

## Northwest Tribal Vision Project: The Comparative Effectiveness of Telemedicine to Detect Diabetic Retinopathy

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## Partners

- Devers Eye Institute (DEI)
- Legacy Health Systems (LHS)
- American Recovery and Reinvestment Act (ARRA)
- Northwest Portland Area Indian Health Board (NPAIHB)
- Oregon Health & Science University (OHSU)
- CDC-funded Prevention Research Center, the Center for Healthy Communities at OHSU



## Disclosures

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- Research Support: National Eye Institute, ARRA, AHRQ, Centers for Disease Control and Prevention, Merck

## Topic Overview

- Background: Common Eye Diseases in American Indians and results
- Current CER Study Design
- Current Results
- Dissemination
- Future Directions



## What is the most common cause of visual impairment in AI/AN in the NW?

1. Angle Closure glaucoma
2. Diabetic Retinopathy
3. Uncorrected refractive error
4. Open Angle glaucoma
5. None of the above



## Vision-related quality of life is improved most by:

1. Providing eye glasses
2. Performing cataract surgery
3. Macular Hole surgery
4. Both 1 and 2
5. 1, 2, and 3
6. None of the above

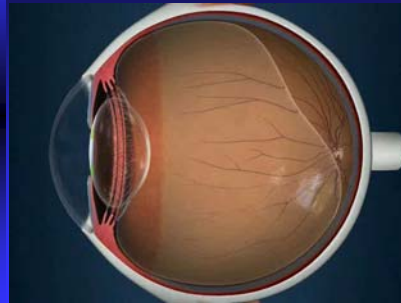


## Using telemedicine to screen for diabetic retinopathy in IM clinics:

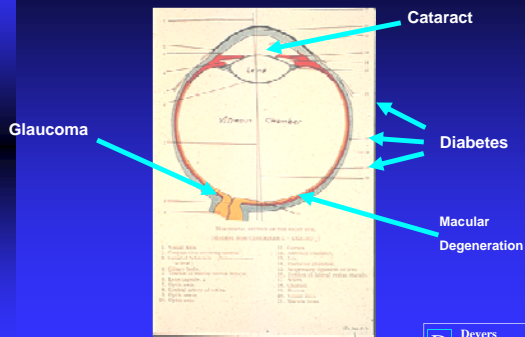
1. Requires 50% of patients to see an eye care provider
2. Can detect glaucoma, macular degeneration, and diabetic retinopathy
3. Stage of "Trough of disillusionment"
4. 2 and 3
5. 1, 2, and 3



## Eye Anatomy

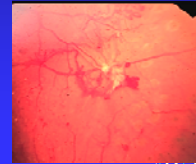
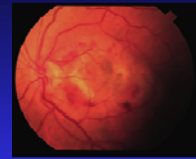


## Eye Anatomy



## Diabetic Eye Disease

- ▶ Hemorrhage
- ▶ Swelling
- ▶ Blurred Vision



## Northwest Tribal Vision Project

- ▶ The Northwest Tribal Vision Project (NWTVP) was designed to determine the prevalence and severity of various eye diseases in AI/AN populations.
- ▶ AIMS
  - Obtain preliminary data on the age-specific prevalence of visual impairment, blindness, and ocular disease in a sample of AI/AN 40 years and older.
  - Compare telemedicine and use of non-mydratic cameras to current surveillance methods for sensitivity to detect progressive diabetic retinopathy.



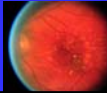
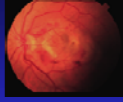
## What is the Prevalence of Eye disease in Native Americans?

- Vision is the second leading cause of impairment
- Studies in Native Americans have been chart reviews or convenience Samples
  - ◆ Navajo/Pima: diabetic retinopathy, cataracts, and trauma
  - ◆ Alaskan Eskimos: angle closure glaucoma



## Retinal Diseases in AI/AN

- Diabetic Retinopathy
  - ◆ 6.0% (Mansberger, 2005)
  - ◆ 20.1% (Oklahoma, Lee, 2005)
- ARMD
  - ◆ 16.9% (NW AI/AN, Mansberger, 2005)
  - ◆ 33.6% (Oklahoma, Lee, 2005)



