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Hub North West	Host University University of Liverpool
Supervisor Keith Bodger kbodger@liverpool.ac.uk	Co-supervisors Paula Williamson Bridget Young Sara Brookes
Is the project clinical or non-clinical? Clinical	
Title of PhD project Record-keeping in patients with inflammatory bowel disease (IBD) within electronic patient record systems: Current practice and motivations for collecting structured data	

Background: Electronic patient records (EPRs) allow collection of digital health information for individual patients with the primary purpose of providing clinical care. EPRs have significant potential in future clinical trials and outcomes research but a number of barriers need to be overcome. Adoption of systems for capturing structured clinical data at point-of-care has been slow, EPR systems vary widely between providers and consensus is often lacking on minimum or core datasets to be captured for specific conditions. As EPR provision increases in secondary care, it is important to understand how information is collected within the consultation and utilised within the record. While clinical care needs to be patient centred, data collection for research needs to be performed in a similar way across all patients to avoid selection bias, or missing data that are 'missing not at random' - both of which affect internal validity.

What the studentship will encompass: Using the Inflammatory Bowel Diseases as exemplars of life-long, chronic conditions managed mainly in secondary care, this PhD will explore these barriers and aim to identify ways to address them and recommendations to inform evolution of the UK IBD Registry. The **first phase** will involve ethnographic observations of information collection and recording during clinical consultations between hospital healthcare professionals and IBD patients. Questions to be explored include:

- *How is historical information in the EPR utilised within the consultation?*
- *What information is collected within the consultation?*
- *How is that data captured and recorded?*
- *What is this data used for?*
- *What factors influence data collection (e.g. disease severity, patient preferences)?*
- *What knowledge do healthcare professionals have of emerging consensus on minimum electronic datasets for IBD (as promoted by the UK IBD Registry programme) and Core Outcome Sets (as considered recently by ICHOM)?*

If EPR systems are to be configured to collect a greater amount of structured data, any change needs to be viewed positively by clinicians and either time-saving or time-neutral. Hence, the **second phase** will involve semi-structured qualitative interviews with a purposefully selected clinician sample to explore their possible incentives, motivations and ranked benefits of collecting structured information in EPRs. To explore transferability of findings to other chronic diseases, interviews will be extended to include clinicians from two other specialities (Rheumatology and Diabetes). The **third phase** will comprise user testing of a prototype enhanced EPR for IBD in clinical practice (informed by phases one & two), based on modifications to the current UK IBD Registry's disease-specific EPR (Web Tool).

Supervision: Dr K Bodger (Primary Supervisor; SL in Medicine; Hon. Cons. Gastroenterologist; Dept of Biostatistics, UoL) will provide expertise in IBD and related outcomes research. He leads the analytical hub for UK IBD Registry (based at UoL; funded by an award from Crohn's & Colitis UK). Prof B Young (Prof. of Psychology) will provide expertise in qualitative methods, clinical trials and communication in clinical settings; Prof P Williamson (HoD, Biostatistics) will provide expertise in Core Outcome Sets (COS), quantitative methods and clinical trials methods. Collaboration and supervision will be provided by Dr S Brookes (Bristol Hub), joint lead for ConDuCT-II Hub outcomes theme, an experienced trial methodologist and contributor to development and methodology of a number of COSs.

Planned Field Work: Direct ethnographic observation, surveys and interviews of front-line hospital teams at hospital sites (gastroenterologists and specialist nurses) in an outpatient setting, and opportunities to work directly with the UK IBD Registry team.

Supplementary information

1. Describe the alignment of the project with the HTMR Network strategy

The project aligns with HTMR Network strategy to "promote high quality methodological research relevant to trials." The importance of capturing relevant outcomes in clinical practice and research was demonstrated by a recent HTMR Network Delphi survey of Directors of registered CTUs (Tudor Smith C *et al*, Trials 2014). Out of the dozens of methodological topics identified, Directors ranked "choosing appropriate outcomes to measure" one of their top three priorities for trials methodology research. The project also aligns with the strategy to develop "innovative methods, and extension of existing methods for the clinical trials community" by informing better ways to make use of EPR for research by identifying technical and human barriers to embedding the digital capture of structured clinical data and outcome measures into routine practice – supporting the evolution of Learning Healthcare Systems for specific conditions.

2. Does this project align with the work of a HTMR Working Group; if so, which?

The work aligns both with the Informatics WG, which aims to "harness advanced health informatics and EHR data to improve the design and conduct of trials …" and with the "Outcomes" WG which includes work on COS and the reporting of outcomes.

3. Describe how this project aligns with the host Hub strategy

Yes, this is relevant to Theme 2 (Later Phase Trial Design & Analysis), specifically the COMET initiative and COS and also with Health Informatics focus.

4. Detail of any Project specific training offered in the studentship

The student will be offered project specific training in qualitative observation, interviewing and analysis and user testing of prototype EPR. They will have access to advice and support from the UK IBD Registry team and access to an associated network of UK clinicians involved in adapting local EPR systems to align with emerging consensus on core datasets.

5. Are there any prerequisite qualifications or experience for this studentship?

Candidates for an MRC-funded studentship must meet residence eligibility and hold qualifications in a relevant subject at the level of, or equivalent to, a good honours degree from a UK academic institution (see methodology website for more details- www.methodologyhubs.mrc.ac.uk).

For this project: Applicants do not need to have held a position with formal research time (e.g. an academic foundation or academic clinical fellowship (ACF) post).
Training will be offered in qualitative research therefore experience in this is not a prerequisite.