Methods: Process standardization has been developed in seven stages: (i) definition of scope, objectives and creation of working groups; (ii) mapping and analysis of all ongoing processes to determine whether they needed improvement or were already optimal; (iii) creation of new processes by evaluating the inclusion of automatic tools and their possible digitization; (iv) creation of the process map; (v) communication to the team for its implementation after training; (vi) dissemination on corporate website; (vii) monitoring and evaluation of their impact.
Results: The creation of AQuAS' HTA report development process map has involved 14 people over the past two years. After an initial two-day workshop, the team was organized in working groups of two to three people, with regular monitoring and the creation of a specific knowledge management unit led by the AQuAS' evaluation manager. The process map was configured based on three axes. The strategic axis contains legal frameworks, ethical principles, good practices and methodological frameworks (29 specific for HTA reports). The key axis presents in an integrated way the process and methodology followed from the request of the HTA report to the final product's dissemination. The support axis includes, among other, the management of 31 requests, information specialist processes (37 searches), training (51 courses) and 6 internal procedures with their corresponding 26 templates and 27 tools.
Conclusions: With a process reengineering approach, HTA reporting has become more efficient. We believe this approach can help other agencies improve their internal processes and subsequently improve team and customer satisfaction.

PP151 HTA Of Fast Track Hip And Knee Joint Replacement

Giuseppe Banfi (banfi.giuseppe@unisr.it), Stefano Borghi, Susan Bernareggi, Umberto Restelli and Jacopo Vitale

Introduction: This retrospective study was conducted, in accordance with the STROBE guidelines, (Vandenbroucke et al., 2007), considering patients receiving surgical interventions for hip and knee replacement at the IRCCS Orthopedic Institute Galeazzi, located in Milan (Italy), between 1 January 2016 and 31 December 2019 (two years of traditional procedure, and two years of new one).
Methods: We evaluated 10,922 patients treated for hip or knee joint replacement; there were 5,085 treated following the traditional procedure and 5,837 treated by fast track procedure. Excluding cases which could not satisfy the study criteria we evaluated finally 697 with traditional procedure and 1120 with the new one.
Results: With the new fast track procedure, knee replacement mean costs were decreased by an average of EUR1,112.4 (-19.9%). Excluding the cost of prostheses from the analysis, the mean costs in the pre fast-track period for knee replacement are equal to EUR3,918.1, while the mean cost of the intervention in the fast-track period was equal to EUR3,245.8, being EUR572.3 lower (-17.2%). Considering the number of days of hospitalization, the adoption of fast-track leads to a decrease of -2.8 days (-37.6%) in knee replacement, from a mean number of days of 7.6 (± 2.8), to a mean number of days of 4.8 (± 1.8), and of – 2.9 days (-39.2%) in hip replacement, from a mean number of days of 7.3 (± 2.7) to a mean number of days of 4.4 (± 2.0).
Conclusions: We performed a study over four years, with a wide number of cases treated by various teams in the hospital having the highest workload on hip and knee joint replacements in Italy.
The new fast-track procedure is efficient; the length of stay was decreased by the procedure; the direct and indirect costs were decreased; the hospital organization was improved; the increase of care intensity did not modify efficiency and costs; the effectiveness was similar to the traditional procedure as defined by outcomes collected in a registry, including patient reported outcome measures (PROMs); legal and social effects were not modified.

PP152 Evaluation Of Reimbursement Periods In The Turkish Biosimilar Product Market (1995-2022)

Sena Unluler Deger and Elif Hilal Vural
(elif.vural@lokmanhekim.edu.tr)

Introduction: Biosimilar products that would enhance the patient's access to treatments have emerged as a product group that is becoming more widespread globally. Since Turkiye is an emerging market in the pharmaceutical area in the Middle East and North Africa region, and being a reference country in pricing processes for some countries, the number of products in the market and reimbursement decisions are important. The aim of this study is to evaluate duration of inclusion of biosimilars into reimbursement lists after registration in Turkiye.
Methods: This study used website-based information (Turkish Medicine and Medical Devices Agency Registered Products List and Detailed Pharmaceutical Price List, Social Security Institution Reimbursed Product List) to analyze the reimbursement approval duration for registered biosimilars in Turkiye after receiving registration approval. A study has been conducted on the launch period of biosimilar products to patients access with reimbursement and the evaluation period of reimbursement applications after registration approval. Even though they might not be active on the reimbursement list right now, products that have previously been approved for payment have been included.
Results: Between 1995-2022, biosimilars of 13 active substances in total were registered by the Ministry of Health in Turkiye. Thirty-three different brands and 105 biosimilars with all pharmaceutical forms are registered. As of November 2022, 72 biosimilars were in the reimbursement list. Twenty-two of reimbursed biosimilars were deactivated or excluded from reimbursement. It is calculated that the average evaluation and approval timeline for reimbursement of biosimilars between 2009 and 2022 is 9 months. When biosimilars in the European Medicines Agency (EMA) and Turkiye are compared, 13 biosimilar active substances are licensed in Turkiye compared to 19 for the EMA. When the total number of brands is compared, it has been observed that while 33 brands are registered in Turkiye, this number is 73 for the EMA.
Conclusions: This study, in which reimbursement approval dates for registered biosimilars in Turkiye have been compared based on years

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and access timelines of biotechnological products, shows that biosimilars have been launched to patients access with reimbursement much faster than biotechnological products.

