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Title **Remote Monitoring for Patients With Implanted Defibrillator. Technology Evaluation and Broader Regulatory Framework**

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Aim

To describe the technology of remote monitoring systems specifically for implantable cardioverter defibrillators (ICDs); to systematically review the evidence on clinical and cost effectiveness; and to study broader organizational, reimbursement, and legal aspects of emerging technologies in remote monitoring.

Conclusions and results

Scant evidence is available on direct patient benefits, although the partial replacement of in-clinic follow-up by remote monitoring seems reasonably safe in ICD patients with no, or mild, symptoms. Legal and organizational hurdles hamper the integration of remote cardiac monitoring.

Recommendations

- Specific legal guidance for interpreting and applying relevant legislation should be developed. To prevent defensive practices, detailed clinical guidelines should address how to deal with this emerging technology. - In the absence of proven safety, effectiveness, and cost effectiveness, conditional reimbursement of remote monitoring could be considered once there are sufficient indications of efficacy and safety.

Methods

Technology: Conversations with physicians and staff of implanting centers; the involved ICD manufacturers; peer-reviewed overview literature and a recent NHS report.

Clinical effectiveness and safety: Systematic reviews and horizon scanning reports for 2006 to 2010 through the CRD databases and the Cochrane Library; websites of INAHTA member organizations; incremental search to identify additional clinical trials and studies; EUnetHTA Joint Action database; INAHTA 'List Serv' network; and US registration site of clinical trials.

Economic literature review: MEDLINE, Econlit, Psychinfo, EMBASE, the NHS Economic Evaluation Database (NHS EED), the Health Technology Assessment (HTA) database, the Cochrane Database of Systematic Reviews, the Cochrane Central Register of Controlled Trials and the Database of Abstracts of Reviews of Effects (DARE) performed in July 2009 and updated in June 2010. Legal aspects: Standard European legal databases; records of the European Court of Justice; Juridat and Jura databases and the national websites of the courts.

Organizational aspects: Scientific and grey literature and contacts with ICD manufacturers.

Further research/reviews required

If the large ongoing trials would offer indications of relevant patient benefits or efficiency gains, a conditional reimbursement scheme might be considered with limited access and evidence collection on safety, quality of life, and health outcomes. This should allow for further exploration to what extent follow-up visits can be effectively and safely reduced for those patients.

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