We're very honored to have Doctor McGovern join us today.

Doctor McGovern received her PhD in Genetics from the Mount Sinai Graduate School of Biomedical Sciences and her MD from Mount Sinai School of Medicine.

She completed her residency in Pediatric Pediatrics and Fellowship in Clinical and Molecular Genetics at Mount Sinai.

Before joining Yale, Dr. McGovern was the NAP Professor of Pediatrics and Dean of Clinical Affairs at the Renaissance School of Medicine.
at Stony Brook and vice president of the Stony Brook Medicine Health System Clinical Programs and Strategy.

Prior to assuming those roles, in 2018 she was chair of Pediatrics and Physician in chief at Stony Brook Children’s Hospital.

In 2022, Doctor McGovern was appointed the deputy Dean for clinical affairs at the Yale School of Medicine, the Chief Executive Officer of Yale Medicine and the executive vice president and chief physician for Yale New Haven Health.
00:01:01.968 --> 00:01:03.679 to have her join us today.

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00:01:09.640 --> 00:01:11.440 Thank you. And thanks for

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00:01:11.440 --> 00:01:13.491 inviting me to talk and be

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00:01:13.491 --> 00:01:14.997 the final speaker of the day.

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00:01:15.000 --> 00:01:17.079 But you’re all still alert and awake,

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00:01:17.080 --> 00:01:18.160 so this is a good sign.

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00:01:21.320 --> 00:01:23.480 I’m going to tell you a little bit about

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00:01:23.480 --> 00:01:25.523 some of the work we’ve been doing over

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00:01:25.523 --> 00:01:28.412 the past year to better support clinical

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00:01:28.412 --> 00:01:30.334 research throughout the enterprise.

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00:01:30.334 --> 00:01:32.469 So inclusive of the school

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00:01:32.469 --> 00:01:34.360 and the health system.

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00:01:34.360 --> 00:01:38.490 And this is, was identified as a

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00:01:38.490 --> 00:01:40.360 pillar of alignment between the School

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00:01:40.360 --> 00:01:42.000 of Medicine and the health system,

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an important pillar to leverage
the intellectual infrastructure and innovation and the efforts of the faculty in the School of Medicine and bring the findings that you all make to the bedside of the patients that are cared for within the health system.
So the rationale for this joint strategic approach, I find it interesting that we had to have a rationale that is completely obvious. We should be doing this work together. But the rationale to drive this work because historically this wasn’t really the philosophy here is to support the health system.
and the school’s common mission of innovation in the development of preventive diagnostic and therapeutic modalities and improve systems of care to enhance health outcomes for populations of patients. Also to improve patient outcomes by accelerating the implementation of innovative new diagnostic and therapeutic approaches. I think we have huge opportunity here. The keyword in this one being accelerating that we should be nimble, we should have these systems in place to bring to the bedside discoveries that
we make here in our own School of Medicine.

You know one frankly that sticks out of my mind was the development of the drug here to delay the onset of diabetes in children. And we were not the first people in the country to give that drug to a patient. So that’s our lack of nimbleness to be able to stand up a program supported, get it done, get it over the finish line. And I know we can do this work. We just have to have the systems in place.

