

WEBVTT

NOTE duration:"01:09:48.1000000"

NOTE language:en-us

NOTE Confidence: 0.92574674

00:00:03.900 --> 00:00:07.548 OK, I think we're going to get started.

NOTE Confidence: 0.92574674

00:00:07.550 --> 00:00:09.265 Good evening, my name is

NOTE Confidence: 0.92574674

00:00:09.265 --> 00:00:10.637 Mark Mercury on director,

NOTE Confidence: 0.92574674

00:00:10.640 --> 00:00:12.255 the program for Biomedical Ethics

NOTE Confidence: 0.92574674

00:00:12.255 --> 00:00:15.008 and I want to welcome you tonight to

NOTE Confidence: 0.92574674

00:00:15.008 --> 00:00:16.803 our Evening Ethics seminar series.

NOTE Confidence: 0.92574674

00:00:16.810 --> 00:00:19.281 In looking forward to this talk for

NOTE Confidence: 0.92574674

00:00:19.281 --> 00:00:22.359 quite some time and I want to get to

NOTE Confidence: 0.92574674

00:00:22.359 --> 00:00:24.700 introducing our speaker in just a minute.

NOTE Confidence: 0.92574674

00:00:24.700 --> 00:00:27.185 Wanna welcome have myself on the associate

NOTE Confidence: 0.92574674

00:00:27.185 --> 00:00:29.159 director Jack Hughes and Serra Hall,

NOTE Confidence: 0.92574674

00:00:29.160 --> 00:00:31.896 as well as our program manager Karen Cole.

NOTE Confidence: 0.92574674

00:00:31.900 --> 00:00:34.676 Thanks so much for joining us to let

NOTE Confidence: 0.92574674

00:00:34.676 --> 00:00:37.836 you know how this works is we'll have a.

NOTE Confidence: 0.92574674

00:00:37.840 --> 00:00:39.429 Lecture someday the way it works is

NOTE Confidence: 0.92574674

00:00:39.429 --> 00:00:41.089 that we're on a big room together,

NOTE Confidence: 0.92574674

00:00:41.090 --> 00:00:41.798 eating good food,

NOTE Confidence: 0.92574674

00:00:41.798 --> 00:00:43.718 but for a little while longer we do

NOTE Confidence: 0.92574674

00:00:43.718 --> 00:00:45.422 it like this and we'll have a lecture

NOTE Confidence: 0.92574674

00:00:45.422 --> 00:00:47.099 that will last around an hour and

NOTE Confidence: 0.92574674

00:00:47.099 --> 00:00:48.652 then we'll have about 30 minutes

NOTE Confidence: 0.92574674

00:00:48.652 --> 00:00:50.759 or so for a question and answer.

NOTE Confidence: 0.92574674

00:00:50.760 --> 00:00:52.517 And and right now you're all muted,

NOTE Confidence: 0.92574674

00:00:52.520 --> 00:00:54.728 but when the time comes for Q&A will

NOTE Confidence: 0.92574674

00:00:54.728 --> 00:00:56.466 I'll explain to you how we're going

NOTE Confidence: 0.92574674

00:00:56.466 --> 00:00:58.622 to do that so you get a chance to

NOTE Confidence: 0.92574674

00:00:58.622 --> 00:01:00.576 ask your questions as we go sabi

NOTE Confidence: 0.92574674

00:01:00.576 --> 00:01:04.048 calling on you to ask the questions.

NOTE Confidence: 0.92574674

00:01:04.050 --> 00:01:05.114 We will stop at.

NOTE Confidence: 0.92574674

00:01:05.114 --> 00:01:07.386 We have a hard stop at at 5:30  
NOTE Confidence: 0.92574674

00:01:07.386 --> 00:01:08.896 as those you excuse me.  
NOTE Confidence: 0.92574674

00:01:08.900 --> 00:01:09.452 At 6:30,  
NOTE Confidence: 0.92574674

00:01:09.452 --> 00:01:11.660 those of you who've done this with this  
NOTE Confidence: 0.92574674

00:01:11.724 --> 00:01:14.028 before and no so I apologize in advance.  
NOTE Confidence: 0.92574674

00:01:14.030 --> 00:01:16.102 Whoever has the best possible question at  
NOTE Confidence: 0.92574674

00:01:16.102 --> 00:01:18.588 629 'cause you probably won't get to ask it,  
NOTE Confidence: 0.92574674

00:01:18.590 --> 00:01:19.391 but come back,  
NOTE Confidence: 0.92574674

00:01:19.391 --> 00:01:21.591 come back in a couple weeks and ask  
NOTE Confidence: 0.92574674

00:01:21.591 --> 00:01:23.460 a question or the next session you  
NOTE Confidence: 0.92574674

00:01:23.460 --> 00:01:25.905 can see in front of you there the  
NOTE Confidence: 0.92574674

00:01:25.905 --> 00:01:27.425 calendar for upcoming talks and  
NOTE Confidence: 0.92574674

00:01:27.425 --> 00:01:29.420 we're very excited about all of them.  
NOTE Confidence: 0.92574674

00:01:29.420 --> 00:01:31.976 But then I want to talk about my friend.  
NOTE Confidence: 0.92574674

00:01:31.980 --> 00:01:33.465 They only laventhol doctor Naomi  
NOTE Confidence: 0.92574674

00:01:33.465 --> 00:01:34.950 Laventhol is a clinical associate

NOTE Confidence: 0.92574674

00:01:34.995 --> 00:01:36.693 professor of Pediatrics in the division

NOTE Confidence: 0.92574674

00:01:36.693 --> 00:01:38.280 of the United Perinatal Medicine.

NOTE Confidence: 0.92574674

00:01:38.280 --> 00:01:40.584 As well as in the Center for Bioethics

NOTE Confidence: 0.92574674

00:01:40.584 --> 00:01:43.190 and Social Sciences and Medicine at the

NOTE Confidence: 0.92574674

00:01:43.190 --> 00:01:45.160 University of Michigan Medical School,

NOTE Confidence: 0.92574674

00:01:45.160 --> 00:01:46.568 they only attended college.

NOTE Confidence: 0.92574674

00:01:46.568 --> 00:01:48.940 Indiana University and Medical School at LSU.

NOTE Confidence: 0.92574674

00:01:48.940 --> 00:01:50.690 She did her pediatric residency

NOTE Confidence: 0.92574674

00:01:50.690 --> 00:01:52.090 and neonatology Fellowship of

NOTE Confidence: 0.92574674

00:01:52.090 --> 00:01:53.760 Medical Ethics Fellowship an MPH,

NOTE Confidence: 0.92574674

00:01:53.760 --> 00:01:55.818 all at the University of Chicago,

NOTE Confidence: 0.92574674

00:01:55.820 --> 00:01:56.711 and since then,

NOTE Confidence: 0.92574674

00:01:56.711 --> 00:01:58.790 she's been up in Ann Arbor at

NOTE Confidence: 0.92574674

00:01:58.857 --> 00:02:00.637 the University of Michigan,

NOTE Confidence: 0.92574674

00:02:00.640 --> 00:02:02.644 where she's one of the leaders

NOTE Confidence: 0.92574674

00:02:02.644 --> 00:02:04.420 in the ethics endeavors there,  
NOTE Confidence: 0.92574674

00:02:04.420 --> 00:02:07.170 as well as in neonatology.  
NOTE Confidence: 0.92574674

00:02:07.170 --> 00:02:09.221 I am I've been working with Naomi  
NOTE Confidence: 0.92574674

00:02:09.221 --> 00:02:11.735 off and on for years and I've been  
NOTE Confidence: 0.92574674

00:02:11.735 --> 00:02:14.050 wanting to get her here and was  
NOTE Confidence: 0.92574674

00:02:14.050 --> 00:02:16.090 delighted this year when she agreed  
NOTE Confidence: 0.92574674

00:02:16.090 --> 00:02:19.010 to come such as it is to visit us.  
NOTE Confidence: 0.92574674

00:02:19.010 --> 00:02:20.610 In this way they only,  
NOTE Confidence: 0.92574674

00:02:20.610 --> 00:02:22.766 as part of the next generation of  
NOTE Confidence: 0.92574674

00:02:22.766 --> 00:02:24.130 leadership in pediatric ethics.  
NOTE Confidence: 0.92574674

00:02:24.130 --> 00:02:26.770 I will tell you that when the COVID-19  
NOTE Confidence: 0.92574674

00:02:26.770 --> 00:02:28.928 pandemic was upon us in the spring,  
NOTE Confidence: 0.92574674

00:02:28.930 --> 00:02:31.051 and several of us in pediatric ethics  
NOTE Confidence: 0.92574674

00:02:31.051 --> 00:02:32.656 associated with the American Academy  
NOTE Confidence: 0.92574674

00:02:32.656 --> 00:02:34.570 of Pediatrics decided that we needed  
NOTE Confidence: 0.92574674

00:02:34.570 --> 00:02:36.941 to get together to try and write

NOTE Confidence: 0.92574674

00:02:36.941 --> 00:02:38.616 something that provide some guidance.

NOTE Confidence: 0.92574674

00:02:38.620 --> 00:02:39.868 With regard to triage,

NOTE Confidence: 0.92574674

00:02:39.868 --> 00:02:41.740 it was Naomi who led the

NOTE Confidence: 0.8180022

00:02:41.813 --> 00:02:44.733 effort and led the charge in coordinated US,

NOTE Confidence: 0.8180022

00:02:44.740 --> 00:02:46.980 and that was a work that was

NOTE Confidence: 0.8180022

00:02:46.980 --> 00:02:48.820 published with Naomi's first author.

NOTE Confidence: 0.8180022

00:02:48.820 --> 00:02:50.520 She's smart, she's hard working,

NOTE Confidence: 0.8180022

00:02:50.520 --> 00:02:52.560 and she gives a great talk.

NOTE Confidence: 0.8180022

00:02:52.560 --> 00:02:54.940 So we're in for a treat tonight.

NOTE Confidence: 0.8180022

00:02:54.940 --> 00:02:56.962 Tonight we're going to hear about

NOTE Confidence: 0.8180022

00:02:56.962 --> 00:02:58.310 contemporary pediatric research ethics

NOTE Confidence: 0.8180022

00:02:58.363 --> 00:03:00.379 lessons learned from the COVID-19 pandemic.

NOTE Confidence: 0.8180022

00:03:00.380 --> 00:03:02.080 Naomi I'm delighted you're here.

NOTE Confidence: 0.8180022

00:03:02.080 --> 00:03:05.140 Thank you so much for joining us take over.

NOTE Confidence: 0.85238516

00:03:06.300 --> 00:03:08.134 Well, that was a lovely introduction mark.

NOTE Confidence: 0.85238516

00:03:08.140 --> 00:03:09.100 Thank you so much.  
NOTE Confidence: 0.85238516

00:03:09.100 --> 00:03:10.891 I'm going to go ahead and share  
NOTE Confidence: 0.85238516

00:03:10.891 --> 00:03:12.346 my slides and get started.  
NOTE Confidence: 0.85238516

00:03:12.350 --> 00:03:14.107 It is a pleasure to be here  
NOTE Confidence: 0.85238516

00:03:14.107 --> 00:03:15.240 and you know when.  
NOTE Confidence: 0.85238516

00:03:15.240 --> 00:03:17.344 When I was first invited to do this,  
NOTE Confidence: 0.85238516

00:03:17.350 --> 00:03:19.282 I think we really were hopeful that  
NOTE Confidence: 0.85238516

00:03:19.282 --> 00:03:21.583 that we would be able to do with this  
NOTE Confidence: 0.85238516

00:03:21.583 --> 00:03:23.658 in person and that wasn't meant to be,  
NOTE Confidence: 0.85238516

00:03:23.660 --> 00:03:25.724 but it's great to be here and you  
NOTE Confidence: 0.85238516

00:03:25.724 --> 00:03:27.536 guys have a good setup. I am.  
NOTE Confidence: 0.85238516

00:03:27.536 --> 00:03:29.360 Not able to see you guys right now  
NOTE Confidence: 0.85238516

00:03:29.420 --> 00:03:31.436 so if something funny is happening  
NOTE Confidence: 0.85238516

00:03:31.436 --> 00:03:33.130 someone beginning let me know.  
NOTE Confidence: 0.85238516

00:03:33.130 --> 00:03:34.660 Can everybody see my slides OK?  
NOTE Confidence: 0.8720776

00:03:37.310 --> 00:03:40.020 OK, I see you mark, thank you.

NOTE Confidence: 0.8720776

00:03:40.020 --> 00:03:41.665 Alright, so as I was saying before

NOTE Confidence: 0.8720776

00:03:41.665 --> 00:03:42.760 before the recording started,

NOTE Confidence: 0.8720776

00:03:42.760 --> 00:03:44.640 this is a new talk for me and it's a

NOTE Confidence: 0.8720776

00:03:44.693 --> 00:03:46.590 talk that I've really wanted to write

NOTE Confidence: 0.8720776

00:03:46.590 --> 00:03:48.565 for quite some time because it comes

NOTE Confidence: 0.8720776

00:03:48.565 --> 00:03:50.478 out of some ideas and questions that

NOTE Confidence: 0.8720776

00:03:50.478 --> 00:03:51.718 I've had throughout this pandemic.

NOTE Confidence: 0.8720776

00:03:51.720 --> 00:03:53.584 And I'll tell you that in other research

NOTE Confidence: 0.8720776

00:03:53.584 --> 00:03:55.907 I did to prepare this I thought I would

NOTE Confidence: 0.8720776

00:03:55.907 --> 00:03:57.949 find more answers than I ended up finding,

NOTE Confidence: 0.8720776

00:03:57.950 --> 00:03:59.957 and so I really hope that I leave plenty

NOTE Confidence: 0.8720776

00:03:59.957 --> 00:04:01.830 of time in the discussion for us to

NOTE Confidence: 0.8720776

00:04:01.830 --> 00:04:03.918 try to come to those answers together.

NOTE Confidence: 0.8720776

00:04:03.920 --> 00:04:05.414 I have nothing to disclose except

NOTE Confidence: 0.8720776

00:04:05.414 --> 00:04:06.410 as I mentioned earlier.

NOTE Confidence: 0.8720776

00:04:06.410 --> 00:04:08.250 I do have five and eight year old  
NOTE Confidence: 0.8720776

00:04:08.250 --> 00:04:10.158 boys in the house right now, so.  
NOTE Confidence: 0.8720776

00:04:10.158 --> 00:04:12.434 If you hear a loud crash, that's them.  
NOTE Confidence: 0.8720776

00:04:12.434 --> 00:04:14.416 Um and I, did you know I've  
NOTE Confidence: 0.8720776

00:04:14.416 --> 00:04:15.536 overtime is that given talks.  
NOTE Confidence: 0.8720776

00:04:15.540 --> 00:04:16.890 I've tried to view this objectives.  
NOTE Confidence: 0.8720776

00:04:16.890 --> 00:04:19.023 Idea is really not just like this is a  
NOTE Confidence: 0.8720776

00:04:19.023 --> 00:04:20.936 thing I have to turn in for the CME,  
NOTE Confidence: 0.8720776

00:04:20.940 --> 00:04:22.896 but you really think about what  
NOTE Confidence: 0.8720776

00:04:22.896 --> 00:04:25.608 do I want to do with this time?  
NOTE Confidence: 0.8720776

00:04:25.610 --> 00:04:26.990 And so today I'm really hoping  
NOTE Confidence: 0.8720776

00:04:26.990 --> 00:04:28.581 that we explore key principles of  
NOTE Confidence: 0.8720776

00:04:28.581 --> 00:04:30.435 research ethics that have emerged as  
NOTE Confidence: 0.8720776

00:04:30.435 --> 00:04:32.070 important themes during this pandemic.  
NOTE Confidence: 0.8720776

00:04:32.070 --> 00:04:33.702 And we're going to talk specifically  
NOTE Confidence: 0.8720776

00:04:33.702 --> 00:04:35.134 about children and their unique

NOTE Confidence: 0.8720776

00:04:35.134 --> 00:04:36.898 aspects as a special population of

NOTE Confidence: 0.8720776

00:04:36.898 --> 00:04:38.324 research participants in general and

NOTE Confidence: 0.8720776

00:04:38.324 --> 00:04:39.794 in the context of this pandemic.

NOTE Confidence: 0.8720776

00:04:39.800 --> 00:04:41.584 And we're going to reflect a bit on

NOTE Confidence: 0.8720776

00:04:41.584 --> 00:04:43.233 the tensions related to racism and

NOTE Confidence: 0.8720776

00:04:43.233 --> 00:04:44.961 socioeconomic inequity as they relate to

NOTE Confidence: 0.8720776

00:04:45.015 --> 00:04:46.965 the historical context of research ethics.

NOTE Confidence: 0.8720776

00:04:46.970 --> 00:04:47.246 Clearly,

NOTE Confidence: 0.8720776

00:04:47.246 --> 00:04:48.626 that's several hours worth of

NOTE Confidence: 0.8720776

00:04:48.626 --> 00:04:49.454 talks unto itself.

NOTE Confidence: 0.8720776

00:04:49.460 --> 00:04:51.385 It's not my specific area of expertise,

NOTE Confidence: 0.8720776

00:04:51.390 --> 00:04:53.370 but I do think this is important as we

NOTE Confidence: 0.8720776

00:04:53.370 --> 00:04:55.483 think about the research ethics of this

NOTE Confidence: 0.8720776

00:04:55.483 --> 00:04:57.460 pandemic and about children in particular,

NOTE Confidence: 0.8720776

00:04:57.460 --> 00:04:59.236 even though the attention I will

NOTE Confidence: 0.8720776

00:04:59.236 --> 00:05:00.763 tell you hasn't really been  
NOTE Confidence: 0.8720776

00:05:00.763 --> 00:05:02.198 on children with regard to.  
NOTE Confidence: 0.8720776

00:05:02.200 --> 00:05:06.250 Uh, racial tensions and vaccine research.  
NOTE Confidence: 0.8720776

00:05:06.250 --> 00:05:07.962 So here are the things we're going to  
NOTE Confidence: 0.8720776

00:05:07.962 --> 00:05:10.149 do when I'm not necessarily going to go  
NOTE Confidence: 0.8720776

00:05:10.149 --> 00:05:11.770 through through these things in order,  
NOTE Confidence: 0.8720776

00:05:11.770 --> 00:05:13.240 but these are the ways we're  
NOTE Confidence: 0.8720776

00:05:13.240 --> 00:05:14.530 going to talk about this.  
NOTE Confidence: 0.8720776

00:05:14.530 --> 00:05:15.785 We're going to talk about  
NOTE Confidence: 0.8720776

00:05:15.785 --> 00:05:16.789 principles that were reinforced.  
NOTE Confidence: 0.8720776

00:05:16.790 --> 00:05:18.428 We're going to talk about new complexities  
NOTE Confidence: 0.8720776

00:05:18.428 --> 00:05:20.059 that arose in public health ethics.  
NOTE Confidence: 0.8720776

00:05:20.060 --> 00:05:21.810 We will talk a bit about race,  
NOTE Confidence: 0.8720776

00:05:21.810 --> 00:05:22.563 racism and inequity,  
NOTE Confidence: 0.8720776

00:05:22.563 --> 00:05:23.818 and will talk about children.  
NOTE Confidence: 0.8720776

00:05:23.820 --> 00:05:25.458 I'm going to talk both about clinical

NOTE Confidence: 0.8720776

00:05:25.458 --> 00:05:27.078 trials and about pre approval access,

NOTE Confidence: 0.8720776

00:05:27.080 --> 00:05:28.335 which is something I had

NOTE Confidence: 0.8720776

00:05:28.335 --> 00:05:29.590 to learn a lot about,

NOTE Confidence: 0.8720776

00:05:29.590 --> 00:05:31.096 as as this pandemic going on.

NOTE Confidence: 0.8720776

00:05:31.100 --> 00:05:31.940 And if there's time,

NOTE Confidence: 0.8720776

00:05:31.940 --> 00:05:33.200 I'll talk a bit about research

NOTE Confidence: 0.8720776

00:05:33.247 --> 00:05:34.607 integrity and publication ethics,

NOTE Confidence: 0.8720776

00:05:34.610 --> 00:05:36.402 because there are some things that came

NOTE Confidence: 0.8720776

00:05:36.402 --> 00:05:38.058 out during this pandemic that are.

NOTE Confidence: 0.8720776

00:05:38.060 --> 00:05:38.992 I think are important,

NOTE Confidence: 0.8720776

00:05:38.992 --> 00:05:40.945 but if I have not gotten my timings

NOTE Confidence: 0.8720776

00:05:40.945 --> 00:05:42.929 right and it looks like that would cost

NOTE Confidence: 0.8720776

00:05:42.988 --> 00:05:44.724 us too much of the discussion time,

NOTE Confidence: 0.8720776

00:05:44.730 --> 00:05:48.030 I'll skip that for another day.

NOTE Confidence: 0.8720776

00:05:48.030 --> 00:05:48.251 Alright,

NOTE Confidence: 0.8720776

00:05:48.251 --> 00:05:49.798 so I start here with this picture  
NOTE Confidence: 0.8720776

00:05:49.798 --> 00:05:50.650 of New Orleans.  
NOTE Confidence: 0.8720776

00:05:50.650 --> 00:05:52.072 This is my hometown and what  
NOTE Confidence: 0.8720776

00:05:52.072 --> 00:05:53.020 I'll tell you is  
NOTE Confidence: 0.85294926

00:05:53.073 --> 00:05:55.107 that for the first time in about 20 years  
NOTE Confidence: 0.85294926

00:05:55.107 --> 00:05:57.550 I was in this scrum with my family in 2020,  
NOTE Confidence: 0.85294926

00:05:57.550 --> 00:05:59.216 and while we were in the scrum,  
NOTE Confidence: 0.85294926

00:05:59.220 --> 00:06:01.124 at a certain point I looked around and  
NOTE Confidence: 0.85294926

00:06:01.124 --> 00:06:02.790 I thought, gosh, it's a good thing.  
NOTE Confidence: 0.85294926

00:06:02.790 --> 00:06:03.738 All these worries about  
NOTE Confidence: 0.85294926

00:06:03.738 --> 00:06:04.449 coronavirus are overblown,  
NOTE Confidence: 0.85294926

00:06:04.450 --> 00:06:07.438 or we're all really in trouble.  
NOTE Confidence: 0.85294926

00:06:07.440 --> 00:06:09.456 And it turned out that we really  
NOTE Confidence: 0.85294926

00:06:09.456 --> 00:06:11.388 were in trouble and I just have  
NOTE Confidence: 0.85294926

00:06:11.388 --> 00:06:13.512 this year to sort of think about my  
NOTE Confidence: 0.85294926

00:06:13.512 --> 00:06:15.444 own life is a private citizen and

NOTE Confidence: 0.85294926

00:06:15.444 --> 00:06:17.100 how this pandemic started for me.

NOTE Confidence: 0.85294926

00:06:17.100 --> 00:06:18.756 And, you know, we were lucky.

NOTE Confidence: 0.85294926

00:06:18.760 --> 00:06:20.398 We didn't get covid during this

NOTE Confidence: 0.85294926

00:06:20.398 --> 00:06:22.069 during Mardi Gras at last year,

NOTE Confidence: 0.85294926

00:06:22.070 --> 00:06:24.070 but a lot of people did because there

NOTE Confidence: 0.85294926

00:06:24.070 --> 00:06:26.155 wasn't a lot of warning about the

NOTE Confidence: 0.85294926

00:06:26.155 --> 00:06:28.257 seriousness of this pandemic as it was

NOTE Confidence: 0.85294926

00:06:28.257 --> 00:06:30.084 spreading out of Asia and there was

NOTE Confidence: 0.85294926

00:06:30.084 --> 00:06:31.894 there some public health opportunities

NOTE Confidence: 0.85294926

00:06:31.894 --> 00:06:35.170 that were missed in the lead up to Michael.

NOTE Confidence: 0.85294926

00:06:35.170 --> 00:06:36.796 But so to frame research ethics

NOTE Confidence: 0.85294926

00:06:36.796 --> 00:06:38.819 in the context of clinical ethics,

NOTE Confidence: 0.85294926

00:06:38.820 --> 00:06:40.446 my general way of thinking about

NOTE Confidence: 0.85294926

00:06:40.446 --> 00:06:42.917 this and this has really been my big

NOTE Confidence: 0.85294926

00:06:42.917 --> 00:06:44.572 approach to thinking about research

NOTE Confidence: 0.85294926

00:06:44.572 --> 00:06:47.029 ethics during this pandemic is that you know,

NOTE Confidence: 0.85294926

00:06:47.030 --> 00:06:48.550 as as Mark was saying,

NOTE Confidence: 0.85294926

00:06:48.550 --> 00:06:50.503 as we were writing these papers about

NOTE Confidence: 0.85294926

00:06:50.503 --> 00:06:51.729 resource allocation and workforce

NOTE Confidence: 0.85294926

00:06:51.729 --> 00:06:53.409 redeployment and shortages of PPE,

NOTE Confidence: 0.85294926

00:06:53.410 --> 00:06:54.930 those were things that we've

NOTE Confidence: 0.85294926

00:06:54.930 --> 00:06:56.450 never had to think about,

NOTE Confidence: 0.85294926

00:06:56.450 --> 00:06:57.970 or at least not so.

NOTE Confidence: 0.85294926

00:06:57.970 --> 00:06:58.312 Specifically,

NOTE Confidence: 0.85294926

00:06:58.312 --> 00:07:01.048 they were hypotheticals an we had to go

NOTE Confidence: 0.85294926

00:07:01.048 --> 00:07:03.213 back an do this normative re analysis

NOTE Confidence: 0.85294926

00:07:03.213 --> 00:07:05.728 of things that we thought we knew and

NOTE Confidence: 0.85294926

00:07:05.728 --> 00:07:07.636 rethink them in this modern world.

NOTE Confidence: 0.85294926

00:07:07.640 --> 00:07:09.744 And we this was really new and different

NOTE Confidence: 0.85294926

00:07:09.744 --> 00:07:12.200 for a lot of us and we had to pivot

NOTE Confidence: 0.85294926

00:07:12.200 --> 00:07:13.758 to thinking more deliberately about

NOTE Confidence: 0.85294926

00:07:13.758 --> 00:07:16.159 public health ethics that many of us

NOTE Confidence: 0.85294926

00:07:16.160 --> 00:07:17.840 have in our lifetime and children

NOTE Confidence: 0.85294926

00:07:17.840 --> 00:07:19.644 really occupied a unique and complex

NOTE Confidence: 0.85294926

00:07:19.644 --> 00:07:21.528 and often polarizing role in these

NOTE Confidence: 0.85294926

00:07:21.528 --> 00:07:22.949 considerations and the most polarizing

NOTE Confidence: 0.85294926

00:07:22.949 --> 00:07:24.964 role of children I can think of in

NOTE Confidence: 0.85294926

00:07:24.964 --> 00:07:26.668 this pandemic has been school closure,

NOTE Confidence: 0.85294926

00:07:26.670 --> 00:07:28.332 school reopening and what are we

NOTE Confidence: 0.85294926

00:07:28.332 --> 00:07:29.778 really talking about when we're

NOTE Confidence: 0.85294926

00:07:29.778 --> 00:07:31.500 talking about kids in this pandemic?

NOTE Confidence: 0.85294926

00:07:31.500 --> 00:07:34.027 And I do think that that recapitulates

NOTE Confidence: 0.85294926

00:07:34.027 --> 00:07:35.630 into the research ethics.

NOTE Confidence: 0.85294926

00:07:35.630 --> 00:07:37.184 So where is the clinical ethics

NOTE Confidence: 0.85294926

00:07:37.184 --> 00:07:39.530 in covid I think have let us into

NOTE Confidence: 0.85294926

00:07:39.530 --> 00:07:40.782 this really uncharted territory

NOTE Confidence: 0.85294926

00:07:40.782 --> 00:07:42.826 to mean research ethics has largely  
NOTE Confidence: 0.85294926

00:07:42.826 --> 00:07:44.866 reinforced what we already knew and  
NOTE Confidence: 0.85294926

00:07:44.870 --> 00:07:46.808 shown these principles that we already  
NOTE Confidence: 0.85294926

00:07:46.808 --> 00:07:48.430 understood playing out logically in  
NOTE Confidence: 0.85294926

00:07:48.430 --> 00:07:50.104 this modern time with modern technology.  
NOTE Confidence: 0.85294926

00:07:50.110 --> 00:07:52.294 And I will say access versus protection  
NOTE Confidence: 0.85294926

00:07:52.294 --> 00:07:54.208 several times in this talk because  
NOTE Confidence: 0.85294926

00:07:54.208 --> 00:07:56.044 it keeps coming back to access  
NOTE Confidence: 0.85294926

00:07:56.044 --> 00:07:57.810 versus protection an in my view,  
NOTE Confidence: 0.85294926

00:07:57.810 --> 00:07:59.350 when you talk about yes.  
NOTE Confidence: 0.85294926

00:07:59.350 --> 00:07:59.650 So  
NOTE Confidence: 0.83980346

00:07:59.650 --> 00:08:02.053 sorry to do this, but I just got a  
NOTE Confidence: 0.83980346

00:08:02.053 --> 00:08:04.645 text from a friend of mine in the  
NOTE Confidence: 0.83980346

00:08:04.645 --> 00:08:07.048 audience that they can't see the slide.  
NOTE Confidence: 0.83980346

00:08:07.050 --> 00:08:08.230 So I'm asking Kyle.  
NOTE Confidence: 0.83980346

00:08:08.230 --> 00:08:10.691 Give us and give us just a few

NOTE Confidence: 0.83980346

00:08:10.691 --> 00:08:12.854 seconds here in Kyle if you could

NOTE Confidence: 0.83980346

00:08:12.854 --> 00:08:14.905 figure out why that is the case,

NOTE Confidence: 0.83980346

00:08:14.910 --> 00:08:16.608 I can see the slides just

NOTE Confidence: 0.8738857

00:08:16.610 --> 00:08:18.030 fine. Yeah, I can tell.

NOTE Confidence: 0.80427164

00:08:20.450 --> 00:08:23.060 OK so my buddy who knows who he is is

NOTE Confidence: 0.80427164

00:08:23.135 --> 00:08:25.889 something with your connection I guess.

