

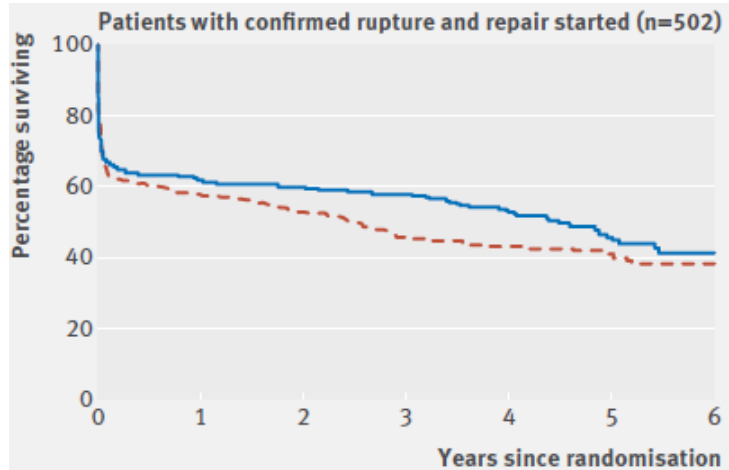
# The ICVR Prospective rAAA Project

# Comparative clinical effectiveness and cost effectiveness of endovascular strategy v open repair for ruptured abdominal aortic aneurysm: three year results of the IMPROVE randomised trial

IMPROVE Trial Investigators

[thebmj](#) | *BMJ* 2017;359:j4859 | doi: 10.1136/bmj.j4859

# Mortality and QALY



No at risk							
Endovascular strategy	259	161	154	148	108	50	21
Open repair	243	139	127	110	84	56	23

Fig 2 | Kaplan-Meier estimates for overall survival by randomised group (log rank P=0.40 for all 613 randomised patients and P=0.19 for 502 patients with confirmed rupture in whom repair was started)

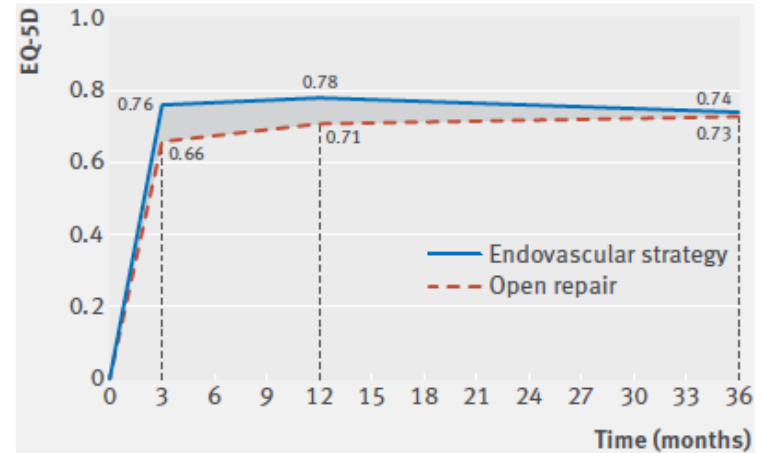
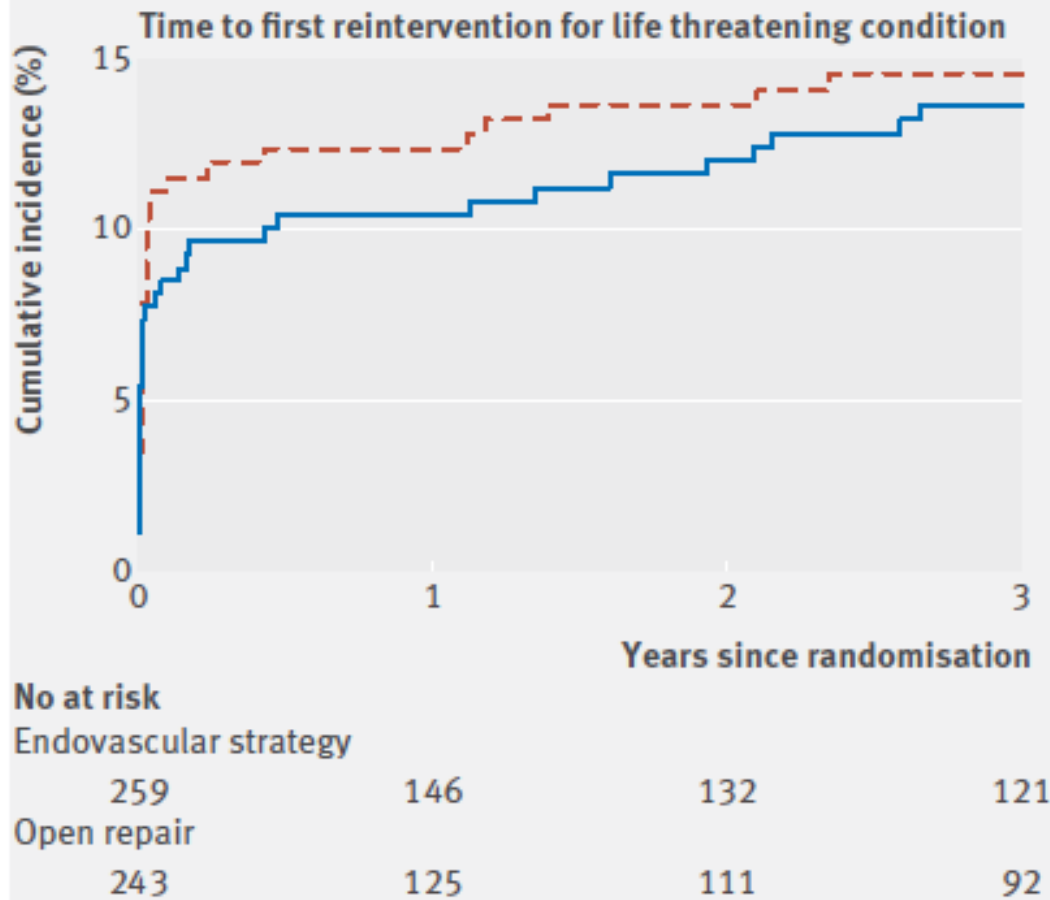


