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ANTICIPATING THE CLINICAL DELIVERY OF REGENERATIVE MEDICINES CHALLENGES, TENSIONS & OPPORTUNITIES

OR

THE PROBLEM OF TECHNOLOGY ADOPTION

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REGenableMED





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Overview

1. The general problem of technology adoption in healthcare
2. Technology adoption in Regenerative Medicine – **innovation niche**
3. Proposed Centres for Cell and Gene Therapy
4. Precedents and affordances for RM treatment centres
5. Insights from the social sciences
 - Institutional Readiness

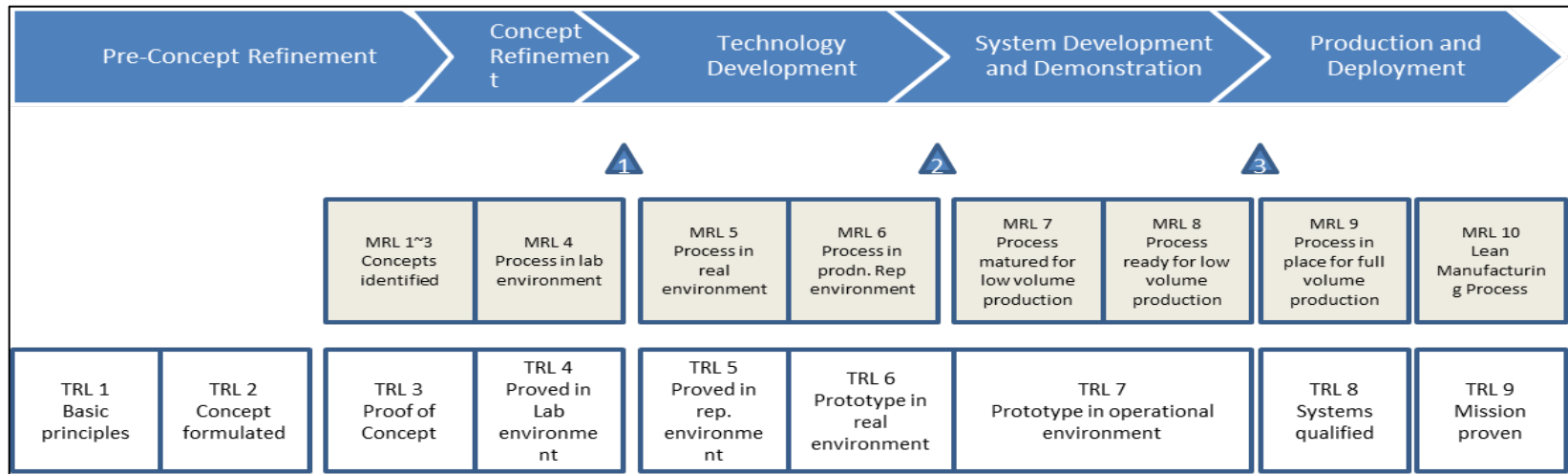
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Technology adoption in healthcare

Adoption processes have been overlooked in the past...

- e.g linear conceptualisations of innovation (TRLs)



Now recognised as an important & problematic aspect of innovation

- High-profile adoption failures e.g National NHS IT programme
- Emphasis on translational medicine (bench to bedside, bedside to bench)
- Recent HoC Science and Technology Committee Report on Regen Med.

Some case studies of technology adoption in healthcare:

- Intraoperative Breast Lymph Node Assay (BLNA) (Llewellyn et al 2014)
- The da Vinci robot for prostatectomy (Ulucanlar et al 2013)
- E-health patient records (Greenhalgh et al 2010; 2013)
- Chronic wound care technologies (Madden 2012)
- Cytori Celution® System (Gardner et al 2017)
- Paediatric deep brain stimulation (Gardner 2016; 2017)

