Trial, By Desire

One FQHC's Research Trial Experience

Re: COVID-19 Vaccine

An interview with Beth Wrobel
CEO, HealthLinc, Inc.
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One FQHC's Research Trial Experience RE: COVID-19 Vaccine

An interview with Beth Wrobel, CEO, HealthLinc, Inc, a FQHC in Indiana
as part of NACHC's Leadership Development Technical Assistance Program

"Like Dorothy in *The Wizard of Oz,* I've gotten to peer behind the clinical research curtain – and I've seen that it's all good stuff," says Beth Wrobel, CEO of HealthLinc, Inc., one of the larger multi-site FQHCs in Indiana. HealthLinc serves roughly 40,000 medically underserved patients in northern Indiana through a network of 11 medical sites, five dental clinics, and a medical/dental mobile van.

HealthLinc provides COVID-19 testing utilizing the Abbott ID NOW™, BinaxNOW™, and QuestDiagnostics™ tests. In 2020, the organization decided to partner with Velocity Clinical Research in a research trial to study the effectiveness, safety, and possible side effects of a potential COVID-19 vaccine developed by Johnson & Johnson Janssen (hereafter "J&J") originally to fight Ebola and SARS that has been modified to address the novel coronavirus. The trial will ultimately utilize 1,000-1,500 HealthLinc and community volunteers.

While COVID-19 vaccine candidates from two companies – Pfizer (in partnership with German firm BioNTech), and Moderna – were first in line for Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA), both require two injections three-four weeks apart. In addition, at the time of this writing Pfizer's must be stored at -94°F, a logistical problem for many providers.

If approved, the J&J vaccine would have two significant advantages: just one injection and requiring only normal refrigeration.

HealthLinc became involved with the J&J vaccine trial in summer 2020, when Dr. Robert Buynak, an Internist having a strong interest in clinical research, approached Ms. Wrobel with the offer. Dr. Buynak had previously worked at HealthLinc as both a volunteer and paid part-time provider and had generated a high degree of trust and respect. He had also founded Buynak Clinical Research in 2005; this company was recently incorporated into the national clinical research organization Velocity Clinical Research, which has a relationship with J&J to help with that company's COVID-19 vaccine trial, branded ENSEMBLE.

In part due to the strong trust Dr. Buynak had earned with the organization's staff, Ms. Wrobel agreed to HealthLinc's participation in the ENSEMBLE trial. As of this writing, two of HealthLinc's 11 sites (which in total cover five counties in northern Indiana) are actively participating, with an additional site serving a large Hispanic population scheduled to come on board soon.

Two prominent volunteer participants in the HealthLinc trial are Ms. Wrobel and her son David, who is in his mid-20s. For Ms. Wrobel, the trial to date has been a very positive experience, both personally and for HealthLinc as an organization.

However, the current reality is that both for individuals and for health care providers (including health centers), the idea of participating in a clinical research vaccine trial has not had a positive uptake. A

number of possible reasons for this have been put forward: fear; lack of knowledge; politicization of issues surrounding the novel coronavirus; a generalized distrust of institutions as reflected in what has been termed "social waves"; and so forth.

To find out more about J&J's ENSEMBLE vaccine trial, the potential benefits of clinical research generally for health centers, and possible reasons for resistance to COVID vaccine research specifically, NACHC held an extended Zoom call with Ms. Wrobel in late November 2020. Below are salient excerpts:

NACHC: *Given that there has been some resistance in the health center community to participating in clinical research in general and COVID-19 vaccine trials specifically, why did you make the decision to participate in J&J's* ENSEMBLE *trial?*

Beth Wrobel (BW): For several reasons. First, it was simply an opportunity to do some good in a time of national emergency. Second, participation in clinical research has been on HealthLinc's radar for some time as a potential source of significant opportunity for the organization, and this seemed like a good first step into that world. Third, it was a way to give something back to Dr. Buynak, who has served HealthLinc over the years and whose level of trust within our organization was a huge plus. Finally, several HealthLinc team members, including myself, have participated in leadership trainings through the J&J/UCLA Health Care Executive Program, and this seemed like a good way to repay the company for that privilege.

