ESC Sudden Cardiac Death Guidelines:

From the theory to the real life?

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SUDDEN CARDIAC DEATH

Sudden cardiac death is defined as the *unexpected* death due to a cardiac cause, in patient with or without cardiac disease, which occurs *within one hour* from the appearance of the *first* clinical symptoms.

My task

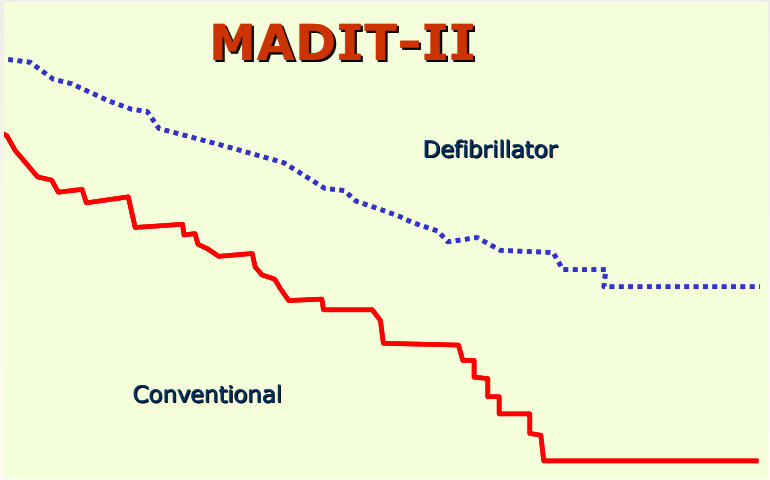
- To briefly highlight the main messages derived from SCD Guidelines.
- I will focus on primary prevention of SCD and the use of ICD devices in patients with DCM (of ischemic and non-ischemic origin).
- I will also briefly discuss the varying implementation of these guidelines in different European countries and ICD cost effectiveness issues.

