

WEBVTT

1 00:00:00.090 --> 00:00:03.060 <v ->For joining our CMIPS seminar.</v>
2 00:00:03.060 --> 00:00:04.740 It's really a pleasure to have you all
3 00:00:04.740 --> 00:00:06.000 and most importantly,
4 00:00:06.000 --> 00:00:09.450 a pleasure to have Dr. Brian Mittman,
5 00:00:09.450 --> 00:00:11.820 who we've been talking about bringing over here
6 00:00:11.820 --> 00:00:15.600 to CMIPS and Yale for quite some time.
7 00:00:15.600 --> 00:00:18.660 Dr. Mittman is a distinguished
8 00:00:18.660 --> 00:00:22.170 longstanding implementation scientist,
9 00:00:22.170 --> 00:00:24.540 I might even say one of the founders
10 00:00:24.540 --> 00:00:28.083 of implementation science as a formal discipline.
11 00:00:29.700 --> 00:00:33.000 He is a research scientist
12 00:00:33.000 --> 00:00:35.550 in the Department of Research and Evaluation
13 00:00:35.550 --> 00:00:37.350 with additional affiliations
14 00:00:37.350 --> 00:00:40.410 at the US Department of Veteran Affairs,
15 00:00:40.410 --> 00:00:43.800 which is another place where a huge amount
16 00:00:43.800 --> 00:00:47.130 of some of the best implementation science,
17 00:00:47.130 --> 00:00:50.310 thinking and research has emanated over the
years,
18 00:00:50.310 --> 00:00:52.650 the University of Southern California
19 00:00:52.650 --> 00:00:55.620 and the University of California Los Angeles,
20 00:00:55.620 --> 00:00:56.490 where he co-leads
21 00:00:56.490 --> 00:01:01.200 the UCLA Clinical and Translational Science
Institute
22 00:01:01.200 --> 00:01:04.710 Implementation and Improvement Science Ini-
tiative.
23 00:01:04.710 --> 00:01:06.840 And I find that very interesting
24 00:01:06.840 --> 00:01:09.870 in that the implementation and improvement
science
25 00:01:09.870 --> 00:01:11.490 are linked in the same name,
26 00:01:11.490 --> 00:01:15.270 which is also something we at CMIPS are very
interested

27 00:01:15.270 --> 00:01:19.917 in the kind of continuum between implementation science

28 00:01:19.917 --> 00:01:22.500 and improvement science, quality improvement,

29 00:01:22.500 --> 00:01:24.900 and what are the commonalities and differences

30 00:01:24.900 --> 00:01:28.380 and where does one end and the other begin.

31 00:01:28.380 --> 00:01:29.370 So I don't know if that's something

32 00:01:29.370 --> 00:01:32.163 Dr. Mittman is gonna touch upon in his talk today.

33 00:01:33.060 --> 00:01:34.830 He chaired the planning committee

34 00:01:34.830 --> 00:01:37.500 that launched the journal, "Implementation Science,"

35 00:01:37.500 --> 00:01:40.080 which now has a sort of spinoff journal,

36 00:01:40.080 --> 00:01:43.140 I forget its name, but now there's two of them,

37 00:01:43.140 --> 00:01:46.050 and served as co-editor in chief of that journal

38 00:01:46.050 --> 00:01:49.590 from 2005 to 2012.

39 00:01:49.590 --> 00:01:50.820 He was a founding member

40 00:01:50.820 --> 00:01:53.190 of the US Institute of Medicine Forum

41 00:01:53.190 --> 00:01:57.690 on the science of quality improvement and implementation

42 00:01:57.690 --> 00:02:00.390 and chair at the National Institutes of Health

43 00:02:00.390 --> 00:02:02.670 Special Emphasis Panel

44 00:02:02.670 --> 00:02:05.430 on Dissemination and Implementation Research in Health

45 00:02:05.430 --> 00:02:07.940 in 2007 and 2010.

46 00:02:07.940 --> 00:02:10.830 And for those of us in the audience

47 00:02:10.830 --> 00:02:14.160 who are thinking about NIH grants,

48 00:02:14.160 --> 00:02:17.491 what I've very recently learned is now that

49 00:02:17.491 --> 00:02:19.650 the DNI panel, as we call it,

50 00:02:19.650 --> 00:02:21.360 has been renamed.

51 00:02:21.360 --> 00:02:23.190 Maybe Dr. Mittman knows the name,

52 00:02:23.190 --> 00:02:25.290 I don't remember the name,

53 00:02:25.290 --> 00:02:28.443 and maybe even there's multiple ones of it now.

54 00:02:29.280 --> 00:02:30.330 But if you're interested,
55 00:02:30.330 --> 00:02:32.490 maybe write to me later and we can figure that
out
56 00:02:32.490 --> 00:02:33.750 because it's very important
57 00:02:33.750 --> 00:02:37.740 for our implementation dissemination science
applications
58 00:02:37.740 --> 00:02:39.720 to NIH here at Yale.
59 00:02:39.720 --> 00:02:41.040 Dr. Mittman directed
60 00:02:41.040 --> 00:02:44.340 the VA's Quality Enhancement Research Ini-
tiative
61 00:02:44.340 --> 00:02:47.100 from 2002 to 2004.
62 00:02:47.100 --> 00:02:50.130 His research examines innovative approaches
63 00:02:50.130 --> 00:02:52.740 to healthcare delivery and improvement
64 00:02:52.740 --> 00:02:55.830 and efforts to strengthen learning healthcare
systems,
65 00:02:55.830 --> 00:02:59.490 another area in which we're very interested in
CMIPS
66 00:02:59.490 --> 00:03:01.890 and many others at Yale are as well.
67 00:03:01.890 --> 00:03:04.920 So today, Dr. Mittman is gonna talk to us
68 00:03:04.920 --> 00:03:08.040 about Addressing Heterogeneity and Adapt-
ability
69 00:03:08.040 --> 00:03:10.380 and Multi-Component Implementation
70 00:03:10.380 --> 00:03:12.360 and HIV Interventions:
71 00:03:12.360 --> 00:03:14.640 Emerging Frameworks for Research
72 00:03:14.640 --> 00:03:16.380 on Complex Health Interventions.
73 00:03:16.380 --> 00:03:18.510 And actually, I wanted to say one thing
74 00:03:18.510 --> 00:03:20.100 before I turn it over to him.
75 00:03:20.100 --> 00:03:21.940 He also serves as a consultant
76 00:03:23.531 --> 00:03:25.110 for our R3EDI Hub,
77 00:03:25.110 --> 00:03:27.670 which is a technical support hub
78 00:03:28.770 --> 00:03:30.780 that supports seven projects
79 00:03:30.780 --> 00:03:33.870 devoted to ending the AIDS epidemic

80 00:03:33.870 --> 00:03:38.280 under a general coordinating center based in Illinois.

81 00:03:38.280 --> 00:03:40.140 And it's been a pleasure to have Brian

82 00:03:40.140 --> 00:03:42.720 as a part of our R3EDI Hub team as well.

83 00:03:42.720 --> 00:03:44.970 So without any further ado now,

84 00:03:44.970 --> 00:03:47.700 I will turn things over to Dr. Mittman.

85 00:03:47.700 --> 00:03:49.500 <v ->Great, thank you, Donna,</v>

86 00:03:49.500 --> 00:03:50.970 both for the kind introduction

87 00:03:50.970 --> 00:03:55.170 as well as more importantly the opportunity to present

88 00:03:55.170 --> 00:03:58.811 and to meet with some of your colleagues today and tomorrow.

89 00:03:58.811 --> 00:04:01.173 As we were saying before we started,

90 00:04:02.070 --> 00:04:03.540 my hope is to have the opportunity

91 00:04:03.540 --> 00:04:06.720 to join you in person at some point down the line,

92 00:04:06.720 --> 00:04:08.010 but I know we all share that hope

93 00:04:08.010 --> 00:04:10.560 for lots of in-person gatherings.

94 00:04:10.560 --> 00:04:13.350 You touched on several of my favorite topics,

95 00:04:13.350 --> 00:04:16.590 including implementation science, improvement science.

96 00:04:16.590 --> 00:04:19.050 I'll mention that I think very briefly

97 00:04:19.050 --> 00:04:21.450 as well as other topics.

98 00:04:21.450 --> 00:04:24.270 And I'm glad to schedule follow-up talks

99 00:04:24.270 --> 00:04:25.710 to speak about them.

100 00:04:25.710 --> 00:04:28.713 One quick comment on some of your kind remarks.

101 00:04:30.030 --> 00:04:32.340 I always counsel junior colleagues

102 00:04:32.340 --> 00:04:35.610 to pick a very small field that's likely to grow

103 00:04:35.610 --> 00:04:37.290 and get in on the ground floor

104 00:04:37.290 --> 00:04:39.210 because it makes you look important.

105 00:04:39.210 --> 00:04:42.660 That's sort of the big fish, small pond kind of idea.

106 00:04:42.660 --> 00:04:46.200 But also, the fact that I spend much more of my time
107 00:04:46.200 --> 00:04:48.670 advocating and helping to develop and expand
108 00:04:49.730 --> 00:04:53.760 fields that I'm interested in sometimes
109 00:04:53.760 --> 00:04:55.290 rather than actually doing the research,
110 00:04:55.290 --> 00:04:58.020 although I do have a research portfolio.
111 00:04:58.020 --> 00:05:00.210 So implementation science is a field
112 00:05:00.210 --> 00:05:04.710 that I was able to, again, get in on the ground floor
113 00:05:04.710 --> 00:05:06.810 and help to wave the flag,
114 00:05:06.810 --> 00:05:09.990 promote interest and advocate at NIH,
115 00:05:09.990 --> 00:05:12.540 at PCORI and many other places.
116 00:05:12.540 --> 00:05:14.905 And used to spend a lot of time
117 00:05:14.905 --> 00:05:16.920 on the freeways in Los Angeles
118 00:05:16.920 --> 00:05:19.890 traveling between different facilities and institutions
119 00:05:19.890 --> 00:05:21.690 as well as in planes trying to,
120 00:05:21.690 --> 00:05:24.060 again, advocate and promote interest
121 00:05:24.060 --> 00:05:25.890 in implementation science.
122 00:05:25.890 --> 00:05:27.510 But the implementation science field,
123 00:05:27.510 --> 00:05:30.270 in my view, is well established.
124 00:05:30.270 --> 00:05:33.390 There are many of us who are interested
125 00:05:33.390 --> 00:05:35.430 and have active research portfolios.
126 00:05:35.430 --> 00:05:37.470 I don't know that I have that much to offer at this point
127 00:05:37.470 --> 00:05:39.480 as far as new ideas,
128 00:05:39.480 --> 00:05:41.370 but I have a different view about the field
129 00:05:41.370 --> 00:05:43.140 of complex health interventions
130 00:05:43.140 --> 00:05:47.490 where I think there is a need to continue to think hard
131 00:05:47.490 --> 00:05:50.430 and promote some of the newer emerging frameworks
132 00:05:50.430 --> 00:05:53.940 and point out that as researchers are tasked

133 00:05:53.940 --> 00:05:56.390 in studying complex health interventions
134 00:05:56.390 --> 00:05:57.870 is a bit different from our tasks
135 00:05:57.870 --> 00:05:59.970 and studying other kinds of interventions.
136 00:06:02.670 --> 00:06:05.880 I think my most important focus lately in my research
137 00:06:05.880 --> 00:06:08.700 is trying to help, again, advocate
138 00:06:08.700 --> 00:06:12.360 and share information on some of these emerging frameworks
139 00:06:12.360 --> 00:06:15.120 and encourage more development.
140 00:06:15.120 --> 00:06:17.790 One more comment in terms of the truth in advertising.
141 00:06:17.790 --> 00:06:19.900 I actually won't spend much time at all
142 00:06:21.030 --> 00:06:23.460 talking about specific implementation science
143 00:06:23.460 --> 00:06:26.400 or HIV/AIDS intervention examples,
144 00:06:26.400 --> 00:06:28.050 but I think it'll be very clear
145 00:06:28.050 --> 00:06:31.230 as to how and why the comments that I will make
146 00:06:31.230 --> 00:06:35.340 are directly relevant to both of those bodies of activity.
147 00:06:35.340 --> 00:06:36.990 So let me move on
148 00:06:36.990 --> 00:06:41.130 and I try to remember which button allows me to advance.
149 00:06:41.130 --> 00:06:44.217 So let me start with a very high-level question,
150 00:06:44.217 --> 00:06:46.890 and that is ask us all to think a little bit
151 00:06:46.890 --> 00:06:49.650 about what we as researchers do
152 00:06:49.650 --> 00:06:53.970 in addition to producing scientific generalizable knowledge,
153 00:06:53.970 --> 00:06:56.940 what we do to support policy decision makers
154 00:06:56.940 --> 00:06:59.190 and practice decision makers questions.
155 00:06:59.190 --> 00:07:02.520 And much of the research that's conducted in medical schools
156 00:07:02.520 --> 00:07:05.190 and on other health-related institutions
157 00:07:05.190 --> 00:07:06.960 pursues these questions.

