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INVESTIGATING REGIONAL VARIATION OF CARDIAC IMPLANTABLE ELECTRICAL DEVICE IMPLANT RATES IN EUROPEAN HEALTHCARE SYSTEMS: WHAT DRIVES DIFFERENCES?

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ABSTRACT

Despite established efficacy for cardiac implantable electrical devices (CIEDs), large differences in CIED implant rates have been documented across and within countries. The aim of this paper is to investigate the influence of socio-economic, epidemiological and supply side factors on CIED implant rates across 57 Regions in 5 EU countries and to assess the feasibility of using administrative data for this purpose. A total of 1 330 098 hospitalizations for CIED procedures extracted from hospital discharge databases in Austria, England, Germany, Italy and Slovenia from 2008 to 2012 was used in the analysis. Higher levels of tertiary education among the labour force and percent of aged population are positively associated with implant rates of CIED. Regional per capita GDP and number of implanting centres appear to have no significant effect. Institutional factors are shown to be important for the diffusion of CIED. Wide variation in CIED implant rates across and within five EU countries is undeniable. However, regional factors play a limited part in explaining these differences with few exceptions. Administrative databases are a valuable source of data for investigating the diffusion of medical technologies, while the choice of appropriate modelling strategy is crucial in identifying the drivers for variation across countries. © 2017 The Authors. *Health Economics* published by John Wiley & Sons, Ltd.

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1. INTRODUCTION

Extensive empirical evidence shows that access to different types of medical technologies varies across countries and within countries (Willeme & Dumont, 2015; Bech *et al*., 2009). Large differences in implant rates have been documented for cardiac implantable electrical devices (CIEDs) despite their established and internationally recognized efficacy for the management of arrhythmias (Valzania *et al*., 2015). Studies of trends in CIED implants have shown rates consistently rising over time in virtually all countries. However, these rising trends have not brought implant rates in various countries to similar levels, but quite contrarily, the differences have persisted and, in some cases, even increased (Arribas *et al*., 2014; Valzania *et al*., 2015).

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The reasons for the great disparity in CIED implantation rates are not entirely known. Many factors are presumed to be involved, and their relative contributions vary across the countries. A number of studies have examined determinants of variation in CIED implant rates and in particular the impact of clinical guidelines adoption and economic and organizational factors (Hatala *et al*., 2015). Available studies focused on different types of CIED: pacemakers (PMs), implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT).

The majority of existing analysis investigated the issue at the country level and tested for correlations between country-level socio-economic indicators and implant rates. For instance, Vardas and Ovsyscher (2002) found significant differences among countries in PM implant rates and that first PM implants were strongly correlated with gross domestic product (GDP) and the number of pacing centres. Ovsyshcher and Furman (2003) found modest correlation between PM and ICD implant rates and economic (GDP and health expenditures) and demographic factors, stressing the importance of comparing groups of patients of similar age. In a study investigating ICD implants among European Society of Cardiology member nations, Lubinski *et al*., 2015, found that implant rates per million inhabitants correlated with GDP, GDP per capita, health expenditure, life expectancy and the number of implanting centres. Finally, Merkely *et al.* (2010) investigated differences in implant rates of CRT devices and found that local reimbursement practices and clinical guideline diffusion had some impact, but that GDP and healthcare spending did not greatly affect implant rates.

Although a consensus on determinants of variation has not emerged as a result of comparison studies on PM and ICD implant rates across nations, several nations have sought to investigate the reasons behind their lower than expected implant rates in comparison with other countries (Lang, 2005). McComb *et al.* (2009) looked at geographic variation in ICD implants among regions in the UK using data from public and private hospitals, but through correlation analysis found no significant relationship between economic (deprivation index), health (index for health), need (patients presenting with approved indications) or supply related (number of cardiologists, implanting hospitals) factors to explain wide geographic variation observed within the UK and low rates compared with other nations. A study in France using hospital discharge data linked with insurance claims data highlighted large regional variation but did not perform statistical analysis to investigate the determinants of such variation (Tuppin *et al*., 2011). A number of studies in the USA have looked at geographic variation and hospital type, age, gender and race as factors potentially limiting access to PMs and ICDs (El-Chami *et al*., 2007; Groeneveld *et al*., 2005; Scott *et al*., 2009).

In addition to a lack of conclusive empirical evidence on factors explaining variation, research up to now has not provided a universal method for identifying determinants of diffusion of CIED that could be of use in policymaking. The studies investigating differences among nations have relied on heterogeneous data sources, mostly registry or survey data, where differences in collection methods and a lack of complete information for each country make results difficult to interpret. In addition, within-country data on regional differences as well as demographic information on patients are often missing, limiting interpretation of the results. Furthermore, the statistical techniques used to investigate determinants are generally confined to a simple correlation analysis. A notable exception is the study by Bech et al. that investigated the influence of economic incentives and regulatory factors on the adoption of treatment technologies used to treat heart attacks, using unique patient-level data and solid econometric methods (Bech *et al*., 2009).

To our knowledge, no studies so far have used individual records data based on hospital discharges nor panel data regression techniques to empirically investigate the factors that influence diffusion of medical technology in Europe.

Our objectives in undertaking the present study were to investigate the use of effective medical technology in the field of electrophysiology to generate evidence on geographical variation and its determinants using a reliable data source, a common protocol for extracting data and robust statistical methods for analyzing results. More specifically, we have sought to produce evidence regarding differences in the use of CIED between and within European member states using hospital discharge datasets available in five countries and to investigate the determinants of differences in access to these technologies to aid policymakers in determining where intervention is needed. We additionally aimed to assess the potential and limitations of administrative databases for the analysis of implant rates of these medical devices.

