

## Research on Methods – Conceptual Papers

## PRM5

## INCORPORATING EQUITY INTO DEVELOPING AND IMPLEMENTING EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

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**BACKGROUND:** Clinical practice guidelines (CPG) are useful tools for clinical decision making, processes standardization and quality of care improvements. The current General Social Security and Health System (GSSHS) in Colombia is promoting the initiative of developing and implementing CPG based on evidence in order to improve efficiency and quality of care. The reduction of inequalities in health should be an objective of the GSSHS. **OBJECTIVES:** The main propose of this analysis is to argue why it is necessary to consider the incorporation of equity considerations in the development and implementation of clinical practice guidelines based on the evidence. **METHODS:** A series of reflections were made. Narrative description was used for showing the arguments that support the main findings. **RESULTS:** Among the main findings are: 1) Differential effectiveness by social groups of interventions could diminish final effectiveness of CPG in the GSSHS; 2) To not consider geographical, ethnic, socioeconomic, cultural and access diversity issues within the CPG could have a potential negative impacts of the CPG; 3) Overall effectiveness of CPG could be better if equity issues are included in the quality verification checklist of the guideline questions; and 4) Incorporating equity issues in the process of developing CPG could be cost effective, because improve overall effectiveness of CPG. **CONCLUSIONS:** To include equity issues in CPG and can help in achieving more equitable health outcomes. From this point of view CPG could be key tools to promote equity in care and health outcomes. Keywords: health inequalities, clinical practice guidelines, essay (Source: MeSH, NLM).

## PRM6

## TRANSLATION OF PATIENT-REPORTED OUTCOMES MEASURES

## TRANSLATABILITY REVIEW AND ITEM DEFINITION

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Translatability Review and Item Definition documents are key components to any successful Patient Reported Outcome (PRO) translation and are especially relevant in item banking initiatives. Translatability review helps to ensure concepts, constructs and phrasing in the source language are appropriate for translation into other languages and for multicultural contexts. Identifying potential issues during item development can result in improvement of the source item. When modification of the source is not possible or necessary, translatability review can be seen as a first step towards identifying acceptable translation alternatives which can be used by linguists. The assessment of item translatability before the translation process begins also facilitates the creation of item definitions, a critical tool for increasing translation accuracy. The Item Definition document refers to the identification and clarification of concepts the items are trying to measure. The development of item definitions is an iterative process combining efforts by translation coordinators and item/questionnaire developers as well as input from linguists. These steps are especially essential in item banking initiatives in which items are frequently made available by different developers and sources on behalf of varying patient populations, with disparate answer categories. As translation of PRO measures is much more than just a literal, word for word translation process, these steps are fundamental in furthering the equivalence, comparability and data poolability of translated language versions. This presentation will provide information regarding when to carry out these steps, how to carry them out and who should be involved in them. Linguistic issues such as, but not limited to, sentence structure, register and ambiguity will be discussed. Examples from National Institutes of Health Spanish translation projects Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) and The Patient-Reported Outcomes Measurement Information System (PROMIS) will be highlighted.

## Respiratory-Related Disorders – Cost Studies

## PRS1

## BUDGET IMPACT ANALYSIS OF FLUTICASONE FUROATE (FFNS) IN TREATMENT OF ALLERGIC RHINITIS PATIENTS IN MEXICO

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**OBJECTIVES:** To estimate the 5-year projected impact on the annual pharmacy budget for allergic rhinitis (AR) patients in Mexico. **METHODS:** Mexican prevalence and treatment data for AR patients were obtained from published and nonpublished sources. The model considered 2 scenarios—without (pre) and with (post) FFNS. Market share data for corticosteroid treatment options for AR pre-FFNS and in the first year post-FFNS were obtained from non-published, real-world drug utilization data collected by GSK. Market shares for the second until fifth years post-FFNS were forecasted by the study authors. Drug costs were based on the Mexican Social Security Institute (IMSS). Wholesale Acquisition Cost was accessed on March 2010. The results for each indication were analyzed individually and summed to reflect the total impact of FFNS. Results were also considered on a per member per month (PMPM) basis to examine the relative impact on the plan. Sensitivity analyses were performed by varying several model input parameters. **RESULTS:** The estimated prevalence of AR in 2010 was 10%. In the year after its introduction, 60% of the AR population filled a prescription for FFNS. The estimated total cost for AR treatment prior to introduction of FFNS was

\$ 552 million and (532 to \$ 384 million post FFNS. The incremental decrease in pharmacy benefit cost was (\$ 20 to \$ 84 millions) in 2010 dollars. These reductions translated to a medical care cost saving of \$ 266 millions over 5 years. **CONCLUSIONS:** Model results suggest that increasing the use of fluticasone furoate decreases total budget costs due to decreased acquisition drug costs.