158 00:07:06.960 --> 00:07:09.090 Does it work or is it effective?
 159 00:07:09.090 --> 00:07:10.710 The FDA of course would like to know
 160 00:07:10.710 --> 00:07:12.570 if a new drug should be approved.
 161 00:07:12.570 --> 00:07:14.310 CMS and others would like to know
 162 00:07:14.310 --> 00:07:16.800 if it should be funded and promoted.
 163 00:07:16.800 --> 00:07:18.810 Should it even be mandated?
 164 00:07:18.810 --> 00:07:19.800 Within health systems,
 165 00:07:19.800 --> 00:07:21.900 P&T committees have decisions to make
 166 00:07:21.900 --> 00:07:25.680 about inclusion of new drugs in a formulary.
 167 00:07:25.680 --> 00:07:28.980 And frontline practicing clinicians need to know
 168 00:07:28.980 --> 00:07:31.200 whether they should use a new drug
 169 00:07:31.200 --> 00:07:32.640 or another intervention.
 170 00:07:32.640 --> 00:07:36.360 So much of the questions here
 171 00:07:36.360 --> 00:07:39.780 in the guidance that we endeavor to provide
 172 00:07:39.780 --> 00:07:43.440 to our policy and practice decision maker colleagues
 173 00:07:43.440 --> 00:07:45.900 is a set of answers to these questions.
 174 00:07:45.900 --> 00:07:46.740 Does it work?
 175 00:07:46.740 --> 00:07:48.090 Is it effective?
 176 00:07:48.090 --> 00:07:51.360 Or in the case of comparative effectiveness research,
 177 00:07:51.360 --> 00:07:53.820 is intervention A better than B?
 178 00:07:53.820 --> 00:07:57.330 And of course, we focus on outcomes and impacts
 179 00:07:57.330 --> 00:08:00.660 when we try to answer this yes/no question.
 180 00:08:00.660 --> 00:08:02.940 We often have the sample size and the funding
 181 00:08:02.940 --> 00:08:05.880 and the ability to examine heterogeneity
 182 00:08:05.880 --> 00:08:08.520 and subgroup effects and so on,
 183 00:08:08.520 --> 00:08:10.050 and whether contextual factors
 184 00:08:10.050 --> 00:08:12.660 influence the effects and outcomes.

185 00:08:12.660 --> 00:08:17.550 And of course, our gold standard research method of RCTs

186 00:08:17.550 --> 00:08:19.500 and similar experimental methods

187 00:08:19.500 --> 00:08:22.290 where we randomize and measure outcome differences,

188 00:08:22.290 --> 00:08:25.650 that's how we go about conducting this research.

189 00:08:25.650 --> 00:08:28.890 But again, the focus is on impact and outcomes.

190 00:08:28.890 --> 00:08:32.670 Are the outcomes better for those in the intervention group

191 00:08:32.670 --> 00:08:33.960 versus the control group?

192 00:08:33.960 --> 00:08:35.700 And if the answer is yes,

193 00:08:35.700 --> 00:08:37.950 then the intervention is effective,

194 00:08:37.950 --> 00:08:39.450 it's approved by the FDA,

195 00:08:39.450 --> 00:08:42.903 it's promoted, it's reimbursed and it's used.

196 00:08:43.860 --> 00:08:48.210 And there are in fact many examples of magic bullets

197 00:08:48.210 --> 00:08:51.420 or very strong robustly effective drugs

198 00:08:51.420 --> 00:08:54.480 for which we can produce a clear answer to that question.

199 00:08:54.480 --> 00:08:56.700 Yes, this drug is very effective.

200 00:08:56.700 --> 00:08:58.230 Precision medicine, of course,

201 00:08:58.230 --> 00:09:01.980 is leading us down the path for drugs and interventions

202 00:09:01.980 --> 00:09:04.110 for which there isn't a clear answer

203 00:09:04.110 --> 00:09:07.470 where there are high levels of heterogeneity.

204 00:09:07.470 --> 00:09:10.950 And we do need to tailor the interventions

205 00:09:10.950 --> 00:09:13.563 and that's really the theme of this talk.

206 00:09:14.460 --> 00:09:16.010 When we think about complex interventions

207 00:09:16.010 --> 00:09:17.910 or complex health interventions,

208 00:09:17.910 --> 00:09:20.190 and I'll define them more formally in a minute,

209 00:09:20.190 --> 00:09:24.900 but health promotion programs, HIV/AIDS prevention,

210 00:09:24.900 --> 00:09:28.920 treatment programs, implementation strategies,

211 00:09:28.920 --> 00:09:32.100 there are some examples of highly robust,

212 00:09:32.100 --> 00:09:34.290 highly effective complex health interventions

213 00:09:34.290 --> 00:09:38.010 for which we can produce a strong answer.

214 00:09:38.010 --> 00:09:40.770 Yes, this intervention tends to be effective

215 00:09:40.770 --> 00:09:43.059 across multiple settings

216 00:09:43.059 --> 00:09:46.140 and in multiple sets of circumstances.

217 00:09:46.140 --> 00:09:48.780 But by and large, for most complex health interventions,

218 00:09:48.780 --> 00:09:51.390 when we ask the question, is it effective?

219 00:09:51.390 --> 00:09:53.280 The answer that comes out of our research

220 00:09:53.280 --> 00:09:55.470 is sometimes or it depends.

221 00:09:55.470 --> 00:09:56.520 The heterogeneity,

222 00:09:56.520 --> 00:09:59.370 I'll sometimes use the term extreme heterogeneity,

223 00:09:59.370 --> 00:10:04.370 is just so great that the impacts vary considerably

224 00:10:04.530 --> 00:10:07.290 and it's impossible to produce a simple answer,

225 00:10:07.290 --> 00:10:10.830 yes or no, it is effective or it's not effective.

226 00:10:10.830 --> 00:10:14.430 So there is no formal established definition

227 00:10:14.430 --> 00:10:16.650 of complex health interventions at this point,

228 00:10:16.650 --> 00:10:18.960 but here are some of the key features

229 00:10:18.960 --> 00:10:22.380 that tend to be mentioned in most discussions

230 00:10:22.380 --> 00:10:24.090 of complex health interventions.

231 00:10:24.090 --> 00:10:26.070 The fact that there are multiple components

232 00:10:26.070 --> 00:10:28.620 and those components interact.

233 00:10:28.620 --> 00:10:31.590 The intervention, the multi-component intervention

234 00:10:31.590 --> 00:10:34.560 tends to target multiple levels,

235 00:10:34.560 --> 00:10:37.200 not always, but certainly multiple entities.

236 00:10:37.200 --> 00:10:39.450 So we have interventions that target patients

237 00:10:39.450 --> 00:10:42.810 and family caregivers and other peers
238 00:10:42.810 --> 00:10:45.783 as well as clinicians and other health system
staff,
239 00:10:46.620 --> 00:10:48.240 as well as in many cases,
240 00:10:48.240 --> 00:10:51.303 communities and even regulatory levels.
241 00:10:52.380 --> 00:10:55.650 These interventions tend to be highly adapt-
able.
242 00:10:55.650 --> 00:10:56.730 They're not fixed.
243 00:10:56.730 --> 00:10:59.880 So unlike a drug that comes from the factory
244 00:10:59.880 --> 00:11:03.046 in a very consistent chemical formulation
245 00:11:03.046 --> 00:11:06.510 with a high degree of consistency and homo-
geneity,
246 00:11:06.510 --> 00:11:09.000 these interventions adapt.
247 00:11:09.000 --> 00:11:11.940 And that's the case even when we try to
achieve fidelity
248 00:11:11.940 --> 00:11:13.560 to the manualized intervention
249 00:11:13.560 --> 00:11:17.700 and prevent adaptations and modifications,
250 00:11:17.700 --> 00:11:20.610 and that's another theme I'll come back to.
251 00:11:20.610 --> 00:11:22.110 Because of all of these features,
252 00:11:22.110 --> 00:11:25.110 the interventions tend to achieve their effects
253 00:11:25.110 --> 00:11:26.820 through multiple pathways
254 00:11:26.820 --> 00:11:28.620 and they tend to be mediated.
255 00:11:28.620 --> 00:11:31.200 So it's not a drug that has a direct impact
256 00:11:31.200 --> 00:11:32.970 on a physiologic process,
257 00:11:32.970 --> 00:11:34.770 but instead an intervention
258 00:11:34.770 --> 00:11:38.040 that changes attitudes or beliefs,
259 00:11:38.040 --> 00:11:40.170 those changes in attitudes and beliefs
260 00:11:40.170 --> 00:11:42.780 lead to changes in knowledge and intentions.
261 00:11:42.780 --> 00:11:44.610 Those changes in knowledge and intentions
262 00:11:44.610 --> 00:11:46.950 eventually lead to changes in behavior.
263 00:11:46.950 --> 00:11:50.130 But those behaviors are influenced by multiple
factors.

264 00:11:50.130 --> 00:11:52.560 So it's not only the patient's own beliefs
265 00:11:52.560 --> 00:11:54.270 and knowledge and attitudes,
266 00:11:54.270 --> 00:11:57.123 but peer influence, clinician influence,
267 00:11:57.990 --> 00:12:00.330 social influence from key opinion leaders
268 00:12:00.330 --> 00:12:01.380 and a number of others.
269 00:12:01.380 --> 00:12:04.530 So the causal pathways tend to be very complex
270 00:12:04.530 --> 00:12:07.080 and I'll illustrate that in a few minutes.
271 00:12:07.080 --> 00:12:09.390 So when we think about a comparison
272 00:12:09.390 --> 00:12:12.330 between simple interventions like drugs
273 00:12:12.330 --> 00:12:14.070 versus complex interventions,
274 00:12:14.070 --> 00:12:16.387 these are some of the key dimensions
275 00:12:16.387 --> 00:12:18.480 where there are differences.
276 00:12:18.480 --> 00:12:20.820 The difference between a single fixed
277 00:12:20.820 --> 00:12:23.790 and highly stable and homogeneous drug
278 00:12:23.790 --> 00:12:27.750 that targets a single stable physiologic process
279 00:12:27.750 --> 00:12:31.680 to achieve a simple goal such as reducing blood pressure
280 00:12:31.680 --> 00:12:35.670 in patients that are not always homogeneous.
281 00:12:35.670 --> 00:12:37.140 There are differences,
282 00:12:37.140 --> 00:12:40.230 but the argument is that patients,
283 00:12:40.230 --> 00:12:42.360 despite genetic profile differences
284 00:12:42.360 --> 00:12:43.740 and other physiologic,
285 00:12:43.740 --> 00:12:46.980 as well as clearly socioeconomic status
286 00:12:46.980 --> 00:12:51.570 in neighborhood and contextual differences,
287 00:12:51.570 --> 00:12:53.940 those differences tend to be somewhat smaller
288 00:12:53.940 --> 00:12:55.260 than the differences we see
289 00:12:55.260 --> 00:12:57.753 across communities and organizations.
290 00:12:58.620 --> 00:13:00.360 And again, we can argue that point,
291 00:13:00.360 --> 00:13:02.730 but these are the key distinctions
292 00:13:02.730 --> 00:13:05.610 between these two categories of interventions.

293 00:13:05.610 --> 00:13:07.230 And the consequences, of course,
294 00:13:07.230 --> 00:13:09.723 or the implications for research are that,
295 00:13:10.620 --> 00:13:12.930 when we study drugs, oftentimes,
296 00:13:12.930 --> 00:13:15.330 not always, but oftentimes we do see
297 00:13:15.330 --> 00:13:18.180 a relatively high level of homogeneity
298 00:13:18.180 --> 00:13:20.820 with very consistent and often strong,
299 00:13:20.820 --> 00:13:23.040 easily detected main effects.
300 00:13:23.040 --> 00:13:25.170 Whereas again, with complex interventions,
301 00:13:25.170 --> 00:13:26.850 we get the answer along the lines
302 00:13:26.850 --> 00:13:28.950 of it depends or sometimes.
303 00:13:28.950 --> 00:13:32.580 We see lots of complexity, instability and
heterogeneity.
304 00:13:32.580 --> 00:13:33.990 And the average effects,
305 00:13:33.990 --> 00:13:36.693 because of the heterogeneity, tend to be very
weak.
306 00:13:37.680 --> 00:13:40.230 We have many subjects or targets in the in-
tervention
307 00:13:40.230 --> 00:13:43.110 that do very well, others that do very poorly,
308 00:13:43.110 --> 00:13:45.630 but on average, an average effect size estimates
309 00:13:45.630 --> 00:13:47.550 that are close to zero.
310 00:13:47.550 --> 00:13:49.680 One key point, and that is,
311 00:13:49.680 --> 00:13:53.010 this is not a dichotomy, but instead of a
continuum.
312 00:13:53.010 --> 00:13:56.370 There are elements of complexity in all inter-
ventions.
313 00:13:56.370 --> 00:13:58.110 The key question is,
314 00:13:58.110 --> 00:14:00.900 when is an intervention sufficiently complex
315 00:14:00.900 --> 00:14:03.690 that we can't study it through an RCT
316 00:14:03.690 --> 00:14:06.690 with a focus on average effect sizes,
317 00:14:06.690 --> 00:14:09.870 but instead need to use the more complex
kinds of approaches
318 00:14:09.870 --> 00:14:12.420 that I'll talk about over the next several min-
utes.

