

# CAUSES OF DIFFERENCES IN THE UPTAKE OF CARDIAC IMPLANTATION ELECTRONIC DEVICES IN SLOVENIA IN COMPARISON TO OTHER COUNTRIES

## VZROKI RAZLIK V UPORABI VSADNIH SRČNIH ELEKTRONSKIH NAPRAV MED IZBRANIMI DRŽAVAMI IN SLOVENIJO

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### ABSTRACT

#### Keywords:

cardiac implantation electronic devices, Slovenia, pacemaker, automatic implantable cardioverter defibrillator, accessibility, health care technology, MedtechHTA

**Introduction:** The purpose of this study is to analyse and present the causes of the differences in crude utilization rate in cardiac implantation electronic devices, specifically pacemakers and automatic implantable cardioverter-defibrillators, across 5 European countries, with a specific emphasis on Slovenia.

**Methods:** Based on the results of the analysis of the uptake of cardiac implantation electronic devices across countries studied in MedtechHTA project, the targeted interviews were conducted to explain the factors that impact the differences and explain data in Slovenia.

**Results:** The reasons for the differences in crude utilization rate across 5 European countries were multiple: the first group of differences refers to the coding system and linkages between coding and financing of health care. The second group of reasons can be qualitatively ascribed to the economic situation, financial situation in health care, and its impact on decision-making. The last reason is the non-existence of the golden rule for optimal crude utilisation rate.

**Conclusions:** It is evident that the differences in the uptake of cardiac implantation electronic devices among the countries are of organisational nature: they refer to the system of coding, the importance attached to correct coding practices, the link between coding and financing of health care as well as the availability of private clinics and private insurance. According to the interviews, the economic development of the country also impacts those differences, whereas the differences in clinical practice and guidelines are claimed not to play a role in the explanation of the differences.

### IZVLEČEK

#### Ključne besede:

vsadne srčne elektronske naprave, Slovenija, srčni spodbujevalnik, avtomatski srčni vsadni defibrilator, dostopnost, zdravstvena tehnologija, MedtechHTA

**Namen:** Namen raziskave je analizirati in predstaviti vzroke za razlike v stopnji izkoriščenosti in uporabe srčnih spodbujevalnikov in avtomatskih vsadnih srčnih defibrilatorjev med petimi evropskimi državami s poudarkom na Sloveniji.

**Metode:** Na osnovi rezultatov analize uporabe in izkoriščenosti vsadnih srčnih elektronskih naprav med državami v okviru projekta MedtechHTA smo izvedli targetirane osebne intervjuje, s katerimi smo želeli razložiti faktorje, ki vplivajo na razlike v stopnji uporabe, in s katerimi bi lahko razložili razlike v slovenskih podatkih.

**Rezultati:** Razlike v stopnji uporabe med petimi evropskimi državami so posledica več faktorjev. V prvo skupino spadata predvsem sistem kodiranja in povezanost med kodiranjem in financiranjem zdravstvenih storitev. Drug razlog je ekonomski razvoj gospodarstva, ki vpliva na finančno situacijo v zdravstvu in na sprejemanje odločitev o financiranju. Ne nazadnje pa je treba omeniti tudi dejstvo, da ni zlatega pravila o optimalni stopnji uporabe izbranih pripomočkov.

**Zaključek:** Iz podatkov je razvidno, da so razlogi za razlike v uporabi izbranih pripomočkov med državami posledica organizacijskih odločitev: sistem kodiranja, pomen, ki ga pravilnemu kodiranju pripisuje medicinsko osebje, povezava med kodiranjem in financiranjem ter organizacija sistema v smislu stopnje privatizacije zdravstva in zasebnega zavarovanja. V intervjujih se je izkazalo tudi, da ima stopnja gospodarskega razvoja vpliv na razlike, zagotovljeno pa je bilo, da razlike v klinični praksi in smernicah ne igrajo vloge v obrazložitvi ugotovljenih razlik.