NOTE Confidence: 0.80427164

00:08:25.890 --> 00:08:28.270 Thank you and I'm sorry to interrupt

NOTE Confidence: 0.80427164

00:08:28.270 --> 00:08:32.090 Ono trouble. Call you OK. Art over

NOTE Confidence: 0.8002616

00:08:32.090 --> 00:08:34.598 your doing. I won't so access

NOTE Confidence: 0.8002616

00:08:34.598 --> 00:08:36.790 versus protection again and again,

NOTE Confidence: 0.8002616

00:08:36.790 --> 00:08:39.250 and the unique vulnerabilities of

NOTE Confidence: 0.8002616

00:08:39.250 --> 00:08:41.710 children imparted moral and regulatory

NOTE Confidence: 0.8002616

00:08:41.786 --> 00:08:43.906 challenges to research ethics

NOTE Confidence: 0.8002616

00:08:43.906 --> 00:08:46.026 research uncovered for children.

NOTE Confidence: 0.8002616

00:08:46.030 --> 00:08:47.715 And our history and current

NOTE Confidence: 0.8002616

00:08:47.715 --> 00:08:49.400 struggles with racism and inequity  
NOTE Confidence: 0.8002616

00:08:49.459 --> 00:08:51.307 wear sailing as they've ever been.  
NOTE Confidence: 0.8002616

00:08:51.310 --> 00:08:53.587 But so so when I started writing this talk,  
NOTE Confidence: 0.8002616

00:08:53.590 --> 00:08:55.354 I really thought there's nothing new here.  
NOTE Confidence: 0.8002616

00:08:55.360 --> 00:08:56.836 But then I thought more about  
NOTE Confidence: 0.8002616

00:08:56.836 --> 00:08:58.140 this public health ethics issue,  
NOTE Confidence: 0.8002616

00:08:58.140 --> 00:08:59.904 and I think even in research ethics,  
NOTE Confidence: 0.8002616

00:08:59.910 --> 00:09:02.766 there is a lot that's new.  
NOTE Confidence: 0.8002616

00:09:02.770 --> 00:09:05.087 So after I've done all this myself,  
NOTE Confidence: 0.8002616

00:09:05.090 --> 00:09:07.738 I found out that someone had published it,  
NOTE Confidence: 0.8002616

00:09:07.740 --> 00:09:09.720 and after I've done my own  
NOTE Confidence: 0.8002616

00:09:09.720 --> 00:09:10.710 diving into [clinicaltrials.gov](http://clinicaltrials.gov),  
NOTE Confidence: 0.8002616

00:09:10.710 --> 00:09:12.325 I found exactly the figure  
NOTE Confidence: 0.8002616

00:09:12.325 --> 00:09:14.360 that I was hoping to make,  
NOTE Confidence: 0.8002616

00:09:14.360 --> 00:09:16.448 which is this dismal and hopefully  
NOTE Confidence: 0.8002616

00:09:16.448 --> 00:09:18.924 drawing realization about how few of the

NOTE Confidence: 0.8002616

00:09:18.924 --> 00:09:20.634 interventional studies in for COVID-19

NOTE Confidence: 0.8002616

00:09:20.634 --> 00:09:22.960 have included children under the age of 17.

NOTE Confidence: 0.8002616

00:09:22.960 --> 00:09:25.529 I'll tell you almost none of them

NOTE Confidence: 0.8002616

00:09:25.529 --> 00:09:27.598 included children under the age of 12,

NOTE Confidence: 0.8002616

00:09:27.600 --> 00:09:29.917 but this to me as a pediatrician

NOTE Confidence: 0.8002616

00:09:29.917 --> 00:09:30.910 is really depressing.

NOTE Confidence: 0.8002616

00:09:30.910 --> 00:09:31.452 We just.

NOTE Confidence: 0.8002616

00:09:31.452 --> 00:09:33.078 Didn't include children in these trials

NOTE Confidence: 0.8002616

00:09:33.078 --> 00:09:35.185 and I think there were a few reasons

NOTE Confidence: 0.8002616

00:09:35.185 --> 00:09:37.071 about for that that will get to, but

NOTE Confidence: 0.8002616

00:09:37.071 --> 00:09:39.499 I want this is the framing of my talk is why?

NOTE Confidence: 0.8002616

00:09:39.500 --> 00:09:40.576 Why is this true?

NOTE Confidence: 0.8002616

00:09:40.576 --> 00:09:43.150 Was it the right thing was at the wrong

NOTE Confidence: 0.8002616

00:09:43.150 --> 00:09:45.243 thing and could we have done better?

NOTE Confidence: 0.8002616

00:09:45.250 --> 00:09:46.906 And so I'll say the thing I'll say

NOTE Confidence: 0.8002616

00:09:46.906 --> 00:09:48.917 again and again in this talk is that

NOTE Confidence: 0.8002616

00:09:48.917 --> 00:09:50.569 children should be protected by research,

NOTE Confidence: 0.8002616

00:09:50.570 --> 00:09:51.296 not from it.

NOTE Confidence: 0.8002616

00:09:51.296 --> 00:09:52.990 And I could kind of stop here,

NOTE Confidence: 0.8002616

00:09:52.990 --> 00:09:54.466 and we could probably spend the

NOTE Confidence: 0.8002616

00:09:54.466 --> 00:09:56.329 next hour and a half talking about

NOTE Confidence: 0.8002616

00:09:56.329 --> 00:09:58.240 whether or not we agree with this

NOTE Confidence: 0.8002616

00:09:58.293 --> 00:10:00.129 and how to make it so if it's true.

NOTE Confidence: 0.8002616

00:10:00.130 --> 00:10:01.446 One thing I want to be clear

NOTE Confidence: 0.8002616

00:10:01.446 --> 00:10:02.889 about is I read this phrase,

NOTE Confidence: 0.8002616

00:10:02.890 --> 00:10:04.102 sort of in relation to pregnant

NOTE Confidence: 0.8002616

00:10:04.102 --> 00:10:05.173 women saying that pregnant women

NOTE Confidence: 0.8002616

00:10:05.173 --> 00:10:06.278 should be protected by research,

NOTE Confidence: 0.8002616

00:10:06.280 --> 00:10:07.968 not from it, and so it's very clever,

NOTE Confidence: 0.8002616

00:10:07.970 --> 00:10:09.454 and I wish I'd said it first,

NOTE Confidence: 0.8002616

00:10:09.460 --> 00:10:10.874 but I want to be a friend

NOTE Confidence: 0.8002616

00:10:10.874 --> 00:10:12.210 that I didn't say it first.

NOTE Confidence: 0.8308763

00:10:14.950 --> 00:10:17.734 So this is a slide that I actually

NOTE Confidence: 0.8308763

00:10:17.734 --> 00:10:19.778 use quite a bit when I do.

NOTE Confidence: 0.8308763

00:10:19.780 --> 00:10:21.688 My introductory talks for students and

NOTE Confidence: 0.8308763

00:10:21.688 --> 00:10:23.320 learners about pediatric research ethics,

NOTE Confidence: 0.8308763

00:10:23.320 --> 00:10:26.218 and I've beautified it a little bit for you,

NOTE Confidence: 0.8308763

00:10:26.220 --> 00:10:28.532 but I'll start by saying this in the

NOTE Confidence: 0.8308763

00:10:28.532 --> 00:10:29.760 contemporary research environment.

NOTE Confidence: 0.8308763

00:10:29.760 --> 00:10:31.048 Enrollment in special populations

NOTE Confidence: 0.8308763

00:10:31.048 --> 00:10:32.983 is usually required, by which I

NOTE Confidence: 0.8308763

00:10:32.983 --> 00:10:34.588 mean it's a regulatory requirement.

NOTE Confidence: 0.8308763

00:10:34.590 --> 00:10:35.505 It's necessary morally,

NOTE Confidence: 0.8308763

00:10:35.505 --> 00:10:38.130 and that are the integrity of our science.

NOTE Confidence: 0.8308763

00:10:38.130 --> 00:10:40.860 Depends on it and that sometimes it

NOTE Confidence: 0.8308763

00:10:40.860 --> 00:10:43.950 really can be procedurally difficult.

NOTE Confidence: 0.8308763

00:10:43.950 --> 00:10:45.786 The big picture principle here is

NOTE Confidence: 0.8308763

00:10:45.786 --> 00:10:47.710 that research should be done with

NOTE Confidence: 0.8308763

00:10:47.710 --> 00:10:49.320 participants who stand to benefit

NOTE Confidence: 0.8308763

00:10:49.320 --> 00:10:50.688 or who represent populations

NOTE Confidence: 0.8308763

00:10:50.688 --> 00:10:52.758 that could benefit in the future.

NOTE Confidence: 0.8308763

00:10:52.760 --> 00:10:53.202 Now ethics,

NOTE Confidence: 0.8308763

00:10:53.202 --> 00:10:54.749 we say good ethics rely on good

NOTE Confidence: 0.8308763

00:10:54.749 --> 00:10:56.666 facts and I think it's also true that

NOTE Confidence: 0.8308763

00:10:56.666 --> 00:10:58.050 good medicine relies on good facts.

NOTE Confidence: 0.8308763

00:10:58.050 --> 00:10:59.568 And generally I think it's true

NOTE Confidence: 0.8308763

00:10:59.568 --> 00:11:01.132 that patients are better off when

NOTE Confidence: 0.8308763

00:11:01.132 --> 00:11:02.626 their medical care is informed by

NOTE Confidence: 0.8308763

00:11:02.626 --> 00:11:04.079 high quality scientific evidence.

NOTE Confidence: 0.8308763

00:11:04.080 --> 00:11:05.900 We shouldn't be excluding unique

NOTE Confidence: 0.8308763

00:11:05.900 --> 00:11:07.356 populations with unique complexities

NOTE Confidence: 0.8308763

00:11:07.356 --> 00:11:09.016 because it's difficult we shouldn't

NOTE Confidence: 0.8308763

00:11:09.016 --> 00:11:09.949 be excluding them.

NOTE Confidence: 0.8308763

00:11:09.950 --> 00:11:10.650 For convenience,

NOTE Confidence: 0.8308763

00:11:10.650 --> 00:11:12.750 we should be getting over that

NOTE Confidence: 0.8308763

00:11:12.750 --> 00:11:14.430 inconvenience and bringing them in.

NOTE Confidence: 0.8308763

00:11:14.430 --> 00:11:16.635 There are some specific regulatory

NOTE Confidence: 0.8308763

00:11:16.635 --> 00:11:17.958 and institutional considerations

NOTE Confidence: 0.8308763

00:11:17.958 --> 00:11:20.426 that we have to take into account.

NOTE Confidence: 0.8308763

00:11:20.430 --> 00:11:20.978 So again,

NOTE Confidence: 0.8308763

00:11:20.978 --> 00:11:22.348 access versus protection when you

NOTE Confidence: 0.8308763

00:11:22.348 --> 00:11:23.720 think about vulnerable populations.

NOTE Confidence: 0.8308763

00:11:23.720 --> 00:11:24.524 It's and research.

NOTE Confidence: 0.8308763

00:11:24.524 --> 00:11:26.400 The question is always going to be

NOTE Confidence: 0.8308763

00:11:26.455 --> 00:11:27.945 is research this fundamentally good

NOTE Confidence: 0.8308763

00:11:27.945 --> 00:11:30.000 thing that makes us all healthier?

NOTE Confidence: 0.8308763

00:11:30.000 --> 00:11:32.682 That's that we should want to be involved in.

NOTE Confidence: 0.8308763

00:11:32.690 --> 00:11:34.685 Or is it at its core dangerous  
NOTE Confidence: 0.8308763

00:11:34.685 --> 00:11:36.279 and a little bit scary,  
NOTE Confidence: 0.8308763

00:11:36.280 --> 00:11:38.068 and we should all be wary.  
NOTE Confidence: 0.8308763

00:11:38.070 --> 00:11:39.870 And the answer clearly is yes,  
NOTE Confidence: 0.8308763

00:11:39.870 --> 00:11:41.360 but you know to both.  
NOTE Confidence: 0.8308763

00:11:41.360 --> 00:11:43.334 But I think this is the tension  
NOTE Confidence: 0.8308763

00:11:43.334 --> 00:11:45.248 that comes up again and again.  
NOTE Confidence: 0.8308763

00:11:45.250 --> 00:11:46.858 And as we've thought about this  
NOTE Confidence: 0.8308763

00:11:46.858 --> 00:11:49.168 in the context of Covid an in the  
NOTE Confidence: 0.8308763

00:11:49.168 --> 00:11:50.643 context of children that access  
NOTE Confidence: 0.8308763

00:11:50.643 --> 00:11:52.040 versus protection balance.  
NOTE Confidence: 0.8308763

00:11:52.040 --> 00:11:56.690 Stasin but.  
NOTE Confidence: 0.8308763

00:11:56.690 --> 00:11:57.414 But um.  
NOTE Confidence: 0.8308763

00:11:57.414 --> 00:11:59.224 There's also this other tension  
NOTE Confidence: 0.8308763

00:11:59.224 --> 00:12:00.870 which suddenly I've lost the  
NOTE Confidence: 0.8308763

00:12:00.870 --> 00:12:04.100 ability to show you hang on.

NOTE Confidence: 0.8308763

00:12:04.100 --> 00:12:05.300 Between individual child health

NOTE Confidence: 0.8308763

00:12:05.300 --> 00:12:07.100 and an public health more broadly,

NOTE Confidence: 0.8308763

00:12:07.100 --> 00:12:08.870 and I mean public health and

NOTE Confidence: 0.8308763

00:12:08.870 --> 00:12:10.400 the really big picture here.

NOTE Confidence: 0.8308763

00:12:10.400 --> 00:12:12.108 And thinking about what is the role

NOTE Confidence: 0.8308763

00:12:12.108 --> 00:12:14.190 of children in this pandemic and what

NOTE Confidence: 0.8308763

00:12:14.190 --> 00:12:15.805 moral obligation to children's have

NOTE Confidence: 0.8308763

00:12:15.805 --> 00:12:17.600 towards population health in general.

NOTE Confidence: 0.8308763

00:12:17.600 --> 00:12:18.473 In most situations.

NOTE Confidence: 0.8308763

00:12:18.473 --> 00:12:19.928 We don't think of children

NOTE Confidence: 0.8308763

00:12:19.928 --> 00:12:21.199 as owing adults much,

NOTE Confidence: 0.8308763

00:12:21.200 --> 00:12:22.504 but in this pandemic,

NOTE Confidence: 0.8308763

00:12:22.504 --> 00:12:24.460 in some sense kids were asked

NOTE Confidence: 0.8308763

00:12:24.528 --> 00:12:25.998 to do a lot for adults,

NOTE Confidence: 0.8308763

00:12:26.000 --> 00:12:28.912 and I think that's one of the most

NOTE Confidence: 0.8308763

00:12:28.912 --> 00:12:30.381 interesting ethical issues that  
NOTE Confidence: 0.8308763

00:12:30.381 --> 00:12:32.740 come out of this pandemic for me.  
NOTE Confidence: 0.8308763

00:12:32.740 --> 00:12:35.308 So I won't talk about all these populations,  
NOTE Confidence: 0.8308763

00:12:35.310 --> 00:12:36.910 but just to remind you,  
NOTE Confidence: 0.8308763

00:12:36.910 --> 00:12:38.986 there are some very specifically bend  
NOTE Confidence: 0.8308763

00:12:38.986 --> 00:12:40.698 categories of special populations when  
NOTE Confidence: 0.8308763

00:12:40.698 --> 00:12:42.366 it comes to research that children,  
NOTE Confidence: 0.8308763

00:12:42.370 --> 00:12:43.012 pregnant women,  
NOTE Confidence: 0.8308763

00:12:43.012 --> 00:12:43.654 incarcerated individuals,  
NOTE Confidence: 0.8308763

00:12:43.654 --> 00:12:44.617 individuals with cognitive  
NOTE Confidence: 0.8308763

00:12:44.617 --> 00:12:45.580 and motor disabilities,  
NOTE Confidence: 0.8308763

00:12:45.580 --> 00:12:46.992 and we're increasingly aware  
NOTE Confidence: 0.8308763

00:12:46.992 --> 00:12:48.404 of economically and socially  
NOTE Confidence: 0.8308763

00:12:48.404 --> 00:12:49.676 disadvantaged persons as also  
NOTE Confidence: 0.8308763

00:12:49.676 --> 00:12:50.716 being a special population.  
NOTE Confidence: 0.8308763

00:12:50.720 --> 00:12:52.640 And when we say special population,

NOTE Confidence: 0.8308763

00:12:52.640 --> 00:12:54.590 I think it's important to be

NOTE Confidence: 0.8308763

00:12:54.590 --> 00:12:56.489 cognizant of what do we mean?

NOTE Confidence: 0.8308763

00:12:56.490 --> 00:12:57.774 We're generally talking about

NOTE Confidence: 0.8308763

00:12:57.774 --> 00:12:59.058 medically medical complexity or,

NOTE Confidence: 0.84826833

00:12:59.060 --> 00:13:01.545 for example, in the for the patients

NOTE Confidence: 0.84826833

00:13:01.545 --> 00:13:03.748 that mark and I take care of.

NOTE Confidence: 0.84826833

00:13:03.750 --> 00:13:04.546 Physiologic vulnerability,

NOTE Confidence: 0.84826833

00:13:04.546 --> 00:13:07.332 one thing I say about premature infants

NOTE Confidence: 0.84826833

00:13:07.332 --> 00:13:09.934 is that all of their organ systems are

NOTE Confidence: 0.84826833

00:13:09.934 --> 00:13:12.179 immature and that makes them vulnerable.

NOTE Confidence: 0.84826833

00:13:12.180 --> 00:13:14.056 Now vulnerability in a more legal and

NOTE Confidence: 0.84826833

00:13:14.056 --> 00:13:16.156 social sense has to do with the patients

NOTE Confidence: 0.84826833

00:13:16.156 --> 00:13:17.850 risk of being exploited or coerced,

NOTE Confidence: 0.84826833

00:13:17.850 --> 00:13:19.290 and this violates the fundamental

NOTE Confidence: 0.84826833

00:13:19.290 --> 00:13:20.730 principle that I'm sure we

NOTE Confidence: 0.84826833

00:13:20.778 --> 00:13:22.170 all in this group know about,  
NOTE Confidence: 0.84826833

00:13:22.170 --> 00:13:24.060 which is that research should be voluntary.  
NOTE Confidence: 0.84826833

00:13:24.060 --> 00:13:25.916 We also want to be clear that the  
NOTE Confidence: 0.84826833

00:13:25.916 --> 00:13:27.762 people who are taking on the burdens  
NOTE Confidence: 0.84826833

00:13:27.762 --> 00:13:29.744 of research are the same people who  
NOTE Confidence: 0.84826833

00:13:29.744 --> 00:13:31.550 benefit and that we're not burdening  
NOTE Confidence: 0.84826833

00:13:31.550 --> 00:13:32.979 one group while benefiting another.  
NOTE Confidence: 0.84826833

00:13:32.979 --> 00:13:34.617 And this really I don't talk  
NOTE Confidence: 0.84826833

00:13:34.617 --> 00:13:35.670 about can't very much,  
NOTE Confidence: 0.84826833

00:13:35.670 --> 00:13:37.182 but this is where in our  
NOTE Confidence: 0.84826833

00:13:37.182 --> 00:13:38.640 hearts we talk about cotton.  
NOTE Confidence: 0.84826833

00:13:38.640 --> 00:13:40.692 We think about how people shouldn't  
NOTE Confidence: 0.84826833

00:13:40.692 --> 00:13:43.278 be used as a means to an end.  
NOTE Confidence: 0.84826833

00:13:43.280 --> 00:13:44.855 The problem with this is that once  
NOTE Confidence: 0.84826833

00:13:44.855 --> 00:13:46.169 you get designated as vulnerable,  
NOTE Confidence: 0.84826833

00:13:46.170 --> 00:13:47.514 that makes it harder for you

NOTE Confidence: 0.84826833

00:13:47.514 --> 00:13:48.820 to be in a study.

NOTE Confidence: 0.84826833

00:13:48.820 --> 00:13:50.030 That means you're not recruited,

NOTE Confidence: 0.84826833

00:13:50.030 --> 00:13:51.422 and that means the care that

NOTE Confidence: 0.84826833

00:13:51.422 --> 00:13:52.893 you get isn't informed by data

NOTE Confidence: 0.84826833

00:13:52.893 --> 00:13:54.128 that involved people like you,

NOTE Confidence: 0.84826833

00:13:54.130 --> 00:13:56.720 and that makes her care less good.

NOTE Confidence: 0.84826833

00:13:56.720 --> 00:13:58.856 The other thing is that we have to

NOTE Confidence: 0.84826833

00:13:58.856 --> 00:14:01.261 be really careful not to conflate

NOTE Confidence: 0.84826833

00:14:01.261 --> 00:14:02.614 vulnerability and stupidity,

NOTE Confidence: 0.84826833

00:14:02.620 --> 00:14:04.796 and I think one of the things that

NOTE Confidence: 0.84826833

00:14:04.796 --> 00:14:06.891 his anger pregnant women over the

NOTE Confidence: 0.84826833

00:14:06.891 --> 00:14:09.117 centuries is that pregnancy and it's

NOTE Confidence: 0.84826833

00:14:09.184 --> 00:14:11.289 sort of designation is vulnerable.

NOTE Confidence: 0.84826833

00:14:11.290 --> 00:14:13.798 Got misclassified as a state of

NOTE Confidence: 0.84826833

00:14:13.798 --> 00:14:15.470 cognitive impairment as opposed

NOTE Confidence: 0.84826833

00:14:15.543 --> 00:14:17.469 to physiologic vulnerability.  
NOTE Confidence: 0.84826833

00:14:17.470 --> 00:14:19.815 So I'll talk very briefly about oversight.  
NOTE Confidence: 0.84826833

00:14:19.820 --> 00:14:21.092 This is pretty dry,  
NOTE Confidence: 0.84826833

00:14:21.092 --> 00:14:23.432 but I do think you have to  
NOTE Confidence: 0.84826833

00:14:23.432 --> 00:14:25.526 think about this a little bit,  
NOTE Confidence: 0.84826833

00:14:25.530 --> 00:14:27.889 especially as you think about vaccine shop.  
NOTE Confidence: 0.84826833

00:14:27.890 --> 00:14:29.078 And generally speaking,  
NOTE Confidence: 0.84826833

00:14:29.078 --> 00:14:30.662 HHS empowers individual institutional  
NOTE Confidence: 0.84826833

00:14:30.662 --> 00:14:33.131 review boards to approve three categories  
NOTE Confidence: 0.84826833

00:14:33.131 --> 00:14:34.759 of research involving children.  
NOTE Confidence: 0.84826833

00:14:34.760 --> 00:14:36.930 This should be familiar to most people,  
NOTE Confidence: 0.84826833

00:14:36.930 --> 00:14:38.480 but as we think about,  
NOTE Confidence: 0.84826833

00:14:38.480 --> 00:14:40.363 we think about this in terms of  
NOTE Confidence: 0.84826833

00:14:40.363 --> 00:14:42.200 balancing risk and potential benefit.  
NOTE Confidence: 0.84826833

00:14:42.200 --> 00:14:43.750 An as a general rule,  
NOTE Confidence: 0.84826833

00:14:43.750 --> 00:14:45.920 we don't get to do research that's

NOTE Confidence: 0.84826833

00:14:45.920 --> 00:14:47.820 risky for children and less they

NOTE Confidence: 0.84826833

00:14:47.820 --> 00:14:49.948 stand to benefit an in all situations.

NOTE Confidence: 0.84826833

00:14:49.950 --> 00:14:52.308 Research needs to be accompanied by

NOTE Confidence: 0.84826833

00:14:52.308 --> 00:14:54.672 formal informed consent by parents and

NOTE Confidence: 0.84826833

00:14:54.672 --> 00:14:56.856 a sense of children when possible.

NOTE Confidence: 0.84826833

00:14:56.860 --> 00:14:58.785 Now there are lots of situations in

NOTE Confidence: 0.84826833

00:14:58.785 --> 00:15:01.607 which we do allow for more risk than minimal,

NOTE Confidence: 0.84826833

00:15:01.610 --> 00:15:03.507 but here we have this pretty stringent

NOTE Confidence: 0.84826833

00:15:03.507 --> 00:15:04.698 requirement that there's anticipated

NOTE Confidence: 0.84826833

00:15:04.698 --> 00:15:06.654 benefit that's proportional to that risk.

NOTE Confidence: 0.84826833

00:15:06.660 --> 00:15:08.865 This is in my gut where I think most

NOTE Confidence: 0.84826833

00:15:08.865 --> 00:15:11.118 of the vaccine trials have fallen,

NOTE Confidence: 0.84826833

00:15:11.120 --> 00:15:12.814 although I will tell you I had

NOTE Confidence: 0.84826833

00:15:12.814 --> 00:15:15.032 a heck of a hard time finding

NOTE Confidence: 0.84826833

00:15:15.032 --> 00:15:16.456 that written down anywhere.

NOTE Confidence: 0.84826833

00:15:16.460 --> 00:15:17.945 There are other types of  
NOTE Confidence: 0.84826833

00:15:17.945 --> 00:15:19.133 vaccine research which have,  
NOTE Confidence: 0.84826833

00:15:19.140 --> 00:15:20.724 which has specifically not  
NOTE Confidence: 0.84826833

00:15:20.724 --> 00:15:22.308 falling into this category.  
NOTE Confidence: 0.84826833

00:15:22.310 --> 00:15:22.531 Finally,  
NOTE Confidence: 0.84826833

00:15:22.531 --> 00:15:23.857 there is this funny sort of  
NOTE Confidence: 0.84826833

00:15:23.857 --> 00:15:25.388 case in which there's a minor  
NOTE Confidence: 0.84826833

00:15:25.388 --> 00:15:26.476 increase over minimal risk,  
NOTE Confidence: 0.84826833

00:15:26.480 --> 00:15:28.251 and books and articles and seminars have  
NOTE Confidence: 0.84826833

00:15:28.251 --> 00:15:29.930 been given over how do you quantify  
NOTE Confidence: 0.84826833

00:15:29.930 --> 00:15:31.869 what exactly is a minor risk over minimal,  
NOTE Confidence: 0.84826833

00:15:31.870 --> 00:15:33.455 and what does that look  
NOTE Confidence: 0.84826833

00:15:33.455 --> 00:15:35.040 like and what kind of  
NOTE Confidence: 0.83357686

00:15:35.116 --> 00:15:36.876 kid are we talking about?  
NOTE Confidence: 0.83357686

00:15:36.880 --> 00:15:38.966 But we do allow for this little  
NOTE Confidence: 0.83357686

00:15:38.966 --> 00:15:40.640 caveat of ultraism by children,

NOTE Confidence: 0.83357686

00:15:40.640 --> 00:15:43.504 and say that children can take on a

NOTE Confidence: 0.83357686

00:15:43.504 --> 00:15:46.173 little bit of risk to benefit children

NOTE Confidence: 0.83357686

00:15:46.173 --> 00:15:48.979 who are like them in the future.

NOTE Confidence: 0.83357686

00:15:48.980 --> 00:15:49.996 This is, I think,

NOTE Confidence: 0.83357686

00:15:49.996 --> 00:15:51.826 a really interesting idea and we do

NOTE Confidence: 0.83357686

00:15:51.826 --> 00:15:53.350 know from some studies that young

NOTE Confidence: 0.83357686

00:15:53.350 --> 00:15:55.404 kids are able to articulate a notion

NOTE Confidence: 0.83357686

00:15:55.404 --> 00:15:56.954 of altruism and understand this.

NOTE Confidence: 0.83357686

00:15:56.960 --> 00:15:58.878 So I think this is fundamentally good,

NOTE Confidence: 0.83357686

00:15:58.880 --> 00:16:01.310 but it's also quite nuanced.

NOTE Confidence: 0.83357686

00:16:01.310 --> 00:16:02.742 So I'm gonna pause here for a little

NOTE Confidence: 0.83357686

00:16:02.742 --> 00:16:04.345 bit of humor and tell you a story

NOTE Confidence: 0.83357686

00:16:04.345 --> 00:16:05.728 that just happened to me last week,

NOTE Confidence: 0.83357686

00:16:05.730 --> 00:16:07.354 and I thought this is great and

NOTE Confidence: 0.83357686

00:16:07.354 --> 00:16:08.918 I got permission from my friend

NOTE Confidence: 0.83357686

00:16:08.918 --> 00:16:10.544 to use these screenshots of text  
NOTE Confidence: 0.83357686

00:16:10.544 --> 00:16:12.025 messages to send me in this talk.  
NOTE Confidence: 0.83357686

00:16:12.030 --> 00:16:13.710 So this is my good friend who had  
NOTE Confidence: 0.83357686

00:16:13.710 --> 00:16:15.250 her second vaccine a couple of last  
NOTE Confidence: 0.83357686

00:16:15.250 --> 00:16:16.950 week and she said it was no joke.  
NOTE Confidence: 0.83357686

00:16:16.950 --> 00:16:18.240 I had chills and muscle aches.  
NOTE Confidence: 0.83357686

00:16:18.240 --> 00:16:18.882 I felt terrible,  
NOTE Confidence: 0.83357686

00:16:18.882 --> 00:16:20.380 and it felt like a head covid.  
NOTE Confidence: 0.83357686

00:16:20.380 --> 00:16:21.658 And before you get all mad.  
NOTE Confidence: 0.83357686

00:16:21.660 --> 00:16:23.158 So I got mad all the time.  
NOTE Confidence: 0.83357686

00:16:23.160 --> 00:16:24.623 When people say that having the flu  
NOTE Confidence: 0.83357686

00:16:24.623 --> 00:16:26.148 shot is worse than having the flu.  
NOTE Confidence: 0.83357686

00:16:26.150 --> 00:16:27.590 And I will tell you that this friend  
NOTE Confidence: 0.83357686

00:16:27.590 --> 00:16:29.128 is my friend from Mardi Gras who  
NOTE Confidence: 0.83357686

00:16:29.128 --> 00:16:30.767 actually did have covid so she didn't  
NOTE Confidence: 0.83357686

00:16:30.767 --> 00:16:32.147 know what she was talking about,

NOTE Confidence: 0.83357686

00:16:32.150 --> 00:16:32.562 but you.

