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Interoperability: COVID-19 as an Impetus for Change.
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Guest: Dr. Thomas Durant is an assistant professor of laboratory medicine and informatics researcher at the Yale School of Medicine and the Medical Director of Chemical Pathology and Laboratory Information Technology at Yale New Haven Hospital.

Bob Barrett: This is a podcast from *Clinical Chemistry* sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I'm Bob Barrett.

The COVID-19 pandemic has exposed many weaknesses in 21st century society and systems from supply chain logistics, to testing, to well, basically everything. The pandemic has particularly highlighted the challenges that are involved with the documentation, distribution and follow up of diagnostic test results across different entities. It has exposed an unfortunate situation regarding the interoperability of medical data within the United States. On one hand showing its importance to the overall public good, but on the other that in its current form, it is remarkably deficient.

An opinion piece on the importance of interoperability of medical data appears in the April 2021 issue of *Clinical Chemistry*. Its senior author, Dr. Thomas Durant is an assistant professor of laboratory medicine and informatics researcher at the Yale School of Medicine and the Medical Director of Chemical Pathology and Laboratory Information Technology at Yale New Haven Hospital. Dr. Durant is our guest in this podcast. So doctor, first of all, what is the take home message of your opinion paper for our readers and our listeners?

Thomas Durant: Sure. So the overall message for that paper was to try to shed some light on a problem that is universal to laboratory medicine, in clinical medicine, and we try to use COVID as sort of the example to sort of frame that discussion around. And within the COVID context, there's a number of current solutions which have been used to try to improve interoperability with varying degrees of success. Again, the overall message I think within that framework was just to highlight that it's an issue, potentially raise some of the opportunities for improvement, and again, just using COVID as the fulcrum for the discussion.

Bob Barrett: Let's get basic here. What exactly is interoperability and didn't Henry Ford solve that problem at the beginning of the last century?

Thomas Durant: So interoperability from a laboratory IT standpoint is the sharing of data between disparate systems and if we take it one step further, it means to do it in a way that is useful. In other words, it's not just sending the result across, but maybe also including some relevant metadata that clinicians or pathologists or people designing clinical decision support systems within the EHR can use to filter or select the most appropriate results that are coming in from outside institutions. You can sort of imagine that as these verticals, these silos that exist, wherein you have a vertical that goes from the instrument all the way out to the EHR, possibly even to the patient portal where the patient is accessing their data, and then you might have just multiple of those verticals that exists between disparate healthcare delivery organizations and how do you get data to persist from instrument to EHR/patient portal and then be able to transition between the two disparate silos or any number of disparate silos.

Bob Barrett: So what were the major interoperability challenges you saw with COVID testing?

Thomas Durant: The primordial challenge for us was ordering and resulting and again, I think that's something I probably left out in my previous answer which is another component of it is -- it's not just about the result, but it's about having the capability for orders to sort of flow seamlessly between one system and another system. So for us, when we were meeting with officials in March 2020 talking about ways that we can scale out COVID community testing, the clear and consistent message we're trying to convey was that the analytic piece was generally straightforward. If we had the reagents and materials available, once we have the sample, that was easy.

The harder parts were before we got the sample and then after we got the results, so the pre and post analytical pieces, how do we, as an institution, reach out to a skilled nursing facility that's in the community that has no EHR, no electronic medical record, no electronic ordering capabilities and provide them access to testing from our institution? And how do we, as an institution, give them results back? Well, what that looked like in the beginning of the pandemic was paper ordering, so paper acquisitions to our lab and then fax result reports back to the skilled nursing facility.

So, interoperability would basically say, "Okay, maybe there's a way that we can provide an ordering portal and a result portal for a skilled nursing facility that's in the community wherein the paper can be eliminated." Another good example was sort of outside of that framework of trying to expand access to community health care settings was on the internal side wherein we were very interested in trying to capture all of the external COVID test results that were being performed

on patients who were enrolled in our EHR/healthcare delivery organization.

