the submissions that failed to demonstrate efficacy (52%). Characteristics associated with a FFR being a biologic product, having an appropriate comparator, showing sufficient clinical evidence and being priced at a similar/lower price than the comparator. CONCLUSIONS: The presence of patient input was not associated with a FFR. The lack of significant association could be attributed to external factors. The lack of sufficient data in the CMS summary reports and the limited sample size of data available. It remains unclear how patient input is integrated into the decision making process.

HEALTH CARE USE & POLICY STUDIES – Disease Management

PHP5 STUDY OF THE SANITARY GEOGRAPHY OF COLOMBIA: A BIG DATA APPROACH
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OBJECTIVES: This study aims to propose a new geographic administrative organization of Colombian municipalities for health care management purposes. Rather than responding to arbitrary political boundaries, this division should answer to health needs and capacities, in order to facilitate the development of targeted policies to reach universal coverage and improve access to health services. METHODS: To achieve this, a big database was created: it contains information about different health-affecting topics: economic development, socio-cultural background, public and transportation services, environmental conditions and health indicators, supply and demand. These topics were measured with over 70 variables. After that, using a principal-component analysis, one or two indicators were created per topic. These indicators were used to build clusters that allowed the development of sanitary regions. Afterwards, another study was made in which people were tracked from their residence to the places where they received health services. Then, the country was divided into regions reflecting the migration flows: the sanitary geography of Colombia. RESULTS: Using the methodology, this study proposes a medical model and a disease map that are statistically significant and consistent with the reality of Colombia. Also, many networks were proposed, but 5 of them represented the national situation closely. Combining these alternatives, the study achieves its goal and creates a satisfactory segmentation of the country that is valuable for public policy. CONCLUSIONS: The proposed categories serve well the needs that originated this study and are an appropriate framework for health care management purposes. In fact, the Colombian Ministry of Health has used it as an input for telemedicine and first infancy projects and health care reform. Its main conclusion is that health cannot be worked using political divisions. It is fundamental to use supply, demand and context criteria to determine regions useful for policymakers.

HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP7 UNDERSTANDING STAKEHOLDER PERSPECTIVES ON MEDIICARe’S COVERAGE WITH EVIdENCE DEVELOPMENT (CED) POLICY
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OBJECTIVES: To understand key stakeholder recommendations for the Centers for Medicare & Medicaid Services (CMS) regarding the application of its CED policy, the principles of evidence development determinations (NCD) in which Medicare makes coverage contingent on additional evidence collection through a registry or prospective trials, and identify primary concerns with the policy across various stakeholders. METHODS: Unlike most markets where an FDA or CE mark is sufficient, Japan. CONCLUSIONS: It is important for foreign manufacturers to understand the implications of the Japanese regulatory barriers and address them in their foreign market strategies allowing them to assess product viability early on.

PHP10 PRICE DYNAMICS OF EXTERNAL REFERENCE PRICING-BASED SYSTEMS IN EUROPE
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OBJECTIVES: Concerns due to external reference pricing (ERP) have been expressed by industry regarding spill-over effects. It is also argued that ERP can lead to a downward price convergence. The objective of this project was to improve the better understanding of price dynamics of ERP-based systems using a simulation model. METHODS: A simulation model (developed for the EU Commission) was built to evaluate the impact of ERP as main criterion to set drug price across 28 European Union Member States, Iceland, Norway and Switzerland. Base case scenario simulated ERP price for a fictitious drug based on real ERP characteristics. Twenty fictitious scenarios simulated ERP price when introducing changes in ERP characteristics and/or exogenous effects such as genericisation, changes in exchange rates, price cuts. These scenarios were chosen based on the potential rapid and important price erosion attributed to ERP. Impacts of these scenarios were classified depending on changes in average drug price versus the base case. RESULTS: Applying solely ERP led to a low average drug price decrease (about 15% at 10 years), with an apparent equilibrium reached in approximately 7-8 years. Price differentials between countries remained substantial over 10 years (about 30%), suggesting a limited impact of ERP in price convergence. Even if impacted differently depending on scenarios, all tested scenarios induced price decreases and demonstrated the spillover effects of ERP. Frequent price revisions, iterative price cuts, large country baskets, price calculation methods, genericisation impact and prices’ sources were among the most influential parameters on the evolution of the drug price over time through ERP-based systems. The repetition and combination of various policies generated average price decrease of 92% at 10 years. CONCLUSIONS: This study is the first that quantifies the impact of various ERP policies on price erosion. This is a useful tool to support policy decision making.

PHP11 TIME LAGS FROM FDA DRUG APPROVAL TO PUBLICATION OF COST-UTILITY ANALYSIS
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OBJECTIVES: Cost-utility analysis (CUA) provides valuable information on the value of medical technology and is used by many payers to inform coverage and decision making. The objective of this project was to...