

Division of Diabetes Treatment and Prevention

Treating Hypertension in the Indian Health System

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Dr. Ann Bullock:

Welcome everyone. Sure appreciate you attending today's session. Not only is this an Advancements in Diabetes webinar, but it's also part of Indian Health Services' work around the Million Hearts' Initiative, which of course is for Health and Human Services, all Agencies, and even beyond to non-profits, organizations like American Diabetes Association and many others are partners of Million Hearts. But certainly, blood pressure control is one of the cornerstones of Million Hearts and we'll talk about that a little bit later in the presentation.

So delighted to have you all here. As Jan said, I'm Ann Bullock. I'm a family doctor who just yesterday crossed 25 years with the Indian Health Service. It's been my privilege to be based here at the Eastern Band of Cherokee Indians for my entire career, though I am enrolled at the Minnesota Chippewa Tribe, Fond du Lac Band. Certainly had a long history of working with diabetes and related issues like many of you have and hypertension is certainly part of that. Luckily, we're not only going to be just talking about diabetes today with hypertension but of course the targets now for adults with and without diabetes are basically the same. So this information is not just about diabetes but goes beyond.

Some of data I'll show is diabetes specific but I'll specify when that's the case. So after I do my presentation, I will turn it over to my esteemed colleague and friend, Chris Lamer, who will talk to you about an incredibly important aspect of all of this, which is medication adherence. We can do all the right things that I'm going to be taking about with measuring and diagnosing and treating hypertension, but if we have created a medication regimen which is too difficult for our patients to deal with whether because of side effects or cost or inconvenience, then all of our good efforts will not result in benefit for our patients. He will be talking about that for the second part of this webinar today.

Neither of us, as Jan said, have anything to disclose. The objectives for this session Jan showed you before.

So what I'm going to be covering of course is hypertension, one of the most important modifiable risk factors for cardiovascular disease and chronic kidney disease and other conditions too of course. But those two are just huge issues for all patients. Of course cardiovascular disease being the number one killer of all people in this country including American Indian and Alaska Native people, and of course CKD being a big issue in diabetes for sure. And it's important that we obtain good blood pressure data on which to base diagnostic and treatment decisions. Sometimes we think that it's based on one blood pressure which may have not have been obtained in the most accurate manner, we're using that for our blood pressure decisions and we need to make sure we're getting great data on which we're committing our patients to taking medications or not.

I'll talk a little bit about treatment guidelines, targets, and clinical tools. So to follow-up that statement that blood pressure is among the most important things that will help us reduce cardiovascular disease risk, I've shown this slide for a few years because it's so graphic to show that yes, it's important for cardiovascular disease that we of course get hemoglobin A1Cs down on our patients who have diabetes, but it's not as powerful of course for cardiovascular events as it is for some of the microvascular complications. But blood pressure is even more powerful in terms of CVD risk reduction than even cholesterol reduction as important as that is. If we only had one thing that we control in our patients with and without diabetes, blood pressure would be a really good candidate for that one thing. Luckily we don't have to focus as one but it's an awfully important one, as you all know.

So this is data from our diabetes audit, which of course does come just from patients with diabetes going all way back to 1997 up to our most recent audit data. We are seeing really good control overall in our patients with diabetes looking at a systolic about 131 over diastolic of about 75. So that is a remarkable average for our patients with diabetes and we know that has had real impact across the system overall.

We've been doing a good job and some of you have seen this graph before which is from the United States Renal Data System which collects data on all patients who are on dialysis or about to start dialysis and looking at populations by race for starting dialysis in patients who have diabetes. Our numbers are on the red line there. And you can see that in the late 80's into the 90's, our rates of people having to start dialysis who have diabetes was just going straight up, right up to the sky. And then right around the year 2000 is when that turned around and in fact, the incidence of end-stage renal disease in American Indian and Alaska Native people with diabetes fell by 43% between 2000 and 2011 which is just a remarkable decline and a much greater decline than for any other racial group. And as we know, blood pressure is hugely central to risk for chronic kidney disease. So we can all say, pat on the back for so much that we've done right, done well over the years across the system.

So blood pressure measurement which we all learn to do in our clinical training, whatever type of school we went to, medical school, nursing school, et cetera and usually don't spend a lot of time on it because it's pretty simple and straightforward isn't it? Well it is, but it also has opportunity for error to creep in pretty easily. So for blood pressure measurement, we know that we should be checking blood pressure as often as we can then get the most complete picture of how blood pressure is going to that patient.

So when we see patients in clinic and then the numbers on the paper or in our electronic health record for the blood pressure that was checked at that visit, make sure we are re-checking them especially if they are higher but also lower than our target range. We're so used to thinking of high blood pressure as being a problem, but for our patients, sometimes it's the lower blood pressures. Perhaps we are over treating unintentionally, that really cause a lot of symptoms, dizziness and even possibly falls and injury. So making sure that we're not only looking at blood pressures that are on the higher side than we like but also those are on the lower side. And if we're going to be making a treatment decision based on those blood pressures, be sure we are re-checking them to make sure that they were done accurately.

