RADIO FREQUENCY IDENTIFICATION (RFID)
IN HEALTHCARE

BENEFITS, LIMITATIONS, RECOMMENDATIONS

A HIBCC White Paper

HEALTH INDUSTRY BUSINESS
COMMUNICATIONS COUNCIL

FOREWORD

This paper was created by individuals representing the global affiliates of the Health Industry Business Communications Council (HIBCC). It is intended to inform the global healthcare industry about the application, benefits and challenges of Radio Frequency Identification (RFID) in healthcare. It also presents basic RFID concepts and discusses existing standards to help the reader develop a reasonable understanding of RFID and its suitability for specific healthcare applications.

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I. INTRODUCTION

Radio Frequency Identification (RFID) is the new breed of Auto-ID technology that promises to deliver the next wave of productivity improvements to supply chain and other processes where tracking of products and assets or identification of people is required.

While RFID technology is being called a "new" technology, in fact, its applications have been in existence for more than a decade in one-chip configurations and even longer in lesser integrated technology. Well-known and proven applications that use radio frequency technology include:

- Security cards used for control of access to buildings and secure areas
- Electronic tolling for roads
- Automatic ticketing systems
- Container and returnable tagging
- Animal identification
- Item identification

RFID has gained more publicity in recent times because of its potential to improve supply chain processes. Contributing to the current wave of interest in RFID are retail industry pilot projects, such as Wal Mart's use of RFID for supply chain improvements. This increased publicity has led to further RFID research and development activity and the introduction of a number of commercially available RFID systems and solutions.

RFID offers more advanced resource and patient tracking capabilities than manual or barcode efforts. In fact, it is already being used by some organizations for select applications. Examples of this include wristbands for patient identification, processes for implantable medical devices, and RFID-enabled sterilization trays. Other applications include those that protect manufacturers from counterfeiting and product tagging for asset management. There are also regulatory pressures by U.S. Food and Drug Administration (FDA) and other agencies to explore RFID and other technologies to help improve patient safety.

To help the healthcare industry implement RFID into its current practice, a solution that uses standards that have already been developed for barcoding processes has been created. Using product identification standards developed by the International Organization for Standardization/ International Eurotechnical Commission (ISO/IEC), this ISO-based solution offers a direct migration path from barcoding to RFID that is practical and easily achieved.

Another organization, EPCglobal, is currently promoting a different approach. It involves replacing the actual item identification with a fee-based, coded serial number, which would be placed on every RFID tag. Important supply chain information would therefore not reside directly on the tag, but instead on databases that would be connected via EPCglobal's proprietary network that mimics the World Wide Web. This approach would require significant investment by supply chain participants for integration fees, hardware and software to make the system work. It does not achieve any benefits over the decentralized ISO-based approach, which relies on the inclusion of this data directly on the tag.

While there are obvious benefits of implementing RFID, assessment of the technology's maturity for widespread adoption in supply chain and asset management processes, as measured by the "Gartner Hype Cycle Curve," is that the interest has probably reached its "Peak of Inflated Expectation." By the end of 2006, the business community will enter the "Trough of Disillusionment," where initial enthusiasm is tempered by practical cost-benefit considerations. This assessment of RFID in relation to the Gartner Hype Cycle is supported by the 2004 paper "Prepare for Disillusionment With RFID."

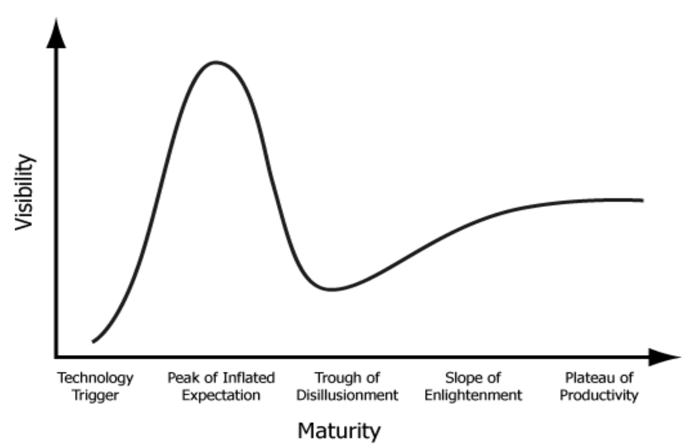


Figure 1 - Gartner Hype Cycle Curve

Implementation of a successful RFID solution requires considerable investment in:

- Systems design, engineering, and physical integration
- Business process redesign and implementation
- IT data management integration

The current technology options have not reached a point of economic viability for widespread adoption at the individual item level for Fast Moving Consumer Goods (FMCG). While there is speculation that the cost of RFID tags will soon drop to $US .05 per tag, this is not achievable in the short term and could not be sustained by major chip manufacturers to generate sound return on investment. At the current price of greater than $US .20 per tag, with many early adopters reporting the cost per tag including handling at $US 1.00, RFID applications cannot be sustained by low-cost, high-volume items in the supply chain.