Fig 4 | Mean quality of life (EQ-5D score) by randomised group for 502 patients with repair of rupture started, alive and eligible for follow-up at specified time points. Randomisation of critically ill patients needing urgent surgery to avoid death meant that baseline EQ-5D scores were not obtained and set at zero. Average utility scores shown at 3 months and 1 and 3 years. In endovascular strategy versus open repair group mean difference was 0.097 (95% confidence interval 0.031 to 0.163; P=0.004, n=318) at 3 months; 0.068 (0.002 to 0.134; P=0.045, n=301) at 1 year; and 0.013 (-0.069 to 0.096; P=0.751, n=262) at 3 years

**Table 2 | Causes of death in patients randomised to treatment with endovascular strategy (endovascular repair if aortic morphology is suitable, open repair if not) or open repair by group by time period for all randomised patients (n=613)**

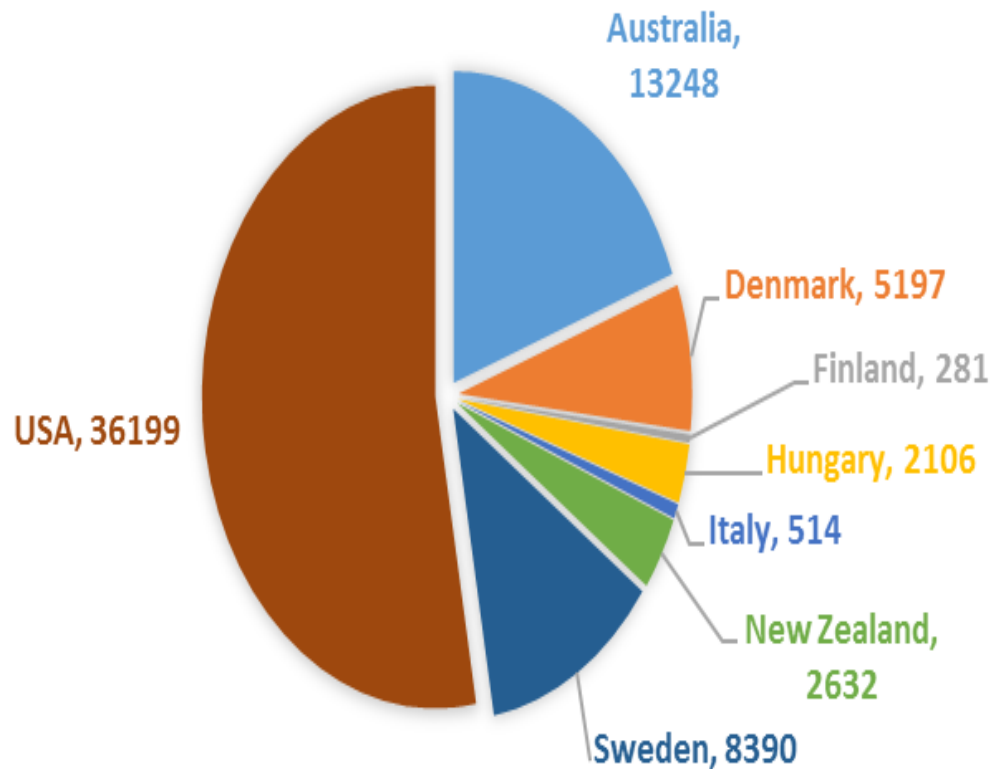
	Endovascular strategy (n=316)	Open repair (n=297)	Unadjusted hazard ratio (95% CI)	P value
<b>All follow-up</b>				
Related to the aneurysm	112	120	0.92 (0.75 to 1.13)	0.41
