People join.

We can just let them in.

So I just wanna say good afternoon.

My name is Christine Simon.

I am an associate research scientist in the Department of Social and Behavioral Sciences.

and at the Center for Methods in Implementation

and Prevention Science here at Yale School of Public Health.

I am delighted to introduce our Ready Hub webinar presentation and presenter, Dr. LaRon Nelson.

But before I do that, I just wanted give you a little bit more information about our hub.

Leveraging the expertise of Yale Center for Methods in Implementation and Prevention Science

and Center for Interdisciplinary Research on AIDS,

Ready, R3EDI, the Rigorous, Rapid and Relevant Evidence Adaptation and Implementation

to Ending the HIV Epidemic.

Implementation Science Hub provides technical assistance to more than 10 Ending the HIV Epidemic projects.

we have so many acronyms. (chuckles)

Ready does this in collaboration with the Implementation Science Coordination,
Consultation and Collaboration Initiative, also called ISC3I, creating opportunities to translate local knowledge into generalizable knowledge whenever possible. Ready offers comprehensive expertise in implementation science methods, frameworks and outcomes in HIV AIDS research.

I just also wanna let everyone know that this event is co-sponsored by the Yale Center for Methods in Implementation and Prevention Science, also known as CMIPS, and Yale Center for Interdisciplinary Research on AIDS, CIRA and ISC3I. So if you would like to know more about future Ready Hub webinar events, please notify Dr. Debbie Humphries in the chat, and she’ll make sure that you’re added to our email list.

So today’s presentation is titled "No Black Men Left Behind: Conundrums and Considerations for Designing a Multi-Level Hybrid HIV Implementation/Efficacy Trial." And it is being presented by Dr. LaRon Nelson, who is the Associate Dean for Global Affairs and Planetary Health and Independence Foundation Associate Professor of Nursing.
He has so many accomplishments, but just to highlight a few. Dr. Nelson’s domestic and international research investigates the implementation and effectiveness of multi-level intervention strategies to reduce race and sexuality-based disparities in HIV outcomes. He’s recognized as the world’s leading authority on the application of self-determination theory for HIV prevention and care. His research also involves identifying interventions to address intersectional stigma at the organizational level and treating the traumatic effects of intersectional stigma that manifests at the individual level. His work in research and implementation science spans multiple countries.

He co-founded the Central and West Africa Implementation Science Alliance, a collaboration of implementation scientists in implementing agencies from Cameroon, Congo, Ghana and Nigeria, aimed to improve HIV-related outcomes among adolescents in the region. He is also leading implementation science efforts to reduce racial disparities in HIV incidence, treatments and viral suppression.
His work in the US focuses on the use of multilevel social, structural, behavioral and clinical interventions to reduce HIV infections among black MSM. He’s also currently part of a multiple EEG supplement addressing rapid PrEP and HIV prevention.

It is with great pleasure that I turn this presentation over to Dr. Nelson. Thank you so much for doing this.

Welcome, everyone. Thank you for making time with this presentation.

