**Standardization of a tool for micro-level HTA of Medical Devices**

Authors:

Campanale Cristina*, Carpenzano Alessandro*, Dulmin Riccardo*, Faggioni Lorenzo*, Lazzini Simone*, Mancino Massimo*, Mastroeni Giandomenico*, Pellegrini Luisa*, Tallarico Salvatore*

*University of Pisa, Italy

## 1) Background

Health Technology Assessment (HTA), using Multi-Criteria Decision Analysis (MCDA), allows to evaluate different aspects of new innovative medical devices (MD) also in the field of micro-level HTA (or local/hospital-based HTA) (e.g., clinical value, safety, effectiveness, economic/organizational impact, and burdens the end user suffers).

However, these studies differ in terms of both the MCDA technique, and the utilized criteria. Such diversity is not only due to a lack of clear guidance at the (inter)national level as, first, only a small proportion of MD used in hospitals are actually assessed by national Italian health authorities. Secondly, HTA of MD has been largely developed with the evaluation of drugs in mind, so overlooking differences between drugs and devices, and neglecting pivotal aspects of MD.

## 2) Methods

After a literature review to identify significant experiences of hospital-based HTA for MD, and the identification of the relevant stakeholders (e.g., hospitals, institutions, local health companies, bodies) that build on micro-level HTA, a preliminary case study protocol will be applied to at least 6 case studies to investigate, check and fine-tuning variables and key aspects to develop and validate tools for a more extensive data collection.

## 3) Results

Compliant with the EU Parliament requirement (adopted by EUnetHTA), we will develop a software to be adopted for a standardized micro-level HTA of MD to avoid bespoke criteria, introduce a standardized set of criteria, usable for all devices, and identifies the most suitable MCDA technique to use, according to the suggestions the National Anti-Corruption Authority (ANAC)'s code of conduct while considering the characteristics of the assessed MD and the idiosyncratic characteristics of the context.

## 4) Conclusion

The proposed software aims to help local institutions to avoid time-consuming phases (criteria design and validation), speeding up the introduction of MD and improving public health.

MD manufacturers will benefit from a standardized tool, if employed internationally, as it will avoid them to cope with different assessment processes.