Beth Wrobel, CEO, HealthLinc, Inc.

NACHC: *Can you describe the process HealthLinc went through in starting up its* ENSEMBLE *participation?*

BW: When Dr. Buynak first approached me in summer 2020, HealthLinc was of course dealing with the pandemic itself. We managed to keep all of our clinics open except one, which we consolidated with another clinic. We were using both telehealth and monitored in-person visits; were deep cleaning the clinics each night; and were partnering with a regional ambulance company to facilitate home-and-telehealth visits, through a program called paramedicine, for our patients who should not or could not go out during the pandemic. So we had COVID-19 very much on our minds.

In the spring of 2020, we had purchased a parcel of land behind our corporate headquarters and were intending to build a storage facility for our mobile medical/dental van and other storage needs. Once we accepted Dr. Buynak's offer to participate in the ENSEMBLE trial, he needed an area for five trailers on the property for trial-related pharmacy functions, waiting space, patient intake areas, and so on. HealthLinc will most likely be able to use these trailers after the trial for community vaccinations.

The build-out was handled by Department of Defense (DoD) personnel through the Federal "Operation Warp Speed" program. Dr. Buynak was also able to effectively lease some of HealthLinc's staff, primarily pharmacy employees who rotate through the trial activities.

All participant contact is handled through a web site and an 800-number provided and managed by J&J and Velocity Research, so we don't have to worry about those processes.

NACHC: *Do you have any partners in this trial?*

BW: I believe that having strong working partnerships is key to making this kind of clinical research effort truly effective and efficient for health centers. In this trial, HealthLinc's primary direct partner is Dr. Buynak, through Velocity's relationship with J&J; HealthLinc now has a contract with Velocity for the space and pharmacy staff.

NACHC: *Is trial documentation, either at the front end or throughout the program, a significant obstacle for HealthLinc?*

BW: Not at all. Both front-end assurance documentation and ongoing reporting are handled by Velocity and J&J. While as I said, we did need a formal contract for space and staff with Velocity, the main work there was just to have our attorney review and approve the contract. Of course, individual participants need to complete informed consent documentation – but again, that's not our direct responsibility.

NACHC: *Was HealthLinc part of the development of the study design?*

BW: No, that was done by J&J and Velocity.

NACHC: *What about any significant liability concerns for HealthLinc?*

BW: We made sure to confirm that recruitment of volunteers was covered for us by the Federal Tort Claims Act (FTCA). It is. In addition, our supplemental commercial insurance vendors assured us that they would participate as necessary.

NACHC: *How is recruiting for trial participants carried out?*

BW: J&J has a major ENSEMBLE web site/app called Study Hub with lots of trial information. HealthLinc has used the J&J/ENSEMBLE-developed brochures promoting the trial to distribute within our eligible communities, and Velocity Research has a corporate Uber account through which we can offer trial-related transportation to volunteer participants. And while we can't – and certainly don't want to – bring any sort of coercion to bear within our HealthLinc family, we do encourage trial participation with our roughly 420 employees, and we offer some paid time off for those who volunteer.

NACHC: *Both you and your son David have participated in this trial. Can you describe your personal experience so far?*

BW: Well, it's been only a week since I got my injection, so I can't tell you too much yet other than that I'm healthy and so far the only side effect has been a sore arm – and David didn't even get that. Of course, since this is a randomized double-blind study, neither David nor I know if we got the actual vaccine or a saline placebo.

Like all volunteers, we went through a three-hour intake process involving a history and physical, blood work, and verifying our understanding of the basic aspects of the trial including the need for up to 10 visits with the researchers over roughly two years. We'll need to periodically complete electronic questionnaires on how we're feeling, and we'll get continuing measurements of our vital signs including breathing rates and oxygen saturation levels. It was made clear that we can stop our participation at any time without losing participant benefits.

