



Diabetes Eye Care Best Practices

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March 2013

My name is Mark Horton, I'm an optometrist and an ophthalmologist at the Phoenix Indian Medical Center where I've been the Chief of the Eye and Ear Department for a bunch of years, but recently resigned that position to spend full time with my other full time job, which was Director of the IHS/JVN Teleophthalmology Program. I do that full time now. In support of that position, I also participate in standards development for telemedicine and telemedicine-related entities like electronic health records. I deal with HL7 DICOM and clinical terminology development for SNOMED. That's just a real quick rundown. I've been in federal service since 1973 and at Phoenix since 1986.

Today, Jan should I go ahead and proceed now? I've already put her to sleep. Okay. I'm going to discuss today diabetes eye care from the vantage of best practices in Indian country. Everyone on this call needs no introduction to the first slide, which is the epidemic nature of diabetes, much more common among American Indians and Alaska Natives. The prevalence doubles in Indian country about every 10 years. The epidemic in diabetes is paralleled by the epidemic in diabetic eye disease.

Like the rest of the body, every single cell is touched by diabetes and that's true to the eye as well. Every layer of the eyes is affected, but when we talk about diabetic eye disease, we tend to be concentrating on the irreversible blindness components of it and that's fundamentally is the retinopathy. Now, there is lesser involvement of other components of the eye that can result to permanent vision loss, but generally speaking when we're going for the big bear, it's for the retinal issues, which is retinopathy, maculopathy, vascular occlusions and ischemic syndromes.

For the purpose of this discussion, we're going to be talking to the "big daddy" which is diabetic retinopathy. There is again an increase of diabetic retinopathy for individuals over 40 since 2000 even though we've become much more skilled in decreasing the onset and progression of diabetic retinopathy through application of standards of care for the management of comorbidities of diabetes. There's been nonetheless a rise in prevalence of non-refractive visual impairment in this country predominantly due to the rise of prevalence and duration of diabetes as we made a lot of our patients to survive their disease. They're more susceptible to the microvascular end organ damage in case of the eye thereby diabetic retinopathy and associated visual loss.

Now, everything we're going to be talking about today is evidence-based. We're talking about best practices and those best practices come from the body of science. Here are a few of the landmark studies that establish that body of science and we pretty much know what diabetes looks like, it's natural history, ways to treat it, how to treat it, what to expect to get out of treatment. So most everything we're going to discuss today, particularly the best practices, are evidence-based and primarily from these and a few other landmark studies.

We've developed the best practices for eye care. This is our second version and I think everyone has access to this, there's the URL, everybody write that down real quick. In there, you'll find that the diabetes eye care is defined and basically it says diabetes eye care is eye care. If diabetes touches every cell of the eye then pretty much you've got to examine the eye completely in order to do a



complete diabetic eye exam. However, we recognize that the big players are retinopathy, cataract, and glaucoma. Nonetheless, that takes a complete eye exam in order to really nail that down, but there are a number of ways that we can get at that and we're going to be talking about how that's done, the best way to get that accomplished in Indian country.

The goal of the best practices is to improve the eye care for all of our patients and decrease vision loss due to diabetic retinopathy.

This is entirely possible. It sometimes appears to be a very arduous task, and it is, but there are ways that we can deal with this and decrease avoidable vision loss at our patients. Here's what diabetic retinopathy education is; for the patient and providers. And all that points toward better implementation, better conformance with the evidence-based standards of care.

Fundamentally, that's timely diagnosis and timely treatment. It's easy to say but that's basically where we're going. And the final bullet is monitor and manage the risk factors for diabetic retinopathy onset and progression. Now the easy way to describe that last bullet is when you take care of diabetes, you're taking care of diabetic retinopathy. That is just the basic truth and that requires a good coordination through the primary care team for the diabetic patient and the eye care provider with the end goal being, "Good systemic control of the diabetes, timely diagnosis of the diabetic retinopathy and bringing the patient to treatment." I hit "early" there, but it literally means timely. We know when to treat from our science, we know when to treat the patient and that treatment is very effective as Jan said earlier. It almost eliminates serious visual loss or blindness due to diabetic retinopathy.

