David: It’s really my delight to introduce our plenary speaker, Doctor Harlan Krumholz. Doctor Krumholz is probably familiar to many of you. He’s a cardiologist, a healthcare researcher, a leading spokesperson for the role of research and improving healthcare in his position at Yale where he’s the Harold Hines Professor of Medicine and the director of their Center for Outcomes Research and Evaluation at Yale New Haven Healthcare System. Many of you may be familiar with Harlan’s work published in New England Journal and JAMA promoting the value of open data access, the role of data sharing and early sharing of results both to promote the importance of replication, the ability to replicate, and the ability to test and validate research results. He is also at the center of many important activities on the national research front. He was a founding member of the Board of Governors of the Patient Centered Outcomes Research Institute and a member of the National Academy of Medicine. To sort of flip on what John Kennedy once said when he was given an honorary degree at Yale, he has the best of both worlds. Actually, Harlan has the best of both worlds. He has both a Yale education and a Harvard education. He comes to us to talk about, really, the future of research and sort of next generation research and I think the comments he’ll make will really tee up some ideas that will run throughout the session and I think will be echoed in comments Amy and I will make this afternoon. Thank you. Welcome, Harlan.

Harlan Krumholz: Thank you, David.

[Applause]

Harlan Krumholz: Well, it’s a pleasure to be here. Let me just teach back what I heard when David first started. So, budget was tight, a lot of great people weren't invited, a lot of great speakers we wanted couldn't come, but we got Harlan Krumholz here. When I heard from David, he said, would you be willing to come for the—the budgets tight and there’re just going to be a few people there. Would you be willing to come? I was thrilled to come. I don’t care if there’re two people here because I think that the HSR&D and QUERI programs of the VA are the jewel of the nation’s researchers who are focusing on how to do pragmatic work that has direct impact on people and communities and populations, and my work has been so influenced by the spirit of the work that's come out of the VA.

I'm a graduate of West Rocks and Fort Mylan [PH] with Leo \_\_\_\_\_ [00:02:59] but more than that, so many of the people in the VA have been my teachers. They've taught me research with the generosity of spirit with a focus on what it's going to do for people, and also, if you look at the community of people working in VA research, you guys set the example for interdisciplinary work. There are PHDs and nurses and doctors and a whole range of others that are working together and they're working to think about the hospital and the community and the whole range of venues where people live, not just where the clinical encounters take place. And you are in a healthcare system that has always been focused on what the value is, not what the volume is, and so, for me, it was a distinct pleasure to be invited and I didn't care whether one or two or three or as many of you showed up as you did because I wanted to be here. I wanted to feel the energy and resonate with you about what the work could be.

I will say that—my closure slide. I'm glad to post these slides up but the deep respect for the VA, like I said, is personal because of the people that I know that are working here, the relationships that I have, people that have taught me, but I was so happy to see this conference focusing on the twin issues of innovation and implementation. And I say that because, in some ways, these terms become a little hackneyed after a while, but the truth is they need to be paired because what we're ultimately doing is work on complex interventions. And for way too long, the idea about what the implementation was, the scalability, the applicability, the way in which things would actually change on the ground had been far too neglected, and the notion of coming up with new ideas and showing how they work in rarefied atmosphere of a specific clinical trial in a place with people who got specific expertise and extra resources to study it is very different than what happens when you're trying to implement something in the real world with real world constraints and distractions.

And so, the notion, again, I think it's reflective of what's going on in the VA and the pairing of the research and the query, the quality and the knowledge generation merges out of this notion that the innovation and the implementation have to be closely tied because who cares about the innovation if it can't truly be implemented. So, I was thrilled to see that as a piece of this. I was also humbled as I looked through the book and I saw—and I just threw out—it’s hard to see probably throughout here but look in the book. When I saw the presentations that were being made here, I was so impressed because anything from a case for a VA home-based primary care expansion, comparison of observed harms, expected mortality for the veterans in VHA's low-dose CT lung cancer screening project. I just threw up a lot here, the right idea and the wrong patient results of the national survey and stopping PPIs. Well, I just threw out some of them. I could have thrown out all of them and for me, the issue is that you guys are doing this kind of work. In fact, the kind of work that you do needs to spread dramatically, but I also am hopeful that the administration, the organization—there's lots of jokes around budgets and to the degree to what you guys are valued externally.

I know internally you’re valued quite a lot by this community, but this is the path forward. This is the path forward for healthcare reform, which is the generation of strong knowledge, the testing of new ideas, the evaluation of those ideas, their continual refinement and a focus of their implementation, not just at the point of care but in the communities, as well, and it's a notion that's already been embraced here. So, I'm just going to ask your indulgence because for me, this talk was a little bit about just going on a bit of a riff about my thoughts about research in the state we’re at but knowing that, I'm humbled by the fact that this group already embraces a lot of what I think is most important, so I’m not here to convince you of anything so much as to just, I think, reflect back to you what's on my mind about where the research enterprise writ large needs to go, and I believe strongly that you need to be an important part of that, not just as individuals doing research but as promoting the underlying ideas that thread through the research that you do. It's not enough for you to do great work. It's not enough for you to continue to improve the VA, but your work needs to reflect largely on the healthcare system outside, the research that’s being funded, the way in which the work is being done because I believe that the philosophical approach that is emblematic of the work done by HSR&D in the VA is what needs to spread throughout the entire healthcare system in a way just as some of the principles and values of the healthcare system itself need to spread to the healthcare system outside of the VA.

