When worlds collide: reconciling methodological differences in healthcare service innovation

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Abstract
Recent UK research council initiatives have encouraged the formation of mixed discipline teams to address complex and perplexing societal issues such as those associated with an ageing population recognising that for new thinking and innovation to occur a mix of disciplines require to work together. Despite the inclusive design community’s long-held interest in this area, very few designers lead or are involved in mixed discipline teams within these types of initiatives. In this context, what do people-centred design methods have to offer and could these be assimilated into a complex healthcare project’s over-arching research methodology? What effect would the way that design thinking and methods are integrated into the study have on the ability to generate innovative outcomes? To explore these questions, the author discusses methodological issues using two studies, funded through recent initiatives, to discuss how design research methods have been employed, one using an open innovation approach where a range of qualitative people-centred methods was central to the design of the research, and the second which took a much more cautious approach to integrating design and people-engagement methods. The likely impact of these different approaches on generating innovative solutions and the lessons to be drawn are discussed.

Keywords
Research methodology, healthcare, service design, open innovation

Introduction
Recent UK research council initiatives have encouraged the formation of mixed discipline teams to address complex societal issues such as the healthcare challenges associated with an ageing population. These initiatives have been created in the recognition that new thinking is required to address perplexing problems and that, to encourage innovative solutions, a range of disciplines will require to work together. The Medical Research Council’s Lifelong Health and Wellbeing (MRC LLHW) and the cross-research council New Dynamics of Ageing (NDA) initiatives are two such examples.

Despite the inclusive design community’s long-held interest in this area, very few designers lead or are involved in - as distinct from working as consultants for - mixed discipline teams within these types of initiatives. This may be due to mistrust, misunderstanding, ignorance of design methodologies, a lack of a proven track record of
research or the less than robust evaluation of the outputs of design research in this context.

With regard to the Include 2011 conference theme of ‘social innovation’ and the role of inclusive design in making this happen, social innovation is defined as “… new ideas (products, services and models) that simultaneously meet social need and create new social relationships or collaborations.” [1] In this context, what do people-centred design methods have to offer? How can ‘inclusive’ and people-centred design methods be integrated into a complex healthcare research project’s over-arching methodology? Could these design methods help create new social relationships to assist collaboration not only within healthcare research teams but also with their audiences (i.e., healthcare’s end-users - the public, service workers and patients)? What effect would these methods have on the ability to generate innovative outcomes that meet perplexing healthcare challenges?

To explore these questions the author uses two case studies, funded through current cross-research council initiatives, to discuss the types of social innovation that can result from the way that the research is designed. The role of design methods within the over-arching research methodologies is discussed for both cases. To assist the discussion reference is also made to methodological considerations which explore: i) the value of mixed methods; ii) the flexibility of the design of the research; and iii) the extent of public or patient involvement, each of which has the potential to influence the extent of social innovation.

**Methodological issues**

**A case for mixed methods**

In the ‘medical model’ of much clinical healthcare research, the evidence-based random control trial (RCT) informed by a systematic review of previously published trials still tends to be regarded as the research ‘gold standard’. Clinical research progress tends to be incremental and to test and build on prior evidence. By comparison, evidence-based forms of design research are still relatively recent and rare. Design might also tend towards more radical approaches in reconceptualising a product or service and can often be much more speculative in approach using less ‘formal’ and more socially-oriented methods to enable a process of forward thinking. Can these two approaches ever be reconciled within a single study?

In healthcare research it is unlikely that the best clinical trial design can ever be totally uninfluenced by environmental or social influences, or by the complexity of the different motivational factors and personal circumstances of the individuals (who tend to be regarded as ‘subjects’) involved. Less formal design methods, although bringing a useful ‘user/human’ perspective into a research proposal, have often lacked robust evaluation. This can often prove problematic for reviewers and research funders with a ‘clinical’ tradition and disposition.