So according to the American Diabetes Association recommendations around blood pressure monitoring in people of course ideally, patient has come in and sat down and rested for five minutes. And of course they're not at all worried about their medical appointment or anything else in their life. They're sitting there quietly and calmly for a whole five minutes with their feet on the floor. And then when their blood pressure is taken, their arm is supported at heart level. I'm sure that we all know that this is an ideal situation, which doesn't always happen in our frenzied clinics sometimes. For sure, the cuff size should be appropriate for the upper arm. I'll mention that again in just a moment. And of course we should not be basing our treatment decisions, especially where medications are involved, on one number alone. We should be confirming values on different days.

Sometimes, it's hard to do when we only see our patients once every few months. And this is an important one, there are three main categories or types of blood pressure devices. Of course we all know that our blood pressure measurement is based on millimeters of mercury and some of us who've been in healthcare for a long time actually have seen and used actual mercury-based blood pressure devices. They are not used very much for the simple reason that mercury is a toxic substance and so when these devices break, that mercury spills. And so our aneroid devices, which are those bladder filled, air filled cuffs that we're all used to seeing of course are the most frequently used now and are correlated with mercury-based device readings.

Our electronic blood pressure devices, those have been nice, convenient and in many ways are useful, but the accuracy of electronic blood pressure cuffs is incredibly variable. And even if you have one that starts out being good, if it is not maintained and calibrated properly then an electronic cuff can show some significant problems as time goes by. It would be really wise for any of you who are using electronic blood pressure cuffs in your clinics to be sure that you are re-checking any blood pressure especially those that are out of your target range for a patient. Re-check with a standard manual cuff to be sure you have an accurate blood pressure reading.

So common sources of blood pressure measurement errors in addition to what we've talked about. So we briefly mentioned the incorrect cuff size. Some of our patients have very large upper arms but by time they get down to the elbow, very narrow and we sometimes select a cuff which is too small for the blood pressure check just because it seems to stay on their arm better because the bottom part of their upper arm is much smaller. However, the correct cuff size should be sized for the mid upper arm, not for the elbow or just above the elbow. And for our clinics we need to have all sizes of adult and of course for our child patients, pediatric cuffs, but all sizes of adult cuffs available wherever we're measuring blood pressures or at least really close by so the people who are very busy getting our patients in and screened can quickly grab the correct size cuff. Because if they have to go very far to find it, we know that they are less likely to do that. So we need both small, regular, and large adult cuffs and many of you also use adult side cuffs for some of your patients with very large upper arms and indeed we do need to make sure we're measuring with the correct size cuff.

And this is an interesting one. We are all more likely to write down a number that ends in a zero. So if we're quickly going through and measuring a blood pressure and we see that it's sort of close to that, maybe 140 or 150 or whatever number, we are much more likely, studies have shown to write down a number which ends in a zero than to write down a number which ends in some other digit. So being sure that we're very aware of that as we are taking blood pressures and if indeed we're going to write down a number that ends in a zero, that it's really where we heard the blood pressure reading be.

A lot of times, our staff even though we learned at one point or rather how to take a blood pressure accurately, we need to be reminded and reminded how important this is and reminded not to get sloppy about some parts about blood pressure. And of course as I mentioned a minute ago especially about electronic cuffs but also true for aneroid cuffs, we need to make sure that our equipment is maintained and calibrated.

A common problem is talking or listening. Maybe the patients telling a story or a colleague runs in to tell you about the next patient you're about to screen right while you've got the stethoscope in your ears and you're listening for that blood pressure reading. All these things have been shown in studies to not only be distracting but to make it more likely that an error will occur in that blood pressure reading. And then this is something we often do especially in the winter months when it's colder and our patients have more layers on, is putting the blood pressure cuff over clothing even a shirt is enough to sometimes make it more difficult to either hear or get an accurate reading on that blood pressure.

If the patient has had a cigarette or had a cup of coffee or other caffeinated beverage within 30 minutes about blood pressure reading. This is hard for us to control. How many of our patients

while they're waiting for us after they have signed in go outside for a smoke or had stopped at 7/11 on their way in and grabbed the big Gulp of regular Coke or some equivalent. So but just be aware that it can indeed alter blood pressure readings and we want to be sure that if we're seeing higher than expected readings that we are checking on this is as a possible source.

If our patients are sitting on the exam table when their blood pressure is taken, that means their back and arm are both unsupported. Again, the back should be supported and the arm should be resting on the arm of a chair or other type of device. And of course if they're also sitting on the exam table, their feet are crossed or dangling. So you can see how easy it would be in a busy clinic for many of these issues to arise to each of which can contribute to inaccuracy in blood pressure readings.

