Tagging products and people

Despite much controversy, radiofrequency identification chips have great potential in healthcare

In May 2006, William Koretsky made medical history when he became the first emergency patient to be identified from an implanted radiofrequency identification (RFID) chip. Koretsky, a 44-year-old sergeant with the Bergen County Police Department (NJ, USA), had crashed his car into a tree during a high-speed chase. When he was taken to hospital, an emergency-room scan revealed an RFID chip in his arm, which had been implanted in 2004 for identification purposes at the suggestion of his police chief. Doctors retrieved the ID number, identified Koretsky using an online database, reviewed his health history and learned that he had type 1 diabetes. While treating his other injuries, physicians quickly began monitoring Koretsky's blood sugar level. The RFID chip, which was manufactured by VeriChip (Delray Beach, FL, USA), might have saved his life. "I was unable to communicate, but the chip talked for me," Koretsky said. "I couldn't lose the chip, like I could a MedicAlert® bracelet. The VeriChip™ was a home run."

RFID chips are increasingly exploited in healthcare, but not always under such dramatic circumstances. They are being used, for example, to address the emerging threats of diversion, theft and counterfeit of medications—from commonly used drugs, such as statins, to narcotics that are resold on the street. However, while politicians and government agencies consider their use in healthcare settings, privacy and consumer advocates worry about the safety and the possible abuse of RFID technology.

As prices for RFID chips and readers have fallen, the technology has been taken up commercially, especially by retail giants such as Wal-Mart in the USA, Tesco and Marks & Spencer in the UK, and Metro in Germany, which use them to track their inventory from suppliers, through their warehouses and into stores. The US Department of Defense is also a big fan, using RFID technology to identify food, munitions and other items inside the containers that it ships all over the world. The healthcare industry is looking to RFID

not only to manage their supply chain, but also to prevent infants from being switched in hospital nurseries, to track Alzheimer's sufferers and to link patients to their medical records. Robert Cornick, Vice President of Zebra Technologies (Vernon Hills, IL, USA), the leading manufacturer of systems to print RFID tags, said, "Healthcare is an emerging market for RFID. It is expected to become a very close number two after retail." IDTechEx, a market research firm in Cambridge, UK, estimates that the market for RFID systems in healthcare will rise from US\$90 million in 2006 to US\$2.1 billion in 2016.

Although most RFID applications have garnered little criticism, VeriChip's efforts to implant humans with chips have been highly debated. VeriChip and its parent company Applied Digital have been developing implantable RFID chips for the past 15 years, primarily to tag livestock and pets. The company began marketing its technology for humans after the US Food and

Drug Administration (FDA; Rockville, MD) approved its VeriMed™ RFID system as a medical device in 2004. About 200 people in the USA now carry the chip, which contains a 16-digit identifier linked to their individual medical record in a central database. According to Kevin McLaughlin, President of VeriChip, "We are in our first roll-out phase here in the USA. We will get to Europe eventually, probably within three years."

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The chips, which measure 12 mm by 2.1 mm, are treated with a chemical before implantation to discourage their migration within the body. The procedure costs US\$200–400 and recipients must pay an annual fee to maintain their records on VeriChip's password-protected online database. According to McLaughlin, the company charges US\$20 a year for a basic record, and US\$80 a year for a complete personal health record. "What [VeriChip is] offering now is a patient health record that could save somebody's life in an emergency situation," McLaughlin said. "There are 45 million at-risk patients in the US today. These are people with diabetes, cancer, coronary heart disease, stroke, chronic obstructive pulmonary disease, cognitive impairments, seizure disorders and Alzheimer's, and people with complex medical device implants, such as pacemakers, stents, joint replacements and organ transplants. There are just so many in the group that could wind up in an emergency room, unconscious and unable to communicate for themselves."

McLaughlin added that the chips could serve various purposes, such as linking to credit cards or controlling access, as does his own implant through his office door. After Hurricane Katrina, a Mississippi coroner tagged 300 corpses with donated microchips to help with the identification process. VeriChip has also been in talks with the US Department of Defense about

using its chips to replace soldiers' dog tags, and has recommended tagging guest workers as part of an effort to resolve the USA's illegal immigrant problem.

