Global Journal of Nanomedicine
ISSN: 2573-2374

Juniper Publishers
key to the Researchers

Mini Review
Volume 3 Issue 1 - September 2017
DOI: 10.19080/GJN.2017.03.555601

Glob J Nanomed

A Promising Application of Nanomedicine in Nanotechnology

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Submission: July 03, 2017; **Published:** September 19, 2017

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Abstract

Nanomedicine is a promising and revolutionary field to improve medical diagnoses and therapies leading to a higher quality of life for everybody. Huge benefits are expected from nanomedicine applications such as in diagnostic and therapeutic field. However, nanomedicine poses several issues on risks to the human health. This mini review aims to defense a perspective of risk governance that sustains scientific knowledge process by developing guidelines and providing the minimum safety standards acceptable to protect the human health. Newer and improved methods of cancer detection based on nanoparticles are being developed. They are used as contrast agents, fluorescent materials, molecular research tools and drugs with targeting antibodies. Although, nanomedicine is in an early stage of its discovery, some cautious measures are required to provide regulatory mechanisms able to response to the unique set of challenges associated to nanomedicine. However, it is possible that nanomedicine in future would play a crucial role in the treatment of human diseases and also in enhancement of normal human physiology. Nanotechnology offers a unique opportunity to intensify a major interplay between different disciplines such as nanomedical science. This multidisciplinary approach can positively contribute and finding reliable regulatory choices and responsive normative tools in dealing with challenges of novel technologies.

Abbreviations: MRI: Magnetic Resonance Imaging; QDs: Quantum Dots; UV: Ultra Violet; SPIO: Super Paramagnetic Iron Oxide; BBB: Blood Brain Barrier

Globalization of Nanomedicine Research

Nanotechnology is a revolutionary way of understanding technology and the process of manufacturing it in different sectors of industries such as transportation, nuclear weapons, detection systems, and telecommunications to name of the few sectors which nanotechnology will have a major impact. Specifically, nanomedicine, which is the application of nanotechnologies to medicine, is considered the field where nanotechnologies may noticeably improve medical practice for prevention and therapeutic purposes. The vastness of nanotechnology applications leaves many unanswered questions about the hazards related to human health from exposure of nanoparticles on the human body. The novelty of nanotechnologies demands a new approach in order to fully understand its broad applications, evaluate potential benefits, and assess potential risks to human health. However, because nanomedicine is a nascent science its risks and benefits are only hypothetical assessed at this stage. The lack of consolidated knowledge and the extensive medical literature of experimental data do not allow a clear assessment of the risks-benefits associated with this new technology. This lack of knowledge that currently surrounds the area of nanomedicine makes it difficult to anticipate adequate regulatory responses in nanomedicine and raises several regulatory questions. This short review aims to raise awareness of the main challenges that nanomedicine applications encounter from a regulatory perspective. Exploring different strategies and methods to deal with nanomedicine, this review will attempt to provide an answer on what is the appropriate regulatory approach at the early stages of this novel technology.

Ambiguities in the definition of nanotechnologies

Nanomedicine is a generic term to indicate products, processes, and properties of the nano/micro scale. Finding a general definition of nanomedicine is a difficult task because

of its hybrid nature and broad range of applications in different fields such as biology, chemistry, mathematics, and bio-engineering. This broad application of nanomedicine creates challenges in identifying nanomedicine but also in evaluating its novelty. At this stage, nanomedicine is not a delineated field because it could converge with drugs, with medical devices or it could be a combination of the two. From this perspective, one of the main challenges encountered in nanomedicine is the identification and thus the legal evaluation of a final medical product that can result from the combination of different types of components. In fact, most of the nanomedicine technologies challenge the boundaries between different areas of science, such as: chemistry, biology or engineering because they do not fall in the traditional classifications of drugs or medical devices. Conversely, nanomedicine applications demand an accurate understanding of the complex processes that involves different expertise and disciplines.

Properties of nanotechnologies

The characteristics of nanoparticles are the ultra small size, large surface area to mass ratio, high reactivity and, ultimately, no solubility. The small size property means that they deal with structures measuring less than 100 nanometers about a thousand of the diameter of a human hair. These properties allow nanomedicine to differ completely from equally shaped macroscopic structures and to perform exceptional tasks in medical practice. Furthermore, these properties make nanoparticles significantly innovative in the sense that they are able to overcome some of the limitations that affect traditional diagnostic and therapeutic agents [1]. In fact, at this scale nanoparticles match the typical size of natural functional units in living organisms. The small size property provides nanoparticles an extreme mobility and the capacity to interact with the biology of living organisms.

Characteristics of nanomedicine applications

Nanomedicine carries a great hope for the cure of life-threatening and disabling diseases. Numerous benefits have been discovered in Nanomedicine such as the improvement of diagnostic, techniques and imaging, biomaterials, drug development and delivery, regenerative medicine, stem cell therapy, implants, and cosmetic applications. Nanomedicine holds great expectations for scientific advances in the area of regenerative medicine - tissue engineering - and cancer therapy enabling techniques that cannot be performed otherwise. The use of nanomedicine has made tremendous advances in the treatment of severe and disabling diseases. nanomedicine applications relate to novel therapies and diagnostic techniques in three major areas such as molecular imaging agents, drug delivery systems and bio-sensors. The description of the novel medical applications in the following sections is not exhaustive, but is intended to illustrate some advances obtained by the use of nanotechnologies in medicine.

