
ISPOR Abstract

Evidence Development Timeline of Medical Devices in the UK: Where do MedTech Innovation Briefings Fit?

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Objectives

MedTech Innovation Briefings (MIBs) are evidence summaries published by NICE for medical device and diagnostic technologies, to support local decision-making. In comparison, Medical Technology Guidance documents (MTGs) and Diagnostic Guidance documents (DGs) are outputs of formal NICE Health Technology Assessment (HTA). Our study objective was to evaluate the evidence included in MIBs vs MTGs/DGs, to better understand how these programmes fit into the evidence development timelines of medical devices and diagnostics.

Methods

The 10 most recent MIBs and 5 most recent MTGs and DGs were reviewed to extract the technology, volume and quality of supporting evidence and CE mark date. All MIBs, MTGs and DGs published before May 2018 were also reviewed to identify any technologies that had been evaluated both in a MIB and a subsequent MTG/DG.

Results

Compared to MIBs, MTGs and DGs considered 7.5x (2 vs 15) and 3.0x (2 vs 6) more studies per technology, and 6.3x (465 vs 2,947) and 5.1x (465 vs 2,358) more study participants per technology. Studies were predominantly observational for all programs: 48% (MIBs), 81% (MTGs) and 66% (DGs). MIB publication dates were 1–12 years after CE mark date, whereas the delay between CE marking and MTG/DG publication was 8–21 years. Two technologies were identified as having been reviewed in MIBs and then subsequently evaluated in DGs. The DGs considered additional studies not reported in the MIBs, including studies available at the time of the MIB publication.

Conclusions

MIBs are typically published closer to the CE mark date than MTGs and DGs and the volume and quality of evidence considered in MIBs are smaller than those of the MTGs and DGs. This suggests MIBs to be a helpful program for technologies at an early stage of evidence development and that the evidence requirements for MIBs are less than that for more formal HTA through the MTEP and DAP.

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