Exploratory Brief

EXPLORATORY BRIEF ON NANOMEDICINE OR THE APPLICATION OF NANOTECHNOLOGY IN HUMAN HEALTH CARE

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EXPLORATORY BRIEF ON NANOMEDICINE OR THE APPLICATION OF NANOTECHNOLOGY IN HUMAN HEALTH CARE

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Competing interest is considered to be financial interest, either direct or indirect, that would be affected by the research contained in this report, or creation of a situation where an author's and/or external reviewer's judgment could be unduly influenced by a secondary interest such as personal advancement.

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EXECUTIVE SUMMARY

Healthcare planners and decision-makers in Alberta have a great interest in identifying the opportunities that nanotechnology offers for the early detection and intervention of diseases and, furthermore, in foretelling those opportunities over the next five to 10 years. This exploratory brief consists of two parts: the first part provides an overview of what was found from a literature search and the second part provides an inventory of resources on nanotechnology and nanomedicine.

Nanotechnology is described as the application of scientific knowledge to develop new materials and products and involves the manipulation of matter at the nanometre scale where unique phenomena enable new applications. Nanomedicine is a development of nanotechnology and refers to its application in medical science and the healthcare sector. Nanotechnology is a rapidly growing area that could touch upon every aspect of modern life and human health.

A vast literature exists in the field of nanotechnology and its application in medical science and the healthcare sector. In order to acquire some insights about where the field of nanomedicine currently stands and what is its anticipated future for human health care, a limited literature search was conducted of familiar 'horizon' scanning databases in health technology assessment. Seven reports that were published in English from 2006 onwards are briefly summarized in Part I. Four of the reports summarize proceedings and materials shared at numerous workshops and panels of leading international experts from academia, industry and government. The other three reports compiled by the RAND Corporation, the Ontario Health Technology Advisory Committee and the Adelaide Health Technology Assessment Program, are based on a review of major scientific and technology journals and magazines or of selected studies that were identified through a specific search of selected databases.

According to these documents, significant research has been and continues to be conducted in nanomedicine worldwide, in both the public and private sectors. Promising application areas include molecular diagnostics and imaging, theranostics (individual diagnostics and testing of the effects of treatment), nanobiosystems and biomarker patterning and discovery. Promising applications have also been reported in nanotechnology-based devices for drug, protein and gene delivery, implant technology and tissue engineering. It is expected that, within the next 5 to 10 years, these results will lead to early detection and treatment of different types of cancer.

It is clear that although many nanomedicine applications are still in their infancy, an increasing number is currently under clinical investigation and some products are already available on the market, such as contrast-enhancing agents for magnetic resonance imaging, wound dressings and chips for in vitro molecular diagnostics. Within the next 5 to 10 years, advances in nanomedicine will include new drugs, drug delivery systems and diagnostic devices as well as multifunctional medical devices for improved detection, treatment and monitoring of treatment for various chronic conditions including cancer, cardiovascular, neurodegenerative, inflammatory and infectious diseases. Nanotechnology is also expected to be used for regenerative medicine and enhanced surgical procedures.

Through new and continual improvement in nanomaterials and nanomanufacturing processes, nanotechnology applications hold promise to provide breakthroughs in medical research and human health care and are expected to lead to clinical solutions in preventive medicine, diagnostics, therapeutics and follow-up care services within the next 5 to 10 years.

Part II of the brief identifies a variety of resources such as specific informative websites and online journals, conferences and proceedings that are available to inform and update health planners and policy-makers regarding the applications of nanotechnology in human health care.

Continual scanning and updating will be required to keep current in this vast and quickly advancing field.

ABBREVIATIONS

AHTA	Adelaide Health Technology Assessment
AFM	atomic force microscope
AHS	Alberta Health Services
CNS	central nervous system
CT	computer tomography
DNA	deoxyribonucleic acid
ECM	extracellular matrix
ETP	European technology platform
FDA	The United States Food and Drug Administration
HTA	health technology assessment
IHE	Institute of Health Economics
LOC	lab-on-a-chip
MEMS	micro-electromechanical systems
MRI	magnetic resonance imaging
NCI	National Cancer Institute
NEMS	nano-electromechanical systems
NIH	National Institute of Health
Nm	nanometre
NMR	nuclear magnetic resonance
NNI	National Nanotechnology Initiative
NINT	National Institute for Nanotechnology
OHTAC	Ontario Health Technology Advisory Committee
PCR	polymerase chain reaction
PET	positron emission tomography
QD	quantum dots
RNA	ribonucleic acid
siRNA	small interfering ribose nucleic acid
SPIO	superparamagnetic iron oxide
SPR	surface plasmon resonance
US	United States
WTEC	World Technology Center
yr	year(s)

GLOSSARY/DICTIONARY

The terms listed below were obtained and adapted from the following sources:[1,2]

http://www.nanotech-now.com/nanotechnology-medicine-glossary.htm

http://www.nanomedicine.com/NMI/Glossary.htm

Atomic force microscope: an instrument that uses atomic forces between a sample and a sharp scanning needle tip to image surfaces to molecular accuracy by mechanically probing their surface contours; the AFM measures the tiny upward and downward motions of the tip as the tip is dragged over the surface, producing an atomic-resolution topographic map of the surface. The AFM has also been used to physically manipulate individual molecules.

Biocompatibility: the ability of the body to tolerate the presence or implantation of foreign objects.

Biomaterial: a material intended to interface with biological systems to evaluate, treat, augment or replace any tissue, organ or function of the body; a nonviable material used in a medical device, intended to interact with biological systems.

Biomimetic: an approach to bioengineering in which artificial materials are selected to mimic as closely as possible the desired structure or function of natural biological components; mimicking biology.

Biosensor: a device that senses and analyzes biological information (e.g., temperature, pressure, chemical content, etc.), commonly using a biological recognition mechanism combined with a physical transduction technique.

