The limits of responsible innovation: Exploring care, vulnerability and precision medicine

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A B S T R A C T

Drawing on insights from feminist and Science and Technology Studies writing on care and vulnerability, this paper will critically explore conceptualisations of responsibility, care and vulnerability in relation to contemporary approaches to Responsible Innovation (RI). Drawing on examples of some of the social and ethical challenges of precision medicine, we highlight the on-going, distributed and complex nature of innovation and responsibilities in relation to markets, patient and carer experience and data practices associated with these new technologies to highlight some of the limits of RI. We end by reflecting on the implications of our analysis for the social and ethical challenges of precision medicine and RI more generally.

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1. Introduction

Public and policy concerns about the risks of emergent technologies have lead to the development of a range of policy tools to guide the innovation process. One such approach which has gained popularity in recent years is Responsible Innovation (RI). A variety of frameworks and initiatives have emerged under this broad banner. For example, public research funding organisations such as the UK's Engineering and Physical Sciences Research Council have developed a range of RI agendas aimed at the research community. Typically these are focused on encouraging, supporting or in some cases requiring researchers to be reflexive about their research practices, to consider the implications and applications of their actions, and to involve and engage with publics and their concerns through the research process (see for example [W1]. Social scientists have been actively involved in developing and embedding these initiatives in Higher Education and research funding institutions across Europe and the USA. Their work has focused on helping researchers and innovators to assess and respond to a plethora of evidence concerning the extent to which emergent innovation meet societies' needs, and fostering appropriate modes of engagement for stakeholders to help to anticipate and mitigate the risks which might arise from the development of the technology [1—3]. In one of the most influential contributions on the subject, Von Schomberg describes Responsible Research and Innovation 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) [2].

RI has had particular currency in research and policy communities concerned with environmental and bio-technologies such as synthetic biology, nanotechnology and geoengineering, especially those associated with large EU and/or national research funding programmes. A range of detailed models or frameworks for RI have been proposed in order to achieve the dual goals of more ethical and engaged research and innovation. For example, Fisher [4] has developed a 'decision model' for the purpose of encouraging researchers' reflection on the process of innovation based on the principle of 'midstream modulation'. The model can be embedded into the research process in the form of an interview protocol which functioned as a feedback mechanism, thus 'creating a more self-critical environment for knowledge production, and perturbing the system in research-tolerable ways' [4].

Building on this, Owen et al. have suggested a framework for RI based on three dimensions: anticipation of potential impacts; reflection on underlying purposes; inclusive opening up of reflection to broad, collective deliberation [3]. This, they suggest, needs to

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be an 'iterative, continuous and flexible process of adaptive learning' (755) [3]. For Owen et al. [3], rather than researchers following rules it is necessary to emphasise values of care and responsiveness. They stress the importance of collective future-oriented care, characterised by anticipation (rather than prediction) of potential problems and the intertwining of the futures of all relevant stakeholders broadly defined. In this framework, more responsive processes of innovation not only prevent risks and promote safe and effective technologies, they also bring brings jobs, prosperity and social benefits.

The broad consensus around the benefits of these approaches to research and funding processes notwithstanding, a range of critical concerns have been raised about the limits and problems of the notions of responsibility and innovation which underpin these kinds of approaches to RI.

In one recent article, de Saille and Medvecky [5] have argued, that RI offers a limited view of how we might exercise our responsibilities for the future via innovation. They note that RI tends to equate innovation with positive economic growth, but that this does not tackle the problematic consequences of economic growth for society or the environment:

once RI is unpacked to reveal the moral underpinnings of its original formulation − in which 'responsible' has a caretaker mission to ensure that new technologies are both environmentally safe and sustainable (the requirements for which are not necessarily commensurate) − the relationship between RI and economic growth can become very unhappy indeed (5−6) [5].

In their exploration of what might constitute 'responsible stagnation', de Saille and Medvecky [5] consider how RI might involve less, not more, technological innovations, and focus on the kinds of social innovations that could be more 'responsible' by virtue of their judicious slowing down of the innovation and profit cycles, e.g. the case of Patagonia, which sells outdoor equipment using re-cycled materials using a business model with a modest price and profit margin.

