RFID in Life Science Series: Part 2

RFID in Clinical Settings

New Dimensions in the Chain of Care

Authored By: Carla Reed

June, 2006

About ChainLink Research

ChainLink Research, Inc. is a Supply Chain research organization dedicated to helping executives improve business performance and competitiveness through an understanding of real-world implications, obstacles and results for supply-chain practices, processes, and technologies. The ChainLink Inter-Enterprise Model is the basis for our research; a unique, real-world framework that describes the multi-dimensional aspect of links between supply chain partners.

For more information, contact ChainLink Research at Harvard Square Center
124 Mount Auburn Street, Suite 200 N., Cambridge, MA 02138.
Tel: (617) 762-4040. Email: info@clresearch.com. Website: www.clresearch.com.

RFID in Life Science Series: Part 2

RFID in Clinical Settings

New Dimensions in the Chain of Care

Authored By: Carla Reed

June, 2006

Table of Contents

Cont. Table of Contents

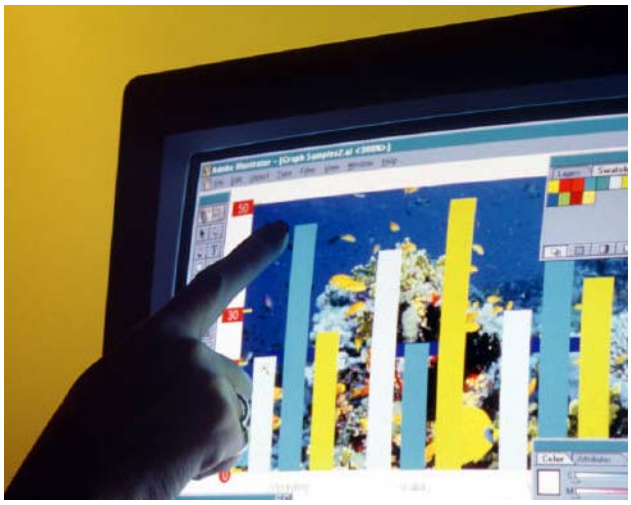
[This page intentionally left blank]

RFID - New Dimensions in the Chain of Care

Hurricane! - That was the resounding headline in the USA during the summer and fall of 2005. Records were broken as the string of hurricanes pounded the Gulf Coast, the Caribbean and the Eastern USA. The unbelievable happened when the levies in New Orleans failed to hold back the surging tide of Hurricane Katrina. Like Atlantis, the city was swallowed by water. TV screens reflected the plight of those unable to evacuate the city. Families were torn apart, loved ones lost to the water or the frenzy that followed. In the aftermath of the storm the good citizens of the US reached out – offering hearth and home to those who had lost everything. The residents of New Orleans were cast like seeds across the country. Some of the refugees from Hurricane Katrina brought more than their gratitude into the communities that took them in.. In many cases victims brought with them illnesses that could be transmitted to those in their new community, the result of exposure to polluted water, bacteria and other factors that manifested themselves in disease.

MEDICAL SYSTEMS CREATE A SINGLE VERSION OF THE TRUTH[1]

The good news is that authorities in States like North Carolina and Florida – locales that have a relatively large migrant population – had taken steps to create medical information networks in which patients with unusual diseases could be monitored. Specific symptoms are triggers to alert the system that there is a potential problem, enabling healthcare workers to 'dig a little deeper' into the patient history, identifying similarities in terms of medical history, places visited, etc. with other patients. In this manner it is possible to treat these patients more effectively, matching symptoms and cure with previous medical cases. Supported by similar initiatives in other locations in the US and endorsed by Federal agencies, these systems leverage the state of the art in technology in order to share this information across a national network of healthcare providers.



1 This is outlined in the ChainLink Report – "*Single Version of the Truth"*
http://www.chainlinkresearch.com/research/detail.cfm?guid=F6F06550-A81A-4F05-EF17-F501BAD84E68

A Digital Case Book for Healthcare Providers

Authorities across the globe recognize the value of sharing patient and remedy data across a network of expert medical practitioners. The concept of 'tele-medicine' has been positively received in several geographies, with medical teams collaborating across digital networks – sharing patient data, radiology and exploratory test results. A Single Version of the Truth - SVOT - in order to enable health care practitioners to work in collaboration, across the Chain of Care (Care Chain) is a vision that is achievable through the combination of wireless, wired and network technologies. The potential rewards are great - the key is ensuring that the information available in these systems is accurate, timely and accessible. This requires very detailed and specific data, captured at the point of care, versus the traditional transmission of information from one system to another. Radio Frequency Identification (RFID) provides capabilities that meet this need. RFID enables identification and tracking of events, activities and entities at the unique item, patient and incident level – providing sensory data to manage the critical links in the Care Chain – real time – across a global network of care givers.

Spiraling Healthcare Costs

Healthcare costs in the United States have always been a 'bone of contention' irrespective of the incumbent political party. Healthcare costs have been cited as a major reason for the reduction in US industrial competitiveness, an increasing problem as the cost of healthcare becomes an every growing percentage of both private sector and US government spend. A major driver is the cost of liability insurance, escalating in relation to perceived risk. This Achilles heel of the US medical system is not evident in other nations, reflected in lower healthcare costs and in many cases more innovative medical procedures. A potential solution is a 'Single Version of the Truth' across the Chain of Care, creating consistency while reducing risk and related costs.

DIGITAL FORENSICS –VISIBILITY INTO THE CHAIN OF CARE

The world of forensics has been brought to life on the small screen through a series of popular television programs. This has created a new interest in science, and what is possible through gathering and analyzing evidence. The real world equivalent is equally exciting. Much can be learned through the examination and analysis of pathology samples. In the digital equivalent of the physical world, data captured through the Care Chain should be available for scientific review. The analysis of this digital trail of symptoms, patient data, and remedy can be compared to the forensic process that takes into account physical evidence. Digital forensics – the analysis of data streams, looking for patterns and similarities across the Care Chain – has exciting implications for patients and care givers alike. The inclusion of RFID in this process has the promise of making this information more readily available, whether the situation is the containment of a potential outbreak of a deadly virus, or something more mundane. This has important implications for all. Especially in view of the ongoing risk of health hazards on a global scale.

Tuberculosis, virtually eliminated in many geographic regions, is on the rise, and standard regimes are not working – nor necessarily available to those in need. The fear of a global resurgence is now a reality. Global travelers have returned home with more than just the spoils of trade. SARS, yet another mysterious epidemic, challenged the medical world and spurred investigations into the source of the disease. And now bird flu is threatening to cause a much bigger crisis[2]. The list of potential threats goes on.

In the next pages we will explore the use of RFID and related auto identification technology in the Care Chain. RFID is an enabler for process transformation – on the front lines of medicine today – across the Chain of Care – from product manufacturing, through each of the intricate processes in the clinical environment – to the last inch, the patient experience and cure.

---

2 For more information, see report — *"Proactive Pandemic Planning"*
http://www.chainlinkresearch.com/research/detail.cfm?guid=F4BF147D-FAEB-2444-5F67-79F729DFB2AB

How This Report is Organized:

DEFINITION OF A CLINICAL SETTING

USING RFID TO FORGE THE LINKS IN THE CARE CHAIN:

- Patient monitoring and tracking
- Asset control
- Pharmaceutical control
- Control of supplies
- Procedure control
- Cost control

OBSTACLES TO ACHIEVING THE VISION FOR RFID IN CLINICAL SETTINGS

- Network issues – medical grade network
- Frequency issues – interference and human interaction with RF
- Orientation and training of clinical practitioners
- FDA compliance and control – regulated industry
- Privacy issues – patient records/HIPPA

DEVELOPING A MODEL FOR A FUTURE FORWARD CARE CHAIN – TAKING THE 3PE APPROACH

Who Should Read this Report?

- Medical practitioners – doctors, nurses, radiologists, medical core, emergency service providers
- Clinical environment management personnel
- RFID vendors – wireless technology providers, middleware vendors
- Software/Solution providers companies – across the medical spectrum
- Sales and Marketing – medical devices and pharmaceutical companies
- Health Insurance carriers
- Government, Policy and Trade associations

Because it is all about managing risk and saving lives

The Clinical Setting in the Mobile World of the 21st Century

Time for a Definition

Perusing through a series of both American and European dictionaries, I found that there were variants in definition related to the term 'clinic' as well as the concept of a clinical environment. The one that I believe best illustrates the clinical environment in which the primary focus is the care and well being of the patient, is an extract from the Oxford English Dictionary – *"observation and treatment of patients as distinct from theoretical study of medical science."* This is the point where the provider meets the patient, the true test of success for research, development, training and supply chain preparedness in the medical profession.

Different Elements within the Clinical Setting

The actual 'clinic' or facility can take many forms – from the 'state of the art' medical facilities to informal 'field hospitals' – in both military and civilian settings. The primary objective in all cases is to 'heal the sick' – one patient at a time. And each patient and medical situation is unique, with unlimited permutations in terms of symptom, care and cure. As such, all the processes and procedures that take place, from patient admission, supply chain fulfillment, surgical procedure, equipment maintenance, patient care to release, need to be carefully recorded, monitored and controlled. This is no small task – in many cases each of the key processes is recorded by interdependent but separate functional entities with disintegrated information systems. Synchronizing data and information to ensure contextual relevance is important, maintaining a balance between identity, location, time and state – at the patient, equipment and caregiver level. This is a challenge in a high paced environment where every second counts.

Extreme Situations within the Care Chain

As highlighted in the prelude, the accuracy of the data captured at the time of patient admission is critical to the success of each of the processes that follows. One of the most extreme links in the Care Chain[3] – the Emergency Room, highlights the need for real time and accurate information – both at the equipment and patient level. For example, demand for critical, life saving equipment cannot be predicted – having access to what is available and the location of each item is required in split seconds (we cover this in more detail later in the document). And patient data is equally important in an emergency environment – especially in cases of national emergency, like hurricane evacuation scenarios or a pandemic.

---

3 An even more extreme environment is the field hospitals deployed at times of war or major disasters.

The typical Emergency Room (ER) patient is normally resident in the locale of the hospital, and as such, there are relatives or other sources of information that can 'fill in the gaps' once the emergency is over. In the case of a visitor, or a refugee, the ability to gather information is more challenging. Care cannot be denied (in theory), even if the paperwork has to be neglected. However, the requirement for a means to identify and track patients that fall into this category cannot be ignored. In common with potentially 'at risk' ER patients (those who could do themselves harm or go missing), there is a need for clinical environments to closely monitor the movement of these patients, ensuring that their location, as well as each procedure and pharmaceutical administration is tracked. In the past, this has necessitated a 'one on one' patient security monitor, in most cases a manual process, including the assignment of human resources to observe these patients. The introduction of technology to replace the current process would have many benefits – both in process efficiency and in the ongoing capture of data in digital format that could be integrated into the patient record in real time.

MONITORING AND CONTROL – REFLECTIONS OF THE CARE CHAIN

The need to create a paper trail to monitor and manage patient and drug administration is one of the largest frustrations of healthcare workers – across the globe. One of the most regulated industries in the world, the healthcare industry is plagued with reports to file in every link in the chain – in compliance with government, insurance carrier, manufacturer and other interested party requirements. Every medical device, every pharmaceutical and every medical supply needs to be recorded and monitored. And yet, it is very hard to get accurate and timely information at the time it is needed to care for the patient. This requirement is primarily for patient safety but an additional element is a detailed list of procedures and supplies for reimbursement for services. Whatever the reason, these administrative tasks burden an industry that is faced with a shortage of qualified personnel, as well as a lack of profitability – compounded by spiraling healthcare costs.

