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Promissory identities: Sociotechnical representations & innovation in regenerative medicine

John Gardner [a, *], Ruchi Higham [a], Alex Faulkner [b], Andrew Webster [a]

[a] Science and Technology Studies Unit, Department of Sociology University of York, Heslington, York, YO10 5DD United Kingdom
[b] Centre for Global Health Policy, University of Sussex, Falmer Brighton, BN1 9RH, United Kingdom

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ABSTRACT

The field of regenerative medicine (RM) is championed as a potential source of curative treatments and economic wealth, and initiatives have been launched in several countries to facilitate innovation within the field. As a way of examining the social dimensions of innovation within regenerative medicine, this paper explores the sociotechnical representations of RM technologies in the UK, and the tensions, affordances and complexities these representations present for actors within the field. Specifically, the paper uses the Science and Technology Studies-inspired notions of 'technology identity' and 'development space' to examine how particular technologies are framed and positioned by actors, and how these positionings subsequently shape innovation pathways. Four developing RM technologies are used as case studies: bioengineered tracheas; autologous chondrocyte implantation; T-cell therapies; and a 'point-of-care' cell preparation device. Using these case studies we argue that there are particular identity aspects that have powerful performative effects and provide momentum to innovation projects, and we argue that there are particular stakeholders in the UK RM landscape who appear to have considerable power in shaping these technology identities and thus innovation pathways.

1. Introduction

Innovation in healthcare has become the subject of considerable critical attention in many industrialised countries. Within political and policy discourse, medical innovation is framed as providing improved clinical outcomes and generating economic wealth, but also as a problematic, complex process hindered by institutional, regulatory and cultural constraints. This narrative is particularly strong in the emerging field of regenerative medicine (RM), which entails the use of cells, tissues or genetically-edited elements as therapeutic agents. RM is championed as a potential source of curative treatments for a wide range of ailments, and it has been identified by governments as part of their economic growth strategies: the UK has identified RM as one of 'eight great technologies' which has the potential to become the basis of a high-wealth, knowledge-based economy (Willetts, 2013). Initiatives have been launched to identify innovation challenges within RM, and to devise strategies for managing these (Department for Business Innovation and Skills, 2011; UK Research Councils, 2012; Regenerative Medicine Expert Group, 2015; House of Lords Science and Technology Committee, 2013). The perceived challenges identified include: bureaucratic research governance frameworks and inflexible clinical trial methodologies; a complex and inconsistent EU-level regulatory framework; manufacturing and scale-up of live-tissue production; uncertainties over cost-effectiveness and reimbursement; the implementation of potentially disruptive systems within busy, resource-strained clinical contexts; and a lack of investment from private funders (Gardner et al., 2015). Indeed, commentators have suggested that the emerging RM field is to some degree incommensurable with the current healthcare system and governance structures that have emerged to accommodate drug and device-based therapies (Omidvar et al., 2014).

In this paper, we explore the social and cultural dimensions of innovation within the emerging field of RM, focusing predominately on developments in the UK. Specifically, we examine the sociotechnical representations and positionings of RM technologies to interrogate the tensions, affordances and complexities of innovation in the field. To do so, we draw on and adapt Science and

* Corresponding author.
E-mail addresses: john.gardner@york.ac.uk (J. Gardner), rh955@york.ac.uk (R. Higham), A.Faulkner@sussex.ac.uk (A. Faulkner), andrew.webster@york.ac.uk (A. Webster).

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Technology Studies (STS) -inspired concepts of *technology identity* and *adoption space* (Tomlin et al., 2013; Peirce et al., 2015; Ulucanlar et al., 2013). The advantage of this framework is that it brings to light the mutually configuring relationship between a technology and actors in a specific sociotechnical context, and the effect that this has on the technology's ongoing development. It enables us to examine how RM technologies are understood by those in the field in terms of perceived challenges, affordances and expectations, and thus how innovation pathways are collectively negotiated. We use these analytical concepts to explore four developing RM technologies: bioengineered tracheas; autologous chondrocyte implantation (ACI); T-cell therapies; and a 'point-of-care' cell preparation device. Using these case studies we will show that there are particular identity aspects that have powerful performative effects and provide momentum to innovation projects, and we argue that there are particular stakeholders in the RM landscape who appear to have considerable power in shaping these technology identities and thus innovation pathways.

2. Innovation, technology, and identity

Technology identity and *adoption space*, as conceptualised by Tomlin and colleagues (Tomlin et al., 2013), have their theoretical foundations in sociology and in Science and Technology Studies (STS). To introduce these concepts, we provide a summary of some key theoretical tenets of these fields (and STS in particular) as they relate to the study of innovation.

