CREATING COORDINATED REGISTRY NETWORKS & UTILIZING ROUTINELY AVAILABLE DATA FOR DEVICE RESEARCH

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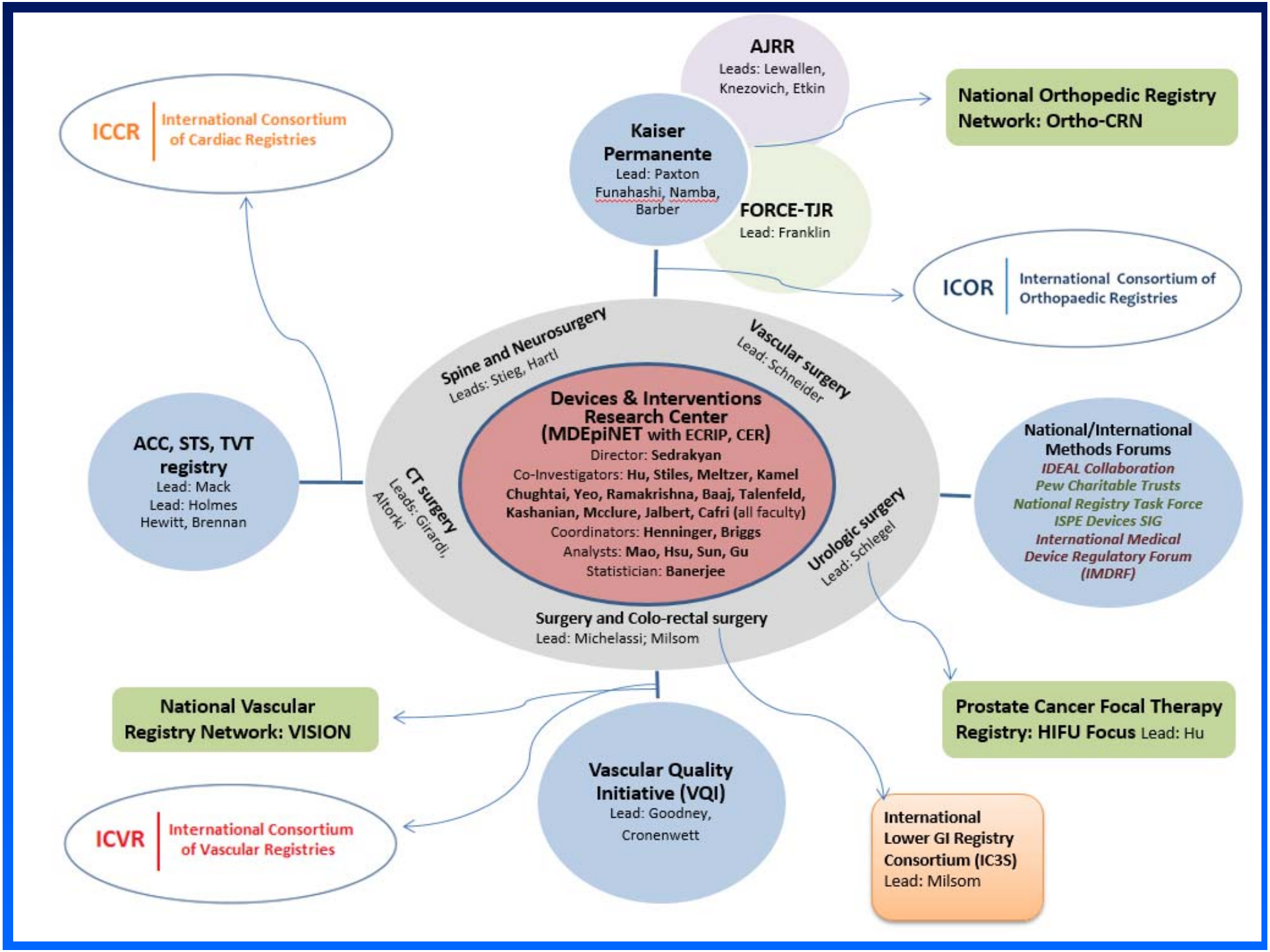

AJRR
Leads: Lewallen, Knezovich, Etkin
National Orthopedic Registry Network: Ortho-CRN
ICCR
International Consortium of Cardiac Registries
Kaiser Permanente
Lead: Paxton
Funahashi, Namba, Barber
FORCE-TJR
Lead: Franklin
ICOR
International Consortium of Orthopaedic Registries
Spine and Neurosurgery
Leads: Stieg, Hartl
Vascular surgery
Lead: Schneider
Devices & Interventions Research Center (MDEpiNET with ECRIP, CER)
Director: Sedrakyan
Co-Investigators: Hu, Stiles, Meltzer, Kamel Chughtai, Yeo, Ramakrishna, Baaj, Talenfeld, Kashanian, Mcclure, Jalbert, Cafri (all faculty)
Coordinators: Henninger, Briggs
Analysts: Mao, Hsu, Sun, Gu
Statistician: Banerjee
CT surgery
Leads: Girardi, Altorki
Urologic surgery
Lead: Schlegel
Surgery and Colo-rectal surgery
Lead: Michelassi; Milsom
ACC, STS, TVT registry
Lead: Mack
Lead: Holmes
Hewitt, Brennan
National/International Methods Forums
IDEAL Collaboration
Pew Charitable Trusts
National Registry Task Force
ISPE Devices SIG
International Medical Device Regulatory Forum (IMDRF)
National Vascular Registry Network: VISION
Prostate Cancer Focal Therapy Registry: HIFU Focus Lead: Hu
Vascular Quality Initiative (VQI)
Lead: Goodney, Cronenwett
ICVR
International Consortium of Vascular Registries
International Lower GI Registry Consortium (IC3S)
Lead: Milsom

GRADE Evidence Levels

Observational studies	Quality of Evidence	RCTs
Very strong association	High	Well designed studies
Strong, consistent association with no or little confounding Dose-response	Moderate	Study flaws Inconsistent Indirect Sparse data Publication bias
Well-designed studies	Low	
Few/inconsistent studies	Very Low	

Power and Limits of Evidence Appraisal

BMJ 2014;349:g5133 doi: 10.1136/bmj.g5133 (Published 9 September 2014)

thebmj RESEARCH

Appraisal of evidence base for introduction of new implants in hip and knee replacement: a systematic review of five widely used device technologies

Marc J Nieuwenhuijse *research fellow ICOR and FDA*[1 2 3], R G H H Nelissen *professor*[2], J W Schoones *information specialist*[4], A Sedrakyan *associate professor*[1 3]

Most innovative orthopedic devices did not achieve expected improvements

ICOR | International Consortium of Orthopaedic Registries

Started May 9-10, 2011 Meeting at FDA
Series of meetings in Europe and USA
2012-2013 Joint Congresses with ISAR
Major Update at AAOS 2014

American Joint Replacement Registry
Austrian Arthroplasty Register
C
H
Hospital for Special Surgery
Kaiser Permanente
Mayo Clinic
New Zealand Joint Register
OrthoCarolina
Rush University Med. Ctr. Joint Registry
ScFCOT THA Registry
Scottish Arthroplasty Project
Virginia State Registry

Australian Orthopaedic Assoc. Registry
California Joint Replacement Registry
Italian Register of Orthopaedic Implants
Massachusetts General Hospital
New England Baptist Hospital Registry
Norwegian Arthroplasty Register
Portuguese Arthroplasty Register
Slovakian Arthroplasty Register
Swedish Hip and Knee Registers
UMass FORCE Registry
Western Slope Study Group

>3,500,000 Patients Worldwide

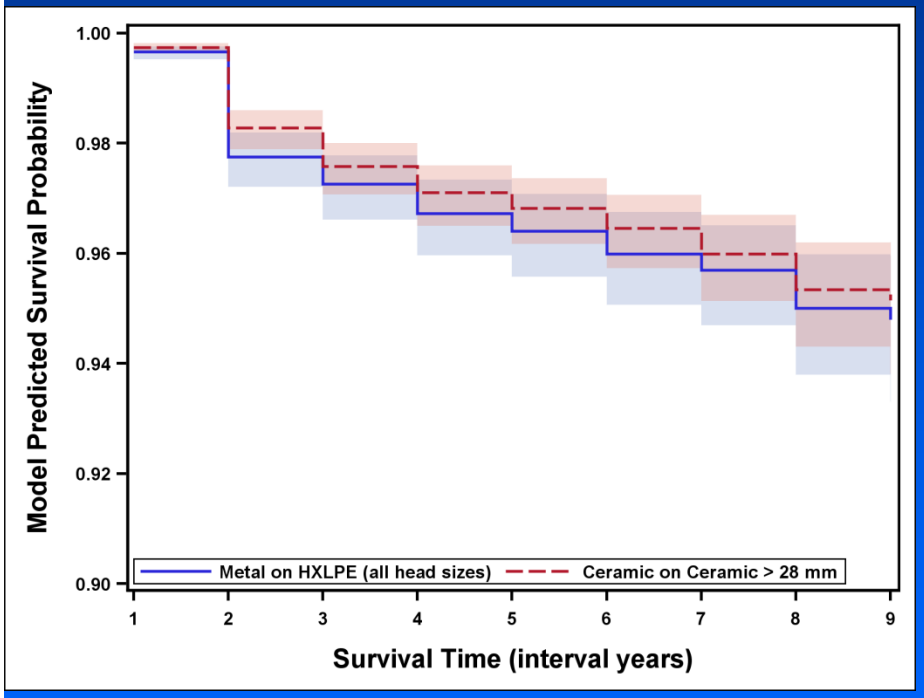
Evidence on revision from the literature

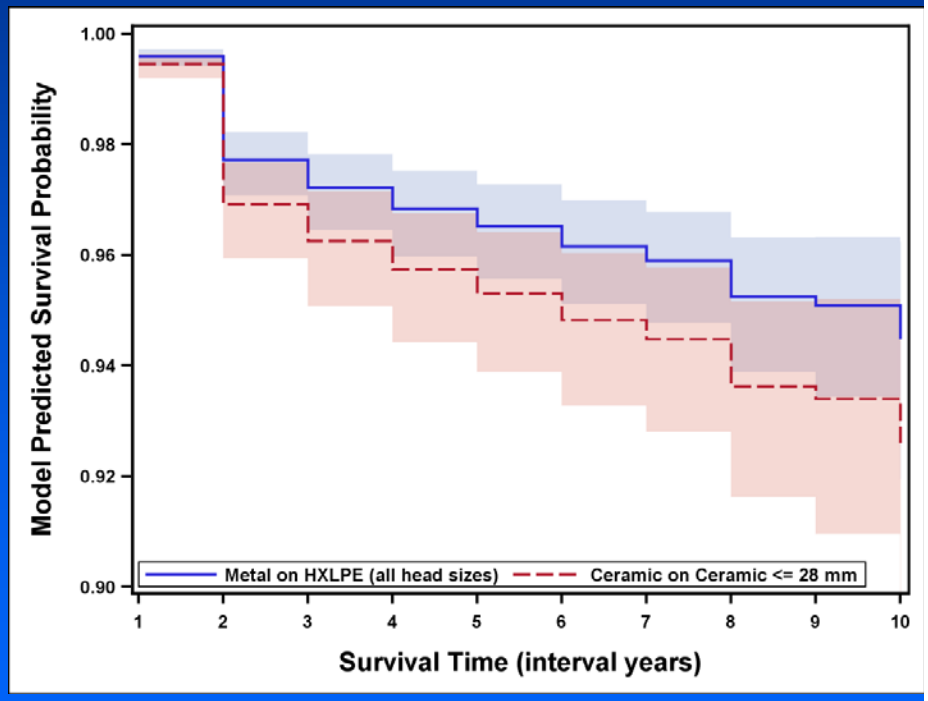
Study (year), country	Revision Surgery (reported dislocation)		
	C - C	M - P	C - P
Bascarevic et al (2010), Serbia	2/82 = 2.4% (1/82 = 1.2%)	2/75 = 2.7% (2/75 = 2.7%)	N/A
Capello et al (2008), D'Antonio et al (2005) (2 papers) USA	6/349 = 1.7%* (10/349 = 2.9%)	10/165 = 6.1%* (7/165 = 4.2%)	N/A
Capelllo et al (2008) (Addition of 4th system, Trident),	1/186 = 0.5%*	10/165 = 6.1%* (7/165 = 4.2%)	N/A
Hamilton et al (2			
Kim et al (2009			
Lewis et al (2010),			
Lombardi et al (2			
Poggie et al (20			

bearing surfaces, thus corroborating the simulator testing results. Since the time of enrollment in this study, newer, highly cross-linked polyethylene bearings [8,9] have emerged on the market, and it remains to be seen how these new polyethylene liners will compare to ceramic bearings with regard to wear and debris-induced cortical erosion.