Cardiovascular	26	23		
Pulmonary	13	15		
Cancer	19	13		
Other	9	12		
Total	179	183		
<b>0-3 months</b>				
Related to the aneurysm	104	112	0.98 (0.76 to 1.26)	0.88
Cardiovascular	8	3		
Pulmonary	5	0		
Cancer	1	0		
Other	2	3		
Total	120	118		
<b>3 months-3 years</b>				
Related to the aneurysm	5	5	0.57 (0.36 to 0.90)	0.015
Cardiovascular	12	16		
Pulmonary	5	10		
Cancer	7	10		
Other	2	6		
Total	31	47		
<b>&gt;3 years</b>				
Related to the aneurysm	3	3	1.44 (0.80 to 2.62)	0.23
Cardiovascular	6	4		
Pulmonary	3	5		
Cancer	11	3		
Other	5	3		
Total	28	18		



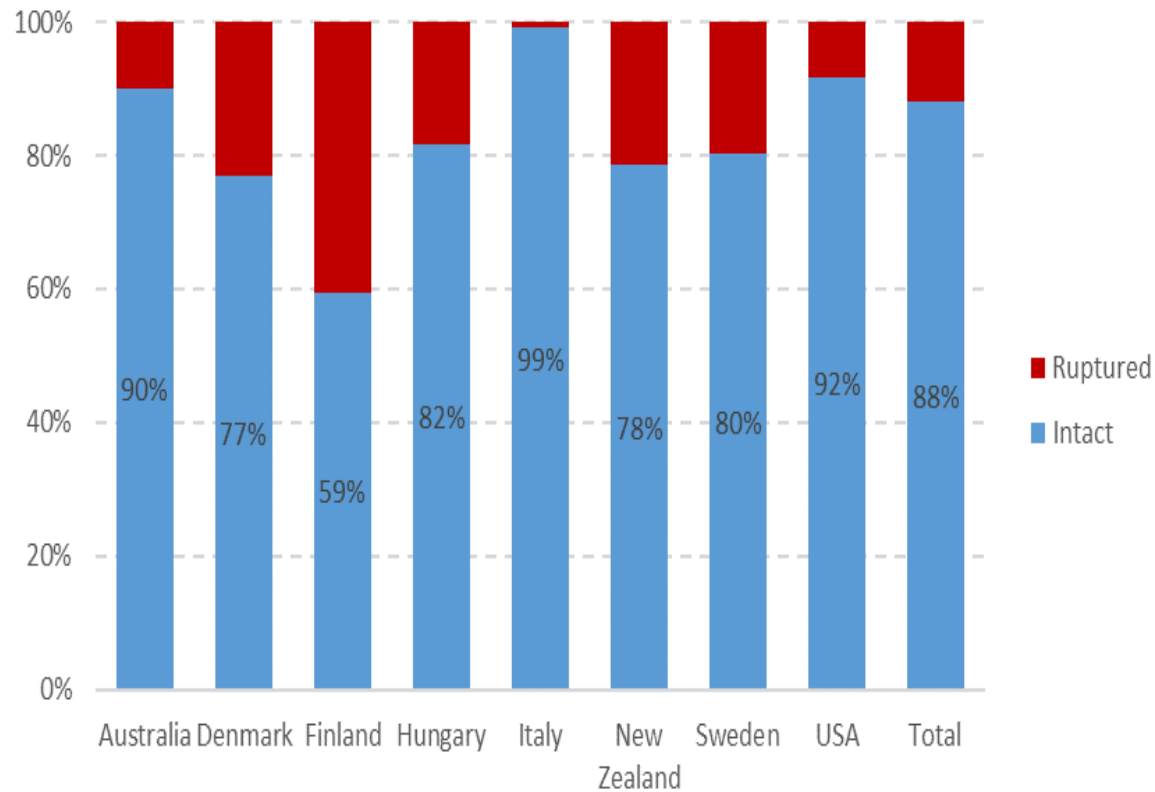
**Fig 3 | Cumulative incidence of reinterventions in 502 patients in whom repair of rupture was started. Gray's test for testing equality of cumulative incidence curves:  $P=0.643$  for time to first reintervention;  $P=0.713$  for time to reintervention for life threatening condition (included hindquarter amputation, colectomy with stoma for mesenteric or colonic ischaemia, graft infection, secondary rupture, and repeat aneurysm repairs (full list in table A in appendix 1)**

