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IRIS Registry: Beyond Devices and Drugs An Innovative Game Changer

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AAO Medical Director of Health Policy

- Dr. Rich has no financial conflicts

Innovation in Eye Care

- Public/population health
- RCTs
- CER
- 21st Century ?

Public heath

- Alfred Sommer, MD, MHS described the impact of small doses of vitamin A given to infants and pregnant women. This brilliant intervention resulted in a 40% decrease in infant mortality and has prevented blindness in tens of millions of children over the last thirty years at a yearly cost per patient of $0.02! Dr. Sommer was awarded the Lasker Prize, the nation's most prestigious public health award.

Mid-late 20th Century: Role of Ophthalmology

- In the years between 1941 and 1953 there was a worldwide epidemic of childhood blindness in premature infants. Arnold Patz, MD hypothesized the role of oxygen. He and a staff pediatrician at the DC public hospital, Dr. Leroy Hoeck, designed the first randomized clinical trial. The results proved the importance of oxygen levels. Within a few years there was a 60% reduction in childhood blindness. Dr. Patz was awarded the Lasker prize.

Role of ophthalmology

- Mathew Davis, MD, designed the DRS and Early Treatment Diabetic Retinopathy Study that have been hailed as the gold standard of RCTs. Treatment advances for diabetic retinopathy decreased the five year incidence of blindness from 50% to 5%.
- ETDRS stimulated further studies that evaluated the impact of better medical control of the diabetic patient. In 1993 the Diabetes Control and Complication Trial was published that demonstrated the importance of good glycemic control. Over the past twenty years the incidence of eye disease has decreased 76%, kidney disease 50%, progression of diabetic retinopathy 54% and major CV events 42%!

Early 21st Century: Question

- How are professionals to succeed in this new environment that emphasizes the need for the **measurement** of a physician's quality, outcomes, resource use and patient quality of life?

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IRIS:

Intelligent Research in Sight

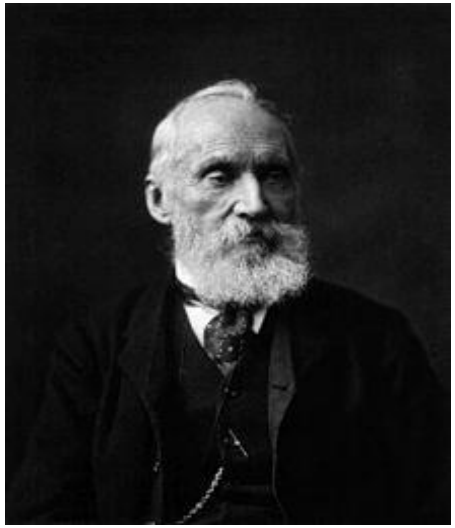
An 0phthalmic Clinical Registry

Why a Registry?

The Big Idea: The Hawthorne Effect!

- *"If you can't measure it, you can't improve it."*

  - Lord Kelvin, 1880



The IRIS™ Registry

A Focus on Quality Improvement

"When people and organizations focus primarily on quality, quality tends to increase and costs fall over time. When people and organizations focus primarily on costs, costs tend to rise and quality declines over time."

