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Foreword

The European Heart Rhythm Association (EHRA), a branch of the European Society of Cardiology (ESC), in observance to its mission - To improve the quality of life of the European population by reducing the impact of cardiac arrhythmias and reduce sudden cardiac death – is proudly announcing the launch of a Supplement to EP Europace Journal dedicated to the EHRA White Book entitled: *Statistics on the Use of Cardiac Electronic Devices and Electrophysiological Procedures in the ESC 54 countries: 2012 Report from the European Heart Rhythm Association*.

The report represents a structured analysis of data collected in the EHRA White Book, an important monograph published by EHRA since 2008. The current report brings together the most up-to-date statistics on electrophysiological procedures including the implantation of cardiovascular electronic devices in the 54 ESC countries and includes all data of the first five Editions of the EHRA White Book. The report has been arranged to present the full information about the historical perspective of the EHRA White Book, the methodological aspects of the data collection and analysis of major treatments of heart rhythm disorders: Implantable Pulse Generators (IPGs), Implantable Cardioverter Defibrilators (ICDs), Cardiac Resynchronization Therapy (CRTs) and Catheter Ablation Procedures. Moreover, the increasing relevance of societal and economic implications of life-saving therapies led EHRA to give particular emphasis to them in a section of the current report.

The figures and tables of this report speak by themselves and clearly highlight significant inequalities in healthcare In Europe, with an additional very large treatment gradient from West to East. These inequalities in healthcare are not specific of one treatment but equally apply to all therapies considered in the EHRA White Book. Barrier to access to different therapies are not only represented by the heterogeneous reimbursement system in ESC countries or by other country-specific economic considerations; there is a lack of proper infrastructures, of properly trained healthcare professionals, and appropriate dissemination of information about efficacy of many electrical therapies for cardiac rhythm disorders.

We are convinced that the current report may be a valuable resource for researchers, clinicians, healthcare policy makers, media professionals, the lay public, and many others who seek the best European data available on national centers availability performing electrophysiological procedures, number of electrophysiological procedures and implanted electronic devices for heart rhythm management, key economic aspects related to the management of cardiac rhythm disorders, and important insights in the gaps of guidelines implementation in each of ESC countries.

Historical background and methodology

The idea to create a White Book was born when preparing the EHRA Spring Summit in 2007 which was held under the motto "*Education and Guideline Implementation*". Just a short time before this event, new guidelines on cardiac pacing and cardiac resynchronization therapy had been published. It was hypothesized that education and guideline implementation were heterogeneous within the 51 countries then represented by the European Society of Cardiology (ESC). In order to focus the summit discussion, it was deemed more than necessary to assess the *status quo* for the whole ESC countries. Therefore, it was planned to have a certain number of countries to present their current status of activity in the field of arrhythmia treatment encompassing number of centres, number of procedures, number of physicians, obstacles to guideline implementation, type of health care insurance system etc. This snapshot should enable to identify future needs for action. During the meeting, it became immediately obvious that a large gap in both education and guideline implementation exists between the different European region, including Middle East, Central and Eastern Europe. Moreover, the significant inequality in arrhythmia management by device could not be explained only by the different the economic status of the various countries.

At the beginning of the EHRA White Book project a task force was formed out with members of the EHRA National Societies Committee. The first action of the task force was to develop a comprehensive questionnaire to be sent to each ESC national working group or national society. This questionnaire included key aspects related to the national practice of device implantation as well as to education of device implanters and guidelines implementation.

The first edition was published in 2008 and contained data from 2007. A total number of 37 out of 51 countries participated in the EHRA White Book by submitting their country data for the first edition. The voluntary participation then grew from year to year especially due to the increasing intensity of communication between EHRA and the national working groups or national societies. On the occasion of each annual EHRA Spring Summit new countries presented their data. The deadline for data provision, for data validation and printing became a routine process so that each country chair or president is now used to fill in the national data into EHRA White Book in the first quarter of the new year. National registries when in place are synchronised to the EHRA White Book. Noteworthy, the increasing use of EHRA White Book data by different stakeholders operating in the national health care system has significantly motivated the participating countries now leading to a closer adherence to the data collection process.

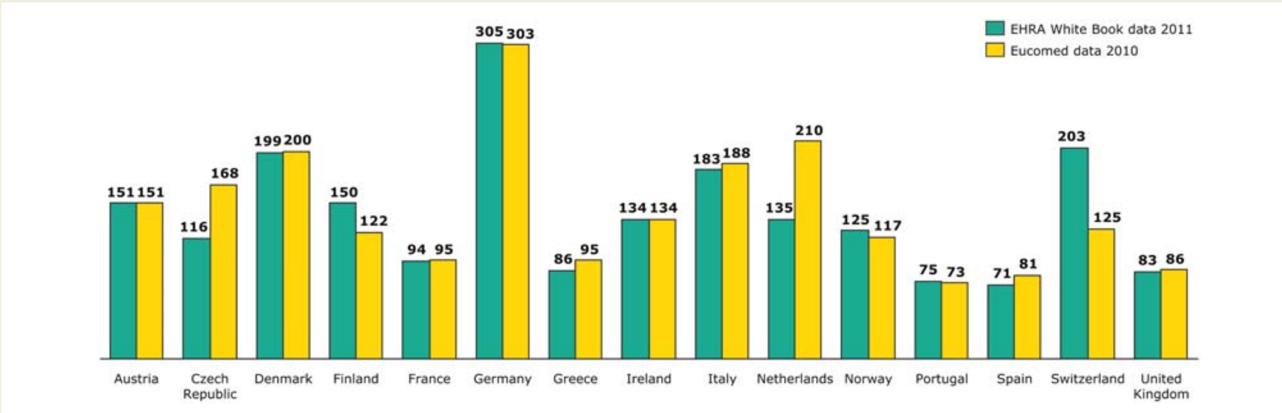

Figure 1. Comparison of ICD implantation rate as reported by EHRA White Book 2011 Edition with Eucomed 2010 implantation rate. The Eucomed data underline the consistency of EHRA White Book data and the reciprocal use would have led to similar results. **URL:** http://www.eucomed.org/uploads/_medical_technology/facts_figures/110518_statistics_for_cardiac_rhythm_management_products_20052010.pdf; February 01, 2012

Since then, the EHRA White Book has been used by many national societies for negotiations with governmental bodies, health care providers, insurance companies and the EHRA White Book has become a benchmark for other scientific societies operating in the field of cardiovascular medicine, such as the British Cardiovascular Society. On February 20th 2012 and for the first time, the EHRA White Book has appeared on the European Union Health web-portal. This historical step opens the access to a significantly larger group of user including European healthcare governmental agencies, international healthcare organizations, regulatory bodies and media organization. Finally, the EHRA White Book data have been reorganized in such a way to provide clinically meaningful trend in the use of cardiac implantable electronic devices and catheter ablation procedures. The current publication represents the result of this effort.

Methodology

Starting in 2008, a European wide survey of electrophysiological procedures in all ESC country members has been performed annually to record temporary trends in different electrophysiological procedures in Europe. Moreover, the data collection included the number of centers performing different interventions and implantations, the profile of implanting physicians, and the availability of reimbursement for some electrical therapies has been collected. Therefore, the report of these interventions and implantation procedures in 2012 represent the 5th edition of the yearly census (EHRA White Book 2012).

Data research was conducted using a primary and secondary approach which will be briefly described.

Primary research is conducted within national cardiology societies and working groups of cardiac pacing and electrophysiology of each country. Each chairman of the societies and/or working groups were asked to compile information about their country based on a detailed questionnaire, together with instructions and examples for completion. The repeating data for the past years are prefilled in the questionnaire. The data gathered by the societies and working groups were from a number of national sources, but mainly national registries and national health institutions. Some countries, however, did not have available data for all of the sections of the book.

Secondary research has been conducted with the help of reliable official online databases to cross verify and build the quantitative and qualitative information contained in the book. Three major source of information have been used: healthcare data were extracted from the World Health Organization (WHO) - European health for all database (http://data.euro.who.int), whereas demographic information were taken by the United States Census Bureau International Database (http://www.census.gov), and finally, the source of economic information has been the International Monetary Fund (IMF) World Economic Outlook Databases (http://www.imf.org).

A detailed overview with the sources that were used for the EHRA White Book 2012 edition can be found in the appendix. For some information the last available values were used.

Once the primary and secondary research has been completed, the national societies or working groups are asked to verify and authorize the publication of the information. All data were entered into a central database. In case of missing or incomplete data, the national representatives were reminded repeatedly for completion or correction.

In the first edition of EHRA White Book, a total number of 37 out of 51 ESC countries submitted to EHRA the data. Since then, the participation was growing. In the year 2012, 46 out of 54 ESC countries reported their data. In the year 2012 complete or usable data were available in 2012 for the following countries:

Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia & Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Egypt, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, FYR Macedonia, Malta, Montenegro, Morocco, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, San Marino,

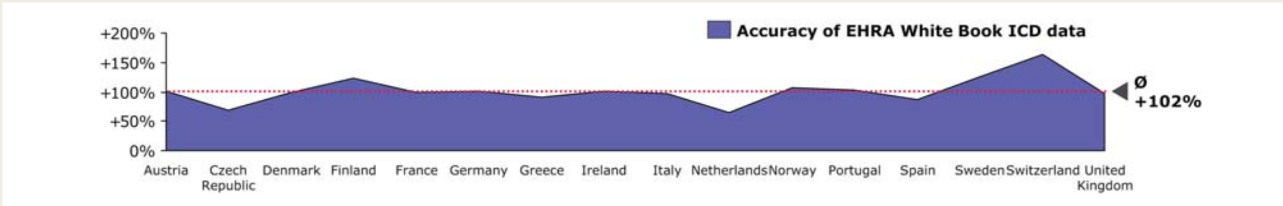

Figure 2. High accuracy of the EHRA White Book implant rates in comparison with Eucomed data. **URL:** http://www.eucomed.org/uploads/_medical_technology/facts_figures/110518_statistics_for_cardiac_rhythm_management_products_20052010.pdf; February 01, 2012

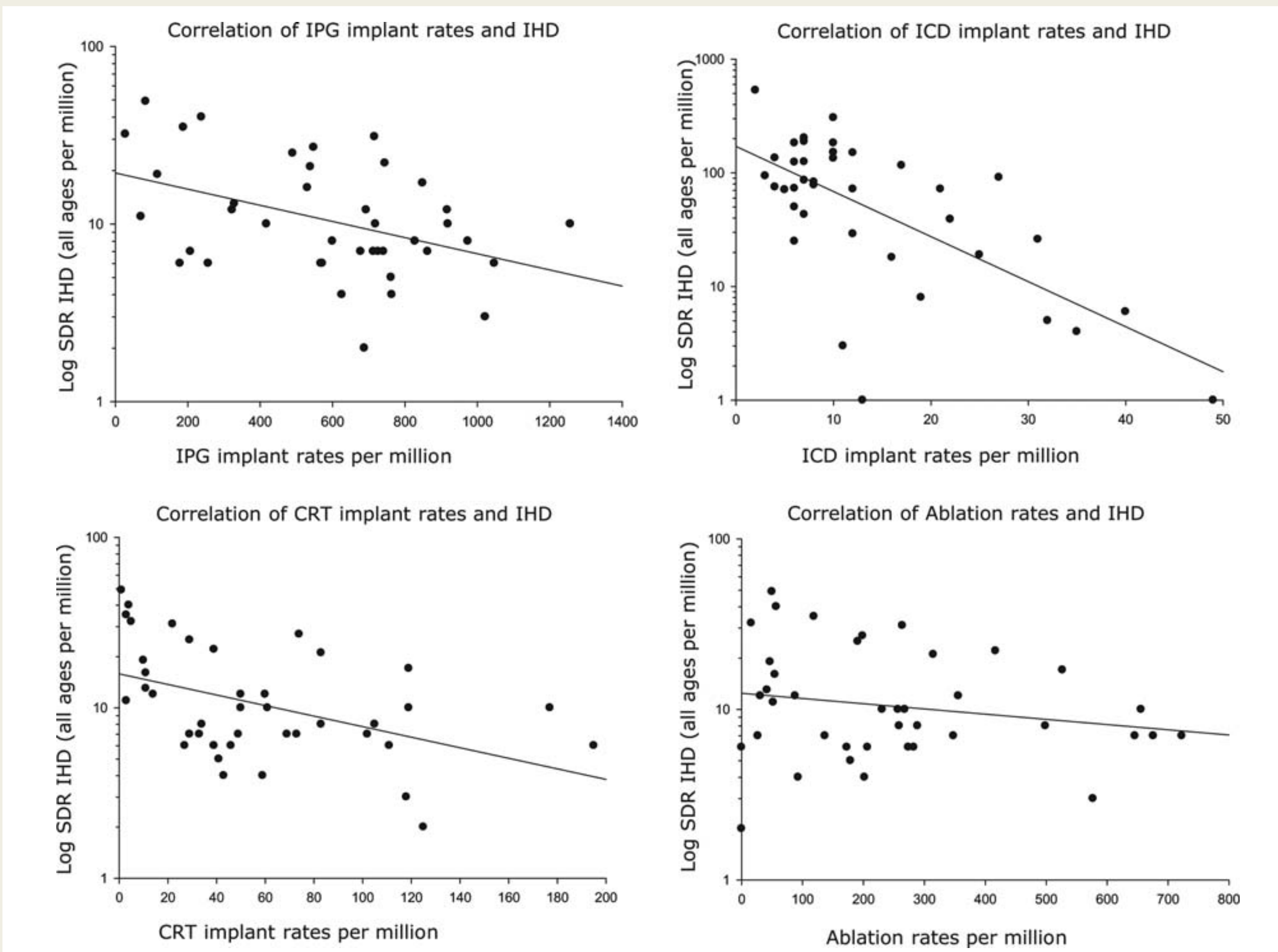

Figure 3. Calculations for correlations between implant rates dealing with SDR-Ischemic Heart Disease (IHD) for people of all ages. "All ages" being included, for the IPG, ICD and CRT implant rates significant negative correlations were found. It does matter which age group is being considered. For people of all ages, there were moderate to medium sized correlations.

Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tunisia, Ukraine, and United Kingdom.

In contrast, no data were available for the following countries:

Albania, Algeria, Kosovo, Lebanon, Libya, Republic of Moldava, Syria, and Turkey.

The EHRA White Book database as source of many analysis presented here has been carefully checked and cleaned. Additionally, many data had to be inferred from databases as IMF, WHO and EUROSTAT. Reliability cannot be guaranteed in every case especially for the North African and Near East Countries. Officially published and available data from Eucomed (http://www.eucomed.org/uploads/_medical_technology/facts_figures/110518_statistics_for_cardiac_rhythm_management_products_20052010.pdf) have been used as benchmark for consistency with EHRA White Book 2011 data. When comparing the Eucomed 2010 data with the EHRA White Book 2011 data (using 2010 data) a high

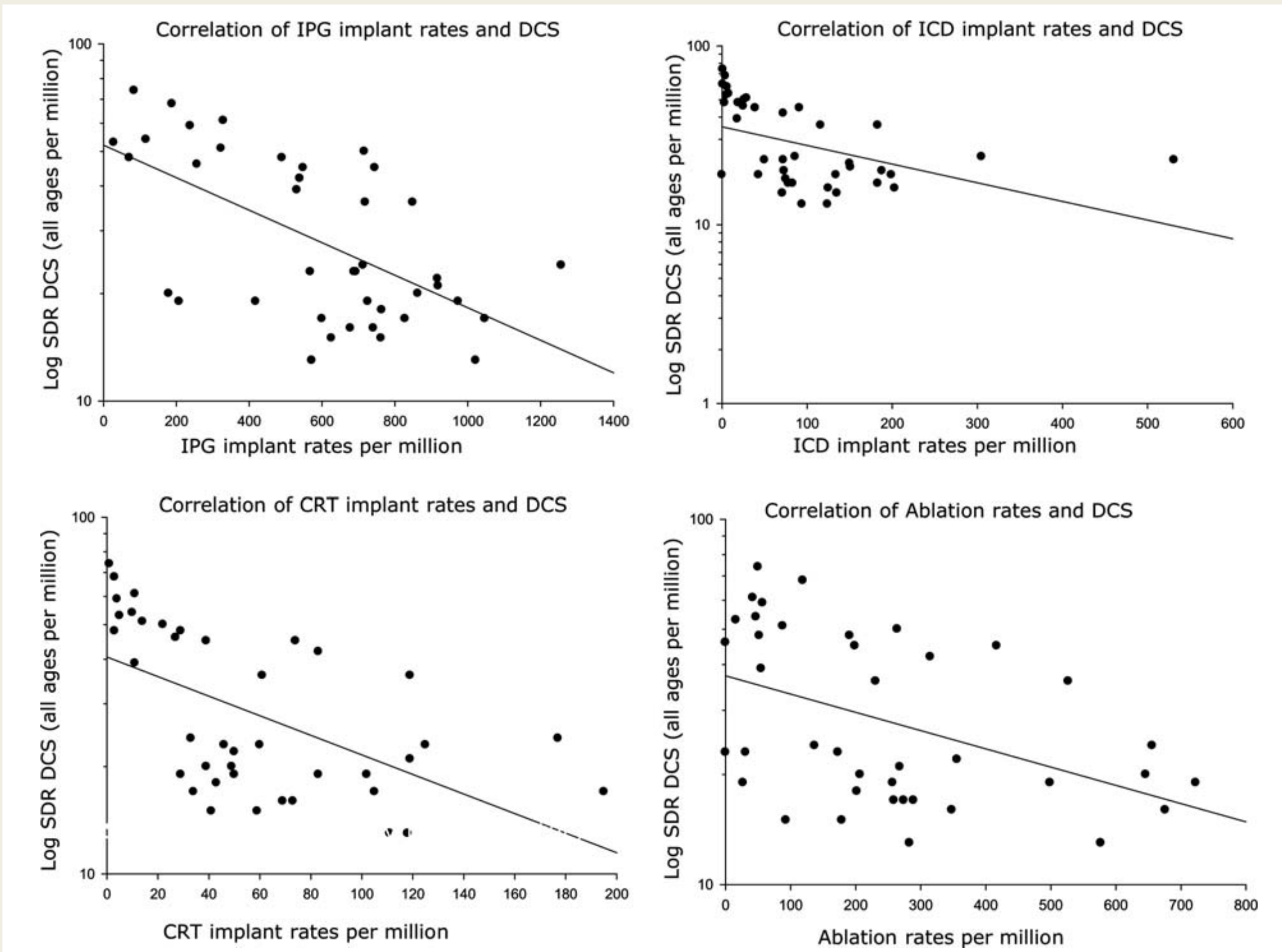

Figure 4. Calculations for correlations between implant rates dealing with SDR-Diseases caused by the Circulatory System (DCS) for people of all ages. The IPG, ICD and CRT implant rates exhibit highly significant negative correlations with regard to diseases of circulatory system for people of all ages in 2011. In this case, the ablation rate is also significant. For people of all ages, there were moderate to medium sized correlations.

level of accuracy is apparent. The level of accuracy of EHRA White Book has been recently tested for selected countries for device therapies used in 2010 and is presented as an example for ICD in Figure 1 as well as in Figure 2. Overall, there was a very high consistency in the implantation rates of implantable pulse generators, implantable cardioverter-defibrillator, and cardiac resynchronization therapy reported by Eucomed in 16 European countries and those reported the national working groups or societies. Eucomed IPG, ICD, and CRT data underline the consistency of EHRA White Book data. The level of accuracy for ICD was 102% (Figure 2).

The EHRA White Book 2008-2012 analysis has been based on latest available numbers. The primary and secondary research were undertaken from February 2012 until May 2012. The main methodology of the analysis was to find strong statistically significant correlations across all available European EHRA countries between implant rates and pre-defined main influencing variables. The following variables have been included in the analysis: Country specific information including healthcare overall data, demographic and economic information, healthcare system, implant rates for pacemaker devices, implant rates for cardiac resynchronization therapy devices, implant rates for implantable cardiac defibrillator devices, ablation rates for electrophysiology catheters.

The data has been carefully checked before running the analysis, some missing values have been replaced mainly by IMF, WHO and EUROSTAT data. This was mainly done for countries from South Mediterranean or Near East Region. Values which have been found to be highly implausible were then either deleted or replaced by the subsequent valid information of the above stated retrospective search algorithm.

Starting from 2012, an analysis between EHRA White Book IPG, ICD, CRT, ablation rates and the two selected WHO variables standardized death rate based on diseases of circulatory system and standardized death rate based on ischemic heart diseases has been performed. It was questioned whether diseases of circulatory system and ischemic heart diseases correlate with some types of implant rates (as IPG, ICD, CRT and ablations) on a global scale (Figures 3 and 4). The country-specific data about all four types of implant rates was collected from EHRA White Books, years 2008-2011. Highly implausible values were either

Table 1 Pacemaker facilities and IPG implantations in 2011

Country	ISO Code	Population 2008	Population 2009	Population 2010	Population 2011	Number of IPG implanting centers: Absolute number	Number of IPG implanting centers: per mil inhabitants	Specialty performing implants (%): Cardiologists	Specialty performing implants (%): Surgeons	Specialty performing implants (%): Other	National Registry for IPG implants	IPG implantations: Absolute number	IPG implantations: per mil inhabitants	IPG implantations per mil inhabitants 2008	IPG implantations per mil inhabitants 2009	IPG implantations per mil inhabitants 2010	IPG implantations per mil inhabitants 2011
Armenia	AM	3,234,031	3,243,729	3,092,000	2,967,975	2	0.67	97	3			396	133	92	65	124	133
Austria	AT	8,336,549	8,363,040	8,394,000	8,217,280	61	7.42	30 - 50	50 - 70		Yes	7,810	950	908	948	919	950
Azerbaijan	AZ				9,397,279	5	0.53	90	10			141	15				15
Belarus	BY	9,680,841	9,665,120	9,595,000	9,577,552	10	1.04		100		Yes	2,474	258	164	196	238	258
Belgium	BE	10,480,393	10,646,804	10,712,000	10,431,477			75	25		Yes				589	580	
Bosnia & Herzegovina	BA	3,842,265	3,838,161	3,760,000	4,622,163	6	1.30	20	80			636	138			205	138
Bulgaria	BG	7,623,395	7,585,131	7,494,000	7,093,635	14	1.97	99	1		Yes	2,730	385	320	360	329	385
Croatia	HR	4,434,508	4,429,078	4,403,000	4,483,804	16	3.57	87	13		Yes	2,532	565	488	513	531	565
Cyprus	CY	793,007	803,147	1,104,000	1,120,489	5	4.46	100				250	223	315	249	208	223
Czech Republic	CZ	10,429,692	10,491,492	10,493,000	10,190,213	37	3.63	90	10		Yes	8,980	881	805	859	849	881
Denmark	DK	5,489,022	5,519,441	5,550,000	5,529,888	14	2.53	100			Yes	4,397	795	737	713	744	795
Egypt	EG																
Estonia	EE	1,340,675	1,340,271	1,341,000	1,282,963	5	3.90	80	20		Yes	983	766	830	770	745	766
Finland	FI	5,313,399	5,338,871	5,365,000	5,259,250	25	4.75	95	5	5- Internist		4,852	923	793	796	917	923
France	FR	62,130,520	62,342,668	62,787,000	65,102,719	492	7.56	95	5		Yes	63,100	969	1,014	1,029	1,022	969
Georgia	GE	4,383,750	4,410,900	4,352,000	4,585,874	8	1.74	90	10			383	84	63	60	71	84
Germany	DE	82,119,776	81,874,768	82,302,000	81,471,834	1,041	12.78	58	30	12 - Surgeons, pediatric surgeons, pediatric cardiologist	Yes	106,953	1,313	1,197	1,248	1,257	1,313
Greece	GR	11,237,068	11,282,751	11,359,000	10,760,136	56	5.20	95	5		Yes	7,548	701	679	611	713	701
Hungary	HU	10,038,188	10,022,650	9,984,000	9,976,062	16	1.60	90	5	5 - Anaesthesiologists	Yes	5,822	584	466	532	539	584
Iceland	IS	319,355	319,246	320,000	311,058	2	6.43	100			Yes	313	1,006	855	836	828	1,006
Ireland	IE	4,422,077	4,459,305	4,470,000	4,670,976	17	3.64	100			Yes	2,367	507	396	457	418	507
Israel	IL	7,308,795	7,485,600	7,418,000	7,473,052	22	2.94	5	5	90 - Cardiac electrophysilogists		3,737	500	445	567		500
Italy	IT	59,832,180	60,192,696	60,551,000	61,016,804	400	6.56	99	1		Yes	63,100	1,034	1,025	1,047	1,047	1,034
Latvia	LV	2,266,094	2,254,834	2,252,000	2,204,708	3	1.36	60	40		Yes	1,213	550	483	450	490	550
Lithuania	LT	3,358,114	3,339,455	3,324,000	3,535,547	4	1.13	100	1			2,526	714	596	662	716	714
Luxembourg	LU	488,650	486,181	507,000	503,302	5	9.93	97	3			169	336	190	200	179	336
FYR Macedonia	MK	2,039,961	2,042,485	2,061,000	2,077,328	2	0.96	100				362	174	110	119	150	174
Montenegro	ME	628,804	631,536	631,000	661,807	1	1.51	50	50			175	264	191	253	257	264
Morocco	MA				31,968,361	13	0.41	95	5			1,240	39				39
Netherlands	NL	16,445,594	16,445,593	16,613,000	16,653,734	87	5.22	90	5	5 - Nurse practitioners	Yes	9,736	585	632		600	585
Norway	NO	4,768,212	4,828,726	4,883,000	4,691,849	23	4.90	100	0		Yes	3,169	675	574	630	678	675
Poland	PL	38,115,908	38,153,388	38,277,000	38,441,588			99	<1	<1 Pediatrics	Yes	27,294	710	715	713	719	710
Portugal	PT	10,622,412	10,632,482	10,676,000	10,760,305	43	4.00	97	3		Yes	6,400	595	770	686	764	595
Romania	RO	21,504,442	21,469,960	21,431,298	21,904,551	21	0.96	99	1		Yes	3,051	139	109	140	117	139
Russian Federation	RU	141,956,416	141,909,248	142,958,000	138,739,892	108	0.78	70	30		Yes	30,006	216	167	186	188	216
San Marino	SM	28,775	28,976	32,000	31,817	1	31.43	100			Yes	16	503		380	688	503
Serbia	RS	7,350,222	7,320,807	7,291,436	7,310,555	18	2.46	100			Yes	3,277	448	465	446	323	448
Slovakia	SK	5,406,972	5,418,374	5,462,000	5,477,038	13	2.37	80	20		Yes	3,382	617	495	513	548	617
Slovenia	SI	2,039,399	2,042,335	2,030,000	2,000,092	5	2.50	10	89	1 - Internists in the intensive care unit	Yes	1,295	647	539	458	568	647
Spain	ES	45,593,384	45,929,476	46,077,000	46,754,784	180	3.85	60	30	10	Yes	34,299	734	717	747	762	734

Continued

Table 1 Continued

Country	ISO Code	Population 2008	2009	2010	2011	Number of IPG implanting centers: Absolute number	per mil inhabitants	Specialty performing implants (%): Cardiologists	Surgeons	Other	National Registry for IPG implants	IPG implantations: Absolute number	per mil inhabitants	IPG implantations per mil inhabitants: 2008	2009	2010	2011
Sweden	SE	9,219,638	9,298,515	9,380,000	9,088,728	43	4.73	95	4	1 -Anaesthesiologists	Yes			951	983	973	
Switzerland	CH	7,512,123	7,567,659	7,664,000	7,639,961	76	9.95	95	5		Yes	6,044	791	717	713	741	791
Tunisia	TN				10,629,186	19	1.79	95	5			1,650	155				155
Ukraine	UA	46,077,832	45,872,976	45,448,000	45,134,707	36	0.80	3	97			5,064	112		85	103	112
United Kingdom	GB	61,383,156	61,791,956	62,036,000	62,698,362	207	3.30	99	1		Yes	38,239	610	661	645	600	610
Malta	MT	412,001	413,290	417,000	408,333	2	4.90	100				302	740		675	686	740

INFO: No data available for Albania, Algeria, Lebanon, Libya, Republic of Moldavia, Syria, Kosovo, Turkey.
Source: EHRA White Book 2012; Population 2008-2010 WHO data, 2011 US Census.

deleted or replaced by the subsequent valid information. This allowed for consistency in comparison of data across countries as well as means to establish accurate trends. The data with regards to the standardized death rates (SDR) were extracted from the officially available WHO database. For both variables the groups "all ages per 100000" and "0-64 per 100000" were considered. Rank correlational analysis was performed on pairs of variables. The analysis cannot so far account for factors which may influence CHD-Mortality as for example health behavior, laboratory and physician qualifications or accreditations. This in turn could render the correlations found in the analysis less powerful. Moreover, the analysis presented lacks a dynamic perspective so up to now we cannot answer the question what exactly causes inequality and to what extent. This would require significantly longer time series than currently available.

In accordance with the commitment of EHRA with the *"Eastern Countries Initiative"* a sample of some countries has been selected to perform individual analysis in order to gain knowledge on the state of the art of cardiac rhythm management over Europe.

Finally, the so-called *"development potential"* has been first introduced. Although this measure has currently been applied to a selected number of countries, it is universally applicable and quantifies the additional number of centers needed in an individual country for a specific therapy to attain mean ESC area or mean EU-27 center availability, respectively. We have applied the evaluation of the development potential to both, centers performing device implantation (IPG, CRT, ICD) and catheter ablations. The development potential, e.g. for additional IPG centers is calculated according to the following formulae:

$$DP_{IPG,Cx,ESC} = rni\ ((MNC_{IPG,ESC} * INH_{Cx}) - NC_{IPG,Cx}))$$
$$DP_{IPG,Cx,EU-27} = rni\ ((MNC_{IPG,EU-27} * INH_{Cx}) - NC_{IPG,Cx}))$$

Abbreviations:

$DP_{IPG,\ Cx,\ ESC}$ development potential for IPG centers in country X (to attain mean ESC area center availability)

$DP_{IPG,\ Cx,\ EU\text{-}27}$ development potential for IPG centers in country X (to attain mean EU-27 center availability)

rni round up to nearest integer

$MNC_{IPG,\ ESC}$ mean number of IPG centers in ESC area [centers per million inhabitants]

$MNC_{IPG,\ EU27}$ mean number of IPG centers in EU-27 countries [centers per million inhabitants]

INH_{Cx} inhabitants in country X [millions]

$NC_{IPG,\ Cx}$ absolute number of IPG centers in country X [1]

The development potential for other therapies (CRT, ICD or ablation) can be calculated by replacing the IPG-related parameters with the respective CRT-, ICD- or ablation-related numbers. Calculation of all ESC area mean values is based on data of ESC member countries with consistent data reporting for all therapies, i.e. 45 (of 54) countries with 795 million inhabitants in total. The EU-27 mean values are calculated from all 27 EU member countries (503 million inhabitants).

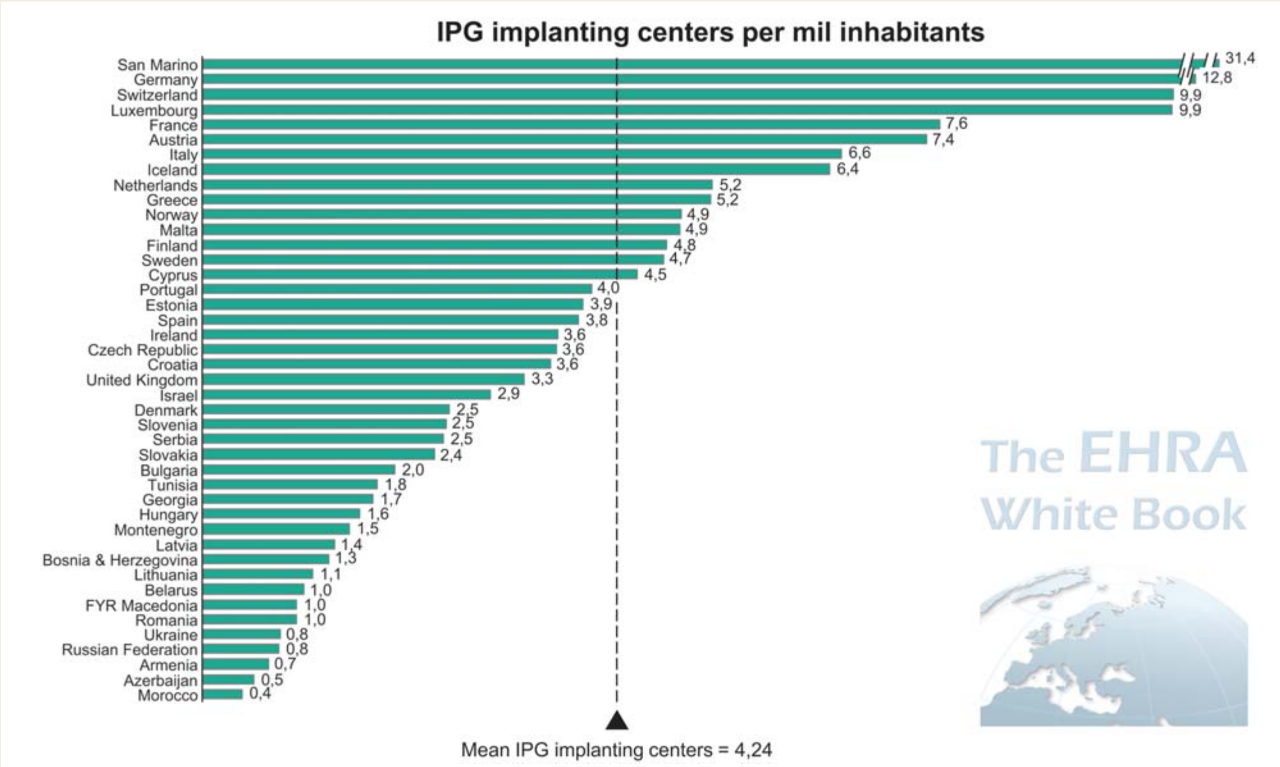

Figure 5. Rate of IPG implanting centers per million inhabitants. Displayed are only those countries with available number of IPG implantation center in 2011. The mean number of implantation centers is weighted by population. The following countries were excluded: AL, DZ, BE, EG, LB, LY, MD, SE, SY, TR, XK.