2. METHODS

2.1. Selection of technologies

The scope of our analysis is to investigate all types of CIED technologies available in the EU market that include different devices: PMs, ICDs and, separately, the CRT subtypes of each of these devices (CRT-P and CRT-D). Both ICDs and PMs continuously monitor cardiac rhythm. A PM is an implantable electrical device able to deliver electrical impulses to regulate heart beating. An ICD is an implantable cardiac device that continuously monitors cardiac rhythm and uses electrical pulses or shocks to help control life-threatening arrhythmias, especially those that can cause sudden cardiac arrest. Thus, ICDs are more sophisticated technologies than PMs because they can provide both pacing and anti-tachycardia therapies (anti-tachycardia pacing and defibrillating shocks), while PMs can only provide pacing in the event of bradyarrhythmias. Consequently, ICDs are more expensive than PMs because of their additional features and technology. CRT is a stimulation technique based on right and left ventricular pacing, delivered by a PM (CRT-P) or a cardioverter-ICD defibrillator (CRT-D) (Brignole *et al.*, 2013; Priori *et al.*, 2015). CRT is currently indicated for some specific groups of chronic heart failure patients (Brignole *et al.*, 2013).

Clinical guidelines represent a general recommendation for physicians' decision-making in the choice of which type of CIED is most appropriate. In routine clinical practice, indications for CIED are usually patient tailored, taking into consideration age, general clinical status and comorbidities. Therefore, there is a certain degree of discretion in physicians' decision-making, which is related to the clinical context of the single patient (i.e. the patient's arrhythmic events and structural heart disease).

In a first CIED implant, both generator and leads are implanted. After the first implant, replacement may be needed and usually involves only the generator. The reasons leading to device replacement vary, although battery depletion is the most common (after 5–10 years from the first implant). Device malfunction or infection are less frequent events. Thus, factors affecting the implant rates for first implant and replacement may substantially vary across different CIEDs. Given that the indications for the first implant and for replacement are naturally diverse, there is a significant difference between them in terms of clinical and economic impact. First implants are inherently more complicated procedures leading to higher complication rates, procedure costs and length of stay.

2.2. Data sources and country selection

Hospital discharge record databases from 2008 to 2012 in Austria, England, Germany, Italy and Slovenia were interrogated, and data regarding all hospitalizations associated with CIED implants and replacements were extracted using direct cross-referencing of procedure codes from each country's coding system. The device types were identified as PMs, ICDs, CRT-Ps or CRT-Ds. Codes for removals, lead extractions, loop recorders, temporary implantation or pocket revision were excluded.

The five countries were selected with the aim to capture, as much as possible, different European healthcare systems across the following dimensions: (i) institutional set-up (national health system versus social health insurance system); (ii) markets of different sizes; and (iii) level of decentralization. While these criteria allowed us to define a larger pool of EU countries to be included in the analysis, our final choice was determined by the existence of a nationally standardized list of procedure codes reflecting the choice of interventions and feasibility of data access.

Exhaustive lists of procedural codes for implants and replacements of CIED were gathered from each distinct coding system, compared and cross-referenced. A common protocol was developed to extract all hospital discharge records using the procedure code fields for the years 2008–2012 in all countries (data for 2012 were unavailable in England). Limited patient characteristics (residency, gender, age or age class and comorbidities) and patient management measures (hospital code and location, length of stay and discharge type) were available for each record (individual hospital codes were not available for Austria). Subsequent common protocols were developed to aggregate data and form a central database by country and by region. Regions were identified using the large regions classification (TL2) from OECD and Eurostat (Nuts 2) for a total of 57 regions among the five countries (Austria – nine regions; England – nine regions; Germany – 16 regions; Italy – 21 regions; and Slovenia – two regions).

Crude implant rates per 100 000 inhabitants were calculated for each device and device subtype using the aggregate database and regional and national population figures from the Eurostat website. Crude regional implant rates per 100 000 inhabitants were also adjusted for gender and age by the direct standardization method using the Revised European standard population, 2013. This adjustment was deemed necessary to provide a meaningful comparison across countries in the descriptive analysis at the country level. Regional socio-economic and organizational indicators for each year were gathered from OECD sources for GDP per capita, the level of tertiary education expressed as a percentage of the total work force; and population density expressed as the number of inhabitants per square kilometre. Eurostat sources were used for life expectancy at birth in years, and the percentage of the population over 74 years of age was calculated from Eurostat population figures (Eurostat, 2015).

2.3. Data analysis

A panel data regression model was designed to investigate drivers of variations in CIED implant rates across and within 57 EU regions in the observation period 2008–2012. For all types of CIED technologies (PMs, ICDs, CRT-PM and CRT-D), we estimate separate models for first implant and replacement rates using the following:

$$y_{\mathrm{it}} = \beta_{\mathrm{i}} + \beta X_{\mathrm{it}} + \delta T + \varepsilon_{\mathrm{it}}$$

The dependent variable (y_{it}) in all models was the crude implant rate of one of four types of CIED (number of implants/100 000 inhabitants at regional level). β_{i} is the unobserved time-invariant regional effect; β is the vector of time-variant parameters investigated, while δ is the vector of parameters for time effects. The model tests the influence of economic and demographic factors (i.e. regional GDP per capita, percent of the resident labour force with tertiary education, population density and percentage of patients over 74 years of age); epidemiological (i.e. life expectancy) and supply side variables (i.e. number of implanting centres in the region). Including dummies for each year allows our models to control for temporal variation in implant rates across all regions. The error term $\varepsilon_{\mathrm{it}}$ in the model is a linear function of two components.