319 00:14:13.560 --> 00:14:15.510 So getting back to this question,
320 00:14:15.510 --> 00:14:16.767 does it work, is it effective?
321 00:14:16.767 --> 00:14:19.980 And the answer being sometimes or it depends,
322 00:14:19.980 --> 00:14:21.000 that answer, of course,
323 00:14:21.000 --> 00:14:23.160 is not at all useful for decision makers.
324 00:14:23.160 --> 00:14:25.050 So we need to think about a different way
325 00:14:25.050 --> 00:14:27.630 of designing, conducting our studies
326 00:14:27.630 --> 00:14:29.520 and a different type of evidence
327 00:14:29.520 --> 00:14:32.790 or a set of insights and findings
328 00:14:32.790 --> 00:14:35.550 that we need to produce for science,
329 00:14:35.550 --> 00:14:38.250 but also for policy and practice.
330 00:14:38.250 --> 00:14:40.080 So let me back up and illustrate
331 00:14:40.080 --> 00:14:41.700 some of the challenges that we face
332 00:14:41.700 --> 00:14:43.590 when we deal with complex health interventions.
333 00:14:43.590 --> 00:14:47.190 So this is a pattern of results from a hypothetical study
334 00:14:47.190 --> 00:14:50.412 that could be a guideline implementation study.
335 00:14:50.412 --> 00:14:53.310 We are attempting to improve adherence
336 00:14:53.310 --> 00:14:56.250 to evidence-based clinical practice guidelines.
337 00:14:56.250 --> 00:15:00.450 In the blue sample,
338 00:15:00.450 --> 00:15:02.340 the blue bars in this histogram
339 00:15:02.340 --> 00:15:04.860 shows that all of the sites
340 00:15:04.860 --> 00:15:07.500 in the intervention group did very well.
341 00:15:07.500 --> 00:15:09.120 Our intervention managed
342 00:15:09.120 --> 00:15:12.150 to significantly improve rates of adherence
343 00:15:12.150 --> 00:15:14.160 among all the intervention physicians
344 00:15:14.160 --> 00:15:16.380 or clinics or hospitals,
345 00:15:16.380 --> 00:15:19.440 whereas the sites in the yellow or light green
346 00:15:19.440 --> 00:15:22.500 are all scattered around zero.

347 00:15:22.500 --> 00:15:25.920 So on average, we saw no change in adherence levels
348 00:15:25.920 --> 00:15:29.640 among the usual care comparison sites,
349 00:15:29.640 --> 00:15:31.560 although some of course did better and some did worse.
350 00:15:31.560 --> 00:15:34.860 It's just because of random variation.
351 00:15:34.860 --> 00:15:37.440 I don't know that we've ever seen findings
352 00:15:37.440 --> 00:15:39.120 from any implementation study
353 00:15:39.120 --> 00:15:42.330 that resembled this kind of pattern
354 00:15:42.330 --> 00:15:43.830 or anything close to it.
355 00:15:43.830 --> 00:15:46.320 This clearly would be "New England Journal"
356 00:15:46.320 --> 00:15:49.170 or "Lancet" caliber work
357 00:15:49.170 --> 00:15:51.450 if we had a strong finding of this sort,
358 00:15:51.450 --> 00:15:53.910 but that's what we would hope to see with our interventions,
359 00:15:53.910 --> 00:15:56.880 that we would find or design an intervention
360 00:15:56.880 --> 00:16:01.440 and see very robust, very significant effects.
361 00:16:01.440 --> 00:16:03.180 This is what we tend to see more often
362 00:16:03.180 --> 00:16:05.160 when we study complex health interventions.
363 00:16:05.160 --> 00:16:06.840 There's almost complete overlap
364 00:16:06.840 --> 00:16:10.950 between the blue and the light green yellow sites.
365 00:16:10.950 --> 00:16:13.050 If you are an intervention site,
366 00:16:13.050 --> 00:16:16.290 you are almost as likely to show
367 00:16:16.290 --> 00:16:17.640 reduced rates of adherence
368 00:16:17.640 --> 00:16:19.140 as you are increases.
369 00:16:19.140 --> 00:16:21.960 And similarly, the usual care sites,
370 00:16:21.960 --> 00:16:24.450 many of them did show rates of improvement
371 00:16:24.450 --> 00:16:27.750 that are comparable to those in the intervention site.
372 00:16:27.750 --> 00:16:30.303 So when you have a pattern of results like this,
373 00:16:31.620 --> 00:16:34.110 you can't say to decision makers,

374 00:16:34.110 --> 00:16:35.760 my complex health intervention,
 375 00:16:35.760 --> 00:16:38.340 my HIV/AIDS prevention program
 376 00:16:38.340 --> 00:16:40.350 or my implementation strategy
 377 00:16:40.350 --> 00:16:43.320 or quality improvement program is highly
 effective,
 378 00:16:43.320 --> 00:16:44.793 I would advise you to use it.
 379 00:16:45.634 --> 00:16:46.890 As a decision maker,
 380 00:16:46.890 --> 00:16:48.510 if I know I'm almost likely
 381 00:16:48.510 --> 00:16:50.370 to end up spending a lot of money
 382 00:16:50.370 --> 00:16:53.520 and staff time and disruption
 383 00:16:53.520 --> 00:16:56.490 and end up with decreased performance,
 384 00:16:56.490 --> 00:16:58.920 obviously, I'm not going to be interested in
 this program.
 385 00:16:58.920 --> 00:17:01.740 So what is our goal then as a researcher?
 386 00:17:01.740 --> 00:17:03.180 Our goal, of course, is to understand
 387 00:17:03.180 --> 00:17:06.120 who ended up on the right hand side of this
 distribution,
 388 00:17:06.120 --> 00:17:08.520 what the factors were that led to those im-
 provements
 389 00:17:08.520 --> 00:17:11.247 for both intervention as well as control sites,
 390 00:17:11.247 --> 00:17:14.460 and what can we do to counsel decision makers
 391 00:17:14.460 --> 00:17:17.550 to allow them to end up on the right hand
 side
 392 00:17:17.550 --> 00:17:20.433 rather than the left hand side of the distribu-
 tion.
 393 00:17:21.570 --> 00:17:24.870 So when we think about finding
 394 00:17:24.870 --> 00:17:27.600 or designing developing complex health inter-
 ventions
 395 00:17:27.600 --> 00:17:28.623 that are effective,
 396 00:17:29.580 --> 00:17:31.410 one position that we could take
 397 00:17:31.410 --> 00:17:34.680 is our goal as researchers is to develop
 398 00:17:34.680 --> 00:17:37.350 and generate the evidence showing
 399 00:17:37.350 --> 00:17:41.220 that our interventions are highly effective,

400 00:17:41.220 --> 00:17:44.490 but that assumes that those interventions exist.

401 00:17:44.490 --> 00:17:46.623 Hang on one second, I will be right back.

402 00:17:53.100 --> 00:17:54.150 <v ->While he's out,</v>

403 00:17:54.150 --> 00:17:57.420 I can say if people have questions or comments,

404 00:17:57.420 --> 00:17:59.880 why don't you put them in the chat as we go along

405 00:17:59.880 --> 00:18:02.760 and then at the end of Brian's talk,

406 00:18:02.760 --> 00:18:06.180 I'll pose some of the questions and comments to him.

407 00:18:06.180 --> 00:18:07.860 Go ahead, Brian. <v ->Thank you.</v>

408 00:18:07.860 --> 00:18:09.420 Yeah, so my apologies.

409 00:18:09.420 --> 00:18:10.290 For those who joined earlier,

410 00:18:10.290 --> 00:18:12.640 we were talking about the renovations under-way.

411 00:18:13.800 --> 00:18:15.330 My wife was stuck outside

412 00:18:15.330 --> 00:18:17.370 because I forgot to open the door

413 00:18:17.370 --> 00:18:19.980 for the second pathway into the kitchen

414 00:18:19.980 --> 00:18:24.980 because the main path is covered with paint paraphernalia.

415 00:18:25.140 --> 00:18:28.860 So again, because complex health interventions

416 00:18:28.860 --> 00:18:30.240 tend not to be robust

417 00:18:30.240 --> 00:18:31.860 and we tend not to have the ability

418 00:18:31.860 --> 00:18:35.680 to find or develop the needle in the haystack

419 00:18:37.230 --> 00:18:38.700 or they don't exist at all,

420 00:18:38.700 --> 00:18:40.700 that a robust complex health intervention

421 00:18:40.700 --> 00:18:42.273 is a mythical beast,

422 00:18:43.650 --> 00:18:46.470 we need to take a different strategy

423 00:18:46.470 --> 00:18:47.490 and a different approach

424 00:18:47.490 --> 00:18:49.920 in designing and conducting research

425 00:18:49.920 --> 00:18:53.580 and supporting health decision makers.

426 00:18:53.580 --> 00:18:55.770 So rather than pursuing questions

427 00:18:55.770 --> 00:18:58.020 such as is it effective or does it work
 428 00:18:58.020 --> 00:19:00.060 or which is more effective,
 429 00:19:00.060 --> 00:19:02.490 we need to be thinking about deriving
 430 00:19:02.490 --> 00:19:05.760 and developing insights and guidance for practice,
 431 00:19:05.760 --> 00:19:08.730 such as how does it work, why does it work?
 432 00:19:08.730 --> 00:19:09.840 Where, when and for whom,
 433 00:19:09.840 --> 00:19:12.960 the realistic evaluation key questions,
 434 00:19:12.960 --> 00:19:15.360 but also how can we enhance its effectiveness?
 435 00:19:15.360 --> 00:19:18.393 Which again gets back to this issue of adaptability.
 436 00:19:19.350 --> 00:19:21.210 We'd have very few degrees of freedom
 437 00:19:21.210 --> 00:19:24.060 to enhance the effectiveness of a drug.
 438 00:19:24.060 --> 00:19:25.920 We can obviously titrate the dose
 439 00:19:25.920 --> 00:19:29.550 and we can prescribe supportive interventions,
 440 00:19:29.550 --> 00:19:32.493 but we can't modify the chemical formulation of the drug.
 441 00:19:33.390 --> 00:19:36.600 We can modify the so-called chemical formulation
 442 00:19:36.600 --> 00:19:37.950 of a complex health intervention.
 443 00:19:37.950 --> 00:19:40.920 So our goal and our task as researchers
 444 00:19:40.920 --> 00:19:43.983 is to guide that tailoring and that adaptation.
 445 00:19:45.030 --> 00:19:49.830 So we should strive to support decision makers
 446 00:19:49.830 --> 00:19:52.110 as they try to answer these questions.
 447 00:19:52.110 --> 00:19:55.920 How do I choose an appropriate complex health intervention?
 448 00:19:55.920 --> 00:19:58.380 How do I implement or deploy that program
 449 00:19:58.380 --> 00:20:01.890 and tailor it to increase its effectiveness?
 450 00:20:01.890 --> 00:20:04.980 But also how do I modify or manage the organization?
 451 00:20:04.980 --> 00:20:08.610 Oftentimes just as we can improve health outcomes
 452 00:20:08.610 --> 00:20:11.670 by changing diet and exercise

453 00:20:11.670 --> 00:20:15.570 and changing the social surroundings of our patients,

454 00:20:15.570 --> 00:20:18.330 we can certainly improve outcomes

455 00:20:18.330 --> 00:20:19.950 for complex health interventions

456 00:20:19.950 --> 00:20:22.110 by modifying the organization.

457 00:20:22.110 --> 00:20:24.930 So again, another task for researchers.

458 00:20:24.930 --> 00:20:26.790 But back to the key questions.

459 00:20:26.790 --> 00:20:29.880 We need to understand and develop insights

460 00:20:29.880 --> 00:20:33.090 and provide guidance regarding how, when, why

461 00:20:33.090 --> 00:20:35.070 and where do these interventions work

462 00:20:35.070 --> 00:20:38.013 and how can we modify them to make them work.

463 00:20:39.210 --> 00:20:44.210 So the focus here instead of on impact in simply asking,

464 00:20:44.370 --> 00:20:46.110 does intervention A produce

465 00:20:46.110 --> 00:20:48.990 a greater impact or outcome than intervention B,

466 00:20:48.990 --> 00:20:52.170 we need to instead focus on the black box.

467 00:20:52.170 --> 00:20:55.080 We need to understand the mediators and the moderators,

468 00:20:55.080 --> 00:20:56.910 the mechanisms of effect.

469 00:20:56.910 --> 00:20:59.700 We need to explicitly study adaptation

470 00:20:59.700 --> 00:21:02.190 and we need to study context

471 00:21:02.190 --> 00:21:03.540 and how to manage context.

472 00:21:03.540 --> 00:21:07.110 So again, another point related to the key theme

473 00:21:07.110 --> 00:21:09.870 of different types of research,

474 00:21:09.870 --> 00:21:11.670 not a focus on measuring impact,

475 00:21:11.670 --> 00:21:16.503 but instead to focus on understanding and studying process.

