Aims Recent guidelines have recommended more wide-ranging indications for the use of implantable cardioverter defibrillator (ICD) therapy, yet even more restrained previous guidelines have not been implemented for a variety of reasons.

Methods and results This brief review critically examines the reasons most frequently put forward to explain this failure. Contrary to the frequently repeated speculation that the risk stratification for sudden death and hence prophylactic placement of ICDs is reasonably accurate, there is little cost difference between pharmacotherapy and ICD treatment over the long term. ICD therapy does not utilize an undue proportion of the healthcare budget, and the healthcare systems in Europe can afford this therapy.

Conclusion Financial reasons are neither accurate nor adequate explanations for the failure of the European medical community to implement European guidelines for the implantation of ICDs for primary and secondary prevention of sudden cardiac death.

KEYWORDS
ICD; Sudden death; Health economics; Cost-efficacy

Introduction
Implantable cardioverter defibrillators (ICD) have now been in clinical practice for 25 years.1 Despite great scepticism and opposition in the early years, the sheer weight of irrefutable data from thousands of patients and multiple prospective randomized clinical trials2,3 has proved beyond any doubt that ICD therapy is highly effective in reducing sudden cardiac death and all-cause mortality in patients with a great variety of cardiac pathologies. Faced with ‘evidence-based medicine’, our guidelines have become increasingly clear, and we all now recognize that there are patients for whom there is no other therapeutic choice other than the ICD. Even if there is another choice, it is clear, following multiple trials of ICD treatment compared with drugs, that ICD therapy is often far superior to drugs. However, except in the USA and, to a lesser extent, in Canada or Germany, physicians often seem reluctant to accept and act on the evidence to implant ICDs according to internationally recognized guidelines.

With each new positive ICD trial, it has become increasingly difficult to doubt the scientific/clinical foundation of ICD therapy, so more recently some people have turned their attention to the cost-effectiveness of ICD therapy. These challenges are phrased in a variety of ways: (i) ‘the number needed to treat (NNT) to save one life is too high’; (ii) ‘drug therapy costs significantly less than ICD treatment’; (iii) ‘a disproportionate amount of healthcare resource is spent on sudden cardiac death’; (iv) ‘healthcare systems cannot afford increased ICD usage’. As these are important issues, we have taken the time to examine each of them in an attempt to separate reality from mistaken perception.

’NNT to save one life is too high’
This criticism is expressed in different ways, but clearly points to whether the number of patients receiving an ICD is excessive relative to the number of lives saved by the therapy. The only way to objectively examine this question is to compare the NNT for ICDs with that for other well-accepted medical therapies. Figure 1 shows the NNT for ICDs alongside those for ACE-inhibitors, beta-blockers, and statins, for a variety of populations, as defined by the respective studies.4–11 Clearly, at first sight, many more patients need treatment with these medications to save one life, than with an ICD.

On this important question of NNT, Salukhe et al.12 demonstrated that the NNT ‘...is dramatically dependent on the time window over which the benefit is assessed.’ To cite one example, for patients in the MADIT II trial6, the NNT at 1 year is very large (133 patients), but this apparently unacceptable number decreases to 17 at 2 years of follow-up and to a very reasonable NNT of 8 by the end of 3 years. In AVID,7 the NNT drops from 21 at 1 year of follow-up to just 4.5 at 3 years. Such a result is inevitable if increasing therapeutic benefit is time dependent. It is...
therefore difficult to compare different studies where endpoints and NNT estimates are made at different time periods. There is no easy way to ‘normalize’ such data except by recourse to short-term estimates to allow even short-duration trials to be included in the comparison. However, it is clear that, for a therapy such as ICD, with high up-front costs (pre-implant work-up, device purchase, and implantation), and for which the benefit increases significantly with time, the true cost (and the true NNT) can only be assessed over several years.

'Drug therapy costs significantly less than ICDs'

We will examine this question in two ways: on a ‘cost-per-day-of-use’ basis and total costs to the health system for a year. Figure 2A compares cost-per-day of various cardiovascular and other pharmaceuticals to those for ICDs. The ICD costs include device and implantation, as well as costs for follow-up,13 and the ICD costs assume an ICD lifetime of 6 years. On a per-day basis, ICDs are more expensive than ACE-inhibitors or statins, somewhat more expensive than beta-blockers, and on a par with antibiotics and anti-epileptic drugs14,15; however, they are far less expensive than interferon-beta (for multiple sclerosis), imatinib mesylate (for chronic myelocytic leukaemia), or anti-AIDS drugs.16–18 When comparing the cost of therapies in this way (daily cost), it is important to bear in mind that the device costs, implant costs, device longevity, and patient longevity may all have a major impact when the cost is front-loaded. Thus if ICD therapy keeps the patient alive for a long period, the cost per day of therapy will be relatively low. However, even if the therapy is applied to patients who remain alive for a long period without any benefit from, or even despite, the treatment, a low daily cost of therapy will also be achieved.

Another way to compare the costs of therapy is to estimate the overall costs of the various therapies for an entire year. Figure 2B illustrates such a comparison of 2004 for four major European countries (France, Germany, Italy, UK).15,19–22 Clearly, the amount paid by the health system for these well-accepted cardiovascular drugs far exceeds that expended on ICD therapy. These costs are dependent on the prices set by the manufacturers and the volume of therapy purchased by the healthcare payers and tend to vary year on year depending on the patent lifetime, comparator availability, and so on.

