indicators for the Clearing House and the measures could complement indicators on clinical quality of providers from the NIH Promis initiative in the United States (or the NHS Proms in the UK). **METHODS:** The concept development is relevant for chronic care. Five domains represent outpatient drug care: information, communication access, trust and clinical quality. Four process measures and one access measure are proposed with series of 5 -7 items, tested on pharmacy delivery systems and dispensing doctors.The trust indicator has been identified as critical for the US drug delivery system and discussed as an example. **RESULTS:** Trust adresses the potential patient mistrust when cost interfere with clinical judgement. The process measure is calculated for prescribing and treatment decisions for Hypertension, Diabetes and Asthma.It is a rate base measure . The Facct scoring method is modified to integrate minima in low score values. Mean scores are calculated on samples per practice. Missing values are replaced by mean value. The evidence from the UK PCT on a scale of 0-100, for three practices show scores of 66.78; 63.82;73.92 and 67.72 for the whole sample with a Cronbach of 0.70. **CONCLUSIONS:** A composite indicator is envisaged for diffferent decision points in clinical practices. It is to be linked to clinical decision points from the Adaptive Knowledge Platform (AKP) (Huttin, Liebamn, 2011) on breast cancer and could fit the requirements for the 12 rules for EGD in cancer. Validations in additional organisations of care and delivery systems are planned in further validation stages.

RESEARCH POSTER PRESENTATIONS – SESSION II
SELECTED HEALTH CARE TREATMENT STUDIES

MEDICAL DEVICE/DIAGNOSTICS – Clinical Outcomes Studies

PMD1
HISTORICAL TRENDS IN OUTCOMES FOLLOWING AORTIC AND MITRAL HEART VALVE REPLACEMENT PROCEDURES: A POPULATION-BASED STUDY OF 29,582 MEDICARE PATIENTS FROM 1997 TO 2009

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OBJECTIVES: To serve as comparative data for percutaneous valve replacements, this study sought to characterize the historical outcomes for aortic and mitral valve replacement surgery in a large, nationally representative population. **METHODS:** Patients undergoing aortic or mitral valve replacement were identified from the 5% national Medicare data (1997-2009) using ICD-9-CM codes 35.21 to 35.24. The subsequent rates of mortality, mechanical complications, infection, and valve re-implantation/reoperation, and infective endocarditis were evaluated. Hospitalization charges and reimbursements (in Jan 2011 dollars) for the index procedure were also assessed. **RESULTS:** The patient cohort included 12,202 aortic bioprosthesis, 9,757 aortic mechanical valves, 3,222 mitral bioprosthesis, and 4,401 mitral mechanical valves. The ten-year Kaplan-Meier mortality, mechanical complication, infection, re-implantation/reoperation, and infective endocarditis rates for aortic bioprosthesis were 64.4%, 4.41%, 4.54%, 1.50%, and 8.34%, respectively, and for aortic mechanical valves were 63.9%, 5.23%, 4.71%, 1.84%, and 9.08%, respectively. The corresponding ten-year Kaplan-Meier rates for mitral bioprosthesis were 74.8%, 8.02%, 6.29%, 2.81%, and 12.90%, respectively, and for mitral mechanical valves were 64.7%, 7.60%, 6.06%, 2.87%, and 12.24%, respectively. The average hospitalization reimbursements for procedures involving aortic bioprostheses, aortic mechanical valves, mitral bioprostheses, and mitral mechanical valves were $54.3k, $54.6k, $64.1k, and $62.2k, respectively. **CONCLUSIONS:** The crude risks of mortality and complications, as well as payer costs, were found to be higher for mitral valve replacements compared with aortic valve replacements. This study provides baseline data for evaluating the comparative effectiveness of percutaneous valve replacement to "traditional" approaches, especially since the percutaneous approach may have inherently different levels of performance or expanded indications.

