

The updated version of Charlson Comorbidity Index (CCI), for predicting resource utilisation, was never considered in such studies.

PRM60

THE PEDIATRIC ASTHMA PATIENT REGISTRY IN IMPLEMENTATION OF LONG TERM FOLLOW UP

Vishneva E, Namazova-Baranova L V, Alekseeva A, Levina J, Efendieva K, Tomilova A, Voznesenskaya N, Dobrynya E, Selimzianova L, Promyslova E
Scientific Centre of Children Health, Moscow, Russia

OBJECTIVES: The randomized clinical trials (RCT), as gold standard for evidence-based medicine, have a number of shortcomings, and their results do not fully reflect actual clinical practice. In cases where RCTs are difficult to conduct because of ethical or other aspects, data bases of clinical cases - medical registries are used to determine the effectiveness and safety of any medical intervention in long-term observation. Due to heterogeneity of clinical symptoms in different groups of patients with bronchial asthma (BA), to assess the efficacy and safety of treatment of severe persistent uncontrolled asthma in the real clinical practice, the best practice is to use a long-term clinical monitoring. Aim - to create patient registry for children and adolescents with severe persistent uncontrolled BA. **METHODS:** By experts of center in the result of system work software was created. It was shell for management of database of clinical cases - patient registry of children with uncontrolled severe persistent BA, who received Omalizumab as addition to basis therapy. **RESULTS:** The database included information about 64 children (62.5% boys) from 6 to 17 y 11 mo (mean age 12.9 y) with severe persistent uncontrolled BA, who received / receive (31 patients, 70.9% boys) bioengineered treatment (duration of treatment from 1 till 70 mo). During the analyzed period of treatment safety of Omalizumab was confirmed: more than 5384 injections were conducted. Local adverse events were registered at frequency of 1/100 and were manifested as light redness, induration and light edema, were realized in 1-1.5 days after Omalizumab administration. Local allergic reactions such as rash were observed in two patients and were stopped by antihistamines. **CONCLUSIONS:** The patient registry will help in solving problems as epidemiological, and in order to achieve optimal endpoints for monitoring and analysis of efficacy and safety of innovative high-tech medications and approaches which have been used previously for long time.

PRM61

THE NATIONWIDE OSMED HEALTH-DB DATABASE. A TOOL TO SUPPORT HEALTHCARE DECISION-MAKING AND REAL-WORLD EVIDENCE GENERATION

Degli Esposti L¹, Saragoni S¹, Sangiorgi D¹, Buda S¹, Cangini A², Russo P²

¹CliCon S.r.l., Ravenna, Italy, ²Italian Medicines Agency (AIFA-Agenzia Italiana del Farmaco), Roma, Italy

OBJECTIVES: Since 2012, the Italian Medicines Agency (AIFA-Agenzia Italiana del Farmaco), with the cooperation of CliCon, has been providing and updating the OsMed Health-DB Database, a nationwide standardized monitoring system to provide analyses, reports, and trends on appropriateness of medicines' use and medication persistence, to inform decision-makers in order to improve health outcomes and to avoid wasting of health-care resources. **METHODS:** The OsMed Health-DB Database has two main components with distinct but complementary functions: a data-warehouse, a repository containing the integrated demographic, pharmaceutical and hospital discharges administrative data kept by Local Health Units (LHUs) and Regional Health Units (RHUs) and a dashboard, a set of performance indicators, with updates scheduled every six months, evaluating the prescription adherence to preset standards of some chronic pathologies at the local, regional, and national level. In 2014, 36 LHUs and 5 RHUs provided data, covering all Italian Regions and the data-warehouse stored information of about 30 million patients (almost the 50.0% of the entire Italian population). **RESULTS:** The 2014 OsMed Report reported the trend of 34 indicators on appropriateness and adherence of 10 chronic diseases: hypertension, hypercholesterolemia, diabetes mellitus, COPD, osteoporosis, depression, ulcers and esophagitis, anemia, psoriasis and rheumatoid arthritis. The average age of the LHU sample resulted 44.0 years versus 43.7 years of the Italian population. The percentage of males resulted 48.5%, in accordance with the national data available. Medication persistence rate for all studied diseases averaged 43.3%, with a range of 13.9% of respiratory system drugs and 62.2% of anti-diabetic drugs. Results will be reported on "National Report on medicines use in Italy" available at AIFA website. **CONCLUSIONS:** Findings from the OsMed Health-DB Database highlighted that the majority of indicators is changing toward appropriateness and adherence. These findings prove that continuous monitoring of appropriateness and adherence is a driver for improving real-world use of medicines.

