

Nanomedicine: Ethical and Societal Challenges to Major Stakeholders

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Nanomedicine is one of the most promising areas of nanotechnology. The revolutionary impacts of nanotechnology on medicine are discernible in the three aspects of medical practice - diagnosis, treatment and monitoring. Nanoparticles used for image enhancement will improve the visibility of internal bodily structures. Active ingredients of drugs can be packaged and delivered to the precise location where treatment is necessary. Treatments could be tailored according to the specific biology of the individual patient. Furthermore, monitoring and patient care will be decentralized. The Rathenau Institute of the Netherlands envisions that nanomedicine will be predictive, preventive, personalized and participatory. These thrusts were driven by the unprecedented advances in genomics and proteomics which will lead to an improved understanding, mitigation, prevention and control of the diseases at the molecular levels.

While the accelerated pace of nanomedicine continues to conquer new borders, it likewise raises potential societal and ethical concerns which will affect cultures, institutions and individuals differently. Nanomedicine will pose a challenge to the current medical practices by redefining roles and responsibilities of hospitals and clinics, recasting the model of patient-physician relationship and introducing shifts in the understanding of human values. This paper will focus on the ethical and societal challenges of nanomedicine to pharmaceutical industries, governments, hospitals, patients and physicians as the major players or stakeholders of nanomedicine.

Keywords: *nanomedicine, stakeholders of nanomedicine, targeted drug delivery, tailored therapies, privacy & confidentiality, standard of care, theranostics, safety & toxicity*

Introduction

Nanomedicine is one of the most promising areas of nanotechnology. It emerged as an ambitious venture supported by the various sectors of the society with focused interest in developing ways of addressing the formidable challenges of health care. The Rathenau Institute of the Netherlands, an independent body dedicated to monitor the societal significance of technological advances, has articulated its technological vision of nanomedicine, as identified by 4Ps, namely, predictive, preventive, personalised and participatory nanomedicine.¹ These thrusts were driven by the unprecedented advances in genomics and proteomics which will lead to an improved understanding, mitigation, prevention and control of the diseases at the molecular levels.

Nanomedicine is expected to reconfigure the health care delivery system because of its enabling capacity. It will create opportunities for nanomedical related industries like the pharmaceutical firms and medical equipment providers. It will challenge current practices in the medical field. It will redefine roles and responsibilities of hospitals and clinics. It will recast the model of patient-physician relationship in many ways. Just as nanomedicine will provide a constellation of opportunities for various individual groups, it is also expected to introduce potential threats and incalculable risks to society. The potential impacts of nanomedicine to society should be carefully deliberated even before the technology is applied lest we regret our actions or failure to do concrete actions which are most of the time “too little, too late reactions”. To achieve these ends, it is important to establish, not only the topography of nanomedicine, but to ascertain the roles of the major players, their dynamics and interplay to determine the future course of nanomedicine.

The framework that will be used in developing the paper will go beyond the purview of bioethics but will examine the issues and concerns from the standpoint of nanoethics. Broadly defined, nanoethics is an umbrella term that designates the various ethical and social implications of nanotechnology. Often these implications are clustered as SEIN (social and ethical implications of nanotechnology), ELSI (ethical, legal and social implications), which was originally associated with the Human Genome Project, or its variation NELSI (nanotechnology’s ethical, legal and social implications). Still, others used the acronym NE³LS (nano-ethical, environmental, economic, legal and social issues).

¹ *Nanomedicine in the Netherlands. Social and Economic Challenges*, Rathenau Instituut-Technology Assessment, May 31, 2010, Accessed at <http://www.etp-nanomedicine.eu/public/news-events/news/related-content/Nanomedicine%20in%20The%20Netherlands%20-20Rathenau%20Instituut.pdf>, Accessed on August 12, 2010.

The Major Players of Nanomedicine

In the field of nanomedicine, the pharmaceutical industry is one of the eager beaver respondents of the ostentatious promises of nanotechnology. The industry is engaged in the development, manufacturing and marketing of licensed drugs to diagnose, treat or prevent diseases. Nanotechnology's application in medicine will "enhance discovery process through miniaturization, automation speed and reliability of assays and reduced cost of drug discovery design and development which will enable faster introduction of new cost effective products in the market."² It is not surprising why the market forecast for nano-enabled pharmaceuticals is expected to reach 53 billion US dollars in 2011 and 110 billion US dollars in 2016.³

Social policy and law influence the future directions of any given technology. But in most cases they lag behind the advances in science and technology. Take for instance, the need to promulgate new laws during the nascent stage of the information era in order to address the increasing number of cybercrimes in its various forms. Regulation in the form of new laws was put to place only as an afterthought in order to address the problems that were not yet there before the deployment of technology in the society. This would likely be the case for nanotechnology. Concerned government agencies should keep up with technological developments.