476 00:21:17.610 --> 00:21:22.410 So again, rather than thinking about evidence-based practice

477 00:21:22.410 --> 00:21:26.910 and generating or producing an estimate of effect sizes,

478 00:21:26.910 --> 00:21:30.030 to me, research on complex health interventions

479 00:21:30.030 --> 00:21:31.860 should focus on deriving

480 00:21:31.860 --> 00:21:34.470 or developing insights and guidance.

481 00:21:34.470 --> 00:21:37.830 So it's insights and guidance rather than evidence

482 00:21:37.830 --> 00:21:40.180 in the way that we typically think of evidence.

483 00:21:41.730 --> 00:21:44.280 So, getting back to the features

484 00:21:44.280 --> 00:21:46.650 or the characteristics of complex health interventions

485 00:21:46.650 --> 00:21:50.640 and why they tend to have such weak average effect sizes

486 00:21:50.640 --> 00:21:52.950 and such extreme heterogeneity,

487 00:21:52.950 --> 00:21:55.159 we know as I argued that,

488 00:21:55.159 --> 00:21:57.000 or we believe or I would assert

489 00:21:57.000 --> 00:21:59.280 that the intervention targets and settings

490 00:21:59.280 --> 00:22:01.290 are much more heterogeneous.

491 00:22:01.290 --> 00:22:04.440 Communities differ, individuals differ,

492 00:22:04.440 --> 00:22:06.860 and the same behavioral approach that we use

493 00:22:06.860 --> 00:22:10.560 or the same implementation strategy for one hospital

494 00:22:10.560 --> 00:22:13.320 is not likely to be effective

495 00:22:13.320 --> 00:22:16.080 or to work in the same way as in another hospital.

496 00:22:16.080 --> 00:22:19.860 Differences in hospital leadership and culture

497 00:22:19.860 --> 00:22:23.130 and staffing patterns and resources and so on

498 00:22:23.130 --> 00:22:27.210 all mediate and moderate the effects of the intervention.

499 00:22:27.210 --> 00:22:28.860 If we think about health psychology

500 00:22:28.860 --> 00:22:30.603 and patient behavior change,

501 00:22:30.603 --> 00:22:32.550 and one of the topics that we're studying

502 00:22:32.550 --> 00:22:35.970 in Kaiser Southern California, which is HPV vaccination,

503 00:22:35.970 --> 00:22:38.100 we know that clinician brief interventions

504 00:22:38.100 --> 00:22:41.610 are likely to be effective for some patients and parents

505 00:22:41.610 --> 00:22:44.340 who retain respect for their physicians

506 00:22:44.340 --> 00:22:46.710 and will follow their advice.

507 00:22:46.710 --> 00:22:48.000 But for other patients,

508 00:22:48.000 --> 00:22:49.620 that physician brief intervention

509 00:22:49.620 --> 00:22:51.750 can in fact be counterproductive

510 00:22:51.750 --> 00:22:53.430 because it reinforces a patient's

511 00:22:53.430 --> 00:22:55.440 or parent's op priori belief

512 00:22:55.440 --> 00:22:57.990 that these vaccines are poison

513 00:22:57.990 --> 00:23:01.170 and my physician is sort of an agent

514 00:23:01.170 --> 00:23:05.100 of the drug company trying to enhance profits.

515 00:23:05.100 --> 00:23:06.990 So again, lots of heterogeneity

516 00:23:06.990 --> 00:23:09.450 in the targets in the settings.

517 00:23:09.450 --> 00:23:11.790 We also know that the underlying pathologies,

518 00:23:11.790 --> 00:23:13.920 their etiology, their root causes differ.

519 00:23:13.920 --> 00:23:16.683 And again, the vaccine example is a good one.

520 00:23:16.683 --> 00:23:20.130 When we're dealing with low vaccination rates

521 00:23:20.130 --> 00:23:22.710 in a set of clinics or hospitals

522 00:23:22.710 --> 00:23:25.860 where patients tend to be respectful

523 00:23:25.860 --> 00:23:28.560 and responsive to brief interventions,

524 00:23:28.560 --> 00:23:33.090 we can suspect that the reason for low rates of adherence

525 00:23:33.090 --> 00:23:35.250 don't relate to patient resistance,

526 00:23:35.250 --> 00:23:38.370 but instead, physicians and staff or the systems

527 00:23:38.370 --> 00:23:41.730 not necessarily optimizing their activities.

528 00:23:41.730 --> 00:23:45.720 Whereas in other parts of Kaiser Southern California,

529 00:23:45.720 --> 00:23:48.060 we know that the hospitals and the clinics
 530 00:23:48.060 --> 00:23:49.800 and the organizational policies
 531 00:23:49.800 --> 00:23:52.560 and the clinicians are doing everything in their
 power
 532 00:23:52.560 --> 00:23:55.020 to improve vaccination rates.
 533 00:23:55.020 --> 00:23:56.940 The reason for low vaccination rates
 534 00:23:56.940 --> 00:23:59.370 is patient and parent resistance
 535 00:23:59.370 --> 00:24:02.100 that is tied to their own beliefs.
 536 00:24:02.100 --> 00:24:03.737 So understanding differences
 537 00:24:03.737 --> 00:24:08.737 in the root causes of low adherence rates
 538 00:24:08.880 --> 00:24:10.585 or quality or outcomes
 539 00:24:10.585 --> 00:24:12.870 or poor patient behavior
 540 00:24:12.870 --> 00:24:15.360 and recognizing the heterogeneity,
 541 00:24:15.360 --> 00:24:16.377 again, is important.
 542 00:24:16.377 --> 00:24:17.880 And that's one of the reasons
 543 00:24:17.880 --> 00:24:21.870 for the highly variable effects of interventions
 544 00:24:21.870 --> 00:24:23.520 because they sometimes address
 545 00:24:23.520 --> 00:24:25.170 the root causes and solve the problem,
 546 00:24:25.170 --> 00:24:28.260 but other times the same intervention does
 not.
 547 00:24:28.260 --> 00:24:29.970 And then finally, as I've said,
 548 00:24:29.970 --> 00:24:32.880 the interventions themselves tend to be highly
 variable
 549 00:24:32.880 --> 00:24:34.530 and irrespective of our efforts
 550 00:24:34.530 --> 00:24:37.750 to achieve adherence to a manualized inter-
 vention
 551 00:24:38.640 --> 00:24:41.070 and achieve high rates of fidelity,
 552 00:24:41.070 --> 00:24:44.520 we know that we won't always see that inter-
 vention
 553 00:24:44.520 --> 00:24:46.683 be delivered the same way across sites.
 554 00:24:47.670 --> 00:24:49.260 There's drift over time,
 555 00:24:49.260 --> 00:24:50.760 there are local adaptations,

556 00:24:50.760 --> 00:24:52.110 but again, more importantly,
557 00:24:52.110 --> 00:24:55.230 we shouldn't try to achieve fidelity
558 00:24:55.230 --> 00:24:56.910 because one version of intervention
559 00:24:56.910 --> 00:25:00.150 that does match local circumstances in one
setting
560 00:25:00.150 --> 00:25:01.830 is not likely to be effective
561 00:25:01.830 --> 00:25:04.260 and match local circumstances elsewhere.
562 00:25:04.260 --> 00:25:08.130 So the adaptability of interventions,
563 00:25:08.130 --> 00:25:10.530 their heterogeneity across place,
564 00:25:10.530 --> 00:25:13.470 but also across time is a challenge.
565 00:25:13.470 --> 00:25:14.970 But we should view it as a strength
566 00:25:14.970 --> 00:25:18.930 that we need to embrace and use to our ad-
vantage.
567 00:25:18.930 --> 00:25:22.290 So some of you who are in my generation or
have kids
568 00:25:22.290 --> 00:25:24.060 because I believe this game is still sold,
569 00:25:24.060 --> 00:25:26.860 will recognize the image in the upper right
hand corner.
570 00:25:27.720 --> 00:25:29.040 And this is the way that I often think
571 00:25:29.040 --> 00:25:31.320 about complex health interventions,
572 00:25:31.320 --> 00:25:34.260 that if we were to watch the very beginning
573 00:25:34.260 --> 00:25:36.270 of the mouse trap contraption
574 00:25:36.270 --> 00:25:37.980 where we drop the marble
575 00:25:37.980 --> 00:25:41.100 and then focus only on the very end
576 00:25:41.100 --> 00:25:43.203 and whether the trap falls or not,
577 00:25:44.040 --> 00:25:45.840 sometimes it will, sometimes it won't.
578 00:25:45.840 --> 00:25:48.570 But that set of empirical observations
579 00:25:48.570 --> 00:25:49.980 doesn't help us at all
580 00:25:49.980 --> 00:25:53.790 in improving the performance of this mouse
trap.
581 00:25:53.790 --> 00:25:57.120 We need to follow every step in the causal
chain
582 00:25:57.120 --> 00:25:59.310 and understand which part of the contraption

583 00:25:59.310 --> 00:26:00.720 was not built correctly
 584 00:26:00.720 --> 00:26:02.970 or where things are going wrong.
 585 00:26:02.970 --> 00:26:05.700 So again, the question is not,
 586 00:26:05.700 --> 00:26:07.920 is it effective, but how does it work?
 587 00:26:07.920 --> 00:26:10.770 And we need to shine our spotlight,
 588 00:26:10.770 --> 00:26:13.290 our flashlight and our research attention
 589 00:26:13.290 --> 00:26:15.510 in terms of data collection analysis
 590 00:26:15.510 --> 00:26:18.241 on the mechanisms of effect.
 591 00:26:18.241 --> 00:26:20.940 As I've said, we need to,
 592 00:26:20.940 --> 00:26:24.630 rather than try to ignore adaptations or sup-
 press them,
 593 00:26:24.630 --> 00:26:26.010 we need to embrace them.
 594 00:26:26.010 --> 00:26:29.580 We need to study and guide those adaptations.
 595 00:26:29.580 --> 00:26:31.740 The concept of a manualized intervention,
 596 00:26:31.740 --> 00:26:33.660 I think for a complex health intervention
 597 00:26:33.660 --> 00:26:35.490 requires rethinking.
 598 00:26:35.490 --> 00:26:37.440 My favorite example here is a story
 599 00:26:37.440 --> 00:26:39.330 that I believe is accurate
 600 00:26:39.330 --> 00:26:41.970 of one of the sites
 601 00:26:41.970 --> 00:26:46.740 in one of the patient self-management studies
 602 00:26:46.740 --> 00:26:51.000 where the patient self-management program
 603 00:26:51.000 --> 00:26:54.540 had a highly detailed manualized intervention,
 604 00:26:54.540 --> 00:26:57.540 including a very clear script
 605 00:26:57.540 --> 00:27:02.160 for the leader of a patient self-management
 education group
 606 00:27:02.160 --> 00:27:06.480 to use in educating members of the group.
 607 00:27:06.480 --> 00:27:09.000 And the story is that members of the study
 team
 608 00:27:09.000 --> 00:27:10.800 were observing a leader
 609 00:27:10.800 --> 00:27:13.560 deliver the patient self-management program
 610 00:27:13.560 --> 00:27:16.122 in an African American church in Baltimore.

611 00:27:16.122 --> 00:27:21.090 And the leader of that program was not following the script.

612 00:27:21.090 --> 00:27:24.540 She was making up the comments

613 00:27:24.540 --> 00:27:27.180 and the educational content as she went along

614 00:27:27.180 --> 00:27:29.580 and the research assistants who were observing

615 00:27:29.580 --> 00:27:30.930 came up to her afterwards

616 00:27:30.930 --> 00:27:33.900 and congratulated her on a successful session,

617 00:27:33.900 --> 00:27:34.733 but said,

618 00:27:34.733 --> 00:27:37.590 "I noticed that you were deviating from the script.

619 00:27:37.590 --> 00:27:38.580 Why is that?

620 00:27:38.580 --> 00:27:41.340 Don't you know that this is an evidence-based intervention?

621 00:27:41.340 --> 00:27:42.870 And if you follow the manual

622 00:27:42.870 --> 00:27:44.730 and follow the script to the letter,

623 00:27:44.730 --> 00:27:47.070 you're guaranteed to see positive outcomes,

624 00:27:47.070 --> 00:27:48.990 but if you deviate from it,

625 00:27:48.990 --> 00:27:51.720 we don't know what sort of outcomes you will observe."

626 00:27:51.720 --> 00:27:53.797 And the leader of the church group said,

627 00:27:53.797 --> 00:27:57.150 "Well, as you know, your manual and your script

628 00:27:57.150 --> 00:27:59.400 was written in Stanford English.

629 00:27:59.400 --> 00:28:00.990 We don't speak Stanford English here.

630 00:28:00.990 --> 00:28:03.690 So I was using language and concepts

631 00:28:03.690 --> 00:28:04.950 and ideas and examples

632 00:28:04.950 --> 00:28:09.150 that I felt were more suitable for my local circumstances.

