Results. Up to five of ten value elements are unlikely to be considered by JCVI or NICE, including patient and carer productivity, enablement value, impact on antimicrobial resistance and transmission value. Of vaccines studied, 100 percent will potentially generate value on at least one broader value element that is currently ignored; 60 percent to 80 percent may increase vaccinee/patient or carer productivity respectively.

Conclusions. There is a substantial gap between value generation and value recognition of vaccines in HTA in England. This might lead to undervaluation and underutilization of vaccines, leaving societies more vulnerable than needed when faced with infectious diseases.

OP267 Evidence for Health Technology Assessment: The Capability Approach

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Introduction. Healthcare services, such as cochlear implants and subsequent rehabilitation, aim to increase valuable activities and opportunities of those affected. Their impact may be inferred from the extent that they protect or restore capability, which reflects the real freedoms that people have to be or do things they have reason to value. Capability emerges from the dynamic interaction between available resources, individual, social, and environmental conversion factors, and functionings. This model sets the informational requirements of the capability approach.

Methods. On the basis of interviews with thirty-three hearing impaired children and thirty hearing peers, information on capability elements (values, resources, conversion factors, and functionings) was collected. Qualitative results were triangulated with standardized clinical audiological and psycholinguistic quantitative measures.

Results. Hearing impaired children and their hearing peers concurred in terms of the doings and beings they valued, but differed in terms of conversion factors to realize capability. Parents of hearing impaired children played a more upfront role, hearing impairment predominated many areas of life, and communicating through hearing aids required more energy than was usually acknowledged by the people around them.

Conclusions. The capability approach offers opportunities not only to assess impact of technology on dimensions that are important to patients, but also to better understand the mechanisms that are involved in value generation.

OP277 Rapid Development Of An Evaluation Framework: Capturing The Impact Of COVID-19 Activities By A Health Technology Assessment Body

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Introduction. Health Technology Wales (HTW) is committed to evaluating the impact of our work. In March 2020, HTW directed efforts to support Welsh Government and health and social care providers in response to the COVID-19 pandemic. We adapted the HTW evaluation framework to specifically capture the impact of our additional COVID-19 work. Here we analyze data collected since the framework was implemented.

Methods. Both formal and informal feedback was analyzed. Formal feedback was obtained through the HTW Impact Questionnaire, which was developed to support more formalized data capture for all HTW workstreams and to facilitate feedback from all stakeholder groups. It was piloted with a targeted list of individuals and responses were received for COVID-19 work. Informal feedback included feedback received via email or through word of mouth.

Results. HTW COVID-19 products to date include Topic Exploration Reports, rapid evidence summaries and an Evidence Appraisal Report (EAR) on COVID-19 diagnostic tests (molecular and antibody tests). Stakeholders were positive about these outputs, describing them as valuable and informative. Reported impacts included informing policy and decision making, reducing duplication of efforts and helping to target development. The EAR received national and international focus, leading to HTW involvement in the European Network for Health Technology Assessment (EUnetHTA) COVID-19 reviews. Survey participants who gave feedback on COVID-19 activities included two members of Health Technology Assessment organizations, a health board representative and an industry representative; all agreed that HTW's COVID-19 work was useful, that the methods were reliable and robust and that HTW is responsive. All participants also felt that HTW's COVID-19 work had a positive impact in the wider health and social care context.

Conclusions. HTW was able to respond rapidly to the COVID-19 pandemic and adapt current evaluation practices to capture the impact of COVID-19 work. We will continue to evaluate our COVID-19 activities. Future work will involve following up on the developing impact of our COVID-19 work and expanding our methods for data capture, for example conducting stakeholder interviews.

OP279 Data Protection In The European Union Post-General Data Protection Regulation (GDPR): A Barrier Or An Enabler Of Pharmaceutical Innovation?

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Introduction. The expansion of health data offers exciting opportunities to support better and more efficient drug discovery, development and implementation. Data protection and governance provide the legal framework to balance safeguarding patients' privacy with the benefits to society of medical research. Our aim is to highlight current legal barriers to the better use of health data and propose ways to address them.

Methods. Analysis of the relevant legislative texts was supplemented by interviews with external experts in data protection, health research, informatics and cyber security and a workshop with pharmaceutical industry members. We investigated the

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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

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