EMCA Gestión de la Calidad Asistencial

Boletín de Artículos Científicos

Octubre 2014
Número 86

Subdirección General de Planificación, Calidad e Investigación

1. **ARTÍCULO Nº: 4450**

Kieft RA, de Brouwer BB, Francke AL, Delnoij DM. ***How nurses and their work environment affect patient experiences of the quality of care: a qualitative study.*** BMC.Health Serv.Res. 2014; 14: 249

BACKGROUND: Healthcare organisations monitor patient experiences in order to evaluate and improve the quality of care. Because nurses spend a lot of time with patients, they have a major impact on patient experiences. To improve patient experiences of the quality of care, nurses need to know what factors within the nursing work environment are of influence. The main focus of this research was to comprehend the views of Dutch nurses on how their work and their work environment contribute to positive patient experiences. METHODS: A descriptive qualitative research design was used to collect data. Four focus groups were conducted, one each with 6 or 7 registered nurses in mental health care, hospital care, home care and nursing home care. A total of 26 nurses were recruited through purposeful sampling. The interviews were audiotaped, transcribed and subjected to thematic analysis. RESULTS: The nurses mentioned essential elements that they believe would improve patient experiences of the quality of nursing care: clinically competent nurses, collaborative working relationships, autonomous nursing practice, adequate staffing, control over nursing practice, managerial support and patient-centred culture. They also mentioned several inhibiting factors, such as cost-effectiveness policy and transparency goals for external accountability. Nurses feel pressured to increase productivity and report a high administrative workload. They stated that these factors will not improve patient experiences of the quality of nursing care. CONCLUSIONS: According to participants, a diverse range of elements affect patient experiences of the quality of nursing care. They believe that incorporating these elements into daily nursing practice would result in more positive patient experiences. However, nurses work in a healthcare context in which they have to reconcile cost-efficiency and accountability with their desire to provide nursing care that is based on patient needs and preferences, and they experience a conflict between these two approaches. Nurses must gain autonomy over their own practice in order to improve patient experiences.

2. **ARTÍCULO Nº: 4451**

Krucien N, Le VM, Pelletier-Fleury N. ***Adaptation and validation of the patient assessment of chronic illness care in the French context.*** BMC.Health Serv.Res. 2014; 14: 269

BACKGROUND: Chronic diseases are major causes of disability worldwide with rising prevalence. Most patients suffering from chronic conditions do not always receive optimal care. The Chronic Care Model (CCM) has been developed to help general practitioners making

quality improvements. The Patient Assessment of Chronic Illness Care (PACIC) questionnaire was increasingly used in several countries to appraise the implementation of the CCM from the patients' perspective. The objective of this study was to adapt the PACIC questionnaire in the French context and to test the validity of this adaptation in a sample of patients with multiple chronic conditions. METHODS: The PACIC was translated into French language using a forward/backward procedure. The French version was validated using a sample of 150 patients treated for obstructive sleep apnea syndrome (OSAS) and having multiple chronic co-morbidities. Several forms of validity were analysed: content; face; construct; and internal consistency. The construct validity was investigated with an exploratory factorial analysis. RESULTS: The French-version of the PACIC consisted in 18 items, after merging two pairs of items due to redundancy. The high number of items exhibiting floor/ceiling effects and the non-normality of the ratings suggested that a 5-points rating scale was somewhat inappropriate to assess the patients' experience of care. The construct validity of the French-PACIC was verified and resulted in a bi-dimensional structure. Overall this structure showed a high level of internal consistency. The PACIC score appeared to be significantly related to the age and self-reported health of the patients. CONCLUSIONS: A French-version of the PACIC questionnaire is now available to evaluate the patients' experience of care and to monitor the quality improvements realised by the medical structures. This study also pointed out some methodological issues about the PACIC questionnaire, related to the format of the rating scale and to the structure of the questionnaire.

3. **ARTÍCULO Nº: 4452**

Holt PJ, Sinha S, Ozdemir BA, Karthikesalingam A, Poloniecki JD, Thompson MM. ***Variations and inter-relationship in outcome from emergency admissions in England: a retrospective analysis of Hospital Episode Statistics from 2005-2010***. BMC.Health Serv.Res. 2014; 14: 270

BACKGROUND: The quality of care delivered and clinical outcomes of care are of paramount importance. Wide variations in the outcome of emergency care have been suggested, but the scale of variation, and the way in which outcomes are inter-related are poorly defined and are critical to understand how best to improve services. This study quantifies the scale of variation in three outcomes for a contemporary cohort of patients undergoing emergency medical and surgical admissions. The way in which the outcomes of different diagnoses relate to each other is investigated. METHODS: A retrospective study using the English Hospital Episode Statistics 2005-2010 with one-year follow-up for all patients with one of 20 of the commonest and highest-risk emergency medical or surgical conditions. The primary outcome was in-hospital all-cause risk-standardised mortality rate (in-RSMR). Secondary outcomes were 1-year all-cause risk-standardised mortality rate (1 yr-RSMR) and 28-day all-cause emergency readmission rate (RSRR). RESULTS: 2,406,709 adult patients underwent emergency medical or surgical admissions in the groups of interest. Clinically and statistically significant variations in outcome were observed between providers for all three outcomes ($p < 0.001$). For some diagnoses including heart failure, acute myocardial infarction, stroke and fractured neck of femur, more than 20% of hospitals lay above the upper 95% control limit and were statistical outliers. The risk-standardised outcomes within a given hospital for an individual diagnostic group were significantly associated with the aggregated outcome of the other clinical groups. CONCLUSIONS: Hospital-level risk-standardised outcomes for emergency admissions across a range of specialties vary considerably and cross traditional speciality boundaries. This suggests that global institutional infra-structure and processes of care influence outcomes. The implications are far reaching, both in terms of investigating performance at individual hospitals and in understanding how hospitals can learn from the best performers to improve outcomes.

4. **ARTÍCULO Nº: 4453**

Sanchez SH, Sethi SS, Santos SL, Boockvar K. ***Implementing medication reconciliation from the planner's perspective: a qualitative study.*** BMC.Health Serv.Res. 2014; 14(1): 290

BACKGROUND: Medication reconciliation can reduce adverse events associated with prescribing errors at transitions between sites of care. Though a U.S. Joint Commission National Patient Safety Goal since 2006, at present organizations continue to have difficulty implementing it. The objective of this study was to examine medication reconciliation implementation from the perspective of individuals involved in the planning process in order to identify recurrent themes, including facilitators and barriers, that might inform other organizations' planning and implementation efforts. METHODS: We performed semi-structured interviews with individuals who had a role in planning medication reconciliation implementation at a large urban academic medical center in the U.S. and its affiliated Veterans Affairs hospital. We queried respondents' perceptions of the implementation process and their experience with facilitators and barriers. Transcripts were coded and analyzed using a grounded theory approach. The themes that emerged were subsequently categorized using the Consolidated Framework for Implementation Research (CFIR). RESULTS: There were 13 respondents, each with one or more organizational roles in quality improvement, information technology, medication safety, and education. Respondents described a resource- and time- intensive medication reconciliation planning process. The planning teams' membership and functioning were recognized as important factors to a successful planning process. Implementation was facilitated by planners' understanding of the principles of performance improvement, in particular, fitting the new process into the workflow of multiple disciplines. Nevertheless, a need for significant professional role changes was recognized. Staff training was recognized to be an important part of roll-out, but training had several limitations. Planners monitored compliance to help sustain the process, but acknowledged that this did not ensure that medication reconciliation actually achieved its primary goal of reducing errors. Study findings fit multiple constructs in the CFIR model. CONCLUSIONS: Study findings suggest that to improve the likelihood of a successful implementation of medication reconciliation, planners should, among other considerations, involve a multidisciplinary planning team, recognize the significant professional role changes that may be needed, and consider devoting resources not just to compliance monitoring but also to monitoring of the process' impact on prescribing.

5. **ARTÍCULO Nº: 4454**

Weedon-Fekjaer H, Romundstad PR, Vatten LJ. ***Modern mammography screening and breast cancer mortality: population study.*** BMJ. 2014; 348: g3701

OBJECTIVE: To evaluate the effectiveness of contemporary mammography screening using individual information about screening history and breast cancer mortality from public screening programmes. DESIGN: Prospective cohort study of Norwegian women who were followed between 1986 and 2009. Within that period (1995-2005), a national mammography screening programme was gradually implemented, with biennial invitations sent to women aged 50-69 years. PARTICIPANTS: All Norwegian women aged 50-79 between 1986 and 2009. MAIN OUTCOME MEASURES: Multiple Poisson regression analysis was used to estimate breast cancer mortality rate ratios comparing women who were invited to screening (intention to screen) with women who were not invited, with a clear distinction between cases of breast cancer diagnosed before (without potential for screening effect) and after (with potential for screening effect) the first invitation for screening. We took competing causes of death into account by censoring women from further follow-up who died from other causes. Based on the observed mortality reduction combined with the all cause and breast cancer specific mortality in Norway in 2009, we used the CISNET (Cancer Intervention and Surveillance

Modeling Network) Stanford simulation model to estimate how many women would need to be invited to biennial mammography screening in the age group 50-69 years to prevent one breast cancer death during their lifetime. RESULTS: During 15 193 034 person years of observation (1986-2009), deaths from breast cancer occurred in 1175 women with a diagnosis after being invited to screening and 8996 women who had not been invited before diagnosis. After adjustment for age, birth cohort, county of residence, and national trends in deaths from breast cancer, the mortality rate ratio associated with being invited to mammography screening was 0.72 (95% confidence interval 0.64 to 0.79). To prevent one death from breast cancer, 368 (95% confidence interval 266 to 508) women would need to be invited to screening. CONCLUSION: Invitation to modern mammography screening may reduce deaths from breast cancer by about 28%.