633 00:28:09.150 --> 00:28:11.730 So that's a somewhat extreme example, of course,

634 00:28:11.730 --> 00:28:14.700 but it does point out that a manualized intervention

635 00:28:14.700 --> 00:28:17.900 typically was developed from a study

636 00:28:17.900 --> 00:28:21.090 at a specific point in time in a specific region,
637 00:28:21.090 --> 00:28:23.280 in a specific set of settings.
638 00:28:23.280 --> 00:28:26.220 And the details of that intervention
639 00:28:26.220 --> 00:28:31.220 might in fact be highly optimal for that particular setting,
640 00:28:31.350 --> 00:28:33.600 but are not likely to be feasible
641 00:28:33.600 --> 00:28:36.810 and certainly not optimal for other settings.
642 00:28:36.810 --> 00:28:38.730 So again, we have to rethink the concept
643 00:28:38.730 --> 00:28:40.440 of manualized interventions.
644 00:28:40.440 --> 00:28:44.100 Similarly, we have to rethink the concept of core components
645 00:28:44.100 --> 00:28:45.360 and the term, core components,
646 00:28:45.360 --> 00:28:47.550 that concept is used relatively broadly,
647 00:28:47.550 --> 00:28:52.140 but oftentimes it talks about the intervention activities,
648 00:28:52.140 --> 00:28:55.680 the scripts, the tools, the protocols, the procedures.
649 00:28:55.680 --> 00:28:59.310 And again, those tend to be highly idiosyncratic
650 00:28:59.310 --> 00:29:01.590 and often optimized and developed
651 00:29:01.590 --> 00:29:06.590 by and for a specific set of settings
652 00:29:06.690 --> 00:29:08.370 in target audiences.
653 00:29:08.370 --> 00:29:12.690 So the alternative to the concept of core components
654 00:29:12.690 --> 00:29:15.720 and that way of thinking about complex health interventions
655 00:29:15.720 --> 00:29:19.920 is to specify a set of core functions in a menu of forms.
656 00:29:19.920 --> 00:29:22.500 And I'll talk through that in a few minutes.
657 00:29:22.500 --> 00:29:25.080 But let me just briefly point out
658 00:29:25.080 --> 00:29:27.690 that in the implementation field,
659 00:29:27.690 --> 00:29:30.870 and again using guideline adherence as an example,
660 00:29:30.870 --> 00:29:33.330 as I said, we often have very complex,

661 00:29:33.330 --> 00:29:35.730 multi-path, mediated

662 00:29:35.730 --> 00:29:40.290 and highly moderated sorts of causal pathways.

663 00:29:40.290 --> 00:29:44.580 And a typical multi-component guideline adherence program

664 00:29:44.580 --> 00:29:47.070 targeting physicians has to worry

665 00:29:47.070 --> 00:29:48.930 about the physician's attitudes and norms

666 00:29:48.930 --> 00:29:50.340 and try to address them

667 00:29:50.340 --> 00:29:51.870 as well as their knowledge and skill,

668 00:29:51.870 --> 00:29:54.270 as well as their motivation of their activation.

669 00:29:55.200 --> 00:29:58.830 And many of these are influenced

670 00:29:58.830 --> 00:30:02.670 by, again, multiple mediated pathways,

671 00:30:02.670 --> 00:30:06.030 but also some of those causal effects are highly moderated.

672 00:30:06.030 --> 00:30:10.800 We know that a financial incentive to follow the guideline

673 00:30:10.800 --> 00:30:13.500 that consists of a \$20,000 bonus

674 00:30:13.500 --> 00:30:16.200 is likely to be highly effective

675 00:30:16.200 --> 00:30:19.050 for a junior family physician

676 00:30:19.050 --> 00:30:22.440 with an income in the \$150,000 range.

677 00:30:22.440 --> 00:30:24.600 But for the senior surgeon

678 00:30:24.600 --> 00:30:28.410 with a multimillion dollar income

679 00:30:28.410 --> 00:30:32.760 who knows how to practice and doesn't need the guidelines,

680 00:30:32.760 --> 00:30:35.250 that bonus is not likely to have much effect.

681 00:30:35.250 --> 00:30:39.090 So again, highly heterogeneous effects

682 00:30:39.090 --> 00:30:43.053 in complex causal pathways that we need to understand.

683 00:30:44.070 --> 00:30:46.290 So let me again, as an aside,

684 00:30:46.290 --> 00:30:49.140 briefly present the PCORI method standards

685 00:30:49.140 --> 00:30:51.420 for complex health interventions.

686 00:30:51.420 --> 00:30:52.950 I actually won't talk about these,

687 00:30:52.950 --> 00:30:57.480 but there is both a PCORI methodology report

688 00:30:57.480 --> 00:30:59.010 that provides some supportive detail

689 00:30:59.010 --> 00:31:02.010 as well as an article that came out in JGIM

690 00:31:02.010 --> 00:31:03.000 several months ago

691 00:31:03.000 --> 00:31:06.150 that discusses each of these in more detail.

692 00:31:06.150 --> 00:31:07.860 But it's the issue of core functions

693 00:31:07.860 --> 00:31:11.670 that I wanted to talk about for a bit.

694 00:31:11.670 --> 00:31:13.230 And again, the underlying motivation

695 00:31:13.230 --> 00:31:16.860 is the fact that complex interventions can be adapted.

696 00:31:16.860 --> 00:31:20.100 They will be adaptive irrespective of our efforts

697 00:31:20.100 --> 00:31:21.510 to achieve fidelity,

698 00:31:21.510 --> 00:31:24.540 but more importantly they should be adapted.

699 00:31:24.540 --> 00:31:27.060 Now I'll often say adaptation happens.

700 00:31:27.060 --> 00:31:30.090 We should embrace it and study it and ultimately guide it.

701 00:31:30.090 --> 00:31:33.300 We should not be trying to ignore or suppress it.

702 00:31:33.300 --> 00:31:36.660 So the concepts of core functions and forms

703 00:31:36.660 --> 00:31:38.250 were introduced by Penelope Hall

704 00:31:38.250 --> 00:31:40.830 a good 15 years ago

705 00:31:40.830 --> 00:31:43.440 without a whole lot of attention

706 00:31:43.440 --> 00:31:46.350 and follow-up activity in the intervening years

707 00:31:46.350 --> 00:31:47.970 until relatively recently

708 00:31:47.970 --> 00:31:51.180 where researchers who study complex health interventions,

709 00:31:51.180 --> 00:31:52.860 implementation strategies,

710 00:31:52.860 --> 00:31:55.200 health promotion programs began to realize

711 00:31:55.200 --> 00:31:57.513 that they have a lot of relevance and value.

712 00:31:58.440 --> 00:32:03.030 And this is a short list of publications.

713 00:32:03.030 --> 00:32:04.470 There actually are many more

714 00:32:04.470 --> 00:32:06.630 just within the last year or two

715 00:32:06.630 --> 00:32:09.693 that have applied concepts of core functions and forms.

716 00:32:10.650 --> 00:32:15.650 So forms are the specific detailed activities.

717 00:32:15.780 --> 00:32:18.510 So if we think about physical activity as a broad category,

718 00:32:18.510 --> 00:32:19.680 walking, running, swimming

719 00:32:19.680 --> 00:32:23.040 are all examples of physical activity.

720 00:32:23.040 --> 00:32:27.360 And the argument is that our manualized intervention

721 00:32:27.360 --> 00:32:30.660 should not specify 20 minutes of walking,

722 00:32:30.660 --> 00:32:33.830 but instead should specify physical activity.

723 00:32:33.830 --> 00:32:35.700 In the case of patient education,

724 00:32:35.700 --> 00:32:37.710 the underlying core function again

725 00:32:37.710 --> 00:32:40.230 is to educate patients and their parents.

726 00:32:40.230 --> 00:32:43.830 The different forms we can use are listed here.

727 00:32:43.830 --> 00:32:45.690 And again, selecting a form

728 00:32:45.690 --> 00:32:50.130 that matches the particular features of the target audience

729 00:32:50.130 --> 00:32:52.560 is important in increasing fidelity.

730 00:32:52.560 --> 00:32:55.200 So we should not be providing a script,

731 00:32:55.200 --> 00:32:57.270 a strict script,

732 00:32:57.270 --> 00:33:00.780 but instead laying out the goals of the education

733 00:33:00.780 --> 00:33:03.240 and providing a menu of different strategies

734 00:33:03.240 --> 00:33:07.683 for achieving those goals through different kinds of forms.

735 00:33:09.360 --> 00:33:12.030 So I won't spend a lot of time on this,

736 00:33:12.030 --> 00:33:13.530 but encourage those of you interested

737 00:33:13.530 --> 00:33:15.180 to both look at the articles

738 00:33:15.180 --> 00:33:17.100 as well as these slides in more detail.

739 00:33:17.100 --> 00:33:20.910 But the general approach that we advocate

740 00:33:20.910 --> 00:33:25.590 is to think about, again, a set of core functions

741 00:33:25.590 --> 00:33:29.160 and think through all the different kinds of forms

742 00:33:29.160 --> 00:33:30.660 that might be available

743 00:33:30.660 --> 00:33:33.630 to operationalize those core functions.

744 00:33:33.630 --> 00:33:36.330 And then, also think about how to decide

745 00:33:36.330 --> 00:33:38.370 which form to select,

746 00:33:38.370 --> 00:33:40.080 and that's the purpose of research.

747 00:33:40.080 --> 00:33:41.910 In addition to identifying

748 00:33:41.910 --> 00:33:43.890 and describing the core functions,

749 00:33:43.890 --> 00:33:47.700 also to provide guidance for the local tailoring,

750 00:33:47.700 --> 00:33:51.723 which item from the menu is optimal for particular setting.

751 00:33:52.950 --> 00:33:55.050 Now we know that if we think only

752 00:33:55.050 --> 00:33:57.870 about core components or activities,

753 00:33:57.870 --> 00:34:01.560 we often can go down the route

754 00:34:01.560 --> 00:34:04.020 of modifying those forms or components

755 00:34:04.020 --> 00:34:06.450 in what appears to be a very minor way,

756 00:34:06.450 --> 00:34:09.300 but in fact completely eliminate

757 00:34:09.300 --> 00:34:11.070 achievement in one of the core functions.

758 00:34:11.070 --> 00:34:15.780 So if you think about drug detailing or academic detailing,

759 00:34:15.780 --> 00:34:18.450 that academic detailing interaction

760 00:34:18.450 --> 00:34:21.930 conveys information and education and knowledge,

761 00:34:21.930 --> 00:34:23.730 but also conveys professional norms.

762 00:34:23.730 --> 00:34:26.040 So that's an activity or a form

763 00:34:26.040 --> 00:34:30.210 that actually operationalizes two core functions.

764 00:34:30.210 --> 00:34:32.190 Audit and feedback is another example.

765 00:34:32.190 --> 00:34:34.950 Audit and feedback conveys information,

766 00:34:34.950 --> 00:34:37.350 but it also conveys professional norms

767 00:34:37.350 --> 00:34:39.330 and leadership expectations.

768 00:34:39.330 --> 00:34:43.170 And if you're focused only on the information function,

769 00:34:43.170 --> 00:34:44.610 you could easily decide,

770 00:34:44.610 --> 00:34:47.580 rather than convey the audit and feedback information

771 00:34:47.580 --> 00:34:50.070 in a departmental meeting,

772 00:34:50.070 --> 00:34:52.830 to convey that information via memo.

773 00:34:52.830 --> 00:34:56.970 If you do that, you weaken the professional norm function.

774 00:34:56.970 --> 00:34:59.460 One of the advantages of an audit and feedback session

775 00:34:59.460 --> 00:35:01.890 that's conducted in the departmental meeting

776 00:35:01.890 --> 00:35:03.570 is the physicians have an opportunity

777 00:35:03.570 --> 00:35:05.970 to talk about the guideline,

778 00:35:05.970 --> 00:35:08.040 the performance metrics or benchmarks

779 00:35:08.040 --> 00:35:09.963 and the variation of performance,

780 00:35:10.980 --> 00:35:13.140 and ideally help convince each other

781 00:35:13.140 --> 00:35:15.420 that maybe there is room for improvement.

782 00:35:15.420 --> 00:35:19.380 Whereas if you receive your own performance via a memo,

783 00:35:19.380 --> 00:35:23.010 you're not likely to be influenced in quite the same way.

