

legal issues arising for six key activities along the pharmaceutical lifecycle, from identifying unmet need through to health technology assessment and pharmacovigilance.

Results. The General Data Protection Regulation (GDPR) was introduced in May 2018 to Harmonise data protection across Europe. However, considerable ambiguity remains, particularly around the appropriate legal bases for data processing in the absence of consent: scientific research, public interest, or provision of health or social care. Other key themes included data subject rights, anonymization, compatibility of primary and secondary (re-)use of data, heterogeneity arising from divergent interpretation, the need for guidance on digital health, and the importance of trust.

Conclusions. We speculate which legal bases are most appropriate for the six pharmaceutical activities studied, but clear guidance and consensus is required. The GDPR was not designed to hamper scientific research, and the issues identified arose from uncertainties rather than barriers per se. Industry and academic researchers should therefore deal proactively with the prevailing uncertainties, share good practice, and engender trust by co-creating a code of conduct and outlining principles of responsible use. Engagement with patients will be critical in encouraging a shared understanding of the value to society of health data for research.

OP303 Do You Get The Message? Making HTA Findings Easier For Decision-Makers To Implement

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Introduction. Often health technology assessment (HTA) products developed by the Scottish Health Technologies Group (SHTG) did not reach clear directive conclusions because the evidence base for a technology was weak. Despite being methodologically robust, these products did not meet the needs of decision-makers and may have had negligible impact.

Methods. SHTG set out to equip and empower the recommendation-making council (that is, appraisal committee) to reach clear conclusions. SHTG broadened the HTA components and types of evidence that could be considered. The increased breadth of evidence included: clinicians attending council meetings to respond to questions; patient groups making submissions and presenting at council meetings; Scotland-specific economic modelling; and consultation on draft recommendations. SHTG also restructured the council for improved deliberative decision-making.

Results. Clear directive conclusions were reached in a substantially higher proportion of HTA products (eighty-eight percent in 2019 compared with eight percent in 2017). It became possible for decision-makers to implement findings. It also became feasible to assess the impact and implementation of recommendations.

Conclusions. Broadening SHTG's consideration of HTA components has led to a clearer conclusion being reached and stronger messaging for decision makers. This positions SHTG to increase its influence in the use of health technologies in Scotland.

OP305 A Systematic Approach To Include Ethical Aspects In Health Technology Assessments – Experiences And Evaluation

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Introduction. The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) is commissioned to assess ethical aspects in their health technology assessment (HTA) reports, in addition to effects and health economic aspects of the examined interventions. For this purpose, a framework for systematic evaluation of ethical aspects of healthcare technologies has been developed and used at SBU since 2014. With seven years of practice, we decided it was time to evaluate experiences from using the ethical framework and consider possible adjustments to improve future use.

Methods. SBU reports in the time period 2014–2020 were systematically screened for ethical content. Focus group meetings with users of the framework (mainly HTA project managers) were held where opinions regarding usability and possible obstacles were collected. A revised version of the document was sent for consultation to relevant stakeholders (possible users, reviewers and recipients) in order to collect additional views.

Results. Of fifty-eight HTA reports produced in the time frame, ethical aspects were evaluated in fifty-five reports (ninety-five percent), and in most cases, the framework had been used as support. In twenty-one cases (thirty-six percent), a professional ethicist had been engaged in the work. In twelve cases (twenty-one percent), ethical aspects were presented in the main conclusions of the report. Opinions from users and reviewers revealed that the framework was generally regarded as a helpful tool, but problems regarding interpretation of specific questions were highlighted and subjected to revision.

Conclusions. The ethical framework is a valuable tool for systematic and transparent identification and discussion of ethical aspects in the HTA context, and it has been well implemented at SBU. A systematic approach to assess ethical aspects can facilitate the communication and dissemination of ethical aspects as principal results from the HTA project.

OP310 Challenges Raised By The Economic Evaluation Of CAR-T-cell therapies: The Review By The French National Authority For Health

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Introduction. Since 2013, the coverage of innovative and expensive drugs by the French National Health Insurance considers cost-effectiveness and budget impact, as assessed by the National Authority for Health (HAS) on the basis of an evaluation submitted by the firm. First CAR-T cell therapies were subject to economic evaluation in 2019 in France. We aim at

describing the process and results of the economic evaluation of tisagenlecleucel and axicabtagene ciloleucel and the challenges these evaluations raised.

