ONE PATIENT, MANY DIAGNOSES: THE CASE FOR INTEGRATED CHRONIC DISEASE CARE

Sarah Wells Kocsis 00:11

Good morning, everyone. Welcome to day two of the Future of Health Summit. I'm Sarah Wells Kocsis. I lead the public health team at the Milken Institute, and I'm super excited about this conversation, "One Patient, Many Diagnoses: The Case for Integrated Chronic Disease Care." So, the Milken Institute does a lot of research in chronic disease prevention, and a lot of our work keeps coming back to a patient, and that patient is like this one. We're going to call her Dana. Dana is in her early 50s. She manages type 2 diabetes. She has high blood pressure. Her doctor just flagged that she has early kidney disease. She's going through menopause. She helps care for her father. He has Parkinson's. And she's seeing four to five different doctors, and they're each just treating one piece of her, and she has to hold it all together. So, Dana's conditions aren't separate problems that just show up together. Each one of those conditions is actually making it worse for her, and our system is still treating her as one organ at a time, one diagnosis at a time. And so, this session is really about what would it take to organize care around Dana? And this expert panel is here to share their insights and help us find some solutions around that. We also want to bring you into the conversation. There will be a QR code on the screen. You can submit questions at any time, and we will come back to that before we close. So, I'd like to start this discussion with each of you really telling us who you are, what your connection to a patient like Dana is, and then is there sort of a single barrier that you're seeing from where you sit that is really impacting how Dana is being treated as a patient, and separate diagnoses, as opposed to one patient? And please, I'd love any perspective you'd love to bring, whether it's around innovation, access to care, the systems around her. So, I'm going to actually start at the other end. Thomas, we'd love to start with you.

Thomas Keane 03:00

Well, first of all, thank you everybody for attending this session, and thank you for hosting me. I appreciate it. My name's Tom Keane. My title is national coordinator for health information technology. And can I just ask by a show of hands, does anybody know what the Office of the National Coordinator is? Okay, great. So, basically, in 2009, President Obama passed the HITECH Act, which allocated both money and mandates to allow for the rapid adoption of electronic health records in hospitals. At the time, only about 15 percent of hospitals and providers had electronic health records. After $30 billion and multiple

mandates were issued, by 2015, about five, six years later, that number was up to 90 percent, and now as of 2026, it's about 99 percent. The thing that made the rapid adoption of electronic health records unique is that in 2016, Congress passed a law essentially saying that health data had to move privately and securely for the benefit of the patient at the direction of the patient. And this is really different from any other industry. Right now, if you do a Google search, Google can capture the information from your search and use that to optimize subsequent searches. It can have a monopoly on that information because there's no law and no regulation that compels them to share the data they get from their customers. By contrast, health systems and physicians are required to share that data in the interest of the patient. So, in answer to your question, you said, "What is a major barrier to the patient like Dana being treated comprehensively?" She's got hypertension, diabetes, early kidney failure. She's caring for a father with Parkinson's, and she's at the age where menopause is starting to become an issue. And she sees multiple different practitioners. The equity that my office is most interested in is making sure that data moves, that data is interoperable. And this means setting up standards so that data is represented in a uniform way, so that one hospital system or one physician is talking about the patient in exactly the same way as another hospital system. The second is that the transport mechanisms exist. This means application programming interfaces—which is a fancy way of saying a login and password screen so that computers can talk to each other—as well as portals for the patient to access their information, and portals for the patient to download their own information into their phone, so that they can manage their care between visits. So, the data standards, the data transport and accessibility interfaces, and also enforcement of our information blocking rule to make sure that the holders of data are willing to share that data for the benefit of the patient. So, our major equity is making sure that this data moves, so that when the endocrinologist sees Dana, the endocrinologist can think, "Oh, Dana is facing menopause," and that has a different implication for her endocrinologic treatment. Similarly, she's caring for a father who has Alzheimer's, and she may need some social support, and we can put her in touch with those. All of that information, interoperating, not just between doctors and hospitals and the patient, but also between community-based organizations and other organizations that can help the patient. Getting all of this to interoperate and talk to each other is really our equity and the focus of what we're doing in our office.

Sarah Wells Kocsis 06:32

Thank you. Brian?

Brian Foard 06:35

Thank you so much, Sarah. And actually, this gives us great hope because data, especially in a world today when we're talking about AI, without this data, the application of AI is relatively useless, quite frankly. So, this is going to be a common theme, hopefully, for this discussion today. Thank you again for this session. Thank you for everybody for being here. And I think it's a really important topic because if you think about this population that we're talking about today, nearly half of all adults in the US actually self-report to having at least multiple chronic—at least two chronic conditions. Over 80 percent of individuals of seniors do. So, this is not just Dana. There's many Danas out there, I think, in the US. So, it's a really relevant topic, I think, for us today. So, my name is Brian Foard. I'm the president of—I work at Merck or MSD outside of the United States and Canada, which is sometimes complicated. But I run one of our business units. We're in a business unit construct, and I represent our specialty business or specialty products for specialty therapies, pharma, vaccines, and infectious diseases. And, again, we tend to produce a lot of the products that might actually affect Dana across a whole host of those diseases.