Manufacturing processes may also need to be modified to include RFID tags on individual items, since it is unlikely in the short term that the tag can simply be embedded in an existing label. This would significantly increase manufacturing costs for basic items, and it is unlikely that savings due to productivity improvements would achieve a return on investment for the supplier or applicator of technology.

Nevertheless, there are some promising short-term applications for RFID, and successful implementation with business benefits is likely where certain conditions are met. For example:

- "Closed-system" applications where productivity and working capital improvements for an individual organization's internal processes can result.
- Specialized, high-cost equipment, where reduced loss and obsolescence may lead to significant financial benefits.
- High-cost items or applications that require a high degree of traceability. These items include medical devices such as pacemakers, defibrillators, and other implanted prostheses.

II. TECHNOLOGY OVERVIEW

Barcode technology relies on optics, and therefore requires "line of sight," meaning that the barcode must be visible to the reader. Conversely, RFID tags can be invisible to the reader because they transmit information on demand using radio waves. A tag consists of a microchip applied to a miniaturized antenna, which carries a "unique tag ID" but can be programmed with other information. RFID offers advantages over barcode technology when:

- Invisible (or no line of sight) reading is required. For example, products within a box can be individually read or located with no line of sight to the reader.
- Multiple items must be read simultaneously.
- Read and write capability is required on the data carrier.

Figure 2 - RFID tag communicates with a mobile reader

RFID is not merely a computer chip and antenna placed on a product, but rather it is an entire infrastructure that requires investment in many components and systems to make it work. This includes hardware, middleware and software components.

A. RFID COMPONENTS

Any RFID system comprises a tag, which holds data about an item; a reader, which will read the data stored on a tag; and software/databases that act on the information.

A reader can be stationary or mobile, simple or smart. It will typically need to be connected to a network, especially within an infrastructure that captures data from different sites. In this scenario, the network of readers will be served by a host server, which will manage all data transfer between the readers and a central database. Depending on the project requirements, the infrastructure can vary, but the principles remain the same.

Figure 3 shows a simplified schematic of a typical multi-reader RFID system infrastructure.

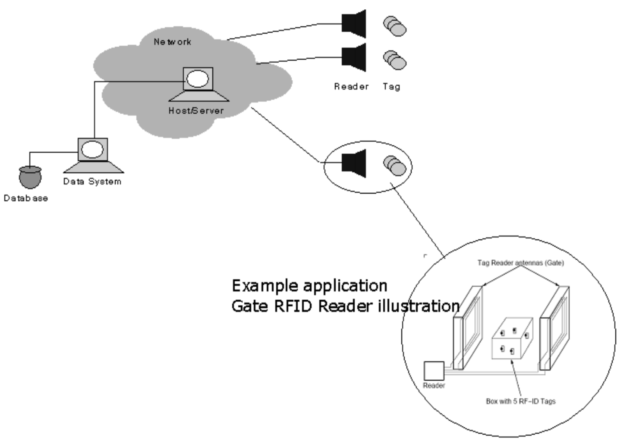


Figure 3 - Schematic of RFID enabled system

Deciding which type of tag to use determines to a large extent the rest of the infrastructure required in an RFID system. Tags can be either passive or active. Active tags include an internal power supply. An example of an active tag is the "e-tag" used in vehicles for automatic toll collection. Passive tags do not contain an internal power source. Their power is derived from the creation of an electromagnetic field by the reader when it is brought in proximity to the tag. This electromagnetic field needs to generate sufficient energy to "power up" the tag, and create the communication channel between the tag and reader.

Because passive tags do not have a power supply, they are generally smaller in size than active tags, and are more suitable for tagging individual items in the supply chain. For this reason, the focus of this paper is geared toward passive tags.

B. PASSIVE TAGS

Typically, passive tags are made up of several components, consisting of an integrated circuit (IC)--or computer chip--as a module, and an antenna, all packaged in a tag casing. Data is stored on the chip, which is physically carried inside the module. The module is responsible for connecting the chip (and data) to the antenna. Tags can also consist of an inlay, on which the antenna is printed and the chip is glued or bonded. The antenna is the interface to the reader and therefore to the outside world. Figure 4 shows a typical tag using a module and an antenna.

