00:00:00.030 --> 00:00:19.780 When was that she had this additional work sort of a separate life working in implementation science? Which is such an important area. Now I think across Medison in general, but certainly in Cancer Research and so we've asked Donna to share with us. Her ongoing work and implementation science, O'Donnell welcome.

00:00:21.450 --> 00:00:24.070 Thanks very much traveling.

00:00:24.910 --> 00:00:53.360 And I thank you all for being here. It's a pleasure to be here and to be able to discuss this topic with you all so I imagine that implementation science probably what I was going to start out by doing is just giving it over all introduction to basic concepts, which is kind of at the whole other end of the Cancer Research spectrum.

00:00:54.150 --> 00:01:20.390 This might be a little better, yes, so at the whole other end of the Cancer Research spectrum than our previous speaker. Andrew, who was talking from the basic science send so here's a cartoon that kind of embodies what implement what motivated research and implementation science. It says here the latest.

00:01:20.920 --> 00:01:52.230 Wait, a second the latest research shows that we really should do something about all this research and what we mean by this is this is a very famous slide in implementation science. It's called the publication pathway and it shows that this is sort of the Cascade from when say original research is funded then submitted accepted published appears in a bibliographic database is taken up and reviews guidelines and textbooks.

00:01:52.230 --> 00:02:13.680 And actually implemented and I think it's something like going from here, uh when funded research is funded to hear when positive findings are actually implemented. It's about 14% of all research. It's been estimated that makes it from the research stage to the implementation stage and.
Um it takes 17 years to get from here to there with this 14% and so the NIH an MCI and many others have become aware of this in are very concerned that we’re sinking. All this money into doing all this great work but it never is making it into public practice the bedside. And so forth and so implementation science is about speeding this up and increasing this percentage.

So here uh another sort of phrase that’s coming in the implementation science well does the know, do gap and the idea is here that we know so much about how to prevent screen and treat say cancer. But yet the doing of it. There’s a big gap between that knowing Anne that doing an SO3 big examples and cancer. It’s been found in randomized trials that.

Probably more than 50% of colorectal cancer mortality is preventable by following the US Prevention task force recommendations for screening as I’m sure many of you know, probably 90% or more of cervical cancer is preventable through regular screening. Bipap or other modalities followed by effective high quality treatment of abnormalities and or by HPV vaccination and 90% of cigarette smoking is I mean?

That should say actually 90% of lung cancer is preventable by eliminating tobacco use get deaths from these 3 cancers are widely prevalent in the United States. At least color rectal and long are among our Top causes of cancer incidence and mortality and cervical cancer is the first or second, leading cause of cancer incidence and mortality in most low and middle income countries around the world in Africa, Asia and Latin America so.

This is why we say an implementation science. We have these very simple proven interventions that could eliminate most of these cancers. Yet these cancers are still a leading forms of cancer incidence and mortality, so implementation science rather than more sort of basic science research could be used to address many of these problems. Another example that’s important is obesity.

We have basically a global obesity epidemic, which is I’m sorry, which is leading which is leading to Sky. Rocketing rates of diabetes. Cardiovascular disease and cancer in the USN worldwide. So MCI regards. We usually think of obesity as you know the leading cause of diabetes and then somewhat to a lesser extent cardiovascular disease, but many of you probably know it’s also strongly associated with colorectal cancer endometrial cancer.
And possibly other cancers on NCI does regard they prevention and reduction of obesity as something well within the realm of what it’s interested in from an implementation science perspective and otherwise and yet, there’s been again proven interventions. The lifestyle interventions that have reduced diabetes incidents through primarily obesity reduction by 58% in the US 29% in India.

And 42% in China and just again to mention that the obesity epidemic is not just a problem here in the United States, where it’s a very big problem, but it’s also a skyrocketing problem throughout Latin America and China, India and other places in the world.