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## 1 INTRODUCTION

The use of medical devices in the field of electrophysiology or cardiac implantation electronic devices (CIEDs) affects a large number of patients and contributes significantly to health expenditure (1-3). However, the uptake of CIEDs proved to vary across countries (4). In this paper, we investigate the causes of the differences in pacemakers (PMs) and automatic implantable cardioverter-defibrillators (ICDs), based on the results of the analysis of administrative hospital discharge (HD) databases in five European nations (Austria, England, Germany, Italy and Slovenia) over five years (2008-2012), performed in the frame of MedtechHTA project. Moreover, to further validate the statistics, the data from national registries were compared to figures published in the European Heart Rhythm Association - EHRA White Books. This finding has motivated the present study.

The goal of the article is to analyse and present the causes of the differences in crude utilisation rate in medical devices, specifically PMs and ICDs, among studied countries, as reported in HD databases of respective countries, with a specific emphasis on Slovenia. The research was focused on the selected CIEDs because of three salient characteristics of the devices used in this field, namely: a) randomised clinical trials for some devices have produced significant outcome measures (for some of these devices there is strong evidence of efficacy for specific indications); b) they represent a significant outlay of resources and, given high implantation rates, contribute to increases in the overall health expenditure; c) they have induced relevant organisational changes as they often require more multidisciplinary expertise in patient management.

Comparisons of administrative HD data at the international level and analyses of utilisation rates of CIEDs across countries are rare and great effort was invested to assure their comparability. This empirical exercise has been carried out in the framework of MedtechHTA project. As it proved, final results could not fully overcome the national differences and our aim is to further investigate some of these differences through interviews with Slovenian experts in the field. However, as our qualitative research derives from the mentioned empirical work, we should first present it properly.

The findings of this study will provide insight into the data evidencing and collecting, indicate the potentials of using administrative databases in health policy and decision-making as well as give an overview of the researched topic.

Returning to the presentation of MedtechHTA empirical results (5), the comparison of data on the use of ICDs and PMs, obtained from HD databases, across 5 countries, from 2008 to 2012, showed very high crude utilisation

rate in Germany, followed by Italy, England and Austria, and very low crude utilisation rate in Slovenia in PM implants as well as in ICD implants (for details see Table 1 in Appendix).

A threefold lag in PM implants and fourfold lag in ICD implants utilisation of Slovenia behind leading Germany rate can be noticed. The comparison of the annual average increase in utilisation rate in pacemakers from 2008 to 2012, across countries, shows the lowest growth rate in Italy, where the utilisation rate is already high, followed by Austria, Slovenia and Germany, with growth rates from 1.84 to 2.54, and the highest increase in England, where the annual growth rate in 4 years was 11.91%. In ICD implants the growth rate is generally higher due to the fact that ICD technology is more demanding and newer. The growth rates range between 3.17 in Italy and 14.42 in Slovenia, where the starting point of crude utilisation rate in 2008 was much lower.

To validate the data on crude utilisation rates obtained from hospital DRG database, the data were compared to figures published in the EHRA White Book (6). The comparisons showed fairly similar numbers for some countries, but disagree on totals for PM in Slovenia by as much as 100%. There were also differences in other categories, yet not that large (for details see Table 2 in Appendix).

Analysing the differences in the uptake of CIEDs across the countries shows there are differences in usage according to the age groups and gender (see Figure 1 in Appendix). The ICDs implementation rates in the highest age group almost level up with the previous age group for male, while considerable decline can be observed in case of female patients in all five countries. Regarding PMs, it is evident that Austria, England, Germany and Italy have quite similar implementation rate patterns across age groups, while in Slovenia the implementation rates of PMs in the age groups 65-74 years and over 75 years are almost twice lower than in other countries. On the other hand, much smaller differences between countries can be observed in the age groups 0-44 years and 45-64 years. Regarding gender, the ratio of PM uptake in men and women in all studied countries is approximately 2:1, while a much wider gap between male and female can be observed in ICDs. Namely, implementation rates of ICDs in all five countries are almost four times higher for men than for women. These gender inequalities are most prominent in the age groups 65-74 years and over 75 years.

Analysis using the Charlson Comorbidity Index (CCI) methodology was used to investigate the types and severity of diseases observed among patients treated with PM/ICD (for details see table 3 in Appendix). The disease categories that were most evident among patients with implants were acute myocardial infarction (AMI), congestive heart failure and diabetes. The presence of

these diseases was measured as the percentage of all hospitalizations where one of the CCI disease codes was observed in at least one of the primary or secondary diagnostic codes. Prevalence of AMI is highest for PMs and ICDs in Germany, followed by Slovenia and Italy. The comorbidities are very low in Austria, but the data are not realistic as Austrian database only has one possible field available for diagnosis coding. Congestive heart failure is present in 32% of PM implanted patients in Germany, followed by 23% in Slovenia with England and Italy at 15% and 13%, respectively. In ICDs the prevalence of AMI is much higher than in PMs, again highest in Germany, followed by Slovenia.