However, in seeking to address complex healthcare challenges, progress and innovation will likely come from using a mix of methods. This issue is discussed by Lewin, Glenton & Oxman in a recent British Medical Journal (BMJ) paper. [2] This reviewed published studies of the use of qualitative methods in RCTs where, indeed,
RCTs can be regarded as unreliable and best used in conjunction with other methods. “Complex healthcare interventions involve social processes that can be difficult to explore using quantitative methods alone. Qualitative research can support the design of interventions and improve understanding of the mechanisms and effects of complex healthcare interventions”. This BMJ paper concludes: “… qualitative studies alongside [RCTs] remain uncommon, even when relatively complex interventions are being evaluated. Most of the qualitative studies were carried out before or during the trials with few studies used to explain trial results. The findings of the qualitative studies seemed to be poorly integrated with those of the trials and often had major methodological shortcomings.”

Qualitative studies are not the exclusive domain of design research and much valuable non-design healthcare research is ‘social’ and qualitative in nature (e.g., ethnographic and social-science-based), but with the emergence of co-design, participative and service design, the clarification and articulation of the range and value of qualitative design methods has greatly improved.

Flexibility in the design of the research
A second issue for consideration in this paper is that of the flexibility in the design of the research, i.e., how much is predetermined at the outset, and what ‘shape’ the research takes, whether this has a predominance of - or is exclusively using - either quantitative or qualitative methods and also when these types of methods are used in a study. Here, Poggenpohl and Sato (P&S) [3] provide two models, for convenience here named P&S1 and P&S2. P&S1 will “… often be less rigorous [than quantitative research] in its early design, with the research design evolving as experience develops … the analysis of qualitative work is time consuming and exacting … qualitative work starts fitfully at the beginning”. P&S2, is where “…considerable creativity and effort is required in the early stage of developing a quantitative experiment, but once constructed, the data collection and analytical tools provide for fairly quick and reliable results”. This consideration will have a bearing on what happens, when and how in the programme of research.

Extent of public or patient involvement
A final issue the author will consider here is the type and extent of patient or public involvement (PPI) in the research, reflecting an approach to the design of research that acknowledges and understands (or not) how to harness the considerable value of front-line staff's and patients' own tacit experiences and insights. Savory describes a framework for differentiating levels of PPI in ‘translative’ healthcare research. [4] He presents these as four idealised PPI strategies, summarised in brief as follows. “Strategy A represents PPI strategies that focus on the participation of patients with the primary purpose of collecting data.” …” – which and may also include focus groups. Strategy C is one “where the mode of patient involvement is complex …” with their involvement “in the design, conduct and even analysis of the research” (i.e. a ‘patient-led’ strategy). Strategy D involves “…public involvement and education” which is “concerned with widespread public involvement in translative research”. Savory also discusses the open innovation model and the shift from closed to open innovation paradigms. Although Savory states
that these represent ideal types and that in practice any research would likely not be so clearly defined, they do help us think about the level and type of PPI.

As the NHS Act 2006 now places a legal expectation that NHS organisations will promote PPI and as the National Institute for Health Research (NIHR) now requires that researchers show how PPI will be incorporated into the research it commissions, Savory’s categorisation of strategy will be useful in a) locating the level of PPI within a proposal and b) allowing collaborating disciplines to clearly articulate and reach a working consensus of their different approaches to PPI.

Two healthcare case studies

The design of the research for two healthcare projects is now discussed. In Case 1, a more ‘open innovation’ approach is taken where a range of qualitative people-centred methods and flexibility of engagement of PPI is central to the design of the research. Case 2 reflects a much more cautious approach to integrating design methods as the research was initially conceived as a ‘medical model’ of research where PPI is very ‘formal’ and limited in extent and where outcomes would be measured quantitatively but, as the project evolves, the value of more qualitative methods is recognised. The likely impact of these different approaches on generating innovative solutions and the lessons to be drawn from these are discussed.

