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Andrew Webster & John Gardner

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Aligning technology and institutional readiness: the adoption of innovation

Andrew Webster[a] and John Gardner [b]

[a]Department of Sociology, University of York, York, UK; [b]School of Social Sciences, Monash University, Melbourne, Australia

ABSTRACT

This paper explores and develops the concept of 'readiness' as it relates to the adoption of innovation. In particular, the paper discusses readiness in regard to the notion of 'technology readiness' levels, widely used today by both producers and users to monitor and manage emergent innovation. The paper argues that, while useful, this notion needs to be informed by and subsumed within a broader concept of 'institutional readiness'. The latter is especially important in conceptualising how new technologies are actually adopted in organisational settings. The paper develops a model of institutional readiness that recognises the saliency of technology readiness but which embeds it within a broader socio-technical framework. This is illustrated with reference to the emerging field of regenerative medicine.

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Introduction

The challenge associated with novel technology and its adoption is one that has figured for many years in the policy domain. It is often argued, especially in the UK context but also elsewhere (e.g. ACOLA 2015), that innovation systems can be highly generative of new technologies but equally very poor in ensuring they are taken up and implemented at scale within national settings (Edquist 1997).

It is this concern over the failure of innovative ideas and technologies to be successfully deployed that has generated the extensive literature on the challenge of adoption and implementation (see review by Nilsen 2015), which often makes references to the 'valley of death' (Butler 2008), the problems of market failure (Martin and Scott 2000) and the 'barriers' (e.g. Antoniou and Ansoff 2004; Baldwin and Lin 2002; Meijer 2015; Mohnen et al. 2008) working against technological innovation and its 'diffusion' (Rogers 1995). Similar concerns underpin the perceived need for agencies facilitating technology transfer (Rogers, Takegami, and Yin 2001), and the widely used notion today of technology 'translation'. Not surprisingly, within science and technology policy, we see a wide variety of initiatives designed to bridge between the supply of and the demand for innovation, including the establishment of dedicated translational centres (Edler and Yeow 2016).

In many ways these arguments and policy initiatives suggest a strongly held view that there is a lack of receptivity *for* new technologies. The explanations for this vary. Most of these commentaries contrast a person's or group's preparedness to be innovative with being risk-averse or cautious about new ideas (see e.g. Elliott, Hall, and Meng 2008; Khalil 2011; Kuo, Liu, and Ma 2013; Rojas-Méndez, Parasuraman, and Papadopoulos 2017). Elsewhere, contributions in management studies focus on the organisational receptivity for new technology (whether that technology be incremental or

CONTACT Andrew Webster andrew.webster@york.ac.uk Department of Sociology, University of York, York YO10 5DD, UK

radical in nature) that stress the need in particular for 'change managers' to open a pathway for adoption (Shaw 2012).

It is then somewhat surprising that these contributions have failed to engage with and consider the merits of the concept of 'technology readiness', since this idea, initially developed over forty years ago in the USA, is primarily about how to prepare a new technology such that it is made ready for its deployment in a very specific (organisational) setting. It involves a detailed and highly deliberate process for determining the technology readiness level (TRL) of an innovative product (or practice) and the range of material and informational resources needed to develop the product to completion. As such, in principle such an approach should help to address some if not all of the concerns outlined above. What is even more surprising is that, though relatively ignored in the academic literature, TRLs are routinely used today in different industrial sectors in gauging the development and prospective market value of innovative developments, and as a touchstone by those accessing or buying-into such innovation as markers of utility and reliability. They are also used by funding agencies when advising developers and innovators on how their products need to be de-risked as they move up the TRLs (e.g. EPSRC 2018).

In light of this, it seems important to look at TRLs more closely from within a science, technology and innovation studies (STS) perspective, in order to both unpack the concept more fully, and to determine how it might benefit from being anchored in an STS-informed understanding of the context of readiness itself. This takes us away from the concept of 'barriers to innovation' which often carries negative connotations in regard to users' conservatism in response to supply-side innovation. Rather, readiness looks at the specific contexts within which innovation is engaged with and made sense of, and how, in doing so, is often adapted in order to be adopted. It also moves away from seeing technological innovation as an object or process that has a defined and stable set of properties which must be embraced by users: instead, innovations are re-configured by users as part of their 'normalisation' (May et al. 2011).

