WEBVTT

NOTE duration:"00:58:06"

NOTE recognizability:0.875

NOTE language:en-us

NOTE Confidence: 0.88321682875

00:00:00.000 --> 00:00:02.382 I'm delighted to introduce our first

NOTE Confidence: 0.88321682875

00:00:02.382 --> 00:00:04.143 speaker today, Doctor Joel Ross.

NOTE Confidence: 0.88321682875

00:00:04.143 --> 00:00:06.390 He's a professor of medicine in general

NOTE Confidence: 0.88321682875

00:00:06.447 --> 00:00:08.505 medicine and professor of public health

NOTE Confidence: 0.88321682875

00:00:08.505 --> 00:00:10.560 and health policy and management.

NOTE Confidence: 0.88321682875

00:00:10.560 --> 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 --> 00:00:16.960 Doctor Ross came to Yale.

NOTE Confidence: 0.88321682875

00:00:16.960 --> 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 --> 00:00:28.344 with a focus on examining factors that

NOTE Confidence: 0.88321682875

00:00:28.344 --> 00:00:31.166 affect use or delivery of recommended

NOTE Confidence: 0.88321682875

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

NOTE Confidence: 0.88321682875

00:00:33.340 --> 00:00:36.500 as well as clinical outcomes of such care.

NOTE Confidence: 0.88321682875

00:00:36.500 --> 00:00:39.800 Today his topic is leveraging real-world

NOTE Confidence: 0.88321682875

00:00:39.800 --> 00:00:42.620 data through pragmatic clinical trials.

NOTE Confidence: 0.88321682875

00:00:42.620 --> 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 --> 00:00:49.967 speak before the Cancer Center and

NOTE Confidence: 0.825991351428572

00:00:49.967 --> 00:00:51.410 part of the grand rounds today.

NOTE Confidence: 0.825991351428572

00:00:51.410 --> 00:00:54.042 I'm delighted to share some of the

NOTE Confidence: 0.825991351428572

00:00:54.042 --> 00:00:56.066 work that I've been working on

NOTE Confidence: 0.825991351428572

00:00:56.066 --> 00:00:57.837 over the past several years and to

NOTE Confidence: 0.825991351428572

00:00:57.837 --> 00:00:59.409 identify potential opportunities for

NOTE Confidence: 0.825991351428572

00:00:59.409 --> 00:01:00.675 collaboration with investigators

NOTE Confidence: 0.825991351428572

00:01:00.675 --> 00:01:02.363 throughout the Cancer Center.

NOTE Confidence: 0.825991351428572

00:01:02.370 --> 00:01:04.008 I also could not be happier to

NOTE Confidence: 0.825991351428572

00:01:04.008 --> 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 --> 00:01:10.930 kind of lost looking for a mentor.

NOTE Confidence: 0.825991351428572

00:01:10.930 --> 00:01:13.485 Way back almost 20 years ago now,

NOTE Confidence: 0.825991351428572

00:01:13.490 --> 00:01:15.008 Susan was the only person to

NOTE Confidence: 0.825991351428572

00:01:15.008 --> 00:01:16.250 open her door to me.

NOTE Confidence: 0.825991351428572

00:01:16.250 --> 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 --> 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 --> 00:01:25.075 So I'm just going to get started

NOTE Confidence: 0.825991351428572

00:01:25.075 --> 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 --> 00:01:28.810 jump in with questions through the chat.

NOTE Confidence: 0.825991351428572

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 --> 00:01:33.174 some of the potential competing

NOTE Confidence: 0.825991351428572

00:01:33.174 --> 00:01:34.640 interests that inform the work that

NOTE Confidence: 0.825991351428572

00:01:34.640 --> 00:01:36.008 I'm going to be presenting today.

NOTE Confidence: 0.825991351428572

00:01:36.010 --> 00:01:38.230 I do get research grant funding

NOTE Confidence: 0.825991351428572

00:01:38.230 --> 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 --> 00:01:45.090 and Innovation.

NOTE Confidence: 0.825991351428572

00:01:45.090 --> 00:01:46.826 I'll talk a little bit about that work.

NOTE Confidence: 0.825991351428572

00:01:46.830 --> 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 --> 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 --> 00:01:55.638 trial data sharing initiatives

NOTE Confidence: 0.825991351428572

00:01:55.638 --> 00:01:57.144 at federal government awards,

NOTE Confidence: 0.825991351428572

00:01:57.144 --> 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 --> 00:02:02.190 So this is just,

NOTE Confidence: 0.825991351428572

00:02:02.190 --> 00:02:02.590 you know,

NOTE Confidence: 0.825991351428572

00:02:02.590 --> 00:02:04.186 to get us started you know here

NOTE Confidence: 0.825991351428572

00:02:04.186 --> 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 --> 00:02:08.550 for evidence to,

NOTE Confidence: 0.825991351428572

00:02:08.550 --> 00:02:09.910 you know as they have a clinical question,

NOTE Confidence: 0.825991351428572

00:02:09.910 --> 00:02:10.870 they're trying to make a decision

NOTE Confidence: 0.825991351428572

00:02:10.870 --> 00:02:12.158 about what to do for their patients.

NOTE Confidence: 0.825991351428572

00:02:12.160 --> 00:02:13.410 Or to then, you know,

NOTE Confidence: 0.825991351428572

00:02:13.410 --> 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 --> 00:02:18.885 around a drug to use and you know,

NOTE Confidence: 0.825991351428572

00:02:18.890 --> 00:02:20.480 typically you know when we think

NOTE Confidence: 0.825991351428572

00:02:20.480 --> 00:02:22.122 about this sort of the hierarchy

NOTE Confidence: 0.825991351428572

00:02:22.122 --> 00:02:23.712 of evidence and you know what

NOTE Confidence: 0.825991351428572

00:02:23.712 --> 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 --> 00:02:27.298 we look for evidence that you

NOTE Confidence: 0.825991351428572

00:02:27.298 --> 00:02:28.958 know is at this level or higher.

NOTE Confidence: 0.825991351428572

00:02:28.960 --> 00:02:31.450 You know randomized control trials.

NOTE Confidence: 0.825991351428572

00:02:31.450 --> 00:02:33.914 You know to guide our decisions or

NOTE Confidence: 0.825991351428572

00:02:33.914 --> 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 --> 00:02:39.090 and ideally when it's been meta

NOTE Confidence: 0.825991351428572

00:02:39.090 --> 00:02:41.480 analyzed to put it all together.

NOTE Confidence: 0.825991351428572

00:02:41.480 --> 00:02:43.279 But there's been a lot of changes

NOTE Confidence: 0.825991351428572

00:02:43.279 --> 00:02:45.458 in the way we understand evidence,

NOTE Confidence: 0.825991351428572

00:02:45.460 --> 00:02:47.602 in part because of the advancement

NOTE Confidence: 0.825991351428572

00:02:47.602 --> 00:02:50.519 and methods to use a large data sources,

NOTE Confidence: 0.825991351428572

00:02:50.520 --> 00:02:53.022 but also because of other challenges

NOTE Confidence: 0.825991351428572

00:02:53.022 --> 00:02:56.160 that have faced both the FDA and others.

NOTE Confidence: 0.825991351428572

00:02:56.160 --> 00:02:58.254 But what you'll have noticed over

NOTE Confidence: 0.825991351428572

00:02:58.254 --> 00:03:00.466 the past decade is, you know,

NOTE Confidence: 0.825991351428572

00:03:00.466 --> 00:03:01.690 increasingly thinking about.

NOTE Confidence: 0.825991351428572

00:03:01.690 --> 00:03:04.961 A new and novel ways to evaluate

NOTE Confidence: 0.825991351428572

00:03:04.961 --> 00:03:07.516 medical products and the the.

NOTE Confidence: 0.825991351428572

00:03:07.520 --> 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 --> 00:03:16.109 about what's being called a

NOTE Confidence: 0.825991351428572

00:03:16.109 --> 00:03:17.965 lifecycle approach to evaluation.

NOTE Confidence: 0.825991351428572

00:03:17.970 --> 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 --> 00:03:23.598 it's going to inform use and in part

NOTE Confidence: 0.837503126

00:03:23.598 --> 00:03:25.554 that was because premarket studies that

NOTE Confidence: 0.837503126

00:03:25.554 --> 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 --> 00:03:30.770 limited in the end points

NOTE Confidence: 0.837503126

00:03:30.770 --> 00:03:31.880 on which they're focused on.

NOTE Confidence: 0.837503126

00:03:31.880 --> 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 --> 00:03:36.388 identify important safety concerns,

NOTE Confidence: 0.837503126

00:03:36.390 --> 00:03:37.322 and sometimes they're not

NOTE Confidence: 0.837503126

00:03:37.322 --> 00:03:38.254 even studies that are.

NOTE Confidence: 0.837503126

00:03:38.260 --> 00:03:39.980 Guaranteed to confirm the

NOTE Confidence: 0.837503126

00:03:39.980 --> 00:03:41.700 efficacy of a product.

NOTE Confidence: 0.837503126

00:03:41.700 --> 00:03:43.190 They're they're focusing on surrogate

NOTE Confidence: 0.837503126

00:03:43.190 --> 00:03:45.220 markers as endpoints in order to project,

NOTE Confidence: 0.837503126

00:03:45.220 --> 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 --> 00:03:51.740 and then those are supposed to be done

NOTE Confidence: 0.837503126

00:03:51.740 --> 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 --> 00:03:56.326 trials that are going to happen

NOTE Confidence: 0.837503126

00:03:56.326 --> 00:03:58.430 after the the approval and but the

NOTE Confidence: 0.837503126

00:03:58.430 --> 00:04:00.506 problem has been that those trials

NOTE Confidence: 0.837503126

00:04:00.506 --> 00:04:02.660 frequently are delayed and they're

NOTE Confidence: 0.837503126

00:04:02.660 --> 00:04:04.935 just not even consistently completed.

NOTE Confidence: 0.837503126

00:04:04.940 --> 00:04:06.578 This in combination with the fact

NOTE Confidence: 0.837503126

00:04:06.578 --> 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 --> 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 --> 00:04:14.944 opportunities for you know

NOTE Confidence: 0.837503126

00:04:14.944 --> 00:04:16.108 what you're hearing now.

NOTE Confidence: 0.837503126

00:04:16.110 --> 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 --> 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 --> 00:04:26.746 this is this quote from a high level

NOTE Confidence: 0.837503126

00:04:26.746 --> 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 --> 00:04:31.544 using RWE to begin to address

NOTE Confidence: 0.837503126

00:04:31.544 --> 00:04:33.788 these questions as preferable to

NOTE Confidence: 0.837503126

00:04:33.788 --> 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 --> 00:04:39.116 you know industry and FDA talking

NOTE Confidence: 0.837503126

00:04:39.116 --> 00:04:40.260 more about real-world data.

NOTE Confidence: 0.837503126

00:04:40.260 --> 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 --> 00:04:44.440 up that you know promising.

NOTE Confidence: 0.837503126

00:04:44.440 --> 00:04:45.936 We're world analytics to

NOTE Confidence: 0.837503126

00:04:45.936 --> 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 --> 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 --> 00:04:54.199 This is a big problem that where the

NOTE Confidence: 0.837503126

00:04:54.199 --> 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 --> 00:04:59.348 you know what we're capable of,

NOTE Confidence: 0.837503126

00:04:59.350 --> 00:05:00.560 and what we're capable of,

NOTE Confidence: 0.837503126

00:05:00.560 --> 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 --> 00:05:05.780 what we're talking about now are the use of.

NOTE Confidence: 0.837503126

00:05:05.780 --> 00:05:07.760 You know cohort studies case control studies.

NOTE Confidence: 0.837503126

00:05:07.760 --> 00:05:08.572 You know,

NOTE Confidence: 0.837503126

00:05:08.572 --> 00:05:10.196 leveraging observational data resources

NOTE Confidence: 0.837503126

00:05:10.200 --> 00:05:12.032 and and in part this is not only

NOTE Confidence: 0.837503126

00:05:12.032 --> 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 --> 00:05:17.212 but also you know a major advocacy

NOTE Confidence: 0.837503126

00:05:17.212 --> 00:05:18.462 push that's happening towards

NOTE Confidence: 0.837503126

00:05:18.462 --> 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 --> 00:05:22.737 new legislation the 21st Century

NOTE Confidence: 0.837503126

00:05:22.737 --> 00:05:25.252 Cures Act that passed at the tail

NOTE Confidence: 0.837503126

00:05:25.252 --> 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 --> 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 --> 00:05:34.344 including requiring the FDA

NOTE Confidence: 0.837503126

00:05:34.344 --> 00:05:36.288 to establish a program.

NOTE Confidence: 0.837503126

00:05:36.290 --> 00:05:38.040 To evaluate real-world evidence which

NOTE Confidence: 0.837503126

00:05:38.040 --> 00:05:40.229 that was defined in the legislation

NOTE Confidence: 0.837503126

00:05:40.229 --> 00:05:42.840 as data regarding the usage or the

NOTE Confidence: 0.837503126

00:05:42.840 --> 00:05:44.776 potential benefits or risks of a

NOTE Confidence: 0.837503126

00:05:44.776 --> 00:05:46.462 drug or device derived from sources

NOTE Confidence: 0.837503126

00:05:46.470 --> 00:05:49.230 other than randomized control trials.

NOTE Confidence: 0.837503126

00:05:49.230 --> 00:05:51.085 Now, this isn't to say that you

NOTE Confidence: 0.837503126

00:05:51.085 --> 00:05:53.068 know all real world data are bad.

NOTE Confidence: 0.837503126

00:05:53.070 --> 00:05:55.583 The typical or traditional PWB of today

NOTE Confidence: 0.837503126

00:05:55.583 --> 00:05:58.670 is work that you know many investigators,

NOTE Confidence: 0.837503126

00:05:58.670 --> 00:06:00.510 including my group at Yale,

NOTE Confidence: 0.837503126

00:06:00.510 --> 00:06:01.222 do right.

NOTE Confidence: 0.837503126

00:06:01.222 --> 00:06:02.646 So it's advanced observation.

NOTE Confidence: 0.837503126

00:06:02.650 --> 00:06:03.674 ULL research,

NOTE Confidence: 0.837503126

00:06:03.674 --> 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 --> 00:06:11.868 prognosis and treatment adherence.

NOTE Confidence: 0.885214616111111

00:06:11.870 --> 00:06:14.628 This type of evidence is generally used

NOTE Confidence: 0.885214616111111

00:06:14.628 --> 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 --> 00:06:21.244 diseases that are with well understood

NOTE Confidence: 0.885214616111111

00:06:21.244 --> 00:06:22.576 pathophysiology and progression,

NOTE Confidence: 0.885214616111111

00:06:22.580 --> 00:06:25.620 and it's very limited and it's used for

NOTE Confidence: 0.885214616111111

00:06:25.620 --> 00:06:27.699 initial regulatory approval decisions,

NOTE Confidence: 0.885214616111111

00:06:27.700 --> 00:06:29.800 mostly because those products are

NOTE Confidence: 0.885214616111111

00:06:29.800 --> 00:06:31.895 not used in such widespread way

NOTE Confidence: 0.885214616111111

00:06:31.895 --> 00:06:33.677 that you can actually leverage

NOTE Confidence: 0.885214616111111

00:06:33.677 --> 00:06:36.299 existing data sources to study there,

NOTE Confidence: 0.885214616111111

00:06:36.300 --> 00:06:38.025 that the effectiveness and safety

NOTE Confidence: 0.885214616111111

00:06:38.025 --> 00:06:39.060 of the product.

NOTE Confidence: 0.885214616111111

00:06:39.060 --> 00:06:40.092 And of course,

NOTE Confidence: 0.885214616111111

00:06:40.092 --> 00:06:42.500 most commonly of these types of studies

NOTE Confidence: 0.885214616111111

00:06:42.569 --> 00:06:44.704 are used for safety surveillance

NOTE Confidence: 0.885214616111111

00:06:44.704 --> 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 --> 00:06:50.854 your attention to some of the work

NOTE Confidence: 0.885214616111111

00:06:50.854 --> 00:06:53.014 that we've done as part of our group.