SUDDEN CARDIAC DEATH

Primary prevention

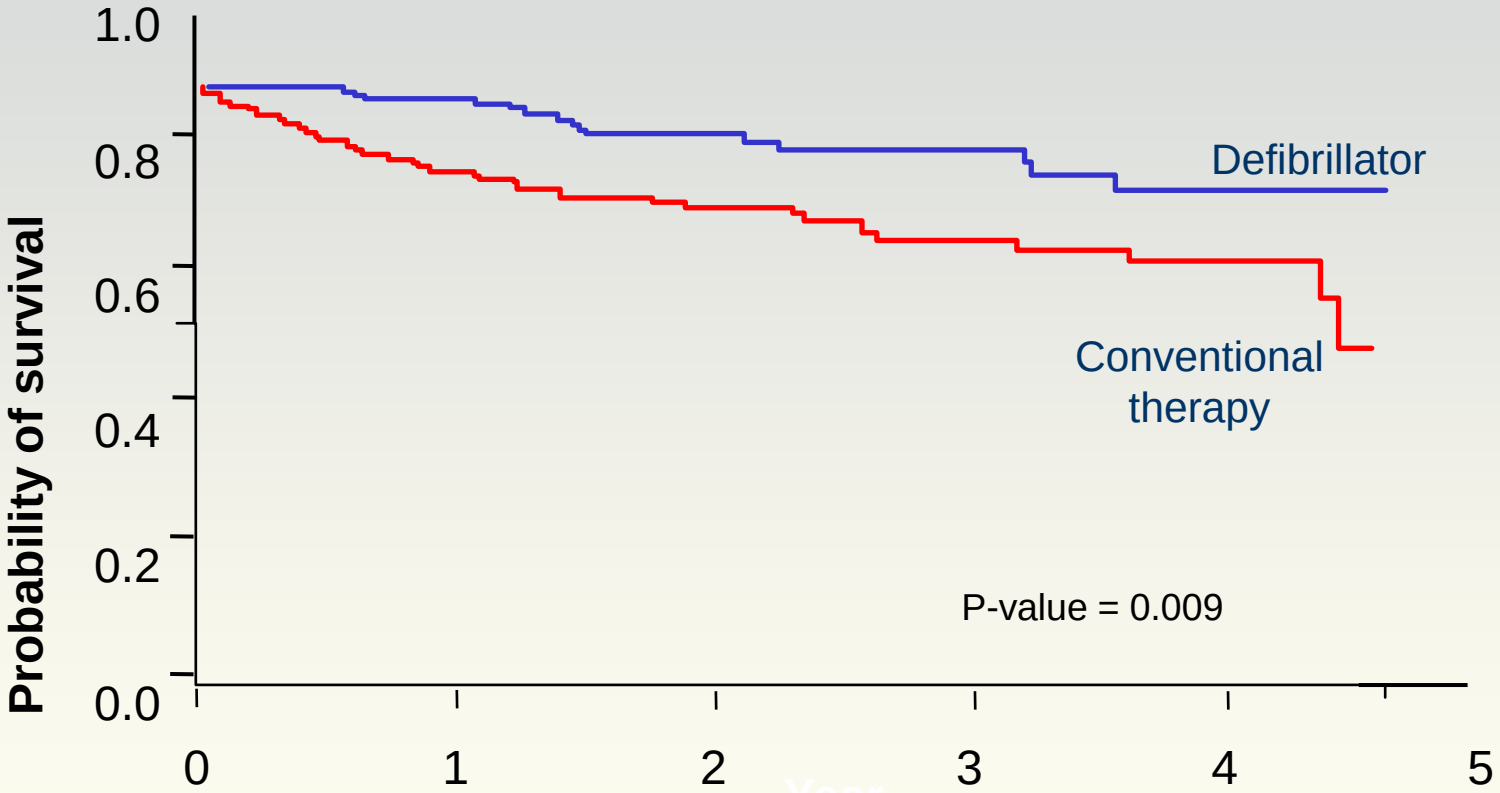
The main Clinical Trials

The Guidelines Orders



MADIT I

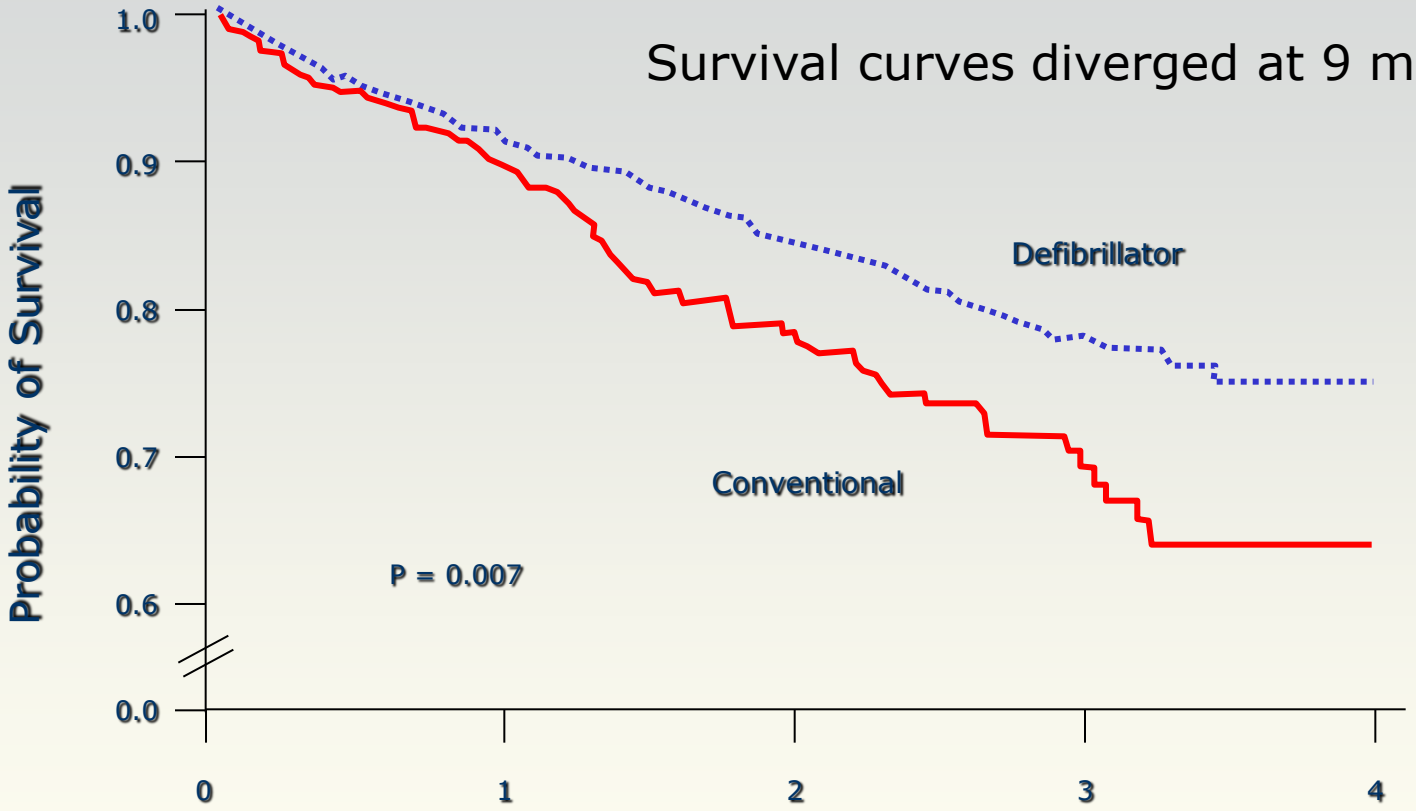
Moss AJ. N Engl J Med. 1996; 335:1933-40



No. of patients						
Defibrillator	95	80	53	31	17	3
Conventional therapy	101	67	48	29	17	0

MADIT-II

Moss AJ. N Engl J Med. 2002;346:877-83.

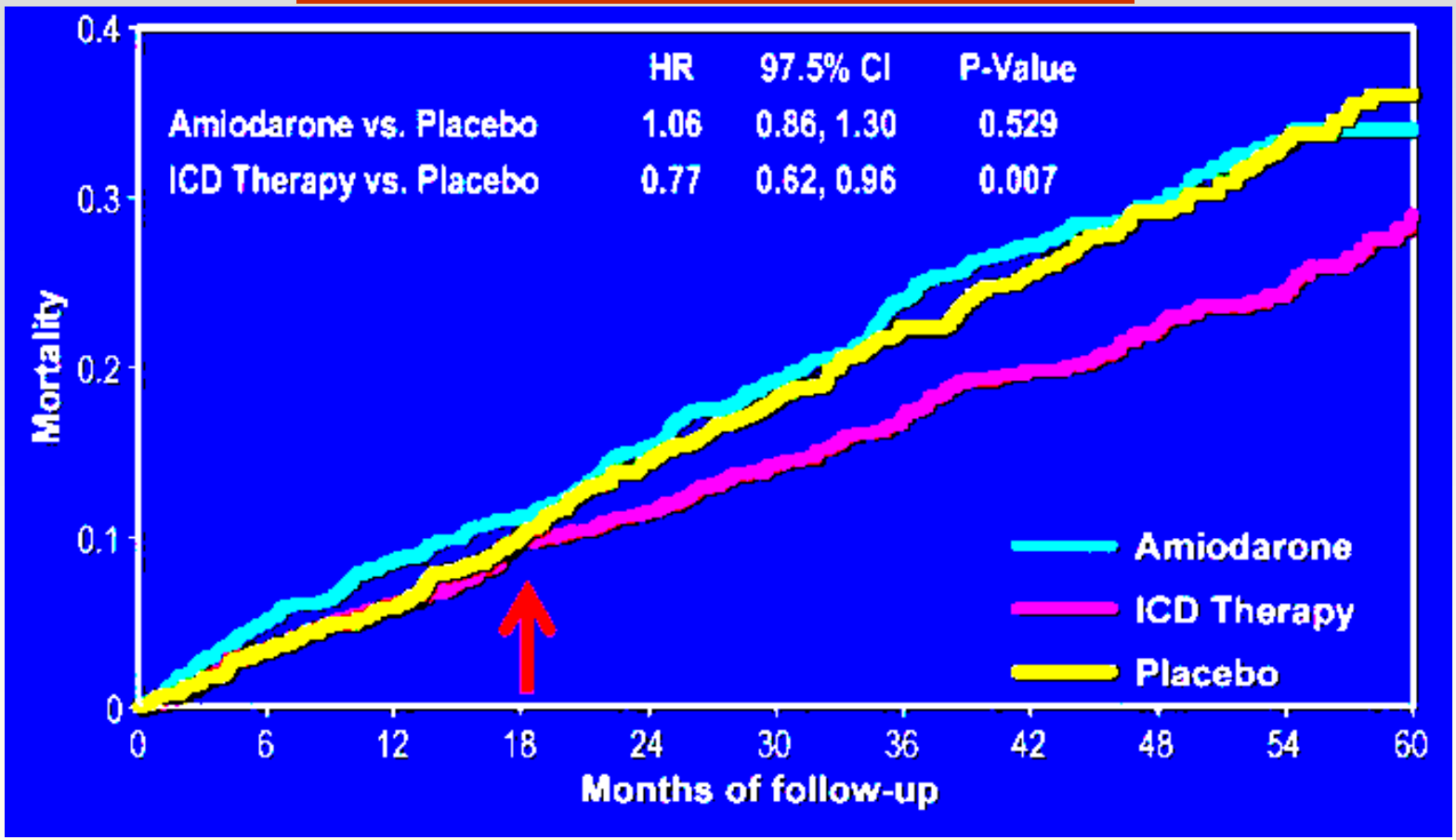


No. At Risk					
Defibrillator	742	502 (0.91)	274 (0.94)	110 (0.78)	9
Conventional	490	329 (0.90)	170 (0.78)	65 (0.69)	3

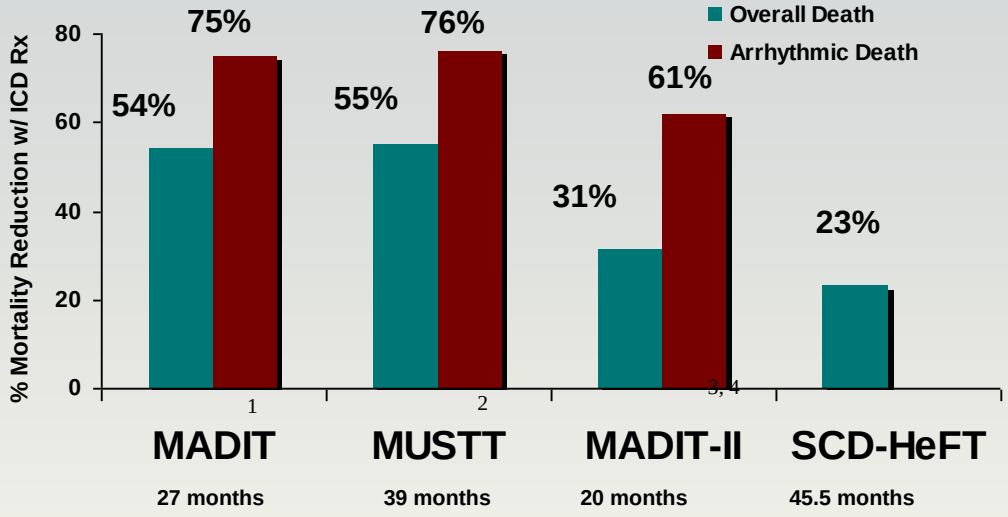
Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)