Biotechnology: the application of biological systems and organisms to technical and industrial processes, with production carried out using intact organisms (e.g., yeasts and bacteria) or natural substances from organisms (e.g., enzymes), or by modifying the genetic structure of organisms (genetic engineering); most generally, the engineering of all biological systems, even completely artificial organic living systems, using biological instrumentalities.

Bulk technology: technology in which atoms and molecules are manipulated in bulk, rather than individually.

Carbon nanotube: a nanotube consisting of cylindrically arranged graphite carbon.

Cell engineering: deliberate artificial modifications to biological cellular systems on a cell-by-cell basis.

Dendrimers: large, regularly-branching molecules (man-made macromolecular compounds that comprise a series of branches around an inner core).

Deoxyribonucleic acid: a complex molecule of very high molecular weight encoding genetic information.

Extracellular matrix: an extracellular fibrous scaffolding that helps organize cells into tissues.

***Ex vivo*:** outside of the living human body.

Fullerene: a closed-cage molecule consisting of linked pentagons, hexagons, heptagons or other polygonal elements; the term originally referred to carbon-only structures but has since been broadened to represent the entire class of molecules having this geometry, regardless of atomic constituency.

Functionalized: in chemistry, an otherwise chemically inert structure is functionalized when a chemically active ligand or moiety is covalently bonded to it.

***In vitro*:** in glass, as in a test tube; performed in the laboratory, usually involving isolate tissue, organ or cell preparations.

***In vivo*:** inside the living human body; performed on a living organism.

Liposomes: the sealed concentric microscopic shells formed when certain lipid substances are in an aqueous solution; they are small (100 nm), spherical, lipid bilayers produced from non-toxic phospholipids and cholesterol, which self-assemble and can be used to deliver drugs or genes.

Macromolecule: a molecule of colloidal size, typically 1–100 nm in diameter or length, consisting most notably of proteins, nucleic acids and polysaccharides.

Micelle: a self-assembling, hollow, spheroidal aggregate of amphipathic lipids in a polar liquid (e.g., aqueous) medium.

Microelectromechanical systems: micron-scale devices combining electronic and mechanical elements.

Micron: one-millionth of a meter; a micrometer.

Moiety: a portion of a molecular structure having some property of interest.

Molecular medicine: a variety of pharmaceutical techniques and gene therapies that address specific molecular diseases or molecular defects in biological systems.

Molecular mill: a mechanochemical molecular transport and processing system characterized by limited motions and repetitive operations without programmable flexibility.

Molecular nanotechnology: thorough, inexpensive control of the structure of matter based on molecule-by-molecule control of products and byproducts; the products and processes of molecular manufacturing, including molecular machinery; a technology based on the ability to build structures to complex, atomic specifications by mechanosynthesis or other means; most broadly, the engineering of all complex mechanical systems constructed from the molecular level.

Nano: a prefix meaning one billionth (1/1,000,000,000); it may refer to sizes of $\sim 10^{-9}$ meters or to physical objects constructed or processes performed at the atomic or molecular level.

Nanocapsules: vesicular systems in which the drug is confined to a cavity surrounded by a unique polymer membrane.

Nanomaterial: a material that has engineered properties because of nanometer scale structuring.

Nanomedicine: (1) the comprehensive monitoring, control, construction, repair, defense and improvement of all human biological systems, working from the molecular level, using engineered nanodevices and nanostructures; (2) the science and technology of diagnosing, treating and preventing disease and traumatic injury, of relieving pain, and of preserving and improving human health, using molecular tools and molecular knowledge of the human body; (3) the employment of molecular machine systems to address medical problems, using molecular knowledge to maintain and improve human health at the molecular scale.

Nanometer: one one-billionth of a metre.

Nano-organs: organs comprised of nanocomponents; nanorobotic organs.

Nanoparticle: a particle that is 1 to 100nm in diameter.

Nanophase: having nanoscale features or components.

Nanopore: a small pore in an electrically insulating membrane, which can be used as a molecular probe; it has a hole that allows DNA to pass through one strand at a time to identify the shape and electrical properties of each base on the strand.

Nanorobot: a computer-controlled robotic device constructed of nanometer-scale components, to molecular precision, usually microscopic in size (often abbreviated as "nanobot").

Nanoscale cantilevers: flexible beams anchored at one end resembling a row of diving boards that are engineered to bind to molecules associated with cancer**.**

Nanosensor: a chemical or physical sensor constructed using nanoscale components, usually microscopic or submicroscopic in size.

Nanoshells: layered nanoparticles (which have a silica core and metallic outer layer) with optical resonances that can be “tuned” by controlling the relative size of their layers.

Nanosieving: in medical nanorobotics, a nanodevice that can sort molecules or other nanoscale objects by physical sieving.

Nanospheres: matrix systems in which the drug is physically and uniformly dispersed.

Nanosystem: a set of nanoscale components, characterized by precise molecular order, working together to serve a set of purposes; complex nanosystems can be of macroscopic size.

Nanotechnology: engineering and manufacturing at nanometer scales; applications developed using materials that have at least one critical dimension on the nanometre length scale.

Nanotubes: hollow fullerene tubes, including but not limited to single- and multi-walled carbon nanotubes, with submicroscopic, often nanoscale, diameters and a wide range of continuous lengths.

Nanowire: is a nanostructure made of carbon, silicon and other materials that have unique properties; when used as a sensor, nanowires lay across a small fluid channel.

Nuclear magnetic resonance: in physics and radiology, an analytical technique that relies on the absorption of certain electromagnetic frequencies by atomic nuclei.

Parenteral: denoting any medication route other than the alimentary canal, such as intravenous, subcutaneous, intramuscular or mucosal.

Pharmacokinetics: study of the metabolism of drugs with particular emphasis on the time required for absorption, duration of action, distribution in the body and method of excretion.

Quantum dots: nanocrystalline semiconductor particles used for testing and diagnosis; a zero-dimensional quantum system.

Ribonucleic acid: the ribonucleotide polymer into which DNA is transcribed.