'A disproportionate amount of healthcare resources is spent on sudden cardiac death'

One criticism regarding ICD therapy suggests that more money is spent on addressing the problem of sudden cardiac death than is warranted. This view may be based on the fact that substantial reduction in mortality has been achieved recently by improved primary prophylaxis of underlying cardiac disease and the early and effective management of acute myocardial infarction. However, the residual huge epidemiological problem presented by sudden cardiac death is not always well appreciated. In the USA, the number of sudden cardiac deaths annually (450 000) exceeds the number of patients who die annually from stroke, lung cancer, breast cancer, and AIDS all together.23–26 Although we do not have officially published data from Europe, Europeans and Americans have similar cardiovascular risk profiles, and it is reasonable to expect that the incidences (per million population) or at least the trend should also be very similar.

'The healthcare system cannot afford increased ICD usage'

Probably the most common concern that is expressed by both physicians and hospital administrators concerns whether the health system (or individual hospital budgets) can continue paying for ICDs as their use rapidly increases. In 2004, the total healthcare expenditures for in-patient
interventions in western Europe amounted to 286.7 billion Euros\(^2\) (Figure 3). Of this, total expenditures for ICD therapy (including implantation and follow-up costs) amounted to 0.493 billion Euros,\(^2\) or 0.2% of the total (in-hospital) healthcare costs. As shown by the right-hand figure, even if ICDs were to increase by three-fold (highly unlikely within the next few years, as the current rate of increase in Europe is \(~15\%\) annually), the overall portion of the health system budget would still be only \(~0.5\%\). By comparison it has been estimated recently that \(>1\%\) of the British healthcare budget is spent on the care of patients with atrial fibrillation (AF).\(^{28}\) Similar data exist in France.\(^{29}\) It is clear from these observations that ICD therapy is not currently 'breaking the bank', nor risks to do so in the near future.

To illustrate this in a different way, we have examined the total costs in western Europe for various well-accepted interventions and compared them with the outlay for ICDs (Figure 4). The fact is that ICD expenditures are far smaller than for pacemakers, bypass surgery, or PTCA,\(^{30-35}\) and very small compared with the other expenditures shown on the right, in particular, healthcare inefficiencies and inappropriate therapeutic applications.\(^{36,37}\)
The concerns about the cost of ICD therapy are not unique to Europe—it is a topic of animated discussion at multiple forums in the USA. The Centers for Medicare and Medicaid Services (CMS) recently extended the insurance coverage for ICDs to a much larger population of patients\textsuperscript{38} and openly acknowledged that ‘...this policy may increase the number of Medicare beneficiaries who are eligible for an ICD to more than 500 000—two to three times the number who are currently eligible’.\textsuperscript{39} However, in Europe, no single large healthcare payer (government, government agency such as NICE, or private insurer) has made such a declaration despite the availability of the same published evidence database and cost–efficacy analyses.

Discussion

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In Europe, as we pointed out several years ago,\textsuperscript{40} relatively few ICDs are implanted. Although the implant numbers have increased, they still lag substantially behind those of the USA. In 2004, the number of ICDs (including ICDs combined with cardiac resynchronization pacemakers) per million capita was approximately 100 in western Europe compared with 550 in the USA. In our earlier article, we noted that this difference could not be explained by epidemiological factors and that it was far greater than for other cardiovascular device interventions (pacemakers, PTCA, heart valves). As reasons, we identified scepticism on the part of physicians, lack of professional guidelines, poor education, and inadequacy of professional bodies representing cardiac electrophysiology. Progressively, all of these factors have been addressed, notably the recent...
updating of the European Society of Cardiology heart failure guidelines, which now include ICDs as class I or class IIa recommendations, depending on the indication.4 These new guidelines reflect much new and convincing clinical trial data supporting broader ICD indications,2,4,37 on top of the previous data. It is now clear that most who oppose ICD therapy do so on the grounds of their ‘perceptions’ concerning the expense of such treatment.

The most immediate conclusion from examining the costs for ICD therapy, within the context of overall health costs, is that ICD therapy represents a small, and not a major burden to the health economy. This conclusion is independent of considerations relating to the efficacy of therapy, where we know that ICDs reduce mortality by approximately one-third over and above optimal medical therapy.2,3,6,7,42,43 Indices such as the ‘number needed to treat’ are highly sensitive to the time of follow-up and impact on the assessment of the cost considerations of ICD therapy.2,12,44 Specific to cost considerations, Nanthakumar et al.4 stated, ‘...Not only is ICD therapy nonlinear with regard to cost; ... it is [also] nonlinear with regard to life-years saved ... This exponential growth of benefit suggests that our analysis represents a conservative conclusion of the benefit of a strategy of implanting ICDs for the prevention of death in patients with LV systolic dysfunction.’ Our analysis has also shown that—relative to other well-accepted therapies—the annual costs as well as the ‘cost-effectiveness’ in terms of costs per life-year saved is on par or even more favourable than with these other therapies. Considering that sudden cardiac death claims more lives annually than stroke, AIDS, and cancer, it would appear appropriate—certainly not inappropriate—to allocate our healthcare expenditures accordingly. Following this logic, because ICDs have proved to be the best, and often the only therapeutic option for at-risk patients, our healthcare systems need to accommodate for their expenditures.

We believe that there is another inescapable and important implication of the results we have observed: the already substantial health budgets in developed western European economies do not need to be increased much in order to accommodate appropriate ICD therapy, as ICDs today make up only a small portion of these budgets, and even with the necessary increase in use, will still not greatly impact the overall health expenditures. However, the need to better allocate already available health expenditures is essential. Although we cannot minimize the difficulties in reaching agreement on changes in budget allocation, the necessity of making available the funds needed for the provision of proven life-saving therapy is obvious. It is well known that there is a great deal of money tied up in healthcare system inefficiencies and inappropriate therapies, that freeing up just part of these wasted resources would easily provide the funds needed to allow proper implementation of ICD therapy.2,6,7

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