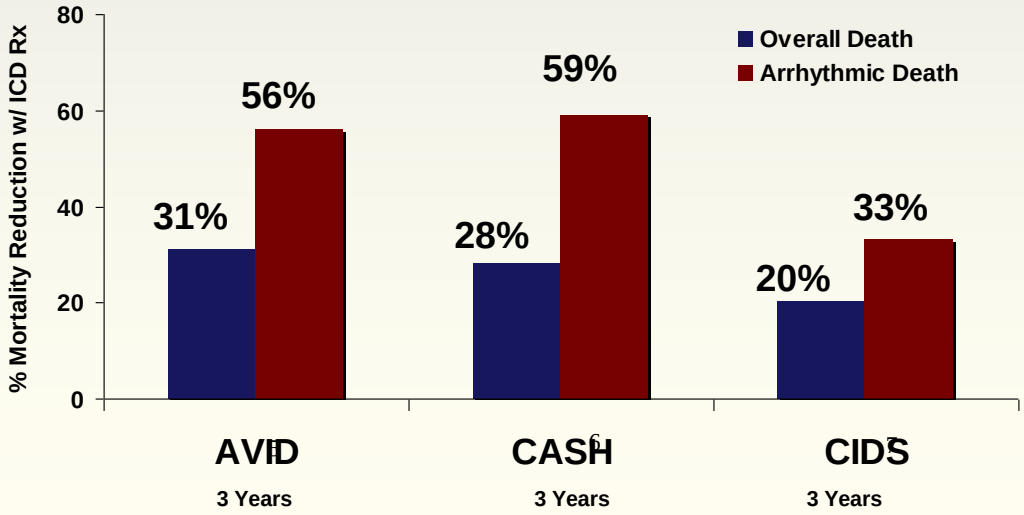
Bardy GH . N Engl J Med. 2004;352(3):225-37

ICD reduced mortality by 23%



MORTALITY RATE REDUCTION WITH ICDs





ICD mortality reductions in primary prevention trials <u>are equal to or greater</u> than those in secondary prevention trials

ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

POST-INFARCTION DILATED CARDIOMYOPATHY

Class I, level of evidence A

ICD therapy is recommended in patients with:

- ***Left ventricular dysfunction due to an earlier myocardial infarction, 40 days post MI***
- ***An ejection fraction of ≤ 30 – 40 %***
- ***NYHA class II or III***
- ***Receiving optimal pharmaceutical therapy***

Patients should have reasonable expectation of survival with a good functional status (> 1 year)

ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

NON ISCHAEMIC CARDIOMYOPATHY

Class I, level of evidence B

ICD Therapy is recommended for primary prevention, to reduce total mortality by reducing SCD in patients with:

- **Non ischaemic dilated cardiomyopathy**
- **LVEF ≤ 30 – 35 %**
- **NYHA class II – III**
- **Optimal Pharmaceutical Therapy**

Patients should have reasonable expectation of survival with a good functional status (> 1 year)

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

Post MI cardiomyopathies

Class I, level of evidence A

- **ICD therapy is indicated in patients with LVEF less than 35% due to prior MI who are at least 40 days post-MI and are in NYHA II or III.**
- **ICD therapy is indicated in patients with LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF less than 30%, and are in NYHA I.**

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

NON ISCHAEMIC CARDIOMYOPATHY

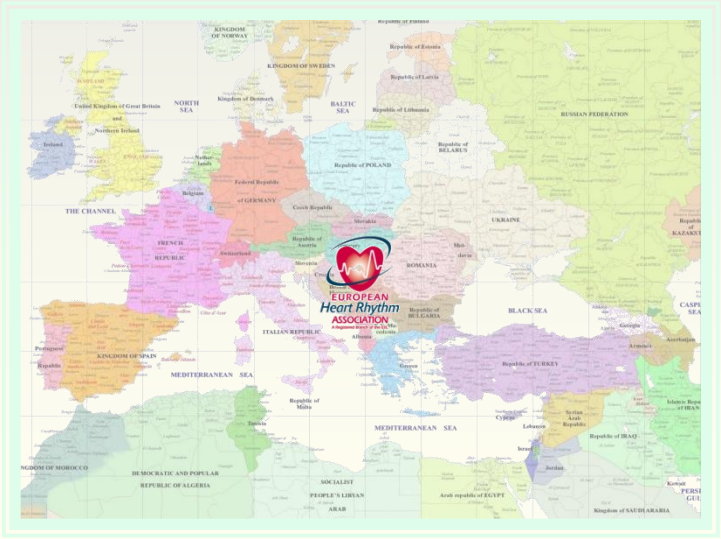
Class I, level of evidence A

ICD therapy is indicated in patients with non-ischemic DCM who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III

