

ISRAEL HEART SOCIETY האיגוד הקרדיולוגי בישראל  
החוג הישראלי לקיצוב ואלקטרופיזיולוגיה



THE ISRAELI WORKING GROUP ON PACING AND ELECTROPHYSIOLOGY

# Worldwide ICD's Registries

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# Topics

- Worldwide Registries
- Performance and Outcome Data
- Adherence to Guidelines
- Comparison to National ICD Registry



# The Rational Behind Registries

1. How do we practice medicine in the real world?
2. To what extent do we adhere to practice recommendations/guidelines?
3. How do we perform in comparison to others?



# Leading Regions

- North America
- Europe



# North America

- U.S.
- Canada



# U.S. Registry

- National Cardiovascular Data Registry (NCDR)
- Mandated by Centers for Medicare and Medicaid Services (CSM)
- Year of Initiation: 2006
- Last Year Reported: 2009
- Hospitals Reporting: 1489

Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345



# U.S. Registry

- Cumulative Implants: 550000
- Includes 90% of ICDs in the U.S.
- ICDs Replacements/Upgrades/Failure: 30%/486000 Implants (2006-2009)

Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345



**Table 2** National ICD Registry (2006 to 2009): medical history and baseline tests

Total implants (N)	486,025
Hypertension (%)	75.3
Diabetes (%)	36.7
Chronic lung disease (%)	22.8
Ischemic heart disease (N, %)	317,168 (65.3)
Previous myocardial infarction	259,557 (53.4)
Previous coronary artery bypass grafting	170,793 (35.1)
Previous percutaneous intervention	157,706 (32.4)
Non-ischemic dilated cardiomyopathy (N, %)	152,672 (31.4)
History of syncope (N, %)	95,081 (19.6)
History of cardiac arrest (N, %)	55,432 (11.4)
History of congestive heart failure (N, %)	375,935 (77.4)
NYHA Class I (%)	14
NYHA Class II (%)	36
NYHA Class III (%)	46
NYHA Class IV (%)	4
QRS duration (ms)	129.3 ± 35.7
Ejection fraction (%)	28.6 ± 11.6

Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345





**Table 1** National ICD Registry (2006 to 2009): demographics, ICD indication

Age, mean (yrs)	68.1 ± 12.8
Male/female (%)	73.8/26.2
Race (%)	
White	82.8
Black/African American	12.1
Asian	1.0
American Indian/Alaska Native	0.4
Native Hawaiian	0.1
Other	3.4
Hispanic	4.9
Total implants (N)	486,025
ICD indication (N, %)	
Primary prevention	378,363 (77.9)
Secondary prevention	107,662 (22.2)
Primary insurance payor (%)	
Medicare/Medicaid	67.7
Other payor	32.3

CMS includes Government Insurance for Medicare and Medicaid patients.

Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345



**Table 4** National ICD Registry (2006 to 2009): physician training and implantation volume

Training category	Physicians, N (%)	Implants performed by category, N (%)
Total	5,246	486,025
EP Fellowship + CCEP Boards	2,386 (49.6)	361,242 (77.7)
EP Fellowship only	313 (6.5)	25,377 (5.5)
Thoracic/Cardiac Surgery Residency	620 (12.9)	10,299 (2.2)
Pediatric EP Fellowship	12 (0.2)	253 (0.1)
HRS ICD Implantation Guidance <sup>17</sup>	822 (17.1)	42,046 (9.0)
None of the above	655 (13.6)	25,446 (5.5)
Missing data*	438	21,362

CCEP = Clinical Cardiac Electrophysiology; EP = Electrophysiology.  
\*% calculations made excluding missing data.

Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345



**Table 3** National ICD Registry (2006 to 2009): ICD type and adverse events

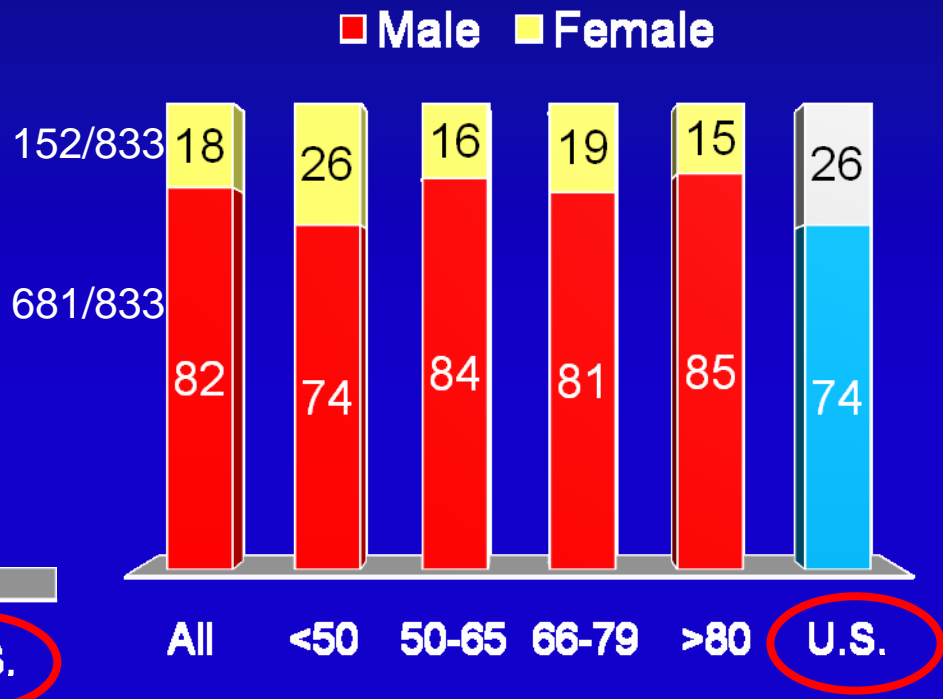
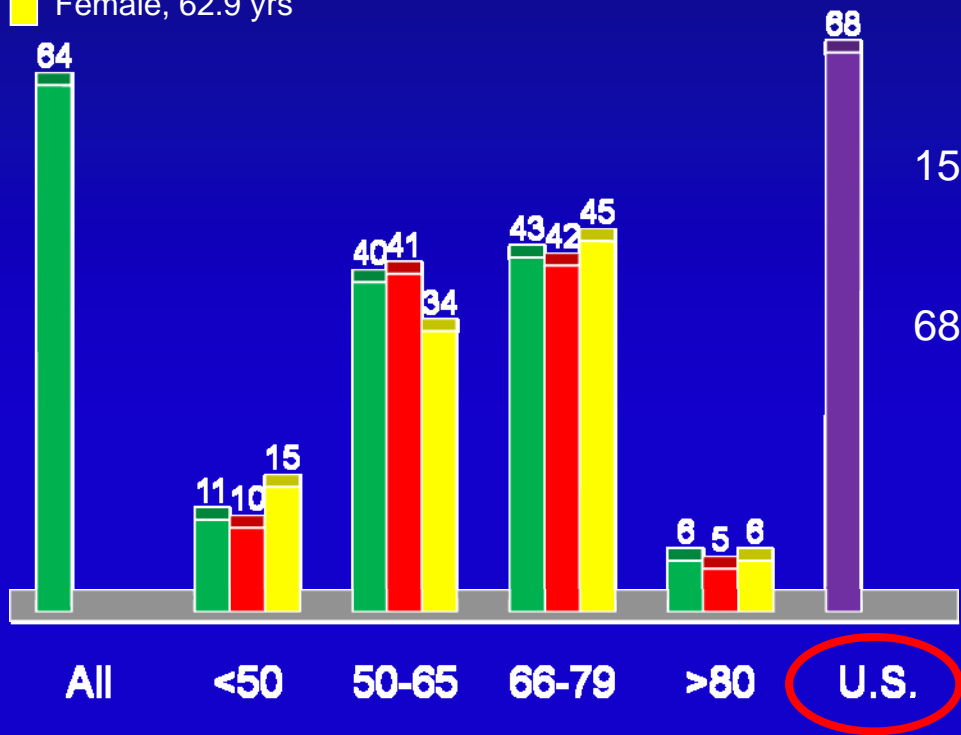
	Year				
	2006	2007	2008	2009	2006–2009
Total implants (N, for each year and cumulative for 2006–2009)	92,897	120,668	131,086	141,374	486,025
Single chamber ICD (%)	23.4	21.9	20.5	18.9	20.9
Dual chamber ICD (%)	39.1	39.1	39.8	39.3	39.3
Biventricular ICD (%)	37.4	38.9	39.6	41.7	39.6
Adverse procedure-related event (%) (for new ICD implants only)	3.77	3.34	3.01	2.87	3.22
Death in laboratory	0.02	0.02	0.03	0.02	0.02
Cardiac perforation	0.09	0.08	0.09	0.06	0.08
Hematoma	1.18	0.96	0.8	0.71	0.89
Lead dislodgement	1.11	1.08	1.02	1.01	1.05
Hemo/pneumothorax	0.66	0.54	0.50	0.466	0.53
Transient ischemic attack/stroke	0.10	0.08	0.07	0.07	0.08
Other	0.61	0.58	0.50	0.53	0.57

Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345



# Age Groups and Sex Israel vs. U.S.

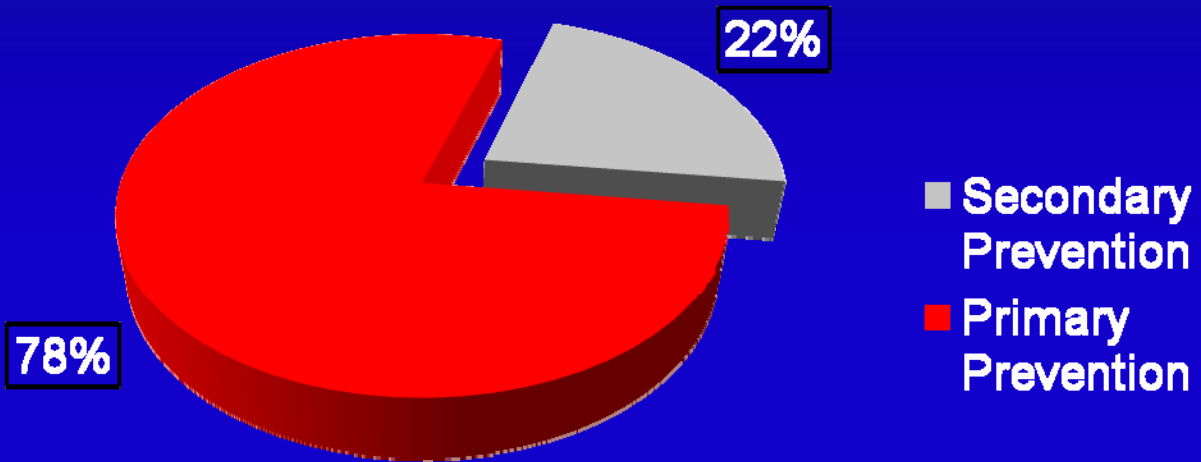
- All, 64 yrs
- Male, 64.3 yrs
- Female, 62.9 yrs



ICD National Registry-Israel 2010-2011  
 Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345



# First ICD/CRTD Implantation by Indication



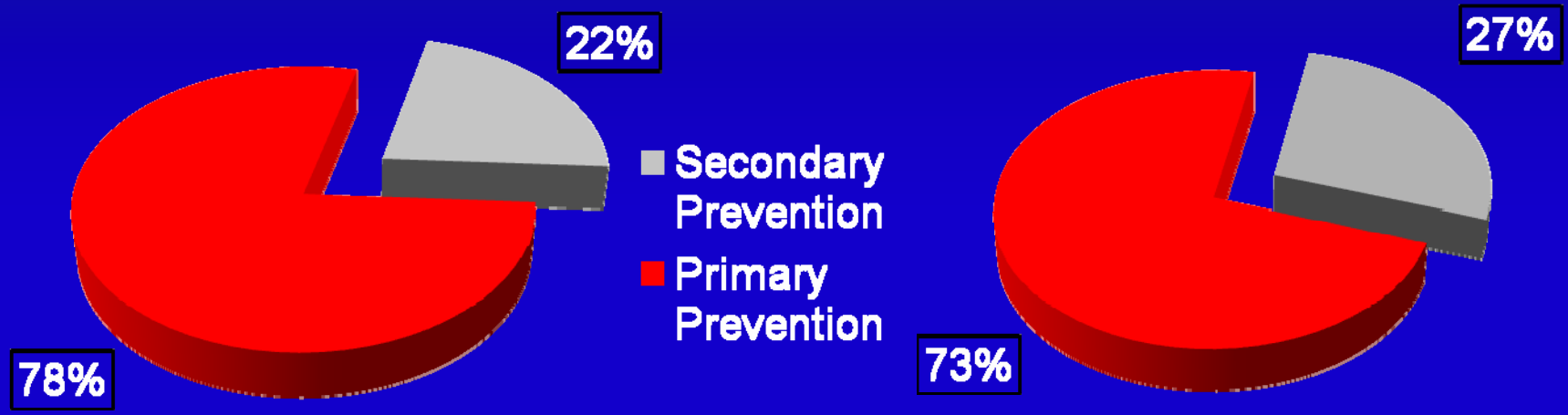
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# Primary vs. Secondary Prevention

U.S.

