INTERVIEW WITH

DR. CLARE HELMINIAK

H1N1 ORAL HISTORY PROJECT

Interviewed By Sheena Morrison

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Interview with Dr. Clare Helminiak
Interviewed at Dr. Helminiak's Office
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Interviewed by Sheena Morrison

Dr. Clare Helminiak: CH
Sheena Morrison: SM

Sheena Morrison: The following interview was conducted with Dr. Clare Helminiak, Deputy Director for Medical Surge in the Office of Preparedness and Emergency Operations. It is being conducted on behalf of the National Library of Medicine for the Making History: H1N1 Oral History Project. It took place on July 9, 2010, at Dr. Helminiak's office in Washington, D.C., and the interviewer is Sheena Morrison.

May I call you Clare?

Clare Helminiak: Mm-hmm.

SM: Okay.

Let's begin with some biographical information first. How long have you been in your current role as Deputy Director?

CH: Since January of 2009.

SM: And can you explain to me your role in the federal government's planning and response efforts to the 2009 outbreak?

CH: My day job is Deputy Director for Medical Surge, so I have three programs: the National Disaster Medical System; the Hospital Prepared Grant Program, which includes [unclear]; and the Emergency Care Coordination Center. So I have the whole medical surge piece of ASPR/OPEO.

And then, in late June of last year, Dr. Lurie asked me to head up a task force for ASPR, and the charge for the task force was to help integrate all of the activities going on throughout the various federal agencies within HHS, and to coordinate and integrate activities. So, from June until Christmas of '09, I was in charge of the task force, and then from Christmas to current, I'm in charge of writing the retrospective, which is the after-action report on HHS's H1N1 response.

SM: Okay. So, can you tell me at what point you actually became involved? I know you just explained to me what your role was, but at what point did you become involved actively?

CH: It would have been the end of June of last year. We set up the task according to the national framework document for H1N1, the response, which was written by the National Security staff at the White House. And we identified staff to task each of the pillars for the response and coordinated all of our activities in that manner.

SM: And this document that was written at the State Department was it--?

CH: The White House.

SM: The White House. Was that something that everyone contributed to, or was that something that specifically came out of the White House?

CH: It was written by the National Security staff at the White House and given to the interagency as the directed

document about how the government was going to respond to H1N1.

SM: Is that unusual for that entity to take on something that seems more technical than scientific?

CH: No, it's not at all unprecedented for them to write a document. I did not participate in writing that. Others may have from HHS and other departments, but I was not involved. So, by the time the document came to ASPR, it was already a done deal.

SM: Okay. Can you recall when you first became aware of the possibility that efforts to protect the public would command the kind of resources that it has?

CH: It was in the early spring, because right when the outbreak started in April, OPEO became engaged in the national response, so I was already involved on the OPEO level. And we knew that, depending on the virulence of the virus and the mortality rate and the extent of the spread of the disease, that it might take a lot of resources.

SM: In what way were you first involved? Was there an email, and someone said, "Okay, we need you right now, right here at this moment?" Or, was there a predetermined process that was followed?

CH: Right. It's the OPEO response process. So whenever something happens, whether it's a disease or an earthquake or a terrorist attack, the SOC stands up meetings directed by Dr. Yeskey, and he convenes calls with the entire interagency: What's the problem? What's the response? And since this was public health and medical under ESF8, ASPR had the lead. So, from April on, we were heavily engaged in H1N1 activities right from the start.

SM: What were some of your immediate concerns in your role?

CH: Emergency-room overcrowding; stress on hospitals and ambulatory-care facilities; how to allow the HPP grant money to be used, because the HPP grant is for a certain amount of activity defined in legislative language, and we needed to decide if states and locals could use that money for other things related to H1N1; and then, we needed to know about deployment. Would MBMS have to be activated and

deployed to help hospitals or emergency rooms or state and locals?

SM: Can you tell me about some of the actions taken to secure effective communication amongst all the stakeholders? And, for you, that would be the state and locals as well as the sister agencies, right?

