A WORLD BEYOND HUMANS

AS ROBOT, DRONE, AND 3D PRINTING TECHNOLOGIES ADVANCE, HUMAN INVOLVEMENT AND LIABILITY CONCERNS CHANGE

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Technological advancements in medical uses of robots, drones, and 3D printing continue at an impressive pace. Devices leveraging these advancements will enter mainstream medicine over the next five years, by some estimates.

The increasing use of advanced medical devices will reduce the need for certain staff, and will likely decrease available jobs for health care providers. The advent of new technology also poses new liability concerns due to a shift in the delivery of care.

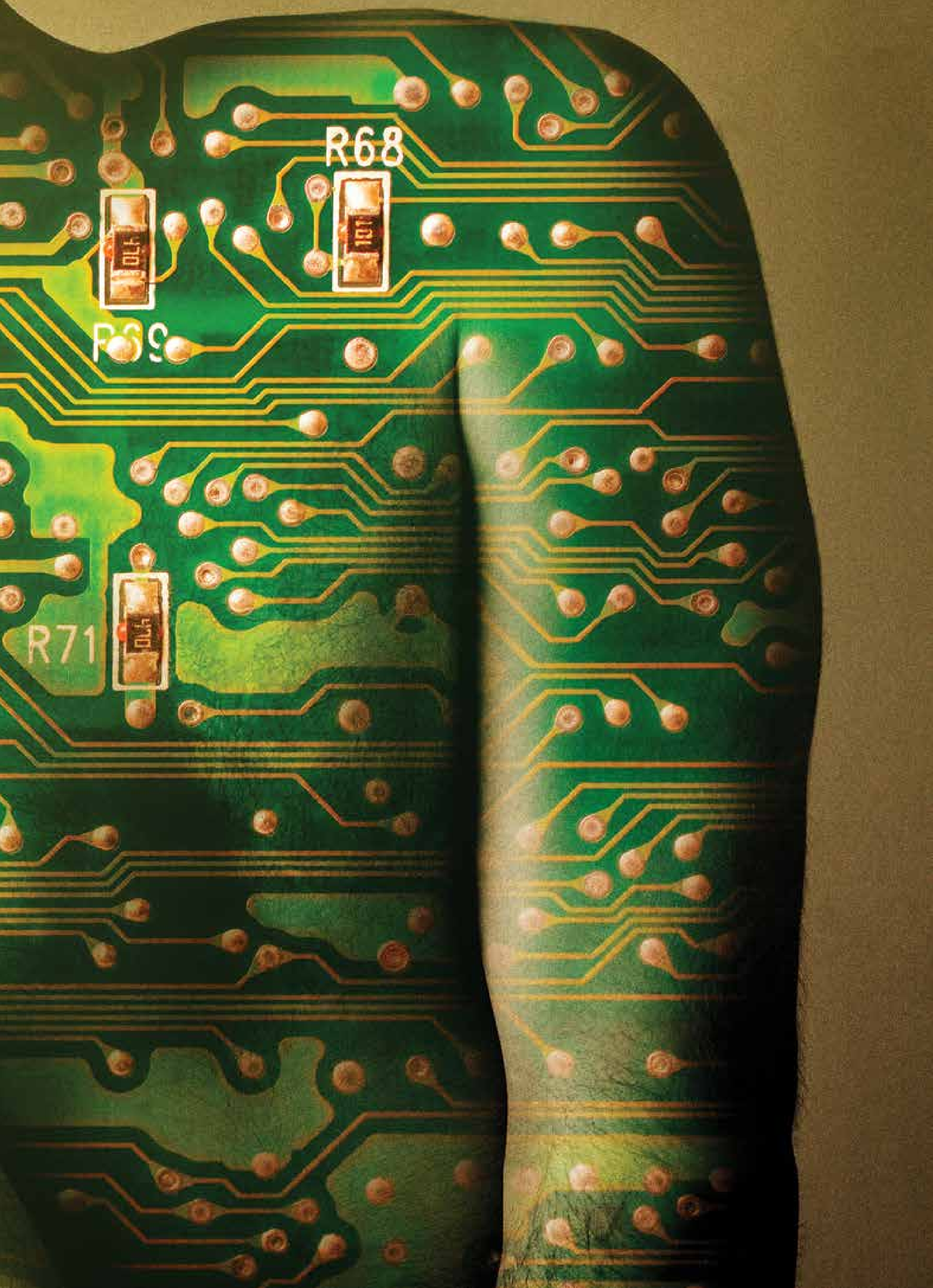
To utilize this technology effectively, mitigate risk, and reduce job security fears, it is important to understand both the benefits of these advancements and the liabilities associated with their use, based upon current evidence.

Robots

Robots can be used to support, assist, and extend medical services. Robots are widely used in jobs requiring the monotonous and repetitive activities that lead to fatigue and burnout, high turnover, and on-the-job injuries when performed by humans.