What I’m gonna do today is perhaps a little bit different because I won’t be presenting on outcomes of research, but this is essentially a presentation and discussion about research and progress. Slides are loading in progress. Let’s see if we can get ’em up here. And so this is the title, "No Black Man Left Behind.” Really thinking about what were some of the conundrums and things we should be thinking about for designing.
98 00:05:06.480 --> 00:05:10.860 a multi-level hybrid HIV implementa-
99 00:05:10.860 --> 00:05:13.710 tion/efficacy trial.
100 00:05:13.710 --> 00:05:16.710 And hopefully some of what we’re learning,
101 00:05:16.710 --> 00:05:18.781 those of you out there who are thinking
102 00:05:18.781 --> 00:05:23.250 about similar types of work and the opportu-
103 00:05:23.250 --> 00:05:25.350 nities it offers,
104 00:05:27.420 --> 00:05:30.510 but also the challenges that are involved.
105 00:05:30.510 --> 00:05:33.960 The work today I’ll talk about was done in collaboration
106 00:05:33.960 --> 00:05:35.670 with a lot of people, but principally with Chris
107 00:05:35.670 --> 00:05:39.150 Beyrer
108 00:05:39.150 --> 00:05:40.710 who’s at Duke University.
109 00:05:40.710 --> 00:05:42.270 He’s the director of Duke Institute for Global
110 00:05:42.270 --> 00:05:45.750 Health,
111 00:05:45.750 --> 00:05:48.630 and Bob Remien.
112 00:05:48.630 --> 00:05:50.780 They’re not here today presenting today,
113 00:05:50.780 --> 00:05:52.020 because this webinar we’ll talk exclusively
114 00:05:52.020 --> 00:05:55.170 about HPTN 096, it’s important for you to
115 00:05:55.170 --> 00:05:57.330 know
116 00:05:57.330 --> 00:06:00.450 that three of us are leading that together.
117 00:06:00.450 --> 00:06:04.920 So right now there’s still a marked racial disparity
118 00:06:04.920 --> 00:06:09.330 in the coverage of PrEP.
119 00:06:09.330 --> 00:06:11.830 If we look at the most recent data from the
120 00:06:11.830 --> 00:06:14.431 CDC,
121 00:06:14.431 --> 00:06:18.810 this is what the slide is showing.
122 00:06:18.810 --> 00:06:21.750 And this is from 2019.
123 00:06:21.750 --> 00:06:25.830 Overall, the nation is still at about a quarter
124 00:06:25.830 --> 00:06:11.830 of people who are eligible for PrEP
125 00:06:11.830 --> 00:06:14.431 have been prescribed PrEP.
126 00:06:14.431 --> 00:06:18.810 So that’s about halfway towards the EHE goal
127 00:06:18.810 --> 00:06:21.750 of getting to 50% by 2030.
However, that 23% really is driven principally by the high degree of PrEP prescription among whites. So that is 63%. If you look at Hispanic and Latino, is 14%, and blacks including African-Americans are not even 1/10. And so the large number among whites mask the disparity that exists, black folks who are eligible for PrEP are not being prescribed PrEP and thus black not using PrEP.

We see similar, although not as stark source of patterns, with viral suppression, there are still racial gaps. You see overall the rate is about, the proportion is about 66% of people with HIV being virally suppressed in 2019. But if you look across three racial groups, just social groups, mind you, that blacks and African-Americans represent 61%. Only 61% of those with HIV are virally suppressed compared to Hispanics and Latino, which is slightly higher and then highest among people who are white. And then the HIV epidemic itself is also, there are disparities geographically. We know that the epidemic really is concentrated in southern US states.
Ton of social, structural and behavioral reasons for that also, but what you see on the map on the left is the HIV prevalence.

And you can see that it really does pool along the South Atlantic seaboard, even Atlantic Coast more generally, across the Gulf of Mexico states. The map on the right shows you a similar pattern. These are HIV diagnoses by US county. And again, along the southeastern Atlantic coastline across the Gulf of Mexico, you see that those where we’re having the most cases.

And then if we look more specifically at black MSM in the South, you find that they are highly overrepresented in new HIV cases. So what you see on this slide are cases of HIV, new diagnoses of HIV among men who have sex with men, grouped by region: Northeast, Midwest, South and West.

