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Responsible impact and the reinforcement of responsible innovation in the public sector ecosystem: cases of digital health innovation

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ABSTRACT

Responsible innovation is an important consideration for digital health innovation. This study explores the responsible innovation processes of digital health innovators, and the reinforcement of responsible innovation practices. Using semi-structured qualitative interviews followed by a thematic analysis and narrative enquiry, we understand the lived experiences of innovators in the UK and Norway. We suggest three contributions. (1) That Responsible Innovation occurs as a process in practice, and we suggest a framework to outline that process. (2) We suggest that 'responsible impact' is the fifth domain and the output of RI. (3) We suggest that responsible impact may be a natural reinforcer of the RI process. We suggest that innovators who recognise the impact of their RI practice are more likely to continue those responsible processes. Finally, based on our study we provide an RI action plan framework to encourage the funding of responsible innovators.

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Digital health; responsible innovation; responsible impact; public sector

Introduction

Considering the rapid growth of digital innovation, and societies growing sustainability concerns there is increasing pressure on public sector ecosystems i.e. academics, innovative researchers, public organisations and private companies with close ties to public organisations, to be responsible as depicted by Scherer and Palazzo (2007 & 2011). There is also pressure on firms to be responsible from activists as discussed by Waldron et al. (n.d.). Empirically, there have been recent advances in digital healthcare innovation, including artificial intelligence, machine learning, drones in healthcare delivery, and blockchain technology. These innovations, alongside the changing role of healthcare users, have furthered calls for Responsible Innovation (RI) practice in the digital healthcare context (Iakovleva, Oftedal, and Bessant 2021). These calls include a

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‘Hippocratic Digital Oath’ which encourages scientists to take a vow of responsibility when innovating as described by Harrison (n.d.) and Sutcliffe (n.d.).

The academic literature explains that RI is focussed on governance and is made up of four core concepts, namely Anticipatory Governance, Inclusivity, Reflexivity, and Responsiveness. These concepts are repeated throughout the academic literature in studies by Burget, Bardone, and Pedaste (2017), Owen et al. (2021) Schuijff & Dijkstra (2020), Stilgoe, Owen, and Macnaghten (2013), and many others. What we don’t know is how these concepts contribute to a Responsible Innovation (RI) process in practice and what the product or impact of that process is. It is usual to examine innovation in terms of inputs, processes, and outcomes. We recognise the importance of inputs or determinants of innovation as covered by Osborne and Brown (2011) and Walker (2014). Kuipers et al. (2014), Pettigrew, Woodman, and Cameron (2001) and Van de Ven (1986) describe the importance of understanding process, and outputs within the broader innovation literature. Although there has been a concentration in the wider innovation literature concerning inputs, process, and outputs there is limited focus on the relationship between the RI concepts, the innovation process and the outcomes, or their relationship to each other.

RI faces several challenges to adoption, maintenance, and evaluation. ‘Frame shifts’ which encourage the adoption of RI as described by Rauch and Ansari (2022) can be complex to understand and facilitate. Even if an initial frame shift is successful, responsible innovation practice is not always maintained. We saw during the Ebola outbreak whereby a crisis increased innovation but at a cost to responsible innovation (Arslan and Tarakci 2022). RI also faces measurement challenges as described by Iakovleva, Oftedal, and Bessant (2019) and Oftedal et al., in the digital health sector (2019); and Yaghmaei and Poel (2020) in the food sector. In summary there is growing pressure for further RI, a lack of understanding surrounding the processes of RI, and challenges to its measurement and ‘Frame shifts’. To address the challenges of RI adoption, maintenance and measurement we need to explore further the process and practical drivers of RI.

There are growing calls to identify how RI practice can be motivated (Gurzawska, Mäkinen, and Brey 2017; Porcari et al. 2020). Gurzawska et al., outlines factors for the realisation of successful incentives for RRI in industry. Although this work is useful and exhaustive, in some ways, it doesn’t completely translate to start-ups and smaller firms as they are often the only internal stakeholder and in the case of start-ups can often be made up by just one or two entrepreneurs (Gurzawska, Mäkinen, and Brey 2017). Instead of focussing on incentives, Genus and Stirling (2018) explains that one of the most important properties of responsibility lies in the reinforcing of accountabilities. These two papers and the lack of evidence concerning RI in practice motivate this study. We consider the outputs of responsible innovation processes and their role in reinforcing the RI processes themselves. Our research questions, are as follows:

1. Do digital health firms perform responsible innovation processes? And if so, how?
2. How might responsible innovation processes be reinforced?

Empirical context: The public sector centred ecosystem

The empirical context of this study is a public sector centred ecosystem. What we mean by this is an ecosystem with public sector organisations at its heart. A business ecosystem

is an accumulation of organisations within an industry which interact and rely on each other (Rinkinen and Harmaakorpi 2018; Schoeman et al. 2012). Like an ecological ecosystem, firms have direct and indirect effects on each other. They depend on each other to survive and grow (Clarysse, Tartari, and Salter 2011; Pouder and St. John 1996; Robins, Bates, and Pattison 2011). We define the concept of a public sector centred ecosystem as an accumulation of small, medium, and large healthcare firms which are centred around and rely on one or more public sector organ[1]isations for advice and guidance, grant funding, governance, or sales. The reliance of digital healthcare firms on the public sector is unsurprising considering that healthcare is an experimental context with high levels of engagement between universities and private firms (Perkmann et al. 2013). The same can be said in reverse. Public sector organisations rely on private technology firms e.g. electronic records and prescribing in hospitals or video consultations during the COVID-19 epidemic (Greenhalgh et al. 2020; Ohannessian, Duong, and Odone 2020).

Theoretical context: responsible innovation

The concept of responsibility has existed in business for decades, and has increased in popularity in the last 50 years (Carroll 1999; Gray 1939; McNally 2018; Owen, Macnaghten, and Stilgoe 2012; Stilgoe, Owen, and Macnaghten 2013). Arguably the most common conceptual reference to responsibility in a business context is corporate social responsibility, which focusses on sustainability and people (Amran, Lee, and Devi 2014; Burget, Bardone, and Pedaste 2017; Markard, Raven, and Truffer 2012; Ram Nidumolu 2009; Scherer and Palazzo 2007; Schrempf 2014). Responsible Innovation (RI), which contributes to corporate social responsibility is a newer term, whose antecedents have grown out of the science and technology studies stream of research and are centred around innovation governance (Freeman 1984). RI is also closely aligned with the concept of collaborative governance but with a focus on innovation (Ansell and Gash 2007; Emerson, Nabatchi, and Balogh 2012). RI has developed from the understanding that technology implementation is constantly changing and that innovation does not have neutral effects (Dosi 1982). Instead, it can have both positive and negative, unexpected effects and requires governance. Building upon the science and technology research antecedents, there has been a new wave of interest in RI amongst academic management scholars (Stilgoe, Owen, and Macnaghten 2013; Waldron et al. n.d.). This new wave includes an emerging focus on ways to identify and mitigate future, unanticipated innovation impacts (Arnaldi and Gorgoni 2016; Davis and Laas 2014; Iakovleva, Oftedal, and Bessant 2019; Oftedal, Foss, and Iakovleva 2019). However, there is a lack of empirical and practice-based evidence to understand RI processes and the factors that re-enforce RI amongst innovators and entrepreneurs in small and medium sized organisations with close public sector ties, in a way that delivers a sustainable double bottom line i.e. benefit to both society and firm profitability (Blok, Hoffmans, and Wubben 2015; Lubberink et al. 2017; Porcari et al. 2020, 2020; Wilburn and Wilburn 2014).