So what just to be a little more specific what do we mean by implementation science so multiple definitions have been given and there? Is no one single definition that is universally agreed upon. That’s sort of correct definition, but they’re all pretty much getting at the same underlying ideas, which are systematic scientific approach to ask and answer questions about how to get what works to people who need it with greater speed.

Fidelity efficiency quality and relevant coverage and then down here isn’t even simpler definition that I like a lot implementation. Science is about determining what works in real life full scale settings and I’m going to elaborate on this a little bit and then it following few slides so here again is the implementation research definition. This is from a standing program announcement from the NIH dissemination. Implementation research in health.

Where they say implementation research is the scientific study of the use of strategies to adopt and integrate evidence based health interventions to clinical and community settings in order to improve patient and population outcomes and now the field has kind of evolved so that often and it certainly from an NIH perspective. They don’t just even say implementation science. They say dissemination implementation science because it seems that it’s not just enough to be able to.

Study how to do these things to adapt and integrate but it’s also being able to distribute those and increase the uptake at a large scale and an research how that can happen. So there’s this sort of sister area to implementation research called dissemination research.
And so they’re talking about how to spread and sustain knowledge and associated evidence based interventions well beyond sayeth. The study population on which an implementation research project might be conducted.

So this is the way that I kind of think about this so we know actually even before this might be some of the work that Andrew is showing in many other people here, probably which is the basic science piece, but once we get to a point where there is some kind of intervention. The first thing that usually happens is an efficacy trial so that’s usually an individually. Randomized controlled trial were very familiar with those a great deal of Biostatistics is focused on.

The design and analysis of our cities and they’re usually done in sort of under the very best circumstances. Can we demonstrate the biological efficacy of a particular drug or treatment or intervention of some kind, then the next step would be what we might call and effectiveness trial and effectiveness trial. Sometimes they’re also called pragmatic trials, you might have heard that term and from my perspective.

Effectiveness trials and pragmatic trials are very similar if not the same thing and they’re usually done at a much larger scale than efficacy trial. There are usually cluster, randomized, so facilities. Hospitals clinics practices communities villages would be randomized, rather than individual patients and they’re usually done with much less stringent exclusion criteria.

Open to the whole population open to practitioners and providers who are not necessarily at sort of elite institutions such as here, but could be throughout the community and that’s to assess whether these efficacious interventions can actually shown to be effective kind of in real life settings and often times as many of you might know were disappointed in that efficacious interventions aren’t shown to be effective.

In large scale community based settings.

Um in terms of policy and adaptation cost effectiveness is also an important aspect of this, oftentimes there could be alternative interventions and maybe 1 is has been shown to be somewhat more effective, but it’s much more expensive and it might be that the overall population health
could be better improved by choosing a swim lot less effective intervention that could have much wider distribution so.

NOTE Confidence: 0.922320485115051

00:11:01.870 --> 00:11:32.960 You can see that once I say cost effectiveness. You can see that implementation science becomes an interdisciplinary field. It doesn’t just here we might be talking about clinical people. Basic scientists and bio statisticians, but now we’ve brought in health economists as well. ’cause they’re the ones who have the expertise in cost effectiveness. So we’ve added a whole. Other discipline to that aim ineffectiveness trials usually the candidate intervention.

NOTE Confidence: 0.9357008934021

00:11:32.960 --> 00:12:04.110 Is compared to standard of care or some kind of placebo or control but once the intervention passes the effectiveness and cost effectiveness test we would move on to implementation research so an implementation research. We don’t have a control group anymore, which standard of care is in part of the equation. We’re actually comparing alternative strategies for rolling out proven interventions.

NOTE Confidence: 0.918774425983429

00:12:04.110 --> 00:12:35.450 To ensure that they are taken up at scale with wide coverage, etc. And so we might be comparing. I’ll show some examples option B. T ord implementing a certain intervention and then finally once the optimal strategy is found through implementation. Research then the question is how to disseminate this and get it out widely across the entire population so these coming down from here to here to here.

