I'm delighted to introduce our first speaker today, Doctor Joel Ross. He's a professor of medicine in general medicine and professor of public health and health policy and management. After receiving his medical degree at the Albert Einstein College of Medicine, Doctor Ross came to Yale. Follow in the Robert Wood Johnson Clinical Scholars Program in 2004. He has had a very distinguished career since, with a focus on examining factors that affect use or delivery of recommended.
hospital and ambulatory care, as well as clinical outcomes of such care. Today his topic is leveraging real-world data through pragmatic clinical trials. Doctor Ross the floor is yours. Thank you chairman. Thank you for inviting me to speak before the Cancer Center and part of the grand rounds today. I’m delighted to share some of the work that I’ve been working on over the past several years and to identify potential opportunities for collaboration with investigators throughout the Cancer Center. I also could not be happier to
be sharing the stage with Susan today because, you know, when I was a clinical scholar, kind of lost looking for a mentor. Way back almost 20 years ago now, Susan was the only person to open her door to me. When she got she helped me get my career started so I couldn’t be more grateful for everything she’s done to help me get started in my career. So I’m just going to get started and talk about this work. Please you know, jump in with questions through the chat.
I’ll try to keep an eye on it just to note, some of the potential competing interests that inform the work that I’m going to be presenting today. I do get research grant funding through Yale from the FDA as part of the Yale Mayo Clinic Center for Excellence in Regulatory Science and Innovation. I’ll talk a little bit about that work. As well as from the medical Devices Innovation Consortium to run something called Nest along with some funds from Johnson and Johnson for clinical trial data sharing initiatives at federal government awards.
as well as the Laura and John Arnold Foundation. So this is just,
you know, to get us started you know here you see some pictures of
individuals you know searching for evidence to, you know as they have a clinical question, they’re trying to make a decision about what to do for their patients. Or to then, you know, sit down with their patient and make a suggestion or recommendation around a drug to use and you know,
typically you know when we think about this sort of the hierarchy of evidence and you know what we want to guide our decisions. You know randomized control trials. You know to guide our decisions or perhaps systematic reviews that are aggregating RCT evidence, and ideally when it’s been meta analyzed to put it all together. But there’s been a lot of changes in the way we understand evidence, in part because of the advancement.
and methods to use a large data sources, but also because of other challenges that have faced both the FDA and others. But what you’ll have noticed over the past decade is, you know, increasingly thinking about. A new and novel ways to evaluate medical products and the lifecycle approach to evaluation. So it’s not just about that first RCT evidence,
it’s going to inform use and in part

that was because premarket studies that
inform FDA approval are often limited,
limited in size, limited in scope,
limited in the end points

They’re not looking at the kind of
they’re not big enough studies to
identify important safety concerns,
and sometimes they’re not
even studies that are.

Guaranteed to confirm the
efficacy of a product.
They’re focusing on surrogate
markers as endpoints in order to project,
benefit through these markers, and then those are supposed to be done in tandem with postmarket studies. You know, trials that are going to happen after the approval and but the problem has been that those trials frequently are delayed and they’re just not even consistently completed. This in combination with the fact that we were never ever going to be able to address each remaining uncertainty through clinical trials, has led to, you know, opportunities for you know
what you’re hearing now.

Kind of real world data.

Real-world data as a the way forward,

And you know,

this is this quote from a high level official at the FDA is illustrative.

You know, using RWE to begin to address these questions as preferable to having no evidence whatsoever.

And you know, with the advent of, you know industry and FDA talking more about real-world data.

You’re starting to see you know more and more companies popping
up that you know promising.

We're world analytics to deliver real-world evidence.

And you know, I'll just sort of say, this is, you know, buzzword alert, right?

This is a big problem that where the sort of the promise is getting way ahead of what is actually, you know what we're capable of, and what we're capable of, sort of understanding reliably.

Really, what we're talking about now are the use of cohort studies case control studies. You know cohort studies case control studies.
You know, leveraging observational data resources and in part this is not only a recognition of the limitations of premarket regulatory approval, but also you know a major advocacy push that’s happening towards real-world data that has led to, had very clear goals that to push towards a real-world data use, including requiring the FDA.
00:05:34.344 --> 00:05:36.288 To establish a program.

00:05:36.290 --> 00:05:38.040 To evaluate real-world evidence which was defined in the legislation.

00:05:38.040 --> 00:05:40.229 as data regarding the usage or the potential benefits or risks of a drug or device derived from sources other than randomized control trials.

00:05:40.229 --> 00:05:42.840 Now, this isn’t to say that you know all real world data are bad.

00:05:42.840 --> 00:05:44.776 The typical or traditional PWB of today is work that you know many investigators, including my group at Yale, do right.

00:05:44.776 --> 00:05:46.462 So it’s advanced observation.
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
00:06:38.025 --> 00:06:39.060 of the product.

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

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

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

00:06:44.704 --> 00:06:46.839 or registry registry based medical

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

00:06:48.888 --> 00:06:50.854 your attention to some of the work

00:06:50.854 --> 00:06:52.014 that we’ve done as part of our group.

00:06:52.020 --> 00:06:54.784 And I did want to just sort of flag

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

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

00:06:57.981 --> 00:06:59.877 may be interested in collaborating.