## 2 MATERIALS AND METHODS

To find out the possible reasons for such high differences in CIEDs utilization data (between different data sources and across different countries) a qualitative research study was adopted using in-depth interviewing as a data collection technique. The main purpose of the interviews was to find possible answers to explain and understand the underlying differences in the results that were generated in the analysis of administrative HD database.

### 2.1 Subjects

The qualitative research was aimed at cardiologists in Slovene hospitals who personally execute the procedures of PM and/or ICD implants on adult population. The initial objective was to include five cardiologists from different hospitals in a study sample. However, after we had interviewed four cardiologists (three from the two university medical centres and one from the regional hospital) it became clear that cardiologists had insufficient information about the coding procedures. Hence, we were advised to contact hospital administrators involved in coding procedures who had the knowledge and information to give us further insight into the matter. Finally, another two interviews were conducted with a coding administrator and a statistician who were both employed at one of the two university medical centres in Slovenia. In the end, six respondents were included in a study sample. The selection of respondents was not random; in fact, we used non-probability convenient sampling that was combined with a snowball sampling technique.

### 2.2 Method

A scenario with questions for the semi-structured qualitative interviews was grounded on key results of MedtechHTA project. It was divided into four sections, as follows: (a) coding of implanted CIEDs and related procedures, (b) inconsistencies between national hospital discharge data and EHRA database, (c) differences in

crude utilization rates for CIEDs across countries (with reference to age and gender) and d) comorbidity of patients with CIEDs.

The main goal of the interviews was to highlight and evaluate possible reasons for observed differences in data. The reasons were divided in two groups. The first group includes the administrative reasons, such as coding procedures, coding system, accuracy of coding due to financing system, reporting system etc. The second group consists of contextual factors that hinder the access to CIEDs in Slovenia, such as economic development, differences in clinical guidelines and treatment pathways. Both groups of reasons can present valuable ground for further policy actions.

The interviews were carried out by market research company Interstat d.o.o. between March and May 2015. The interviewer is a psychologist with years of professional experience in qualitative research. The interviews were conducted face-to-face and lasted between 30 and 45 minutes. The permission for recording was not obtained for all the interviews, which was the reason why the answers were written down by pencil at the time of the interviews.

### 2.3 Data Analysis

All the notes were first re-written in electronic format. Then, the answers and explanations from the respondents were rearranged according to the four main sections and their corresponding subsections of the interviewing scenario (see 2.2 for details). Within each subsection data were first clustered in terms of similarity/difference, then the key findings/messages were identified and finally, they were illustrated by the most relevant and interesting literal citations.

## 3 RESULTS

Results of the interviews were organized according to the four scenario sections. In the first section, considering the coding of implanted CIEDs and related procedures as a reason for differences in data, the first reason explaining the differences is diagnosis related groups (DGR) coding system that was valid until December 31, 2012 in which no codes for PM replacement existed. As the hospitals did not have a possibility to enter the code for PM replacements, they used different ways to approach the issue. Some of them did not code the procedure at all and some of them coded it as "unspecified PM first implant". Furthermore, some codes in the old coding system (38253-01 to 38253-10; insertion of permanent single/dual chamber PM) were only valid until December 31, 2010, which means that these procedures were then evidenced under various other codes.

The coding of ICDs is better managed mostly due to the low number of centres in Slovenia that perform ICD surgeries (2 centres) and the codes exist for all the ICD procedures. The difference between the number of procedures in HD database and EHRA database was hence not that large (ICD category includes also CRT-D procedures, so altogether the numbers for ICD are quite correct, although not dispersed across various subcategories within ICDs). However, the codes were again not specific enough: there were no codes to indicate the use of the four types of device (single chamber, dual chamber, BV/CRT and unspecified) as Australian coding system is not specific enough (e.g. there is no code for CRT\_P or CRT\_D procedures and according to one of the interviewees “all such procedures are coded under ICD which is wrong”).