Van Oudheusden [6] has also argued that responsible innovation agendas do not tend to engage with how innovations are produced or marketed and what kinds of social and political consequences this brings, because they focus on the ethical rather than the economic. The operationalisation of RI frameworks in activities such as Technology Assessment, do not tend to address the processes through which power is distributed and contested: 'Rather, these frameworks largely ignore questions about the politics in and of deliberation, the authoritative allocation of values, and the institutional uptake of deliberative engagements' (67) [6]. Di Guilio et al. [7] have also drawn attention to the need to engage with marginalised perspectives in RI and to move from frameworks and methodologies based around 'idealised rational forms of deliberation' to include more marginalised perspectives which recognise vulnerability.

Drawing on a rich vein of feminist scholarship, other Science and Technology Studies scholars have further troubled the idea of RI as matter of collective care for the future as proposed by Owen et al. [3]. Groves points out, the emphasis in much RI on consulting and engaging with a wide array of stakeholders stops short of critical engagement with the ways in which society is organised around 'living the future' via imaginaries which drive particular practices of investment and growth. Instead Groves suggests we need 'a new ethos for living with technology' (13) [8] and a more thorough consideration of how subjects and material arrangements interact [9].

These critical interventions suggest that contemporary RI agendas might be based on rather limited conceptualisation of responsibility, innovation and care for the future. Although these approaches champion researchers', innovators' and funders' responsibilities to consider the consequences of their work for society, there is little scope for these and other involved actors to engage with or intervene in the wider systems of distribution or exchange of any products or technologies which might arise from their efforts. Although there is clearly an openness to mitigating risks or slowing the innovation process, the emphasis in much of RI remains on investment in technological (as opposed to social) innovation and on innovation rather than ethical forms of inaction. And efforts at deliberation or public engagement conceived around 'stakeholders' and consensus limit the kinds of voices and considerations of responsibility and innovation.

In order to further our understanding of the limits of contemporary approaches to RI, we can also turn to feminist and STS writings on innovation, care and vulnerability.

Following Puig de la Bellacasa [10], in a recent special issue on care and technology, Martin et al. [11] argued that to fully engage with what care might mean in relation to science and technology we need to focus on who is asked to or able to care, for what kinds of things and futures and to open up consideration of the kinds of social actors, things and contexts we engage with as part of these processes. So rather than thinking primarily in terms of stakeholders and technological innovations, we need to consider those who might be absent or marginalised from engagement processes or markets through which technologies might develop, and care about these markets and other kinds of things and processes they involve or interact with too. Feminist STS writing also stresses the importance of a careful consideration of the 'dark side' of care:

Care is a selective mode of attention: it circumscribes and cherishes some things, lives, or phenomena as its objects. In the process, it excludes others. Practices of care are always shot through with asymmetrical power relations: who has the power to care? Who has the power to define what counts as care and how it should be administered? Care can render a receiver powerless or otherwise limit their power. It can set up conditions of indebtedness or obligation. It can also sediment these asymmetries by putting recipients in situations where they cannot reciprocate. Care organizes, classifies, and disciplines bodies (625) [11].

This warns us to take care around ideas such as 'care for the future' and its articulation in RI agendas, drawing attention to the dangers and damage of particular ways of caring and those it diminishes. As STS researchers who have become enrolled in responsible innovation agendas have also argued, care can all too readily become a matter of 'observation' at a distance - a performance of concern - rather than critical intervention which reshapes technological innovation [12]. Martin et al. conclude: 'The lesson here is that an ethic of response-ability, and thus an ethic of care, cannot be institutionalized or standardized' (641) [11] as the process of standardisation or institutionalisation inevitably involves acts of caring less or carelessness, problematising RI which seeks to embed 'care for the future' in institutional processes.

These arguments are also developed in a rich and diverse literature on vulnerabilities, which has grown from feminist work on the ethics of care [13] and STS analyses of innovation [7] [14]. The starting point for many feminist analyses of vulnerability is that the human body and subject is inherently vulnerable, and in need of care [15–17]. Vulnerability, or the human capacity to suffer, therefore brings with it certain kinds of moral and political obligations to intervene, innovate, care. This reminds us to consider how innovations, be they technological or social, address vulnerabilities, meet material, bodily and psychological needs; how they prevent exploitation; and how they protect us from hazards. However, thinking with vulnerability also focuses attention on the

dynamics of inequality, power and dependency. Crucially, this invites us to consider what kinds of vulnerabilities might be produced by innovations, once more extending the 'matters of care' that RI typically focuses on — risks, benefits and impacts - to consider how innovations impinge on the psychosocial and existential as well as the values and dynamics of the collective.

