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OBJECTIVOS: El síndrome coronario agudo (SCA) representa alta carga de la enfermedad para México. Los biomarcadores cardiacos Point of Care Testing (POCT) mejoran la oportunidad diagnóstica, permiten acelerar el tratamiento y reducen la mortalidad. El propósito del estudio fue evaluar, desde la perspectiva del proveedor de servicios de salud, su impacto clínico y económico en los servicios de urgencias en México. **METODOLOGÍAS:** Estudio comparativo, en situaciones habituales, del servicio de urgencias del Hospital General de Zona No. 1-A del Instituto Mexicano del Seguro Social (IMSS) en México, D.F. Los grupos de comparación fueron: sin disponibilidad de biomarcadores POCT, que incluyó pacientes adultos, sin distinción de género, que acudieron al hospital por dolor torácico agudo (DTA) entre marzo y abril de 2012; y con disponibilidad de biomarcadores POCT, que incluyó pacientes que acudieron entre junio y septiembre de 2012. Se realizó seguimiento durante la estancia en urgencias. El resultado de interés fue la identificación de pacientes con SCA. Los costos se calcularon con los recursos utilizados durante la estancia en urgencias; se expresaron de dólares norteamericanos (tasa de cambio 12.65 pesos/dólar). **RESULTADOS:** Se incluyeron 336 pacientes, edad promedio 55±18 años, 52% hombres. El grupo sin POCT incluyó 148 pacientes y con POCT 188. Con POCT se identificaron 50 pacientes con SCA (0.27, IC95% 0.20–0.33) vs 21 sin POCT (0.14, IC95% 0.08–0.19), p=0.006. El costo promedio de la atención en urgencias con POCT fue US$178 (IC95% US$161-US$ 340) y sin POCT fue de US$168 (IC95% US$152-US$320), p=0.93. El costo-efectividad promedio para identificar un paciente con SCA sin POCT fue US$1,206 y con POCT fue US$661. **CONCLUSIONES:** La disponibilidad de biomarcadores POCT en urgencias es costo-efectivo, ya que mejora la probabilidad de identificar SCA en pacientes con DTA y no existe diferencia en el costo de su implementación para el IMSS.

CV2

ESTIMATION OF THE COST-EFFECTIVENESS OF APIXABAN IN NON-VALVULAR ATRIAL FIBRILLATION IN ARGENTINA

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OBJECTIVES: Atrial Fibrillation (AF) affects about 2% of the population and increases 5-fold the risk of stroke and systemic embolism. This risk is managed with vitamin K antagonists (VKA) or aspirin for patients according to their suitability to receive oral anticoagulants (OA) but with several limitations. Therefore, novel OAs have become a treatment option. Apixaban is the most recent drug approved for thrombotic prevention in AF. Our aim is to estimate the cost-effectiveness (CE) of apixaban in AF in Argentina. **METHODS:** We conducted a literature review of published epidemiological AF, and stroke data from Argentina. Data about apixaban, warfarin, rivaroxaban, dabigatran and aspirin were obtained from published trials and indirect comparisons. Two Delphi Panels, with local experts representing private, public and social security health subsectors were held and reviewed and validated data collected and provided information on local treatment patterns. Costs, expressed in 2012U$S, were gathered from published reports and a local database. Apixaban was compared with each available AF treatment option allocating them into a simulated cohort of 1,000 patients per treatment group (according with their suitability for OA) over a lifetime horizon using an MS EXCEL based Markov model. We adopted payer's perspective reporting weighted mean costs for QALY gained. CE threshold for Argentina was considered as per WHO-CHOICE and World Bank data (ranging from 9740 to 29220U$S). **RESULTS:** For the suitable population, the cost per QALY gained with apixaban was U$S 9938 and 1131 versus warfarin and dabigatran 150 mg respectively, and dominant compared to dabigatran 110 mg and rivaroxaban. For the unsuitable population, apixaban was dominant compared to available alternatives: aspirin, dabigatran 110 mg, dabigatran 150 mg, and rivaroxaban. **CONCLUSIONS:** on the model using local inputs, apixaban is dominant or cost-effective according to local CE thresholds becoming the treatment choice in Argentina both in the suitable and unsuitable populations

CV3

PULSE PRESSURE AND STROKE RISK: DEVELOPMENT AND VALIDATION OF A STROKE RISK EQUATION

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OBJECTIVES: Previous stroke risk equations identified systolic blood pressure (SBP) as a key predictive factor. Recent evidence suggests that pulse pressure (PP), defined as the difference between SBP and diastolic blood pressure, could be a new risk factor. This project aims at developing and validating a new stroke risk equation incorporating PP as a potential risk factor. **METHODS:** Electronic medical records including laboratory data of a random sample of 97,237 hypertensive patients from a US integrated health delivery system were analyzed (01/2004-05/2012). Patients with ≥1 peripheral PP (PPP) reading and ≥6 months of observation (baseline period) prior to the first evidence of hypertension were randomly split into the development (two-thirds of sample) and validation (one-third of sample) datasets. Stroke events were identified using ICD-9-CM 433.xx-436.xx. Cox proportional hazards models assessed time to first stroke event based on baseline risk factors, including PPP, age, gender, SBP, smoking status, BMI, diabetes, and cardiac comorbidities. The optimal risk equation was selected using the least absolute shrinkage and selection operator (LASSO); performance was evaluated by the c-statistic. **RESULTS:** A total of 30,525 patients without stroke (mean age 58.2, 48% male) and 4,272 patients with stroke (mean age 67.3, 48% male) were selected. Average observation was 3.89 years. PPP was higher among patients who developed stroke (mean [SD] PPP, stroke: 62.0 [15.3] mmHg; non-stroke: 58.1 [14.0] mmHg, p<.001). The best performing risk equation (c-statistic, development: 0.732; validation: 0.722) included PPP (hazard ratio per 10 mmHg increase: 1.0676, p<.001) as a significant risk factor for stroke in addition to age and diabetes, among others. **CONCLUSIONS:** This stroke risk equation shows that greater PP is a significant predictive factor for increased stroke risk, even in the presence of known risk factors, including SBP. PP should be considered by practitioners along with traditional risk factors in treatment strategies to prevent stroke.