So you can see clearly that most of the new diagnoses are happening in the South among MSM. That accounts for more than all the diagnoses in other regions put together is in the South. And if you look specifically in the South among MSM,
black MSM represent the vast majority of the cases among MSM in that region. And then this is perhaps one of the most important slides I’ll show you in terms of background, is that there have been several innovations, biomedical innovations that should have an impact on HIV incidence. There’s some things that are done in HPTN, the HIV Prevention Trials Network. So in a 052 study, they establish U=U, that if a person is virally suppressed and undetectable, they cannot transmit the virus. There was discovery of the efficacy of oral Truvada for PrEP and then the introduction of rapid HIV test cases that could be taken at home. All very important innovations. And what you see that between 2010 and 2019, that those innovations, you know, we can’t say that it was a direct link to it, but if you just look at how the graph along that timeline, you see that the HIV incidence among white MSM declined over time pretty much corresponding with introduction of these new innovations. And that’s not unusual, that’s not unexpected.
That’s the reason why we do, scientists do this type of research to have an observable impact. So you’ve seen that among white MSM. But at the same time, that trend among black MSM from 2010 to 2019 is relatively unchanged. Even with the evidence of U=U, even with the introduction of Truvada for PrEP, even with the introduction of rapid home test kits that those, the introduction of those innovations into the health system or the healthcare marketplace has not seemed to have any impact on the HIV incidence among black MSM in that 10-year time period. And so there are reasons for that. And I think in the HIV prevention world, many of the reasons that we’ve investigated for many years have been behavioral reasons ‘cause they must be have more sex than the white MSM, or that’s probably the principle reason that we’ve investigated and ways to sort of minimize people’s exposure to HIV through sexual behavior. But through a lot of work, including some work that’s happened at Yale,
we know that there are other factors that are structural factors and social factors. I won’t even give an examples of them right now, but, or maybe I will give an example. So even more recently in the US District Court out of Tarrant County, Texas, that’s Fort Worth, there was a recent ruling that employers were no longer obligated to provide coverage for PrEP as part of their insurance plans. And so if they’re black men, white men, black women, Hispanic women who wanted to take PrEP, there will be barriers to taking it if their employer didn’t cover it, right? That’s not a behavioral factor. That’s a structural factor that can impede the ability for communities to achieve prevention goals. And so that’s just one very recent example. But there are a number of examples that, over time, we’ve come to understand that the situation is much more complex than getting a person to do a thing, that the way systems and social norms, stigmas confront and constrain people’s ability to enact the behavioral goals has an impact on this epidemic. And we contend that this is, more than contend,
we understand that this is part of what is happening
with why we can have the development of these types
of innovations and not have an impact on black MSM
in terms of what we see with the viral suppression data
or the incidence data is because there are structural factors that are making that very difficult to attain.
So what we decided to do with HPTN 096 was to develop and test an integrated strategy that dealt both with behavioral factors, that dealt with social factors, and that dealt with structural factors.
And so we identified interventions that address all of those things.
And we're testing this, well,
there are four components of that intervention.
The first is social media influencers.
So I thought was that we have to tackle this at multiple levels.
We can't just have another study where we enroll a cohort of black men and zero in on an intervention on them and follow them over time.
Because that that essentially is a behavioral-focused intervention.
They needed something that addressed these issues at multiple levels.
And so the first component was to use social media influencers who could really have an impact on norms, norms around stigma, norms around HIV prevention and HIV treatment.

A second component to that was a culturally-responsive intersectional stigma prevention, or CRISP for short. That is an intervention that is targeted specifically at healthcare facilities. Because the experience that black men have when they’re going to facilities can either optimize their prevention goals or treatment outcomes or can undermine it.

And so we thought, beyond doing something that was at the community level, that it needed to be something that was focused at transforming healthcare environments, so intervention focused at the organizational or institution level. There’s a peer support component which is a behavioral-focused intervention that is targeted towards black men, black MSM specifically in this study, that’s designed to offer them access to peer support that’s not, doesn’t require them to have to meet in person,
which is de facto disclosing people’s sexual identity,

which may not be acceptable in some of the places

where the study is happening.

And then the last one is the health equity-focused intervention, which is the structural intervention.

This is a coalition model where people are coming together,

people, organizations are coming together and finding different ways to cooperate, right?

The system is the design a particular way,

but we’re saying the system’s not serving black men,

they’re not serving black MSM in particular.

And so how might you cooperate, the church,

the employment agency, the immigration office,

the health department, the police department,

the rape trauma center, how might you, the food bank?

Is there a way to restructure how you work together

that’s gonna help bridge these gaps that the men are falling through and it’s contributing to the reason

that we’re not seeing incidence decrease and viral suppression rates increase?

So those are the four components of the intervention.