So I want to recommend to you a really excellent toolkit, the State of Wisconsin put together just a few years ago. So some of their blood pressure targets especially for diabetes have come before JNC 8 but what they have to say otherwise is incredibly good and well thought out. And in fact, they even provide, for those of you who are involved with IPC-like programs of "plan, do, study, act" framework for improving clinic processes around blood pressure measurement. When you download the slides, there's the link to that excellent booklet.

So even beyond the exam room, we want to make sure we are monitoring blood pressure wherever we can, home and ambulatory blood pressure measurement of course that we've heard more about that in the literature in the last few years. For some reason coming in and seeing us with our white coats and our needles makes people nervous, "go figure". And so sometimes, getting their blood pressures in other settings can give us a better picture and more accurate of what their average blood pressures are.

Some of you are starting and then some of our colleagues outside of the Indian Health System are moving toward telehealth and tele-monitoring where patients can measure their blood pressures at home and have them automatically transmitted to the clinic. So wherever it's possible to get blood pressure readings are good. And of course we often use our public health nurses, home health nurses, CHRs or whoever we can to go out and get blood readings on our patients to give us that more full picture of what is going on for them.

It's especially important because circadian rhythm does change throughout the day and blood pressures are normally higher in the morning and lower at other points in the day. And if we only see our patients first thing in the morning, if you have someone who likes to come bright and early every time, you're going to catch them at the higher point in their circadian rhythm part of their day for their blood pressure. Be good to make sure that we're not treating that part of the blood pressure cycle to more intensively than will be tolerated at four o'clock in the afternoon.

Of course, we also need to make sure we're treating blood pressure, we always think about medications but we never want to forget about lifestyle interventions whether we've added medications or not. These are both preventive for blood pressure problems and of course help us treat them. Our dietitians can go over sodium and other types of dietary issues, which affect blood pressure, physical activity specialists, health educators; we have a lot of folks on the team who can help with the lifestyle part of blood pressure control.

And of course, we should be titrating blood pressure meds relatively frequently at least every few weeks to few months if possible. And that may be too tough to get people in the clinic that often so some of you have started pharmacy-based clinics, where pharmacists can measure and use protocols for adjusting medications. Also a lot of our registered nurses and others may be doing that. So this is a good approach to help us to control a problem, which many of our colleagues can help us with.

So once we've got good blood pressure numbers, how do we measure this? I've got here "guidelines and targets and measures - oh my!" Just like back in the Wizard of Oz with lions and

tigers and bears, but sometimes it feels like these guidelines and targets and measures can sometimes feel pretty overwhelming. Luckily, the major national organizations, which put out guidelines and many of our clinical measures, are now much more in alignment.

Many of us remember the JNC 7 recommendation, The Joint National Commission on Treatment of Hypertension. The seventh edition came out in 2003 where they recommended less than 140 for the general population but less than 130/80 for patients with diabetes or renal disease. Even at that time, even the committee acknowledged there was not a lot of evidence for that less 130/80, expert opinion said that's what we should be using as our target for people with diabetes.

And then I'm sure most of you are aware that the JNC 8 Panel, the panel appointed to the JNC 8, published their findings in JAMA last year and they recommended also less than 140/90 for the general population who is at least those are under 60 but they said this should be the same target overall for patients with diabetes or renal disease at least for adults. And has been famously noted that less than 150/90 may be more appropriate for our older patients.

So the JNC 8 Panel, that's the reference in JAMA and it was the Panel that was appointed to the JNC 8 work, as many of you know. NIH did not publish the JNC 8 as JNC 8. They decided just before it was about to be published to give all of the work of that committee to the American College of Cardiology and the American Heart Association and recommend that they then put out guidelines just as they did for lipids. But the Panel members themselves of JNC 8 decided to publish their findings on their own. And they had gone through a very rigorous guideline development process for this, really closely evaluating the literature and making sure that any conflicts of interest on the Panel were addressed just living up to the letter of the law on recommendations for guideline development.

And their recommendations for adults over 60 or at least 60 years of age that you might consider the less than 150/90 for those who need it and those who are otherwise, less than 140/90. It made a little bit of change in some of the recommended medications. The three first line classes of antihypertensive medications: thiazides, ACEIs and ARBs, since we don't use them for the same patient, it's an "either or", and then calcium channel blockers. They did say that if someone had chronic kidney disease, they should certainly start with an ACEI or ARB.

The major change was really that beta-blockers were no longer recommended for initial treatment of hypertension. Notice, this is hypertension not cardiovascular disease. If a patient has another reason to be on a beta-blocker then certainly, they should have that added into their regimen and of course will affect their blood pressure as well as their CVD risk.

American Diabetes Association with their 2015 Clinical Practice Recommendations agreed for the first time that it should be less than 140/90. They still say that lower targets including perhaps less than 130/80 could be used for younger patients, if the treatment did not cause undue burden and otherwise, a less than 140/90 is what they are agreeing with too.