The next reason referred to the low interest in proper coding. It was stated in the interviews that the interest for proper coding is not there as it represents only additional administrative work for the coder nurse. The hospitals are not paid entirely according to the DRG system in Slovenia, which means that lack of motivation for proper coding is present. According to the interviews we could conclude that the data that we obtained from HD database are less reliable and accurate than the data that are submitted to EHRA, in which physicians take their professional interest and pride in submitting.

While the two above mentioned reasons refer to data inaccuracy and incomparability, third obvious reason for the differences in the implantation of CIEDs among studied countries, as conveyed by the respondents, is that no golden rule for optimal crude utilization rate exists. According to the respondents in the interviews conducted there is “no golden rule, which would define the optimal crude utilization rate”. “In Italy the number of implants seems too high, PMs are implanted into patients who do not need implant. Italy, as well as Germany, is obviously confronted with the phenomenon of overtreatment, which is a consequence of having numerous private implementation centres”. “England, on the other hand, is not the best country to base comparisons on as the system is too strict and restricted with high demands for savings.”

Clearly, as the last reason for the differences, the respondents conveyed the conviction of economic reasons playing a role in the implantation rate. If there was reasonable doubt about the necessity and/or benefits of a CIED, Slovene cardiologists would rather wait and postpone implantation, especially in the case of ICDs being more expensive, which may explain a substantial lag of Slovenia behind other economically more developed countries. According to respondents, other differences among countries such as clinical guidelines, incidence and prevalence do not play a role in explaining observed differences in crude utilization rates of CIEDs. However,

any further analysis on the differences in uptake of PM and ICD due to factors such as economic development measured by GDP is not possible as the data provided in Slovene HD database are too unreliable due to reasons cited above (underreporting, data inaccuracy and incomparability).

The interviewees explained that the policy regarding ICDs implants is very restrictive due to their high price, especially in elderly over 80 years of age. Indications for the ICD implants are very strict, the patients need to be in good condition and their medical states have good prognoses (hence one could expect higher utilization rates for women, especially in ICDs, due to longer life-expectancy; however, the results are just the contrary). Comorbidities are important factor in decision making. As elderly often have lots of comorbidities, this might explain the stagnation or a slight decline in implants crude rates in the oldest age group. One of the interviewees explained that “in Slovenia ICDs are generally not implanted in patients with life expectancy up to maximally one year as this would not be justifiable for the insurance”. “In Germany, on the other hand, which has the highest implementation rate for ICDs in the oldest age group, the high ICD crude rate is the consequence of numerous private insurance policies which cover these procedures that the public insurance would not want to cover anymore - due to higher risk in older patients with many comorbidities.” “The implantation of ICD in high age and in patients who do not have good prognoses would mean an agony for the patients and their relatives as the ICD would react non-stop”. “Regarding the youngest group of patients in Slovenia, implanting of ICD and PM is very restrictive. If the implants are inserted in young age heart's condition deteriorates with all the replacements as some electrodes cannot be pulled out, which can cause heart failure. So the age plays an important role in the youngest (up to 44 years of age) and oldest (80+ years of age) patients.” The main reasons for differences in data on CIEDs uptake across studied countries are summarised in Table 1.

According to the interviewees, at least in Slovenia, the patients who are candidates for PMs and ICDs are carefully screened and “only those with absolute indication” receive the implant. Although there is no economic limitation for CIED implantation when medically indicated, the patients in Slovenia are in a worse baseline health state, in comparison to other countries (except Germany), as confirmed by Charlson Comorbidity Index (see Table 3 in Appendix).

The correlation between CIEDs implants and AMI or other heart conditions seems reasonable according to one of the interviewees: “AMI is the reason the patient has received an ICD in the first place.” Diabetes prevalence rates in ICD and PM patients do not differ much. Regarding diabetes, one needs to be aware of the fact that there is no direct