And so, I would say to your question, as we sit here today, what gives us great hope is the innovation that's happening. I don't think that's really the challenge today. We have really incredible therapies that are being advanced. We have incredible work that's being done like this to help pull data together for patients. I do still think the system for the patients is really complicated. Number one, I think access to care is really complicated, and it seems to be getting a bit more challenging. And I think then managing it. I think these patients, the Danas of the world, are really struggling to manage across the various specialists of how can I inform myself? Because they are commonly the one that is managing it today. So, I think those are the biggest challenges that we really need to break down. Access to care, I think, quality care, and then how do we help create an infrastructure that supports the reality of many of these patients that are dealing with chronic conditions and many specialists, many therapies, being able to afford their therapies too, and care. I think that's the challenge that hopefully discussions like this will lead to actions that actually can help transform that.

Sarah Wells Kocsis 08:47

Thank you. Neerja?

Neerja Balachander 08:48

Perfect segue. Again, I echo the sentiment of gratitude for this conversation, for inviting us here. I'm very close to Dana. I feel she's a little too close to me. I'm a couple of diagnoses away from her. I'm also a primary care physician. I have the opportunity—so, I'm Neerja Balachander. I'm a primary care physician by training, and I lead the cardio-renal-metabolic and obesity liver franchise at Boehringer Ingelheim for the medicine in US. And we deal with Danas all the time. The problem is—I can see the problem that a doctor, Neerja Balachander, has with a patient like Dana. Let's say that Dana comes into the office and starts speaking about how anxious she is about her dad. So, now, Dr. Balachander has to uptitrate her medication, make sure that she's treated for chronic kidney disease, perhaps because she's now perimenopausal or even menopausal, see if she has any metabolically active fat that's going to increase her cardiovascular risk. Take a look at her liver because she has hypertension and she has metabolic syndrome, so she probably has some involvement of her liver as well. And now in the eight minutes that I have left, or maybe seven and a half between EMR and her complaints about her anxiety, where do I do all this? The reality of the situation today is that we're putting too much on the patient. We have put too much on primary care. And then we have a word for it. We call it clinical inertia, and we just blame it on clinical inertia. So, we know, for instance, that a primary care physician deals with more than 10 different classes of diseases, more than 100 diagnoses, and more than 20 risk scores that they have to coalesce. How do we go from that to a simplistic, holistic care of the patient? So, nothing is more relevant. And I think to your point, Brian, I think you're absolutely spot on. I think the power of data, traveling with the patient, ownership of the patient for that would help. But I also think that technology can make massive assistance for and of the physicians because we can put some of these consolidated guidelines in their hands. We already are working with organizations like the AHA that are trying to simplify care. You heard that 80 percent of senior adults have two or more of these situations. I can tell you 90 percent of all US adults are at least at stage 1 of the CKM syndrome, according to the AHA. Which means if you look to the right of you and the left of you, all three of you have something. And I think we need to solve this together. And I think the starting point is data, it is empowerment, and definitely it's simplification and consolidation of care.

Sarah Wells Kocsis 11:57

Thank you. Warren.

Warren Czerniak 11:59

Yeah. So, my name's Warren Czerniak. I'm with a company called Gedeon Richter. We are a 125-year-old company headquartered in Budapest, Hungary. And our primary areas of focus are women's health, particularly reproductive medicine, and neuroscience, with a large focus in neuropsychiatry. A lot of the important things have already been mentioned, so I won't be redundant, but I think one of the key things that I've learned through working together with Milken and the menopause reimbursement session about a month or so ago is there's a major problem in terms of access. And it's not only access, it's reimbursement. In the case of menopause, menopause is not even in the code. The word menopause is not in the code. So, it's difficult for clinicians to actually do an in-depth analysis or in-depth discussion with patients, because it's just too hard. This is not a five-minute discussion. And when you layer on multiple other diseases on top of it, when is there time to get an understanding of what the impact is? So, what I've learned throughout the last day or two here and at the women's session on Tuesday is the fact that this is a hugely complex problem. Right? Women comprise 50 percent of the population. But these disease states roll over and impact everyone, right? So, we have to figure out a better way to be able to get reimbursement, to get access. You have areas that are considered to be called meno deserts, where there is no care. There's no place for patients to go. And quite often what happens is then they go to social media. And what they get may or may not be helpful. Eventually, they cycle back to clinicians, which could create a worse situation. So, it's complicated at best. But if it were for me, I think the primary focus needs to really be on more time being able to be spent with patients. For patients to be able to be reimbursed, and bottom line, patients to be able to have access to the kind of coverage that they need.

Sarah Wells Kocsis 14:09

Thank you, all of you. I'd like to talk next a little bit about chronic disease as an interconnected system. The Milken Institute has just done some in-depth analysis of prevalence and economic burden data, and we found that cardiometabolic disease is now the single largest category of chronic disease costs in this country. About $805 billion a year, roughly a quarter of the total. Neerja, I know that at Boehringer Ingelheim, you all are treating heart, kidney, metabolic disease as an interconnected condition. I'd love for you to talk a little bit about the changes of when clinicians start thinking about these diseases as a continuum. And also that perspective you bring as a physician. And how is that shifting the conversation right now, from treating an organ to managing the whole patient?