NOTE Confidence: 0.83357686

00:16:32.562 --> 00:16:34.709 So she tells me this and then she tells me,

NOTE Confidence: 0.83357686

00:16:34.710 --> 00:16:35.349 now blurted out,

NOTE Confidence: 0.83357686

00:16:35.349 --> 00:16:37.280 I've blocked out the name of her son here,

NOTE Confidence: 0.83357686

00:16:37.280 --> 00:16:38.624 but she says I'm trying to convince

NOTE Confidence: 0.83357686

00:16:38.624 --> 00:16:40.285 my son that he wants to do good

NOTE Confidence: 0.83357686

00:16:40.285 --> 00:16:41.117 for humanity and participate

NOTE Confidence: 0.83357686

00:16:41.117 --> 00:16:42.518 in the pediatric vaccine trial.

NOTE Confidence: 0.83357686

00:16:42.520 --> 00:16:43.920 But after seeing me yesterday,

NOTE Confidence: 0.83357686

00:16:43.920 --> 00:16:45.690 he's unwilling.

NOTE Confidence: 0.83357686

00:16:45.690 --> 00:16:47.433 This friend is not a pediatrician and

NOTE Confidence: 0.83357686

00:16:47.433 --> 00:16:49.212 I'm really proud of her because she

NOTE Confidence: 0.83357686

00:16:49.212 --> 00:16:50.682 really understood in her core that

NOTE Confidence: 0.83357686

00:16:50.729 --> 00:16:52.346 this thing called child dissent is a

NOTE Confidence: 0.83357686

00:16:52.346 --> 00:16:54.755 thing and her child isn't more than 10 or 11.

NOTE Confidence: 0.83357686

00:16:54.760 --> 00:16:57.160 But he had this sense that this was a choice

NOTE Confidence: 0.83357686

00:16:57.222 --> 00:16:59.409 that he was allowed to make and he said,

NOTE Confidence: 0.83357686

00:16:59.410 --> 00:16:59.635 Nah,

NOTE Confidence: 0.83357686

00:16:59.635 --> 00:17:01.660 I don't want to do it and she said

NOTE Confidence: 0.83357686

00:17:01.725 --> 00:17:03.750 I can't make you and I was proud of

NOTE Confidence: 0.83357686

00:17:03.750 --> 00:17:05.944 her and I was really pleased to have

NOTE Confidence: 0.83357686

00:17:05.944 --> 00:17:08.032 this very real life example of this

NOTE Confidence: 0.83357686

00:17:08.032 --> 00:17:09.622 kind of intuitive ascent discussion

NOTE Confidence: 0.83357686

00:17:09.622 --> 00:17:11.813 between a child and his mother about

NOTE Confidence: 0.83357686

00:17:11.813 --> 00:17:13.025 participating in research study.

NOTE Confidence: 0.83357686

00:17:13.030 --> 00:17:14.773 And so I once gave a 90

NOTE Confidence: 0.83357686

00:17:14.773 --> 00:17:16.110 minute talk on a sense,

NOTE Confidence: 0.83357686

00:17:16.110 --> 00:17:18.294 so I've gone way down this rabbit hole

NOTE Confidence: 0.83357686

00:17:18.294 --> 00:17:20.739 before and I've only got 1 slide on it here.

NOTE Confidence: 0.83357686

00:17:20.740 --> 00:17:22.385 But this is just to remind you

NOTE Confidence: 0.83357686

00:17:22.385 --> 00:17:24.036 that ascent in Pediatrics in 2021

NOTE Confidence: 0.83357686

00:17:24.036 --> 00:17:25.818 is much more nuanced than just

NOTE Confidence: 0.83357686

00:17:25.818 --> 00:17:27.167 getting a nod from the kid,

NOTE Confidence: 0.83357686

00:17:27.170 --> 00:17:28.920 or determine at what age you do

NOTE Confidence: 0.83357686

00:17:28.920 --> 00:17:30.508 this and what age you don't.

NOTE Confidence: 0.83357686

00:17:30.510 --> 00:17:31.374 What age you don't,

NOTE Confidence: 0.83357686

00:17:31.374 --> 00:17:33.624 and if you're going to be in the business

NOTE Confidence: 0.83357686

00:17:33.624 --> 00:17:35.124 of enrolling children in research,

NOTE Confidence: 0.83357686

00:17:35.130 --> 00:17:37.130 you really do have to think about how

NOTE Confidence: 0.83357686

00:17:37.130 --> 00:17:38.728 you're going to engage that child,

NOTE Confidence: 0.83357686

00:17:38.730 --> 00:17:40.320 how you're going to determine their

NOTE Confidence: 0.83357686

00:17:40.320 --> 00:17:41.560 assessment of what's going on,

NOTE Confidence: 0.83357686

00:17:41.560 --> 00:17:43.024 and how you're going to allow

NOTE Confidence: 0.83357686

00:17:43.024 --> 00:17:44.000 them to be active

NOTE Confidence: 0.8427263

00:17:44.058 --> 00:17:45.618 participants in this decision.

NOTE Confidence: 0.8427263

00:17:45.620 --> 00:17:47.060 And just to be very clear,

NOTE Confidence: 0.8427263

00:17:47.060 --> 00:17:50.822 ascent forms are not the way to do this.

NOTE Confidence: 0.8427263

00:17:50.830 --> 00:17:52.699 But getting back to the regulatory bit,

NOTE Confidence: 0.8427263

00:17:52.700 --> 00:17:54.170 there is this other category and

NOTE Confidence: 0.8427263

00:17:54.170 --> 00:17:55.777 this comes up with some versions

NOTE Confidence: 0.8427263

00:17:55.777 --> 00:17:57.505 of some sorts of vaccine research,

NOTE Confidence: 0.8427263

00:17:57.510 --> 00:17:59.904 which is why I wanted to bring it up,

NOTE Confidence: 0.8427263

00:17:59.910 --> 00:18:01.723 which is there are situations in which

NOTE Confidence: 0.8427263

00:18:01.723 --> 00:18:03.901 an IRB can look at the protocol for

NOTE Confidence: 0.8427263

00:18:03.901 --> 00:18:05.775 a child research study and say, wow,

NOTE Confidence: 0.8427263

00:18:05.775 --> 00:18:07.560 this doesn't fit neatly into any of

NOTE Confidence: 0.8427263

00:18:07.560 --> 00:18:09.249 those three categories and say HHS,

NOTE Confidence: 0.8427263

00:18:09.250 --> 00:18:12.030 you have to help me.

NOTE Confidence: 0.8427263

00:18:12.030 --> 00:18:14.305 There are two mechanisms by which HHS

NOTE Confidence: 0.8427263

00:18:14.305 --> 00:18:16.429 can then approve a study like this.

NOTE Confidence: 0.8427263

00:18:16.430 --> 00:18:18.308 One is by saying, actually no.

NOTE Confidence: 0.8427263

00:18:18.310 --> 00:18:19.195 On further review,

NOTE Confidence: 0.8427263

00:18:19.195 --> 00:18:21.260 this does mean one of the previous

NOTE Confidence: 0.8427263

00:18:21.323 --> 00:18:23.129 categories and the other is by

NOTE Confidence: 0.8427263

00:18:23.129 --> 00:18:24.733 saying the potential to address

NOTE Confidence: 0.8427263

00:18:24.733 --> 00:18:26.785 the health and welfare of children.

NOTE Confidence: 0.8427263

00:18:26.790 --> 00:18:28.656 In this scientifically sound study is

NOTE Confidence: 0.8427263

00:18:28.656 --> 00:18:31.179 so great that we will allow some risk,

NOTE Confidence: 0.8427263

00:18:31.180 --> 00:18:33.392 even though this doesn't meet some of

NOTE Confidence: 0.8427263

00:18:33.392 --> 00:18:35.270 the other categories we talked about.

NOTE Confidence: 0.8427263

00:18:35.270 --> 00:18:37.979 So I think that this is a really again

NOTE Confidence: 0.8427263

00:18:37.979 --> 00:18:39.882 interesting nod towards this sense that

NOTE Confidence: 0.8427263

00:18:39.882 --> 00:18:42.389 there are some cases in which children.

NOTE Confidence: 0.8427263

00:18:42.390 --> 00:18:44.046 Can do things for the good of community,

NOTE Confidence: 0.8427263

00:18:44.050 --> 00:18:46.300 even if there's a net risk

NOTE Confidence: 0.8427263

00:18:46.300 --> 00:18:48.150 to them in doing it.

NOTE Confidence: 0.8427263

00:18:48.150 --> 00:18:49.029 So to recap,

NOTE Confidence: 0.8427263

00:18:49.029 --> 00:18:50.494 all of this background stuff  
NOTE Confidence: 0.8427263

00:18:50.494 --> 00:18:52.010 in pediatric research ethics,  
NOTE Confidence: 0.8427263

00:18:52.010 --> 00:18:53.948 children should be protected by research,  
NOTE Confidence: 0.8427263

00:18:53.950 --> 00:18:54.946 not from it.  
NOTE Confidence: 0.8427263

00:18:54.946 --> 00:18:56.606 Healthy children may not participate  
NOTE Confidence: 0.8427263

00:18:56.606 --> 00:18:58.550 in research protocols and telling more  
NOTE Confidence: 0.8427263

00:18:58.550 --> 00:19:00.710 than minimal risk most of the time,  
NOTE Confidence: 0.8427263

00:19:00.710 --> 00:19:02.950 but sick children may be permitted to  
NOTE Confidence: 0.8427263

00:19:02.950 --> 00:19:04.289 participate in protocols involving  
NOTE Confidence: 0.8427263

00:19:04.289 --> 00:19:06.564 slightly more risk if they may receive  
NOTE Confidence: 0.8427263

00:19:06.564 --> 00:19:08.507 direct benefit or a vital information  
NOTE Confidence: 0.8427263

00:19:08.507 --> 00:19:10.361 about their disorder can be gathered.  
NOTE Confidence: 0.8427263

00:19:10.370 --> 00:19:11.333 Pediatric research requires  
NOTE Confidence: 0.8427263

00:19:11.333 --> 00:19:12.296 stringent oversight is.  
NOTE Confidence: 0.8427263

00:19:12.300 --> 00:19:14.732 I've just reviewed an this nice quote quote  
NOTE Confidence: 0.8427263

00:19:14.732 --> 00:19:17.219 from her friend Renee Boss in Baltimore.

NOTE Confidence: 0.8427263

00:19:17.220 --> 00:19:17.542 Pediatricians,

NOTE Confidence: 0.8427263

00:19:17.542 --> 00:19:17.864 researchers,

NOTE Confidence: 0.8427263

00:19:17.864 --> 00:19:19.474 Arby's and parents must work

NOTE Confidence: 0.8427263

00:19:19.474 --> 00:19:21.258 together to refine and apply the

NOTE Confidence: 0.8427263

00:19:21.258 --> 00:19:22.543 principles of respect for persons,

NOTE Confidence: 0.8427263

00:19:22.550 --> 00:19:24.030 justice and medicines to children.

NOTE Confidence: 0.8427263

00:19:24.030 --> 00:19:26.095 I really couldn't say that better myself,

NOTE Confidence: 0.8427263

00:19:26.100 --> 00:19:29.000 so I didn't try.

NOTE Confidence: 0.8427263

00:19:29.000 --> 00:19:31.420 So I want to move now out of this classic

NOTE Confidence: 0.8427263

00:19:31.487 --> 00:19:33.497 example of clinical trials though,

NOTE Confidence: 0.8427263

00:19:33.500 --> 00:19:34.700 and talk about investigational

NOTE Confidence: 0.8427263

00:19:34.700 --> 00:19:36.200 therapies in pre approval access,

NOTE Confidence: 0.8427263

00:19:36.200 --> 00:19:38.251 because I think probably many of you

NOTE Confidence: 0.8427263

00:19:38.251 --> 00:19:40.850 like me got a crash course in pre

NOTE Confidence: 0.8427263

00:19:40.850 --> 00:19:43.093 approval access as this pandemic is gone

NOTE Confidence: 0.8427263

00:19:43.093 --> 00:19:45.718 and forgive me if this is too basic for you.

NOTE Confidence: 0.8427263

00:19:45.718 --> 00:19:48.217 I found that I really had to go back

NOTE Confidence: 0.8427263

00:19:48.217 --> 00:19:50.389 and understand this and there's some

NOTE Confidence: 0.8427263

00:19:50.389 --> 00:19:52.870 great folks at Penn who work on this

NOTE Confidence: 0.8427263

00:19:52.870 --> 00:19:55.097 a lot and this does apply to children.

NOTE Confidence: 0.8427263

00:19:55.097 --> 00:19:56.592 There are emergency use authorizations

NOTE Confidence: 0.8427263

00:19:56.592 --> 00:19:58.398 that have been granted for children,

NOTE Confidence: 0.8427263

00:19:58.400 --> 00:19:59.288 usually older kids.

NOTE Confidence: 0.8427263

00:19:59.288 --> 00:20:00.176 But I won.

NOTE Confidence: 0.8427263

00:20:00.180 --> 00:20:01.456 I distinguish expanded access

NOTE Confidence: 0.8427263

00:20:01.456 --> 00:20:03.051 and early use authorization as

NOTE Confidence: 0.8427263

00:20:03.051 --> 00:20:05.060 two mechanisms by which the FDA

NOTE Confidence: 0.8427263

00:20:05.060 --> 00:20:06.368 authorizes pre approval access.

NOTE Confidence: 0.8427263

00:20:06.370 --> 00:20:08.326 There are other ways that pre

NOTE Confidence: 0.8427263

00:20:08.326 --> 00:20:09.630 approval access can happen,

NOTE Confidence: 0.8427263

00:20:09.630 --> 00:20:11.622 but the other thing that's important

NOTE Confidence: 0.8427263

00:20:11.622 --> 00:20:13.957 here is this is not FDA approval

NOTE Confidence: 0.8427263

00:20:13.957 --> 00:20:16.148 and I encourage you to be really

NOTE Confidence: 0.8427263

00:20:16.214 --> 00:20:18.128 careful in which words you use

NOTE Confidence: 0.8427263

00:20:18.128 --> 00:20:20.266 when you talk about this because.

NOTE Confidence: 0.8427263

00:20:20.266 --> 00:20:21.978 An early use authorization,

NOTE Confidence: 0.87106836

00:20:21.980 --> 00:20:25.070 for example, is not an approval.

NOTE Confidence: 0.87106836

00:20:25.070 --> 00:20:27.260 So expanded access usually allows a

NOTE Confidence: 0.87106836

00:20:27.260 --> 00:20:29.961 drug or device that is currently under

NOTE Confidence: 0.87106836

00:20:29.961 --> 00:20:31.916 some kind of systematic evaluation

NOTE Confidence: 0.87106836

00:20:31.916 --> 00:20:34.526 to be made available to someone for

NOTE Confidence: 0.87106836

00:20:34.526 --> 00:20:37.038 who suffer who for some reason is

NOTE Confidence: 0.87106836

00:20:37.038 --> 00:20:39.656 not eligible to enroll in the trial.

NOTE Confidence: 0.87106836

00:20:39.660 --> 00:20:42.644 We often refer to this as compassionate use.

NOTE Confidence: 0.87106836

00:20:42.650 --> 00:20:45.698 Usually the way this works is that the

NOTE Confidence: 0.87106836

00:20:45.698 --> 00:20:48.477 drug company directly supplies the the.

NOTE Confidence: 0.87106836

00:20:48.480 --> 00:20:50.960 The drug of the device to the prescriber,  
NOTE Confidence: 0.87106836

00:20:50.960 --> 00:20:52.820 without a middleman like the federal  
NOTE Confidence: 0.87106836

00:20:52.820 --> 00:20:54.370 government, through some sort of  
NOTE Confidence: 0.87106836

00:20:54.370 --> 00:20:55.610 boarding and four agreements,  
NOTE Confidence: 0.87106836

00:20:55.610 --> 00:20:57.780 and even though this is technically speaking,  
NOTE Confidence: 0.87106836

00:20:57.780 --> 00:20:59.640 not research and does not require  
NOTE Confidence: 0.87106836

00:20:59.640 --> 00:21:00.570 an informed consent,  
NOTE Confidence: 0.87106836

00:21:00.570 --> 00:21:02.768 there is usually you do need to  
NOTE Confidence: 0.87106836

00:21:02.768 --> 00:21:05.219 get your IRB to sign off on this,  
NOTE Confidence: 0.87106836

00:21:05.220 --> 00:21:07.610 and there's some reporting to  
NOTE Confidence: 0.87106836

00:21:07.610 --> 00:21:09.522 the IRB that's required.  
NOTE Confidence: 0.87106836

00:21:09.530 --> 00:21:11.282 And what I just learned is that the  
NOTE Confidence: 0.87106836

00:21:11.282 --> 00:21:12.405 manufacturer can actually quite  
NOTE Confidence: 0.87106836

00:21:12.405 --> 00:21:13.365 require additional information  
NOTE Confidence: 0.87106836

00:21:13.365 --> 00:21:14.965 that the FDA isn't interested,  
NOTE Confidence: 0.87106836

00:21:14.970 --> 00:21:17.146 but it's still not considered to be research.

NOTE Confidence: 0.87106836  
00:21:17.150 --> 00:21:18.752 This is also not the same  
NOTE Confidence: 0.87106836  
00:21:18.752 --> 00:21:20.140 thing as right to try,  
NOTE Confidence: 0.87106836  
00:21:20.140 --> 00:21:23.596 which I'll come back to in a minute.  
NOTE Confidence: 0.87106836  
00:21:23.600 --> 00:21:24.234 So early,  
NOTE Confidence: 0.87106836  
00:21:24.234 --> 00:21:25.185 this authorization is  
NOTE Confidence: 0.87106836  
00:21:25.185 --> 00:21:26.136 actually pretty different.  
NOTE Confidence: 0.87106836  
00:21:26.140 --> 00:21:28.219 It's a different form of pre approval  
NOTE Confidence: 0.87106836  
00:21:28.219 --> 00:21:30.382 access in which that the FDA concludes  
NOTE Confidence: 0.87106836  
00:21:30.382 --> 00:21:32.599 that a product may be effective and  
NOTE Confidence: 0.87106836  
00:21:32.599 --> 00:21:34.651 that it's known and potential benefits  
NOTE Confidence: 0.87106836  
00:21:34.651 --> 00:21:37.270 outweigh the risks with a pretty low bar.  
NOTE Confidence: 0.87106836  
00:21:37.270 --> 00:21:39.214 And one thing that's really clear  
NOTE Confidence: 0.87106836  
00:21:39.214 --> 00:21:41.488 about this is that for a patient  
NOTE Confidence: 0.87106836  
00:21:41.488 --> 00:21:43.312 to get something under an EUA,  
NOTE Confidence: 0.87106836  
00:21:43.320 --> 00:21:44.910 this is a clinical decision.  
NOTE Confidence: 0.87106836

00:21:44.910 --> 00:21:46.806 This is not a research decision,  
NOTE Confidence: 0.87106836

00:21:46.810 --> 00:21:47.384 you know,  
NOTE Confidence: 0.87106836

00:21:47.384 --> 00:21:49.106 as we're all getting our vaccines  
NOTE Confidence: 0.87106836

00:21:49.106 --> 00:21:50.948 that are released under anyway.  
NOTE Confidence: 0.87106836

00:21:50.950 --> 00:21:52.174 We're not signing.  
NOTE Confidence: 0.87106836

00:21:52.174 --> 00:21:53.806 Research consents were not  
NOTE Confidence: 0.87106836

00:21:53.806 --> 00:21:56.050 participating in a research study.  
NOTE Confidence: 0.87106836

00:21:56.050 --> 00:21:57.856 And in the case of vaccines,  
NOTE Confidence: 0.87106836

00:21:57.860 --> 00:21:59.360 Pfizer and Moderna for example,  
NOTE Confidence: 0.87106836

00:21:59.360 --> 00:22:01.481 are supplying millions of doses to the  
NOTE Confidence: 0.87106836

00:22:01.481 --> 00:22:03.322 federal government were supplying it to  
NOTE Confidence: 0.87106836

00:22:03.322 --> 00:22:05.373 states who are supplying it to institutions.  
NOTE Confidence: 0.87106836

00:22:05.380 --> 00:22:08.229 So the supply chain is also really  
NOTE Confidence: 0.87106836

00:22:08.229 --> 00:22:10.719 different than under expanded access.  
NOTE Confidence: 0.87106836

00:22:10.720 --> 00:22:12.766 So in the time of kovid,  
NOTE Confidence: 0.87106836

00:22:12.770 --> 00:22:14.320 institutions about to decide whether

NOTE Confidence: 0.87106836

00:22:14.320 --> 00:22:16.962 or not they want how they are going

NOTE Confidence: 0.87106836

00:22:16.962 --> 00:22:19.020 to make EUA approval UA authorized

NOTE Confidence: 0.87106836

00:22:19.020 --> 00:22:20.947 interventions available to their patients,

NOTE Confidence: 0.87106836

00:22:20.950 --> 00:22:23.374 and they can choose to say we're only

NOTE Confidence: 0.87106836

00:22:23.374 --> 00:22:25.948 going to our patients to get this in

NOTE Confidence: 0.87106836

00:22:25.948 --> 00:22:28.064 the context of which about clinical

NOTE Confidence: 0.87106836

00:22:28.064 --> 00:22:30.787 trial and then this nice paper that

NOTE Confidence: 0.87106836

00:22:30.787 --> 00:22:33.082 accorded here at the bottom the authors

NOTE Confidence: 0.87106836

00:22:33.082 --> 00:22:35.269 talk about about appropriate limitations too.

NOTE Confidence: 0.87106836

00:22:35.270 --> 00:22:36.806 Too easy way use,

NOTE Confidence: 0.87106836

00:22:36.806 --> 00:22:38.726 and when it's justifiable to

NOTE Confidence: 0.87106836

00:22:38.726 --> 00:22:41.116 you to limit this to a trial.

NOTE Confidence: 0.87106836

00:22:41.120 --> 00:22:43.024 And usually this has to do with,

NOTE Confidence: 0.87106836

00:22:43.030 --> 00:22:43.576 you know,

NOTE Confidence: 0.87106836

00:22:43.576 --> 00:22:45.214 my favorite word and research ethics.

NOTE Confidence: 0.87106836

00:22:45.220 --> 00:22:45.566 Equipois.  
NOTE Confidence: 0.87106836

00:22:45.566 --> 00:22:47.296 We're really not sure whether  
NOTE Confidence: 0.87106836

00:22:47.296 --> 00:22:49.767 or not there's a net benefit to  
NOTE Confidence: 0.87106836

00:22:49.767 --> 00:22:51.467 be derived from getting this.  
NOTE Confidence: 0.87106836

00:22:51.470 --> 00:22:53.326 This can also be a way to make  
NOTE Confidence: 0.87106836

00:22:53.326 --> 00:22:55.020 sure that these trials happen,  
NOTE Confidence: 0.87106836

00:22:55.020 --> 00:22:56.394 because one thing we always have  
NOTE Confidence: 0.87106836

00:22:56.394 --> 00:22:57.896 to worry about is once everyone  
NOTE Confidence: 0.87106836

00:22:57.896 --> 00:22:59.246 can get something before the  
NOTE Confidence: 0.87106836

00:22:59.246 --> 00:23:01.110 trials have been done to finish  
NOTE Confidence: 0.87106836

00:23:01.110 --> 00:23:02.115 scientifically validating it.  
NOTE Confidence: 0.87106836

00:23:02.120 --> 00:23:04.010 It's really hard to go back and  
NOTE Confidence: 0.87106836

00:23:04.010 --> 00:23:05.120 randomize people after that,  
NOTE Confidence: 0.87106836

00:23:05.120 --> 00:23:07.010 and so if you think it's really  
NOTE Confidence: 0.87106836

00:23:07.010 --> 00:23:08.416 important that at some point  
NOTE Confidence: 0.87106836

00:23:08.416 --> 00:23:10.030 this trial needs to be done,

NOTE Confidence: 0.86173505

00:23:10.030 --> 00:23:14.260 the way might be your only chance to do it.

NOTE Confidence: 0.86173505

00:23:14.260 --> 00:23:16.220 The problem with this is,

NOTE Confidence: 0.86173505

00:23:16.220 --> 00:23:19.041 on the one hand, you potentially answer

NOTE Confidence: 0.86173505

00:23:19.041 --> 00:23:21.057 the unanswered questions by bringing

NOTE Confidence: 0.86173505

00:23:21.057 --> 00:23:23.277 a higher level of scientific rigor,

NOTE Confidence: 0.86173505

00:23:23.280 --> 00:23:25.444 but there's concerns about

NOTE Confidence: 0.86173505

00:23:25.444 --> 00:23:27.608 voluntariness and fairness here.

NOTE Confidence: 0.86173505

00:23:27.610 --> 00:23:29.055 And so, particularly when we're

NOTE Confidence: 0.86173505

00:23:29.055 --> 00:23:30.839 thinking about using any UA in

NOTE Confidence: 0.86173505

00:23:30.839 --> 00:23:32.269 the context of limited supplies.

NOTE Confidence: 0.86173505

00:23:32.270 --> 00:23:35.000 So the only way you can get

NOTE Confidence: 0.86173505

00:23:35.000 --> 00:23:38.328 this is if you're in the trial.

NOTE Confidence: 0.86173505

00:23:38.330 --> 00:23:40.370 The plus side is that it solves your

NOTE Confidence: 0.86173505

00:23:40.370 --> 00:23:42.578 problem that FDA does not tell you

NOTE Confidence: 0.86173505

00:23:42.578 --> 00:23:43.894 anything about resource allocation.

NOTE Confidence: 0.86173505

00:23:43.900 --> 00:23:45.658 You know when when there isn't.  
NOTE Confidence: 0.86173505

00:23:45.660 --> 00:23:47.120 Any way for convalescent plasma,  
NOTE Confidence: 0.86173505

00:23:47.120 --> 00:23:49.496 and you know we had six doses for  
NOTE Confidence: 0.86173505

00:23:49.496 --> 00:23:51.516 300 people who needed it or my.  
NOTE Confidence: 0.86173505

00:23:51.520 --> 00:23:53.266 I don't want to send it,  
NOTE Confidence: 0.86173505

00:23:53.270 --> 00:23:55.028 but might have benefited from it.  
NOTE Confidence: 0.86173505

00:23:55.030 --> 00:23:57.557 FDA didn't tell us how to allocate  
NOTE Confidence: 0.86173505

00:23:57.557 --> 00:23:58.640 our six doses.  
NOTE Confidence: 0.86173505

00:23:58.640 --> 00:24:00.400 Using a trial can be one way to  
NOTE Confidence: 0.86173505

00:24:00.400 --> 00:24:02.215 bring some structure and fairness and  
NOTE Confidence: 0.86173505

00:24:02.215 --> 00:24:04.195 criteria to how to distribute those,  
NOTE Confidence: 0.86173505

00:24:04.200 --> 00:24:06.685 but it does raise access to raise  
NOTE Confidence: 0.86173505

00:24:06.685 --> 00:24:08.478 questions about whether there really  
NOTE Confidence: 0.86173505

00:24:08.478 --> 00:24:10.788 is fair access to that trial and  
NOTE Confidence: 0.86173505

00:24:10.788 --> 00:24:12.866 whether or not people are going to.  
NOTE Confidence: 0.86173505

00:24:12.870 --> 00:24:13.940 Inadvertently be coerced into participating

NOTE Confidence: 0.86173505

00:24:13.940 --> 00:24:15.220 because they really want the thing.

NOTE Confidence: 0.86173505

00:24:15.220 --> 00:24:18.667 And that's the only way they can get it.

NOTE Confidence: 0.86173505

00:24:18.670 --> 00:24:20.674 So do you want to distinguish

NOTE Confidence: 0.86173505

00:24:20.674 --> 00:24:22.360 this from right to try?

NOTE Confidence: 0.86173505

00:24:22.360 --> 00:24:24.712 Because I think right to try is

NOTE Confidence: 0.86173505

00:24:24.712 --> 00:24:26.655 when people talk about only plus

NOTE Confidence: 0.86173505

00:24:26.655 --> 00:24:29.117 lay press and I had to go back

NOTE Confidence: 0.86173505

00:24:29.117 --> 00:24:31.397 and remind myself how this works.

NOTE Confidence: 0.86173505

00:24:31.400 --> 00:24:33.536 So right to try is even less regulated

NOTE Confidence: 0.86173505

00:24:33.536 --> 00:24:35.594 than an expanded access in which

NOTE Confidence: 0.86173505

00:24:35.594 --> 00:24:37.790 terminally ill patients can get things

NOTE Confidence: 0.86173505

00:24:37.848 --> 00:24:40.368 after a phase one trial without any

NOTE Confidence: 0.86173505

00:24:40.368 --> 00:24:42.122 further communication from the FDA.

NOTE Confidence: 0.86173505

00:24:42.122 --> 00:24:43.130 So there's no,

NOTE Confidence: 0.86173505

00:24:43.130 --> 00:24:44.800 there's no communication information back.

NOTE Confidence: 0.86173505

00:24:44.800 --> 00:24:45.805 This isn't I.  
NOTE Confidence: 0.86173505

00:24:45.805 --> 00:24:47.815 There's no IRB checkpoint on this,  
NOTE Confidence: 0.86173505

00:24:47.820 --> 00:24:50.668 and I think this was viewed as a  
NOTE Confidence: 0.86173505

00:24:50.668 --> 00:24:53.118 strong thing for patient advocacy.  
NOTE Confidence: 0.86173505

00:24:53.120 --> 00:24:54.928 My take on this is that we have  
NOTE Confidence: 0.86173505

00:24:54.928 --> 00:24:57.246 to be really careful and I liked  
NOTE Confidence: 0.86173505

00:24:57.246 --> 00:24:58.686 this description about it,  
NOTE Confidence: 0.86173505

00:24:58.690 --> 00:24:59.268 but fundamentally,  
NOTE Confidence: 0.86173505

00:24:59.268 --> 00:25:01.940 right to try had a lot to do with  
NOTE Confidence: 0.86173505

00:25:01.940 --> 00:25:04.541 politics and not a lot to do with science.  
NOTE Confidence: 0.86173505

00:25:04.550 --> 00:25:06.308 And if you think critically about  
NOTE Confidence: 0.86173505

00:25:06.308 --> 00:25:07.480 the benefits from this,  
NOTE Confidence: 0.86173505

00:25:07.480 --> 00:25:09.496 it's not really clear what right to try  
NOTE Confidence: 0.86173505

00:25:09.496 --> 00:25:11.869 ads in the setting of compassionate use.  
NOTE Confidence: 0.86173505

00:25:11.870 --> 00:25:12.872 An easy way,  
NOTE Confidence: 0.86173505

00:25:12.872 --> 00:25:14.876 and there's been some really interesting

NOTE Confidence: 0.86173505

00:25:14.876 --> 00:25:17.209 and compelling writing I think about.