$$\varepsilon_{\mathrm{it}} = \zeta_{\mathrm{i}} + \mu_{\mathrm{it}}$$

The first component (the unobserved heterogeneity ζ_i) represents the unobserved time-constant factors shared between the five observation occasions on the same region that affect the implant rate (e.g. institutional contexts). The second component (μ_{it}) is the unobserved time-varying factors, unique for each occasion *t* and region *i*, and might include economic and health shocks. Assumptions about the error term determine whether we apply fixed effects (FEs) or random effects (RE) estimators. Before choosing between RE and FE estimation, we made several considerations. RE rely on the challenging assumption that unobserved heterogeneity is uncorrelated with the regressors included in the model. Failure to meet such an assumption leads to inconsistent estimates because of omitted variables. Given the great deal of potentially relevant information that is not captured by the available set of regressors, this assumption is potentially critical in the present context. On the other hand, the FE model may not perform well because we have little within subject variability (the CIED implant rates do not change significantly over time as much as they change across regions). Furthermore, we wish to estimate the effects of covariates that are virtually time-invariant in our time frame (i.e. number of hospitals in the region), and this is not possible with the FE estimator. Given the important advantages and disadvantages of both models, we also performed the Hausman test for all models, to further inform our choice.

In addition to panel regression models on crude implant rates, we ran additional specifications on alternative dependent variables: negative binomial on count data (number of implants), regression models on age and sex adjusted implant rates as robustness checks for our findings (available as supplemental material). All statistical analyzes were performed using the software package STATA 13.0 (StataCorp, College Station, TX, USA).

3. RESULTS

3.1. Descriptive statistics at country level

National hospital discharge databases were interrogated and information from 1 338 199 hospitalizations associated with PM, and ICD procedures from 2008 to 2012 were gathered in country databases in Austria, Germany, Italy and Slovenia, and from 2008 to 2011 in England. After excluding records with incomplete information on patient residence and age class, the combined database consisted of 1 330 098 (99.4%) records, 1 017 441 associated with PM procedures and 312 657 associated with ICD procedures. On average, 211 531 PM and 62 132 ICD procedures/year were performed for the 204.5 million of EU residents, translating to crude implant rates per 100 000 inhabitants of 103.5 for PMs and 30.4 for ICDs. Over the observation period, PM implant rates rose from 97.9 to 108.4 per 100 000 inhabitants, and ICD implant rates rose from 25.7 to 34.2 for the five countries combined.

Overall, the average length of stay (excluding outliers at the 99th percentile) was 8.72 and 3.75, respectively, for first implants and replacements of PMs, and 9.85 and 4.55, respectively, for first implants and replacements of ICDs. More specifically, the average length of stay for PM first implants ranged from 6.09 days in Slovenia to 10.43 days in Germany, while average hospital stay for PM replacement was significantly shorter (ranging from 2.54 days in England to 4.25 days in Austria). The same pattern was observed for ICDs (7.04 days in England and 11.23 days in Slovenia, respectively, for first implants and 3.49 days in England and 7.13 days in Slovenia, respectively, for replacements).

Table I illustrates crude and standardized first implant and replacement rates per 100 000 inhabitants for the four types of CIED in each of the five countries across the study period. England and Germany registered the greatest changes over time in first implant rates of PMs, although replacement rates remained fairly stable. ICD implant rates have risen over the study period in all countries but marked differences in rates between countries remained with England and Slovenia showing significantly lower values compared with other countries. Germany registered the highest implant rates for almost all types of technologies.

Codes were available for discerning CRT devices in all countries except Slovenia, and because of the extension of clinical indications for CRT-P and CRT-D in recent years, these technologies were analyzed separately. Crude first implant and replacement rates have increased over the period for CRT-P (+54% in Austria, +49% in England and nearly doubling in Germany and Italy) and particularly for CRT-D (+64% in Austria, +89% in Germany, +143% in Italy and increased more than 10-fold in England).

All independent variables across five countries are displayed in Table I. Unfortunately, the number of implanting centres was not available for Austria at the time of the analysis.

3.2. Model estimation at regional level

The 57 regions in the datasets showed considerable variation in first implant and replacement rates per 100 000 inhabitants for all types of CIED, especially for PMs. For ICDs, crude and adjusted implant rates exhibited large differences across regions in Germany and Italy, and a more contained range of values for Austria. England showed much less variation in implant rates in comparison with all countries except Slovenia (with only two regions). The largest differences among regions were observed for crude and adjusted implant rates for CRT-P and CRT-D devices.

Table I. Descriptive statistics of the dependent and independent variables

	Austria		England		Germany		Italy		Slovenia		Overall	
	Crude	Standardized[b]	Crude	Standardized[b]	Crude	Standardized[b]	Crude	Standardized[b]	Crude	Standardized[b]	Crude	Standardized[b]
Dependent variables[a]	Mean											
PM (first implants)	66.3	77.7	71.2	84.3	96.5	95.2	73.4	71.1	30.9	39.8	77.1	79.8
PM (replacements)	25.3	29.2	17.2	20.2	23.7	23.0	29.0	28.0	NA	NA	25.2	25.6
ICD (first implants)	15.6	17.5	9.8	11.8	35.8	34.9	23.8	24.7	8.1	9.1	23.5	24.3
ICD (replacements)	4.4	5.2	3.7	4,4	9.4	8.8	6.9	7.1	1.0	1.2	6.6	6.7
CRT-P (first implants)	2.7	3.3	3.6	4.4	1.8	1.6	1.7	1.6	NA	NA	2.2	2.3
CRT-P (replacements)	0.8	0.9	NA	NA	0.5	0.4	1.0	1.0	NA	NA	0.8	0.7
CRT-D (first implants)	5.7	6.5	2.8	3.4	12.2	11.8	6.7	6.8	NA	NA	7.7	7.9
CRT-D (replacements)	1.6	1.9	NA	NA	3.1	2.8	2.9	3.0	NA	NA	2.7	2.7
Independent variables	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
GDP per capita (1000s)	34.7	6.4	31.7	9.9	32.6	9.1	26.9	6.8	25.8	5.0	30.5	8.4
% of labour force with tertiary education	18.1	3.4	33.1	6.0	26.9	3.9	16.3	2.4	26.2	5.0	22.2	7.2
Population density	554	1337	859	1462	670	1032	181	113	104	16	469	969
Percentage of population over 74 years	8.0	1.0	7.9	1.0	9.1	0.9	10.4	1.5	7.5	0.3	9.2	1.6
Life expectancy at birth	81.1	0.76	80.7	1.0	80.3	0.76	82.3	0.76	79.9	1.3	81.2	1.2
Number implanting centres	NA	NA	27.2	9.7	64.6	65.7	24.4	21.6	2.9	1.1	37.8	45.9