Israel

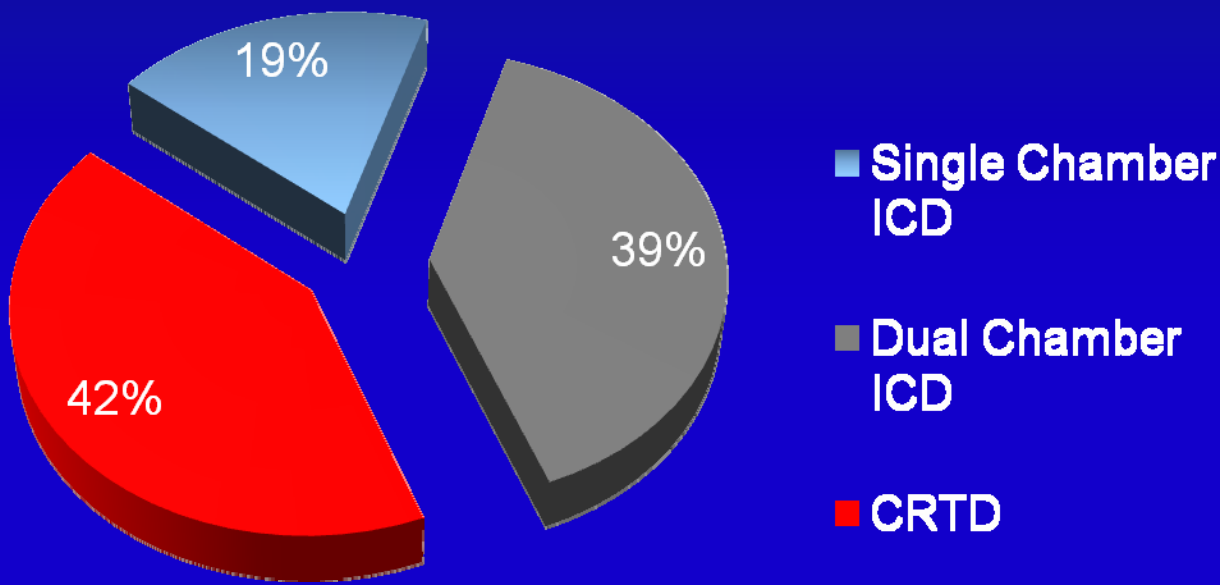


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Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345  
ICD National Registry-Israel 2010-2011