The general concept of innovation is broad and concerns the development and implementation of new ideas, and places emphasis on the product rather than the purpose or the process of developing that idea into an output (Stilgoe, Owen, and Macnaghten 2013; Van de Ven 1986). In contrast, Von Schomberg, who acknowledges the importance of having the right impacts which they tie to European Values, describes responsible innovation as;

A transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view on 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 2012, 50)

Stilgoe attempts to move this definition forward and recognises RI as ‘Taking care of the future through collective stewardship of science and innovation in the present’ (Stilgoe, Owen, and Macnaghten 2013). RI is an innovation process whereby the purpose and process of innovation is as important as the product. That is to say, when it comes to innovation, the ends should not be used to justify irresponsible means. Although the definitions of responsible innovation by Von Schomberg and Stilgoe are useful, we propose that each lacks a strong enough appreciation of innovation outputs and their relationship to the RI process.

The dimensions of responsible innovation

In order to explore RI processes and sustainable reinforcers of responsible innovation we first examine the different dimensions of RI, described in the literature, which have been mentioned above as Anticipatory Governance, Inclusivity, Reflexivity, and Responsiveness. Anticipation revolves around governance and anticipating the potential impacts of an innovation on society or the firm. The aim of this dimension is to use methods such as foresight to identify perceived negative societal impacts from emerging technologies or associated processes (Guston 2012, 2014; Stilgoe, Owen, and Macnaghten 2013). Inclusivity aims to bring relevant stakeholders and the public to the table to engage, identify and address unforeseen, ungoverned, or ethical issues, as well as challenging assumptions and the innovations purpose, which is commonly the case with emerging technology, and has been one of the most widely covered domains in recent years (Gudowsky and Peissl 2016; Kulve and Rip 2011; Malsch 2015; Rose 2012; Owen, Macnaghten, and Stilgoe 2012, 2021; Smith, Voß, and Grin 2010; Voegtlin et al. 2022; von Hippel 1976; Waldron et al. n.d.). Reflexivity is an important aspect of any innovation (Morlacchi and Martin 2009), which Stilgoe, Owen, and Macnaghten (2013) describes as holding a mirror up to one’s self. It is described as a process whereby one’s own activities, considerations, commitments, and assumptions are challenged. Responsiveness involves reaction to influencing factors which may include political and social agendas or the thoughts and concerns of stakeholders and the public (Felt 2017). We agree that these are the core domains of responsible innovation. However, in this paper we are interested in adding value by describing the relationship between these domains.

When considering the ‘Purpose, Process and Product’ framework (Stilgoe, Owen, and Macnaghten 2013), ‘Purpose’ concerns the reason for embarking on the innovation journey, it involves the firms ‘raison d’être’, their mission statement and their loyalty to both. Evidence from the literature supports the presence of purpose amongst digital healthcare firms. The majority of which begin with the purpose of having a positive impact on society, which is the driving force behind the establishment of the business’s (Iakovleva, Oftedal, and Bessant 2019). ‘Process’ concerns the four domains of anticipatory governance, inclusivity, reflexivity, and responsiveness, and ‘Product’ refers to the output of the innovation which is explored further in this paper.

Although the existing conceptualisation of responsible innovation by Stilgoe et al. covers the main concepts of responsible innovation, it does not describe a responsible innovation process in any detail or order and does not consider the re-enforcing nature of RI in practice. Our article focusses on the relationship between the process and product or Our article focusses on the relationship between the process and product or outputs of RI. It builds on the work of stilgoe, OWen, and McNaughton and aims to go of responsible innovation and identify the benefits and reinforcers of responsible innovation (Genus and Stirling 2018).

Materials and methods

A qualitative interview and narrative enquiry approach was selected to investigate the relationship between processes of responsible innovation and their outputs (Pentland 1999). This study began with the aim of understanding the process of RI in practice, and the journeys of firms from initial idea through to commercialisation. Importantly, this is a qualitative study which asks if and how these participants innovate responsibly, rather than asking quantitative questions like how much or how often they innovate.

Research design

The UK and Norway were chosen for this study as they have similar public sector ecosystems which are largely state funded and are politically driven to encourage digital innovation. Both healthcare systems also exist as large hierarchical structures which make them similar from an organisational perspective. They are also European countries with similar levels of economic wealth. With this in mind, we believed that these were suitable countries in which to examine responsible innovators in a public sector ecosystem. The firms in this study operated in the digital healthcare sector and had strong links to public sector organisations. Two firms in this study emerged from UK universities. The other firms maintained key relationships with or relied upon institutions such as hospitals, universities and publicly funded incubators, or grant providers, for guidance or support throughout the innovation journey (Table 1).

The boundaries between some commercialising academic groups, also known as 'Quasi firms', and enterprises are blurring which encourages commercialisation within academic groups (Etzkowitz 2003; Shinn and Lamy 2006). We therefore included innovators from these quasi firms in our sample and conducted semi-structured interviews to understand their lived innovation experiences and narratives from idea to commercialisation, structured by the four main dimensions of RI, namely, anticipatory governance, inclusivity, reflexivity, and responsiveness (Pentland 1999). We relied on qualitative interviews and were supported by publicly available data from companies' house, and in some cases grant providers (as directed by grant funded firms) and company websites, to triangulate the accounts of firm level practice. We used open questions to explore the firm's innovation practices and processes. Initial purposive sampling was conducted with a small number of firms closely linked to public sector organisations, followed by the selection of similar firms with a higher perceived societal impact, such as those dealing with drones and AI. These firms were identified through snowball sampling. This approach allowed us to gain a broad initial understanding of the landscape, and to

Table 1. A description of the 18 firms interviewed.