# ICVR AAA Data

# TOTAL PROCEDURES = 68567

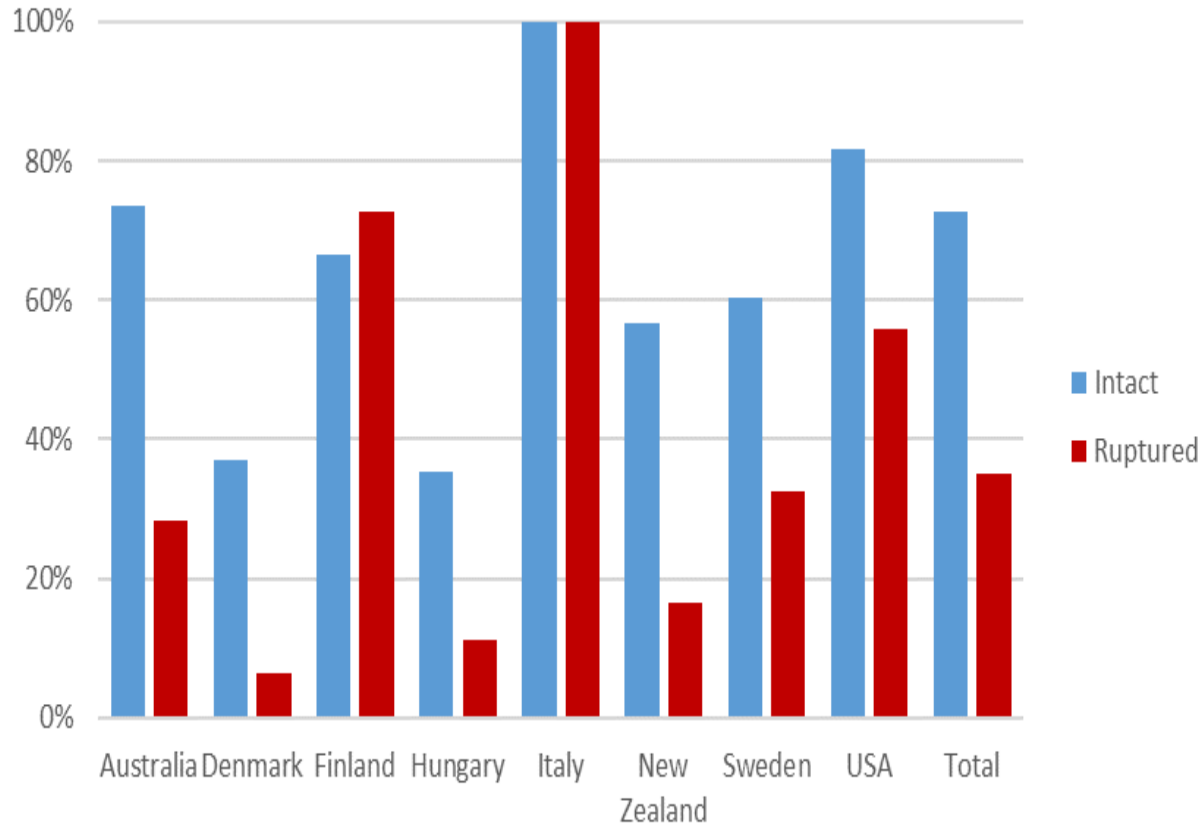


# Intact vs. Ruptured





# % EVAR



# Number of procedures

	Australia	Denmark	Finland	Hungary	Italy	New Zealand	Sweden	USA	Total
<b>Intact</b>									
Open	3144	2516	56	1113	0	892	2678	6025	16424
EVAR	8789	1475	111	609	510	1174	4057	27062	43787
Total	11933	3991	167	1722	510	2066	6735	33087	60211
<b>Ruptured</b>									
Open	943	1128	31	341	0	472	1117	1311	5343
EVAR	372	78	83	43	4	94	536	1660	2870
Total	1315	1206	114	384	4	566	1653	2971	8213

# 2016 rAAA

	Australia	Denmark	Finland	Hungary	New Zealand	Sweden	USA	Total
Open	115	145	4	36	53	103	241	697
EVAR	62	14	31	11	13	72	357	560
