Okay, great.

So good morning and good evening to our friends joining from China.

Welcome all, my name is Maur Desai. I'm a faculty member in the Department of Chronic Disease Epidemiology at the Yale School of Public Health and also the school’s Associate Dean.

But first I’d like to acknowledge that this seminar is co-sponsored by the Yale Center for Methods and Implementation and Prevention Science, also known as CMIPS, which Professor Spigelman directs.

The seminar is co-sponsored by the Department of Chronic Disease Epidemiology and the global health concentration at YSPH, as well as the newly funded NIHT 32 training grant Implementation Science Research.

Based at the Yale School of Public Health, CMIPS develops and disseminates innovative methodological approaches to address implementation gaps and improve public health.
worldwide strategically selecting the issues that carry the greatest burden and hold the greatest promise for amelioration right now.

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Professor Roman Xu is one of the foremost science researchers and methodologists in China. His research focuses on health system innovations and implementation science, particularly those involving chronic diseases quality of primary health care and eHealth in the context of global health.

He’s leading several large studies including primary healthcare quality cohort in China, the Silk Road Labs for health system strengthening in Nepal and Mozambique, an implementation trial for stroke guidelines in China, and the shared medical appointment trial for diabetes and smart trial.

Professor Xu received his PhD in global health implementation Science from the University of Washington and his master’s in Public Policy from Harvard University.
The title of his talk today is Use PEDALs Model to PEDAL for Implementation Research.

Roman, over to you.

Thank you Maur.

Thank you very much for the very nice introduction.

let me share my screen first.

Okay, I suppose you can now see my screen.

Today I’m going to talk about the PEDALs model.

and in that process I will use one of our ongoing,

Oh, sorry, Roman.

Roman, do you want to put it in presentation mode?

It is not in presentation mode now?

On my screen it is in the presentation mode,

it’s a little strange.

Ahh.

Let me share again.

Okay and while you’re doing that,

I’ll just say very quickly, if you have questions,

please hold them to the end, but you’re welcome to put them

in the chat and then when we get to the Q&A,

you can use the raise hand feature, just unmute yourself,

jump right in and we’ll make sure that we get to

as many questions as possible.

Can see now.
68 00:03:26.520 --> 00:03:28.380 <v Maur>I don’t know about others, but I’m still seeing it</v>

69 00:03:28.380 --> 00:03:31.630 in sort of the regular mode, not the presentation mode.

70 00:03:31.630 --> 00:03:35.070 <v Roman>Okay, just one second, sorry for that</v>

71 00:03:35.070 --> 00:03:40.070 it’s a little I tried but just one second.

72 00:03:52.860 --> 00:03:54.603 Sorry for that everybody.

73 00:03:56.744 --> 00:03:57.577 <v Maur>No problem.</v>

74 00:03:59.370 --> 00:04:02.046 <v Roman>Let me share my screen to see whether</v>

75 00:04:02.046 --> 00:04:02.879 this will be better.

76 00:04:12.660 --> 00:04:14.580 Now, can you see my screen now?

77 00:04:14.580 --> 00:04:16.880 <v Maur>Yes and you may want to, we’re seeing</v>

78 00:04:17.730 --> 00:04:20.460 also the preview slide, so if you swap display

79 00:04:20.460 --> 00:04:23.103 maybe that would help, that would help at the top.

80 00:04:25.680 --> 00:04:27.030 <v Roman>Does it work now?</v>

81 00:04:31.887 --> 00:04:34.252 <v Maur>And we can start, if it’s gonna be a</v>

82 00:04:34.252 --> 00:04:36.468 you don’t wanna create too much delay,

83 00:04:36.468 --> 00:04:38.010 but if at the top, I think it’s the second tab,

84 00:04:38.010 --> 00:04:41.010 if you say switch display, we should be able

85 00:04:41.010 --> 00:04:44.190 to then see it in full mode.

86 00:04:44.190 --> 00:04:49.127 So it was fine, but we were just seeing

87 00:04:49.127 --> 00:04:50.333 your previous slide as well.

88 00:05:19.740 --> 00:05:22.563 There we go, perfect.

89 00:05:32.930 --> 00:05:34.582 <v Donna>Oh, Dr Xu, you on mute?</v>

90 00:05:34.582 --> 00:05:39.582 <v Maur>Oh, you’re on mute.</v>

91 00:05:43.027 --> 00:05:44.280 <v Roman>Okay, now it’s good.</v>

92 00:05:44.280 --> 00:05:45.835 <v Maur>Perfect.</v>
Ah, technology, I am supposed to know this well.

So today I’m going to talk about the PEDALs model, which is a model we have developed essentially at the beginning for our students so they can understand quickly with a nice acronym about the general procedures of conducting implementation research. And we’ll use one of our ongoing trials for shared medical appointment for the management of diabetes as an illustration.

In that process I will talk about some of the common designs for implementation research and the choices and the rationale we choose some of the designs versus others in this presentation.

But before that, let me spend a few minutes on some of the advertisement.

I’m currently the principal investigator for a lab called Acacia lab, which is sort of the child of a parent study called Acacia Study. In that study we have set up a consortium of researchers from 10 universities in China. And gradually because of using that study we have formed strong collaborative team in China.
for primary healthcare and implementation science.

So looking to the future, we really want to use this platform to collaborate more with all of you.

I’m also leading the Southern Medical University Institute for Global Health site.

