**Health Technology Assessment Guidance In The United Kingdom: Addressing Issues Specific To Medical Devices**

Scott Gibson, Sita J. Saunders, Maximilian Bluher, Rafael Torrejon Torres, Amanda Hansson Hedblom, Rhodri Saunders

1. Coreva Scientific, Königswinter, Germany

**Objective**
- The aim of this study was to evaluate published NICE technology assessment; EAC (External Assessment Centre) guidelines and HTA (Health Technology Assessment) guidance for medical devices and diagnostics, and in particular, to better understand the key challenges faced by stakeholders when submitting an economic evaluation to the MTEP.

**Background**
- The NICE TA process for pharmaceuticals is clearly defined.
- The NICE MTEP program was launched in 2009 to evaluate new and innovative medical devices and diagnostics and diagnostic with the aim of supporting the NHS in the efficient uptake of cost-saving or cost-neutral technologies.

**Methods**
- All available MTEP evaluations were downloaded from the NICE website in November 2020.
- First, to obtain an impression of the NICE MTEP submission landscape, key characteristics of each appraisal were identified and extracted in line with the framework proposed by Bluher 2020.
- Second, challenges to stakeholders' economic analyses raised by the reviewing committee (that is, the EAC), were assessed and categorized into groups for all submissions.

**Abbreviations**
- EAC — External Assessment Centre;
- HTA — Health technology assessment;
- MTEP — Medical Technologies Evaluation Programme;
- NHS — National Health Service;
- NICE — National Institute for Health and Care Excellence;
- TA — Technology appraisal;
- UK — United Kingdom.

**Results**
- Between November 2009 and October 2020 only 45 medical technologies have been appraised through the NICE MTEP program (in comparison to 415 pharmaceutical TAs).
- Figure 1 summarizes the key extracted characteristics of these MTEP submissions.
- Figure 2 provides a summary of the key critiques of stakeholders’ economic analyses as well as the frequency with which critiques were raised.
  - 18 submissions (40%) used a health-economic model which the EAC deemed to be inappropriate for decision making.
  - Model inputs and assumptions were criticized in every submission. In 37 submissions (82%), the EAC revised the stakeholders’ base case.

**Conclusion**
- Despite the launch of the MTEP process, medical-device and diagnostic HTA is not well-established and is underutilized by stakeholders (45 MTEP versus 415 TAs).
- There were very few highly innovative technologies; most included one or two incremental improvements to existing technologies.

**References**
1. National Institute for Health and Care Excellence. Medical technologies guidance 2021

**Disclosure**
- RS is the owner of Coreva Scientific.
- G, SJS, MB, RTT and AHH are employees of Coreva Scientific.