Trip Database, DynaMed, the Cochrane Library, the International Clinical Trials Registry Platform, and ClinicalTrials.gov. Early assessments of fcMRI analysis were identified through the Early Awareness and Alert System of the Agencia de Evaluación de Tecnologías Sanitarias.

Results. Only one prospective study of 59 infants at 6-months of age was retrieved. A fcMRI analysis was performed to identify 2,635 pairs of functional connections from 230 brain regions. The infants were subsequently assessed for autism at 24 months of age using gold standard tests. The functional connections correlated with at least one of the behaviors related to autism evaluated at 24 months of age. Eleven infants (19%) were diagnosed with autism at 24 months. Compared with the gold standard test results, the predictive model achieved the following: sensitivity 0.82 (95% confidence interval [CI]: 0.52 - 0.95); specificity 1.00 (95% CI: 0.93–1.00); positive predictive value 1.00 (95% CI: 0.70–1.00); negative predictive value 0.96 (95% CI: 0.87–0.99); and negative likelihood ratio 0.18 (95% CI: 0.05–0.64). Adverse effects were not reported in the study.

Conclusions. The fcMRI analysis could help in early detection of autism and the development of preventive interventions. However, the evidence is sparse and more well-designed studies are needed.

PP142 Health Technology Assessment – A Major Bottleneck In Patient Access?

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Introduction. Conditional marketing authorization (CMA) and accelerated assessment (AA) have been introduced to expedite the development of and access to therapies in Europe. However, to reach patients medicines must also be publicly reimbursed. This research evaluated the reimbursement of therapies which have received European CMA or underwent AA.

Methods. Medicines that received CMA or underwent AA between January 2012 and December 2017 were identified. Appraisals of these medicines conducted by major European payer bodies were obtained from relevant websites and key data were extracted.

Results. Out of the 38 medicines that received a CMA, 83 percent (19/23) were assessed by the National Institute for Health and Care Excellence (NICE) and received positive decisions, compared with 57 percent (16/26) by the Scottish Medicines Consortium (SMC) (defined as recommended/restricted), 74 percent (14/19) by Gemeinsamer Bundesausschuss (G-BA) (defined as any level of additional benefit), and 29 percent by Haute Autorité de Santé (HAS) (amélioration du service médical rendu I-III). The median delay between CMA approval and positive health technology assessment (HTA) outcome was 13 months for NICE, 11 months for SMC, 7 months for G-BA, and 5 months for HAS. Thirty-two medicines underwent AA. Of these, 68 percent (17/25) were appraised by G-BA and received positive outcomes, compared with 29 percent (7/24) by HAS, 90 percent (19/21) by SMC, and 86 percent (18/21) by NICE. The median delay between AA approval and positive HTA outcome was 7.4 months for G-BA, 7.9 months for HAS, 11.7 months for SMC, and 11.8 months for NICE.

Conclusions. CMA has expedited regulatory approval for products that address severe unmet needs. However, many of these products fail to gain public reimbursement, and even when they do there is a significant delay. AA provides market authorizations two months earlier than standard centralized assessment. Although high rates of positive payer outcomes have been achieved, the products typically experience substantial additional delays in securing public reimbursement. A parallel, cooperative approach among regulatory and HTA bodies across Europe is required to truly expedite patient access.

PP148 A Stakeholder-Informed Strategy For Effective Communication

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Introduction. Effective communication is vital for engaging stakeholders in health technology assessment (HTA), as well as the successful dissemination and adoption of HTA research and guidance. As a relatively new organization, Health Technology Wales (HTW) has an ideal opportunity to take an effective, strategic approach to communication and stakeholder engagement from the outset.

Methods. HTW commissioned Pagoda Public Relations to develop an informed communications strategy and delivery framework. The strategy used OASIS methodology for public relations planning: Objectives, Audience insight, Strategy, Implementation, and Scoring (evaluation). Initial objectives were developed with input from the HTW team and members of the HTW Assessment Group and Appraisal Panel. Stakeholder insights were collected through an online survey and telephone interviews. These insights were used to inform the communications strategy and framework, outlining key audiences, key messages, communication objectives, methods, tactics, and evaluations.

Results. Seven key objectives were identified, each of which were supported by recommended actions. These were underpinned by the key aims and messages reflecting how we will achieve these objectives. National Health Service boards, government, clinicians, the technology and research sector, patients, and the general public were identified as priority audiences. Various different communication channels and activities were identified, aimed at various audiences. These included the website, social media, traditional media, and exhibitions or workshops, as well as targeted e-mail dissemination of guidance. Evaluation of HTW communications will be aligned with the wider HTW evaluation strategy, and evidence will be recorded through OutNav software (Matter of Focus Ltd).

Conclusions. HTW is committed to a strategic, effective approach to communication and engagement. We now have an audience-informed communications strategy and plan that outlines our key objectives, and how to achieve and evaluate these objectives. Successful implementation will raise awareness of

https://doi.org/10.1017/S0266462319002563 Published online by Cambridge University Press