Case 1: nutrition in hospitals

The aim of this project is to address the crisis in malnutrition in older hospital patients, focusing on those identified as being particularly vulnerable, i.e., stroke, dementia and hip fracture patients. [5] [6] Due to the inappropriateness of current meal provision, of central concern to the food scientists and dietitians in the team has been the ‘design’ of new foods with the appropriate texture, swallowability, aroma, flavour, nutritional density, temperature and appearance. These new foods have been evaluated for these qualities through the use of, e.g., a tasting panel and through scientific evaluation for their various ‘functional’, nutritional, and sensory properties.

However, as it was also recognised from the outset that partial solutions had previously failed, the design and supply of, e.g., new foods needed to be seen in the wider context of a redesigned ‘food service’ which would present the foods in a more conducive setting and manner and where foods would require to be appropriately customised for patient preference and need, delivered ‘on demand’, and nutritional intake monitored on a per-patient basis. To this end, the design of a new prototype food service was the goal of this project. The design of the research to deliver this prototype would entail a ‘socially-oriented’ approach to gather the necessary qualitative evidence.

The project’s principal investigator (PI) is a dietitian and the focus is primarily on dietary requirements and nutritional intake. However, from the outset dietitians, food scientists, medical sociologists, designers, ergonomists, and technologists have been working along with key stakeholders and a ‘food family’ (FF), i.e. food producers, caterers ward staff, nurses, dietitians, physicians, speech and language therapists, occupational therapists, carers and older people, to understand the more holistic needs of the food provision from patients’ perspectives, to ‘map’ the existing food service and
to identify opportunities for improving the service for all. A comprehensive understanding both of the status quo of the existing service and the desired qualities of a new food service has been gained. The process of open engagement with the FF, by means of series of interviews and participative workshops, has therefore been fundamental and central to the project. This has required the different specialisms in the research team to work together in preparation for these workshops. Major opportunities for service redesign guided by a set of service principles have been generated through a participative co-research and co-design methodology.

With reference to the BMJ paper [2], the design and sociological / ethnographic methods used by the different disciplines have had a high degree of overlap and are predominantly qualitative across the different disciplines, allowing a relatively easy discourse, and employing a ‘social model’ approach. By means of a co-design process which has empowered, trained, inspired, facilitated and guided the wider research team and FF in the use of design tools, these individuals have been ‘recruited’ as co-researchers and co-designers into the design team. This has been a particularly synergistic process enabling the investigators and researchers, and the FF, to reach a gradually more shared, comprehensive and focused understanding and consensus as the basis for the emergence and development of innovative ideas. This participative co-research and co-design approach is an ongoing iterative process throughout the project with food service redesign prototype concepts being brought to the FF for comment and evaluation.

With reference to Poggenpohl & Sato’s discussion [3], a very extensive investigation of the status quo of the existing service and an engagement with the FF was required. This suited a qualitative methodological approach to explore questions and issues in the early stages which provided the platform for subsequent research, i.e. the P&S1 model.

With reference to Savory’s PPI framework [4], this study has largely used Strategy B (e.g. using focus groups within workshops to determine priorities and soliciting feedback on concepts through interviews) with some elements of Strategy C (e.g. where we have been training the FF to use design tools and methods as the means to ‘prototype’ their own ideas).

**Case 2: physical rehabilitation using visualisation methods**

A second and separate project is set within the context of the current epidemic of long-term health conditions significantly impacting on people’s physical functional ability and their ability to work. This project is led by a rehabilitation bioengineer whose profession would normally assess an individual’s functional capability following, e.g., illness, accident or surgery to determine the best way to rehabilitate that individual to their optimum functionality.

The project is concerned with evaluating the efficacy of an innovative method of visualising biomechanical data within programmes of physical rehabilitation for, e.g., recovery from stroke or surgery, to minimise falls or to encourage exercise. There is evidence from previous work that the innovative visualisation method might assist this goal: a prototype of this visualisation method has already been evaluated and found to be easy to understand by a wide rage of rehabilitation professions and also by lay people. [7] Using an understanding of biomechanical principles such as force, momentum and dynamics, a series of therapeutic interventions using the generic
The visualisation method to hopefully achieve that rehabilitation goal is to be evaluated through a set of five RCTs. These will measure the method’s effectiveness (or not) in improving the rate or degree of rehabilitation, e.g., for recovery from stroke or after knee replacement surgery using the visualisation method. Outcomes would be evaluated through analysis of typical (medical model) quantitative outcome metrics such as extent of knee flexion, or stride length.