And then of course to increase access to patients who were seeking enrollment in clinical research protocols.
Also to increase recruitment and retention of outstanding clinicians, staff and trainees by providing these opportunities to innovate and making it easy for them to see their work realized in the clinical environment. And I’ve spoken to a lot of mid career faculty in the 8-9 to 20 months or so that I’ve been here. And I’ve heard from many of them that this is they find it very difficult to navigate our complex health system to bring to the bedside or to bring their programs or their ideas to fruition. And we really have to do a better
job with that on the clinical side
also to devote some attention to
increasing industry sponsored clinical research to provide all relevant trial modalities for our patients and balance our clinical research finances to release more opportunities for highly innovative research projects.
So you know like in most things in life, one also has to be fiscally responsible, have financial models that are sustainable and diversifying our research portfolio is another way to do that.
Want to leverage the broad diversity of academic strength across the university and health system and enhance clinical
00:04:31.430 --> 00:04:33.740 value in systems of care through research
00:04:33.800 --> 00:04:35.880 related to healthcare delivery science.
00:04:35.880 --> 00:04:38.519 So there was a work group constituted
00:04:38.520 --> 00:04:42.120 to take these rationale and principles
00:04:42.120 --> 00:04:46.420 and try to bring life to them in
00:04:46.420 --> 00:04:49.354 meaningful ways that would impact how we
00:04:49.354 --> 00:04:50.873 do this work across the health system.
00:04:50.880 --> 00:04:53.244 And this was a collaborative effort
00:04:53.244 --> 00:04:56.013 with Brian Smith and Dave Coleman and
00:04:56.013 --> 00:04:58.624 Yolanda London who did a stellar job
00:04:58.698 --> 00:05:01.260 helping to coordinate this group on one
00:05:01.260 --> 00:05:03.720 of the first things we went out with,
00:05:03.720 --> 00:05:05.550 which was trying to wrestle the
00:05:05.550 --> 00:05:07.519 issue of having a single IRB.
00:05:07.520 --> 00:05:11.212 But there is a whole work plan for this
NOTE Confidence: 0.9272505133333333
that this group developed to really
figure out how do we do a better job
in Bend embedding clinical research
I've also met a lot of you who are
looking for spaces to bring your
research patients in a proper clinical
environment where it’s not just a
room with no windows and no sink,
but it’s a proper place to bring a patient,
which is what we need to be doing.
And everyone trying to figure
that that out for themselves,
which you know is really unnecessary
if we could get it together to
identify these spaces,
00:05:43.920 --> 00:05:46.032 you know strategically place them across
our geography in our outpatient locations available to any investigator to come.
So everyone's not sort of trying to create that for themselves and with great difficulty I might add in great expense and sometimes bringing patients to places that you know you really don’t want to bring them, you know they should come to a setting that’s like any clinical setting. They’d go for their care so that you have all of that respect and infrastructure built into the encounter with your research patients.
So some of the strategic objectives of this work group were to create a governance structure to facilitate and coordinate clinical research across the entire enterprise, build extended infrastructure to support clinical research throughout our catchment area, enhance discovery through strength and biomedical informatics, data science and precision medicine. Sort of getting to Holland’s comment about getting access to data and how do we, doing it in a safe, responsible, compliant way,
but not putting so many barriers in place that it makes it very difficult for people to access information they need to do their research and foster an understanding of an engagement and research across the health system. We’ve got, we’ve got a fair bit to do there. You know the leadership in the health system is has not been well connected back to what goes on, what goes on across the street and school medicine. And they really need to gain an understanding of an engagement and research across the health system.
appreciation of what your work is,
NOTE Confidence: 0.855387948
how you spend your time,
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what it takes to write in an IH grant,
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which is a huge piece of work and and
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to really understand the power of the
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research that’s going on in the school.
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And I think,
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there’s been a lot of progress made
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as we’ve been taking this alignment
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path at one of the health system
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about what innovation and
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science is going on in the school.
That was I think one of the most popular things the trustees had heard in a long time.

They were very excited by this.

It was like wow, you know, this is right here and we haven’t been leveraging and capitalizing on it and you know, and celebrating, you know this work and how we can bring it to the bedside of the patients in our own health system.

And it’s not just you know, patient, direct, patient oriented research.

I’ve heard a lot about some of the
work that goes on in our division of general internal medicine and some of the work that they do that nationally is recognized, embraced and integrated into thinking about planning for healthcare. And a lot of those initiatives we don’t deploy here. I mean you know, this doesn’t really make sense. So we have to line these things up better that you know, we’re really leveraging all of the assets that we have at our disposal. So the specific goals of this work group or you know to develop governance,
you need strong governance to make something sustainable and to get buy in.

