

WEBVTT

NOTE duration:"00:12:31.0400000"

NOTE language:en-us

NOTE Confidence: 0.86054856

00:00:00.000 --> 00:00:03.880 Thank you for for the for the invitation.

NOTE Confidence: 0.86054856

00:00:03.880 --> 00:00:07.086 I'll be. Brief,

NOTE Confidence: 0.86054856

00:00:07.086 --> 00:00:10.138 with the time that I have today,

NOTE Confidence: 0.86054856

00:00:10.140 --> 00:00:13.185 I'm going to be talking about effectiveness,

NOTE Confidence: 0.86054856

00:00:13.190 --> 00:00:15.338 so going from efficacy to effectiveness

NOTE Confidence: 0.86054856

00:00:15.338 --> 00:00:18.800 I I was a principle investigator in a

NOTE Confidence: 0.86054856

00:00:18.800 --> 00:00:21.245 randomized clinical trial for fieser

NOTE Confidence: 0.86054856

00:00:21.245 --> 00:00:24.483 an I've participated as a speaker in

NOTE Confidence: 0.86054856

00:00:24.483 --> 00:00:27.476 educational events for both Merck and Sanofi.

NOTE Confidence: 0.86054856

00:00:27.476 --> 00:00:29.486 So we're talking about going

NOTE Confidence: 0.86054856

00:00:29.486 --> 00:00:31.500 from efficacy to effectiveness.

NOTE Confidence: 0.86054856

00:00:31.500 --> 00:00:32.470 Strictly speaking,

NOTE Confidence: 0.86054856

00:00:32.470 --> 00:00:34.410 efficacy and effectiveness have

NOTE Confidence: 0.86054856

00:00:34.410 --> 00:00:36.856 very different meanings in the

NOTE Confidence: 0.86054856

00:00:36.856 --> 00:00:38.620 context of vaccine development.

NOTE Confidence: 0.86054856

00:00:38.620 --> 00:00:40.764 But there oftentimes they're

NOTE Confidence: 0.86054856

00:00:40.764 --> 00:00:42.375 used interchangeably, so,

NOTE Confidence: 0.86054856

00:00:42.375 --> 00:00:45.050 so in terms of similarities,

NOTE Confidence: 0.86054856

00:00:45.050 --> 00:00:49.004 they both present or represent the

NOTE Confidence: 0.86054856

00:00:49.004 --> 00:00:52.540 percentage reduction of disease amongst.

NOTE Confidence: 0.86054856

00:00:52.540 --> 00:00:54.745 People who are who are vaccinated but

NOTE Confidence: 0.86054856

00:00:54.745 --> 00:00:57.109 but there are obviously differences.

NOTE Confidence: 0.86054856

00:00:57.110 --> 00:00:57.874 Vaccine efficacy.

NOTE Confidence: 0.86054856

00:00:57.874 --> 00:00:59.020 As you've heard,

NOTE Confidence: 0.86054856

00:00:59.020 --> 00:01:00.860 the previous speakers refer to

NOTE Confidence: 0.86054856

00:01:00.860 --> 00:01:02.700 how well the vaccines perform

NOTE Confidence: 0.86054856

00:01:02.765 --> 00:01:04.730 under the most ideal conditions,

NOTE Confidence: 0.86054856

00:01:04.730 --> 00:01:06.635 and these are mostly randomized

NOTE Confidence: 0.86054856

00:01:06.635 --> 00:01:07.397 clinical trials.

NOTE Confidence: 0.86054856

00:01:07.400 --> 00:01:08.764 These are experimental studies  
NOTE Confidence: 0.86054856

00:01:08.764 --> 00:01:10.469 that are considered the gold  
NOTE Confidence: 0.86054856

00:01:10.469 --> 00:01:11.969 standard vaccine effectiveness,  
NOTE Confidence: 0.86054856

00:01:11.970 --> 00:01:13.986 which I'll talk about in the few  
NOTE Confidence: 0.86054856

00:01:13.986 --> 00:01:15.985 minutes that I have remaining refers  
NOTE Confidence: 0.86054856

00:01:15.985 --> 00:01:18.477 to how well a vaccine performs under  
NOTE Confidence: 0.86054856

00:01:18.539 --> 00:01:21.521 real world conditions under less than  
NOTE Confidence: 0.86054856

00:01:21.521 --> 00:01:23.012 perfectly controlled circumstances.  
NOTE Confidence: 0.86054856

00:01:23.020 --> 00:01:25.630 So what happens when a vaccine?  
NOTE Confidence: 0.86054856

00:01:25.630 --> 00:01:27.850 Is given to individuals who have  
NOTE Confidence: 0.86054856

00:01:27.850 --> 00:01:29.796 comorbidities, who are different ages.  
NOTE Confidence: 0.86054856

00:01:29.796 --> 00:01:32.160 When the very strict criteria of  
NOTE Confidence: 0.86054856

00:01:32.237 --> 00:01:34.661 all of us who've gotten are some of  
NOTE Confidence: 0.86054856

00:01:34.661 --> 00:01:37.098 us have gotten our covid vaccine,  
NOTE Confidence: 0.86054856

00:01:37.100 --> 00:01:38.580 I counting the interval.  
NOTE Confidence: 0.86054856

00:01:38.580 --> 00:01:42.280 did I get this one? You know how many days?