SUDDEN CARDIAC DEATH

Primary prevention

Clinical practice in Europe

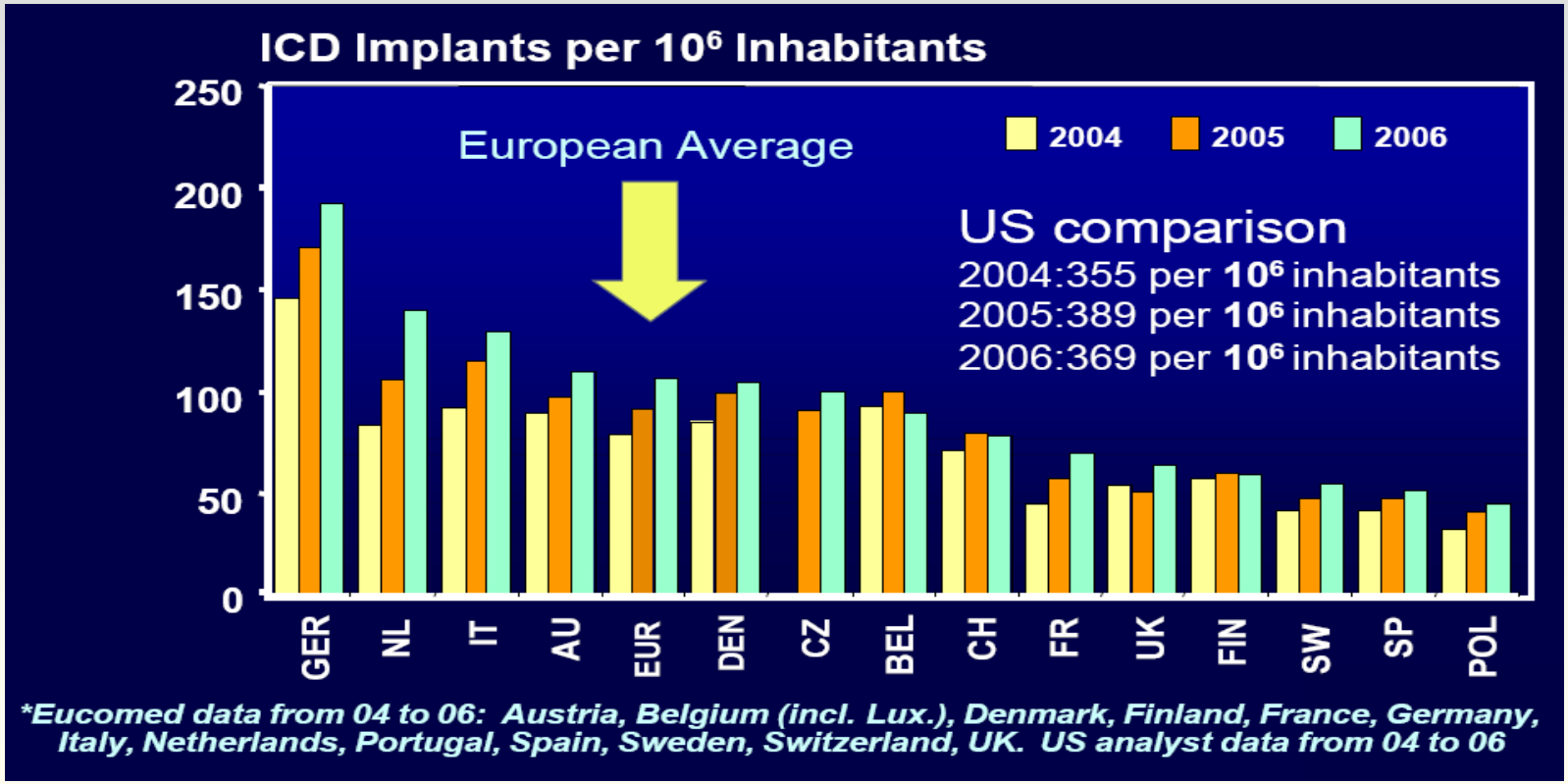


Introductory comments

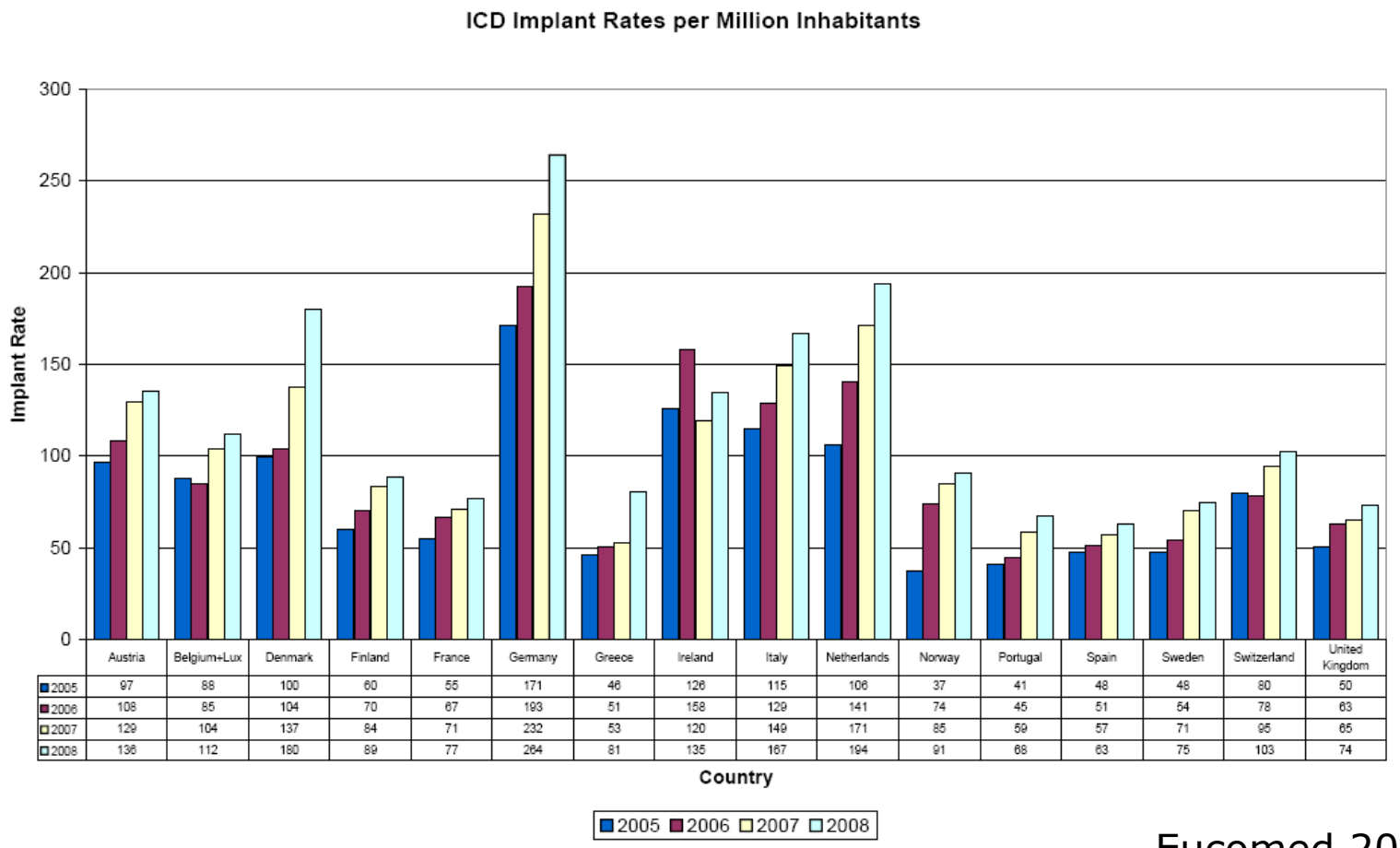
- Clinical decisions that concern the use of ICD, CRT-P and CRT-D devices in the various European countries are characterized by significant heterogeneity.
- The Guidelines that are followed are usually those of the ESC, in their unadulterated form or altered, sometimes national Guidelines (e.g. NICE) and not infrequently, the American Guidelines.
- The patient access to advanced medical technology and especially ICD, CRT-P and CRT-D varies significantly in different European countries as a result of numerous causes and reasons.