	C-C >28 mm vs All head size Metal on HXLPE	C-C ≤ 28 mm vs All head size metal on HXLPE
Effect:	HR (95% LB-UB)	HR (95% LB-UB)
Time (reference: [0, 1) years)		
[1, 2) years	6.72 (5.07-8.92)	5.74 (4.2-7.8)
[2, 3) years	8.24 (6.16-11.01)	7.00 (5.11-9.59)
[3, 4) years	9.88 (7.37-13.24)	7.98 (5.82-10.95)
[4, 5) years	10.84 (8.08-14.55)	8.80 (6.40-12.08)
[5, 6) years	12.11 (9.00-16.30)	9.73 (7.07-13.40)
[6, 7) years	13.04 (9.64-17.63)	10.41 (7.54-14.36)
[7, 8) years	15.19 (11.12-20.75)	12.08 (8.67-16.83)
[8, 9) years	15.84 (11.29-22.21)	12.52 (8.65-18.11)
[9, 10) years	n/a	14.09 (9.10-21.81)
Female (reference: Male)	1.09 (0.93-1.28)	0.98 (0.81-1.19)
55-64 years (reference: 45-54 years)	0.80 (0.66-0.96)	0.89 (0.71-1.12)
Fixed Registry Effects[a]	-	-
Bearing Surface/Size	**n/a**	1.36 (1.09-1.68)
Bearing Surface/Size at Time [0, 2)[b]	**0.77 (0.63-0.93)**	n/a
Bearing Surface/Size at Time [2, 6)[b]	**0.88 (0.74-1.05)**	n/a
Bearing Surface/Size at Time [6, 9)[b]	**0.93 (0.77-1.12)**	n/a
Intercept Estimate (SE):	-5.69 (0.17)	-5.51 (0.19)

Ceramic on Ceramic Sizes ≤ 28 And > 28mm vs Metal on HXLPE

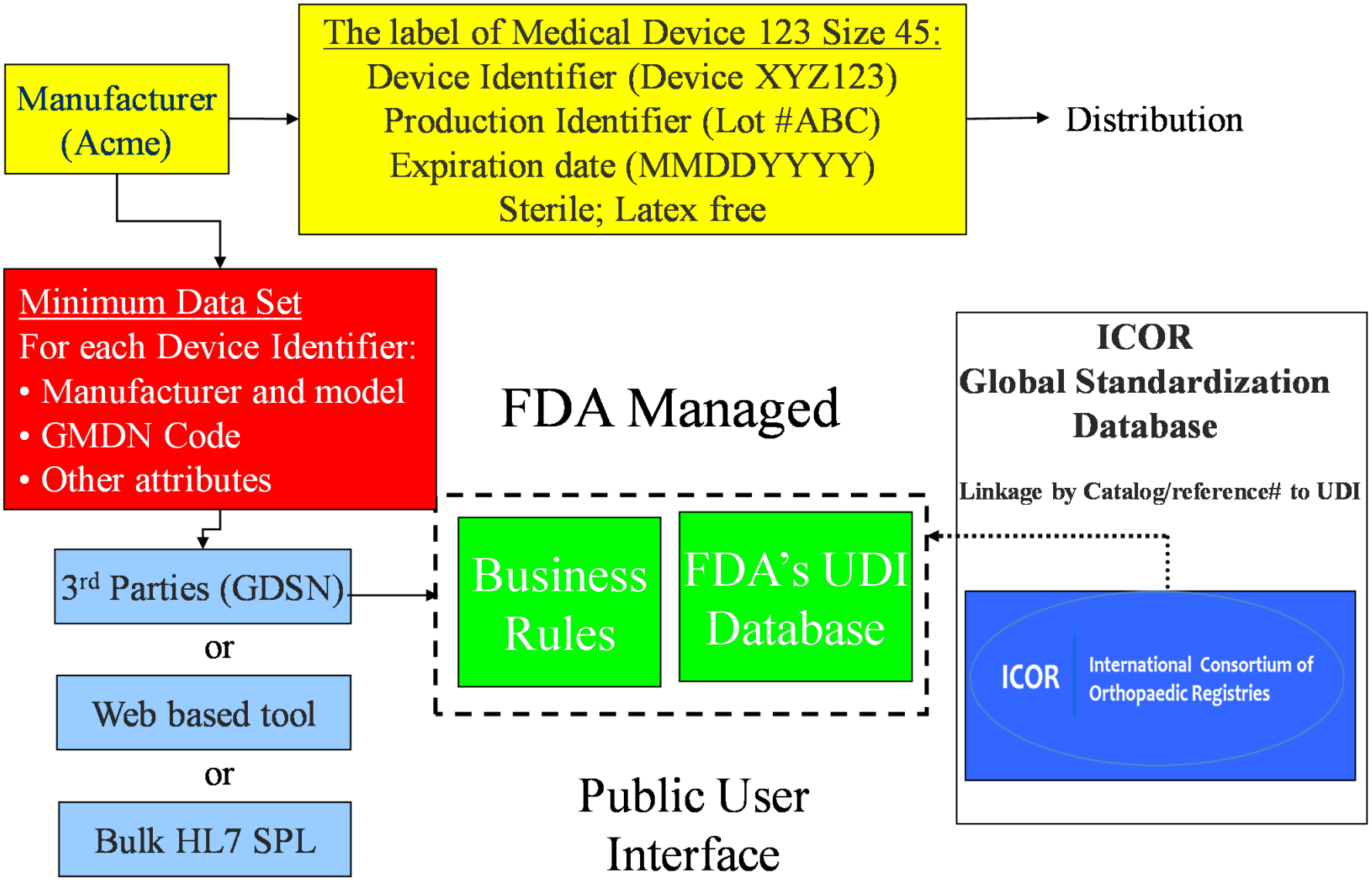




ICOR Implant Library

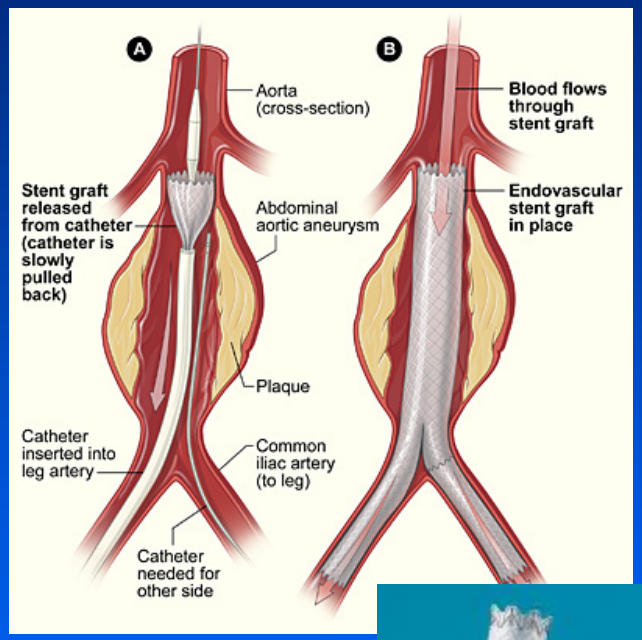
- Develop global, standardized classification system of hip and knee implantable devices and include all their clinical attributes and characteristics to advance the implementation of UDI and FDA post-market surveillance
- Key for ICOR future– more active surveillance and potentially device specific surveillance

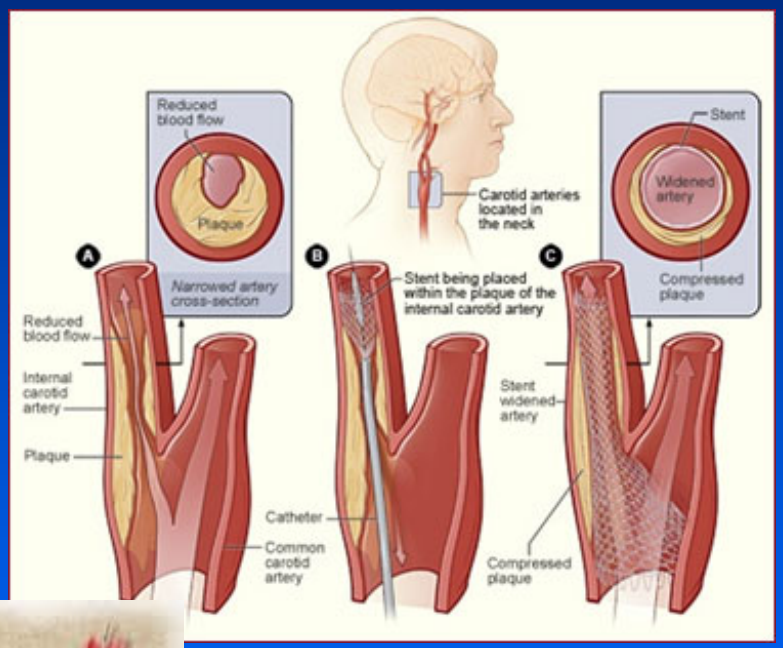
FDA's UDI Database

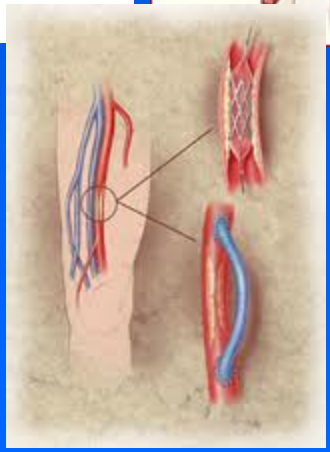


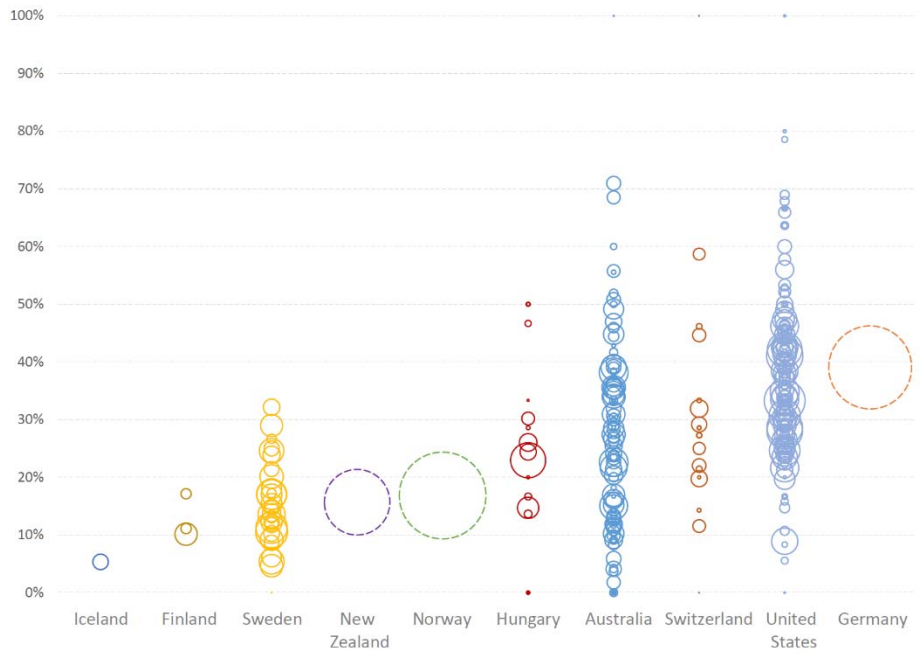
International Consortium of Vascular Registries (ICVR)