So, just to go—go back. The first slide I had there, which—yeah, so when I'm teaching about research, what I try to convey to younger folks is make sure your research is with intent. That is, the goal isn’t to publish a paper. The goal is to take a step back and to think about what is it that you truly want to accomplish, what is the knowledge generation that you’re trying to produce and why are you doing it and so that there is a larger, latent objective to all the research. And then I also say is there alignment of that research with potential partners, and I say this because when I first got into research, I saw arm wrestling about access to data and a lot of this arm wrestling, actually, I saw between academics and some places I saw were between CMS or other groups and they would get lawyers talking to lawyers. And if I think about one of the key features of any success that I've had, it's trying to find alignment with the partners and not trying to get something from them, but actually trying to figure out whether or not we have a vision together of trying to accomplish something.

So, while people were fighting with lawyers, I would go to CMS and recognize that the agency was trying to improve care, and so the work that we always did was not trying to get data from them but to work with them to achieve shared purpose, to try to convince them that generating the new knowledge was going to be fundamental to the foundation of any efforts to try to build policy and practice that was going to improve care. I think some of my colleagues, my more senior colleagues who were annoyed by our access to CMS data, felt that we had done an end-around because while they were fighting with lawyers, very famous organizations were fighting lawyers to lawyers with the government to get data access, we were forming alignments and partnerships and collaborations to try to do so, and it wasn't part of a clever strategy to say how can we get the data. It actually was a part of, if I look back, a clever strategy to actually see that our research would matter because what we wanted to do was ask the kind of questions that was this far from policy, a nano-space between our work and actually seeing something done with the work. It was always the central driver for us, which was to say I don't want to throw rocks from outside the wall.

When I look at so many colleagues, I see them writing papers and they’re just lobbing a rock over the wall and they're hoping to hit somebody in the head and then all of a sudden they think that's a great idea, and often not in a way that's ultimately going to be constructive in trying to shift the policy. Now, that’s not always easy because we're not always happy with the way the policies are unfolding, but ultimately, our work needs to be defined by the degree to which we're able to have science and facts and knowledge help guide wise decisions at the policy and practice level, and even help us reengineer and re-architect the way in which the care’s being delivered. And that requires us a degree of humility of not knowing all the answers even though we're the smart researchers. In fact, \_\_\_\_\_ [00:11:49] to say that, actually, our jobs are a lot easier than the people who actually have to make the operational decisions and run organizations. And so, it's a matter of trying to match and align like that that I think was so important. Sorry to keep looking back but I haven’t memorized all my slides. I don’t have them in front of me.

So, the other point is about this alignment with understanding who the end users of it are. I wrote this piece and I said what if we took our papers and we weren't funded before but we were given the opportunity to put our papers without the results section up on eBay and see who would bid for them. I said if we really want to know the value of information that we’re producing, what would you pay for it? You want to know valuable information, what would somebody have paid on September 10th, 2001 for knowledge about what was going to happen on September 11th? Of course, an infinite amount of money, right? So, information has value. How much value does our information have? When we generate a paper, who would pay for it and how much would they pay for it if we gave them the introduction, the methods and we say we will unveil to you the results for a price if we put it out for market? If you're wondering whether you would even raise a dollar, which I have on some of my papers, it should give you reflection on what the value of the information that were producing is. Who are the end users? Who’s going to care about the results? Who's going to act on those results? Who’s waiting for those results? To what degree have they been cultivated? I think these are all parts of our responsibility.

Ultimately, we're not solving the mysteries of the universe. We're not in theoretical physics. We're not trying to produce facts that help us understand nature as much as we're trying to practically improve the lives of people today and tomorrow. In fact, a lot of our research doesn’t age that well. It's because it's about today, if we're lucky, if we’ve got data that's timely. It may be medical history if it's about data from five or even ten years ago, but it's up to us to figure out where's the application of it because it's unlikely that ten years from now, at least most of the work I do, that someone’s going to discover it and say, wow, that's something I can apply in 2027. I think if it doesn't have application this year or next year then I haven't succeeded. Now, that doesn't have to mean changing practice, but at least somebody else has to take the baton and say I see that and I’m taking it to here and I'm taking it to here. If you can't in your mind work that out then it's legitimate to ask what are you doing, and now, you could be gaining skills, you could be getting practice of writing papers. You could be learning the mechanics of statistics in epidemiology and health services research. That's good. Those are some good first papers. But that's not going to sustain you and like I said, I’m asking your indulgence because when I look at the book and I see what's being presented here, this has been widely integrated into the soul of this conference and of this group of investigators.

So, for me, the journey was about thinking I graduate—I enter medical school in 1981, BHAT trial comes out, stopped early. 26 percent reduction in heart attacks with beta-blockers at discharge, and then just in my residency, ISIS-2 comes out and shows about a 20 percent reduction in risk with aspirin, about a 20 percent reduction in risk with streptokinase. It was an amazing thing. Before that, before BHAT comes out, we almost have no tools. We don’t even really understand heart attacks as being caused by blood clots, and we start having these tools but when I start getting out into my career, we start realizing that 60 percent of ideal patients are not getting aspirin. This is the beginning of these projects I’m doing with CMS. They’re descriptive at first but they're a remarkable opportunity for a young investigator to start saying I thought we just have to talk about trials in the publications. And I start realizing that this issue about the implementation is a huge gap. When we did these studies, ideal meant you had nothing in the chart. We had, I don’t know, 300 variables. We way overreached the data abstraction on this, but in part because we wanted to prove if we identified a cohort that didn't have one iota of information in the chart about why they might not get this including a note that said I've decided not to give them aspirin, what percent of those patients got it? Only 60 percent got aspirin. Only 50 percent get beta-blockers, beta-blocker is almost 15 years after BHAT. Aspirin is ten years after ISIS. And this seems rudimentary now but I'm just at least talking about my own journey about thinking about where the real gaps are. I’m thinking that we're here trying to make new discoveries and we haven't closed the loop on the old discoveries. We haven’t been thoughtful enough about how this fits. I start getting interested in the time to treatment and I saw that, well, we got this great medication that we know is basically ineffective after six to 12 hours and most people are getting it after six or 12 hours, and only a third of the patients are getting timely treatment with the reperfusion therapies.