NOTE Confidence: 0.86173505

00:25:17.210 --> 00:25:18.506 About the unintended consequences

NOTE Confidence: 0.86173505

00:25:18.506 --> 00:25:19.478 of Rachel tries.

NOTE Confidence: 0.86173505

00:25:19.480 --> 00:25:21.112 So I really like this piece

NOTE Confidence: 0.86173505

00:25:21.112 --> 00:25:22.855 talking about how right to try

NOTE Confidence: 0.86173505

00:25:22.855 --> 00:25:24.051 can inadvertently exclude people

NOTE Confidence: 0.86173505

00:25:24.051 --> 00:25:26.079 from the kind of comprehensive and

NOTE Confidence: 0.86173505

00:25:26.079 --> 00:25:28.024 really high quality palliative care

NOTE Confidence: 0.86173505

00:25:28.024 --> 00:25:30.352 that's available in the 21st century

NOTE Confidence: 0.86173505

00:25:30.352 --> 00:25:33.040 and just a lot of writing about.

NOTE Confidence: 0.86173505

00:25:33.040 --> 00:25:34.671 When we start to make these drugs

NOTE Confidence: 0.86173505

00:25:34.671 --> 00:25:36.467 available like this in this unregulated way,

NOTE Confidence: 0.86173505

00:25:36.470 --> 00:25:37.640 are we really undermining what

NOTE Confidence: 0.86173505

00:25:37.640 --> 00:25:39.361 we owe to patients in terms of

NOTE Confidence: 0.86173505

00:25:39.361 --> 00:25:40.879 science and regulation of new drugs?

NOTE Confidence: 0.86173505

00:25:40.880 --> 00:25:42.595 So this is just food for thought.  
NOTE Confidence: 0.86173505

00:25:42.600 --> 00:25:44.560 I haven't heard a lot of talk about,  
NOTE Confidence: 0.86173505

00:25:44.560 --> 00:25:44.805 right,  
NOTE Confidence: 0.86173505

00:25:44.805 --> 00:25:46.275 right to try in the context  
NOTE Confidence: 0.86173505

00:25:46.275 --> 00:25:47.010 of covered specifically,  
NOTE Confidence: 0.86173505

00:25:47.010 --> 00:25:49.882 but I thought this was a good opportunity  
NOTE Confidence: 0.86173505

00:25:49.882 --> 00:25:52.079 to review pre approval access.  
NOTE Confidence: 0.8263457

00:25:52.080 --> 00:25:54.928 And the question that has been bugging me  
NOTE Confidence: 0.8263457

00:25:54.928 --> 00:25:57.674 for the last six months that I thought  
NOTE Confidence: 0.8263457

00:25:57.674 --> 00:26:00.578 I was going to have answers for you.  
NOTE Confidence: 0.8263457

00:26:00.580 --> 00:26:03.868 For as I came to this talk was how do we  
NOTE Confidence: 0.8263457

00:26:03.868 --> 00:26:06.948 feel about kids and expanded access anyways,  
NOTE Confidence: 0.8263457

00:26:06.950 --> 00:26:08.930 in particular for for COVID-19 infection  
NOTE Confidence: 0.8263457

00:26:08.930 --> 00:26:11.942 and what do we think about kids getting  
NOTE Confidence: 0.8263457

00:26:11.942 --> 00:26:13.982 recipe or convalescent plasma or  
NOTE Confidence: 0.8263457

00:26:13.982 --> 00:26:16.010 monoclonal antibody as under anyway and

NOTE Confidence: 0.8263457

00:26:16.010 --> 00:26:18.764 I expected to find this deep and rich

NOTE Confidence: 0.8263457

00:26:18.764 --> 00:26:21.984 seam of writing by all the ethicists I

NOTE Confidence: 0.8263457

00:26:21.984 --> 00:26:24.744 know who are so much smarter than me.

NOTE Confidence: 0.8263457

00:26:24.750 --> 00:26:26.919 To explain this to me and I found that

NOTE Confidence: 0.8263457

00:26:26.919 --> 00:26:29.002 this really just hasn't been front and

NOTE Confidence: 0.8263457

00:26:29.002 --> 00:26:30.979 center in the minds of bioethicists

NOTE Confidence: 0.8263457

00:26:30.979 --> 00:26:33.426 right now, and there's a lot of potential

NOTE Confidence: 0.8263457

00:26:33.426 --> 00:26:36.059 reasons for that is one is no mark described.

NOTE Confidence: 0.8263457

00:26:36.060 --> 00:26:38.090 We've been really busy doing other things.

NOTE Confidence: 0.8263457

00:26:38.090 --> 00:26:38.586 You know.

NOTE Confidence: 0.8263457

00:26:38.586 --> 00:26:40.895 The other is that a lot of these trials

NOTE Confidence: 0.8263457

00:26:40.895 --> 00:26:43.235 do include kids as young as 12 in the

NOTE Confidence: 0.8263457

00:26:43.298 --> 00:26:45.392 ways usually don't grant permission to

NOTE Confidence: 0.8263457

00:26:45.392 --> 00:26:47.950 use the drug outside of those and ranges,

NOTE Confidence: 0.8263457

00:26:47.950 --> 00:26:49.400 so the other is just.

NOTE Confidence: 0.8263457

00:26:49.400 --> 00:26:50.850 It's not really an issue,  
NOTE Confidence: 0.8263457

00:26:50.850 --> 00:26:52.880 but you do wonder about whether we  
NOTE Confidence: 0.8263457

00:26:52.880 --> 00:26:54.740 should be imposing. I think different.  
NOTE Confidence: 0.8263457

00:26:54.740 --> 00:26:57.050 Thresholds or what's the role of assent?  
NOTE Confidence: 0.8263457

00:26:57.050 --> 00:26:57.652 For example,  
NOTE Confidence: 0.8263457

00:26:57.652 --> 00:26:59.458 for a teenager to get experimental,  
NOTE Confidence: 0.8263457

00:26:59.460 --> 00:27:00.104 convalescent plasma,  
NOTE Confidence: 0.8263457

00:27:00.104 --> 00:27:02.358 and so I'm hoping that you guys  
NOTE Confidence: 0.8263457

00:27:02.358 --> 00:27:04.266 will engage with me on this one.  
NOTE Confidence: 0.8263457

00:27:04.270 --> 00:27:06.214 We're able to talk at the end of  
NOTE Confidence: 0.8263457

00:27:06.214 --> 00:27:07.935 the session because I have been  
NOTE Confidence: 0.8263457

00:27:07.935 --> 00:27:10.108 really trying to think about what is  
NOTE Confidence: 0.8263457

00:27:10.108 --> 00:27:12.232 a framework to think about guiding  
NOTE Confidence: 0.8263457

00:27:12.232 --> 00:27:14.096 pediatric clinicians about use of  
NOTE Confidence: 0.8263457

00:27:14.096 --> 00:27:15.688 of pre approval access.  
NOTE Confidence: 0.8263457

00:27:15.690 --> 00:27:17.208 Outside of the confines of cancer,

NOTE Confidence: 0.8263457

00:27:17.210 --> 00:27:19.250 which is when we usually talk about it,

NOTE Confidence: 0.8263457

00:27:19.250 --> 00:27:21.070 but unfortunately I don't have 10 nice

NOTE Confidence: 0.8263457

00:27:21.070 --> 00:27:22.797 editorials to share with you about this.

NOTE Confidence: 0.8263457

00:27:22.800 --> 00:27:25.115 'cause it doesn't seem like

NOTE Confidence: 0.8263457

00:27:25.115 --> 00:27:26.967 people are writing them.

NOTE Confidence: 0.8263457

00:27:26.970 --> 00:27:28.302 So now I wanna really shift

NOTE Confidence: 0.8263457

00:27:28.302 --> 00:27:29.799 gears and talk about the vaccine.

NOTE Confidence: 0.8263457

00:27:29.800 --> 00:27:31.582 'cause if you want to think about where is

NOTE Confidence: 0.8263457

00:27:31.582 --> 00:27:33.339 the money in pediatric research ethics,

NOTE Confidence: 0.8263457

00:27:33.340 --> 00:27:35.356 it is in vaccines which are at

NOTE Confidence: 0.8263457

00:27:35.356 --> 00:27:37.570 the heart of every pediatrician.

NOTE Confidence: 0.8263457

00:27:37.570 --> 00:27:39.400 So.

NOTE Confidence: 0.8263457

00:27:39.400 --> 00:27:41.650 I will admit that I have bristled at the

NOTE Confidence: 0.8263457

00:27:41.650 --> 00:27:44.018 term operation warp speed this whole time.

NOTE Confidence: 0.8263457

00:27:44.020 --> 00:27:45.760 There's something that about it that

NOTE Confidence: 0.8263457

00:27:45.760 --> 00:27:48.988 I don't like, a feel like it kind of.  
NOTE Confidence: 0.8263457

00:27:48.990 --> 00:27:51.643 Is antithetical to what you want and  
NOTE Confidence: 0.8263457

00:27:51.643 --> 00:27:53.734 methodical and careful research and  
NOTE Confidence: 0.8263457

00:27:53.734 --> 00:27:55.949 that nothing involving human subjects  
NOTE Confidence: 0.8263457

00:27:55.949 --> 00:27:58.698 research should be happen at warp speed.  
NOTE Confidence: 0.8263457

00:27:58.700 --> 00:28:00.820 But now with two doses of vaccine in  
NOTE Confidence: 0.8263457

00:28:00.820 --> 00:28:03.079 my arm and looking at this figure,  
NOTE Confidence: 0.8263457

00:28:03.080 --> 00:28:05.278 I'm starting to wonder if maybe my  
NOTE Confidence: 0.8263457

00:28:05.278 --> 00:28:07.472 approach to this is a little antiquated  
NOTE Confidence: 0.8263457

00:28:07.472 --> 00:28:10.067 and I should view this as a good thing  
NOTE Confidence: 0.8263457

00:28:10.067 --> 00:28:12.424 and a bad thing and I'll get back to  
NOTE Confidence: 0.8263457

00:28:12.424 --> 00:28:14.176 operation warp speed in a minute.  
NOTE Confidence: 0.8263457

00:28:14.180 --> 00:28:16.210 But this is just a comparison of  
NOTE Confidence: 0.8263457

00:28:16.210 --> 00:28:17.430 previous historical viral epidemics  
NOTE Confidence: 0.8263457

00:28:17.430 --> 00:28:19.230 and the time from first observation  
NOTE Confidence: 0.8263457

00:28:19.230 --> 00:28:21.180 of the disease to having a vaccine.

NOTE Confidence: 0.8263457

00:28:21.180 --> 00:28:23.300 Ann and I just it really did happen

NOTE Confidence: 0.8263457

00:28:23.300 --> 00:28:25.559 at warp speed for stars coming too,

NOTE Confidence: 0.8263457

00:28:25.560 --> 00:28:28.188 and I think this figure shows it really well,

NOTE Confidence: 0.8263457

00:28:28.190 --> 00:28:28.762 I'm sorry.

NOTE Confidence: 0.8263457

00:28:28.762 --> 00:28:31.050 If the person who can't see it still

NOTE Confidence: 0.858805792307692

00:28:31.117 --> 00:28:33.250 can't see it, but the idea here is,

NOTE Confidence: 0.858805792307692

00:28:33.250 --> 00:28:35.394 you know, we've known about Merge for six

NOTE Confidence: 0.858805792307692

00:28:35.394 --> 00:28:37.555 years and we still don't have a vaccine.

NOTE Confidence: 0.858805792307692

00:28:37.560 --> 00:28:39.168 It was 15 years from it,

NOTE Confidence: 0.858805792307692

00:28:39.170 --> 00:28:41.582 took 15 years to get A Bola vaccine approved,

NOTE Confidence: 0.858805792307692

00:28:41.590 --> 00:28:43.599 and it wasn't like the laughable outbreak

NOTE Confidence: 0.858805792307692

00:28:43.599 --> 00:28:45.340 was the first of all app, right?

NOTE Confidence: 0.858805792307692

00:28:45.340 --> 00:28:47.590 We knew about it for a long time after

NOTE Confidence: 0.858805792307692

00:28:47.646 --> 00:28:49.935 that before that, and so this is really

NOTE Confidence: 0.858805792307692

00:28:49.935 --> 00:28:51.280 happening in an unprecedented way.

NOTE Confidence: 0.858805792307692

00:28:51.280 --> 00:28:53.422 And of course the research ethics  
NOTE Confidence: 0.858805792307692

00:28:53.422 --> 00:28:56.308 was going to be a little different.  
NOTE Confidence: 0.858805792307692

00:28:56.310 --> 00:28:57.920 So this is a refresher,  
NOTE Confidence: 0.858805792307692

00:28:57.920 --> 00:29:00.181 an vaccine development and testing isn't a  
NOTE Confidence: 0.858805792307692

00:29:00.181 --> 00:29:02.409 ton difference than other new drug testing,  
NOTE Confidence: 0.858805792307692

00:29:02.410 --> 00:29:04.657 and then it goes through many phases,  
NOTE Confidence: 0.858805792307692

00:29:04.660 --> 00:29:06.260 including laboratory and animal studies,  
NOTE Confidence: 0.858805792307692

00:29:06.260 --> 00:29:08.304 in which you do in vitro and  
NOTE Confidence: 0.858805792307692

00:29:08.304 --> 00:29:10.110 then in vivo and animals,  
NOTE Confidence: 0.858805792307692

00:29:10.110 --> 00:29:12.036 and you apply for your Ind.  
NOTE Confidence: 0.858805792307692

00:29:12.040 --> 00:29:14.608 An vaccine studies have the same Phase 1,  
NOTE Confidence: 0.858805792307692

00:29:14.610 --> 00:29:16.906 two and three that other drugs do the  
NOTE Confidence: 0.858805792307692

00:29:16.906 --> 00:29:19.098 same process for approval and licensure,  
NOTE Confidence: 0.858805792307692

00:29:19.100 --> 00:29:20.690 but there are some additional  
NOTE Confidence: 0.858805792307692

00:29:20.690 --> 00:29:23.150 steps here and a lot of these come  
NOTE Confidence: 0.858805792307692

00:29:23.150 --> 00:29:25.573 out come from in the time of post

NOTE Confidence: 0.858805792307692  
00:29:25.573 --> 00:29:27.509 licensure monitoring in vaccines.  
NOTE Confidence: 0.858805792307692  
00:29:27.510 --> 00:29:29.586 So we think about the classic  
NOTE Confidence: 0.858805792307692  
00:29:29.586 --> 00:29:30.624 phase four trials,  
NOTE Confidence: 0.858805792307692  
00:29:30.630 --> 00:29:33.052 in which we look at how these  
NOTE Confidence: 0.858805792307692  
00:29:33.052 --> 00:29:34.800 vaccines are functioning in public.  
NOTE Confidence: 0.858805792307692  
00:29:34.800 --> 00:29:37.248 But we also have systems in place for  
NOTE Confidence: 0.858805792307692  
00:29:37.248 --> 00:29:39.310 adverse event reporting for vaccines.  
NOTE Confidence: 0.858805792307692  
00:29:39.310 --> 00:29:41.040 There's a vaccine safety data  
NOTE Confidence: 0.858805792307692  
00:29:41.040 --> 00:29:42.078 safety data link,  
NOTE Confidence: 0.858805792307692  
00:29:42.080 --> 00:29:44.168 which is like spotty and told,  
NOTE Confidence: 0.858805792307692  
00:29:44.170 --> 00:29:46.252 but allows for this real coordination  
NOTE Confidence: 0.858805792307692  
00:29:46.252 --> 00:29:47.640 of vaccine adverse events.  
NOTE Confidence: 0.858805792307692  
00:29:47.640 --> 00:29:49.704 And there's also this really interesting  
NOTE Confidence: 0.858805792307692  
00:29:49.704 --> 00:29:51.450 history about the vaccine court,  
NOTE Confidence: 0.858805792307692  
00:29:51.450 --> 00:29:54.586 but so thinking about this you sort of  
NOTE Confidence: 0.858805792307692

00:29:54.586 --> 00:29:58.006 wonder how warp speed can this possibly be.

NOTE Confidence: 0.858805792307692

00:29:58.010 --> 00:30:00.257 Some of the reason this happened quickly.

NOTE Confidence: 0.858805792307692

00:30:00.260 --> 00:30:02.248 Apparently in the time of Comet isn't

NOTE Confidence: 0.858805792307692

00:30:02.248 --> 00:30:04.446 just because we were so so so motivated,

NOTE Confidence: 0.858805792307692

00:30:04.450 --> 00:30:06.396 but also because of the nature of

NOTE Confidence: 0.858805792307692

00:30:06.396 --> 00:30:08.378 the RNA vaccine and just ability to

NOTE Confidence: 0.858805792307692

00:30:08.378 --> 00:30:10.300 speed this up in a different way.

NOTE Confidence: 0.858805792307692

00:30:10.300 --> 00:30:11.664 But it really is.

NOTE Confidence: 0.858805792307692

00:30:11.664 --> 00:30:13.369 Amazing and astonishing to think

NOTE Confidence: 0.858805792307692

00:30:13.369 --> 00:30:16.050 of how fast we went from first

NOTE Confidence: 0.858805792307692

00:30:16.050 --> 00:30:17.935 observation of COVID-19 disease to

NOTE Confidence: 0.858805792307692

00:30:17.935 --> 00:30:20.007 a vaccine in the arms of millions

NOTE Confidence: 0.858805792307692

00:30:20.007 --> 00:30:21.578 of people around the world.

NOTE Confidence: 0.8836073

00:30:23.750 --> 00:30:25.592 So this is where it starts

NOTE Confidence: 0.8836073

00:30:25.592 --> 00:30:26.820 to get really interesting.

NOTE Confidence: 0.8836073

00:30:26.820 --> 00:30:29.039 I think for children in vaccines and

NOTE Confidence: 0.8836073

00:30:29.039 --> 00:30:30.913 immediately when we think of vaccines

NOTE Confidence: 0.8836073

00:30:30.913 --> 00:30:33.007 are supposed to be for kids, right?

NOTE Confidence: 0.8836073

00:30:33.007 --> 00:30:34.792 That's this intuitive sense that

NOTE Confidence: 0.8836073

00:30:34.792 --> 00:30:36.992 vaccines are supposed to be for kids

NOTE Confidence: 0.8836073

00:30:36.992 --> 00:30:38.762 and our kids are home, darn it.

NOTE Confidence: 0.8836073

00:30:38.762 --> 00:30:40.508 And. And they can't go to

NOTE Confidence: 0.8836073

00:30:40.508 --> 00:30:42.169 school because of this pandemic.

NOTE Confidence: 0.8836073

00:30:42.170 --> 00:30:43.910 And couldn't we get them

NOTE Confidence: 0.8836073

00:30:43.910 --> 00:30:46.190 vaccinated and send them to school?

NOTE Confidence: 0.8836073

00:30:46.190 --> 00:30:48.214 And so this was so apparent so early.

NOTE Confidence: 0.8836073

00:30:48.220 --> 00:30:49.998 And it was so painfully out clear,

NOTE Confidence: 0.8836073

00:30:50.000 --> 00:30:51.988 so early that we were going to

NOTE Confidence: 0.8836073

00:30:51.988 --> 00:30:53.835 have a vaccine for adults months

NOTE Confidence: 0.8836073

00:30:53.835 --> 00:30:55.689 before we had it for kids.

NOTE Confidence: 0.8836073

00:30:55.690 --> 00:30:57.225 Amen, I learned a really

NOTE Confidence: 0.8836073

00:30:57.225 --> 00:30:58.146 interesting thing here.  
NOTE Confidence: 0.8836073

00:30:58.150 --> 00:30:59.690 I learned this term called  
NOTE Confidence: 0.8836073

00:30:59.690 --> 00:31:00.922 the age D escalation,  
NOTE Confidence: 0.8836073

00:31:00.930 --> 00:31:02.995 which wasn't a term that I knew  
NOTE Confidence: 0.8836073

00:31:02.995 --> 00:31:03.880 specifically which describes  
NOTE Confidence: 0.8836073

00:31:03.936 --> 00:31:05.511 this intuitive walking down the  
NOTE Confidence: 0.8836073

00:31:05.511 --> 00:31:07.086 age spectrum of vaccine testing,  
NOTE Confidence: 0.8836073

00:31:07.090 --> 00:31:09.853 and I want to work through this with you,  
NOTE Confidence: 0.8836073

00:31:09.860 --> 00:31:11.702 'cause I think it's kind of  
NOTE Confidence: 0.8836073

00:31:11.702 --> 00:31:12.623 tricky and important,  
NOTE Confidence: 0.8836073

00:31:12.630 --> 00:31:13.599 but generally speaking,  
NOTE Confidence: 0.8836073

00:31:13.599 --> 00:31:15.860 it's the case for vaccines that Phase  
NOTE Confidence: 0.8836073

00:31:15.914 --> 00:31:17.498 1 two trials are conducted first  
NOTE Confidence: 0.8836073

00:31:17.498 --> 00:31:19.409 in adults than in older children,  
NOTE Confidence: 0.8836073

00:31:19.410 --> 00:31:20.950 and finally in progressively younger  
NOTE Confidence: 0.8836073

00:31:20.950 --> 00:31:22.490 children as it becomes relevant.

NOTE Confidence: 0.8836073

00:31:22.490 --> 00:31:23.465 So for example,

NOTE Confidence: 0.8836073

00:31:23.465 --> 00:31:25.740 there's not a lot of reason to.

NOTE Confidence: 0.8836073

00:31:25.740 --> 00:31:28.981 Test HPV vaccine in the youngest kids

NOTE Confidence: 0.8836073

00:31:28.981 --> 00:31:31.002 right now. Epidemiology of the disease.

NOTE Confidence: 0.8836073

00:31:31.002 --> 00:31:32.640 The risk benefits of the vaccine.

NOTE Confidence: 0.8836073

00:31:32.640 --> 00:31:34.005 There's need to be calculated

NOTE Confidence: 0.8836073

00:31:34.005 --> 00:31:35.097 for each age group.

NOTE Confidence: 0.8836073

00:31:35.100 --> 00:31:36.498 The safety profile of all the

NOTE Confidence: 0.8836073

00:31:36.498 --> 00:31:38.166 factors need to be taken into

NOTE Confidence: 0.8836073

00:31:38.166 --> 00:31:39.186 account in deescalation,

NOTE Confidence: 0.8836073

00:31:39.190 --> 00:31:41.230 and this is due to this classic thing

NOTE Confidence: 0.8836073

00:31:41.230 --> 00:31:43.559 that we say in Pediatrics all the time,

NOTE Confidence: 0.8836073

00:31:43.560 --> 00:31:46.760 which is the kids aren't just little adults.

NOTE Confidence: 0.8836073

00:31:46.760 --> 00:31:47.055 Now,

NOTE Confidence: 0.8836073

00:31:47.055 --> 00:31:49.120 there are situations in which it really

NOTE Confidence: 0.8836073

00:31:49.120 --> 00:31:51.247 makes sense to vaccinate young children,

NOTE Confidence: 0.8836073

00:31:51.250 --> 00:31:52.805 because young children those are

NOTE Confidence: 0.8836073

00:31:52.805 --> 00:31:55.299 the ones who get this and so there

NOTE Confidence: 0.8836073

00:31:55.299 --> 00:31:57.057 you can raise a moral argument

NOTE Confidence: 0.8836073

00:31:57.057 --> 00:31:58.828 against testing a vaccine in

NOTE Confidence: 0.8836073

00:31:58.828 --> 00:32:00.240 an older patient population.

NOTE Confidence: 0.8836073

00:32:00.240 --> 00:32:01.845 If that population really won't

NOTE Confidence: 0.8836073

00:32:01.845 --> 00:32:03.450 derive any benefit from it.

NOTE Confidence: 0.8836073

00:32:03.450 --> 00:32:04.738 There are some situations,

NOTE Confidence: 0.8836073

00:32:04.738 --> 00:32:05.060 Interestingly,

NOTE Confidence: 0.8836073

00:32:05.060 --> 00:32:07.307 in which adults can do this for

NOTE Confidence: 0.8836073

00:32:07.307 --> 00:32:08.270 an altruistic reason,

NOTE Confidence: 0.8836073

00:32:08.270 --> 00:32:10.494 and a group of adults can say we

NOTE Confidence: 0.8836073

00:32:10.494 --> 00:32:12.518 think it's worth having some safety

NOTE Confidence: 0.8836073

00:32:12.518 --> 00:32:15.010 data in adults before we test this.

NOTE Confidence: 0.8836073

00:32:15.010 --> 00:32:15.678 In kids,

NOTE Confidence: 0.8836073

00:32:15.678 --> 00:32:17.014 understanding that we will

NOTE Confidence: 0.8836073

00:32:17.014 --> 00:32:18.350 never benefit from this.

NOTE Confidence: 0.8836073

00:32:18.350 --> 00:32:20.663 I don't have a good modern example of this,

NOTE Confidence: 0.8836073

00:32:20.670 --> 00:32:23.442 but I think this is an

NOTE Confidence: 0.8836073

00:32:23.442 --> 00:32:24.828 interesting moral idea.

NOTE Confidence: 0.8836073

00:32:24.830 --> 00:32:26.776 And there are some situations in which

NOTE Confidence: 0.8836073

00:32:26.776 --> 00:32:28.669 there just isn't a lot of scientific

NOTE Confidence: 0.8836073

00:32:28.669 --> 00:32:30.181 or moral validity in testing a

NOTE Confidence: 0.8836073

00:32:30.240 --> 00:32:32.058 vaccine in adults or older children.

NOTE Confidence: 0.8836073

00:32:32.060 --> 00:32:33.728 Some of this has to do.

NOTE Confidence: 0.8836073

00:32:33.730 --> 00:32:34.308 For example,

NOTE Confidence: 0.8836073

00:32:34.308 --> 00:32:35.753 if adults are previously vaccinated

NOTE Confidence: 0.8836073

00:32:35.753 --> 00:32:37.340 or previously immune to it exposures,

NOTE Confidence: 0.8836073

00:32:37.340 --> 00:32:38.640 there might be situations in

NOTE Confidence: 0.8836073

00:32:38.640 --> 00:32:40.292 which you can make a scientific

NOTE Confidence: 0.8836073

00:32:40.292 --> 00:32:42.044 case that you really have to  
NOTE Confidence: 0.8836073

00:32:42.044 --> 00:32:43.180 test younger children first.  
NOTE Confidence: 0.82600236

00:32:45.510 --> 00:32:47.918 And just drive home this point about  
NOTE Confidence: 0.82600236

00:32:47.918 --> 00:32:49.890 children not being little adults.  
NOTE Confidence: 0.82600236

00:32:49.890 --> 00:32:52.104 There's some data that they express  
NOTE Confidence: 0.82600236

00:32:52.104 --> 00:32:53.910 different antibodies in different ways,  
NOTE Confidence: 0.82600236

00:32:53.910 --> 00:32:56.100 and this is important in thinking  
NOTE Confidence: 0.82600236

00:32:56.100 --> 00:32:57.560 about things like vaccine.  
NOTE Confidence: 0.82600236

00:32:57.560 --> 00:32:59.495 It's also thinking important thing  
NOTE Confidence: 0.82600236

00:32:59.495 --> 00:33:01.794 about the clinical trials for testing  
NOTE Confidence: 0.82600236

00:33:01.794 --> 00:33:04.210 and I will say that I didn't find  
NOTE Confidence: 0.82600236

00:33:04.210 --> 00:33:06.936 anything really in the in the literature  
NOTE Confidence: 0.82600236

00:33:06.936 --> 00:33:08.508 talking about child participation  
NOTE Confidence: 0.82600236

00:33:08.510 --> 00:33:10.990 in vaxin in the test in the clinical  
NOTE Confidence: 0.82600236

00:33:10.990 --> 00:33:12.889 trials of covenanting tests,  
NOTE Confidence: 0.82600236

00:33:12.890 --> 00:33:16.040 I just didn't see that anywhere.

NOTE Confidence: 0.82600236

00:33:16.040 --> 00:33:18.416 And there have been a lot of studies.

NOTE Confidence: 0.82600236

00:33:18.420 --> 00:33:20.196 If you look at what's currently

NOTE Confidence: 0.82600236

00:33:20.196 --> 00:33:20.788 in clinicaltrials.gov,

NOTE Confidence: 0.82600236

00:33:20.790 --> 00:33:23.126 there are a lot of studies of particularly

NOTE Confidence: 0.82600236

00:33:23.126 --> 00:33:24.949 rapid antibody type tests of children,

NOTE Confidence: 0.82600236

00:33:24.950 --> 00:33:26.500 and this difference an antibody

NOTE Confidence: 0.82600236

00:33:26.500 --> 00:33:28.386 expression might be a really good

NOTE Confidence: 0.82600236

00:33:28.386 --> 00:33:30.374 reason that you would want to include

NOTE Confidence: 0.82600236

00:33:30.374 --> 00:33:32.079 children and say an antibody test.

NOTE Confidence: 0.82600236

00:33:32.080 --> 00:33:34.159 Generally, the testing is pretty low risk,

NOTE Confidence: 0.82600236

00:33:34.160 --> 00:33:36.528 so it doesn't generate a lot of controversy.

NOTE Confidence: 0.86498797

00:33:39.190 --> 00:33:41.780 But this is where to me this

NOTE Confidence: 0.86498797

00:33:41.780 --> 00:33:44.420 gets so so interesting so.

NOTE Confidence: 0.86498797

00:33:44.420 --> 00:33:46.852 We are now desperate to get children tested

NOTE Confidence: 0.86498797

00:33:46.852 --> 00:33:49.519 and were desperate for a couple of reasons.