The principal questions this paper asks are what can we learn from exploring the relationship between technology readiness and work in STS which has examined the context of application of innovation; and, can we build a more nuanced model of technology/institutional readiness that draws on both? In doing so we move from an emphasis on the TRL's supply-side perspective to one that gives equal weight to the user-side perspective. The paper begins with an account of the origin of TRLs, then moves on to discuss their use and limitations before discussing the contrasting notion of institutional readiness. The term 'institutional readiness' has been used in specific fields (e.g. philanthropic studies) to explore field-specific organisational features are likely to increase the 'success' of an organisation (Barnes and Brayley 2007). Here, we develop a concept of IR that is theoretically grounded in STS and innovation studies, and we show how it can be usefully aligned with TRLs through drawing on empirical material from a recently completed research project that has examined the emergence of regenerative medicine. We conclude by arguing for a more complex but thereby more serviceable account of 'readiness'.

Technology readiness levels: origins and use

The TRL concept, which can be traced back to 1974, has its origins in NASA and subsequently the US DoD, used to monitor the progress of space and defence programmes to ensure any risks are known and manageable (though clearly in light of a number of tragic events, not always successfully so). Since then it has been widely embraced and enshrined in criteria that evaluate an emergent innovation in terms of its 'technology readiness level'. There are nine TRLs, from initial conception of an idea through to its deployment and actual use (see Figure 1), thus passing through levels which indicate significant steps as the technology 'matures'. This involves increasingly real-time demonstrator stages that validate the technology within its envisaged environment (such as within spacecraft). Technology adoption is thus a series of sign-offs to move through one risk-gate to the next and integrate innovation within a developing technology regime or system. Typically

9 Actual system "flight proven" through successful mission operations
8 Actual system completed and "flight qualified" through test and demonstration (ground or flight)
7 System prototype demonstration in a target/space environment
6 System/subsystem model or prototype demonstration in a relevant environment (ground or space)
5 Component and/or breadboard validation in relevant environment
4 Component and/or breadboard validation in laboratory environment
3 Analytical and experimental critical function and/or characteristic proof-of-concept
2 Technology concept and/or application formulated
1 Basic principles observed and reported

Figure 1. Technology readiness levels: NASA's original definitions.

this involves the approval of both hardware and software elements at ever higher levels of specificity in terms of their material configuration and performance (Lee, Chang, and Chien 2011).

TRL assessment commands considerable influence in innovation policy and procurement. For example, in the US, the Federal Aviation Authority and the Department of Energy use TRLs to assess and triage prospective technology developments, while in the UK the Nuclear Decommissioning Authority uses TRLs to assess component systems being prepared for decommissioning plants (NDA 2014). The European Commission's Horizon 2020 research programme (European Commission 2015) has also recently adopted TRLs within its COSMOS space research network. Given the context within which TRL modelling has developed, it is no surprise that its use has been principally in large-scale, high cost and high-risk settings, such as the development of the Space Shuttle (Mankins 2009). But it has not been restricted to these settings: elsewhere, TRLs have been adopted and adapted to serve more medium range/scale needs by international agencies (such as the OECD [Ekins 2010]), government departments, large companies and innovation agencies promoting early stage product development, such as the Cell and Gene Therapy Catapult in the UK (C&GTC 2017), to determine whether moves towards the market/end users by emerging products are likely to be timely, and technically and economically robust, as well as risk-managed.

Related approaches, though not using the language of TRLs as such, can be found in national public bodies that seek to embed emerging innovation within their constituent organisations. For example, US hospitals have adopted the Healthcare Information and Management Systems (HIMSS) Programme. This was originally concerned with appropriate digital standards, and is now used to define how digital systems meet specific organisational needs and at the same time how hospitals need to adjust to deploy new IT systems: HIMSS Level 7 is the current target for leading US hospitals. The UK's NHS has adopted a slimmed down version of this via its 'Digital Maturity Index' (NHS 2018).

As a technology management tool, technology readiness assessment is conducted at different stages in a developing technology system to determine its technical and economic costs, prospective economic value and possible risks. The TRLs also act to provide a common framework or management platform through which a very diverse range and large numbers of actors – designers, regulators, funding agencies, engineers etc. – can cooperate and communicate via shared TRL standards.

