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Cover Page Footnote

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Understanding Regenerative Medicine and Its Position in Healthcare

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Abstract: *Regenerative medicine is an emerging field of the healthcare industry that has the potential to treat a myriad of health conditions. Induced pluripotent stem cells, human embryonic stem cells, and tissue engineering are a few of the treatment methods that may be delivered by healthcare professionals in personalized medicine. Food and Drug Administration (FDA) approval is necessary within the United States before any of these treatment options are available. Specific cellular therapies are currently undergoing clinical trials and it may be years before approval is acquired. The National Institute of Health is proactively working to ensure that healthcare policies, costs, regulations, protocols, and provisions are implemented to ensure that risks are minimized in the case of FDA approval. Regenerative rehabilitation will improve traditional healthcare delivery, increasing health, function, and quality of life for patients with a variety of conditions.*

Keywords: regenerative medicine, regenerative rehabilitation, stem cells, stem cell, personalized medicine, regenerative cells, induced pluripotent stem cells, embryonic stem cells, regenerative therapy, stem cell therapy, cellular therapy, regenerative cell therapy, stem cell rehabilitation, cell rehab, regenerative healthcare, stem cells impact

Regenerative Medicine

Throughout the years, medicine has begun to advance at an astounding rate. Consequently, these rapid advancements have led to emerging and polarizing therapies within the field of regenerative medicine. Notably within this sector, stem cell therapies are surfacing that allow medical professionals to target and treat the human body in ways that were once considered impossible. Hanley, Rastegarleri, and Nathwani (2010) discuss the ability of induced pluripotent stem cells and human embryonic stem cells to differentiate into every type of cell. Stem cell capabilities reveal that anatomical structures within the body could be regenerated and

rehabilitated. Spinal cord injuries, congenital defects, cognitive deficits, cardiac disease, anatomical abnormalities and amputations are just some of the types of conditions that regenerative medicine could treat and heal. Induced pluripotent stem cells will likely focus more on disease treatment while embryonic stem cells will concentrate on debilitating injuries and degenerative disorders (Hanley, Rastegarhari, Nathwani, 2010). Ethical concerns primarily center on the acquisition of human embryonic stem cells rather than induced pluripotent stem cells. King and Perrin (2014) outline that stem cell opposition regards a human embryo as having moral standing because it may form into a human, therefore it would be unethical to harm an embryo to harvest stem cells. Despite current opposition, this groundbreaking therapy should be fully supported through its infancy because the therapeutic use of stem cells possesses the potential to revolutionize medicine and rehabilitation.

Regenerative Therapy

Cellular therapies that focus on the use of stem cells are emerging which will allow medical professionals to target and heal injuries and other physical conditions. According to the Mayo Clinic (n.d.), rejuvenation, replacement, and regeneration are the three interrelated approaches used to create and establish effective regenerative medicine for the future. This is a dynamic method towards an emerging field of medicine and therapy that has the potential to address every physical issue or disability that an individual may encounter. For example, stem cells are able to differentiate into any somatic cell such as skin cells, brain cells, and lung cells (Mayo Clinic, n.d.). According to the National Institute of Biomedical Imaging and Bioengineering (2017), an alternative to stem cells for regenerative medicine is tissue engineering in which biomaterials are used to develop functional tissues through a combination of scaffolding with cells. Regenerative medicine is an exciting and emerging field of healthcare that has the potential to heal every condition imaginable.

National and Community Healthcare Issue

Healthcare commonly draws criticism within the United States, however few topics within the industry create the polarizing and heated discussions as regenerative therapies. Bioethics represent the foundation in which regenerative medicine opposition resides, and fear on both a national and local level fuels the debates about accessing the benefits of stem cell therapy. Stock (2003) acknowledged a variety of fears in healthcare and provides an interesting perspective that describes issues and concerns surrounding the field of regenerative medicine. Abuse of regenerative technologies, philosophical implications based on regenerative therapy, and recognizing that we do not control our future even with regenerative medicine are three of the fears that were analyzed by Stock (2003). Nationally, the

United States would have to regulate and control regenerative technologies to prevent abuse; it is safe to assume that America is not currently capable or prepared to control such a task. Medicine and therapies require the implementation of protocols, guidelines, and procedures to minimize risk, however since regenerative therapy is an ever-changing and emerging field that has not yet attained FDA approval it would be fruitless to create such precise provisions. Locally, fear extends to individuals on a philosophical level, it is difficult to predict whether an individual would be able to accept a regenerative body part (Stock, 2003). Also, it could in turn make individuals question their identity as humans because of the regenerative change they will undergo (Stock, 2003). On a long-term global scale, evolution will be strongly impacted by the decision made to utilize such a therapy and it is unclear what will be achieved because it is currently unknown how future technologies will impact self-directed evolution through the use of regenerative medicine (Stock, 2003). Deliberation of pros and cons will be a continuous and enduring effort of individuals and this nation, however the immense benefits to human life and the ever changing nature of humans will certainly push regenerative medicine into the practical world.