So that if they showed up to our ED or they were transferred to our hospital, we had a clear picture of what their COVID testing status was. And so when we were looking at results that were coming in through the EHR, one of the primordial questions was, "Where are these results coming from? Are these PCR test? Or if it was a PCR test, was it this certain type of PCR test or was it this point of care test? Can we trust the sensitivity of this assay?" All this extra information that clinicians, I think at a patient-to-patient level don't really think about when you're thinking about making decisions at scale for healthcare delivery organizations. You want a little bit more resolution in terms of -- and a little bit more information in terms of where these test results are coming from and what sort of metadata is associated with them.

Bob Barrett: Do interoperability issues plague all of medicine or is it just particularly hard when it comes to laboratory data?

Thomas Durant: That's a good question. So there are some similarities and some differences. One of the major differences with laboratory data is that the majority of our data is discrete and it is generally expected to be searchable and trendable. It's already in a format that's ready to be shared in other words, whereas interoperability solutions for progress notes and patient care notes within some of the commercially available EHR systems today and I think it's a little bit more straightforward to share those because you're basically sharing a document and all the data that's relevant to that document are contained within that document. Whereas laboratory result has a little bit more complexity to it in terms of what kind of instrument was this done on, what kind of method was performed.

Sometimes there might be questions about from the laboratory side, probably not the clinician side, but was QC performed and done appropriately? Did this come from a CLIA lab? Or if you get a COVID PCR test that says positive or something, if you're getting that from external organization at least with some of the commercial EHR solutions that are out there today, you're relying on the external organization sending you that data to have accurately coded it to say that this is a COVID PCR test as opposed to, for example, a COVID serology test.

So there's a certain level of trust there because of the human component that is required to do this sort of code mapping for incoming external results and conversely outgoing external results. As a sending institution, we also want to ensure good practices that allow us to have some confidence in the results that we may be sending out to outside

institutions. And then, radiology, I don't know if they really share images per se. I don't know how interoperability really works there.

Bob Barrett: So is this a particular challenge here in the US or do other jurisdictions also find it challenging, for example in European countries or the entire European Union for that matter?

Thomas Durant: I'm not an expert on international interoperability, so I'm speculating a bit here, but given that we, as domestic and abroad, share similar hardware, instrumentation, we use Roche, they use Roche. There are going to be similarities in terms of the problems that we have in persisting data from instrument to EHR. As far as the specifics of that, I don't really know.

Bob Barrett: Sure. Well finally then, how do we move forward with meaningful interoperability improvement here in the US?

Thomas Durant: Yes. So I think that right now some of the conversations that I've been having and thinking about were oriented towards trying to achieve small steps or small wins. One thing, that might be interesting to try and do is to get a unique device identifier to persist from instrument to EHR in a laboratory section that's highly integrated with the existing IT infrastructure such as the Autocam area. But even something small like that, like getting the unique device identifier or the UDI to persist all the way from instrument to EHR, comes with major complexities even within chemistry.

But then if you try to expand that out to other areas of the lab, it becomes much more challenging, particularly for instruments wherein there is no interface between instruments and the LIS and maybe there's the manual transcription step between the instrument and LIS. It's a complex problem that there's a number of things that need to happen in all the software layers that go between each of the systems to allow a place for that data to be stored and to have it be readily available for retrieval later when it is needed.

Again, this is just speaking to the metadata component of the laboratory result to give it some additional inherent meaning. There's a whole another conversation around how do we improve the interoperability between healthcare delivery organizations for the purposes of ordering and resulting, particularly in the context of their being disparate EHRs or EHR vendors between Healthcare Delivery Organization A and Healthcare Delivery Organization B.

Bob Barrett: That was Dr. Thomas Durant, assistant professor of laboratory medicine and informatics researcher at the Yale School of Medicine and the Medical Director of Chemical

Pathology and Laboratory Information Technology at Yale New Haven Hospital. His opinion piece on interoperability and COVID-19 appears in the April 2021 issue of *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.