A small design team is part of the larger investigation team due to its origination and development of the visualisation method and also for its development of a qualitative methodology of user engagement for evaluation purposes in previous related work. Rather than an early engagement with end-users (patients, clinicians, healthcare and rehabilitation staff) as in Case 1, the traditional ‘medical model’ favoured a systematic review of published previous trials to determine if any form of visualisation has been used as an intervention and if so, how effective this had been. However, given that the visualisation method used here is itself innovative, this type of review would tend to reveal results of limited or only generic value. As a result, the way the research was originally designed largely assigned PPI to pre- and post-RCT interviews with predetermined questions, a minor consultation where the end-users are not viewed as part of the development team. This is a typical ‘medical model’ approach where the client/patient has little or no input to the design of the study itself (i.e., in this case, the rehabilitation intervention) and is treated as a subject to be ‘experimented on’. This would fit very clearly into Savory’s Strategy A which “requires very little input from the patient in terms of designing the conduct of the research…” and which “…can be characterised as concerned with ‘collecting patient data.’ ” Although the quantitative data might be able to give some indication as to the ‘what’, e.g., improved walking rates or more controlled movements, it would not be able to determine the ‘why’ (particularly in a case where there had been no improvement), i.e., factors important to innovation.

However, as the project commences it has become apparent that crucial to the visualisations presented in the RCTs is an understanding of what information (i.e. biomechanical principles) is to be communicated, how best this can be communicated (i.e. mode of visualisation), and if the same or different information requires to be communicated in specific ways to each of the patient, healthcare worker, carer and clinician cohorts involved in the rehabilitation process, i.e., acknowledging the different levels of technical expertise, different contexts and different lay and professional goals.

As a consequence, a qualitative methodological strand evolved and was assimilated into the original design of the research through pre-RCT focus groups. So, although originally designed with a (in Savory’s terms) Strategy A level of PPI, the research team began to value and embody, albeit in a limited manner, elements of Strategy B.

With reference to Poggenpohl & Sato’s models, although this started as a P&S2, a P&S1 strand has also had to be evolved reflecting the growing perception and recognition of the need for a more mixed methods approach, although this is somewhat compromised by the project’s original schedule.

Discussion: the extent of and conditions for social innovation

To return to the issue of social innovation, what can be learnt from the way that the research has been designed in both Cases 1 and 2 above on the generation of “…new
ideas (products, services and models) that simultaneously meet social need and create new social relationships or collaborations”?

Case 1
Design methods such as visualisation of data, and the design of a participative methodology of co-research and co-design have easily dovetailed into ethnographic methods used by the medical sociologists, such as interviews and observational studies, to provide much qualitative data. The FF, having been empowered and facilitated by the designers through previous workshops to think ‘out-of-the-NHS-box’ and to use creative innovation methods, has become receptive to this type of approach and embraced the idea of speculative thinking. Campbell discusses this idea of the wider sharing, beyond the design profession, of design thinking and skills to improve resourcefulness: “Design can re-awaken citizens’ own resourcefulness. The profession of design is common resourcefulness refined by a technical education’. It is possible to share aspects of this technical education with non-professionals to increase their resourcefulness, and persuade them that they know more than they think about how problems might be solved”. [8]

In Case 1, the nature of the design of the research from the outset made it not only much easier for the designers to share their methods with the rest of the research team and the FF, but for early stage PPI to tap into the considerable tacit resource represented by the FF. In a sense, as the research team as a whole were more open to co-research and co-design methods, the move to ‘employ’ the FF as de facto members of the research team using participative methods was not that difficult to achieve.

