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Improving Reliability of Medical Device Tracking Using Unique Device Identification

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Abstract

The term “disruptive innovation” has been the buzzword of industries looking to create technological advancements in their respective fields ever since the term was first coined in 1995. In order to invest in the future of the industry, companies are beginning to focus on new, innovative ideas that come into the market as a low-cost alternative to the sustaining innovations currently in place. Similar business-models can be seen in the healthcare industry, as physicians look to disruptive innovations to provide methods of diagnosis and treatment that are easier to perform and maintain. Companies, from medical device manufacturers to the hospitals using these devices, are now working to comply with the Federal Drug Administration Amendments Act of 2007’s requirements of Unique Device Identifiers on all equipment – a new, standardized identification system to ensure all necessary information about a device is provided. This honors thesis analyzes the recent history of disruptive innovations, in all industries and specifically healthcare, and the emergence and benefits of Unique Device Identification. Modeling of the implementation of Unique Device Identifiers in an industrial setting resulted in a 16.55% time improvement of the affected phases of the recall process, preventing 30 fatalities. When a benefit-cost analysis was performed – comparing the value of a human life to the cost of UDI implementation – the benefit of implementation outweighed the costs by 277%.

Keywords

Disruptive Innovation; Healthcare; Transportation; Reliability; Medical Devices; Real-Time Location Systems; FDAAA; Unique Device Identification; Agent Based Modeling

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Introduction

In the past 40 years, the healthcare industry has seen tremendous growth in technological advancements, revolutionizing medical care and the management of health information. The quality of equipment used in hospitals and clinics is unparalleled by its predecessors, contributing to quicker diagnoses and more effective treatment of patients. Upgraded computer-based methods of record keeping and data transfer between doctors and patients have made medical information accessible with the click of a button. These advancements to the very framework of the world's healthcare systems have been possible only through the design and implementation of disruptive innovations – convenient and affordable innovations that gain popularity as sustaining innovations eventually overshoot the needs of the majority of the market. These innovations improve over time until they take over as the standard product – put in place to make patient treatment both more efficient and more affordable (Hwang & Christensen, 2008).

While the healthcare industry's rapid modernization is being driven by disruptive innovations, consider the state of the industry decades ago and the medical field becomes drastically different: effective and efficient medical equipment of the time was too expensive for most family clinics and even some hospitals to own and operate, and computer-aided bookkeeping and data transfer was nowhere near being universally accepted and used. Most family clinics and many hospitals keep patient information on physical charts, requiring vast amounts of space for storage, and information transfer through fax was the disruptive innovation of the time. For many years, the industry retained the sustaining innovations of the period, working on improving methods that were already in place. The market was stable and effective

enough for the time, until new disruptive technologies began taking form and reshaping the industry.

Recently, concern has risen over the transportation of medical equipment to and from healthcare systems and the storage of this equipment – as a lack of visibility has frequently led to misplaced or stolen equipment – and work has been done to create a way to track this equipment throughout transportation and its working lifespan. Many technologies have been adopted to accomplish this, including Radio-Frequency Identification (RFID) chips, integration of Wi-Fi technology, and many other methods put in place to make tracking of equipment much more accessible to clinics and hospitals. One of the newest disruptive innovations to emerge in this area of focus is Unique Device Identification (UDI), a system being established by the FDA that will standardize the labeling of medical devices in the United States; this system will be used to track all devices from the manufacturer to the customer and continue to do so post-transportation.

This honors thesis analyzes the importance of disruptive technologies in the healthcare industry, as well as all industries, and discusses specific innovations affecting the tracking and management of medical devices in the U.S. market. This analysis will also delve into Unique Device Identification, considering the system design and regulations placed on labelers of medical devices, and evaluate the benefits of UDI over other disruptive technologies that are in use today. Then UDI implementation will be modeled and the benefits seen through this implementation will be discussed.

Importance of Disruptive Technologies to the Market

Disruptive technologies – though often opposed by businesses comfortably using sustaining innovations – are vital to the development and enhancement of any industry, paving the way for new and improved methods of completing complex tasks in a simpler, more efficient way. These innovations can even create an entirely new market that changes the way the world works: the Wright brothers' dream of flight established the foundation for an entirely new form of transportation, unparalleled in speed and convenience still to this day.

According to Clayton Christensen, professor of business administration at Harvard Business School and a world leader in innovative thinking, and well known for his Theory of Disruptive Innovation, there are two types of innovations: sustaining innovations and disruptive innovations (Christensen, Bohmer, & Kenagy, 2000). Sustaining innovations are new technologies that improve on the technologies already in place in a market, such as a new home computer with improved features (e.g. more storage, faster processor). Disruptive innovations, on the other hand, come into the market generally unknown, but eventually rise to take over the older technologies in place (the creation of portable laptop computers). **Figure 1** shows Christensen's depiction of the "Progress of Disruptive Innovation," and shows that eventually, a sustaining technology will surpass the needs of the market. As sustaining innovations surpass the needs of the consumers they are intended for, the price of these products continue to rise. Eventually, the cost for these items proves too much for consumers to continue purchasing them. This is when disruptive technologies start to emerge onto the scene, better serving customers that were left behind by sustaining innovations.

While disruptive technologies prove to be crucial to the continued advancement of technology – in so improving the overall well-being of the market and the consumers of the market – there will always be opposition; corporations commanding the industry will attempt to hinder these new technologies from entering the market, as they pose a financial threat to the current operational structure. Christensen illustrates why this happens with the following hypothetical situation: an entrepreneur designs a new, portable X-ray machine that costs less than a conventional X-ray machine and could be used by any clinic, saving patients the hassle of going somewhere else. The only problem is that he faces many barriers, including X-ray equipment suppliers who are threatened by this new technology, radiologists fighting for their jobs, and hospitals that rely on patients coming to them for X-rays for the profit (Christensen, Bohmer, & Kenagy, 2000).

This scenario is seen much too often in all industries: a new, innovative idea is born that could change the way the industry works for the better; however, this innovation threatens the business-model in place. The controlling parties of the industry note the financial threat that this innovation poses to their operations and work to impede the idea's progression. Change is vital to the continuous improvement of the market, regardless of what market is being affected by these disruptive technologies. While these innovations may affect the companies in the market, they prove to benefit the consumer and ensures the future of the industry, both key components to the longevity of industries.

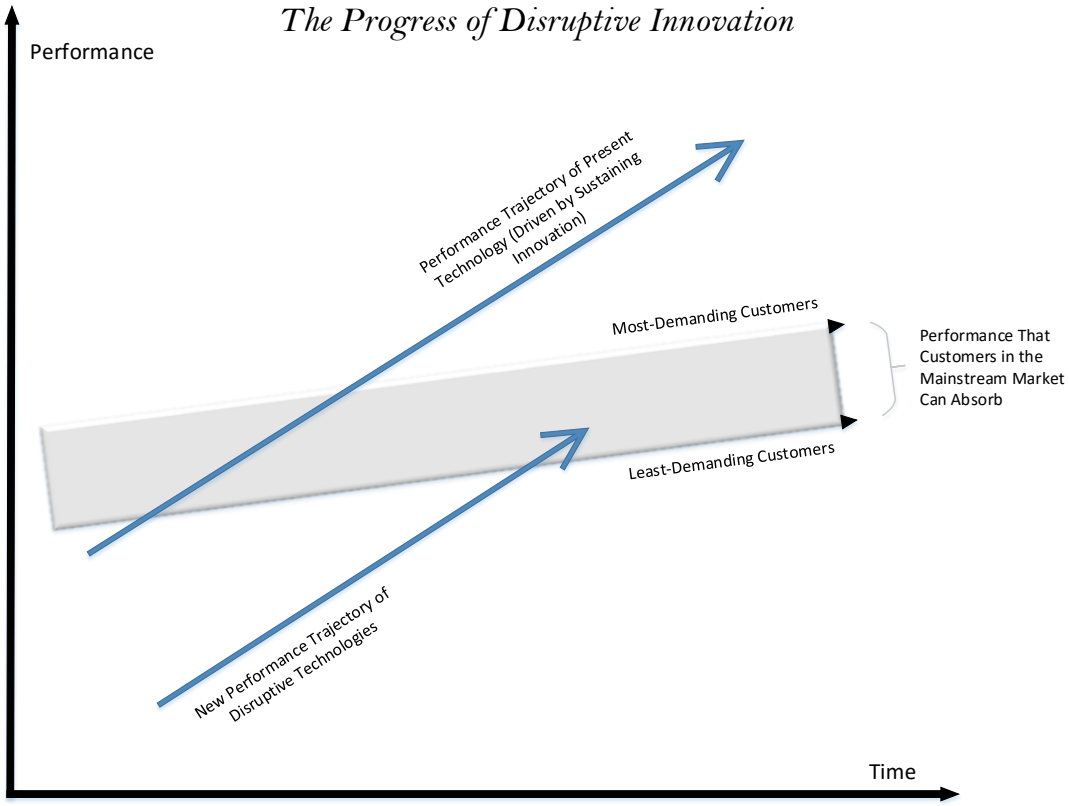


Figure 1: Christensen's Theory of Disruptive Innovation. Adapted from *Will Disruptive Innovations Cure Health Care?* by Christensen, C., Bohmer, R., & Kenagy, J. Harvard Business Review, 102-112

Disruptive Innovation in Healthcare

Disruptive technologies have always paved the way for the future of markets worldwide and will continue to do so; new, innovative ideas will always arise that will change the way a system or an industry is run. In the healthcare industry, however, disruptive innovations are not as commonplace. While methods of diagnosing and treating patients have improved over time, these improvements seem to be a continuation of sustaining technologies, instead of completely redefining the way the industry works.

Professor Christensen's model of disruptive innovation shows that disruptive technologies, while providing an improved method of performing the tasks associated with the innovation, come into the market as a cheaper alternative to the sustaining technologies. Sustaining technologies, on the other hand, continue to increase in cost as the technologies improve, making these technologies increasingly more unobtainable by the common consumer. With the large costs associated with it, the modern healthcare industry more closely follows the path of sustaining technologies.

Costs for healthcare treatment have been growing constantly for so long that people focus more on the "rate of increase of costs" than simply the change in costs. Recently, this rate of increase has started to drop, but consumers still seem to be paying much more than expected for healthcare in the form of out-of-pocket payments and deductibles. Drew Altman, President of the Kaiser Family Foundation, notes that "even though [health costs] have been growing at record low rates in recent years…the gap is widening between growth in wages and what workers pay for health premiums and deductibles" (Altman, 2015). The average worker's wages have grown 23% since 2006, but the average deductible price has increased over four times as much at a

staggering 108%. The increasing costs of medical treatments is surpassing the financial abilities of most consumers, making healthcare treatment continually more difficult for consumers to afford.

Despite the difficulties disruptive innovations seem to have in breaking into the medical field, some technologies have broken the mold of common healthcare environments and made an impact on the way medical institutions run. For example, electronic health records (EHRs) have changed the way that doctors store and distribute patient information by transitioning from the sustained idea of physical file storage to a modern, computerized method. While the concept of EHRs has been around since the 1960s, the idea didn't really stick until the 1990s, when the Institute of Medicine (IOM) started arguing, through multiple studies, the need to seriously consider the use of computerized health records in the industry (Atherton, 2011). These studies opened the industry up to the benefits of using EHRs, and many organizations sought to integrate this technology into their systems. Many modern hospitals and clinics now use EHRs to more easily store all of the information about a patient – including demographics, medical history, previous medications, etc. – which can be effortlessly distributed to a patient's other doctors safely and securely. This improved method of distribution and storage of information can be seen as a disruptive innovation to the industry itself, saving money for hospitals and clinics by allowing instantaneous transferring of information without the variable costs of time and money associated with delivery of physical information through mail or fax. While these costs are generally low, the complete elimination of them can accumulate to a substantial amount over time.

A primary focus of disruptive innovation in healthcare is the diagnosis and treatment of simple ailments; if assistant physicians and nurse practitioners could take over the simpler cases

and be able to diagnose and treat them appropriately, the primary physicians can focus on diagnosing the complex cases that a physician's office would see. A worthy indicator of positive innovation, especially in healthcare, is the push to "innovate downward in order to enable those with less-specialized training to deliver top-flight care" (Brill & Robbins, 2005). An excellent example of this is the website WebMD.com, where anyone with an Internet connection can access "credible information, supportive communities, and in-depth reference material about health subjects that matter to you," all offered by "board-certified physicians, award-winning journalists, and trained community moderators" to provide reliable information to help people better understand what their health conditions might be (WebMD, 2014). While this website was not intended to be a reliable replacement for diagnosis and treatment by a certified doctor, WebMD offers reliable information pertaining to what a person's symptoms could correspond to – keeping patients with very mild symptoms out of doctors' offices so they can focus on patients that are more in need of their services. This innovation allows for free information distribution to all people with Internet access, lightening the burden on the healthcare industry and spreading basic knowledge of medical practices globally.