PMD2
ADMISSION TO CORONARY ANGIOGRAPHIC CATHETERIZATION IN ARMENIA AT NORK MARASH MEDICAL CENTER: CHARACTERISTICS AND OUTCOMES

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OBJECTIVES: The importance of avoiding unnecessary diagnostic invasive angiography is emphasized based on risks associated with test and costs. At the same time, early interventions are important to reduce negative outcomes of coronary artery disease (CAD). Objective of this study was to analyze the characteristics and outcomes of cases with possible CAD that underwent coronary angiography catheterization (CAG) from December 2006 to February 2007 consecutively in Nork Marash Medical Center (NMMC). **METHODS:** This was a retrospective study of newly admitted cohort. Predefined exclusion criteria were CAG in other clinic, CAG for other then CAD reasons and non Armenian residency. **RESULTS:** Only 200 records were corresponding to the criteria. The mean age of cases was 52.91±10 years and 85% were males (RR=0.93). The mean age of women was higher (≈60 vs ≈50). Only 10.5% of participants had normal BMI. Current smokers comprised 60 %(RR=1.17), 74% had hypertension (RR=1.165), 30.5% hypercholesterolemia (RR=2.5) and 14.5% Diabetes Mellitus (RR=4.26). In 26(13%) cases catheterization detected no CAD at all and 13(6.5%) patients had stenosis<50%. Most catheterizations were elective (68%).There were 2 urgent admissions among patients with CAD<50%. Significantly diseased left anterior descending (LAD) proximal was detected most frequently (52%).Among patients with stenosis≥50% 24% of cases underwent PCI, 75% CABG, and 5% bridge to CABG procedure. Thirty two people (20%) were not treated with revascularization: among them 7 (21.9%) with multivessel disease. 15% of patients with indication to revascularization refused to be treated with any of procedures. **CONCLUSIONS:** There is gender inequality in CAG utilization, early cholesterol control should be encouraged by primary care professionals, patient preferences play significant role in a treatment decision process in Armenia.

PMD3
DOES CURRENT PERCEPTION THRESHOLD TEST CAN DIFFERENTIATE CATEGORIES OF MECHANICAL NECK DISORDER?

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OBJECTIVES: To differentiate three types of Mechanical Neck Disorders (MND) by Current Perception Threshold (CPT). Specific aims were to: 1) Look whether differences in CPT exist in MND categories, and 2) Estimate the predicted probability of the neurological symptoms in type-3 of MND. **METHODS:** The study design was a laboratory based cross-sectional discriminative analysis. Patients with MND (N = 106) were assessed for CPT into three groups: MND-mixed (N=60), MND-2 (N=29), MND-3 (N=17). CPT testing was performed in a standard Quantatative Sensory Testing laboratory. A one-way ANOVA with post hoc was done for compare the mean CPT score between the groups. An independent sample t-test was done to compare the mean CPT and estimated effect size between MND-2 and MND-3 group. The discriminative analysis predicted the group membership in one of the categories. A binary logistic regression model predicted probability of higher CPT in MND-3, where CPT score counted as the risk factor to having neurological symptoms. A Receiver Operating Characteristic (ROC) curve was created from predicted probability by binary covariate. **RESULTS:** Mean CPT differed significantly across the three groups (F 2, 96 = 6.69, p = 0.002), with a significant higher preference rating in MND-3 (p = 0.004). Moderate discriminates and a small to medium effect size found between the MND-2 and MND-3. Model discrimination (between MND-2 and MND-3) showed 86.2% specificity and 64.7% sensitivity, where an area under the ROC curve was 0.836 (95% CI = 0.716 - 0.956, p = 0.000). **CONCLUSIONS:** CPT test was capable of differentiate MND categories. CPT might be a potential tool for evaluating neurological involvement or hypersensitivity in neck pain.

PMD4
QUALITATIVE MOLECULAR TESTS FOR CONFIRMATION OF THE DIAGNOSIS OF HEPATITIS C IN SEROPOSITIVE PATIENTS: A SYSTEMATIC REVIEW

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OBJECTIVES: Hepatitis C represents a serious Public Health problem. In approximately 80% of cases, the disease becomes chronic and the diagnosis can sometimes be made before the disease becomes severe. In 1993, the Brazilian government adopted a screening system with serological kits for hepatitis C diagnosis in blood donors. A positive screening, however, should be confirmed with another type of test since they do not distinguish active infection from past infection. So, molecular tests are very important to establish actual viremia and the hepatitis c diagnosis. Many guidelines throughout the world recommend the molecular test in various settings, including the confirmation of HCV in seropositive people. There are different qualitative molecular tests available for detecting HCV. The aim of this study was to conduct a systematic review of the accuracy of these different tests for confirmation of the diagnosis of HCV in seropositive people. **METHODS:** We searched MEDLINE, SCOPUS and the Cochrane Library. QUADAS was the tool used for quality assessment of the studies. **RESULTS:** The search resulted in 1222 articles for evaluation. Only 2 studies were included in the systematic review, according to the established inclusion and exclusion criteria. Both COBAS AMPLICOR and AMPLICOR tests had high sensitivity and specificity in one of the studies. The second study, presented accuracy data regarding an "in house" PCR test, which presented overall accuracy of 75%. **CONCLUSIONS:** Although we identified many articles in our search, the vast majority addressed analytical sensitivity, therefore not meeting our criteria, especially because they did not present accuracy data according to an established a gold standard. Furthermore, the 2 studies included did not present a good methodological quality according to QUADAS. These findings show the urgent need of studies with appropriate design for extraction of accuracy data of molecular tests.