Country	Number	Stage	Number of employees (including part time and freelancers)	Date of Establishment	Market
Norway	1	Start-up	6	2016	Volunteering
Norway	2	Established	100+	1980s	Mobility aids
Norway	3	Start-up	15	2014	Hiking
Norway	4	Launched	16	2015	Health monitoring
Norway	5	Launched	8	2012	Lifestyle and health monitoring
Norway	6	Start-up	2	2015	Knowledge sharing
Norway	7	Established	1400	1940	Healthcare training
Norway	8	Established	1200	1999	Technology for elderly care
Norway	9	Launched	10–20	2012	Assisted living monitoring
Norway	10	Established	250	1998	Video conferencing
UK (Quasi- Firm)	1	Established	3–8	1999	Healthcare education
UK	2	Launched	3–5	2011	Health monitoring
UK	3	Launched	3–5	2017	Medicine traceability
UK	4	Start-up	2	2018	Drone industry
UK	5	Start-up	2	2017	Health monitoring
UK (Quasi- Firm)	6	Established	65–70	2009	Digital cognitive behavioural therapy
UK	7	Start-up	2	2018	Relationship management in primary care
UK	8	Launched	2	2013	Medicine supply

subsequently challenge our ideas with firms which had products with a higher perceived societal impact and governance issues (Chun Tie, Birks, and Francis 2019). Interviews were transcribed by a professional transcriber and all coding was performed using NVivo multi-coding software. The most suitable quotes were extracted to demonstrate the relationships between concepts and our contribution, on the micro level of digital healthcare firms.

This study employed qualitative in-depth semi-structured interviews ($n = 25$) with innovative founders, co-founders, or senior leaders of 18 innovative firms (Norway $N = 10$, UK $N = 8$) from November 2017 to January 2019. For the most part these were interviews with one member of the firm with the same participant or a colleague was performed. These interviews lasted between 30 and 80 min and generated 647 pages of interview transcripts. Our sample included start-up firms, launched firms, and established firms which varied in size and stage of maturity. Data collection and analysis occurred in tandem i.e. analysis occurred between interviews. Data collection ceased once we reached data saturation. Interviews were conducted in the participants native language by a Norwegian speaker in Norway, and English speaker in the UK and all transcripts were subsequently translated to English.

Analysis

Initial coding and categorisation were performed based on the narratives surrounding the four RI concepts and other emerging concepts. Coding was iterative, it developed as analysis progressed, it was performed on all interviews, and included ongoing refinement. Initial coding was followed by intermediate coding, which included the grouping

and regrouping of emerging concepts from the innovators narratives and recoding the data. Advanced coding then focussed on the concept of innovation impact, which was the most commonly occurring emergent dimension, and its relationship to the initial four concepts of anticipatory governance, inclusivity, reflexivity, and responsiveness (Chun Tie, Birks, and Francis 2019; Corbin and Strauss 2008; Ritz 2011). Throughout the stages of coding, the research team performed inductive analysis to explore how these firms performed RI, and the subjective relationship between the emerging concept of impact, and the four original dimensions of RI described by the innovators narrative (Chun Tie, Birks, and Francis 2019; Pentland 1999). Inductive logic was employed due to its sensitivity to institutional features, when compared to deductive approaches (Heracleous and Lan 2012). An inductive approach was used as we did not aim to make generalisable propositions, outside of the boundary conditions and we wanted to explore what other codes naturally emerged from our data.

Results

The responsible innovation process and responsible impact output

When thematic analysis was performed through the RI lens it was clear that all firms practiced elements of responsible innovation. Some firms practiced it more than others and while many had a strong focus on anticipatory governance in their planning stages, anticipatory governance did not always feature in their innovation processes. Similarly, for some firms there was less emphasis on impact. Table 2 demonstrates the link between the direct quotes, primary themes, secondary themes, and the aggregate dimensions.

During advanced coding, we found narrative pathways in practice which present an innovators natural transition from anticipatory governance (anticipation), to including stakeholders and the public (inclusivity), to reflecting on their own and the considerations of others (reflexivity), to acting accordingly in response to internal and external stakeholders (responsivity), which resulted in an impact which came about as a result of anticipation, inclusivity, reflexivity, and responsiveness. In this study we call this ‘Responsible Impact’. Although the transition from anticipatory governance through to responsible impact is not always so straight forward and linear, the innovators tended to see and describe their innovation process in that way and vignette 1 demonstrated the clearest evidence of the responsible innovation process. (Vignette 1 and Figure 1).

1. Anticipation

Professor A practices anticipatory governance in his university department before taking on big projects. If the Professor in an industry funded project, he always passes the proposal by his colleagues to get an outside view. Please see the example below.’ ... [Pharma Company A] brought out another drug type {drug name removed} which they claimed was bigger, better, faster, and said, “we’d like to run an outcome guarantee project on this, and we’ve got a £1 million budget for it. So, we’ll give you a million quid to run this”; not me personally but my school. So, “okay, exciting, a nice wodge of money into the school, I can do a lot with £1 million in the school”. So, I took it back to my team and said, “here’s the proposition, it’s from Company X and it’s for drug Y” and they went “nah”. I said why? They said, “we’re not at all happy about the bounds for risk and benefits and they’ve got the dosing wrong and there’s quite high instances of something called {condition removed} – which is {side-effect removed} – we don’t want to do it”’. (UK #1 Established)

2. Inclusivity

Professor A has a team of stakeholders which he calls upon when starting an innovative project. ‘So, the first thing we’ll do is we’ll establish a stakeholder group. So, we’ll get, say,

3. Reflexivity

Professor A will reflect on the contributions of his stakeholder group which will include patients and the public. ‘So, we had a focus group; kids are very

a lead clinician, if we were doing something on atrial fibrillation, for instance, we'd get a haematologist and cardiologist. Then, we'd think where's it going to be use in primary care, we'd get a general practitioner involved; we would probably get a clinical pharmacist involved and then we'd use technical experts from here and the animation team and we sit together and identify what the set of needs are' (UK #1 Established)

4. Responsiveness

This Professors reflection is often followed by a response to the unanticipated problem identified through inclusion and reflexivity.

'So, I thought "that's a really good question" but you can't say 1:10,000 chances to a six-year-old. So, we came up with this idea which is a football stadium (representing the chances of a side-effects as people entering and leaving a football stadium)' [UK #1 established]

straightforward; one of the first questions "am I going to die?" The other one was "you keep saying there's all these medicines that are really good" little kids, six-year-old called [Child A], said "yeah, but what about the side-effects." I said, "of course there's some side effects." Gave him a nice ... he said, "what is the chances of that happening to me?" (UK #1 Established)

5. Responsible Impact

As part of his recipe for impact he ensures that there are ways to measure impact for the REF.

'It was endorsed by a national [organisation]... it was launched late, well effectively, 2016. So far, we've had 15,500 sessions on it from 11,000 different users and because we know who the providers are, they're always exclusively NHS. So, it's obviously done what it was designed to do which was help support prescribers in primary/secondary care.' [UK #1 established]

Vignette I: A narrative example of the clearest process from Anticipation to Responsible Impact

Vignette 1 depicts a remarkably clear example of transition from anticipation through the different stages of RI, culminating in what we label as 'Responsible Impact' (Vignette 1 and [Figure 1](#)). This single vignette identified a link between each of the dimensions identified in our thematic analysis. This is a case of an innovator in a quasi-firm that had a distinct awareness of impact, which is likely due to the UK universities emphasis on impact for the national research excellence framework. Their efforts to assess impact are for university 'kudos and financial reward' for the school which has encouraged them to practice responsible innovation successfully (vignette 1.0.). UK established firm #1 has adopted an innovation process and when seen through a responsible innovation lens we recognise that this process includes anticipation, leading to inclusivity, leading to reflexivity, and responsiveness which produces responsible impact. This approach has not only generated responsible innovations and responsible impacts but has aided implementation, commercialisation, and future research income, as depicted in the quote below.

