**International Consortium of Vascular Registries**

- A collaboration of national vascular registries that share data to improve vascular health care.
- ESVS Vascunet + SVS VQI + Others
- Focus:
  - Improve the safety and effectiveness of vascular devices
  - Define optimal patient and pathology selection for devices
  - Identify potential device problems as soon as possible
- Described in EJVES + JVS Special Communications 2017:

  www.icvr-initiative.org

**ICVR Contributing Registries - Representatives**

- Australian Vascular Audit
  - Barry Beiles, MB, BCh
- Danish Vascular Registry
  - Nikolaj Eldrup, MD, PhD
- Helsinki Vascular Registry
  - Maarit Venermo, MD, PhD
- German Vascular Registry
  - Sebastian Debus, MD
- Hungarian Vascular Registry
  - Gabor Menyhei, MD, PhD
- Icelandic Vascular Registry
  - Elin Laxdal, MD
- Italian Vascular Registry
  - Carlos Setacci, MD
- New Zealand Vascular Audit
  - Ian Thomson, MBBS
- Norwegian Vascular Registry
  - Martin Aamdal, MD
- Swedish Vascular Registry
  - Kevin Mari, MD, PhD
- Swiss Vascular Registry
  - Georg Heiber, MD
- United States, SVS VQI
  - Adam Beck, MD
- United Kingdom Vascular Registry
  - Jon Boyle, MD

**ICVR Participating Registries - Representatives**

- Dutch Vascular Registry
  - Jaap Hamming, MD, PhD
- Japanese Vascular Registry
  - Masaki Kato, MD
- Spanish Vascular Registry
  - Cristina Lopez Espada, MD, PhD
- United Kingdom Vascular Registry
  - Jon Boyle, MD

**IVCR Structure**

- Governance: leadership board with one representative from each national registry; co-chairs selected by Vascunet and VQI
- Analytic Center: MDEpiNet Science and Infrastructure Center at Weil Cornell University, New York City
  - Co-Chairs: Maarit Venermo MD and Jack Cronenwett MD
  - Director, Analytic Center: Art Sedrakyan MD, PhD
- Funding: FDA-MDEpiNet for Analytic Center, Logistics
- Methods: Semi-annual workshops, with work groups for specific projects; submission of data by each national registry for analysis at the Cornell Analytic Center

**ICVR Semi-Annual Meetings**

- Nov, 2014: New York City
- May, 2015: Uppsala, Sweden
- Nov, 2015: New York City
- May, 2016: Hamburg, Germany
- Nov, 2016: New York City
- May, 2017: Helsinki, Finland
- Today: New York City

Representatives of:
- National Registries
- Regulators
- Industry
ICVR Initial Projects
Variation in patient selection and treatment of AAA and carotid disease

International Consortium of Vascular Registries (ICVR)
- 12 National registries submitted blinded data to ICVR Analytic Center at Cornell for statistical analysis
- Compared variation between countries, and between centers within countries
- Compared practice variation against:
  - Vascular society practice guidelines
  - National health payment systems

ICVR Initial Projects
Variation in AAA and carotid disease

- 51,153 procedures, 11 countries, 2010-2013
- 86% Intact AAA, EVAR used in 65% overall
- Variation in EVAR use for Intact AAA (vs. open repair):

<table>
<thead>
<tr>
<th>Country</th>
<th>Patients</th>
<th>% EVAR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hungary</td>
<td>640</td>
<td>23% (14%-32%)</td>
</tr>
<tr>
<td>Norway</td>
<td>2065</td>
<td>26% (15%-34%)</td>
</tr>
<tr>
<td>Denmark</td>
<td>2239</td>
<td>33% (10%-53%)</td>
</tr>
<tr>
<td>Finland</td>
<td>481</td>
<td>23% (0%-50%)</td>
</tr>
<tr>
<td>Switzerland</td>
<td>2174</td>
<td>50% (30%-74%)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>1214</td>
<td>31% (24%-38%)</td>
</tr>
<tr>
<td>Iceland</td>
<td>76</td>
<td>53% (21%-65%)</td>
</tr>
<tr>
<td>Sweden</td>
<td>804</td>
<td>48% (21%-66%)</td>
</tr>
<tr>
<td>Germany</td>
<td>15172</td>
<td>68% (64%-71%)</td>
</tr>
<tr>
<td>Australia</td>
<td>1026</td>
<td>73% (67%-77%)</td>
</tr>
<tr>
<td>United States</td>
<td>1812</td>
<td>80% (75%-84%)</td>
</tr>
</tbody>
</table>

- 80% vs 28%


ICVR Initial Projects
Variation in AAA and carotid disease

International Variation in AAA Repair
- 51,153 procedures, 11 countries, 2010-2013
- 14% Ruptured AAA, EVAR used in 30% overall
- Variation in EVAR use for Ruptured AAA (vs. open repair):

