Nanomed Res J 9(4):339-347, Autumn 2024

REVIEW ARTICLE

A review on the importance of standardization in nanotoxicology for promoting safe and sustainable nanotechnology: Benefits, challenges, and solutions

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ARTICLE INFO

Article History:
Received 18 Jun 2024
Accepted 21 Sep 2024
Published 01 Dec 2024

Keywords:
Standardization
Nanotoxicology
Benefits
Challenges
Nanotechnology

ABSTRACT

The growing application of nanotechnology across different industries necessitates a comprehensive understanding of nanomaterial toxicity to ensure safety and sustainability. Despite its transformative potential, the unique properties of nanomaterials pose significant health and environmental risks, necessitating the emergence of nanotoxicology as a critical discipline. Nanotoxicology investigates the safety and impacts of nanomaterials, and its advancement depends heavily on the establishment of robust standardization practices. Standardization delivers multiple advantages, including global harmonization of safety protocols, enhanced reproducibility of toxicity studies, and facilitation of international trade by aligning regulatory frameworks. It fosters public trust by ensuring rigorous evaluation of nanoparticles and encourages innovation by providing predictable guidelines for developers. Moreover, standardized methodologies promote collaboration across disciplines and geographies, advancing research and enabling the sustainable integration of nanotechnology into diverse industries. However, several challenges impede progress, including the diverse nature of nanomaterials, complex biological interactions, and inconsistent regulatory frameworks. Additionally, the lack of standardized methods for long-term risk assessments and limited accessibility to advanced characterization tools present significant barriers. Overcoming these challenges requires interdisciplinary collaboration, investment in advanced testing and calibration techniques, and international cooperation to harmonize regulations. Ethical considerations and transparent stakeholder communication are also crucial to building public confidence. This review focuses on the benefits, challenges and solutions in the field of nanotoxicology standardization and calls for a concerted global effort to overcome barriers, setting a strong foundation for a safer and more sustainable nanotechnology future.

How to cite this article
Zayerzadeh E., Koohi M.K. A review on the importance of standardization in nanotoxicology for promoting safe and sustainable nanotechnology: Benefits, challenges, and solutions. Nanomed Res J, 2024; 9(4): 339-347. DOI: 10.22034/nmrj.2024.04.001

INTRODUCTION

Nanotechnology is the science of designing and developing new materials and devices, using structures on the nanometer scale, typically between 1 and 100 nanometers. The term "nanotechnology" was first presented by the Japanese scientist Norio Taniguchi in 1974, who applied it to define precision machining at the nanometer scale [1]. Then, nanotechnology has developed and has various applications in different fields such as biomedicine and healthcare, materials and processes, environmental remediation, agriculture, energy, transportation, food processing and IT and, electronics (Figure 1). Some applications of this science are to produce more efficient electronics, to develop novel materials with more strength or conductivity and creating drug delivery systems that can target specific cells

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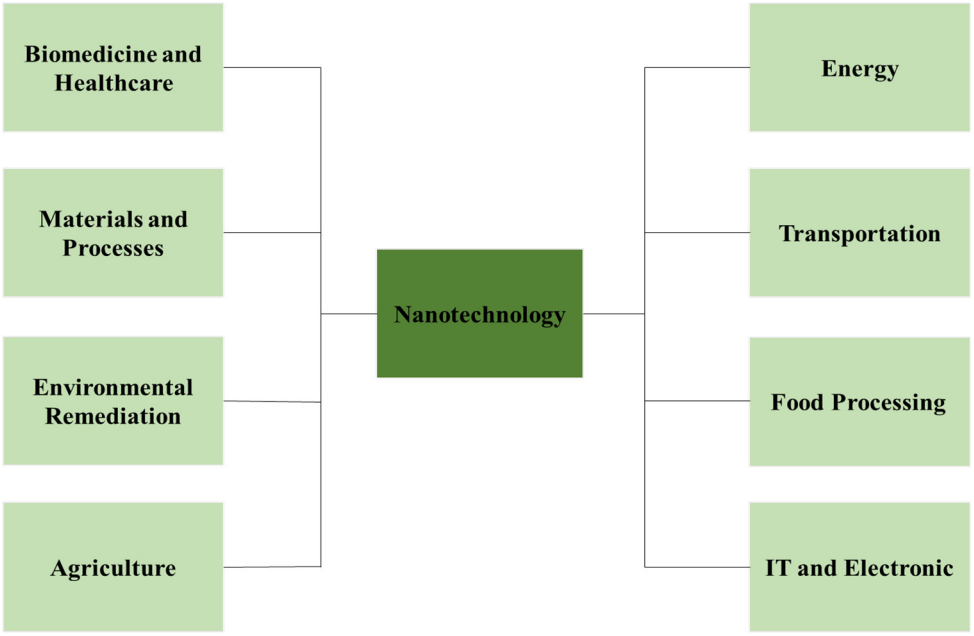