**Table 1.** Main reasons for difference in data in CIEDs uptake in 5 European countries (2008-2012).

| The reason for the difference in the data                                                                | A description                                                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The use of Australian coding system valid until 21 December in Slovenia                                  | <ul style="list-style-type: none"> <li>No codes for PM replacement</li> <li>Some codes were valid only until 31 December 2010</li> <li>Not specific enough (no codes for single chamber, dual chamber, BV/CRT, CRT_P or CRT_D procedures)</li> </ul>           |
| Only a partial link between financing and DRG coding in Slovenia                                         | <ul style="list-style-type: none"> <li>In Slovenia, coding is considered as an additional administrative burden</li> </ul>                                                                                                                                     |
| No golden rule for the optimal crude utilisation rate                                                    | <ul style="list-style-type: none"> <li>In Slovenia, an absolute indication is needed to receive the implant</li> </ul>                                                                                                                                         |
| Variations in relative indications, financial restrictions and other contextual factors across countries | <ul style="list-style-type: none"> <li>Differences in political priorities</li> <li>Different economic developments across countries</li> <li>Differences in decision-making rules on including health care programmes in the basic benefit package</li> </ul> |

linkage to CIEDs. According to one of the interviewees, “diabetes is not a single predictor of CIEDs implants, as it strongly correlates with AMI”.

The overall CCI weighted scores indicate the relative health state of patients receiving both types of devices, and serve mainly to illustrate whether patients receiving a certain type of CIED have a higher or lower average CCI weighted score. Slovenia and Germany do implant less healthy patients. This can be due to economic restrictions, as presumably is the case in Slovenia. The high CCI score in Slovenia would mean a carefully implemented restriction on the implant use, especially in ICDs. The ICDs are expensive and their use is carefully considered, ICDs would only be implanted in patients with absolute indications. In Germany, such a high CCI score could be interpreted as the possibility to implant very weak and older patients as well, which is possible especially due to a high number of private clinics, where the implantations are undertaken.

#### 4 DISCUSSION

Based on our qualitative analysis, it can be observed that the largest differences in Slovenian HD and EHRA data are the consequences of the DRG coding system and coding practices (e.g. ambivalence in coding and data inaccuracy). The DRG coding system that was valid until 21 December 2012 contained no codes for PM replacement. As a result, the hospitals used various approaches to code their work. The coding of ICDs in Slovenia is better managed mostly due to the low number of centres that perform ICD surgeries and the fact that the codes exist

for all the ICD procedures. However, they are still not specific enough. Consequently, until 2013, HD database had limited analytical value (7).

Coding practices are irrevocably connected to the system of financing health care: it is of utmost importance to implement the HD system fully in Slovenia, and use AR-DRG 6.0 version for payments to providers.

The analysis of differences in the uptake of CIEDs according to gender and age shows similar trends across five analysed countries. Specifically, for Slovenia, more strict indications for implanting ICDs as well as PMs can be observed. The differences can be observed in ICD implants in elderly male group, where the implant rate continues to increase in some countries, but decreases in Slovenia and Austria. Interestingly, the implant rates in females decrease in all countries. Such a decrease in both genders in the oldest age group of patients, particularly in Slovenia, can be attributed to the combination of factors: savings, careful examination of the health status and life expectancy of a patient, and to weighting the pros and cons of ICD implants. The ratio for ICDs between both genders is even 4:1 in favour of male patients and the ratio equally persists in all five investigated countries. Similarly, surprising results regarding the gender differences have also been found in previous large-scale studies (8, 9). The authors of these studies claim that observed gender disparities could not be attributable to different heart failure prevalence across gender, different proportions of male and female subgroups in study samples, or to any other similar contextual factors, which might indicate that cardiologists adhere to different standards and/or guidelines while treating either male or female patients. Unfortunately, the present study cannot provide a solid

explanation for the observed gender inequalities, as this was not the prime objective of our research. Further research would be required to investigate the reasons behind different crude utilisation rates for CIEDs in male and female patients.

The interviewees had various explanations for observed differences in comorbidities across countries: one possible explanation is that some countries decide to use implants much earlier than others do, even when patients are in relative need or when patients are older or weaker, which can depend on the system (private vs. public) and resources available.