Started in late 2014








100%
90%
80%
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Iceland
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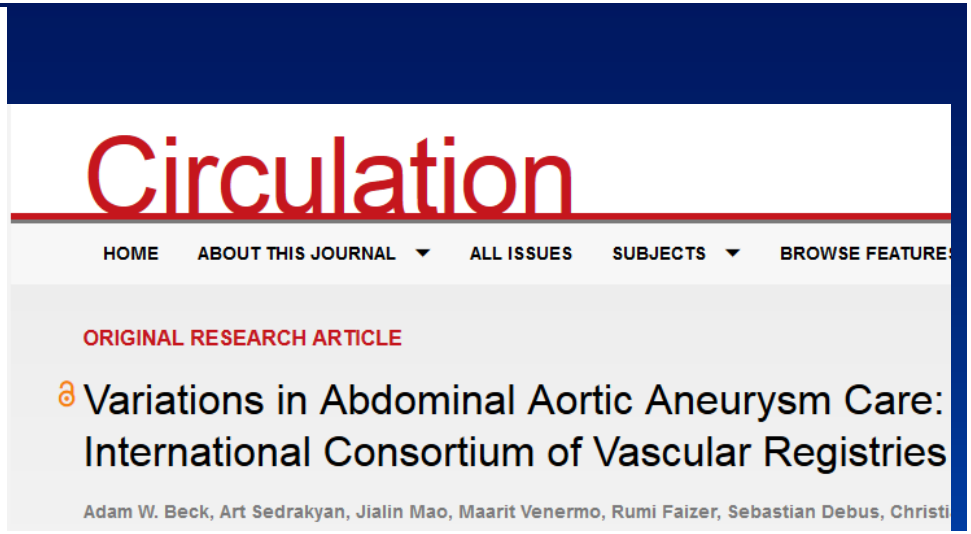
United States
Germany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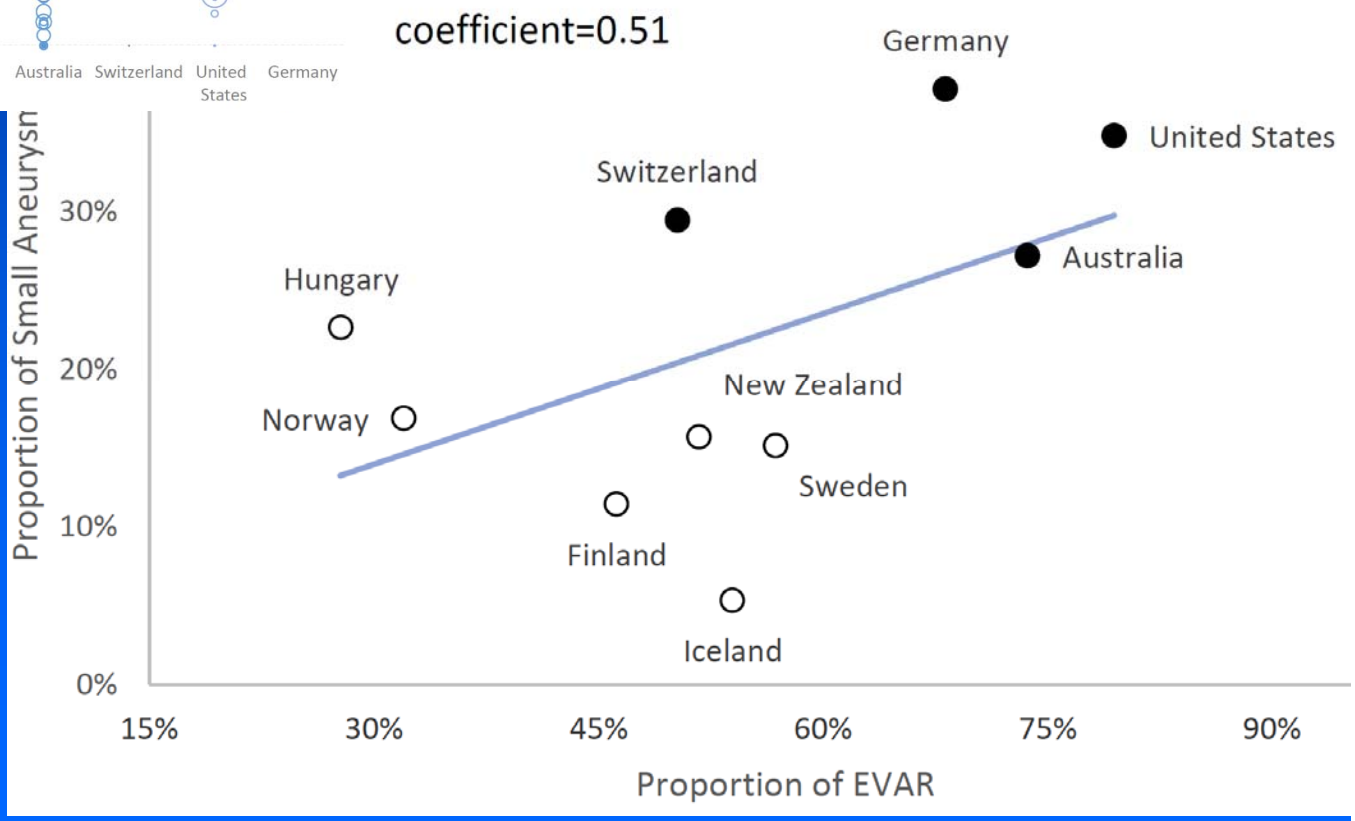
Variations in Abdominal Aortic Aneurysm Care: International Consortium of Vascular Registries
Adam W. Beck, Art Sedrakyan, Jialin Mao, Maarit Venermo, Rumi Faizer, Sebastian Debus, Christi


coefficient=0.51
Germany
United States
Switzerland
Australia
Hungary
New Zealand
Norway
Sweden
Finland
Iceland
Proportion of Small Aneurysm
30%
20%
10%
0%
15%
30%
45%
60%
75%
90%
Proportion of EVAR

COORDINATED REGSITRY NETWORK (CRN) SOLUTIONS IN OTHROPEDIC & VASCULAR AREAS WOMEN'S HEALTH DEVICES (NEW)

- Our focus is to provide timely information on performance of specific medical devices for decision making by patients, physicians, regulators and all other stakeholders
- Approach is to facilitate and/or leverage national investments in registries and other relevant data systems (dual purposing) to create '*National Medical Device Evaluation System on a fairly immediate basis, greatly minimizing the cost or development resources needed*'

CRN Is Realistic

Having few national registries, and none collecting detailed device information we need to integrate relevant data

- Major ‘Quality and safety’ registries initiated by professional societies, states, healthcare systems, NIH/AHRQ, other
- CMS claims including Part A,B,C,D
- Commercial claims
- PCORI CDRNs
- All payer State databases
- Comprehensive EHRs

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ICOR-USA Collaboration

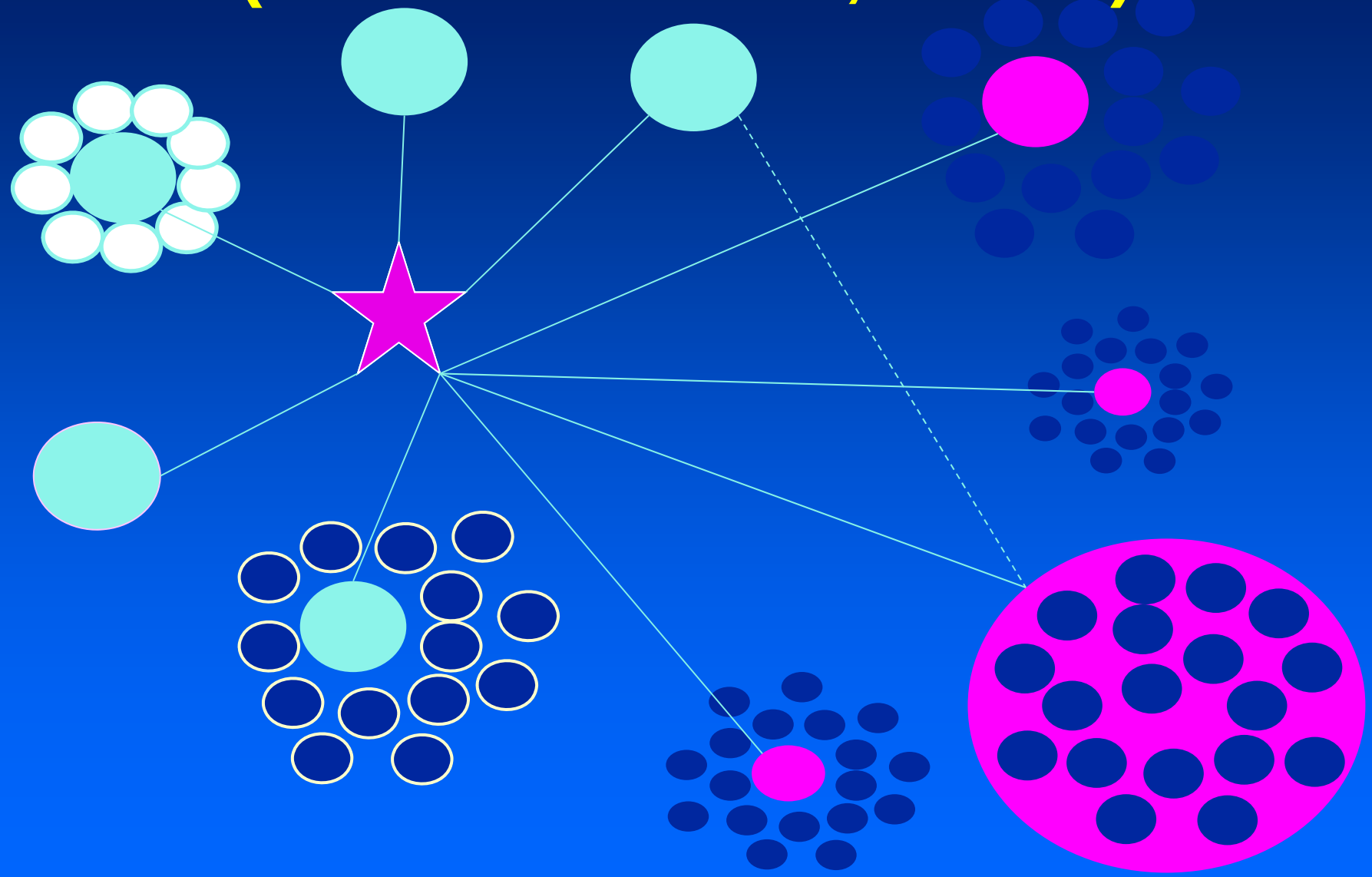
The International Consortium of Orthopedic Registries' USA Collaboration (ICOR-USA) aims to develop a US national device surveillance network in the orthopedic device space. ICOR-USA is a collaborative effort between the FDA's MDEpiNet-Weill Cornell Medicine Science and Infrastructure Center, and orthopedic registries such as the American Joint Replacement Registry, Kaiser Permanente's Total Joint Replacement Registry, the FORCE-TJR project, and HealthEast.

