IRIS
Intelligent Research in Sight

A Clinical Registry Case Study
Patient Registries Summit

William L. Rich III, MD, FACS
AAO Medical Director Health Policy
Chair, IRIS Executive Committee
Gaps in Current Care

- No easy way to track performance and patient outcomes
- No feedback loop to improve performance
- No national benchmarks for comparison
- EHRs not targeting performance improvement
- Quality of care defines the AAO culture
The Big Idea: The Hawthorne Effect!

- “If you can’t measure it, you can’t improve it.”

- Lord Kelvin, 1880
Solution: IRIS Registry

- Captures performance rates on accepted quality measures
- Provides real-time feedback
- Drives true improvements in quality and outcomes
Introduction to IRIS Registry

IRIS Registry (Intelligent Research In Sight) is the nation’s first comprehensive eye disease clinical database

• Enables ophthalmologists to use clinical data to improve care delivery and patient outcomes

• Uses HIPAA-compliant methods to collect data from patient records directly from electronic health record (EHR) systems

• Utilizes an EHR agnostic systems integrator
IRIS Chronology

- November 2011-registry task force formed
- February 2012-development plan presented to Board
- November 2012- Board approved funding
- December 2012-December 2013-measures selected and tested, communication strategy delineated, data dictionary established
Launch March 2014

- Goal: 2200 ophthalmologists by 2017 with 18 million patients
Current Stats
December 6, 2015

Contracted

• 10,180 physicians from 3,555 practices

Number of patient visits

72.57 million, representing 20.64 million unique patients
Integrated with 39 EHRs

- Amazing Charts
- ChartMaker Medical Suite
- Compulink
- Cybax
- DoctorSoft
- eClinicalWorks
- EyeDoc EMR
- Eyefinity ExamWRITER
- EyeMD EMR
- GE Centricity EMR
- Greenway Intergy
- Greenway/Primesuite
- HCIT EHR
- ifa systems EMR
- iMedicWare
- Integrity EMR for Eyes
- IO Practiceware
- KeyChart EMR
- Lytec
- ManagementPlus
- MaximEyes by First Insight
- Mastermind EHR
- MDIntelleSys
- MDoffice
- MedEvolve
- Medent
- Medflow
- Medinformatix EHR
- My Vision Express
- NexTech
- NextGen
- Origin
- Prime Clinical System
- PrognoCIS
- SRS
- TriMed EHR
- VersaSuite
- Vitera EHR
- WebChart by MIE
Unique Patients and Visits

Timeline

Millions

Patient Visits
Unique Patients


61
17.58
Advantages of Clinical Registry Data

- Real world
- Big data
  - Estimated 49% of national visit volume (2013-present)
  - World’s largest clinical registry
- Current data
- Estimates are now 48m patients and 148m visits 1/18
- Clinical data: outcomes, VA, IOP, free text
- Across all payers
Why the rapid uptake?
Value Proposition

- Financial
- MOC-Part IV
- Better outcomes
- Research
- Informing public policy
- Population Health
- Surveillance
Financial
Quality Reporting Requirements

IRIS Registry submits on behalf of members:

- **Meaningful Use**-
  - Meaningful Use Clinical Quality Measures
  - Meaningful Use Objective 10 - Public Health Reporting: Specialized Registry Reporting

- **PQRS** -
  - Physician Quality Reporting System (PQRS) and PQRS reporting for the Value-Based Modifier
  - Includes Patient Reported Outcome Measures for Cataract Measures Group
IRIS enables ophthalmologists to avoid Medicare penalties for PQRS, VBM, MU, and survive in the new MACRA world.
Inform Public Policy
Anti-VEGF Agents

- 2013-2014
- 1,084,306 injections provided to 174,891 unique patients
- Average age = 75.7 years
- Male = 41.9% ; Female = 58.1%
## Endophthalmitis Rates

<table>
<thead>
<tr>
<th>Anti-VEGF Agents</th>
<th>Injections</th>
<th>Unique Patients</th>
<th>Endophthalmitis at 30 days</th>
<th>Rates (30 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab</td>
<td>490,799</td>
<td>95,651</td>
<td>391</td>
<td>0.080%</td>
</tr>
<tr>
<td>Ranibizumab</td>
<td>295,025</td>
<td>44,868</td>
<td>212</td>
<td>0.072%</td>
</tr>
<tr>
<td>Aflibercept</td>
<td>298,482</td>
<td>34,372</td>
<td>202</td>
<td>0.068%</td>
</tr>
</tbody>
</table>
Improved Outcomes