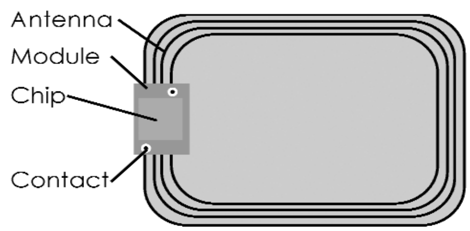


Figure 4 - Illustration of a Typical RFID tag

Tag packages come in a number of styles, which vary depending upon the tag's intended use. These include round tags, which come in different sizes, as well as tags in tubes or cylindrical packages made out of glass or ceramic. Tag configurations can vary, so different tags may respond in different ways--or not at all-to readers. In fact, it is reasonable to assume that every tag will be different in its response to a given reader. As the tag size and shape change, so does its resonance to the reader. Therefore, tag/reader configuration may require some tuning.

This is not the only condition where retuning needs to occur. Changes in the field between reader and tag can occur due to environmental conditions. The functionality of the system may show performance within a field that differs from any "laboratory trial."

Most passive tags signal by backscattering the carrier signal from the reader. This means that the reader has to be designed to both collect power from the incoming signal and also to transmit the outbound backscatter signal. The response of a passive RFID tag is not just an identification number. The tag chip contains nonvolatile Electrically Erasable Programmable Read-Only Memory (EEPROM) for storing data. Lack of an onboard power supply means that the device can be quite small: commercially available products exist that are the size of a grain of rice. Passive tags have practical read distances ranging from about .3 inch up to about 3 feet. Due to their simplicity in design they are also suitable for manufacture with a printing process.

The other variable with tag design is with the chip, which holds the data. Typically, low-capacity chips can store up to 128 bits of data, enough for the item's product code or serial number. For most supply chain applications, this amount of data is sufficient, since additional product information is contained within organization databases. Since this product information is available through the organization only, data between sellers and buyers needs to be synchronized so that both parties are using consistent identifiers.

High-capacity chips can store up to several hundred bytes, and would be used in applications that require all product data to be written to the tag. For example, specimen containers sent to a pathology lab may include detailed patient information, which can be written to the tags.

C. ACTIVE TAGS

Active RFID tags have an internal source used to power ICs and generate the outgoing signal. They may have longer range and larger memories than passive tags. At present, the smallest active tags are about the size of a coin. They have read ranges of 30 feet or more, and a battery life of up to 10 years.

Active tags are not adequate for tracking single items of lower value and generally can not be used in an autoclave. Active tags are beneficial where intelligent features are required such as data logging by help of integrated sensors for temperature and pressure.

D. COMMON RFID FREQUENCIES FOR SUPPLY CHAIN AND ASSET MANAGEMENT

The frequency and parameters at which a chip communicates with a reader are also variables that are considered in overall chip and tag design. This is referred to as the air interface. The ISO/IEC 18000, Information technology - Radio frequency identification for item management defines the parameters for different frequencies. The common frequencies defined by these standards for item management are:

- Parameters for air interface communications below 135kHz (LF) ISO/IEC 18000-2 applies for small devices and low distance reading.
- Parameters for air interface communications at 13.56MHz (HF) ISO/IEC 18000-3 applies for products, wristbands and containers as a universal frequency.
- Parameters for air interface communications at 2.45GHz (Microwave) ISO/IEC 18000-4. Microwave is not typical for healthcare applications.
- Parameters for air interface communications at 860MHz to 960MHz (UHF) ISO/IEC18000-6 applies for long distance reading, as it would be used in transportation.
- Parameters for air interface communications below 433MHz ISO/IEC 18000-7 does not yet apply to healthcare applications. They are used primarily for freight containers.

Since every frequency has different physical features, not every air interface is practical for the whole range of applications that may apply in asset management and supply chains. For example, Ultra High Frequency (UHF) is extremely sensitive to water and high humidity, which absorbs higher frequencies. Conversely, High Frequency (HF) is less sensitive in these environments. However, UHF offers a much greater reading distance, if the conditions are properly set. The HIBCC joint committee for product packing and containers has established the following frequencies for typical RFID applications.

- Product tagging: HF 13,56 MHz (or LF <135KHz under mutual agreement)
- Product packaging: HF 13,56MHz (or UHF, under mutual agreement)
- Transport Labeling: UHF 860-960MHz (or HF 13,56 MHz, under mutual agreement)

E. UNDERSTANDING RFID IN THE CONTEXT OF ENTERPRISE INFORMATION MANAGEMENT

RFID is merely one component of an enterprise-wide system. It needs to work in harmony with other systems within the enterprise, specifically within the Information and Communications Technology (ICT) infrastructure. It does not replace any of the existing systems, but it may improve the performance and productivity of the entire system.

Figure 5 illustrates a typical hospital's ICT infrastructure. This diagram helps put RFID in the context of the entire system.

