Responsible innovation in healthcare – the case of digital TV

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Abstract: The paper explores the application of responsible innovation (RI) principles in the design and implementation of innovation in the context of digital healthcare. In particular we are interested in the scope for bringing in RI considerations at various stages in the innovation process and in the relevant tools and frameworks which might facilitate this. Using the particular example of a detailed longitudinal case of the development and diffusion (with subsequent modification and 're-innovation') of a digital health information platform we identify a number of key points at which the innovation concept 'pivoted' to reflect new information, some of which resulted from a wider level of inclusion (one of the core RI principles). The paper explores the role played by structured frameworks (such as the 'Business Model Canvas') with which to work with the development of other digital healthcare innovations at an early stage.

Keywords: responsible innovation, digital healthcare, business model canvas.

1 The promise – and the problem – in digital healthcare

There is little doubt that healthcare is in crisis. Whilst there have been enormous advances in the nature and quality of care these are offset by powerful forces on the demand side. Estimates suggest that public spending on healthcare consumes around 10% of GDP on average and this situation is likely to worsen as a result of ageing populations, rising prices and increasing complexity of healthcare technology. Despite wide variations in the healthcare funding system, from largely public as in the UK to strongly private, the underlying trends are the same.

Against this backdrop the need for radical innovation is clear and extensive efforts are being made to find a way out of the crisis through new approaches. One powerful candidate within this field is the application of information and communication technologies on a wide scale – what we term 'digital healthcare'. Examples include:

- Robot surgery

- Telemedicine

- Electronic medical records

- Smart homes

- Wearable health support technology

- Connected medicine

- Health education and information

- Etc.

Over the past twenty years these technologies have matured and converged to the point that there is now an explosion of innovative application. Their potential is significant – not just in terms of improving productivity within the healthcare delivery sector but also in offering better outcomes, higher quality and reliability, greater patient autonomy and higher quality of life. Taken at face value digital healthcare appears to offer a rosy future for patient-centred high quality healthcare delivery at an affordable cost and open to all.

But although there seems a strong logic in favour of rapid adoption and diffusion questions should be raised. Whilst it is clear that early examples show promise the underlying design of these applications reflects a particular set of interests and viewpoints – a dominant logic. There is a risk that alternative designs might be excluded at an early stage as a trajectory emerges, which defines the form and implementation mode of the technology – the challenge of 'technological determinism' (Braverman, 1974).

There are parallels to this in a number of other fields. Early adoption of computer-aided production management systems in the 1970s and 1980s involved an embedded model of how organizations worked and were structured which suited certain kinds of application but limited the effectiveness of the technology in other contexts (Bessant and Buckingham, 1993). Similarly flexible automation technologies during the 1990s often failed to deliver their potential because of the inbuilt design logic, which assumed certain forms of work organization (Bessant, Smith et al. 1992). Indeed the emergence of 'lean manufacturing;' with its emphasis on team working within flexible and autonomous

teams owed much to its ability to deliver the flexibility which expensive but rigidly designed technologies could not (Womack and Jones, 1996).

Experiences like these suggest that there is an initial 'design space' associated with novel technological opportunities but that this can quickly become colonised by a dominant design and force out other options (Bessant and Buchanan, 1983). A counter-strategy is to engage in extensive engagement with stakeholders who will operate or be affected by these technologies at an early stage (Mumford 1979; Eason 1988; Leonard-Barton, 1988).

Even allowing for a degree of user input in this design space the logic of procurement in many healthcare systems is one of centralisation and scale. Although programmable and flexible in theory the nature of this logic argues for one size fits many kinds of solution. Pilots are then rolled out without subsequent tailoring or configuration to suit differing local circumstances.

A third point of relevance in the healthcare field concerns who is undertaking the design activity. Unlike consumer markets where the interests of the user are important input to early design since this will shape downstream adoption and diffusion, in the medical field there is a two-step model in operation. Ideas are often initially developed with the concerns of clinicians in mind who are assumed to act on behalf of the end-recipient of care – the patient. The risk here is that one group of users is consulted but another is disenfranchised from participating in the design; the result can be a 'doctors know best' solution, which may not meet the underlying patients needs or concerns.

