WEBVTT

NOTE duration:"00:58:06"

NOTE recognizability:0.875

NOTE language:en-us

NOTE Confidence: 0.88321682875

 $00:00:00.000 \rightarrow 00:00:02.382$ I'm delighted to introduce our first

NOTE Confidence: 0.88321682875

 $00{:}00{:}02{.}382 \dashrightarrow 00{:}00{:}04{.}143$ speaker today, Doctor Joel Ross.

NOTE Confidence: 0.88321682875

 $00{:}00{:}04{.}143 \dashrightarrow 00{:}00{:}06{.}390$ He's a professor of medicine in general

NOTE Confidence: 0.88321682875

 $00{:}00{:}06{.}447 \dashrightarrow 00{:}00{:}08{.}505$ medicine and professor of public health

NOTE Confidence: 0.88321682875

 $00:00:08.505 \rightarrow 00:00:10.560$ and health policy and management.

NOTE Confidence: 0.88321682875

 $00:00:10.560 \dashrightarrow 00:00:12.900$ After receiving his medical degree at

NOTE Confidence: 0.88321682875

00:00:12.900 --> 00:00:15.240 the Albert Einstein College of Medicine,

NOTE Confidence: 0.88321682875

 $00:00:15.240 \longrightarrow 00:00:16.960$ Doctor Ross came to Yale.

NOTE Confidence: 0.88321682875

 $00{:}00{:}16{.}960 \dashrightarrow 00{:}00{:}19{.}552$ Follow in the Robert Wood Johnson

NOTE Confidence: 0.88321682875

00:00:19.552 --> 00:00:21.775 Clinical Scholars Program in 2004.

NOTE Confidence: 0.88321682875

00:00:21.775 --> 00:00:25.735 He has had a very distinguished career since,

NOTE Confidence: 0.88321682875

 $00{:}00{:}25.740 \dashrightarrow 00{:}00{:}28.344$ with a focus on examining factors that

NOTE Confidence: 0.88321682875

 $00:00:28.344 \rightarrow 00:00:31.166$ affect use or delivery of recommended

00:00:31.166 --> 00:00:33.334 hospital and ambulatory care,

NOTE Confidence: 0.88321682875

 $00{:}00{:}33{.}340 \dashrightarrow 00{:}00{:}36{.}500$ as well as clinical outcomes of such care.

NOTE Confidence: 0.88321682875

 $00{:}00{:}36{.}500 \dashrightarrow 00{:}00{:}39{.}800$ Today his topic is leveraging real-world

NOTE Confidence: 0.88321682875

 $00:00:39.800 \rightarrow 00:00:42.620$ data through pragmatic clinical trials.

NOTE Confidence: 0.88321682875

 $00:00:42.620 \rightarrow 00:00:44.450$ Doctor Ross the floor is yours.

NOTE Confidence: 0.825991351428572

00:00:46.460 --> 00:00:47.156 Thank you chairman.

NOTE Confidence: 0.825991351428572

00:00:47.156 --> 00:00:48.548 Thank you for inviting me to

NOTE Confidence: 0.825991351428572

 $00{:}00{:}48.548 \dashrightarrow 00{:}00{:}49.967$ speak before the Cancer Center and

NOTE Confidence: 0.825991351428572

 $00{:}00{:}49{.}967 \dashrightarrow 00{:}00{:}51{.}410$ part of the grand rounds today.

NOTE Confidence: 0.825991351428572

 $00:00:51.410 \dashrightarrow 00:00:54.042$ I'm delighted to share some of the

NOTE Confidence: 0.825991351428572

 $00:00:54.042 \longrightarrow 00:00:56.066$ work that I've been working on

NOTE Confidence: 0.825991351428572

 $00:00:56.066 \dashrightarrow 00:00:57.837$ over the past several years and to

NOTE Confidence: 0.825991351428572

 $00:00:57.837 \rightarrow 00:00:59.409$ identify potential opportunities for

NOTE Confidence: 0.825991351428572

 $00:00:59.409 \longrightarrow 00:01:00.675$ collaboration with investigators

NOTE Confidence: 0.825991351428572

 $00:01:00.675 \dashrightarrow 00:01:02.363$ throughout the Cancer Center.

NOTE Confidence: 0.825991351428572

 $00:01:02.370 \longrightarrow 00:01:04.008$ I also could not be happier to

 $00:01:04.008 \longrightarrow 00:01:05.710$ be sharing the stage with Susan

NOTE Confidence: 0.825991351428572

00:01:05.710 --> 00:01:07.230 Bush today because, you know,

NOTE Confidence: 0.825991351428572

00:01:07.230 --> 00:01:08.970 when I was a clinical scholar,

NOTE Confidence: 0.825991351428572

 $00:01:08.970 \longrightarrow 00:01:10.930$ kind of lost looking for a mentor.

NOTE Confidence: 0.825991351428572

 $00:01:10.930 \longrightarrow 00:01:13.485$ Way back almost 20 years ago now,

NOTE Confidence: 0.825991351428572

 $00{:}01{:}13.490 \dashrightarrow 00{:}01{:}15.008$ Susan was the only person to

NOTE Confidence: 0.825991351428572

 $00{:}01{:}15{.}008 \dashrightarrow 00{:}01{:}16{.}250$ open her door to me.

NOTE Confidence: 0.825991351428572

 $00:01:16.250 \longrightarrow 00:01:18.186$ When she got she helped me get my

NOTE Confidence: 0.825991351428572

00:01:18.186 --> 00:01:20.143 career started so I couldn't be more

NOTE Confidence: 0.825991351428572

 $00:01:20.143 \rightarrow 00:01:21.558$ grateful for everything she's done

NOTE Confidence: 0.825991351428572

00:01:21.610 -> 00:01:23.426 to help me get started in my career.

NOTE Confidence: 0.825991351428572

 $00{:}01{:}23.430 \dashrightarrow 00{:}01{:}25.075$ So I'm just going to get started

NOTE Confidence: 0.825991351428572

 $00{:}01{:}25{.}075 \dashrightarrow 00{:}01{:}26{.}340$ and talk about this work.

NOTE Confidence: 0.825991351428572

00:01:26.340 --> 00:01:27.081 Please you know,

NOTE Confidence: 0.825991351428572

 $00{:}01{:}27.081 \dashrightarrow 00{:}01{:}28.810$ jump in with questions through the chat.

00:01:28.810 --> 00:01:31.909 I'll try to keep an eye on it just to note,

NOTE Confidence: 0.825991351428572

 $00{:}01{:}31{.}909 \dashrightarrow 00{:}01{:}33{.}174$ some of the potential competing

NOTE Confidence: 0.825991351428572

 $00{:}01{:}33{.}174 \dashrightarrow 00{:}01{:}34{.}640$ interests that inform the work that

NOTE Confidence: 0.825991351428572

 $00:01:34.640 \rightarrow 00:01:36.008$ I'm going to be presenting today.

NOTE Confidence: 0.825991351428572

 $00:01:36.010 \dashrightarrow 00:01:38.230$ I do get research grant funding

NOTE Confidence: 0.825991351428572

 $00:01:38.230 \longrightarrow 00:01:40.514$ through Yale from the FDA as part NOTE Confidence: 0.825991351428572

00:01:40.514 --> 00:01:42.836 of the Yale Mayo Clinic Center for

NOTE Confidence: 0.825991351428572

00:01:42.836 --> 00:01:44.220 Excellence in Regulatory Science

NOTE Confidence: 0.825991351428572

 $00:01:44.278 \longrightarrow 00:01:45.090$ and Innovation.

NOTE Confidence: 0.825991351428572

 $00:01:45.090 \rightarrow 00:01:46.826$ I'll talk a little bit about that work.

NOTE Confidence: 0.825991351428572

 $00{:}01{:}46.830 \dashrightarrow 00{:}01{:}48.944$ As well as from the medical Devices

NOTE Confidence: 0.825991351428572

00:01:48.944 --> 00:01:50.510 Innovation Consortium to run something

NOTE Confidence: 0.825991351428572

 $00{:}01{:}50{.}510 \dashrightarrow 00{:}01{:}52{.}322$ called Nest along with some funds

NOTE Confidence: 0.825991351428572

00:01:52.322 --> 00:01:54.310 from Johnson and Johnson for clinical

NOTE Confidence: 0.825991351428572

 $00:01:54.310 \longrightarrow 00:01:55.638$ trial data sharing initiatives

NOTE Confidence: 0.825991351428572

 $00:01:55.638 \rightarrow 00:01:57.144$ at federal government awards,

 $00:01:57.144 \longrightarrow 00:02:00.063$ as well as the Laura and John

NOTE Confidence: 0.825991351428572

00:02:00.063 --> 00:02:01.390 Arnold Foundation.

NOTE Confidence: 0.825991351428572

 $00:02:01.390 \longrightarrow 00:02:02.190$ So this is just,

NOTE Confidence: 0.825991351428572

 $00:02:02.190 \longrightarrow 00:02:02.590$ you know,

NOTE Confidence: 0.825991351428572

 $00:02:02.590 \longrightarrow 00:02:04.186$ to get us started you know here

NOTE Confidence: 0.825991351428572

 $00{:}02{:}04{.}186 \dashrightarrow 00{:}02{:}06{.}291$ you know we see some pictures of

NOTE Confidence: 0.825991351428572

00:02:06.291 --> 00:02:07.651 individuals you know searching

NOTE Confidence: 0.825991351428572

 $00:02:07.651 \longrightarrow 00:02:08.550$ for evidence to,

NOTE Confidence: 0.825991351428572

 $00:02:08.550 \rightarrow 00:02:09.910$ you know as they have a clinical question,

NOTE Confidence: 0.825991351428572

 $00:02:09.910 \longrightarrow 00:02:10.870$ they're trying to make a decision

NOTE Confidence: 0.825991351428572

 $00:02:10.870 \dashrightarrow 00:02:12.158$ about what to do for their patients.

NOTE Confidence: 0.825991351428572

 $00{:}02{:}12.160 \dashrightarrow 00{:}02{:}13.410$ Or to then, you know,

NOTE Confidence: 0.825991351428572

 $00{:}02{:}13{.}410 \dashrightarrow 00{:}02{:}15{.}084$ sit down with their patient and

NOTE Confidence: 0.825991351428572

00:02:15.084 --> 00:02:16.549 make a suggestion or recommendation

NOTE Confidence: 0.825991351428572

 $00:02:16.549 \longrightarrow 00:02:18.885$ around a drug to use and you know,

 $00:02:18.890 \rightarrow 00:02:20.480$ typically you know when we think

NOTE Confidence: 0.825991351428572

 $00{:}02{:}20{.}480 \dashrightarrow 00{:}02{:}22{.}122$ about this sort of the hierarchy

NOTE Confidence: 0.825991351428572

 $00:02:22.122 \longrightarrow 00:02:23.712$ of evidence and you know what

NOTE Confidence: 0.825991351428572

 $00:02:23.712 \longrightarrow 00:02:25.487$ we want to guide our decisions.

NOTE Confidence: 0.825991351428572

00:02:25.490 --> 00:02:25.942 You know,

NOTE Confidence: 0.825991351428572

 $00{:}02{:}25{.}942 \dashrightarrow 00{:}02{:}27{.}298$ we look for evidence that you

NOTE Confidence: 0.825991351428572

 $00:02:27.298 \dashrightarrow 00:02:28.958$ know is at this level or higher.

NOTE Confidence: 0.825991351428572

 $00:02:28.960 \dashrightarrow 00:02:31.450$ You know randomized control trials.

NOTE Confidence: 0.825991351428572

 $00:02:31.450 \dashrightarrow 00:02:33.914$ You know to guide our decisions or

NOTE Confidence: 0.825991351428572

 $00:02:33.914 \dashrightarrow 00:02:35.420$ perhaps systematic reviews that

NOTE Confidence: 0.825991351428572

00:02:35.420 --> 00:02:36.988 are aggregating RCT evidence,

NOTE Confidence: 0.825991351428572

 $00:02:36.990 \longrightarrow 00:02:39.090$ and ideally when it's been meta

NOTE Confidence: 0.825991351428572

 $00:02:39.090 \longrightarrow 00:02:41.480$ analyzed to put it all together.

NOTE Confidence: 0.825991351428572

 $00{:}02{:}41{.}480 \dashrightarrow 00{:}02{:}43{.}279$ But there's been a lot of changes

NOTE Confidence: 0.825991351428572

 $00:02:43.279 \rightarrow 00:02:45.458$ in the way we understand evidence,

NOTE Confidence: 0.825991351428572

 $00:02:45.460 \rightarrow 00:02:47.602$ in part because of the advancement

- NOTE Confidence: 0.825991351428572
- $00{:}02{:}47.602 \dashrightarrow 00{:}02{:}50.519$ and methods to use a large data sources,
- NOTE Confidence: 0.825991351428572
- $00:02:50.520 \rightarrow 00:02:53.022$ but also because of other challenges
- NOTE Confidence: 0.825991351428572
- $00{:}02{:}53{.}022 \dashrightarrow 00{:}02{:}56{.}160$ that have faced both the FDA and others.
- NOTE Confidence: 0.825991351428572
- $00:02:56.160 \dashrightarrow 00:02:58.254$ But what you'll have noticed over
- NOTE Confidence: 0.825991351428572
- $00:02:58.254 \rightarrow 00:03:00.466$ the past decade is, you know,
- NOTE Confidence: 0.825991351428572
- $00:03:00.466 \longrightarrow 00:03:01.690$ increasingly thinking about.
- NOTE Confidence: 0.825991351428572
- $00:03:01.690 \longrightarrow 00:03:04.961$ A new and novel ways to evaluate
- NOTE Confidence: 0.825991351428572
- $00:03:04.961 \longrightarrow 00:03:07.516$ medical products and the the.
- NOTE Confidence: 0.825991351428572
- $00:03:07.520 \longrightarrow 00:03:09.746$ With failings of the past to
- NOTE Confidence: 0.825991351428572
- 00:03:09.746 --> 00:03:11.860 identify a safety issues earlier,
- NOTE Confidence: 0.825991351428572
- 00:03:11.860 00:03:14.135 you began to see ways to think
- NOTE Confidence: 0.825991351428572
- $00{:}03{:}14.135 \dashrightarrow 00{:}03{:}16.109$ about what's being called a
- NOTE Confidence: 0.825991351428572
- $00:03:16.109 \rightarrow 00:03:17.965$ lifecycle approach to evaluation.
- NOTE Confidence: 0.825991351428572
- $00{:}03{:}17{.}970 \dashrightarrow 00{:}03{:}19{.}878$ So it's not just about that
- NOTE Confidence: 0.825991351428572
- 00:03:19.878 --> 00:03:20.832 first RCT evidence,
- NOTE Confidence: 0.837503126

 $00:03:20.840 \rightarrow 00:03:23.598$ it's going to inform use and in part

NOTE Confidence: 0.837503126

 $00{:}03{:}23{.}598 \dashrightarrow 00{:}03{:}25{.}554$ that was because premarket studies that

NOTE Confidence: 0.837503126

 $00:03:25.554 \rightarrow 00:03:27.677$ inform FDA approval are often limited,

NOTE Confidence: 0.837503126

00:03:27.680 --> 00:03:29.660 limited in size, limited in scope,

NOTE Confidence: 0.837503126

 $00:03:29.660 \longrightarrow 00:03:30.770$ limited in the end points

NOTE Confidence: 0.837503126

 $00:03:30.770 \longrightarrow 00:03:31.880$ on which they're focused on.

NOTE Confidence: 0.837503126

 $00{:}03{:}31.880 \dashrightarrow 00{:}03{:}33.392$ They're not looking at the kind of

NOTE Confidence: 0.837503126

00:03:33.392 -> 00:03:35.076 they're not big enough studies to

NOTE Confidence: 0.837503126

 $00:03:35.076 \rightarrow 00:03:36.388$ identify important safety concerns,

NOTE Confidence: 0.837503126

 $00:03:36.390 \rightarrow 00:03:37.322$ and sometimes they're not

NOTE Confidence: 0.837503126

 $00:03:37.322 \longrightarrow 00:03:38.254$ even studies that are.

NOTE Confidence: 0.837503126

 $00{:}03{:}38{.}260 \dashrightarrow 00{:}03{:}39{.}980$ Guaranteed to confirm the

NOTE Confidence: 0.837503126

 $00:03:39.980 \longrightarrow 00:03:41.700$ efficacy of a product.

NOTE Confidence: 0.837503126

 $00:03:41.700 \rightarrow 00:03:43.190$ They're they're focusing on surrogate

NOTE Confidence: 0.837503126

 $00:03:43.190 \rightarrow 00:03:45.220$ markers as endpoints in order to project,

NOTE Confidence: 0.837503126

 $00:03:45.220 \longrightarrow 00:03:46.592$ benefit, predict,

- NOTE Confidence: 0.837503126
- 00:03:46.592 -> 00:03:49.336 benefit through these markers,
- NOTE Confidence: 0.837503126
- $00{:}03{:}49{.}340 \dashrightarrow 00{:}03{:}51{.}740$ and then those are supposed to be done
- NOTE Confidence: 0.837503126
- $00{:}03{:}51{.}740 \dashrightarrow 00{:}03{:}53{.}540$ in tandem with postmarket studies.
- NOTE Confidence: 0.837503126
- 00:03:53.540 --> 00:03:54.340 You know,
- NOTE Confidence: 0.837503126
- $00{:}03{:}54{.}340 \dashrightarrow 00{:}03{:}56{.}326$ trials that are going to happen
- NOTE Confidence: 0.837503126
- $00{:}03{:}56{.}326 \dashrightarrow 00{:}03{:}58{.}430$ after the the approval and but the
- NOTE Confidence: 0.837503126
- $00:03:58.430 \dashrightarrow 00:04:00.506$ problem has been that those trials
- NOTE Confidence: 0.837503126
- $00:04:00.506 \rightarrow 00:04:02.660$ frequently are delayed and they're
- NOTE Confidence: 0.837503126
- $00:04:02.660 \rightarrow 00:04:04.935$ just not even consistently completed.
- NOTE Confidence: 0.837503126
- $00:04:04.940 \longrightarrow 00:04:06.578$ This in combination with the fact
- NOTE Confidence: 0.837503126
- $00{:}04{:}06{.}578 \dashrightarrow 00{:}04{:}08{.}655$ that we were never ever going to
- NOTE Confidence: 0.837503126
- 00:04:08.655 $-\!>$ 00:04:10.515 be able to address each remaining
- NOTE Confidence: 0.837503126
- $00:04:10.515 \rightarrow 00:04:12.139$ uncertainty through clinical trials,
- NOTE Confidence: 0.837503126
- 00:04:12.140 --> 00:04:13.780 has led to, you know,
- NOTE Confidence: 0.837503126
- $00:04:13.780 \longrightarrow 00:04:14.944$ opportunities for you know
- NOTE Confidence: 0.837503126

 $00:04:14.944 \longrightarrow 00:04:16.108$ what you're hearing now.

NOTE Confidence: 0.837503126

 $00{:}04{:}16.110 \dashrightarrow 00{:}04{:}17.320$ Kind of real world data.

NOTE Confidence: 0.837503126

00:04:17.320 --> 00:04:21.086 Real-world data as a the way forward,

NOTE Confidence: 0.837503126

 $00:04:21.090 \rightarrow 00:04:23.340$ and regulatory science and evaluation.

NOTE Confidence: 0.837503126

00:04:23.340 --> 00:04:24.282 And you know,

NOTE Confidence: 0.837503126

 $00{:}04{:}24{.}282 \dashrightarrow 00{:}04{:}26{.}746$ this is this quote from a high level

NOTE Confidence: 0.837503126

 $00{:}04{:}26.746 \dashrightarrow 00{:}04{:}28.474$ official at the FDA is illustrative.

NOTE Confidence: 0.837503126

00:04:28.480 --> 00:04:29.246 You know,

NOTE Confidence: 0.837503126

 $00{:}04{:}29{.}246 \dashrightarrow 00{:}04{:}31{.}544$ using RWE to begin to address

NOTE Confidence: 0.837503126

 $00:04:31.544 \longrightarrow 00:04:33.788$ these questions as preferable to

NOTE Confidence: 0.837503126

 $00:04:33.788 \longrightarrow 00:04:35.660$ having no evidence whatsoever.

NOTE Confidence: 0.837503126

00:04:35.660 --> 00:04:37.396 And you know, with the advent of,

NOTE Confidence: 0.837503126

 $00{:}04{:}37{.}400 \dashrightarrow 00{:}04{:}39{.}116$ you know industry and FDA talking

NOTE Confidence: 0.837503126

 $00:04:39.116 \longrightarrow 00:04:40.260$ more about real-world data.

NOTE Confidence: 0.837503126

 $00{:}04{:}40{.}260 \dashrightarrow 00{:}04{:}41{.}772$ You're starting to see you know

NOTE Confidence: 0.837503126

00:04:41.772 --> 00:04:43.100 more and more companies popping

- NOTE Confidence: 0.837503126
- $00:04:43.100 \longrightarrow 00:04:44.440$ up that you know promising.

 $00{:}04{:}44{.}440 \dashrightarrow 00{:}04{:}45{.}936$ We're world analytics to

NOTE Confidence: 0.837503126

 $00:04:45.936 \longrightarrow 00:04:47.058$ deliver real-world evidence.

NOTE Confidence: 0.837503126

00:04:47.060 --> 00:04:49.164 And you know, I'll just sort of say,

NOTE Confidence: 0.837503126

 $00:04:49.170 \longrightarrow 00:04:50.238$ you know, this is, you know,

NOTE Confidence: 0.837503126

00:04:50.240 --> 00:04:51.428 buzzword alert, right?

NOTE Confidence: 0.837503126

 $00:04:51.428 \longrightarrow 00:04:54.199$ This is a big problem that where the

NOTE Confidence: 0.837503126

 $00:04:54.199 \longrightarrow 00:04:56.040$ the sort of the promise is getting

NOTE Confidence: 0.837503126

00:04:56.097 --> 00:04:57.705 way ahead of what is actually,

NOTE Confidence: 0.837503126

 $00:04:57.710 \longrightarrow 00:04:59.348$ you know what we're capable of,

NOTE Confidence: 0.837503126

 $00:04:59.350 \longrightarrow 00:05:00.560$ and what we're capable of,

NOTE Confidence: 0.837503126

 $00{:}05{:}00{.}560 \dashrightarrow 00{:}05{:}02{.}512$ sort of understanding reliably.

NOTE Confidence: 0.837503126

00:05:02.512 --> 00:05:03.000 Really,

NOTE Confidence: 0.837503126

 $00{:}05{:}03{.}000 \dashrightarrow 00{:}05{:}05{.}780$ what we're talking about now are the use of.

NOTE Confidence: 0.837503126

 $00:05:05.780 \dashrightarrow 00:05:07.760$ You know cohort studies case control studies.

- 00:05:07.760 --> 00:05:08.572 You know,
- NOTE Confidence: 0.837503126
- $00:05:08.572 \rightarrow 00:05:10.196$ leveraging observational data resources
- NOTE Confidence: 0.837503126
- $00:05:10.200 \longrightarrow 00:05:12.032$ and and in part this is not only
- NOTE Confidence: 0.837503126
- $00:05:12.032 \rightarrow 00:05:13.655$ a recognition of the limitations
- NOTE Confidence: 0.837503126
- 00:05:13.655 --> 00:05:15.135 of premarket regulatory approval,
- NOTE Confidence: 0.837503126
- $00:05:15.140 \dashrightarrow 00:05:17.212$ but also you know a major advocacy
- NOTE Confidence: 0.837503126
- $00:05:17.212 \rightarrow 00:05:18.462$ push that's happening towards
- NOTE Confidence: 0.837503126
- $00:05:18.462 \longrightarrow 00:05:20.274$ real-world data that has led to,
- NOTE Confidence: 0.837503126
- 00:05:20.280 --> 00:05:20.982 you know,
- NOTE Confidence: 0.837503126
- $00:05:20.982 \rightarrow 00:05:22.737$ new legislation the 21st Century
- NOTE Confidence: 0.837503126
- $00{:}05{:}22.737 \dashrightarrow 00{:}05{:}25.252$ Cures Act that passed at the tail
- NOTE Confidence: 0.837503126
- $00:05:25.252 \rightarrow 00:05:26.997$ end of the Obama administration,
- NOTE Confidence: 0.837503126
- 00:05:27.000 --> 00:05:27.862 you know,
- NOTE Confidence: 0.837503126
- $00:05:27.862 \rightarrow 00:05:30.614$ had very clear goals that to push
- NOTE Confidence: 0.837503126
- 00:05:30.614 --> 00:05:32.396 towards a real world data use,
- NOTE Confidence: 0.837503126
- $00:05:32.400 \rightarrow 00:05:34.344$ including requiring the FDA

 $00:05:34.344 \longrightarrow 00:05:36.288$ to establish a program.

NOTE Confidence: 0.837503126

 $00:05:36.290 \longrightarrow 00:05:38.040$ To evaluate real-world evidence which

NOTE Confidence: 0.837503126

 $00:05:38.040 \rightarrow 00:05:40.229$ that was defined in the legislation

NOTE Confidence: 0.837503126

 $00:05:40.229 \rightarrow 00:05:42.840$ as data regarding the usage or the

NOTE Confidence: 0.837503126

 $00{:}05{:}42.840 \dashrightarrow 00{:}05{:}44.776$ potential benefits or risks of a

NOTE Confidence: 0.837503126

 $00{:}05{:}44.776 \dashrightarrow 00{:}05{:}46.462$ drug or device derived from sources

NOTE Confidence: 0.837503126

 $00{:}05{:}46{.}470 \dashrightarrow 00{:}05{:}49{.}230$ other than randomized control trials.

NOTE Confidence: 0.837503126

 $00:05:49.230 \longrightarrow 00:05:51.085$ Now, this isn't to say that you

NOTE Confidence: 0.837503126

 $00{:}05{:}51.085 \dashrightarrow 00{:}05{:}53.068$ know all real world data are bad.

NOTE Confidence: 0.837503126

 $00:05:53.070 \rightarrow 00:05:55.583$ The typical or traditional PWB of today

NOTE Confidence: 0.837503126

 $00{:}05{:}55{.}583 \dashrightarrow 00{:}05{:}58{.}670$ is work that you know many investigators,

NOTE Confidence: 0.837503126

 $00{:}05{:}58{.}670 \dashrightarrow 00{:}06{:}00{.}510$ including my group at Yale,

NOTE Confidence: 0.837503126

 $00{:}06{:}00{.}510 \dashrightarrow 00{:}06{:}01{.}222$ do right.

NOTE Confidence: 0.837503126

 $00{:}06{:}01.222 \dashrightarrow 00{:}06{:}02.646$ So it's advanced observation.

NOTE Confidence: 0.837503126

 $00:06:02.650 \rightarrow 00:06:03.674$ ULL research,

 $00:06:03.674 \rightarrow 00:06:05.210$ including clinical epidemiology,

NOTE Confidence: 0.837503126

 $00{:}06{:}05{.}210$ --> $00{:}06{:}06{.}790$ to inform product development.

NOTE Confidence: 0.837503126

00:06:06.790 --> 00:06:09.160 You know issues around disease prevalence,

NOTE Confidence: 0.837503126

 $00:06:09.160 \rightarrow 00:06:11.868$ prognosis and treatment adherence.