Implantable Pulse Generator (IPG)

General information

Table 1 lists the 46 countries (85% of all ESC countries) which submitted potentially relevant data to the purpose of the EHRA White Book related to IPG implantation. In 30 countries a national registry for IPG implantation was present. According to national Working Group on Pacing (Appendix), no official IPG registry existed in 2011 in Armenia, Azerbaijan, Bosnia Herzegovina, Cyprus, Egypt, Finland, Georgia, Israel, Lithuania, Luxembourg, FYR Macedonia, Malta, Montenegro, Morroco, Tunisia, and Ukraine (Table 1). The vast majority of implants were performed by cardiologists (>80%), and the remaining implantation were performed by physicians having various training background including surgeons, anaestesiologists, pediatricians, and internists (Table 1). However, in some countries (Austria, Bosnia Herzegovina, Israel, Montenegro, Slovenia, and Ukraine) the proportion of implanting cardiologists approached 50% or was less (Table 1). According to the United States Census, in 2011 749′859′018 people lived in the 45 countries (no data available for Egypt); however, when excluding Belgium and Sweden for which the number of IPG implanting centers was not reported, the population covered in 2011 by the EHRA White Book was 745’985’953.

IPG facilities and IPG implantation rate

It was reported that in 3’164 national centers a total number of 468’413 IPG were implanted (Table 1). Comparing the available datasets for 41 countries for 2010 with 2011, the mean number of centers implanting pulse generators per million inhabitants in 2011 was 4.40 and remained substantially unchanged (4.49) as compared to previous year 2010 (Table 2). After excluding San Marino, the country with highest density of facilities was recorded in Germany (12.8) and the lowest one in Morocco (0.4) (Figure 5).

In 2011, the mean IPG implantation rate of the available 43 countries was 604 units (median value 584) per million inhabitants with the highest reported implantation rate in Germany (1313) and the lowest in Azerbaijan (15). Figures 6 and 7 show the overview of IPG rate per million inhabitant for each nation which reported its data in 2010 and 2011 to EHRA White Book. The countries were further stratified by quartile of IPG rate and the boundaries of each quartile are given in Figures 6 and 7 as well. Across the 43 countries, a marked heterogeneity was observed in the geographic distribution of IPG rate per million inhabitants.

Compared to 2010 (625 IPG units per million inhabitants), there was an overall increase in the mean IPG implantation rate of about 2% to 638 IPG units per million inhabitants in 2011 (40 countries with comparable datasets). Figure 8 displays the change over the last 4 years in IPG procedures in selected countries.

Table 2 Pacemaker centers and IPG procedures in year 2011 versus 2010

Country	ISO Code	2010 Pacemaker implanting centres	2010 Population	2010 Number of implanting centers per mil inhabitants 2010	2011 Pacemaker implanting centres	2011 Population	2011 Number of implanting centers per mil inhabitants 2011	change %
Armenia	AM	3	3,092,000	0.97	2	2,967,975	0.67	-31%
Austria	AT	61	8,394,000	7.27	61	8,217,280	7.42	2%
Azerbaijan	AZ				5	9,397,279	0.53	
Belarus	BY	8	9,595,000	0.83	10	9,577,552	1.04	25%
Belgium	BE	94	10,712,000	8.78		10,431,477		
Bosnia & Herzegovina	BA	6	3,760,000	1.60	6	4,622,163	1.30	-19%
Bulgaria	BG	10	7,494,000	1.33	14	7,093,635	1.97	48%
Croatia	HR	13	4,403,000	2.95	16	4,483,804	3.57	21%
Cyprus	CY	5	1,104,000	4.53	5	1,120,489	4.46	-1%
Czech Republic	CZ	37	10,493,000	3.53	37	10,190,213	3.63	3%
Denmark	DK	14	5,550,000	2.52	14	5,529,888	2.53	0.4%
Egypt	EG	28						
Estonia	EE	5	1,341,000	3.73	5	1,282,963	3.90	5%
Finland	FI	25	5,365,000	4.66	25	5,259,250	4.75	2%
France	FR	520	62,787,000	8.28	492	65,102,719	7.56	-9%
Georgia	GE	7	4,352,000	1.61	8	4,585,874	1.74	8%
Germany	DE	1,041	82,302,000	12.65	1,041	81,471,834	12.78	1%
Greece	GR	61	11,359,000	5.37	56	10,760,136	5.20	-3%
Hungary	HU	15	9,984,000	1.50	16	9,976,062	1.60	7%
Iceland	IS	2	320,000	6.25	2	311,058	6.43	3%
Ireland	IE	16	4,470,000	3.58	17	4,670,976	3.64	2%
Israel	IL	17	7,418,000	2.29	22	7,473,052	2.94	28%
Italy	IT	400	60,551,000	6.61	400	61,016,804	6.56	-1%
Latvia	LV	3	2,252,000	1.33	3	2,204,708	1.36	2%
Lithuania	LT	4	3,324,000	1.20	4	3,535,547	1.13	-6%
Luxembourg	LU	5	507,000	9.86	5	503,302	9.93	1%
FYR Macedonia	MK	2	2,061,000	0.97	2	2,077,328	0.96	-1%
Montenegro	ME	1	631,000	1.58	1	661,807	1.51	-5%
Morocco	MA				13	31,968,361	0.41	
Netherlands	NL	100	16,613,000	6.02	87	16,653,734	5.22	-13%
Norway	NO	24	4,883,000	4.92	23	4,691,849	4.90	-0.3%
Poland	PL	116	38,277,000	3.03		38,441,588		
Portugal	PT	43	10,676,000	4.03	43	10,760,305	4.00	-1%
Romania	RO	20	21,431,298	0.93	21	21,904,551	0.96	3%
Russian Federation	RU	101	142,958,000	0.71	108	138,739,892	0.78	10%
San Marino	SM	1	32,000	31.25	1	31,817	31.43	1%
Serbia	RS	18	7,291,436	2.47	18	7,310,555	2.46	35%
Slovakia	SK	13	5,462,000	2.38	13	5,477,038	2.37	0%
Slovenia	SI	5	2,030,000	2.46	5	2,000,092	2.50	1%
Spain	ES	123	46,077,000	2.67	180	46,754,784	3.85	44%
Sweden	SE	43	9,380,000	4.58	43	9,088,728	4.73	3%
Switzerland	CH	73	7,664,000	9.53	76	7,639,961	9.95	4%
Tunisia	TN	19	10,525,041	1.81	19	10,629,186	1.79	-1%
Ukraine	UA	35	45,448,000	0.77	36	45,134,707	0.80	4%
United Kingdom	GB	219	62,036,000	3.53	207	62,698,362	3.30	-6%
Malta	MT	2	417,000	4.80	2	408,333	4.90	2%

INFO: Mean values are based on available and comparable complete datasets for each year-over-year comparison. No comparable dataset (2010 vs 2011) is available for Albania, Algeria, Azerbaijan, Belgium, Egypt, Lebanon, Libya, Republic of Moldavia, Morocco, Syria, Kosovo, Poland, Turkey; population data from 2010 WHO and from 2011 US Census.

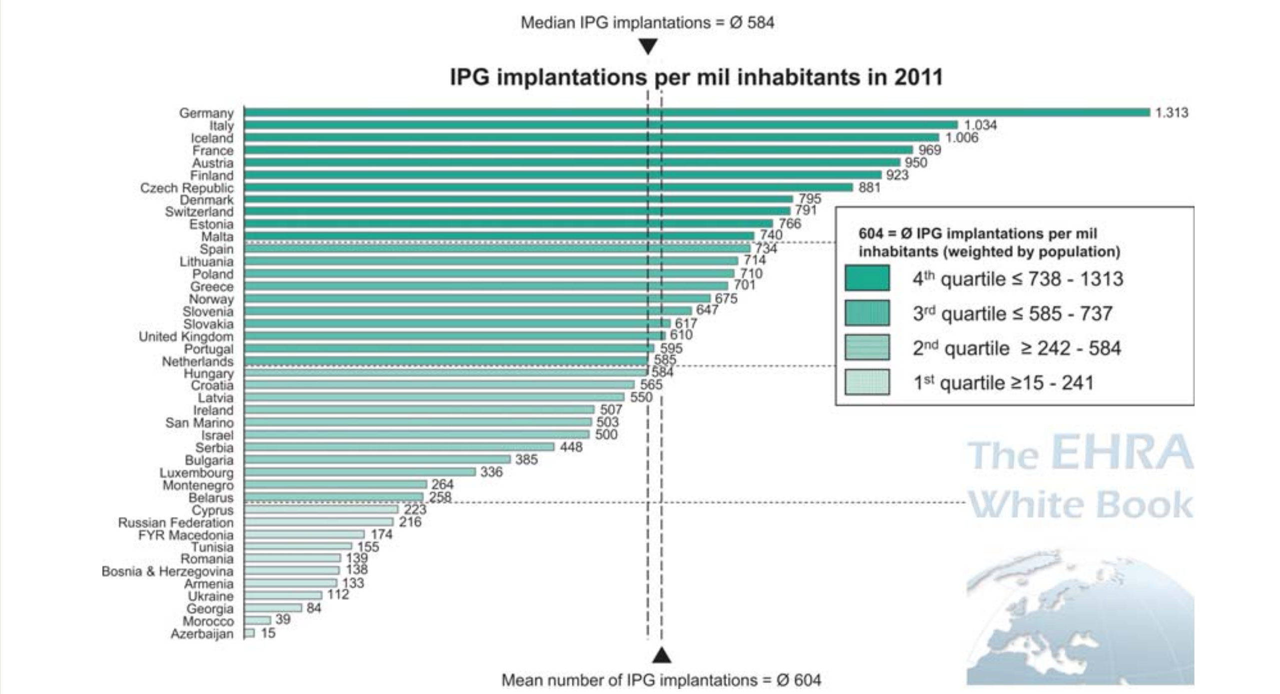

Figure 6. IPG implantation rate per million inhabitants in 2011. Displayed are only countries with available numbers for 2011. The median IPG implantation rate in 2010 was 584, and mean per million inhabitants in 2011 was 604. Mean number of implantations is weighted by population excluding AL, DZ, BE, EG, LB, LY, MD, SE, SY, TR, XK. The countries were color-coded according to each quartile.

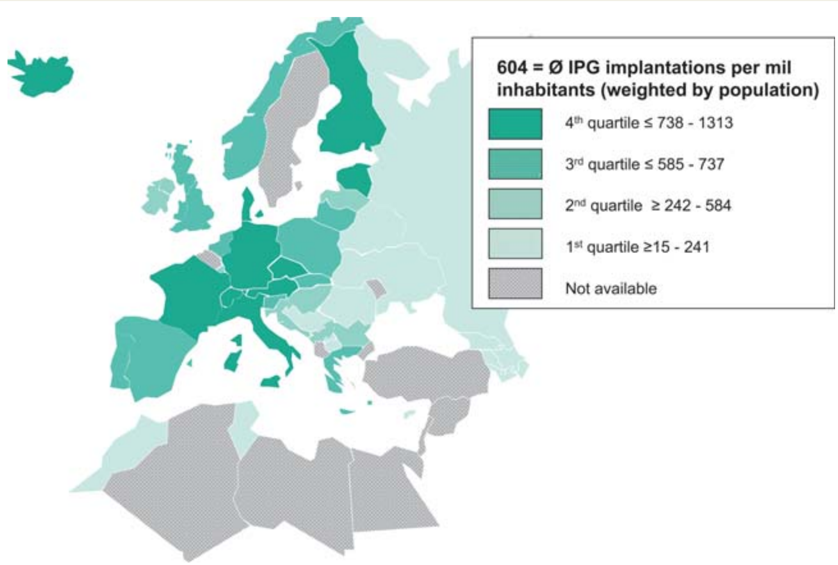

Figure 7. Geographic representation of ESC countries covered in 2012. The countries were color-coded according to each quartiles of IPG implantation rate. A significant heterogeneity in IPG implantation rate can be observed. Displayed are only countries with available numbers for 2011, mean number of implantations is weighted by population. The following countries were excluded: AL, DZ, BE, EG, LB, LY, MD, SE, SY, TR, XK.

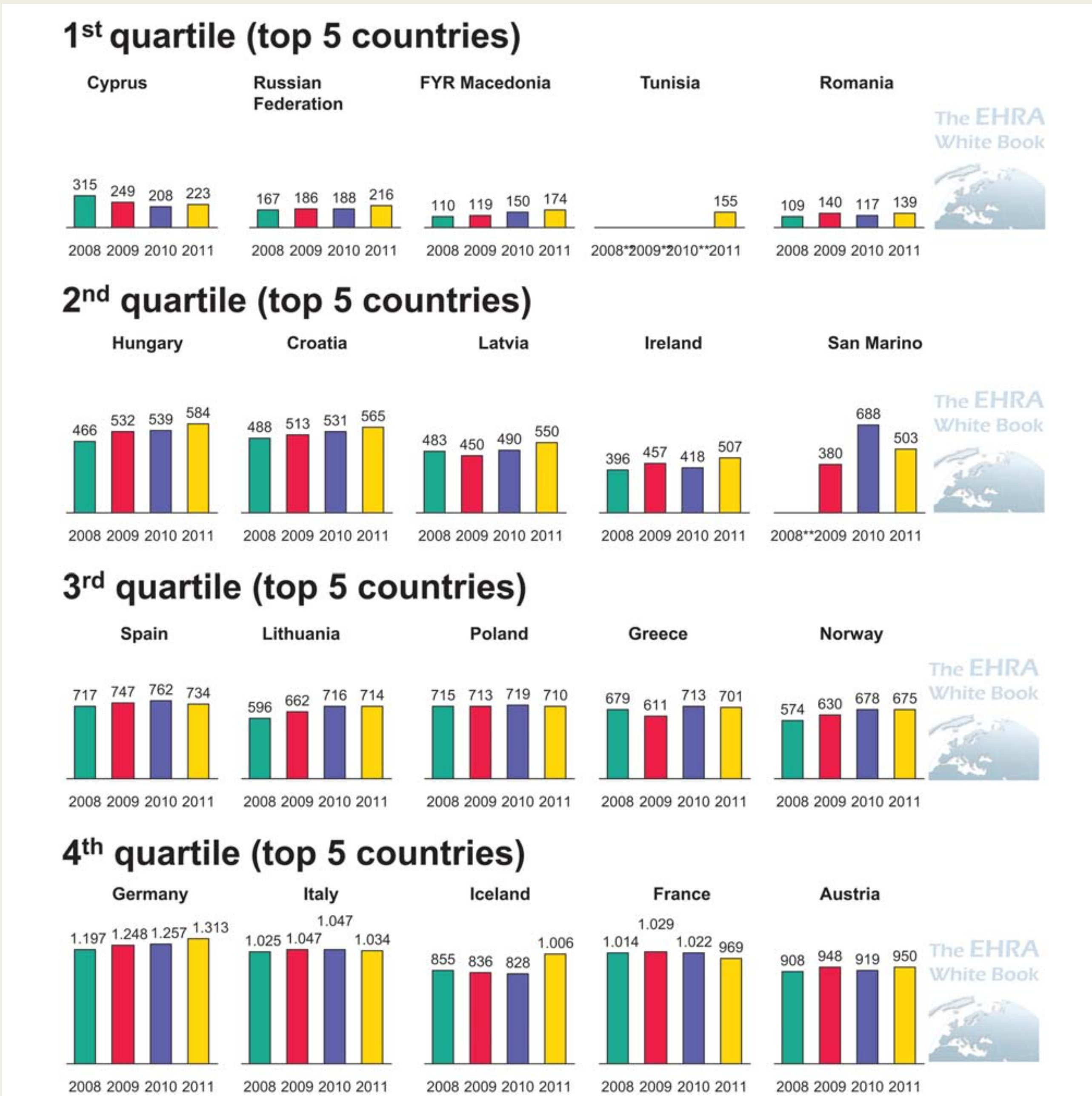

Figure 8. Change in IPG procedures in top 5 countries of the 1st, 2nd, 3rd and 4th quartile since 2008 ranked by implantation rate in 2011. Within each quarter, only those countries with available IPG implantation numbers for at least 3 years between 2008 and 2011 are displayed. ** indicated no data available in that particular year.

Figure 9 shows that for the comparison of 2010 versus 2011 with the exception of Lithuania, Norway, Poland, Italy, Greece, Netherlands, Spain, France, Portugal, and Bosnia & Herzegovina, in the vast majority of ESC countries the total implantation rate of IPGs per million inhabitants increased. The increase was markedly evident for Luxembourg (+87,1%) and for Serbia (+38,7%). Similar trends were observed for de-novo implantation rates (Figure 10) and for device replacements (Figure 11).

Evolution of IPG implantion rate and centers in selected countries

Figure 12 shows the relationship between the annual IPG implantation rate per million inhabitants and the number of IPG implanting center per million inhabitants in the EU-27 countries and ESC area.

In Figure 13, the IPG centers and implantation rates in selected countries are compared to mean ESC area and EU-27 levels. The large gap between individual countries and the ESC area or EU-27

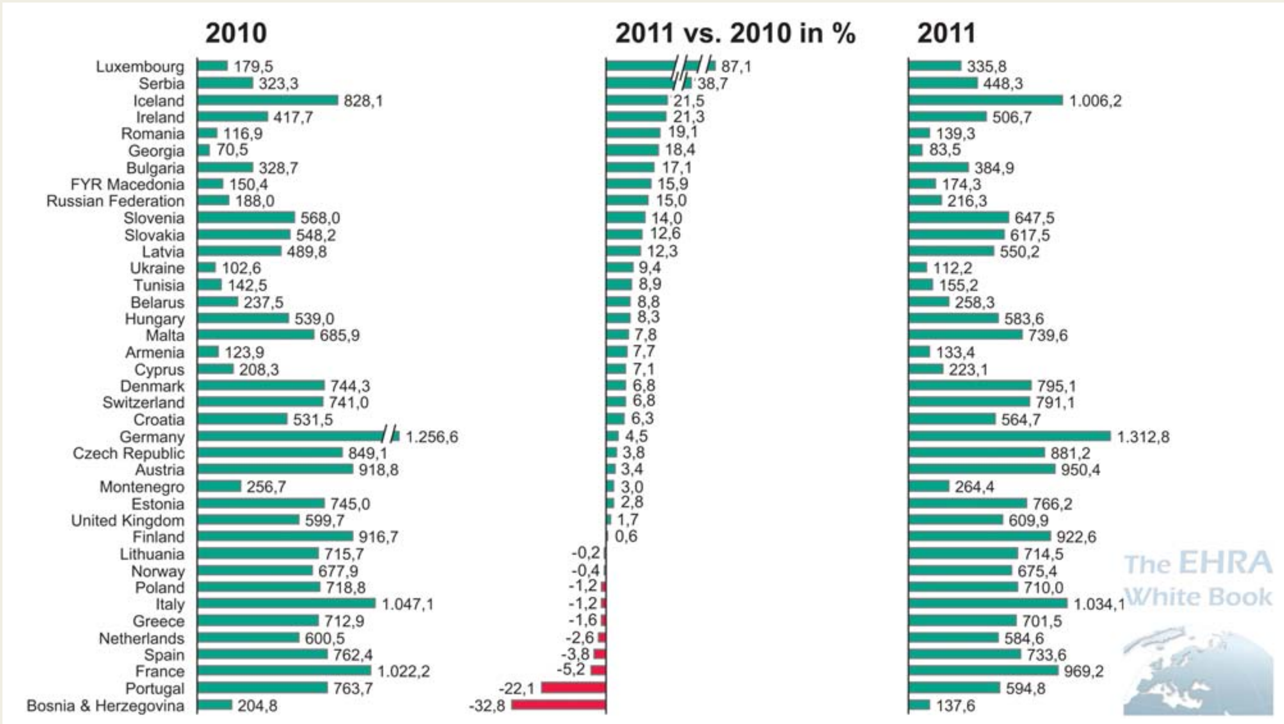

Figure 9. Change 2011 versus 2010 in the total number of IPGs per million inhabitants. Displayed are only countries with available IPG implantation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. The following countries were excluded: AL, AZ, BE, DZ, EG, IL, LB, LY, MA, MD, SE, SM, SY, TR, XK.

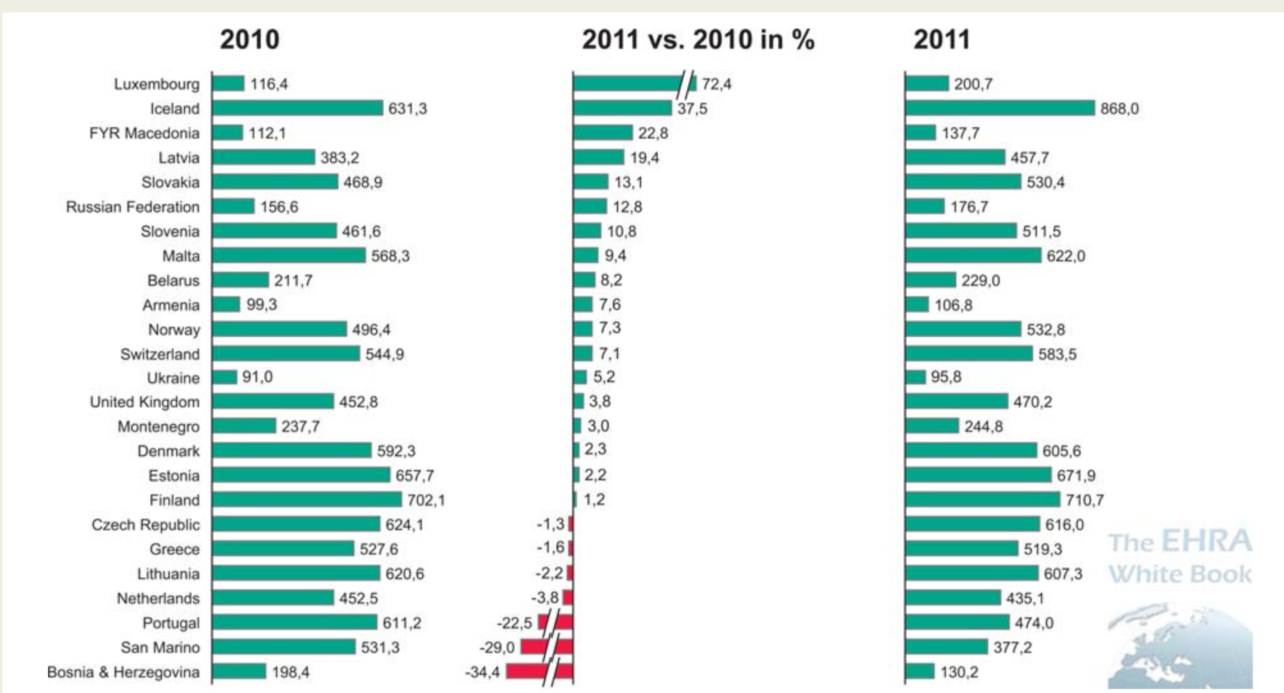

Figure 10. Change 2011 versus 2010 in the number of de-novo IPGs per million inhabitants. Displayed are only countries with available IPG implantation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. The following countries were excluded: AL, AT, AZ, BE, BG, CY, DE, DZ, EG, ES, FR, GE, HR, HU, IE, IL, IT, LB, LY, MA, MD, PL, RO, RS, SE, SY, TN, TR, XK.

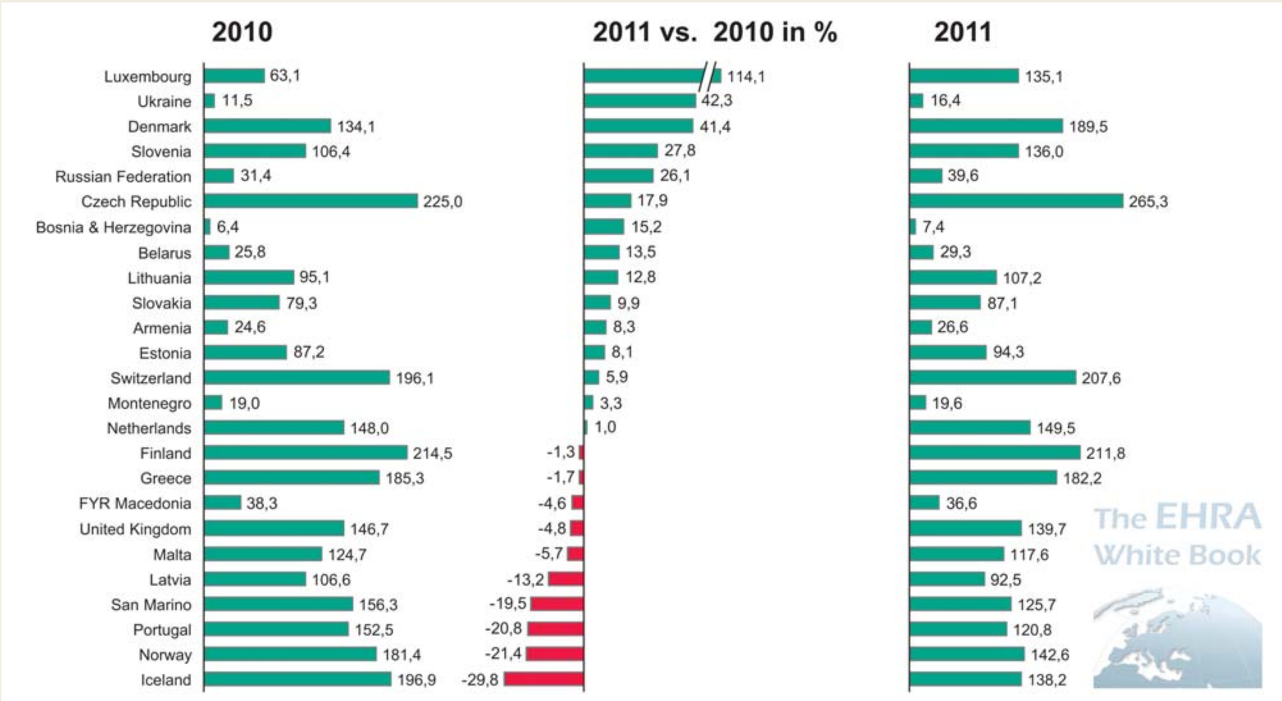

Figure 11. Change 2011 versus 2012 in the number of device replacements of IPGs per million inhabitants. Displayed are only countries with available IPG implantation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. The following countries were excluded: AL, AT, AZ, BE, BG, DZ, CY, BE, DE, EG, ES, FR, GE, HR, HU, IE, IL, IT, LB, LY, MA, MD, PL, RO, RS, SE, SY, TN, TR, XK.

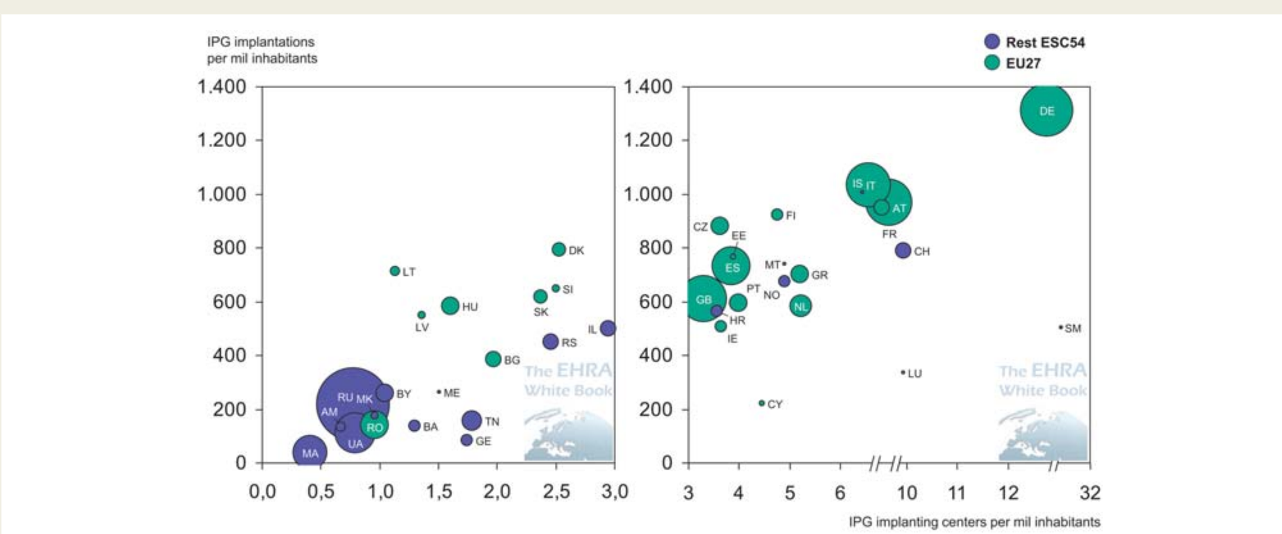

Figure 12. IPG centers and implantation rate in each of the 42 countries. The EU-27 countries are indicated by the green bubble, and the remaining ESC countries in blue color. The circular areas are proportional to the normalized annual implantation numbers.