Southern Medical University is one of the first and largest medical centers receiving international patients, especially from low and middle income countries.

And in terms of education, we are one of the four and one of the earliest programs for international MPH, giving 25 scholarships to people from low and middle income countries to study MPH in China.

I’m also the co-editor in chief along with the professor Ann Sales for a new journal called implementation science communications, which is a facial companion journal to implementation science.

We are a brand new journal two years, but so far we have received last year we have received almost
135 00:08:15.763 --> 00:08:19.950 a 400 submission, which is quite good for new journal
136 00:08:19.950 --> 00:08:24.900 and the downloads are also increased dramatically from
137 00:08:24.900 --> 00:08:26.493 two years ago to last year.
138 00:08:27.436 --> 00:08:30.790 So yeah, welcome to submit your work to our journal
139 00:08:31.795 --> 00:08:33.631 and thank you so much.
140 00:08:33.631 --> 00:08:36.840 So now before I talk about the PEDALs model, I’d like
141 00:08:36.840 --> 00:08:40.860 to go over a few key concepts in implementation science.
142 00:08:40.860 --> 00:08:44.043 That is very much related to my model as well.
143 00:08:45.360 --> 00:08:47.163 So what is implementation science?
144 00:08:48.510 --> 00:08:53.510 This is a the question that I normally get in China
145 00:08:53.550 --> 00:08:57.720 and sometimes I find it’s not so easy as it appears
146 00:08:57.720 --> 00:08:59.790 to discuss.
147 00:08:59.790 --> 00:09:04.290 According to a review in last HIV journal,
148 00:09:04.290 --> 00:09:08.700 they have identified 73 unique definitions
149 00:09:08.700 --> 00:09:10.773 for implementation science.
150 00:09:11.700 --> 00:09:16.050 So this definition I like it quite a bit
151 00:09:16.050 --> 00:09:19.890 but I still feel it is a little long, I prefer a much
152 00:09:19.890 --> 00:09:23.820 shorter definition modified on the definition given
153 00:09:23.820 --> 00:09:25.710 by the authors of this review.
154 00:09:25.710 --> 00:09:29.040 In my view, implementation science is a multidisciplinary
155 00:09:29.040 --> 00:09:32.490 specialty to seek generalized ology.
156 00:09:32.490 --> 00:09:34.830 So implementation science, one of the questions
157 00:09:34.830 --> 00:09:37.770 I got in China is it a field?
Is it a discipline?
Is it just a method?
I would say it’s a multidisciplinary specialty

I would say it’s a multidisciplinary specialty to seek generalizable knowledge, because it is a science

so it has to generate generalizable knowledge,
it is about the scale of reasons for the strategies
to close the evidence to practice gap.

So what implementation science is about is really to

put evidence-based practice into routine practice

and our research is trying to understand how large

that gap is and what are the determinants barriers

and the facilitators for implementing that evidence-based

practice and making it to a routine practice

and what are the implementation strategies which are also

intervention but we distinguish that from

the health intervention, so we call it

implementation strategies.

What are the implementation strategies which can help

close this gap?

So that is about implementation science,

so some of the other key concepts.

In order to do implementation research,

we have to start with health interventions

and those healthy, not all of the health

interventions can go into the process
We have to first have evidence this health intervention can be regarded as evidence-based practice (EBP). Once we have that, we need to understand the determinants of implementation, then based on that we will develop implementation strategies. We which we will tackle the barriers and the facilitators for implementing the EBP, some of them may come in from the health intervention itself, some are contextual factors. Then we need to understand the implementation outcomes which are different from the health outcomes and the clinical outcomes, then after that we make it into routine practice. Now let’s talk the PEDALs models we have developed.