PM, pacemaker; ICD, implantable cardioverter defibrillator; CRT-P, cardiac resynchronization therapy pacemaker; CRT-D, cardiac resynchronization therapy with defibrillator; GDP, gross domestic product.

[a] Values for number of implants x 100 000 inhabitants.

[b] Standardization for gender and age by the direct standardization method using the Revised European standard population, 2013. Models with standardized rates as dependent variable are available in the Appendix.

The potential drivers of these differences were investigated in a series of panel regression models. Hausman test confirmed consistency of RE estimation for the majority of the models, but not for all. Based on this test result, and in addition to the reasons outlined earlier, we refrained from estimating only RE models in order to provide consistent estimates of the parameters. We adopt a more conservative approach and run both specifications of the models (FE and RE) and discuss the results. Tables II–V display the results of all models across four different types of CIED (PMs, ICDs, CRT-P and CRT-D, respectively).

The percentage of population with tertiary education among the labour force of the regions had a positive impact on PM first implants (both FE and RE model) and replacements (only in RE). The percentage of population over 74 appears to have a positive impact on both first and replacement PM rates but only in the RE model. GDP per capita has counterintuitive negative signs for both first and replacement PM implant rates (but the result is significant only in the RE model). The time trends did not have any significant impact on the first implant rates of PMs across regions nor did the number of implanting centres. On the other hand, country effect was strong in all RE models, suggesting strong influence of time-invariant factors captured at the country level.

The findings for ICD implant rates suggest slightly different insights (Table III). Population over 74 years had a significant positive effect across all specifications, while tertiary education had positive effects only for first ICD implants. We found no significant effect for per capita GDP across all models. The number of implanting hospitals did not have a significant impact on ICD implant rates either. Interestingly, the time trend was very strong for both first implant (only in RE) and replacement ICD rates (both FE and RE), that is,

Table II. Determinants of diffusion of PM across EU regions 2008–2012 (first implants and replacements)

	FE		RE		FE		RE	
	PM first implants		PM first implants		PM replacements		PM replacements	
Slovenia (dummy)			0.000	(.)				
England			36.044***	(9.642)			0.000	(.)
Germany			67.221***	(9.765)			7.412**	(2.525)
Italy			47.321***	(11.842)			12.112**	(3.777)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	0.318	(2.029)	−0.194	(1.337)	0.795	(0.792)	0.215	(0.529)
2010	0.904	(2.386)	1.117	(1.619)	−0.238	(0.924)	−0.693	(0.648)
2011	1.880	(3.124)	2.396	(2.030)	−1.639	(1.205)	−2.019*	(0.825)
2012	0.344	(3.979)	0.320	(2.354)	−1.213	(1.526)	−1.705	(0.961)
GDP per capita (1000s)	−0.133	(0.771)	−0.674**	(0.260)	−0.084	(0.303)	−0.338**	(0.111)
Tertiary education	1.290**	(0.479)	1.583***	(0.378)	0.105	(0.190)	0.376*	(0.154)
Population density	0.012	(0.035)	−0.007*	(0.003)	0.002	(0.013)	−0.001	(0.001)
Population over 74	1.747	(2.891)	3.098*	(1.385)	0.798	(1.094)	1.248*	(0.578)
Life expectancy	4.186	(2.444)	1.311	(1.775)	1.115	(0.934)	0.511	(0.726)
Number of implanting centres	0.209	(0.142)	0.002	(0.042)	−0.077	(0.053)	0.013	(0.018)
_cons	−316.933	(199.060)	−121.133	(137.602)	−70.408	(75.994)	−34.417	(57.103)
N	231		231		221		221	
r2_within	0.374		0.359		0.106		0.079	
r2_between	0.003		0.730		0.003		0.600	
r2_overall	0.013		0.706		0.005		0.556	
Rho (ICC)[a]	0.961		0.816		0.948		0.858	

FE, fixed effect; RE, random effect; PM, pacemaker; GDP, gross domestic product.
Standard errors are in parentheses.
[a]Intraclass correlation.
*$p < 0.05$;
**$p < 0.01$;
***$p < 0.001$.