## 5 CONCLUSIONS

The comparison of crude utilisation rates of CIED uptake across 5 European countries between 2008 and 2012 revealed a substantial lag of Slovenia behind other developed countries. Several potential reasons for such a discrepancy have been explored and identified in the literature, including coding practices (and, consequently, data inaccuracy), economic factors, hospital and regional differences and evidencing as well as different adherence to clinical guidelines (10, 11). The results have been mixed on how and how much economic factors affect access to technologies such as PMs and ICDs (11, 12). It is difficult and too simple to attach the difference to economic factors and development (GDP) of the countries entirely. To better differentiate between administrative peculiarities, malfunctions or incompleteness of the system of evidencing CIEDs, health care system financing and factors like variations in clinical guidelines or lack of access to CIEDs due to economic factors, the research results of MedtechTA project were topped up by interviews with cardiologists and administrative personnel in Slovenia. First, the available data from Slovene HD database have been proved incorrect and hence unreliable, especially in the segment of PMs uptake due to several reasons (incomplete coding system, lack of interest and motivation for proper coding as financing is not directly linked to the number of CIEDs actually being implanted, etc.). In other words, the comparison of HD database with EHRA database has shown that almost one half of PM implants are not reported in the Slovene HD database, while the discrepancy in the number of ICD implants in both databases is smaller. Observed disparities in case of PM implants can be attributed to the problem of underreporting. Doubling crude utilisation rates for PM implants in Slovenia would substantially reduce discrepancies across countries. However, Slovenia would still remain a country with the lowest crude utilisation rates. Underreporting surely plays a major role, but it is

definitely not the only reason for low PM implant rates. The physicians claimed that clinical guidelines and protocols used do not vary across countries.

Data on ICD implants, on the other side, is more reliable. In case of ICD implants, the lowest crude utilisation rate in Slovenia can be interpreted primarily in the context of economic factors. As ICDs are much more expensive than PMs, patients are carefully scanned for absolute indications, taking into account the health status and patient's life-expectancy. In case of doubt and/or relative indications, a patient would normally not receive the implant, which is not necessarily the case in other developed countries with numerous "high volume centres" and extensive private insurances that cover procedures that public insurance would not approve. Financial deficits in economically less developed countries, however, do not impose different clinical guidelines regarding the treatment of patients with heart failure and related conditions. Those with absolute indications would definitely receive a proper CIED, but due to financial restrictions, practitioners are expected to be more stringent in case of relative indications. Such restrictions, on the other hand, also impose protection for patients, as the rather invasive CIEDs are not implanted regardless of the costs/benefits for the patients, but with careful consideration and only in absolute need. This also contributes to the prevention of the overuse of ICDs, which might have considerable negative impacts on health and life-quality if decisions are not in line with professional standards.

To sum up, it can be concluded that economic development (e.g. measured in GDP per capita) to a certain extent predicts the crude utilisation rates of CIEDs; however, the size of the effect is hard to identify as the available data in HD database is incomplete and unreliable. Hence, we recommend the following: (a) to implement the coherent DRG system in all hospitals, with claims for concise and consistent reporting and the need to establish transparent linkage between coded procedures and financial reimbursements; (b) to continuously monitor the advances in the field of CIED development and innovation, and to update the DRG codes regularly so as to avoid delays that would hinder the quality of reported data and realistically reflect the work performed.

Moreover, MedtechTA project revealed some interesting results regarding gender inequalities in CIEDs utilisation rates, which persist in all 5 studied countries and cannot be fully explained. We recommend designing an additional in-depth research to uncover the reasons for the observed differences between male and female patients, primarily in those being older than 64 years, where largest discrepancies have been identified.

## CONFLICTS OF INTEREST

The authors declare that no conflicts of interest exist.

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## ETHICAL APPROVAL

The ethical approval for the study was not required.

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## APPENDIX

**Table 1.** Main reasons for difference in PM and ICD implants crude utilization rate (number of devices/100.000 inhabitants) across 5 European countries, 2008-2012.

|      | Pacemaker implants |         |         |       |          |
|------|--------------------|---------|---------|-------|----------|
|      | Austria            | England | Germany | Italy | Slovenia |
| 2008 | 67.3               | 60.0    | 87.2    | 74.3  | 29.9     |
| 2009 | 66.5               | 68.9    | 90.6    | 74.6  | 32.7     |
| 2010 | 70.5               | 75.7    | 94.5    | 75.1  | 31.2     |
| 2011 | 71.0               | 84.1    | 96.0    | 75.8  | 29.7     |
| 2012 | 72.4               | N/A     | 96.4    | 77.6  | 32.7     |
| AGR* | 1.84               | 11.91   | 2.54    | 1.09  | 2.26     |
|      | ICD implants       |         |         |       |          |
|      | Austria            | England | Germany | Italy | Slovenia |
| 2008 | 15.4               | 8.3     | 28.7    | 23.3  | 5.6      |
| 2009 | 16.7               | 9.7     | 32.3    | 24.1  | 7.7      |
| 2010 | 16.8               | 11.1    | 35.1    | 25.1  | 9.0      |
| 2011 | 18.3               | 11.5    | 37.3    | 26.1  | 8.5      |
| 2012 | 19.0               | N/A     | 38.9    | 26.4  | 9.6      |
| AGR* | 5.39               | 11.48   | 7.90    | 3.17  | 14.42    |