Yes, I don't know why I've not added it up recently but the last count I think I made, probably over my career £32 million for the university. Something like that. It's not a huge amount but I very rarely make them less than £1 million per year [UK #1 Established]

This remarkable vignette encouraged us to explore the other interviews to understand if this link between the dimensions was represented elsewhere. There is evidence of responsible innovation activity within the other firms also, either through the entire innovation process described in vignette 1.0, or in a more fragmented way, whereby the RI dimension of anticipatory governance or responsible impact was omitted. With the latter often lacking in the youngest firms.

In this section we move on from the clear RI process covered in vignette 1 and explore both complete and more 'fragmented' responsible innovation narratives. These narrative innovation pathways follow the process described in figure I and concern a tool to monitor falls (Norwegian firm 4), a tool to predict the onset of a life-threatening condition (UK firm 5), a drone app used to find an injured person(s) for the emergency services (UK firm 4), and a medical app to support exercise (Norway Firm 1), amongst other innovations.

Table 2. Coding tree and representative data.

Selected Evidence	1 st Order Codes	2 nd Order Codes	Aggregate Theoretical dimensions
<p>If somebody downloads something and it's buggy or it's just not how they would...it's just not useful to them, or it may be useful to them but they find it really frustrating to use, then they'll give up on it and it just won't be used again. That's why we really wanted the feedback from these guys UK6</p>	<p>Concerns of how their innovation may negatively affect company success</p>	<p>Avoiding company harm</p>	<p>Anticipatory Governance</p>
<p>Also, I think a problem in Norway is that no-one wants to work in start-ups, because people are used to jobs, and being paid fairly and everything like this. So there's a lot of politicians and people in Norway want start-ups to succeed, and they're very good at building the infrastructure around start-up ecosystem, but there is not anything from the bottom up. You don't have enough people that want to</p>	<p>Concerns of how the ecosystem context may negatively affect their success</p>	<p>Avoiding societal harm</p>	
<p>The way I reflect is that it's a force for good, it's a force for change and if it means that this app will provide better use cases for emergency services and potentially save lives, then it's worth it UK4</p>	<p>A driving goal of demonstrating value to society.</p>		
<p>'I think it's very important that you're aligned with making the right decisions for society as an organisation, whether you're a private organisation or a public organisation' UK3</p>	<p>Motivation to solve healthcare challenges without causing harm</p>		
<p>We're still developing new features and we're developing features and testing features at the same time, together with early customers N1</p>	<p>Engaging with customers, users or payers</p>	<p>Bringing together external communities and stakeholders</p>	<p>Inclusivity</p>
<p>We are connected with the international scientists that can support and help us to describe the need of users so we can use this know-how in regards to developing our products further N2</p>	<p>Engaging with their team and collaborators on the innovation journey</p>	<p>Bringing together internal stakeholder communities</p>	
<p>Sure, it will vary completely from product to product. So, the first thing we'll do is we'll establish a stakeholder group. So, we'll actually get, say, a lead clinician, if we were doing something on atrial fibrillation, for instance, we'd get a haematologist and cardiologist. Then, we'd think where's it going to be used in primary care, we'd get a general practitioner involved; we would probably get a clinical pharmacist involved and then we'd use technical experts from here and the animation team and we sit together and identify what the set of needs are UK1</p>			
<p>So, one of the questions we had from the kids was about side-effects. So, we had a focus group; kids are very straightforward; one of the first questions "am I going to die?" The other one was "you keep saying there's all these medicines that are really good" little kids, six-year-old called Max, said "yeah, but what about the side-effects." I said of course there's some side effects... he said "what is the chances of that happening to me?"</p> <p>So, I thought "that's a really good question" but you can't say 1:10,000 chances to a six-year-old. So, we came up with this idea which is a football stadium (to describe the risk) UK1</p>	<p>Reflecting on the feedback from customers, users, funders or other stakeholders who are external to the firm</p>	<p>External reflection</p>	<p>Reflexivity</p>
<p>And we know that... if you look at this, this is a prototype, but it would look almost the same. It's quite a large watch, for a very small lady in her 80s this is of course a large piece, so we are thinking of making a version without the blood measuring units, because that takes a lot of space, and then we can make it like half this one. So, we're thinking of it, yes N4</p>	<p>Reflecting upon their own ideas, considering the challenges facing their innovations, considered action and challenging their assumptions on a personally or internal team level</p>	<p>Internal reflection</p>	
<p>On high level the service is done according to the regulations N2</p>			
<p>Anyway, we kind of designed these Bluetooth scanners were really expensive, a bit flimsy because they're... and then one of the IT guys said, "well you're not going to have... you know one advantage, you're not going to use those are you?" I'm like well why not? And they said 'Well anything that isn't taped down will just grow legs and walk away' UK2</p>			
<p>The reality was all these companies were like, well this is great guys, it makes a lot of sense but you know, you're two years old, two years too late. Then we had to go back to the drawing board and understand what other low hanging fruits were UK3</p>	<p>Changing strategy based on strong external stakeholder challenge, or changes in legislation or policy</p>	<p>Pressured action</p>	<p>Responsibility</p>
<p>Then from that we've built a product to meet the needs of those personas and then continuously gone back and forth with these companies and shown them a new demo and got the feedback with the things they don't like or different features within the products UK3</p>	<p>Making unpressured, user suggested changes to improve the innovation</p>	<p>Voluntary action</p>	
<p>We're going back some time, right to the beginning here but we did hundreds, hundreds of sessions with people, watched their behaviour on the app, presented different aspects to them, asked them to comment on it UK5</p>			
<p>We had a lots of good feedback from customers, they saved a lot of money and a lot of stress due to the system N10</p>			
<p>Latterly, probably the most successful one we've done to date is an (condition X) decision support tool. And I can tell you, because I've just done the slides for it, how many downloads that's had in the UK. It was endorsed by a national body... it was launched late, well effectively, 2016. So far we've had 15,500 sessions on it from 11,000 different users and because we know who the providers are they're always exclusively NHS. So, it's obviously done what it was designed to do which was help support prescribers in primary/secondary care. UK 1</p>	<p>Focus on generating impact for patients, the public, the healthcare system or their peers.</p>	<p>External impact</p>	<p>Responsible Impact</p>
<p>What we have now is that its going to be the pilot that we do with the municipality and they have said in the agreement that when the pilot is successful, they have intention to buy this solution to the whole of the region N3</p>	<p>Focusing on outcomes that directly affected profitability, reputation or future success of the entrepreneur or business</p>	<p>Internal impact</p>	
<p>I am not sure which of these is in the public domain, to be honest and that we could mention. Companies with anything between 10-200,000, 300,000 employees. We now have several dozen companies, large employers (who have said for their product and services) UK 6</p>			