While disruptive innovations are still not as commonplace as one would hope in the healthcare industry, new and exciting ideas are being generated that have the potential to change the way healthcare is provided, both for the good of the consumer and for the good of those providing these services. The goal of disruptive innovations in the healthcare industry is to make services, such as diagnosing and treatment of ailments, easier to perform so that less severe cases can be treated by less specialized individuals; this leaves the more complex issues to the most experienced doctors and clinicians. Ultimately, most ailments should be able to be treated by

family doctors and nurses, while only the extreme cases would need the services of a hospital or specialty clinic.

Disruptive Technologies Associated with Medical Device Tracking

With the advancement of medical equipment being integrated into many hospitals, health clinics, and special care units, progress must also be made in the handling, transportation, and tracking of these devices. While there has been no standardized method of tracking devices in the medical industry, a few technologies have emerged that have made tracking possible and relatively easy for clinics and hospitals to perform. Among those technologies include Radio-Frequency Identification (RFID), integration of Wi-Fi technology, Ultrasound, and Infrared systems – all of which are classified as Real-Time Location Systems. RFID's and Wi-Fi systems are the most commonplace amongst industry and healthcare systems, but there are other technologies being used, including Bluetooth, ZigBee, and Cellular tracking.

Real-Time Location Systems (RTLS) are a form of Automatic Identification and Data Capture (AIDC) – methods of identifying objects and collecting and storing data about them. AIDC's can be defined as "local systems for the identification and tracking of the location of assets and/or persons in real or near-real-time" (Kamel Boulos & Berry, 2012). The basic components of RTLS consist of a location sensor that receives a wireless signal from an identification tag which is attached to the object being tracked. The location sensor then transmits the information to the engine software, which translates the information and displays it in the application software. **Figure 2** illustrates the components of RTLS. Whether the assets being tracked are patients or machinery, RTLS have made tracking and maintenance of medical assets a much simpler and more reliable computerized process.

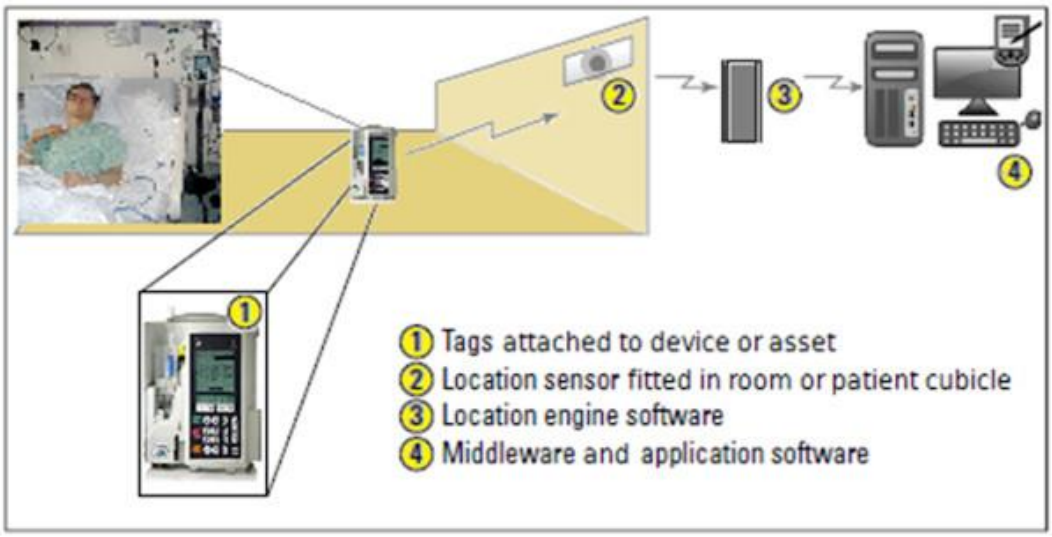


Figure 2: Basic Components of an RTLS. Reprinted from Real-time locating systems (RTLS) in healthcare: a condensed primer by Kamel Boulos, M. N., & Berry, G. *International Journal of Health Geographics, 11*, 25. http://doi.org/10.1186/1476-072X-11-25

RFIDs are used in all industries for the tracking of items and as a means to improve the process of inventory management and control. Whether it is a retail store (such as Wal-Mart) tracking all of the different SKUs that travel through their distribution centers and stores, or a transportation company (such as J.B. Hunt) using advanced RTLS technologies to bypass weigh stations, RFIDs have been integrated into a wide variety of industries to save money and improve performance. The same can be said for the healthcare industry, as RFID technology is used to both track patients within a hospital setting and machine inventory. Radio waves are transmitted from an identification tag at a specific frequency, either at specified intervals or only when needed, and sensors set to pick up waves of that frequency will gather the information and store it in the local system. RFID technology is being used in the healthcare industry for multiple purposes, from reducing inventory costs through automated replenishment requests to keeping

track of people who come into contact with potentially dangerous, infectious diseases in order to alert the hospital of who needs to be screened (Baum, 2013). The Health Industry Business Communications Council (HIBCC) cites one drawback of RFIDs as being their lack of compatibility between each other; with different standards for different RFID systems, interoperability is currently not possible, and any future innovation will most likely increase the already large cost of these systems (Figarella, Kikirekov, & Oehlmann, n.d.).

Some RTLS systems are deployed over Wireless Local Area Networks (WLAN) through Wi-Fi Access Points, allowing easy integration of tracking systems through networks already established. Ekahau, Incorporated – a leader in Wi-Fi design solutions based out of Reston, Virginia – is a large provider of RFID-over-Wi-Fi™ RTLS systems, which consist of battery-powered Wi-Fi tags attached to the devices compatible with many of the largest WLAN providers, including Cisco and Motorola. One of their systems can support up to 50,000 different tags, helping to identify the location of devices, staff, and any other equipment a company wishes to track (Ekahau, 2015). Some Wi-Fi systems, such as Ekahau's, are used with the additional incorporation of RFID technologies. However, Wi-Fi RTLS systems can also be stand-alone systems, with tags being tracked solely through the WLAN Access Points. This increases the ease of implementation, but also makes the system completely reliant on the reliability of the WLAN being used.

All of these technologies vary in mechanisms and methods, but they are all used to perform the same main task of identifying the location of assets and reporting this information to a main software system, displaying this information to the user, and performing this task as precisely as needed. It is up to the hospital or clinic to determine which type of RTLS is best for them based on qualitative/quantitative analyses, risk identification methods, and cost/benefit

analyses that will provide management with the information they need to make the right decision. With the right real-time location systems in place, and with the future complete integration of unique device identification into the healthcare industry, tracking medical devices will become quicker and easier for both manufacturers and hospitals alike.

Unique Device Identification (UDI)

In 2004, the FDA Center for Drug Evaluation and Research developed regulations requiring "drug and biological product labels contain a bar code consisting of, at a minimum, the National Drug Code (NDC) number" in order to help verify that the right drugs are being used on the right patients at the right time, in order to "reduce the number of medication errors that occur in hospitals and health care settings" (FDA, 2011). The NDC numbers are used as a standardized method of determining what exactly a drug is before treating a patient with it. Likewise, the Center for Devices and Radiological Health sought to create a standardized method of labeling medical devices that device manufacturers produce and deliver to hospitals and clinics. This new method would be used to verify products and improve patient safety by knowing exactly what is being used on or put into them.

On September 27, 2007, President George W. Bush signed into federal law the Food and Drug Administration Amendments Act (FDAAA). Part of this law "establishes a unique identifier system for all medical devices. Specifically, the FDA is directed to promulgate regulations requiring an identifier on the label of each medical device that is specific enough to identify the device through distribution and use." The law was finalized on September 24, 2013, requiring a unique device identifier (UDI) on all device labels and packages, barring any exceptions provided by the law. Before this legislation was passed, there had been no standardization concerned with the labeling of medical devices, creating ambiguity and a large variety of different labeling methods. One of the key reasons for the creation of a unique device identification system is to create a clearer, standardized method of identifying medical devices for the sake of all parties involved, including manufacturers, insurance providers, customers (hospitals, clinics, etc.), and the patients that are being treated with these devices. Before Unique

Device Identification, labeling and means of identifying medical devices and their packaging varied from manufacturer to distributor to providers, creating clashing methods between all of them. **Figure 3** provides an example of the variation of "current" methods and compares it to the standardized UDI method. When all methods coincide like the UDI method, flow of devices becomes quicker and easier throughout the supply chain. Because of this standardization of labeling, the healthcare industry should find an increase in the reliability and speed of device recalls – an issue that has threatened the safety of the patients and the credibility of the devices used on these patients.

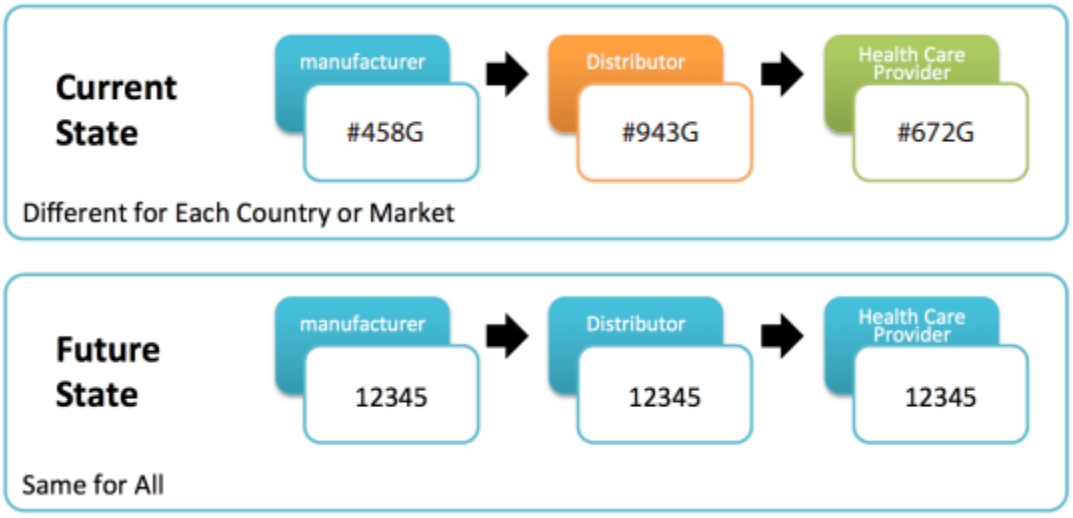


Figure 3: Comparison of the "Current" Methods to the "Future" UDI Methods. Reprinted from Improving Patient Safety Using Unique Device Identification. (n.d.). Retrieved October 16, 2015, from http://marketo.spartasystems.com/rs/spartasystems2/images/Whitepaper - UDI.pdf

A UDI consists of two major components – a Device Identifier (DI) and a Production Identifier (PI). The Global Language of Business (GS1), who is, as of December 17, 2013, the issuing agency accredited for UDI's, considers DI as a Global Trade Item Number (GTIN), which are used to "identify products and services that are either sold, delivered or invoiced at any point in the supply chain" (GS1, 2015). In other words, a GTIN is used to determine which unique product the device is, usually through barcode systems. PI consists of any additional information that appears on the device label or the packaging; this extra information could be expiration date, lot number, serial number, manufacturing date, or distinct identification codes. DI's are always necessary in a UDI – both in human-readable form and in AIDC form – while PI's are required only if the extra information is provided. **Figure 4** provides an example of a proper UDI label provided by the FDA. Note the text-based representations of the product's name, physical parameters, and storage requirements, along with a barcode that can be scanned to collect this information automatically.