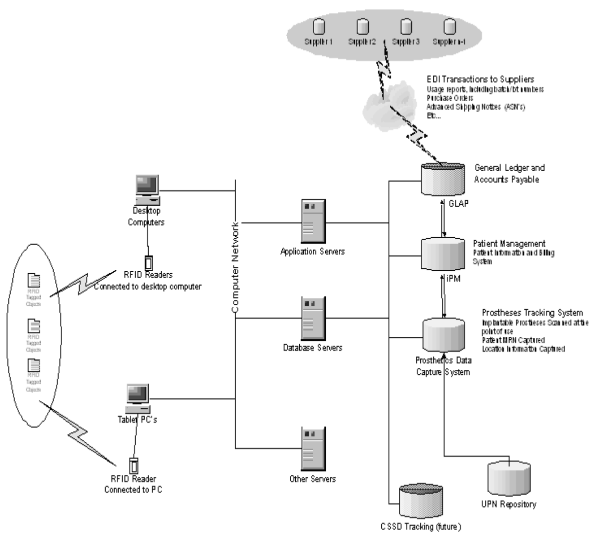


Figure 5 -Enterprise Systems Architecture Example

F. SOFTWARE AND MIDDLEWARE

Typically, an RFID enabled system will require middleware to enable its function with the organization's enterprise of systems. The role of RFID middleware is to serve as the interface between software for the reader and applications within the organization that use the data received from transactions with RFID tags.

The reader software interprets the signals from the chip within the RFID tag, and translates them into a data string. For example, the product identification may be the data string that resides on the chip, and this data is interpreted by the software.

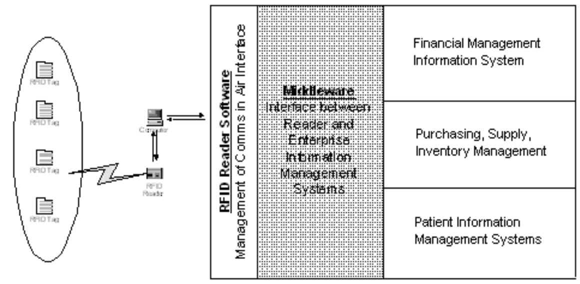


Figure 6 - Illustration of the role of middleware in the interface between RFID readers and enterprise applications

Tag reading needs to be organized in a meaningful way in order to make it practical. Middleware applications organize the reading of many tags and pass information to the organization's information management systems in a sequential way to prevent "collision" from occurring. There may also be applications that require communication from the information management systems back to the tag. This can happen when an item has been used or consumed, and data to indicate the consumption of the item needs to be written to the tag. In this instance, the middleware would need to have a bi-directional interface.

G. INTEROPERABILITY BETWEEN RFID TECHNOLOGIES

RFID technologies have been largely advanced by technology companies, which means that their intellectual property is protected by patents. There has been some attempt to standardize, particularly in air interface protocols. But this still does not always make chips developed by different companies interoperable.

Interoperability across frequencies is also complicated. Some vendors claim to have developed readers that can read multiple frequencies. These readers are programmed to interrogate through all standard frequencies and protocols until a "handshake" with the tag is achieved. However, this type of reader is slow, and would be problematic in situations where multiple tags need to be read simultaneously.

Other variables that present difficulties for interoperability are size, shape and design of the tag antenna. Readers need to be tuned to a specific tag design and in genaral do not easily accommodate design variations. Therefore, in open systems where there may be a variety of frequencies, protocols, and tag antenna design, interoperability is extremely complicated.

EPCglobal is attempting to standardize the frequency, protocols and tag design for consumable products for use in its system. Due to pressure from chip manufacturers, this approach is also being merged into the ISO/IEC regulatory framework. But trials to date have been performed only for pallet-level tracking to warehouses and distribution centers. Applying this approach for single items, particularly medical products, will be difficult because:

- Products of different sizes will require different tag antenna designs.
- Products made of or packaged in metal can cause interference with the tag.
- Products containing fluids can present challenges for UHF-RFID.

III. RFID STANDARDS -- WHERE, HOW AND WHY THEY ARE APPLIED

A. ISO 18000 SERIES

The most common standard utilized in relation to RFID for item management is the ISO/IEC 18000 series (Information technology - Radio frequency identification for item management). The following common RFID frequencies and parameters for communication across the air interface offer best features for product, package and transport tagging:

- Part 1: Reference architecture and definition of parameters to be standardized
- Part 2: Parameters for air interface communications below 135 kHz (LF)
- Part 3: Parameters for air interface ommunications at 13,56 MHz (HF)
- Part 6: Parameters for air interface communications at 860 MHz to 960 MHz (UHF)

This technical standard was created for developers and system integrators to achieve communication across the air interface for specific frequencies between the IC in the RFID tag and reader. It includes parameters for physical and media access control, protocols and collision management parameters. Some of the protocols that are defined in the standard include:

- Who Talks First (WTF). Determines whether the tag starts transmitting as soon as it is remotely powered by the interrogator-Tag Talks First (TTF), or if it waits for a command from the reader before starting the transmission-Reader Talks First (RTF).
- Tag Unique Identifier (UID). A binary value that ensures worldwide uniqueness for the tag. This identifier is at the chip level, and is assigned by the IC manufacturer. For this reason, it is not the unique product identifier that may be assigned by a product manufacturer for the supply chain tracking purposes.
- Memory size. Indicates the minimum and maximum memory size that can be accessed using read and write functions. A minimum sized chip contains typically 96 Bit, which is enough memory for a serial number. But a chip with larger capacity--128 or 256 Bits--or more could carry variable data and even data resulting from transaction processes.
- Command structure and extensibility. Describes the structure of the command code from the reader to the tag and indicates how many positions are available for future extensions.

