INTRODUCTION:

With the possibility to analyze gene expression a plethora of new genomic tests are surging into the medical market. The assessment of these new technologies in Health Technology Assessment (HTA) reports is challenging and we need international consensus on uniform criteria to support HTA, but also to establish clear and standardized requirements for clinical studies.

METHODS:

The German Institute for Quality and Efficiency in Health Care (IQWiG) has been commissioned to assess the benefits and harms of biomarkers to predict which women would benefit from chemotherapy treatment after surgery of primary breast cancer. The final report was published in October, 2016 (1).

RESULTS:

Only eight studies complied with the inclusion criteria of the systematic review. No prognostic study fulfilled the inclusion criteria. Only two randomized controlled trials (RCTs) delivered information utilizable for benefit assessment. Based mainly on 5-year results from the MINDACT trial, the report concluded that there currently is not enough information to support a positive decision on biomarkers in this specific indication. Ongoing randomized controlled trials like TailorX, PlanB, RxPONDER, ADAPT or OPTIMA are expected to provide some additional evidence in the near future. After publication of the IQWiG report an extensive debate on several methodological characteristics of this report was fuelled. In addition, some other HTA agencies, such as the National Institute for Health and Care Excellence (NICE) made slightly different conclusions.

CONCLUSIONS:

The presentation will give a résumé of the main arguments and focus on differences between the IQWiG report and other HTA reports. Questions, like the required study type, study characteristics (for example, attrition rate, follow up, outcomes), data quality, cut-offs or patient preferences in diagnostic information will be provided. The aim of the presentation and discussion is to get a step forward in defining key characteristics and elements of benefit assessment and primary studies for these new technologies. A consensus among HTA reviewers in these approaches seems to be essential in the near future.

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VP94 Framework Of High-Quality Value Assessment Criteria In Health Care

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INTRODUCTION:

No single assessment can evaluate the wide spectrum of health technologies pending access to healthcare systems. It is important to envision a complex systematic framework, in which different instruments are used for different purposes - all criteria should be used to ensure the transparency of the process, and should model good assessment and implementation practices (1,2).

METHODS:

A cross-sectional web-based survey was conducted from September 2013 to May 2015 which was designed to gain information about the present status of Health Technology Assessment (HTA) activities; to examine its institutional contexts and the kind of application of its principles, logic, assessment methods, tools and best practices.

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RESULTS:

A total number of 161 questionnaires from 39 countries on 6 continents were received representing a 41.7 percent response rate. Based on analysis of the results, a complex systematic framework for value assessment was designed. Five major features define the framework that can fully measure the common and support the evaluation of more complex health technologies: (i) implementation of higher-order evaluation approaches that support complex multi-criteria assessment, rather than emphasizing only the use of basic evaluation procedures; (ii) precise evaluation of critical criteria, that measure technologies directly as they will be used in actual practical settings; (iii) assessment approaches, based on international best HTA practices that are accurate, in terms of the content and context of the evaluated technology, as well as the expected performance; (iv) high-fidelity priority-setting elements that are evaluation sensitive; and (v) assessments that are sound, unbiased, and transparent – in order to be truly valid for a wide range of technologies, assessments should evaluate them accurately and do so reliably across technology content and context. They should be unbiased and accessible and used in ways that support superior outcomes and higher quality for healthcare systems.

CONCLUSIONS:

The healthcare systems that decide to use this framework should evaluate the set of assessments they select and develop them against the standards required, and should use them in ways for which they have been appropriately validated and in contexts that ensure a transparent evaluation process (3).

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VP95 The Monetary Value Of A Statistical Life Year: A Systematic Review

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INTRODUCTION:

Among economists, there is widespread agreement that the monetary valuation of health gains should reflect the preferences of those who will be affected by resource allocation decisions. In the context of Health Technology Assessments (HTAs), this view implies a need for reliable empirical estimates of the value of statistical life year (VSLY), which should provide a useful point of reference for cost benefit analyses.

METHODS:

We conducted a systematic review of the literature on the economic value of a statistical life (VSL). We searched in the EconBiz and EconLit databases for studies, which reported VSL estimates based on original research and were published between 1995 and 2015. We classified studies by methodology, that is, revealed preference (RP) or stated preference (SP; that is, CV, contingent valuation, or DCE (discrete choice experiment) approach, and by regional origin of data. We transformed VSL estimates into VSLY expressed in year 2014 Euros, using life expectancy tables for the populations studied, a real discount rate of 3 percent, national Consumer Price Indices for inflating, and purchasing power parities for currency conversion. In addition, we calculated ratios of VSLY to gross domestic product (GDP) per capita.

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