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EDITORIAL

Regenology: Time for a New Specialty?

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Current medical literature is full of examples of stem cell and regenerative medicine treatments that are emerging from basic science labs and being proven effective in clinical trials. As these treatments are commercialized and become more broadly available, an important question arises: Is regenerative medicine ready for "specialty status" and what will its practitioners be called? Although the field has many challenges ahead, we contend that it is time to consider specialty status and suggest the name "Regenology" in keeping with the medical linguistic tradition of deriving specialty names from Latin and Greek root words.

Specialization unquestionably plays a preponderant role in contemporary medicine [1] and has a long history. In Galen's era, choosing a specialty was commonplace among Roman physicians, long before they became organized into formal, standardized professional groups [1]. Specialization was ultimately the result of a new understanding of disease that created "foci of interest" around which the various professional groups could grow. The ontologies associated with these organ systems and associated new technologies would eventually evolve into the medical specialties as they are known today [2].

Although technological innovations and new therapeutic techniques improved the quality of care in specific foci of interest, they did not transform these foci into medical specialties on their own accord. Instead, this process began when physicians recognized the necessity of formal training and practices based on solid scientific principles. Specialization emerged in its modern configuration initially in early 19th century Paris as a form of knowledge production and diffusion among scholars focused around a specific scientific research imperative [1]. Once the scientific and educational benefits of specialization were recognized by Western physicians, the process was then mirrored in North America in the 1850s and 1860s [1].

In 1845, physician Nathan Davis introduced a resolution to the New York Medical Society calling for physicians to establish a national professional association to help regulate the practice of medicine, which later became known as the American Medical Association [3]. In the 1880s, specialties in the US were largely accepted as distinct disciplines that functioned to produce and disseminate the knowledge that future practitioners would need to possess [1]. The first official medical specialty board was formed by Ophthalmology in 1916 [3].

Moving ahead to the biotechnology boom of the latter half of the 20th century, the term "regenerative medicine" first came into common use [4, 5] as considerable knowledge was gained about stem cells and progenitor cells. Regenerative medicine efforts are currently underway experimentally for virtually every type of tissue and organ within the human body. Applications of regenerative medicine technologies may offer novel therapies for patients with injuries, end-stage organ failure, or other clinical problems. The clinical aim of regenerative medicine has been to restore aberrant anatomy and physiology at the cellular, tissue, and even genetic levels, and therefore it presents a significant shift from the goal of conventional medical therapy [6]. The main defining feature of regenerative medicine is not the use of a specific technology, but the use of diverse technologies to restore impaired anatomy as well as physiological dysfunction [7]. Although some of these therapies may appear to be "standard care," in fact, the purpose and action of these therapies differ from conventional therapeutics regarding their production and mode of delivery [6]. Indeed, living cells have been described by the European Union's Committee for Advanced Therapies as "being among the most complex pharmaceuticals" [8]. For example, some bioengineered products require cell culture technology, but are also regulated as "living drugs" [9].

The rise of regenerative medicine has been due to the convergence of many factors, not the least of which is new enabling technologies. This is quite different from the manner in which some of the other medical specialties have evolved over the centuries. Regenerative medicine is a multidisciplinary field, spanning a wide range of the basic and clinical sciences. When it comes to understanding regenerative treatment modalities in relation to the patient,

there is not currently a single point of care expert, or specialist, who understands the unique challenges that these therapies pose during their clinical development and delivery.

Indeed, regenerative medicine is a new paradigm of medicine that will require specialists who are uniquely positioned to understand the distinctive needs of patients who need these therapies, and can make the appropriate recommendations to both patients and their referring practitioners. Patients would benefit from having medical experts who understand the complex landscape of regenerative medicine therapies. As some individuals start to use the term "regenerative and cellular medicine specialists" [10] to describe themselves, the need to distinguish between regenerative medicine as an applied science and translational research undertaking from regenerative medicine as a medical specialty becomes even more important. In keeping with the medical linguistic tradition of deriving specialty names from Latin and Greek root words, we propose the designation of "Regenology" (from Latin *regeneratus*, "regenerate" and Greek -λογία *-logia*, "study").

Because of its unique development and complexity, Regenology would not be classified as an organ-specific or therapy-specific specialty. Instead, it would be broad-based and analogous to family medicine in that practitioners will address a variety of disease states and organ systems. Similar to procedure-based specialties, such as interventional radiology, Regenologists will perform certain procedures, such as injections and minimally invasive procedures, as well as to refer patients to specialists for more complex treatments.

Some may argue that rather than creating a new specialty, existing system-specific specialists could receive training in the field and fill the role of "regenerative medicine specialist." However, it is less likely that a large number of existing organ- and system-specific specialists would be prepared to effectively integrate evidence-based regenerative medicine into their existing practice framework because of the requirement for competence in multiple diverse areas, such as cellular biology, tissue engineering, biomaterials sciences, pharmacology, and biochemistry.

Although the field of regenerative medicine has made enough progress to argue for its emergence as a specialty, there are obviously hurdles to overcome, including defining the appropriate clinical target dosing of these treatments, whether cell, cytokine, or small molecule-based [8], and addressing the measurement of long-term clinical outcomes. It has been well documented that agreement on capabilities and indications of new medical technologies often trails significantly behind diffusion into practice [11]. Also, the field has its share of over-zealous practitioners and unethical offerings [12]. With these and other remaining challenges, some may question whether the timing is right for specialty status, or whether conferring the field with specialty status will paradoxically increase public skepticism of its merits. Leroy D. Vandam, M.D., stated that "professionalism in any field entails study with consequent progress, the teaching and recruitment of others, integration with the other branches of medicine and devotion to the kind of investigation that solves its own problems" [13]. The concept of professionalism suggests that the time is right for us to begin considering a new specialty.

Regenology, as a specialty, would be dedicated to providing evidence-based care and standardizing new treatment indications and procedures. The knowledge gained by physicians and scientists who are developing therapies and overseeing their testing in clinical trials will form the foundation from which regenerative medicine will rise to specialty status. If Regenologists understand the specific physiological and therapeutic functions of each therapy based on its design and method of manufacturing, they will also understand the potential adverse effects that may arise and will learn to stratify patient candidacy for therapies based on individual risk.

Although the extent and scope of practice of a Regenologist remains to be fully determined and is sure to evolve over time, it is not too early to start defining the field. These specialists should be equipped to ensconce themselves in collegial professionalism and be ready to accept the responsibilities involved. Just as a "fundamental transformation of intellectual perspective" lay behind the rise of specialties in the past, specialties of the future, including Regenology, will be an extension of new knowledge and new techniques and are a natural process [1, 14]. Furthermore, the creation of Regenology as a specialty should help to facilitate public understanding and engagement, and may garner support among policymakers, funding agencies, and individuals from both scientific and medical disciplines regarding the field's potential [7].

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