ICD use in Europe vs USA

2004 - 2006



ICD use in Europe
2005 - 2008

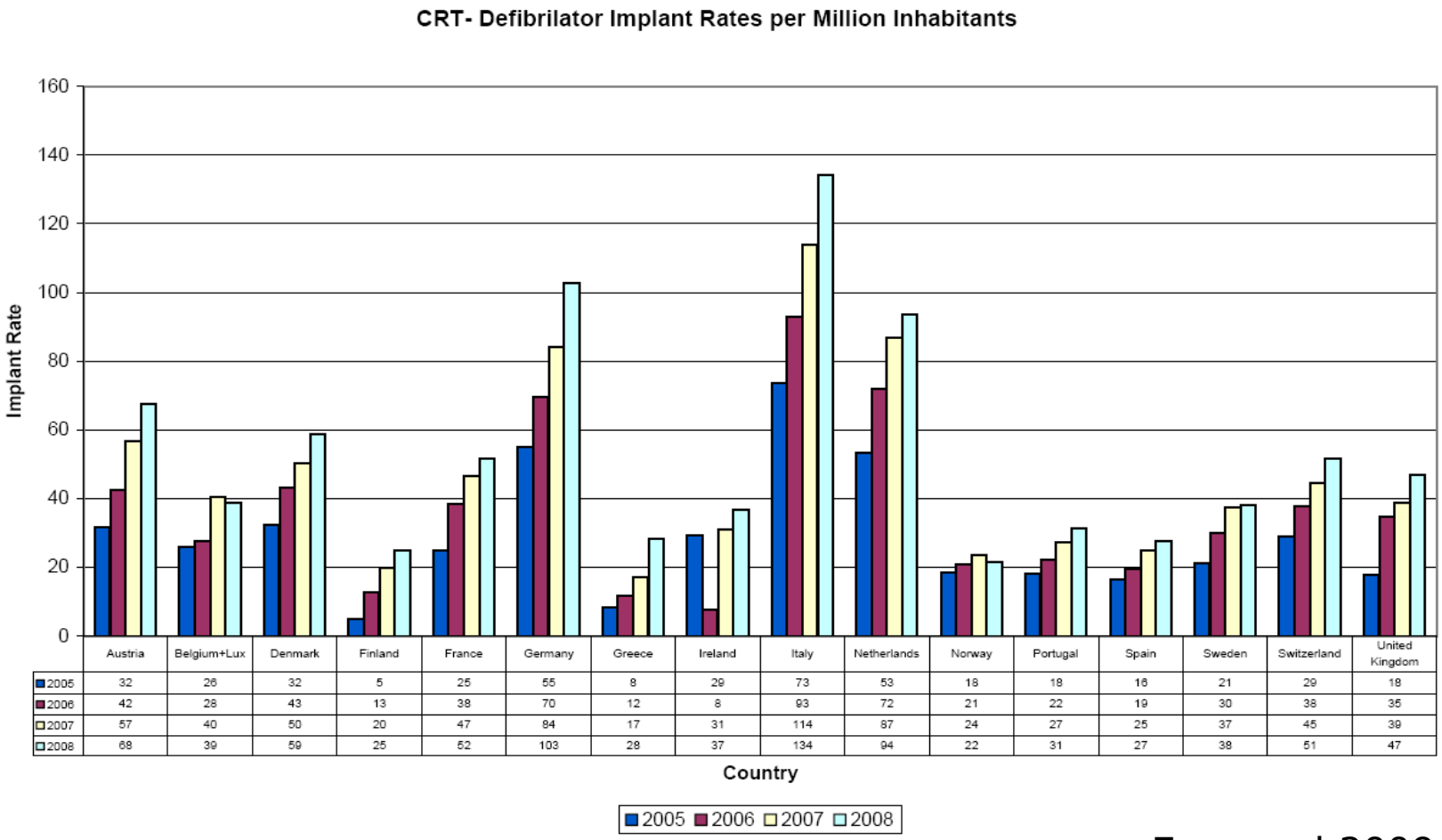


	Austria	Belgium+Lux	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
2005	97	88	100	60	55	171	46	126	115	106	37	41	48	48	80	50
2006	108	85	104	70	67	193	51	158	129	141	74	45	51	54	78	63
2007	129	104	137	84	71	232	53	120	149	171	85	59	57	71	95	65
2008	136	112	180	89	77	264	81	135	167	194	91	68	63	75	103	74

Eucomed 2009

CRT-D use in Europe

2005 - 2008

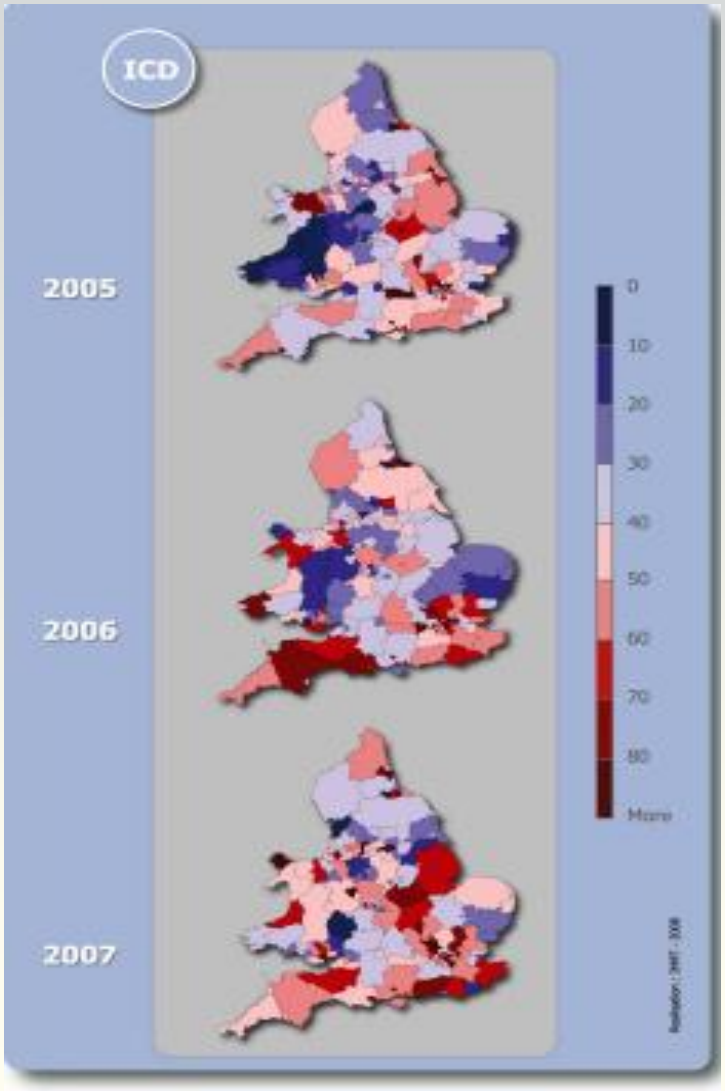


	Austria	Belgium+Lux	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Netherlands	Norway	Portugal	Spain	Sweden	Switzerland	United Kingdom
2005	32	26	32	5	25	55	8	29	73	53	18	18	16	21	29	18
2006	42	28	43	13	38	70	12	8	93	72	21	22	19	30	38	35
2007	57	40	50	20	47	84	17	31	114	87	24	27	25	37	45	39
2008	68	39	59	25	52	103	28	37	134	94	22	31	27	38	51	47

