A Survey of RFID in the Medical Industry

With Emphasis on Applications to Surgery and Surgical Devices

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Contents

1. Purpose

This report is prepared for submission as the final project in MAE 188, to Dr. Rajit Gadh at UCLA. This report seeks to address the following topic:

> RFID in healthcare – RFID in healthcare is being used increasingly for monitoring patients, medications, supplies, etc. The state of the art in RFID as used in healthcare will be studied. The technologies, applications, standards and benefits will be investigated. A given application will be selected and evaluated in detail.

2. Introduction

According to the Institute of Medicine, as many as 98,000 people die annually in United States hospitals due to medical errors [1]. In addition to the alarming cost in human lives, preventable medical errors have been estimated to have a total cost to society (in terms of additional care necessitated by the errors, lost income, disability, etc.) of up to $29 billion per year [1]. In order to improve public health and safety, healthcare providers must explore any means possible to reduce these alarming statistics. One extremely promising approach to improving safety, quality, and the overall value of health care is the implementation of Radio Frequency Identification (RFID) technologies to address a wide array of issues facing the medical industry.

To date, most applications of RFID technologies in hospital settings are small-scale trials [2]. As this is the case, there are currently no universal standard RFID products or practices used by the medical industry. For this reason, it is difficult to formulate general conclusions about what types of technologies are used for any particular application; at this point, individual healthcare providers are exploring options and attempting to determine which products and techniques are most effective for medical applications. This report is not an exhaustive examination of every case of RFID usage in the medical industry. In the report that follows, I will detail many of the technologies available as well as some of the cases of current implementation of RFID technology in the medical industry.

According to IDTechEx, a consulting company that specializes in RFID technologies and applications, healthcare RFID was a $90 million industry in 2006 [3]. IDTechEx projects that expenditures for RFID in the healthcare industry will grow to $2.1 billion by 2016. According to an IDTechEx study of over 2000 cases of RFID implementation in all fields, medical applications of RFID make up 8% of all uses of RFID [3]. IDTechEx examined each of these cases of RFID in the medical field and determined that RFID has been applied in the following ways:

Application	**Proportion of Medical RFID Cases**	**Comment**
People Tagging	26%	Mainly patients for error prevention followed by staff for location/alarm
Assets	16%	Mainly fixed assets and valuable consumables for preventing theft and misplacement and for rapid location
Pharmaceuticals	13%	Anti-counterfeiting, error prevention
Blood	4%	Error prevention mainly
Other	41%	Cards, key fobs, pendants and badges for secure access, health records and payment. Supply chain management (pallets, cases and vehicles)

Source: [4]

Although IDTechEx considered pharmaceutical applications as part of the healthcare RFID category, convention in the RFID industry is to consider pharmaceuticals as a separate category. For this reason, pharmaceutical applications will not be considered in this report. The subsequent sections of this report will explore several of the applications described in the above table—particularly patient verification, tracking (both people and assets), and supply chain. After exploring the major applications of RFID in the medical field, this report will focus on a very small niche of RFID use in the medical field: surgery and surgical (implantable) devices.

3. RFID in the Medical Industry

3.1 Patient Verification

Common experience tells us that the vast majority of hospitals use visual inspection of printed wristbands as the primary means of patient identification or verification inside a hospital. This is a slow and inaccurate identification method. Two competing technologies are now vying to improve the errors associated with this process: barcodes and RFID [5]. Presently, roughly 5% of American hospitals have begun identifying patients using barcodes on wristbands, and far fewer hospitals have begun using RFID-enabled wristbands for patient identification [5]. Barcodes are currently more common than RFID in identification bracelets because barcodes are generally more well-known (as they are more common in everyday life) and less expensive than RFID. In many ways, the capabilities of barcodes and RFID pertaining to identification are identical. For instance, either a barcode or an RFID tag can be queried to obtain a unique number, which can then be used by authorized staff to access a patient's computerized profile (perhaps including a photograph along with pertinent medical record information). Barcodes are less reliable than RFID, however, because barcodes are susceptible to wrinkling, tearing, and wetting [6]. Additionally, unlike RFID tags, barcodes require line-of-site for readability. This is not always an option. For example, while prepping a patient for some types of surgery, the site is sterilized and the patient is wrapped in a drape to maintain the sterility. Lifting this drape to scan a barcode on a bracelet would destroy the sterile field, which is not allowed [5].