Neerja Balachander 15:09

Fantastic place to start, I would say. Because, again, we are not created as organs. And somewhere along the line, we've started to specialize about less and less until we know everything about nothing sort of a situation. And I think where we at Boehringer Ingelheim are going to walk this back a little bit. And we're doing it in partnership with everyone because it takes all of us. This is not something, as you just heard, it's not a simple problem that one of us can just own and then solve. I think that kind of hubris serves no one, especially the patient. Where we are starting is in partnership with professional societies. And there's an increasing recognition now that the cardio-kidney-metabolic—if I may—liver continuum is actually one massive disease. And while we start to code and treat patients as when you have a heart failure event, or when you have diabetes, or your hypertension is uncontrollable, the problem actually starts way before. According to the CKM continuum, if you actually had either overweight or the problem of obesity, then

you probably also have insulin resistance, and that is actually the beginning of the story. So, if you've had, let's say, an angina today, that is a heart attack, today, that means 10 years ago is when that problem should've been started to be solved. So, how can we actually go backwards and put that emphasis on prevention rather than catastrophic treatment, which is both expensive and at best it is reparative. That is, once your heart muscle is damaged, once you've had a stroke, there is no going back. There is no bringing back your filtration rate in your kidney back to normal once it's slid down that slide. But fortunately for us, there's plenty of signs that the body sends out way earlier, when it's actually reversible. And I think that's what we are actually interested in working, and we'd partner with any sort of organization that is ready to embark on this journey. And I think that's where I think organizations like yours actually have a key role to play. Because we just talked about access being a huge issue. One of the biggest problems is that our system is feeding off of treating problems after they have already been established. So, how do we reverse this trajectory and go back to prevention? And I will leave you with the very, very positive news. We have more tools than we have ever had in the history of medicine, in modern medicine, to treat some of those things and nip these complications in the bud.

Sarah Wells Kocsis 17:56

Thank you so much. Thomas, I'm going to come back to you because I'm guessing that Dana's records are scattered across four or maybe five practices, so none of her doctors might be seeing the whole picture. I understand that HHS has been building something called the Trusted Exchange Framework and Common Agreement. Is that TEFCA?

Thomas Keane 18:20

That's right.

Sarah Wells Kocsis 18:26

To help change all of that. So, can you explain what that is? What it means for a patient like Dana? And is that going to help us take that more whole-person view so that clinicians can do exactly what Neerja was saying, is be more at the point of care?

Thomas Keane 18:39

Sure. When I first started in government some years ago, I was frustrated by all the acronyms because I couldn't navigate what the heck was going on, and I would just kind of sit there in meetings and nod and write the acronym down. Now, given that it gives me job security, I am 100 percent for it. So, TEFCA is the Trusted Exchange Framework and Common Agreement, and in 2016, Congress passed a law saying that the government had to stand up a network that allowed for information to be exchanged between various providers and also between the provider and the patient, and between providers and any other trusted entity that could pass the vetting process for getting on the network. So, this was originally mandated in 2016. In 2023, my predecessor, Micky Tripathi, stood it up. When I took office, we had about 10 million documents exchanged on it, and as of this morning, I think we're up to about 2.2 billion.

Sarah Wells Kocsis 19:40

Wow.

Thomas Keane 19:40

So, just really in about a year, a little over a year, the exchange has really exploded. And what this means—so, I work at the University of Maryland as a physician, and—Neerja, I'm sure that you have this experience—Friday night at about six o'clock, every hospital in the state of Maryland calls me and wants to transfer their patients to me—

Neerja Balachander 20:00

Of course.

Thomas Keane 20:01

—for the weekend. And some of them are appropriate for transfer, and some of them are not. And because I can leverage the TEFCA network, I'm actually allowed to see what's going on with that patient in real time. I can actually pull their data from the hospital they're at, and I can assemble a team of physicians who can provide a consult to the physician at the outlying hospital, that says, "Yes, this patient is appropriate for transfer," or, "No, but here's how you take care of the patient in place." So, that network is robust. We want to make sure that it's 100 percent reliable. Currently, we have two use cases on it. The first is treatment, which is to say physician to physician, provider to provider, to allow for the patient to be treated. We also have, very excitingly, one called Individual Access Services. So, you probably read that the LLM company, Anthropic, through its chatbot, Claude, or the LLM company, OpenAI, through its ChatGPT chatbot, now allows people to download their medical records and put those medical records into an LLM to help them manage their health. For the most part, those are being obtained directly through TEFCA. Individual access service providers, as we call them, third-party companies, will actually go through the vetting process, get the patient's consent and permission in a private and secure way, pull that data, so that it can be leveraged by chatbots. So, we're going to add public health use cases, payment use cases, and our goal is to really have a trusted network that the government administers, that people can really use to exchange their information where privacy and security are respected and are paramount to the mission.

Sarah Wells Kocsis 21:45

Thank you so much. I think everybody appreciates hearing more about that program. Brian, your portfolio at Merck spans beyond cardiometabolic. It includes respiratory, immunology, infectious disease. And many patients live with these conditions for many of these areas. So, what are you seeing in terms of patients being an interconnected system when it's broader like that? And talk to us a little bit about how that impacts how you're approaching development and partnerships.