Optical Imaging

Nanotechnologies can provide improvements in imaging the human body by using fluorescence microscopy or magnetic resonance imaging (MRI). Quantum dots (QDs) are inorganic particles with luminescence properties which are employed for novel diagnostic purposes. These types of nanoparticles are able to emanate strong fluorescent light under ultraviolet (UV) illumination, and the wavelength (color) of the fluorescent light emanated depends sensitively on particle size. The main advantages associated with quantum dot technologies are to image tissues and cells, such as: lymph nodes and tumors. Other types of nanoparticles known as super paramagnetic iron oxide (SPIO) have recently been recognized as a capable way of detecting cancer. The outcomes of these studies have shown that SPIO nanoparticles can accurately detect metastases that otherwise would be undetectable [2]. As a result of this, patients are being treated for their cancers at an early stage and thus this is impeding the proliferation of other metastases. In addition to that, patients have the option to treat the cancer detected at an early stage with surgery intervention rather than having radiation therapy which is commonly used in the advanced cancer therapy.

Drug Delivery System

Several studies have been made in different areas of medicine have shown that nanoparticle- based drug delivery systems can be employed in different ways to improve the efficacy and performance of drugs and to eliminate the adverse effects of drugs already in use today. Some studies have shown that nano-sized polymer based pharmaceuticals are successful for the treatment of several types of cancer such as skin, ovarian and lung cancer [3]. Nanoparticles used in cancer therapies have the ability to carry the drug only to treat the cancerous cells without interfering with the surrounding parts or organs. In addition to this, some studies have shown how nanoparticle- based drug delivery can be employed in different ways to improve the performance of cancer therapy [4]. In fact, one of the major challenges for drug delivery system to the brain is the presence of the blood brain barrier (BBB) which is a natural brain protection against foreign substances and blood infections. As a result, it becomes necessary to administer higher doses of drugs with an increase in adverse effects. Conversely, the use of polymer nanoparticles in drug delivery to the brain has demonstrated the potential to administer non- invasive nanotechnologies to penetrate the BBB [5]. Moreover, one of the major challenges affecting the efficacy of HIV anti –viral agents are the poor water solubility. Some experiments conducted on dogs were successful in demonstrating that the employment of nanoparticles is a more efficient way to distribute HIV anti -viral agents [6].

Role and scope of guidelines in the context of nanomedicine

Nanomedicine drug delivery system is blurring the borderline

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between medical products and devices. However, legislations and regulatory sources are not sufficiently responsive in dealing with these challenges. As more nanoproducts and technologies are introduced into the market, it is extremely important for researchers, jurists, and manufacturers to know what is the legislative or regulatory framework involved with a specific product or technology. Furthermore, both systems are based on a classical model of drugs, medical devices and combined products without taking into considerations the novel challenges coming from the advancement of nanomedicine. From this point of view, detailed guidelines that clarify legal requirements and criteria for nanomedicine legislation are required. The borderline products that incorporate medical devices and drugs is a guideline intended to clarify what requirements a nanomedicine combined product has to fulfill in order to be considered subject under the Medical Devices Directive or Medicinal Product directive. At this stage of the advancement of nanomedicine an appropriate regulatory approach should address flexible guidelines as a helpful information source on the most challenging Nanotechnology applications, but with a regulatory mechanism that enables regulatory bodies and legislators to intervene whereas an authoritative interpretation of legal provisions is required.

Conclusive Considerations

Nanomedicine offers the possibility of preventing, diagnosing and treating very disabling diseases and thus opens up very promising area in the field of medicine. However, limited knowledge and lack of scientific data on nanomedicine poses novel challenges. The first challenges that researchers, jurists and legal scholars have encountered with nanomedicine is how to identify nanomedicine and evaluate its novelty since Nanomedicine is across different disciplines such as biology, chemistry, and bio-engineering. This means that nanomedicine applications require a deep understanding of the processes involved in each application and challenges the boundaries between inter- and multi-disciplinary research areas of science. On the one hand, the ultra small size of nanoparticles is significantly innovative in the area of diagnosis and therapy due to this scale nanoparticles match the typical size of natural functional units in living organisms. However, the ultra small size of nanoparticles is the most worrying concern for scientists and experts because of the risks to the human health associated with a more intense interaction between nanoparticles and living orgamisms. This property is surprisingly ambivalent in its positive and negative implications. Conversely, a more reliable and realistic risk-benefit analyses should integrate scientific data with legal, social and ethical values even in the risk-assessment [7-9]. Such an approach aims to pursue an assessment of the magnitude of risks, but it also helps in investigating more complex questions related to the risks and its variable factors. This approach gives a more realistic picture of risks and its interdependencies because it takes into consideration concrete situations. Ultimately, nanotechnological innovations are transformative in the sense that they result from an assemblage of complex dynamics and variable processes that go beyond the classical way of understanding science. This revolutionary dimension inborn in Nanotechnology, but common to other emergent technologies triggers a more responsive mechanism able to deal with these challenges [10]. The challenge is to envision a technological pathway in which a fragile and fragmented scientific knowledge can benefit the value and capability of different disciplines that continually interact in response to the evolution of knowledge with a positive impact on policy choices and normative framework.

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