NOTE Confidence: 0.885214616111111

 $00:06:11.870 \rightarrow 00:06:14.628$ This type of evidence is generally used

NOTE Confidence: 0.885214616111111

 $00:06:14.628 \rightarrow 00:06:16.209$ for secondary indication approvals

NOTE Confidence: 0.885214616111111

00:06:16.209 --> 00:06:18.575 for rare diseases or for you know,

NOTE Confidence: 0.885214616111111

 $00:06:18.580 \rightarrow 00:06:21.244$ diseases that are with well understood

NOTE Confidence: 0.885214616111111

 $00:06:21.244 \rightarrow 00:06:22.576$ pathophysiology and progression,

NOTE Confidence: 0.885214616111111

 $00{:}06{:}22.580 \dashrightarrow 00{:}06{:}25.620$ and it's very limited and it's used for

NOTE Confidence: 0.885214616111111

 $00:06:25.620 \rightarrow 00:06:27.699$ initial regulatory approval decisions,

NOTE Confidence: 0.885214616111111

 $00:06:27.700 \rightarrow 00:06:29.800$ mostly because those products are

NOTE Confidence: 0.885214616111111

 $00:06:29.800 \dashrightarrow 00:06:31.895$ not used in such wides pread way

NOTE Confidence: 0.885214616111111

 $00:06:31.895 \rightarrow 00:06:33.677$ that you can actually leverage

NOTE Confidence: 0.885214616111111

 $00:06:33.677 \rightarrow 00:06:36.299$ existing data sources to study there,

NOTE Confidence: 0.885214616111111

 $00:06:36.300 \rightarrow 00:06:38.025$ that the effectiveness and safety

 $00:06:38.025 \longrightarrow 00:06:39.060$ of the product.

NOTE Confidence: 0.885214616111111

 $00:06:39.060 \rightarrow 00:06:40.092$ And of course,

NOTE Confidence: 0.885214616111111

 $00:06:40.092 \rightarrow 00:06:42.500$ most commonly of these types of studies

NOTE Confidence: 0.885214616111111

 $00:06:42.569 \rightarrow 00:06:44.704$ are used for safety surveillance

NOTE Confidence: 0.885214616111111

 $00{:}06{:}44.704 \dashrightarrow 00{:}06{:}46.839$ or registry registry based medical

NOTE Confidence: 0.885214616111111

00:06:46.907 --> 00:06:48.888 device studies and just to bring

NOTE Confidence: 0.885214616111111

 $00{:}06{:}48.888 \dashrightarrow 00{:}06{:}50.854$ your attention to some of the work

NOTE Confidence: 0.885214616111111

 $00:06:50.854 \rightarrow 00:06:53.014$ that we've done as part of our group.

NOTE Confidence: 0.885214616111111

 $00{:}06{:}53.020 \dashrightarrow 00{:}06{:}54.784$ And I did want to just sort of flag

NOTE Confidence: 0.885214616111111

 $00{:}06{:}54.784 \dashrightarrow 00{:}06{:}56.013$ this because there's individuals

NOTE Confidence: 0.885214616111111

 $00:06:56.013 \rightarrow 00:06:57.981$ here attending the grand rounds who

NOTE Confidence: 0.885214616111111

 $00{:}06{:}57{.}981 \dashrightarrow 00{:}06{:}59{.}877$ may be interested in collaborating.

NOTE Confidence: 0.885214616111111

00:06:59.880 --> 00:07:02.372 I lead a couple of efforts that

NOTE Confidence: 0.885214616111111

 $00{:}07{:}02.372 \dashrightarrow 00{:}07{:}04.545$ essentially work closely with FDA to

NOTE Confidence: 0.885214616111111

00:07:04.545 --> 00:07:06.609 generate evidence to address kind of

 $00:07:06.609 \rightarrow 00:07:09.434$ unmet needs at the At the Agency this often.

NOTE Confidence: 0.885214616111111

 $00:07:09.440 \longrightarrow 00:07:10.840$ This is through our Searcy.

NOTE Confidence: 0.885214616111111

 $00{:}07{:}10.840 \dashrightarrow 00{:}07{:}12.608$ We are one of four that are funded

NOTE Confidence: 0.885214616111111

 $00:07:12.608 \longrightarrow 00:07:14.714$ by the FDA to do collaborative

NOTE Confidence: 0.885214616111111

00:07:14.714 --> 00:07:15.917 regulatory science research,

NOTE Confidence: 0.885214616111111

00:07:15.920 --> 00:07:17.240 but it's also through nest,

NOTE Confidence: 0.885214616111111

 $00{:}07{:}17.240 \dashrightarrow 00{:}07{:}19.872$ which is a a network of health systems

NOTE Confidence: 0.885214616111111

 $00:07:19.872 \longrightarrow 00:07:22.083$ that are working with real world data.

NOTE Confidence: 0.885214616111111

00:07:22.083 --> 00:07:22.716 Or, you know,

NOTE Confidence: 0.885214616111111

 $00:07:22.720 \longrightarrow 00:07:23.005$ essentially,

NOTE Confidence: 0.885214616111111

 $00{:}07{:}23.005 \dashrightarrow 00{:}07{:}24.715$ we're working with our health system

NOTE Confidence: 0.885214616111111

 $00:07:24.715 \longrightarrow 00:07:26.526$ data to try to evaluate medical

NOTE Confidence: 0.885214616111111

 $00{:}07{:}26.526 \dashrightarrow 00{:}07{:}28.682$ devices in practice and these types

NOTE Confidence: 0.885214616111111

 $00{:}07{:}28.682 \dashrightarrow 00{:}07{:}31.580$ of studies you know tend to look

NOTE Confidence: 0.885214616111111

 $00:07:31.674 \rightarrow 00:07:33.760$ like this project where we look,

NOTE Confidence: 0.885214616111111

 $00:07:33.760 \longrightarrow 00:07:35.630$ try to better understand the

 $00:07:35.630 \rightarrow 00:07:37.500$ safety and efficacy of individuals

NOTE Confidence: 0.885214616111111

 $00:07:37.566 \dashrightarrow 00:07:39.406$ who are switching from branded.

NOTE Confidence: 0.885214616111111

 $00{:}07{:}39{.}410 \dashrightarrow 00{:}07{:}42{.}062$ We both are rocks into generic

NOTE Confidence: 0.885214616111111

 $00:07:42.062 \rightarrow 00:07:44.859$ looking at its impact and effect.

NOTE Confidence: 0.885214616111111

 $00:07:44.860 \rightarrow 00:07:46.716$ Thyroid stimulation hormone levels

NOTE Confidence: 0.885214616111111

 $00{:}07{:}46.716$ --> $00{:}07{:}49.036$ and other markers of efficacy.

NOTE Confidence: 0.885214616111111

00:07:49.040 --> 00:07:49.828 This project,

NOTE Confidence: 0.885214616111111

 $00:07:49.828 \rightarrow 00:07:51.798$ where we're where we're aggregating

NOTE Confidence: 0.885214616111111

 $00:07:51.798 \dashrightarrow 00:07:54.318$ data across the state of Connecticut,

NOTE Confidence: 0.885214616111111

 $00{:}07{:}54{.}320$ --> $00{:}07{:}56{.}525$ including hospital data and mortality

NOTE Confidence: 0.885214616111111

 $00{:}07{:}56.525 \dashrightarrow 00{:}07{:}59.120$ data and other vital statistic data,

NOTE Confidence: 0.885214616111111

 $00{:}07{:}59{.}120$ --> $00{:}08{:}02{.}064$ then even EMS data to try to better

NOTE Confidence: 0.885214616111111

 $00{:}08{:}02{.}064 \dashrightarrow 00{:}08{:}04{.}280$ understand opioid use disorder and

NOTE Confidence: 0.885214616111111

00:08:04.280 --> 00:08:06.850 overdose including, uh, you know,

NOTE Confidence: 0.885214616111111

 $00:08:06.850 \longrightarrow 00:08:08.500$ throughout the state.

 $00:08:08.500 \rightarrow 00:08:10.789$ Work like this where we're trying to

NOTE Confidence: 0.885214616111111

 $00{:}08{:}10.789 \dashrightarrow 00{:}08{:}12.185$ understand the comparative effectiveness

NOTE Confidence: 0.885214616111111

 $00:08:12.185 \longrightarrow 00:08:14.363$ of safety of oral anticoagulants in

NOTE Confidence: 0.885214616111111

 $00:08:14.363 \rightarrow 00:08:15.880$ patients with a trial fibrillation

NOTE Confidence: 0.885214616111111

00:08:15.880 --> 00:08:17.740 who have poor kidney function.

NOTE Confidence: 0.885214616111111

 $00{:}08{:}17.740 \dashrightarrow 00{:}08{:}19.504$ These types of patients are often

NOTE Confidence: 0.885214616111111

00:08:19.504 --> 00:08:20.680 excluded from clinical trials,

NOTE Confidence: 0.885214616111111

 $00:08:20.680 \rightarrow 00:08:22.647$ but FDA is often tasked with trying

NOTE Confidence: 0.885214616111111

 $00{:}08{:}22.647 \dashrightarrow 00{:}08{:}24.117$ to understand and give direction

NOTE Confidence: 0.885214616111111

 $00:08:24.117 \longrightarrow 00:08:25.833$ on their safety and benefits for

NOTE Confidence: 0.885214616111111

 $00:08:25.833 \longrightarrow 00:08:27.627$ use of this kind of research,

NOTE Confidence: 0.885214616111111

 $00{:}08{:}27.630 \dashrightarrow 00{:}08{:}29.182$ as well as this.

NOTE Confidence: 0.885214616111111

 $00{:}08{:}29{.}182 \dashrightarrow 00{:}08{:}31{.}510$ This registry based study where you

NOTE Confidence: 0.885214616111111

 $00:08:31.591 \rightarrow 00:08:34.879$ know we looked at different types of cardio.

NOTE Confidence: 0.885214616111111

 $00:08:34.880 \dashrightarrow 00:08:36.680$ Cardiac pump devices and looking

NOTE Confidence: 0.885214616111111

 $00:08:36.680 \longrightarrow 00:08:37.760$ at their safety,

00:08:37.760 - 00:08:39.495 especially for patients who are

NOTE Confidence: 0.885214616111111

00:08:39.495 --> 00:08:41.230 having acute heart attack and

NOTE Confidence: 0.885214616111111

00:08:41.295 --> 00:08:42.719 are in cardiogenic shock,

NOTE Confidence: 0.885214616111111

 $00:08:42.720 \longrightarrow 00:08:44.490$ so lots of individuals are doing

NOTE Confidence: 0.885214616111111

 $00:08:44.490 \rightarrow 00:08:46.407$ work like this that are leveraging

NOTE Confidence: 0.885214616111111

 $00{:}08{:}46{.}407 \dashrightarrow 00{:}08{:}48{.}787$ existing data sources to try to bring

NOTE Confidence: 0.885214616111111

 $00:08:48.787 \rightarrow 00:08:50.548$ greater insights into the safety

NOTE Confidence: 0.885214616111111

 $00:08:50.548 \dashrightarrow 00:08:53.558$ and benefit of various products.

NOTE Confidence: 0.885214616111111

00:08:53.560 --> 00:08:54.400 But I think you know,

NOTE Confidence: 0.885214616111111

 $00:08:54.400 \longrightarrow 00:08:56.312$ as the sort of the call for real

NOTE Confidence: 0.885214616111111

 $00:08:56.312 \rightarrow 00:08:57.460$ world evidence gets louder.

NOTE Confidence: 0.885214616111111

 $00{:}08{:}57{.}460 \dashrightarrow 00{:}08{:}59{.}076$ You know one caution to keep in mind

NOTE Confidence: 0.885214616111111

00:08:59.076 --> 00:09:00.651 is that observation ULL data sources

NOTE Confidence: 0.885214616111111

 $00{:}09{:}00{.}651 \dashrightarrow 00{:}09{:}02{.}686$ should not be expected to answer the

NOTE Confidence: 0.885214616111111

 $00{:}09{:}02.686 \dashrightarrow 00{:}09{:}04.201$ same clinical questions that are

 $00:09:04.201 \rightarrow 00:09:05.700$ being answered by traditional clinical.

NOTE Confidence: 0.885214616111111

 $00:09:05.700 \longrightarrow 00:09:07.100$ Clinical trials and we have

NOTE Confidence: 0.885214616111111

 $00:09:07.100 \longrightarrow 00:09:08.220$ to think about ways

NOTE Confidence: 0.939815838421053

 $00:09:08.275 \rightarrow 00:09:10.489$ to make sure that the evidence is being used.

NOTE Confidence: 0.939815838421053

 $00:09:10.490 \longrightarrow 00:09:11.855$ Compliment you know,

NOTE Confidence: 0.939815838421053

 $00:09:11.855 \dashrightarrow 00:09:14.585$ to complement the existing RCT evidence.

NOTE Confidence: 0.939815838421053

 $00{:}09{:}14.590 \dashrightarrow 00{:}09{:}16.414$ This is an example of a project that

NOTE Confidence: 0.939815838421053

 $00:09:16.414 \rightarrow 00:09:18.342$ a student working with me did a couple

NOTE Confidence: 0.939815838421053

 $00{:}09{:}18.342 \dashrightarrow 00{:}09{:}20.013$ of years ago trying to understand

NOTE Confidence: 0.939815838421053

 $00:09:20.013 \rightarrow 00:09:21.673$ the feasibility of using real-world

NOTE Confidence: 0.939815838421053

 $00{:}09{:}21.673 \dashrightarrow 00{:}09{:}23.498$ data to replicate clinical trial

NOTE Confidence: 0.939815838421053

 $00:09:23.498 \dashrightarrow 00:09:26.396$ evidence and what she did is she

NOTE Confidence: 0.939815838421053

 $00:09:26.396 \rightarrow 00:09:28.082$ identified among all the clinical

NOTE Confidence: 0.939815838421053

 $00:09:28.082 \longrightarrow 00:09:29.990$ trials that had been published in

NOTE Confidence: 0.939815838421053

 $00:09:30.054 \rightarrow 00:09:32.740$ high impact medical journals in 2017.

NOTE Confidence: 0.939815838421053

 $00:09:32.740 \longrightarrow 00:09:34.800$ She determined what proportion

- NOTE Confidence: 0.939815838421053
- $00:09:34.800 \longrightarrow 00:09:36.848$ had and in clinical intervention.
- NOTE Confidence: 0.939815838421053
- $00{:}09{:}36{.}848 \dashrightarrow 00{:}09{:}39{.}552$ The clinical indication of the of the
- NOTE Confidence: 0.939815838421053
- $00:09:39.552 \rightarrow 00:09:41.296$ patients who were studied enrollment
- NOTE Confidence: 0.939815838421053
- $00:09:41.296 \rightarrow 00:09:43.312$ criteria as well as a primary
- NOTE Confidence: 0.939815838421053
- $00:09:43.312 \rightarrow 00:09:45.260$ endpoint that could be successfully
- NOTE Confidence: 0.939815838421053
- $00:09:45.260 \longrightarrow 00:09:47.028$ in routinely ascertained from
- NOTE Confidence: 0.939815838421053
- $00:09:47.028 \dashrightarrow 00:09:48.796$ either electronic health records.
- NOTE Confidence: 0.939815838421053
- 00:09:48.800 --> 00:09:50.360 Structured electronic health records,
- NOTE Confidence: 0.939815838421053
- 00:09:50.360 --> 00:09:51.920 data or claims data,
- NOTE Confidence: 0.939815838421053
- $00:09:51.920 \longrightarrow 00:09:54.424$ and what we found is that only 15%
- NOTE Confidence: 0.939815838421053
- $00:09:54.424 \rightarrow 00:09:57.328$ of these trials could feasibly have
- NOTE Confidence: 0.939815838421053
- $00:09:57.328 \dashrightarrow 00:09:59.725$ been replicated using this kind
- NOTE Confidence: 0.939815838421053
- 00:09:59.725 --> 00:10:01.880 of real world data resource.
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}01{.}880 \dashrightarrow 00{:}10{:}04{.}554$ When the 21st Century Cures Act passed,
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}04{.}560 \dashrightarrow 00{:}10{:}07{.}040$ the FDA was actually pretty quick to say,
- NOTE Confidence: 0.939815838421053

 $00:10:07.040 \longrightarrow 00:10:07.419$ listen,

NOTE Confidence: 0.939815838421053

 $00:10:07.419 \rightarrow 00:10:09.693$ real-world data should be defined by

NOTE Confidence: 0.939815838421053

 $00{:}10{:}09{.}693 \dashrightarrow 00{:}10{:}11{.}958$ the context in which the evidence

NOTE Confidence: 0.939815838421053

00:10:11.958 --> 00:10:14.076 is gathered in clinical care or

NOTE Confidence: 0.939815838421053

00:10:14.076 --> 00:10:15.980 home and community settings,

NOTE Confidence: 0.939815838421053

 $00:10:15.980 \longrightarrow 00:10:18.245$ as opposed to necessarily in

NOTE Confidence: 0.939815838421053

 $00:10:18.245 \rightarrow 00:10:20.057$ research or academic environments,

NOTE Confidence: 0.939815838421053

 $00{:}10{:}20.060 \dashrightarrow 00{:}10{:}22.082$ and the distinction is not based

NOTE Confidence: 0.939815838421053

 $00{:}10{:}22.082 \dashrightarrow 00{:}10{:}23.833$ necessarily on the presence or

NOTE Confidence: 0.939815838421053

 $00:10:23.833 \rightarrow 00:10:25.855$ absence of a planned intervention or

NOTE Confidence: 0.939815838421053

 $00{:}10{:}25.855 \dashrightarrow 00{:}10{:}27.720$ use of randomization randomization.

NOTE Confidence: 0.939815838421053

00:10:27.720 --> 00:10:28.776 Essentially, they're saying,

NOTE Confidence: 0.939815838421053

 $00:10:28.776 \longrightarrow 00:10:29.480$ you know,

NOTE Confidence: 0.939815838421053

 $00:10:29.480 \rightarrow 00:10:31.370$ continue to seek out opportunities

NOTE Confidence: 0.939815838421053

 $00{:}10{:}31{.}370 \dashrightarrow 00{:}10{:}32{.}126$ to conduct.

NOTE Confidence: 0.939815838421053

 $00:10:32.130 \rightarrow 00:10:33.462$ Randomized evaluations using

- NOTE Confidence: 0.939815838421053
- $00:10:33.462 \rightarrow 00:10:35.682$ pragmatic trials that better leverage
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}35.682 \dashrightarrow 00{:}10{:}38.319$ kind of the existing data resource
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}38.319 \dashrightarrow 00{:}10{:}40.419$ infrastructure to make them perhaps
- NOTE Confidence: 0.939815838421053
- $00:10:40.419 \rightarrow 00:10:42.167$ cheaper or easier to conduct.
- NOTE Confidence: 0.939815838421053
- 00:10:42.170 --> 00:10:44.840 But it's not just about substituting
- NOTE Confidence: 0.939815838421053
- $00:10:44.840 \longrightarrow 00:10:45.285$ observation,
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}45{.}290 \dashrightarrow 00{:}10{:}47{.}800$ ULL data analysis for randomized
- NOTE Confidence: 0.939815838421053
- 00:10:47.800 --> 00:10:48.804 control trials,
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}48.810 \dashrightarrow 00{:}10{:}51.148$ and I'm always reminded of this quote.
- NOTE Confidence: 0.939815838421053
- 00:10:51.150 --> 00:10:51.616 You know,
- NOTE Confidence: 0.939815838421053
- $00:10:51.616 \rightarrow 00:10:53.247$ if you want more evidence based practice,
- NOTE Confidence: 0.939815838421053
- $00:10:53.250 \rightarrow 00:10:56.430$ you need more practice based evidence.
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}56{.}430 \dashrightarrow 00{:}10{:}58{.}086$ So in in the next 10 minutes I'm
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}58.086 \dashrightarrow 00{:}10{:}59.691$ going to talk a little bit about
- NOTE Confidence: 0.939815838421053
- $00{:}10{:}59.691 \dashrightarrow 00{:}11{:}01.322$ some of the work that we've been
- NOTE Confidence: 0.939815838421053

 $00:11:01.322 \rightarrow 00:11:03.186$ doing to try to better leverage.

NOTE Confidence: 0.939815838421053

00:11:03.186 --> 00:11:06.144 Kind of pragmatic clinical trials in

NOTE Confidence: 0.939815838421053

 $00:11:06.144 \dashrightarrow 00:11:08.510$ the hopes of showing you what I think is,

NOTE Confidence: 0.939815838421053

00:11:08.510 --> 00:11:09.416 I think,

NOTE Confidence: 0.939815838421053

 $00{:}11{:}09{.}416 \dashrightarrow 00{:}11{:}12{.}587$ the future of real world data investigations.

NOTE Confidence: 0.939815838421053

00:11:12.590 --> 00:11:14.730 It's not just about leveraging

NOTE Confidence: 0.939815838421053

 $00{:}11{:}14.730 \dashrightarrow 00{:}11{:}16.014$ observational data resources.

NOTE Confidence: 0.939815838421053

 $00:11:16.020 \longrightarrow 00:11:19.758$ This this is a slide from Cuba.

NOTE Confidence: 0.939815838421053

 $00{:}11{:}19.760 \dashrightarrow 00{:}11{:}21.908$ Take a data warehouse company that

NOTE Confidence: 0.939815838421053

 $00:11:21.908 \rightarrow 00:11:23.610$ aggregates information across of you,

NOTE Confidence: 0.939815838421053

 $00{:}11{:}23.610 \dashrightarrow 00{:}11{:}25.345$ know multiple multiple sources and

NOTE Confidence: 0.939815838421053

 $00{:}11{:}25{.}345 \dashrightarrow 00{:}11{:}27{.}657$ you know they talk about kind of

NOTE Confidence: 0.939815838421053

 $00{:}11{:}27.657 \dashrightarrow 00{:}11{:}29.721$ all the real world data that are out

NOTE Confidence: 0.939815838421053

 $00{:}11{:}29.789 \dashrightarrow 00{:}11{:}32.260$ there for for an individual from pharmacy,

NOTE Confidence: 0.939815838421053

00:11:32.260 --> 00:11:32.820 data,

NOTE Confidence: 0.939815838421053

 $00:11:32.820 \rightarrow 00:11:36.740$ lab and biomarker data to mortality data,

00:11:36.740 --> 00:11:39.100 hospital data claims data survey

NOTE Confidence: 0.939815838421053

00:11:39.100 -> 00:11:40.988 data disease registry data.

NOTE Confidence: 0.939815838421053

 $00:11:40.990 \rightarrow 00:11:42.455$ All these things could ideally

NOTE Confidence: 0.939815838421053

 $00:11:42.455 \rightarrow 00:11:43.334$ be linked together,

NOTE Confidence: 0.939815838421053

 $00:11:43.340 \rightarrow 00:11:44.820$ including even potentially social

NOTE Confidence: 0.939815838421053

00:11:44.820 --> 00:11:47.040 media data or wearables data or

NOTE Confidence: 0.939815838421053

00:11:47.105 --> 00:11:48.965 or even you know something like

NOTE Confidence: 0.939815838421053

00:11:48.965 --> 00:11:49.895 credit card data.

NOTE Confidence: 0.939815838421053

 $00:11:49.900 \dashrightarrow 00:11:52.172$ And this kind of is like the optimal

NOTE Confidence: 0.939815838421053

 $00:11:52.172 \rightarrow 00:11:53.960$ environment when you talk to people

NOTE Confidence: 0.939815838421053

00:11:53.960 --> 00:11:55.700 like the future of clinical trials,

NOTE Confidence: 0.939815838421053

 $00:11:55.700 \rightarrow 00:11:56.996$ it's going to pull all this

NOTE Confidence: 0.939815838421053

 $00:11:56.996 \longrightarrow 00:11:57.428$ information together.

NOTE Confidence: 0.939815838421053

00:11:57.430 --> 00:11:59.470 Putting the patient at the center

NOTE Confidence: 0.939815838421053

 $00{:}11{:}59{.}470 \dashrightarrow 00{:}12{:}02{.}055$ and mostly people talk about that as

 $00:12:02.055 \rightarrow 00:12:04.365$ being idealistic and not really achievable.

NOTE Confidence: 0.939815838421053

 $00:12:04.370 \longrightarrow 00:12:06.554$ But we've been working with a group

NOTE Confidence: 0.939815838421053

 $00{:}12{:}06{.}560 \dashrightarrow 00{:}12{:}09{.}549$ called Hugo that actually does just this.

NOTE Confidence: 0.939815838421053

 $00:12:09.550 \rightarrow 00:12:11.765$ It aggregates multiple data platforms

NOTE Confidence: 0.939815838421053

 $00{:}12{:}11.765 \dashrightarrow 00{:}12{:}13.980$ into a patient centered medical

NOTE Confidence: 0.906489560909091

 $00{:}12{:}14.046 \dashrightarrow 00{:}12{:}16.335$ record that the patient can then share

NOTE Confidence: 0.906489560909091

 $00{:}12{:}16.335 \dashrightarrow 00{:}12{:}18.944$ out with the research team as part of a,

NOTE Confidence: 0.906489560909091

00:12:18.944 --> 00:12:20.324 you know, our research project.

NOTE Confidence: 0.906489560909091

 $00{:}12{:}20{.}324 \dashrightarrow 00{:}12{:}23{.}170$ And so we this is the first study

NOTE Confidence: 0.906489560909091

 $00:12:23.170 \rightarrow 00:12:25.594$ we did at leveraging this platform.

NOTE Confidence: 0.906489560909091

 $00:12:25.600 \rightarrow 00:12:27.696$ It was done as part of our city.

NOTE Confidence: 0.906489560909091

 $00:12:27.700 \longrightarrow 00:12:30.115$ Our FT had funded center where

NOTE Confidence: 0.906489560909091

 $00:12:30.115 \longrightarrow 00:12:32.605$ we aggregated data for just 60

NOTE Confidence: 0.906489560909091

 $00:12:32.605 \rightarrow 00:12:34.678$ patients who were getting care

NOTE Confidence: 0.906489560909091

 $00:12:34.678 \rightarrow 00:12:37.303$ at Yale and at the Mayo Clinic.

NOTE Confidence: 0.906489560909091

 $00:12:37.310 \longrightarrow 00:12:39.914$ We recruited 15 patients at each

- NOTE Confidence: 0.906489560909091
- $00:12:39.914 \rightarrow 00:12:42.246$ site who are undergoing bariatric
- NOTE Confidence: 0.906489560909091
- 00:12:42.246 --> 00:12:44.444 surgery or A-fib ablation procedures.
- NOTE Confidence: 0.906489560909091
- 00:12:44.444 --> 00:12:46.384 A 59 patients under actually
- NOTE Confidence: 0.906489560909091
- $00:12:46.384 \rightarrow 00:12:48.253$ underwent the procedure and completed
- NOTE Confidence: 0.906489560909091
- $00:12:48.253 \longrightarrow 00:12:49.973$ our eight week follow up.
- NOTE Confidence: 0.906489560909091
- $00:12:49.980 \longrightarrow 00:12:50.684$ And what's?
- NOTE Confidence: 0.906489560909091
- $00:12:50.684 \rightarrow 00:12:53.148$ The beauty of this platform for research
- NOTE Confidence: 0.906489560909091
- $00:12:53.148 \rightarrow 00:12:55.345$ purposes is you sit down with a patient.
- NOTE Confidence: 0.906489560909091
- $00{:}12{:}55{.}350 \dashrightarrow 00{:}12{:}57{.}426$ You enroll them in the platform
- NOTE Confidence: 0.906489560909091
- $00:12:57.430 \longrightarrow 00:12:59.445$ you link their electronic health
- NOTE Confidence: 0.906489560909091
- 00:12:59.445 --> 00:13:01.878 record data from any health system
- NOTE Confidence: 0.906489560909091
- $00:13:01.878 \longrightarrow 00:13:03.623$ from which they're gaining care
- NOTE Confidence: 0.906489560909091
- $00:13:03.623 \rightarrow 00:13:06.350$ or as well as their pharmacy data
- NOTE Confidence: 0.906489560909091
- $00{:}13{:}06{.}350 \dashrightarrow 00{:}13{:}08{.}450$ and and other information.
- NOTE Confidence: 0.906489560909091
- $00{:}13{:}08{.}450 \dashrightarrow 00{:}13{:}09{.}450$ And that takes time.
- NOTE Confidence: 0.906489560909091

 $00:13:09.450 \longrightarrow 00:13:11.276$ It took a little over an hour

NOTE Confidence: 0.906489560909091

 $00{:}13{:}11{.}276 \dashrightarrow 00{:}13{:}12{.}616$ for all of our patients,

NOTE Confidence: 0.906489560909091

 $00:13:12.620 \longrightarrow 00:13:14.110$ but once you do that,

NOTE Confidence: 0.906489560909091

 $00:13:14.110 \rightarrow 00:13:15.935$ everything that happens next over

NOTE Confidence: 0.906489560909091

 $00{:}13{:}15{.}935 \dashrightarrow 00{:}13{:}18{.}620$ the 88 week follow up for the

NOTE Confidence: 0.906489560909091

 $00{:}13{:}18.620 \dashrightarrow 00{:}13{:}20.580$ patients is all passive patient

NOTE Confidence: 0.906489560909091

 $00:13:20.580 \rightarrow 00:13:22.560$ their patients data aggregates.