So for our adult patients, our target should be less than 140/90. I say for most, not everybody but for the vast majority because we know that good blood pressure control definitely reduces CVD and CKD risks, but we need the balance that need for good control with the risk of problems. We're very good at measuring in our electronic records what blood pressures are and medications and things like that. We're not as good at documenting and collecting for population-based assessments, how many of our patients we have actually caused to be hypotensive or orthostatic, to be tired and not be able to get out of the arm chair during the day and of course, to be on multiple medications each of which singularly and in combination can cause side effects and problems.

So we need to be sure that while we are aiming for this less than 140/90 target that we use caution in patients who have symptoms either at that blood pressure number or with the medications required to achieve it. We often have to use three, four and occasionally five

antihypertensive medications to control blood pressure. And again, those can have additive symptom effects. No surprise, the folks who are at highest risk from or for having a problems with medication or with that blood pressure target, are older patients with stiffer carotid arteries perhaps, those who have multiple comorbidities, those who have had diabetes for example for a long time because of autonomic neuropathy. We don't talk about that one an awful lot but it's one of the many complications of diabetes and autonomic neuropathy can make for even wider blood pressure swings throughout the day. If we see someone on the real upswing of their blood pressure in clinic and then increase their medication then later when they go home and their blood pressure drops, we might make them fall over and hit their head or break a hip or something. So we need to be sure that we're getting a clear picture of what the blood pressure is throughout the day for some of these higher risk patients. And indeed, a number of studies have shown that antihypertensive medications especially in combination can increase problems. And then this study was looking at falls or injuries in elderly patients. So again, being very careful here.

So we wanted to make sure that there was an opportunity for providers to have a distillation of current guidelines, and so we have a number of what we call algorithm cards on our IHS Division of Diabetes website. And our website main address is just "diabetes.ihs.gov" and that'll take you to our homepage. But the algorithm I'm about to show you, which is now being considered Indian Health Service's treatment protocol for hypertension is available specifically at that web address. So you can link directly to that address where you download the slides or get there through our homepage for our clinical tools and algorithms page. It's also available for mobile devices. I'll show you quickly slides that will tell you how to put on a little icon on your screen that you can go to this directly if you wish to. So if you're in clinic and you have your tablet or smartphone device, you can get to this either through our website or directly through the icon you can put on your desktop.

So our algorithm includes the hypertension treatment protocols addressed in the JNC 8 Panel's recommendations and we also include medications and dosing references. We focus on IHS national core formulary medications but I've also included a few others that are commonly prescribed. So that when you're seeing a patient, if you have this with you or either in paper form or on your smartphone or tablet that you can take a look to see what the dosing ranges are for the medications you may wish to adjust in case you don't have those at the tip of your fingers in some other way or in your head.

So it'll be hard for some of you to see all the details on this, but this is the hypertension management algorithm. So the recommendations for lifestyle changes at the top on the left, going to the three categories of first line medication: ACEIs and ARBs on the left, diuretics in the center, and calcium channel blockers. And then the recommendation that when one of these is no longer adequate for controlling blood pressure that the other two categories be used before moving on to the additional medication classes of beta blockers and alpha blockers.

Of course the general target of less than 140/90 is there in the bottom left hand box along with the caveat to be sure that this is not too tight a target for some of your older and sicker patients. On the right side, you can see the different classes of antihypertensive medications and recommendations for starting and usual dosing ranges. The one that has the most variability are the many preparations of diltiazem and so we try our best to give you a hint about some of the main ones for that.

So we hope you will find this useful and for those of you who would like to have it on your smartphone, the instructions on how get an icon on your desktop are there. I won't go over those. You're welcome to look at those on the slides that you download and for those of you who have an android type smartphone device, that's the instructions for you on how to do that if you would like.

So we've talk about clinical guidelines and targets and a little bit on some clinical tools, and our performance measures around blood pressure in the Indian Health system of course include our GPRA measures both for blood pressure for people with diabetes as well our Million Hearts Initiative

GPRO measure. And also for those of you who do the diabetes audit in our diabetes audit, and all are focused around a less than 140/90 target. What we need to remember is that performance measures look at the care provided to groups or populations of patients and are not themselves clinical practice guidelines for the care of the individual patient that's sitting, looking at you in the exam room.

For most of our patients less than 140/90 is a perfectly great target but indeed, we need to be sure that we are not using those numbers to beat our patients over the head sometimes when they really are amongst those who should have a little bit looser target because of their many other risk factors. We don't want to minimize that we will over treat or harm anyone. And we need to make sure our patients, we're consulting with them, on how they're feeling and what they would like to see and whether they are willing to go on another medication.

JNC 8 Panel said that their recommendations are not a substitute for clinical judgment and decisions about care and must carefully consider and incorporate clinical characteristics and circumstances of each individual patient. So performance measures are awfully important and we know how much our Clinical Directors focus on these because we're all held accountable for these measures. But of course for the individual patients that we see, we have to make sure that we find those patients and take care of them appropriately when this target is too stringent.