First of all why we developed this model. Implementation science has already been inundated by the theories, models and the framework. A 2012 review identified more than 100 frameworks and it has ever since been increasing, why we are getting another framework. The motivation is from our students because when we are
teaching implementation science to a master
and an undergraduate students, very often we are challenged
to give them a quick way to understand the essence
of conducting implementation research.
PEDALs has been developed as a teaching tool
to wrap essential steps of conducting implementation
in an easy to remember acronym
and also this acronym supposedly need to have an appropriate
metaphor which can encompass
the implementation science essence.
This model has not yet been used, has not yet been published
or peer reviewed, but we have been using it
for our teaching already, so what is the PEDALs?
PEDALs has some of the letters and but first off
it’s when your PEDAL, your bike,
which has a image of a cycling forward with
PEDALs
which has a metaphor of moving forward with the
short cycles, which indicates implementation science
is very often indicating continued improvement.
This is not a graphical representation of a model.
So for the PEDALs for implementation science,
we have to start with your problems in your work, which can be a clinical problem, which can be a public health problem. Once you have identified this problem, you need to search for whether or not there are existing evidence-based practice EBP, which can address the problem you have encountered after you have identified an EBP. To address your problem we have to think about how to, what are the barriers and the determinants to implementing this EBP in your work setting. So after the good understanding of the determinants to the implementation of the EVP, we need to develop implementation strategies which can facilitate the adoption and uptake of this EVP, then finally we hope it can get into sustained use. All across this process there is a S for the PEDALs, a small s some has two meanings here for one way it is plural form so means this might be a cycle, a continuous improvement. Another meaning of small s is it is a scale so it is indicating we need to have monitoring and evaluation designs and the methods for particularly in the last two process of EBP.
developing of the determined determinants of EBP and also developing implementation strategy and also to test the effectiveness of the implementation strategy. All of that need to have a strong monitoring and evaluation design. So that’s use our shared medical appointment to illustrate those process first work challenges and problems starting with P. In China, China is facing with a severe diabetic epidemic. In 2000 we only have 22 meaning people with diabetes. But in 2019 it is already 116 meaning the prevalence has increased dramatically from 2.7% to almost 10%. And the way to deal with the diabetic management in China is primary is through primary healthcare. However, we have a challenging here in China with a very much overburdened public health and clinical workforce and there is also reported very poor quality of care and insufficient communication between care providers and the patients, there is also a very much lack of patient centered care. So the service model is insufficient to really integrate public health work and also the curative services
in diabetic management here in China. So we performed this gap analysis and we trying to identify whether there is other service model which has evidence which can meet and solve the problem we have encountered in this work setting. So that’s come to the second step evidence-based practice EBP. So in order to do that, first we need to have some understanding to what extent health intervention can be considered EBP, I don’t think we have some consensus on that, but most of the people I believe are familiar with this evidence pyramids evidence can change from expert opinions to cross-sectional studies all the way up to individual studies to synthesis of know to systematic reviews on the top. So normally for the journal implementation science and the implementation science communications, we will regard some health intervention as a EBP if they at least have several randomized control studies to support them in a health setting. But I have to say different settings, different studies, like some of the policy study, it’s very difficult to have randomized control studies.
295 00:17:17.280 --> 00:17:21.715 But normally in the healthcare vicinities in this setting we
296 00:17:21.715 --> 00:17:24.801 consider several randomized control studies or even better,
297 00:17:24.801 --> 00:17:28.560 more since that systematic reviews is good to prove it
298 00:17:28.560 --> 00:17:29.703 is an EBP.
299 00:17:31.111 --> 00:17:34.020 So with that standard, fortunately we have identified
300 00:17:34.020 --> 00:17:37.320 systematic review for shared medical appointment
301 00:17:37.320 --> 00:17:41.490 which has approved SMA is a good way to tackle
302 00:17:41.490 --> 00:17:45.690 diabetic management in countries outside of china,
303 00:17:45.690 --> 00:17:47.973 so what is the shared medical appointment?
304 00:17:48.895 --> 00:17:50.700 Shared medical appointment is a new method
305 00:17:50.700 --> 00:17:52.800 of managing your patients.
306 00:17:52.800 --> 00:17:55.410 In traditionally in China, patients are managed
307 00:17:55.410 --> 00:17:59.280 under one-on-one consultation.
308 00:17:59.280 --> 00:18:02.190 So one patient go to see the doctor one-on-one,
309 00:18:02.190 --> 00:18:04.830 but for shared medical appointment patients
310 00:18:04.830 --> 00:18:07.800 with similar conditions are grouped together
311 00:18:07.800 --> 00:18:11.760 and they go and see doctor together and sometimes also
312 00:18:11.760 --> 00:18:14.761 it’s not only one doctor, it’s a group of
313 00:18:14.761 --> 00:18:16.290 a multidisciplinary team come together.
314 00:18:16.290 --> 00:18:20.250 So it becomes a group and group consultation between
315 00:18:20.250 --> 00:18:22.050 and the education and the management
316 00:18:22.892 --> 00:18:24.930 between the clinicians and the patient.
317 00:18:24.930 --> 00:18:27.990 And there are systematic reviews suggest shared
and medical appointment has substantially improved clinical outcomes in terms of glucose control and blood pressure control and also it improves, it has a lot of benefits to improve patient behavior, self-management and also to improve (indistinct) adherence to best practice and adherence to clinical guidelines. And the very good is the study also suggests shared medical appointment for diabetic does not really increase the economics. So you don’t really spend extra money, have extra expenditures to manage your patients with a shared medical appointment model. So it looks like it is effective and it does not increase your expenditure. It is no brainer we should use SMA but unfortunately in China, China we don’t really use it a lot actually it is not used at all in all across China. So that’s why we need to go to the third step. We need to understand what are the determinants various and facilitators which are determine the implementation of SMA shared medical appointment in China in our setting, in our primary care.
So there are two types of barriers in the facilitators in my view. One is embedded with the shared medical appointment itself. So the health intervention itself can be a strong barrier then it moves to contextual factors. First let’s talk about shared medical appointment itself and what we need to do is we need to optimize SMA for the context of China. In that we’re going to use the method proposed by Professor Linda Conius. Linda Conius is proposing a method she has developed a code optimizing of bio behavior and biomedical interventions, the multi-phase optimization strategy call it MOST. So according to MOST, we have to first come up with a conceptual model for SMA for the setting of China because almost all of the health interventions are sort of the complex intervention for shared medical appointment it’s the same thing, it has many components. We need to decide what individual components for SMA can be combined together and it can be configured in a way which is best suited for the setting of China.
So we have developed this conceptual model, at least it has four components which are important for SMA, one is you put patients with similar conditions together so they go to see the doctor together. So this component can be versus individual one-on-one session. The second component is the patient can go accompanied by their family members. The third component it is a multidisciplinary team from the clinicians come to see the patient. The fourth is the education for diabetes can be either online or offline, so we have at least four components. So in this conceptual model, those campaign, those components works through one of those nine mechanisms, through those two types of mediators finally it can improve self-management of the patients in theory and finally to improve primary outcome of glucose control. So for the conceptual model it is good in a view, you have your components layout clearly and also have your mediators layout clearly. But mostly important, you have all of the mechanisms which are supposed to work to connecting each
385 00:22:17.340 --> 00:22:20.130 of the individual component to the mediators
386 00:22:20.130 --> 00:22:23.110 and in the end to the outcome health outcome
387 00:22:24.178 --> 00:22:26.370 and the clinical outcome you are trying to
389 00:22:29.970 --> 00:22:33.030 So with the development of this SMA conception model,
390 00:22:33.030 --> 00:22:35.670 we can develop with the information from
391 00:22:35.670 --> 00:22:39.255 literature and also with consultation with clinicians
392 00:22:39.255 --> 00:22:42.540 and the stakeholders, we need to really have
393 00:22:42.540 --> 00:22:45.750 optimization trial to really understand whether or not
394 00:22:45.750 --> 00:22:49.260 those individual components can work and
395 00:22:49.260 --> 00:22:52.020 whether you combine those individual components
together,
396 00:22:52.020 --> 00:22:55.290 they can be working together rather than
canceling
397 00:22:55.290 --> 00:22:57.690 each other out.
398 00:22:57.690 --> 00:22:59.970 So in order to do that we are going to do a
399 00:22:59.970 --> 00:23:01.890 factorial design while we are going to do a factorial design,
400 00:23:01.890 --> 00:23:05.250 because we have four components.
401 00:23:05.250 --> 00:23:08.430 Let’s say if we only have three components
402 00:23:08.430 --> 00:23:11.970 with the three components you can have eight
different configuration of those components and making
403 00:23:11.970 --> 00:23:13.560 them into an complex intervention.
404 00:23:13.560 --> 00:23:18.210 If we are going to do in the individual two
405 00:23:18.210 --> 00:23:22.320 arm trial, we need to do three separate randomized
406 00:23:22.320 --> 00:23:26.910 control study that is very time consuming and a very re-