Arguably, when evidence demonstrates the superiority of robotics to human action, use of robotics must be employed for legal and ethical reasons. For example, studies show the use of robotics for systematic disinfection of health care facilities results in a dramatic 70 percent drop in hospital infections. The robot glides through the hospital and destroys deadly microorganisms by utilizing ultraviolet disinfection methodologies.

Robots have also been used for quite some time in minimally invasive surgery. Major advances now include unmanned surgery. The robot is equipped with a high definition visual system and near microscopic instruments that maneuver with dramatic precision compared to the human hand. Robotic surgery, whether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manned or unmanned, results in smaller incisions, decreased pain and blood loss, a lower infection rate, and a speedier recovery time. The use of robots in surgery is already a billion-dollar industry.

Robots are also becoming an integral part of nursing care. Robots will ultimately be able to draw blood within 60 seconds, with more precision and fewer needle sticks than when the task is performed by humans. Currently, one robot system is able to detect the best vein for blood withdrawal with 83 percent accuracy, which is said to be about the same as a well-trained phlebotomist.

Robots are being used not only for their "brain" power, but also for their brawn—transporting everything from blood and tissue samples to medication and supplies. The robot's strength allows it to push carts that can weigh up to 1,000 pounds. The robot receives its computerized delivery instructions via touchscreen and proceeds on its mission throughout the facility to make its deliveries.

These robots work around the clock so fewer employees are needed, providing relief from last-minute short staffing and reducing the need for difficult-to-fill night shifts. Staff is freed up to spend more time with patients providing hands-on care. Additionally, nurses do not have to push heavy carts or carry heavy items, resulting in fewer on-the-job injuries.

Other robots are built to lift, turn, and reposition patients, and can aid in lifting patients out of their beds and wheelchairs. The physicality required for lifting and repositioning patients has become a leading cause of on-the-job injuries for nursing staff. Robots can relieve staff from performing these strenuous and repetitive motions. Such robots can also be used in the home to provide assistance when the daily cost of personal nursing care is unaffordable or when providers are incapable of heavy lifting. These robots are equipped to move and lift patients out of bed 40 times a day.

Perhaps the most astonishing advancement—although still in the experimental stage—is the development of robots that are under a millimeter in size and can "swim" through our bodily fluids, such as the bloodstream and the lymphatic system, to deliver medication to targeted areas.

While robots can help improve quality of care, manufacturers—as well as the professionals using the robots—must be aware of potential legal exposures. Medical professionals are still required to operate tools attached to robotic arms, and are certainly responsible for determining whether contraindications exist in using robotic surgical methods. One must consider application of the "captain of the ship" doctrine, which may make the surgeon ultimately liable for surgical mishaps. Moreover, the learned intermediary doctrine renders the physician ultimately responsible for communicating the risks of robotic devices to patients.

Neither doctrine protects the robot's manufacturer from liability should a defect in the robot's hardware or software cause harm to the patient. The manufacturer is also responsible for training surgeons to use the devices. Intuitive Surgical, the manufacturer of the well-known da Vinci robot, has faced multiple lawsuits over the years, with its robots being linked to over 70 deaths as well as to adverse events such as burns, tears, organ ruptures, internal bleeding, and infection. However, with recent advancements, the number of adverse events has fallen.

Drones

Drones are widely used recreationally and are finally finding use in dire medical situations at home and abroad. In future medical emergencies, the most expeditious means of transporting medical necessities like blood, medications, vaccines, and organs will likely will be drones.

According to the Journal of the American Medical Association, a team of researchers in Sweden simulated the emergency transport of defibrillators by ambulance and by drone. The drones were able to deliver the equipment 16 minutes faster than the ambulances, which, in the event of a heart attack, can be life-saving minutes.

The United Nations has used drones to airdrop medical supplies over underdeveloped countries. These deliveries occur in a matter of minutes versus conventional air transportation, which can take days. Similarly, providers working in remote areas can request, via text, blood for transfusions and receive units by airdrop in as little as 15 minutes, versus the hours it would take by automobile. Moreover, unmanned drones can fly over rugged terrain and airdrop goods without risking the lives of a flight crew.

Drones are also being used to provide blood products and medicine to our local rural areas. In an initial effort, a Virginia-based medical clinic partnered with NASA researchers to obtain Federal Aviation Administration (FAA) approval to deliver medication to rural areas where those in need reside miles away from a clinic or hospital. Similarly, a California-based company is sharing its drone delivery system with other states in need. The drones are navigated through cellular networks and GPS and can make deliveries within 30 minutes.

Although drones will increasingly be employed for medical purposes, their use is limited due to certain restrictions. There will be weight and size restrictions that will limit the ability of a drone to safely transport certain medical equipment. Additionally, there are challenges with the transportation of blood products and certain medications that require safe temperatures and sterile packaging. And the drones themselves may not be able to tolerate certain extreme weather conditions. Furthermore, if the drones are carrying hazardous materials, the risk of a crash must be considered due to the potential exposure to those on the ground below.