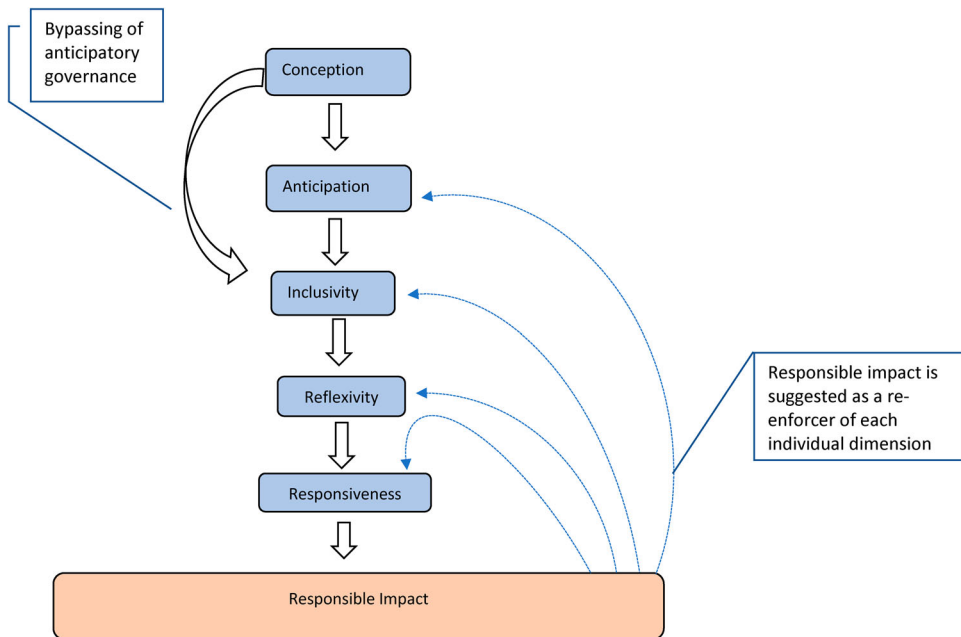


Figure 1. Responsible Innovation Model which emerges from the study data.

Narrative innovation pathway 1

We are taking full responsibility for the working conditions of it and ... but if they use data from the watch in a not appropriate manner, they might ... they have to take responsibility themselves (**Anticipatory governance**) ... Yes, we have been testing at several elderly homes, and both dementia and heart conditions, (**Inclusivity with users**) that kind of thing and then we also have a lot of ... or a handful of private persons that we know. It's a bit easier with the private persons because we can easily make adjustments (**Reflexivity**) ... Absolutely and we've also added a new ... a few new features but I think maybe the main thing has been the design adjustments. Making it look like a watch, not like a big, large grey thing with a red button on (**Responsivity**) ... So, then we were in the private sector, and we had ... in two or three weeks we had almost 15,000 not followers but they wrote their names and address on a list because they wanted the product (**Responsible Impact**). [Norway #4 Launched]

In this narrative we see evidence of internal anticipatory governance, internal reflexivity, responsiveness, and responsible internal impact from Norwegian Firm 4.

Narrative innovation pathway 2

So, a couple of those that are always on our radar are things to do with data privacy and security and this is very, very important to us to ensure that we have all the systems in place to ensure that no-one's health data or private data is released in any way (**Anticipatory Governance**) ... For actual patients or families, let's say consumers, for them they ... for people with ... family members who have family with asthma, particularly parents, they see it very quickly (**Inclusivity to involve patients and their family**). For them they're like actually this really directly addresses a problem I see. It's very difficult ... you get worried about your child, it's very difficult to objectively know what's happening with your child and for them they get it very quickly (**Reflexivity – seeing the users perspective**).

That's most likely going to be our initial target customer, consumer customer group anyway ... The patients, I would say, give the initial insights quite well because they face the problem most directly. They allow you to develop the right sort of solution (**Responsiveness**). However, the key opinion leaders are more important in actually being able to give momentum to your project. Connections, links, funding, all those sort of things. [UK #5B Start-up]

UK Firm #5 discusses how they speak to multiple stakeholders including clinicians and patients, to generate their innovation. They believe that this approach helped them create a solution which was more likely to be accepted by society and their target customers. The firm appreciates the risks associated with their approach. However, their responsiveness is nuanced, whereby they prioritise the views of key opinion leaders above those of the patients. This firm provides evidence of anticipatory governance which avoids harm to society, external inclusion, internal reflection, and responsiveness without evidence of responsible impact. Subsequent to this study we can see that they have gone on to be awarded multiple UK grants, they have developed their first prototype, they have conducted clinical studies and have been awarded a CE mark for their product which are all markers of responsible impact. This suggests that responsible impact is not always evident in young start-up firms.

Narrative innovation pathway 3

The impact on society I think would be extremely beneficial because ... let's take an example of ... I want to say it was [UK county], the police used a drone in order to look for, I believe it was a pensioner that had wandered into a swamp and they just got lost and collapsed. They wouldn't have been able to find them without the use of a drone (**Anticipatory Governance**). ... We've just got a very small base of people at the minute that are testing it, but there's a wider group of people that are looking to test, including members of the fire service, police and search and rescue (**Inclusivity**) ... But one of the hindrances is, is that that drone feed is reliant on one pilot to fly it and also see the feed (**Reflexivity**). So, they said look, you know, a search and rescue environment, you know, they were involved in ... there was a missing person's case up in New Orleans that they were involved in, and they used drones. They successfully found someone. But there was ... yeah, the issue was of just getting that stream out to everyone. They said a map would be really valuable. So, we stripped it back and we made those changes. (**Responsivity**) ... They can potentially have someone operating the camera but that's a maximum of two people. So, if you can relay that footage to everyone who's on the ground searching for that person, they'll be found quicker and more effectively' [UK #4 Start-up]

UK Firm #4 has demonstrated anticipatory governance to avoid societal harm when they use foresight to reflect upon future use case scenarios. They take an external inclusive approach not only to gather feedback from the emergency services but also to build an online following, through regular posting in popular internet drone blogs. This innovator shows external reflection when considering the thoughts of his stakeholders and pressured responsiveness to implement some key changes to the company product which has helped them to differentiate themselves from their competitors. Due to the perceived societal impact of their context (the drone industry) they have been more naturally anticipatory, however at the point of interview there was not much impact described.

