

M. HAWLEY (Convener). **Health-services research in gerontechnology.** *Gerontechnology* 2012;11(2):233; doi:10.4017/gt.2012.11.02.122.00 **Participants:** G. MOUNTAIN, K. EASTON, S. CREER, C. BENTLEY (all from UK) **ISSUE** Presenting the value of Health Services Research in Gerontechnology in improving the development of, and strengthening the evidence base for, complex gerontechnology interventions. **CONTENT** The recently updated UK Medical Research Council Framework (MRC) for Developing and Evaluating Complex Interventions (2008)¹ extends previous guidelines on the development, evaluation and implementation of complex health interventions outside the health service using both experimental and non-experimental methods. Many gerontechnology interventions are considered complex, with several interacting mechanisms, presenting challenges for researchers including complexity in standardising the design and delivery of interventions and their sensitivity to particular local services and populations². The MRC framework for the systematic development of interventions follows a flexible process of development, evaluation and implementation, which—when supported through the use of health service research (HSR) methods—can facilitate the development of, and strengthen the evidence base for, complex gerontechnology interventions. Interventions are to be developed to the point where they can be expected to have a meaningful effect: identifying the evidence base, developing theory, modelling processes and measuring outcomes. The feasibility of an intervention should be estimated with pilot evaluations: sample size, recruitment and retention, the acceptability and compliance with an intervention, economic costs and variations in local context should be considered. An intervention should be evaluated using the most appropriate methods. Finally, interventions should be successfully implemented into practice. The Rehabilitation and Assistive Technology Research (RAT) Group at the University of Sheffield is one of few groups currently developing new user-friendly technologies and technology-supported services in aging populations using a whole systems perspective to map complex gerontechnology interventions to the MRC framework³. In order to take gerontechnology further through the developmental and implementation life cycle we adopt a wide range of research methods to steer the development of innovative technologies, realistically appraise the impact of such technologies and strengthen the evidence base. **STRUCTURE** Four speakers from the RAT Research Group at The University of Sheffield will discuss the application of specific HSR methods in a range of ongoing or recently completed projects. An overview of the MRC framework for complex interventions and HSR methods in Gerontechnology will be presented followed by a presentation of the development, evaluation and implementation of gerontechnology interventions supported by HSR method; in particular systematic review, realistic evaluation, pragmatic RCTs, participant and patient involvement in research and novel dissemination used in our programme of research. Following presentations there will be opportunity to discuss and debate the role of HSR methods in the life cycle of Gerontechnology research and development. **CONCLUSION** The purpose of the symposium is to generate debate regarding the current state of Gerontechnology research. The importance of HSR methods mapped onto a research framework will be discussed. The MRC framework for complex interventions is not without its shortcomings⁴; these too will be considered and discussed.

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G. MOUNTAIN, N. NASR, K. EASTON, C. BENTLEY. **Evaluation of technology for use by health services for aging populations or those with long term conditions.** *Gerontechnology* 2012;11(2):234; doi:10.4017/gt.2012.11.02.339.00 **Purpose** To introduce the symposium, describe the challenges and propose a framework for technology evaluation. **Method** Technology evaluation poses specific challenges for developers. Those devices that will eventually be prescribed through health services demand a specific type of evidence if they are to be successfully adopted. Not surprisingly, the extent of technological development that has taken place over recent years has not been matched by investment in evaluation. The evidence base, where it exists, is dominated by small-scale pilot and qualitative studies and there is a paucity of generalisable evidence. This is confirmed by Whetton¹ who examined the results of several reviews of Telehealth evaluations and identified shortfalls in reported research including ‘insufficient or inadequate data to substantiate claims’, ‘a focus on pilots and/ or short-term perspectives with limited analysis of long-term or routine use’ and ‘a focus on descriptive rather than analytic evaluation criteria.’ The quality and nature of the existing evidence base is therefore in conflict with that demanded by health services; for example UK health commissioners continue to base their judgements upon systematic reviews such as those produced through the National Institute for Clinical Excellence (NICE), with trial evidence being considered to be the most reliable evidence. Things are however beginning to improve and confidence in trial methodology is exemplified by the UK government investment in the Whole Systems Demonstrator Programmes of research into telecare which used trial methodology concurrently in three UK sites, involving 6,200 participants². At a population level, trial evidence is prioritised. However it is well-recognised that this methodology has limitations. The paradox of the clinical trial is that it is considered the ‘gold standard’ of intervention efficacy, but arguably the worst way to assess who will benefit from it³. These observations are magnified for complex interventions like telehealth where the issues that determine success extend far beyond the technology to the individualised service systems within which the technology is to be used, including the knowledge and experience of the staff and whether or not the device is accepted and then used by patients. Nevertheless it is also true that reliance upon qualitative studies does not provide confidence in the ability to generalise benefit to a wider population. In acknowledgement of the many variables which have to be taken into account in the evaluation of complex interventions, The UK Medical Research Council (MRC) have produced an updated framework for evaluation of complex interventions (through randomised controlled trials) which places greater emphasis upon the development, feasibility and evaluation phases⁴. The framework recognises the need for early testing and the importance of contextual factors and proposes work on development and feasibility/ piloting should be undertaken prior to population based evaluation. These two phases are convergent with those frequently used for the formative and summative evaluation of prototypes, thereby providing the underpinning for robust evaluation within this framework. **Results & Discussion** The Rehabilitation and Assistive Technologies Group at the University of Sheffield UK have significant experience of developing and testing technologies for use with older populations in health settings and as a consequence have invested in the identification of appropriate methodologies which are nested within the MRC Complex Intervention framework. The three papers following this introduction will demonstrate how this is being achieved and provide a forum for a methodological discussion.