NOTE Confidence: 0.86054856

00:01:42.280 --> 00:01:43.692 But as we know,

NOTE Confidence: 0.86054856

00:01:43.692 --> 00:01:46.281 in real in in real practice this

NOTE Confidence: 0.86054856

00:01:46.281 --> 00:01:48.196 is not often adhere to,

NOTE Confidence: 0.86054856

00:01:48.200 --> 00:01:51.398 so this slide shows you the.

NOTE Confidence: 0.86054856

00:01:51.400 --> 00:01:53.060 Scheme of randomized clinical trials.

NOTE Confidence: 0.86054856

00:01:53.060 --> 00:01:55.251 When you have a large group of

NOTE Confidence: 0.86054856

00:01:55.251 --> 00:01:56.590 susceptible individuals and those

NOTE Confidence: 0.86054856

00:01:56.590 --> 00:01:58.630 are randomized to receive or not

NOTE Confidence: 0.86054856

00:01:58.630 --> 00:02:00.359 receive the intervention in question.

NOTE Confidence: 0.86054856

00:02:00.360 --> 00:02:03.141 In this case it will be a vaccine and

NOTE Confidence: 0.86054856

00:02:03.141 --> 00:02:05.892 the direction of the study is looking

NOTE Confidence: 0.86054856

00:02:05.892 --> 00:02:08.900 forward in time to try to figure out.

NOTE Confidence: 0.86054856

00:02:08.900 --> 00:02:10.564 Which the proportion of.

NOTE Confidence: 0.86054856

00:02:10.564 --> 00:02:14.111 In each one of these groups of individuals

NOTE Confidence: 0.86054856

00:02:14.111 --> 00:02:17.959 who develop disease and is the vaccine works.

NOTE Confidence: 0.86054856

00:02:17.960 --> 00:02:20.102 Obviously, those who receive the vaccine  
NOTE Confidence: 0.86054856

00:02:20.102 --> 00:02:23.127 are going to have lower rates of infection,  
NOTE Confidence: 0.86054856

00:02:23.130 --> 00:02:24.970 but even though these studies  
NOTE Confidence: 0.86054856

00:02:24.970 --> 00:02:26.442 are the gold standard,  
NOTE Confidence: 0.86054856

00:02:26.450 --> 00:02:27.930 they have certain disadvantages.  
NOTE Confidence: 0.86054856

00:02:27.930 --> 00:02:29.406 Their advantages, well, we've.  
NOTE Confidence: 0.86054856

00:02:29.406 --> 00:02:30.510 I've mentioned before.  
NOTE Confidence: 0.86054856

00:02:30.510 --> 00:02:32.360 They are the gold standard.  
NOTE Confidence: 0.86054856

00:02:32.360 --> 00:02:34.155 Their experimental studies where the  
NOTE Confidence: 0.86054856

00:02:34.155 --> 00:02:35.950 allocation or the intervention is  
NOTE Confidence: 0.86054856

00:02:36.009 --> 00:02:37.890 given randomly, which minimizes bias,  
NOTE Confidence: 0.86054856

00:02:37.890 --> 00:02:39.740 and for the most part,  
NOTE Confidence: 0.86054856

00:02:39.740 --> 00:02:42.026 these studies are blinded, so it.  
NOTE Confidence: 0.86054856

00:02:42.030 --> 00:02:44.880 Really ask helps you an unbiased  
NOTE Confidence: 0.86054856

00:02:44.880 --> 00:02:46.780 ascertainment of the outcome,  
NOTE Confidence: 0.86054856

00:02:46.780 --> 00:02:48.640 but they have disadvantages.

NOTE Confidence: 0.86054856

00:02:48.640 --> 00:02:52.010 They have poor statistical power for things,

NOTE Confidence: 0.86054856

00:02:52.010 --> 00:02:54.380 diseases that are buried rare.

NOTE Confidence: 0.86054856

00:02:54.380 --> 00:02:56.760 You need very large samples.

NOTE Confidence: 0.86054856

00:02:56.760 --> 00:02:59.952 They are very costly an oftentimes to

NOTE Confidence: 0.86054856

00:02:59.952 --> 00:03:02.460 selected population is studied again,

NOTE Confidence: 0.86054856

00:03:02.460 --> 00:03:03.408 sort of.