NOTE Confidence: 0.885214616111111

00:06:53.020 --> 00:06:54.784 And I did want to just sort of flag

NOTE Confidence: 0.885214616111111

00:06:54.784 --> 00:06:56.013 this because there's individuals

NOTE Confidence: 0.885214616111111

00:06:56.013 --> 00:06:57.981 here attending the grand rounds who

NOTE Confidence: 0.885214616111111

00:06:57.981 --> 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 --> 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

NOTE Confidence: 0.885214616111111

00:07:06.609 --> 00:07:09.434 unmet needs at the at the Agency this often.

NOTE Confidence: 0.885214616111111

00:07:09.440 --> 00:07:10.840 This is through our Searcy.

NOTE Confidence: 0.885214616111111

00:07:10.840 --> 00:07:12.608 We are one of four that are funded

NOTE Confidence: 0.885214616111111

00:07:12.608 --> 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 --> 00:07:19.872 which is a a network of health systems

NOTE Confidence: 0.885214616111111

00:07:19.872 --> 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 --> 00:07:23.005 essentially,

NOTE Confidence: 0.885214616111111

00:07:23.005 --> 00:07:24.715 we're working with our health system

NOTE Confidence: 0.885214616111111

00:07:24.715 --> 00:07:26.526 data to try to evaluate medical

NOTE Confidence: 0.885214616111111

00:07:26.526 --> 00:07:28.682 devices in practice and these types

NOTE Confidence: 0.885214616111111

00:07:28.682 --> 00:07:31.580 of studies you know tend to look

NOTE Confidence: 0.885214616111111

00:07:31.674 --> 00:07:33.760 like this project where we look,

NOTE Confidence: 0.885214616111111

00:07:33.760 --> 00:07:35.630 try to better understand the

NOTE Confidence: 0.885214616111111

00:07:35.630 --> 00:07:37.500 safety and efficacy of individuals

NOTE Confidence: 0.885214616111111

00:07:37.566 --> 00:07:39.406 who are switching from branded.

NOTE Confidence: 0.885214616111111

00:07:39.410 --> 00:07:42.062 We both are rocks into generic

NOTE Confidence: 0.885214616111111

00:07:42.062 --> 00:07:44.859 looking at its impact and effect.

NOTE Confidence: 0.885214616111111

00:07:44.860 --> 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 --> 00:07:51.798 where we're where we're aggregating

NOTE Confidence: 0.885214616111111

00:07:51.798 --> 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 --> 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 --> 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 --> 00:08:08.500 throughout the state.

NOTE Confidence: 0.885214616111111

00:08:08.500 --> 00:08:10.789 Work like this where we're trying to

NOTE Confidence: 0.885214616111111

00:08:10.789 --> 00:08:12.185 understand the comparative effectiveness

NOTE Confidence: 0.885214616111111

00:08:12.185 --> 00:08:14.363 of safety of oral anticoagulants in

NOTE Confidence: 0.885214616111111

00:08:14.363 --> 00:08:15.880 patients with atrial 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 --> 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 --> 00:08:22.647 but FDA is often tasked with trying

NOTE Confidence: 0.885214616111111

00:08:22.647 --> 00:08:24.117 to understand and give direction

NOTE Confidence: 0.885214616111111

00:08:24.117 --> 00:08:25.833 on their safety and benefits for

NOTE Confidence: 0.885214616111111

00:08:25.833 --> 00:08:27.627 use of this kind of research,

NOTE Confidence: 0.885214616111111

00:08:27.630 --> 00:08:29.182 as well as this.

NOTE Confidence: 0.885214616111111

00:08:29.182 --> 00:08:31.510 This registry based study where you

NOTE Confidence: 0.885214616111111

00:08:31.591 --> 00:08:34.879 know we looked at different types of cardio.

NOTE Confidence: 0.885214616111111

00:08:34.880 --> 00:08:36.680 Cardiac pump devices and looking

NOTE Confidence: 0.885214616111111

00:08:36.680 --> 00:08:37.760 at their safety,

NOTE Confidence: 0.885214616111111

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 --> 00:08:44.490 so lots of individuals are doing

NOTE Confidence: 0.885214616111111

00:08:44.490 --> 00:08:46.407 work like this that are leveraging

NOTE Confidence: 0.885214616111111

00:08:46.407 --> 00:08:48.787 existing data sources to try to bring

NOTE Confidence: 0.885214616111111

00:08:48.787 --> 00:08:50.548 greater insights into the safety

NOTE Confidence: 0.885214616111111

00:08:50.548 --> 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 --> 00:08:56.312 as the sort of the call for real

NOTE Confidence: 0.885214616111111

00:08:56.312 --> 00:08:57.460 world evidence gets louder.

NOTE Confidence: 0.885214616111111

00:08:57.460 --> 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 --> 00:09:02.686 should not be expected to answer the

NOTE Confidence: 0.885214616111111

00:09:02.686 --> 00:09:04.201 same clinical questions that are

NOTE Confidence: 0.885214616111111

00:09:04.201 --> 00:09:05.700 being answered by traditional clinical.

NOTE Confidence: 0.885214616111111

00:09:05.700 --> 00:09:07.100 Clinical trials and we have

NOTE Confidence: 0.885214616111111

00:09:07.100 --> 00:09:08.220 to think about ways

NOTE Confidence: 0.939815838421053

00:09:08.275 --> 00:09:10.489 to make sure that the evidence is being used.

NOTE Confidence: 0.939815838421053

00:09:10.490 --> 00:09:11.855 Compliment you know,

NOTE Confidence: 0.939815838421053

00:09:11.855 --> 00:09:14.585 to complement the existing RCT evidence.

NOTE Confidence: 0.939815838421053

00:09:14.590 --> 00:09:16.414 This is an example of a project that

NOTE Confidence: 0.939815838421053

00:09:16.414 --> 00:09:18.342 a student working with me did a couple

NOTE Confidence: 0.939815838421053

00:09:18.342 --> 00:09:20.013 of years ago trying to understand

NOTE Confidence: 0.939815838421053

00:09:20.013 --> 00:09:21.673 the feasibility of using real-world

NOTE Confidence: 0.939815838421053

00:09:21.673 --> 00:09:23.498 data to replicate clinical trial

NOTE Confidence: 0.939815838421053

00:09:23.498 --> 00:09:26.396 evidence and what she did is she

NOTE Confidence: 0.939815838421053

00:09:26.396 --> 00:09:28.082 identified among all the clinical

NOTE Confidence: 0.939815838421053

00:09:28.082 --> 00:09:29.990 trials that had been published in

NOTE Confidence: 0.939815838421053

00:09:30.054 --> 00:09:32.740 high impact medical journals in 2017.

NOTE Confidence: 0.939815838421053

00:09:32.740 --> 00:09:34.800 She determined what proportion

NOTE Confidence: 0.939815838421053

00:09:34.800 --> 00:09:36.848 had and in clinical intervention.

NOTE Confidence: 0.939815838421053

00:09:36.848 --> 00:09:39.552 The clinical indication of the of the

NOTE Confidence: 0.939815838421053

00:09:39.552 --> 00:09:41.296 patients who were studied enrollment

NOTE Confidence: 0.939815838421053

00:09:41.296 --> 00:09:43.312 criteria as well as a primary

NOTE Confidence: 0.939815838421053

00:09:43.312 --> 00:09:45.260 endpoint that could be successfully

NOTE Confidence: 0.939815838421053

00:09:45.260 --> 00:09:47.028 in routinely ascertained from

NOTE Confidence: 0.939815838421053

00:09:47.028 --> 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 --> 00:09:54.424 and what we found is that only 15%

NOTE Confidence: 0.939815838421053

00:09:54.424 --> 00:09:57.328 of these trials could feasibly have

NOTE Confidence: 0.939815838421053

00:09:57.328 --> 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 --> 00:10:04.554 When the 21st Century Cures Act passed,

NOTE Confidence: 0.939815838421053

00:10:04.560 --> 00:10:07.040 the FDA was actually pretty quick to say,

NOTE Confidence: 0.939815838421053

00:10:07.040 --> 00:10:07.419 listen,

NOTE Confidence: 0.939815838421053

00:10:07.419 --> 00:10:09.693 real-world data should be defined by

NOTE Confidence: 0.939815838421053

00:10:09.693 --> 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 --> 00:10:18.245 as opposed to necessarily in

NOTE Confidence: 0.939815838421053

00:10:18.245 --> 00:10:20.057 research or academic environments,

NOTE Confidence: 0.939815838421053

00:10:20.060 --> 00:10:22.082 and the distinction is not based

NOTE Confidence: 0.939815838421053

00:10:22.082 --> 00:10:23.833 necessarily on the presence or

NOTE Confidence: 0.939815838421053

00:10:23.833 --> 00:10:25.855 absence of a planned intervention or

NOTE Confidence: 0.939815838421053

00:10:25.855 --> 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 --> 00:10:29.480 you know,

NOTE Confidence: 0.939815838421053

00:10:29.480 --> 00:10:31.370 continue to seek out opportunities

NOTE Confidence: 0.939815838421053

00:10:31.370 --> 00:10:32.126 to conduct.

NOTE Confidence: 0.939815838421053

00:10:32.130 --> 00:10:33.462 Randomized evaluations using

NOTE Confidence: 0.939815838421053

00:10:33.462 --> 00:10:35.682 pragmatic trials that better leverage

NOTE Confidence: 0.939815838421053

00:10:35.682 --> 00:10:38.319 kind of the existing data resource

NOTE Confidence: 0.939815838421053

00:10:38.319 --> 00:10:40.419 infrastructure to make them perhaps

NOTE Confidence: 0.939815838421053

00:10:40.419 --> 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 --> 00:10:45.285 observation,

NOTE Confidence: 0.939815838421053

00:10:45.290 --> 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 --> 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 --> 00:10:53.247 if you want more evidence based practice,

NOTE Confidence: 0.939815838421053

00:10:53.250 --> 00:10:56.430 you need more practice based evidence.

NOTE Confidence: 0.939815838421053

00:10:56.430 --> 00:10:58.086 So in in the next 10 minutes I'm

NOTE Confidence: 0.939815838421053

00:10:58.086 --> 00:10:59.691 going to talk a little bit about

NOTE Confidence: 0.939815838421053

00:10:59.691 --> 00:11:01.322 some of the work that we've been

NOTE Confidence: 0.939815838421053

00:11:01.322 --> 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 --> 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 --> 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 --> 00:11:16.014 observational data resources.

NOTE Confidence: 0.939815838421053

00:11:16.020 --> 00:11:19.758 This this is a slide from Cuba.

NOTE Confidence: 0.939815838421053

00:11:19.760 --> 00:11:21.908 Take a data warehouse company that

NOTE Confidence: 0.939815838421053

00:11:21.908 --> 00:11:23.610 aggregates information across of you,

NOTE Confidence: 0.939815838421053

00:11:23.610 --> 00:11:25.345 know multiple multiple sources and

NOTE Confidence: 0.939815838421053

00:11:25.345 --> 00:11:27.657 you know they talk about kind of

NOTE Confidence: 0.939815838421053

00:11:27.657 --> 00:11:29.721 all the real world data that are out

NOTE Confidence: 0.939815838421053

00:11:29.789 --> 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 --> 00:11:36.740 lab and biomarker data to mortality data,

NOTE Confidence: 0.939815838421053

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 --> 00:11:42.455 All these things could ideally

NOTE Confidence: 0.939815838421053

00:11:42.455 --> 00:11:43.334 be linked together,

NOTE Confidence: 0.939815838421053

00:11:43.340 --> 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 --> 00:11:52.172 And this kind of is like the optimal

NOTE Confidence: 0.939815838421053

00:11:52.172 --> 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 --> 00:11:56.996 it's going to pull all this

NOTE Confidence: 0.939815838421053

00:11:56.996 --> 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 --> 00:12:02.055 and mostly people talk about that as

NOTE Confidence: 0.939815838421053

00:12:02.055 --> 00:12:04.365 being idealistic and not really achievable.

NOTE Confidence: 0.939815838421053

00:12:04.370 --> 00:12:06.554 But we've been working with a group

NOTE Confidence: 0.939815838421053

00:12:06.560 --> 00:12:09.549 called Hugo that actually does just this.

NOTE Confidence: 0.939815838421053

00:12:09.550 --> 00:12:11.765 It aggregates multiple data platforms

NOTE Confidence: 0.939815838421053

00:12:11.765 --> 00:12:13.980 into a patient centered medical

NOTE Confidence: 0.906489560909091

00:12:14.046 --> 00:12:16.335 record that the patient can then share

NOTE Confidence: 0.906489560909091

00:12:16.335 --> 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 --> 00:12:23.170 And so we this is the first study

NOTE Confidence: 0.906489560909091

00:12:23.170 --> 00:12:25.594 we did at leveraging this platform.

NOTE Confidence: 0.906489560909091

00:12:25.600 --> 00:12:27.696 It was done as part of our city.

NOTE Confidence: 0.906489560909091

00:12:27.700 --> 00:12:30.115 Our FT had funded center where

NOTE Confidence: 0.906489560909091

00:12:30.115 --> 00:12:32.605 we aggregated data for just 60

NOTE Confidence: 0.906489560909091

00:12:32.605 --> 00:12:34.678 patients who were getting care

NOTE Confidence: 0.906489560909091

00:12:34.678 --> 00:12:37.303 at Yale and at the Mayo Clinic.

NOTE Confidence: 0.906489560909091

00:12:37.310 --> 00:12:39.914 We recruited 15 patients at each

NOTE Confidence: 0.906489560909091

00:12:39.914 --> 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 --> 00:12:48.253 underwent the procedure and completed

NOTE Confidence: 0.906489560909091

00:12:48.253 --> 00:12:49.973 our eight week follow up.

NOTE Confidence: 0.906489560909091

00:12:49.980 --> 00:12:50.684 And what's?

NOTE Confidence: 0.906489560909091

00:12:50.684 --> 00:12:53.148 The beauty of this platform for research

NOTE Confidence: 0.906489560909091

00:12:53.148 --> 00:12:55.345 purposes is you sit down with a patient.

NOTE Confidence: 0.906489560909091

00:12:55.350 --> 00:12:57.426 You enroll them in the platform

NOTE Confidence: 0.906489560909091

00:12:57.430 --> 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 --> 00:13:03.623 from which they're gaining care

NOTE Confidence: 0.906489560909091

00:13:03.623 --> 00:13:06.350 or as well as their pharmacy data

NOTE Confidence: 0.906489560909091

00:13:06.350 --> 00:13:08.450 and and and other information.

NOTE Confidence: 0.906489560909091

00:13:08.450 --> 00:13:09.450 And that takes time.

NOTE Confidence: 0.906489560909091

00:13:09.450 --> 00:13:11.276 It took a little over an hour

NOTE Confidence: 0.906489560909091

00:13:11.276 --> 00:13:12.616 for all of our patients,

NOTE Confidence: 0.906489560909091

00:13:12.620 --> 00:13:14.110 but once you do that,

NOTE Confidence: 0.906489560909091

00:13:14.110 --> 00:13:15.935 everything that happens next over

NOTE Confidence: 0.906489560909091

00:13:15.935 --> 00:13:18.620 the 88 week follow up for the

NOTE Confidence: 0.906489560909091

00:13:18.620 --> 00:13:20.580 patients is all passive patient

NOTE Confidence: 0.906489560909091

00:13:20.580 --> 00:13:22.560 their patients data aggregates.