NOTE Confidence: 0.86498797

00:33:49.520 --> 00:33:51.640 One is that I think as people think  
NOTE Confidence: 0.86498797

00:33:51.640 --> 00:33:53.353 about kids with unique vulnerabilities  
NOTE Confidence: 0.86498797

00:33:53.353 --> 00:33:55.585 and even if the overall never.  
NOTE Confidence: 0.86498797

00:33:55.590 --> 00:33:57.180 I haven't said this explicitly,  
NOTE Confidence: 0.86498797

00:33:57.180 --> 00:33:59.735 but even if the overall burden of  
NOTE Confidence: 0.86498797

00:33:59.735 --> 00:34:02.040 this epidemic seems to be low on  
NOTE Confidence: 0.86498797

00:34:02.040 --> 00:34:04.389 kids and the kids don't seem to get  
NOTE Confidence: 0.86498797

00:34:04.389 --> 00:34:06.426 sick and die as much as adults,  
NOTE Confidence: 0.86498797

00:34:06.430 --> 00:34:08.782 parents of kids with a lot of magic  
NOTE Confidence: 0.86498797

00:34:08.782 --> 00:34:10.702 medical frailty are terrified of this  
NOTE Confidence: 0.86498797

00:34:10.702 --> 00:34:13.041 and really worry about about what if  
NOTE Confidence: 0.86498797

00:34:13.041 --> 00:34:15.267 my child with chronic respiratory failure.  
NOTE Confidence: 0.86498797

00:34:15.270 --> 00:34:17.195 Gets a terrible case of COVID-19 and  
NOTE Confidence: 0.86498797

00:34:17.195 --> 00:34:19.176 becomes really sick and you can imagine  
NOTE Confidence: 0.86498797

00:34:19.176 --> 00:34:20.826 how sailing at this was particularly  
NOTE Confidence: 0.86498797

00:34:20.883 --> 00:34:22.808 the beginning of pandemic when it also

NOTE Confidence: 0.86498797

00:34:22.808 --> 00:34:25.375 wasn't clear that we were going to have

NOTE Confidence: 0.86498797

00:34:25.375 --> 00:34:27.110 ventilators for all those children.

NOTE Confidence: 0.86498797

00:34:27.110 --> 00:34:28.856 And so we do see a lot of push

NOTE Confidence: 0.86498797

00:34:28.856 --> 00:34:30.719 from parents who want this vaccine

NOTE Confidence: 0.86498797

00:34:30.719 --> 00:34:32.680 for direct benefit for their kid

NOTE Confidence: 0.86498797

00:34:32.680 --> 00:34:34.150 because they're so desperate for

NOTE Confidence: 0.86498797

00:34:34.150 --> 00:34:35.916 the child not to get covered.

NOTE Confidence: 0.86498797

00:34:35.916 --> 00:34:37.967 And in fact there are some some

NOTE Confidence: 0.86498797

00:34:37.967 --> 00:34:39.700 interesting claims coming out of China

NOTE Confidence: 0.86498797

00:34:39.700 --> 00:34:41.720 that one of their vaccines is testing.

NOTE Confidence: 0.86498797

00:34:41.720 --> 00:34:42.473 Really young kids,

NOTE Confidence: 0.86498797

00:34:42.473 --> 00:34:44.526 and I read this and my first response

NOTE Confidence: 0.86498797

00:34:44.526 --> 00:34:46.422 to this was why can they do it?

NOTE Confidence: 0.86498797

00:34:46.430 --> 00:34:48.362 And we can't and why clearly other

NOTE Confidence: 0.86498797

00:34:48.362 --> 00:34:50.335 people have got this right and have

NOTE Confidence: 0.86498797

00:34:50.335 --> 00:34:52.275 figured out that we should be trying

NOTE Confidence: 0.86498797

00:34:52.275 --> 00:34:54.339 to find a way to test younger kids.

NOTE Confidence: 0.86498797

00:34:54.340 --> 00:34:56.111 This is where I think this tension

NOTE Confidence: 0.86498797

00:34:56.111 --> 00:34:57.666 of individual and public health

NOTE Confidence: 0.86498797

00:34:57.666 --> 00:34:58.776 gets really interesting,

NOTE Confidence: 0.86498797

00:34:58.780 --> 00:35:00.844 and the quote on the right of the

NOTE Confidence: 0.86498797

00:35:00.844 --> 00:35:02.722 screen comes from that article about

NOTE Confidence: 0.86498797

00:35:02.722 --> 00:35:04.672 the Chinese vaccine and the trials

NOTE Confidence: 0.86498797

00:35:04.737 --> 00:35:06.781 of early kids and what they're really

NOTE Confidence: 0.86498797

00:35:06.781 --> 00:35:08.840 thinking of is how can we control

NOTE Confidence: 0.86498797

00:35:08.840 --> 00:35:10.315 this epidemic in our population?

NOTE Confidence: 0.86498797

00:35:10.320 --> 00:35:12.516 And is one way to do that to get

NOTE Confidence: 0.86498797

00:35:12.516 --> 00:35:14.470 younger kids vaccinated with quick?

NOTE Confidence: 0.86498797

00:35:14.470 --> 00:35:15.654 And this, I mean,

NOTE Confidence: 0.86498797

00:35:15.654 --> 00:35:17.430 talk about ripped from the headlines,

NOTE Confidence: 0.86498797

00:35:17.430 --> 00:35:18.036 this article.

NOTE Confidence: 0.86498797  
00:35:18.036 --> 00:35:19.854 On the left I found yesterday  
NOTE Confidence: 0.86498797  
00:35:19.854 --> 00:35:21.637 talking about when we can expect  
NOTE Confidence: 0.86498797  
00:35:21.637 --> 00:35:22.753 results of the vaccine,  
NOTE Confidence: 0.86498797  
00:35:22.760 --> 00:35:24.806 but I just want to call  
NOTE Confidence: 0.86498797  
00:35:24.806 --> 00:35:26.170 your attention to this.  
NOTE Confidence: 0.86498797  
00:35:26.170 --> 00:35:27.546 For that, I've highlighted,  
NOTE Confidence: 0.86498797  
00:35:27.546 --> 00:35:28.578 which is vaccinating.  
NOTE Confidence: 0.86498797  
00:35:28.580 --> 00:35:30.638 Kids could be key to halting,  
NOTE Confidence: 0.86498797  
00:35:30.640 --> 00:35:32.408 spread and herd immunity.  
NOTE Confidence: 0.86498797  
00:35:32.408 --> 00:35:34.176 And this to me,  
NOTE Confidence: 0.86498797  
00:35:34.180 --> 00:35:35.344 that might be true,  
NOTE Confidence: 0.86498797  
00:35:35.344 --> 00:35:37.457 but I think that we really need  
NOTE Confidence: 0.86498797  
00:35:37.457 --> 00:35:39.245 to stop and reflect on this,  
NOTE Confidence: 0.86498797  
00:35:39.250 --> 00:35:41.038 because then we're not really talking  
NOTE Confidence: 0.86498797  
00:35:41.038 --> 00:35:42.230 about kids getting vaccinated,  
NOTE Confidence: 0.86498797

00:35:42.230 --> 00:35:44.316 so they don't get covid and they  
NOTE Confidence: 0.86498797

00:35:44.316 --> 00:35:45.210 don't get sick.  
NOTE Confidence: 0.86498797

00:35:45.210 --> 00:35:46.998 We're talking about kids getting vaccinated,  
NOTE Confidence: 0.86498797

00:35:47.000 --> 00:35:48.866 so their teachers and their parents  
NOTE Confidence: 0.86498797

00:35:48.866 --> 00:35:50.570 and their grandparents in the bus.  
NOTE Confidence: 0.86498797

00:35:50.570 --> 00:35:52.376 Drivers don't get sick and we  
NOTE Confidence: 0.86498797

00:35:52.376 --> 00:35:53.917 can certainly make arguments for  
NOTE Confidence: 0.86498797

00:35:53.917 --> 00:35:55.597 why children are better off when  
NOTE Confidence: 0.86498797

00:35:55.597 --> 00:35:57.398 their parents are healthy and are  
NOTE Confidence: 0.86498797

00:35:57.398 --> 00:35:59.204 better off on their parents have  
NOTE Confidence: 0.86498797

00:35:59.204 --> 00:36:00.404 financial stability because they're  
NOTE Confidence: 0.86498797

00:36:00.404 --> 00:36:01.596 not losing their jobs.  
NOTE Confidence: 0.86498797

00:36:01.600 --> 00:36:02.736 So there are certainly.  
NOTE Confidence: 0.86498797

00:36:02.736 --> 00:36:04.782 Lots of lines to direct benefit to  
NOTE Confidence: 0.86498797

00:36:04.782 --> 00:36:06.468 kids for having this pandemic ends,  
NOTE Confidence: 0.86498797

00:36:06.470 --> 00:36:08.234 but it's a little more direct and

NOTE Confidence: 0.86498797

00:36:08.234 --> 00:36:09.989 I really hope we can talk about

NOTE Confidence: 0.86498797

00:36:09.989 --> 00:36:11.405 this because in the in our

NOTE Confidence: 0.870443399999999

00:36:11.459 --> 00:36:13.636 discussion 'cause I find this to be

NOTE Confidence: 0.870443399999999

00:36:13.636 --> 00:36:16.440 incredibly complex and thought provoking.

NOTE Confidence: 0.870443399999999

00:36:16.440 --> 00:36:18.552 So again, you know I threatened

NOTE Confidence: 0.870443399999999

00:36:18.552 --> 00:36:20.953 to talk about this a lot and

NOTE Confidence: 0.870443399999999

00:36:20.953 --> 00:36:22.783 I'm talking about this a lot,

NOTE Confidence: 0.870443399999999

00:36:22.790 --> 00:36:24.435 but there's a great article

NOTE Confidence: 0.870443399999999

00:36:24.435 --> 00:36:26.812 that's still in the all you can

NOTE Confidence: 0.870443399999999

00:36:26.812 --> 00:36:28.798 get is the Word document version,

NOTE Confidence: 0.870443399999999

00:36:28.800 --> 00:36:30.360 but it's free access in Pediatrics

NOTE Confidence: 0.870443399999999

00:36:30.360 --> 00:36:32.145 from some of our lawyer friends

NOTE Confidence: 0.870443399999999

00:36:32.145 --> 00:36:33.529 talking about different ways

NOTE Confidence: 0.870443399999999

00:36:33.529 --> 00:36:35.432 that our regulatory body could

NOTE Confidence: 0.870443399999999

00:36:35.432 --> 00:36:36.809 approach vaccinating children,

NOTE Confidence: 0.870443399999999

00:36:36.810 --> 00:36:38.910 and at what stage of safety and  
NOTE Confidence: 0.8704433999999999

00:36:38.910 --> 00:36:40.636 efficacy should we be including  
NOTE Confidence: 0.8704433999999999

00:36:40.636 --> 00:36:42.156 children in these trials?  
NOTE Confidence: 0.8704433999999999

00:36:42.160 --> 00:36:44.652 And I think they find this really  
NOTE Confidence: 0.8704433999999999

00:36:44.652 --> 00:36:46.300 nice and tabular way of.  
NOTE Confidence: 0.8704433999999999

00:36:46.300 --> 00:36:48.520 Weighing out the pros and cons  
NOTE Confidence: 0.8704433999999999

00:36:48.520 --> 00:36:50.925 of a very conservative versus a  
NOTE Confidence: 0.8704433999999999

00:36:50.925 --> 00:36:53.055 very effective approach and the  
NOTE Confidence: 0.8704433999999999

00:36:53.055 --> 00:36:55.183 tradeoffs of slowing down vaccine  
NOTE Confidence: 0.8704433999999999

00:36:55.183 --> 00:36:57.530 into the arms of children, but.  
NOTE Confidence: 0.849388

00:36:59.610 --> 00:37:01.240 That on the one hand,  
NOTE Confidence: 0.849388

00:37:01.240 --> 00:37:02.860 but potentially having more risks,  
NOTE Confidence: 0.849388

00:37:02.860 --> 00:37:05.308 on the other hand.  
NOTE Confidence: 0.849388

00:37:05.310 --> 00:37:07.494 And I thought this was a great read.  
NOTE Confidence: 0.849388

00:37:07.500 --> 00:37:09.330 I thought this was really interesting  
NOTE Confidence: 0.849388

00:37:09.330 --> 00:37:10.827 and particularly this point about

NOTE Confidence: 0.849388

00:37:10.827 --> 00:37:12.423 the risk to lots of public trust.

NOTE Confidence: 0.849388

00:37:12.430 --> 00:37:13.800 If you get this wrong,

NOTE Confidence: 0.849388

00:37:13.800 --> 00:37:15.501 and so there's really not one answer

NOTE Confidence: 0.849388

00:37:15.501 --> 00:37:17.178 to what should the regulatory approach

NOTE Confidence: 0.849388

00:37:17.178 --> 00:37:19.278 be to enrolling kids in vaccine trials?

NOTE Confidence: 0.849388

00:37:19.280 --> 00:37:21.746 Or when is the right time to do it?

NOTE Confidence: 0.849388

00:37:21.750 --> 00:37:23.752 But I think that some really smart

NOTE Confidence: 0.849388

00:37:23.752 --> 00:37:25.178 and interesting people are starting

NOTE Confidence: 0.849388

00:37:25.178 --> 00:37:27.226 to tease this out in a systematic way.

NOTE Confidence: 0.849388

00:37:27.230 --> 00:37:31.326 That's going to help us think about this.

NOTE Confidence: 0.849388

00:37:31.330 --> 00:37:33.589 So now I have to talk about the part

NOTE Confidence: 0.849388

00:37:33.589 --> 00:37:35.908 of this that's the hardest for me,

NOTE Confidence: 0.849388

00:37:35.910 --> 00:37:37.620 and it's the hardest for me.

NOTE Confidence: 0.849388

00:37:37.620 --> 00:37:39.489 I think both because it's not a

NOTE Confidence: 0.849388

00:37:39.489 --> 00:37:41.339 strong area of expertise for me,

NOTE Confidence: 0.849388

00:37:41.340 --> 00:37:43.524 but also just because this has been so  
NOTE Confidence: 0.849388

00:37:43.524 --> 00:37:45.626 painful in America over the last year,  
NOTE Confidence: 0.849388

00:37:45.630 --> 00:37:47.340 and not only because we've seen  
NOTE Confidence: 0.849388

00:37:47.340 --> 00:37:48.195 these disparities now,  
NOTE Confidence: 0.849388

00:37:48.200 --> 00:37:50.400 but was we've been forced to contend with  
NOTE Confidence: 0.849388

00:37:50.400 --> 00:37:52.778 how long they've been there and how long.  
NOTE Confidence: 0.849388

00:37:52.780 --> 00:37:53.129 Race,  
NOTE Confidence: 0.849388

00:37:53.129 --> 00:37:55.223 racism and inequity have played a  
NOTE Confidence: 0.849388

00:37:55.223 --> 00:37:57.329 role in American research ethics.  
NOTE Confidence: 0.849388

00:37:57.330 --> 00:37:59.577 So this started coming out really early.  
NOTE Confidence: 0.849388

00:37:59.580 --> 00:38:02.073 This was a slide I made for my very  
NOTE Confidence: 0.849388

00:38:02.073 --> 00:38:04.319 early talks on Covid in the spring  
NOTE Confidence: 0.849388

00:38:04.319 --> 00:38:06.734 and summer when we were really talking  
NOTE Confidence: 0.849388

00:38:06.734 --> 00:38:09.240 about how are we going to grapple  
NOTE Confidence: 0.849388

00:38:09.240 --> 00:38:11.346 with the historical unease that the  
NOTE Confidence: 0.849388

00:38:11.346 --> 00:38:13.080 black community has with research

NOTE Confidence: 0.849388

00:38:13.080 --> 00:38:15.232 in America and how are we going to

NOTE Confidence: 0.849388

00:38:15.232 --> 00:38:16.895 be trustworthy and be transparent

NOTE Confidence: 0.849388

00:38:16.895 --> 00:38:19.734 and make sure that we come up with

NOTE Confidence: 0.849388

00:38:19.734 --> 00:38:22.653 a vaccine that people want to take?

NOTE Confidence: 0.849388

00:38:22.660 --> 00:38:24.688 Informed by by studies that reflect

NOTE Confidence: 0.849388

00:38:24.688 --> 00:38:26.810 who we are as a country,

NOTE Confidence: 0.849388

00:38:26.810 --> 00:38:29.057 and this this has been such a

NOTE Confidence: 0.849388

00:38:29.057 --> 00:38:30.620 deeply held fearing concern.

NOTE Confidence: 0.849388

00:38:30.620 --> 00:38:32.930 I think even though most of the

NOTE Confidence: 0.849388

00:38:32.930 --> 00:38:35.120 writing about this isn't about kids,

NOTE Confidence: 0.849388

00:38:35.120 --> 00:38:38.410 but we really can't skip this part.

NOTE Confidence: 0.849388

00:38:38.410 --> 00:38:40.552 And no where more than I think

NOTE Confidence: 0.849388

00:38:40.552 --> 00:38:42.869 in this issue of recent research,

NOTE Confidence: 0.849388

00:38:42.870 --> 00:38:44.928 is this issue of access versus

NOTE Confidence: 0.849388

00:38:44.928 --> 00:38:45.957 protection more salient?

NOTE Confidence: 0.849388

00:38:45.960 --> 00:38:48.344 And one thing that kind of gets under

NOTE Confidence: 0.849388

00:38:48.344 --> 00:38:51.198 my skin a little bit is when I see

NOTE Confidence: 0.849388

00:38:51.198 --> 00:38:53.010 these headlines that really boil

NOTE Confidence: 0.849388

00:38:53.010 --> 00:38:55.440 this down to something like black

NOTE Confidence: 0.849388

00:38:55.440 --> 00:38:57.618 community won't be in research trial,

NOTE Confidence: 0.849388

00:38:57.618 --> 00:38:58.986 because Tuskegee and distrust.

NOTE Confidence: 0.849388

00:38:58.990 --> 00:39:01.482 And that's not to downplay that deep

NOTE Confidence: 0.849388

00:39:01.482 --> 00:39:03.450 and painful history of test Kyan,

NOTE Confidence: 0.849388

00:39:03.450 --> 00:39:05.508 that mistrust that's been so so

NOTE Confidence: 0.849388

00:39:05.508 --> 00:39:06.537 hard to recover.

NOTE Confidence: 0.849388

00:39:06.540 --> 00:39:08.658 But I really think it's important

NOTE Confidence: 0.849388

00:39:08.658 --> 00:39:09.717 to think about.

NOTE Confidence: 0.849388

00:39:09.720 --> 00:39:11.918 Other ways that we have created and

NOTE Confidence: 0.849388

00:39:11.918 --> 00:39:13.646 allowed for barriers of historically

NOTE Confidence: 0.849388

00:39:13.646 --> 00:39:16.180 disadvantaged groups to be part of trials.

NOTE Confidence: 0.849388

00:39:16.180 --> 00:39:18.469 And if you think about hidden costs

NOTE Confidence: 0.849388  
00:39:18.469 --> 00:39:20.475 of participating in research such as  
NOTE Confidence: 0.849388  
00:39:20.475 --> 00:39:22.722 coming back to the hospital for extra  
NOTE Confidence: 0.849388  
00:39:22.784 --> 00:39:24.636 research, paying for extra visits,  
NOTE Confidence: 0.849388  
00:39:24.636 --> 00:39:26.610 paying for parking is a huge  
NOTE Confidence: 0.849388  
00:39:26.679 --> 00:39:28.419 issue at my own institution.  
NOTE Confidence: 0.849388  
00:39:28.420 --> 00:39:30.800 Buying lunch when you're at the hospital.  
NOTE Confidence: 0.849388  
00:39:30.800 --> 00:39:32.840 If you have to travel far.  
NOTE Confidence: 0.849388  
00:39:32.840 --> 00:39:35.059 Concerns about access to to poor health  
NOTE Confidence: 0.849388  
00:39:35.059 --> 00:39:36.920 literacy or lack of information,  
NOTE Confidence: 0.849388  
00:39:36.920 --> 00:39:38.660 and various ways that implicit  
NOTE Confidence: 0.849388  
00:39:38.660 --> 00:39:40.052 biases play in this.  
NOTE Confidence: 0.849388  
00:39:40.060 --> 00:39:41.944 It is certainly about mistrust and  
NOTE Confidence: 0.849388  
00:39:41.944 --> 00:39:43.690 certainly about a nasty history,  
NOTE Confidence: 0.849388  
00:39:43.690 --> 00:39:46.660 but it's also got a lot of other things.  
NOTE Confidence: 0.86043406  
00:39:46.660 --> 00:39:48.310 And the other thing is,  
NOTE Confidence: 0.86043406

00:39:48.310 --> 00:39:49.960 it's about the funding pipeline,  
NOTE Confidence: 0.86043406

00:39:49.960 --> 00:39:52.151 and it's about who gets funded an  
NOTE Confidence: 0.86043406

00:39:52.151 --> 00:39:54.908 WHO is in a position to be funded,  
NOTE Confidence: 0.86043406

00:39:54.910 --> 00:39:57.110 an how lack of diversity  
NOTE Confidence: 0.86043406

00:39:57.110 --> 00:39:58.430 among principle investigators.  
NOTE Confidence: 0.86043406

00:39:58.430 --> 00:40:00.326 Is part of the problem that.  
NOTE Confidence: 0.86043406

00:40:00.330 --> 00:40:01.750 Impacts what gets funded,  
NOTE Confidence: 0.86043406

00:40:01.750 --> 00:40:02.815 particularly the NIH.  
NOTE Confidence: 0.86043406

00:40:02.820 --> 00:40:05.046 And so the issue of bringing the  
NOTE Confidence: 0.86043406

00:40:05.046 --> 00:40:07.240 diversity to our trials and having  
NOTE Confidence: 0.86043406

00:40:07.240 --> 00:40:08.800 our trial populations represent  
NOTE Confidence: 0.86043406

00:40:08.800 --> 00:40:11.010 who we are in the country.  
NOTE Confidence: 0.86043406

00:40:11.010 --> 00:40:12.790 It's really thorny and complicated,  
NOTE Confidence: 0.86043406

00:40:12.790 --> 00:40:15.002 and all of the things that we've  
NOTE Confidence: 0.86043406

00:40:15.002 --> 00:40:17.132 been talking about in this really  
NOTE Confidence: 0.86043406

00:40:17.132 --> 00:40:18.620 complicated time in American

NOTE Confidence: 0.86043406

00:40:18.620 --> 00:40:20.980 history play out in research ethics.

NOTE Confidence: 0.82339334

00:40:23.030 --> 00:40:25.946 And one more thing to kind of bring this

NOTE Confidence: 0.82339334

00:40:25.946 --> 00:40:28.528 point home is just thinking you know.

NOTE Confidence: 0.82339334

00:40:28.530 --> 00:40:30.594 So black people make up about

NOTE Confidence: 0.82339334

00:40:30.594 --> 00:40:33.010 13% of the population in the US,

NOTE Confidence: 0.82339334

00:40:33.010 --> 00:40:35.074 but have accounted for 21% of

NOTE Confidence: 0.82339334

00:40:35.074 --> 00:40:37.136 the deaths of covid. And sadly,

NOTE Confidence: 0.82339334

00:40:37.136 --> 00:40:39.537 only 3% of enrollees in vaccine trials.

NOTE Confidence: 0.82339334

00:40:39.540 --> 00:40:41.260 This threatens the validity and

NOTE Confidence: 0.82339334

00:40:41.260 --> 00:40:44.160 generalizability of the trial, and.

NOTE Confidence: 0.82339334

00:40:44.160 --> 00:40:46.384 And you know, I won't belabor this any

NOTE Confidence: 0.82339334

00:40:46.384 --> 00:40:48.616 further, but this is not a small issue,

NOTE Confidence: 0.82339334

00:40:48.620 --> 00:40:50.300 and so I really like this.

NOTE Confidence: 0.82339334

00:40:50.300 --> 00:40:52.268 You know, I harped earlier about my dislike

NOTE Confidence: 0.82339334

00:40:52.268 --> 00:40:54.198 of the phrase operation warp speed,

NOTE Confidence: 0.82339334

00:40:54.200 --> 00:40:55.880 but I really liked this phrase.  
NOTE Confidence: 0.82339334

00:40:55.880 --> 00:40:57.714 Trust could be earned more quickly by  
NOTE Confidence: 0.82339334

00:40:57.714 --> 00:40:58.950 a collaboratively designed operation.  
NOTE Confidence: 0.82339334

00:40:58.950 --> 00:41:00.600 Build trust with worthiness that matches  
NOTE Confidence: 0.82339334

00:41:00.600 --> 00:41:02.289 the seriousness and scope of operation,  
NOTE Confidence: 0.82339334

00:41:02.290 --> 00:41:02.822 Warp speed.  
NOTE Confidence: 0.82339334

00:41:02.822 --> 00:41:03.354 And again,  
NOTE Confidence: 0.82339334

00:41:03.354 --> 00:41:05.360 I couldn't have said it better myself,  
NOTE Confidence: 0.82339334

00:41:05.360 --> 00:41:07.788 so I didn't try.  
NOTE Confidence: 0.82339334

00:41:07.790 --> 00:41:10.724 But the sad so sorry before my sad thing.  
NOTE Confidence: 0.82339334

00:41:10.730 --> 00:41:12.725 One of the things that's been really  
NOTE Confidence: 0.82339334

00:41:12.725 --> 00:41:14.356 interesting is I think different  
NOTE Confidence: 0.82339334

00:41:14.356 --> 00:41:16.876 approaches that that leaders in the black  
NOTE Confidence: 0.82339334

00:41:16.876 --> 00:41:18.906 community have taken to addressing this,  
NOTE Confidence: 0.82339334

00:41:18.910 --> 00:41:20.947 and one strategy has been to people  
NOTE Confidence: 0.82339334

00:41:20.947 --> 00:41:23.256 in positions of leadership and sort of

NOTE Confidence: 0.82339334

00:41:23.256 --> 00:41:25.708 figures of respect and authority have said

NOTE Confidence: 0.82339334

00:41:25.708 --> 00:41:28.060 we're going to volunteer for these trials,

NOTE Confidence: 0.82339334

00:41:28.060 --> 00:41:30.492 and we think we owe it to ourselves

NOTE Confidence: 0.82339334

00:41:30.492 --> 00:41:33.300 and one another to be in these trials.

NOTE Confidence: 0.82339334

00:41:33.300 --> 00:41:36.234 And there's a big case that cost my eye.

NOTE Confidence: 0.82339334

00:41:36.240 --> 00:41:37.628 'cause I'm from Louisiana.

NOTE Confidence: 0.82339334

00:41:37.628 --> 00:41:39.710 But the presidents of two historically

NOTE Confidence: 0.82339334

00:41:39.763 --> 00:41:41.521 black universities in New Orleans said

NOTE Confidence: 0.82339334

00:41:41.521 --> 00:41:43.980 we were going to enroll in these trials,

NOTE Confidence: 0.82339334

00:41:43.980 --> 00:41:45.834 and we recommend that our student

NOTE Confidence: 0.82339334

00:41:45.834 --> 00:41:47.070 bodies do this too.

NOTE Confidence: 0.82339334

00:41:47.070 --> 00:41:49.226 And this was not met without controversy,

NOTE Confidence: 0.82339334

00:41:49.230 --> 00:41:51.006 and there was some some significant

NOTE Confidence: 0.82339334

00:41:51.006 --> 00:41:52.569 bash backlash from parents of

NOTE Confidence: 0.82339334

00:41:52.569 --> 00:41:53.869 students at these institutions.

NOTE Confidence: 0.82339334

00:41:53.870 --> 00:41:55.340 So this wasn't universally welcomed  
NOTE Confidence: 0.82339334

00:41:55.340 --> 00:41:58.190 as a as a way to address this issue,  
NOTE Confidence: 0.82339334

00:41:58.190 --> 00:42:01.172 but I find this to be interesting  
NOTE Confidence: 0.82339334

00:42:01.172 --> 00:42:02.450 and thought provoking.  
NOTE Confidence: 0.82339334

00:42:02.450 --> 00:42:03.814 But for all this,  
NOTE Confidence: 0.82339334

00:42:03.814 --> 00:42:05.860 unfortunately the news isn't very good  
NOTE Confidence: 0.82339334

00:42:05.930 --> 00:42:08.074 and this was a figure I found that  
NOTE Confidence: 0.82339334

00:42:08.074 --> 00:42:10.567 thought I thought laid out really nicely.  
NOTE Confidence: 0.82339334

00:42:10.570 --> 00:42:12.466 The proportion of people in different  
NOTE Confidence: 0.82339334

00:42:12.466 --> 00:42:14.095 states who have been vaccinated  
NOTE Confidence: 0.82339334

00:42:14.095 --> 00:42:16.265 who are black set up against the  
NOTE Confidence: 0.82339334

00:42:16.265 --> 00:42:17.965 proportion of residents of that  
NOTE Confidence: 0.82339334

00:42:17.965 --> 00:42:19.665 state for black and importantly,  
NOTE Confidence: 0.82339334

00:42:19.670 --> 00:42:21.656 of the proportion of health care  
NOTE Confidence: 0.82339334

00:42:21.656 --> 00:42:23.900 workers in that state who are black.  
NOTE Confidence: 0.82339334

00:42:23.900 --> 00:42:26.154 And that's important when the people who

NOTE Confidence: 0.82339334

00:42:26.154 --> 00:42:28.448 have been vaccinated for health care workers.

NOTE Confidence: 0.82339334

00:42:28.450 --> 00:42:30.400 And as you can see here,

NOTE Confidence: 0.82339334

00:42:30.400 --> 00:42:32.458 we're not doing great here and.

NOTE Confidence: 0.82339334

00:42:32.460 --> 00:42:33.735 There are some states where

NOTE Confidence: 0.82339334

00:42:33.735 --> 00:42:35.010 we're doing better than others,

NOTE Confidence: 0.82339334

00:42:35.010 --> 00:42:36.962 but even in states where a huge proportion

NOTE Confidence: 0.82339334

00:42:36.962 --> 00:42:38.580 of health care workers are black,

NOTE Confidence: 0.82339334

00:42:38.580 --> 00:42:39.948 there are a very small fraction

NOTE Confidence: 0.82339334

00:42:39.948 --> 00:42:41.380 of people who've been vaccinated,

NOTE Confidence: 0.82339334

00:42:41.380 --> 00:42:42.376 and so to me,

NOTE Confidence: 0.82339334

00:42:42.376 --> 00:42:44.185 this says that our fears were warranted

NOTE Confidence: 0.82339334

00:42:44.185 --> 00:42:46.480 and we've got a lot of work to do.

