MedtecHTA

Methods for Health Technology Assessment of Medical Devices: a European Perspective

The diffusion of cardiac implantable electrical devices in Europe: what drives the differences?

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Background and rationale

- A steady increase in cardiac implantable electrical devices (CIEDs) has occurred 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 to investigate access to CIEDs across countries.

- Available evidence shows that there is a significant heterogeneity in implant rates of CIEDs across and between countries

- While differences in guideline recommendations, budget constraints and professional expertise are assumed to influence access, few studies have empirically investigated the factors that influence implant rates CIEDs in Europe.

- Available studies relied on **sample data or registries** with different coverage rates and measurement protocols, making comparisons difficult.

- No studies to date have used *individual patient data with national coverage* to investigate differences in utilization rates of CIEDs

Objectives

- To investigate the implant rates of implantable cardiac devices in Europe and generate evidence on geographical variation and its determinants.

- More specifically, study aims to:

  1. produce evidence about differences in access to medical devices in electrophysiology (e.g. pacemakers and ICDs) between and within European member states using national datasets available in 5 countries;

  2. investigate the determinants of differences in access to CIEDs

  3. assess the potential and limitations of administrative databases for the analysis of rates of utilization of medical devices in electrophysiology.

Methods

- The analysis focused on medical devices widely used in Europe and for which solid scientific evidence of efficacy was available - pacemakers and implantable defibrillators - highlighting within these categories the three subtypes of device:

- **Pacemakers (PM)**

  - Single chamber – *1 lead in upper or lower chamber*

  - Dual chamber – *2 leads; 1 for atrium and 1 for ventricle*

  - Biventricular (Cardiac resynchronization therapy, CRT-P) - *3-lead system, for the atrium, right ventricle and left ventricle.*

- **Implantable cardioverter defibrillators (ICDs)**

  - Single/Ventricular chamber (monocameral) - *1-lead (wire) system for ventricle*

  - Dual chamber (bicameral)- *2-lead (wire) system: 1 for atria and 1 for right ventricle*

  - Biventricular (Cardiac resynchronization therapy, CRT-D)- *3-lead system, for the atrium, right ventricle and left ventricle.*
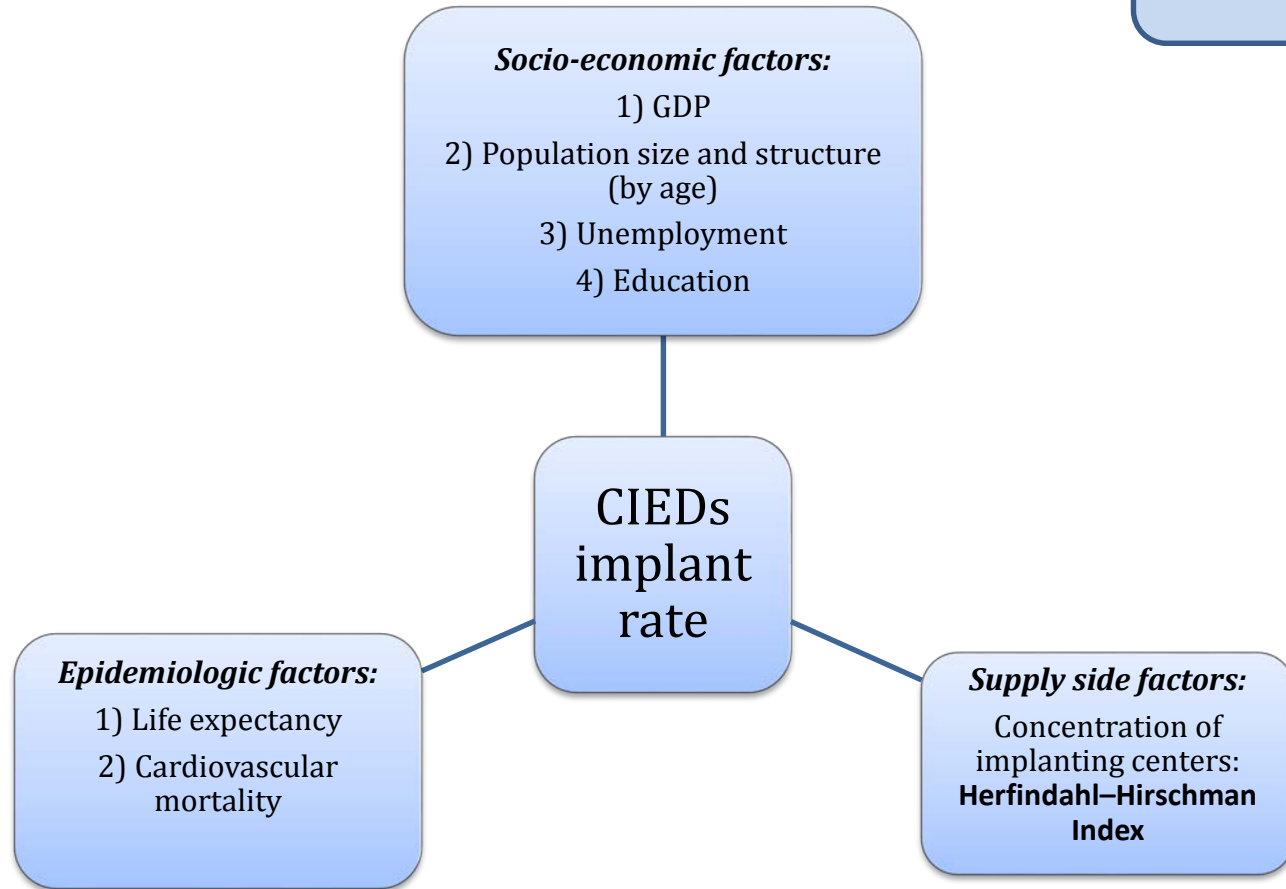
Study sample: 5 EU countries ; 57 regions

