

Responsibly accelerating the translation of regenerative medicines

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Regenerative medicine and responsible research and innovation: proposals for a responsible acceleration to the clinic

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The field of regenerative medicine faces many challenges in translating innovations and discoveries into clinical treatments and technologies. Combining 'Responsible research and innovations' and 'Science and Technology Studies' principles and approaches can foster better preparation for clinical translation by identifying, discussing and addressing many different issues and concerns with a diversity of stakeholders.



What questions & challenges are raised?

Regenerative medicine (RM) is a novel and complex field at the intersection of science and medicine that aims to treat or cure medical conditions with living cells and tissues. Excitement over RM and its economic potential for businesses has prompted demands to quickly get RM therapies on the market by passing new regulations and changing how treatments are evaluated for safety and effectiveness. However, focusing on rapidly translating technologies into market products doesn't consider many factors that will affect the success, demand for and adoption of new therapies. In his recent perspective article, Professor Andrew Webster from the University of York notes that although the field of RM has several unique features, many of the discussions about implementing new technologies and anticipating their impact have occurred in other emerging fields, such as nanotechnology and synthetic biology. Dr Webster explains that principles from Science and Technology Studies (STS) and Responsible Research and Innovation (RRI) could greatly help the field of RM successfully bring new treatments into clinical use by bringing stakeholders together to identify a range of obstacles, coordinate solutions and collectively consider potential risks.

Considering STS and RRI principles may require slowing down progress at times to better understand and address the needs and effects new technologies bring. Dr Webster points to the recently formed 'Accelerated Access Partnership' (AAP) established by the UK National Health Service as an example of what an RRI/STS approach might look like for RM. The AAP is made up of a large number of RM stakeholders who will be collaborating to bring new innovations and technologies into clinical use and examine how they can be integrated into the current systems and infrastructure. Dr Webster asserts that a combined RRI/STS approach with active organisation and partnership between stakeholders will help the field of RM advance new technologies to the market more slowly, but more effectively – what Dr Webster calls 'responsible acceleration'.

What insight & direction does this give for research policies?

Dr Webster illustrates the approach of RRI and STS by discussing multiple examples of how these approaches apply to the field of RM. Three particular challenges that Dr Webster believes would benefit from RRI-style open discussions (with patients, medical professionals and other stakeholders) are the clinical trials process for new treatments, the classification/regulatory process, and how the manufacturing of new treatments using living cells is going to be scaled-up. Individuals examining these challenges with the RRI principle of anticipation might consider: patient populations and locations for treatment, the need for specific resources and skilled professionals at clinical centres, and facilities to generate cells for treatment. Reflexivity will be needed to identify assumptions in the clinical trials process and discuss what can be adjusted to better accommodate living cell therapies. Inclusive discussions between researchers, policymakers, medical professionals, patients, and patient representatives (such as disease oriented charities) can help reassess what forms of evidence can and should be considered when evaluating new therapies. A responsive approach to policies will ensure appropriate and clearly understood regulation that is debated and critically reviewed over time.

Dr Webster highlights that the use of living cells for RM makes STS principles and considerations particularly important because current healthcare systems are largely based on drug- and device-based

What background and point are discussed?

Many areas of research, funding bodies and governments have adopted principles of RRI into their operations. Professor Webster explains that an RRI approach allows members of science and society (the public, businesses, and others) to examine and discuss the ethical nature, inherent risks and complex implications of scientific research and technologies. If started early, RRI discussions can help anticipate positive and negative implications, unconsidered risks and broader considerations, such as how innovations should be governed. This approach moves science and industry towards slower more considered innovation with greater emphasis on its direction, rather than rapid 'innovation-at-all-costs'. The theory of RRI is built on four principles: 'anticipation', 'reflexivity', 'inclusion' and 'responsiveness'. These principles direct individuals to: consider the risks and opportunities of technological advances, openly discuss different groups' interests and values (e.g. companies, researchers and the public may all hold different views), involve different groups in deciding how new technologies are governed, and build ways to reassess and change policies as situations change. Dr Webster notes that equally important are several principles of STS, which generally recognise that innovations and emerging technologies are a "non-linear, complex and messy process". STS approaches recognise that new ideas and technologies can result in many different outcomes (some of which may never happen). STS also acknowledges that 'recursive relations' occur in markets; this is where makers of products respond to what the market wants, and the market responds to what is being made. STS approaches account for innovations being adopted by consumers in a totally different way than what the innovation was intended for. Considering all of this, Dr Webster states that new technologies and their industries need to be flexible, serve a function, create demand and integrate with the circumstances and infrastructure of the people who will use it.