

RFID Pharmaceutical Tracking: From Manufacturer Through In Vivo Drug Delivery

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Advances in medical technology rely heavily on the collection and analysis of measured data to facilitate patient diagnosis and business decisions. The healthcare industry, particularly pharmaceuticals and diagnostic processes, has an ongoing need to improve item tracking and data collection to improve the quality of care while reducing cost. The remote, non-invasive characteristics of radio frequency identification (RFID) can facilitate the information needs of healthcare without imposing additional burden onto the patient or the staff. Properly deployed RFID enabled devices can provide convenient and accurate data for disease diagnosis, evaluation of prescription noncompliance, and identification of medication dosage errors. This paper describes an overview of the concept of an all-encompassing RFID pharmaceutical tracking system that begins with compliance documentation from the drug manufacturer and continues through the confirmation of patient compliance by capsule extraction from the bottle into a pill case and ultimately ingested or inserted into the body. This system also facilitates compliance with Food and Drug Administration proposed e-pedigree requirements and provides data for healthcare decision making. An introduction to healthcare trends is provided in order to communicate the need for such a biocompatible

RFID pharmaceutical tracking system. Also presented in this paper is the overall scope of research and in vitro test method to develop biocompatible RFID tag components for use in a “pharmaceutical supply chain system” beginning with the manufacturer, continuing through distribution, and ending at the point of interest within the patient’s body. [DOI: 10.1115/1.4000495]

Keywords: *RFID, e-pedigree, pharmaceuticals, tracking*

1 Introduction

Technological advances such as microelectromechanical systems (MEMS), digital communications, and global positioning system (GPS)/radio frequency identification (RFID) applications coincide with the induction of electronic prescriptions, targeted drug delivery, nanoparticles, and biocompatible biosensors to create a new standard for medical service and a new paradigm for personalized medical care for the patient. This paradigm shift to improve the quality of healthcare is toward more intimate patient-provider relationships and better medication management. The demand for improved communication between patients, doctors, medical insurance providers, and pharmacists now includes pharmaceutical manufacturers since the requirement for electronic-pedigree (e-pedigree) documentation of pharmaceuticals was instituted by the Food and Drug Administration (FDA).

Chronic and communicable diseases negatively affect a patient's quality of life and increase the financial impacts of continued patient care. Future improvements in treatment methods and healthcare management rely on the collection of reliable data for decision making. Preventable medication administration errors and patient noncompliance impose additional burdens to patients. Development of devices and systems for improved convenient data collection, automated positive identification of medication, and patient status can eliminate some of this burden. This paper outlines a comprehensive view of pharmaceutical tracking and monitoring from the manufacturer to ingestion by the patient.

Biocompatible RFID tracking and monitoring systems can be used safely to facilitate the non-invasive collection of information to improve the quality of care to the patient. Integration of RFID technology for pharmaceutical tracking provides an immediate increased potential to optimize product delivery and logistics, ensure product safety, monitor product administration, enhance patient compliance, and ultimately improve drug effectiveness. Such an integrated RFID system capable of tracking patients, their medications, and their prescription compliance would also eliminate errors in medication administration, improper dosages, and adverse reactions to pharmaceuticals, which disproportionately affect the aging population. A wireless system capable of measuring and reporting physiologic data will not only facilitate current monitoring systems and data collection but may also create real-time methods to assess therapy and control chronic illnesses and communicable diseases. The benefits of a non-invasive, biocompatible RFID pharmaceutical tracking system along with a broader RFID application in healthcare extend beyond the clinic where potentially large amounts of data can be collected and transmitted and into the daily activities of the patient. Such RFID systems offer potentially invaluable tools to support the medical industry in its pursuit of error-free patient care.

RFID-Tagged Pharmaceuticals. The first goal in a RFID integrated system is to develop a multipurpose, ingestible RFID tag and biosensor to facilitate tracking and data collection at the tablet level from the manufacturing lot, through the pharmacy, to consumption by the patient. This involves the development and validation of a manufacturable, biocompatible RFID tag/sensor device for pills. This component of the system must be miniaturized to a scale easily incorporated into the pharmaceutical target and must maintain electronic performance while posing minimal risks to the patient. Consideration must be given to electronic effects upon

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existing diagnostic techniques, such as magnetic resonance imaging (MRI).