However, civil libertarians, consumer advocates and other critics are not so keen. "[T]ake a look at the terms and conditions that one must sign off on when one consents to the VeriChip process, to begin with. What you'll see is that VeriChip excludes itself from any liability with respect to the database, both in terms of it being hacked, its security, but also in terms of the accuracy of the information," commented Ian Kerr, a law professor at the University of Ottawa, Canada. Kerr heads the On the Identity Trail project, which focuses on the impact of information and authentication technologies on identity, and the right to be anonymous. "In my view, it seems to be a solution in search of a problem. It's not really an electronic healthcare record. It's only a technological link to it. It only provides a number and certainly that can be done with less invasive and less threatening and much smarter technologies than what it currently utilizes."

Similarly, Ann Cavoukian, Information and Privacy Commissioner for Ontario, Canada, who recently announced guidelines for RFID chips (Cavoukian, 2006), urges people to consider carefully the implications of RFID implants while technical and legal problems persist. "The routine use of the subdermal chips is premature," she said. "Ten years from now, you might want to have your RFID chip extracted." She expects that, on the basis of their countries' strong privacy traditions, Europeans and Canadians will be more resistant to being tagged than Americans. "I think the States are a little bit more open to considering the possibilities," she said. However, even in the USA, not everyone is convinced; in May 2006, Governor Jim Doyle of Wisconsin signed a state law to prohibit the implantation of RFID chips into people without their consent.

The European Union (EU) has also begun to look at the medical, legal and ethical aspects of RFID technology. The European Group on Ethics in Science and New Technologies (EGE; Brussels, Belgium) presented a report in March 2005 that examined a range of information and communications technology (ICT) implants,

from cardiac pacemakers to brain implants and subcutaneous identification chips (EGE, 2005a). In a memorandum accompanying the release of the report, the EGE stated that "...although particular ICT implants may be used to repair deficient bodily capabilities, others are ethically more problematic, particularly if such devices are accessible via digital networks. ICT implants, due to their network capability could be misused in several ways for all kinds of social surveillance or manipulation" (EGE, 2005b).

Citing an FDA report that the VeriChip might cause a range of adverse reactions, technical failures and compromised information security, the EGE report states that "One might wonder that the tests on the VeriChip were authorised for medical purposes in the face of such a detailed list of potential risks," and raises concerns about ICT devices threatening human dignity and the integrity of the human body. Calling for legislative initiatives, the report summarizes: "Currently, non-medical ICT implants in the human body are not explicitly covered by existing legislation, particularly in terms of privacy and data protection. [...] In the EGE's view, implantable devices for medical purposes should be regulated in the same way as drugs..." (EGE, 2005a).

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However, Richard Seelig, VeriChip's Vice President for medical applications, said that it is routine to list potential risks when applying for FDA approval. "Many of the items listed are typical of any implanted medical device [and] are potential risks or adverse outcomes of the VeriMed system," he said. "The fact of the matter is that VeriMed met the established FDA medical device category requirements and was therefore granted clearance to go to market." McLaughlin also dismissed concerns about chipping being dehumanizing. "This is just another means of identification, a foolproof way of identification," he said. "I'm not suggesting it should be mandatory. [...] If you think this is something that can save your life, then this may be something for you. It's up to individuals themselves."

A less contested application is the use of RFID chips to control the fate of prescription medications, to prevent diversion, theft and fraud. According to Cornick, 2% of key medications in the USA are counterfeit. "In some territories in Asia, as much as 25% is counterfeit," he added. Tagging medications would allow manufacturers, repackagers, distributors and pharmacists to track their drugs, particularly as some medicines change hands as many as ten times between the manufacturer and the pharmacy.