And, of course, there are FAA restrictions, although the various uses of drones for medical purposes are expected to increasingly gain clearance.

3D Printing

3D printing, also known as additive manufacturing, involves the production of three dimensional objects from a digital file. Through the use of special software, a blueprint of the desired object is created and the completed design is sent to a specialized printer. The printer contains an application that moves the data through a melting process, followed by application to a rapid cooling plate. It leads to the design and engineering of parts in a more economical and timely fashion than other manufacturing methods.

The potential uses of 3D printing are endless and include not only the reproduction of anatomical models and medication, but also organs and tissue.

With 3D printing, one can build an exact replica of an organ, enabling a surgeon to study the model in preparation for surgery. Prosthetics and implants can also be created with the use of this technology. In one known case, a 22-year-old female suffered a rare condition that caused her skull to grow extraneous bone, which ultimately placed damaging pressure on her brain, resulting in a loss of vision and motor control. In a life-saving procedure, Dutch surgeons replaced the entire top portion of the patient's skull with a customized printed implant.

Many amputees around the world lack access to modern prosthetics. Traditional prosthetics are not only costly, but also require a time consuming process of tailoring the prosthetic to the individual and her needs. 3D printers have been provided to war-torn countries to create replacement limbs where amputation is common. These are patient-specific limbs produced swiftly and with little expense.

Other uses include the enhancement of implantable orthopedic devices. At Washington State University, chemicals combined with a ceramic powder are used to create ceramic scaffolds that promote bone growth. This extends, and possibly doubles, the life of cemented implants used in hip and knee replacements, which currently have life spans of approximately 10 years.

Thousands of patients awaiting organ placement for transplant will benefit once the synthetic organ is perfected and approved by the FDA. At Cornell University, heart valves tested in sheep are anticipated to be perfected for use in humans within five years. Researchers have also been able to replicate human ears through the use of 3D photographs. In addition, synthetic organs such as livers, hearts, and kidneys—once perfected—can be used for various testing in lieu of live animals.

At Wake Forest School of Medicine, 3D printers have been used to create synthetic skin deemed adequate for transplantation to patients who suffered burn injuries. Synthetic skin can also be used to test chemical, pharmaceutical, and cosmetic products.

Perhaps the most impressive use is the advent of tissue engineering. Researchers at Harvard University were the first to create a swatch of tissue that contains skin cells interwoven with structural material that can potentially function as blood vessels. The vascularity of the tissue allows for the perfusion of fluids, nutrients, and cell growth components.

Finally, chemists are also working with 3D printing to develop chemical compounds at the molecular level for printable medication. With a digital prescription, patients will be allowed to purchase the blueprint and chemical ink from an online pharmacy and print the drug at home. Such ability would provide ease for the homebound as well as those in rural areas.

In the United States, medical device manufacturing is a $150 billion industry. It follows that the use of 3D printers in this industry is on the rise and that costs will fall dramatically.

For all of its benefits, 3D printing raises some novel questions of liability concerning whether it should be deemed a product or service. The answer will provide resolution regarding whether legal principles of product liability versus professional negligence apply.

If the answer is product liability, one will need to ascertain the identity of the "manufacturing" party. Since there are many moving parts involved in 3D printing, questions will arise about whether liability attaches to not only the manufacturer of the 3D printer, but also to the provider who ordered the printing, the technician who uploaded the CAD file, and the technician who caused the machine to print, to name a few potential defendants. Obviously, informed consent and notification of all applicable warnings is key no matter which principle applies.

Applying Evidence-Based Medicine

As the adage goes, "Medicine is not an exact science." Rather, it constantly evolves as technology advances. Application of evidence-based medicine is an effective way to determine whether providers can benefit from new technology.

The purpose of evidence-based medicine is to ensure that known science regarding optimal management of a patient's condition is applied both reasonably and consistently. It combines clinical expertise, patient values and preferences, and ongoing research-based developments.

Evidence-based medicine offers a model of improved quality of care, improved patient satisfaction, and reduced costs. The provider must assess the strength of the evidence as well as the risks and benefits. When evidence-based medicine demonstrates that benefits outweigh the risks, the integration of medical technology is required.

Due to ongoing medical advancements, there is an increasing need for clinicians to stay apprised of developments and consider them in the overall assessment and care plan for the patient. As the application of robotics, drones, and 3D printing becomes more widespread, the clinician will be obligated to consider these methods of treatment as they apply to patients' needs.

Therefore, although new technology likely will reduce the need for humans for certain health care processes and procedures, best practices will prevail and the application of new advances will continue to improve our health care system. The extent of the potential liability associated with the use of these novel technologies, though, remains to be seen. ■

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