Nanomedicine: Obtaining the Benefits, Managing the Risks

The phrase "small is beautiful" has taken on new meaning to those involved in the scientific field known as *nanotechnology*, which involves engineering and utilizing materials at the nanometer scale – that is, as small as one-billionth of a meter. Reduced to these minute dimensions, substances often undergo significant changes – for example, carbon becomes stronger than steel and copper is transparent.

The increasing ability of science to compress materials to the submicroscopic level is affecting many fields of human endeavor. Current and emerging nanotechnology applications include advanced energy generation and storage systems, as well as new chemical additives and industrial materials. More than 300 products with nano-scale ingredients are already on the market, ranging from sunscreens to bowling ball coatings.

One rapidly developing area of nanotechnology research is *nanomedicine*, the process of "using molecular tools and molecular knowledge of the human body" for the purpose of diagnosing and treating illness. (Freitas, R., *Nanomedicine, Vol. 1: Basic Capabilities,* Georgetown, Texas: Landes Bioscience, 1999.) The swift progress of nanomedicine research makes it necessary to understand the risks and begin the process of limiting potential exposure.

Nanomedicine Applications

Nanomedicine may potentially revolutionize our ability to screen, diagnose and treat conditions ranging from cancer to cardiovascular disease to diabetes. Scientists are at work on the following projects, among many others:

- **infection and genetic testing tools** that are faster, more accurate and less invasive than conventional methods
- **nanoneedle and pulsed laser surgery** that alters cell structures without damaging surrounding areas
- **targeted drug-delivery systems** that transport the drug exactly where needed and monitor its effect
- **nanotube-based biosensing devices** that provide in vivo diagnostic testing capabilities, such as tracking electrolyte and blood glucose levels
- **gold-coated nanoparticles** that destroy individual tumor cells while leaving nearby healthy cells unharmed
- **"intelligent" synthetic biomaterials** that mimic body tissues and may eventually enable organ regeneration

Some nanomedicine drug-delivery systems and anti-cancer drugs are already in use. Many other applications are in various phases of clinical or pre-clinical testing, and, if found safe and effective, may reach the market in five to 12 years. More advanced nanomedicine products – such as biocontainers for medical diagnostics and cell treatment – are in earlier stages of development.

Regulatory and Risk Issues

Despite the accelerating pace of nanotechnology progress, many fundamental regulatory issues are only now being addressed by the U.S. Food and Drug Administration (FDA). These include defining what constitutes a nanotechnology product, establishing regulatory authority over various types of products, adopting labeling requirements, and calculating the health and environmental impact of emerging applications.

Risk assessment is one of the major challenges facing the FDA, as techniques designed for macroscopic materials may be unreliable for nanotechnology products. A National Research Council report (available at **http://www.nap.edu/catalog.php?record_id=11752**) noted that until the risks associated with nanotechnology are more clearly understood, "it is prudent to employ some precautionary measures to protect the health and safety of workers, the public and the environment."

This precautionary philosophy applies equally to healthcare organizations. While the promise of nanomedicine is bright, the risks and ethical questions posed by these advances must be considered carefully. Major potential risks include

- **possibly heightened toxicity of free nanoparticles,** which may be able to bypass the body's defenses and interfere with basic biological processes
- **genetic alteration,** as some therapies operate at the chromosomal level and hence raise complex ethical questions, ranging from informed consent of the unborn to the prospect of genetic enhancement for the few to the issues surrounding stem cell research
- **environmental and workplace impact,** as the particles are often too small to be trapped by available filtration systems and may accumulate in water, air or plants, with unpredictable consequences

- **healthcare paradigm shift,** as new technologies possibly result in obsolescence for some established therapeutic modalities, creating new financial and administrative demands in terms of equipment, care settings, and staff training and competencies.

Strategies

As the nanomedicine revolution unfolds, healthcare organizations must find effective ways to ensure patient safety and reduce the liability risks inherent in adopting cutting-edge diagnostic and treatment techniques. The following proactive measures can assist your healthcare organization in maximizing the potential benefits of nanomedicine while minimizing associated risks:

- **Create a nanomedicine task force** composed of clinical and administrative leaders with a high level of scientific sophistication to research nanomedicine prospects, benefits, costs and risks, and incorporate the group's findings into the strategic planning process.
- **Undertake prospective risk analysis to address areas of potential enterprise liability,** including adverse outcomes, environmental hazards, and implicit warranties or guarantees contained within marketing materials.
- **Initiate a discussion with the ethics committee regarding emerging nanomedicine issues,** including use of stem cells and the question of genetic enhancement.
- **Develop a risk posture vis-à-vis nanomedicine,** in collaboration with legal counsel, and ensure that risk and insurance coverage issues are factored into decisions involving nanomedicine. Recognize that insurers may not be able to make a blanket generalization concerning coverage for nanomedicine risks, which at this point are difficult to predict and/or quantify. As with all legal causes of action, nanomedicine-related claims would be assessed on an individual basis.
- **Adapt your organization's informed consent policies to the new realities,** taking into account the generally low state of consumer awareness regarding nanomedicine and the unknowns that accompany a radically new technology. Specifically, your informed consent process for nanomedicine therapies should encompass an extensive educational component for patients and acknowledge the limitations of current knowledge and experience in this area.
- **Strengthen policies and systems designed to track patients within the institution, report adverse events, and monitor equipment and suppliers.** Designate those responsible for reporting incidents to the FDA and/or the manufacturer and ensure that personnel understand internal reporting rules and procedures.
- **Revise competency and credentialing models for providers and staff to include emerging technologies and approaches.** Ensure that staff members are familiar with policies regarding nanotechnology applications and acceptable off-label uses.
- **Manage the product supply chain** and establish policies regarding the presence of vendor representatives in clinical settings where treatment is rendered.
- **Advocate for more basic scientific and safety research on nanomedicine and nanotoxicology,** as sound regulation and more manageable risk will require a deeper level of theoretical and empirical knowledge.

Resources

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