General findings: complexity & heterogeneity

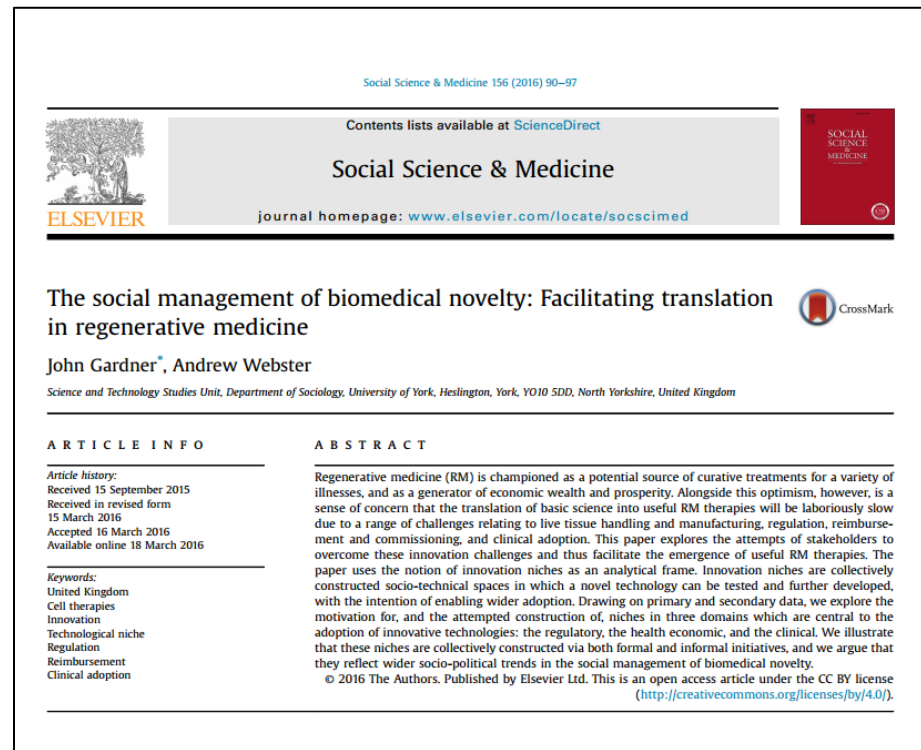
- New technologies must align with institutional & professional interests
- Distinction between cost effectiveness & affordability is highly relevant
- A good business case!
- What counts as 'evidence' is not always clear. Professional differences, reliance on informal networks...

Specific challenges for regenerative medicines

- Live tissues/cells require specialist **infrastructure & skills for transportation** and preparation at the clinic
 ➔ flexible GMP facilities
- New manufacturing & logistics arrangements. **Clinic as site of partial or full manufacturing.**
- Onsite manufacturing will require **expensive bioprocessing equipment** such as cell separation & expansion systems, systems for transfection etc.
- Hospitals may need to act as procurement service for third party. **Contract arrangements for this can be complex.** How might QA and liabilities be distributed among parties?
- Some proposed **risk-sharing commissioning schemes need coordinated data-collection** infrastructures.
- Emerging therapies are diverse and will present varying levels of distribution.

The delivery of regenerative medicines will require significant organisational/institutional adjustments

Constructing an 'innovation niche' for new technologies/techniques



Gardner, J. & Webster, A. (2016). The Social Management of Biomedical Novelty: Facilitating translation in regenerative medicine. *Social Science & Medicine*. 156: 90-7

Proposed Centres for Cell and Gene Therapy Treatment

Recommended by RMEG and ATM Taskforce

- Consolidate resources at several coordinated clinical sites
- ATMT recommends £30 Million administered by Innovate UK
- Represent partnerships between NHS & industry



Clinic of the future. Centre for Process Engineering

➔ Provide stability, enabling consolidation of supply chains, data collection infrastructures & trailing and consolidation of business models.

Precedents & affordances for treatment centres

1. Haematological services, NHSBT, SNBTS

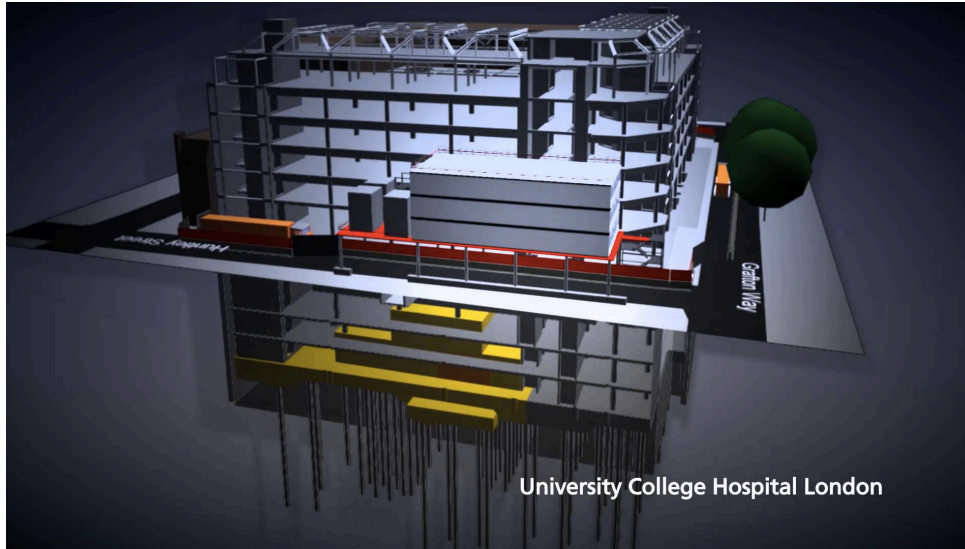
- Reservoir of infrastructure & expertise (see Lowdell & Thomas 2017)
 - Procurement, transportation, administering, patient preparation
 - Familiarity with HTA, MHRA, GMP etc
- NHSBT & SNBTS already partnered in RM innovation alliances