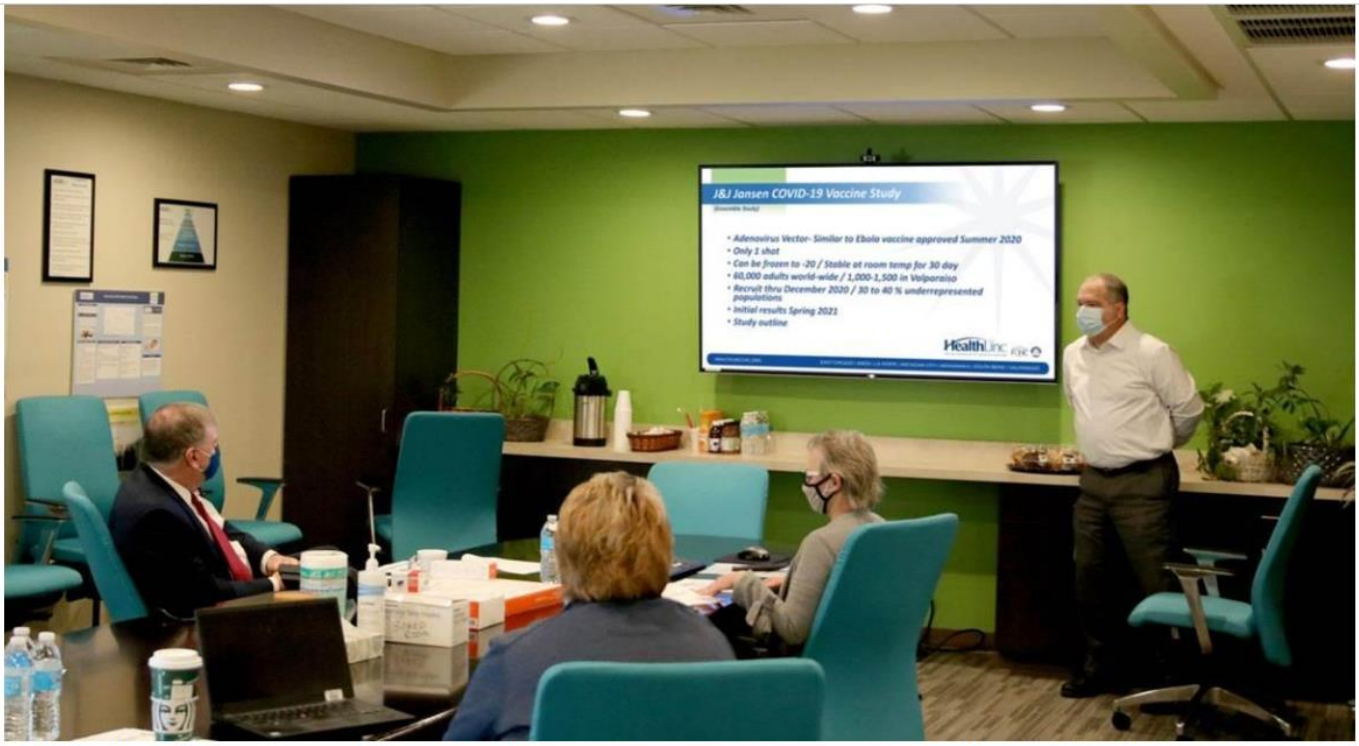
Volunteers get a "goody box" that includes a thermometer with covers, a pulse oximeter, nasal swabs, and an electronic reporting app. We also receive $150 per visit, to cover time and travel.

NACHC: *What benefits have you seen so far from participation in the* ENSEMBLE *vaccine trial?*

BW: I'll answer from two perspectives – as an individual participant, and as a health center CEO.

Personally, while I've witnessed the amazing things our clinical staff has done during this pandemic, I've been frustrated because I could personally do nothing to help make this terrible thing go away – except to actively participate in vaccine research. So again, it's my way of just trying to do some good in this awful time. For *all* volunteers, there's the distinct benefit of continuing medical monitoring for COVID-19 and medical help if a participant actually gets the illness. In addition, J&J will un-blind the results at the end of the trial, and if the vaccine is ultimately successful, participants who got a placebo will immediately go to the head of the line for getting the real vaccine.