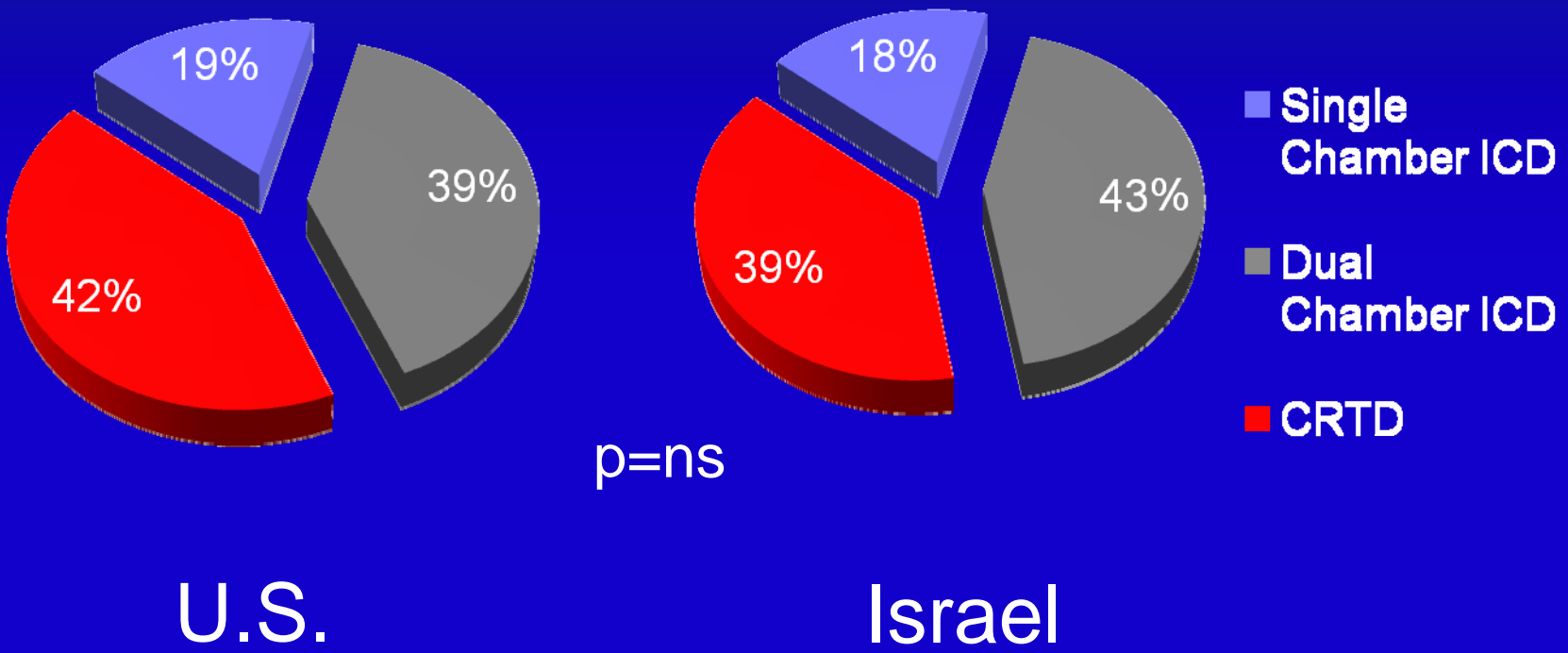


# Distribution of Implantations by Type of Device-U.S.





# Distribution of Implantations by Type of Device



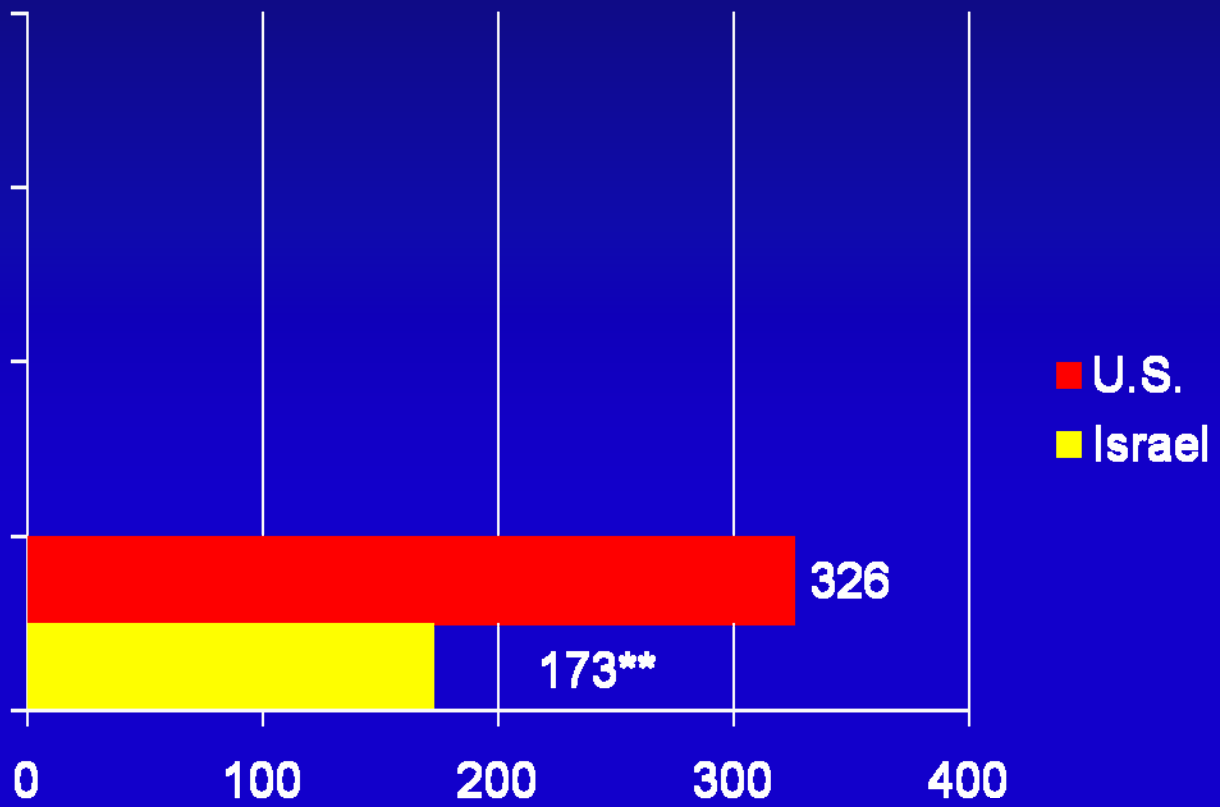
U.S.

Israel





# ICD/CRT Implantations\*/Million Inhabitants



\*First Implantation  
\*\* Estimate

Hammill SC, et al. *Heart Rhythm* 2010;7:1340-1345  
ICD National Registry-Israel 2010-2011



# Medical Practice and Outcomes



# Complications Stratified by Physician Certification and Device Type

%

Complication	EP	Non-EP cardiologist	Thoracic surgeon	Other	p
Any complication, all ICDs	3.5	4.0	5.8	4.0	<0.001
Major complication, all ICDs	1.3	1.7	2.5	1.7	<0.001
Any complication, dual-chamber ICDs	3.1	3.7	5.7	3.4	<0.001
Major complication, dual-chamber ICDs	1.3	1.7	2.7	1.4	<0.001
Any complication, CRT-D	4.8	5.4	8.9	5.8	<0.001
Major complication	1.8	2.1	3.3	2.3	0.01

Major complications include in-hospital death, cardiac arrest, cardiac perforation, cardiac valve injury, coronary venous dissection, hemothorax, pneumothorax, deep phlebitis, transient ischemic attack, stroke, MI, pericardial tamponade, and arterial-venous fistula. Any complication also includes minor complications, such as drug reactions, conduction block, lead dislodgement, and nerve injury, among others.

Curtis JP et al. *JAMA* 2009; 301:1661-1670.



# Multivariate Analysis of Complication Risks, Use of CRT, and Physician Certification

	RR (95% CI)			
Measure	EP	Non-EP cardiologist	Thoracic surgeon	Other
Complications	1 (reference)	1.11 (1.01–1.21)	1.44 (1.15–1.79)	1.09 (0.94–1.26)
Use of CRT	1 (reference)	0.93 (0.91–0.95)	0.81 (0.74–0.88)	0.97 (0.94–0.99)

Curtis JP et al. *JAMA* 2009; 301:1661-1670.



# Ontario Registry

- Since 2006
- Outcomes: ICD Rx (e.g., shock or antitachycardia pacing), morbidity, and death.
- Primary prevention: 63.3%
- Secondary prevention: 21.6%
- Mean age: 64 yrs
- Men: 79%
- IHD: 66%
- Perioperative complications: 3.6%

Lee D, et al. *Heart Rhythm*. *Heart Rhythm* 2008;5:1250-1256



**Table 3** Characteristics of ICD patients with implants in US and Canadian ICD registries

Country	United States	Ontario, Canada
Duration	2006–present	2007–present
Mean age (SD)	68.3 (12.5)	63.8 (12.7)
Male, %	74.1	79.0
Primary prevention,* %	79.2	72.5
Secondary prevention,* %	20.8	27.5
Ischemic heart disease, %	66.5	65.6
Prior MI, %	55.3	59.7
LV ejection fraction, mean (SD)	27 (11)	30 (13)
LVEF <30%	n/a	71.8*
Type of ICD		
Single chamber, %	23.4	42.9
Dual chamber, %	38.8	33.7
Biventricular, %	37.5	23.4
Adverse event rate, † %	3.63	3.69
Longitudinal component planned		
Device therapy/shock	Yes	Yes
Survival	Yes	Yes
Study sample	Subset	All

Abbreviations as in Table 1.