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N. NASR, S. MAWSON, G. MOUNTAIN. **A realist evaluation of a self-management technology.** *Gerontechnology* 2012;11(2):235; doi:10.4017/gt.2012.11.02.221.00 **Purpose** The aim of the present paper is to draw on Realist Evaluation methodology¹ to evaluate the SMART system², a prototype of integrated technology developed for the self-management of long-term conditions. The purpose of using this innovative method is to understand the conditions under which this technology has an impact on the target users' behaviour. We argue that, contrary to traditional outcome evaluation in which no contextual information is needed to explain the relationship between the intervention and the outcome³, the realist evaluation stresses the significance of 'context' and 'mechanism' to explain the outcomes. The approach addresses why a programme works, and how programmes change understanding and reasoning of their users. **Method** The Realist Evaluation with its root in philosophy, sociology, and evaluation, is performed as the systematic interplay between the three elements of 'context', 'mechanism' and 'outcome'¹. The Realist Evaluation as a theory-driven methodology requires us to understand mechanisms. Mechanisms encourage new ways of thinking, reasoning and provide means of change, which subsequently can lead to gaining a new understanding¹. Realist Evaluation also tries to explain those contexts that are 'conductive' or 'resistant' to change under the action of the mechanisms triggered by the programme⁴. The approach allows the researcher to take into account the complexity of real world contexts without restricting the evaluation to control groups or comparing it with predefined interventions. Unlike experimental control design, evaluation studies where the observed change or lack of change in intervention group is attributed only to the intervention and the explanatory possibilities are limited to 'one-variable-at-a-time' strategy, realist evaluation seeks to address the question of why a programme or an intervention works⁴. The purpose of the Realist Evaluation is not to discover whether an intervention has worked, but to ask what works for whom and under what circumstances, in what respect and how. In other words, the evaluators need to be aware of micro- and macro-processes, influences at the individual as well as at the institution level, and the causal powers coming from both reasoning and resources¹. **Results & discussion** The realist evaluation methodology was applied in two phases. In phase 1 the initial conjectured 'context', 'mechanism', 'outcome' configurations (CMOs) were elicited based on the theories underpinning the SMART system. A 'variable book'¹ was generated and was further refined and validated through a focus group with clinicians in the field. The findings of the focus group identified 'folk' theories¹ indicating that the system would have great scope and potential for physically impaired mild stroke patients with no cognitive or psychological impairment. In phase 2 following the deployment of the SMART system into the patient's homes, qualitative one-to-one interviews and quantitative measures were used to investigate the causal relationships between the context and the mechanisms. The users of the system were offered a body of theory translated in questions within an interview guide. We used the 'here's-my theory-what's-yours'¹ strategy and asked the users to verify or falsify the theory or the CMOs. A final analysis is being carried out to establish whether the system has created change in users' behaviours concerning the self-management of their long-term conditions. In other words, to identify whether the theories supporting self-management programmes have been refuted or confirmed. An analysis of data to examine whether it has induced change will be completed and presented at the time of the presentation.