784 00:35:23.010 --> 00:35:24.240 One final example,

785 00:35:24.240 --> 00:35:26.850 and that is quality improvement collaboratives

786 00:35:26.850 --> 00:35:30.510 where we know that having a multidisciplinary team

787 00:35:30.510 --> 00:35:32.790 and ensuring that the collaborative that's focusing,

788 00:35:32.790 --> 00:35:37.497 for example, on high contamination rates

789 00:35:40.350 --> 00:35:42.060 in the OR,

790 00:35:42.060 --> 00:35:45.420 that the QI team needs not only surgeons and nurses,

791 00:35:45.420 --> 00:35:47.530 but also members of the housekeeping staff

792 00:35:49.410 --> 00:35:52.200 because they collectively will develop

793 00:35:52.200 --> 00:35:55.080 a better understanding of the root causes
 794 00:35:55.080 --> 00:35:57.930 of those infection rates of contamination
 795 00:35:57.930 --> 00:35:59.880 than the physicians alone.
 796 00:35:59.880 --> 00:36:04.200 But the other core function of that multidis-
 ciplinary team
 797 00:36:04.200 --> 00:36:06.330 is the focus on acceptability
 798 00:36:06.330 --> 00:36:08.520 of the findings and the recommendations.
 799 00:36:08.520 --> 00:36:11.880 If a QI team consisting only of surgeons comes
 out
 800 00:36:11.880 --> 00:36:13.560 and says that the high infection rates
 801 00:36:13.560 --> 00:36:16.050 are due to the fact that the housekeeping staff
 802 00:36:16.050 --> 00:36:18.360 are not wiping down the walls properly,
 803 00:36:18.360 --> 00:36:20.280 you can be sure that the housekeeping staff
 804 00:36:20.280 --> 00:36:23.310 are going to discount that
 805 00:36:23.310 --> 00:36:25.350 because they know that they do their job
 properly
 806 00:36:25.350 --> 00:36:27.450 and in their minds the problem
 807 00:36:27.450 --> 00:36:29.430 is that the hand washing practices
 808 00:36:29.430 --> 00:36:32.190 of the surgeons are deficient.
 809 00:36:32.190 --> 00:36:35.160 So again, it's a single component
 810 00:36:35.160 --> 00:36:37.320 or feature of intervention
 811 00:36:37.320 --> 00:36:40.080 that operationalizes two different core func-
 tions.
 812 00:36:40.080 --> 00:36:42.540 And understanding those core functions
 813 00:36:42.540 --> 00:36:44.580 allows us to avoid making mistakes
 814 00:36:44.580 --> 00:36:47.670 when we modify the intervention activity
 815 00:36:47.670 --> 00:36:49.740 in a way that we think may be minor,
 816 00:36:49.740 --> 00:36:54.180 but again can completely eliminate its ability
 817 00:36:54.180 --> 00:36:58.500 to successfully carry out one of the core func-
 tions.
 818 00:36:58.500 --> 00:37:00.540 So I think I've covered each of these already,
 819 00:37:00.540 --> 00:37:02.370 but let me walk through them quickly.

820 00:37:02.370 --> 00:37:04.470 Again, the way that we typically think
821 00:37:04.470 --> 00:37:06.990 of a manualized intervention is highly detailed,
822 00:37:06.990 --> 00:37:11.990 is in fact more likely to do harm in many cases
than value.
823 00:37:13.710 --> 00:37:16.650 Core components should be replaced by core
functions.
824 00:37:16.650 --> 00:37:18.900 There are many implications of that rethink-
ing,
825 00:37:18.900 --> 00:37:22.470 one of which of course is that a measurement
of fidelity
826 00:37:22.470 --> 00:37:24.990 is not a measurement of whether you followed
the script,
827 00:37:24.990 --> 00:37:28.020 but instead whether you successfully opera-
tionalized
828 00:37:28.020 --> 00:37:30.060 or carried out the core function.
829 00:37:30.060 --> 00:37:31.860 I've already talked about the fact
830 00:37:31.860 --> 00:37:34.590 that main effect estimates are not very helpful
831 00:37:34.590 --> 00:37:37.050 in evidence as we typically think of it.
832 00:37:37.050 --> 00:37:38.970 And again, it gets back to the point
833 00:37:38.970 --> 00:37:40.140 I've made a couple of times
834 00:37:40.140 --> 00:37:44.460 on the need to rethink the purpose of our
research.
835 00:37:44.460 --> 00:37:46.900 So let me wrap up with just a few more slides
836 00:37:47.880 --> 00:37:51.150 that list some of the kinds of analytic ap-
proaches
837 00:37:51.150 --> 00:37:55.140 and research approaches that we need to be
leveraging
838 00:37:55.140 --> 00:37:58.470 in order to, again, shine our flashlight
839 00:37:58.470 --> 00:38:01.440 on the processes and the mechanisms of effect
840 00:38:01.440 --> 00:38:03.101 rather than outcomes.
841 00:38:03.101 --> 00:38:06.300 These are some of the quantitative methods,
842 00:38:06.300 --> 00:38:10.080 qualitative comparative analysis is becoming
more popular.
843 00:38:10.080 --> 00:38:11.010 There are also, of course,

844 00:38:11.010 --> 00:38:14.160 a number of qualitative methods as well.

845 00:38:14.160 --> 00:38:17.370 Process evaluation, theory-based evaluation

846 00:38:17.370 --> 00:38:19.830 and the continued emergence

847 00:38:19.830 --> 00:38:24.480 and illustrations of approaches to adaptation.

848 00:38:24.480 --> 00:38:26.280 Here are some examples of publications

849 00:38:26.280 --> 00:38:28.720 that are now quite dated that illustrate

850 00:38:29.670 --> 00:38:32.130 and talk about some of these approaches

851 00:38:32.130 --> 00:38:35.850 for measuring and taking into account context

852 00:38:35.850 --> 00:38:38.640 for examining moderator effects and mediator effects

853 00:38:38.640 --> 00:38:40.503 and mechanisms of effect.

854 00:38:41.970 --> 00:38:45.000 Here's some examples of implementation studies

855 00:38:45.000 --> 00:38:48.690 that have embraced and studied adaptation

856 00:38:48.690 --> 00:38:51.063 rather than suppressing it or ignoring it.

857 00:38:52.020 --> 00:38:55.110 Theory-based evaluation, realistic evaluation,

858 00:38:55.110 --> 00:38:57.450 again, are relatively new

859 00:38:57.450 --> 00:39:00.540 or underutilized approaches in the qualitative realm

860 00:39:00.540 --> 00:39:02.913 to study mechanisms of effect.

861 00:39:03.810 --> 00:39:05.610 There's still a lot of development work

862 00:39:05.610 --> 00:39:07.650 to be done, in my view, in these methods

863 00:39:07.650 --> 00:39:10.320 to get to the level of transparency

864 00:39:10.320 --> 00:39:13.443 and reproducibility that we need,

865 00:39:14.400 --> 00:39:17.250 but valuable approaches.

866 00:39:17.250 --> 00:39:18.600 And then, if we look outside

867 00:39:18.600 --> 00:39:21.960 the typical conventional toolkit

868 00:39:21.960 --> 00:39:23.250 to some of the other approaches

869 00:39:23.250 --> 00:39:26.250 such as statistical process control that are implemented,

870 00:39:26.250 --> 00:39:28.980 I'm sorry, our improvement science colleagues use

871 00:39:28.980 --> 00:39:30.510 as well as others,
 872 00:39:30.510 --> 00:39:33.000 these represent other approaches.
 873 00:39:33.000 --> 00:39:35.370 So just to wrap up,
 874 00:39:35.370 --> 00:39:37.620 when we study complex health interventions,
 875 00:39:37.620 --> 00:39:40.830 again, we need to begin by identifying the
 core functions
 876 00:39:40.830 --> 00:39:42.870 and developing the menu of forms.
 877 00:39:42.870 --> 00:39:46.890 Ideally, our research would validate
 878 00:39:46.890 --> 00:39:48.180 our list of core functions
 879 00:39:48.180 --> 00:39:49.710 or allow us to revise it
 880 00:39:49.710 --> 00:39:51.420 so that we understand all the functions
 881 00:39:51.420 --> 00:39:53.100 that need to be included
 882 00:39:53.100 --> 00:39:56.673 and also provide evidence that guides the local
 tailoring.
 883 00:39:58.500 --> 00:40:00.690 It would be documented
 884 00:40:00.690 --> 00:40:03.900 in a set of adaptation or tailoring algorithms.
 885 00:40:03.900 --> 00:40:07.110 And the bottom line, again, is a goal of un-
 derstanding
 886 00:40:07.110 --> 00:40:09.720 how complex interventions achieve their effects
 887 00:40:09.720 --> 00:40:11.490 and how to modify them
 888 00:40:11.490 --> 00:40:13.500 rather than pursuing the simpler question
 889 00:40:13.500 --> 00:40:15.990 of whether they are effective.
 890 00:40:15.990 --> 00:40:18.540 So I will stop there and open up
 891 00:40:18.540 --> 00:40:22.590 for what I hope will be some robust discussion
 892 00:40:22.590 --> 00:40:24.573 and comments and questions.
 893 00:40:29.580 --> 00:40:30.753 <v ->Thanks, Brian.</v>
 894 00:40:31.770 --> 00:40:35.580 That was a really kind of interesting and
 important talk
 895 00:40:35.580 --> 00:40:37.440 at sort of the cutting edge
 896 00:40:37.440 --> 00:40:40.650 of where implementation science is today,
 897 00:40:40.650 --> 00:40:43.470 and with a lot of information packed in
 898 00:40:43.470 --> 00:40:46.170 and concepts and things like that

899 00:40:46.170 --> 00:40:47.310 for us to think about

900 00:40:47.310 --> 00:40:50.820 and potentially absorb into our own work.

901 00:40:50.820 --> 00:40:55.170 So maybe I might start with this first question

902 00:40:55.170 --> 00:40:56.120 which is...

903 00:40:57.030 --> 00:40:59.550 Actually, I'll even integrate something else

904 00:40:59.550 --> 00:41:01.380 that probably is worth both of us mentioning,

905 00:41:01.380 --> 00:41:04.710 which is that Brian is actually the co-founder and director

906 00:41:04.710 --> 00:41:06.630 of the Multilevel Training Institute

907 00:41:06.630 --> 00:41:10.800 that's offered every year in collaboration with NCI.

908 00:41:10.800 --> 00:41:12.990 And Raul Hernandez-Ramirez,

909 00:41:12.990 --> 00:41:15.510 who's one of our CMIPS primary faculty

910 00:41:15.510 --> 00:41:17.310 is a graduate of that institute.

911 00:41:17.310 --> 00:41:19.800 And I'm actually one of the instructors

912 00:41:19.800 --> 00:41:24.800 teaching about the analysis of multilevel interventions.

913 00:41:24.930 --> 00:41:27.150 But the question is,

914 00:41:27.150 --> 00:41:29.850 my thought and I think a lot of us out here think

915 00:41:29.850 --> 00:41:31.020 that the reason,

916 00:41:31.020 --> 00:41:33.540 sort of the opposite of what you said,

917 00:41:33.540 --> 00:41:36.300 that the reason we like multilevel interventions

918 00:41:36.300 --> 00:41:39.240 is because it seemed like the medical model

919 00:41:39.240 --> 00:41:41.190 of isolating one,

920 00:41:41.190 --> 00:41:43.950 like what we would've said before in the past component

921 00:41:43.950 --> 00:41:47.070 and maybe right now you might say function

922 00:41:47.070 --> 00:41:50.910 and studying it and holding everything else constant,

923 00:41:50.910 --> 00:41:53.430 these sorts of implementation studies

924 00:41:53.430 --> 00:41:55.020 have been disappointing.

925 00:41:55.020 --> 00:41:58.590 And so, the thought was that actually,

926 00:41:58.590 --> 00:42:01.020 first of all, it's totally unrealistic in real life.

927 00:42:01.020 --> 00:42:03.000 You don't just have one thing.

928 00:42:03.000 --> 00:42:05.970 All of these public health interventions are complex,

929 00:42:05.970 --> 00:42:08.220 whether we choose to study them or not.

930 00:42:08.220 --> 00:42:11.070 And so, the idea then evolved

931 00:42:11.070 --> 00:42:13.920 to that it might make sense

932 00:42:13.920 --> 00:42:16.320 to intervene on an entire,

933 00:42:16.320 --> 00:42:18.360 sometimes we might say package of components,

934 00:42:18.360 --> 00:42:20.520 which now you're kind of redefining

935 00:42:20.520 --> 00:42:22.563 as package of forms maybe.

936 00:42:24.480 --> 00:42:26.100 Or maybe it's package of functions

937 00:42:26.100 --> 00:42:29.250 and then the forms are the specific ways

938 00:42:29.250 --> 00:42:30.810 that the functions are ways

939 00:42:30.810 --> 00:42:32.760 that functions can be implemented.

940 00:42:32.760 --> 00:42:35.070 If I caught all of that very quickly, I think I did,

941 00:42:35.070 --> 00:42:36.300 and I think we're somewhat familiar

942 00:42:36.300 --> 00:42:38.910 with this idea in our center as well.

943 00:42:38.910 --> 00:42:41.460 So that would strengthen

944 00:42:41.460 --> 00:42:44.850 the ability to see an impactful intervention

945 00:42:44.850 --> 00:42:47.910 and allow us to translate

946 00:42:47.910 --> 00:42:52.910 into practice evidence-based interventions as a whole.

947 00:42:53.160 --> 00:42:54.300 But now you're saying

948 00:42:54.300 --> 00:42:57.060 that because of the adaptations

949 00:42:57.060 --> 00:42:59.250 and the variability and the heterogeneity,

950 00:42:59.250 --> 00:43:02.310 actually these kinds of approaches also

951 00:43:02.310 --> 00:43:03.690 are giving weak results.