Since 1987, the FDA has struggled to implement the Prescription Drug Marketing Act (PDMA), which requires a 'pedigree' document to prove each sale through the wholesale and retail channels. In June 2006, the FDA finally concluded that the time for electronic pedigrees (or e-pedigrees) had arrived, with a major emphasis on RFID technology. "We continue to believe that RFID is the most promising technology for implementing electronic track and trace in the drug supply chain and that stakeholders should move quickly to implement this technology," the FDA stated (FDA, 2006). The FDA plans to focus initially on the products that are most susceptible to counterfeiting and diversion, including cholesterol-lowering statins, Viagra®, several acquired immune-deficiency syndrome (AIDS) medications, immunizing agents, the hormone Lupron®, the anti-nausea drug Zofran® and anti-anaemia drugs. Still, concerns about costs and questions over the advantages of an e-pedigree have led some manufacturers and distributors to resist this move. While praising the RFID pilot schemes run by a handful of manufacturers, the FDA said it would soon publish final guidelines on compliance policy and would begin enforcing the PDMA on 1 December 2006, with a view towards widespread use of the e-pedigree during 2007.

A contentious issue is whether RFID tags should be deactivated after the product has been purchased

So far, only three major drug companies have used RFID to tag select drugs for distribution within the USA: Purdue Pharma LP (Stamford, CT, USA) tags its pain reliever OxyContin®, which is a

controlled substance that has been the subject of abuse, theft and diversion; Pfizer (New York, NY, USA) now tags Viagra, which is often targeted by counterfeiters; and GlaxoSmithKline (Middlesex, UK) tags its human immunodeficiency virus (HIV) medication Trizivir®. "This is one more step toward safeguarding Americans' supply of medicine," said Mark Shaefer, Vice President of GlaxoSmithKline's HIV Infectious Disease Medicine Development Center (Research Triangle Park, NC, USA). "The hope is that RFID tags can tighten the supply chain even further to help assure patients that the medicine they buy is indeed the medicine their doctor has prescribed."

A contentious issue is whether RFID tags should be deactivated after the product has been purchased. Proponents contend that an activated tag could aid with recalls and in other ways. For example, Accenture, a global management consulting company, has developed a prototype 'online medicine cabinet' that helps individuals to take the correct medication at the right time; a built-in camera identifies the patient, and prescription drugs are tagged with RFID chips. Cornick also said that Zebra Technology's chips can be linked with a voice synthesizer to read prescription labels to visually impaired patients.

However, leaving active chips on medications and other products worries privacy advocates. "RFID-tracking of prescriptions in warehouses and back rooms is fine, provided the radio waves don't affect the efficacy of the medicines themselves," said Liz McIntyre, co-author of *Spychips: How Major Corporations and Government Plan to Track Your Every Move with RFID*. "We draw the line where RFID tags are placed on individual items that consumers buy, wear, carry and interact with. [...] Since RFID tags contain unique identification numbers, they can be used to track us as we move about, and to allow third parties to monitor our behaviour and preferences whenever we are in range of reader devices." McIntyre added that RFID chips could help with drug recalls, but warned that the technology is not foolproof. "Relying on RFID alone to ensure the purity of the pharmaceutical supply chain would be foolhardy."

In Europe, industry and government interest in adopting RFID technology has

been lukewarm, but the European Commission (EC) is moving ahead with healthcare applications. The EC held a public debate in 2006 to smooth the introduction of the technology, so that Europe will receive "maximum possible economic and social benefit", according to Martin Selmayr, a spokesman for the EC Directorate General Communication. The first report is expected in October 2006, with policy recommendations for the European Parliament scheduled for December 2006.

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Until now, European countries have handled anti-counterfeiting efforts independently. "Most available data show that it is not yet a large problem in the EU member states. And few European countries have introduced traceability solutions enhancing authentication and/or serializing product packaging," Selmayr said. "However, the solutions defined so far are not compatible among different member states, leading to additional costs for pharmaceutical companies." A panel held as part of an extensive public consultation on RFID policy concluded that drug authentication services are useful, and should be used with or without RFID.

Selmayr also noted that the panel advocated compatibility across Europe to minimize costs to pharmaceutical companies. He added, "On the role of RFID in this authentication service, the opinion was much less clear. Most speakers found the technology too expensive and even not mature enough. Therefore the industry seemed to prefer technology-neutral solutions [RFID alongside other possibilities, such as two-dimensional and linear bar codes]."