So, this was, I think, one of the great stumbles in cardiology, was that we started to produce—we embraced trials, we started to produce remarkable results, and over the next ten years, despite the fact we’re trying to write guidelines and promulgate this, on the ground, this stuff’s not getting out and when you looked across the country, there were places in the Southeast, many states where only one in three people were getting prescribed—ideal patients, not one contraindication to therapy, were getting beta-blockers at discharge. It was a remarkable revelation. I will tell you that I'm now of the mind that MI, I believe, is a very different entity than it was back then, and with our proliferation of revascularization, I'm not even sure BHAT’s valid anymore. But at that time, we were pretty sure that we were still dealing with people being admitted to the ICU, marked arrhythmias, a wild ride, a lot of people not being re-vascularized, a lot of ischemia people going home with ischemia and incomplete use of the evidence. When we started looking at the treatment for PCIs that came out, we saw it was taking almost two hours to open the arteries for door to balloon time. And again, this was kind of this revelation when we started looking at the distribution of times across sites that there were some sites in the nation that were getting it done in less than 50 minutes, but there were a whole lot of places that the average was over two hours. At my own place in 1997, we first started looking at this. It was taking two and a half hours for someone with an acute myocardial infarction that came to the emergency department to get to the cath lab and have the lesion opened, two and a half hours.

When we talked to people about it, they would say you cannot go any faster than this. They said you don't understand what our lives our like trying to do this. Nobody's going out for a cigarette break. We are all running around trying to get this done. And so, it wasn't like we didn't try to climb the hill. Several times we tried to go faster so people coming into our place with a heart attack, two and a half hours later, the guideline said 90 minutes, when I asked the people who wrote those guidelines why did you put 90 minutes, what was the magic about 90, they said, well, it was our impression that we couldn't ask people to go any faster than that. That seemed like the limits of what people could achieve. Well, we start thinking about this idea of positive deviance and we said, well, why don’t we start thinking about mixed method studies, qualitative, quantitative studies, visiting these places, doing field work, trying to elicit what it was that enabled them to go faster?

And so, we started doing studies. We started identifying features of these places like one call to activate the cath lab instead of like our place where not only was it ten calls but you had to call the page operator to figure out who was on-call. We were inventing it with each patient. That's why it was taking two and a half hours, and then we worked with the American College of Cardiology and the American Heart Association did this. We had sites all around the country and we started taking the knowledge about what represented best performance as positive deviance and just spreading it. We also started measuring, reporting, increasing the accountability and we also started talking metaphors. What I think one of the best things about the work that we did in door to balloon was we got away from the fact that the cardiologists upstairs were always taking pot shots at the person from the emergency department. Those idiots in the emergency department, they don't know how to read ECGs. No appreciation for what it was like for emergency department people to see, I don't know, 100 to one people who really has an authentic heart attack or what the price was of a false positive versus a false negative.

And we start talking about this construct, if the pit crew—and the reason I bring it us is it doesn’t matter how good a driver you are. You can be the best driver in the world but if your pit crew is slow, you will never win a race because they say it's won and lost in the pits. The drivers are all this different in their competence, but the pit crews, it’s those seconds that are lost in the pit crew that matter. We were able to take this concept to the cardiologist and said you fashion yourself as one of the best interventional cardiologists? Most would reply yes. That's my humble field. But, you would say to them, if you get the patient late, it doesn't matter how good you are because the technical skill that you apply in the cath lab to a patient who’s gotten there too late is lost. The end result for the patient is to open an artery to myocardium that’s been irreversibly damaged, so what's the use?

And so, you can only be good if you have the opportunity to save myocardium and then save lives and improve function, and so, it flipped the switch for the entire construct of this that actually this team needed to work together or else no one in the cath lab could claim to be the best cardiologist. They could only claim to be the best team. They couldn’t do it if it wasn't a team and I think this was just a very important, at least within cardiology, change because I never hear them taking pot shots at the ED docs anymore. They need the ED docs to work well to deliver that part of the chain in order for the success to occur. And at our place now, this line at the top is 90 minutes but we're regularly under it and this woman had a cardiac arrest and a STEMI on the streets of New Haven. She was brought into New Haven Hospital immediately. Within 15 minutes, her artery was open. I don't even know how to label her. There was no evidence of damage. We pre-empted the acute myocardial infarction. 15 minutes for a hospital that said two and a half hours was just about what was going to be possible, maybe 2 hours and a half, 15 minutes. Maybe we could shave ten minutes off.