NOTE Confidence: 0.929320275783539

00:12:35.450 --> 00:12:45.880 Might be things that maybe some people in the audience haven’t really thought about before but this is where This Is This is the space that implementation science sets.

NOTE Confidence: 0.902340531349182

00:12:47.070 --> 00:13:17.680 So there are certain features of implementation and dissemination science research that have that are somewhat different from say advocacy research and some of the antecedents to that, so there are things that I’ve had to learn about as I’ve moved into this implementation science world, so the first thing is theory, driven so because we’re talking about.

NOTE Confidence: 0.932274699211121

00:13:17.680 --> 00:13:48.570 Uh alternate strategies for uptake of proven effective interventions. It involves aspects of human behavior. Health systems organizations financing and so forth and by by bringing in the social scientists. They operate from sort of more of a theory driven perspective, where they have different theories of behavioral change an organizational change.
In conceptualising implementation and dissemination research, it’s considered very important to have these theories featured kind of first and foremost in terms of guiding the design of the interventions. Another aspect of the research is something called mixed methods research again. If we’re concerned about say, why did it take 17 years to get from doing this research to actually having it implemented on a wide scale?

There are all sorts of barriers that might be superstitions. There might not be the right equipment in the facilities. The providers may not be trained properly, there might be certain trepidations that patients have and there’s a certain point at which quantitative data has its limits. And it’s necessary to actually talk to people and talking to people is the realm of social scientists and they actually have.

Very well worked out their own rigorous methods for conducting what’s called Qualitative research which involves talking to people in groups or one on one recording the conversations that are structured in certain ways transcribing the data, analyzing it and so forth and when we use qualitative methods along with quantitative methods in implementation research. It becomes mixed methods research and that’s an important aspect of.

Implementation science in general, another aspect is adaptation versus Fidelity. So when we when I talked about implementation and dissemination here it might be that in a complex intervention, one size may not fit all? What works in a rural health clinic in northern Maine might not work in the center of the city of New Haven, even though we want to basically sort of get everybody who’s.

Eligible to be screened every 2 years for colorectal cancer starting from the age of 50 how we reach out to people bring them in follow up with them and so forth might vary quite a bit and that’s called adaptation. If you adapt these interventions to the local context. An implementation science. It’s generally believed that context is very important on the other hand, you don’t want to change things too much. Otherwise, we’re just talking about a whole new intervention.

So maybe hasn’t been studied at all, so this is
sort of an active area of implementation science, which is at what point does adaptation straight into infidelity and there’s not a right answer to that either. It’s something actively discussed. They’re working groups about it. People writing about it and so forth, but one very least, there’s general agreement that adaptation should be systematic sort of well thought out well recorded with good data on.

NOTE Confidence: 0.931524276733398

00:16:57.190 --> 00:17:27.200 What the adaptations were so that later on if things don’t work as well or they work better it might be possible to use a quantitative methods or even qualitative methods to understand what? What aspects of the adaptation were either useful or not so useful OK. So I talked about context in relation to adaptation versus Fidelity. And then of course, there’s the question of external validity, which is somewhat related to.

NOTE Confidence: 0.929645955562592

00:17:27.200 --> 00:18:02.210 Maybe a possible issue with translation of the results of efficacy trials to effectiveness and beyond in that when there’s a lot of exclusion criteria and only sort of the very best. Doctors and health providers are rolling out the intervention is will these results be externally valid sort of wider groups and in general. It’s often been found to not be the case so implementation science scientists are very interested in the subject of external validity.

NOTE Confidence: 0.941650092601776

00:18:02.210 --> 00:18:06.950 How to design studies to increase their external validity?

NOTE Confidence: 0.925031065940857

00:18:07.840 --> 00:18:38.550 I mentioned economic evaluation and cost effectiveness sustainability, you can come up with great ideas. You might show that they are effective in a certain context with a lot of resources even still you know funded with research dollars, but is the intervention sustainable beyond that. Once the researchers go away will people keep doing this and how and then finally diffusion for effective interventions.