\*average growth rate

Source: MedtechTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for Medical Devices in Electrophysiology, 2015.

**Table 2.** Comparison of the data on numbers of PMs and ICDs from national hospital discharge database with the data published in the European Heart Rhythm Association (EHRA) of the European Society of Cardiology (ESC).

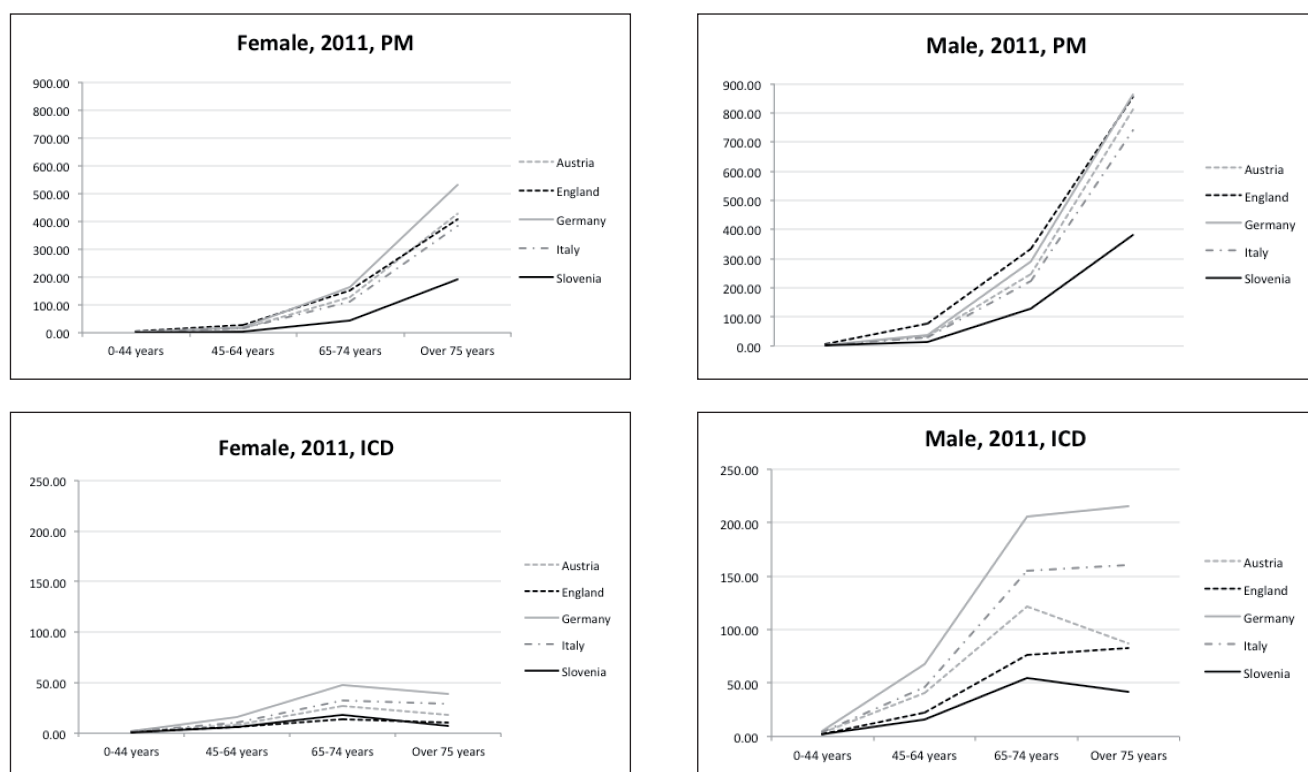
| Year              | Slovenia |           |       | Austria |           |      | All UK England |           |      | Germany |           |      | Italy |           |      |
|-------------------|----------|-----------|-------|---------|-----------|------|----------------|-----------|------|---------|-----------|------|-------|-----------|------|
|                   | EHRA     | Hospitals | Diff  | EHRA    | Hospitals | Diff | EHRA           | Hospitals | Diff | EHRA    | Hospitals | Diff | EHRA  | Hospitals | Diff |
| <b>Pacemakers</b> |          |           |       |         |           |      |                |           |      |         |           |      |       |           |      |
| 2008              | 1100     | 586       | -88%  | 7570    | 7690      | 2%   | 40570          | 37734     | -8%  | 98300   | 89194     | -10% | 61300 | 62220     | 2%   |
| 2009              | 935      | 652       | -43%  | 7930    | 7500      | -6%  | 39850          | 42701     | 7%   | 102177  | 92215     | -11% | 63000 | 62215     | -1%  |
| 2010              | 1153     | 602       | -92%  | 7712    | 7589      | -2%  | 37194          | 45636     | 18%  | 103423  | 94659     | -9%  | 63400 | 62202     | -2%  |
| 2011              | 1295     | 604       | -114% | 7810    | 7870      | 1%   | 38239          | 50540     | 24%  | 106953  | 96013     | -11% | 63100 | 62141     | -2%  |
| 2012              | 1333     | 667       | -100% | 7870    | 7950      | 1%   | 38770          | 0         |      | 106567  | 96403     | -11% | 61300 | 62098     | 1%   |
| <b>ICDs</b>       |          |           |       |         |           |      |                |           |      |         |           |      |       |           |      |
| 2008              | 96       | 103       | 7%    | 1100    | 1104      | 0%   | 7403           | 5086      | -46% | 21600   | 20948     | -3%  | 18000 | 16554     | -8%  |
| 2009              | 111      | 145       | 23%   | 1290    | 1157      | -11% | 5077           | 5376      | 6%   | 23574   | 22940     | -3%  | 10500 | 15100     | 30%  |
| 2010              | 101      | 176       | 43%   | 1268    | 1176      | -8%  | 5175           | 5344      | 3%   | 25071   | 24422     | -3%  | 11100 | 13933     | 20%  |
| 2011              | 144      | 174       | 17%   | 1805    | 1195      | -51% | 5404           | 5467      | 1%   | 26579   | 25219     | -5%  | 11970 | 14106     | 15%  |
| 2012              | 122      | 196       | 38%   | 1195    | 1296      | 8%   | 5762           | 0         |      | 26536   | 25956     | -2%  | 12000 | 13943     | 14%  |