Two fundamental objectives must be accomplished. The first objective addresses the industrial application. The objective is to develop a biocompatible, micro-RFID tag/biosensor, incorporated into a pharmaceutical matrix, to create a system that will improve the traceability, e-pedigree, and control of prescription medication. The second objective addresses *in vivo* applications. The objective is to develop an ingestible, biocompatible RFID-tagged pharmaceutical and biosensor (BRTP) to provide confirmation of ingestion by the patient, to improve the non-invasive collection of data, and to monitor internal body conditions, such as pH, temperature, and, perhaps one day, the amount of drug released into the patient's system. This paper describes a comprehensive view of pharmaceutical tracking and monitoring from the pharmaceutical manufacturer to ingestion by the patient that meets these two objectives. In addition, the FDA e-pedigree requirements and current research uses of RFID in medical practice are described and are part of the rationale for our research objectives.

2 Background

2.1 Impact of Chronic Diseases. "Most chronic diseases do not result in sudden death. Rather, they are likely to cause people to become progressively ill and debilitated. This is especially true if their illness is not managed correctly" [1]. Chronic noncommunicable diseases account for 60% of the deaths worldwide and include cardiovascular diseases (heart disease and strokes), cancers, chronic respiratory conditions, and type II diabetes. These chronic diseases affect everyone [2] and are a significant cause of premature disability and death, as indicated by the disability adjusted-life year (DALY) statistics in epidemiological studies [3].

2.2 Impact of Medication Errors and Patient Noncompliance. Errors in medication administration, improper dosages, and adverse drug affects have been reported to occur at a rate of over 1.5×10^6 medication errors annually [4,5]. Medical errors and noncompliance disproportionately affect elderly and chronically ill patients and can have a huge impact on the spread of highly communicable diseases [6,7]. Elderly patients have a higher risk of miscommunication with their doctors and often have multiple doctors treating a variety of age-related illnesses. Annual costs are associated with reducing medication errors, monitoring dosages and dispensation, and confirming proper drug administration of patient medication is over \$1 billion [5]. There is a critical need to address these health issues using the technological resources available. A RFID biosensor that can confirm the ingestion of medications and is able to transmit that information back to the provider would be invaluable.

2.3 Data Collection Needs for Healthcare Systems. The implementation of convenient and non-invasive methods for patient care and data collection will provide information upon which to make informed policy and healthcare decisions. The entire medical community can utilize the data collected in this way to improve the care provided to the patient from the context of a business plan to providing efficient, accurate diagnosis of chronic conditions and reliable methods improving the quality of life for those affected. RFID systems are an effective means to meet these objectives.

2.4 RFID Technology. RFID is a unique identifier, similar to a bar code, generated by data-associated radio signals. The advantages of RFID over the bar code and other identification systems include the elimination of a required unobstructed visual line of sight and a significantly larger capacity to collect and communicate information. A RFID system consists of a host computer, an interrogator or reader, a media (air) interface, and a transponder or tag. RFID tags can be passive or active. Passive tags utilize the energy of a reflected signal through inductive coupling to transmit information to the initiating interrogator; active tags are powered

Table 1 FCC limits for human exposure to radio frequency radiation (adapted from Ref. [8])

Frequency range (MHz)	Electric field strength (<i>E</i>) (V/m)	Magnetic field strength (<i>H</i>) (A/m)	Power density (<i>S</i>) (mW/cm ²)	Averaging time <i>E</i> ² , <i>H</i> ² , or <i>S</i> (min)
(A) Limits for occupational/controlled exposure				
0.3–3.0	614	1.63	(100) ^a	6
3.0–30	1842/ <i>f</i>	4.89/ <i>f</i>	(900/ <i>f</i>) ^a	6
30–300	61.4	0.163	1.0	6
300–1500	—	—	<i>f</i> /300	6
1500–100,000	—	—	5	6
(B) Limits for general population/uncontrolled exposure				
0.3–1.34	614	1.63	(100) ^a	30
1.34–30	824/ <i>f</i>	2.19/ <i>f</i>	(180/ <i>f</i>) ^a	30
30–300	27.5	0.073	0.2	30
300–1500	—	—	<i>f</i> /1500	30
1500–100,000	—	—	1.0	30

f=frequency in MHz

^aPlane-wave equivalent power density.

by batteries and can support larger memory chips for longer transmission distance and submit more information. A well-planned design and utilization of RFID systems can fulfill RFID mandates and provide value-added data for business and healthcare organizations.

The real-time experiences between service providers and future customers have the potential to improve data collection and tracking of assets, patients, and patient healthcare providers in the healthcare arena. We hypothesize that these have the ability to improve efficiency in all aspects of the healthcare supply chain.