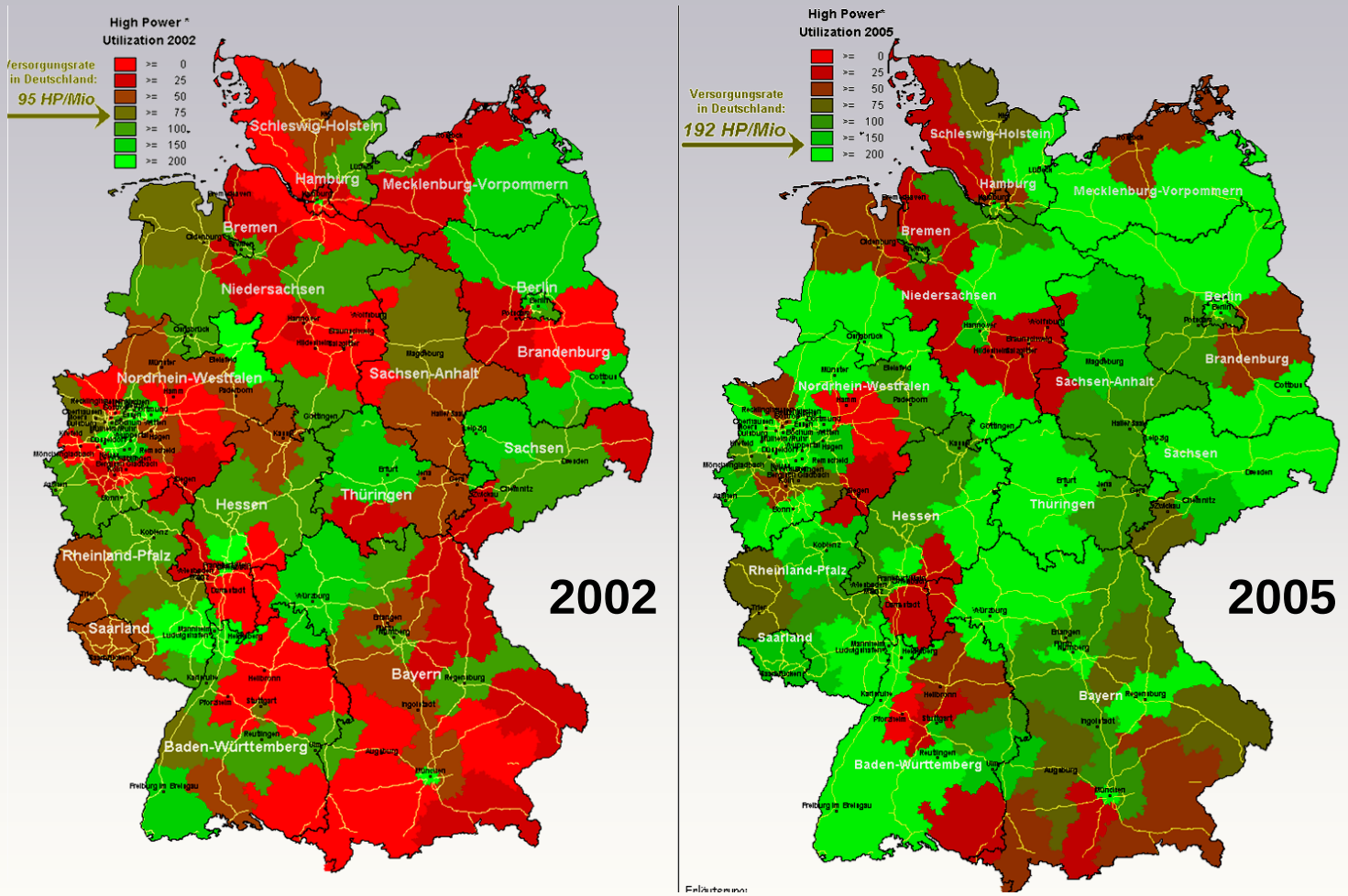
Eucomed 2009

Regional differences in ICDs implanation in UK.

Data from Heart Rhythm Devices: UK National Survey 2007

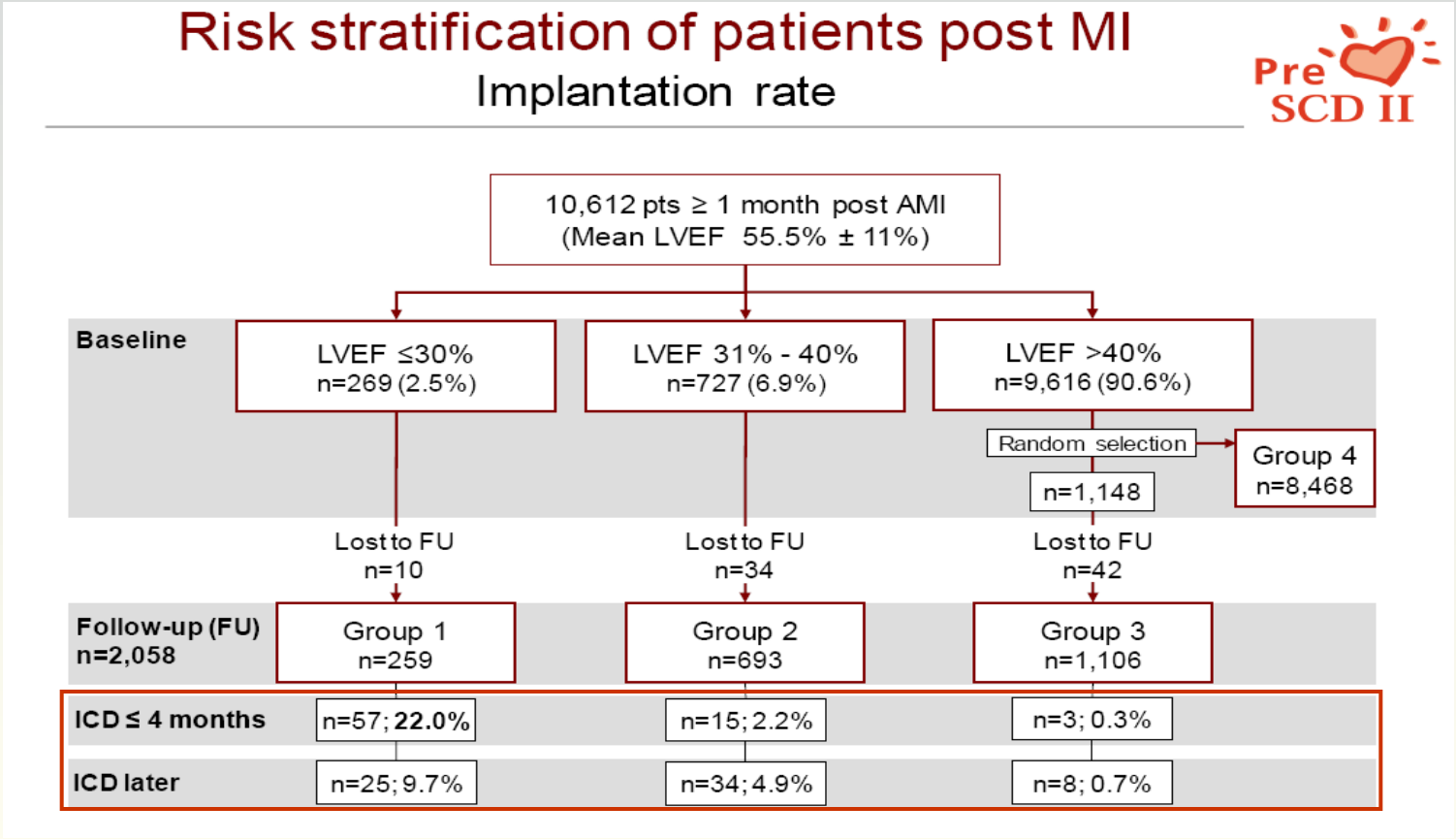


ICD implantation rate per million population in Germany in 2002 - 2005



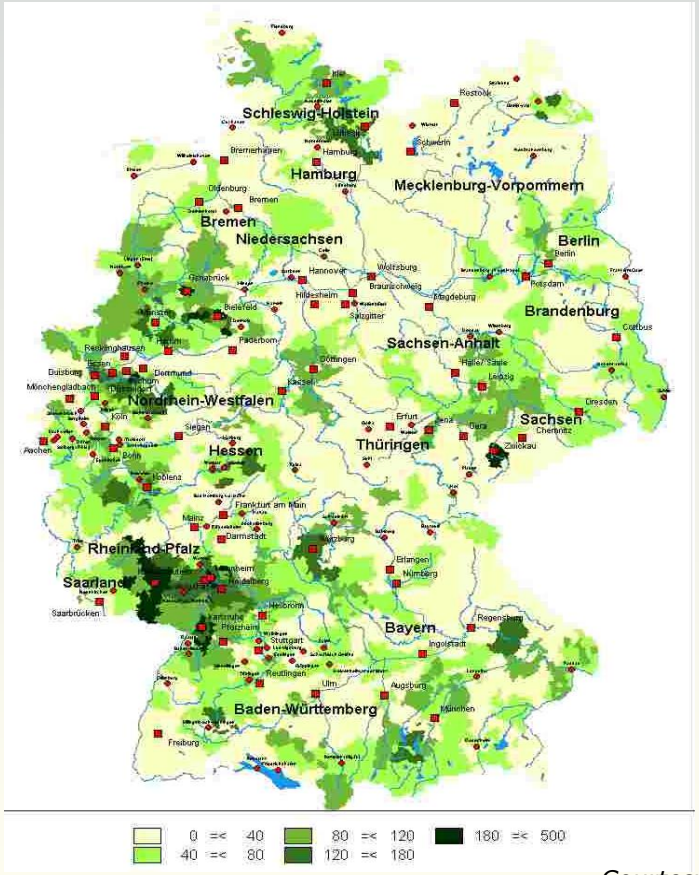
We need to recognize that even in Germany there remains a significant difference in implantation rates in the various regions