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But with the factorial design as proposed by Professor Linda Conius, we can use one trial the same sample size, but we can deal with all three or four components, so with that study we can understand whether each individual component in your complex study is effective or not.

And even better with the design of a factorial design, they can also test interaction between those individual components. So that is important for implementation science because sometimes individual component can work, but if you put different individual components together, they may cancel out the effects from each other or they can virtually reinforce, so one plus one may be larger than two or less than two, so factorial design can deal with all those issues, so that is very good.

And also good to remember is most it’s not only concerning factorial design because it is optimization, optimization means not the best if it is not optimization.

We are only looking for health interventions which works
best in terms of improving health outcomes, but with optimization we are looking for under the resource constraints which we have agreed upon with the stakeholders what is working best. So we have to set clear, something we call optimization criteria, which can be money, which can be time to implementing SMA. So once you have those criteria set, we can do the factorial design we and the way we are going to pick up the configuration which best suited the resource concentration constraints. But under that umbrella, whatever configuration works best can be picked up for our final traditional randomized control study. So that is what we are going to do to select the components for our SMA in that way we can reconfigure SMA to the context of China. So suppose after we have optimized SMA itself for the context of China, we still need to understand this reconfigured and optimized SMA and what are the other contextual factors which can determine the implementation of this optimized SMA.
In order to do that we will use a lot of the frameworks.

You know, implementation science is inundated by frameworks, but use of frameworks is really the essence of implementation research.

I very much use this when I’m talking about implementation science theories, models and a framework without a theory.

Think about if you have many pieces of clothing, shoes, juries and you do not have really a very nichey and very neat, very nice walking closet, then you are buried in your clothing and if you want to walk up and do an interview, it’s very difficult for you.

But if you have a very good framework, which is almost like your walking closet, you can organize the things systematically and you can also standing on the shooters of many giants because other people have done the work of for you what are the items that you need.