Given its use in a diverse range of systems within which technology is being developed, procured, and readied for market, it is surprising that TRLs have had relatively little consideration

in the field of innovation studies. Indeed, the possible contribution that TRL analysis might make is suggested by Nakamura, Kajikawa, and Suzuki (2012) who argue that the multilevel perspective (MPL) developed within innovation studies (Geels 2006; Kern 2012) should be complemented by a TRL approach. They argue that TRLs are useful in understanding how technologies are developed in fine-grained detail within a specific industrial sector, and how they might vary within that. This points to an important aspect of TRL; namely its attention to the specific material and technological characteristics of innovation, such as its component parts and their integration. This might then be of value in the broader analysis of 'emerging' technologies (Rotolo, Hicks, and Martin 2015).

At first sight, then, the TRL approach which envisages specific settings wherein the technology will be most effectively (and least riskily) used, might be seen as a useful adjunct to work in innovation studies. But this begs the question of how effective it actually is as a 'tool' in practice. There has been only one detailed qualitative analysis of the use of TRL by companies, provided by Olechowski, Eppinger, and Joglekar (2015). They find that there are three areas where problems arise in the application of TRL which relate to 'system complexity, planning and review, and validity of assessment' (2084). In brief, the first relates in particular to questions they raise about the need to recognise the growing complexity of a system as 'levels' combine and the discrete components become more plastic in doing so at their interfaces, such that an overall 'system measure' is a more useful marker of a workable technology. The second points up the difficulties associated with failure to integrate the TRL process within an organisation's business model and processes, while the third draws attention to the lack of precision in assessing TRLs and the 'tests' used to do so such that validation measures are open to doubt.

Despite this TRLs are used to underpin decisions to invest, further develop and deploy new technology. Such decisions are based on metrics of risk and technical standards for discrete components which are seen to confirm the 'maturity' of a particular piece of equipment at a particular point in time. What is important to note here is that the maturation process directly implies that the material properties of a technology change over time as tests are carried out and risks reduced. However, TRL also assumes that a technology/component is materially *the same* across different contexts of use as its materiality 'matures', otherwise there would be no basis for it to be signed-off at different stages for systemic use by multiple parties.

Despite their shortcomings TRLs at least direct attention to this materiality of technical systems – components, tools, devices etc. – and their technical configuration. They are, however, limited in regard to the assumptions they make about how this configuration comes about, its meanings and practices, and in particular how we need to understand the inter-relation between multiple technologies (Nelson 1994) and the 'natural and social factors' that shape their development and adoption. This requires an examination of those socio-technical processes associated with the implementation and adoption of innovation.

Attention turns then to the milieu within which novel technologies are developing, being enabled, embraced, marginalised or side-lined. It is this institutional domain and its practices, routines, resources and values that determine what can be called 'institutional readiness' (IR). We propose the term 'institutional' rather than simply 'organisational' because we want to stress both the intra- and extra-organisational dynamics that shape the ways in which innovative technologies are given meaning, adopted and implemented. DiMaggio and Powell (1983) coined the phrase 'institutional life' which points us in this direction, suggesting a broad range of interacting processes and practices found within and between related organisations (such as public-private networks, regulatory agencies and materials suppliers) at a field level. The substantive aspects of this will vary by sector, as Malerba (2002) has argued, noting that different sectors – say medicine, transport or energy – have distinct 'knowledge bases, technologies, inputs and demand' (248). We now discuss the IR concept and how and why this was developed, moving on to discuss its relation to TRLs and exemplifying this through drawing on some of the empirical material from a major UK-based research project on regenerative medicine.

Developing the concept of institutional readiness

The concept of institutional readiness was developed through a research project the authors undertook between 2014 and 2017 that explored the emergence of regenerative medicine (RM). This field has been associated with huge promise – notably the move from therapy to cure – and an ability to tackle not merely rare diseases, where much of the early investment has been made, but more common conditions, such as macular degeneration and diabetes. As a result, we have seen a rapid growth in speculative, large-scale financing, the creation of specialist research and clinical centres, and new regulatory vehicles to help create a bio-clinical pathway for promising treatments. Recent government reports in the Australia, the UK and USA describe the field as 'revolutionary' and one of the '8 Great Technologies' shaping the future (Willetts 2013). State investment in the field has grown rapidly, such as in the UK, with investment in the Cell and Gene Therapy Catapult and its new manufacturing centre near Stevenage, as well as three new Advanced Therapy Treatment Centres linked to the Catapult which are funded by Innovate UK to the tune of £30 m over 5 years from 2018 (Innovate UK 2018).