952 00:43:03.690 --> 00:43:07.230 So I'm just wondering if you can comment on that.

953 00:43:07.230 --> 00:43:08.250 <v ->Sure.</v>

954 00:43:08.250 --> 00:43:11.442 No, I would concur with everything that you've said

955 00:43:11.442 --> 00:43:13.833 and I think the main point is that,

956 00:43:14.670 --> 00:43:17.730 it's really that the argument that one size doesn't fit all.

957 00:43:17.730 --> 00:43:20.220 But to begin with, I do agree that,

958 00:43:20.220 --> 00:43:22.410 for most of these kinds of problems,

959 00:43:22.410 --> 00:43:24.840 the barriers are multi-component and multi-level,

960 00:43:24.840 --> 00:43:26.580 and we definitely need multi-level,

961 00:43:26.580 --> 00:43:29.970 multi-component complex health interventions.

962 00:43:29.970 --> 00:43:32.027 The simple example goes back to the studies

963 00:43:32.027 --> 00:43:36.050 in the 1970s and 1980s of CME

964 00:43:36.050 --> 00:43:38.610 as a method for improving physician practices.

965 00:43:38.610 --> 00:43:41.250 And the dominant finding from that body of research

966 00:43:41.250 --> 00:43:44.400 was physician knowledge and education changed

967 00:43:44.400 --> 00:43:46.590 and sometimes physician attitudes changed,

968 00:43:46.590 --> 00:43:48.630 but practices didn't change at all

969 00:43:48.630 --> 00:43:50.610 because the practices are held in place

970 00:43:50.610 --> 00:43:52.440 by multiple barriers.

971 00:43:52.440 --> 00:43:54.210 And if you don't provide the equipment

972 00:43:54.210 --> 00:43:56.100 or the staff support or the time

973 00:43:56.100 --> 00:43:59.491 or as I said, work on the patient resistance,

974 00:43:59.491 --> 00:44:02.040 no amount of educating physicians is likely

975 00:44:02.040 --> 00:44:05.040 to lead to the outcomes that we want.

976 00:44:05.040 --> 00:44:07.170 And in the causal diagram,

977 00:44:07.170 --> 00:44:09.480 the diag that I showed again is an example of that.

978 00:44:09.480 --> 00:44:12.480 If we focus on only one of those causal pathways,

979 00:44:12.480 --> 00:44:14.280 believe the other's untouched.

980 00:44:14.280 --> 00:44:19.020 So the point though is that we absolutely do need

981 00:44:19.020 --> 00:44:23.130 multi-component, often multi-level interventions.

982 00:44:23.130 --> 00:44:25.977 The issue though is the need to adapt and tailor them

983 00:44:25.977 --> 00:44:28.110 and the same mix of components

984 00:44:28.110 --> 00:44:30.750 or the same mix of forms and activities

985 00:44:30.750 --> 00:44:33.150 that is highly effective in one setting

986 00:44:33.150 --> 00:44:35.370 is not likely to be effective elsewhere.

987 00:44:35.370 --> 00:44:38.307 And when we take a complex health intervention

988 00:44:38.307 --> 00:44:41.100 and we try to scale it and spread it,

989 00:44:41.100 --> 00:44:45.150 or we move from efficacy research to effectiveness research,

990 00:44:45.150 --> 00:44:47.790 we are often disappointed in the findings.

991 00:44:47.790 --> 00:44:51.570 And that is because of the erroneous belief

992 00:44:51.570 --> 00:44:53.190 that one size fits all

993 00:44:53.190 --> 00:44:55.890 and that an so-called evidence-based practice

994 00:44:55.890 --> 00:44:57.990 is going to be evidence-based and robust

995 00:44:57.990 --> 00:45:00.450 and effective across multiple settings.

996 00:45:00.450 --> 00:45:01.890 It has to be tailored

997 00:45:01.890 --> 00:45:04.440 and we as researchers have to guide that tailoring.

998 00:45:06.690 --> 00:45:08.220 <v ->Thanks.</v>

999 00:45:08.220 --> 00:45:09.390 I have lots of questions,

1000 00:45:09.390 --> 00:45:11.160 but I don't wanna hog the time.

1001 00:45:11.160 --> 00:45:13.503 So we have lots of people on here.

1002 00:45:14.340 --> 00:45:16.560 Do others have any questions they'd like to ask?

1003 00:45:16.560 --> 00:45:19.260 I think you can simply unmute yourself

1004 00:45:19.260 --> 00:45:20.673 and ask your question.

1005 00:45:26.250 --> 00:45:28.920 <v ->Sure, thank you for the wonderful talk.</v>

1006 00:45:28.920 --> 00:45:30.450 I am an investigator working a lot

1007 00:45:30.450 --> 00:45:31.800 in low and middle income countries

1008 00:45:31.800 --> 00:45:33.810 and I was interested at the beginning of your talk

1009 00:45:33.810 --> 00:45:36.150 when you were using the term impact.

1010 00:45:36.150 --> 00:45:39.870 I think it's often used as a synonym for effectiveness.

1011 00:45:39.870 --> 00:45:41.760 But I think sometimes with public health

1012 00:45:41.760 --> 00:45:44.250 or even population health interventions,

1013 00:45:44.250 --> 00:45:46.680 we're thinking about numbers of people that can be served.

1014 00:45:46.680 --> 00:45:47.970 I think this is particularly relevant

1015 00:45:47.970 --> 00:45:49.620 if you think about communicable diseases

1016 00:45:49.620 --> 00:45:52.470 because there may be indirect benefits for addressing that.

1017 00:45:52.470 --> 00:45:55.890 And so, I guess that's sort of a very general question,

1018 00:45:55.890 --> 00:45:57.270 just curious if you've encountered that,

1019 00:45:57.270 --> 00:45:59.040 but maybe the more specific question

1020 00:45:59.040 --> 00:46:00.740 related to your research would be,

1021 00:46:02.978 --> 00:46:05.220 if volume then is kind of really important

1022 00:46:05.220 --> 00:46:06.630 about how we deliver interventions,

1023 00:46:06.630 --> 00:46:08.970 how do you think about that

1024 00:46:08.970 --> 00:46:11.426 with regard to understanding the fidelity?

1025 00:46:11.426 --> 00:46:14.100 Are we looking at sort of the contextual factors

1026 00:46:14.100 --> 00:46:17.197 related to how many people are served

1027 00:46:17.197 --> 00:46:19.080 maybe when we pilot an intervention,

1028 00:46:19.080 --> 00:46:21.930 but when we think about taking it to scale,

1029 00:46:21.930 --> 00:46:24.150 what are some of the considerations

1030 00:46:24.150 --> 00:46:26.190 about kind of understanding the impact of volume

1031 00:46:26.190 --> 00:46:28.680 on fidelity and adaptation?

1032 00:46:28.680 --> 00:46:29.871 Thank you so much.

1033 00:46:29.871 --> 00:46:32.687 <v ->Yeah, so first of all,</v>

1034 00:46:32.687 --> 00:46:37.200 I'm a strong fan of the REAM framework

1035 00:46:37.200 --> 00:46:38.100 and I think to think

1036 00:46:38.100 --> 00:46:40.710 about the different dimensions of impact

1037 00:46:40.710 --> 00:46:43.800 and how they relate to one another is critically important,

1038 00:46:43.800 --> 00:46:45.570 that we focus only on effectiveness

1039 00:46:45.570 --> 00:46:47.550 and ignore the other issues.

1040 00:46:47.550 --> 00:46:49.560 The ultimate societal impact

1041 00:46:49.560 --> 00:46:52.860 that we are seeking will not be seen.

1042 00:46:52.860 --> 00:46:55.950 And I think the heterogeneity

1043 00:46:55.950 --> 00:46:58.988 may apply differently across different outcomes

1044 00:46:58.988 --> 00:47:00.930 in the kind of approach that we need

1045 00:47:00.930 --> 00:47:04.240 in order to engage a high volume

1046 00:47:04.240 --> 00:47:07.230 and a high proportion of the target audience

1047 00:47:07.230 --> 00:47:09.270 versus the approach that we need to use

1048 00:47:09.270 --> 00:47:12.030 to ensure that the intervention is effective

1049 00:47:12.030 --> 00:47:15.720 across a large proportion of the target audience

1050 00:47:15.720 --> 00:47:20.720 which does have its own heterogeneity in subgroups.

1051 00:47:20.760 --> 00:47:22.053 Those may be different.

1052 00:47:24.810 --> 00:47:26.760 And this may or may not be an answer,

1053 00:47:26.760 --> 00:47:29.910 but at least this is the way that I would think about it,

1054 00:47:29.910 --> 00:47:32.220 the vast majority if not all of these studies,

1055 00:47:32.220 --> 00:47:34.020 we need to begin with REAM

1056 00:47:34.020 --> 00:47:37.560 and explicitly think about all the different dimensions

1057 00:47:37.560 --> 00:47:42.210 that contribute to the overall impact and outcomes.

1058 00:47:42.210 --> 00:47:45.360 And then, we need to recognize and anticipate

1059 00:47:45.360 --> 00:47:48.870 and explicitly address the heterogeneity

1060 00:47:48.870 --> 00:47:51.540 across all of those different dimensions

1061 00:47:51.540 --> 00:47:55.260 and know that as we again scale up and spread

1062 00:47:55.260 --> 00:47:57.240 and adapt and tailor interventions

1063 00:47:57.240 --> 00:48:00.780 from one setting to another,

1064 00:48:00.780 --> 00:48:04.830 that tailoring and adaptations are likely to be needed

1065 00:48:04.830 --> 00:48:08.040 in different ways and different facets of the intervention

1066 00:48:08.040 --> 00:48:11.620 in order to ensure that we maximize

1067 00:48:12.960 --> 00:48:14.250 outcomes and success

1068 00:48:14.250 --> 00:48:16.950 across all the REAM dimensions.

1069 00:48:16.950 --> 00:48:19.530 So again, it's just a very different way

1070 00:48:19.530 --> 00:48:23.310 of thinking about research and interventions

1071 00:48:23.310 --> 00:48:26.040 compared to the typical evidence-based practice

1072 00:48:26.040 --> 00:48:27.480 that we develop an intervention,

1073 00:48:27.480 --> 00:48:29.490 we can describe it very simply

1074 00:48:29.490 --> 00:48:31.980 and we can deploy it anywhere

1075 00:48:31.980 --> 00:48:35.340 and we will see the same kinds of results.

1076 00:48:35.340 --> 00:48:36.300 And that's not the case,

1077 00:48:36.300 --> 00:48:39.180 both because we can't deploy the interventions

1078 00:48:39.180 --> 00:48:40.680 as we were designed elsewhere,

1079 00:48:40.680 --> 00:48:42.117 and that's especially true of course.

1080 00:48:42.117 --> 00:48:45.510 And we take US-designed interventions,

1081 00:48:45.510 --> 00:48:48.150 try to deploy them in low resource settings
1082 00:48:48.150 --> 00:48:50.100 within the US and elsewhere,
1083 00:48:50.100 --> 00:48:51.890 but even if we could deploy them
1084 00:48:51.890 --> 00:48:54.540 in the same way and implement them,
1085 00:48:54.540 --> 00:48:56.990 the effectiveness is likely to vary considerably.
1086 00:49:01.200 --> 00:49:03.600 <v ->Thanks so much, that's really interest-
ing.</v>
1087 00:49:03.600 --> 00:49:05.010 <v ->Okay, thank you.</v>
1088 00:49:05.010 --> 00:49:05.843 That was a good answer.
1089 00:49:05.843 --> 00:49:08.040 Luke, do you have a follow-up question?
1090 00:49:08.040 --> 00:49:09.450 <v ->Yeah, I mean I would be curious</v>
1091 00:49:09.450 --> 00:49:11.767 maybe just to think a little bit
1092 00:49:11.767 --> 00:49:14.160 about operationalizing some of these things.
1093 00:49:14.160 --> 00:49:17.730 Obviously, you work with one of the premier
organizations
1094 00:49:17.730 --> 00:49:20.383 about thinking about how to answer these
questions.
1095 00:49:20.383 --> 00:49:22.770 In terms of Kaiser,
1096 00:49:22.770 --> 00:49:26.070 very large health system, many different
units,
1097 00:49:26.070 --> 00:49:27.390 however you'd wanna define those,
1098 00:49:27.390 --> 00:49:31.263 whether those are sites or providers and so
on so forth.
1099 00:49:32.310 --> 00:49:34.800 I know I'm just curious
1100 00:49:34.800 --> 00:49:36.210 about how you think about integrating
1101 00:49:36.210 --> 00:49:38.010 quantitative and qualitative data
1102 00:49:38.010 --> 00:49:41.010 with respect to certain types of problems of
this nature.
1103 00:49:41.010 --> 00:49:43.140 Maybe if there's any examples
1104 00:49:43.140 --> 00:49:46.290 that you might be able to share from your
work in Kaiser.
1105 00:49:46.290 --> 00:49:49.350 <v ->So I think that integration is criti-
cal.</v>

1106 00:49:49.350 --> 00:49:52.170 And this actually relates to the point that Donna raised

1107 00:49:52.170 --> 00:49:54.090 about implementation science and improvement science.

