

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

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## Disclosures

- Advisory Boards: Santen, Allergan, Genentech, Glaukos
- Lecture fees: Merck, Allergan
- Research Support: National Eye Institute, ARRA, AHRQ, Centers for Disease Control and Prevention, Merck

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## Topic Overview

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



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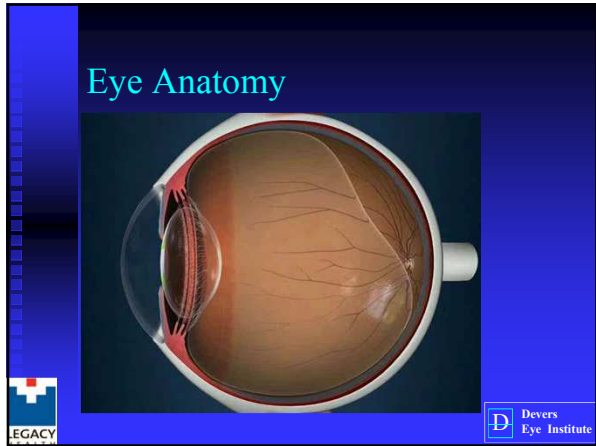
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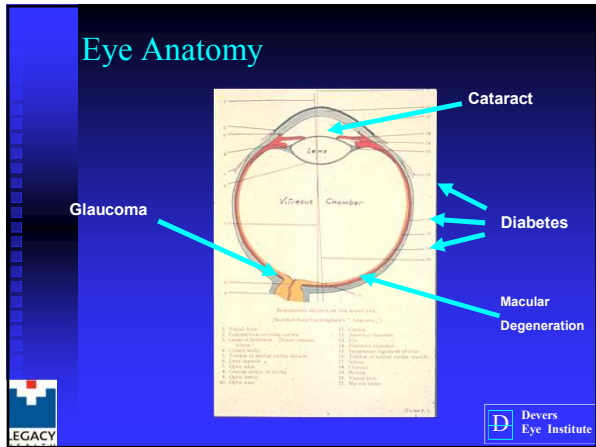
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## Why CER in Diabetic Retinopathy?

- 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. Elish 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



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## NonMydriatic Camera (without Dilation)

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



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## 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.



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## Methods-Randomized Controlled Trial with Staged Intervention

- Participants randomly assigned to one of two groups
  - ◆ The Telemedicine group
  - ◆ The Traditional provider group
- 2 locations: Umatilla (Pendleton, OR) and Hunter Health Clinic (Wichita, KS) in May of 2006.



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## 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.

### Despite All the Hype, Getting Your Software On the Web Has Limits

IN THE BAD old days of corporate software — all that is, before “software as a service” arrived on the scene to save the day — getting a big piece of new software running inside a company had numerous pitfalls and pain points. Consultants raved on the bills, and programs from different vendors didn't always work well together. In the end, the implementation often cost more and delivered less than anyone expected.

Now, though, that “SAAS” is here, what are we starting to see?

“Software as a service” is one of those trends that rolls through the technology world every few years, promising an end to everything that people don't like about how an issue is handled.

Typically, these new approaches deliver on some, but not all, of the promises, often while creating new problems of their own.

The difference between traditional and SAAS-style software is usually the difference between



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## Telemedicine Client

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




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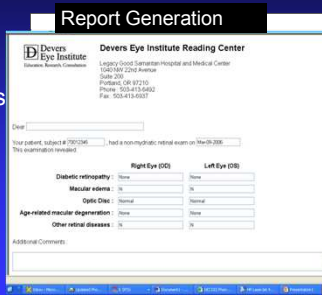
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## Devers SAAS software

- 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




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## 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.



<sup>62</sup> Report Number 7. Invest Ophthalmol Vis Sci 1981;21:1-226. <sup>63</sup> Moss SE, Meier SM, Klein R, Hubbard LD, et al. Arch Ophthalmol. 1989;107:1023-8.

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## 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 panretinal 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.

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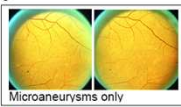
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## Staging of DR

International Classification of Diabetic Retinopathy Scale (Wilkinson, 2003)

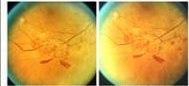
**Stage 1-Mild NPDR**



Microaneurysms only

**Stage 4 Proliferative Diabetic Retinopathy**

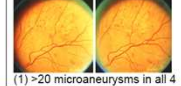
Any one of the following:



(1) Neovascularization of the disc or elsewhere

**Stage 3-Severe NPDR**

Any one of the following:



(1) >20 microaneurysms in all 4

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## 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

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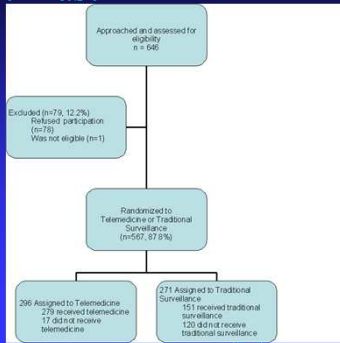
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## Recruitment Bias?