So whilst it is possible to envisage a utopian world of great healthcare for all at affordable prices, there is at least the possibility that an alternative dystopian view night also emerge. Examples might include 'smart' homes, which limit the autonomy of residents – effectively becoming high tech prisons. Or privacy issues associated with misuse of electronic medical records. Or decision-making about access to healthcare being linked to algorithms within machine learning systems and disenfranchising access to care. Given this risk we suggest that digital healthcare is one of many technologies around which concerns of responsible innovation could be raised.

2 Responsible innovation

Concern about the implications of technological decisions and the identification of mechanisms through which such decisions could be modulated by consideration of alternative outcomes and engagement of multiple stakeholders is not new. Discussion and exploration round this theme goes back at least to the 1970s with the STS (Science, technology and society') movement and the establishment of key influential organizations such as the Science Policy Research Unit at Sussex University (Cole, Freeman, Jahoda, & Pavitt, 1973).

The RRI debate has always argued not against technological progress but around asking key decisions shaping those development and application at an early enough stage to influence the design and implementation. RI can be defined as *...'a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)* (Von Schomberg, 2011).

Its most recent manifestation can be seen in work on' responsible innovation' (Owen, Bessant, & Heintz, 2013). In particular Owen and colleagues offers a helpful framework (which has been adopted widely by the EU and several major research funding agencies) which sets out some key questions which should be addressed in the development and

This paper was presented at The XXVIII ISPIM Innovation Conference – Composing the
Innovation Symphony, Austria, Vienna on 18-21 June 2017. The publication is available to ISPIM
members at www.ispim.org.

implementation of innovations (Stilgoe, Owen, & McNaghten, 2013). They suggest four key areas:

- Anticipation – describing and analysing those intended and potentially unintended impacts that might arise, be these economic, social, environmental, or otherwise.

- Reflection - reflecting on underlying purposes, motivations, and potential impacts, and on associated uncertainties, risks, areas of ignorance, assumptions, questions, and dilemmas.

- Deliberation – inclusively opening up visions, purposes, questions, and dilemmas to broad, collective deliberation through processes of dialogue, engagement, and debate, inviting and listening to wider perspectives from public and diverse stakeholders.

- Responsiveness – using this collective process of reflexivity to both set the direction and influence the subsequent trajectory and pace of innovation.

3 Inclusiveness as a core dimension

In this paper we will focus particularly on the 'inclusiveness' dimension. As indicated above there is a long-running strand in innovation studies which highlights the importance of bringing multiple perspectives into design decisions at an early stage. Whether we are talking about early involvement of functions in product development or participative design of technological systems there is clear evidence that taking time to engage different perspectives not only improves the quality of the final design but also accelerates its downstream acceptance (Bødker, Kensing et al. 2004; Baskerville and Myers 2009).

Set against this is, of course, the challenge of doing so within a design space which is often seen as bounded by time, resources and dominant strategic trajectories. But a major advantage of digital technologies is their malleability; software can be adapted and configured to accommodate different perspectives within a contested design space.

The second literature strand relates to the potential for digital technologies to change the balance between 'richness' and 'reach', effectively opening up the innovation process to more players who can play an active role in shaping the outcomes (Evans & Wurster, 2000). As discussions of 'open innovation' mature so it is becoming clear that there are modes of 'crowdsourcing' which can contribute both at the front (idea generation) end of innovation and also in downstream modification and diffusion (Brabham, Ribisi, Kirchner, & Bernhardt, 2014; Harhoff & Lakhani, 2016). This opens scope for 'democratization of innovation' within the field (Von Hippel, 2005) and specifically for the engagement of more and different stakeholder perspectives – the 'inclusiveness' dimension in the Owen and Stilgoe framework for responsible innovation.

This intersects with a third contributing literature stream dealing with user involvement in the innovation process. Medical innovations have been widely studied within this context (Von Hippel, 1988; Herstatt & von Hippel, 1992). As a growing range of studies have shown users can represent an important force in shaping a wide range of product and process innovations; emphasis has now shifted to understanding the segmentation across user populations in terms of their interest in participating and in the toolkits available to enable wider user innovation (Von Hippel, 2016). Within this context a number of studies explore the ways in which patients (and their carers) as 'end-users'

can play a significant role in developing and modulating innovations (Bate & Robert, 2006; Bessant & Maher, 2009; Pickles, Hide, & Maher, 2008); Habicht, Oliveira, & Scherbatuik, 2012). Once again we try to link this to 'inclusiveness' within responsible innovation.