6. **ARTÍCULO Nº: 4455**

Dormuth CR, Filion KB, Paterson JM, James MT, Teare GF, Raymond CB et al. ***Higher potency statins and the risk of new diabetes: multicentre, observational study of administrative databases.*** BMJ. 2014; 348: g3244

OBJECTIVE: To evaluate the incremental increase in new onset diabetes from higher potency statins compared with lower potency statins when used for secondary prevention. DESIGN: Eight population based cohort studies and a meta-analysis. SETTING: Six Canadian provinces and two international databases from the UK and US. PARTICIPANTS: 136,966 patients aged >/= 40 years newly treated with statins between 1 January 1997 and 31 March 2011. METHODS: Within each cohort of patients newly prescribed a statin after hospitalisation for a major cardiovascular event or procedure, we performed as-treated, nested case-control analyses to compare diabetes incidence in users of higher potency statins with incidence in users of lower potency statins. Rate ratios of new diabetes events were estimated using conditional logistic regression on different lengths of exposure to higher potency versus lower potency statins; adjustment for confounding was achieved using high dimensional propensity scores. Meta-analytic methods were used to estimate overall effects across sites. MAIN OUTCOME MEASURES: Hospitalisation for new onset diabetes, or a prescription for insulin or an oral antidiabetic drug. RESULTS: In the first two years of regular statin use, we observed a significant increase in the risk of new onset diabetes with higher potency statins compared with lower potency agents (rate ratio 1.15, 95% confidence interval 1.05 to 1.26). The risk increase seemed to be highest in the first four months of use (rate ratio 1.26, 1.07 to 1.47). CONCLUSIONS: Higher potency statin use is associated with a moderate increase in the risk of new onset diabetes compared with lower potency statins in patients treated for secondary prevention of cardiovascular disease. Clinicians should consider this risk when prescribing higher potency statins in secondary prevention patients.

7. **ARTÍCULO Nº: 4456**

Rajasingam D, Harding K. ***NICE's draft guideline on intrapartum care.*** BMJ. 2014; 348: g4279

8. **ARTÍCULO Nº: 4457**

Patorno E, Neuman MD, Schneeweiss S, Mogun H, Bateman BT. ***Comparative safety of anesthetic type for hip fracture surgery in adults: retrospective cohort study.*** BMJ. 2014; 348: g4022

OBJECTIVE: To evaluate the effect of anesthesia type on the risk of in-hospital mortality among adults undergoing hip fracture surgery in the United States. DESIGN: Retrospective cohort study. SETTING: Premier research database, United States. PARTICIPANTS: 73,284 adults undergoing hip fracture surgery on hospital day 2 or greater between 2007 and 2011. Of those, 61,554 (84.0%) received general anesthesia, 6939 (9.5%) regional anesthesia, and 4791 (6.5%) combined general and regional

anesthesia. MAIN OUTCOME MEASURE: In-hospital all cause mortality. RESULTS: In-hospital deaths occurred in 1362 (2.2%) patients receiving general anesthesia, 144 (2.1%) receiving regional anesthesia, and 115 (2.4%) receiving combined anesthesia. In the multivariable adjusted analysis, when compared with general anesthesia the mortality risk did not differ significantly between regional anesthesia (risk ratio 0.93, 95% confidence interval 0.78 to 1.11) or combined anesthesia (1.00, 0.82 to 1.22). A mixed effects analysis accounting for differences between hospitals produced similar results: compared with general anesthesia the risk from regional anesthesia was 0.91 (0.75 to 1.10) and from combined anesthesia was 0.98 (0.79 to 1.21). Findings were also consistent in subgroup analyses. CONCLUSIONS: In this large nationwide sample of hospital admissions, mortality risk did not differ significantly by anesthesia type among patients undergoing hip fracture surgery. Our results suggest that if the previously posited beneficial effect of regional anesthesia on short term mortality exists, it is likely to be more modest than previously reported.

9. **ARTÍCULO Nº: 4458**

Hopewell S, Collins GS, Boutron I, Yu LM, Cook J, Shanyinde M et al. ***Impact of peer review on reports of randomised trials published in open peer review journals: retrospective before and after study***. BMJ. 2014; 349: g4145

OBJECTIVE: To investigate the effectiveness of open peer review as a mechanism to improve the reporting of randomised trials published in biomedical journals. DESIGN: Retrospective before and after study. SETTING: BioMed Central series medical journals. SAMPLE: 93 primary reports of randomised trials published in BMC-series medical journals in 2012. MAIN OUTCOME MEASURES: Changes to the reporting of methodological aspects of randomised trials in manuscripts after peer review, based on the CONSORT checklist, corresponding peer reviewer reports, the type of changes requested, and the extent to which authors adhered to these requests. RESULTS: Of the 93 trial reports, 38% (n=35) did not describe the method of random sequence generation, 54% (n=50) concealment of allocation sequence, 50% (n=46) whether the study was blinded, 34% (n=32) the sample size calculation, 35% (n=33) specification of primary and secondary outcomes, 55% (n=51) results for the primary outcome, and 90% (n=84) details of the trial protocol. The number of changes between manuscript versions was relatively small; most involved adding new information or altering existing information. Most changes requested by peer reviewers had a positive impact on the reporting of the final manuscript--for example, adding or clarifying randomisation and blinding (n=27), sample size (n=15), primary and secondary outcomes (n=16), results for primary or secondary outcomes (n=14), and toning down conclusions to reflect the results (n=27). Some changes requested by peer reviewers, however, had a negative impact, such as adding additional unplanned analyses (n=15). CONCLUSION: Peer reviewers fail to detect important deficiencies in reporting of the methods and results of randomised trials. The number of these changes requested by peer reviewers was relatively small. Although most had a positive impact, some were inappropriate and could have a negative impact on reporting in the final publication.

10. **ARTÍCULO Nº: 4459**

Hurley R. ***Can doctors reduce harmful medical overuse worldwide?*** BMJ. 2014; 349: g4289

11. **ARTÍCULO Nº: 4460**

Simonet-Aineto P, Marzo-Castillejo M. ***Evidencias de los nuevos medicamentos para la enfermedad pulmonar obstructiva crónica.*** FMC. 2014; 21(6): 347-354.

La enfermedad pulmonar obstructiva crónica (EPOC) es una dolencia muy heterogénea y por ello no es posible categorizarla utilizando solo el volumen espirado forzado en el primer segundo. La denominación de fenotipo se utiliza para referirse a las formas clínicas de presentación. En todo paciente con EPOC siempre se han de tener en cuenta el abandono del tabaco, una nutrición adecuada, la actividad física regular y la vacunación antigripal y antineumocócica. El tratamiento farmacológico en los pacientes con EPOC ha de ser progresivo, adecuándose a la gravedad de la obstrucción y a los síntomas. Los broncodilatadores de acción larga deben utilizarse en pacientes con EPOC y síntomas permanentes. Los corticoides inhalados deben utilizarse en pacientes con EPOC estable grave o muy grave (volumen espirado forzado en el primer segundo < 50%) que sufren frecuentes exacerbaciones. El tratamiento del fenotipo no agudizador, sea enfisema o bronquitis crónica, se basa en el uso de los broncodilatadores de larga duración en combinación. El tratamiento del fenotipo mixto se basa en la utilización de broncodilatadores de larga duración combinados con corticoides inhalados. El indacaterol es un beta adrenergico de larga duración. El bromuro de aclidinio y el bromuro de glicopirronio son anticolinérgicos de larga duración. Los nuevos broncodilatadores no han demostrado una mayor eficacia y seguridad respecto a los ya existentes. Utilizan sistemas de inhalación, en principio, más fáciles de usar y más seguros. El roflumilast es un antiinflamatorio perteneciente al grupo de los inhibidores de la fosfodiesterasa 4, cuya indicación es como fármaco de segunda línea en el fenotipo agudizador tipo bronquitis crónica.

12. **ARTÍCULO Nº: 4461**

Coderch J, Sanchez-Perez I, Ibern P, Carreras M, Perez-Berruezo X, Inoriza JM. ***[Predicting individual risk of high healthcare cost to identify complex chronic patients]***. Gac.Sanit. 2014; 28(4): 292-300.

OBJECTIVE: To develop a predictive model for the risk of high consumption of healthcare resources, and assess the ability of the model to identify complex chronic patients. METHODS: A cross-sectional study was performed within a healthcare management organization by using individual data from 2 consecutive years (88,795 people). The dependent variable consisted of healthcare costs above the 95th percentile (P95), including all services provided by the organization and pharmaceutical consumption outside of the institution. The predictive variables were age, sex, morbidity-based on clinical risk groups (CRG)-and selected data from previous utilization (use of hospitalization, use of high-cost drugs in ambulatory care, pharmaceutical expenditure). A univariate descriptive analysis was performed. We constructed a logistic regression model with a 95% confidence level and analyzed sensitivity, specificity, positive predictive values (PPV), and the area under the ROC curve (AUC). RESULTS: Individuals incurring costs >P95 accumulated 44% of total healthcare costs and were concentrated in ACRG3 (aggregated CRG level 3) categories related to multiple chronic diseases. All variables were statistically significant except for sex. The model had a sensitivity of 48.4% (CI: 46.9%-49.8%), specificity of 97.2% (CI: 97.0%-97.3%), PPV of 46.5% (CI: 45.0%-47.9%), and an AUC of 0.897 (CI: 0.892 to 0.902). CONCLUSIONS: High consumption of healthcare resources is associated with complex chronic morbidity. A model based on age, morbidity, and prior utilization is able to predict high-cost risk and identify a target population requiring proactive care.

13. **ARTÍCULO Nº: 4462**

caniz-Zanon M, Mompart-Penina A, Guillen-Estany M, Medina-Bustos A, ragay-Barbany JM, Brugulat-Guiteras P et al. ***[New design of the Health Survey of Catalonia (Spain, 2010-2014): a step forward in health planning and evaluation]***. Gac.Sanit. 2014; 28(4): 338-340.

