

professional time and increasing productivity, improving access and equity, and reducing costs. However, before their systematic implementation a contextualization of the apps using the regional epidemiological profile must be performed.

OP184 Strengthening Patient Outcome Evidence In Health Technology Assessments: A Co-Production Approach

Mark Rasburn (mark.rasburn@nice.org.uk), Heidi Livingstone and Gillian Leng

Introduction. Involving patients is a core principle which governs the work of the National Institute for Health and Care Excellence (NICE). To improve how patient evidence is identified and considered in health technology assessments (HTAs), NICE worked with patient organizations to review existing HTA methods and co-designed proposals for change.

Methods. A working group, including six patient organizations, oversaw the project, identifying and co-designing options for improvement. We held a stakeholder event with twenty-two patient organizations to identify themes for improving how we find and use patient evidence. We then ran an online quantitative and qualitative survey for targeted consultation with patient organizations to capture broader views.

Results. The fifty-two people who responded to the consultation made the following suggestions:

- (i) Provide information about uncertainties that patient evidence might help to address;
- (ii) Explore the role of real-world evidence in patient involvement;
- (iii) Provide training and support to patient organizations;
- (iv) Create inclusive committee cultures; and
- (v) Include additional touchpoints during HTAs to incorporate patient evidence.

Conclusions. This work identified improvements in seeking and incorporating patient evidence into HTA processes. Precise guidance for patient organizations will help them to submit evidence that will make the most impact. This is particularly important when assessing disruptive technologies where there are likely to be greater uncertainties and cost pressures. The results of this work will be developed into formal options for NICE to consider when updating its methods guides.

OP206 Expert Elicitation Of Probabilistic Distributions to Inform Survival Modelling of CD19 Chimeric Antigen Receptor T-Cell Therapies

Niamh Carey (nicarey@tcd.ie), Conor Hickey, Laura Mc Cullagh and Michael Barry

Introduction. In 2018, the National Centre for Pharmacoeconomics (NCPE) was commissioned to conduct a

health technology assessment (HTA) of one of the first commercially available chimeric antigen receptor (CAR) T-cell therapies, tisagenlecleucel. CAR T-cells are a major advance in personalized cancer treatment, demonstrating promising outcomes in relapsed/refractory pediatric acute lymphoblastic leukemia (pALL). However, the results are based on short-term follow up, limiting their value in predicting long-term survival and leading to uncertainty about the most appropriate survival modeling method to employ. This study aimed to address these limitations by means of expert elicitation.

Methods. An expert elicitation method, the histogram technique, was employed. A predefined discrete numerical scale was presented in Microsoft Excel® and the expert was asked to place twenty crosses on a frequency chart. These crosses represented the expert's beliefs about the distribution of particular quantities. Each cross represented five percent of the probabilistic distribution. Individual distributions were then aggregated across experts using linear pooling.

Results. A total of seventeen experts were invited to take part; eight agreed to participate and five completed the exercise. Three experts did not consider tisagenlecleucel to be a "curative" therapy because patients had a higher risk of death, compared with the age- and sex-matched general population. The aggregated distributions indicated the five-year overall survival rate to be thirty-three percent (95% CI 8.65–56.88) in patients who do not receive a subsequent stem cell transplant and twenty percent (95% CI 2.38 -52.04) in those who do.

Conclusions. The results of this study will be used to calibrate CD19 CAR T-cell therapy survival estimates presented in HTA submissions to the NCPE to ensure more robust assessments. They will also be used to inform the construction of a de novo cost-utility model for examining the cost effectiveness of CD19 CAR T-cell therapies for relapsed/refractory pALL in the Irish healthcare setting.

OP230 How Legitimate Is The Process Of Updating the Benefits Package In Israel? A 20 Year Overview

Dan Greenberg (dangr@bgu.ac.il) and Yael Assor

Introduction. The National Health Insurance Law enacted in 1995 stipulates a minimum list of health services (benefits package) that the four health plans in Israel have to provide to their members. The recommendations on which new technologies or new indications for existing ones should be added every year to the benefits package, subject to a predetermined budget, are made by a public committee that evaluates and prioritizes candidate technologies according to their clinical merit, economic (mainly budget impact), social, ethical and other aspects. We assessed the legitimacy of this coverage decision process over the past 20 years.

Methods. The legitimacy of the process was assessed by adherence to the conditions outlined in the accountability for reasonableness (A4R) framework. A4R defines four conditions for legitimate and fair healthcare coverage decision processes: relevance, publicity, appeals/reversibility, and enforcement. We reviewed the changes made in the coverage decision process over the past 20 years and examined whether these changes have changed its legitimacy.

Results. Our analysis suggests that despite several changes made over the years in the process for updating the benefits package, for example, increase in transparency, introducing a structured appeal process, it only partially fulfills the four A4R conditions. In order to accomplish these goals more fully, several widely used considerations such as cost-effectiveness analysis and incorporating views from patients should be included. Additionally, this decision-making process should become even more transparent than it currently is.

