The pediatric and adult patient registries in long-term follow-up


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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 RC(T)s 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 blood flow abnormalities (BA), the assessment of efficacy and safety of medical 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: In the Pediatric Asthma Patient Registry in China, for management of database of clinical cases – patient registry of children with uncontrolled severe persistent BA, who received Omalizumab as addition to basic 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 / received (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 584 injections were conducted. Local adverse events were registered at frequency of 1/100 and were manifested as light redness, induration and light edema, were observed 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 reporting and analysis efficacy and safety of long-term use of high-tech medica-
tions and approaches which have been used previously for long time.

The nationwide OSMED health-db database. A tool to support healthcare decision-making and real-world evidence generation

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OBJECTIVES: Since 2012, the Italian Medicines Agency (AIFA-Agenzia Italiana del Farmaco), with the cooperation of ClIcon, has been providing and updating the OsMed database (DbD): a nationwide data source for real-world evidence analyses, reports, and trends on appropriateness of medicines’ use and medica-
tion 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, pharmaceuti-
cal and hospital discharges administrative data kept by Local Health Units (LHUs) and Regional Health Units (RHUs) and a database, 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. 12,615 LHUs, 124 RHUs and covering all Italian data. The database includes data-warehouse stored information of about 30 million patients (almost the 50.0% of the entire Italian population). RESULTS: The 2014 OsMed Database reported the trend of 5 main chronic pathologies: hypertension, hypercholesterolemia, diabetes mellitus, COPD, osteoporosis, depres-
ion, 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 popula-
tion. The median of females results 55.5%, 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 appropriatedness and adherence. These findings prove that continuous monitoring of appropriatedness and adherence is a driver for improving real-world use of medicines.

Development of an international observational study programme to describe the management and outcomes of mild stroke and transient ischaemic attack in routine clinical practice

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OBJECTIVE: In 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 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 searches. These were supplemented with data sources recommended if they were active, representative, accessible, recorded National Institutes of Health Stroke Scale (NIHSS) scores or ABCD2 scores, and reported health resources utilization, ischaemic events and death wing 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 3 websites were screened, and 17 registries and 43 data- bases 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 Japan (57 stroke centres), Stroke Registry in Sweden (7 stroke centres); Clinical Research Centre for Stroke – StDivision Registry in South Korea (12 stroke centres); Riks-Stroke in Sweden (all Swedish hospitals admitting patients with stroke); and, Erlangen Stroke Registry in Germany (Erlangen 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 stroke or TIA in real-world clinical practice. Studies will be presented individu-
ally owing to differences in the nature of the data sources.

Health Technology Assessment needs information technology: the experience from the first Italian study on the da Vinci surgical robot

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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 HTA data, enhancing data quality from storage to processing. The database design 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 research-
ers 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 restructured 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 implementation of the automatic process of HTA.
telemedicine (evaluation of usefulness). • the view of information systems or archi-
tectures. The following characteristics were taken: • purpose of the system, • inter-
action of patients and physicians; • training and impact on lifestyle – the formation
of health-preserving behaviors (with the exception of smoking, adequate physical
activity, etc.); • self-management.

RESULTS: The following problems of implemen-
tation of the above-listed methods were identified: • the lack of special equip-
ment and devices; • the need for training and motivation of both staff
and patients; • lack of a unified architecture, protocol stack and hardware-software
platform for the integration of systems at all stages of the process – from data collec-
tion to its processing, decision-making and patient feedback. Despite the far
amount of existing telemonitoring systems almost all of it provide only data collection,
while the entire analytical part falls on the doctor. Almost all of studies were focused on the
elderly and adults.

CONCLUSIONS: A promising direction is the development of a
prototype system for remote health monitoring in pediatric patients. The study was
supported by the Russian Foundation for Basic Research, the project ¹ 13-04-12055.

PM66
USING MACHINE LEARNING TO POPULATE A MARKOV MODEL BY MINING BIG
DATA DIRECTLY FROM HOSPITAL EHRS – AN APPLICATION TO DYNAMICALLY
PREDICT HAPU RISK

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OBJECTIVES: Real-world big data accessible through electronic health record (EHR)
systems offer opportunities to collect generalizable information to populate econ-
omic models. Using a supervised machine learning approach, the objectives were:
(a) to mine a hospital EHR for transition probabilities of high-risk patients for
decaying ulcer risk; (b) to assess the required pressure ulcers (HAPUs); and (c) to compare
efficiency and accuracy of predictive methods between Markov modeling and
Bayesian inference with EHR data.

METHODS: This study used a de-identified panel of EHRs from 14 hospitals since 2010 in a U.S. tertiary academic medi-
cal center EHR to study Braden scores of patient risk for developing HAPUs. The
study focused on patients hospitalized for ≥5 days and at least two Braden scores.
Braden scores were converted from an ordered scale into five categories (i.e. mini-
mal risk, at risk, moderate risk, high risk, very high risk). A 10-stage Markov model
was constructed via supervised machine learning using R software designating the
five Braden categories as transition states, as well as end-states for discharge
or HAPU. Results from the fully developed model were adjusted to the patients
at-pair to prior probabilities of HAPU risk derived from naive and full Bayesian
inference. Measures of computational accuracy and efficiency were derived to
compare the burden of this disease both between conditions and between geo-
ographical boundaries. With improving data on disease incidence and prevalence
in Colombia, we can refine our DALYs-based estimates.

METHODS: Using different strategies, including the official healthcare provision database (called RIPS) and
death certificates, as well as extrapolation from published neuroepidemiologic
studies, we estimated the incidence and prevalence by age groups, the disease
duration and the attributable mortality. Based on previous studies, we assumed
an average disability weight of 0.113. With this information, and using the clas-
sic methodology described by Murray & Lopez, we calculated DALYs for the year
2013 in general. Disability adjusted life years (DALYs) have been developed to
calculate the burden of disease both between conditions and between geo-
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