NOTE Confidence: 0.906489560909091

 $00{:}13{:}22.560 \dashrightarrow 00{:}13{:}25.656$ Automatically into the the system

NOTE Confidence: 0.906489560909091

 $00{:}13{:}25.660 \dashrightarrow 00{:}13{:}27.140$ being shared with the research

NOTE Confidence: 0.906489560909091

 $00:13:27.140 \longrightarrow 00:13:28.920$ team for research purposes and the

NOTE Confidence: 0.906489560909091

00:13:28.920 --> 00:13:30.378 patient never has to come back,

NOTE Confidence: 0.906489560909091

00:13:30.380 --> 00:13:31.288 and so you know,

NOTE Confidence: 0.906489560909091

 $00:13:31.288 \rightarrow 00:13:33.528$ this shows you that we were able to do this.

NOTE Confidence: 0.906489560909091

00:13:33.530 --> 00:13:34.410 You know,

NOTE Confidence: 0.906489560909091

 $00{:}13{:}34{.}410 \dashrightarrow 00{:}13{:}36{.}845$ with 60 patients you know we've had a

NOTE Confidence: 0.906489560909091

 $00:13:36.845 \rightarrow 00:13:38.660$ nice sort of broad spectrum of age ranges.

- NOTE Confidence: 0.906489560909091
- 00:13:38.660 --> 00:13:39.174 You know,
- NOTE Confidence: 0.906489560909091
- 00:13:39.174 --> 00:13:40.459 including a number of patients
- NOTE Confidence: 0.906489560909091
- $00:13:40.459 \longrightarrow 00:13:42.231$ over the age of 65 who were
- NOTE Confidence: 0.906489560909091
- $00:13:42.231 \rightarrow 00:13:43.416$ able to do this successfully.
- NOTE Confidence: 0.906489560909091
- $00:13:43.420 \rightarrow 00:13:45.149$ And here are the data we aggregated
- NOTE Confidence: 0.906489560909091
- $00:13:45.149 \longrightarrow 00:13:46.877$ and I'll start at the bottom left.
- NOTE Confidence: 0.906489560909091
- $00{:}13{:}46.880 \dashrightarrow 00{:}13{:}49.100$ The electronic health record data.
- NOTE Confidence: 0.906489560909091
- 00:13:49.100 00:13:50.915 So everyone was getting care
- NOTE Confidence: 0.906489560909091
- $00:13:50.915 \longrightarrow 00:13:52.730$ at either the Yale at.
- NOTE Confidence: 0.906489560909091
- $00:13:52.730 \longrightarrow 00:13:54.599$ Ill or the Mayo Clinic for their
- NOTE Confidence: 0.906489560909091
- $00:13:54.599 \rightarrow 00:13:56.240$ specialty care for this procedure,
- NOTE Confidence: 0.906489560909091
- $00{:}13{:}56{.}240 \dashrightarrow 00{:}13{:}57{.}766$ but also and so every one you know
- NOTE Confidence: 0.906489560909091
- $00{:}13{:}57.766 \dashrightarrow 00{:}13{:}59.209$ their care is managed through Epic
- NOTE Confidence: 0.906489560909091
- $00{:}13{:}59{.}209 \dashrightarrow 00{:}14{:}00{.}685$ and they have access to their
- NOTE Confidence: 0.906489560909091
- 00:14:00.685 00:14:02.165 my chart and they connect their
- NOTE Confidence: 0.906489560909091

 $00:14:02.165 \rightarrow 00:14:03.734$ my chart to their Hugo account,

NOTE Confidence: 0.906489560909091

 $00{:}14{:}03{.}734 \dashrightarrow 00{:}14{:}05{.}654$ but also individuals who have

NOTE Confidence: 0.906489560909091

 $00:14:05.654 \rightarrow 00:14:07.552$ primary care elsewhere were able

NOTE Confidence: 0.906489560909091

 $00:14:07.552 \rightarrow 00:14:09.334$ to link their my charts either

NOTE Confidence: 0.906489560909091

 $00{:}14{:}09{.}334 \dashrightarrow 00{:}14{:}11{.}384$ through Epic or Cerner based systems

NOTE Confidence: 0.906489560909091

 $00:14:11.384 \rightarrow 00:14:12.848$ from any health system.

NOTE Confidence: 0.906489560909091

 $00:14:12.850 \longrightarrow 00:14:14.858$ So if we were taking care of a

NOTE Confidence: 0.906489560909091

00:14:14.858 --> 00:14:15.890 patient who was getting there,

NOTE Confidence: 0.906489560909091

 $00{:}14{:}15{.}890 \dashrightarrow 00{:}14{:}17{.}060$ a FIB ablation here at Yale,

NOTE Confidence: 0.906489560909091

 $00:14:17.060 \rightarrow 00:14:19.106$ but they're there, their primary care,

NOTE Confidence: 0.906489560909091

00:14:19.110 --> 00:14:20.510 perhaps was at Hartford Hospital.

NOTE Confidence: 0.906489560909091

 $00:14:20.510 \longrightarrow 00:14:22.235$ For whatever reason they could

NOTE Confidence: 0.906489560909091

 $00:14:22.235 \longrightarrow 00:14:23.615$ link that system too.

NOTE Confidence: 0.906489560909091

 $00{:}14{:}23.620 \dashrightarrow 00{:}14{:}23.955$ Also,

NOTE Confidence: 0.906489560909091

00:14:23.955 --> 00:14:25.630 we linked their pharmacy data,

NOTE Confidence: 0.906489560909091

 $00:14:25.630 \rightarrow 00:14:27.518$ so that's not the upper right and so

 $00:14:27.518 \rightarrow 00:14:29.627$ this was individuals were getting care.

NOTE Confidence: 0.906489560909091

 $00:14:29.630 \longrightarrow 00:14:31.406$ Their pharmacies met their

NOTE Confidence: 0.906489560909091

 $00:14:31.406 \rightarrow 00:14:33.626$ medications through CVS or Walgreens.

NOTE Confidence: 0.906489560909091

 $00:14:33.630 \longrightarrow 00:14:35.290$ They also use a mark.

NOTE Confidence: 0.906489560909091

 $00{:}14{:}35{.}290 \dashrightarrow 00{:}14{:}37{.}446$ My chart based system that allows this.

NOTE Confidence: 0.906489560909091

 $00:14:37.450 \longrightarrow 00:14:39.042$ They're essentially their health

NOTE Confidence: 0.906489560909091

00:14:39.042 --> 00:14:41.810 record to get linked right into Hugo.

NOTE Confidence: 0.906489560909091

 $00:14:41.810 \rightarrow 00:14:45.104$ We also then used Hugo to send out surveys.

NOTE Confidence: 0.906489560909091

 $00{:}14{:}45{.}110 \dashrightarrow 00{:}14{:}47{.}190$ Patient reported outcome measures.

NOTE Confidence: 0.906489560909091

 $00{:}14{:}47{.}190 \dashrightarrow 00{:}14{:}49{.}790$ Both short questions post procedure

NOTE Confidence: 0.906489560909091

 $00:14:49.790 \rightarrow 00:14:52.354$ along with longer questions at 148

NOTE Confidence: 0.906489560909091

 $00:14:52.354 \rightarrow 00:14:54.298$ weeks and patients get a link.

NOTE Confidence: 0.906489560909091

 $00:14:54.300 \rightarrow 00:14:55.800$ Right to their phone they they.

NOTE Confidence: 0.906489560909091

 $00{:}14{:}55{.}800 \dashrightarrow 00{:}14{:}56{.}748$ They signify their preference.

NOTE Confidence: 0.906489560909091

 $00{:}14{:}56{.}748 \dashrightarrow 00{:}14{:}58{.}170$ If they want a text message

 $00:14:58.212 \rightarrow 00:15:00.062$ or email, they click the link and they

NOTE Confidence: 0.91233572

 $00:15:00.062 \rightarrow 00:15:02.138$ fill it all out right on their phone

NOTE Confidence: 0.91233572

 $00:15:02.138 \rightarrow 00:15:04.530$ and and and it's all kind of easy peasy.

NOTE Confidence: 0.91233572

00:15:04.530 --> 00:15:06.609 They don't have to come back to go through,

NOTE Confidence: 0.91233572

 $00{:}15{:}06{.}610 \dashrightarrow 00{:}15{:}08{.}260$ you know a structured question naire with

NOTE Confidence: 0.91233572

 $00:15:08.260 \rightarrow 00:15:10.620$ a nurse or any other study coordinator.

NOTE Confidence: 0.91233572

00:15:10.620 --> 00:15:12.340 They can just do it on their own,

NOTE Confidence: 0.91233572

 $00{:}15{:}12{.}340 \dashrightarrow 00{:}15{:}14{.}110$ fill it out and that allows

NOTE Confidence: 0.91233572

 $00{:}15{:}14.110 \dashrightarrow 00{:}15{:}16.050$ you to ask more questions.

NOTE Confidence: 0.91233572

 $00:15:16.050 \rightarrow 00:15:18.122$ And then we also gave every patient

NOTE Confidence: 0.91233572

 $00{:}15{:}18{.}122 \dashrightarrow 00{:}15{:}19{.}800$ some two different digital devices.

NOTE Confidence: 0.91233572

00:15:19.800 --> 00:15:22.578 Everyone got a Fitbit in order to track

NOTE Confidence: 0.91233572

 $00{:}15{:}22.578 \dashrightarrow 00{:}15{:}24.224$ activity and patients who underwent

NOTE Confidence: 0.91233572

 $00{:}15{:}24{.}224 \dashrightarrow 00{:}15{:}26{.}210$ bariatric surgery got a Withings scale.

NOTE Confidence: 0.91233572

 $00:15:26.210 \longrightarrow 00:15:27.894$ Digital scale and people.

NOTE Confidence: 0.91233572

 $00:15:27.894 \longrightarrow 00:15:29.834$ Patients who underwent the 8th

 $00:15:29.834 \rightarrow 00:15:32.193$ ablation procedure got us a two finger,

NOTE Confidence: 0.91233572

00:15:32.200 --> 00:15:34.768 a single lead EKG that you

NOTE Confidence: 0.91233572

00:15:34.768 --> 00:15:36.480 measured through Kardia mobile.

NOTE Confidence: 0.91233572

 $00:15:36.480 \rightarrow 00:15:37.943$ And this is just some quick results

NOTE Confidence: 0.91233572

 $00:15:37.943 \dashrightarrow 00:15:39.740$ to show you kind of what we could do.

NOTE Confidence: 0.91233572

 $00{:}15{:}39{.}740 \dashrightarrow 00{:}15{:}42{.}232$ Again, this was really just figuring out

NOTE Confidence: 0.91233572

 $00{:}15{:}42.232 \dashrightarrow 00{:}15{:}44.638$ the feasibility of doing work like this,

NOTE Confidence: 0.91233572

 $00{:}15{:}44.640 \dashrightarrow 00{:}15{:}46.611$ but we were able to link health records for

NOTE Confidence: 0.91233572

 $00{:}15{:}46.611 \dashrightarrow 00{:}15{:}48.600$ 100% of patients who underwent procedures.

NOTE Confidence: 0.91233572

00:15:48.600 --> 00:15:51.024 A 55% of patients also had a primary

NOTE Confidence: 0.91233572

 $00:15:51.024 \rightarrow 00:15:53.407$ care that was based at Yale or Mayo,

NOTE Confidence: 0.91233572

 $00:15:53.410 \longrightarrow 00:15:55.776$ so all of their electronic health records

NOTE Confidence: 0.91233572

 $00{:}15{:}55{.}776$ --> $00{:}15{:}58{.}459$ get pulled in for purposes of the study.

NOTE Confidence: 0.91233572

00:15:58.460 --> 00:16:00.233 10 patients, LinkedIn,

NOTE Confidence: 0.91233572

 $00{:}16{:}00{.}233 \dashrightarrow 00{:}16{:}03{.}426$ additional 13 portals and then we had

 $00:16:03.426 \longrightarrow 00:16:06.054 40\%$ of patients who are getting their

NOTE Confidence: 0.91233572

 $00:16:06.054 \rightarrow 00:16:08.250$ prescriptions through CVS or Walgreens.

NOTE Confidence: 0.91233572

00:16:08.250 --> 00:16:11.258 Now, Walmart also has a my chart like

NOTE Confidence: 0.91233572

 $00{:}16{:}11.258 \dashrightarrow 00{:}16{:}14.387$ function that allows you to pull in

NOTE Confidence: 0.91233572

 $00{:}16{:}14.387 \dashrightarrow 00{:}16{:}16.223$ information like medication names,

NOTE Confidence: 0.91233572

 $00:16:16.230 \longrightarrow 00:16:16.642$ dosages,

NOTE Confidence: 0.91233572

 $00:16:16.642 \rightarrow 00:16:19.526$ start and end dates along with refills,

NOTE Confidence: 0.91233572

00:16:19.530 --> 00:16:20.170 and again,

NOTE Confidence: 0.91233572

 $00{:}16{:}20{.}170 \dashrightarrow 00{:}16{:}21{.}770$ all these data were passively

NOTE Confidence: 0.91233572

 $00{:}16{:}21.770$ --> $00{:}16{:}23.789$ aggregated after our initial enrollment,

NOTE Confidence: 0.91233572

00:16:23.790 --> 00:16:26.328 allowing for Neil near real time,

NOTE Confidence: 0.91233572

 $00:16:26.330 \longrightarrow 00:16:27.795$ streaming data aggregation and this

NOTE Confidence: 0.91233572

00:16:27.795 --> 00:16:30.144 just kind of shows you kind of how it

NOTE Confidence: 0.91233572

 $00{:}16{:}30{.}144 \dashrightarrow 00{:}16{:}32{.}149$ worked at the time when we did the study,

NOTE Confidence: 0.91233572

 $00:16:32.150 \rightarrow 00:16:35.727$ people had to actually sync their Fitbits.

NOTE Confidence: 0.91233572

 $00:16:35.730 \rightarrow 00:16:36.942$ Now that happens automatically,

 $00:16:36.942 \rightarrow 00:16:38.760$ but this shows you of course.

NOTE Confidence: 0.91233572

00:16:38.760 --> 00:16:40.200 Of things tail off over time,

NOTE Confidence: 0.91233572

00:16:40.200 - 00:16:41.960 but even over the eight weeks we had,

NOTE Confidence: 0.91233572

 $00{:}16{:}41{.}960 \dashrightarrow 00{:}16{:}45{.}324$ well more than half of patients syncing

NOTE Confidence: 0.91233572

 $00{:}16{:}45{.}324 \dashrightarrow 00{:}16{:}47{.}568$ their Fitbits their their cardio mobile

NOTE Confidence: 0.91233572

 $00{:}16{:}47.568 \dashrightarrow 00{:}16{:}49.926$ devices and their withing scale which

NOTE Confidence: 0.91233572

00:16:49.926 --> 00:16:53.334 allows you to kind of project you know.

NOTE Confidence: 0.91233572

 $00:16:53.340 \longrightarrow 00:16:53.742$ Scraf,

NOTE Confidence: 0.91233572

 $00:16:53.742 \longrightarrow 00:16:56.154$ the sort of trajectories of recovery.

NOTE Confidence: 0.91233572

 $00:16:56.160 \longrightarrow 00:16:58.077$ So on the top you can see kind of

NOTE Confidence: 0.91233572

 $00{:}16{:}58.077 \dashrightarrow 00{:}17{:}00.061$ average steps per day for patients

NOTE Confidence: 0.91233572

00:17:00.061 --> 00:17:01.429 who underwent bariatric surgery,

NOTE Confidence: 0.91233572

00:17:01.430 --> 00:17:02.204 you know,

NOTE Confidence: 0.91233572

 $00{:}17{:}02{.}204 \dashrightarrow 00{:}17{:}04{.}139$ kind of visually demonstrating the

NOTE Confidence: 0.91233572

 $00{:}17{:}04{.}139 \dashrightarrow 00{:}17{:}05{.}940$ how patients recovered over time.

00:17:05.940 --> 00:17:08.226 The bottom half on the left is the the

NOTE Confidence: 0.91233572

00:17:08.226 --> 00:17:10.739 steps per day for patient patients who

NOTE Confidence: 0.91233572

 $00{:}17{:}10.739 \dashrightarrow 00{:}17{:}12.797$ underwent a fibrillation on the right.

NOTE Confidence: 0.91233572

 $00:17:12.797 \rightarrow 00:17:15.030$ Is that the cumulative weight change for NOTE Confidence: 0.91233572

00:17:15.095 --> 00:17:16.926 patients undergoing bariatric surgery

NOTE Confidence: 0.91233572

 $00{:}17{:}16.926 \dashrightarrow 00{:}17{:}19.397$ on the lower right is the patient.

NOTE Confidence: 0.91233572

 $00{:}17{:}19{.}400 \dashrightarrow 00{:}17{:}20{.}840$ The average heart rate and again,

NOTE Confidence: 0.91233572

 $00:17:20.840 \longrightarrow 00:17:22.358$ this is more just to determine,

NOTE Confidence: 0.91233572

 $00{:}17{:}22.360 \dashrightarrow 00{:}17{:}23.828$ you know, the accuracy.

NOTE Confidence: 0.91233572

 $00:17:23.828 \longrightarrow 00:17:26.030$ That the integrity of the data

NOTE Confidence: 0.91233572

 $00{:}17{:}26{.}107 \dashrightarrow 00{:}17{:}28{.}191$ that was being aggregated here.

NOTE Confidence: 0.91233572

 $00:17:28.191 \rightarrow 00:17:30.858$ Our response rate to the patient reported NOTE Confidence: 0.91233572

 $00{:}17{:}30.858 \dashrightarrow 00{:}17{:}32.988$ outcome measures consistently above 80%

NOTE Confidence: 0.91233572

 $00:17:32.990 \longrightarrow 00:17:36.030$ for all the patients for all the surveys,

NOTE Confidence: 0.91233572

 $00{:}17{:}36{.}030 \dashrightarrow 00{:}17{:}38{.}694$ and it allows you also to to to determine

NOTE Confidence: 0.91233572

00:17:38.694 --> 00:17:41.105 how patients are doing so you know,
- NOTE Confidence: 0.91233572
- $00:17:41.110 \rightarrow 00:17:44.365$ we're over time graphing estimates of pain,
- NOTE Confidence: 0.91233572
- $00{:}17{:}44.370 \dashrightarrow 00{:}17{:}46.110$ appetite and palpitations
- NOTE Confidence: 0.91233572
- $00:17:46.110 \longrightarrow 00:17:49.010$ in the two patient groups,
- NOTE Confidence: 0.803564338888889
- $00:17:49.010 \rightarrow 00:17:51.560$ but this is really just more
- NOTE Confidence: 0.803564338888889
- $00:17:51.560 \longrightarrow 00:17:52.835$ for illustrative purposes.
- NOTE Confidence: 0.803564338888889
- $00{:}17{:}52{.}840 \dashrightarrow 00{:}17{:}54{.}577$ And this has led to a lot of future
- NOTE Confidence: 0.803564338888889
- 00:17:54.577 --> 00:17:56.027 work that I'm really proud of,
- NOTE Confidence: 0.803564338888889
- $00:17:56.030 \longrightarrow 00:17:57.370$ and I'm really excited.
- NOTE Confidence: 0.803564338888889
- $00:17:57.370 \longrightarrow 00:17:59.380$ It's all kind of coming soon,
- NOTE Confidence: 0.803564338888889
- 00:17:59.380 --> 00:18:01.260 but I did want a sort of flag
- NOTE Confidence: 0.803564338888889
- 00:18:01.260 --> 00:18:02.890 for people in case it prompts
- NOTE Confidence: 0.803564338888889
- $00:18:02.890 \longrightarrow 00:18:03.580$ potential collaborations,
- NOTE Confidence: 0.803564338888889
- $00{:}18{:}03{.}580 \dashrightarrow 00{:}18{:}06{.}012$ but this is the biggest of the
- NOTE Confidence: 0.803564338888889
- $00{:}18{:}06{.}012 \dashrightarrow 00{:}18{:}07{.}800$ studies that we're working on now.
- NOTE Confidence: 0.803564338888889
- $00{:}18{:}07{.}800 \dashrightarrow 00{:}18{:}09{.}320$ Also funded through the Searcy,
- NOTE Confidence: 0.803564338888889

 $00:18:09.320 \rightarrow 00:18:12.748$ it's a where aggregating sensually

NOTE Confidence: 0.803564338888889

00:18:12.748 --> 00:18:16.094 a large cohort study of more than

NOTE Confidence: 0.803564338888889

00:18:16.100 --> 00:18:17.970 1500 patients who are receiving

NOTE Confidence: 0.803564338888889

00:18:17.970 --> 00:18:19.840 a new opioid prescription for

NOTE Confidence: 0.803564338888889

 $00:18:19.906 \longrightarrow 00:18:21.300$ acute pain recruiting from sites

NOTE Confidence: 0.803564338888889

 $00{:}18{:}21{.}300 \dashrightarrow 00{:}18{:}22{.}860$ across the United States and Yale

NOTE Confidence: 0.803564338888889

 $00:18:22.860 \longrightarrow 00:18:24.340$ at the University of Alabama.

NOTE Confidence: 0.803564338888889

00:18:24.340 --> 00:18:24.803 Birmingham,

NOTE Confidence: 0.803564338888889

00:18:24.803 --> 00:18:27.118 including from their network of

NOTE Confidence: 0.803564338888889

 $00:18:27.120 \longrightarrow 00:18:29.190$ dental practices that run up the

NOTE Confidence: 0.803564338888889

 $00{:}18{:}29{.}190 \dashrightarrow 00{:}18{:}30{.}570$ Appalachian Mountains from the

NOTE Confidence: 0.803564338888889

00:18:30.630 --> 00:18:32.440 Mayo Clinic from Monument Health,

NOTE Confidence: 0.803564338888889

 $00{:}18{:}32{.}440 \dashrightarrow 00{:}18{:}34{.}280$ which is basically South Dakota

NOTE Confidence: 0.803564338888889

 $00:18:34.280 \rightarrow 00:18:36.407$ and Cedar Sinai in Los Angeles.

NOTE Confidence: 0.803564338888889

00:18:36.407 --> 00:18:38.102 Patients are being recruited for

NOTE Confidence: 0.803564338888889

 $00:18:38.102 \rightarrow 00:18:40.138$ in the urgent care settings,

- NOTE Confidence: 0.803564338888889
- 00:18:40.140 --> 00:18:41.082 emergency departments,
- NOTE Confidence: 0.803564338888889
- $00:18:41.082 \longrightarrow 00:18:43.437$ dental care and patients post
- NOTE Confidence: 0.803564338888889
- 00:18:43.437 --> 00:18:44.379 cesarean section.
- NOTE Confidence: 0.803564338888889
- $00{:}18{:}44{.}380 \dashrightarrow 00{:}18{:}45{.}995$ We started recruitment in about
- NOTE Confidence: 0.803564338888889
- $00:18:45.995 \longrightarrow 00:18:46.964$ in September 2020.
- NOTE Confidence: 0.803564338888889
- $00:18:46.970 \longrightarrow 00:18:48.578$ We now have more than 1000
- NOTE Confidence: 0.803564338888889
- 00:18:48.578 --> 00:18:49.114 patients recruited.
- NOTE Confidence: 0.803564338888889
- $00:18:49.120 \rightarrow 00:18:51.675$ Even with all the challenges from COVID.
- NOTE Confidence: 0.803564338888889
- $00:18:51.680 \longrightarrow 00:18:53.220$ Our primary endpoint is the
- NOTE Confidence: 0.803564338888889
- $00:18:53.220 \rightarrow 00:18:54.452$ number of days using.
- NOTE Confidence: 0.803564338888889
- $00:18:54.460 \rightarrow 00:18:55.560$ Opioids and we're following
- NOTE Confidence: 0.803564338888889
- $00:18:55.560 \rightarrow 00:18:56.935$ up patients over six months,
- NOTE Confidence: 0.803564338888889
- $00:18:56.940 \longrightarrow 00:18:58.155$ including additional measures
- NOTE Confidence: 0.803564338888889
- $00{:}18{:}58{.}155 \dashrightarrow 00{:}19{:}00{.}180$ for patient or outcome measures,
- NOTE Confidence: 0.803564338888889
- $00:19:00.180 \longrightarrow 00:19:01.740$ from pain and anxiety.
- NOTE Confidence: 0.803564338888889

 $00:19:01.740 \longrightarrow 00:19:03.690$ Other measures of health care

NOTE Confidence: 0.803564338888889

00:19:03.690 --> 00:19:05.053 utilization activity measured

NOTE Confidence: 0.803564338888889

00:19:05.053 --> 00:19:07.318 using Fitbits and opioid disposal,

NOTE Confidence: 0.803564338888889

 $00:19:07.320 \longrightarrow 00:19:08.984$ and just to give you a sense of

NOTE Confidence: 0.803564338888889

 $00{:}19{:}08{.}984 \dashrightarrow 00{:}19{:}10{.}842$ the kind of data that this allows

NOTE Confidence: 0.803564338888889

 $00:19:10.842 \longrightarrow 00:19:12.222$ us to aggregate on patients.

NOTE Confidence: 0.803564338888889

 $00:19:12.230 \rightarrow 00:19:13.940$ This is mean daily pain,

NOTE Confidence: 0.803564338888889

 $00:19:13.940 \longrightarrow 00:19:15.544$ reportings among those reporting

NOTE Confidence: 0.803564338888889

 $00{:}19{:}15{.}544 \dashrightarrow 00{:}19{:}17{.}148$ they are in pain,

NOTE Confidence: 0.803564338888889

 $00:19:17.150 \longrightarrow 00:19:19.622$ and you can just see how

NOTE Confidence: 0.803564338888889

 $00:19:19.622 \rightarrow 00:19:20.858$ pain essentially persists.

NOTE Confidence: 0.803564338888889

 $00:19:20.860 \longrightarrow 00:19:22.840$ This is over 180 days.

NOTE Confidence: 0.803564338888889

 $00:19:22.840 \longrightarrow 00:19:24.828$ The average pain dots are in blue.