From an STS perspective, Hommels et al. [14] emphasises the 'natural', social and the technical dimensions of vulnerability, casting vulnerability as an 'emergent property of systems' which is neither intrinsically positive or negative (6). These scholars are particularly interested in the vulnerabilities engendered by *dependency* on complex technological systems, highlighting the problems of 'rule following' in engendering a lack of care or responsiveness in relation to hazards as they develop. They also explore the creative possibilities of vulnerability — the impetus to learn and innovate in flexible and open ways, including via 'breaking the rules' imposed to protect against vulnerability and the benefits of being sensitive to a diversity of perspectives shaped by vulnerability in being reflexive about innovation priorities [7]. Once more this asks us to engage with a wider repertoire of caring practices and responsibilities than RI agendas might suggest. It also raises the possibility that innovations and indeed frameworks for RI might engender carelessness — i.e. dependency, insensitivity and a lack of reflexivity - despite the best intentions of their innovators.

Together these critical approaches to responsible innovation, care and vulnerability raise three particular challenges to frameworks for responsible innovation which emphasise responsiveness and collective care for the future.

Firstl, they suggest the need to engage more fully with the power and knowledge politics involved in the innovation process: or as van Oudheusden [6] put it, economics rather than ethics. This requires that we consider the role of the market in addressing and generating vulnerabilities and what this means for responsible innovation. We also need to consider how the market provides technological solutions to want and disease via innovations sold as commodities and how these processes can generate vulnerabilities because they distribute resources unevenly on the basis of ability to consume not on the basis of need [5,18].

Secondly, these literature suggests the need to grapple with the problems that arise when innovations designed to empower or enable individuals or groups labelled as vulnerable or in need of care are experienced by individuals as disempowering, or paternalistic [17]. For example, as Brown's work [19] suggests, technologies that are focused on 'giving back' autonomy to vulnerable individuals tend to focus attention on 'fixing' individuals, rather than the structures that generate their vulnerability. We need to consider what this kind of disconnection between the intentions of innovators and the experiences of users means for agendas for responsible innovation.

A third area for further consideration is the vulnerability of innovations and the technological systems they are part of and how this impacts on users and innovators alike. Innovations can also produce dependencies which, in turn, produce vulnerabilities when innovations or markets fail [20]. Users can be rendered vulnerable when they can no longer access the technologies, and technologies and market are also rendered vulnerable when the infrastructure they are part of fails. Similarly, innovators, producers and providers are vulnerable to a decline in uptake or failing infrastructures and to the lack of flexibility in rule-bound systems [14]. This raises the question of who cares and how care is distributed across networks of engineers, markets and innovations as well as their users [21]. In the landscape of new technologies it is especially important to consider the vulnerabilities associated with the data that many of these technologies and the innovators and users they are connected to generate, distribute and utilise [22,23].

In the remainder of this paper we explore the complexities of responsibility, innovation, care and vulnerability by reflecting on the social and ethical context of precision medicine in an effort to further elaborate the limits of responsible innovation. Precision medicine is an exemplar of the kind of multi-layered processes of technological and social innovation, and the complex regulatory and market systems in which innovators are currently working. It is also an example replete with numerous vulnerable actors, and complex dynamics of care. As such it provides fertile ground for thinking about the conceptual and practical limits of RI. Here we seek to move beyond thinking of responsibility and innovation only in relation to technological innovations, or innovations which generate economic growth, at the same time as reflecting on the complexities and paradoxes of care involved in innovation practices. We then turn to explore complexities of vulnerabilities associated with markets, patient and carer experiences and data networks. Note that our purpose is not to present a case study of precision medicine or systematic analysis of RI frameworks; nor do we seek to develop a refined framework for RI. Instead we are offering a critical exploration of responsibility and innovation via some illustrative examples of the complexities of precision medicine in an effort to better understand the limits of contemporary RI agendas.