Delivery of Healthcare

Contemporary healthcare delivery methods will be implemented for regenerative therapy and it will strongly differ from that of traditional healthcare delivery. The National Institute of Health examined business models and settings in which regenerative medicine could operate. Rao (2015) acknowledges that hospital based services and the idea of homegrown tissues are two potential therapeutic settings for regenerative medicine, and a new stem cell therapy would significantly impact healthcare delivery. Rao (2015) acknowledges the inevitable difficulty that traditional pharmacological institutes would experience when trying to deliver and manufacture regenerative therapies. Regenerative medicine is personalized medicine, therefore large manufacturing companies would struggle to transition from indirect consumer delivery because they tend to the condition and not the individual. The National Institute of Health is proactively working to prevent such a delivery issue and is analyzing potential solutions for the future of regenerative healthcare delivery (Rao, 2015). It is important to realize that today's pharmacological approach to healthcare delivery is based on automatic machinery that produces its supply of products in bulk for a range of conditions. Alternative settings like hospital based services, institutional based services, and home settings will work best because individuals are directly tending to their therapeutic needs with professional guidance (Rao, 2015). Distributing revolutionary regenerative therapies is a difficult proposition since it has never been done, ultimately, new and safe delivery methods will emerge to meet its demand.

Distribution of cell therapy is not the only concern, as healthcare delivery also encompasses the application of the therapy for the patient.

Silva and Lederman (2004) acknowledge the methods of cellular therapy delivery include systemic delivery, local delivery, surgical delivery, and catheter delivery. Methods of delivery would be dependent upon the patient's condition, preference, and location. Each delivery method possesses their own unique benefits and risks. Systemic delivery would be used for cardiovascular application via placement of stem cells within intravenous infusion (Silva & Lederman, 2004). Local delivery would take place through a needle into the injection site, this would allow for a larger and more accurate treatment (Silva & Lederman, 2004). Surgical stem cell implantation is a highly targeted method of delivery that would take place in high demanding circumstances so that the best results may be obtained (Silva & Lederman, 2004). Catheter delivery is an alternative option to the previous methods that percutaneously sends stem cells into a region of the body (Silva & Lederman, 2004). Cell therapy has yet to establish itself as a reliable and sanctioned method of treatment, it is important to realize that these methods of deliveries will evolve and adapt to the demands of patients as regenerative medicine evolves in the future.

Impacted Populations

Various populations of individuals with physical disabilities, diseases and injuries would be overwhelmingly impacted by the arrival of regenerative therapies. Cellular therapy is an expanding and inclusive market that will target specific diseases across a spectrum of illnesses and conditions. Syed and Evans (2013) state that in 2011 the stem cell market was worth \$2.7 billion and projected that in 2016 it would have been worth \$8.8 billion. While these markets are not based on the United States, they are based off of regenerative markets and provide an idea of the impact it would have within the United States' healthcare sector. For example, orthopedic injuries regularly involve musculoskeletal structures; these conditions would be cured if regenerative medicine were accessible. Greco (2015) outlines and focuses on types of arthritis and how this population would utilize stem cell therapy to enhance their quality of life. Osteoarthritis, traumatic arthritis, and rheumatoid arthritis were highlighted within the article and each of these possess structural damage, yet the author discusses instances in which experimental use of stem cells improves a participant's health (Greco, 2015). Current surgical treatments include microfracture surgery, arthroplasty, osteotomy, and osteochondral autograft transfer system surgery. During microfracture surgery, a doctor drills microscopic holes in the bone to stimulate inflammation for cartilaginous healing in a localized area. Arthroplasty requires a surgeon to reshape bones to reconstruct a joint. An osteotomy dictates that a surgeon removes part of a bone, and then stabilize the remaining bone with pins to reduce weight bearing on the injured area (Greco, 2015). Osteochondral autograft transfer system surgery involves moving healthy cartilage to a damaged site to reduce pain (Greco, 2015). Stem cell therapy would be a desirable alternative to the current

traumatic surgical treatments. In theory, any disease could be reversible or curable by stem cells, however clinical trials for this therapy are immature and need to establish efficacy before being able to reach the broader market.