- W. Edwards Deming, PhD, statistician, 1900-1993

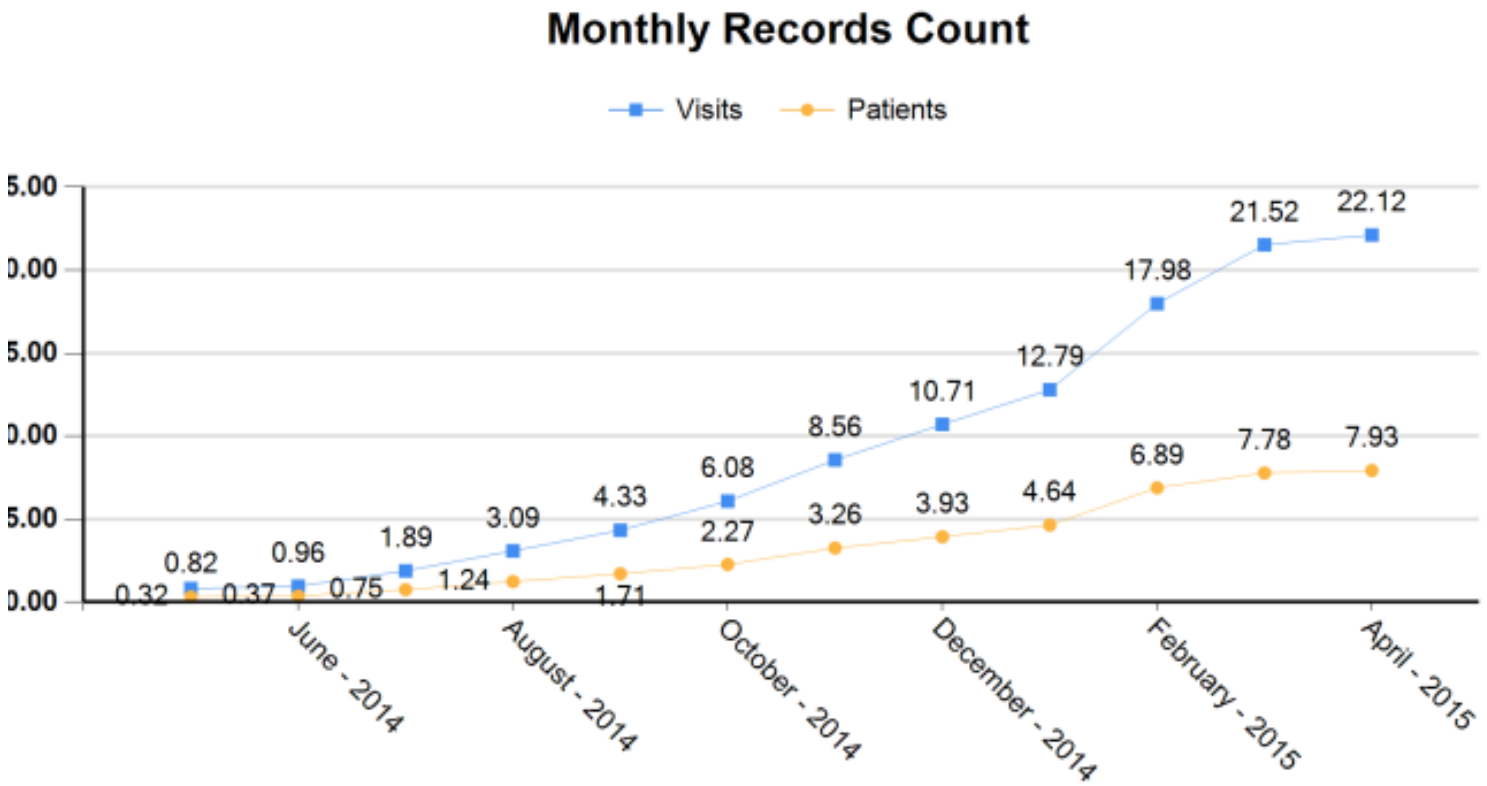
Why Now?

- Capitalize on lessons learned by other societies- STS, ACC
- Ability to develop a medical “game changer”
- EHR adoption at 40% and rising
- IT advances -**systems integrator**- little/no data entry-permits the longitudinal evaluation of a patient/disease and the impact of interventions: never been done.
- Opportunity to coalesce around one registry
- Increased demands for MOC and licensure

Launch Goal-March 2014

- 2200 ophthalmologists by 2017 with 18 million patients

April 7, 2015


Monthly Records Count
Visits
Patients
5.00
0.00
5.00
0.00
5.00
0.00
0.32
0.82
0.37
0.96
0.75
1.89
1.24
3.09
1.71
4.33
2.27
6.08
3.26
8.56
3.93
10.71
4.64
12.79
6.89
17.98
7.78
21.52
7.93
22.12
June - 2014
August - 2014
October - 2014
December - 2014
February - 2015
April - 2015

IRIS Status April 2015

- 40 different EHR systems integrated
- 2 Epic Academic Medical Centers with signed contracts and active discussions on integration
- 80% of ophthalmologists and practice ODs on EHR participating in IRIS

