Nanotechnology: The coming revolution and its implications for consumers, clinicians, and informatics

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Nanotechnology promises to revolutionize manufactured materials as we know them, creating a vast array of new products, drug delivery devices, and monitoring mechanisms. The promise of these products and devices is tremendous. Likewise, the implications of this technology are immense, ranging across consumers, clinicians, and the practice of informatics. Specific implications include opportunities for education of health care consumers and clinicians about the safe and ethical use of nanomaterials, a requirement for new policies and regulations, potential radical role changes for both consumers and clinicians, and new demands in the practice of informatics. The most pressing concern for health applications is the safe use of nanomaterials. Given the promise of nanomaterials and the implications across at least these 3 areas, nurses need to understand the capabilities and limitations of nanomaterials, proceed with reasoned caution, and plan now for its wide-ranging impacts.

Nanotechnology promises to revolutionize products everywhere. It is likely to found new industries in electronics, devices, drugs, inks, dyes, protective coatings and energy—some of which are already available today. In fact, nanotechnology could change the nature of almost every manufactured object.[1] Because of this, nanotechnology may have more influence than the silicon integrated circuit, medical imaging, and computer-aided engineering combined.[2] Clearly, such significant technology could have vast impacts on health care and nursing. Yet, little has been published in nursing literature about nanotechnology. To that end, the purposes of this article are to: (1) define and briefly describe nanotechnology; (2) outline potential applications to health care; (3) describe initial implications of nanotechnology to patients, patient care and nursing informatics, and (4) outline cautions about the new technology.

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DEFINITION

Nanotechnology is defined as the design and manipulation of materials at the atomic and molecular scale.[3] Nanotechnology is, essentially, the use of atomic and molecular structures as core building blocks to create new products and devices. These resulting products and devices are collectively called nanomaterials and each element a nanoparticle. The actual scale of nanomaterials may be difficult to understand. The prefix "nano" means 1 billionth; therefore, a nanometer is 1 billionth of a meter. To provide some perspective, the thickness of a single sheet of paper is 100 000 nanometers. At its largest, nanomaterials are 100 nanometers or 1 one hundredth of the thickness of a sheet of paper. These minute particles are being used to develop products in many fields today, including engineering, chemistry, electronics, and medicine.

NANOTECHNOLOGY APPLICATIONS

Nanotechnology has been available for at least 20 years. Yet, only within the past decade have scientists understood how to leverage nanotechnology to create new products. Scientists discovered that at the nanoscale, materials possess novel properties, including increased strength, resiliency, and electrical conductivity.[4,5] Amazingly, $>$ 500 commercial nanomaterial-based products are already available. Probably the most familiar of these is the iPod Nano. This device uses microscopic memory chips, increasing the storage capability for files and music and significantly shrinking

the overall size of the device. In another example, nanoparticles are being used in improved lotions. Because the nanoparticles in these lotions are so small, lotions are more easily absorbed, penetrating the top layers of skin to moisturize more effectively.[6]

Most of the available nanomaterial-based products are outside health care; however, many products have emerged for health applications. An online publication, *Nanomedicine: Nanotechnology for Health* provides an excellent overview of products for health.[7] Three health-related categories are discussed here: new pharmaceuticals and drug delivery mechanisms, patient monitoring devices, and regenerative sciences. New pharmaceuticals include silver-based products. Silver nanoparticles retain their infection-inhibiting properties while allowing greater penetration into other organic or inorganic materials. These silver nanoparticles can be useful in eliminating fungi and preventing odors in shoes or refrigerators.[5] Scientists hope that, in the future, silver nanoparticles can be applied to bedding to prevent the spread of Methicillin-Resistant Staphlococcus Aureus in hospitals. Likewise, the same silver-based compounds could be used to prevent infections in burn patients.[6]