2. Precision medicine

Recent developments in high throughput genomic sequencing, coupled with rapid advances in understanding of the genomic basis of diseases like cancer have transformed biomedical research. In countries like the UK and USA high profile national initiatives have been launched to harness the power of patient data to identify genes involved in disease and develop targeted treatments and therapies (see for example [W2, W3]). These initiatives seek to build on the paradigm of personalised or targeted medicine in fields such as oncology where some cancer patients, for example breast cancer patients with HER2 positive or oestrogen receptor positive cancers are offered targeted treatments as part of their care. A growing list of drugs have been developed, particularly for blood, breast, colorectal, kidney, lung and skin cancers (see [W4]). Some of these drugs are available to patients in publically funded health care systems, but costs are high and benefits difficult to quantify without controversy, leading to high profile disputes between some regulators and pharmaceutical companies such as the recent dispute between the UK's National Institute for Health and Care Excellence which approves medicines for NHS use, and Roche, the manufacturer of Kadcyla, a treatment which costs approximately £90,000 per patient (see [W5]). Precision medicine also has implications for biomarker monitoring for patients, including those at risk of cancer developing or returning. This can involve the identification of new subtypes of cancer which may be treated differently. It can also apply to monitoring the progression of disease. A particular promise of these approaches is that they could help to minimise the use of invasive tissue biopsies, using blood tests instead.

For the most part, precision medicine is a research initiative, and its impact on routine diagnosis and treatment in the clinic has been relatively modest. Patients are increasingly involved in providing data for these programmes via large scale clinical trials and studies which produce, link and share increasingly detailed clinical, social and biological patient data. Although the collection and use of this data has caused concerns and anxieties around privacy and exploitation [24], participation is key: precision medicine has also enrolled patients as participants, as described in the 'P4' paradigm of precision medicine as 'predictive, preventative, personalised and participatory'. Here patients and publics are not only providing

data, but participating as campaigners, advocates and commentators on trials, treatments and tests [25].

2.1. What kinds of innovation are involved in precision medicine?

Precision medicine is typically framed as a set of technological innovations which are responsive to the needs of the population in a way which traditional forms of medicine have not been. To realise these benefits, emphasis is placed on 'scaling up' tests and treatments via a range of state and industry programmes and investments. For example, the Precision Medicine Catapult, aims to 'make the UK a world-leading centre for precision medicine' [W6] by accelerating precision medicine so that the advances of research and innovation can be more widely available. Stratified Medicine Scotland [W7] is a 'platform for collaboration linking Scotland's expertise, data assets and delivery infrastructure to accelerate the real world adoption of Precision Medicine'. Emphasis is placed on innovations in the life sciences, genomics and data analytics.

These characterisations of innovation in precision medicine also involve discussion of the ethical or responsible innovation of tests and treatments, in particular the need to accelerate developments so that they can be accessed by more patients (e.g. Ref. [26]) and the need to store and share data responsibly (e.g. Ref. [27]). RI agendas for precision medicine focus on these kinds of issues through public deliberation and engagement around what kinds of data ought to be collected and shared for the public good (e.g. [W9]).

When we broaden our conceptualisation of innovation beyond these core technologies, we nevertheless find that a range of other issues around how to care for participants, data, technologies, citizens and healthcare processes and practitioners arise. Precision medicine involves innovations in the role of patients, publics, scientists and healthcare professionals, as well as in the stewardship of data. As Keating and Cambrosio's [28] analysis of contemporary oncology suggests, it is part of a platform of technological innovations which have transformed the nature and scope of clinical trials and studies and given them a prominent place in the institutions of healthcare, so much so that for patients experiencing diseases like cancer, it is becoming more of an expectation rather than an exception for them to be part of a trial or study during their treatment. Precision medicine requires this industry of trialists and research participants in order to be a successful innovation. These 'upscaled' trials are an innovation in their own right and they bring with them innovations in terms of the flow of information, consent procedures, and professional practices, e.g. multidisciplinary team meetings and procedures for removing, transporting and storing tissue. In addition, in order to recruit patients to these studies and trials, healthcare organisations are developing increasingly sophisticated public relations and media campaigns, often in partnership with patient organisations as co-producers. This constitutes an innovation in ways of working with patients or interested publics but it also constitutes an innovation in the nature of patienthood.

Through these broader social and technical innovations, patient, public and practitioner responsibilities are developing and changing, as are the practices of care with which they are involved. Patients are no longer simply responsible for their own health but for future patients — be they family members or wider groups of strangers sharing a similar genotype. Patients and associated publics have acquired responsibilities as co-innovators rather than as passive recipients of these technologies. And healthcare managers, scientists and other actors involved in the delivery of precision medicine have taken on responsibilities for transforming the health service to make precision medicine workable. This might involve reworking or restaging information, data or research protocols, as

well as recycling of old materials and infrastructures, including, for example, biological samples and health records, albeit with the innovation of new ways of seeking and securing consent for such processes. Deliberation is also a new kind of responsibility which comes alongside technologies like precision medicine.