Tissue engineering: elaboration of cells and tissues outside a living organism, intended for use as components of a viable biomaterial or replant, by use of engineering methods and techniques.

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INTRODUCTION

The field of nanomedicine or the application of nanotechnology in human health care is rapidly developing and diffusing across many medical fields. Due to the continuing advances in nanotechnology development, there is currently great interest in Alberta, in Canada, and in many other countries worldwide in the field of nanomedicine and in the implications nanotechnology will have for the future in the human healthcare sector.

This information paper has been produced in response to a request from Alberta Health Services (AHS), Health Technology Assessment & Innovation Department, to conduct an exploratory brief on the opportunities the application of nanotechnology in human health care may offer over the next 5 and 10 years.

OBJECTIVE AND SCOPE

The objectives of this exploratory brief were to inform the following questions:

1. What opportunities does nanotechnology offer in the early detection and intervention of diseases?
2. What opportunities does nanotechnology offer health care in the areas of diagnostic and therapeutic services over the projected time periods of 5 years and 10 years?

A prospectively designed protocol was used to map some of the recently published information regarding the opportunities nanotechnology may offer in the human healthcare sector in the areas of diagnostic and therapeutic services within the next 5 and 10 years (up to 2021). Elements of this exploratory brief include:

- an inventory of published horizon scanning, foresight, forecast, and/or roadmapping studies reporting on the present and future clinical applications of nanotechnology;
- an inventory of resources on nanomedicine or the application of nanotechnology in health care (websites and open access journals) that may be useful for monitoring the latest developments.

Because of the vast scope of nanomedicine, and due to time constraints, this exploratory brief is not an exhaustive and systematic review of the literature on leading research opportunities offered by the applications of nanotechnology in medical science and human health care. It is not a systematic review of the rate of progress and development of nanomedicine research or a comprehensive assessment of the current applications of nanomedicine. Neither does it focus on the research that is currently being conducted in nanomedicine in Canada or on the leading Canadian researchers and research institutes/organizations/companies currently pursuing nanomedicine applications.

This exploratory brief does not address the systemic effects of the various applications of nanotechnology in human health care (for example, the implications of the emergence of nanotechnology with integrated applications that target, image and deliver drugs on health human resources training, new specialties, etc.). Neither does this exploratory brief address the barriers and drivers for the use of nanotechnology in human health care or the environmental, health, safety, ethical, social, and/or legal risks and issues associated with the application of nanotechnology in human health care, or the regulatory mechanisms needed to address them.

More details on the literature search strategy and study selection process used for this exploratory brief are provided in Appendix A.

BACKGROUND: NANOTECHNOLOGY AND ITS APPLICATIONS IN HUMAN HEALTH CARE

Nanotechnology is rapidly expanding worldwide and is emerging as one of the key technologies of the 21st century that is expected to enable developments across a wide range of industrial sectors to benefit people (www.nano.gov) (www.nrc-cnrc.gc.ca).[1–21]

What is Nanotechnology?

Although there is as yet no commonly accepted definition of nanotechnology, it may be described as the application of science, engineering and technology at dimensions between approximately 1 and 100 nanometers (a nanometer is one-billionth of a metre) to develop new materials and products (www.nano.gov) (www.nrc-cnrc.gc.ca).[1,2,10–21] It involves the manufacturing, manipulation, and control of matter at scales ranging from single atoms and molecules to micrometer-sized objects.

By manipulating and controlling individual atoms and molecules, nanotechnology enables the miniaturisation of many existing structures, devices, and systems and facilitates the development of new functional materials, devices, and systems, resulting in faster operation or the integration of several operations.[1,2,10–14,17–21] At the nanometre scale (also referred to as nanoscale) man-made structures match sizes of natural functional units in living organisms, allowing them to interact with the biology of living organisms. Particles of nanoscale chemical substances, or nanomaterials, reveal different physical, chemical, and biological properties as compared to micro- or macro-sized particles of the same material. At nanoscale, quantum effects begin to dominate the behaviour of matter, which may also affect the optical, electrical and magnetic properties of materials. Due to these aspects, nanomaterials are anticipated to have a wide range of new and powerful applications in many sectors including medicine, science, biotechnology, human health care, energy, environment, computing, and telecommunications.

However, nanotechnology is still in its early stages of development, and much remains to be discovered (www.nano.gov) (www.nrc-cnrc.gc.ca).[5–8,11–14,17–19] Building new and useful nanomaterials, devices and systems is technically challenging and many of the principles of how matter functions and organizes on the nanoscale have yet to be developed. Determining how to assemble different types of nanosized particles and devices into more complex systems that perform new and useful activities and applications safely is a major challenge. Another challenge is connecting these systems to the outside world so they can be controlled and monitored, and can provide useful information.

Nanomedicine or application of nanotechnology in human health care

By taking advantage of the new properties of nanomaterials and nanostructures, nanomedicine has the potential to enable early detection and prevention of various diseases, and to effectively improve diagnosis, treatment and follow-up.[1,2,10–14,17–19,21] Its aim may be broadly defined as the comprehensive monitoring, control, construction, repair, defence and improvement of all human biological systems, working from the molecular level using engineered devices and nanostructures, ultimately to achieve medical benefit. For the purpose of this exploratory brief, nanomedicine is defined as the application of nanotechnology to achieve breakthroughs in the human healthcare environment.

Nanomedicine is a major research sector covered by research and development (R&D) programs in many countries, including Canada (www.nano.gov) (www.nrc-cnrc.gc.ca).[1,2,5,6,8,10–14,17–19,21–23] It raises high expectations with regard to its potentials in diagnostics, drug development and delivery, targeted therapy, imaging, and other health-related applications including tissue engineering and regenerative medicine, since far-reaching claims are made by both opponents and proponents.[1,2,10–14,17–19,21] However, it is difficult to describe state of the art accurately as it is difficult to distinguish between current status, what may be possible to achieve in the short-, medium-, and longer-term, and what remains highly speculative.