ISO/IEC 18000 does not address requirements for the system specification, application, implementation, and information and data architectures.

B. APPLICATIONS LEVEL STANDARDS--INFORMATION AND DATA

While ISO 18000 addresses protocols and parameters relating to air interface, it does not address the overall interoperability of RFID systems within the enterprise, and the applications for which RFID would be deployed. There are specific standards that could also be included in the design and development of RFID systems.

Item level identification coding takes place at the application level. The HIBCC RFID standard, for example, defines the coding structure for the identification of items, products and logistical units. This enables the creation of a virtual relationship between the tag and the item to which it is attached. This relationship needs to be identified by the information management systems.

Most RFID applications for item management will only require a "license plate" coding for the product or logistical unit, and any product details will reside in information management systems. Therefore, the role of the RFID system is simply to identify the item, and then pass the data to the information management systems.

The manner in which application data is stored and organized on the RFID tag, and the protocols for transferring data from the tag to the application, also need to be defined. ISO/IEC 15961 and 15962 address this requirement:

- ISO/IEC 15961 - Information technology - Radio frequency identification (RFID) for item management - Data protocol: application interface.
  Focuses on the interface between the application and the data protocol processor, and includes the specification of the transfer syntax and definition of application commands and responses. It allows data and commands to be specified in a standardized way, independent of the particular air interface.
- ISO/IEC 15962 - Information technology - Radio frequency identification (RFID) for item management - data encoding rules and logical memory functions.
  Focuses on encoding the transfer syntax, as defined in ISO/IEC 15961, according to the application commands defined.

The HIBCC standards for identification coding are included within ISO application guidelines for RFID for Supply Chain Applications based on these technical standards:

- ISO 17367 RFID for product tagging
- ISO 17366 RFID for product packaging (Complementary Barcode Standard ISO 22742)
- ISO 17365 RFID for transport units (Complementary Barcode under ISO 15394)
- ISO 17364 RFID for Returnable Transport Items (RTI)
- ISO 17363 RFID for freight containers (does not apply for healthcare directly).

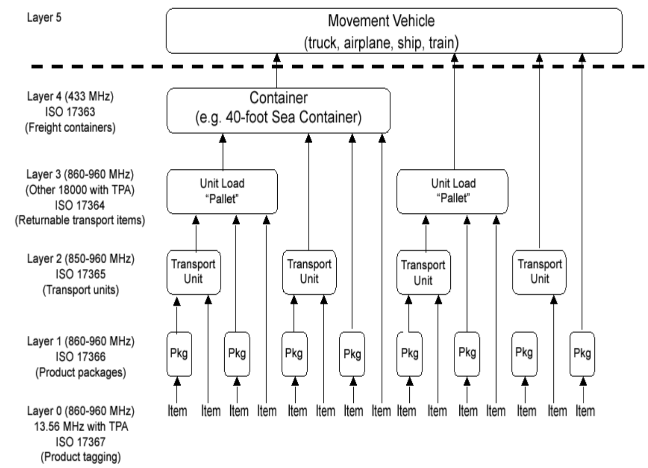
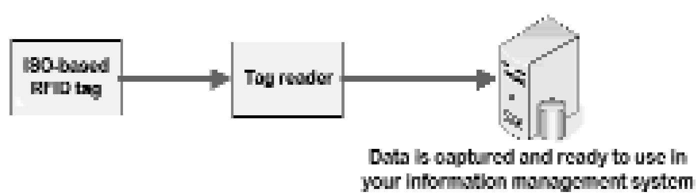


Figure 7 - ISO Schema, RFID for the supply chain management levels (Source: ISO 17363)