Traditional healthcare is a competent method of healthcare delivery for a variety of health conditions, however as life evolves newer conditions will surface. Emerging cellular therapies offers the opportunity to respond to life's demands while also improving upon the healthcare industry within the United States. Personalized medicine via induced pluripotent stem cells, human embryonic stem cells, and tissue engineering possesses the ability to enhance healthcare delivery. Regenerative rehabilitation is a potentially life transforming area of medicine that will rapidly improve one's quality of life while also improving an individual's ability to complete their daily occupations. Regenerative medicine is the next sector of the healthcare industry so individuals should currently have professionally administered and controlled access to the treatment in order to expedite the FDA approval process.

Method

Academic journals were researched through EBSCOhost and Academic Search Complete databases for this literature review. Keywords and phrases commonly used included: regenerative, medicine, stem cells, adult stem cells, injuries, conditions, target population, therapy, corporatization, regenerative medicine practice, and uses of stem cells. Additionally, websites with government domains or websites of professionally accepted practices were accessed for research. Information was then gathered to be analyzed, interpreted, and synthesized for discussion within the article.

Relationship

Healthcare Industry

The history of the healthcare industry from the late 1900's on is known as the corporatization era, during this period large companies controlled the healthcare scene and instituted the use of advanced technology (Shi & Singh, 2015). Regenerative medicine is on the cusp of reaching government approval; it could become a dynamic, vital and profitable sector of the healthcare industry within America that relies solely on advanced technology. Rao (2015) acknowledges that the National Institute of Health provides the most research dollars in the United States and that the organization is a strong supporter of regenerative medicine. As discussed earlier, the traditional healthcare companies may not hold a place in the commercialization of regenerative medicine because of the unique nature of its delivery, however for those that adapt to the demands of delivery, there will be a vast amount of revenue and profit available. Regenerative medicine will be an exciting, challenging, polarizing, and profit driven field

of medicine that relies on competition to enhance the quality of the product for therapeutic use.

Occupational Science Connection

Christensen and Townsend (2010) recognize that occupational deprivation takes place when an individual is not able to participate in their valued occupations for a sustained period of time. Injuries and illnesses limit one's ability to perform daily functions as well as other life functions, consequently these individuals will experience a decreased quality of life. Occupations are an integral part of one's life, and without them one's identity and psychosocial processes may become just as impacted as their physical deficits. This is another powerful reason that stem cell therapy should be considered as a viable treatment for affected individuals. Regenerative therapy is dynamic, it extends to all parts of life for individuals and it can help eliminate unnecessary occupational injustices that individuals will experience throughout their lifetime.

Communication is an essential occupation of humans, and without it there is an occupational disruption that extends into every interaction that one will experience within a given day. Wormal, Fishman, Tolly and Birchall (2015) explore how regenerative medicine is being implemented in otorhinolaryngology and the potential impact that would take place from being able to acutely treat a condition. Communication is frequently disrupted with any condition related to otorhinolaryngology so it would be powerful to observe successful results in regenerative treatment for one of these conditions. Despite the complexity of the circumstances, tissue engineering, cellular therapies and other regenerative approaches are targeting many of the diseases in this specialty field (Wormal, Fishman, Tolly & Birchall, 2015). Reestablishing communication after injury or disease would signify a significant and monumental moment for regenerative therapy to address social participation as a valued occupation.

Connection as a Future Healthcare Provider

Future healthcare providers will encounter and interact with individuals undergoing a stem cell intervention. Therapists must be able to provide competent and comprehensive rehabilitation to these individuals to ensure their rehabilitation is successfully completed. For example, individuals who undergo regeneration of their third phalanx will be relearning a skill like writing or typing that they had possessed before the amputation. Ambrosio et al. (2010) recognize that stem cells are capable of undergoing rehabilitation it is essential that the regenerative and rehabilitative fields work in synchronization to ensure that they complement one another for high quality future healthcare. Lyons et al. (2009) discussed that stem cell rehabilitation is psychologically demanding too because individuals undergo a gradual recovery back into their ADL's and IADL's. Although

one may quickly regain a physical function they still must undergo rehabilitation and learn to reuse the regenerated body part, this is as demanding on the body as it is the mind. There is a myriad of conditions that could benefit from regenerative rehabilitation and it is critical that clinically relevant strategies are recognized and implemented to ensure that individuals are delivered the highest quality of healthcare to improve their quality of life.