NOTE Confidence: 0.86054856

00:03:03.408 --> 00:03:05.778 Drawing parallels with Covid vaccine.

NOTE Confidence: 0.86054856

00:03:05.780 --> 00:03:08.160 Young individuals were not studied.

NOTE Confidence: 0.86054856

00:03:08.160 --> 00:03:10.530 Pregnant women were not studied.

NOTE Confidence: 0.86054856

00:03:10.530 --> 00:03:12.502 An individuals with significant

NOTE Confidence: 0.86054856

00:03:12.502 --> 00:03:14.474 comorbidities are oftentimes excluded.

NOTE Confidence: 0.86054856

00:03:14.480 --> 00:03:16.172 The follow-up is limited.

NOTE Confidence: 0.86054856

00:03:16.172 --> 00:03:18.287 Usually these are conducted for

NOTE Confidence: 0.86054856

00:03:18.287 --> 00:03:19.818 one of three years.

NOTE Confidence: 0.86054856

00:03:19.820 --> 00:03:22.697 Again, if you think of covid vaccine,

NOTE Confidence: 0.86054856

00:03:22.700 --> 00:03:24.760 everything was done much quicker,  
NOTE Confidence: 0.86054856

00:03:24.760 --> 00:03:27.220 but for the most part there  
NOTE Confidence: 0.86054856

00:03:27.220 --> 00:03:28.450 follow-up is limited,  
NOTE Confidence: 0.86054856

00:03:28.450 --> 00:03:30.916 and this leads us to think  
NOTE Confidence: 0.86054856

00:03:30.916 --> 00:03:31.738 about generalizability.  
NOTE Confidence: 0.859969

00:03:31.740 --> 00:03:34.862 How how did those results from the  
NOTE Confidence: 0.859969

00:03:34.862 --> 00:03:36.640 randomized clinical trial translate  
NOTE Confidence: 0.859969

00:03:36.640 --> 00:03:39.544 to the patient that we see and an?  
NOTE Confidence: 0.859969

00:03:39.550 --> 00:03:42.546 What is the the efficacy in in  
NOTE Confidence: 0.859969

00:03:42.546 --> 00:03:44.590 the general clinical setting?  
NOTE Confidence: 0.859969

00:03:44.590 --> 00:03:46.684 So, so the questions that remain  
NOTE Confidence: 0.859969

00:03:46.684 --> 00:03:49.029 on answers would be the efficacy.  
NOTE Confidence: 0.859969

00:03:49.030 --> 00:03:50.880 In actual practice, its efficacy,  
NOTE Confidence: 0.859969

00:03:50.880 --> 00:03:53.100 overtime, what happens five years later?  
NOTE Confidence: 0.859969

00:03:53.100 --> 00:03:55.676 What happens 10 years later and then when  
NOTE Confidence: 0.859969

00:03:55.676 --> 00:03:58.277 you start thinking of subgroup analysis,

NOTE Confidence: 0.859969

00:03:58.280 --> 00:04:01.003 so populations if all of a sudden

NOTE Confidence: 0.859969

00:04:01.003 --> 00:04:02.577 cardiac patients seemed to

NOTE Confidence: 0.859969

00:04:02.577 --> 00:04:04.569 have a higher rates of disease,

NOTE Confidence: 0.859969

00:04:04.570 --> 00:04:06.894 will it work as well in patients

NOTE Confidence: 0.859969

00:04:06.894 --> 00:04:09.378 will have that type of comorbidity?

NOTE Confidence: 0.859969

00:04:09.380 --> 00:04:10.619 As I mentioned,

NOTE Confidence: 0.859969

00:04:10.619 --> 00:04:13.097 different age groups and ethnic groups

NOTE Confidence: 0.859969

00:04:13.097 --> 00:04:15.849 which is very important especially now.

NOTE Confidence: 0.859969

00:04:15.850 --> 00:04:18.290 In the face of COVID-19,

NOTE Confidence: 0.859969

00:04:18.290 --> 00:04:20.984 where we see an infection that

NOTE Confidence: 0.859969

00:04:20.984 --> 00:04:24.439 seems to to affect both in morbidity

NOTE Confidence: 0.859969

00:04:24.439 --> 00:04:27.559 and mortality in in higher rates,

NOTE Confidence: 0.859969

00:04:27.560 --> 00:04:30.670 certain a certain ethnic group.