- Multivariate analysis: age, poor preop visual acuity, glaucoma diagnosis, lower volume hospitals.
- Overtime, all decreased.
EUREQUO project: European Registry of Quality Outcomes for Cataract and Refractive Surgery
368,258 cataract surgeries

<table>
<thead>
<tr>
<th>Variable</th>
<th>20/40 or Better</th>
<th>20/20</th>
<th>No. of pts</th>
</tr>
</thead>
<tbody>
<tr>
<td>without ocular comorbidity</td>
<td>98.2 %</td>
<td>69.9 %</td>
<td>274,155</td>
</tr>
<tr>
<td>with ocular comorbidity</td>
<td>82.6</td>
<td>35.9</td>
<td>94,103</td>
</tr>
<tr>
<td>Comorbidity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macular degeneration</td>
<td>80.7</td>
<td>30.2</td>
<td>35,029</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>89.7</td>
<td>47.2</td>
<td>21,088</td>
</tr>
<tr>
<td>Diabetic retinopathy</td>
<td>83.7</td>
<td>37.8</td>
<td>11,299</td>
</tr>
<tr>
<td>Amblyopia</td>
<td>58.7</td>
<td>16.1</td>
<td>6,650</td>
</tr>
<tr>
<td>Other</td>
<td>81.1</td>
<td>34.8</td>
<td>27,214</td>
</tr>
<tr>
<td>ID</td>
<td>MEASURE</td>
<td>PERFORMANCE</td>
<td></td>
</tr>
<tr>
<td>----</td>
<td>------------------------------------------------------------------------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>IRIS 1</td>
<td>Primary Open Angle Glaucoma (POAG): Optic Nerve Evaluation</td>
<td>94.17%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 79.42%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 2</td>
<td>Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy</td>
<td>13.72%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 38.91%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 3</td>
<td>Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 27.17%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 4</td>
<td>Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery</td>
<td>79.51%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 86.28%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 5</td>
<td>Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 0.62%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 6</td>
<td>Diabetes: Eye Exam</td>
<td>80.92%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 87.05%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 14</td>
<td>Preventive Care and Screening Tobacco Use: Screening and Cessation Intervention</td>
<td>87.96%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 82.20%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 15-1</td>
<td>Use of High-Risk Medications in the Elderly</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 1.71%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 15-2</td>
<td>Use of High-Risk Medications in the Elderly</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 0.28%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 16</td>
<td>Falls: Screening for Future Fall Risk</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 2.38%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 17</td>
<td>Documentation of Current Medications in the Medical Record</td>
<td>94.69%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 88.57%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 18</td>
<td>Controlling High Blood Pressure</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 19.41%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRIS 19</td>
<td>Closing the referral loop: receipt of specialist report</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Registry Benchmark: 21.00%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
IRIS 3: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Performance Trend

<table>
<thead>
<tr>
<th>Quarter</th>
<th>All</th>
<th>(+)</th>
<th>(-)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015Q3</td>
<td>2533</td>
<td>491</td>
<td>2042</td>
<td>19.38%</td>
</tr>
<tr>
<td>2015Q2</td>
<td>2363</td>
<td>382</td>
<td>1981</td>
<td>16.17%</td>
</tr>
<tr>
<td>2015Q1</td>
<td>2212</td>
<td>251</td>
<td>1961</td>
<td>11.35%</td>
</tr>
<tr>
<td>2014Q4</td>
<td>2058</td>
<td>57</td>
<td>2001</td>
<td>2.77%</td>
</tr>
</tbody>
</table>
## Retinal Detachment Surgery

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Frequency</th>
<th>% of RD Surgeries</th>
</tr>
</thead>
<tbody>
<tr>
<td>67101</td>
<td>1,038</td>
<td>1.74%</td>
</tr>
<tr>
<td>67104</td>
<td>6,116</td>
<td>10.23%</td>
</tr>
<tr>
<td>67107</td>
<td>2,690</td>
<td>4.50%</td>
</tr>
<tr>
<td>67108</td>
<td>12,581</td>
<td>21.05%</td>
</tr>
<tr>
<td>67112</td>
<td>192</td>
<td>0.32%</td>
</tr>
<tr>
<td>67113</td>
<td>8,624</td>
<td>14.43%</td>
</tr>
<tr>
<td>67141</td>
<td>1,726</td>
<td>2.89%</td>
</tr>
<tr>
<td>67145</td>
<td>26,797</td>
<td>44.84%</td>
</tr>
</tbody>
</table>
## Return to OR in 90 Days