Other new drug delivery mechanisms include targeted pharmaceuticals. For instance, Abraxis Bioscience created a chemotherapeutic agent called Abraxane® using a protein-based, nanoparticle compound. The size of the nanoparticles allows them to use the tumor's own cell structure to destroy it. The tiny particles are able to penetrate cell membranes, delivering the chemotherapy directly into the tumor cell. Previously, large chemotherapy compounds were incapable of this lethal mechanism of action and they also affected non-tumor cells, creating the typical side effects of chemotherapy. Abraxane has already received FDA approval for its use in the treatment of breast cancer patients.[8] Similar nanotechnology agents may revolutionize chemotherapy because they target tumors specifically and eliminate the devastating systemic effects of current chemotherapy agents.

Other promising nanomaterial medications include those for glaucoma patients and vaccine delivery.[9] Topical eye drops for glaucoma can be very abrasive and cause patients discomfort. New nanoparticle eye drops are able to penetrate directly into the eye structures, eliminating the discomfort. Vaccine researchers are optimistic about the potential use of nanotechnology for vaccine delivery. Nanotechnology vaccines can be used to combat diseases such as hepatitis and malaria. Because of the small volume of vaccine required, vaccine pricing may be as low as $1.00 per injection. Also, patients may need only a single injection, a benefit in situations where patients might be unable or unwilling to return for subsequent boosters.

Nanomaterial vaccines can allow patients to create greater immunity to pathogens by delivering medications directly to specialized dendritic cells in the immune system. In a current study, authors found that the new vaccines can penetrate skin cells and migrate to lymph nodes. There, the nanomaterials produce a more intense immune response than current delivery mechanisms.[10]

A second broad area of development is the use of nanotechnology for patient monitoring devices. In a study at the pre-clinical trial stage, researchers are using smart nanodevices to monitor patients' glucose levels.[11] The products are inhaled. Then, they circulate in a patient's blood stream and monitor blood glucose levels. These miniature biochips can detect an increase in glucose levels and release insulin in precise amounts to regulate levels. This mechanism of action more closely mimics the natural functioning of the body's pancreas, avoiding the devastation of variable glucose levels and the long term side effects associated with diabetes today.

Nano-sized monitoring research is also being done with epileptic individuals. Implants detect seizure activity before it is manifested and release medication to prevent the attack.[12] Last, Clemson University was awarded a grant to develop an implantable biochip that would relay vital health information to a remote location. Applications of this technology include the capability to monitor soldiers wounded in battle or civilians hurt in traumatic events such as car accidents.[13]

A third area of nanomaterial development is in regenerative science. Among other things, researchers are creating artificial skin, cartilage and bone for human use.[7] The hope of regenerative science is to use nanomaterials to work with or even substitute for human organs and systems, preventing or treating many chronic diseases, such as diabetes and neurodegenerative diseases.[14]

As may be seen, the promise for nanotechnology applications in health care is immense. Given its extensive potential, what might the implications of this new technology be for healthcare consumers, clinicians and the practice of informatics? The following sections discuss implications for these 3 areas.

THE IMPLICATIONS OF NANOTECHNOLOGY FOR HEALTHCARE CONSUMERS

Nanotechnology promises to move healthcare delivery away from treating diseases in populations to tailoring treatment explicitly and precisely to individual health care consumers. Nanotransmitters and nanosensors implanted within individuals would be able to provide significant new ways of diagnosing, treating and monitoring individuals, specifically targeting their unique needs. Then, individuals with chronic diseases could be monitored and treated at the microscopic level with the use of nanodevices.

An obvious implication of this embedded technology is that it creates person-centered versus location-specific monitoring devices, crossing traditional boundaries of care in the hospital, home, physician's office, work or even the local grocery store.[15] This kind of monitoring transparency is unprecedented. Individuals at home could have access to data transmitted from biochips that might monitor for a familial disease such as hypercholesterolemia, alerting them when critical levels are attained. For individuals with chronic diseases, a click of a computer mouse could send pertinent information, such as a glucose level beyond a pre-set threshold, to a clinician for prompt initiation of a customized treatment plan based on the individuals' specific pathology. Or the nanoparticles could be programmed to administer medications without a clinician's direct intervention.