NOTE Confidence: 0.859969

00:04:30.670 --> 00:04:32.295 So effectiveness studies and now

NOTE Confidence: 0.859969

00:04:32.295 --> 00:04:33.920 use the case control methodology,

NOTE Confidence: 0.859969



00:04:33.920 --> 00:04:35.906 'cause that's the one that my  
NOTE Confidence: 0.859969

00:04:35.906 --> 00:04:38.150 collaborators and I have used for many,  
NOTE Confidence: 0.859969

00:04:38.150 --> 00:04:39.770 many years, is an observation.  
NOTE Confidence: 0.859969

00:04:39.770 --> 00:04:41.720 ULL study an in this case.  
NOTE Confidence: 0.859969

00:04:41.720 --> 00:04:43.718 This is the schematic of what  
NOTE Confidence: 0.859969

00:04:43.718 --> 00:04:45.300 case control study would be,  
NOTE Confidence: 0.859969

00:04:45.300 --> 00:04:47.162 and this is the study that we  
NOTE Confidence: 0.859969

00:04:47.162 --> 00:04:48.870 used to assess effectiveness.  
NOTE Confidence: 0.859969

00:04:48.870 --> 00:04:50.495 You select cases you select  
NOTE Confidence: 0.859969

00:04:50.495 --> 00:04:52.120 participants based on the outcomes.  
NOTE Confidence: 0.859969

00:04:52.120 --> 00:04:54.070 So the direction of the observation  
NOTE Confidence: 0.859969

00:04:54.070 --> 00:04:55.370 is completely the opposite.  
NOTE Confidence: 0.859969

00:04:55.370 --> 00:04:57.358 The cases are going to be the  
NOTE Confidence: 0.859969

00:04:57.358 --> 00:04:58.630 individuals who develop the  
NOTE Confidence: 0.859969

00:04:58.630 --> 00:05:00.425 disease in question controls other  
NOTE Confidence: 0.859969

00:05:00.425 --> 00:05:01.861 persons without the disease.

NOTE Confidence: 0.859969

00:05:01.870 --> 00:05:04.495 And then you look backwards in time.

NOTE Confidence: 0.859969

00:05:04.500 --> 00:05:06.588 To try to ascertain which proportion

NOTE Confidence: 0.859969

00:05:06.588 --> 00:05:09.619 in each one of these groups developed,

NOTE Confidence: 0.859969

00:05:09.620 --> 00:05:11.590 sorry were that were vaccinated,

NOTE Confidence: 0.859969

00:05:11.590 --> 00:05:13.960 and if the vaccine is effective,

NOTE Confidence: 0.859969

00:05:13.960 --> 00:05:15.922 then you would expect fewer of

NOTE Confidence: 0.859969

00:05:15.922 --> 00:05:18.236 the cases to have been previously

NOTE Confidence: 0.859969

00:05:18.236 --> 00:05:21.044 vaccinated as compared to the controls.

NOTE Confidence: 0.859969

00:05:21.050 --> 00:05:23.450 And these studies have many advantages

NOTE Confidence: 0.859969

00:05:23.450 --> 00:05:24.650 there statistically powerful

NOTE Confidence: 0.859969

00:05:24.650 --> 00:05:26.557 with much smaller sample sizes,

NOTE Confidence: 0.859969

00:05:26.560 --> 00:05:29.544 and I'll show you in some of the

NOTE Confidence: 0.859969

00:05:29.544 --> 00:05:32.078 examples in the next few slides,

NOTE Confidence: 0.859969

00:05:32.080 --> 00:05:34.185 you don't need longitudinal follow-up

NOTE Confidence: 0.859969

00:05:34.185 --> 00:05:36.290 because there is no intervention.

NOTE Confidence: 0.859969

00:05:36.290 --> 00:05:37.758 They are ethically acceptable  
NOTE Confidence: 0.859969

00:05:37.758 --> 00:05:39.226 because let's face it,  
NOTE Confidence: 0.859969

00:05:39.230 --> 00:05:41.060 after a vaccine is licensed  
NOTE Confidence: 0.859969

00:05:41.060 --> 00:05:42.524 and recommended for use,  
NOTE Confidence: 0.859969

00:05:42.530 --> 00:05:45.509 nobody is going to want to do a randomized  
NOTE Confidence: 0.859969

00:05:45.509 --> 00:05:48.055 trial where some people get something  
NOTE Confidence: 0.859969

00:05:48.055 --> 00:05:50.590 that is recommended and others are  
NOTE Confidence: 0.859969

00:05:50.590 --> 00:05:53.166 are going to are going to be withheld,  
NOTE Confidence: 0.859969

00:05:53.170 --> 00:05:54.638 something that that the  
NOTE Confidence: 0.859969

00:05:54.638 --> 00:05:55.739 scientific groups recommends,  
NOTE Confidence: 0.859969

00:05:55.740 --> 00:05:57.208 but they have disadvantages.  
NOTE Confidence: 0.859969

00:05:57.208 --> 00:05:58.309 They're not experimental,  
NOTE Confidence: 0.859969

