Introduction: Outcome-based commissioning – a set of arrangements to define and pay for a service based on pre-agreed outcomes – has been operationalized in some regional care settings (e.g., adult social care). However, it remains largely aspirational due to operational considerations and challenges. Outcomes-based commissioning shares a common goal with economic evaluation alongside health technology appraisal (HTA): to achieve value for money for outcomes from a finite budget.
Methods: We explored the considerations, implications, and challenges regarding the practical role of relevant outcomes in economic evaluation, relative to care commissioning, using England as a case study. Our exploration bridges a gap between economic evaluation evidence and practical resource allocation decision-making, focusing on conceptual (e.g., what are 'relevant' outcomes), practical considerations (e.g., quantifying and using relevant endpoints or surrogate outcomes alongside costs), and pertinent issues when linking these to commissioning based payment mechanisms.
Results: Firstly, there is a disconnect between existing economic evaluation approaches and commissioning processes. For example, using a single quality-adjusted life-year (QALY) maximum and limited consideration of affordability relative to cost effectiveness. Secondly, service-focused outcomes (e.g., seeing a specialist team) rather than person-focused outcomes (e.g., QALYs) are often desirable from a practical commissioning and service provider perspective as they make it easier to measure key performance indicators. Thirdly, both person- and service-focused payment structures could lead to market inefficiencies when activity is focused on only people for whom a prespecified outcome can be achieved or service delivered; these approaches require additional efficiency-equity tradeoff considerations (e.g., using distributional cost-effectiveness analyses).
Conclusions: We highlight payment structures as a major and complex consideration for commissioning, for which economic evaluation provides little to no consideration. Service-related outcomes and payments can be used as surrogate outcomes within economic modeling frameworks, while monitoring and evaluation can still be based on economic outcomes (e.g., QALYs and aggregated costs). Accounting for and explaining direct links from payment structures to economic outcomes is a major step to bridging a gap between economic evaluation evidence and practical resource allocation.

OP45 HTA And Gender Medicine: Time To Take Action!

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Introduction: Gender medicine responds to the need for a reassessment of the medical-scientific approach in a gender perspective, to increase knowledge of the different aspects underlying gender differences and the appropriateness/ effectiveness of health interventions.
Methods: A policy review of documents prepared by the Italian Ministry of Health on gender medicine was carried out, to investigate the possible areas of intervention of health technology assessment in the development of this interdisciplinary dimension. The areas of highest priority for action have been identified.
Results: In Italy, the Ministry of Health, with the support of the National Institute of Health, issued a Plan for Application and Dissemination of Gender Medicine in June 2019. Our review shows that for the development of research on the mechanisms of pathogenesis the Italian Plan gives indications on the identification of diagnostic markers, prognostic and predictive response in a gender perspective, but there are no formalized rules that constitute a constraint or an obligation to do so. In Horizon Europe calls, for example, "Pragmatic trials on minimally invasive diagnostics" (HORIZON-MISS-2023-CANCER-01-03) on the other hand, it is required that gender and gender issues should be taken into account in all projects and all data should be disaggregated by gender, socio-economic status and ethnicity. Separating subjects into two groups in the analysis leads to greater complexity. This is even more true when considering the different types of gender. The total number of subjects to be included must likely increase to maintain statistical power in evaluating effects in subgroups. This increase leads to an increase in time and cost, if one needs to provide separate data by sex and even more so by gender. Different statistical tests to be used, according to the type of variables of the primary endpoint, should be considered in the study protocols.
Conclusions: It seems appropriate to suggest reviewing upcoming health technology assessments with an eye to gender medicine. Gender medicine should become a strategic goal of prevention in public health and will strengthen the concept of the patient centrality until the personalization of therapies is achieved.

OP46 The Decision Uncertainty Toolkit: Risk Measures And Visual Outputs To Support Health Technology Decision-making During Public Health Crises

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Introduction: During public health crises such as the COVID-19 pandemic, decision-makers have relied on infectious disease models to predict and estimate the impact of various health technologies. The difficulties associated with capturing and representing uncertainty using infectious disease models leads to a high risk of making decisions that are misaligned to policy objectives. Even when uncertainty is adequately captured in the analysis, the tools for communicating the risks and harms of making wrong decisions have proved inadequate, which can lead to the suboptimal adoption of critical health technologies including vaccines and antivirals. We aim to adapt and extend health economic methods for the characterization, estimation, and communication of uncertainty to infectious disease modeling.
Methods: Economic and infectious disease models share many features, including the comparison of policy alternatives on outcomes