Table III. Determinants of diffusion of ICDs across 57 EU regions 2008–2012 (first implants and replacements)

	FE		RE		FE		RE	
	ICD first implants		ICD first implants		ICD replacements		ICD replacements	
Slovenia (dummy)			0.000	(.)			0.000	(.)
England			0.652	(5.068)			3.148*	(1.586)
Germany			26.726***	(5.136)			7.133***	(1.611)
Italy			23.173***	(6.275)			3.788	(2.037)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	0.713	(1.020)	0.846	(0.723)	1.807***	(0.392)	1.400***	(0.258)
2010	1.160	(1.200)	2.982***	(0.872)	3.000***	(0.461)	2.806***	(0.305)
2011	0.772	(1.570)	4.276***	(1.090)	3.492***	(0.603)	3.438***	(0.375)
2012	−1.032	(2.000)	4.486***	(1.261)	3.726***	(0.768)	3.895***	(0.429)
GDP per capita (1000s)	0.246	(0.387)	−0.185	(0.138)	0.183	(0.149)	−0.048	(0.044)
Tertiary education	0.551*	(0.241)	0.726***	(0.204)	−0.212*	(0.092)	−0.042	(0.071)
Population density	0.012	(0.018)	−0.001	(0.002)	−0.002	(0.007)	0.000	(0.000)
Population over 74	7.816***	(1.453)	2.175**	(0.735)	1.469**	(0.558)	0.785**	(0.239)
Life expectancy	−1.413	(1.228)	−2.631**	(0.952)	−0.131	(0.472)	−0.259	(0.325)
Number of implanting centres	−0.063	(0.071)	0.003	(0.022)	0.004	(0.027)	0.005	(0.007)
_cons	42.611	(100.056)	185.227*	(73.752)	1.575	(38.413)	15.773	(25.052)
N	231		231		231		231	
r2_within	0.536		0.457		0.748		0.730	
r2_between	0.000		0.749		0.072		0.628	
r2_overall	0.003		0.713		0.122		0.645	
Rho (ICC)[a]	0.978		0.805		0.946		0.744	

FE, fixed effect; RE, random effect; ICDs, implantable cardioverter defibrillators; GDP, gross domestic product.
Standard errors are in parentheses.
[a] Intraclass correlation.
$^{*}p < 0.05$;
$^{**}p < 0.01$;
$^{***}p < 0.001$.

parameters were positive and significant for almost all years, suggesting the importance of some common trends across EU regions. Country effect was significant for Italy and Germany for ICD first implants, and Germany and England for replacements.

Models for CRT-P and CRT-D further confirm the importance of time trends across EU regions, but to a lesser extent (Tables IV and V). It is worth noting that for these two categories of devices we had fewer observations because not all countries had available codes for CRT-D and CRT-P devices for both first implants and replacements. In addition, the overall rate of CRT-P was affected by the level of tertiary education among the labour force only in one model specification, while the number of implanting hospitals resulted non-significant. Population over 74 resulted positive and significant only for CRT-Ds. Population density had a weak effect, and per capita GDP was not significant across models for both device categories.

4. DISCUSSION

A steady increase in CIED has been observed in Europe over the last decades as a consequence of the results of large clinical trials, the development of scientific guidelines and the implementation of knowledge in clinical practice. With the increase in clinical indications and cardiac pacing practice, there has been growing interest in investigating access to CIED across countries. Available evidence shows that there is significant heterogeneity in implant rates of CIED across and between countries, while few studies have empirically investigated the

Table IV. Determinants of diffusion of cardiac resynchronization therapies (CRT-P) across 57 EU regions 2008–2012 (CRT-P)

	FE		RE		FE		RE	
	CRT PM first implants		CRT PM first implants		CRT PM replacements		CRT PM replacements	
England (dummy)			0.000	(.)				
Germany			−1.713***	(0.463)			0.000	(.)
Italy			−0.926	(0.844)			0.339	(0.504)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	0.202	(0.243)	0.152	(0.157)	−0.120	(0.159)	0.041	(0.112)
2010	0.757**	(0.283)	0.701***	(0.178)	0.140	(0.177)	0.226	(0.125)
2011	0.984**	(0.362)	0.900***	(0.209)	0.256	(0.223)	0.304*	(0.145)
2012	1.170*	(0.453)	1.007***	(0.233)	0.302	(0.278)	0.351*	(0.162)
GDP per capita (1000s)	0.048	(0.086)	0.035	(0.021)	−0.109	(0.057)	0.007	(0.015)
Tertiary education	0.067	(0.061)	0.080*	(0.039)	0.082	(0.050)	0.011	(0.030)
Population density	−0.005	(0.004)	−0.001*	(0.000)	−0.001	(0.003)	-0.000	(0.000)
Population over 74	−0.171	(0.307)	0.079	(0.110)	−0.092	(0.201)	0.031	(0.077)
Life expectancy	−0.004	(0.265)	−0.194	(0.159)	0.074	(0.186)	0.038	(0.124)
Number of implanting centres	0.011	(0.015)	−0.001	(0.003)	−0.001	(0.010)	−0.002	(0.002)
_cons	2.479	(21.346)	14.970	(12.340)	−2.406	(14.841)	−3.334	(9.606)
N	199		199		161		161	
r2_within	0.455		0.442		0.293		0.250	
r2_between	0.000		0.545		0.001		0.224	
r2_overall	0.004		0.511		0.004		0.233	
Rho (ICC)[a]	0.985		0.700		0.961		0.751	

FE, fixed effect; RE, random effect; GDP, gross domestic product.
Standard errors are in parentheses.
[a] Intraclass correlation.
*$p < 0.05$;
**$p < 0.01$;
***$p < 0.001$.

factors that might influence these implant rates in Europe by employing comprehensive databases and robust statistical methods.