NOTE Confidence: 0.803564338888889

 $00:19:24.830 \longrightarrow 00:19:26.680$ Worst pain or in red?

NOTE Confidence: 0.803564338888889

 $00{:}19{:}26.680 \dashrightarrow 00{:}19{:}28.205$ Here's the median days elapsed

NOTE Confidence: 0.803564338888889

 $00:19:28.205 \longrightarrow 00:19:30.481$ to 1st report of no pain among

 $00:19:30.481 \rightarrow 00:19:32.191$ patients with pain fully resolved

NOTE Confidence: 0.803564338888889

 $00{:}19{:}32{.}191 \dashrightarrow 00{:}19{:}34{.}820$ and you can see the difference in

NOTE Confidence: 0.803564338888889

 $00:19:34.820 \longrightarrow 00:19:36.745$ pain experienced by patients in

NOTE Confidence: 0.803564338888889

 $00:19:36.745 \rightarrow 00:19:38.324$ different settings with patients

NOTE Confidence: 0.803564338888889

 $00{:}19{:}38{.}324 \dashrightarrow 00{:}19{:}40{.}712$ who are recruited either from the

NOTE Confidence: 0.803564338888889

 $00:19:40.712 \longrightarrow 00:19:42.552$ inpatient setting or a primary

NOTE Confidence: 0.803564338888889

 $00:19:42.552 \rightarrow 00:19:44.272$ care having longer median days

NOTE Confidence: 0.803564338888889

 $00:19:44.272 \longrightarrow 00:19:46.365$ until the first report of no pain.

NOTE Confidence: 0.803564338888889

 $00{:}19{:}46.370 \dashrightarrow 00{:}19{:}48.770$ Whereas patients for the dentist

NOTE Confidence: 0.803564338888889

00:19:48.770 --> 00:19:50.690 heading having slightly shorter

NOTE Confidence: 0.803564338888889

 $00:19:50.690 \longrightarrow 00:19:52.250$ durations and then this shows

NOTE Confidence: 0.803564338888889

 $00:19:52.250 \rightarrow 00:19:53.870$ you the mean daily pain ratings

NOTE Confidence: 0.803564338888889

 $00:19:53.931 \longrightarrow 00:19:54.939$ among those taking.

NOTE Confidence: 0.803564338888889

 $00{:}19{:}54{.}940 \dashrightarrow 00{:}19{:}56{.}065$ A treatment for pain and

NOTE Confidence: 0.803564338888889

 $00:19:56.065 \rightarrow 00:19:57.190$ this could be any treatment.

 $00:19:57.190 \longrightarrow 00:19:59.215$ It could be tylanol it could be an opioid,

NOTE Confidence: 0.803564338888889

 $00:19:59.220 \longrightarrow 00:20:00.112$ it could be anything,

NOTE Confidence: 0.803564338888889

 $00:20:00.112 \longrightarrow 00:20:01.986$ but you can see here the blue dots

NOTE Confidence: 0.803564338888889

 $00:20:01.986 \rightarrow 00:20:03.438$ are patients who are not using

NOTE Confidence: 0.803564338888889

 $00:20:03.438 \longrightarrow 00:20:05.026$ an opioid for treatment and the

NOTE Confidence: 0.803564338888889

 $00{:}20{:}05{.}026 \dashrightarrow 00{:}20{:}06{.}598$ yellow dots are patients who are

NOTE Confidence: 0.803564338888889

 $00:20:06.600 \rightarrow 00:20:08.448$ using an opioid for treatment and

NOTE Confidence: 0.803564338888889

 $00:20:08.448 \rightarrow 00:20:11.056$ you can see how the on average the

NOTE Confidence: 0.803564338888889

 $00{:}20{:}11.056 \dashrightarrow 00{:}20{:}13.018$ patients who are taking an opioid

NOTE Confidence: 0.803564338888889

 $00:20:13.085 \rightarrow 00:20:15.095$ are having higher rates of pain.

NOTE Confidence: 0.803564338888889

 $00:20:15.100 \longrightarrow 00:20:17.536$ All of this is being done in

NOTE Confidence: 0.803564338888889

 $00{:}20{:}17.536 \dashrightarrow 00{:}20{:}19.341$ collaboration with the FDA as

NOTE Confidence: 0.803564338888889

 $00:20:19.341 \longrightarrow 00:20:21.393$ part of their efforts to better

NOTE Confidence: 0.803564338888889

 $00{:}20{:}21{.}393 \dashrightarrow 00{:}20{:}23{.}553$ address and understand the risks

NOTE Confidence: 0.803564338888889

 $00{:}20{:}23.553 \dashrightarrow 00{:}20{:}25.429$ associated with opioid use.

NOTE Confidence: 0.803564338888889

 $00:20:25.430 \longrightarrow 00:20:26.822$ Couple of other things,

- NOTE Confidence: 0.803564338888889
- $00:20:26.822 \rightarrow 00:20:29.145$ just to mention briefly one is these
- NOTE Confidence: 0.803564338888889
- $00:20:29.145 \longrightarrow 00:20:30.790$ are projects that are funded by Nest.
- NOTE Confidence: 0.803564338888889
- $00:20:30.790 \rightarrow 00:20:33.319$ This is what we call the sleep I study.
- NOTE Confidence: 0.803564338888889
- $00:20:33.320 \longrightarrow 00:20:35.558$ It's a prospective RCT of 100
- NOTE Confidence: 0.803564338888889
- $00{:}20{:}35{.}558 \dashrightarrow 00{:}20{:}37{.}050$ patients with depression receiving
- NOTE Confidence: 0.871263695714286
- $00{:}20{:}37.108 \dashrightarrow 00{:}20{:}39.088$ outpatient treatment for insomnia,
- NOTE Confidence: 0.871263695714286
- $00:20:39.090 \longrightarrow 00:20:41.376$ comparing usual care of a prescription
- NOTE Confidence: 0.871263695714286
- 00:20:41.376 --> 00:20:43.429 digital therapeutic device that's essentially
- NOTE Confidence: 0.871263695714286
- $00{:}20{:}43{.}429 \dashrightarrow 00{:}20{:}45{.}809$ cognitive behavioral therapy for insomnia,
- NOTE Confidence: 0.871263695714286
- $00:20:45.810 \longrightarrow 00:20:47.100$ following patient treating
- NOTE Confidence: 0.871263695714286
- $00:20:47.100 \longrightarrow 00:20:48.820$ patients over 9 weeks.
- NOTE Confidence: 0.871263695714286
- $00{:}20{:}48.820 \dashrightarrow 00{:}20{:}50.584$ With the primary endpoint of insomnia
- NOTE Confidence: 0.871263695714286
- $00{:}20{:}50{.}584 \dashrightarrow 00{:}20{:}52{.}475$ severity index and we're following them up
- NOTE Confidence: 0.871263695714286
- $00{:}20{:}52{.}475 \dashrightarrow 00{:}20{:}54{.}560$ over a year and again just to emphasize.
- NOTE Confidence: 0.871263695714286
- $00:20:54.560 \rightarrow 00:20:56.720$ All of this is done using the Hugo platform,
- NOTE Confidence: 0.871263695714286

 $00:20:56.720 \longrightarrow 00:20:58.958$ so we enroll patients at baseline.

NOTE Confidence: 0.871263695714286

 $00:20:58.960 \longrightarrow 00:21:01.300$ They're randomized to one treatment or

NOTE Confidence: 0.871263695714286

 $00:21:01.300 \rightarrow 00:21:03.846$ another they undergo, you know, they they.

NOTE Confidence: 0.871263695714286

 $00:21:03.846 \rightarrow 00:21:05.566$ They undergo the treatment associated

NOTE Confidence: 0.871263695714286

00:21:05.566 --> 00:21:07.480 with that arm, and they get, you know,

NOTE Confidence: 0.871263695714286

00:21:07.480 --> 00:21:08.800 serving questions out, you know,

NOTE Confidence: 0.871263695714286

00:21:08.800 --> 00:21:10.720 through their phone or via email,

NOTE Confidence: 0.871263695714286

 $00:21:10.720 \longrightarrow 00:21:12.889$ and all of their data that the health care,

NOTE Confidence: 0.871263695714286

00:21:12.890 --> 00:21:13.844 utilization data,

NOTE Confidence: 0.871263695714286

 $00:21:13.844 \longrightarrow 00:21:15.275$ and other information

NOTE Confidence: 0.871263695714286

 $00:21:15.275 \rightarrow 00:21:16.706$ otherwise passively aggregates.

NOTE Confidence: 0.871263695714286

00:21:16.710 --> 00:21:17.739 It's you know,

NOTE Confidence: 0.871263695714286

 $00{:}21{:}17.739 \dashrightarrow 00{:}21{:}19.454$ a pragmatic RCT that's leveraging.

NOTE Confidence: 0.871263695714286

 $00:21:19.460 \rightarrow 00:21:22.076$ Real world data for all of our endpoints,

NOTE Confidence: 0.871263695714286

 $00:21:22.080 \longrightarrow 00:21:23.060$ we're doing another study that

NOTE Confidence: 0.871263695714286

 $00:21:23.060 \rightarrow 00:21:24.300$ we call the Heart Watch study,

- NOTE Confidence: 0.871263695714286
- $00{:}21{:}24{.}300 \dashrightarrow 00{:}21{:}26{.}477$ which is essentially an RCT of the
- NOTE Confidence: 0.871263695714286
- 00:21:26.477 --> 00:21:28.702 Apple Watch where we're perspective
- NOTE Confidence: 0.871263695714286
- 00:21:28.702 --> 00:21:31.100 prospectively enrolling 150 patients
- NOTE Confidence: 0.871263695714286
- $00:21:31.100 \rightarrow 00:21:33.440$ undergoing cardioversion for AFIB.
- NOTE Confidence: 0.871263695714286
- $00:21:33.440 \rightarrow 00:21:35.512$ They either get an Apple Watch or they
- NOTE Confidence: 0.871263695714286
- $00:21:35.512 \rightarrow 00:21:38.216$ get a Withings watch without any activity.
- NOTE Confidence: 0.871263695714286
- $00{:}21{:}38{.}220 \dashrightarrow 00{:}21{:}41{.}202$ That's just an activity tracker without an
- NOTE Confidence: 0.871263695714286
- 00:21:41.202 --> 00:21:44.578 EKG and abnormal rhythm notification feature.
- NOTE Confidence: 0.871263695714286
- $00{:}21{:}44.580 \dashrightarrow 00{:}21{:}45.804$ We're enrolling patients at
- NOTE Confidence: 0.871263695714286
- 00:21:45.804 --> 00:21:47.640 Yale Duke in the Mayo Clinic.
- NOTE Confidence: 0.871263695714286
- $00:21:47.640 \rightarrow 00:21:49.856$ We have about 40 patients enrolled thus far.
- NOTE Confidence: 0.871263695714286
- 00:21:49.860 --> 00:21:52.164 Our primary endpoint is the the
- NOTE Confidence: 0.871263695714286
- $00{:}21{:}52{.}164 \dashrightarrow 00{:}21{:}54{.}093$ effect Global Score questionnaire is
- NOTE Confidence: 0.871263695714286
- $00{:}21{:}54.093 \dashrightarrow 00{:}21{:}56.417$ essentially at A-fib quality of life prom,
- NOTE Confidence: 0.871263695714286
- $00:21:56.420 \longrightarrow 00:21:56.894$ and again,
- NOTE Confidence: 0.871263695714286

 $00:21:56.894 \rightarrow 00:21:58.553$ we're following up patients over a year,

NOTE Confidence: 0.871263695714286

00:21:58.560 --> 00:22:00.740 including additional prompts for anxiety.

NOTE Confidence: 0.871263695714286

 $00:22:00.740 \longrightarrow 00:22:02.390$ Other measures of health care utilization,

NOTE Confidence: 0.871263695714286

 $00:22:02.390 \longrightarrow 00:22:04.900$ as well as cagey accuracy.

NOTE Confidence: 0.871263695714286

 $00{:}22{:}04{.}900 \dashrightarrow 00{:}22{:}05{.}602$ And then last,

NOTE Confidence: 0.871263695714286

 $00{:}22{:}05{.}602 \dashrightarrow 00{:}22{:}07{.}738$ I just want to note this one this

NOTE Confidence: 0.871263695714286

00:22:07.738 --> 00:22:09.918 project we're doing in collaboration

NOTE Confidence: 0.871263695714286

00:22:09.918 --> 00:22:11.226 with numerous investigators

NOTE Confidence: 0.871263695714286

 $00:22:11.226 \longrightarrow 00:22:12.379$ associated with copper,

NOTE Confidence: 0.871263695714286

 $00:22:12.380 \longrightarrow 00:22:14.068$ the cancer outcomes public

NOTE Confidence: 0.871263695714286

 $00{:}22{:}14.068 \dashrightarrow 00{:}22{:}15.756$ policy and effectiveness Research

NOTE Confidence: 0.871263695714286

00:22:15.756 --> 00:22:17.610 Center led by Carrie Gross,

NOTE Confidence: 0.871263695714286

00:22:17.610 --> 00:22:20.070 Sarah McLachlan and Scott Huntington.

NOTE Confidence: 0.871263695714286

00:22:20.070 --> 00:22:22.190 Where we're quantifying a physical

NOTE Confidence: 0.871263695714286

 $00:22:22.190 \rightarrow 00:22:24.310$ function in cancer patients undergoing

NOTE Confidence: 0.871263695714286

 $00:22:24.369 \rightarrow 00:22:26.169$ chemotherapy using a clinician,

 $00:22:26.170 \longrightarrow 00:22:27.658$ reported patient reported and

NOTE Confidence: 0.871263695714286

 $00{:}22{:}27.658 \dashrightarrow 00{:}22{:}29.146$ we arable device data sources.

NOTE Confidence: 0.871263695714286

 $00:22:29.150 \rightarrow 00:22:31.606$ This is done being done through our Searcy.

NOTE Confidence: 0.871263695714286

 $00:22:31.610 \longrightarrow 00:22:33.106$ The FDA funded center.

NOTE Confidence: 0.871263695714286

 $00:22:33.106 \rightarrow 00:22:35.350$ We're doing it directly with collaborators

NOTE Confidence: 0.871263695714286

 $00:22:35.416 \rightarrow 00:22:37.546$ at the oncology Center of Excellence,

NOTE Confidence: 0.871263695714286

 $00:22:37.550 \rightarrow 00:22:40.826$ a prospective study of 200 cancer patients

NOTE Confidence: 0.871263695714286

00:22:40.826 --> 00:22:42.810 undergoing frontline cytotoxic therapy.

NOTE Confidence: 0.871263695714286

 $00{:}22{:}42.810 \dashrightarrow 00{:}22{:}45.505$ Rolling patients at Yale and Mayo Clinic,

NOTE Confidence: 0.871263695714286

 $00:22:45.510 \longrightarrow 00:22:46.874$ 100 solid tumor patients.

NOTE Confidence: 0.871263695714286

00:22:46.874 --> 00:22:48.579 Breast cancer patients stage one

NOTE Confidence: 0.871263695714286

 $00{:}22{:}48.579 \dashrightarrow 00{:}22{:}50.230$ through three, as well as a hunt.

NOTE Confidence: 0.871263695714286

00:22:50.230 --> 00:22:52.636 100 high grade B cell lymphoma

NOTE Confidence: 0.871263695714286

 $00{:}22{:}52.636 \dashrightarrow 00{:}22{:}54.755$ patients and our primary endpoint is

NOTE Confidence: 0.871263695714286

 $00:22:54.755 \rightarrow 00:22:56.470$ physical function over nine months

 $00:22:56.534 \rightarrow 00:22:58.298$ that's being measured weekly for

NOTE Confidence: 0.871263695714286

 $00:22:58.298 \rightarrow 00:23:00.494$ two months and then monthly again,

NOTE Confidence: 0.871263695714286

 $00:23:00.500 \rightarrow 00:23:03.220$ all leveraging the Hugo platform

NOTE Confidence: 0.871263695714286

 $00:23:03.220 \rightarrow 00:23:05.396$ for measurements with patient

NOTE Confidence: 0.871263695714286

 $00{:}23{:}05{.}396 \dashrightarrow 00{:}23{:}07{.}319$ reported outcome measures.

NOTE Confidence: 0.871263695714286

 $00{:}23{:}07{.}320 \dashrightarrow 00{:}23{:}08{.}824$ Clinician reported outcome measures

NOTE Confidence: 0.871263695714286

 $00{:}23{:}08{.}824 \dashrightarrow 00{:}23{:}11{.}080$ to the E COG performance measurement.

NOTE Confidence: 0.871263695714286

 $00:23:11.080 \rightarrow 00:23:13.061$ The six minute walk test at baseline

NOTE Confidence: 0.871263695714286

 $00{:}23{:}13.061 \dashrightarrow 00{:}23{:}15.320$ and at the at the end of two

NOTE Confidence: 0.871263695714286

 $00:23:15.320 \longrightarrow 00:23:16.920$ months and then again later on,

NOTE Confidence: 0.871263695714286

 $00{:}23{:}16{.}920 \dashrightarrow 00{:}23{:}18{.}775$ as well as activity measured

NOTE Confidence: 0.871263695714286

 $00:23:18.775 \longrightarrow 00:23:19.888$ as every patient,

NOTE Confidence: 0.871263695714286

00:23:19.890 --> 00:23:22.970 has a daily Fitbit to measure daily

NOTE Confidence: 0.871263695714286

 $00{:}23{:}22{.}970 \dashrightarrow 00{:}23{:}24{.}952$ steps and again part of the purpose

NOTE Confidence: 0.871263695714286

 $00{:}23{:}24{.}952 \dashrightarrow 00{:}23{:}27{.}910$ of this is to work with the FDA to to

NOTE Confidence: 0.871263695714286

 $00:23:27.910 \rightarrow 00:23:29.592$ better understand a physical function

00:23:29.592 --> 00:23:31.848 as a surrogate measure of recovery.

NOTE Confidence: 0.871263695714286

 $00{:}23{:}31.850 \dashrightarrow 00{:}23{:}33.970$ Compare these data sources identifying

NOTE Confidence: 0.871263695714286

 $00{:}23{:}33{.}970 \dashrightarrow 00{:}23{:}35{.}666$ change thresholds and inform

NOTE Confidence: 0.871263695714286

 $00:23:35.666 \rightarrow 00:23:37.650$ the way the FDA thinks about.

NOTE Confidence: 0.8087537375

 $00:23:37.650 \longrightarrow 00:23:38.631$ Of these measures,

NOTE Confidence: 0.8087537375

00:23:38.631 --> 00:23:40.266 as part of clinical trials,

NOTE Confidence: 0.8087537375

 $00{:}23{:}40{.}270 \dashrightarrow 00{:}23{:}44{.}015$ so I will stop there and I hope that if

NOTE Confidence: 0.8087537375

 $00:23:44.015 \rightarrow 00:23:46.029$ anyone has questions you can follow up.

NOTE Confidence: 0.8087537375

 $00{:}23{:}46.030 \dashrightarrow 00{:}23{:}49.510$ But thanks for the time, show me.

NOTE Confidence: 0.8087537375

 $00:23:49.510 \longrightarrow 00:23:50.200$ I'll stop sharing.

NOTE Confidence: 0.797580482727273

00:24:01.850 --> 00:24:04.580 Thank you very much Doctor Ross for

NOTE Confidence: 0.797580482727273

 $00{:}24{:}04{.}580 \dashrightarrow 00{:}24{:}06{.}710$ this very informative presentation.

NOTE Confidence: 0.797580482727273

00:24:06.710 --> 00:24:07.994 Renee, I was wondering,

NOTE Confidence: 0.797580482727273

 $00{:}24{:}07{.}994 \dashrightarrow 00{:}24{:}10{.}380$ do we ask people to raise hands?

NOTE Confidence: 0.80891063125

 $00{:}24{:}15.560 \dashrightarrow 00{:}24{:}18.456$ I'm not sure how this is really handled.

 $00:24:18.460 \longrightarrow 00:24:20.504$ Oh, post your questions in the chat.

NOTE Confidence: 0.750768902857143

00:24:24.940 --> 00:24:27.929 I do have a question as we're

NOTE Confidence: 0.750768902857143

 $00:24:27.930 \longrightarrow 00:24:30.120$ waiting for others to pitch in.

NOTE Confidence: 0.750768902857143

 $00:24:30.120 \longrightarrow 00:24:32.610$ I wonder when you submit

NOTE Confidence: 0.750768902857143

 $00{:}24{:}32{.}610 \dashrightarrow 00{:}24{:}34{.}104$ work for publication.

NOTE Confidence: 0.750768902857143

 $00:24:34.110 \longrightarrow 00:24:36.102$ Is it subject to more scrutiny

NOTE Confidence: 0.750768902857143

 $00{:}24{:}36{.}102 \dashrightarrow 00{:}24{:}37{.}892$ because it's not the traditional

NOTE Confidence: 0.750768902857143

 $00:24:37.892 \longrightarrow 00:24:40.238$ trial that people are used to?

NOTE Confidence: 0.909681722857143

 $00{:}24{:}43.020 \dashrightarrow 00{:}24{:}45.064$ Yes, there's a lot of explaining going

NOTE Confidence: 0.909681722857143

 $00:24:45.064 \rightarrow 00:24:47.707$ on when we you know when we're putting

NOTE Confidence: 0.909681722857143

 $00{:}24{:}47.707 \dashrightarrow 00{:}24{:}50.174$ these papers together and and even just

NOTE Confidence: 0.909681722857143

 $00:24:50.174 \rightarrow 00:24:52.280$ proposing them for funding right now,

NOTE Confidence: 0.909681722857143

 $00:24:52.280 \longrightarrow 00:24:53.996$ as people kind of question like,

NOTE Confidence: 0.909681722857143

 $00:24:54.000 \rightarrow 00:24:55.250$ well, how is this done?

NOTE Confidence: 0.909681722857143

 $00:24:55.250 \rightarrow 00:24:56.120$ I don't get it. You know,

NOTE Confidence: 0.909681722857143

 $00:24:56.120 \rightarrow 00:24:58.376$ how are you pulling in these data sources?

00:24:58.380 -> 00:25:01.228 But when you talk to people who are

NOTE Confidence: 0.909681722857143

 $00:25:01.228 \longrightarrow 00:25:03.119$ clinical trialists and explain the

NOTE Confidence: 0.909681722857143

 $00:25:03.119 \rightarrow 00:25:05.393$ difference in the approach and the

NOTE Confidence: 0.909681722857143

 $00:25:05.393 \rightarrow 00:25:07.558$ efficiency that comes with it and the

NOTE Confidence: 0.909681722857143

 $00{:}25{:}07{.}558 \dashrightarrow 00{:}25{:}09{.}176$ the you know the kind of trade offs that

NOTE Confidence: 0.909681722857143

00:25:09.176 --> 00:25:10.739 are always happening in any clinical trial,

NOTE Confidence: 0.909681722857143

 $00:25:10.740 \rightarrow 00:25:13.236$ but the you know how much more information.

NOTE Confidence: 0.909681722857143

 $00:25:13.240 \rightarrow 00:25:15.490$ You can aggregate passively and not

NOTE Confidence: 0.909681722857143

 $00:25:15.490 \longrightarrow 00:25:17.360$ requiring patients to come back,

NOTE Confidence: 0.909681722857143

 $00:25:17.360 \longrightarrow 00:25:19.625$ minimizing the burden on patients

NOTE Confidence: 0.909681722857143

 $00:25:19.625 \longrightarrow 00:25:21.437$ in terms of participation.

NOTE Confidence: 0.909681722857143

00:25:21.440 --> 00:25:23.239 People see. Ah, I get it now.

NOTE Confidence: 0.909681722857143

 $00:25:23.240 \longrightarrow 00:25:24.164$ There's a there's there's,

NOTE Confidence: 0.909681722857143

 $00{:}25{:}24{.}164 \dashrightarrow 00{:}25{:}25{.}319$ there's great promise to this,

NOTE Confidence: 0.909681722857143

 $00:25:25.320 \longrightarrow 00:25:27.196$ and it's not to say that that

00:25:27.196 --> 00:25:28.260 we've worked everything out,

NOTE Confidence: 0.909681722857143

 $00{:}25{:}28{.}260 \dashrightarrow 00{:}25{:}30{.}445$ but I feel like we're kind of pilot

NOTE Confidence: 0.909681722857143

 $00:25:30.445 \rightarrow 00:25:33.525$ testing new ways to do trials like this,

NOTE Confidence: 0.909681722857143

 $00:25:33.530 \rightarrow 00:25:35.516$ which I hope are going to,

NOTE Confidence: 0.909681722857143

00:25:35.520 --> 00:25:35.980 you know,

NOTE Confidence: 0.909681722857143

 $00{:}25{:}35{.}980 \dashrightarrow 00{:}25{:}37{.}360$ be useful and informative and and

NOTE Confidence: 0.909681722857143

 $00{:}25{:}37{.}360 \dashrightarrow 00{:}25{:}38{.}905$ and set the stage for the future

NOTE Confidence: 0.909681722857143

 $00:25:38.905 \longrightarrow 00:25:40.399$ so it doesn't need to be kind

NOTE Confidence: 0.909681722857143

 $00{:}25{:}40{.}399 \dashrightarrow 00{:}25{:}41{.}617$ of an all or nothing either.

NOTE Confidence: 0.909681722857143

 $00{:}25{:}41.620 \dashrightarrow 00{:}25{:}43.780$ Do a kind of a traditional clinical trial.

NOTE Confidence: 0.909681722857143

 $00{:}25{:}43.780 \dashrightarrow 00{:}25{:}45.058$ Bringing patient back every couple of

NOTE Confidence: 0.909681722857143

 $00:25:45.058 \rightarrow 00:25:46.880$ weeks for kind of standardized assessment,

NOTE Confidence: 0.909681722857143

 $00:25:46.880 \longrightarrow 00:25:48.464$ or we're doing observation,

NOTE Confidence: 0.909681722857143

 $00{:}25{:}48{.}464 \dashrightarrow 00{:}25{:}50{.}840$ ULL data source and data analysis.

NOTE Confidence: 0.909681722857143

 $00{:}25{:}50{.}840 \dashrightarrow 00{:}25{:}53{.}885$ There's there's kind of a middle Rd.

NOTE Confidence: 0.909681722857143

 $00{:}25{:}53.890 \dashrightarrow 00{:}25{:}55.640$ I do see there was one question

- NOTE Confidence: 0.909681722857143
- $00{:}25{:}55{.}640 \dashrightarrow 00{:}25{:}57{.}770$ from Doctor Boffa on how to handle
- NOTE Confidence: 0.909681722857143
- 00:25:57.770 --> 00:25:59.420 contradicted data from different sources,
- NOTE Confidence: 0.909681722857143
- $00{:}25{:}59{.}420 \dashrightarrow 00{:}26{:}01{.}510$ and that's an interesting challenge,
- NOTE Confidence: 0.909681722857143
- $00:26:01.510 \longrightarrow 00:26:04.429$ right in the sense of you know,
- NOTE Confidence: 0.909681722857143
- 00:26:04.430 --> 00:26:06.356 how do you if you see,
- NOTE Confidence: 0.909681722857143
- $00{:}26{:}06{.}360 \dashrightarrow 00{:}26{:}08{.}675$ you know essentially prescription data
- NOTE Confidence: 0.909681722857143
- $00:26:08.675 \rightarrow 00:26:11.590$ in the electronic health record at Yale,
- NOTE Confidence: 0.909681722857143
- $00:26:11.590 \longrightarrow 00:26:13.654$ but not in the pharmacy data
- NOTE Confidence: 0.909681722857143
- $00:26:13.654 \longrightarrow 00:26:15.450$ and how to understand that.
- NOTE Confidence: 0.909681722857143
- $00:26:15.450 \rightarrow 00:26:17.298$ And some of it is about understanding
- NOTE Confidence: 0.909681722857143
- $00{:}26{:}17.298 \dashrightarrow 00{:}26{:}18.365$ the various functions that
- NOTE Confidence: 0.909681722857143
- $00{:}26{:}18.365 \dashrightarrow 00{:}26{:}19.709$ are used for the data sources.
- NOTE Confidence: 0.909681722857143
- $00:26:19.710 \longrightarrow 00:26:20.040$ Right?
- NOTE Confidence: 0.909681722857143
- $00{:}26{:}20.040 \dashrightarrow 00{:}26{:}21.690$ Prescription is ordered by a
- NOTE Confidence: 0.909681722857143
- $00{:}26{:}21.690 \dashrightarrow 00{:}26{:}23.608$ physician at Yale and it's filled
- NOTE Confidence: 0.909681722857143

 $00:26:23.608 \rightarrow 00:26:25.498$ at a pharmacy so that it's at.