Pre SCD Registry



Voller H et al. ESC 2009

Pre SCD Registry



Courtesy of C. Wolpert

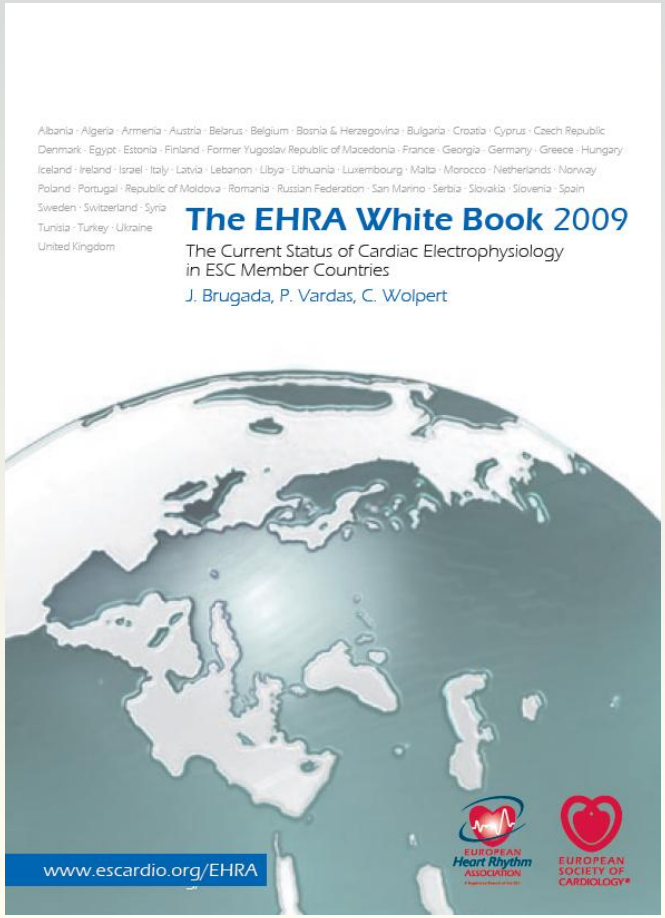
- **Showed a reduction in total mortality of 20.2 % at 36 months post MI (in pts with LVEF ≤ 30 %)**
- **Benefit restricted mainly to those patients who received an ICD at 11 months post MI**
- **Few patients with guideline-based ICD indications received ICD therapy**

European Heart Rhythm Association
Main Actions

- One of the main roles of EHRA, is to promote equal access to therapy for all patients across Europe.

- The first step was to compile data on the current situation in various ESC membership countries, compare them, and propose actions to move towards harmonization.

The European White Book of Electrophysiology:
The first necessary step towards equal access to therapy in Europe



The Value of the White Book
Observations

Significant diversity exists among European countries in:

- The age distribution of the population
- Gross Domestic Product (GDP)
- The percentage of the GDP devoted to health expenditure
- Health systems (Private vs Public)
- Medical education and EP training

The Value of the White Book
Observations

Significant diversity exists among European countries in:

- **Healthcare data**
  - Hospitals (per 100.000 population)
  - Beds (per 100.000 population)
  - Density of physicians (per 1.000 population)
  - Density of nurses (per 1.000 population)
- **Pacemaker –ICD-CRT implantation rates**
- **Number of Ablations performed**

CRT-D use in Europe in 2007

The highest CRT-D implantation rate per million (upper quartile)		The lowest CRT-D implantation per million (lower quartile)	
Italy	93,47	Georgia	1,08
Netherlands	85,63	Slovenia	1,00
Germany	84,13	Tunisia	0,96
Israel	68,33	Russian Federation	0,43
Czech Republic	58,57	Estonia	0,37
Austria	57,44	Lithuania	0,28
Denmark	50,11		
France	46,34		
United Kingdom	38,83		

EHRA White Book

Europe
GDP/Health expenditure %

	Country	Total expenditure on health as % of GDP	GDP/head ($)
	Austria	10.3	45,181
	Croatia	7.7	14,414
	France	10.5	41,511
	Germany	10.6	40,415
	Greece	9.9	33,433
	Norway	9.7	83,922
	Russia	6	9,075
	Spain	8.1	32,066
	Turkey	7.7	9,629

EHRA White Book

SUDDEN CARDIAC DEATH

Primary prevention

Cost-Effectiveness Issues

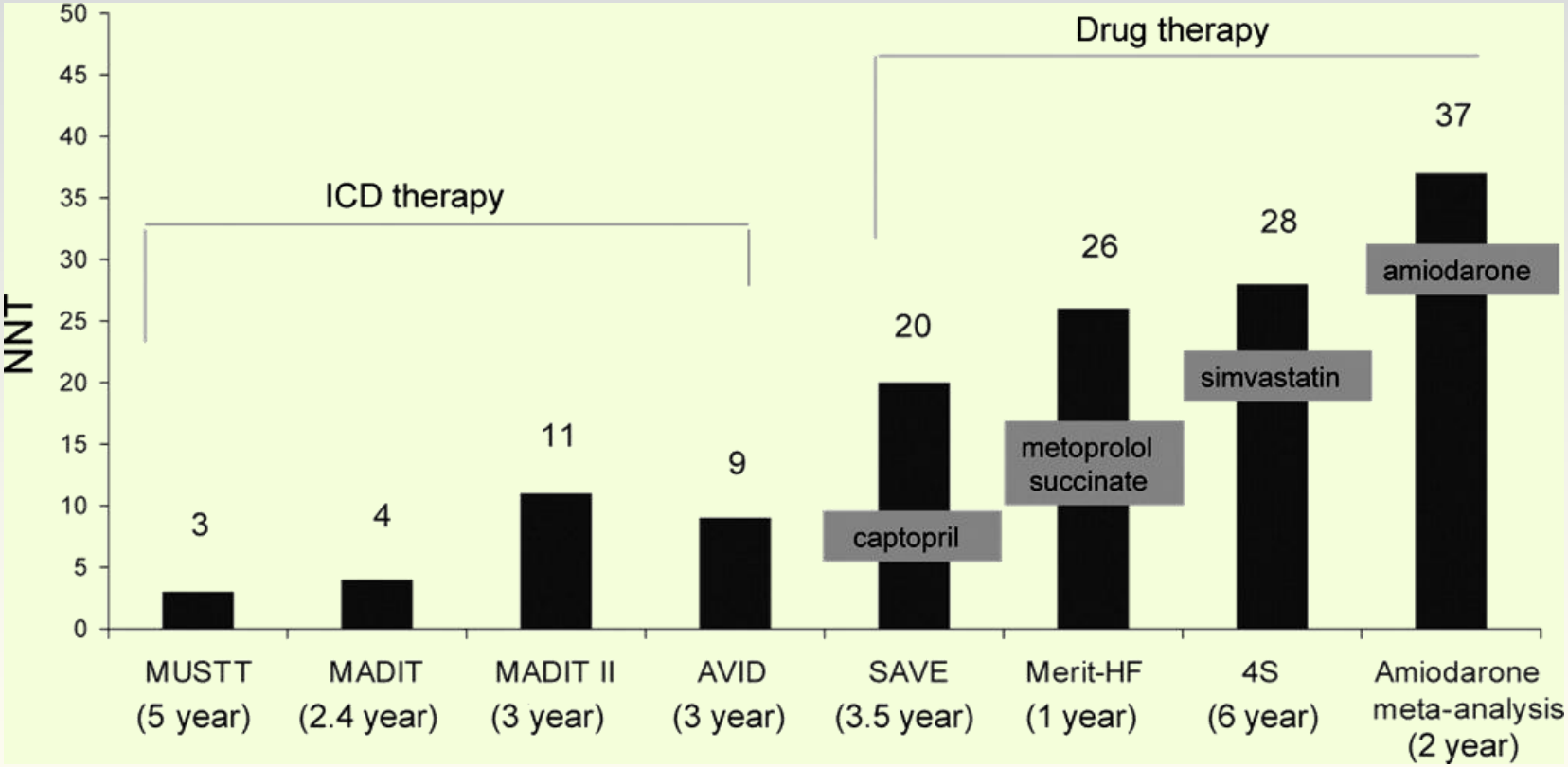
IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