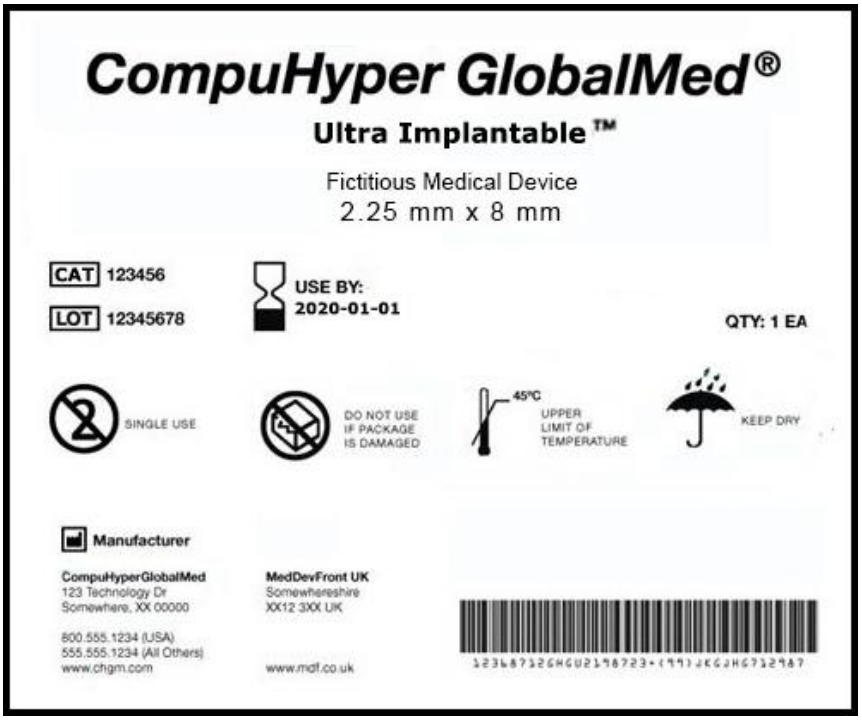


Figure 4: Example of a Unique Device Identifier. Reprinted from UDI Basics, In *U.S. Food and Drug Administration, 2015,* Retrieved October 20, 2015, from http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIBasics/default.htm

There are three classes of medical devices, based on the level of risk and amount of control required with the devices: Class I, Class II, and Class III. Class I devices generally are the most low-risk devices – such as bandages and examination gloves – and therefore have the least regulations imposed on them. Class III devices require the most regulatory control on them, due to the large risk involved with their transportation and use; examples of Class III devices include devices that are surgically placed in a patient's body, such as heart valves and prosthetics, and potentially hazardous devices that pose a high risk to those handling it. The FDA's final ruling in 2013 included different compliance dates for each class of device. All

Class III device labels and packages must bear a Unique Device Identifier by September 24, 2014 – one year after the final ruling. Class II device labels and packages must do the same two years later in 2016, and all other devices – including Class I – must have UDI's on their labels and packaging by 2018. The devices themselves must have permanent UDI labels on them if they are to be used more than once by 2016, 2018, and 2020 respectively. Therefore, by 2020, the FDA's rule of Unique Device Identification systems should be fully integrated into the United States healthcare system.

Unique Device Identifiers will eventually be integrated into Electronic Health Records in order to create an all-encompassing post-market surveillance system to track all patient information, including devices that were used on them or implanted into them. UDI will play a vital role in the development and continuous improvement of the FDA's National Medical Device Postmarket Surveillance System. This will be integrated with many forms of data – such as Medical Device Reporting (MDR), a strong surveillance network, administrative and claims data, and other tools and studies that can all be incorporated with tracking systems and UDI to provide an effective post-market surveillance system that will increase patient safety while retaining their privacy of information (FDA, 2013). This surveillance system is summarized in **Figure 5**.

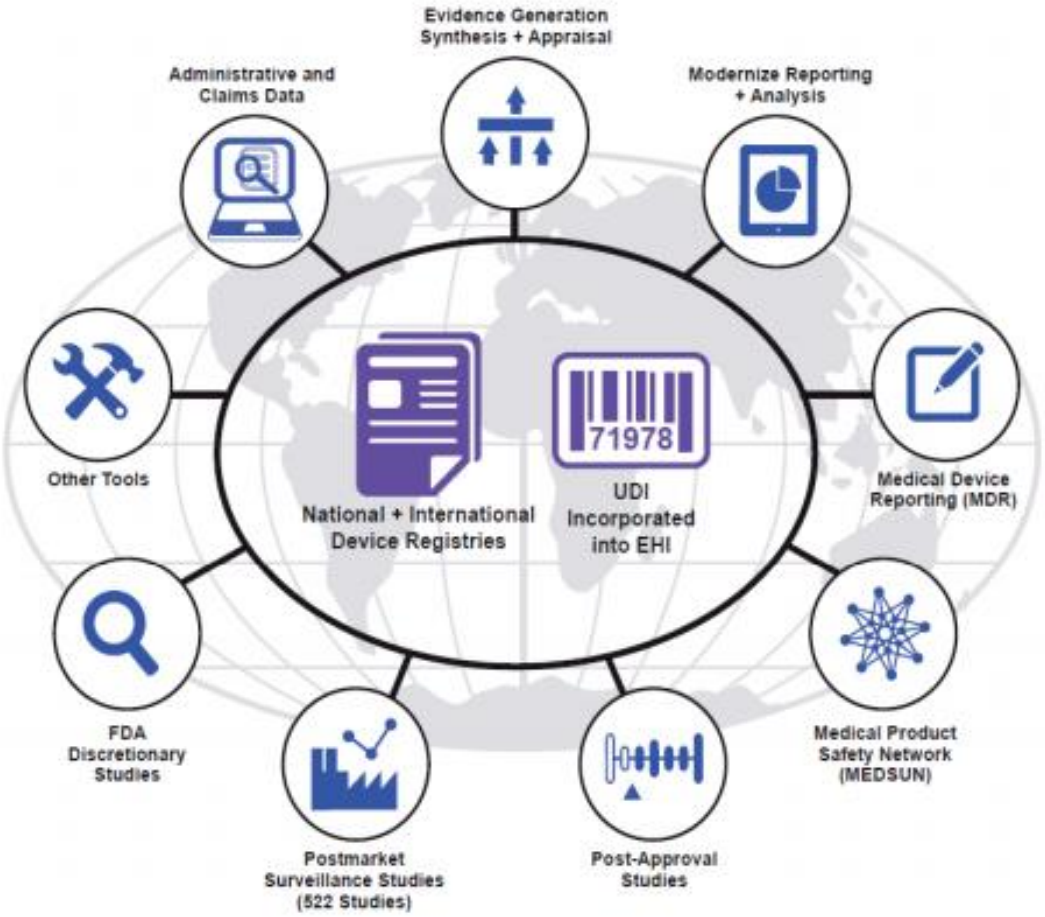


Figure 5: FDA's Planned Components of a National Medical Device Postmarket Surveillance System. Reprinted from Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps, In *U.S. Food and Drug Administration, 2013,* Retrieved October 25, 2015, from http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf

Benefits of UDI

As UDI begins to integrate into the healthcare industry, benefitting factors associated with this innovation should be apparent. UDI can be integrated with RTLS technologies to become a standardized tracking system, which can be used in multiple ways to help reduce risk involved with procedures and improve inventory control methods. UDI can also be integrated into EHR's to provide more detailed information of patients' histories for the use of doctors and their patients. The FDA is also currently creating and maintaining a universal database for information storage about all UDI's that can be accessed by anyone. This database – known as the Global Unique Device Identification Database (GUDID) – will help labelers and hospitals distinguish between devices and help define how to properly label devices. One of the UDI rule's ultimate goals is to increase the reliability of medical device tracking, ensuring that recalls of medical equipment are completed soundly and efficiently, with no devices left in the market – or worse, in a patient.

Mary Baum, chief healthcare officer at Connexall USA Inc., stresses the important roles that UDI's can play in a healthcare environment when incorporated with RTLS technologies, as it can "dramatically improve real-time decision support to deliver better outcomes" by "bridging information silos" to allow quicker decision making in the hospital (Baum, 2011). Baum illustrates this advantage with examples highlighting the potential uses in different areas of a hospital setting. RFID and UDI technologies can be integrated together to help properly identify patients and devices before going into surgery. Connecting the device to the patient before the surgery occurs can prevent cases of "wrong procedure/wrong patient" incidents, saving time and money for the hospital by preventing the need for surgery to remove the device and saving the patient from potential difficulties associated with the wrong device implants. UDI

implementation can also assist in security purposes, automatically notifying security teams if a device is taken out of the facility so they can act quickly to prevent burglaries. If technology is used to keep track of temperature in storage facilities, departments can be automatically updated by the UDI system, alerting them to a dangerous temperature change in time to relocate the devices if necessary. These three examples help to emphasize how important UDI implementation can be when used with RTLS systems in place – as safety precaution, security measurement, and risk mitigation tools.

Electronic Health Records provide doctors, hospitals, and patients with all available information about a patient, including treatments, prescriptions, number of visits, and conditions vital to the treatment of patients. One thing that EHR's do not contain at the time, however, is a list of medical devices used on, or implanted in, a patient. This information will be documented using the Unique Device Identifiers in the GUDID, and can also be integrated into EHR's in order to provide patients and doctors with all of the information necessary to better treat patients. Since EHR's can be easily distributed through multiple healthcare systems securely, doctors would be able to quickly access this information in order to help make better decisions regarding patient treatment. For example, patients that have undergone a heart valve transplant in the past need to be closely monitored during pregnancy, as the treatment during pregnancy and the birthing process have much larger risks associated with them after heart valve transplant surgeries have occurred (Butchart, 2005). In this scenario, doctors and patients would greatly benefit from UDI information in EHR's, which would immediately inform the doctors that the patient will need to be treated differently, removing the threat of mistreatment due to lack of information.

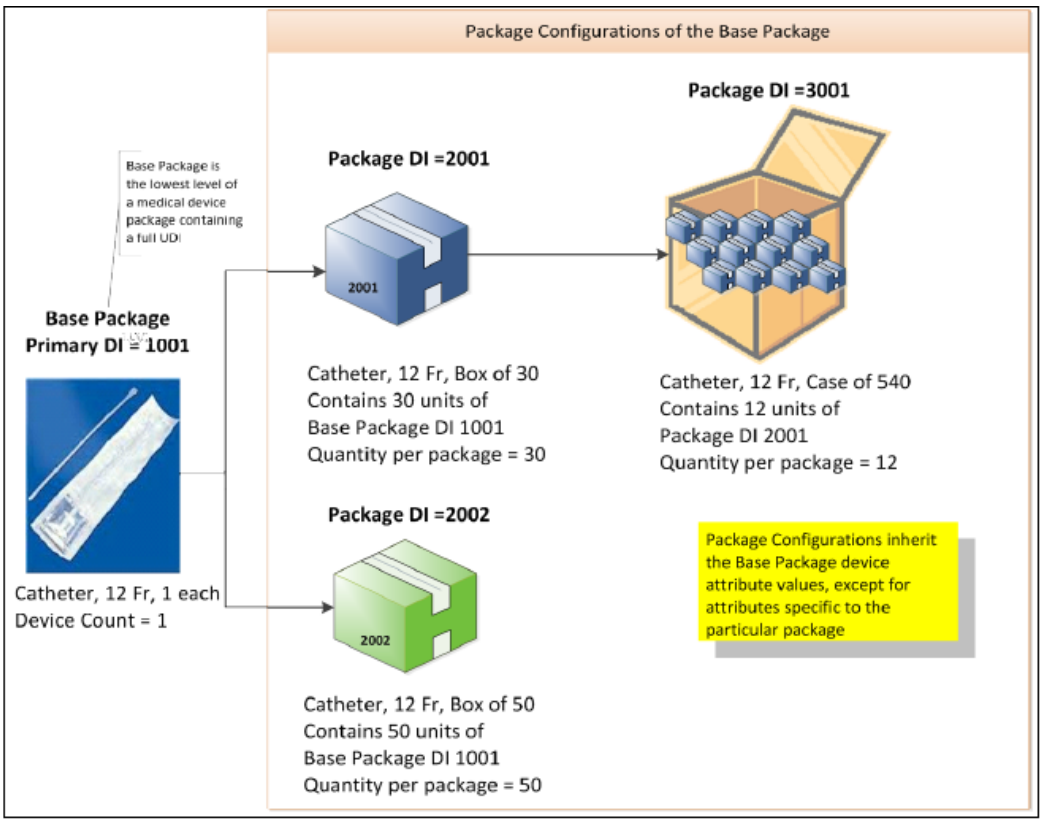
With the creation of a new method of identifying and keeping track of medical devices, the FDA decided that the next logical step would be to implement a universal database for information storage associated with medical devices and the new style of labeling. The Global Unique Device Identification Database is being created in order to store the data associated with medical devices and make this data available to everyone. The FDA will work with device labelers to ensure that all necessary information is uploaded to the GUDID and that all information uploaded is accurate and relevant to the devices.

The GUDID will only store detailed information on the Device Identifier (DI), which will serve as "the primary key to obtain device information in the database" (Center for Devices and Radiological Health, 2014). The GUDID will also provide information pertaining to what types of Production Identifiers (PI) are on the device labels, but not the exact PI's. Each submission to the GUDID will require all of the information designated in Title 21 of the Code of Federal Regulations, Part 830.310 – including, but not limited to, the name of the labeler, the DI, the name of the device, the model number, and the type of PI's that appear on the label of the device, such as serial numbers, expiration dates, and batch numbers (Code of Federal Regulations, 2014). The GUDID will ensure that all DI's are unique to the device so that DI's are not used as identifiers for multiple devices, regardless of whether or not the device is still in commercial distribution. The GUDID will note whether or not a device is still in commercial distribution as well.