In summary, within Case 1, the methods used have facilitated the disparate disciplines within the research team to communicate and collaborate in a synergistic manner, and also to create productive engagement with the FF. This, in turn, has helped lead the team towards innovative ideas for the prototype food service. As “…much innovation comes from creating a blend of ideas from multiple sources” [1], the process of innovation was able to start at a much earlier stage. This process has led to a total food service prototype which will empower healthcare professionals, older adults and their carers and provide the means to monitor and respond to individual nutritional need and preference in the hospital and other care environments.

Case 2
In Case 2, the process of evolving the traditional ‘medical’ culture into one with a recognisable ‘social’ dimension of PPI took much longer to manifest than in Case 1. This was essentially because qualitative methods were not familiar (or usual) for most of the main investigators in the Case 2 research team. As a consequence, the first challenge was to change the perception and understanding of the value of these qualitative methods in the scientist, engineer and technologist team members’ minds whose primary preoccupation had been with the technologies of position sensing and quantitative (biomechanical) data-capture. However, as the questions gradually emerged about ‘what to show?’ to the end-users (patients, therapists and clinical staff), ‘how to show?’, and questions such as ‘how do we know what they will understand by this?’, the realisation grew for the need for methods which would help answer these questions. As
a result, the design researchers developed a qualitative dimension to the research to enable the larger team to benefit from the flagging up of problematic issues, such as the perception, comprehension and interpretation of the visualisations and how this might translate into the desired actions in terms of correct movements or appropriate exercise. This was achieved through a series of focus groups. Now, various options for the visualisation method are being explored through a participatory co-design stage, albeit much less developed than in Case 1. Responses from focus groups representing end-users are helping the team move somewhat closer to an understanding of the problems, behaviours and motivators for end-users and to help select and develop models of visualisation appropriate for testing in each of the RCTs. This process is also helping shift the team’s perception of end-users from ‘subjects’ to ‘people’.

In summary, in Case 2, as the research team as a whole has had to be brought up to speed with the value of qualitative methods, and as the various users will not have been involved until later on in the project, this may have potentially limited the extent of innovation in the visualisation method that might have been achieved through the earlier engagement of end-users and more flexibility in the design of the research. In a sense, there has been a degree of innovation already in the original design of the generic visualisation method but this is requiring further innovation and development for the individual application within each of the RCTs.

Conclusions

It would appear that a number of factors may influence the extent of innovation within these types of research: the mix of methods (and by implication disciplines) [2]; flexibility in the design of the research [3]; the timing and level of PPI [4]; and also the idea of sharing design thinking and approaches more widely [8].

As stated earlier, there is a recognition that new thinking is required to address perplexing healthcare problems and that, to innovate in research, a range of disciplines will require to work together. The opportunity for optimum innovation will surely come from employing as many minds as possible together in addressing that challenge (“much innovation comes from creating a blend of ideas from multiple sources…”) [1] and for the best chance for innovation to occur, this engagement should happen as early as possible using appropriate participative methods and processes which enable a wider team to assist the researchers in co-research and co-design.

This additional mind-power should include not only a range of different specialisms within the research team but also those who work with patients and – ideally - patients themselves (where possible) each of whom will have different insights, experience and ideas to contribute. As Savory states, “where higher orders of change are sought through PPI, a critical dimension is the point in the research cycle in which PPI is included”. He goes on to say that in the “open innovation paradigm the role of users and customers is central to the development of innovations”.

So, in traditional ‘medical model’ research studies such as in Case 2, factoring in additional time ‘up front’ for – and giving greater priority to – people-centred qualitative and participative processes would enhance the opportunities for real innovation. For non-design healthcare researchers the value of the increasing involvement of designers and use of their people-centred design methods in healthcare innovation should be
recognised. On the design side, design researchers need to gain a better understanding of and to better articulate the value of their contribution in the over-arching design of research methodologies in healthcare, not only in the area of PPI but in helping to create a different social dynamic within the research team itself.

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