Chang-Gung Memorial Hospital (CGMH) in Taipei, Taiwan, has begun using passive HF RFID to identify surgical patients [7]. The 13.56 MHz tags used in this application are embedded in plastic wristbands manufactured by Precision Dynamics Corp., and are compliant withhttp://www.iso.org/iso/en/ISOOnline.frontpage ISO standard 15693 [7]. Surgical patients are issued a wristband upon arrival. A nurse scans the wristband to capture the patient's arrival, and then the wristband is scanned several subsequent times at key points before, during and after the operation. For verification purposes, the software records the time of each scan as well as identification of the doctor or nurse that performed the scan [8]. All scans are performed using Hewlett-Packard iPAQ PDAs, which are equipped with RFID interrogators [8].

Although the manufacturers of many patient verification RFID tags choose to store only an ID number on the tag which is then used to access a secure remote database, this particular tag actually has patient identification information written to the tag. As a security precaution, only readers in the possession of authorized personnel have access to the password-protected information on the wristband [8]. Although the data may potentially be accessed from the tag by an unscrupulous third party, this wristband is still far more secure than the visual wristbands it replaces. With visual wristbands, patient identification is printed directly onto the bracelet which can be viewed by anyone in the patient's vicinity. Since implementing this technology, Chang-Gung Memorial Hospital has saved an average of 4.3 minutes per patient in performing patient verification and identification procedures, and patient identification has been 100% accurate [7]. Although 4.3 minutes may seem like a small amount of time, this time savings multiplied by hundreds of daily patients can bring dramatic savings and better healthcare.

3.2 Tracking Staff, Patients and Assets

Despite the level of technology that is ubiquitous in everyday life today, tracking staff, patients, charts, and medical equipment within hospitals and other health care facilities is mostly done through a combination of hand written information on white boards and manual entry within the hospital's information system [9]. This current system places an undue burden on nursing staff and is prone to human error. Although these errors likely do not contribute to the accidental deaths discussed in this report's introduction, these errors certainly do damage a hospital's bottom line. Below I have summarized some of the reasons why tracking is essential in a hospital setting, and I will ultimately demonstrate that RFID technology currently exists that can relieve the staffing burden, cost, and errors associated with manual recording of tracking information.

3.2.1 The Need for Tracking within Hospitals

There are several compelling reasons to use RFID technology to track doctors, nurses and patients inside hospitals. By tracking doctors on a real time basis, a hospital can ensure that there is always a sufficient number of doctors in any given area of a hospital to take care of potential emergencies. Although there are usually far more nurses than doctors and the above justification does not likely apply to nurses, it is still equally justifiable to track nurses. A primary need for this information is in the event of an infectious disease outbreak. For instance, RFID tracking of healthcare personnel became an important tool in fighting the outbreak of SARS in eastern Asia in 2003 [2]. In hospitals in which all staff was tracked using RFID, all staff members who came into close contact with a SARS patient were able to be quickly identified and appropriately treated [2].

Privacy concerns may potentially make it more difficult to justify using RFID to track patients, but there can certainly be some very real benefits to such tracking. For instance, if every patient in a hospital wears an RFID tag, his/her medical records can be placed in a central database which could be accessed by any authorized doctor or nurse. Additionally, a hospital that tags its patients could be alerted if a patient wanders into a potentially dangerous area. Furthermore, RFID tagging of patients could ensure that elderly patients do not wander away from a facility and that infants are not removed from a hospital without authorization.

In addition to the benefits of tracking people within hospitals, it may be extremely useful to track equipment. Theft of equipment and supplies costs U.S. hospitals an incredible $3.9 billion annually [10]. If each of these pieces of equipment is equipped with an RFID tag as part of a hospital-wide real-time tracking system, hospitals would benefit in two ways. Not only can theft be reduced or eliminated, but these critical objects could be easily located in times of emergencies.

3.2.2 Tracking: Technology and Cases

RFID-enabled systems used for tracking people and assets are known as Real Time Locating Systems (RTLS). RTLS systems consist of active RFID tags placed on the people or assets to be tracked, a network of RFID interrogators, and a communications system that allows the interrogators to talk to a server where transmissions from the tag can be interpreted to determine tag location. Below I explore several cases of implementation of RTLS systems in hospitals.