NOTE Confidence: 0.906489560909091

00:13:22.560 --> 00:13:25.656 Automatically into the the the system

NOTE Confidence: 0.906489560909091

00:13:25.660 --> 00:13:27.140 being shared with the research

NOTE Confidence: 0.906489560909091

00:13:27.140 --> 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 --> 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 --> 00:13:36.845 with 60 patients you know we've had a

NOTE Confidence: 0.906489560909091

00:13:36.845 --> 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 --> 00:13:42.231 over the age of 65 who were

NOTE Confidence: 0.906489560909091

00:13:42.231 --> 00:13:43.416 able to do this successfully.

NOTE Confidence: 0.906489560909091

00:13:43.420 --> 00:13:45.149 And here are the data we aggregated

NOTE Confidence: 0.906489560909091

00:13:45.149 --> 00:13:46.877 and I'll start at the bottom left.

NOTE Confidence: 0.906489560909091

00:13:46.880 --> 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 --> 00:13:52.730 at either the Yale at.

NOTE Confidence: 0.906489560909091

00:13:52.730 --> 00:13:54.599 Ill or the Mayo Clinic for their

NOTE Confidence: 0.906489560909091

00:13:54.599 --> 00:13:56.240 specialty care for this procedure,

NOTE Confidence: 0.906489560909091

00:13:56.240 --> 00:13:57.766 but also and so everyone you know

NOTE Confidence: 0.906489560909091

00:13:57.766 --> 00:13:59.209 their care is managed through Epic

NOTE Confidence: 0.906489560909091

00:13:59.209 --> 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 --> 00:14:03.734 my chart to their Hugo account,

NOTE Confidence: 0.906489560909091

00:14:03.734 --> 00:14:05.654 but also individuals who have

NOTE Confidence: 0.906489560909091

00:14:05.654 --> 00:14:07.552 primary care elsewhere were able

NOTE Confidence: 0.906489560909091

00:14:07.552 --> 00:14:09.334 to link their my charts either

NOTE Confidence: 0.906489560909091

00:14:09.334 --> 00:14:11.384 through Epic or Cerner based systems

NOTE Confidence: 0.906489560909091

00:14:11.384 --> 00:14:12.848 from any health system.

NOTE Confidence: 0.906489560909091

00:14:12.850 --> 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 --> 00:14:17.060 a FIB ablation here at Yale,

NOTE Confidence: 0.906489560909091

00:14:17.060 --> 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 --> 00:14:22.235 For whatever reason they could

NOTE Confidence: 0.906489560909091

00:14:22.235 --> 00:14:23.615 link that system too.

NOTE Confidence: 0.906489560909091

00:14:23.620 --> 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 --> 00:14:27.518 so that's not the upper right and so

NOTE Confidence: 0.906489560909091

00:14:27.518 --> 00:14:29.627 this was individuals were getting care.

NOTE Confidence: 0.906489560909091

00:14:29.630 --> 00:14:31.406 Their pharmacies met their

NOTE Confidence: 0.906489560909091

00:14:31.406 --> 00:14:33.626 medications through CVS or Walgreens.

NOTE Confidence: 0.906489560909091

00:14:33.630 --> 00:14:35.290 They also use a mark.

NOTE Confidence: 0.906489560909091

00:14:35.290 --> 00:14:37.446 My chart based system that allows this.

NOTE Confidence: 0.906489560909091

00:14:37.450 --> 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 --> 00:14:45.104 We also then used Hugo to send out surveys.

NOTE Confidence: 0.906489560909091

00:14:45.110 --> 00:14:47.190 Patient reported outcome measures.

NOTE Confidence: 0.906489560909091

00:14:47.190 --> 00:14:49.790 Both short questions post procedure

NOTE Confidence: 0.906489560909091

00:14:49.790 --> 00:14:52.354 along with longer questions at 148

NOTE Confidence: 0.906489560909091

00:14:52.354 --> 00:14:54.298 weeks and patients get a link.

NOTE Confidence: 0.906489560909091

00:14:54.300 --> 00:14:55.800 Right to their phone they they.

NOTE Confidence: 0.906489560909091

00:14:55.800 --> 00:14:56.748 They signify their preference.

NOTE Confidence: 0.906489560909091

00:14:56.748 --> 00:14:58.170 If they want a text message

NOTE Confidence: 0.91233572

00:14:58.212 --> 00:15:00.062 or email, they click the link and they

NOTE Confidence: 0.91233572

00:15:00.062 --> 00:15:02.138 fill it all out right on their phone

NOTE Confidence: 0.91233572

00:15:02.138 --> 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 --> 00:15:08.260 you know a structured questionnaire with

NOTE Confidence: 0.91233572

00:15:08.260 --> 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 --> 00:15:14.110 fill it out and that allows

NOTE Confidence: 0.91233572

00:15:14.110 --> 00:15:16.050 you to ask more questions.

NOTE Confidence: 0.91233572

00:15:16.050 --> 00:15:18.122 And then we also gave every patient

NOTE Confidence: 0.91233572

00:15:18.122 --> 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 --> 00:15:24.224 activity and patients who underwent

NOTE Confidence: 0.91233572

00:15:24.224 --> 00:15:26.210 bariatric surgery got a Withings scale.

NOTE Confidence: 0.91233572

00:15:26.210 --> 00:15:27.894 Digital scale and people.

NOTE Confidence: 0.91233572

00:15:27.894 --> 00:15:29.834 Patients who underwent the 8th

NOTE Confidence: 0.91233572

00:15:29.834 --> 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 --> 00:15:37.943 And this is just some quick results

NOTE Confidence: 0.91233572

00:15:37.943 --> 00:15:39.740 to show you kind of what we could do.

NOTE Confidence: 0.91233572

00:15:39.740 --> 00:15:42.232 Again, this was really just figuring out

NOTE Confidence: 0.91233572

00:15:42.232 --> 00:15:44.638 the feasibility of doing work like this,

NOTE Confidence: 0.91233572

00:15:44.640 --> 00:15:46.611 but we were able to link health records for

NOTE Confidence: 0.91233572

00:15:46.611 --> 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 --> 00:15:53.407 care that was based at Yale or Mayo,

NOTE Confidence: 0.91233572

00:15:53.410 --> 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 --> 00:16:03.426 additional 13 portals and then we had

NOTE Confidence: 0.91233572

00:16:03.426 --> 00:16:06.054 40% of patients who are getting their

NOTE Confidence: 0.91233572

00:16:06.054 --> 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 --> 00:16:14.387 function that allows you to pull in

NOTE Confidence: 0.91233572

00:16:14.387 --> 00:16:16.223 information like medication names,

NOTE Confidence: 0.91233572

00:16:16.230 --> 00:16:16.642 dosages,

NOTE Confidence: 0.91233572

00:16:16.642 --> 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 --> 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 --> 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 --> 00:16:32.149 worked at the time when we did the study,

NOTE Confidence: 0.91233572

00:16:32.150 --> 00:16:35.727 people had to actually sync their Fitbits.

NOTE Confidence: 0.91233572

00:16:35.730 --> 00:16:36.942 Now that happens automatically,

NOTE Confidence: 0.91233572

00:16:36.942 --> 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 --> 00:16:45.324 well more than half of patients syncing

NOTE Confidence: 0.91233572

00:16:45.324 --> 00:16:47.568 their Fitbits their their cardio mobile

NOTE Confidence: 0.91233572

00:16:47.568 --> 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 --> 00:16:53.742 Scraf,

NOTE Confidence: 0.91233572

00:16:53.742 --> 00:16:56.154 the sort of trajectories of recovery.

NOTE Confidence: 0.91233572

00:16:56.160 --> 00:16:58.077 So on the top you can see kind of

NOTE Confidence: 0.91233572

00:16:58.077 --> 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 --> 00:17:04.139 kind of visually demonstrating the

NOTE Confidence: 0.91233572

00:17:04.139 --> 00:17:05.940 how patients recovered over time.

NOTE Confidence: 0.91233572

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 --> 00:17:12.797 underwent a fibrillation on the right.

NOTE Confidence: 0.91233572

00:17:12.797 --> 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 --> 00:17:19.397 on the lower right is the patient.

NOTE Confidence: 0.91233572

00:17:19.400 --> 00:17:20.840 The average heart rate and again,

NOTE Confidence: 0.91233572

00:17:20.840 --> 00:17:22.358 this is more just to determine,

NOTE Confidence: 0.91233572

00:17:22.360 --> 00:17:23.828 you know, the accuracy.

NOTE Confidence: 0.91233572

00:17:23.828 --> 00:17:26.030 That the integrity of the data

NOTE Confidence: 0.91233572

00:17:26.107 --> 00:17:28.191 that was being aggregated here.

NOTE Confidence: 0.91233572

00:17:28.191 --> 00:17:30.858 Our response rate to the patient reported

NOTE Confidence: 0.91233572

00:17:30.858 --> 00:17:32.988 outcome measures consistently above 80%

NOTE Confidence: 0.91233572

00:17:32.990 --> 00:17:36.030 for all the patients for all the surveys,

NOTE Confidence: 0.91233572

00:17:36.030 --> 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 --> 00:17:44.365 we're over time graphing estimates of pain,

NOTE Confidence: 0.91233572

00:17:44.370 --> 00:17:46.110 appetite and palpitations

NOTE Confidence: 0.91233572

00:17:46.110 --> 00:17:49.010 in the two patient groups,

NOTE Confidence: 0.803564338888889

00:17:49.010 --> 00:17:51.560 but this is really just more

NOTE Confidence: 0.803564338888889

00:17:51.560 --> 00:17:52.835 for illustrative purposes.

NOTE Confidence: 0.803564338888889

00:17:52.840 --> 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 --> 00:17:57.370 and I'm really excited.

NOTE Confidence: 0.803564338888889

00:17:57.370 --> 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 --> 00:18:03.580 potential collaborations,

NOTE Confidence: 0.803564338888889

00:18:03.580 --> 00:18:06.012 but this is the biggest of the

NOTE Confidence: 0.803564338888889

00:18:06.012 --> 00:18:07.800 studies that we're working on now.

NOTE Confidence: 0.803564338888889

00:18:07.800 --> 00:18:09.320 Also funded through the Searcy,

NOTE Confidence: 0.803564338888889

00:18:09.320 --> 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 --> 00:18:21.300 acute pain recruiting from sites

NOTE Confidence: 0.803564338888889

00:18:21.300 --> 00:18:22.860 across the United States and Yale

NOTE Confidence: 0.803564338888889

00:18:22.860 --> 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 --> 00:18:29.190 dental practices that run up the

NOTE Confidence: 0.803564338888889

00:18:29.190 --> 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 --> 00:18:34.280 which is basically South Dakota

NOTE Confidence: 0.803564338888889

00:18:34.280 --> 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 --> 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 --> 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 --> 00:18:45.995 We started recruitment in about

NOTE Confidence: 0.803564338888889

00:18:45.995 --> 00:18:46.964 in September 2020.

NOTE Confidence: 0.803564338888889

00:18:46.970 --> 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 --> 00:18:51.675 Even with all the challenges from COVID.

NOTE Confidence: 0.803564338888889

00:18:51.680 --> 00:18:53.220 Our primary endpoint is the

NOTE Confidence: 0.803564338888889

00:18:53.220 --> 00:18:54.452 number of days using.

NOTE Confidence: 0.803564338888889

00:18:54.460 --> 00:18:55.560 Opioids and we're following

NOTE Confidence: 0.803564338888889

00:18:55.560 --> 00:18:56.935 up patients over six months,

NOTE Confidence: 0.803564338888889

00:18:56.940 --> 00:18:58.155 including additional measures

NOTE Confidence: 0.803564338888889

00:18:58.155 --> 00:19:00.180 for patient or outcome measures,

NOTE Confidence: 0.803564338888889

00:19:00.180 --> 00:19:01.740 from pain and anxiety.

NOTE Confidence: 0.803564338888889

00:19:01.740 --> 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 --> 00:19:08.984 and just to give you a sense of

NOTE Confidence: 0.803564338888889

00:19:08.984 --> 00:19:10.842 the kind of data that this allows

NOTE Confidence: 0.803564338888889

00:19:10.842 --> 00:19:12.222 us to aggregate on patients.

NOTE Confidence: 0.803564338888889

00:19:12.230 --> 00:19:13.940 This is mean daily pain,

NOTE Confidence: 0.803564338888889

00:19:13.940 --> 00:19:15.544 reportings among those reporting

NOTE Confidence: 0.803564338888889

00:19:15.544 --> 00:19:17.148 they are in pain,

NOTE Confidence: 0.803564338888889

00:19:17.150 --> 00:19:19.622 and you can just see how

NOTE Confidence: 0.803564338888889

00:19:19.622 --> 00:19:20.858 pain essentially persists.

NOTE Confidence: 0.803564338888889

00:19:20.860 --> 00:19:22.840 This is over 180 days.

NOTE Confidence: 0.803564338888889

00:19:22.840 --> 00:19:24.828 The average pain dots are in blue.

NOTE Confidence: 0.803564338888889

00:19:24.830 --> 00:19:26.680 Worst pain or in red?

NOTE Confidence: 0.803564338888889

00:19:26.680 --> 00:19:28.205 Here's the median days elapsed

NOTE Confidence: 0.803564338888889

00:19:28.205 --> 00:19:30.481 to 1st report of no pain among

NOTE Confidence: 0.803564338888889

00:19:30.481 --> 00:19:32.191 patients with pain fully resolved

NOTE Confidence: 0.803564338888889

00:19:32.191 --> 00:19:34.820 and you can see the difference in

NOTE Confidence: 0.803564338888889

00:19:34.820 --> 00:19:36.745 pain experienced by patients in

NOTE Confidence: 0.803564338888889

00:19:36.745 --> 00:19:38.324 different settings with patients

NOTE Confidence: 0.803564338888889

00:19:38.324 --> 00:19:40.712 who are recruited either from the

NOTE Confidence: 0.803564338888889

00:19:40.712 --> 00:19:42.552 inpatient setting or a primary

NOTE Confidence: 0.803564338888889

00:19:42.552 --> 00:19:44.272 care having longer median days

NOTE Confidence: 0.803564338888889

00:19:44.272 --> 00:19:46.365 until the first report of no pain.

NOTE Confidence: 0.803564338888889

00:19:46.370 --> 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 --> 00:19:52.250 durations and then this shows

NOTE Confidence: 0.803564338888889

00:19:52.250 --> 00:19:53.870 you the mean daily pain ratings

NOTE Confidence: 0.803564338888889

00:19:53.931 --> 00:19:54.939 among those taking.

NOTE Confidence: 0.803564338888889

00:19:54.940 --> 00:19:56.065 A treatment for pain and

NOTE Confidence: 0.803564338888889

00:19:56.065 --> 00:19:57.190 this could be any treatment.

NOTE Confidence: 0.803564338888889

00:19:57.190 --> 00:19:59.215 It could be tylanol it could be an opioid,

NOTE Confidence: 0.803564338888889

00:19:59.220 --> 00:20:00.112 it could be anything,

NOTE Confidence: 0.803564338888889

00:20:00.112 --> 00:20:01.986 but you can see here the blue dots

NOTE Confidence: 0.803564338888889

00:20:01.986 --> 00:20:03.438 are patients who are not using

NOTE Confidence: 0.803564338888889

00:20:03.438 --> 00:20:05.026 an opioid for treatment and the

NOTE Confidence: 0.803564338888889

00:20:05.026 --> 00:20:06.598 yellow dots are patients who are

NOTE Confidence: 0.803564338888889

00:20:06.600 --> 00:20:08.448 using an opioid for treatment and

NOTE Confidence: 0.803564338888889

00:20:08.448 --> 00:20:11.056 you can see how the on average the

NOTE Confidence: 0.803564338888889

00:20:11.056 --> 00:20:13.018 patients who are taking an opioid

NOTE Confidence: 0.803564338888889

00:20:13.085 --> 00:20:15.095 are having higher rates of pain.

