

## ICD Implantation Practice Within Europe: How To Explain The Differences Beyond Economy?

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### Abstract

Implantable cardioverter defibrillators (ICD) offer the potential to prevent sudden cardiac death and demonstrated a survival benefit in high risk cardiac patients. ICD implantation rates vary significantly throughout the countries all over Europe although there are no major differences in cardiovascular morbidity among countries. ICD implantation rates in each European country may be influenced by economic factors, including the gross domestic product, its percentage devoted to public health, and organization of the health system. However, ICD implantation rates vary substantially also among countries with a high gross domestic product. Beyond economy, other important factors that may influence ICD implantation rates are lack of guidelines awareness and poor guidelines adherence especially when treating specific subgroup of patients (such as elderly and those with non ischemic cardiomyopathies).

### Introduction

Implantable cardioverter defibrillators (ICDs) have been associated with an improvement in survival due to a reduction in sudden cardiac death (SCD) rate in selected patients.<sup>1</sup> In the early years of their development there have been great skepticism and opposition and nearly 4 decades have been needed for their current acceptance in various clinical settings. Randomized multicentre clinical trials in primary prevention (MADIT,<sup>2</sup> MUSTT,<sup>3</sup> MADIT 2,<sup>4</sup> and SCD-HeFT<sup>5</sup>) and in secondary prevention (AVID,<sup>6</sup> CIDS,<sup>7</sup> and CASH<sup>8</sup>) patients have demonstrated high efficacy in terminating potentially life-threatening arrhythmias. The evidence favoring ICD therapy, coming from accumulated clinical experience, has moved the medical community to recognize the role of this device for prevention of SCD in at-risk patients. Current guidelines now recommend ICD implantation in patients at high risk of SCD with either ischemic or non-ischemic heart diseases, both for primary and secondary prevention,<sup>1,9,10</sup> and most of the European countries officially adopted the 'global' guidelines, or developed their own national guidelines (Figures 1-3).

Cost-effectiveness of this therapy has already been evaluated in the American health-care system,<sup>11-13</sup> but information about the

### Key Words:

Sudden Cardiac Death, Implantable Cardioverter Defibrillators, Primary Prevention, Secondary Prevention, Arrhythmic Death.

### Disclosures:

None.

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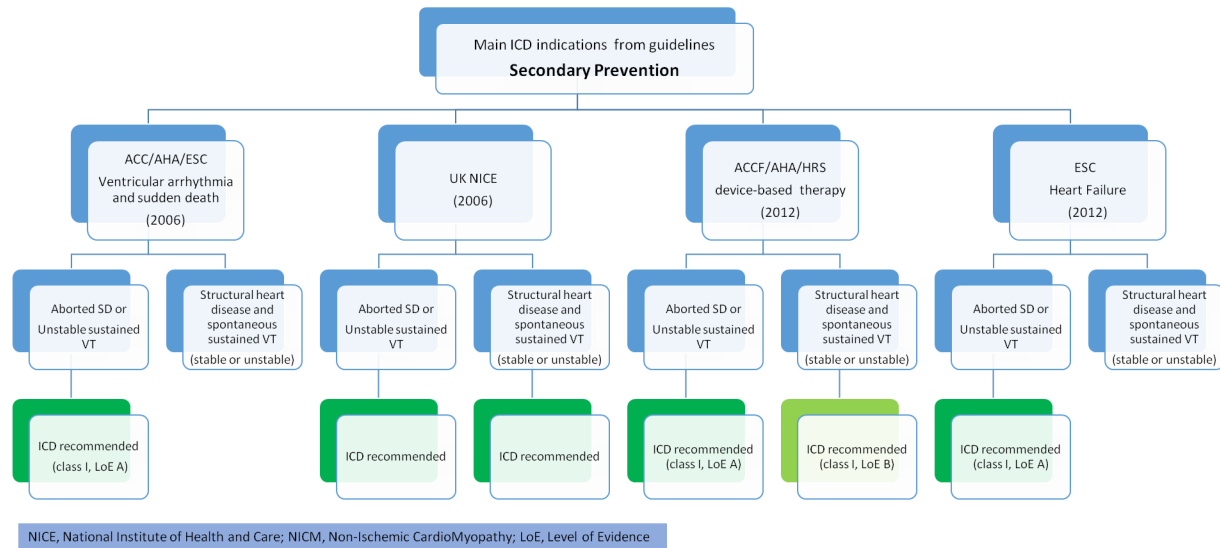
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costs and benefits of prophylactic ICD implantation in Europe were lacking until a few years ago. Cowie et al.<sup>14</sup> first showed that cost-effectiveness of ICD implantation is influenced most by device efficacy, time to replacement, utility, and age at implantation; the authors concluded that in European healthcare setting, prophylactic ICD implantation may be cost-effective when current guidelines are followed.