So the final national GPRO dashboard for GPRO Year 2015 is not yet released. So this is the most current data from the third quarter of GPRO for this year we just finished. The GPRO year, goes July to July. And we weren't quite on track with getting in our patients with diabetes getting people down to less than 140/90 and even our Million Hearts measure was not on track. And again, this is looking at less than 140/90 in our patients. So we know we have work to do. I showed you data at the beginning, which shows that we're doing well overall but there's a lot more to do.

So I mentioned the Million Hearts' Initiative, which is something that Department of Health and Human Services, particularly the Centers of Disease Control, are leading. And the goal is to prevent a million heart attacks and strokes by 2017.

Indian Health Service as I said is very involved with this as well and our Improving Patient Care program is in fact as part of their IPC 2.0 changes for IPC are starting a Million Hearts Intensive group. So this is going to be focusing on the main part the ABCS's of Million Hearts campaign, which includes aspirin for appropriate patients, blood pressure control, cholesterol management, and smoking cessation. So if any your sites are interested in being part of this IPC Intensive, there's a little bit of the information about it. It's going to be starting very soon. So if your site is interested and you've not yet signed up, please get a hold of CAPT Cheryl Peterson at cheryl.peterson@ihs.gov and she'll be happy to get your site signed up and get you started on the pre-intensive work for that.

So to sum up the important things of what I've tried to communicate today, we need to of course measure blood pressure correctly and often. Make sure we're training and re-training our staff who take blood pressures on a regular basis, and we have to make sure that the equipment that they are using are properly maintained, calibrated and that we have good protocols in place for the blood pressure re-checks for blood pressures that are out of the target range on any clinic visit. And we should be making our treatment decisions based on several blood pressures whenever possible, not just one that may not have been accurately taken or give a true picture of the patient's hypertension status.

We need to select treatment targets based on the guidelines we've talked about, but of course also on individual patient needs and preferences. We want to neither under treat nor over treat our patients. And use the whole healthcare team so that they can help us with medication adjustment and of course all the lifestyle changes that really do help with blood pressure management.

We have some good tools in this effort. I've shown you one - the IHS Hypertension Protocol that you can get off of the Division of Diabetes website. Also the IPC Million Hearts Intensive that we just talked about. These are great tools. But a huge issue here is medication adherence. We said at the outset if we do all of these things correctly and our patients find the medication regimen too burdensome or for whatever reason, then they will not get the benefit of all this blood pressure control work we're going to do. So with that, I want to turn it over to my excellent colleague, Chris Lamer, who will tell you a lot more about medication adherence in general and in our Indian health system in particular. Chris, thanks so much for being part of this today.

Dr. Chris Lamer:

Thank you Dr. Bullock. To start off my part of the presentation, I just want to begin with a couple of the definitions. Words like "medication adherence" and "compliance" tend to have a negative connotation both among clinicians and patients because it sounds very paternalistic and judgmental or we're judging somebody based upon whether they're doing what we told them to do or not to do. And adherence does have a lot to do with the patient following a clinician's recommendations but it's really a collaborative process where a clinician and a patient must establish and develop a care plan on what their treatment is going to be and what the patient is going to agree to follow.

The literature has one definition and a numerical definition of medication adherence and that is the number of pills that are absent over a period of time divided by the number of pills that are dispensed over a period of time, times a hundred, and that gives us a percentage. And patients who are taking their medications or at least do have their medications, greater than or equal to 80% percent of time are deemed to have good medication adherence. Now, this isn't a really high expectation. Eighty percent is kind of like coming into work four out five days a week. It's not great but this is the number that the literature is looking at. So when we talk about patients having good adherence, it is not really great adherence, it's just 80%.

How many people actually take their medication as it's prescribed? There are a number of different articles in the literature and they are all fairly consistent. This is a national problem. Let's say there are a hundred prescriptions that are prescribed by a clinician. Of those, and the numbers I apologize are a little hard to read, they should be in blue or in black, but the numbers are those that actually make it to the pharmacist, only about 88% make it. Twelve percent of prescriptions are never ever filled or picked up and this is called primary non-adherence where the medication is never taken, never retrieved, and this could be intentional or unintentional. Unintentional being the patient forgot about it or the patient didn't even know that the provider prescribed the medication for them, or intentional being that the patient found out that this medication cost much more money than they planned on spending and decided not to pick it up.

Next, we go to having the medication are actually getting filled and being taken by the patient. That drops down to about 76%, so roughly 25% or a quarter of all the prescriptions that are written never even get started by a patient. Next, we take a look at those medications that are chronic or have medication refills. Of those about 50% continue on with therapy. This is called secondary non-adherence, and it's been estimated up to 80% of secondary non-adherence is an intentional choice that is made by the patient. So to kind of summarize that, one quarter of all prescriptions written are never filled. And one-half of chronic medications that are prescribed are not taken.