00:05:58.310 --> 00:06:02.335 and there are susceptible to bias so.  
NOTE Confidence: 0.859969

00:06:02.340 --> 00:06:04.080 Is it really?  
NOTE Confidence: 0.859969

00:06:04.080 --> 00:06:06.728 When we now put this into into context  
NOTE Confidence: 0.859969

00:06:06.728 --> 00:06:09.389 with what's happening with Kovid vaccine,

NOTE Confidence: 0.859969

00:06:09.390 --> 00:06:11.304 even though CDC and many others

NOTE Confidence: 0.859969

00:06:11.304 --> 00:06:13.560 plan to track the effectiveness,

NOTE Confidence: 0.859969

00:06:13.560 --> 00:06:16.284 we know that randomized clinical trials

NOTE Confidence: 0.859969

00:06:16.284 --> 00:06:19.575 for covid vaccine have shown that this

NOTE Confidence: 0.859969

00:06:19.575 --> 00:06:21.910 vaccine is highly highly effective.

NOTE Confidence: 0.859969

00:06:21.910 --> 00:06:25.366 But it remains to be seen if indeed

NOTE Confidence: 0.859969

00:06:25.366 --> 00:06:28.184 this efficacy of about 90% or higher

NOTE Confidence: 0.859969

00:06:28.184 --> 00:06:30.596 in the ideal setting will will

NOTE Confidence: 0.859969

00:06:30.596 --> 00:06:33.343 remained in everyday practice an we

NOTE Confidence: 0.859969

00:06:33.343 --> 00:06:36.127 know that ongoing studies are needed

NOTE Confidence: 0.859969

00:06:36.213 --> 00:06:38.866 to be able to address the questions

NOTE Confidence: 0.859969

00:06:38.866 --> 00:06:41.694 that from the get go we have,

NOTE Confidence: 0.859969

00:06:41.694 --> 00:06:43.799 but also unexpected relevant clinical

NOTE Confidence: 0.859969

00:06:43.799 --> 00:06:46.326 clinical questions that that remain so.

NOTE Confidence: 0.859969

00:06:46.330 --> 00:06:48.838 Our research team at Yale with

NOTE Confidence: 0.859969

00:06:48.838 --> 00:06:50.510 collaborators over many years  
NOTE Confidence: 0.86888796

00:06:50.580 --> 00:06:52.752 in other medical centers such as  
NOTE Confidence: 0.86888796

00:06:52.752 --> 00:06:54.801 CDC and others have conducted  
NOTE Confidence: 0.86888796

00:06:54.801 --> 00:06:56.917 studies of effectiveness of.  
NOTE Confidence: 0.86888796

00:06:56.920 --> 00:06:59.755 Vaccines for multiple vaccines over the year,  
NOTE Confidence: 0.86888796

00:06:59.760 --> 00:07:02.808 and I will share for this talk just  
NOTE Confidence: 0.86888796

00:07:02.808 --> 00:07:05.849 one or two studies due to time,  
NOTE Confidence: 0.86888796

00:07:05.850 --> 00:07:08.910 but show you how results of a study on  
NOTE Confidence: 0.86888796

00:07:08.910 --> 00:07:11.633 this slide of effectiveness of varicella  
NOTE Confidence: 0.86888796

00:07:11.633 --> 00:07:15.599 vaccine and as you can see here under 1000,  
NOTE Confidence: 0.86888796

00:07:15.600 --> 00:07:18.030 subjects were included in the study,  
NOTE Confidence: 0.86888796

00:07:18.030 --> 00:07:20.262 and even though the number of  
NOTE Confidence: 0.86888796

00:07:20.262 --> 00:07:22.900 participants was small by enrolling cases,  
NOTE Confidence: 0.86888796

00:07:22.900 --> 00:07:24.528 children with varicella and  
NOTE Confidence: 0.86888796

00:07:24.528 --> 00:07:25.749 controls children without,  
NOTE Confidence: 0.86888796