But focusing on management of the diabetes with comorbidities or decrease the onset in progression of diabetic retinopathy, we know from DCCT that if you control the A1C, you get intensive control of the glucose, you're going to protect the end organ disease particularly retinopathy and neuropathy. Clearly, as the A1C goes up, the risk for inter-organ disease, the retinopathy goes up. We need to take care of the A1C in order to protect the retina. There are clear long-term benefits from improved control, the DCCT was continued for another 10 years (EDIC study) and we know that from these two studies that the effects of control are sustained even after some slippage in the degree of control. If diabetics are brought under good glycemic management early in the course of the disease, even when that tight control is lost, perhaps later on, the eye tends to remember the effects for early control and there is some protection. However, once the process leading to microvascular complications are initiated, they are self-perpetuating.

The UKPDS was a similar study done on Type 2 Diabetics as compared to Type 1 with EDIC and DCCT, and it gave us very similar source of outcomes. We know from these two studies that the importance of glucose control covers how well we treat it now as well how it was treated early and in the past. Blood pressure control is extremely important. It doesn't seem to have a memory of how well we treat it currently. Now, regardless of how we manage the comorbidities and resist the onset of progressive diabetic retinopathy, virtually all diabetics eventually get diabetic retinopathy. It is the leading cause of new blindness in adults. Diabetic retinopathy is a leading cause of new blindness at working age adults in all developed countries including the U.S. and in the Indian country. The crazy part of that is blindness due to diabetic retinopathy can very nearly be eliminated, almost eliminated, 95% of the cases.

So here we have a situation, the leading cause of blindness doesn't have to be, but it continues because we're not doing timely diagnosis and treatment. The graph at the bottom of the slide here shows that for a long, long time, over two decades, we've been examining patients with diabetes in Indian country. We've only been examining about half of that population. And because of this we have a large amount of avoidable vision loss due to diabetes.

So the discussion today is how to get out of that rut. Now, how do we get out of that rut is following standard of care. Our best practices are based upon this. It is an annual eye exam. Everybody agrees, virtually everybody agrees in one form or the other, that every diabetic, every Type 2, needs an eye exam once a year or sooner depending on the level of diabetic retinopathy. So there is no argument about that. But half of our patients do not get timely diagnosis and we have to ask ourselves why not?

Well, Donald Berwick the previous director of CMS and also CEO of IHI, makes an observation that every system is perfectly designed to achieve the result that it gets, and ours are the same. The reason why we only exam on half of our patients is because our system is designed to do that. Now, we don't want to do that, but we have a system that there is absolutely no question if you look at this data, 20 plus years of data says we're doing the wrong thing or at least we're doing the perfect thing to only examine half of our patients.

Now, something that I've pointed out to everyone is that this is not a problem just for Indian country. This is everywhere. This is everywhere, not just at the bottom of the Grand Canyon or some remote village in Alaska, but half of all diabetics in this country fail to get standard of care. We have the Medicare data here. We see that in this population over age 65, about 60% or so of that population gets an annual exam. But in Indian country, in Medicaid environments and in managed care involvement, HMOs it's about 50% of the population gets an eye exam for diabetic retinopathy on an annual basis. Why is that? Because the system is designed to get that, not because we wanted to get that, because it does. So, we have designed a better system.