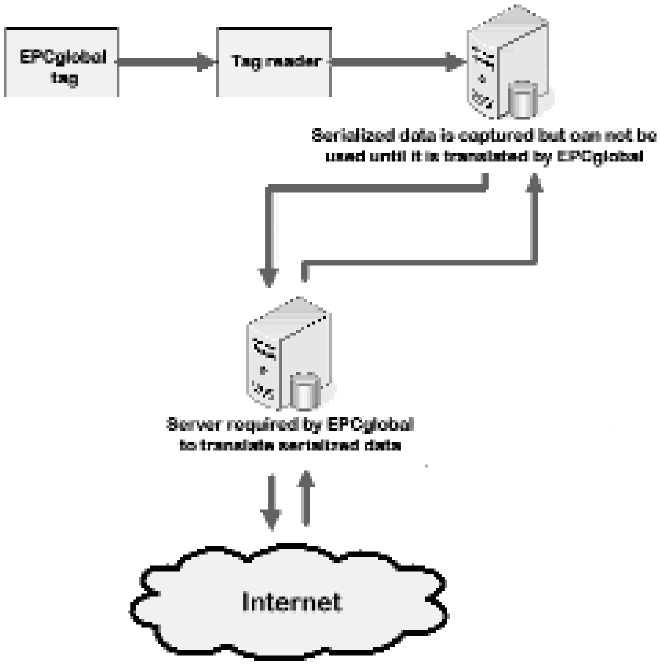
C. DIFFERENCES BETWEEN THE ISO-BASED AND EPCglobal APPROACHES

The ISO approach to RFID implementation is based upon healthcare product supplier migration from existing barcode or 2-D symbologies to RFID. This can be accomplished by leveraging approved ISO standards and using Data Identifiers (DI) to code important medical supply chain data, such as lot/batch number, serial number, and expiration date. As the product moves through the supply chain, this important data can be captured directly from the product and used in information management systems. This approach is similar to that which has been used in barcoding applications, and has proven over time to be robust, reliable, safe and cost-effective.



The ISO approach is based on simplicity and direct access to information. The ISO tag is self-contained with all required information.

A contrasting approach being promoted by EPCglobal requires placing a fee-based, coded serial number on every RFID tag, which would replace the actual information. Important supply chain information would therefore not reside directly on the tag, but on databases that would be connected via EPCglobal's network that mimics the World Wide Web. This proposed service, called the Object Naming Service (ONS), does not currently exist, and will likely present practical issues and challenges. It would require that variable data such as lot/batch and expiration data be referenced and maintained on databases that would have to be continually accessed via ONS.



The EPCglobal approach requires numerous steps to access information. Because the EPCglobal tag contains a coded serial number, it must be cross-referenced to yield the required data

The complexity and cost of the EPCglobal approach has recently led to its rejection by the Joint Automotive Industry Organization (JAI), which is composed of the major automotive industry associations in the United States, Europe, United Kingdom and Japan. The group announced its intention to support alphanumeric data and open standard symbologies, like those utilized in the ISO-based approach.

Despite obvious differences, both the ISO-based and EPCglobal approaches conform to the same air interface specifications defined by ISO/IEC 18000. Consequently, both systems are interoperable.

IV. BENEFITS OF RFID IN HEALTHCARE

Proponents of RFID cite many potential advantages over existing and conventional Auto-ID technologies, such as barcoding, that can improve supply chain and other processes. For example:

- Barcode labels are "read only," while RFID tags can have both read and write capability, making them more versatile.
- Unlike barcode scanning, which requires that labels be individually read, groups of RFID tags can be read simultaneously, there by enhancing productivity.
- Using "smart shelves," which have RFID readers embedded within them, it will be possible to obtain real-time inventory status by using RFID tags.
- The U.S. Food and Drug Administration (FDA) is evaluating the use of RFID tags for verifying product pedigree. This can be accomplished by encrypting information in the tag to eliminate counterfeiting of products, such as drugs and high-cost medical devices.
- Critical data such as temperature monitoring for sensitive products like blood can be automatically logged using RFID tags.
- RFID tags allow for invisible but resistant marking for special applications, such as wristbands.
- Unlike barcoding, there is no line of sight required to read an RFID tag. The use of RFID tags permits reading orientation directly through materials like boxes and textiles.

Some proponents have suggested extremely broad possibilities for RFID, such as EPCglobal's promotion of an "Internet of things," in which "every single object would be connected to the Internet through a wireless address and unique identifier."

From a more realistic perspective, the primary benefit of RFID at its current maturity level is its potential for productivity improvement, and thus reduction in deployed working capital. The most obvious areas are those in which barcode technology has limitations.

V. LIMITATIONS OF RFID

There are a number of challenges posed by RFID implementation in healthcare:

- Cost. RFID is still expensive, not plug-and-play, and has not yet proven its reliability in large-scale implementations.

■ Environmental conditions. Tag reliability can be impacted by humidity, metal surfaces, and more. Current RFID tags cannot withstand extreme temperatures withouttemperature-resistant housing. For that reason, using them for items like surgical instruments is complicated.

■ Limited application. It is difficult to apply and read RFID tags on metal and fluids. This currently limits tag application to cardboard, paper and plastic packaging.

■ Technology incompatibilities. Interoperability between different RFID standards--for example, the ability for a single reader to read tags from multiple frequencies--is not available at this stage, and will be technologically difficult to achieve.