Looking at innovation across this suite of interlinked activities suggests that responsibilities for professionals, participants, and publics are proliferating in the precision medicine era, but a narrower focus on precision medicine as a form of technological innovation which in turn places emphasis on responsibilities for risk mitigation via engagement leaves little space to consider the implications of these changes and the kinds of burdens, responsibilities and unintended consequences they might bring to an array of involved and marginalised actors. Instead we need to look at how these developments are reconfiguring practices of care more broadly: who cares, what do they care about, and what kinds of carelessness does this engender?

2.2. What kinds of care does precision medicine involve and for whom?

Fostering awareness of the kinds of individuals, institutions and things that innovations allow to flourish is, of course, a laudable aim of RI. But it is also important to ask who does this work of caring for the future, and who experiences or is likely to experience these ways of caring as positive or negative? We already know that care is often devalued work, performed by the socially marginalised. Does this happen in the case of responsibility-work conducted in relation to precision medicine? Are particular kinds of scientific and healthcare workers, or indeed volunteers, doing this work more than others, and is this work performative, i.e. happening at a distance from the main innovation process, with little profound effect on how it unfolds?

There are reasons to think that this might be the case, when we look at the kinds of public caring about the future of healthcare that particular actors are performing in relation to precision medicine: former patients, journalists and scientific commentators are involved in a wide array of public discussions about these important innovations, fostering debate and critical dialogue with interested patients and their carers and families. Caring in these ways is a time-consuming business for some of these actors, who can develop a portfolio of commitments to various involvement initiatives and events. This inevitably means that certain kinds of people become more involved than others — participants are more likely to have reserves of social and financial capital to draw upon than others who have less time and feel that they have less to contribute. This then shapes the kinds of cares being articulated through these processes, as well as creating a group of more marginalised actors who might be cared about in their absence, for example people living in poverty. It also generates a need to care for the carers, who devote their time and energy to these processes. For example the nurses and administrators involved in engagement activities perform the bulk of this kind of emotional labour ontop of an increasing patient case load, and there is a need to distribute and recognise this work properly. As Sinding and colleagues [29] have also documented, tensions and inequalities that come with patients taking on responsibilities to represent the views of other patients in consultation processes, in particular, 'initiatives that endorse and promote 'the involved patient' can function to exacerbate health care and social disparities' (400).

At the same time, this public engagement care work does not capture the messy kinds of care work required of research participants in precision medicine. As Day et al. (2016) [30] have recently noted, precision medicine intensifies the navigation labour for patients and their carers, due to the increasing levels of work. There

is a lot of work involved in keeping a person on a trial: managing side-effects, ensuring transport is available, waiting around whilst treatments are administered, keeping a watchful eye on how things progress. This is the emotional, often dirty side of care-work, that tends to fall to women and other low paid or unpaid kinds of workers [31,32], but it does not often figure in the kinds of 'collective care for the future' associated with frameworks for responsible innovation.

Another feature of care work also requires some consideration here: namely its potentially oppressive qualities: to be 'in care' or 'in need of care' can restrict freedoms. Surveillance can be positioned as a form of care, as can restrictions on diet or movement, but these practices might not be experienced as caring. Might then the kinds of regimes associated with participation in precision medicine be experienced as restrictive by some kinds of patients or participants? Could taking up the opportunity for better care via new tests or treatments, or participating in studies or trials associated with precision medicine, actually be experienced as less than care, particularly if the person concerned is participating out of a sense of obligation, or compliance, for example with the wishes of family? This suggests the need to reconsider what kind of collective care RI demands and of whom, as well as its 'dark side'.

2.3. An exploration of vulnerabilities associated with precision medicine

Precision medicine is often billed as a surgical strike on faulty genes or other kinds of biological functions gone awry — or as a means of protecting the body from these vulnerabilities. It nevertheless introduces a complexity of vulnerabilities through these processes, given the dynamism of the social and biological arrangements of which it is a part. In this section we explore some key features of this complexity of vulnerability and what it means for RI.