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

00:07:02.372 --> 00:07:04.545 essentially work closely with FDA to

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

NOTE Confidence: 0.885214616111111
unmet needs at the Agency this often.

This is through our Searcy.

We are one of four that are funded by the FDA to do collaborative regulatory science research, but it’s also through nest, which is a network of health systems that are working with real world data.

Or, you know, essentially, we’re working with our health system data to try to evaluate medical devices in practice and these types of studies you know tend to look like this project where we look, try to better understand the
safety and efficacy of individuals who are switching from branded. We both are rocks into generic looking at its impact and effect. Thyroid stimulation hormone levels and other markers of efficacy. This project, where we're aggregating data across the state of Connecticut, including hospital data and mortality. data and other vital statistic data, then even EMS data to try to better understand opioid use disorder and overdose including, uh, you know, throughout the state.
Work like this where we’re trying to understand the comparative effectiveness of safety of oral anticoagulants in patients with atrial fibrillation who have poor kidney function. These types of patients are often excluded from clinical trials, but FDA is often tasked with trying to understand and give direction on their safety and benefits for use of this kind of research, as well as this. This registry based study where we looked at different types of cardio. Cardiac pump devices and looking at their safety,
especially for patients who are having acute heart attack and are in cardiogenic shock, so lots of individuals are doing work like this that are leveraging existing data sources to try to bring greater insights into the safety and benefit of various products. But I think you know, as the sort of the call for real world evidence gets louder. You know one caution to keep in mind is that observation ULL data sources should not be expected to answer the same clinical questions that are
being answered by traditional clinical.

Clinical trials and we have to think about ways to make sure that the evidence is being used.

To complement the existing RCT evidence.

This is an example of a project that a student working with me did a couple of years ago trying to understand the feasibility of using real-world data to replicate clinical trial evidence and what she did is she identified among all the clinical trials that had been published in high impact medical journals in 2017. She determined what proportion...
had and in clinical intervention.
The clinical indication of the patients who were studied enrollment criteria as well as a primary endpoint that could be successfully in routinely ascertained from either electronic health records. Structured electronic health records, data or claims data,
and what we found is that only 15% of these trials could feasibly have been replicated using this kind of real world data resource. When the 21st Century Cures Act passed, the FDA was actually pretty quick to say,
listen,

real-world data should be defined by the context in which the evidence is gathered in clinical care or home and community settings, as opposed to necessarily in research or academic environments, and the distinction is not based necessarily on the presence or absence of a planned intervention or use of randomization.

Essentially, they’re saying, you know, continue to seek out opportunities to conduct.

Randomized evaluations using
pragmatic trials that better leverage kind of the existing data resource infrastructure to make them perhaps cheaper or easier to conduct. But it’s not just about substituting observation, ULL data analysis for randomized control trials, and I’m always reminded of this quote. You know, if you want more evidence based practice, you need more practice based evidence. So in the next 10 minutes I’m going to talk a little bit about some of the work that we’ve been
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 you know they talk about kind of
NOTE Confidence: 0.939815838421053
00:11:25.345 --> 00:11:27.657 all the real world data that are out
NOTE Confidence: 0.939815838421053
00:11:27.657 --> 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,
All these things could ideally be linked together, including even potentially social media data or wearables data or even you know something like credit card data. And this kind of is like the optimal environment when you talk to people like the future of clinical trials, putting the patient at the center and mostly people talk about that as.
But we’ve been working with a group called Hugo that actually does just this. It aggregates multiple data platforms into a patient centered medical record that the patient can then share out with the research team as part of a, you know, our research project. And so this is the first study we did at leveraging this platform. It was done as part of our city. Our FT had funded center where we aggregated data for just 60 patients who were getting care at Yale and at the Mayo Clinic.
site who are undergoing bariatric surgery or A-fib ablation procedures. A 59 patients under actually underwent the procedure and completed our eight week follow up. And what’s? The beauty of this platform for research purposes is you sit down with a patient. You enroll them in the platform you link their electronic health record data from any health system or as well as their pharmacy data and and and other information. And that takes time.
It took a little over an hour for all of our patients, but once you do that,
everything that happens next over the 88 week follow up for the patients is all passive patient data aggregates. Automatically into the system being shared with the research team for research purposes and the patient never has to come back, with 60 patients we’ve had a nice sort of broad spectrum of age ranges.
You know, including a number of patients over the age of 65 who were able to do this successfully. And here are the data we aggregated and I’ll start at the bottom left. The electronic health record data. So everyone was getting care at either the Yale at or the Mayo Clinic for their specialty care for this procedure, but also and so everyone you know their care is managed through Epic and they have access to their my chart and they connect their.
my chart to their Hugo account, but also individuals who have primary care elsewhere were able to link their my charts either through Epic or Cerner based systems from any health system. So if we were taking care of a patient who was getting there, a FIB ablation here at Yale, but they’re there, their primary care, perhaps was at Hartford Hospital. For whatever reason they could link that system too. Also, we linked their pharmacy data, so that’s not the upper right and so
00:14:27.518 --> 00:14:29.627 this was individuals were getting care.

00:14:29.630 --> 00:14:31.406 Their pharmacies met their medications through CVS or Walgreens.

00:14:31.406 --> 00:14:33.626 They also use a mark.

00:14:33.630 --> 00:14:35.290 My chart based system that allows this.