Despite the promise and levels of support being received, our research, which drilled down into the field through extensive empirical fieldwork over three years (authors' REF/anon),[1] identified three specific challenges not found elsewhere in other novel fields of biomedicine. All novel therapies have to confront similar issues such as their perceived utility, novelty, regulatory burden (such as conforming to Good Manufacturing Practice [GMP]), cost, and skill demands. Regenerative medicine however, encounter three additional challenges relating to the stabilising of live tissue (the cell lines) at quality thresholds that meet clinical standards, scaling up and manufacturing the many trillions of cells needed for patient therapies without losing efficacy or quality of the cell lines, and finding the right regulatory framework for this form of medicine beyond the conventional pharmaceutical models which have driven most of the regulatory agenda this past 40 years. Such challenges are specific to RM given its whole basis is the identification, manipulation, scaling up and deployment in the clinic of live tissue, sometimes derived from the patient (autologous) or from others (allogeneic).

In exploring these specific RM challenges it became clear that the actual promise of the therapy would depend on understanding the innovation pathways driving corporate investment and how these would ultimately relate to existing, and the possible need for new, clinical adoption processes. The specificity of the field was recognised by the UK government which established a RM 'expert group' (REF) (one of the authors was a member of the group) which called for new approaches to be considered in regard to appropriate forms of regulation and experimental forms of reimbursement (to be met by the NHS for the costs of using early, experimental forms of treatment). However, there was little or no attention given in this policy-related work to the granularity of clinical adoption in hospitals and what sort of organisational changes, resources, and new practices might be needed there. For example, the Catapult, a key driver of the industrial application of RM and promoter of new products, saw its remit as lying outside of the clinic, and indeed its contractual terms with government reinforced this boundary.

This question of how might clinical adoption be achieved can be partly addressed through drawing on related studies within STS and medical sociology. Previous work has examined in detail those factors that affect take-up (Greenhalgh et al. 2015) and adoption (Ulucanlar et al. 2013). These show that technology never speaks for itself, neither does evidence (or evidentiary claims), but rather organisational practices, localised values and professional interests, alongside limited resources, are key in determining implementation and adoption. Moreover, as May et al. (2011) have shown through the development of 'normalisation process theory', what implementation means in practice depends on the play of processes that enable new technologies or techniques to be normalised, or routinised in clinical (and indeed other) settings. Such settings or contexts should not be seen as static, or in some sense (pre-)given but are process-driven, changing and reshaped over time.

Nevertheless, key players such as the UK's Catapult use the TRL model to assess and determine the readiness for RM products/therapies to be deployed in clinical settings. The Catapult's subscription to TRLs as a vehicle through which to triage promising but not yet 'ready' therapies plays a key role in determining the support it gives to prospective 'clients', typically UK and potentially international SMEs. As we saw above, TRLs do provide an important marker of the relative maturity of an innovation and in their focus on risk assessment play a valuable role in assessing technical aspects that are key (here) to safer medicine. This is allied to the regulatory framework provided by the UK regulatory authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

What was needed then was a framework that could engage with the TRL model yet at the same time locate that within an organisational context seen through the recent work on adoption referred to above. To develop this, we sought to identify the key intra – and extra-organisational dimensions that shape adoption and implementation processes, and as both play a role make a case for seeing these in terms of not merely an organisational but an 'institutional readiness'. Building on the different contributions made by STS and innovation studies literature discussed we have sought to construct a broad model of readiness that includes both internal (such as routines, practices and values) and external (such as standards and regulatory) processes. We outline the principal features of the model in Figure 2 below.

These eight categories of IR and their operational definitions focus our attention on how new technologies are engaged with and made sense of through cultural processes and institutional structures within and outside of specific organisations.

A central difference to the TRL model is that these categories are orthogonal to each other rather than a sequence of 'levels' – one does not necessarily presuppose the other(s): it would be possible, for example, for a hospital or similar clinical setting to show evidence for 'adoptive capacity' but *not* necessarily have a strong strategic focus or formal evaluation processes in place. Clearly, the more of these dimensions that are operant, the more one can argue that a specific organisation is institutionally readied (intra-and extra-organisationally) for innovation.