Brian Foard 22:26

Yeah. It's a great question, and still, honestly, we don't have the answers. This is a daily struggle, I think, for us because commonly, each of those are thought of as individual, just as I think as you nicely said. So, if you take it all the way back, we've been around for about 140 years, and our first approach to everything is going to be being led by the science. So, I'd say that won't change, I think, in a moment that we're in today. So, we just think the science is actually accelerating. That's why I said at the beginning, this is not really our problem right now, innovation. The second piece of it is that we're always focused deeply on where is the highest unmet medical need. And so, we allow that science, of course, to try and take us into

high unmet medical need areas. So, those are the things that aren't changing at Merck. That's how we're kind of focused and how we've been focused forever. The third thing for us that hasn't changed also is we've collaborated for many, many, many years with other stakeholders that share similar values and similar ambitions, if you will. It's just the types of partnerships that we're seeing these days differ. Actually, a lot of our partnerships actually now are around collaborating with organizations that have data because it helps further inform our ability to develop interesting, innovative therapies for the future. And so, I think that's the one piece that has actually changed for us over the last couple of years, is the types of partnerships or collaborations that we are in are different than maybe we've had in the past. But I'd say our position on this is, as an organization, we think that for us to really make really meaningful change in this particular patient population, we believe a couple of things. One, you need to have a really strong regulatory body, and today we've seen really great progress with the FDA when they put their minds to it and they innovate in an area. Look at what's happened in rare diseases. Look at what's happened in cell and gene therapy. When we really tried to innovate in this and tried to say, "Hey, can we accelerate innovative therapies for patients in these areas?" They've made really meaningful progress. We need regulatory bodies to turn their attention to these chronic conditions, because they've gotten a little less focus over the last years, I think, certainly than they deserve. Because you're seeing the cost, as you articulated, to the system. I'd say, one, that's a big piece of it. I think the second piece of it that we'd like to see more being done—and it's going to require collaborations—is really meeting those patients where they are. Today, it's much easier, from a clinical trial network and setting up clinical trials that represent those patients. Today, it's actually—you can advance rare disease trials a little quicker than you can actually chronic conditions, number one. And number two, a lot of these chronic conditions, a lot of these patients can't qualify for the clinical trials that we've set up.

Brian Foard 25:03

We've seen this in IBD, as a matter of fact. About 80 percent or greater than 80 percent of patients with IBD don't qualify for many of the IBD trials, because of other comorbidities they might have, previous therapies they've been on. And so, I think we really need to adjust the parameters for these clinical trials, and that requires a strong collaboration, I think, with regulatory bodies. Because commonly, we are getting therapies approved for one of the conditions, and it doesn't take into consideration the others.

Sarah Wells Kocsis 25:30

Great. Warren, I'd love for you to speak to the partnership piece, the regulatory piece. I know you were talking about thinking about women and how they can be treated as a whole patient. So, what are your thoughts there?

Warren Czerniak 25:45

At Richter, we spend a tremendous amount of time—we run the gamut, by the way, from fertility to endometriosis, uterine fibroids, contraception, and menopause. And we continue to do new work, working in ways to find disease-modifying treatments, ways to approach endometriosis and ovarian sparing, and effectively trying to even improve access to fertility. We do a lot of work based upon what we feel are the needs. Brian said it, I think, great, is the fact that our focus really is on unmet medical needs and how we can make improvements. Right? And we do that through partnerships. And the partnerships extend not only through other companies in our industry based upon what they bring to the table. In women's health, for example, we might acquire an early-stage company like Celmatix, which we did earlier this year,

bringing some interesting technology and opportunities to us. We'll build upon that and hopefully get regulatory approval. In other areas like neuroscience—which, by the way, disproportionately affects women with mood disorders, where about 60 to 70 percent of patients are typically women—we work in a different approach. We do the early-stage discovery work, and then we have partnerships with companies like AbbVie, where we've brought Vraylar to market, for example. And that, I talked about the collaboration and the partnership. A lot of these partnerships are built upon trust and flexibility. That's a partnership that's over 20 years old and started with Forest Labs and went to Actavis and then went to Allergan, and then it went to AbbVie. Oh, by the way, in the middle of COVID. And yet that relationship was able to build and gain additional indications and bring to the market and help patients. And now we've treated over two million patients in that space with that drug. So, we work at the collaboration from both ends. And also the reason for the partnership is not just to say the science or the capabilities, but it's also the different skills that come to the table. So, when we're partnered with AbbVie, for example, part of that is what they bring to the table in terms of their clinical development skills and their resources, and the relationship with the FDA, and ultimately the commercial point of it. When we look at any opportunity, we're always looking at, first off, where there's a need. Number two, is it something that's scientifically feasible? Is there regulatory feasibility? And is there commercial feasibility? So, is there a market? Are there patients that need help? So, that's where we try to center the focus. In a space like menopause, menopause is interesting because I think people think of menopause as just a point in time. But this is a big deal. If you went back several generations, women didn't go into menopause because they only lived till they were 40 years old. Menopause wasn't a thing. Now, women get to a point where they're typically in their early or mid-40s, and they start experiencing symptoms, perimenopause. That can go from two to 10 years, depending on the individual. And so, this is when you start experiencing hot flashes, brain fog, weight gain in some cases. And there's a myriad of symptoms that start affecting patients. Part of the problem is, is that over 90 percent of women in a survey came back and said they were never educated about their body and how menopause and perimenopause and postmenopause works.

