

- Adrian H.: [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](http://rethinkingclinicaltrials.org). Thanks for joining.
- Hi, this is Adrian Hernandez. I'm today's a host for NIH Collaboratory Podcast and we're here with Nigam Shah who recently did a Grand Rounds on something very interesting in terms of how could you leverage data from patient's experience in the past to inform care decisions today. His talk was entitled It's Time To Learn From Patients Like Mine, and he discussed something that they're doing at Stanford with a green button. Nigam, thanks for joining us.
- Nigam Shah: [01:00](#) It's great to be here. Thank you for having me.
- Adrian H.: [01:03](#) So, tell us a little bit about what's the problem that you're aiming to solve.
- Nigam Shah: [01:08](#) I think the core idea here is that when clinicians are faced with an ambiguous situation, our natural tendency is to consult our colleagues to seek their opinion. And given the adoption of electronic health records, the collective opinion of the colleagues is recorded in the data warehouse and we wanted to set up a mechanism where you could consult that collective wisdom of your institution to help inform the decisions you would make.
- Adrian H.: [01:36](#) Well, that's quite interesting. I mean, it's a huge problem here. What have you done to try to address it?
- Nigam Shah: [01:45](#) So, we've been at it for a couple of years. Our original vision was to think of it as a tool, and then very quickly we realized that given all of the issues in the data and the nuances around it. Instead of a tool mindset, it's better to set it up as a service. And so, just like we have specialty services for pathology, for radiology, we sort of piggyback on the sub specialty of informatics and set it up in a way that a clinician can consult the informatics specialist, who would be the person who then elucidates the situation, writes the unnecessary queries from the data, does the analysis and the report out is again a physical report with an interpretation of what are the data saying given the context and what can and cannot be inferred or concluded from the analysis.

- Adrian H.: [02:38](#) Well, that's quite interesting. So, kind of a combination of data analytics in a consultative service. Is that right?
- Nigam Shah: [02:46](#) Absolutely. So, there's some tools, there's data and then there's qualified people and all three of them together, all three things together, comprise the service.
- Adrian H.: [02:58](#) Can you give me an example? How does this actually work in real time?
- Nigam Shah: [03:03](#) So for example, we had a clinician who saw a patient who had a mild elevation of the kappa and gamma light chains, but the serum electrophoresis ratio was normal. And the question they had was, what is the increased risk of hematological malignancy for this patient? And the driver for that question was when to seek followup. And so when they reached out to us in the conversation, we learned that the main concern is, we're seeing this slight lab normality, everything else looks normal. When should we see the patient again? And based on our data warehouse, we found based on roughly a thousand patients, that those who had this particular kind of result had a very high chance of having an hematological malignancy in the next six months. And so we said, have a shorter followup and not a one or two year followup.
- Adrian H.: [03:57](#) Huh. So that's really interesting because originally I was thinking that what you're aiming to do is answer questions about whether a therapy works or not. But that's a great illustration of just something that helps guide practice and give someone an answer that they wouldn't have otherwise known.
- Nigam Shah: [04:17](#) Absolutely. So when we started, we started with the same mindset that you illustrated, that we thought people would ask us questions about what therapies to choose. But the majority of the questions ended up of a slightly different nature, which is how often does something happen.
- Adrian H.: [04:34](#) Wow. Give me a idea of what's the size of the data that you all are working with. How many patients or how's this work?
- Nigam Shah: [04:46](#) So we have about three data sources that we go to for provisioning this service. The core sources, the Stanford Clinical Data Warehouse, which has data from our pediatric hospital and the adult hospital and the outpatient clinics. That's about 3 million lives over eight to 10 years. And then we also have access to commercial claims data from Truven MarketScan and from Optum Clinmark. And those we go to in situations where

either the outcome is rare or it is possible to phrase the question using variables found in the claims data set. So collectively it's about 200 million patients, but about 3 million is EHR data and the rest is claims.

Adrian H.: [05:32](#) Wow. And then what's the turnaround, like, how fast does this go?

Nigam Shah: [05:40](#) So anywhere from 24 to 72 hours. So think of it like a send out lab. Depending on the complexity of the question we could get back in the day. Sometimes the cohort is really big and we have to do a high dimensional propensity based matching. It could take a couple of days, but yeah, less than 72 hours for the most part.

Adrian H.: [06:00](#) That's pretty incredible. And then in terms of service areas or clinical areas, what areas have you guys covered?

