American Medical Association boards implantable chip wagon

The influential American Medical Association (AMA) has thrown its weight behind what might be called medical human bar-coding by adopting a policy that endorses the provisional use of implantable radio frequency identification tags, or microchips, to store medical information under the skin of patients.

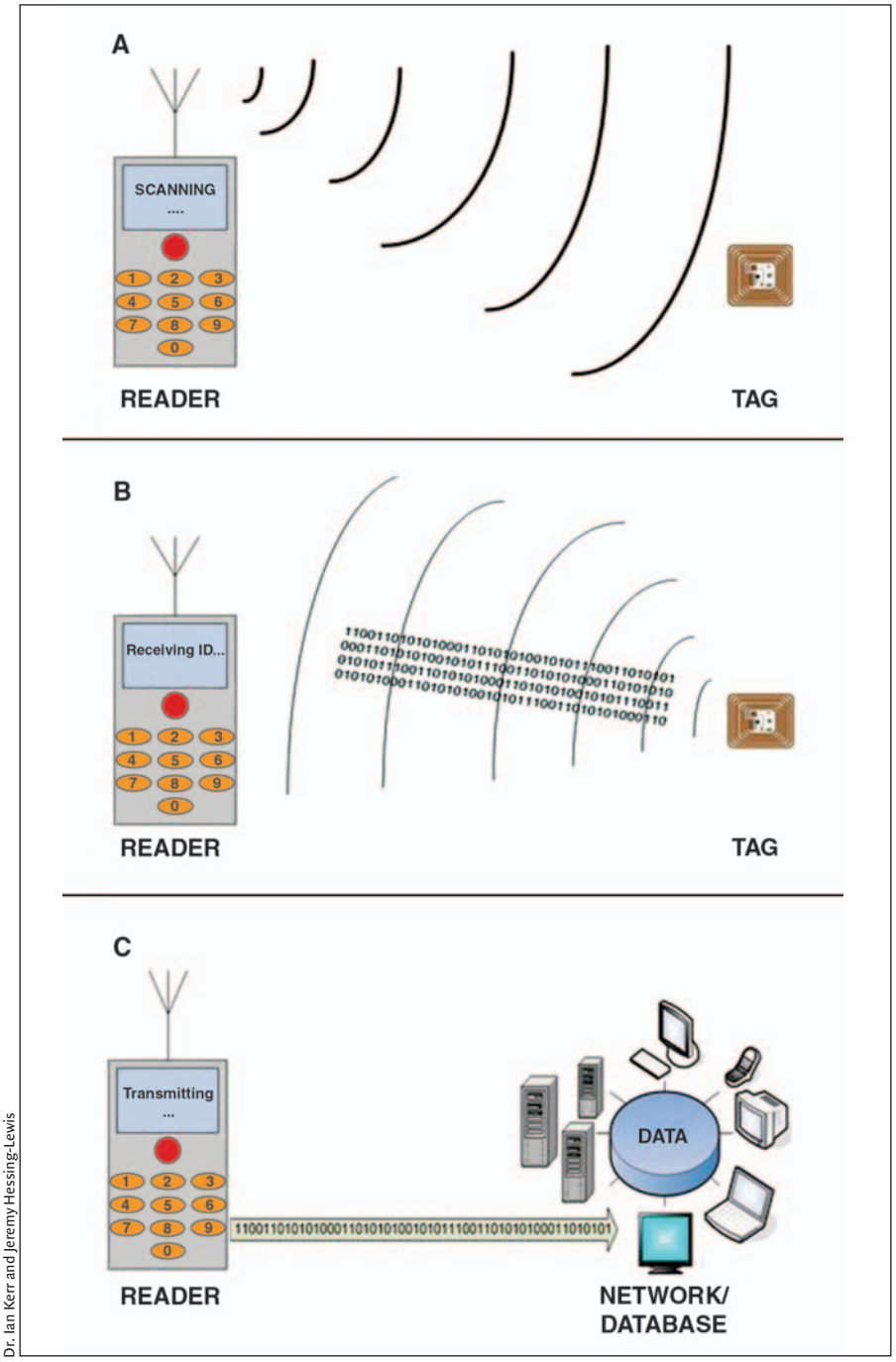
But delegates to the 2007 Annual Meeting of the AMA House of Delegates held in Chicago in June recommended approaching the brave new world of microchipping humans with caution.

The association's 162nd annual meeting adopted a policy that approves the use of the microchips "to identify patients, thereby improving the safety and efficiency of patient care and may be used to enable secure access to patient clinical information."

But delegates also cautioned that the efficacy and security of the microchips "have not been established. Therefore, physicians implanting such devices should take certain precautions:

1. The informed consent process must include disclosure of medical uncertainties associated with these devices.
2. Physicians should strive to protect patients' privacy by storing confidential information only on [the] devices with informational security similar to that required of medical records.
3. Physicians should support research into the safety, efficacy and potential non-medical uses of [the] devices in human beings."

Dr. Steven Stack, a member of the AMA board of trustees and an emergency department physician at St. Joseph Hospital East in Lexington, Ky., said the AMA's stance is both "permissive and cautious in that it says we've got to make sure we protect people's privacy rights so bad things don't happen, kind of like George Orwell and Big Brother in *1984*."