In 2003, 3 Virginia hospitals operated by Bon Secours Richmond Health System awarded a 5-year, $3.9 million contract to Agility Healthcare Solutions to design and implement an RFID-based RTLS system to track more than 10,000 pieces of equipment [10]. The hardware involved was active 303 Mhz tags and hundreds of readers deployed throughout the 3 hospitals—each with Wi-Fi capabilities to connect to the hospitals' existing networks. This connection allowed the tags to be located in real time using the central inventory management software system, Agility's proprietary AgileTrac Enterprise [10]. This system has successfully allowed Bon Secours to track inventory and operate with optimal levels of equipment on hand. The hospital saw a net savings of $3 million over the first 3 years after implementation [11].

As was mentioned in section 4.1, some countries in eastern Asia have implemented RTLS systems to help combat SARS and other infectious diseases. Taipai Medical University Hospital (TMUH) is one hospital that had particular success using an RFID system to combat SARS [2]. In order to identify patients who were potentially afflicted with SARS, TMUH used active tags with embedded thermometers (because fever is a strong indicator of SARS). The TMUH system was the first RTLS system to combine location tracking with real time patient symptom tracking [2]. Data was filtered according to pre-set rules before being transmitted and stored. The system automatically retrieved patient medical records and analyzed information to judge whether there was a likely infectious event. When the system detected an infectious event, a message to that effect was dispatched immediately to medical personnel via alarm, email, and short message services [2]. This allowed for immediate treatment and/or quarantine of affected patients and medical staff. This system worked precisely as planned, and it was deemed an overwhelming success by the hospital's management [2].

3.3 RTLS meets Patient Verification

Exavera Technologies, another RFID-enabled RTLS enterprise solutions provider, has developed a system known as eShepherd. Similar to the AgileTrac system described above, eShepherd merges RFID technology with readers that are able to connect to existing Wi-Fi networks. By placing 433 MHz active tags on patient bracelets, staff ID badges, and hospital equipment, Exavera claims that an average-sized hospital can save nearly $4 million annually with an initial investment of only $400,000 to cover the equipment and installation [10]. Exavera's systems include middleware to link in to a hospital's electronic health records system. Doctors wearing RFID-tagged badges will carry PDAs that will allow access to a patient's record whenever the doctor is in the patient's vicinity. This will ensure that patients get the correct treatment, reduce medical errors, and increase efficiency because doctors do not have to go to a central area to retrieve the patient's paper chart. Exavera's system is currently being tested in two hospitals, and specific outcomes of these tests are yet to be determined [10].

3.4 Supply Chain

As will be explained below, the supply chains associated with medical products are extremely complicated. RFID is slowly creeping in to the medical supply chain in suppliers' distribution centers and in hospitals. In the subsequent paragraphs I will explore some ways in which RFID has been implemented into medical product supply chains. Because the emphasis in the latter half of this report pertains to surgical devices, I have selected a distributor of orthopedic implants for the following case study.

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3.4.1 Medical Device Manufacturer's Distribution Center

Because people come in all shapes and sizes, medical implants and other surgical devices must also come in all shapes and sizes. Before a surgeon actually cuts a patient open, it is impossible to know precisely what size the necessary implant must be for that particular patient. For this reason, the supplier of the medical devices needed for that surgery must ship a variety of devices in a wide range of sizes. Most of these devices will not be used in a particular operation, and they are then returned from the hospital to the supplier's distribution center. For some orthopedic implants, for example, each surgery kit contains around 100 parts, and multiple kits of various sizes must be sent for each surgery [12]. When the kits are returned to the distribution center, there are several hundred parts that must then be counted and inventoried. This is a very tedious, time consuming, and error-prone manual process.

Medical device manufacturers that do not currently utilize RFID technology are forced to attempt to manage the complicated supply chain described above by scanning barcodes on each and every part as it leaves the distribution center and when it returns back after a surgery. This requires staff to scan several hundred barcodes before and after every single surgery. This leads to a bottleneck, and devices required for emergency surgery often cannot be scanned as they leave distribution centers, making it nearly impossible to track these devices [12].

In 2006, orthopedic implant manufacturer Biomet began using RFID to identify items included in its knee implant kits. Passive 13.56 MHz tags are placed on the plastic packaging surrounding each part, not on the actual part that is implanted into a patient [12]. Biomet placed interrogators at critical points throughout their distribution centers in order to ensure that kits are complete before shipping them to hospitals. At the other end of the supply chain, when a partially depleted kit is returned after a surgery, Biomet reads its tags to instantly determine which items have been removed from the kit so that it can quickly and accurately invoice and replenish the kits as needed [12].