So frameworks provide us with more systematic and comprehensive way of looking at it, the things you want to look at.
And we have very good taxonomy of series models and the frameworks and for the PEDALs we are going to use a determinants frameworks for the understanding of barriers and the facilitators and we will use process models and implementation series to understand how to develop implementation strategy. Then we are going to use evaluation frameworks for the evaluation of your implementation strategy. So for specifically for SMA, we are going to use a concern related framework for implementation research. Why we use this very commonly used framework, CFIR is probably most widely used implementation framework. Why we choose it, one of the biggest reason is it is very comprehensive and the second is it has a really nice website which has layout all of the tools and options and the literature concerning this framework and also the tutorials available, so it’s very easy to find resources. So once we have a implementation team and the research team if we use safer is much easier to teach the entire team how to use CFIR.
But CFIR is a framework, it is not a model. So by that it does not really suggest causal linkage between the components and the outcome. We are also considering use normalization process theory as a complementary framework to CFIR. However, I have to say, even though normalization process theory is very nice in terms of illustrating the causal linkage of implementing process and the outcome, sometimes it is not so easy to use. For instance, in this picture is one of our reconfiguration of the domains and the constructs from normalization process theory. We have spent quite a bit of time in studying and understanding NPT and organize it in a way our students and the research team can understand better. But even with that we still found some of the constructs of this model is a little difficult to distinguish like inter action workability relational integration and skillset workability, those constructs can be very easily like confusing for our researchers. However, it is still one of the rare implementation science theories specifically for implementation, so we are considering using it for SMA as well.
So how we are going to use it, this is a picture from the journey to the west, one of the very famous Chinese classic. It has many of the stakeholders for the journey from China to India to fit the classic scripts for Buddhism, so you can get the Buddhism back to China and implementing that. So essentially we want to do stakeholder analysis to determine and engage the community. We want to have community engagement involvement and engage in your stakeholders so we can determine what are possible the facilitators and the barriers for your implementation of SMA, so in this process we will use CFIR and NPT and use them to design or survey form. So those can be used as a quantitative survey form, but we will also use them to design interview guides. So we can use them to do in-depth interview or even use it for focus group and we’ll also use those frameworks to analyze data. So implementation science framework, CFIR and NPT.
We actually guide us throughout the entire process of our study. This is the barriers and the facilitators we have identified from the literature, not from a actual study as our study is currently ongoing. But now think if we have already determined the barriers and the facilitators to normalize EBP of SMA in our clinical setting in primary healthcare, now we need to develop implementation strategies to deal with each of the barriers. In order to identify implementation techniques, you can package those individual techniques into the package we call implementation strategy, which can deal with the implementation barriers effectively so we can improve uptake. We already have good studies in developing taxonomy of implementation strategies which are expert recommendation for implementation change. The ERIC, so ERIC is one of the popular framework which have categorized all the available implementation technique they can identify. But the key is really to, I identify those
available implementation technique which very often have already some evidence-based and match them to your implementation barrier. So this is a step critical in developing your action, which means developing your implementation strategy. But the key, the big challenge is what are the methods you can use to match entertainer implementation strategies to your barriers in your setting. This is a really a under-researched area in implementation science. However, one of the researcher has suggest four methods we can consider, one is called concept mapping, which is a visual mapping using mixed and methods. The map here is one of the visualization of the barriers in implementing some EBP. Then the second method is group model building, which is sort of the a causal loop diagram of complex problems. The third is a conjoint analysis, conjoint analysis has different forms. One of the most popular form is called a discrete choice.
experiment, which we are going to talk a little later

because we have opted for DCE Discrete Choice Experiment

for our study.

The last one is intervention mapping,

which is a systematic and multi-step development

of interventions.

All of those four methods have been extensively used in

other fields but not as much in implementation research.

So I'm really highly encouraging all of us

in doing implementation research to use some

of those methods in systematically match and retainer implementation

strategies to the barriers you have identified

in your study.

So for us, we are going to use a difficult choice experiment

tailor implementation strategies for SMA,

DCE is widely used in health economics,

but not as much in implementation science.

DCE belongs to the method in conjoin analysis,

in our team we have used the DCE before

in understanding healthcare professionals preference

for working in the primary care setting job preferences.

According to review, they have identified
DCE studies comparing different implementation strategies.
So it is not so much used as much in other field of work.
So use of DCE in our SMA study is like this in basically in DC you it’s a combination of a quantitative
and a quantitative work.
You first it’s most likely we’ll use a quantitative work and also literature review to identify what are the
possible implementation techniques to be developed.
So we develop those implementation strategies.
the techniques through initial review of literature
and expert consensus.
So for instance, if we have identified through this process
audit and feedback is one of the major implementation
strategy to deal with this barriers,
we have identified the DCE then can do the work of
to implementing SMA, because why we are going to do this,
because even it is called audit and feedback,
it actually has many components.
This is very much like EBP of SMA can be complex
Our implementation strategy can also have many components. So we can develop these different components of audit and feedback including format of feedback. Is it a verbal or written recipients of feedback? Do we feedback to individual clinician or feedback to the entire group? The source of feedback, is the feedback coming from that influential source like their peers or supervisor or is it coming from the researchers? How are we going to deliver the feedback by emails, by letter or in person? How frequent your feedback should be monthly or every four months. Now how the instruction for feedback need to be developed. Will it be explicit, measurable, targeted but no action plan or should it be accompanied with action plan, but no explicit target or in addition to audit and feedback, do we need to copy that with another implementation strategy? Say giving people financial incentive. If we are going to do the SMA, we give them extra money to do that.
Okay, so the audit and feedback and our implementation strategy have all those individual attributes and all those attributes have levels. So we can based on those, we can develop different choices.

We can present those choices side by side to our respondents, so they can choose between those two choices. Which set would you prefer is our approach to improve SMA in your organization. So they can make the choice, after the respondents the stakeholders have making all those choices from those choices then we can do a statistical analysis. With that we can determine how preference are influenced.

By each attributes and we can also give the relative importance of those attributes. And in particular, once we give a financial incentive here we can actually measure and transform a dollar amount, we can actually measure and transform all those attributes into something called the willingness to pay. So we can precisely quantify the value of all those individual attributes. So after we have done this exercise,
we can understand the preference of our stakeholders, what kind of audit and feedback they think might work best even though this is pre-implementation, so after doing this we can develop a complete package of implementation strategy. So after we have done this, the important thing before we can move this to sustain the use is to come up with very good monitoring and evaluation plan, which will entail to develop evaluation designs implementation outcomes and measurement tools. So let’s focus on this S part of the S model. First we need to understand what kind of design we want to tailor this into. There are something called a hybrid design. Hybrid design is sort of the design you are trying to balance to what extent you want to have this study as a effectiveness study of your EBP, which is SMA or to what extent you want to test the implementation outcome of your implementation strategy, which in our case can be audited the feedback. So depending on the priority of set to those two outcomes, it can be type one, type two or type three hybrid design.
For type two hybrid design, you are going to test both the effectiveness of the EBP and also to test the effectiveness of your implementation strategy, because SMA has not yet been done in China before. So it’s very important for us to test the factories of SMA, but it is also important for us as an implementation scientist to test the implementation strategy in implementing SMA. So we opted for type two hybrid design for implementation. For the use of a step wedge design, eventually everybody in your setting in your S participants will receive SMA. So this give the gradual implementation of SMA has some advantage, because then we can facing our manpower so we can ensure we really implement SMA in our institutions.
step by step gradually.