PMD5
USE AND FINDINGS OF K-RAS IN COLORECTAL CANCER (CRC) TESTING IN ADMINISTRATIVE AND ELECTRONIC MEDICAL RECORDS (EMR) DATA FROM 2005 THROUGH 2010

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OBJECTIVES: The use of K-ras testing in clinical decision-making has grown over the past few years. The objective of this study was to evaluate, in a real world context, the trends and diagnostic findings of K-ras testing using managed care and EMR data. **METHODS:** The Georgia Cancer Specialists Database EMR (2005-2010) and administrative data from the MarketScan and IMPACT database(s) was used to select patients with newly diagnosed colorectal cancer (CRC). We looked for trends in use of K-ras in relation to timing of chemotherapy administration. The EMR data provided information on k-ras mutation type. **RESULTS:** In MarketScan, of the 23,548 patients with a diagnosis of CRC, 1,730 (7.3%) patients had a test ordered for K-ras between 2005 and 2010. The number of patients receiving K-ras increased with line of therapy: first line 336 patients (8.2%) of 4098 treated, second line 455

patients (15.2%) of 2984 treated, and third line 529 patients (33%) of 1603 treated. We found similar results using the IMPACT database: 2,256 (7.8%) CRC patients had a test ordered for K-ras between 2005 and 2010. K-ras testing increased with line of therapy: first line 244 patients (7.8%), second line 510 (14.6%), and third line 650 patients (33.1%). EMR lab results from stage IV disease (n=349) consisted of 15% mutated type, 60% unknown and 25% wild type. For confirmed test results wild type represented 62.5% and mutated type 37.5%. **CONCLUSIONS:** Over the last six years, use of K-ras testing has increased in use in patients with CRC. The increase has occurred in later lines of therapy. The timing occurring late in therapy may limit the use of agents specific for this test.

PMD6

THE CLINICAL USEFULNESS OF CT CORONARY ANGIOGRAPHY FOR THE DIAGNOSIS OF ISCHEMIC HEART DISEASE IN PATIENTS WITH CHEST PAIN

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OBJECTIVES: The aim of this study is to evaluate the accuracy of non-invasive diagnosis methods for ischemic heart disease in patients with chest pain. **METHODS:** A retrospective cohort study was performed on new patients who have not received any diagnosis of ischemic heart disease or treatment before among those over 30 years of age who visited the cardiology outpatient clinic between 2006 to 2008 in a single medical institution. Among non-invasive diagnostic methods, stress ECG(sECG), myocardial SPECT, and CT coronary angiography(CTCA) were included in our study. Since coronary angiography(CAG) was not performed in all patients, the comparison of test accuracy was calculated by correcting referral bias to CAG depending on non-invasive test results based on the Bayes Theorem, and by reflecting the 1-year follow-up results. **RESULTS:** Among 4743 patients selected, 2485 patients received more than one of the following non-invasive tests: sECG, SPECT, and CTCA for differential diagnosis. sECG was performed in 853 patients(34.3%), SPECT in 997 patients(40.1%), and CTCA in 635 patients(25.6%). A total of 592 patients(23.8%) received CAG among the 2485 patients. Test indices adjusted for referral bias using the 2 methods were a sensitivity of 49% or 80% in sECG, 46% or 75% in SPECT and 57% or 88% in CTCA, a specificity of 65% or 62%, 81% or 78% in SPECT and 96% or 81% in CTCA. A likelihood ratio for a positive test were 1.39 or 2.08 in sECG, 2.47 or 3.38 in SPECT and 14.14 or 4.65 in CTCA, and a likelihood ratio for a negative test were 0.79 or 0.33 in sECG, 0.66 or 0.32 in SPECT and 0.45 or 0.14 in CTCA. **CONCLUSIONS:** In conclusion, the accuracy of diagnosing ischemic heart disease was the highest in CTCA, followed by myocardial SPECT and sECG by correcting referral bias to CAG.