\*Initial implants only, excludes replacements.

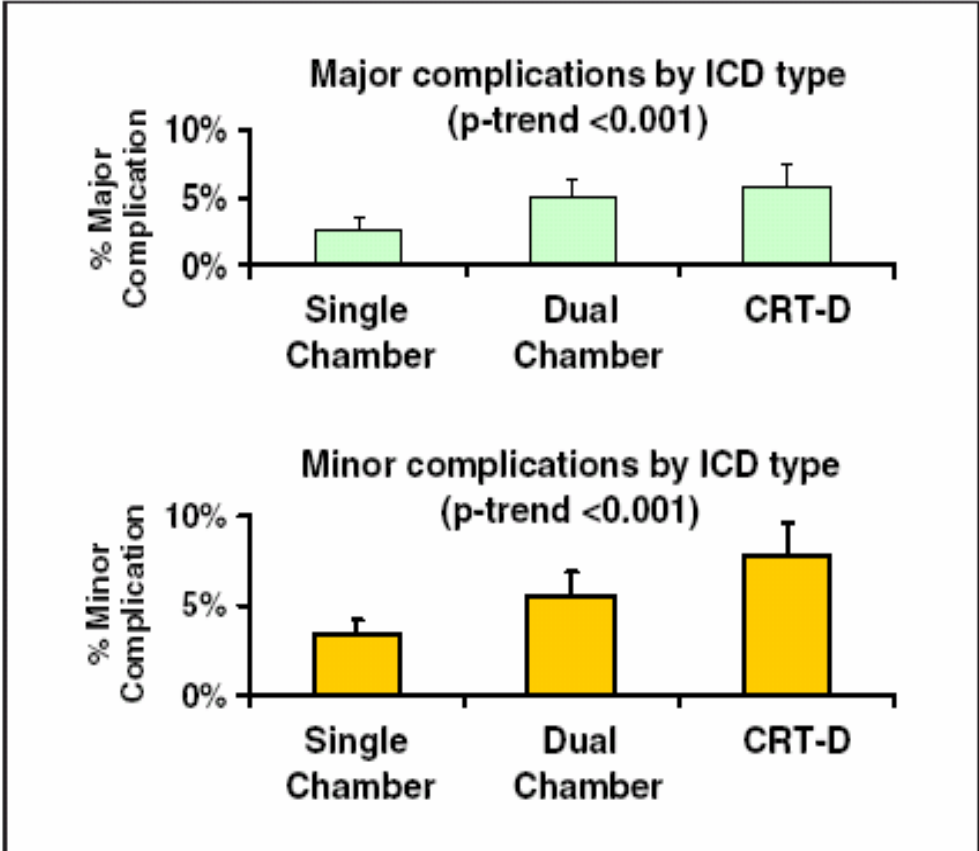
†Includes death, cardiac perforation, hematoma, lead dislodgement, hemothorax/pneumothorax, and transient ischemic attack/stroke.



# Early ICD Implantation Complications

- 3340 patients at 18 centers in Ontario from 2007 to 2009.
- Major complications occurred in 4.1% of de novo ICD implant procedures
- The most significant factor associated with complications is the type of ICD implanted.

Lee D, et al. *J Am Coll Cardiol* 2010; 55:774-782



**Figure 1** Rates of 45-Day Complications by Defibrillator Type

Rates of major (top) and minor (bottom) 45-day complications by defibrillator type. CRT-D = cardiac resynchronization therapy defibrillator; ICD = implantable cardioverter-defibrillator.

Lee D, et al. *J Am Coll Cardiol* 2010; 55:774-782





# Acute ICD Lead Dislodgement

- Acute lead dislodgements and in-hospital mortality in patients enrolled in the NCDR ICD Registry
- 2628/226764 cases of ICD between 2006 and 2008
- Acute lead dislodgements occur more often in patients with more **comorbidities** and in patients undergoing implants by **non electrophysiology-trained implanters**.
- These events were strongly associated with increased odds for in-hospital death.

Cheng A, et al. *J Am Coll Cardiol* 2010;56:1651-1656.



# Higher ICD Volumes Linked to Better Outcomes

- The relation between hospital procedure volume and complications of cardioverter-defibrillator implantation from the implantable cardioverter-defibrillator registry.\*
- The relation between patients' outcomes and the volume of cardioverter-defibrillator implantation procedures performed by physicians treating Medicare beneficiaries.\*\*

\*Freeman J et al. *J Am Coll Cardiol* 2010; 56:1133-1139.

\*\*Al-Khatib SM, et al. *J Am Coll Cardiol* 2005; 46:1536-1540.



# Guidelines Implementation



# Non–Evidence-Based ICD Implantations in the United States

- **Context:** Practice guidelines *do not recommend* use of an implantable cardioverterdefibrillator (ICD) *for primary prevention* in patients recovering from a *myocardial infarction* or *coronary artery bypass graft surgery* and those with *severe heart failure symptoms* or a *recent diagnosis of heart failure*.
- **Objective** To determine the number, characteristics, and in-hospital outcomes of patients who receive a non–evidence-based ICD and examine the distribution of these implants by site, physician specialty, and year of procedure.
- **Design:** Retrospective cohort study of cases submitted to the National Cardiovascular Data Registry-ICD Registry between January 1, 2006, and June 30, 2009.
- **Main Outcome Measure:** In-hospital outcomes.

Al Khatib S et al. *JAMA* 2011 5;305(1):43-9.



# Non–Evidence-Based ICD Implantations in the United States

- **Results** Of 111 707 patients, 25 145 received non–evidence-based ICD implants (22.5%). Patients who received a non–evidence-based ICD compared with those who received an evidence-based ICD had a significantly higher risk of in-hospital death (0.57% vs. 0.18%  $P < .001$ ) and any post procedure complication (3.23% vs. 2.41%];  $P < .001$ ).
- **Conclusion** Among patients with ICD implants in this registry, ***22.5% did not meet evidence-based criteria for implantation.***

Al Khatib S et al. *JAMA* 2011 5;305(1):43-9.