And also all sites eventually receive SMA means ethically it is better than some people only serving as controls.

Also it says the step wedge design has a great statistical property so with the same sample size, normally it has a much higher statistical power than conventional two (indistinct) control study.

But the complications of step wedge design is the analysis plan is much more complicated than the two randomized study and also the length of your study is much longer than your study.

So in our specific for SMA study in the study we are going to do the effectiveness trial for SMA.

So five counties in China, each county have two primary healthcare centers.

So we will randomize those five counties in those six steps, randomize them into receiving SMA gradually until in the end all of them are receiving SMA.

But for each of the county, one of the primary care centers, one of them will receive the audit and the feedback as a implementation strategy.
The other will receive another type of usual implementation strategy, so we can compare in this study both the effectiveness of SMA but also can use experimental design to compare the effectiveness of implementation outcomes for audit and feedback versus usually of implementation.

I just wanted to let you know we have less than 15 minutes, so I just wanted to make sure.

Sure, sure, sure.

I only need two more minutes to wrap this up.

I have a big timer on my side.

Oh perfect.

Reminding of that.

So we also have implementation outcomes, which I think people are already familiar with. The one thing I want to emphasize is for implementation outcomes, and also for patient and the service outcomes, they all have two dimensions, the absolute obtainment and also the equity which is the distribution of your outcomes among your stakeholders.

We’re going to use the RE-AIM as well, but there are many challenges actually in using a RE-AIM, RE-AIM is not as simple as it appears, because it is sometimes
756 00:43:55.350 --> 00:43:57.930 it’s difficult to operationalize say
757 00:43:57.930 --> 00:44:01.920 the implementation outcome for RE-AIM
framework,
758 00:44:01.920 --> 00:44:06.000 say how do you measure fidelity of delivering
SMA?
759 00:44:06.000 --> 00:44:09.571 One of the things we’re considering the mea-
760 00:44:09.571 --> 00:44:11.329 surement tool
761 00:44:11.329 --> 00:44:13.260 We have not yet decided on this yet, but
because
762 00:44:13.260 --> 00:44:18.060 we have already been the conducting a very
massive study
763 00:44:18.060 --> 00:44:23.060 of using standardized patients in assess quality
of care
764 00:44:23.130 --> 00:44:26.130 in China, which is a fake patients, but they
are trained
765 00:44:26.160 --> 00:44:29.970 so they control the case mix and there is no
766 00:44:29.970 --> 00:44:33.510 Hawthorne effects compared with other direct
observation
767 00:44:33.510 --> 00:44:38.510 of your clinical practice and using standard-
768 00:44:40.620 --> 00:44:43.980 ized patients
can also enable quick audit and feedback work.
769 00:44:43.980 --> 00:44:47.670 So we are considering seriously because of our
experiences
770 00:44:47.670 --> 00:44:50.490 and the expertise in using this method
771 00:44:50.490 --> 00:44:54.510 in assessing primary care quantity, we are
considering
772 00:44:54.510 --> 00:44:58.320 using this as a quantity outcome collecting
tool
773 00:44:58.320 --> 00:45:03.320 to understand the fidelity and implementation
process
774 00:45:03.510 --> 00:45:06.570 of SMA for our settings.
775 00:45:06.570 --> 00:45:08.790 If we are interested in this method further,
776 00:45:08.790 --> 00:45:12.180 you can check out two of the papers that we
have published

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to illustrating how this can be used in other setting.

So that is what I am trying to talk about this PEADLs model.

So basically this is the model is to give researchers and students to think about your thought implementation research from identifying the problem in your work. Then you need to identify EBP to address that problem, but you really need to understand what might be the barriers and the facilitators and based on that to develop your implementation strategy in order to achieve sustained use.

But all across this process you have to have a very sound and a good evaluation design plans and measurement tools.

So thank you so much, I hope this presentation can motivating some people to come for our program.

We give very nice benefits for people coming to China to do two to three year postdoctoral fellowship in implementation science, all of you are welcome to apply.

Thank you so much.
Great, thank you Roman, that was fantastic.
really a terrific presentation.
I’ll go ahead and open it up to questions.
If you have any questions feel free to just unmute yourself,
introduce yourself and ask or I see Donna has raised her hand.
Donna, why don’t please go ahead.
Hi everybody, sorry I’m on the train actually,
sorry I’m on the train actually,
I had to go into New York City today for an appointment,
so there’s some background noise I apologize for.
But Roman, I just wanna say that this was just an
absolutely brilliant talk where you walked us through all
of the essential aspects of implementation science
from the beginning to end and connected.
How these various theories and frameworks where they jump in
where we need ’em, what might be a recommended approach.
I mean just absolutely fantastic and I’m sure
the audience learned very much from this talk.
I know all of us struggle with the confusions
of these theories and models and frameworks and where they
fit in what is implementation science and the steps of it.
You just laid it out so clearly it’s just,
I’m just floored at how nice this was.
So thank you so much and on behalf of all of us for this, I have two questions actually. One comment you mentioned, you know I'm somebody who's done research on developing statistical methods for step wedge design, you mentioned two drawbacks. One is that it takes longer, which I completely agree with and I think it's worth documenting that better, because I'm not sure there's any kind of papers or publications that actually show that trade off. And then the other is, and people ask me and I know it's longer but I can't really say how much longer exactly. So I think it probably gets the longer, the more step times you have. But anyway, I'm not gonna speculate right now. But the other thing you mentioned was that the analysis was more complicated and it's true that in a parallel cluster randomized design, which is usually the other alternative, you can just basically compare the mean outcome rates, whether they're continuous or binary at the end of the study using a two sample tests, but you do have to account for clustering even there.
And then with the step wedge design, it’s only one step.