Because there are hundreds of tags that need to be read very quickly, most interrogators would have been completely inadequate for this task. In fact, Biomet's initially chose to implement EPC 1 UHF tags which resulted in an extremely low read rate [13]. Accepting that the issue was because they chose poorly, and not because of intrinsic limitations of RFID technology, Biomet resumed their search for RFID solutions. Ultimately, Biomet chose to purchase interrogators from Magellan Technology, which achieved the 100% read rates necessary for this application [13]. Magellan's readers are unique in that they leverage phase-jitter modulation (PJM) technology, which complies with ISO 18000 Part 3 Mode 2 protocol [14]. The use of phase-jitter modulation as the communication method between tags and readers, as opposed to the ASK or Amplitude Modulated transmission used with all other RFID technologies, allows for data transfer rates of up to 424 kbit/s [14]. This, combined with a command structure that allows for 8 independent high-speed reply channels, allows Magellan's system to be 10-times faster and more robust than other RFID systems, according to the manufacturer [14].

3.4.2 Smart Cabinets

RFID-enabled solutions to manage supply chains are also useful after products enter inventory at a hospital. RFID smart cabinets create real-time visibility of the tagged items within them, which enables hospitals to track their inventories of medical devices and other assets [15]. Currently, there are approximately 20 companies that provide smart cabinet solutions in a customized, case-by-case basis. For the most part, these solutions are extremely expensive and are not readily available in production quantities. There are only 3 manufacturers of RFID-enabled smart cabinets that have readily available standard configurations and product literature: Mobile Aspects, TAGSYS RFID, and Terso Solutions, Inc. [15]. The smart shelves sold by each of these companies have been sold between 100 and 400 times, at an average price of about $25,000 [15]. Clearly, RFID-enabled smart cabinets are much more expensive than other cabinets. According to Diane Hage of RFID solutions provider ODIN Technologies, there are three main reasons why hospitals are willing to pay for these products: to ensure patient safety, to improve billing efficiency and inventory management, and to minimize the time-consuming, error-prone manual labor involved in documenting inventory [15].

In order to justify the seemingly high cost of a smart cabinet, the products being stored inside the cabinet must necessitate extremely careful inventory control. Examples of such products are the intravenous contrast solutions used for MRI and CAT scans, manufactured by Bayer HealthCare Pharmaceuticals [16]. Each bottle contains enough contrast solution for approximately 25-30 patients, at a price of $1000 per bottle [16]. These bottles, once opened, must be used the same day due to the atomic decay of the solutions. Therefore, it is extremely costly to mismanage this inventory. Bayer Healthcare Pharmaceuticals, as a service to its customers, partnered with smart cabinet manufacturer Mobile Aspects. The resulting cabinet, called VistaTrak, recently completed pilot trials in two hospitals and is currently seeking FDA certification [16].

Each vial of contrast solution is tagged with a passive 13.56 MHz ISO 15693 chip containing the National Drug Code (NDC) of the solution, as well as the lot number and expiration date [16]. Only hospitals that specifically request the tagged vials will receive them, and other customers will continue to receive bottles without RFID-enabled labels [16]. When the radiologist gains access to the cabinet through RFID verification or by entering a personal identification number on the cabinet's keypad, the cabinet's screen displays a list of patients scheduled for procedures that day. After the radiologist chooses the patient, the patient's dosage recommendation is displayed on the screen. When the radiologist removes a vial from the shelf, the interrogator ceases to receive transmission of that RFID label and instantly sends an alert to the VistaTrak software system indicating that the bottle has been removed. The system then generates an invoice for cost of the dose used. If a bottle is opened and then returned to the cabinet, the system will track the bottle's expiration and alert the next radiologist who opens the cabinet that there is an open bottle available [16].

4. RFID Applications to Surgical Procedures and Devices

The above section concludes my remarks about healthcare RFID in general. The items that follow explore several different current and possible future uses of RFID pertaining to surgery and surgical (implanted) devices, a very small niche within the medical realm. Sections 3.1-3.3 describe RFID enabled products that are currently available for surgical applications. Note that sections 3.4 and 3.5 describe recently patented concepts which have not yet been brought to market, but are currently in active development. These devices represent an exciting possible future for RFID technology pertaining to implanted devices. Discussion of these devices will be brief due to the limited amount of information available. Additionally, it is recognized that these devices are in development and any information discussed herein may change slightly or significantly during the development process.