Nigam Shah: [06:10](#) So we've done at least one question from pretty much all clinical specialties on campus. The majority of the questions have been internal medicine, hospitalist medicine, which could be just be an artifact of the fact that I'm appointed in the department of medicine. The next big is cardiology oncology, a decent amount of pediatrics questions as well, and a couple from the surgical disciplines.

Adrian H.: [06:34](#) Interesting. And then one thing that's really important here is, as I understand it, is that you've done a lot of work in terms of understanding data quality. Can you talk a little about that? How do you ensure that there's data quality?

Nigam Shah: [06:50](#) Absolutely. So I think data quality is key. So we rely quite heavily on our institutional groups funded by the Dean's office and the CTSA, that provision the data warehouse. So that's sort of the first line of defense. Then we adopt the practices from the observational health data science and informatics group. So where there's these data quality tools, ACHILLES being an example, and there's equivalent such tools in the PCORNet and Mini-Sentinel communities. And it readily running those tools and then you fix some editors and that leads to some more, it took us a couple of years to get to a stage where the core data, our of a sufficient enough quality that we're comfortable offering this. So it's not easy. And without data quality checks, I think it would be a little bit risky to do something like this.

Adrian H.: [07:46](#) Now, people are very interested in having everything automated around healthcare. Do you think this could ever be

fully automated or is it really important to have some human interface or judgment here as you go forward?

- Nigam Shah: [08:04](#) I mean, I would love for this to be automated. I mean that's what we envisioned it. But very quickly we realized that if doctors could be automated, we would have been automated many years ago. I think, and I'm a huge fan of having a human in the loop for several reasons. Data quality being one of them, not anticipating the kinds of things that a computer can automatically anticipate. Just being aware of the clinical circumstance, the social circumstance. There's a lot of other contextual things that a human can pick up in a 15, 20 minute conversation that would be very difficult for a computer to use and factor in when giving the response. So I think for the foreseeable future, I imagine this to be a human in the loop endeavor the rather than a fully automated thing.
- Adrian H.: [08:56](#) And then I guess the question is that, as people think about advances in terms of health technology and bringing in data and answering questions like this, some things, if you were to think about the extreme, just like search, someone will always get an answer. And here, will you ever give an answer of, I don't know?
- Nigam Shah: [09:20](#) Absolutely. So that is one of the crucial reasons to have a human in the loop, particularly someone who understands data and statistics so they can look at all of the different diagnostics and say, "you know, yes, the algorithm did return a number and the number could be 2.6 but looking at everything else, I'm telling you we shouldn't be believing that number." And so there's often situations where the human will override and say, "You know, these analysis are not that reliable and we should not be attention to the final inference."
- Adrian H.: [09:53](#) It sounds like you've had an exciting start and a journey around the green button. What's it going to look like in the next three or five years?
- Nigam Shah: [10:03](#) That's a great question. So our immediate next step is that now we've convinced ourselves that we can do this technologically and that the information we provide is well received by the clinicians. So that in my mind is step one. So immediate next thing we want to do is to examine if, by having this service, do we make care better. And it's very hard to design a study that can attribute the improvement to like one intervention. So that's what we're spending most of our effort right now. We call this phase quality testing or efficacy testing where we want to collect information that given the information from the consult,

what did the clinicians do and follow that over time to see does that lead to any change in a measurable metric.

Adrian H.: [10:56](#) That is a pretty ambitious goal. So we'll look forward to seeing what you do there and sharing it with us. Especially with what you've described as really being open-ended in terms of the types of questions, the types of areas from pediatrics to all sorts of specialties. That'll be hard to address, but I know you all will do it. So I look forward to that.

Nigam Shah: [11:24](#) Oh yeah, we were excited and scared at the same time that given the breadth, it's very hard to quantify improvement. But at the same time, the exciting part is that again, as a country, we've been talking about learning health system for a while now and this is in my mind, a great example of that. And so even if we can show utility conclusively at one site, maybe we can partner with other academic centers, piggybacking on the CTSA network for example, to see that, can we treat this as a meta analysis? So for example, ask the same question at multiple sites and see what answers we get and how often are they consistent with each other?

Adrian H.: [12:05](#) Well, this certainly will push the frontiers and look forward to you all continue to advance so-called data and to action and a learning healthcare system.

Nigam Shah: [12:16](#) Absolutely. Well, wish us luck.

Adrian H.: [12:19](#) Well, thanks Nigam for joining us on this podcast. Thanks for everyone listening to this, and please join us for our next podcast as we continue to highlight fascinating, informative changes in the research world, especially to advance health.

Nigam Shah: [12:36](#) Thank you.

Adrian H.: [12:40](#) Thanks for joining today's and 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.