NOTE Confidence: 0.909681722857143

00:26:25.500 --> 00:26:27.876 It actually gives you a sense of you know,

NOTE Confidence: 0.909681722857143

 $00:26:27.880 \longrightarrow 00:26:28.203$ adherence,

NOTE Confidence: 0.909681722857143

 $00:26:28.203 \rightarrow 00:26:30.141$ like our patients going and filling

NOTE Confidence: 0.909681722857143

 $00:26:30.141 \longrightarrow 00:26:32.180$ their their their their prescriptions.

NOTE Confidence: 0.909681722857143

00:26:32.180 --> 00:26:34.830 But other times you know if there's you know,

NOTE Confidence: 0.909681722857143

 $00:26:34.830 \longrightarrow 00:26:36.405$ particularly for the physical

NOTE Confidence: 0.909681722857143

 $00:26:36.405 \longrightarrow 00:26:38.122$ function we're going to have to

NOTE Confidence: 0.909681722857143

 $00:26:38.122 \longrightarrow 00:26:39.562$ decide exactly what does it mean.

NOTE Confidence: 0.909681722857143

 $00:26:39.570 \longrightarrow 00:26:41.560$ If if different you know,

NOTE Confidence: 0.909681722857143

 $00:26:41.560 \longrightarrow 00:26:43.096$ patient reported outcome measures

NOTE Confidence: 0.909681722857143

00:26:43.096 --> 00:26:44.632 or clinician reported outcome

NOTE Confidence: 0.909681722857143

 $00:26:44.632 \longrightarrow 00:26:45.969$ measures do not align.

NOTE Confidence: 0.8007884375

00:26:51.850 --> 00:26:54.685 I see Kerry Gross asked a question

NOTE Confidence: 0.8007884375

 $00{:}26{:}54.685 \dashrightarrow 00{:}26{:}57.290$ around thinking about ways to

NOTE Confidence: 0.8007884375

 $00{:}26{:}57{.}290 \dashrightarrow 00{:}26{:}59{.}474$ adapt the EHR and its interface

 $00:26:59.474 \longrightarrow 00:27:01.100$ in order to be more proactive

NOTE Confidence: 0.8007884375

00:27:01.156 --> 00:27:02.856 in terms of making information

NOTE Confidence: 0.8007884375

 $00:27:02.856 \longrightarrow 00:27:04.556$ like this more readily available.

NOTE Confidence: 0.8007884375

00:27:04.560 --> 00:27:06.246 And I, I couldn't agree more.

NOTE Confidence: 0.8007884375

 $00{:}27{:}06.250 \dashrightarrow 00{:}27{:}09.290$ Some of the challenges and part of the

NOTE Confidence: 0.8007884375

 $00:27:09.290 \rightarrow 00:27:11.612$ reason why we're using survey questions

NOTE Confidence: 0.8007884375

00:27:11.612 --> 00:27:13.789 out to patients is because it's not,

NOTE Confidence: 0.8007884375

00:27:13.790 --> 00:27:15.006 you know, you know,

NOTE Confidence: 0.8007884375

 $00{:}27{:}15.006 \dashrightarrow 00{:}27{:}16.526$ uniformly collected as part of

NOTE Confidence: 0.8007884375

 $00{:}27{:}16.526$ --> $00{:}27{:}18.582$ the HR and then extracted and

NOTE Confidence: 0.8007884375

 $00{:}27{:}18.582 \dashrightarrow 00{:}27{:}20.272$ available to investigators who are

NOTE Confidence: 0.8007884375

 $00{:}27{:}20.332 \dashrightarrow 00{:}27{:}22.247$ leveraging health system data for.

NOTE Confidence: 0.8007884375

 $00:27:22.250 \longrightarrow 00:27:23.750$ For research or for you know,

NOTE Confidence: 0.8007884375

 $00{:}27{:}23.750 \dashrightarrow 00{:}27{:}25.118$ to inform clinical practice.

NOTE Confidence: 0.8007884375

 $00{:}27{:}25.118 \dashrightarrow 00{:}27{:}27.170$ The more structured data we think

 $00:27:27.234 \longrightarrow 00:27:29.088$ about embedding within our reach are

NOTE Confidence: 0.8007884375

 $00{:}27{:}29.088 \dashrightarrow 00{:}27{:}31.269$ the better the data are going to be,

NOTE Confidence: 0.8007884375

 $00:27:31.270 \longrightarrow 00:27:33.566$ the more it's going to allow us to

NOTE Confidence: 0.8007884375

00:27:33.566 --> 00:27:36.199 use kind of actually more typical

NOTE Confidence: 0.8007884375

 $00{:}27{:}36.199 \dashrightarrow 00{:}27{:}38.684$ observational data resources for research.

NOTE Confidence: 0.8007884375

00:27:38.690 --> 00:27:40.986 One of the things when and when I

NOTE Confidence: 0.8007884375

 $00{:}27{:}40{.}986 \dashrightarrow 00{:}27{:}43{.}009$ presented that project done by the

NOTE Confidence: 0.8007884375

 $00:27:43.009 \rightarrow 00:27:45.091$ medical student who identify that only

NOTE Confidence: 0.8007884375

 $00{:}27{:}45{.}151 \dashrightarrow 00{:}27{:}46{.}810$ 15% of clinical trials could actually

NOTE Confidence: 0.8007884375

 $00{:}27{:}46.810 \dashrightarrow 00{:}27{:}49.234$ be routinely or fees abli done today

NOTE Confidence: 0.8007884375

 $00:27:49.234 \rightarrow 00:27:51.010$ using routinely ascertainable information.

NOTE Confidence: 0.8007884375

 $00{:}27{:}51{.}010 \dashrightarrow 00{:}27{:}53{.}400$ Part of it is because.

NOTE Confidence: 0.8007884375

 $00{:}27{:}53{.}400 \dashrightarrow 00{:}27{:}55{.}060$ Like patient reported outcome measures

NOTE Confidence: 0.8007884375

 $00{:}27{:}55{.}060 \dashrightarrow 00{:}27{:}57{.}091$ are not routinely included as part

NOTE Confidence: 0.8007884375

00:27:57.091 -> 00:27:58.379 of structured data elements,

NOTE Confidence: 0.8007884375

 $00:27:58.380 \rightarrow 00:27:59.880$ so there's a real opportunity there.

 $00:28:09.950 \longrightarrow 00:28:12.050$ And then I'll the last question

NOTE Confidence: 0.876349984705882

 $00{:}28{:}12.050 \dashrightarrow 00{:}28{:}14.461$ I see is about addressing self

NOTE Confidence: 0.876349984705882

 $00{:}28{:}14.461 \dashrightarrow 00{:}28{:}16.796$ selection bias in our data.

NOTE Confidence: 0.876349984705882

 $00:28:16.800 \rightarrow 00:28:19.250$ I think what Doctor Hooley is referring

NOTE Confidence: 0.876349984705882

 $00{:}28{:}19{.}250 \dashrightarrow 00{:}28{:}22{.}254$ to is the participation bias that

NOTE Confidence: 0.876349984705882

 $00:28:22.254 \rightarrow 00:28:24.415$ individuals are going to be more

NOTE Confidence: 0.876349984705882

 $00:28:24.415 \rightarrow 00:28:26.390$ likely to participate in the study.

NOTE Confidence: 0.876349984705882

 $00:28:26.390 \longrightarrow 00:28:29.015$ And that raises an issue of bias.

NOTE Confidence: 0.876349984705882

 $00{:}28{:}29{.}020 \dashrightarrow 00{:}28{:}31{.}426$ I don't think that the selection into

NOTE Confidence: 0.876349984705882

 $00{:}28{:}31{.}426 \dashrightarrow 00{:}28{:}33{.}544$ our studies is different any different

NOTE Confidence: 0.876349984705882

 $00:28:33.544 \rightarrow 00:28:35.847$ than the selection of any individual

NOTE Confidence: 0.876349984705882

00:28:35.847 --> 00:28:37.772 individual into a clinical trial,

NOTE Confidence: 0.876349984705882

 $00:28:37.780 \longrightarrow 00:28:40.768$ but hopefully ideally by lowering the

NOTE Confidence: 0.876349984705882

 $00{:}28{:}40.768 \dashrightarrow 00{:}28{:}43.679$ barriers to participation and making

NOTE Confidence: 0.876349984705882

 $00{:}28{:}43.679 \dashrightarrow 00{:}28{:}46.626$ it easier on patients to participate by.

 $00:28:46.630 \rightarrow 00:28:48.622$ By diminishing that burden of kind

NOTE Confidence: 0.876349984705882

 $00:28:48.622 \longrightarrow 00:28:50.720$ of haven't come in our trials.

NOTE Confidence: 0.876349984705882

 $00{:}28{:}50{.}720 \dashrightarrow 00{:}28{:}53{.}800$ Using this this type of approach may be

NOTE Confidence: 0.876349984705882

 $00:28:53.875 \rightarrow 00:28:56.970$ more representative of clinical practice,

NOTE Confidence: 0.876349984705882

 $00:28:56.970 \rightarrow 00:28:58.776$ although that's that remains to be seen,

NOTE Confidence: 0.876349984705882

 $00{:}28{:}58{.}780 \dashrightarrow 00{:}29{:}00{.}565$ and it's an important issue

NOTE Confidence: 0.876349984705882

 $00{:}29{:}00{.}565 \dashrightarrow 00{:}29{:}02{.}350$ for us to address so.

NOTE Confidence: 0.876349984705882

 $00{:}29{:}02{.}350 \dashrightarrow 00{:}29{:}03{.}610$ I'll stop there so that Susan

NOTE Confidence: 0.876349984705882

 $00{:}29{:}03.610 \dashrightarrow 00{:}29{:}05.026$ Bush has plenty of time to

NOTE Confidence: 0.876349984705882

 $00:29:05.026 \rightarrow 00:29:06.078$ go through her presentation.

NOTE Confidence: 0.892838413333333

 $00:29:07.510 \longrightarrow 00:29:08.578$ Thank you Joe.

NOTE Confidence: 0.9374417666666667

 $00{:}29{:}11{.}400 \dashrightarrow 00{:}29{:}13{.}451$ It is my pleasure to introduce our

NOTE Confidence: 0.9374417666666667

00:29:13.451 --> 00:29:15.213 next speaker, doctor Susan Bush,

NOTE Confidence: 0.9374417666666667

 $00:29:15.213 \rightarrow 00:29:17.950$ who is Professor Public House in House

NOTE Confidence: 0.9374417666666667

 $00{:}29{:}18.027 \dashrightarrow 00{:}29{:}20.600$ Policy and professor in the Institution

NOTE Confidence: 0.9374417666666667

00:29:20.600 --> 00:29:22.760 for social and Policy Studies.

- NOTE Confidence: 0.9374417666666667
- 00:29:22.760 --> 00:29:24.902 She received a master degree in House
- NOTE Confidence: 0.9374417666666667
- $00{:}29{:}24.902 \dashrightarrow 00{:}29{:}27.319$ policy in a PhD in House Economics.
- NOTE Confidence: 0.9374417666666667
- $00{:}29{:}27{.}320 \dashrightarrow 00{:}29{:}28{.}884$ Those from Harvard University.
- NOTE Confidence: 0.9374417666666667
- $00{:}29{:}28{.}884 \dashrightarrow 00{:}29{:}31{.}669$ A number of us have been lobbying
- NOTE Confidence: 0.9374417666666667
- 00:29:31.669 00:29:34.210 for her to join the Cancer Center
- NOTE Confidence: 0.9374417666666667
- $00{:}29{:}34{.}210 \dashrightarrow 00{:}29{:}36{.}997$ and very happy when she did recently.
- NOTE Confidence: 0.9374417666666667
- $00:29:37.000 \rightarrow 00:29:39.640$ Doctor Bush's research examines the effects
- NOTE Confidence: 0.9374417666666667
- $00:29:39.640 \rightarrow 00:29:42.399$ of policies and regulations on health care,
- NOTE Confidence: 0.9374417666666667
- $00:29:42.400 \longrightarrow 00:29:43.948$ cost and quality,
- NOTE Confidence: 0.9374417666666667
- $00:29:43.948 \rightarrow 00:29:47.044$ and she's a renowned and highly
- NOTE Confidence: 0.9374417666666667
- $00:29:47.044 \rightarrow 00:29:49.796$ respected expert in this field today.
- NOTE Confidence: 0.9374417666666667
- 00:29:49.796 --> 00:29:51.776 Her topic is insurance coverage,
- NOTE Confidence: 0.9374417666666667
- $00{:}29{:}51.780 \dashrightarrow 00{:}29{:}53.895$ mandates and the adoption of
- NOTE Confidence: 0.9374417666666667
- $00{:}29{:}53{.}895 \dashrightarrow 00{:}29{:}55{.}587$ digital breast Tomo synthesis.
- NOTE Confidence: 0.441354562
- $00:29:57.790 \longrightarrow 00:29:59.720$ Doctor Bush for as yours.
- NOTE Confidence: 0.865376265454545

00:30:00.250 --> 00:30:02.320 OK, thank you. Thank you so

NOTE Confidence: 0.865376265454545

00:30:02.320 --> 00:30:03.970 much Johnny for inviting me.

NOTE Confidence: 0.865376265454545

 $00{:}30{:}03{.}970 \dashrightarrow 00{:}30{:}04.650$ I just wanna make sure.

NOTE Confidence: 0.865376265454545

00:30:04.650 --> 00:30:06.634 Can you see my slide show it's working?

NOTE Confidence: 0.79118421125

 $00:30:11.590 \rightarrow 00:30:14.070$ Some show me you can see my slideshow.

NOTE Confidence: 0.79118421125

00:30:14.070 --> 00:30:17.488 Yes, OK perfect. So first,

NOTE Confidence: 0.79118421125

00:30:17.488 - 00:30:19.280 for those of you who don't know me,

NOTE Confidence: 0.79118421125

 $00{:}30{:}19.280 \dashrightarrow 00{:}30{:}21.152$ I'm a health service researcher and

NOTE Confidence: 0.79118421125

 $00{:}30{:}21.152 \dashrightarrow 00{:}30{:}22.636$ health economist, and I teach at

NOTE Confidence: 0.79118421125

 $00{:}30{:}22.636 \dashrightarrow 00{:}30{:}23.920$ the Yale School of Public Health.

NOTE Confidence: 0.79118421125

 $00:30:23.920 \longrightarrow 00:30:25.996$ I teach advanced health economics here,

NOTE Confidence: 0.79118421125

00:30:26.000 --> 00:30:28.616 and most of my work is really around

NOTE Confidence: 0.79118421125

00:30:28.616 --> 00:30:30.696 mental health and substance use disorder

NOTE Confidence: 0.79118421125

 $00{:}30{:}30{.}696 \dashrightarrow 00{:}30{:}34{.}239$ with a focus on access to care and how we

NOTE Confidence: 0.79118421125

 $00{:}30{:}34{.}239 \dashrightarrow 00{:}30{:}36{.}393$ can optimize benefit design to increase

NOTE Confidence: 0.79118421125

 $00:30:36.400 \rightarrow 00:30:38.200$ the value of the healthcare system.

 $00{:}30{:}38{.}200 \dashrightarrow 00{:}30{:}40{.}873$ So I sort of took my knowledge about those

NOTE Confidence: 0.79118421125

 $00{:}30{:}40{.}873 \dashrightarrow 00{:}30{:}43{.}538$ issues and and now I'm applying it to cancer.

NOTE Confidence: 0.79118421125

 $00:30:43.540 \rightarrow 00:30:45.605$ So generally I'm interested when you think

NOTE Confidence: 0.79118421125

 $00:30:45.605 \rightarrow 00:30:48.129$ about is as we change payment mechanisms.

NOTE Confidence: 0.79118421125

 $00{:}30{:}48{.}130 \dashrightarrow 00{:}30{:}50{.}338$ What are the impacts on access to care,

NOTE Confidence: 0.79118421125

 $00:30:50.340 \longrightarrow 00:30:51.790$ cost of care and value?

NOTE Confidence: 0.79118421125

 $00:30:51.790 \rightarrow 00:30:53.428$ And it's always really tough to get at that.

NOTE Confidence: 0.79118421125

 $00:30:53.430 \longrightarrow 00:30:54.770$ You know idea of value,

NOTE Confidence: 0.79118421125

00:30:54.770 --> 00:30:57.325 but I I really do strive in

NOTE Confidence: 0.79118421125

 $00:30:57.325 \longrightarrow 00:30:59.289$ my work to do that.

NOTE Confidence: 0.79118421125

00:30:59.290 --> 00:31:00.790 So if anybody has any problem

NOTE Confidence: 0.79118421125

 $00{:}31{:}00{.}790 \dashrightarrow 00{:}31{:}01{.}790$ projects related to that,

NOTE Confidence: 0.79118421125

 $00{:}31{:}01.790 \dashrightarrow 00{:}31{:}04.100$ I would love to meet with them.

NOTE Confidence: 0.79118421125

00:31:04.100 --> 00:31:06.260 I also have several projects related

NOTE Confidence: 0.79118421125

 $00{:}31{:}06{.}260 \dashrightarrow 00{:}31{:}08{.}412$ to to bacco control that people that

 $00:31:08.412 \longrightarrow 00:31:10.350$ might be of interest to people.

NOTE Confidence: 0.79118421125

00:31:10.350 --> 00:31:11.610 I'm not going to go into

NOTE Confidence: 0.79118421125

 $00:31:11.610 \longrightarrow 00:31:12.450$ detail here about those,

NOTE Confidence: 0.79118421125

 $00:31:12.450 \longrightarrow 00:31:15.114$ but if you're interested I would love to

NOTE Confidence: 0.79118421125

 $00:31:15.114 \rightarrow 00:31:18.179$ meet with you and talk about that about that.

NOTE Confidence: 0.79118421125

 $00{:}31{:}18{.}180 \dashrightarrow 00{:}31{:}21{.}176$ So over the past several years wanna

NOTE Confidence: 0.79118421125

 $00:31:21.176 \longrightarrow 00:31:24.359$ say it's really been a delight to get

NOTE Confidence: 0.79118421125

 $00{:}31{:}24{.}359 \dashrightarrow 00{:}31{:}27.660$ to know the faculty at the Cancer Center

NOTE Confidence: 0.79118421125

 $00{:}31{:}27.660 \dashrightarrow 00{:}31{:}29.956$ both at the medical school and also

NOTE Confidence: 0.79118421125

 $00{:}31{:}29{.}960 \dashrightarrow 00{:}31{:}31{.}759$ here at the School of Public Health?

NOTE Confidence: 0.79118421125

 $00:31:31.760 \longrightarrow 00:31:32.780$ So in particular,

NOTE Confidence: 0.79118421125

00:31:32.780 --> 00:31:34.820 I want to mention Carrie Gross,

NOTE Confidence: 0.79118421125

 $00{:}31{:}34{.}820 \dashrightarrow 00{:}31{:}37{.}592$ who invited me to work with his

NOTE Confidence: 0.79118421125

 $00{:}31{:}37{.}592 \dashrightarrow 00{:}31{:}40{.}694$ team a couple of years ago and has

NOTE Confidence: 0.79118421125

 $00:31:40.694 \rightarrow 00:31:43.592$ really taught me a lot about both

NOTE Confidence: 0.79118421125

 $00:31:43.592 \rightarrow 00:31:45.961$ breast cancer screening and about

 $00:31:45.961 \longrightarrow 00:31:48.367$ how to use health care claims.

NOTE Confidence: 0.79118421125

 $00{:}31{:}48{.}370 \dashrightarrow 00{:}31{:}50{.}162$ Related to some of the issues that

NOTE Confidence: 0.79118421125

 $00:31:50.162 \rightarrow 00:31:52.098$ we're going to talk about today and

NOTE Confidence: 0.79118421125

 $00:31:52.098 \rightarrow 00:31:54.510$ also I want to give a big shout out.

NOTE Confidence: 0.79118421125

 $00{:}31{:}54{.}510 \dashrightarrow 00{:}31{:}57{.}163$ I hope she's on the call to Alana

NOTE Confidence: 0.79118421125

 $00:31:57.163 \dashrightarrow 00:31:59.041$ Richmond and this is very specifically

NOTE Confidence: 0.79118421125

 $00:31:59.041 \dashrightarrow 00:32:01.369$ related to the work of presenting today.

NOTE Confidence: 0.79118421125

 $00:32:01.370 \dashrightarrow 00:32:03.365$ Elan is an internal medicine and she

NOTE Confidence: 0.79118421125

 $00:32:03.365 \longrightarrow 00:32:05.509$ is the first author on this paper,

NOTE Confidence: 0.79118421125

 $00:32:05.510 \dashrightarrow 00:32:07.568$ and I can't emphasize enough how

NOTE Confidence: 0.79118421125

00:32:07.568 --> 00:32:09.339 much I've learned from having

NOTE Confidence: 0.79118421125

 $00{:}32{:}09{.}339 \dashrightarrow 00{:}32{:}11{.}325$ the opportunity to work with her

NOTE Confidence: 0.79118421125

 $00:32:11.325 \longrightarrow 00:32:13.380$ over the past couple of years.

NOTE Confidence: 0.79118421125

 $00{:}32{:}13{.}380 \dashrightarrow 00{:}32{:}15{.}046$ So the paper that I'm going to

NOTE Confidence: 0.79118421125

 $00{:}32{:}15.046 \dashrightarrow 00{:}32{:}16.516$ talk about today is the latest

 $00:32:16.516 \longrightarrow 00:32:18.147$ in a series of papers related to

NOTE Confidence: 0.79118421125

 $00{:}32{:}18.202 \dashrightarrow 00{:}32{:}20.140$ breast cancer screening related to

NOTE Confidence: 0.79118421125

 $00:32:20.140 \rightarrow 00:32:21.680$ issues around patient preferences,

NOTE Confidence: 0.79118421125

 $00:32:21.680 \longrightarrow 00:32:23.876$ diffusion of new technologies and cost.

NOTE Confidence: 0.79118421125

00:32:23.880 --> 00:32:24.618 And you know,

NOTE Confidence: 0.79118421125

 $00:32:24.618 \rightarrow 00:32:26.700$ this paper is not really focused on value,

NOTE Confidence: 0.79118421125

 $00:32:26.700 \longrightarrow 00:32:29.101$ but also a lot of our papers

NOTE Confidence: 0.79118421125

 $00:32:29.101 \longrightarrow 00:32:30.610$ are focused on that.

NOTE Confidence: 0.79118421125

 $00{:}32{:}30{.}610 \dashrightarrow 00{:}32{:}32{.}680$ So this paper has not yet it's been accepted

NOTE Confidence: 0.79118421125

 $00:32:32.680 \rightarrow 00:32:34.499$ for publication at that not out yet,

NOTE Confidence: 0.79118421125

 $00:32:34.500 \rightarrow 00:32:36.404$ but we're thinking it's going to be out

NOTE Confidence: 0.79118421125

 $00{:}32{:}36{.}404 \dashrightarrow 00{:}32{:}38{.}395$ even in just the next couple of days,

NOTE Confidence: 0.79118421125

 $00:32:38.400 \longrightarrow 00:32:38.790$ so.

NOTE Confidence: 0.86517097

 $00:32:42.160 \rightarrow 00:32:44.659$ OK, so these are some our collaborators,

NOTE Confidence: 0.86517097

 $00:32:44.660 \longrightarrow 00:32:45.660$ my collaborators, on this paper.

NOTE Confidence: 0.86517097

00:32:45.660 --> 00:32:47.308 Alana, as I mentioned,

- NOTE Confidence: 0.86517097
- 00:32:47.308 --> 00:32:48.956 Jessica Long Kelly Kenco,

00:32:48.960 --> 00:32:51.697 who is at NYU. She's a primary

NOTE Confidence: 0.86517097

00:32:51.697 --> 00:32:53.920 care physician at NYU and Xiaoju,

NOTE Confidence: 0.86517097

 $00:32:53.920 \longrightarrow 00:32:56.080$ who is also here at Yale,

NOTE Confidence: 0.86517097

00:32:56.080 --> 00:32:57.328 and of course Kerry.

NOTE Confidence: 0.938326144285714

00:33:00.460 - 00:33:02.616 So you know, over the past decade,

NOTE Confidence: 0.938326144285714

 $00:33:02.620 \rightarrow 00:33:05.180$ cancer screening has undergone substantial

NOTE Confidence: 0.938326144285714

 $00:33:05.180 \longrightarrow 00:33:08.067$ technological shift in the US in

NOTE Confidence: 0.938326144285714

 $00{:}33{:}08.067 \dashrightarrow 00{:}33{:}10.029$ which digital breast tone was insist.

NOTE Confidence: 0.938326144285714

 $00{:}33{:}10{.}030 \dashrightarrow 00{:}33{:}12{.}910$ DBT has supplanted standard 2D2 dimensional

NOTE Confidence: 0.938326144285714

 $00{:}33{:}12.910 \dashrightarrow 00{:}33{:}16.567$ Mogra fi alone as the standard of care.

NOTE Confidence: 0.938326144285714

00:33:16.570 $\operatorname{-->}$ 00:33:19.235 Advantages of DBT are that

NOTE Confidence: 0.938326144285714

00:33:19.235 --> 00:33:21.367 DBT may reduce recall.

NOTE Confidence: 0.938326144285714

 $00{:}33{:}21.370 \dashrightarrow 00{:}33{:}23.826$ That is that fewer women are called back

NOTE Confidence: 0.938326144285714

 $00:33:23.830 \longrightarrow 00:33:26.170$ for additional testing after screening,

 $00:33:26.170 \rightarrow 00:33:28.732$ and also that it may improve sensitivity

NOTE Confidence: 0.938326144285714

 $00{:}33{:}28{.}732 \dashrightarrow 00{:}33{:}31{.}758$ that we may identify more breast cancers

NOTE Confidence: 0.938326144285714

00:33:31.758 --> 00:33:34.542 using DBT compared to 2D mammography.

NOTE Confidence: 0.938326144285714

 $00{:}33{:}34{.}550 \dashrightarrow 00{:}33{:}36{.}664$ Yet DBT is still not rated A

NOTE Confidence: 0.938326144285714

 $00:33:36.664 \rightarrow 00:33:39.509$ or B by the US United Service.

NOTE Confidence: 0.938326144285714

00:33:39.510 --> 00:33:42.096 United States Preventive Services Task Force.

