VISUAL FIELD INTERPRETATION IN GLAUCOMA

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FINANCIAL DISCLOSURE

In the past, I have received consulting or speaking fees from Carl Zeiss Meditec, Alcon Laboratories, Pfizer, and Inspire.

Visual Field Interpretation

• Methods of Data Presentation
• Systematic Strategy for Interpreting Visual Field / Recognizing Visual Field Loss
• Diagnostic Criteria for Glaucoma
• Classification of Visual Field Loss
• Identifying Progression
• Alternative Perimetry
RELIABILITY

- CATCH TRIALS
  - FIXATION LOSSES (20%)
  - FALSE POSITIVES (20%)**
  - FALSE NEGATIVES (33%)
- GAZE TRACKER

METHODS OF DATA PRESENTATION

- GRAYSCALE
  - GIVES A PICTURE RESEMBLING ISOPTERS IN A GRAY TONE
  - QUICKLY IDENTIFIES OVERALL DEPRESSIONS

- NUMERIC GRID
  - RAW DATA (THRESHOLD LEVELS)
METHODS OF DATA PRESENTATION

• TOTAL DEVIATION PLOT
  – DIFFERENCE BETWEEN PATIENT’S RESPONSES AND AGE-MATCHED NORMAL POPULATION
• TOTAL DEVIATION PROBABILITY PLOT
  – SIGNIFICANCE OF THE TOTAL DEVIATION PLOT

METHODS OF DATA PRESENTATION

• PATTERN DEVIATION
  – ADJUSTS THE TOTAL DEVIATION FOR THE OVERALL HEIGHT OF THE HILL OF VISION
  – CAN BE ADJUSTED UP OR DOWN
• PROBABILITY PLOT
METHODS OF DATA PRESENTATION

- GLOBAL INDICES
  - SINGLE NUMBER REPRESENTATIONS OF THE VISUAL FIELD
  - OVERALL GUIDELINES TO HELP ASSESS FIELD
  - PROBABILITY VALUES GIVEN WHEN NUMBERS REACH SIGNIFICANT VALUES
GLOBAL INDICES

• MEAN DEVIATION (MD)
  – HEIGHT OF THE HILL OF VISION
    COMPARED TO AGE-MATCHED
    NORMALS
• PATTERN STANDARD DEVIATION
  (PSD)
  – DEGREE TO WHICH THE SHAPE OF THE
    VISUAL FIELD DIFFERS FROM
    REFERENCE FIELD
  – DOES NOT CHANGE WITH MEDIA

Glaucoma Hemifield Test

• Mirror Image Analysis
  Compares Superior to
  Inferior Field
  – Within Normal Limits
  – Borderline
  – Outside Normal Limits
  – Abnormally High
    Sensitivity
  – General Reduction In
    Sensitivity

INTERPRETATION OF THE
AUTOMATED VISUAL FIELD

• RELIABILITY
  – MUST KNOW WHETHER OR NOT THE
    DATA YOU ARE ANALYZING IS
    RELIABLE
  • FIXATION LOSSES (20%)
  • FALSE POSITIVES (20%)
  • FALSE NEGATIVES (33%)
RECOGNIZING VISUAL FIELD DEFECTS

• GRAYSCALE: NOT APPROPRIATE FOR MAKING DIAGNOSIS
• MUST CONCENTRATE PRIMARILY ON THE DEVIATION PLOTS AND GLOBAL INDICES, SOME ATTENTION TO RAW (THRESHOLD) DATA

RECOGNIZING VISUAL FIELD DEFECTS

• USING RAW DATA (THRESHOLD NUMBERS):
  – CENTRAL FOUR POINTS
  – POINTS ACROSS THE HORIZONTAL MIDLINE, ESPECIALLY IN NASAL HEMIFIELD
RECOGNIZING VISUAL FIELD DEFECTS

• USING THE TOTAL OR PATTERN DEVIATION PLOTS:
  – FIND MOST DEPRESSED POINTS; EXAMINE POINTS SURROUNDING THOSE
  – LOOK FOR PATTERNS CONSISTENT WITH GLAUCOMA
    • NASAL STEP
    • ARCUATE BUNDLE
    • PARACENTRAL

RECOGNIZING VISUAL FIELD DEFECTS

• Look at Global Indices & GHT
  – For diagnosis, look to see if they reach statistical significance
  – For following over time, look for change

| MD | -0.31 dB |
| P30 | 2.80 dB |
RECOGNIZING VISUAL FIELD DEFECTS

• SCOTOMAS AND DEPRESSIONS IN AREAS KNOWN FOR GLAUCOMA (PARACENTRAL, NASAL STEP, ARCUATE BUNDLE)

ALWAYS:
1. LOOK AT BOTH FIELDS TOGETHER
2. LOOK AT FIELD WITH RELATION TO OTHER CLINICAL FINDINGS - DOES THIS MAKE SENSE, IS IT CONSISTENT WITH THE DIAGNOSIS OF GLAUCOMA?
3. DON'T OVERLOOK OTHER CAUSES OF VISUAL FIELD DEFECTS

KEY POINTS TO INTERPRETATION

• MAKE SURE YOU ARE LOOKING AT TRUSTWORTHY DATA
• WILL PROBABLY TAKE 3-4 TESTS TO ACHIEVE APPROPRIATE BASELINE
• MAKE SURE IT MAKES SENSE WITH OTHER CLINICAL FINDINGS
STRATEGY DECISIONS

• 30-2 vs. 24-2
• Size III vs. Size V
• 24-2 vs. 10-2
• SITA-Standard vs. SITA-Fast (vs. Threshold or FastPac)
Customizable Test Grids

• Octopus perimetry allows custom test grids to decrease separation between points in areas of concern

Minimum Criteria for Diagnosis of Glaucoma VF Defect
(HODAPP, ET AL, 1993)

1. GHT OUTSIDE NORMAL LIMITS ON AT LEAST TWO OCCASIONS -OR-

Minimum Criteria for Diagnosis of Glaucoma VF Defect
(HODAPP, ET AL, 1993)

2. CLUSTER OF 3 OR MORE NON-EDGE POINTS (in a typical location for glaucoma), ALL OF WHICH ARE IDENTIFIED AS SIGNIFICANT, WITH AT LEAST ONE AT THE p<1% ON TWO CONSECUTIVE TESTS -OR-
Minimum Criteria for Diagnosis of Glaucoma VF Defect (HODAPP, ET AL, 1993)

3. (C)PSD FLAGGED AT p<5% OR WORSE ON TWO CONSECUTIVE FIELDS
   • USE PSD IF NO SHORT TERM FLUCTUATIONS USED
CLASSIFICATION OF FIELD LOSS
(Hodapp, et al)

• MILD (all 3 criteria must be met):
  • FOR 24-2 SITA STANDARD
    – MD DEPRESSED BY <-5dB AND
    – ON PD PLOT, <25% (14) POINTS ARE
      DEPRESSED BELOW THE 5% SIGNIFICANCE LEVEL and fewer than half of those points are depressed below the 1% LEVEL AND
    – NONE OF CENTRAL FOUR POINTS
      HAS SENSITIVITY OF <20dB

CLASSIFICATION OF VISUAL FIELD LOSS

• MODERATE (24-2 Sita)
  – MD -5dB TO -10dB OR
  – ON PD PLOT, <50% (14-28) POINTS ARE
    DEPRESSED BELOW 5% LEVEL, OR 8-16 POINTS ARE BELOW THE 1% LEVEL OR
  – CENTRAL POINTS BETWEEN 10-20dB
    IN ONE HEMIFIELD (NO POINTS IN CENTRAL 5 DEGREES WITH <10dB)
CLASSIFICATION OF VISUAL FIELD LOSS

- **SEVERE (24-2 Sita)**
  - MD DEPRESSED BY MORE THAN -10dB OR
  - ON PD PLOT, GREATER THAN 50% (28) POINTS ARE DEPRESSED BELOW 5% OR MORE THAN 16 POINTS ARE BELOW THE 1% LEVEL OR
  - BOTH HEMIFIELDS IN THE CENTRAL 5 DEGREES HAVE <20dB OR
  - ANY POINT IN THE CENTRAL 5 DEGREES HAS A VALUE <10dB
INTERPRETATION TEMPLATE

- Look at reliability
- Look at central levels
- For variations of >4dB across horizontal midline nasally
- Total / pattern deviation plot - most depressed point and surrounding points
- Global indices (MD, PSD, GHT)

FOR THE RECORD

- Statement with respect to reliability
- Statement with respect to pattern, depth, and size of visual field loss
- Statement that correlates other examination findings with visual field

IDENTIFYING PROGRESSION

- Much more difficult than detecting loss
- Background of dynamic “noise”
- No algorithm uniformly agreed upon for detecting change
- Three main changes:
  - Deepening of defect
  - Enlargement of defect
  - New defect
IDENTIFYING PROGRESSION

• Long-term fluctuation
  – The single biggest problem in determining progression
  – Deeper defects: more long term fluctuation
  – More advanced glaucoma: more long term fluctuation, more fatigue

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IDENTIFYING PROGRESSION

• Overview printout
  – Grayscale
  – Threshold values
  – Total and pattern deviation plots
  – GHT, global indices, reliability

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![Figure 1: Trend-based variability in Pattern V](image-url)
OVERVIEW

Overview Plot

IDENTIFYING PROGRESSION

- Total /Pattern Deviation Probability Plots
  - Once a black box...
- Grayscale
- Threshold values
NTGS Criteria for Progression

• Previously normal area (baseline):
  – Three contiguous points, same side of horizontal meridian now abnormal
    • One point changed by 10dB on total deviation plot
    • Two points changed by 5dB on total deviation plot

• Previously abnormal area (baseline of 3 tests averaged):
  – Two contiguous points same side of horizontal meridian decrease by ≥= 10dB or 3x avg STF in baseline
  – Suspected point’s value must be lower than ANY value obtained for that point in the baseline tests

• TO CONFIRM, CHANGE MUST BE PRESENT IN FOUR OUT OF FIVE CONFIRMING TESTS
GUIDED PROGRESSION ANALYSIS (GPA)

- Humphrey Field Analyzer
  - Based on results of GLAUCOMA patients from mild to advanced disease
  - Patients took 12 different visual field tests within a 4 week period
  - Developed a model for what is “expected” test-test variation for patients with glaucoma

GPA

- Uses 2 baseline exams (any strategy)
  - Follow up tests must be SITA-Standard or SITA-Fast (all same strategy)
- Symbols used on Follow Up Tests
  - Open Triangles
  - Half Triangles
- Messages
  - Possible Progression
  - Likely Progression
- Rate of Progression
CRITERIA FOR CHANGE

- Minimum of three tests required: 2 baseline and 1 follow-up exam
- Each follow-up compared to averaged thresholds of 2 baseline exams
- Additional follow-up compared both to baseline and to 2 most recent follow-ups
- Symbols:
  - ▲: Progression at 95% significance level
  - ▼: Progressing point repeated in two consecutive exams
  - ▼▼: Progressing point repeated in three consecutive exams
- GPA Alert™: Three ▲ in one exam denotes “Possible Progression” and three ▼ indicates “Likely Progression”

HFA Guided Progression Analysis

New global metric - VFI - optimized for progression analysis

- Visual Field Index
- Calculated for all available reliable fields.
- Age-adjusted & center-weighted to better reflect ganglion cell loss.
- Reduced sensitivity to cataracts.
- 100% = normal function
- 0% = perimetric blindness

Elements of GPA 1-Page Summary Report

- Baseline Tests
- VFI (Trend Analysis)
- Today’s VF
HFA GPA
VFI Summary - Interpretation at a Glance

ALTERNATIVE PERIMETRY

• Frequency Doubling Perimetry (FDP, FDT)
  – Matrix
• Short Wavelength Automated Perimetry (SWAP)
• Static vs. Kinetic
• Heidelberg Edge Perimetry
• GATE strategy

Frequency Doubling Technology (FDT)

• Based on frequency doubling illusion
  – Low spatial frequency grating flickered at high temporal frequency (>15Hz) – image is seen as a doubled spatial grating
FDT

- Originally thought to target My cells
- Now thought to preferentially stimulate the magnocellular processing system
- Original test: up to 19 test points, 10° x 10° in threshold or screening mode
- Reported to have high specificity and sensitivity for detection of glaucoma
- Resistant to blur, illumination, small pupils, etc.
- No advantage for following for progression

Humphrey FDT Sample Printouts

FDT as a screening tool for glaucoma

- There is significant evidence in the literature that FDT is a sensitive test that is able to detect early glaucomatous defects.
- In most of the studies, there are very strict inclusion/exclusion criteria, including experience with perimetry, clear media, low refractive errors
Flicker Perimetry - Octopus

Matrix – Hybrid FDT/SAP

• Uses FDT stimulus presentation
• Smaller 5° targets presented in 24-2 pattern

Humphrey Matrix Test Strategies

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Time, min</th>
<th>Stimulus</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-30-F</td>
<td>Screening</td>
<td>&lt;1</td>
<td>19.8' x10'</td>
</tr>
<tr>
<td>24-2</td>
<td>Screening</td>
<td>1</td>
<td>55.3' x10'</td>
</tr>
<tr>
<td>24-2</td>
<td>Threshold</td>
<td>4 – 5</td>
<td>55.3' x10'</td>
</tr>
<tr>
<td>30-2</td>
<td>Threshold</td>
<td>5 – 6</td>
<td>69.5' x10'</td>
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<tr>
<td>N-30-F</td>
<td>Threshold</td>
<td>2 – 3</td>
<td>19.8' x10'</td>
</tr>
<tr>
<td>10-2</td>
<td>Threshold</td>
<td>4</td>
<td>44.2' x2'</td>
</tr>
<tr>
<td>Macula</td>
<td>Threshold</td>
<td>1.5</td>
<td>16.2' x2'</td>
</tr>
</tbody>
</table>
Short Wavelength Automated Perimetry (SWAP)

- Large blue target presented on bright yellow background
- Theory: selectively tests blue cones and the koniocellular pathway
- Several studies: SWAP detects defects earlier than SAP
- Limitations: cataract/media opacity, compressed dynamic range, increased test time
- Indications: glaucoma suspect who has normal SAP
- Available in HFA and Octopus perimeters

Traditional SWAP Weaknesses Compared to W-W

- More time consuming, 15-17% longer using the same threshold strategy (Wild et al 1998)
- General depression of the hill of vision smaller dynamic range (no benefit of SWAP in patients with moderate to advanced field loss)
- More sensitive to cataract
- Larger intersubject variability wider normal limits for threshold values

Expected Improvements with SITA SWAP:
Speed and Sensitivity

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Time (min)</th>
<th>Stimulus</th>
<th>Background</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Threshold</td>
<td>12:50</td>
<td>V, Blue</td>
<td>Yellow</td>
</tr>
<tr>
<td>Fastpac</td>
<td>7:50</td>
<td>V, Blue</td>
<td>Yellow</td>
</tr>
<tr>
<td>SITA</td>
<td>3:56</td>
<td>V, Blue</td>
<td>Yellow</td>
</tr>
</tbody>
</table>
Heidelberg Edge Perimetry (HEP)

- Disclaimer: device not FDA-approved and not commercially available in the US
- A type of flicker perimetry based on an illusionary stimulus
  - "Flicker-defined form"
  - 5° stimulus shown on background of flickering dots
  - Stimulus is flickered in counterphase at high temporal frequency
  - Phase difference between background and stimulus gives rise to an illusionary "edge" or border (circle)
  - Reported to detect early, pre-SAP defects
  - Defects are deeper than SAP

Stimulus - Flicker Defined Form (FDF)

Contour-Illusion Stimulus

Phase 1 + Phase 2 = Illusory "Edge" or Contour

Data Display – OU Results

OD results

OS results

Patient and test information
OU Printout

Patient and Test Information
Est. Sensitivity
Grayscale
Total Deviation
Pattern Deviation
Reliability Parameters

A Combined Approach to Structure & Function

Structure Function Map

Structure & Function Map

Inner Ring:
HRT MRA
Structure Classification

Outer Ring:
HEP
Function Classification

Legend: Within Normal Limits | Borderline | Outside Normal Limits
Structure Function Reports: HRT & HEP

- Combined structure-function plot
  - Initially with MRA baseline data
  - Eventually hope to include progression analysis
- Currently available in several European countries
- Hope to have roll-out in USA in 2010

THANK YOU FOR YOUR ATTENTION.

QUESTIONS????

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Glaucoma Case Analysis
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**CASE 1: NA, 18 yo HF**
POH: IOPs consistently in mid-high 20’s since first exam at age 11
- Slit Lamp: Normal OU
- IOP: 24mmHg OD 25mmHg OS
- Gonioscopy: open 360 OU
- See ONH and VF

**Case 2: DW, 65yo WM**
- POH: (-) injury, (-) surgery
- PMH: (+) DM2, (+) Systemic HTN
- FH: (-) glaucoma
- Meds: metformin, HCTZ
- All: None
- BVA: 20/25 OD 20/20 OS
- Pupils: 3mm, 3+ D/C OD/OS, (-) RAPD
- CVF: FTFC OD, OS
- Slit lamp: mild nuclear sclerosis OD>OS
- IOP: 31mmHg OD, 30mmHg OS
- See ONH and VF

**Case 3: MC, 45yo Hispanic female**
- CC: referred for glaucoma evaluation
- POH: unremarkable, no trauma, no surgery
- PMH: unremarkable, no vascular disease
- FH: no known glaucoma, most family in Mexico
- Meds: None
- All: None
- BVA: 20/20 OD, OS
- Pupils: 3mm, 3+ D/C OD/OS, (-) RAPD
- Slit Lamp: normal, no secondary signs, open angles
- Gonioscopy: open to CB, no secondary findings
- IOP: 24mmHg OD 23mmHg OS
- See ONH and VF
Is this glaucoma?

• If there is characteristic optic nerve damage…
  • “Yes”
• If there are no characteristic optic nerve or VF changes …
  • Usually “No”

Characteristic Optic Nerve Changes

• Large C/D ratio FOR THE SIZE OF THE OPTIC NERVE
• Focal or diffuse rim thinning
• Focal or diffuse RNFL loss
• Optic disc hemorrhage
• Peripapillary atrophy

Why haven’t we talked about IOP?