Despite a substantial increase in ICDs implantations and updates of guidelines for cardiac implantable electronic device (CIED) implantation and management, there are still limited data on how these indications are applied in clinical practice across Europe. It is noteworthy that ICD implantation rates vary significantly throughout European countries<sup>15</sup> (Figure 4) although among them no major differences in cardiovascular morbidity are observed.<sup>16</sup>

### Economic Restrictions

ICD implantation rates in European countries may be influenced by economic factors, including the gross domestic product, its percentage devoted to health system, and organization of the health system. The recent economic crisis led to substantial healthcare budget cuts in the majority of European countries. At the same time, the elderly population, needing considerable medical and social assistance, is rapidly growing. Given these huge economical imbalances, it is not surprising that ICDs implantation rates vary significantly across different countries and that there is a trend towards higher ICD implantation rates with increasing gross domestic product (Figure 4). Sometimes physicians are forced by administrators to decide when and in which patients to implant an expensive ICD. While the choice for patients in secondary prevention of SCD is mandatory, the clinical opinion could advise or discourage an ICD implantation for primary prevention despite guideline recommendations.<sup>17</sup> National



**Figure 1: Main indications for ICD implantation for secondary prevention according to European, American and British guidelines**

data on health expenditures and CIED implantation rates indicate that a reduced healthcare investment is associated with lower use of device therapy, and lack of refund for the procedure further contributes. Moreover, the number of hospitals and beds are not directly related to financial profile or healthcare funding of a given country, and sometimes infrastructures are insufficient to assure ICD implantation to all patients fulfilling guidelines criteria.<sup>15</sup> In previous years, as reported in the European Heart Rhythm Association (EHRA) White Book that provides information about the status of cardiac electrophysiology, demographic, economic, and healthcare data,<sup>18</sup> the mean CIED implantation rates were twice higher in Western Europe than in all other regions, and lowest rates were found in Eastern Europe and in non-European countries of the European Society of Cardiology. However, gross domestic product and other economic factors alone do not entirely explain the differences among countries. Some countries with similar economic status significantly differ for ICD implantation rates: for example, the UK has much lower implantation rates than Italy or France while Poland and Czech Republic are well above average (Figure 4).