And by the way, the way you shave, go from two and a half hours to 15 minutes, you do it in one minute increments. Every minute counts. You start really dissecting. It's not about taking—there's an hour where everybody just said timeout and didn't pay attention to the patient. It was about 100 minutes that were wasted as one minute increments that just, in the end, led to that delay. And so now we went from a third of the people not getting aspirin to only a few. When you're down to this few number of people, ideal patients not getting it, most of them have stories if you go into the chart that you can't see, same with beta blockers, timeliness of treatment. During this time that so much focus has been on quality, there's been a remarkable change. Acute myocardial infarction mortality has dropped. 30-day mortality has dropped by about 30 to 40 percent. What’s interesting about this is all of this drop, this is from ‘99 to 2011, has occurred without the discovery and implementation and approval of any miracle drug. There wasn't anything—all the new stuff came out in the ‘90s and the ‘80s. All our ideas about how we should treat MI that we're basically using today, I mean at the margin, ticagrelor, this, that, there's really small marginal gains maybe with additional trials, but by and large, this is using the same tools that we had available throughout this entire period, but the quality changed. The workflow changed. The way that the cardiologists begin to think about the systems, the accountability, all changed, and it was during that period that this 30 percent drop occurred.

And in addition, I think this happened throughout the field, both with regard to prevention, other places—Arnie came out with this on there—an email I got yesterday from—on the website that from 2005 to 2014, went from a million hospitalizations for atherosclerotic cardiovascular disease to 400,000 hospitalizations, and this isn't just a matter of putting people in observation wards. This isn't just a matter of keeping people out of the hospital. These are events averted. I think what's interesting in the acute myocardial infarction story which has experienced about a 30 percent reduction is that at a time when we embrace high-sensitivity troponins, so our testing became more sensitive, we had a dramatic drop both and unstable angina and acute myocardial infarction.

This wasn't just shifting categories. This is an ACS came in so unstable angina goes down and they become MIs. This isn't MIs go down because they get shifted somewhere else. This is a real drop. VA has a role in this. You all played a role in improving the care, as well. So, I think this is what we're aspiring to, which is—we can talk about new biomarkers, we can talk about new risk factors, somebody can come out and say we're looking for underlying genetic mechanisms of disease. When Salem Yousef did the inner heart study, he said we think we have identified 90 percent of the attributable risk for heart disease. We can keep going but it’s a matter of applying what it is that we know and making people safe and promoting their health where they live.

We did the same thing with this intent idea with readmissions. There’s still some rumblings about this issue of readmissions but this was bothering me for a long time Earl Steinberg had written a paper in New England Journal in 1981 talking about this issue of readmissions. When I was a resident, we never learned anything about readmissions. We basically were trying to thin the service. We were trying to get people out the door. They showed back up, we go, oh, look who’s back again. It was no sense of the journey this person was experiencing. It was all doctor-centric, like, wow, yeah, that person’s back. Well, that’s an easy write up. I know that person. Or we weren't even aware that the person would come back in.

Started doing studies. Leora Horwitz is at NYU, led a bunch of these at Yale with us and did a terrific job and continues to do a terrific job, now with a large program of her own, and is uncovering a lot of these things that are invisible about the transition process. I never had a question that the issue about readmission had in part quality related to it. People debate about what’s a preventable readmission. It's not about preventability. You can't look at admission and know for sure whether that was preventable. It’s about risk. If you have the right systems in place, you will reduce the risk. You will see fewer. You won't know which ones you prevented. They all have a degree of preventability associated with them. It’s just like if I decrease the number of heart attacks, the heart attacks that were prevented in the ones that came in, if I didn’t prevent them, they looked the same. I can't tell you exactly why. I can tell you people have risk factors, but I can't tell you for sure that would have been a preventable heart attack. I can't tell you for sure it's a preventable readmission. At the far end of the spectrum when we made a big error, sure, and at the far end of the spectrum when it's something like a strike of lightning, sure, but in the great middle, it's about reducing risk.

Now—trying to do my slides. So, I was just saying, yesterday, we published this paper. So, there has been a dramatic decline in readmission rates. This is the paper Arnie Epstein published that showed that with the public reporting and an anticipation of the hospital reduction, readmission reduction act, there had been a decline which has slowed, but people were concerned that reduced access to hospitalization was going to have an adverse effect. We’re going to keep people out who needed to come back in. And yesterday, we published a paper that said—asked about whether there was an association between changing readmission rates and mortality and found no evidence that there was. Among Medicare fee for service beneficiaries hospitalized for heart failure, AMI and pneumonia reductions and 30-day readmission rates were weakly but significantly correlated with reductions in 30-day mortality rates. The hospitals that decreased the readmission rates tended to also decrease their 30-day mortality rates. It all makes sense. If you’re doing the right thing, you’re also going to decrease mortality and we were pretty happy to see this. This again goes to the philosophy of saying, we’ve got to evaluate the policies in place. There was a possibility that we were doing harm. This needed to be looked at very carefully.

Here’s what I’m thinking about where we stand, I start with saying this idea of with intent and of course, that’s going to be pervasive and continue. But, I think the opportunities ahead are with intent. I’m going to add two more. With technology, so a lot of my attention these days is about, what’s the next generation of research look like and how does it leverage what’s going on around us. We can’t continue doing research like it’s the 1950’s while the rest of the world is speeding forward with immense new capabilities that are changing the nature of American and international life while we continue to do thing in an old way. It starts by me saying, there’s also a need. The current medical research enterprise can’t keep pace with the information needs of patients, clinicians, administrators and policy makers. For all the good work you’re doing and for all the good work that’s going on around the world in medical research, the vast majority of decisions are still being made in an absence of good information.

