comparative studies that evaluated the safety and effectiveness of complete nutritional formulas for malnourished adults with CKD. Relevant outcomes included rates of death, hospitalization, and adverse effects, and changes in nutritional status, anthropometrics, and health-related quality of life (HRQoL).

Results. Three systematic reviews and 22 primary studies were identified. The primary studies comprised nine randomized controlled trials, nine non-randomized comparative studies, and four before-after studies (the latter were only included in the safety review). The majority of studies were conducted in patients on hemodialysis. The studies exhibited methodological heterogeneity in terms of the methods used to measure nutritional status and the interventions and comparators evaluated. There was also inconsistency among the results. Adherence to ONS, especially in the long term, can be affected by taste fatigue produced by repeatedly taking the same formula. Some studies recommend supplementation during hemodialysis sessions.

Conclusions. The studies with less risk of bias indicated a trend toward improvements in rates of death and hospitalization, HRQoL and, to a lesser extent, some anthropometric variables and serum markers, such as albumin, when ONS was given to patients with CKD. High quality comparative studies are needed to make conclusive statements about the effectiveness of this intervention.

PP131 Omalizumab And Ciclosporin For Chronic Spontaneous Urticaria

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Introduction. Omalizumab and ciclosporin are recommended in international clinical guidelines for treating antihistamine-resistant chronic spontaneous urticaria (CSU). This meta-analysis aimed to evaluate their comparative efficacy and safety to inform local treatment practices in Singapore.

Methods. The PubMed and EMBASE databases were searched for randomized controlled trials (RCTs) published up to October 2018 involving omalizumab or ciclosporin as an add-on therapy to H1-antihistamines for CSU. Key outcomes were changes in weekly Urticaria Activity Score (UAS7), adverse events, and health-related quality of life. Pairwise meta-analysis was conducted for each outcome. Owing to differences in trial designs and patient characteristics across the studies, a random effects model was employed. In the absence of head-to-head trials, the Bucher method of adjusted indirect comparison was used to estimate the comparative effectiveness between omalizumab and ciclosporin, with placebo as the common comparator.

Results. Eight omalizumab and two ciclosporin placebo-controlled RCTs comprising 1,740 patients were selected. The magnitude of treatment effect for omalizumab was dose-dependent across all efficacy outcomes: 300 mg was superior to 150 mg. Omalizumab 300 mg, although statistically significantly better than placebo for all efficacy outcomes at week 12, did not achieve clinical significance for all measures. The mean change in UAS7 was statistically better for ciclosporin than for placebo (one RCT) at week 4. The indirect comparison between omalizumab and ciclosporin showed no statistically significant differences for mean change in UAS7. Omalizumab had a more favorable short-term safety profile than ciclosporin, but long-term safety data were lacking.

Conclusions. Both omalizumab and ciclosporin were effective in treating CSU, compared with placebo. However, results of the indirect comparison should be interpreted with caution. On the basis of limited available evidence, and taking into account the similar place in therapy of omalizumab and ciclosporin, the results may be considered acceptable to confirm the clinical comparability of the drugs an add-on to H1-antihistamines for CSU.

PP132 Telemedicine Enhances Community Hospital Response Capacity

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Introduction. Telediagnostic apps based on information and communication technology tools can be used to enhance community hospital response capacity. Evidence on how this innovative technology can improve health services is limited, but will likely expand in the new decade. The ability of different telediagnostic methods to enhance the response capacity of community hospitals in rural areas of Paraguay was investigated.

Methods. This descriptive study was carried out by the Telemedicine Unit of the Ministry of Public Health and Social Welfare, in collaboration with the Department of Biomedical Engineering and Imaging of the Health Science Research Institute and the University of the Basque Country, to evaluate the utility of telediagnostic apps for different disciplines in public health. The results from implementing telediagnosis apps in 60 public community hospitals across the country were analyzed and evaluated.

Results. A total of 410,840 diagnoses were performed remotely between January 2014 and August 2018 across 60 rural community hospitals. The diagnoses involved computed tomography (147,627 or 36%), electrocardiography (256,422 or 62%), electroencephalography (6,772 or 2%), and ultrasound (19 or 0.01%). There were no significant differences between the remote and face-to-face diagnoses; remote diagnoses were correct in 93 percent of cases. Utilizing telediagnostic apps reduced costs, which is an important benefit for the 60 communities.

Conclusions. The results showed that telemedicine can significantly enhance the community hospital response capacity of diagnostic services and health programs, making optimal use of professional time and productivity, increasing access and equity, and reducing costs. However, before carrying out the systematic implementation of this technology, contextualization with the regional epidemiological profile must be performed.