In July 2006, the EU announced that it has earmarked €7.5 million from the Sixth Framework Programme for Research and Technological Development to develop RFID in a range of industries, including healthcare. John Jenkins, Project Manager of the Healthcare Initiative, said the project will look at a mixed approach, combining RFID, linear barcodes and

two-dimensional data matrices for a pharmaceutical pedigree. He added that the pharmaceutical industry in Europe feels that RFID "is not sufficiently mature, is less robust and costs more" than other approaches. By itself, he said, RFID is not a panacea, but should be used where it fits best.

Despite the controversy, RFID technology has great potential. "In the context of healthcare, there are enormous gains to be had by increasing patient safety, and certifying the pedigree of pharmaceutical products as they move from the manufacturer to the final user," Cavoukian said. "RFID technology is not a negative, by any means. It all depends on its application."

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Howard Wolinsky

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the conclusion that a product is hazardous and provides little or no benefits, the agency or the EC might ban it for specific or all uses, impose additional safety measures, or give the producer a deadline to substitute the product with a safer alternative. REACH therefore reverses the current procedure—in which regulatory agencies must demonstrate that a specific chemical is hazardous before imposing a ban—and instead places the burden of proof on industry.

Furthermore, REACH will be the first law to require such information on all chemicals that are currently produced and used in the EU—about 100,000 substances overall. Although exceptions exist for synthetic intermediates, medications and substances that are produced in quantities of less than one tonne per year, REACH will still affect about 30,000 products. Less than one percent of these have been thoroughly tested for adverse effects to date, according to David Santillo, senior scientist at Greenpeace Research Laboratories, based at the University of Exeter, UK. For Edward Calabrese, Professor of Toxicology at the University of Massachusetts (Boston, USA), this is not surprising. "Society has not been able to [test all chemicals]. They have done that on the drug side but they haven't done that on the commercial chemicals side. It's kind of a mess," he said.

The first version of REACH was heralded by environmentalist and consumer protection groups, because it meant that industry was obliged to provide information on the safety of many chemicals in daily use. The European Parliament (EP) further strengthened the requirements for the risk assessment and expanded regulatory agencies' ability to ban substances with negative effects. However, the chemical industry, both within and outside Europe, maintain that the costs of providing extended safety data on all chemicals will hamper their international competitiveness. They have also criticized the procedure to ban or substitute a hazardous substance as being too strict. After intense lobbying from all sides, the EC presented its final proposal in October 2003. It now awaits ratification by the EP and the Council of Europe and, if both agree, will go into force in April 2007. It is not yet clear whether the text will undergo an additional round of negotiation; while the Council has taken a more industry-friendly position, the EP still calls for stricter requirements for authorization and substitution.

The costs of REACH

REACH is largely welcomed, but the requirement to test existing chemicals for adverse effects is not good news for all

Early next year, the European Union (EU) plans to implement a major piece of legislation—about 1,200 pages in its current form—to replace 40 different laws regulating the use of chemicals across the member states. When the European Commission (EC) presented its first draft in May 2003 (EC, 2003), it immediately drew huge attention because of its far-reaching consequences, not only economic but also on human health and the environment. If passed, the REACH legislation will require the chemical industry to provide information on the potential negative effects—most of which are still unknown—of a vast number of chemicals used throughout the EU. Not surprisingly, this has met with criticism from all quarters. The costs of obtaining this information, and the subsequent effects on the European chemical industry, are hotly disputed.

REACH dictates new rules on the Registration, Evaluation and Authorisation of Chemicals. It requires manufacturers and downstream users of chemicals to register their substances—if they are sold in the EU as isolated compounds or in preparations—either with a national regulatory authority or

a central European Chemical Agency, which the EC plans to establish next year in Helsinki, Finland. Companies are required to submit a registration dossier for each product, listing possible adverse effects on human health or the environment.

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REACH also requires additional authorization for substances that the EC considers of "very high concern": chemicals that are carcinogenic, mutagenic or toxic to the reproductive system; endocrine disruptors; or persistent, bioaccumulative and toxic substances. Producers or downstream users must perform a risk assessment to ascertain whether their product creates risks to human health or the environment, which social benefits it provides, and whether safer alternatives are available. If, on the basis of this assessment, a regulatory agency reaches