So the governance structure proposed is a joint clinical research strategic planning group charging YCCI which is of course the school program with supporting clinical research functions across the entire health system and having that clinical research space planning group that would do what I referenced go out and find what are the appropriate locations to have that touchdown space for research patients.
small lab area in some of these, some of these locations and really understand what are the needs of our clinical investigators and help try to meet those needs and do it in a geographically dispersed way. So that patients don’t have to all travel into New Haven or travel to your one location that you’re able to sort of stand up. But you can go out and recruit patients from lots of locations for infrastructure is what ruined my life for a few months, helped try to create a single system wide Institutional Review Board and oversight structure for all aspects
related to HRPP and leveraging investments in YCCI. We had about 1000 meetings about this topic. But I am incredibly happy to report we got this over the finish line. This is happening. You're going to be hearing a lot about it. It was a lot of work. Obviously there were legal, regulatory, compliance, all sorts of issues. There are cultural issues, there are issues related to how siloed we are across our hospitals. There are proprietary issues and people feeling like they own this or that.
Somehow we’ll mess it up by making it a single IRB.

We got past all those things and it required a lot of conversation, a lot of buy in.

We twisted a couple of people’s arms also.

We are there and we are going to have a single system wide IRIRB and I think the more of our faculty who are working sometimes exclusively in the other hospitals in the health system.

You know this is a big responsibility to our faculty to make it easy for them to be in those other settings, to be able to do their research and not have to be trying to navigate...
you know a system in one of the so-called DN hospitals that sometimes were not created in a way that would feel familiar to someone coming out of a university setting. Because it sort of a very different mindset and approach about the responsibility for overseeing research that involves human beings also trying to create a single feasibility review framework for research. And what we found when we were doing the one IRB work there were a lot of things being classified as
human research mostly in the other
hospitals that really warrant,
you know, they were really performance
improvement or quality improvement.
They don’t need full IRB review.
So there’s a lot to do here to
really make this process nimble,
keep it focused on what it needs
to focus on and to take care of
the other things in a way that’s more nimble,
less resource intense.
And also and we have not done this yet,
putting in place you know how we
can expand the investigational
drug service across the health system in a seamless way. So if your clinical trial involves a drug or a new agent, this would be hard to do right now across the entire health system the way it’s structured. But we can make this just like we brought together the one IRB concept much more nimble for investigators. And also a big goal is enhancing discovery through biomedical informatics, data science and precision medicine. And get then gets back a
little bit to Harlan’s issue.

And trying to do all these things,

increase awareness training

and participation in biomedical

informatics and data science research.

Not just increase that awareness,

but make it easy to do that,

develop increased capacity for

AI and digital technologies

and implementation science.

And you know,

I think you’re probably all aware

that the Provost has convened a

committee to look at AI and what

does the university

want to do in this space?
Increased partnership with the Yale School of Medicine Library. We took a big step towards this just in the past week or so with really trying to get to a single library platform across the entire health system with common resources available to faculty no matter where their privileges are right now. This is very arcane system that you know what access you get to hospital you have your prudential in as a physician you know which really doesn’t serve us very well.
So how do we make progress on that? How do we modernize the library function at places like Bridgeport and Greenwich and LMH that you know clearly aren’t going to have the resources and infrastructure to develop a library like like we have here. Make HIPAA compliant electronic health record data more accessible to investigators while you know building those standards to keep it safe. That around usage and training and compliance, redesigned the research function of the so-called JDAT, this joint data management group and streamline decision making for data access.
We have a huge opportunity here. JDAT gets requests for all sorts of things. I’d say 75% of which don’t have the value proposition for the resource that goes into them. In fact, they are asked to pull data and reports and information, a lot of it for trainees that those same people who requested never access it. So you know, this really needs to be cleaned up. This is a really powerful tool and it’s fantastic that we have this group here. But access to that group and
the work that they’re doing, you know needs a little bit more governance. Recruiting a leader to implement precision medicine that’s obviously the Dean’s office function not this group’s. But was in the mix of the thinking about what do we need to support such a person. And expanding the Yale School of Medicine biorepository making it increasingly accessible while consolidating individual biorepositories as you know an efficiency measure. And to make sure that we’re building something that will be a powerful tool for investigators across the school.
and finished on time

and thanking thank you for asking

me to talk to you about this is

real important work a little bit

tedious a little bit in the weeds

but really important and it’s a nice

bright spot in my day to think about

something other than revenue cycle.