Information on packaging of medical devices will also be stored in the GUDID so that hospitals and distributors will know exactly what to look for; for a device sold in boxes of thirty packages, which are sold in cartons of twelve boxes, "a different DI would be required to appear on the individual device package, on the box of thirty packages, and on the carton of twelve

boxes of thirty device packages" (Center for Devices and Radiological Health, 2014). This will ensure that any faulty packaging can be easily detected by distributors, guaranteeing the quality of the devices being shipped. The primary DI of a device will be the lowest level of packaging for it and will be used as the main identifier of the device in the GUDID. All other DI's associated with the device will be listed as secondary DI's. **Figure 6** illustrates the different types of DI's and how they will be uploaded to the GUDID. For all of the detailed information about DI records and the GUDID as a whole, visit the FDA's website and refer to the GUDID Compliance Guide.

With integration into RTLS and EHR's and the implementation of the Global Unique Device Identification Database, specifications and locations of medical devices all across the U.S. can be tracked by labelers, distributors, doctors, and patients in order to improve the overall reliability of these devices. The ultimate goal of any healthcare system is to provide reliable and safe treatment of patients, and the implementation of Unique Device Identifiers will serve only as a boost to provide safe and reliable treatment by making the location of devices as transparent as possible to all parties involved.



Base Package

Primary Device Identifier	Device Count
1001	1

Package DI

Package DI	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
2001	30	1001	Box		In Commercial Distribution
3001	12	2001	Case		In Commercial Distribution
2002	50	1001	Box		In Commercial Distribution

Figure 6: Package Configuration Example. Reprinted from Global Unique Device Identification Database (GUDID) Guidance for Industry and Food and Drug Administration Staff. (2014, June 27). Retrieved November 15, 2015, from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

Types of Modeling

In order to support the notion that UDI implementation will increase the reliability of medical device tracking through a decrease in recall time and in the number of fatalities because of a poor recall process, some type of model needs to be made and run; an abstract representation of a real-world healthcare environment can provide insight into how the system runs before implementation and how it will run after implementation. The AnyLogic Company, one of the leading simulation software providers for dynamic simulation tools, will be used to model a healthcare system setting – from the manufacturer to the consumer – both before and after UDI is implemented into the system to highlight the benefits associated with UDI implementation. These systems will be analyzed to determine the significance of this improvement for the doctors, patients, manufacturers, and every other component of the system. Ilya Grigoryev (2015), Head of Training Services at The AnyLogic Company, provides great insight into the need of modeling software and how the AnyLogic simulation software is used to model different methods of simulation modeling.

Modeling, in its many different forms, is simply a method of abstracting real-world scenarios in a virtual setting; this virtual model can then be manipulated, risk free, to find the best solution to the real-world problem. Models have always been used by people to make decisions; deciding whether or not to go to class is an example of the most fundamental form of modeling – mental modeling. This type of modeling typically involves deciding between multiple options by comparing the consequences of each alternative, which can be compared to an IF-THEN statement in most programming languages. Now, with advancements in technology, anyone can develop different kinds of models on a computer. With computers and advanced processors readily at hand, analytical models and simulation models can be quickly created and

ran to provide a much more accurate representation of the real world, increasing reliability of the results. Analytical, or "spreadsheet-based modeling," is used when relatively simple formulas can be used to adequately describe the system in question. When the system becomes too complicated to model by simple functions and becomes more dynamic in nature, simulation models can be used to monitor these complex changes in the system. Grigoryev explains that "a simulation model is always an executable model: running it builds you a trajectory of the system's state changes" (p. 10). These changes cannot be monitored with a simple analytical model, as the inner mechanisms of the model are not simple formulas, but complex rules that the system has to follow to transform an input into an output. For the UDI implementation, a simulation model will be created and ran to better abstract the complexity of a healthcare system.

Simulation modeling provides a large advantage compared to other forms of modeling in that, while mathematically providing solutions to difficult problems, they are also structured in a way that mirrors the real world system, providing a visual representation of the system as well. While analytical models are generally purely computational, simulation models can provide a representation of the flow of objects through the system while also recording data from the objects, or system, for computational analysis. Simulation modeling provides multiple modes of comprehension for the user to better reflect the real-world system in a virtual world, providing a more accurate representation of the real world.

A simulation model can be abstracted in a variety of ways, and the level of abstraction can be used to determine which method of simulation modeling to use, as each method proves useful only for a range of abstractions. Abstraction level ranges from a low abstraction of reality to a high abstraction. Low abstraction models are the most highly-detailed models, where "physical interaction, dimensions, velocities, distances, and timings" are important to model, as

all of these interactions can largely affect the system (p. 11). This high level of detail is suited best for small or microsystems, as smaller systems are more largely affected by these details. An assembly line in a facility would be modeled with a low abstraction in order to minimize bottlenecking. High abstraction models, on the other hand, provide the minimum amount of details required to model the system. These systems are normally macro in scale as compared to the low abstraction models, and are used to better understand relationships; for example, high abstraction models can be used to model "how the money [a] company spends on advertising influences [their] sales," as the main focus of the model is the company as a whole (p. 12). For this UDI implementation model, an intermediate level of abstraction will be used, as the physical space of the system is irrelevant, but the focus is still on the objects moving through the system.

AnyLogic's simulation software allows a user to choose one of three methods, or frameworks "to map a real world system to its model," of simulation modeling: System Dynamics, Discrete Event Modeling, and Agent Based Modeling (p. 13). Each method provides beneficial insight into the structure and mechanisms of a real-world system; however, a user should carefully choose which method to use based on the abstraction desired of the model.

System dynamics is a "methodology to study dynamic systems" assuming "high levels of object aggregation" and is generally used for high abstraction levels (p. 101). Large, complex systems are modeled with system dynamics to determine stocks – the characteristics of the system states – and flows – the rate of change of these system states. System dynamics models are suitable for large-scale scenarios, such as modeling population changes of a city due to industrialization in the area or environmental conditions before and after a natural disaster.

Discrete event modeling focuses more on the process that objects, or agents, flow through to move from the beginning of the system to the end. As agents move through the system, they

must pass through each process of the system. Each process requires some amount of time to accomplish; these times are normally stochastic, making the discrete model itself a stochastic model. Discrete event models are generally used for mid to low levels of abstraction where details become increasingly more important in the design of the system. Outputs gained from a discrete event model include "utilization of resources, time spent in the system or its part by an agent, waiting times, queue lengths, system throughput, bottlenecks" (p. 135-136). Examples of discrete event models include modeling the receiving dock of a distribution center or modeling the drive-thru of a fast food restaurant.

Agent based modeling is a newer form of simulation modeling that became feasible to perform because of advancements in technology that allowed models of their kind to be created and manipulated. Agent based modeling should be used when "you may not know how a system behaves, be able to identify its key variables and their dependencies, or recognize a process flow, but you may have insights into how the system's objects behave" (p. 20). The behavior of the system as a whole is irrelevant in agent based modeling compared to the agents, as it is the behavior of the agents themselves that are worth modeling. Agents can interact in agent based models, but it is not a requirement of them to do so. Agents also are not required to adapt to changes, but they can adapt to changes between each other or environmental changes as well. Examples of agent based models include modeling the adoption of a product through means of advertisement or through word-of-mouth. The Bass Diffusion Model is often used to model the diffusion of innovation and product growth and is a form of agent based modeling.

For the modeling of UDI implementation in a healthcare environment, agent based modeling will be used to focus on the flow of agents, or medical devices, throughout the market and patients and understand the influence that the Unique Device Identifiers – a change in the

healthcare environment – affects the flow of these agents. As each type of medical device has its own characteristics when it comes to their flow through the system, the focus is primarily on the behavior of these agents and not on the system as a whole. The agent based model will be able to distinguish between different classes of recalls and be able to clearly show the advantages of UDI implementation by illustrating the quantitative improvement in the recall process as seen through the medical devices.

Pre-UDI Model

In order to illustrate the advantages of incorporating UDI into the healthcare system, a model has to be designed that depicts both pre-integration and post-integration, whereby a comparison can be properly made. Before the system can be appropriately defined and modeled, an analysis of the process of recalls in the U.S. healthcare system first needs to be performed. Once the process is clearly defined, the system itself can be defined and data can be used to create a model that accurately represents the pre-integration system. Once this system is created, valid assumptions can be determined and used to create the post-integration system, which will be used to determine the benefits of UDI integration.

UDI implementation has been predicted to vastly improve the process of recalling faulty medical devices – both from hospital settings and from patients. For this reason, the main focus of this model will revolve around the recall process and the improvements to the total time required to perform a recall, efficiency of recalls, and mortality rates that the implementation of UDI is expected to bring. The model will accurately depict the recall process currently used by hospitals and the FDA, and utilize data compiled by the FDA to determine the speed of this process and the amount of deaths caused by this process. The model will then take the expected benefits of UDI implementation to determine, through valid assumptions, the expected decrease in the average time required to perform a recall and, through that, the expected decrease in deaths of patients.

The FDA's "Medical Device Recall Report" compiles information regarding the process associated with recalls, along with data of all the medical device recalls ranging from 2003-2012; this document will be used for the majority of the information for the model (FDA, 2012). The

recall process is divided into four main phases, defined by the different groups involved in each phase. This process is depicted in **Figure 7** below. Phase I begins when the manufacturer of the device becomes aware of the faulty device and initiating the recall process. The manufacturer then alerts the Office of Regulatory Affairs (ORA) district office of the issue, initiating Phase II. The district office issues a 24-hour alert to the FDA's Center for Devices and Radiological Health (CDRH), including a recommendation of the classification of recall. Now in Phase III, the CDRH then performs a final review of the issue and releases a final classification of the recall. Notices are then posted online and word is spread. Phase IV involves the physical removal of the recalled products from the environment. The recall process is not terminated until the "FDA determines that manufacturers have completed all reasonable efforts to remove or correct the product in accordance with the recall strategy, and that proper disposition or correction has been made commensurate with the degree of hazard of the recalled product" (p. 6).

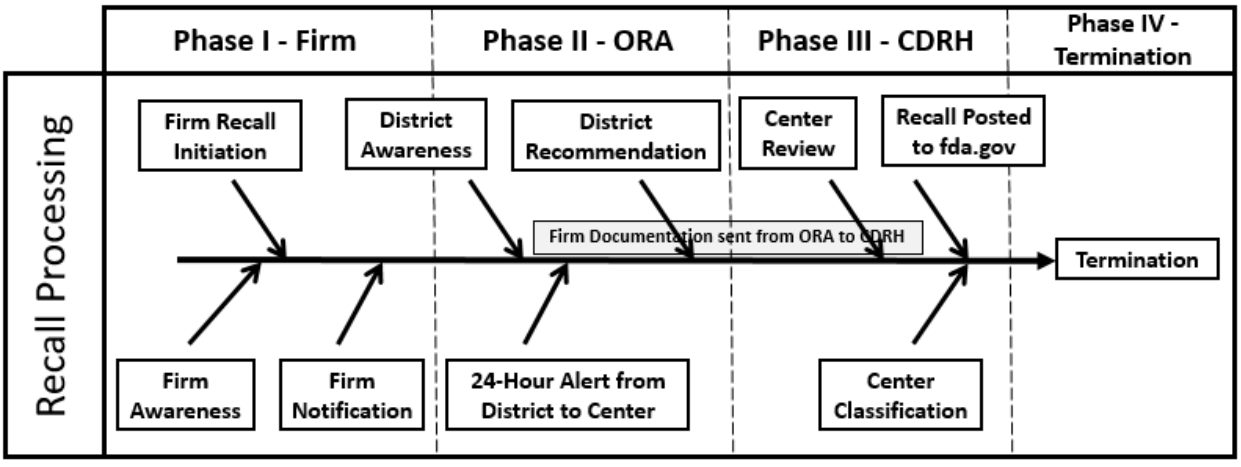


Figure 7: FDA's Recall Process. Adapted from Medical Device Recall Report: FY2003 – FY2012. Retrieved October 25, 2015, from http://www.fda.gov/downloads/aboutfda/centers offices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm388442.pdf

Medical device recalls can be classified into one of three classes, Class I – Class III, based on the severity of the consequences associated with the product being recalled. A Class I recall is issued when "there is a reasonable probability that use of or exposure to a violative product will cause serious adverse health consequences or death" (p. 4). Class II recalls are issued when the product may cause "temporary or medically reversible adverse health consequences" to patients (p. 4). A Class III recall is issued when it is "not likely [for a product] to cause adverse health consequences" (p. 4). Each process varies in time required to complete based on multiple factors – including number of products to recall, complexity of the recall, and information available to the recalling firms. As the model this thesis will focus on is interested in only the potentially lethal cases of recalls, Class III recalls will not be considered.

