

Introduction. In the past decade, health technology assessment (HTA) has narrowed its scope to the analysis of mainly clinical and economic benefits. However, twenty-first century technology challenges require the need for more holistic assessments to obtain accurate recommendations for decision-making, as it was in HTA's foundations. VALUES In Doing Assessments of health TEchnologies (VALIDATE) methodology approaches complex technologies holistically to provide a deeper understanding of the problem through analysis of the heterogeneity of stakeholders' views, allowing for more comprehensive HTAs. This study aimed to assess a pharmaceutical clinical decision support system (CDSS) using VALIDATE.

Methods. A systematic review of the empirical evidence on CDSS was conducted according to PRISMA guidelines. PubMed, the Cochrane Library, and Web of Science databases were searched for literature published between 2000 and 2020. Additionally, a review of grey literature and semi-structured interviews with different hospital stakeholders (pharmacists, physicians, computer engineers, etc.) were conducted. Content analysis was used for data integration.

Results. Preliminary literature results indicated consensus regarding the effectiveness of CDSS. Nevertheless, when including multistakeholder views, CDSS appeared to not be fully accepted in clinical practice. The main reasons for this appeared to be alert fatigue and disruption of workflow. Preliminary results based on information from the literature were contrasted with stakeholder interview responses.

Conclusions. Incorporation of facts and stakeholder values into the problem definition and scoping for a health technology is essential to properly conduct HTAs. The lack of an inclusive multistakeholder scoping can lead to inaccurate information, and in this particular case to suboptimal CDSS implementation concerning decision-making for the technology being evaluated.

PP146 Use Of Carbon Dioxide In Endovascular Surgery To Prevent Contrast-Induced Nephropathy

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Introduction. Interventional procedures often use iodinated contrast media (ICM) to visualize the area of interest. However, the use of ICM can cause contrast-induced nephropathy (CIN), which is a frequent complication after catheterization and is associated with morbidity and mortality. CIN is also a common complication in patients with pre-existing chronic kidney disease, diabetes, and heart failure. The purpose of this analysis was to compare carbon dioxide (CO₂) with conventional contrast agents.

Methods. To assess the clinical effectiveness of CO₂ in preventing CIN, a systematic review of relevant literature, including international guidelines, from the Medline database was conducted. Imaging of the chest, aorta, coronary arteries, and cerebral circulation with CO₂ is limited, so effectiveness was determined in the

field of renal and peripheral artery angioplasty. The effect on intervention cost was the main outcome.

Results. Use of CO₂ generally reduced renal toxicity and anaphylactic reaction, but the benefits remain controversial. Angiography with CO₂ is reasonable when image accuracy is not crucial due to its low informative value. Strategies for preventing acute kidney injury demonstrated the effectiveness of sodium chloride administration before and after the procedure. Additionally, the absence of risk factors for kidney disease significantly reduced the risk of impaired renal function.

Conclusions. Although CO₂ is one of the alternative methods for visualization, it is not pivotal in preventing CIN, even though the manufacturers recommend CO₂ as the preferred contrast agent in patients with renal insufficiency who are allergic to ICM. The economic indicators for the use of CO₂ are similar to traditional visualization methods.

PP148 Liquid Biopsy For The Detection Of Ovarian Or Endometrial Cancer In Samples Taken From The Pap Smear: PapSEEK

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Introduction. The PapSEEK test is an emerging minimally invasive technique in which samples are collected from the endocervical or intrauterine cavity with the Papanicolaou (Pap) brush or the Tao brush to detect somatic mutations or aneuploidies indicating the presence of endometrial or ovarian cancer.

Methods. We systematically searched for articles published up to October 2020 in the following electronic databases: Medline, Embase, the Cochrane Library, and the Centre for Reviews and Dissemination. We included experimental studies, observational primary studies, and cost-effectiveness studies evaluating the safety, effectiveness, and cost effectiveness of the PapSEEK test for the early detection of ovarian or endometrial cancer. Relevant outcomes included sensitivity, specificity, the coefficient of variation, re-test rates, the incremental cost-effectiveness ratio, the incremental cost-utility ratio, and the cost of each alternative.

Results. A single relevant retrospective study was identified. In this study, samples from women with endometrial cancer (n = 656) and ovarian cancer (n = 254) were collected with the Pap brush and Tao brush and compared with samples from healthy women (n = 1,002). The diagnostic validity for somatic mutation or aneuploidies obtained with a Pap brush had a sensitivity of 81% for endometrial cancer and 33% for ovarian cancer, and a specificity of 99% for both conditions. When samples were collected from the intrauterine cavity with a Tao brush, the sensitivity increased to 93% for endometrial cancer and to 45% for ovarian cancer. The sensitivity of the PapSEEK test increased only for ovarian cancer when plasma samples to detect circulating tumor DNA were collected in addition to Pap smear samples.