PMD7

LONG-TERM CLINICAL OUTCOMES AFTER CORONARY BARE-METAL AND DRUG-ELUTING STENTING

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OBJECTIVES: To evaluate long-term clinical outcomes of elderly Medicare beneficiaries who underwent non-emergent coronary stenting. **METHODS:** This population-based prospective study analyzed patients in a large nationally representative administrative claims database. The sample consisted of Medicare patients aged 65+ who underwent a non-emergent coronary stent between 2006 and 2010. Patients were identified by existence of a hospital claim for a bare metal stent (ICD-9-CM procedure code 36.06) or drug-eluting stent (ICD-9-CM procedure code 36.07 or codes 36.06 and 36.07). Eligible patients were followed one to five years after stenting to assess risk of revascularization, myocardial infarction (MI), coronary artery bypass surgery (CABG), and death. Long-term clinical outcomes were based on HEDIS 2010 technical specifications. **RESULTS:** The study population included 26,023 patients that underwent a coronary bare-metal stent (female = 40.15%, age = 75.38 (± 6.66), history of MI = 7.97%, history of CABG = 1.01%) and 74,448 patients that underwent a coronary drug-eluting stent (female = 40.17%, age = 73.78 (± 6.19), history of MI = 7.39%, history of CABG = 1.27%). Patients with drug-eluting stents had a lower risk of revascularization (29.57% vs. 31.65%, $p < 0.001$), CABG (1.40% vs. 2.57%, $p < 0.001$), and mortality (4.96% vs. 9.25%, $p < 0.001$) within one year follow-up after stenting. There was no significant difference in the risk for MI within one to four years follow-up (3.35% vs. 3.29%, $p > 0.05$), but there was a significant difference in risk of MI at five year follow-up (7.33% vs. 3.36%, $p < 0.001$). Mortality rates significantly increased over time in patients with a bare-metal stent while mortality rates for those with a drug-eluting stent remained relatively stable. **CONCLUSIONS:** The use of drug-eluting stents was significantly correlated with a decline in long-term risk of revascularization, CABG, MI and death in comparison to bare-metal stents.

PMD8

EFFICACY OF SYSTEMIC HYPERBARIC OXYGEN THERAPY FOR NON-HEALING DIABETIC ULCERS OF THE LOWER LIMB: SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: About 10-15% of individuals with diabetes mellitus develop foot ulcers which precede 85% of amputations. Increased oxygen exposure, through the use of hyperbaric oxygen therapy (HBOT), has been suggested to encourage ulcer healing thus reducing the risk of amputation. The objective of this systematic review is to evaluate the efficacy of systemic HBOT for non-healing ulcers of the lower limb in diabetes patients. **METHODS:** A systematic search of the published literature was conducted using controlled and keyword terms focusing on "HBOT" and "lower limb diabetic ulcers". Databases searched included Medline, EMBASE, CINAHL, PubMed, Wiley's Cochrane Library, and Biosis. Randomized controlled trials (RCTs) and observational studies were included and no year or language limits were employed. Two reviewers screened the articles. Pooled estimates of outcomes were calculated using Review Manager when appropriate. **RESULTS:** Of the 543 citations identified, 152 articles underwent full-text review. Data was abstracted from 27 publications (7 RCTs, 9 comparative observational, and 11 non-comparative observational studies). Primary outcomes of rates of amputation (major or minor) and wound healing were identified. Relative risk (RR) estimates from RCTs in the pooled analysis reflect a significant reduction in major amputation (RR = 0.32, 95% CI 0.11 to 0.91) with HBOT. For the proportion of unhealed wounds, HBOT is also favoured (RR = 0.45, 95% CI 0.32 to 0.64). **CONCLUSIONS:** The limited RCT evidence surrounding the efficacy of HBOT favours the use of HBOT for non-healing wounds of the lower limb for diabetes patients. Rigorous clinical trials with larger sample sizes, however, need to be conducted to more conclusively establish the benefits and harms of treating diabetic lower limb ulcers with HBOT.