With my CEO hat on, I can tell you that ENSEMBLE has already primed HealthLinc for future participation in clinical research, which has been on our wish list for some time. A research component has in fact already been developed as part of our new Strategic Plan. Aside from the community good and the promotional benefits clinical research provides, there's also significant financial opportunity. As I mentioned earlier, through this vaccine trial HealthLinc received funding both for the parking lot space housing the five trial trailers – effectively paying off our purchase of that land – and for "leasing" of rotating HealthLinc staff who are helping with the trial. Finally, an added benefit from the vaccine trial was that HealthLinc came to the immediate attention of HRSA, leading to an in-person visit from HRSA Administrator Thomas Engels.



HRSA Administrator Tom Engels at HealthLinc for a vaccine trial presentation by Dr. Buynak of Velocity Research

NACHC: *How will HealthLinc continue to address COVID-19 as vaccines are actually rolled out and other therapeutic avenues are pursued?*

BW: As you know, the National Institutes of Health is pursuing a broad-based, five-pronged approach to national coordination of COVID-related development of various therapeutics, known as "Accelerating COVID-19 Therapeutic Interventions and Vaccines", or ACTIV. One prong, spearheaded by Eli Lilly and Co., is ACTIV-2, addressing outpatient monoclonal antibodies and other therapies. HealthLinc has worked to identify local hospitals participating in this research.

Of course, once proven vaccines are ready for distribution, HealthLinc staff will tackle the logistics of vaccine storage, injections, and dissemination of public information. We want to partner with area hospitals, to be "that resource" for addressing COVID-19 issues with medically under-served populations. Our Community Health Workers will be part of the community education effort, as will our front-desk staff who are highly trusted by our patients.

NACHC: *Finally, you're aware that resistance to participation in COVID-19 vaccine trials has met resistance from both health centers and potential participants. What are your thoughts on this?*

BW: I'll answer from both a participant and health center perspective.

For potential trial participants, I think that simple *fear* is a real issue. Like the virus itself, much is still unknown about the vaccine candidates, especially since the two earliest ones – from Pfizer and Moderna – employ essentially a new method of action, the "messenger RNA" (mRNA) technology. Added to that, of course, is the unprecedented speed with which these new vaccines have gone through the development and testing phases. Personally, I think the name "Operation Warp Speed" is

unfortunate, since it implies a process that many might fear is too fast. Also, information about *everything* related to the novel coronavirus has been seemingly ever-changing since the early days of the pandemic, and that scares people craving certainty in a deeply uncertain time. And finally, the unfortunate politicization of COVID, perhaps best exemplified by the masking issue and propelled by social media, combines with the already existing "anti-vax" movement to create further fear around what should be very promising vaccine developments.

These personal and political issues also influence organizations, including health centers. In addition, everybody's head is already spinning anyway in the health center world. We're all dealing with unprecedented COVID-19 treatment urgencies, other new initiatives, and everything else that normally goes on in health centers. Taking on one more thing, especially something as seemingly complex as clinical research, may simply seem overwhelming.

But the reality – especially if a health center has the right partner(s), as we do – is that this need not be the case at all. For HealthLinc, partnering for this vaccine trial has *not* been a major time drain. And as I've said, it has provided a number of real and substantial organizational benefits. Frankly, for HealthLinc, there has only been an upside.

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Related Web Sites:

J&J Janssen ENSEMBLE Trial Web Site
https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol

J&J Janssen Study Protocol for Trail COVID-19 Vaccine
https://www.jnj.com/coronavirus/covid-19-phase-3-study-clinical-protocol

***Activ* Trials: Overviews (2)**
https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials#activ1

https://fnih.org/what-we-do/programs/activ-partnership#activ3

***Activ-2* Outpatient Trial**
https://clinicaltrials.gov/ct2/show/NCT04518410

HealthLinc Web Site
https://healthlincchc.org/