We can summarise here what we argue are the key features of IR compared with TRL. It is important to do this if we are to find a way of aligning them productively. Figure 3 below offers such a summative account.

IR Category	Operationally defined
Demand for new technology	Institution has key actors engaging with and identifying new technologies that meet field/organisational needs
Strategic focus	Institution has identified potential new technologies and determined their relation to existing ones.
Relative need and benefit of new technology	Institution has key actors assessing capacity to take-on and develop new technologies within current and future contexts
(E)valuation processes in place	Assessments of the (diverse) values of new technologies are undertaken and shared
IR enacted through specific enablers within and outside of the organisation	Key individuals/groups are formally tasked to enable adoption especially in regards to meeting standards and regulatory requirements
Receptivity	Novel institutional structures are created, in anticipation of expected challenges/affordances presented by new technology. These structures reflect the need to retrain staff, the construction of new innovation spaces and new technology platforms etc
Adoptive capacity	Novel technology aligns with institutional priorities and organisational capacities. Initial problems and unanticipated challenges/affordances are identified and seen to be manageable.
Sustainability	Novel technology is routinely produced/used/assessed within institution. Current institutional arrangements and resources are sufficient for routine and ongoing production, assessment and deployment.

Figure 2. Key aspects of institutional readiness.

	Institutional readiness	Technology readiness
Categorical relation	Orthogonal	Sequential hierarchy
Criterion	Organisational functionality	Risk reduction
Adoption via	Normalisation	Assessment of maturity of technology
Materiality of technology	Co-produced and localised	Stable and standardised
Implementation	Learning by trying	Incorporation of working technology

Figure 3. Comparing IR and TRL.

Our comparison here emphasises the main differences in analytical terms between the two approaches. We have already commented on the first three of these. In regard to the last two, the IR approach draws attention to the ways in which the material and the social are co-produced. From an STS perspective, (see e.g. Hoeyer 2013; Law 2010) materiality is defined through the relationship between things, and most importantly, as Law argues, 'materials – technologies – are moulded by the intersection of natural and social factors'. We can see materiality as an expression of what Sørensen (2007) calls a 'distributed effect' (45). For example, banked cell lines only perform as, i.e. only *become* 'lines' for use where they meet biological quality, regulatory and ethical provenance requirements, each recursively related to the other. This has implications for what we understand as a test or a demonstration of TRL since, in this sense a test is an assessment of a distributed effect and how that is 'read' by different actors involved with diverse interests. These may relate to intellectual property, regulation and quality standards.

TRLs are then perhaps best understood as reflecting that 'intersection' Law speaks of, whereby the material and its social framing and meaning are enacted at each of the different 'Levels'. These cannot though be seen to be completely elastic or open-ended, for the socio-material renders obdurate boundary effects too that make a technology workable and that makes 'material sense' with quite specific affordances (Hutchby 2003): the material shapes the social, and the social shapes the material but not in an unbounded way. Here we begin to see how in regard to materiality TRLs and IR might be constructively aligned.

In a similar and related fashion, the implementation of novel technologies typically requires trial and error, or what Fleck (1994) has called 'learning by trying', but he goes further to argue that in this process 'significant innovation [takes place] during implementation itself' (638) inasmuch as getting this 'to work' actually generates new insights about the innovative potential of a new technology. This is distinct from the comparable concept in TRLs, namely, implementation as the incorporation of an already 'working' technology. The assumption here is that users get to grips with the innovation through 'learning by doing'. The principal contrast between the two approaches is that of TRLs' notion of a technically *working* technology and an IR approach which emphasises the *workability* of a technology in a given context, and given Fleck's commentary, one that has additional value as a result. By paying attention to a technical configuration that ensures that a working innovation is one that is made workable through the practices of its users, we begin to see how implementation carries both TRL and IR dimensions. Overall, this alignment encourages us to see assessment as a socio-technical process. The question then is raised, how might this con-joint approach be used in practice? We try to illustrate this below through drawing on our recently completed project on regenerative medicine.

An example from the field of regenerative medicine

In the UK there has been a number of initiatives designed to increase the pace at which access to new medicines occurs, as enshrined in the Accelerated Access Report (AAR 2016). Among the

recommendations in the report was the identification of what were called 'transformative products' that should be given special attention and support across government bodies, industry and the NHS. A new 'Accelerated Access Partnership' (AAP), made up of a large and diverse range of stakeholders would be created, responsible for identifying innovations that can be given a 'transformative' designation. They would be assisted in this process through engaging with existing and newly created Biomedical Research Centres based on university/hospital collaboration.