**Table 3.** In-hospital Outcomes

Outcome	ICD Implant, No. (%) [95% CI]		P Value	
	Non-Evidence-Based (n = 25 145)	Evidence-Based (n = 86 562)	Unadjusted	Adjusted <sup>a</sup>
Overall population				
Postprocedural complications (including death)	813 (3.23) [3.01-3.45]	2085 (2.41) [2.31-2.51]	<.001	<.001
Hematoma	219 (0.87) [0.76-0.99]	615 (0.71) [0.65-0.77]	.009	.07
Death	143 (0.57) [0.48-0.66]	153 (0.18) [0.15-0.20]	<.001	<.001
Pneumothorax	111 (0.44) [0.36-0.52]	359 (0.41) [0.37-0.46]	.56	.64
Cardiac tamponade <sup>b</sup>	14 (0.06) [0.03-0.08]	76 (0.09) [0.07-0.11]	.11	NA
Device infection <sup>b</sup>	9 (0.04) [0.02-0.07]	14 (0.02) [0.01-0.03]	.06	NA
Population excluding patients with NYHA class IV symptoms	(n = 22 123)	(n = 86 562)		
Postprocedural complications (including death)	659 (2.98) [2.75-3.20]	2085 (2.41) [2.31-2.51]	<.001	<.001
Hematoma	188 (0.85) [0.73-0.97]	615 (0.71) [0.65-0.77]	.03	.12
Death	93 (0.42) [0.34-0.51]	153 (0.18) [0.15-0.20]	<.001	<.001

Abbreviations: CI, confidence interval; ICD, implantable cardioverter-defibrillator; NYHA, New York Heart Association; NA, data not applicable.

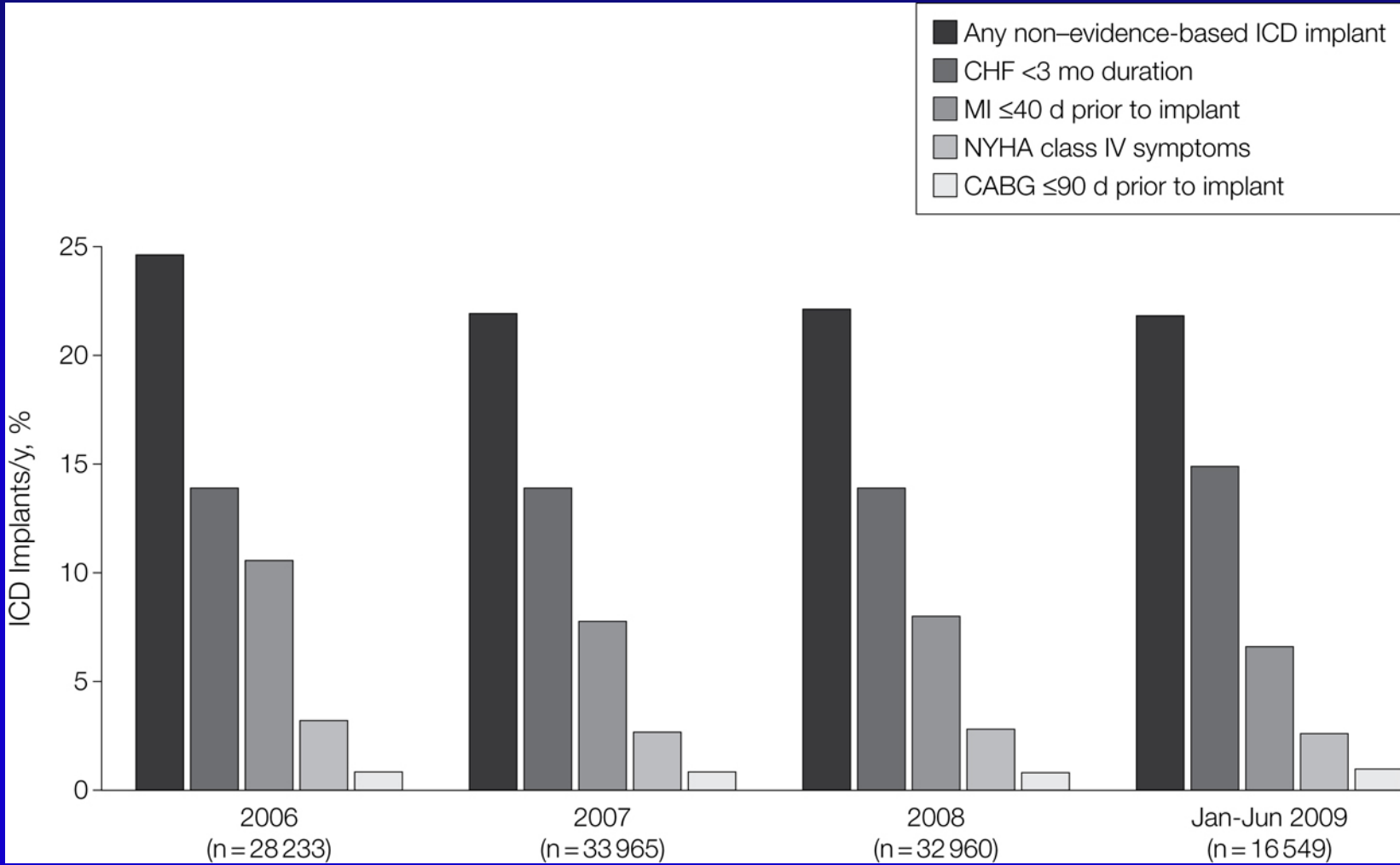
<sup>a</sup>Adjusted in a logistic regression model for age, sex, atrial fibrillation or flutter, prior ventricular tachycardia, cerebrovascular disease, chronic lung disease, diabetes, end-stage renal disease, and left ventricular ejection fraction.

<sup>b</sup>Pericardial tamponade and infection were too rare to provide a valid multivariable model fit.

Al Khatib S et al. *JAMA* 2011 5;305(1):43-9.