Narrative innovation pathway 4

For instance, these e-journal systems, they will never provide an opportunity for a small company to exchange data with the system, which is just something that you have to do if you're going to use any kind of device or software in the healthcare sector. So it's very difficult to get to try out new things within the healthcare sector (**Anticipatory Governance**). Now we're in pilot stage. In terms of software development, you would say that we are in alpha stage. We're still developing new features and we're developing features and testing features at the same time, together with early customers, and trying to improve the features as we go along (**Inclusivity** with customers, **reflexivity** to their feedback and **responsiveness** to change the product). So yes, we have gotten some customers, (location removed) municipality and (location removed) municipality and (location removed) municipality, and also the church mission, the mission here in (location removed) and the national organisation for people's health. Also, this umbrella organisation called the (NGO name removed), where we are ... but that's actually on ... we're doing some consulting work for them (**Responsible Impact**), because they have this portal called (removed for anonymity) which is a very big recruiting channel for volunteers to organisations. We helped them ... we're developing that side for them. [Norway Firm #1 Start-up]

In Norwegian firm #1 we see clear evidence of anticipatory governance to avoid company harm, inclusivity with external stakeholders, external reflection on the thoughts of stakeholders and the voluntary responsiveness to the implementation of their suggestions. There is also evidence of commercial impact whereby they have generated consulting business from taking a responsible approach.

Narrative innovation pathway 5

We think that how it is today is wrong in the society and if we continue that way we will end up with a few superpowers with ... that are ... today we have a few companies, the most valuable companies today are the ones that have collected the most data about you ... I mentioned that, GDPR. So, we have continued to work around that issue, and we see that our platform is solving GDPR by outsourcing the customer relationship to the customer. So, the customer is collecting the data and is also in control of the terms and conditions, and you can know all the time what you are sharing and who you are sharing with, and you can also withdraw that data (**Anticipatory Governance**) ... Then ... but we will be testing it, and using it, and iterating all the time until we're happy with what we have, so that's kind of the process, that we will do this in close relationship with the customer or the end-user to be able to get feedback (**Inclusivity, Reflexivity, and Responsiveness**) What we have now is that its going to be the pilot that we do with municipality and they have said in the agreement that when the pilot is successful, they have intention to buy this solution to whole region (**Responsible Impact**). [Norway Firm #3 Start-up]

In Norwegian firm #3 we see another responsible innovation process whereby the firm recognises the current governance to avoid harm to society concerning individual data issues and anticipates a way to solve this governance inadequacy through the creation of their solution. Their description describes that they are externally inclusive, externally reflective, and externally responsive as they pilot and iterate their innovation. They also demonstrate internal responsible impact.

Narrative innovation pathway 6

Because I think there was a strong clinical drive on the team, you know, I think we had all suffered from rubbish healthcare IT and you know, really wanted to make something good,

and really wanted to make something easy. So, we had a very strong focus on the clinical end user (**Inclusivity**), which is pretty rare in healthcare IT despite what, you know, everyone said. So, everybody on their kind of brochure said it's all wonderfully usable ... Yeah, and so you know to start off with the research nurses do the observations in the ... so the staff you know. Then when you're at a stage of maturity where it's not breaking down all the time, then you actually give it to the staff to do, and then you watch them do it (**Reflexivity**). Then you know, it's a continual process of iteration ... (**Responsiveness**) and then you get the Life Sciences Minister come down and visit it and tweet about it (**Impact**). [UK firm #2 Launched]

In this instance the firm doesn't demonstrate any strong evidence of anticipatory governance to avoid societal harm, they do demonstrate external inclusivity to gain feedback from external stakeholders, external reflexivity, followed by voluntary responsiveness and internal responsible impact. This lack of anticipatory governance is reflected in other firms also.

Discussion

Responsible innovation process and responsible impact

This section focusses on RI, and how the innovators' narratives described a process linking the four RI dimensions with responsible impact (figure 1.0). The first research question in this study asked do innovators in digital health innovate responsibly and if so how? We observed in our data that all the healthcare innovators had a responsible purpose to their innovations. Within our data set, some firms did not focus on impact or practice anticipatory governance, however all firms exercised inclusivity, reflexivity, and responsiveness within their innovation practice.

When it comes to the question of how they innovated responsibly, we used the innovators narratives to describe five domains as a process rather than five distinct dimensions. The firms described a process which began with anticipatory governance, followed by inclusivity, then reflexivity and then responsiveness resulting in a responsible impact, and occurring as a stepwise process, as depicted by the thick white arrows in figure 1.0. We see in this model and in our data that anticipatory governance can be bypassed (depicted by the looping white arrow) and in some cases responsible impact was not mentioned, most likely due to the firm being more recently incorporated (Slávik et al. 2021). Therefore, the presence of responsible impact may be aligned to a company's maturity, a concept which is which is aligned to the work of Slávik et al. (2021). We also observed some examples in our study of how this responsible impact may reinforce practice, either the whole process from start to finish, or in part whereby the responsible impact reinforced the relevant dimension practiced by the firm as depicted by the dashed arrows, which we discuss later in this paper

Our study moves the academic topic of responsible innovation away from RI that focusses solely on society. Instead, we describe how RI for society (external responsible impact) exists alongside personal or firm benefit (internal responsible impact). We identify this as a far more organically forming and self-sustaining practice. That is to say that firms that create both internal and external responsible impact from practicing RI are more likely to continue to innovate responsibly. This is reflected in our analysis and our second order themes which focus on both the innovator side and the society side. Our findings are

aligned with the call from the responsible innovation literature to find a way of seeing RI as being enacted through a process over time. We include the four most common dimensions of responsible innovation, which exist in the literature, and in our process model i.e. Anticipation, Inclusivity, Reflexivity, and Responsiveness. We see narrative threads which link these four domains together as a process which can provide practical guidance to firms (Porcari et al. 2020). We also identify and introduce a new construct which we have labelled ‘responsible impact’ as the fifth domain which has emerged from this study data. What we mean by responsible impact is the direct and indirect, internal and external, positive and negative effects of responsible innovation outputs, on their micro, meso, and macro contexts.

The introduction of this new construct of ‘responsible impact’ encourages one not to focus on the process alone but also the purpose and the product. A firm can have an economic, social, environmental, cultural, or technological impact which can be positive or negative, and can affect the firm’s micro, meso or macro contexts, but unless the purpose (*raison d’être*, mission statement and the firm’s loyalty to both) and the process are responsible, the product cannot truly be responsible. The examples of responsible impact observed in our study included institutional impact e.g. developing learning resources for the NHS and pharmaceutical industry (UK established #1), organisational impact e.g. collaborating with other organisations to deliver a service (Norwegian established #10), pathway impact e.g. creating the first app to connect to a national platform and as a result creating the pathway for future apps (UK start-up #18) and societal impact e.g. allowing the elderly to engage in entertainment experiences with their family at a distance (Norwegian established #8). But impact types could be much wider ranging. For example the theoretical concepts of ‘care’ and ‘sustainability’ which are proposed within the responsible innovation literature, which are linked to responsible innovation, could be seen as more granular examples of responsible impact (Burget, Bardone, and Pedaste 2017). This framework is particularly useful for small and medium sized organisations, who may use it as a structured reflection tool to challenge their RI practices and guide them to the generation of responsible impact. This model takes into consideration that responsible impact is usually a product of the complete RI process as depicted in our model (Figure I). Our study suggests that there may also be a feedback loop between responsible impact and each of the four other domains either individually or as a complete process, as evidenced in Vignette 1.0 and depicted in Figure I. The model in figure 1.0 could be implemented as a responsible innovation tool to guide other firms through a responsible innovation process, and answer academic calls for models which consider process and product (Iakovleva, Oftedal, and Bessant 2019; Stahl et al. 2017; Stilgoe, Owen, and Macnaghten 2013) (Figure I).