VI. WILL BARCODING BE SUPERSEDED BY RFID?

Barcoding will continue to be used in the future, and will co-exist with RFID. As with all technologies, each will be utilized in the functions for which it offers the highest benefit/cost ratio and comparative advantage.

Consideration of the following will help determine which technology is used:

■ The marginal cost of including a barcode on a product label. For low-cost items sold in high volumes, barcoding is still a viable and cost-effective option.

■ There will always be applications that do not require many items to be read simultaneously. In these cases, RFID offers only a small benefit over barcoding.

■ Barcoding is a mature technology, and its scanning reliability has proven to be high in broad-scale implementations. By contrast, RFID is relatively immature, and is yet to be proven in widespread usage.

■ Because some members of the supply chain may not have the capability to implement RFID, a second means of identification would need to be applied to all RFID-tagged products. This is not necessary for barcoding or other 2D options.

VII. APPLICATIONS OF RFID IN HEALTHCARE

RFID applications in healthcare could include:

■ Supply chain applications. This includes high-cost items like pacemakers, defibrillators, and artificial joints. The supply chain for these items is complex, and they are often supplied on consignment. They also require a high degree of traceability from the supplier to the patient.

■ Patient safety applications. This may include improved patient identification using RFID tags in patient wristbands.

■ Quality assurance applications. This may include improved instrument tracking for infection control purposes. Some vendors supply RFID-enabled trays that can be tracked through central sterilizing departments.

A. SUPPLY CHAIN AND ASSET AND MATERIALS MANAGEMENT

Use of RFID for supply chain applications will likely be implemented by manufacturers and distributors of high-cost medical devices that require a high degree of traceability. This includes implanted devices such as pacemakers, defibrillators, artificial joints, vascular stents, and intraocular lenses. Because of their high cost, these devices are typically supplied to hospitals on consignment, which means that the hospital does not purchase them until they have been used.

1. Orthopaedics Implants Example

Orthopaedics implant suppliers typically supply products on a "loan set" arrangement. This involves a supplier lending the instruments required to perform a procedure, along with a full set of implants, to the hospital for a specific case. Below is an example of how the loan set process works:

1) Surgeon books patient for procedure, and instructs hospital to order loan set for procedure.
2) Hospital orders loan set from supplier
3) Supplier assembles loan set and records lot/serial numbers of all items supplied.
4) Supplier has loan set delivered to hospital. Loan set is often "split," meaning that multiple logistical units make up one loan set. When a loan set is split, the non-sterile surgical instruments are placed in a

separate logistical unit than the sterile implants.
5) Hospital receives loan set and sterilizes components.
6) Hospital performs procedure, and records details of implants and other items used in the procedure.
7) Hospital returns remainder of loan set to supplier.
8) Supplier receives loan set and scans all items that remain. By deduction, they determine which items have been used.
9) Hospital prepares purchase order to send to loan set supplier.
10) Supplier invoices the hospital for loan set components used.

Each supplier stocks a large amount of inventory; the effort required to manage the logistics is also significant.

Using RFID tagging on the loan set implants can lead to substantial improvements to supplier productivity and inventory, thereby improving the working capital deployed. This is because processing the returned portion of a loan set takes a considerable amount of time and effort. RFID enables suppliers to simultaneously read all tags on the implants returned, determine the implants used in a procedure and make returned implants re-available quickly.

In this example, the benefit of RFID is the ability to simultaneously read many tags. With barcode scanning, the supplier would need to scan each implant individually. This is time-consuming, and ties up inventory that could otherwise be available for distribution to other customers.

This example is also a closed-loop application, since it serves only the organization that has implemented the solution. All development with this application is within the control of the supplier concerned.

2. Cardiac Catheterization Laboratory Example

A U.S.-based vendor of RFID for healthcare applications is implementing RFID reader-equipped cabinets within cardiac catheterization laboratories. Each cabinet is also equipped with an embedded computer and an SQL-based application. The system is linked to the hospital's physical security system.

Staff members swipe their identification badges to access the supply cabinets, input patient information, and remove devices needed for the procedure. All devices are tagged with an RFID tag. The items used are logged, and the system records who retrieved the items and for which patient. If the item is returned-or even moved to another cabinet-the system records its whereabouts. In this way the catheterization lab always has an accurate inventory and charges patients only for equipment used. The cabinets also track the expiration dates of stocked products.

This application, however, is dependent on all medical device suppliers tagging their products using the same technology and standards including frequency, antenna design, etc. Currently, manufacturers of these devices are not attaching RFID tags to their products; hence, hospitals implementing this kind of system need to apply the tags to the products when they are received, or else require that the distributor of the products do this post-manufacture.