## PRS2

## COSTOS DE ATENCION MEDICA ATRIBUIBLES AL CONSUMO DE TABACO EN MÉXICO

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**OBJECTIVOS:** Estimar la carga económica, en términos de costos de atención médica que las enfermedades atribuibles al consumo de tabaco representan para el sistema de salud Mexicano. **METODOLOGÍAS:** La estimación del costo directo de atención médica atribuible al tabaquismo se realizó con las enfermedades: CP, IAM, EPOC y EVC, en 2009. Instituciones de salud participantes: institutos nacionales (INNN, INCAN, INER e INCAR), Hospital Central Militar (HCM), Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (sólo incluye al CMN "20 de Noviembre" y al HRZ "1.º de Octubre" del ISSSTE) e Instituto Mexicano del Seguro Social (IMSS). El análisis de costos fue realizado desde la perspectiva del proveedor de servicios, utilizando la metodología Cost of Illness, basada en la prevalencia así como la creación de un panel de expertos multidisciplinario, que clasificó la atención médica: Ambulatoria, Urgencias, Hospitalización, Quirófano, Unidad de Cuidados Intensivos, Quimioterapia, Cuidados Paliativos y Radioterapia. Finalmente empleamos la fracción atribuible por tabaco para estimar dichos costos. Los costos están expresados en pesos mexicanos (\$) y en dólares americanos (USD) del 2009. **RESULTADOS:** Los costos institucionales de atención médica por tabaquismo ascendieron a \$459,026,446.2 (35,131,636.3 USD); Institutos Nacionales, \$92,016,175.0 (7,042,467.4 USD); HCM, \$103,483,466.1 (7,920,117.7 USD); ISSSTE y \$9,564,089,959.0 (731,988,608.4 USD); IMSS, respectivamente. Los costos nacionales por tabaquismo oscilaron entre \$30,213,184,046.5 (2,312,369,147.7 USD) y \$44,484,500,278.1 (3,404,625,802.9 USD). El IAM y el CP fueron los más caros. **CONCLUSIONES:** Nuestros resultados muestran la elevada carga económica que representan para el sistema de salud mexicano el tabaquismo y son evidencia científica sobre la magnitud del problema. Como las enfermedades asociadas al tabaquismo son prevenibles, una adecuada política de salud para el control del tabaco, produciría una reasignación de los recursos económicos que actualmente se destinan al tratamiento de las enfermedades provocadas por el tabaco hacia otros programas institucionales.

## PRS3

## COSTOS DE ATENCION MEDICA DE LA ENFERMEDAD PULMONAR OBSTRUCTIVA CRONICA ATRIBUIBLES AL TABACO

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**OBJECTIVOS:** Estimar los costos directos de atención médica de la Enfermedad Pulmonar Obstructiva Crónica (EPOC) asociados al consumo de tabaco, en el Instituto Nacional de Enfermedades Respiratorias. **METODOLOGÍAS:** Durante el 2009 se estimaron los costos directos de la EPOC de los pacientes que fueron atendidos en el año 2008 en el Instituto. El análisis de costos se hizo desde la perspectiva del proveedor de servicios, considerando el enfoque de la metodología Cost of Illness (COI), basada en la prevalencia así como la creación de un panel de expertos multidisciplinario, que clasificó la atención médica en 4 eventos: Ambulatoria, Urgencias, Hospitalización y Unidad de Cuidados Intensivos. Finalmente empleamos la fracción atribuible por tabaco para estimar los costos por consumo de tabaco. El costo además se estima de acuerdo a la gravedad de la enfermedad con los criterios GOLD. **RESULTADOS:** El costo anual de la EPOC atribuible al tabaco fue de \$36 millones. El costo promedio por paciente, de acuerdo a GOLD fue de \$30 mil; estadio I, \$37 mil; estadio II, \$84 mil; estadio III y \$288 mil; estadio IV. Entre más grave fue la enfermedad, (III y IV) mayores costos resultaron. **CONCLUSIONES:** La evaluación económica de los costos directos que ocasiona el EPOC debido al tabaquismo, confirma la gran carga económica que representan estos pacientes para el presupuesto del INER y del sistema de salud mexicano. Estos resultados proveen suficiente evidencia científica para apoyar la implementación de políticas del sector salud relacionadas con el tabaco.

## PRS4

## ECONOMIC EVALUATION OF THE USE OF PALIVIZUMAB AS PROPHYLACTIC TREATMENT FOR THE REDUCTION OF COMPLICATIONS ASSOCIATED WITH RESPIRATORY SYNCYTIAL VIRUS IN PRE-TERM PATIENTS

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**OBJECTIVES:** To determine the incremental cost-effectiveness ratio (ICER) of the use of palivizumab as prophylaxis for the reduction of complications associated with respiratory syncytial virus (RSV) in pre-term patients <29 weeks of gestational age (WGA) under the Mexican public health sector perspective. **METHODS:** A cost-utility model was developed based on a decision tree that evaluated both scenarios of prophylaxis and no-prophylaxis. Epidemiological and cost data were obtained from different Mexican sources such as the Mexican Institute of Social Security (IMSS) by analysing birth rates. Clinical effectiveness was obtained from the international literature (Cardiac Synagis Study Group, The IMPact-RSV Study Group MEDI-493 Study Group). Prophylaxis therapy consisted of 5 applications of palivizumab during the winter season in Mexico. The dose scheme considered was 15 mg/kg. The effectiveness outcomes were quality adjusted life years (QALYs). Since