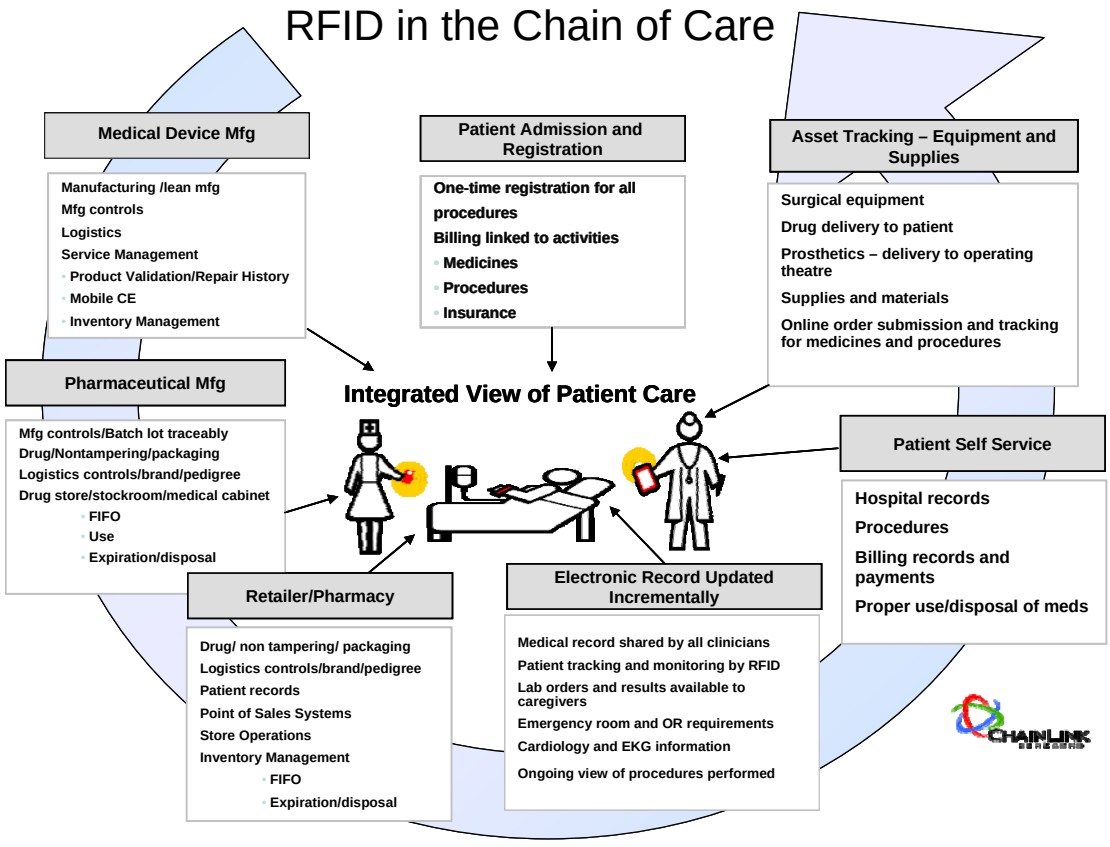
Despite these precautions, people die each day as a result of mistakes in clinical settings, the very environments that are designed to save lives. The stakes are high, and are reflected in both medical and liability insurance costs. Not to mention the loss of market credibility when a pharmaceutical or other product fails to deliver as promised. In cases like this, the decades of effort and billions of dollars spent in product research and development are lost – as are the potential profits, the promise of block-buster drugs.

Data captured during these processes has many uses. Success can potentially be repeated through studying and emulating diagnostic approaches, admission of drugs and medical products. In addition, although clinical trials have explored the impact of medical devices and pharmaceuticals in multiple instances, the value of recording and sharing drug and other patient interactions, in a real world setting, is invaluable. Potential adverse reactions can be identified, monitored and controlled – preventing potential danger and hazard to future recipients of these products. The very detailed and COMPLETE record of each patient/

pharmaceutical interaction, possible through the introduction of RFID to capture data at the unique patient/drug/dosage level, is a potential goldmine for pharmaceutical companies. Data related to demographics, patient profile, medical conditions and be environment can analyzed, and associations can be made between patient age, state of health and drug interaction. This is consistent with new developments in medical research where specific drugs are developed for infants, adolescents, mature adults and the elderly. Field level information could provide much richer and deeper data than a clinical trial environment, reducing the risk inherent in newer drugs – currently an area of contention in certain circles.

The obvious beneficiary is the patient, as well as related doctors, nurses and other care providers. But there are many other constituents that have an interest in the flow of information. These include the hospital or clinical administration, pharmaceutical and device manufacturers, associated care givers and insurance carriers – all constituents in the Chain of Care – or Care Chain. An overview of the inter-relationship between each of these entities, as well as information level requirements, is included in Figure 1.

Information requirements, as well as information system interfaces for each of these parties varies. However, the most important factor is to maintain a detailed record of each process in order to satisfy all requirements, whether these are quality control, patient monitoring, pharmaceutical and dispensing record, asset control or, ultimately, cost control.



— Figure 1 —

Using RFID to Forge the Links in the Care Chain

While bar codes, with their universal application as an auto-identification technology, were well received into the clinical environment, there have been some reservations related to the introduction of RFID. Concerns expressed relate primarily to the effect of radio waves on patients or personnel. But there are other concerns, related to privacy, interference with equipment and related information systems.

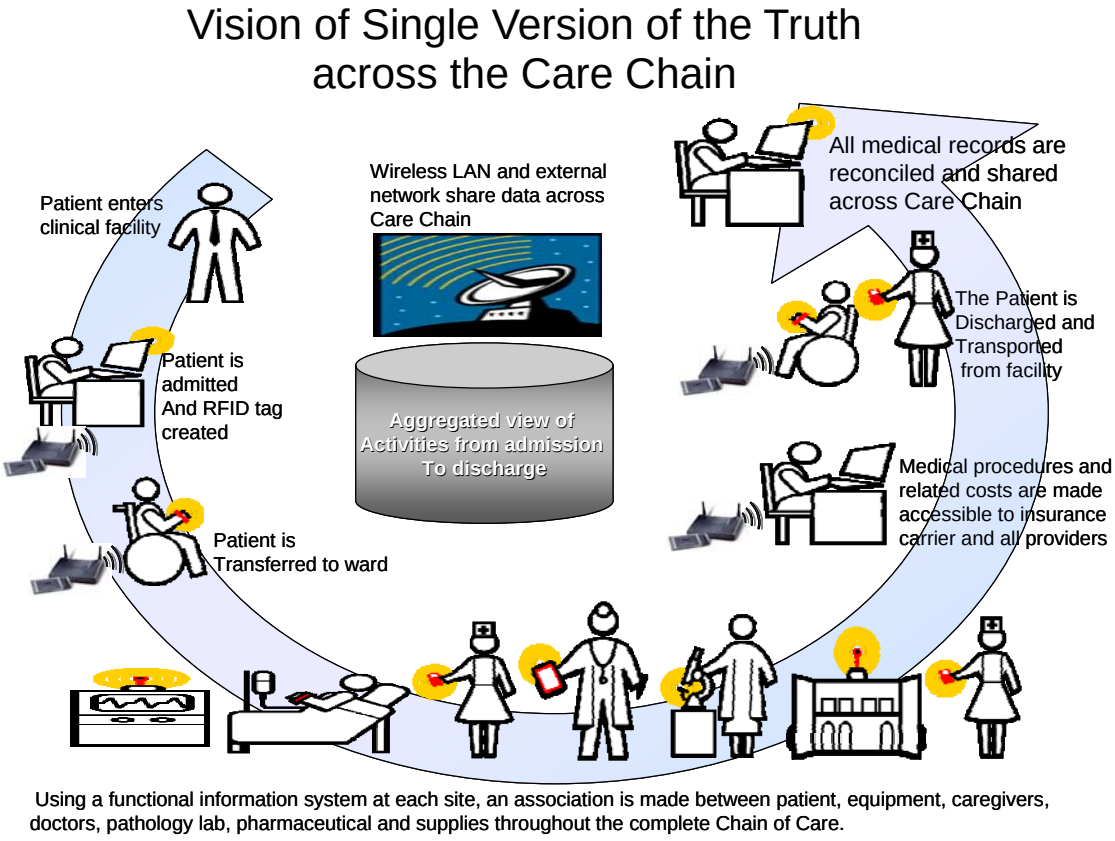
We have evaluated the potential use of RFID in each of the key functional areas within a clinical Environment. Considerations include the areas of risk within the detailed business process, impact on related technologies, and qualitative and quantitative benefits that can be achieved.

- Patient monitoring and tracking
- Asset control
- Pharmaceutical control
- Control of supplies
- Procedure control
- Cost control

At the forefront of each process enhancement is the value and benefit to the patient – the focus of the healthcare system.

PATIENT MONITORING AND TRACKING

The primary focus of the medical system is the patient. As such, the location, care and recovery of each patient needs to be carefully recorded and monitored. In addition to maintaining a detailed record of each clinical procedure, administration of pharmaceuticals and other medical supplies, it is necessary for caregivers to know where each patient is currently located in the medical facility. Various technologies have been adopted in order to gather more accurate and timely information in these areas. The result is an environment that includes a combination of barcodes, hand-held wireless data-capture devices and various levels of networked information systems. This creates the baseline on which the implementation of RFID and related technologies can build, creating an environment in which it is possible to have access to real-time information as the patient passes through each of the functional areas of the Care Chain.



— Figure 2 —

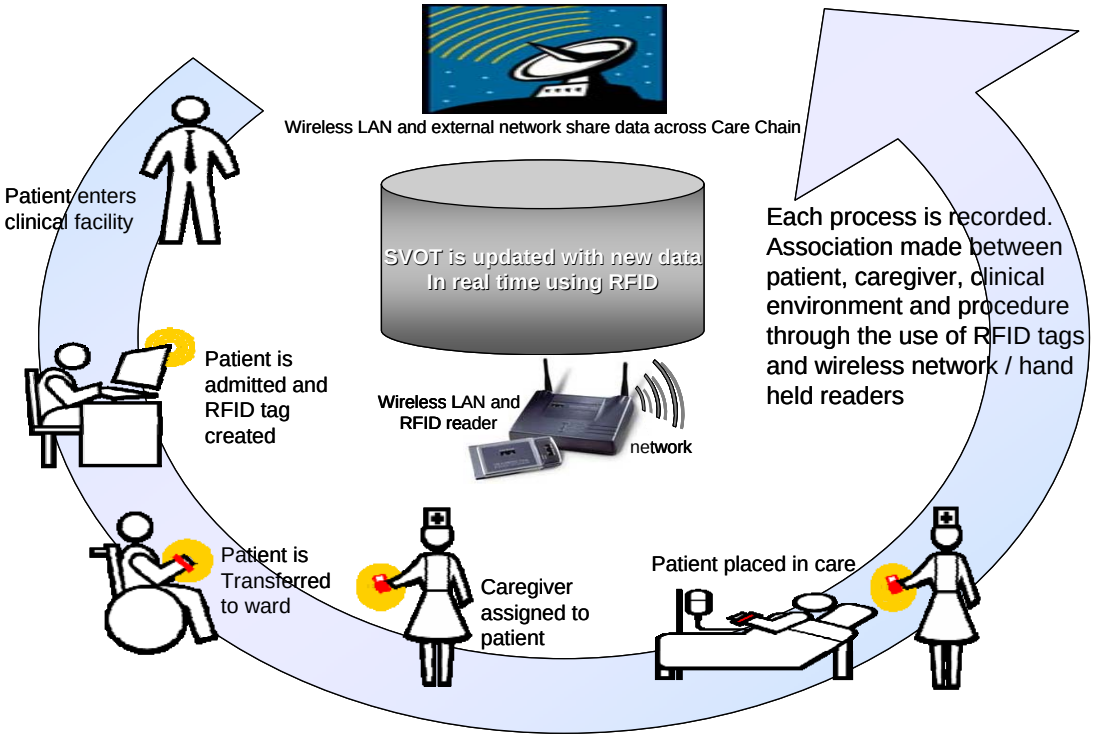
The following is a conceptual view of how RFID and network technologies could be used to create a SVOT for the Chain of Care.

Patient admission process

When the patient is admitted, all data is entered into a centralized data repository. The patient is issued a RFID enabled wristband that includes a unique patient code. This is used to monitor each process and procedure, linking additional events directly to the patient throughout the clinical process.

The automation of this process through the introduction of RFID will have the added benefit of eliminating redundant process and data entry, reducing time to care. In addition to creating an audit trail, this ensures that procedures are billed for correctly (after all, this is not an altruistic industry).