Warren Czerniak 29:35

And so you have this transition, and the fact that it's not considered a disease creates a problem for reimbursement. This goes back to the access problem, right? So, women go through the perimenopause, the symptoms get worse, and I always say this affects everyone. Every single woman goes through this, and consequently, everybody else goes through it. *[Laughter]* It does. I sat in a room once, and there was a guy at the table—this is with a potential partner—and we talked about menopause, and the commercial guy on the other side of the table, he said, "I don't know everything about menopause. I don't know a lot about menopause. What I know is I'm married to a 55-year-old woman, and I'm not allowed to touch the thermostat." So, this is a real thing. And then you transition. Once there's no menstrual cycles for 12 months, now it's menopause. Now it becomes postmenopause. This is where you start having problems with bone density loss. Can lose up to 20 percent of your bone density within five to seven years. Cardiovascular problems come because estrogen is gone. You don't have the cardio-protective aspect of estrogen. So, I bring all this up because this is a process. It takes time over years. What we're doing, we're not directly in the market in the United States. We are here through partners, but outside the US we are. So, one of the things we're working on is with clinicians, is to have a modernized menopause counseling tool. And what that's all about is coming in—and it takes a little time. You need 30 to 45 minutes, and that's a problem—but to discuss symptoms that women are experiencing. Listening to their stories as to how it impacts them, because there's a huge economic impact of women and menopause and lost work and lost promotions and all kinds of issues that are related to the symptoms. And then trying to find some sort of a solution that works, and whether that's medication or lifestyle or a combination. So, that's where we focus

a lot of time, particularly in menopause. And this change with the removal of the black box in HRTs has opened up the floodgates. And so, I'll stop in just a second, but one key thing to note, gynecology, OB-GYN residency programs in this country right now, only 31 percent of them spend any time teaching about menopause. Thirty-one percent. Of the 31 percent, 70 percent say it's two lectures or less. One hundred percent of them is five lectures or less. So, because of this whole history of the last 20 years, there's an education issue, and ACOG and other organizations are working on that, and there's a tremendous amount of enthusiasm to do that. But it's also patients. So, it's knowledge, it's bringing it all together, and so, that's where we have a tremendous amount of our focus.

Sarah Wells Kocsis 32:39

Thank you. No, I think that was so helpful. It's a great segue to what I want to talk about next, which is education and earlier detection. So, Neerja, Brian, and Thomas, if you'd like to jump in too, but I'd really love to hear more about what we can do for earlier intervention, whether that's education or actually earlier screening or detection. And Neerja, you mentioned sort of the role of prevention and where we really need to move upstream and focus on that. So, love to hear your thoughts.

Neerja Balachander 33:13

Absolutely. And I'd like to pull a couple of threads that I just heard, such interesting topics, both from Thomas and Brian, as well as from Warren. I'll start off with saying, to Warren's point, that I think women are long overdue, a trial for themselves and for us. At Boehringer Ingelheim, for instance, we are doing one side. This is an opportunity for partnership with organizations, because even in something like a perimenopausal situation, I do think it's important to actually have comprehensive understanding of both the biology as well as updating the education. I—and I'm sure, Thomas, you would agree—I don't think we dedicated anything, not just to menopause, or to obesity either. I don't think that was even a lecture when I was in med school. And now I think we are having to update those programs. Now, as we are coming up with chronic, this whole spectrum of disease as cardio-kidney-metabolic disease spectrum, we're going to have to update the education on that as well. As I said before, we have plenty of tools for screening. For instance, Boehringer Ingelheim was recently involved in a campaign and still is involved in a campaign called SOS, where your kidney is sending an SOS to your heart. And this is through a simple signal called the UACR. That is, when you start to leak a small protein called albumin—which is the protein in egg whites—when you start to leak that in your urine, that tells you that something's wrong with your endothelium. If there are holes in your endothelium, the window into that is your kidney, and you're able to see this in the urine. You know that when this happens, there is a multifold increase in your heart risk. All it takes is a simple urine test, which could be part of your regular panel, but is not. It is not expensive. Every clinician you speak to will tell you, "Yes, of course. It is an important test." Then when you ask them, "Do you do it?" "No." And that is because it's an extra added check mark that they have to put. So, simplification becomes a huge part of it. That's one. The second one is, for instance, right now, we are headed to also a liver crisis, if you will. And this is not from alcoholism, and that's another stigma that has to be fought. A majority of patients who are going to need a liver transplant are going to go through it because of their metabolic disease. So, metabolic-associated steatohepatitis, or MASH, is going to be soon the number one cause of liver failure and liver transplant. And yet, we were doing a recent data survey from an academic institution, that I will not name, not because it's one academic institution. Because it's a systemic problem everywhere, and this is a top-level academic institution where 56 percent of the patients who were ultimately diagnosed with MASH happened because of accidental findings. Only 2 percent of those patients were actually risk-screened for that disease. I think we have a massive loss. And we know,

for instance, that 75 percent of patients with obesity—and a good overlap of them, if they have hypertension and diabetes—there's a very good chance that you are not just at risk for liver disease, but you already probably have some degree of liver dysfunction. So, now it becomes a hugely important device to screen.

Neerja Balachander 37:01

And then as I'm piling on, I'm just thinking about the workflow. How many conditions can the primary care clinician be asked to be responsible for? So, I think here's where I go back to something, Thomas, that you brought up, the power of data, and I think, Brian, you alluded to it, the power of AI. There are companies right now that are working on simplifying these workflows and giving a simple checklist for cardio-kidney-metabolic workups, and I think that's going to be hugely important. The second one is that there are more than 80 guidelines that a primary care physician has to digest. And I can tell you, it's impossible. With any amount of education, that's going to be impossible. So, I think it really becomes important for all of us to be able to utilize these AI tools to simplify these guidelines and say, "Here's your patient." Then why not just make it so that they're able to do it already? None of this is actually super expensive, but I think it definitely takes the force of will to be able to bring this to bear in real practice.

