

established the selected hospitals provide the technology according to a common protocol and register outcomes until the required sample size is reached.

Methods. The PLEG studies are prospective, observational and single arm studies on safety, effectiveness and cost-effectiveness of a technology in real practice. The technology is selected because of the identification of an evidence gap, usually through a health technology assessment (HTA) report made by an agency of the Spanish Network of HTA Agencies (RedETS). The execution of a PLEG is assigned to one of the RedETS Agencies, which is responsible of delivering annual reports and a final report when the objectives are reached.

Results. The following six PLEG studies, all of them on medical devices, have been launched in Spain so far, i) Endobronchial valve for patients with persistent air leak; ii) Biodegradable esophageal stent; iii) Percutaneous mitral valve repair system by clip; iv) Left Atrial Appendage Closure Device; v) Sensor-based glucose monitoring systems for children with type 1 diabetes mellitus; vi) Left ventricular assist devices for destination therapy. Five studies will finish their data collection by the end of 2020 or during 2021.

Conclusions. A new national procedure using PLEG has been made available in Spain facilitating the use of real-world evidence to inform national decision-making on the financing of selected technologies due to uncertainties about their effectiveness, safety, cost-effectiveness and organizational impact. The studies are requiring a high amount of coordination tasks, as they are involving an average of 21 hospitals each. The usefulness and suitability of this procedure to achieve its objectives must be evaluated once their results are available.

OP196 Clinical Decision Support Systems (CDSS) For Antibiotic Management: Factors Limiting Sustainable Digital Transformation

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Introduction. Clinical decision support systems (CDSS) are being developed to support evidence-based antibiotic prescribing and reduce the risk of inappropriate or over-prescribing; however, adoption of CDSS into the health system is rarely sustained. We aimed to understand the implementation challenges at a macro (policymakers), meso (organizational) and micro-level (individual practices) to identify the drivers of CDSS non-adoption.

Methods. We have adopted a mixed-method study design which comprised of: (i) systematic review and meta-analysis to assess the impact of CDSS on appropriate antibiotic prescribing, (ii) Online survey of clinicians in Australia from hospitals and primary care to identify drivers of CDSS adoption and (iii) in-depth interviews with policymakers to evaluate policy-level challenges and opportunities to CDSS implementation.

Results. CDSS implementation can improve compliance with antibiotic prescribing guidelines, with a relative decrease in mortality, volume of antibiotic use and length of hospital stay.

However, CDSS provision alone is not enough to achieve these benefits. Important predictors of clinicians' perception regarding CDSS adoption include the seniority of clinical end-users (years), use of CDSS, and the care setting. Clinicians in primary care and those with significant clinical experience are less likely to use CDSS due to a lack of trust in the system, fear of comprising professional autonomy, and patients' expectations. Lack of important policy considerations for CDSS integration into a multi-stakeholder healthcare system has limited the organizational capacity to foster change and align processes to support the innovation.

Conclusions. These results using multiple lines of evidence highlight the importance of a holistic approach when undertaking health technology management. There needs to be system-wide guidance that integrates individual, organizational and system-level factors when implementing CDSS so that effective antibiotic stewardship can be facilitated.

OP199 From Pilot Studies To System-Wide Innovation: Challenges And Opportunities For Clinical Decision Support Systems (CDSS) Implementation In Australia

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Introduction. The clinical data is increasing at a considerably higher rate than the capacity of the healthcare system and clinicians to manage this data. Digital tools such as clinical decision support systems (CDSS) provide opportunities for evidence-based patient care by intelligently filtering and presenting the information required for clinical decision making at the point of care. Despite the success of pilot projects, CDSS have had limited implementation in broader health systems. We aimed to identify challenges faced by policymakers for CDSS implementation and to provide policy recommendations.

Methods. We conducted eleven semi-structured interviews with Australian policymakers from state and national committees involved in digital health activities. The data were analyzed using reflexive thematic analysis to identify policy priorities.

Results. Our findings indicate that fragmentation of care processes and structures in the digital health ecosystem is one of the main impediments to delivering coordinated care using CDSS. Five themes for policy action were identified: (i) establishing a shared conceptual framework for user-centered design of CDSS that is aligned with stakeholders' priorities, (ii) maintaining the right balance between the customization and standardization of systems, (iii) developing mutually agreed semantic interoperability standards at the local, state and national level, allowing generation and exchange of information across the health system without changing its context and meaning, (iv) reorienting organizational structures to build capacity to foster change, and (v) developing collaborative care models to avoid conflicting interests between stakeholders.