The FDA provides statistics for the average time it takes for each phase to occur for the fiscal years 2010 – 2012 for all classes of recalls. These numbers are provided in **Table 1** below. Since the recalls are not classified into Class I – III types until Phase III of the recall process, Phase I and Phase II recall time is assumed to be equal for all classes of recalls. While the time it takes for the CDRH to review and classify the recall is decreasing annually, the overall time from the initial firm awareness to the posting of the recall is growing steadily. Since Phase I and Phase II times are considered to be equal for all classes of recalls, the only variance in classes occurs in Phase III. These differences are shown in **Table 2**. The FDA keeps records of all medical device recalls in their Medical Device Recall Database, which can be accessed on their website. In 2012, on average, it took 64 and 56 days respectively for Class I and Class II recalls between the ORA being notified of a recall and it being publicly posted online.

Table 1: Average Days by Phase and Year. Adapted from Medical Device Recall Report: FY2003 – FY2012. Retrieved October 25, 2015, from http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm388442.pdf

Year	Number of Recalls	Phase I - Firm Awareness to District Awareness (mean days)	Phase II - District Awareness until Recommendation Sent to CDRH (mean days)	Phase III - CDRH Receipt to Classification and Posting (mean days)	Phase I - III Total Recall Days to Posting (mean days)
FY2010	876	85.7	99.7	48.3	233.7
FY2011	1271	98.2	111.6	37.1	246.9
FY2012	1190	99.4	135.9	21.3	256.6

Table 2: Average Phase III Days by Class and Year. Adapted from Medical Device Recall Report: FY2003 – FY2012. Retrieved October 25, 2015, from http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm388442.pdf

	FY2010	FY2011	FY2012
Class I Mean, Days	37.4	32.8	28.1
Class I Range, Days	7 - 137	10 - 90	2 - 159
Class II Mean, Days	47	37.3	21.1
Class II Range, Days	2 - 301	0 - 476	2 - 232
Class III Mean, Days	68.7	36.1	19.6
Class III Range, Days	8 - 208	8 - 208	2 - 57

Each recall can encompass multiple medical devices that are out in the field, requiring more effort and time to perform a recall. **Figure 8** shows the average number of products per recall for each fiscal year from 2003 to 2012; data was obtained from the FDA website to create this figure, along with **Table 3**, which contains the data for this graph. The number of products per recall activity varies greatly with Class I recalls, but there is not much variation in the Class II recalls, which tend to stay around 2.5 products per recall.

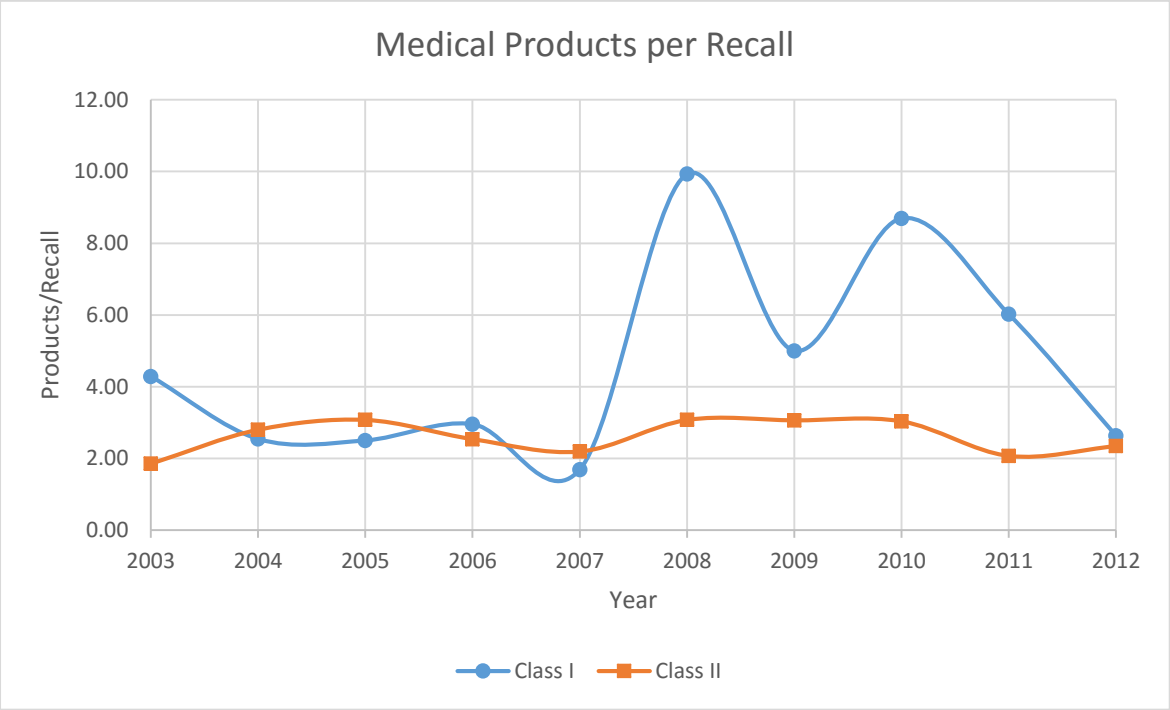


Figure 8: Trend of Products per Recall by Class and Fiscal Year

Table 3: Number of Products per Recall by Class and Fiscal Year

Products per Recall		
Year	Class I	Class II
2003	4.29	1.85
2004	2.54	2.80
2005	2.50	3.08
2006	2.95	2.54
2007	1.69	2.19
2008	9.93	3.08
2009	5.00	3.07
2010	8.69	3.04
2011	6.02	2.07
2012	2.63	2.35
Average	**4.62**	**2.61**

The FDA claims that, for the duration of the 10-year report, deaths were associated with 25% of Class I products to be recalled and 1% of Class II products, meaning that in 2012, there were 38 Class I recalled products with fatal instances associated with them and 24 Class II recalled products with the same. Since there is no specific data available for the actual number of deaths caused by these products, each product will be modeled as one product that either causes a death or does not. These fatal occurrences can be attributed to the length of time necessary for a recall event to be made publicly aware. A faulty implant can be put into a patient over 200 days after the manufacturing firm realizes the dangers of that implant, which is unacceptable if patient safety is to be valued as highly as it should. With the implementation of UDI technologies into the healthcare industry, these deaths could be avoided by ensuring a quicker response to faulty equipment and minimizing the number of devices used before the recall is made aware.

The major assumption of this model will be that the fatal incidences that occurred because of faulty medical devices were largely due to the time it took for the recall process to transpire, and that these fatal instances were attributed to the recalls that took the longest time to be posted. While time may not be the main attributing factor for all recall fatalities, it is undeniably a negative factor that affects mortality rates in many instances. Time is also a factor that UDI implementation can help to reduce drastically. It will be assumed that since 25% of Class I recalls and 1% of Class II recalls resulted in deaths, the fatal instances occurred in the top 25^{th} percentile and top 1^{st} percentile of time for each class respectively. From 2010 – 2012, it took on average 243 days to post a Class I recall and 245 days to post a Class II recall; by calculating each respective percentile, it can be concluded that – once the ORA became aware of the recall – Class I recalls that took over 97 days to post from that point were likely to result in deaths and Class II recalls that took over 1,104 days to post from that point were likely to result in deaths.

Minitab, the statistical analysis software, was used to analyze the recall data obtained from the FDA's database. An "Individual Distribution Identification" test was performed on both the Class I and Class II sets of data to determine the distribution that best fit each set. For the Class I data, recalls within the FDA that took longer than 1,000 days were considered outliers, as their presence in the data set highly skewed the statistical results (8 data points out of the 1,464 points were removed as outliers). With those points removed, it was determined that the Class I data best follows a Lognormal distribution with a location of 3.94 and a scale of 0.7765. A histogram of the data set is shown in **Figure 9**. For the Class II data – as there were many points that surpassed 1,000 days between ORA notification and the recall's posting – all of the points were considered in the analysis. The Class II data best follows a Weibull distribution with an

alpha value of 0.9694 and a beta value of 138.5. A histogram of these data points is shown in **Figure 10**. These distributions were used to determine the time of transitions between the beginning of Phase II and the posting of the recall in the AnyLogic model.

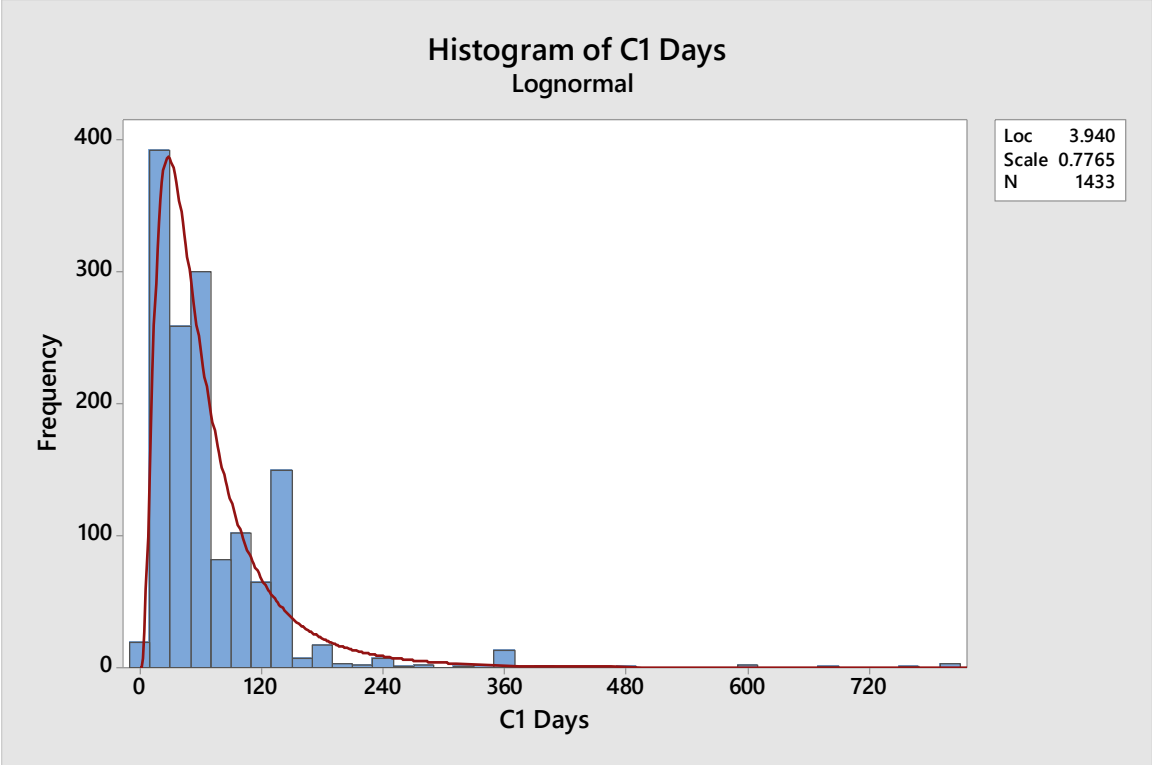


Figure 9: Distribution of Class I Recall Data

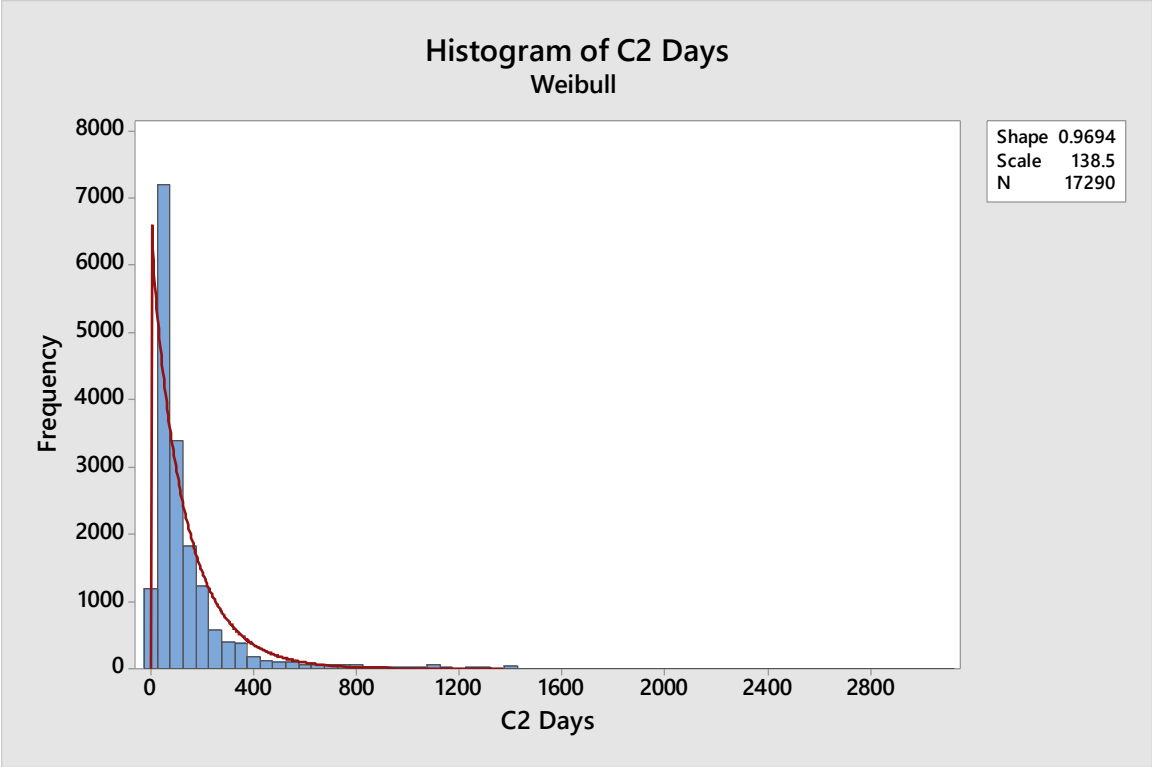


Figure 10: Distribution of Class II Recall Data

Each important phase of the recall process is depicted in AnyLogic as a "state" with which an item (or a medical device) is in. An item enters the first state – "Phase_1" – at the beginning of the model, then stays in that state until the transition period has passed. For Phase I, the transition period is a set 99.4 days, as this portion of the recall process is not the focus. The item then enters the next state – "Phase_2_3" – and remains in this state until one of two things happens: the time for the recall to be posted (determined by the two distributions above) passes, allowing the item to pass into the "Posted" state, or the item stays in this state for too long, becoming a fatal instance and passing into the "Fatalities" state. This transition is determined by the percentiles of days to posting as stated above (97 and 1,104 days, respectively). Class I's state flow chart is shown in **Figure 11** and an example of the usage of transition times is shown