Sarah Wells Kocsis 38:08

Thank you. Thomas, you want to jump in?

Thomas Keane 38:11

Sure. I'll add, we're in a really exciting time in the development of health information technology. Technology is advancing, and we've now introduced to the market wearable devices, be it your phone, your Apple Watch, the Oura Ring, that can continuously monitor and capture data from the patient. And we have to think about how we can integrate this data into the traditional health-care system. And it's something we're looking at in both our standards work and our regulatory work. And it can be a complicated issue because you want to make sure that you don't turn the patient's electronic medical record or the patient's medical record more generally into a graffiti wall in which any sort of information is thrown into it willy-nilly. So, we're thinking about how we can make the information reliable, interpretable, and how we can get it integrated in a rational way. But this presents a great opportunity. As you know, I think the Apple Watch has been approved to detect atrial fibrillation. Typically, the way you detected atrial fibrillation is through a routine physical, which you would have once a year if they did an EKG, or sadly, you would have a stroke or some sort of complication of the atrial fibrillation. You wouldn't be able to walk upstairs as quickly because you weren't getting the atrial kick. Atrial fibrillation is a shaking of the top part of your heart. Now, this can be detected by a watch, and a chronic disease or a complication of a chronic disease can be detected earlier because of these wearables. So, that's one promise. The other is, with the advent of AI, you can build models that make predictions about what's going to happen to a patient based on the patterns in their data. This is already being deployed in the hospitals. It's known that if a patient has sepsis or is about to become septic, if you intervene on that patient earlier, the outcomes can be better. And in places where they've done great predictive sepsis algorithms, they've been able to lower their death rate from sepsis substantially, in many cases by double digits. And so the predictive power of data is a second opportunity to really manage disease before it tips over to the point where, as Neerja said, you're not able to recover from it because it's too late. And these are two things that we're looking at in the programs that we administer and the standards we develop.

Brian Foard 40:38

Yeah. I would just add one additional point to this. And I agree with you. I think it's probably one of the most exciting times where we can really start to talk about health care. So much of it is truly sick care. The questions whenever you're met with the patients are, "How are you feeling? What's wrong with you?" Whatever. A lot of these preventative things aren't, "What's wrong with you?" They're not going to bring up, "Oh, I think I might have a cardiovascular condition in the future, but I don't feel anything about it." You think about lipid-lowering therapies. We know that that's one of the most meaningful ways to reduce your risk of a cardiovascular event, but yet you don't feel it every single day. It's the highly symptomatic disease states that you tend to see patients presenting with. But I do think because of the notion that you just mentioned, again—I'm upset you didn't mention Whoop. I get sponsored by that. No, I'm just kidding. But it is. It's more than 100—so, a third of the US population at some point has some sort of wearable device capturing data just like you're talking about. So, it could be a data feed. I get feeds that tell me already when I'm starting to feel ill based upon my respiratory rate, my skin temperature. I can tell I'm getting something before I even get something. But I do think it is a moment where truly prevention could become a real thing. But one of the biggest issues we face is in symptoms are misaligned.

Sarah Wells Kocsis 41:53

Yes.

Brian Foard 41:54

That is the biggest challenge, I find, right now, because the individuals that tend to put policies in place or reimbursement in place for these things, they're thinking of the benefit of that might be 20 years down the road, way past when they're in the role that they're in making decisions. And they're making decisions around budgets that are right in front of them. And so I think we really need to have that discussion around how do you realign incentives around prevention? Because it shouldn't be about paying more, it should be reducing health-care costs, but prevention is probably one of the best ways to do it.

Warren Czerniak 42:26

If I can jump in. The perfect example to that is in female health, when I was talking this whole story about menopause. If you can address it early on, alleviate some of the symptoms—there's the economic piece, but there's also issues with bone loss. Well, if the policy is that you don't allow to do a DEXA scan until you're 65, it's too late. The damage has already started to be done. So, the concept of preventative medicine is perfect. It's brilliant. But you're right. There's a misalignment, and people want to treat and want to pay once somebody has got a serious illness. Right?

Neerja Balachander 43:05

If I can—again, there's another problem. I think you brought it up before this, Brian. It's also about how we're actually studying clinical trials. If it's only targeted remaining unmet need, which means that we're saying all the problems are solved. You were talking about—and that really resonated with me—you were saying something about how 80 percent of the patients are not qualified for the trials that are ongoing. If you looked at the discrepancy between the utilization of certain drugs—let's say, if it's diabetes or hypertension, you looked at the latest medications, whether it's SGLT2s or GLPs, you looked at the percentage of patients with diabetes, or even PCSK9s—if you're looking at these classes and looking at

what percentage of patients are getting these drugs, you'd find this to be a tiny percentage. It would not be upwards of 20 percent. I'm being very generous here. But if you looked at the clinical trial, your expectation is that your benefit is on top of all of those, as if everyone is getting them. Which makes two things really a big challenge for us. One is studying these patients, because then you are artificially studying a patient population that doesn't exist in your clinic. And two, your risk that you're reducing becomes that much more difficult, so it makes your clinical trial population extremely large and also the clinical trial extremely expensive. But the most important damage is that you are not actually addressing the complexity of the patients. I think there is a huge important need for our ability with the AI, with the data complexity, to be able to live in the space of gray. And I think this is a collaboration with regulators. It has to be a collaboration with policymakers that: (a) we are able to take real-world cases, take real-world solutions, and to be able to live in that gray, and to be able to pay for it in some reasonable manner. Because we should not be saying that, because your disease doesn't come for 10 years—which is what risk scores do—well, I can wait to pay for that in 10 years.