• IOP no longer defines glaucoma
• Is IOP important?
  • Higher IOP = greater risk of damage and/or progression
  • Suggestion that greater fluctuation in IOP= greater risk of damage and/or progression
  • Multiple clinical trials show benefit of lowering IOP in terms of progression

What if only the IOP is high?

• Ocular Hypertension Treatment Study (OHTS)
  • To evaluate safety and efficacy of topical ocular hypotensive agents in delaying/preventing onset of glaucoma damage in individuals with moderately elevated IOP
  • To produce natural history data to aid in identifying patients at highest risk for development of POAG
• Baseline factors that predict POAG:
  • Multivariate analyses:
    • Older age
    • Larger vertical or horizontal c/d ratio
    • Higher IOP
    • Greater PSD on HVF
    • Thinner CCT
**OHTS**

- Conclusions:
  - Lowering IOP may prevent/delay the development of POAG in patients at risk
  - Must take into account risk factors for the development of POAG
  - Must weigh risk/benefit of chronic medication use
  - Consider: cost, inconvenience, side effects
  - Consider: age, IOP, CCT, C/D ratio
  - Pachymetry has now become standard of care in evaluation of OH patients
  - Is pachymetry important in other forms of glaucoma/glaucoma suspects?
  - OHTS RISK CALCULATORS

**Case 4**

- 67 yo HM dx POAG, missed last 2 follow-up visits
- Highest IOP 25mmHg
- Target IOP mid-teens
- Treated with prostaglandin once daily OU
- Today, reports no problems;
  - Last dose of meds yesterday evening
  - No missed doses in last 1 wk, 2 wks, or 1 month
- Today’s IOP 14mmHg OD, 16mmHg OS
- See ONH & VF
- **WHAT DO WE DO NOW?**
  - Re-set target to low teens
  - Add another med
  - Send pt for SLT
  - Send pt for filtering surgery
  - Other???

**GAPS**

- Better patient self-report than medication refill data suggested
- Higher adherence rates than persistence rates – suggests “starts and stops”
in therapy
• Are there factors that can predict adherence/persistence?

**GAPS – lower adherence / persistence profile:**
• Not believing that vision loss is a possible result of not using medications
• Traveling/ time away from home
• Hearing all of what you know about glaucoma from your doctor
• Not acknowledging stinging/burning
• Cost / payment issues
• Being non-white
• Receiving free samples of medications
• Not receiving phone call reminders of follow-up visits

**Case 5**
• 60 year old Asian Male
• Referred for glaucoma evaluation due to optic disc and IOP of 22 mmHg OU
• Medical history: (+) Systemic HTN
• Ocular history: unremarkable
• Fam Hx: No glaucoma
• BVA: 20/20 OD, OS
• Pupils normal, (-) RAPD
• SLE: Normal
• IOP: 22mmHg OD 20mmHg OS
• See ONH and VF

• Multiple Visits Over Several Years:
  • IOP Range:
    • On Xalatan: 9-12 mmHg OD, OS
    • Off Xalatan: 19-22 mmHg OD, OS
  • Reports difficulty with compliance
  • See VF
SELECTIVE LASER TRABECULOPLASTY

- Specially designed laser used to treat pigmented trabecular meshwork cells
- Application of laser is same technique as for Argon Laser Trabeculoplasty (ALT)
- Differences:
  - Very short pulse (3 nanoseconds)
  - Eliminates collateral “burn” damage
  - Mechanism appears to be cytokine-mediated macrophage recruitment
  - Can be repeated
- Post-Op Care
  - Similar to ALT (? steroid)
- Complications:
  - Similar to ALT
  - Include:
    - Corneal abrasion
    - Uveitis
    - Scattered PAS
    - Transient IOP rise

SLT/MED STUDY

- Multicenter, prospective, randomized study to compare SLT vs. Meds as first treatment of POAG
- Sponsor: Lumenis Inc.
- Coordinator: Wills Eye Hospital, Tulane
- Outcome Measures: IOP response, quality of life assessment, cost analysis, perimetry/ONH analysis, response to repeat SLT

SELECTIVE LASER TRABECULOPLASTY

- Consider when:
  - Non-compliance is an issue
  - There are undesirable or intolerable side effects from medications
  - Patient is on maximum tolerated medical therapy
Case 6

- 32 yo HF referred to Medical Eye Service from Family Practice Service of UEI for glaucoma evaluation

- HPI:
  - Exam in FPS found IOP 28mmHgOU, large C/D

- POH:
  - Several years since last exam
  - Spectacle wearer
  - No surgery, trauma
  - Refractive amblyopia OS (20/80)

- PMH:
  - 22 weeks pregnant, no complications to date
  - Seeking regular prenatal care
  - History of 3 previous miscarriages in first/early second trimester
  - No other significant medical history

- FH: unknown
- Meds: prenatal vitamins, calcium
- ALL: NKDA

**Case 6: Exam Findings**

- BCVA: 20/15 OD, 20/80 OS
- EOMS: Full OU
- CVF: FTFC OD, OS
- Pupils: 5mm OU, 4+ D/C OD, OS; (-)RAPD
- SLE: normal OU
- Ta: 27mmHg OD, 26 mmHg OS
- See ON and VF

**Question:**

How do you wish to manage this patient?
- Begin medical therapy
- Laser trabeculoplasty
- Filtering surgery
- Close follow up
- Refer for second opinion

**Question:**
Which (if any) medications are safe to use during pregnancy?

- Beta blockers
- Prostaglandin analogs/prostamides
- Alpha-adrenergic agonists
- Carbonic anhydrase inhibitors
- Pilocarpine

**Use of Pharmaceutical Agents in Pregnancy**

“…extreme caution should be used in administering any sort of medication to a pregnant woman.”


“A recent review article suggested that most topical ophthalmic drugs pose little risk to the mother and developing fetus.”


**FDA Pregnancy Categories**

- **Category A**
  - Adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).

- **Category B**
  - Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

- **Category C**
  - Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

- **Category D**
  - There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

- **Category X**
• Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

**Ocular Hypotensives**

• Beta Blockers
  • Category C
  • Associated with fetal cardiac arrhythmia
  • Timolol is approved by AAP during lactation
• Prostaglandin Analogs
  • Category C
  • Some concern for pregnancy loss
• Brimonidine
  • Category B
  • Potential toxicity when nursing
• Carbonic Anhydrase Inhibitors
  • Category C
  • Acetazolamide associated with neonatal acidosis
  • Acetazolamide approved by AAP during lactation
• Cholinergics (Miotics)
  • Category C

**Case 7**

• RD, 58 year old AA male
• Referred to UEI Med Eye Service from FPS due to
  • IOP 24 mmHg OD, 26 mmHg OS @9:30am
  • C/D 0.85/0.85 OD, OS
• POH:
  • (-) surgery, trauma, inflammation
• PMH:
  • (+) Systemic HTN dx 1 month prio
  • (-) DM, cardiovascular disease, other
• FH:
  • (+) glaucoma (sister)
• (+) blindness (unknown cause – father/gf)
• Meds: Toprol XL
• All: NKDA
• Exam Findings:
  • VA: 20/20 OD, OS (mild SH)
  • Pupils: 3mm, 3+ D/C, (-) RAPD
  • EOMS – Full OU CVF: FTFC OD, OS
  • Color: Normal OD, OS
  • BP 164/100
• Slit Lamp:
  • Mild anterior blepharitis OU
  • Clear cornea
  • Deep AC
  • Normal iris
  • Mild NS OU
• IOP: 23 mmHg OD 24mmHg OS @ 4:25 pm
• Pach: 562 OD 566 OS

**Goal of Glaucoma Therapy**

• Maintain functional vision for the rest of the patient’s life
• Limit side effects and cost of therapy

**Target IOP**

• Target IOP = best guess at IOP where we balance the risk of future vision loss with the side effects of treatment
• Should our goal be NO progression?
  • At what cost ($$, side effects, inconvenience) are we “saving vision”?  
  • Does everybody with glaucoma go blind?
  • Should we focus on NO more progression or on the rate of progression?

**Setting a Target IOP**

• Baseline IOP
• Amount of optic nerve damage
• Rate of progression (if known)
• Consider:
  • Age of patient
• Health of patient
• Status of fellow eye
• In general
  • Mild disease or OHTN: ~30% reduction
  • Moderate disease: ~40% reduction
  • Severe disease: 50% or more, or very low teens

**Setting a Target IOP**
• Target IOP is IOP at which you expect to maintain functional vision
• Target IOP is set according to patient age, severity of disease, and other factors
• Target IOP is not set in stone, should be re-analyzed periodically
• Target IOP must balance benefit of preserving vision with safety of tx

**Target IOP**
• Age:
  • Younger patients have longer to become visually impaired, and may have more aggressive glaucoma --SET TARGET LOW
• Rate of Progression (if known)
• Stage of Disease
  • More advanced disease requires more aggressive therapy
  • Based on optic nerve and visual field

**Target IOP**
• Stage of Disease:
  • Mild: ~30% IOP drop from high
  • Moderate: 30-40% drop
  • Severe Loss: 40-50% drop
• Stage of Disease:
  • Mild: high teens
  • Moderate: mid teens
  • Severe loss: low teens

**Target IOP**
• Other Considerations:
  • Race
  • Level of IOP
• Family history of blindness from glaucoma
• Monocular status
• Poor visual field taker
• Other optic nerve or retinal disease
• Life expectancy/systemic disease

**Advanced Glaucoma Intervention Study (AGIS)**

• Important results:
  • Patients with IOP <18mmHg at 100% of visits
    • Average of this group was ~12mmHg
  • IOP <18mmHg at 75-99% of visits
  • IOP <18mmHg at 50-75% of visits
  • IOP<18mmHg at less than 50% of visits

**Initiating Therapy**

• Options:
  • Medical Therapy
  • Laser Trabeculoplasty (argon or SLT)
  • Trabeculectomy
• Most patients can be managed with medication alone (?)
• Maximum therapy is debatable

**Case 7 (continued)**

• Monocular trial Xalatan OD
• Target IOP lower = 30%
• RTC 1 month
  • Good compliance, mild redness
  • IOP 12 mmHg OD  19mmHg OS @3:00 pm
• WHAT IS NEXT? F/U when?

• Begin Xalatan OS as well
• RTC 2 months IOP check
  • 12mmHg OD  11mmHg OS
• Next Follow Up?

• Follow-Up 4 months for IOP check
• Good compliance, no complaints with Xalatan
• IOP 16mmHg OD, OS @3PM
• Q: Do you have any concerns?
• On questioning, patient reported a recent switch of systemic HTN meds from Toprol XL to hydrochlorothiazide

**Case 8**

61 year old Hispanic female referred to glaucoma service for evaluation

• Abnormal FDT
• Asymmetric, large C/D
• History of being told she was a glaucoma suspect 6 years
• POH:
  • Never followed up on recommendations for glaucoma evaluation
  • No surgery, trauma
• PMH:
  • (-) HTN, CVD, DM
  • (+) Migraine
• FH: (+) Aunt with glaucoma

**Case 8**

• BVA: 20/20 OD, OS
• Pupils: normal, (-) RAPD
• SLE: normal OU
• IOP: 14 mmHg OD, OS
• See ONH & VF

**NORMAL TENSION GLAUCOMA (NTG)**

• Many different definitions
• Litwak:
  • Disease in which the anterior chamber angle is normal, the IOP on diurnal testing never exceeds 21mmHg, and changes in the optic nerve head and visual field occur that are consistent with glaucoma

**EPIDEMIOLOGY OF NTG**

• Prevalence varies depending on definition used
• Used to be considered rare
Now recognized to be a common form of glaucoma
• Probably accounts for 25-30% of OAG
• High rate of NTG in Japan
• Refractive error: myopia may be risk
• Gender: women may be affected more often, with worse prognosis than men
• Age: unusual in persons <50 years old

**CLINICAL FEATURES OF NTG**

• IOP
  • What is normal?
    • High percentage of NTG have IOP in high teens
  • Diurnal fluctuations
    • Average diurnal is 5mmHg
    • Similar diurnal in NTG (sitting)
    • Baltimore Eye Study: >50% of patients had initial IOP less than 21
      – Need multiple IOP readings
  • Corneal Thickness
    • NTG patients tend to have thinner corneas
    • Pachymetry may reveal falsely low IOPs
    • Photorefractive surgery patients

**ROLE OF IOP IN NTG**

• Conflicting studies about IOP level and severity of damage in NTG patients
• IOP may play a role in some patients, maybe not in the majority
• IOP is not considered the primary factor in developing NTG

**IOP REDUCTION IN NTG**

• Numerous studies have shown that lowering IOP slows the rate of progression of NTG
• Collaborative Normal Tension Study Group (CNTGS)

**OPTIC NERVE HEAD IN NTG**

• Some optic nerve findings occur more frequently in NTG than in POAG
  • Larger disc size
• Thinner temporal NRR
• Disc hemorrhage
• APON
• PPA
• Focal NFLDO (IOP <18)

**VISUAL FIELD LOSS IN NTG**

• Large overlap between VF of NTG and POAG
• In general, NTG patients exhibit:
  • Localized defects
  • Steeper slope of defect
  • Closer to fixation

**COLLABORATIVE NORMAL TENSION GLAUCOMA STUDY (CNTGS)**

• Question:
  • Does substantial IOP lowering slow the rate of glaucomatous optic nerve damage in patients with NTG?

• Methods:
  • Randomize one eye of each subject to either lowering IOP by 30% or observation
  • Randomization criteria:
    • Documented VF progression –OR-
    • VF defect threatening fixation –OR-
    • New disc hemorrhage

• IOP Lowering Procedure:
  • Medications
  • Laser Trabeculoplasty
  • Filtering Surgery

• Outcome Measures:
  • Disc changes
  • Visual field progression

• Results:
  • 35% of untreated (control) eyes showed progression
• 12% of treated eyes showed progression
• Significantly higher rate of cataract development in treated group
• Subsequent findings:
  • Faster progression in:
    • Women
    • Patients with migraine headaches
    • Presence of disc hemorrhage at baseline

**DIFFERENTIAL DIAGNOSIS IN NTG**

• POAG
• Physiologic cupping with abnormal initial VF
• Undetected high IOP
  • Intermittent angle closure
  • Uveitic glaucoma
  • Steroid-induced glaucoma
  • Burned out glaucoma
• Non-glaucomatous conditions
  • Large physiologic cupping
  • Myopic discs
  • ONH coloboma
  • Optic pits
  • Tilted disc
  • ONH drusen
• Vascular lesions:
  • AION
  • Retinal embolic disease
  • Single events that compromise blood supply to ONH
    • Blood loss
    • Blood dyscrasias
    • Carotid artery disease
• Neurologic Conditions
• Compressive lesions
  • Younger
  • Reduced visual acuity
  • Visual fields that respect vertical midline
  • Pallor of ONH
• Consider neuro-imaging if above occur
• Easy mnemonic:
  • S
  • H
  • U
  • T

**Evaluation of NTG patient**

• Diagnosis
  • Medical history
    • Medications
    • Blood loss
  • Color Vision
  • Diurnals
  • Gonioscopy!!!
  • ONH/VF
  • WATCH for PROGRESSION

**SUMMARY OF NTG**

• Management:
  • Patients with definitive PROGRESSIVE glaucomatous damage and normal IOP should have IOP lowered by at least 30%
  • Patients without definitive progressive damage may be followed closely without treatment
  • Avoid beta blockers and non-selective adrenergic agonists

**Thank you for your attention!**

Questions?

DMarrelli@uh.edu
EXPECTEDS

The following are general levels of expected visual ability by age for each of the assessment areas.

A. General Considerations and History

A newborn is regarded as fully matured if the birth weight is not less than 2500 grams (5 lb 8 oz). Maturity of the newborn can also be described by weeks of gestation. Generally, infants less than 37 weeks of gestation are regarded as premature.

The general health status of the newborn is assessed by the Apgar score which ranges from 0-10. It is an evaluation of the infant’s heart rate, respiratory effort, muscle tone, reflexes and color. The Apgar scores, usually recorded at one, three and five minutes after birth, can be a good indicator of possible neurological disorders or a difficult birth. An Apgar score greater than 7 after three minutes is considered normal.

B. Ocular Health

1. One Month
   - Eyes open for short periods only
   - Eyes open with sucking reflex and when infant held vertically upright
   - Foveal reflex not present, disc normally pale in color, grayish look to fundus
   - Pupils miotic and reactive to light (pupils less than 1.8mm or more than 5.4mm suggest the possibility of neurological damage). Average diameter is 3.6mm± 0.9mm in 10 footcandles of light
   - Stenosis of the nasolacrimal canal is often seen
   - Non-alignment or failure to maintain fixation is normal

2. Three Months
   - Pupils normal in size and reactive to light
   - Foveal reflex difficult to see if present
   - Stenosis of the nasolacrimal canal is observed frequently

3. Six Month
   - Pupils normal in size and reactive to light
   - Nasolacrimal canal should be patent

4. Nine Months
   - Foveal reflex present in 50% of infants

5. Twelve Months
   - Foveal reflex present in 90% of infants
C. **Alignment and Ocular Motility**

1. **One Month**
   - Fixates briefly on a bright object in the line of sight
   - Briefly follows a slowly moving stimulus
   - Best target for under one year is the parent’s face
   - Slow and sluggish eye movements often opposite to head movement
   - Nearpoint of convergence generally absent – may sometimes converge to 50cm.

2. **Two Months**
   - Follows a bright object past the midline in all planes
   - Full versions – still slightly slow and sluggish – better horizontally than vertically
   - Nearpoint of convergence to nose
   - Versions full in all directions – with head movement
   - Any persistent strabismus or temporary misalignment of the eyes should be considered abnormal.

3. **Six Months**
   - Begins to follow moving object when in sitting position
   - Versions full and smooth in all directions with accompanied head movements
   - Nearpoint of convergence to nose
   - Begins to show reaching response to stereo testing

4. **Nine to Twelve Months**
   - Versions full, normal and smooth in all directions
   - Nearpoint of convergence to noise – adult like
   - Good response to stereo testing

D. **Visual Acuity and Refractive Status** (based on non-cycloplegic findings)

Hyperopia, myopia, astigmatism and anisometropia show marked variation during the first year of life. The presence of strabismus or a stable refractive measurement over a three-month period should be cause for immediate concern.