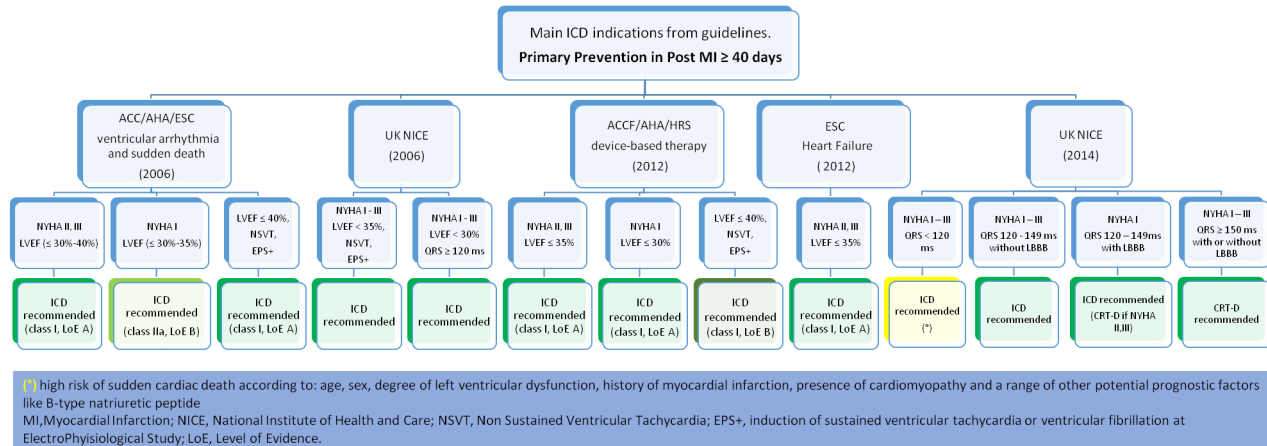
**Guidelines Awareness**

Another important factor that may limit ICD implantation beyond

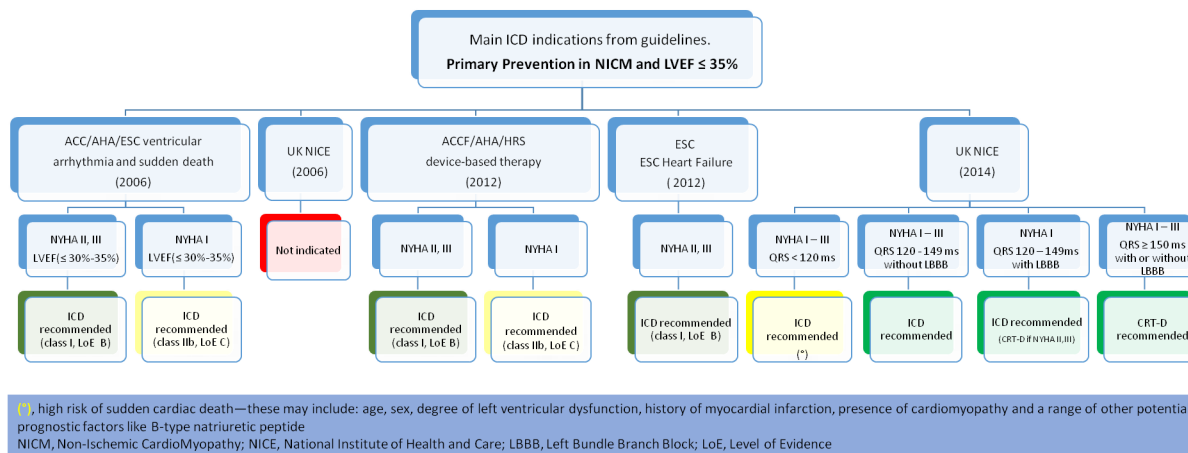
economic restrictions is poor guidelines knowledge. This issue seems to be particularly important among general cardiologists and general practitioners, i.e. those who should refer their patients to implanting physicians. In 2008–2009, Sherazi et al.<sup>19</sup> conducted a survey of United Kingdom (UK) primary care physicians and cardiologists regarding knowledge and attitudes towards ICD therapy. They found that a significant minority of physicians, particularly primary care physicians, were unaware of the ICD clinical guidelines and that more than 25% were unsure about benefits of ICDs in women and blacks. Another UK survey<sup>17</sup> showed that complete awareness of ICD indications was present in only 45% of responders and that cardiologists that do not perform implantations have significantly lower guidelines knowledge than implanters. These findings are in agreement with USA and New Zealand data showing that a substantial number of physicians fail to refer their patients for ICD implantation even if they fulfill the guidelines.<sup>20,21</sup>

**Guidelines Adherence**

Guidelines knowledge does not necessarily mean that they are followed, especially in primary prevention patients. Current ICD guidelines do not identify a clear “age limit”, and exclude any implant indications only in patients with severe co-morbidities and expected



**Figure 2: Main indications for ICD implantation for primary prevention in ischemic cardiac disease according to European, American and British guidelines**



**Figure 3: Main indications for ICD implantation for secondary prevention in non-ischemic dilated cardiomyopathy according to European, American and British guidelines**