Responsible impact as a theoretical reinforcer of responsible innovation

So far, we have described a novel responsible innovation process which produces a fifth construct of responsible impact, which is an important construct to add to the RI framework. Next, we discuss how to encourage firms to continue with such responsible innovation practices. We do this by addressing our second research question, which explores the re-enforcers of RI processes. This question leaves us with a proposition, further questions and a future research agenda.

Our proposition is that responsible impact may be a reinforcer of RI processes, on a micro level, within firms that are already innovating responsibly. Our narrative data describes that positive impact which emerges from responsible innovation (which we call responsible impact). We have recognised that this can be both external (having an impact on society) and internal (having an impact on the firm). We propose that by firms recognising the impact that emerges from responsible innovation, it may act as a naturally occurring reinforcer of RI, helping them to see value in RI practice and encouraging them to continue to innovate responsibly. This was identified by Norwegian firm 4 when they described how they reached out to their consumer base to gain feedback.

So, then we were in the private sector, and we had ... in two or three weeks we had almost 15,000 not followers but they wrote their names and address on a list because they wanted the product.

Norwegian firm 4 go on to then describes how the firm's inclusivity has generated responsible impact.

So, we opened our eyes for another market which is private direct sales market. So, we started to work with distributors for that market as well because we think that that's a larger market and it's easier to penetrate for us than the official market. [Norway #4 – Launched]

If firms like Norway #4 above can recognise the positive commercial impacts (i.e. a new market and increased number of followers) that have resulted from taking an open and inclusive approach to business (inclusivity), then we suggest that they are more likely to continue the practice of inclusivity.

In Norwegian Company 1 we see the contrary. When the firm paraphrases what investors think of them.

Investors think 'These guys at [Company N1], they are only motivated by the social impact, they say they want us to make a profit and have a sustainable company, but they just care about the impact really'. [Norway #1 Start-up]

These investors work mostly in the oil and gas industry, who predominantly see social impact as being at odds with profit. In this case the firm is discouraged from appreciating and communicating their impact to those investors which is theorised to disincentivise the firm from focussing on that particular impact. The interviewee themselves from firm 1 goes on to speak further about the investor's views and explain as follows.

As long as the company's run properly, they care about the impact. But especially in (location removed), with the oil industry and everything, people are very motivated by money and they have no understanding for social impact at all. So, trying to explain that is a waste of time. They will only look at the companies like ... if you talk about social impact they will think that it won't make money, so they see those two as opposites, making money and social impact, because they think of social impact as charity and bad for business. But in (another location) there are some social impact investors who also think that sustainable businesses ... it's both social impact and profitable [Norway #1 Start-up]

Norway Firm #1 describes the current situation in practice very well. Many investors separate making profit with being responsible. In this case, Norwegian firm 1 experienced negative impact from being socially impactful with this particular investor. This negative impact is likely to negatively reinforce their attitude to the inclusivity dimension of responsible innovation practice with similar investors.

In a healthcare setting, being responsible often benefits the double bottom line, by generating a more contextually suitable product with better commercialisation prospects (Wilburn and Wilburn 2014). The same can be said for UK firm #1 which has been described in vignette 1.0. This firm developed a responsible innovation approach, recognised the positive impact from the RI approach, and that impact reinforced the firm's RI practice. The innovator continues with that approach today. And is a positive example of how 'Responsible Impact' can re-enforce different elements of RI practices.

A major gap within the literature concerning the normative nature of RI is a lack of re-enforcement of RI amongst firms who practice some elements of RI. It is argued that financial interests motivate corporations to be responsible, or that the stigmatisation of irresponsible behaviour is effective, while others propose that national governments need to enforce legal standards for responsibility (Winston 2002). Some studies also discuss outside agents influencing or pressuring a firm into being responsible (Waldron et al. n.d.). In order for a firm to continue to implement the RI principles they need to see the value of the process. Assessing the responsible impact might help them (as well as external stakeholders) to recognise the value of the RI exercise. In order to ensure responsible innovation continues organically as an organisational norm, reinforcing factors need to be highlighted. Gurzawska, Mäkinen, and Brey (2017) discusses the role of incentives for delivering RRI. They propose evidence of responsible practice as a criterion for public funding and discuss the firm's size. Gurzawska, Mäkinen, and Brey (2017) proposes a matrix of incentives for stimulating the adoption of RRI and categorises incentives according to three dichotomies: external and internal, instrumental, and non-instrumental, direct, and indirect. The incentives are formalised in a causal loop diagram, which can be used to demonstrate the sound character of investing in RRI from a business perspective. They discuss examples of incentives, including corporate reputation and critical consumerism, certification, employee engagement, and governance. To ensure effective implementation of RRI, Gurzawska et al., outlines factors for the realisation of successful incentives for RRI in industry. Although this work is useful and exhaustive, in some ways, it doesn't completely translate to start-ups and SME's as they are often the only internal stakeholder and in the case of start-ups can often consist of just one or two entrepreneurs (Gurzawska, Mäkinen, and Brey 2017). In this case we argue that the Gurzawska model is too complex for high level, generalisable use and will struggle to have a long-term impact on policy and practice on a micro level. Instead of focussing on incentives, Genus and Stirling (2018) explains that one of the most important properties of responsibility lies in the reinforcing of accountabilities. They explain that first there is a need to develop and invigorate more concrete and assertive frameworks for enabling practice of critical citizen engagement and participatory deliberation (Genus and Stirling 2018). Our study builds on this contribution by Genus and Sterling and proposes that Responsible Impact, when recognised by innovators may be a reinforcer of responsible innovation and help with the reuse of RI processes in practice.

In another study by Porcari et al. (2020) we observe a conceptual model which is built on the work of Van de Poel et al. (2017). This model by Porcari et al. supports the concept that RI strategies are re-enforced by the outcomes generated by RI through a feedback loop. On a high level, Porcari's contribution is aligned to our own, however there are some key differences. Porcari focussed on a feedback loop between RI outcomes and

the RI strategy. In contrast, our study explores the feedback loop between responsible impact and RI practice in less mature public sector centred firms. This is an important distinction for two reasons. Firstly, smaller firms or those new to RI practice are unlikely to have a formal corporate RI strategy, which makes Porcari et al.'s study and model more applicable to more mature firms both in terms of size and RI practice (Porcari et al. 2020). Secondly the Porcari model concerns itself with re-enforcing corporate strategy which may not necessarily be the same as a translation to practice, as a corporate strategy does not always translate into firm practice. We see Porcari's approach as being more of a top-down approach to encourage RI reinforcement as it is more strategic and planned. This is in contrast to our approach which encourages the appreciation of existing practice to encourage or reinforce RI practice, which we see as a more bottom up and organically occurring approach to the reinforcement of RI. In addition to these points, Porcari's conceptual model suggests that outcomes feedback into the RI dimensions as a whole, whereas our work is focussed on a more micro or granular level which suggests that impact generated from the practice of a particular RI dimension is more likely to reinforce that specific dimension rather than re-enforcing all RI dimensions. In addition, our model recognised that the omission of RI dimensions also occurs.