4 Research design

The study involves a detailed case study of the development and diffusion (with subsequent modification and 're-innovation') of a digital health information platform. This platform uses a wide range of short video and web-enabled information tools diverse across which users and providers can share information and improve awareness of key approaches, communicate across relevant communities and in other ways enhance the availability and application of health education. The platform is growing rapidly and has widespread support across users and healthcare agencies; as such it represents a good case in which to explore the extent to which responsible innovation principles are or could be included.

Our study is based on a series of interviews with the founders and key stakeholders involved in the early development (15 interviews) and with users and others who have shaped its subsequent development and diffusion (12 interviews). The case is supported by archive and other relevant documentary data. We began interviewing four years ago and have been tracking the evolution of both the innovation and the ways in which different stakeholders have shaped and modified it; this process is continuing, providing a useful longitudinal perspective.

5 The story

The origins of the innovation in question go back to 2012 and its subsequent development can be mapped across three phases:

Early stage

In late 2012 Peter Smith was motivated to try and develop improved access to medical information. Working within the healthcare system he was aware of the extensive specialised knowledge available but was concerned that its accessibility was often limited, needing expertise in both finding and understanding it. He had a particular interest since his father was a diabetic and Peter wanted him to understand more about his condition and how he could manage it. He conceived of the idea of HealthTV as a way of opening up access to such information. The core value proposition was based on providing reliable health formation to those who needed it and in a form which they could use.

Early work with a local college helped explore the possibility of producing videos to meet these needs but it quickly became apparent after a couple of pilots that this route would prove too expensive. At a networking event Peter met with James Wilson who had recently founded a company specialising in short high impact videos – MiniTV. There seemed to be scope for exploring collaboration. Their discussions led to a revised concept – Librio – which by January 2013 based on providing short video-based information in three forms:

- general public health and wellbeing education

- providing specific 'pathway' knowledge, for example to parents learning how to look after sick child

- patient-focused information about their treatment journey through the NHS.

Interest grew in the concept within the healthcare delivery Trust in which Peter worked. A number of individuals and groups became involved, bringing experience and perspectives, including several user groups based within the education directorate for the entire Trust (covering hospitals, primary and community care, etc.). Several avenues were explored including e- learning, podcasts, online and mobile device formats, etc. Involvement of this kind brought with it a variety of experience about different delivery channels and media and the revised business model could be explored and tested.

The concept was elaborated during a variety of design sessions where it was challenged and improved. External events also provided a focus; a major review of healthcare in 2013 (the Francis Enquiry) argued strongly for improved health information and education and Librio played to the emerging strategic agenda for healthcare providers in responding to this.

And on the technology side increasing growth in the idea of live streaming TV led to a derivative of Librio – Livestream – coming out in March 2013, using (and providing learning opportunities around) web streaming.

Funding for these development initiatives had been coming in ad hoc fashion from the healthcare trust with a significant investment of time and personal resource from Peter. In particular the Trust provided protected time for Peter and additional secondments to his team of 2 people for 0.4 of their time. It also provided development finding for developing a prototype Librio Public Health website, develop a test site for Librio Educate and commission content by working in partnership with MiniTV.

Between October and December 2013 various versions of a bid for formal Business Development support were put together to try to secure a stronger funding base. The first part of the proposal highlighted progress made so far since Librio was launched in April 2013, with over 70,000 visitors to the website. This level of traffic enabled a robust test of the Librio Educate offering with potential customers and pilot activities (such as the 'Preparing Children for Paediatric Daycase Surgery') resulted in demonstrable cost savings for the Trust through reduced surgery cancellations.

The proposed next step was based on a streamlined business model with three core target 'businesses':

- Librio Public Health – drawing on a library of video, and other learning resources and delivered via multiple channels

- Librio Educate – as above but more specifically targeted to key groups

- Librio Digital Services – including video production, website development, app development, etc. Effectively making Librio's experience available to others on a contract basis.

On February 2014 this was presented to the Board of the Regional Health Authority.