CH: Right. There were several processes: Under the task force, we have those 12:30 chief-of-staff meetings, so the communications and messaging was coordinated there for all of HHS. And then, in separate meetings, the communications about the grant money had to be coordinated with HPP and CDC, because we have a grant and they have a grant; they have several grants. And also, DHS-FEMA has grants. So, independent of that 12:30 chief-of-staff meeting, we coordinated the messaging about how federal grant money could be used. So that was kind of a separate effort, and we had to make sure that the guidances went out at the same time and they said essentially the same thing.

SM: In terms of preparing the states?

CH: Mm-hmm.

SM: Were there any other systems in place to help anticipate and respond to the needs of local states and other stakeholders during the response efforts?

CH: Well, there were already established communication mechanisms, like CDC talks to their grantor [unclear]; HPP has regular calls with their grants at the state and local level. CMS had regular calls with their constituents. So, it was more a matter of continuing the regular communication mechanisms and then bringing it up to that senior leadership level at the 12:30 meeting so we were sure that the senior leaders, whatever they were saying, everybody else was saying. So, everything kind of streamlined down from that 12:30 meeting to everybody else, all the other programs.

SM: Were you able to anticipate any of their needs, how you would respond based on things that were already in place?

CH: Well, our grant program, all of the grant programs, whether they're at FEMA or ASPR or CDC, they know their constituencies. So they know what their capabilities are

because we measure those regularly. So they had a pretty good idea of which state and municipalities could handle the response and which ones were going to have trouble. So we had a pretty good idea about that.

The Emergency Care Coordination Center kept in good contact with the American College of Emergency Physicians, so we had a pretty good idea of what was going on in emergency rooms, along with the CDC data.

And then, we tried to work with the NIH research network that works with ICU doctors, so we knew what was going on in the intensive-care units. We tried to anticipate who was having trouble at any given time.

SM: Were there any signs of trouble early on?

CH: Well, emergency-room overcrowding. But in the United States, there's no surveillance system that tells the status of the American healthcare system because 90 percent of healthcare is in the private sector. So, you don't know because you don't have the data. CDC gets some data, ASPR gets some data, but there's no one system that says, "How are all American hospitals doing today?" because hospitals

don't share that data. It's proprietary data. So there is no canary in the coal mine to know that the country is getting in trouble with healthcare. That's one of the big challenges with any response, but it really showed up in H1N1.

SM: And how did you deal with that uncertainty? I mean, I was there in some of the meetings, so I know in real time, but how did you deal with it?

CH: You just try to give the senior leadership the best sense of what's happening based on what all of these different people throughout HHS know. And they're the senior leaders. They have to know that there isn't always data upon which to make a decision, and they have to go with the best decision that they can make. And then, a week later, if you get some additional information or additional data, they can always change their decision or re-message it or refocus it. But it's very difficult because there were things we found out along the way that you didn't know last week, and that was very, very challenging.

SM: Were there any things that kept you up at night?

CH: Oh, yeah, lots of things: worrying about what was the status of the hospital systems; the death rate in the OB patients and in children was very high; and getting the vaccine out there on time, which wasn't quite what we would have wanted. That was a huge issue.

SM: Well, if you had direct communication--I'm not sure if this was the case--but how did the states respond to the fact that the vaccine supply was not available when the manufacturers predicted it would be? What was their response?

CH: Well, they were very upset because they couldn't plan. Because they didn't trust the projections, they couldn't commit money and staff to being somewhere next week to do a vaccination clinic because they were never sure the vaccine was going to be there, because the vaccine ran behind schedule. So it made their planning very, very difficult, and they complained about that.

SM: Did it have an effect on the pre-established relationship between the agencies--CDC and ASPR in particular--and the state health officers?

CH: Well, I think overall the relationship is pretty good, but, obviously, they were upset throughout the entire process, and I think a lesson learned is that we overpromised and then couldn't deliver for a variety of reasons, and next time we're not going to do that.

SM: What was done to appease or mitigate their discontent?

CH: Along the way, CDC made some adjustments in the way they were bringing in the orders for vaccine from the states and delivering the supplies, and that moved everything along a little better, so that helped. They made some minor adjustments to the distribution of vaccine, and that helped. But there really wasn't a lot we could do.

SM: Right.

CH: We were pretty far down the road at that point.

SM: But you knew it was coming.

CH: Yup.

SM: So, what kind of assistance did local, states, tribal, and territorial communities need from the federal government during the different phases of the campaign?