One outcome of this was the provision of £30 m of funding over 3 years from 2018 by the government agency, Innovate UK, to support the establishment of three new 'Advanced Therapy Treatment Centres' (ATTC). These will be the organisational sites which will have to encapsulate and address the challenges noted above and so make regenerative medicine workable within the clinic. The proposed ATTCs are in effect pilots of central importance to the development of the field. The centres will provide key sites through which institutional readiness at the level of the organisation will be crafted. This will include specific clinical competences, a role for relevant patient associations in providing patient input, the integration of diverse forms of data (beyond trials data, including evidence from registries, hospital exemption, and compassionate use records [Papadaki 2017]), an alignment between the new centres and existing rare-disease treatment centres, and strong links to regional cell therapy product manufacturing sites (such as the CGTC). The centres will need to ensure that they create additional knowledge and skills and leverage existing infrastructure, while being geographically accessible within the UK. The ways these are organised and coordinated will be key to creating an adoptive capacity within, and longer term sustainability for, the field, and especially how they can be models for elsewhere in the clinical system beyond specialist treatment centres *per se*.

Earlier we gave a broad and rather abstract account of IR, and its main categorical dimensions. Here we provide a more substantive account of IR as we interpret its role in the new ATTCs. Figure 4 below, based on our fieldwork, puts some flesh on the IR concept.

We have sought to operationalise each of the IR categories as they would apply to a newly created ATTC, identifying those key socio-technical processes and practices that will help to build readiness for regenerative medicine. A range of social actors are included, not least relevant patient groups who will share some of the burden of risk in their participation in clinical trials. Other key issues relate to ensuring the skills base is developed and equally importantly a new data-collection infrastructure is put in place to capture the supply, storage, use and clinical effectiveness of cell lines. The challenges above are made especially difficult given that each of the ATTCs comprises a regional consortium of players from clinical, academic through to corporate actors. Building the new 'institutional logic' for the ATTCs will require new architectures of production, distribution and delivery that are stable and integrated.

Discussion: aligning IR and TRLs

The development of new technologies poses technical, production and marketing challenges within a wider regulatory and user-context which might – especially in more radical areas of innovation that carry new uncertainties, such as regenerative medicine – be relatively unreceptive or even if not, still lacking in institutional readiness to embrace, adopt and implement novel socio-technical systems. The question remains then how might technology readiness levels relate to our characterisation of institutional readiness? Does our initial critique mean that the TRL model should be abandoned?

The limitation of the TRL approach relates principally to its failure to make explicit the socio-technical infrastructure in which TRLs are embedded. The 'risks' they envisage as being under control (or not) tend to be defined in purely technical terms, whereas such risks are related to socio-technical infrastructures. Whether we are talking about 'complex', emergent technologies or more mature technologies, risks need to be understood in these terms. This means a 'mature' technology as defined solely in TRL terms may itself not be 'ready' for use in certain systemic conditions. Secondly, readiness in TR terms relates to signing-off risks (as manageable/known) whereas IR is about a move towards a broader understanding of (e)valuation, which encompasses perceived risks, benefits,

workability and crucially how these interact or are recursive. Moreover, TRL approaches fail to consider how contexts change over time, and indeed presume 'context' itself is a fixed, pre-given state. Key here too is that *a* technology has to be understood as a tool/process/system that makes sense only in relation to *other* technologies and institutional milieu.

What then might constitute a useful TRL/IR alignment? We illustrate this by discussing the TRL level which is at the threshold of component scale-up across a technological system. This is TRL7, viz. 'Component validation in relevant environment' (NASA 2007). There are two key terms here – 'component validation' and 'relevant environment'. These two relate to the 'demonstration' process through which a novel technology can be assessed and seen to fit the context of its application. With regard to regenerative medicine, component validation is highly problematic since the 'components' comprise manipulated cells that must be produced in single or multiple batches to a quality level whose validation can only be determined through late Phase (Phase 3 +) clinical trials, where controlling for endpoint and outcome measures *in vivo* is challenging and can only be resolved via IR-related measures, especially those concerned with a data-collection infrastructure for monitoring outcomes (see Figure 4).