2. Existing risk-sharing commissioning arrangements

- Provision of some high cost cancer drugs in Scotland, enabled by integrated EPR infrastructure
- Elsewhere in Europe, eg Italy. GSK 'money-back guarantee' on Strimvelis for ADA-SCID

Precedents & affordances for treatment centres

3. Establishment of a UK Proton Beam Therapy Service



From <https://www.england.nhs.uk/commissioning/spec-services/highly-spec-services/pbt/>

- High cost, requiring new infrastructures, patient-pathways, & associated skills and training www.england.nhs.uk/
- Considerable investment required: £250 million
- Coordinated action from various agencies – NHS England, Foundation Trusts, Health Education England, etc

Similar level of investment & coordination may be required for implementing some highly disruptive regen meds

Also...

meaningful patient engagement in service design

- Regional distribution of Regenerative medicine treatment centres
- Are outcome measures relevant to patients and their families? Infrastructure for these measures?
- Psycho-social dimensions – appropriate support? Appropriate links with community services?

RM technologies/techniques should not be seen as a technological fix – **they should be approached as part of an ongoing regime of care**

Institutional Readiness (IR)

In parallel with Technology Readiness

the degree to which organisations or groups are willing to deploy, and are capable of implementing, a novel technology or practice.

- A (novel) technology is a relational product, embedded in a material-semiotic network.
- Adoption is the result of active, ongoing work by creative agents with bounded rationality and limited resources.
- Diverse agents need to be actively enrolled in the embedding process - align workloads and expectations.
- Requires regular opportunities for reflexive evaluation, monitoring

See also May 2013

Institutional Readiness & Regenerative Medicine

What parameters might be relevant?

RM Technology/Technique	Context (Clinical Setting)
Prevalence of indication	Appropriate capacity
	Opportunities for meaningful patient/public involvement & collaboration?
Place & mode of manufacturing (e.g centralised? on-site?)	GMP clean room access; Bioprocessing capacity
Preparation required (product, patient...)	Appropriately trained QP? Infrastructure for QA
Clinical skill required for administering	Appropriate reservoir of skills, opportunities for training
Monitorable	Infrastructures for assessment & monitoring
	Time for monitoring & collective evaluation
Quality of supporting evidence	Institutional Strategy/Priorities
	Stakeholder alignment (e.g managers, frontline staff, patients & families)
Affordability	Payment structures (e.g. tariffs), other revenue sources (e.g charitable grants).

Institutional Readiness Levels...

IR-L	Institutional Readiness Categories in healthcare
1	Institutions have operational groups tasked with engaging and identifying new technologies
2	Institution has identified potential new therapeutic technologies.
3	Institution has an operational group tasked with assessing institutional capacity/readiness for new therapeutic technologies
4	Assessments of current institutional arrangements for new technology have been made Formal guidelines exist for 'readying' those institutional structures in which the technology will be used/produced/assessed
5	Key individuals/groups tasked with readying institutions (in which technology will be used/ produced, assessed) according to guidelines.
6	Novel institutional structures exist, in anticipation of expected challenges/ affordances presented by novel technology. These structures result from retraining of staff, construction of new spaces etc
7	Novel technology is being produced/used/assessed within institution. Teething problems and unanticipated challenges/affordances are noted.
8	Novel technology is routinely produced/used/assessed within institution. Current institutional arrangements are sufficient for routine production /assessment/ deployment.