NOTE Confidence: 0.87287372

00:33:46.050 - 00:33:49.648 This map is from an earlier paper,

NOTE Confidence: 0.87287372

 $00:33:49.650 \longrightarrow 00:33:52.442$ so just to get a sense of the

NOTE Confidence: 0.87287372

 $00{:}33{:}52{.}442 \dashrightarrow 00{:}33{:}55{.}350$ variation in DBT adoption, this paper

NOTE Confidence: 0.87287372

 $00:33:55.350 \rightarrow 00:33:57.950$ looks at hospital referral regions,

NOTE Confidence: 0.87287372

00:33:57.950 --> 00:34:00.050 so the different geographic regions you can

NOTE Confidence: 0.87287372

 $00{:}34{:}00{.}050 \dashrightarrow 00{:}34{:}02{.}408$ see here are hospital referral regions,

NOTE Confidence: 0.87287372

 $00{:}34{:}02{.}410 \dashrightarrow 00{:}34{:}04{.}394$ and we look at three years of data

NOTE Confidence: 0.87287372

 $00{:}34{:}04{.}394 \dashrightarrow 00{:}34{:}07{.}793$ from 2015 to 2017 and over this time

NOTE Confidence: 0.87287372

00:34:07.793 --> 00:34:11.459 period over the US in the US over the

NOTE Confidence: 0.87287372

 $00:34:11.459 \rightarrow 00:34:15.278$ whole USDBT increase from 13 to 43%.

- NOTE Confidence: 0.87287372
- $00:34:15.278 \rightarrow 00:34:19.406$ Of screenings, so this looks very

 $00{:}34{:}19{.}406 \dashrightarrow 00{:}34{:}21{.}470$ specifically at trajectories,

NOTE Confidence: 0.87287372

 $00:34:21.470 \longrightarrow 00:34:23.346$ and we know by the end of 2017

NOTE Confidence: 0.87287372

 $00{:}34{:}23{.}346 \dashrightarrow 00{:}34{:}26{.}202$ the lowest use HRR's hospital for

NOTE Confidence: 0.87287372

00:34:26.202 --> 00:34:28.830 regions are about only about 4%

NOTE Confidence: 0.87287372

00:34:28.830 --> 00:34:30.750 of screenings where DBT, well,

NOTE Confidence: 0.87287372

 $00:34:30.750 \rightarrow 00:34:34.031$ the highest where it was at 68% of screening.

NOTE Confidence: 0.87287372

 $00:34:34.031 \rightarrow 00:34:36.780$ So there really is significant variation.

NOTE Confidence: 0.920689943846154

 $00{:}34{:}46{.}260 \dashrightarrow 00{:}34{:}48{.}195$ So related to insurance coverage

NOTE Confidence: 0.920689943846154

 $00:34:48.195 \dashrightarrow 00:34:50.130$ really today we're talking about

NOTE Confidence: 0.920689943846154

 $00:34:50.192 \longrightarrow 00:34:51.800$ private insurance coverage.

NOTE Confidence: 0.920689943846154

 $00{:}34{:}51{.}800 \dashrightarrow 00{:}34{:}53{.}748$ And private insurers are

NOTE Confidence: 0.920689943846154

 $00:34:53.748 \longrightarrow 00:34:56.017$ not required to cover DBT,

NOTE Confidence: 0.920689943846154

 $00{:}34{:}56{.}017 \dashrightarrow 00{:}34{:}58{.}236$ and that's because it doesn't have the

NOTE Confidence: 0.920689943846154

 $00:34:58.236 \dashrightarrow 00:35:00.990$ A or B recommendation by the USPSTF.

00:35:00.990 --> 00:35:02.460 So absent a federal mandate,

NOTE Confidence: 0.920689943846154

 $00:35:02.460 \rightarrow 00:35:04.450$ many private insurers didn't immediately

NOTE Confidence: 0.920689943846154

 $00:35:04.450 \rightarrow 00:35:07.000$ cover DBT characterizing it as elective,

NOTE Confidence: 0.920689943846154

 $00:35:07.000 \rightarrow 00:35:09.768$ or citing that there might not be long

NOTE Confidence: 0.920689943846154

 $00:35:09.768 \dashrightarrow 00:35:12.269$ term data and states got involved.

NOTE Confidence: 0.920689943846154

 $00{:}35{:}12.270 \dashrightarrow 00{:}35{:}13.830$ To date, 17 states.

NOTE Confidence: 0.920689943846154

00:35:13.830 - 00:35:16.560 I think it's actually maybe 19 now.

NOTE Confidence: 0.920689943846154

 $00:35:16.560 \rightarrow 00:35:18.296$ It's 17 states where the paper was written,

NOTE Confidence: 0.920689943846154

00:35:18.300 - > 00:35:20.280 have enacted laws that require

NOTE Confidence: 0.920689943846154

 $00:35:20.280 \rightarrow 00:35:22.260$ private health insurance cover DBT.

NOTE Confidence: 0.920689943846154

 $00:35:22.260 \rightarrow 00:35:23.732$ Without any cost sharing,

NOTE Confidence: 0.920689943846154

 $00:35:23.732 \longrightarrow 00:35:26.698$ so of course self insured plans are not

NOTE Confidence: 0.920689943846154

 $00:35:26.698 \dashrightarrow 00:35:28.780$ covered due to the ERISA exemption,

NOTE Confidence: 0.920689943846154

00:35:28.780 --> 00:35:31.425 but generally privately insured individuals

NOTE Confidence: 0.920689943846154

 $00:35:31.425 \rightarrow 00:35:35.297$ and women in these states do not have to.

NOTE Confidence: 0.920689943846154

00:35:35.300 --> 00:35:37.826 Pay any out of pocket payments

 $00:35:37.826 \rightarrow 00:35:40.410$ when they receive DVT screening.

NOTE Confidence: 0.920689943846154

 $00{:}35{:}40{.}410 \dashrightarrow 00{:}35{:}44{.}397$ So this figure just gives you a sense of

NOTE Confidence: 0.920689943846154

 $00:35:44.397 \rightarrow 00:35:48.370$ the variation in timing of these laws,

NOTE Confidence: 0.920689943846154

 $00:35:48.370 \longrightarrow 00:35:50.421$ so we're going to study laws that

NOTE Confidence: 0.920689943846154

 $00:35:50.421 \longrightarrow 00:35:52.756$ occurred from 2016 to 2019, and you can.

NOTE Confidence: 0.920689943846154

 $00:35:52.760 \longrightarrow 00:35:55.384$ You can see it really is like a

NOTE Confidence: 0.920689943846154

 $00:35:55.384 \rightarrow 00:35:57.123$ staggered implementation that's really

NOTE Confidence: 0.920689943846154

 $00:35:57.123 \rightarrow 00:35:59.155$ important for identification strategy.

NOTE Confidence: 0.920689943846154

 $00{:}35{:}59{.}160 \dashrightarrow 00{:}36{:}01{.}195$ Connecticut was the 3rd state

NOTE Confidence: 0.920689943846154

 $00:36:01.195 \longrightarrow 00:36:03.250$ to adopt in 2017.

NOTE Confidence: 0.88362951111111

 $00:36:11.930 \longrightarrow 00:36:14.210$ So insurance benefit mandates such as

NOTE Confidence: 0.883629511111111

 $00:36:14.210 \longrightarrow 00:36:16.744$ these have been widely used in other

NOTE Confidence: 0.88362951111111

 $00:36{:}16.744 \dashrightarrow 00{:}36{:}18.956$ contexts as a policy tool to protect

NOTE Confidence: 0.88362951111111

 $00:36:19.028 \rightarrow 00:36:21.688$ consumers against high out of pocket cost,

NOTE Confidence: 0.883629511111111

 $00:36:21.690 \longrightarrow 00:36:23.695$ so it reduces their financial

 $00:36:23.695 \longrightarrow 00:36:25.700$ burden and also to facilitate

NOTE Confidence: 0.883629511111111

 $00:36:25.771 \rightarrow 00:36:28.216$ access to important health services.

NOTE Confidence: 0.88362951111111

00:36:28.220 $\operatorname{-->}$ 00:36:30.914 However, you know these types of

NOTE Confidence: 0.883629511111111

 $00:36:30.914 \dashrightarrow 00:36:33.226$ benefit mandates have have been

NOTE Confidence: 0.88362951111111

 $00{:}36{:}33{.}226 \dashrightarrow 00{:}36{:}35{.}744$ criticized by some because they

NOTE Confidence: 0.883629511111111

 $00:36:35.744 \dashrightarrow 00:36:38.754$ may have some complex effects.

NOTE Confidence: 0.88362951111111

00:36:38.760 --> 00:36:41.450 Potentially, if you mandate may

NOTE Confidence: 0.883629511111111

 $00:36:41.450 \rightarrow 00:36:43.602$ contribute to higher insurance

NOTE Confidence: 0.88362951111111

 $00{:}36{:}43.602 \dashrightarrow 00{:}36{:}45.960$ premiums and thereby this may increase

NOTE Confidence: 0.88362951111111

 $00{:}36{:}45{.}960 \dashrightarrow 00{:}36{:}47{.}780$ uninsurance rates as if insurance

NOTE Confidence: 0.88362951111111

 $00{:}36{:}47.841 \dashrightarrow 00{:}36{:}49.977$ premiums get prohibitively expensive.

NOTE Confidence: 0.88362951111111

 $00{:}36{:}49{.}980 \dashrightarrow 00{:}36{:}52{.}010$ There's been some criticism that

NOTE Confidence: 0.883629511111111

 $00{:}36{:}52.010 \dashrightarrow 00{:}36{:}54.040$ they may reduce plan design,

NOTE Confidence: 0.883629511111111

 $00:36:54.040 \dashrightarrow 00:36:55.900$ plan benefit, design, flexibility.

NOTE Confidence: 0.88362951111111

 $00:36:55.900 \rightarrow 00:36:59.148$ And also that increasing the price of

NOTE Confidence: 0.883629511111111

 $00{:}36{:}59{.}148 \dashrightarrow 00{:}37{:}01{.}452$ the specific of a specific mandated

 $00:37:01.452 \rightarrow 00:37:03.254$ service may reduce negotiating power

NOTE Confidence: 0.883629511111111

 $00{:}37{:}03{.}254 \dashrightarrow 00{:}37{:}05{.}508$ and this is going to be particularly

NOTE Confidence: 0.88362951111111

00:37:05.508 --> 00:37:08.248 problematic for a service or a drug,

NOTE Confidence: 0.88362951111111

 $00:37:08.250 \longrightarrow 00:37:10.375$ potentially where they have the

NOTE Confidence: 0.88362951111111

 $00:37:10.375 \rightarrow 00:37:12.500$ supplier has some monopoly power.

NOTE Confidence: 0.8959906066666667

 $00:37:14.830 \longrightarrow 00:37:17.462$ So our goal in this paper was

NOTE Confidence: 0.8959906066666667

 $00:37:17.462 \longrightarrow 00:37:19.336$ to evaluate the relationship

NOTE Confidence: 0.8959906066666667

00:37:19.336 --> 00:37:21.948 between DBT coverage laws.

NOTE Confidence: 0.8959906066666667

 $00{:}37{:}21{.}950 \dashrightarrow 00{:}37{:}24{.}477$ The 17 laws that I noted in

NOTE Confidence: 0.8959906066666667

 $00{:}37{:}24.477 \dashrightarrow 00{:}37{:}26.598$ the last slide and DBT use

NOTE Confidence: 0.8959906066666667

00:37:26.600 --> 00:37:28.300 DBT out of pocket payments,

NOTE Confidence: 0.8959906066666667

 $00{:}37{:}28.300 \dashrightarrow 00{:}37{:}30.188$ and also DBT price.

NOTE Confidence: 0.884796792

 $00:37:34.310 \longrightarrow 00:37:37.326$ So to study this, we use data from

NOTE Confidence: 0.884796792

00:37:37.326 $\operatorname{-->}$ 00:37:40.509 Blue Cross Blue Shield access data set,

NOTE Confidence: 0.884796792

 $00{:}37{:}40{.}510 \dashrightarrow 00{:}37{:}43{.}162$ which is a a deidentified database

 $00:37:43.162 \longrightarrow 00:37:44.930$ of health insurance claims.

NOTE Confidence: 0.884796792

 $00:37:44.930 \longrightarrow 00:37:47.366$ There are claims from all 50 states,

NOTE Confidence: 0.884796792

 $00:37:47.370 \rightarrow 00:37:50.009$ so the geographic diversity of this sample,

NOTE Confidence: 0.884796792

 $00:37:50.010 \longrightarrow 00:37:51.459$ along with the fact that has a

NOTE Confidence: 0.884796792

 $00{:}37{:}51{.}459 \dashrightarrow 00{:}37{:}52{.}330$ longitudinal structure so you

NOTE Confidence: 0.884796792

 $00{:}37{:}52{.}330 \dashrightarrow 00{:}37{:}53{.}375$ can follow patients over time.

NOTE Confidence: 0.884796792

 $00:37:53.380 \longrightarrow 00:37:56.264$ It makes it really well suited to

NOTE Confidence: 0.884796792

 $00:37:56.264 \rightarrow 00:37:58.608$ evaluate policies that vary by state.

NOTE Confidence: 0.884796792

 $00{:}37{:}58.610 \dashrightarrow 00{:}38{:}00.605$ Within this data set we identified screening.

NOTE Confidence: 0.884796792

00:38:00.610 --> 00:38:03.235 Mammography is performed among women

NOTE Confidence: 0.884796792

 $00{:}38{:}03{.}235 \dashrightarrow 00{:}38{:}07{.}510$ ages 40 to 64 between January 2015 and

NOTE Confidence: 0.884796792

00:38:07.510 --> 00:38:10.420 July 1st up through June 30th, 2019,

NOTE Confidence: 0.884796792

 $00{:}38{:}10.420 \dashrightarrow 00{:}38{:}12.555$ and we have a a standard validated

NOTE Confidence: 0.884796792

00:38:12.555 --> 00:38:14.242 algorithm that we've been using

NOTE Confidence: 0.884796792

 $00:38:14.242 \rightarrow 00:38:15.902$ to identify a screen mammography.

NOTE Confidence: 0.884796792

00:38:15.910 - 00:38:18.038 I won't get into details on that
- NOTE Confidence: 0.884796792
- $00:38:18.038 \longrightarrow 00:38:18.950$ in this talk,
- NOTE Confidence: 0.884796792
- $00:38:18.950 \longrightarrow 00:38:21.150$ so we did exclude women 65 and over,
- NOTE Confidence: 0.884796792
- $00{:}38{:}21{.}150 \dashrightarrow 00{:}38{:}23{.}438$ and the reason we did that is because
- NOTE Confidence: 0.884796792
- $00:38:23.438 \rightarrow 00:38:25.497$ Medicare is not really represented in
- NOTE Confidence: 0.884796792
- 00:38:25.497 --> 00:38:27.990 these data or Medicare Advantage as well,
- NOTE Confidence: 0.884796792
- $00{:}38{:}27{.}990 \dashrightarrow 00{:}38{:}29{.}118$ and we felt that.
- NOTE Confidence: 0.884796792
- $00{:}38{:}29{.}118 \dashrightarrow 00{:}38{:}30{.}970$ Older women that were then included in
- NOTE Confidence: 0.884796792
- $00:38:30.970 \dashrightarrow 00:38:34.617$ the BCBS data might be highly selected.
- NOTE Confidence: 0.884796792
- 00:38:34.620 --> 00:38:36.188 So we use the patient level data
- NOTE Confidence: 0.884796792
- $00:38:36.188 \longrightarrow 00:38:37.249$ to describe the characteristics
- NOTE Confidence: 0.884796792
- $00:38:37.249 \longrightarrow 00:38:38.959$ of the women and mammograms,
- NOTE Confidence: 0.884796792
- $00:38:38.960 \longrightarrow 00:38:40.370$ including the study.
- NOTE Confidence: 0.884796792
- $00:38:40.370 \longrightarrow 00:38:43.088$ But when we do our additional analysis,
- NOTE Confidence: 0.884796792
- 00:38:43.088 --> 00:38:44.396 our event study design,
- NOTE Confidence: 0.884796792
- $00:38:44.400 \longrightarrow 00:38:45.856$ we perform it at the state level.
- NOTE Confidence: 0.884796792

 $00:38:45.860 \rightarrow 00:38:48.804$ That is, we collapse cells to the state.

NOTE Confidence: 0.884796792

 $00{:}38{:}48.810 \dashrightarrow 00{:}38{:}51.000$ We aggregated data to the state

NOTE Confidence: 0.884796792

 $00:38:51.000 \dashrightarrow 00:38:53.426$ and six month period and use use

NOTE Confidence: 0.884796792

 $00:38:53.426 \rightarrow 00:38:55.036$ the data in that way.

NOTE Confidence: 0.855158512666667

 $00{:}39{:}02{.}470 \dashrightarrow 00{:}39{:}04{.}030$ So the exposure that we're interested

NOTE Confidence: 0.855158512666667

 $00{:}39{:}04{.}030 \dashrightarrow 00{:}39{:}05{.}709$ in this study was a legislative

NOTE Confidence: 0.855158512666667

 $00:39:05.709 \dashrightarrow 00:39:07.174$ mandate requiring a whether the

NOTE Confidence: 0.855158512666667

 $00{:}39{:}07{.}174 \dashrightarrow 00{:}39{:}09{.}528$ patient lived in a state that had a

NOTE Confidence: 0.855158512666667

00:39:09.528 --> 00:39:10.664 legislative mandate requiring coverage

NOTE Confidence: 0.855158512666667

 $00:39:10.664 \rightarrow 00:39:14.430$ of DVT during the study period.

NOTE Confidence: 0.855158512666667

00:39:14.430 --> 00:39:16.940 All states included as mandate

NOTE Confidence: 0.855158512666667

 $00:39:16.940 \longrightarrow 00:39:18.948$ states in this analysis.

NOTE Confidence: 0.8551585126666667

00:39:18.950 - > 00:39:20.894 Also, a limited cost sharing with

NOTE Confidence: 0.855158512666667

00:39:20.894 --> 00:39:22.190 the exception of Connecticut,

NOTE Confidence: 0.855158512666667

 $00:39:22.190 \dashrightarrow 00:39:23.858$ which eliminated cost sharing

NOTE Confidence: 0.855158512666667

00:39:23.858 - 00:39:25.943 one year after passage of

- NOTE Confidence: 0.855158512666667
- $00:39:25.943 \dashrightarrow 00:39:28.209$ the general coverage mandate.
- NOTE Confidence: 0.855158512666667
- $00:39:28.210 \rightarrow 00:39:30.847$ So in these laws when we say cost sharing,
- NOTE Confidence: 0.855158512666667
- $00:39:30.850 \dashrightarrow 00:39:33.148$ these are including out of pocket
- NOTE Confidence: 0.855158512666667
- $00:39:33.148 \longrightarrow 00:39:34.297$ payments towards deductibles,
- NOTE Confidence: 0.8551585126666667
- $00{:}39{:}34{.}300 \dashrightarrow 00{:}39{:}36{.}156$ coinsurance or coherence similar
- NOTE Confidence: 0.855158512666667
- $00:39:36.156 \dashrightarrow 00:39:39.430$ to what the ACA law would have is
- NOTE Confidence: 0.855158512666667
- $00:39:39.430 \dashrightarrow 00:39:41.929$ for services that are rated A or B.
- NOTE Confidence: 0.855158512666667
- $00{:}39{:}41{.}930 \dashrightarrow 00{:}39{:}43{.}687$ The control states were states that did
- NOTE Confidence: 0.855158512666667
- $00{:}39{:}43.687 \dashrightarrow 00{:}39{:}46.097$ not pass a mandate during the study period.
- NOTE Confidence: 0.855158512666667
- $00:39:46.100 \rightarrow 00:39:47.285$ And we assigned mammograms were
- NOTE Confidence: 0.855158512666667
- $00:39:47.285 \longrightarrow 00:39:48.769$ assigned to a state based on
- NOTE Confidence: 0.855158512666667
- $00:39:48.769 \dashrightarrow 00:39:50.019$ location of the billing provider.
- NOTE Confidence: 0.944120425
- $00{:}39{:}52{.}550 \dashrightarrow 00{:}39{:}53{.}946$ So, as I noted,
- NOTE Confidence: 0.944120425
- $00{:}39{:}53{.}946 \dashrightarrow 00{:}39{:}56{.}478$ the outcomes we looked at were DBT.
- NOTE Confidence: 0.944120425
- $00:39:56.478 \dashrightarrow 00:39:58.668$ Use the proportion of screening
- NOTE Confidence: 0.944120425

 $00:39:58.668 \rightarrow 00:40:00.420$ mammograms performed with DVT

NOTE Confidence: 0.944120425

00:40:00.495 --> 00:40:01.983 among all screening mammograms

NOTE Confidence: 0.944120425

 $00{:}40{:}01{.}983 \dashrightarrow 00{:}40{:}04{.}750$ for estate in a six month period.

NOTE Confidence: 0.944120425

00:40:04.750 --> 00:40:06.470 So DBT is many people,

NOTE Confidence: 0.944120425

 $00:40:06.470 \longrightarrow 00:40:07.618$ probably on the call,

NOTE Confidence: 0.944120425

 $00{:}40{:}07{.}618$ --> $00{:}40{:}09{.}723$ probably know is typically read and built

NOTE Confidence: 0.944120425

00:40:09.723 --> 00:40:11.709 in conjunction with standard 2D imaging,

NOTE Confidence: 0.944120425

 $00{:}40{:}11.710 \dashrightarrow 00{:}40{:}13.810$ so we consider DBT to have been

NOTE Confidence: 0.944120425

 $00{:}40{:}13.810 \dashrightarrow 00{:}40{:}15.582$ performed when there was a claim

NOTE Confidence: 0.944120425

 $00:40:15.582 \longrightarrow 00:40:17.208$ for DBT in conjunction with a

NOTE Confidence: 0.944120425

 $00{:}40{:}17.208 \dashrightarrow 00{:}40{:}19.039$ claim for screening mammography.

NOTE Confidence: 0.944120425

 $00{:}40{:}19{.}040 \dashrightarrow 00{:}40{:}20{.}986$ We looked at the proportion of women

NOTE Confidence: 0.944120425

 $00{:}40{:}20.986 \dashrightarrow 00{:}40{:}22.909$ with any out of pocket payment.

NOTE Confidence: 0.944120425

 $00{:}40{:}22{.}910 \dashrightarrow 00{:}40{:}23{.}946$ We did also look at the mean

NOTE Confidence: 0.944120425

 $00{:}40{:}23.946 \dashrightarrow 00{:}40{:}24.710$ out of pocket payment,

NOTE Confidence: 0.944120425

 $00:40:24.710 \longrightarrow 00:40:25.988$ but it became not that relevant.

- NOTE Confidence: 0.944120425
- 00:40:25.990 --> 00:40:28.489 So today I'm just going to present
- NOTE Confidence: 0.944120425
- $00:40:28.489 \longrightarrow 00:40:30.474$ results on the proportion that
- NOTE Confidence: 0.944120425
- $00:40:30.474 \longrightarrow 00:40:32.988$ had any out of pocket payment.
- NOTE Confidence: 0.944120425
- $00:40:32.990 \longrightarrow 00:40:33.758$ This is people,
- NOTE Confidence: 0.944120425
- $00:40:33.758 \rightarrow 00:40:35.550$ women that had out of pocket payment.
- NOTE Confidence: 0.944120425
- $00:40:35.550 \longrightarrow 00:40:37.632$ We only looked at those with
- NOTE Confidence: 0.944120425
- $00{:}40{:}37.632 \dashrightarrow 00{:}40{:}39.196$ DVT because women screened with
- NOTE Confidence: 0.944120425
- 00:40:39.196 --> 00:40:40.716 2D mammography already had no
- NOTE Confidence: 0.944120425
- $00{:}40{:}40{.}716$ --> $00{:}40{:}42{.}232$ cost sharing which is mandated
- NOTE Confidence: 0.944120425
- $00:40:42.232 \longrightarrow 00:40:43.677$ by the Affordable Care Act.
- NOTE Confidence: 0.8980734456
- 00:40:48.080 00:40:50.705 So we used an event study design
- NOTE Confidence: 0.8980734456
- $00{:}40{:}50.705 \dashrightarrow 00{:}40{:}52.579$ which estimates changes in an
- NOTE Confidence: 0.8980734456
- $00{:}40{:}52{.}579 \dashrightarrow 00{:}40{:}54{.}625$ outcome among states that pass a
- NOTE Confidence: 0.8980734456
- $00{:}40{:}54.625 \dashrightarrow 00{:}40{:}56.920$ law relative to states that did not.
- NOTE Confidence: 0.8980734456
- $00{:}40{:}56{.}920 \dashrightarrow 00{:}40{:}59{.}545$ At each six month interval
- NOTE Confidence: 0.8980734456

 $00:40:59.545 \longrightarrow 00:41:01.120$ after law implementation.

NOTE Confidence: 0.8980734456

 $00{:}41{:}01{.}120 \dashrightarrow 00{:}41{:}02.870$ So this specification allows for

NOTE Confidence: 0.8980734456

 $00:41:02.870 \longrightarrow 00:41:05.072$ the effective laws to vary by

NOTE Confidence: 0.8980734456

 $00:41:05.072 \rightarrow 00:41:06.636$ the time since implementation.

NOTE Confidence: 0.8980734456

 $00{:}41{:}06{.}640 \dashrightarrow 00{:}41{:}08{.}201$ So basically what you do in event

NOTE Confidence: 0.8980734456

00:41:08.201 --> 00:41:09.940 study design is you line up the

NOTE Confidence: 0.8980734456

 $00{:}41{:}09{.}940 \dashrightarrow 00{:}41{:}11{.}215$ implementation dates and look at

NOTE Confidence: 0.8980734456

 $00{:}41{:}11{.}215 \dashrightarrow 00{:}41{:}12.660$ whether there are changes in our

NOTE Confidence: 0.8980734456

 $00{:}41{:}12.660 \dashrightarrow 00{:}41{:}14.106$ outcomes in the first six months

NOTE Confidence: 0.8980734456

00:41:14.106 --> 00:41:15.942 post implementation that in the next

NOTE Confidence: 0.8980734456

 $00{:}41{:}15{.}942 \dashrightarrow 00{:}41{:}17{.}700$ six months post implementation.

NOTE Confidence: 0.8980734456

 $00:41:17.700 \rightarrow 00:41:21.179$ And this also has the advantage of.