NOTE Confidence: 0.933914601802826

00:18:38.550 --> 00:19:06.300 It’s of great interest to see how do these spread there can be active and passive ways of spreading there’s such a thing as a certain types of index providers or index. Members of an intervention who could be very effective in sharing the benefits of the intervention to their peers whether they’re professional pairs friends, family and neighbors and these kinds of things can be incorporated into interventions.

NOTE Confidence: 0.929093420505524
So hybrid designs is another important concept, and implementation research, especially for those who are interested. In designing implementation. Science studies and submitting them for funding because it’s actually shocking and very hard for a lot of us myself included. Although I’ve now gotten used to it that if you’re if you’re designing a pure implementation trial. There literally should not be a control group it’s really about.

In comparing alternative ways of implementing a proven intervention and if a control group is added. Then it starts to be called something like a hybrid type. One design and by hybrid they mean. It’s hybrid between an implementation study and and effectiveness study and so in a hybrid type, one design. We’re still testing the clinical intervention that is comparing it maybe to some sort of control or standard of care but we’re also gathering information on the implementation.

And then a hybrid type 3 design is sort of at the other end, where the focus is on process outcomes like? How many people were screened what was their satisfaction with the process and so forth and we’re not if the cancer was prevented or treated that would be a secondary outcome at best, and then that becomes a hybrid type 3 design, whereas a pure implementation study wouldn’t even look at health outcome at all, it would only evaluate.

Improvements in the uptake of the proven intervention with no health outcome and especially let’s say the National Cancer Institute has a lot of interest right now and implementation science whole program on it, and when I’ve seen this myself first hand when grants or written and people don’t understand. These distinctions, they end up getting dinged because there are people there who really know this stuff and you can’t say you’re doing implementation science and then have a

Primary clinical outcome compared to an intervention versus control. They would say this is not implementation science. So it’s good to know about these things here in terms of the models and frameworks, there, so this is a website where you can actually you can. There’s many, many of these social science theories of behavioral change and frameworks for change and this website.
I don’t recommend this approach. I recommend anytime you’re basically doing implementation. Science research a social scientists really needs to be involved, and preferably one who has some background in implementation science.

NOTE Confidence: 0.939199209213257

00:22:18.150 --> 00:22:29.310 And they’ll know all this stuff and they’ll lend that expertise to choosing the right theory in framework and making sure it’s very well integrated into the research and so forth.

NOTE Confidence: 0.923115074634552

00:22:29.840 --> 00:23:01.810 Mixed methods, I already talked about that and there. There’s a whole sort of pathway in mixed methods where qualitative research can be conducted to understand barriers to uptake of a proven intervention than quantitative research could assess alternative implementation modes to improve process outcomes and health impacts. Qualitative research can be undertaken. While I’m going to understand Fidelity, meaning is the intervention being implemented as it should be.

NOTE Confidence: 0.937930643558502

00:23:01.810 --> 00:23:32.340 Acceptability to both those delivering it as well as those receiving it and feasibility and then at the end. Qualitative research to understand sustainability. An it’s very important. I think especially to have the ongoing qualitative research because there’s a lot of examples. Unfortunately, a failed prevention trials and implementation trials an A. Big study is run a lot of money is put into it. There’s no difference between the two groups.

NOTE Confidence: 0.927990643558502

00:23:32.340 --> 00:24:02.470 And nobody knows why and then we’re just kind of stuck even though the intervention was already proven to be efficacious in an individually. Randomized trial so we kind of know that it works. But something is happening in the implementation and at the community level. That’s leading to the failure and the qualitative data can be very useful in getting a handle on that, so we’re already at is this over at one so.

NOTE Confidence: 0.914504766464233

00:24:02.470 --> 00:24:40.010 Well, well well, I guess I’ll skip a lot of things like dissemination research as Charlie mentioned. I was brought into as the inaugural director of a new center at the school of public health see Maps. The Center for methods on implementation in prevention science and our focus is exactly that to develop methods refined methods and adapt methods to do this kind of work. It’s an interdisciplinary center. We have 3 faculty bio statisticians one.