Fig. 1. Nanotechnology applications in different sections.

or organs in the body [2]. However, alongside these benefits, there are considerable concerns about the safety of nanomaterials which leads to introduce nanotoxicology. This science is the study of the health and environmental potential impacts of nanoparticles and nanomaterials, which is urgent for sustainable development of nanotechnology. The first nanotoxicology investigations appeared in the 1990s and early 2000s when scientists understood that nanoparticles could affect biological systems [3, 4]. These initial studies emphasized that nanoparticles could cause unique toxicity signs, particularly in terms of cellular damage, and the potential to induce inflammatory responses [4-6]. In recent decades, nanotoxicology expanded to the study of absorption, distribution, metabolism, and excretion of the nanoparticles and nanomaterials in the body, and also acute, subacute, subchronic, chronic, mutagenicity, carcinogenicity, teratogenicity studies and potential risks to public health and the environment [6-8]. This science has different branches including in vivo nanotoxicology, environmental nanotoxicology, Aquatic nanotoxicology, in silico nanotoxicology, genetic Nanotoxicology, in vitro nanotoxicology, occupational nanotoxicology, regulatory nanotoxicology (Figure 2). Nowadays, nanotoxicology is recognized as an essential field for developing standards and guidelines for the safe use of nanotechnology [9, 10]. Standardization is the process of implementing, developing and promoting technical standards based on the consensus of different parties, including users, interest groups, stakeholders, regulators, standards organizations and governments. Standardization maximizes compatibility, interoperability, safety, repeatability, efficiency, and quality [11, 12]. Different fields such as health, industries, human life, environment, education, transportation, politics, economy and so forth are affected by standardization (Figure 3). Standardization in nanotoxicology was started in the early 2000s. The need for standardization arose due to different factors. First of all, without accepted standards, nanotoxicology studies demonstrated inconsistent results because of variability in the nanomaterials used, test protocols, and characterization techniques. This difference made it tough to compare results between studies to assess the potential risks associated with nanomaterials. Secondly, regulatory bodies needed standard requirements to ensure for safe use of nanomaterials in consumer products. Finally, for improvement of nanotoxicology research reliability, the scientific communities realized the importance of standardization [4, 10, 13]. Standardization activities are performed by international organizations such as the international organization for standardization (ISO) and the organization for economic cooperation and development

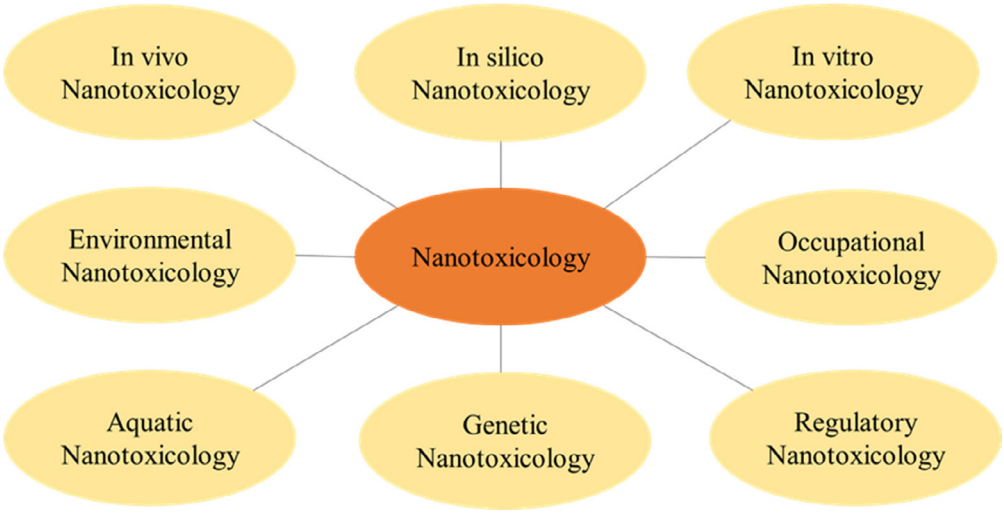

Fig. 2. Some branches of nanotoxicology

Fig. 3. Different subjects which are affected with standardization

(OECD). Approximately, there are 110 published ISO standards in the field of nanotechnology and among these standards about 28 standards are in the field of nanotoxicology. These organizations have developed different types of standard documents in the field of nanotechnology and nanotoxicology. In the present unique review, we focus particularly on the benefits, challenges and solutions in the field of nanotoxicology standardization.