Our study is the first empirical analysis to use national, hospital discharge datasets to investigate variation in implant rates of CIED across EU countries at the regional level. Although methodologies employed in our analysis are rather different from those used in previous studies, our findings partially confirm previous results. More specifically, the portion of residents over 74 years of age is significantly and positively associated with implant rates for ICDs and CRT-Ds, similar to the analysis on western European countries and the USA (Ovsyshcher & Furman, 2003). However, the number of implanting centres was identified as an important factor for diffusion of CIED in several studies (Lubinski *et al*., 2011; Merkely *et al*., 2010; Wolpert *et al*., 2011), which has not been confirmed in our investigation. In our analysis, the level of tertiary education among the regional labour force showed positive association with implant rates in almost all models. This result might suggest that regions where levels of education are generally higher play an important role in access to innovative medical technologies. Indeed, the lower levels of educational attainment have been put forward by Camm and Nisam (2010) among potential explanatory factors for significantly lower rates of ICDs in Europe versus the USA. The authors argue that in Europe (differently from the USA) neither the patients nor their relatives and friends are usually well informed about medical opportunities in the field, suggesting that education may affect access to highly specialized care (Camm & Nisam, 2000; 2010. Our study is the first European investigation that gives further insights into this important issue on the role of education and access to medical technologies and warrants further research.

Table V. Determinants of diffusion of cardiac resynchronization therapies across 57 EU regions 2008–2012 (CRT-D)

	FE		RE		FE		RE	
	CRT- D first implants		CRT- D first implants		CRT-D replacements		CRT-D replacements	
England (dummy)			0.000	(.)				
Germany			8.457***	(1.520)			0.000	(.)
Italy			1.449	(2.637)			−2.189	(1.189)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	0.630	(0.620)	1.371**	(0.445)	0.372	(0.382)	0.414	(0.266)
2010	2.229**	(0.729)	3.635***	(0.518)	1.414**	(0.425)	1.394***	(0.295)
2011	2.231*	(0.935)	4.380***	(0.623)	1.948***	(0.536)	1.856***	(0.344)
2012	1.327	(1.169)	4.470***	(0.703)	2.500***	(0.667)	2.382***	(0.383)
GDP per capita (1000s)	−0.270	(0.218)	−0.108	(0.068)	−0.188	(0.130)	-0.045	(0.034)
Tertiary education	−0.001	(0.157)	0.104	(0.118)	−0.141	(0.116)	−0.037	(0.071)
Population density	0.004	(0.009)	0.000	(0.001)	0.001	(0.007)	−0.000	(0.000)
Population over 74	3.963***	(0.788)	1.092**	(0.356)	0.429	(0.484)	0.330	(0.181)
Life expectancy	0.773	(0.681)	−0.095	(0.491)	0.506	(0.448)	0.281	(0.294)
Number of implanting centres	0.014	(0.039)	−0.000	(0.010)	0.040	(0.023)	0.001	(0.005)
_cons	−87.807	(54.913)	−0.722	(38.113)	−37.258	(35.578)	−21.224	(22.804)
N	200		200		164		164	
r2_within	0.741		0.709		0.690		0.673	
r2_between	0.008		0.635		0.000		0.125	
r2_overall	0.031		0.657		0.040		0.378	
Rho (ICC)[a]	0.966		0.789		0.930		0.737	

FE, fixed effect; RE, random effect; GDP, gross domestic product.
Standard errors are in parentheses.
[a] Intraclass correlation.
*$p < 0.05$;
**$p < 0.01$;
***$p < 0.001$.

Our study only partially confirms the results of previous investigations showing the importance of economic factors for the diffusion of CIED. More specifically, Ovsyscher and Furman showed a significant, although modest, correlation between economic indices such as GNP and per capita annual health expenditures with European first time PM ($r = 0.61$, $p < 0.01$) and ICD implant rates (0.66, $p < 0.01$) (Ovsyscher & Furman, 2003). The correlation is modest because some countries with similar economic indices have significantly different implant rates. For example, the Czech Republic, with a considerably lower economic status, has much higher PM and ICD implant rates than the UK, which in turn was most likely influenced by rather restrictive NICE guidelines. Merkely et al. (2010) argue that, while countries with higher GDP or healthcare spending per capita generally had a higher number of CRT implantations, because of large variations, the correlation between these factors and the number of CRT implantations was weak. In our study, regional per capita GDP did not have any impact on CIED implant rates in any of the FE models. It resulted significant only in RE models investigating the implant rate of PMs, with a counterintuitive negative sign. We believe that this result highlights the importance of appropriate model estimation in order to obtain consistent parameter estimates.

More importantly than partially confirming the results of previous studies, our study brings in relevant methodological advancements to the literature investigating the variations in medical device implant rates across countries. Moreover, our analysis is the first cross-country investigation of factors driving CIED utilization rates at regional levels. The methodology employed is innovative in two aspects: the data sources used and statistical methods employed. As a data source, considerable effort has been made to assess and test the potential and reliability of using national hospital discharge records to study diffusion of CIED. Hospital discharge databases have a great advantage over other sources of data (i.e. registries) because they ensure national coverage and are completed according to standardized methods. Other data sources often come from registry or survey data, which can mean significant variation in data collection methods, quality and completeness, inconsistent reporting of specific device types and an absence of patient and clinical information. By leveraging on this great potential, we developed a common protocol to identify diagnostic and procedure codes across countries using different coding systems. We believe that the study reported here provides a compelling argument for the use of hospital discharge data to analyze trends in implant rates and clinical practices for selected MDs. Further analysis is encouraged to expand use of administrative data for other technologies and to more closely monitor differences among regions and hospitals within countries.