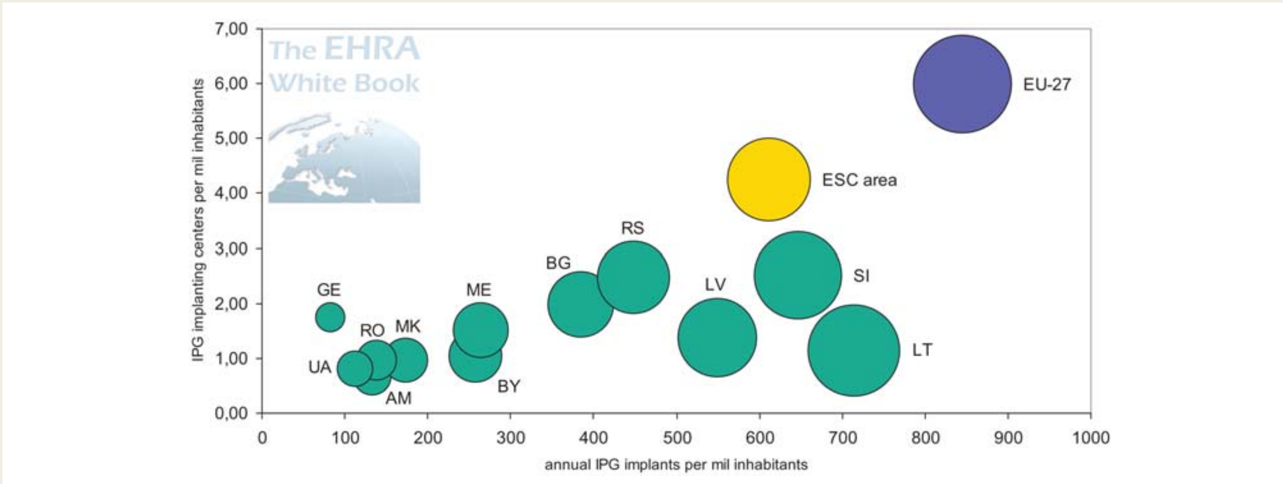

Figure 13. IPG centers and implantations in selected countries compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

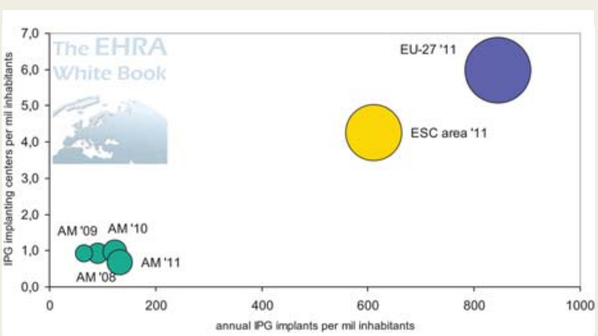

Figure 14. Evolution of IPG implantation in Armenia (AM) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

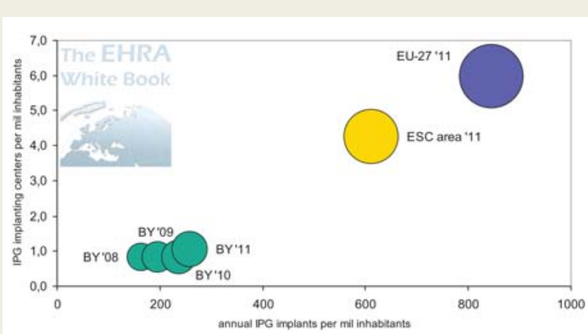

Figure 15. Evolution of IPG implantation in Belarus (BY) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

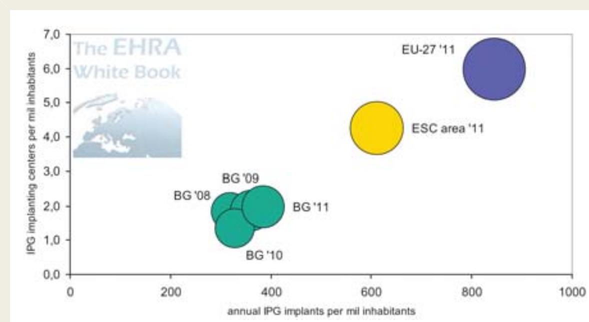

Figure 16. Evolution of IPG implantation in Bulgaria (BG) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

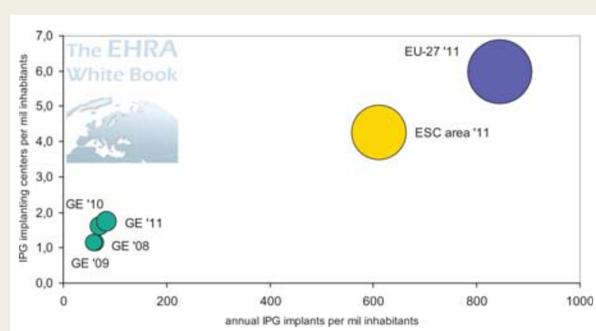

Figure 17. Evolution of IPG implantation in Georgia (GE) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

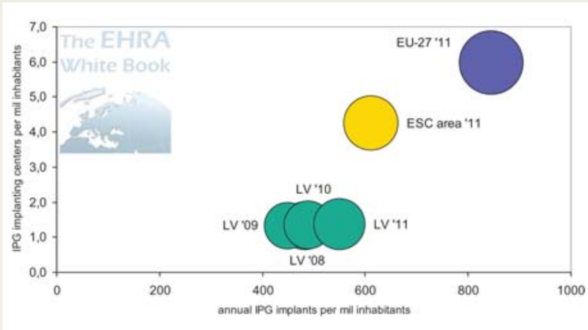

Figure 18. Evolution of IPG implantation in Latvia (LV) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

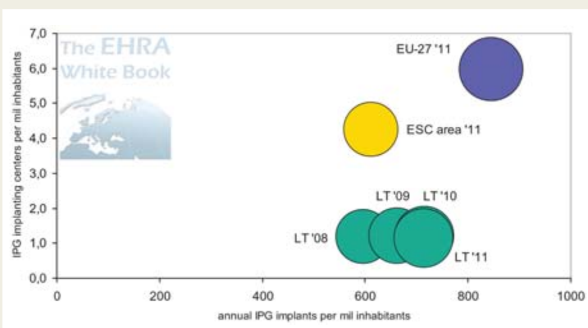

Figure 19. Evolution of IPG implantation in Lithuania (LT) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

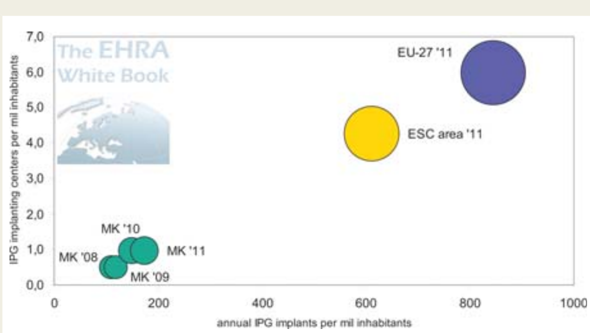

Figure 20. Evolution of IPG implantation in the FYR Macedonia (MK) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

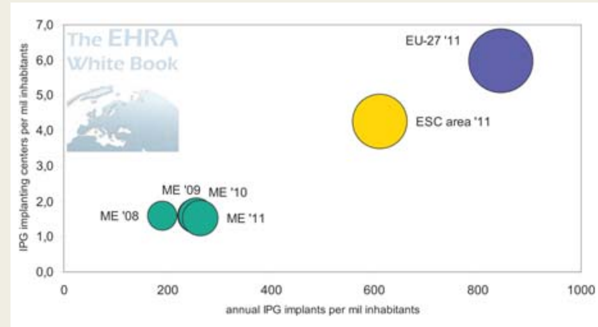

Figure 21. Evolution of IPG implantation in Montenegro (ME) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

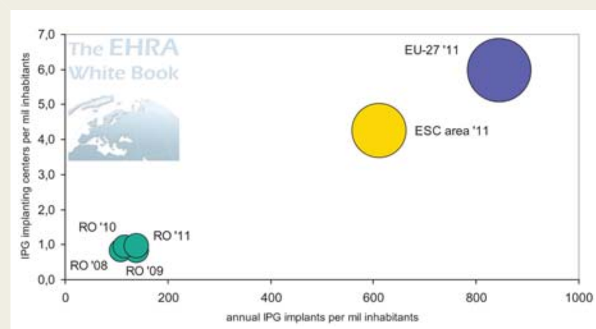

Figure 22. Evolution of IPG implantation in Romania (RO) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

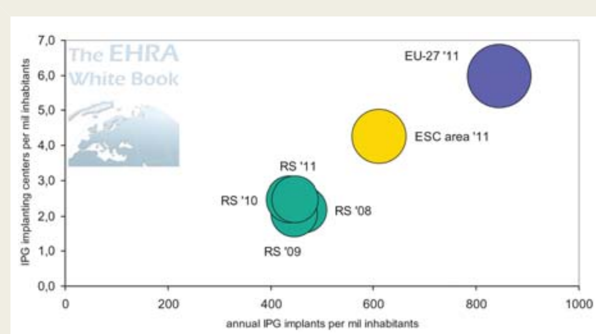

Figure 23. Evolution of IPG implantation in Serbia (RS) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

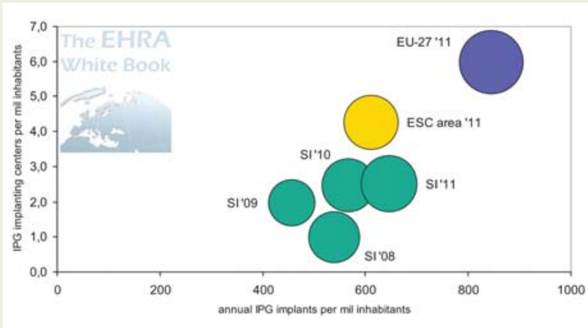

Figure 24. Evolution of IPG implantation in Slovenia (SI) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

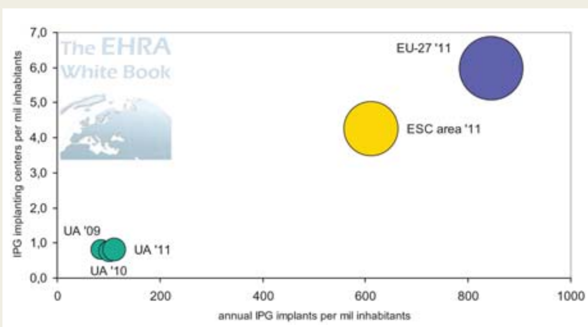

Figure 25. Evolution of IPG implantation in Ukraine (UA) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers. No 2008 data available.

values was mostly due to lack of infrastructures (Y axis, or number of IPG implanting centers per million inhabitants) and low referral rate (X axis, or number of IPG implants per million inhabitants) in each respective country.

As show in Figures 14 to 25, in the vast majority of countries there was a minimal change over the past 4 years in each country. Thus, unless significant investment in infrastructure and in training programme for both professional and allied professional is conducted along with more awareness and implementation of clinical practice guidelines, the existing gap will remain.

The development potential for IPG centers is given in Table 3. Overall, in the selected countries, the development potential of centers ranges between 346 and 533 additional IPG centers depending upon the target of ESC-54 or EU-27 countries. These data clearly underline the need for significant investments in EP infrastructure in order to close the existing gap.

Implantable Cardioverter Defibrilators (ICD)

General information

Table 4 lists the 46 countries (out of all 54 ESC countries) included for the analysis in the purpose of the EHRA White Book 2011 related to ICD implantation. In 32 countries a national registry for ICD implantation was present. According to national Working Group on Pacing (Appendix), no official ICD registry existed in 2011 in Armenia, Azerbaijan, Bosnia & Herzegovina, Cyprus, Egypt, Finland, Georgia, Lithuania, FYR Macedonia, Malta, Montenegro, Morocco, Tunisia and Ukraine (Table 1). In some countries (Austria, Belarus, Belgium, Germany, Iceland, Israel, Latvia, Slovenia and Ukraine) the percentage of implanting cardiologists was 50% or less (Table 4). No data were available for Egypt. According to the United States Census, in 2011 794′859′018 people lived in the 46 countries.

ICD facilities and ICD implantation rate

It was reported that in 1.824 national centers a total number of 81.229 ICD were implanted (Table 4). The mean number of centers implanting ICD per million inhabitants in 42 countries in 2011 was 2,4. When comparing the 41 countries with available datasets for 2011 and 2010 the mean value remained substantially unchanged (2.6 in 2011 versus 2,4 in 2010). (Table 5). This calculation was done excluding the countries that did not report the number of centers implanting ICD: Azerbaijan, Egypt, Morocco, Poland and Sweden.

After excluding San Marino, the countries with highest density of facilities of the 44 available countries for 2011 were Germany (7,5), Italy (5,9) and Switzerland (4,8) and the countries with lowest density of facilities were Ukraine (0,2), Azerbaijan (0,2), and the Russian Federation (0,4) (Figure 26). The mean number of ICD

Table 3 **Development potential for IPG centers in selected countries reflecting the additional number of centers needed to attain mean ESC area or mean EU-27 IPG center availability**

Development potential - additional number of ...	AM	BY	BG	GE	LV	LT	MK	ME	RO	RS	SI	UA	∑
... IPG implanting centers to attain mean ESC area level	11	31	17	12	7	12	7	2	73	14	4	156	346
... IPG implanting centers to attain mean EU-27 level	16	48	29	20	11	18	11	3	110	26	7	234	533

Table 4 ICD facilities and ICD implantations in 2011

Country	ISO Code	Population 2008	Population 2009	Population 2010	Population 2011	Number of ICD implanting centers: Absolute number	Number of ICD implanting centers: per mil inhabitants	Specialty performing implants (%): Cardiologists	Specialty performing implants (%): Surgeons	Specialty performing implants (%): Other	National Registry for ICD implants	ICD implantations: Absolute number	ICD implantations: per mil inhabitants	ICD implantations per mil inhabitants 2008	2009	2010	2011
Armenia	AM	3,234,031	3,243,729	3,092,000	2,967,975	2	0.7	100				36	12	32	10	11	12
Austria	AT	8,336,549	8,363,040	8,394,000	8,217,280	30	3.7	30	70		yes	1,805	220	132	154	151	220
Azerbaijan	AZ				9,397,279	2	0.2	100				22	2				2
Belarus	BY	9,680,841	9,665,120	9,595,000	9,577,552	6	0.6		100		yes	131	14	4	5	6	14
Belgium	BE	10,480,393	10,646,804	10,712,000	10,431,477	23	2.2	30	70		yes	2,060	197	167	169	188	197
Bosnia & Herzegovina	BA	3,842,265	3,838,161	3,760,000	4,622,163	5	1.1	55	45			61	13			8	13
Bulgaria	BG	7,623,395	7,585,131	7,494,000	7,093,635	4	0.6	99	1		yes	59	8	1	1	1	8
Croatia	HR	4,434,508	4,429,078	4,403,000	4,483,804	12	2.7	100			yes	84	19	19	24	18	19
Cyprus	CY	793,007	803,147	1,104,000	1,120,489	3	2.7	100				65	58	44	45	43	58
Czech Republic	CZ	10,429,692	10,491,492	10,493,000	10,190,213	17	1.7	95	5		yes	2,751	270	193	117	251	270
Denmark	DK	5,489,022	5,519,441	5,550,000	5,529,888	5	0.9	100			yes	1,095	198	223	181	194	198
Egypt	EG																
Estonia	EE	1,340,675	1,340,271	1,341,000	1,282,963	2	1.6	72	28		yes	58	45	13	15	39	45
Finland	FI	5,313,399	5,338,871	5,365,000	5,259,250	16	3.0	100				703	134	110	120	150	134
France	FR	62,130,520	62,342,668	62,787,000	65,102,719	141	2.2	100			yes	6,672	102		88	94	102
Georgia	GE	4,383,750	4,410,900	4,352,000	4,585,874	6	1.3	100				24	5	3	2	3	5
Germany	DE	82,119,776	81,874,768	82,302,000	81,471,834	607	7.5	30	50	20 - Other	yes	26,579	326	263	288	305	326
Greece	GR	11,237,068	11,282,751	11,359,000	10,760,136	24	2.2	99	1		yes	892	83	89	102	86	83
Hungary	HU	10,038,188	10,022,650	9,984,000	9,976,062	13	1.3	90	5	5 - Other: Anaesthesiologist	yes	794	80	54	61	72	80
Iceland	IS	319,355	319,246	320,000	311,058	1	3.2	50	50		yes	35	113	135	88	78	113
Ireland	IE	4,422,077	4,459,305	4,470,000	4,670,976	17	3.6	100			yes	654	140	175	144	134	140
Israel	IL	7,308,795	7,485,600	7,418,000	7,473,052	22	2.9	5	5	90 - Other: Cardiac electrophysilogists	yes	1,164	156	105	109	178	156
Italy	IT	59,832,180	60,192,696	60,551,000	61,016,804	360	5.9	99	1		yes	11,970	196	301	174	183	196
Latvia	LV	2,266,094	2,254,834	2,252,000	2,204,708	3	1.4	50	50		yes	63	29	17	16	19	29
Lithuania	LT	3,358,114	3,339,455	3,324,000	3,535,547	3	0.8	100				117	33	15	19	26	33
Luxembourg	LU	488,650	486,181	507,000	503,302	1	2.0	100			yes	50	99	84	86	73	99
FYR Macedonia	MK	2,039,961	2,042,485	2,061,000	2,077,328	2	1.0	100				26	13	1	2	7	13
Malta	MT	412,001	413,290	417,000	408,333	1	2.4	100				29	71		82	72	71
Montenegro	ME	628,804	631,536	631,000	661,807	1	1.5	60	40			31	47	19	29	29	47
Morocco	MA				31,968,361			95	5			40	1				1
Netherlands	NL	16,445,594	16,445,593	16,613,000	16,653,734	30	1.8	90	5	5 (Nurse practitioners)	yes	2,577	155	197		171	155
Norway	NO	4,768,212	4,828,726	4,883,000	4,691,849	9	1.9	100			yes	863	184	116	110	125	184
Poland	PL	38,115,908	38,153,388	38,277,000	38,441,588			99		<1 - Other: Pediatrics, pediatrics cardiac surgeons	yes	6,042	157	92	138	183	157
Portugal	PT	10,622,412	10,632,482	10,676,000	10,760,305	22	2.0	98	2		yes	1,017	95	68	69	75	95
Romania	RO	21,504,442	21,469,960	21,431,298	21,904,551	19	0.9	100			yes	167	8	5	6	8	8
Russian Federation	RU	141,956,416	141,909,248	142,958,000	138,739,892	57	0.4	70	30		yes	1,355	10	4	4	4	10
San Marino	SM	28,775	28,976	32,000	31,817	1	31.4	100			yes	19	597		656	625	597
Serbia	RS	7,350,222	7,320,807	7,291,436	7,310,555	8	1.1	100			yes	322	44	32	52	39	44

Continued

Slovakia	SK	5,406,972	5,418,374	5,462,000	5,477,038	4	0.7	86	14		yes	545	100	104	82	91	100
Slovenia	SI	2,039,399	2,042,335	2,030,000	2,000,092	2	1.0	14	86		yes	144	72	47	54	50	72
Spain	ES	45,593,384	45,929,476	46,077,000	46,754,784	167	3.6	78	15	2,67 - Other	yes	3,481	74	76	84	71	74
Sweden	SE	9,219,638	9,298,515	9,380,000	9,088,728			80	20		yes			112	71	114	
Switzerland	CH	7,512,123	7,567,659	7,664,000	7,639,961	37	4.8	97	3		yes	1,088	142	157	176	203	142
Tunisia	TN				10,629,186	8	0.8	100				90	8				8
Ukraine	UA	46,077,832	45,872,976	45,448,000	45,134,707	8	0.2		100			45	1		0	1	1
United Kingdom	GB	61,383,156	61,791,956	62,036,000	62,698,362	123	2.0	99	1		yes	5,404	86	121	82	83	86

INFO: No data available for Albania, Algeria, Lebanon, Libya, Republic of Moldavia, Syria, Kosovo, Turkey
Source: EHRA White Book 2012; Population 2008-2010 WHO data, 2011 US Census

implanting centers per million inhabitants in 2011 for the 44 countries that submitted data is 2.4 (Figure 26).

In 2011, the mean ICD implantation rate of 44 countries was 103 units (Figure 27) (median value 77) per million inhabitants. This calculation was done excluding the countries that did not report the number of implanted ICD's in 2011: Egypt and Sweden. After excluding San Marino, the countries with the highest reported ICD implantation rate were Germany (326), Czech Republic (270) and Austria (220) and the lowest in Ukraine (1), Morocco (1) and, Azerbaijan (2). Figure 27 and 28 show the overview of ICD implantation rates per million inhabitants for each nation that reported its data to EHRA White Book 2011. The countries were further stratified by quartile of ICD rate and the boundaries of each quartile are given in Figure 27 as well. Across the countries, a marked heterogeneity was observed in the geographic distribution of ICD rate per million inhabitants.

Comparing available 2010 ICD implantation data with 2011 ICD implantation data, we have 42 countries that submitted data and a mean ICD implantation rate of 103 ICD implantations per million inhabitants in 2010 and a mean of 109 ICD implantations per million in 2011. However, in this calculation Egypt, Azerbaijan, Morocco and Sweden were excluded for lack of data, making meaningful interpretation more difficult.

Figure 29 displays the change over the last 4 years in ICD procedures in selected countries with a heterogeneous behavior.

This pattern can be appreciated when splitting data for new implants and replacements of ICD. Figure 30 and 31. The number of implanting centers shows a general trend to increase but with different strength.

Evolution of ICD implantation rate and centers in selected Eastern and Central Europe countries

Figure 32 shows the relationship between the mean annual ICD implantation rate per million inhabitants and the number of ICD implanting center per million inhabitants in the EU-27 countries and ESC area (Figure 32) as well as in selected countries (Figure 33). The large gap between selected countries and the ESC-54 or EU-27 countries seems to be mostly due to lack of infrastructures (Y axis, or number of ICD implanting centers per million inhabitants) but also to low referral rate (X axis, or number of ICD implants per million inhabitants) in each respective country.

As show in Figures 34 to 45, in the vast majority of countries there was a minimal change over the last 5 years in each country. Thus, unless significant investment in infrastructure and in training programme for both professional and allied professional is conducted along with more awareness and implementation of clinical practice guidelines, the existing gap will remain.

The development potential for ICD center is given in table 6. Overall, in the selected Eastern and Central Europe countries, the development potential of centers shows a wide range also depending upon the target of ESC-54 or EU-27 countries.

Table 5 ICD centers and ICD procedures in year 2011 versus 2010

Country	ISO Code	2010 ICD implanting centres	2010 Population	2010 Number of implanting centers per mil inhabitants 2010	2011 ICD implanting centres	2011 Population	2011 Number of implanting centers per mil inhabitants 2011	change %
Armenia	AM	2	3,092,000	0.6	2	2,967,975	0.7	4%
Austria	AT	30	8,394,000	3.6	30	8,217,280	3.7	2%
Azerbaijan	AZ	1			2	9,397,279	0.2	
Belarus	BY	2	9,595,000	0.2	6	9,577,552	0.6	201%
Belgium	BE	23	10,712,000	2.1	23	10,431,477	2.2	3%
Bosnia & Herzegovina	BA	3	3,760,000	0.8	5	4,622,163	1.1	36%
Bulgaria	BG	3	7,494,000	0.4	4	7,093,635	0.6	41%
Croatia	HR	9	4,403,000	2.0	12	4,483,804	2.7	31%
Cyprus	CY	3	1,104,000	2.7	3	1,120,489	2.7	-1%
Czech Republic	CZ	16	10,493,000	1.5	17	10,190,213	1.7	9%
Denmark	DK	5	5,550,000	0.9	5	5,529,888	0.9	0.4%
Egypt	EG	10						
Estonia	EE	2	1,341,000	1.5	2	1,282,963	1.6	5%
Finland	FI	16	5,365,000	3.0	16	5,259,250	3.0	2%
France	FR	80	62,787,000	1.3	141	65,102,719	2.2	70%
Georgia	GE	4	4,352,000	0.9	6	4,585,874	1.3	42%
Germany	DE	607	82,302,000	7.4	607	81,471,834	7.5	1%
Greece	GR	24	11,359,000	2.1	24	10,760,136	2.2	6%
Hungary	HU	12	9,984,000	1.2	13	9,976,062	1.3	8%
Iceland	IS	1	320,000	3.1	1	311,058	3.2	3%
Ireland	IE	16	4,470,000	3.6	17	4,670,976	3.6	2%
Israel	IL	17	7,418,000	2.3	22	7,473,052	2.9	28%
Italy	IT	400	60,551,000	6.6	360	61,016,804	5.9	-11%
Latvia	LV	3	2,252,000	1.3	3	2,204,708	1.4	2%
Lithuania	LT	3	3,324,000	0.9	3	3,535,547	0.8	-6%
Luxembourg	LU	1	507,000	2.0	1	503,302	2.0	1%
FYR Macedonia	MK	2	2,061,000	1.0	2	2,077,328	1.0	-1%
Malta	MT	1	417,000	2.4	1	408,333	2.4	2%
Montenegro	ME	1	631,000	1.6	1	661,807	1.5	-5%
Morocco	MA					31,968,361		
Netherlands	NL	19	16,613,000	1.1	30	16,653,734	1.8	58%
Norway	NO	9	4,883,000	1.8	9	4,691,849	1.9	4%
Poland	PL	92	38,277,000	2.4		38,441,588		
Portugal	PT	20	10,676,000	1.9	22	10,760,305	2.0	9%
Romania	RO	14	21,431,298	0.7	19	21,904,551	0.9	33%
Russian Federation	RU	49	142,958,000	0.3	57	138,739,892	0.4	20%
San Marino	SM	1	32,000	31.3	1	31,817	31.4	1%
Serbia	RS	8	7,291,436	1.1	8	7,310,555	1.1	-0.3%
Slovakia	SK	4	5,462,000	0.7	4	5,477,038	0.7	-0.3%
Slovenia	SI	2	2,030,000	1.0	2	2,000,092	1.0	1%
Spain	ES	145	46,077,000	3.1	167	46,754,784	3.6	14%
Sweden	SE	30	9,380,000	3.2		9,088,728		
Switzerland	CH	30	7,664,000	3.9	37	7,639,961	4.8	24%
Tunisia	TN	8	10,525,041	0.8	8	10,629,186	0.8	1%
Ukraine	UA	8	45,448,000	0.2	8	45,134,707	0.2	1%
United Kingdom	GB	114	62,036,000	1.8	123	62,698,362	2.0	7%

INFO: Mean values are based on available and comparable complete datasets for each year-over-year comparison. No comparable dataset (2010 vs 2011) is available for Azerbaijan, Egypt, Morocco and Sweden.

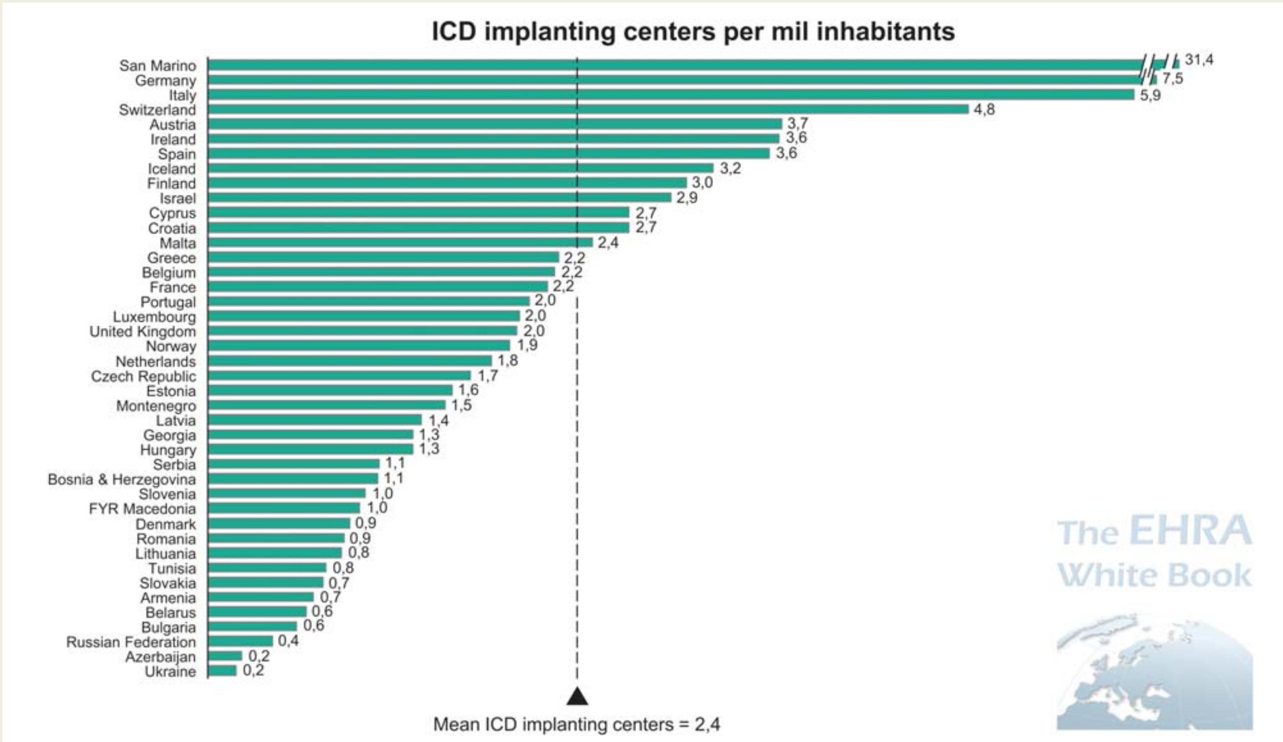

Figure 26. Rate of ICD implanting centers per million inhabitants. Displayed are only those countries with available number of ICD implantation center in 2011. The mean number of implantation centers is weighted by population. The following countries were excluded: AL, DZ, EG, LB, LY, MD, MA, PL, SE, SY, TR, XK.

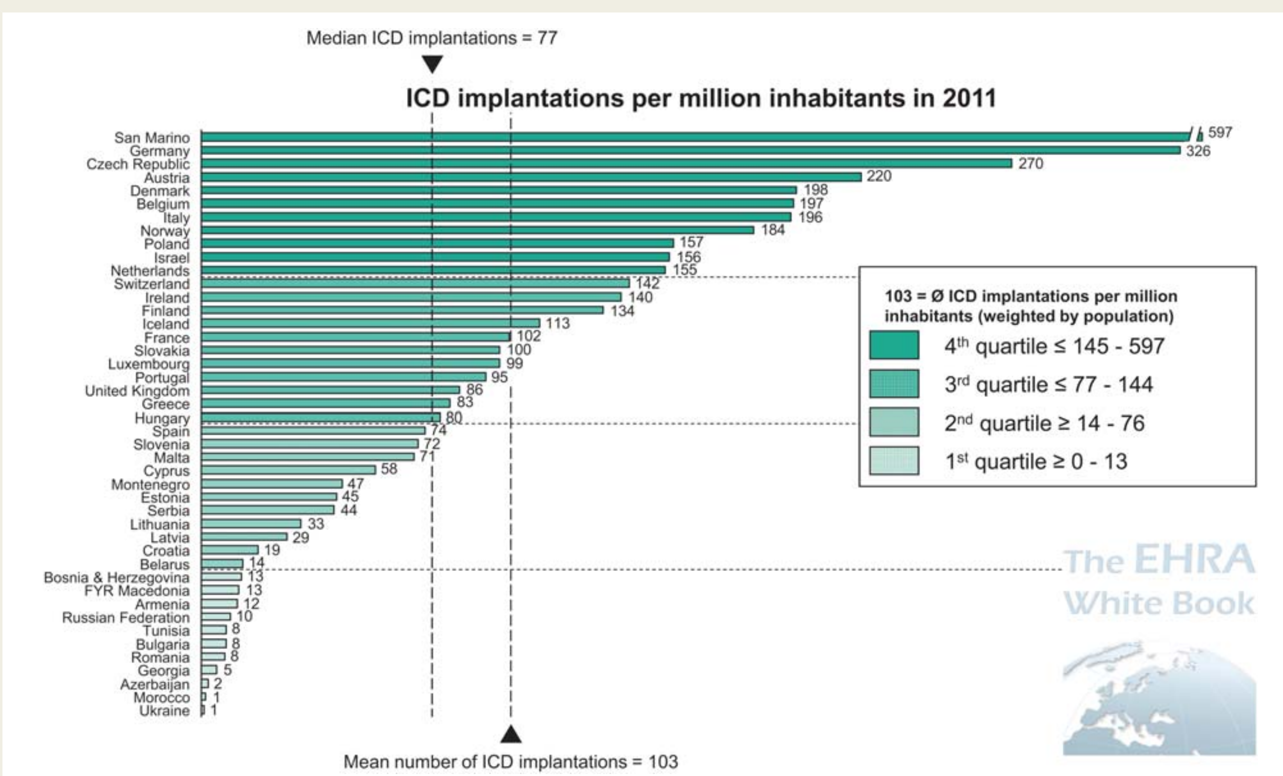

Figure 27. ICD implantation rate per million inhabitants in 2011. Displayed are 44 countries with available numbers for 2011. The median ICD implantation rate in 2011 was 77 and mean per million inhabitants in 2011 was 103. Mean number of implantations is weighted by population excluding AL, DZ, EG, LB, LY, MD, SE, SY, TR, XK. The countries were color-coded according to each quartiles.

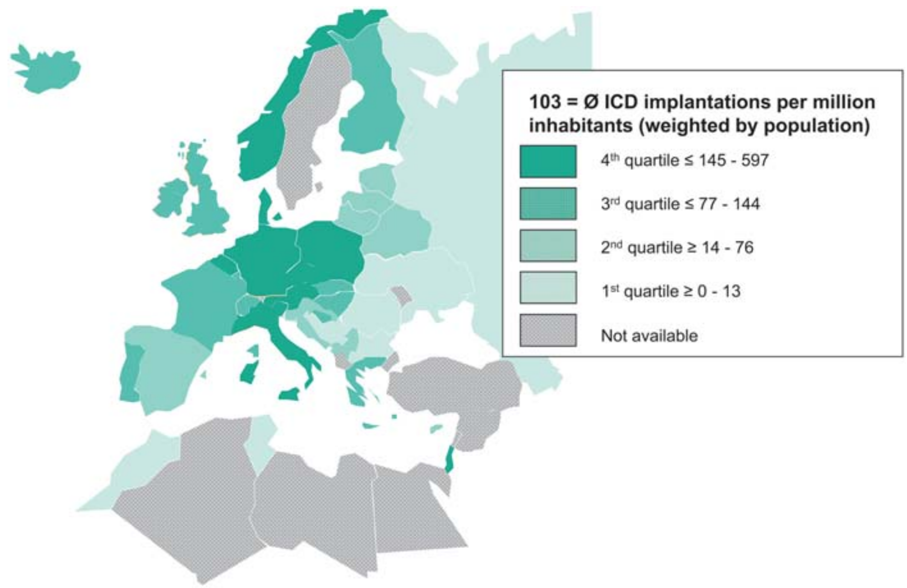

Figure 28. Geographic representation of 44 ESC countries with available ICD data. The countries were color-coded according to each quartiles of ICD implantation rate. A significant heterogeneity in ICD implantation rate can be observed.

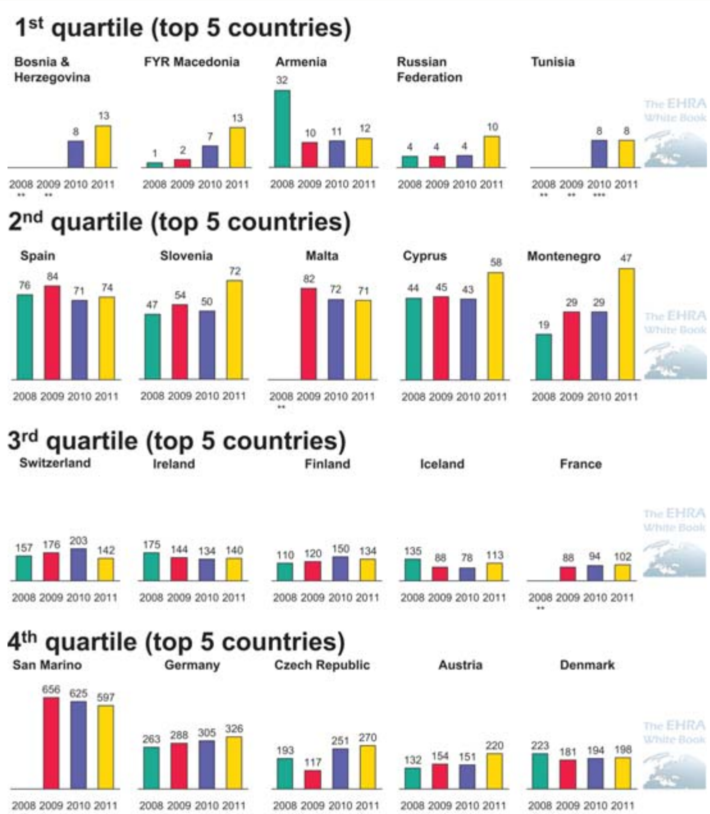

Figure 29. Change in ICD procedures in top 5 countries of the 1st, 2nd, 3rd and 4th quartile since 2008 ranked by ICD implantation rate in 2011 of the 44 available countries in 2011. The following countries were excluded: AL, DZ, EG, LB, LY, MD, SE, SY, TR, XK.Within each quarter, only those countries with available ICD implantation numbers for at least 3 years between 2008 and 2011 are displayed. ** indicated no data available in that particular year; ***TN 2010 with population according to EHRA White Book 2011.