(More work to be done on this... watch this space)

Institutional Readiness Levels		Examples		
		Clinical institutional context	Governance institutional context	Commercial institutional context
1	Institutions have operational groups tasked with engaging and identifying new technologies	Clinician(s) constantly looking for novel interventions for existing conditions/illnesses.	Government bodies/policy makers concerned with cost of healthcare and national economic performance. These bodies/policy makers actively promote innovation in healthcare.	Employees or R&D division of companies/ academic groups actively looking for new products. Or, individuals/groups within companies actively scouting for small companies with novel products to align with.
2	Institution has identified potential new therapeutic technologies.	Clinician(s) become aware of new intervention – perhaps in developmental stage and/or used in other healthcare settings	Government body/policy makers identify and promote particular technologies –such as RM - as part of their push for innovation.	Potential new technology identified and is being developed within company, or one company has identified potential technology produced by another, and thus establishes an alliance.
3	Institution has an operational group tasked with assessing institutional capacity/readiness for new therapeutic technologies	Formulation of specialist group (which may only include ‘pioneering’ clinician and clinical director) tasked with examining how well existing NHS hospital workflows/structures will accommodate new technology. Inevitably this will involve assessing whether such a clinical service would be financially self-sustaining within the tariff system.	Government-appointed group tasked with assessing the suitability of current healthcare system arrangements for facilitating of new technologies. This may include an assessment of current governance structures (regulatory agencies and appraisal bodies).	Group within company assesses current capacity of further development/production of novel technology. This includes assessing current manufacturing platforms, expertise, component suppliers, possible market etc.
4	Assessments of current institutional arrangements for new technology have been made Formal guidelines exist for ‘readying’ those institutional structures in which the technology will be used/ produced/assessed	Establishment of proposal for adjusting NHS clinical sites so that the new technology can be integrated into a new/existing clinical service. Such proposals will outline the various resources required: staff, supporting technologies, clinical architecture etc	Government appointed group proposes formal changes to current governance structures. Such proposals may include new regulatory classification system, new forms of cost-effectiveness analysis, the appointment of individuals/groups with particular expertise to regulatory agencies and appraisal bodies.	Company has business plan/viable economic model for developing and producing new technology.
5	Key individuals/groups tasked with readying institutions (in which technology will be used/ produced, assessed) according to guidelines.	Pioneering clinician (or clinical leads are appointed) and/or manager tasked with bringing these resources together.	Individuals/groups within governance structures (such as EMA, NICE, MHRA) are tasked with bringing about required changes. These individuals/groups may engage in public consultation as part of their ‘readying activities’.	Key manager(s) are tasked with enacting business plan. This may include securing additional capital.
6	Novel institutional structures exist, in anticipation of expected challenges/affordances presented by novel technology. These structures result from retraining of staff, construction of new spaces etc	Appropriate clinical space/niche is created for the novel technology, according to the specialist group proposal. This clinical space may be particularly novel (such as the formulation of a new multidisciplinary team, or the construction of a new material environment to house the technology), ore relatively minor (retraining one/several staff members of existing clinical team).	New governance arrangements are formally established. This may include the establishment of new classificatory system for novel technologies or a new committee with specific expertise.	Sufficient investment is secured and business plan is enacted - this involves securing appropriate suppliers of cGMP-compliant supplies, constructing material infrastructure for technology production, hiring & training staff.
7	Novel technology is being produced/used/assessed within institution. Teething problems and unanticipated challenges/affordances are noted.	New technology is deployed in an actual clinical setting. While working with the technology, clinicians become aware of (inevitable) problems/affordances requiring small-scale, ad-hoc alterations to existing structures/routines etc.	The governance structures are ‘processing’ the new technology: regulatory agencies and appraisal bodies are assessing the new ‘class’ of technologies. However, key individuals/groups have noted that further minor adjustments may be necessary. For example, it might be noted that the classificatory system is unclear and requires further ‘tweaking’.	Novel technology is produced by the company. Further ad-hoc adjustments are necessary before efficient production can be routinized.
8	Novel technology is routinely produced/used/assessed within institution. Current institutional arrangements are sufficient for routine production /assessment/ deployment.	New technology is routinely deployed. Staff have appropriate expertise, training and tacit/embodied knowledge required to operationalise new technology.	Governance structures routinely ‘process’ the new class of technology. While there may be some individuals or groups (such as industry) that believes the current structures are inadequate, such viewpoints do not carry sufficient weight to prompt change within governance structures.	Novel technology is routinely produced by the company. Company has a proven manufacturing platform and a viable, proven economic model.

(More work to be done on this... watch this space)

THANK YOU



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