Relevance

Current Healthcare Policies

Healthcare policies and cost are a multidimensional topic of regenerative medicine that will take some experience to establish into effective law and regulation. Creating policies for a therapy still in the clinical trial phase is a demanding and difficult task, however there are many policies, guidelines, and business models projected with FDA approval. French (2016) discusses two different business models projected for stem cell therapy. One option is for the patient to pay one sum as if it were a surgical operation while the other entertains the idea of making annual payments due to the therapy's unique and time sensitive nature of regeneration (French, 2016). Health insurance companies will be needed to ensure that healthcare providers are reimbursed for their cellular treatments. The most direct route of payment would be the same as treating it like an operation, this would prevent the logistical complication of switching health insurance plans while making payments during a patient's stem cell intervention. It will be an interesting debate to follow as regenerative medicine progresses through the trial and challenges of the Food and Drug Administration. Levine (2008) surveyed stem cell scientists about national stem cell policies and through this survey it was verified that the United States' policies are currently considered as too restrictive. Consequently, many of these individuals are moving to other countries to study with more freedom and autonomy. Overall, policies, guidelines, and cost is currently a fluid situation that will require some trial runs to be able and recognize what works best for patients and healthcare providers alike.

Implications on Healthcare Delivery

Personalized medicine through regenerative stem cells is an unparalleled treatment and cure for a countless number of diseases, defects, disabilities, conditions, and injuries. Pluripotent stem cells are able to differentiate into every type of human cell, therefore they have the most potential benefits within regenerative medicine. Dr. O' Brien and Dr. Barry (2009) claim that enormous potential has been demonstrated in preclinical animal studies, but that early human studies have not been quite as promising. Delivery of this pioneering and innovative healthcare will

possess unrivaled challenges because there has been no experience within the field of rehabilitative regenerative therapy. In theory, every aspect of regenerated structures would react as if they were the original structures, yet it is unbeknownst how a regenerated structure will handle stress over time, how it will develop strength and endurance over time, how it will age over time, how to conduct therapy if there were complications, how it will react to an injury and numerous other difficulties that may arise. Essentially, regenerative structures are ideal on paper, but reality places demands that will eventually demonstrate the strengths and weaknesses of regenerating human structures. As a future healthcare provider, it would be extremely interesting to work in regenerative therapy, and hopefully regenerated tissues function as if they were original tissues. Despite the uncertainty, any unexpected challenges that arise from regenerative medicine would be received and addressed to the best of the ability of a therapist to enhance the client's quality of life

Consequence on Healthcare Delivery

Risks are inherent with all forms of healthcare delivery, and with a groundbreaking field of regenerative therapy emerging the risks are even more notorious and prominent. Minimal understanding of such a powerful therapy should always be considered a risk itself and it is important that it is fully understood before being implemented into practice. Preynant-Seauve and Karl-Heinz (2011) highlight the infamous complication of autoimmune rejection of stem cells in patients. In order to circumvent the risk, one can try a immunosuppressant with a similar risk as any organ transplant recipient (Preynant-Seauve & Karl-Heinz, 2011) or autograft stem cells from themselves; however, the issue surrounding the decision to autograft is that an individual will not be able to target genetic diseases because their stem cells are susceptible to the same genetic makeup that made their condition possible (French, 2016). If this complication were to arise, it would need to be immediately addressed or there would risk of losing the regenerated body structure, as well as, risk to the patient's overall health and well-being. Healthcare delivery is a dynamic intervention that relies on knowledgeable and competent health professionals that are able to recognize risks, complications, and progress for their clients.

Conclusion

Therapeutic intervention through stem cells is a powerful therapy that could potentially eliminate illnesses, alleviate injuries, minimize chronic conditions and treat a variety of other physical deficits. Bioethical debates will continue throughout the years of regenerative medicine's infancy, however there is little debate that humans would minimize such a life changing technology. Policies and the delivery of healthcare will evolve

and adapt to meet the demands of regenerative medicine as it emerges. Occupational injustices will exist as long as physical disabilities, injuries, and other conditions prevent individuals from participating in their valued occupations; however, regenerative therapy can help reintroduce an individual to their occupations, subsequently improving their quality of life. This unique type of therapy has implications for healthcare beyond that of any modern therapy and it will be interesting to see what emerges in the next few years.

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