Now, I'll tell you, when I explained this to folks, it makes me feel like this cat down here, talking to folks, telling them stuff that just sound like hearsay. Here is the deal. We are not examining our patients not because of eye doctors. This is not a problem with eye doctors or it's not even an eye doctor problem. This is a primary care diabetes management problem. So, the first thing we have to do is we have to find out where this system is broke. We know it's broken. We've got 20 plus years of data saying, "We only examine half of our patients." If we keep on doing what we did, we keep on expecting to get what we got and so we have to stop it. We have to stop it and the first step is to say, "This is not an eye doctor problem. Eye doctors are involved in the solution but this is not where we put the screwdriver to make this adjustment at the primary care environment." If an eye clinic-based eye care program is the only approach for diabetic retinopathy surveillance then we just need to accept that half our patients are going to need standard of care then we're going to retain diabetic retinopathy as the leading cause of blindness.

Expanding an in-house eye service is great, an eye doctor twice, an optometrist and ophthalmologist. I like it when there is more eye care providers out there but it's not going to solve the problem. What we need to do is we have the need to adopt the principles of William Sutton. William Sutton was a bank robber in the 30s. When asked William why he kept robbing banks, he said, "Well, that's where the money is." It's right that is where the money was. He didn't rob 7-Eleven; he robbed the banks because that's what he wanted. He wanted to get money and that's where the money was. All of our diabetics reside in the primary care department, 100% of the ones we know about fundamentally comes to our primary care department. Half of them find their way to eye clinic. So what we need to do is we need to focus on an activity that generates high returns like William said, and fish in the right time.

Now, others are doing that. Others are going to a primary care environment. The Veterans Administration is using telemedicine that's based of primary care environment. They get over 500,000 telemedicine exams last year in the UK. This in the United Kingdom is how they survey for diabetic retinopathy in their country. The 2.10 million diabetics, they examined 1.8 million of them.

So telemedicine can insert eye doctors virtually into a normal clinical work flow of diabetic patients and thereby fish in the right pond. Fish where all of the fish are that we want to catch.

Now, we are required to report to Congress on how well we're doing in the variety of areas, diabetic retinopathy examination is one of them. And there are three legitimate ways that we can count an exam for diabetic retinopathy. Not everything counts. We can do a dilated exam by an optometrist or ophthalmologist. That is the conventional method. That is the method that has failed 50% of our population. Now, we can't just dispense with them obviously, we've got to have a right doctor out there doing this exam. But there's two other ways we can deliver standard of care: We can do a research photographic protocol. That is the photographic established out of science. All we can do in the other photographic method that's scientifically validated to be equivalent to EDTRS. So not just any photograph will do, you just can't take a picture and look at it and say I'm done. We have to have photographic methodologies that are carefully studied and validated to be effective as effective as the gold standard, which is the EDTRS methodology.

Now, if we examine our patients, this is what we can expect to happen. The red curve here is what happens to diabetic patients, high-risk disease if you do not treat them. That is the event rate of blindness. You could say in three years, a non-treated diabetic retinopathy, a high-risk configuration is blind. Now if you simply pick up those patients instead of not letting them be treated, you bring them to treatment, you reduce it to 95% of that or you reduce it by 95%. All it takes is for us to diagnose the patient in a timely fashion and we can essentially eliminate the most common cause of blindness, new blindness, among the diabetic patients in our country.

Now we're all public health providers and we embrace that fundamentally just on its own public health merits but understand that there is great economic wisdom in doing that. Because we know from these studies and others that it is far cheaper to spend the money it takes to examine all the patients, diagnose all those with high risk disease and bring them all to treatment. It is cheaper to do that than it is to let those go blind and deal with the collateral cause of a blind patient, most of whom have some other form of chronic disease. When the diabetic goes blind, it's much more expensive to take care of their congestive heart failure, their ulcers on their feet, and high blood pressure, et cetera. So we need this to prevent the enormous public health, social, cultural, and economic impact of failure in the standards of care. We need to do the smart thing to examine the patient to take care of them.