Dr. Ian Kerr and Jeremy Hessing-Lewis

Passive implantable radio frequency identification microchips or "tags," which are currently in medical use, operate as a link to a patient's medical records. The process is simple. A device called a "reader" sends a pulse of radio energy (illustration A) to the implanted microchip. The microchip responds by emitting a unique patient identifier, essentially a password, back to the reader (illustration B). The reader then transmits that identifier to the computer network or database where the patient's medical records are stored (illustration C), bringing the information up on screen for use by the physician. The next generation of "active" microchips are expected to be rewritable and encrypted, essentially allowing the physician to directly access a patient's medical records contained on the implanted microchip itself.

The US Food and Drug Administration has already approved the limited use of so-called"passive tags." These unencrypted microchips, which are roughly the size of a grain of rice, cannot be re-written or modified once they've been implanted with a needle and have limited storage and transmission range (a few metres). They can contain basic biometric and medical information, such as whether a patient has a chronic disease or an implanted medical device, such as a pacemaker. They typically do not contain a patient's medical records. Instead they contain a unique identification number that allows a radio frequency identification microchip reader to access existing health records contained within a local computer database (see illustration on previous page).

The US Food and Drug Administration is now considering whether to allow "active" battery-equipped identification microchips that can be rewritten and constantly updated with a patient's medical record and have significantly more storage capacity and a greater transmission range (as far as several kilometres).

In Canada, radio frequency identification microchips are not considered medical devices by Health Canada's Therapeutic Drugs Directorate, so there's no requirement to obtain licences for their sale or use. Health Canada spokesperson Carole Saindon says the devices do not have a therapeutic use, so they fall outside the ambit of the Food and Drugs Act. "Health records, or the mechanism by which they are stored or retrieved, are not considered to be medical devices," says Saindon. Because this microchip technology is unregulated, it isn't known whether any Canadian facilities have implanted chips in humans. But they are in use externally. Toronto's St. Michael's Hospital uses surgical tape to attach microchips to the arms or legs of babies to track their movement from the hospital's obstetrics ward.

Stack says the basic technology underpinning the microchips is now in widespread medical use in the form of "pacemakers, defibrillators and other electronic medical devices that store a wealth of information."

The microchips could potentially result in enormous medical benefits, including a significant reduction in medical error and adverse drug reactions, Stack says (Box 1). "In an emergency department ... people come in very sick, with little to no information on them. They and their families are not familiar with the names of their long list of medications and complex medical problems." The microchip technology could provide immediate access to vital information, such as allergies or the patient's last heart catheterization report."

"That information, absolutely, could save lives by preventing errors and also by facilitating the next step" in treatment, Stack added.

But given that there are so many concerns surrounding privacy and security, widespread use of the microchips likely won't occur until manufacturers provide "compelling evidence" that the devices are secure, adds Stack.

"This certainly gives the green light to proceed with the exploration and use of these devices. But it also provides a very strong yellow light for caution, that we don't go too far, too fast and cause harm at the same time."

A report by the AMA's ethical and judicial committee submitted to the annual meeting indicates there are also potential physical risks to patients with the implanted chips.

"Their small size allows them to migrate under the skin, making them potentially difficult to extract," says Stack. The tags may also cause electromagnetic interference with electrosurgical devices and defibrillators. And it is not yet known whether tags affect the efficacy of pharmaceuticals.

Canadian experts say that as the technology evolves, the use of microchips will become more common, and the ethical and security issues trickier. "I don't think we really know how things are going to play out with this technology," says University of Ottawa Professor of Law Dr. Teresa Scassa. "I think people have consistently underestimated the ability of hackers to break encryption, to infiltrate systems, to extract data from systems."

As well, medical coercion could become an issue as patients find themselves caught between demands to have chips implanted in the interest of medical safety and efficiency, and a desire for privacy, Scassa says. "Those are the things that are really hard to assess, prior to the rolling out of a technology."

The problems will doubtless be compounded in Canada by jurisdictional differences in privacy legislation, particularly with respect to health information, Scassa adds. "It's very patchwork and what rules will apply, or what protections are available, will vary from one jurisdiction to another. I would say, almost universally, except perhaps for the Ontario legislation, [provincial and federal privacy law] really doesn't contemplate things like implantable chips."

University of Ottawa professor and Canada Research Chair in Ethics, Law and Technology, Dr. Ian Kerr, notes that the passive chips now in use were deliberately designed so that they could be accessed by any reader, which in turn gives anyone access to an individual's health records in an external database. "They are both informationally insecure and a risk to the confidentiality of the database and the privacy of the individual."

Future generations of health chips may be encrypted and rewritable, Kerr adds. "We're not there yet but I don't doubt that that day will come because we're getting very good at miniaturizing devices and also very good at increasing and maximizing storage capacity on devices." — Wayne Kondro, *CMAJ*

Box 1: The implantable chip debate

Potential benefits

Rapid access to vital medical information may:

- Reduce adverse events, including drug reactions
- Heighten efficiency in trauma centers
- Facilitate treatment of unresponsive patients
- Improve management of patients with chronic illnesses

Potential risks

- Chips may migrate under skin
- Chips may interact with medical devices or pharmaceuticals
- There could be a breach in privacy through a system infiltration

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