## Proportion with Visual Impairment/Blindness

- 6.9% (20/288) with visual Impairment of the better eye with correction (20/40 vision or worse)
- 21% (61/288) visual impairment without correction
- 0.9% (3/288) Blind in the better seeing eye (20/200 or worse)
- Greater than U.S. population (Haymes, et al *Ophthalmic Epi* 2009)



## Accuracy of screening procedure

- Important not to miss eye disease
  - ◆ 100% (12/12) of those with normal screening had normal exam
  - ◆ 100% sensitivity
- High proportion of false positives
  - ◆ 175 (60%) had full eye exams including dilation
- Further studies in the combination of tests with the highest diagnostic precision



## Glaucoma in AI/AN

- Alaskan Eskimos: 0.6% (Arkell, 1987)
- Northwest AI/AN: 6.2% (Mansberger, 2005)
- Oklahoma AI/AN: 5.6% (Lee, 2005)

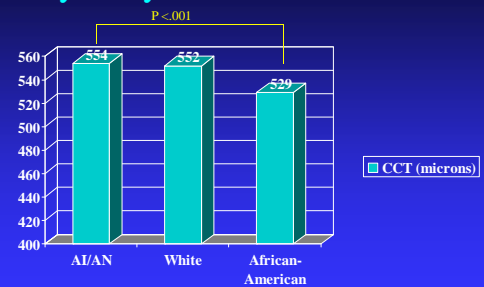


## Differences Exist in AI/AN anatomy and Eye Disease

- OD IOP = 12.9 +/- 3.0 (range 8-23)
- OD Vertical C/D = 0.48 +/- .18 (range 0.0-0.9)
- One person (0.3%) had IOP > 21 mm Hg (95%CI=0-1.0%)
- 15 (6.2%) participants had glaucomatous optic discs and visual fields (95%CI=2.1-7.8%).
  - ◆ None with an IOP greater than 20 mm Hg.



## Pachymetry in AI/AN



Torres, Jones, Edmunds B, et al. Am J Ophthalmol. Nov; 146(5): 747-51. 2008.



## Epidemiology

Source: Genetree.com <http://www.genetree.com/product/native-american-test.asp>

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## Polynesian canoes relive epic Pacific migration

AFP  
Monday, 19 April 2010

Nearly 1,000 years after the last of the great Polynesian migrations, a group of researchers has relived the journey.

Hawaiian canoe completes voyage across Pacific

By Eric Talmadge  
Associated Press  
Last updated 01:34pm (Mia time) 06/09/2007

YOKOHAMA, Japan — The Hawaiian canoe Hokule'a sailed into the Japanese port of Yokohama on Saturday, completing a five-month journey of more than 13,600 kilometers (8,500 miles) across the Pacific.

Kennewick Man

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## Background continued:

- Eyeglasses- measure the change in quality of life with the provision of eye glasses in Alaska Native/American Indians

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## Eyeglasses study

- NEI- VFQ-25
- Two groups:
  - ◆ 20/40 or worse that could be improved by 2 lines on chart or more
  - ◆ 20/30 or better or those who could not improve their vision by two lines on chart with glasses

McClure, et al. Am J Ophthalmol. 2011 Jan;151(1):175-182

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## Eyeglasses study-results

Score change (in points) over time

Legend: □ Control Group, ■ UICRE group

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## Why CER in Diabetic Retinopathy?

- Leading cause of blindness in working-age adults and disproportionately affect American Indians and Alaskan Natives (AI/AN) and other minorities
  - ◆ greater difficulty with transportation<sup>10</sup>, ability to access eye care providers,<sup>11</sup> co-pays and other costs of the eye exam,<sup>12</sup> and/or lack of health insurance.<sup>12</sup>
- Laser treatment results in a 10-fold reduction in vision loss from PDR and a 3-fold reduction from DME.
- Diabetic eye exams would save the government an estimated \$472 million dollars per year.

10. Owsley C, et al. Invest Ophthalmol Vis Sci. 2006.; 11. Shah BR. J Public Health (Oxf). 2008.; 12. Ellish NJ, et al. Invest Ophthalmol Vis Sci. 2007.

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## Why CER in Telemedicine?