Poor medication adherence, will lead to increased morbidity and death, is estimated to have healthcare costs of around \$300 billion, and is the reason for up to one-third to two-thirds of all medication-related hospitalizations.

In the Clinical Reporting System, which is the recording tool within the RPMS, there is a report called the other national measures. These are collected nationally and used internally for program purposes. There's a group of measures that are part of a Pharmacy Quality Alliance report that's

made up of a number of group of measures. And within that group of measures are two distinct measures around medication adherence: the Proportion of Days Covered or PDC and Gaps in Therapy.

PDC looks at patients who are taking a specific medication class chronically and have had enough medications that cover at least 80% of the days during the reporting period. So if the patient has been prescribed the medication for an entire year, it's looking for patients who had enough medication on hand for 292 out of 365 days during that year. This is sometimes referred to as medication possession ratio. It's not a true measure of adherence. We don't know if the patient is actually taking it or not but we at least know that the patient has it and hopefully, that they are taking it. Actual adherence rates are going to be likely lower.

The Gaps in Therapy is looking at patients who had a 30 or more days between the time they ran out of the medication and the time that they got a new prescription.

So basically, these are patients who haven't had the medication for 30 or more days. Just trying to sum up some of the logic of how this measure is made and then I'm not going to through to the details on it, the logic looks at a drug class, again, not just a drug. So if you switch the patient from one ACE inhibitor or ARB to another, that will still get counted and picked up by the measure as being one drug class. There must be two dispensing dates for the drug class during the reporting period meaning the patient must have gotten it at least twice so you that it's an ongoing medication, and the days included in the calculation are going to run until the end of the reporting period or until the medication is discontinued and another medication from that same class is not started.

And here, the results from 2014 looking at the portion of days covered in blue and the gaps in therapy in red and this is looking at the diabetes medications by group. So we have the Biguanides, Sulfonylureas, Thiazolidinediones, and the DPP 4 inhibitors. On average, about 40% of patients have their diabetes medication in their possession for at least 80% of the days during reporting period. More than half of patients went 30 days or more without taking their diabetes medication. This is really important to consider as we talked about guidelines and algorithms. If patients are not taking their medications regularly, we could be advancing on medications and adding medications to a patient's regimen and they really may not be needing it because they weren't taking the first medication in the first place.

Here's the data on hypertension medications and statins. As you can see, it looks very similar to diabetes, a little bit better, but not by much. Again, less than half of our patients are meeting a proportion of days covered threshold of greater than or equal to 80%, and we've been looking at these measures for about four years. And this is showing the data from 2011 to 2014. So again in blue are the proportion of days covered the first bar is 2011 then 2012, 2013, and 2014 and then in red and just to see that this is been a consistent and ongoing problem, it's not something that's just suddenly popped up out of the blue or something that was just aberrant and just a bad calculation. It's very similar between the years.

Next, we have our hypertension medications. Again, fairly consistent between 2011 and 2014 for both proportion of days covered in gaps in therapy. Roughly around 50%, half of our patients having it, having their medications for at least 80% of the days. And about half of our patients going through a time period in the year where they ran out of medications for 30 or more days.

Statin medications, nothing different. And then finally, we also take a look at anti-retroviral medications and even the numbers here are a little lower and they are a little different. For the anti-retroviral medications, the proportion of days covered must be greater than 90% and that's because these medications rely heavily on ongoing adherence for them to be useful and to work. But with this one here, I'm not quite sure that I believe in these results and that is because you and I don't have proof. I think that patients often with this class of drug are getting their medications somewhere else and utilizing other resources, different assistance programs< external doctors or external pharmacies and that may be leading to lower rates in this drug class.

Barriers to medication adherence are diverse and so when we look at barriers that were the reasons why some days, they may not be taking their medications, we really need to do a pretty thorough assessment of the patient. Because there are many reasons and many factors that can affect the patient's ability or willingness to be able to take their medications as prescribed. There have been five dimensions to barriers for medication adherence identified.

The first one is social and economic related barriers - things like low health literacy, lack of insurance, not being able to pay for their medications, lack of support, not having a family support that is helping the patient to remember to take their medications, we think of children who -- and the other parent don't see much value in the medication to pay attention to it and the child not likely to take it. The same goes true with other family members as well in the house. Also, there are cultural issues that may prevent somebody from taking their medications.

The healthcare system can be a barrier. Not receiving appropriate health education, not understanding why they are taking the medication or what medication does or the benefits that they should be receiving from the medication. Not getting positive reinforcement for taking the medication, showing, "Look, you're taking this and this is what's happening." Things are looking great and also having access to care or access to medication refills. The harder it is for patients to break away from work or other activities during the day, the less likely, they are to be able to pick up their medications, make new appointments and so forth. All of these healthcare system barriers can come into play.