2.3.1. Markets

We focus first on the vulnerabilities addressed and introduced by the market in precision medicine: a political economic arrangement which has profound and particular implications for how the benefits of precision medicine are distributed, but which is not fully considered in RI frameworks which privilege the ethical over the economic [6]. Precision medicine is often presented as an important stimulus for economic growth in particular national contexts. However, patients' access to these treatments is also limited by affordability [33]. The state is investing research resources and in some cases public infrastructure (e.g. UK National Health Service) in an effort to stimulate this market, but is also regulating the technologies to ensure that public money is spent wisely — this means that not all patients are able to access these treatments funded by the state [34,35]. There is a pathogenic vulnerability [14] here: innovation which benefits the economy may be stimulated by the market system but their value in terms of patient benefit is not being realised across the nation. Reduced access to these treatments renders already vulnerable patients, particularly those with limited resources, more vulnerable as compared with wealthier others who are able to benefit from these treatments. Within this kind of market system, the innovation process means that only certain futures are cared for.

As Day et al. [30] have also noted in their study of precision medicine in breast cancer, the processes of specialisation stimulate outsourcing of particular aspects of care work to external parties, contributing to the marketisation of public health systems like the UK NHS. This has wider ramifications for patient care across the health system, as private providers take on an increasingly prominent role in care. They note:

the practices of stratified medicine have an elective affinity with both the outsourcing of particular support services and occupational specialisation, suggesting that an indirect relationship exists between developments in these different forms of stratification. As far as clinicians and patients were concerned, the spaces for holistic care have become more and more restricted. (10) [30].

Thinking through responsibilities and innovation in precision medicine requires that we grapple with how the market operates as well as the implications of these developments for social justice and equity. However, there is little scope for engaging with these issues within RI frameworks which conceptualise innovations, responsibilities, care and futures primarily in terms of technology, ethics and stakeholder engagement. RI frameworks which focus on intervening in the activities of a limited range of innovators - such as scientists and engineers working in universities - are not well positioned to engage with the market in these ways, not least because of the way responsibilities for the market are so ambiguous and diffuse. There is also the challenge in giving voice to people's experiences of new technologies when they do not conform to the promissory agendas of market and state providers, especially when they contradict their stated aims and benefits. A thoroughgoing analysis of responsibility and innovation also require that we engage seriously with the 'dark sides' of markets and their potential undermining of public systems and resources.

2.3.2. Experiencing precision medicine

We also need to consider the vulnerabilities that patients and carers experience when encountering precision medicine, particularly in relation to the emphasis on individualisation in precision medicine. As patients negotiate the 'political economy of hope' [36] around treatment, their expectations are raised and sometimes dashed as their treatment progresses, including when they seek out access to experimental medicines through trials, sometimes far from home. Day et al. [30] note that patients in their study experienced a less rather than a more personalised service because they were often on the move between different kinds of specialists and care providers. More generally, other studies suggest that patients or people who have experienced diseases like cancer can also be rendered vulnerable by discourses of empowerment or survivorship, which emphasise the need to be active, informed and participating in the latest tests, treatments and public discourses of triumph and solidarity [37,38]. Although images of suffering can be a force for social solidarity and concern [39], they can also be experienced as alienating for those in the same situation, who are unable or do not wish to share in this way [40]. These patients are vulnerable to feelings of being 'out of place' as well as experiencing stigma and social opprobrium should they not wish to participate in heroic, experimental or tailored treatments.

Precision medicine is very much focused upon offering patients choices around their treatment to tailor their treatment more effectively. This is part of a wider menu of choices which patients navigate in the course of their treatment: choice about what trials or studies to participate in, what hospital to attend, what consultant to see, what treatments to take, what information to access, what support groups to attend, what data or tissue to share or donate, what information to discover. Choice is often held up as a means by which to protect against vulnerabilities [41]. However, choice, like care and markets, has its dark side. Choice can be experienced as an onslaught of options and opportunities, which can render patients and their families feeling vulnerable, despite the best intentions of care providers and the scientists they work with [42]. Too much of an emphasis or reliance on informed choice

as a way of managing decisions about tests and treatments can also lead to problems with over-diagnosis and a transfer of responsibility from physicians to patients in a way that causes anxiety and feelings of guilt or regret for patients experiencing the 'diagnostic cascade' which follows [43]. It is also well documented that an individual's capacity to choose is limited by a range of cognitive, health and psychosocial factors, so choice does not provide a 'level playing field' in the battle for health [44]. The tensions around choice also extend to the period before or after treatment — when individuals are 'at risk' or 'in remission'. How to choose the best lifestyle and monitoring regime to ensure continued health? Hallowell et al. [45] have amply demonstrated the anxieties and responsibilities towards family members which these kinds of tests and information can generate, as individuals make choices about when to know and when to share information of relevance. This also applies to the disclosure of 'incidental findings' generated by precision medicine, whereby patients have to make complex decisions about what they may want to know about their or a members of their families' risks of developing other diseases in the future at a point at which they are particularly vulnerable because they are suffering from the effects of their disease and treatments [46]. Here the benefits patients might derive from information about their health is potentially undercut by the problems of providing information which is upsetting or difficult to manage within the family, putting secure identities and relationships at risk.