Conclusions. The annual process of updating the benefits package in Israel where hundreds of technologies are “competing” with each other for coverage under a pre-defined budget is unique and not without merit. This process has been operating in the same pattern with only minor changes made since 1999. The main barriers for fulfilling all A4R conditions may relate in part to the large number of technologies assessed each year within a short time frame. Several changes in the process including the assessment of societal values, involvement of diverse stakeholders including patient advocate groups should be made to improve its legitimacy.

OP270 Why The Haute Autorité de Santé Rejects the Widespread Use Of “Mini-Bypass”/One Anastomosis Gastric Bypass For Obesity In France

Jean-Charles Lafarge (jc.lafarge@has-sante.fr), Denis-Jean David and Cédric Carbonneil

Introduction. One anastomosis gastric bypass (OAGB) has become a widespread technique over the last few years in France, without any prior assessment and despite existing controversies among bariatric surgeons. An older bypass technique for treating obesity, the Roux-en-Y gastric bypass (RYGB), is available and reimbursed, having been assessed and approved for use in 2005. In 2019, the French Haute Autorité de Santé (HAS) assessed OAGB for the treatment of severe and massive obesity. This assessment, the first in the world, was undertaken for OAGBs carried out with a 200- or 150-centimeter biliopancreatic-limb (BP-limb) length.

Methods. A systematic review (SR) of the literature and consultation of a working group consisting of both healthcare professionals (clinician and surgeons) and patients were carried out. The primary aim of our assessment was to determine whether the OAGB technique can replace RYGB. The efficacy and safety profile of OAGB was compared with RYGB in adult patients with massive, severe obesity. Complications and postoperative follow up specific to OAGB were identified.

Results. The three selected randomized controlled trials (RCTs) could not confirm the superiority or the non-inferiority of OAGB, compared with RYGB, on the selected efficacy endpoints of weight loss, resolution of comorbidities, and quality of life. Adverse events reported for OAGB included severe nutritional complications and bile reflux that could potentially lead to lower esophageal cancer. In one RCT, the frequency of serious adverse events in the OAGB group was almost two times higher than in the RYGB group.

Conclusions. HAS considered that OAGB carried out with a longer (200 centimeter) BP-limb is not a validated technique for the

surgical treatment of massive, severe obesity. Thus, it cannot be considered an alternative to RYGB. There were insufficient data available on OAGB performed with a 150-centimeter BP-limb. Thus, HAS recommended undertaking a multicenter RCT to assess the efficacy and safety of OAGB. Patients who have already undergone OAGB should receive the same follow up as patients who have received RYGB, including close monitoring for nutritional complications and lower esophageal cancer and an endoscopic examination five years after surgery.

OP272 Two-Year Within-Trial And Estimated Lifetime Cost Effectiveness Of The Weight Management Program In The Diabetes Remission Clinical Trial (DiRECT)

Yiqiao Xin (yiqiao.xin@glasgow.ac.uk), Andrew Davies, Andrew Briggs, Louise McCombie, C. Martina Messow, Eleanor Grieve, Wilma S. Leslie, Roy Taylor and Michael E. J. Lean

Introduction. Type 2 diabetes results mainly from weight gain in adult life and affects one in twelve people worldwide. In the Diabetes REmission Clinical Trial (DiRECT), the primary care-led Counterweight-Plus weight management program achieved remission of type 2 diabetes (for up to six years) for forty-six percent of patients after one year and thirty-six percent after two years. The objective of this study was to estimate the implementation costs of the program, as well as its two-year within-trial cost effectiveness and lifetime cost effectiveness.

Methods. Within-trial cost effectiveness included the Counterweight-Plus costs (including training, practitioner appointments, and low-energy diet), medications, and all routine healthcare contacts, combined with achieved remission rates. Lifetime cost per quality-adjusted life-year (QALY) was estimated according to projected durations of remissions, assuming continued relapse rates as seen in year two of DiRECT and the consequent life expectancy, quality of life and healthcare costs.

Results. The two-year intervention cost was EUR 1,580 per participant, with over eighty percent of the costs incurred in year one. Compared with the control group, medication savings were EUR 259 (95% confidence interval [CI]: 166–352) for anti-diabetes drugs and EUR 29 (95% CI: 12–47) for anti-hypertensive medications. The intervention was modeled with a lifetime horizon to achieve a mean 0.06 (95% CI: 0.04–0.09) gain in QALYs for the DiRECT population and a mean total lifetime cost saving per participant of EUR 1,497 (95% CI: 755–2,331), with the intervention becoming cost-saving within six years.

Conclusions. The intensive weight loss and maintenance program reduced the cost of anti-diabetes drugs through improved metabolic control, achieved diabetes remission in over one-third of participants, and reduced total healthcare contacts and costs over two years. A substantial lifetime healthcare cost saving is anticipated from periods of diabetes remission and delaying complications. Healthcare resources could be shifted cost effectively to establish diabetes remission services, using the existing DiRECT intervention, even if remissions are only maintained for limited durations. However, more research investment is needed to further improve weight-loss maintenance and extend remissions.