Position of nanomedicine in the current human healthcare environment

Nanomedicine is currently deemed as an essential field through which to address many existing and future unmet clinical needs and is expected to contribute significantly to the overall human healthcare environment.[1,2,10–16,18,19,21] Due to its specific aspects, it offers opportunities to improve health care in all phases by leading to clinical solutions within preventive medicine, medical diagnostics and imaging, therapeutics and follow-up care services.

Diagnostics (including *in vitro* and *in vivo* diagnostics), therapeutics (including targeted drug/therapy delivery and drug discovery and development) and regenerative medicine (including tissue engineering and repair) constitute three main application areas of nanomedicine.[1,2,8,10–14,17–21] All these areas have different priorities for different diseases but they promise to impact conditions that currently have a very high prevalence, strongly reduce patient quality of life, and impose a high socio-economic burden on society. Thus, nanotechnology is expected to have a significant impact on the healthcare process for conditions such as cancer and cardiovascular, musculoskeletal, neurodegenerative, inflammatory, and infectious diseases.

Diagnostics

The application of nanotechnology in medical diagnostics and imaging (nanodiagnostics) aims to identify disease as early as possible, preferably at a level of a single cell, which relies on the development of molecular imaging and minimally invasive, implantable devices.[1,2,8,10–14,17–21] Nanodiagnostics can be subdivided into *in vitro* and *in vivo* diagnostics. In the area of *in vitro* diagnostics, nanotechnology is used for the development of new sensors, and, *in vitro* tests, to improve and make existing tests more sensitive, to allow for point-of-care applications or to develop new diagnostic test platforms. Several complex preparation and analytical steps can be incorporated into lab-on-a-chip technology, which can mix, process and separate fluids before carrying out sample identification and quantification. Integrated devices can measure tens to thousands of signals from one sample. Nanoarrays, nanowire sensors, surface plasmon resonance sensors and cantilever sensors are all nanotechnology-based sensors that currently have applications in biomedical research.

In vivo diagnostics refers to imaging techniques and also covers implantable devices and surgical tools.[1,2,10–14,17–19,21] Nanoimaging, or molecular imaging, includes techniques for the study of molecular events *in vivo* and for molecule manipulation, and is expected to lead to personalized medicine and real-time assessment of therapeutic effect. These techniques can be both *in vivo*, using contrast agents, and *ex vivo*, using specific markers. The nanoparticles used in molecular imaging include gold nanoparticles, quantum dots and magnetic nanoparticles. *In vivo* diagnosis is expected to become more sensitive and specific thanks to new imaging techniques and nanoparticles to be used in targeted diagnostic imaging.

Therapeutics

The main areas of the application of nanotechnology in therapeutics (nanotherapeutics) are drug and gene therapies.[1–4,10–19,21] In drug therapy, the size reduction or encapsulation of drug particles may improve the therapeutic potential of water insoluble and unstable drugs and may also facilitate the delivery of drugs/pharmaceuticals (small molecules) across biological barriers (such as the blood–brain barrier). Drugs embedded in targeted nanocarriers can deliver therapeutic molecules directly across biological barriers by bearing specific molecules or charges on their outer shell. The outer shell can include specific reagents (such as antibodies) that bind to specific targets. Nanocarriers can be made of physiologically stable material that only disintegrates on binding to its target or on receiving an external signal. In gene therapy, nanocarriers (such as the DNA nanoparticle) can deliver functional genes to correct genetic disorders. Nanoparticles and nanosystems such as nanosomes, nanocapsules, nanocages, micelles, nanoporous material, nanocrystals (quantum dots), molecular conjugates, and dendrimers are some of the delivery possibilities that offer potential to send drugs and genes through the body undetected until they reach the intended site.

Drug delivery via nanotechnology allows targeted delivery of high-potency drugs/pharmaceuticals that either could have adverse effects when administered systemically or may not be administered successfully by conventional methods.[1–4,10–19,21] The delivery systems are designed to achieve disease-specific targeting, control the release of the drug so that a therapeutic concentration is maintained over a period of time, provide more convenient routes of administration, and reach locations in the body that are difficult to access.

Nanotechnologies (including nanoparticles, nanoscale molecular structures, and nanodevices such as nanobiosensors and nanobiochips) are also used to improve drug discovery and development.[1,2,10–14,17–21] Drugs that are developed through nanotechnology are expected to have advantages over normal drugs, i.e., arrive in appropriate concentrations at the target tissues without a major loss of their therapeutic efficacy whilst in circulation. Dendrimers and fullerenes are examples of molecular nanoscale entities that are used for developing drugs.

Nanotherapeutics may be multifunctional, namely a single molecule can permit detection, diagnosis, transport and the controlled release of drugs, because many nanoparticles can be functionalised with several different molecules (such as DNA, RNA, targeting molecules and peptides) simultaneously.[1,2,10–14,17–19,21] These molecules can be manufactured to destroy only specific abnormal or diseased cells. In the future, with advances in nanotechnology-based targeted delivery, a nanoparticle, or a combination of nanoparticles may be designed to search for and destroy a single diseased cell—a major step forward for preventative medicine.

Regenerative medicine

Regenerative medicine addresses the repair, replacement or regeneration of damaged tissues or organs, or the restoration of function through a combination of natural and bioengineered approaches (including the use of smart biomaterials and advanced cell therapy).[1,10–14,17,18,21,22] It is deemed as being able to cure specific diseases or repairing damaged tissues (such as cartilage, bone, tooth, muscle or nerve) as well as to promote health and prevent disease, with the overarching goal being to develop innovative treatments to improve quality of life. There is consensus that regenerative medicine will have a potentially disruptive impact on the healthcare system, along with high costs.[12,13]

The potential applications of nanotechnology in regenerative medicine include improvement in the activation of genes that stimulate regeneration of living tissues, improvement in the performance and duration of neural prostheses, and faster regeneration of new bone substitutes.[1,2,11–13,17,18,21,22]

Nanotechnology may allow for improvement of nonresorbable biomaterials and effective manipulation of biological interactions at nanoscale to increase the functionality and longevity of implanted tissues. It may also be possible in the future to surround implanted tissues with a nanomanufactured barrier that would prevent activation of the rejection mechanisms of the host.