This article presents the genesis of the Health Survey of Catalonia (Spain, 2010-2014) with its semiannual subsamples and explains the basic characteristics of its multistage sampling design. In

comparison with previous surveys, the organizational advantages of this new statistical operation include rapid data availability and the ability to continuously monitor the population. The main benefits are timeliness in the production of indicators and the possibility of introducing new topics through the supplemental questionnaire as a function of needs. Limitations consist of the complexity of the sample design and the lack of longitudinal follow-up of the sample. Suitable sampling weights for each specific subsample are necessary for any statistical analysis of micro-data. Accuracy in the analysis of territorial disaggregation or population subgroups increases if annual samples are accumulated.

14. **ARTÍCULO Nº: 4463**

Smischney NJ, Cawcutt KA, O'Horo JC, Sevilla Berrios RA, Whalen FX. ***Intensive care unit readmission prevention checklist: is it worth the effort?*** J.Eval.Clin.Pract. 2014; 20(4): 348-351.

RATIONALE, AIMS AND OBJECTIVES: Checklists have been adopted by various institutions to improve patient outcomes. In particular, readmission prevention checklists may be of potential value to improve patient care and reduce medical costs. As a result, a prior quality improvement study was conducted to create an intensive care unit readmission prevention checklist. The previous pilot demonstrated zero readmissions when the readmission prevention checklist was utilized but yielded low compliance (30%). Thus, a subsequent quality initiative was undertaken to refine the readmission prevention checklist with the primary aim of improved compliance while maintaining a reduced readmission rate that was observed with the original quality improvement study. METHOD: A single-centre, cross-sectional study for assessing baseline data and a prospective observational study to assess the effectiveness of a refined readmission prevention checklist tool in a 20-bed tertiary medical-surgical intensive care unit at an academic medical centre in Rochester, MN was conducted. Medical patients admitted through the emergency department, upon direct transfer from outside facility, and post-operative surgical patients at our institution were included. A refined readmission prevention checklist tool was administered during an 8-week pilot period for medical and post-operative surgical patients. RESULTS: The refined readmission prevention checklist resulted in an even lower compliance (10.5%) from the initial phase likely resulting from utilization of a paper readmission prevention checklist in an electronic medical environment. Moreover, the refined readmission prevention checklist demonstrated a 22% unplanned readmission rate for patients in which the tool was utilized. CONCLUSIONS: In conclusion, the findings of the current quality improvement study may serve to rethink the process of health care delivery that applies paper tools in an electronic medical environment.

15. **ARTÍCULO Nº: 4464**

Manzano F, Perez-Perez AM, Martinez-Ruiz S, Garrido-Colmenero C, Roldan D, Jimenez-Quintana MM et al. ***Hospital-acquired pressure ulcers and risk of hospital mortality in intensive care patients on mechanical ventilation***. J.Eval.Clin.Pract. 2014; 20(4): 362-368.

RATIONALE, AIMS AND OBJECTIVES: Pressure ulcers (PUs) are a common and serious complication in critically ill patients. The aim of this study was to evaluate the relationship between the development of a PU and hospital mortality in patients requiring mechanical ventilation (MV) in an intensive care unit (ICU). METHODS: A prospective cohort study was performed over two years in patients requiring MV for >/= 24 hours in a medical-surgical ICU. Primary outcome measure was hospital mortality and main independent variable was the development of a PU grade >/= II. Hazard ratios (HRs) were calculated using a Cox model with time-dependent covariates. RESULTS: Out of 563 patients in the study, 110 (19.5%) developed a PU. Overall hospital mortality was 48.7%. In the adjusted multivariate

model, PU onset was a significant independent predictor of mortality (adjusted HR, 1.28; 95% confidence interval, 1.003-1.65; P = 0.047). The model also included the Acute Physiology and Chronic Health Evaluation II score, total Sequential Organ Failure Assessment on day 3, hepatic cirrhosis and medical admission. CONCLUSION: Within the limitations of a single-centre approach, PU development appears to be associated with an increase in mortality among patients requiring MV for 24 hours or longer.

16. **ARTÍCULO Nº: 4465**

Frendl DM, Sokoloff MH. ***Clinical and policy perspectives on the adoption of active surveillance for low-risk prostate cancer.*** Med Care. 2014; 52(7): 576-578.

17. **ARTÍCULO Nº: 4466**

Kim SP, Gross CP, Nguyen PL, Smaldone MC, Shah ND, Karnes RJ et al. ***Perceptions of Active Surveillance and Treatment Recommendations for Low-risk Prostate Cancer: Results from a National Survey of Radiation Oncologists and Urologists.*** Med Care. 2014; 52(7): 579-585.

BACKGROUND: With the growing concerns about overtreatment in prostate cancer, the extent to which radiation oncologists and urologists perceive active surveillance (AS) as effective and recommend it to patients are unknown. OBJECTIVE: To assess opinions of radiation oncologists and urologists about their perceptions of AS and treatment recommendations for low-risk prostate cancer. RESEARCH DESIGN: National survey of specialists. PARTICIPANTS: Radiation oncologists and urologists practicing in the United States. MEASURES: A total of 1366 respondents were asked whether AS was effective and whether it was underused nationally, whether their patients were interested in AS, and treatment recommendations for low-risk prostate cancer. Pearson's chi test and multivariate logistic regression were used to test for differences in physician perceptions on AS and treatment recommendations. RESULTS: Overall, 717 (52.5%) of physicians completed the survey with minimal differences between specialties (P=0.92). Although most physicians reported that AS is effective (71.9%) and underused in the United States (80.0%), 71.0% stated that their patients were not interested in AS. For low-risk prostate cancer, more physicians recommended radical prostatectomy (44.9%) or brachytherapy (35.4%); fewer endorsed AS (22.1%). On multivariable analysis, urologists were more likely to recommend surgery [odds ratio (OR): 4.19; P<0.001] and AS (OR: 2.55; P<0.001), but less likely to recommend brachytherapy (OR: 0.13; P<0.001) and external beam radiation therapy (OR: 0.11; P<0.001) compared with radiation oncologists. CONCLUSIONS AND RELEVANCE: Most prostate cancer specialists in the United States believe AS effective and underused for low-risk prostate cancer, yet continue to recommend the primary treatments their specialties deliver.

18. **ARTÍCULO Nº: 4467**

Sanfelix-Gimeno G, Franklin JM, Shrank WH, Carlo M, Tong AY, Reisman L et al. ***Did HEDIS get it right? Evaluating the quality of a quality measure: adherence to beta-blockers and cardiovascular outcomes after myocardial infarction.*** Med Care. 2014; 52(7): 669-676.

BACKGROUND: As an example of the process that could be used to evaluate and optimize the performance of quality measures in routine practice, we evaluated whether the Healthcare Effectiveness Data and Information Set (HEDIS) measure assessing the "persistence of beta-blocker treatment after a heart attack" correlates with post-myocardial infarction (MI) outcomes and whether or not there are alternative specifications of this construct which are better predictors and/or may be more easily applied. RESEARCH DESIGN: The study included a retrospective cohort of 8672 post-MI patients 18 years old and above. We assessed the strength of the association between the different

adherence measures and the composite clinical outcome using multivariable Cox models. We compared the predictive capacity of each adherence definition model to one that did not contain adherence by computing the change in C-statistics and the continuous net reclassification improvement indices (NRIs). RESULTS: Adherence was associated with clinical outcome reductions, with hazard ratios ranging from 0.48 (95% CI, 0.27-0.85) to 0.81 (95% CI, 0.67-0.99). None of the adherence measures, including the HEDIS definition, significantly changed the C-statistic relative to a model that did not include adherence. However, the short-term adherence measure (having 72 d covered during the first 90 d postdischarge) showed a large change in NRI (correctly reclassifying 12% of cases and 16% of noncases; NRI: 28%; 95% CI, 22%-38%), although did not significantly differ from the change in NRI with the HEDIS measure. CONCLUSIONS: We identified an adherence measure that showed a predictive ability as good as that of the HEDIS definition to measure beta-blocker use after MI, halving the time of assessment required, and thus, allowing for the implementation of quality improvement interventions in a more timely manner.

19. **ARTÍCULO Nº: 4468**

Alegre Del Rey EJ, Fenix CS, Castano LR, Sierra GF. ***[Assessment and positioning of drugs as equivalent therapeutic alternatives]***. Med Clin.(Barc.). 2014; 143(2): 85-90.

20. **ARTÍCULO Nº: 4469**

Dominguez-Rodriguez A, breu-Gonzalez P. ***Dynamic prognostic stratification in ST-elevation myocardial infarction***. Rev.Esp.Cardiol.(Engl.Ed). 2014; 67(7): 587

21. **ARTÍCULO Nº: 4470**

Ruiz-Nodar JM, Marin F, Sionis A, Fernandez-Ortiz A. ***Dynamic prognostic stratification in ST-elevation myocardial infarction. Response***. Rev.Esp.Cardiol.(Engl.Ed). 2014; 67(7): 588

22. **ARTÍCULO Nº: 4471**

Martin G, Ozieranski P, Willars J, Charles K, Minion J, McKee L et al. ***Walkrounds in practice: corrupting or enhancing a quality improvement intervention? A qualitative study***. Jt.Comm J.Qual.Patient.Saf. 2014; 40(7): 303-310.

BACKGROUND: Walkrounds, introduced as Leadership (or Executive) WalkRounds, are a widely advocated model for increasing leadership engagement in patient safety to improve safety culture, but evidence for their effectiveness is mixed. In the English National Health Service (NHS), hospitals have been strongly encouraged to make use of methods closely based on the walkrounds approach. A study was conducted to explore how walkrounds are used in practice and to identify variations in implementation that might mediate their impact on safety and culture. METHODS: The data, collected from 82 semistructured interviews in the English NHS, were drawn from two components of a wider study of culture and behavior around quality and safety in the English system. Analysis was based on the constant comparative method. FINDINGS: Our analysis highlights how local, pragmatic adjustments to the walkrounds approach could radically alter its character and the way in which it is received by those at the front line. The modification and expansion of walkrounds to increase the scope of knowledge produced could increase the value that executives draw from them. However, it risks replacing the main objectives of walkrounds--specific, actionable knowledge about safety issues, and a more positive safety culture and relationship between ward and board--with a form of surveillance that could alienate frontline staff and produce fallible insights. CONCLUSION: The studys findings suggest some plausible explanations for the mixed evidence for walkrounds' effectiveness in creating a safety culture. On a practical level, they point to critical questions that executives must ask

themselves in practicing interventions of this nature to ensure that adaptations align rather than conflict with the intervention's model of change.