Patient Admission into Clinical Environment



— Figure 3 —

ER Environment

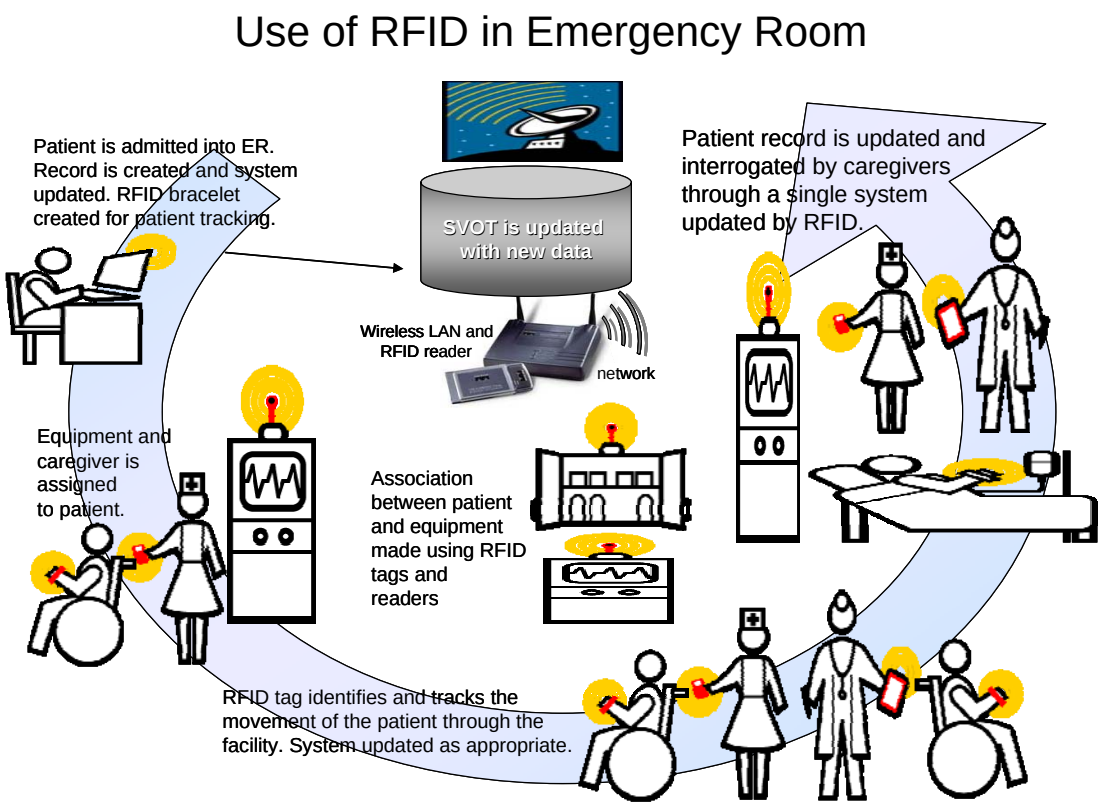
This is truly the EXTREME area of the clinical environment. The use of RFID to capture patient admission information (see admission process, above) as well as the allocation of equipment, resources and supplies to the patient would relieve care givers of this task, enabling them to concentrate on medical care. In addition to the need to monitor patients in this environment, RFID could be used to manage supplies and equipment, identifying location of critical equipment, updating inventory systems through 'smart shelf' and other RFID technologies. Also, in this fast paced environment, it may be harder to accurately record all treatment that was given to the patient – RFID could help automate that.

In addition to the use of RFID for the monitoring of equipment and supplies, it is possible to use a combination of RFID tags and sensors to monitor and track the patient as they are moved through the ER process. This has additional value in the case of high risk patients, for example diabetics, where the current state of the patient needs to be carefully controlled.

Coupled with the shared 'system of record' or SVOT – the use of RFID will provide caregivers access to detailed past and current patient records, enabling a more effective triage process.

Another key area is the dispensing and control of medical supplies that are necessary for each medical procedure. In many cases there are specific 'kits' that include most items required in each patient situation. The introduction of RFID during the kitting process would enable a line item view of what has been consumed, enabling a more accurate view of what the true level of consumable is. (Versus the items that in many cases find their way into the disposal units, untouched). Added to which, emergency room personnel need every precious minute that an automated process would give them – versus the current necessity of a paper trail.

A conceptual view of the 'RFID enabled ER environment is depicted below:



— Figure 4 —

Operating Room

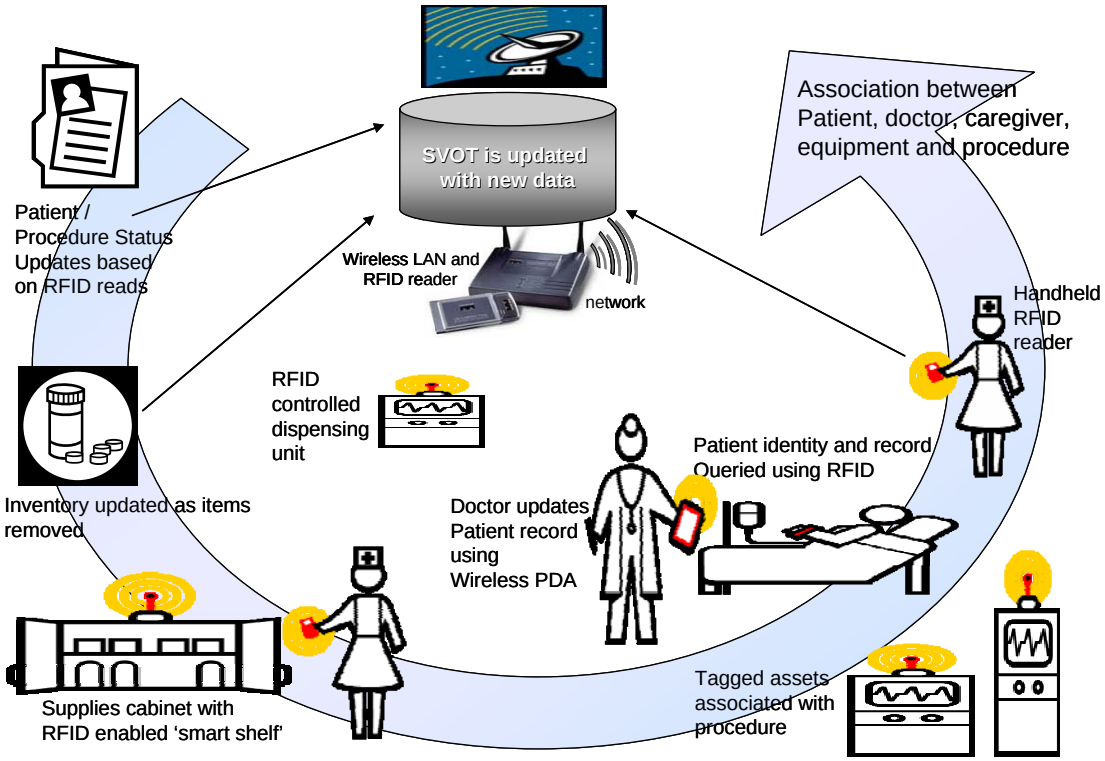
Challenges exist related to the need to monitor and control the use of pharmaceuticals, surgical equipment, and devices used in the operating room environment. In view of the high cost of many of these items (antibiotic coated stents cost approximately $5000 each), there are additional cost factors that need to be taken into account. The introduction of RFID can assist in identifying the patient – additional technologies are available in order to identify the specific location of the surgical procedure – for example left breast[4]. Additional benefits in-

4 Reference SurgiChip case study, on page 23 of this document

clude the monitoring of all equipment and supplies used in a surgical procedure – and making sure that they are all accounted for once the surgery is complete. (And that none of them have inadvertently found their way into the body of the patient – something that has been known to happen!)

Another important aspect where RFID can be leveraged relates to the tagging of critical equipment and related supplies. Having access to this information in real time is critical when performing surgical procedures – either in a planned manner or in response to a medical emergency. The following overview illustrates how RFID could be used to monitor and control the OR environment.

Use of RFID in Operating Room Environment

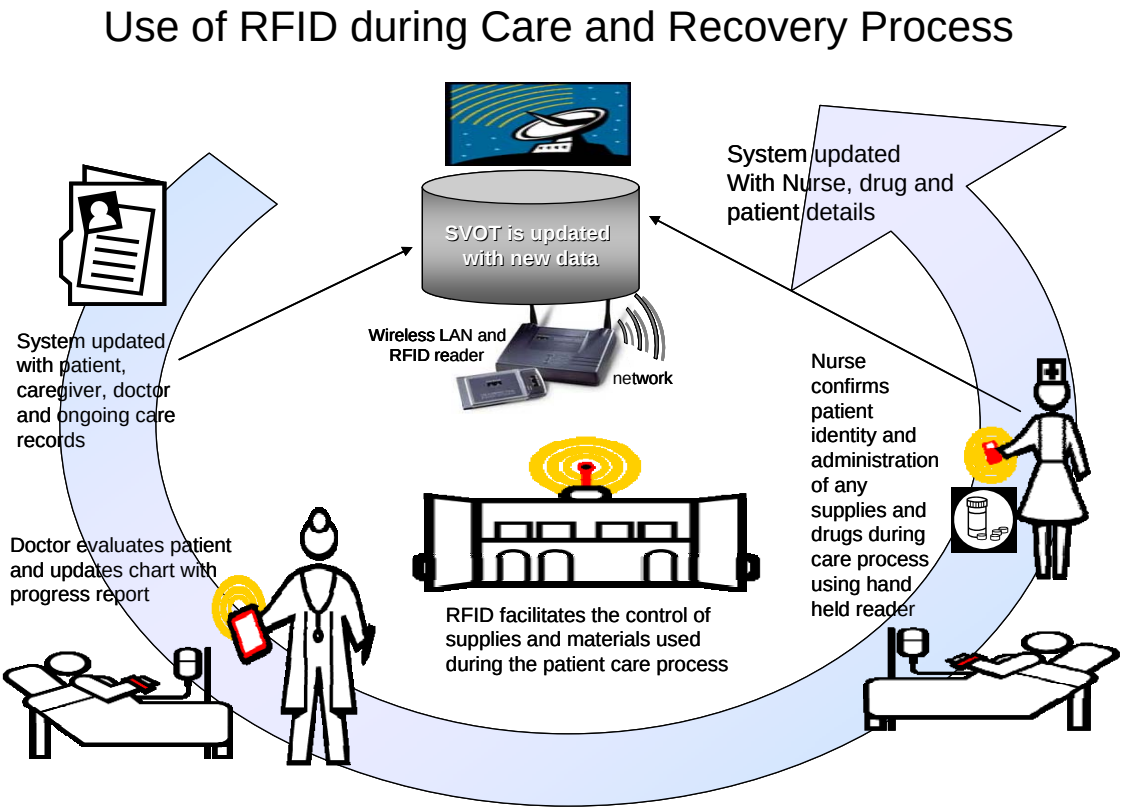


— Figure 5 —

Patient Recovery

The magic ingredient of any recovery program is nurse 'care time'. As such, anything that would release more time to spend caring for the patient versus updating paper work would be welcomed by nursing staff and patients alike. The RFID enabled 'bracelet' that has been issued at the time of patient admission is the key to monitoring each procedure during the recovery process. (Or, in the case of an infant, ankle bracelets with RFID tags.)

A combination of RFID readers, wireless networks, hand held devices for care givers, and a centralized data repository provide the key to creating a SVOT at the 'point of care' in the Care Chain.

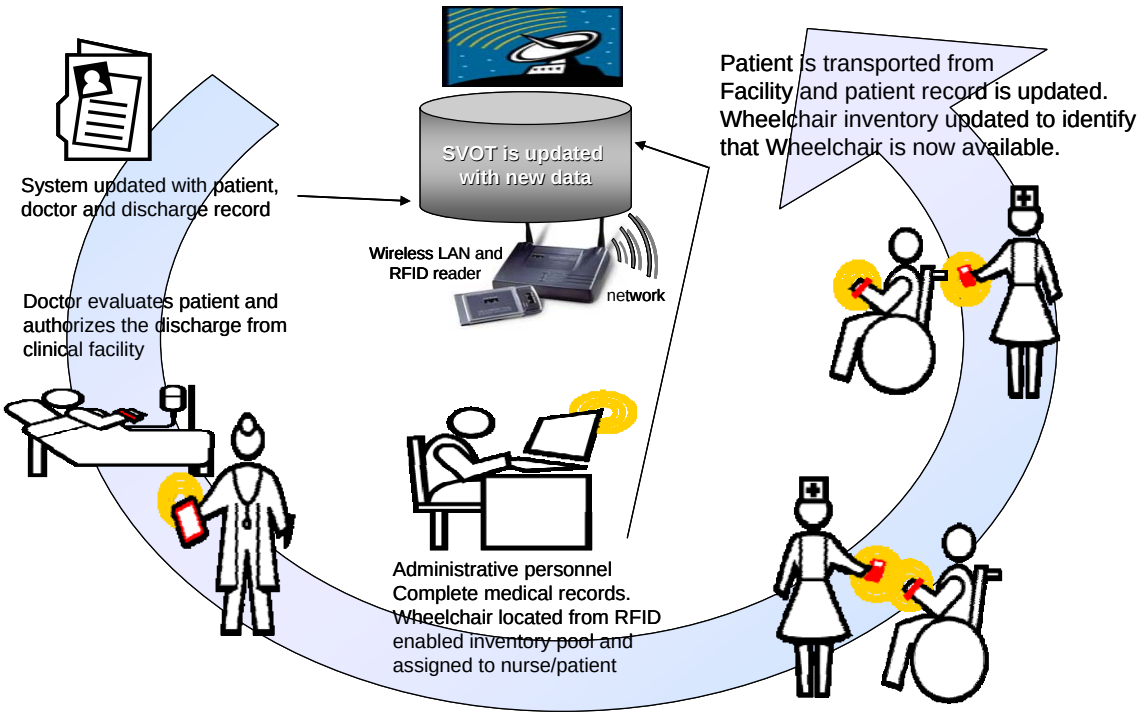


— Figure 6 —

Patient Discharge

It is important to have a system of record to track all charges to patient (or insurance carrier) as well as ensuring that any after care and home health requirements are noted at time of discharge. The use of the RFID enabled bracelet in tracking each process and procedure has the final benefit of ensuring that the correct patient is discharged, and leaves the premises under the surveillance of the caregivers, in accordance with the doctor's instructions. A further value of RFID relates to the management and control of wheelchairs – assets that tend to become misplaced. As can be imagined, lack of wheelchairs can delay the patient discharge process as well as tying up valuable resources.