CRISP, peer support, social media influence and health equity.
So we said, "Okay, if we do these four things together," right, if we do this multi-level strategy that are addressing issues that we know are complicating us achieving this goal with black MSM, we can increase rates for HIV testing. And then among those who don’t have HIV increased the use of PrEP. At the time we only had oral PrEP, but even with injectable PrEP. We can increase that and then increase the proportion of black MSM who are protected from acquiring an HIV infection if they’re exposed. And then among those who are diagnosed, we can increase the uptake in adherence to ART and increase the proportion of those black MSM who are virally suppressed. And if we can do these things, which is consistent with the EHE strategy, these are three parts of the pillar, that we can reduce HIV incidence among black MSM in the South, because that’s personally concentrated. So we’re testing this, the things I described to you. We don’t know that it will work. We hypothesize that it will work, but we don’t know.
How we plan to know what’s doing testing it in this cluster randomized controlled trial. It involves 16 communities. It involves delivering the integrated strategy and the intervention communities. And the communities who are randomized to standard of care will continue to do whatever it is that they’re doing in their communities to advance their EEG goals, but without the added, the addition of the integrated strategy. And then we’re measuring our endpoints at, in two ways. The first is we’re looking at viral suppression through partnership with the Centers for Disease Control. So we’ll look at surveillance data to see whether or not our intervention, the way that is applied, can have an impact on CDC surveillance of HIV viral suppression among black MSM. And then we are doing an assessment, a cross-sectional assessment of black MSM sampled from each community to determine the prevalence of PrEP uptake in those communities. So these are the 16 communities. We group them into pairs, and we randomized within each pair. May not be able to see it well,
but the communities that have the stars next to it
are the ones who are randomized to the intervention community.
And we started this in a pilot.
So we started a pilot maybe earlier 2022,
seems like longer than that.
So we’re piloting it and two pairs,
which is about coming to an end of that phase.
That’s Dallas and Houston, Texas being one pair,
with Dallas as the intervention community.
And then Montgomery, Alabama and Greenville
being the second pair in Montgomery was the,
or is the intervention community.
I think we developed this beautiful logic model.
This is based on the implementation research logic model
that I think came out of the team at Northwestern,
which is also part of ISC3I.
So we use this to think about how would we implement these,
this intervention strategy given that’s gonna be implemented
in places where it requires people who work in organizations to take the intervention and use it.
So it’s not a sort of classic drug trial
where you enroll people, you give them an intervention
or a pill and you see the outcome.
These organizations have some role in taking these strategies and improving their practice for us to see the outcomes. So we need to think about what are the things that are gonna influence that, what are the determinants? How might we influence that? That’s the implementation strategies. That’s what our integrated strategy is, an integrated implementation strategy. And then we map the outcomes based on what we think the mechanism of action will be. And so again, in this study, we’re not testing the efficacy of the biomedical innovation. These clinical interventions exist. What we’re trying to do, in a sense, is test how we can get them scaled, taking the scale in these communities, and can we also observe the impact of scaling in these communities in our final outcomes which are viral suppression and PrEP uptake. So these are the considerations that I wanted to sort of get into. So the first thing in doing something complex as this is community engagement is very important. Neither Bob or Chris or I live, Chris lives there now, but live in this place where we’re gonna do this study.
And even if we did, we didn’t live in all the places that,
we didn’t live in every neighborhood.
We weren’t familiar with every place in this region.
And so community engagement was gonna be key.
We needed people who knew what it was to live in the South,
who knew what it was to live the black social experience
in the South, who knew what it was to be a man
who has such desired for other men,
or who engaged in sex with other men,
or who identifies as gay bisexual in that geographic context.
We spent a lot of time designing a strategy that would really infuse community engagement throughout everything that we did.
It was really a three-level strategy.
The first was helping to raise general awareness
about the study through local stakeholders
and through national stakeholders
who were recognized members of the community.
Then we had a community specific-engagement component,
which is really designed to make sure folks understood these different elements of the integrated strategy,
but also that community members could inform our development of these elements of the integrated strategy. And then the third was making sure we could identify people who could participate in the cross-sectional assessment, or baseline survey and sampling. And, initially, we had three types of groups that we identified or assembled: a community strategies group which was really a group that provided strategic guidance to us. These were folks who were involved in healthcare and policy and research in different parts of the country, mostly in the South but not exclusively in the South. It helped us think about how we were designing this study, what we should be pursuing, what pitfalls we should avoid. A community advisory group, which was our primary advisory body for the study. These were made up of people who really had to live in the community. So we had at least two individuals, not all black men, but mostly black men who were from each of the 16 communities where the study was being conducted.
It didn’t matter whether it was the intervention community or standard of care.

We needed people from there who could really help us understand what we needed to be doing or be aware of in these communities.

And then finally, we had community liaisons who really were our gatekeepers. These were the people, you see them across the bottom of the screen, who were our connection to the communities, both me as one of the protocol chairs and also our senior research managers. They helped us understand what was going on and were really the ambassadors, if you will, for the study in their communities.

These represent Dallas, Texas, Montgomery, Greenville and Houston, Texas.

And we obviously had to do a lot of communications. And so this is just showing a couple things, a website was developed to make sure people could go to it and understand aspects of the study.

