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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**Conclusions.** Database screening tools are the most commonly used digital tool for recruitment, with clear success criteria and certainty about effectiveness. Our detailed definition of what constitutes a digital tool, with examples, will inform the NIHR research community about choices and help them identify potential tools to support recruitment and retention.

## VP55 Trial Recruitment & Retention Using Digital Tools: A Qualitative Study

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**Introduction.** Recruitment of participants and their retention in randomized controlled trials (RCTs) is key for research efficiency. However, for many trials, recruiting and retaining participants meeting the eligible criteria is extremely challenging. Digital tools are increasingly being used to identify, recruit and retain participants. While these tools are being used, there is a lack of quality evidence to determine their value in trial recruitment.

**Methods.** The aim of the main study was to identify the benefits and characteristics of innovative digital recruitment and retention tools for more efficient conduct of RCTs. Here we report on the qualitative data collected on the characteristics of digital tools required by trialists, research participants, primary care staff, research funders and Clinical Trials Units (CTUs) to judge them useful. A purposive sampling strategy was used to identify 16 participants from five stakeholder groups. A theoretical framework was informed from results of a survey with UKCRC registered CTUs. Semi-structured interviews were conducted and analysed using an inductive approach. A content and thematic analysis was used to explore the stakeholder's viewpoint and the value of digital tools.

**Results.** The content analysis revealed that 'barriers / challenges ' and 'awareness of evidence' were the most commonly discussed areas. Three key emergent themes were present across all groups: 'security and legitimacy of information', 'inclusivity', and 'availability of human interaction'. Other themes focused on the engagement of stakeholders in their use and adoption of digital technology to enhance the recruitment/retention process. We also noted some interesting similarities and differences between practitioner and participant groups.

**Conclusions.** The key emergent themes clearly demonstrate the use of digital technology in the recruitment and retention of participants in trials. The challenge, however, is using these existing tools without sufficient evidence to support the usefulness compared to traditional techniques. This raises important questions around the potential value for future research.

## VP57 Using Capital Bids For Hospital-Based Health Technology Assessment

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**Introduction.** The Evelina London Children's Hospital (ELCH) is undergoing a period of growth, including a new building planned to be completed within the next five years. Due to limited space and ambitions to be a state-of-the-art hospital, Horizon Scanning (HS) was considered important to 'future-proof' new facilities. As the aim of HS is to identify signals of coming change, 'scanning' the previous five years' trends may be beneficial to an iterative HS methodology. Thus, it was thought that capital bids could provide a range of useful information required to make procurement decisions.

**Methods.** King's Technology Evaluation Centre (KiTEC) provided hospital-based HTA and HS support for the expansion of a London-based paediatric hospital. KiTEC focused on imaging technology due to its large spatial requirements and high-costs and assessed all capital bids made over the previous five years. A capital bidding system is used within GSTT to allocate funding for medical equipment that costs more than GBP5000 (USD 6540.70). Information was collated for all imaging equipment bid for over the previous five years and assessed for trends in imaging modalities and purchase costs.

**Results.** A total of 135 bids were made in the period 2013-2018, eight of which were by ECLH. Bids for ultrasound equipment were most common and rose over the period. Bids for CT scanners also rose, while bids for MRI scanners and x-ray technology were consistent and bids for fluoroscopy fell. The total cost of imaging bids over the interval rose steadily from GBP5.4 million to GBP6.9 million.

**Conclusions.** Due to the lifespan of imaging technology, some trends may not emerge within a five year window. While some interesting findings were made, a ten to fifteen year period may require to be scanned for a robust analysis. This methodology is best applied in an iterative fashion along with standard HS techniques.

## VP59 The MedicineWise App: Extended Applications Beyond Medicine Management

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**Introduction.** The MedicineWise app is a free consumer health and medicine management app developed by NPS MedicineWise. With 107,000+ downloads and 78,000+ active sessions per month, the MedicineWise app's core functions include: keeping track current medicines lists, medicine dose reminders and recording health conditions, allergies, test results and other health information. Recent enhancements also enabled the app to deliver featured health- and medicine-related content to users based on their medicines and/or health conditions. The goal is to maximise the MedicineWise app's capabilities by personalizing to users' needs and combining with health professional interventions when needed, to encourage better delivery of health and medicines information and improve medication adherence and health outcomes.

**Methods.** A number of personalized medicines management service offerings were created by combining a technology solution using the MedicineWise app (including the app's core functions as well as added targeted content delivery capability) with a humanistic solution (a health professional-mediated phone-based

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