Experiences of precision medicine are diverse, unpredictable and contradictory; they are part of an ongoing and dynamic process of distributing responsibilities, sometimes in uncomfortable and unwelcome ways. Greater choice can be experienced as a burden rather than a benefit. Yet there is very little space to consider and explore these complex and often highly personal decisions and experiences within contemporary agendas for responsible innovation focused on 'collective care for the future'. Although emphasis is placed on inclusivity in these deliberations, there are numerous challenges in enabling individuals to appreciate or even voice feelings and concerns about their responsibilities for care, treatment, diagnosis and research in frameworks designed to address responsibilities at this meta-level. There is also a lack of scope for critically reflecting on the wider issue of how being involved in deliberation is itself a kind of responsibility which is differentially distributed and rewarded.

2.3.3. Data

There is an extensive literature on how to ensure the security of personal and health data in genomic and biobank research [47]. There is also considerable public concern about the sharing of personal health data, especially with insurance providers and other commercial organisations, as the debacle over the recently closed UK government's Care. data initiative demonstrates [48]. However, there are powerful and concurrent drivers of health and social data integration and sharing, which concerns around protecting individual privacy are unlikely to quash: scientific, public health and commercial organisations are heavily invested in capitalising on the enormous wealth of data which could be used to develop new health interventions and treatments in the public and patients' interests. The UK's 100,000 Genomes project [W9], which will harness patient records and genetic information on cancer and rare diseases to generate targeted treatments, is an example of this kind of initiative in precision medicine. This involves a collaboration between the UK NHS and Illumina, a private company providing the high through put sequencing technologies required to analyse this data, requiring extensive revisions to participating institutions' laboratory, data and information management practices to enable the data to be collected and shared in timely fashion. This initiative

is rightly concerned with public engagement in order to secure patient participation and trust in its practices. As part of this a range of public education and consultations activities are embedded in the project, activities which mirror the wider emphasis on public consultation on data security and consent processes for participants (as highlighted in the Caldicott review [W10]).

Although there is a clear engagement with responsibilities here, vulnerability is being constituted in a limited manner as belonging to individual patients or research participants who need to be protected from inappropriate use of their data by a range of institutional processes of consultation, engagement, involvement, protocols and procedures. Framing vulnerabilities in this narrow way places considerable reliance on patients or research participants taking the ultimate responsibility for their choices through the informed consent process. But as Dijck [22] argues, the lack of transparency around how data is used means this consent is not always well informed. Narrow framings of vulnerabilities as a matter of informed consent for particular uses of individual health data also fail to take account of all of the other kinds of personal data and processes of collecting and profiting from that data which might evolve alongside this initiative. As recent controversy over the ownership of a database of the DNA of Sardinian residents reveal, even when private companies are not initially part of research consortia, they can become involved when the data is sold on [49]. As Lupton [23] has suggested, as sickness is monetised patients are often unaware of how their data is being used.

Processes such as informed consent, which are designed to mitigate particular, largely individual, vulnerabilities, but do not take account of how vulnerabilities manifest in complex ways, have the potential to create other kinds of vulnerabilities for collectives too. In the case of large scale state-market collaborations such as the 100,000 Genomes Project there is also the vulnerability of the health service to consider. This is under particular strain due to population ageing and pressures on public finances, but new initiatives such as this project require considerable investment in new processes and arrangements which go beyond project support to encompass widespread transformations in the way services are offered. There is, however, little sustained reflection on this implementation challenge in the public sphere; indeed our research experiences suggest it can be difficult for senior managers to articulate these concerns publically because of the need to promote the benefits of the programme inside and beyond their organisations. This involves professional, institutional and organisational vulnerabilities which are not readily addressed in current efforts to involve stakeholders and anticipate risks, focused as they are on the business of patient recruitment.