We presented at multiple conferences at community events. And then we had to also in some ways sponsored community events.

I mean, I think typically,
and I think we suffer from this also in this study, is we see the community component as a bit of an added benefit or a luxury. And what it means is that when we allocate budget, we allocate it towards the things that are key or important. And if there’s money left over to do the nice-to-have things, then you might sprinkle, but not essential things, then you might sprinkle, (chuckles) you might put some money in those areas. But I think that’s a mistake. The community engagement part is essential. There’s no way we could even get to these places and try to implement half of what we’ve done were it not been for our engagement. And it also can’t just be transactional. And I mentioned this because I mentioned a few moments ago about the need to sponsor events. So the trials and investment in the community had to be more than you being able to bring us participants. So we had to be there and also show interesting things that they were doing, even if it was not directly tied to the study, that they can be constrained to that, if your grant funder doesn’t approve for you
to do certain things with the fund that promote this.

But had we not done these things, I think it’s quite likely that we would not have been welcomed or not seen as serious partners in some of these community areas.

And so the community investment is a key consideration, I think is also a common pitfall that happens when you’re designing studies and particularly how you’re resourcing trials.

So we did the baseline cross-sectional assessment in four communities.

And three of the four, we’ve already reached our target.

So we did this because the intervention is being applied at the community level, as I mentioned before, we’re not following a cohort.

So because we’re not doing that, we needed to use a sampling method that we thought could give us (sneezes), that we thought could give us a population estimate we could sample this way and have a pretty good sense that this is what’s happening in the community, both that baseline and when we do our follow-up assessment.
And so we use this Starfish sampling method. And what you’ll see, this is data as of Monday that we’ve reached our target. The target is 100 people per community in the four that were in the pilot. So we reached our target three of the four communities, in some ways exceeded the target. Are there reasons that we had to always (indistinct) some places, but at least in three, we have reached at least 100 people that were enrolled. And in one community we’re a little bit ways away from reaching the 100 ’cause we’re currently at about 80. So here is the challenge. We think there are some assumptions about Starfish sampling that, not even some assumptions about that might be cultural that might not really reflect the way that black communities operate or move about in the South. And there are also some constraints. So for example, in order to try to reach a representative sample, you can’t just go to a party or event and talk to every person that you encounter, right? In some sense, that becomes a convenient sample.
And so they’ve had to space out how many people they could when they would count a person. So every third person could be recruited, and then up to 10 people per event. And then you would stop recruiting, and you wait for another event. You’d approach every third person, up to a certain number of people at a time. And so, from a statistical standpoint, you can understand why that would be important to do if you’re trying to achieve what Starfish is supposed to provide in terms of representativeness. But it does create challenges because it does not, it imposes constraints. So for example, it takes much longer to recruit people in these contexts using Starfish because, especially in COVID, there are not sort of regular normal places where black gay men or black MSM can gather in a place like Montgomery, Alabama or a place like Greenville, South Carolina, or even some parts of Texas. And so the opportunities to recruit become smaller in places where you don’t have an infrastructure that’s set up where there’s normal gathering places.
for black sexual minority men, right?
So this was a conundrum.
We want to use this strategy because we wanna have
some rigor and understanding that the sample
that we got
represents the community overall.
But it’s hard to implement this (chuckles)
because of the parameters of how you have to
operate it,
which means it’s gonna take us a much longer
time to do it,
and the studies already started.
And so we don’t wanna still be recruiting a
baseline sample
at the point that we already had to,
we don’t wanna be recruiting the baseline
sample
at the point where we’ve already had to start
implementing the study because it’s taking so
long
and we can’t wait to get the sample
before we can start because of timelines.
So that was a conundrum but something to
consider.
For social media influencers,
we had influencers
from at least each community.
This was also very exciting for us
because of the potential impact
and reach of social media influencers.
But it also had some conundrums for us, some
challenges.
So the first is that because we are testing this
In a randomized controlled trial, we were very concerned about contamination, that we have to find social media influencers whose influence is really isolated to the intervention communities, because we didn’t want them influencing people in our standard of care communities, not for the intervention component. And so the first is that is hard to do. The people that have the most influence, their influence is not isolated. (chuckles) Their influence is broad, and having people like that violates one of the principles of conducting a randomized controlled trial. But if you can identify influencers who have very limited reach, which can allow you to have a social media influencer that will not have such a broad reach that they would contaminate other communities, it doesn’t really allow you to, (chuckles) it doesn’t really meet the intent of the social media influence because you need somebody with limited influence in order to conform the parameters of a trial. And if you got influencers who really have broad influence and people would listen to,
that would quite easily violate the parameters of conducting a randomized controlled problem. So we've had to learn from this. One of the ways that we thought about is that we might have to relax that and think about, you know, what we would lose by having a broad influencer who might have influence in some of the other communities compared to what we would gain by having an influencer that could really represent what this intervention is supposed to be.