23. **ARTÍCULO Nº: 4472**

Shamji H, Baier RR, Gravenstein S, Gardner RL. ***Improving the quality of care and communication during patient transitions: best practices for urgent care centers***. Jt.Comm J.Qual.Patient.Saf. 2014; 40(7): 319-324.

BACKGROUND: Although high-quality care transitions require timely and accurate communication of clinical information between providers, such communication is inconsistent, and there are few established guidelines outside the hospital setting. METHODS: Using a systematic, collaborative quality improvement process, Healthcentric Advisors (Providence, Rhode Island) undertook a multistage approach to define best practices for care transitions in the urgent care setting. This approach entailed review of the medical literature to identify processes that improve care transitions outcomes, gathering of information about clinicians' preferences, and a statewide community meeting with urgent care clinicians and other stakeholders to vet draft guidelines and obtain consensus on the concepts. RESULTS: Because of an inability to identify any guidelines or research that globally addressed care transitions from the urgent care setting, information was gathered from studies on patient discharge instructions and extrapolated from the evidence base available for related settings. The resulting set of eight best practices for urgent care center transitions focuses on clinician-to-clinician communication and patient activation, which can be implemented to establish measurable, communitywide expectations for communication. CONCLUSION: This set of best practices constitutes the first known guidelines to establish expectations and measures tailored specifically to transitions from the urgent care setting to the emergency department or primary care office. They can serve as a resource and a framework for urgent care clinicians expanding their collaboration with community partners, such as emergency departments and primary care providers, particularly in the context of emerging payment models.

24. **ARTÍCULO Nº: 4473**

Catala-Lopez F, Peiro S, Hutton B, Perez AC, Moher D. ***[Declaration of transparency: promoting a more complete, honest and adequate publication of scientific articles]***. Rev.Esp.Salud Publica. 2014; 88(2): 181-186.

25. **ARTÍCULO Nº: 4474**

Artells JJ, Peiro S, Meneu R. ***[Barriers for introducing a health technology assessment organization to inform health care decision-making in the Spanish National Health System]***. Rev.Esp.Salud Publica. 2014; 88(2): 217-231.

BACKGROUND: To identify difficulties, obstacles and limitations to establish an organizational structure devoted to the evaluation of healthcare technologies for incorporation, maintenance or removal from the services portfolio of the Spanish National Health System (sNHS). METHODS: Panel of 14 experts, structured according to processes adapted from brainstorming, nominal group, and Rand consensus method techniques. RESULTS: The panel proposed 77 items as potential obstacles to the establishment of an official and independent "agency" able to inform on sNHS healthcare benefits funding or selective disinvestment. These items were focused on: 1) lack of political motivation to introduce the cost-effectiveness analysis from the state and regional governments and lack of independence and transparency of the evaluation processes, 2) the tension between a decentralized health system and evaluation activities with significant scale economies, 3) technical difficulties of the

evaluation processes, including their ability to influence decision making and 4) social and professional refusal to the exclusion of healthcare benefits when it is perceived as indiscriminate. CONCLUSION: Although there is a different number and type of obstacles for developing the capacity of the sNHS to include or exclude healthcare benefits based on the evaluation of their effectiveness and efficiency, experts place in the political arena (political motivation, transparency, governance) the main difficulties to advance in this field.

26. **ARTÍCULO Nº: 4475**

Antonanzas VF, Rodriguez-Ibeas R, Juarez-Castello CA, Lorente Antonanzas MR. ***[Impact of the Royal Decree-Law 16/2012 on the number of prescriptions and pharmaceutical expenditures]***. Rev.Esp.Salud Publica. 2014; 88(2): 233-249.

BACKGROUND: this research aims to understand if the consequences on drug expenditures and number of prescriptions of Royal Decree-Law 16/2012 as estimated by the Ministry of Health, Social Services and Equality (MHSSE) are similar to those found by using common statistical approaches. In addition, several models have been built to forecast the evolution of both variables for the period September 2013-December 2014. METHODS: the Box-Jenkins methodology and the Box-Tiao intervention analysis were applied to data of the period 2003-13 to forecast the monthly values of the number of prescriptions and pharmaceutical expenditures. Forecasts were used in a counter-factual analysis to be compared to the actual values of prescriptions and drug expenditures. Moreover, forecasts for the period September 2013 to December 2014 were obtained to observe the impact of the policy in the future. RESULTS: the counterfactual analysis estimated a decrease in the number of prescriptions of 12.18% and 12.83% in the pharmaceutical expenditure; these figures were 12,75% and 14,03% respectively, when the intervention analysis was used. CONCLUSION: the estimated reduction in the number of prescriptions for the period June 2012-August 2013 was similar to the figure offered by the MHSSE, while the reduction in the drug expenditure series was smaller. The Box-Jenkins methodology generated low forecast errors (less than 3%) what makes this procedure useful to reliably anticipate future consumptions.

27. **ARTÍCULO Nº: 4476**

Orueta Mendia JF, Garcia-Alvarez A, onso-Moran E, Nuno-Solinis R. ***[Development of a predictive risk model for unplanned admissions in the Basque Country]***. Rev.Esp.Salud Publica. 2014; 88(2): 251-260.

BACKGROUND: Hospitalizations are undesirable events that can be avoided to some degree through proactive interventions. The objective of this study is to determine the capability of models based on Adjusted Clinical Groups (ACG), in our milieu, to identify patients who will present unplanned admissions in the following months to their classification, in both the general population and in subpopulations of chronically ill patients (diabetes mellitus, chronic obstructive pulmonary disease and heart failure). METHODS: Cross-sectional study which analyzes data from a two year period, of all residents over 14 years old in the Basque Country (N = 1,964,337). Data from the first year (demographic, deprivation index, diagnoses, prescriptions, procedures, admissions and other contacts with the health service) were used to construct the independent variables; hospitalizations of the second year, the dependent ones. We used the area under the ROC curve (AUC) to evaluate the capability of the models to discriminate patients with hospitalizations and calculated the positive predictive value and sensitivity of different cutoffs. RESULTS: In the general population, models for predicting admission at 6 and 12 months, as well as long-term hospitalizations showed a good performance (AUC> 0.8), while it was acceptable (AUC 0.7 to 0.8) in the groups of chronic patients. CONCLUSION: A hospitalization risk stratification system, based on ACG, is valid and applicable in our

milieu. These models allow classifying the patients on a scale of high to low risk, which makes possible the implementation of the most expensive preventive interventions to only a small subset of patients, while other less intensive ones can be provided to larger groups.

28. **ARTÍCULO Nº: 4477**

Cook D, Rocker G. ***Dying with dignity in the intensive care unit***. N.Engl.J.Med. 2014; 370(26): 2506-2514.

29. **ARTÍCULO Nº: 4478**

Bauer UE, Briss PA, Goodman RA, Bowman BA. ***Prevention of chronic disease in the 21st century: elimination of the leading preventable causes of premature death and disability in the USA***. Lancet. 2014; 384(9937): 45-52.

With non-communicable conditions accounting for nearly two-thirds of deaths worldwide, the emergence of chronic diseases as the predominant challenge to global health is undisputed. In the USA, chronic diseases are the main causes of poor health, disability, and death, and account for most of health-care expenditures. The chronic disease burden in the USA largely results from a short list of risk factors--including tobacco use, poor diet and physical inactivity (both strongly associated with obesity), excessive alcohol consumption, uncontrolled high blood pressure, and hyperlipidaemia--that can be effectively addressed for individuals and populations. Increases in the burden of chronic diseases are attributable to incidence and prevalence of leading chronic conditions and risk factors (which occur individually and in combination), and population demographics, including ageing and health disparities. To effectively and equitably address the chronic disease burden, public health and health-care systems need to deploy integrated approaches that bundle strategies and interventions, address many risk factors and conditions simultaneously, create population-wide changes, help the population subgroups most affected, and rely on implementation by many sectors, including public-private partnerships and involvement from all stakeholders. To help to meet the chronic disease burden, the US Centers for Disease Control and Prevention (CDC) uses four cross-cutting strategies: (1) epidemiology and surveillance to monitor trends and inform programmes; (2) environmental approaches that promote health and support healthy behaviours; (3) health system interventions to improve the effective use of clinical and other preventive services; and (4) community resources linked to clinical services that sustain improved management of chronic conditions. Establishment of community conditions to support healthy behaviours and promote effective management of chronic conditions will deliver healthier students to schools, healthier workers to employers and businesses, and a healthier population to the health-care system. Collectively, these four strategies will prevent the occurrence of chronic diseases, foster early detection and slow disease progression in people with chronic conditions, reduce complications, support an improved quality of life, and reduce demand on the health-care system. Of crucial importance, with strengthened collaboration between the public health and health-care sectors, the health-care system better uses prevention and early detection services, and population health is improved and sustained by solidifying collaborations between communities and health-care providers. This collaborative approach will improve health equity by building communities that promote health rather than disease, have more accessible and direct care, and focus the health-care system on improving population health.

30. **ARTÍCULO Nº: 4479**

Lorenzoni L, Belloni A, Sassi F. ***Health-care expenditure and health policy in the USA versus other high-spending OECD countries***. Lancet. 2014; 384(9937): 83-92.