Despite the comparisons and contrasts between our model and that of Porcari, one could be seen as being linked to the other. In our model we propose that responsible impact could reinforce practice, which in turn could encourage the translation of that practice into a more formal RI strategy within the firm. In turn the outcomes of a formal RI strategy could then re-enforce said RI strategy as portrayed in the Porcari et al. (2020) study. A further study could be explored to understand the relationship between the reinforcement of RI practice and the generation of a formal RI strategy.

We previously mentioned that while exploring the reinforcers of RI process we were left with propositions, questions and a future research agenda. We have put together a logical explanation for why responsible impact may reinforce RI processes, and aligned it to the recent work of Porcari et al. (2020). However, some future research questions remain, which we explore in the next section.

Limitations, boundary conditions and future research agendas

Although our contributions have the potential to translate across contexts, this study is, in the first instance, bounded to the context of digital healthcare firms (including quasi firms) operating in public sector centred ecosystems. This study takes an inductive reasoning approach and therefore does not aim to demonstrate generalisability beyond the studies context i.e. Innovators within public sector centred ecosystems in the digital healthcare context. These contributions are also bounded to micro-level innovations rather than large scale macro-level innovations such as nuclear power, climate engineering, shale gas exploration or nano-technology which has been previously covered in the literature (Pandza and Ellwood 2013; Poel 2011; Stilgoe, Owen, and Macnaghten 2013; Taebi et al. 2014).

This study demonstrates that digital health innovators are naturally responsible innovators and regularly follow similar responsible innovation processes. This study has also outlined responsible impact as a fifth dimension which now requires further investigation in the RI literature. Other related research questions include, what are the other re-enforcers of responsible practice? And does assessing responsible impact help

society to recognise and reward firms that achieved this responsible impact? These questions remain unanswered and therefore, more research regarding the reinforcing nature of responsible impact is required. Future RI frameworks may also benefit from considering the re-enforcing effects of responsible impact on RI practice. This research is especially important for firms with lower financial security, as they may be less likely to prioritise responsible innovation practice if there are no clear internal rewards from such activities (Porcari et al. 2020).

The findings of this study could be applied to other contexts to test for its generalisability. It could be logically conceived that this model may be applicable with other innovations which are created in typically ethical or highly regulated sectors such as medicines development or renewable energy technology. If organisations recognise ‘Responsible Impact’ as a product of responsible innovation it may be a useful approach to slowly encourage and maintain a culture of responsibility in other sectors. Reinforcing responsible innovation practices will become increasingly important as organisations experience pressure to deliver on the UN sustainable development goals. Further research could be performed to explore how our contributions apply to other settings or why some innovator groups are more responsible than others. Other research might include a longitudinal study to follow up firms to better understand how their ongoing responsible impact affected their RI processes. Moreover, responsible innovation and responsible leadership are intertwined in small teams. When innovating responsibly the firm is likely to also be leading responsibly. Further research and analysis which considers the RI model in this paper through the lens of responsible leadership may be useful.

Recommendations for practice and public sector policy

There have been calls for actions plans to guide the translation of RI principles into action (Porcari et al. 2020). In this section we propose an action plan to encourage firms within public sector centred ecosystems to adopt an RI approach. Public organisations often try to select partners with values which align with their own, and their tendering process often includes questions regarding responsible business practice. We propose a set of action plan questions (appendix 1.0) to help organisations, both grant funders, and publicly funded organisations engaging with contractors on innovation projects, to ensure that successfully contracted firms or research groups have the same responsible innovation values as the funders. These questions are based on our model (figure I) and evidence within this paper and aim to encourage firms to reflect on what it means to be a responsible innovator, to help them to create innovations which are contextually suitable, responsible, and well received by the public and their future customers.

Conclusions

RI is largely a normative concept, however, not much is known about how firms practice it. We asked if and how RI was practiced in digital health firms. We identified that RI processes are common in digital health innovation. We then explained that although the literature on responsible research and innovation mentions impact, it is not a central dimension of RI. We contributed a Responsible Innovation Model which describes the process of RI, based on the most common RI concepts and a new fifth

concept of ‘Responsible Impact’. This model appreciates responsible impact as a fifth construct and product of the RI process amongst digital health firms and proposes its value as an organic or bottom up reinforcer of the RI process. Although this new area requires further research, we propose that recognising the value of responsible impact such as commercial impact, societal impact, organisational impact, or environmental impact, may help firms to create products, which provide commercial and impactful outputs, that are in unison with their product context.

This study also proposes a set of questions (appendix 1.0) to help innovators create a responsibility action plan for innovation funding applications. This approach could be adopted by large research and innovation grant providers, or tender providers, as part of funding applications. This would encourage organisations, at the centre of their ecosystems to improve RI when funding digital innovation projects, contracting private firms, or getting involved in collaborations with other organisations.

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Appendix 1: Responsible innovation action plan for innovation projects or initiatives

Anticipation

1. What do you see as the potential, immediate, short term and long-term societal impacts of this project or initiative? How do you plan to explore these impacts?
2. Can you describe an example of where your firm has practiced anticipatory governance as part of an innovation process? If so, what have the impacts of this practice been?

Inclusivity

3. What measures will you take to identify and include relevant stakeholders in this project or initiative?
4. There are risks associated with including other firms or investors in the innovation process. Considering the stakeholders mentioned in question three, what measures will you take to manage the tensions of inclusivity?
5. What is your stakeholder engagement plan, how often will the stakeholder team meet, what is the scope of their involvement? Are there limitations to their contributions?
6. Can you describe an example of where your firm has been inclusive as part of the innovation process, and what has been the impact of this practice on your firm or the product?

Reflexivity

7. Can you describe your plans to reflect on your innovation practices? i.e. how will you reflect upon the input of your stakeholders?
8. Can you describe an example of where your firm has been reflexive as part of the innovation process, and what the impact of this practice has been?

Responsiveness

9. It can be difficult to include the right stakeholders and manage the expectations of all stakeholders while delivering an effective innovation or project. What is your stakeholder response plan and how will you manage the contributions and expectations of your stakeholders?
10. Can you describe an example of where your firm has been responsive as part of the innovation process, and what has been the impact of this practice?

Responsible Impact

11. How do you aim to assess the impact of your project on relevant stakeholders including society? How will you ensure that your impact will be responsible? What will your impact assessment report include and how will it be disseminated?
12. Can you describe an example of where your firm has demonstrated responsible impact in the past? How will you reinforce the need for responsible innovation within this project and your future work?