For peer support, these are, the pictures that you’re seeing are the people on the team. And so these are our six peer supporters, Antoine Jackson who is their clinical supervisor. As I mentioned, the peer support is designed for, it’s online, and you don’t have to be signed up with any particular agency to receive the support.

We train them, we train them intensely, over 40 hours of training, And we develop a comprehensive promotional program to get people to participate. And we didn’t have, at least right now, robust participation.
And we try to understand mostly with the help of our community advisory group why that might be the case.

Partly because peer support requires trust, and trust takes time to build.

And that this trust building really was not aligned with the study timeline.

In some of these places where there’s high degrees of stigma where living as an out black gay man, or even if you’re not out, people finding out about your sexuality if it’s a minoritized sexuality, can have very serious consequences for people.

And so for folks to access these things, folks have to trust that it’s not gonna get them in some type of trouble or situation.

They don’t want to be in.

And that building that type of trust takes time, and more time than we had (chuckles) for the study timeline.

And so we didn’t have great uptake.

In this particular component in the timeframe.

That we were trying to look for, which I think it was probably too narrow.

And so one of the things that we considered is that we probably don’t need a centralized...
The peer support program was not connected to an agency. The reason we had a centralized program is because people were concerned that in order to get peer support, you had to go to the Spiegelman clinic. If you're not a patient at the Spiegelman clinic, you don't have to become a patient just to get peer support. And if you wanted a patient there or if you didn't like going there, you could go to the Nelson Health Center to get peer support.

If we anchored it to a clinic, we thought it may be better to not anchor it into a particular clinic but to offer the program to resource multiple organizations in the community. Because those clinics and organizations were trusted, hopefully trusted organizations, that this could facilitate the implementation in ways that trying to do it centrally from a research site.
cannot accomplish in the timeframe
And this next one is really the CRISP.
Again, CRISP is focused on healthcare facilities,
really to reduce the amount of stigma
that people experience when they go there,
both in interpersonal interactions
but also in how services might be delivered.
And CRISP has these five components:
client observation visits,
which are simulated clients that we train
who go in as patients, simulated patients,
and have an experience in that clinic
and then have the ability to offer feedback
about what it was like to be a black gay man
playing that character in that clinic space,
or CBO space, but mostly these have been clinics.
Or providing a foundational training
which is basically 12 contact hours of stigma reduction
intervention workshop.
And then quality improvement, which is how we take
what we’ve learned and translate that into service changes.
So we worked, we tried this with four facilities.
One is Parkland Hospital,
which is a large public safety hospital in Dallas, Texas,
and Abounding Prosperity, which is a community-based clinic,
organization with the clinic in Dallas, Texas,
and then MAO, which is in Montgomery, Alabama.
They have a treatment facility and a prevention facility.
So we were able to, this green that you see is showing that we completed surveys,
we had simulated client instructors,
observers go in and make those visits.
And we met all our training goals,
which really was that we could get 75% of people in those facilities who do HIV prevention work
or are along that HIV prevention or treatment pathway,
that we could get at least 75% of those people trained.
And we had as much as 99% coverage in some places.
Parkland was at 77%, and Abounding Prosperity at 83%.
But those are great successes,
but they’re also challenges to it.
The first is that
we have to have a pretty strong business case
for doing this
in healthcare facilities or a pretty substantial incentive
because the time that the facilities take out
to participate in this, the stigma reduction intervention,
which is important, but it is time that they’re not spending doing things that they could be billing for and generating revenue, which is not trivial. So it’s something we have to think about to do. We did provide an intended, which we thought was fair, in the design. But in the implementation, it is becoming clear to us that sites are feeling that they’re giving up a bit more to participate in this than is covered by the compensation that we provided them for participating. So it’s something to think about because we couldn’t do, we can’t force the clinics to do it, to participate in this, but in order for us to reach black men and black MSM, we really have to be working in clinics where we know they’ll go, they’ll likely have to pass through to get care. Related to that is (chuckles) one of the things that we thought about is how can we, what number of clinics do we need to target to maximize the reach that it will get to black MSM? Is it 10, is it 20, is it 100? We can’t afford 100 in each city, but we need some way of figuring out how we do that.
For HIV primary care, that’s a bit easier because those sites are relatively few in each city.