00:14:35.290 --> 00:14:37.446 They’re essentially their health record to get linked right into Hugo.

00:14:37.450 --> 00:14:39.042 We also then used Hugo to send out surveys.

00:14:39.042 --> 00:14:41.810 Patient reported outcome measures.

00:14:41.810 --> 00:14:45.104 Both short questions post procedure along with longer questions at 148 weeks and patients get a link.

00:14:45.110 --> 00:14:47.190 Right to their phone they they.

00:14:47.190 --> 00:14:49.790 They signify their preference. If they want a text message

NOTE Confidence: 0.91233572
or email, they click the link and they fill it all out right on their phone and it’s all kind of easy peasy.

They don’t have to come back to go through, you know a structured questionnaire with a nurse or any other study coordinator. They can just do it on their own, fill it out and that allows you to ask more questions. And then we also gave every patient some two different digital devices. Everyone got a Fitbit in order to track activity and patients who underwent bariatric surgery got a Withings scale.

Digital scale and people. Patients who underwent the 8th
Ablation procedure got us a two-finger, a single lead EKG that you measured through Kardia mobile. And this is just some quick results to show you kind of what we could do. Again, this was really just figuring out the feasibility of doing work like this, but we were able to link health records for 100% of patients who underwent procedures. A 55% of patients also had a primary care that was based at Yale or Mayo, so all of their electronic health records get pulled in for purposes of the study. 10 patients, LinkedIn, additional 13 portals and then we had
40% of patients who are getting their prescriptions through CVS or Walgreens. Now, Walmart also has a my chart like function that allows you to pull in information like medication names, dosages, start and end dates along with refills, and all these data were passively aggregated after our initial enrollment, allowing for near real time streaming data aggregation and this just kind of shows you kind of how it worked at the time when we did the study, people had to actually sync their Fitbits. Now that happens automatically,
but this shows you of course. Of things tail off over time, but even over the eight weeks we had, well more than half of patients syncing their Fitbits their cardio mobile devices and their withing scale which allows you to kind of project you know. So on the top you can see kind of trajectories of recovery. So on the top you can see kind of average steps per day for patients who underwent bariatric surgery, kind of visually demonstrating the how patients recovered over time.
The bottom half on the left is the the steps per day for patient patients who underwent a fibrillation on the right. Is that the cumulative weight change for patients undergoing bariatric surgery on the lower right is the patient. The average heart rate and again, this is more just to determine, you know, the accuracy. That the integrity of the data that was being aggregated here. Our response rate to the patient reported outcome measures consistently above 80% for all the patients for all the surveys, and it allows you also to determine how patients are doing so you know,
we’re over time graphing estimates of pain,
appetite and palpitations in the two patient groups,
but this is really just more for illustrative purposes.
And this has led to a lot of future work that I’m really proud of,
and I’m really excited.
It’s all kind of coming soon,
but I did want a sort of flag for people in case it prompts potential collaborations,
but this is the biggest of the studies that we’re working on now.
Also funded through the Searcy,
it's a where aggregating sensually

a large cohort study of more than 1500 patients who are receiving a new opioid prescription for acute pain recruiting from sites across the United States and Yale, the University of Alabama, Birmingham, including from their network of dental practices that run up the Appalachian Mountains from the Mayo Clinic from Monument Health, which is basically South Dakota and Cedar Sinai in Los Angeles. Patients are being recruited for 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
Other measures of health care utilization activity measured using Fitbits and opioid disposal, and just to give you a sense of the kind of data that this allows us to aggregate on patients. This is mean daily pain reportings among those reporting they are in pain, and you can just see how pain essentially persists. This is over 180 days. The average pain dots are in blue. Worst pain or in red? Here’s the median days elapsed. 00:19:30.481 to 1st report of no pain among patients.
patients with pain fully resolved and you can see the difference in pain experienced by patients in different settings with patients who are recruited either from the inpatient setting or a primary care having longer median days until the first report of no pain. Whereas patients for the dentist having slightly shorter durations and then this shows you the mean daily pain ratings among those taking. A treatment for pain and this could be any treatment.
It could be tylanol it could be an opioid, it could be anything, but you can see here the blue dots are patients who are not using an opioid for treatment and the yellow dots are patients who are using an opioid for treatment and you can see how the on average the patients who are taking an opioid are having higher rates of pain. All of this is being done in collaboration with the FDA as part of their efforts to better address and understand the risks associated with opioid use.
just to mention briefly one is these projects that are funded by Nest. This is what we call the sleep I study. It's a prospective RCT of 100 patients with depression receiving outpatient treatment for insomnia, comparing usual care of a prescription digital therapeutic device that's essentially cognitive behavioral therapy for insomnia, following patient treating patients over 9 weeks. With the primary endpoint of insomnia and we're following them up over a year and again just to emphasize. All of this is done using the Hugo platform,
so we enroll patients at baseline.

They're randomized to one treatment or another they undergo, you know, they they.

They undergo the treatment associated with that arm, and they get, you know,

serving questions out, you know,

through their phone or via email,

and all of their data that the health care, utilization data,

and other information otherwise passively aggregates.

It’s you know,

a pragmatic RCT that’s leveraging.

