curative stem cell transplant (SCT) post-BV (from patients who received BV in the old CDF) were accepted to provide sufficient evidence on the post-BV SCT rate by NICE. Meanwhile, for pembrolizumab, long-term survival benefit was the key clinical uncertainty; the primary data collection source was updated phase III randomized controlled trial data. At re-appraisal no reference was made to the observational data component; more mature survival data reduced uncertainty over survival benefits and were sufficient to support a positive NICE recommendation.

Conclusions. Of the twenty-two MAAs to date, only two drugs have been re-appraised thus far, with both receiving positive NICE recommendations. Observational data were successfully used to address key clinical uncertainties regarding subsequent real-world treatment patterns for BV, but observational data were not referred to in the NICE recommendation for pembrolizumab. The re-appraisal of more drugs in the future will clarify the importance being placed on observational data collection requested by NICE for existing MAAs.

PP192 An Institutional Ethical Framework For HTA: Stakeholder Participation

Mireille Goetghebeur, Olivier Demers-Payette, Marie-Pascale Pomey, Isabelle Ganache (isabelle.ganache@inesss.qc.ca) and Denis Roy

Introduction. In a context of rapidly evolving technologies and growing evaluative challenges, the National Institute of Excellence in Health and Social Services (INESSS) is developing an institutional ethical framework making explicit and transparent the guiding principles and new modalities of process for health technology assessment for public coverage.

Methods. This framework is co-built by the INESSS experts - drugs, social services, technology and health services and cross-cutting methodologies - through literature and practice reviews as well as a consultative process on key topics with external collaborators.

Results. The development process aims to: (i) identify the principles applicable to all the objects evaluated, (ii) define the evaluation strategies used to appropriately address evaluation challenges in the clinical, organizational, economic and societal dimensions, (iii) equip the scientific teams to successfully integrate diversified knowledge from the literature, stakeholders participation and medico-administrative data banks, and (iv) facilitate deliberation leading to evidence-informed recommendations. It is envisioned as a fully integrated process rooted in a reflexive multi-criteria approach supporting fair and reasonable decision. The presentation will focus on one of the key aspects of this framework, i.e., the development of principles for stakeholder participation based on a recent INESSS methodological forum on the topic, and the agile deployment of innovative processes and tools in various projects, including the patient partnership developed with a pioneering academic centre.

Conclusions. This framework provides explicit, transparent and cross-cutting processes and a framework for continuous improvement. The goal is to promote stakeholder engagement and enable increasingly complex arbitration aimed at equity and social justice, in a context of rising costs and uncertainty, and focused on the creation of value for our fellow citizens.

PP193 How Does HTA Address Social Expectations Now? An International Survey.

Hubert Gagnon (hubert.gagnon@usherbrooke.ca), Christian Bellemare, Georges-Auguste Legault, Suzanne K.-Bédard, Jean-Pierre Béland, Louise Bernier, Pierre Dagenais, Charles-Etienne Daniel, Danielle Tapin, Monelle Parent and Johane Patenaude

Introduction. After surveying its members on ethical issues (2003), the International Network of Agencies for Health Technology Assessment (INAHTA) mandated its Ethics Working Group (2005) to reflect on the role of health technology assessment (HTA) organizations in meeting social expectations. Some aspects of these have since been clarified by two studies addressing either the official position of INAHTA's members or the publication authors. An international survey was carried out on the perception of HTA professionals' expectations when producing HTA reports: how to fulfil HTA's social role, which value judgments should be made explicit and what should be the status of ethical analysis.

Methods. A twenty-two question, web-based, anonymous survey was devised from our recent systematic review on the integration of ethics into HTA and carried from April to July 2018. The information on 328 HTA agencies/contact persons from seventy-five countries was collected from the website of INAHTA, Health Technology Assessment International (HTAi), the European Network for Health Technology Assessment (EUnetHTA), EuroScan International Network, the HTA Network of the Americas (RedETSA) and the HTA Network of Asia (HTAsiaLink), a 2015 World Health Organization survey, HTAi members, and our local HTA network (Québec, Canada).

Results. Eighty-nine participants completed and submitted a finalized survey for a 27 percent participation rate representing thirty-three countries. Regarding how the HTA reports should fulfil their social role, our results showed that over 84 percent of the respondents agreed upon the necessity to address it to decision makers, patients and citizens. At a lower and more variable level, the same result was found about the necessity to make value judgements explicit in different sections of the report, including ethical analysis. This contrasts with the variability of responses obtained on the status of ethical analysis although an agreement on the expertise required was observed. Variability in the usefulness of patient, public or stakeholder participation was observed.

Conclusions. At the dawn of this decade, this study reveals high expectations on context-dependent decisions in HTA: the necessity to integrate the 'explicitation' of value judgements and systematic ethical analysis to fulfil HTA's social role.

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