PART I: LITERATURE SEARCH RESULTS

The results of the literature search conducted for this exploratory brief revealed 30 documents published since 2000 by various groups from Europe, the United States, Canada, and Australia that described the broad scope of nanotechnology and the applications that the integration of nanotechnology and medicine research has generated.[1–5,8–32] For the purpose of this report, selected for the inventory were seven horizon scanning, foresight, forecast, and road-mapping studies that were based on information collected since 2006 and/or reported on opportunities offered by nanomedicine or the applications of nanotechnology in health care within the next 5 to 10 years (2016 to 2021).[1,2,10–14] The main characteristics of the selected studies are summarized in Table B1 (Appendix B).

The literature search also identified a number of online resources and journal and book titles that may be useful to healthcare planners and policy-makers to inform questions regarding the applications of nanotechnology in human health care. An inventory of these resources is provided in Appendix C.

The following commentary summarizes the information provided by the reviewed literature regarding the current status of research in nanomedicine and the opportunities the application of nanotechnology may offer in the areas of diagnostics and therapeutics within the next 5 to 10 years (up to 2021).

Current status of research in nanomedicine

According to the expert opinion and the background information contained in the reviewed reports, although it is still considered to be in a formative phase, since 2000, nanomedicine has made significant breakthroughs in the laboratory and advanced rapidly in clinical trials with several applications in diagnostics and therapeutics. Emergence of new nanomaterials and nanodevices was required to bring *in vitro* and *in vivo* diagnostics, drug delivery systems, and surgical tools into clinical practice. The nanomaterials and nanodevice research field has rapidly moved from the development of individual building blocks to multifunctional, often biomimetic and bioresponsive, systems.

Many current applications are based upon "passive" (steady function) nanostructures used as components to enable or improve healthcare technologies. Early application of nanotechnology-enabled products involved drug reformulation to deliver some otherwise toxic drugs (e.g., antifungal and anticancer agents) in a safer and more effective manner and development of *in vivo* imaging agents that provide better contrast and more effective targeting. Examples include: liposomes, albumin bound nanoparticles, gadolinium chelate for magnetic resonance imaging (MRI), iron oxide particles for MRI, and silver nanoparticles (antibacterial wound dressing).

Since 2005, more sophisticated products with "active" nanostructures and nanodevices have been introduced to meet needs not addressed by existing healthcare technologies. The second generation of nanotechnology-enabled products includes more sophisticated nanotechnologies due to new molecular engineering that enables the devices to target a clinical problem (e.g. tumour), image, deliver a therapeutic agent and monitor therapeutic efficacy in real time. Examples include quantum dots for imaging, nanoshells that destroy tumour cells in the presence of a magnetic field, and multifunctional nanodevices that combine imaging and therapeutic capabilities all in one device (theranostics).

Currently, advanced nanotherapeutics and nanotechnology-enabled point-of-care diagnostic tools are being used worldwide for patient care. Nanotechnology-enabled structures are being used in the development of tools for manipulating and studying cellular systems, in *in vitro* diagnostics that can track indications of disease at very early stages, in *in vivo* imaging agents that provide better contrast and more effective targeting compared to molecular systems, in new therapeutics for cancer and cardiovascular disease and in regenerative medicine. Over 50 cancer-targeting drugs based on nanotechnology are in clinical trial in the United States alone.

Due to advances in biotechnology, nanotechnology, nanomanufacturing and nanomaterials, progress has also been made in surgical methods, tissue engineering, implants and prosthetics. Nanostructured or nanocomposite materials have been used to improve performance of surgical tools. Nanoscale assemblies for ligand display are already emerging as multicomponent three-dimensional architectures able to assist tissue engineering and promote tissue repair.

A Forward Look

According to the reviewed reports, over the next five to 10 years the application of nanotechnology in diagnostics and therapeutics is anticipated with a multitude of new capabilities. It is envisioned that nanomedicine will play a significant role in overcoming existing and future challenges in health care. By 2020, nanomedicine is expected to revolutionize the way health care is practiced, and to create new diagnostic and therapeutic applications and great advances in molecular and cell biology. Through the use of advanced nanomaterials and nanodevices capable of performing analytical and imaging functions, targeted drug/therapy delivery, imaging plus delivery functions (theranostics) and nano-enabled material surfaces for tissue engineering will be possible. All these advances are expected to make biomedicine more predictive, preventive, personalized, and regenerative.

Nanomedicine is expected to have a major impact by significantly improving prevention, early detection, diagnosis and treatment of cancer and cardiovascular, musculoskeletal, neurodegenerative, inflammatory and infectious diseases. The most promising future nanotechnology-based applications include multiplexed diagnostics, drug delivery and development, and targeted therapy of cancer, cardiovascular conditions, and infectious diseases. Opportunities for nanotechnology in the early detection, diagnosis, and treatment of cancer are many fold and are expected to have a significant impact over the next 5 to 10 years. To facilitate this development, it will be necessary to implement new nanomanufacturing approaches and all new nanotechnology-enabled products will have to address rigorous safety and biocompatibility standards that are being challenged by the new properties of nanomaterials and by the potential that these may introduce new biohazards.

In the areas of *in vitro* and *in vivo* diagnostics, within the next 5 to 10 years, nanotechnology is expected to enable the improvement of current and future imaging systems, the design of new contrast agents, the improvement of diagnosis in general (in the *in vitro* diagnostic area), and the facilitation of safe and effective point-of-care applications. Opportunities exist for both invasive and noninvasive clinical imaging, e.g., endoscopy for targeted imaging, use of optical catheters and development of nanosized systems allowing manipulation, target selection, local stimulation and potentially local modification. Advances in nanotechnology and a better understanding of the bio-nano interface are expected to provide multiplexed diagnostic assays. Future imaging tools—such as multicomponent systems combining contrast agents and tracking probes (e.g., quantum dots, magnetic and superparamagnetic beads, nanoshells and nanocolloids) with new targeting ligands—will be more complex.