Source: MedtecHTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for Medical Devices in Electrophysiology, 2015.

**Table 3.** Charlson Comorbidity Index - average of weighted CCI scores for each category of device, by country for the year 2011.

|                           |                                   | Austria | England | Germany | Italy | Slovenia |
|---------------------------|-----------------------------------|---------|---------|---------|-------|----------|
| <b>Overall CCI scores</b> |                                   |         |         |         |       |          |
| PM implants               |                                   | 0.10    | 0.90    | 1.63    | 0.96  | 1.07     |
| ICD implants              |                                   | 0.58    | 1.32    | 2.50    | 1.27  | 1.52     |
| PM implants               | Acute myocardial infarction (AMI) | 1%      | 1%      | 9%      | 5%    | 6%       |
|                           | Congestive Heart Failure          | 4%      | 15%     | 32%     | 13%   | 23%      |
|                           | Diabetes                          | N/A     | 17%     | 20%     | 11%   | 22%      |
| ICD implants              | AMI                               | 2%      | 5%      | 35%     | 14%   | 26%      |
|                           | Congestive Heart Failure          | 54%     | 60%     | 91%     | 73%   | 63%      |
|                           | Diabetes                          | 0%      | 20%     | 25%     | 13%   | 16%      |

Source: MedtecHTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for medical Devices in Electrophysiology.



Source: MedtechHTA Report on Geographic variation in Utilisation Rates and Determinants of Access across European Countries for Medical Devices in Electrophysiology, 2015.

**Figure 1.** Crude utilisation rates of PMs and ICDs in 2011, in 5 European countries according to age group, gender and country.