Use of Stated Preferences in the European Union Working Group

Background continued

To date, there is no systematic mapping of initiatives and pilot projects within the EU member states. As patient advisory groups, industry, and regulatory agencies conduct more preference studies, stakeholders across the European member states need a better understanding of the methods and practices for systematically incorporating preferences into the development and assessment of new health technologies.

Compared to Europe, the US FDA is significantly advanced in its use of patient preferences for the identification, weighting and prioritization of multiple endpoints in the development and assessment of new health technologies, especially in the medical device area. For example, see FDA's Medical Device Patient Preference Initiative http://www.ispor.org/sigs/MedDevicesDiag/FDa-Med-Device-Patient-Pref-Initiative-Presentation-Philadelphia2015.pdf; Incorporating patient-preference evidence into regulatory decision making. Surg Endosc. 2015 Oct;29(10):2984-93. doi: 10.1007/s00464-014-4044-2. Epub 2015 Jan 1. https://www.ncbi.nlm.nih.gov/pubmed/25552232; guidance publications: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm418448.htm and the Medical Device Innovation Consortium's Patient Centered Benefit-Risk Assessment http://mdic.org/pcbr/

Because preference studies are increasingly used in Europe, stakeholders across the European member states need a better understanding of: 1) the diversity of stated preference methods being applied in regulatory decision making and 2) the practices for systematically incorporating stakeholder preferences in medical technology assessment.