Use of RFID in Patient Discharge Process



— Figure 7 —

Home Health

Assuming that all data related to patient care chain processes have been updated in the Care Chain SVOT, it will be possible for both patients and care givers to access and update these records using networked technologies.

RFID enabled products are available to ensure that patients self administer drugs and other medical supplies in the correct dosage, at the correct time – see Addendum A for examples of products available.

Unfortunately, many patients are discharged from clinical settings but still require medical attention in their home environment. As such, it is important to have tools to monitor the visits of home health professionals. It is increasingly more common for nurses to make house calls to do examinations, take tests, deliver and administer pharmaceutical products and medical equipment. Not to mention the growing number of patients who are dependant on life support and medical equipment that needs to be maintained and repaired. The use of RFID can be extended to this environment, creating an integrated data view via wireless devices (for example iPods, PDAs), as well as applications that are accessible through the internet. In this manner, the actual location of the patient is transparent to the network of caregivers, all sharing the SVOT in terms of patient treatment and progress.

EMERGENCY RESPONSE

In an increasingly mobile society, clinical environments need to be available in both emergency and scheduled situations (for example blood drives, mammograms etc.) Again, the use of RFID can assist in tracking both assets and patients, as well as creating an up to date medical record that is accessible to care givers. A potential scenario relates to emergency response vehicles equipped with RFID and related technology, enabling a mobile 'emergency room' where doctors, nurses and emergency response personnel can collaboratively perform triage – saving precious minutes that are the difference between life and death.

CLINICS / DOCTORS OFFICES

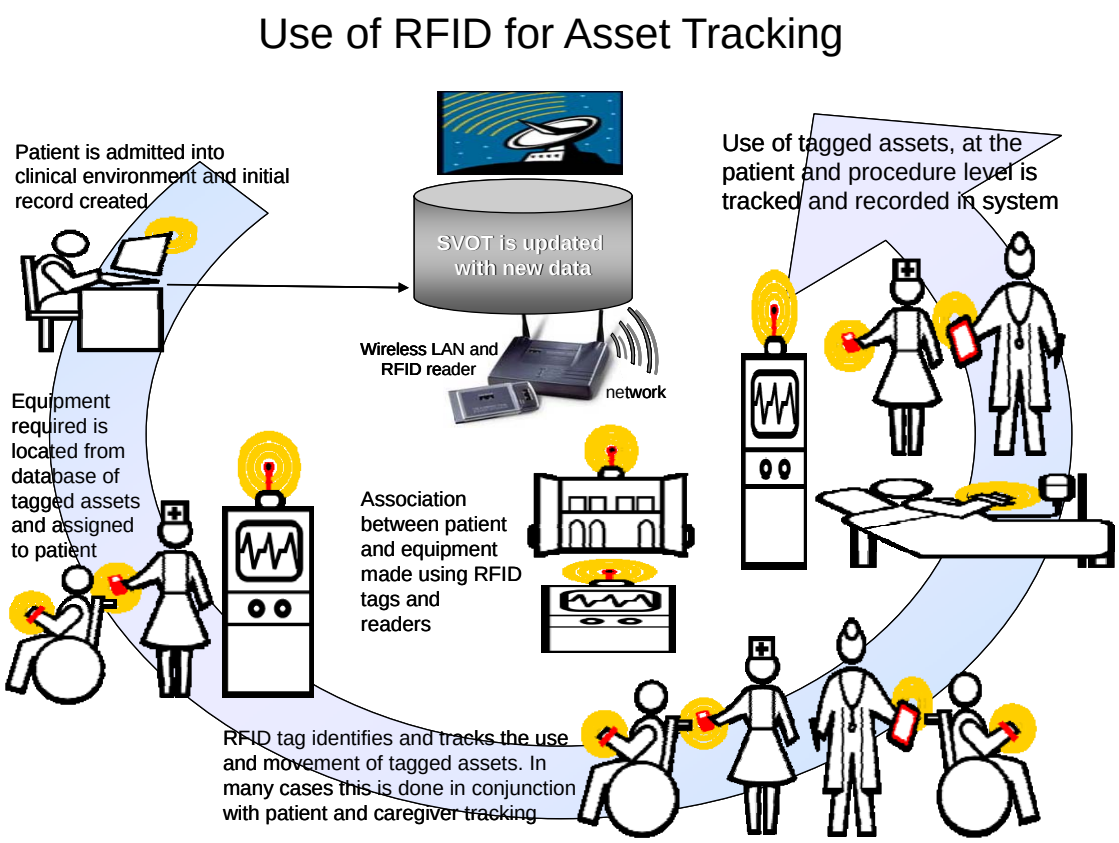
As with other clinical settings, local doctor's offices and smaller clinics can benefit from the innovation possible through the data capture and integration possible through RFID. All the scenarios that have been outlined in a larger clinical setting are applicable in these localized settings.

ASSET CONTROL

Medical equipment is expensive ***- Very***.

As such, most hospital management is careful to ensure that only necessary and correct equipment is procured. One of the challenges is in predicting use of key items, for example respirators and other equipment that is essential in ER (and other critical care) environments. Peaks and valleys in terms of demand for this equipment need to be taken into account, the result of which is a situation in many cases where there is a shortage of equipment at the most critical times. Nursing personnel are painfully aware of this fact, and it is known in certain cases that they have even been known to 'divert and hide' key equipment from other areas to ensure that they have what is needed in times of emergency. One of the immediate benefits of RFID in this scenario is the fact that the location of all equipment would be known, practically eliminating the need for personnel to 'stockpile' equipment – in addition to which 'diversion' of equipment would be identified and noted. The use of GPS technologies or other less expensive locating systems, coupled with RFID at the item and unit level, would enable an environment in which it is possible to have access to the status and location of all equipment at all times.

The following is a potential scenario that illustrates the use of these technologies.



— Figure 8 —

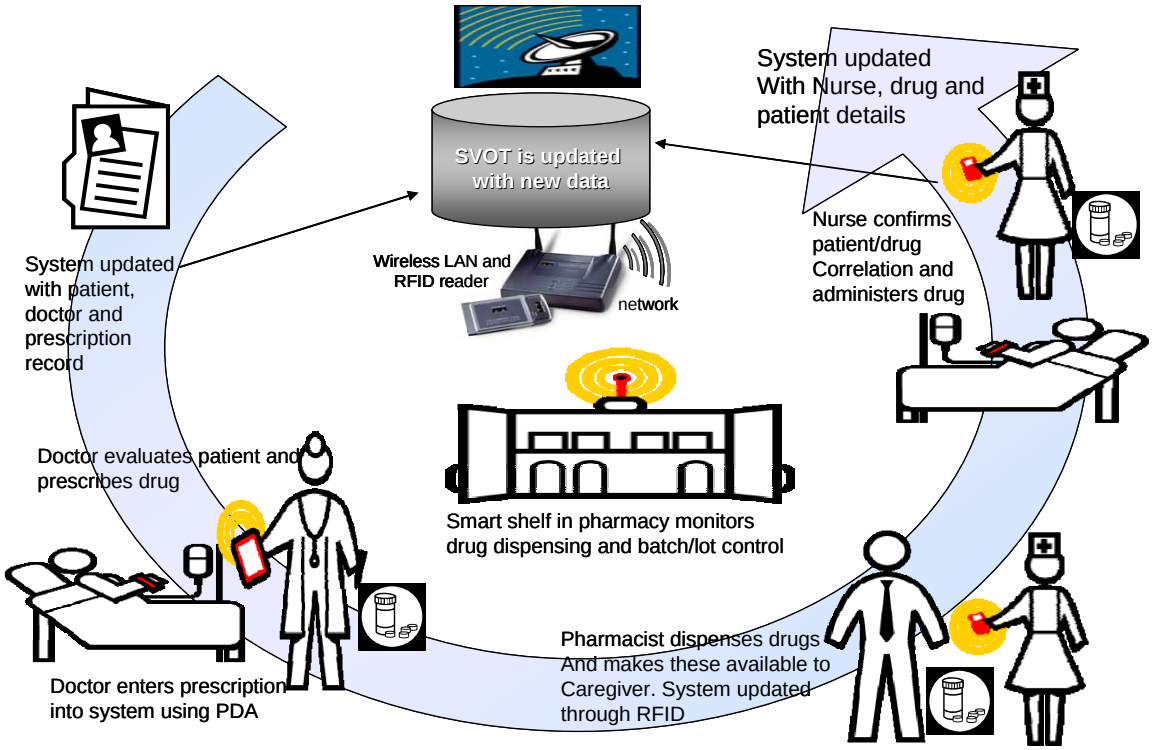
PHARMACEUTICAL CONTROL

In a recent study in the British medical system, it was stated that eleven percent (11%) of emergency room cases are associated with improper use of drugs. In the US medical system drug dispensing errors lead to seven thousand (7,000) deaths per year as well as a financial loss in the billions of dollars. One of the highest risks in a clinical environment is the incorrect dispensing and administering of drugs. Accurate statistics in terms of loss of human life as a result of this factor are not available. However, the areas of error have been allocated as follows:

- 39% in prescribing (reduced with computerized provider order entry – CPOE)
- 12% in transcribing (reduced with appropriate pharmacy information systems)
- 11% in dispensing (reduced with automation)
- 38% in administration (reduced with bar code)

Auto ID/Bar-code enabled medication administration – or ABMA – systems have already provided enormous value to the early adopters who have implemented this technology. Introducing RFID into the equation – in conjunction with the initiatives already in place with Pharmaceutical manufacturers – would assist in ensuring that the right drug, in the right dose is administered to the right patient at the right time. RFID has many advantages over the use of barcodes, specifically related to not needing to have line of sight in order to 'read' item level details. This is important at both the dispensing as well as the patient administration level. The ability to confirm that patient identity through a RFID enabled bracelet, making the association between the patient record, the drug dose and the care giver (even if the bracelet is obscured by bedclothes) is valuable in reducing patient disruption, an issue with elderly patients.

Use of RFID for Pharmaceutical Dispensing and Control



— Figure 9 —

CONTROL OF SUPPLIES

Having an accurate inventory of critical parts – especially surgical parts, for example pace makers, replacement joints and ancillary supplies – is imperative for successful patient care as well as cost control.

Of almost equal importance is control of the supplies and ancillary medications that are required during surgical and other procedures. Currently the control of these items is limited to those really high dollar items that need to be monitored and controlled. The most common method uses a combination of secured cabinets and barcodes in order to catalog and control the dispensing and use of these items. This process is labor intensive with few checks and balances. In most cases each of the items has a bar code sticker that is removed when the item is used. The barcode is placed on the patient paperwork and entered into the administrative information system once the procedure is complete. This process is potentially prone to error, in addition to which in some cases the healthcare provider neglects to update the information systems with inventory adjustments. As a result, the on hand inventory is frequently inaccurate – in many cases compensated for by higher inventory holdings than necessary.