NOTE Confidence: 0.82339334

00:42:46.480 --> 00:42:46.990 You know,

NOTE Confidence: 0.82339334

00:42:46.990 --> 00:42:49.030 we didn't solve this on the 1st pass,

NOTE Confidence: 0.82339334

00:42:49.030 --> 00:42:51.505 and we have a lot more work to do

NOTE Confidence: 0.82339334

00:42:51.505 --> 00:42:54.390 to figure out how to do better here.  
NOTE Confidence: 0.82339334

00:42:54.390 --> 00:42:56.806 So if your question is what on Earth  
NOTE Confidence: 0.82339334

00:42:56.806 --> 00:42:59.646 does this have to do with pediatric ethics?  
NOTE Confidence: 0.82339334

00:42:59.650 --> 00:43:01.570 That's fair and I didn't find  
NOTE Confidence: 0.82339334

00:43:01.570 --> 00:43:02.850 anything in the literature  
NOTE Confidence: 0.8435062

00:43:02.908 --> 00:43:05.556 specifically in or in the Lane press really  
NOTE Confidence: 0.8435062

00:43:05.556 --> 00:43:07.880 about children of color and vaccine trials,  
NOTE Confidence: 0.8435062

00:43:07.880 --> 00:43:10.472 but I think there's no reason to think  
NOTE Confidence: 0.8435062

00:43:10.472 --> 00:43:12.809 that they would be immune to this,  
NOTE Confidence: 0.8435062

00:43:12.810 --> 00:43:15.155 and that the forces that impact their  
NOTE Confidence: 0.8435062

00:43:15.155 --> 00:43:17.089 parents aren't going to infect them.  
NOTE Confidence: 0.8435062

00:43:17.090 --> 00:43:19.334 And in the really compelling letter  
NOTE Confidence: 0.8435062

00:43:19.334 --> 00:43:22.378 from the AP to the to the Health  
NOTE Confidence: 0.8435062

00:43:22.378 --> 00:43:24.580 and Human services and the FDA.  
NOTE Confidence: 0.8435062

00:43:24.580 --> 00:43:26.536 This difference in mortality among black  
NOTE Confidence: 0.8435062

00:43:26.536 --> 00:43:28.700 Matlack Latin X children was highlighted,

NOTE Confidence: 0.8435062

00:43:28.700 --> 00:43:30.746 and I thought said really nicely.

NOTE Confidence: 0.8435062

00:43:30.750 --> 00:43:32.934 The population studied must reflect the

NOTE Confidence: 0.8435062

00:43:32.934 --> 00:43:35.361 racial and ethnic diversity of the US

NOTE Confidence: 0.8435062

00:43:35.361 --> 00:43:37.185 population and not exclude populations at

NOTE Confidence: 0.8435062

00:43:37.185 --> 00:43:39.667 risk that may greatly benefit from Maxine's,

NOTE Confidence: 0.8435062

00:43:39.670 --> 00:43:41.860 including children.

NOTE Confidence: 0.8435062

00:43:41.860 --> 00:43:45.208 So we know this is a vulnerability for us.

NOTE Confidence: 0.8435062

00:43:45.210 --> 00:43:47.070 We know that health disparities

NOTE Confidence: 0.8435062

00:43:47.070 --> 00:43:48.930 impact children in devastating ways,

NOTE Confidence: 0.8435062

00:43:48.930 --> 00:43:51.527 and we seem to not have quite,

NOTE Confidence: 0.8435062

00:43:51.530 --> 00:43:54.840 not quite not at all figured out what to do

NOTE Confidence: 0.8435062

00:43:54.919 --> 00:43:58.223 to realize the dream of the vaccine trials.

NOTE Confidence: 0.8435062

00:43:58.230 --> 00:44:01.500 Reflecting the diversity of this country.

NOTE Confidence: 0.8435062

00:44:01.500 --> 00:44:03.795 So I wish I had happier news on this.

NOTE Confidence: 0.8435062

00:44:03.800 --> 00:44:05.550 This is a little bit of a

NOTE Confidence: 0.8435062

00:44:05.550 --> 00:44:07.388 dark place to wrap up my part.

NOTE Confidence: 0.8435062

00:44:07.390 --> 00:44:09.161 My talking about vaccines but but I

NOTE Confidence: 0.8435062

00:44:09.161 --> 00:44:11.133 think this is this is part of what

NOTE Confidence: 0.8435062

00:44:11.133 --> 00:44:13.019 we've got to do together as ethicists.

NOTE Confidence: 0.8435062

00:44:13.020 --> 00:44:13.538 So finally,

NOTE Confidence: 0.8435062

00:44:13.538 --> 00:44:15.840 because I think I've got time to do it,

NOTE Confidence: 0.8435062

00:44:15.840 --> 00:44:17.883 I want to talk a little bit about research

NOTE Confidence: 0.8435062

00:44:17.883 --> 00:44:19.418 integrity in public publication ethics.

NOTE Confidence: 0.8435062

00:44:19.420 --> 00:44:21.598 I spent a lot of time on this for

NOTE Confidence: 0.8435062

00:44:21.598 --> 00:44:23.519 those folks who are who do this,

NOTE Confidence: 0.8435062

00:44:23.520 --> 00:44:25.038 I don't know if your program

NOTE Confidence: 0.8435062

00:44:25.038 --> 00:44:26.589 is is where people get this,

NOTE Confidence: 0.8435062

00:44:26.590 --> 00:44:28.446 but if you have a K award you're

NOTE Confidence: 0.8435062

00:44:28.446 --> 00:44:30.342 required to get 10 hours of in

NOTE Confidence: 0.8435062

00:44:30.342 --> 00:44:31.442 person training on research,

NOTE Confidence: 0.8435062

00:44:31.450 --> 00:44:32.488 ethics and integrity.

NOTE Confidence: 0.8435062

00:44:32.488 --> 00:44:34.910 Um and so at University of Michigan.

NOTE Confidence: 0.8435062

00:44:34.910 --> 00:44:36.905 RC TSA takes responsibility for making sure

NOTE Confidence: 0.8435062

00:44:36.905 --> 00:44:39.300 that all our categories get that training,

NOTE Confidence: 0.8435062

00:44:39.300 --> 00:44:41.838 and I teach it with my good friend Kate

NOTE Confidence: 0.8435062

00:44:41.838 --> 00:44:43.620 Spectre Baghdadi and we always have

NOTE Confidence: 0.8435062

00:44:43.620 --> 00:44:45.840 a lot of fun talking about research

NOTE Confidence: 0.8435062

00:44:45.840 --> 00:44:48.360 ethics and integrity and in the covid

NOTE Confidence: 0.8435062

00:44:48.360 --> 00:44:51.611 vaccine then the covid era I would say

NOTE Confidence: 0.8435062

00:44:51.611 --> 00:44:54.830 it wasn't fun but it was relevant.

NOTE Confidence: 0.8435062

00:44:54.830 --> 00:44:58.316 So when I teach people about falsification,

NOTE Confidence: 0.8435062

00:44:58.320 --> 00:44:59.560 plagiarism, fabrication,

NOTE Confidence: 0.8435062

00:44:59.560 --> 00:45:04.520 I use this like you know this lingo

NOTE Confidence: 0.8435062

00:45:04.632 --> 00:45:07.530 of too long didn't read and.

NOTE Confidence: 0.8435062

00:45:07.530 --> 00:45:10.170 Really. Just don't steal \*\*\*\*.

NOTE Confidence: 0.8435062

00:45:10.170 --> 00:45:11.134 Don't make \*\*\*\* up,

NOTE Confidence: 0.8435062

00:45:11.134 --> 00:45:12.580 don't change it and I've got  
NOTE Confidence: 0.8435062

00:45:12.631 --> 00:45:14.587 permission from Doctor Mirror to swear,  
NOTE Confidence: 0.8435062

00:45:14.590 --> 00:45:16.417 but I think it's important for this  
NOTE Confidence: 0.8435062

00:45:16.417 --> 00:45:18.437 to be funny because it really needs  
NOTE Confidence: 0.8435062

00:45:18.437 --> 00:45:20.510 to go in 'cause everyone says I  
NOTE Confidence: 0.8435062

00:45:20.510 --> 00:45:21.486 would never do this.  
NOTE Confidence: 0.8435062

00:45:21.490 --> 00:45:23.146 This could never happen to me.  
NOTE Confidence: 0.8435062

00:45:23.150 --> 00:45:25.976 I know better this this won't happen and it  
NOTE Confidence: 0.8435062

00:45:25.976 --> 00:45:28.516 happens and it happens over and over again.  
NOTE Confidence: 0.8435062

00:45:28.520 --> 00:45:30.354 So we use the example of hydroxychloroquine,  
NOTE Confidence: 0.8435062

00:45:30.360 --> 00:45:32.047 so all of you guys will remember  
NOTE Confidence: 0.8435062

00:45:32.047 --> 00:45:33.674 the great hope about this at  
NOTE Confidence: 0.8435062

00:45:33.674 --> 00:45:35.084 the beginning of the pandemic,  
NOTE Confidence: 0.8435062

00:45:35.090 --> 00:45:35.873 and this cheap,  
NOTE Confidence: 0.8435062

00:45:35.873 --> 00:45:37.178 widely available drug was going  
NOTE Confidence: 0.8435062

00:45:37.178 --> 00:45:39.036 to be the Savior for this thing.

NOTE Confidence: 0.8435062

00:45:39.040 --> 00:45:41.049 And then you look at the cumulative

NOTE Confidence: 0.8435062

00:45:41.049 --> 00:45:43.177 trials and you see a peak in the

NOTE Confidence: 0.8435062

00:45:43.177 --> 00:45:44.933 spring of new trials and it starts

NOTE Confidence: 0.8435062

00:45:44.933 --> 00:45:46.397 to go down and you know.

NOTE Confidence: 0.8377

00:45:46.400 --> 00:45:48.224 And then our hopes came crashing

NOTE Confidence: 0.8377

00:45:48.224 --> 00:45:50.394 down and this just wasn't the panacea

NOTE Confidence: 0.8377

00:45:50.394 --> 00:45:52.720 that we thought it was going to be.

NOTE Confidence: 0.8377

00:45:52.720 --> 00:45:53.900 And if you follow this,

NOTE Confidence: 0.8377

00:45:53.900 --> 00:45:55.090 it was super dramatic, right?

NOTE Confidence: 0.8377

00:45:55.090 --> 00:45:56.058 It works, it doesn't.

NOTE Confidence: 0.8377

00:45:56.058 --> 00:45:58.170 It works it doesn't it see if it's not,

NOTE Confidence: 0.8377

00:45:58.170 --> 00:45:59.871 you know, and it ended up being

NOTE Confidence: 0.8377

00:45:59.871 --> 00:46:01.488 this sort of 1 two punch of.

NOTE Confidence: 0.8377

00:46:01.490 --> 00:46:02.906 It's not clear that it works,

NOTE Confidence: 0.8377

00:46:02.910 --> 00:46:04.806 and it's also not clear that it's safe,

NOTE Confidence: 0.8377

00:46:04.810 --> 00:46:07.750 but in the middle of all this.

NOTE Confidence: 0.8377

00:46:07.750 --> 00:46:09.042 I started paying attention

NOTE Confidence: 0.8377

00:46:09.042 --> 00:46:10.334 to this delightful website,

NOTE Confidence: 0.8377

00:46:10.340 --> 00:46:12.115 an organization called Retraction Watch

NOTE Confidence: 0.8377

00:46:12.115 --> 00:46:14.928 that is a group that that sort of its

NOTE Confidence: 0.8377

00:46:14.928 --> 00:46:17.186 aim is to share with the public sort

NOTE Confidence: 0.8377

00:46:17.186 --> 00:46:19.406 of the process of Journal retractions.

NOTE Confidence: 0.8377

00:46:19.410 --> 00:46:21.522 How many get retracted and what

NOTE Confidence: 0.8377

00:46:21.522 --> 00:46:23.304 happens when they get retracted

NOTE Confidence: 0.8377

00:46:23.304 --> 00:46:25.995 and what I want to point out to you

NOTE Confidence: 0.8377

00:46:26.068 --> 00:46:28.210 here is this is refreshed a couple

NOTE Confidence: 0.8377

00:46:28.210 --> 00:46:29.778 of days ago Journal retractions

NOTE Confidence: 0.8377

00:46:29.778 --> 00:46:32.370 to date an we had gotten to 62.

NOTE Confidence: 0.8377

00:46:32.370 --> 00:46:34.687 This is a lot of retractions and

NOTE Confidence: 0.8377

00:46:34.687 --> 00:46:36.423 this doesn't include some more

NOTE Confidence: 0.8377

00:46:36.423 --> 00:46:38.118 benign versions of this and.

NOTE Confidence: 0.8377

00:46:38.120 --> 00:46:39.955 People behind Retraction Watch have

NOTE Confidence: 0.8377

00:46:39.955 --> 00:46:41.790 been looking empirically to say.

NOTE Confidence: 0.8377

00:46:41.790 --> 00:46:44.359 Is there really an uptick in this?

NOTE Confidence: 0.8377

00:46:44.360 --> 00:46:46.316 And it really seems like there

NOTE Confidence: 0.8377

00:46:46.316 --> 00:46:49.325 is an that in this race to learn

NOTE Confidence: 0.8377

00:46:49.325 --> 00:46:50.953 more about this pandemic.

NOTE Confidence: 0.8377

00:46:50.960 --> 00:46:54.326 We've gotten a little sloppy sometimes.

NOTE Confidence: 0.8377

00:46:54.330 --> 00:46:56.280 And if what you're thinking is,

NOTE Confidence: 0.8377

00:46:56.280 --> 00:46:58.152 this happens to those disreputable journals

NOTE Confidence: 0.8377

00:46:58.152 --> 00:47:00.179 that email me saying dear Leventhal,

NOTE Confidence: 0.8377

00:47:00.180 --> 00:47:00.824 Naomi T.

NOTE Confidence: 0.8377

00:47:00.824 --> 00:47:02.756 We would love to review your

NOTE Confidence: 0.8377

00:47:02.756 --> 00:47:05.047 paper and publish it in two days.

NOTE Confidence: 0.8377

00:47:05.050 --> 00:47:05.724 Think again.

NOTE Confidence: 0.8377

00:47:05.724 --> 00:47:07.746 This happened to the New England

NOTE Confidence: 0.8377

00:47:07.746 --> 00:47:09.929 Journal in The Lancet and you know,  
NOTE Confidence: 0.8377

00:47:09.930 --> 00:47:11.122 not too shabby journals.  
NOTE Confidence: 0.8377

00:47:11.122 --> 00:47:13.328 The you know the source of respect  
NOTE Confidence: 0.8377

00:47:13.328 --> 00:47:15.128 and dignity around the world.  
NOTE Confidence: 0.8377

00:47:15.130 --> 00:47:17.882 And both of them got into trouble with  
NOTE Confidence: 0.8377

00:47:17.882 --> 00:47:19.810 datasets that couldn't be verified  
NOTE Confidence: 0.8377

00:47:19.810 --> 00:47:22.150 and had to retract their papers.  
NOTE Confidence: 0.8377

00:47:22.150 --> 00:47:24.160 And this is a big deal.  
NOTE Confidence: 0.8377

00:47:24.160 --> 00:47:26.836 This is an overwhelmingly big deal.  
NOTE Confidence: 0.8377

00:47:26.840 --> 00:47:27.308 And.  
NOTE Confidence: 0.8377

00:47:27.308 --> 00:47:30.584 One of the other ways that this  
NOTE Confidence: 0.8377

00:47:30.584 --> 00:47:33.578 is a big deal is that.  
NOTE Confidence: 0.8377

00:47:33.580 --> 00:47:34.788 Retractions don't necessarily mean  
NOTE Confidence: 0.8377

00:47:34.788 --> 00:47:36.600 that people stop citing the articles,  
NOTE Confidence: 0.8377

00:47:36.600 --> 00:47:39.016 and there's a couple of reasons for this.  
NOTE Confidence: 0.8377

00:47:39.020 --> 00:47:41.127 Summer has to do with the whale.

NOTE Confidence: 0.8377

00:47:41.130 --> 00:47:42.780 It searches show you whether or

NOTE Confidence: 0.8377

00:47:42.780 --> 00:47:44.450 not something has been retracted,

NOTE Confidence: 0.8377

00:47:44.450 --> 00:47:46.871 so like if you go to The Lancet it

NOTE Confidence: 0.8377

00:47:46.871 --> 00:47:49.280 says in huge letters that it's red,

NOTE Confidence: 0.8377

00:47:49.280 --> 00:47:51.394 but people cut corners in this area.

NOTE Confidence: 0.8377

00:47:51.400 --> 00:47:52.910 A lot of the time,

NOTE Confidence: 0.8377

00:47:52.910 --> 00:47:56.546 and it's actually the case that.

NOTE Confidence: 0.8377

00:47:56.550 --> 00:47:57.906 Citing a reference that you haven't

NOTE Confidence: 0.8377

00:47:57.906 --> 00:47:59.372 actually gone to and verified yourself

NOTE Confidence: 0.8377

00:47:59.372 --> 00:48:00.920 is on the spectrum of plagiarism,

NOTE Confidence: 0.8377

00:48:00.920 --> 00:48:02.378 but people tend not to think

NOTE Confidence: 0.8377

00:48:02.378 --> 00:48:04.082 about it this way, and sort of,

NOTE Confidence: 0.8377

00:48:04.082 --> 00:48:04.570 you know,

NOTE Confidence: 0.8377

00:48:04.570 --> 00:48:06.682 if you if you're trying to cite something

NOTE Confidence: 0.8377

00:48:06.682 --> 00:48:08.935 and you're in a hurry and you don't have it,

NOTE Confidence: 0.8377

00:48:08.940 --> 00:48:10.155 'cause you know the reviewers  
NOTE Confidence: 0.8377

00:48:10.155 --> 00:48:11.127 wanted to decide it.  
NOTE Confidence: 0.8377

00:48:11.130 --> 00:48:11.871 You're like alright,  
NOTE Confidence: 0.8377

00:48:11.871 --> 00:48:12.118 fine.  
NOTE Confidence: 0.8377

00:48:12.118 --> 00:48:13.600 You might not follow those links  
NOTE Confidence: 0.8377

00:48:13.649 --> 00:48:14.529 to their logical end,  
NOTE Confidence: 0.8377

00:48:14.530 --> 00:48:16.582 and you might well be citing  
NOTE Confidence: 0.8377

00:48:16.582 --> 00:48:18.327 something that was retraction and  
NOTE Confidence: 0.8377

00:48:18.327 --> 00:48:20.199 not realize that you're doing it.  
NOTE Confidence: 0.8377

00:48:20.200 --> 00:48:21.277 And that's problem.  
NOTE Confidence: 0.8377

00:48:21.277 --> 00:48:23.790 If there is a question about the  
NOTE Confidence: 0.8377

00:48:23.860 --> 00:48:26.070 scientific integrity of the the.  
NOTE Confidence: 0.8377

00:48:26.070 --> 00:48:27.138 Of the paper that you're signing,  
NOTE Confidence: 0.81664336

00:48:27.140 --> 00:48:28.316 I'm gonna pause just to say there's  
NOTE Confidence: 0.81664336

00:48:28.316 --> 00:48:29.290 somebody in the waiting room.  
NOTE Confidence: 0.81664336

00:48:29.290 --> 00:48:31.690 I'm happy to let them in but I don't know

NOTE Confidence: 0.81664336

00:48:31.754 --> 00:48:34.157 if I'm supposed to be the one doing that.

NOTE Confidence: 0.81664336

00:48:34.160 --> 00:48:35.936 So to wrap up on this,

NOTE Confidence: 0.81664336

00:48:35.940 --> 00:48:37.430 you know don't feel stuff,

NOTE Confidence: 0.81664336

00:48:37.430 --> 00:48:38.321 don't change stuff,

NOTE Confidence: 0.81664336

00:48:38.321 --> 00:48:40.400 don't mix them up the stuff up,

NOTE Confidence: 0.81664336

00:48:40.400 --> 00:48:42.254 but the other thing about research

NOTE Confidence: 0.81664336

00:48:42.254 --> 00:48:44.550 integrity that I just want to stay here.

NOTE Confidence: 0.81664336

00:48:44.550 --> 00:48:46.326 And this is true in so many ways

NOTE Confidence: 0.81664336

00:48:46.326 --> 00:48:48.135 as you are responsible for your

NOTE Confidence: 0.81664336

00:48:48.135 --> 00:48:50.085 own stuff and what happened with

NOTE Confidence: 0.81664336

00:48:50.147 --> 00:48:52.133 these retractions in The Lancet in

NOTE Confidence: 0.81664336

00:48:52.133 --> 00:48:54.044 the New England Journal was that

NOTE Confidence: 0.81664336

00:48:54.044 --> 00:48:55.504 they contractid with private data

NOTE Confidence: 0.81664336

00:48:55.504 --> 00:48:57.325 sources and then couldn't vouch for

NOTE Confidence: 0.81664336

00:48:57.325 --> 00:48:59.107 the sanctity of those data sources.

NOTE Confidence: 0.81664336

00:48:59.110 --> 00:49:01.140 But the same thing happens when you  
NOTE Confidence: 0.81664336

00:49:01.140 --> 00:49:02.968 cite something that you haven't read.  
NOTE Confidence: 0.81664336

00:49:02.970 --> 00:49:05.010 That's a failure to be responsible  
NOTE Confidence: 0.81664336

00:49:05.010 --> 00:49:06.370 for your own check.  
NOTE Confidence: 0.81664336

00:49:06.370 --> 00:49:07.486 And that, I think,  
NOTE Confidence: 0.81664336

00:49:07.486 --> 00:49:09.834 is another is a is a authentic  
NOTE Confidence: 0.81664336

00:49:09.834 --> 00:49:12.238 problem with research integrity.  
NOTE Confidence: 0.81664336

00:49:12.240 --> 00:49:13.976 So thanks for granting me that it's a  
NOTE Confidence: 0.81664336

00:49:13.976 --> 00:49:15.710 little outside of the scope of I think  
NOTE Confidence: 0.81664336

00:49:15.710 --> 00:49:17.297 probably what you expected me to talk about,  
NOTE Confidence: 0.81664336

00:49:17.300 --> 00:49:18.875 but I do think it's part of the cadence  
NOTE Confidence: 0.81664336

00:49:18.875 --> 00:49:20.469 of research ethics of this pandemic,  
NOTE Confidence: 0.81664336

00:49:20.470 --> 00:49:22.661 and so I'm I'm glad I got  
NOTE Confidence: 0.81664336

00:49:22.661 --> 00:49:24.538 a chance to fit it in.  
NOTE Confidence: 0.81664336

00:49:24.540 --> 00:49:27.390 But so I think this is where I can wrap  
NOTE Confidence: 0.81664336

00:49:27.470 --> 00:49:30.400 up and we can have lots of time to talk.

NOTE Confidence: 0.81664336

00:49:30.400 --> 00:49:31.276 So to conclude,

NOTE Confidence: 0.81664336

00:49:31.276 --> 00:49:32.736 the COVID-19 pandemic is required.

NOTE Confidence: 0.81664336

00:49:32.740 --> 00:49:33.912 Reexamination of long established

NOTE Confidence: 0.81664336

00:49:33.912 --> 00:49:35.084 principles of research ethics,

NOTE Confidence: 0.81664336

00:49:35.090 --> 00:49:36.346 largely reinforcing the fundamental

NOTE Confidence: 0.81664336

00:49:36.346 --> 00:49:37.602 tension between advancing population

NOTE Confidence: 0.81664336

00:49:37.602 --> 00:49:39.059 health through rigorous science and

NOTE Confidence: 0.81664336

00:49:39.059 --> 00:49:40.643 acknowledging the inherent risks of research.

NOTE Confidence: 0.8477347

00:49:43.280 --> 00:49:45.629 I hope that you'll take away if you hadn't

NOTE Confidence: 0.8477347

00:49:45.629 --> 00:49:48.060 already that pre approval access requires

NOTE Confidence: 0.8477347

00:49:48.060 --> 00:49:49.752 particular attention and understanding.

NOTE Confidence: 0.8477347

00:49:49.760 --> 00:49:52.752 Come and join me in re examining the

NOTE Confidence: 0.8477347

00:49:52.752 --> 00:49:54.656 foundational ethical principles that inform

NOTE Confidence: 0.8477347

00:49:54.656 --> 00:49:57.648 the way we do research and think about

NOTE Confidence: 0.8477347

00:49:57.648 --> 00:50:00.406 this harsh light on the historical record.

NOTE Confidence: 0.8477347

00:50:00.410 --> 00:50:02.660 Version of children from research and  
NOTE Confidence: 0.8477347

00:50:02.660 --> 00:50:04.575 the entrenched racism and injustice  
NOTE Confidence: 0.8477347

00:50:04.575 --> 00:50:06.681 problems that have plagued our society  
NOTE Confidence: 0.8477347

00:50:06.681 --> 00:50:09.290 for a long time and persist in 2021.  
NOTE Confidence: 0.8477347

00:50:09.290 --> 00:50:11.866 Um public health crisis is also demonstrated.  
NOTE Confidence: 0.8477347

00:50:11.870 --> 00:50:13.922 The complex role of children and  
NOTE Confidence: 0.8477347

00:50:13.922 --> 00:50:15.290 infectious epidemic and raises  
NOTE Confidence: 0.8477347

00:50:15.353 --> 00:50:17.037 questions without easy answers.  
NOTE Confidence: 0.8477347

00:50:17.040 --> 00:50:19.170 It's really hard to know  
NOTE Confidence: 0.8477347

00:50:19.170 --> 00:50:21.300 what our children owe us.  
NOTE Confidence: 0.8477347

00:50:21.300 --> 00:50:23.204 And finally, when we go too fast,  
NOTE Confidence: 0.8477347

00:50:23.210 --> 00:50:25.499 we make some mistakes and sometimes those  
NOTE Confidence: 0.8477347

00:50:25.499 --> 00:50:27.560 mistakes are really deeply regrettable.  
NOTE Confidence: 0.8477347

00:50:27.560 --> 00:50:29.136 So I'm going to wrap up there and  
NOTE Confidence: 0.8477347

00:50:29.136 --> 00:50:31.012 leave my email address up for a second  
NOTE Confidence: 0.8477347

00:50:31.012 --> 00:50:32.862 and my Twitter handle up for a second

NOTE Confidence: 0.8477347

00:50:32.862 --> 00:50:34.536 and then I'll stop sharing so I can

NOTE Confidence: 0.8477347

00:50:34.536 --> 00:50:35.754 see your smiling faces and hopefully

NOTE Confidence: 0.8477347

00:50:35.754 --> 00:50:37.200 we can have a great discussion.

NOTE Confidence: 0.8140002

00:50:45.390 --> 00:50:47.478 Thank you Naomi, that was terrific.

NOTE Confidence: 0.8140002

00:50:47.480 --> 00:50:48.521 Children should be.

NOTE Confidence: 0.8140002

00:50:48.521 --> 00:50:50.256 Make sure I remember this.

NOTE Confidence: 0.8140002

00:50:50.260 --> 00:50:52.216 This quote which is memory children

NOTE Confidence: 0.8140002

00:50:52.216 --> 00:50:54.090 should be protected by research,

NOTE Confidence: 0.8140002

00:50:54.090 --> 00:50:56.866 not from research that was at the exact.

NOTE Confidence: 0.8140002

00:50:56.870 --> 00:50:58.266 That's that's very memorable.

NOTE Confidence: 0.8140002

00:50:58.266 --> 00:51:00.360 I'll take the prerogative I get

NOTE Confidence: 0.8140002

00:51:00.426 --> 00:51:02.086 of asking the first question,

NOTE Confidence: 0.8140002

00:51:02.090 --> 00:51:06.059 but then I'm going to invite others in the

NOTE Confidence: 0.8140002

00:51:06.059 --> 00:51:09.855 way we're going to do this is you can.

NOTE Confidence: 0.8140002

00:51:09.860 --> 00:51:12.910 How you can raise your hand and then I will.

NOTE Confidence: 0.8140002

00:51:12.910 --> 00:51:14.584 Then my friend Kyle will then  
NOTE Confidence: 0.8140002

00:51:14.584 --> 00:51:16.260 enable you to unmute yourself.  
NOTE Confidence: 0.8140002

00:51:16.260 --> 00:51:17.532 Right now everybody's muted,  
NOTE Confidence: 0.8140002

00:51:17.532 --> 00:51:19.740 but if you raise your hand that  
NOTE Confidence: 0.8140002

00:51:19.740 --> 00:51:21.636 I call on you then you'll be able  
NOTE Confidence: 0.8140002

00:51:21.636 --> 00:51:24.017 to unmute yourself and you can ask  
NOTE Confidence: 0.8140002

00:51:24.017 --> 00:51:25.715 Naomi your question directly or  
NOTE Confidence: 0.8140002

00:51:25.715 --> 00:51:27.240 share your comments about this.  
NOTE Confidence: 0.8140002

00:51:27.240 --> 00:51:29.340 Lots of people on this call with  
NOTE Confidence: 0.8140002

00:51:29.340 --> 00:51:30.900 with expertise in this area,  
NOTE Confidence: 0.8140002

00:51:30.900 --> 00:51:32.425 so we're interested in hearing  
NOTE Confidence: 0.8140002

00:51:32.425 --> 00:51:33.645 from all of you.  
NOTE Confidence: 0.8140002

00:51:33.650 --> 00:51:35.972 Then I'd love to see people are  
NOTE Confidence: 0.8140002

00:51:35.972 --> 00:51:37.576 formulating their questions is  
NOTE Confidence: 0.8140002

00:51:37.576 --> 00:51:40.270 one of the things that struck me.  
NOTE Confidence: 0.8140002

00:51:40.270 --> 00:51:42.244 During the early part of the pandemic

NOTE Confidence: 0.8140002

00:51:42.244 --> 00:51:44.579 and still to this day was the

NOTE Confidence: 0.8140002

00:51:44.579 --> 00:51:46.364 remarkable lack of centralized guidance.

NOTE Confidence: 0.8140002

00:51:46.370 --> 00:51:48.125 There was no president's Commission

NOTE Confidence: 0.8140002

00:51:48.125 --> 00:51:50.199 on Bioethics that there had better

NOTE Confidence: 0.8140002

00:51:50.199 --> 00:51:51.499 had been in the past.

