Studies have shown generally homogenous results in reduction of rectal toxicity across assessed subgroups, but the requirement to prioritize remains. One way of addressing the appropriate use of beneficial health technologies is the inclusion of end-user experts in decision-making. The study aim was to identify consensus among radiation oncologists on patient prioritization for rectal hydrogel spacers.

Methods. We conducted a Delphi study where six leading clinical oncologists and one urologist from across the UK experienced in using rectal hydrogel spacers participated in two rounds of online questionnaires and two virtual advisory board meetings.

Results. The experts estimated that 83 percent of patients who could potentially benefit from a spacer were denied access. Overall, ten points of consensus were reached. Key ones concerning patient-access were:

- Spacer use in eligible patients significantly reduces radiation dose to the rectum and toxicity-related adverse events.
- Increased benefit is expected in patients on anticoagulation, with diabetes and with inflammatory bowel disease.
- Increased benefit can be expected with ultra-hypofractionated radiotherapy, but radiotherapy modality is not a key consideration for patient selection.
- Patients should have the opportunity to actively participate in the discussion regarding the use of a spacer.

Conclusions. Currently, not all patients who would benefit can access funding for hydrogel spacers. Consensus in this study indicates that appropriate health policy and funding mechanisms are warranted for patients, to provide equitable access to technologies improving quality of life.

PP151 VALIDATE Methodology On A Medication-Related Clinical Decision Support System: Holistic Assessment For Optimal Technology Adoption

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Introduction. In the past decade, health technology assessment (HTA) has narrowed its scope to analyses of mainly clinical and economic benefits. Technology challenges in the 21st century emphasize the need for holistic assessments to obtain accurate recommendations for decision-making, as in HTA's foundations. Using the VALues In Doing Assessments of health TEchnologies (VALIDATE) methodology for complex technologies provides a deeper understanding of problems through analysis of stakeholders' views, allowing for more comprehensive HTAs. This study aimed to assess a pharmaceutical clinical decision support system (CDSS) using VALIDATE.

Methods. Semi-structured interviews with different stakeholders were conducted in the following domains: problem definition (medication error [ME] occurrence and prevention); judgement of solution (existing preventive methods and previous experiences of the CDSS); background theories (future impact and personal beliefs); and barriers to and facilitators of implementation. The following individuals were interviewed: medical informatic specialists (n=3), pharmacists (n=2), nurses (n=2), physicians (n=2), CDSS company representatives (n=1), electronic health record developer (n=1), and health consultancy firm representatives (n=1). Content analysis was used to integrate and analyze the data.

Results. The multistakeholder interviews identified various barriers to the acceptance and implementation of a pharmaceutical CDSS that were different from those reported in the literature. These included: (i) occurrence of ME (no traceability of medication taken or poor patient medication empowerment); (ii) perception of current level of MEs (huge improvement from ten years ago); (iii) perception of technology as a tool to prevent ME (not enough if only implemented at one point of care); (iv) previous experiences with a CDSS (low rates of development of CDSSs are due to medication prescriptions being digitalized last in hospitals); (v) CDSS metrics (input data should be measured to control CDSS performance); and (vi) other barriers.

Conclusions. Including facts and stakeholders' values in problem definition and the scoping of health technologies is essential for the proper conduct of HTAs. Incorporating views from multiple stakeholders when scoping the assessment of health technologies brings additional values to literature findings, resulting in a more holistic evaluation. The lack of multistakeholder scoping can lead to inaccurate information and result in wrong decisions about if, when, and how to adopt a CDSS.

PP152 The Assessment Of The Price Of A Medicine: The Possible Application Of Cost-Based Pricing Methods

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Introduction. Before admission to the insured package, the price of a medicine is usually assessed on the basis of the value of the medicine for the patient: the effect size on health and survival must be in line with the costs. That seems like a fair starting point, but the use of such 'value-driven' models sometimes results in unrealistic prices. These prices in turn lead to discussions about limitations within the healthcare budget and may result in delays in the accessibility of medicines. The aim of this study was to review several alternative pricing models and propose possible applications of the models.

Methods. Six pricing models were selected that encompassed cost-based or cost- and value-based aspects. The models were reviewed within the context of the published group of medicines, followed by a discussion on their potential to aid in creating benchmarks for pricing negotiations.