more complicated in that that comparison has to adjust

the time effect.

But there’s very standard statistical methods

that basically every kind of software to do a
generalized linear model or a regression model

that accounts for clustering and allows for

a binary intervention effect and then indicator variables

for every time effect and then perform the test

of the difference between the two groups based

on the regression coefficient using either a robust wall

or a robust square tests.

So I’m not sure why you felt it was like an actual barrier,

I just don’t feel that that should be so,

and then my last comment, because we’ve been chatting about

this is the issue of quality and how that fits into,

especially in low and middle income countries,

I think it’s sort of assumed in the United States

all you have to do is get the service out to somebody

and the quality is already very high,

we don’t have to worry about that.

It’s probably not true, but that’s the assumption.

But in low and middle income countries may be,
and it may not even be true, the quality issue is even bigger and it doesn’t seem to be something, it seems to be addressed in the health systems research field but not, I haven’t heard any chatter about it.

So anyway, my question was complexity of step wedge design analysis and then this issue of quality. And just thank you so much again for an absolutely like fantastic crystal clear talk.

Thank you Donna. I think I’m not a statistician, but I think this is precisely where statisticians like Donna, you can play a really big role in help strengthening the methods in implementation science.

Step wedge design has a lot of potential for implementation science, I think that is my understanding, but statistician can correct me.

I think it’s generally longer than traditional two RCT. The reason is for the steps, like the step here, we allow it three months for one phase, one step because for each step you have to have long enough a duration to allow SMA effect to be fully released.

If the effect cannot be fully released during one step,
you have to use even more complicated statistical method for analysis. So because in theory if it is a two arm RCT in three months you can wrap up this study. But for implementation for step wedge it is much longer, so that is one reason. In terms of analysis, I agree with Donna now compared with the several years ago there now have been many software R package coming out, which can enable analysis much easier. But still sometimes it’s difficult for researchers which have no statistical background to understand why they need to do this and why not. Sometimes it’s always good to embed some good statistician in your team even though the software can do a lot of work for you. In terms of quality of care, I agree with Donna, it’s a severe issue, increasing coverage is not the only thing to do in low income countries. The coverage without a quality service can be harmful and the risk of your resources. So that’s why our research team case study focus,
a lot of our study we use as standardized patient
to assess quality of care across seven provinces in China,
which is unprecedented, because of the implementation
of standardized patients is really very difficult
to that scale, but we have demonstrated it's possible even
using in that setting.
So we now have a precise understanding of the quality
in China, which is, I have to say very, very poor.
We have not yet get this paper out,
but once it is out we'll share, thank you so much.
Great, thank you.
I don’t know if there, we have a couple minutes left.
I think this is a great talk.
I really learned a lot about implementation science
and as I can see, I actually have a question about
the third stage in PEDALs, the third stage is determinants.
So I can see you list health intervention factors and also contextual factors.
So I would like to know whether you have insights on how to analyze or disentangle the relationship between health intervention factors and contextual factors, how would you consider their relationship? Like whether contextual factors can be considered as mediators or whether it’s hierarchical design. That contextual factors need to be on a higher level and whether it involve very complex analysis. Yeah, like what we want to get out of this analysis. Thank you Pungfe, actually in most of the implementation science framework, they put the barriers associated with health intervention itself and the contextual factors together in the framework like CFIR and TDF, many other frameworks, which already wrapped both elements in one framework. but I have tear them apart because in our SMA study, we essentially have decided to do this in two steps. One is to optimize SMA so it can work better in the Chinese setting, as I have described in the past SMA, although there are many RCTs to prove its effectiveness,
but most of them are in high income countries and almost none of them have compared head to head,

the individual components in that complex SMA study,

so we don’t really know what individual components can work best.

So after we have done that, then we go to understand for the optimized package complex intervention,

what are the contextual factors which can contribute in to the implementation of that health intervention SMA.

So in our study we sort of have clearly divided those into two steps even though the optimized SMA can still be a factor, which can create barriers in our final study I have to say.

The other thing is it’s very difficult to distinguish sometimes, sometimes people use contextual factors, sometimes environmental factors, settings.

Sometimes it is very difficult to distinguish the difference between them. I tend to not to distinguish them, because different people have different ideas whether one off to use other hierarchical analysis for the intervention factor and the contextual factor, I can’t answer that
because I need more time to think about that. I don’t yet have a clear answer to that yet, but I tend to think it may not be a hierarchical analytical question here. Thank you Pungfe.

I don’t yet have a clear answer to that yet, but I tend to think it may not be a hierarchical analytical question here. Thank you Pungfe.