1. **One Month**
   - Visual acuity: responsive to 20/600 to 20/800 ( Preferential Looking – PL)
   - Retinoscopy: -1.00 with up to 3.00 variability often not dependent upon the target

2. **Three Months**
   - Visual acuity: responsive to 20/200 to 20/400 (PL)
   - Retinoscopy: -0.50 with up to 2.00 variability with good attention to the target

3. **Six Months**
   - Visual acuity: responsive to 20/80 to 20/200 (PL)
   - Retinoscopy: plano with up to 1.25 variability with good attention to the target

4. **Nine Months**
   - Visual acuity: responsive to 20/50 to 20/100 (PL)
   - Scopes: +0.50 with up to 1.00 variability with good attention to the target

5. **Twelve Months**
   - Visual acuity: responsive to 20/50 to 20/80 (PL)
   - Scopes: ±0.50 with up to 1.00 variability with good attention to the target
LETTER OF AGREEMENT FOR PARTICIPATION IN InfantSEE

I, Dr. _________________________, a member of the American Optometric Association (AOA), with my principal practice located at: ____________________________, agree voluntarily to participate in the AOA InfantSEE program commencing on the following date: __________________. I further agree to adhere to and abide by all the conditions and requirements of the InfantSEE program as set forth in this Letter of Agreement, understanding and acknowledging that failure to do so shall result in my immediate and automatic termination from the InfantSEE program.

Conditions and Requirements

1. I shall provide at least one no-cost, comprehensive eye assessment to a child within that child’s first year of life. At my sole discretion, I may choose to provide additional no-cost, comprehensive eye assessments to other children within their first year of life under the InfantSEE program.

2. At no time will I charge any fee for the eye assessment offered through the InfantSEE program. At no time may I represent that any eye assessment that I provide for which I do charge any fee is an assessment being provided through the InfantSEE program. At no time will I condition the eye assessment offered through the InfantSEE program upon the provision of any other services.

3. I shall follow and adhere to the optometric practice standards set forth in the AOA Clinical Practice Guidelines, including the Guideline for Pediatric Eye and Vision Examinations, when practicing as part of the InfantSEE program, and shall document in writing in my patient records sound medical justifications for any departures from those guidelines that I deem necessary for a patient in the exercise of my professional medical judgment.

4. I am duly licensed and authorized by my state optometric practice act to provide comprehensive eye assessments to a child within the child’s first year of life.

5. If, in my professional medical judgment, I determine to recommend that the infant patient receive additional examinations, treatments, or therapies, I will both verbally and in writing advise the infant’s parent or legal guardian that he or she is free to choose any practitioner for those additional services.

6. I will share with the InfantSEE program the outcomes of the eye assessments that I perform through the InfantSEE program. Such data shall be shared in a blind manner that does not violate the patient privacy rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The InfantSEE program, where practicable, may require that I fill out reporting forms to comply with this requirement.

7. I agree that I will protect and use the trademarked InfantSEE name and logo only as expressly permitted in this Letter of Agreement, as follows:

COPY A
a) Until such time as the InfantSEE program, in its sole and exclusive discretion, determines to officially launch the InfantSEE program nationally, I am granted a limited, non-exclusive, license to use the trademarked InfantSEE name and logo only for purposes of locally advertising that I am participating in a limited, local trial of the InfantSEE program. Upon the date of the official national launch of the InfantSEE program, I will be granted a limited, non-exclusive license to use the trademarked InfantSEE name and logo only for purposes of generally advertising that I am participating in the InfantSEE program. Advertisements may contain the official description of the InfantSEE program that has been approved by the InfantSEE program. No advertisement shall contain any other references or make any other statements concerning the InfantSEE program, unless expressly approved in advance in writing by the InfantSEE program. No advertisements containing a reference to the InfantSEE program shall contain any other material that would violate state or federal laws or state professional conduct laws, regulations, or rules applicable to optometrists.

b) Until such time as the InfantSEE program, in its sole and exclusive discretion, determines to officially launch the InfantSEE program nationally, I will make clear in any media inquiries or interviews that I am only a participant in a limited, local trial of the InfantSEE program as a public health initiative, and that questions about specific details of the InfantSEE program and any national launch must be addressed to the InfantSEE program through the American Optometric Association.

c) Whenever using the InfantSEE name or logo, I will ensure that the appropriate trademark symbol is attached. This symbol consists of the small, uppercase letters TM immediately to the upper right of the name of the program, as used throughout this Letter of Agreement. Should that symbol change, the InfantSEE program will so advise and will provide a different symbol for my use.

d) I shall use the InfantSEE name and logo only as exactly provided to me by the InfantSEE program, with no alterations of any kind unless expressly approved in advance in writing by the InfantSEE program.

8. I shall at all times treat my InfantSEE patients professionally and shall, where required by the InfantSEE program, undergo the education and training provided by the InfantSEE program for performing a comprehensive eye assessment for a child during the child’s first year of life.

WHEREFORE, I hereby sign and agree to the terms of this Letter of Agreement effective the date first set forth above:

____________________
Signature

COPY A
Patient Name: _________________________________________________ D.O.B.: ____/____/_____ Age:_____months

Parent(s) Name: _______________________________________________________________

Premature? Yes__No__

Gender: □M □F Ethnic Origin (from History Form): □H □C □AA □NA □A □PI

Reason for Visit:
□ Requested InfantSEE™ Assessment
□ Referred; reported problem: ________________________

Heard about program from:
□ current patients □ family/friends
□ print ads □ TV □ radio ads □ website
□ story in newspaper □ referred by pediatrician/MD

Visual Acuity
Fix & Follow Method:       OD □ Y □ N OS □ Y □ N
Resistance to Occlusion:    OD □ OS □ None
10 Vertical Prism Test:     □Pass □Fail
                          OD___________ OS___________ OU___________ □ Teller □ Richman

Ocular Motility
□ Full Range of Motion (FROM) □ Motility Limitation: ______________________

Alignment / Binocular Potential
Hirschberg: □ Aligned □ Misaligned
Cover Test: □ Normal Alignment □ Strabismus: ______________________
             □ Phoria: ______________________
Convergence Estimate: □ Normal □ Inadequate
10 Vertical Prism Test: □ Pass □ Fail
Brückner       □ Equal reflexes Whiter and Brighter: □ R □ L

Refractive Status
Manifest OD __________ __________ __________ Additional OD __________ __________ __________
Retinoscopy OS __________ __________ __________ Retinoscopy OS __________ __________ __________
                          □ Mohindra □ Cycloplegic: Agent: ______________________

External/ Anterior Segment Evaluation: □ Normal Problem Noted: ______________________
Visual Field Assessment: □ Full OU □ Full OD □ Full OS Problem Noted: ______________________
Pupil Evaluation: □ Normal Problem Noted: ______________________

Internal Assessment

CL   Lens   CL
CL   Vitreous   CL
Disc___________
Vessels_________
CL   Macula   CL
+ Foveal Reflex +
Peripheral Retina_________
□ dilated □ non-dilated

Assessment:
Visual Acuity □ Normal □ Problem: ______________________
Ocular Motility □ Normal □ Problem: ______________________
Binocularity □ Normal □ Problem: ______________________
Ref refractive Status □ Normal □ Problem: ______________________
Strabismus: □ Esotropia □ Exotropia
Ocular Health □ Normal □ Problem: ______________________

Plan: □ No Concerns □ Concerns □ Recommended follow-up at __________
□ Comments: ______________________

Optometrist Name (Please print) State Signature Date
Name: ___________________________________________       Male ___ Female___      DOB:_______/_______/_______
Home Phone: _______________________________ Hispanic | Caucasian | African American | Native American | Asian | Pacific Islander
Home Address: _________________________________________________________________________________________
Street     City   State             Zip Code
Parent(s) or Guardian(s): ______________________________________Adult(s) Occupation:__________________________________
How did you learn about our program? ☐Current patients ☐Referred by friends/family  ☐Print Ads ☐Radio Ads
☐Website  ☐Story in Newspaper/on TV  ☐Referred by Dr.__________________________________
Eye History
Have you ever noticed any of the following happening with your baby's eyes?      (please check any that apply)
Eye turn: ☐ in ☐ out   ☐ Eyes watering    ☐ Eyes red   ☐ Swelling around the eyes   ☐ White appearance in pupil
Explain any eye concerns noted by observing child:  ___________________________________________________________
______________________________________________________________________________________________________
Developmental and Health History
PREGNANCY
Length of pregnancy: ____ weeks    List any complications during pregnancy: ________________________________________
Other pregnancy issues:  ____________________________________________________________
DElivery
Birth Weight __________________                                  Parents ages at time of birth:  Mother _____  Father _____
List any complications during delivery:  ____________________________________________________________
Was oxygen used? ☐ No ☐ Yes   APGAR score at birth: _______ (if known)
MEDICAL
Child’s Doctor: __________________________ Last Exam Date: ____________  Are immunizations up to date? ☐ Yes ☐ No
Does your baby have any known food or drug allergies? ☐ No ☐ Yes: __________________________________________
List ALL medications taken regularly: ☐ None      List:  ________________________________________________________
List any developmental delays:  ____________________________________________________________
Check all of the following that your baby can do at this time: ☐ Roll Over ☐ Sit ☐ Crawl ☐ Stand ☐ Walk
Has your baby ever had a high temperature (fever)? ☐ No ☐ Yes, how high? __________
Please list any childhood illnesses your baby has had:
_________________________________________ Illness _____ Age at the time.   Was the illness? ☐ Mild ☐ Moderate ☐ Severe
_________________________________________ Illness _____ Age at the time.   Was the illness? ☐ Mild ☐ Moderate ☐ Severe
List any accidents, eye, or head injuries, and age they occurred:__________________________________________________
Please list any other conditions we should know about:_________________________________________________________
Family History
Do any family members have: Lazy eye (amblyopia) Yes No Eye turn (strabismus) Yes No Eye tumor Yes No
Please list any family members with a history of other eye or medical problems. List the relation and type of problem:

_________________________________________ Illness _____ Age at the time.   Was the illness? ☐ Mild ☐ Moderate ☐ Severe
_________________________________________ Illness _____ Age at the time.   Was the illness? ☐ Mild ☐ Moderate ☐ Severe
I acknowledge that this information is accurate to the extent that I can be certain, and will disclose additional information as necessary. This information can only be used in the management of my child's eyes and vision.  
I understand that the InfantSEE™ vision assessment is without charge. If further services or treatments are recommended, I may choose any eye care professional to provide those services.

_________________________________________     Date: _______/_______/__________
Parent/Guardian Signature

Thank you for carefully completing this confidential questionnaire. This information will allow for a more efficient use of examination time and will contribute to the understanding of infant eye and vision development.
Cases From Joslin Diabetes Center: An Optometrist’s Point of View

W. Lee Ball, Jr., OD, FAAO

Beetham Eye Institute
Joslin Diabetes Center
Division of Ophthalmology
Beth Israel Deaconess Medical Center
Boston, MA

Acknowledgements

Tony Cavallerano, OD, FAAO
Gerry Selvin, OD, FAAO
Paul Chous, MA, OD, FAAO
Jeff Gerson, OD, FAAO

Learning Objectives/Outcomes

Upon completion of this program, participants will be able to:

1. Review current epidemiology of diabetes in U.S.
2. Discuss Pre-diabetes and the Diabetes Prevention Program
3. Recognize sentinel lesions of Diabetic Retinopathy
4. Classify clinical level of Diabetic Retinopathy and Diabetic Macular Edema (DME)
5. Discuss nation-wide clinical trials for Diabetes and the impact on patient care
6. Describe relationships between A1C, Blood pressure and Cholesterol on the development of Diabetes, DR and DME
7. Explain the impact of lifestyle choices, including diet and tobacco use, on the development of Diabetes
8. How to Build the “Medical Home” Without Walls in your community using NDEP materials

Understand the compounding effects of A+B+C

Nadeem N. Vaidya, M.D.
What is Diabetes?

Diabetes is a group of diseases resulting from problems with insulin production, insulin action, or both.

Diabetes can lead to serious health problems and premature death.

Diabetes is common, costly, controllable.

Common Types of Diabetes

Type 1 diabetes
- 5% to 10% of diagnosed cases of diabetes

Type 2 diabetes
- 90% to 95% diagnosed cases of diabetes


Obesity Trends

1990 2001

Diabetes Trends

Prevalence of Diabetes

Persons over 20 Years of Age

Increased Incidence in DM by Age

Since 1990

It is estimated that of persons born in 2002, 1 in 3 will develop diabetes in his or her lifetime… unless something changes.

Be part of that something!
Common Types of Diabetes

- Gestational Diabetes occurs during pregnancy
  - 5 to 10% of women with gestational diabetes are found to have type 2 diabetes
  - Increased lifelong risk for mother and child for developing type 2 diabetes
  - 40-60% women with gestational diabetes will develop diabetes in the next 5 to 10 years

NIDDK, National Diabetes Statistics 2007

The Diabetes Epidemic – the "perfect storm"
- Significant increase in the incidence of diabetes during the last decade
- Increase across all regions, demographic groups, ages, genders, racial/ethnic groups and subpopulations
- 800,000 new cases/year in U.S.

National Diabetes Fact Sheet, 2007

Pre-Diabetes

Approximately 57 million U.S. adults age 20 and older have pre-diabetes, which raises their risk for type 2 diabetes and cardiovascular disease


What is Pre-Diabetes?

- People with pre-diabetes have blood glucose levels higher than normal but not high enough to be diagnosed with DM
- Pre-diabetes includes Impaired Fasting Glucose (IFG) & Impaired Glucose Tolerance (IGT)
- Most people have pre-diabetes before they develop type 2 diabetes
- Most people with pre-diabetes develop type 2 within 10 years
- Progression to diabetes is NOT inevitable
Risk Factors for Diabetes

- Age 45 and older
- Overweight (BMI ≥ 25)
- Hypertension
- Abnormal lipid levels
- Family history of diabetes
- Race/ethnicity
- History of gestational diabetes


A1C Update

- Recently advocated by ADA to screen for DM
- A1C assay, expressed as % glycated hemoglobin, measures chronic glycemia
- Widely used to judge adequacy of DM tx and adjust therapy
- The A1C-Derived Average Glucose (ADAG) Study Group recently translated A1C assay into estimated average glucose values.

Translating the A1C Assay Into Estimated Average Glucose Values

- Study sought to define the mathematical relationship between A1C and average glucose (AG) levels to determine whether A1C could be reported in the same units used in self-monitoring of capillary glucose concentrations (milligrams per deciliter or millimoles per liter)
- 507 subjects: 268 (type 1), 159 (type 2), 80 (no DM) from 10 international centers
- A1C levels obtained at end of 3 months compared with AG levels during previous 3 months
- AG calculated by combining weighted results from last 2 days of CGM with 7-point daily self monitoring of capillary finger sticks

Conclusion: A1C levels can be expressed as eAG for most patients with type 1 and 2 DM

What Does the A1C Mean?

<table>
<thead>
<tr>
<th>A1C %</th>
<th>eAG</th>
<th>Glucose Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>298</td>
<td>240-340</td>
</tr>
<tr>
<td>11</td>
<td>269</td>
<td>217-314</td>
</tr>
<tr>
<td>10</td>
<td>240</td>
<td>193-282</td>
</tr>
<tr>
<td>09</td>
<td>212</td>
<td>170-249</td>
</tr>
<tr>
<td>08</td>
<td>183</td>
<td>147-217</td>
</tr>
<tr>
<td>07</td>
<td>154</td>
<td>123-185</td>
</tr>
<tr>
<td>06</td>
<td>126</td>
<td>100-152</td>
</tr>
<tr>
<td>05</td>
<td>97</td>
<td>76-120</td>
</tr>
</tbody>
</table>
Diabetes and Cardiovascular Disease

Cardiovascular disease is the leading cause of death for people with diabetes.

In adults with diabetes:
- 68% die of heart disease or stroke
- the risk for stroke is two to four times higher
- 75% have high blood pressure
- smoking doubles the risk for heart disease

Diabetes Complications

Diabetes is the leading cause of:
- kidney failure
- new cases of adult blindness
- nontraumatic lower-limb amputations

In adults with diabetes:
- the risk of periodontal (gum) disease is two to three times higher
- 60 to 70% have mild to severe nervous system damage

The Science of DM Control

Good Glycemic Control (Lower HbA1c) Reduces Incidence of Complications

<table>
<thead>
<tr>
<th>HbA1c</th>
<th>DCCT2 9-7%</th>
<th>Kumamoto1 9-7%</th>
<th>UKPDS6 9-7%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinopathy</td>
<td>63%</td>
<td>69%</td>
<td>17-21%</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>54%</td>
<td>70%</td>
<td>24-33%</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>60%</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Macrovascular Disease</td>
<td>41%*</td>
<td>—</td>
<td>16%*</td>
</tr>
</tbody>
</table>

*HbA1c: significantly lower

Kumamoto: Japanese Diabetes, 1994;44:50-57
UKPDS: British Medical Journal, 1998;316:703-713

DCCT Findings

Glucose control is key to preventing or delaying complications of diabetes.

Any sustained lowering of blood glucose helps, even if the person has a history of poor control.