- Poor research designs (no randomized controlled trials)
- No long-term follow-up
- No evaluation of cost-effectiveness using actual patient data
- No adoptable telemedicine system
- No estimation of the health behavior for annual eye exams



## NonMydriatic Camera (without Dilation)

- Able to view retina without dilation
- Better than ophthalmologist
- Digitally stored
- Potential for teleophthalmology



## IOM CER recommendations

- 1<sup>st</sup> quartile priority topic: Compare the effectiveness of interventions to reduce health disparities in cardiovascular disease, *diabetes*,....
- 2<sup>nd</sup> quartile priority topic: Compare the effectiveness of new remote monitoring and management technologies (e.g. *telemedicine*, *internet*, *remote sensing*) and usual care in managing chronic diseases, especially in rural settings.



## Methods-Randomized Controlled Trial with Staged Intervention

- Participants randomly assigned to one of two groups
  - ◆ The Telemedicine group
  - ◆ The Traditional provider group
- 2 locations in May of 2006.



## Devers Software as a Service (SAAS) Telemedicine Program

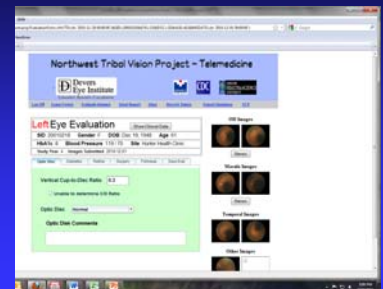
- Web-based- end-user accesses using only a web browser
  - ◆ Minimizes the software required on each workstation
  - ◆ Works with Firefox and IE
- Troubleshoot remotely
- 10-20% of the cost of traditional software and service
- No expertise need from the enduser for installing and troubleshooting software conflicts.



WSJ 4/12/2006 itute

## Devers Telemedicine System

- FTP protocol
- Encryption
- HIPAA-compliant relational database
- Image assignment



## Devers SAAS software

- Data monitoring page
- Emails our clinicians when new images are ready to be reviewed.
- Clinicians fill out a data review form
- Final reports by fax, and email

Report Generation

Devers Eye Institute  
Devers Eye Institute Reading Center  
1500 Ave. 22nd Street  
July 2011  
Patient: 123 456789  
Phone: 508-833-8238  
Fax: 508-833-8237

Your patient address is 123456789. Your telemedicine service expires on 12/31/2011.

Diabetic retinopathy:  None  Mild  Moderate  Severe  PDR

Macular edema:  No  Yes

Optic Disc:  Normal  Abnormal

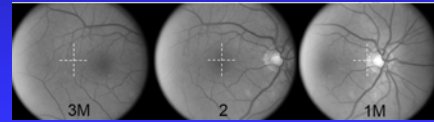
Age-related macular degeneration:  No  Yes

Other retinal diseases:  No  Yes

Additional Comments:

## Imaging

- Modified Diabetic Retinopathy Study protocol.<sup>62, 63</sup>
  - ◆ Six fundus photographs:
    - ◆ two stereoscopic photographs centered on the optic disc; two centered on the macula; one centered on the superior temporal retina; one centered on the inferior temporal retina.
    - ◆ kappa level greater than 0.9.<sup>62, 63</sup>
- The research assistant also has the option of photographing suspicious areas on the retina such as choroidal tumors.



62. Report Number 7. Invest Ophthalmol Vis Sci 1981;21:1-226. 63. Moss SE, Meunier SM, Klein R, Hubbard LD. Ophthalmol Vis Sci 1989;30:823-8.

## Staging of DR

Description of stages of retinopathy and macular edema, Tribal Vision Project 2011

Table 1: Description of stages of retinopathy\* (NPDR = nonproliferative diabetic retinopathy; PDR=proliferative diabetic retinopathy) and macular edema, Tribal Vision Project 2011.

Stage	Description
Stage 0	No abnormalities
Stage 1-Mild NPDR	Small microaneurysms only
Stage 2-Moderate NPDR	More than just microaneurysms (such as venous beading) but less than severe NPDR
Stage 3-Severe NPDR	Contains one of the three characteristics termed the 4:2:1 rule: 1) approximately 20 dot blot hemorrhages in all 4 midperipheral quadrants; 2) venous beading in 2 quadrants; 3) or severe intraretinal microvascular abnormalities in 1 quadrant without PDR
Stage 4-PDR	Neovascularization of the optic disc or elsewhere; vitreous hemorrhage associated with neovascularization of any part of the eye; or evidence of previous preretinal photocoagulation
Macular Edema	Retinal edema within 500 microns of the fovea; exudates associated with retinal edema within 500 microns of the fovea; or retinal edema 1500 microns in size within 1500 microns of the fovea

\*Adapted from an International Classification Scale and the Proliferative Diabetic Retinopathy study.