PRM62

DEVELOPMENT OF AN INTERNATIONAL OBSERVATIONAL STUDY PROGRAMME TO DESCRIBE THE MANAGEMENT AND OUTCOMES OF MILD STROKE AND TRANSIENT ISCHAEMIC ATTACK IN ROUTINE CLINICAL PRACTICE

Johansson S¹, Westergaard M², Young K³, Becher A⁴, Winchester CC⁴, Jennings E²

¹AstraZeneca R&D, Mölndal, Sweden, ²AstraZeneca R&D, Cambridge, UK, ³Research Evaluation Unit, Oxford PharmaGenesis, Newtown, PA, USA, ⁴Research Evaluation Unit, Oxford PharmaGenesis Ltd, Oxford, UK

OBJECTIVES: Patients with mild stroke or transient ischaemic attack (TIA) are at high risk of recurrent stroke and other cardiovascular events. The Assessment of Real-world Evidence in Stroke/TIA (ARES) programme aims to characterize the management and outcomes of patients with mild stroke/TIA in real-world clinical practice using the most suitable data sources. **METHODS:** In an initial Systematic Understanding of Real-world Evidence (SURE) assessment, suitable data sources (cohorts, registries and databases) were identified and characterized by systematic literature and web searches supplemented with e-mail and telephone contact. Data sources were recommended if they were active, representative, accessible, recorded National Institutes of Health Stroke Scale (NIHSS) scores or ABCD2 scores, and reported health resource utilization, ischaemic events and death during follow-up of at least 90 days (either direct or via linkage). The programme of included studies was

finalized with input from principal investigators. **RESULTS:** More than 2900 publications and 300 websites were screened, and 16 registries, 17 cohort studies and 43 databases were reviewed. Nine data sources from seven countries were recommended, of which six complementary sources were included: Get With The Guidelines-Stroke in the USA (an in-hospital database including about 1600 hospitals); National Stroke Registry in China (132 hospitals); Fukuoka Stroke Registry in Japan (seven stroke centres); Clinical Research Centre for Stroke - 5th Division Registry in South Korea (12 stroke centres); Riks-Stroke in Sweden (all Swedish hospitals admitting patients with acute stroke); and Erlangen Stroke Registry in Germany (Erlanger community). Based on a globally agreed study design concept, protocols for each data source have been developed locally and are now being implemented. **CONCLUSIONS:** The ARES programme will provide global, observational data from contemporary populations with mild stroke/TIA in real-world clinical practice. Studies will be presented individually owing to differences in the nature of the data sources.

PRM63

HEALTH TECHNOLOGY ASSESSMENT NEEDS INFORMATION TECHNOLOGY: THE EXPERIENCE FROM THE FIRST ITALIAN STUDY ON THE DA VINCI SURGICAL ROBOT

Manetti S¹, Palla I¹, Freschi C², Cuschieri A³, Turchetti G¹

¹Scuola Superiore Sant'Anna, Pisa, Italy, ²University of Pisa, Pisa, Italy, ³University of Dundee, Dundee, UK