Real world data for all of our endpoints,

we’re doing another study that

we call the Heart Watch study,
which is essentially an RCT of the Apple Watch where we’re prospectively enrolling 150 patients undergoing cardioversion for AFIB. They either get an Apple Watch or they get a Withings watch without any activity. That’s just an activity tracker without an EKG and abnormal rhythm notification feature. We’re enrolling patients at Yale Duke in the Mayo Clinic. We have about 40 patients enrolled thus far. Our primary endpoint is the Global Score questionnaire essentially at A-fib quality of life.
we’re following up patients over a year, including additional prompts for anxiety. Other measures of health care utilization, as well as cagey accuracy. And then last, I just want to note this one this project we’re doing in collaboration with numerous investigators associated with copper, the cancer outcomes public policy and effectiveness Research Center led by Carrie Gross, Sarah McLachlan and Scott Huntington. Where we’re quantifying a physical function in cancer patients undergoing chemotherapy using a clinician,
00:22:26.170 --> 00:22:27.658 reported patient reported and
00:22:27.658 --> 00:22:29.146 wearable device data sources.
00:22:29.150 --> 00:22:31.606 This is done being done through our Searcy.
00:22:31.610 --> 00:22:33.106 The FDA funded center.
00:22:33.106 --> 00:22:35.350 We’re doing it directly with collaborators
00:22:35.416 --> 00:22:37.546 at the oncology Center of Excellence,
00:22:37.550 --> 00:22:40.826 a prospective study of 200 cancer patients
00:22:40.826 --> 00:22:42.810 undergoing frontline cytotoxic therapy.
00:22:42.810 --> 00:22:45.505 Rolling patients at Yale and Mayo Clinic,
00:22:45.510 --> 00:22:46.874 100 solid tumor patients.
00:22:46.874 --> 00:22:48.579 Breast cancer patients stage one
00:22:48.579 --> 00:22:50.230 through three, as well as a hunt.
00:22:50.230 --> 00:22:52.636 100 high grade B cell lymphoma
00:22:52.636 --> 00:22:54.755 patients and our primary endpoint is
00:22:54.755 --> 00:22:56.470 physical function over nine months
00:22:56.470 --> 00:22:57.996
that’s being measured weekly for two months and then monthly again, all leveraging the Hugo platform for measurements with patient reported outcome measures. Clinician reported outcome measures to the E COG performance measurement. The six minute walk test at baseline and at the at the end of two months and then again later on, as well as activity measured as every patient, has a daily Fitbit to measure daily steps and again part of the purpose of this is to work with the FDA to to better understand a physical function.
as a surrogate measure of recovery.

Compare these data sources identifying change thresholds and inform the way the FDA thinks about.

Of these measures, as part of clinical trials,

so I will stop there and I hope that if anyone has questions you can follow up.

But thanks for the time, show me.

I’ll stop sharing.

Thank you very much Doctor Ross for this very informative presentation.

Renee, I was wondering, do we ask people to raise hands?

I’m not sure how this is really handled.
Oh, post your questions in the chat.

I do have a question as we’re waiting for others to pitch in.

I wonder when you submit work for publication.

Is it subject to more scrutiny because it’s not the traditional trial that people are used to?

Yes, there’s a lot of explaining going on when we know when we’re putting these papers together and even just proposing them for funding right now, as people kind of question like,

well, how is this done?

I don’t get it. You know, how are you pulling in these data sources?
But when you talk to people who are clinical trialists and explain the difference in the approach and the efficiency that comes with it and the kind of trade offs that are always happening in any clinical trial, you know how much more information. People see. Ah, I get it now. There's a great promise to this, and it's not to say that that
we’ve worked everything out,

but I feel like we’re kind of pilot
testing new ways to do trials like this,

which I hope are going to,

you know,

be useful and informative and and

and set the stage for the future

so it doesn’t need to be kind

of an all or nothing either.

Do a kind of a traditional clinical trial.

Bringing patient back every couple of

weeks for kind of standardized assessment,

or we’re doing observation,

ULL data source and data analysis.

There’s there’s kind of a middle Rd.

I do see there was one question
from Doctor Boffa on how to handle contradicted data from different sources, and that’s an interesting challenge, right in the sense of you know, how do you if you see, you know essentially prescription data in the electronic health record at Yale, but not in the pharmacy data and how to understand that. And some of it is about understanding the various functions that are used for the data sources. Right?
at a pharmacy so that it’s at.

It actually gives you a sense of you know, adherence, like our patients going and filling their prescriptions. But other times you know if there’s you know, particularly for the the physical function we’re going to have to decide exactly what does it mean. If different you know, patient reported outcome measures or clinician reported outcome measures do not align.

I see Kerry Gross asked a question around thinking about ways to adapt the EHR and its interface.
in order to be more proactive in terms of making information like this more readily available. And I, I couldn’t agree more. Some of the challenges and part of the reason why we’re using survey questions out to patients is because it’s not, uniformly collected as part of the HR and then extracted and available to investigators who are leveraging health system data for research or for you know, to inform clinical practice. The more structured data we think
about embedding within our reach are the better the data are going to be, the more it’s going to allow us to use kind of actually more typical observational data resources for research. One of the things when and when I presented that project done by the medical student who identify that only 15% of clinical trials could actually be routinely or fees abli done today using routinely ascertainable information. Part of it is because. Like patient reported outcome measures are not routinely included as part of structured data elements, so there’s a real opportunity there.
And then I’ll the last question. I see is about addressing self selection bias in our data. I think what Doctor Hooley is referring to is the participation bias that individuals are going to be more likely to participate in the study. And that raises an issue of bias. I don’t think that the selection into our studies is different any different than the selection of any individual into a clinical trial, but hopefully ideally by lowering the barriers to participation and making it easier on patients to participate by.
By diminishing that burden of kind

Using this this type of approach may be

more representative of clinical practice,

although that’s that remains to be seen,

and it’s an important issue

for us to address so.

