Purpose

Objectives
- To demonstrate safety and effectiveness of a digital retinopathy screening aid to physicians at Clínicas del Ázucar (CDA)
- To provide an update on our operational teleretinal screening service in Monterrey, Mexico
- To describe the implementation of our automatic retinopathy screening process at five clinics in Mexico
- To present the results of the operation of the automatic screening process

Background
- Diabetes is an epidemic in Mexico
  - Number of patients expected to increase from 15.3M in 2010 to 18.4M in 2020
- CDA provides a new model for diabetes care
  - One-stop-shop for middle and low income patients
- Evidence-based patient care
- Annual, fixed fees with unlimited follow ups and education
- Access to referral network for follow up care
- CDA expects to service 200,000 members in 200 clinics by 2020
  - At will require at least one retinal screen per year
  - This volume will require automatic screening to maintain quality of care

This is the fourth year that VisionQuest Biomedical provides teleretinal screening services to CDA

In 2015, our automatic DR screening software tool, DR-RACS was cleared for commercialization in Mexico by its regulatory agency, COFEPRIS

We have now fully implemented DR-RACS as part of CDA’s clinical workflow

Methods

Clinic Requirements
- Save vision through early detection of diabetic retinopathy and other complications of diabetes
- Increase access to specialty eye care by increasing the number of diabetic screening, while reducing the number of non-urgent or non-severe patients referred to the ophthalmologist
- Triage patients into: 1) return for annual exam; 2) return in six months for eye exam; or 3) urgent referral to ophthalmology

Solution/Approach
- Assess a three referral stage automatic eye screening system
  - Class I: Urgent referral: patients with severe disease (International level 3 or suspect for CSM)
  - Class II: Intermediate referral: patients with moderate non-proliferative retinopathy (International level 2)
  - Class III: Refer for annual exam: International level 0 or 1
- Give physician / care giver a probability or risk factor based on automatic screening results

Clinic Flow
- Patients are imaged using VisionQuest’s telemedical screening system for assessment of diabetic retinopathy as standard of care. Retinal camera is a Canon CR-2, 45-degree, non-photographic camera. Imaging protocol includes two images of the retina, one macula-centered and one optic-disc-centered, and one anterior image, for each eye. All images are uploaded to a cloud-based PACS
- All images are automatically processed by DR-RACS at VisionQuest
- DR-RACS results are sent back to the clinic electronically
- CDA’s reading center uses DR-RACS results as a tool to speed up and complete the screening process
- Screening results are entered into CDA’s proprietary health record system
- Each clinic arranges follow up with ophthalmology, when needed
- A QA process runs continuously to assess any deviations from screening protocol

DR-RACS: System Description

Results

Table 1. Data Distribution.

<table>
<thead>
<tr>
<th>DR Level</th>
<th>Number of Cases</th>
<th>% of Total</th>
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<tbody>
<tr>
<td>DR-1</td>
<td>787</td>
<td>61</td>
</tr>
<tr>
<td>DR-2</td>
<td>101</td>
<td>8</td>
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<td>DR-3</td>
<td>288</td>
<td>22</td>
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<td>DR-4</td>
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<td>DR-5</td>
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<td>3</td>
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<tr>
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<td>2</td>
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<tr>
<td>Total</td>
<td>1,281</td>
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</tbody>
</table>

Figure 3. Bilateral hemorrhage. Low chance of progression.

Workload reduction is critical because in Mexico only ophthalmologists can do retinal screening and follow up
- Only 5,000 for a population of 127 million
- Less than 7% practice growth vs. 12% population growth and 14.6% DM prevalence among adults

Conclusions
- We have demonstrated that automatic DR screening is safe, effective, and scalable in a clinical setting
- Automatic DR screening provides measurable, consistent, and critical resource savings where these are scarce

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