The introduction of bar codes has assisted in streamlining the control and administration of critical supplies. An enhancement through the introduction of RFID would have many benefits: to include better material control as well as elimination of many labor and time intensive tasks that take critical caregivers away from their primary role. (One nurse that I spoke to estimated that as much as 70% of her time is taken up with administration and paper work.) As with the monitoring and control of critical assets, the combination of RFID, Smart shelf and other technologies would create an environment in which it is possible to have total inventory accuracy, while at the same time creating a link between patient and consumables.

PROCEDURE CONTROL – ADMINISTRATION / ENSURE CORRECT PATIENT / PORRECT PROCEDURE

Anyone who has been through a surgical procedure can testify to the fact that the actual 'surgeon time' is a relatively small portion of the clinical experience. In many cases the surgeon never gets to meet the patient prior to the procedure, relying on the information on the patient's chart in terms of what needs to take place and what the problem areas are. Introducing RFID into the process has many benefits.

The value and use of 13.56 MHz RFID tags for critical processes in the clinical environment is reflected in the newly approved Tag Surgical Marker system (referenced later in table of examples). This system includes a tag with an integrated passive transponder. The system includes an RFID reader, an encoder and a printer.

Here's how it works:

- The patient's name and surgical site are printed on the tag. The inside of the tag is encoded with the date of surgery, type of procedure and name of surgeon. The tag is scanned with a desktop RFID reader for confirmation by the patient and is then placed in the patient's hospital file.
- On the day of surgery, the tag is removed from the file and scanned again, and the encoded information is verified by the patient. The tag, which has an adhesive backing, is then placed on the patient's body near the surgical site.

In the operating room, the tag is again scanned and the encoded information is verified with the patient's chart. The tag is removed just before surgery and returned to the patient's hospital file.

There are several RFID applications available in order to mark the procedure, linking this with the patient record. In this manner it is possible to ensure that the surgeon performs the appropriate procedure, that any supplies and pharmaceuticals are noted, and that the record is meticulously updated.

In addition, the use of RFID can streamline the administration of supplies, surgical implants, and related tools and equipment. Tracking each item through the process – to include the sterilization process if applicable, can be achieved through the use of RFID. This may require specialized RFID tags that can withstand the sterilization process, such as SAW-based technology[5].

COST CONTROL

There are many areas within a clinical environment where process efficiencies can be translated into cost savings. For example:

- Better visibility of where everything is makes a more cost efficient operation, saving both labor and materials
- Reduction in manual and time intensive processes would reduce costs
- Reduction in liability/insurance costs, better asset utilization, and reduction in inventory – all drivers for cost reduction.

---

5 SAW = surface acoustic wave. This type of RFID device can withstand extremes in temperature and gamma ray exposure, unlike the standard silicon-based RFID technology.

CARE CHAIN NIRVANA OR REAL VIRTUALITY?

The previous pages depict an information Nirvana for the Care Chain. Or is it? The introduction of RFID into a medical and clinical environment is in fact not a pipe dream – there are many 'real world' implementations where each of the challenges outlined above have been addressed through the introduction of RFID and networked technologies. The pharmaceutical industry has already adopted RFID to secure the Chain of Custody for high risk drugs, creating an electronic audit trail – or e-pedigree. Mandates from retailers and the US Department of Defense have created additional catalysts for the more widespread adoption of RFID – many of which have a potential impact on the life sciences industry.

Although there are no specific mandates in place for the introduction of RFID into the clinical environment, there are many instances where this and related technologies have been adopted to track patients and assets, as well as to monitor the dispensing and administration of drugs and medical devices. In many cases the primary drivers have been financial – in others they are motivated by risk reduction and other concerns[6].

A series of examples of the use of RFID in clinical settings is included in Table 1 below:

— Table 1 — Examples of the use of RFID in Clinical Environments

Application	Case Study	Technology Components
Patient and Caregiver Tracking	VeriChip –	http://www.verichipcorp.com The chip, approximately the size of a grain of rice, includes a unique serial number. In interrogation, this reference ties back to data maintained in a subscriber supplied data base. The chip is inserted under the skin (in a simple surgical procedure) and can be interrogated by a proprietary VeriChip reader. VeriChip security systems are used in approx. 900 U.S. hospitals, http://www.verichipcorp.com/content/solutions/1111170295 including: St. Elizabeth Medical Center, Northern Kentucky http://www.stelizabeth.com Wuesthoff Medical Center, Rockledge, FL http://www.wuesthoff.com/default.aspx Doctors Hospital of Dallas, Dallas, TX http://www.doctorshospitaldallas.com Northside Hospital, Atlanta, GA http://www.verichipcorp.com/files/hugs_news_q3_2003.pdf Bayfront Medical Center, St. Petersburg, FL http://www.verichipcorp.com/files/bayfront.pdf MountainView Hospital, Las Vegas, NV http://www.verichipcorp.com/files/mountainview.pdf Firelands Regional Medical Center, Sandusky, OH http://www.verichipcorp.com/files/firelands.pdf

6 See figure 8 on page 34 — Creating a Future Forward Care Chain – taking the 3Pe approach.

Application	Case	Technology Components
Cont. **Patient and Caregiver Tracking**	Cont. VeriChip –	Crouse Hospital, Syracuse, NY http://www.verichipcorp.com/files/crouse.pdf Jackson County Schneck Memorial Hospital, Seymour, IN http://www.verichipcorp.com/files/schneck.pdf Brighton Gardens of Towson, Baltimore, MD http://www.verichipcorp.com/files/brighton.pdf Silver Creek Leisure Living, Bull Head, AZ http://www.verichipcorp.com/files/silvercreek.pdf Folsom Convalescent Hospital, Folsom, CA http://www.verichipcorp.com/files/wm_companion_issue1_2001.pdf
	Chang-Gung Memorial Hospital, in Keelung, Taiwan, has begun issuing RFID wristbands to its surgical patients.	http://www.cgmh.org.tw/eng2002/intr_kel.htm The RFID-based system provided by Precision Dynamics Corp. (PDC) http://www.pdcorp.com/ includes RFID embedded wristbands that are updated during patient admission. The tags used allow hospital administrators to encrypt a portion of the data, so that if the wristband is lost, it cannot be deciphered by another party. In addition, some data (such as blood type) is read-only and cannot be changed, while other data can be updated by surgeons, nurses and other hospital staff. Enhancements to the system will enable healthcare providers to use the RFID enabled wristbands for tracking a patient's data throughout his or her stay in a hospital. The wristbands will be used in conjunction with RFID-enabled patient-monitoring devices, including those that measure a patient's blood pressure or enzyme levels. In a cardiac unit, for example, medical personnel would be able to update such tag data as a patient's enzyme level in real-time.
	Xtag Infant Security System	The Xtag system consists of a bracelet with an embedded battery-powered tag that operates at 433.92 MHz, with readers placed at doorways and in hospital hallways, and software that manages the system. The transponder in a baby's or patient's bracelet or a staff member's ID badge emits a signal every two seconds. Readers placed throughout the facility pick up the signal and transmit location data to the software.
	Ekahau	Ekahau provides real-time locating (c.1-meter accuracy) using existing Wi-Fi (802.11) access points that are already installed in many, if not most healthcare institutions. The RFID tags use the signal strength from multiple access points to triangulate their own position in the facility. Used for tracking elderly patients or those with Alzheimers, through a combination of active tags and software that is installed in the wireless network. Another application of this technology relates to the provisioning of caregivers in the ER environment with active tags that are fitted with an alert button or "panic button". The location of each tag and communication of data is done through the 802.11 W-Lan. In the case of an emergency problem situation the caregiver presses the panic button on their RFID tag, which notifies security personnel and gives them the exact location of the tag generating the alarm.

— Table 1 Cont. —

Application	Case Study	Technology Components
Asset Control	Massachu-setts General Hospital	Mobile Aspects deployed the first trial system of " iRIS" for managing inventory and access to medical supplies and surgical parts (includes TI 13.56 RFID components).
	University of Maryland	Asset tracking of critical equipment used in critical care and emergency set-tings. Active 433MHz technology from NaviTag is used.
	Ekahau	Wheelchairs in the patient discharge area are tagged and monitored through the W-LAN (providing the ability to monitor assets even when in the parking area of the facility). This provides better control of wheelchairs, an asset that is critical to the efficient discharge of patients.
	Reading Hospital (Reading, PA) and Catholic Medical Center- Kang-Nam St. Mary's Hospital (Seoul, Korea).	AeroScout Wi-Fi-based Active RFID solution is integrated with the Cisco 2700 Series Wireless Location Appliance to provide asset tracking, locating and management capabilities. equipment costs.
Pharmaceu-tical Control (linked into patient re-cords and bill-ing systems)	Mobile Aspects – One System of Control is in-stalled at King's Daughters Medi-cal Center Heart and Vascular Center	Integrated with the Patient Tracking System, the Drug Delivery and Anesthesia Workstation calls up pertinent information regarding the patient to whom the drugs are being administered. Because it is linked to the hospital's physician order-entry system, where doctors enter drug prescriptions, the workstation alerts a user if he or she removes the wrong drug, or one that will cause a drug reaction or allergy in the patient, or if the physician's prescription conflicts with another drug the patient is already receiving. The workstation also updates the patient's electronic medical record with all drugs and supplies administered.
Control of Supplies (with the ad-ditional bene-fits of patient care tracking)	The King's Daughters Medical Cen-ter (KDMC)	http://www.kdmc.com/ Introduced a RFID system to track the addition and removal of cardiac medical devices from a storage cabinet, and to assist with billing and the tracking of patient care. With the new system, cardiac nurses use their proximity ID cards to open a locked cabinet in which devices such as coronary artery stents are stored. The devices are used by the cardiac, electrophysiology and vascular catheteriza-tion labs located on the second and fourth floors of the hospital. After an ISO 15693 standard 13.56 MHz RFID interrogator (reader) built into the cabinet scans a nurse's proximity card, the nurse uses a computer touchpad to enter the name of the patient. A tagged device is removed from the shelf in the cabi-net, and that same RFID interrogator reads all the other tagged items remain-ing in the cabinet, thereby determining which device was taken. The patient and medical device data goes to the Mobile Aspects database, where it is analyzed and routed to the appropriate departments at the hospital for billing, inventory tracking and patient-care tracking.

— Table 1 Cont. —

Application	Case Study	Technology Components
Procedure Control	Keelung Chang Gung Memorial Hospital, Taiwan	Precision Dynamics Corp. (PDC) http://www.pdcorp.com/, automatic wrist-band identification RFID enabled systems will be used in the hospital's operating room to identify the correct patient, surgical site, nurse, blood type and doctor, in order to help reduce human errors and enhance patient safety.
	SurgiChip – Patent pending but approved by FDA	http:/www.surgichip.com SurgiChip Tag Surgical Marker system. This product, manufactured by SurgiChip of Palm Beach Gardens, Florida, includes a tag with an integrated passive transponder. The system includes an RFID reader, an encoder and a printer.
	Ekahau	An additional application of the combination of the software and the active tags (operating at 802.11) relates to the patient throughout monitoring in both outpatient and Operating Room environments. The software component identifies bottlenecks and provides tools for scheduling patient processing based on FIFO principles.
Record Tracking	London Health Sciences Centre and St. Joseph's Health Care	Radiology and Imaging Services wanted to Create an eRadiology suite where images are stored and accessed online for easy access by caregivers. This was supported by the use of RFID for data capture. RFID tags are used to track patients from admission to discharge and make an association to the images that are then made available to appropriate diagnostic personnel. Using RFID for accuracy at the patient/image level ensures that there are no errors when reviewing these records.
Tracking of Pathology Samples	La Timone, Marseille Medical Faculty, Hospital La Conception and the Paoli Calmettes Institute.	TAGSYS ARIO™ SDM (Small Disc Module) 13.56 MHz High-Frequency RFID tags are used to reliably, accurately and securely track and manage invaluable pathology samples.
W-LAN in support of RFID	Washington Hospital Center in Washington, D.C.	Parco Wireless http://www.parcomergedmedia.com/, a developer of an ultra-wideband RFID system for healthcare facilities, has sold its first commercial installation. In October, Parco will oversee the deployment of more than 20 readers and around 100 tags for patients and staff as well as tags for equipment throughout the emergency department of the center. The inclusion of RFID for data capture will enable personnel to track patients, from admission to discharge, using the WLAN infrastructure to share data. This will streamline processes for multiple entities, to include administrative personnel, physicians, caregivers, radiology and lab personnel, as well as pharmacy dispensing and recording processes.