00:07:25.750 --> 00:07:28.252 we were able to assess the

NOTE Confidence: 0.86888796  
00:07:28.252 --> 00:07:29.920 effectiveness of this vaccine.  
NOTE Confidence: 0.86888796  
00:07:29.920 --> 00:07:33.175 With great certainty the the method of  
NOTE Confidence: 0.86888796  
00:07:33.175 --> 00:07:36.420 measure that's used is the Max odds ratio,  
NOTE Confidence: 0.86888796  
00:07:36.420 --> 00:07:38.580 and that's what's used on  
NOTE Confidence: 0.86888796  
00:07:38.580 --> 00:07:39.876 case control studies,  
NOTE Confidence: 0.86888796  
00:07:39.880 --> 00:07:43.513 and we were able to assess the  
NOTE Confidence: 0.86888796  
00:07:43.513 --> 00:07:45.990 effectiveness of the vaccine.  
NOTE Confidence: 0.86888796  
00:07:45.990 --> 00:07:46.355 Furthermore,  
NOTE Confidence: 0.86888796  
00:07:46.355 --> 00:07:48.910 not only are we able to assess  
NOTE Confidence: 0.86888796  
00:07:48.910 --> 00:07:50.640 the overall effectiveness,  
NOTE Confidence: 0.86888796  
00:07:50.640 --> 00:07:53.178 but we are able to target  
NOTE Confidence: 0.86888796  
00:07:53.178 --> 00:07:54.870 important questions in subgroups,  
NOTE Confidence: 0.86888796  
00:07:54.870 --> 00:07:56.985 so again using the varicella  
NOTE Confidence: 0.86888796  
00:07:56.985 --> 00:07:58.677 vaccine as the example,  
NOTE Confidence: 0.86888796  
00:07:58.680 --> 00:08:01.272 we were able to evaluate the  
NOTE Confidence: 0.86888796

00:08:01.272 --> 00:08:03.483 effectiveness by time elapsed from  
NOTE Confidence: 0.86888796

00:08:03.483 --> 00:08:06.290 the time of vaccination in this study,  
NOTE Confidence: 0.86888796

00:08:06.290 --> 00:08:09.602 led in part to changes in actual vaccine  
NOTE Confidence: 0.86888796

00:08:09.602 --> 00:08:11.788 recommendation in the United States.  
NOTE Confidence: 0.86888796

00:08:11.790 --> 00:08:13.646 Originally this vaccine was  
NOTE Confidence: 0.86888796

00:08:13.646 --> 00:08:16.430 recommended just to receive one dose.  
NOTE Confidence: 0.86888796

00:08:16.430 --> 00:08:19.346 And then with data from studies  
NOTE Confidence: 0.86888796

00:08:19.346 --> 00:08:20.318 of effectiveness,  
NOTE Confidence: 0.86888796

00:08:20.320 --> 00:08:24.166 the recommendation changed to include two  
NOTE Confidence: 0.86888796

00:08:24.166 --> 00:08:28.059 doses routinely to Everett to everybody.  
NOTE Confidence: 0.86888796

00:08:28.060 --> 00:08:30.727 Another one of the of the analysis  
NOTE Confidence: 0.86888796

00:08:30.727 --> 00:08:33.866 that can be done an and we're done,  
NOTE Confidence: 0.86888796

00:08:33.870 --> 00:08:35.805 is questions that arise that  
NOTE Confidence: 0.86888796

00:08:35.805 --> 00:08:37.740 we didn't even think about.  
NOTE Confidence: 0.86888796

00:08:37.740 --> 00:08:39.670 So in the varicella vaccine  
NOTE Confidence: 0.86888796

00:08:39.670 --> 00:08:40.828 in after licensure,

NOTE Confidence: 0.86888796

00:08:40.830 --> 00:08:43.868 there were questions of whether what was

NOTE Confidence: 0.86888796

00:08:43.868 --> 00:08:47.015 the ideal age to give it to a child.

NOTE Confidence: 0.86888796

00:08:47.020 --> 00:08:47.818 Then again,

NOTE Confidence: 0.86888796

00:08:47.818 --> 00:08:51.010 at that point it would have been impossible

NOTE Confidence: 0.86888796

00:08:51.086 --> 00:08:53.990 to then go back to the randomized trial,

NOTE Confidence: 0.86888796

00:08:53.990 --> 00:08:56.312 but using the same methodology with

NOTE Confidence: 0.86888796

00:08:56.312 --> 00:08:58.470 data that were already accrued.

NOTE Confidence: 0.86888796

00:08:58.470 --> 00:09:01.389 Our team was able to answer this

NOTE Confidence: 0.86888796

00:09:01.389 --> 00:09:03.820 question an address whether the

NOTE Confidence: 0.86888796

00:09:03.820 --> 00:09:06.004 effectiveness in different groups

NOTE Confidence: 0.86888796

00:09:06.004 --> 00:09:08.188 by age were different,

NOTE Confidence: 0.86888796

00:09:08.190 --> 00:09:12.166 which ended up not not being different.