Now, we've have modality, we've had a kind of modality so for a little over a decade now and it's been incompletely adopted and when adopted, it's been incompletely utilized and headquarters is somewhat frustrated by that. In the middle of last year, Dr. Karol, CMO, issued a directive that said, "All agency hospitals will have this telemedicine modality by the end of 2013 and all facilities, all agency facilities with a prevalence of over 500 will have the modality by the end of 2014 and they must use it to prescribe a level of function which is about a 125% of the pre-deployment rate or the equivalent of it, whichever is higher. She also expects these to be reported to headquarters on a regular basis.

We have a methodology. We have a mandate to use it and use it in a meaningful fashion. As I mentioned we have over a decade worth of experience with telemedicine modality and we like it for a bunch of reasons. It's quick and painless because it uses low level of illumination, no pupil dilation, and consequently patients like it because none of this is non-invasive and we can use it in a primary care environment without disturbing the normal workflow of a patient and so providers like it and it's validated. So consequently, it needs standards of care. It's validated to the gold standard. That is it's been validated to a standard that's better than a live eye exam and it's important to understand that, that for the sole narrow purpose of meeting the standard of care for diabetic retinopathy surveillance

and diagnosing diabetic retinopathy and directing patients to appropriate care, it is better than a live eye exam. Better than a live eye exam and that's not intuitive but the science is there.

Now this is what the program looks like, we have remote imaging programs. We have some portable systems out there and additional ones that are in a fixed fashion in clinics. We have an reading center in Phoenix and we also have a secondary reading center in Flagstaff, Arizona. We have peripheral support for the program. The images are acquired. This was an older piece of technology, but it looks about like that. The images are acquired up here on our monitor; the demographics are harvested from RPMS.

There's some education that takes place, some supplementation of the history and images along with the patient's health summary are transferred to readers at the reading center and so images like you see here are transmitted to the reading center and those appear in a very special diagnostic display and analyzed in a very specific standardized fashion including an automated computerized diagnostics methodology. And then there is some automated documentation that takes place and that's returned to the hosting site about 85% within 24 hours of receiving them.

A report is written and this is delivered through the hosting site as well. We are currently in the beta stage testing of an interface right now that will move this directly back into the RPMS EHR system that's available without any other manual import method. There is great deal of science we have for this specific program in Indian country that supports it on an evidence basis, we have a validated study that show that it is equivalent to the ETDRS. We also have a validation study that show that it's equivalence to a live eye exam that surprisingly was equivalent as well. And we have data that also show that not only will it diagnose accurately diabetic retinopathy at a very high level, we'll also detect a non-diabetic pathology that happens to be evident in the field that are gathered.

We have a methodology that takes care of diabetic retinopathy and non-diabetic retinopathy like you see here. Here's a patient who had a stroke in their eye. And this was gathered during a routine diabetic retinopathy JVN exam and this was actually a retinopathy that the imager saw it and it looks funny to him so he called up for a staff report and in fact he did have a problem and we said that in all reports, what the problem was and told them how to manage it. Now this is important for sites that may not have positions. We deploy this at some very remote sites, at some of our sites in Alaska where the images are gathered in the absence of a physician provider. The recommendations here are not only what the problem has, what the problem the patient has, but also some management recommendations that could be very valuable.

We have validation studies that show that the JVN is correlating very well with the gold standard, also with the clinical standard and takes care of non-diabetic pathologies as well. So on the basis of this, we can use the JVN system and we were authorized to use these tallies for satisfaction of the GPRA. And we can also be comforted by the notion that this is going to be found for non-diabetic pathology that is, we can take care of that as well. Now, the issue that we started out discussing was a low examination rate and looking for a way to improve that. We've done studies that assess the JVN ability to do that. This is our pilot study, an initial pilot study looked at a JVN unit deployed at a primary care environment in a large agency hospital and the pre-deployment rate was about 45%.

Now, here's a situation that really highlights an earlier in the comment I made: if you have a box of screws and all you have is a hammer, you're probably not going to do a better job of buying more hammers. We had 11 eye doctors at this site; six ophthalmologists, five optometrists, a 45% exam rate. You could not sling a dead cat without hitting an eye doctor at this facility but still only had a 45% exam rate. We were never going to solve this problem with only eye doctors. We introduced the JVN in the primary care environment and now are looking at almost 70%.