This in turn relates to the 'relevant environment' within which the 'component' is assessed: as we saw above in our discussion of the UK context, while the 'environment' for regenerative medicine has begun to move towards a more enabling one in which a series of policy and funding initiatives have helped to build momentum in the field, it is still clear that the key clinical structures are yet to appear. There will need to be an articulation between the *provisionally* ready technology, and the emerging organisational framework that can handle uncertainties in the clinical adoption and use of regenerative medicine therapies and that is likely to require a new overall accountability and risk framework, as operationalised in the IR category related to the development of novel institutional structures to do this (Figure 4). Without this, it is likely that there will be considerable difficulties in regard to

IR Category	Operationally defined
Demand for new technology	Prevalence of target indication and capacity to treat expected patient cohort
Strategic focus	Ensure opportunities for staff training and skills in logistical coordination
	Appropriate infrastructure for administering treatments
	Tie-in with the Cell and Gene Therapy Catapult
Relative need and benefit of new technology	Appropriately trained Qualified Persons and appropriate quality assurance staff and systems to determine benefit
(E)valuation processes in place	Assessments of the RM therapies are undertaken and shared
	Agreement among stakeholders on what constitutes evidence of success/cost effectiveness of RM therapies.
IR enacted through specific enablers within and outside the ATTC organisation	Alignment of new therapy with clinicians, administrators, managers and external regulators; Flexibility for aligning/modifying work practices across these groups
Receptivity of the ATTC	Novel institutional structures are created, in anticipation of expected challenges/affordances presented by new technology: Access to GMP-licensed facility (and associated GMP expertise)
	Access to and capacity for appropriate bioprocessing systems
	Capacity and resource of data-collection infrastructures for monitoring outcomes
Adoptive capacity of the ATTC	Novel technology aligns with institutional priorities and organisational capacities: ATTC consortium embedded in wider hospital delivery system
	Opportunities for meaningful patient involvement in organizational design and service improvement
Sustainability	Novel technology is routinely produced/used/assessed within institution. Clinical skills for preparing patients and administering treatments within regional and national clinical trials networks

Figure 4. Developing IR within ATTCs.

'translational medicine' and so likely non–adoption: in that regard, 'clinical utility' is a relational property rather than intrinsic to the technology. If a technology is not workable (i.e. has low IR), it has little utility.

Beyond this specific framing of a TRL/IR alignment at 'Level 7', there are a number of important generic issues that need to be noted. First, TRL are sequential over time whereas IR categories are not. What we want to suggest here is that the spatio-temporal points (TRLs) when boundaries to the next level are to be crossed are those where TRL/IR alignment questions need to be asked, as indicated in our discussion of TRL 7 above. This would help to ensure that a particular feature of a technology does not become entrenched and subsequently generate major problems when adopted in institutional settings. Secondly, TRLs are typically strongly quantitative measures of risk/relative maturity of a product etc, whereas IR relates more to qualitative processes and practices.

The performative utility of TRLs should not be undermined by combining with IR: the alignment would ensure a socio-technical consolidation of any specific TRL, so the risk calculus (the figures) takes account of and anticipates the wider dimension. This is a more organisationally robust approach. It is also worth noting that in the UK NICE (National Institute for Health and Care Excellence) is emphasising the importance of qualitative evidence (in conjunction with quantitative data) for making decisions about commissioning new products, and indeed healthcare commentators more generally are calling for more qualitative evidence to inform implementation practices (e.g. Carroll 2017).

Finally, at each TRL/IR juncture the actors responsible will vary according to the specific challenges that need addressing. IR is about marshalling trans-organisational expertise and participation in helping to 'ready' diverse actors to undertake more workable, doable technological innovation. This is why we speak of institutional and not 'organisational' readiness. In Level 7 discussed above, the key actors in the ATTC will be those responsible for building an appropriate data infrastructure and those staff associated with quality assurance, GMP, trials design and monitoring outcomes. These will be drawn from clinical research, technical support and commercial staff. IR is about marshalling trans-organisational expertise and participation in helping to 'ready' diverse actors to undertake more workable, doable technological innovation.