in **Figure 12** below. Once an agent passes into the Phase_2_3 state, the agent has 97 or 1,104 days, depending on the class, to make the ORA_to_Posting transition and be "posted." If the number of days above passes, the agent takes the Lethality transition instead, and becomes a "fatality."

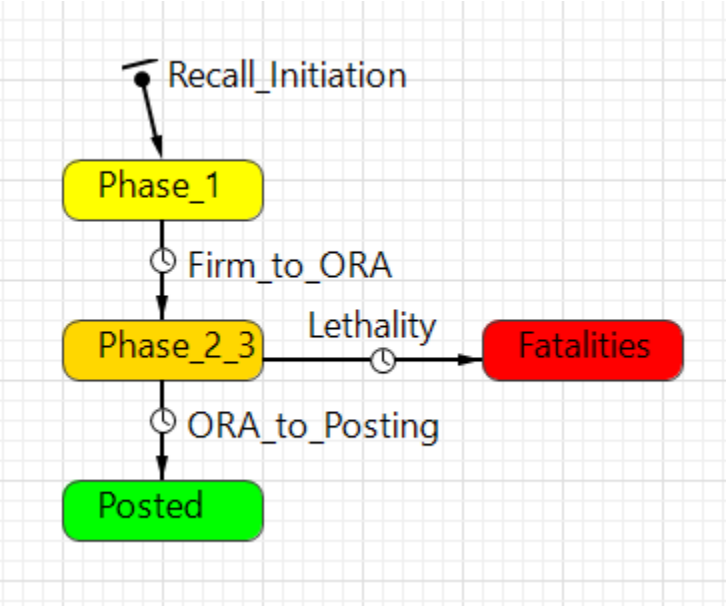


Figure 11: State Flow Chart of Class I Products in AnyLogic

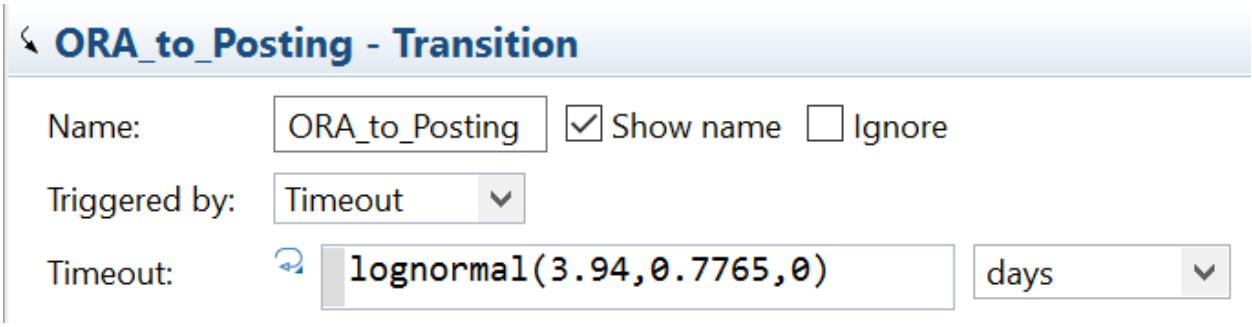


Figure 12: Transition from Phase_2_3 to Posting in AnyLogic

The results from the model prove to be an accurate representation of the actual recall results from 2012, varying only very slightly from the number of deaths that were seen. While 38 deaths and 24 deaths were observed in 2012 from Class I and Class II recalls, respectively, the model projected, on average of 80 replications, 31 deaths and 2 deaths out of 150 and 2,447 products, with standard deviations of 5.00 and 0.98 respectively; this proved to be within 4.13% and 0.94% of the actual results. These numbers are shown in **Table 4** below. The model itself is displayed in the Appendix.

Table 4: Actual Fatalities vs. AnyLogic's Projected Fatalities

Number of Fatalities					
Class	Actual	% of Total	Model	% of Total	Variance
I	38	25.33%	31	20.67%	4.67%
II	24	0.98%	2	0.08%	0.90%

Post-UDI Model

The post-implementation model will be projected forward to the year 2020, the year that the FDAAA final ruling requires that UDI be fully implemented for all types of medical devices. In order to project the model forward, the amount of recalls need to be determined for both Class I and Class II recall devices, along with the number of products per recall for the year 2020 and the average number of days for a recall process to reach Phase IV. The number of recalls and number of products per recall can be forecasted using the data from the figures above; however, determining the average number of days to complete a recall will be more difficult, as time valuations concerning the effects of UDI implementation will need to be carefully made and validated.

To determine the number of products and the number of recalls for the year 2020, a regression analysis was performed on the data for products and recalls from the fiscal years 2003 – 2012. The data for this regression analysis is shown in **Table 5**, and the ANOVA tables for each regression analysis are provided in the Appendix. The P-Values for each analysis are less than the desired confidence interval of 95%, so all of the regression equations are suitable for forecasting the number of products and the number of recalls for each class, respectively. **Table 6** provides the forecasted number of products and recalls found using the appropriate regression equations for each class.

Table 5: Products per Year and Recalls per Year for Class I and Class II Recalls

Products per Year			Recalls per Year		
Year	Class I	Class II	Year	Class I	Class II
2003	30	853	2003	7	460
2004	61	1309	2004	24	467
2005	65	1299	2005	26	422
2006	65	1283	2006	22	505
2007	44	1185	2007	26	540
2008	139	2185	2008	14	710
2009	160	2076	2009	32	677
2010	426	2288	2010	49	753
2011	301	2388	2011	50	1152
2012	150	2447	2012	57	1043

Table 6: Forecasted Number of Products and Recalls for F.Y. 2020

Forecasted Products and Recalls for 2020			
Products		Recalls	
Class I	Class II	Class I	Class II
519	4021	89	1611

In order to determine the effectiveness of UDI implementation, one must look closely at the process in which a recall occurs. Phase I occurs solely in the manufacturing firm, as the firm initially becomes aware of a potential issue. In this moment, the firm is normally not sure on whether or not a recall needs to occur, prompting an evaluation of the potential health hazards associated with a faulty product. Manufacturing firms will not have access to patients' EHR's, so they will not have complete visibility as to where these products are; they will only have access

to their customers, as before. Once the evaluation is complete and a recall is deemed appropriate, the ORA is notified. This is where UDI implementation may prove beneficial, as determination of the recalling strategy occurs here. This includes determining the depth of the recall, how to alert the public of the recall, and notifying all required parties of the recall. UDI implementation can make this process almost instantaneous, as there is clear visibility on where these products are being used, whether it be in a hospital or in a patient. Notification can also occur through the GUDID so that all hospitals that frequently use it will be notified much quicker than through a public advertisement or mailing of recall information. The CDRH will be able to more easily verify the classification made and make quicker postings that hospitals will see. Because of these expected benefits, UDI implementation is anticipated to positively affect Phase II and Phase III of the recall process, reducing the time necessary to complete each phase and working toward the prevention of patient injuries and deaths.

The modeling of the post-UDI system will be designed exactly like the pre-UDI system so that the only varying aspects of the system are the number of agents in the system and the time it takes for an agent to transition from the beginning of Phase II to the posting of the recall. This change in time between states is expected to decrease, as the transition time to a fatality remains the same for each class of product. This is expected to decrease the number of agents to finish off in the "Fatalities" state, and therefore decrease the number of deaths associated with medical device recalls.

The initial post-UDI implementation model will be run without a change in time between states to form a basis of comparison. This unaltered model will represent the healthcare system in the year 2020 if UDI implementation did not occur and all recalls were performed as they currently are. When the model is run without the time change, there are 106 (20.42%) fatalities

associated with Class I recalls, and 3 (0.075%) fatalities associated with Class II recalls. While this signifies an increase in deaths from the 2012 results, it does show a slight decrease in the percentage of deaths. With the expected decrease in time between the beginning of Phase II of the recall process and the public posting of the recall, these percentages should decrease even more.

To properly estimate the effectiveness of UDI implementation, we can look into similar technologies and their effectiveness to the healthcare industry. Since EHR's have been implemented, there have been multiple studies on the effectiveness of them pertaining to reducing the risk on patients. A study performed on Pennsylvania hospitals concluded that EHR implementation provided a "27% decline in overall patient safety events and a 30% decline in medication errors" (Hydari, 2015). Similarly, a study was conducted on a general hospital in China with similar results, concluding that "ADEs [adverse drug events] would be reduced by approximately 40% as a result" (Li, 2012). These values are associated not with a time improvement, but with a decrease in the number of events that occur, signifying that these improvements will correspond to the number of lives saved, as opposed to the amount of time saved. A minimalistic approach will be taken in this study, taking the minimum value of 27% as the expected percentage of lives saved from UDI implementation.

Running the model with a 27% decrease in the number of deaths associated with medical device recalls resulted in 29 less Class I fatalities and one less Class II fatality. These results – compared to the result of the model when UDI is not implemented – are displayed in **Table 7** below. This corresponds to a 16.55% improvement in recall time.

Table 7: Number of Fatalities without UDI vs. with UDI (Assuming a 27% Fatality Decrease)

Number of Fatalities				
Class	No UDI	% of Total	UDI	% of Total
I	106	19.65%	77	14.84%
II	3	0.07%	2	0.050%

Discussion

In order to better visualize the effectiveness of UDI implementation on the national healthcare system, one needs to see how sensitive the system is to change; specifically, a sensitivity analysis needs to be performed on the time from the beginning of Phase II and the posting of the recall to be made publicly aware. This analysis – along with a proper cost model of implementation vs. the valuation of a human life – can be used together to determine the exact increase in efficiency needed for UDI implementation to be deemed beneficial to the system as a whole.

The sensitivity analysis can be performed on the post-UDI implementation model by first assuming that there is no change in time between the pre-UDI model and the post-UDI model and run the model, again with 80 replications, to see how many fatalities occur. This process can be repeated, with the only difference being a percentage improvement in time between the beginning of Phase II and the public posting of the recall. The results of the sensitivity analysis are graphed in **Figure 13** and quantified in **Table 8** below. Note that the Class II products are generally insensitive to the change in time, as the number of fatalities associated with them are already significantly low. Class I products, however, prove to be quite sensitive to the change, illustrating that UDI implementation could potentially be very effective pertaining to these products. More detailed statistics of the replications of data for the sensitivity analysis of the model are displayed in the Appendix. Descriptive statistics were only taken for Class I products, since Class II products had very little deviation.