— End of Table 1 —

As is apparent from the above series of examples, the application and value of RFID in clinical settings has vast potential in many functional areas. Although the application of RFID in clinical settings is still in early stages and is not yet in widespread use, there has already been a broad array of environments and applications where it has been implemented, proving that the technology works and can provide high value. The primary business driver for the implementation of RFID is increased patient safety – with secondary objectives of asset tracking, and control of clinical process and procedures. It is anticipated that there will be many ancillary benefits through the adoption of this technology. These include process efficiencies, better inventory control, better utilization of critical assets, and a more productive work environment for care givers. Improvements in each of these key areas should have associated cost savings – an added bonus. Implementations of the technology are relatively immature, and it is therefore difficult to obtain quantitative evidence of savings achieved. Whatever the numbers, estimates are that they will more than offset the up front investment in appliances and associated networks.

Obstacles to Implementing RFID in Clinical Settings

Whether considering the implementation of RFID from a user or a provider perspective, there are several considerations that need to be taken into account. Some of these are technical, others are regulatory, and yet others are philosophical. They can be summarized in the following categories:

- Cost of technology and implementation resources
- Privacy issues – patient records/HIPAA
- Interference with other equipment and human interaction
- Orientation and Training of Healthcare Providers

COST OF TECHNOLOGY AND IMPLEMENTATION RESOURCES

In many cases, benefits that can be achieved come at a high financial cost – an inhibitor of more widespread adoption of RFID in clinical environments. The RFID mandates from Wal-Mart, DoD, and other major retailers is increasing the number of passive tags consumed by several orders of magnitude. This, combined with standardization, is resulting in dramatic reductions in cost[7], which enables a much broader set of items to be tagged. As more institutions adopt the technology, it will be more apparent that this technology can enhance the efforts of care givers to reduce risk while achieving efficiencies across the industry.

---

7 Passive tags cost more than $1 just a few years ago. They are now available for $0.15 in quantities of a million. The price will drop even more during the next few years as production ramps from hundreds of millions of tags up to hundreds of billions of tags.

An additional issue relates to the maturity of existing information systems within the clinical environment. As an industry, Healthcare and Lifesciences have tended to be 'laggards' with regard to the adoption of information technology – other than applications related to billing and compliance. Coupled with a lack of internal expertise with regard to RFID and related technologies, the lack of systems needed to process and diffuse data captured with RFID could be an inhibitor that needs to be considered.

The implementation of RFID is a tricky process. In contrast to conventional IT projects where the bulk of the work is in the digital domain (e.g. software development and configuration), RFID projects require a lot of work in the physical domain—the quirky world of RF. Implementations still require a non-trivial amount of custom engineering to make everything work, although each year the amount of custom engineering required is reduced. Although this technology has been in existence for many years, there is still a shortage of skilled personnel who understand both the science and the physics of RFID. In addition, it is important to develop a detailed process and procedure map, at both a before and after level. And it is equally important to ensure that there are no loose ends upon completion, and that a change management plan is developed.

PRIVACY ISSUES – PATIENT RECORDS / HIPAA

One of the most sensitive areas in the healthcare industry relates to the privacy and control of patient and medical information. This challenges the vision we have outlined, with information streaming through a myriad of information systems, making unique patient level data available to care givers across an extended Care Chain. The Health Insurance Portability and Accountability Act (HIPAA) has very specific requirements related to the sharing of patient and procedure information. The introduction of RFID, with the possible unintended transmission of healthcare-related data through wireless networks has raised a new level of concern. Of equal concern is the issue of 'intellectual property – IP" – a much debated issue, especially in view of the growing use of tele-medicine at a global level. The debate continues: "Who owns the information? The patient? The doctor? The pharmaceutical company?" Heated discussion aside, these are issues that need to be considered when gathering data in a digital format, potentially making this available to many in a ubiquitous manner.

And then there are issues that are of concern to privacy advocates – for example, spychips.com and CASPIAN. These organizations have an arena, and their influence cannot be ignored in the healthcare industry, where they have already expressed some interest and concern. However, despite the raised awareness of the potential impact of RFID from a privacy perspective, this has not impacted the roll-out of this technology where this makes sense.

EPCglobal privacy recommendations apply. The use of RFID should not be made secret to the patients. Information on the safety and use of RFID and the information collected should be clearly described and prominently made available to patients.

Privacy is a subject worthy of a whole separate discussion. Areas of possible risk related to privacy issues, as well as remedial action, should be taken into account when introducing RFID into a clinical environment.

INTERFERENCE WITH OTHER EQUIPMENT AND HUMAN INTERACTION

There is another concern about possible health risk from wireless devices – to include RFID – on personnel and patients in clinical environments. This appears to be unfounded, but needs to be considered. Available evidence today suggests that there is no clear correlation between low-power wireless use and health issues.

Recent studies strongly suggest that the use of RF related technologies does not create health risks. Two important recent studies and a white paper that reached this conclusion:

- A report written by Dr. John D. Boice, Jr. and Dr. Joseph K. McLaughlin of the International Epidemiology Institute in the United States in September 2002 for the Swedish Radiation Protection Authority. http://www.ssi.se/ssi_rapporter/pdf/ssi_rapp_2002_16.pdf
- A report to the European Commission from the Scientific Committee on Toxicity, Ecotoxicity, and the Environment, titled "Opinion on Possible Effects of Electromagnetic Fields, Radio Frequency Fields, and Microwave Radiation on Human Health." http://ec.europa.eu/comm/food/fs/sc/sct/out128_en.pdf
- A whitepaper from Cisco Systems on Wireless Systems and RF Safety Issues: **http://www-europe.cisco.com/application/pdf/en/us/guest/products/ps4076/c1244/ccmigration_09186a0080088791.pdf**

Few studies deal directly with the effects of WLAN devices. The emission levels of WLAN and RFID tags are below RF emission levels from typical cellular telephones. Therefore, any conclusions relating to the safety of cellular telephone equipment can almost certainly be applied to WLAN or RFID devices.

The RF emission levels from a typical WLAN are well within the safety emission level thresholds set by the World Health Organization (WHO).

As referenced in this document, there are several initiatives within the FDA to utilize auto identification technology and associated software to secure the healthcare supply chain. Although there are no specific FDA mandates in this regard as yet, the FDA has provided guidelines in terms of appropriate frequencies for RFID implementation – see next page:

"The tag readers will work by emitting electromagnetic energy at radio frequencies of 13.565 megahertz, 902-928 megahertz or 2.4 gigahertz, and at powers in compliance with regulatory requirements of the Federal Communications Commission (i.e. 1-4 watts effective isotropically radiated power)." FDA

"A further consideration is the potential interference of RFID with other equipment in the clinical environment. All applications for RFID that are in place as evidenced in the list of examples have no adverse affect on the equipment, assets or networked devices. More evidence from the implementation of wireless LANS in a clinical environment indicates no negative impact on Medical Devices." FDA

IMPACT ON MEDICAL DEVICES
Another concern about cellular telephones has been their potential impact on medical devices. Many hospitals ban such phones from emergency rooms or other sensitive areas. Again, this has led some to question whether wireless networking devices can be used in proximity to medical equipment.
To address these concerns, manufacturers of wireless networking devices have to design systems that reduce emissions that could interfere with medical devices and that comply with both the FCC and European Commission emission levels required for devices operating in a medical environment, specifically the EN 55011 emission standards.
Tests in clinical environments indicate that a wireless network device operating at 2.4GHz had no negative impact on pacemakers and other medical implant devices. Further tests indicated that there was no negative impact on MRI suite performance – another area of concern.

Cisco Systems

These guidelines and recommendations will need to be taken into account when implementing RFID into a clinical environment.

ORIENTATION AND TRAINING OF CLINICAL PRACTITIONERS

As the old adage states:

'You can take a horse to water but you cannot make it drink!'

The message is clear - no matter how great the value of the solution, it is imperative to make sure that all parties involved understand the issues and the benefits and are committed to the success of the project. Starting at the top of the organizational hierarchy, it is important that management understand the potential return on investment and the time involved before this can be realized. Another key issue relates to the education and orientation of personnel on the basic components of RFID technology. Fears of potential radiation need to be addressed, as well as any other concerns that caregivers may have related to what they perceive to be a new technology. Also what needs to be addressed is change management related to the replacement of inventory with information, elimination of paper based processes, and other areas that may cause concern for nurses, doctors and administration personnel.

We should never underestimate the power of the front-line workers to sabotage an implementation if they are afraid it will compromise their work or their job. Nurses and doctors may be wary of exposing their secret stashes. The benefits to caregivers and to the quality of care need to be clearly articulated, *repeatedly*.

It is therefore important to create an orientation and training program that takes into account the technical competence of all participants (as well as any areas of concern), and tailoring the program to the audience.

Developing a Model for a Future Forward Care Chain – Taking the 3Pe Approach

ChainLink Research has developed a high performance model for supply chain that is useful across different industry or geographic environments. Adoption of this model, evaluating the key elements of Policy, Process, Performance and Enablers – and integrating these into a collaborative environment will enable supply chain monitoring and control.

As with any collaborative relationship, it is important that all players are aware of the needs, expectations and metrics that are applicable. In this manner, it is possible to create an integrated flow of people, products and information, from patient admission to discharge and a state of wellness. This includes taking into account the key elements of 3Pe – Policy, Process, Performance and Enablers.

POLICY – PLAYING BY THE RULES AND WORKING WITH THE RULE MAKERS

As outlined in the previous sections, the clinical environment is highly regulated and requires multiple levels of reporting throughout the patient treatment process. In the United States, the key policy maker is the FDA. The primary goal of this organization is risk mitigation, ensuring that every possible precaution is taken to ensure the safety and effectiveness of the healthcare system. As such, the potential benefits of auto ID technologies in general and RFID in particular have been evaluated by this organization in the context of this goal. A candid perspective is reflected in a recent report on unique device identification, conducted in April 2005 [8]. This document evaluates each component of auto identification in great detail, taking into account benefits from the perspective of all constituents, as well as identifying potential challenges and constraints.

Ensuring that any RFID implementation takes into account rules, regulations and guidelines of authorities and regulatory bodies, and incorporating these into a strategic plan will assist in highlighting areas of immediate opportunity as well as potential risks.

Table 2 on the next page identifies the primary constituents in the Care Chain, together with roles, responsibilities and performance measurement criteria.

8 FDA Report on Unique Device Identification, April 2005
http://www.fda.gov/cdrh/ocd/uidevices011606.html

KEY PLAYERS IN THE CHAIN OF CARE		
Constituent Profile	Role and Responsibilities	Care Chain Performance
Patient	• Provide accurate personal information to care givers • Communicate medical symptoms and concerns • Follow prescribed treatments Obtain insurance and/or pay for treatment	• Efficacious cost-effective treatment • Detailed record of each patient's medical history, related family medical history and areas of concern/ potential hazard
Hospital / Clinical Setting	Provide clean and safe environment, effective processes, and proper equipment and supplies for the care of sick, and protection of caregivers	• Zero deaths and disabilities as a result of negligent care • Preferred provider – ease of admission, success of care, cost of treatment
Medical Specialists / Doctors	Diagnose and treat ailments in patients	Patient restored to good health with zero side effects or complications
Pharmacies / Pharma mfg	Dispensing of drugs and supplies in compliance with prescriptions	• Correct drug in correct dose for correct patient • Zero counterfeit, expired or compromised drugs
Care givers / Nursing Staff	Provide appropriate care at the patient and bedside level	Patient responds to care and is discharged in good health
Regulatory and Control Agencies	Ensure a safe and secure environment for the prescription of drugs, performance of surgical procedures	Zero irregular deaths or disablement as a result of negligence or lack of control
Healthcare Insurance Providers	Compensate medical community for services rendered according to agreed rates and schedules	Correct processing of claims and timely reimbursement to patient as appropriate
Medical Device Manufacturers	Manufacture and supply effective equipment in compliance with specifications	• Equipment is available, operational, and effective. • All related supplies are available as required • Use of equipment is not hazardous to providers or patients

— Table 2 —

PROCESS – DEFINING THE LINKS IN THE CARE CHAIN

In order to understand the inter-dependencies of each of the processes and procedures that take place in the clinical environment, it is important to review each of the critical areas from patient administration to discharge and home health administration. The following chart outlines each of the key functional areas, responsible parties and areas for improvement.

