ernment in better health system performance, as well as the positive effect of increased public investment in health over the decade in health indicators and process insurance in the last 5 years. **CONCLUSIONS:** The results suggest a positive effect of central government spending on health and a negative effect of income inequality and margination index on maternal and infant mortalities, clearly mediated by socioeconomic factors characteristic of each state. This methodological approach is proposed to evaluate the relationships of the different levels of functioning of a health system and the dynamics with the social determinants of these levels.

HC3

PAYER AND PHYSICIANS EVIDENCE AND DISCOUNT EXPECTATIONS FOR BIOSIMILARS IN SIX LATIN AMERICAN COUNTRIES

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OBJECTIVES: As follow-up to prior work, investigate what evidence is required for reimbursement and prescribing of biosimilar drugs from four key therapy areas in six Latin American countries (Argentina, Brazil, Chile, Colombia, Mexico and Venezuela). Explore how these requirements may correspond to the regulatory pathways across the different countries. **METHODS:** Conduct secondary research to determine any recent changes to biosimilar regulation in the six studied countries. Conduct targeted primary research with payers and physicians in the six counties exploring: 1) The therapy areas that payers and physicians consider most attractive for biosimilars; 2) The baseline evidence (bioequivalence, comparative trial data, extrapolation of indications, etc.) that stakeholders require across the key therapy areas and across countries; 3) The level of discount, below the branded equivalent, that payers and physicians would require to consider biosimilars for access or to prescribe to their patients; 4) The expected access level and prescribing decisions for those biosimilars that meet these evidence and discount criteria; and 5) The degree to which payer and physician evidence expectations for biosimilars map to our understanding of the evolution of biosimilar regulatory environment. **RESULTS:** Public payers across the region see biosimilars as an opportunity to provide broader access to needed medications, although some stakeholders are more receptive than others and have lower requirements to prove comparability. Clinicians in general have concerns about safety and efficacy, however, their willingness to prescribe biosimilars correlates inversely with the degree of access and affordability of the branded agents. **CONCLUSIONS:** The regulatory and access environment for biosimilars in Latin America can be expected to be more favorable than in the US but not too dissimilar from Europe. However there are systematic differences across countries and therapy areas.

HC4

ANÁLISIS DE COSTO-EFECTIVIDAD DE LAS VACUNAS NEUMOCÓCICAS 13-VALENTE Y 23-VALENTE PARA ADULTOS DE ALTO RIESGO EN COLOMBIA

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OBJECTIVOS: El *Streptococcus pneumoniae* causa una importante morbilidad y mortalidad a nivel mundial, tanto en niños como en adultos. El objetivo de este análisis es estimar la costo-efectividad de la vacuna conjugada 13-valente (PCV13) vs la vacuna neumocócica polisacárida 23-valente (PPSV23) y vs no vacunación en los adultos de alto riesgo (inmunocomprometidos) >50 años en Colombia, desde la perspectiva del tercero pagador. **METODOLOGÍAS:** Se adaptó un modelo de Markov con horizonte de tiempo de la expectativa de vida y tasa de descuento 3% anual. Los comparadores fueron PCV13, PPSV23 y no vacunación (NV), cobertura estimada del 70%; revacunación a los 5 años con PPSV23 para >65 años según criterios del CDC. Se utilizó la población >50 años de alto riesgo en Colombia. Las probabilidades de transición, incidencia de enfermedades y efectividades de las vacunas fueron extraídas de la literatura (para PCV13 se utilizaron datos de PCV7 ajustados por inmunosenescencia), los costos médicos fueron proveídos por una EPS de cobertura nacional; los precios de las vacunas fueron tomados de la OPS para 2013. Los costos se presentan en US$ 2013. Las medidas de efectividad fueron número de casos evitados de enfermedad neumocócica invasiva – ENI (meningitis y bacteremia), neumonía invasiva, muertes y años de vida ganados (AVG). **RESULTADOS:** Vacunar con PCV13 vs NV y PPSV23 previene 4.389 y 4.134 casos de ENI; 2594 casos de neumonía invasiva y 550 y 536 muertes respectivamente. PCV13 genera 199 AVG más que PPSV23 y 4.712 AVG más que NV. El ahorro total esperado (vacunación + costos médicos) con PCV13 fue US$18,254,171 vs NV y US$26,204,251 vs PPSV23. **CONCLUSIONES:** Vacunar adultos inmunocomprometidos >50 años con PCV13 en Colombia es una alternativa costo-ahorradora en comparación con NV y con PPSV23 (US$12.57 y US$18.08 ahorrados por paciente respectivamente). Los hallazgos de este estudio soportan una toma de decisión a favor de PCV13.