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important to decision-makers (such as hospital census, total infections), but each takes a different approach to analysis of uncertainty. We extend best practices from health economics to infectious disease modeling and develop a suite of tools and visualization techniques which represent parameter uncertainty and the risk these unknowns present to decision-makers.
Results: In consultation with decision-makers and infectious disease modeling experts we developed the 'Decision Uncertainty Toolkit' of model outputs and visuals. Visual tools for uncertainty are developed to: (i) accurately capture uncertainty in key infectious disease model outputs, and (ii) support intuitive and direct interpretation by infectious disease modelers and decision-makers. We also developed quantitative measures for the downside risk of policy alternatives, specified to capture both the probability and magnitude of losses relative to policy targets for a range of infectious disease model outputs. Together, these outputs can support decision-making by quantifying outcome uncertainty and the risks associated with policy alternatives.
Conclusions: We developed the toolkit visuals and risk measures alongside infectious disease modelers and decision makers. The toolkit is designed to improve decision-maker understanding of decision risk in order to improve outcomes during future public health crises.

OP47 The Risk-Based Price: Incorporating Uncertainty And Risk Attitudes In Health Technology Pricing

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Introduction: Decision makers often use value-based decision rules to determine whether technologies offer good value for money and should therefore be adopted, comparing cost-effectiveness analysis results with a threshold value. This assumes that decision makers are indifferent to interventions with the same expected value but different levels of underlying uncertainty. Such indifference is unlikely to hold in practice. We propose a risk-based price and accompanying decision rules to address this limitation.
Methods: We characterized risk using the per-patient expected value of perfect independent information (EVPII), a modification of a standard output from value of information analysis. The EVPII estimates the expected value of net benefit losses caused by uncertainty related to a technology, independent of the uncertainty related to alternative treatments. 'Payer risk tolerance' is then defined as the maximum per-patient risk of making wrong decisions that payers are willing to accept, expressed in monetary terms. The risk-based price is the price at which the EVPII is equal to the payer risk tolerance.
Results: The risk-based pricing decision rules are as follows: (i) a technology is acceptable for adoption at the submitted price if the incremental net benefit of the technology is greater than or equal to zero and the EVPII is less than or equal to the payer risk tolerance; and (ii) the optimal technology has the greatest expected net benefit at the lowest of the sponsor submitted, value-based, or risk-based price at a given cost-effectiveness threshold value.
Conclusions: The risk-based price incorporates uncertainty and risk attitudes into decision-making. We demonstrate that both risk-averse and risk-neutral payers prefer the outcomes of risk-based pricing. Risk-based decision rules incentivize sponsors to develop evidence. Implementation of the risk-based price improves outcomes for patients by increasing health system net benefits under constrained resources, with better alignment to decision maker risk attitudes.

OP51 Use Of Real-World Data In Cost-effectiveness Analysis Of Sequential Biologic Treatment For Rheumatoid Arthritis

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Introduction: In health technology assessment (HTA), economic evaluations assessing biologic drugs for rheumatoid arthritis (RA) involve modeling patients' responses to multiple treatments given sequentially over a lifetime horizon. When data from randomized controlled trials (RCTs) are scarce, data from non-randomized studies (e.g., single-arm trials [SATs] and disease registries) can be used to supplement the evidence base. This research aimed to demonstrate meta-analytic methods for combining effectiveness data from randomized and non-randomized studies and their corresponding impact on cost-effectiveness estimates.
Methods: Data comparing patients receiving second-line rituximab with continued background non-biologic treatment were extracted from one RCT and six SATs identified in an HTA assessing second-line rituximab for RA, and from the British Society for Rheumatology Biologics Register-Rheumatoid Arthritis, by applying a target trial emulation approach. A binomial meta-analysis model was used to estimate the probabilities of achieving the European League against Rheumatism (EULAR) response criteria by pooling data from the RCT, SATs, and the registry. The probabilities were entered into a decision model from a previous HTA to derive incremental cost-effectiveness ratio (ICER) estimates for treatment strategies with and without biologic drugs.
Results: Compared with the original analysis, the estimated probability of at least a moderate EULAR response on rituximab from combined sources was substantially lower. For example, the probability obtained from an RCT was 0.68 (95% credible interval [CrI]: 0.345, 0.907), but only 0.29 (95% [CrI]: 0.242, 0.333) when using RCT plus registry data and 0.29 (95% CrI: 0.244, 0.336) for combined RCT, registry, and SAT data. In the cost-effectiveness analysis, the median ICERs were higher when including real-world data.
Conclusions: Synthesis of all relevant data, including RWD, provides additional information regarding the variability in cost-effectiveness estimates and can be considered in sensitivity analyses for HTA decision-making.

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