The USA has exceptional levels of health-care expenditure, but growth has slowed dramatically in recent years, amidst major efforts to close the coverage gap with other countries of the Organisation for Economic Co-operation and Development (OECD). We reviewed expenditure trends and key policies since 2000 in the USA and five other high-spending OECD countries. Higher health-sector prices explain much of the difference between the USA and other high-spending countries, and price dynamics are largely responsible for the slowdown in expenditure growth. Other high-spending countries did not face the same coverage challenges, and could draw from a broader set of policies to keep expenditure under control, but expenditure growth was similar to the USA. Tightening Medicare and Medicaid price controls on plans and providers, and leveraging the scale of the public programmes to increase efficiency in financing and care delivery, might prevent a future economic recovery from offsetting the slowdown in health sector prices and expenditure growth.

31. **ARTÍCULO Nº: 4480**

Cals JW, Kotz D. ***Effective writing and publishing scientific papers, part X: choice of journal***. J.Clin.Epidemiol. 2014; 67(1): 3

32. **ARTÍCULO Nº: 4481**

Watine J, Wils J, Augereau C. ***Clinical practice guidelines: potential misconceptions of the GRADE approach***. J.Clin.Epidemiol. 2014; 67(1): 7-9.

OBJECTIVE: To challenge the Grading of Recommendations Assessment, Development and Evaluation (GRADE) group to address the potential misconceptions about their approach to grading the strength of recommendations in clinical practice guidelines. STUDY DESIGN AND SETTING: Based on our own expertise of health care professionals trying to think in depth about, and using, guidelines, we have identified four such misconceptions. RESULTS: These potential misconceptions are: (1) evidence in medicine means factual or scientific evidence; (2) opinions are a subcategory of evidence; (3) the most important evidence is related to clinical benefits and harms; (4) being virtuous, and principled, does not particularly help in developing the best possible guidelines. CONCLUSION: We call on the GRADE leadership to address all the above-mentioned misconceptions. These need explicit answers in their manuscript series.

33. **ARTÍCULO Nº: 4482**

Kunz R, Schunemann HJ, Guyatt GH. ***Perceived disagreement (mostly) not confirmed by evidence... A reply to Watine et al.: Clinical practice guidelines: myths and misconceptions***. J.Clin.Epidemiol. 2014; 67(1): 10-14.

34. **ARTÍCULO Nº: 4483**

Becker M, Neugebauer EA, Eikermann M. ***Partial updating of clinical practice guidelines often makes more sense than full updating: a systematic review on methods and the development of an updating procedure***. J.Clin.Epidemiol. 2014; 67(1): 33-45.

OBJECTIVES: To conduct a systematic review of the methods used to determine when and how to update clinical practice guidelines (CPGs) and develop a procedure for updating CPGs. STUDY DESIGN AND SETTING: We searched MEDLINE, Embase, and the Cochrane Methodology Register for methodological publications on updating CPGs. Guideline development manuals were obtained from the Web sites of guideline-developing organizations. Using the information obtained from these records, a procedure for updating CPGs was developed. RESULTS: A total of 5,116 journal articles were screened, and seven articles met the criteria for inclusion. Forty-seven manuals were included; of

these, eight included details about the methods used to update the guidelines. Most of the included publications focused on assessing whether the CPGs needed updating and not on how to update them. The developed procedure includes a systematic monitoring system and a scheduled process for updating the CPGs, which includes guidance on how to determine the type and scope of an update. CONCLUSION: Partial updating often makes more sense than updating the whole CPG because topics and recommendations differ in terms of the need for updating. Guideline developers should implement a systematic updating procedure that includes an ongoing monitoring system that is appropriate for the nature of the guideline topics and the capabilities of the developers.

35. **ARTÍCULO Nº: 4484**

Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D. ***The CARE guidelines: consensus-based clinical case report guideline development***. J.Clin.Epidemiol. 2014; 67(1): 46-51.

BACKGROUND: A case report is a narrative that describes, for medical, scientific, or educational purposes, a medical problem experienced by one or more patients. Case reports written without guidance from reporting standards are insufficiently rigorous to guide clinical practice or to inform clinical study design. PRIMARY OBJECTIVE: Develop, disseminate, and implement systematic reporting guidelines for case reports. METHODS: We used a three-phase consensus process consisting of (1) pre-meeting literature review and interviews to generate items for the reporting guidelines, (2) a face-to-face consensus meeting to draft the reporting guidelines, and (3) post-meeting feedback, review, and pilot testing, followed by finalization of the case report guidelines. RESULTS: This consensus process involved 27 participants and resulted in a 13-item checklist-a reporting guideline for case reports. The primary items of the checklist are title, key words, abstract, introduction, patient information, clinical findings, timeline, diagnostic assessment, therapeutic interventions, follow-up and outcomes, discussion, patient perspective, and informed consent. CONCLUSIONS: We believe the implementation of the CARE (CAse REport) guidelines by medical journals will improve the completeness and transparency of published case reports and that the systematic aggregation of information from case reports will inform clinical study design, provide early signals of effectiveness and harms, and improve healthcare delivery.

36. **ARTÍCULO Nº: 4485**

Murad MH, Altayar O, Bennett M, Wei JC, Claus PL, Asi N et al. ***Using GRADE for evaluating the quality of evidence in hyperbaric oxygen therapy clarifies evidence limitations***. J.Clin.Epidemiol. 2014; 67(1): 65-72.

OBJECTIVES: The current evidence rating for hyperbaric oxygen therapy indications uses the American Heart Association system, which mainly depends on the study design. STUDY DESIGN AND SETTING: We systematically reviewed the literature and applied the Grading of Evidence, Assessment, Development and Evaluation (GRADE) approach to the main patient-important outcomes in each indication. RESULTS: We included 17 systematic reviews that synthesized 44 randomized trials and 131 observational studies enrolling 8,145 participants. The quality of evidence for seven indications with category A was high (1), moderate (2), low (2), and very low (2); for 10 indications with category B, it was moderate (1), low (5), and very low (4); and for 1 indication with category C, it was high. The quality of evidence was rated down for the risk of bias and imprecision for most indications and rated up because of large effect size for some indications. Most discrepant ratings were in the indications of decompression illness (C, high), carbon monoxide poisoning (A, very low), and later presentations of idiopathic sudden hearing loss (A, very low). CONCLUSION: The GRADE approach uncovered factors

affecting the quality of evidence that were otherwise implicit. Knowing these factors can influence clinicians' confidence in applying hyperbaric oxygen therapy and orient the research agenda.

37. **ARTÍCULO Nº: 4486**

King MT, Bell ML, Costa D, Butow P, Oh B. ***The Quality of Life Questionnaire Core 30 (QLQ-C30) and Functional Assessment of Cancer-General (FACT-G) differ in responsiveness, relative efficiency, and therefore required sample size***. J.Clin.Epidemiol. 2014; 67(1): 100-107.

OBJECTIVES: Quality of Life Questionnaire Core 30 (QLQ-C30) and Functional Assessment of Cancer Therapy-General (FACT-G) are widely used cancer-specific health-related quality of life (HRQOL) questionnaires. We aimed to compare their responsiveness with clinically important effects and statistical efficiency to detect such effects. STUDY DESIGN AND SETTING: Secondary analysis of QLQ-C30 and FACT-G data from a randomized controlled trial of Medical Qigong (n = 162 heterogeneous cancer patients). Difference in responsiveness (DR) and relative efficiency (RE) were calculated for five domains. RESULTS: FACT-G total score was more efficient than QLQ-C30 global scale for detecting change within the intervention arm [RE = 0.31 (0.083, 0.69)] and comparing change between trial arms [RE = 0.17 (0.009, 0.58)]. In the social domain, the QLQ-C30 scale was more responsive [DR = 0.28 (0.024, 0.54)] and more efficient within arm only [RE = 5.25 (1.21, 232.26)]. In the physical, functional/role, and emotional domains, neither questionnaire was more responsive or efficient. CONCLUSION: FACT-G would require about one-third the sample of QLQ-C30 to detect a given change in overall HRQOL, whereas in the social domain, it would require five times the sample size. FACT-G won advantage in overall HRQOL by reduced "noise" (smaller standard deviation achieved by summing across 27 items), whereas QLQ-C30 won advantage in the social domain via a larger "signal" (achieved through well-targeted item content).

38. **ARTÍCULO Nº: 4487**

Bjorner JB, Rose M, Gandek B, Stone AA, Junghaenel DU, Ware JE, Jr. ***Method of administration of PROMIS scales did not significantly impact score level, reliability, or validity***. J.Clin.Epidemiol. 2014; 67(1): 108-113.

OBJECTIVES: To test the impact of the method of administration (MOA) on score level, reliability, and validity of scales developed in the Patient Reported Outcomes Measurement Information System (PROMIS). STUDY DESIGN AND SETTING: Two nonoverlapping parallel forms each containing eight items from each of three PROMIS item banks (Physical Function, Fatigue, and Depression) were completed by 923 adults with chronic obstructive pulmonary disease, depression, or rheumatoid arthritis. In a randomized crossover design, subjects answered one form by interactive voice response (IVR) technology, paper questionnaire (PQ), personal digital assistant (PDA), or personal computer (PC) and a second form by PC, in the same administration. Method equivalence was evaluated through analyses of difference scores, intraclass correlations (ICCs), and convergent/discriminant validity. RESULTS: In difference score analyses, no significant mode differences were found and all confidence intervals were within the prespecified minimal important difference of 0.2 standard deviation. Parallel-forms reliabilities were very high (ICC = 0.85-0.93). Only one across-mode ICC was significantly lower than the same-mode ICC. Tests of validity showed no differential effect by MOA. Participants preferred screen interface over PQ and IVR. CONCLUSION: We found no statistically or clinically significant differences in score levels or psychometric properties of IVR, PQ, or PDA administration compared with PC.

39. **ARTÍCULO Nº: 4488**

Keurentjes JC, Fiocco M, Nelissen RG. ***Willingness to undergo surgery again validated clinically important differences in health-related quality of life after total hip replacement or total knee replacement surgery***. J.Clin.Epidemiol. 2014; 67(1): 114-120.