Cost - Effectiveness Issues

- ICD therapy generally costs more than conventional management of cardiac arrhythmias but is more effective as compared to the therapy with amiodarone
- The cost-effectiveness ratio of ICD therapy and Annual All Cause Cardiac Mortality has a U shape
- The cause-effectiveness ratio becomes non-profitable at either low or very high percentages of Annual All Cause Cardiac Mortality

PRIMARY PREVENTION OF SCD AND ICDs

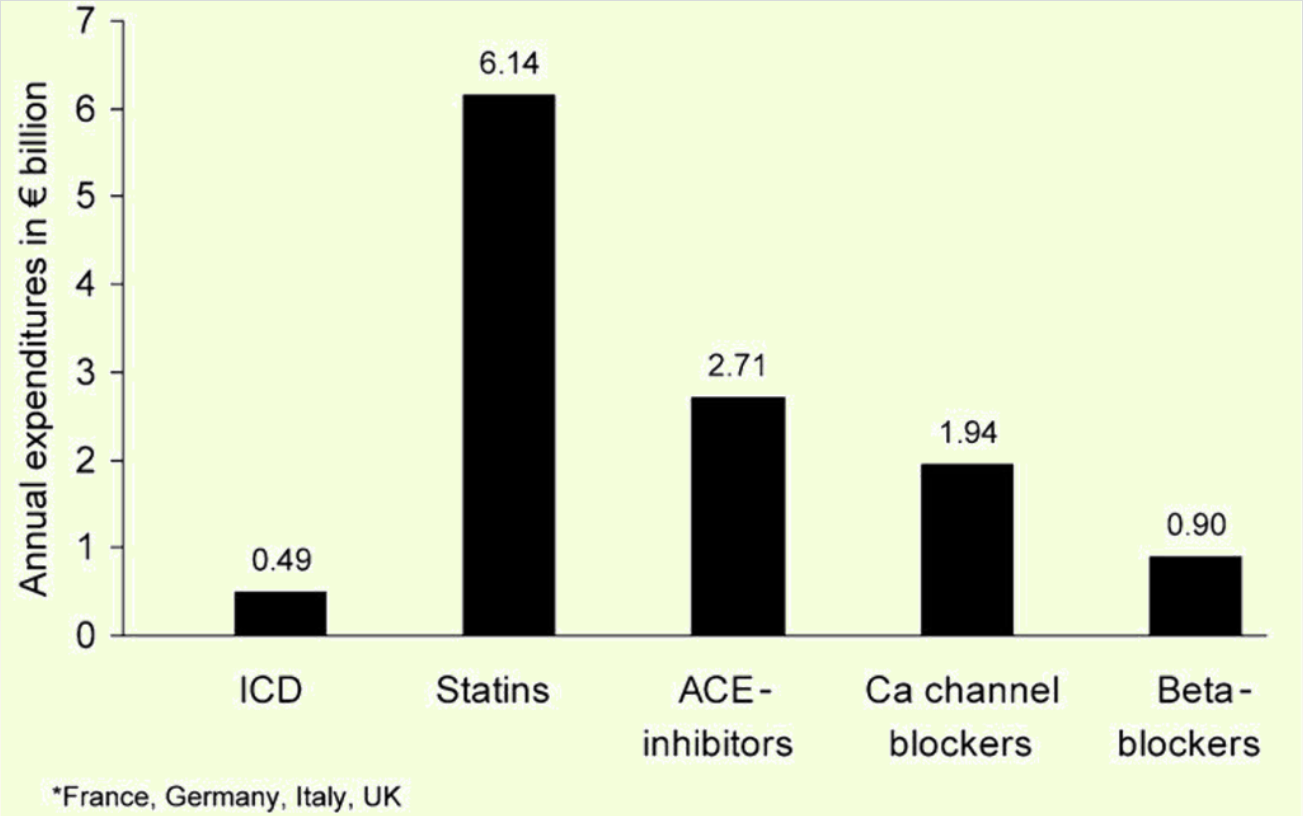
Is the NNT too high?



Camm J. et al, *European Heart Journal* (2007) 28, 392–397

PRIMARY PREVENTION OF SCD AND ICD COST

What is the relationship between drug therapy and ICDs?



This figure compares various therapy costs for 2004 in four major European countries

Camm J. et al, *European Heart Journal* (2007) 28, 392–397

SUDDEN CARDIAC DEATH

Implementation of ESC SCD Guidelines

Is it Primarily a Scientific, Political, or Financial Matter?

Implementation of ESC SCD Guidelines
A lack of education?

- A large number of cardiologists, perhaps even the majority, in various European countries are unaware of significant parts of the guidelines.
- It must become more widely known that the guidelines have been proved to contribute to improvement in patients' quality of life and life expectancy.
- We must overcome the reservations of those who question or reject the guidelines without providing clear justification, simply expressing their flat disbelief, for this or that reason.

Implementation of ESC SCD Guidelines
A political matter?

- Most governments in ESC countries give priority to limiting health care expenditure and are aggrieved when faced with the increased expenses that the guidelines often entail.
- It must be admitted here that the cost of implementing guidelines is indeed often insupportable for a significant number of countries in the European Union.
- Very often the policies of some governments disregard and diverge widely from the recommendations issued by their own national cardiological societies with regard to such topics.

Implementation of ESC SCD Guidelines
A financial problem?

- The cost of complete implementation of the guidelines often stands as an insurmountable obstacle for the economies of many countries of the European Union.
- The map of European economies shows material differences, where countries with a per capita income of €70,000 coexist besides those with a per capita income of €4,000.
- I personally believe that for countries with a per capita income below €25,000 the cost is the main reason for non-implementation of the guidelines.

CONCLUSIONS

- Clinical effectiveness of ICD for the primary prevention of SCD is proven.
- Therapy cost effectiveness continues to be a thorny issue.

CONCLUSIONS

- The implementation of the current guidelines is expensive.
- The MADIT II criteria can only be universally implemented in a limited number of countries.
- This life saving, but relatively expensive treatment with ICDs, needs to be implemented with caution, thoroughness and knowledge.

CONCLUSIONS

- The ESC has as a strategic priority, not only the production of high-quality guidelines, but also their correct implementation.
- The national societies have shown interest and understanding with regard to the need for implementation.
- What is needed is systematic and organised collaboration between national societies and the ESC and an assessment of the results on an annual basis.

Government dilemma

Spending the taxpayers' money

4.5 million €

14-18 million €

14 million € annual front cost for UK