NOTE Confidence: 0.803564338888889

00:20:15.100 --> 00:20:17.536 All of this is being done in

NOTE Confidence: 0.803564338888889

00:20:17.536 --> 00:20:19.341 collaboration with the FDA as

NOTE Confidence: 0.803564338888889

00:20:19.341 --> 00:20:21.393 part of their efforts to better

NOTE Confidence: 0.803564338888889

00:20:21.393 --> 00:20:23.553 address and understand the risks

NOTE Confidence: 0.803564338888889

00:20:23.553 --> 00:20:25.429 associated with opioid use.

NOTE Confidence: 0.803564338888889

00:20:25.430 --> 00:20:26.822 Couple of other things,

NOTE Confidence: 0.803564338888889

00:20:26.822 --> 00:20:29.145 just to mention briefly one is these

NOTE Confidence: 0.803564338888889

00:20:29.145 --> 00:20:30.790 are projects that are funded by Nest.

NOTE Confidence: 0.803564338888889

00:20:30.790 --> 00:20:33.319 This is what we call the sleep I study.

NOTE Confidence: 0.803564338888889

00:20:33.320 --> 00:20:35.558 It's a prospective RCT of 100

NOTE Confidence: 0.803564338888889

00:20:35.558 --> 00:20:37.050 patients with depression receiving

NOTE Confidence: 0.871263695714286

00:20:37.108 --> 00:20:39.088 outpatient treatment for insomnia,

NOTE Confidence: 0.871263695714286

00:20:39.090 --> 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 --> 00:20:45.809 cognitive behavioral therapy for insomnia,

NOTE Confidence: 0.871263695714286

00:20:45.810 --> 00:20:47.100 following patient treating

NOTE Confidence: 0.871263695714286

00:20:47.100 --> 00:20:48.820 patients over 9 weeks.

NOTE Confidence: 0.871263695714286

00:20:48.820 --> 00:20:50.584 With the primary endpoint of insomnia

NOTE Confidence: 0.871263695714286

00:20:50.584 --> 00:20:52.475 severity index and we're following them up

NOTE Confidence: 0.871263695714286

00:20:52.475 --> 00:20:54.560 over a year and again just to emphasize.

NOTE Confidence: 0.871263695714286

00:20:54.560 --> 00:20:56.720 All of this is done using the Hugo platform,

NOTE Confidence: 0.871263695714286

00:20:56.720 --> 00:20:58.958 so we enroll patients at baseline.

NOTE Confidence: 0.871263695714286

00:20:58.960 --> 00:21:01.300 They're randomized to one treatment or

NOTE Confidence: 0.871263695714286

00:21:01.300 --> 00:21:03.846 another they undergo, you know, they they.

NOTE Confidence: 0.871263695714286

00:21:03.846 --> 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 --> 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 --> 00:21:15.275 and other information

NOTE Confidence: 0.871263695714286

00:21:15.275 --> 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 --> 00:21:19.454 a pragmatic RCT that's leveraging.

NOTE Confidence: 0.871263695714286

00:21:19.460 --> 00:21:22.076 Real world data for all of our endpoints,

NOTE Confidence: 0.871263695714286

00:21:22.080 --> 00:21:23.060 we're doing another study that

NOTE Confidence: 0.871263695714286

00:21:23.060 --> 00:21:24.300 we call the Heart Watch study,

NOTE Confidence: 0.871263695714286

00:21:24.300 --> 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 --> 00:21:33.440 undergoing cardioversion for AFIB.

NOTE Confidence: 0.871263695714286

00:21:33.440 --> 00:21:35.512 They either get an Apple Watch or they

NOTE Confidence: 0.871263695714286

00:21:35.512 --> 00:21:38.216 get a Withings watch without any activity.

NOTE Confidence: 0.871263695714286

00:21:38.220 --> 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 --> 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 --> 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 --> 00:21:54.093 effect Global Score questionnaire is

NOTE Confidence: 0.871263695714286

00:21:54.093 --> 00:21:56.417 essentially at A-fib quality of life prom,

NOTE Confidence: 0.871263695714286

00:21:56.420 --> 00:21:56.894 and again,

NOTE Confidence: 0.871263695714286

00:21:56.894 --> 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 --> 00:22:02.390 Other measures of health care utilization,

NOTE Confidence: 0.871263695714286

00:22:02.390 --> 00:22:04.900 as well as cagey accuracy.

NOTE Confidence: 0.871263695714286

00:22:04.900 --> 00:22:05.602 And then last,

NOTE Confidence: 0.871263695714286

00:22:05.602 --> 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 --> 00:22:12.379 associated with copper,

NOTE Confidence: 0.871263695714286

00:22:12.380 --> 00:22:14.068 the cancer outcomes public

NOTE Confidence: 0.871263695714286

00:22:14.068 --> 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 --> 00:22:24.310 function in cancer patients undergoing

NOTE Confidence: 0.871263695714286

00:22:24.369 --> 00:22:26.169 chemotherapy using a clinician,

NOTE Confidence: 0.871263695714286

00:22:26.170 --> 00:22:27.658 reported patient reported and

NOTE Confidence: 0.871263695714286

00:22:27.658 --> 00:22:29.146 wearable device data sources.

NOTE Confidence: 0.871263695714286

00:22:29.150 --> 00:22:31.606 This is done being done through our Searcy.

NOTE Confidence: 0.871263695714286

00:22:31.610 --> 00:22:33.106 The FDA funded center.

NOTE Confidence: 0.871263695714286

00:22:33.106 --> 00:22:35.350 We're doing it directly with collaborators

NOTE Confidence: 0.871263695714286

00:22:35.416 --> 00:22:37.546 at the oncology Center of Excellence,

NOTE Confidence: 0.871263695714286

00:22:37.550 --> 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 --> 00:22:45.505 Rolling patients at Yale and Mayo Clinic,

NOTE Confidence: 0.871263695714286

00:22:45.510 --> 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 --> 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 --> 00:22:54.755 patients and our primary endpoint is

NOTE Confidence: 0.871263695714286

00:22:54.755 --> 00:22:56.470 physical function over nine months

NOTE Confidence: 0.871263695714286

00:22:56.534 --> 00:22:58.298 that's being measured weekly for

NOTE Confidence: 0.871263695714286

00:22:58.298 --> 00:23:00.494 two months and then monthly again,

NOTE Confidence: 0.871263695714286

00:23:00.500 --> 00:23:03.220 all leveraging the Hugo platform

NOTE Confidence: 0.871263695714286

00:23:03.220 --> 00:23:05.396 for measurements with patient

NOTE Confidence: 0.871263695714286

00:23:05.396 --> 00:23:07.319 reported outcome measures.

NOTE Confidence: 0.871263695714286

00:23:07.320 --> 00:23:08.824 Clinician reported outcome measures

NOTE Confidence: 0.871263695714286

00:23:08.824 --> 00:23:11.080 to the E COG performance measurement.

NOTE Confidence: 0.871263695714286

00:23:11.080 --> 00:23:13.061 The six minute walk test at baseline

NOTE Confidence: 0.871263695714286

00:23:13.061 --> 00:23:15.320 and at the at the end of two

NOTE Confidence: 0.871263695714286

00:23:15.320 --> 00:23:16.920 months and then again later on,

NOTE Confidence: 0.871263695714286

00:23:16.920 --> 00:23:18.775 as well as activity measured

NOTE Confidence: 0.871263695714286

00:23:18.775 --> 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 --> 00:23:24.952 steps and again part of the purpose

NOTE Confidence: 0.871263695714286

00:23:24.952 --> 00:23:27.910 of this is to work with the FDA to to

NOTE Confidence: 0.871263695714286

00:23:27.910 --> 00:23:29.592 better understand a physical function

NOTE Confidence: 0.871263695714286

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

NOTE Confidence: 0.871263695714286

00:23:31.850 --> 00:23:33.970 Compare these data sources identifying

NOTE Confidence: 0.871263695714286

00:23:33.970 --> 00:23:35.666 change thresholds and inform

NOTE Confidence: 0.871263695714286

00:23:35.666 --> 00:23:37.650 the way the FDA thinks about.

NOTE Confidence: 0.8087537375

00:23:37.650 --> 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 --> 00:23:44.015 so I will stop there and I hope that if

NOTE Confidence: 0.8087537375

00:23:44.015 --> 00:23:46.029 anyone has questions you can follow up.

NOTE Confidence: 0.8087537375

00:23:46.030 --> 00:23:49.510 But thanks for the time, show me.

NOTE Confidence: 0.8087537375

00:23:49.510 --> 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 --> 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 --> 00:24:10.380 do we ask people to raise hands?

NOTE Confidence: 0.80891063125

00:24:15.560 --> 00:24:18.456 I'm not sure how this is really handled.

NOTE Confidence: 0.80891063125

00:24:18.460 --> 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 --> 00:24:30.120 waiting for others to pitch in.

NOTE Confidence: 0.750768902857143

00:24:30.120 --> 00:24:32.610 I wonder when you submit

NOTE Confidence: 0.750768902857143

00:24:32.610 --> 00:24:34.104 work for publication.

NOTE Confidence: 0.750768902857143

00:24:34.110 --> 00:24:36.102 Is it subject to more scrutiny

NOTE Confidence: 0.750768902857143

00:24:36.102 --> 00:24:37.892 because it's not the traditional

NOTE Confidence: 0.750768902857143

00:24:37.892 --> 00:24:40.238 trial that people are used to?

NOTE Confidence: 0.909681722857143

00:24:43.020 --> 00:24:45.064 Yes, there's a lot of explaining going

NOTE Confidence: 0.909681722857143

00:24:45.064 --> 00:24:47.707 on when we you know when we're putting

NOTE Confidence: 0.909681722857143

00:24:47.707 --> 00:24:50.174 these papers together and and even just

NOTE Confidence: 0.909681722857143

00:24:50.174 --> 00:24:52.280 proposing them for funding right now,

NOTE Confidence: 0.909681722857143

00:24:52.280 --> 00:24:53.996 as people kind of question like,

NOTE Confidence: 0.909681722857143

00:24:54.000 --> 00:24:55.250 well, how is this done?

NOTE Confidence: 0.909681722857143

00:24:55.250 --> 00:24:56.120 I don't get it. You know,

NOTE Confidence: 0.909681722857143

00:24:56.120 --> 00:24:58.376 how are you pulling in these data sources?

NOTE Confidence: 0.909681722857143

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

NOTE Confidence: 0.909681722857143

00:25:01.228 --> 00:25:03.119 clinical trialists and explain the

NOTE Confidence: 0.909681722857143

00:25:03.119 --> 00:25:05.393 difference in the approach and the

NOTE Confidence: 0.909681722857143

00:25:05.393 --> 00:25:07.558 efficiency that comes with it and the

NOTE Confidence: 0.909681722857143

00:25:07.558 --> 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 --> 00:25:13.236 but the you know how much more information.

NOTE Confidence: 0.909681722857143

00:25:13.240 --> 00:25:15.490 You can aggregate passively and not

NOTE Confidence: 0.909681722857143

00:25:15.490 --> 00:25:17.360 requiring patients to come back,

NOTE Confidence: 0.909681722857143

00:25:17.360 --> 00:25:19.625 minimizing the burden on patients

NOTE Confidence: 0.909681722857143

00:25:19.625 --> 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 --> 00:25:24.164 There's a there's there's,

NOTE Confidence: 0.909681722857143

00:25:24.164 --> 00:25:25.319 there's great promise to this,

NOTE Confidence: 0.909681722857143

00:25:25.320 --> 00:25:27.196 and it's not to say that that

NOTE Confidence: 0.909681722857143

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

NOTE Confidence: 0.909681722857143

00:25:28.260 --> 00:25:30.445 but I feel like we're kind of pilot

NOTE Confidence: 0.909681722857143

00:25:30.445 --> 00:25:33.525 testing new ways to do trials like this,

NOTE Confidence: 0.909681722857143

00:25:33.530 --> 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 --> 00:25:37.360 be useful and informative and and

NOTE Confidence: 0.909681722857143

00:25:37.360 --> 00:25:38.905 and set the stage for the future

NOTE Confidence: 0.909681722857143

00:25:38.905 --> 00:25:40.399 so it doesn't need to be kind

NOTE Confidence: 0.909681722857143

00:25:40.399 --> 00:25:41.617 of an all or nothing either.

NOTE Confidence: 0.909681722857143

00:25:41.620 --> 00:25:43.780 Do a kind of a traditional clinical trial.

NOTE Confidence: 0.909681722857143

00:25:43.780 --> 00:25:45.058 Bringing patient back every couple of

NOTE Confidence: 0.909681722857143

00:25:45.058 --> 00:25:46.880 weeks for kind of standardized assessment,

NOTE Confidence: 0.909681722857143

00:25:46.880 --> 00:25:48.464 or we're doing observation,

NOTE Confidence: 0.909681722857143

00:25:48.464 --> 00:25:50.840 ULL data source and data analysis.

NOTE Confidence: 0.909681722857143

00:25:50.840 --> 00:25:53.885 There's there's kind of a middle Rd.

NOTE Confidence: 0.909681722857143

00:25:53.890 --> 00:25:55.640 I do see there was one question

NOTE Confidence: 0.909681722857143

00:25:55.640 --> 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 --> 00:26:01.510 and that's an interesting challenge,

NOTE Confidence: 0.909681722857143

00:26:01.510 --> 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 --> 00:26:08.675 you know essentially prescription data

NOTE Confidence: 0.909681722857143

00:26:08.675 --> 00:26:11.590 in the electronic health record at Yale,

NOTE Confidence: 0.909681722857143

00:26:11.590 --> 00:26:13.654 but not in the pharmacy data

NOTE Confidence: 0.909681722857143

00:26:13.654 --> 00:26:15.450 and how to understand that.

NOTE Confidence: 0.909681722857143

00:26:15.450 --> 00:26:17.298 And some of it is about understanding

NOTE Confidence: 0.909681722857143

00:26:17.298 --> 00:26:18.365 the various functions that

NOTE Confidence: 0.909681722857143

00:26:18.365 --> 00:26:19.709 are used for the data sources.

NOTE Confidence: 0.909681722857143

00:26:19.710 --> 00:26:20.040 Right?

NOTE Confidence: 0.909681722857143

00:26:20.040 --> 00:26:21.690 Prescription is ordered by a

NOTE Confidence: 0.909681722857143

00:26:21.690 --> 00:26:23.608 physician at Yale and it's filled

NOTE Confidence: 0.909681722857143

00:26:23.608 --> 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 --> 00:26:28.203 adherence,

NOTE Confidence: 0.909681722857143

00:26:28.203 --> 00:26:30.141 like our patients going and filling

NOTE Confidence: 0.909681722857143

00:26:30.141 --> 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 --> 00:26:36.405 particularly for the the physical

NOTE Confidence: 0.909681722857143

00:26:36.405 --> 00:26:38.122 function we're going to have to

NOTE Confidence: 0.909681722857143

00:26:38.122 --> 00:26:39.562 decide exactly what does it mean.

NOTE Confidence: 0.909681722857143

00:26:39.570 --> 00:26:41.560 If if different you know,

NOTE Confidence: 0.909681722857143

00:26:41.560 --> 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 --> 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 --> 00:26:57.290 around thinking about ways to

NOTE Confidence: 0.8007884375

00:26:57.290 --> 00:26:59.474 adapt the EHR and its interface

NOTE Confidence: 0.8007884375

00:26:59.474 --> 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 --> 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 --> 00:27:09.290 Some of the challenges and part of the

NOTE Confidence: 0.8007884375

00:27:09.290 --> 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 --> 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 --> 00:27:20.272 available to investigators who are

NOTE Confidence: 0.8007884375

00:27:20.332 --> 00:27:22.247 leveraging health system data for.

NOTE Confidence: 0.8007884375

00:27:22.250 --> 00:27:23.750 For research or for you know,

NOTE Confidence: 0.8007884375

00:27:23.750 --> 00:27:25.118 to inform clinical practice.