4.1 Patient and Surgical Site Identification

Despite the best efforts of surgery teams, 5 to 8 wrong-site surgeries occur each month in the United States [17]. In an attempt to combat this alarming fact, the Joint Commission on

Accreditation of Healthcare Organizations (JCAHO) established a universal protocol as part of their national patient safety goal to prevent wrong site, wrong procedure, and wrong person surgery [18]. This standard mandates that the site, procedure, and patient must be accurately identified and actively communicated during a final verification process before the start of any surgery [18]. In response to this initiative, a new technology has been developed.

In November of 2004, the FDA approved SurgiChip, a patented system that uses RFID to assist surgeons in decreasing wrong site and wrong procedure surgery [17]. The SurgiChip is an RFID-enabled "smart" label, which is affixed directly on the site of the planned incision and read as part of the JCAHO mandated final verification process. Once the patient, site, and surgery have been verified, the label is removed from the patient and placed on his/her chart [17]. The names of the patient and the surgeon, description of the surgical site and side (left, right, or bilateral), and the date of the surgery are always encoded on the SurgiChip. If desired, the patient's birth date and medical record number may also be encoded. Much of the same information is written on the visual label, but space constraints may not allow for detailed surgical instructions such as those that can be encoded on the chip [19]. The SurgiChip products utilize Zebra RFID printers/encoders, Feig desktop readers/encoders, Jett DataLogic handheld readers, Texas Instruments "Smart Tag" transponders and SurgiChip's proprietary software programs to coordinate the printers and the readers [20]. The tags are ISO 15693 compliant 13.56 MHz HF tags [21]. The system is password protected and the tag data is encrypted; only readers that know the encryption algorithm can read the data on the tags [18].

JCAHO has approved SurgiChip as a part of the "time out" process, but JCAHO does not endorse SurgiChip as the sole source of patient/site/surgery verification [19]. Other identification must also be utilized, such as marking the physician's initials or the word "YES" on the proper surgical site [18]. Occasionally, these techniques are inadequate and mistakes occur regardless. According to SurgiChip's website, their product is intended as a backup system to help avoid these types of errors. It is not likely that the surgical team will forget to read the SurgiChip tag because it is placed directly on the surgical site. For verification purposes, the RFID reader makes a record of who read the tag and when it was read [19]. Although it is impossible to prove that SurgiChip has actually prevented a surgical error from occurring, it is true that no errors have occurred in surgeries that utilized SurgiChip [17]. The cost of the SurgiChip system depends on how large the system is going to be. The bulk of the cost for this system is software licensing, followed by the purchase of the necessary printers and readers.

For an average sized operating system, the cost amounts to approximately $8 per procedure [17].

4.2 Surgical Sponges

According to a study in the New England Journal of Medicine, surgical sponges are inadvertently left inside of patients in 1 of every 1,000 or 1,500 abdominal surgeries [22]. Manual counting of surgical sponges (as they are placed in the patient and removed) is currently the most common method for keeping track of sponges, but this comes with an enormous cost. Nurses spend between 15 and 30 minutes counting surgical sponges and other instruments during each procedure [23]. When multiplied by the over 10 million procedures performed each year in the U.S., and considered along with the high overhead costs to run operating rooms, it can be determined that the current method for accounting for surgical sponges costs more than $1 billion annually [23]. Because counting is known to be unreliable, x-rays are taken when manual counts do not match. The 1.5 million x-rays taken each year to look for surgical sponges and other retained items cost $375 million. Metal objects show up in these x-rays, but there is a false negative rate of up to 20% for sponges! Further, the cost of litigation of medical malpractice suits pertaining to retained sponges combined with the costs to remove retained objects costs $125 million each year in the U.S. [23]. Clearly there is a very strong financial incentive to establish more effective techniques for keeping track of surgical sponges during operations.

ClearCount, a medical startup which began at Carnegie-Mellon University, has created an FDA-approved, patented product known as the SmartSponge System which uses RFID tags on sponges to ensure that surgical teams do not inadvertently leave tags inside of patients. The two cofounders of ClearCount attempted to create this system using commercially available products from existing RFID tag and reader manufacturers, but ultimately opted to design their own products [24]. The technical specifications of ClearCount's products have not been publicly divulged.