Development of molecular imaging diagnostics is expected to have a major impact on health care in the future. The opportunities are summarised below:

Screening	Specific (bio)markers (molecular imaging diagnostics)
Diagnosis and staging	Molecular imaging diagnostics (quantitative, whole-body) Cancer diagnosis
Treatment and monitoring	Mini-invasive surgery Local/targeted drug delivery & tracing Tissue analysis (molecular imaging diagnostics)
Follow-up	Molecular imaging diagnostics Non-invasive, quantitative imaging

SUMMARY

This exploratory brief has summarized some of the published information regarding the current status of research in and the potential future sphere of activity of nanomedicine, which is an emerging multidisciplinary field that builds on existing expertise in other scientific fields including biotechnology, nanotechnology, materials technology, and information technology.

The reviewed literature suggests that since 2000 there have already been substantial developments in nanobiosystems and nanomedicine, which have led to the nanotechnology-enabled diagnostic, therapeutic, and imaging agents and devices that are currently being used in patient care. Building upon these advances, according to the most recent developments, the translation of nanomedicine therapeutic and diagnostic applications into clinical use looks promising.

Over the next 5 to 10 years it is expected that the overall impact of the application of nanotechnology in human health care will be multifaceted, with significant advances in patient screening, diagnosis, staging, treatment, and monitoring. Opportunities include more sensitive and reliable diagnostics and biosensors, improved imaging techniques, and innovative therapeutics to more safely and effectively predict and manage various chronic conditions including cancer and cardiovascular, neurodegenerative, inflammatory, and infectious diseases.

APPENDIX A: METHODOLOGY

A prospectively designed protocol was used to briefly explore some of the recently published information regarding the opportunities nanotechnology may offer in human health care in the areas of diagnostic and therapeutic services over the next 5 to 10 years (up to 2021).

Search strategy

A literature search of horizon scanning databases and related agencies' websites was conducted in November 2011 in order to identify relevant reports. The search strategy was designed by an information specialist at IHE with no date, language, or study design restrictions.

Data sources include:

- Euroscan
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Agency for Healthcare Research and Quality (AHRQ)
- Australian Safety and Efficacy Register of New Interventional Procedures–Surgical
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- National Horizon Scanning Centre-National Health Service (NHS)
- New York Academy of Medicine Grey Literature Collection
- Sigma Scan

In addition, Internet searches via Google were carried out, and reference lists of relevant studies were perused to identify further studies.

The following search terms were used:

- nanotechnology OR nanotech OR nanomedicine OR nanoparticles OR nanotubes OR nanomaterials OR nanodevices OR nanocomposites OR nanodiagnostics OR nanotherapeutics

—AND—

- foresight OR future OR roadmap OR horizon OR forecast

Study selection process

The studies included in the report were selected and evaluated by one reviewer using a predefined set of inclusion and exclusion criteria to identify potentially relevant documents.

Inclusion criteria

Considered for inclusion were all articles/documents satisfying the following criteria:

- reported findings from horizon scanning, foresight, forecast, and/or roadmap/roadmapping studies conducted on nanomedicine or application of nanotechnology in human health care
- were published in English between 2006 and present

- reported on opportunities offered by nanomedicine and the projected timelines to clinical use within the next 5 and 10 years (by 2016 and 2021)
- described the study design and methods used

Exclusion criteria

Excluded were:

- non-English language articles/documents
- articles/documents reporting findings from animal and *in vitro* (laboratory) studies
- articles/documents that did not identify developments perceived as critical (main priorities) for the clinical uses of nanomedicine and the expected clinical advantages with reference to targeted diseases and use, as well as the timeframes of possible clinical applications in the next 5 to 10 years (by 2016 and 2021)
- primary research studies, systematic reviews, narrative reviews, overview articles, commentaries, position papers, editorials, and letters.

Data extraction

The information regarding the study (authors, source, and publication date) and its main characteristics (objectives and methods) from the selected horizon scanning, forecast, foresight, and roadmap/roadmapping studies was collected by one reviewer (PC) using a data extraction form and summarized in Table B1 (Appendix B). The same reviewer summarized, in the text of this report, the information on nanomedicine or the application of nanotechnology in human health care reported by the authors of the selected studies.

Methodological quality assessment

No formal assessment was carried out to evaluate the methodological quality of the selected studies.

Data analysis and statistical methods

Data from the included studies was not synthesized.

External review

This exploratory brief was not externally reviewed.

APPENDIX B: SUMMARY OF SELECTED STUDIES

Table B1: Horizon scanning, forecast, foresight, and road mapping studies on nanomedicine