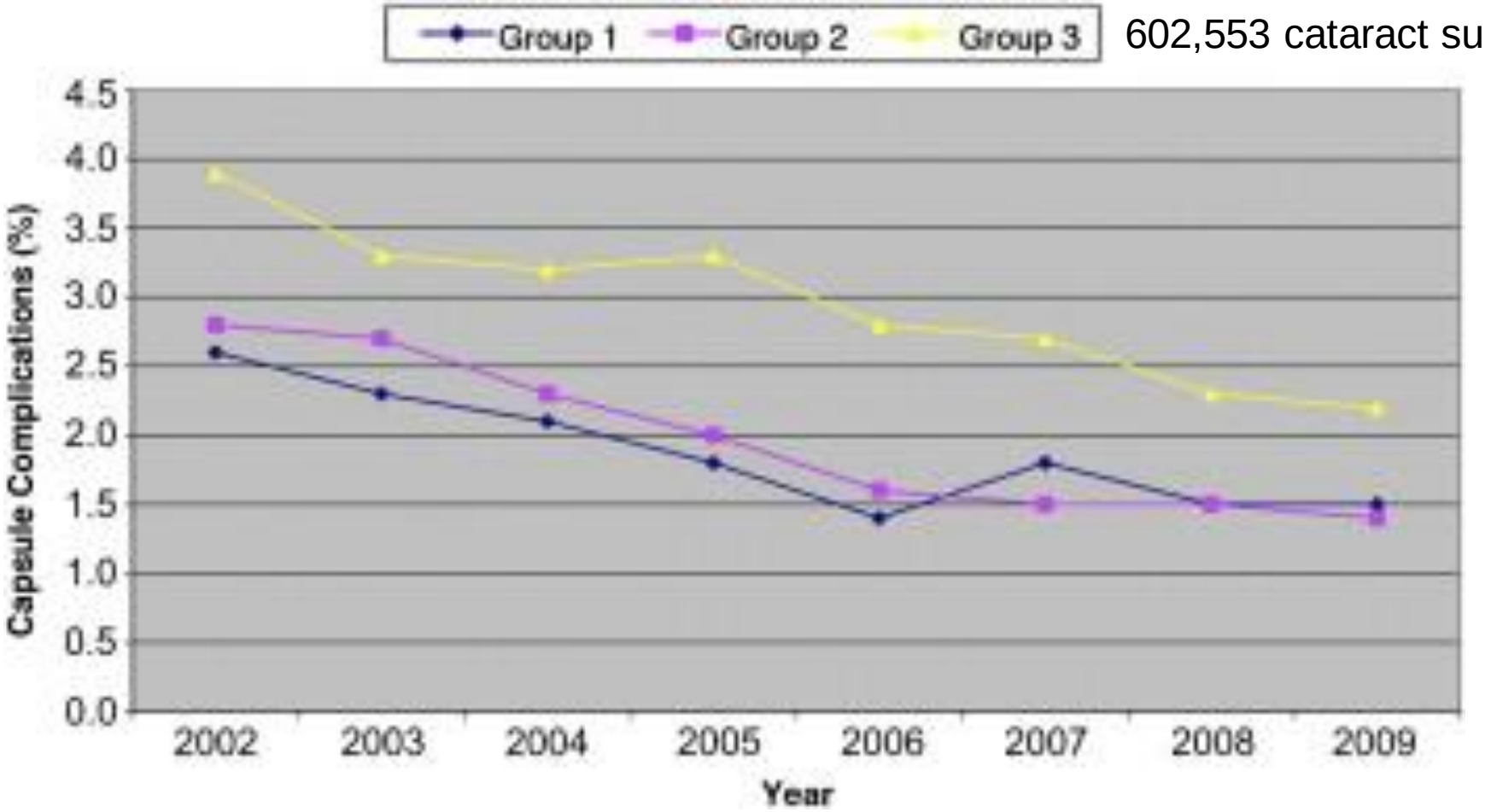
IRIS 2015 Projection

- In 2015 - doubling of integrated docs on EHR to 6,000 and total of 8,000 utilizing IRIS for quality reporting
- New goal? 8,000 docs and 48 million patients by 2017
- If we reach this new goal in 2017 the number of patient visits that year will approach 152 million.

Value Proposition

- Better outcomes
- Research
- Informing public policy
- Population Health
- Surveillance

Improved Outcomes



602,553 cataract surgeries

- Multivariate analysis: age, poor preop visual acuity, glaucoma diagnosis, **lower volume hospitals.**
- Overtime, all decreased.

Lundstrom M, et al. Decreasing rate of capsule complications in cataract surgery : Eight-year study of incidence, risk factors, and data validity by the Swedish National Cataract Register
JCRS, Volume 37, Issue 10, 2011, 1762 - 1767


FOCUS ON EYE HEALTH
National Summit
GAME Changers in Vision

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

- *The Randomized Registry Trial-The Next Disruptive Technology in Clinical Research* --Lauer & D'Agostino, *NEJM*, Sept 2013
- 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."