LINK LEVEL PROCESS	PARTICIPANTS AND CONSTITUENTS	COLLABORATIVE ATTRIBUTES	ACTIVE METRICS	ROLE OF RFID
Patient Admission	• Admission personnel • Patient • Nursing personnel • Insurance carrier	• Unique patient level information, to include health insurance details • Patient medical history (Allergies and special considerations) • Symptoms of specific medical inci-	• Correct patient, correct data • No redundant data entry • Special considerations communicated to all • Patient history updated in real time	• Patient data recorded on RFID enabled bracelet • Patient can be located as they are moved through the clinical process through a combination of RFID tags and readers
Triage and Diagnosis	• Patient • Nurses • Doctors • Clinicians • Radiologists • Pathologists	Digital view of patient history, symptoms, administration of pharmaceuticals as well as all procedures that take place	Single version of the truth – at the patient and procedure level	RFID enabled bracelet identifies patient and can be associated with online medical record and history of care in
Operating room	• Patient • Doctor • Nurses • Representatives from medical device company (if applicable)	• Detailed patient and diagnostic record available to all • Link between patient, medical devices and supplies at unique instance level	• All personnel are on the same page with regard to treatment, history and any precautions necessary • Patient record reflects specific instance of implants, supplies, medications	• RFID enabled bracelet identifies patient • RFID 'label' when placed on location for procedure ensures accuracy • RFID control for equipment and supplies – inventory and location
Pharmaceutical and Supplies administration and control	• Nurses • Doctors • Patient • Manufacturer of drugs and devices/ supplies	• Inventory control – lot and batch control • Link between nurse, supplies and patient at unique instance level • Automated billing of supplies to patient account	• Inventory accurate and no out of stocks • FEFO – reduced obsolescence • Correct dose, correct patient on schedule • Accurate medical record and health insurance submis-	• RFID on dispensing equipment – for example smart shelf • RFID on pharmaceutical at the unit level • RFID link between patient, nurse and drug administered
Recovery and patient care	• Patient • Nurse • Doctor • Hospital • Health Insurance carrier	Patient history and care updated in real time	Accurate medical records, accurate bill	RFID provides unique record for all process and procedures at specific patient level

— Table 3 —

LINK LEVEL PROCESS	PARTICIPANTS AND CONSTITUENTS	COLLABORATIVE ATTRIBUTES	ACTIVE METRICS	ROLE OF RFID
Patient release	• Patient • Clinical Administration	Patient history and home care, follow up shared with appropriate family members and care givers	Detailed record of drugs and other medical products administered as well as recovery program as appropriate	RFID enables data capture at the specific instance and updates information system environment
Billing and Health insurance filing	• Clinical Administration • Health Insurance Provider • Patient	Accurate list of procedures, services and supplies according to patient record and agreed rates and schedules	Accurate billing record in compliance with agreements and regulations	Records are created as part of RFID audit trail – in real time, related to specific instances of each process and proce-
Home care as applicable	• Patient • Home care nurse	Continued care program as prescribed by medical personnel in clinical environment	Consistent care and total recovery / stabilization for patient (dependant on medical situation)	RFID enabled devices for patient monitoring, drug dispensing and equipment control (subject to HIPAA and other restrictions)

— End of Table 3 —

PERFORMANCE – DEVELOPING A FUTURE FORWARD MODEL

In order to move from the current practice to a high performance Care Chain environment, it is necessary to follow a clearly defined roadmap. This Future Forward model will enable all participants to transition from their current practices and procedures to a highly automated environment with minimal disruption.

Step 1 – Enhanced Process and Control

Key process and procedures across the Chain of Care should be agreed upon and carefully monitored to ensure compliance

- Review current data capture and reporting points
- Identify areas of constraint and remedial action
- Review current information system requirements – internally and externally to Care Chain
- Ensure that all metrics are aligned across the Care Chain
- Engage and involve stakeholders and caregivers in upfront definition throughout the process, so that they take ownership and don't feel threatened.

Step 2 – Introduction of RFID, Sensing and Monitoring Technologies

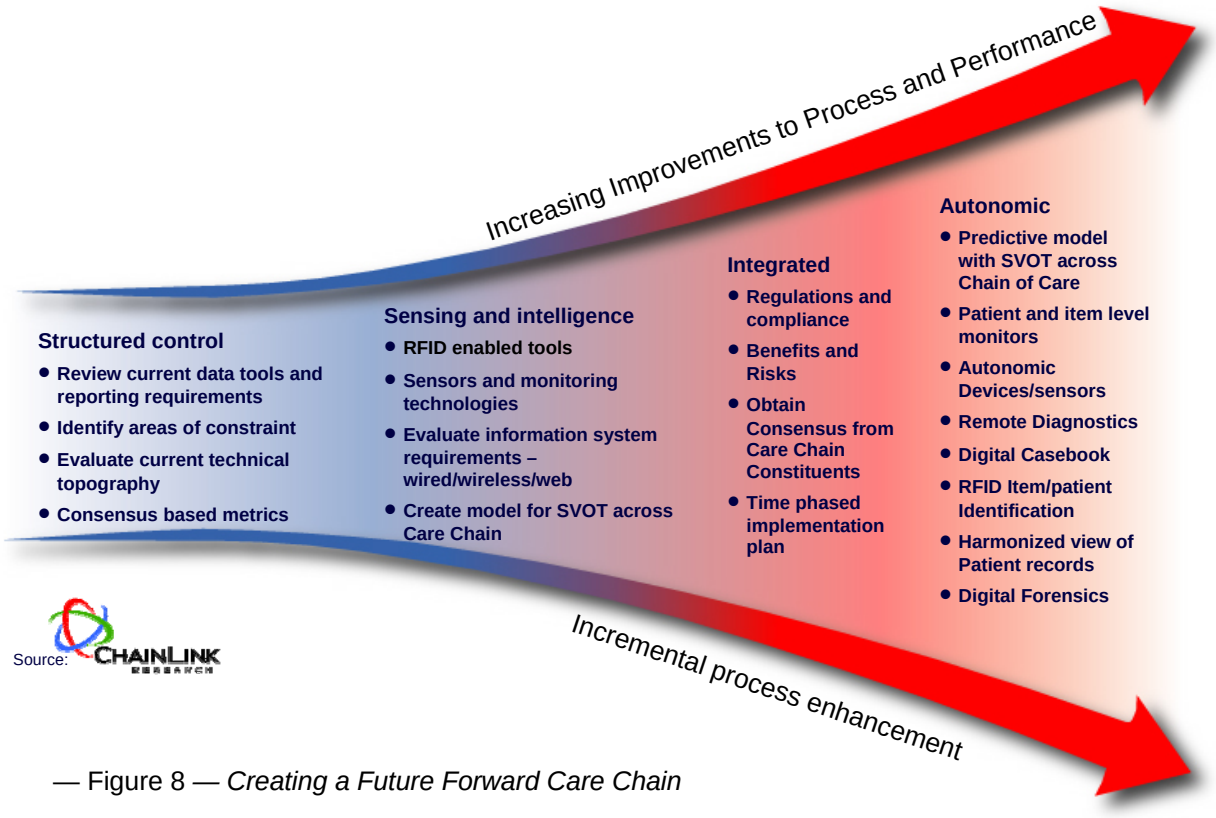
- Introduce RFID for data capture and update – need to implement at Process 1 – Patient Admission
- Evaluate existing infrastructure and data sources in order to identify intersection points for additional data capture during Care Chain processes
- Evaluate the use of sensors and monitoring devices as additional sources of data capture
- Develop implementation plan in order to create 'Single Version of the Truth' across specific links in the Care Chain

Step 3 – Integrated and Collaborative Care Chain

- Review regulatory and technical constraints to creating an integrated view across the Care Chain
- Evaluate benefits and risks and develop implementation plan
- Obtain consensus from Care Chain constituents regarding information sharing and control
- Develop time phased implementation plan for creation of 'Chain of Care' at the shared information and collaborative level

Step 4 – Autonomic Care Chain Model

Create an autonomous environment leveraging a combination of RFID, sensors, readers, wired and wireless networks in order to enable the monitoring and control of patients, equipment, pharmaceuticals and supplies throughout the Care Chain without human intervention.



— Figure 8 — *Creating a Future Forward Care Chain*

ENABLERS

Having defined the business issues, at the policy and process level, it is appropriate to review the technical components of a potential solution. Key elements for consideration include:

- RFID tags and readers
- Networks
- Frequencies
- Databases and applications

RFID Tags and Readers

RFID tags and sensor technologies can be broken into two primary categories:

- Passive tags – Smaller than active tags, and relatively inexpensive, passive-RFID tags have no internal power and must be brought close to an antenna/reader in order to be interrogated (ranges can be a few inches up to 10 meters, depending on the technology used). Passive tags are useful for identifying people and objects in controlled settings and over relatively short distances.

- Active tags – These tags include a battery and transmit a signal over a relatively long range (up to 100 meters), making them useful for identifying and locating personnel and equipment over relatively large distances.
- RFID Readers – There are a variety of RFID readers available, ranging from handheld devices, RFID enabled PDAs to fixed and mounted readers, located in key areas of the facility.

Due to the relatively 'closed loop' nature of clinical environments (i.e. tags don't generally leave the facility or they are often returned), the use of active RFID tags, in particular reusable tags, is preferred over the use of passive tags. This is true when tracking assets and in many cases personnel. The combination of these more robust and functional units and smaller passive tags (attached to patient bracelets, etc.) enables a solution that is cost effective and scaleable.

Networks

Gathering data through RFID and related technologies has many merits. Ensuring that this is transmitted and integrated into the desired information systems requires consideration of what is required to co-exist with other network components that support the sharing of information within a hospital, clinic or other locale within the Care Chain.

Wireless technology has been universally adopted by the healthcare community – both within and outside clinical environments. Hand held wireless PDAs are as common as stethoscopes and thermometers – nurses and doctors carry portable computers to access and update patient information, mobile phones have replaced pagers and older telephony instruments – the list goes on. Wireless local area networks (W-LAN) are becoming increasingly more common in clinical environments. A further advantage of wireless networks relates to the convergence of network security, access control and application functionality with network components. In many cases it is possible to leverage existing investments in W-LAN technologies for an RFID implementation, reducing the 'total cost of ownership' TCO. Guidelines for the 'Medical Grade Network' include specifications for appropriate network components and software applications[9].

9 The requirement for the provision of a 'Medical Grade Network" has been acknowledged and network service providers have responded by developing tools and technologies to create the desired elements of this network. See Addendum for providers

Frequencies

There is a very rich range of frequencies that RFID legally operates within the Electro magnetic Spectrum. The range is from low frequency (125 kHz) to microwave frequencies (2.45 GHz & 5.8 GHz,).

Frequency and Wave Lengths

FREQUENCY	DESIGNATION	ABBR	WAVELENGTH
3-30 kHz	Very low frequency	VLF	100,000-10,000
30-300 kHz	Low frequency	LF	10,000-1,000 m
300-3000	Medium frequency	MF	1,000-100 m
3-30 MHz	High frequency	HF	100-10 m
30-300 MHz	Very high frequency	VHF	10-1 m
300-3000	Ultra high frequency	UHF	1 m-10 cm
3-30 GHz	Super high frequency	SHF	10-1 cm
30-300 GHz	Extremely high frequency	EHF	1 cm-1 mm

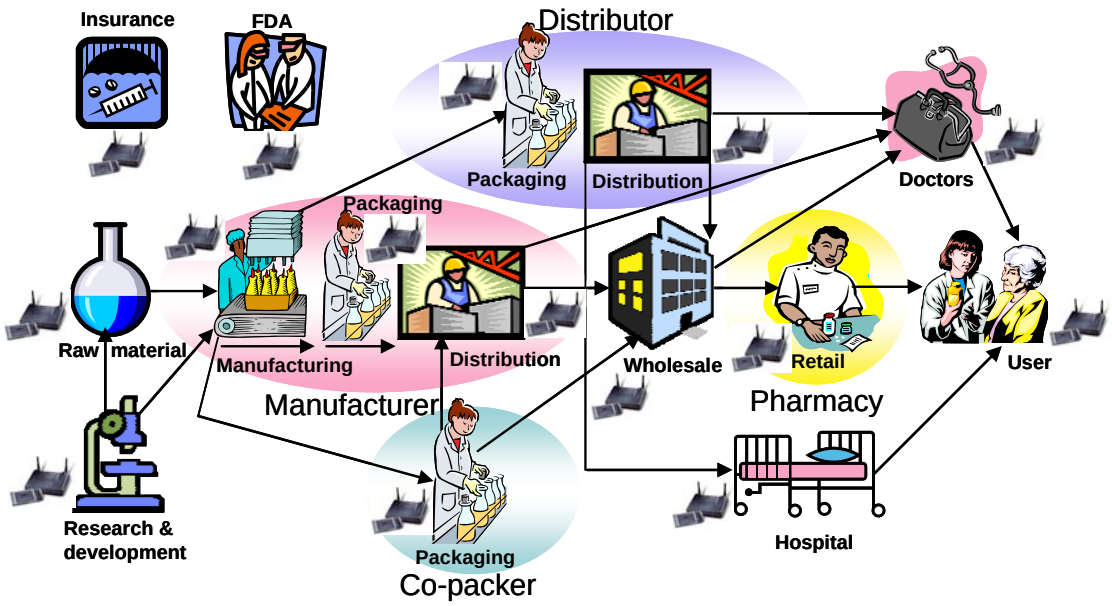
kHz=kilohertz or 1,000 Hz; MHz=megahertz or 1,000 kHz; GHz=gigahertz or 1,000 MHz

Databases — Information Systems

The information gathered through the use of RFID will need to be integrated into current and future information systems in place within the clinical environment. As with all system integration, it is important to ensure that data is available in real time and is synchronized, in order to support the goal of a 'Single Version of the Truth' related to each stage in the clinical process. Applications that could benefit from RFID captured data include the following (not a comprehensive list).