Conclusion: theoretical and policy implications

The paper has developed a new model of institutional readiness in order to build on recent work in STS and innovation studies that has examined the difficulties of adopting innovative technologies. We suggest a range of core institutional characteristics that can be applied to any socio-technical domain to determine what components are in place, need to be built, can be modified and so on to create a framework through which innovations can be more likely to succeed. While the specific features of the field of regenerative medicine pose their own challenges for the TRL model, the broader lesson is that in any field of innovation which is disruptive of existing socio-technical approaches, the actual value of TRLs will depend on how well they incorporate a focus on (trans) organisational integration.

Moreover, the IR framework is itself strengthened by opening up a conceptual dialogue with TRLs: TRLs draw attention to and are premised upon understanding the material/technological development of new products/processes. IR points up the contingencies here yet in doing so recognises the need to understand and engage with the technical claims/practices that building new technologies requires.

The paper explored how this approach might be used in the example of the specialist ATTCs. That raises the question of whether the work involved in TRL/IR alignment can *only* be undertaken in such settings, i.e. those designed from the start with a sense of how best to deal with uncertain, emergent technologies. We suggest that the role of specialist centres should be to determine what can be black-boxed in regard to the IR/TRL assessment and so the (reduced human/technical) resources needed to implement new technologies *outside* specialist centres where the early TRL/IR work is

done. While the IR model is best seen to work most effectively in contexts such as the Centres, lessons learned therein can be generalised elsewhere and made relevant. This argument also enables us to practice what we preach – i.e. that the IR approach cannot be parachuted in and made to work without recognising the context that makes it most workable. This would also highlight where and what capacity for innovation needs to be built elsewhere. This is a core issue that resonates with the journal's focus on both technology analysis and strategic management and indeed how the two are co-related.

From a policy perspective, within or between organisations, those using TRLs should seek to develop their assessments based on an understanding of the socio-technical field's IR profile, and so develop guidelines relating to readiness that are informed by this. In many ways this would ensure sensitivity to the fact that any TRL assessment is a test of a distributed effect that can be 'read' quite differently by those actors involved. We have shown how using both TRLs and IR can provide the condition for an alignment of both a *working* and a *workable* technology.

Note

1. Fieldwork generated an extensive data set based on over 80 interviews with diverse actors in the area – research scientists, clinicians, key regulatory and commercial agencies, and research procurement and management groups in hospital and wider NHS contexts.

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Data available on request due to privacy/ethical restrictions

The data that support the findings of this study are available on request from the corresponding author, AW. The data are not publicly available due to [restrictions e.g. their containing information that could compromise the privacy of research participants].

Notes on contributors

Andrew Webster is a member of Science and Technology Studies Unit (SATSU) and Department of Sociology at the University of York. He was Director of the £5 m ESRC/MRC Innovative Health Technologies Programme, is member of various national Boards and Committees (including the UK Stem Cell Bank Steering Committee, and the Regenerative Medicine Expert Group, and was Specialist Advisor to the House of Commons Health Select Committee). He was national co-ordinator the ESRC's £3.5 m Stem Cells Initiative (2005–9) and is PI on a £1.5 m ESRC-funded project on regenerative medicine, 'REGenableMED'. He is also Co-I on a recently started project exploring gene therapy, and collaborating with colleagues at the University of Montreal on research relating to 'responsible health innovation'. He is Co-Editor of the Health Technology and Society Series published by Palgrave Macmillan. His recent books include The Global Dynamics of Regenerative Medicine (2013) and he has published widely in social science and science journals. He was elected a Fellow of the Academy of Social Sciences in 2006. He was Head of the Department of Sociology 2005–9 and Dean of Social Sciences, 2009–13 at York. He is Co-Chair of the Association for Studies in Innovation, Science and Technology-UK.

John Gardner is based at Monash University in the School of Social Sciences. He has undergraduate degrees in both Science and Social Science. In 2010 he was awarded a Wellcome Trust PhD Studentship in Sociology to explore an innovative clinical team providing Deep Brain Stimulation to children and young people with severe movement disorders. In 2014 he joined the Science and Technology Studies Unit at the University of York, UK, to work on the ESRC-funded 'REGeneableMED' project exploring the social dynamics of innovation in regenerative medicine. He has published in a range of social science and medical practitioner journals. His monograph, Rethinking the Clinical Gaze (Palgrave) draws on ethnographic research of an innovative clinical team to examine the biopolitical implications of patient-centred medicine.

ORCID

John Gardner http://orcid.org/0000-0001-7417-348X

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