Regarding the methods applied for data analysis, our study is considerably different from the current empirical studies that analyzed geographical variations in CIED implantation. All other studies relied on relatively simple statistical methods to test correlation between utilization rates and potential explanatory variables (i.e. Spearman's correlation test). Merkely et al. (2010) used stepwise multiple regression analysis to identify independent factors that affect the number of CRT implantations per capita. These methods have considerable drawbacks and fall short in explaining the actual impact of selected covariates on the outcome variable. Our analysis is the first to use panel data regression methods, using both RE and FE estimation models, to investigate within (temporal) and between (geographical) variations of CIED utilization rates in 57 European regions. Our results shed light on the importance of appropriate model estimation. A different choice of empirical model may lead to different findings that could translate to diverse policy recommendations. The FE estimator provides the most consistent parameter estimates in the context in which the likelihood of omitted variable bias is very high, which is particularly relevant in international comparative studies. However, its estimation may pose several challenges.

4.1. Study limitations

The present study is based on the use of administrative data for exploring implant rates but did not assess outcome, as was carried out in other studies using hospital discharge data (Ghislandi *et al*., 2013). The accuracy of the administrative data that we consider can be variable, for complex reasons that cannot be analyzed in depth. With this regard, one of the sources of data may have a higher degree of approximation, as we reported. Furthermore, it should be noted that we were able to include only a limited set of independent variables because the data at the regional level are not readily available. For example, other variables such as the education level of physicians and their attitudes toward specific devices may play an important role in explaining differences in implant rates of these technologies. Finally, we did not discuss an optimal or appropriate CIED implant rate in our paper. All of these issues should be investigated in further research efforts aimed to uncover drivers of differences in implant rates of CIED across countries.

5. CONCLUSIONS

The implant rates of CIED are a very relevant policy topic for investigation because these devices represent compelling examples of health technologies that have been proven to remarkably improve health outcomes of populations while, at the same time, increasing barriers that prevent their full diffusion into clinical practice. Given the epidemiological and demographic trends, it is essential that policymakers search for explanations for the observed variations. Timely and comprehensive data reporting is necessary to keep abreast of the situation, and administrative databases are a valid and reliable source to investigate the issue at national and international levels. We believe that these methods could be implemented for further analyses on determinants of medical device diffusion and possibly extended to additional databases collecting administrative health information within an international, national or regional context.

APPENDIX A: REGRESSION MODELS WITH AGE-STANDARDIZED AND SEX-STANDARDIZED IMPLANT RATES AS DEPENDENT VARIABLES

Table AI. Determinants of diffusion of PM across EU regions 2008–2012 (first implants and replacements)

	FE		RE		FE		RE	
	PM first implants		PM first implants		PM replacements		PM replacements	
Slovenia (dummy)			0.000	(.)				
England			40.162***	(9.144)			0.000	(.)
Germany			65.389***	(9.275)			5.634*	(2.393)
Italy			53.296***	(11.477)			12.310***	(3.604)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	−0.006	(2.102)	−0.459	(1.368)	0.660	(0.759)	0.167	(0.508)
2010	0.449	(2.472)	0.488	(1.640)	-0.447	(0.886)	−0.748	(0.622)
2011	1.789	(3.236)	1.897	(2.038)	−1.832	(1.155)	−1.971*	(0.790)
2012	0.586	(4.121)	−0.380	(2.347)	−1.472	(1.463)	−1.620	(0.918)
GDP per capita (1000s)	−0.229	(0.798)	−0.681**	(0.252)	−0.104	(0.290)	−0.334**	(0.106)
Tertiary education	1.480**	(0.496)	1.732***	(0.383)	0.059	(0.183)	0.341*	(0.148)
Population density	0.031	(0.037)	−0.006*	(0.003)	0.002	(0.013)	−0.001	(0.001)
Population over 74	−6.056*	(2.994)	−3.255*	(1.346)	−0.922	(1.049)	−0.748	(0.550)
Life expectancy	5.341*	(2.531)	2.309	(1.776)	1.410	(0.895)	0.699	(0.696)
Number of implanting centres	0.212	(0.147)	0.017	(0.040)	−0.079	(0.051)	0.021	(0.017)
_cons	−346.449	(206.178)	−147.739	(137.350)	−76.508	(72.847)	−30.135	(54.654)
N	231		231		221		221	
r2_within	0.267		0.245		0.192		0.160	
r2_between	0.044		0.671		0.023		0.501	
r2_overall	0.048		0.642		0.012		0.470	
Rho (ICC)[a]	0.982		0.784		0.951		0.853	

FE, fixed effect; PM, pacemaker; RE, random effect; GDP, gross domestic product.
Standard errors are in parentheses.
[a] Intraclass correlation.
*$p < 0.05$;
**$p < 0.01$;
***$p < 0.001$.

Table AII. Determinants of diffusion of ICDs across 57 EU regions 2008–2012 (first implants and replacements)

	FE		RE		FE		RE	
	ICD first implants		ICD first implants		ICD replacements		ICD replacements	
Slovenia (dummy)			0.000	(.)			0.000	(.)
England			1.259	(4.863)			3.387*	(1.494)
Germany			26.297***	(4.933)			6.444***	(1.518)
Italy			26.405***	(6.118)			4.304*	(1.940)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	0.363	(1.056)	0.590	(0.734)	2.045***	(0.388)	1.324***	(0.253)
2010	0.914	(1.242)	2.760**	(0.879)	3.289***	(0.457)	2.678***	(0.298)
2011	0.600	(1.626)	4.115***	(1.091)	3.911***	(0.598)	3.291***	(0.364)
2012	−1.387	(2.070)	4.214***	(1.255)	4.460***	(0.761)	3.825***	(0.414)
GDP per capita (1000s)	0.130	(0.401)	−0.224	(0.134)	0.288	(0.147)	−0.052	(0.042)
Tertiary education	0.584*	(0.249)	0.750***	(0.205)	−0.270**	(0.092)	−0.044	(0.069)
Population density	0.018	(0.018)	−0.001	(0.002)	0.007	(0.007)	0.001	(0.000)
Population over 74	6.559***	(1.504)	0.666	(0.718)	0.423	(0.553)	0.326	(0.227)
Life expectancy	−1.267	(1.272)	−2.164*	(0.950)	0.025	(0.468)	0.020	(0.313)
Number of implanting centres	−0.080	(0.074)	0.016	(0.021)	0.008	(0.027)	0.011	(0.007)
_cons	44.013	(103.573)	160.774*	(73.448)	−7.671	(38.089)	−2.654	(24.135)
N	231		231		231		231	
r2_within	0.438		0.344		0.726		0.706	
r2_between	0.004		0.739		0.003		0.566	
r2_overall	0.001		0.693		0.019		0.600	
Rho (ICC)[a]	0.983		0.780		0.982		0.724	