HEALTH TECHNOLOGY ASSESSMENT STUDIES

HT1

EFFICACY AND SAFETY OF NEW ANTICOAGULANTS IN THE TREATMENT OF ATRIAL FIBRILLATION: A HEALTH TECHNOLOGY ASSESSMENT

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Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia. Patients with AF have a 4-5 times larger risk of stroke than age-matched controls. Anticoagulation with warfarin is currently the standard of care but the requirement for routine monitoring and drug and food interactions, makes its use is suboptimal. New anticoagulants were developed to eliminate these barriers and the results are promising. However, the incorporation of these technologies within the Brazilian Unified Health System (SUS) demands proper consideration. **OBJECTIVES:** To evaluate the efficacy and safety of new anticoagulants in the treatment of AF. **METHODS:** Health Technology Assessment of multiple technologies. We searched the electronic databases Cochrane Library, CRD, Pubmed, Embase and Lilacs, to search for the best available evidence assessing the new oral anticoagulants, compared with warfarin in patients with AF. **RESULTS:** Three randomized controlled trials evaluating dabigatran (110mg e 150mg), rivaroxaban 20mg and apixaban 5mg were included, all of them compared with warfarin. In this regard, dabigatran 110mg was associated with similar rates of stroke or systemic embolism and with a 20% relative risk reduction (RRR) of major hemorrhage compared with warfarin. Dabigatran 150mg was associated with a 34% RRR of stroke or systemic embolism and similar rates of major hemorrhage. Rivaroxaban 20mg was associated with similar rates of the primary efficacy and safety outcomes. Finally, apixaban was associated with a 21% RRR of stroke or systemic embolism and with 31% RRR of major bleeding compared with warfarin. **CONCLUSIONS:** There is strong evidence supporting these new technologies, especially regarding safety. Further studies are needed to support decision making, especially with regards to cost-effectiveness issues.

HT2

HEALTH TECHNOLOGY ASSESSMENT REPORT FOR POSITRON EMISSION TOMOGRAPHY IN PATIENTS WITH CANCER

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OBJECTIVES: Positron Emission Tomography (PET) might be useful for cancer staging and follow-up. The objetive was to assess the available evidence on efficacy, safety and coverage policies for use of PET in oncology. **METHODS:** A bibliographic search was carried in PubMed, DARE, NHS EED, in health technology assessment (HTA) agencies and health insurers. Priority was given to systematic reviews; randomized clinical trials (RCTs); HTA; clinical practice guidelines (CPGs) and coverage policies (CPs). **RESULTS:** Thirty-seven systematic reviews, 3 RCTs and 32 observational studies, 51 CPGs, 15 HTAs and 28 CPs were included. Breast Cancer (17 studies):There is no evidence of its use as routine practice. Some CPGs and CPs recommend it for suspicious images that could not be clarified through conventional studies. PET is not recommended for axillary staging or neodadyuvant response prediction. Lung Cancer (44 studies):The accuracy for lung nodule is similar to conventional methods. Most CPGs do not recommend the use of PET for lung cancer staging except in some non-small cell lung cancer with previous negative tests for metastasis. Colorectal Cancer (20 studies): There is no evidence of its use as routine practice. It might be used in patients with suspected recurrence and non-conclusive images. Genitourinary Tumors (70 studies): PET might be associated with changes in diagnosis or therapeutic only in specific cases, such as ovarian cancer with suspected recurrence and normal conventional images, in residual tumors due to seminoma and cervical cancer recurrence eligible for curative treatment. Primary Tumors of the Central Nervous System (15 studies):PET is not recommended as routine practice. CPGs, RCTs and CPs recognize its usefulness for differential diagnosis between relapse and radionecrosis. **CONCLUSIONS:** There is no evidence to support the use of PET in cancer patients as routine practice. At present, its use should be restricted to specific patients.

HT3

FORMULATIONS OF AMPHOTERICIN B FOR THE TREATMENT OF FUNGAL INFECTIONS IN PATIENTS WITH HIV/AIDS

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OBJECTIVES: To evaluate the efficacy, safety and cost-effectiveness data of lipid formulations of amphotericin B to establish which should be used for the treatment of systemic fungal infections in patients with HIV/AIDS in Brazil. **METHODS:** We searched The Cochrane Library, Centre for Reviews and Dissemination, Tripdatabase, Medline and LILACS databases aiming to find systematic reviews (SRs) and economic evaluations (EE) comparing liposomal amphotericin B (L-AmB) or amphotericin B lipid complex (ABLC). Health Technology Assessments (HTA) were searched on agencies websites. Quality of the evidence and strength of recommendation were evaluated using the GRADE system. **RESULTS:** We selected five SRs, in which one evaluated only safety data, and two economic evaluations. Four SRs were classified as poor quality and the strength of recommendation was considered weak in favor of L-AmB in all studies. In general there were no statistically significant differences in terms of survival and response to treatment ($p<0,05$). However, L-AmB was associated with a lower risk of nephrotoxicity and increased serum creatinine. The two economic studies included had conflicting results. In the cost-minimization study there was no difference in total costs of the therapies, but the daily cost of acquisition and concomitant antifungal therapy and adverse events were lower for ABLC (0,002 and 0,027). The incremental cost-effectiveness analysis favored the L-AmB (€41734 *vs.* €51724). Both studies showed important limitations and there were no studies considering the Brazilian context. **CONCLUSIONS:** Considering all the studies found, as well as their limitations, there is a lack of evidence to support the spread use of L-amB in patients with HIV/AIDS affected by fungal infections, unless strictly in cases where patients have abnormal renal function. Also, L-AmB could be used in case of intolerance to conventional amphotericin B.

HT4

EFICÁCIA E SEGURANÇA DE RANIBIZUMABE E BEVACIZUMABE NO TRATAMENTO DE DEGENERAÇÃO MACULAR RELACIONADA A IDADE

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