The FDA's new post-market surveillance vision highlights the importance of national registries and linkages with detailed datasets such as billing or administrative claims data and other routinely collected electronic data for the creation of a national system for post-market surveillance. Total joint replacement is the fastest growing elective device based surgery in the nation, if not in the world, with over 1.2 million hip and knee replacements performed annually in the U.S. With the aging of the baby boomer generation, higher rates of osteoarthritis diagnoses, innovative treatment options, and the growing demand for improved mobility and quality of life, procedure volumes are projected to reach 3 million annually in the next two decades. The performance of thousands of hip and knee devices is the most critical device safety issue in the U.S. today.

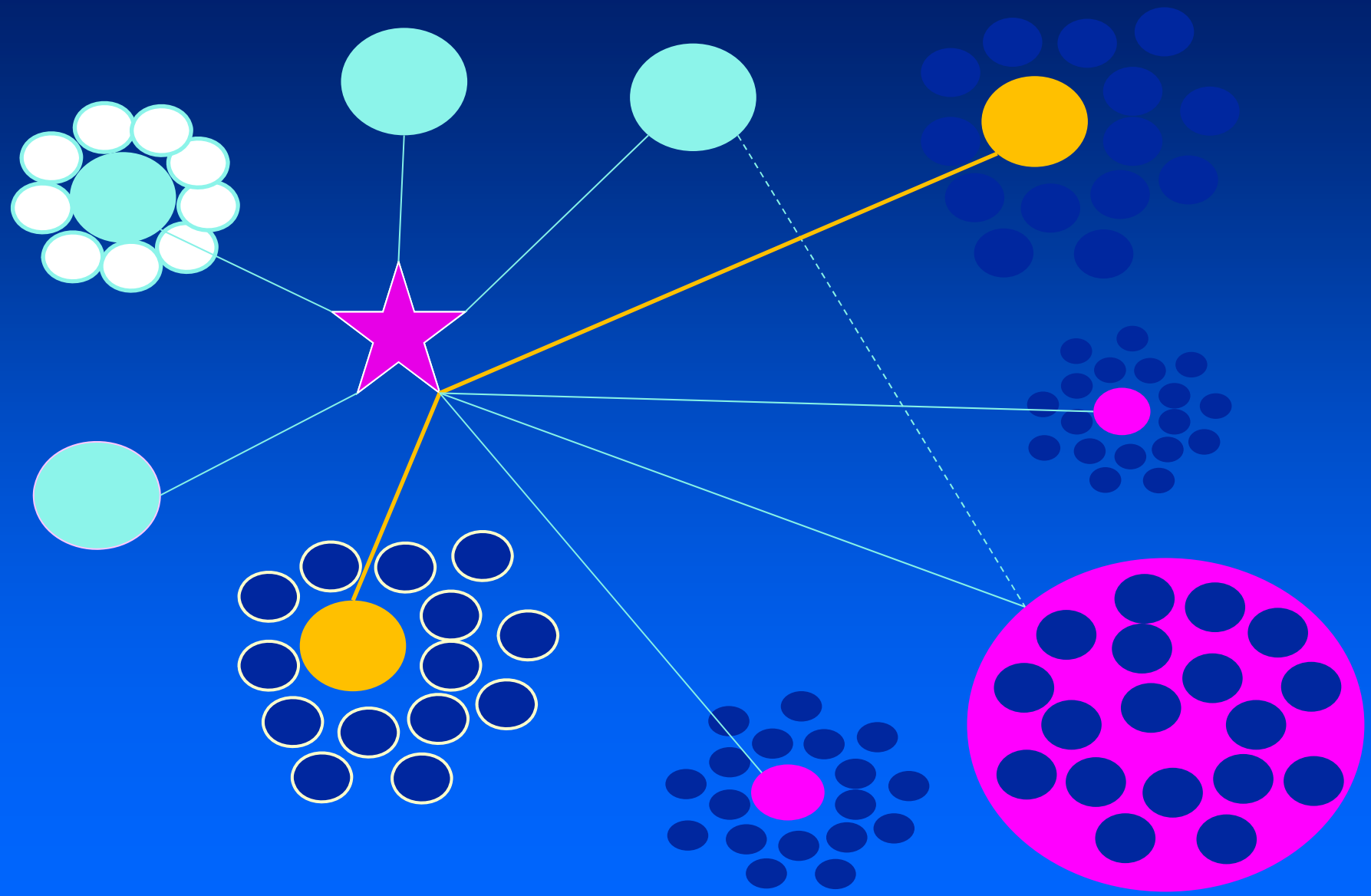
Major evidence gaps in device performance exist and, through this project, we will capitalize on a novel partnership within the FDA's Medical Device Epidemiology Network (MDEpiNet) to build a national infrastructure and fill the gaps in evidence. Our initiative aims to bring together registries in a systematic way and obtain longer, more complete patient follow-up via data linkages. Our network will be a resource to address the safety and effectiveness of new devices as they enter routine usage. Using this data network, researchers will be able to conduct comparative effectiveness studies within a short period after their market entry. Linkages between registries and state/national claims datasets will also significantly benefit registry efforts, including validation of complications, increased follow-up rate, ability for risk adjustment, and increased information about patient characteristics. This in turn will allow the registries to better serve their contributing hospitals by providing more detailed, useful reports.

By harmonizing and linking clinical registry information from diverse registries in the orthopedic setting, we aim to share knowledge about best practices for data collection, linkages with claims and other data systems, analytics, and dissemination. Moreover, the collaboration and demonstration of the value of registries will strengthen support from stakeholders. The consortium can serve as a basis for fulfillment of pre- and post-approval requirements related to orthopedic devices.

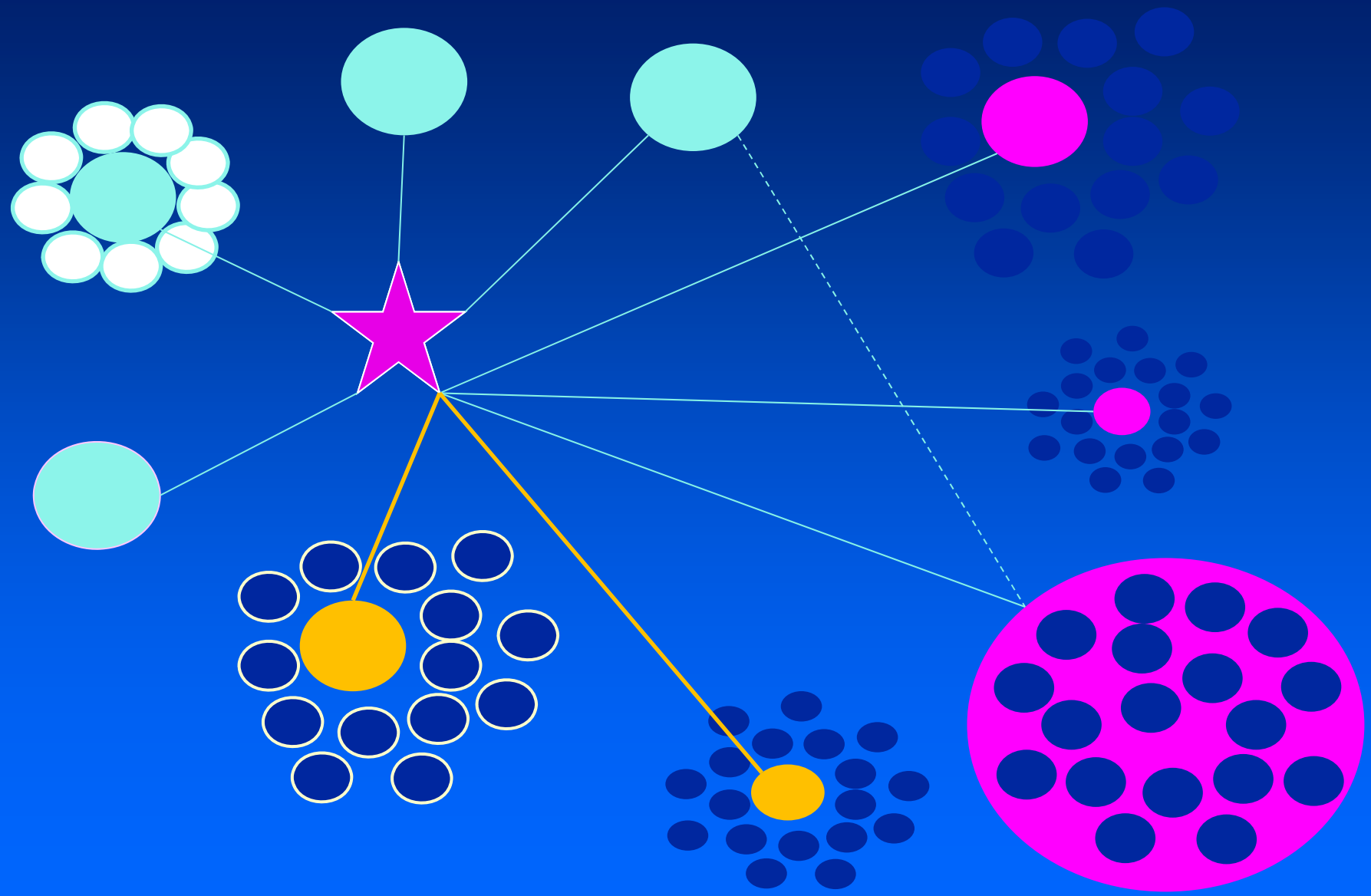
CRN in Orthopedics
(Co-PI Liz Paxton, Kaiser)