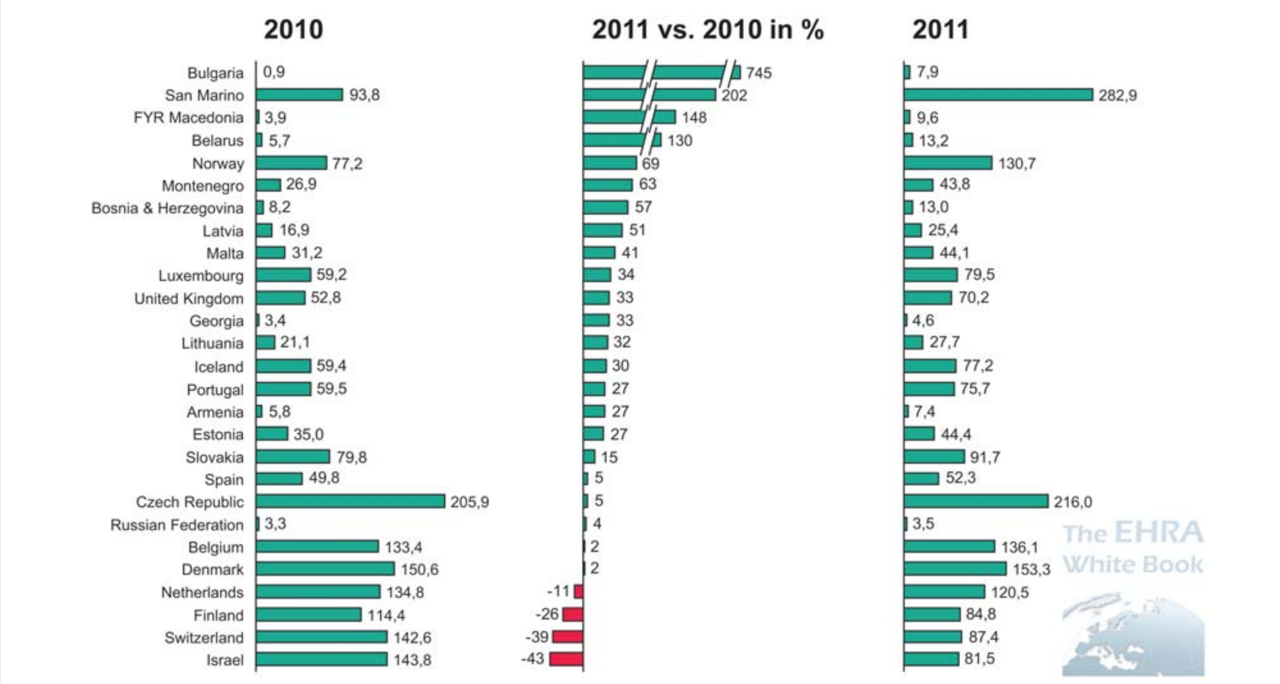

Figure 30. Change 2011 versus 2010 in the number of de-novo ICDs per million inhabitants. Displayed are only countries with available ICD implantation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. The following countries were excluded: AL, DZ,AT, AZ, HR, CY, EG, FR, DE, GR, HU, IE, PL,SE, IT, XK, LB, LY, MD, MA, RO, RS, SI, SY, TN, TR, UA.

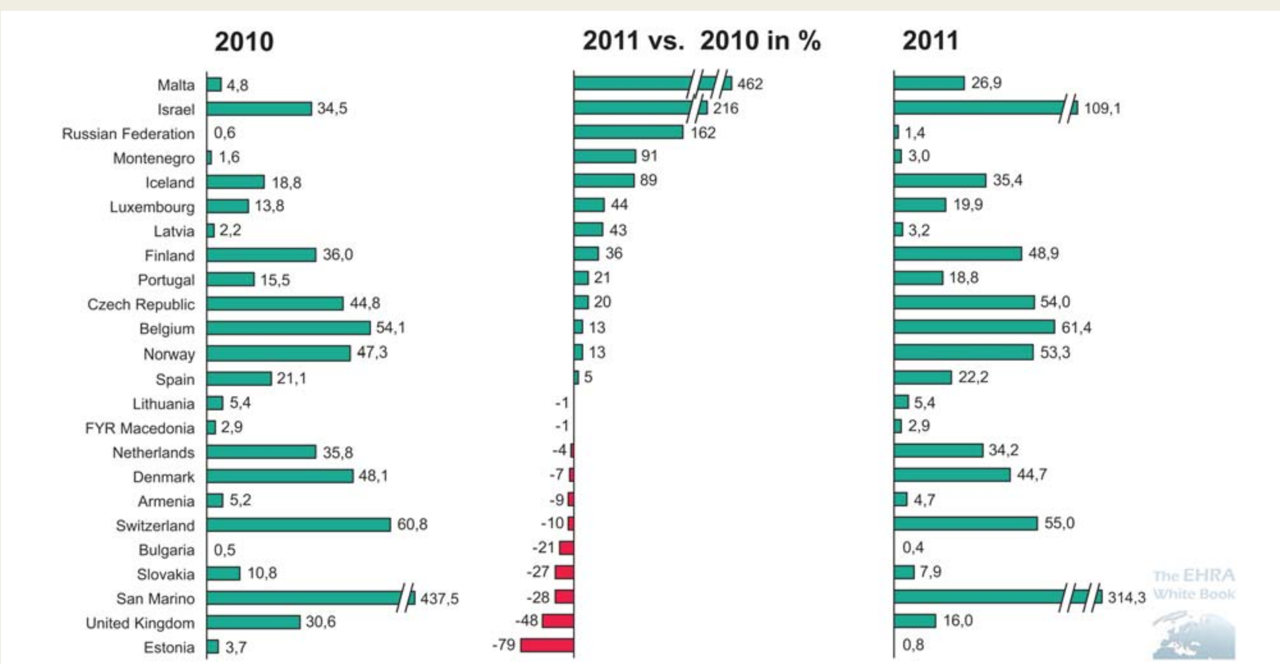

Figure 31. Change 2011 versus 2010 in the number of device replacements of ICDs per million inhabitants. Displayed are only countries with available ICD implantation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. The following countries were excluded: AL, DZ, AT, AZ, HR, CY, EG, FR, DE, GR, HU, IE, PL,SE, IT, XK, LB, LY, MA, MD, RO, RS, SI, SY, TN, TR, UA, BY, BA, GE.

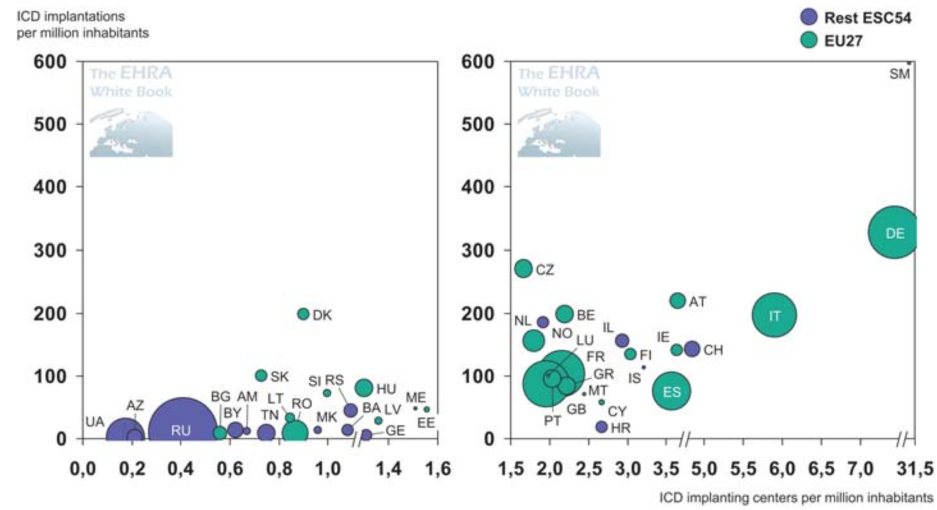

Figure 32. ICD centers and implantation rate in each of the available 42 countries. The EU-27 countries are indicated by the green bubble, and the remaining ESC countries in blue color.

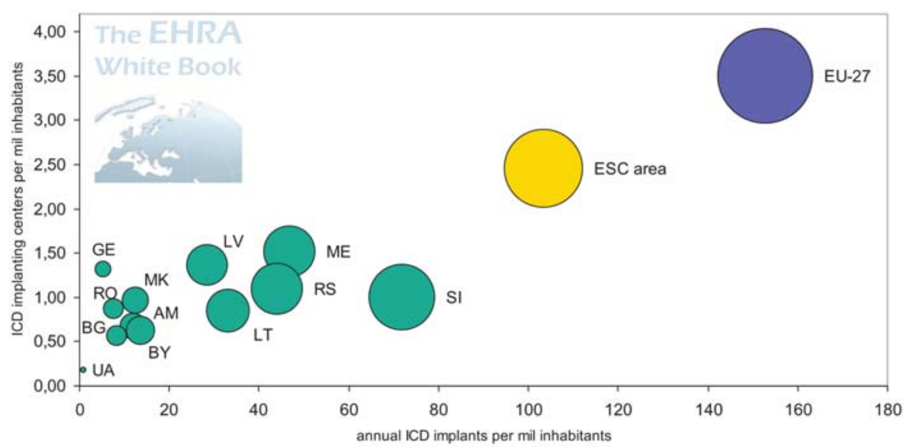

Figure 33. ICD centers and implantation rate in selected countries of Eastern and Central Europe compared to mean ESC area and to EU-27 values. The circular areas are proportional to the normalized population.

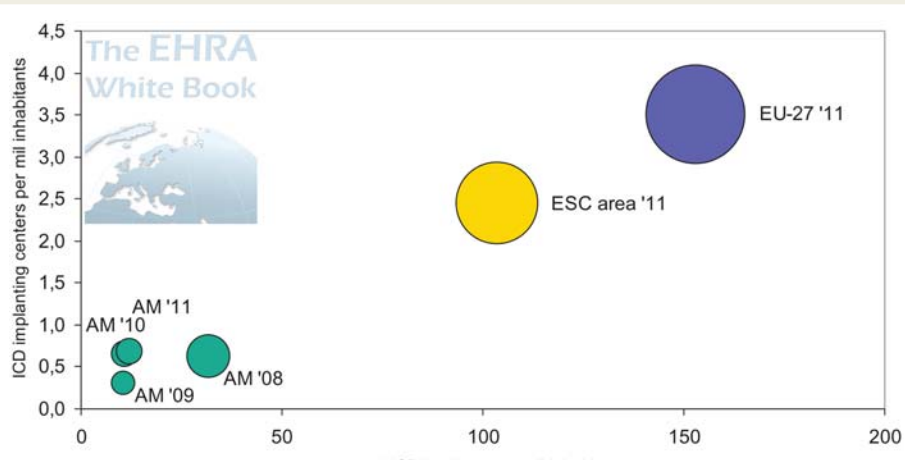

Figure 34. Evolution of ICD implantation in Armenia (AM) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

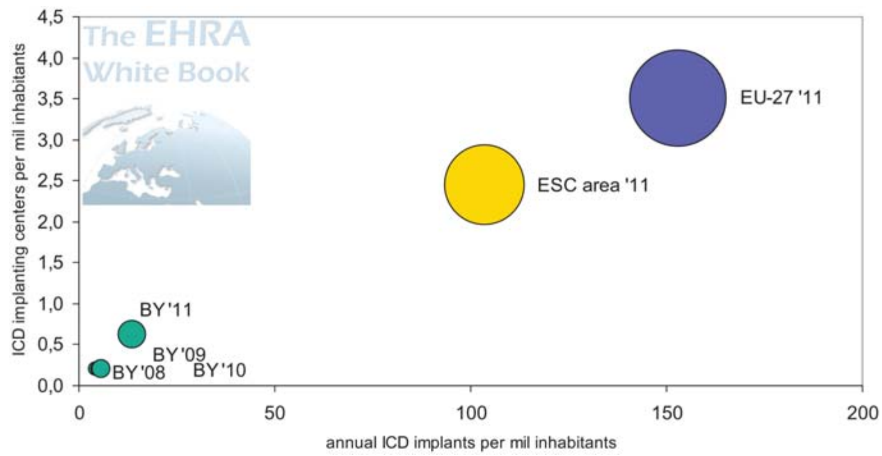

Figure 35. Evolution of ICD implantation in Belarus (BY) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

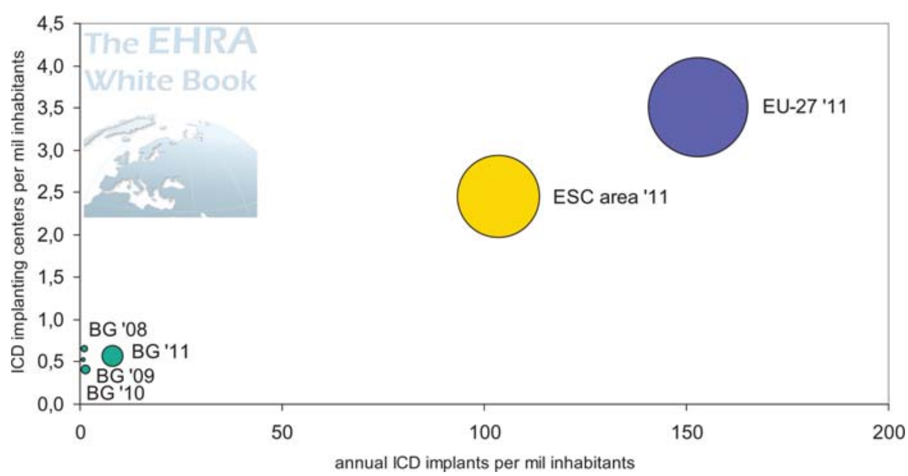

Figure 36. Evolution of ICD implantation in Bulgaria (BG) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

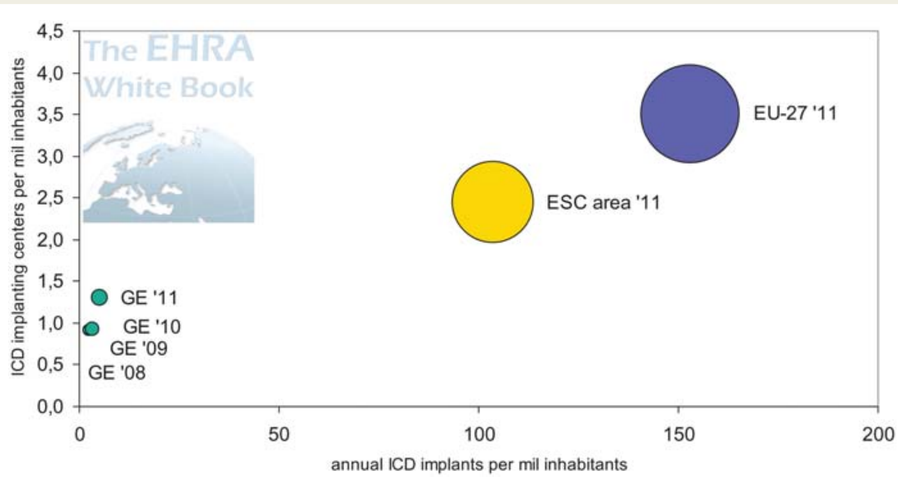

Figure 37. Evolution of ICD implantation in Georgia (GE) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

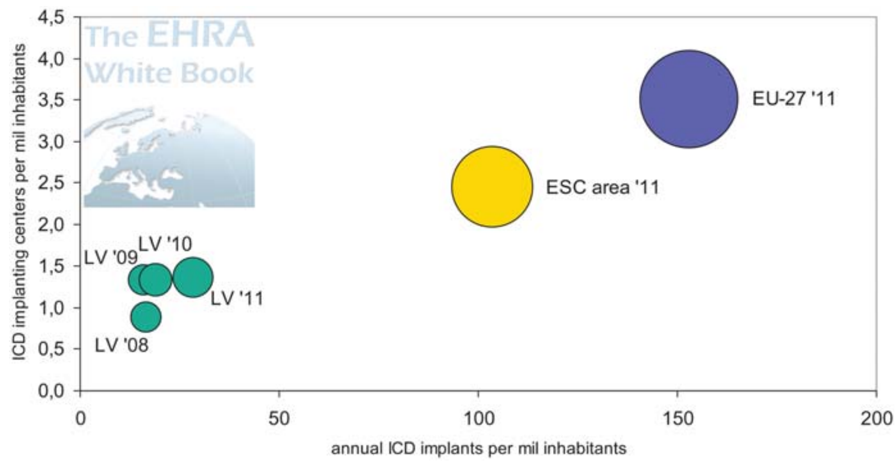

Figure 38. Evolution of ICD implantation in Latvia (LV) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

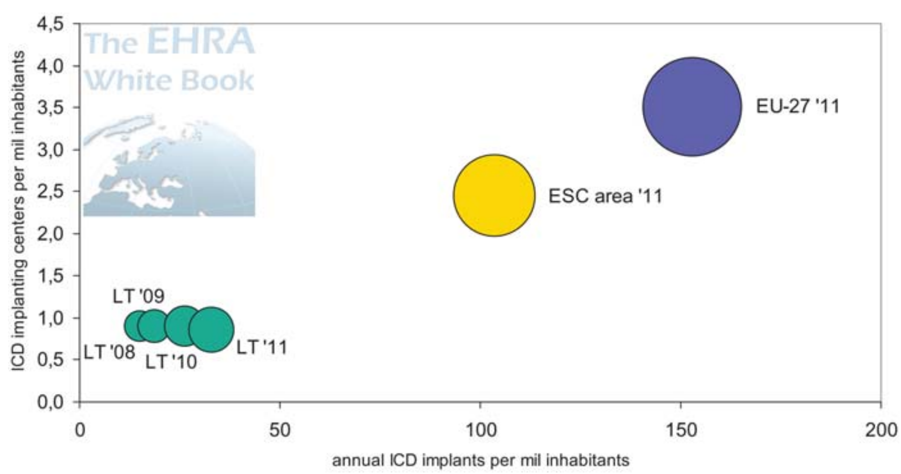

Figure 39. Evolution of ICD implantation in Lithuania (LT) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

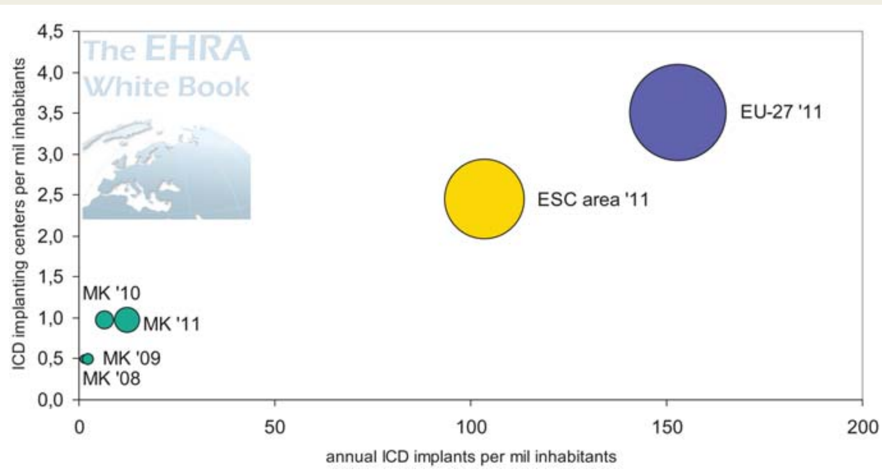

Figure 40. Evolution of ICD implantation in the FYR Macedonia (MK) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

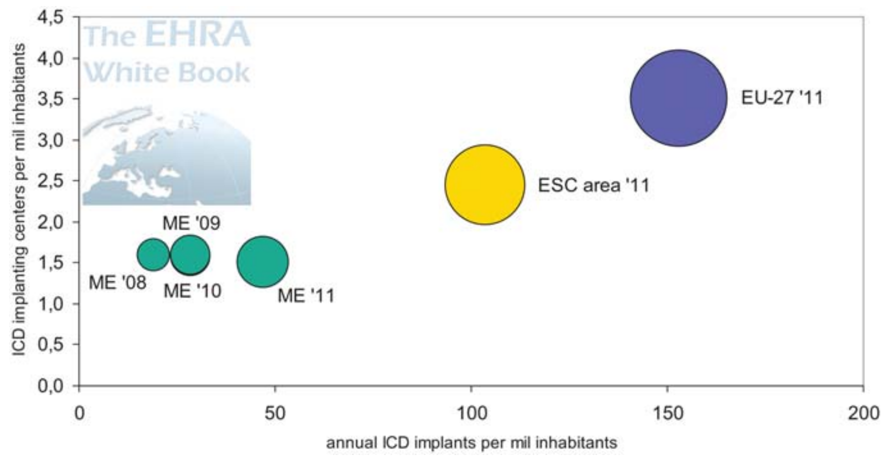

Figure 41. Evolution of ICD implantation in Montenegro (ME) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

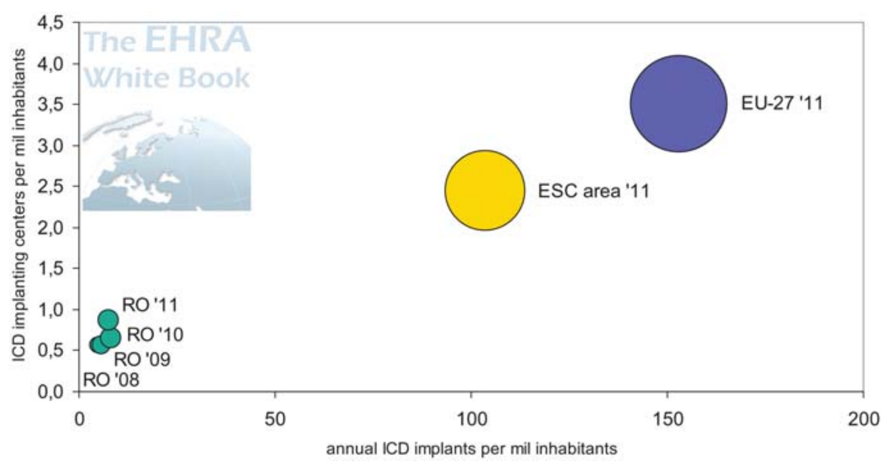

Figure 42. Evolution of ICD implantation in Romania (RO) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

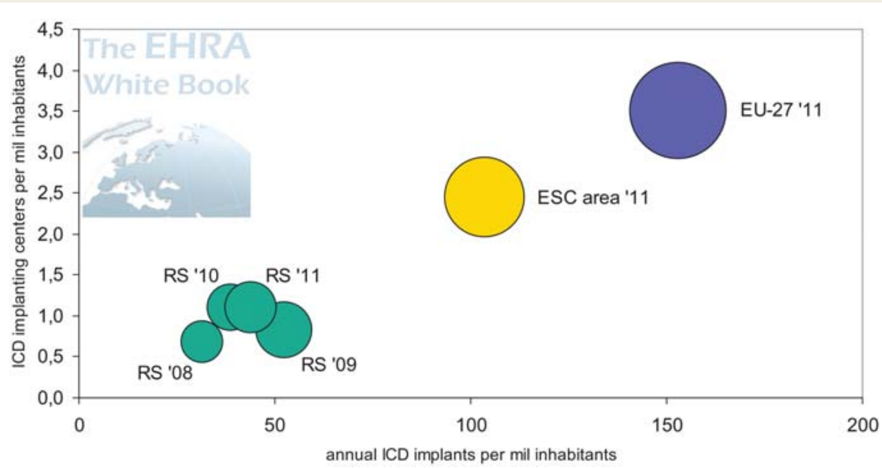

Figure 43. Evolution of ICD implantation in Serbia (RS) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

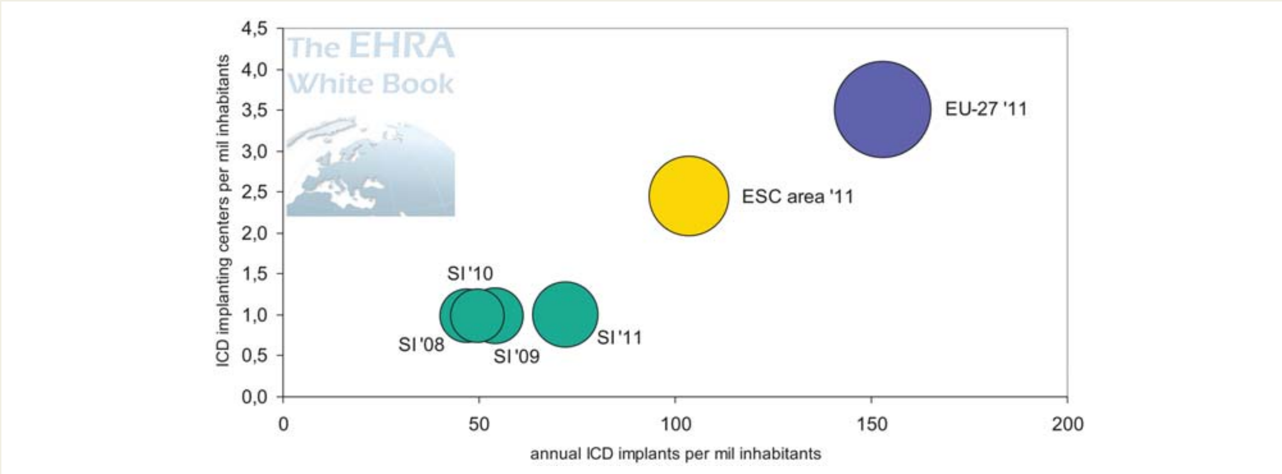

Figure 44. Evolution of ICD implantation in Slovenia (SI) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

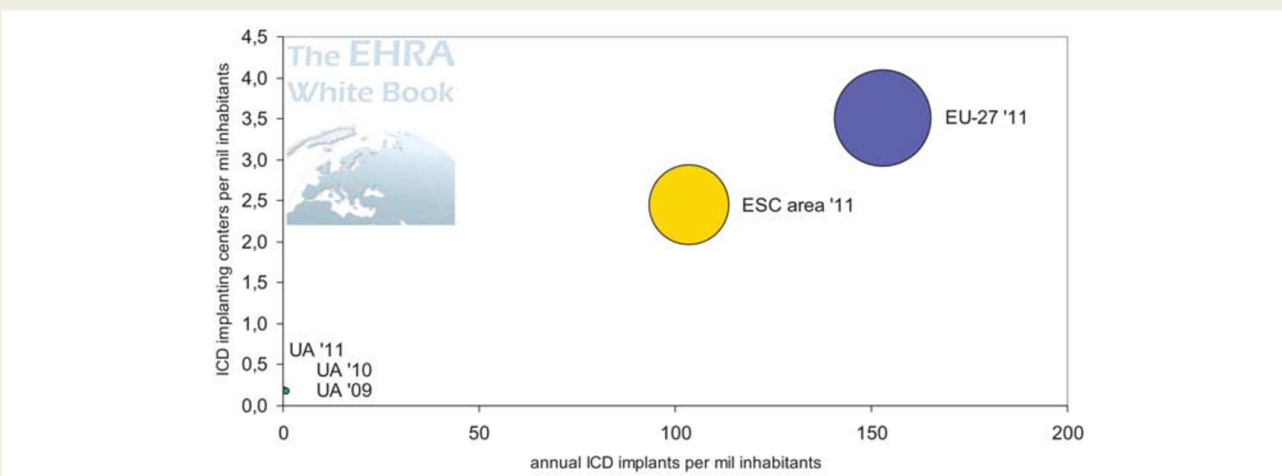

Figure 45. Evolution of ICD implantation in Ukraine (UA) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers. No 2008 data available.

Table 6 Development potential for ICD centers in selected countries reflecting the additional number of centers needed to attain mean ESC area or mean EU-27 ICD center availability

Development potential - additional number of ...	AM	BY	BG	GE	LV	LT	MK	ME	RO	RS	SI	UA	∑
... ICD implanting centers to attain mean ESC area level	6	18	14	6	3	6	4	1	35	10	3	103	209
... ICD implanting centers to attain mean EU-27 level	9	28	21	11	5	10	6	2	58	18	5	150	323

Cardiac Resynchronization Therapy devices (CRT)

CRT utilization in ESC member countries

The number of CRT implants was 76/million capita in 2008 for the 31 ESC member countries where data was available – there was a 43% increase from 2006 (few large countries, such as Russia and Turkey were excluded due to lack of data, resulting in a population of 518 million. Including these countries with data from 2007, the number of implants was 42/million capita). Significant geographical differences were noted, 163 implants/million capita were performed in Italy, while Georgia had only 0.4. There was significant variability in the ratio of CRT-D/CRT-P implants (on average 60-70% CRT-D). The number of CRT implants or its growth between 2006 and 2008 was higher in countries with greater number of implanting centers/capita, where the devices were reimbursed or who adhered to a national guideline. Average healthcare spending per capita was not a significant factor.

By 2011, the average number of CRT implants rose to 77/million capita for the 42 countries where data were available (large countries, such as Russia with 6/million and Ukraine with 1/million included, Figure 46). The ratio of CRT-D implants was 80% (19 CRT-P/million – Figure 47, and 62 CRT-D/million – Figure 48). The average implantation numbers in 2011 were 115/million for the EU-27 and 75/million for the ESC-45 – this has been consistently increasing since 2006.

The number of implants shows great geographical variability, from as low as 1/million (Morocco) to as high as 203/million (Italy). The distribution is skewed, the median number of implants is only 43/million – several large countries have very low implant numbers. Countries in the upper quartile implant between 83 and 203 devices/million, however, the lower quartile only 1-11 – including huge populations such as Russia, Belarus and Ukraine (Figure 49). These significant differences have been noted and lead to the development of a joint EHRA effort to improve utilization of implantable cardiac devices in some Central and Eastern European countries (Figure 50).

CRT implantation is still technically challenging and is not performed in all IPG implanting centers. "CRT centers" are usually located in tertiary care facilities, and their number shows great geographical variability (Figure 50). On average, European Union member countries (27 countries, 503 million population) have 3/million, while ESC member countries, where data is available (45 countries out of 54, 795 million population) have 2/million (Figure 51). By excluding EU-27 from ESC-45, the number is less than 0.5. A few countries significantly lack adequate number of CRT facilities: in Romania, an additional 31 centers would be required to reach ESC-45 level, while in Ukraine, 84. For EU-27 levels, these numbers would be 50 and 123, respectively (Figure 52).

The number of centers correlates with the number of implants performed, although significant variations have been found. From countries with high number of implanting centers, Germany had

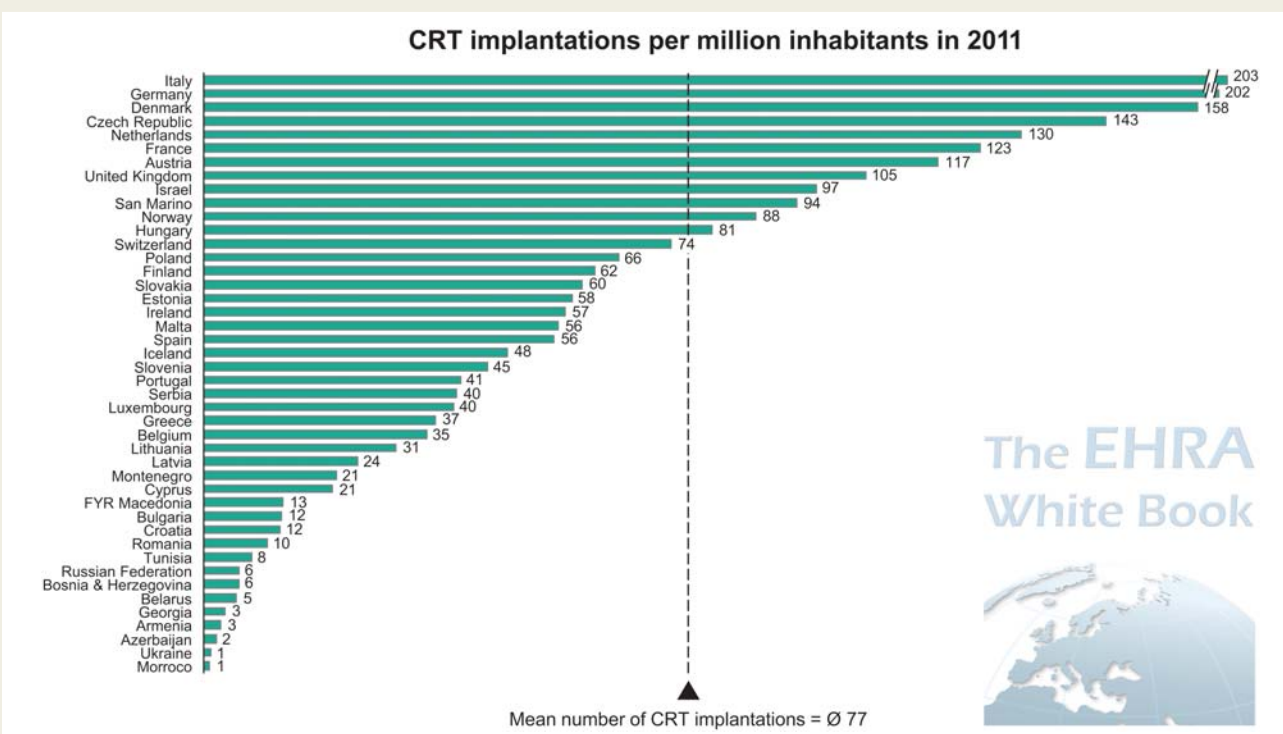

Figure 46. Standardized number of CRT implants/million capita in 2011 (CRT-P and CRT-D combined) CRT implantation rate per million inhabitants in 2011. Displayed are only countries with available numbers for 2011. The mean CRT implantation rate in 2011 was 77. Mean number of implantations is weighted by population excluding AL, DZ, EG, LB, LY, MD, SE, SY, TR, XK.