Significant implications exist for individuals as they integrate nanomaterials into their daily routine, whether that involves the application of lotions containing nanoparticles to treat eczema or the manipulation of devices implanted within their bodies to monitor or treat conditions. Implications for patients or clients include the need for education, increased individual responsibilities, and provisions for safety.

A gap currently exists between the scientific advancements in nanomaterials and the level of consumer education related to those advancements. In fact, up to 80% of consumers have heard very little about nanotechnology.[4] On a positive note, authors of a 2006 survey of consumers' perceptions of nanotechnology revealed a general openness to using nanomaterials. On a more cautionary note, other consumers had reservations about nanomaterials, saying that they would only assume health risks after the benefits are fully explained and shown to outweigh the risks. Authors of a separate study in England indicated that people are generally positive toward the use of nanotechnology but they interpret the term "safe" to mean that all risks have been eliminated. This erroneous perception indicates the need for more communication and public education.[16]

Individuals will need education about general and specific nanomaterials as they apply to their conditions. One general educational resource is a brochure developed by the National Nanotechnology Coordination Office with input from scientists representing the 26 agencies in the National Nanotechnology Initiative. The brochure, "Nanotechnology: Big Things from a Tiny World," provides an overview of nanotechnology using concrete, easily understood examples.[5] It explains applications, the role nanotechnology will play in addressing global issues, associated risks and the need for ongoing research in this emerging field. Beyond general education, even experts may be challenged in educating the public about nanomaterials because the experts themselves will be developing educational tools while simultaneously discovering important issues.

Nanomaterials could place additional burdens on health care consumers. They would be expected to assume some level of responsibility for monitoring nanodevice functions, such as screening the data from the device, deciding upon a course of action, and/or communicating with care clinicians or initiating treatment themselves. As nanoparticles are introduced into the human body, the amount and sources of patient information will increase. Unlike other technologies, an individual may be the first person viewing the device information. They might need to be: (1) more highly educated about interpreting device information, or (2) have greater levels of decision support available to manage these conditions safely.

A related consideration is that different human capabilities and limitations have to be taken into account when people use devices across settings and services. For instance, devices would require simple user interfaces with understandable, customized instructions for lay consumers. User interfaces would need to be designed for consumers with differing educational levels, disease progression and cultural needs.

The introduction of nanomaterial-based products into health care may imply an entire role change for healthcare consumers. They would likely be empowered in decision-making about their own care. Consumers may well be considered a full member of the clinical team in the future. This increased responsibility for collaboration and communication may also lead to increased accountability for taking appropriate actions. For individuals who choose not to assume this responsibility, or are unable to assume this level of responsibility, questions remain: What options will be available for caregivers and consumers themselves? What consequences will occur if individuals cannot or choose not to accept increased responsibilities?

The advent of nanotechnology could create policy implications for consumers, especially for privacy and ethical issues that are only just beginning to be addressed in health care in the era of electronic health records. Policy implications for nanotechnology are just now being considered. For example, an insurance company might refuse to pay for advanced treatments if an individual did not respond to initial nanomaterial monitoring warnings. In fact, Thompson speculates that new ethical guidelines will have to be developed to deal with nanomaterial issues.[17]

A second policy implication is in the regulatory arena. The Food and Drug Administration (FDA) is carefully analyzing the benefits and risks of medical devices that use nanotechnology to determine a plan for their regulation. Nanomaterials span the current boundaries of products that the FDA has regulated to date–pharmaceuticals, medical and biological devices. The FDA currently plans to regulate nanomaterials as "combination products."[18] The main action of the product will be determined, and the product will be evaluated

under that group. As may be seen, nanodevices and nanomaterials create new challenges for agencies based upon older technologies.