FCC Regulations and Standards for RFID Applications. Part 15 of the Federal Communications Commission (FCC) regulation for low-powered devices applies to RFID technologies. In this safety regulation, intentional radiators are recognized as posing no serious interference with other devices but must meet RF emission limitations and power restrictions. In addition to these limitations, the FCC outlines rules for human exposure to radiation in its bulletins 56 and 65, summarized in Table 1. Passive RFID systems are relatively low power; therefore, it is unlikely that these limits will be reached in most circumstances [8]. FDA has only issued draft guidelines and implications are that there is a low risk profile for low frequency radio frequencies to the body [9]. It is important to note that a study initiated by the Center for Devices and Radiological Health (CDRH) and the FDA found that radio waves have no adverse affects on drug stability and are of no risk to product quality [10].

2.5 Biocompatibility. The biocompatibility and biostability are of highest priority in developing an ingestible RFID-tagged pharmaceutical device and reader. Similar devices have successfully been implemented, such as implantable RFID chips utilized for the tracking of livestock and household pets. The development of a RFID tag has challenges inherently unique to the intended functional environment. These challenges include issues of safety, toxicity, carcinogenicity, and physiologic responses. Manufacturers of medical devices must demonstrate device biocompatibility to ensure patient safety, guarantee proper device function, and fulfill FDA regulatory requirements. The ISO 10993 standard provides principles for the evaluation of devices, including *in vitro* and *in vivo* scenarios that can be applied, in order to meet regulatory requirements.

For the development of the proposed RFID tag/biosensor, lubricity, blood compatibility, drug delivery, and antimicrobial surface properties are important considerations to reduce the chance of adverse reactions.

3 Designing for Industrial Applications

A biocompatible micro-RFID system must be designed and incorporated into a pharmaceutical matrix to improve the traceability, e-pedigree, and control of prescription medication.

Pharmaceutical Regulations (FDA) and E-pedigree. The FDA regulates the commerce of pharmaceuticals and medical devices. The Prescription Drug Marketing Act of 1987 (PDMA) [11] and the Prescription Drug Amendments of 1992 (PDA) address the regulations enforceable by the FDA. Title 21, Code of Federal Regulations (CFR) parts 203 and 205 specify that pharmaceutical wholesalers provide a statement, referred to as the pedigree, prior to each distribution of a product. The pedigree requirements include information about the wholesaler, the name of the drug, dosage, strength of the drug, and the national drug code (NDC) number [12,13]. E-pedigree has been proposed to meet the requirements of Title 21, CFR part 203. In the addendum to the FDA's Guidance for Industry, it is strongly recommended that prior transactions and lot control also be included in the e-pedigree.

RFID technology has been discussed as a viable method to meet the pharmaceutical e-pedigree mandate. One force driving pedigrees from paper to electronic forms is the concern about counterfeit drugs and forgery of paper pedigrees. The FDA's Counterfeit Drugs Task Force stated in a 2004 report that "FDA has concluded that this e-pedigree approach is a much more reliable direction for assuring the legitimacy of a drug than paper record-keeping requirements" [14]. RFID technologies can provide a platform to meet FDA requirements and are commonly suggested for both e-pedigree requirements and protection against counterfeiting [13–16].

4 Current RFID Tracking in Healthcare

4.1 Medical Resource Tracking. Tracking strategies for patients, staff members, equipment, and information can be implemented to increase the efficiency of healthcare, as well as facilitate better patient outcomes. Studies have been performed to demonstrate the opportunity for resource utilization and efficiency increases when equipment location is facilitated with a RFID system [17]. Sangwan et al. [18] proposed a RFID system for patients, charts, and equipment location within a multilevel hospital setting. This system includes an alert system to notify staff members when a tracked item is removed from defined boundaries. CYPACK has embedded RFID chips into pharmaceutical packaging to track patient compliance by monitoring when the package is opened but has not integrated it into the actual medication [19]. For surgical procedures, RFID tags have been tested for tracking and tracing surgical sponges in order to eliminate errors due to manual counting at the completion of a procedure [20].

RFID tracking systems for patients have been suggested for the containment of infectious diseases [21]. Regular monitoring of noncompliant individuals has been identified as a method to limit exposure risks. RFID systems can allow for this type of monitoring without the need for dedicated personnel.

4.1.1 Medical Record Data Collection. In addition to performing tasks in a clinical environment, the staff is required to maintain records of many activities, including the patient's vital signs and administered medications. Accurate documentation of medications and blood products is critical for patient safety and is mandated by regulatory bodies. Majority of these records are written manually or scanned with a bar code. The information contained in the bar code improves the identification of the units; however, the amount of information contained in the bar code is limited in volume and can only contain information available at the time the label is printed.