NOTE Confidence: 0.8007884375

00:27:25.118 --> 00:27:27.170 The more structured data we think

NOTE Confidence: 0.8007884375

00:27:27.234 --> 00:27:29.088 about embedding within our reach are

NOTE Confidence: 0.8007884375

00:27:29.088 --> 00:27:31.269 the better the data are going to be,

NOTE Confidence: 0.8007884375

00:27:31.270 --> 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 --> 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 --> 00:27:43.009 presented that project done by the

NOTE Confidence: 0.8007884375

00:27:43.009 --> 00:27:45.091 medical student who identify that only

NOTE Confidence: 0.8007884375

00:27:45.151 --> 00:27:46.810 15% of clinical trials could actually

NOTE Confidence: 0.8007884375

00:27:46.810 --> 00:27:49.234 be routinely or fees abli done today

NOTE Confidence: 0.8007884375

00:27:49.234 --> 00:27:51.010 using routinely ascertainable information.

NOTE Confidence: 0.8007884375

00:27:51.010 --> 00:27:53.400 Part of it is because.

NOTE Confidence: 0.8007884375

00:27:53.400 --> 00:27:55.060 Like patient reported outcome measures

NOTE Confidence: 0.8007884375

00:27:55.060 --> 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 --> 00:27:59.880 so there's a real opportunity there.

NOTE Confidence: 0.876349984705882

00:28:09.950 --> 00:28:12.050 And then I'll the last question

NOTE Confidence: 0.876349984705882

00:28:12.050 --> 00:28:14.461 I see is about addressing self

NOTE Confidence: 0.876349984705882

00:28:14.461 --> 00:28:16.796 selection bias in our data.

NOTE Confidence: 0.876349984705882

00:28:16.800 --> 00:28:19.250 I think what Doctor Hooley is referring

NOTE Confidence: 0.876349984705882

00:28:19.250 --> 00:28:22.254 to is the participation bias that

NOTE Confidence: 0.876349984705882

00:28:22.254 --> 00:28:24.415 individuals are going to be more

NOTE Confidence: 0.876349984705882

00:28:24.415 --> 00:28:26.390 likely to participate in the study.

NOTE Confidence: 0.876349984705882

00:28:26.390 --> 00:28:29.015 And that raises an issue of bias.

NOTE Confidence: 0.876349984705882

00:28:29.020 --> 00:28:31.426 I don't think that the selection into

NOTE Confidence: 0.876349984705882

00:28:31.426 --> 00:28:33.544 our studies is different any different

NOTE Confidence: 0.876349984705882

00:28:33.544 --> 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 --> 00:28:40.768 but hopefully ideally by lowering the

NOTE Confidence: 0.876349984705882

00:28:40.768 --> 00:28:43.679 barriers to participation and and making

NOTE Confidence: 0.876349984705882

00:28:43.679 --> 00:28:46.626 it easier on patients to participate by.

NOTE Confidence: 0.876349984705882

00:28:46.630 --> 00:28:48.622 By diminishing that burden of kind

NOTE Confidence: 0.876349984705882

00:28:48.622 --> 00:28:50.720 of haven't come in our trials.

NOTE Confidence: 0.876349984705882

00:28:50.720 --> 00:28:53.800 Using this this type of approach may be

NOTE Confidence: 0.876349984705882

00:28:53.875 --> 00:28:56.970 more representative of clinical practice,

NOTE Confidence: 0.876349984705882

00:28:56.970 --> 00:28:58.776 although that's that remains to be seen,

NOTE Confidence: 0.876349984705882

00:28:58.780 --> 00:29:00.565 and it's an important issue

NOTE Confidence: 0.876349984705882

00:29:00.565 --> 00:29:02.350 for us to address so.

NOTE Confidence: 0.876349984705882

00:29:02.350 --> 00:29:03.610 I'll stop there so that Susan

NOTE Confidence: 0.876349984705882

00:29:03.610 --> 00:29:05.026 Bush has plenty of time to

NOTE Confidence: 0.876349984705882

00:29:05.026 --> 00:29:06.078 go through her presentation.

NOTE Confidence: 0.892838413333333

00:29:07.510 --> 00:29:08.578 Thank you Joe.

NOTE Confidence: 0.937441766666667

00:29:11.400 --> 00:29:13.451 It is my pleasure to introduce our

NOTE Confidence: 0.937441766666667

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

NOTE Confidence: 0.937441766666667

00:29:15.213 --> 00:29:17.950 who is Professor Public House in House

NOTE Confidence: 0.937441766666667

00:29:18.027 --> 00:29:20.600 Policy and professor in the Institution

NOTE Confidence: 0.937441766666667

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

NOTE Confidence: 0.937441766666667

00:29:22.760 --> 00:29:24.902 She received a master degree in House

NOTE Confidence: 0.937441766666667

00:29:24.902 --> 00:29:27.319 policy in a PhD in House Economics.

NOTE Confidence: 0.937441766666667

00:29:27.320 --> 00:29:28.884 Those from Harvard University.

NOTE Confidence: 0.937441766666667

00:29:28.884 --> 00:29:31.669 A number of us have been lobbying

NOTE Confidence: 0.937441766666667

00:29:31.669 --> 00:29:34.210 for her to join the Cancer Center

NOTE Confidence: 0.937441766666667

00:29:34.210 --> 00:29:36.997 and very happy when she did recently.

NOTE Confidence: 0.937441766666667

00:29:37.000 --> 00:29:39.640 Doctor Bush's research examines the effects

NOTE Confidence: 0.937441766666667

00:29:39.640 --> 00:29:42.399 of policies and regulations on health care,

NOTE Confidence: 0.937441766666667

00:29:42.400 --> 00:29:43.948 cost and quality,

NOTE Confidence: 0.937441766666667

00:29:43.948 --> 00:29:47.044 and she's a renowned and highly

NOTE Confidence: 0.937441766666667

00:29:47.044 --> 00:29:49.796 respected expert in this field today.

NOTE Confidence: 0.937441766666667

00:29:49.796 --> 00:29:51.776 Her topic is insurance coverage,

NOTE Confidence: 0.937441766666667

00:29:51.780 --> 00:29:53.895 mandates and the adoption of

NOTE Confidence: 0.937441766666667

00:29:53.895 --> 00:29:55.587 digital breast Tomo synthesis.

NOTE Confidence: 0.441354562

00:29:57.790 --> 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 --> 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 --> 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 --> 00:30:21.152 I'm a health service researcher and

NOTE Confidence: 0.79118421125

00:30:21.152 --> 00:30:22.636 health economist, and I teach at

NOTE Confidence: 0.79118421125

00:30:22.636 --> 00:30:23.920 the Yale School of Public Health.

NOTE Confidence: 0.79118421125

00:30:23.920 --> 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 --> 00:30:34.239 with a focus on access to care and how we

NOTE Confidence: 0.79118421125

00:30:34.239 --> 00:30:36.393 can optimize benefit design to increase

NOTE Confidence: 0.79118421125

00:30:36.400 --> 00:30:38.200 the value of the healthcare system.

NOTE Confidence: 0.79118421125

00:30:38.200 --> 00:30:40.873 So I sort of took my knowledge about those

NOTE Confidence: 0.79118421125

00:30:40.873 --> 00:30:43.538 issues and and now I'm applying it to cancer.

NOTE Confidence: 0.79118421125

00:30:43.540 --> 00:30:45.605 So generally I'm interested when you think

NOTE Confidence: 0.79118421125

00:30:45.605 --> 00:30:48.129 about is as we change payment mechanisms.

NOTE Confidence: 0.79118421125

00:30:48.130 --> 00:30:50.338 What are the impacts on access to care,

NOTE Confidence: 0.79118421125

00:30:50.340 --> 00:30:51.790 cost of care and value?

NOTE Confidence: 0.79118421125

00:30:51.790 --> 00:30:53.428 And it's always really tough to get at that.

NOTE Confidence: 0.79118421125

00:30:53.430 --> 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 --> 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 --> 00:31:01.790 projects related to that,

NOTE Confidence: 0.79118421125

00:31:01.790 --> 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 --> 00:31:08.412 to tobacco control that people that

NOTE Confidence: 0.79118421125

00:31:08.412 --> 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 --> 00:31:12.450 detail here about those,

NOTE Confidence: 0.79118421125

00:31:12.450 --> 00:31:15.114 but if you're interested I would love to

NOTE Confidence: 0.79118421125

00:31:15.114 --> 00:31:18.179 meet with you and talk about that about that.

NOTE Confidence: 0.79118421125

00:31:18.180 --> 00:31:21.176 So over the past several years wanna

NOTE Confidence: 0.79118421125

00:31:21.176 --> 00:31:24.359 say it's really been a delight to get

NOTE Confidence: 0.79118421125

00:31:24.359 --> 00:31:27.660 to know the faculty at the Cancer Center

NOTE Confidence: 0.79118421125

00:31:27.660 --> 00:31:29.956 both at the medical school and also

NOTE Confidence: 0.79118421125

00:31:29.960 --> 00:31:31.759 here at the School of Public Health?

NOTE Confidence: 0.79118421125

00:31:31.760 --> 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 --> 00:31:37.592 who invited me to work with his

NOTE Confidence: 0.79118421125

00:31:37.592 --> 00:31:40.694 team a couple of years ago and has

NOTE Confidence: 0.79118421125

00:31:40.694 --> 00:31:43.592 really taught me a lot about both

NOTE Confidence: 0.79118421125

00:31:43.592 --> 00:31:45.961 breast cancer screening and about

NOTE Confidence: 0.79118421125

00:31:45.961 --> 00:31:48.367 how to use health care claims.

NOTE Confidence: 0.79118421125

00:31:48.370 --> 00:31:50.162 Related to some of the issues that

NOTE Confidence: 0.79118421125

00:31:50.162 --> 00:31:52.098 we're going to talk about today and

NOTE Confidence: 0.79118421125

00:31:52.098 --> 00:31:54.510 also I want to give a big shout out.

NOTE Confidence: 0.79118421125

00:31:54.510 --> 00:31:57.163 I hope she's on the call to Alana

NOTE Confidence: 0.79118421125

00:31:57.163 --> 00:31:59.041 Richmond and this is very specifically

NOTE Confidence: 0.79118421125

00:31:59.041 --> 00:32:01.369 related to the work of presenting today.

NOTE Confidence: 0.79118421125

00:32:01.370 --> 00:32:03.365 Elan is an internal medicine and she

NOTE Confidence: 0.79118421125

00:32:03.365 --> 00:32:05.509 is the first author on this paper,

NOTE Confidence: 0.79118421125

00:32:05.510 --> 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 --> 00:32:11.325 the opportunity to work with her

NOTE Confidence: 0.79118421125

00:32:11.325 --> 00:32:13.380 over the past couple of years.

NOTE Confidence: 0.79118421125

00:32:13.380 --> 00:32:15.046 So the paper that I'm going to

NOTE Confidence: 0.79118421125

00:32:15.046 --> 00:32:16.516 talk about today is the latest

NOTE Confidence: 0.79118421125

00:32:16.516 --> 00:32:18.147 in a series of papers related to

NOTE Confidence: 0.79118421125

00:32:18.202 --> 00:32:20.140 breast cancer screening related to

NOTE Confidence: 0.79118421125

00:32:20.140 --> 00:32:21.680 issues around patient preferences,

NOTE Confidence: 0.79118421125

00:32:21.680 --> 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 --> 00:32:26.700 this paper is not really focused on value,

NOTE Confidence: 0.79118421125

00:32:26.700 --> 00:32:29.101 but also a lot of our papers

NOTE Confidence: 0.79118421125

00:32:29.101 --> 00:32:30.610 are focused on that.

NOTE Confidence: 0.79118421125

00:32:30.610 --> 00:32:32.680 So this paper has not yet it's been accepted

NOTE Confidence: 0.79118421125

00:32:32.680 --> 00:32:34.499 for publication at that not out yet,

NOTE Confidence: 0.79118421125

00:32:34.500 --> 00:32:36.404 but we're thinking it's going to be out

NOTE Confidence: 0.79118421125

00:32:36.404 --> 00:32:38.395 even in just the next couple of days,

NOTE Confidence: 0.79118421125

00:32:38.400 --> 00:32:38.790 so.

NOTE Confidence: 0.86517097

00:32:42.160 --> 00:32:44.659 OK, so these are some our collaborators,

NOTE Confidence: 0.86517097

00:32:44.660 --> 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,

NOTE Confidence: 0.86517097

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 --> 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 --> 00:33:05.180 cancer screening has undergone substantial

NOTE Confidence: 0.938326144285714

00:33:05.180 --> 00:33:08.067 technological shift in the US in

NOTE Confidence: 0.938326144285714

00:33:08.067 --> 00:33:10.029 which digital breast tone was insist.

NOTE Confidence: 0.938326144285714

00:33:10.030 --> 00:33:12.910 DBT has supplanted standard 2D2 dimensional

NOTE Confidence: 0.938326144285714

00:33:12.910 --> 00:33:16.567 Mogra fi alone as the standard of care.

NOTE Confidence: 0.938326144285714

00:33:16.570 --> 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 --> 00:33:23.826 That is that fewer women are called back

NOTE Confidence: 0.938326144285714

00:33:23.830 --> 00:33:26.170 for additional testing after screening,

NOTE Confidence: 0.938326144285714

00:33:26.170 --> 00:33:28.732 and also that it may improve sensitivity

NOTE Confidence: 0.938326144285714

00:33:28.732 --> 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 --> 00:33:36.664 Yet DBT is still not rated A

NOTE Confidence: 0.938326144285714

00:33:36.664 --> 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 --> 00:33:52.442 so just to get a sense of the

NOTE Confidence: 0.87287372

00:33:52.442 --> 00:33:55.350 variation in DBT adoption, this paper

NOTE Confidence: 0.87287372

00:33:55.350 --> 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 --> 00:34:02.408 see here are hospital referral regions,

NOTE Confidence: 0.87287372

00:34:02.410 --> 00:34:04.394 and we look at three years of data

NOTE Confidence: 0.87287372

00:34:04.394 --> 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 --> 00:34:15.278 whole USDBT increase from 13 to 43%.

NOTE Confidence: 0.87287372

00:34:15.278 --> 00:34:19.406 Of screenings, so this looks very

NOTE Confidence: 0.87287372

00:34:19.406 --> 00:34:21.470 specifically at trajectories,

NOTE Confidence: 0.87287372

00:34:21.470 --> 00:34:23.346 and we know by the end of 2017

NOTE Confidence: 0.87287372

00:34:23.346 --> 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 --> 00:34:34.031 the highest where it was at 68% of screening.

NOTE Confidence: 0.87287372

00:34:34.031 --> 00:34:36.780 So there really is significant variation.

NOTE Confidence: 0.920689943846154

00:34:46.260 --> 00:34:48.195 So related to insurance coverage

NOTE Confidence: 0.920689943846154

00:34:48.195 --> 00:34:50.130 really today we're talking about

NOTE Confidence: 0.920689943846154

00:34:50.192 --> 00:34:51.800 private insurance coverage.

NOTE Confidence: 0.920689943846154

00:34:51.800 --> 00:34:53.748 And private insurers are

NOTE Confidence: 0.920689943846154

00:34:53.748 --> 00:34:56.017 not required to cover DBT,

NOTE Confidence: 0.920689943846154

00:34:56.017 --> 00:34:58.236 and that's because it doesn't have the

NOTE Confidence: 0.920689943846154

00:34:58.236 --> 00:35:00.990 A or B recommendation by the USPSTF.

NOTE Confidence: 0.920689943846154

00:35:00.990 --> 00:35:02.460 So absent a federal mandate,

NOTE Confidence: 0.920689943846154

00:35:02.460 --> 00:35:04.450 many private insurers didn't immediately

NOTE Confidence: 0.920689943846154

00:35:04.450 --> 00:35:07.000 cover DBT characterizing it as elective,

NOTE Confidence: 0.920689943846154

00:35:07.000 --> 00:35:09.768 or citing that there might not be long

NOTE Confidence: 0.920689943846154

00:35:09.768 --> 00:35:12.269 term data and states got involved.