DCCT Findings

Lowering blood glucose reduced risk of:
- Eye disease by 76%
- Kidney disease by 50%
- Nerve disease by 60%

Nadeem N. Vaidya, M.D.
Preventing Diabetes Complications

- A1C: Glucose control (micro 40%)
- Blood pressure control (CVD/CVA 33-50%; micro 33%)
- Cholesterol: blood lipid control (CVD 20-50%)

United Kingdom Prospective Diabetes Study (UKPDS)

20 Year Clinical Trial

Looked at intensive management of blood glucose levels and long term risk-factors for diabetes complications in type 2 diabetes

UKPDS Findings

Mirrored the findings of DCCT in people with type 2 diabetes—better glucose control reduced development of microvascular complications

Demonstrated the need for management of high blood pressure and cholesterol as well as blood glucose levels (the ABCs of diabetes)

UKPDS Findings

Risk reduction with 1% decline in annual mean A1C

- Microvascular Disease: 37% reduction
- PVD: 43% reduction
- MI: 14% reduction
- Stroke: 14% reduction
- Heart Failure: 19% reduction
- Cataract Extraction: 15% reduction

Epidemiology of Diabetes Interventions and Complications Study (EDIC)

Ongoing Observational study
DCCT participants (type 1 diabetes)
Looked at risk factors for long-term incidence of cardiovascular disease

EDIC Findings: Intensive Therapy and Diabetes Complications

Participants continue to benefit years later from period of intense glucose control

Years after intensive therapy:
- Lasting benefits for eye, nerve, and kidney disease
- Reduces CVD events by more than half
EDIC Findings: Cardiovascular Events

Cumulative Incidence of Any Event

- Risk reduction 42%
- 95% CI: 9% to 63%
- P = 0.02

UKPDS 10 yr Follow-Up Study-
mεtformin group

- Differences in A1C between intensive & standard glycemic control treatment groups were lost after one year
- Relative risk reductions at 10 yr in intensive metformin group:
  - 21% for any diabetes end point (P=0.01)
  - 33% myocardial infarction (P=0.005)
  - 21% death from any cause (P=0.002)

UKPDS 10 yr Follow-Up Study-
Blood Pressure findings

- Between group differences lost within 2 yrs
- Significant relative risk reductions in tight control group were not maintained
- Benefits of BP control do not extend beyond intensive therapy period & ongoing treatment is essential

Recent Clinical Trial Findings:

- Intensive glucose control in type 2 diabetes:
  - lowers risk of new or worsening microvascular complications (ADVANCE)
  - was associated with increased mortality in patients with longstanding DM and known CVD (ACCORD)
  - increases risk of severe hypoglycemia (ADVANCE, ACCORD and VADT)

Key points of recent findings:

- Intensive glucose control in newly diagnosed type 1 or type 2 diabetes has benefits during intensive therapy AND a legacy effect for later micro- and macrovascular benefits
- Optimal glucose management should start as early as possible & continue as long as possible
- While the A1C goal for the general population is <7%, treatment must be individualized.

SEARCH For Diabetes in Youth Study

- Observational study funded by CDC and NIH
- Physician-diagnosed diabetes in youth ages 0-19
- Data will help researchers better understand and treat diabetes in young people

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SEARCH Findings

Determine prevalence and correlates of selected CVD risk factors among youth with diabetes

21% of young people with diabetes had at least two CVD risk factors

Prevalence of CVD risk factors was higher among youth aged 10-19 years and among girls


SEARCH Findings

In young people with type 2 diabetes:
- 92% had at least two CVD risk factors

In young people with type 1 diabetes:
- 14% had at least two CVD risk factors


UKPDS 10 yr Follow-Up Study - insulin/sulfonylurea group

Differences in A1C between intensive & standard glycemic control treatment groups were lost after one year

Relative risk reductions at 10 yr in intensive insulin/sulfonylurea group:
- 9% for any diabetes end point (P=0.04)
- 24% microvascular disease (P=0.001)
- 15% myocardial infarction (P=0.01)
- 13% death from any cause (P=0.007)


Vision Loss From Diabetes

- Vitreous Hemorrhage
- Traction Retinal Detachment
- Diabetic Macular Edema

Pathophysiologic Processes of DR

- Alterations in retinal blood flow
- Loss of pericytes of retinal capillaries
- Outpouchings of capillary walls to form microaneurysms
- Closure of retinal capillaries and arterioles
- Breakdown of blood-retinal barrier
- Proliferation of new vessels and fibrous tissue
- Contracture of vitreous and fibrous proliferation

Retinal Signs of Hypoxia (sentinel lesions of DR)

- Cotton wool spots
- Venous caliber abnormalities (VCAB)
- Venous tortuosity
- Arteriolar abnormalities (H/MAs)
- Intraretinal microvascular abnormalities (IRMA)
- Featureless retina
ETDRS Classifications of DR

- No DR
- Mild NPDR
- Moderate NPDR
- Severe NPDR
- Very Severe NPDR
- High Risk Proliferative
  - With or without CSME

No Diabetic Retinopathy
- No clinical signs of DR
- Early changes in retinal blood flow
- Nondiabetic changes and complications may be present

Mild Nonproliferative DR
- At least one microaneurysm
- Criteria not met for more severe levels of Diabetic Retinopathy

Moderate Nonproliferative DR
- \( H/Ma \geq \text{standard photo 2A in 1-3 retinal quadrants or} \)
- Soft exudate, venous beading, or IRMA definitely present
- Criteria not met for more severe levels of DR

Severe Nonproliferative DR
- The 4-2-1 Rule
- \( H/Ma \geq \text{standard 2A in all 4 retinal quadrants or} \)
- Venous beading (VB) in 2 or more retinal quadrants or
- IRMA \( > \text{standard 8A in at least 1 retinal quadrant} \)
- Criteria not met for more severe levels of DR

PDR (1 yr.): 5%  HR-PDR (5 yr.): 15%
PDR (1 yr.): 12-27%  HR-PDR (5 yr.): 33%
PDR (1 yr.): 52%  HR-PDR (5 yr.): 60%
Very Severe Nonproliferative DR

- Any 2 or more criteria of Severe NPDR
- Criteria not met for more severe DR

**High-Risk Proliferative DR**

- NVD ≥ standard 10A (i.e., > 1/4-1/3 disc area)
- NVD < standard 10A with fresh preretinal or vitreous hemorrhage
- NVE with fresh preretinal or vitreous hemorrhage

Clinically Significant Macular Edema

- Macular edema that involves or threatens the center of the macula
- CSME can be present with any level of DR

Clinically Significant Macular Edema

- Retinal thickening at or within 500 µm from the center of the macula
- Hard exudates at or within 500 µm from the center of the macula if accompanied by thickening of the adjacent retina
- A zone of retinal thickening, 1 disc area or larger in size, located 1 disc diameter or less from the center of the macula

Treatment Options

- Laser
  - PRP
  - Focal
  - Grid

Treatment

- Intravitreal injections
  - 25 mg of triamcinolone acetonide for clinically significant diffuse DME
  - 1.25 mg bevacizumab treatment for retinal neo and vit heme in PDR
    (Clinical Ophthalmology 2007:1(2)149-155.)

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Blood Pressure and the Eye

- Hypertensive Retinopathy
  - Vasoconstriction
  - Leakage
  - Arteriosclerosis

Grading Hypertensive Retinopathy

- Grade 1 – mild generalized arteriolar attenuation
- Grade 2 – more severe arteriolar constriction
  - Salus’ sign
  - Gunn’s sign

Grading Hypertensive Retinopathy

- Grade 3
  - copper wiring of arterioles
  - Hemes
  - Cotton-wool spots
  - hard exudates
- Grade 4 (malignant)
  - Bilateral disc swelling

Other Ocular Manifestation of HTN

- Retinal vein occlusion – branch or central
  - Age
  - Systemic hypertension
  - Blood abnormalities (chronic leukemia, polycythema)
  - Elevated IOP
  - Hyperopia
  - Congenital abnormality of central retinal vein

Central Retinal Vein Occlusion

- Ischemic
- Non-ischemic

CRVO

- Ischemic
  - Vision often < 20/200
  - rAPD
  - Greater VF deficits
  - Diminished b-wave on ERG
  - > 10 DD of nonperfusion on angiography
  - Note: CWS and disc edema do not have adequate sensitivity or specificity for predicting ischemia
- Nonischemic
  - 14% convert to ischemic within 4 months
  - 1/3 with NVI / NVA
  - Overall, 1/3 convert to ischemic within 3 years
**HRVO and BRVO**

- **HRVO**
  - Up to 20% of people have 2 separate trunks of the central retinal vein that enter the lamina cribosa separately then join together
  - Patients with this anomaly may get HRVO

- **BRVO**
  - From thrombus formation at A-V crossings where arteries and veins have a common adventitial sheath

**Treatment: Branch Vein Occlusion Study and Neovascularization**

- For > 5 DD of nonperfusion, follow every 4 months to monitor for neovascularization
- If neovascularization develops, scatter photocoagulation to the involved quadrant
- Scatter reduces VH rate by 50%

**Treatment: Branch Vein Occlusion Study and Macular Edema**

- For perfused macular edema and vision ≤/= 20/40 persisting over 3 months -> grid photocoagulation
  - 65% gain 2 or more lines of vision vs. 37% of controls
- If macular nonperfusion causes vision decrease
  - No treatment
  - Majority will gain some vision
  - Median time of 14 months
- If combined ischemic and nonischemic macular edema
  - May wait 6-12 months for ischemia to resolve

**Experimental Treatments: SCORE Study - CRVO and BRVO**

- The Standard Care vs. Corticosteroid for Retinal Vein Occlusion Study
- NEI study with 1260 patients
- Expected completion date: 10/07
- Macular edema from CRVO and BRVO
- Standard of care vs. 4 mg IV triamcinolone vs. 1 mg IV triamcinolone
- Protocols for repeating laser or IV injections
- Outcomes: vision, retinal thickness, adverse effects

**Intravitreal bevacizumab (Avastin)**

- For macular edema from CRVO
- Rosenfeld et al. 2005
  - Patient who had become resistant to IV steroids
  - 1 mg of IV bevacizumab improved vision from 20/200 to 20/50 after 1 week
  - CME resolved by OCT
  - Improvement maintained for at least 3 weeks
bevacizumab

- Iturralde, Spaide, et al. 2006
  - 16 eyes of 15 patients
  - Previous IV triamcinolone in 9
  - Mean 2.8 injections of 1.25 mg of bevacizumab
  - Mean visual acuity 20/600 -> 20/200 at 1 month
  - Mean central retinal thickness 887 microns -> 327 at 1 month
  - At last follow-up (mean 3 months)
    - Improvement of halving of the visual angle: 14/16 eyes
    - No adverse effects

Prophylactic IOP Reduction Rationale

- Glaucoma and OHTN are associated with CRVO and BRVO in older patients
- Chew et al. 1987
  - Younger CRVO patients had abnormal IOP with diurnal measurements
- Since higher IOP may be related to vein occlusion development, some clinicians will start IOP-lowering meds for possible prophylaxis

Other Ocular Effects of HTN

- Retinal Arterial Macroaneurysm
- Non-arteritic Anterior Ischemic Optic Neuropathy
- CN III Palsy
- Exudative Retinal Detachment

Cholesterol and the Eye

- Atherosclerosis
  - common in patients with DM, produces most of the circulatory problems
  - plaque builds up within the walls of arteries between the basement membrane and the endothelial cells of the tunica intima and in time may completely prevent blood flow
  - A plaque consists of lipid, or cholesterol fused with proteins, and a fibrous cap of connective tissues

Cholesterol and the Eye

Conclusions

- New therapies may make significant advances in the treatment of macular edema secondary to CRVO, BRVO and DME
- DPP summary….prevention vs treatment
Diabetes Prevention Program (DPP) Lifestyle Intervention

A comprehensive program with the following specific aims:
- Reduction of fat and calorie intake
- Physical activity at least 150 minutes / wk
- 5-7% loss of body weight
  - Reduced risk of developing diabetes by 58%
  - Worked in all ethnicities, all ages


Why Does Diabetes Continue to Command Our Attention?

- Because EVERY 24 HOURS there are:
  - 4,100 new cases of diabetes,
  - 810 deaths due to diabetes,
  - 230 amputations,
  - 120 kidney failures, and
  - 55 new cases of blindness

Diabetes Mellitus

- Diabetes is the leading cause of preventable new-onset blindness in the United States.
- Approximately 40% of Americans who would benefit from sight preserving treatment for diabetic retinopathy do not receive necessary care.

Joslin Vision Network

- In June 1999 the first Joslin patient was imaged using the Joslin Vision Network (JVN).
- Idea of Dr. Lloyd M. Aiello; ran by Dr. Jerry Cavallarano
- In 2007 alone, nearly 4,000 Joslin Clinic patients received eye care through the Joslin Vision Network Diabetes Eye Care Program. To date, more than 35,000 patients worldwide have been imaged.

JVN

- This course highlights some interesting cases from the Beetham Eye Institute archives of patients evaluated by the JVN program at Joslin and HealthCare Associates. These are examples of the positive impact that the JVN Diabetes Eye Care Program has made on the care of these patients and the importance of regular eye care for patients with diabetes.
Case 1: Severe Asymptomatic Retinopathy Four Months after Diagnosis of Diabetes

- Examination identified sight-threatening retinopathy in this patient with recent-onset type 2 diabetes, no visual symptoms, and no history of recent eye exam.
- The access and immediacy of diagnosis provided by JVN allowed disease detection and reduced the risk of loss to follow-up or treatment delay.
- Focused education regarding the importance of diabetes eye care and diabetic changes already present reinforced the urgency of care for this patient whose risk of vision loss was reduced 50% or more by this intervention.

Case 2 Pregnancy and DR
Asymptomatic Proliferative Retinopathy During Pregnancy Despite 'No Retinopathy' at Eye Exam Elsewhere One Year Earlier

- 28-y.o. Caucasian woman in the 34th week of pregnancy with 22 years of type 1 DM and an A1C of 6.4 reported no eye problems and no hx of diabetic retinopathy (DR) at eye exam elsewhere one year ago.
- Severe nonproliferative DR and early diabetic macular edema in the right eye and proliferative DR in the left eye.
- Hard exudates (HE) in the right eye and new vessels elsewhere (NV/IEV) in the left eye.
- To reduce the substantial risk of vision loss associated with this severity of retinopathy, she received prompt scatter (panretinal) laser treatment in her left eye.

Case 1

- JVN imaging identified sight-threatening retinopathy in a patient with recently diagnosed diabetes, even with the complete absence of visual symptoms.
- JVN provided prompt, accurate identification of presence & level of retinopathy and macular edema.
- JVN exam prevented delay in appropriate eye care for this patient.

Case 2 Pregnancy and DR
Asymptomatic Proliferative Retinopathy During Pregnancy Despite 'No Retinopathy' at Eye Exam Elsewhere One Year Earlier

- JVN imaging identified sight-threatening proliferative DR in this patient with no prior history of DR despite outside eye exam 1 year earlier.
- Prompt laser treatment decreased the risk of severe vision loss in this patient by >90%.
- The immediacy of JVN diagnosis reduced delay in subsequent eye exam and laser treatment while focused education on the severity of this situation reinforced the urgency of care.
Focused education reinforced the ocular follow-up as recommended additional 8 or more months for vision loss if she had waited an patient had a 60% risk of severe vision loss if she had waited an additional 8 or more months for.

Without urgent treatment, this patient had a 60% risk of severe vision loss if she had waited an additional 8 or more months for.

Sight-threatening macular edema, demonstrated extensive sight-threatening macular edema, both of which were past the stage for optimal laser treatment. Both of which were advanced proliferative diabetic retinopathy (DR) can be difficult to detect without proper examination. Severe DR can progress rapidly and may be present despite lack of visual symptoms and history of recent eye exam.

Certain risk factors increase the likelihood of DR progression, including poor glycemic control, dyslipidemia, hypertension, and renal disease.

**Case 2 Key Messages**
- Diabetic retinopathy can progress rapidly during pregnancy.
- Frequent careful monitoring and prompt treatment of diabetic patients during pregnancy is essential for optimal protection of vision.
- Co-morbidities, such as fluid retention and elevated blood pressure may contribute to worsening of diabetic retinopathy during pregnancy.

**Case 2 Key Messages**
- JVN identified advanced bilateral sight-threatening proliferative diabetic retinopathy in this patient with history of recent eye exam elsewhere and no reported DR.
- JVN imaging prevented delay in appropriate eye care for this patient.
- JVN impact in this case:
  - JVN identified advanced bilateral sight-threatening proliferative diabetic retinopathy in this patient with history of recent eye exam elsewhere and no reported DR.
  - JVN imaging prevented delay in appropriate eye care for this patient.
  - JVN impact in this case:
    - JVN identified advanced bilateral sight-threatening proliferative diabetic retinopathy in this patient with history of recent eye exam elsewhere and no reported DR.
    - JVN imaging prevented delay in appropriate eye care for this patient.
    - JVN impact in this case:
      - JVN identified advanced bilateral sight-threatening proliferative diabetic retinopathy in this patient with history of recent eye exam elsewhere and no reported DR.
      - JVN imaging prevented delay in appropriate eye care for this patient.

**Case 2 Key Messages**
- JVN identified advanced proliferative diabetic retinopathy in this patient with history of recent eye exam elsewhere and no reported DR.
- JVN provided prompt, accurate identification of presence and level of retinopathy and macular edema.
- JVN imaging prevented delay in appropriate eye care for this patient.

**Case 3: Advanced Asymptomatic Bilateral Sight-Threatening Proliferative Diabetic Retinopathy Despite Recent Outside Eye Exam**
- Despite evaluation elsewhere according to the recommended schedule of eye care with no reported diabetic retinopathy or visual symptoms, JVN identified extensive sight-threatening proliferative diabetic retinopathy in this asymptomatic pregnant patient despite reportedly normal eye exam one year previously.
- This case reinforces the ADA recommendation of diabetes eye exam prior to planned pregnancy, in the first trimester, routinely throughout pregnancy and for one year post partum.

**Case 3: Advanced Asymptomatic Bilateral Sight-Threatening Proliferative Diabetic Retinopathy Despite Recent Outside Eye Exam**
- JVN impact in this case:
  - JVN imaging prevented delay in appropriate eye care for this patient.
  - JVN identified advanced bilateral sight-threatening proliferative diabetic retinopathy in this patient with history of recent eye exam elsewhere and no reported DR.
  - JVN imaging prevented delay in appropriate eye care for this patient.

**Case 3: Advanced Asymptomatic Bilateral Sight-Threatening Proliferative Diabetic Retinopathy Despite Recent Outside Eye Exam**
- JVN impact in this case:
  - JVN identified advanced bilateral sight-threatening proliferative diabetic retinopathy in this patient with history of recent eye exam elsewhere and no reported DR.
  - JVN imaging prevented delay in appropriate eye care for this patient.

**Case 3 Key Messages**
- Even advanced diabetic retinopathy (DR) can be difficult to detect without proper examination.
- Severe DR can progress rapidly and may be present despite lack of visual symptoms and history of recent eye exam.
- Certain risk factors increase the likelihood of DR progression, including poor glycemic control, dyslipidemia, hypertension, and renal disease.

**Case 4: Advanced Diabetic Retinopathy Detected in Patient Reluctant to Have Dilated Eye Exam**
- JVN identified advanced proliferative diabetic retinopathy in the right eye, severe nonproliferative diabetic retinopathy in the left eye, and vision threatening clinically significant macular edema in both eyes. In both eyes there were hard exudates (HE) with associated retinal thickening threatening vision.