NOTE Confidence: 0.86888796

00:09:12.170 --> 00:09:14.582 Once a vaccine is licensed and

NOTE Confidence: 0.86888796

00:09:14.582 --> 00:09:16.990 recommended for the population in general,

NOTE Confidence: 0.86888796

00:09:16.990 --> 00:09:18.184 as I mentioned,

NOTE Confidence: 0.86888796



00:09:18.184 --> 00:09:20.174 it's unethical to conduct a  
NOTE Confidence: 0.86888796

00:09:20.174 --> 00:09:21.420 randomized clinical trial,  
NOTE Confidence: 0.86888796

00:09:21.420 --> 00:09:23.736 so figuring out whether using two  
NOTE Confidence: 0.86888796

00:09:23.736 --> 00:09:26.587 doses was better than one would have  
NOTE Confidence: 0.86888796

00:09:26.587 --> 00:09:28.647 been would have been impossible.  
NOTE Confidence: 0.86888796

00:09:28.650 --> 00:09:31.408 But given the fact that when the  
NOTE Confidence: 0.86888796

00:09:31.408 --> 00:09:33.880 recommendation for two doses came about,  
NOTE Confidence: 0.86888796

00:09:33.880 --> 00:09:36.239 not everybody at once got to doses  
NOTE Confidence: 0.86888796

00:09:36.239 --> 00:09:38.699 using the case control methodology,  
NOTE Confidence: 0.86888796

00:09:38.700 --> 00:09:41.598 we were able to compare the effectiveness  
NOTE Confidence: 0.86888796

00:09:41.598 --> 00:09:43.460 of individuals with Windows.  
NOTE Confidence: 0.86888796

00:09:43.460 --> 00:09:46.589 Versus Versus 2 doses. So you know.  
NOTE Confidence: 0.86888796

00:09:46.590 --> 00:09:47.075 Again,  
NOTE Confidence: 0.86888796

00:09:47.075 --> 00:09:49.500 studies of Affectedness are very  
NOTE Confidence: 0.86888796

00:09:49.500 --> 00:09:52.665 useful in being able to to acquire  
NOTE Confidence: 0.86888796

00:09:52.665 --> 00:09:54.189 data like this one,

NOTE Confidence: 0.86888796

00:09:54.190 --> 00:09:57.465 and then another example from

NOTE Confidence: 0.86888796

00:09:57.465 --> 00:09:59.970 a different study. Is that?

NOTE Confidence: 0.86888796

00:09:59.970 --> 00:10:02.130 We can even conduct an be able to

NOTE Confidence: 0.86888796

00:10:02.200 --> 00:10:04.745 assess effectiveness for individuals who

NOTE Confidence: 0.86888796

00:10:04.745 --> 00:10:07.290 never received the vaccine themselves,

NOTE Confidence: 0.86888796

00:10:07.290 --> 00:10:09.318 and this study was done about

NOTE Confidence: 0.86888796

00:10:09.318 --> 00:10:12.005 10 years ago when the topic of

NOTE Confidence: 0.86888796

00:10:12.005 --> 00:10:14.095 vaccination during pregnancy was not

NOTE Confidence: 0.86888796

00:10:14.095 --> 00:10:17.131 well and graced by patients and not

NOTE Confidence: 0.86888796

00:10:17.131 --> 00:10:19.256 by the entire medical community,

NOTE Confidence: 0.86888796

00:10:19.260 --> 00:10:21.250 and the rates of influenza

NOTE Confidence: 0.86888796

00:10:21.250 --> 00:10:22.444 vaccination were low,

NOTE Confidence: 0.86888796

00:10:22.450 --> 00:10:24.748 and for this study we set

NOTE Confidence: 0.86888796

00:10:24.748 --> 00:10:26.280 out to evaluate whether

NOTE Confidence: 0.8919878

00:10:26.362 --> 00:10:28.798 one vaccine given to a pregnant

NOTE Confidence: 0.8919878

00:10:28.798 --> 00:10:31.759 mother would be able to protect both.  
NOTE Confidence: 0.8919878

00:10:31.760 --> 00:10:33.530 The mother and the infant,  
NOTE Confidence: 0.8919878

00:10:33.530 --> 00:10:35.654 which is not only very important  
NOTE Confidence: 0.8919878

00:10:35.654 --> 00:10:37.070 in terms of protection,  
NOTE Confidence: 0.8919878

00:10:37.070 --> 00:10:39.194 but also in terms of in  
NOTE Confidence: 0.8919878

00:10:39.194 --> 00:10:40.610 terms of cost effectiveness,  
NOTE Confidence: 0.8919878

00:10:40.610 --> 00:10:42.380 where you have one vaccine,  
NOTE Confidence: 0.8919878

00:10:42.380 --> 00:10:44.480 being able to to protect two  
NOTE Confidence: 0.8919878

00:10:44.480 --> 00:10:46.629 individuals for briefly for this study.  
NOTE Confidence: 0.8919878

00:10:46.630 --> 00:10:48.400 We did very similar structure.  
NOTE Confidence: 0.8919878

00:10:48.400 --> 00:10:50.320 A case control study where the  
NOTE Confidence: 0.8919878

00:10:50.320 --> 00:10:52.049 cases were infants who were  
NOTE Confidence: 0.8919878

00:10:52.049 --> 00:10:53.979 hospitalised due to influenza and  
NOTE Confidence: 0.8919878

00:10:53.979 --> 00:10:56.269 controls were infants who were very  
NOTE Confidence: 0.8919878

00:10:56.269 --> 00:10:58.303 similar who did not have influence.  
NOTE Confidence: 0.8919878

00:10:58.310 --> 00:11:00.788 And again we look backwards in time.