Results. Five cost-based pricing models and one value-based model with a cost-based aspect were found with potential applications. (i) The AIM-model for innovative medicines. (ii) The adjusted AIM-model for repurposed medicines. (iii) The Cancer drug pricing model for innovative oncolytics with information about health

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benefit. (iv) The discounted cash flow model for orphan medicines with information about health benefit. (v) The value-based rate of return pricing for innovative orphan medicines with information about health benefit. (vi) The P-quad model for drugs with a high budget impact for which there is no generic competition after intellectual property an regulatory exclusivity end.
Conclusions. We argue that it would be more logical for different categories of medicines to base prices on average costs, possibly combined with a bonus for innovation: the cost-based pricing method. The next step is to discuss the possible application of cost-plus methods with stakeholders including patients, industry, payers, and healthcare professionals.

PP153 The Economic And Fiscal Impact Of Public Health Programs For Diabetic Patients In Italy

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Introduction. Technological innovations in the health sector have economic implications that go beyond their effects on health expenditure, expanding into other areas of the state budget (e.g., the social security system). Furthermore, innovation can affect the production of wealth by workers and companies, which in turn affects tax revenues. In addition, the presence of chronic diseases tends to reduce the propensity to consume and changes the allocation of consumption between the different sectors. Allocative decisions in the health system are rarely supported by an analysis that combines the health effects of innovations and their consequences in the economic system.
Methods. The objective of this study was to estimate the value of management programs for patients suffering from type 2 diabetes mellitus that involved different levels of use of innovative technologies and drugs. A tax impact assessment methodology was adopted in the context of chronic conditions to analyze the effect of adopting alternative management models for patients with diabetes on the broader economic system.
Results. Assuming a policy that reduces annual complications by 0.42 percent, there was an increase in tax revenue (cumulative value) of approximately EUR 28,175 and a reduction in productivity losses (cumulative value) of EUR 4,049,890. Projecting the impact on the age trend of the population up to 65 years of age with these estimates, it is possible to have an increase in tax revenue (cumulative value) equal to approximately EUR 7,050,598 and a reduction in productivity losses (cumulative value) equal to EUR 140,235,923.
Conclusions. In light of this work, providing remote patient support (telemedicine) and expanding the provision of innovative oral antidiabetic drugs to family physicians could improve care for patients with type 2 diabetes mellitus. This study provides decision makers with an immediately usable model to broaden the information base for planning and regulatory choices. In addition, it supports the use of economic evaluations that calculate the entire value of a technological innovation or health program.

Poster Debate

PD01 Using ELISA Tests For Monitoring Response To Anti-TNFs In Rheumatoid Arthritis: Findings From A NICE Health Technology Assessment

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Introduction. Patients with severe rheumatoid arthritis (RA) disease may be treated with tumor necrosis factor (TNF)-α inhibitors. However, their efficacy is reduced by the presence of anti-drug antibodies. The objective of this HTA was to conduct a systematic review to investigate the effectiveness of using enzyme-linked immunosorbent assay (ELISA) tests (Promonitor, IDKmonitor, LISA-TRACKER, RIDASCREEN, MabTrack, and Sanquin Diagnostic Services) to measure levels of the drug and anti-drug antibodies for monitoring response to TNF-α inhibitors in patients with RA.
Methods. A range of bibliographic databases including MEDLINE, EMBASE and CENTRAL were searched from inception to November 2018. Studies were eligible for inclusion if they investigated ELISA tests in RA patients receiving treatment with a TNF-α inhibitor who had achieved the treatment target (remission or low disease activity [LDA]) or experienced a primary or a secondary non-response. The tests must compare with standard care where treatment decisions are based on clinical judgements and monitoring using a composite score such as the disease activity score 28 joints (DAS28). Risk of bias was assessed using the Cochrane (ROBINS-1) tool for non-randomized studies.
Results. Two studies were included. One non-randomized controlled trial (non-RCT) compared standard care with therapeutic drug monitoring using Promonitor test kits in RA patients in remission/LDA receiving adalimumab, and a historically controlled study investigated Sanquin ELISA kits. The non-RCT study showed that there was a non-significant reduction in the risk of flare in the intervention group compared with the control group. Patients' health-related quality of life outcomes were higher in the intervention group at all visits compared with the control group. However, this study had serious limitations because analyses were not performed using an intention-to-treat approach. The historically controlled study did not provide valid evidence on whether ELISA-based monitoring is clinically effective.
Conclusions. There is only limited, poor evidence available. There are considerable uncertainties on the effectiveness of using ELISA tests for monitoring response to TNF-α inhibitors in RA. Further controlled trials are required.

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