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



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## 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)



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## 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,  $p=.03$ ).



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## 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.



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## 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'



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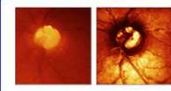
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## 'Unable to determine'

- 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%



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## 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 ( $p < 0.001$ )  
(Prevalence for non-whites was 59.7% vs. 43.3% for whites)


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## 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.


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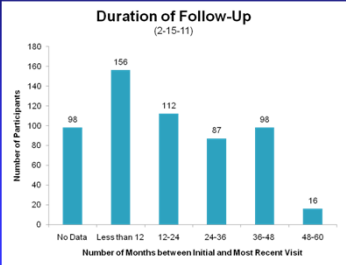
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## Duration of Follow-up



Number of Months between Initial and Most Recent Visit	Number of Participants
No Data	98
Less than 12	156
12-24	112
24-36	87
36-48	98
48-60	16


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## 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



## Dissemination

### Blinding problem

Partnership between hospitals, tribes keeps an eye on vision problems.



### Distance vision: Retina scans from tribal members in remote cities are flashed to Portland doctors

Published: Wednesday, July 28, 2010, 9:15 AM Updated: Wednesday, July 28, 2010, 9:15 AM



Tipler, S. The East Oregonian. Blinding problem. Partnership between hospitals, tribes keeps an eye on vision problems. Published: Saturday, August 28, 2010. [http://www.eastoregonian.com/news/article\\_4f369456-b31c-11d1-a9d7-001cc4c02600.html](http://www.eastoregonian.com/news/article_4f369456-b31c-11d1-a9d7-001cc4c02600.html)

Dworkin, A. The Oregonian. Distance vision: Retina scans from tribal members in remote cities are flashed to Portland doctors. Published: Wednesday, July 28, 2010. [http://www.oregonlive.com/health/index.ssf?919/07/distance\\_vision\\_retina\\_scans\\_f.html](http://www.oregonlive.com/health/index.ssf?919/07/distance_vision_retina_scans_f.html)



## Dissemination

OregonLive.com

### Lower costs, better technology enable Portland hospitals to extend telemedicine links across Oregon

Published: Tuesday, July 27, 2010, 7:14 AM Updated: Wednesday, July 28, 2010, 9:32 AM

By Joe Rojas-Burke, The Oregonian



When Patricia Dittman suffered a stroke last week at her home, she was 40 miles from a hospital with a specialized center capable to treat the one medical emergency. But she was still treated within minutes by means of an interactive video link from the hospital in Beaverton to a stroke neurologist in Portland.

Dr. Lisa Varase noted the one-sided paralysis of Dittman's face and tried to ask her questions. Using a laptop computer linked by a high-speed wireless Internet connection, Varase viewed a camera in the emergency room in Beaverton and zoomed in to view her patient's medical chart. Then Varase turned the camera to observe the 65-year-old woman's face.

"It puts a specialist who is miles away right in the room with you," said Frank Dittman, 51. "She introduced herself. She asked me about my recent condition, her job, what happened that morning."

Telemedicine has long held promise as a way to provide better medical care to rural communities. High costs, technical hurdles and uncertainty about getting paid by insurers for virtual visits have stood in the way. But advances in computer technology have reduced costs of the equipment, Internet connections have grown faster and more reliable, and Oregon lawmakers have mandated reimbursement. Now all the big hospital systems in Portland are extending telemedicine links across the state.

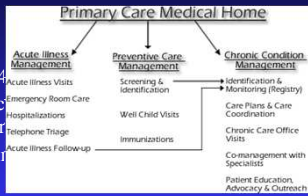
Rojas-Burke, J. The Oregonian. Lower costs, better technology enable Portland hospitals to extend telemedicine links across Oregon. Published: Tuesday, July 27, 2010. [http://blogs.oregonlive.com/health\\_impact/9191.html?entryid=2010/07/27/lower\\_costs\\_better\\_technology.html](http://blogs.oregonlive.com/health_impact/9191.html?entryid=2010/07/27/lower_costs_better_technology.html)



## Dissemination

### Diabetes

- ▶ 23.7 million in 2009 to 4
- ▶ Diabetic retinopathy occurs in 15% of people with diabetes 15 or more years
- ▶ The leading cause of blindness in adults
- ▶ New Paradigm for diabetic retinopathy?
- ▶ Triage first with telemedicine?



1. 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
2. Rein DB, ..., Saaddine JB. *Health Serv Res*. 2011



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## 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



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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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