NOTE Confidence: 0.8140002

00:51:51.500 --> 00:51:53.270 There was nothing like that to

NOTE Confidence: 0.8140002

00:51:53.270 --> 00:51:55.887 guide us in terms of how we write

NOTE Confidence: 0.8140002

00:51:55.887 --> 00:51:57.597 our critical care protocols right?

NOTE Confidence: 0.8140002

00:51:57.600 --> 00:51:59.940 Our triage protocols.

NOTE Confidence: 0.8140002

00:51:59.940 --> 00:52:01.108 Or our allocation protocols?

NOTE Confidence: 0.8140002

00:52:01.108 --> 00:52:03.519 Is there an analogy to be drawn here?

NOTE Confidence: 0.8140002

00:52:03.520 --> 00:52:05.779 When we try to figure out how much is

NOTE Confidence: 0.8140002

00:52:05.779 --> 00:52:08.879 a minimal increase in risk you know is there,

NOTE Confidence: 0.8140002

00:52:08.880 --> 00:52:11.049 is there a place that we could go in

NOTE Confidence: 0.8140002

00:52:11.049 --> 00:52:13.055 New Haven that people in Ann Arbor

NOTE Confidence: 0.8140002

00:52:13.055 --> 00:52:15.680 could also go to where someone is kind

NOTE Confidence: 0.8140002

00:52:15.680 --> 00:52:17.816 of made this judgment or adjudicated?

NOTE Confidence: 0.8140002

00:52:17.820 --> 00:52:19.906 Or is it every man for himself?

NOTE Confidence: 0.83526444

00:52:20.520 --> 00:52:22.392 Well, I think the answer is

NOTE Confidence: 0.83526444

00:52:22.392 --> 00:52:24.370 kind of in that there is,

NOTE Confidence: 0.83526444

00:52:24.370 --> 00:52:25.980 I think, our renewed pathway.

NOTE Confidence: 0.83526444

00:52:25.980 --> 00:52:27.580 An interest in centralized IRB,

NOTE Confidence: 0.83526444

00:52:27.580 --> 00:52:29.190 at least for multicenter studies,

NOTE Confidence: 0.83526444

00:52:29.190 --> 00:52:31.633 because one of the things that happens

NOTE Confidence: 0.83526444

00:52:31.633 --> 00:52:33.679 when each institution is on their own.

NOTE Confidence: 0.83526444

00:52:33.680 --> 00:52:35.848 Deciding. Well, I think this is a more

NOTE Confidence: 0.83526444

00:52:35.848 --> 00:52:38.496 than a minor increase above minimal risk,

NOTE Confidence: 0.83526444

00:52:38.500 --> 00:52:41.060 and you know, as one center will say,

NOTE Confidence: 0.83526444

00:52:41.060 --> 00:52:42.790 that another center will say

NOTE Confidence: 0.83526444

00:52:42.790 --> 00:52:45.162 it's not right because it is so

NOTE Confidence: 0.83526444

00:52:45.162 --> 00:52:47.157 subjective and it is hard to know.

NOTE Confidence: 0.83526444

00:52:47.160 --> 00:52:49.407 So at least within one multicenter trial.

NOTE Confidence: 0.83526444

00:52:49.410 --> 00:52:52.090 If you can have an expert IRB that.

NOTE Confidence: 0.83526444

00:52:52.090 --> 00:52:53.800 Is going to think about that

NOTE Confidence: 0.83526444

00:52:53.800 --> 00:52:55.789 one way for the whole trial.

NOTE Confidence: 0.83526444

00:52:55.790 --> 00:52:58.184 I think that can at least deal

NOTE Confidence: 0.83526444

00:52:58.184 --> 00:52:59.784 with that Inter institution

NOTE Confidence: 0.83526444

00:52:59.784 --> 00:53:02.778 variability in the way that people.

NOTE Confidence: 0.83526444

00:53:02.780 --> 00:53:05.102 And the way that people make

NOTE Confidence: 0.83526444

00:53:05.102 --> 00:53:06.263 these determinations about

NOTE Confidence: 0.83526444

00:53:06.263 --> 00:53:08.490 what's going to be approved, but.

NOTE Confidence: 0.83526444

00:53:08.490 --> 00:53:10.330 But to your point.

NOTE Confidence: 0.83526444

00:53:10.330 --> 00:53:10.742 I mean,

NOTE Confidence: 0.83526444

00:53:10.742 --> 00:53:13.135 I think what we had before for the this was

NOTE Confidence: 0.83526444

00:53:13.135 --> 00:53:14.855 the President's Commission on Bioethics,

NOTE Confidence: 0.83526444

00:53:14.860 --> 00:53:15.920 and that you know,

NOTE Confidence: 0.83526444

00:53:15.920 --> 00:53:16.450 the last,  
NOTE Confidence: 0.83526444

00:53:16.450 --> 00:53:17.518 the administration that ended  
NOTE Confidence: 0.83526444

00:53:17.518 --> 00:53:19.120 this morning was the first one  
NOTE Confidence: 0.83526444

00:53:19.174 --> 00:53:21.174 in a long time that didn't have a  
NOTE Confidence: 0.83526444

00:53:21.174 --> 00:53:22.299 president's Commission on Bioethics.  
NOTE Confidence: 0.83526444

00:53:22.300 --> 00:53:24.640 And I do think that one thing that you  
NOTE Confidence: 0.83526444

00:53:24.640 --> 00:53:27.089 could do is if it rose to the interesting,  
NOTE Confidence: 0.83526444

00:53:27.090 --> 00:53:29.218 they serve at the pleasure of the president.  
NOTE Confidence: 0.83526444

00:53:29.220 --> 00:53:30.600 But things could make it to  
NOTE Confidence: 0.83526444

00:53:30.600 --> 00:53:32.150 the desk of that Commission,  
NOTE Confidence: 0.83526444

00:53:32.150 --> 00:53:33.851 and they could do a deep dive  
NOTE Confidence: 0.83526444

00:53:33.851 --> 00:53:35.070 and give a report.  
NOTE Confidence: 0.83526444

00:53:35.070 --> 00:53:36.918 And so they did that, for example,  
NOTE Confidence: 0.83526444

00:53:36.918 --> 00:53:38.472 when there was talk of testing  
NOTE Confidence: 0.83526444

00:53:38.472 --> 00:53:40.000 a smallpox vaccine in children.  
NOTE Confidence: 0.83526444

00:53:40.000 --> 00:53:42.401 And they wrote 150 page report on

NOTE Confidence: 0.83526444

00:53:42.401 --> 00:53:44.332 the ethical considerations of of the

NOTE Confidence: 0.83526444

00:53:44.332 --> 00:53:46.640 vaccine of a smallpox vaccine trial for kids.

NOTE Confidence: 0.83526444

00:53:46.640 --> 00:53:47.435 So you know,

NOTE Confidence: 0.83526444

00:53:47.435 --> 00:53:49.736 I think that this is an area where

NOTE Confidence: 0.83526444

00:53:49.736 --> 00:53:52.010 organizations like the AP can help.

NOTE Confidence: 0.83526444

00:53:52.010 --> 00:53:54.538 I haven't seen us too much of that,

NOTE Confidence: 0.83526444

00:53:54.540 --> 00:53:55.488 but you know,

NOTE Confidence: 0.83526444

00:53:55.488 --> 00:53:57.700 maybe mark you and I already stated.

NOTE Confidence: 0.83526444

00:53:57.700 --> 00:53:59.868 Now you know, I think some of the

NOTE Confidence: 0.83526444

00:53:59.868 --> 00:54:01.490 child advocacy organizations can,

NOTE Confidence: 0.83526444

00:54:01.490 --> 00:54:03.392 and there are some organizations within

NOTE Confidence: 0.83526444

00:54:03.392 --> 00:54:05.910 NIH that really focus on the research ethics,

NOTE Confidence: 0.83526444

00:54:05.910 --> 00:54:07.320 but.

NOTE Confidence: 0.83526444

00:54:07.320 --> 00:54:10.544 The every man or woman for them self.

NOTE Confidence: 0.83526444

00:54:10.550 --> 00:54:12.570 IRB approach to this I

NOTE Confidence: 0.83526444

00:54:12.570 --> 00:54:14.590 think is a huge problem.  
NOTE Confidence: 0.83526444

00:54:14.590 --> 00:54:15.799 An contemporary research.  
NOTE Confidence: 0.7532168

00:54:16.440 --> 00:54:17.824 So we, Marcella Nunez  
NOTE Confidence: 0.7532168

00:54:17.824 --> 00:54:19.554 Smith is on our faculty.  
NOTE Confidence: 0.7532168

00:54:19.560 --> 00:54:21.636 And who is President Biden's Co.  
NOTE Confidence: 0.7532168

00:54:21.640 --> 00:54:23.144 Chair for his COVID-19?  
NOTE Confidence: 0.7532168

00:54:23.144 --> 00:54:24.648 Will then transition communities  
NOTE Confidence: 0.7532168

00:54:24.648 --> 00:54:26.851 for the leadership for the COVID-19  
NOTE Confidence: 0.7532168

00:54:26.851 --> 00:54:28.933 effort we we've made this point  
NOTE Confidence: 0.7532168

00:54:28.992 --> 00:54:30.822 with her an hopefully it eventually  
NOTE Confidence: 0.7532168

00:54:30.822 --> 00:54:33.350 finds its way to the ears of some  
NOTE Confidence: 0.7532168

00:54:33.350 --> 00:54:35.300 people who can respond and give  
NOTE Confidence: 0.7532168

00:54:35.372 --> 00:54:37.610 us some of that central guidance.  
NOTE Confidence: 0.7532168

00:54:37.610 --> 00:54:40.378 I want to invite Doctor Tom Murray too.  
NOTE Confidence: 0.7532168

00:54:40.380 --> 00:54:42.894 Hung up on mutual here or  
NOTE Confidence: 0.7532168

00:54:42.894 --> 00:54:44.570 askyouthere.com if you can.

NOTE Confidence: 0.7532168

00:54:44.570 --> 00:54:46.370 If you can unmute yourself,

NOTE Confidence: 0.7532168

00:54:46.370 --> 00:54:47.818 please ask your question.

NOTE Confidence: 0.8625356

00:54:49.880 --> 00:54:52.620 Hi I'm I was trying to show my face,

NOTE Confidence: 0.8625356

00:54:52.620 --> 00:54:54.734 I apologize I I can't do that.

NOTE Confidence: 0.8625356

00:54:54.740 --> 00:54:56.917 My name is I'm on my infectious

NOTE Confidence: 0.8625356

00:54:56.917 --> 00:54:58.194 disease physician who's been

NOTE Confidence: 0.8625356

00:54:58.194 --> 00:54:59.609 working a lot with covid.

NOTE Confidence: 0.8625356

00:54:59.610 --> 00:55:02.034 Thank you for such a thought provoking talk.

NOTE Confidence: 0.8625356

00:55:02.040 --> 00:55:04.168 Two different areas that really struck me.

NOTE Confidence: 0.8625356

00:55:04.170 --> 00:55:06.090 The first is I think one of the

NOTE Confidence: 0.8625356

00:55:06.090 --> 00:55:07.709 issues around vaccination and kids

NOTE Confidence: 0.8625356

00:55:07.709 --> 00:55:09.519 for this particular infection really

NOTE Confidence: 0.8625356

00:55:09.519 --> 00:55:11.793 relates to the quote you showed about

NOTE Confidence: 0.8625356

00:55:11.793 --> 00:55:13.594 who's getting the sickest and who

NOTE Confidence: 0.8625356

00:55:13.594 --> 00:55:15.418 is bearing the burden of disease.

NOTE Confidence: 0.8625356

00:55:15.420 --> 00:55:17.534 And so I actually have been one  
NOTE Confidence: 0.8625356

00:55:17.534 --> 00:55:19.438 of the pediatricians in favor of  
NOTE Confidence: 0.8625356

00:55:19.438 --> 00:55:21.003 starting with the adults because  
NOTE Confidence: 0.8625356

00:55:21.003 --> 00:55:23.114 they bear the burden of disease and  
NOTE Confidence: 0.8625356

00:55:23.114 --> 00:55:24.863 kind of working it back because.  
NOTE Confidence: 0.8625356

00:55:24.863 --> 00:55:27.447 I don't think children are where the money  
NOTE Confidence: 0.8625356

00:55:27.447 --> 00:55:29.928 is in terms of stopping this pandemic.  
NOTE Confidence: 0.8625356

00:55:29.930 --> 00:55:31.946 I think there are other reasons  
NOTE Confidence: 0.8625356

00:55:31.946 --> 00:55:33.959 around school and things like that,  
NOTE Confidence: 0.8625356

00:55:33.960 --> 00:55:36.312 and I'm all in favor of vaccination  
NOTE Confidence: 0.8625356

00:55:36.312 --> 00:55:38.558 of children. But I do think.  
NOTE Confidence: 0.8625356

00:55:38.558 --> 00:55:41.572 The Epidemiology of this disease is very  
NOTE Confidence: 0.8625356

00:55:41.572 --> 00:55:44.457 different than something like influenza.  
NOTE Confidence: 0.8625356

00:55:44.460 --> 00:55:47.190 Where we know kids are the cesspool.  
NOTE Confidence: 0.8625356

00:55:47.190 --> 00:55:48.225 The second thing.  
NOTE Confidence: 0.8625356

00:55:48.225 --> 00:55:50.640 So this is going to be totally

NOTE Confidence: 0.8625356

00:55:50.718 --> 00:55:51.870 unrelated thing,

NOTE Confidence: 0.8625356

00:55:51.870 --> 00:55:54.600 but with respect to the EUA data,

NOTE Confidence: 0.8625356

00:55:54.600 --> 00:55:57.408 I just pulled it up while you were

NOTE Confidence: 0.8625356

00:55:57.408 --> 00:55:59.731 talking about the distribution of who

NOTE Confidence: 0.8625356

00:55:59.731 --> 00:56:02.964 were in those trials and they did do

NOTE Confidence: 0.8625356

00:56:02.964 --> 00:56:05.460 a reasonable job of representing the

NOTE Confidence: 0.8625356

00:56:05.460 --> 00:56:07.860 US population in the Moderna trial

NOTE Confidence: 0.8625356

00:56:07.860 --> 00:56:10.474 it was 10% black and 20% Hispanic.

NOTE Confidence: 0.8625356

00:56:10.474 --> 00:56:12.640 The challenge I think has been

NOTE Confidence: 0.8625356

00:56:12.710 --> 00:56:14.650 translating that and helping.

NOTE Confidence: 0.8625356

00:56:14.650 --> 00:56:16.990 Get people to trust that we

NOTE Confidence: 0.8625356

00:56:16.990 --> 00:56:18.550 can provide this vaccine.

NOTE Confidence: 0.8625356

00:56:18.550 --> 00:56:21.077 So even if you're doing a better

NOTE Confidence: 0.8625356

00:56:21.077 --> 00:56:23.075 job of enrolling the right

NOTE Confidence: 0.8625356

00:56:23.075 --> 00:56:25.180 people in the clinical trials,

NOTE Confidence: 0.8625356

00:56:25.180 --> 00:56:27.868 it's not translating to getting those  
NOTE Confidence: 0.8625356

00:56:27.868 --> 00:56:30.940 populations that need the vaccine the most.  
NOTE Confidence: 0.8625356

00:56:30.940 --> 00:56:33.172 To have the trust to get it so  
NOTE Confidence: 0.8625356

00:56:33.172 --> 00:56:34.745 I'm wondering what your thoughts  
NOTE Confidence: 0.8625356

00:56:34.745 --> 00:56:36.964 are around even when you have a  
NOTE Confidence: 0.8625356

00:56:37.030 --> 00:56:39.438 reasonable distribution of population,  
NOTE Confidence: 0.8625356

00:56:39.440 --> 00:56:41.205 how to translate that into  
NOTE Confidence: 0.8625356

00:56:41.205 --> 00:56:42.264 better vaccine uptake?  
NOTE Confidence: 0.85948807

00:56:43.380 --> 00:56:45.156 Thanks for both of those comments,  
NOTE Confidence: 0.85948807

00:56:45.160 --> 00:56:47.520 which are both really good and and helpful.  
NOTE Confidence: 0.85948807

00:56:47.520 --> 00:56:50.520 And yeah, I think that.  
NOTE Confidence: 0.85948807

00:56:50.520 --> 00:56:52.160 It does seems you know,  
NOTE Confidence: 0.85948807

00:56:52.160 --> 00:56:54.140 the more we know about this,  
NOTE Confidence: 0.85948807

00:56:54.140 --> 00:56:56.149 the more it seems like the people  
NOTE Confidence: 0.85948807

00:56:56.149 --> 00:56:58.562 you know lives are saved by keeping  
NOTE Confidence: 0.85948807

00:56:58.562 --> 00:57:00.054 adults from getting COVID-19.

NOTE Confidence: 0.85948807

00:57:00.060 --> 00:57:02.524 And I I didn't exactly mean to give

NOTE Confidence: 0.85948807

00:57:02.524 --> 00:57:05.091 the impression that I think it was a

NOTE Confidence: 0.85948807

00:57:05.091 --> 00:57:06.970 miscalculation not to include children.

NOTE Confidence: 0.85948807

00:57:06.970 --> 00:57:08.630 I actually think the most

NOTE Confidence: 0.85948807

00:57:08.630 --> 00:57:10.590 interesting thing is that even now,

NOTE Confidence: 0.85948807

00:57:10.590 --> 00:57:12.312 as we're including children that still

NOTE Confidence: 0.85948807

00:57:12.312 --> 00:57:14.269 with an eye on general infection

NOTE Confidence: 0.85948807

00:57:14.269 --> 00:57:16.507 control more than saving child lives.

NOTE Confidence: 0.85948807

00:57:16.510 --> 00:57:19.570 But so now your point about

NOTE Confidence: 0.85948807

00:57:19.570 --> 00:57:21.610 that as well taken.

NOTE Confidence: 0.85948807

00:57:21.610 --> 00:57:23.150 And you know that thanks for the

NOTE Confidence: 0.85948807

00:57:23.150 --> 00:57:24.798 clarity on the way for the moderna,

NOTE Confidence: 0.85948807

00:57:24.800 --> 00:57:26.700 I think that that is.

NOTE Confidence: 0.85948807

00:57:26.700 --> 00:57:29.148 That to me I think is such a recapitulation

NOTE Confidence: 0.85948807

00:57:29.148 --> 00:57:31.199 of what a major problem we have.

NOTE Confidence: 0.85948807

00:57:31.200 --> 00:57:32.880 In that quote I shared about,  
NOTE Confidence: 0.85948807

00:57:32.880 --> 00:57:33.442 you know,  
NOTE Confidence: 0.85948807

00:57:33.442 --> 00:57:34.566 sort of that operation.  
NOTE Confidence: 0.85948807

00:57:34.570 --> 00:57:37.167 Build trust that should have gone along  
NOTE Confidence: 0.85948807

00:57:37.167 --> 00:57:39.499 with operation work speed so you know  
NOTE Confidence: 0.85948807

00:57:39.499 --> 00:57:41.988 my thoughts about this is is a bit that.  
NOTE Confidence: 0.85948807

00:57:41.990 --> 00:57:43.866 We still have so far to go.  
NOTE Confidence: 0.85948807

00:57:43.870 --> 00:57:45.725 I do think some of these you  
NOTE Confidence: 0.85948807

00:57:45.725 --> 00:57:47.374 know these public campaigns I I  
NOTE Confidence: 0.85948807

00:57:47.374 --> 00:57:49.229 didn't have time to fit this in,  
NOTE Confidence: 0.85948807

00:57:49.230 --> 00:57:50.903 but there's a big push among black  
NOTE Confidence: 0.85948807

00:57:50.903 --> 00:57:52.220 physicians to tweet out their  
NOTE Confidence: 0.85948807

00:57:52.220 --> 00:57:53.332 pictures of themselves getting  
NOTE Confidence: 0.85948807

00:57:53.332 --> 00:57:54.850 their vaccines and key leaders.  
NOTE Confidence: 0.85948807

00:57:54.850 --> 00:57:55.350 You know,  
NOTE Confidence: 0.85948807

00:57:55.350 --> 00:57:57.350 I think that was really what drove those

NOTE Confidence: 0.85948807

00:57:57.406 --> 00:57:59.408 presidents of Xavier and Dillard to say.

NOTE Confidence: 0.85948807

00:57:59.410 --> 00:58:01.286 We're going to be in these trials.

NOTE Confidence: 0.85948807

00:58:01.290 --> 00:58:03.426 And this is this is good for us.

NOTE Confidence: 0.85948807

00:58:03.430 --> 00:58:04.770 So I guess you know,

NOTE Confidence: 0.85948807

00:58:04.770 --> 00:58:06.770 if you look at that figure I showed

NOTE Confidence: 0.85948807

00:58:06.770 --> 00:58:08.250 about just the uptake rates.

NOTE Confidence: 0.85948807

00:58:08.250 --> 00:58:10.394 I guess it hasn't been as fruitful as

NOTE Confidence: 0.85948807

00:58:10.394 --> 00:58:12.954 we were hoping it was going to be, but.

NOTE Confidence: 0.85948807

00:58:12.954 --> 00:58:15.852 I think that needs to come from

NOTE Confidence: 0.85948807

00:58:15.852 --> 00:58:18.410 every angle we can think of to,

NOTE Confidence: 0.85948807

00:58:18.410 --> 00:58:20.100 really.

NOTE Confidence: 0.85948807

00:58:20.100 --> 00:58:22.404 Think about how do we move on from

NOTE Confidence: 0.85948807

00:58:22.404 --> 00:58:24.555 this really painful history and and

NOTE Confidence: 0.85948807

00:58:24.555 --> 00:58:26.435 overcome the barriers to getting

NOTE Confidence: 0.85948807

00:58:26.435 --> 00:58:28.575 our whole country to believe that

NOTE Confidence: 0.85948807

00:58:28.575 --> 00:58:30.610 this vaccine is safe for them.

NOTE Confidence: 0.8413944

00:58:32.090 --> 00:58:33.680 You know Stephen Thomas at University

NOTE Confidence: 0.8413944

00:58:33.680 --> 00:58:35.349 of Maryland was a speaker in

NOTE Confidence: 0.8413944

00:58:35.349 --> 00:58:36.729 this forum earlier this year.

NOTE Confidence: 0.8413944

00:58:36.730 --> 00:58:39.019 It's a name that either or both

NOTE Confidence: 0.8413944

00:58:39.019 --> 00:58:41.321 you might want to consider in

NOTE Confidence: 0.8413944

00:58:41.321 --> 00:58:42.985 terms of rebuilding trust.

NOTE Confidence: 0.8413944

00:58:42.990 --> 00:58:46.670 And he is. Interested in an,

NOTE Confidence: 0.8413944

00:58:46.670 --> 00:58:48.220 he's actually piloted a program

NOTE Confidence: 0.8413944

00:58:48.220 --> 00:58:49.950 going into particularly of Barber

NOTE Confidence: 0.8413944

00:58:49.950 --> 00:58:52.056 shops that are primarily for African

NOTE Confidence: 0.8413944

00:58:52.056 --> 00:58:53.992 American men and also salons for

NOTE Confidence: 0.8413944

00:58:53.992 --> 00:58:55.517 there primarily for American women.

NOTE Confidence: 0.8413944

00:58:55.520 --> 00:58:57.776 And he thinks that this is where so

NOTE Confidence: 0.8413944

00:58:57.776 --> 00:59:00.024 much of the culture happens where so

NOTE Confidence: 0.8413944

00:59:00.024 --> 00:59:02.689 much of the trust is actually built,

NOTE Confidence: 0.8413944

00:59:02.690 --> 00:59:04.320 and so he's actually piloted.

NOTE Confidence: 0.8413944

00:59:04.320 --> 00:59:06.276 This program. It's, and it was.

NOTE Confidence: 0.8413944

00:59:06.280 --> 00:59:08.338 It was about trying to get people

NOTE Confidence: 0.8413944

00:59:08.338 --> 00:59:09.972 to participate in clinical research

NOTE Confidence: 0.8413944

00:59:09.972 --> 00:59:11.702 projects about trying to get

NOTE Confidence: 0.8413944

00:59:11.702 --> 00:59:13.780 people to get tested for kovid,

NOTE Confidence: 0.8413944

00:59:13.780 --> 00:59:16.380 and so he gave a great presentation here,

NOTE Confidence: 0.8413944

00:59:16.380 --> 00:59:19.444 which I think is available on our website.

NOTE Confidence: 0.8413944

00:59:19.450 --> 00:59:20.610 But but stay tuned,

NOTE Confidence: 0.8413944

00:59:20.610 --> 00:59:22.721 you're going to hear from more from

NOTE Confidence: 0.8413944

00:59:22.721 --> 00:59:24.870 from Stephen Thomas on this in the

NOTE Confidence: 0.8413944

00:59:24.870 --> 00:59:26.970 work he's doing to rebuild that trust.

NOTE Confidence: 0.85150915

00:59:26.970 --> 00:59:28.480 And there are some interesting,

NOTE Confidence: 0.85150915

00:59:28.480 --> 00:59:30.419 you know when you think about a

NOTE Confidence: 0.85150915

00:59:30.419 --> 00:59:32.592 disease where the hallmark of of of

NOTE Confidence: 0.85150915

00:59:32.592 --> 00:59:34.192 saving lives is not congregating,  
NOTE Confidence: 0.85150915

00:59:34.200 --> 00:59:36.608 how do you get that sort of community  
NOTE Confidence: 0.85150915

00:59:36.608 --> 00:59:38.205 participation when people aren't going  
NOTE Confidence: 0.85150915

00:59:38.205 --> 00:59:40.389 to church and they're not there aren't  
NOTE Confidence: 0.85150915

00:59:40.446 --> 00:59:42.329 as many of them in that barbershop,  
NOTE Confidence: 0.85150915

00:59:42.330 --> 00:59:44.378 and you know, not being able to get  
NOTE Confidence: 0.85150915

00:59:44.378 --> 00:59:46.342 groups of people together to sort  
NOTE Confidence: 0.85150915

00:59:46.342 --> 00:59:48.342 of rally that enthusiasm? That's it.  
NOTE Confidence: 0.85150915

00:59:48.342 --> 00:59:50.780 That's another barrier to doing that, but I.  
NOTE Confidence: 0.85150915

00:59:50.780 --> 00:59:53.300 My intuition is that he's on the right.  
NOTE Confidence: 0.85150915

00:59:53.300 --> 00:59:54.884 You know him clearly knowing much  
NOTE Confidence: 0.85150915

00:59:54.884 --> 00:59:56.762 more about this than me that getting  
NOTE Confidence: 0.85150915

00:59:56.762 --> 00:59:58.547 to people where they are in settings  
NOTE Confidence: 0.85150915

00:59:58.596 --> 01:00:00.458 that they feel comfortable is how you.  
NOTE Confidence: 0.85150915

01:00:00.460 --> 01:00:01.680 Start to build that  
NOTE Confidence: 0.80013156

01:00:01.680 --> 01:00:02.592 trust again. Yeah,

NOTE Confidence: 0.80013156

01:00:02.592 --> 01:00:04.416 that seems to show promise now.

NOTE Confidence: 0.80013156

01:00:04.420 --> 01:00:06.324 Charles Hughes has a question for us

NOTE Confidence: 0.80013156

01:00:06.324 --> 01:00:08.390 here so I'm gonna unmute Charles.

NOTE Confidence: 0.8381716

01:00:12.010 --> 01:00:13.492 Charles, you should be able to

NOTE Confidence: 0.8381716

01:00:13.492 --> 01:00:14.760 unmute yourself now and then.

NOTE Confidence: 0.79132205

01:00:18.190 --> 01:00:19.896 I'm trying to hear me.

NOTE Confidence: 0.79132205

01:00:19.896 --> 01:00:22.280 Yeah, OK we can. My question is,

NOTE Confidence: 0.79132205

01:00:22.280 --> 01:00:25.010 even if you get kids to consent to

NOTE Confidence: 0.79132205

01:00:25.010 --> 01:00:27.059 being tested to be affecting trial,

NOTE Confidence: 0.79132205

01:00:27.060 --> 01:00:28.760 what about the power relation?

NOTE Confidence: 0.79132205

01:00:28.760 --> 01:00:31.120 I mean you got a kid being confronted

NOTE Confidence: 0.79132205

01:00:31.120 --> 01:00:33.108 by parents and doctors saying you

NOTE Confidence: 0.79132205

01:00:33.108 --> 01:00:35.100 believe we really need you this

NOTE Confidence: 0.79132205

01:00:35.169 --> 01:00:37.461 the population here with do they

NOTE Confidence: 0.79132205

01:00:37.461 --> 01:00:38.989 really have conformed consent

NOTE Confidence: 0.79132205

01:00:38.990 --> 01:00:41.036 or or do they feel pressure?  
NOTE Confidence: 0.8723283

01:00:42.580 --> 01:00:44.526 Yeah, I mean that I think is,  
NOTE Confidence: 0.8723283

01:00:44.530 --> 01:00:46.406 you know we got lots and lots  
NOTE Confidence: 0.8723283

01:00:46.406 --> 01:00:47.880 of ethics concepts about this.  
NOTE Confidence: 0.8723283

01:00:47.880 --> 01:00:50.680 I think that. This.  
NOTE Confidence: 0.84204936

01:00:52.870 --> 01:00:54.970 This is where ascent has to  
NOTE Confidence: 0.84204936

01:00:54.970 --> 01:00:56.370 be a meaningful process.  
NOTE Confidence: 0.84204936

01:00:56.370 --> 01:00:57.770 Just like informed consent  
NOTE Confidence: 0.84204936

01:00:57.770 --> 01:00:59.170 isn't signing a form,  
NOTE Confidence: 0.84204936

01:00:59.170 --> 01:01:00.920 it's a conversation you know.  
NOTE Confidence: 0.84204936

01:01:00.920 --> 01:01:04.070 Really, I think taking the time if you can,  
NOTE Confidence: 0.84204936

01:01:04.070 --> 01:01:07.370 if you can achieve it.  
NOTE Confidence: 0.84204936

01:01:07.370 --> 01:01:09.505 Getting that child sort of alone in  
NOTE Confidence: 0.84204936

01:01:09.505 --> 01:01:11.883 the room like we do in our lesson  
NOTE Confidence: 0.84204936

01:01:11.883 --> 01:01:14.075 visits and sort of asking them and  
NOTE Confidence: 0.84204936

01:01:14.075 --> 01:01:15.895 giving them that opportunity to.

