comparison of HER2 tests indicated that overall CISH performance exceeds that of SISH. However, low agreement between SISH and FISH in equivocal cases affects these comparative estimates. The pooled estimates from this meta-analysis can help inform future HER2 test selection decisions.

PP08 Health Technology Assessment Of Autologous Chondrocyte Implantation

AUTHORS:

Hema Mistry (Hema.Mistry@warwick.ac.uk), Martin Connock, Pamela Royle, Norman Waugh

INTRODUCTION:

Microfracture (MF) has been the main intervention in symptomatic articular cartilage knee defects. Autologous chondrocyte implantation (ACI) has looked promising, but was not recommended by the UK National Institute for Health and Care Excellence (NICE) in 2015 due to the short-term follow-up data from trials.

METHODS:

Most long-term data comes from observational studies. We provided new unpublished analyses to NICE based on survival data of these studies, with appropriate caveats. They included: a large ACI study by Nawaz with useful subgroup data by osteoarthritis Kellgren-Lawrence stage and previous repair attempts; a very large MF study by Layton, and a small RCT by Knutsen indicating MF was as 'good' as ACI. A Markov model explored the cost-effectiveness of ACI vs. MF. Different scenarios were explored: ACI or MF as a first procedure, followed by ACI or MF in those needing a second repair. A NHS England perspective was adopted. Health outcomes were expressed as quality-adjusted life-years (QALYs).

RESULTS:

The revised base-case analysis, used a list price of £16,000 (EUR 17,380 in 2013 prices) for cells, used ACI failure data from Nawaz with no previous procedures for ACI, and pooled MF failure data from two studies-Saris and Knutsen. ACI was more expensive but provided more QALYs. The incremental cost-effectiveness ratio comparing ACI then MF with MF then ACI was £8,000 (EUR 8,690) per QALY. Various sensitivity analyses were conducted assuming a threshold of £20,000 (EUR 21,730) per QALY: previous repair attempts reduced success of ACI (£22,000 (EUR 23,900) per QALY); reducing cell costs, ACI improved its cost-effectiveness; and limiting intervention to patients with higher Kellgren-Lawrence score did not appear cost-effectiveness.

CONCLUSIONS:

The final NICE guidance published in October 2017 approved the use of ACI for patients who had no previous knee repairs, for people with minimal osteoarthritic damage to the knee, and for people with articular defects of over $2cm^2$.

PP11 Would A Highly Specialized Technology Be Approved In England Under The New NICE Guidance?

AUTHORS:

Erika Turkstra (erika.turkstra@PAREXEL.com), Silvy Mardiguian, Sangeeta Budhia

INTRODUCTION:

In April 2017, the National Institute for Health and Care Excellence (NICE) updated its guidance for highly specialized technology (HST) appraisals, whereby it would automatically fund technologies for very rare diseases that fall below a threshold of an incremental cost-effectiveness ratio (ICER) of GBP 100,000 (USD 133,000) per quality-adjusted life year (QALY). In addition, NICE proposed to introduce a 'QALY modifier', weighting QALYs gained by the size of gain, which will advantage treatments that offer greater QALY gains.

METHODS:

We reviewed all technologies reviewed through the NICE HST process until November 2017 and assessed whether additional QALYs may be awarded, and subsequently result in ICERs below the new NICE threshold.

RESULTS:

Six products (eculizumab, elosulfase alfa, ataluren, migalistat, eliglustat, and asfotase alfa) have been through HST process. Within the appraisal documents, most analyses were cost consequence analyses with no ICERs reported. The estimated cost per patient per year

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ranged from approximately GBP 100,000 (USD 133,000) to GBP 400,000 (USD 532,000; listed prices). Of the six technologies, three resulted in at least ten incremental QALYs (eclizumab, elosulfase alfa and asfotase alfa). From the information in the public domain, it is unclear whether this would result in ICERs below GBP 100,000 (USD 133,000) per QALY.

CONCLUSIONS:

It may become more difficult for HSTs to get recommended by NICE under the new guidance, which requires cost-effectiveness analyses, whereas previously there was no official ICER threshold. The additional weighting of QALYs may be insufficient to meet an ICER threshold of GBP 100,000 (USD 133,000) per QALY.

PP14 Development Of The European Network For Health Technology Assessment Standards Tool For Registries In Health Technology Assessment

AUTHORS:

Emmanuel Gimenez Garcia (epuigdomenech@gencat.cat), Mireia Espallargues, Jae Long, Maja Valentic, Irena Guzina, Jorge Rodrigues, Leonor Varela-Lema, Toni Dedeu

INTRODUCTION:

Bridging gaps between registry-holders, Health Technology Assessment (HTA) producers and users is one of the aims of the European Network for HTA (EUnetHTA) Joint Action 3. In this context, a post-launch evidence generation tool is being developed, including a quality standards tool for registries in HTA. The standards tool for registries in HTA will enable, among others, registry owners to consistently collect high quality registry data, and HTA agencies to use proper registry data collected by others as evidence for their assessments. The objective is to present the first draft version of the tool structure, which is going to be piloted during the forthcoming months.

METHODS:

A review and description of the currently available first version (November 2017) sections, items and criteria for HTA studies.

RESULTS:

The tool is divided in three sections; "Methodological Information", "Essential Standards" and "Additional Requirements". The first section enables users to analyze not only the ability of the registry to answer to research questions but also to check the registry transparency. The second section encloses the essential elements of good practice and evidence quality (therefore all of them must be met before an HTA report can use the registry data). Finally, the third section includes elements of good practice and evidence quality useful to consider in planning and evaluating registries for specific purposes. Although suggestions are defined, the third section item requirements could depend on the individual HTA agency perspectives and needs.

CONCLUSIONS:

There is a clear growing availability and requirement for real world data for health technology assessment. A piloted and robust registry standards tool for HTA can provide a relevant basis to improve both the evidence generation but also to make more trustful and excellent evaluations.

PP15 Incorporating Participatory Design Approaches Into HTA

AUTHORS:

David Peddie (dpeddie@sfu.ca), Serena Small, Maeve Wickham, Katherin Badke, Stephanie Woo, Corinne Hohl, Ellen Balka

INTRODUCTION:

To address local workability, cross-setting variation, and clinician and patient perspectives, health technology assessment (HTA) practitioners and health system decision-makers incorporate varying forms of qualitative evidence into evaluations of novel health technologies. Employing principles and methods from long-established sociotechnical fields such as participatory design (PD) may help HTA teams in the production of formal, rigorous 'practice-based evidence'.

METHODS:

We draw on a theoretical review of foundational PD literature and experiences using PD for a large-scale health information technology project to summarize

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