This example illustrates how institutional approaches to managing risks and responsibilities of research and innovation in precision medicine can frame responsibilities in limited ways and place considerable burdens on patients and participants in the process. We suggest that there are parallels here with how RI frameworks operate, typically in institutional contexts which are designed as part of planning for public investment in particular initiatives, suggesting that these initiatives might also take a limited approach to responsibility and innovation by framing these developments narrowly in terms of participation in programmes and projects, and using established tools for addressing this, such as informed consent processes, for example. As with engagement activities more generally, this limits RI in that it is not well placed to capture and engage with the complexities of data practices and the vulnerabilities they bring, especially when potential participants are not sufficiently aware of or do not feel able to articulate the risks these technologies might bring.

3. Vulnerabilities and possibilities

How, then, might a better appreciation of the distributed and ongoing processes of responsibility and innovation, and the political and economic dynamics of care and vulnerabilities enable new insights into how to engender responsible innovation of precision medicine and other related technologies? In this paper we have explored how responsibilities, care and vulnerabilities can be framed in somewhat narrow ways in agendas for RI, and tried to widen the field of consideration by exploring the dynamic features of socio-political, institutional sociotechnical assemblages in which these technologies and the people who might use them are involved via the case of precision medicine. We have outlined the nexus of technological and social innovations of which precision medicine is a part, and the reconfigured caring responsibilities that this has involved, particularly for patients and their carers navigating complex care pathways and being involved in deliberation and consultation exercises. We have also explored how efforts to mitigate but also moderate the vulnerabilities of the body to disease via more targeted diagnostics and therapies can magnify other kinds of private and public vulnerabilities, particularly for individuals affected by disease, but also for the practitioners and institutions trying to help them. An important theme in this paper has been the importance of considering vulnerabilities as relational, dynamic and inter-connected, and of looking beyond simplistic approaches to their solution based on novel technologies, greater choice or institutional procedures. We have argued that it is important to consider the different kinds of demands, care and emotional work and choices that patients and practitioners, as well as families and policy and public actors more generally, must face when negotiating precision medicine and its possibilities, and how these practices can mediate, but also exacerbate, particular vulnerabilities. These kinds of considerations need to be more effectively woven into policy and institutional discourses and processes, decisions and practices, in order to minimise vulnerabilities locally and further afield.

Exploring vulnerabilities has helped to flesh out the range, possibilities and pitfalls of collective caring for the future suggested by RI frameworks with respect to different social groups, technological entities and spaces/timeframes of care. A vulnerabilities heuristic places social, technical and biological contingency and dynamism centre stage and protects against any simplistic forms of determinism or naive consensus around what constitutes responsible innovation. By attending to how it feels to be sick or to be in treatment, or worried about potential illness in the future, and exploring a wider set of institutional and politico-economic arrangements through which these concerns and experiences are configured, the lens of vulnerability also allows us to approach responsiveness with both the individual and the social order in mind: to 'care with' rather than 'for' the future [13]. Vulnerability is also a good heuristic for thinking about the pernicious and unintended consequences of some efforts to respond to vulnerability and, on the other hand, the positive outcomes which can arise from individual experiences of vulnerability where these give rise to efforts to improve social solidarity and social justice.

Thinking with vulnerability also draws our attention to two of the most overlooked dynamics of the contemporary age — first the limits of choice as a form or a goal of responsiveness, and secondly the dangers of social control arising from efforts to identify and intervene in the lives of so-called vulnerable individuals and social groups. Attending to the limits of these strategies is important for RI more generally, given the extent to which choice has come to dominate a range of life strategies in contemporary consumer society and persistent challenges of social marginalisation and inequality for those experiencing poverty, disability and discrimination, practices which limit both the possibilities of technological innovation and the good society.

This suggests that responsible innovation initiatives need to be more open ended and creative about the ways in which they provoke new ways of thinking about and practicing innovation, including alternative social innovations which complement or address other kinds of needs. There is a pressing need to critically engage with markets and the kinds of choices and responsibilities they bring, and to exercise caution around involvement and engagement agendas which create more work for particular kinds of patients and publics. There is also a need to consider the dependencies and inter-actions between different kinds of innovations, both social and technical, and to think about the sorts of innovations in, for example, healthcare delivery, financial models, data and profit sharing and other infrastructures of care that need to co-evolve alongside technical innovations to ensure their benefits are widely distributed and shared. At the same time, there is a need to appreciate the limits of what any kind of responsible innovation agenda might achieve: it is possible for critical reflection to stimulate other ways of innovating and supporting individuals and communities affected by ill-health, but RI needs to be part of a wider programme of social change in order to be successful in this regard.

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