FE, fixed effect, ICDs, implantable cardioverter defibrillators; RE, random effect; GDP, gross domestic product.
Standard errors are in parentheses.
[a] Intraclass correlation.
*$p < 0.05$;
**$p < 0.01$;
***$p < 0.001$.

Table AIII. Determinants of diffusion of cardiac resynchronization therapies (CRT-P) across 57 EU regions 2008–2012 (CRT-P)

	FE		RE		FE		RE	
	CRT-P first implants		CRT-P first implants		CRT-P replacements		CRT-P replacements	
England (dummy)			0.000	(.)				
Germany			−2.461***	(0.499)			0.000	(.)
Italy			−1.133	(0.910)			0.648	(0.519)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	0.266	(0.263)	0.166	(0.169)	−0.067	(0.161)	−0.023	(0.115)
2010	0.785*	(0.306)	0.705***	(0.192)	0.235	(0.179)	0.192	(0.127)
2011	0.968*	(0.392)	0.874***	(0.226)	0.367	(0.226)	0.257	(0.148)
2012	1.110*	(0.490)	0.928***	(0.252)	0.510	(0.281)	0.331*	(0.165)
GDP per capita (1000s)	0.088	(0.093)	0.040	(0.022)	−0.037	(0.058)	0.020	(0.015)
Tertiary education	0.080	(0.066)	0.097*	(0.042)	0.080	(0.052)	0.010	(0.032)
Population density	−0.005	(0.004)	−0.000	(0.000)	−0.001	(0.003)	−0.000	(0.000)
Population over 74	−0.362	(0.332)	−0.065	(0.118)	−0.413	(0.209)	−0.052	(0.079)
Life expectancy	0.058	(0.286)	−0.174	(0.172)	0.043	(0.189)	−0.020	(0.126)
Number of implanting centres	0.010	(0.016)	0.000	(0.003)	−0.002	(0.010)	−0.002	(0.002)
_cons	−2.188	(23.099)	14.519	(13.308)	0.970	(15.044)	1.719	(9.784)
N	199		199		160		160	
r2_within	0.372		0.359		0.229		0.181	
r2_between	0.005		0.668		0.053		0.238	
r2_overall	0.000		0.610		0.026		0.232	
Rho (ICC)[a]	0.982		0.698		0.931		0.754	

FE, fixed effect, RE, random effect, GDP, gross domestic product.
Standard errors are in parentheses.
[a] Intraclass correlation.
$*p < 0.05$;
$**p < 0.01$;
$***p < 0.001$.

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Table AIV. Determinants of diffusion of cardiac resynchronization therapies across 57 EU regions 2008–2012 (CRT-D)

	FE		RE		FE		RE	
	CRT-D first implants		CRT-D first implants		CRT-D replacements		CRT-D replacements	
England (dummy)			0.000	(.)				
Germany			8.568***	(1.477)			0.000	(.)
Italy			2.617	(2.615)			−1.554	(1.189)
2008 (dummy)	0.000	(.)	0.000	(.)	0.000	(.)	0.000	(.)
2009	0.483	(0.658)	1.108*	(0.456)	0.323	(0.399)	0.231	(0.276)
2010	2.244**	(0.774)	3.420***	(0.526)	1.404**	(0.443)	1.193***	(0.304)
2011	2.394*	(0.993)	4.197***	(0.627)	2.041***	(0.559)	1.682***	(0.352)
2012	1.571	(1.241)	4.192***	(0.704)	2.699***	(0.696)	2.205***	(0.389)
GDP per capita (1000s)	−0.307	(0.231)	−0.131*	(0.066)	−0.158	(0.136)	−0.037	(0.034)
Tertiary education	−0.013	(0.167)	0.140	(0.118)	−0.146	(0.121)	−0.031	(0.072)
Population density	0.011	(0.010)	0.000	(0.001)	0.006	(0.007)	0.000	(0.000)
Population over 74	2.863***	(0.836)	0.405	(0.348)	−0.133	(0.505)	0.124	(0.179)
Life expectancy	1.159	(0.723)	0.341	(0.490)	0.646	(0.467)	0.389	(0.295)
Number of implanting centres	0.005	(0.041)	0.002	(0.010)	0.037	(0.024)	0.002	(0.005)
_cons	−110.857	(58.304)	−30.202	(37.967)	−46.149	(37.114)	−28.759	(22.931)
N	200		200		164		164	
r2_within	0.697		0.671		0.646		0.625	
r2_between	0.002		0.611		0.022		0.028	
r2_overall	0.001		0.632		0.000		0.312	
Rho (ICC)[a]	0.976		0.759		0.962		0.708	

FE, fixed effect; RE, random effect; GDP, gross domestic product.
Standard errors are in parentheses.
[a] Intraclass correlation.
*$p < 0.05$;
**$p < 0.01$;
***$p < 0.001$.

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