NOTE Confidence: 0.920689943846154

00:35:12.270 --> 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 --> 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 --> 00:35:22.260 private health insurance cover DBT.

NOTE Confidence: 0.920689943846154

00:35:22.260 --> 00:35:23.732 Without any cost sharing,

NOTE Confidence: 0.920689943846154

00:35:23.732 --> 00:35:26.698 so of course self insured plans are not

NOTE Confidence: 0.920689943846154

00:35:26.698 --> 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 --> 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

NOTE Confidence: 0.920689943846154

00:35:37.826 --> 00:35:40.410 when they receive DVT screening.

NOTE Confidence: 0.920689943846154

00:35:40.410 --> 00:35:44.397 So this figure just gives you a sense of

NOTE Confidence: 0.920689943846154

00:35:44.397 --> 00:35:48.370 the variation in timing of these laws,

NOTE Confidence: 0.920689943846154

00:35:48.370 --> 00:35:50.421 so we're going to study laws that

NOTE Confidence: 0.920689943846154

00:35:50.421 --> 00:35:52.756 occurred from 2016 to 2019, and you can.

NOTE Confidence: 0.920689943846154

00:35:52.760 --> 00:35:55.384 You can see it really is like a

NOTE Confidence: 0.920689943846154

00:35:55.384 --> 00:35:57.123 staggered implementation that's really

NOTE Confidence: 0.920689943846154

00:35:57.123 --> 00:35:59.155 important for identification strategy.

NOTE Confidence: 0.920689943846154

00:35:59.160 --> 00:36:01.195 Connecticut was the 3rd state

NOTE Confidence: 0.920689943846154

00:36:01.195 --> 00:36:03.250 to adopt in 2017.

NOTE Confidence: 0.883629511111111

00:36:11.930 --> 00:36:14.210 So insurance benefit mandates such as

NOTE Confidence: 0.883629511111111

00:36:14.210 --> 00:36:16.744 these have been widely used in other

NOTE Confidence: 0.883629511111111

00:36:16.744 --> 00:36:18.956 contexts as a policy tool to protect

NOTE Confidence: 0.883629511111111

00:36:19.028 --> 00:36:21.688 consumers against high out of pocket cost,

NOTE Confidence: 0.883629511111111

00:36:21.690 --> 00:36:23.695 so it reduces their financial

NOTE Confidence: 0.883629511111111

00:36:23.695 --> 00:36:25.700 burden and also to facilitate

NOTE Confidence: 0.883629511111111

00:36:25.771 --> 00:36:28.216 access to important health services.

NOTE Confidence: 0.883629511111111

00:36:28.220 --> 00:36:30.914 However, you know these types of

NOTE Confidence: 0.883629511111111

00:36:30.914 --> 00:36:33.226 benefit mandates have have been

NOTE Confidence: 0.883629511111111

00:36:33.226 --> 00:36:35.744 criticized by some because they

NOTE Confidence: 0.883629511111111

00:36:35.744 --> 00:36:38.754 may have some complex effects.

NOTE Confidence: 0.883629511111111

00:36:38.760 --> 00:36:41.450 Potentially, if you mandate may

NOTE Confidence: 0.883629511111111

00:36:41.450 --> 00:36:43.602 contribute to higher insurance

NOTE Confidence: 0.883629511111111

00:36:43.602 --> 00:36:45.960 premiums and thereby this may increase

NOTE Confidence: 0.883629511111111

00:36:45.960 --> 00:36:47.780 uninsurance rates as if insurance

NOTE Confidence: 0.883629511111111

00:36:47.841 --> 00:36:49.977 premiums get prohibitively expensive.

NOTE Confidence: 0.883629511111111

00:36:49.980 --> 00:36:52.010 There's been some criticism that

NOTE Confidence: 0.883629511111111

00:36:52.010 --> 00:36:54.040 they may reduce plan design,

NOTE Confidence: 0.883629511111111

00:36:54.040 --> 00:36:55.900 plan benefit, design, flexibility.

NOTE Confidence: 0.883629511111111

00:36:55.900 --> 00:36:59.148 And also that increasing the price of

NOTE Confidence: 0.883629511111111

00:36:59.148 --> 00:37:01.452 the specific of a specific mandated

NOTE Confidence: 0.883629511111111

00:37:01.452 --> 00:37:03.254 service may reduce negotiating power

NOTE Confidence: 0.883629511111111

00:37:03.254 --> 00:37:05.508 and this is going to be particularly

NOTE Confidence: 0.883629511111111

00:37:05.508 --> 00:37:08.248 problematic for a service or a drug,

NOTE Confidence: 0.883629511111111

00:37:08.250 --> 00:37:10.375 potentially where they have the

NOTE Confidence: 0.883629511111111

00:37:10.375 --> 00:37:12.500 supplier has some monopoly power.

NOTE Confidence: 0.895990606666667

00:37:14.830 --> 00:37:17.462 So our goal in this paper was

NOTE Confidence: 0.895990606666667

00:37:17.462 --> 00:37:19.336 to evaluate the relationship

NOTE Confidence: 0.895990606666667

00:37:19.336 --> 00:37:21.948 between DBT coverage laws.

NOTE Confidence: 0.895990606666667

00:37:21.950 --> 00:37:24.477 The 17 laws that I noted in

NOTE Confidence: 0.895990606666667

00:37:24.477 --> 00:37:26.598 the last slide and DBT use

NOTE Confidence: 0.895990606666667

00:37:26.600 --> 00:37:28.300 DBT out of pocket payments,

NOTE Confidence: 0.895990606666667

00:37:28.300 --> 00:37:30.188 and also DBT price.

NOTE Confidence: 0.884796792

00:37:34.310 --> 00:37:37.326 So to study this, we use data from

NOTE Confidence: 0.884796792

00:37:37.326 --> 00:37:40.509 Blue Cross Blue Shield access data set,

NOTE Confidence: 0.884796792

00:37:40.510 --> 00:37:43.162 which is a a deidentified database

NOTE Confidence: 0.884796792

00:37:43.162 --> 00:37:44.930 of health insurance claims.

NOTE Confidence: 0.884796792

00:37:44.930 --> 00:37:47.366 There are claims from all 50 states,

NOTE Confidence: 0.884796792

00:37:47.370 --> 00:37:50.009 so the geographic diversity of this sample,

NOTE Confidence: 0.884796792

00:37:50.010 --> 00:37:51.459 along with the fact that has a

NOTE Confidence: 0.884796792

00:37:51.459 --> 00:37:52.330 longitudinal structure so you

NOTE Confidence: 0.884796792

00:37:52.330 --> 00:37:53.375 can follow patients over time.

NOTE Confidence: 0.884796792

00:37:53.380 --> 00:37:56.264 It makes it really well suited to

NOTE Confidence: 0.884796792

00:37:56.264 --> 00:37:58.608 evaluate policies that vary by state.

NOTE Confidence: 0.884796792

00:37:58.610 --> 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 --> 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 --> 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 --> 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 --> 00:38:18.950 in this talk,

NOTE Confidence: 0.884796792

00:38:18.950 --> 00:38:21.150 so we did exclude women 65 and over,

NOTE Confidence: 0.884796792

00:38:21.150 --> 00:38:23.438 and the reason we did that is because

NOTE Confidence: 0.884796792

00:38:23.438 --> 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 --> 00:38:29.118 and we felt that.

NOTE Confidence: 0.884796792

00:38:29.118 --> 00:38:30.970 Older women that were then included in

NOTE Confidence: 0.884796792

00:38:30.970 --> 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 --> 00:38:37.249 to describe the characteristics

NOTE Confidence: 0.884796792

00:38:37.249 --> 00:38:38.959 of the women and mammograms,

NOTE Confidence: 0.884796792

00:38:38.960 --> 00:38:40.370 including the study.

NOTE Confidence: 0.884796792

00:38:40.370 --> 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 --> 00:38:45.856 we perform it at the state level.

NOTE Confidence: 0.884796792

00:38:45.860 --> 00:38:48.804 That is, we collapse cells to the state.

NOTE Confidence: 0.884796792

00:38:48.810 --> 00:38:51.000 We aggregated data to the state

NOTE Confidence: 0.884796792

00:38:51.000 --> 00:38:53.426 and six month period and use use

NOTE Confidence: 0.884796792

00:38:53.426 --> 00:38:55.036 the data in that way.

NOTE Confidence: 0.855158512666667

00:39:02.470 --> 00:39:04.030 So the exposure that we're interested

NOTE Confidence: 0.855158512666667

00:39:04.030 --> 00:39:05.709 in this study was a legislative

NOTE Confidence: 0.855158512666667

00:39:05.709 --> 00:39:07.174 mandate requiring a whether the

NOTE Confidence: 0.855158512666667

00:39:07.174 --> 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 --> 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 --> 00:39:18.948 states in this analysis.

NOTE Confidence: 0.855158512666667

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 --> 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 --> 00:39:28.209 the general coverage mandate.

NOTE Confidence: 0.855158512666667

00:39:28.210 --> 00:39:30.847 So in these laws when we say cost sharing,

NOTE Confidence: 0.855158512666667

00:39:30.850 --> 00:39:33.148 these are including out of pocket

NOTE Confidence: 0.855158512666667

00:39:33.148 --> 00:39:34.297 payments towards deductibles,

NOTE Confidence: 0.855158512666667

00:39:34.300 --> 00:39:36.156 coinsurance or coherence similar

NOTE Confidence: 0.855158512666667

00:39:36.156 --> 00:39:39.430 to what the ACA law would have is

NOTE Confidence: 0.855158512666667

00:39:39.430 --> 00:39:41.929 for services that are rated A or B.

NOTE Confidence: 0.855158512666667

00:39:41.930 --> 00:39:43.687 The control states were states that did

NOTE Confidence: 0.855158512666667

00:39:43.687 --> 00:39:46.097 not pass a mandate during the study period.

NOTE Confidence: 0.855158512666667

00:39:46.100 --> 00:39:47.285 And we assigned mammograms were

NOTE Confidence: 0.855158512666667

00:39:47.285 --> 00:39:48.769 assigned to a state based on

NOTE Confidence: 0.855158512666667

00:39:48.769 --> 00:39:50.019 location of the billing provider.

NOTE Confidence: 0.944120425

00:39:52.550 --> 00:39:53.946 So, as I noted,

NOTE Confidence: 0.944120425

00:39:53.946 --> 00:39:56.478 the outcomes we looked at were DBT.

NOTE Confidence: 0.944120425

00:39:56.478 --> 00:39:58.668 Use the proportion of screening

NOTE Confidence: 0.944120425

00:39:58.668 --> 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 --> 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 --> 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 --> 00:40:13.810 so we consider DBT to have been

NOTE Confidence: 0.944120425

00:40:13.810 --> 00:40:15.582 performed when there was a claim

NOTE Confidence: 0.944120425

00:40:15.582 --> 00:40:17.208 for DBT in conjunction with a

NOTE Confidence: 0.944120425

00:40:17.208 --> 00:40:19.039 claim for screening mammography.

NOTE Confidence: 0.944120425

00:40:19.040 --> 00:40:20.986 We looked at the proportion of women

NOTE Confidence: 0.944120425

00:40:20.986 --> 00:40:22.909 with any out of pocket payment.

NOTE Confidence: 0.944120425

00:40:22.910 --> 00:40:23.946 We did also look at the mean

NOTE Confidence: 0.944120425

00:40:23.946 --> 00:40:24.710 out of pocket payment,

NOTE Confidence: 0.944120425

00:40:24.710 --> 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 --> 00:40:30.474 results on the proportion that

NOTE Confidence: 0.944120425

00:40:30.474 --> 00:40:32.988 had any out of pocket payment.

NOTE Confidence: 0.944120425

00:40:32.990 --> 00:40:33.758 This is people,

NOTE Confidence: 0.944120425

00:40:33.758 --> 00:40:35.550 women that had out of pocket payment.

NOTE Confidence: 0.944120425

00:40:35.550 --> 00:40:37.632 We only looked at those with

NOTE Confidence: 0.944120425

00:40:37.632 --> 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 --> 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 --> 00:40:52.579 which estimates changes in an

NOTE Confidence: 0.8980734456

00:40:52.579 --> 00:40:54.625 outcome among states that pass a

NOTE Confidence: 0.8980734456

00:40:54.625 --> 00:40:56.920 law relative to states that did not.

NOTE Confidence: 0.8980734456

00:40:56.920 --> 00:40:59.545 At each six month interval

NOTE Confidence: 0.8980734456

00:40:59.545 --> 00:41:01.120 after law implementation.

NOTE Confidence: 0.8980734456

00:41:01.120 --> 00:41:02.870 So this specification allows for

NOTE Confidence: 0.8980734456

00:41:02.870 --> 00:41:05.072 the effective laws to vary by

NOTE Confidence: 0.8980734456

00:41:05.072 --> 00:41:06.636 the time since implementation.

NOTE Confidence: 0.8980734456

00:41:06.640 --> 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 --> 00:41:11.215 implementation dates and look at

NOTE Confidence: 0.8980734456

00:41:11.215 --> 00:41:12.660 whether there are changes in our

NOTE Confidence: 0.8980734456

00:41:12.660 --> 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 --> 00:41:17.700 six months post implementation.

NOTE Confidence: 0.8980734456

00:41:17.700 --> 00:41:21.179 And this also has the advantage of.

NOTE Confidence: 0.8980734456

00:41:21.180 --> 00:41:22.772 It allows you to see if there were

NOTE Confidence: 0.8980734456

00:41:22.772 --> 00:41:24.110 changes in the six months prior

NOTE Confidence: 0.870000174285714

00:41:36.430 --> 00:41:38.600 Which you would not necessarily expect us,

NOTE Confidence: 0.870000174285714

00:41:38.600 --> 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 --> 00:41:42.774 and models were weighted by the

NOTE Confidence: 0.870000174285714

00:41:42.774 --> 00:41:45.748 screened population in each state.

NOTE Confidence: 0.870000174285714

00:41:45.750 --> 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 --> 00:41:53.926 so we also are not so for outcomes,

NOTE Confidence: 0.870000174285714

00:41:53.930 --> 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 --> 00:42:03.658 women and in mandate and non

NOTE Confidence: 0.886004735555556

00:42:03.658 --> 00:42:05.300 mandate states had similar age.

NOTE Confidence: 0.886004735555556

00:42:05.300 --> 00:42:09.372 Mean age was 53 in both among women in

NOTE Confidence: 0.886004735555556

00:42:09.372 --> 00:42:11.555 mandate states 42% lived in the northeast

NOTE Confidence: 0.886004735555556

00:42:11.555 --> 00:42:14.230 versus 12% in the non mandate states.

NOTE Confidence: 0.886004735555556

00:42:14.230 --> 00:42:17.934 In early 2015, women living in states that

NOTE Confidence: 0.886004735555556

00:42:17.934 --> 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 --> 00:42:26.470 were screened with DVT.

NOTE Confidence: 0.886004735555556

00:42:26.470 --> 00:42:28.438 Versus among women living in states

NOTE Confidence: 0.886004735555556

00:42:28.438 --> 00:42:30.650 that never passed a mandate 11% so

NOTE Confidence: 0.886004735555556

00:42:30.650 --> 00:42:32.330 the screen was a little bit lower in

NOTE Confidence: 0.886004735555556

00:42:32.380 --> 00:42:34.090 states that never passed a mandate.

NOTE Confidence: 0.886004735555556

00:42:34.090 --> 00:42:35.608 Note, this is before the mandate,

NOTE Confidence: 0.886004735555556

00:42:35.610 --> 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 --> 00:42:46.985 out of pocket payment for DVT only 7% in

NOTE Confidence: 0.886004735555556

00:42:46.985 --> 00:42:49.700 both mandate and eventual mandate and

NOTE Confidence: 0.886004735555556

00:42:49.700 --> 00:42:52.570 eventual non and and non mandate states.

NOTE Confidence: 0.886004735555556

00:42:52.570 --> 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 --> 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

NOTE Confidence: 0.886004735555556

00:43:01.090 --> 00:43:06.140 $311.00 versus for two D $266.

