Lithuania Innovation Dialog 2

Organised by Lithuanian University of Health Sciences (LUHS)

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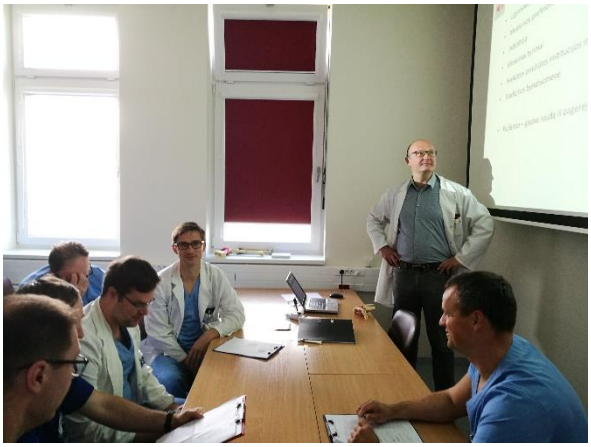
Summary

The 2nd Lithuanian Innovation Dialog dealt with infection prevention and quality criteria of medical implants.

Infection prevention

Implant-related infections after fractures are important to understand as it requires repeated surgeries, hospitalizations, secondary complications, sometimes amputations, chronic morbidity, and mortality related to the systemic antibiotic treatment and immobilization. Infection prevention principles vary between closed and open fractures. For open fractures, the principles are following: careful patient and injury evaluation, early administration of systemic antibiotics supplemented by local delivery of antibiotics in severe injuries, thorough surgical debridement, wound management with soft tissue coverage if needed, and stable fracture fixation. Also, preoperative, perioperative, intraoperative, and postoperative strategies/measures to decrease infection rate are discussed. These measures suggest that infection prevention requires a multidisciplinary approach with various strategies. However, some infection prevention strategies are supported by the literature whereas others remain unproven.



There are numerous reports/guidelines in infection prevention/treatment strategies, however, with a huge variability between continents, countries or even hospitals. This may be affected by the lack of randomized controlled trials in infection field, as it is may be bioethically difficult to approve them. This makes large cohort studies crucial. Countries with implemented well defined infection prevention/treatment algorithms may have significantly lower infection rates as compared to countries which have no algorithms established on national level. This can be evaluated in international collaboration projects.

There is a need for international collaboration to perform large cohort studies analysing the infection prevention strategies.

- REDUCE – the clinically unproven variables between participating hospitals.
- ELIMINATE – identify and discontinue harmful infection prevention measures as early as possible.
- STRENGHTEN – unified infection data measures form must be used in order to reinforce the analysis.
- CREATE – a platform which enables large international cohort studies.

Quality criteria of medical implants

The annual number of fractures in the EU will rise up to 28% from 3.5 million in 2010 to 4.5 million in 2025 (1). As the result, the use of surgically implanted devices is also increasing. Surgical fracture treatment with various types of implants is usually successful. However, like every medical intervention it is associated with various complications. Any complications result in the overall increase of total healthcare costs and length of stay. Thus, there is a special interest to decrease complications and requirements for medical devices are increasing. Safe implants could be understood in terms of sterile, biomechanically durable and demonstrating good clinical results. However, there is a lack of knowledge, what are the quality criteria which define good clinical outcome. There are clinical trials or register studies which demonstrates revision and/or reoperation rates. The increased demand for international performance standards in implant use emphasizes the need for a standardized benchmarking system.

When defining the quality criteria, it is important to ensure the development of a transparent, evidence-based system that is acceptable to concerned parties and relevant stakeholders worldwide. In some countries there are institutions evaluating the quality of joint arthroplasty implants. In UK ODEP (Orthopaedic Data Evaluation Panel) was set up by National Health Purchasing and Supply Agency (PASA, subsequently replaced by NHS Supply Chain) as a response to National Institute for Health and Care Excellence (NICE) issuing guidance relating to Total joint replacement. ODEP ratings provide a simple, independently verified assessment as to the performance of an implant, assessed against national clinical best practice guidelines. This enables clinicians to ensure that the implants that they use comply with the guidelines.

There is a need to create international performance standards in implant use and benchmarking system. Implant benchmarking may be useful for many stakeholders. Also, when tested implants are used it helps all concerned parties (patient, surgeon, hospital, insurance and government) to choose the device which has been independently assessed as having an acceptable and proven quality of performance.

- REDUCE – the incomplete data collection.
- ELIMINATE – unrelevant, obscure data collection.
- STRENGHTEN – ensure independent, transparent and evidence-based system when registering the outcome. Ensure the completeness and validity of the registry.
- CREATE – a platform registering clinical data of primary, revision procedures, complications in fractured patients. Regarding the outcomes to create a benchmarking system.