**Case 4: Advanced Diabetic Retinopathy Detected in Patient Reluctant to Have Dilated Eye Exam**
- JVN imaging demonstrated proliferative diabetic retinopathy in the right eye, severe nonproliferative diabetic retinopathy in the left eye, and vision threatening clinically significant macular edema in both eyes. In both eyes there were hard exudates (HE) with associated retinal thickening threatening vision.

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Nadeem N. Vaidya, M.D.
Case 4: Advanced Diabetic Retinopathy Detected in Patient Reluctant to Have JVN Imaging

- JVN imaging identified advanced sight-threatening retinopathy in this patient who was reluctant to have JVN imaging because he had a recent eye examination elsewhere.
- JVN imaging alerted this patient to the seriousness of his eye disease and the need for prompt sight-preserving laser treatment. With appropriate laser surgery, the risk of vision loss from diabetic macular edema and proliferative retinopathy is reduced by more than 50% and 90%, respectively.

Case 4 Key Messages

- Patients are sometimes reluctant to have JVN imaging due to their receiving eye care elsewhere.
- Despite reported recent eye exam, JVN imaging can be an effective method of detecting severe undiagnosed eye disease.
- JVN imaging should be considered even if a patient reports eye care elsewhere.

Case 5: Advanced Macular Edema Detected in Patient Eligible for Clinical Trial

- A 56-year-old Hispanic man with a 2-year history of type 2 diabetes reported no visual symptoms other than requiring reading glasses.
- Routine JVN imaging demonstrated proliferative diabetic retinopathy and clinically significant macular edema in both eyes.
- Both eyes had extensive hemorrhages and microaneurysms and hard exudates (HE) with associated retinal thickening (TH-dotted area) threatening vision.

Case 5 Key Messages

- JVN imaging identified advanced sight-threatening retinopathy in this asymptomatic patient and detected specific ocular characteristics which were eligible for participation in a nationwide clinical trial. These lesions of advanced retinopathy required prompt focal laser treatment in both eyes to reduce the risk of vision loss from macular edema.
- These ocular characteristics also allowed enrollment in a NEI-sponsored nationwide Diabetic Retinopathy Clinical Research Network (DRCR.net) clinical trial of laser, intravitreal steroid (triamcinolone), and intravitreal anti-VEGF agent (lucentis®) evaluating novel state-of-the-art treatment modalities.
- Thus, the JVN imaging resulted in prompt comprehensive eye evaluation and provided the opportunity to benefit from evolving novel treatment modalities.
Case 6: Clinically Significant Diabetic Macular Edema in an 18-year-old Patient

- 18-y.o. female patient with 13 years of type 1 diabetes and an A1C of 16.3 referred dilated eye exam
- Over the last seven years of medical follow-up, she had received only one eye exam which occurred 3 years ago.
- Demonstrated mild nonproliferative diabetic retinopathy in each eye, early diabetic macular edema in the right eye, and clinically significant macular edema in the left eye.
- There were more extensive hemorrhages and microaneurysms and one pinpoint hard exudate in the right eye.
- There were more extensive exudates with associated mild retinal thickening in the left eye.

Case 6: Clinically Significant Diabetic Macular Edema in an 18-year-old Patient

- JVN Impact in this Case:
  - JVN identified sight-threatening retinopathy in a young patient.
  - JVN provided prompt, accurate identification of the presence of clinically significant diabetic macular edema.
  - JVN imaging provided an opportunity for focused patient education and reinforced the need for improved glycemic control and eye care.

Case 6 Key Messages

- Young patients are also at risk of developing sight-threatening diabetic retinopathy, especially with poor glycemic control and elevated blood pressure.
- Despite routine medical care, this patient did not adhere to the recommendation of annual retinal assessment for diabetic retinopathy.
- Dilated eye exam should be considered in any patient who has reached the age of puberty and has not had a retinal exam within the past year.

Case 7: Primary Open-Angle Glaucoma Detected in Patient Evaluated for Diabetic Retinopathy

- A 58-y.o. African-American man with a 6-year history of type 2 diabetes reported that his last eye exam was two years ago.
- DFE found no diabetic retinopathy in either eye, but there was modest enlargement of both optic cups and mild cup-disc asymmetry, both findings suspicious for glaucoma.
- Retinal examination and evaluation for glaucoma at the BEI showed intraocular pressure of 18 mm Hg in each eye.

Case 7: Primary Open-Angle Glaucoma Detected in Patient Evaluated for Diabetic Retinopathy

- Visual field exam showed some constriction of the visual fields with early glaucomatous field defects in the right eye and a nasal-step defect in the left eye related to glaucoma.
- The patient was treated with Travatan eye drops 0.004% at bedtime in each eye and continues to be monitored for glaucoma and diabetic retinopathy.
- JVN imaging identified sight-threatening glaucoma in this asymptomatic patient with no diabetic retinopathy, permitting prompt comprehensive glaucoma evaluation and initiation of treatment before significant vision loss.

Nadeem N. Vaidya, M.D.
A 35-y.o. male patient with 18 years of type 1 diabetes and an A1C of 8.5 was referred for an asymptomatic patient overdue for eye examination. He is also treated for hypertension, hyperlipidemia, and had a cardiac stent placed in 2006.

The patient reported that he had recent dilated eye exam, was complaint with the recommended annual eye examinations recommended to him by outside eye care providers and who was unaware of any diabetic eye disease. He is also treated for hypertension, hyperlipidemia, neuropathy, and cardiac disease, and had a cardiac stent placed in 2006.

The patient reported that he was unaware of any eye disease and his ophthalmologist suggested annual eye exam. He is also treated for hypertension, hyperlipidemia, and had a cardiac stent placed in 2006.

Careful monitoring of eye disease was recommended, as well as ongoing diabetes care and management of his numerous comorbid risk factors for progression of retinopathy and visual loss.

Case 7 Key Messages

- Sight-threatening nondiabetes-related eye disease may be present even in the absence of diabetic retinopathy.
- Many treatable retinal conditions, including glaucoma, may be present in the absence of ocular or visual symptoms.
- JVN imaging has demonstrated the ability to identify nondiabetes eye conditions.

Case 8: Severe Retinopathy and Macular Edema in a Patient with Recent Eye Exam

Case 7: Primary Open-Angle Glaucoma Detected in Patient Evaluated for Diabetic Retinopathy

JVN Impact in this Case:
- JVN has been validated to identify nondiabetes related eye disease
- JVN identified sight-threatening glaucoma in an asymptomatic patient overdue for eye examination
- JVN imaging allowed the opportunity for the patient to begin treatment for glaucoma prior to significant vision loss

JVN imaging demonstrated severe nonproliferative diabetic retinopathy in the right eye, moderate nonproliferative diabetic retinopathy in the left eye, and diabetic macular edema in each eye.

Careful monitoring of eye disease with consideration of early treatment was recommended, as well as ongoing diabetes care and management of his numerous comorbid risk factors for progression of retinopathy and visual loss.

Case 8 Key Messages

- Intensive glycemic control in the DCCT reduced the risk of progression to proliferative diabetic retinopathy by 48%.
- JVN Impact in this Case:
  - JVN identified advanced retinopathy in a patient with recent eye exam.
  - JVN imaging provided an opportunity for focused patient education and reinforced the need for improved glycemic control and management of comorbidities that are risk factors for progression of retinopathy.
Case 8 Key Issues

- JVN imaging identified advanced retinopathy and macular edema in a patient with recent eye exam who was unaware of any eye disease.
- JVN imaging can be useful in identifying severe eye disease even when patients have been compliant with recent eye examinations elsewhere.

Case 9: Proliferative Diabetic Retinopathy and Diabetic Macular Edema in a 22-y.o. Patient

- A 22-year-old female patient with 17 years of type 1 diabetes and an A1C of 12.5 was referred for JVN imaging.
- Her A1C was reduced from 14.8 at exam 5 months previously.
- She had JVN imaging 5 years ago that showed no evidence of diabetic retinopathy and reported that her last eye examination was 9 months ago with recommendation for annual exam.
- She had never been examined at the Beetham Eye Institute.

Case 9: Proliferative Diabetic Retinopathy and Diabetic Macular Edema in a 22-y/o Patient

- JVN imaging identified sight-threatening retinopathy in a 22-year-old patient who had JVN imaging 5 years previously and eye examination elsewhere 9 months ago.
- JVN imaging alerted this patient to the seriousness of her eye disease and the need for urgent laser photocoagulation.
- With appropriate laser surgery, the risk of vision loss from proliferative diabetic retinopathy is reduced by more than 90%. Intensive glycemic control in the DCCT reduced the risk of progression to proliferative diabetic retinopathy by 48%.

Case 9 Key Issues

- Young patients are also at risk of developing sight-threatening diabetic retinopathy, especially with poor glycemic control.
- The BEI care team is sensitive to systemic risk factors for onset and progression of DR and will work collaboratively with Joslin caregivers so they can optimize these factors.
- JVN imaging should be considered, when appropriate, in patients at the age of puberty or older.

Case 9: Proliferative Diabetic Retinopathy and Diabetic Macular Edema in a 22-y/o Patient

- JVN imaging demonstrated proliferative diabetic retinopathy and diabetic macular edema, with new vessels on the disc (NVD) in the right eye that were not present in the previous JVN images 5 years ago.
- Prompt laser photocoagulation for proliferative retinopathy was recommended.

Case 9: Proliferative Diabetic Retinopathy and Diabetic Macular Edema in a 22-y/o Patient

JVN Impact in this Case:
- JVN identified sight-threatening retinopathy in a young patient.
- JVN provided opportunity for prompt sight-savin laser therapy.
- JVN imaging provided an opportunity for focused patient education and reinforced the need for improved glycemic control and eye care.
Case 10: Clinically Significant Macular Edema in recently evaluated 43-y/o Patient

- A 43-year-old Caucasian male with 3 years of type 2 diabetes and an A1C of 8.6 was referred for JVN imaging at his first Joslin visit, despite having a dilated retinal exam 2.5 months previously with a recommendation for annual eye follow-up.
- Daily medications were actos, glipizide, and 81 mg aspirin. Pertinent laboratory findings were cholesterol 183, HDL 39, LDL 115, triglycerides 143, and urine albumin 10.5.

Case 10: Clinically Significant Macular Edema in recently evaluated 43-y/o Patient

- JVN imaging demonstrated very mild nonproliferative diabetic retinopathy in each eye with clinically significant diabetic macular edema in the right eye and macular edema approaching clinically significant in the left eye with an area of thickening and hard exudates (HE) in the right eye (circle) threatening the center of the macula and hard exudates close to the center of the macula in the left eye.
- Based on the JVN imaging, prompt ophthalmic exam for consideration of laser treatment was scheduled rather than delaying for scheduled ophthalmic exam in 9 months.

Case 10 Key Issues

- Referring new Joslin patients for JVN imaging helps preserve vision, even if there is history of recent dilated eye examination.
- The BEI care team is sensitive to systemic risk factors for onset and progression of DR and will work collaboratively with Joslin caregivers so they can optimize these factors.
- JVN imaging is an integral part of Joslin Care for new Joslin patients, even if patients have had a recent eye exam.

Case 12: Diabetic and Nondiabetic Eye Disease and Ocular Manifestations of Systemic Disease in a 55 Year-Old Patient Overdue for Eye Examination

- A 55-year-old male with a 12-year history of type 2 diabetes was referred for JVN imaging.
- His last eye exam was 15 months previously with no reported findings of diabetic retinopathy or other eye disease.
- JVN imaging demonstrated moderate nonproliferative diabetic retinopathy (NPDR) in each eye with clinically significant diabetic macular edema in each eye.
Case 12: Diabetic and Nondiabetic Eye Disease and Ocular Manifestations of Systemic Disease in a 55-Year-Old Patient Overdue for Eye Examination

- There were hard exudates (HE) and thickening in the macula area of each eye. Cotton wool spots (CWS) surrounding the optic disc suggested a renal and hypertensive component to the retinopathy.
- The appearance of the optic disc with a moderately large optic cup (dotted circle) was suggestive of glaucoma in each eye.

- JVN imaging identified ocular manifestations of systemic disease requiring prompt medical intervention.
- JVN identified diabetic macular edema and suspicion of glaucoma in a patient unaware of his eye disease.
- JVN identified ocular manifestations of systemic disease requiring prompt medical intervention.

**Case 12 Key Issues**

- JVN provided care to a patient overdue for annual eye exam.
- The BEI care team is sensitive to ocular signs of systemic disease and works collaboratively with Joslin caregivers so they can optimize care of these factors.

- Elliott P. Joslin born 1869 Oxford, MA became a front runner in revolutionizing the care of diabetes with patients. At the time of his practice, insulin had not yet become available. Joslin synthesized knowledge on the effect of diet on diabetes, and showed that under nutrition and an emphasis on regular exercise, resulted in longer survival. Ahead of his time in utilizing a team approach to patient care, Joslin formed a strong partnership with nurses, who trained patients how to care of their diabetes when not hospitalized.
How can we harness our efforts into true multidisciplinary team care?

NDEP Goal
- To reduce the morbidity and mortality associated with diabetes and its complications by changing the way diabetes is treated

NDEP structure
- Joint initiative of the National Institutes of Health and the Centers for Disease Control and Prevention
- Partners with over 200 other organizations:
  - State Diabetes Prevention and Control Programs
  - Public and private organizations (e.g. AOA)
  - Traditional (e.g., American Diabetes Association) and non-traditional partners (e.g., National Urban League)

NDEP Objectives
- To improve understanding about diabetes and its control among people with diabetes and members of their social support systems
- To improve health care providers' understanding of comprehensive diabetes care and to promote an integrated approach to care
- To promote health care policies that improve the quality of, and access to, diabetes care
- To increase awareness of the seriousness of diabetes, its risk factors, and prevention strategies

Birth of NDEP
- NDEP was originally born as a result of the DCCT; showed the impact of tight glycemic control on prevention of primarily microvascular complications in type 1 diabetes
- Task “translate” these results into public health action and messages

Pharmacy, Podiatry, Optometry and Dental (PPOD) Role in NDEP
- Need and opportunity identified:
  - Many people with diabetes or at risk don’t access a primary care provider
  - Many seek services of a PPOD provider for diabetes-related concerns
  - PPOD providers are well-positioned to deliver NDEP messages
PPOD Goal
Promote the objectives of NDEP by utilizing Pharmacy, Podiatry, Optometry and Dentistry organizations and providers to increase awareness of and access to quality care for persons with diabetes

Working Together Key Messages
- Recommend routine exams for complication prevention: oral health, comprehensive foot, dilated eye
- Reinforce self-exams
- Recognize danger signs
- Pharmacist role in diabetes care team: medications management, individualized plans, use of glucose meter and other supplies
- Importance of metabolic control (ABCs)

<table>
<thead>
<tr>
<th>Agent</th>
<th>Daily Dose</th>
<th>Administration</th>
<th>Side Effects</th>
<th>Precautions</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>BYETTA (exenatide)</td>
<td>100mcg, 50mcg</td>
<td>Prefilled pen subcutaneously</td>
<td>Hypoglycemia, nausea, vomiting, diarrhea, dizziness, headache, weight loss</td>
<td>Prescriber by 0.6 mg/ml.</td>
<td>Requires 5 ml vials, temperature, refrigerate.</td>
</tr>
<tr>
<td>SYMLIN (pramlintide)</td>
<td>15–30mcg/kg</td>
<td>Prefilled pen subcutaneously</td>
<td>Hypoglycemia, nausea, vomiting, diarrhea, dizziness, headache</td>
<td>Not for use with 100 insulin, 0.6 mg/ml.</td>
<td>Requires 50mg/day, 5 mcg/ml.</td>
</tr>
<tr>
<td>SIQLOGTIN (sitagliptin)</td>
<td>100mg</td>
<td>PO qD</td>
<td>Diabetes, infections, hypoglycemia</td>
<td>Requires with sulfonylureas, insulin, TZDs.</td>
<td>Requires 50mg/day, 10 mcg.</td>
</tr>
</tbody>
</table>
Sample vignette—Team Care

A 40 year old woman asks her local pharmacist for advice on reading glasses. She says, “I must be getting older, everything is just blurry.” The pharmacist uncovers a history of diabetes diagnosed the previous year, but that the patient never returned for follow up. The pharmacist advises the woman that her blurred vision may be a sign of diabetes and arranges for the woman to be seen by a primary care provider and eye care provider for follow up.

How Do I Get Materials?

All NDEP materials are copyright-free and available by calling toll free 1-800-438-5383 or downloading from www.ndep.nih.gov

Thank you

W. Lee Ball, Jr., OD, FAAO
wball@bidmc.harvard.edu

Hypothetical scenarios

“I had diabetes when I was pregnant, but I thought that was all in the past. When my dental hygienist found out that I’d had gestational diabetes she told me I was at risk for developing type 2 diabetes. I am so glad she did! I am walking more and watching what I eat. I’m halfway to my goal of losing 15 pounds.”

It is estimated that of persons born in 2002, 1 in 3 will develop diabetes in his or her lifetime … unless something changes.

Be part of that something!
Case 1: Severe Asymptomatic Retinopathy Four Months after Diagnosis of Diabetes

- Examination identified sight-threatening retinopathy in this patient with recent-onset type 2 diabetes, no visual symptoms, and no history of recent eye exam.
- The access and immediacy of diagnosis provided by JVN allowed disease detection and reduced the risk of loss to follow-up or treatment delay.
- Focused education regarding the importance of diabetes eye care and diabetic changes already present reinforced the urgency of care for this patient whose risk of vision loss was reduced 50% or more by this intervention.

Case 2 Pregnancy and DR

- Asymptomatic Proliferative Retinopathy During Pregnancy Despite ‘No Retinopathy’ at Eye Exam Elsewhere One Year Earlier

- 28 y.o. Caucasian woman in the 34th week of pregnancy with 22 years of type 1 DM and an A1C of 6.4 reported no eye problems and no hx of diabetic retinopathy (DR) at eye exam elsewhere one year ago.
- severe nonproliferative DR and early diabetic macular edema in the right eye and proliferative DR in the left eye.
- hard exudates (HE) in the right eye and new vessels elsewhere (NV/HE) in the left eye.
- To reduce the substantial risk of vision loss associated with this severity of retinopathy, she received prompt scatter (panretinal) laser treatment in her left eye.