## Staging of DR

International Classification of Diabetic Retinopathy Scale (Wilkinson, 2002)

**Stage 1-Mild NPDR**  
Microaneurysms only

**Stage 3-Severe NPDR**  
Any one of the following:  
(1) >20 microaneurysms in all 4

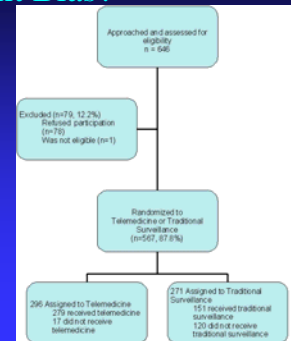
**Stage 4 Proliferative Diabetic Retinopathy**  
Any one of the following:  
(1) Neovascularization of the disc or elsewhere

## Participants

- ▶ N=567 diabetic patients
  - 296 in the Camera Group (52%)
  - 271 in the Provider Group (48%)
- ▶ Diabetes
  - ▶ HbA1c: 8.3% (4-5.9% with recommended <7.0%)
  - ▶ Diabetes for mean 9.5 years.
- ▶ Age
  - Range: 23 to 83 years old
  - Mean Age = 54.5 (SD = 12.0)
- ▶ Gender
  - ▶ 48% Male
  - ▶ 52% Female
- ▶ Ethnicity
  - ▶ 50.3% AI/AN
  - ▶ 72.3% non-white race/ethnicity



## Recruitment Bias?

- Age: p=.57
- Duration of diabetes: p=.52
- HbA1c: p=.80
- Gender: 52% women (enrolled) vs. 38% (not included), p=.03.





## Baseline Results

- ▶ Telemedicine Group
  - 94.2% had baseline images evaluated
  - 75% Acceptable, 16% poor but gradeable, and 9% too poor to grade. Overall, 91% of images were of gradeable
- ▶ Provider Group
  - 55.7% had a baseline eye exam
- ▶  $p < 0.001$  (Telemedicine had a higher proportion of screening exams)



## Bias for attaining exam?

- Those with (n=430) and without (n= 137) a diabetic retinopathy screening exam
- No statistical differences in age, gender, primary ethnicity, systolic blood pressure, HbA1c, or duration of diabetes.
- Diastolic blood pressure was slightly higher in those without an exam (78.9 vs. 76.2 mm Hg,  $p = .03$ ).

## Other biases?

- Insurance status?
  - ◆ Those without insurance less likely to f/u
  - ◆ RCT so unlikely to alter
- Distance from home? to medical clinic, to eye clinic, or medical clinic to eye clinic
  - ◆ What if ECP onsite?
    - ◆ Need appointments, dilation, cost
- Currently measuring distance



## Baseline Prevalence of DR

- ▶ All Participants

DR Not Present	71.6%
DR Present	21.4%
Mild Non-Proliferative	13.7%
Moderate Non-Proliferative	4.7%
Severe Non-Proliferative	0.7%
Proliferative DR	2.3%
Unable to Determine	7%



Need to see an ophthalmologist

- ▶ Overall: 92.3% of those had levels of diabetic retinopathy not requiring an evaluation by an eye care provider.

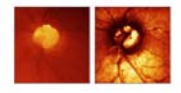


## Other definitions for triaged screening

- 7.7%: based on moderate diabetic retinopathy or worse
- 19.4%: Moderate diabetic retinopathy, macular edema, or 'unable to determine'
- 26.7%: above criteria, or glaucomatous optic neuropathy or 'unable to determine'

## 'Unable to determine'

- 15.8% with telemedicine
- 55.0 vs. 50.9 years,  $p = 0.008$  was the only demographic or clinical variable associated with an 'unable to determine' result.
- Instruments or protocols to decrease 'unable to determine' would decrease the referral proportion ~ 75%

