Barriers to implementation of evidence-based electrical therapies and the need for outcome research: role of European registries

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Although clinical trial results and the implementation of current guidelines appear to have encouraged progress in the treatment of arrhythmias, great discrepancies still exist between European Society of Cardiology (ESC) member countries. Guidelines are not adhered to for a variety of reasons. This cannot be explained only by economic factors, although these obviously play a substantial role. Other factors responsible for adequate guideline implementation appear to be the lack of trained personnel, the lack of infrastructure, or different health insurance systems. In this complex scenario, the data based on European registries are useful for creating standards and harmonizing the treatment of arrhythmias. Moreover, a summary of registry data, such as presented in the European Heart Rhythm Association (EHRA) White Book, can provide the opportunity to share and exchange information among ESC member countries on specific needs for improvements, reimbursement policy, and training issues.

Keywords
Registries • Guidelines • Implantable cardioverter defibrillator • Cardiac resynchronization therapy • Geographic variations

The cornerstone of progress in medicine is continuous research and studies leading to scientific evidence for or against any type of treatment. Results from large randomized trials and experience from large observations result in medical treatment guidelines that are supposed to be followed by everyone, especially when they are based on strong evidence and broad consensus. Whenever we have guidelines at hand, we tend to prescribe the given treatment or perform the recommended diagnostic measure.

Guidelines are not adhered to for a variety of reasons. There is more to it than money; there is also the lack of trained personnel, the lack of infrastructure, the lack of awareness, language barriers, and different health insurance systems. This is why, even if there are guidelines, many other parameters will decide upon a treatment or measure in an individual patient or patient population.

In the recent past, we have fortunately encountered dramatic progress in technology for the treatment of arrhythmias, be it the introduction of ever smaller implantable defibrillators, resynchronization devices, new ablation technologies, or implantable diagnostic devices.

Their development has been much faster and tangible than any progress in pharmacological treatment, where development of new drugs is tedious, takes many more years and resources and they often do not make it all the way to market introduction.

With the upcoming technologies, we have seen more and more large trials such as SCD-HeFT¹, COMPANION², MADIT II³, DEFINITE⁴, etc., e.g. in the field of primary and secondary prophylaxis of both sudden death and heart failure. These large-volume trials have led to a very rapid change and adaptation of the treatment guidelines.

In the field of catheter ablation and treatment of atrial fibrillation, we have witnessed a promotion of catheter ablation to a class IIa recommendation reaching the same level as drugs.⁵

Most of the guidelines have been produced by either the European Society of Cardiology (ESC) or one of its branches such as European Heart Rhythm Association (EHRA) and/or in cooperation with the Heart Rhythm Society (HRS), American College of Cardiology (ACC), or American Heart Association (AHA). Whenever we publish new guidelines that have undergone a long, strict process or review, we try to spread the message by flyers, pocket guidelines, internet presence, etc., and in large conferences to make everyone aware of the recommended change in practice. The guidelines are then discussed in the scientific community and are adopted or not
in everyday practice. However, we have no real control of what we call penetration or better implementation of guidelines.

The ESC started the EuroHeart survey several years ago, which was a first attempt to screen the use of therapy and diagnostics recommended by the ESC guidelines for a variety of therapies such as treatment of acute coronary syndromes, use of anticoagulants in atrial fibrillation, and others.

Especially in the field of anticoagulant use in atrial fibrillation it became obvious that there is a large gap between guidelines and everyday practice not only among general practitioners but also among specialists. In the field of arrhythmia treatment, the cardiac resynchronisation therapy (CRT) survey, executed by EHRA, followed last year.6

With respect to antiarrhythmic treatment, we have little experience except for some years of registry work in the area of pacemaker implantation. This is why EHRA deemed it to be absolutely necessary, especially due to the growing expansion of the ESC family for which the guidelines are created, to assess the clinical practice, coverage, and access to certain therapeutic options across the ESC hemisphere. One of the first steps was to ask for cooperation from the national societies and working groups in gathering the data on different items, even if the results demonstrated that the guidelines are not or cannot be followed.