The most important of these tenets is *relationality*. According to this, the meaning of an entity (whether it be a molecule, a technology, or social organisation) is not the result of its inner 'essence'; rather, it is a consequence of its immersion within networks of other technologies and systems of meaning making. These networks render entities intelligible by foregrounding certain potentialities (or what DeLanda (2006) has called capacities for interaction) and endowing them with meaning, while eliding other potentialities (Latour and Woolgar, 1986). In effect, then, the intelligibility of an entity such as a healthcare technology depends on the context within which it is immersed, and the same entity may be thus rendered intelligible in multiple ways. Hence, the second tenet is an acceptance of *multiplicity*: co-existing socio-technical networks may produce divergent renderings, sometimes in tension with one another (Mol, 2002; Pollock and Williams, 2010). Third, the definition of what constitutes an *'actor' does not exclude non-human entities*. A healthcare technology, for example, can be said to have agency in that it prompts, guides, constraints and transmutes the action of other entities including human agents (Latour, 2005). This is not to say that such entities determine the action of others; rather, an entity possesses affordances for further action, along with *interpretive flexibility* (Pinch and Bijker, 1984) - the fourth tenet. This means that precisely how an entity such as a healthcare technology prompts action will depend on the local meanings within which it is immersed. Combined, these tenets characterise the world as being constituted by heterogeneous material and discursive networks which produce and reproduce various kinds actors: technologies, individuals, social groups, and so on (Law, 2008).

The concepts of technology identity and adoption space reflect these key tenets. In their study of medical device adoption in healthcare, Tomlin and colleagues argued that technologies acquire particular identities that shape their adoption and dissemination (Tomlin et al., 2013; Ulucanlar et al., 2013). Technology identities are heuristic narratives; they are, as Ulucanlar and colleagues define them:

> A narrative or discursive presence of the technology that delineates a particular set of attributed characteristics and performative expectancies as representative of the technology's distinctiveness and value (2013, 98).

Identities are forged and contested within what Tomlin et al. (2013) define as the *adoption space*: the institutional context and socio-political environment within which the technology is mobilised. The former is composed of socio-technical infrastructures including technologies and tools, protocols, professional interests and institutional strategies, while the latter is composed of, for example, media coverage, public attitudes, and political discourses. Collectively, these elements imbue a technology with identity attributes; they render it intelligible as being, say, 'revolutionary', 'cost-effective', 'difficult to use' or 'implausible', by foregrounding some attributes of the technology while eliding others. Adoption spaces are also dynamic: a new policy initiative, the emergence of competing technology or some other contextual change may radically affect a technology's identity. Importantly, these identities inform decision-making processes regarding the adoption of the technology in clinical contexts: they shape "perceptions in ways that are instrumental in decisions about its use" (Ulucanlar et al., 2013, 98).

We believe that with some minor adjustment, this framework can provide a fruitful analytical vehicle for exploring healthcare technologies that are still being developed. As the sociology of expectations literature has made clear, the 'momentum' of innovation is often the result of promissory, future-orientated representations which function to align diverse interests (Borup et al., 2006). This has certainly been the case with RM (Morrison, 2012; Oerlemans et al., 2014; Gardner and Webster, 2016), characterised by high expectations but no widely-implemented routine therapeutic technologies. We suggest that emerging RM technologies inhabit a *development space*, conceptually complementary with the notion of adoption space, but likely to include the characterisation and positioning of novel technologies in anticipation of their adoption in a clinical setting. It can be defined using a slightly adjusted (in italics) definition of adoption space (Ulucanlar et al., 2013, 98):

> A spatial and temporal space transcending organisational and geographic boundaries and populated by human and non-human actors from different social worlds, where attitudes, practices, interactions and events, together with the *developing* technology's material features, shape technology perceptions in ways that are instrumental in decisions about its *further development and* use.

In this paper, we apply this analytical frame based on *technology identities* and *development spaces* to interrogate four case-study RM technologies and techniques. These are case studies which have what can be described as promissory identities: considerable (although not uncontested) high expectation surrounds their envisaged potential.

The case studies are paradigmatic of emerging areas within RM: they inhabit a field that is rich with 'matters of concern' (Latour, 2005), including, for example: the safety of therapeutic cells; the acceptable level of uncertainty regarding clinical effectiveness, safety, and cost effectiveness; and a concern that the promise of RM will fail to materialise. Development spaces potentially include the various bodies that have emerged to address such concerns (for instance cell and tissue banks, and innovation accelerator agencies), as well as pre-existing actors within the healthcare landscape (regulatory agencies such as the European Medicines Agency, patient charities, professional associations, hospitals, health technology assessment bodies, and the media). RM