# Temporal Changes in Non-Evidence-Based Implantable Cardioverter-Defibrillators

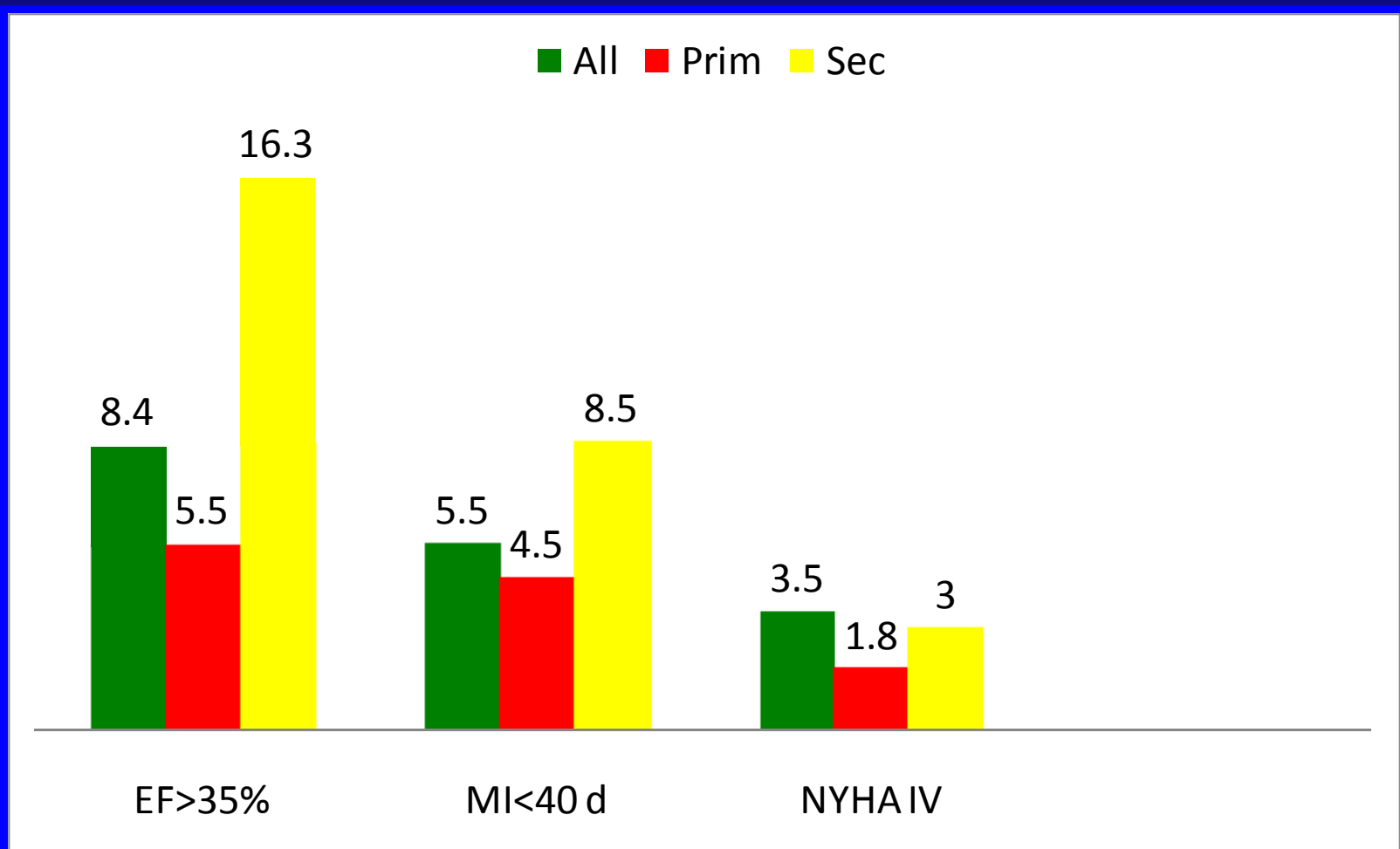


Al Khatib S et al. *JAMA* 2011 5;305(1):43-9.



