

Using DECIDE for coverage decision making in the real world: the experience of the Modena Local Health Service Trust

The role of medical devices in health care is crucial. Many of them are highly innovative and the regulatory system for the placing on the market is much less regulated than for drugs. These two characteristics of medical devices are the basis of the particular challenges in coverage decision.

In November 2013, the Chief Executive of Modena Local Health Service Trust (Italy) decided to use the 'Evidence to Decision Coverage' framework (EtCD) produced by WP2 of the DECIDE project, focused on evidence-based policy, in order to make decisions with respect to the coverage of medical devices in scope of the Medical Device Commission, which is made up of a multidisciplinary working group that acts on behalf of the Chief Executive of Local Health Service Trust .

This decision aims to increase the use of evidence-based interventions in a sustainable way and to reduce the use of interventions where benefits are uncertain and to increase transparency in the medical devices decision process, also in accordance with Law 190/2012 on the transparency, which aims to prevent corruption in the NHS.

To date, we have applied the EtCD to the robot-assisted surgery, the local hemostatic surgical sealants and MRI compatible pacemaker. In the coming months we will apply it on pacemaker for remote monitoring, BAHA hearing aids and other surgical devices.

The EtCDs were produced by a methodologist, an health economist, both expert in GRADE methodology and participant with WP2, and an economist expert in research on equity in National Health Systems.

What we learned from this experience:

- **About EtCD drafting and contents:** there is lack of evidence and low or very low quality of evidence . Source of evidence most of the time are provided by medical devices industry.
- **About the acceptability and feasibility:** there is lack of evidence in order to understand local contest, and the need to draw information from current data, opinion of experts and practitioners and evaluation of the health system locally
- **About the equity information:** there is lack of evidence, the need to find epidemiological data on socio-cultural characteristics of the local population and the assessment of the local organization of the health system . In both cases, the retrieval of this information requires time and a specific skills
- **About the resource use:** the method allow to overcome traditional problems of economic evaluation, showing difference of resources data and effectiveness in a way that is more transparent and reproducible compared to traditional economic evaluation
- **About coverage decision:** policy makers always decided to cover conditionally, in the context of a clinical trial, generally because of the paucity of evidence about benefits and harms and considering possible inequity in the use of the device
- **About policy makers satisfaction in receiving information through the EtCD framework:** high degree of satisfaction with this tool, which they regard as a quick reference, full of useful information, and transparent.

References:

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- Brunetti M, Shemilt I, Pregno S, Vale L, Oxman AD, Lord J, et al. GRADE guidelines: 11. Special challenges – quality of evidence for resource use. *J Clin Epidem* 2013 140-50



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