We’ve got to figure out a way to go faster, better, cheaper. I mean, we have an imperative to go faster, better, cheaper, when it comes to research. The better is an important piece to this and some people only think you can do two of the faster, better, cheaper, but we’ve got to figure out how we’re going to do all three. And I would say, medicine in my view more than ever is an information science and increasingly it’s going to be a digital information science. Clinical skills, tactile skills are going to continue to be somewhat important. We’re always going to need the humanity within medicine, the human touch, the relationships, the connection, but what’s going to underlie the way in which medicine’s going to work is the way we’re going to manage information, the way we’re going to learn from information, way we’re going to take data that’s generated in the everyday practice of medicine to learn, both through experiments and through observational methods, but this is what lies in front of us is our ability to think of medicine as an information science and being able to triangulate on that.

You guys have had a digital system for a long time. You’re about to get a new one. That’s going to present an immense opportunity to lead Vista. The rest of the world has moved in this direction, but we outside the VA continue to live in a paper culture. We are not leveraging to any extent, maybe one percent the possibilities of what exists, by the fact that we digitize almost all the information in medicine. And who should be leading the charge and figuring out how to leverage that for the best possible purposes? It ought to be the people in this room. People in this room in the end are data scientists, information scientists, they need to figure out how that’s going to work and fit together.

As I look around I see this is—we also need to be able to be thinking about how we’re going to meet people where they live and how this has changed the nature of, not only data collection, but the nature of people’s lives, time spent per adult with digital media. This is showing an inexorable rise from 2008 to 2016, saying on average—the average adult is spending 5.6 hours on digital media a day, 5.6 hours a day. How is that changing the way we’re thinking about interventions, data collection leveraging? We’ve got to move outside the clinical encounters and think about people’s lives. How is this, in any way, putting for us—smartphone adoption among seniors has nearly quadrupled in the last five years? This puts to rest the myth that while the older patients, the veterans, they’re not using this stuff. That’s just not true. And every year, more and more of them will as it becomes an integral and important part and affordable part of their lives. Tech use is up among the 75 and older. Intercom conversations growing tremendously people are no longer talking on the phone. They’re using their smartphones in conversations in ways that we never envisioned before. Well, you all are too as means of communication.

Again, where’s medicine in this equation? I’m not suggesting veterans are using Peloton, but seeing the growth of this company is making me think about home use of devices in monitoring and coaching in ways that we’ve never envisioned, both generating data but providing the opportunities for interventions. How is this going to be driven down to cheap and inexpensive and again, meeting people where they are and trying to figure out how we can decentralize? One of the great mega themes of the future will be the decentralization of healthcare. The same time we built these cathedrals, these hospitals, these cathedrals, the truth is that we’re going to start decentralizing in a major way. Again, the VA leads this \_\_\_\_\_ [00:35:46] telemedicine efforts and work in the community and so forth. But, the opportunity for you to set the standards, the models, test the approaches, is beyond what exists in most of the other sectors.

This is Google machine learning on voice and the notion of the spread of things like Alexa and Google, people are going to be talking to machines, the machines are going to be talking back. It’s going to be a means of collecting information and data. It’s going to be a means of coaching, of promoting behaviors, of changing the nature by which the healthcare system and health promotion occurs for the population. How are we thinking about that, catching up to that? Google assistance, wearable sensors, devices on phones. And meanwhile, where are we? When all this data and all this stuff is going to lead to the personalization of this, where we are, is putting together blood pressure algorithms, let’s say, basically, if you’re over a certain age or you’re African American you get this and that. We’re putting people into boxes in ways that don’t make any sense. The CHADS-VASc scores a particular nick for me. It’s like, I’m going to give you a point if you’re a woman no matter who you are. I’m going to give you a point if you’re hypertensive whether you were hypertensive ten years ago and are diet controlled or if your blood pressure’s way out of control, heart failure. And I don’t know, this come from thinking we can’t give you people—you have to be able to calculate it on your fingers and everyone’s carrying around computers and the world’s surrounded by computers, who needs to know what’s going on under the hood? I mean what if Amazon were like this? How would it work? You get a point for being male in a certain age and it would make some recommendations to you based on that box. I mean, it doesn’t make any sense or they’d say this is what’s being sold today so that’s probably what you want.

You’re surrounded by a personalization and precision that’s leveraging information in ways unimaginable. Amazon’s got a patent on this sort of algorithm that says, we know you’re going to buy something before you purchase it, we’ll ship it before you even buy it. I’m not kidding. And what have we got? CHADS-VASc two. It doesn’t make any sense. The taxonomies are outdated. The labeling of disease doesn’t make any sense. The categories we put people in where there’s immense heterogeneity within those categories, we’re starting to enter a phase with computational phenotyping, but it’s largely within bioinformatics. But, we know that the features that really matter to people’s lives are largely social and the clinical phenotypic. It may be that the bioinformatics helps us with future targets, but I don’t believe they’re ever going to—I was going to say trump. They’re never going to overcome or be more important than the factors that we know that are directly impacting people’s lives, like whether they can afford food, whether they’re homeless or whether their diabetes is out of control.

We’re already seeing the implications of that and as we start seeing these clusters things look the same, but when are we going to start understanding the heterogeneity, who really belongs with who and deep minds working with NHS. You see people like Joe Dudley’s group at Sinai, trying to use deep learning to vectorize a large high-dimensional amount of data. I can tell you as I look around to this stuff, I see some places where it’s being used to great effect. I’m seeing other places where they’re longing for the right question and they’re taking data and producing answers to which it’s not clear what the right question was in the beginning. But, this is a good one where people can start taking skin lesions. Why do you need a dermatology consult anymore? In ten years, you will not. You will take a picture of the lesion. The consult will be about let’s think about what the treatment strategies might be or how best to communicate with the patients. But, the actual diagnostic piece of this, you will be as if you’re with the best dermatologist in the nation immediately by being able to use these algorithms that do this. And by the way, you don’t need to know, if it’s black that’s one point, if it’s got irregular edges that’s two points. There’s going to be a sophisticated underlying algorithm that could replicate the read of some of the best dermatologists in the country and you won’t need to know how many points it is. It won’t be relevant.