6 Phase two – Emerging split

Although recognising the significant progress which had been made the Board also had access to a strategic review which had been commissioned and which highlighted a number of concerns which would need to be addressed in taking the business forward. In particular these included:

- Lack of focus in the core strategy, trying to hit too many targets simultaneously

- Scale of the challenge at national level and concern about resourcing to meet this

- Strong competition in the existing education market.

The overall conclusion was to push for a more targeted and focused strategy; after exploring several options for this focus including a narrower version of the public health offering and the use of tailored training packages within Librio Educate the main recommendation was a clear concentration on the Librio Pathway model. The argument behind this was based on the relative lack of competition in this space and the potential of a targeted set of products; importantly the concept of 'pathway' was redefined to have a narrower meaning linked to the clinical pathway rather than the wider patient experience pathway.

The discussion which followed this recommendation highlighted a number of strategic tensions amongst those involved. For Peter there was a growing tension between his vision – of providing wide-ranging access to health information – and that emerging around a tightly focused business proposition targeted principally at clinicians and people working within the health sector. For the Trust there was concern that the current model for Librio lacked clear strategy or focus and risked becoming a drain on resources with impact which was too diffuse.

This tension became a fault-line along which two differing models of how the business could develop began to emerge'. An indication of this can be gained from analysing the content of the discussion and the issues raised – for example:

- Peter wanted to move to an inclusive TV environment in which people could discuss their condition with links enabling them to access specific pathway resources. Concerns here were around the scale of doing this and the use of the term 'pathway' to describe the whole patient experience rather than a narrower clinical defintion

- Tension around clarity of the business model, especially on whether Librio was offering a clear product or a range of services – part of the proposed new business plan involved offering a range of contract video and learning resource production services to others

- Developing the business further would require an increased scale of investment, especially in areas like IP, commercial support, marketing and website development support. Spread across the whole range of activities proposed in the new business plan this would involve a significant investment so the preference was for a smaller more focused input.

- One of the options in moving to a business model focused tightly on pathways was the possibility of using video to help recruit to and manage clinical trials. This offered significant possibilities in terms of recruitment but also in terms of creating

an income stream for the product. However moves in this focused and commercial direction ran up against Peter's vision of a more open and inclusive model of disseminating health information.

The outcome of the meeting was a revised strategy involving several key decisions shaping the future of the business:

- **Live-Stream** – continue under review since the majority of the financial investment required for the live TV has already been made

- **Pathway Video** – exploring the concept of bespoke clinical trials films as a separate, potentially licensable innovation.

- **Librio** – focus on patient Pathway films aimed at Prepare, Support and Recover.

- **MiniTV** – priority should be given to an assessment of whether or not a partnership between the Trust and MiniTV would be possible based on a formal contract.

During the following months these themes were explored further but it became increasingly clear that there were now two different business models involved. From Peter's side there was a change in direction and focus around Librio as a web-based TV provider of health information services. He wanted to develop this further and curate the material available, both in terms of the library developed so far and future offerings. From the Trust side the preferred model was pathway focused and managed in more formal way; there was also a potential brand management problem in continuing to offer two different approaches under the same label.

7 Phase three – Divergence

By October 2014 the decision to support the pathway model had been made but Peter's increasing discomfort with this solution led to his deciding to split off Librio and his health information model from the programme. Negotiations with Paul around intellectual property etc. led to him being paid off and Librio continued to develop as an independent venture. Internally the Trust moved to create a new partnership with MiniTV to offer Health & Care videos for patient pathways – Southwest Health Video services. They developed a revised business model and tested the concept on clinicians during November 2014; responses were favourable and during 2015 the new business developed via some pilot projects using internal funding from the Trust and MiniTV development resources. By July 2016 the model was formally signed off by the senior management of the Trust.

Early operating experience highlighted a number of development points, especially around clinician support for learning how to use the resource effectively. The revised business model, including a clear strategic plan, pricing structure, marketing and technical development strategy, etc. involved:

- Targeting 5 key business lines
    - Secondary care (e.g. hospitals)
    - Support to general practitioners
    - Clinical trials recruitment
    - Support to social care staff

- Support for obtaining consent from people for procedures (including preparing patients for discussion with physician and letting people know about risks)

- Doubling turnover from the 2016 base

- Extending the reach by aiming for 40% of commissioning to come from other healthcare Trusts

- Operating a for-profit business model but with a high degree of social consciousness

Current progress of SDHV has followed this model, but with some revisions. Sales have come more from new products than from 'rebadged' stock in the old Librio library. The market has expanded to include several major Trusts in the UK, other actors in the healthcare space including publishers, pharmaceutical companies and healthcare platform providers) and, importantly, other sector agencies with a similar education/information challenge. There is still an issue around adoption, especially in getting clinicians and practitioners to use the videos easily within daily practice.