NOTE Confidence: 0.8980734456

 $00{:}41{:}21{.}180 \dashrightarrow 00{:}41{:}22{.}772$ It allows you to see if there were

NOTE Confidence: 0.8980734456

 $00:41:22.772 \longrightarrow 00:41:24.110$ changes in the six months prior

NOTE Confidence: 0.870000174285714

 $00:41:36.430 \rightarrow 00:41:38.600$ Which you would not necessarily expect us,

NOTE Confidence: 0.870000174285714

 $00:41:38.600 \rightarrow 00:41:40.065$ as is typical in any

- NOTE Confidence: 0.870000174285714
- 00:41:40.065 --> 00:41:40.944 different difficulty level,
- NOTE Confidence: 0.870000174285714
- $00:41:40.950 \longrightarrow 00:41:42.774$ and models were weighted by the
- NOTE Confidence: 0.870000174285714
- $00{:}41{:}42.774 \dashrightarrow 00{:}41{:}45.748$ screened population in each state.
- NOTE Confidence: 0.870000174285714
- $00{:}41{:}45.750 \dashrightarrow 00{:}41{:}48.300$ So this table represents our patient
- NOTE Confidence: 0.870000174285714
- 00:41:48.300 --> 00:41:50.630 characteristics and outcomes at baseline,
- NOTE Confidence: 0.870000174285714
- $00{:}41{:}50{.}630 \dashrightarrow 00{:}41{:}53{.}926$ so we also are not so for outcomes,
- NOTE Confidence: 0.870000174285714
- $00:41:53.930 \longrightarrow 00:41:55.640$ it is the outcomes at baseline, so.
- NOTE Confidence: 0.886004735555556
- 00:41:59.480 --> 00:42:01.658 Right, OK at the start of the study period,
- NOTE Confidence: 0.886004735555556
- $00:42:01.660 \longrightarrow 00:42:03.658$ women and in mandate and non
- NOTE Confidence: 0.88600473555556
- $00{:}42{:}03.658 \dashrightarrow 00{:}42{:}05.300$ mandate states had similar age.
- NOTE Confidence: 0.886004735555556
- $00:42:05.300 \longrightarrow 00:42:09.372$ Mean age was 53 in both among women in
- NOTE Confidence: 0.886004735555556
- $00{:}42{:}09{.}372 \dashrightarrow 00{:}42{:}11.555$ mandate states 42% lived in the northeast
- NOTE Confidence: 0.886004735555556
- $00{:}42{:}11.555 \dashrightarrow 00{:}42{:}14.230$ versus 12% in the non mandate states.
- NOTE Confidence: 0.886004735555556
- $00:42:14.230 \longrightarrow 00:42:17.934$ In early 2015, women living in states that
- NOTE Confidence: 0.886004735555556
- $00:42:17.934 \rightarrow 00:42:21.277$ eventually pass a DBT coverage mandate 16%.
- NOTE Confidence: 0.886004735555556

00:42:21.277 --> 00:42:24.162 Of women who underwent mammography

NOTE Confidence: 0.886004735555556

 $00:42:24.162 \longrightarrow 00:42:26.470$ were screened with DVT.

NOTE Confidence: 0.886004735555556

 $00:42:26.470 \longrightarrow 00:42:28.438$ Versus among women living in states

NOTE Confidence: 0.886004735555556

 $00:42:28.438 \rightarrow 00:42:30.650$ that never passed a mandate 11% so

NOTE Confidence: 0.886004735555556

 $00{:}42{:}30{.}650 \dashrightarrow 00{:}42{:}32{.}330$ the screen was a little bit lower in

NOTE Confidence: 0.886004735555556

 $00:42:32.380 \rightarrow 00:42:34.090$ states that never passed a mandate.

NOTE Confidence: 0.886004735555556

 $00:42:34.090 \rightarrow 00:42:35.608$ Note, this is before the mandate,

NOTE Confidence: 0.886004735555556

 $00:42:35.610 \rightarrow 00:42:38.350$ though important to our study.

NOTE Confidence: 0.886004735555556

00:42:38.350 --> 00:42:43.012 Really very few women in 2015 had any

NOTE Confidence: 0.886004735555556

 $00{:}42{:}43.012 \dashrightarrow 00{:}42{:}46.985$ out of pocket payment for DVT only 7% in

NOTE Confidence: 0.886004735555556

 $00:42:46.985 \rightarrow 00:42:49.700$ both mandate and eventual mandate and

NOTE Confidence: 0.88600473555556

 $00{:}42{:}49.700 \dashrightarrow 00{:}42{:}52.570$ eventual non and and non mandate states.

NOTE Confidence: 0.88600473555556

 $00{:}42{:}52{.}570 \dashrightarrow 00{:}42{:}54{.}810$ You can see that the DBT price was

NOTE Confidence: 0.886004735555556

00:42:54.810 --> 00:42:56.529 higher than the mean 2D price.

NOTE Confidence: 0.886004735555556

 $00:42:56.530 \longrightarrow 00:42:58.070$ For example, in mandate states,

NOTE Confidence: 0.886004735555556

00:42:58.070 - 00:43:01.088 the man demean DPT price was

 $00:43:01.090 \longrightarrow 00:43:06.140$ \$311.00 versus for two D \$266.

NOTE Confidence: 0.473313885

 $00:43:08.940 \longrightarrow 00:43:10.140$ Pre mandate.

NOTE Confidence: 0.7924049916666667

 $00{:}43{:}17{.}480 \dashrightarrow 00{:}43{:}20{.}288$ So next we look at DBT, use and here's

NOTE Confidence: 0.792404991666667

 $00:43:20.288 \dashrightarrow 00:43:21.660$ our first outcome that we look at.

NOTE Confidence: 0.7924049916666667

00:43:21.660 --> 00:43:23.388 So let me Orient you 'cause the next

NOTE Confidence: 0.7924049916666667

 $00{:}43{:}23{.}388 \dashrightarrow 00{:}43{:}25{.}049$ couple of slides all have the same

NOTE Confidence: 0.7924049916666667

 $00:43:25.049 \longrightarrow 00:43:26.560$ sort of framework as this slide.

NOTE Confidence: 0.792404991666667

 $00:43:26.560 \rightarrow 00:43:29.200$ So we lined up implementation dates

NOTE Confidence: 0.792404991666667

00:43:29.200 - 00:43:31.783 with the period labeled here years

NOTE Confidence: 0.792404991666667

 $00{:}43{:}31{.}783 \dashrightarrow 00{:}43{:}34{.}394$ from LA negative .5 being the period

NOTE Confidence: 0.7924049916666667

 $00:43:34.394 \rightarrow 00:43:37.077$ in which the law was implemented.

NOTE Confidence: 0.7924049916666667

 $00{:}43{:}37.080 \dashrightarrow 00{:}43{:}39.006$ So this shows the percentage point

NOTE Confidence: 0.7924049916666667

00:43:39.006 --> 00:43:41.660 change in DBT use in the period before,

NOTE Confidence: 0.792404991666667

 $00{:}43{:}41.660$ --> $00{:}43{:}43.996$ and the period after the law was implemented NOTE Confidence: 0.7924049916666667

 $00:43:43.996 \rightarrow 00:43:46.248$ relative to states with no law implemented,

 $00:43:46.250 \longrightarrow 00:43:47.860$ which is our comparison group.

NOTE Confidence: 0.792404991666667

00:43:47.860 --> 00:43:48.769 So by construction,

NOTE Confidence: 0.792404991666667

 $00:43:48.769 \longrightarrow 00:43:50.890$ the value for the period in which

NOTE Confidence: 0.7924049916666667

 $00:43:50.954 \rightarrow 00:43:52.956$ the law is enacted is basically 0%,

NOTE Confidence: 0.792404991666667

 $00{:}43{:}52{.}960 \dashrightarrow 00{:}43{:}54{.}700$ because you're sort of normalizing

NOTE Confidence: 0.7924049916666667

00:43:54.700 - 00:43:57.424 everything to be to for them to be the

NOTE Confidence: 0.7924049916666667

 $00:43:57.424 \rightarrow 00:44:00.310$ same in that in that moment of enactment.

NOTE Confidence: 0.792404991666667

 $00:44:00.310 \longrightarrow 00:44:02.270$ So first thing to look at is if you look

NOTE Confidence: 0.7924049916666667

 $00{:}44{:}02{.}325 \dashrightarrow 00{:}44{:}04{.}213$ at the three periods that we can measure

NOTE Confidence: 0.7924049916666667

 $00:44:04.213 \rightarrow 00:44:06.108$ here in the period prior to the law,

NOTE Confidence: 0.792404991666667

 $00{:}44{:}06{.}110 \dashrightarrow 00{:}44{:}09{.}288$ you see that there was no significant

NOTE Confidence: 0.7924049916666667

 $00:44:09.290 \rightarrow 00:44:13.589$ effects of eventually passing a law.

NOTE Confidence: 0.7924049916666667

 $00:44:13.589 \rightarrow 00:44:16.604$ We find no significant changes in DB use, D.

NOTE Confidence: 0.7924049916666667

 $00:44:16.604 \rightarrow 00:44:18.728$ Use relative to the comparison test.

NOTE Confidence: 0.7924049916666667

 $00:44:18.730 \longrightarrow 00:44:20.518$ So this is really equivalent to

NOTE Confidence: 0.7924049916666667

 $00:44:20.518 \longrightarrow 00:44:21.710$ the standard parallel trends,

00:44:21.710 -> 00:44:23.411 test apparel pre trans test that you

NOTE Confidence: 0.7924049916666667

 $00{:}44{:}23{.}411 \dashrightarrow 00{:}44{:}25{.}708$ see in a different different analysis

NOTE Confidence: 0.7924049916666667

 $00:44:25.710 \longrightarrow 00:44:28.059$ in the periods after the law we do see

NOTE Confidence: 0.7924049916666667

 $00:44:28.059 \rightarrow 00:44:30.256$ you can see a steady increases in.

NOTE Confidence: 0.7924049916666667

 $00{:}44{:}30{.}260 \dashrightarrow 00{:}44{:}32{.}318$ Mandate states relative to other states.

NOTE Confidence: 0.792404991666667

 $00{:}44{:}32{.}320 \dashrightarrow 00{:}44{:}35{.}152$ So by one year post law these differences

NOTE Confidence: 0.7924049916666667

 $00:44:35.152 \rightarrow 00:44:36.640$ are statistically significant.

NOTE Confidence: 0.792404991666667

 $00:44:36.640 \longrightarrow 00:44:38.290$ One year after enactment of

NOTE Confidence: 0.7924049916666667

 $00:44:38.290 \longrightarrow 00:44:39.280$ a coverage mandate,

NOTE Confidence: 0.792404991666667

00:44:39.280 --> 00:44:44.110 DBT use increased 7.6 percentage points.

NOTE Confidence: 0.792404991666667

 $00{:}44{:}44{.}110 \dashrightarrow 00{:}44{:}45{.}418$ Relative to other states.

NOTE Confidence: 0.9174258866666667

00:44:48.180 --> 00:44:49.590 Compared to states without a mandate,

NOTE Confidence: 0.9174258866666667

00:44:49.590 --> 00:44:52.020 I'm sorry 7.6% greater than states

NOTE Confidence: 0.9174258866666667

 $00{:}44{:}52.020 \dashrightarrow 00{:}44{:}54.560$ without a mandate, and after two years,

NOTE Confidence: 0.9174258866666667

00:44:54.560 --> 00:44:56.981 D BTU's had risen 9 percentage points

 $00:44:56.981 \rightarrow 00:44:59.195$ more in mandate states compared to

NOTE Confidence: 0.9174258866666667

 $00:44:59.195 \rightarrow 00:45:01.540$ states that did not pass mandates.

NOTE Confidence: 0.813745443333333

 $00:45:05.580 \longrightarrow 00:45:09.660$ Next we look at DBT price.

NOTE Confidence: 0.813745443333333

 $00:45:09.660 \dashrightarrow 00:45:13.071$ And so it's the same format I noted before

NOTE Confidence: 0.813745443333333

 $00:45:13.071 \rightarrow 00:45:14.856$ from our patient characteristics table,

NOTE Confidence: 0.813745443333333

 $00:45:14.860 \rightarrow 00:45:17.527$ the average cost of a DVT was \$311.00

NOTE Confidence: 0.813745443333333

 $00{:}45{:}17.527 \dashrightarrow 00{:}45{:}19.462$ among maintenance performed in states

NOTE Confidence: 0.813745443333333

 $00:45:19.462 \rightarrow 00:45:21.679$ that eventually passed a mandate and

NOTE Confidence: 0.813745443333333

 $00:45:21.680 \longrightarrow 00:45:24.200$ 347 states that did not pass a mandate.

NOTE Confidence: 0.813745443333333

 $00{:}45{:}24{.}200 \dashrightarrow 00{:}45{:}26{.}032$ And here we find that two years post

NOTE Confidence: 0.813745443333333

 $00:45:26.032 \rightarrow 00:45:27.775$ mandate and this was a surprise to us.

NOTE Confidence: 0.813745443333333

 $00{:}45{:}27.780 \dashrightarrow 00{:}45{:}30.265$ DBT Price had declined in mandate states

NOTE Confidence: 0.813745443333333

 $00{:}45{:}30{.}265 \dashrightarrow 00{:}45{:}33{.}085$ compared to the change in price in nine

NOTE Confidence: 0.813745443333333

 $00:45:33.085 \rightarrow 00:45:35.412$ non mandate states about \$38.00 and I

NOTE Confidence: 0.813745443333333

 $00:45:35.412 \rightarrow 00:45:37.980$ don't have a graph here to show it.

NOTE Confidence: 0.813745443333333

 $00:45:37.980 \rightarrow 00:45:39.040$ 'cause we have limited time,

- NOTE Confidence: 0.813745443333333
- $00:45:39.040 \longrightarrow 00:45:40.708$ but we also did not observe.
- NOTE Confidence: 0.813745443333333
- $00:45:40.710 \longrightarrow 00:45:42.552$ A significant change in the price
- NOTE Confidence: 0.813745443333333
- $00:45:42.552 \longrightarrow 00:45:43.473$ of 2D mammography.
- NOTE Confidence: 0.90999358
- $00:45:45.590 \longrightarrow 00:45:47.690$ Next we look at weather.
- NOTE Confidence: 0.936356683333333
- $00:45:50.020 \rightarrow 00:45:54.284$ Here it is. At the percent of DBT DBT
- NOTE Confidence: 0.936356683333333
- $00{:}45{:}54{.}284 \dashrightarrow 00{:}45{:}57{.}229$ exams with any added pocket payment.
- NOTE Confidence: 0.819973345625
- $00:45:59.310 \rightarrow 00:46:01.366$ Among women's group with CBT and we found
- NOTE Confidence: 0.819973345625
- $00:46:01.366 \longrightarrow 00:46:03.245$ that even at the start of the study,
- NOTE Confidence: 0.819973345625
- $00{:}46{:}03.250 \dashrightarrow 00{:}46{:}05.842$ as I said earlier, only a minority of women
- NOTE Confidence: 0.819973345625
- $00:46:05.842 \rightarrow 00:46:08.404$ had any out of pocket payments with DVT.
- NOTE Confidence: 0.819973345625
- $00{:}46{:}08{.}410 \dashrightarrow 00{:}46{:}10{.}510$ We did not observe a statistically
- NOTE Confidence: 0.819973345625
- 00:46:10.510 --> 00:46:12.606 significant change in the proportion of
- NOTE Confidence: 0.819973345625
- $00{:}46{:}12.606 \dashrightarrow 00{:}46{:}15.418$ women who had any out of pocket payments for
- NOTE Confidence: 0.819973345625
- $00{:}46{:}15{.}418 \dashrightarrow 00{:}46{:}17{.}797$ DVT even as we go to two years post mandate.
- NOTE Confidence: 0.819973345625
- $00{:}46{:}17.797 \dashrightarrow 00{:}46{:}20.086$ We did also look among those that
- NOTE Confidence: 0.819973345625

 $00:46:20.086 \rightarrow 00:46:22.406$ did have an out of pocket payment.

NOTE Confidence: 0.819973345625

 $00{:}46{:}22{.}410 \dashrightarrow 00{:}46{:}24{.}210$ The mean out of pocket payment and we

NOTE Confidence: 0.819973345625

 $00:46:24.210 \longrightarrow 00:46:26.298$ did not find a statistic statistically

NOTE Confidence: 0.819973345625

 $00:46:26.298 \rightarrow 00:46:27.878$ significant change there either.

NOTE Confidence: 0.9692511

 $00:46:34.260 \longrightarrow 00:46:38.040$ So. A central policy objective of the

NOTE Confidence: 0.9692511

00:46:38.040 --> 00:46:40.035 coverage, mandates or any coverage mandate

NOTE Confidence: 0.9692511

 $00{:}46{:}40.035 \dashrightarrow 00{:}46{:}42.631$ is to ensure access to a particular

NOTE Confidence: 0.9692511

 $00:46:42.631 \rightarrow 00:46:45.840$ medical technology or service by protecting

NOTE Confidence: 0.9692511

00:46:45.840 --> 00:46:48.840 patients against financial liability,

NOTE Confidence: 0.9692511

 $00{:}46{:}48{.}840 \dashrightarrow 00{:}46{:}50{.}514$ and indeed, our results suggest that

NOTE Confidence: 0.9692511

 $00{:}46{:}50{.}514$ --> $00{:}46{:}52{.}217$ women in states with coverage mandates

NOTE Confidence: 0.9692511

 $00:46:52.217 \rightarrow 00:46:54.337$ were more likely to begin to use DBT

NOTE Confidence: 0.9692511

 $00{:}46{:}54{.}386 \dashrightarrow 00{:}46{:}55{.}758$ for breast cancer screening,

NOTE Confidence: 0.9692511

 $00:46:55.760 \longrightarrow 00:46:57.070$ which probably is one of

NOTE Confidence: 0.9692511

 $00{:}46{:}57{.}070 \dashrightarrow 00{:}46{:}58{.}380$ the intents of the law.

NOTE Confidence: 0.9692511

 $00:46:58.380 \longrightarrow 00:47:01.418$ And this finding is consistent with other

- NOTE Confidence: 0.9692511
- $00:47:01.418 \rightarrow 00:47:04.179$ studies across other types of services

 $00{:}47{:}04{.}179$ --> $00{:}47{:}06{.}494$ that found that expanding coverage,

NOTE Confidence: 0.9692511

 $00:47:06.500 \rightarrow 00:47:08.858$ and in particular eliminating cost sharing,

NOTE Confidence: 0.9692511

00:47:08.860 --> 00:47:10.265 can increase the use of

NOTE Confidence: 0.9692511

 $00{:}47{:}10.265 \dashrightarrow 00{:}47{:}11.389$ specific cell health services.

NOTE Confidence: 0.9692511

 $00{:}47{:}11{.}390 \dashrightarrow 00{:}47{:}14{.}052$ I'll say it's very difficult in many cases

NOTE Confidence: 0.9692511

 $00:47:14.052 \rightarrow 00:47:16.180$ to get patients to change their behavior,

NOTE Confidence: 0.9692511

00:47:16.180 - 00:47:17.800 but changing even by very small

NOTE Confidence: 0.9692511

 $00:47:17.800 \longrightarrow 00:47:19.325$ amounts the amount they have to

NOTE Confidence: 0.9692511

00:47:19.325 -> 00:47:20.893 pay is one way you can get them.

NOTE Confidence: 0.9692511

00:47:20.900 --> 00:47:21.233 Generally,

NOTE Confidence: 0.9692511

 $00{:}47{:}21{.}233 \dashrightarrow 00{:}47{:}22{.}898$ the literature is found to

NOTE Confidence: 0.9692511

 $00{:}47{:}22.898 \dashrightarrow 00{:}47{:}23.897$ change their behavior,

NOTE Confidence: 0.9692511

 $00:47:23.900 \longrightarrow 00:47:26.042$ but in our study this really

NOTE Confidence: 0.9692511

 $00{:}47{:}26.042 \dashrightarrow 00{:}47{:}28.373$ raises some new questions about the

 $00:47:28.373 \longrightarrow 00:47:30.045$ mechanism by which mandates.

NOTE Confidence: 0.9692511

 $00{:}47{:}30{.}050 \dashrightarrow 00{:}47{:}32{.}552$ May increase use of an emerging

NOTE Confidence: 0.9692511

 $00{:}47{:}32{.}552 \dashrightarrow 00{:}47{:}34{.}667$ technology because we didn't find NOTE Confidence: 0.9692511

 $00:47:34.667 \rightarrow 00:47:36.917$ changes in out of pocket payments NOTE Confidence: 0.9692511

00:47:36.917 -> 00:47:39.159 and even before these mandates,

NOTE Confidence: 0.9692511

 $00{:}47{:}39{.}160 \dashrightarrow 00{:}47{:}41{.}750$ the out of pocket payment was low, NOTE Confidence: 0.9692511

 $00:47:41.750 \longrightarrow 00:47:44.459$ so it it's unlikely that a change

NOTE Confidence: 0.9692511

 $00:47:44.459 \longrightarrow 00:47:47.203$ in what the patient had to pay

NOTE Confidence: 0.9692511

 $00{:}47{:}47{.}203 \dashrightarrow 00{:}47{:}49{.}672$ is what led to these changes.

NOTE Confidence: 0.9692511

 $00{:}47{:}49.672 \dashrightarrow 00{:}47{:}53.284$ So one explanation for these findings

NOTE Confidence: 0.9692511

 $00{:}47{:}53.290 \dashrightarrow 00{:}47{:}55.786$ is that by ensuring payment coverage,

NOTE Confidence: 0.9692511

00:47:55.790 - 00:47:57.278 mandates may have encouraged

NOTE Confidence: 0.9692511

 $00{:}47{:}57{.}278 \dashrightarrow 00{:}47{:}59{.}138$ radiologists and other health care

NOTE Confidence: 0.9692511

 $00{:}47{:}59{.}138 \dashrightarrow 00{:}48{:}00{.}537$ institutions to enter the market.

NOTE Confidence: 0.9692511

 $00{:}48{:}00{.}540 \dashrightarrow 00{:}48{:}02{.}880$ And offer DBT and this may have led to

NOTE Confidence: 0.9692511

 $00:48:02.880 \rightarrow 00:48:05.558$ a relative price in at least two ways.

- NOTE Confidence: 0.9692511
- $00:48:05.560 \rightarrow 00:48:09.340$ One when more radiologists offer DBT,
- NOTE Confidence: 0.9692511
- 00:48:09.340 --> 00:48:11.205 insurers really may have greater
- NOTE Confidence: 0.9692511
- $00:48:11.205 \rightarrow 00:48:13.070$ ability to negotiate lower prices
- NOTE Confidence: 0.9692511
- $00{:}48{:}13.135 \dashrightarrow 00{:}48{:}14.997$ and this could lead to lower prices
- NOTE Confidence: 0.9692511
- $00{:}48{:}14{.}997 \dashrightarrow 00{:}48{:}17{.}246$ or at least slower growth in prices
- NOTE Confidence: 0.9692511
- $00:48:17.246 \rightarrow 00:48:18.290$ over all providers.
- NOTE Confidence: 0.9692511
- $00:48:18.290 \longrightarrow 00:48:18.525$ Second,
- NOTE Confidence: 0.9692511
- $00:48:18.525 \longrightarrow 00:48:20.170$ it could be the case that early
- NOTE Confidence: 0.9692511
- $00:48:20.170 \longrightarrow 00:48:21.503$ entrance we would expect the
- NOTE Confidence: 0.9692511
- $00:48:21.503 \rightarrow 00:48:22.858$ early entrance in this market.
- NOTE Confidence: 0.9692511
- $00:48:22.860 \longrightarrow 00:48:24.930$ When DBT first started to be
- NOTE Confidence: 0.9692511
- $00{:}48{:}24{.}930 \dashrightarrow 00{:}48{:}26{.}960$ providers that have higher prices.
- NOTE Confidence: 0.9692511
- $00:48:26.960 \rightarrow 00:48:29.426$ So for example, academic medical centers,
- NOTE Confidence: 0.9692511
- 00:48:29.430 --> 00:48:31.890 if mandates incentivize new entrants who
- NOTE Confidence: 0.9692511
- $00:48:31.890 \rightarrow 00:48:34.988$ tend to offer services at lower prices
- NOTE Confidence: 0.9692511

- $00:48:34.988 \rightarrow 00:48:36.844$ compared to established providers,
- NOTE Confidence: 0.9692511
- $00{:}48{:}36{.}850 \dashrightarrow 00{:}48{:}37{.}510$ the average market,
- NOTE Confidence: 0.9692511
- $00:48:37.510 \longrightarrow 00:48:38.830$ the average price in the market
- NOTE Confidence: 0.9692511
- 00:48:38.830 --> 00:48:39.960 will decrease mechanically,
- NOTE Confidence: 0.9692511
- $00{:}48{:}39{.}960 \dashrightarrow 00{:}48{:}41{.}577$ so you have a high price pipe,
- NOTE Confidence: 0.9692511
- $00{:}48{:}41{.}580 \dashrightarrow 00{:}48{:}42{.}760$ high price providers, low,
- NOTE Confidence: 0.9692511
- 00:48:42.760 --> 00:48:43.645 lower price providers,
- NOTE Confidence: 0.9692511
- $00:48:43.650 \rightarrow 00:48:46.660$ the average is going to go down.
- NOTE Confidence: 0.9692511
- $00{:}48{:}46.660 \dashrightarrow 00{:}48{:}47.912$ But in that scenario,
- NOTE Confidence: 0.9692511
- $00:48:47.912 \rightarrow 00:48:50.160$ no provider has actually changed their price,
- NOTE Confidence: 0.9692511
- $00:48:50.160 \longrightarrow 00:48:50.425$ right?
- NOTE Confidence: 0.9692511
- $00{:}48{:}50{.}425 \dashrightarrow 00{:}48{:}52{.}280$ But the the price that is paid
- NOTE Confidence: 0.9692511
- $00{:}48{:}52{.}280 \dashrightarrow 00{:}48{:}54{.}080$ in the market will decline,
- NOTE Confidence: 0.9692511
- $00:48:54.080 \rightarrow 00:48:56.420$ so other explanations are possible.
- NOTE Confidence: 0.9692511
- $00{:}48{:}56{.}420 \dashrightarrow 00{:}48{:}57{.}388$ For example,
- NOTE Confidence: 0.9692511
- $00:48:57.388 \rightarrow 00:48:59.808$ it's possible that coverage mandates

- NOTE Confidence: 0.9692511
- $00:48:59.808 \rightarrow 00:49:02.934$ might be perceived by patients or others

 $00{:}49{:}02{.}934 \dashrightarrow 00{:}49{:}05{.}328$ as an endorsement of this service.

NOTE Confidence: 0.9692511

 $00{:}49{:}05{.}330 \dashrightarrow 00{:}49{:}06{.}995$ And this could increase interest

NOTE Confidence: 0.9692511

 $00:49:06.995 \longrightarrow 00:49:08.327$ in this new technology,

NOTE Confidence: 0.9692511

 $00{:}49{:}08{.}330 \dashrightarrow 00{:}49{:}09{.}941$ so we can't say for certain that this is

NOTE Confidence: 0.9692511

 $00{:}49{:}09{.}941 \dashrightarrow 00{:}49{:}11.626$ one of the two things that is happening.

NOTE Confidence: 0.9692511

 $00:49:11.630 \longrightarrow 00:49:14.210$ Unfortunately we don't have a provider

NOTE Confidence: 0.9692511

 $00{:}49{:}14.210 \dashrightarrow 00{:}49{:}16.642$ identifier in our data that would

NOTE Confidence: 0.9692511

 $00:49:16.642 \rightarrow 00:49:18.889$ allow us to say whether it is.

NOTE Confidence: 0.9692511

00:49:18.890 --> 00:49:20.518 Different lower price providers

NOTE Confidence: 0.9692511

 $00:49:20.518 \longrightarrow 00:49:21.739$ entering the market.

NOTE Confidence: 0.937304973333333

00:49:23.820 --> 00:49:25.983 Hey, I think we need to note

NOTE Confidence: 0.937304973333333

 $00:49:25.983 \rightarrow 00:49:27.620$ some limitations to the paper,

NOTE Confidence: 0.937304973333333

 $00{:}49{:}27.620 \dashrightarrow 00{:}49{:}30.056$ so there definitely could be some

NOTE Confidence: 0.937304973333333

 $00:49:30.056 \rightarrow 00:49:31.274$ issues with generalizability.

