**Introduction.** Qualitative research is being increasingly integrated in heath technology assessments (HTA) within the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS). Qualitative research methodological guidelines are given in RedETS HTA guidelines and the Patient Involvement Strategy. A specific methodological guideline to systematically review qualitative studies was published in 2007 and is pending its update. The impact of their implementation is unknown. The aim of this work is to analyze the techniques, impact and reporting of qualitative research (primary and secondary) in HTAs.
**Methods.** A manual search of the HTAs published in the last 5 years in RedETS was conducted to locate assessments that include qualitative research. To ensure a complete identification, RedETS agencies and units were consulted to provide information about the assessments that have used qualitative techniques in their development over the past 5 years. A content analysis of the selected assessments was conducted to analyze the techniques, impact and reporting of qualitative research in HTA.
**Results.** In the past five years, focus groups, semi-structured interviews, evidence synthesis of observational studies including qualitative studies have been used and integrated in HTA in RedETS. Most of them have been linked to patient involvement facilitation or the inclusion of patient perspectives in HTA. Qualitative research has been used to analyze patient's experiences and values, to elicit and select important outcome measures for patients, to research for barriers-facilitators for technology implementation and to inform evidence to decision frameworks.
**Conclusions.** Qualitative primary and secondary research is being used in HTA in Spain. It is mainly linked to patient involvement strategies both to elicit patient perspectives directly or to collect patient-based evidence. The impact of qualitative research in HTA is broad and diverse, extending from the scope of the assessments to the drafting of the recommendations.

## PP12 Challenges In Assessing The Efficacy Of Non-Pharmacological Measures In The Context Of The COVID-19 Pandemic

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**Introduction.** The outbreak of the COVID-19 global pandemic in 2020 has been a major challenge for the world's population and governments. The lack of vaccines, the saturation of health systems, and its rapid spread forced governments to take non-pharmacological interventions (NPI) that had a high impact on the population. Assessing the efficacy of these measures is a challenge for health technology assessment bodies.
**Methods.** The main NPIs for which assessment was required were: mobility restrictions, social distancing, cancellation of events or reduction of seating capacity, closure or reduction of seating capacity in non-essential businesses, closure or limitation of seating capacity in educational establishments, and promotion of teleworking in potential jobs. The implementation of these measures at a global level provides a large population for the study of the impact of these measures. However, the challenges for their evaluation are numerous:

- The joint implementation of these measures makes it difficult to evaluate them in an isolated manner.
- The heterogeneity between countries and regions of the pandemic situation at the time when these measures are initiated and terminated.
- The different accuracy in the application of the measures.
- Heterogeneity in the quality and accessibility of public health services for citizens.

**Results.** Outcome variables to assess the effectiveness of these measures should include parameters related to:

- Incidence variables: the number of new or accumulated cases in a given time range, the variation in the number of cases in a given time range and the proportion of positive tests.
- Transmission variables: the basic reproductive number (R0) and the effective reproductive number (Rt).
- Severity and mortality variables: the number or variation of hospitalizations, the number or variation of intensive care unit (ICU) hospitalizations and the number or variation of deaths.

**Conclusions.** The large number of available data, the heterogeneity of the measures, the differences between populations, the numerous outcome variables and the possible inclusion of mathematical modelling studies, are a methodological challenge for the HTA bodies.

## PP13 Development Of Recommendations And Proposal For A Value-Based Managed Entry Agreement For Italian Setting

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**Introduction.** The continuous and pressing challenge that the drug regulatory authorities in Italy and in Europe are facing is that of guaranteeing patients' quick access to new drugs, ensuring the economic sustainability of the system at the same time. In recent years, flexible and diversified approaches have been developed known as Managed Entry Agreements (MEA).
**Methods.** We performed an analysis of the Italian legislative and regulatory aspects in reference to a new Value-based Managed Entry Agreement (VBMEA) pathway. Thus, we tried to investigate the rationale for a new pathway analyzing three main dimensions related to the new medical product (MP): value; time to entry access; and, data quality and registry design. Moreover, we shared the discussion of the proposal with an international experts' panel.
**Results.** The proposal for a new pathway of VBMEA from a procedural point of view shows the novelty related to the possibility to organize joint CTS (Technical Scientific Committee) and CPR (Price