I think Gloria was next. Great, I see a couple of other hands raised. I think Gloria was next. Great, I see a couple of other hands raised. I think Gloria was next. Great, I see a couple of other hands raised.

Thank you very much Maur, thank you very much. Very nice talk, I really enjoyed. You mentioned several techniques in order to choose the implementation strategies. And this is, you know very complex issue because you have a lot of implementation strategies that how to use them in the context or with the problem that you have and how to choose them, right? Is a like a real point in implementation process. Can you please elaborate on that? Thank you. I have some challenges of understand the question. Maur, can you paraphrase the question? Yeah. So basically, you know, you mentioned that you use several techniques to choose the implementation strategies.
So can you please elaborate on those techniques or methods that you use to choose the implementation strategies?

<v Roman>Oh, okay. </v>

Okay, thank you.

Thank you, sorry for that.

That’s okay, thank you.

<v Roman>Yeah, there are many implementation,</v>

to map your strategies to barriers.

I would say the simplest strategy is not one of those four.

The simplest strategy is simply stakeholder consensus.

For many time, if people do not have a higher level of methods, you can simply have a group consensus to be achieved through a Delphi process or a nominal group process.

There are many simple way of achieving stakeholder consensus on what type of implementation techniques, which you can select from the ERIC framework to match each of the barriers you have identified.

but the four methods here listed on this slide are more methods driven and I have never used
a concept mapping group model building and intervention mapping, but we have used a conjoint analysis in a way to use difficult choice experiments. So as I’ve discussed earlier, which is the sort of the questionnaire you have developed (indistinct). So you present those products, each product consists of different attributes of your implementation strategy. So you’ll present those products side by side to your stakeholders. They make a choice out of the two, but you have many of them. So once they have complete data, all of the choices, then you can perform a logistical regression and other statistical methods to really evaluate and quantify the value of those individual attributes. So then you can choose the attributes with the highest valuation and package them into the packaging of your implementation strategy, I hope this helps a bit. A lot if you, thank you. There are lots of literature. I’m using DCE in health economics and health service.
literature, it is not really a very difficult method to understand, so I can send out some of the literature as well.

Okay, you thank you very much.

Roman, thank you.

I know it’s very late where you’re now in China, but we have one last question if you wouldn’t mind.

Mariana, go ahead.

Yes, thank you so much for these great talk.

Mariano Kaori from the University of Miami Miller School of Medicine.

I just have a quick question.

Can you implement this very comprehensive study in five years?

Ah, that’s a good question.

That’s our hope in five years, but let me share the story.

I used to do a study using texting as a reminder for people with schizophrenia in the rural Chinese village to take medication.

The implementation is for six months and we thought
we are going to have that done simply within eight months, but it takes us three years. So implementation of those trials always take longer than we thought, but I have to say we are exactly trying to do this within four years time. But with, I think one of the element is the pandemic. A (indistinct) know China is fortunate in a way. We are not very much affected by the pandemic for the past two years. Our life here in China is essentially normal for majority of the people, so we are able to done a lot of the field work. But now with the omicron all the other part of the world are opening up, China has some challenges. So we don’t know whether in the future years whether this will be playing a part, but even without pandemic, sometimes it’s difficult to get the implementation done. However, what I have to say is we have develop it and really excellent consortium of collaborators in China. We have 12 research teams in China. We have always been working together and many of the health service and implementation research,
even without any grant support, our teams are working together, so we know each other extremely well. So when we are doing those multi-site trial, it’s almost much easier now to set up your team, because it’s communication is a simple and how to divide up your work is already established and how to share your intellectual property is prior grade upon and how to mobilize your resources and what are the statistical data management platform, all this has already been been constructed in our prior studies. So very easy for us to conduct multi-site study in China because of our existing work of the Acacia Labs with those a dozen research teams always be working together. We also have very strong support from the clinical centers, because we work with some of the clinical centers in many other ways, so we get to know them much better and we can get a support from them as well. So hopefully we can get this done within four years. But I have to say things happens, it may get longer than we thought, thank you.
1113 01:04:21.817 --> 01:04:22.870 <v Maur>Great.</v>
1114 01:04:22.870 --> 01:04:24.438 Great, well thank you again.
1115 01:04:24.438 --> 01:04:28.020 I don’t wanna cut off the discussion and the comments,
1116 01:04:28.020 --> 01:04:29.770 but I know it’s getting late there.
1117 01:04:31.080 --> 01:04:35.220 If there are no other questions, I’ll just end by thanking
1118 01:04:35.220 --> 01:04:36.990 you again, Roman, for being with us today,
1119 01:04:36.990 --> 01:04:41.130 it was a fantastic presentation, really enjoyed it
1120 01:04:41.130 --> 01:04:44.724 and learned a lot as I know everybody else did on the call.
1121 01:04:44.724 --> 01:04:46.710 So thanks so much for being with us
1122 01:04:46.710 --> 01:04:51.710 and see you all again soon, thanks everyone.
1123 01:04:52.140 --> 01:04:54.132 <v Roman>Thank you, bye-Bye</v>
1124 01:04:54.132 --> 01:04:55.098 <v Donna>bye.</v>
1125 01:04:55.098 --> 01:04:57.319 <v Roman>Thank you, bye-Bye, bye-Bye.</v>
1126 01:04:57.319 --> 01:04:58.152 <v Maur>Bye everyone.</v>