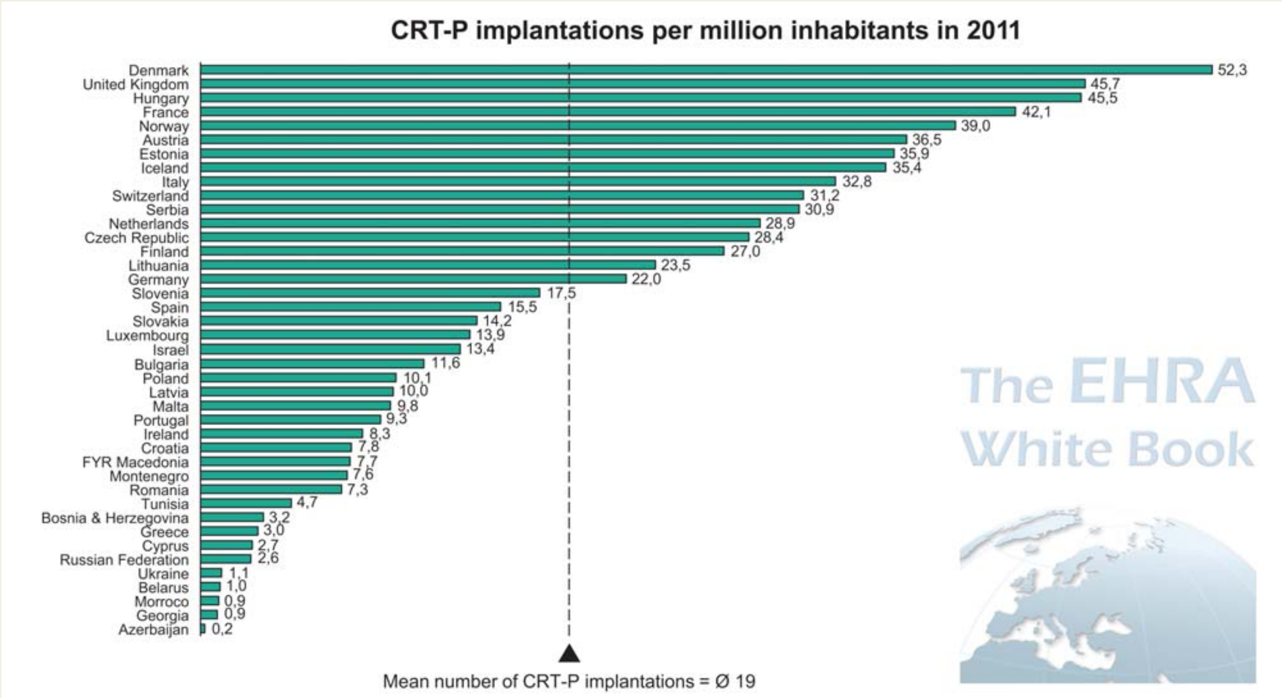

Figure 47. Standardized number of new CRT-P implantations in the ESC member countries, 2011. Displayed are only countries with available numbers for 2011, mean number of implantations is weighted by population (excluding AL, DZ, EG, LB, LY, MD, SE, SY, TR, XK); Source: EHRA White Book 2012.

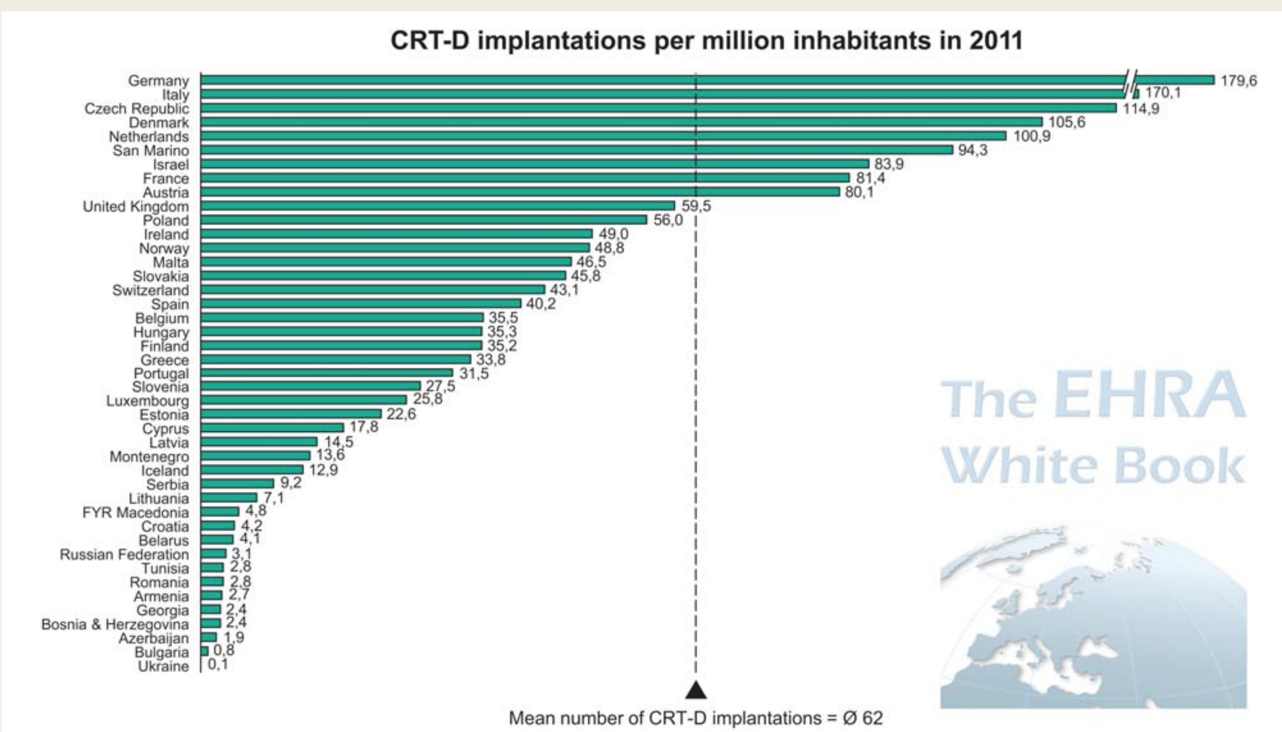

Figure 48. Standardized number of CRT-D system implantations in the ESC member countries, 2011. Displayed are only countries with available numbers for 2011, mean number of implantations is weighted by population (excluding AL, DZ, EG, LB, LY, MA, MD, SE, SY, TR, XK).

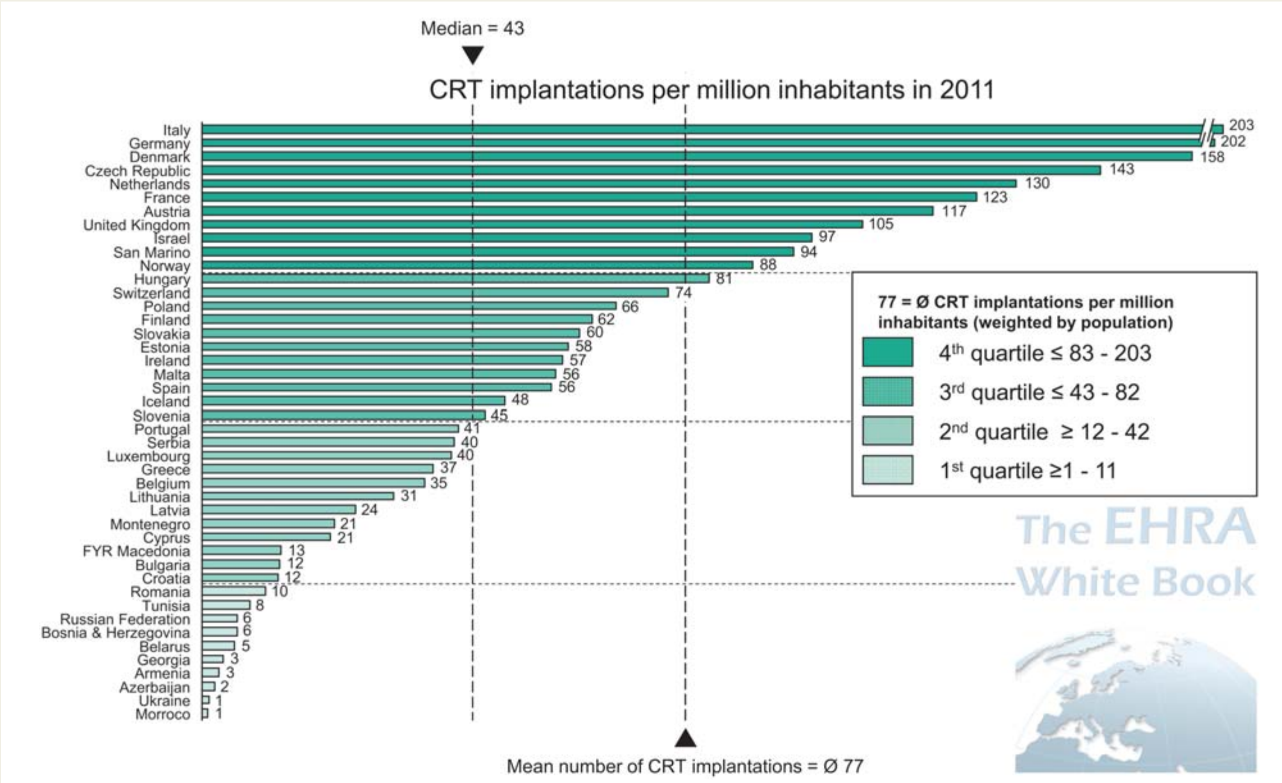

Figure 49. Standardized number of CRT implants in the ESC countries – the distribution is skewed with a median number lower than the average number – several large countries have very low implantation numbers.

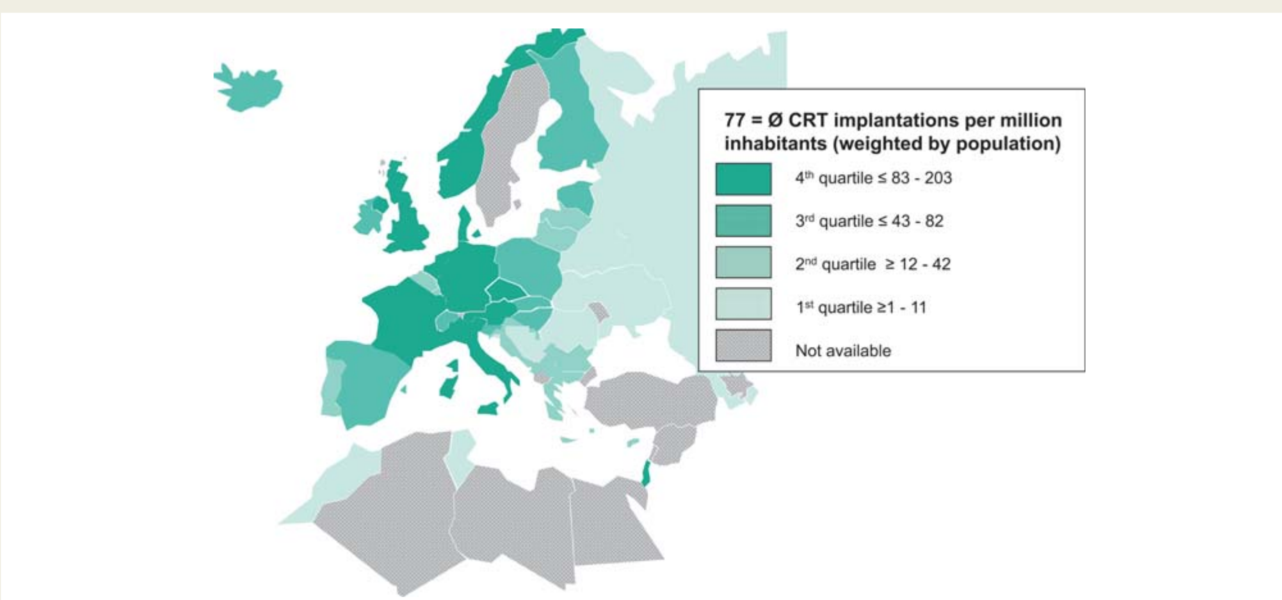

Figure 50. Geographical variation in standardized CRT implantation numbers. Easter and Central European countries are mostly in the lower quartile groups. Displayed are only countries with available numbers for 2011, mean number of implantations is weighted by population (excluding AL, DZ, EG, LB, LY, MD, SE, SY, TR, XK).

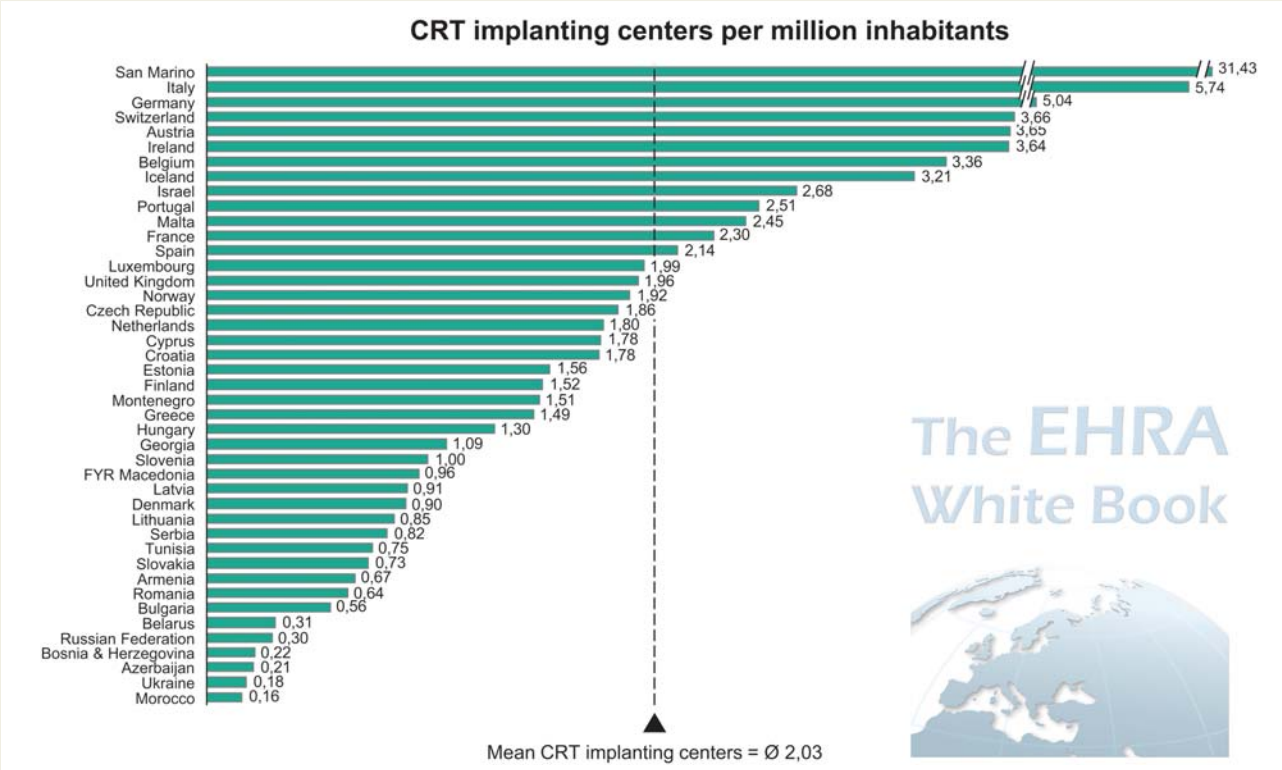

Figure 51. Geographical variation in the standardized number of CRT implant centers shows similarly wide distribution, as the number of CRT implants. Displayed are only countries with available CRT implantation center numbers for 2011, mean number of implantation centers is weighted by population, excluding AL, DZ, EG, LB, LY, MD, PL, SE, SY, TR, XK).

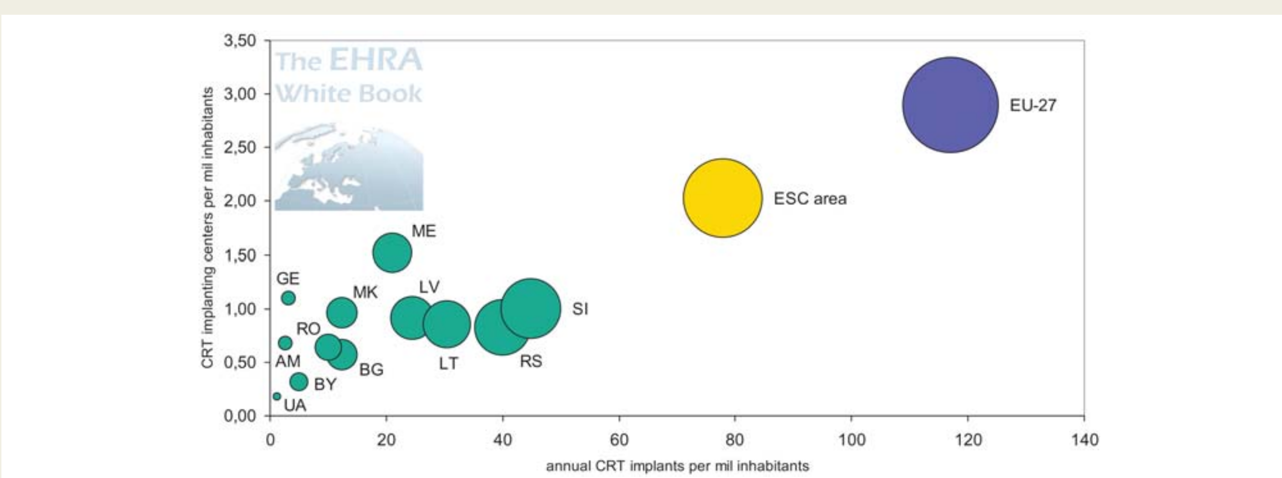

Figure 52. CRT centers and implantations in selected countries compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

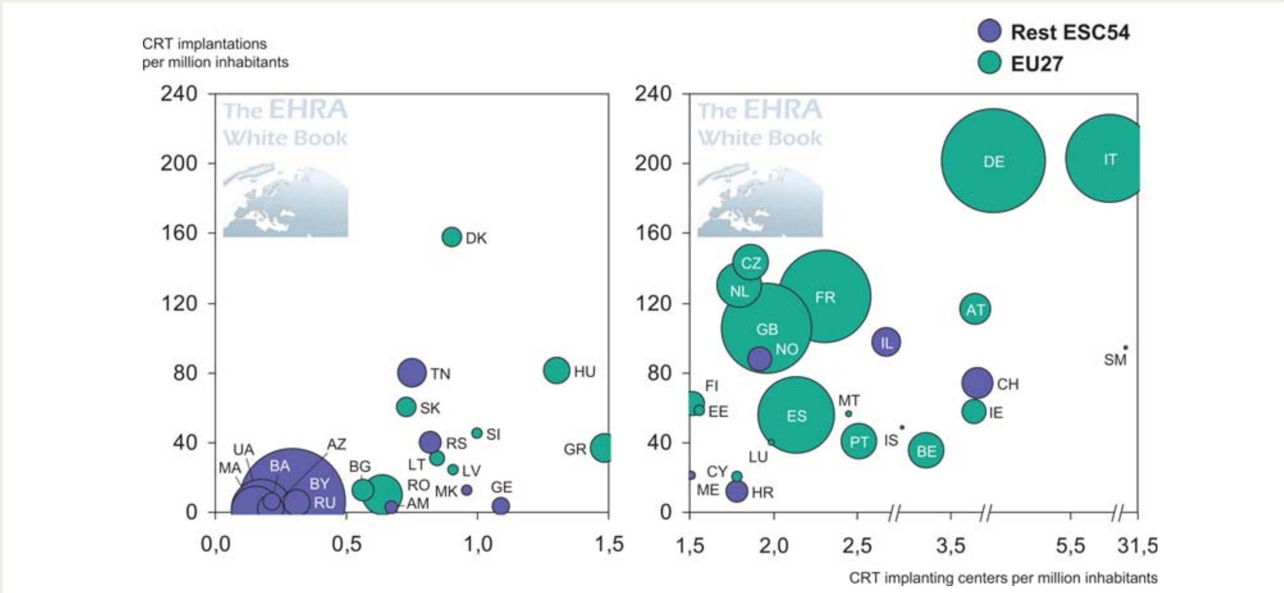

Figure 53. Number of implantation centers/million capita vs. number of CRT implants/capita in 2011. Displayed are only available numbers for 2011 in EU27 and rest of ESC area countries. The bubble size is in correlation to population. The following countries were excluded: AL, DZ, EG, LB, LY, MD, PL, SE, SY, TR, XK). The number of CRT centers in a country correlates with the number of implants performed, however, several outliers can be identified on both end of the spectrum.

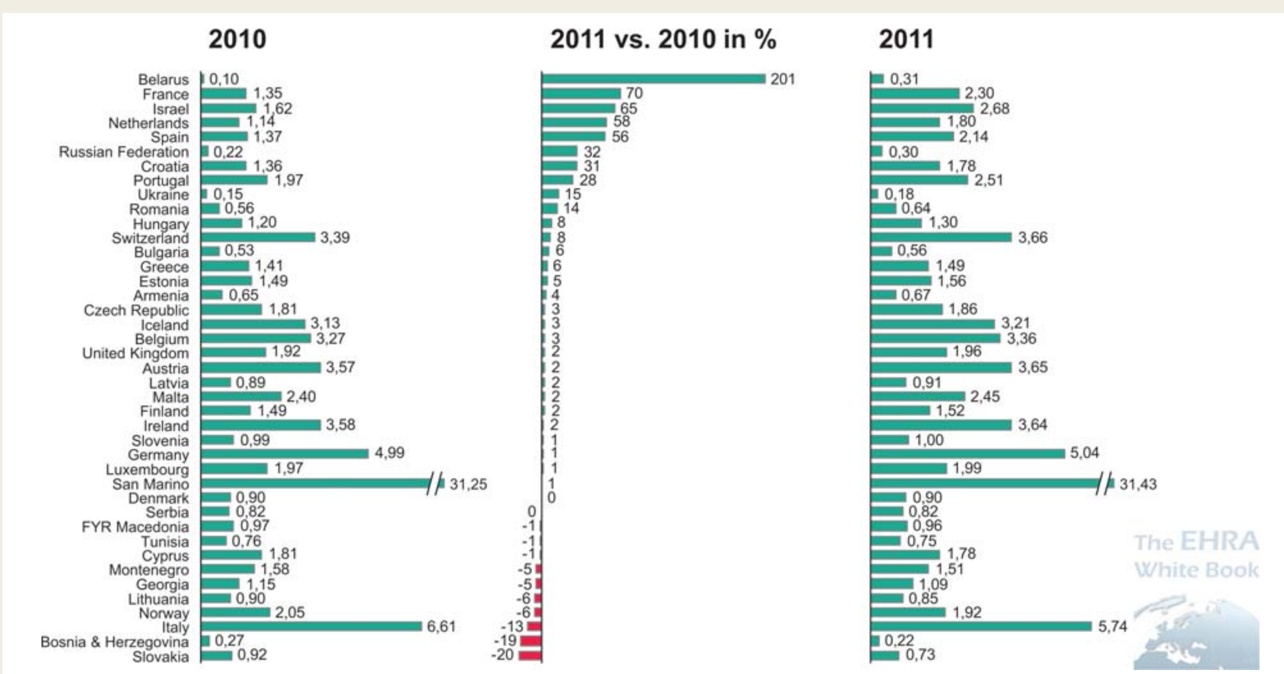

Figure 54. Change 2011 vs 2010 number of CRT implanting centers per million inhabitants. The number of CRT centers is increasing in most ESC member countries.

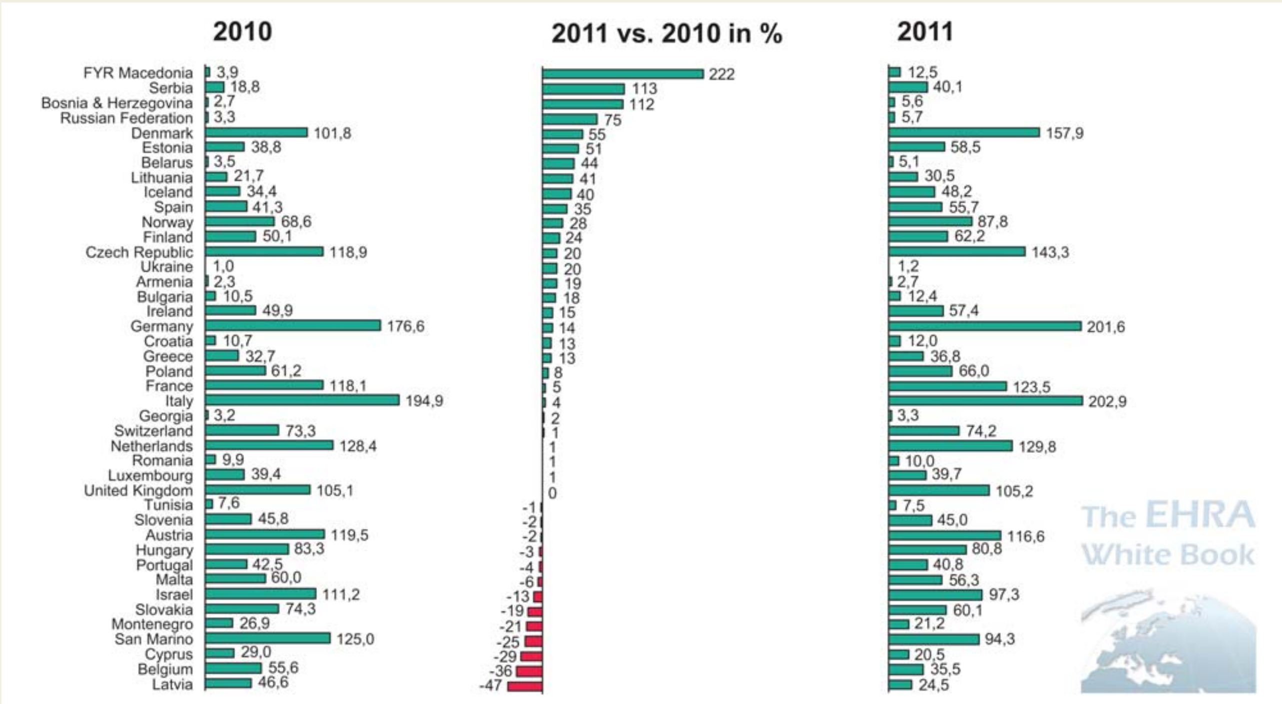

Figure 55. Change 2011 vs 2012 number of CRT implantations per million inhabitants. Growth of CRT utilization in Europe, 2010 to 2011. Change 2011 versus 2010 in the total number of CRTs per million inhabitants. Displayed are only countries with available CRT implantation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. The following countries were excluded: AL, AZ, DZ, EG, LB, LY, MA, MD, SE, SY, TR, XK. Most countries reported growth in the number of CRT implants between 2010 and 2011, correlating with the increasing number of CRT centers.

Table 7 Development potential for CRT centers in selected countries reflecting the additional number of centers needed to attain mean ESC area or mean EU-27 CRT center availability

Development potential - additional number of...	**AM**	**BY**	**BG**	**GE**	**LV**	**LT**	**MK**	**ME**	**RO**	**RS**	**SI**	**UA**	**?**
...CRT implanting centers to attain **mean ESC area level**	4	17	11	5	3	5	3	1	31	9	3	84	176
...CRT implanting centers to attain **mean EU-27 level**	7	25	17	9	5	8	5	1	50	16	4	123	270

201.6 implants/million capita (40.3/center), while Ireland only 57.4 (15.9/center in 3.6 centers/million). From countries with low number of implanting centers, extremes are represented by Denmark (0.9 centers/million, 157.9 implants/million, 175.9 implants/center) and Georgia (1.1 centers/million, 3.3 implants/million, 3 implants/center). Only a few, mostly smaller EU-27 countries have less CRT implant centers that countries outside this group (Figure 53).

The number of CRT centers is growing in most ESC member countries (Figure 54). This correlates with the increasing number of both CRT-P and CRT-D implantations, however, fewer countries reported growth here (Figures 55,56).

Countries in the upper 50th percentile significantly increased the number of CRT implants, however, fluctuations may be observed in Denmark and the Czech Republic, while Slovakia decline in 2011. Countries in the 2nd quartile experience even more pronounced year-to-year variation, while to growth was only minimal in the lowest quartile (Figure 57).

CRT implantation numbers are still low in non-EU-27 countries. As the disease burden and population characteristics are comparable, this implies that a significant number of eligible patients are not able to benefit from this effective and cost-effective treatment modality. It was shown previously that average healthcare spending or GDP did not correlate strongly with implant numbers, while other factors, such as local guidelines, device reimbursement and the number of implant centers did. Focusing on changing local policies to achieve a more uniform approach to CRT, and bringing experience to these countries may increase implant numbers and decrease the persisting, significant geographical differences. Table 7 shows development potential for CRT centers in selected countries and figures 58 to 69 show the evolution in CRT therapy in selected countries.

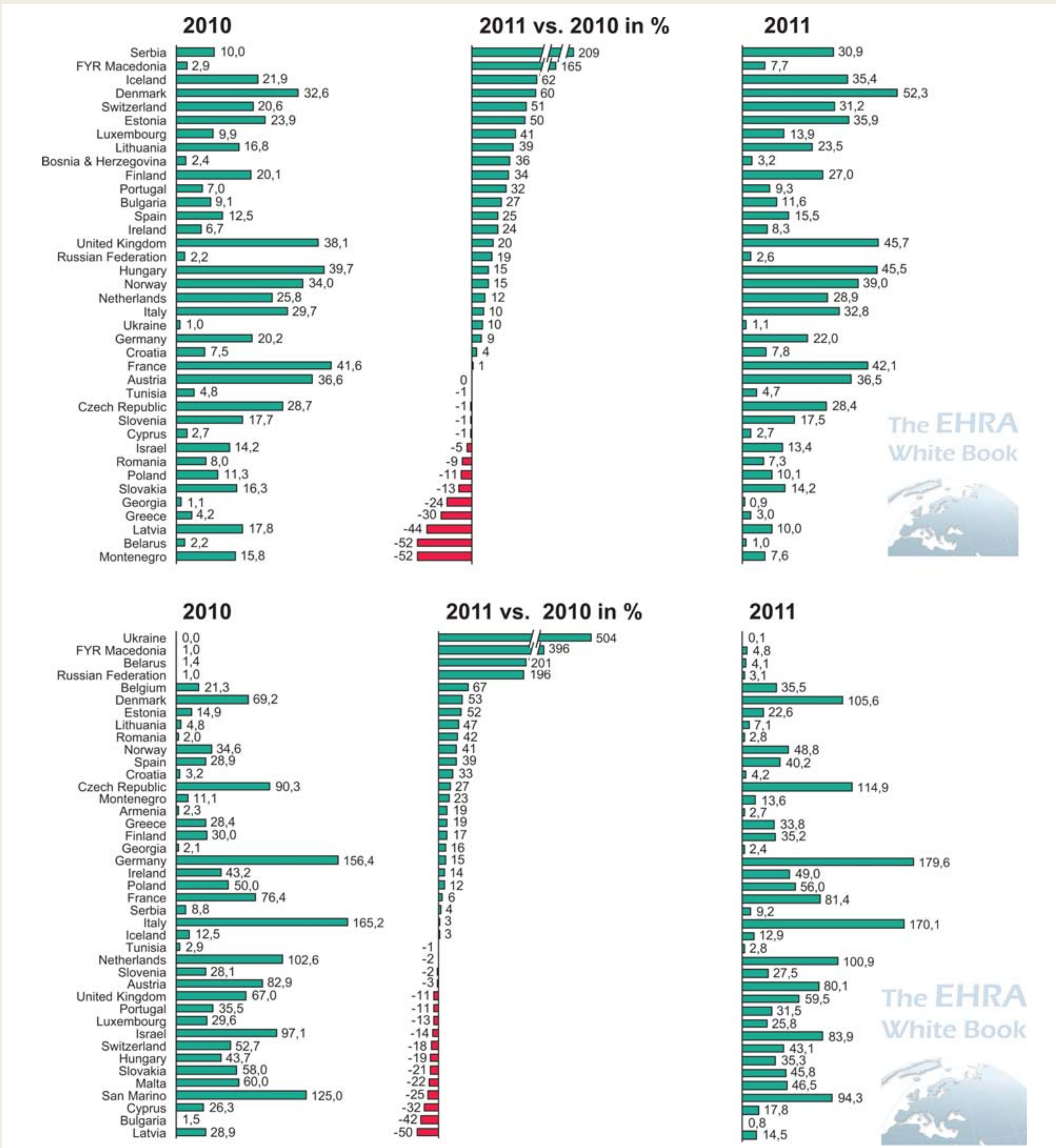

Figure 56. Change 2001 vs 2010 number of CRT-P and CRT-D per million inhabitants. Geographical differences exist between the growth rate of CRT-P and CRT-D implants.