I’m going to just try to slide through these fast, but I just think—another feature of this is going to be how do we communicate information? They figured this out in weather. How many people took the course to figure these maps out? How long was the course—so, this is high-dimensional information, where the snowfall’s going to be, the location, the depth. We look at hurricanes. You can look, even uncertainty. You know that we don’t have any training programs for people to understand this and people do. I had to take a whole day course on Epic and I still didn’t understand what happened that day. We’ve got to figure out how we’re going to communicate information faster, better. I’ll just bring up the car thing. They started putting together all this information for the traffic. Do you have any idea how many different sources of information are feeding into that, including from your own phone contributing to this? But then, they decide to bring it out. Now, they had all these classes and training and certification so you’d be able to read this and understand what it was about because this is high-dimensional data from a wide variety of sophisticated sources funneled through complicated algorithms. But, nobody had to teach anybody how to do this because it was obvious what it meant.

My third piece of this in my last seven minutes is, with intent, with technology, you guys have to figure out how we’re going to leverage immense possibilities without taking wrong turns, wasting money or answering questions that are just so obvious. By the way, that’s the other thing, false precision, where we come up with a really precise answer when we didn’t even need to know that precisely what the answer was, honing the question. But, the last piece of this that I’m firmly convinced that we need to do is with people. This notion of participant partnered research, of actually not treating people as subjects and the days where we never even told people what the answers to the studies were, let alone asked them what they thought the important research questions might be, we routinely disrespected the community that was donating their time and effort and bio specimens and everything, the intimate details of their lives is over because that also lead to loss of follow up, lack of engagement, lack of adherence, loss of information, alienation. The next era is one in which we’re working closely with people. We are aligned and this comes also from this notion that I’ve learned that time moves differently for people with progressive, debilitating or life-threatening disease. You’re around the people that you’re trying to help and it puts a jump in your step that they are eager for answers and they want to work with people who want to help provide them, whether that’s about improving systems or whether it’s about coming up with cures.

We have yet to tap the potential of communities and individuals who want to work with us if we’ll just create the right milieu and if we’ll respect them and be worthy of their trust. That’s where we need to go. They say, hashtag, we can’t wait. They’re in great need of this kind of partnership, too. You’re seeing people like Sharon Terry, right, participants want not only to be invited to the table, but also to design and host the meal with other stakeholders. The leaders are saying, if you really talk to people, they want to be partners in this endeavor. When you looked at the All of Us initiative, Sue Desmond, who was my chief president when I was an intern and now the head of Gates, made, I think, an astute observation. When All of Us was put forward—and we’ll see if it stays to this—it was all about putting people in the middle as partners. And she said, I believe the most important requirement for new knowledge and that work envisioned by precision medicine, is that it be driven by patients, that they be involved, engaged and full partners in the effort. For the benefits of digital medicine be fully realized, we need not only find a shared home for personal health data but give individual a right to own them. Tip the balance of power, enable people to have some agency over their health assets and we need to be good partners for them to help them understand how it might be used in virtuous ways.

Actually, patients’ rights here in Privacy Rule 2000, there’s a well-established principal that people have a right to their digital data. Meanwhile, \_\_\_\_\_ [00:44:36] hospital, you still will be funneled to the basement and told for 39 cents a patient up to 400 bucks. We’ll give you paper records even though the federal law says you have a right to your digital record in full for not more than six dollars and fifty cents. We’ve got to flip this so that we can enable people to get their data and become full partners with us in research. In the VA, I think this is as important as anywhere because people are getting care at multiple places. If their data can coalesce with them and they can push it back to you, you can see the full picture of their care when they’re bouncing between the VA and non-VA sites. And not only that, there’s the opportunity to do more. This is—in full disclosure, this is something I’ve been working on to try to provide an information fiduciary for patients. It’s sort of a data asset manager for people, a way for them to be able to get their data and I hope other apps and platforms will emerge that will do the same. But, when people can pick where their data are, enable it to be organized, curated, and harmonized in a central location and then be able to share it with researchers or others if they want, I believe this is what you’re going to see in the future and in addition, provide the means to push surveys and questions to people so that by the time they show up for clinical appointments, you’ve got a picture of what’s been going on with people before. In research studies, we have the true longitudinal record that’s comprehensive because there’s only one source of comprehensive information, that’s the person, otherwise they’re flipping in and out of different paces and venues and you can’t get the full picture.

Here’s the vision for me, and again, not necessarily tied to what I’m doing, but here’s the bigger vision that needs to be accomplished in some way or another, communities of people empowered with their data assets, harboring a knowledge generation, producing a healthier future. Communities, not cohorts, not our cohorts, not my cohort, not my subjects. Communities, not cohorts. Participants and partners, not subjects. Frictionless, digital, real time, data flow, not episodic root force data collection. Rapid AB testing, which is possible with the digital platforms, not large cumbersome clinical trials. Modern technology enabled research, not clunky outdated techniques. What’s it like with—we’re doing it with, not to people. Bidirectional information flow, mutual respect, common goals, permission-based on their side, we ask their permission, technology enabled and data fueled, and finally, focusing on the end result.