THE IMPLICATIONS OF NANOTECHNOLOGY FOR CLINICIANS

With the advent of nanomaterials in healthcare, care at the bedside could usher in a new era of implications for clinicians. A number of immediate implications are evident for clinicians' roles: changes in decision-making and clinician productivity. The power base in health care may change as the technology emerges and the care venue shifts with more empowered health care consumers at the center of the care team. This continues a role change that began with consumers accessing health information on the Internet. Individuals, empowered with Internet information about new developments in health, already bring this information to their clinician appointments, at times questioning and challenging clinicians about the information. Clinicians may find their roles changing into participants, coordinators or coaches instead of experts. Perhaps this role shift may be more difficult for physicians than nurses because nurses have historically enacted more supportive roles such as educator and care coordinator. Team and interdisciplinary care would become even more imperative as sources of data increase. The role of the case manager or coordinator of care may be more prominent in the age of absolute individualized care. Nanotechnology scientists might even have a role on future interdisciplinary teams.

Obviously, today's concept of routine care would no longer exist in a world where everything is customized to the individual. Individuals could present with mysterious symptoms or even new diseases directly related to their embedded technology. Nanomaterials could have "bugs" in minute software or technology circuits. Disease management could occur in a very individualized, customized, or boutique fashion. There may no longer be a standard way to approach any given health condition. The requisite level of knowledge about drug actions, nuances about the nanomaterials themselves and generated information would impact clinicians, perhaps adding to existing cognitive burdens. Ultimately, this could increase the levels of required knowledge across clinicians. New knowledge about drug acquisition, storage, and dispensing would be needed; new methods of waste disposal for discarded products would be needed across all care settings from the hospital to home. New safety considerations for clinicians would be necessary, and protection would be needed when clinicians deliver therapies to avoid inadvertent ingestion of nanomaterials.

The impact of nanomaterials on evidence-based practice and concepts would need to be analyzed and discussed. One implication might be that highly individualized care lessens broad evidence-based practice findings and applications. On the other hand, perhaps nanomaterials will drive evidence-based care to a highly personalized level of data analysis and application of evidence. This latter notion would have implications for immense data analysis needs, for example.

Clinicians' critical thinking and decision-making could be impacted as more and better targeted data, information, and knowledge is known about patients and their disease processes. Information overload and issues with information synthesis could occur. More important, new policy decisions should be made—for example, who will ultimately be responsible for warehousing, owning, and interpreting nanomaterial data?[19]

Differing capabilities and limitations of care clinicians would need to be considered and educational programs developed. Device interfaces would need to be understandable by both caregivers and clinicians as well as patients. Informaticists may need to consider providing more available decision support at the intersection of nanomaterial and care. Clinicians may need to increase their vigilance in monitoring individuals' decision-making and help them understand the consequences of poor decisions. For instance, a financial penalty might occur if a decision has an adverse outcome. As Slater stated, "What if insurance companies can monitor your health at a cellular level and deny your care based on poor genetics or poor lifestyle choices?"[20]

If non-experts become care team members, clinician productivity may be negatively impacted. Care episodes may consume more time as more individualized data and information is sought, analyzed and then assimilated into creating the therapeutic plan.

Nanotechnology could lead to an over-reliance on the devices both for the healthcare consumer and the clinician. Clinicians might assume that they are receiving all information when, in fact, that is not the case.[21] Technology dependence could also lead to a decrease in clinician-clinician communication or clinician-consumer communication. Inaccuracies with monitoring devices might be challenging to detect, and education will be necessary for expert problem-solving for the nanodevices.

An obvious implication is the need for 24/7/365 nanotechnology support for both consumers and clinicians. A model for this kind of intense decision support has yet to be created. This support would be complicated by information generated by multiple devices from multiple manufacturers in a distributed environment. Information synthesis will be an even greater challenge for clinicians.

These implications also apply to clinician education and curricular design. Nanomaterials could be the impetus for new curricular modifications to educate students and practitioners about the applications, control, and safe and ethical uses of nanomaterials. Faculty

development on the topic will be required, and thoughtful curricular redesign will be needed.