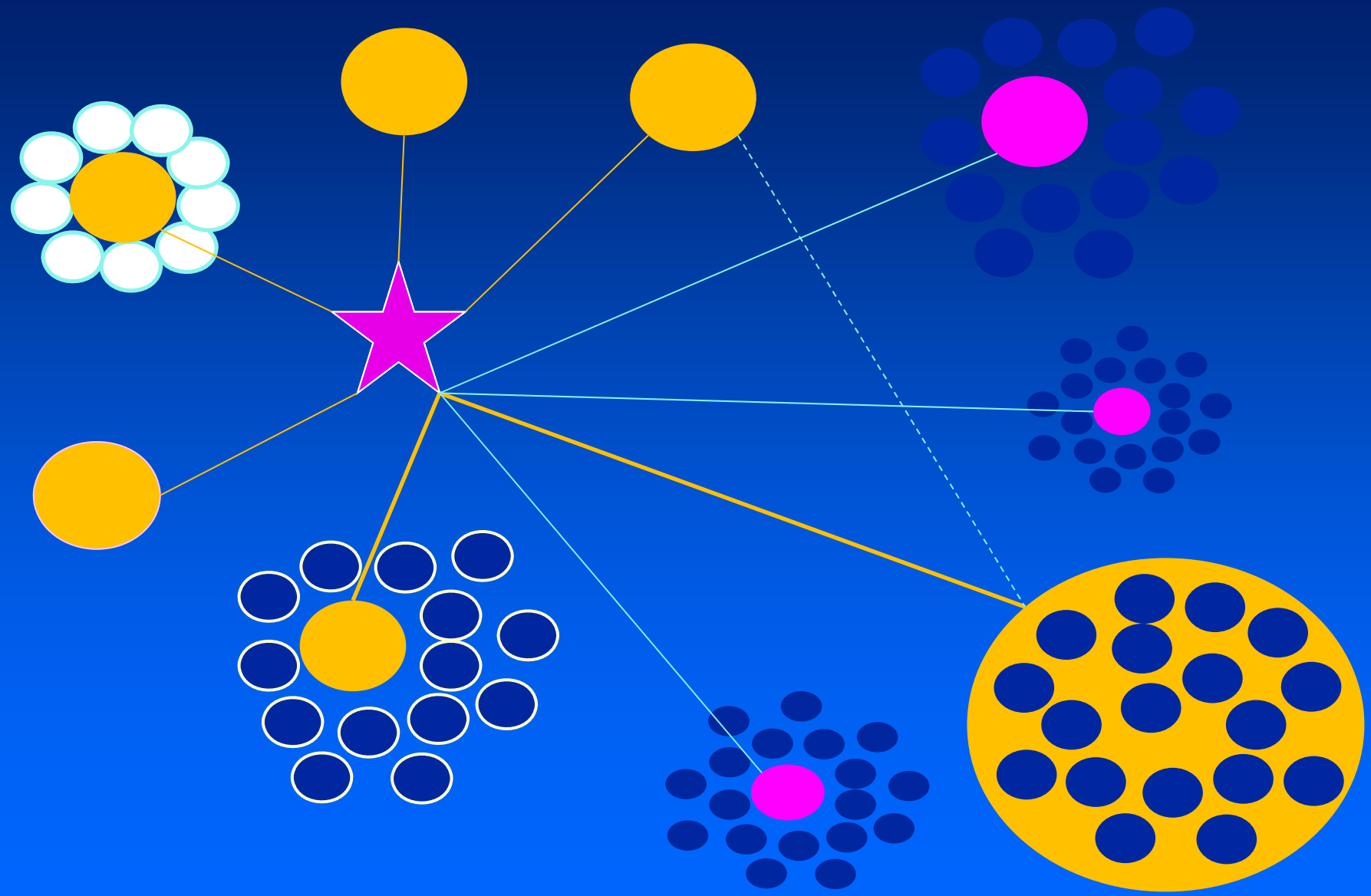
CRN in Orthopedics



CRN in Orthopedics



CRN in Orthopedics



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VISION in USA

The Vascular Implant Surveillance and Interventional Outcomes Network (VISION) Initiative aims to develop a US national device surveillance network in the vascular device space. VISION is a collaborative effort between the FDA's MDEpiNet-Weill Cornell Medicine Science and Infrastructure Center, and vascular registries such as the Vascular Quality Initiative and the NYC Coordinated Data Registry Network.

The FDA's new post-market surveillance vision highlights the importance of national registries and linkages with detailed datasets such as billing or administrative claims data and other routinely collected electronic data for the creation of a national system for post-market surveillance. Vascular implants are of particular importance, as vascular disease is a common, progressively debilitating disease with a high prevalence in older Americans, and vascular devices are used in millions of Americans annually.

Major evidence gaps in device performance exist and, through this project, we will capitalize on a novel partnership within the FDA's Medical Device Epidemiology Network (MDEpiNet) to build a national infrastructure and fill the gaps in evidence. Our initiative aims to bring together registries in a systematic way and obtain longer, more complete patient follow-up via data linkages. Our network will be a resource to address the safety and effectiveness of new devices as they enter routine usage. Using this data network, researchers will be able to conduct comparative effectiveness studies within a short period after their market entry. Linkages between registries and state/national claims datasets will also significantly benefit registry efforts, including validation of complications, increased follow-up rate, ability for risk adjustment, and increased information about patient characteristics. This in turn will allow the registries to better serve their contributing hospitals by providing more detailed, useful reports.

By harmonizing and linking clinical registry information from diverse registries in the vascular setting, we aim to share knowledge about best practices for data collection, linkages with claims and other data systems, analytics, and dissemination. Moreover, the collaboration and demonstration of the value of registries will strengthen support from stakeholders. The consortium can serve as a basis for fulfillment of pre and post-approval requirements related to vascular devices.

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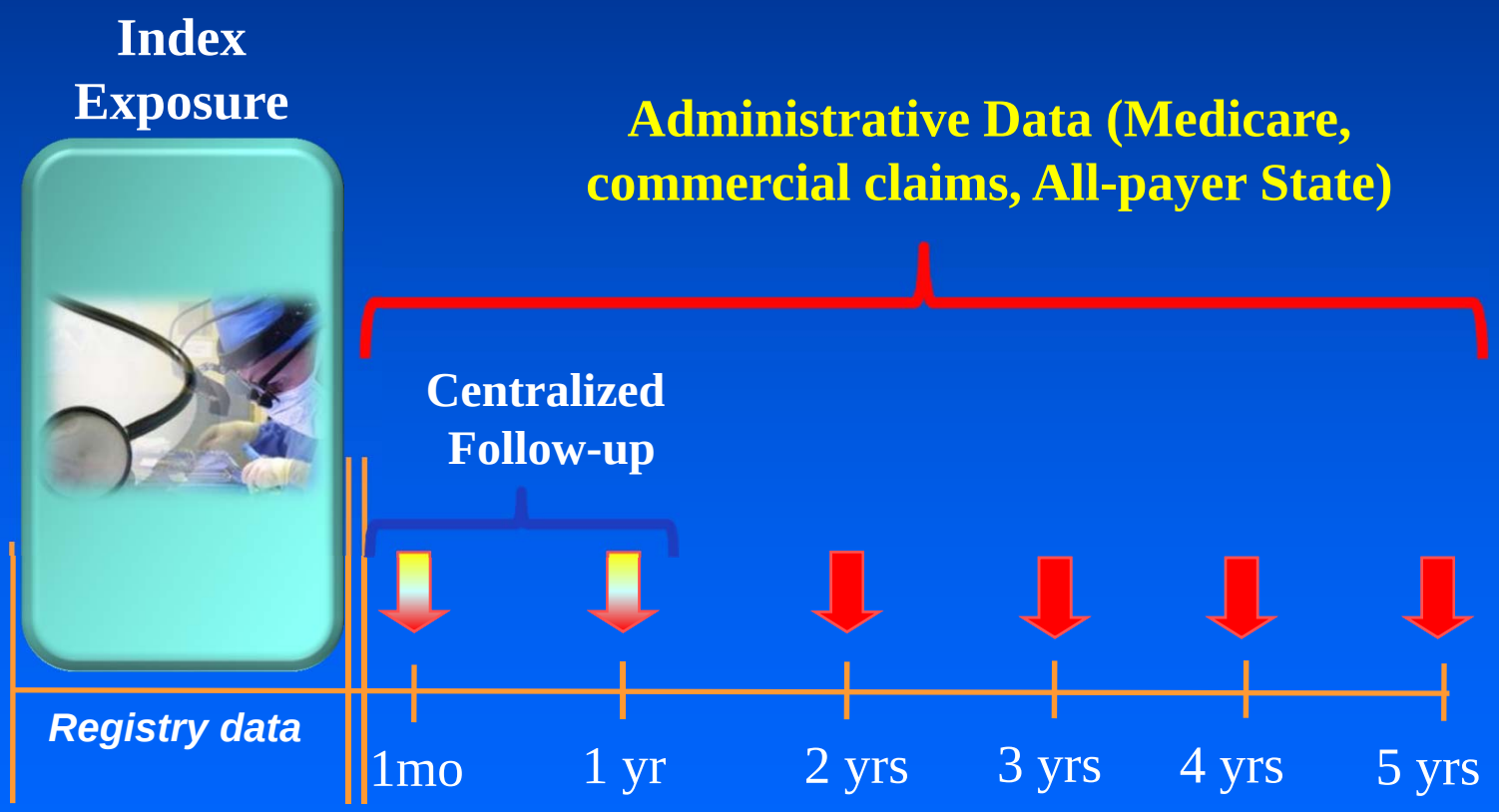
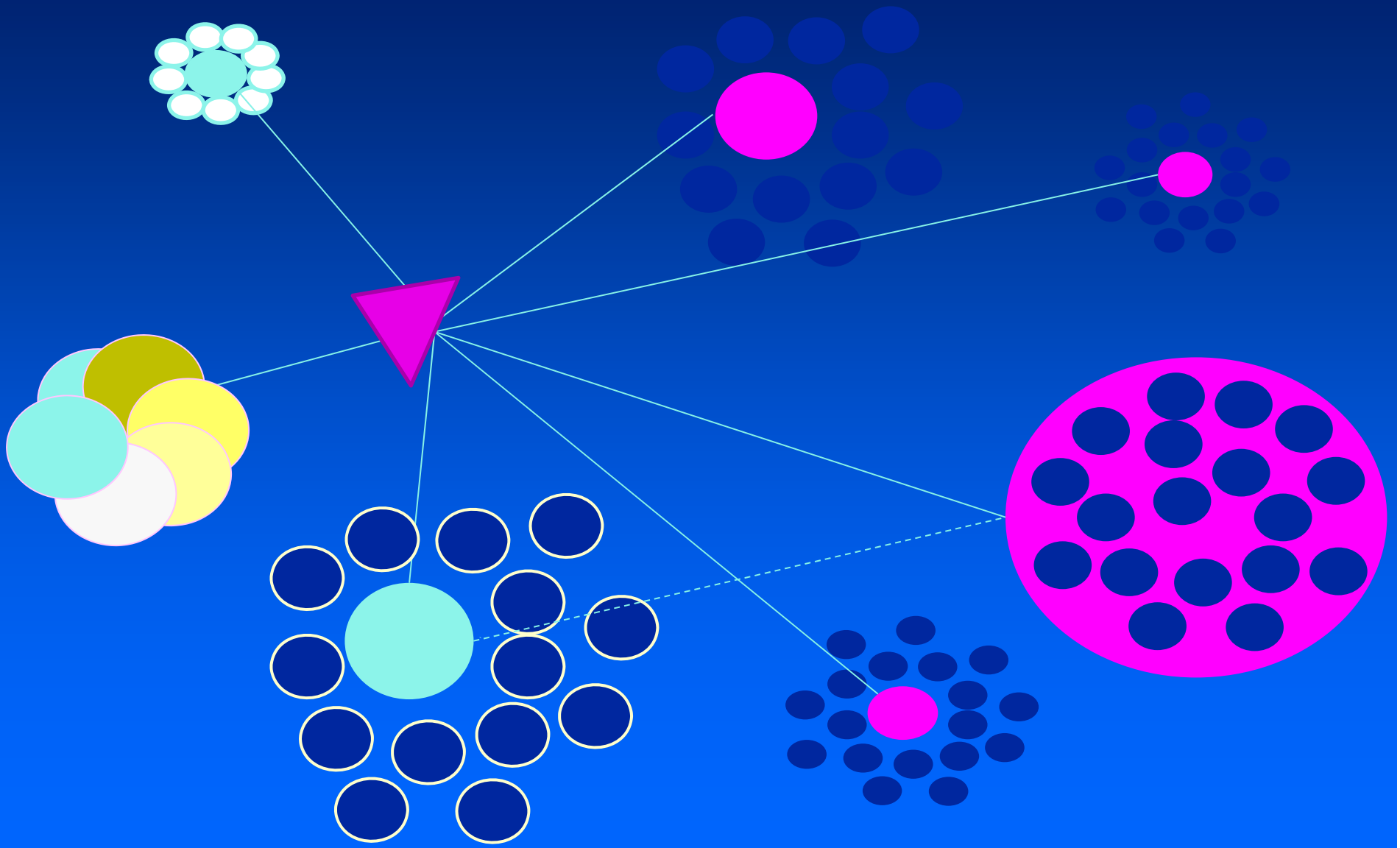
Vascular CRN
(Co-PI, Phil Goodney, VQI)