The third one listed here is condition-related barriers. Patients who are taking medications and there's no symptoms associated with it. So you have hypertension, you take your blood pressure pill, nothing happens. Well, that can be a barrier because the patient isn't seeing a benefit. There's no perceived reason for them to be taking it. Also, the patient could be depressed or have other conditions taking place where really it's hard for them taking their medications. Somebody who's depressed probably isn't going to be worrying that much about getting the blood pressure medications then. They have other issues that they have to deal with that are more important for them at that time.

There are therapy-related barriers. There could be complex medication regimens that the patient just can't follow. Changes to therapy, lack of immediate benefit, social stigma, and of course one of the big one's being side effects. Side effects are often the reason people don't take their medications.

And that leads us into our next piece, which is the patient-related barriers. Those are going to be broken down by two different categories. Physical barriers, the physical impairments, which are the patient may not be able to walk, may not be able to read or hear or has some other impairment that prevents them from maybe being able to take their medications as they would have been if they didn't have that impairment and also psychological impairments that may cause the patient to not be able to take their medications. Psychological, does not necessarily have to mean mental health. It could be substance abuse, frustration, the patient could be afraid of the medication, being afraid of side effects or being afraid of becoming addicted to the medication. All of these are patient-related issues that are psychological.

It's also important to remember that patients may not be able to recall everything from their appointment. On average, people tend to remember three things from their healthcare visit, or less than 50% of what's being told to them.

Finally, adherence decreases as the number of barriers for the patient or provider increases. So the more barriers you have, it makes sense, the less likely you are to be adherent with your medication therapy. The fewer the barriers, the more likelihood you have. It's really important to be able to talk with the patient and identify what that patient's individualized barriers may be that may be preventing them from taking their medications.

Because every patient has a different barrier, there is that fear of their ability to take their medications. There's no magic bullet or no one way to improve medication adherence. There's not an assessment form or a treatment that is going to magically get the patient taking their medications all the time.

But there are methods and tools that we can use to help promote medication adherence. "SIMPLE" is a mnemonic then is a way to remember some of the key activities that can be done. The "S" is for simplifying the patient's regimen, and these are things such as reducing polypharmacy. Polypharmacy is greater than four medications. How many of our patients are undergoing polypharmacy. They may have chronic diseases, typically on four or more medications these days. We can consider use of combination therapy. The combination therapy has its pros and cons. It could be one tablet instead of two or three. On the other hand, it could be much more expensive. Also, if you want to titrate one of the medications in that combination pill based on the formulations they have, you may or may not be to do that.

Limiting the number of medication behavioral changes that are being made at the same time is another way to simplify the regimen. When a patient comes in and they may have diabetes and it's their first diagnosis, and they talk about lifestyle changes, exercise, nutrition, or take their aspirin, "Here's your cholesterol pill. Here's your blood pressure medicine." Doing too much at once is certainly going to overwhelm the patient. And it's also not something that's going to encourage them to actively participate in the whole treatment regimen to the full extent. Making small changes and just starting with the most necessary changes first and then making other changes overtime is the way to help the patient out.

"I" stands for imparting knowledge. This is your basic patient education, letting the patients know why they're taking the medication, what to expect, what to expect therapeutically, and what to expect in regards to side effects, and how to take the medication, when to take it. If there's nothing that they should be expecting to happen while they take those medications, they should know that. They have an idea of what's going on.

"M" is modifying the patient's beliefs. And it maybe easiest to explain this one with an example. In a study, patients were interviewed about diabetes medication adherence and a predictor of poor adherence was the belief of how the medication worked when it was needed. Some patients believe they only had to take their diabetes medication when their blood sugar was high, and if their blood sugar was okay, there's no need for it. Normal glucose levels meant don't take the pills. They only have to take it when it got really high. This is a situation where somebody's beliefs about what needs to happen can be changed. Again, we can go back into imparting knowledge and letting the patient know that these are how these medications work and this is what needs to be done.

Ask the patient what can help them take their prescribed treatments, ensure that they understand what may happen if they don't take it. Oftentimes, it's not just a matter of taking the medication, but if you don't take this, these are the negative consequences you might face.

"P". Provide communication and trust. This is different than providing education. Communication and trust is using health literacy and empathy to actively listen to and talk to the patient so that you have good channels of health communications open. You want to ask the patient questions, look into concerns, and then use a variety of communication tools to continue communicating with the patient, whether that be face-to-face, by phone or by using secure email services which are now becoming available. There are plenty of ways to open up communication with the patient. Communicating with people following up does begin to establish trust and trust in the healthcare program is another factor that's going to help improve adherence with patients.

"L". Leaving the bias. As I started off saying that adherence has some negative connotations. There are many main reasons a patient may not be taking their medication. Again, up to 80% of the time, it's a conscious decision for them not to take it, and again it's based upon maybe their

concerns, experiences or their beliefs in what the medications going to do and how their body is. Not taking their medications is not necessarily bad. We often sometimes hear stories where people are supposed to start their medication, they never take it and then things turnout really well. Not taking the medication for specific reasons or concerns, it is not always a bad thing. We're not here to punish people for not taking them. But we do need to talk to the patient and understand why. Identify the best approach to modify the treatment plan to accommodate that.