Nurses should be in a prime position to influence and advocate for the safe and ethical use of these new technologies. For example, as patients increase their involvement in care decisions, nurses will need to create plans of care to assist them in their new roles. This presupposes that nurses are educated about nanotechnology and willing to be involved in their professional policy-making organizations. Educated and involved nurses would then be able to assist patients to understand and consent to uses of their data, protect privacy, and ensure existence of mechanisms for patients to opt out of participation. Patients, clinicians, public health agencies, the healthcare industry, consumers, and society will all need advocates for the safe and ethical use of nanomaterials.[22] Advocacy will be required in terms of medical care, the environment, industrial health, and allocation of research dollars.

IMPLICATIONS FOR NURSING INFORMATICS

Nanotechnology would have substantial implications for nursing informatics. These implications may be organized into electronic health record (EHR) design, systems interoperability and safety controls. Most obviously, EHR design would need to incorporate the data and information relayed from nanomaterials. Perhaps inventive architecture will be created to sense and transfer data automatically to EHRs, much like Bluetooth devices sense each other now. No matter the method, for patients within facilities, the individually tailored data and information will require massive storage capability, given the amount of information that will be generated.

Across facilities, electronic orders and patient documentation will be individualized in ways never before accommodated in electronic systems. A common method today is to craft several hundred generic order sets and documentation templates as part of systems implementation. New projects in the nanotechnology era will require new implementation methods to accommodate the intentional variability in patient-centered information and the individually-tailored orders. Another implication for EHRs concerns the basic data structures that comprise these systems. An analysis of implications is needed to outline: (1) whether new forms of data are required for storage in all databases, and (2) how nanomaterial data and information should be structured and integrated within existing data elements. Will the current taxonomies and data structures be sufficient or will new terminology structures be required? Once the taxonomies and data structure issues are determined, implications for data mining and knowledge development should be discussed. Massive amounts of time-series data would be available in these systems. Data ownership, data quality, data cleaning and other issues important to knowledge development and data mining would need to be considered.

Systems interoperability will continue to be a challenge for nursing informatics. The actual nanotechnology devices will need to be standardized if they are to be interfaced and integrated into multiple EHRs in any useful manner. Informative knowledge representation methods and robust information structures will be imperative to integrate data and information from huge numbers of devices. Data retrieval will be taken to another level as search engines scour enormous data warehouses for pertinent information.

Safety controls will be a critical element for nanotechnology-enabled systems. New monitoring mechanisms would be needed to assure that the devices are precisely controlled and calibrated within safe limits. Electronic health record systems testing would need to incorporate new layers of testing to assure that nanomaterial safety is highly engineered within EHRs. Obviously, continual uptime is implied for future EHRs because nanodevices will be monitoring life-critical events, much like the functions physiological monitors perform now. As mentioned earlier, this kind of continual support model is not yet available.

CAUTIONS ABOUT NANOTECHNOLOGY

As with all new technology, cautions are in order. Risks can occur anywhere that nanomaterials can come into contact with people, animals or the environment.[23] Key risks relate to liability, privacy, financing, and the effectiveness and safety of products.[4,21] For the health arena, the most immediate concerns are likely the safe and ethical use of nanomaterials. The microscopic size of nanoparticles makes them difficult to detect and control. Researchers, staff, consumers or patients may inadvertently inhale therapeutic products. The larger number of atoms on the surface of nanomaterials also make the interaction between materials more likely.[4] The models and predictability of these molecular interactions are not yet known. Thus, precautions to avoid inhalation and emergency methods to disable the technology will be needed. Current gloves, masks, and gowns may not provide adequate protection, creating a need for new evaluation research, new protective equipment, and a calculation of the associated costs before the technology is widely used.[24]

Only a few research findings are available about the safety of nanomaterials. Researchers found that nanoparticles can provoke increased inflammatory responses and potentiate the effect of medications[23]; however, the overall behavior of nanomaterials in mammals is not yet well understood. One researcher found that nanoparticles placed near rodents' nares traveled up the olfactory nerves into the brain, easily bypassing the blood-brain barrier.[25] Although alarming, this kind of mechanism is not completely new in the arena of

ultra-fine particles. After all, asbestos inhalation has been a known danger for decades. However, the intentional engineering of products would greatly expand the availability of materials with as yet unknown properties and risks.

