

Title	The Implantable Cardioverter Defibrillator:
	A Health Technology Assessment
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# Aim

To study the use of the implantable cardiac defibrillator (ICD) in primary prevention of sudden cardiac death (SCD) in patients with ischemic or nonischemic cardiomyopathy. (Devices incorporating cardiac resynchronization therapy were not considered.)

## Conclusions and results

Clinical evidence for implanting an ICD for primary prevention of SCD is robust in only a small share of high-risk patients, ie, patients with ischemic heart disease and severely depressed left ventricular function with symptomatic heart failure, not worse than NYHA class III. Most patients with an ICD implant never receive an appropriate shock from the device, stressing the need for better preimplant risk stratification. Our economic study, provides a 95% CI for the base-case ICER of EUR 40 600 to EUR 136 000 per QALY and indicates that ICD use in primary prevention of SCD is an inefficient therapy. From our model and a predicted 2000 new ICD patients annually, we conclude that after a stabilization period of 15 years after extending ICD reimbursement to primary prevention, the projected net cost to the health authorities would be extremely high (EUR 154 000 000 per year).

### Recommendations

- 1. Further extension of reimbursement for ICDs in primary prevention of SCD would expand a technology toward an indication with an average ICER of EUR 72 000 per QALY.
- 2. No evidence shows that ICDs incur more benefit than harm in the very elderly. It is unclear how to implement this into reimbursement criteria and whether an age criterion would be acceptable.
- 3. ICD longevity is a major determinant to cost effectiveness of ICD therapy, and increasing battery capacity would improve efficiency. ICD longevity should exceed a patient's life, obviating device replacement. Manufacturers should be encouraged to increase

device longevity by imposing a longer device warranty period (5 or more years, or lifetime).

4. The Belgian reimbursement procedures and limiting the number of implant centers have prevented unrestrained growth in ICD implants. This should continue to optimize the concentration of expertise and prevent an inappropriate increase in ICD implants.

## Methods

Electronic databases were searched for RCTs, systematic reviews and HTAs with the following general limits: English language, from July 1, 2003 to January 8, 2007, humans. We searched MEDLINE (PubMed), EMBASE, Econlit, Cochrane Library, NHS CRD Database (DARE, NHS EED, HTA). Reference lists of retrieved papers were hand searched. Expert slide presentations were consulted online from tctmd.com. ICD manufacturers were contacted.

A cost-effectiveness analysis was performed from the perspective of the Belgian health insurance system. Only the direct costs of medical care are included, excluding patients' out-of pocket payments. Indirect productivity costs were ignored.

# Further research/reviews required

Given the increasing use of device therapy in patients with heart failure, the clinical effectiveness and efficiency of cardiac resynchronization therapy (CRT) in these patients and the incremental benefit of combined CRT plus ICD devices need to be critically evaluated.