

# Investigating user needs and integration of Remote Measuring Technologies into Clinical Practice

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**Abstract.** The abstract should summarize the contents of the paper in short terms, i.e. 150-250 words.

**Keywords:** remote measuring technologies, mhealth, user centred design, clinical pathways, socio-technical systems, value

## 1 Background

### 1.1 Remote Measuring Technologies (RMT) and Clinical pathways

Digital mobile and wearable technologies are increasingly being utilised in health and social care provision and there are statements of need for the continued and expedited embedding mHealth technologies into overall health systems and policies [1]. To enable successful uptake of these technologies, the challenges of real-world use, user acceptance, integration with existing systems and sustainability must be examined and understood before use in practice. The recent review and publication of the Accelerated Access Review (AAR) [2] in the UK proffers three pathways of innovation to optimise the development and appropriation of medical devices, digital healthcare technologies and pharmaceutical products. However, in practice, the exploration of potential value and risks can be difficult because interdependence of current practice, user behaviour and integration with multiple systems and services makes testing and development of new products particularly difficult.

There is not much clinical pathway guidance for the use of digital mobile technology innovations; specifically for remote measuring of patient health state, outside of drug-device combination products. An investigation of the literature, guidance and current practice around the design, deployment and integration of these novel technologies into clinical practice unearths studies of clinical process innovation (CPI) which encompasses the planned implementation and evaluation of a variety of interventions such as

clinical pathways, electronic workstations, and various forms of information technology [3]. CPI measures innovation adoption against innovation emergence, growth, maturity and crossroads, within a lifecycle based on the variables of ‘experience of innovation’ and ‘tolerance for change’. It therefore differs in its outcomes measures to a Human Factors approach focusing on the performance, safety and user experience of the technology within the system.

There is much more to understand about how service providers can optimize the utility of RMT for different types of patient users and how to design the multimodal and multidirectional human computer interactions to optimize benefit to all stakeholders and the healthcare system more generally. Gee et al [4] considers the need for a curriculum of training for patients, consumers and healthcare providers, for the successful implementation of mHealth interventions. However, the role of HF in the development of RMT and design of clinical pathways with ICT interventions will reduce the need for and reliance on training, due to the improved design of the socio-technical systems delivering care [5].

This submission provides an overview of how one large scale RMT development project is using HF and user-centred design practices to elicit and investigate use scenarios in context of the clinical pathways and system of health service delivery, prior to and during the technical system development. It provides insight on how HF methods give prospective insight into real-world practice.

## 1.2 RADAR-CNS

The EU funded RADAR-CNS project [6] is prospectively investigating these challenges in parallel with the design of a novel mHealth (mobile health) remote measuring technology (RMT) for longitudinal data collection in the detection and prediction of relapse in three distinct medical conditions, epilepsy, multiple sclerosis and depression. Fit to existing clinical pathways and potential for change to pathways are examined as a likely indicator of RMT adoption.

The project is underpinned by the involvement of and consultation with a wide range of stakeholders – patients, carers, healthcare professionals and managerial, procurement and administrative healthcare providers. This contribution details the clinical facing Human Factors (HF) studies in RADAR –CNS. They include:

- Eliciting clinical professional requirements of the technology through in depth interviews and the development of use scenarios.
- Investigating alignment and disparities with current clinical practice, or understanding ‘Work as Done’ (WAD) v.s. ‘Work as Imagined’ (WAI) [7] via clinical pathway visualisation and exploration.

- Analysing how RMT provides added value beyond existing practices by using the use scenarios and the outputs of the WAD/WAI investigation to inform a large scale Delphi enquiry. This Delphi study will utilize Conjoint Analysis to understand the priorities, values and consensus points of different user populations. This will be the basis of the technology value proposition.

This Human Factors approach will be carried out to demonstrate benefit to the development in clinical pathways and demonstrate how lessons from systems based learning can provide holistic development and evaluation processes which might accelerate the use of clinical pathways and associated resources in tandem with the development of novel ICT healthcare interventions such as RMT.

### 1.3 Clinical pathways

The European Pathways Association (EPA) (<http://e-p-a.org/>) defines a clinical pathway as,

‘A complex intervention for the mutual decision making and organization of predictable care for a well-defined group of patients during a well-defined period.’ [8].

This definition presents the concept of ‘clinical pathways’ as a process of care delivery as a whole and alludes to the multiplicity of stakeholders involved within it. Vanhaecht [9] describes how clinical pathways “are complex interventions that keep the structure, process and outcomes of care in motion....and that they should be used as a method to achieve a particular goal” in this case providing patient benefit. NICE in the UK state that the purpose of these pathways is to assess quality of care against defined care standards, facilitate equality of healthcare provision (by reducing variations in practice) and provide structures from which to evaluate clinical and cost effectiveness and that they are “both a tool and a concept that embed guidelines, protocols and locally agreed, evidence-based, patient-centred, best practice, into everyday use for the individual patient” [10].

#### **Human Factors and Clinical Pathways.**

Research into clinical pathways [11, 12] highlights the importance of the interactions between multiple stakeholders and parts of the healthcare system which provide the framework for pathways to be a tool for care planning and management. This wider framework – or socio-technical system [13] - takes into account the tasks, people, artifacts, procedures, decision points, and context and considers the wider environments of care, all in respect to delivery of care on a continuum, over time.

