Transition of government
- Concern about formal PHEIC announcement
- Communications systems
    - National focal points
    - IHR channels
    - Trilateral calls – Canada, Mexico, U.S.

    - IHR contact point
        - WHO regional office
- Global Health Security Initiative – G7 + Mexico Health Ministers
- Contact tracing
- CDC as lead responder versus operating divisions within HHS – OPDIVS
- Communications
    - Emergency Support Function 8 calls – ESF-8 calls
    - Large interagency calls
- Continued reporting – impact on
    - Case counts
    - Haiti
    - National capacity
- International donations by U.S.
- Underlying assumptions of decision making process
    - Geography of outbreak
    - Border screening
- Strategic National Stockpile
- Messaging
- Uniqueness of pandemics
- Medical countermeasures sharing – vaccine

- International coordination team – combination of OGHA international influenza unit and the international group within ASPR.
- International emergency response framework for U.S.G.

Names

- Dr. Maria Julia Marinissen – project officer for capacity building program in Mexico and Senior Advisor for International Affairs, in Ministry of Health, Mexico.
- Margaret Chan, Director General, WHO
- John Monahan, HHS Counselor
- Dora Hughes, HHS Counselor
- Rich Besser, Acting CDC Director
- Craig Vanderwagen, ASPR

Documents

None