1. England (9)
2. Germany (16)
3. Austria (9)
4. Slovenia (2)
5. Italy (21)

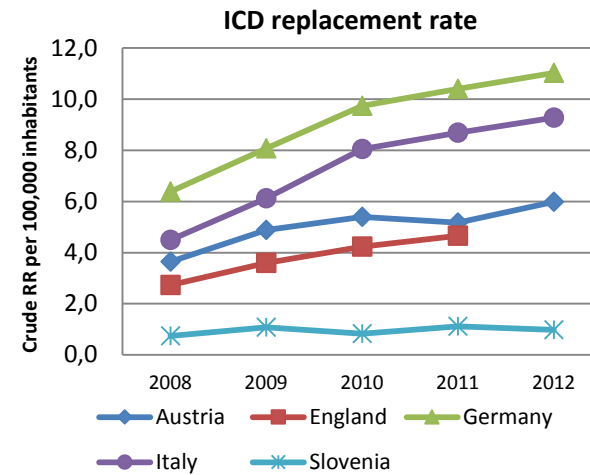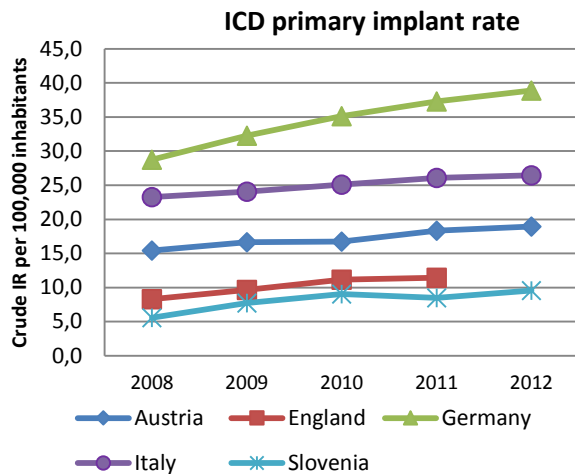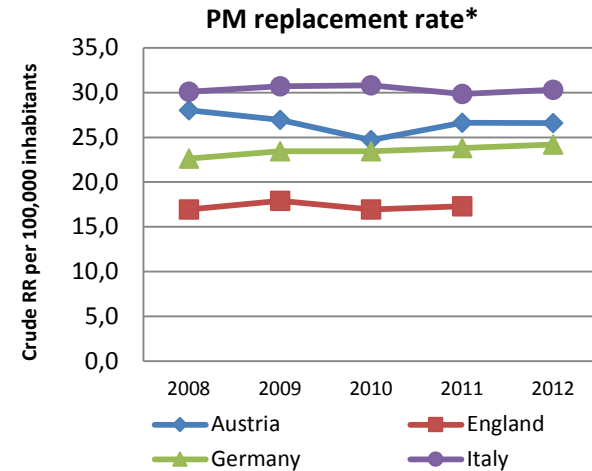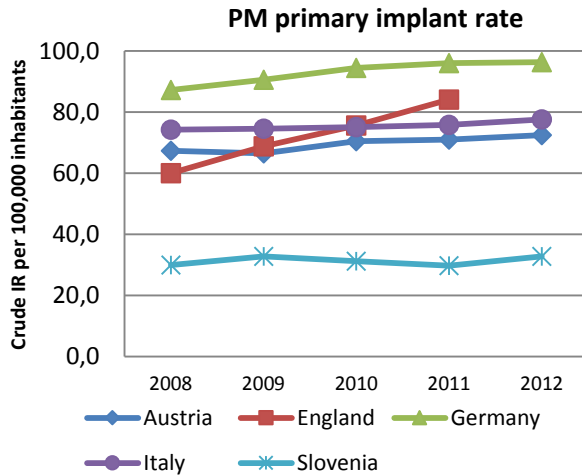# Data source: Hospital Discharge Databases in 5 countries