# Off Label Implantations-Israel

%

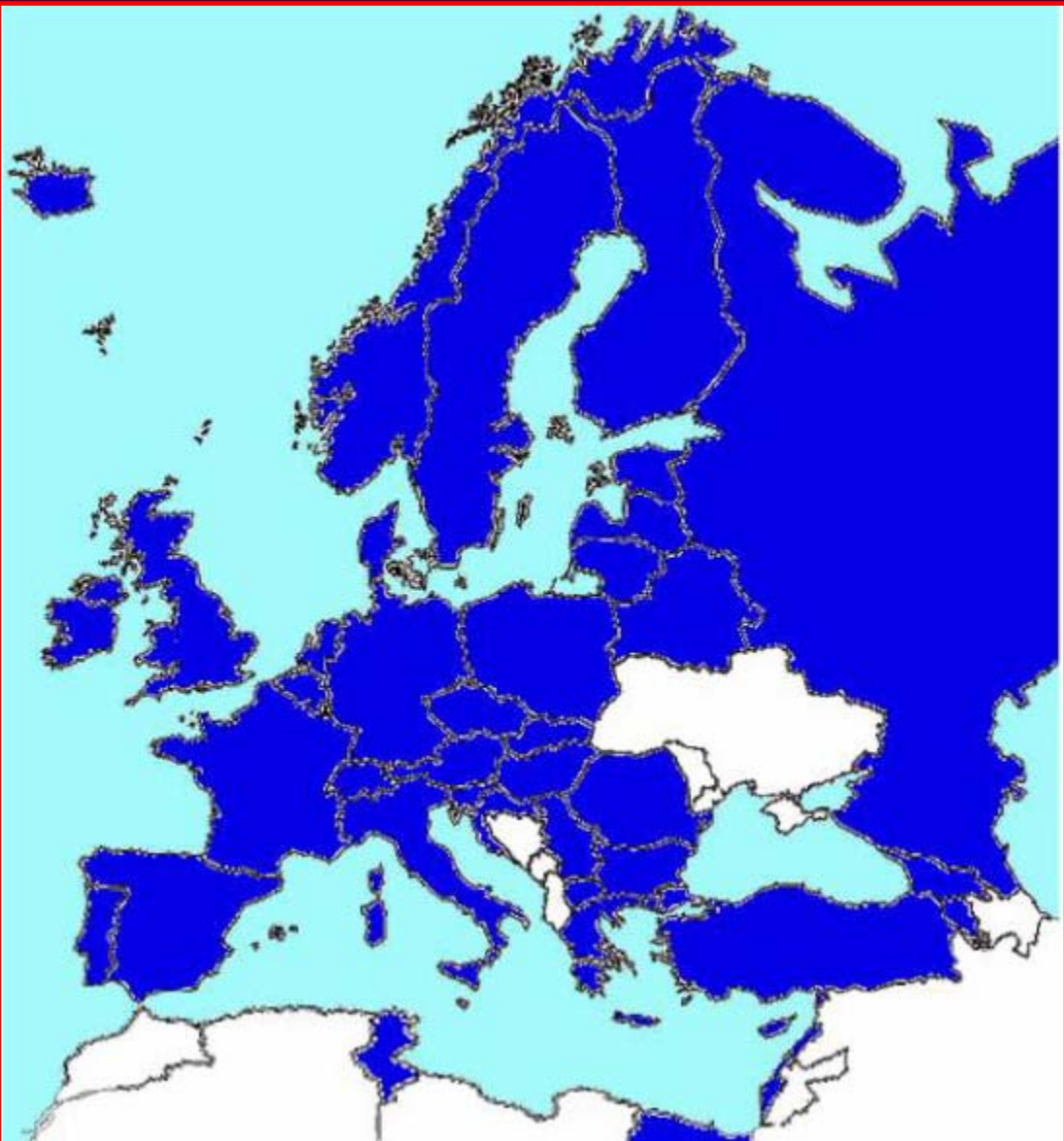






# Europe

- Which countries?





# Data Sources

- EHRA White Book: First publication 2008. Last 2010
- Summary of current EP status in Europe
- Countries > 50 (ESC members)
- Source of information: national societies
- Statistics: demography, economy, education, health system
- EP and device registries in some countries

European Heart Rhythm Association (EHRA) White Book 2010



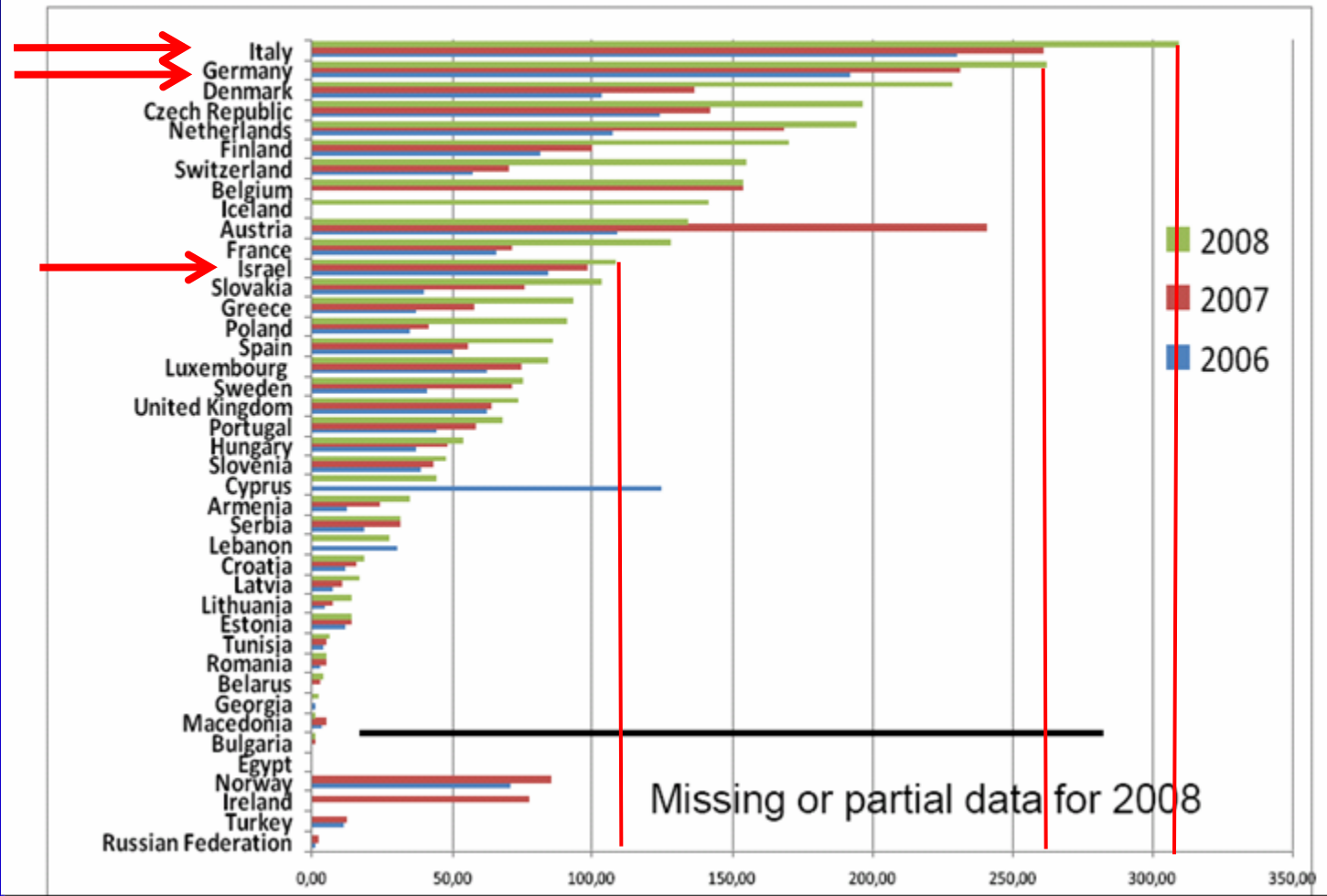
# Determinants of Geographic Variations in ICD Implantations in ESC Member Countries

- Great differences in implanting rates among EHRA members
- The number of ICD implants is increasing in almost all countries
- There are discrepancies in the number of implanting centers/million inhabitants. Their number correlate with implantation rates
- National economic status and healthcare expenses are related to implantation rates

Lubinski A, et al, Europace 2011



## Number of ICD implantations per million inhabitants in the years 2006-2008



Lubinski A, et al, Europace 2011



# Future

- Patients will probably benefit from inclusion of ***complications and outcomes*** in the National ICD registry



*“Science tells us what we can do;  
guidelines what we should do; and  
registries what we are actually doing”*



**THANK YOU FOR YOUR  
ATTENTION**