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

Lauren Elston (lauren.elston@wales.nhs.uk), Ruth Louise Poole, Barbara Fraser, Ian Coldwell and Susan Myles

**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

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and value in profile and outputs of HTW, both in Wales and internationally.

## PP150 Bevan Health Technology Exemplars: Early Dialogue To Systematize HTA

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**Introduction.** Wales has ambitious health, wealth, and innovation policies and a clear goal to use the economic muscle of the Welsh National Health Service (NHS) to support its strong life sciences sector. Health Technology Wales (HTW) has a clear remit to appraise technologies over the span of their lifecycle from innovation to obsolescence. HTW is collaborating with the Bevan Commission through their national Health Technology Exemplars (HTEs), which partners NHS and industry stakeholders to strengthen innovation within the Welsh health system.

**Methods.** Health technology assessment (HTA) methods were used to produce topic exploration reports for assessing the evidence underpinning applicant innovations. A "Dragons' Den" expert panel was convened to select the successful HTEs.

**Results.** Fourteen Bevan HTEs were awarded funds, which were matched by industry partners. Application of HTA methods resulted in more critical consideration of technology value propositions, including: developing pull models of innovation focused on delivering health technology solutions for current problems facing NHS Wales; supporting early dialogue between the NHS and industry partners around demonstrating evidence of improved patient outcomes; and focusing on transformative rather than incremental innovation. The most promising innovations will progress to rapid HTA, where the evidence generated will be used to develop guidance for NHS Wales.

**Conclusions.** HTA methods were productively deployed at the innovation phase of the technology lifecycle to support evidence-informed allocation of scarce innovation resources. In this way, HTW is working with key stakeholders to identify and offer early support to the most promising innovations, with the aim of expediting their adoption and realizing health benefits for patients as quickly as possible. The Bevan Commission has partnered with HTW to routinely build in HTA and evidence considerations in its future innovation calls and competitions. Thus, HTW has established a "feeder" pipeline for assessing bottom-up service-led innovations and encouraging evidence consideration throughout the lifecycle of innovative technologies.

## PP151 Establishing Health Technology Assessment Impact Evaluation With Stakeholder Input From Day One

Ruth Louise Poole (Ruth.Poole2@wales.nhs.uk), Sophie Hughes, Lauren Elston and Susan Myles

**Introduction.** Health Technology Wales (HTW) is a relatively new Health Technology Assessment (HTA) agency which focuses on non-medicines. In common with other HTA organizations, it identifies and appraises a range of technologies. However, HTW is also looking beyond the publication of guidance, to assess the adoption of advice and its eventual impact.

**Methods.** HTW commissioned development of an Evaluation Plan from independent experts (Matter of Focus). A literature review was carried out to inform an options appraisal of methods for assessing impact. The selected approach was Contribution Analysis, which estimates the counterfactual through engagement of stakeholders.

**Results.** Whilst it is too early to report the full impact of HTW's guidance, a number of activities have taken place to prepare for evaluation. The core HTW team developed a series of logic models to describe the anticipated impact, the mechanisms by which it would be achieved, and key assumptions. Stakeholders were consulted for insight from a range of perspectives, and to manage expectations. This was achieved through individual interviews, presentation and discussion at committee meetings, and the sharing of written materials for feedback. This information was collated to populate bespoke software (OutNav). The collection of data relating to processes, outputs and outcomes is already an ongoing routine task of researchers and support staff.

**Conclusions.** HTW has an opportunity to build impact evaluation into its culture from the beginning. This will facilitate the future reporting of HTW's influence using a well-designed, evidence-based approach. Furthermore, this pioneering work will clearly demonstrate the value of HTA to funders, commissioners, governments, and other decision-making bodies.

## PP155 Demand Side And Supply Side Of Healthcare Supply Chain

Isotta Triulzi (i.triulzi@sssup.it), Flavia Di Pasquale, Leopoldo Trieste, Andrea Antonel, Ettore Rossi and Giuseppe Turchetti

**Introduction.** The re-organization of the supply chain (SC) of medicines and medical devices may improve the efficacy and efficiency of the National Health Service (NHS). The aims of this study were to (i) identify the offers provided by private operators to NHS, and (ii) analyze the organizational model of the public healthcare SC system and its criticalities.

**Methods.** Two online surveys have been designed. Regarding the first survey, managers of private providers associated with the National Association of Commercial and Logistic Operators (ASSORAM) have been interviewed to identify the offers provided to the NHS. The second has been submitted to managers of local health authorities and university hospitals associated to the Italian Association of Hospitals (FIASO) to gather both organizational/managerial information (warehouse capacity, purchasing, registry, security) and qualitative aspects of the SC. Data was collected in 2015.

**Results.** On the supply side, 41 providers have been interviewed. More than 70 percent of associates managed mainly hospital

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