Here’s what my suggestion is to—finally I’m at the end, don’t worry. Here’s my suggestion for the VA. I couldn’t sell it to PCORI. Simplify the grant application. This is grant applications with a results-based orientation. I said, this is what I want you to submit. And by the way, we’ll be with partners. A draft manuscript of what it’s going to look like if you fund me, what’s my New England Journal paper going to look like, make up the results, tell me what it’s going to look like, that’s it. That’s the application. Here’s what I think is the main paper. You can say there’ll be 15, 20, 100 papers, here’s the main impact of the paper, supplemental appendix about what methods you used for that paper like you would for a Neecham paper. A dissemination plan, how do you know that if you do this paper anyone’s going to care? What’s the plan to make sure that people are going to act on it? A media packet, what’s the headline, what’s the press release and what’s the budget? That’s it. No other application, just give me the sample paper that looks like—because I think as a reviewer, if I look at that paper, I’m going, I’m given a million dollars for this paper? That’s nuts. I couldn’t sell it to PCORI. They were too afraid. I think the researchers would like it, too, because it forces us to say, what’s the end product look like? And, of course our end product’s not really papers. But, we need to show what the knowledge generation’s going to be from the grant, but that’s why there’s a dissemination plan and a link piece that says, well, who’s going to do something with it and what are we going to tell the public.

I’m just going to take one big push of this open science, you guys are a wonderful community, embrace open science. It’s not about sequestering the data. It’s about how we can work together and move fast, quickly. Let’s figure out the issue of the incentives, but let’s not say that we can’t share data because it’s going to screw up my promotion, then we have to change the promotion process. We have to give people a lot of credit. If a thousand articles are written from data you produce, I need to give you a thousand-X credit for being a progenitor, a critical feature of what followed. Let’s not accept the status-quo on this. We’ve got to figure out how to fix the system so everyone is incentivized to create the API so the data can move safely, securely, in accordance with the consensus, but so that we can learn faster. You have been leaders of this already by the data you share throughout the VA.

And then my final one is just this piece that I wrote about to my younger colleagues to be brave. Be fearless. Try to make the changes that are necessary. Do not accept the way it’s been done. Don’t do it the way I did it. Figure out the way that it needs to be done for the future and recognize you’ll get resistance, but no matter because your North Star is to make things better for the people who need your help, who may never know you, but for whose lives you’re trying to improve and the health system you’re trying to make better. So, I say I think the keys to meaningful research is with intent. These days, it’s going to be with technology and the only path forward here is with people in a way that we’ve never done before. So, this human aspect is going to be important but we need to combine it with new ways to generate knowledge, faster, better, cheaper. You guys are an important part of that. You just have to be willing not just to go where everyone else is going. Thank you.

[Applause]

David: Thank you. We have seven minutes, I hope people will come to the mike with some questions. Identify yourself please, Steve.

Steve: Hi, I’m Steve.

Harlan Krumholz: Are you Steve?

Steve: Hey, Harlan.

Harlan Krumholz: Hi, Steve.

Steve: I love your talk, just like I love just about every talk I’ve ever heard you give. Seriously, what a wonderful and inspiring talk and I share your enthusiasm for big data, but I’m worried that it’s becoming a victim of its own hype because more data isn’t necessarily better data and the way that the empirical analysis of this data has been proceeding without reference to theory a lot of times, I’m worried that it’s going to guide us in the wrong direction if we’re not careful. What are the guideposts that we can use to prevent that from happening?

Harlan Krumholz: Yeah and that’s what I think—when I talk about this to my group, I say immense opportunities, but it always comes back to being clear that we’re defining the problem we’re trying to solve. And this issue about reference to theory, I think we have to be willing to say that there’s some work that we don’t care about theory. I get this is a Netflix thing where they were predicting movies and they had the competition. In our world, what would we have done? We say, we want to predict movie selection better so let’s start interviewing a bunch of people and let’s—maybe it’s the fact that people who like horror movies had some trauma in their childhood so let’s try to figure out questionnaires that give us a whole range of risk factors for wanting this movie versus that movie or we can just see what people select and we can see what they select before and after and create an algorithm that may be agnostic to theory but works really well. And so, I think if we’re trying to predict something, it may or may not—what we care about is time in, time out, does it validate, who’s it working? Other times when we’re doing comparative effectiveness or we’re asking questions or we’re testing hypotheses, that’s different. And then, we have to figure out is this helping us get rid of bias and confounding better and to what extent can we use these analytics and the data to do that? To what extent is it hurting us, but I fully agree with you that the notion of just diving in and saying this is going to solve all of our problems is false. But, the fact that it can be a new tool for us and if we’re smart enough to figure out the right questions to ask, can help us. I mean, I don’t know what the theory is behind being able to diagnose those lesions. That’s using deep learning that, actually, in that hidden layer, people don’t even know what’s going on believe it or not. I mean, I’m talking applied math guys at Yale and they’re like, yeah, that’s a hidden layer. But, time in and time out, it can match what the dermatologists say. It’s about knowing what can these tools do and that’s why this community is ideal for that, figuring out where are the limitations. We have to start creating the standards in teachings about how do we use these in wise ways and how do we avoid pitfalls.

Steven: Thank you.

Harlan Krumholz: I don’t want to—Rod asks too hard questions.