NOTE Confidence: 0.906282603740692

00:24:40.010 --> 00:24:40.010 Another one in the audience here xinjiao, we have a faculty qualitative social scientists and.
Help wanted we’re still looking for our health economist. If anyone, knows of anybody who might be suitable with an interest in strengthening methodology for empirical cost effectiveness analysis and we have another a number of other affiliated scientists at different levels. And so forth so I guess I will skip this, I will well this was this is an example. I’ll just quickly show you so one of the things we’re doing is looking at the impact of the Affordable Care Act on reducing color rectal cancer incidence and mortality as you may know Cala colonoscopies or you know at a fairly pretty expensive prevention modality that before the Affordable Care Act. Many people weren’t covered for so basically weren’t getting them and now with the Affordable Care Act. Everybody is entitled to screening colonoscopies, according to the US preventive task forces guidelines. I think up to the age of 70, so we’re looking in the Kaiser Permanente of Northern California. Database is 4 million members were following people between 2000 and 2017. There’s about a million members. There, an 220 person months of follow-up and we’re looking to see before the ACA and then after was there a change in colorectal cancer incidence and or mortality, which could show at a population level and impact on the. Of the ICA so here’s a graph and this is just showing the monthly color rectal cancer. Incidence rates and then the ACA came into effect around here and then you can see that we see this drop in rates with a lot of the usual variability that we would have in monthly rates were also looking at the same thing in relation to mortality. So I’ll skip this, I’ll skip this uh and then I’m Charlie mentioned that I along with Yahoo Asian are the Co directors of the global oncology initiative of the L Cancer Center. We’re very excited about this and one of the things we’re doing to give you an example. We won one of the pilot projects this year on cervical cancer prevention. I pilot implementation trial in a pool and the Copia is sing kennisha through some of you might know from.
like we’re evaluating the implementation of the VI. A cryotherapy intervention among women’s age 30 to 60 and roll in a pool and then we say evaluate these are the things that are evaluated acceptability adoption feasibility Phil Fidelity penetration costs.

NOTE Confidence: 0.891916453838348

00:27:38.590 --> 00:27:46.490 And to Saint Sustainability and I don’t have time to go over how these are measured and then.

NOTE Confidence: 0.902062654495239

00:27:47.000 --> 00:28:17.010 Our 2nd is to do the qualitative research in focus group discussions with people at different levels of delivery as well as receiving excuse me. The intervention so global oncology where having a seminar series save the date were having Jorge Sal Marone from Mexico, who is an expert in cervical cancer screening and cervical cancer screening and treatment and then.

NOTE Confidence: 0.908895552158356

00:28:17.010 --> 00:28:44.230 Halibut feta, um associate director for global oncology at Mount Sinai and then we’re having a global oncology. Symposium on May 6 and of course, implementation science prevention and screening is going to feature prominently at these various events. But if anyone would like to work with us on the program committee for the Oncology Symposium. You’re more than welcome you please be in touch with Maine and.

NOTE Confidence: 0.921711325645447

00:28:45.060 --> 00:29:17.340 I guess our implementation science or growing areas of research, ideally situated for cancer prevention screening and treatment. There’s many new opportunities. And here to major focus as I said at the NCI. This is the link to the implementation science website from NCI and then here are funding announcements at different levels for both trials as well as observation. Ull research and implementation science and cancer. So I hope this gave you a little bit of a feel for Watt.

NOTE Confidence: 0.9196575888005066

00:29:17.340 --> 00:29:28.670 Implementation science is what mine is center is doing and what we’re trying to do in the global oncology program man thanks very much for being here today.

NOTE Confidence: 0.701948583126068

00:29:29.270 --> 00:29:37.750 I think you’re right, I know where yeah questions. You want to come up.