OBJECTIVES: To determine clinically important differences (CIDs) in health-related quality of life (HRQoL) after total hip replacement (THR) or total knee replacement (TKR) surgery, using the Short Form 36 (SF-36). STUDY DESIGN AND SETTING: SF-36 scores were collected 2 weeks before and at 1.5-6 years after joint replacement in 586 THR and 400 TKR patients in a multicenter cohort study. We calculated distribution-based CIDs (0.8 standard deviations of the preoperative score) for each SF-36 subscale. Responders (patients with an improvement in HRQoL >/= CID of a particular subscale) were compared with nonresponders using an external validation question: willingness to undergo surgery again. RESULTS: CIDs for THR/TKR were physical functioning (PF), 17.9/16.7; role-physical (RP), 31.1/33.4; bodily pain (BP), 16.8/16.2; general health, 15.5/15.7; vitality, 17.3/16.7; social functioning (SF), 22.0/19.9; role-emotional, 33.7/33.6; and mental health, 14.8/14.1. CIDs of PF, RP, BP, and SF were validated by the validation question. CONCLUSION: Valid and precise CIDs are estimated of PF, RP, BP, and SF, which are relevant in HRQoL subscales for THR and TKR patients. CIDs of all other subscales should be used cautiously.

40. **ARTÍCULO Nº: 4489**

Kotz D, Cals JW. ***Effective writing and publishing scientific papers, part XI: submitting a paper***. J.Clin.Epidemiol. 2014; 67(2): 123

41. **ARTÍCULO Nº: 4490**

Haines T, O'Brien L, McDermott F, Markham D, Mitchell D, Watterson D et al. ***A novel research design can aid disinvestment from existing health technologies with uncertain effectiveness, cost-effectiveness, and/or safety***. J.Clin.Epidemiol. 2014; 67(2): 144-151.

OBJECTIVES: Disinvestment is critical for ensuring the long-term sustainability of health-care services. Key barriers to disinvestment are heterogeneity between research and clinical settings, absence of evidence of effectiveness of some health technologies, and exposure of patients and organizations to risks and poor outcomes. We aimed to develop a feasible research design that can evaluate disinvestment in health technologies of uncertain effectiveness or cost-effectiveness. STUDY DESIGN AND SETTING: This article (1) establishes the need for disinvestment methodologies, (2) identifies the ethical concerns and feasibility constraints of conventional research designs for this issue, (3) describes the planning, implementation, and analytical framework for a novel disinvestment-specific study design, and (4) describes potential limitations in application of this design. RESULTS: The stepped-wedge, roll-in cluster randomized controlled trial can facilitate the disinvestment process, whereas generating evidence to determine whether the decision to disinvest was sound in the clinical environment. A noninferiority research paradigm may be applied to this methodology to demonstrate that the removal of a health technology does not adversely affect outcomes. CONCLUSION: This research design can be applied across multiple fields and will assist determination of whether specific health technologies are clinically effective, cost-effective, and safe.

42. **ARTÍCULO Nº: 4491**

Bell KJ, Glasziou PP, Hayen A, Irwig L. ***Criteria for monitoring tests were described: validity, responsiveness, detectability of long-term change, and practicality***. J.Clin.Epidemiol. 2014; 67(2): 152-159.

OBJECTIVES: To describe how evidence from trials and cohort studies may be used to guide choice of test for monitoring patients with chronic disease. STUDY DESIGN AND SETTING: Exploration of potential criteria for choosing the best monitoring test. Criteria are defined and options for assessment measures for test performance on each criterion discussed. RESULTS: Monitoring in clinical practice occurs in three main phases: before treatment, response to treatment, and long-term monitoring. Four important criteria may be used to choose the best test for monitoring a patient in each of these phases. Clinical validity describes the ability of the test to predict the clinically relevant outcome that we are trying to control or prevent. Responsiveness describes how much the test changes in response to an intervention relative to background random variation. Detectability of long-term change describes the size of changes in the test over the long term relative to background random variation. Practicality describes the ease of use, invasiveness, and cost of the test. Test performance generally requires longitudinal data from trial and/or cohort studies using statistical methods such as those discussed. CONCLUSION: Four specific criteria can help clinicians inform evidence-based decisions on which monitoring test to use.

43. **ARTÍCULO Nº: 4492**

Kotz D, Cals JW. ***Effective writing and publishing scientific papers, part XII: responding to reviewers***. J.Clin.Epidemiol. 2014; 67(3): 243

44. **ARTÍCULO Nº: 4493**

Prados-Torres A, Calderon-Larranaga A, Hancco-Saavedra J, Poblador-Plou B, van den AM. ***Multimorbidity patterns: a systematic review***. J.Clin.Epidemiol. 2014; 67(3): 254-266.

OBJECTIVES: The aim of this review was to identify studies on patterns of associative multimorbidity, defined as the nonrandom association between diseases, focusing on the main methodological features of the studies and the similarities among the detected patterns. STUDY DESIGN AND SETTING: Studies were identified through MEDLINE and EMBASE electronic database searches from their inception to June 2012 and bibliographies. RESULTS: The final 14 articles exhibited methodological heterogeneity in terms of the sample size, age and recruitment of study participants, the data source, the number of baseline diseases considered, and the statistical procedure used. A total of 97 patterns composed of two or more diseases were identified. Among these, 63 patterns were composed of three or more diseases. Despite the methodological variability among studies, this review demonstrated relevant similarities for three groups of patterns. The first one comprised a combination of cardiovascular and metabolic diseases, the second one was related with mental health problems, and the third one with musculoskeletal disorders. CONCLUSION: The existence of associations beyond chance among the different diseases that comprise these patterns should be considered with the aim of directing future lines of research that measure their intensity, clarify their nature, and highlight the possible causal underlying mechanisms.

45. **ARTÍCULO Nº: 4494**

McCambridge J, Witton J, Elbourne DR. ***Systematic review of the Hawthorne effect: new concepts are needed to study research participation effects***. J.Clin.Epidemiol. 2014; 67(3): 267-277.

OBJECTIVES: This study aims to (1) elucidate whether the Hawthorne effect exists, (2) explore under what conditions, and (3) estimate the size of any such effect. STUDY DESIGN AND SETTING: This systematic review summarizes and evaluates the strength of available evidence on the Hawthorne effect. An inclusive definition of any form of research artifact on behavior using this label, and without

cointerventions, was adopted. RESULTS: Nineteen purposively designed studies were included, providing quantitative data on the size of the effect in eight randomized controlled trials, five quasiexperimental studies, and six observational evaluations of reporting on one's behavior by answering questions or being directly observed and being aware of being studied. Although all but one study was undertaken within health sciences, study methods, contexts, and findings were highly heterogeneous. Most studies reported some evidence of an effect, although significant biases are judged likely because of the complexity of the evaluation object. CONCLUSION: Consequences of research participation for behaviors being investigated do exist, although little can be securely known about the conditions under which they operate, their mechanisms of effects, or their magnitudes. New concepts are needed to guide empirical studies.

46. **ARTÍCULO Nº: 4495**

Stuck AK, Fuhrer E, Limacher A, Mean M, Aujesky D. ***Adjudication-related processes are underreported and lack standardization in clinical trials of venous thromboembolism: a systematic review.*** J.Clin.Epidemiol. 2014; 67(3): 278-284.

OBJECTIVES: Although the use of an adjudication committee (AC) for outcomes is recommended in randomized controlled trials, there are limited data on the process of adjudication. We therefore aimed to assess whether the reporting of the adjudication process in venous thromboembolism (VTE) trials meets existing quality standards and which characteristics of trials influence the use of an AC. STUDY DESIGN AND SETTING: We systematically searched MEDLINE and the Cochrane Library from January 1, 2003, to June 1, 2012, for randomized controlled trials on VTE. We abstracted information about characteristics and quality of trials and reporting of adjudication processes. We used stepwise backward logistic regression model to identify trial characteristics independently associated with the use of an AC. RESULTS: We included 161 trials. Of these, 68.9% (111 of 161) reported the use of an AC. Overall, 99.1% (110 of 111) of trials with an AC used independent or blinded ACs, 14.4% (16 of 111) reported how the adjudication decision was reached within the AC, and 4.5% (5 of 111) reported on whether the reliability of adjudication was assessed. In multivariate analyses, multicenter trials [odds ratio (OR), 8.6; 95% confidence interval (CI): 2.7, 27.8], use of a data safety-monitoring board (OR, 3.7; 95% CI: 1.2, 11.6), and VTE as the primary outcome (OR, 5.7; 95% CI: 1.7, 19.4) were associated with the use of an AC. Trials without random allocation concealment (OR, 0.3; 95% CI: 0.1, 0.8) and open-label trials (OR, 0.3; 95% CI: 0.1, 1.0) were less likely to report an AC. CONCLUSION: Recommended processes of adjudication are underreported and lack standardization in VTE-related clinical trials. The use of an AC varies substantially by trial characteristics.

47. **ARTÍCULO Nº: 4496**

Treweek S, Bonetti D, MacLennan G, Barnett K, Eccles MP, Jones C et al. ***Paper-based and web-based intervention modeling experiments identified the same predictors of general practitioners' antibiotic-prescribing behavior.*** J.Clin.Epidemiol. 2014; 67(3): 296-304.

OBJECTIVES: To evaluate the robustness of the intervention modeling experiment (IME) methodology as a way of developing and testing behavioral change interventions before a full-scale trial by replicating an earlier paper-based IME. STUDY DESIGN AND SETTING: Web-based questionnaire and clinical scenario study. General practitioners across Scotland were invited to complete the questionnaire and scenarios, which were then used to identify predictors of antibiotic-prescribing behavior. These predictors were compared with the predictors identified in an earlier paper-based IME and used to develop a new intervention. RESULTS: Two hundred seventy general practitioners completed the questionnaires and scenarios. The constructs that predicted simulated behavior and

intention were attitude, perceived behavioral control, risk perception/anticipated consequences, and self-efficacy, which match the targets identified in the earlier paper-based IME. The choice of persuasive communication as an intervention in the earlier IME was also confirmed. Additionally, a new intervention, an action plan, was developed. CONCLUSION: A web-based IME replicated the findings of an earlier paper-based IME, which provides confidence in the IME methodology. The interventions will now be evaluated in the next stage of the IME, a web-based randomized controlled trial.