NOTE Confidence: 0.84204936  
01:01:15.900 --> 01:01:16.959 To the eye,  
NOTE Confidence: 0.84204936  
01:01:16.959 --> 01:01:18.371 the contemporary thinking about  
NOTE Confidence: 0.84204936  
01:01:18.371 --> 01:01:20.489 ascent really has to do with this  
NOTE Confidence: 0.84204936  
01:01:20.489 --> 01:01:22.361 read back and that it's not that  
NOTE Confidence: 0.84204936  
01:01:22.361 --> 01:01:24.269 the kid nodding is insufficient and  
NOTE Confidence: 0.84204936  
01:01:24.269 --> 01:01:26.785 that they need to sort of tell you  
NOTE Confidence: 0.84204936  
01:01:26.785 --> 01:01:28.340 these affirmative things you know,  
NOTE Confidence: 0.84204936  
01:01:28.340 --> 01:01:31.749 and I think that that is always.  
NOTE Confidence: 0.84204936  
01:01:31.750 --> 01:01:32.940 That is always an issue,  
NOTE Confidence: 0.84204936  
01:01:32.940 --> 01:01:34.536 whether the parent really does want  
NOTE Confidence: 0.84204936  
01:01:34.536 --> 01:01:36.527 the child to enroll or not is sort of.  
NOTE Confidence: 0.84204936  
01:01:36.530 --> 01:01:37.958 Can that child really say no,  
NOTE Confidence: 0.84204936  
01:01:37.960 --> 01:01:39.656 but that I think the onus of that  
NOTE Confidence: 0.84204936  
01:01:39.656 --> 01:01:41.156 is mostly on the research team  
NOTE Confidence: 0.84204936  
01:01:41.156 --> 01:01:42.692 to be as careful and thoughtful  
NOTE Confidence: 0.84204936

01:01:42.748 --> 01:01:44.176 about about that as they can,

NOTE Confidence: 0.84204936

01:01:44.180 --> 01:01:45.112 and also weighing risks.

NOTE Confidence: 0.84204936

01:01:45.112 --> 01:01:46.797 So when someone pointed out to me

NOTE Confidence: 0.84204936

01:01:46.797 --> 01:01:47.997 about my friends example about,

NOTE Confidence: 0.84204936

01:01:48.000 --> 01:01:49.926 you know my son doesn't want

NOTE Confidence: 0.84204936

01:01:49.926 --> 01:01:52.470 to be in the vaccine trials.

NOTE Confidence: 0.84204936

01:01:52.470 --> 01:01:55.669 'cause he saw me being so miserable.

NOTE Confidence: 0.84204936

01:01:55.670 --> 01:01:58.015 She probably you know he's going to

NOTE Confidence: 0.84204936

01:01:58.015 --> 01:01:59.306 get vaccinated eventually, right?

NOTE Confidence: 0.84204936

01:01:59.306 --> 01:02:00.164 And so on.

NOTE Confidence: 0.84204936

01:02:00.164 --> 01:02:02.290 Some level like the I worry a

NOTE Confidence: 0.84204936

01:02:02.290 --> 01:02:04.348 little bit less about coercion for

NOTE Confidence: 0.84204936

01:02:04.348 --> 01:02:06.719 something that he will get eventually.

NOTE Confidence: 0.84204936

01:02:06.720 --> 01:02:07.344 But yeah,

NOTE Confidence: 0.84204936

01:02:07.344 --> 01:02:09.216 I think that that is an

NOTE Confidence: 0.84204936

01:02:09.216 --> 01:02:10.410 incompletely answered question,

NOTE Confidence: 0.84204936  
01:02:10.410 --> 01:02:12.610 but the age of modern  
NOTE Confidence: 0.84204936  
01:02:12.610 --> 01:02:14.810 understanding of assent and really.  
NOTE Confidence: 0.84204936  
01:02:14.810 --> 01:02:16.520 Sufficient by and I mean I  
NOTE Confidence: 0.84204936  
01:02:16.520 --> 01:02:18.010 still see things about like.  
NOTE Confidence: 0.84204936  
01:02:18.010 --> 01:02:19.470 This is our sent former.  
NOTE Confidence: 0.84204936  
01:02:19.470 --> 01:02:21.222 This is where they sign or  
NOTE Confidence: 0.84204936  
01:02:21.222 --> 01:02:22.670 they have to be 14.  
NOTE Confidence: 0.84204936  
01:02:22.670 --> 01:02:24.590 So I think as we lean into this  
NOTE Confidence: 0.84204936  
01:02:24.590 --> 01:02:26.433 more nuanced and sort of laborious  
NOTE Confidence: 0.84204936  
01:02:26.433 --> 01:02:28.068 way of determining a child's  
NOTE Confidence: 0.84204936  
01:02:28.068 --> 01:02:29.630 emotional readiness to give assent  
NOTE Confidence: 0.84204936  
01:02:29.630 --> 01:02:31.394 will get better at better and  
NOTE Confidence: 0.84204936  
01:02:31.400 --> 01:02:33.266 screening for that sense of this  
NOTE Confidence: 0.84204936  
01:02:33.266 --> 01:02:35.178 kid doesn't really want to do this,  
NOTE Confidence: 0.84204936  
01:02:35.180 --> 01:02:36.020 but it's a.  
NOTE Confidence: 0.84204936

01:02:36.020 --> 01:02:37.700 It's a good question that I  
NOTE Confidence: 0.84204936

01:02:37.700 --> 01:02:39.540 don't have a short answer for.  
NOTE Confidence: 0.9278922

01:02:41.320 --> 01:02:41.870 Thank you.  
NOTE Confidence: 0.812704335

01:02:44.540 --> 01:02:48.200 OK, thank you. Still thank you.  
NOTE Confidence: 0.812704335

01:02:48.200 --> 01:02:49.930 Um, I'm looking at that.  
NOTE Confidence: 0.812704335

01:02:49.930 --> 01:02:54.186 I see no other questions at this point.  
NOTE Confidence: 0.812704335

01:02:54.190 --> 01:02:58.280 This is a. This is a huge problem going  
NOTE Confidence: 0.812704335

01:02:58.280 --> 01:03:01.164 forward and what I think is an important  
NOTE Confidence: 0.812704335

01:03:01.164 --> 01:03:03.818 thing which I think most people on  
NOTE Confidence: 0.812704335

01:03:03.818 --> 01:03:06.226 this call can appreciate is is this  
NOTE Confidence: 0.812704335

01:03:06.226 --> 01:03:08.480 isn't this isn't just about COVID-19,  
NOTE Confidence: 0.812704335

01:03:08.480 --> 01:03:11.197 but COVID-19 is afford us the opportunity  
NOTE Confidence: 0.812704335

01:03:11.197 --> 01:03:13.951 to take a hard look at how we do  
NOTE Confidence: 0.812704335

01:03:14.027 --> 01:03:16.126 things and you know, we sometimes,  
NOTE Confidence: 0.812704335

01:03:16.126 --> 01:03:18.597 especially when we're really under the gun.  
NOTE Confidence: 0.812704335

01:03:18.600 --> 01:03:20.945 You know the old thing that there

NOTE Confidence: 0.812704335

01:03:20.945 --> 01:03:22.849 are no atheists in foxholes.

NOTE Confidence: 0.812704335

01:03:22.850 --> 01:03:25.265 I have used the comment as we

NOTE Confidence: 0.812704335

01:03:25.265 --> 01:03:27.229 were rushing in the spring.

NOTE Confidence: 0.812704335

01:03:27.230 --> 01:03:29.253 To try and get a triage protocol

NOTE Confidence: 0.812704335

01:03:29.253 --> 01:03:30.878 prepared very quickly as you don't,

NOTE Confidence: 0.812704335

01:03:30.880 --> 01:03:32.285 it seems that there's no

NOTE Confidence: 0.812704335

01:03:32.285 --> 01:03:33.411 contents in foxholes, either.

NOTE Confidence: 0.812704335

01:03:33.411 --> 01:03:35.097 We all became utilitarians in hurry.

NOTE Confidence: 0.812704335

01:03:35.100 --> 01:03:37.348 We changed the way we looked at things.

NOTE Confidence: 0.812704335

01:03:37.350 --> 01:03:39.030 Some of us did I think,

NOTE Confidence: 0.812704335

01:03:39.030 --> 01:03:39.834 to some extent,

NOTE Confidence: 0.812704335

01:03:39.834 --> 01:03:42.045 but we felt the pressure of the enormity

NOTE Confidence: 0.812704335

01:03:42.045 --> 01:03:44.237 of the problem as well as the the

NOTE Confidence: 0.812704335

01:03:44.237 --> 01:03:46.340 speed at which we needed the answers.

NOTE Confidence: 0.812704335

01:03:46.340 --> 01:03:48.026 So so many people in publications

NOTE Confidence: 0.812704335

01:03:48.026 --> 01:03:49.150 and their clinical research.  
NOTE Confidence: 0.812704335

01:03:49.150 --> 01:03:50.274 It's the same thing.  
NOTE Confidence: 0.812704335

01:03:50.274 --> 01:03:52.800 So the lessons here, Naomi as your title is,  
NOTE Confidence: 0.812704335

01:03:52.800 --> 01:03:55.048 is that if you talk to so actors,  
NOTE Confidence: 0.812704335

01:03:55.050 --> 01:03:56.450 it's not just about COVID-19,  
NOTE Confidence: 0.812704335

01:03:56.450 --> 01:03:58.590 but lessons learned from that.  
NOTE Confidence: 0.812704335

01:03:58.590 --> 01:04:01.050 It will apply to other things  
NOTE Confidence: 0.812704335

01:04:01.050 --> 01:04:02.690 as we move forward.  
NOTE Confidence: 0.812704335

01:04:02.690 --> 01:04:03.950 So much to be learned.  
NOTE Confidence: 0.812704335

01:04:03.950 --> 01:04:05.215 This has been a great  
NOTE Confidence: 0.812704335

01:04:05.215 --> 01:04:06.480 talk and a great evening,  
NOTE Confidence: 0.812704335

01:04:06.480 --> 01:04:08.286 and I want to thank Doctor Leventhal  
NOTE Confidence: 0.812704335

01:04:08.286 --> 01:04:09.769 so what's supposed to happen now?  
NOTE Confidence: 0.812704335

01:04:09.770 --> 01:04:11.375 Naomi's I'm supposed to take  
NOTE Confidence: 0.812704335

01:04:11.375 --> 01:04:14.229 out a few of us taking up for  
NOTE Confidence: 0.812704335

01:04:14.229 --> 01:04:16.189 a wonderful New Haven dinner.

NOTE Confidence: 0.812704335

01:04:16.190 --> 01:04:18.854 So now we officially owe you 1 when you

NOTE Confidence: 0.77638435

01:04:18.860 --> 01:04:20.939 already you will recall owed me a.

NOTE Confidence: 0.77638435

01:04:20.940 --> 01:04:22.716 What was it? A pina colada?

NOTE Confidence: 0.8077416

01:04:24.110 --> 01:04:26.022 So sad, because that was in the spring

NOTE Confidence: 0.8077416

01:04:26.022 --> 01:04:28.089 when we were scrambling all of us to

NOTE Confidence: 0.8077416

01:04:28.089 --> 01:04:29.789 get the prepared for the charges,

NOTE Confidence: 0.8077416

01:04:29.790 --> 01:04:31.568 and I said well by the fall

NOTE Confidence: 0.8077416

01:04:31.568 --> 01:04:33.139 meetings this is fall of 2020.

NOTE Confidence: 0.8077416

01:04:33.140 --> 01:04:34.946 I said well, by the fall meetings,

NOTE Confidence: 0.8077416

01:04:34.950 --> 01:04:36.486 which were going to San Diego,

NOTE Confidence: 0.8077416

01:04:36.490 --> 01:04:37.972 the AP meetings were all going

NOTE Confidence: 0.8077416

01:04:37.972 --> 01:04:39.551 to relax and have Pina coladas

NOTE Confidence: 0.8077416

01:04:39.551 --> 01:04:40.876 and talk about the war,

NOTE Confidence: 0.8077416

01:04:40.880 --> 01:04:42.686 and you know and how it went,

NOTE Confidence: 0.8077416

01:04:42.690 --> 01:04:44.746 but as it turned out in the fall,

NOTE Confidence: 0.8077416

01:04:44.750 --> 01:04:46.274 we were still not even all  
NOTE Confidence: 0.8077416

01:04:46.274 --> 01:04:47.850 the way into the war, much  
NOTE Confidence: 0.8077416

01:04:47.850 --> 01:04:49.386 less through it. Yeah, so Mark,  
NOTE Confidence: 0.8077416

01:04:49.390 --> 01:04:51.052 I think our talk about drinking  
NOTE Confidence: 0.8077416

01:04:51.052 --> 01:04:52.673 together has prompted someone else to  
NOTE Confidence: 0.8077416

01:04:52.673 --> 01:04:54.297 make us stop and ask another question,  
NOTE Confidence: 0.799616884444445

01:04:54.300 --> 01:04:56.960 good. Let me see if I can if I can  
NOTE Confidence: 0.799616884444445

01:04:57.042 --> 01:04:59.938 get myself to this and he would have.  
NOTE Confidence: 0.799616884444445

01:04:59.940 --> 01:05:03.230 It's Tom OK Tom please. Yeah,  
NOTE Confidence: 0.867142

01:05:03.230 --> 01:05:05.358 I'm sorry I I would much rather go  
NOTE Confidence: 0.867142

01:05:05.358 --> 01:05:07.214 out drinking, but there was one other  
NOTE Confidence: 0.867142

01:05:07.214 --> 01:05:09.370 thing you brought up that I thought  
NOTE Confidence: 0.867142

01:05:09.370 --> 01:05:11.590 was really interesting and I love your  
NOTE Confidence: 0.867142

01:05:11.590 --> 01:05:13.750 insight on and that is even in the.  
NOTE Confidence: 0.867142

01:05:13.750 --> 01:05:15.930 Slide that you showed with  
NOTE Confidence: 0.867142

01:05:15.930 --> 01:05:17.238 the retracted papers.

NOTE Confidence: 0.867142  
01:05:17.240 --> 01:05:19.988 Several of them were from metrics  
NOTE Confidence: 0.867142  
01:05:19.988 --> 01:05:23.200 and from the non peer reviewed.  
NOTE Confidence: 0.867142  
01:05:23.200 --> 01:05:24.370 Journal depositories that  
NOTE Confidence: 0.867142  
01:05:24.370 --> 01:05:26.320 you can make anything on.  
NOTE Confidence: 0.867142  
01:05:26.320 --> 01:05:27.564 It's not peer reviewed,  
NOTE Confidence: 0.867142  
01:05:27.564 --> 01:05:30.486 and then it goes on and gets cited  
NOTE Confidence: 0.867142  
01:05:30.486 --> 01:05:32.946 subsequently in peer reviewed literature.  
NOTE Confidence: 0.867142  
01:05:32.950 --> 01:05:34.162 I just wondered.  
NOTE Confidence: 0.867142  
01:05:34.162 --> 01:05:36.990 Kind of what you think about that,  
NOTE Confidence: 0.867142  
01:05:36.990 --> 01:05:38.400 and whether those are good.  
NOTE Confidence: 0.867142  
01:05:38.400 --> 01:05:40.656 I mean, I know why they're out there,  
NOTE Confidence: 0.867142  
01:05:40.660 --> 01:05:42.627 but I also see a potential downside.  
NOTE Confidence: 0.9252029  
01:05:43.640 --> 01:05:46.800 Yeah, I mean it's really.  
NOTE Confidence: 0.9252029  
01:05:46.800 --> 01:05:49.023 We are in this very strange time of I  
NOTE Confidence: 0.9252029  
01:05:49.023 --> 01:05:51.237 think publication integrity and ethics,  
NOTE Confidence: 0.9252029

01:05:51.240 --> 01:05:54.111 and you know, I I spend time talking about

NOTE Confidence: 0.9252029

01:05:54.111 --> 01:05:56.939 how we came to have peer review at all,

NOTE Confidence: 0.9252029

01:05:56.940 --> 01:05:58.746 which came out of when scientific

NOTE Confidence: 0.9252029

01:05:58.746 --> 01:05:59.950 proceedings stop being housed

NOTE Confidence: 0.9252029

01:06:00.006 --> 01:06:01.377 in monastic libraries, right?

NOTE Confidence: 0.9252029

01:06:01.377 --> 01:06:03.279 So we got a printing press.

NOTE Confidence: 0.9252029

01:06:03.280 --> 01:06:05.188 We can circulate the the mark.

NOTE Confidence: 0.9252029

01:06:05.190 --> 01:06:07.092 You would enjoy this I think

NOTE Confidence: 0.9252029

01:06:07.092 --> 01:06:08.360 for your historical history,

NOTE Confidence: 0.9252029

01:06:08.360 --> 01:06:08.998 medicine stuff.

NOTE Confidence: 0.9252029

01:06:08.998 --> 01:06:10.912 But we gotta we gotta printing

NOTE Confidence: 0.9252029

01:06:10.912 --> 01:06:12.692 press suddenly everyone can share

NOTE Confidence: 0.9252029

01:06:12.692 --> 01:06:14.136 their scientific findings widely

NOTE Confidence: 0.9252029

01:06:14.136 --> 01:06:15.538 in the scientific community

NOTE Confidence: 0.9252029

01:06:15.538 --> 01:06:17.110 and a little bit of like.

NOTE Confidence: 0.9252029

01:06:17.110 --> 01:06:17.662 Slobbering, snobbery,

NOTE Confidence: 0.9252029

01:06:17.662 --> 01:06:19.318 and wanting to control this says,

NOTE Confidence: 0.9252029

01:06:19.320 --> 01:06:21.315 no, no, we gotta make sure we're

NOTE Confidence: 0.9252029

01:06:21.315 --> 01:06:22.629 controlling the quality of this.

NOTE Confidence: 0.9252029

01:06:22.630 --> 01:06:24.303 And the interesting thing is the move

NOTE Confidence: 0.9252029

01:06:24.303 --> 01:06:26.219 to an even more accessible format,

NOTE Confidence: 0.9252029

01:06:26.220 --> 01:06:26.496 right?

NOTE Confidence: 0.9252029

01:06:26.496 --> 01:06:27.600 So, like you know,

NOTE Confidence: 0.9252029

01:06:27.600 --> 01:06:29.456 one as the print Journal has been going

NOTE Confidence: 0.9252029

01:06:29.456 --> 01:06:31.645 down an online only journals or only

NOTE Confidence: 0.9252029

01:06:31.645 --> 01:06:33.624 everywhere you know the democratization of

NOTE Confidence: 0.9252029

01:06:33.624 --> 01:06:35.592 this might end up being our undoing right?

NOTE Confidence: 0.9252029

01:06:35.600 --> 01:06:36.704 And you do have.

NOTE Confidence: 0.9252029

01:06:36.704 --> 01:06:38.088 I mean, I really do.

NOTE Confidence: 0.9252029

01:06:38.088 --> 01:06:40.565 I mean, I'm sure you guys get them too.

NOTE Confidence: 0.9252029

01:06:40.570 --> 01:06:43.045 I get, I think 10 to 20 invitations today,

NOTE Confidence: 0.9252029

01:06:43.050 --> 01:06:43.326 too.  
NOTE Confidence: 0.9252029  
01:06:43.326 --> 01:06:44.430 You know, they will,  
NOTE Confidence: 0.9252029  
01:06:44.430 --> 01:06:44.724 too.  
NOTE Confidence: 0.9252029  
01:06:44.724 --> 01:06:46.488 Submit my article that they seem  
NOTE Confidence: 0.9252029  
01:06:46.488 --> 01:06:48.902 to think I just have ready to go  
NOTE Confidence: 0.9252029  
01:06:48.902 --> 01:06:50.684 that they will peer review and  
NOTE Confidence: 0.9252029  
01:06:50.684 --> 01:06:52.692 get me a decision on in 48 hours.  
NOTE Confidence: 0.9252029  
01:06:52.700 --> 01:06:53.047 Right,  
NOTE Confidence: 0.9252029  
01:06:53.047 --> 01:06:55.476 and so whether it's peer reviewed at  
NOTE Confidence: 0.9252029  
01:06:55.476 --> 01:06:58.856 all or fake peer reviewed, I think.  
NOTE Confidence: 0.9252029  
01:06:58.856 --> 01:07:00.800 How do you?  
NOTE Confidence: 0.9252029  
01:07:00.800 --> 01:07:03.092 What is the history of the good  
NOTE Confidence: 0.9252029  
01:07:03.092 --> 01:07:04.790 quality lit review with sort  
NOTE Confidence: 0.9252029  
01:07:04.790 --> 01:07:06.698 of like all these walls down?  
NOTE Confidence: 0.9252029  
01:07:06.700 --> 01:07:10.486 But again, I mean if you're.  
NOTE Confidence: 0.9252029  
01:07:10.490 --> 01:07:10.986 I mean,

NOTE Confidence: 0.9252029  
01:07:10.986 --> 01:07:12.722 when I read a paper I look  
NOTE Confidence: 0.9252029  
01:07:12.722 --> 01:07:14.578 at where it was published,  
NOTE Confidence: 0.9252029  
01:07:14.580 --> 01:07:16.035 write an when I'm deciding  
NOTE Confidence: 0.9252029  
01:07:16.035 --> 01:07:16.908 on citing something,  
NOTE Confidence: 0.9252029  
01:07:16.910 --> 01:07:18.398 I look at where is published  
NOTE Confidence: 0.9252029  
01:07:18.398 --> 01:07:20.420 and I try to discern between,  
NOTE Confidence: 0.9252029  
01:07:20.420 --> 01:07:21.002 you know,  
NOTE Confidence: 0.9252029  
01:07:21.002 --> 01:07:22.166 'cause sometimes things by  
NOTE Confidence: 0.9252029  
01:07:22.166 --> 01:07:23.667 famous people on important topics  
NOTE Confidence: 0.9252029  
01:07:23.667 --> 01:07:24.815 or publishing really weird  
NOTE Confidence: 0.9252029  
01:07:24.815 --> 01:07:25.963 journals and you know.  
NOTE Confidence: 0.9252029  
01:07:25.970 --> 01:07:27.716 And sometimes I think like wow,  
NOTE Confidence: 0.9252029  
01:07:27.720 --> 01:07:29.568 they must have just like submitted  
NOTE Confidence: 0.9252029  
01:07:29.568 --> 01:07:31.142 and resubmitted until they found  
NOTE Confidence: 0.9252029  
01:07:31.142 --> 01:07:32.840 someone to take this and that  
NOTE Confidence: 0.9252029

01:07:32.840 --> 01:07:34.019 happens to everybody versus  
NOTE Confidence: 0.9252029

01:07:34.019 --> 01:07:35.384 what's wrong with this paper  
NOTE Confidence: 0.9252029

01:07:35.384 --> 01:07:37.368 that this is where it is right?  
NOTE Confidence: 0.9252029

01:07:37.368 --> 01:07:39.440 And so I will say that when  
NOTE Confidence: 0.9252029

01:07:39.518 --> 01:07:41.366 you write up the sort of.  
NOTE Confidence: 0.9252029

01:07:41.370 --> 01:07:44.268 The right answer is when you write a paper,  
NOTE Confidence: 0.9252029

01:07:44.270 --> 01:07:45.880 you're responsible for your citations.  
NOTE Confidence: 0.820834616

01:07:47.920 --> 01:07:50.408 My dismay is that.  
NOTE Confidence: 0.820834616

01:07:50.408 --> 01:07:54.140 Editors seem to have put the  
NOTE Confidence: 0.820834616

01:07:54.273 --> 01:07:57.715 job of looking for this. Um?  
NOTE Confidence: 0.820834616

01:07:57.715 --> 01:07:59.570 An entirely on the backs of peer  
NOTE Confidence: 0.820834616

01:07:59.570 --> 01:08:01.481 reviewers and not taking a lot  
NOTE Confidence: 0.820834616

01:08:01.481 --> 01:08:02.805 of responsibility for themselves.  
NOTE Confidence: 0.820834616

01:08:02.810 --> 01:08:04.455 And so when you look at this,  
NOTE Confidence: 0.820834616

01:08:04.460 --> 01:08:06.584 it seems like so now as a peer reviewer,  
NOTE Confidence: 0.820834616

01:08:06.590 --> 01:08:07.770 I'm supposed to run every

NOTE Confidence: 0.820834616  
01:08:07.770 --> 01:08:08.478 single citation myself,  
NOTE Confidence: 0.820834616  
01:08:08.480 --> 01:08:10.112 and you know, see if it it checks  
NOTE Confidence: 0.820834616  
01:08:10.112 --> 01:08:11.540 out as a real publication.  
NOTE Confidence: 0.820834616  
01:08:11.540 --> 01:08:13.094 I mean, like I don't have time  
NOTE Confidence: 0.820834616  
01:08:13.094 --> 01:08:14.847 to do that as a peer reviewer,  
NOTE Confidence: 0.820834616  
01:08:14.850 --> 01:08:16.495 I do a lot of peer review.  
NOTE Confidence: 0.820834616  
01:08:16.500 --> 01:08:16.964 You know,  
NOTE Confidence: 0.820834616  
01:08:16.964 --> 01:08:18.820 I'm I'm reading the paper to see if  
NOTE Confidence: 0.820834616  
01:08:18.877 --> 01:08:20.565 I think it's good and if I happen  
NOTE Confidence: 0.820834616  
01:08:20.565 --> 01:08:22.566 to Nova reference that I want to see  
NOTE Confidence: 0.820834616  
01:08:22.566 --> 01:08:24.288 or I'm curious about a reference outlook,  
NOTE Confidence: 0.820834616  
01:08:24.288 --> 01:08:25.940 but I can't cross reference all that,  
NOTE Confidence: 0.820834616  
01:08:25.940 --> 01:08:26.993 so I think.  
NOTE Confidence: 0.820834616  
01:08:26.993 --> 01:08:29.099 We're gonna have to answer the  
NOTE Confidence: 0.820834616  
01:08:29.099 --> 01:08:30.826 question of whose job is it?  
NOTE Confidence: 0.820834616

01:08:30.830 --> 01:08:31.733 And you know,  
NOTE Confidence: 0.820834616

01:08:31.733 --> 01:08:34.290 my sense is we're headed for some rules,  
NOTE Confidence: 0.820834616

01:08:34.290 --> 01:08:36.288 and that journals will start to  
NOTE Confidence: 0.820834616

01:08:36.288 --> 01:08:38.292 say these are our requirements  
NOTE Confidence: 0.820834616

01:08:38.292 --> 01:08:40.080 for your bibliography.  
NOTE Confidence: 0.820834616

01:08:40.080 --> 01:08:41.346 Um, but I hadn't thought about  
NOTE Confidence: 0.820834616

01:08:41.346 --> 01:08:42.750 that much from that perspective,  
NOTE Confidence: 0.820834616

01:08:42.750 --> 01:08:43.970 so thank you for that.  
NOTE Confidence: 0.820834616

01:08:43.970 --> 01:08:47.300 'cause I think that is a.  
NOTE Confidence: 0.820834616

01:08:47.300 --> 01:08:49.796 It's so hard to know now what's a  
NOTE Confidence: 0.820834616

01:08:49.796 --> 01:08:51.408 quality reference and what's not.  
NOTE Confidence: 0.7589752

01:08:53.760 --> 01:08:56.245 It's a little bit scary  
NOTE Confidence: 0.7589752

01:08:56.245 --> 01:08:58.020 asking these things. Yeah,  
NOTE Confidence: 0.8428791

01:08:58.020 --> 01:08:59.124 I think so too.  
NOTE Confidence: 0.8428791

01:08:59.124 --> 01:09:00.504 Publication ethics is like super  
NOTE Confidence: 0.8428791

01:09:00.504 --> 01:09:01.618 interesting stuff these days.

NOTE Confidence: 0.8428791

01:09:01.620 --> 01:09:03.950 There's like a lot of.

NOTE Confidence: 0.8428791

01:09:03.950 --> 01:09:06.290 Cool things to do in that area, I think.

NOTE Confidence: 0.88159215

01:09:07.020 --> 01:09:09.850 And there's just so many ways to mess up and

NOTE Confidence: 0.88159215

01:09:09.850 --> 01:09:12.106 so many ways to mess up by accident,

NOTE Confidence: 0.88159215

01:09:12.110 --> 01:09:14.250 I think, is the other.

NOTE Confidence: 0.88159215

01:09:14.250 --> 01:09:15.510 Other big thing you know,

NOTE Confidence: 0.88159215

01:09:15.510 --> 01:09:17.673 I think when people cite a reference

NOTE Confidence: 0.88159215

01:09:17.673 --> 01:09:19.120 that they haven't checked.

NOTE Confidence: 0.88159215

01:09:19.120 --> 01:09:21.424 That's sloppiness, not malice.

NOTE Confidence: 0.88159215

01:09:21.424 --> 01:09:23.694 Right, and so an it's a sort of

NOTE Confidence: 0.88159215

01:09:23.694 --> 01:09:24.420 particularly problematic kind

NOTE Confidence: 0.88159215

01:09:24.472 --> 01:09:25.816 of Attribution that we all do.

NOTE Confidence: 0.88159215

01:09:25.820 --> 01:09:27.243 'cause we're in a hurry, right?

NOTE Confidence: 0.88159215

01:09:27.243 --> 01:09:28.358 Not because we're trying to

NOTE Confidence: 0.88159215

01:09:28.358 --> 01:09:29.650 pull one over on someone.

NOTE Confidence: 0.88581777

01:09:31.640 --> 01:09:33.960 Excellent point, excellent point.

NOTE Confidence: 0.88581777

01:09:33.960 --> 01:09:35.396 Well, I think.

NOTE Confidence: 0.88581777

01:09:35.396 --> 01:09:38.392 Are scanning quickly over my list here?

NOTE Confidence: 0.88581777

01:09:38.400 --> 01:09:40.425 I think folks who wanted to speak

NOTE Confidence: 0.88581777

01:09:40.425 --> 01:09:42.756 at the opportunity to speak it was a

NOTE Confidence: 0.88581777

01:09:42.756 --> 01:09:44.709 wonderful talk and they only we look

NOTE Confidence: 0.88581777

01:09:44.709 --> 01:09:46.578 forward to hosting you in person.

NOTE Confidence: 0.88581777

01:09:46.580 --> 01:09:48.100 New Haven after the storm.