Study	Study's objectives	Study's methods
Schmidt[10] **Source:** NanoFrontier workshop **Date:** 2006	The objective of this science journalist's report was to summarize the visions for the future of nanotechnology presented and discussed during and immediately after a two-day NanoFrontier workshop that took place in February 2006.	The premise of the 2006 NanoFrontier workshop was to explore the scientific and technological advancements and promises of nanotechnology with a wide range of experts from various disciplines. The workshop included 50 attendees (researchers and engineers from physical and biological sciences, social scientists, ethicists, historians of science and public policy-makers) and brought together the National Science Foundation (NSF) and the National Institutes of Health (NIH). It was co-sponsored by the Project on Emerging Nanotechnologies at the Woodrow Wilson Center, NSF and NIH. The report summarizes information from papers written by 15 participating scientists, and their visions on the future of nanotechnology, as well as those discussed during and after the workshop.
Silberglitt et al.[14] **Source**: RAND Corporation **Date:** 2006	The objective of this RAND technology trend foresight report was to update a previous foresight study and extend its time horizon to 2020.	The RAND foresight report was based on a set of foresights into global technology trends in biotechnology, nanotechnology, materials technology and information technology and their implications for the world in the year 2020. The foresights were complemented by an analysis of data on current and projected science and technology capabilities, drivers and barriers in countries across the globe. The authors reviewed major science and technology journals and magazines, assessing the viability of projected technology trends based on the degree to which real progress was made in research and development laboratories, the degree of interest and investments in these trends, and their expert judgments of the overall likelihood of the applications having a significant impact on major global demand sectors and policy drivers. The National Intelligence Council (NIC) in the US sponsored the RAND foresight report to inform the NIC's 2020 project and help provide US policy-makers with a view of how world developments could evolve, identifying opportunities and potentially negative developments that might warrant policy action.
Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care[2] **Source:** Ontario Health Technology Advisory Committee (OHTAC) **Date:** 2006	One objective of this horizon scanning appraisal report was to assess the current status of scientific developments in nanotechnology that were designed for human diagnostic and therapeutic purposes, and their projected timeline to clinical utilization.	The horizon scanning appraisal report was developed from an analysis, interpretation and comparison of scientific research and/or technology assessments conducted by other organizations, which were identified through a literature search of relevant databases. Outcomes of interest were improved imaging, improved sensitivity or specificity, improved response rates to therapeutic agents and decreased toxicity. The literature search conducted for this appraisal was focused on English language articles published between January 2000 and June 2006. One health technology assessment on nanotechnology published in 2003 by The Centre for Technology Assessment TA-Swiss, the 2006 RAND foresight report,[14] and 2001 and 2004 data from the National Cancer Institute in US formed the basis for the conclusions of the report.

Table B1: Horizon scanning, forecast, foresight, and road mapping studies on nanomedicine (cont'd)

Study	Study's objectives	Study's methods
Mundy et al.[1] **Source:** Adelaide Health Technology Assessment (AHTA) **Date:** 2007	The objective of this Emergency Technology Bulletin was to inform health planners and policy-makers about the state of play of the introduction and use of nanomedicine in Australia and New Zealand.	This Emergency Technology Bulletin is primarily a briefing document aimed at providing a non-systematic overview of the rate of progress or development of nanomedicine, its applications and its potential impact (based on information available at the time of research). For the purpose of this bulletin the medical literature was searched until July 2006. The majority of papers included for assessment in this Bulletin were published in countries other than Australia. However, specific Australian research projects have been included in some, but not all sections.
Battelle Memorial Institute and Foresight Nanotech Institute; Editors: Drexler et al.[11] **Source:** Roadmap project **Date:** 2007	The roadmap document brings together threads from meetings and workshops of a roadmap project, which explored atomically precise technologies (APT) and atomically precise manufacturing (APM) process, pointing to promising research directions.	The roadmap project provided a cross-disciplinary process for exploring current capabilities and near-term opportunities in APT, as well as pathways leading toward advanced APM. The roadmap development process included four workshops held from October 2005 through December 2006. One part of the roadmap document presents a set of papers, extended abstracts and personal perspectives contributed by participants in the roadmap workshops and subsequent online exchanges. One of these papers, "Nanomedicine Roadmap: New Technology and Clinical Applications," presented opportunities in the application of nanotechnology in health care within the next 10 to 20 years (2017 to 2027).
European Technology Platform (ETP) Nanomedicine Secretariat[12] **Source:** 2009 Expert Workshop **Date:** 2009	The ETP Nanomedicine roadmap report aimed to summarize the discussions during the 2009 Expert Workshop on the application of nanotechnology in diagnostics, drug delivery and regenerative medicine, and to present timelines that roughly estimate when each specific topic is expected to become relevant for industrial R&D between 2010 and 2020.	The 2009 Expert Workshop, organized by the European Commission and the ETP – Nanomedicine, aimed to consolidate and extend the understanding of nanomedicine as well as to identify industrial, application-driven roadmaps that will help focus future requirements in the European Research Framework Program FP7 and beyond. Approximately 50 invited experts from academia and industry presented their views on applications product-driven industrial roadmaps that they foresee as being of interest to research and industry stakeholders. The workshop comprised six round table sessions on the application of nanotechnology in the areas of diagnostics, drug delivery and regenerative medicine.

Table B1: Horizon scanning, forecast, foresight, and road mapping studies on nanomedicine (cont'd)

Study	Study's objectives	Study's methods
Roco, Mirkin, & Hersam[13] **Source:** World Technology Center (WTEC) Study **Date:** 2010	The WTEC study aimed to document the progress made in nanotechnology from 2000 to 2010 and to uncover new opportunities for nanotechnology development from 2010 to 2020, in the US and around the world.	The WTEC panel report incorporates the views of 250 leading experts from academia, industry, and government, shared among US representatives and those from over 35 other countries in four forums held between March and July, 2010. These included an initial meeting in the US and three US–multinational workshops in Germany (involving European Union and US representatives), Japan (involving Japan, South Korea, Taiwan, and US representatives), and Singapore (involving Singapore, Australia, China, India, Saudi Arabia, and US representatives). Participants came from a wide range of disciplines, including the physical and biological sciences, engineering, medicine, social sciences, economics, and philosophy. The report looks at all aspects of nanotechnology development and aims specifically to provide input for planning of nanotechnology R&D programs to those producing, using, and governing this emerging field.

PART II: AN INVENTORY OF RESOURCES ON NANOTECHNOLOGY AND NANOMEDICINE

The following section provides an annotated listing of some of the most comprehensive and current online resources, journals, and conferences that focus on nanotechnology and nanomedicine. To obtain the latest information on what is happening in these fields it is recommended that these resources be consulted on a regular basis.

Websites

The Project on Emerging Nanotechnologies: http://www.nanotechproject.org/

The Project on Emerging Nanotechnologies was established in April 2005 as a partnership between the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts. This project is dedicated to helping ensure that as nanotechnologies advance, possible risks are minimized, public and consumer engagement remains strong, and the potential benefits of these new technologies are realized.

