evaluating the efficacy and safety of a treatment intervention. The low external validity of RCTs and the general shortage of clinical evidence available to support the use of many medical devices have emphasized the necessity for exploring the use of real-world data (RWD) as a complementary source to RCTs data for establishing a more robust evidence base on the effectiveness of medical devices. The aim of the present project is to assess in a comprehensive way the existing sources of real world data on medical devices in Europe.

Methods. The guidelines to the mapping exercise have been outlined in a research protocol. First, all national relevant sources (e.g. website of Ministry of Health, national institutions, research bodies) are screened, both in local language and English. Second, we perform a systematic search on PubMed using a set of key words for each case study, adapted to each country setting. Finally, we seek advice from key actors in the field of the device and clinical conditions, such as manufacturers or clinicians.

Results. Information on existing sources of RWD for each case studies are provided in a template including details on the key features of the source (e.g. data producer, data collection period, sample size, study design, geographical coverage) and the main content of the dataset, distinguishing socio-demographic information, clinical and epidemiological data, data on resource use and health outcomes. The data mapping includes all countries of the project participants, i.e. Italy, UK, Netherlands, Switzerland, Germany, Hungary, and we enlarge the scope of our mapping including other countries: Spain, France, Denmark, Finland, Sweden, Poland and Hungary as well as international databases at pan-EU level. The number of available sources of RWD and their quality vary depending on case study and across countries. For example, in the case of orthopaedics, many countries have a national registry and administrative data, such as hospital discharge, contain useful information, although not as detailed. When a registry is not available, it is often the case that more observational studies are available; this occurs for example in France.

Conclusions. In this work we shows the importance of RWE and map in an accurate and comprehensive way which source of RWD are currently available and to what extent they are known and used in medical, epidemiological and economic research.

VP53 Long-Acting Insulin Analogues In Brazil: Clinical And Economic Impact

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Introduction. The aim was to evaluate the effectiveness, safety and economic impact of long-acting insulin analogues (LAIA) compared to NPH for type 1 diabetes mellitus (DM1).

Methods. A search was performed in five electronic databases to find systematic reviews (SR) comparing at least a LAIA to NPH insulin for DM1. Budget impact analysis was performed from the perspective of Brazilian public health system (SUS), with NPH insulin as the base scenario. The costs were extracted from the Integrated System of Administration of General Services (SIASG). The market share was calculated per month, using a logarithmic function with maximum diffusion of 50% at the end of the time horizon - five years.

Results. A total of 160 studies were identified and seven SR of low to uncertain risk of bias were selected. LAIA have shown modest clinical benefit and its effect is more prominent for the control of severe and nocturnal hypoglycaemia. Insulins glargine and detemir compared to NPH were associated with reduction in HbA1c levels between 0.16% and 0.40% and associated with lower risk of episodes of severe hypoglycemia. Insulin degludec compared to NPH showed no statistically significant difference in the reduction of HbA1c levels and in the episodes of severe hypoglycemia. The budget impact ranges from USD 210 million (detemir) to USD 670 million (degludec) over five years.

Conclusions. The use of LAIA as a basal insulin regimen for DM1 may benefit more patients with recurrent episodes of hypoglycemia. However, the fragility of the outcomes considered to evaluate the clinical impact of LAIA and the high budget impact with its use should be considered, and may compromise SUS sustainability. In view of these aspects, CONITEC recommended the incorporation of one of the LAIA, if the treatment is equal to or less than that of NPH insulin and according to the criteria established by a guideline.

VP54 Digital Tools For More Efficient Conduct Of RCTs: Trials Unit Survey

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Introduction. Recruitment of participants to, and their retention in, Randomized Controlled Trials (RCTs) is a key determinant of research efficiency, but is challenging. Digital tools and media are increasingly used to reduce costs, waste and delays in the conduct and delivery of research. The aim of this UK Clinical Trials Unit (CTU) survey was to identify which digital recruitment and retention tools are being used to support RCTs, their benefits and success characteristics.

Methods. A survey was sent to all UK Clinical Research Collaboration (UKCRC)-registered CTUs with a webinar to help increase completion. A logic model and definitions of a "digital tool" were developed by iterative refinement by project team members, the Advisory Board (NIHR Research Design service, NHS Trust, NIHR Clinical Research Networks and patient input) and CTUs.

Results. A total of 24/52 (46%) CTUs responded, 6 (25%) of which stated no prior use. Database screening tools (e.g. CPRD, EMIS) were the tool most widely used (45%) for recruitment and were considered very effective (67%). The most mentioned success criteria were saving GP time and reaching more patients. Social media was second (27%), but estimated effectiveness varied considerably, with only 17% stating very effective. Fewer retention tools were used, with SMS / email reminders reported most (10/15 67%), but certainty about effectiveness varied. A detailed definition on what constitutes a digital tool with examples and a logic model showing relationships between the resources, activities, outputs and outcomes for digital tools was developed.

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