I’ll stop there so that Susan

Bush has plenty of time to

go through her presentation.

Thank you Joe.

It is my pleasure to introduce our

next speaker, doctor Susan Bush,

who is Professor Public House in House

Policy and professor in the Institution

for social and Policy Studies.
She received a master degree in House policy in a PhD in House Economics. Those from Harvard University. A number of us have been lobbying for her to join the Cancer Center and very happy when she did recently. Doctor Bush’s research examines the effects of policies and regulations on health care, cost and quality, and she’s a renowned and highly respected expert in this field today. Her topic is insurance coverage, mandates and the adoption of digital breast Tomo synthesis. Doctor Bush for as yours.
OK, thank you. Thank you so much Johnny for inviting me. I just wanna make sure. Can you see my slide show it's working? Some show me you can see my slideshow. Yes, OK perfect. So first, for those of you who don’t know me, I’m a health service researcher and health economist, and I teach at the Yale School of Public Health. I teach advanced health economics here, and most of my work is really around mental health and substance use disorder with a focus on access to care and how we can optimize benefit design to increase the value of the healthcare system.
So I sort of took my knowledge about those issues and now I'm applying it to cancer. Generally I'm interested when you think about is as we change payment mechanisms. What are the impacts on access to care, cost of care and value? And it's always really tough to get at that. You know idea of value, but I really do strive in my work to do that. So if anybody has any problem related to that, I would love to meet with them. I also have several projects related to tobacco control that people that
might be of interest to people.

I’m not going to go into detail here about those,

but if you’re interested I would love to meet with you and talk about that.

So over the past several years wanna say it’s really been a delight to get to know the faculty at the Cancer Center both at the medical school and also here at the School of Public Health?

So in particular, I want to mention Carrie Gross, who invited me to work with his team a couple of years ago and has really taught me a lot about both breast cancer screening and about...
00:31:45.961 --> 00:31:48.367 how to use health care claims.

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

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

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

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

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

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

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

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

00:32:05.510 --> 00:32:07.568 and I can’t emphasize enough how

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

00:32:09.339 --> 00:32:11.325 the opportunity to work with her

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

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

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

NOTE Confidence: 0.79118421125
in a series of papers related to breast cancer screening related to issues around patient preferences, diffusion of new technologies and cost.

And you know, this paper is not really focused on value, but also a lot of our papers are focused on that. So this paper has not yet it’s been accepted for publication at that not out yet, but we’re thinking it’s going to be out even in just the next couple of days, so.

OK, so these are some our collaborators, my collaborators, on this paper. 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
cancer screening has undergone substantial
NOTE Confidence: 0.938326144285714
00:33:05.180 --> 00:33:08.067 technological shift in the US in
technological shift in the US in
NOTE Confidence: 0.938326144285714
00:33:08.067 --> 00:33:10.029 which digital breast tone was insist.
which digital breast tone was insist.
NOTE Confidence: 0.938326144285714
00:33:10.030 --> 00:33:12.910 DBT has supplanted standard 2D2 dimensional
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.
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
Advantages of DBT are that
NOTE Confidence: 0.938326144285714
00:33:19.235 --> 00:33:21.367 DBT may reduce recall.
DBT may reduce recall.
NOTE Confidence: 0.938326144285714
00:33:21.370 --> 00:33:23.826 That is that fewer women are called back
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,
for additional testing after screening,
NOTE Confidence: 0.938326144285714

65
and also that it may improve sensitivity

NOTE Confidence: 0.938326144285714

that we may identify more breast cancers

NOTE Confidence: 0.938326144285714

using DBT compared to 2D mammography.

NOTE Confidence: 0.938326144285714

Yet DBT is still not rated A

NOTE Confidence: 0.938326144285714

or B by the US United Service.

NOTE Confidence: 0.938326144285714

United States Preventive Services Task Force.

NOTE Confidence: 0.87287372

This map is from an earlier paper,

NOTE Confidence: 0.87287372

so just to get a sense of the

NOTE Confidence: 0.87287372

variation in DBT adoption, this paper

NOTE Confidence: 0.87287372

looks at hospital referral regions,

NOTE Confidence: 0.87287372

so the different geographic regions you can

NOTE Confidence: 0.87287372

see here are hospital referral regions,

NOTE Confidence: 0.87287372

and we look at three years of data

NOTE Confidence: 0.87287372

from 2015 to 2017 and over this time

NOTE Confidence: 0.87287372

period over the US in the US over the

NOTE Confidence: 0.87287372

whole USDBT increase from 13 to 43%.
Of screenings, so this looks very specifically at trajectories, and we know by the end of 2017 the lowest use HRR’s hospital for regions are about only about 4% of screenings where DBT, well, the highest where it was at 68% of screening. So there really is significant variation. So related to insurance coverage really today we’re talking about private insurance coverage. And private insurers are not required to cover DBT, and that’s because it doesn’t have the A or B recommendation by the USPSTF.
So absent a federal mandate, many private insurers didn’t immediately cover DBT characterizing it as elective, or citing that there might not be long term data and states got involved. To date, 17 states have enacted laws that require private health insurance cover DBT. Without any cost sharing, so of course self insured plans are not covered due to the ERISA exemption, but generally privately insured individuals and women in these states do not have to. 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
burden and also to facilitate access to important health services.

