suggested as a way to incorporate uncertainty in the measurement of societal value when setting the price of a new pharmaceutical. An alternative approach would be to use a range and identify the WTP range for a unit of health benefit. This is then converted to a threshold and the lower and upper bounds of the WTP range are used to estimate the full potential of HTA for the generation and translation of evidence in TR. However, the WTP range also needs to be considered in the context of different factors and their potential impact on the translation process.

PHP158 DETERMINING THE MONETARY VALUE OF A QUALITY-ADJUSTED LIFE YEAR (QALY): SYSTEMATIC REVIEW OF THE EVIDENCE
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OBJECTIVES: To determine the monetary value of a QALY, varying between countries and jurisdictions, without however clear evidence of the valuation process. The objective of this study was to systematically review the literature for the evidence on the monetary valuation of a QALY.
METHODS: OVID MEDLINE® was independently searched for 1996-2011 by two reviewers using the keywords [QALY or (Quality and Adjusted and Life and Years)] and [Monetary and Valuation or Value or (Value estimation) or (Value determination)]. Included articles had to have applied a technique to determine the monetary value of a QALY, either on patients, the public, both, or through other statistical means. RESULTS: From 174 articles yielded by the review, 6 met the criteria, 4 were European studies (Denmark, The Netherlands, the UK and Spain), and 1 from each USA and China. None of them targeted only patients for the valuation, 4 targeted the general public, 2 studies focused on both. Three studies targeted a specific disease while 3 did not limit to any condition. Willingness-to-pay technique was the most common valuation method (5/6) and QALYs were determined with various direct or indirect elicitation measures. The average value for a QALY raised from the equivalent of less than USD$5,000 to more than USD$100,000. While some authors stated that preference valuation can lead to meaningful QALY values, the majority agreed on the large variability of the results depending on many factors such as income level, age, gender or disease condition and method of elicitation.
CONCLUSIONS: The literature on monetary valuation of a QALY is very limited, and the range of reported values is very wide and can be differently impacted by the survey tools used and by the characteristics of the population of interest.

PHP159 STRUCTURES FOR THE ROLE OF HEALTH TECHNOLOGY ASSESSMENT IN TRANSLATIONAL RESEARCH
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OBJECTIVES: Translational Research (TR) comprises activities aiming at the generation of biomedical knowledge, its transfer into clinical practice, and the take-up of research questions in biomedical research. It is described as a non-unidirectional process where innovation, diffusion and dissemination of a technology are focused. METHODS: Within the ILSA-GEN research collaboration, institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen). We performed literature search and expert interviews to build a concept that institutional and social aspects of TR in genomic medicine were investigated (TRiGen).

PHP160 INTRODUCING THE EUROPEAN NETWORK FOR PHARMAÇOEPIDEMIOLOGY AND PHARMACOVIGILANCE (ENCEPP): A BRIDGE BETWEEN MEDICINES REGULATION AND HEALTH OUTCOMES RESEARCH
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ATTAINING PATIENT HEALTH OUTCOMES (HO) is the underlying purpose of any health care intervention, including drug therapy. The measurement of HO is the basis for evaluating the quality of health services, and a key element in determining the value of health interventions. Along with effectiveness, long term safety is an integral component of HO of new authorized human medicines. The explicit assessment of the sustained benefit-risk trade-off of new authorised products must be undertaken to ensure that unintended harmful consequences are not offsetting the intended clinical benefits. Spontaneous reporting schemes provide an essential and continuous surveillance of the safety of medicines that is important for raising early signals of safety concerns, but ad-hoc post-authorisation safety studies (PASS) may be necessary to evaluate the safety of medicines more accurately. The European Network of Centres for Pharmacoeconomics and Pharmacovigilance (ENCEPP) is an initiative led by the European Medicines Agency aimed at further strengthening post-authorisation medicines research in Europe by facilitating the conduct of multi-centre, independent PASS focusing on safety and on benefit-risk. Specifically, ENCePP provides a unique point of access for all involved stakeholders seeking collaboration for the commissioning or the conduct of PASS. This is achieved by offering access to available expertise and research experience in the fields of pharmacoeconomics and pharmacovigilance across Europe brought together into a functioning network of excellence. It is anticipated that ENCePP will add to knowledge and the EU capacity to conduct PASS studies in the light of shared methodological and expertise. In doing so, ENCePP can serve as a bridge between medicines regulation and HO research in fostering risk/benefit management planning to minimise adverse events and maximise the benefit of marketed medicines.

PHP161 TOWARDS AN EFFICIENT NATIONAL DRUG POLICY IN THE RUSSIAN FEDERATION
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OBJECTIVES: Russia has a severe access to medicines problem. Of the 142 million people in Russia, only 20 million are eligible for outpatient medicines coverage as part of the Supplementary Medicines Cover (SDO) programme. More than half of the eligible opt-out for cash. The current government’s goal is to eventually establish universal outpatient medicines coverage. This study explores pharmaceutical policy options for Russia to improve efficiency and access to medicines. We employ a conceptual framework to explain Russia’s priorities and the weighing of each health policy component in developing policy approaches. Based on Russia’s particular policy needs, as well as economic environment and market structure, we provide policy options anchored in lessons from the European Union and the United States. Overall, Russia requires more efficient pricing policies to increase coverage and access to medicines. METHODS: Our findings suggest that, although generic market shares are high, there is room for lower generic prices. In order to address this inefficiency, we propose the adoption of tenders for high-selling off-patent molecules, and free pricing for molecules with sufficient market competition. A prioritization of direct or indirect elicitation measures can raise the average value for a QALY raised from the equivalent of less than USD$5,000 to more than USD$100,000. While some authors stated that preference valuation can lead to meaningful QALY values, the majority agreed on the large variability of the results depending on many factors such as income level, age, gender or disease condition and method of elicitation.

CONCLUSIONS: The literature on monetary valuation of a QALY is very limited, and the range of reported values is very wide and can be differently impacted by the survey tools used and by the characteristics of the population of interest.

PHP162 IMPACT OF AMNOG ON PHARMACEUTICAL PRICING TRENDS IN GERMANY
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OBJECTIVES: Understand the impact of AMNOG on pharmaceutical pricing trends. METHODS: The reforms implemented by AMNOG were reviewed by analysing recent changes in German healthcare system. A basket of five branded products was chosen to analyse pricing trends for past four quarters (Q3 2010, Q4 2010, Q1 2011, Q2 2011) and three quarters (Q3 2011, Q4 2011, Q1 2012) respectively. The price changes were calculated for all five drugs.

RESULTS: AMNOG introduced major changes in German healthcare system. Traditionally Germany was one of the highest priced pharmaceutical markets in Europe, with significant price inflation. However, since the implementation of AMNOG, there has been no price inflation for the selected five branded products. Our analysis indicates that AMNOG has significantly altered the pricing landscape in Germany. An unexpected finding was that the price of some products such as Aranesp saw significant price decreases (5-9% per quarter), driven by AMNOG and by launch of cheaper biosimilar products. Other products saw deflation of 0.6-1% per quarter. CONCLUSIONS: Pharmaceutical pricing landscape in Germany has significantly altered due to the implementation of AMNOG. Newer products would need to demonstrate innovation in comparative efficacy to command premium launch price or increase in price.