So somebody who's caught not taking the medication because they associate it with a negative side effect that they saw with a loved one, it may not be good to push that on them. It may not put them in the most positive of moods. So you might want to try other ways to treat the patient.

Finally, the "E" in "SIMPLE" is evaluating the adherence. There's a number of ways to evaluate adherence. Again, it often has a negative connotation, but it is something that we need to look at every time the patient comes in. There are subjective ways to look at adherence. We can ask the patients questions. We can ask their family members or caregivers, "Do you have your medication? Do you take it? Is it working?" and bring that up at every encounter. Talk to patients about adherence and what they're doing.

There are objective measures, and some of the objective measures are a little bit intrusive, like pill counting. If you have the patient bringing their medications and you count their pills out, that's a little bit paternalistic maybe in cases where it's something like controlled substances, there maybe a need, but generally pill counting isn't a recommended way to objectively evaluate somebody's adherence. But there are other objective methods, such as looking at the RPMS medication history to see if they're getting their refills regularly. These measures are not always perfect. Patients can move their medications, they can be thrown away, a number of issues that can happen, but at least looking at their medication history can give you an idea of how consistent they are with taking their medications.

And then there's a third way that we can look at evaluating medication adherence, and that is through biometric tests. These are not necessarily the best tools either, but with some things we can do tests to see if the patient's taking their medication, such as when the patients start with blood pressure medication, we could check their blood pressure to see if it's dropping. When they started the cholesterol medication, we can check their lipid panel to see if they are improving.

Medication synchronization has shown some promise in encouraging medication adherence. Medication synchronization is the process of lining up the patients' medication so they can all be refilled at the same time. So in this example, the patient is getting four medications. In theory depending on the time, they could be coming into the pharmacy four different times to pick up each one whenever it's running out. Medication synchronization is the process of giving the patient enough medications so that they all end on the exact same day.

The National Community of Pharmacists Association observed that synchronization led to a 32% increase in adherence among over 1,000 patients. And, there's a number of different ways that synchronization to take place. One way is that the pharmacist can identify when the last prescription is going to run out and then refill the other prescriptions up until that date. In some cases, the clinician could then write an order for all of those medications with eleven refills if they're chronic medications and they are not expected to change. Not only can this help the patient, because now the patient's run out of all their medications at one time and make one trip to the pharmacy to pick them all up. That also makes it a lot easier for the healthcare team. The pharmacist knows when the patient's going to be coming back and what medications they're going to need. There is not going to have to be calls, "This one needs renewed. This one, no refills left. This one, it's too soon because your insurance is not going to pay for it until next week. So you got to come back next week again." They are all going to end at the same time, and they can go ahead and be refilled.

For the clinician, the provider, they need to get the medications lined up once. If you put them in there with eleven refills, you're set for the next year unless there are changes. In the next year, you can select all the medications. They're all going to be on one place on your med list as the active meds and renew them all. The patient's good for another year. Any time you make changes, you just want to make sure that you realign your synchronizations so that it keeps going on. So it makes it easier for a lot of people.

Medication adherence is not just a problem in IHS. It's a problem across the country, probably throughout the world. Medicare recognizes this and they have included three of the Pharmacy Quality Alliance measures around the PDC reports in their Medicare Advantage and prescription drug use evaluation program. Now, we in IHS are not participating in this program to my knowledge. There maybe some sites, but for the most part, we are not. But this shows that poor adherence is a national problem, and there's a lot of work that can be done to improve awareness.

I think that looking at programs like the IPC program and using their perspective is something that we need to address adherence by raising awareness not only in the healthcare system but also throughout the home and the community. It is a diverse problem, so we need a broad perspective on recognizing it and addressing it.

In conclusion, I hope that I was able to give you some take-home points. Medication adherence is important to the patient, clinician, and the healthcare system. We're not immune to poor adherence in the IHS. We're not doing worse. We're not doing better. We're doing about the same as the rest of the country. There are a lot of people who are doing a lot of work on improving medication adherence and setting up medication synchronization programs, and showing some really good benefit. I wish that we had more time today to ask them to come and join us. But at this point, I just want to bring up the topic and raise your awareness. We need to look at barriers on an individual level through patients and think about simple approaches to addressing those barriers.

Finally, I have here some resources for learning more about medication adherence. There are a lot. I just want to put two out there. One is from a website called Script Your Future. This is a great website for patients to go to. They can learn about medication adherence and they can even sign up to get text reminders. So if they want text reminders of when to take their pills, they can click that up on the site. Finally, is the National Diabetes Education Program and this site has links and information for patients, clinicians, and a listing of a lot of good, peer reviewed references from the literature. With that, I want to thank you very much.