PMD9

AN INNOVATIVE DISCUSSION ON PET- SCAN: IS IT THE POSITRON EMISSION TOMOGRAPHY A COST EFFECTIVE ALTERNATIVE IN THE PRE-TREATMENT EVALUATION OF CERVICAL CARCINOMA COMPARED TO FIGO STAGING?

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OBJECTIVES: The increasing use of both PET scan and surgical lymph node evaluation in the cervical cancer (CC) treatment has led to a clinical debate. The objective of this study is to provide a cost analysis of routine PET imaging in the work-up of CC. **METHODS:** A decision-tree model was designed to compare pre-treatment evaluation including PET-scan versus FIGO staging. Primary outcome was correct primary treatment (CPT) due to the use of PET or FIGO. Cost effectiveness ratios were calculated and results were expressed in terms of incremental cost effectiveness ratio (ICER). The model used the SEER 2011 database (n=12,200), for number, incidence, and stage distribution of CC. Medicare reimbursement rates were used for costs. Lymph node metastasis rates for each stage, and performance characteristics of PET were abstracted from published data. Cited values were used and varied over for sensitivity analysis. **RESULTS:** The addition of PET-scan to FIGO clinical staging for IA1 CC resulted in 6(0.5%) more CPTs than FIGO staging at baseline. In stage IA2, 75(6%) more CPT were performed and 187(14%) in stage IB1, and an additional 322(24%) in IB2. In stage IIA, PET-scan resulted in an additional 50(3%) CPT (ICER=$75,575), compared to 234(12%) CPT (ICER=$61,509) in stage IIB, and 333(26%) additional CPT in stage IIIA, (ICER= $48,293). In stage IIIB and IVA the addition of PET resulted in 240(19%) more CPT, and 41(8%) additional CPT in stage IVA (ICER=$52,791 vs.$71,810). Outcomes were sensitive to changes in prevalence and PET performance in the sensitivity analysis. **CONCLUSIONS:** Routine pre-treatment PET-scan may be cost effective for stage IA2-IB2 CC. The inclusion of PET-scan in the pre-treatment evaluation of stage I CC increased the number of CPT with an elevated ICER. The findings of this model need to be validated in the clinical-setting to generate knowledge on best resources' allocation.

PMD10

THE ROLE OF BIOMARKERS IN LUNG CANCER SCREENING: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Low dose computed tomography (CT) is the current recommended lung cancer screening modality for selected high risk population. The role of biomarkers is not clear. The objective of our study is to investigate the role of biomarkers in lung cancer screening via a systematic review and meta-analysis. **METHODS:** A systematic review is performed by reviewing primary studies focusing on biomarkers for lung cancer screening using the following keywords (lung cancer) AND ((screen*) OR (diagnosis) OR (diagnostic) OR (prediagnostic) OR (detection) OR (predict*) OR (development)) AND ((biomarker) OR (blood) OR (serum) OR (sera) OR (plasma) OR (antibodies) OR (urin*) OR (sputum) OR (exhale*) OR (volatile) OR (epithelium) OR (epithelial) OR (bronchial) OR (airway)) in the title/abstract in Pubmed® on December 31, 2011. We further limited our search to clinical trials, meta-analysis, or randomized controlled trials published for the past 5 years in English. Two independent reviewers identified studies compatible for selection criteria and data extraction after consensus was reached. Manual searching for relevant studies was also performed from relevant studies. A random effect model was used to calculate the pooled diagnostic performance of biomarker screening. **RESULTS:** Among the identified studies (n=172), three studies were included. In total, 1932 participants received various kinds of biomarkers screening. By using these biomarkers to differentiate cancer from non-cancer, the estimated pooled sensitivity and specificity with 95% confidence interval was 40% (24% ~ 57%) and 96% (94% ~ 97%) respectively. **CONCLUSIONS:** The diagnostic performance of biomarkers for lung cancer screening is fair based on very limited data as found in this systematic review. The role of biomarkers in lung cancer screening deserves further studies.

MEDICAL DEVICE/DIAGNOSTICS – Cost Studies

PMD11

BUDGET IMPACT OF CONVERTING STANDARD TREATMENT OF MENORRHAGIA FROM ROLLERBALL TO THERMAL BALLOON ABLATION IN CANADIAN HOSPITALS

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