B. PATIENT SAFETY AND QUALITY ASSURANCE APPLICATIONS

Another area in which RFID may benefit healthcare is in improvement of patient safety. This may include patient bracelets embedded with RFID tags. RFID tags that have "write" capability can have key information written to the tag, including drug allergies, blood type and other important patient data.

Quality assurance within hospitals is also a key area of concern, particularly for infection control. Surgical hospitals generally have a Central Sterilizing Services Department (CSSD) to sterilize surgical instruments and other devices for use by hospital operating rooms.

Each sterilization "batch" needs to be appropriately identified. Surgical instruments and devices are placed in trays, which are then sterilized using an autoclave machine. Once the items have been sterilized, the trays are assigned a batch number, and the serial number on each instrument in the tray is related to this batch number. This way, if an infection resulted from the surgical procedure, the instruments used in the procedure can be recalled for further examination and testing.

This application is particularly useful for identifying individual instruments that may be subject to Creutzfeldt-Jakob disease (CJD). Risks associated with an infection can be more accurately addressed. This can also lead to cost savings in the case of a CJD outbreak. If the patient and surgical instruments can be identified, then the elimination of surgical instruments can be confined. *(NOTE: I'm not sure that this is making the point.)*

However, tracing individual instruments to specific trays is very challenging. Instruments cannot be barcoded. While new symbologies, such as 2-D symbologies can be etched to metal surfaces, the scanning reliability is low, and the expense is high. Furthermore, each individual instrument needs to be scanned to the tray, to form a link between the instrument and the tray, a labor-intensive process.

The CSSD process is ideally suited to RFID. If each instrument was embedded with an RFID tag, and the tray in which the instruments are placed retrofitted with a RFID reader, instruments can be identified and logged the moment they are placed in the tray. However, this is also a very challenging proposition given current limitations with RFID technology:

- The IC within commercially available RFID tags is based on the conventional Complementary Metal Oxide Semiconductor (CMOS). Unless developed to military specifications, CMOS is not able to withstand the high temperatures of the autoclave process. Claiming several benefits over CMOS is Micro Electro Mechanical Systems (MEMS), which is currently in research stage and is expected to be commercially available in 2007. MEMS-based RFID claims to withstand extreme temperatures.
- Embedding RFID tags to metal objects is a challenge because its antenna design and reader configuration need to be customized. This can be very costly, and the reliability is unknown.

VIII. CONCLUDING REMARKS AND RECOMMENDATIONS

In healthcare, RFID has the potential to achieve improvements in both supply chain productivity and patient safety applications. However, the technology is more likely to be successful if evaluated for closed-system applications first, where deployment and subsequent changes are within the control of the individual organization.

The introduction of a new technology like RFID often causes a stir of interest and excitement about its capabilities. However, RFID will likely go through a stage where initial enthusiasm is tempered by practical cost-benefit considerations. The outcome of these will be appropriate deployment of the technology.

Well-developed standards already exist at different technology levels, including the protocol, communication, and data levels. Using the existing ISO specifications, data can be encoded to RFID tags to guarantee continuity worldwide. This approach also ensures that RFID will be able to co-exist with current barcode standards, which will likely be required for the foreseeable future. The ISO-based RFID standard is also independent of technology, so the data structure can be coded to any of the accepted frequencies and protocols under ISO 18000.

Healthcare organizations considering RFID-enabled solutions should carefully address the following questions:

- Do you have needs for automatic data capture that barcoding does not address?
- Will RFID deliver greater benefits than existing, more mature technologies like barcoding?
- The key benefit of RFID that will deliver productivity and inventory improvements is the ability to read multiple tags instantaneously. Will your organization benefit from this important feature? If not, then barcoding or 2-D symbologies may present a less expensive alternative.
- Are there environmental and other factors that may impact the reliability or success of your RFID implementation?

IX. ABOUT HIBCC

The Health Industry Business Communications Council® (HIBCC®) is an industry-sponsored, ANSI-accredited standards development organization. Our primary function is to facilitate electronic communications by developing appropriate standards for information exchange among all health care trading partners.

Our broad mission has consistently expanded to meet industry requirements and has involved HIBCC in a number of critical areas, including electronic data interchange message formats, bar code labeling data standards, universal numbering systems, and the provision of databases that ensure common identifiers.

Our current major activities have emerged as a result of this broadening focus:

- Standardized manufacturer, customer, and product identification codes, including the Labeler Identification Code (LIC), Health Industry Number (HIN®), and Universal Product Number (UPN®) and the Health Industry Bar Code (HIBC) Standards
- Computerized EDI protocols in ASC X12 approved message formats
- Participation in national and international organizations working to further enhance electronic communications standards.

Perhaps most important, HIBCC is a nonprofit organization that plays a major advocacy and educational role in the health care industry and serves as the forum through which consensus can be reached as it electronically transforms itself for twenty-first century commerce.

X. ABOUT THE AUTHORS

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