CH: Well, they needed all the guidances that CDC wrote about who gets antivirals, who gets vaccine, the vaccine priority groups, and all the technical and scientific information. And I think we got that out on the website pretty expeditiously. All the UA information was out there pretty quickly.

Sometimes they needed extra staff, so we did deploy MBMS(?) to go out and vaccinate people if states needed staff. A lot of times they just needed money because the states are in an economic downturn and they just needed that grant money out there so they could pay their nurses and people to vaccinate.

SM: And what was that process like? You spoke about it earlier. How about getting the funding, handling the grants? What was it like eventually? How did they eventually receive their funds?

CH: They did, but this was a non-Stafford Act event, so our normal process for moving money really quickly in an event wasn't there. We had to move money through slower channels, through IAAs with other departments, which took forever to get signed. And then we had to move money through these grant processes. And no matter how quickly we did that, that's still a pretty slow process. It's not like the Stafford Act where you just turn on the money and you can dispense it. So that took a lot of paperwork, a lot of people's time and effort. It's a pretty slow process in an emergency.

SM: Was this something that you were able to anticipate? I mean, did this ever come up in terms of, well, medical surge?

CH: In terms of moving money?

SM: Mm-hmm.

CH: Well, people had talked about it in prior years: what would we do if we had an event with no Stafford Act money? But nobody had really moved forward on that planning, so

that was a problem. We sort of invented it as we went along.

SM: That seems to be the case with a lot of things. It was totally a new process.

CH: It was.

SM: So, what were some of the differences in the policies and actions taken by you and your staff between the spring and the fall, as you responded to the first wave and prepared for the second?

CH: Our staff and my programs, we didn't really change policy. The best that we did was continue communications and make sure that we had given all the assistance to state and locals that they needed. We did work a lot with CMS on that 1135 waiver process, making sure that materials were out there. We had stakeholder meetings to explain that to people if they needed to use the process. I don't think we really were involved in any major policy changes at the late part of the summer.

SM: How about technical?

CH: We already have technical assistance staff that works with state and locals, so I don't think they did anything different than their... They already had an increased level of communication, so we just kept that up, getting ready for the second wave.

SM: Well, in terms of states and locals being prepared, how were you able to determine? Was there sort of a checklist that would help to ensure that, okay, this state is prepared and you don't have to give them as much assistance, or this one is somewhat ill-prepared and we need to focus our attention on them?

CH: No. We pretty much had to trust CDC because they really are the conduit to the state public health departments. You know, we conduit to the hospitals, really, from the hospital preparedness programs. So they communicated with the state. And, of course, we were on all those calls, so they pretty much left it up to the state public health director to say what they needed. I mean, we sent out, like, the regional emergency coordinators and we worked with the regional health administrators to go talk to the states to try to see if they needed anything. But

that's really a CDC process, so we kind of let them do their own thing, and then they just reported back to everybody at the chief-of-staff meetings.

SM: Okay. Well, you've been involved in responding to other manmade and natural disasters prior to this pandemic, right?

CH: Mm-hmm.

SM: Do you think there's been much difference in the degree of senior-level and White House involvement in the response efforts when compared to the government strategy to deal with other disasters?

CH: I was actually quite surprised at how much involvement there was on the part of senior leadership. I thought that was unusual. And maybe it's just that we had a new team of political appointees, and I thought they were much more involved in the nitty-gritty details than in the past at that level, so that was sort of interesting.

But this, again, was sort of a unique response because it was a public health event. It wasn't an earthquake or a

hurricane, which is a little bit different. It's more time-constrained: it sort of happens and you plan and you deal with it, and it's over. This went for many months, so they were very involved at a lot of levels. So, in past events, I think it would have been run more at the deputy's level rather than at the assistant-secretary-and-above level. It's just a different leadership style.

SM: Well, what kind of impact--and you touched on it a little bit--but what kind of impact did the fact that many federal agencies were moving from transitional leadership in the spring to its current leadership by the fall have on your efforts to prepare and respond to the needs of locals and states?