Sandler et al. [22] discussed a multiwrite, passive RFID system to track and record unit information from the manufacturer through administration to the patient. The potential benefits of

such a system include reduction in incidences of incorrect medication or dosages, accurate documentation in patient records, and consistent information delivery for a diagnosis. A RFID system that also incorporates e-pedigree information can reduce the response time for a diagnosis in emergency situations. The creation of a host system software to complement the collection and application of the data is limited only by the vision of system planners to impact day-to-day operations within a clinic. The large-scale implementation of RFID tracking systems in hospitals must overcome the physical limitations of current systems. However, currently available system components can be adapted for localized installation of systems in a clinical environment.

4.1.2 Patient Behavior Assessment. The assessment of a patient's behavior outside the clinical atmosphere has a large potential for accurate diagnosis and treatment. Common methods for data collection outside the clinical atmosphere are limited and are often inconvenient and not representative of the true condition or behavior of interest. A non-invasive RFID monitoring system has been investigated for the purpose of evaluation of a person's ability to continue independent living [23]. The RFID system is equipped with a sensor to detect the motion of the individual and tagged items of interest. The data provide numerical evidence to evaluate the behavior and capability of the individual, while reducing the labor required to perform the observation and to evaluate the patient's capacity to continue independent living.

Similarly, epidemiologic evaluation of the effectiveness, where the tagged item of interest is the pharmaceutical, could be determined from a RFID system that tracks the behavior of patients with respect to the administration of prescribed medications outside the clinical setting. The data collected could also be used as evidence of the dosage protocol for epidemiological studies or as evidence of patient compliance and the effectiveness of treatment plans for clinics or public health policies.

4.1.3 Implantable RFID Tags. RFID tags have been accepted as a means to identify and locate both wild and domestic animals. Recently, RFID tags were placed into rice sized ($2.5 \times 1.3 \text{ mm}^2$) glass capsules for subcutaneous implantation for the purpose of tracking livestock and other animals [24]. The device is biocompatible as a subcutaneous, implantable tracking device. However, adaption is not directly applicable to oral pharmaceuticals.

5 Designing for In Vivo Applications

Our goal is to design an ingestible, biocompatible RFID-tagged pharmaceutical and biosensor that is implemented and utilized to improve the non-invasive collection of data and to monitor internal body conditions, such as pH, temperature, and mass of drug released into the gastrointestinal (GI) tract. Diagnosis of patient status requires accurate information about the patient's physiologic state. Healthcare providers generally prefer less invasive techniques when the function is of better or equal benefit to the patient. Consequently, new techniques and technological innovation tools for healthcare continue to emerge for corrective and diagnostic procedures.

Current Non-Invasive Measurement Techniques in Healthcare

Measurements in the Acidic GI Tract Environment. The acidic environment of the GI tract poses challenges to designers to develop devices that can survive in the harsh environment. Ativanchayaphong et al. [25] and Fontanazza [26] investigated an implantable RFID tag for the task of diagnosing esophageal reflux. This device is viable for approximately 2 weeks in the gastrointestinal tract environment and has a footprint of 40 mm^2 . A reduction in the amplitude of the signal transmitted from the tag to the interrogator indicated the presence of acid.

A wireless endoscopy system known as the PillCam SB® used for gastrointestinal disease diagnosis has received FDA approval.

Table 2 Internationally used ISO standards

RFID technology	Pharmaceutical tracking system component	Protocol/specification	Read and/or range
Low frequency (LF)	RFID pill/bottle	ISO-18000 Part 2 (124–134 kHz)	Read
High frequency (HF)	RFID pill/bottle	ISO-18000 Part 3 (13.0–56 MHz)	Read
UHF	RFID cases and packaging	ISO-18000 Part 6 (EPC) (915 MHz)	Read
Ultrahigh frequency (active)	RFID transportation vehicles (i.e., container trailers, etc.)	ISO-18000 Part 7 (433 MHz)	Read/range

This device is comprised of a silicon chip camera, a lens, a light emitting diode (LED), a silver oxide battery, and an ultrahigh frequency (UHF) band radio telemetry transmitter, which operates at a frequency of 433 MHz and is encapsulated in a disposable, biocompatible plastic capsule ($11 \times 26 \text{ mm}^2$). It passes through the GI tract within 72 h while transmitting color images [27,28]. Another GI tract diagnostic tool, known as the SmartPill® GI monitoring system, a $13 \times 26 \text{ mm}^2$ ingestible pill, has been developed that utilizes MEMS sensors to measure pH, pressure, and transit time within the GI tract [29].