48. **ARTÍCULO Nº: 4497**

Pieper D, Antoine SL, Mathes T, Neugebauer EA, Eikermann M. ***Systematic review finds overlapping reviews were not mentioned in every other overview***. J.Clin.Epidemiol. 2014; 67(4): 368-375.

OBJECTIVES: The objective of this study was to determine if the authors mention overlapping reviews in overviews (reviews of reviews). In addition, we aimed to calculate the actual overlap in published overviews using newly introduced, validated measures. STUDY DESIGN AND SETTINGS: We systematically searched for overviews from 2009 to 2011. Reviews included in the overviews were obtained. Tables (reviewxprimary publication) were generated for each overview. The first occurrence of a primary publication is defined as the index publication. We calculated the "corrected covered area" (CCA) as a measure of overlap by dividing the frequency of repeated occurrences of the index publication in other reviews by the product of index publications and reviews, reduced by the number of index publications. Subgroup analyses were performed to investigate further differences in the overviews. RESULTS: Only 32 of 60 overviews mentioned overlaps. The median CCA was 4.0. Validation of the CCA and other overlap measures was in accordance with our predefined hypotheses. The degree of overlap tended to be higher in health technology assessment reports than in journal publications and was higher with increasing numbers of publications. CONCLUSIONS: Overlaps must be reported in well-conducted overviews, and this can comprehensively be accomplished using the CCA method.

49. **ARTÍCULO Nº: 4498**

Achana F, Hubbard S, Sutton A, Kendrick D, Cooper N. ***An exploration of synthesis methods in public health evaluations of interventions concludes that the use of modern statistical methods would be beneficial***. J.Clin.Epidemiol. 2014; 67(4): 376-390.

OBJECTIVES: To review the methods currently used to synthesize evidence in public health evaluations and demonstrate the availability of more sophisticated approaches. STUDY DESIGN AND SETTING: A systematic review of National Institute for Health and Care Excellence (NICE) public health appraisals published between 2006 and 2012 was performed to assess the methods used for the synthesis of effectiveness evidence. The ability of new developments in evidence synthesis methodology to address the challenges and opportunities present in a public health context is demonstrated. RESULTS: Nine (23%) of the 39 NICE appraisals included in the review performed pairwise meta-analyses as part of the effectiveness review with one of these also including a network meta-analysis. Of the remainder, 29 (74.4%) presented narrative summaries of the evidence only, and 1 (2.6%) appraisal did not present any review of effectiveness and/or cost-effectiveness evidence. Heterogeneity of outcomes, methods, and interventions were the main reasons given for not pooling the data. Exploration of quantitative synthesis methods shows that pairwise meta-analyses can be extended to incorporate individual participant data (when it is available), extend the number of interventions being compared using a network meta-analysis, and adjust for both subject- and summary-level covariates. All these can contribute to ensuring the analysis answers directly the policy-relevant questions.

CONCLUSION: More sophisticated methods in evidence synthesis should be considered to make evaluations in public health more useful for decision makers.

50. **ARTÍCULO Nº: 4499**

Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM et al. ***Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies.*** J.Clin.Epidemiol. 2014; 67(4): 401-409.

OBJECTIVE: To investigate how consensus is operationalized in Delphi studies and to explore the role of consensus in determining the results of these studies. STUDY DESIGN AND SETTINGS: Systematic review of a random sample of 100 English language Delphi studies, from two large multidisciplinary databases [ISI Web of Science (Thompson Reuters, New York, NY) and Scopus (Elsevier, Amsterdam, NL)], published between 2000 and 2009. RESULTS: About 98 of the Delphi studies purported to assess consensus, although a definition for consensus was only provided in 72 of the studies (64 a priori). The most common definition for consensus was percent agreement (25 studies), with 75% being the median threshold to define consensus. Although the authors concluded in 86 of the studies that consensus was achieved, consensus was only specified a priori (with a threshold value) in 42 of these studies. Achievement of consensus was related to the decision to stop the Delphi study in only 23 studies, with 70 studies terminating after a specified number of rounds. CONCLUSION: Although consensus generally is felt to be of primary importance to the Delphi process, definitions of consensus vary widely and are poorly reported. Improved criteria for reporting of methods of Delphi studies are required.

51. **ARTÍCULO Nº: 4500**

Gademan MG, Hosper K, Deutekom M, Engelbert RH, Myers J, Stronks K. ***A poor association was found between self-reported physical activity and estimated maximal oxygen uptake of sedentary multiethnic women.*** J.Clin.Epidemiol. 2014; 67(4): 462-467.

OBJECTIVES: In health evaluations, physical activity (PA) and cardiorespiratory fitness (maximal oxygen uptake [VO2max]) are important variables. It is not always possible to assess both of them. If the association between self-reported PA and VO2max was strong, it would be possible to use the information on PA to make assumptions about VO2max and vice versa. However, little is known about this relation, in particular among women at high risk for cardiovascular disease. Our aim was to study the association between self-reported PA (Short QUestionnaire to ASses Health enhancing PA) and fitness (determined using the Siconolfi step test) among sedentary women in a multiethnic population. STUDY DESIGN AND SETTING: Participants were sampled from an exercise program for sedentary women (The Netherlands, 2008-09). Linear regression was performed with VO2max (dependent variable) and self-reported PA (independent variable); covariates were age and body mass index. RESULTS: One hundred ninety-seven women from different ethnic backgrounds were included. No significant association was found between VO2max and PA (R(2) = 0.60). CONCLUSION: A poor association was found between self-reported PA and estimated VO2max. Hence, PA and VO2max represent two different aspects of health in sedentary women and cannot be used interchangeably. This should be taken into account when evaluating health promotion interventions or when making health risks statements in sedentary women in a multiethnic population.

52. **ARTÍCULO Nº: 4501**

Bolt EE, van der HA, Onwuteaka-Philipsen BD. ***Reducing questionnaire length did not improve physician response rate: a randomized trial.*** J.Clin.Epidemiol. 2014; 67(4): 477-481.

OBJECTIVES: To examine the effect of reducing questionnaire length on the response rate in a physician survey. STUDY DESIGN AND SETTING: A postal four double-page questionnaire on end-of-life decision making was sent to a random sample of 1,100 general practitioners, 400 elderly care physicians, and 500 medical specialists. Another random sample of 500 medical specialists received a shorter questionnaire of two double pages. After 3 months and one reminder, all nonresponding physicians received an even shorter questionnaire of one double page. RESULTS: Total response was 64% (1,456 of 2,269 eligible respondents). Response rate of medical specialists for the four double-page questionnaire was equal to that of the two double-page questionnaire (190 and 191 questionnaires were returned, respectively). The total response rate increased from 53% to 64% after sending a short one double-page questionnaire (1,203-1,456 respondents). CONCLUSION: The results of our study suggest that reducing the length of a long questionnaire in a physician survey does not necessarily improve response rate. To improve response rate and gather more information, researchers could decide to send a drastically shortened version of the questionnaire to nonresponders.

53. **ARTÍCULO Nº: 4502**

Rose M, Bjorner JB, Gandek B, Bruce B, Fries JF, Ware JE, Jr. ***The PROMIS Physical Function item bank was calibrated to a standardized metric and shown to improve measurement efficiency***. J.Clin.Epidemiol. 2014; 67(5): 516-526.

OBJECTIVE: To document the development and psychometric evaluation of the Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function (PF) item bank and static instruments. STUDY DESIGN AND SETTING: The items were evaluated using qualitative and quantitative methods. A total of 16,065 adults answered item subsets (n>2,200/item) on the Internet, with oversampling of the chronically ill. Classical test and item response theory methods were used to evaluate 149 PROMIS PF items plus 10 Short Form-36 and 20 Health Assessment Questionnaire-Disability Index items. A graded response model was used to estimate item parameters, which were normed to a mean of 50 (standard deviation [SD]=10) in a US general population sample. RESULTS: The final bank consists of 124 PROMIS items covering upper, central, and lower extremity functions and instrumental activities of daily living. In simulations, a 10-item computerized adaptive test (CAT) eliminated floor and decreased ceiling effects, achieving higher measurement precision than any comparable length static tool across four SDs of the measurement range. Improved psychometric properties were transferred to the CAT's superior ability to identify differences between age and disease groups. CONCLUSION: The item bank provides a common metric and can improve the measurement of PF by facilitating the standardization of patient-reported outcome measures and implementation of CATs for more efficient PF assessments over a larger range.

54. **ARTÍCULO Nº: 4503**

Hawthorne G, Sansoni J, Hayes L, Marosszeky N, Sansoni E. ***Measuring patient satisfaction with health care treatment using the Short Assessment of Patient Satisfaction measure delivered superior and robust satisfaction estimates***. J.Clin.Epidemiol. 2014; 67(5): 527-537.

OBJECTIVES: Reviews of patient satisfaction suggest seven dimensions, each of which should be assessed. This study reports development of a short generic patient satisfaction measure for use in routine clinical practice. STUDY DESIGN AND SETTINGS: Participants were randomly recruited from two Australian incontinence clinics. Participants completed a follow-up questionnaire including patient satisfaction items. Iterative Mokken and Rasch analyses derived the Short Assessment of

Patient Satisfaction (SAPS) scale from the item bank. RESULTS: The SAPS psychometric properties illustrated the following features, namely its descriptive system covers all seven patient satisfaction dimensions, there were no misfitting items, and the scale exceeded the Loevinger H criteria for a strong unidimensional scale. The reliability of the SAPS was Cronbach alpha=0.86. When discriminatory function was examined, the SAPS scale was more sensitive than two other generic patient satisfaction instruments. CONCLUSION: The SAPS scale is based on a firm theoretical model of patient satisfaction and its descriptive system covers the known dimensions contributing to patient satisfaction. Its internal psychometric properties exceeded standard psychometric standards, and it discriminated at least as well as other longer patient satisfaction measures. Although it needs further validation, the study results suggest that it may be useful for assessing patient satisfaction with health care.