However, you know these types of benefit mandates have have been criticized by some because they may have some complex effects. Potentially, if you mandate may contribute to higher insurance premiums and thereby this may increase uninsurance rates as if insurance premiums get prohibitively expensive. There's been some criticism that they may reduce plan design, plan benefit, design, flexibility. And also that increasing the price of the specific of a specific mandated
service may reduce negotiating power and this is going to be particularly problematic for a service or a drug, potentially where they have the supplier has some monopoly power.

So our goal in this paper was to evaluate the relationship between DBT coverage laws. The 17 laws that I noted in the last slide and DBT use the last slide and DBT use DBT out of pocket payments, and also DBT price. So to study this, we use data from Blue Cross Blue Shield access data set, which is a deidentified database.
There are claims from all 50 states, so the geographic diversity of this sample, along with the fact that has a longitudinal structure so you can follow patients over time. It makes it really well suited to evaluate policies that vary by state. Within this data set we identified screening. Mammography is performed among women ages 40 to 64 between January 2015 and July 1st up through June 30th, 2019, and we have a standard validated algorithm that we’ve been using to identify a screen mammography.
in this talk, so we did exclude women 65 and over, and the reason we did that is because Medicare is not really represented in these data or Medicare Advantage as well, and we felt that. Older women that were then included in the BCBS data might be highly selected. So we use the patient level data to describe the characteristics of the women and mammograms, including the study. But when we do our additional analysis, our event study design, we perform it at the state level.
That is, we collapse cells to the state. We aggregated data to the state and six month period and use the data in that way. So the exposure that we're interested in this study was a legislative mandate requiring a whether the patient lived in a state that had a legislative mandate requiring coverage of DVT during the study period. All states included as mandate one year after passage of Connecticut, which eliminated cost sharing one year after passage of
the general coverage mandate.

So in these laws when we say cost sharing, these are including out of pocket payments towards deductibles, coinsurance or coherence similar to what the ACA law would have is for services that are rated A or B. The control states were states that did not pass a mandate during the study period. And we assigned mammograms were assigned to a state based on location of the billing provider. So, as I noted, the outcomes we looked at were DBT. Use the proportion of screening
mammograms performed with DVT among all screening mammograms for estate in a six month period.

So DBT is many people, probably know is typically read and built in conjunction with standard 2D imaging, so we consider DBT to have been performed when there was a claim for DBT in conjunction with a claim for screening mammography.

We looked at the proportion of women with any out of pocket payment. We did also look at the mean out of pocket payment,
So today I’m just going to present results on the proportion that had any out of pocket payment. This is people, women that had out of pocket payment. We only looked at those with DVT because women screened with 2D mammography already had no cost sharing which is mandated by the Affordable Care Act.

So we used an event study design which estimates changes in an outcome among states that pass a law relative to states that did not. At each six month interval.
after law implementation. So this specification allows for the effective laws to vary by the time since implementation. So basically what you do in event study design is you line up the implementation dates and look at whether there are changes in our outcomes in the first six months post implementation. And this also has the advantage of. It allows you to see if there were changes in the six months prior changes in any
different difficulty level, and models were weighted by the screened population in each state. So this table represents our patient characteristics and outcomes at baseline, so we also are not so for outcomes, it is the outcomes at baseline, so.

Right, OK at the start of the study period, women and in mandate and non mandate states had similar age. Mean age was 53 in both among women in mandate states 42% lived in the northeast versus 12% in the non mandate states. In early 2015, women living in states that eventually pass a DBT coverage mandate 16%.
Of women who underwent mammography versus among women living in states that never passed a mandate, the screen was a little bit lower in states that never passed a mandate. Note, this is before the mandate, though important to our study.

Really very few women in 2015 had any out of pocket payment for DVT only 7% in both mandate and eventual mandate and eventual non and non mandate states. You can see that the DBT price was higher than the mean 2D price.
$311.00 versus for two D $266.

Pre mandate.

So next we look at DBT, use and here’s our first outcome that we look at.

So let me Orient you 'cause the next couple of slides all have the same sort of framework as this slide.

So this shows the percentage point change in DBT use in the period before, and the period after the law was implemented relative to states with no law implemented,
which is our comparison group.

So by construction,

the value for the period in which

because you're sort of normalizing

So first thing to look at is if you look

at the three periods that we can measure

here in the period prior to the law,

you see that there was no significant

effects of eventually passing a law.

We find no significant changes in DB use, D.

Use relative to the comparison test.

So this is really equivalent to

the standard parallel trends,
00:44:21.710 --> 00:44:23.411 test apparel pre trans test that you

00:44:23.411 --> 00:44:25.708 see in a different different analysis

00:44:25.710 --> 00:44:28.059 in the periods after the law we do see

00:44:28.059 --> 00:44:30.256 you can see a steady increases in.