PP133 Ensuring Secure Health Data Exchange Across Europe. The SHIELD Project

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https://doi.org/10.1017/S0266462319002502 Published online by Cambridge University Press

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Introduction. Data exchange protection is one of the main challenges in e-health. Nowadays, many people move from one country to another for various reasons, even though they may have chronic diseases or multiple pathologies. The main objective of the SHIELD project is to create an open and extendable security architecture, with supported privacy mechanisms that citizens can trust, to provide systematic protection for the storage and exchange of health data across European borders.

Methods. epSOS is a European project that deals with the security and interoperability of e-health data, and has developed an Open National Contact Point (OpenNCP) architecture. For the initial validation of the framework, two OpenNCP virtual nodes were used to simulate the real nodes between Italy and Spain. For secure data exchange, different prototype tools were designed: end-to-end user interfaces (profiles for administrative staff, nurses, physicians, etc.); sensitivity and data hiding tools; consent management tools; report translation tools; and mobile device tampering detection tools.

Results. Validation scenarios (realistic use cases) were developed in Italy, Spain, and the United Kingdom. The first scenario was an Italian citizen traveling to Spain who has an acute emergency episode (e.g. stroke) and loses consciousness. The Spanish emergency department physician assisting the patient checks the patient´s health record. The first round of SHIELD framework validations was successfully completed, and the results were presented to the European Commission.

Conclusions. Security challenges need to be addressed when assessing e-health solutions. The challenges include issues with interoperability, confidentiality, availability, integrity, privacy, ethics, regulations, and e-health data. In addition, decisions must be made as to which data will be shared and how. The results of the initial validations provide a basis for the in-depth requirements analysis and for setting the main pillars of the SHIELD architecture design.

PP135 Setting The Scope For Assessing e-Health Technologies In Hungary

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Introduction. E-health and m-health are emerging health technology fields that could possibly give a new scope to health technology assessment (HTA). The Division for Health Technology Assessment (DfHTA) is currently assessing medicines and non-drug technologies (medical devices intended for patient use or for use in hospitals). The experience assessing medical devices for use in hospitals yielded difficulties which could also arise from the critical appraisal of e-health or m-health technologies. The objective of this study was to explore the foundations for HTA guidance on e-health or m-health technologies.

Methods. A targeted literature review was conducted to map the current status of technology assessment practices for e-health and m-health technologies and to assess its concordance with current reimbursement processes in countries belonging to the Organisation for Economic Co-operation and Development. Experiences from past evaluations of other medical devices that could not be evaluated under the current guidance guided the literature search. The findings of this research were used to create a recommendation to amend the current Hungarian Guideline for Health Economic Analyses.

Results. The resulting articles of the targeted literature review provided an insight into current practices on of assessing e-health and m-health products, particularly with respect to the domains of safety, quality, and impact. Recommendations suggested including a list of requirements for companies to submit for critical evaluations of e-health and m-health technologies, in support of a self-assessment approach.

Conclusions. As for other HTA bodies, there is an urgent need for the DfHTA to increase its capacity to assess digital health technologies for entry into the healthcare system, with a focus on the relevant clinical domains. The reimbursement process for these technologies remains a challenge for public funding bodies.

PP136 How To Apply Health Technology Assessment To Large Scale e-Health Processes

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Introduction. There are enormous expectations for e-health solutions to support high quality healthcare services, with accessibility, and effectiveness as key goals. E-health encompasses a wide range of information and communication technologies applied to health care, and focuses on combining clinical activity, technical development, and political requirements. Hence, e-health solutions must be evaluated in relation to the desired goals, to justify the high costs of such solutions.

Methods. Health technology assessment (HTA) aims to produce rational decisions for purchasing new technologies and evaluating healthcare investments, like drugs and medical equipment, by measuring added value in relation to clinical effectiveness, safety, and cost effectiveness. It is desired to also apply HTA assessment on large scale e-health solutions, but traditional quantitative HTA methodology may not be applicable to complex e-health systems developed and implemented as ongoing processes over years. Systematic reviews and meta-analyses of these processes risk being outdated when published, therefore action research designed to work with complex, large scale programs may be a more suitable approach.

Results. In the project, we followed the development of a new process-oriented electronic patient record system (EPR) in northern Norway. Part of the process was structuring clinical data to be used in electronic forms within the system. This was the first time a health region structured the clinical data and designed the forms; receiving feedback alongside the process was very important. The goal was to use structured forms as a basis for reusing EPR data within and between systems, and to enable clinical decision support.

Discussion. After designing a prototype of a structured form, we wrote an assessment report focusing on designing a methodology

https://doi.org/10.1017/S0266462319002502 Published online by Cambridge University Press