In a second step a questionnaire was created and then annually updated, containing questions on training centres, implanting centres, centres of electrophysiological studies, or catheter ablation. It also asked for the number of implantable cardioverter-defibrillator (ICD) or CRT implantations, the number of implanting centres, the number of loop recorder implants, and information on the presence of a quality control system, national guidelines, and subjective interpretation of the obstacles to guideline implementation by the national presidents of each country.

Due to the incredible enthusiasm and dedication of each national society, we were able to collect data from 38 out of 51 countries in the year 2008 and from 39 out of 53 countries in the year 2010, so that we can now also trace the changes in the last 3 years in implant rates and the evolution of implanting and training centres.7,8

The first publication on the use of CRT is already available,9 the other one on the use of ICDs is in press, and we will soon be providing data on catheter ablation and pacemakers.

What became quite clear right from the start of the investigation was that it is not only the gross domestic product (GDP) or reimbursement that decides implant rates or access to therapy, but also other ‘softer’ factors such as the lack of trained personnel, the lack of awareness, and sometimes also seemingly different national opinions or interpretations of the guidelines.

A good example is the difference in the implant rates of ICDs in Italy, Germany, France, and the UK, where the GDP per capita is clearly not the only reason for the vast differences e.g. in ICD implantation rates. The analysis of ICD implantations based on data gathered from the EHRA White Book7,8 revealed significant differences in implantation rates between the countries.
in cardiac electrophysiology had no influence on implantation indices like density of physicians, number of hospitals or beds, and implanting centres per million and ICD implantations per million. A strong positive correlation was observed between the number of CRT implantations per centre varies from 2 to 251, and the median is 43. A mean number of implanted per million population to over 6. The mean number of implantations from the year 2006 and 2008 was about 90%. Some countries, such as Switzerland, Slovakia, or Poland, had increased their implantation rate by 1.5 times.

The analysis of the relationship between ICD implantations per million population in 2008 with economic data revealed significant positive correlations between the number of ICD implantations and GDP ($r = 0.55, P = 0.0006$), GDP per capita ($r = 0.6, P < 0.0001$) (Figure 2), and expenditure on health ($r = 0.58, P = 0.0004$).

The analysis also revealed that the number of ICD implanting centres significantly varies between countries, from lower than 1 per million population to over 6. The mean number of implantations per centre varies from 2 to 251, and the median is 43. A strong positive correlation was observed between the number of implanting centres per million and ICD implantations per million population ($r = 0.67, P < 0.0001$).

Surprisingly, no correlation was found between such healthcare indices like density of physicians, number of hospitals or beds, and ICD implantation rates. In addition, the presence of a subspecialty in cardiac electrophysiology had no influence on implantation rates.

Merkely et al. revealed that, similar to ICD, countries with a higher GDP or healthcare spending per capita generally had a higher number of CRT implantations, but the correlation between these factors and the number of CRT implantations was weak. There was a stronger correlation between per capita CRT implantations and the number of ICD implantations. Multiple regression analysis showed that the number of CRT implantations per capita was significantly affected by local CRT reimbursement ($P < 0.023$), the number of CRT centres per capita ($P < 0.001$), adherence to national guidelines ($P = 0.002$), and adherence to European or US guidelines (negative effect, $P < 0.001$). Accredited electrophysiology subspeciality and healthcare spending per capita were not significant factors ($P = 0.668$ and $P = 0.899$, respectively).

**Conclusion**

The present analysis confirmed that not only economical factors have an influence on implementation of evidence-based electrical therapies across Europe.

Data such as those presented in the EHRA White Book can provide the opportunity to share and exchange information from ESC member countries on specific needs for improvements, reimbursement policy, and training issues. Therefore, data based on European registries can be used to create standards for education and training and offer assistance necessary to harmonize the treatment of arrhythmias.

**Conflict of interest:** none declared.

**Funding**

The EHRA White Book project was made possible by an unrestricted educational grant from BIOTRONIK SE & Co. KG, Germany.

**References**