BENEFITS OF STANDARDIZATION

Harmonization across borders

Standardization ensures that the test methods, specifications, guidelines, code of practices and criteria used to evaluate nanosafety and nanotoxicity are consistent worldwide. This

harmonization allows for the comparison of data and results across various countries. As a result, facilitating a more comprehensive knowledge of nanoparticle safety [14].

Facilitating trade and innovation

When companies adhere to international standards, their products are more likely to be accepted in international markets. This declines the need for repeated testing and approval processes in different countries, thereby speeding up the time to market. In addition, international accepted standards provide a predictable regulatory environment, which persuades innovation in the development and use of nanotechnology [12].

Boosting safety and public trust

International standards build monotonous safety criteria that must be met, ensuring that nanoparticles are evaluated precisely for potential risks to human health and the environment, regardless of where they are manufactured or applied. Also, public confidence in nanotechnology is increased when it is clear that nano-products are subject to careful, internationally accepted safety assessments. This trust is essential for the widespread adoption of nanotechnology in different areas [7, 10].

Promoting collaboration and research

International standards facilitate the sharing of resources, including reference materials and databases, among researchers internationally. This cooperation boosts scientific advancement and the development of new testing methods and safety protocols. Moreover, using standardized methodologies, scientists from various countries can work towards common purposes, cooperating to a strong and comprehensive knowledge of nanotoxicology [12, 15, 16].

Facilitating sustainable development

Standardization ensures that the development and use of nanoparticles do not destroy the environment, ecosystems or causes pollution by safety assessment of nano-based products using international standards. It also encourages the adoption of legal standard practices in the production and disposal of nanoparticles, supporting global efforts to reduce environmental problems [17, 18].

Providing quality control

Quality control in the context of standardization in nanotoxicology refers to ensuring that the processes, methods, and outcomes associated with evaluating the safety and risks of nanomaterials are reliable, consistent, and accurate. Standardization plays a crucial role in achieving this by establishing uniform procedures and criteria [19].

Consistency in testing protocols

Standardized testing methods ensure that experiments are conducted consistently between different laboratories and studies. This consistency helps in comparing results and drawing valid conclusions about the toxicity of nanomaterials. Therefore, it is the cornerstone to advancing nanotoxicology and ensuring the safe and reliable development and application of nanomaterials in different industries. In addition, as characterization of nanomaterials is a fundamental step in nanotoxicology, standardization provides guidelines for the characterization of nanomaterials. Appropriate characterization is urgent for evaluating the safety and efficacy of nanomaterials [9, 20, 21].

To guarantee reproducibility of results

Reproducibility is a cornerstone of scientific studies, ensuring that experiments can be repeated with the same results by various researchers and laboratories across the globe. In nanotoxicology, reproducibility is essential because it validates results, causes confidence in toxicity assessments, and supports regulatory decisions. Reproducibility allows researchers to confirm that toxicity observations are consistent and not due to random chance or experimental errors. This validation is crucial for establishing reliable conclusions about the toxicity of nanomaterials [13, 22].

Validation and calibration

Another important criteria is method validation using standard test methods which involves checking that they produce reliable and reproducible results. In addition, regular calibration of equipment and instruments in accordance with standardized protocols is vital to ensure that measurements are accurate and consistent in nanotoxicology field [23, 24].

Data quality and quality assurance

Applying standardized reporting formats is

essential to ensure that presented data is clear and consistent. This comfort better interpretation and comparison of results between different laboratories and regulatory documents. Moreover, implementing standard quality assurance procedures, including internal audits and proficiency testing is foundation to maintain high standards in data collection, analysis, and reporting [19, 21].

Reducing uncertainty and bias

Using standardized protocols reduces the variability and bias that occur from various testing conditions or methodologies. This leads to more reliable and interpretable results [23, 25].

Continuous improvement

As new scientific knowledge and technologies appear, standardized methods are continuously updated. This ensures that quality control practices remain more efficient [26].

Documentation and record-keeping

Standardized documentation practices ensure that all procedures, results, and alterations are recorded extensively and regularly. This traceability is crucial for auditing, validation, and reproducibility [26].