6 Designing the RFID Pharmaceutical

Realization of a functional biocompatible RFID system can be achieved with the development of a biocompatible RFID-tagged pharmaceutical and biosensor utilizing existing technological developments from MEMS, antenna design, biomaterials, material selection techniques, interdisciplinary engineering (industrial, electrical, biomedical, and manufacturing), biochemistry, and medical research. However, any RFID system designed must consist of individual components, including a tag, a transmission medium, an interrogator, and a host system, that perform predictably and reliably in the environment of intended use. Multiple tags used in interchangeable parent-child relationships will be utilized as appropriate for application in the RFID pharmaceutical tracking system.

Transmission strength and ranges, reproducibility and reliability, performance in specified environments, measurement capabilities, and durability in vivo will be considered in the experimental designs. Biocompatibility testing will be performed as necessary utilizing ISO 10993 as a guide (see Table 2). We focus on the ISO standard because it promotes interoperability. Interoperability means that multiple manufacturers can design to that standard, which reduces costs. Different tags are required every time a different frequency is utilized. Successful tabletop testing of compo-

nents and systems precludes any in vivo testing in humans or other living organisms. Figure 1 demonstrates a conceptualized progression of the biocompatible RFID-tagged pharmaceutical and biosensor for research and development. Advancement of the tag's capabilities will build upon the technology developed during earlier phases of research. The advantage of this approach is the relatively quick development of tracking systems that can be utilized for anticontrol, FDA e-pedigree, and collection business metrics at the completion of the first phase: the biocompatible RFID tag. Conceptualized biocompatible RFID systems are pictured in Fig. 2. Optimization and acceptance of this moderately simple system component will improve the technology base for the development of a pass-through RFID-tagged pharmaceutical and biosensor. The implantation of RFID tags in humans is not widely accepted; evidence of the value and biocompatibility of a RFID-tagged pharmaceutical and biosensor in the GI tract will help answer concerns about the effects of RFID technology in close proximity of tissues in living beings. The ultimate goal is to develop a RFID-tagged pharmaceutical and biosensor that can safely pass through the GI tract and then be safely eliminated from the body.

The design for six sigma research (DFSSR) methodology utilized by the RFID Supply Chain Laboratory (RfSCL) at the University of Nebraska-Lincoln is an ideal approach for the development of the RTP. This methodology provides a flexible roadmap for effective designs and can be summarized as the 3Ps (plan, predict, and perform) (refer to Fig. 3) [8].

Retail and warehouse RFID systems utilize an air interface as the transmission medium between the interrogator and the tag. The electrochemical nature and high water content of the human body pose challenges to RFID transmissions. Previous research has been conducted on the interaction of RFID communication in the presence of humans. Tabletop simulation models have been created for compliance testing of mobile communication devices

