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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

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