OBJECTIVES: Health Technology Assessment of innovative biomedical devices still requires the effort to introduce dedicated Information Technology tools able to support the implementation of the evaluation process. The aim of the study was to systematize the collection, the management and the analysis of large volumes of multidimensional data in order to optimally conduct an HTA study of emerging technologies. **METHODS:** We designed a relational database, subsequently we developed and implemented a centralized, web-based user-friendly data entry for Case Report Form (CRF) data collection. (i) The development of User Interface (UI), (ii) data anonymization, (iii) differentiate accesses, (iv) automated quality control checks for data entry, (v) appropriate system tables to make data entry uniform, and (vi) the possibility of creating final reports were addressed. In the data extraction phase, we used MySQL computer languages and combined PHP and HTML codes. Knowledge Discovery in Data process was implemented with different software and programming languages for automation of the data collection, extraction and analysis. **RESULTS:** The IT tools have been applied to the first multicenter prospective Italian study of HTA on the da Vinci surgical system, obtaining meaningful end points in terms of costs and clinical outcomes. The study involved the enrolment of 699 patients from the 8 Italian Teaching Hospitals in the period 2011-2014. Patients were enrolled and prospectively evaluated from the preoperative work-up till six months after the discharge. **CONCLUSIONS:** The IT tools developed allow researchers to more efficiently and effectively manage large volumes of various source of HTA data, enhancing data quality from storage to processing. The database design could be empowered and readjusted for other HTA studies in near future and the entire approach generalized. In the immature field of HTA of innovative biomedical devices, this example of application could promote the automation of the implementation process of HTA.

PRM64

MANAGEMENT OF SOFT TISSUE SARCOMA (STS) IN FRANCE - A RETROSPECTIVE ANALYSIS OF THE FRENCH CLINICAL BIOLOGICAL SARCOMA DATABASE (GSF-GETO)

Longin J

Merck Serono, Lyon, France

OBJECTIVES: The primary objective is to describe how patients with advanced STS are managed in France. The secondary objectives are to describe the epidemiological characteristics, the diagnostic procedures as well as the therapeutic strategy for the management of patients with STS. **METHODS:** This observational, retrospective and national study will use the patient databases of the European CONTICANET "CONNECTIVE TISSUE CANCER NETWORK" network and of the French networks: RRePS and NetSarc (Pathological and Clinical Reference Networks for Soft Tissues and Visceral Sarcomas). All the data collected in these networks and compiled in the "Sarcoma clinicobiological database" will allow good national representativity of STS. The study period was defined to reflect the current situation in terms of diagnosis and disease management in France. **RESULTS:** The European database currently contains data from 12,485 patients (pts) registered by the French Sarcoma Group centers with 9,736 soft tissues and visceral sarcomas. Data from STS patients, who were diagnosed between 2012 and 2013, will be extracted from the Conticabase database. Part of these data will be "chained" with the shared database from the French networks RRePS (24,000 pts) and NetSarc (28,000 pts). Results are expected at the end of 2015. **CONCLUSIONS:** This pharmacoepidemiological study shows how useful high-quality medical databases are to study rare diseases and their management in real life. This study is carried out as part of a public/private partnership.

PRM65

THE REMOTE MONITORING TECHNOLOGIES IN THE PATIENT RISK MANAGEMENT

Namazova-Baranova L¹, Vishneva E¹, Antonova E¹, Smirnov V¹, Suvorov R², Smirnov I², Molodchenkov A²

¹Scientific Centre of Children Health, Moscow, Russia, ²The Institute for system analysis of Russian Academy of Sciences, Moscow, Russia

OBJECTIVES: Due to high prevalence of socially significant chronic diseases among children the introduction of information technologies in the process of interaction between doctor and patient is important. The aim: to analyze the prospects of the development of remote monitoring systems, to identify their shortcomings and to propose solutions. **METHODS:** The review had included 36 publications, 1 meta-analysis concerning telemedicine from 2001 to 2014 y. In the evaluated studies the following questions were explored: • research of social and economic aspects of