Building Vascular CRN



Key Points for Discussion

- Even with optimistic expectations about registry and related data maturity our efforts should be scaled up to create appropriately-targeted CRNs that are powerful enough to address particular device-related questions (e.g. outlier performance)
- For effective CRN seamless access to key national data sources must be achieved and stakeholder alignment and support is critical
  - The process has to be inexpensive and not burdensome to justify data quality sacrifices made compared to direct data collection
- Sufficient device and clinical outcome data will always be a challenge and we have be able to make decisions based on CRN data

Claims as Adjunct System/Model For Infrastructure Investment Examples

thebmj RESEARCH

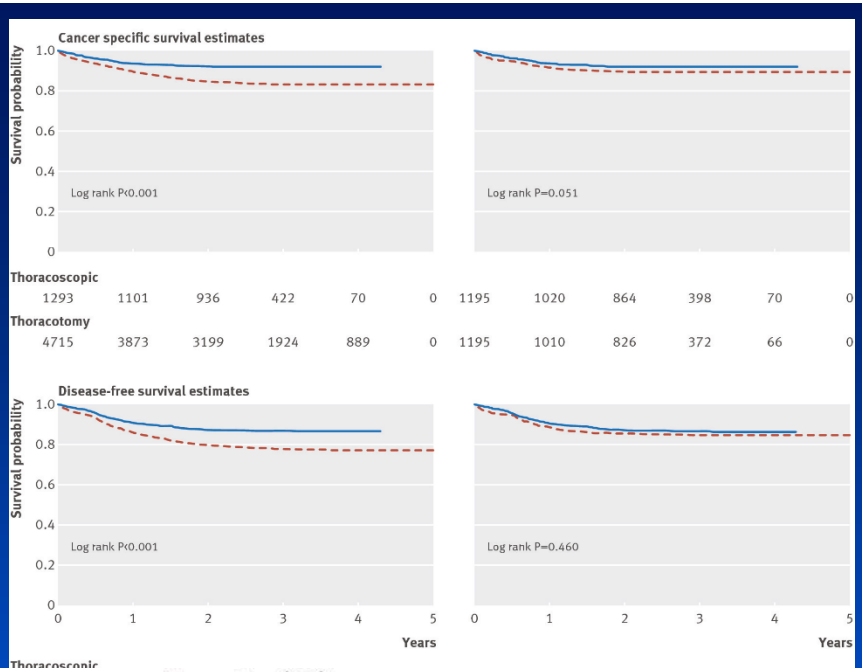
BMJ 2014;349:g5575 doi: 10.1136/bmj.g5575 (Published 2 October 2014) Page 1 of 11

Long term survival with thoracoscopic versus open lobectomy: propensity matched comparative analysis using SEER-Medicare database

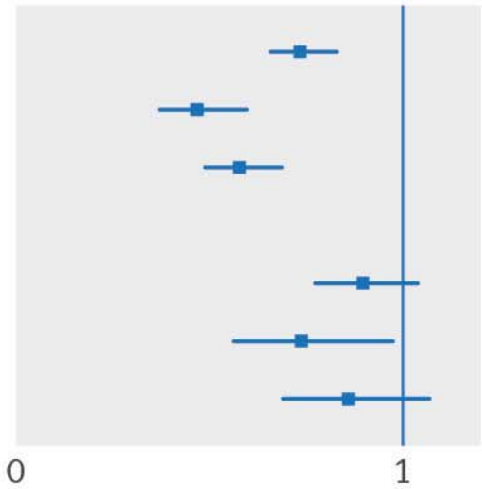
Subroto Paul *associate professor*[1 2], Abby J Isaacs *senior analyst*[1], Tom Treasure *professor*[3], Nasser K Altorki *professor*[2], Art Sedrakyan *associate professor and director*[1 2]

In-hospital outcomes	Propensity matched cohort		
	Thoracoscopy (n=1195)	Thoracotomy (n=1195)	P value
Mean (SD) nodes examined	19.9 (27.5)	17.6 (26)	0.0327
Median (interquartile range) nodes examined	10 (5-18)	9 (5-15)	0.0004
≥12 nodes examined, No (%)	398/1072 (37.1)	317/1090 (29.1)	<0.0001
Mean (SD) length of stay	6.6 (6)	8.7 (6.6)	<0.0001
Median (interquartile range) length of stay	5 (3-8)	7 (5-10)	<0.0001
In-hospital mortality, No (%)	25 (2.1)	43 (3.6)	0.0290
Complications, No (%):			
Arrhythmia	229 (19.2)	265 (22.2)	0.0690
Pneumonia	74 (6.2)	100 (8.4)	0.0423
Atelectasis	125 (10.5)	176 (14.7)	0.0013
Ventilation	32 (2.7)	48 (4.0)	0.07
Sepsis	16 (1.3)	32 (2.7)	0.0209

No significant differences werothorax, pulmonary edema, empyema, renal failure, accidente puncture, or bleeding.



	Events (%)			
	Thoracoscopy	Thoracotomy	Hazard ratio (95% CI)	Hazard ratio (95% CI)
All patients				
Overall survival	357 (27.6)	1849 (39.2)		0.74 (0.66 to 0.83)
Cancer specific survival	96 (7.4)	720 (15.3)		0.47 (0.37 to 0.60)
Disease-free survival	159 (12.3)	965 (20.5)		0.58 (0.49 to 0.69)
Propensity matched cohort				
Overall survival	339 (28.3)	371 (31.1)		0.90 (0.78 to 1.04)
Cancer specific survival	90 (7.5)	120 (10.0)		0.74 (0.56 to 0.97)
Disease-free survival	149 (12.5)	171 (14.3)		0.86 (0.69 to 1.07)



Example in Urology

RESEARCH

thebmj

Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: population based cohort study

Bilal Chughtai,[1] Jialin Mao,[2] Jessica Buck,[1] Steven Kaplan,[1] Art Sedrakyan[2]

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[2]Patient-Centered Comparative Effectiveness Program and MDEpiNet Science and Infrastructure Centre, Department of Healthcare Policy and Research at Weill Cornell Medical College and New York Presbyterian, New York, NY 10065, USA

Correspondence to: A Sedrakyan ars2013@med.cornell.edu

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ABSTRACT

OBJECTIVE

To assess the use of mesh in pelvic organ prolapse surgery, and compare short term outcomes betweer procedures using and not using mesh.

DESIGN

All inclusive, population based cohort study.

SETTING

Statewide surgical care captured in the New York Statewide Planning and Research Cooperative Syste

PARTICIPANTS

Women who underwent prolapse repair procedures New York state from 2008 to 2011.

MAIN OUTCOMES MEASURES

within 90 days (mesh 7.5% *v* no mesh 5.6%, risk ratio 1.33 (95% confidence interval 1.18 to 1.51)), compared

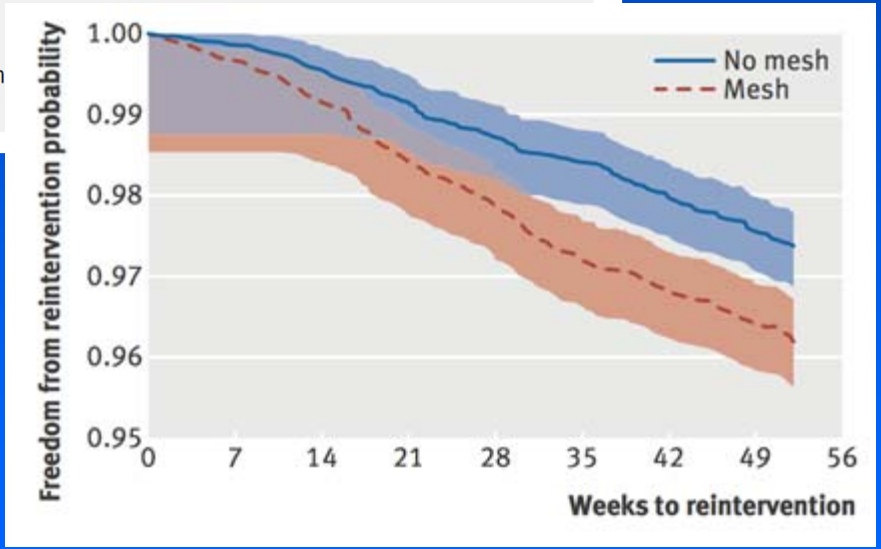
Analyses

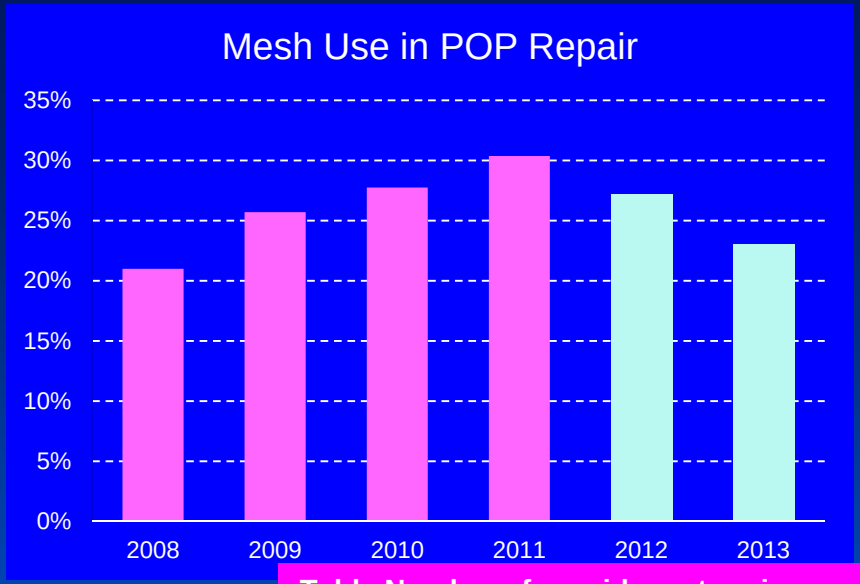
- Safety events/complications within 90 days and re-intervention within 1 year were determined before and after propensity score matching
- Propensity score matching was used to adjust for differences in baseline characteristics between mesh and no-mesh groups
- Kaplan-Meier curves were constructed to determine freedom from re-intervention within 1 year following procedure. Cox proportional hazard model was used to assess the differences in risks of re-intervention between groups

Table 2 | 90 day safety events and one year follow-up of reintervention following POP surgery with or without mesh, placed between 2008 and 2011 in New York state

	Before propensity score matching			After propensity score matching*		
	Mesh (n=7338)	No mesh (n=20 653)	Risk ratio (95% CI)	Mesh (n=7295)	No mesh (n=7295)	Risk ratio (95% CI)
90 day safety						
Medical complications	186 (2.5)	451 (2.2)	1.16 (0.98 to 1.37)	185 (2.5)	173 (2.4)	1.07 (0.87 to 1.31)
Bleeding	110 (1.5)	316 (1.5)	0.98 (0.79 to 1.22)	110 (1.5)	97 (1.3)	1.13 (0.87 to 1.49)
Urinary tract infection	249 (3.4)	662 (3.2)	1.06 (0.92 to 1.22)	247 (3.4)	229 (3.1)	1.08 (0.90 to 1.29)
Urinary retention	551 (7.5)	1106 (5.4)	1.40 (1.27 to 1.55)‡	554 (7.5)	408 (5.6)	1.33 (1.18 to 1.51)‡
Bladder injury	59 (0.8)	93 (0.5)	1.79 (1.29 to 2.47)‡	59 (0.8)	42 (0.6)	1.40 (0.95 to 2.09)
Other surgical complications	172 (2.3)	436 (2.1)	1.10 (0.93 to 1.31)	170 (2.3)	147 (2.0)	1.16 (0.93 to 1.44)
Inpatient readmission	392 (5.3)	1042 (5.0)	1.06 (0.95 to 1.19)	390 (5.3)	365 (5.0)	1.07 (0.93 to 1.23)
Emergency room readmission	633 (8.6)	1997 (9.7)	0.89 (0.82 to 0.97)	631 (8.6)	601 (8.2)	1.05 (0.94 to 1.17)
One year follow-up						
Reintervention†	241 (3.3)	419 (2.0)	1.66 (1.41 to 1.94)‡	240 (3.3)	164 (2.2)	1.47 (1.21 to 1.79)‡
Reintervention with mesh	53 (0.7)	104 (0.5)	—	53 (0.7)	42 (0.6)	—

Data are no (%) of events unless stated otherwise.
*Risk ratios and P values calculated using the stratified Mantel-Haenszel test.
†Effect measure presented is hazard ratio, P value obtained using the Cox proportional hazard m
‡P<0.05.