The Project on Emerging Nanotechnologies collaborates with researchers, government, industry, NGOs, policymakers, and others to look long term, to identify gaps in knowledge and regulatory processes, and to develop strategies for closing them. The Project will provide independent, objective knowledge and analysis that can inform critical decisions affecting the development and commercialization of nanotechnologies.

Our goal is to inform the debate and to create an active public and policy dialogue. It is not an advocate either for, or against, particular nanotechnologies. We seek to ensure that as these technologies are developed, potential human health and environmental risks are anticipated, properly understood, and effectively managed.

All research results, reports, and the outcomes of our meetings and programs are made widely available through publications and over the web. We include a wide variety of stakeholders, both domestically and internationally, in our work.

We also are committed to engaging a new generation of young people interested in working at the interface of public policy and nanoscience and nanoengineering. We run an active program with university researchers, educators, and students to further that objective.

National Nanotechnology Initiative: http://www.nano.gov/

Welcome to the National Nanotechnology Initiative (NNI) website. The NNI serves as the central point of communication, cooperation, and collaboration for all Federal agencies engaged in nanotechnology research, bringing together the expertise needed to advance this broad and complex field.

The Initiative has had strong, bipartisan support from the Executive and Legislative branches of Government since its creation in 2000. The NNI involves the nanotechnology-related activities of 25 Federal agencies, 15 of which have specific budgets for nanotechnology R&D. The agencies involved allocate expenditures from their core budgets, demonstrating nanotechnology's importance to their mission.

NanoEthicsBank: http://ethics.iit.edu/research/nano-ethics-bank/

The NanoEthicsBank is a database conceived as a resource for researchers, scholars, students, and the general public who are interested in the social and ethical implications of nanotechnology. Items in the database include normative documents, such as guidelines for safety in the workplace, and descriptive materials, such as analysis of the U.S. government's capacity for oversight and studies of the media coverage of nanotechnology. For more resources on nanotechnology research and development, please see our collection of further resources that includes links to databases of research projects on environmental health and safety implications of nanotechnology, and links to other nano institutes and organizations.

Cordis: http://cordis.europa.eu/nanotechnology/

This web service provides an overview of nanotechnology related activities at the European Commission. The information provided on this portal website does not replace or supersede similar information in other CORDIS or EUROPA websites. Rather, it highlights elements specifically relevant to nanotechnology in Europe such as the European strategy and the Action Plan, projects and funding opportunities in the Framework Programmes and related publications and events.

Nanowerk: http://www.nanowerk.com/

Welcome to Nanowerk – Enjoy exploring the world's most comprehensive nanotechnology and nanoscience resources.

Nanowerk is the premier and most popular source for nanotechnology information. Apart from our unique Nanomaterial Database™, the most extensive industry directory, a packed conference calendar, complete nanotechnology news coverage, and business resources, we offer Nanowerk Spotlight: Our Nanowerk-exclusive nanotechnology feature looks behind the buzz and the hype. What's hot and new from around the globe. Some stories are more like an introduction to nanotechnology, some are about understanding current developments, and some are advanced reviews of leading edge research.

Nanotechweb: http://nanotechweb.org/

Nanotechweb.org is a unique global portal for the nanotechnology community. It provides news, events calendar, product information, jobs and a free weekly news alert highlighting key research worldwide. Now with more than 55,000 unique visitors each month, and a weekly e-mail newswire to more than 30,000 opt-in subscribers, nanotechweb.org is a key information source for the nanotechnology community.

Nanotec.org.uk

This website is about a UK Government report on nanotechnology and the methodology used to produce it.

What did the study look at?

We supplied the Government with an independent, authoritative, representative, and above all fact-based report on nanotechnology and the health and safety, environmental, ethical and social issues that might stem from it. Our final report assesses how this emerging field should be regulated as it develops.

The aims of the Royal Society and Royal Academy of Engineering study were to:

1. define what is meant by nanoscience and nanotechnology;
2. summarise the current state of scientific knowledge about nanotechnology;
3. identify the specific applications of the new technologies, in particular where nanotechnology is already in use;
4. carry out a forward look to see how the technology might be used in future, where possible estimating the likely time scales in which the most far-reaching applications of the technology might become reality;
5. identify what environmental, health and safety, ethical or societal implications or uncertainties may arise from the use of the technology, both current and future;
6. identify areas where regulation needs to be considered.

At the launch of the study we issued an initial call for views (which is now closed). Responses from stakeholders were used to further define the terms of reference.

Online Journals

- ACS Nano
- Cancer nanotechnology: basic, translational, and clinical research
- International Journal of Nanomedicine
- Journal of nanotechnology in engineering and medicine
- Nanobiotechnology: the journal at the intersection of nanotechnology, molecular biology, and biomedical sciences
- Nanomedicine: nanotechnology, biology and medicine
- Nanotoxicology
- Nature Nanotechnology: Nanomedicine archive
- Open Nanomedicine Journal

Nanomedicine Conferences

- European Conference for Clinical Nanomedicine
- International Congress of Nano Technology
- Sydney 2011 International Nanomedicine Conference
- World Conference on Nanomedicine and Drug Delivery
- World Congress of Nanomedicine

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Author Contribution Statements

Paula Corabian contributed to study conception and design, data analysis and interpretation, and approved the final version for publication.

Dagmara Chojecki contributed to the literature search, data analysis and interpretation, and approved the final version for publication.

Christa Harstall contributed to study conception and design, revision of manuscript for critical content, and approved the final version for publication.

This exploratory report provides a summary of some of the published information on the current status of research in and potential future sphere of activity of nanomedicine (Part I) and an inventory of resources on nanotechnology and nanomedicine (Part II). Over the next 5 to 10 years it is expected that the overall impact of nanomedicine will be multifaceted, with significant advances in patient screening, diagnosis, staging, treatment, and monitoring. Opportunities include more sensitive and reliable diagnostics and biosensors, improved imaging techniques, and innovative therapeutics to enhance the safety and effectiveness in predicting and managing diseases.

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