	ITALY	ENGLAND	GERMANY	SLOVENIA	AUSTRIA
Name	Scheda Dimissione Ospedaliera-(SDO)	Hospital Episode Statistics (HES)	National hospital discharge DB	National hospital database	National hospital database
Coverage	National	National	National	National	National
Available years	Since 2000; 2008-2012 (full set)	Since 1990	Since 2007	Since 2004	Since 1989 (ICD-10 since 2001)
Coding system for diagnoses	ICD-9-CM	ICD-10	ICD-10	ICD-10-AM	ICD-10
Coding system for procedures	**ICD-9-CM**	**Operating Procedure Codes (OPCS)**	**Operating Procedure Codes (OPCS)**	**ICD-10- ACHI (Australian Classification of Health Interventions)**	**Country-specific classification**

Data analysis (regional level)

Socio-economic factors:
1) GDP
2) Population size and structure (by age)
3) Unemployment
4) Education

CIEDs implant rate

Epidemiologic factors:
1) Life expectancy
2) Cardiovascular mortality

Supply side factors:
Concentration of implanting centers: **Herfindahl–Hirschman Index**

Crude primary implant rates (PIR) and crude replacement rates (RR) for pacemakers and ICDs, by country

*There are no codes for PM replacements in Slovenia.

Implant and replacement rates adjusted for age and sex

Crude versus adjusted (for age and sex) primary implant rates (IR) and replacement rates (RR) for PMs and ICDs overall and for the subset of BV/CRT PMs and ICDs combined, 2008-2012 .
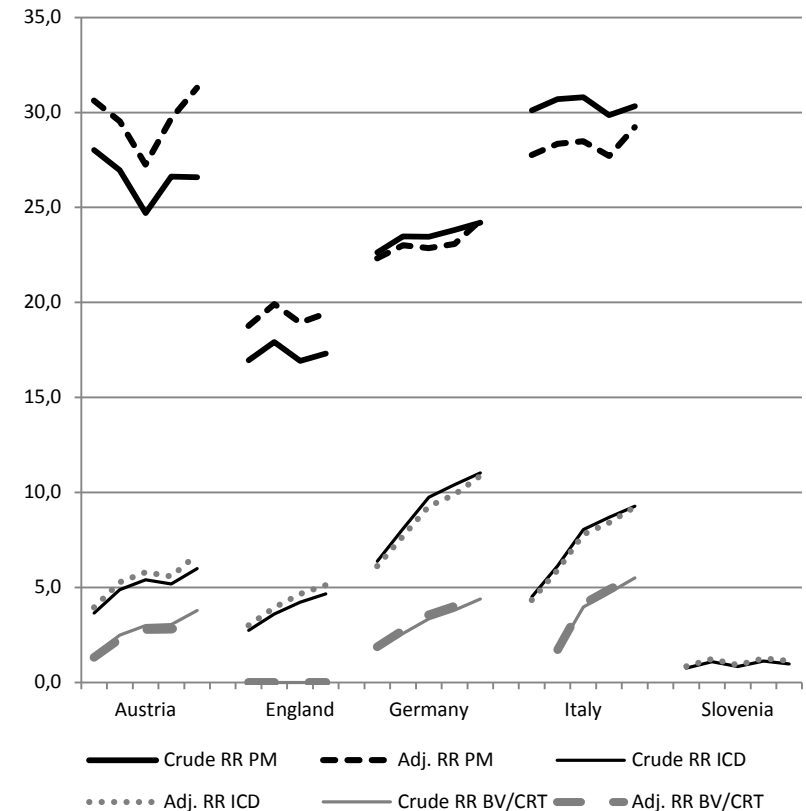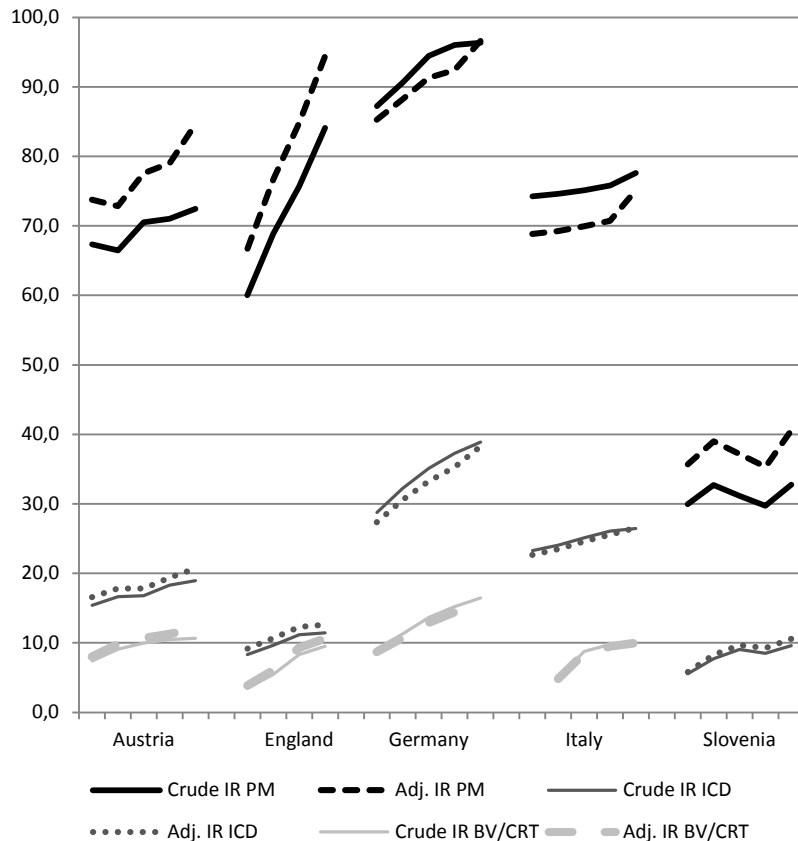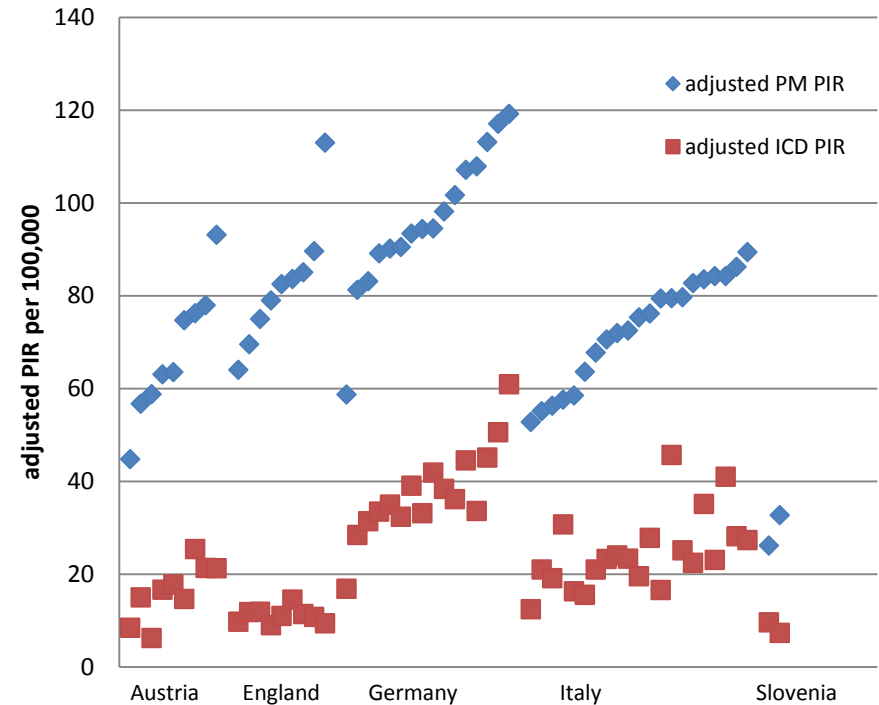
Within country variation