In the early stages of product development, the founders of ClearCount turned to researchers at Stanford University to evaluate economic feasibility and clinical accuracy. Harrison Chow conducted an economic analysis and concluded that "RFID-tagged surgical sponges appear to be economically attractive from society's perspective, as long as this new technology approximately cuts in half the time nurses spend counting sponges in the OR" [24]. After receiving this economic green light, ClearCount contacted Stanford physician and professor Alex Macario who oversaw a clinical trial involving tagged and untagged (control) sponges in 8 volunteer patients during actual surgeries. Dr. Macario published his findings with two coauthors – using the ClearCount system, scanning 8 control sponges and 28 RFID sponges yielded 100% accuracy, 0 false positives and 0 false negatives [25].

4.3 Implantable RFID Tag for Patient Identification

In 2004, the FDA approved a device consisting of a small glass capsule, about the size of a grain of rice, enclosing an RFID tag for human implantation [26]. This tag, manufactured by VeriChip and branded as VeriMed, is the first and only FDA approved implantable tag of its kind [26]. If a patient with a VeriMed implant arrives to a hospital unconscious, unresponsive, or confused, the chip can be interrogated in order to access the patient's identification and other information. VeriChip uses passive 134 kHz (LF) chips compliant with the ISO 11784 and 11785 standards [27]. Each chip is encoded with a unique 16-digit ID number, which is associated with the patient's medical record and other information in a secure online database maintained by VeriChip [27]. The tag contains no information other than the 16-digit number, and the data is encrypted such that the tag can only be read by an official VeriChip interrogator. The VeriMed implant is injected into a patient's upper arm, just below the skin, in a procedure that is essentially identical to getting a shot [28].

VeriChip sells this implant for $149 [27]. With physician's fees, it typically costs a patient between $200 and $300 to have this chip implanted [26]. Beyond the initial cost of implantation, the patient must pay a database maintenance fee to VeriChip for hosting the online medical record database. For an annual fee of $20, the patient's profile can include any or all of the following information (at the patient's discretion) [26]:

- Name
- Phone number and address
- Physician contact information
- Emergency Contact information
- Known allergies
- Advanced directives (living will, power of attorney, health care agent, do-not-resuscitate request, organ/tissue donor card)

For an annual fee of $80, the patient's profile can include all of the above, plus detailed information about the patient's personal health record—medical conditions, medications, medical device implants, previous surgeries, recent hospital admissions, specialty programs, and recent medical tests [26]. If the patient fails to pay the annual fee, the patient's profile will default to basic status and will only include the patient's name, address and photo [26].

As of April 2008, 900 hospitals have partnered with VeriChip and acquired RFID interrogators—yet only 600 people in the United States have been embedded with VeriChip transponders [27]. This is far lower than initial projections, and VeriChip announced in May 2008 that it was exploring various options for eliminating debt and would potentially sell its VeriMed division, or the entire company [29]. Overall, from the time of VeriChip's initial public offering (IPO) in 2007 up to the time of this announcement, VeriChip's stock price had declined roughly 70% [30].

It is quite apparent that the VeriChip implant could *potentially* save lives by allowing access to the medical information of anyone admitted to an emergency room unconscious or otherwise unable to communicate. Why, then, has this device not proven to be commercially successful? Perhaps this is because individuals recognize that there are several factors beyond their control that would render the VeriChip device completely ineffective. For example, the VeriChip devices are rendered ineffective if the chipped patient happens to be admitted to a hospital that does not have VeriChip interrogators. Yet, unless a significant portion of individuals have been chipped, hospitals have little incentive to invest in the hardware and staff training necessary to implement the VeriChip system. Also, unless the VeriChip implant is common enough that there is a good likelihood that any given patient has the implant, it is perhaps ill-advised for hospital staff to routinely scan each and every patient for a VeriChip—more likely than not, this would be a fruitless routine that would do nothing more than waste a few vital seconds in an emergency situation. These factors combine to create a chicken-and-egg dilemma for patients and hospitals. Unfortunately, although both patients and hospitals could benefit from a widespread implementation of the VeriChip system, neither party can unilaterally make the VeriChip implant effective. Hoping to build momentum and slowly diffuse the issues presented above, in April 2008 VeriChip began a 3-month, direct-to-consumer advertising campaign consisting of television and newspaper advertisements in southern Florida [27]. This region is unique because a particularly high percentage of the area's hospitals participate in VeriChip's system; this minimizes the risk that residents of this region will be admitted to a hospital that does not participate. If this campaign proves successful, it will likely serve as a model for the next region that VeriChip systematically chooses for expansion. If this campaign proves unsuccessful, despite targeting a region with such a high number of affiliated hospitals (which minimizes the risks discussed above), the future will look quite bleak for VeriChip.