Whilst initially the proposition emphasized a mix of benefits it has become more targeted on improving care pathways from an operational sense, with a strong focus on the cost saving potential. Better-informed patients are more able to care for themselves avoiding the need to interact with services or when they do need to interact the duration is shortened. This generates capacity and delivers cost avoidance.

8 Discussion

Viewed as a case history of a start-up we can see a number of interesting features. First is the emergence of clear business model – this was not planned in detail at the outset but evolved through experience; the initial vague model was regularly reviewed and discussed amongst a growing number of stakeholders. It follows the typical pattern suggested by the 'lean start-up' model of probing and learning through frequent interaction with the environment – albeit at the early stages this was a trial and error process rather than having a structure. But as the venture developed so the use of a formal framework (based around the Business Model Canvas BMC) helped facilitate this since they made explicit many assumptions. This is important in the RRI context since it suggests that tools of this kind can help develop both reflexiveness and flexibility in the early design.

Analysis of the case also identifies a number of key points at which the innovation concept 'pivoted'. In particular these pivot points gave rise to a number of interventions in the design of the innovation. We can think of a malleable innovation design space in which things are not yet established but where different stakeholder perspectives can and do shape the innovation. This is well-known in entrepreneurship literature but suggests that early stage innovation has a strong potential for RRI considerations if relevant tools can bring the key questions onto the discussion.

It was also possible to identify a trade-off underpinning the pivots. In the early stages the challenge is around shaping the idea into something which actually works, using early market testing as a way of 'hunting' towards an optimum. But later pivots were more concerned with underlying values and beliefs; the original entrepreneur had deep views about the nature of the project but others were concerned about is business viability. This is perhaps a classic version of the 'heart vs. head' challenge facing social entrepreneurs –

trying to do good may force uncomfortable compromises in order to maintain viability and long term sustainability. In this case two complementary models emerged, one well fitted to its funding environment and run by medical staff largely for medical staff. And the other, operating on a more precarious funding regime, concerned with a bigger social agenda around empowering patients.

Mapping this case on to the Owen/Stilgoe framework we can see:

- Anticipation – here the very process of developing a new venture requires imagining different futures. The power of a structured approach like BMC is that it brings key questions into this discussion and provides a relevant anticipatory overview. However even though questions may be raised the ways in which they are answered may still reflect underlying beliefs or motives which are not open to challenge, effectively introducing an element of cognitive dissonance to the exploration. So it is important in using such frameworks to have diversity and perhaps even an explicit devil's advocate role, in order to challenge rigorously.

- Reflection – here the underlying values held by the players and their organizations took time to emerge and were in conflict at key decision points, leading eventually to the splitting. Once again this argues for a structured review process which brings in and articulates different positions; essentially there emerged two competing business logics, one socially driven and one practically driven.

- Deliberation and inclusiveness – here the BMC framework which underpinned the emerging model highlighted these differences – essentially the core value proposition began to change as the question of 'value for whom' was explored empirically. 'Value' moved from being a theoretical construct to how the project would continue to be funded – and this forced the issue around who to include or exclude in the design. Once again the framework and ancillary questions becomes a valuable device for exploring this and checking that different perspectives have been brought to bear. But again there is a need for facilitation and support for doing so in robust fashion.

- Responsiveness – as suggested above the process which any start-up has to go through offers a number of decision points where these issues can be considered. Structured frameworks like BMC offer a powerful enabling device for developing responsiveness but the underlying political and personal drivers remain. This means that there will always be a 'contested' aspect to exploring the 'design space' – and again argues strongly for careful and experienced facilitation of the process.

The continuing research suggests there may be considerable value in using structured frameworks like the Business Model Canvas as an aid to ensuring early and extensive discussion of key RI questions.

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Acknowledgement