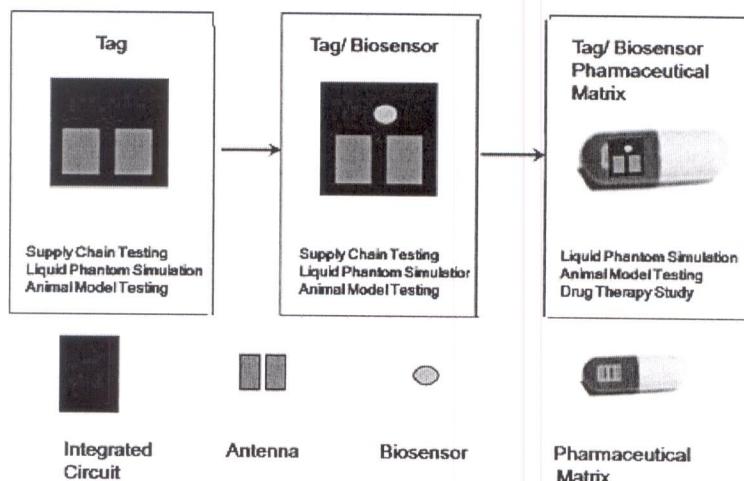


Fig. 1 Progressive research plan

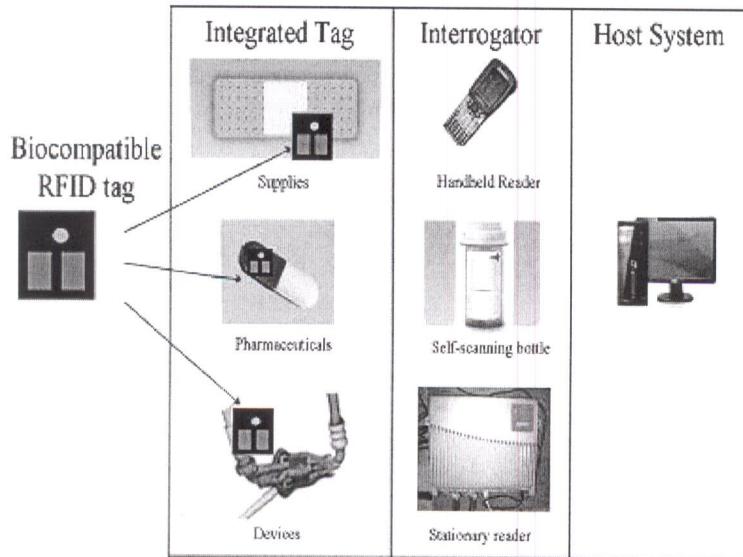


Fig. 2 Biocompatible RFID systems

[30,31], evaluation of antenna designs in close proximity to the human body [32], and evaluation of RFID sensors in the acidic GI tract environment [25]. A liquid phantom model, similar to that shown in Fig. 4, can be utilized to evaluate RFID-tagged pharmaceutical and biosensor performance.

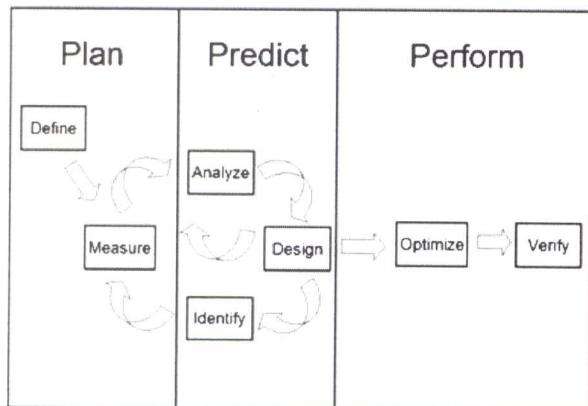


Fig. 3 DFSSR methodology

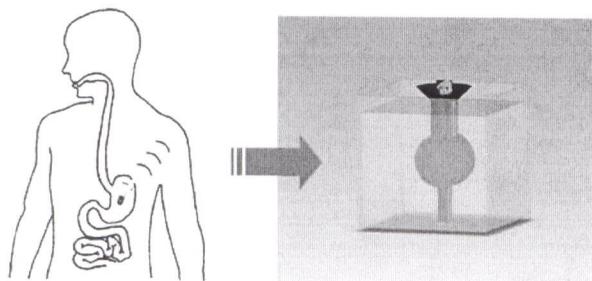


Fig. 4 Liquid phantom test apparatus for simulation of performance in human body. Reprinted with permission from Thoratec Corporation.

7 Proposed Integrated RFID Pharmaceutical System

7.1 Flowchart Diagram and Discussion of Supply Chain Including E-pedigree Integration. The flowchart diagram, shown in Fig. 5, describes how the BRTP can be integrated into the pharmaceutical supply chain. We envision that the manufacturer will program the BRT that is embedded in the pharmaceutical pills in our example. These pills then can be tracked through the supply chain from the manufacturer, through the transportation system, to the storage facility, to the distributor, and finally to the consumer until ingestion. At different parts of the supply chain, different frequencies are promoted. As the BRTP moves through the supply chain (see Fig. 5), parent-child relationships are established at the pill bottle, at the case level, at the pallet level, at the tractor trailer ship container level, and at the rail container level. The interchanging of roles takes place as required. A RFID system