CH: Well, there are a lot of people that say that although the money and time and energy spent on H5N1 was totally wasted because we did things differently for H1N1, that's really not true, because the relationships and the experience gained and the documents created during H5N1 the last three to four years was really, really, really beneficial for H1N1. And I think unless you had been involved in the H5N1 process, you don't see how important that foundational work really was because it was all done.

And we just pulled it in and said, "This works, this doesn't work. Let's do this, let's do that. We already thought about that."

And, more importantly, there was a whole group of people at the interagency level who had done flu for years, and they were up to speed. Whether they worked at DOD or the Department of Transportation or FEMA, they knew a little bit about flu, so we really, really started from a better place.

So, I know you see a lot of complaints in the press that, oh, we wasted money and we wasted time on bird flu, and then we got swine flu, and that's really a wrong way to look at this. There was a real good foundation there laid all across the country, at the state level, the local level, the White House level, the interagency level, so all of those people were still there, and they just sort of moved en bloc to working on H1N1, and that was really fascinating.

And what that allowed is the new politicals that came in that maybe didn't know anything about flu. They already had an entire staff, like at the Commerce Department or at

Agriculture, that was extremely experienced in flu. And they just stood up and said, "Oh, yeah, we'd do this," and "What do you need to know? We'll tell you." And within a day or two or a week, they got their principals all spun off, and they were all ready to go.

I'm not sure the Secretary of Education had ever done anything with the flu before he came from Illinois to Washington, but he had an entire staff that had been working on flu for years. So he immediately was engaged, and then went on to do some interesting things with Secretary Sebelius and Secretary Napolitano. And if that had been a cold start, that would have been really difficult. And everybody knew each other, so it's like we just called up, meetings happened, stuff happened. It was great!

SM: Well, you also touched on this too, but I wanted to know how unusual it was for the Department of Homeland Security to be so intimately involved in responding to contagious epidemics. For example, their role in the establishment of a common operating picture to display relevant information or to help facilitate collaborative planning and situational awareness, in particular for H1N1.

It just seems that they would not be the designated entity to for such a task. Can you weigh in on this?

CH: Well, the relationship between the Office of Health Affairs in the Department of Homeland Security and ASPR has been contentious, obviously, for many years because they have struggled to figure out what their role is in a public health and medical event, because HHS is really the lead agency in public health medical events, although DHS handles events. So there was, at times, a very stormy relationship ever since ASPR was created between the Office of Health Affairs at DHS and ASPR. And defining those roles and responsibilities of who does what was getting to be defined but wasn't completely defined when H1N1 hit.

Now, they changed political leadership and they have a new political appointee in the Office of Health Affairs, and I think his vision is a little bit different than his predecessor. And I think his office has reached out to ASPR and is working very closely with ASPR, but that's just my opinion. I don't know how the senior leadership looks at that, but I think from this point on, that unfinished definition of who does what when will evolve and get fixed, because people get along together better now than they did.

SM: Well, you had to. Things were moving pretty fast.

Acknowledging that hindsight is 20/20, is there anything that you would have done differently?

CH: Yeah. I think that if they were going to set up a task force, they set this one up way too late, because there were too many activities already underway, and the coordination and integration should have been done in April. So ASPR tried to set up this task force. It was almost July; it was way too late because then a lot of things were damage control. And some of the liaisons that were sent up from CDC weren't the right people, so that just made the problem worse. So if you're going to try to set up interagency communication in HHS, you have to have real senior people engaged from the start, and you have to have the right people exchanged as liaisons.

SM: For example?

CH: You just have to get the right people on your task force or work group that are part... If you're talking about flu, they have to be part of the flu structure from

FDA or CDC or NIH, and they have to come in earlier. There were a lot of things that were already operational in a different way. And then ASPR setting up a task force at the end of June, it was virtually impossible to try to integrate all those processes at that late date. It really should have been done in April. But that's when our leadership was changing over, and so I understand why that happened, but it was pretty far down the road. It's better to do that right away.

SM: You mentioned pillars. Which one of them commanded the most resources? And I understand there were communication--

CH: Community mitigation, vaccine, education. It was the vaccine distribution and all of that.

SM: And how did you respond to it? What demanded your attention most, besides it being late?

CH: That was it, trying to make small changes in a system that CDC already had set up and was operational, to make it more streamlined and operate better and faster. That was very difficult.