4.4 RFID-Enabled Implantable Blood-Sugar Sensor

Digital Angel Corp., which manufactures RFID tags for identifying and tracking animals and assets, has been awarded a patent for an implantable RFID-enabled sensor tag that will make it easier for diabetics to monitor their blood sugar levels [31]. This system, if successful, has the potential to relieve diabetics of the pain and inconvenience of having to prick themselves several times a day to check blood-sugar levels. Instead, the 10 to 13 million people in the United States who currently spend an estimated $2 billion per year on glucose measuring strips will be able to pass a scanner over their skin to painlessly and accurately measure their current blood-sugar level [31]. They would then administer insulin, as needed, in the same manner as they do presently.

The tag, being developed in conjuncture with VeriChip, will be similar (perhaps identical) in size, appearance and operation to the VeriMed implant discussed in the previous section. The glass-encased passive RFID tag will have protruding metal filaments, exposed to human tissue when the tag is implanted, that act as transducers to measure and translate glucose levels into electrical conductivity. When an RFID interrogator queries the tag, the RF signal energizes the passive tag's circuitry, which provides the current required for the filaments to determine the blood-glucose level [32].

A significant design concern for this sensor tag is related to the body's natural reaction to foreign objects. Whenever the body senses a foreign object (an implant, for example) scarring occurs to protect the body from possible ill-effects of the foreign object. Scarring around this device can dramatically decrease the transducer filaments' functionality [32]. Scarring is not a major concern for the VeriChip implant because the glass casing protects the circuitry; in this glucose sensor, however, the filaments are in direct contact with body tissue, so the glass provides no protection to the filaments [32]. The engineers working on development of this sensor are seeking to develop a bio-compatible, semi-permeable membrane to surround the entire sensor tag device [33]. This will shield the tag assembly from the body's detrimental effects, yet glucose will be able to pass through the membrane so functionality will not be adversely affected by the presence of the membrane.

Digital Angel has been relatively quiet about the progress of development of this product. According to their most recent press release discussing the implantable glucose sensing microchip, released December 5, 2007, Digital Angel anticipated creating a functioning prototype within 6 months from that date [34]. At the time of this writing, it has been just slightly more than 6 months from the date of that press release and there have been no updates about the status of the prototype.

4.5 Orthopedic Implants with RFID-Enabled Sensors

In March 2008, orthopedic surgeon and inventor Dr. Lee Berger announced that he has successfully developed a prototype of an orthopedic implant that is equipped with RFID-enabled sensors to assess the function of the implanted device and the surrounding tissue [35]. Berger's announcement came on the heels of the approval of his patent for the same device, which was granted in February 2008 [36].

This device uses several different sensors which will be able to sense pressure on the implant—to monitor whether the implant has shifted—as well as chemical balance, temperature and the presence of microorganisms—to track the presence of an infection around the implant [35]. The details of these sensors have not been released, except that they will be powered by passive RFID circuitry. In addition to the RFID-enabled sensors, this implant features an electric stimulator which can generate 20 to 40 microamps of current from the reader's signal [35]. This current passes through the bone near the implant to promote healing. Orthopedic surgeons currently sometimes use electrical bone-growth stimulators to promote healing, but these devices must presently be implanted during a second operation, after the initial operation to implant the orthopedic device [35].

Berger has developed his prototype using passive EPC Gen 2 UHF tags and sensors [35]. Of course, product development is still ongoing, and Berger has said that he is completely willing to explore using different frequencies if the needs of a particular implant necessitate this [35]. This is a good thing, too, because it seems apparent that an HF (or even LF) tag would function much more reliably surrounded by liquid in the human body. Also, it is somewhat curious that

Berger chose to use EPC protocol because ISO is the protocol of choice for all of the medical and surgical applications of RFID studied in preparation for this report.

5. Conclusion

This report has explored many of the current uses of RFID technology in the healthcare field. Specifically, this report examined how RFID is being used for patient verification, tracking people and equipment within hospitals, and managing medical device supply chains. As each of these tasks are currently being accomplished using a wide variety of RFID products, frequencies, and protocols, specific individual cases have been selected for detailed study. Additionally, this report explored several ways in which RFID technologies have been, or are being, adapted for use with surgical procedures and devices.

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