PP153 Efficacy And Safety of Onasemnogene Abeparvovec For The Treatment Of Patients With Spinal Muscular Atrophy Type 1: Meta-Analysis

Stefani Borges (borgestefani@gmail.com), Brígida Fernandes, Fernanda Rodrigues, Bárbara Krug, Hérica Núbia Cirilo, Ida Vanessa Schwartz, Livia Probst and Ivan Zimmermann

Introduction: Onasemnogene abeparvovec has been approved for the treatment of spinal muscular atrophy 5q (SMA) type 1 in several countries, which calls for an independent assessment of its evidence regarding efficacy and safety.
Methods: This study results from searches conducted on databases MEDLINE, Embase, LILACS and Cochrane Library up to November 2022, supported by additional searches on registry databases and by manual searches of references listed in eligible studies. Outcomes of interest were global survival and mechanical-ventilation-free survival, improvement in motor function and treatment-related adverse events. Risk of bias was assessed via ROBINS-I and certainty of evidence via GRADE. Proportional meta-analysis models were performed when applicable.
Results: Four reports of three open-label, non-comparative clinical trials (START, STR1VE-US and STR1VE-EU) covering 67 patients were included in review. Meta-analyses of data available in a 12-month follow-up estimate a global survival of 97.6% (95% confidence interval [CI]: 92.6, 99.9; I2 = 0%, n=67), an event-free survival of 96.5% (95%CI: 90.8, 99.5; I2 = 32%, n=66) and a CHOP-INTEND score of 40 points or less proportion of 87.3% (95%CI: 69.8, 97.8; I2 = 69%, n=67). Proportions of 61.1% (95%CI: 40, 80.2; I^2 = 62%, n=67) of serious adverse events and of 58.4% (95%CI: 46.5, 69.8; I2 = 78%, n=67) of treatment-related adverse events are estimated. Despite the significant effect magnitude, reviewed studies were assessed as high risk of bias and as having very low certainty of evidence due to imprecision and risk of bias.
Conclusions: Reduced sample size and follow-up time offer uncertainties as regards the long-term benefits of the gene therapy, which strongly calls for the monitoring and assessment of results in clinical practice.

PP155 Should Breast Cancer Patients Avoid Venipuncture In The Ipsilateral Arm? A Rapid Review Of The Evidence

Keng Ho Pwee (keng_ho_pwee@cgh.com.sg)

Introduction: This rapid review clarified the evidence supporting avoidance of venipuncture on the ipsilateral arm in breast cancer patients who have had sentinel lymph node biopsy (SLNB) or axillary lymph node clearance (ALNC), as a preventive measure against lymphoedema.
Methods: A systematic search was carried out for systematic reviews with the following elements:

- Population – breast cancer patients who had SLNB or ALNC
- Intervention – avoidance of venipuncture in the ipsilateral arm
- Comparator –use of either arm for venipuncture
- Outcomes – risk of lymphoedema in the ipsilateral arm

Databases searched included PubMed (MEDLINE), Epistemonikos and the Cochrane Database of Systematic Reviews. Included reviews were critically appraised with the AMSTAR2 instrument and the primary studies were extracted and tabulated in a narrative synthesis.
Results: Six reviews were included; none of the reviews self-identified as systematic reviews in their titles/abstracts. Four reviews did report methods, including systematic search strategies and describing studies in adequate detail. However, all reviews did not meet most criteria on the AMSTAR2 checklist. The reviews concluded that the evidence base for avoiding venipuncture was inconsistent. An evidence table was consequently drawn up of the primary studies included in the reviews as a narrative synthesis of the primary evidence base.
The primary evidence base comprised 12 observational studies – six prospective cohort or descriptive studies and 6 retrospective studies. These studies were inconsistent and inconclusive; studies that found an association or reported cases following ipsilateral venipuncture were subject to recall bias or other potential confounders. Guidelines or patient information recommending avoidance of ipsilateral venipuncture do so based on expert opinion rather than consistent findings from empirical studies.
Conclusions: All reviews concluded that the evidence base for avoiding venipuncture was inconsistent. Review authors consistently recognized there was no strong basis for the prevalent recommendations to avoid ipsilateral venipuncture to prevent lymphoedema. Such recommendations lead to unnecessary measures that may be detrimental to patients. Stakeholders should reconsider advice to patients in the light of existing evidence and weigh up the uncertain benefits against potential harm to patients.

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