Total	177	159	35	47	66	175	598	1257

# Aims and rationale

## Aim:

- To compile large-scale registry-based data on device performance in rAAA repair in contemporary practice with comparison to open repair

## Rationale:

- International registry-based collaboration offers a unique opportunity for large datasets capturing rare events, with data on denominator of operations performed (in contrast to current MDR reporting standards)

# Aims and rationale

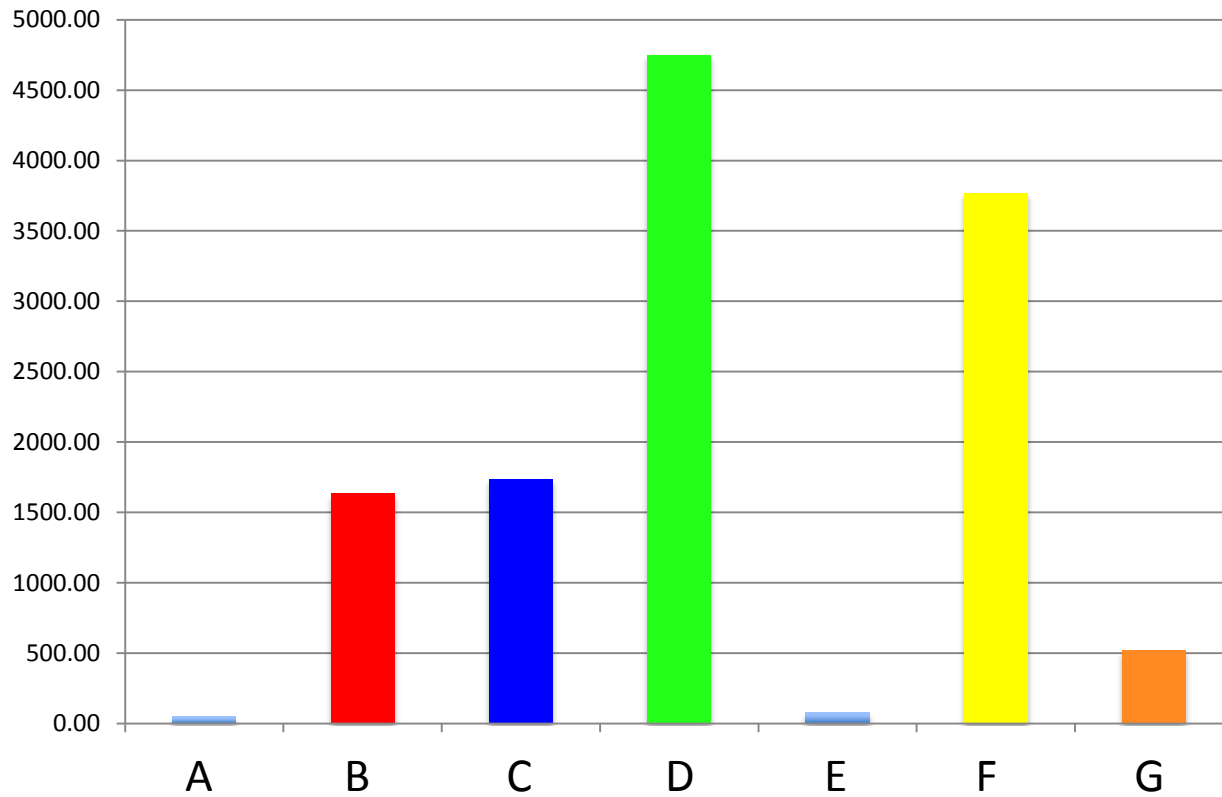
## Rationale:

- International evaluation of EVAR can provide insights into patterns of use and outcomes in multiple practice settings
- Expanded application of EVAR for rupture?