Inform Public Policy

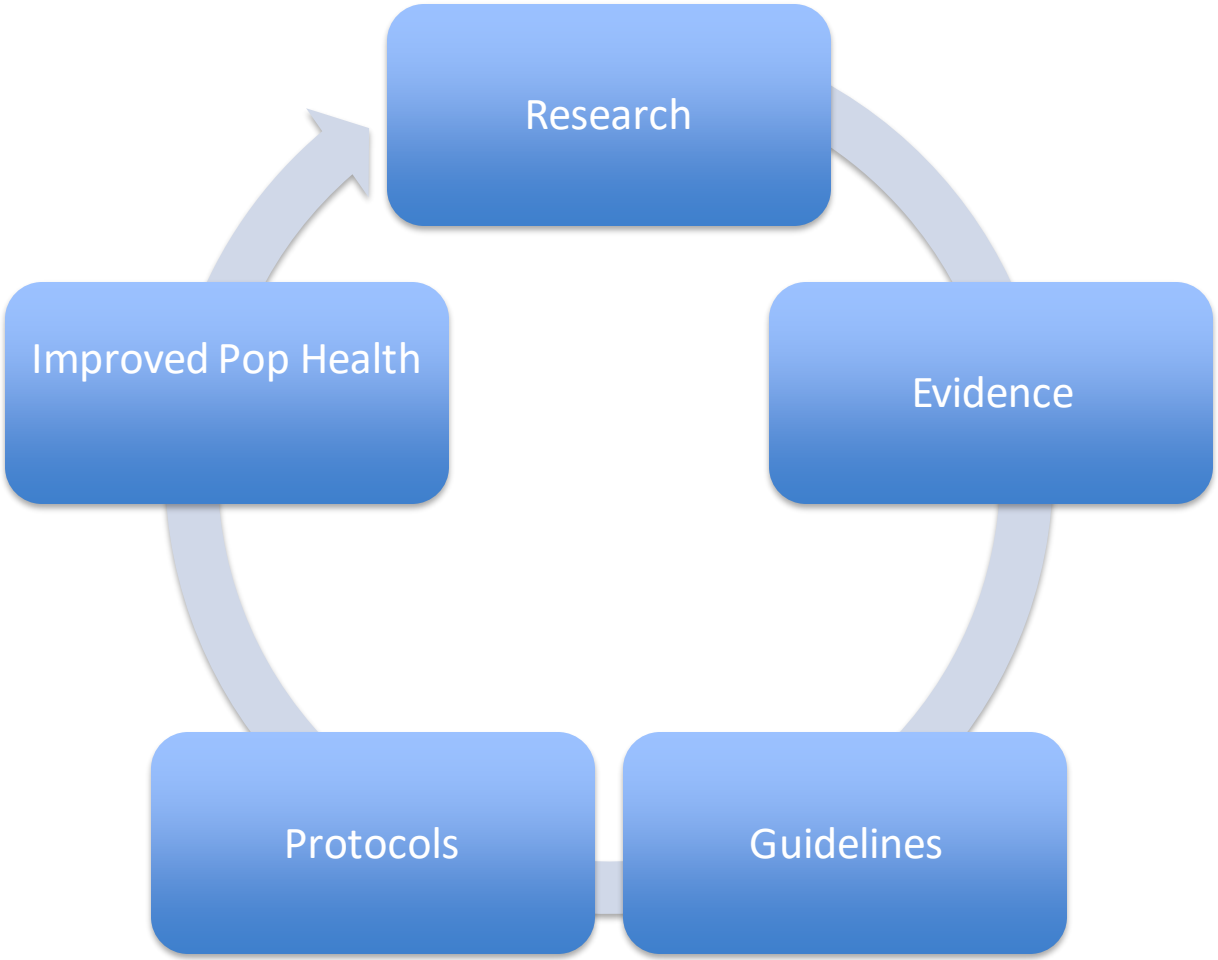
- **Avastin Compounding**

Endophthalmitis Rate

Drug	Injections	%
Avastin	478,381	0.12%
Lucentis	245,381	0.09%
Eylea	103,390	0.12%

Population Health

Improved Population Health



Population Health

Clinical registries may be utilized to evaluate:

1. the impact of RCT recommendations on large heterogeneous populations.
2. The appropriateness of new guidelines or treatment protocols
3. “Personalized” protocols and informed consent

Impact of guidelines

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Surveillance

- Devices and Drugs

Mini-Sentinel Initiative

- The Food and Drug Administration(FDA) now has the capacity to "query" the electronic health information of more than 138 million people, posing specific questions in order to monitor the safety of approved medical products.
- Mini-Sentinel, uses a *distributed data network* rather than a centralized data bank.

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 and can detect early signals. Patient reported outcome tools can pick up early symptoms before device failure occurs.
- Data should be made publicly available

Summary

- The IRIS clinical registry will represent a seminal change in how we improve our performance and outcomes while shortening the timeline for the dissemination of important clinical knowledge, expand research opportunities and facilitate drug and device surveillance.

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

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