Now, the control site was about 15 miles away. It did not have a JVN and it went up a little bit. We're looking at this more closely. These patients here that represent the increase were actually seen as the experimental site, they came over here because this is where the CT scanners, rheumatology and other special consultants were. When they came over for these ancillary studies, the JVN system would occasionally capture them, image them, and then count them but the computer counted them over here.

So, this is a significant increase in the surveillance rate that actually had a geographical spread. We were very pleased with that. We continue the study for four more years and we showed that the examination rate was increased from 50% to 75% over a four-year period. Importantly the laser rate at this same site went from 2% to 3%. Nobody ever got better from a protocol, right? When we did these studies, we wanted to know, did we end up doing more lasers and the answer is yes. You can see the exam rate went up 30%, the laser rate went up 50%. We published this study in *Diabetes Care*. This was a landmark study in Indian country that shows this technology works if you work it.

Pivotal for success, the imaging station must be in a primary care clinic. We'd put a couple of them in the eye clinic and it did absolutely nothing and that makes sense. Once a fish jumps in the boat, there's no reason to bait up a hook so we put it in a primary care clinic, that's the only place that really makes the big difference. The primary care team has to have a sense of ownership in the program. They have to utilize it, believe in it and use it. The imager has got to be accountable for recruitment. It's got to be in their PD, not other duties as assigned and of course there has to be a process for referral of diabetic patients that are at threshold that have high risk disease obviously. We've also done a cost-benefit study that went well. This is a very careful study and it looked at specifics in Indian country specifics, the epidemiology and cost issues and the JVN was less costly and more effective for detecting diabetic retinopathy and taking people to care in preventing visual loss, than a conventional eye exam. So it was a cost effective model as well.

This is an experience we've gathered with this technology in Indian country. We got about 70,000 studies since our pilot study in 2000. You can see the bulk of them are in the past six or seven years. And from this evidence, we've really come to appreciate how best they utilize at JVN to the benefit of our patients. We've deployed this technology at about 86 sites and also about 7 portable sites for 24 states. We have planned deployments at the sites you see here. These planned deployments come from the headquarters directive, but these were hospitals that have not signed up yet but now are required to by headquarters directive. All of these sites are supported centrally. The equipment, the maintenance and support, the reads, the QA, all that is provided by the program by separate appropriations from the IHS budget, but the hosting site does have to have a place to put in the facility. They have to have an imager to take the images, usually a fractional FTE. It's usually three patients in an hour that can be seen. So most only have a part time program and they also have to pay for the training travel.

There are ways to recoup some of these costs as it qualifies for the OMB rate, the all-inclusive rate at most locations, but there are Medicare and private insurance opportunities as well. Now, the idea of all this, the reason why we examine these patients apart from the fact that everybody deserves an eye exam and somebody may need glasses, the dog ate their contacts, but in this case what we're looking at is trying to find the four and a half out of a hundred diabetics that need laser treatment. That is the purpose for doing it. Now if we can do other things as well, we're happy to do that and we take every opportunity while we're doing the JVN. But the full purpose, the intended, prime directive for the JVN is to find four or five patients out of every one hundred of our diabetic patients that needs laser exam like you've seen in here. Now, they get this laser exam, you sit down and an eye microscope that shoots laser beams in the eye, it's two 20-minute sessions, we do the laser treatment. This is the first one that's an older one. Then the patient essentially 95 out of a hundred will not end up losing vision. This is why we do the eye exam.

Now, if you have to examine all hundred to find those four or five. That is just life. I understand that but what the JVN does, I tell them the modality, it operates like the JVN. It takes them a hundred patients and it finds 15 or so that need a live eye exam, move those to the eye clinic, and out of that eye clinic, four or five or so end up getting a laser.