<table>
<thead>
<tr>
<th>Country</th>
<th>Patients</th>
<th>% EVAR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>706</td>
<td>3% (1%-6%)</td>
</tr>
<tr>
<td>Hungary</td>
<td>207</td>
<td>12% (7%-17%)</td>
</tr>
<tr>
<td>Finland</td>
<td>192</td>
<td>5% (4%-7%)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>230</td>
<td>10% (6%-15%)</td>
</tr>
<tr>
<td>Norway</td>
<td>334</td>
<td>11% (7%-15%)</td>
</tr>
<tr>
<td>Iceland</td>
<td>21</td>
<td>10% (7%-21%)</td>
</tr>
<tr>
<td>Sweden</td>
<td>240</td>
<td>24% (10%-38%)</td>
</tr>
<tr>
<td>Germany</td>
<td>1414</td>
<td>29% (25%-32%)</td>
</tr>
<tr>
<td>Australia</td>
<td>1445</td>
<td>33% (28%-38%)</td>
</tr>
</tbody>
</table>

- 52% vs 5%

International Variation in AAA Repair
Countries that repair smaller AAAs more frequently used EVAR

- Fee-for-service vs population-based reimbursement
- Percentage of Small AAA Repairs (< Society Guidelines)
  - < 5 cm women, < 5.5 cm men
  - Fee-for-service vs population-based reimbursement

- Population-based Reimbursement vs Fee-for-Service Reimbursement
  - 43% vs 6%

- Correlation coefficient 0.51
International Variation in Carotid Treatment

- 58,607 procedures, 11 countries
- 48% for asymptomatic disease

Variation in % asymptomatic patients treated by country:

<table>
<thead>
<tr>
<th>Country</th>
<th>Patients</th>
<th>% Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denmark</td>
<td>1519</td>
<td>0.0% (0.0%-0.0%)</td>
</tr>
<tr>
<td>Finland</td>
<td>938</td>
<td>12.4% (10.3%-14.5%)</td>
</tr>
<tr>
<td>Sweden</td>
<td>4047</td>
<td>13.0% (12.0%-14.0%)</td>
</tr>
<tr>
<td>Iceland</td>
<td>78</td>
<td>14.0% (10.0%-18.0%)</td>
</tr>
<tr>
<td>Norway</td>
<td>1033</td>
<td>14.0% (10.0%-18.0%)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>1478</td>
<td>16.0% (14.0%-18.0%)</td>
</tr>
<tr>
<td>Australia</td>
<td>825</td>
<td>18.0% (16.0%-20.0%)</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1831</td>
<td>20.0% (18.0%-22.0%)</td>
</tr>
<tr>
<td>Hungary</td>
<td>5388</td>
<td>34.0% (32.0%-36.0%)</td>
</tr>
<tr>
<td>USA</td>
<td>27353</td>
<td>40.0% (38.0%-42.0%)</td>
</tr>
<tr>
<td>Italy</td>
<td>6887</td>
<td>58.0% (56.0%-60.0%)</td>
</tr>
</tbody>
</table>

- Venermo, Wang, et al, in submission

International Variation in Carotid Treatment

Variation in % asymptomatic patients treated by center within each country: (each circle=1 center)

International Consortium of Vascular Registries (ICVR)

- ICVR has shown large variation in procedure and patient selection between countries
- Many AAAs are treated at diameters smaller than recommended by vascular society guidelines
- Use of EVAR varies substantially between countries
- Treatment of asymptomatic carotid stenosis varies substantially between countries and centers
- Countries with fee-for-service reimbursement are more likely to treat smaller AAAs and asymptomatic carotid stenosis
- Future ICVR studies will compare outcomes and focus on prospective device evaluation

First Prospective Device Evaluation Project

- Evaluate EVAR devices used to treat ruptured AAA
- All devices were approved based on elective repair
- Pragmatic one-year endpoints feasible for registry evaluation
- Death, re-intervention
- Provide important data for surgeons, industry, regulators
- Identify optimal device and patient selection
- Potential for device indication expansion by industry
- Help meet new EU device surveillance requirements
- Planned launch 2018 by those registries able to collect device identifiers and one-year follow-up data
- IPAP Project Leads: Kevin Mani (Vascunet), Adam Beck (VQI)

International Consortium of Vascular Registries (ICVR)

Conclusions

- A well established network of Vascunet countries and VQI sites provides a rich opportunity for collaboration.
- MDEpiNet Analytic Center support provides a mechanism for data analysis across countries.
- ICVR data can help industry meet new European Commission requirements for annual surveillance
- MEDDEV 2.7/1 rev 4 June, 2016
- All countries with vascular registries are welcome to participate in ICVR

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