Rod: Hello, my name’s Rod and some of my best friends are implementation researchers. It’s sort of on the idea of these risk adjusted outcome rates and where we might move that. VA is starting to be pushed to do things similar to what’s being done in other communities. The issue is, we have much better data than CMS has and could do it better. Also, even outside, I think this punitive approach, I would like us to see more cooperative approaches. As you described, when you presented the data to those cardiologists, they got engaged. I’ve seen incredible things with more cooperative use of data that has a lot of err in it because ultimately, what you don’t want to be doing is measuring readmission rates. You want to be measuring how good discharge planning is, and readmission rates could send perverse incentives, particularly in a place like the VA where you can say go to that other VA. What are your thoughts at how we might transform the current consumer approach to a more cooperative approach where everyone’s required to engage in QI, but we acknowledge when we have very good measures, beta blocker post-MI where you don’t need mixed methods versus readmission rates where the social aspects of those people that aren’t in can play incredible roles and we might be punishing those individuals by people not wanting to provide them care because they’re an alcoholic or they don’t care of their diabetes?

Harlan Krumholz: Yeah, I think the two quick things here, one is that on the side of the readmission I argued not to make winners and losers, but if the country moved a certain number of points, no one should get penalized and it would focus people to work together. CBO scored it. They wanted to get money out of it. That’s why they put the winners and losers part in. Ultimately, there are many more than half losers because of the way the payment policy was built. I’m not in agreement with that and I agree with you that we ought to build programs that try to encourage teamwork across institutions and learning. With regard to the way the measures are done, I believe that these claims-based measures are going to fall by the way side. They’re obviously not what we would aspire to have. I think we need to be able to build measures that emerge out of the everyday practice of medicine and the digital data that we’re generating and figuring out how we can make use of that. VA can be leaders in that, figuring out how can we create dashboards and guideposts that are valid, that are streaming much better data from the point of care and I think CMS is—we’ve been advocating moving in that direction, as well, so I don’t think you’ll see these kinds of measures for long. In addition, as fee for service contracts, Medicare program for reporting is going to become less relevant because many more people are in Medicare advantage.

The issue that you bring up about readmission, you and I have a little bit of a disagreement about this. I think people do care about being readmitted. I think they don’t want to come back to the hospital if they don’t have to. I think that there are potential unintended consequences that we have to study carefully and figure out how best to configure it so it saves—to the best of our ability, we’ve see no mortality bump as a result of it, but we have to continue to be vigilant. There are other outcomes that may matter to patients. My own personal theory about this, as many of you know, about post hospital syndrome, I think we take people in the hospital and we sleep deprive them, we under nourish them, we decondition them, we stress them to the max and we put them under the kind of direst that gives them incredible allostatic load that puts them in a position where it deranges all their physiologic symptoms and that’s why when you look at readmission rates, it’s largely not for the reason they came in the hospital in the first place. They become vulnerable to infections, to falls, to all sort of things and it emerged out of people telling me, well, this patient fell, that’s not my fault or this patient got an infection, they came in with heart failure, why are you blaming me. And I’m saying, nobody’s blaming anybody, but when you see the frequency with which people experience these events, the risk that rises after discharge, you’ve got to ask yourself, what’s going on with these people because it’s not just their own progressive illness. But, I think we’re doing something to them by not creating a healing, restful, strengthening experience as they recover from their acute illness. That puts them in a highly vulnerable position.

And so, I think, Rod, it’s just not transition, but we have to be thinking creatively about whether we can strengthen. Meanwhile, we have to be sure that hospitals and health systems aren’t pursuing strategies that make them look good on paper, but bad for people, and so, we have to have checks and balances there to be sure that that’s true. But, I also say, there’s never a defense, by any measure, for nefarious behavior, behavior that’s criminal by trying to disadvantage people so you can look good for some national report. We’ve got to figure out how to detect that, but it’s going to always be hard because people willing to do that, they’re willing to do a lot of other bad things, too. But anyway, I’m in agreement on two out of the three. I think these outcome-based measures can help us understand and get to theories about what’s the underlying cause. I’ll love to see VA investigate this further.

Tom Houston: Hi, name’s Tom Houston and I’m a primary care doc up at the Bedford VA and do implementation science and help informatics, and so, what that means for me is that I really like toys and the newest tech that’s coming out. But, I’ve seen, like being in the field for quite a while now, that—and sometimes when we develop something, then it’s like whack-a-mole. We fix a problem, but then we create one at the same time and I wondered if you had any thoughts about how that informed our evaluation, like when we create these new widgets making sure that we’re not shifting the problem somewhere else.

Harlan Krumholz: Yeah, what I really would love is the VA to be used as a network and a large laboratory for many of these new technologies that are emerging, some of them information-based, some of them device-based and so forth, where you can create standards of their rapid evaluation in multiple venues and one VA may have—one set of investigators may have an idea, but they have ready access to a large network where you can rapidly disseminate and evaluate this idea of unintended consequences as a real one, let alone wasting resources when something seems to make sense and would be cool, but it only works in one little place, the idea of being able to test it at scale across, quickly, rapidly, AB testing, different iterations. The last thing about this is, I believe a lot of these innovations could be effective if they were refined. You take them in a very early stage of development and we start testing them broadly and then we give up on them if they fail, rather than realize that this is really at an early stage. It needs to be refined and iterated, AB rapidly, before it’s something ready to go to phase three testing. It is phase one, well, you need to go how do you phase one test this stuff? Now we’re ready to phase three, how do we use it as a joint laboratory to test it? We need to think of them as if they’re drugs or medical devices, but we want to be able to go rapidly and that can take the coordination of a VA network to be able to create the means by which people can work together to test each other’s ideas and approaches.

David: Thank you.

[End of Audio]