One interpretation of clinical pathways is how they can be described as aiming to achieve the following,

- the right people
- doing the right things
- in the right order
- at the right time
- in the right place
- with the right outcome
- all with attention to the patient experience
- and the ability to compare planned care with care actually given

Such a description resonates with a HF systems perspective of achieving safe, optimal performance with positive user(s) experience, whilst understanding what has been done and if the tasks performed and work done has or has not adhered to how it is understood, imagined and reported/disclosed [14]. Once there is comprehension of these and variance monitoring between planned care and actual care through the ability to “review and update the process with attention to the service-user and other outcomes” [15], then there is opportunity for improvement. This is made all the more complex by the fact that clinical pathways by their nature are multifaceted concepts and no two are the same. All pertain to wide diversity in application, resource, management, skills and timeframe with the collaboration of multidisciplinary teams. Another factor contributing to the variation is that clinical pathways are rarely implemented or followed in isolation.

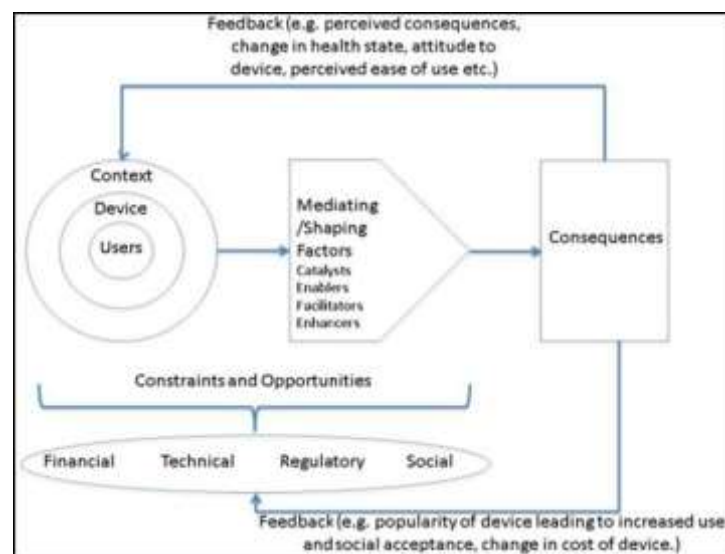
The HF activities being undertaken in the RADAR-CNs project are contributing new knowledge about RMT in practice and are a key contributor to understanding future commercialisation and adoption. Analysis of the HF data allows themes relative to essential and desirable characteristics for the RMT system to be identified and passed on to the technology development teams.

## **2 Methods**

Data from multiple methods will be triangulated to comprehend points of value and risk in the introduction and use of RMT in care provision. Clinical pathway visualisations will support healthcare professionals in considering current practice and the impact of RMT, associated decision making and also user experience of the care service from their and patient perspectives. The development of those visualisations will also enable comparison of healthcare practices in different healthcare systems and jurisdictions.

Figure 1 details the data collection tasks and presents how the data will contribute to an overall picture of how RMT may change clinical pathways and practices.

There are however limitations to the approach being used. Observations would provide the evaluation with improved fidelity and accuracy regarding WAD. In so far as the methods used are more likely to elicit Work as Reported (WAR) rather than WAD. However despite the drawbacks and potential limitations, it does however provide a framework from which to start assessing the potential value of the RMT interventions in clinical care. The following model (Figure 2) suggests four ways in which technology can shape and/ or improve care provision. Whereby innovative solutions can catalyse how work is done, enable a completely new way of working, or facilitate and enhance existing working practices [16].



**Fig. 2.** Medical Device Design in Context model [16]

As such it suggests ways in which technologies; such as RMTs, can positively impact the clinical pathways and care practices experienced by patients and healthcare staff.

With regard to the way in which they might alter clinical pathways, there are several ways in which these novel interventions might impact clinical pathways for which there is currently no detail on RMT use,

- Remote data access
- Simultaneous data access to the same patient record
- Processing of novel bio-signature data
- Patient autonomy in condition management
- Availability of relevant clinical information at the point of patient care

## 2.1 Health Technology Assessment

The implementation of HF methods within the early design stages of RMT development also contributes to other angles of health technology assessment. It provides user-based data to help fulfil the AAR requirement for development of a value proposition and understanding about what could be considered when designing clinical trials for digital health technology interventions once they have been deployed in to practice.

Through a review of the literature and contributions from EFPIA partners it sets out decision points and the role of RMTs, utilizing examples from other medical conditions, and lays the foundations for how RMTs will be translated into clinical practice by developing and designing new remote monitoring pathways (RMPs) in the three disease areas. RMPs refer to modified clinical pathways that integrate RMTs developed by RADAR-CNS into clinical decision-making. These RMPs will form the basis for subsequent clinical and cost-effectiveness trials comparing existing clinical pathway management with management utilizing RMTs developed by the RADAR project. Hence, this deliverable provides the initial direction for further investigation into the requirements of clinicians and healthcare professionals, in regard to how RMTs might be used as decision support systems in clinical pathways to improve the management and outcomes of the RADAR-CNS targeted conditions.

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