Sarah Wells Kocsis 45:16

Yeah. Well, speaking of incentives, we need to reward this audience. I have so many questions on this iPad. I don't know if we're going to have time to address them. So, I'm going to be looking at those, and we're going to conclude the last 15 minutes of the panel answering some audience Q&A. But before we do that, I can't help myself because I lead public health at the Milken Institute. I'm all for prevention, I'm all for moving upstream. But we have to think about population health, too. It can't just be a system designed around individual patients. So, does anyone want to just comment on that while I quickly look at what questions we'll take from the audience?

Neerja Balachander 45:59

Sure. Population health is a critical part of how we're going to address this at scale. I think we do have to balance it in my opinion, however, with the increasing amount of personalized care that we're kind of also pivoting towards. And there is, I think, a happy medium between marrying what can be a marker of disease, let's say, of risk—I think if you just thought about it, about five or six things would capture 80 percent of the risk in majority of patients. And I think these should be sort of socialized, if you will, and made a population health-care business while we balance some of these intricate nuances like genetic testing to personalized care. And I think there is a very sweet medium that has to be had, but I think I will leave that for AI.

Sarah Wells Kocsis 46:50

Okay, great. Thomas, I'm going to direct this one to you. It's about EHR and workflows. Is there a way to speed up the workflows so that they can align with guidelines and quality measures across payer programs and even at the state level? Is there a way to mandate this? Otherwise, it's too hard to educate providers. You can allow for exceptions, but there should be prompts according to joint guidelines.

Thomas Keane 47:27

I'm going to be honest, I'm not exactly sure what the question is asking. What I can say is one of the challenges with electronic health records is they were adopted by subsidy and mandate. And when the electronic health record companies were trying to optimize their software for the initial uptake, they were selling to hospital CEOs and CFOs, and they optimized their software for revenue cycle management.

They wanted to make sure that billing and coding worked out, and it did. In fact, hospitals that installed EHRs saw an increase in their collections and better revenue cycle management. One of the challenges was that the EHRs were not optimized for physician or patient or nurse workflow. And we have tried to work very hard with the electronic health record companies to help them gain insights from what we hear about how to optimize their workflows, and they're highly incentivized to make their software work better for physicians. Probably the best solution is to make the data interoperable so that point solutions can be built on top of the electronic health record. And the perfect example is an AI scribe. Right now, because of the ability to do voice to text and to be able to analyze the text that's created, physicians can now walk into an exam room with a patient, just hold a regular conversation. The AI scribe not only captures that information but structures it into a traditional physician's note, captures orders out of it, captures billing codes out of it, and organizes this all for the benefit of both the physician and the patient. And this is a point solution, a solution that was built on top of the electronic health record, that has been widely adopted by physicians and has been widely embraced by physicians, because it actually makes their workflow easier and makes their workflow more efficient. So, by making data interoperable, we let the market solve that problem for us, and we are really focused on making sure that that happens.

Sarah Wells Kocsis 49:41

Thank you so much. So many questions. So little time. "Community pharmacists provide chronic disease care to patients every day, but we're not included in meaningful use, or are largely disconnected from the health information available to the EHR. What are the highest-value efforts a pharmacy could undertake to contribute their expertise to whole-person care?"

Neerja Balachander 50:20

That's such a great question. I think some organizations are already doing it. The power of the pharmacist is used as a multiplier, if you will, of a specialist. And we know, we were just talking about how there are deserts of specialists. There are multiple places where there is no cardiologist, there might be no nephrologist or endocrinologist. And I think that's where even using some kind of technology, you can multiply the power of pharmacists. And again, that also depends, however, on state law. I think some states allow them to independently prescribe, but some states do not. However, again, if you use it under the supervision of an expert, that's a magnifier. I will also say that it's not so much access to the EMR as it is integration of some kind of workflow. So, you need to have a very clear set of—let's take for instance, even if it's obesity care, we know that specialists do not have the time to go through prior authorizations for these. And the number of patients who are asking for them is exploding. This is exactly where I think a pharmacist model can really smoothen health care.

Brian Foard 51:35

I think it's a gap right now. I think it's actually gotten a little bit worse. We've lost that. Pharmacists were one of the most trusted health professionals for the patients for a long time. And I think one of the things that we're talking about, this particular patient population, the Danas of the world, really relied on their pharmacists to help provide additional information post that seven-and-a-half-minute or 10 minutes that they might have gotten, to answer a lot of the questions that they still walked out of the practice with, because that's really common. Individuals sit in their car in a parking lot and go, "I just got a lot of information. I'm overwhelmed." And a pharmacist used to play a really important role. I think that is a gap right now. Less and less you see that the case for a lot of these chronic conditions. Now, you do see a bit

of a difference on the specialty side. So, just as you were alluding to, I think, perfectly, you're seeing that's actually been a surge. We've seen the specialty pharmacy network has become—and so much so, they even have teams that make calls to clinics to say, "Hey, send your patients to me. I will help support what you're doing in your practice and educate those patients and help them get their therapies, prior authorizations, so on and so forth." So, I think it's a great question, whoever asked that, because I think for this particular patient population, it's gotten actually worse than better. However, I would say for the specialist or for the patient suffering from—or smaller patient populations, high specialty type of disease states—we've seen a surge of people filling the gap, I would say, from a specialty pharmacy standpoint.