Catheter ablation

General information

Table 8 lists the 46 countries (85% of all ESC countries) which submitted potentially relevant data about catheter ablation to the purpose of the EHRA White Book. 22 countries had a national registry on catheter ablation but for the rest of countries data came from estimation done by the national working groups. According to the United States Census, in 2011 749'859'018 people lived in the 45 countries (no data available for Egypt); however, when excluding Egypt, Israel, Netherlands, and San Marino for which the number of ablations or ablation centers were not reported in 2011, the population covered in 2011 by the EHRA White Book for ablation procedures was 770'700'415.

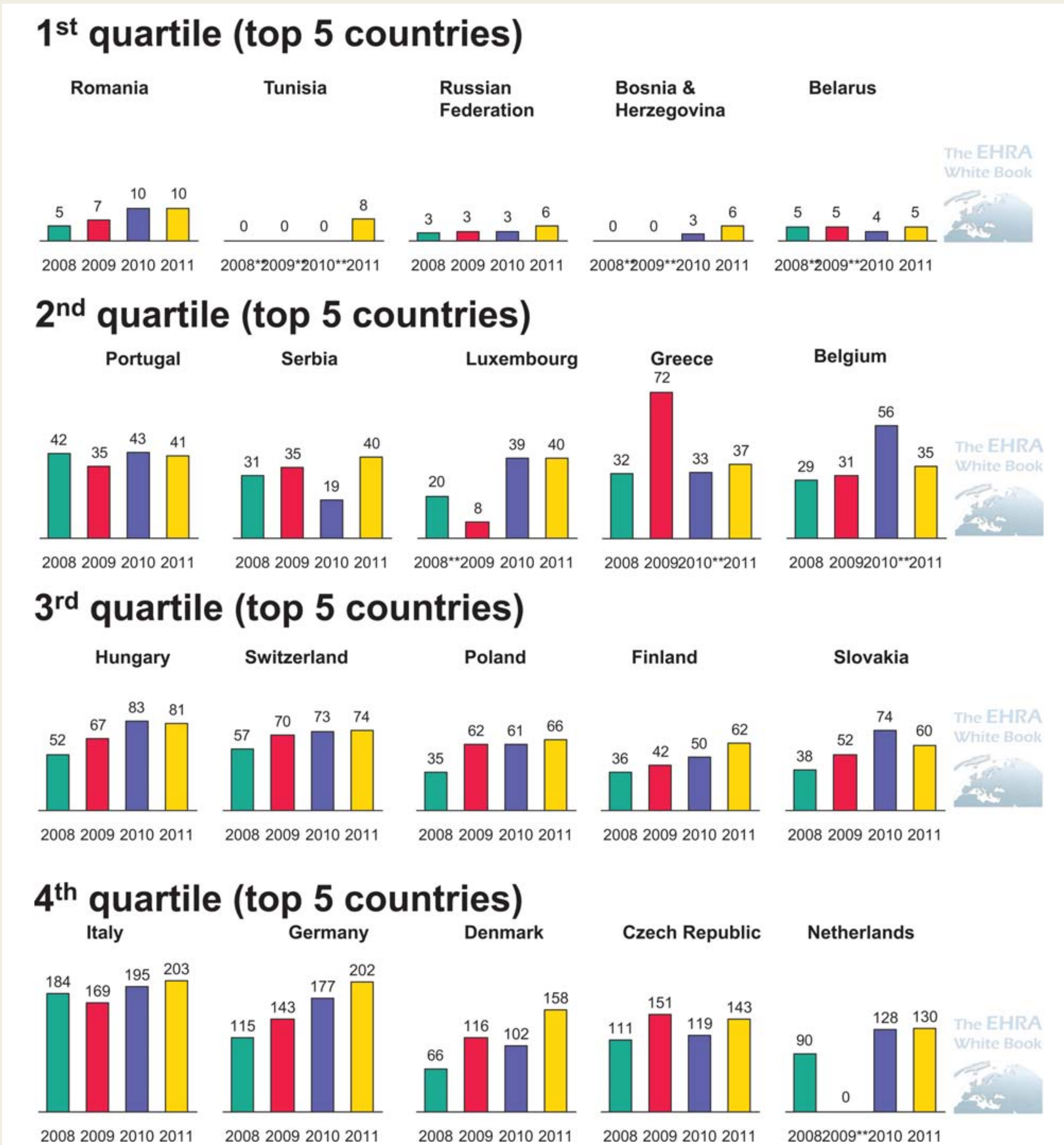

Figure 57. Changes in CRT implantation number for countries in each quartile. Countries in the two lower quartiles showed uniformly poor growth. A slow growth may be observed in the higher quartiles, however, with large geographical variation.

Ablation facilities and procedure rates

A total number of 193.402 ablations and 44.185 of atrial fibrillation (AF) ablations were performed during 2011 in 850 ablation centers in the ESC area (Figures 70 to 73).

The highest number of ablations procedures per million in inhabitans were recorded in Germany, Switzerland, and Belgium respectively and the lowest in Bosnia & Herzegovina and Morocco. Figure 70 shows the overview of ablation rate per million inhabitant for each nation which reported its data to EHRA White Book. The countries were further stratified by quartile of ablation rate and the boundaries of each quartile are given in Figure 71 as well. Across the 42 countries with ablation data, a

Table 8 Ablation facilities and Ablations in 2011

Country	ISO Code	Population 2008	Population 2009	Population 2010	Population 2011	Number of Ablation centers: Absolute number	Number of Ablation centers: per mil inhabitants	National Registry for EP	Ablations: Absolute number	Ablations: per mil inhabitants	Ablations per mil inhabitants 2010	Ablations per mil inhabitants 2009	Ablations per mil inhabitants 2008
Armenia	AM	3,234,031	3,243,729	3,092,000	2,967,975	2	0.7		98	33	16	45	55
Austria	AT	8,336,549	8,363,040	8,394,000	8,217,280	18	2.2	yes	1,805	220	214	167	163
Azerbaijan	AZ				9,397,279	1	0.1		189	20			
Belarus	BY	9,680,841	9,665,120	9,595,000	9,577,552	5	0.5		583	61	51	43	18
Belgium	BE	10,480,393	10,646,804	10,712,000	10,431,477	38	3.6	yes	5,570	534	474	447	361
Bosnia & Herzegovina	BA	3,842,265	3,838,161	3,760,000	4,622,163	1	0.2		21	5	4		
Bulgaria	BG	7,623,395	7,585,131	7,494,000	7,093,635	1	0.1	yes	278	39	40	41	38
Croatia	HR	4,434,508	4,429,078	4,403,000	4,483,804	5	1.1	yes	455	101		55	60
Cyprus	CY	793,007	803,147	1,104,000	1,120,489	2	1.8		40	36	27	25	15
Czech Republic	CZ	10,429,692	10,491,492	10,493,000	10,190,213	20	2.0	yes	4,480	440	416	379	333
Denmark	DK	5,489,022	5,519,441	5,550,000	5,529,888	6	1.1	yes	2,529	457	491	486	422
Egypt	EG												
Estonia	EE	1,340,675	1,340,271	1,341,000	1,282,963	2	1.6		385	300	333	313	371
Finland	FI	5,313,399	5,338,871	5,365,000	5,259,250	7	1.3		1,906	362	284	194	227
France	FR	62,130,520	62,342,668	62,787,000	65,102,719				31,175	479	459	418	
FYR Macedonia	MK	2,039,961	2,042,485	2,061,000	2,077,328	2	1.0		53	26	15	34	25
Georgia	GE	4,383,750	4,410,900	4,352,000	4,585,874	6	1.3		253	55	42	34	25
Germany	DE	82,119,776	81,874,768	82,302,000	81,471,834	200	2.5	yes	50,000	614	510	489	365
Greece	GR	11,237,068	11,282,751	11,359,000	10,760,136	23	2.1	yes	1,400	130	115	106	108
Hungary	HU	10,038,188	10,022,650	9,984,000	9,976,062	10	1.0		2,926	293	266	249	218
Iceland	IS	319,355	319,246	320,000	311,058	1	3.2		63	203	219	294	241
Ireland	IE	4,422,077	4,459,305	4,470,000	4,670,976	11	2.4		1,000	214	179	179	158
Israel	IL	7,308,795	7,485,600	7,418,000	7,473,052	12	1.6						260
Italy	IT	59,832,180	60,192,696	60,551,000	61,016,804	170	2.8	yes	19,000	311			
Latvia	LV	2,266,094	2,254,834	2,252,000	2,204,708	2	0.9	yes	545	247	175	140	134
Lithuania	LT	3,358,114	3,339,455	3,324,000	3,535,547	3	0.8		801	227	242	235	237
Luxembourg	LU	488,650	486,181	507,000	503,302	1	2.0	yes	127	252	183	220	203
Malta	MT	412,001	413,290	417,000	408,333	1	2.4		8	20	31	36	
Montenegro	ME	628,804	631,536	631,000	661,807	1	1.5		7	11			
Morocco	MA				31,968,361	5	0.2		100	3			
Netherlands	NL	16,445,594	16,445,593	16,613,000	16,653,734	15	0.9				344		266
Norway	NO	4,768,212	4,828,726	4,883,000	4,691,849	4	0.9		2,284	487	262	242	252

Continued

Table 8 ***Continued***

Country	ISO Code	Population				Number of Ablation centers		National Registry for EP	Ablations		Ablations per mil inhabitants		
		2008	2009	2010	2011	Absolute number	per mil inhabitants		Absolute number	per mil inhabitants	2010	2009	2008
Poland	PL	38,115,908	38,153,388	38,277,000	38,441,588			yes	8,220	214	200	167	124
Portugal	PT	10,622,412	10,632,482	10,676,000	10,760,305	18	1.7	yes	2,013	187	152	157	150
Romania	RO	21,504,442	21,469,960	21,431,298	21,904,551	14	0.6	yes	1,104	50	47	42	36
Russian Federation	RU	141,956,416	141,909,248	142,958,000	138,739,892	71	0.5	yes	16,380	118	98	94	79
San Marino	SM	28,775	28,976	32,000	31,817			yes					
Serbia	RS	7,350,222	7,320,807	7,291,436	7,310,555	3	0.4	yes	911	125	112	115	83
Slovakia	SK	5,406,972	5,418,374	5,462,000	5,477,038	4	0.7		972	177	176	164	162
Slovenia	SI	2,039,399	2,042,335	2,030,000	2,000,092	2	1.0	yes	324	162	129	120	145
Spain	ES	45,593,384	45,929,476	46,077,000	46,754,784	60	1.3	yes	8,812	188	190	170	155
Sweden	SE	9,219,638	9,298,515	9,380,000	9,088,728	10	1.1	yes	4,089	450	378	313	281
Switzerland	CH	7,512,123	7,567,659	7,664,000	7,639,961	21	2.7	yes	4,679	612	511	506	466
Tunisia	TN				10,629,186	10	0.9		600	56	48		
Ukraine	UA	46,077,832	45,872,976	45,448,000	45,134,707	13	0.3		2,139	47	41		
United Kingdom	GB	61,383,156	61,791,956	62,036,000	62,698,362	49	0.8	yes	15,078	240	229	227	196

INFO: No data available for Albania, Algeria, Lebanon, Libya, Republic of Moldavia, Syria, Kosovo, Turkey.
Source: EHRA White Book 2012; Population 2008-2010 WHO data, 2011 US Census.

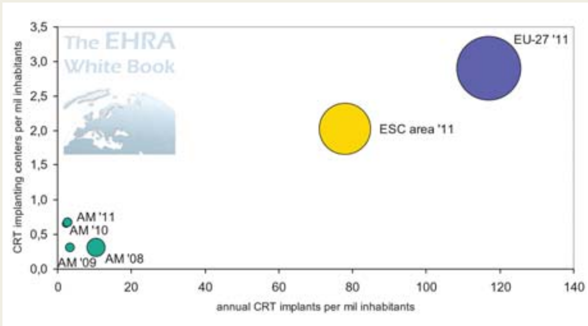

Figure 58. evolution of CRT implantation in Armenia (AM) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

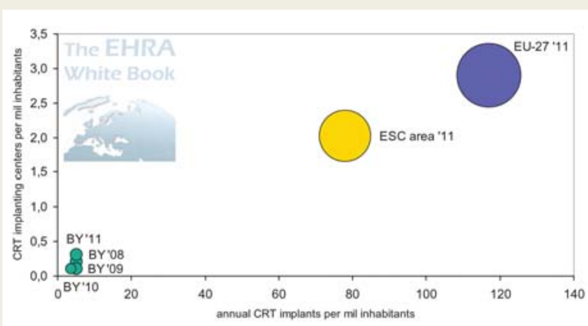

Figure 59. evolution of CRT implantation in Belarus (BY) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

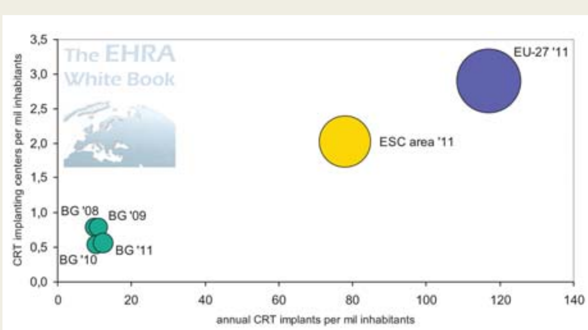

Figure 60. evolution of CRT implantation in Bulgaria (BG) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

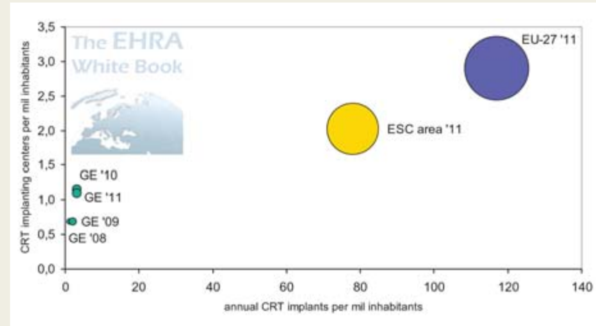

Figure 61. evolution of ICD implantation in Georgia (GE) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

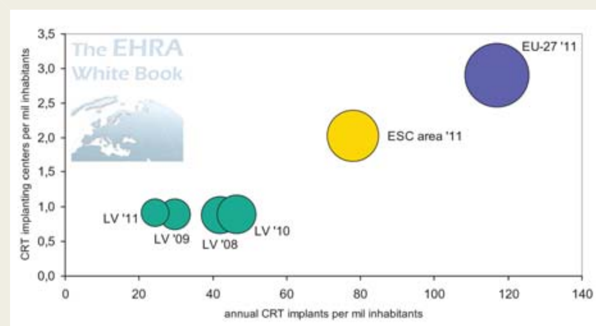

Figure 62. evolution of CRT implantation in Latvia (LV) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

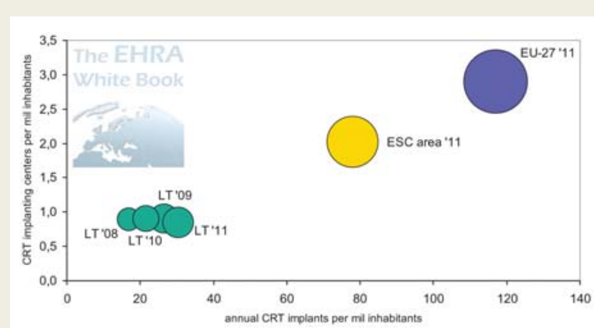

Figure 63. evolution of CRT implantation in Lithuania (LT) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

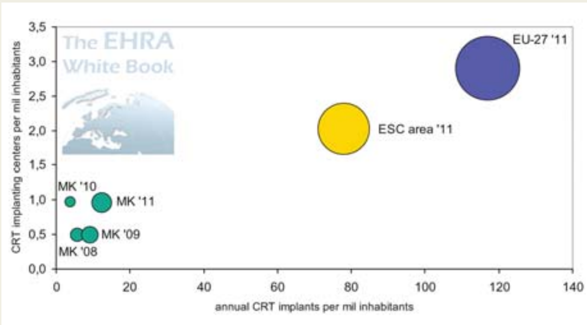

Figure 64. evolution of CRT implantation in the FYR Macedonia (MK) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

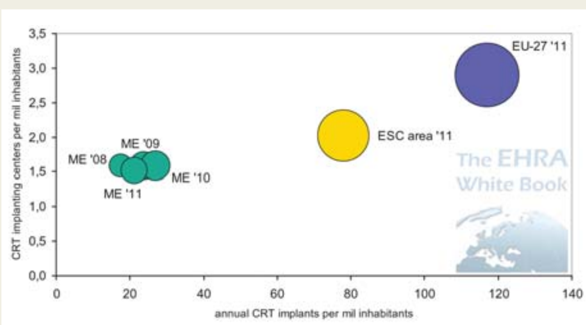

Figure 65. evolution of CRT implantation in Montenegro (ME) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers..

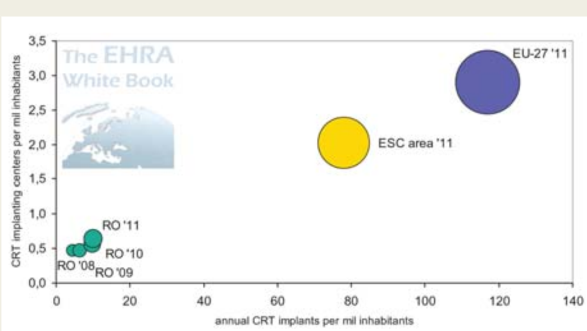

Figure 66. evolution of CRT implantation in Romania (RO) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

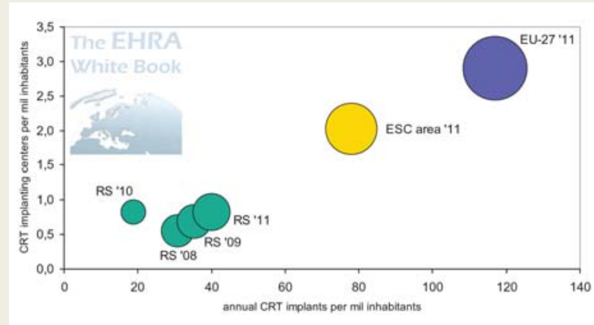

Figure 67. evolution of CRT implantation in Serbia (RS) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

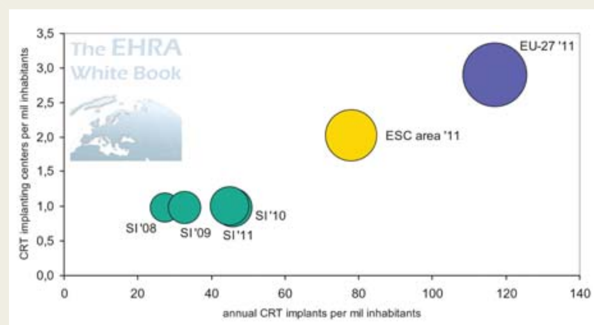

Figure 68. evolution of CRT implantation in Slovenia (SI) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

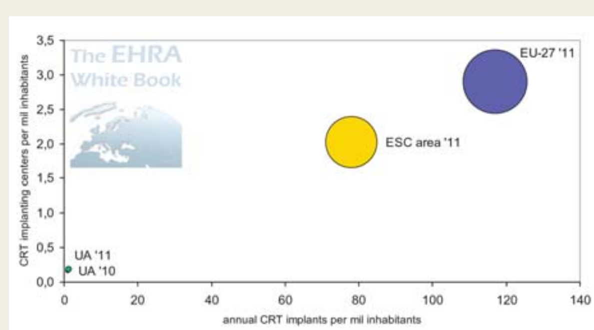

Figure 69. evolution of CRT implantation in Ukraine (UA) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers. No 2008 and 2009 data available.

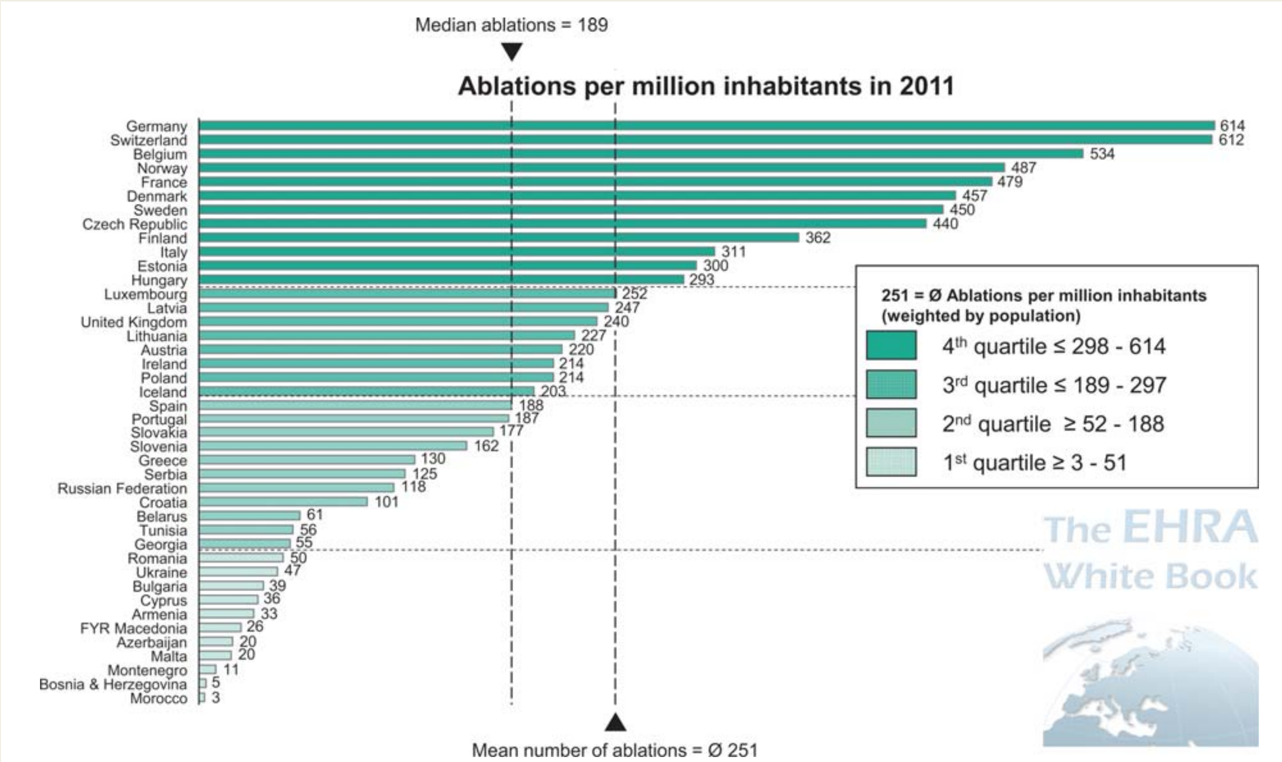

Figure 70. Rate of ablations per million inhabitants in 2011. Displayed are only those countries with available numbers for 2011. The mean number of ablation centers is weighted by population. The following countries were excluded: AL, DZ, LB, LY, MD, SY, TR, XK, EG, IL, NL, SM.

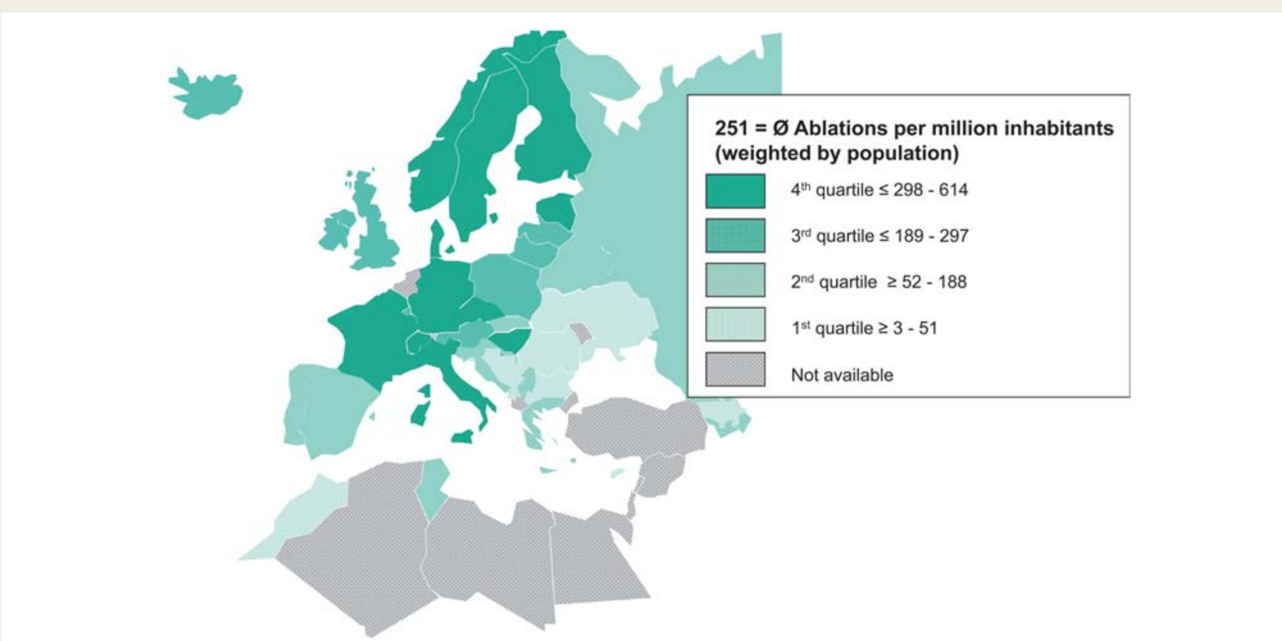

Figure 71. Geographic representation of ESC countries covered in 2012. The countries were color-coded according to each quartiles of ablation rate. A significant heterogeneity in ablation rate can be observed. Displayed are only countries with available numbers for 2011, mean number of ablations is weighted by population. The following countries were excluded: AL, DZ, LB, LY, MD, SY, TR, XK, EG, IL, NL, SM.

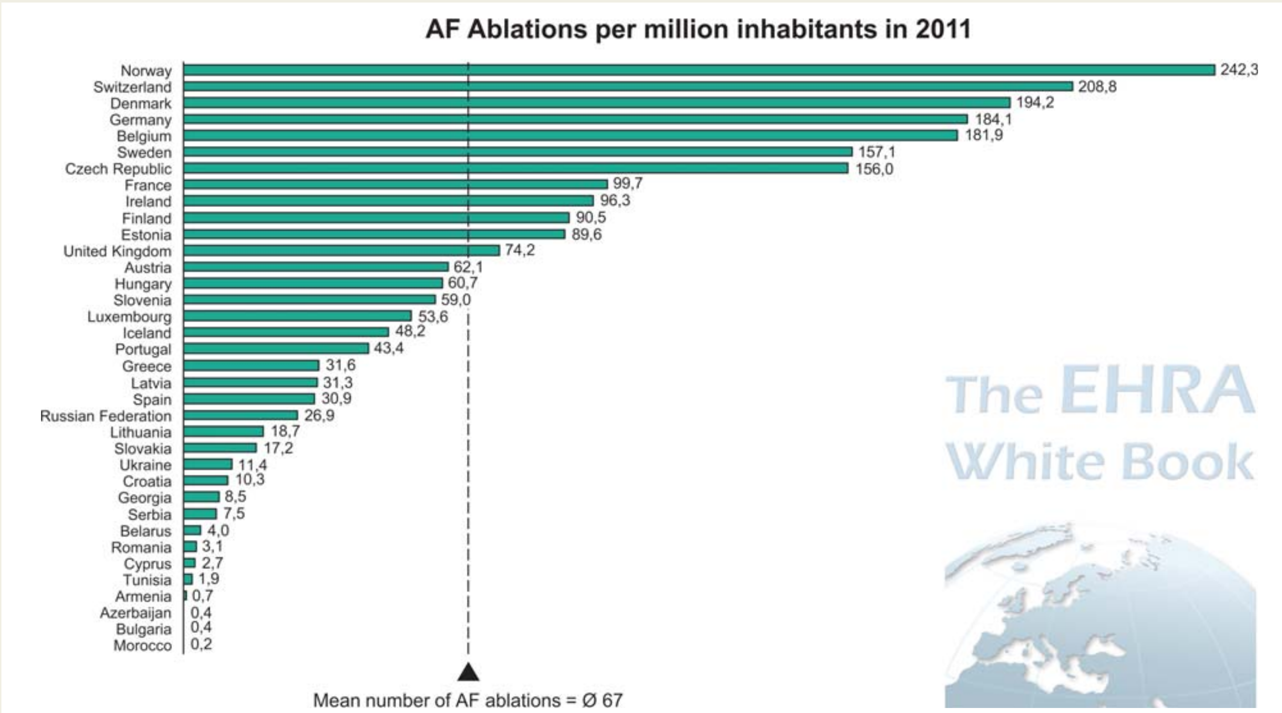

Figure 72. Rate of AF ablations per million inhabitants in 2011. Displayed are only those countries with available numbers for 2011. The mean number of AF ablations is weighted by population. The following countries were excluded: AL, DZ, LB, LY, MD, SY, TR, XK, SM, PL, NL, MT, ME, IL, IT, MK, EG, BA.

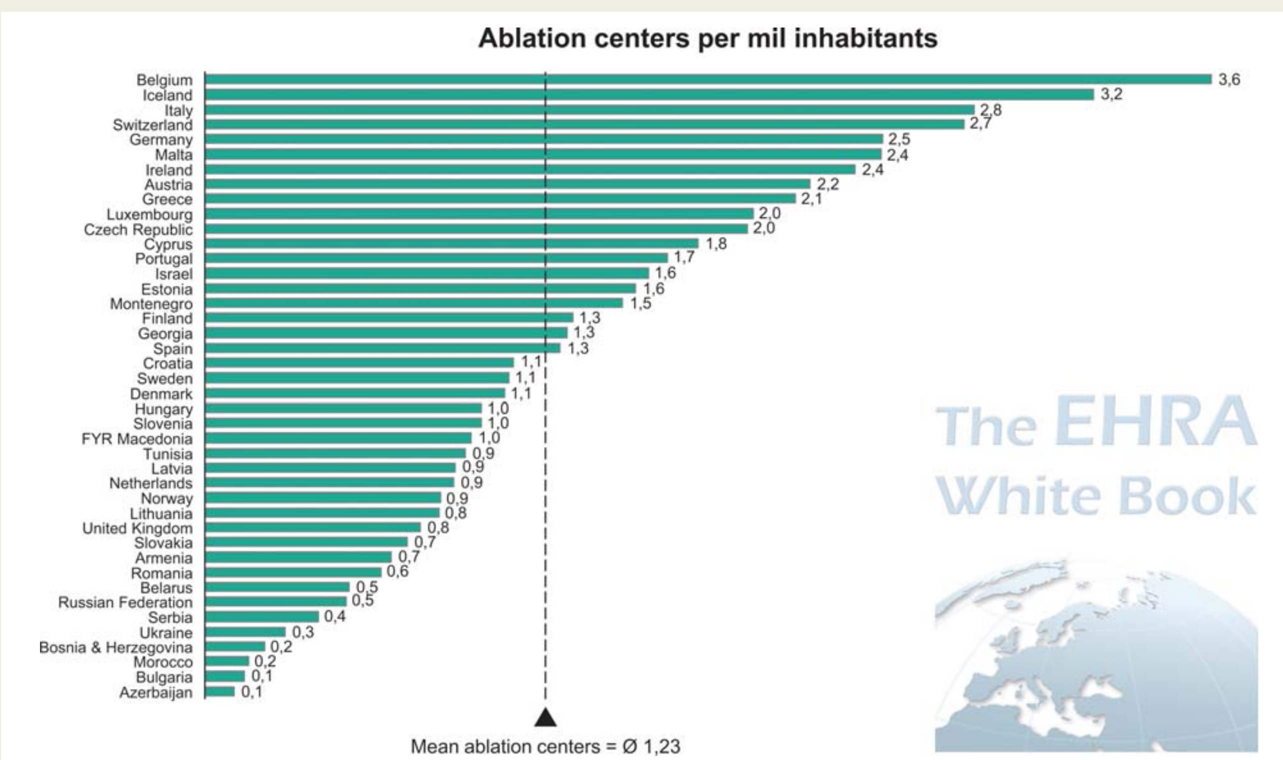

Figure 73. Rate of ablation centers per million inhabitants. Displayed are only those countries with available numbers of ablation center in 2011. The mean number of ablation centers is weighted by population. The following countries were excluded: AL, DZ, EG, FR, SM, LB, LY, MD, PL, SY, TR, XK.

marked heterogeneity was observed in the geographic distribution of ablation rate per million inhabitants.

Regarding ablation centers in 2011, the highest density was recorded in Belgium, Iceland and Italy and the lowest in Azerbaijan, Bulgaria and Morocco.

Compared with 2010 (Figure 74), the mean number of ablation centers in 39 countries with available data (excluded are Azerbaijan, Egypt, France, Montenegro, Morocco, Poland, and San Marino) remained virtually the same and increasing about 4%. There was also an increase of 13% in the number of ablations from 2010 to 2011 in 37 comparable countries (figure 75) and an increase of 11% in the number of AF ablations in 33 available countries (Figure 76). The average number of ablations in 2011 and AF ablations in 2011 done per million of inhabitants of the whole region were 251 (excluding Egypt, Israel, Netherlands, and San Marino) and 67 (excluding Bosnia & Herzegovina, Egypt, FYR Macedonia, Israel, Italy, Malta, Montenegro, Netherlands, Poland, and San Marino). The median values are 189 ablations and 229 AF ablations per million of inhabitants.