These kinds of disquieting behaviors have generated an urgent need for more research about nanomaterials. Much of the current focus is to determine what research should be done about the risks of nanomaterials. The US government requested $58.6 million for research across the 26 Federal agencies involved in the National Nanotechnology Initiative in the next fiscal year.[26] Also, in late 2007, the US House Subcommittee on Research and Science Education conducted a hearing to review nanotechnology and determine current state and future research needs.[27] Leading nanotechnology scientists published 5 grand challenges for the safe handling of nanotechnology in 2006: (1) develop instruments to assess exposure to engineered nanomaterials in air and water in the next 3–10 years, (2) develop and validate methods to evaluate the toxicity of engineered nanomaterials with the next 5–15 years, (3) develop models for predicting the potential impact of engineered nanomaterials on the environment and human health within the next 10 years, (4) develop robust systems for evaluating the health and environmental impacts of engineered nanomaterials over a human lifetime within the next 5 years, and (5) develop strategic programs that enable relevant risk-focused research within the next 12 months.[28]

The ethical use of nanomaterials is a second major area of concern for health care providers. Nanotechnology researchers are beginning needed discussions about this as yet undeveloped area.[7,17,29–32] Authors of the Nanomedicine report[7] and Hastings report[32] suggested that some ethical issues for nanomaterials may be similar to known areas, such as genetics, for which guidelines already exist. Initial work might build upon the principles already available from that field and known guidelines for justice and privacy. Obviously, guidelines should be created to preserve human dignity and integrity, especially given the risks possible with nanomaterials.[29] New areas for nanomaterials will need to be considered, including, in part:

- Informed consent—treatment with nanomaterials would not occur without express consent by health care consumers
- Right not to know—the consumers' right to not receive information, for example, if monitoring for a predisposition for an incurable condition is being considered
- Precautionary principle—the moral duty to monitor for unforeseeable impacts of new technologies is preserved
- Intellectual property, authorship and publication rights
- Access to health care and rights to treatment with nanodevices and nanomaterials

Clearly, the answer to the grand research challenges above—safe and ethical use of nanotechnology—will have implications for nursing in the future.

CONCLUSIONS

Nanotechnology could revolutionize manufactured materials as we know them, creating a vast number of new devices, drug delivery systems, and monitoring mechanisms. The potential benefit of these devices is tremendous because nanomaterials bridge the health sciences and engineering in novel and provocative ways. The implications of this technology are diverse, impacting consumers, clinicians and the practice of informatics. Initial implications include the need for consumer and clinician education about nanomaterials and their actions. Increased individual responsibilities and role changes could occur because consumers would be the first to view information from these tiny devices. New policies and regulations would be needed for individuals' privacy, safety and the ethical use of nanomaterials. Nanotechnology might change the power base of health care, with consumers emerging at the center of the team in an era of highly individualized care. Clinicians might find their roles as experts diminished. Clinicians would need education about nanomaterials with special emphasis on the safe use of the new products. Informatics practice implications would be great, ranging from enhanced system design and intense system support to needed policies surrounding data ownership, longitudinal data stewardship, and an assessment of the adequacy of today's taxonomies to support data and information from nanomaterials. A new era in healthcare devices and products has already begun. This article initiates a discussion about the implications of nanomaterials to health care. The challenge now is to continue the dialogue and analyze implications into the future. A reasoned approach is needed for this exciting new era of nanomaterials.

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