Challenges in applying for ethical approval across jurisdictions as part of an INTERREG Project and how they might be addressed

Kathleen Michelle Friel MBA BSc. (UU), Dr. Claire McCauley (UU), Prof. Paddy Gillespie (NUIG), Dr. Michael McCann (LYIT), Dr. Maurice O'Kane (WHSCT), Prof. Sandra MacRury (UHI), Dr. Janet Heaton (UHI), Dr. Hugo Van Woerden (NHS Highland), Dr, Randal Parlour (LUH), Prof. Vivien Coates (UU & WHSCT)

Ulster University

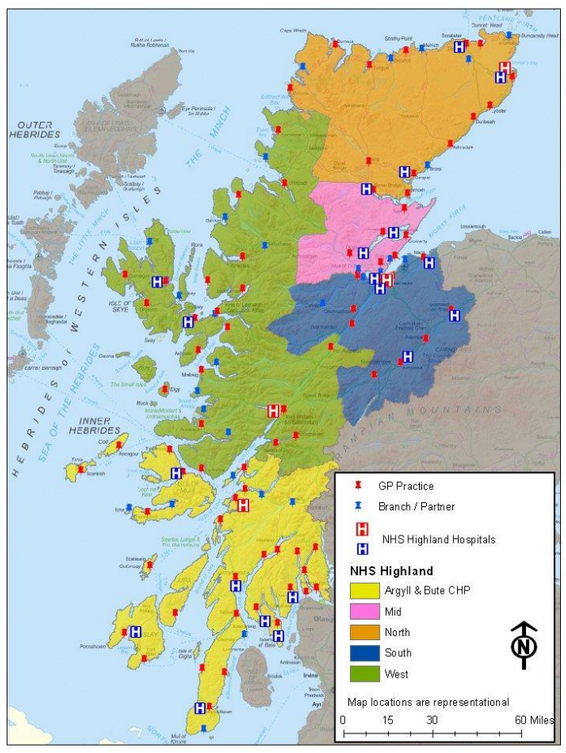
Faculty of Life and Health Sciences

ulster.ac.uk

Introduction

The Centre for Personalised Medicine, Clinical Decision Making and Patient Safety was established in April 2017 following an award of €8.6 million from the EU INTERREG VA programme. This cross-border project includes 14 partner organisations, 80 staff, 10 PhDs and 5 research clusters in disease areas including unscheduled care in diabetes. A major strength of the project is the multidisciplinary team of clinicians, academic and commercial expertise. Exploring the use of *Freestyle Libre* in inpatient diabetes care to improve clinical decision making is one study in this project. This multi-centre study will be carried out in Altnagelvin Area Hospital (Western Health and Social Care Trust), Letterkenny University Hospital (Saolta University Health Care Group) and Raigmore Hospital (NHS highland).

Saolta



NHS Highland Hospital locations and GP Practices

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NHS Highland

Health Intelligence & Knowledge Team
Directorate of Public Health
Assynt House

Date: April 2012

Methods

In the UK and NI, ethics approval is granted by the Research Ethics Service (RES) while research governance approval is given by the Health and Social Care Trust/Board. Multi-centre applications such as this study, are coordinated by the R&D Application Gateway. Processes are underpinned by the UK policy framework for Health and Social Care Research.

An application for this multi-site study was submitted to the North of Scotland RES in February with an unfavourable opinion regarding the study issued in March. In June, changes were unexpectedly introduced to replace site specific information (SSI), a tool that enables the Health Trust to evaluate the impact of a proposed study. This led to a new application for the study to be submitted this month (September).

The Research Ethics Committee at Letterkenny University Hospital (LUH) is responsible for the independent review and approval of research studies conducted in the LUH catchment area. An application for a retrospective data audit and qualitative service evaluation was approved in March and subsequent approval was received for this study in June. LUH issued notification on 4th September for Garda and NI police clearance and honorary contract.

Ethical Challenges

Quarter 4 2018

- PhD registration
- Locating service eval and ethics/governance procedures for LUH
- Engaged PI & study team for LUH service
- WHSCT Honorary Contract requested

Quarter 1 2019

- Multi-centre application submitted
- Locating ethics/governance procedures for LUH
- Service evaluation approved by LUH
- WHSCT Honorary Contract received

Quarter 2 2019

- Unfavourable opinion received for multi-centre application
- HSC R&D replaces SSI process
- LUH REC meeting cancelled April
- LUH REC meeting cancelled May
- Approx. 73 emails; 46 calls, & 8 visits to LUH since Q4 2018
- Vacant Post Doc. post
- Recruitment of research nurses for WHSCT & LUH

Quarter 3 2019

- Multi-centre application submitted
- LUH site initiation meeting
- Honorary contract, Garda & Police clearance requested by LUH
- Hold on further research progress in LUH until contract issued resulting in study delays
- Post Doc. Post filled
- Research Nurse post for WHSCT filled
- Vacant research nurse post for LUH

Results

Challenges have been experienced across the sites and much time and effort dedicated in the first year to locating ethics and governance procedures.

Various issues have led to delays in approvals including different arrangements and timescales in each site; the introduction of changes to SSI; time spent locating procedures; lack of programming of meetings; delays and lack of responses to emails and calls. There is a need for a clear set of procedures to be developed for large projects such as this that are faced with these types of challenges and the impact this has on researchers' workload and progress.

Discussion

As this study has a multi-centre approach, additional ethics applications are needed across different jurisdictions requiring greater ethics preparation time. Time spent locating procedures for service evaluation, ethics and governance, changes to submission processes and following up on delays in responses to emails and calls has slowed approval down. This could in part be due to the different arrangements across sites, staff experience and workload as well as staff changes and unfamiliarity with the study needs. Nonetheless, these challenges identify the need for a clear set of procedures to be developed.

There is growing evidence that research-active hospitals have better outcomes with research providing important information on the outcomes of treatments, interventions and importantly, equity of access to research for patients. A culture of research is critical as it enables patients to benefit from new treatments and improves their health outcomes (SAOLTA University Health Care Group STRATEGY, 2019-2023). But successful research collaboration requires commitment from all parties (Gaskill et al. 2003), so it is important that research procedures are joined up across sites to ensure common standards and requirements, reciprocal arrangements, timely meetings and responses are in place so pressing time lines for PhD researchers and programme targets can be met.

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