1108 00:49:54.090 --> 00:49:57.270 So the improvement science folks do accept

1109 00:49:57.270 --> 00:50:01.137 and anticipate and address the heterogeneity

1110 00:50:01.137 --> 00:50:05.100 and the whole issue of rapid cycle implementation

1111 00:50:05.100 --> 00:50:06.630 and improvement

1112 00:50:06.630 --> 00:50:09.000 where you do something and you sort of see

1113 00:50:09.000 --> 00:50:10.980 what the impacts are and then you refine it.

1114 00:50:10.980 --> 00:50:12.780 That's a form of tailoring.

1115 00:50:12.780 --> 00:50:15.870 So I think they do recognize the heterogeneity

1116 00:50:15.870 --> 00:50:17.730 and that's one way of dealing with it.

1117 00:50:17.730 --> 00:50:19.830 But I think that rapid cycle evaluation,

1118 00:50:19.830 --> 00:50:21.150 any kind of evaluation,

1119 00:50:21.150 --> 00:50:24.810 and understanding the mechanisms of effect.

1120 00:50:24.810 --> 00:50:28.560 We can only learn so much through mediation analysis

1121 00:50:28.560 --> 00:50:29.910 and other quantitative methods.

1122 00:50:29.910 --> 00:50:31.650 And if our goal is ultimately

1123 00:50:31.650 --> 00:50:34.080 to understand how the world works

1124 00:50:34.080 --> 00:50:36.480 and to understand causal pathways

1125 00:50:36.480 --> 00:50:37.983 and causal relationships,

1126 00:50:39.390 --> 00:50:42.450 we do have to mix the quantitative and qualitative.

1127 00:50:42.450 --> 00:50:44.940 And I think all of our projects at Kaiser

1128 00:50:44.940 --> 00:50:47.010 that are embedded research projects

1129 00:50:47.010 --> 00:50:48.570 that are a synthesis

1130 00:50:48.570 --> 00:50:51.660 of quality improvement activity and approaches

1131 00:50:51.660 --> 00:50:54.420 where we're trying to improve things in the near term

1132 00:50:54.420 --> 00:50:57.930 and implementation science and scientific approaches

1133 00:50:57.930 --> 00:51:00.569 where we're trying to generate scientific knowledge,

1134 00:51:00.569 --> 00:51:03.300 I think we almost invariably combine

1135 00:51:03.300 --> 00:51:05.310 quantitative and qualitative

1136 00:51:05.310 --> 00:51:07.290 as a way of, again, trying to understand

1137 00:51:07.290 --> 00:51:08.640 how the world works,

1138 00:51:08.640 --> 00:51:12.240 try to design the intervention, deploy it,

1139 00:51:12.240 --> 00:51:14.010 evaluate it early and often

1140 00:51:14.010 --> 00:51:16.680 in order to refine it and tailor it

1141 00:51:16.680 --> 00:51:17.850 and ultimately generate

1142 00:51:17.850 --> 00:51:20.040 the summative evaluation findings as well.

1143 00:51:20.040 --> 00:51:23.460 And I think we all need more guidance

1144 00:51:23.460 --> 00:51:26.130 and more examples of how this is done

1145 00:51:26.130 --> 00:51:27.750 because there are a lot of moving parts

1146 00:51:27.750 --> 00:51:30.030 and a lot of different factors to think of,

1147 00:51:30.030 --> 00:51:31.980 not only the REAM multiple dimensions,

1148 00:51:31.980 --> 00:51:34.470 but the different kinds of data

1149 00:51:34.470 --> 00:51:36.540 and the different ways of understanding

1150 00:51:36.540 --> 00:51:38.670 and tracking the mechanisms of effect

1151 00:51:38.670 --> 00:51:41.340 and the intermediate or proximal outcomes

1152 00:51:41.340 --> 00:51:43.500 in addition to the distal outcomes.

1153 00:51:43.500 --> 00:51:44.970 So lots of challenges,

1154 00:51:44.970 --> 00:51:47.913 but lots of opportunity for innovation and creativity.

1155 00:51:51.750 --> 00:51:54.453 <v ->Anyone else that wants to ask you questions?</v>

1156 00:51:58.300 --> 00:52:01.140 While we're waiting to see, I have another question.

1157 00:52:01.140 --> 00:52:03.690 So you're probably familiar, Brian,

1158 00:52:03.690 --> 00:52:06.990 with Linda Collins' MOST approach

1159 00:52:06.990 --> 00:52:11.970 to developing and assessing or testing interventions

1160 00:52:11.970 --> 00:52:16.970 and her focus is also with complex multilevel interventions

1161 00:52:17.940 --> 00:52:19.530 where there are the three phases.

1162 00:52:19.530 --> 00:52:21.930 But in the third phase,

1163 00:52:21.930 --> 00:52:25.113 the third phase is kind of a traditional,

1164 00:52:26.820 --> 00:52:28.140 fixed.

1165 00:52:28.140 --> 00:52:29.310 You call it manualized,

1166 00:52:29.310 --> 00:52:31.350 it doesn't necessarily have to just be a manual,

1167 00:52:31.350 --> 00:52:32.520 it could be other things,

1168 00:52:32.520 --> 00:52:37.520 but fixed set of components at certain levels

1169 00:52:37.620 --> 00:52:41.700 and that's kind of tested in a standard RCT-type approach.

1170 00:52:41.700 --> 00:52:43.800 And I'm wondering if you think

1171 00:52:43.800 --> 00:52:48.690 that the MOST design is useful in certain settings

1172 00:52:48.690 --> 00:52:52.680 or do you think that maybe that kind of approach

1173 00:52:52.680 --> 00:52:54.630 has kind of seen its better days

1174 00:52:54.630 --> 00:52:58.860 because of the fact that it doesn't take into account

1175 00:52:58.860 --> 00:53:02.520 sort of the contextual aspects and the need for adaptation.

1176 00:53:02.520 --> 00:53:04.080 But I know among other circles,

1177 00:53:04.080 --> 00:53:06.690 the MOST design is very popular

1178 00:53:06.690 --> 00:53:10.290 and even we've had training in our center in MOST

1179 00:53:10.290 --> 00:53:12.600 and I'm currently discussing

1180 00:53:12.600 --> 00:53:15.810 a possible grant application with some investigators here

1181 00:53:15.810 --> 00:53:16.920 who'd like to use MOST.

1182 00:53:16.920 --> 00:53:20.340 So I'm just wondering what your thinking is about that.

1183 00:53:20.340 --> 00:53:23.830 <v -> Yeah, so I think that approach I think is highly valuable.</v>

1184 00:53:23.830 --> 00:53:26.430 As our standard RCTs,

1185 00:53:26.430 --> 00:53:29.940 as long as we recognize that they need to be augmented

1186 00:53:29.940 --> 00:53:33.510 with additional kinds of data collection analysis activities

1187 00:53:33.510 --> 00:53:36.660 that try to understand the mechanisms of effect.

1188 00:53:36.660 --> 00:53:38.860 But certainly and when I say

1189 00:53:40.070 --> 00:53:43.770 that RCTs and a focus on impact and outcomes

1190 00:53:43.770 --> 00:53:47.850 are not what we should be doing,

1191 00:53:47.850 --> 00:53:49.410 that's probably too extreme.

1192 00:53:49.410 --> 00:53:52.020 I think we obviously need to measure outcomes

1193 00:53:52.020 --> 00:53:55.020 and we need to use traditional quantitative methods,

1194 00:53:55.020 --> 00:53:56.640 but we need to augment them

1195 00:53:56.640 --> 00:53:59.160 and have an equal, in some cases greater focus,

1196 00:53:59.160 --> 00:54:01.260 on the mechanisms of effect.

1197 00:54:01.260 --> 00:54:02.610 And certainly, to try to get a handle

1198 00:54:02.610 --> 00:54:04.440 on some of the heterogeneity

1199 00:54:04.440 --> 00:54:06.330 and some of the factors using MOST

1200 00:54:06.330 --> 00:54:08.790 and other approaches that Linda and others

1201 00:54:08.790 --> 00:54:10.830 have developed and advocated

1202 00:54:10.830 --> 00:54:13.650 I think is quite important and valuable.

1203 00:54:13.650 --> 00:54:15.090 I just think that they're incomplete

1204 00:54:15.090 --> 00:54:16.050 and we need to make sure

1205 00:54:16.050 --> 00:54:19.680 we, again, have the accompanying process evaluation

1206 00:54:19.680 --> 00:54:21.753 and mediation analysis and others.

1207 00:54:23.010 --> 00:54:23.973 <v ->That makes sense.</v>

1208 00:54:26.220 --> 00:54:27.183 Anyone else?

1209 00:54:28.338 --> 00:54:30.663 Okay, so we have a question in the chat.

1210 00:54:33.180 --> 00:54:34.710 What are some other frameworks

1211 00:54:34.710 --> 00:54:36.930 you would consider reviewing

1212 00:54:36.930 --> 00:54:39.720 when considering a multi-component and multi-level study?

1213 00:54:39.720 --> 00:54:44.580 So presumably this question is other than REAM.

1214 00:54:44.580 --> 00:54:45.570 <v ->Sure.</v> <v ->I'm guessing</v>

1215 00:54:45.570 --> 00:54:48.180 and if the person who asked it would like to elaborate

1216 00:54:48.180 --> 00:54:50.250 or if this is totally clear to you,

1217 00:54:50.250 --> 00:54:51.153 Brian. <v ->Yeah,</v>

1218 00:54:51.153 --> 00:54:52.530 let me give it a quick shot

1219 00:54:52.530 --> 00:54:54.990 and then you can elaborate if I'm missing a point.

1220 00:54:54.990 --> 00:54:57.630 But I think that CFIR of course,

1221 00:54:57.630 --> 00:55:00.520 which continues to be the go-to high level framework

1222 00:55:01.650 --> 00:55:03.090 is a way of identifying

1223 00:55:03.090 --> 00:55:05.370 all the different categories of factors.

1224 00:55:05.370 --> 00:55:08.400 So multi-component, multi-level interventions

1225 00:55:08.400 --> 00:55:13.050 address multiple sources of barriers and factors

1226 00:55:13.050 --> 00:55:15.797 that influence the outcomes that we're interested in.

1227 00:55:15.797 --> 00:55:18.990 And CFIR is, in my mind, the best organizing framework

1228 00:55:18.990 --> 00:55:22.080 that gives us that sort of 50,000 foot level.

1229 00:55:22.080 --> 00:55:23.490 Then when we've identified

1230 00:55:23.490 --> 00:55:26.790 the different categories of factors,

1231 00:55:26.790 --> 00:55:29.730 we may need to bring in accompanying frameworks.

1232 00:55:29.730 --> 00:55:31.410 So, behavior change wheel,

1233 00:55:31.410 --> 00:55:36.410 theoretical domains framework is quite useful in identifying

1234 00:55:36.720 --> 00:55:40.290 some of the physician-level behavioral factors.

1235 00:55:40.290 --> 00:55:43.710 So I think it does depend on what CFIR tells us.

1236 00:55:43.710 --> 00:55:45.630 If many of the barriers and influences

1237 00:55:45.630 --> 00:55:48.120 are regulatory or community,

1238 00:55:48.120 --> 00:55:50.730 then we may need to bring in political science frameworks

1239 00:55:50.730 --> 00:55:52.770 or other bodies of theory.

1240 00:55:52.770 --> 00:55:56.220 But we start with CFIR to get sort of the lay of land

1241 00:55:56.220 --> 00:56:00.090 and then we identify frameworks for subsets of factors.

1242 00:56:00.090 --> 00:56:02.250 And to me, REAM and I think to most of us

1243 00:56:02.250 --> 00:56:04.200 is more of an evaluation framework.

1244 00:56:04.200 --> 00:56:07.560 It doesn't really give us the theory,

1245 00:56:07.560 --> 00:56:08.880 but it directs our attention

1246 00:56:08.880 --> 00:56:11.310 to the different categories of outcomes

1247 00:56:11.310 --> 00:56:13.560 that we need to take into account

1248 00:56:13.560 --> 00:56:16.263 and measure and attempt to improve.

1249 00:56:18.090 --> 00:56:20.700 <v ->Great, that was a very clear answer.</v>

1250 00:56:20.700 --> 00:56:21.533 Thank you so much.

1251 00:56:21.533 --> 00:56:24.960 And we're at time, so I think we'll just thank our speaker.

1252 00:56:24.960 --> 00:56:26.760 Hopefully we'll see him again in person

1253 00:56:26.760 --> 00:56:28.920 sometime in the near future

1254 00:56:28.920 --> 00:56:32.760 and we look forward to some of our one-on-one meetings today

1255 00:56:32.760 --> 00:56:34.710 and in a few of the subsequent days.

1256 00:56:34.710 --> 00:56:37.620 So thank you so much, Dr. Mittman.

1257 00:56:37.620 --> 00:56:39.490 <v ->Okay, thank you all.</v> <v ->Bye everybody.</v>

1258 00:56:39.490 --> 00:56:40.533 <v ->Okay, bye-bye.</v>