NOTE Confidence: 0.473313885

00:43:08.940 --> 00:43:10.140 Pre mandate.

NOTE Confidence: 0.792404991666667

00:43:17.480 --> 00:43:20.288 So next we look at DBT, use and here's

NOTE Confidence: 0.792404991666667

00:43:20.288 --> 00:43:21.660 our first outcome that we look at.

NOTE Confidence: 0.792404991666667

00:43:21.660 --> 00:43:23.388 So let me Orient you 'cause the next

NOTE Confidence: 0.792404991666667

00:43:23.388 --> 00:43:25.049 couple of slides all have the same

NOTE Confidence: 0.792404991666667

00:43:25.049 --> 00:43:26.560 sort of framework as this slide.

NOTE Confidence: 0.792404991666667

00:43:26.560 --> 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 --> 00:43:34.394 from LA negative .5 being the period

NOTE Confidence: 0.792404991666667

00:43:34.394 --> 00:43:37.077 in which the law was implemented.

NOTE Confidence: 0.792404991666667

00:43:37.080 --> 00:43:39.006 So this shows the percentage point

NOTE Confidence: 0.792404991666667

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: 0.792404991666667

00:43:43.996 --> 00:43:46.248 relative to states with no law implemented,

NOTE Confidence: 0.792404991666667

00:43:46.250 --> 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 --> 00:43:50.890 the value for the period in which

NOTE Confidence: 0.792404991666667

00:43:50.954 --> 00:43:52.956 the law is enacted is basically 0%,

NOTE Confidence: 0.792404991666667

00:43:52.960 --> 00:43:54.700 because you're sort of normalizing

NOTE Confidence: 0.792404991666667

00:43:54.700 --> 00:43:57.424 everything to be to for them to be the

NOTE Confidence: 0.792404991666667

00:43:57.424 --> 00:44:00.310 same in that in that moment of enactment.

NOTE Confidence: 0.792404991666667

00:44:00.310 --> 00:44:02.270 So first thing to look at is if you look

NOTE Confidence: 0.792404991666667

00:44:02.325 --> 00:44:04.213 at the three periods that we can measure

NOTE Confidence: 0.792404991666667

00:44:04.213 --> 00:44:06.108 here in the period prior to the law,

NOTE Confidence: 0.792404991666667

00:44:06.110 --> 00:44:09.288 you see that there was no significant

NOTE Confidence: 0.792404991666667

00:44:09.290 --> 00:44:13.589 effects of eventually passing a law.

NOTE Confidence: 0.792404991666667

00:44:13.589 --> 00:44:16.604 We find no significant changes in DB use, D.

NOTE Confidence: 0.792404991666667

00:44:16.604 --> 00:44:18.728 Use relative to the comparison test.

NOTE Confidence: 0.792404991666667

00:44:18.730 --> 00:44:20.518 So this is really equivalent to

NOTE Confidence: 0.792404991666667

00:44:20.518 --> 00:44:21.710 the standard parallel trends,

NOTE Confidence: 0.792404991666667

00:44:21.710 --> 00:44:23.411 test apparel pre trans test that you

NOTE Confidence: 0.792404991666667

00:44:23.411 --> 00:44:25.708 see in a different different analysis

NOTE Confidence: 0.792404991666667

00:44:25.710 --> 00:44:28.059 in the periods after the law we do see

NOTE Confidence: 0.792404991666667

00:44:28.059 --> 00:44:30.256 you can see a steady increases in.

NOTE Confidence: 0.792404991666667

00:44:30.260 --> 00:44:32.318 Mandate states relative to other states.

NOTE Confidence: 0.792404991666667

00:44:32.320 --> 00:44:35.152 So by one year post law these differences

NOTE Confidence: 0.792404991666667

00:44:35.152 --> 00:44:36.640 are statistically significant.

NOTE Confidence: 0.792404991666667

00:44:36.640 --> 00:44:38.290 One year after enactment of

NOTE Confidence: 0.792404991666667

00:44:38.290 --> 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 --> 00:44:45.418 Relative to other states.

NOTE Confidence: 0.917425886666667

00:44:48.180 --> 00:44:49.590 Compared to states without a mandate,

NOTE Confidence: 0.917425886666667

00:44:49.590 --> 00:44:52.020 I'm sorry 7.6% greater than states

NOTE Confidence: 0.917425886666667

00:44:52.020 --> 00:44:54.560 without a mandate, and after two years,

NOTE Confidence: 0.917425886666667

00:44:54.560 --> 00:44:56.981 D BTU's had risen 9 percentage points

NOTE Confidence: 0.917425886666667

00:44:56.981 --> 00:44:59.195 more in mandate states compared to

NOTE Confidence: 0.917425886666667

00:44:59.195 --> 00:45:01.540 states that did not pass mandates.

NOTE Confidence: 0.813745443333333

00:45:05.580 --> 00:45:09.660 Next we look at DBT price.

NOTE Confidence: 0.813745443333333

00:45:09.660 --> 00:45:13.071 And so it's the same format I noted before

NOTE Confidence: 0.813745443333333

00:45:13.071 --> 00:45:14.856 from our patient characteristics table,

NOTE Confidence: 0.813745443333333

00:45:14.860 --> 00:45:17.527 the average cost of a DVT was $311.00

NOTE Confidence: 0.813745443333333

00:45:17.527 --> 00:45:19.462 among maintenance performed in states

NOTE Confidence: 0.813745443333333

00:45:19.462 --> 00:45:21.679 that eventually passed a mandate and

NOTE Confidence: 0.813745443333333

00:45:21.680 --> 00:45:24.200 347 states that did not pass a mandate.

NOTE Confidence: 0.813745443333333

00:45:24.200 --> 00:45:26.032 And here we find that two years post

NOTE Confidence: 0.813745443333333

00:45:26.032 --> 00:45:27.775 mandate and this was a surprise to us.

NOTE Confidence: 0.813745443333333

00:45:27.780 --> 00:45:30.265 DBT Price had declined in mandate states

NOTE Confidence: 0.813745443333333

00:45:30.265 --> 00:45:33.085 compared to the change in price in nine

NOTE Confidence: 0.813745443333333

00:45:33.085 --> 00:45:35.412 non mandate states about $38.00 and I

NOTE Confidence: 0.813745443333333

00:45:35.412 --> 00:45:37.980 don't have a graph here to show it.

NOTE Confidence: 0.813745443333333

00:45:37.980 --> 00:45:39.040 'cause we have limited time,

NOTE Confidence: 0.813745443333333

00:45:39.040 --> 00:45:40.708 but we also did not observe.

NOTE Confidence: 0.813745443333333

00:45:40.710 --> 00:45:42.552 A significant change in the price

NOTE Confidence: 0.813745443333333

00:45:42.552 --> 00:45:43.473 of 2D mammography.

NOTE Confidence: 0.90999358

00:45:45.590 --> 00:45:47.690 Next we look at weather.

NOTE Confidence: 0.936356683333333

00:45:50.020 --> 00:45:54.284 Here it is. At the percent of DBT DBT

NOTE Confidence: 0.936356683333333

00:45:54.284 --> 00:45:57.229 exams with any added pocket payment.

NOTE Confidence: 0.819973345625

00:45:59.310 --> 00:46:01.366 Among women's group with CBT and we found

NOTE Confidence: 0.819973345625

00:46:01.366 --> 00:46:03.245 that even at the start of the study,

NOTE Confidence: 0.819973345625

00:46:03.250 --> 00:46:05.842 as I said earlier, only a minority of women

NOTE Confidence: 0.819973345625

00:46:05.842 --> 00:46:08.404 had any out of pocket payments with DVT.

NOTE Confidence: 0.819973345625

00:46:08.410 --> 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 --> 00:46:15.418 women who had any out of pocket payments for

NOTE Confidence: 0.819973345625

00:46:15.418 --> 00:46:17.797 DVT even as we go to two years post mandate.

NOTE Confidence: 0.819973345625

00:46:17.797 --> 00:46:20.086 We did also look among those that

NOTE Confidence: 0.819973345625

00:46:20.086 --> 00:46:22.406 did have an out of pocket payment.

NOTE Confidence: 0.819973345625

00:46:22.410 --> 00:46:24.210 The mean out of pocket payment and we

NOTE Confidence: 0.819973345625

00:46:24.210 --> 00:46:26.298 did not find a statistic statistically

NOTE Confidence: 0.819973345625

00:46:26.298 --> 00:46:27.878 significant change there either.

NOTE Confidence: 0.9692511

00:46:34.260 --> 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 --> 00:46:42.631 is to ensure access to a particular

NOTE Confidence: 0.9692511

00:46:42.631 --> 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 --> 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 --> 00:46:54.337 were more likely to begin to use DBT

NOTE Confidence: 0.9692511

00:46:54.386 --> 00:46:55.758 for breast cancer screening,

NOTE Confidence: 0.9692511

00:46:55.760 --> 00:46:57.070 which probably is one of

NOTE Confidence: 0.9692511

00:46:57.070 --> 00:46:58.380 the intents of the law.

NOTE Confidence: 0.9692511

00:46:58.380 --> 00:47:01.418 And this finding is consistent with other

NOTE Confidence: 0.9692511

00:47:01.418 --> 00:47:04.179 studies across other types of services

NOTE Confidence: 0.9692511

00:47:04.179 --> 00:47:06.494 that found that expanding coverage,

NOTE Confidence: 0.9692511

00:47:06.500 --> 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 --> 00:47:11.389 specific cell health services.

NOTE Confidence: 0.9692511

00:47:11.390 --> 00:47:14.052 I'll say it's very difficult in many cases

NOTE Confidence: 0.9692511

00:47:14.052 --> 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 --> 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 --> 00:47:22.898 the literature is found to

NOTE Confidence: 0.9692511

00:47:22.898 --> 00:47:23.897 change their behavior,

NOTE Confidence: 0.9692511

00:47:23.900 --> 00:47:26.042 but in our study this really

NOTE Confidence: 0.9692511

00:47:26.042 --> 00:47:28.373 raises some new questions about the

NOTE Confidence: 0.9692511

00:47:28.373 --> 00:47:30.045 mechanism by which mandates.

NOTE Confidence: 0.9692511

00:47:30.050 --> 00:47:32.552 May increase use of an emerging

NOTE Confidence: 0.9692511

00:47:32.552 --> 00:47:34.667 technology because we didn't find

NOTE Confidence: 0.9692511

00:47:34.667 --> 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 --> 00:47:41.750 the out of pocket payment was low,

NOTE Confidence: 0.9692511

00:47:41.750 --> 00:47:44.459 so it it's unlikely that a change

NOTE Confidence: 0.9692511

00:47:44.459 --> 00:47:47.203 in what the patient had to pay

NOTE Confidence: 0.9692511

00:47:47.203 --> 00:47:49.672 is what led to these changes.

NOTE Confidence: 0.9692511

00:47:49.672 --> 00:47:53.284 So one explanation for these findings

NOTE Confidence: 0.9692511

00:47:53.290 --> 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 --> 00:47:59.138 radiologists and other health care

NOTE Confidence: 0.9692511

00:47:59.138 --> 00:48:00.537 institutions to enter the market.

NOTE Confidence: 0.9692511

00:48:00.540 --> 00:48:02.880 And offer DBT and this may have led to

NOTE Confidence: 0.9692511

00:48:02.880 --> 00:48:05.558 a relative price in at least two ways.

NOTE Confidence: 0.9692511

00:48:05.560 --> 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 --> 00:48:13.070 ability to negotiate lower prices

NOTE Confidence: 0.9692511

00:48:13.135 --> 00:48:14.997 and this could lead to lower prices

NOTE Confidence: 0.9692511

00:48:14.997 --> 00:48:17.246 or at least slower growth in prices

NOTE Confidence: 0.9692511

00:48:17.246 --> 00:48:18.290 over all providers.

NOTE Confidence: 0.9692511

00:48:18.290 --> 00:48:18.525 Second,

NOTE Confidence: 0.9692511

00:48:18.525 --> 00:48:20.170 it could be the case that early

NOTE Confidence: 0.9692511

00:48:20.170 --> 00:48:21.503 entrance we would expect the

NOTE Confidence: 0.9692511

00:48:21.503 --> 00:48:22.858 early entrance in this market.

NOTE Confidence: 0.9692511

00:48:22.860 --> 00:48:24.930 When DBT first started to be

NOTE Confidence: 0.9692511

00:48:24.930 --> 00:48:26.960 providers that have higher prices.

NOTE Confidence: 0.9692511

00:48:26.960 --> 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 --> 00:48:34.988 tend to offer services at lower prices

NOTE Confidence: 0.9692511

00:48:34.988 --> 00:48:36.844 compared to established providers,

NOTE Confidence: 0.9692511

00:48:36.850 --> 00:48:37.510 the average market,

NOTE Confidence: 0.9692511

00:48:37.510 --> 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 --> 00:48:41.577 so you have a high price pipe,

NOTE Confidence: 0.9692511

00:48:41.580 --> 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 --> 00:48:46.660 the average is going to go down.

NOTE Confidence: 0.9692511

00:48:46.660 --> 00:48:47.912 But in that scenario,

NOTE Confidence: 0.9692511

00:48:47.912 --> 00:48:50.160 no provider has actually changed their price,

NOTE Confidence: 0.9692511

00:48:50.160 --> 00:48:50.425 right?

NOTE Confidence: 0.9692511

00:48:50.425 --> 00:48:52.280 But the the price that is paid

NOTE Confidence: 0.9692511

00:48:52.280 --> 00:48:54.080 in the market will decline,

NOTE Confidence: 0.9692511

00:48:54.080 --> 00:48:56.420 so other explanations are possible.

NOTE Confidence: 0.9692511

00:48:56.420 --> 00:48:57.388 For example,

NOTE Confidence: 0.9692511

00:48:57.388 --> 00:48:59.808 it's possible that coverage mandates

NOTE Confidence: 0.9692511

00:48:59.808 --> 00:49:02.934 might be perceived by patients or others

NOTE Confidence: 0.9692511

00:49:02.934 --> 00:49:05.328 as an endorsement of this service.

NOTE Confidence: 0.9692511

00:49:05.330 --> 00:49:06.995 And this could increase interest

NOTE Confidence: 0.9692511

00:49:06.995 --> 00:49:08.327 in this new technology,

NOTE Confidence: 0.9692511

00:49:08.330 --> 00:49:09.941 so we can't say for certain that this is

NOTE Confidence: 0.9692511

00:49:09.941 --> 00:49:11.626 one of the two things that is happening.

NOTE Confidence: 0.9692511

00:49:11.630 --> 00:49:14.210 Unfortunately we don't have a provider

NOTE Confidence: 0.9692511

00:49:14.210 --> 00:49:16.642 identifier in our data that would

NOTE Confidence: 0.9692511

00:49:16.642 --> 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 --> 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 --> 00:49:27.620 some limitations to the paper,

NOTE Confidence: 0.937304973333333

00:49:27.620 --> 00:49:30.056 so there definitely could be some

NOTE Confidence: 0.937304973333333

00:49:30.056 --> 00:49:31.274 issues with generalizability.

NOTE Confidence: 0.937304973333333

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 --> 00:49:38.034 at these this study because it is from

NOTE Confidence: 0.937304973333333

00:49:38.034 --> 00:49:40.786 all 50 states in a very large data set.

NOTE Confidence: 0.937304973333333

00:49:40.790 --> 00:49:43.080 Also, there are important known

NOTE Confidence: 0.937304973333333

00:49:43.080 --> 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 --> 00:49:50.050 misclassification problems or bias.

NOTE Confidence: 0.937304973333333

00:49:50.050 --> 00:49:52.276 Another issue with this very particular

NOTE Confidence: 0.937304973333333

00:49:52.276 --> 00:49:54.300 setting is our approach focused.