00:49:31.280 --> 00:49:33.065 Since all data was from Blue Cross,

NOTE Confidence: 0.937304973333333

00:49:33.070 -> 00:49:35.518 it is really really good data to look

NOTE Confidence: 0.937304973333333

 $00:49:35.518 \longrightarrow 00:49:38.034$ at these this study because it is from NOTE Confidence: 0.937304973333333

 $00:49:38.034 \rightarrow 00:49:40.786$ all 50 states in a very large data set.

NOTE Confidence: 0.937304973333333

 $00{:}49{:}40.790 \dashrightarrow 00{:}49{:}43.080$ Also, there are important known

NOTE Confidence: 0.937304973333333

 $00{:}49{:}43.080 \dashrightarrow 00{:}49{:}45.370$ limitations to using claims data.

NOTE Confidence: 0.937304973333333

00:49:45.370 --> 00:49:48.178 Claims could be subjected to error

NOTE Confidence: 0.937304973333333

 $00:49:48.178 \rightarrow 00:49:50.050$ misclassification problems or bias.

NOTE Confidence: 0.937304973333333

 $00:49:50.050 \rightarrow 00:49:52.276$ Another issue with this very particular

NOTE Confidence: 0.937304973333333

 $00:49:52.276 \rightarrow 00:49:54.300$ setting is our approach focused.

NOTE Confidence: 0.937304973333333

 $00{:}49{:}54{.}300 \dashrightarrow 00{:}49{:}56{.}200$ We chose to look at the price of the initial

NOTE Confidence: 0.937304973333333

 $00{:}49{:}56{.}245 \dashrightarrow 00{:}49{:}57{.}925$ test rather than the screening episode.

NOTE Confidence: 0.937304973333333

 $00{:}49{:}57{.}930 \dashrightarrow 00{:}49{:}59{.}176$ In some of our papers we have

NOTE Confidence: 0.937304973333333

 $00{:}49{:}59{.}176 \dashrightarrow 00{:}50{:}00{.}500$ looked at the screening episode,

NOTE Confidence: 0.937304973333333

 $00:50:00.500 \longrightarrow 00:50:02.018$ but you know that could be

NOTE Confidence: 0.937304973333333

 $00:50:02.018 \rightarrow 00:50:03.030$ very very different here.

 $00{:}50{:}03{.}030 \dashrightarrow 00{:}50{:}06{.}174$ If DBT does reduce recall and that could

NOTE Confidence: 0.937304973333333

 $00{:}50{:}06{.}174 \dashrightarrow 00{:}50{:}09{.}255$ lead to additional cost savings from for

NOTE Confidence: 0.937304973333333

 $00{:}50{:}09{.}255 \dashrightarrow 00{:}50{:}12.779$ DBT relative to to to 2D mammography.

NOTE Confidence: 0.937304973333333

 $00:50:12.780 \rightarrow 00:50:17.898$ Also this was an an observation ULL study.

NOTE Confidence: 0.937304973333333

 $00:50:17.900 \rightarrow 00:50:19.748$ Although we believe we used to study

NOTE Confidence: 0.937304973333333

00:50:19.748 --> 00:50:21.559 design that intended to limit confounding,

NOTE Confidence: 0.937304973333333

 $00:50:21.560 \rightarrow 00:50:23.572$ unmeasured confounding is always

NOTE Confidence: 0.937304973333333

 $00{:}50{:}23{.}572 \dashrightarrow 00{:}50{:}26{.}087$ a possibility and could explain

NOTE Confidence: 0.937304973333333

 $00:50:26.087 \longrightarrow 00:50:27.830$ some of our findings.

NOTE Confidence: 0.937304973333333

 $00{:}50{:}27.830 \dashrightarrow 00{:}50{:}29.726$ Could be you know other concurrent

NOTE Confidence: 0.937304973333333

00:50:29.726 --> 00:50:30.990 legislative policies or other

NOTE Confidence: 0.937304973333333

 $00{:}50{:}31.046 \dashrightarrow 00{:}50{:}32.528$ things going on in the market.

NOTE Confidence: 0.8368984405

 $00{:}50{:}35{.}310$ --> $00{:}50{:}38{.}418$ Finally, although our event study plots

NOTE Confidence: 0.8368984405

 $00{:}50{:}38{.}418$ --> $00{:}50{:}41{.}239$ didn't show significant differences in DBT

NOTE Confidence: 0.8368984405

 $00:50:41.239 \rightarrow 00:50:43.943$ user price prior to the law being enacted,

 $00:50:43.950 \longrightarrow 00:50:45.762$ it's important to acknowledge that pre

NOTE Confidence: 0.8368984405

 $00:50:45.762 \rightarrow 00:50:48.354$ period trends in DBT use or cost and mandate

NOTE Confidence: 0.8368984405

 $00:50:48.354 \rightarrow 00:50:50.150$ states may may influence our results.

NOTE Confidence: 0.8368984405

 $00:50:50.150 \rightarrow 00:50:51.837$ So there could be some pre-existing trends.

NOTE Confidence: 0.797047572666667

00:50:55.410 --> 00:50:57.138 Hey, just to conclude,

NOTE Confidence: 0.797047572666667

 $00{:}50{:}57{.}138 \dashrightarrow 00{:}50{:}59{.}298$ although DVD mandates were associated

NOTE Confidence: 0.7970475726666667

00:50:59.298 --> 00:51:01.330 with an increase in DBT use,

NOTE Confidence: 0.797047572666667

 $00:51:01.330 \rightarrow 00:51:03.412$ they were not associated with any

NOTE Confidence: 0.797047572666667

 $00{:}51{:}03{.}412 \dashrightarrow 00{:}51{:}06{.}204$ change in out of pocket payments and

NOTE Confidence: 0.797047572666667

 $00{:}51{:}06{.}204 \dashrightarrow 00{:}51{:}07{.}968$ this suggests that mandates and this

NOTE Confidence: 0.797047572666667

 $00{:}51{:}07{.}968 \dashrightarrow 00{:}51{:}09{.}629$ has implications for other services,

NOTE Confidence: 0.7970475726666667

 $00:51:09.630 \rightarrow 00:51:12.006$ well, may influence DBT adoption through

NOTE Confidence: 0.7970475726666667

 $00:51:12.006 \rightarrow 00:51:14.169$ mechanisms other than by reducing

NOTE Confidence: 0.7970475726666667

 $00:51:14.169 \rightarrow 00:51:16.217$ financial liability for patients.

NOTE Confidence: 0.783258507222222

 $00{:}51{:}23.120 \dashrightarrow 00{:}51{:}26.011$ Thank you Susan for a great presentation

NOTE Confidence: 0.783258507222222

 $00:51:26.011 \rightarrow 00:51:28.850$ that clearly damn straight close link

 $00:51:28.850 \rightarrow 00:51:31.390$ between policy and clinical practice.

NOTE Confidence: 0.783258507222222

 $00{:}51{:}31{.}390 \dashrightarrow 00{:}51{:}34{.}840$ I was wondering whether there are

NOTE Confidence: 0.783258507222222

 $00:51:34.840 \rightarrow 00:51:38.731$ studies being planned by you or others

NOTE Confidence: 0.783258507222222

 $00:51:38.731 \rightarrow 00:51:42.203$ to potentially look at the impact of

NOTE Confidence: 0.783258507222222

00:51:42.302 --> 00:51:44.964 DBT of identifying more patients.

NOTE Confidence: 0.783258507222222

00:51:44.964 --> 00:51:47.919 I was thinking that eventually,

NOTE Confidence: 0.783258507222222

 $00:51:47.920 \longrightarrow 00:51:50.750$ if there's evidence that DBT

NOTE Confidence: 0.783258507222222

 $00:51:50.750 \rightarrow 00:51:52.973$ would identify more patients

NOTE Confidence: 0.783258507222222

00:51:52.973 --> 00:51:54.626 because increased sensitivity,

NOTE Confidence: 0.783258507222222

 $00:51:54.630 \rightarrow 00:51:57.114$ that more B might be more

NOTE Confidence: 0.783258507222222

 $00:51:57.114 \longrightarrow 00:51:58.990$ incentive for more states to

NOTE Confidence: 0.783258507222222

 $00{:}51{:}58{.}990 \dashrightarrow 00{:}52{:}00{.}815$ have similar laws mandating it.

NOTE Confidence: 0.712928625

 $00:52:02.490 \rightarrow 00:52:04.446$ When you see identify more patients,

NOTE Confidence: 0.712928625

 $00{:}52{:}04{.}450 \dashrightarrow 00{:}52{:}06{.}277$ are you saying that some people that

NOTE Confidence: 0.712928625

00:52:06.277 --> 00:52:07.683 previously didn't get a mammography

 $00:52:07.683 \rightarrow 00:52:09.862$ would get a mammography because

NOTE Confidence: 0.712928625

 $00:52:09.862 \rightarrow 00:52:12.600$ the the DBT is available? Right,

NOTE Confidence: 0.753284413

 $00:52:12.610 \longrightarrow 00:52:15.298$ I just thinking like like on what

NOTE Confidence: 0.753284413

 $00:52:15.298 \rightarrow 00:52:17.548$ basis would this states that occur,

NOTE Confidence: 0.753284413

 $00:52:17.548 \rightarrow 00:52:19.744$ like not mandating it like what?

NOTE Confidence: 0.753284413

 $00:52:19.750 \rightarrow 00:52:21.774$ Why would they be encouraged to do so?

NOTE Confidence: 0.925469609166667

 $00:52:22.290 \rightarrow 00:52:23.830$ Why would they be mandating so the

NOTE Confidence: 0.925469609166667

 $00:52:23.830 \rightarrow 00:52:25.450$ 1st that is really interesting?

NOTE Confidence: 0.925469609166667

00:52:25.450 --> 00:52:26.650 Especially because we didn't

NOTE Confidence: 0.925469609166667

 $00:52:26.650 \rightarrow 00:52:28.450$ find it like where's the problem?

NOTE Confidence: 0.925469609166667

 $00:52:28.450 \longrightarrow 00:52:31.010$ Out of pocket payments were

NOTE Confidence: 0.925469609166667

 $00:52:31.010 \longrightarrow 00:52:32.546$ not particularly high.

NOTE Confidence: 0.925469609166667

 $00{:}52{:}32{.}550 \dashrightarrow 00{:}52{:}34{.}506$ Sort of before these are mandated.

NOTE Confidence: 0.925469609166667

 $00{:}52{:}34{.}510 \dashrightarrow 00{:}52{:}36{.}286$ Well, you know there might be some insurers,

NOTE Confidence: 0.925469609166667

 $00:52:36.290 \rightarrow 00:52:38.502$ but there might be some fear from

NOTE Confidence: 0.925469609166667

 $00:52:38.502 \rightarrow 00:52:40.423$ suppliers that insurers may stop covering

- NOTE Confidence: 0.925469609166667
- $00:52:40.423 \rightarrow 00:52:42.810$ it or may start implement, you know?
- NOTE Confidence: 0.925469609166667
- $00{:}52{:}42{.}810$ --> $00{:}52{:}46{.}250$ Start putting in some out of pocket payments.
- NOTE Confidence: 0.925469609166667
- 00:52:46.250 --> 00:52:48.280 Yep. You know, I think,
- NOTE Confidence: 0.925469609166667
- $00:52:48.280 \rightarrow 00:52:51.696$ why would a state not pass a mandate?
- NOTE Confidence: 0.925469609166667
- $00:52:51.700 \rightarrow 00:52:53.408$ You know they may be looking to
- NOTE Confidence: 0.925469609166667
- $00:52:53.408 \rightarrow 00:52:54.702$ the evidence and maybe looking
- NOTE Confidence: 0.925469609166667
- $00:52:54.702 \rightarrow 00:52:56.480$ to the USPS TF if they're thought
- NOTE Confidence: 0.925469609166667
- $00:52:56.480 \longrightarrow 00:52:57.957$ of as an independent body,
- NOTE Confidence: 0.925469609166667
- $00:52:57.960 \longrightarrow 00:53:00.108$ they still have not gone up
- NOTE Confidence: 0.925469609166667
- 00:53:00.108 --> 00:53:02.070 to the ARDA or B rating,
- NOTE Confidence: 0.925469609166667
- $00:53:02.070 \rightarrow 00:53:03.310$ suggesting there probably there
- NOTE Confidence: 0.925469609166667
- $00{:}53{:}03{.}310 \dashrightarrow 00{:}53{:}05{.}258$ may be still some uncertainty.
- NOTE Confidence: 0.925469609166667
- $00{:}53{:}05{.}260 \dashrightarrow 00{:}53{:}06{.}910$ Right in in the studies,
- NOTE Confidence: 0.925469609166667
- $00{:}53{:}06{.}910 \dashrightarrow 00{:}53{:}10{.}438$ so that's why you might not mandate the
- NOTE Confidence: 0.925469609166667
- $00{:}53{:}10{.}438 \dashrightarrow 00{:}53{:}14{.}370$ reason that you you know or also because.
- NOTE Confidence: 0.925469609166667

 $00:53:14.370 \longrightarrow 00:53:16.323$ It's not really clear that there's a

NOTE Confidence: 0.925469609166667

 $00:53:16.323 \rightarrow 00:53:18.236$ problem since people are not paying large

NOTE Confidence: 0.925469609166667

 $00:53:18.236 \rightarrow 00:53:20.210$ out of pocket payments for this service.

NOTE Confidence: 0.777921400769231

 $00:53:21.840 \longrightarrow 00:53:25.614$ Sure. Yeah, because the laws are

NOTE Confidence: 0.777921400769231

 $00{:}53{:}25{.}614 \dashrightarrow 00{:}53{:}29{.}618$ at the state level and the

NOTE Confidence: 0.777921400769231

00:53:29.620 --> 00:53:32.000 US preventive task force hasn't

NOTE Confidence: 0.777921400769231

 $00{:}53{:}32{.}000 \dashrightarrow 00{:}53{:}34{.}380$ made a ARB recommendation.

NOTE Confidence: 0.777921400769231

 $00{:}53{:}34{.}380 \dashrightarrow 00{:}53{:}36{.}138$ I think that could be where

NOTE Confidence: 0.777921400769231

 $00{:}53{:}36{.}138 \dashrightarrow 00{:}53{:}37{.}310$ states are looking for.

NOTE Confidence: 0.86811817

 $00:53:39.800 \rightarrow 00:53:40.300$ Yes.

NOTE Confidence: 0.832805011428571

 $00:53:43.420 \dashrightarrow 00:53:44.848$ Am I supposed to look for questions?

NOTE Confidence: 0.827701572

 $00:53:47.990 \longrightarrow 00:53:51.560$ Right? Please feel free to.

NOTE Confidence: 0.827701572

 $00:53:51.560 \dashrightarrow 00:53:53.868$ Type your question through chat.

NOTE Confidence: 0.7095575866666667

 $00{:}53{:}57{.}730 \dashrightarrow 00{:}54{:}00{.}888$ Oh, here's Regina. Thanks so much, Susan.

NOTE Confidence: 0.77775094125

00:54:05.840 --> 00:54:08.576 OK, so Regina Hooley just has a comment

NOTE Confidence: 0.77775094125

 $00:54:08.576 \rightarrow 00:54:10.778$ that Yale they first started using

- NOTE Confidence: 0.77775094125
- 00:54:10.778 --> 00:54:12.855 DBT in 2011 and they didn't charge
- NOTE Confidence: 0.77775094125
- $00{:}54{:}12.855 \dashrightarrow 00{:}54{:}14.540$ patients for insurance for many years.
- NOTE Confidence: 0.77775094125
- $00:54:14.540 \longrightarrow 00:54:16.216$ Probably not until 2018.
- NOTE Confidence: 0.77775094125
- 00:54:16.216 --> 00:54:18.730 So I think Medicare did start
- NOTE Confidence: 0.77775094125
- 00:54:18.810 --> 00:54:20.998 charging to 2:15 till 2015,
- NOTE Confidence: 0.77775094125
- $00:54:20.998 \longrightarrow 00:54:24.346$ so I think few private insurers.
- NOTE Confidence: 0.77775094125
- $00:54:24.350 \rightarrow 00:54:26.300$ Maybe we're charging before that.
- NOTE Confidence: 0.77775094125
- $00:54:26.300 \longrightarrow 00:54:28.676$ I think a lot of I think there
- NOTE Confidence: 0.77775094125
- $00:54:28.676 \longrightarrow 00:54:30.770$ wasn't even a code until 2015
- NOTE Confidence: 0.77775094125
- $00:54:30.770 \longrightarrow 00:54:34.190$ to 2 allow people to charge.
- NOTE Confidence: 0.77775094125
- $00:54:34.190 \longrightarrow 00:54:35.618$ But that is great that Yale
- NOTE Confidence: 0.77775094125
- $00{:}54{:}35{.}618 \dashrightarrow 00{:}54{:}36{.}920$ was able to do that.
- NOTE Confidence: 0.6953895
- $00:54:58.900 \rightarrow 00:55:02.270$ So what are the follow up?
- NOTE Confidence: 0.6217595525
- $00:55:02.270 \longrightarrow 00:55:05.210$ Studies that that you are carrying
- NOTE Confidence: 0.6217595525
- $00{:}55{:}05{.}210 \dashrightarrow 00{:}55{:}07{.}990$ your team is planning. I know Alana
- NOTE Confidence: 0.6217595525

 $00:55:07.990 \longrightarrow 00:55:10.539$ has a huge interest in this too.

NOTE Confidence: 0.95838618

00:55:11.910 --> 00:55:15.408 Yeah, so so that's great and I you know,

NOTE Confidence: 0.95838618

 $00{:}55{:}15{.}408 \dashrightarrow 00{:}55{:}17{.}124$ I think we're talking about that

NOTE Confidence: 0.95838618

 $00:55:17.130 \longrightarrow 00:55:19.194$ right now because this is one of the

NOTE Confidence: 0.95838618

 $00:55:19.194 \dashrightarrow 00:55:21.467$ this is a project I have two minutes.

NOTE Confidence: 0.95838618

 $00:55:21.470 \rightarrow 00:55:23.584$ I'll just describe how this project started.

NOTE Confidence: 0.95838618

00:55:23.590 --> 00:55:24.350 And interestingly,

NOTE Confidence: 0.95838618

 $00:55:24.350 \dashrightarrow 00:55:27.390$ Joe Ross was also on this train ride.

NOTE Confidence: 0.95838618

 $00{:}55{:}27{.}390 \dashrightarrow 00{:}55{:}31{.}026$ I had a personal experience with.

NOTE Confidence: 0.95838618

00:55:31.030 -> 00:55:31.708 Breast ultrasound,

NOTE Confidence: 0.95838618

 $00:55:31.708 \rightarrow 00:55:34.081$ which is what we really the technology

NOTE Confidence: 0.95838618

 $00{:}55{:}34.081 \dashrightarrow 00{:}55{:}36.435$ we were really interested in studying,

NOTE Confidence: 0.95838618

 $00{:}55{:}36{.}435 \dashrightarrow 00{:}55{:}39{.}914$ and Joe Ross and Carrie Gross and I

NOTE Confidence: 0.95838618

 $00{:}55{:}39{.}914 \dashrightarrow 00{:}55{:}41{.}888$ were on the same metro North train down

NOTE Confidence: 0.95838618

 $00{:}55{:}41.888 \dashrightarrow 00{:}55{:}43.667$ to New York for the same meeting and

NOTE Confidence: 0.95838618

 $00:55:43.667 \rightarrow 00:55:45.475$ we were just chatting on the train and

00:55:45.525 --> 00:55:47.022 I said to Kerry, what's up with this?

NOTE Confidence: 0.95838618

 $00{:}55{:}47.022 \dashrightarrow 00{:}55{:}48.340$ You know what's going on this is,

NOTE Confidence: 0.95838618

 $00:55:48.340 \rightarrow 00:55:49.544$ you know, many years ago and I

NOTE Confidence: 0.95838618

 $00:55:49.544 \longrightarrow 00:55:50.920$ said this is so interesting that

NOTE Confidence: 0.95838618

 $00{:}55{:}50{.}920 \dashrightarrow 00{:}55{:}52{.}000$ they're doing this mandate.

NOTE Confidence: 0.95838618

 $00{:}55{:}52{.}000 \dashrightarrow 00{:}55{:}54{.}261$ Let's write a grant and we ended

NOTE Confidence: 0.95838618

 $00:55:54.261 \dashrightarrow 00:55:56.598$ up writing a an ACS grant that

NOTE Confidence: 0.95838618

 $00{:}55{:}56{.}598 \dashrightarrow 00{:}55{:}58{.}536$ was funded to do this work.

NOTE Confidence: 0.95838618

 $00{:}55{:}58{.}540 \dashrightarrow 00{:}56{:}00{.}166$ And then Alana gotten bored and

NOTE Confidence: 0.95838618

 $00:56:00.166 \longrightarrow 00:56:01.470$ we sort of extended it.

NOTE Confidence: 0.95838618

00:56:01.470 --> 00:56:02.388 It's a DBT,

NOTE Confidence: 0.95838618

 $00{:}56{:}02.388 \dashrightarrow 00{:}56{:}04.952$ so it really did start out as this

NOTE Confidence: 0.95838618

 $00{:}56{:}04{.}952 \dashrightarrow 00{:}56{:}07{.}644$ just sort of kind of very random thing

NOTE Confidence: 0.95838618

 $00:56:07.644 \dashrightarrow 00:56:09.288$ that people just sort of talking.

NOTE Confidence: 0.95838618

 $00{:}56{:}09{.}290 \dashrightarrow 00{:}56{:}11{.}642$ It's funny that Joe is here about

 $00:56:11.642 \rightarrow 00:56:13.406$ this and ended up being this project NOTE Confidence: 0.95838618 $00{:}56{:}13.406 \dashrightarrow 00{:}56{:}15.013$ so that project has ended now NOTE Confidence: 0.95838618 $00:56:15.013 \rightarrow 00:56:16.585$ so that ACS project has ended. NOTE Confidence: 0.95838618 $00{:}56{:}16{.}590 \dashrightarrow 00{:}56{:}18{.}066$ So we're really thinking about what NOTE Confidence: 0.95838618 $00:56:18.066 \rightarrow 00:56:20.240$ would be the the best next steps and NOTE Confidence: 0.95838618 $00:56:20.240 \rightarrow 00:56:21.944$ what are the most interesting questions. NOTE Confidence: 0.95838618 $00:56:21.950 \longrightarrow 00:56:23.840$ So I think Regina probably has some NOTE Confidence: 0.95838618 00:56:23.840 --> 00:56:25.759 good ideas so she's sort of been NOTE Confidence: 0.95838618 $00:56:25.759 \rightarrow 00:56:27.458$ involved in this so we we haven't NOTE Confidence: 0.95838618 $00:56:27.458 \rightarrow 00:56:28.970$ sort of gotten to the next project. NOTE Confidence: 0.95838618 $00:56:28.970 \longrightarrow 00:56:30.344$ We're sort of finishing up the NOTE Confidence: 0.95838618 $00{:}56{:}30{.}344 \dashrightarrow 00{:}56{:}31{.}480$ the old project right now. NOTE Confidence: 0.95838618 $00:56:31.480 \longrightarrow 00:56:32.320$ The older project. NOTE Confidence: 0.781166185 00:56:34.790 --> 00:56:36.815 There's a comment from Carrie NOTE Confidence: 0.781166185 00:56:36.815 --> 00:56:38.840 if you could address briefly. NOTE Confidence: 0.913487709 $00:56:42.450 \longrightarrow 00:56:43.690$ I'm not sure that state

- NOTE Confidence: 0.913487709
- $00:56:43.690 \rightarrow 00:56:44.930$ legislatures would look at that,
- NOTE Confidence: 0.913487709
- $00:56:44.930 \longrightarrow 00:56:45.866$ but I do think like that.
- NOTE Confidence: 0.913487709
- $00:56:45.870 \longrightarrow 00:56:47.054$ The advocates when you,
- NOTE Confidence: 0.913487709
- 00:56:47.054 --> 00:56:48.830 if you say you publish something
- NOTE Confidence: 0.913487709
- $00:56:48.888 \rightarrow 00:56:50.473$ that suggests that they're really
- NOTE Confidence: 0.913487709
- $00:56:50.473 \rightarrow 00:56:52.330$ good benefits to passing a law,
- NOTE Confidence: 0.913487709
- $00{:}56{:}52{.}330 \dashrightarrow 00{:}56{:}54{.}199$ I think that the the advocates may
- NOTE Confidence: 0.913487709
- $00:56:54.199 \dashrightarrow 00:56:55.719$ bring that to state legislatures
- NOTE Confidence: 0.913487709
- $00{:}56{:}55{.}719 \dashrightarrow 00{:}56{:}58{.}015$ and that that can be very helpful.
- NOTE Confidence: 0.913487709
- $00:56:58.020 \rightarrow 00:57:00.060$ Especially, I do think like some of the
- NOTE Confidence: 0.913487709
- $00:57:00.060 \rightarrow 00:57:02.022$ state laws were the earlier studies
- NOTE Confidence: 0.913487709
- 00:57:02.022 --> 00:57:04.110 showing that state laws around mammography.
- NOTE Confidence: 0.913487709
- $00:57:04.110 \rightarrow 00:57:07.302$ This is pre ACA and cost sharing that
- NOTE Confidence: 0.913487709
- $00{:}57{:}07{.}302 \dashrightarrow 00{:}57{:}09{.}684$ those actually you know led to more
- NOTE Confidence: 0.913487709
- $00:57:09.684 \rightarrow 00:57:11.472$ movies and potentially had some interest,
- NOTE Confidence: 0.913487709

- $00:57:11.480 \longrightarrow 00:57:12.602$ some effect.
- NOTE Confidence: 0.913487709
- 00:57:12.602 --> 00:57:14.846 On breast cancer identification?
- NOTE Confidence: 0.913487709

 $00:57:14.850 \longrightarrow 00:57:15.184$ Not necessarily.

NOTE Confidence: 0.913487709

00:57:15.184 --> 00:57:16.900 I don't know if they ever got to mortality,

NOTE Confidence: 0.913487709

 $00{:}57{:}16{.}900 \dashrightarrow 00{:}57{:}18{.}676$ but I think those did have an impact.

NOTE Confidence: 0.913487709

 $00:57:18.680 \longrightarrow 00:57:21.360$ Those studies.

NOTE Confidence: 0.913487709

00:57:21.360 --> 00:57:22.830 And there's one more from Alana.

NOTE Confidence: 0.847373147222222

 $00:57:25.030 \longrightarrow 00:57:27.640$ Yes, so a lot of notes and I that

NOTE Confidence: 0.847373147222222

 $00{:}57{:}27{.}640 \dashrightarrow 00{:}57{:}30{.}250$ these implications have other firm

NOTE Confidence: 0.847373147222222

 $00:57:30.250 \rightarrow 00:57:32.486$ or other emerging technologies.

NOTE Confidence: 0.847373147222222

 $00:57:32.490 \longrightarrow 00:57:34.236$ So to thinking about how that

NOTE Confidence: 0.847373147222222

 $00:57:34.236 \longrightarrow 00:57:36.193$ will adopt that, how that those

NOTE Confidence: 0.847373147222222

 $00{:}57{:}36{.}193 \dashrightarrow 00{:}57{:}37{.}637$ influence adoption and price.

NOTE Confidence: 0.875976628125

00:57:39.480 --> 00:57:41.545 Thank you so much Susan for taking

NOTE Confidence: 0.875976628125

 $00:57:41.545 \longrightarrow 00:57:43.949$ the time to share with us your

NOTE Confidence: 0.875976628125

 $00:57:43.949 \rightarrow 00:57:47.508$ important work. Also thanks to Joe.

00:57:47.510 --> 00:57:50.850 Help you both have a nice day. But by.