Case 1

- JVN imaging identified sight-threatening retinopathy in a patient with recently diagnosed diabetes, even with the complete absence of visual symptoms
- JVN provided prompt, accurate identification of presence & level of retinopathy and macular edema
- JVN exam prevented delay in appropriate eye care for this patient

Case 2 Pregnancy and DR

- Asymptomatic Proliferative Retinopathy During Pregnancy Despite ‘No Retinopathy’ at Eye Exam Elsewhere One Year Earlier

- JVN imaging identified sight-threatening proliferative DR in this patient with no prior history of DR despite outside eye exam 1 year earlier.
- Prompt laser treatment decreased the risk of severe vision loss in this patient by >90%
- The immediacy of JVN diagnosis reduced delay in subsequent eye exam and laser treatment while focused education on the severity of this situation reinforced the urgency of care.
Case 2 Key Messages

- Diabetic retinopathy can progress rapidly during pregnancy.
- Frequent careful monitoring and prompt treatment of diabetic patients during pregnancy is essential for optimal protection of vision.
- Co-morbidities, such as fluid retention and elevated blood pressure may contribute to worsening of diabetic retinopathy during pregnancy.

Case 3 Key Messages

- Even advanced diabetic retinopathy (DR) can be difficult to detect without proper examination.
- Severe DR can progress rapidly and may be present despite lack of visual symptoms and history of recent eye exam.
- Certain risk factors increase the likelihood of DR progression, including poor glycemic control, dyslipidemia, hypertension, and renal disease.

Case 4: Advanced Diabetic Retinopathy Detected in Patient Reluctant to Have Dilated Eye Exam

- 51-y.o. man with an 11-year history of type 2 diabetes and A1C of 7.0 was reluctant to undergo dilation since he had a recent eye examination elsewhere.
- The patient reported that his last eye exam did not include dilation and he reported no visual symptoms other than occasional blurring, possibly associated with blood glucose levels.
- Routine JVN imaging demonstrated proliferative diabetic retinopathy in the right eye, severe nonproliferative diabetic retinopathy in the left eye, and vision threatening clinically significant macular edema in both eyes. In both eyes there were hard exudates (HE) with...
Case 4: Advanced Diabetic Retinopathy Detected in Patient Reluctant to Have JVN Imaging

- JVN imaging identified advanced sight-threatening retinopathy in this patient who was reluctant to have JVN imaging because he had a recent eye examination elsewhere.
- JVN imaging alerted this patient to the seriousness of his eye disease and the need for prompt sight-preserving laser treatment. With appropriate laser surgery, the risk of vision loss from diabetic macular edema and proliferative retinopathy is reduced by more than 50% and 90%, respectively.

Case 4 Key Messages

- Patients are sometimes reluctant to have JVN imaging due to their receiving eye care elsewhere.
- Despite reported recent eye exam, JVN imaging can be an effective method of detecting severe undiagnosed eye disease.
- JVN imaging should be considered even if a patient reports eye care elsewhere.

Case 5: Advanced Macular Edema Detected in Patient Eligible for Clinical Trial

- A 56-year-old Hispanic man with a 2-year history of type 2 diabetes reported no visual symptoms other than requiring reading glasses.
- Routine JVN imaging demonstrated proliferative diabetic retinopathy and clinically significant macular edema in both eyes.
- Both eyes had extensive hemorrhages and microaneurysms and hard exudates (HE) with associated retinal thickening (TH-dotted area) threatening vision.
- These lesions of advanced retinopathy required prompt focal laser treatment in both eyes to reduce the risk of vision loss.

Case 5 Key Messages

- JVN imaging identified advanced sight-threatening retinopathy in this asymptomatic patient and detected specific ocular characteristics which were eligible for participation in a nationwide clinical trial. Thus, the JVN imaging resulted in prompt comprehensive eye evaluation and provided the opportunity to benefit from evolving novel treatment modalities.
- JVN Impact in this Case:
  - JVN identified sight-threatening retinopathy in an asymptomatic patient overdue for eye examination
  - JVN provided prompt, accurate identification of the presence of sight threatening macular edema and proliferative retinopathy
  - JVN imaging allowed the opportunity for the patient to be enrolled in a clinical trial that provides novel treatment approaches

Case 5 Key Messages

- Sight-threatening retinopathy is frequently present despite vision of 20/20 or better.
- Laser treatment is the evidence-based standard-of-care for diabetic macular edema and proliferative diabetic retinopathy.
- Clinical trials are currently investigating novel treatments to improve visual outcomes.
- JVN imaging can identify patients who might be eligible to participate in clinical trials of novel retinopathy treatments.

Nadeem N. Vaidya, M.D.
Case 6: Clinically Significant Diabetic Macular Edema in an 18-year old Patient

- 18-y.o. female patient with 13 years of type 1 diabetes and an A1C of 16.3 referred dilated eye exam
- Over the last seven years of medical follow-up, she had received only one eye exam which occurred 3 years ago.
- Demonstrated mild nonproliferative diabetic retinopathy in each eye, early diabetic macular edema in the right eye, and clinically significant macular edema in the left eye.
- There were hemorrhages and microaneurysms and one pinpoint hard exudate in the right eye.
- There were more extensive hemorrhages and hard exudates with associated mild retinal thickening in the left eye.

Case 6 Key Messages

- JVN identified sight-threatening retinopathy in an 18-y.o. patient who had not received recent eye examinations.
- JVN imaging identified sight-threatening diabetic retinopathy, especially with poor glycemic control and elevated blood pressure.
- With appropriate laser surgery, the risk of vision loss from diabetic macular edema is reduced by more than 50%.
- Intensive glycemic control in the DCCT reduced the risk of macular edema progression by 23%.

Case 7: Primary Open-Angle Glaucoma Detected in Patient Evaluated for Diabetic Retinopathy

- A 58-y.o. African-American man with a 6-year history of type 2 diabetes reported that his last eye exam was two years ago.
- DFE found no diabetic retinopathy in either eye, but there was modest enlargement of both optic cups (arrows in the photos below) and mild cup-disc asymmetry, both findings suspicious for glaucoma.
- Retinal examination and evaluation for glaucoma at the BEI showed intraocular pressure of 18 mm Hg in each eye.
- Visual field exam showed some constriction of the visual fields with early glaucomatous visual field loss.

Case 7 Key Messages

- JVN imaging identified sight-threatening glaucoma in this asymptomatic patient with no diabetic retinopathy, permitting prompt comprehensive glaucoma evaluation and initiation of treatment before significant vision loss.

Nadeem N. Vaidya, M.D.
Nadeem N. Vaidya, M.D.

Case 7: Primary Open-Angle Glaucoma Detected in Patient Evaluated for Diabetic Retinopathy

- **JVN Impact in this Case:**
  - JVN has been validated to identify nondiabetes-related eye disease
  - JVN identified sight-threatening glaucoma in an asymptomatic patient overdue for eye examination
  - JVN imaging allowed the opportunity for the patient to begin treatment for glaucoma prior to significant vision loss

Case 7 Key Messages

- Sight-threatening nondiabetes-related eye disease may be present even in the absence of diabetic retinopathy.
- Many treatable retinal conditions, including glaucoma, may be present in the absence of ocular or visual symptoms.
- JVN imaging has demonstrated the ability to identify nondiabetes eye conditions.

Case 8: Severe Retinopathy and Macular Edema in a Patient with Recent Eye Exam

- A 35-y.o. male patient with 18 years of type 1 diabetes and an A1C of 8.5 was referred for JVN imaging.
- Last self-reported eye exam elsewhere was 3-4 weeks prior.
- He is also treated for hypertension, hyperlipidemia, neuropathy, and cardiac disease, and had a cardiac stent placed in 2006.
- The patient reported that he was unaware of any eye disease and his ophthalmologist suggested annual eye exam.
- JVN imaging demonstrated severe nonproliferative diabetic retinopathy in the...

Case 8 Key Issues

- JVN imaging identified advanced eye disease and macular edema in a patient with recent eye exam who was unaware of any eye disease.
- JVN imaging can be useful in identifying severe eye disease even when patients have been compliant with recent eye examinations elsewhere.

Case 9: Proliferative Diabetic Retinopathy and Diabetic Macular Edema in a 22-y.o. Patient

- A 22-year-old female patient with 17 years of type 1 diabetes and an A1C of 12.5 was referred for JVN imaging.
- Her A1C was reduced from 14.8 at exam 5 months previously.
- She had JVN imaging 5 years ago that showed no evidence of diabetic retinopathy and reported that her last eye examination was 9 months ago with recommendation for annual exam.
- She had never been examined at the Beetham Eye Institute.
- JVN imaging demonstrated proliferative diabetic retinopathy and diabetic macular edema, with new...

Case 9 Key Issues

- JVN imaging has demonstrated the ability to identify nondiabetes eye conditions.
- Intensive glycemic control in...
Case 9: Proliferative Diabetic Retinopathy and Diabetic Macular Edema in a 22-y/o Patient

- JVN imaging identified sight-threatening retinopathy in a 22-year-old patient who had JVN imaging 5 years previously and eye examination elsewhere 9 months ago.
- JVN imaging alerted this patient to the seriousness of her eye disease and the need for urgent laser photocoagulation.
- With appropriate laser surgery, the risk of vision loss from proliferative diabetic retinopathy is reduced by more than 90%. Intensive glycemic control in the DCCT reduced the risk of progression to proliferative diabetic retinopathy by 48%.

Case 9 Key Issues

- Young patients are also at risk of developing sight-threatening diabetic retinopathy, especially with poor glycemic control.
- The BEI care team is sensitive to systemic risk factors for onset and progression of DR and will work collaboratively with Joslin caregivers so they can optimize these factors.
- JVN imaging should be considered, when appropriate, in patients at the age of puberty or older.

Case 10: Clinically Significant Macular Edema in recently evaluated 43-y/o Patient

- A 43-year-old Caucasian male with 3 years of type 2 diabetes and an A1C of 6.6 was referred for JVN imaging at his first Joslin visit, despite having a dilated retinal exam 2.5 months previously with a recommendation for annual eye follow-up.
- Daily medications were actos, glipizide and 81 mg aspirin. Pertinent laboratory findings were cholesterol 183, HDL 39, LDL 115, triglycerides 143, and urine albumin 10.5.
- JVN imaging demonstrated very mild nonproliferative diabetic retinopathy in each eye with clinically significant diabetic macular edema.

Case 10: Clinically Significant Macular Edema in recently evaluated 43-y/o Patient

- JVN imaging identified sight-threatening macular edema in a 43-year-old patient who had received recent eye examination elsewhere with suggested follow-up in one year (which would have occurred 9 months after the JVN imaging was done).
- JVN imaging alerted this patient to sight-threatening eye disease and the need for urgent laser photocoagulation.
- Appropriate laser surgery reduces the risk of vision loss from macular edema by 50% or more.
- Dyslipidemia is a risk factor for retinal hard exudates and lipid control is an important factor in treatment.

Case 9: Proliferative Diabetic Retinopathy and Diabetic Macular Edema in a 22-y/o Patient

JVN Impact in this Case:
- JVN identified sight-threatening retinopathy in a young patient.
- JVN provided opportunity for prompt sight-saving laser therapy.
- JVN imaging provided an opportunity for focused patient education and reinforced the need for improved glycemic control and eye care.
Case 10 Key Issues

- Referring new Joslin patients for JVN imaging helps preserve vision, even if there is history of recent dilated eye examination.
- The BEI care team is sensitive to systemic risk factors for onset and progression of DR and will work collaboratively with Joslin caregivers so they can optimize these factors.
- JVN imaging is an integral part of Joslin Care for new Joslin patients, even if patients have had a recent eye exam.

Case 11: Nonproliferative Diabetic Retinopathy and Diabetic Macular Edema in Recently Evaluated 34-y.o. Patient

- A 55-year-old male with a 12-year history of type 2 diabetes was referred for JVN imaging.
- His last eye exam was 15 months previously with no reported findings of diabetic retinopathy or other eye disease.
- JVN imaging demonstrated moderate nonproliferative diabetic retinopathy (NPDR) in each eye with clinically significant diabetic macular edema in each eye.
- There were hard exudates (HE) and thickening in the macula area of each eye.
- Cotton wool spots (CWS) surrounding the optic disc suggested a renal and vascular disease.

This patient was scheduled for focal laser photocoagulation in each eye and comprehensive evaluation for glaucoma.

Case 12: Diabetic and Nondiabetic Eye Disease and Ocular Manifestations of Systemic Disease in a 55-Year-Old Patient Overdue for Eye Examination

- JVN imaging identified diabetic macular edema and suspicion of glaucoma in a patient unaware of his eye disease.
- JVN identified ocular manifestations of systemic disease requiring prompt medical intervention.

Case 12: JVN Impact in this Case:
- JVN identified diabetic macular edema and suspicion of glaucoma in a patient unaware of his eye disease.
- JVN identified ocular manifestations of systemic disease requiring prompt medical intervention.
Case 12 Key Issues

- JVN provided care to a patient overdue for annual eye exam.
- JVN imaging identified sight-threatening diabetic retinopathy, sight-threatening non diabetic-related disease (glaucoma), manifestations of renal disease, and potentially life-threatening cardiovascular disease (retinal embolism).
- The BEI care team is sensitive to ocular signs of systemic disease and works collaboratively with Joslin caregivers so they can optimize care of these factors.
Managing Diabetes: It’s Not Easy But It’s Worth It

The National Diabetes Education Program
Changing the Way Diabetes is Treated
W. Lee Ball, Jr., OD, FAAO

What is Diabetes?
Diabetes is a group of diseases resulting from problems with insulin production, insulin action, or both.

Diabetes can lead to serious health problems and premature death.

About 24 million Americans have diabetes.


Common Types of Diabetes

Type 1 diabetes
• 5% to 10% of diagnosed cases of diabetes

Type 2 diabetes
• 90% to 95% diagnosed cases of diabetes


Common Types of Diabetes

• Gestational Diabetes occurs during pregnancy
  • 5 to 10% of women with gestational diabetes are found to have type 2 diabetes
  • Increased lifelong risk for mother and child for developing type 2 diabetes
  • 40-60% women with gestational diabetes will develop diabetes in the next 5 to 10 years

Risk Factors for Diabetes

• Age 45 and older
• Overweight (BMI ≥ 25)
• Hypertension
• Abnormal lipid levels
• Family history of diabetes
• Race/ethnicity
• History of gestational diabetes

Risk Factors for Diabetes

- History of vascular disease
- Signs of insulin resistance – (such as PCOS or acanthosis nigricans)
- IGT or IFG on previous test
- Inactive lifestyle


Diabetes and Cardiovascular Disease

- Cardiovascular disease is the leading cause of death for people with diabetes
- In adults with diabetes:
  - 68% die of heart disease or stroke
  - the risk for stroke is two to four times higher
  - 75% have high blood pressure
  - smoking doubles the risk for heart disease


Diabetes Complications

- Diabetes is the leading cause of:
  - kidney failure
  - new cases of adult blindness
  - nontraumatic lower-limb amputations

- In adults with diabetes:
  - the risk of periodontal (gum) disease is two to three times higher
  - 60 to 70% have mild to severe nervous system damage


Diabetes Control and Complications Trial (DCCT)

Compared effects of two diabetes treatment regimens – standard therapy and intensive control – on the complications of diabetes in people with type 1 diabetes


DCCT Findings

Glucose control is key to preventing or delaying complications of diabetes

Any sustained lowering of blood glucose helps, even if the person has a history of poor control


DCCT Findings

Lowering blood glucose reduced risk of:

- Eye disease by 76%
- Kidney disease by 50%
- Nerve disease by 60%

United Kingdom Prospective Diabetes Study (UKPDS)

20 Year Clinical Trial

Looked at intensive management of blood glucose levels and long term risk-factors for diabetes complications in type 2 diabetes

UKPDS Findings

Mirrored the findings of DCCT in people with type 2 diabetes—better glucose control reduced development of microvascular complications

Demonstrated the need for management of high blood pressure and cholesterol as well as blood glucose levels (the ABCs of diabetes)

UKPDS Findings

Risk reduction with 1% decline in annual mean A1C

<table>
<thead>
<tr>
<th>Microvascular Disease</th>
<th>PVD</th>
<th>MI</th>
<th>Stroke</th>
<th>Heart Failure</th>
<th>Cataract Extraction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37%</td>
<td>21%</td>
<td>7%</td>
<td>2%</td>
<td>16%</td>
</tr>
<tr>
<td></td>
<td>45%</td>
<td>43%</td>
<td>14%</td>
<td>12%</td>
<td>19%</td>
</tr>
</tbody>
</table>

EDIC Findings: Intensive Therapy and Diabetes Complications

Participants continue to benefit years later from period of intense glucose control

Years after intensive therapy:
- Lasting benefits for eye, nerve, and kidney disease
- Reduces CVD events by more than half

EDIC Findings: Cardiovascular Events

Cumulative Incidence of Any Event

Risk reduction 42%
95% CI: 9% to 63%
P = 0.02

Years from Study Entry
UKPDS 10 yr Follow-Up Study- insulin/sulfonylurea group
Differences in A1C between intensive & standard glycemic control treatment groups were lost after one year
Relative risk reductions at 10 yr in intensive insulin/sulfonylurea group:
- 9% for any diabetes end point (P=0.04)
- 24% microvascular disease (P=0.001)
- 15% myocardial infarction (P=0.01)
- 13% death from any cause (P=0.007)


UKPDS 10 yr Follow-Up Study- metformin group
Differences in A1C between intensive & standard glycemic control treatment groups were lost after one year
Relative risk reductions at 10 yr in intensive metformin group:
- 21% for any diabetes end point (P=0.01)
- 33% myocardial infarction (P=0.005)
- 21% death from any cause (P=0.002)


UKPDS 10 yr Follow-Up Study- Blood Pressure findings
Between group differences lost within 2 yrs
Significant relative risk reductions in tight control group were not maintained
Benefits of BP control do not extend beyond intensive therapy period & ongoing treatment is essential


Recent Clinical Trial Findings:
Intensive glucose control in type 2 diabetes:
- lowers risk of new or worsening microvascular complications (ADVANCE)
- was associated with increased mortality in patients with longstanding DM and known CVD (ACCORD)
- increases risk of severe hypoglycemia (ADVANCE, ACCORD and VADT)


Key points of recent findings:
- Intensive glucose control in newly diagnosed type 1 or type 2 diabetes has benefits during intensive therapy AND a legacy effect for later micro- and macrovascular benefits
- Optimal glucose management should start as early as possible & continue as long as possible
- While the A1C goal for the general population is <7%, treatment must be individualized.