Regulatory compliance

Standardization simplifies compliance with regulatory requirements by providing clear benchmarks for safety assessments. Regulatory agencies can apply these standards to make appropriate decisions about the approval and use of nanomaterials. Regulatory compliance is an essential factor in the development, production, and use of nanomaterials. It involves sticking to guidelines and standards established by national and international regulatory bodies to ensure that nanomaterials are safe for human health and the environment. Regulatory compliance ensures that nanomaterials are assessed for potential health and environmental risks before they are applied in products, medical applications, or industrial processes. This assessment is crucial to prevent toxic effects and protects public health [26].

Public and environmental safety

Standardization is very urgent to protect public and environmental safety by ensuring that nanomaterials are tested for potential hazards comprehensively. This standard monitoring program is crucial to prevent adverse effects on public health and ecosystems [17].

Stakeholder communication

Standardized terminology and methodologies is the best communication route between stakeholders, including manufacturers, researchers, industry professionals, regulators, standardization bodies and the public. Clear communication is essential for developing reliability and transparency among mentioned stakeholders in the field of nanotoxicology (Figure 4) [21].

CHALLENGES AND SOLUTIONS

Standardization in nanotoxicology,

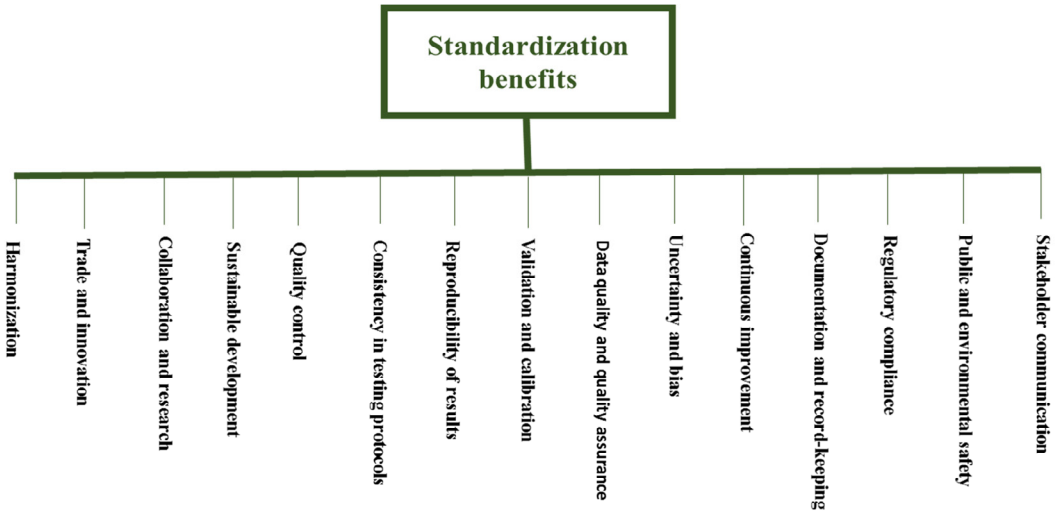

Fig. 4. Schematics of standardization benefits

demonstrates significant challenges. These challenges arise from the unique characteristics of nanomaterials and the complexities involved in assessment of their effects on human health and the environment. Addressing these challenges requires coordinated efforts among standardization agencies, scientists, regulators, governments and all stakeholders to develop efficient and adaptable standards that can accommodate the sustainable progress of nanotoxicology field [3, 27]. In this regard, some of the main challenges and solutions are mentioned below (Figure 5).

Diversity of nanomaterials

Nanomaterials vary extensively in terms of size, shape, surface chemistry, composition, and other physical and chemical properties. This diversity makes it tough to develop standard test methods, guidelines, and specifications, code of practices and, protocols that can be used globally. The best solution to address this challenge is to harmonize measurement and characterization protocols across different laboratories and regions with ISO and OECD [14, 20, 24].

Measurement and characterization

Unique physical and chemical traits of nanomaterials require high-tech equipment's and specific techniques for appropriate and accurate measurement and characterization, which are not often provided in different laboratories across the world. The best ways for coping over this challenge is to invest in the development of advanced and accessible instrumentation and development of reference materials for different types of nanomaterials which can be applied by laboratories globally to calibrate their instruments and validate their methods [20, 24].

Fig. 5. Schematics of standardization challenges (Red circles) and solutions (blue circles)

Biological interaction

Nanomaterials have complex interactions with biological systems which is different from bulk materials. This complexity makes it difficult to assess their toxicity. In addition, the dose metrics standardization for toxicity assay is tough because this index can be changed according to the different types of nanomaterial and the biological system. In this line, there are two solutions to overcome to these challenges. Firstly, support mechanistic studies of nanomaterials to raise knowledge in this field to the development of standardized test methods and guidelines. Secondly, for standardization of dosing guidelines for toxicity assays, researching to determine the most relevant dose metrics for various types of nanomaterials should be encouraged [4, 5, 17, 28].