The top 5 countries on the number of ablations performed per million inhabitans (Germany, Switzerland, Belgium, Norway and France) showed a similar rate of yearly increase over the last 4 years except for Norway which showed and striking increase (85%) in 2011 (figure 77). The top five countries of the first quartile on the number of ablations performed per million inhabitans (Romania, Ukraine, Bulgaria, Cyprus and Armenia) showed a heterogeneous trend of variation over the last 4 years, with countries showing an increasing (Romania and Cyprus), flat (Ukraine and Bulgaria) and decreasing trend (Armenia) (Figure 77).

The vast majority of these countries lack national electrophysiology accreditation programs or EHRA accreditation is not required to perform ablations in them. The only exceptions are Belaurus, Latvia, Lithuania, the Czech Republic, Slovakia, Hungary, Poland, Russia, France, Portugal, Spain, UK and Tunisia which have national electrophysiology accreditation programs and Bosnia, Montenegro, the Czech Republic, Ireland, Israel, Denmark, France, Portugal, and the Netherlands in which electrophysiology accreditation is required for practice. The only country which demands EHRA accreditation for practice is the Netherlands. This apparently plays not a significant role in the number of procedures done in each country. There were 5 countries without centers providing ablation training (Bosnia, Georgia, Iceland, Luxemburg and San Marino) and they were small or in the first quartile on the number of ablations performed per million inhabitants. In addition, FYR Macedonia had no training centers on AF ablation. Therefore training appears to be one factor associated with the level of ablation activity in each country, either because a minimum number of cases is needed to provide training or because the ability to provide training is often associated with both professional motivation and infrastructure to do more procedures.

Evolution of ablation rate and centers in selected Eastern and Central European countries

Figure 78 shows the relationship between the mean annual ablation rate per million inhabitants and the number of ablation center per

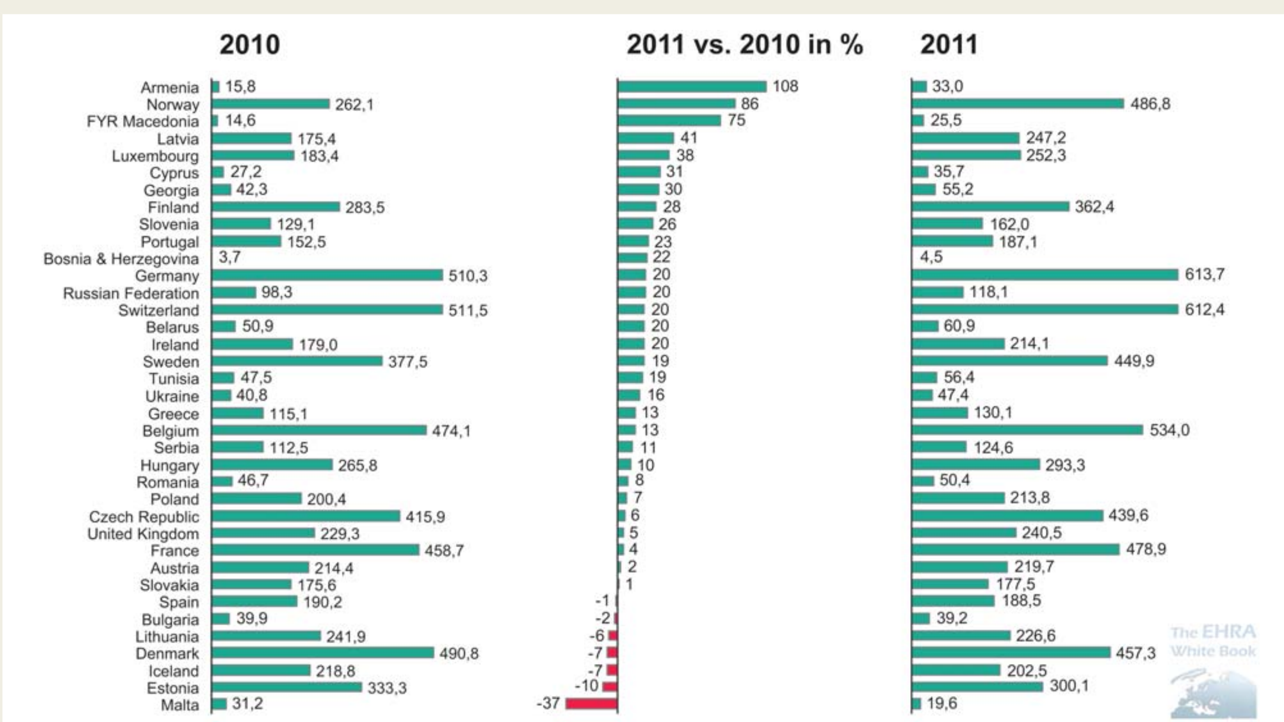

Figure 74. Change 2011 versus 2010 in the number of ablation centers per million inhabitants. Displayed are only countries with available ablation center numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. TN 2010 population data out of EHRA White Book 2011. The following countries were excluded: AL, AZ, DZ, EG, LB, FR, ME, MA, LY, MD, PL, SM, SY, TR, XK.

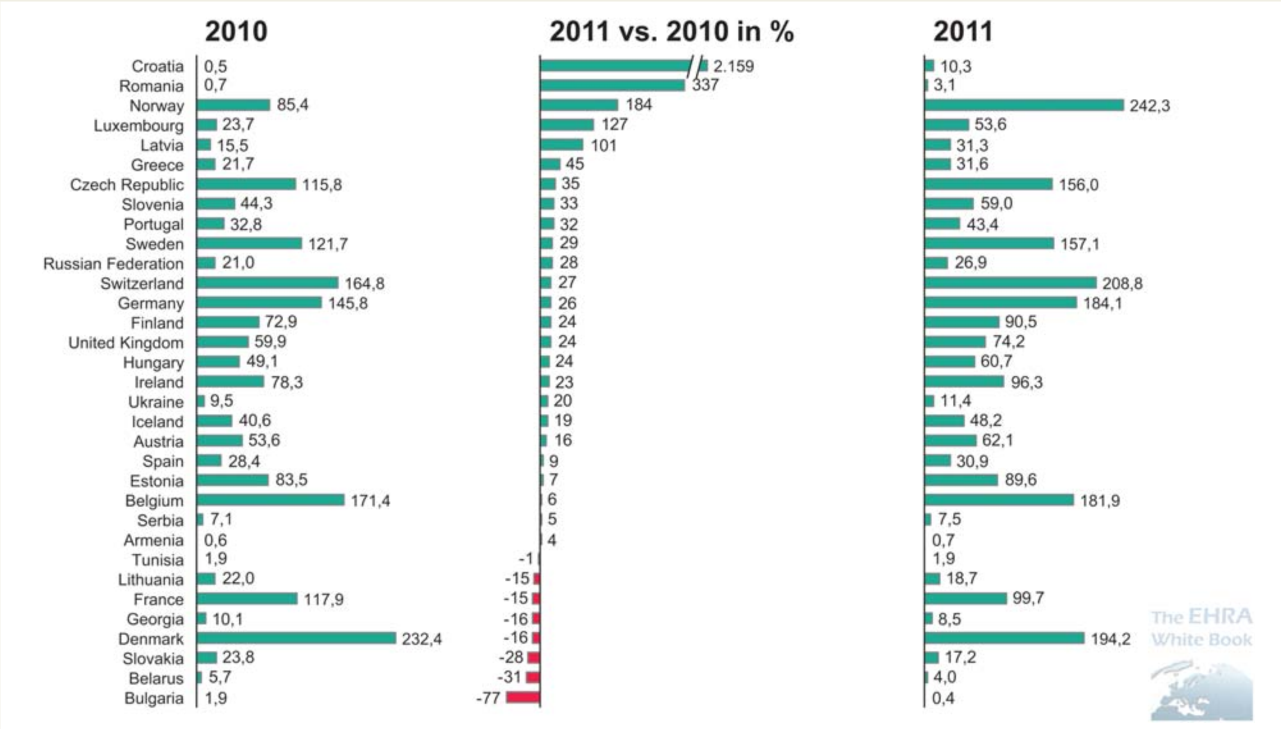

Figure 75. Change 2011 versus 2010 in the number of ablations per million inhabitants. Displayed are only countries with available ablation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. TN 2010 population data out of EHRA White Book 2011. The following countries were excluded: AL, DZ, AZ, EG, HR, IL, IT, LB, LY, MA, MD, ME, NL, SM, SY, TR, XK.

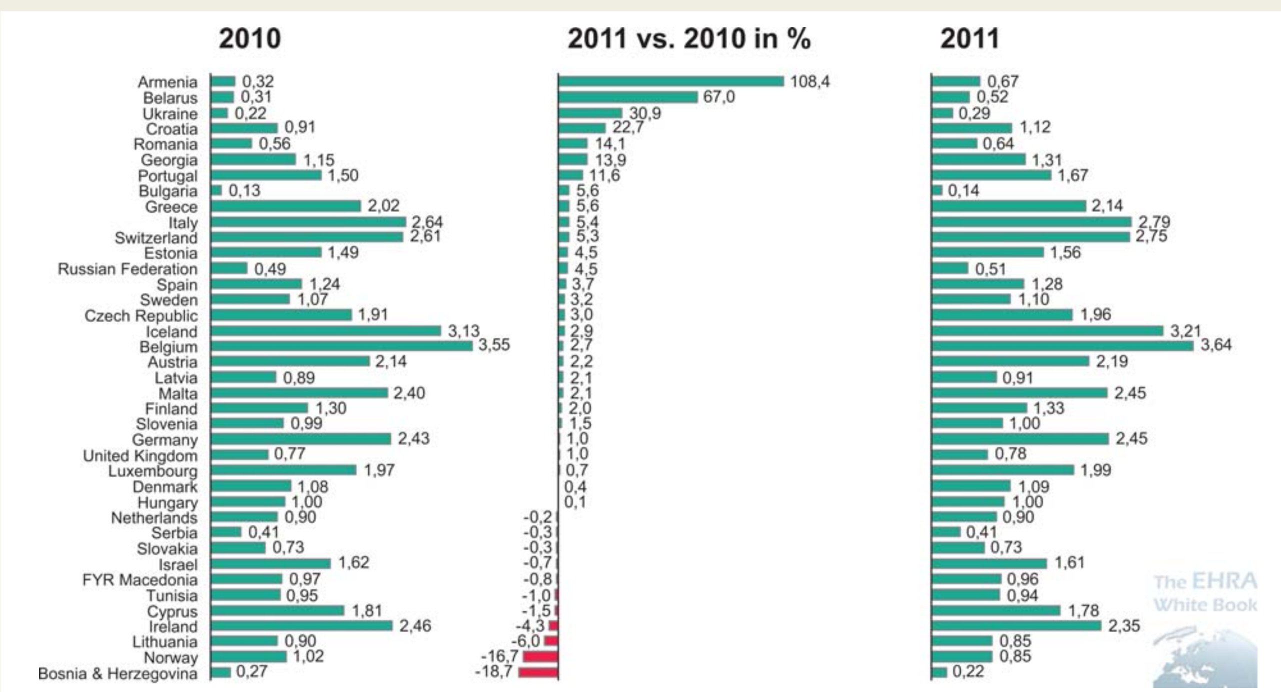

Figure 76. Change 2011 versus 2010 in the number of AF ablations per million inhabitants. Displayed are only countries with available AF ablation numbers for 2011 and 2010. Population for 2010 was estimated according to WHO data, and population for 2011 was given according to US Census Data. TN 2010 population data out of EHRA White Book 2011. The following countries were excluded: AL, AZ, BA, CY, DZ, EG, IL, IT, LB, LY, MA, MD, ME, MK, MT, NL, PL, SM, SY, TR, XK.

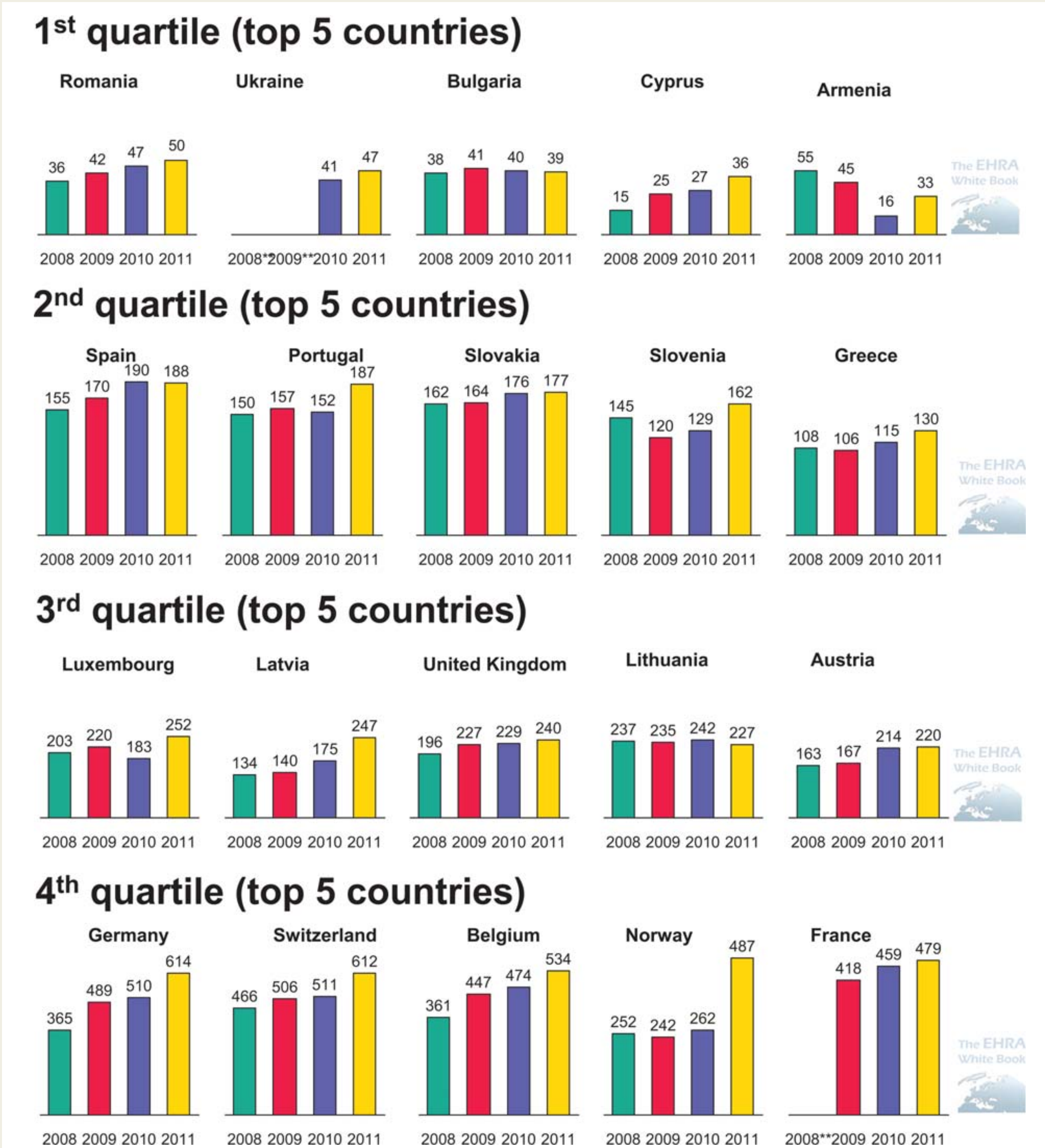

Figure 77. Change in ablation procedures in top 5 countries of each quartile since 2008 (ranked by implantation rate 2011). Change in ablation procedures in top 5 countries of the 1st, 2nd, 3rd and 4th quartile since 2008 ranked by ablation rate in 2011. Within each quarter, only those countries with available numbers for at least 3 years between 2008 and 2011 are displayed. ** indicated no data available in that particular year.

million inhabitants in the EU-27 countries and ESC area as well as in selected countries (figures 82 to 93). As for device implantation, the large gap between selected countries and the ESC-54 or EU-27 countries seems mostly due to the lack of infrastructures (Y axis, or number of ablation centers per million inhabitants) and the low referral rate or work capacity of existing centres (X axis, or number of ablation per million inhabitants) in each respective country.

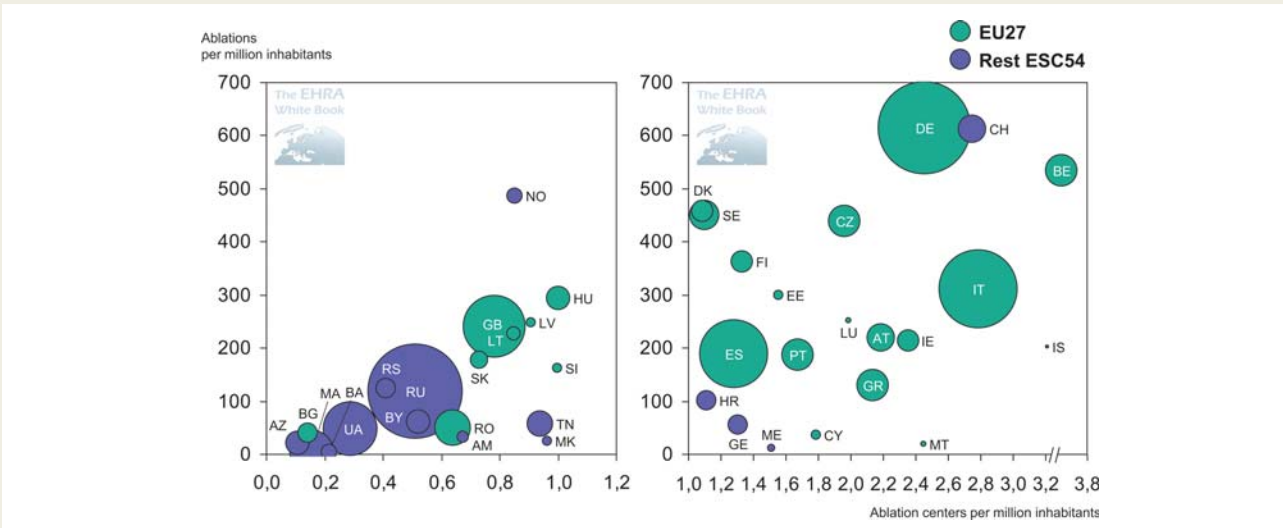

Figure 78. Ablation centers and ablation rate in each of the 42 countries. The EU-27 countries are indicated by the green bubble, and the remaining ESC countries in blue color.

Table 9 Development potential for ablation centers in selected countries reflecting the additional number of centers needed to attain mean ESC area or mean EU-27 ablation center availability

Development potential - additional number of . . .	AM	BY	BG	GE	LV	LT	MK	ME	RO	RS	SI	UA	Σ
. . . ablation centers to attain **mean ESC area level**	2	8	9	0	1	2	1	0	15	7	1	46	92
. . . ablation centers to attain **mean EU-27 level**	4	12	12	2	2	4	2	1	24	10	2	65	140

The development potential of these countries is also shown in Table 9 and figure 79. The table shows the potential number of ablation centers needed in selected countries to reach the mean number of ablation centers per million of inhabitant in the ESC and ESC-27 area. Further evidence of differences in ablation therapy is provided by analysis of the ratio of atrial fibrillation ablation out of total ablation number (Figure 80) and the number of centers performing more than 10 ablations of ventricular tachycardia in structural heart disease (Figure 81). However, as show in Figures 82 to 93, there was a minimal and heterogeneous change over the last 5 years in the vast majority of these countries. Thus, this situation is expected to remain essentially the same unless significant investment in infrastructure, professional training and clinical practice guidelines implementation is undertaken.

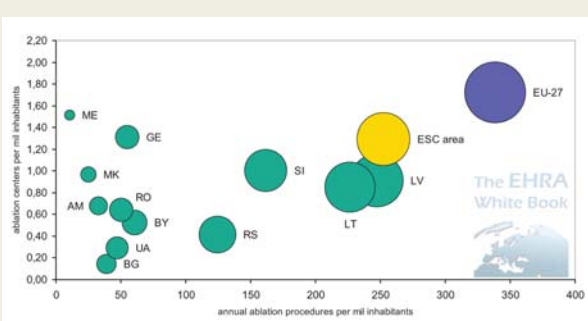

Figure 79. Ablation centers and ablations in selected countries compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual implantation numbers.

Societal and economic aspects

In the last years the economic situation in western countries is characterized by a financial crisis with profound implications on all the aspects of social life, including provision of services for health care. It has been recently reported how in several European countries debt crisis led to budget cuts for health services[1].

The effects of the economic situation are also magnified by the changes in demographic profile of many countries, with an increase in the number of elderly nonproductive persons, who require both medical and social assistance. In this scenario growing socio-economic disparities constitute a worldwide concern, with important influences on health care.

The countries that are affiliated to the European Heart Rhythm Association (EHRA) constitute a group of nations with quite heterogeneous characteristics with regard to the political, financial

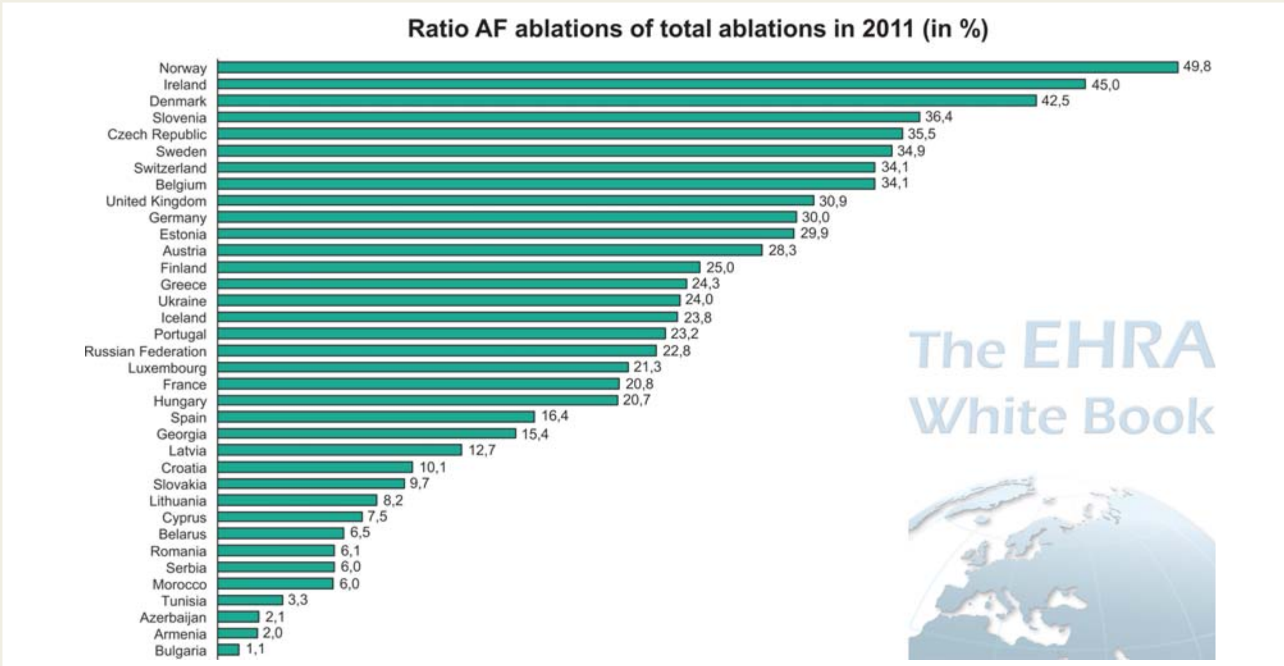

Figure 80. Ratio Atrial Fibrillation ablations out of total ablations in 2011. Displayed are only countries with available data of Atrial Fibrillation ablation and total number of ablations for 2011- The following countries are excluded: AL, BA,, DZ, EG, IL, IT, LB, LY, MD, ME, MK, MT, NL, PL, SM, SY,TR, XK.

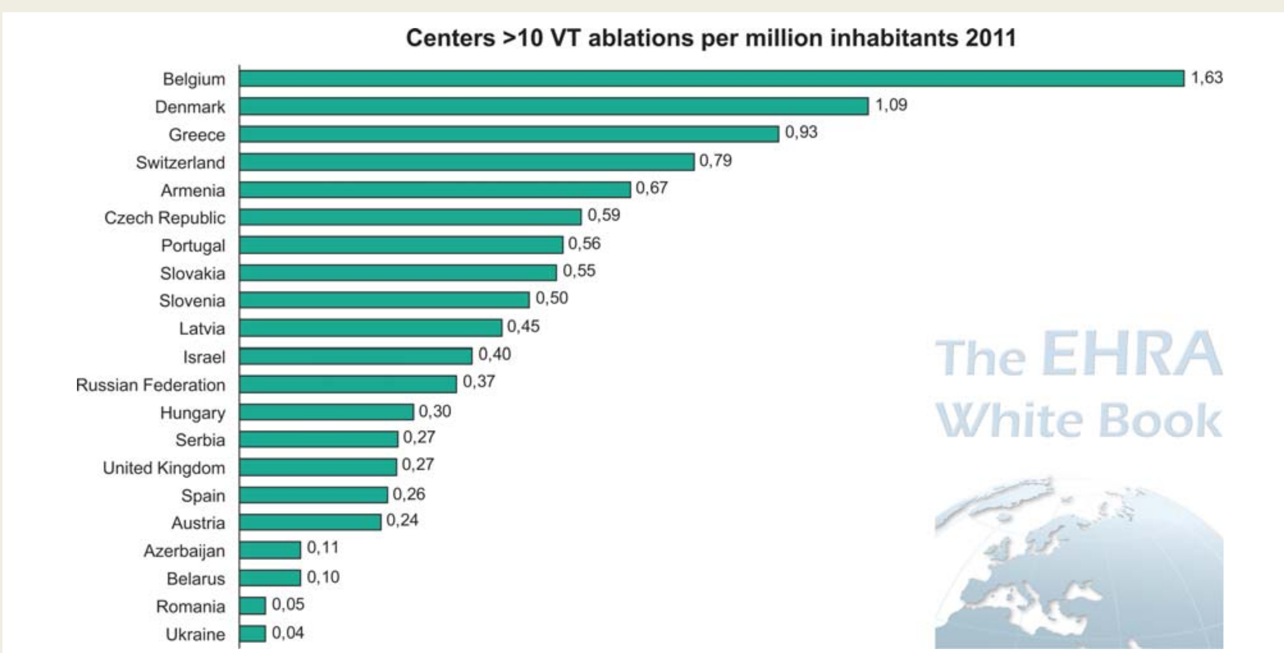

Figure 81. Number of centers performing more than 10 Ventricular Tachycardia ablations on structural heart disease per million inhabitants 2011. Displayed are only countries with available data of Ventricular Tachycardia ablation on structural heart disease and total number of ablations for 2011. The following countries are excluded: AL, BA, BG, CY, DE, DZ, EE, EG, FI, FR, GE, HR, IE, IS, IT,LB, LT, LU, LY, MA, MD, ME, MK, MT, NL, NO, PL, SE, SM, SY, TN, TR, XK.

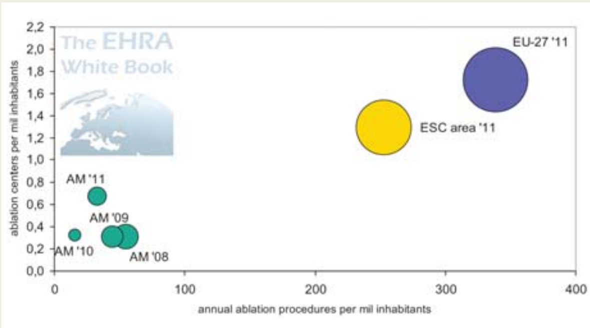

Figure 82. Evolution of ablation procedures in Armenia (AM) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

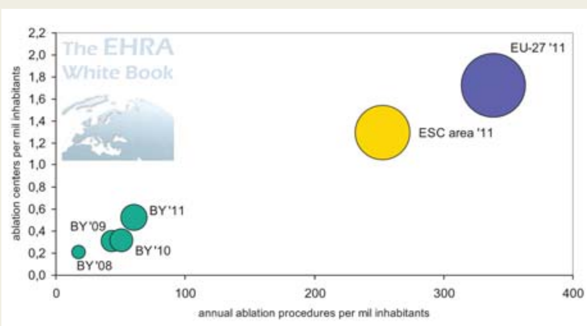

Figure 83. Evolution of ablation procedures in Belarus (BY) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

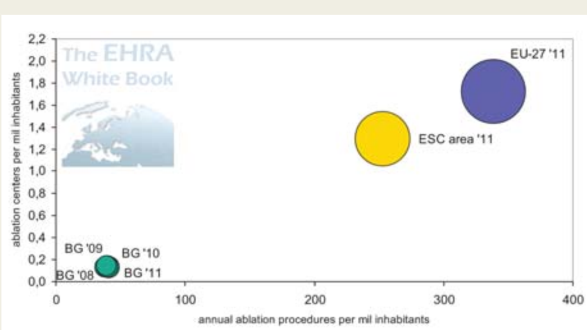

Figure 84. Evolution of ablation procedures in Bulgaria (BG) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

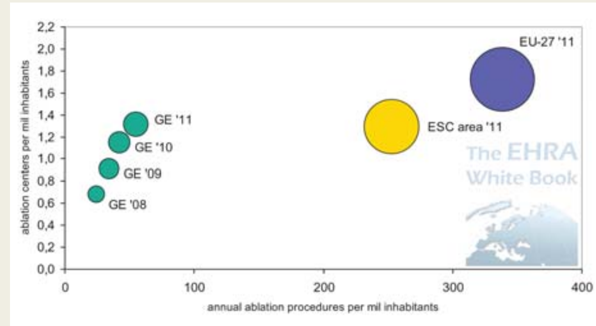

Figure 85. Evolution of ablation procedures in Georgia (GE) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

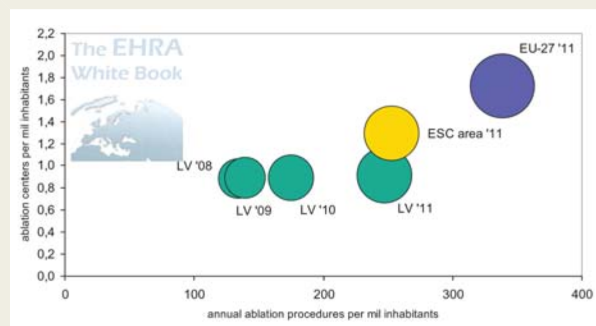

Figure 86. Evolution of ablation procedures in Latvia (LV) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

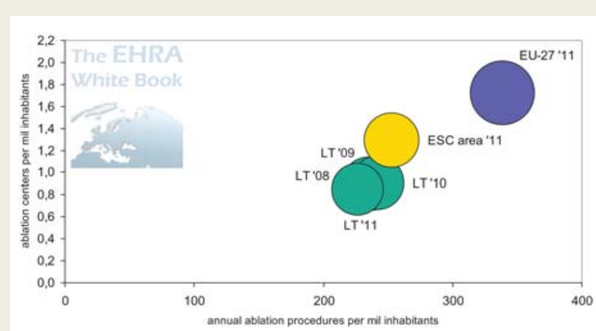

Figure 87. Evolution of ablation procedures in Lithuania (LT) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

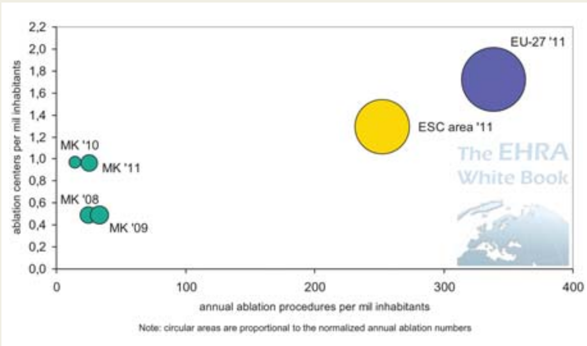

Figure 88. Evolution of ablation procedures in the FYR Macedonia (MK) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

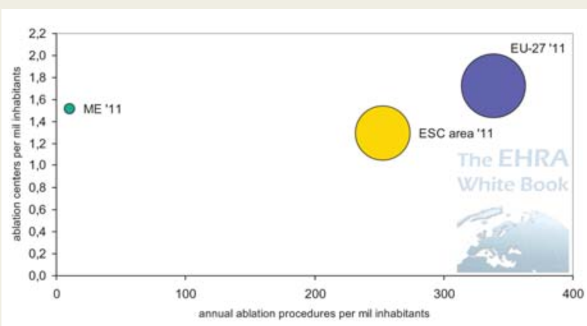

Figure 89. Evolution of ablation procedures in Montenegro (ME) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

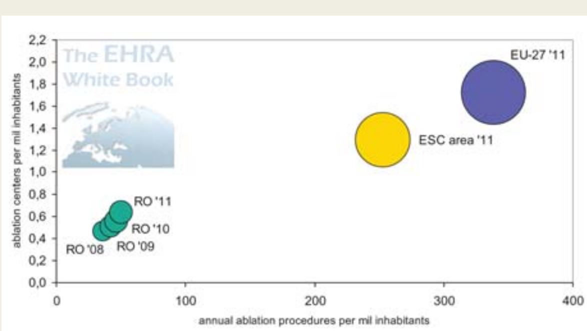

Figure 90. Evolution of ablation procedures in Romania (RO) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

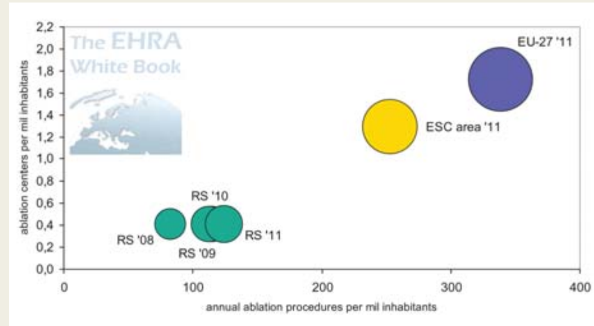

Figure 91. Evolution of ablation procedures in Serbia (RS) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

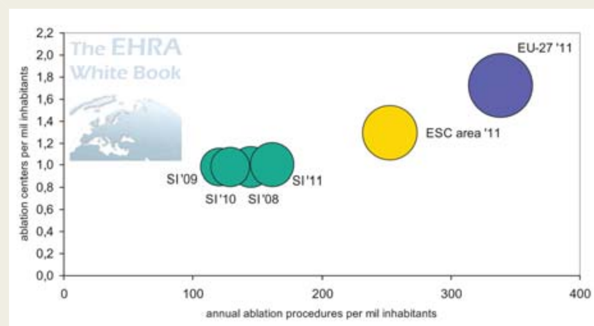

Figure 92. Evolution of ablation procedures in Slovenia (SI) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

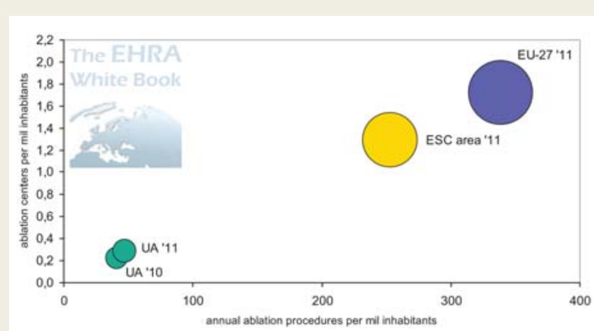

Figure 93. Evolution of ablation procedures in Ukraine (UA) from 2008–2011 as compared to mean ESC area and EU-27 values. The circular areas are proportional to the normalized annual ablation numbers.