## Risk Factors for DR

- ▶ DR was associated with:
  - Higher systolic blood pressure ( $p < 0.001$ )  
(DR Group:  $M = 135.0$ ; No DR Group:  $M = 125.2$ )
  - Higher HgA1c level ( $p = 0.001$ )  
(DR Group:  $M = 9.0$ ; No DR Group:  $M = 8.1$ )
  - Longer duration of diabetes ( $p = 0.001$ )  
(DR Group:  $M = 13.7$  years; No DR Group:  $M = 8.8$  years)
  - Non-white primary ethnicity ( $p = 0.005$ )  
(Prevalence for non-whites was 59.7% vs. 43.3% for whites)

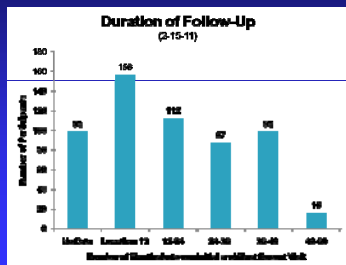


## Future Manuscripts and Analyses

- ▶ Long-term (over 1 year) comparative effectiveness
- ▶ Incidence/Risk factors for Progression of DR
- ▶ Health Behavior Factors related to follow-up
- ▶ Cost-effectiveness using actual patient data.



## Duration of Follow-up



## Progression of Diabetic Retinopathy (preliminary)

- ▶ Included those with 1 follow-up visit (n=226 eyes of 115 patients) with average follow-up of 537 days
- ▶ Progression defined as increased diabetic stage (by 1 stage)
  - 83% had no change in DR stage
  - 12.4% had progression of DR.
  - 4.4% eyes had a decrease in the stage of DR



## Surveys

- ▶ Two new surveys have been created
  - 1) Compliance with Annual Diabetic Eye Exams (CADEES)
    - Determine the factors associated with obtaining an eye exam
  - 2) Cost-Effectiveness (CES)
    - Determine the costs associated with diabetic care
- ▶ The two surveys have been combined to make data collection more efficient.



## Health Belief Factors (n=100, pilot data)

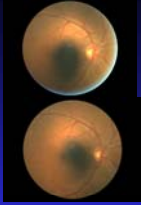


- Poor to moderate agreement (range 0.03 to 0.64) for Health Belief Model
- 24 items classified cases with 83.5% accuracy.
- Highest predictors were (a) satisfaction with eye care provider, (b) confidence in one's ability to make an appointment, and (c) barriers that make obtaining eye exams difficult.






## Challenges

- Acceptance of paying for services
- “Captive” audience
- Not for everyone
  - ◆ Approximately 16% of persons with inadequate images
  - ◆ Traditional eye care provider






## Dissemination




Tipler, S. The Oregonian. Blinding problem. Partnership between hospitals, tribes keeps an eye on vision problems. Published: Saturday, August 24, 2018. <http://www.oregonian.com/news/2018/08/24/blinding-problem-partnership-between-hospitals-tribes-keeps-an-eye-on-vision-problems/>

Dworkin, A. The Oregonian. Distance vision: Retina scans from tribal members in remote cities are flashed to Portland doctors. Published: Wednesday, July 28, 2018. <http://www.oregonian.com/health/2018/07/28/distance-vision-retina-scans-1.html>




## Dissemination

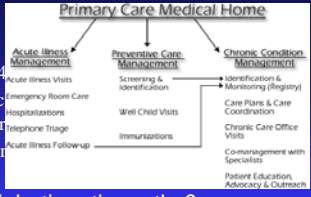


Rojas-Burke, J. The Oregonian. Lower costs, better technology enable Portland hospitals to extend telemedicine links across Oregon. Published: Tuesday, July 27, 2016. [http://www.oregonian.com/health/impactprint.html?story=20160727lower\\_costs\\_better\\_technology.html](http://www.oregonian.com/health/impactprint.html?story=20160727lower_costs_better_technology.html)






## Dissemination

- ▶ Diabetes
  - ▶ 23.7 million in 2009 to 40 million in 2014
  - ▶ Diabetic retinopathy occurs in 15 or more years after diagnosis
  - ▶ The leading cause of blindness in adults
  - ▶ New Paradigm for diabetic retinopathy?
    - ▶ Triage first with telemedicine<sup>2</sup>



- Huang ES, Basu A, O'Grady M, Capretta JC. Projecting the future diabetes population size and related costs for the U.S. *Diabetes Care*. Dec 2009
- Rein DB, ... Saaddine JB. *Health Serv Res*. 2011


## IM clinic at Legacy

- ▶ Clinical Pilot testing
- ▶ Legacy Northwest Internal Medicine Clinic (> 10 doctors and 1500 diabetics)
- ▶ Opportunity to go to over 10 clinics in the region







## IM Clinic



IF YOU ARE INTERESTED IN BEING SCREENED FOR DIABETIC RETINOPATHY, TALK TO YOUR DOCTOR.