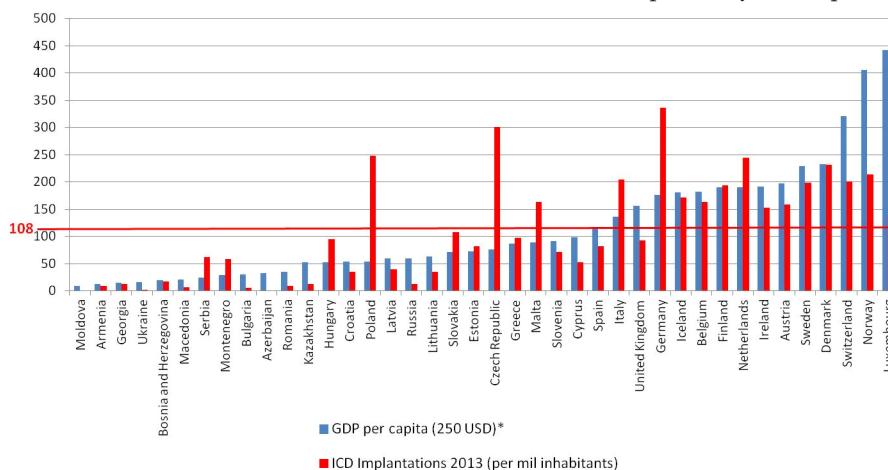
survival of less than one year; moreover, they essentially consider only NYHA class and left ventricular ejection fraction (EF) to identify ICD candidates. However, daily clinical experience often suggests a different, more selective, approach. For example, the low predictive power of EF is well documented: depending on the presence of other risk factors, the mortality and sudden risk of death of some patients with EF from 30 to 40% may exceed those of patients with EF ≤ 30%.<sup>22</sup> As a consequence, many cardiologists use additional tools to stratify the arrhythmic risk of potential ICD candidates. On the other hand, attitudes towards implantation of elderly patients and of those with non-ischemic cardiomyopathy may be low as the scientific evidence for a net survival benefit is less strong in these populations.

An Italian study conducted in 2008-2009 among 220 cardiology departments showed that, in more than 90% of cases, patients fulfilling guidelines indication are considered for ICD implantation. However, in only 18% of centers an ICD was implanted in all patients with non-ischemic dilated cardiomyopathy and ejection fraction of 35% or less, and only 51% of centers answered that all patients with ischemic dilated cardiac disease and ejection fraction of 30% or less should have had an ICD. The majority of centers admitted to routinely use adjunctive risk stratification markers (wide QRS, heart rate variability, ventricular tachycardia inducibility,

presence of non-sustained ventricular tachycardia on 24-hour Holter monitoring) to decide whether to implant an ICD, although these markers have limited prognostic value. In addition, 34% of Italian cardiology departments reported that age ≥ 80 years was deemed as a contraindication to ICD.<sup>23</sup> According to a UK survey, patients age, presence of co-morbidities and impact of ICD on quality of life were important factors that affected the physician's decision to refer patients for ICD implantation.<sup>19</sup> Another UK study found that more than one quarter of those who were aware of guidelines chose an approach that was not guideline-recommended.<sup>17</sup>

**2006 NICE Guidelines**

Despite a gross domestic product above average, ICD implantation rate in the UK is below average and lower than countries such as Italy and Germany (Figure 4). It is of note that, unlike North American and European Guidelines, 2006 UK National Institute of Health and Care (NICE) guidelines considered ICD implantation for primary prevention only in patients with ischemic heart disease and restricted the application of MADIT II criteria to patients with a wide QRS.<sup>24</sup> Only recently those guidelines were amended to include also non-ischemic cardiomyopathy patients and those with narrow QRS (Figures 2 and 3). Together with other factors, NICE guidelines may contribute to explain why UK implantation rates are lower than other



**Figure 4: Gross domestic product (GDP) pro capite and rate of ICD implantation per million of inhabitants among European countries. Countries are ordered according to increasing GDP. The mean rate of ICD implantation, corresponding to 108/million inhabitants, is indicated with a red line. Data from.<sup>15,18</sup>**

Western European countries.

## Conclusion

Economic restrictions can only partially justify the differences in ICD implantation rates across Europe. Other influential factors may be poor guidelines awareness, especially among referring cardiologists and general practitioners, and different guidelines adherence due to lack of strong evidence of a net clinical benefit, especially in specific subgroup of patients (such as the elderly and those with non ischemic cardiomyopathies). With this in mind, implanting physicians should make any effort to promote guidelines knowledge among their colleagues and offer shared management of more complex cases.

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