We and we very much appreciate

you coming and I think

you know for why wait for obesity

research this is absolutely

incredibly important across the

system how do we get our patients

in as participants into these

29
00:15:41.213 --> 00:15:43.399 studies and and so highly relevant.
NOTE Confidence: 0.88275988

00:15:43.400 --> 00:15:44.928 So we thank you.
NOTE Confidence: 0.88275988

00:15:44.928 --> 00:15:46.948 Any quick questions for Doctor
NOTE Confidence: 0.88275988

00:15:46.948 --> 00:15:49.118 McGovern before we continue on?
NOTE Confidence: 0.805036

00:15:51.240 --> 00:15:51.800 Yes.
NOTE Confidence: 0.802117296428571

00:15:55.880 --> 00:15:58.785 So I was wondering like we're studying
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00:15:58.785 --> 00:16:01.527 obesity in the determinants of you
NOTE Confidence: 0.802117296428571

00:16:01.527 --> 00:16:04.338 know outcome in the real world and we
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00:16:04.338 --> 00:16:06.720 need the real data and you mentioned
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00:16:06.720 --> 00:16:09.165 like we can you know use health record
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00:16:09.165 --> 00:16:11.199 data and and and the former speaker
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00:16:11.199 --> 00:16:13.615 also alluded to that that it would be
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00:16:13.682 --> 00:16:15.719 great to have access to these data.
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00:16:15.720 --> 00:16:19.650 But I think we should also then build
NOTE Confidence: 0.802117296428571

00:16:19.650 --> 00:16:22.375 consensus on how to standardize
NOTE Confidence: 0.802117296428571

00:16:22.375 --> 00:16:24.600 how we record data.
But also maybe in case of your interest it would be great to have some very simple questionnaires or any data that would usually not be there in a health record. So.

So do you think it’s possible to create a new data field from every single patient and walks into the health system. Yeah, I mean I think it’s possible to do that throughout, you know, specific departments that deal with people with obesity. So, you know, I think it’s possible to create, you’re talking about collecting a new data field from every single patient and walks into the health system.
would that would go back point back to the governance part of this because on the one hand, you can’t be asking 4000 questions of patients, right. And then there’s privacy and other issues, but on the other hand, we do add things all the time. Right now we ask about social determinants of health. That’s relatively new. So putting these things in is a possibility. The more that our patients engage with the portal or being able to answer some of these things, you know, before they even come to their visit. Those are all tools we need to
leverage to do things like that. But I think in the end, like adding a question that you’re going to ask every patient who comes, you know, there’s got to be some kind of a governance decision. There’s got to be somebody that decides that you know there’s benefit from doing that because you know all of that just adds to the intake time etcetera. So definitely possible and leveraging the EMR to do that, you know I think is is a smart
thing to do when you know I think we're starting to do more and more than that especially in the social determinant space which is probably relevant to obesity research. So I think soliciting input from our clinical investigators about what, what kind of basic information would you like to know about everybody just because you know, it might be useful for a study in the future. You know, I think is, you know, has merit to consider. Great. Thank you so much. And we're going to keep moving along because Dean Brown
00:18:21.180 --> 00:18:22.440 has to get to a meeting.

00:18:22.440 --> 00:18:24.888 But John, I’m sure that Doctor McGovern will answer your question after if that’s OK.

00:18:27.006 --> 00:18:28.638 Thank you so much.