NOTE Confidence: 0.8919878

00:11:00.790 --> 00:11:02.642 But rather than assessing.

NOTE Confidence: 0.8919878

00:11:02.642 --> 00:11:04.957 Influenza vaccine in the infants.

NOTE Confidence: 0.8919878

00:11:04.960 --> 00:11:06.322 It was different.

NOTE Confidence: 0.8919878

00:11:06.322 --> 00:11:09.046 We were assessing influenza vaccination in

NOTE Confidence: 0.8919878

00:11:09.046 --> 00:11:12.338 the in their mothers in the pregnant women,

NOTE Confidence: 0.8919878

00:11:12.340 --> 00:11:14.938 and again the data from this

NOTE Confidence: 0.8919878

00:11:14.938 --> 00:11:16.237 study greatly greatly.

NOTE Confidence: 0.8919878

00:11:16.240 --> 00:11:19.005 It showed that the vaccine given to

NOTE Confidence: 0.8919878

00:11:19.005 --> 00:11:21.710 a mother during pregnancy was highly

NOTE Confidence: 0.8919878

00:11:21.710 --> 00:11:24.110 effective in preventing her infant

NOTE Confidence: 0.8919878

00:11:24.110 --> 00:11:27.612 in the first six months of life from

NOTE Confidence: 0.8919878

00:11:27.612 --> 00:11:30.482 being admitted with lab documented influence,

NOTE Confidence: 0.8919878

00:11:30.482 --> 00:11:32.926 and an these data.

NOTE Confidence: 0.8919878

00:11:32.930 --> 00:11:36.717 Lead to increases in the rate of

NOTE Confidence: 0.8919878

00:11:36.717 --> 00:11:38.957 vaccination during pregnancy and

NOTE Confidence: 0.8919878

00:11:38.957 --> 00:11:42.089 I think have helped move forward  
NOTE Confidence: 0.8919878

00:11:42.089 --> 00:11:43.133 the vaccination.  
NOTE Confidence: 0.8919878

00:11:43.140 --> 00:11:45.666 Program so really just sum up.  
NOTE Confidence: 0.8611988

00:11:48.310 --> 00:11:50.280 After randomized clinical trials are  
NOTE Confidence: 0.8611988

00:11:50.280 --> 00:11:52.250 conducted in Vaccine Start license,  
NOTE Confidence: 0.8611988

00:11:52.250 --> 00:11:54.833 an many other vaccines are going to  
NOTE Confidence: 0.8611988

00:11:54.833 --> 00:11:57.369 continue to come through the market.  
NOTE Confidence: 0.8611988

00:11:57.370 --> 00:11:59.340 There are questions and our  
NOTE Confidence: 0.8611988

00:11:59.340 --> 00:12:00.916 certainties that we have.  
NOTE Confidence: 0.8611988

00:12:00.920 --> 00:12:01.772 At this point.  
NOTE Confidence: 0.8611988

00:12:01.772 --> 00:12:04.961 We can all have them in our heads whatever  
NOTE Confidence: 0.8611988

00:12:04.961 --> 00:12:07.217 questions concerning Covid vaccine.  
NOTE Confidence: 0.8611988

00:12:07.220 --> 00:12:09.590 There are certainly plenty of controversies,  
NOTE Confidence: 0.8611988

00:12:09.590 --> 00:12:12.654 but we know that many other questions will  
NOTE Confidence: 0.8611988

00:12:12.654 --> 00:12:16.340 come up questions that we didn't think about.  
NOTE Confidence: 0.8611988

00:12:16.340 --> 00:12:18.375 An observation ull studies that

NOTE Confidence: 0.8611988

00:12:18.375 --> 00:12:20.410 assess effectiveness of the vaccines,

NOTE Confidence: 0.8611988

00:12:20.410 --> 00:12:22.450 such as case control studies,

NOTE Confidence: 0.8611988

00:12:22.450 --> 00:12:24.634 can be used successfully to address

NOTE Confidence: 0.8611988

00:12:24.634 --> 00:12:26.090 both immediate and long-term

NOTE Confidence: 0.8611988

00:12:26.149 --> 00:12:28.137 questions regarding these vaccines.

NOTE Confidence: 0.8611988

00:12:28.140 --> 00:12:31.040 Thank you very much.