Dr. Hernandez: 00:04 Hey, this is Adrian Hernandez, and welcome to the NIH Collaboratory Grand Rounds Podcast. We're here to give you some extra time with our speaker and ask them the tough and interesting questions you want to hear most. If you haven't already, we hope you'll watch the full Grand Rounds webinar recording to learn more. All of our Grand Rounds content can be found at RethinkingClinicalTrials.org. Thanks for joining.

Hi there. This is Adrian Hernandez with the NIH Collaboratory Grand Rounds, and we are here today with Paul Harris, who did a recent Grand Rounds and will be reflecting on playing with fire, innovative use cases for the new Red Cap EHR integration module. Paul, thanks for joining us.

Paul Harris: 00:47 Thank you, Adrian. I've been looking forward to it.

Dr. Hernandez: 00:51 So Paul, you've been at this for a while in terms of trying to solve the problems of research and electronic health data. Tell us a little more about ... what's a real problem that you're aiming to solve here?

Paul Harris: 01:05 Yeah, so with our current work, and we've been at this for a couple of years with this current body of work. We're trying to solve a problem that really researchers started articulating to me back in 2004 when we were first starting to think about a platform, an electronic data capture platform called Red Cap that we created. And that problem was it's great that you're solving the EDC problem, and our philosophy there was make it easy, give research teams an easy way to do the right thing when planning and conducting studies with respect to data, data management. But one of the earliest questions in the conversations with the research teams were, this would be great if we could figure out a way to get data directly from the electronic health record into the electronic data capture system.

That's a hard problem. It was hard in 2004 and it's hard today. But with some of the newer advances in, I would say the new world of vendors operating and working, the EHR space solidifying, I should say, with at least a couple of vendors here in the US, and also the proliferation of interest in activity around a new standard called HL7 Fire. We've got some opportunities now that were not even dreamable back in 2004. So our current body of work over the last couple of years has really been trying to leverage the Fire ecosystem and the vendor push to get Fire into their systems and to consume that information, making it

easier for research teams to capture and manage data that have an origination source of the electronic health record.

Dr. Hernandez: 03:17 That's terrific. Seems like data is being generated every day by every patient, every clinician in EHR and you're aiming to harness that to actually enable easier research. I understand from your Grand Rounds that some of this has been orchestrated through the Red Cap consortium. Red Cap, can you describe a little bit about what that is and examples from that success.

Paul Harris: 03:47 Sure. So Red Cap started back in 2004 really to fulfill the needs here at Vanderbilt to give research teams a disease neutral platform for planning, collecting, and managing research data. And 2004 was really an important date in informatics because it's when we started needing to deal with HIPAA security rules. We'd all been working in HIPAA privacy for some time, but getting to compliance with HIPAA security rules and really just doing the right thing in terms of protecting data, putting controls around data sets and so forth. Who's doing what when with the data? That was something that we needed to do anyway, but it was a big problem back in 2004, or at least it was here at Vanderbilt.

We solved the problem using the platform called Red Cap, and again, as I mentioned before, the premise there is give researchers an easy way to do the right thing. Let them continue to think about their science, whether that science is autism, or Parkinson's, or even zebra fish. Give them an easy way to create and manage their own data ecosystem, and in the meantime, make it all HIPAA compliant, et cetera. That was really the genesis of Red Cap. About a year later, we started hearing from other institutions that they were having the same issues. We came up with a sharing model where we would give the software and support away at no cost to academics, nonprofit, and government organizations, but there was always this expectation that those partnering institutions would give something back.

In the early, early days, it was a little more rigor around the programming and getting other folks helping with some of the development. Over time, we realized from a project management standpoint, we couldn't really scale that. But I would say that there's still this huge sense of volunteerism and community within the Red Cap consortium itself. We're up to about 3,700 partner institutions in about 131 countries, and at least, I think as of around August, we logged our millionth user

of the Red Cap system across that consortium. The reason that's really, really great is again going back to that central problem that we're solving now with EHR connectivity and researchers asking for that. What we've found in the Red Cap consortium is that if you develop a good product, you make it easy for teams to go off and invent with that product, they'll tell you how to evolve that product. And again, that's a big part of what Red Cap is, the culture and how we've evolved it over time. And again, going back to that central problem that we're discussing today. We started hearing the need for EHR connectivity back in 2004 and that chorus of voices asking for it has just gotten louder and louder over time with the consortium and all of the different groups working in that space.

Dr. Hernandez: 07:19 That's terrific and impressive progress. You touched on this a little bit, but I wonder if you could dive a little deeper on EHR and EDC interoperability. Right now, it seems like we have this parallel universe where research teams are entering data in an electronic data capture literally in a screen next to a screen for the electronic health record. So it's right now, the so-called human interoperability. Are you envisioning where the EHR data transitions with high quality to an EDC system easily? Is that what you're trying to do?