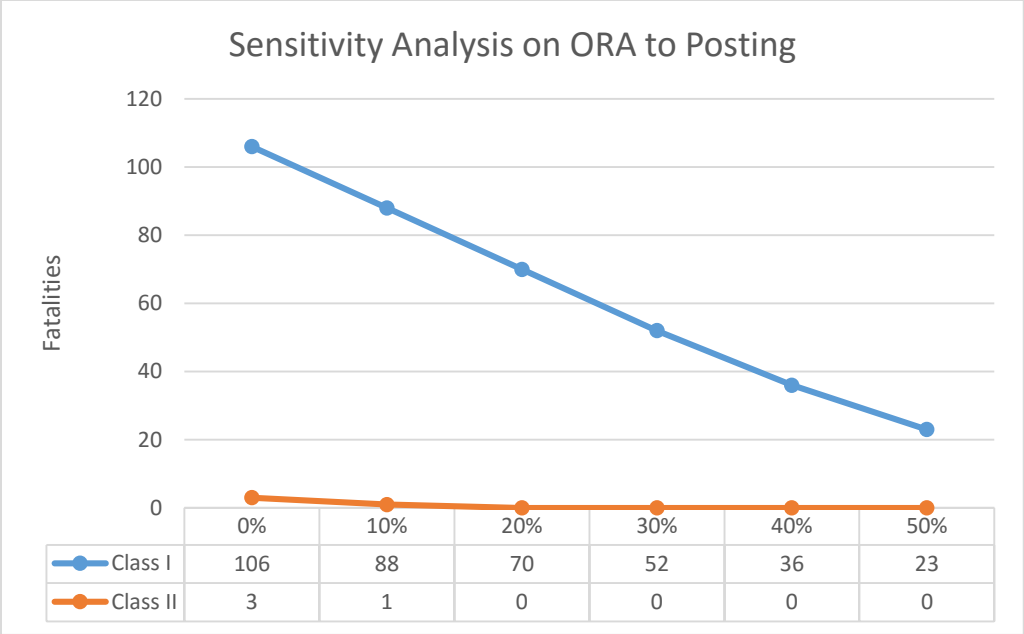


Figure 13: Sensitivity Analysis on the Time Between ORA Notification to Recall Posting

Table 8: Percent of Fatalities for Sensitivity Analysis

Sensitivity Analysis						
Class	0%	10%	20%	30%	40%	50%
I	20.42%	16.96%	13.49%	10.02%	6.94%	4.43%
II	0.075%	0.025%	0.000%	0.000%	0.000%	0.000%

In order to complete a proper analysis on this data, two different costs need to be determined: the expected cost of implementation in a healthcare environment and the valuation of a human life. A benefit/cost analysis can be conducted with these two values – with the cost of UDI implementation as the cost and the expected number of lives saved times the valuation of each life as the benefit. The varying factor here will be the expected number of lives saved, which the sensitivity analysis above is focused on. With all of these factors in place, it can be

determined which percentage value of improvement UDI implementation would have to provide in order for the ratio of benefit to cost to equal one – in order for the system to deem it cost effective to implement UDI.

The valuation of a human life is a dynamic value, due to multiple economic, political, environmental, and moral factors, and has been increasing as of late. There are many different valuations of human lives out there – different U.S. governmental agencies provide different valuations based on their separate evaluations. For this discussion, it is most appropriate to use valuations provided by the FDA over other agencies. As of 2010, "the Food and Drug Administration declared that life was worth $7.9 million" (Appelbaum, 2011). Pertaining to the model above, each life saved by UDI implementation will indirectly save the system $7.9 million. Economically speaking, there is a certain number of lives that need to be saved in order for UDI implementation to be advantageous to the market. Since the value of a life has not changed since then, this same value can be used as the 2012 value of a life for the current cost analysis. To further the minimalistic approach of this study, it will be assumed that there is only one fatal instance per fatal product from the model.

The cost of implementation will affect three different areas, according to a detailed cost analysis developed by the Eastern Research Group, Inc. for the FDA: domestic labelers, issuing agencies, and the FDA itself (Federal Register, 2013). A vast majority of these costs will be incurred by the domestic labelers, which include "manufacturers, re-processors, specification developers, re-packagers and re-labelers that cause a label to be applied to a medical device." The costs were calculated as being incurred over a 10-year life cycle using a 7 percent discount rate, using the 2012 value of money. A summary of the results is displayed in **Table 9** below. Note that the total present value of costs over the 10-year period is $642.2 million.

Table 9: Summary of the Estimated Domestic Regulatory Costs of the Final Rule (2012 dollars). Adapted from Federal Register. (13, September 18). Dodd-Frank Wall Street Reform 270 in the last year. Retrieved March 05, 2016, from https://www.federalregister.gov/articles /2013/09/24/2013-23059/unique-device-identification-system#h-58

Affected Sectors	Total PV of Costs over 10 Years	Total AV of Costs over 10 Years
Domestic Labelers	$620,400,000	$82,600,000
Issuing Agencies	$1,300,000	$200,000
FDA	$20,500,000	$2,900,000
Total Domestic Cost	**$642,200,000**	**$85,700,000**

Now that all of the costs – the cost of a human life and the cost of UDI implementation – have been determined, the number of lives that need to be saved by UDI implementation to economically justify the decision can be determined. In order for UDI implementation to be justified monetarily, the value saved by UDI implementation in human lives must be equal to or greater than the cost of UDI implementation. Projecting the value of a single human life forward 10 years and calculating the net present value of it yields a value of $59,370,335. This is equivalent to saving one human live each year for the next 10 years. **Table 10** displays the net present value of a single human life and the net present value of the number of lives that need to be saved per year in order for the value of those lives to equal that of the cost of implementation, with n representing the number of human lives. If UDI implementation saves the lives of 11 people each year, UDI implementation will be economically justified. This corresponds to a percentage improvement of between only 5% and 6%. A table of the net present values of the

improvements determined in the sensitivity analysis above is displayed in **Table 11** and graphically illustrated – along with the cost of implementation – in **Figure 14** below.

Table 10: Net Present Value of Human Lives (2012 dollars)

Year	Single Life's Value	**n = 10.817**
1	$ 7,900,000	$ 85,453,114
2	$ 7,383,178	$ 79,862,724
3	$ 6,900,166	$ 74,638,059
4	$ 6,448,753	$ 69,755,196
5	$ 6,026,872	$ 65,191,772
6	$ 5,632,591	$ 60,926,889
7	$ 5,264,104	$ 56,941,018
8	$ 4,919,723	$ 53,215,905
9	$ 4,597,872	$ 49,734,491
10	$ 4,297,077	$ 46,480,832
Total Value	**$59,370,335**	**$642,200,000**

Table 11: Net Present Values of the Improvements Determined in the Sensitivity Analysis

Year	Single Life's Value	Value of 10% Improvement	Value of 20% Improvement	Value of 30% Improvement	Value of 40% Improvement	Value of 50% Improvement
1	$ 7,900,000	$ 142,200,000	$ 284,400,000	$ 426,600,000	$ 553,000,000	$ 655,700,000
2	$ 7,383,178	$ 132,897,196	$ 265,794,393	$ 398,691,589	$ 516,822,430	$ 612,803,738
3	$ 6,900,166	$ 124,202,987	$ 248,405,974	$ 372,608,961	$ 483,011,617	$ 572,713,774
4	$ 6,448,753	$ 116,077,558	$ 232,155,116	$ 348,232,674	$ 451,412,726	$ 535,246,518
5	$ 6,026,872	$ 108,483,699	$ 216,967,398	$ 325,451,097	$ 421,881,052	$ 500,230,391
6	$ 5,632,591	$ 101,386,635	$ 202,773,269	$ 304,159,904	$ 394,281,357	$ 467,505,038
7	$ 5,264,104	$ 94,753,864	$ 189,507,728	$ 284,261,593	$ 368,487,250	$ 436,920,596
8	$ 4,919,723	$ 88,555,013	$ 177,110,027	$ 265,665,040	$ 344,380,607	$ 408,337,006
9	$ 4,597,872	$ 82,761,695	$ 165,523,389	$ 248,285,084	$ 321,851,035	$ 381,623,370
10	$ 4,297,077	$ 77,347,378	$ 154,694,756	$ 232,042,135	$ 300,795,360	$ 356,657,355
Total Value	**$ 59,370,335**	**$ 1,068,666,026**	**$ 2,137,332,052**	**$ 3,205,998,077**	**$ 4,155,923,434**	**$ 4,927,737,786**

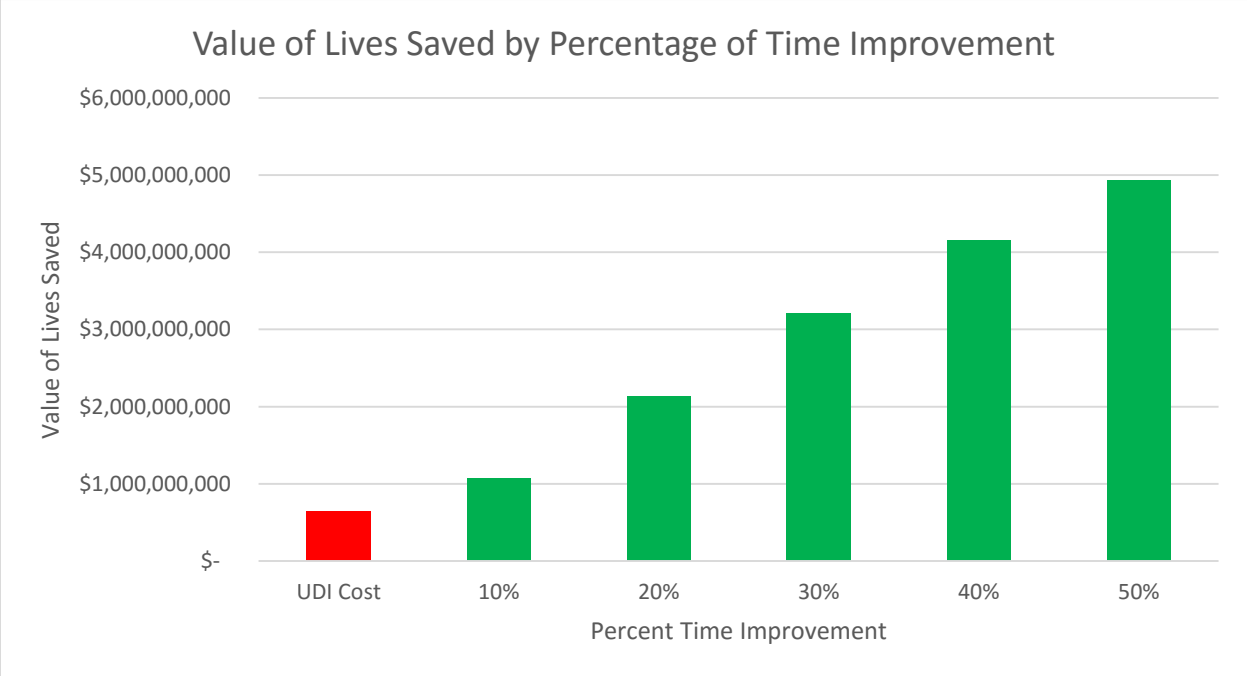


Figure 14: Net Present Values of Improvements with UDI Implementation vs. UDI Cost

UDI implementation can be considered financially beneficial to the healthcare market as a whole if implementation accounts for reducing the number of fatalities of Class I and Class II recalls combined by at least 11. The sensitivity analysis shows that the number of fatalities is significantly affected by the time between the beginning of Phase II of the recall process and the public posting of the recall, assuming that the average time between the two that, if surpassed, indicates a fatality remains constant.

The results of the post-UDI implementation model show that the number of lives saved per year will be 30. The value saved by this implementation is shown in **Table 12** and graphed in **Figure 15** below. This figure compares the cost of UDI implementation to these expected benefits, showing that the number of lives saved proves to be sufficient economically to supplement the costs associated with the implementation. Not only does the benefit outweigh the costs, but it is 177% more than the costs of UDI implementation.