00:44:30.260 --> 00:44:32.318 Mandate states relative to other states.

00:44:32.320 --> 00:44:35.152 So by one year post law these differences

00:44:35.152 --> 00:44:36.640 are statistically significant.

00:44:36.640 --> 00:44:38.290 One year after enactment of

00:44:38.290 --> 00:44:39.280 a coverage mandate,

00:44:39.280 --> 00:44:44.110 DBT use increased 7.6 percentage points.

00:44:44.110 --> 00:44:45.418 Relative to other states.

00:44:48.180 --> 00:44:49.590 Compared to states without a mandate,

00:44:49.590 --> 00:44:52.020 I’m sorry 7.6% greater than states

00:44:52.020 --> 00:44:54.560 without a mandate, and after two years,

00:44:54.560 --> 00:44:56.981 D BTU’s had risen 9 percentage points
more in mandate states compared to states that did not pass mandates.

Next we look at DBT price. And so it’s the same format I noted before from our patient characteristics table, the average cost of a DVT was $311.00 among maintenance performed in states that eventually passed a mandate and $347 states that did not pass a mandate. And here we find that two years post mandate and this was a surprise to us. DBT Price had declined in mandate states compared to the change in price in nine non mandate states about $38.00 and I don’t have a graph here to show it. 'cause we have limited time,
but we also did not observe. A significant change in the price of 2D mammography.

Next we look at weather. Here it is. At the percent of DBT DBT exams with any added pocket payment. Among women’s group with CBT and we found that even at the start of the study, only a minority of women had any out of pocket payments with DVT. We did not observe a statistically significant change in the proportion of women who had any out of pocket payments for DVT even as we go to two years post mandate.

We did also look among those that
did have an out of pocket payment.

The mean out of pocket payment and we did not find a statistic statistically significant change there either.

So. A central policy objective of the coverage, mandates or any coverage mandate is to ensure access to a particular medical technology or service by protecting patients against financial liability, and indeed, our results suggest that women in states with coverage mandates were more likely to begin to use DBT for breast cancer screening, which probably is one of the intents of the law. And this finding is consistent with other
studies across other types of services

that found that expanding coverage,

and in particular eliminating cost sharing,

can increase the use of

specific cell health services.

I’ll say it’s very difficult in many cases

to get patients to change their behavior,

but changing even by very small

amounts they have to pay is one way you can get them.

Generally,

the literature is found to

change their behavior,

but in our study this really

raises some new questions about the
mechanism by which mandates.

May increase use of an emerging technology because we didn’t find changes in out of pocket payments and even before these mandates, the out of pocket payment was low, so it’s unlikely that a change in what the patient had to pay is what led to these changes.

So one explanation for these findings is that by ensuring payment coverage, mandates may have encouraged radiologists and other health care institutions to enter the market. And offer DBT and this may have led to a relative price in at least two ways.
One when more radiologists offer DBT, insurers really may have greater ability to negotiate lower prices and this could lead to lower prices or at least slower growth in prices over all providers.

Second, it could be the case that early entrance in this market would expect the early entrance in this market.

When DBT first started to be providers that have higher prices.

So for example, academic medical centers, if mandates incentivize new entrants who tend to offer services at lower prices.
compared to established providers,
the average market,
the average price in the market
will decrease mechanically,
so you have a high price pipe,
high price providers, low,
lower price providers,
the average is going to go down.
But in that scenario,
no provider has actually changed their price,
right?
But the the price that is paid
in the market will decline,
so other explanations are possible.
For example,
it’s possible that coverage mandates
might be perceived by patients or others as an endorsement of this service.
And this could increase interest in this new technology, so we can’t say for certain that this is one of the two things that is happening. Unfortunately we don’t have a provider identifier in our data that would allow us to say whether it is. Different lower price providers entering the market. Hey, I think we need to note some limitations to the paper, so there definitely could be some issues with generalizability.
Since all data was from Blue Cross, it is really really good data to look at these this study because it is from all 50 states in a very large data set. Also, there are important known limitations to using claims data. Claims could be subjected to error or bias. Another issue with this very particular setting is our approach focused. We chose to look at the price of the initial test rather than the screening episode. In some of our papers we have looked at the screening episode, but you know that could be very very different here.
If DBT does reduce recall and that could lead to additional cost savings from for DBT relative to 2D mammography. Also this was an observation ULL study. Although we believe we used to study design that intended to limit confounding, unmeasured confounding is always a possibility and could explain some of our findings. Could be you know other concurrent legislative policies or other things going on in the market. Finally, although our event study plots didn’t show significant differences in DBT user price prior to the law being enacted,
It's important to acknowledge that pre-period trends in DBT use or cost and mandate states may influence our results. So there could be some pre-existing trends. Although DVD mandates were associated with an increase in DBT use, they were not associated with any change in out of pocket payments and this suggests that mandates and this has implications for other services, well, may influence DBT adoption through mechanisms other than by reducing financial liability for patients. Thank you Susan for a great presentation that clearly damn straight close link
00:51:28.850 --> 00:51:31.390 between policy and clinical practice.

00:51:31.390 --> 00:51:34.840 I was wondering whether there are studies being planned by you or others to potentially look at the impact of DBT of identifying more patients.