The far-reaching effects of nanomedicine will be increasingly evident in hospitals as the primary institution for health care. While the prospects for improved quality health care system through nanotechnology-based imaging and targeted drug delivery are highlighted in research publications, actual clinically relevant applications have not been documented.⁴ Retel et al. suggest that there is a need for evaluating the consequences of using specific technologies in the organizational settings. This should include aspects such as diffusion rate of technology, implementation and logistics.⁵

² Raj Bawa and Summer Johnson, "Emerging Issues in Nanomedicine and Ethics" in *Nanotechnology, Ethics and Society*, ed, Deb-Benett. Woods, (New York: CRC Press, 2008), 212.

³ Ibid.

⁴ Valesca P. Retel, et al, Review on early technology assessments of nanotechnologies in oncology, *Molecular Oncology* 3 (2009) 394.

⁵ Ibid.

Diffusion rate of technology. This indicates the level of acceptance of the technology by patients and practitioners and the pace at which it is integrated in the health care system. In its initial course of introduction, it is likely that only a few experts will adopt the technology, Nevertheless, its potential for wider use should be considered. Also, at the early stage of its deployment, the safety and efficacy of medical interventions should be carefully monitored.

The patient and the physician are the end users of medical nanotechnologies. The success rate of the technology will be measured in terms of meeting their expectations. A common expectation includes safety and efficacy of the medical intervention. Health outcomes are, to a large extent, dependent on this relationship built on mutual respect, caring and trust. Patients are not merely passive receivers of health care or subjects of research but active partners of physicians in the decision-making process.

The Ethical and Societal Challenges of Nanomedicine to Major Stakeholders

While the accelerated pace of nanomedicine continues to conquer new borders, it likewise raises potential societal and ethical concerns which will affect cultures, institutions and peoples differently. Nanomedicine will pose a challenge to the current medical practices by redefining roles and responsibilities of hospitals and clinics, recasting the model of patient-physician relationship and introducing shifts in the understanding of human values.

The major challenges for the pharmaceutical firms include issues of safety and risk assessment, risk communication and misleading claims. Governments, on the other hand, are faced with concerns related to patents, safety and toxicity, risks and uncertainties, fair distribution of medical goods, funding priorities and demographic shift, and regulation in the age of 'theranostics'. For hospitals, nanomedicine will raise issues like further medicalization of society, decentralization of patient care and redefinition of normality and pathology. Meanwhile, for patients and physicians, nanomedicine will enlarge issues concerning assessment of risk and benefit ratio, privacy and confidentiality and redefinition of the standard of care. Evidently, safety is an all-pervading concern among the major actors of nanomedicine.

Implementation. Once it is put into operation, the new technology will likely impact patient communication, guidelines and safety protocols. The huge amount of medical data may pose a major challenge to hospital personnel and may affect data handling from collection, processing, analysis to retrieval and disclosure of results. More stringent safety protocols are needed to protect proprietary or highly sensitive medical records.

Logistics. Investments in health and information infrastructure as well as in staff development should be carefully planned by hospital administrators. Nanomedicine will necessitate the adoption of a medical record system designed to accommodate large medical files which could be processed and analyzed in real time. At the same time, hospitals should invest their resources in highly trained medical staff, capable of using the new medical technologies and with a good background in interdisciplinary nature of nanotechnologies.

Conclusion

Nanotechnology's groundbreaking impacts on medicine enriches the fertile grounds of ethical discussions for bioethics. The ethical and societal concerns generated by nanomedicine are anchored in the crucial roles of major stakeholders, their interactions and dynamics. While it is true that ethics in nanomedicine is an extension of existing debates in bioethics like privacy, confidentiality, informed consent, risk-benefit ratio and safety concerns, the paper shows that nanoethics rests on a broader spectrum of analysis, which includes not only the ethical but the environmental, legal and societal dimensions as well. Its orientation to the “bigger picture” renders a multiperspectival and integral approach towards anticipating the future prospects for nanomedicine in the coming age of nanotechnology. ■