Regulatory framework

There is no international agreement and harmony on the regulatory frameworks for nanomaterials. As a result, it can lead to inconsistent standards throughout the world. Moreover, nanotoxicology science is still evolving, which means that regulations, guidelines and standards must be regularly changed and updated. However, there are some steps to address these challenges. In the first step, international cooperation must develop among standardization agencies, industry, stakeholders and institutions to foster consistent and harmonized regulations for nanomaterials. In the next step, to implement adaptive regulatory frameworks. This would allow regulations to synchronize with the rapidly developing field of nanotoxicology [3, 14, 26].

Uncertainty in risk Assessment

The long-term effects of nanomaterials on human health and the environment are still not well understood, which lead to uncertainty in risk Assessment. There is lack of standardized test methods for assessing long-term toxicity of nanomaterials (chronic, carcinogenicity, teratogenicity, mutagenicity). For solving these challenges, there are two solutions. First is to develop standardized tools and models for risk assessment that consider the unique characteristics of nanomaterials. These tools and models must be accessible and available for regulators, industry, scientists and stakeholders. Second solution is to invest on long-term epidemiological investigations to evaluate the chronic effects of nanomaterial exposure. Collected information about them is very crucial for improvement of risk assessment models which leads better standardization in nanotoxicology [5-7, 29].

Ethical implications and public concerns

The ethical considerations of nanotechnology such as concerns about unforeseen public and health and environmental problems, challenge the development of standards. On the other hand, the lack of standards in this field can lead to public mistrust, which can affect regulatory and standardization programs negatively. For coping these challenges, the best actions is to establish ethical guidelines for using nanomaterials, ensuring that concerns about safety and environmental effects, are accordant with accepted international standards. Another action is to enhance transparency in nanotoxicology researches and regulations by employing public and stakeholders from all around the globe through international communication about the hazards, risks and benefits of nanomaterials [15, 25]

Cross-disciplinary cooperation

Nanotoxicology requires collaboration between different sciences, such as toxicology, chemistry, biology, physics, and engineering. As a result, this issue can lead to challenges in standardization because of different methodologies, terminologies and knowledge among them. The best step for addressing such challenge is to build interdisciplinary networks that bring together experts from different branches of sciences to cooperate in standardization activities. These networks can share knowledge, methodologies, and the best practices and diminish scientific controversies [30, 31].

Economic and practical problems

Development and implementation international standards in nanotoxicology field can be costly. As a result, it will be difficult for some countries to cover the expenses. In addition, ensuring that these standards are accessible and practical for all stakeholders around the globe, is another main problem. One of the best solutions for the first challenge is to support small and medium-sized stakeholders to adopt international standards by funding such as grants, tax incentives, or subsidies. The best solution for the second challenge is to ensure that standardized methods, guidelines, and

reference materials are accessible to researchers and stakeholders universally. Online free platforms and open-access resources could play a key role in addressing this challenge [14, 26].

CONCLUSION

Standardization in nanotoxicology is a cornerstone for the safe and sustainable advancement of nanotechnology. As nanomaterials increasingly influence sectors such as healthcare, electronics, and environmental management, their unique properties demand precise and consistent methods for evaluating their safety. Standardization ensures global harmonization of testing protocols, reproducibility of results, regulatory alignment, and public confidence in nanotechnology applications. It provides a framework for managing the potential risks of nanomaterials while fostering innovation, trade, and sustainable development. Despite its critical importance, achieving comprehensive standardization in nanotoxicology is fraught with challenges. The vast diversity of nanomaterials, coupled with their complex interactions with biological systems, creates significant hurdles in developing universal testing methods. The absence of a unified global regulatory framework and the economic barriers faced by many stakeholders further exacerbate these challenges. Additionally, limited tools for long-term risk assessment and insufficient access to advanced characterization facilities hinder progress. To address these obstacles, a cohesive and collaborative approach is essential. Priorities include harmonizing characterization and testing protocols, advancing risk assessment models, and fostering interdisciplinary cooperation across scientific, regulatory, and industrial domains. International organizations like ISO and OECD must intensify efforts to establish comprehensive guidelines, while governments and stakeholders should prioritize investments in accessible technologies, funding initiatives, and transparent communication to build public trust. By tackling these challenges head-on, the field of nanotoxicology can set the foundation for a safer and more responsible era of nanotechnology, ensuring that its transformative potential is realized without compromising human health or environmental integrity.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest

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