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K. EASTON. *The use of systematic review methods to strength the evidence base of telehealth complex interventions.* *Gerontechnology* 2012;11(2):236; doi:10.4017/gt.2012.11.02.215.00 **Purpose** To examine the origins of the systematic review method, to consider the role the health services research method plays in contributing towards the UK Medical Research Council framework for developing complex interventions and explore its use in current telehealth research designed to improve the lives of older adults. Consideration will be given to the particular challenges faced when systematically reviewing the evidence from complex interventions. **Method** Systematic review methods developed originally to support evidence-based medicine; i.e. the use of current best evidence in making decisions about the healthcare of individual patients. Systematic reviews are considered the highest level of evidence in evidence-based medicine, at the top of a pyramid of hierarchy of evidence¹. The aim of a systematic review is to combine the results of multiple primary studies to provide a more reliable and precise estimate of effect size for an intervention than a single study alone². Systematic reviews are considered key components in developing the evidence base required in the preliminary stages of the Medical Research Council framework for the development of complex interventions. Complex interventions are by definition complex. As a result systematic reviews of complex intervention evidence are also complex. Increasingly systematic reviews need to consider conceptual frameworks and theories underpinning interventions, identify key components of interventions, assess the economic implications of interventions, identify barriers and facilitators to the implementation of interventions, examine users views of an intervention; using both quantitative and qualitative data identified in published and grey literature in order to improve the evidence base for the use of telehealth for older populations. **Results** The development of evidence-based medicine and the need for systematic review methods in evaluating interventions will be explored. The use of the method will be placed within the Medical Research Council framework for complex interventions. Relevant examples of systematic reviews undertaken by The Rehabilitation and Assistive Technology Research (RAT) Group at the University of Sheffield will be presented to showcase the use of this Health Services Research method in evaluating the effectiveness of telehealth intervention in an aging population. The difficulties at various stages of review in conceptualising, searching, screening, and synthesising complex intervention data will be considered, with suggestions on how best to navigate the complexities of reviews in this area³.

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Figure 1. Levels of evidence pyramid¹

C.L. BENTLEY, G.A. MOUNTAIN. **Chicken and egg: Use of pragmatic rct in tele-healthcare.** *Gerontechnology* 2012;11(2):237; doi:10.4017/gt.2012.11.02.210.00 **Purpose** Randomised controlled trials (RCT) are the 'gold standard' health service research method advocated in the UK Medical Research Council framework for informing evidence-based practice. However the method is difficult to apply to complex interventions such as telehealth, even when conducting a pragmatic rather than an explanatory RCT, the former of which holds many advantages for the evaluation of complex interventions within healthcare¹. **Method** The use of trials research methods to test telehealth interventions will be presented, in addition to an examination of the extent to which Medical Research Council guidelines for the development of complex interventions rely on this particular research method in order to generate an evidence base in this area. Examples are taken predominantly from a pilot pragmatic RCT in telemonitoring for early-stage chronic obstructive pulmonary disease (COPD), which is nearing completion². Early-stage COPD patients were defined as having between one and three previous hospital admissions (including the current admission) in the previous twelve months. The study also required participants to have a telephone landline and to be able to communicate in written and spoken English. A feasibility study was conducted to test outcome measures, gain understanding of the local context in which the pilot trial would take place, and to help establish appropriate clinical and trial-related care pathways within the newly formed COPD Community Nursing Team. During the main pilot phase 63 early-stage COPD patients who had just been discharged from hospital were randomised to either Telemonitoring (32 patients) or Standard Care (31 patients). Telemonitoring involved patients inputting daily physiological measures and answers to health-related questions over a period of 8 weeks, which were monitored remotely by a COPD-nurse. Standard Care involved intermittent COPD-nurse visits over the same time period. **Results & Discussion** Numerous implementation issues were encountered during both the feasibility stage and the pilot stage, many of which could not have been anticipated from the results of the feasibility stage. Issues mainly oriented around the necessary mainstreaming of the telehealth intervention alongside establishing care pathways within the COPD-nursing team, unanticipated loss of COPD-nursing team capacity, and structural changes both within involved parties and within the wider NHS. Although measures such as using a larger clinical team and enlisting a research nurse from project initiation would have eased implementation problems, the results indicate that even pragmatic RCTs may offer little insight into the contextual issues of implementing a complex intervention into practice. Debate will focus around the 'chicken and egg' situation commonly found in implementation of telehealth - that tele-healthcare interventions are not generally mainstreamed without RCT-evidence, yet a complex intervention such as this needs to be mainstreamed before an RCT can take place.

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