And then the other 85 get to recirculate out here as long as they don't need an eye exam for another reason. The dog did not eat their contacts. They don't have glaucoma and that sort of thing. So, these patients recirculate and it increases the eye clinic efficiency enormously. So, it allows us to not only increase the examination rate, decrease the volume of vision loss from diabetic retinopathy, increases efficiency by moving the acuity, the disease complex into a higher level and into an eye clinic.

Now, if we fail to do that, what happens is that then you need to play catch up with something called a vitrectomy. They go to an operating room, like you see here and you put instruments inside the eye, and you gobble up all the disease and you do laser from within the eye instead of as a sort of laser delivered device, and this is about the only way you can take care of that problem. Well, the laser treatment costs about a thousand dollars. A vitrectomy cost about \$9,000, and that's if it works in an uncomplicated fashion and you only have to do it once, but I can tell you from experience that many folks can cost well more than that, up to \$20,000. The bad news is if it's our only option, and rarely do you get a 20/20 result. Almost always eventually downstream you get cataracts and you end up buying another cataract operation for \$4,000. So, the real business case for being smart in this process is spend a thousand dollars on a patient instead of \$13,000 for a lesser result.

Now, I've taken agency data. I think the prevalence is somewhere around 160,000 Native Americans with diabetes. Last year we examined of 55.7%. That means we – I think it's about more than 7% – that means we've identified that 4,000 individuals that needed a laser. That left 3,200 or so that we've missed. So, out of those 3,200, they will eventually end up needing this over here. So, I ran the number, and you could do the comparison, you could see that the total cost for taking care of all these patients, just looking at the cost of the laser and the cost of the catch-up operation, or vitrectomy, it's about \$45 million. Now, had we examined them all and didn't let them need vitrectomy, that would have only been \$7 million. So, you could see that the business case is not how much money you can collect for, but how money you can avoid spending playing catch up.

Okay. So, we have a mandated telemedicine program, an agency program. Now, we have plenty of JVN at tribal programs and urban programs that Drs. Roubideaux and Karol can only mandate its use in agency programs. It's not that they don't want the tribal programs certainly; it's just that they can only afford it to be used in agency programs. So, we're moving to that direction, but the bad news is there just is not enough peanut butter for all the sandwiches for the boys and girls. So, we're moving to other methods to spread this peanut butter more thinly and spread them on sandwiches by doing portable deployment, so we have a portable JVN so we can move it between programs. We're also doing consortia deployment, which is kind of a version of a portable deployment where we get multiple site to externally support one program, and that is support it logistically and financially so that the one site could be moved around.

The reality is that this technology is fully suited for less than 500. So, it gets really tough to deploy the JVN at every single site. We're working on better technology, technology that is cheaper, smaller, lighter, easier to use so that we can deploy it at smaller sites. But right now, this is what we have.

So, what about the other sites? Well, consultants with only clinic-based eye care still need to exercise a vigorous program using best practices, but they must rely on a robust educational program, a robust case manager program that can help usher patients with diabetes to annual eye

exams, and other group force methodologies trying to increase the examination rate. Everyone knows that it is very tough. Evidence shows that we only do that in about half the cases.

So, until we can have a primary case based methodology like the JVN, that's more ubiquitous, some sites will be left with non-telemedicine methodologies. The published IHS diabetes eye care best practices addresses this and I encourage everyone to look at that. I would be very happy to help anyone raster up their non-telemedicine program if anyone desires, all you have to do is give me a call. But the practices are here. Please review them. Understand that whether we use telemedicine or not, the idea is education; applying whatever method we have for timely diagnosis of treatment and very important, monitoring and managing risk factors. If we do that, if we comply with all the standards of care, we keep on top of the A1C, the blood pressure, the lipids, and lifestyle, then we can fewer patients that ride on this red curve and more patients riding the curve down here where they don't go blind.

Thank you very much.