Conclusions. Findings highlight the importance of developing system-wide guidance to establish a clear vision for CDSS implementation and alignment of organizational processes across all levels of health care. There is a need to build a shared policy

framework for modelling the innovative activities such as CDSS implementation across the digital health landscape which minimizes the operational and strategic fragmentation of different organizations.

OP208 Did Health Technology Assessments Make the Wrong Call? Quantitative Bias Analysis: Alectinib versus Ceritinib in Non-Small Cell Lung Cancer

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Introduction. The German health technology assessment (HTA) rejected additional benefit of alectinib for second line (2L) ALK+ NSCLC, citing possible biases from missing ECOG performance status data and unmeasured confounding in real-world evidence (RWE) for 2L ceritinib that was submitted as a comparator to the single arm alectinib trial. Alectinib was approved in the US and therefore US post-launch RWE can be used to evaluate this HTA decision.

Methods. We compared the real-world effectiveness of alectinib with ceritinib in 2L post-crizotinib ALK+ NSCLC using the nationwide Flatiron Health electronic health record (EHR)-derived de-identified database. Using quantitative bias analysis (QBA), we estimated the strength of (i) unmeasured confounding and (ii) deviation from missing-at-random (MAR) assumptions needed to nullify any overall survival (OS) benefit.

Results. Alectinib had significantly longer median OS than ceritinib in complete case analysis. The estimated effect size (Hazard Ratio: 0.55) was robust to risk ratios of unmeasured confounder-outcome and confounder-exposure associations of <2.4.

Based on tipping point analysis, missing baseline ECOG performance status for ceritinib-treated patients (49% missing) would need to be more than 3.4-times worse than expected under MAR to nullify the OS benefit observed for alectinib.

Conclusions. Only implausible levels of bias reversed our conclusions. These methods could provide a framework to explore uncertainty and aid decision-making for HTAs to enable patient access to innovative therapies.

OP218 Searching Preprint Repositories For COVID-19 Therapeutics Using A Semi-Automated Text-Mining Tool

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Introduction. The COVID-19 pandemic led to a significant surge in clinical research activities in the search for effective and safe treatments. Attempting to disseminate early findings from clinical trials in a bid to accelerate patient access to promising treatments,

a rise in the use of preprint repositories was observed. In the UK, NIHR Innovation Observatory (NIHRIO) provided primary horizon-scanning intelligence on global trials to a multi-agency initiative on COVID-19 therapeutics. This intelligence included signals from preliminary results to support the selection, prioritisation and access to promising medicines.

Methods. A semi-automated text mining tool in Python3 used trial IDs (identifiers) of ongoing and completed studies selected from major clinical trial registries according to pre-determined criteria. Two sources, BioRxiv and MedRxiv are searched using the IDs as search criteria. Weekly, the tool automatically searches, de-duplicates, excludes reviews, and extracts title, authors, publication date, URL and DOI. The output produced is verified by two reviewers that manually screen and exclude studies that do not report results.

Results. A total of 36,771 publications were uploaded to BioRxiv and MedRxiv between March 3 and November 9 2020. Approximately 20–30 COVID-19 preprints per week were pre-selected by the tool. After manual screening and selection, a total of 123 preprints reporting clinical trial preliminary results were included. Additionally, 50 preprints that presented results of other study types on new vaccines and repurposed medicines for COVID-19 were also reported.

Conclusions. Using text mining for identification of clinical trial preliminary results proved an efficient approach to deal with the great volume of information. Semi-automation of searching increased efficiency allowing the reviewers to focus on relevant papers. More consistency in reporting of trial IDs would support automation. A comparison of accuracy of the tool on screening titles/abstract or full papers may help to support further refinement and increase efficiency gains.

This project is funded by the NIHR [(HSRIC-2016-10009)/Innovation Observatory]. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

OP220 What Factors Do Clinicians Value Most In Selecting Physician Preference Items? A Survey Among Italian Orthopaedists

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Introduction. Physician preference items (PPIs) are high-cost medical devices on which clinicians express firm preferences with respect to a particular manufacturer and a specific product. The aim of this research is to understand what are the most important factors, as well as their relative importance, in the choice of new PPIs (that is, hip or knee prosthesis) adoption on behalf of orthopaedic clinicians in Italy.

Methods. Based on a literature review and clinical experts' opinions, we identified a number of key factors (for example, health technology assessment (HTA) recommendation) and their corresponding levels (for example positive HTA recommendation). We