JAMA Internal Medicine
Formerly *Archives of Internal Medicine*

Table Number of providers stopping use of mesh or decreasing use by over 50% in 2012 and 2013 years when compared to year 2011.

	Total providers	Stopped using mesh		Mesh use decrease >50%	
		2012	*2013**	*2012*	*2013**
Overall	88	9(10.2%)	22(25.0%)	24(27.3%)	40(45.5%)
Hospital Volume					
Low	57	8(14.0%)	21(36.8%)	22(38.6%)	34(59.6%)
Medium	18	1(5.6%)	1(5.6%)	1(5.6%)	5(27.8%)
High	13	0(0.0%)	0(0.0%)	1(7.7%)	1(7.7%)
Teaching Status					
Teaching	32	1(3.1%)	4(12.5%)	4(12.5%)	11(34.4%)
Non-teaching	56	13(23.2%)	18(32.1%)	20(35.7%)	29(51.8%)

*The number of hospitals in 2013 stopping or reducing the use of mesh include those who also stopped in 2012.

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Clipping Versus Coiling

Stroke
American Heart Association | American Stroke Association

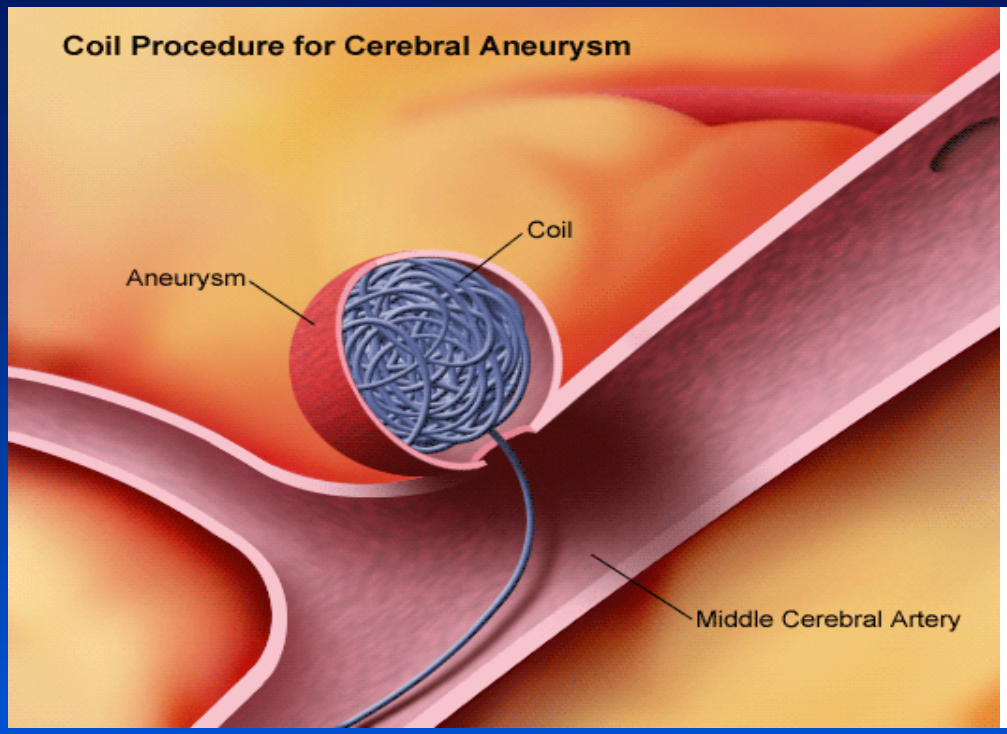
Original Contribution

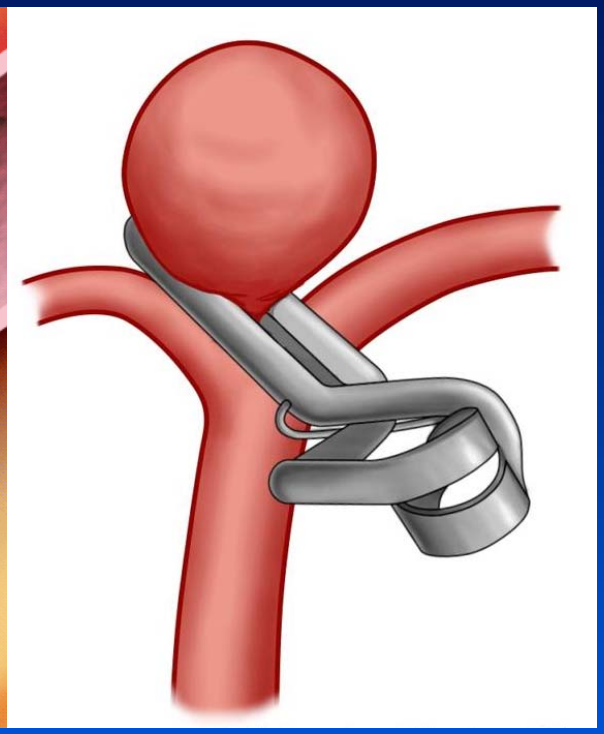
Clipping and Coiling of Unruptured Intracranial Aneurysms Among Medicare Beneficiaries, 2000 to 2010

Jessica J. Jalbert, PhD; Abby J. Isaacs, MSc; Hooman Kamel, MD; Art Sedrakyan, MD, PhD

Abstract

Background and Purpose—Endovascular coiling therapy is increasingly popular for obliteration of unruptured intracranial aneurysms, but older patients face higher procedural risks and shorter periods during which an untreated aneurysm may rupture causing subarachnoid hemorrhage (SAH). We assessed trends in clipping and coiling of unruptured intracranial aneurysms, outcomes after clipping and coiling of unruptured intracranial aneurysms, and in SAH among Medicare beneficiaries.





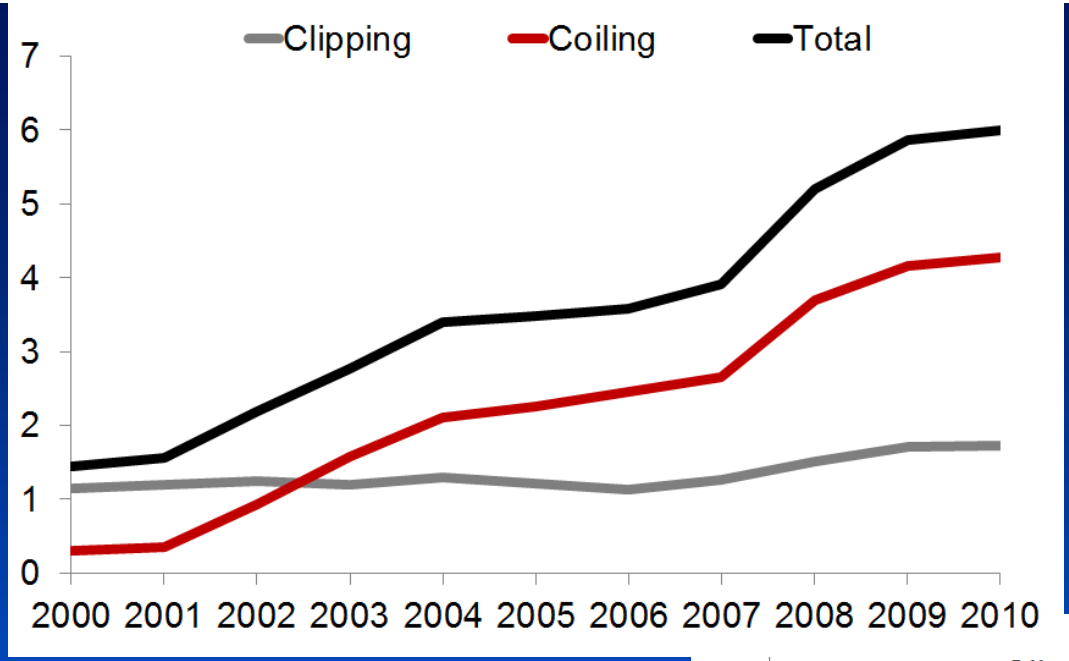
Risks of clipping/coiling must be balanced against risk of procedures

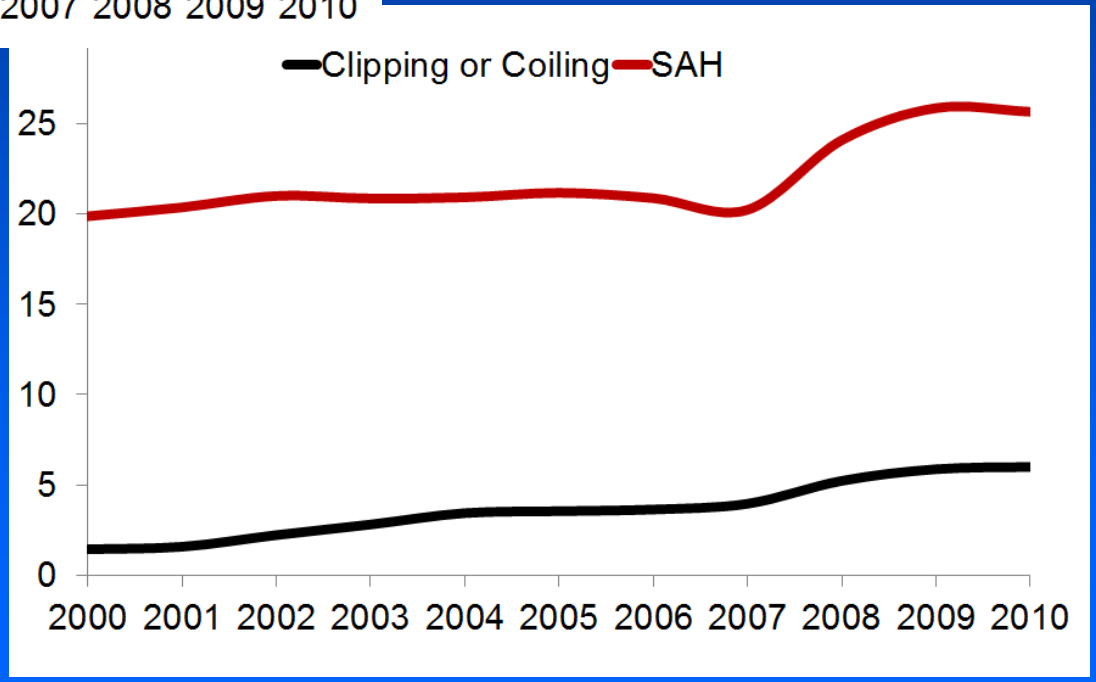
- Annual rupture risk 0.5-1.0%
- 50-80% of aneurisms do not rupture