SEARCH For Diabetes in Youth Study
Observational study funded by CDC and NIH
Physician-diagnosed diabetes in youth ages 0-19
Data will help researchers better understand and treat diabetes in young people

SEARCH Findings

Determine prevalence and correlates of selected CVD risk factors among youth with diabetes

21% of young people with diabetes had at least two CVD risk factors

Prevalence of CVD risk factors was higher among youth aged 10-19 years and among girls

(Diabetes Care 2006 29(8): 1891-6.)

In young people with type 2 diabetes:
- 92% had at least two CVD risk factors

In young people with type 1 diabetes:
- 14% had at least two CVD risk factors

(Diabetes Care 2006 29(8): 1891-6.)

National Diabetes Education Program Materials

Diabetes Control: Patient Materials

Diabetes Control: Health Care Professionals

NDEP Websites
Other NDEP Campaign Tools at www.YourDiabetesInfo.org
• TV, radio, and print PSAs
• Sample feature articles
• Sample press releases and media advisories
• Fact sheets
• Web buttons/blubs
• NDEP logos and banners

For more information about NDEP and to order or download free materials:
Call 1-888-693-NDEP
or
Visit www.YourDiabetesInfo.org

Thank You!

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The U.S. Department of Health and Human Services’ National Diabetes Education Program is jointly sponsored by the National Institutes of Health and the Centers for Disease Control and Prevention with the support of more than 200 partner organizations.
Mission Statement

• InfantSEE™ is a public health program, to ensure that optometric eye and vision care becomes an integral part of infant wellness care to improve a child’s quality of life.

InfantSEE™

• The American Optometric Association encourages all doctors of optometry to participate in InfantSEE™ by providing the initial eye and vision assessment of the infant within the first year of life as a no cost, public health service.

InfantSEE™

InfantSEE™ is a national public health effort to foster expanded eye care for infants, emphasizing early detection of the potential for vision problems, such as the risk factors for amblyopia:

- strabismus
- anisometropia
- ocular health threats

AOA’s Long-Standing Support of Infant Eye Care

• 1992 – AOA Resolution to recommend exams at 6 months of age
• 1998 - Operation Bright Start
• 2002 - Infants Vision Project Team started
• 2003 – AOA House of Delegates passes Resolution Recommending InfantSEE™ Program Development
• Current Clinical Practice Guidelines - eye examinations start at 6 months of age
An Unmet Need...

- 3+ million infants in the first year of life...
  - How many receive the eye care services necessary to ensure proper visual development?
  - Historically... virtually NONE!

The Problems Are Significant

- 1 in 30 will develop Amblyopia
- 1 in 25 will develop Strabismus
- 1 in 33 will show significant Refractive Error
- Eye Diseases will be evident in 1 in 100
- Retinoblastoma – rare but possible
  > 1 in 20,000
- Numbers are irrelevant if infants aren’t seen
- Impact on Infant Development = priceless

Moms Don’t Know...

Focus Groups regarding infant eyes and vision:
- “I never thought about it until today.”
- “It’s a safe area.”
- “My doctor takes care of that.”
- “I’d take my baby to a dentist before an optometrist.”

InfantSEE™

Public Health by Optometry

Adapting a slogan from Vistakon’s Acuvue Eye Health Advisor Program:
It’s not that parents of infants don’t CARE about their baby’s visual future, it’s that they don’t KNOW, and it’s our job to EDUCATE them.

Wellness Care as Part of Optometric Primary Care

- Optometry’s Contribution to Public Health
  - This segment of the population has been left to screening care only, rarely provided by eye care professionals
  - Infants will benefit from optometric primary care as amplification of the pediatric eye care they now receive

Who is providing care now?

- Pediatrician- mostly gross observation for strabismus and a check for a red reflex in a lighted room with an ophthalmoscope.
- Can’t Optometry right now do better?
What we do best!

- No additional training is needed!
- No additional equipment is necessary!
- Penlight, Fixation targets, Retinoscope, trial lenses, loose prism, BIO
- Optional equipment: Teller cards, finger puppets, bluminator, baby rattle

What’s Needed from ODs...

- AOA Member Understanding of Need... like TPA expansion, DFEs for Diabetics
- Appreciation of Public Health Role
- Utilizing Existing Clinical Competency and Confidence in Examining the Infant
  - Retinoscopy
  - Ophthamoscoppy
  - Cover Test, Bruckner, Hirschberg

The Assessment Protocol

- Clinical Practice Guidelines
  - Visual Acuity
    - Fix and Follow, Richman Face Paddles, Vertical Prism
  - Refractive Status
    - Mohindra Retinoscopy, Cycloplegic Retinoscopy
  - Binocularity (alignment)
    - Cover Test, Vertical Prism, Bruckner, Hirschberg
  - Ocular Motility
    - EOM Motilities
  - Ocular Health Assessment
    - Visual Field, Pupils, Gross External, Dilated Internal

Public Health Means Public Education

- Doctors will determine appropriateness of periodic professional care
  - Coordinate referrals to optometry specialty or ophthalmology specialty
  - Follow-up “3x3” – recheck all significant findings every three months until confirmed three times
  - Complete eye examinations at 3 and 5 or as determined by the InfantSEE™ optometrist

The Exam

- Observe baby’s eyes as you greet child.
- Use thumb to do cover test while baby looks at pen light, also noting Hirschberg reflex and checking pupil responses.
- Using a rattle and a finger puppet one in each hand introduce peripherally and note field size and accuracy of fixation.

Video

- Video of InfantSee assessment
Exam

• With a small target introduce a 10 base up prism in front of one eye to note shift in focus between images.
• With direct Ophthal 50cm Bruckner
• Dry Retinoscopy with loose trial lenses
• 1% cyclo. Lay baby in Mom’s arms like feeding. Drop eye closest to Mom first.
• Send out to feed or nap for 45 min.

Exam

• Return to wet Ret
• Internal with BiO have Mom hold baby up over her shoulder. Stand behind her and look in child’s eyes.
• Review findings and Recall

EXPECTED NORMS

6 MOS: PERRL, Foveal Reflex may or may not be present Nasolacrimal canal open, visual acuity responsive to 20/80-20/200 (PL), Dry Ret. Pl to 1.25D variability good attention, follows moving targets while sitting, Versions full and smooth with head movement, NPC to nose, begins to show reaching for stereo targets.

9MOS: Foveal reflex present 50% of time, versions full and smooth in all directions, NPC to nose, good response to stereo, visual acuity responsive to 20/50-20/100 (PL), Dry Ret. +/- 0.50 with up to 1D variability with good attention to target.

EXPECTED NORMS

• 12 MOS: Foveal Reflex present 90% of infants, versions full and smooth in all directions, NPC to nose, good response to stereo, Acuity 20/50-20/80 (PL), Dry Ret. +/- 0.50 up to 1D variability with good attention.

Causes for Concern

• Ocular Motility:
  a. Normal- ability to look at the target, follow and maintain for a brief period or until something else captures attention
  b. Concern- Reduced ability to gain visual attention in primary gaze
  c. Problem- Any limitation of movement in the cardinal meridian

Causes for Concern

• Binocular function (Cover test)
  a. Normal- stereo response on gross targets
  b. Concern- no response
  c. Problem- observable strabismus
  • Refraction
  • Hyperopia
  a. Normal- less than +3.50 discuss emmetropitization and re-eval at age 3
  b. Concern- +3.50-5.00 rule of 3 (recheck in 2m)
  c. Problem- Over +5.00 establish in an Optometric office
Causes for Concern

- **Myopia**
  - a. Normal- less than 1D watch, see at age 3
  - b. Concern- slightly over 1D follow in 6m
  - c. Problem- well over 1D establish in OD practice

- **Astigmatism**
  - a. Normal- less than 2D watch, see at age 3
  - b. Concern- 2.00-3.00D follow in 6m
  - c. Problem- over 3D establish in OD practice

- **Anisometropia**
  - a. Normal- less than 1D see at age 3
  - b. Concern- 1-2D follow in 6m
  - c. Problem- Over 2D establish in OD practice

- **Looking Behavior**
  - a. Concern- reduced ability to fixate recheck in 1m
  - b. Problem- fixation preference for one eye
  - Failed acuity test
  - Establish in OD practice

Ocular Health

- Problem- any noted anomaly- establish in appropriate health care practice

End of Exam

- Discuss pertinent findings with Parents
- Give Visual development suggestions
- Recommend next suggested visit age
- **RETURN FORM SAME DAY TO AOA OFFICE!!!**

Practical Issues

- The Doctor can see whatever number of infants that is comfortable
- AOA Members with strong infant-care background will make themselves available for intra-professional referrals
- Ongoing education and resources (website) will be available

Presents Opportunities...

- Provide Infants Definitive Eye Care
- Educate the American Public
- Further Recognition as Primary Eye Care Providers
- Demonstrate Optometry’s Commitment to the Entire “Lifecycle” of Eye Care
  - Periodic Professional Eye Care

The Primary Benefit

- Identifying Infants at Risk Allows More Time-Appropriate Intervention:
  - Treatment of Amblyopia
  - Treatment of Strabismus
  - Detection of Significant Disease (expected positive findings in <5% of infants)
Why InfantSEETM?

• A Public Health Program That Optometry MUST Develop To Be Done Right
• A National Eye Care Problem That We Know is Not Being Addressed Adequately
  – "Generations of amblyopes" exist due to current screening protocols
• A Responsible Investment by Providing One Eye Assessment at No Cost to the Family

Awareness by Assessment

• America’s parents are not aware of the need for periodic, professional eye care for infants and children
  – Focus groups validate that parents know more about the need to have dental examinations than eye assessments
• By providing the first assessment of life as a public health service, AOA doctors will change the knowledge base of America’s parents

Partnership with J&J Vision Care, Inc.

• Intellectual knowledge on “product launch”
• Formulation of a business plan for project launch
• State grants for doctor enrollment
• Funding for infrastructure development, staffing
1. Descriptive terms

a. RNFL - grass lands (green)

b. Optic disc rim elevation
   i. Mild elevation - hills (dark green)
   ii. Moderate elevation - mountains (red)
   iii. High elevations – snow capped mountains (white)

c. RNFL loss
   i. Moderate – blue river or areas
   ii. Severe – gray river or areas

2. Optic Disc Diseases

a. Glaucoma

   i. Optic disc images with radiating nerve fiber bundle defects (wedge defects)
   ii. Standard OCT images
      1. Optic disc measurements
      2. RNFL
   iii. 3-D images
      1. Height of disc neural rim
      2. Thinning of RNFL
      3. Nerve fiber bundle defects
      4. Over all thinning of RNFL without nerve fiber bundle defects
      5. Horizontal raphe imaged
   iv. New observations of what is happening to the optic nerve head
   v. Visually helping patients to understand their intraocular condition

b. Optic Disc Drusen

   i. Standard OCT images
      1. Elevation of optic disc
   ii. 3-D images
      1. Elevation of optic disc
   iii. Explanation of disease condition
   iv. Visually helping patients to understand their intraocular condition
c. **Tilted Optic Discs/Situs Inversus to the Optic Nerve**

   i. Standard OCT images
      1. Tilted disc imagery
   ii. 3-D images
      1. Unusual shape of optic disc
      2. Decreased retinal thickness surrounding the optic disc

iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

**d. Optic Disc Pit**

i. Standard OCT images
   1. Showing the loss of optic nerve tissue with resultant cavity
ii. 3-D images
   1. Since there is not bottom recognized by the instrument, an area of no information occurs
   2. Decreased retinal thickness surrounding the optic disc

iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

**e. Stroke**

i. Standard fundus images
ii. 3-D images
   1. Overall RNFL loss OD/OS

iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

**f. Pituitary Tumor**

i. Standard fundus images
ii. 3-D images
   1. Nasal RNFL loss OD/OS

iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

**g. Optic Neuritis**

i. Standard OCT images
   1. Elevated swollen discs
ii. 3-D images
1. Elevation of optic disc
2. Subtle swelling of fellow optic disc
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

h. Papilledema

i. Standard OCT images
   1. Elevated swollen discs and adjacent RNFL
   2. Intrapapillary drusen shadows
ii. 3-D images
   1. Elevated swollen discs and adjacent RNFL
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

i. Enlarged Blind Spot

i. 3-D images
   1. Juxtafoveal depression (likely to be congenital)
ii. Standard OCT images
   1. Loss of juxtapapillary photoreceptor layer
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

3. Retinal Disease Conditions

a. Myopic Staphyloma

i. Standard OCT images
   1. Penetration of light into the choroid
   2. Loss of retinal thickness
ii. 3-D images
   1. Excavated ILM and RPE layers
   2. Small areas of deeper tissue loss
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

b. Chorioretinal Atrophy

i. Standard OCT images
   1. Penetration of light into the choroid
   2. Loss of outer retinal thickness
ii. 3-D images
   1. Loss of outer retinal thickness
   2. Residual effect of imagery of choroidal vessels
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

c. Congenital Hypertrophy of the Retinal Pigment Epithelium with Lacunae
   i. Standard OCT images
      1. More reflective RPE
      2. Decreased light penetration to choroid
   ii. 3-D images
      1. Pigmented borders
      2. Loss of outer retinal thickness due to C-R atrophy
   iii. Explanation of disease condition
   iv. Visually helping patients to understand their intraocular condition

d. Choroidal Nevus
   i. Standard OCT images
      1. Aggregation of melanocytes
      2. More reflective choroid and overlying RPE degeneration with drusen
   ii. 3-D images
      1. The nevus can’t be viewed on with the 3-D method
   iii. Help in differential Dx

e. Acquired Hyperplasia of the Retinal Pigment Epithelium
   i. Standard OCT images
      1. Loss of RPE layer in spots with clumps of RPE that have migrated into the overlying sensory retina (anterior limit of the migration is the ILM
   ii. 3-D images
      1. Irregularity of the retinal surface due to reflective distances from the pigment clumps to the ILM
   iii. Explanation of disease condition
   iv. Visually helping patients to understand their intraocular condition

f. Antigen-antibody Reaction
i. Standard OCT images
   1. Degeneration of the RPE with scarring

ii. 3-D images
   1. Depression of retina the retinal surface due to reflective distances from the lesion to the ILM being less than the surrounding retina

iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

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g. Commotio Retinae

i. Standard OCT images
   1. Disruption of the retinal and choroidal tissues due to loss of tissue, scarring, and RPE hyperplasia

ii. 3-D images
   1. Irregularity of the retinal surface due to reflective distances from the RPE to the ILM

iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

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h. Dry AMD

i. Standard OCT images
   1. Degeneration of the RPE with drusen

ii. 3-D images
   1. Depressions in the retinal surface due to reflective distances from the drusen to the ILM that indicate the existence of clinically significant drusen

iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

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i. Epiretinal Membrane (ERM)

i. Standard OCT images
   1. Usually there is a thin membrane on the retinal surface causing tangential traction that produces tiny folds in the superficial retina that is seen as retinal striae. The membrane may be attached or slightly detached from the retinal surface. The traction may result in a partial of full thickness retinal hole.

ii. 3-D images
   1. The folds are easily seen and actually can change in shape over time.
iii. Explanation of disease condition
   1. I have a case of an ERM occurring in less than 24 hours following a traumatic PVD
iv. Visually helping patients to understand their intraocular condition

j. Macular Hole (full thickness)
   i. Standard OCT images
      1. Shows loss of sensory retinal tissue
   ii. 3-D images
      1. Black base of the hole indicates loss of overlying sensory retina
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

k. Peripheral Retinal Tear
   i. Standard OCT images
      1. Shows loss of sensory retinal tissue and localized detachment
   ii. 3-D images
      1. Black base of the hole indicates loss of overlying sensory retina and blue to red indicates lifted margins and white may indicate lifted flap of the tear
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition

l. CRVO
   i. Standard OCT images
      1. Cystoid macular edema
   ii. 3-D images
      1. Elevated irregular retinal surface
      2. Loss of foveal depression
      3. Depression in surface and elevation in RPE layer is due to an artifact. The OCT scan detect and reflection surface above the RPE layer
iii. Explanation of disease condition
iv. Visually helping patients to understand their intraocular condition
Vitreo-Foveal, -Disc-, and Retinal traction. What Every Eye Doctor Should Know.

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A. How the OCT works
   a. OCT imaging has allowed for an understanding of vitreal traction that was only possible in the past by histological sections. OCT imaging is of live tissue, so it is even better than histological sectioning with its inherent artifacts.
   b. Aspects of OCT imaging
      i. Michaelson interferometer
         1. Bright light source (superluminescent diode)
         2. Reference mirror
         3. Fast moving scanning mirror
         4. Detectors
         5. Computer
         6. Monitor

B. Vitreomacular traction
   1. OCT images
      a. Where is the traction taking place?
         a. Due to the bright light source and sensitive light detector, the thin transparent vitreous cortex can be imaged. Thus, traction sites on the vitreous and optic disc can be seen.

C. PVD - how does it start and end. What are the sequence of events in the progression of a PVD?
   a. Partial posterior vitreous separation
      i. Posterior cortical adhesion are in general greatest at the optic disc margin, foveal area, and the posterior vitreous base.
      ii. The early separations occur in areas of the retinal between these firm attachments. Typically it seems to be in arc formations from the margin of the disc to the fovea, from the fovea to a temporal location far short of the equator, and nasal, superior, and inferior location far short of the equator. The direction of the vitreous
separation depends on the adherence to the disc margin and the region to detach first and expands to other directions as the cortex peels in one or both directions from the initial site of separation.

iii. The separating process takes years and is likely the major reason for floaters appearing in people 50 years and older.

iv. It is not until the vitreous fully peels free from the disc margin does a total PVD takes place and the separating to the anterior limit at the vitreous base probably takes weeks.

v. Any firm attachments along the surface of the retina during the total PVD event can be a potential site of retinal bleeding or tearing.

vi. PVDs are not always complete and vitreous adhesion to the margins of the disc may be present in patients in their 70s and 80s.