- Integrated health systems (insurance carrier/hospital/provider)
- Picture Archiving Communication Systems (PACSs)
- Electronic Medical Records (EMRs)
- Computerized Physician Order Entries (CPOEs)
- Test, monitoring, tissue, etc.

The interweaving of many players, each with their own Core Information System



— Chart 11 – Overview of Information Systems in place within Clinical Environment

Conclusion

Over the years, Medical Science has benefited from the collective intellectual capital of scientists and researchers on a global scale. Historical focus has been on the discovery and development of life saving drugs, medical devices, surgical equipment and procedures. More recently, there have been collective efforts to manage and control the distribution of pharmaceuticals and healthcare products across a global network of providers and personnel. A combination of information technology, networks and other technology enablers have been adopted in order to monitor and control this critical supply chain to prevent product tampering, diversion or counterfeit. RFID has provided capabilities for service providers to safeguard the healthcare supply chain, from manufacturer to point of dispensing, ensuring a safe and secure network of pharmaceuticals and supplies. Special care environments, for example Cold Chain[10], have been identified, and specific distribution and storage models and technologies have been developed to meet their needs. This provides a foundation for the implementation of RFID (and other enablers) into the 'last inch' – the Care Chain – creating an environment that can take healthcare providers to the next level of understanding.

10 "*Cold Chains are Hot*" report—www.chainlinkresearch.com/research/detail.cfm?guid=49189262-B102-0E02-9EAC-24A8B4B3F899
"*Cold Chains are Hot*" webinar—www.chainlinkresearch.com/research/detail.cfm?guid=5911D9C0-FEDD-1A1A-8F86-D2C7B2AEBA4C

Each constituent in the Chain of Care has a responsibility to ensure that their actions are correctly recorded and reflected in the medical record. Access to this information in real time will aid in providing a safe and secure environment in which lives can be saved. RFID provides the sensory network for managing this Chain of Care – enabling a more complete and reliable sensing of that "last inch" – the patient touch point – providing a digital view of what is happening, as it happens.

The benefits can be measured at both quantitative and qualitative levels – reducing cost and manual processes, reducing the risk of errors and enhancing the patient care experience. For doctors and other caregivers, RFID provides the tools to enable true 'hands on' patient care – the magic ingredient medical science cannot replace.

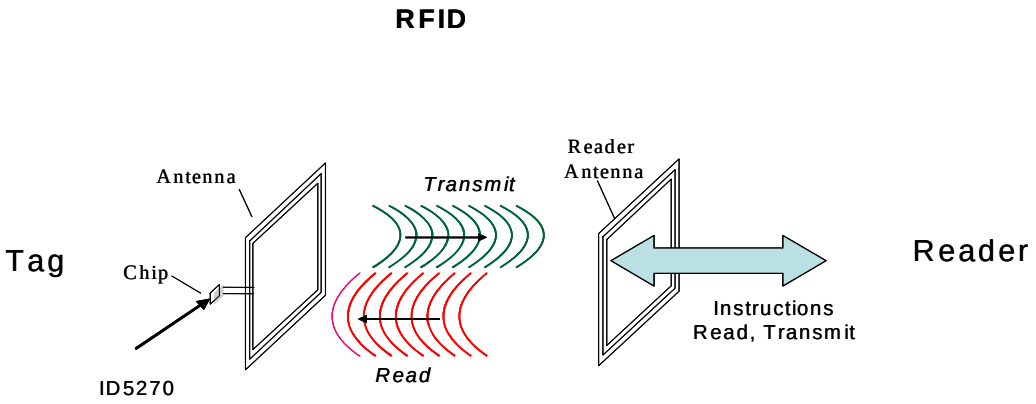
The 'digital case-book' that is facilitated through real time data capture, at the event versus transaction level provides a true reflection of the patient medical history – minute by minute. Diffusing this information across a secure network and making this available to global experts for diagnosis and remedy delivers on the promise of 'tele-medicine'. This digital view – what we call Digital Forensics – presents the evidence to those with the ability to decipher it, who then share their digital diagnosis with other practitioners across the globe.

The potential rewards are great – epidemics prevented, new cures discovered, lives saved, reducing the huge burden of healthcare costs.

Now is the time to take the first step.

Addendum A – RFID Concepts

RFID, or Radio Frequency Identification, is a technology solution based on the use of Radio Waves— (RF) to identify an object in the environment (Identification, or ID).



— Figure 10 —

RFID devices communicate with each other using simple data transfers through radio waves. RFID systems are comprised of “readers” and “transponders”—which are also called “tags.” Tags can be simple un-powered silicon chips, which have **antennas** attached, or fairly powerful ‘active’ technologies that are like small computers or processors that can perform a fair amount of instructions.

RFID tag: A microchip attached to an antenna that picks up signals from and sends signals to a reader. The tag contains Data.

Antenna: The antenna is the conductive element that enables the tag to send and receive data.

Reader (also called an interrogator)**:** The reader communicates with the RFID tag via radio waves and passes the information in digital form to a computer system

How does RFID work?

RFID devices come in many “flavors”; their power, frequency, and antenna design determine the read range of the system (from inches to hundreds of yards). As tags move through facilities such as stores, warehouses or hospitals they communicate with readers, identifying their location and state. As the tags come into **range** of a reader they ‘**activate**’ and power the tag, sending signals back and forth. This data may be as simple as a unique serial number, or may be comprised of many bytes of custom-defined data.

Addendum B – Providers of technology and solutions using RFID and related components for the Clinical Environment

A.C.C. Systems Inc.
One Robert Lane
Glen Head, NY 11545
516.674.0191
www.accsystemsinc.com
Distributor of RFID products for industries including healthcare.

ActiveWave Inc.
Congress Corporate Plaza
902 Clint Moore Road, Suite 118
Boca Raton, FL 33487
561.999.9422
www.activewaveinc.com
Total RFID Solution, using cutting-edge technology to provide 100% complete real-time monitoring of patient information, assets, location of equipment and more.

AeroScout USA (HQ)
901 Mariners Island Blvd.
Suite 725
San Mateo, CA 94404
650.571.0800
650.571.6660 fax
www.aeroscout.com
RFID for tracking medical devices, patients and staff.
Enterprise Visibility solutions for indoor and outdoor environments.

Agility Healthcare Solutions
4441 Cox Road
Glen Allen, VA 23060
804.523.000
804.523.4001 fax
www.trenstar.com/agility
Transforming the way healthcare facilities track, manage, measure and improve utilization of resources including medical equipment and surgical instruments while improving staff workflow and patient throughput.

Awarix
2158 Baneberry Drive
Birmingham, AL 35244
888.257.3868
www.awarix.com
Patient tracking.

Cisco Systems
170 West Tasman Dr.
San Jose, CA 95134
USA
408.526.4000
800.553.NETS
800.553.6387
www.cisco.com
Medical Grade Network.

Ekahau, Inc.
West Coast
12930 Saratoga Avenue, suite B-8
Saratoga, CA 95070
Tel: 1.866.4EKAHAU
Fax: 1.866.435.2428
East Coast
1851 Alexander Bell Drive
Suite 150
Reston, VA 20191
Tel: 1.866.4EKAHAU
Fax: 1,703.860.2028
Europe
Tallberginkatu 2
00180 Helsinki, Finland
Tel: +358.20.743 5910
www.ekahau.com
RTLS solutions for tracking personnel, patients, assets and products.

Hewlett-Packard Company
3000 Hanover Street
Palo Alto, CA 94304-1185 USA
650.857.1501
650.857.5518 fax
www.hp.com
RFID solutions for process improvement.

Information Mediary Corp.
2150 Thurston Drive, Suite 101
Ottowa, Ontario K1G5T9 Canada
613.745.8400
www.informationmediary.com
RFID sensors, readers.

Intermec Technologies Corporation
Corporate World Headquarters
6001 - 36th Avenue West
Everett, WA 98203-1264
425.348.2600
425.355.9551 fax
www.Intermec.com
RFID solutions – devices and implementation resources.

Mobile Aspects
24 S. 18th St., Suite 300
Pittsburgh, PA 15203
412.325.1690
www.mobileaspects.com
Patient and equipment tracking, iRIS System and more.

NaviTag Technologies, Inc.
99 Derby Street
Suite 200
Hingham, MA 02043
781.210.0203 phone or fax
www.navitag.com
RFID solutions for cargo tracking at a global level.

Parco
211 Marginal Way, Suite 207
Portland, ME 04104
646.837.0643
www.parcomergedmedia.com
Wireless healthcare communication systems.

Purdue Pharma L.P.
Purdue Pharmaceutical Products L.P.
Purdue Products L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901-3431
Main Phone: 203.588.8000
www.pharma.com
Innovator in the use of RFID for product lifecycle tracking.

Radianse, Inc.
439 S. Union St., Suite 403
Lawrence, MA 01843
978.974.9300
www.radianse.com
Equipment flow and people tracking.

Sculptor Developmental Technologies
501 Corporate Drive, Suite 105
Canonsburg, PA 15317
412.572.6167
www.sculptorsoftware.com
Providing fault tolerant output management solutions for the secure delivery of information to any of today's popular destinations.

SkyeTek, Inc.
2845 Wilderness Place
Boulder, CO 80301
720.565.0441
www.skyetek.com
Pharmaceutical, healthcare and RFID readers.

Spry Solutions Inc.
3930 Brookline Drive
Alpharetta, GA 30022
www.sprysolutionsinc.com
RFID-based IT solutions for healthcare including asset tracking.

SupplyScape
500 Unicorn Park Drive
Suite 102
Woburn, MA 01801
781.305.8085
www.supplyscape.com
E-pedigree for pharma.

Sure ID
Five Greentree Center
Suite 104, route 73
Mariton, NJ 08053
866.478.7343
856.817.6017 fax
www.SureID.com
Item level RFID and Pharma dispensing solutions.

Texas Instruments
6550 Chase Oaks Blvd., MS 8470
Plano, TX 75023
214.567.2511
www.ti-rfid.com
Transponders and reader systems.

UPM Raflatac (UPM Rafsec)
267 Cane Creek Road
Fletcher, NC 28732
828.651.4788
www.rafsec.com
RFID tag manufacturer.

VerdaSee Solutions, Inc.
3000 Cabot Blvd., Suite 300
Langhorne, PA 19047
215.891.9007
www.verdasee.com
Active and passive solutions including location and patient ID.

VeriChip (eXI Wireless Inc.)
1690 S. Congress Ave.
Delray Beach, FL 33445
561.805.8008
www.verichipcorp.com
RFID security solutions for people, their assets, and their environments. Technology includes the world's first and only FDA-cleared, human-implantable RFID microchip to the only patented active RFID tag with skin-sensing capabilities.

Wavetrend—USA, Canada, South America
11350 Random Hills Road
Suite 800
Fairfax, VA 22030
703.934.6013
703.591.3049 fax
www.wavetrend.net
Design, manufacture and distribution of Active Ultra Long Range (ULR) Radio Frequency Identification technology and solutions in security, defense, health, transport, mining, oil and gas, enabling assets to communicate within their environment..

Harvard Square Center
124 Mount Auburn Street, Suite 200 N.
Cambridge, MA 02138
Tel: (617) 762-4040

Email: info@clresearch.com. Website: www.clresearch.com