## New Telemedicine Client

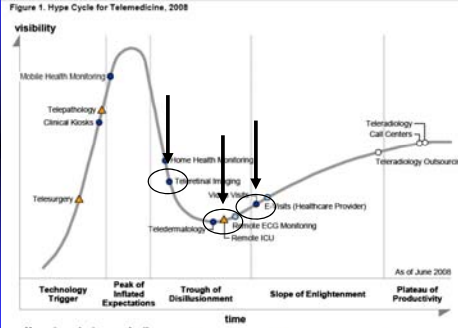
- Secure, encrypted, password protected, HIPAA compliant, and compresses
- Accessible to any clinic or provider



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## Hype Cycle for Telemedicine-2008

Figure 1. Hype Cycle for Telemedicine, 2008



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## Summary

- Most participants did not have levels of diabetic retinopathy requiring an eye care provider
- Progression of diabetic retinopathy was 12.4%, which is lower than previous studies
- Telemedicine with nonmydriatic cameras may increase access and decrease costs for diabetic eye exams

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## Selected Publications and Presentations

Selected Publications:

- Mansberger SL, Romero FC, Smith NH, Johnson CA, Cioffi GA, Edmunds B, Choi D, Becker TM. Causes of Visual Impairment and Common Eye Problems in Northwest American Indians and Alaskan Natives. *American Journal of Public Health*. 2005; 95(5): 881-6.
- Mansberger SL. Normal-tension glaucoma in American Indians/Alaska Natives: a sheep in wolf's clothing. *Glaucoma Today*. March/April 2006. 4(2): 12-14.
- Mansberger SL, Romero FC, Smith NH, Johnson CA, Cioffi GA, Edmunds B, Choi D, Becker T. Causes of Visual Impairment and Common Eye Problems in Northwest American Indian/Alaskan Natives. *American Glaucoma Society Annual Meeting* (abstract) 2005.
- Mansberger SL, Cioffi GA, Choi D, Johnson CA. Screening Tests for Visually Significant Eye Diseases in American Indian/Alaska Native Participants. *ARVO* 2006.
- Torres R, Nguyen H, Mansberger SL. Glaucoma: the sneak thief of sight. *Federal Practitioner*. February 2006. 23(supplement 1): 9-15.
- Torres RJ, Patterson E, Edmunds B, Becker T, Cioffi GA, Mansberger SL. Central Corneal Thickness in Northwestern American/Alaskan Natives and Comparison to White and African Americans. *Am J Ophthalmol*. Nov; 146(5):747-51. 2008.
- McClure TM, Choi D, Becker T, Cioffi GA, Mansberger SL. The Effect of Visual Impairment on Vision-Related Quality of Life in American Indian/Alaska Natives. *Ophthalmic Epidemiology*. In Press. 2009.

Selected Presentations at Regional and National meetings:

- McClure TM and Mansberger SL. The Effect of Visual Impairment on Vision-Related Quality of Life in American Indian/Alaska Native Populations. Poster presentation. *Casey Research Day*. May 2006.
- Mansberger SL, Torres RJ, Patterson E, Edmunds B, Becker T, Cioffi GA. Characterization of CCT in Northwestern American Indian/Alaska Natives and Comparison to Caucasians and African Americans. Poster presentation. *Casey Research Day*. May, 2006.
- McClure TM, Swanson IL, Mansberger SL. Changes in Vision-Related Quality of Life in Native American/Alaska Native Populations After Best-Correction. Poster presentation. *Unité for Sight conference, Stanford University*. April 2007.
- T.M. McClure, I. Swanson, K. Wooten, T.M. Becker, S.L. Mansberger. Proportion of Diabetic Retinopathy Found in Rural and Urban Populations of American Indian/Alaska Natives and Other Ethnicities Using Either a Telemedicine Protocol or Traditional Surveillance Techniques. *ARVO* 2009.

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## THANK YOU...

SUPPORT

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- CDC-funded Prevention Research Center, the Center for Healthy Communities at OHSU



Devers Eye Institute

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