Table 10 Demography and GDP (latest available data per country from EHRA White Book 2008-2012, countries with no data have been taken out of the table).

	Population	Population growth rate (%)	Life expectancy at birth (years)	Death rate (%)*	GDP (x 1000 billion US $)	GDP per capita (US $)
Armenia	2,967,975	0.1	73	8.48	10	3,048
Austria	8,217,280	0	80	9.25	425	50,504
Azerbaijan	9,397,279	1	71	5.9	69	7,510
Belarus	9,577,552	-0.4		14	58	6,118
Belgium	10,431,477	0.1	80	9.5	466	42,630
Bosnia & Herzegovina	4,622,163	0	79		18	4,715
Bulgaria	7,093,635	-0.8	74	14.6	54	7,243
Croatia	4,483,804	-0.1	76	11.8	64	14,529
Cyprus	1,120,489	1.6	78	6.5	26	31,435
Czech Republic	10,190,213	-0.1	77	10.2	220	20,925
Denmark	5,529,888	0.3	79	10.2	349	63,003
Estonia	1,282,963	-0.6	73	11.8	23	16,880
Finland	5,259,250	0.1	79	9.5	271	50,090
France	65,102,719	0.5	81	8.6	2,808	44,401
FYR Macedonia	2,077,328	0.2	75		10	5,012
Georgia	4,585,874	-0.3	77	10.6	14	2,098
Germany	81,471,834	-0.2	80	10.5	3,629	44,556
Greece	10,760,136	0.1	80	9.6	312	27,875
Hungary	9,976,062	-0.2	75	13	148	14,808
Iceland	311,058	0.7	81	6.3	14	43,226
Ireland	4,670,976	1.1	80	6.5	222	48,517
Israel	7,473,052	1.6	81	5.2	245	32,298
Italy	61,016,804	0.4	82	9.7	2,246	37,046
Latvia	2,204,708	-0.6	73	13.3	27	12,226
Lithuania	3,535,547	-0.3	75	12.6	43	13,190
Luxembourg	503,302	1.1	80	7.3	63	122,272
Malta	408,333	0.4	80	7.2	9	22,058
Montenegro	661,807	-0.7	78	9.3	42	6,668
Morocco	31,968,361	1.1	76		102	3,162
Netherlands	16,653,734	0.5	81	8.2	858	51,410
Norway	4,691,849	0.3	80	8.5	479	96,591
Poland	38,441,588	-0.1	76	10.1	532	13,967
Portugal	10,760,305	0.2	79	9.9	242	22,699
Romania	21,904,551	-0.3	74	12.1	185	8,666
Russian Federation	138,739,892	-0.5	66	14.2	1,885	13,236
San Marino	31,817	1	83			
Serbia	7,310,555	0.3	74	14.2	46	6,267
Slovakia	5,477,038	0.1	76	9.8		17,889
Slovenia	2,000,092	-0.2	77	9.2	52	25,939
Spain	46,754,784	0.6	81	8.4	1,534	33,298
Sweden	9,088,728	0.2	81	9.7	57	61,098
Switzerland	7,639,961	0.2	81	8.1	666	84,983
Ukraine	45,134,707	-0.6	69	15.3	163	3,575
United Kingdom	62,698,362	0.6	80	9.1	2,481	39,604

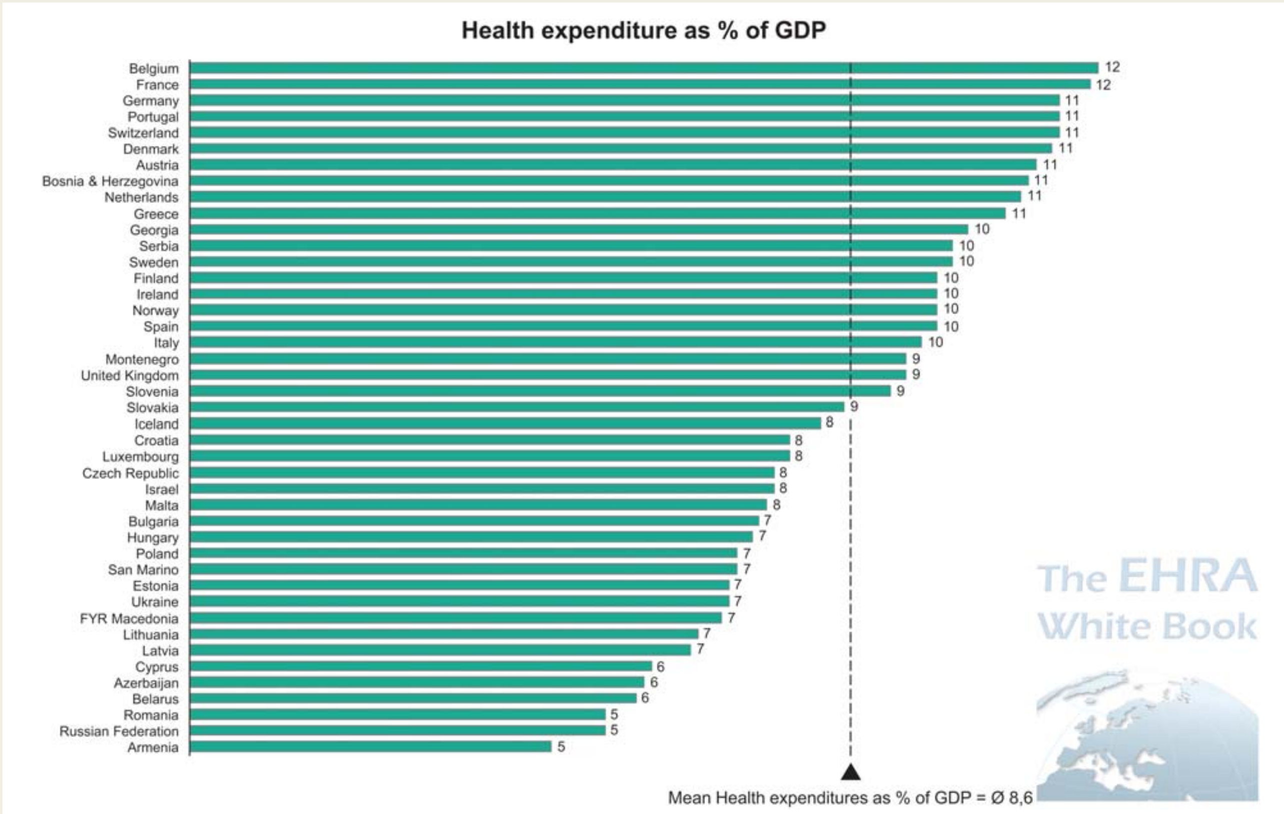

Figure 94. Health expenditures as % of GDP. Displayed are only countries with available rates, mean number of % of expenditure is weighted by population. The following countries are excluded: AL, DZ, EG, LB, LY, MA, MD, SY, TN, TR, XK.

and demographic aspects. All these aspects can have profound implications with regard to provision of services for health care and an additional reason for heterogeneity is the variable picture of health care systems organization, ranging from national health care services with full coverage of the population to systems primarily based on private health insurances, with coverage of only a limited proportion of the whole population.

In this section we will provide a general picture of demographic and financial profile of countries affiliated to EHRA and we will also give a general picture of the organizational aspects of health care across Europe, trying to explore how much the financial context may influence the delivery of therapies in the field of electrophysiology and arrhythmia care. Indeed, as a matter of fact global financial insecurity may have an important impact on healthcare spending in sectors, such as the field of arrhythmia management characterized by an important role of innovative technologies with a relatively high upfront cost[2–4].

It is well known, by WHO publications[5] how high-quality data on cause of death are available in only a minority of countries worldwide, but in most European countries medium to high quality data are available.

Demographic data are shown in Table 10 and the important differences in populations sizes of the analyzed countries, with a life expectancy ≥ 80 years in most EU countries usually associated with an higher GDP per capita. These demographic data suggest a trend towards a progressive aging of the population with important implications for the health care systems. With regard to the financial profile of the different countries it is noteworthy to stress that GDP ranged between 9 (Malta) and 3629 (Germany) trillion US$, while GDP per capita ranged between 2098 (Georgia) and 122 272 (Luxemburg) US$. The GDP per capita in Luxemburg was 58-fold that of Georgia indicating how heterogeneous can the financial profile of analyzed countries.

The issue of health expenditures is addressed by Figure 94 and 95 where health expenditures are shown as a percentage of national gross domestic product (GDP) and as expenditure per capita, respectively. Health expenditure per capita ranged between 143 (Armenia) and around 9 600 US$ in Switzerland and Luxemburg with a 67-fold difference between the lowest and the highest expenditure per capita.

The amount of hospital and beds available for health care is shown in Figure 96 and at first look the heterogeneity that merges does not appear strictly related to the general financial profile of the countries or the expenditures for health. As a matter of fact in terms of beds per 100 000 inhabitants two rich countries such as Germany and Sweden are at the extremes of

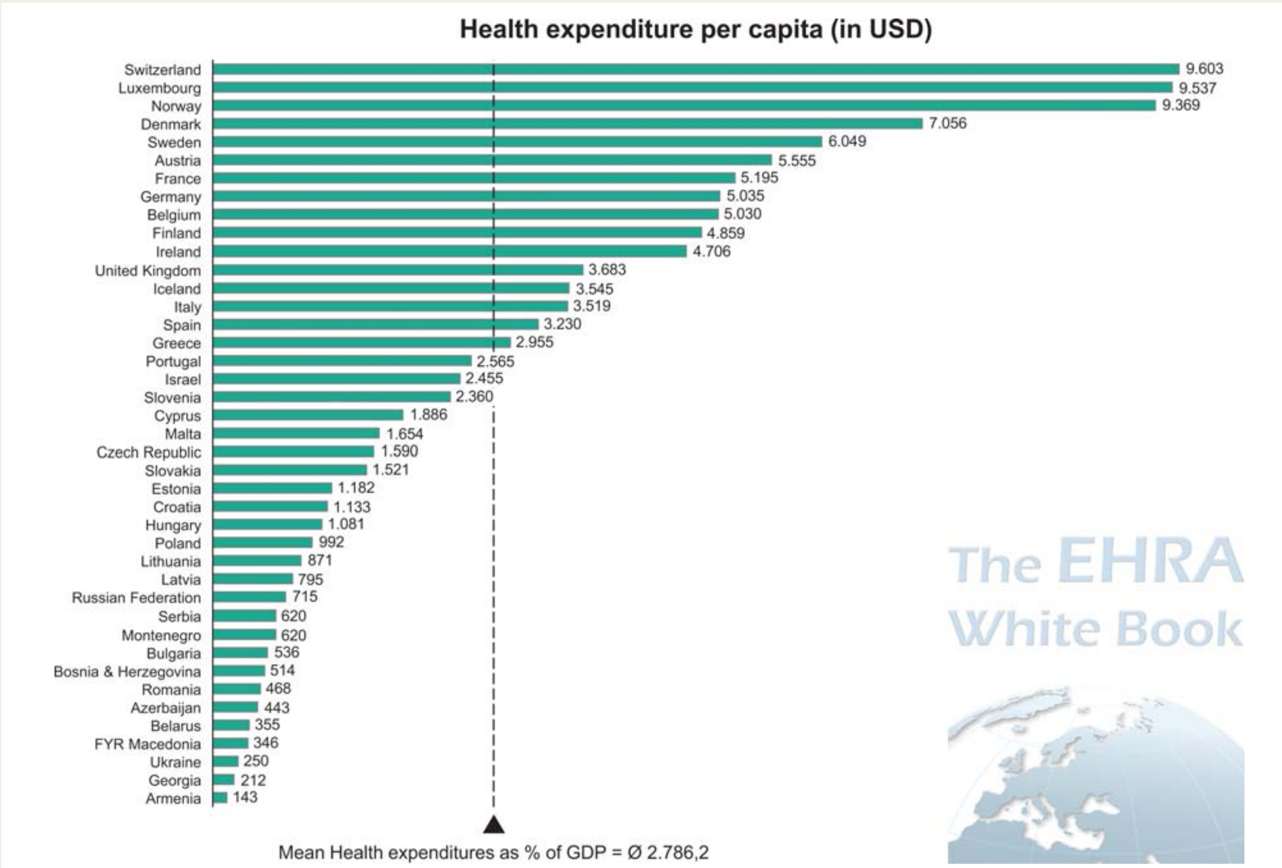

Figure 95. Health expenditures per capita (in USD). Displayed are only countries with available rates, mean number of expenditure is weighted by population. The following countries are excluded: AL, DZ, EG, LB, LY, MA, MD, SY, TN, TR, XK.

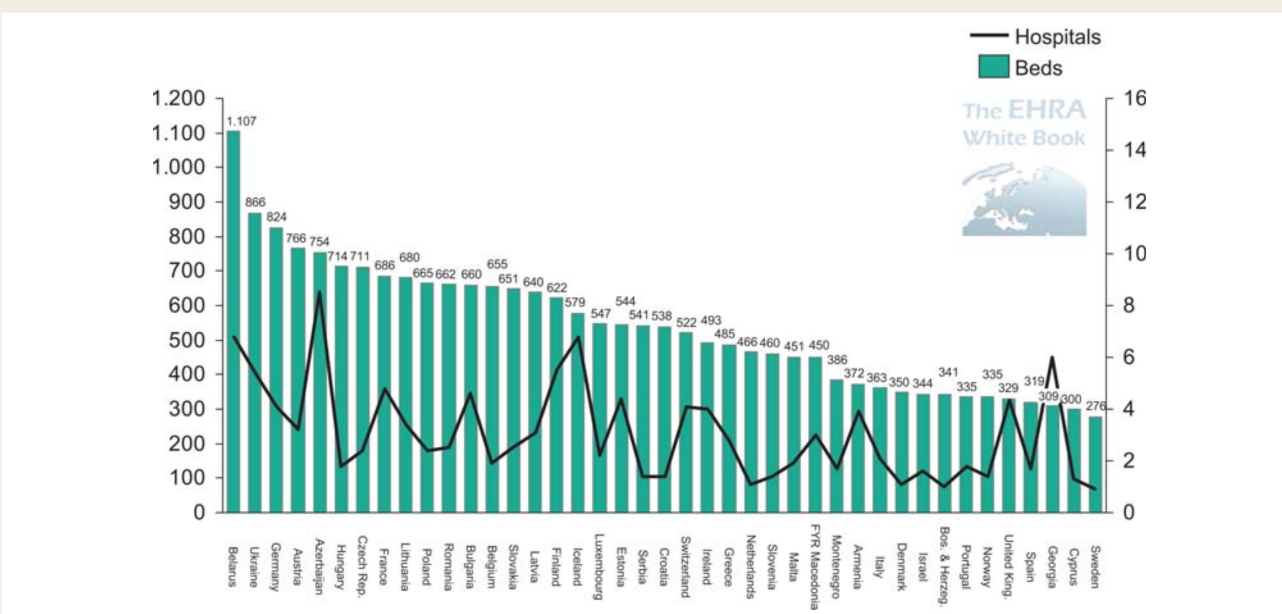

Figure 96. Hospitals and beds per 100 000 inhabitants (latest available data per country from EHRA White Book 2008-2012, for the majority of countries data are related to year 2009). Displayed are only countries with available rates. The following countries are excluded: AL, DZ, EG, LB, LY, MA, MD, SY, TN, TR, XK, RU.

Table 11 Health care systems and Insurances (only countries with data are displayed, latest available data from EHRA White book 2008-2012)

			Distribution of insurance modality (%)				Co-payment necessary for electrophysiological therapies		
Country	**Basic insurance availability**	**Uninsured citizens (% of population)**	**Public insurance company**	**Private insurance company**	**Private copayements**	**Possibility of subscribing to private health insurance plans**	**ICD**	**PM**	**Ablation**
Armenia		93	85	15	40	yes	yes	yes	yes
Austria	yes	3.1	83	17	0	yes			
Azerbaijan	yes	0	90	10	10	yes			yes - only in the private sector.
Belarus	yes	0	100	0	3	yes			
Belgium	yes	1	“ + / - 80”	<1	“ + /- 20”	yes	yes	yes	yes
Bosnia & Herzegovina		26	74	0	26				
Bulgaria	yes	20	75	0.9	24.1	yes	yes	yes	yes
Croatia	yes	9	91	0	9	yes			
Cyprus		15	85	15		yes			
Czech Republic	yes	0.1	99.9	0.1	0.1				
Denmark	yes	0	100			yes			
Egypt		36					yes	yes	
Estonia	yes	5	95	1	1	yes			
Finland	yes	0	75	2	23	yes			
France	yes	0	100	0	40	yes			
Georgia		67	25	60	15	yes	yes	yes	yes
Germany	yes	0.12	85.6	10.8	26.3	yes			
Greece	yes	5	89	10	1	yes			
Hungary	yes	2	99	1	0	yes			
Iceland	yes	0	100	0	0				
Ireland		<70%	32	<47		yes			
Israel	yes	1	85	1	14	yes			
Italy	yes	0	100	0	0	yes			
Latvia	yes	0	90	10	0	yes	yes	yes	
Lebanon		40							
Lithuania	yes	2	100	0	0	yes			
Luxembourg	yes		100	58		yes			
FYR Macedonia	yes	10	90	10	0	yes			
Malta	yes	0	0	25	0	yes			
Montenegro	yes	4	100						
Morocco		70	34	5					
Netherlands	yes	10(eu0,8)	0	100	0				
Norway	yes	0	100	0	3	yes			
Poland	yes	1	65	1	34	yes			
Portugal		0	85	0	15	yes	yes	yes	
Romania	yes	2	57	14	24	yes			yes
Russian Federation		95	90	7	3	yes		yes	
San Marino		0	100			yes			
Serbia	yes	0	100	5	5	yes			
Slovakia	yes	0	72	28	0	yes			
Slovenia		1				yes			

Continued

Table 11 ***Continued***

Country	Basic insurance availability	Uninsured citizens (% of population)	Distribution of insurance modality (%): Public insurance company	Private insurance company	Private copayments	Possibility of subscribing to private health insurance plans	Co-payment necessary for electrophysiological therapies: ICD	PM	Ablation
Spain	yes	0	95	15	15	yes			
Sweden	yes	0	100	5	5	yes			
Switzerland	yes	0	72	0	28	yes			
Tunisia		10							
Ukraine		99.84				yes			
United Kingdom	yes	90	90	10	0	yes			

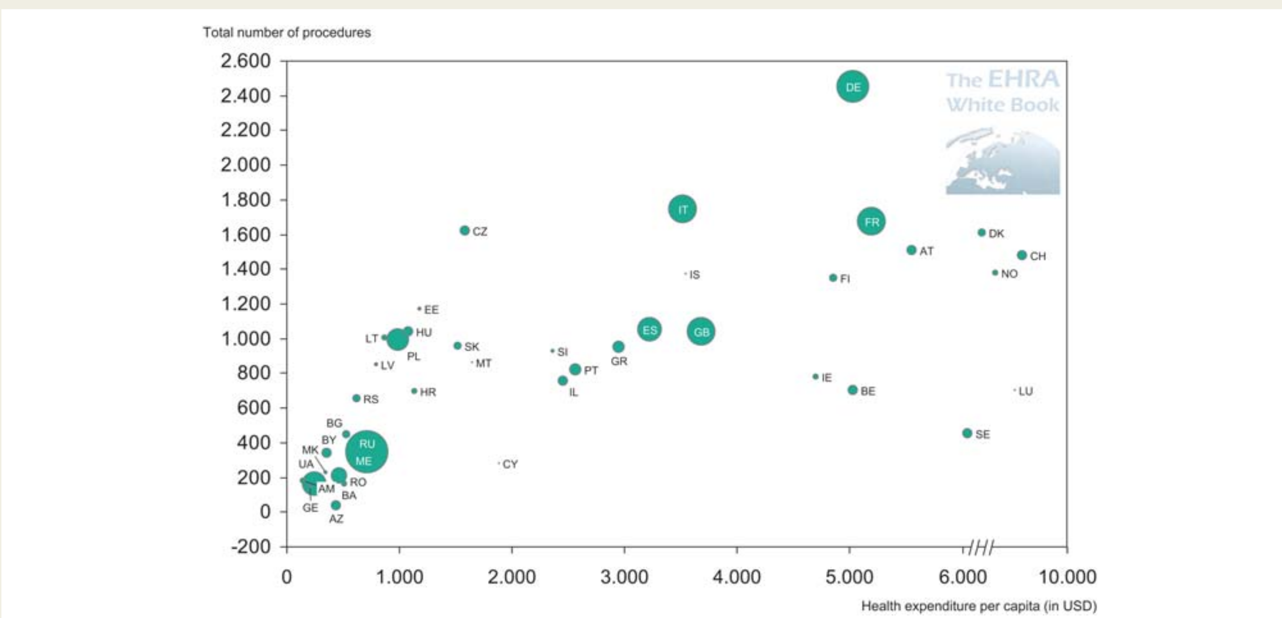

Figure 97. Health care spending per capita and interventional electrophysiology procedures (sum of PM-ICD-CRT-ablation procedures). Displayed are latest available numbers and only available EU27 and rest of ESC area countries with available numbers. Bubble size is in correlation to population. The following countries are excluded: AL, DZ, EG, LB, LY, MA, MD, SY, TN, TR, XK, NL.

the rank. This implies that the organization of hospital care, ambulatory care and home care has many differences in terms of organization even independently on whole national economic status.

There is a wide variety of health systems in terms of organization for delivering health care services, which involve public or private insurances, also with mixed solutions, and co-payments, as shown in Table 11. The table also considers if co-payment are necessary for interventional electrophysiology procedures.

As discussed before both the financial profile and the organization of health care in analyzed countries are quite heterogeneous so the question is how much this may influence the implementation of interventional electrophysiology in clinical practice. In Figure 97 national data on health expenditures per capita were considered and a significant correlation was found with the sum of ICD, pacemakers and ablation procedures (Spearman Rho= 0.718, $p < 0.001$). What clearly emerges is that reduced expenditures for health care are associated with lower use of interventional electrophysiological procedures and this finding is of specific concern in consideration of the current economic downturn.

Conclusive remarks and future vision

The EHRA White Book monography has become a reference for those seeking information about invasive rhythm procedures in Europe and the Mediterranean countries. Beyond that, the present report puts these numbers into perspective and highlights differences between countries. Evolution of therapies along time has also been analyzed when available. This analysis aims to serve as a tool to reduce inequalities across borders. However, this report is only the first step and some points have been already identified as an opportunity for improvement in the near future.

As stated before, the process of gathering the data for the White Book is complex and necessarily involves different sources among which the national societies play a major role. As a consequence, the disparity of data sources may produce heterogeneity and some of them are based on 'best' estimation by the national society. In the future, differences in 'certainty' of the data should be incorporated in the statistical analyses. Moreover, direct access to well-established national cardiovascular registries active in some European countries for many years will be done.

In many European countries, national registries for IPG and ICD implantations have existed for many years. More recently registries containing data on electrophysiological procedures and catheter ablations have also been introduced. National registries use international standards for both the data exchange and the terminology of data of implantable devices. The regularity of the data recorded in these national registries is significantly higher than the current White Book data. IPG, ICD national registry data are usually audited, thus can be considered of high quality.

It is EHRA's goal to create a single common and large European database jointly owned by national working groups on Arrhythmias or national societies and EHRA, easily accessible by single centers and by National Societies.

The central EHRA White Book database should become an on-line database that would present the actual status of arrhythmia healthcare, serving as an on-line comparison and benchmarking tool. Information on demographics, healthcare system specifics, training and certification would complete the picture. EHRA is currently identifying those countries in which national registries exist and is jointly defining the minimum requirement and the minimum dataset to be shared. Once the pilot project has been completed, it is envisioned a progressive inclusion of all 54 ESC countries.

Acknowledgements

EHRA White Book has been made possible thanks to the efforts of several key contributors including all chair and co-chair of national Working Groups of the 54 ESC countries, and EHRA staff at Heart House. We thank Dr. Bernhard Fahn at Siemens GmBH for his contribution. We are grateful to the project sponsor, Biotronik GmbH company, and in particular to Robert Wüstenberg and Arnika Kiel for their dedication and passion in the conduction of the project. To all of them goes our deepest gratitude and appreciation.

Conflict of interest

Fernando Arribas:

A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.

Boston Scientific : Advisory Board fee, Honoraria (2010-2011)
Sanofi Aventis : Advisory Board fee, Honoraria (2010-2011)
Medtronic : Honoraria (2010-2011)
St Jude Medical : Honoraria (2010)
Boehringer-Ingelheim : Speaker fee (2010-2011)
Bayer : Speaker fee (2011)

B - Payment to your Institution: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.

Boston Scientific : Investigator (2010-2011)
Medtronic : Investigator (2010-2011)
St Jude Medical : Investigator (2010-2011)

Angelo Auricchio: Speaker fees, Honoraria, Consultancy (all non significant)

Sorin
Medtronic
Biotronik
EBR Systems
Merck Sharp & Dohme
Daiichi Sankyo
Impulse Dynamics
St. Jude Medical
Abbott
Biologics Delivery Systems, Cordis Corporation (a J&J company)

Boriani Giuseppe

A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.

Medtronic : Pacemaker, cardioverter-defibrillators (2011)

Camm John

A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.

AGA : Amplatzer Cardiac Plug (2011)
Wiley Blackwell : Clinical Cardiology (2011)
Boehringer-Ingelheim : Dabigatran (2011)
BMS : DSMB (2011)
Cameron Health : DSMB (2011)
Biotronik : DSMB – Ablation (2011)
Novartis : DSMB – several (2011)
Oxford University Press : Europace and ESC textbook (2011)
GlaxoSmithKline : General Advice (2011)
Servier : Multiple products (2011)
Sanofi Aventis : Multiple products (2011)
Johnson & Johnson : Oncological Products (2011)
Menarini : Ranolazine (2011)
Bayer : Rivaroxaban (2011)
Merck Sharp & Dohme : Vernakalant (2011)

D - Research funding (departmental or institutional).

Servier : Antiarrhythmic drug (2011)

BMS/Pfizer : Apixaban (2011)
Sanofi Aventis : Clopidogrel (2011)
Daiichi Sankyo : Edoxaban (2011)
Richmond Pharmacology : Many phase 1 NCEs (2011)

Fahn Bernhard
None

Merino Jose Luis
A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
St Jude Medical : Atrial fibrillation (2011)
Magnetecs : CGCI Magnetic Remote Navigation System (2011)
Boston Scientific : Defibrillators (2011)
Sanofi Aventis : Dronedarone (2011)
Merck Sharp & Dohme : Vernakalant (2011)
D - Research funding (departmental or institutional).
Magnetecs : CGCI Magnetic Remote Navigation System (2011)
Boston Scientific : Defibrillators (2011)
Sorin Group : Defibrillators (2011)
E - Research funding (personal).
Sanofi Aventis : Celivarone (2011)
Daiichi Sankyo : Edoxaban (2011)
Sanofi Aventis : Idraparinux (2011)
Bayer : Rivaroxaban (2011)

Merkely Bela
A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
Krka : ACS (2011)
Sanofi Aventis : Atrial Fibrillation (2011)
Boston Scientific : CRT (2011)
Medtronic : CRT course (2011)
St Jude Medical : CRT/ICD (2011)
Servier : Heart Failure (2011)
Biotronik : ICD/CRT (2011)
Abbott : STEMI (2011)
GE Healthcare : STEMI networking (2011)
Duke Institute : Trilogy Study (2011)
B - Payment to your Institution: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
Boston Scientific : CRT (2011)
Biotronik : ICD/CRT Heart Failure (2011)
University of Leuven : NOMI trial (2011)
GE Healthcare : STEMI (2011)
Duke Research Unit : Trilogy Study (2011)

Mont Lluis
A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
St Jude Medical : Atrial Fibrillation, Resynchronization Therapy. (2011)
D - Research funding (departmental or institutional).
Biosense Webster : Atrial Fibrillation (2011)

van der Velde Enno T
None

Vardas Panagiotis
A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
Bayer : Honoraria for participation in "ASP Alliance" and "SPAF Advisory Board". Speaker fees. (2011)
Boehringer-Ingelheim : Honorarium for participation in Advisory Board. Speaker fees (2011)
Menarini : Honorarium for participation in Ranolazine Advisory Board (2011)
Servier : Speaker and article-writing fees (2011)
B - Payment to your Institution: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
Medtronic : Consultancy fee (2011)
Bristol Myers Squibb : Honorarium (2011)
Bayer : Speaker fee (2011)
Boehringer-Ingelheim : Speaker fees and honoraria (2011)
D - Research funding (departmental or institutional).
Amgen : ATOMIC AHF study (institutional) (2011)
Novartis : CANTOS study (institutional) (2011)
Medtronic : MORE CARE study (institutional) (2011)
Servier : SIGNIFY study (institutional) (2011)

Wolpert Christian
A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
Medtronic : ICD Ablation pacemaker (2011)
St Jude Medical : ICD Ablation, Pacemaker (2011)
Sorin Group : ICD Pacemaker (2011)
Biotronik : ICD Pacemaker (2011)

Zeppenfeld Katja
A - Direct Personal payment: Speaker fees, Honoraria, Consultancy, Advisory Board fees, Investigator, Committee Member, etc.
St Jude Medical : Consultancy (2011)
D - Research funding (departmental or institutional).
Boston Scientific : Device (2011)
Medtronic : Device (2011)
Biotronik : Device (2011)
Edwards Lifesciences : Valve (2011)

This table represents the relevant relationships of the above experts with Industries and other entities that were reported to us at the time of publication of the Guidelines.

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Appendix

Eucomed data:

URL:http://www.eucomed.org/uploads/_medical_technology/facts_figures/110518_statistics_for_cardiac_rhythm_management_products_20052010.pdf; February 01, 2012

Overview on sources for demographic data:

- Age Pyramid:
  URL: http://www.census.gov/ipc/www/idb/informationGateway.php; March 07, 2012

Healthcare data

- Hospitals (per 100 000 population)
  URL: http://data.euro.who.int/hfadb/; March 07, 2012
- Beds (per 100 000 population)
  URL: http://data.euro.who.int/hfadb/; March 07, 2012
- Density of physicians (per 1000 population)
  URL: http://data.euro.who.int/hfadb/; March 07, 2012
- Density of nurses (per 1000 population)
  URL: http://data.euro.who.int/hfadb/; March 07, 2012

Demographic information

- Population (2011)
  URL: http://www.census.gov/ipc/www/idb/informationGateway.php; March 07, 2012
  Population (2010)
  URL: http://data.euro.who.int/hfadb/
- Population annual growth rate (%)
  URL: http://www.census.gov/ipc/www/idb/informationGateway.php; March 07, 2012
- Life expectancy at birth (in years)
  URL: http://www.census.gov/ipc/www/idb/informationGateway.php; March 07, 2012
- Death rate (per 1000 population)
  URL: http://data.euro.who.int/hfadb/; March 07, 2012
- Live births (per 1000 population)
  URL: http://data.euro.who.int/hfadb/; March 07, 2012

Economic information

- Gross domestic product (U.S dollar-billions) - IMF estimative data for 2011
  URL: http://www.imf.org/external/ns/cs.aspx?id=28; March 07, 2012
- Gross domestic product per capita (U.S dollar-units) - IMF estimative data for 2011
  URL: http://www.imf.org/external/ns/cs.aspx?id=28; March 07,2012
- Total expenditure on health as % of GDP
  URL: http://data.euro.who.int/hfadb/; March 07, 2012
- General government expenditure on health as % of total expenditure on health
  WHO -World Health Statistics Report 2012; Section 7; March 07,2012
  URL: http://www.who.int/gho/publications/world_health_statistics/en/index.html; March 09; 2012
- Private expenditure on health as % of total expenditure on health
  WHO -World Health Statistics Report 2012; Section 7; March 07, 2012
  URL: http://www.who.int/gho/publications/world_health_statistics/en/index.html; March 09; 2012