CV4

ANÁLISIS DE COSTO-EFECTIVIDAD DEL USO DE ESTATINAS EN LA PREVENCIÓN DE EVENTOS CARDIOVASCULARES EN COLOMBIA

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OBJECTIVOS: Las enfermedades cardiovasculares (ECV) son una de las principales causas de muerte precoz en los países occidentales, los fármacos hipolipemiantes están indicados para disminuir el riesgo cardiovascular V. El objetivo de este análisis es evaluar la costo-efectividad del uso de estatinas en prevención primaria de ECV en Colombia. **METODOLOGÍAS:** Se utilizó un modelo compuesto por un árbol de decisión y un Markov. El horizonte de tiempo fue la expectativa de vida. Los comparadores fueron: atorvastatina (20mg/día) vs. rosuvastatina (20 mg/día). Se simuló una cohorte de 100 pacientes de 62 años con valor inicial de colesterol LDL de 137.28mg/dL y riesgo anual basal de ECV ≤3.5%. Se utilizó una tasa de descuento de 3%. Los datos de utilidad, eficacia y mortalidad por los eventos fueron tomados de la literatura, ajustados por información local. La medida de efectividad empleada fueron los años de vida ganados (AVG), los años de vida ajustados por calidad (AVACs) y los casos de ECV evitados. Los precios de los medicamentos fueron tomados del SISMED y los costos de una EPS de presencia nacional. Se utilizó como umbral de disposición a pagar, el equivalente a 3 PIB per cápita ≈ US$40,000. **RESULTADOS:** En el horizonte de la expectativa de vida, el ahorro total esperado por persona con atorvastatina fue de US$6374 en comparación con rosuvastatina (costos totales: US$8,802 y US$15,176, respectivamente); rosuvastatina obtuvo 0.0108 AVACs, 0.0127 AVG y 0.0023 casos evitados más que atorvastatina por persona; el ICER de rosuvastatina fue de US$507,266/AVAC, US$426,320/AVG y US$2,624,876/casos evitados de ECV. **CONCLUSIONES:** Atorvastatina sería la alternativa de elección en la prevención de ECV. El diferencial de AVG, AVACs y casos de ECV de rosuvastatina es muy bajo para su costo incremental y su ICER se encuentra por encima del umbral definido, por lo que no es una opción costo-efectiva.

HEALTH CARE EXPENDITURE STUDIES

HC1

ADDRESSING CHILDHOOD-OBESITY IN MEXICO: SAVINGS ON HEALTH CARE EXPENDITURES FROM REGULATING FOOD AND BEVERAGE SALES IN BASIC EDUCATION SCHOOLS

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OBJECTIVES: Estimate potential direct savings for the Mexican Healthcare System generated by the operation of the "Technical Guidelines for the Sale or Distribution of Food and Beverages in Establishments of Basic Education". **METHODS:** The microsimulation model "Chronic Disease Prevention (CDP)" developed by OECD-WHO was used for projecting health gains and costs of treatment in a period of 100 years. The model was adjusted to accommodate the range 6-14 years old stated in the Guidelines. Mexican data on incidence, prevalence, mortality, population at risk, annual unit costs and relative risk of selected chronic diseases (diabetes mellitus type 2, hypertension, cardiovascular, hypercholesterolemia) attributable to obesity and the treatment of obesity as disease itself was used. Sensitivity analyses were developed for most variables used in the model. **RESULTS:** Under a base case scenario present value of potential savings in total spending on medical care associated with the implementation of the Guidelines amount to USD$1052.2 million in 2008. Most savings are derived from averted cases of hypertension (32.7%), obesity-overweight (28.6%) and diabetes mellitus type II (17.8%). Results are robust to changes in all parameters analyzed. Amounts obtained are an underestimation of potential savings as neither expensive complications as renal failure nor other chronic diseases attributable to obesity as arthritis, colorectal or breast cancer were included. **CONCLUSIONS:** The Guidelines, —developed by the Ministry of Public Education in coordination with the Ministry of Health—, represent a good example of cooperation among different sectors to solve a complex public health problem. Results shows the importance of implementing preventive interventions aimed at reducing the prevalence of chronic diseases related to poor eating habits, inadequate physical activity and obesity in Mexico. Implementation of the Guidelines involves significant direct savings that can be assigned to other health needs of the Mexican population.

HC2

EFFECT OF HEALTH SPENDING, INCOME INEQUALITY AND MARGINATION INDEX ON THE EFFICIENCY OF THE HEALTH SYSTEM IN MEXICO

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OBJECTIVES: To explore the effect of health spending, income inequality and margination on maternal and child health care in México. **METHODS:** With the 32 Mexican states an ecological multi spatial study was performed. Correlations between maternal and infant mortalities in the total per capita spending (central and state governments from 2000 to 2010), Gini and margination indexes were computed. Conventional and robust multiple linear regressions were used to explore the effects on the technical efficiency of these indicators in the State's health systems. **RESULTS:** Negative correlations with Spearman rho -0.62 and -0.28 near to the margination and Gini indexes respectively (p <0.05), and higher than 0.59 for the margination index (p <0.05) between life expectancy at birth for the first and the last infant mortality. The multiple linear regression models established the relationship between the deprivation and Gini indexes in health indicators. It showed the positive effect of funding from central gov-

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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