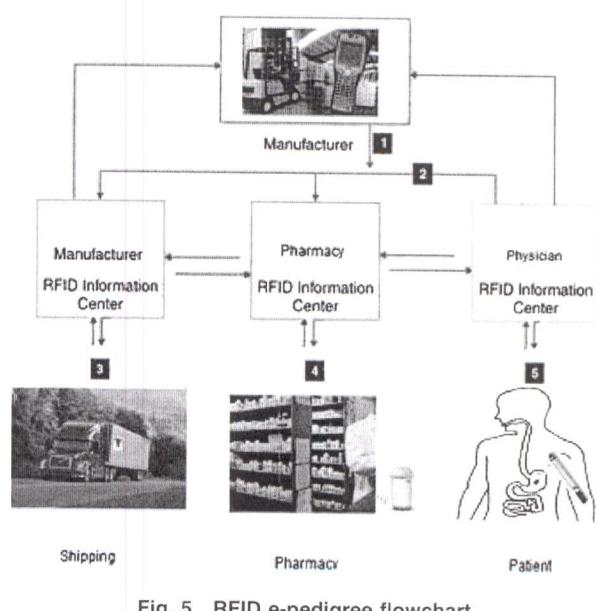


Fig. 5 RFID e-pedigree flowchart

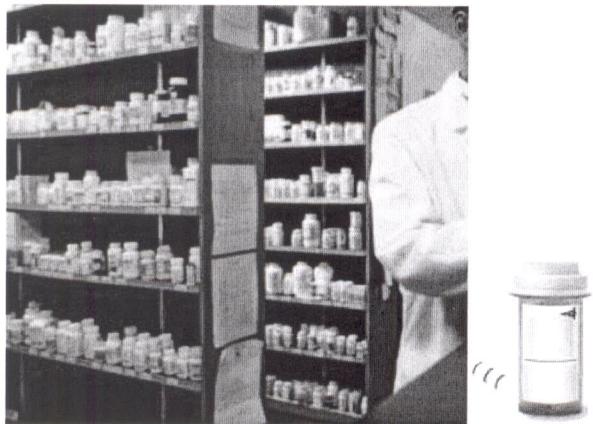


Fig. 6 RFID pharmacy. Track inventory and prescriptions filled.

logic associates the appropriate parent with the appropriate child. The parent tag seeks out the child tag. Near its final destination, this device will facilitate and automate pharmacy inventory reorders, depicted in Fig. 6. Each component of the BRTP system, the devices and scenarios we envision, are described below.

7.2 Device Components

7.2.1 Biocompatible RFID-Tagged Pharmaceutical. This BRTP, the embedded pill, will be able to contain information that includes the lot and manufacturer from which it was created to transmit to the retailer that sells the bottle to the customer. MEMS technology has progressed such that microsized RFID tags have been used to prove patency through the GI tract [33]. Our BRT will be initially designed to be $2.5 \times 1.3 \text{ mm}^2$ and will be protected from the harsh environment of the GI tract using an impermeable, biocompatible plastic membrane. As the pharmaceutical is digested and absorbed into the walls of the GI tract, the BRT will pass safely through the GI tract and will be emitted from the body, thus terminating its tracking. In our design, the pharmaceutical incorporates 13.56 MHz RFID acting as a child tag programmed with the manufacturing information in support of the e-pedigree standards described previously. The BRTP are envisioned to use the interoperable RFID standard transmission frequencies so that it can be scanned throughout the supply chain. These BRTP systems have the ability to create parent-child relationships interchangeably as needed such that information, such as manufacturing lots, can be maintained throughout the supply chain. The BRTP will also contain a temperature sensor to monitor temperature during shipping and storage, following e-pedigree standards. Feedback will confirm delivery to the pharmacy or other retail establishment. It will also allow the supplier and the retailer to monitor inventory, thereby replenishing the stock when a certain set minimum is reached. Physicians and pharmacists will be able to monitor patient compliance with the administration of the drug as directed, and patients will be able to manage their medications with confidence.

7.2.2 BRTP Bottle/Cap Reader. The device shown in Fig. 7 contains an interrogator that scans at 13.56 MHz and records the number of RFID enabled pills within the bottle. The device can transmit this information to a simple computer with downloadable software or Bluetooth.

7.3 BRTP Wand Reader. The BRTP wand will be used to scan the abdominal wall to confirm that a specific pill was ingested, as depicted in Fig. 8. It is also envisioned that the design of the wand will allow for *in vivo* detection for confirmation

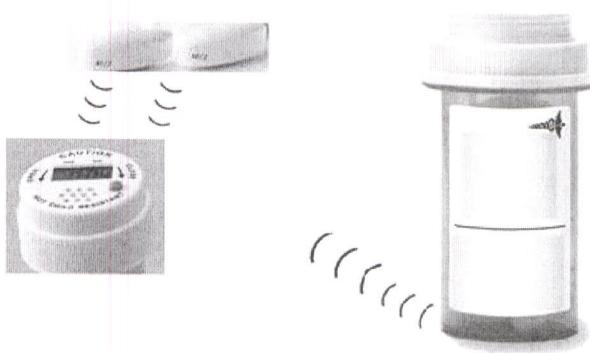


Fig. 7 RFID-tagged bottle with smart cap reader

within 72 h. Interrogation may also be performed during outpatient or surgical procedures.