D. Terminology of various sites of cortical adhesion/traction
   a. Vitreo-foveal (V-F)
      i. Cortical adhesion to the foveal depression
         1. This traction site is the most hazardous due to the thin retina in the area. This can lead to cystoid edema, foveal distortion (possibly convex curvature to the depression on accommodation and looking downward), foveal retinoschisis, macular hole, and epiretinal membrane (ERM) formation. Symptoms may occur and often consist of blurry and distorted vision.

b. Vitreo-parafoveal (V-PF)
   i. Traction on this thicker area of the macular.
      1. It is not nearly as hazardous and not as likely to produce symptoms.

c. Vitreo-disc (V-D)
   i. Traction on the disc margin and often peripapillary retina
      1. May produce superficial retinal peaking and micro tears.

d. Vitreo-retinal (V-R)
   i. Traction at numerous sites of the retina.
      1. Most adhesion sites are weak and break easily but some may be firm and can result in photopsia, hemorrhaging, and tears.

E. Potential consequences of a PVD
   a. Epiretinal membranes (ERM) formation
i. Vitreous traction on the retinal surface results in breaks in the ILM (usually tiny) that allows glial and other retinal cells to migrate unto the retinal surface, proliferate, and organize into a membrane that has contractile properties.

1) Elevation of the macula  
   a. It is the same effect as having a depression in the center of a bed sheet and pulling on the edges of the sheet. This will raise the center depression.

2) Tangential contraction  
   a) retinal striae (folds)  
   b) retinal hemorrhages  
   c) macular distortion

3) Tearing of the macula tissue both vertical and horizontal  
   a) neural bridges (allow for fairly good vision)  
   b) breaking down of neural bridges

4. Vitrectomy with membrane peel

b. Macular hole

1) Anterior-posterior vitreous traction  
   a) More anterior-posterior traction than lateral traction

2) Macular hole development classification  
   a. Stage 1  
      i. Elevation of the macula in the form of a yellow spot  
   b. Stage 2  
      i. Early hole formation  
   c. Stage 3  
      i. Hole fully developed  
   d. Stage 4  
      i. Vitreous cortex completely detached

3) Tearing of the macula tissue  
   a) neural tissue separation (schisis)  
   b) forming neural roof  
   c) breaking down of the roof (can opener effect)  
      i. inner layer hole
ii. operculum
   d) separation of retinal tissue to RPE (full thickness hole)

4) Treatment
   a. Pars plana vitrectomy (PPV)
   b. Vitreous cortex peel
   c. ILM peel

b. Macular hemorrhages
   i. Traction on superficial blood vessels

   c. Serous traction detachments
      i. Traction physically pull the sensory retina from the RPE
      ii. These can be mistaken for a small central serous chorioretinopathy
           but they are usually much smaller

d. Avulsion of superficial retinal layers
   i. Operculated tears
      1. Plug of retina is pulled away from the RPE
      2. Usually circular in configuration but may be oval or irregular in shape
      3. Pigment from previous pigment clumping may be seen on the operculum
      4. Retinal hemorrhages may be seen from a torn vessel
      5. The separated retinal tissue contracts immediately and becomes 1/5 to size of the break with time
      6. The operculum is attached to the vitreous cortex and therefore, will move on eye movements
      7. Traction on the retina is usually relieved when the vitreous cortex separates (less likely to produce a RD than a flap tear).
      8. With time drusen may form in the base of the break

   ii. Flap tears
      1. Horseshoe shaped tear occurs with flap just above it
      2. Almost always the vitreous cortex remains attached to the apex of the flap and therefore can move a small distance on eye movements. This is also the reason why these tears are more likely to progress to a RD.
      3. The separated retinal tissue contracts immediately and can become much thinner than the break with time
      4. Retinal hemorrhages may be seen from a torn vessel
      5. Pigment from previous pigment clumping may be seen on the operculum
Health Information Exchange

Peter J. Cass, OD

HIE structure in Texas

- THSA
- REC
- Governance Model
- Opt in Vs Opt Out
- Data elements shared
- Formatting standards
- Privacy
- Fees
- Training and support
- Timeline

First Steps

- Medicaid
- SureScripts
- Immtrac

National HIE

Optometry Participation

- TOA HIT workgroup
- TOA Advocacy
- Key Contacts

State Incentives
A 360-Degree Approach to EMR Implementation

Daniel J. Marino
Health Directions, LLC

Agenda
- Environmental Overview
- Information on the HITECH Stimulus Opportunities
- Hospitals, Physicians and Interoperability
- Preparing for an EMR Implementation
- Project management and the EMR implementation
- Case study

EMR Trends in Health Care
- The U.S. spent over $2.2 Billion in health care in 2008, yet most of the information exchange is rudimentary
- According to the CDC’s National Center for Healthcare Statistics 2007 survey, only 25.9% of medical practices had some form of EMR
- U.S. is adopting EMR technology at a much slower rate than other industrialized nations
- According to a 2007 study conducted by the Institute of Public Health, Physicians who use electronic health records believe “(EMR) systems improve the quality of care and are generally satisfied with the systems”

Government’s Role in Promoting EMR Technology
- Promoting incentives for quick implementations of EMR in medical practices
- CMS is paying incentives to physicians for reporting quality data using EMR
- Since early 2005 the Department of Veterans Affairs (VA) Hospitals have been adopting an EMR
- Proposed bills introduced to incorporate EMR technology within all physician offices over the next 3 years
- HHS Secretary Mike Leavitt is promoting EMR technology as means of change reimbursement and slowing the rise in health care spending

Proposed Reimbursement Changes
- Government’s position on reducing cost is to tie provider reimbursement to quality data and outcomes
- Medicare (CMS) already began quality based reimbursement with the PQRI program
- Some plans are beginning to follow the government’s lead

What We Hear as Reasons to Not Implement and EMR
- Costs are too high
- Electronic health technology will interfere with my office workflow
- An EMR will slow me down, I’ll see less patients
- I’m going to wait to see the “technology direction” of the hospital
- A huge undertaking and may not practice much longer
Most Common Barriers to EMR Adoption

0% 10% 20% 30% 40%

- Funding
- Anticipation of Difficulty
- Process Flow Redesign
- Compatibility with Existing Systems
- Lack of Support by Medical Staff

MRI 2007 Survey of Electronic Medical Records Trends and Usage

Eventful Times: The Need for Electronic Health Technology is Now

“This will cut waste, eliminate red tape, and reduce the need to repeat expensive medical tests. It just won't save billions of dollars and thousands of jobs -- it will save lives by reducing the deadly but preventable medical errors that pervade our health care system.”

- President Obama


- This legislation includes over $19 billion in funding for health information technology (HIT) infrastructure and adoption. Additional allocations for training, research and quality increasing the total funding for health care initiatives to over $59 billion.
  - Health Information Technology for Economic and Clinical Health Act (HITECH) provides $19.2 billion in funding for HIT.

Breakdown of $19 Billion

$17 billion  
Physician Incentives
Incentive Bonuses from Medicare/Medicaid

+ $2 billion  
HHS Discretionary Funds (For Use By National Coordinator of Health IT)
Standards Development, Grants (AHRQ, HRSA, CMS), HIE Infrastructure, Loans to the States for EHR, Regional HIT Resource Centers, Telemedicine, Efficacy Studies

= $19 billion

HHS = Health and Human Services
AHRQ = Agency for Healthcare Research and Quality
HRSA = Health Resources and Services Administration
CMS = Centers for Medicare and Medicaid Services

Health Information Technology for Economic and Clinical Health Act (HITECH)

- $17 billion in incentives require proof of "meaningful" use
  - Use of a certified product as determined appropriate by the Sec. of HHS
  - The EHR technology must be connected
  - Complies with submission of reports on clinical quality measures

- “Early Adopters”, those that adopt first will benefit the most (declining incentives)
  - Physicians can earn between $44,000 to $64,000 over five years from Medicare / Medicaid if they are utilizing an EHR in 2011
  - Late adopters will receive significantly less
  - Providers may receive incentives under only one of the programs
  - 2015: reductions in Medicare/Medicaid fees for non-EHR users

- Hospitals can earn up to $2,000,000 plus discharge bonuses (total payout to them could be $10 million+)

Medicare Incentive Payments

- Medicare incentive payments will be available to "eligible professionals and hospitals" for the first five years 2011-2015
  - If eligible professionals and hospitals do not demonstrate meaningful use by 2015, Medicare payments will be reduced

- First Payment Year
  - $18,000 if the first payment year is 2011 or 2012
  - $15,000 if the first payment year is 2013
  - $12,000 if the first payment year is 2014

- Second Payment Year: $12,000
- Third Payment Year: $8,000
- Fourth Payment Year: $4,000
- Fifth Payment Year: $2,000
Medicaid Incentive Payment (State/HHS)

- This section authorizes States to pay Medicaid providers no more than 85% of the net average allowable costs for certified EHR technology (maximum of $64,000 over 5 years). Secretary of HHS is to study costs of EHR and determine the “net average cost.”
- Eligible Medicaid providers must first demonstrate use by 2015 and eligibility for incentive ends after 2021
- Eligible providers include:
  - Non-hospital based pediatrician with at least 20% of patient volume receiving medical assistance (Medicaid)
  - Children’s hospitals or an acute care hospital that is not a children’s hospital that has at least 10% of the hospital’s patient volume attributable to individuals receiving medical assistance

Additional Incentives Continue

- Physician Quality Reporting Initiative (PQRI)
  - Eligible Medicare providers who satisfactorily submit quality measures data will earn a 2% incentive payment
- E-Prescribing
  - The E-Prescribing Bonus Program allows eligible Medicare providers to receive incentives for use of qualified e-prescribing software between 2009 and 2013
  - 2009: 2% incentive based on allowed charges for all Physician Fee Schedule (PFS)
  - 2010: 2%
  - 2011: 1%
  - 2012: 1%
  - 2013: 0.5%

Hospitals are Supporting Physician with EMR

- Hospitals are creating electronic health networks for community physicians
- Hospitals, PHOs and IPAs and negotiating on behalf of employed and community physicians
  - Relaxation of Stark regulations are allow hospitals to provide EMR technology to physicians
  - EMR due diligence process is performed by physicians
- Hospitals are providing interoperability and interfaces for physicians
- Health Information Exchange Regional Grants
  - $300,000,000 for regional efforts toward health information exchange
  - Regional Health Information Organizations
  - Health Information Exchanges
  - Regional approach

Summary of Incentive Opportunities

- $44,000 to 64,000 available per physician over 5 years
  - $30,000 of $44,000 is available during the first 2 years (2011, 2012)
- 2% reimbursement of Medicare revenues available from CMS for PQRI reporting
- 2% reimbursement available from Medicare available for e-prescribing
  - Reimbursement begins to decrease in 2011

The Direction EHR Technology

- Promote electronic health technology within physician practices
- Electronic health networks and interoperability platforms are the future of technology
- Allow for efficient and safe transfer of health information

What is Interoperability in Healthcare?

- The ability for EMRs to electronically share data and communicate with one another
- The systemic exchange of patient health information
- The exchange of patient health information between entities, providers, patients, health plans, pharmaceuticals and laboratories
- Regional health information organizations as a means of centralizing patient data exchange for communities
Hospital-Physician Relationship and Electronic Health Technology

- Electronic Medical Records, interoperability and clinical performance outcomes can drive revenue
- Clinical outcomes are becoming a bigger part of reimbursement and quality of care (clinical integration)
- Electronic health technology improves patient care through documentation, coding and reduction of errors
- Pay for performance and evidence based reimbursement will drive future managed care contracting strategies

Community Health Integration Strategy

- Electronically connecting hospitals, IPAs, physicians, patients, payers, labs, pharmacies, into a secured digital networks
- Many stakeholders, but hospital and physicians will take the lead
- Allow for a secured efficient transfer of medical information between entities
- Provide patients with new “healthcare conveniences” through the use of technology
  - Web portals
  - E-mails
  - Text Messaging

Key success of any community health initiative is ensuring the physicians use the technology….it begins with EMR

Successful Components of an EMR

Best Practices
- Clinical workflows
- Revenue cycle processes
- Standardized policies, procedures and work flows

People
- Staff training and education
- Measure outcomes and tracking
- “Patient-focused” approach

Electronic Solutions
- Practice Management
- Electronic Medical Record
- Business Intelligence

Return on Investment (ROI) of an EMR

Revenue Opportunities with an EMR
- Improved accuracy of documentation most of the time leads to better coding, more revenue
- Increase in charge capture of services and improvement accuracy of claims
- Negotiate quality performance outcomes within payer contracts
- Reduce redundancy of diagnostic testing
- Financial incentives for early adopters

Anticipated Savings
- Time and motion studies
  - Cost of charts pull, phone triage, messaging
  - Test results processing
  - Form completion
    - Immunizations forms, etc.
  - Prescription re-issue
  - Chart creation
- Average of cost of staff
  - Patient phone calls
  - Rx refills and pharmacy calls
  - Referring physicians requests
  - Insurance information and referral/pre-cert processing
Anticipated Savings with EMR

- Areas of real savings:
  - Transcription cost
  - Chart creation
  - Physical storage space
  - Medical records FTE
  - Encounter forms
- Time spent looking for lost charts, transferring charts and coding tickets
- Efficiencies and lower costs associated with Rx refill
- Printing of patient education materials

Success Criteria Of EMR Implementation

- Design EMR technology to allow physicians to incorporate “easy-to-retain” functionality as well as clinically intuitive pathways
- Redesign clinical workflows that promote automation and efficiencies
- Don’t forget your revenue cycle
- Adopt an incremental deployment strategy in order to increase comfort level and build confidence in EMR
- Adopt the IDDOINEM principle in building the appropriate content
  - *If Doctors Don’t Use It, Nothing Else Matters*

Implementation Concepts as You Build Your Work plan

- Incorporate the 80-20 Rule in your system design
  - Avoid designing a solution for 20% of the cases
  - Focus on the 20% of cases that represent 80% of your solution
- Create your project team based on expertise and communication
- Project management is critical to your success
- Engage your physicians and key influencers
- Prepare to test and train
- Develop your implementation infrastructure

Physician Involvement

- Common mistakes to avoid
  - Overestimating physician confidence with electronic solutions
  - Under involvement of physicians in the EMR selection and the consensus building process
  - Limiting the physician involvement in the design and implementation phases
- Design the electronic process around the exam room encounter
- Templates and tasks need to support the physician’s specialty and not a generic electronic note

Consider Changes From The Paperwork Workflow Process

- The paper chart versus electronic templates
  - How is the chart set-up and organized for different patient visits?
- Incoming lab and ancillary results
  - Need to consider how they are incorporated into the electronic record versus review and sign-off
- Process to notify patients of results
- Leverage electronic technology with faxes, scanning and e-mail
  - Consideration to HIPAA and patient confidentiality

Document Conversion

- Need to create a plan for conversion of records and incoming information
- Are their archived transcription files?
- Consider how far back in time to begin the patient record conversion
  - 3 year history
  - Appointments for the next 6 months
- Scanning of current and new patients
  - How much of the chart and how far back?
Consider New Ways to Manage the Revenue Cycle

• Evaluate how you managed your Revenue Cycle before an EMR implementation
  – Was/Is it effective?
• Were you effectively using your Practice Management System and/or Business Intelligence tools to manage?
• What tools does your EMR offer to manage the functions you implemented?

Case Study

Background

• 10 provider group practice with 3 clinic locations
• Large amount of managed care contracts and 30% governmental payers
• Few reports were used to manage revenue cycle functions
• Practice management system was underutilized
• The revenue cycle activities required automation and efficiencies in order to maximize outcomes

Implementation Strategy

• Selected a powerful and well respected EMR Vendor
• Phased approach to design and implementation
• Implementation lacked physician input
  – Many of the staff had little working knowledge of EMR
  – Most staff tasked with designing EMR had little knowledge of clinical or revenue cycle operations
• Most physicians were reluctant to adopt EMR, despite a directive from leadership that adoption was mandatory

Outcomes at Go-live

• Lack of workflow redesign led to many operational inefficiencies
• Rather than scan at the clinic sites, all documents were batched and sent to the Business Office, leading to misplaced documents that were often scanned to the wrong chart
• Physicians reluctance and a directive from management to adopt, led to the design committee pacifying physicians rather than implementing the solution to its fullest

Outcomes at Go-live (Con’t)

• Many of the template and edit features of the EMR were disabled for fear of “disrupting the physician’s ability to see patients”
• Features designed to facilitate coding and correct charge capture on the front end were under utilized creating a bottleneck of errors in the business office
  – ROI on staffing in the clinics were countered with an increased need for staff in the business office to manage charge capture process
### EMR Intervention

- Refocused the design team to include a physician champion with a strong clinical support person
- Created detail clinical process flows to identify areas of efficiency and automation
- Implemented e-prescribing with all providers
- Created templates around the physicians practice style allowing for coding and documentation efficiencies

### Current State

- Physicians began to realize efficiencies with EHR technology
- Completed a process redesign of the entire revenue cycle
- Automated many of the manual processes that remained after the go-live
- All Clinical documents are now scanned at the office site
- Physicians went through a reeducation process of clinical workflow and EMR benefits to change attitudes and behaviors
- After 3 months, the EMR begin to contribute to improve revenue for the practice

### Where do you go from here?

- Talk with colleagues and APP to assist with decision making
- Give serious consideration to the hospital preferred vendor solution
- Your decision will come based more about “when” to implement and not “if”
- Begin thinking about your practice’s strategic goals and implementation objectives
- Network, network, network
- When it finally comes down to moving forward, it’s really not about the technology, it’s about the clinical processes and workflows

### Questions
“Federal EHR Incentives - Ensuring You Get Your Share"
Jeff Grant, HCMA, Inc., Medical Practice Management Consultants

Lecture Description:

This course will detail the final Federal requirements for obtaining Federal EHR stimulus money that is available under the HITECH Act. Attendees will learn exactly what to do to meet the requirements for the incentive and the specific actions that need to be taken.

Lecture Objectives:

1. Ensure that each attendee understands the rules and requirements related to HITECH Act Incentive payments
2. Ensure that each attendee understands exactly what actions need to be completed in order to qualify for and begin receiving EHR incentive payments.

Ensure that each attendee understands the pitfalls to avoid in the process.