Table 12: Value of Saving 27% More Lives Using UDI Implementation

Year	Single Life's Value	**Value of 30 Lives Saved**
1	$ 7,900,000	$ 237,000,000
2	$ 7,383,178	$ 221,495,327
3	$ 6,900,166	$ 207,004,979
4	$ 6,448,753	$ 193,462,597
5	$ 6,026,872	$ 180,806,165
6	$ 5,632,591	$ 168,977,725
7	$ 5,264,104	$ 157,923,107
8	$ 4,919,723	$ 147,591,689
9	$ 4,597,872	$ 137,936,158
10	$ 4,297,077	$ 128,912,297
Total Value	**$59,370,335**	**$ 1,781,110,043**

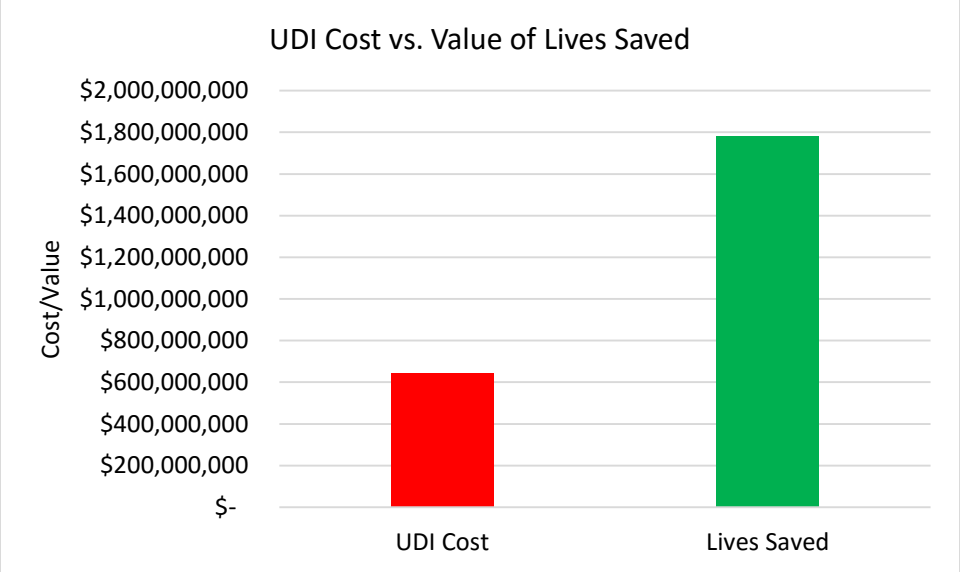


Figure 15: UDI Cost vs. Value of Lives Saved

Conclusion

Disruptive innovations prove to be essential to the progression of modern industries; these efficient ideas keep their respective markets competitive and provide affordable services for consumers. Examples of disruptive innovations can be seen all throughout history, as new, more efficient and effective ideas are implemented and eventually become commonplace in their respective industries. Disruptive innovations can also be completely new ideas that forever change the landscape of its industry, such as the Wright brothers' transformation of the transportation industry through the creation of the airplane, or Alexander Graham Bell developing instantaneous long-distance communication through his invention of the telephone.

The healthcare industry has pushed to improve many aspects of its operations, including the technologies being used, better treatment and diagnostic performance on the patients, and the visibility of the many components surrounding the system. Many innovations have occurred that have reshaped and modernized the healthcare industry as we see it; these innovations help to provide better treatment at a cheaper cost, providing a cost effective alternative to sustaining innovations. Electronic Health Records have made patient information readily available for all doctors that treat said patient, saving the time required to obtain this information from other doctors and decreasing the risk of mistreating a patient because of a lack of information about previous conditions. Real-Time Location Systems have helped improve the visibility of the supply chain, helping to keep track of all equipment and patients throughout a hospital or clinic, as well as during transportation from the manufacturers to the hospitals and clinics. The healthcare industry is progressing towards an all-encompassing surveillance system that will keep track of all equipment, patients, and personnel involved in the supply chain of the entire system.

Unique Device Identification seeks to alter the supply chain network of the healthcare industry, adding much needed visibility to the medical devices that are traveling through this supply chain. Manufacturers and hospitals often lose track of where devices have been used, or which patients have specific devices in them. This lack of visibility leads to many potential risks, including an increase in treatment errors, poor inventory management, and an increase in the time required to classify and complete a recall. These risks cost the healthcare industry immense amounts of money and costs patients their health and, sometimes, their lives.

With Unique Device Implementation expected to be fully implemented in 2020, there has been no formal data on the expected time benefits associated with implementation, although all parties agree that recall times should decrease and, therefore, the number of fatalities associated with lengthy medical device recalls should decrease. This study concludes that UDI implementation should see at least a 27% decrease in fatalities associated with recalls – not only saving those lives, but through that supplementing the cost associated with UDI implementation. The total cost associated with UDI implementation will be saved in the number of lives saved in the first three years after implementation; the annual benefits of UDI implementation outweigh the annual costs by a considerable margin, making UDI implementation both morally sound and financially beneficial to the healthcare industry.

To our knowledge, this is the first study that has attempted to put a monetary value on the benefits associated with Unique Device Identification. Future research should be performed to further analyze the potential benefits in order to further emphasize the positive consequences of implementation. The main conclusions from this study are that Unique Device Identification will decrease the amount of time required for manufacturing firms and the FDA to complete the classification and posting of a recall, and the benefits linked to this decrease in time should

supplement the costs of implementation, making UDI implementation monetarily beneficial and will increase the safety of the patients, all while improving the operations of the healthcare industry as a whole.

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Appendix

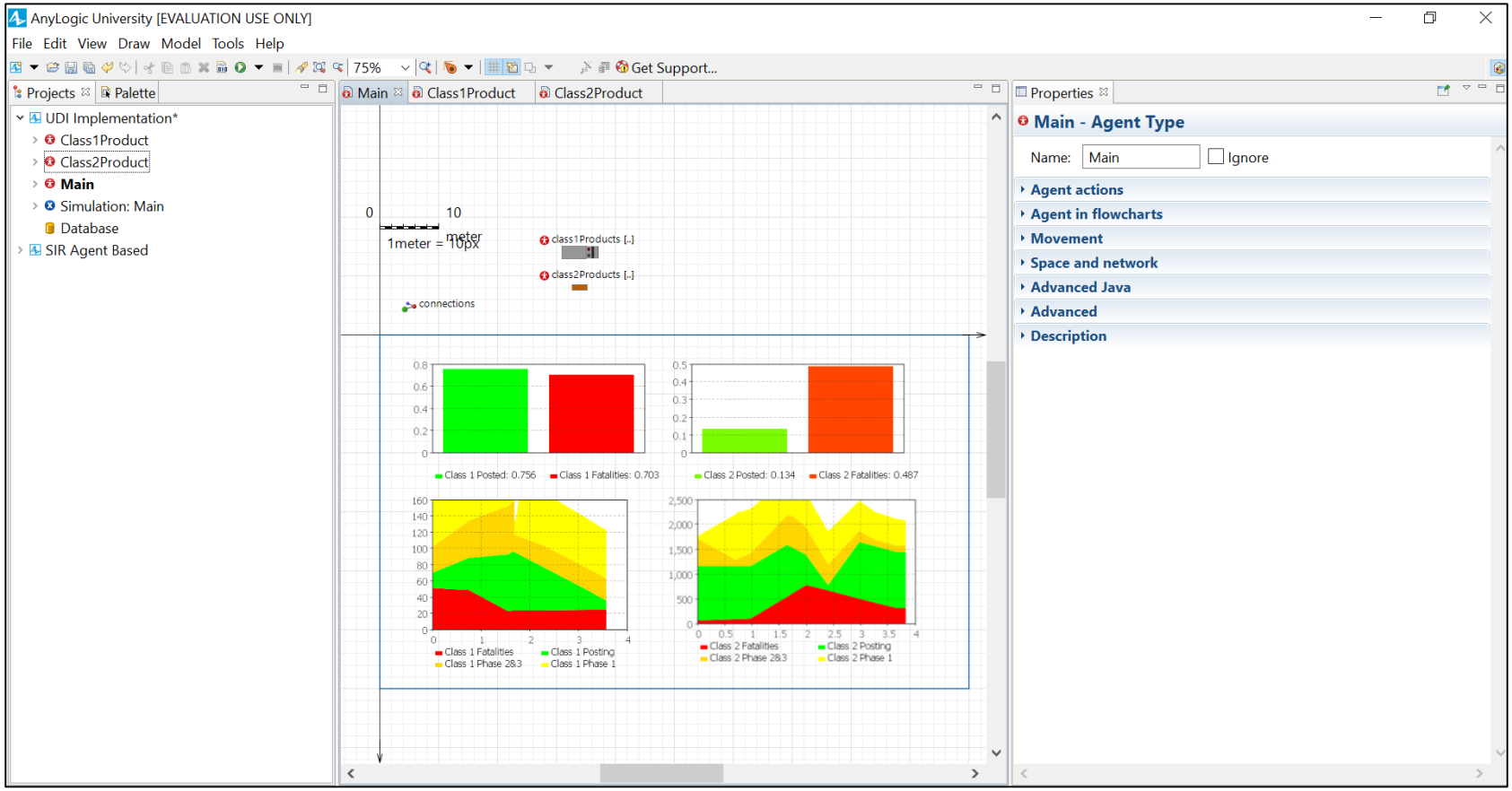

Figure 16: AnyLogic UDI Implementation Model

Table 13: ANOVA Analysis for the Number of Recalled Products per Year for Class I

ANOVA - Products								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	1	74100.07576	74100.07576	8.147697652	0.021333686			
Residual	8	72756.82424	9094.60303					
Total	9	146856.9						
	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Class I	-60020.06667	21077.58735	-2.84757765	0.021559216	-108625.0703	-11415.06307	-108625.0703	-11415.06307
Year	29.96969697	10.4994101	2.854417218	0.021333686	5.758013857	54.18138008	5.758013857	54.18138008

Table 14: ANOVA Analysis for the Number of Recalled Products per Year for Class II

ANOVA - Products								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	1	2767968.876	2767968.876	49.63439454	0.000107685			
Residual	8	446137.2242	55767.15303					
Total	9	3214106.1						
	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Class II	-365981.8667	52193.72117	-7.0119903	0.000111299	-486340.8035	-245622.9298	-486340.8035	-245622.9298
Year	183.169697	25.99933636	7.04516817	0.000107685	123.2151198	243.1242741	123.2151198	243.1242741

Table 15: ANOVA Analysis for the Number of Recalls per Year for Class I

ANOVA - Recalls								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	1	1773.409091	1773.409091	22.42370251	0.001472712			
Residual	8	632.6909091	79.08636364					
Total	9	2406.1						
	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Class I	-9276.8	1965.530683	-4.71974316	0.001502663	-13809.32188	-4744.278116	-13809.32188	-4744.278116
Year	4.636363636	0.979092738	4.735367199	0.001472712	2.378571734	6.894155539	2.378571734	6.894155539

Table 16: ANOVA Analysis for the Number of Recalls per Year for Class II

ANOVA - Recalls								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	1	464662.6939	464662.6939	35.00870522	0.000354961			
Residual	8	106182.2061	13272.77576					
Total	9	570844.9						
	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Class II	-149986.9333	25463.01951	-5.89038285	0.00036569	-208704.7616	-91269.10506	-208704.7616	-91269.10506
Year	75.04848485	12.68393198	5.916815463	0.000354961	45.79928526	104.2976844	45.79928526	104.2976844

Pre UDI	
Mean	30.4375
Standard Error	0.559114
Median	30
Mode	34
Standard Deviation	5.00087
Sample Variance	25.0087
Kurtosis	-0.00184
Skewness	0.237639
Range	25
Minimum	19
Maximum	44
Sum	2435
Count	80
Confidence Level(95.0%)	1.112889

Figure 17: Pre UDI Replication Statistics

Post UDI (No Change)	
Mean	105.925
Standard Error	0.988506
Median	106
Mode	103
Standard Deviation	8.841466
Sample Variance	78.17152
Kurtosis	0.489429
Skewness	-0.25352
Range	45
Minimum	80
Maximum	125
Sum	8474
Count	80
Confidence Level(95.0%)	1.967572

Figure 18: Post UDI Replication Statistics (No Change)

Post UDI (10%)	
Mean	87.9
Standard Error	0.914822
Median	88
Mode	88
Standard Deviation	8.182414
Sample Variance	66.9519
Kurtosis	0.415339
Skewness	-0.02913
Range	44
Minimum	66
Maximum	110
Sum	7032
Count	80
Confidence Level(95.0%)	1.820907

Figure 19: Post UDI Replication Statistics (10% Time Improvement)

Post UDI (20%)	
Mean	69.5
Standard Error	0.728272
Median	70
Mode	70
Standard Deviation	6.513861
Sample Variance	42.43038
Kurtosis	0.162158
Skewness	0.189679
Range	31
Minimum	55
Maximum	86
Sum	5560
Count	80
Confidence Level(95.0%)	1.449589

Figure 20: Post UDI Replication Statistics (20% Time Improvement)

Post UDI (30%)	
Mean	52.0875
Standard Error	0.786193
Median	52
Mode	50
Standard Deviation	7.031923
Sample Variance	49.44794
Kurtosis	0.884471
Skewness	0.416296
Range	40
Minimum	37
Maximum	77
Sum	4167
Count	80
Confidence Level(95.0%)	1.564878

Figure 21: Post UDI Replication Statistics (30% Time Improvement)

Post UDI (40%)	
Mean	36.3625
Standard Error	0.653676
Median	35
Mode	35
Standard Deviation	5.846656
Sample Variance	34.18339
Kurtosis	-0.49923
Skewness	-0.02037
Range	26
Minimum	22
Maximum	48
Sum	2909
Count	80
Confidence Level(95.0%)	1.30111

Figure 22: Post UDI Replication Statistics (40% Time Improvement)

Post UDI (50%)	
Mean	22.775
Standard Error	0.502202
Median	22
Mode	22
Standard Deviation	4.491835
Sample Variance	20.17658
Kurtosis	-0.15246
Skewness	0.166289
Range	20
Minimum	14
Maximum	34
Sum	1822
Count	80
Confidence Level(95.0%)	0.999609

Figure 23: Class I Results (40% Time Improvement)