7.4 Real Case Scenario. Consider a scenario in which a patient is prescribed medicine and must take two pills three times a day. The patient does not recall if they took the medicine. The patient then proceeds to count the pills in the bottle and discovers that two pills are missing. He/she confirms that two pills were taken from the bottle but is still not sure that they ingested the pills. The devices described below will allow that patient to confirm both. The BRTP bottle reader confirms that pills were taken out of the bottle, without the timely inaccurate process of counting pills. The BRT wand confirms that the pills were ingested within 24 h. Of course, this situation does not have to be limited to routinely prescribed medicine, but there is great incentive for patients, physicians, and drug manufacturers who utilize BRTP technology for medicines where compliance is critical to the outcome. For example, in infectious diseases such as tuberculosis, this research could verify that pills were taken and could assist in preventing additional outbreaks or the development of drug resistant strains of the bacteria.

8 Broader Impacts of a RFID Pharmaceutical System in Healthcare

RFID tracking of pharmaceuticals at the pill level through its entire life cycle, from the manufacturer to ingestion by the designated patient, is achievable. The challenge remains to develop and incorporate this technology into the medication in a manner that is suitable for consumption. Pharmaceutical e-pedigree requirements can be fulfilled with minimal labor with the incorporation of a RFID tracking system at the pill level. Once achieved, community health programs and epidemiological studies can utilize data collected by a pill level RFID-tagged pharmaceutical and biosensor

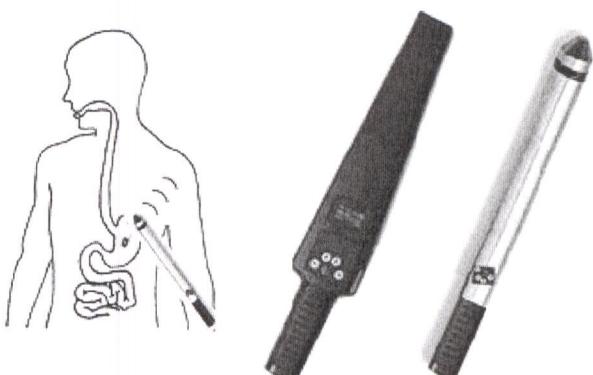


Fig. 8 Wand reader



Fig. 9 RFID pill box

to support policies and study results. Deployment RFID systems with pill level tags in a clinical environment can assist the staff in monitoring inventory, positively identifying medication administered, and confirming that the drug was administered as directed. Potential drug interactions or adverse side effects can be identified quickly to reduce the burden on the patient.

Outside the clinical environment, management of medications can be a challenge for patients. Monitoring and communication with the patient can improve patient compliance, especially in such cases when it is necessary for healthcare professionals to oversee the administration of each dose, a common practice in the treatment of tuberculosis today.

Devices that can measure real-time physiologic conditions have the greatest potential to minimize the impacts of chronic and communicable diseases. Advancing the reach of non-invasive RFID data collection to the *in vivo* point of interest requires the development of unique ingestible biosensors.

The information provided by these biocompatible RFID systems can enable the healthcare provider to make real-time adjustments to suit the individual patient needs and to improve the business dynamics with stakeholders, manufacturers, pharmacists, doctors, patients, insurance carriers, researchers, and patients. Biocompatible RFID tag deployment, via the GI tract, for example, can be more convenient for the medical staff and less painful to the patient than allowed by current measurement techniques. This convenience will increase patient compliance for repeated testing or long term monitoring and, as a result, will improve the quality of life of the patient. Ultimately, the patient is the beneficiary of improved healthcare and overall health.

This biocompatible RFID system is easily adaptable to address the needs of the elderly and those taking medication daily or for extended periods of time. The smart pill box is currently being explored as a method to ensure that seniors are compliant with medications [34]. Therefore, the incorporation of the BRT onto a pill box, as shown in Fig. 9, enhances these efforts to reduce medication errors and to ensure that medication is administered as prescribed by establishing e-pedigree requirements throughout the entire pharmaceutical supply chain. Future goals are to provide a RFID enabled platform for continuous tracking of all life-impacting pharmaceuticals to measure therapeutic impact. We theorized that the potential implementation of targeted, controlled RFID enabled drug delivery systems will one day enable us to monitor the release of drugs through the gastrointestinal tract. This further enhances the medical capability of measuring the bioavailability of drugs that are absorbed into the bloodstream to determine their efficacy.

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