55. **ARTÍCULO Nº: 4504**

Siontis KC, Siontis GC, Contopoulos-Ioannidis DG, Ioannidis JP. ***Diagnostic tests often fail to lead to changes in patient outcomes***. J.Clin.Epidemiol. 2014; 67(6): 612-621.

OBJECTIVES: To evaluate the effects of diagnostic testing on patient outcomes in a large sample of diagnostic randomized controlled trials (D-RCTs) and to examine whether the effects for patient outcomes correlate with the effects on management and with diagnostic accuracy. STUDY DESIGN AND SETTING: We considered D-RCTs that evaluated diagnostic interventions for any condition and reported effectiveness data on one or more patient outcomes. We calculated odds ratios for patient outcomes and outcomes pertaining to the use of further diagnostic and therapeutic interventions and the diagnostic odds ratio (DOR) for the accuracy of experimental tests. RESULTS: One hundred forty trials (153 comparisons) were eligible. Patient outcomes were significantly improved in 28 comparisons (18%). There was no concordance in significance and direction of effects between the patient outcome and outcomes for use of further diagnostic or therapeutic interventions (weighted kappa 0.02 and 0.09, respectively). The effect size for the patient outcome did not correlate with the effect sizes for use of further diagnostic (r = 0.05; P = 0.78) or therapeutic interventions (r = 0.18; P = 0.08) or the experimental intervention DOR in the same trial (r = -0.24; P = 0.51). CONCLUSION: Few tests have well-documented benefits on patient outcomes. Diagnostic performance or the effects on management decisions are not necessarily indicative of patient benefits.

56. **ARTÍCULO Nº: 4505**

Alexander PE, Bero L, Montori VM, Brito JP, Stoltzfus R, Djulbegovic B et al. ***World Health Organization recommendations are often strong based on low confidence in effect estimates***. J.Clin.Epidemiol. 2014; 67(6): 629-634.

OBJECTIVES: Expert guideline panelists are sometimes reluctant to offer weak/conditional/contingent recommendations. Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidance warns against strong recommendations when confidence in effect estimates is low or very low, suggesting that such recommendations may seldom be justified. We aim to characterize the classification of strength of recommendations and confidence in estimates in World Health Organization (WHO) guidelines that used the GRADE approach and graded both strength and confidence (GRADEd). STUDY DESIGN AND SETTING: We reviewed all WHO guidelines (January 2007 to December 2012), identified those that were GRADEd, and, in these, examined the classifications of strong and weak and associated confidence in estimates (high, moderate, low, and very low). RESULTS: We identified 116 WHO guidelines in which 43 (37%) were GRADEd and had 456 recommendations, of which 289 (63.4%) were strong and 167 (36.6%) were conditional/weak. Of the

289 strong recommendations, 95 (33.0%) were based on evidence warranting low confidence in estimates and 65 (22.5%) on evidence warranting very low confidence in estimates (55.5% strong recommendations overall based on low or very low confidence in estimates). CONCLUSION: Strong recommendations based on low or very low confidence estimates are very frequently made in WHO guidelines. Further study to determine the reasons for such high uncertainty recommendations is warranted.

57. **ARTÍCULO Nº: 4506**

Ward MM, Guthrie LC, Alba M. ***Dependence of the minimal clinically important improvement on the baseline value is a consequence of floor and ceiling effects and not different expectations by patients***. J.Clin.Epidemiol. 2014; 67(6): 689-696.

OBJECTIVE: Estimates of minimal clinically important improvements (MCIIs) are larger among patients with higher values at baseline, suggesting that these patients require larger changes to appreciate improvements. We examined if baseline dependency of MCIIs was associated with specific patients across three measures, or was owing to floor and ceiling effects. STUDY DESIGN AND SETTING: We prospectively examined 250 outpatients with active rheumatoid arthritis (RA). We used an anchor-based approach to estimate MCIIs for three measures of RA activity (patient global assessment, swollen joint count, and walking time). We examined if the same patients constituted the baseline subgroups with high MCIIs across measures. RESULTS: The MCIIs were greater for those with higher baseline values of all three measures. At the ceiling, there was little opportunity to improve, and judgments were unrelated to measured changes. At midrange, improvements were balanced by worsenings, including some judged as improvements. At the floor, improvements were not similarly balanced. Patients in subgroups with high MCII for patient global assessment were not also predominantly in subgroups with high MCII for the swollen joint count or walking time, and vice versa. CONCLUSION: Variation in MCII by baseline values is because of floor and ceiling effects rather than expectations of particular patients.

58. **ARTÍCULO Nº: 4507**

Gopalakrishna G, Mustafa RA, Davenport C, Scholten RJ, Hyde C, Brozek J et al. ***Applying Grading of Recommendations Assessment, Development and Evaluation (GRADE) to diagnostic tests was challenging but doable***. J.Clin.Epidemiol. 2014; 67(7): 760-768.

OBJECTIVES: The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group developed an approach to assess the quality of evidence of diagnostic tests. Its use in Cochrane diagnostic test accuracy reviews is new. We applied this approach to three Cochrane reviews with the aim of better understanding the application of the GRADE criteria to such reviews. STUDY DESIGN AND SETTING: We selected reviews to achieve clinical and methodological diversities. At least three assessors independently assessed each review according to the GRADE criteria of risk of bias, indirectness, imprecision, inconsistency, and publication bias. Two teleconferences were held to share experiences. RESULTS: For the interpretation of the GRADE criteria, it made a difference whether assessors looked at the evidence from a patient-important outcome perspective or from a test accuracy standpoint. GRADE criteria such as inconsistency, imprecision, and publication bias were challenging to apply as was the assessment of comparative test accuracy reviews. CONCLUSION: The perspective from which evidence is graded can influence judgments about quality. Guidance on application of GRADE to comparative test reviews and on the GRADE criteria of inconsistency, imprecision, and publication bias will facilitate the operationalization of GRADE for diagnostics.

59. **ARTÍCULO Nº: 4508**

Cheung YT, Foo YL, Shwe M, Tan YP, Fan G, Yong WS et al. ***Minimal clinically important difference (MCID) for the functional assessment of cancer therapy: cognitive function (FACT-Cog) in breast cancer patients***. J.Clin.Epidemiol. 2014; 67(7): 811-820.

OBJECTIVES: This is the first reported study to determine the minimal clinically important difference (MCID) of Functional Assessment of Cancer Therapy-Cognitive Function (FACT-Cog), a validated subjective neuropsychological instrument designed to evaluate cancer patients' perceived cognitive deterioration. STUDY DESIGN AND SETTING: Breast cancer patients (n = 220) completed FACT-Cog and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC-QLQ-C30) at baseline and at least 3 months later. Anchor-based approach used the validated EORTC-QLQ-C30-Cognitive Functioning scale (EORTC-CF) as the anchor for patients who showed minimal deterioration and a receiver operating characteristic (ROC) curve to identify the optimal MCID cutoff for deterioration. Distribution-based approach used one-third standard deviation (SD), half SD, and one standard error of measurement (SEM) of the total FACT-Cog score (148 points). RESULTS: There was a moderate correlation between changes in FACT-Cog and EORTC-CF scores ($r = 0.43$; $P < 0.001$). The EORTC-CF-anchored MCID was 9.6 points (95% confidence interval: 4.4, 14.8). The MCID from the ROC method was 7.5 points (area under the curve: 0.75; sensitivity: 75.6%; specificity: 68.8%). For the distribution-based approach, the MCIDs corresponding to one-third SD, half SD, and one SEM were 6.9, 10.3, and 10.6 points, respectively. Combining the approaches, the MCID identified for FACT-Cog ranged from 6.9 to 10.6 points (4.7-7.2% of the total score). CONCLUSION: The estimates of 6.9-10.6 points as MCID can facilitate the interpretation of patient-reported cognitive deterioration and sample size estimates in future studies.

60. **ARTÍCULO Nº: 4509**

Frei A, Muggensturm P, Putcha N, Siebeling L, Zoller M, Boyd CM et al. ***Five comorbidities reflected the health status in patients with chronic obstructive pulmonary disease: the newly developed COMCOLD index***. J.Clin.Epidemiol. 2014; 67(8): 904-911.

OBJECTIVE: This study aimed to identify those comorbidities with greatest impact on patient-reported health status in patients with chronic obstructive pulmonary disease (COPD) and to develop a comorbidity index that reflects their combined impact. STUDY DESIGN AND SETTING: We included 408 Swiss and Dutch primary care patients with COPD from the International Collaborative Effort on Chronic Obstructive Lung Disease: Exacerbation Risk Index Cohorts (ICE COLD ERIC) in this cross-sectional analysis. Primary outcome was the Feeling Thermometer, a patient-reported health status instrument. We assessed the impact of comorbidities at five cohort assessment times using multiple linear regression adjusted for FEV1, retaining comorbidities with associations P </= 0.1. We developed an index that reflects strength of association of comorbidities with health status. RESULTS: Depression (prevalence: 13.0%; regression coefficient: -9.00; 95% CI: -13.52, -4.48), anxiety (prevalence: 11.8%; regression coefficient: -5.53; 95% CI -10.25, -0.81), peripheral artery disease (prevalence: 6.4%; regression coefficient: -5.02; 95% CI-10.64, 0.60), cerebrovascular disease (prevalence: 8.8%; regression coefficient: -4.57; 95% CI -9.43, 0.29), and symptomatic heart disease (prevalence: 20.3%; regression coefficient: -3.81; 95% CI -7.23, -0.39) were most strongly associated with the Feeling Thermometer. These five comorbidities, weighted, compose the COMorbidities in Chronic Obstructive Lung Disease (COMCOLD) index. CONCLUSION: The COMCOLD index reflects the combined impact of five important comorbidities from patients' perspective and complements existing comorbidity indices that predict death. It may help clinicians focus on comorbidities affecting patients' health status the most.