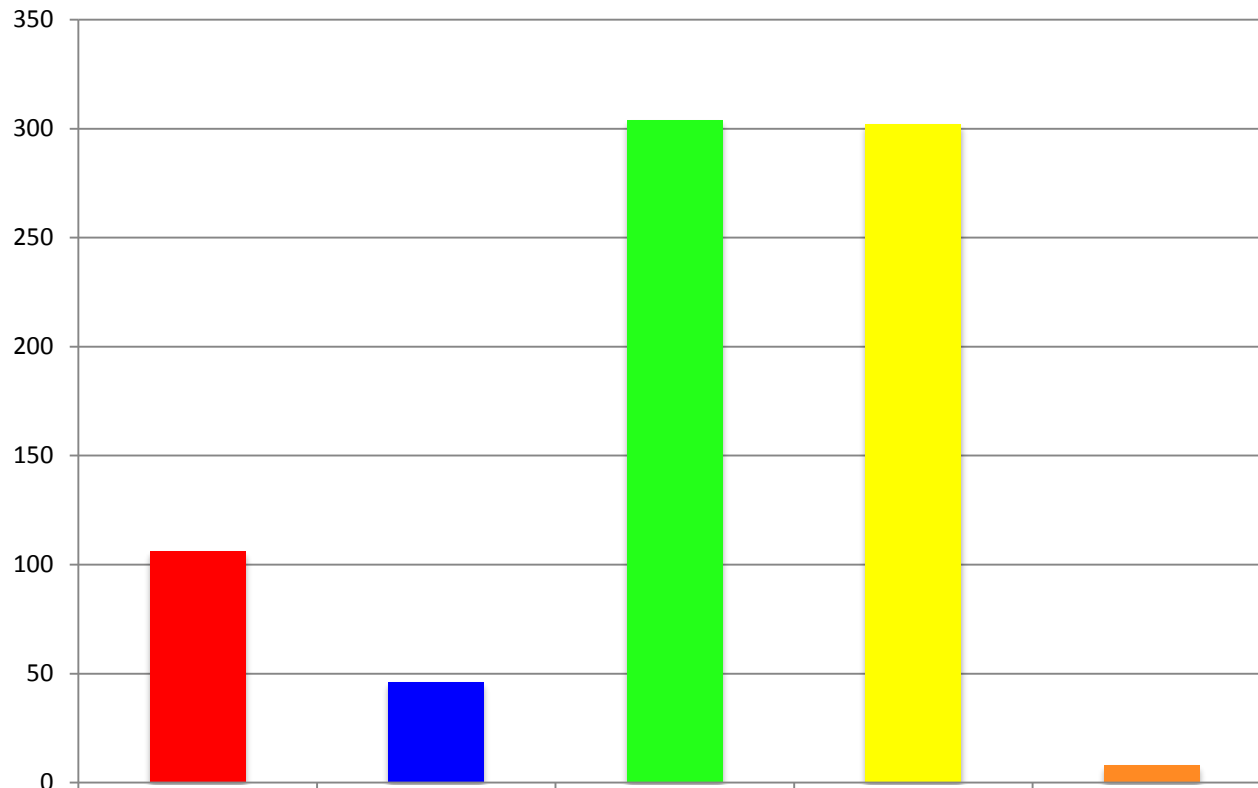
# Sample Size Calculation

- All Years ICVR rAAA Mortality:
  - OAAA 31%
  - EVAR 20.4%
- Approximate sample size per device ~320
- Multiple comparisons will require more patients per device

# VQI Volume by Device (2014-2016)



# Volume by device for rAAA (2015-2016): 766 patients





# VQI Market Share for rAAA (2015-2016)



# ? Participating Countries

- Australasian
- Denmark
- Finland
- France
- Hungary
- Italy
- Malta
- New Zealand
- Norway
- Sweden
- U.S.A. (VQI)

# Discussion

- Validation of key outcomes
  - Mortality (e.g. National death index)
- Sample size
- Enrollment period
- Analytic plan
- Funding