

being used in these ongoing studies will nonetheless be generating evidence for the upcoming years.

## PP186 Telemonitoring With Pacemakers For Patients With Heart Failure

Susan Myles ([susan.myles@wales.nhs.uk](mailto:susan.myles@wales.nhs.uk)), Ruth Louise Poole and Karen Facey

**Introduction.** Evidence supporting the use of pacemakers is well established. However, evidence about the optimal use of pacemaker telemonitoring for disease management in heart failure is not. Health Technology Wales (HTW) held a national adoption event to encourage implementation and best practice in use of pacemaker telemonitoring in the National Health Service (NHS) Wales to improve patient outcomes in heart failure.

**Methods.** Multi-stakeholder national adoption workshop using a mixture of expert presentations, case studies and interdisciplinary group and panel discussions to agree key actions to understand the value and promote optimal use of pacemakers for remote disease monitoring in patients with heart failure in Wales.

**Results.** The workshop was attended by forty-five senior professionals with an interest in improving care of patients with heart failure. Actions to progress included: providing a centralized Welsh system to support technical issues that arise with telemonitoring; considering interoperability with other NHS Wales systems; encouraging value-based procurement with collection of a core outcome set; agreeing implementation issues with both professionals and patients; audit to understand experience, resource use and outcomes; and sharing manufacturer evidence on the accuracy of telemanagement algorithms. It was suggested that these actions be progressed via an All-Wales multi-stakeholder approach, led by the Welsh Cardiac Network.

**Conclusions.** Developing a more agile, lifecycle approach to technology appraisal is currently advocated; recalibrating the focus from technology assessment to technology management across the complete technology lifecycle. HTW will endeavour through regular adoption events to facilitate such a paradigm shift that aims to understand value and optimise use of evidence-based technologies.

## PP187 Robotic Surgery, Any Updates?

Martina Andellini ([martina.andellini@opbg.net](mailto:martina.andellini@opbg.net)), Roxana Di Mauro, Francesco Faggiano, Pietro Derrico and Matteo Ritrovato

**Introduction.** This work aims to update the previous robotic surgery health technology assessment (HTA) study conducted in 2013 in Bambino Gesù Children's Hospital. The study, focused on the evaluation of the newest evidence that have emerged over the last three years, aims to identify if there are new perspectives and advantages of introducing this technology in the hospital.

**Methods.** Decision-oriented HTA (DoHTA) method was applied to conduct the assessment. It involved the integration of the European Network for HTA Core Model® (version 3.0) and the analytic hierarchy process providing the definition and the numerical evaluation of assessment parameters through which it is possible to evaluate the performance of the technologies compared. Three years after the first technology's evaluation, an updated literature review was conducted, using the same 2013 key words, to identify changes in the indicators' performance score. The performance values have been updated through a quantitative and qualitative evaluation of data gathered from the literature review, expert opinion and context analysis. The global weights' system, developed in 2013, has not been updated because the relative importance of each domain remained unchanged. The performance values of safety, efficacy, costs, and social aspects have been estimated, identifying the differences in terms of percentage values in comparison with the previous study.

**Results.** Results showed a slight improvement on safety and organizational aspects in robotic surgery; however, clinical effectiveness and economic, social and legal aspects remained unvaried. More specifically, it has been registered a 3 percent reduction of the difference of the distance between robotic and laparoscopic performance values (2013: 14, 15 percent; 2017: 11, 29 percent).

**Conclusions.** Results highlighted a slight improvement in robotic surgery performances even if it confirmed the previous results for which the laparoscopic system outperformed the others and currently is keeping the best performance techniques. Finally, sensitivity analysis and a Monte Carlo simulation were carried out proving the stability and reliability of the solution.

## PP189 Filling In The Blanks: Is RWE From MAAs Used In NICE Decision Making?

Lok Wan Liu ([LokWan.Liu@PAREXEL.com](mailto:LokWan.Liu@PAREXEL.com)), Adam Hall, Richard Macaulay and Sean Walsh

**Introduction.** The National Institute for Health and Care Excellence (NICE) may recommend temporary funding through managed access agreements (MAAs) for oncology drugs (via the Cancer Drugs Fund [CDF]) and highly specialized therapies for rare diseases. MAAs allow for the collection of evidence to address key areas of clinical uncertainty, while providing access of medicines to patients, prior to re-appraisal by NICE. Observational data and other real-world evidence (RWE) are crucial requirements for all MAAs and herein we examine the extent these data are being used to inform HTA decisions at re-appraisal.

**Methods.** Existing MAAs entered into between the National Health Service (NHS) England and manufacturers as of 30 October 2018 were identified; for drug-indication pairings with NICE re-appraisals, all information was reviewed and the key data extracted.

**Results.** Of the twenty-two MAAs identified, only two drug-indication pairings have been subsequently re-appraised by NICE: BV(brentuximab vedotin):non-Hodgkin lymphoma ('recommended') and pembrolizumab:relapsed or refractory classical Hodgkin lymphoma ('recommended'). Data from a retrospective questionnaire regarding the proportion of patients that received

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](mailto: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](mailto: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.