This strategy provided a diagnostic validity of 43%, which was higher in late-stage ovarian cancer (56% versus 35%), and a specificity of 100%.

Conclusions. Prospectively designed studies are required to assess the safety and effectiveness of the PapSEEK test in screening settings, as well as studies comparing the technology with conventional screening methods. No cost-effectiveness studies have been conducted for the PapSEEK test.

PP152 Epigenetic In Vitro Diagnostic Test For Early Diagnosis In Lung Cancer: An Early Assessment

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Introduction. Lung cancer is a leading cause of morbidity and mortality, and early diagnosis is essential for patient survival. Epigenetics is an innovative discipline that provides biomarkers to aid in early diagnosis, patient risk classification, or outcome prediction. Each type of tumor may present specific patterns of gene methylation, the analysis of which may be useful as a diagnostic tool. The aim of this study was to conduct an early assessment of novel in vitro diagnostic (IVD) tests based on the identification of DNA hypermethylation epigenetic signatures developed for the early detection of lung cancer.

Methods. We identified this technology through the Early Awareness and Alert System “SINTESIS-new technologies” of the Agencia de Evaluación de Tecnologías Sanitarias - Instituto de Salud Carlos III. A literature search of PubMed, the Trip Medical Database, the International Clinical Trials Registry Platform, ClinicalTrials.gov, and the Cochrane Central Register of Controlled Trials was conducted. Studies published up to November 2019 were reviewed.

Results. Three tests were identified. Epi proLung[®] analyzes the hypermethylation status of SHOX2/PTGER4 genes in blood samples using polymerase chain reaction (PCR) and showed good discrimination capacity with respect to healthy controls (area under the curve [AUC] = 0.91) and patients with non-malignant lung diseases (AUC = 0.86). The Epi proLung BL Reflex Assay[®] for determining the hypermethylation state of the SHOX2 gene in bronchoalveolar lavage samples by PCR had modest sensitivity (69%, 95% confidence interval [CI]: 64–75) and high specificity (96%, 95% CI: 97–100). A test in development for determining the hypermethylation state of BCAT1/CDO1/TRIM58/ZNF177 genes in aspirated or bronchoalveolar lavage samples by pyrosequencing yielded a sensitivity of 85 percent and a specificity of 81 percent, with an AUC of 0.91 at the optimal cutoff point.

Conclusions. The evidence for the three tests showed promising results in terms of diagnostic validity. However, although personalized medicine is becoming increasingly widespread in the field of cancer diagnosis, more studies are needed to evaluate the

clinical utility of these diagnostic tests, either as a complementary or a screening test, and the economic impact of their use.

PP162 Use Of The RenalGuard[®] System To Prevent Contrast-Induced Nephropathy

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Introduction. Contrast-induced nephropathy (CIN) is a common cause of hospital-acquired acute kidney injury (AKI) following the administration of contrast media for coronary interventions or procedures such as diagnostic coronary angiography. The optimal way of preventing CIN remains uncertain. However, preliminary intravenous hydration, minimizing the volume of contrast media, and avoiding the use of nephrotoxic drugs are recommended in current management guidelines. The aim of this analysis was to compare the RenalGuard[®] system with standard care.

Methods. A comprehensive literature search was conducted in PubMed and Google Scholar to identify evidence on the clinical and economic effectiveness of forced diuresis with matched hydration using the RenalGuard system for preventing CIN. Multiple criteria decision analysis (MCDA) was used to assess the performance of the method in hospital settings, compared with alternative options.

Results. Several systematic reviews with meta-analyses demonstrated that forced diuresis with matched hydration using the RenalGuard system was associated with a significantly lower relative risk of CIN among high-risk patients with chronic kidney disease. However, the evidence supporting the advantage of the proposed method over current forced diuresis techniques with manual calculation of the volumes for matched hydration in the hospital setting was limited.

Conclusions. Although the effectiveness of the RenalGuard system has been demonstrated in meta-analyses, its clinical advantage over forced diuresis with manual hydration calculation is uncertain. It is also worth noting the lack of evidence to date on this technology, the fact that it is still at the research stage in some countries, and that it is not included in CIN management guidelines.

PP165 Bridging The Gap Of Health Services During The COVID-19 Pandemic Through Telemedicine

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Introduction. Health care for patients with chronic pathologies was scarce and limited worldwide during the COVID-19