Clipping Versus Coiling

Outcomes	2001-2003 N=1134	2004-2007 N=1539	2008-2010 N=1684	P for trend
In-hospital mortality	2.6% (2.1-3.0)	1.5% (1.1-1.9)	1.5% (1.2-1.9)	0.076
In-hospital complications	28.9% (27.6-30.3)	26.4% (25.1-27.8)	25.0% (23.7-26.3)	0.024
30-day mortality	3.2% (2.1-4.2)	1.9% (1.2-2.6)	1.6% (1.0-2.2)	0.007
30-day readmissions	18.8% (16.5-21.2)	16.6% (14.7-18.5)	14.5 (12.8-16.2)	0.003

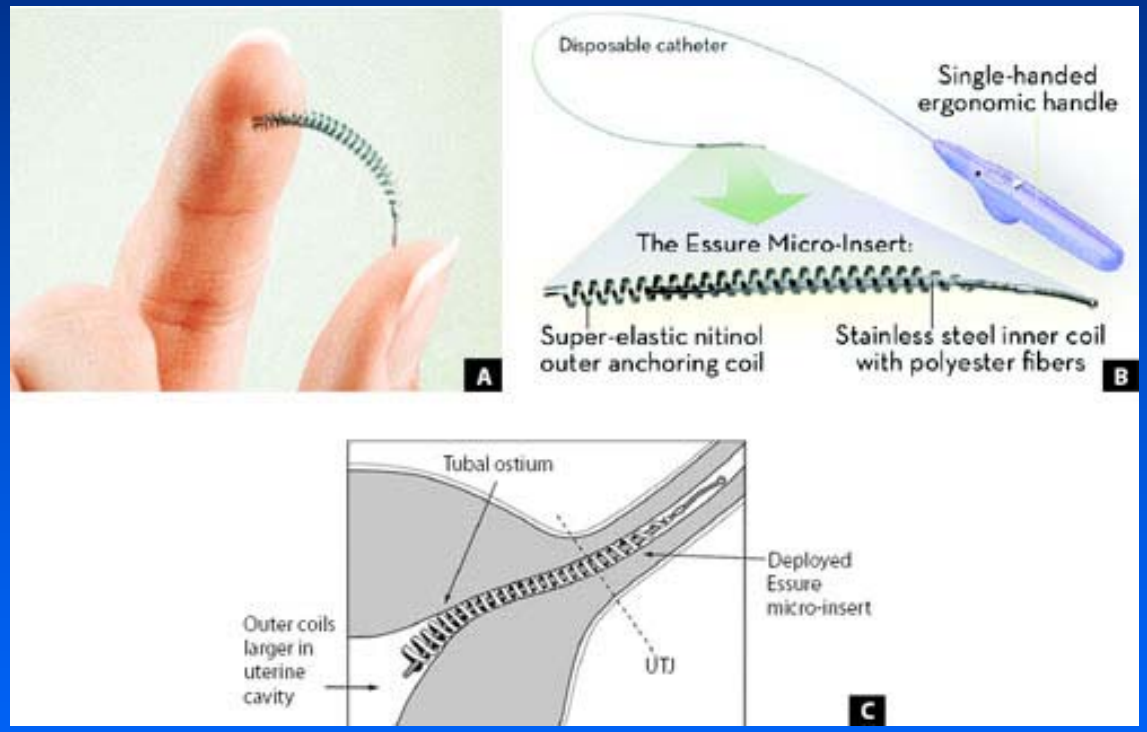
Outcomes	2001-2003 N=977	2004-2007 N=2962	2008-2010 N=4003	P for trend
In-hospital mortality	1.5% (1.3-1.8)	0.8% (0.6-1.0)	0.7% (0.5-0.9)	0.048
In-hospital complications	17.7% (16.9-18.5)	16.4% (15.6-17.2)	13.8% (13.1-14.6)	<0.001
30-day mortality	1.9% (1.1-2.8)	1.4% (1.0-1.8)	1.5% (1.1-1.8)	0.440
30-day readmissions	13.0% (10.9-15.2)	11.8% (10.6-13)	11.0% (10.0-12.0)	0.068


Clipping
Coiling
Total
7
6
5
4
3
2
1
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010


Clipping or Coiling
SAH
25
20
15
10
5
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010

Essure Warning/Labeling Change

- Essure was approved November 4, 2002 and acquired by Bayer
- **October 2013**: patient labeling updated to include risks of chronic pain and device migration
- Over 10,000 adverse events reported up to date



Outcomes in Real World

RESEARCH

OPEN ACCESS

Safety and efficacy of hysteroscopic sterilization compared with laparoscopic sterilization: an observational cohort study

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ABSTRACT

OBJECTIVE

To compare the safety and efficacy of hysteroscopic sterilization with the "Essure" device with laparoscopic sterilization in a large, all-inclusive, state cohort.

DESIGN

Population based cohort study.

SETTINGS

Outpatient interventional setting in New York State.

PARTICIPANTS

Women undergoing interval sterilization procedure, including hysteroscopic sterilization with Essure device and laparoscopic surgery, between 2005 and 2013.

higher risk of unintended pregnancy (odds ratio 0.84 (95% CI 0.63 to 1.12)) but was associated with a substantially increased risk of reoperation (odds ratio 10.16 (7.47 to 13.81)) compared with laparoscopic sterilization.

CONCLUSIONS

Patients undergoing hysteroscopic sterilization have a similar risk of unintended pregnancy but a more than 10-fold higher risk of undergoing reoperation compared with patients undergoing laparoscopic sterilization. Benefits and risks of both procedures should be discussed with patients for informed decisions making.

Use of Essure

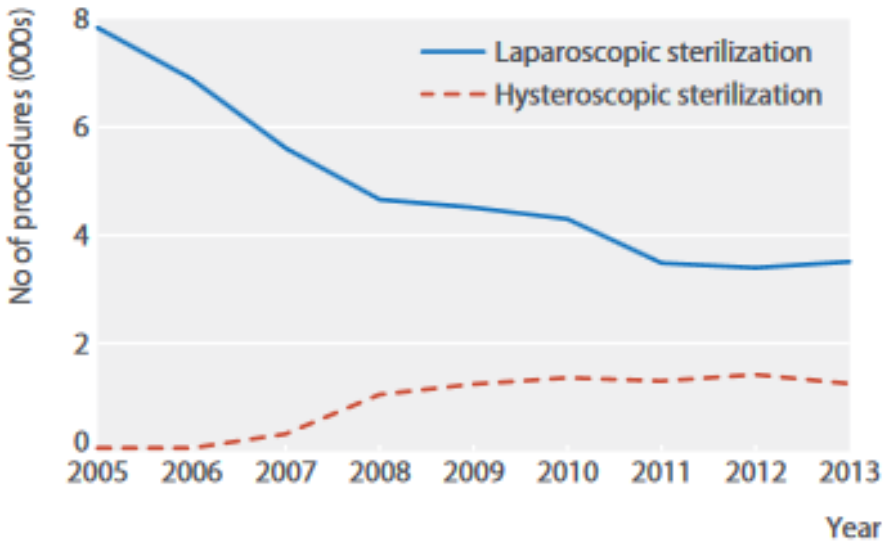
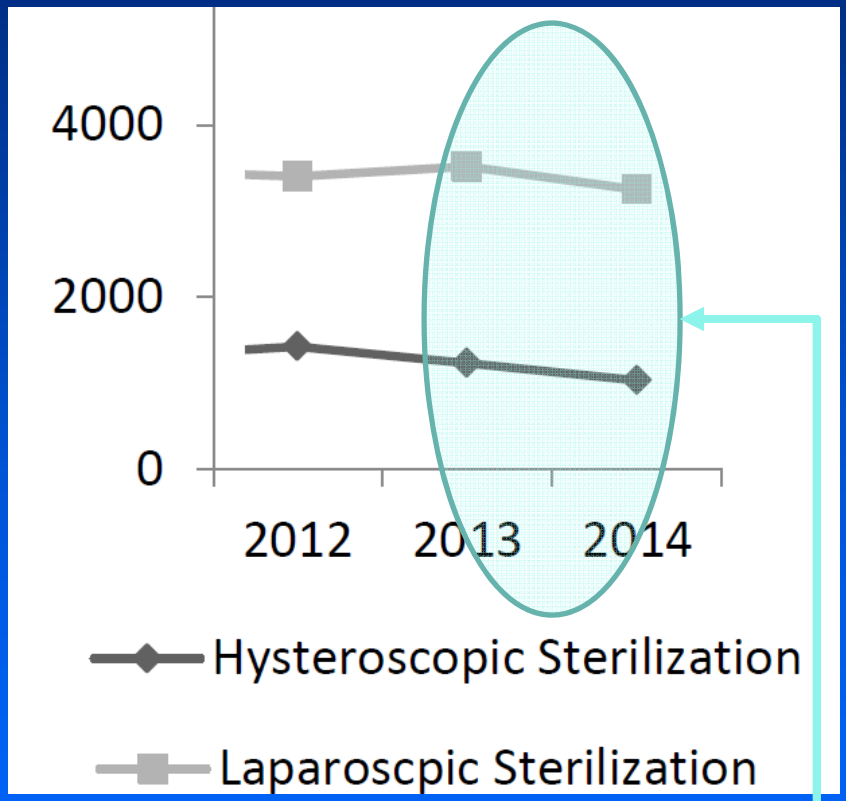


Fig 1 | Number of hysteroscopic sterilization and laparoscopic sterilization procedures between 2005 and 2013 in New York State



40% reduction in 14 months

Da Vinci Robot or Robotic Surgery Overall: Building a Registry

The Journal of Urology

Volume 197, Issue 1, January 2017, Pages 115–121

Adult Urology

Comparative Effectiveness of Cancer Control and Survival after Robot-Assisted versus Open Radical Prostatectomy

Jim C. Hu[a], Padraic O'Malley[a, g], Bilal Chughtai[a], Abby Isaacs[b], Jialin Mao[b], Jason D. Wright[c, d], Dawn Hershman[d, e, f], Art Sedrakyan[b]

Show more

- Quality Registry needed for all clinical areas of adoption with different goals (different IDEAL stages)

http://intuitivesurgical.com/company/media/images/davinci_si_images.html
http://orlive.com/karlstorznetwork1/channels/karl-storz

Focal Therapy for Prostate Cancer and HIFU: Building a Registry

Innovations in Health Care Delivery June 28, 2016

JAMA®
The Journal of the American Medical Association

High-Intensity Focused Ultrasound for Prostate Cancer

Novelty or Innovation?

Jim C. Hu, MD, MPH[1]; Aaron Laviana, MD[2]; Art Sedrakyan, MD, PhD[3]

» Author Affiliations | Article Information

JAMA. 2016;315(24):2659-2660. doi:10.1001/jama.2016.5002

A man diagnosed with prostate cancer currently has a wide spectrum of treatment choices ranging from proton beam and intensity-modulated radiation therapy to robotic-assisted radical prostatectomy and active surveillance.[1] The latest medical device, high-intensity focused ultrasound (HIFU), has some appealing features for patients and urologists. Technically, it is relatively straightforward to insert a transrectal HIFU probe that generates ultrasound waves that thermally ablate prostate tissue. HIFU may be used for focal therapy or for partial or total prostate gland ablation. Partial gland ablation is used to treat biopsy-positive areas, suspicious areas on multiparametric magnetic resonance imaging (mp-MRI), or both. However, HIFU failed to gain US Food and Drug Administration (FDA) approval twice in the past 3 years for prostate cancer indication because of the inabil-

Immediate Future for our Team

- Closer collaboration with **NEST** and all stakeholders: manufacturers, societies, registry umbrella organizations
- Implement more active surveillance platform building on successes up to date and trust established with partners
- Facilitate registry cohesion
- Assist FDA with pre-post market balance initiative and national/international post-market science plan
- Serve as scalable network for other devices

Thank You!

Email: ars2013@med.cornell.edu