So we could essentially target all HIV primary care facilities. And this chart here is showing you what we would do.

So there are four facilities, that if we targeted them and check (indistinct) stigma reduction, we would be in facilities that had patient volume that accounted for 65% of the black MSM living with HIV. This is in Shelby County, Memphis, Tennessee. So for four clinics we could get 65%.

Those clinics would cover 65% of black MSM. And then if we get additional four clinics, we can get as high as 80%.

But then after eight clinics, the additional yield, the additional coverage we would get gets smaller and smaller.

So that’s something to think about is how we, that we’re thinking about, is how do we get coverage in terms of population coverage of black MSM, but we don’t have a lot of time and we don’t have an infinite amount of money to do it.

But we could at least accomplish quite a big yield in HIV primary care.
The larger challenge for us though is in trying to find the right coverage, the maximum coverage for facilities who provide PrEP or who could provide PrEP. Because essentially that’s any primary care facility anywhere should have the capacity to provide PrEP. And so we’re trying to figure out what that is. The other challenge in trying to figure out that number, the imperative, I guess I would say, is that we can’t end up with an intervention strategy that can only be done in the context of a trial like this, or healthcare facility strategy that could never be done. But the CDC would say there’s no way we could support this in our budget, or that agencies in these communities could take this up. So what we’re thinking about now is taking an epi-focused approach to selecting the healthcare facilities.
That is looking at global information systems data, or GIS data that should be available from health departments. Understanding what are the high STI burden census tracts in these areas and what clinics are in those areas. Because the HIV risk, as we saw earlier, is not evenly distributed, even probably across communities. There are probably certain communities where STI as an indicator of risk of acquiring HIV are more concentrated or more prevalent than other parts. So we are thinking we should find out where those places are and what clinics are in those places, and in what proportion of that census in those clinics or the patient role are black men represented? And I say black men because in many of these places, we don’t have a denominator for black MSM for a lot of reasons. Why it doesn’t ask question, or they ask the question and the person is not comfortable telling the provider about that aspect of their behavior for a variety of reasons. And so we don’t have reliable estimates of black MSM
from a prevention side in many of these places in almost all of these places.
And so, but we do know the number of black men.
And so if we can identify the places, the highest number of cases of STIs among black men,
if we can reach those black men, black MSM are a part of that group.
And so we’re trying to figure out ways to determine how can we figure out where the highest need is,
or the biggest impact that does not require us to try to sample all the clinics, which we cannot do.
And even if we could do it, it is not a sound public health strategy because it probably could not be implemented in most places in the United States because of the heavy lift and the cost.
And then we also thought about this idea of spillover.
So if we can identify, let’s say, index clinics that are in these places of high STI burden, then might there be a way to, if we reach those, that there will be some spillover effect in other parts of the community which can also help us reach that coverage.
This is a paper by some of our colleagues at Yale,
including my friend Donna Spiegelman and Sten Vermund that looked at that in one particular study. So it is something that we’re trying to think about, is can we look at, can we use a targeted strategy, identify index healthcare facilities and then estimate some spillover effect to other parts of the community, which I think is likely impossible. And then the last component is the health equity component. Again, these are local community coalitions. They’re both local and regional. In Dallas, we have Abounding Prosperity as the lead organization. In Montgomery with the Medical Advocacy & Outreach, or MAO. And then the regional organizing agency, a coordinating agency is the Southern Black Policy Advocacy Network, which is led by a black openly gay man, open living with HIV. And next week he might be the first openly black gay man with HIV serving in the Texas State House. He’s on the ballot, I think he’s gonna win. So this was also not without challenges. The first is that when we started this, we used a centralized model,
which was with the Black AIDS Institute, which is, many of you may know it. It is a vitally important, famed institution in the black community and for the country. That partnership did not work out. And so the challenge with the centralized model is that, if the partnership doesn’t work out, you have to start all over because if you only had one partner. So we thought that introduced too much instability, but we thought that made us too vulnerable to have one implementing partner. And so we decided to go to a local model, which I think was more culturally appropriate in many of these places to do a local model. So that has worked out well so far. Another challenge is that Medical Advocacy & Outreach, they filed for bankruptcy; I don’t know, a week ago, two weeks ago. And so, we’d already learned from our experience with having our health equity component focused in one agency. And so we expect that for many of these agencies and many of these areas that we will have some that struggle and that might cease operations or change management or change ownership.
So we don’t treat this as an isolated incident. This is one of the structural factors that impacts HIV prevention goals among black MSM. What we had to do was figure out how do we build in some resilience in this model so that when those changes occur, which we expect will continue to occur as we do this in the other cities, that we don’t become so unstable that we can’t complete this intervention in.