Thomas Keane 53:07

Yeah. Count me in agreement that pharmacists are an underutilized resource. And we understand that pharmacists, behavioral health providers, and many other providers of great importance to the patient's well-being were left out of the meaningful use incentives during the rapid phase of adoption of EHRs. What we're trying to do is lower the cost of information exchange so that, say, for example, a pharmacy system can come onto TEFCA and be able to pull patients' information so that this is available to the pharmacist at the time of dispensing or at the time of consult with a patient. And pharmacists, if I'm correct, are HIPAA-covered providers, so it's relatively easy for them to pass the vetting to get onto these networks. We do have a pharmacy work stream. We've worked on trying to get information from the pharmacies, the pharmacy benefit manufacturers, and—I'm sorry, the pharmacy benefit managers and the manufacturers—to the point of care so that physicians, nurse practitioners, and other prescribers can see how much a drug will cost and can choose the lowest-cost therapeutically equivalent option for a patient. We call that our real-time prescription benefit functionality, which we mandated about a year and a half ago and which is now near universal in its uptake. We've also asked electronic health records to subscribe to cash pay data feeds so that they know how much a patient will have to pay if they pay cash. Because about a quarter of the time, it can be even cheaper than what the patient will pay under their prescription drug benefit. So, all of this has actually been implemented. And the next time you go to a doctor, you should ask them is that the cheapest of the various alternative drugs, because typically, that information is available. But it is very much one of our focuses of getting this information before other providers like pharmacists. So, we are thinking about it.

Sarah Wells Kocsis 55:02

I've gotten some interesting questions about other aspects of integrated chronic disease care, mental health, diet, food. Should we keep it open-ended, or are there boundaries around what defines integrated chronic care?

Thomas Keane 55:23

Well, I'll jump in first because nobody listens to me in real life. So, when I have a captive audience, this is very exciting for me. Secretary Kennedy is speaking here later in the day. He's my boss, and he's been a great boss. And he has really undertaken an effort to include things like nutrition, exercise, lifestyle into the overall care and well-being of a patient. It's a huge focus of what we're doing. So, for example, in our interoperable data sets, we've started including nutrition information, which we'd like doctors to capture. So, this is really the administration in which information that determines 85 percent of a patient's health outcomes, that lies outside of the medical system, can be captured and leveraged for the benefit of the

patient. And Secretary Kennedy is really a champion of this. And make sure if you see him, to tell him that I pumped him up or I carried his message, so.

Sarah Wells Kocsis 56:29

I'm going to move to one last lightning round question. Would anybody like to tack on to that last question about mental health or...?

Warren Czerniak 56:40

I'll tack on just from the point of view that it's been highly stigmatized forever. We happen to be focused in the area of mood disorder, so we talk about schizophrenia and bipolar mania and bipolar depression and major depressive disorder. And I think it came from a period where it was a shame, and you were shamed if you had some sort of an issue. Right? And it was also a lack of education. Someone was laying on the couch, and they'd get chastised for being lazy. "Snap out of it." Right? Attention deficit disorder, all these various areas of mental health are real. I think the one thing that came out of COVID, that we saw, was that there was an openness to talk about it. And the reality is there's a significant portion of the population that gets impacted by mental health disorders. So, as far as I'm concerned, it should be much more open. It should be much more integrated. What we see is that it's not just psychiatry. Primary care treats a tremendous amount of these disorders. So, when you get severe diseases like schizophrenia, that has a tendency to be in the hands of the psychiatrist. But these other mood disorders, this becomes a primary care discussion. And it impacts millions and millions and millions of people. So, yes, I'm all for it.

Sarah Wells Kocsis 58:07

This has been a great discussion. We're going to close out with just a one-sentence answer, but if you could change one thing in the next two years in policy, payment, data, practice to make integrated care more of the norm, what would it be? Warren?

Warren Czerniak 58:25

Access. Improving access. That's not an easy thing because it takes time, but access and reimbursement. So, this is not a one solution, right? There's multiple pieces. But if there was one thing, it would be improved access for patients.

Sarah Wells Kocsis 58:40

Thank you. Neerja?

Neerja Balachander 58:41

I'd say simplify screening and pay for prevention.

Sarah Wells Kocsis 58:45

Brian?

Brian Foard 58:46

I would say deep collaboration from all stakeholders.

Sarah Wells Kocsis 58:50

Thomas?

Thomas Keane 58:52

I would say information sharing. The folks who hold information, be it hospital systems or software vendors, I would like them to take a posture of sharing that information, privately and securely, but when it's in the interest of the patient.

Warren Czerniak 59:06

So as you can see, there's no one answer.

Sarah Wells Kocsis 59:08

Well, and thank you all. And I want to—

Neerja Balachander 59:11

Put them all together.

Sarah Wells Kocsis 59:12

—I want to go back to Dana. We can't forget about Dana. Today, she's the care coordinator for her own health. But we have this opportunity in front of us to build a system that can work for her and take a bite out of a $3 trillion problem. So, thank you so much for sharing your insights and helping us get to that place where we need to be for Dana. Thank you all so much for coming.

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