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and Reimbursement Committee) assessment. A 24-month contract with an ex-factory price (PP) equal to X EUR per dose and a transfer price to the National Public Health System (NPHS), following application of a confidential discount for public structures (-X%), of X EUR per dose. After 24-months, an analysis of VBMEA is carried out. The price of the MP is therefore established based on AIFA registries and VBMEA results. The cost value incurred by the NPHS, intended as the difference between the price in market (entry) access phase and the price negotiated (PVB) in the light of the VBMEA results, shall be returned by the pharmaceutical company in the form of a payback.
**Conclusions.** Currently, MEAs represent one of the main topics of discussion between the European National Payers Authorities. There is very little information on product performance that results from MEAs. This research project could provide advice to policy makers to decrease negotiation time by ensuring earlier access to innovation for patients.

## PP14 Value-Based Pricing For Advanced Therapy Medicinal Products: Emerging Affordability Solutions

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**Introduction.** The emergence of advanced therapy medicinal products (ATMPs), a disruptive class of health technologies, is generating important challenges in terms of value assessment, and their high prices introduce critical access and affordability concerns.
**Methods.** The aim of this oral presentation is to expose the challenges of traditional value assessment and pricing and reimbursement methods in the evaluation of ATMPs, and to characterize the current and prospective financing solutions that may ensure patient access to and affordability for these health technologies.
**Results.** Standard health technology assessment (HTA) is not designed for assessing ATMPs and may delay access to these therapies; thus, a broader concept of value is required. As a result, value-based pricing methodologies have been gaining prominence as a way to cope with the specific challenges of ATMPs. The pricing and reimbursement framework should ensure a balance between encouraging innovation and maximizing value for money for payers through the attribution of a fair price to new health technologies. The provision of early scientific advice to developers by regulatory and HTA bodies is key, as it will help diminish the perspective gap between developers, regulators, and payers.
**Conclusions.** The high efficacy and high price dynamic of many ATMPs necessitates novel financing models, both in the European Union and in the USA. Managed entry agreements, where financing is conditional upon the submission of additional evidence, linked with leased payments may offer effective strategies to address the uncertainties caused by the evidence gap associated with ATMPs, ensuring affordable and sustained access to these therapies.

## PP15 The National Pricing And Reimbursement Process In China, A 2021 Update

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**Introduction.** The Chinese National Reimbursement Drug List (NRDL) was established in the early 2000's and includes the drugs both fully and partially covered by National Basic Medicine Insurance. As China's health system has been reformed over the past decade, it is important for manufacturers to understand the ever-changing reimbursement process and its implications on newly launched drugs. This study provides an updated overview of the process based on research conducted in 2021.
**Methods.** Targeted secondary research was undertaken to evaluate the pricing and reimbursement landscape in China. Primary research was conducted to assess the perspectives of three payers and one policy expert.
**Results.** National listing remains the most viable and exclusive pathway to get a product reimbursed by public health insurance in China. Since 2017, the NRDL has been updated annually, and revisions are managed by the National Healthcare Security Administration (NHSA). Insights from 2021 suggests that the process of listing a new product on the NRDL lasts five months (July to November). Manufacturers should ensure that submissions are made when the annual NRDL process formally begins, and clinical and health economic evidence is compulsory. If a successful opinion is made by the assessment board, the manufacturer will be invited to negotiate a price with the NHSA. Data from the NHSA indicated that a total of 704 applications were made in 2020. In addition, 138 exclusive drugs were eligible for price negotiation, of which 96 drugs were successful and added to the NRDL. Findings also suggested that the average discount rate increased from 44.0 percent in 2017 to 50.6 percent in 2020.
**Conclusions.** The national reimbursement process in China has become more transparent overtime. Even so, NRDL listing remains a challenge, with decisions driven by clinical and pharmacoeconomic evidence, and price. Significant price cuts should be considered and anticipated to ensure successful negotiation outcomes.

## PP16 Machine Learning In The Treatment Of Spinal Deformities: Early Life-cycle Economic Analysis In Australia

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