percent; all from the CDF) also required on-going data collection from clinical trials as a key component of the data collection agreement.

CONCLUSIONS:

This research shows that current MAAs have predominantly utilized either ongoing data collection (e.g. from RCTs) or existing registries to date for which limited additional set-up administration and costs would be required. However, NICE plan to increase the use of MAAs, with ongoing NICE consultation for changes in the appraisal process to expand MAAs to include all indications. In future, manufacturers will have more opportunities to explore and leverage innovative and bespoke MAAs to help achieve access.

VP23 The New Cancer Drugs Fund: The Future Model Of Oncology Reimbursement

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INTRODUCTION:

The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable patients to access oncology therapies that are not routinely publicly funded. In April 2016, the CDF became a temporary reimbursement fund under the remit of the National Institute for Health and Care Excellence (NICE) with the aim of collecting observational data to inform subsequent technology appraisals. This study aims to evaluate how the reformed CDF has been utilized in the 18 months since this reform.

METHODS:

NICE Final Appraisal Determinations for Single Technology Appraisals of oncology drugs from (29 July 2016 to 24 November 2017) were identified and key data extracted.

RESULTS:

Seventy-four oncology drug:indication appraisals were identified, 54 (73 percent) were recommended/ optimized, 10 (14 percent) were not recommended and 10 drug:indication pairings (14 percent: osimertinib, brentuximab vedotin, pembrolizumab, olaratumab, obinutuzumab, venetoclax, nivolumab [3 indications], and ibrutinib) were referred to the CDF. For most, the greatest uncertainty in their cost-effectiveness analyses related to their survival benefits, intended to primarily be resolved through subsequent clinical trial readouts. However, for venetoclax, ibrutinib and brentuximab, the main areas of uncertainty (relating to comparative survival benefit, pre-progression mortality, and rate of subsequent stem cell transplants, respectively) are expected to be resolved primarily through observational data collected under the CDF.

CONCLUSIONS:

The newly reformed CDF has been utilized in a minority of cases. Typically, the CDF acts as a temporary access mechanism for treatments that receive market authorization based on early/single-arm trial data until longer-term and/or Phase III data are available. However, venetoclax, brentuximab, and ibrutinib demonstrate how the CDF may address significant areas of uncertainty through the collection of uncontrolled observational data. For venetoclax, with only single-arm supportive clinical trial data, observational data of this intervention and appropriate comparator are to be collected, providing a potential case study of how to appropriately manage reimbursement in the face of significant clinical uncertainty.

VP24 HTA To Assess Esthetic Procedures In France: Haute Autorité de Santé (HAS) Seven Year Experience

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INTRODUCTION:

The Health Technology Assessment (HTA) of esthetic procedures was performed by the French National Authority for Health (HAS), at the request of the French Ministry of Health (MoH), and under a new regulatory framework enabling the government to ban esthetic procedures considered harmful or potentially harmful to patients and consumers by HAS. Objectives: Describe

https://doi.org/10.1017/S026646231800346X Published online by Cambridge University Press

HAS' seven year experience with the safety assessment of four esthetic procedures.

METHODS:

This is an HAS review of its methods used in four HTAs for the following evaluated techniques: lipolysis; cryolipolysis; esthetic mesotherapy; and, ultraviolet (UV) radiation in tanning devices. The review aimed to describe how these assessments have been undertaken and information sources used, from 2010 to 2017, to appreciate the safety profile of these procedures.

RESULTS:

A systematic literature review (SRL) and analysis was performed for all four HTAs. Since findings did not allow for thorough appreciation of safety, additional sources of information were consulted to address evidence gaps. Sources may have included any combination of the following: i) National and international health care authority data and alerts ii) Legal and ethical frameworks iii) Public consultation iv) Expert opinion v) Patient-consumer association opinion vi) Economic analysis

CONCLUSIONS:

An adaptation of the HTA methodology was necessary to meet the specific requirements of these assessments. Despite sources accumulated and consulted within the seven year period, quantitative data were found insufficient to fully appreciate the safety profile for any one of the studied esthetic procedures. National regulatory reinforcement on the reporting of adverse events, with implementation of a centralized online tool, is expected to generate and capture reliable data on the frequency and severity of adverse events associated with esthetic procedures. Recent European Union (EU) regulatory requirements on the safety and performance of medical devices include equipment used for esthetic procedures, indicating agreement and alignment on national and EU-level monitoring efforts.

VP26 A Critical Appraisal Tool For Systematic Mixed Studies Reviews

AUTHORS:

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INTRODUCTION:

Systematic mixed studies reviews are a type of systematic review that combine qualitative, quantitative and mixed methods studies. They are gaining in popularity due to their potential for providing in-depth answers to complex clinical problems and practical concerns. However, several challenges are encountered in systematic mixed studies reviews because of the heterogeneity of included study designs. One of these challenges is related to the quality appraisal of included studies. To address this challenge, a critical appraisal tool for assessing the quality of quantitative, qualitative and mixed methods studies was developed in 2007: the Mixed Methods Appraisal Tool (MMAT). The aim of this project was to strengthen the content validity of the MMAT.

METHODS:

A new version of the MMAT was developed using the results from a literature review on critical appraisal tools and a modified e-Delphi study with methodological experts (n = 73) to identify the core relevant criteria to include in the MMAT.

RESULTS:

The results of this project and the new version of the MMAT will be presented. The MMAT has three main characteristics. First, it can be used for different study designs since it includes criteria for qualitative, quantitative and mixed methods studies. Second, the MMAT focuses on the core relevant methodological criteria and has five criteria per category of study. Third, it includes specific criteria for assessing mixed methods studies.

CONCLUSIONS:

Currently, there exists over 500 critical appraisal tools, making the task of selecting the proper tools for use in systematic mixed studies reviews more difficult. The MMAT offers an alternative solution by proposing a unique tool that can appraise the quality of different study designs. Also, by limiting to core criteria, the MMAT can provide a more time efficient assessment.

https://doi.org/10.1017/S026646231800346X Published online by Cambridge University Press