00:51:42.302 --> 00:51:44.964 I was thinking that eventually, if there’s evidence that DBT would identify more patients because increased sensitivity, that more B might be more incentive for more states to have similar laws mandating it.

00:52:02.490 --> 00:52:04.446 When you see identify more patients, are you saying that some people that previously didn’t get a mammography
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
00:52:40.423 --> 00:52:42.810 it or may start implement, you know?

00:52:42.810 --> 00:52:46.250 Start putting in some out of pocket payments.

00:52:46.250 --> 00:52:48.280 Yep. You know, I think,

00:52:48.280 --> 00:52:51.696 why would a state not pass a mandate?

00:52:51.700 --> 00:52:53.408 You know they may be looking to

00:52:53.408 --> 00:52:54.702 the evidence and maybe looking

00:52:54.702 --> 00:52:56.480 to the USPS TF if they’re thought

00:52:56.480 --> 00:53:00.108 they still have not gone up

00:53:00.108 --> 00:53:02.070 to the ARDA or B rating,

00:53:02.070 --> 00:53:03.310 suggesting there probably there

00:53:03.310 --> 00:53:05.258 may be still some uncertainty.

00:53:05.260 --> 00:53:06.910 Right in in the studies,

00:53:06.910 --> 00:53:10.438 so that’s why you might not mandate the

00:53:10.438 --> 00:53:14.370 reason that you you know or also because.
00:53:14.370 --> 00:53:16.323 It’s not really clear that there’s a problem since people are not paying large out of pocket payments for this service.

00:53:16.323 --> 00:53:20.210

00:53:21.840 --> 00:53:25.614 Sure. Yeah, because the laws are at the state level and and the US preventive taskforce hasn’t made a ARB recommendation.

00:53:25.614 --> 00:53:29.618

00:53:29.620 --> 00:53:32.000 I think that could be where states are looking for.

00:53:32.000 --> 00:53:34.380

00:53:34.380 --> 00:53:36.138

00:53:36.138 --> 00:53:37.310

00:53:39.800 --> 00:53:40.300 Yes.

00:53:40.300 --> 00:53:44.848 Am I supposed to look for questions?

00:53:43.420 --> 00:53:44.848

00:53:47.990 --> 00:53:51.560 Right? Please feel free to.

00:53:51.560 --> 00:53:53.868

00:53:57.730 --> 00:54:00.888 Oh, here’s Regina. Thanks so much, Susan.

00:54:05.840 --> 00:54:08.576 OK, so Regina Hooley just has a comment

00:54:08.576 --> 00:54:10.778 that Yale they first started using
DBT in 2011 and they didn’t charge patients for insurance for many years. Probably not until 2018. So I think Medicare did start charging to 2:15 till 2015, so I think few private insurers. Maybe we’re charging before that. I think a lot of I think there wasn’t even a code until 2015 to allow people to charge. But that is great that Yale was able to do that. So what are the follow up?

Studies that that you are carrying Studies that that you are carrying your team is planning. I know Alana
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
00:55:45.525 --> 00:55:47.022 I said to Kerry, what’s up with this?

00:55:47.022 --> 00:55:48.340 You know what’s going on this is,

00:55:48.340 --> 00:55:49.544 you know, many years ago and I

00:55:49.544 --> 00:55:50.920 said this is so interesting that

00:55:50.920 --> 00:55:52.000 they’re doing this mandate.

00:55:52.000 --> 00:55:54.261 Let’s write a grant and we ended

00:55:54.261 --> 00:55:56.598 up writing a an ACS grant that

00:55:56.598 --> 00:55:58.536 was funded to do this work.

00:55:58.540 --> 00:56:00.166 And then Alana gotten bored and

00:56:00.166 --> 00:56:01.470 we sort of extended it.

00:56:01.470 --> 00:56:02.388 It’s a DBT,

00:56:02.388 --> 00:56:04.952 so it really did start out as this

00:56:04.952 --> 00:56:07.644 just sort of kind of very random thing

00:56:07.644 --> 00:56:09.288 that people just sort of talking.

00:56:09.290 --> 00:56:11.642 It’s funny that Joe is here about

NOTE Confidence: 0.95838618

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this and ended up being this project
so that project has ended now
so that ACS project has ended.
So we’re really thinking about what
would be the the best next steps and
what are the most interesting questions.
So I think Regina probably has some
good ideas so she’s sort of been
involved in this so we we haven’t
sort of gotten to the next project.
We’re sort of finishing up the
the old project right now.
The older project.
The older project.
There’s a comment from Carrie
if you could address briefly.
I’m not sure that state
legislatures would look at that, but I do think like that. The advocates when you, if you say you publish something that suggests that they’re really good benefits to passing a law, I think that the the advocates may bring that to state legislatures and that can be very helpful. Especially, I do think like some of the earlier studies showing that state laws around mammography. This is pre ACA and cost sharing that those actually you know led to more movies and potentially had some interest.
some effect.

On breast cancer identification?

Not necessarily.

I don’t know if they ever got to mortality, but I think those did have an impact.

Those studies.

And there’s one more from Alana.

Yes, so a lot of notes and I that

these implications have other firm

or other emerging technologies.

So to thinking about how that

will adopt that, how that those

influence adoption and price.

Thank you so much Susan for taking

the time to share with us your

important work. Also thanks to Joe.
Help you both have a nice day. But by.