<table>
<thead>
<tr>
<th>Surgery</th>
<th>% return within 90 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>67101</td>
<td>0.76%</td>
</tr>
<tr>
<td>67108</td>
<td>14.66%</td>
</tr>
<tr>
<td><strong>67107</strong></td>
<td><strong>2.06%</strong></td>
</tr>
<tr>
<td>67108</td>
<td>25.15%</td>
</tr>
<tr>
<td>67112</td>
<td>31.30%</td>
</tr>
<tr>
<td>67113</td>
<td>30.29%</td>
</tr>
<tr>
<td>67141</td>
<td>0.92%</td>
</tr>
<tr>
<td>67145</td>
<td>19.00%</td>
</tr>
</tbody>
</table>
Research
Clinical research and registries

- IRIS is an outpatient clinical registry with the ability to follow patients longitudinally using probabilistic matching (94%). Most facility based registries record the short term evaluation of drugs, devices and procedures but are unable to measure their impact on the natural course of disease: IRIS will.
Research and Registries

- Despite rapid advances in the use of clinical registries for CER, surveillance and PBRN (Practice Based Research Network) observational registries studies have historically lacked the rigor of randomization.
Randomized Registry Trial


- Time for recruitment and costs were dramatically less in the randomized registry arm of the trial.

- The incremental cost of the Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia (TASTE) trial was $300,000, or $50 for each participant who underwent randomization!
Randomized Registry Trial

“Today we can no longer afford to undertake randomized effectiveness trials that cost tens or hundreds of millions of dollars. But today we also have registries and other powerful digital platforms. Today it may be possible to design and conduct mega-trials with what we have: bigger data and smaller budgets.”
Population Health Guidelines
Population Health

- IRIS enables real time feedback to physicians to improve care and decision support
- Guideline development time shortened
- IRIS can identify disparities in outcomes for populations are risk and point to new modalities of care.
Surveillance

Devices and Drugs
PEW: Future Directions for Medical Device Registries

- 60% of Class III devices have mandated post market surveillance and only 6% are performed by independent specialty registries.

- UDIs (Unique Device Identifiers) will be included in EHRs in 2015?

- Longitudinal EHR based registries (Pinnacle, IRIS) have the capability to follow devices at the longitudinal point of care and can detect early signals. Patient reported outcome tools can pick up early symptoms before device failure occurs.

- Data should be made publicly available
IRIS and UDIs

- If CDC mandates UDIs in certified EHR fields in the next year, IRIS can extract them.
- Currently IRIS collects device data inputted into a surgical template that is uploaded to the registry.
- The majority of devices are inserted in ASCs without EHRs.
Disease prevalence and surveillance

- CDC is utilizing the IRIS database to establish a updated scan of the prevalence of ophthalmic disease
- IRIS can be used to identify patients with rare diseases for device, drug or biologic research
“Punch list”

- Inadequate data points in EHRs-
- Validation of data-
- Data blocking: vendor fees & refusal to allow export of data - ongoing battle with two large vendors
- Importing UDI
- Implement PBRN-Practice Based Research Network-as a resource for target post market device studies.
Overcoming inadequate data points in EHRs

- Robust data dictionary >900 established upfront
- Process measures that address staging of diseases and actions that improve outcomes
- Mapping of measures from EHRs to the registry provides immediate feedback to practices of missing data points that result in poor performance when compared to national benchmark!
- Docs modify office templates
- Approach vendors on regular basis with “optimal data points” from data dictionary
Summary

- The IRIS ophthalmic clinical registry will represent a seminal change in how ophthalmology will improve performance and outcomes while shortening the timeline for the dissemination of important clinical knowledge, expand research opportunities and facilitate drug and device surveillance. To do so it must have broad input from specialists, have a viable business plan and not adversely affect physician work flow.
“...We’re facing very challenging times in healthcare in the United States today. I believe that ophthalmology has an opportunity not only to play a part in the solution to those challenges, but also to be an example for the health professions in the way forward.”

Harvey Fineberg, MD, PhD
President, Institute of Medicine
Keynote Address
2008 AAO Joint Meeting
Atlanta, GA
Thank You!

- For more information about the IRIS™ Registry
  - Visit www.aao.org/irisregistry
  - For questions, send an email to irisregistry@aao.org
  - wlrich3md@gmail.com