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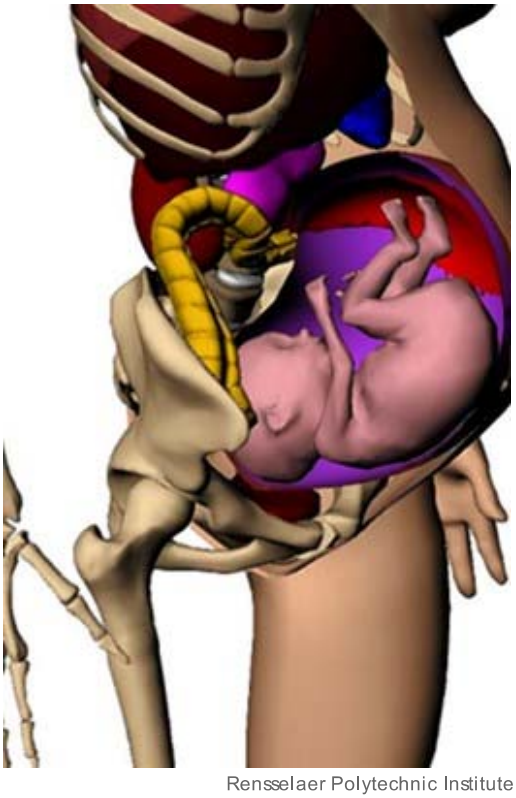
Scientists Find Safer Ways To Test Medical Procedures

By SHIRLEY S. WANG

Scientists are developing ever more sophisticated versions of "virtual patients" with the aim of testing medical devices and procedures that can't readily be assessed in real people.

Medical innovations typically undergo extensive trials before they are approved for use in people. But sometimes such analysis isn't practical because of the risks to patients. Medical testing, for example, is rarely done in children and pregnant women due to worries about what a procedure could do to a growing body.



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Virtual patients can help estimate how much radiation a fetus gets during a mother's CT scan.

Virtual patients are realistic-looking computerized models. They use medical data and computer software and graphics to mimic real people, with skin, bones, fat and organs of realistic size, shape and composition. Scientists are currently testing virtual patients to answer such questions as: How much radiation are various organs in the body exposed to as a result of a CT scan? How risky is it for a pregnant woman to get a scan? Should a heart device like a defibrillator be implanted in a child differently than in an adult?

Virtual patients could allow medical-device companies to test new products earlier, helping the devices get to market more quickly and cheaply, according to the Food and Drug Administration.

Virtual technology also someday could provide opportunities for doctors and medical students to train for certain surgical procedures by seeing and feeling organs virtually while using real tools. Doctors could be able to calculate the probability of a pregnant woman having a high-risk delivery, based on synthesized, three-dimensional images of the pelvic region and fetus, researchers say.

X. George Xu leads a team of nuclear engineers at Rensselaer Polytechnic Institute in Troy, N.Y., studying how radiation interacts with the human body. Computerized tomography, or CT, scans are frequently used in medicine to image tissues and bones in the body. But repeated exposure to

radiation from the scans is believed to raise the risk for cell damage that may cause cancer and other health problems. Such risks also can exist for patients receiving radiation to treat tumors, for example.

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Dr. Xu with a patient model from 20 years ago, behind him, and a computerized patient he works with now.

Virtual Benefits

Defibrillators may help people with irregular heartbeats who don't respond to drugs. Little is known about the best way to implant the device in a child.

- Children's heart anatomy is different from adults
- Defibrillators have been primarily studied for adult use
- Studying defibrillator use in children is risky and expensive
- Using a virtual child patient to determine best practices for defibrillating children…
- Can show where to connect the electrodes on child's heart to best detect abnormal beats that trigger the defibrillator
- Can help calculate how much electrical impulse is needed to regulate a child's heart rhythm while minimizing side effects

Sources: FDA; UCSF; National Heart, Lung, and Blood Institute

In Dr. Xu's lab, virtual patients are exposed to virtual radiation in doses similar to that of a CT scan or cancer-radiation treatment. Simulating a dose of radiation is a complicated process. It involves mapping out the physics of how radiation waves travel through the body and interact with different biological substances. Bones tend to absorb radiation; fat scatters it.

The researchers recently created an obese virtual patient to demonstrate what happens to radiation in this body type. Because fat can disperse the waves, overweight people usually need a higher dose of radiation in medical procedures. The aim is to administer sufficient radiation to achieve an image scan of adequate quality, but not too much to cause harm to the patient. Currently, some doctors may use existing computer software to estimate how much additional radiation is required based on factors such as weight, height and age of the patient.

Dr. Xu's team showed that the virtual patient, using more sophisticated modeling such as how fat is distributed in the body, can provide more accurate calculations of how much additional radiation an overweight person requires. The work was presented early this year at a conference of the American Nuclear Society and has been submitted for publication at a peer-reviewed journal, according to Dr. Xu.

In related work, supported by a $1.2 million government grant, researchers developed computer software that provides readings about how much radiation each organ of the body receives after radiation exposure from a medical procedure, says Aiping Ding, a Rensselaer Polytechnic research associate who is spearheading the project.

The researchers recently tested the new software, called VirtualDose, in a simulation of an abdominal CT scan of a woman in her sixth month of pregnancy. They found that although the fetus did absorb radiation, the dose was 40% less than that calculated by a more rudimentary software tool that is currently in use.

The team hopes that calculations from virtual patients will help guide doctors in targeting tumors or making clinical decisions, like figuring out if the benefits to the mother in getting a CT scan outweigh the risks to the fetus.

Dr. Xu began decades ago creating models of human patients to understand how radiation affects the body. His first-generation designs were models that could be touched and felt. They were built of substances meant to mimic biological materials and had radiation sensors embedded throughout the torso.

Karl, a faceless, putty-colored model Dr. Xu created 20 years ago, still sits on a desk in his lab. It contrasts sharply with the strikingly vivid and anatomically correct virtual patients on the computer screen nearby.

Additional work is being done at the Center for Devices and Radiological Health, part of the FDA. Researchers there have created a "virtual family" of adults and children in order to study how best to implant medical devices in children, such as heart defibrillators. Defibrillators have been mainly studied for adult use, although

children's heart anatomy is different from that of adults.

The FDA also is exploring improved diagnostic techniques using virtual patients. In a virtual catheterization lab, scientists are inserting virtual blockages in blood flow into the heart. They then run a series of scans aimed at determining which images best detect the locations and size of the blockages. The research mimics a clinical trial, but can be performed more quickly and without risk to real patients, says Kyle Myers, director of the Division of Imaging and Applied Mathematics at the FDA division. She says researchers hope in the future to use the techniques to investigate potential treatments.

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