Methods. Primary evaluations were submitted by the firms to be reviewed by HAS. The final analyses were submitted to the Committee of Economic Evaluation and Public Health (CEESP), composed of independent economists, clinicians and patients' representatives. The CEESP issued Opinions related to i) the methodological quality of economic evidence and ii) the cost-effectiveness and budget impact of the drugs under review.

Results. The estimated incremental cost-utility ratio (ICUR) of tisagenlecleucel were rejected, being based on insufficient clinical evidence to estimate and extrapolate the long-term progression and to compare tisagenlecleucel with alternatives. Thus, the CEESP concluded that tisagenlecleucel was not proved cost-effective. The estimated ICUR of axicabtagene ciloleucel at 114,509EUR/QALY vs. chemotherapies was associated with an acceptable level of evidence despite being based on a frail indirect comparison and limited data on quality of life. In a context where France has no official cost-effectiveness threshold, the CEESP considered axicabtagene ciloleucel ICUR to be "very high" and questioned the collective acceptability of the claimed price.

The CEESP stressed that the main source of uncertainty surrounding the ICUR estimates of both drugs was related to the lack of hindsight on effectiveness, especially in terms of overall survival and safety.

Conclusions. The economic evaluation of CAR-T cell therapies highlights the sources of uncertainty underlying the decision and the risk of inefficient resource allocation driven by limited clinical data. It calls for payment schemes accounting for the uncertainty, and effective collection of relevant post-marketing data.

OP312 Developing A Tool-kit For Assessment Of Autism Spectrum Disorder

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Introduction. Before the coronavirus pandemic, children who were on the Early Years Neurodevelopment (EYND) assessment pathway and suspected to have possible Autism Spectrum Disorder (ASD), received clinic based appointments. This process included a parental interview by a doctor, a specialist speech and language therapy assessment, autism diagnostic observation schedule (ADOS), which were all carried out on hospital sites. These were postponed in March following national guidance. Our aim was to continue providing accurate evidence-based service for ASD diagnosis.

Methods. We utilised evidence-based telehealth methods to perform a specialist speech and language assessment in a child's home via video call. Parents were also invited to share videos of everyday activities via a secure portal. We could observe the child in a meaningful setting and witness functional impact of their needs. Each case is discussed by a multiagency panel based on DSM-V criteria.

Online training was undertaken by professionals to deliver the Brief Observation of Autism Symptoms (BOSA) based on the ADOS for COVID times. Parents were coached by the therapist to enable them to become the administrator, rather than a professional.

Results. Telephonic feedback from the first ten parents whose children underwent a telehealth assessment has been positive; the home was deemed more natural and for some less distressing than clinic. Formal patient surveys have been devised for both the telehealth and BOSA clinic assessments. Analysis is expected by the end of March.

To date we have been able to reach an outcome for thirty children, the diagnosis of ASD for twenty-four children and the other six received a diagnosis of global developmental delay or language disorder.

Conclusions. We expect that telehealth will reduce the number of assessments before an ASD diagnosis is made resulting in more prudent healthcare. The new methods have demonstrated clear increased parental participation.

OP314 What Happened Next? Assessing Health Technology Assessment Impact In Scotland

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Introduction. The Scottish Health Technologies Group (SHTG) set out to assess the impact of HTA products. Two questions were posed: Does advice from SHTG have influence? How is SHTG advice used?

Methods. SHTG adapted a tool developed by the International Network of Agencies for Health Technology Assessment (INAHTA). The INAHTA framework investigates indications of impact and categorizes outputs into levels of impact. Over three years, potential users of SHTG advice were contacted six to twelve months after advice was published and asked how the advice had been used. HTA outputs were categorized into the four levels of influence they achieved: 'major influence', 'some influence', 'some consideration' and 'no known influence'.

Results. HTA products were found to have been used in four main ways: 'informed discussion', 'referenced', 'informed policy' or 'directly informed practice'. Levels of influence had steadily increased over the three years assessed. The findings were well received by internal audiences, with particular interest in the various ways HTA recommendations had been used. There was also feedback about 'marking our own homework'. These results have informed a new SHTG strategy and supported clear messaging around the value of HTA.

Conclusions. SHTG has found a pragmatic, resource-light way to explore the impact of HTA outputs, which has proved valuable for driving strategy and messaging.

OP316 Patients' Testimonials In The National Committee For Health Technology Incorporation In Brazilian Public Health System (Conitec) Meetings

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