So what we did was the coalition happened to already be built in Montgomery. MAO had already designed a coalition. And so we tried to center the intervention as part of a co-owned community coalition, that it didn’t belong to the organizing agency. So that if the organizing agency changed hands or for some reason they decided they didn’t want to do it or they didn’t meet grant contract deliverables, that the coalition could still function for a time till we found another agency to lead to serve as the lead organizing agency. And so just things that consider, having gone through all these things. One thing that we realized, even though we’re conducting a randomized control trial, that we have to figure out ways to adapt.
We say sometimes, "We have to bend or we’re gonna break.”

And I think we’ve seen that,

that we try to figure out how we’re gonna sort of adjust as we go along.

So I would consider using a design that will allow you to adjust as you implement.

What you see on the screen, this is a slide from a talk I saw Donna Spiegelman give about this approach.

that her and her team have come up with called Learn as You Go.

And so we are looking at how do we implement this Learn As You Go into the study

that’s already been designed.

It would be best to have thought about this to incorporate

this from the beginning when we’re designing the study,

but we didn’t have that luxury.

We didn’t have that foresight, I should say.

So we’re looking at how do we do this now

so that we’re not just sort of making changes here and there

based on our subjective experience,

but that that we have some data-driven estimates

about where we need to make changes and how much.

So I think this offers great promise
to the work that we’re doing.
Community engagement is key, and has to be integrated with scientific considerations. You can’t do it with just scientific model. You can’t do it with just listening to the community voices without considering the science, you have to do both. There really is a need for more implementation and prevention science methods that respond to the realities of life for black communities. I mentioned the challenges of doing Starfish sampling in some of these places, the challenges of peer support and social media influence in some of these places. So our methods need to really be able to respond to the realities in some of these communities ’cause they’re not always designed with cultural logic in mind. And again, it’s not trivial. Might seem so. When you’re trying to do it, you see where it comes out. And then the last consideration is that we need more rigorous design options that are not limited to the RCT or that can at least enhance the RCT. And I think LAGO might be one thing that could enhance
what we’re trying to do with RCTs. But if RCTs and some are the only things we have, it really is hard for us to test some of these interventions in some of these places, given the constraints that are already embedded within them. So I wanna just acknowledge a lot of people involved in this, including the people who support this through funding. And that’s what you see on your screen, HPTN and many NIH institutes. And then I did want to just say sort of in a way of dedication to Dr. Dawn Smith who was a very key part of this study from the very beginning. She is scienced at the CDC. She led the development of the PrEP guidelines for the US. She died a few days ago, and I will miss her immensely. But the work that you see here and the things we’re doing really is part of her contribution to HIV prevention, practice, but also prevention science. And thank you. Thank you so much, Dr. Nelson. This is such a great presentation. We only have two minutes left, and so I do wanna make sure that there are any questions that you’re able to answer.
Yep, I can stick around and see if there's any questions.

Yeah, we're hitting on. Anyone have any questions in that?

I'm looking. Okay, anyone has any hands up?

Okay, we are like right at the three o'clock mark,

but if there are any questions or anything comes up,

please feel free to email me or, you know,

and I can pass along to Dr. Nelson

Just wanna just thank you again so much.

Yeah, it's my pleasure.

It's always a pleasure working with Ready,

I appreciate all the work that y'all are doing,

including helping us.

I didn't say that we had a Ready consultation,

and it's been very helpful,

so thank you again for the opportunity.

Yeah, great talk. Great work.

Really important work, LaRon.