2011 Crude regional primary implant rates (PIRs) per 100,000 inhabitants - Pacemakers and ICDs
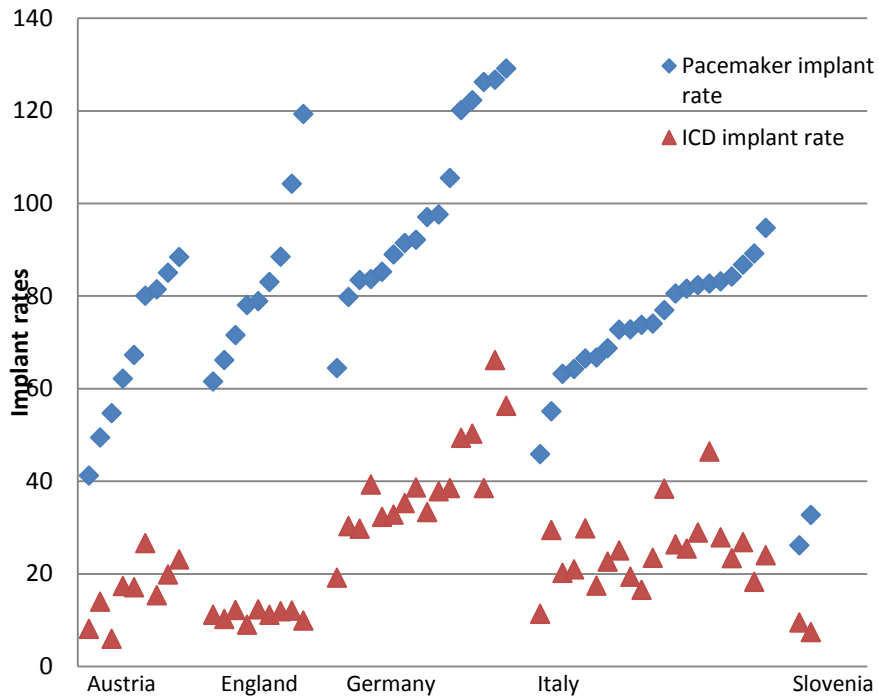
2011 Regional adjusted primary implant rates (PIR) per 100,000 inhabitants - Pacemakers and ICDs

Results of regression models

	Pacemakers		ICDs	
	FIRST IMPLANTS	*REPLACEMENTS*	*FIRST IMPLANTS*	*REPLACEMENTS*
Regional GDP per capita	0.305	0.399*	0.290*	-0.066
Unemployment rate	1.310	-0.115	-0.522	0.112
% Regional population with high education	1.592***	-0.157	0.307**	0.259***
Population Density	-0.009*	0.001	0.003	0.001
Life expectancy at birth	-4.027*	1.518	-4.580***	-0.990*
Regional population over 75	7.952***	0.974*	6.448***	3.028***
Herfindahl–Hirschman Index	-9.608	-13.601***	-12.058*	0.910
N	*192*	*192*	*192*	*192*
r2 within	*0.319*	*0.014*	*0.521*	*0.660*
r2 between	*0.437*	*0.560*	*0.183*	*0.162*
r2 overall	*0.427*	*0.541*	*0.196*	*0.191*

Discussion

❖ Disparities in sudden cardiac death prevention and heart failure treatments within and across countries are a major health care concern and should be the object of dedicated health policy programs targeted to improve equity of access.

❖ This **is the first study** to use *national, hospital discharge datasets* across countries to investigate variation in utilisation rates of cardiovascular medical devices. Overall, the methodology employed here is innovative in the use of cross-referencing of codes and hospital discharge databases

❖ Regional per capita GDP appears to have small, but significant effect on access to implantable cardiovascular devices (probably due to low variation); regions with greater % of residents with higher level of tertiary education, an aged population, and life expectancy all generally influence implant rates of PMs and ICDs. Increased competition (higher numbers of implanting centers in each region) foster access to technologies.

❖ The model, however, explains *only one part of the story*: after controlling for clinical, epidemiologic and (crude) economic indicators, significant variation in implant rates still persists. To get the full picture we need to look closer at the levels of organisations and clinicians adopting the devices.