NOTE Confidence: 0.937304973333333

00:49:54.300 --> 00:49:56.200 We chose to look at the price of the initial

NOTE Confidence: 0.937304973333333

00:49:56.245 --> 00:49:57.925 test rather than the screening episode.

NOTE Confidence: 0.937304973333333

00:49:57.930 --> 00:49:59.176 In some of our papers we have

NOTE Confidence: 0.937304973333333

00:49:59.176 --> 00:50:00.500 looked at the screening episode,

NOTE Confidence: 0.937304973333333

00:50:00.500 --> 00:50:02.018 but you know that could be

NOTE Confidence: 0.937304973333333

00:50:02.018 --> 00:50:03.030 very very different here.

NOTE Confidence: 0.937304973333333

00:50:03.030 --> 00:50:06.174 If DBT does reduce recall and that could

NOTE Confidence: 0.937304973333333

00:50:06.174 --> 00:50:09.255 lead to additional cost savings from for

NOTE Confidence: 0.937304973333333

00:50:09.255 --> 00:50:12.779 DBT relative to to to 2D mammography.

NOTE Confidence: 0.937304973333333

00:50:12.780 --> 00:50:17.898 Also this was an an observation ULL study.

NOTE Confidence: 0.937304973333333

00:50:17.900 --> 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 --> 00:50:23.572 unmeasured confounding is always

NOTE Confidence: 0.937304973333333

00:50:23.572 --> 00:50:26.087 a possibility and could explain

NOTE Confidence: 0.937304973333333

00:50:26.087 --> 00:50:27.830 some of our findings.

NOTE Confidence: 0.937304973333333

00:50:27.830 --> 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 --> 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 --> 00:50:43.943 user price prior to the law being enacted,

NOTE Confidence: 0.8368984405

00:50:43.950 --> 00:50:45.762 it's important to acknowledge that pre

NOTE Confidence: 0.8368984405

00:50:45.762 --> 00:50:48.354 period trends in DBT use or cost and mandate

NOTE Confidence: 0.8368984405

00:50:48.354 --> 00:50:50.150 states may may influence our results.

NOTE Confidence: 0.8368984405

00:50:50.150 --> 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 --> 00:50:59.298 although DVD mandates were associated

NOTE Confidence: 0.797047572666667

00:50:59.298 --> 00:51:01.330 with an increase in DBT use,

NOTE Confidence: 0.797047572666667

00:51:01.330 --> 00:51:03.412 they were not associated with any

NOTE Confidence: 0.797047572666667

00:51:03.412 --> 00:51:06.204 change in out of pocket payments and

NOTE Confidence: 0.797047572666667

00:51:06.204 --> 00:51:07.968 this suggests that mandates and this

NOTE Confidence: 0.797047572666667

00:51:07.968 --> 00:51:09.629 has implications for other services,

NOTE Confidence: 0.797047572666667

00:51:09.630 --> 00:51:12.006 well, may influence DBT adoption through

NOTE Confidence: 0.797047572666667

00:51:12.006 --> 00:51:14.169 mechanisms other than by reducing

NOTE Confidence: 0.797047572666667

00:51:14.169 --> 00:51:16.217 financial liability for patients.

NOTE Confidence: 0.783258507222222

00:51:23.120 --> 00:51:26.011 Thank you Susan for a great presentation

NOTE Confidence: 0.783258507222222

00:51:26.011 --> 00:51:28.850 that clearly damn straight close link

NOTE Confidence: 0.783258507222222

00:51:28.850 --> 00:51:31.390 between policy and clinical practice.

NOTE Confidence: 0.783258507222222

00:51:31.390 --> 00:51:34.840 I was wondering whether there are

NOTE Confidence: 0.783258507222222

00:51:34.840 --> 00:51:38.731 studies being planned by you or others

NOTE Confidence: 0.783258507222222

00:51:38.731 --> 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 --> 00:51:50.750 if there's evidence that DBT

NOTE Confidence: 0.783258507222222

00:51:50.750 --> 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 --> 00:51:57.114 that more B might be more

NOTE Confidence: 0.783258507222222

00:51:57.114 --> 00:51:58.990 incentive for more states to

NOTE Confidence: 0.783258507222222

00:51:58.990 --> 00:52:00.815 have similar laws mandating it.

NOTE Confidence: 0.712928625

00:52:02.490 --> 00:52:04.446 When you see identify more patients,

NOTE Confidence: 0.712928625

00:52:04.450 --> 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

NOTE Confidence: 0.712928625

00:52:07.683 --> 00:52:09.862 would get a mammography because

NOTE Confidence: 0.712928625

00:52:09.862 --> 00:52:12.600 the the DBT is available? Right,

NOTE Confidence: 0.753284413

00:52:12.610 --> 00:52:15.298 I just thinking like like on what

NOTE Confidence: 0.753284413

00:52:15.298 --> 00:52:17.548 basis would this states that occur,

NOTE Confidence: 0.753284413

00:52:17.548 --> 00:52:19.744 like not mandating it like what?

NOTE Confidence: 0.753284413

00:52:19.750 --> 00:52:21.774 Why would they be encouraged to do so?

NOTE Confidence: 0.925469609166667

00:52:22.290 --> 00:52:23.830 Why would they be mandating so the

NOTE Confidence: 0.925469609166667

00:52:23.830 --> 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 --> 00:52:28.450 find it like where's the problem?

NOTE Confidence: 0.925469609166667

00:52:28.450 --> 00:52:31.010 Out of pocket payments were

NOTE Confidence: 0.925469609166667

00:52:31.010 --> 00:52:32.546 not particularly high.

NOTE Confidence: 0.925469609166667

00:52:32.550 --> 00:52:34.506 Sort of before these are mandated.

NOTE Confidence: 0.925469609166667

00:52:34.510 --> 00:52:36.286 Well, you know there might be some insurers,

NOTE Confidence: 0.925469609166667

00:52:36.290 --> 00:52:38.502 but there might be some fear from

NOTE Confidence: 0.925469609166667

00:52:38.502 --> 00:52:40.423 suppliers that insurers may stop covering

NOTE Confidence: 0.925469609166667

00:52:40.423 --> 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 --> 00:52:51.696 why would a state not pass a mandate?

NOTE Confidence: 0.925469609166667

00:52:51.700 --> 00:52:53.408 You know they may be looking to

NOTE Confidence: 0.925469609166667

00:52:53.408 --> 00:52:54.702 the evidence and maybe looking

NOTE Confidence: 0.925469609166667

00:52:54.702 --> 00:52:56.480 to the USPS TF if they're thought

NOTE Confidence: 0.925469609166667

00:52:56.480 --> 00:52:57.957 of as an independent body,

NOTE Confidence: 0.925469609166667

00:52:57.960 --> 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 --> 00:53:03.310 suggesting there probably there

NOTE Confidence: 0.925469609166667

00:53:03.310 --> 00:53:05.258 may be still some uncertainty.

NOTE Confidence: 0.925469609166667

00:53:05.260 --> 00:53:06.910 Right in in the studies,

NOTE Confidence: 0.925469609166667

00:53:06.910 --> 00:53:10.438 so that's why you might not mandate the

NOTE Confidence: 0.925469609166667

00:53:10.438 --> 00:53:14.370 reason that you you know or also because.

NOTE Confidence: 0.925469609166667

00:53:14.370 --> 00:53:16.323 It's not really clear that there's a

NOTE Confidence: 0.925469609166667

00:53:16.323 --> 00:53:18.236 problem since people are not paying large

NOTE Confidence: 0.925469609166667

00:53:18.236 --> 00:53:20.210 out of pocket payments for this service.

NOTE Confidence: 0.777921400769231

00:53:21.840 --> 00:53:25.614 Sure. Yeah, because the laws are

NOTE Confidence: 0.777921400769231

00:53:25.614 --> 00:53:29.618 at the state level and and the

NOTE Confidence: 0.777921400769231

00:53:29.620 --> 00:53:32.000 US preventive taskforce hasn't

NOTE Confidence: 0.777921400769231

00:53:32.000 --> 00:53:34.380 made a ARB recommendation.

NOTE Confidence: 0.777921400769231

00:53:34.380 --> 00:53:36.138 I think that could be where

NOTE Confidence: 0.777921400769231

00:53:36.138 --> 00:53:37.310 states are looking for.

NOTE Confidence: 0.86811817

00:53:39.800 --> 00:53:40.300 Yes.

NOTE Confidence: 0.832805011428571

00:53:43.420 --> 00:53:44.848 Am I supposed to look for questions?

NOTE Confidence: 0.827701572

00:53:47.990 --> 00:53:51.560 Right? Please feel free to.

NOTE Confidence: 0.827701572

00:53:51.560 --> 00:53:53.868 Type your question through chat.

NOTE Confidence: 0.709557586666667

00:53:57.730 --> 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 --> 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 --> 00:54:14.540 patients for insurance for many years.

NOTE Confidence: 0.77775094125

00:54:14.540 --> 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 --> 00:54:24.346 so I think few private insurers.

NOTE Confidence: 0.77775094125

00:54:24.350 --> 00:54:26.300 Maybe we're charging before that.

NOTE Confidence: 0.77775094125

00:54:26.300 --> 00:54:28.676 I think a lot of I think there

NOTE Confidence: 0.77775094125

00:54:28.676 --> 00:54:30.770 wasn't even a code until 2015

NOTE Confidence: 0.77775094125

00:54:30.770 --> 00:54:34.190 to 2 allow people to charge.

NOTE Confidence: 0.77775094125

00:54:34.190 --> 00:54:35.618 But that is great that Yale

NOTE Confidence: 0.77775094125

00:54:35.618 --> 00:54:36.920 was able to do that.

NOTE Confidence: 0.6953895

00:54:58.900 --> 00:55:02.270 So what are the follow up?

NOTE Confidence: 0.6217595525

00:55:02.270 --> 00:55:05.210 Studies that that you are carrying

NOTE Confidence: 0.6217595525

00:55:05.210 --> 00:55:07.990 your team is planning. I know Alana

NOTE Confidence: 0.6217595525

00:55:07.990 --> 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 --> 00:55:17.124 I think we're talking about that

NOTE Confidence: 0.95838618

00:55:17.130 --> 00:55:19.194 right now because this is one of the

NOTE Confidence: 0.95838618

00:55:19.194 --> 00:55:21.467 this is a project I have two minutes.

NOTE Confidence: 0.95838618

00:55:21.470 --> 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 --> 00:55:27.390 Joe Ross was also on this train ride.

NOTE Confidence: 0.95838618

00:55:27.390 --> 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 --> 00:55:34.081 which is what we really the technology

NOTE Confidence: 0.95838618

00:55:34.081 --> 00:55:36.435 we were really interested in studying,

NOTE Confidence: 0.95838618

00:55:36.435 --> 00:55:39.914 and Joe Ross and Carrie Gross and I

NOTE Confidence: 0.95838618

00:55:39.914 --> 00:55:41.888 were on the same metro North train down

NOTE Confidence: 0.95838618

00:55:41.888 --> 00:55:43.667 to New York for the same meeting and

NOTE Confidence: 0.95838618

00:55:43.667 --> 00:55:45.475 we were just chatting on the train and

NOTE Confidence: 0.95838618

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 --> 00:55:48.340 You know what's going on this is,

NOTE Confidence: 0.95838618

00:55:48.340 --> 00:55:49.544 you know, many years ago and I

NOTE Confidence: 0.95838618

00:55:49.544 --> 00:55:50.920 said this is so interesting that

NOTE Confidence: 0.95838618

00:55:50.920 --> 00:55:52.000 they're doing this mandate.

NOTE Confidence: 0.95838618

00:55:52.000 --> 00:55:54.261 Let's write a grant and we ended

NOTE Confidence: 0.95838618

00:55:54.261 --> 00:55:56.598 up writing a an ACS grant that

NOTE Confidence: 0.95838618

00:55:56.598 --> 00:55:58.536 was funded to do this work.

NOTE Confidence: 0.95838618

00:55:58.540 --> 00:56:00.166 And then Alana gotten bored and

NOTE Confidence: 0.95838618

00:56:00.166 --> 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 --> 00:56:04.952 so it really did start out as this

NOTE Confidence: 0.95838618

00:56:04.952 --> 00:56:07.644 just sort of kind of very random thing

NOTE Confidence: 0.95838618

00:56:07.644 --> 00:56:09.288 that people just sort of talking.

NOTE Confidence: 0.95838618

00:56:09.290 --> 00:56:11.642 It's funny that Joe is here about

NOTE Confidence: 0.95838618

00:56:11.642 --> 00:56:13.406 this and ended up being this project

NOTE Confidence: 0.95838618

00:56:13.406 --> 00:56:15.013 so that project has ended now

NOTE Confidence: 0.95838618

00:56:15.013 --> 00:56:16.585 so that ACS project has ended.

NOTE Confidence: 0.95838618

00:56:16.590 --> 00:56:18.066 So we're really thinking about what

NOTE Confidence: 0.95838618

00:56:18.066 --> 00:56:20.240 would be the the best next steps and

NOTE Confidence: 0.95838618

00:56:20.240 --> 00:56:21.944 what are the most interesting questions.

NOTE Confidence: 0.95838618

00:56:21.950 --> 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 --> 00:56:27.458 involved in this so we we haven't

NOTE Confidence: 0.95838618

00:56:27.458 --> 00:56:28.970 sort of gotten to the next project.

NOTE Confidence: 0.95838618

00:56:28.970 --> 00:56:30.344 We're sort of finishing up the

NOTE Confidence: 0.95838618

00:56:30.344 --> 00:56:31.480 the old project right now.

NOTE Confidence: 0.95838618

00:56:31.480 --> 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 --> 00:56:43.690 I'm not sure that state

NOTE Confidence: 0.913487709

00:56:43.690 --> 00:56:44.930 legislatures would look at that,

NOTE Confidence: 0.913487709

00:56:44.930 --> 00:56:45.866 but I do think like that.

NOTE Confidence: 0.913487709

00:56:45.870 --> 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 --> 00:56:50.473 that suggests that they're really

NOTE Confidence: 0.913487709

00:56:50.473 --> 00:56:52.330 good benefits to passing a law,

NOTE Confidence: 0.913487709

00:56:52.330 --> 00:56:54.199 I think that the the advocates may

NOTE Confidence: 0.913487709

00:56:54.199 --> 00:56:55.719 bring that to state legislatures

NOTE Confidence: 0.913487709

00:56:55.719 --> 00:56:58.015 and that that can be very helpful.

NOTE Confidence: 0.913487709

00:56:58.020 --> 00:57:00.060 Especially, I do think like some of the

NOTE Confidence: 0.913487709

00:57:00.060 --> 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 --> 00:57:07.302 This is pre ACA and cost sharing that

NOTE Confidence: 0.913487709

00:57:07.302 --> 00:57:09.684 those actually you know led to more

NOTE Confidence: 0.913487709

00:57:09.684 --> 00:57:11.472 movies and potentially had some interest,

NOTE Confidence: 0.913487709

00:57:11.480 --> 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 --> 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 --> 00:57:18.676 but I think those did have an impact.

NOTE Confidence: 0.913487709

00:57:18.680 --> 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 --> 00:57:27.640 Yes, so a lot of notes and I that

NOTE Confidence: 0.847373147222222

00:57:27.640 --> 00:57:30.250 these implications have other firm

NOTE Confidence: 0.847373147222222

00:57:30.250 --> 00:57:32.486 or other emerging technologies.

NOTE Confidence: 0.847373147222222

00:57:32.490 --> 00:57:34.236 So to thinking about how that

NOTE Confidence: 0.847373147222222

00:57:34.236 --> 00:57:36.193 will adopt that, how that those

NOTE Confidence: 0.847373147222222

00:57:36.193 --> 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 --> 00:57:43.949 the time to share with us your

NOTE Confidence: 0.875976628125

00:57:43.949 --> 00:57:47.508 important work. Also thanks to Joe.

NOTE Confidence: 0.875976628125

00:57:47.510 --> 00:57:50.850 Help you both have a nice day. But by.