Host University University of Bristol	
Co-supervisors Sian Noble, Joanna Thorn	
al	
Title of PhD project Developing a modular resource-use questionnaire for use in RCTs	

## Background to the project:

Participant self-completed resource-use questionnaires (RUQs) are commonly used in economic evaluations alongside RCTs. Health economists typically develop instruments on an ad hoc basis for each new trial, leading to duplication of effort, lack of standardization, and limited validation (DOI: 10.1111/j.1524-4733.2010.00788.x). Existing generic RUQs tend to be lengthy and rarely used (e.g. APCQ) or much modified versions of RUQs developed for specific disease groups (e.g. CSRI – mental health). The MRC network funded DIRUM database has begun to address these problems by providing a repository of RUQs (DOI: 10.1016/j.jval.2012.03.004) and a network workshop identified the need for research on questionnaire design and standardization (DOI: 10.1007/s40258-013-0022-4). Creating a generic resource-use measure is challenging because analyses may be conducted from various perspectives (e.g. NHS, societal), the level of detail required may also vary depending on trial setting (e.g. secondary care, primary care, community interventions), and there are regional and temporal variations in terminology. A well validated generic instrument with a modular structure would be valuable for trialists through reducing unnecessary work and making trial results more transparent and directly comparable with one another. A preliminary Delphi study has been undertaken with a panel of health economics experts to rank the importance of potential resource-use items identified through a review of the content of existing RUQs.

### What the studentship will encompass:

*Aim*: To develop a preliminary generic modular resource-use measure that, after further validation, can be used for economic evaluation in a wide range of RCTs of healthcare. *Methods*: The student will conduct a systematic review of methods used to develop existing generic RUQs (*e.g.* CSRI). In collaboration with the MRC health economics working group, the student will define the objectives of the RUQ (*e.g.* remit, target population, administration modes). In consultation with patients and experts, the student will develop the items identified during the Delphi survey into a core healthcare resource-use module, alongside residential care or social care modules, for example. The student will undertake formulation of specific instructions, questions, and response options. The content validity of the questionnaire will be piloted with experts individually and focus groups of primary and secondary care patients. The face validity (interpretability, clarity) will be assessed through qualitative techniques (*e.g.* think-aloud) in patient interviews. Items will be revised as a result of this process and the preliminary questionnaire will be piloted in a small group of diverse patients to assess acceptability (*e.g.* length). Full empirical validation of the questionnaire (*e.g.* reliability, criterion and construct validity) will be beyond the scope of this PhD.

### Detail of supervision:

Will Hollingworth is Professor of Health Economics at the University of Bristol and deputy director of the ConDuCT Hub. Dr Sian Noble (Senior Lecturer in Health Economics) co-chairs the HTMR Health Economic Resource Use and Costs Working Group. Both have extensive experience of developing resource-use questionnaires for trial-based economic evaluations. Day-to-day supervision will be provided by Dr Joanna Thorn (Senior Research Associate in Health Economics), who has conducted a range of methodological research associated with costing in RCTs, and has a particular interest in improving patient-reported resource use. Additional informal advice will be sought from network health economics working group colleagues in the Northwest (Hughes) and Oxford (Wordsworth), from outcomes working group colleagues in the Northwest (Dodd) and from ConDuCT-II Hub colleagues in the Outcomes theme (Brookes).

# **Detail of any planned field work/ Secondments/industry placement etc:** Described above.

## Supplementary information

1. Describe the alignment of the project with the HTMR Network strategy The project will produce high quality output directly relevant to trials, and will contribute to spreading best practice. The project involves designing an effective and appropriate method for measuring resource use in a clinical trial; the student will ensure researchers are aware of the instrument. The student will consult with external stakeholders, such as NICE, NIHR HTA, to ensure that the items included in the instrument align with research priorities. The project will strengthen research training and capacity in methodology by training the student in trials methodology, health economic methodology, questionnaire design and qualitative methods of

questionnaire validation. Collaboration with the NWHTMR (Hughes, Dodd) and Oxford (Wordsworth) Hubs will be ongoing throughout the project. The PhD also offers scope for further collaboration with other groups through the Health Economic Resource Use and Costs Working Group and the Outcomes Working Group.

2. Does this project align with the work of a HTMR Working Group; if so, which? The project is directly aligned with the aims of the Health Economic Resource Use and Costs Working Group, whose overall objectives include improving methods for resource-use measurement. The student will become a member of this Working Group.

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

The ConDuCT-II Hub is strategically organised into four research themes. This PhD project is directly aligned with the 'Prioritisation and trial design for cost-effectiveness analysis' theme, which is concerned with improving the methodology of RCT resource-use measurement and thereby cost-effectiveness analyses (amongst other key aims). The 'Outcomes in RCTs: selection, reporting and integration in decision making' theme is conducting research in developing core outcome sets and developing and validating outcome measures; this will offer considerable scope for collaboration.

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

The School of Social and Community Medicine at the University of Bristol runs a well established series of short courses that are available at no cost to PhD students. The student will have access to all these courses, but the 'Introduction to Randomised Controlled Trials', 'Questionnaire Design, Application and Data Interpretation', 'Systematic Reviews and Meta-Analysis' and 'Introduction to Qualitative Research Methods' courses will be particularly relevant. External training in online questionnaire development and other skills will be supplied as required.

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 detailswww.methodologyhubs.mrc.ac.uk).

For this project: The student will require a background in health economics, health services research, medical sociology or a similar discipline (an MSc or equivalent experience).