SM: Well, is there anything else you would like to add that you think that a future generation might very well benefit from in your experience with this event?

CH: I thought the most valuable thing were those 12:30 chief-of-staff calls because that got the people who could make decisions in the room in a timely manner, and few decisions were able to be made and teed up, and things that really needed to be handled right away got handled right away. So I think that was really good.

That's a good model, although I would have set the task force up sooner. I would have had the agency send more-senior people to the task force, and I would have had the task force manage the day-to-day stuff. And then maybe have like the chief-of-staff and the agency heads only participate twice a week because I think that would have saved them time. I think they wasted a lot of time being way down in the weeds on issues that, at their level, they should not have been involved in. So, from the get-go, I would have put in a more senior group to manage the whole event, and then they could have sort of just directed it from a higher level on a less frequent basis. Because I think we made the Chief of Staff way too busy and wasted

her time when she had other things to do. I think we wasted Dr. Fauci and Dr. Lurie's time. There are ways that could have been rearranged, but it was what it was, so...

SM: Did you have the opportunity to work with the previous ASPR, Craig Vanderwagen?

CH: Mm-hmm.

SM: Did you attend the initial meeting when Margaret Chan came to announce that this was potentially a public health concern of international concern? Did you attend that meeting?

CH: No. I wouldn't have ranked high enough to attend that meeting, so probably my supervisor, Dr. Yeskey, did. Probably the deputies did.

I've known Admiral Vanderwagen for probably 25 years, but we worked together in the Indian Health Service before we came here, so... And then I worked with him the first year that I was in ASPR. He actually brought me in to work in ASPR, and then I went to the White House and came back.

SM: Yeah, I did have an opportunity to interview him, and he was pretty proud of how things took off based on previous work done by the departments.

CH: Oh, yeah. It was so important. You know, this whole response would not have been as successful as it was without all of that prior work. A lot of people participated in that and deserve a lot of credit.

SM: Perhaps it didn't seem as seamless from the outside, but things went pretty well based on the work that was invested prior.

CH: It really did go well. And I know there's a lot of criticism out there about this that and the other thing, but overall, this was really a successful response.

SM: And it was an amazing thing to observe.

So, is there anything else you'd like to add?

CH: No, not that I can think of.

I'll just say one thing. I think ASPR really needs to stay in its coordination role in these kinds of events. It needs to, that's why it was created. And I know there are a lot of naysayers that say ASPR never should have been created as an organization, but I think we saw a really good reason during H1N1, and then during Haiti, and then now during the oil spill why ASPR was created and why it needs to function the way it does.

And it's only three years old, so we will have these fits and starts that we try things and they don't work, and we try things a different way, and now, during the oil spill, we're using a different model. We're back to the senior-health-official model. And I think that's okay as the organization matures. If it worked well for one thing, we can tweak it and try it a little differently for the next event, and on and on. But its central role as coordinating for the Secretary during events I think is really important. And maybe the agencies didn't like it and they resented ASPR for trying to coordinate, but it was really important that ASPR was there.

CH: So, like it or not, we're still here.

SM: Good to hear. Thank you.

END OF INTERVIEW

Broad Themes

- Medical Surge Program of ASPR/OPEO
    - National Disaster Medical Systems
    - Hospital Prepared Grant Program
    - Emergency Care Coordination Center
- Task force for ASPR – writing of after-action report
- OPEO response process
- Hospital preparedness, emergency rooms capacity
- Communication amongst stakeholders
    - Chief of staff meetings
    - Messaging on DHS-FEMA grants
    - Emergency Care Coordination Center
    - NIH research network
- Assistance to local, state, tribal, territorial communities
    - Grant programs
        - Deployment of MBMS

        - IAAs
- Hospital data
- States' response to delayed vaccine, relationship with HHS agencies
- Differences in response between first and second wave
    - CMS and 11135 waivers
- Senior level and White House involvement in response
- Transitional leadership
- Foundational work on H5N1
- DHS involvement in response, relationship with HHS/ASPR
- Pillars
- Value of Chief of Staff meetings
- Higher level senior level meetings-future response
- ASPR's coordination role

Documents

- National Framework Document for H1N1

Names

- Dr. Yeskey
- Admiral Vanderwagen

- Margaret Chan