Paul Harris: 08:05 Yeah. That's exactly what we're trying to do, and we've all heard or even seen, some of us have participated in that dual screen, let me go to the EHR screens, let me do chart reviews and try to pick off whatever the data element that you're trying to adjudicate into the case report forms. Sounds easy when you're just talking about it, but it's very inefficient, it's prone to errors, and there's the timeliness of data getting from the source system into the research system. So that problem is exactly what we're trying to solve, and we do envision and we're starting to see really good results of basically a priority mapping of data fields between Red Cap and the electronic health record. And again, we've built this technology based on Fire, so it works in Epic, and we have quite a number of folks in the Epic ecosystem that are moving towards migration. We built it on Fire, so it's actually kind of working in the Cerner space as well. We're a little less mature in adoption in the Cerner space, but it's moving, and again, that's only because we've built it on the Fire standards.

But to go back to your central question, Adrian, yeah, there's a reason why it took a long time to get here. It's hard to think about that mapping and things that the researchers don't necessarily know or need to know about way down deep, how

is the data element represented in the EHR system and how do I map that to the EDC system? You've got things like, well, really what I want into the case report form is I want the highest value within 20 minutes of some event that is known in the research system, or the lowest over a 24-hour period. So it's sometimes quite difficult to go in and do those chart reviews and click the necessary screens to go and even get the answer that you want to flow into the EDC system.

But the way we built it out, we've created a process so that the researchers can self-map data fields from the EHR to Red Cap and we built this, basically a data extraction engine that either real time or overnight if you've got data that are dropping into the EHR system from labs, et cetera. Either of those can trigger a harvesting, if you will, into the EDC system. And then we've even built adjudication methods so that we'll go ahead and present all of those, whatever that lab measure is that you want to find that highest within a 24-hour period of an intervention. It'll bring those to you and suggest that this is what we're finding as the highest and allow people, the coordinators, to just adjudicate that data and push it directly into the EDC system.

I don't have exact numbers here. Some of our colleagues at Duke have actually done some nice time and motion studies around time saving and accuracy of direct E-sourcing. I've got some more anecdotal evidence here at Vanderbilt, where people that have moved into this space and started to use this technology, that they're telling us pretty loudly about the time savings and even the accuracy for going directly with these approaches of data transfer rather than the old method of dual screen human interoperability, as you termed it.

Dr. Hernandez: 12:28 Great. So it sounds like the next really huge advance is taking advantage of Fire. There's a lot of unknowns there perhaps, but can you explain what Fire is and what it's going to help us do?

Paul Harris: 12:49 Sure. So HL7 Fire is a standard that the HL7 group oversees. Basically there is a ... as I see it, there's two ways to think about Fire. It's a lightweight standard for representing data in different domains, the Fire group call these resources, but these domains or resources would be things like patient, things that need to be known in the clinical systems, and by extension, in the research system space around a patient. You think about patient, well, you probably need a name, you need a date of birth, the demographic type information, those sorts of things have been standardized, and they are represented in a

standardized way within this Fire standard. Other things might be medications, or procedures, or observations, and the list goes on.

So one part of Fire is just that, what are the elements of data that need to be transferred? And there's also a piece of the Fire standard that deals with, well, how do we actually make the transfer of that information? So here would go into to RESTful web services and coming up and leveraging a common way for systems to express and transfer those data elements around the different resources or domains. Fire is not a perfect standard, it is a really good standard. And one of the really nice things about Fire is it is evolving and it has the support of the vendors, and if you're dealing with any kind of system to system exchange, trying to figure out how to do that in a standardized way is the trick, and I think it's the trick to getting the vendors interested in building more of those interoperability type things, is not having to build 15 different versions, but only build one version.

So it's really exciting because the vendors are jumping behind it, the National Institutes of Health are really ... they're really grasping and they've actually led some of the efforts to promote Fire, and they're very much pivoting now, I think, in the direction of now that Fire is becoming a reality, it has maturity, the vendors are starting to adopt it and use it. How are we going to change the landscape of research? And that, I think, is really a very exciting space, and it's why we're able to get into this innovation that we're talking about today.

Dr. Hernandez: 15:52 Well, this is great. It's pretty amazing what has happened just over the last 10 years and even more so over the last couple years, so I really look forward to seeing these efforts widely in practice for research. So Paul, thanks for spending time with us on the NIH Collaboratory Podcast, it was a terrific discussion.

Paul Harris: 16:21 Yeah. Thank you, Adrian. We really appreciate all your work.

Dr. Hernandez: 16:25 And thanks for listening to this podcast. Please join us for our next podcast as we continue to highlight fascinating and informative changes in the research world that hopefully everyone can use.

Thanks for joining today's NIH Collaboratory Grand Rounds Podcast. Let us know what you think by rating this interview on our website, and we hope to see you again on our next Grand Rounds, Fridays at 1:00 PM Eastern Time.