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A medical device is any device used in the treatment or diagnosis of a patient. This practicum project focuses on assessing the process for medical device translation in an academic setting by summarizing the development pathway of medical devices, identifying common obstacles encountered in this pathway, and assessing the clinician's awareness of the process of medical device translation. This examination was conducted by literature reviews, discussions with professionals, and a clinician survey. Results revealed that successful development of medical devices depends on the cooperation of clinicians and device companies in the coordination of device invention, intellectual property acquisition and regulatory approval. The results indicate that clinicians need to be better educated about medical device research and its hurdles to facilitate medical device development.

TRANSLATION OF MEDICAL DEVICES:
AN ASSESSMENT OF THE COMMON OBSTACLES
PERCEIVED BY CLINICIANS

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the

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By

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INTRODUCTION

Advances in medical device technology have been essential in the advancement of medicine. Medical devices have led to an increase in overall life expectancy.[1] Medical devices are being used to combat obesity[2], and are essential in non-invasive procedures that are becoming more prevalent with the development of new technologies. In a broad sense, a medical device is any physical item used in the diagnosis, treatment, or prevention of disease that does not act through chemical means.[1] This can range from simple cotton balls to complete cardiac devices.[3,4]

Translational research is commonly referred to as "bench to bedside" research, and is the path that a product (pharmaceutical or medical device) must follow to enter into clinical trials. Translational research of medical devices differs from that of pharmaceuticals, in that medical devices are regulated by the FDA's Center for Devices and Radiologic Health (CDRH).[5] The diversity of medical devices as well as their complexity contributes to the need for medical device regulation.

The potential advances to medical devices technology are endless, but there are many obstacles that must be overcome to develop a successful medical device and have it approved for use by the Food and Drug Administration (FDA). In medical device translation the increasing cost of research and development, the time it takes to get applications through regulatory hurdles, and the lack of understanding by clinical researchers to the process all contribute to the delay of FDA approval of new medical devices.[4] The examination of translational research by this practicum project will address specific issues that impede the successful development of medical devices by revealing common obstacles and evaluating clinicians' understanding of the "bench to bedside" process.

BACKGROUND INFORMATION

History of Medical Devices

The earliest recorded use of medical devices was the acupuncture needle used by Chinese physicians in 2720 BC.[6] Thousands of years later, Rene Laenec revolutionized medicine with the invention of the stethoscope in 1816.[7] The stethoscope changed physician-patient interactions by allowing the physician to place an amplifying device on the patient to more accurately hear chest sounds, instead of placing their ears on the patient's chest to do so. At the time, a stethoscope was simply a hollow wooden tube. It has evolved over time into the most recognizable tool of medical professionals.[7]

The discovery of the stethoscope was made while pursuing the solution to a specific problem. Physicians needed to clearly ausculate a patient's chest without invading their privacy.[7] Other medical device advances have been discovered by serendipity. Wilhelm Röntgen was experimenting with a cathode ray apparatus when he discovered a new type of ray that would penetrate some materials, but not others.[7] He recorded his observations on photographic plates. Röntgen named the newly discovered ray an "X-ray" because the origin was unknown.[7] The X-ray apparatus quickly became a prized tool for physicians. They would no longer have to surgically open a broken leg to determine the severity of the break. This new, less invasive way to visualize the interior of the human body had many possibilities. At that time the harmful effects of overexposure to X-rays were unknown, and would not reveal themselves for a few years. When the use of X-rays were published in 1895 there were no requirements for testing the safety of a medical device.[7]

X-rays were rapidly accepted by medical professionals as an objective diagnostic tool. Their widespread use and acceptance by the public only contributed to the damage that X-rays would reveal over time. Within the first year of their use, X-ray operators were reporting burns to their skin and hair, as well as some memory loss.[7] Danger of radiation became more apparent after World War II; nonetheless, the public did not use caution with X-rays. X-rays were being used in shoe stores to ensure that shoes fit properly. Even in the 1950's, well after the dangers of X-ray exposure had been determined, X-rays continued to be overused and placed people at unnecessary risk.[7]

The Evolution of Medical Device Regulation by the US Government

There were no regulations concerning the safety of medical devices until the 20th century. In 1902, the Biologicals Control Act created the Bureau of Chemistry which set out to test the safety of certain food additives and dyes. Their studies drew attention to the growing problem of adulterated food.[8] In 1906, Congress passed the Pure Food and Drugs Act, which set the stage for government regulation of food and drugs by limiting interstate commerce of adulterated or misbranded food and drugs, but this did little to regulate medical devices.[9,10] The Pure Food and Drugs Act was amended several times before the reorganization of the Bureau of Chemistry into the Food, Drug, and Insecticide Administration (FDIA) and the Bureau of Chemistry and Soils. In 1930 the Agriculture Appropriations Act renamed the FDIA the Food and Drug Administration (FDA).[8]

In 1938, the Federal Food, Drug, and Cosmetic Act placed the regulation of medical devices under the aegis of the FDA.[10] Though the FDA had regulatory authority, it lacked regulatory rigor, and medical devices went widely unregulated for many years.[9] Some devices,

such as contact lenses and intrauterine devices (IUDs) were regulated similarly to drugs. But as new technologies emerged and more invasive and risky devices were being used, it was necessary for the FDA to intervene and exercise its authority over devices.[11]

The Medical Device Amendments of 1976 were signed into law by President Gerald R. Ford.[9] These amendments set guidelines to regulate the safety and efficacy of medical devices and introduced two pre-market applications.[10] They also provided three risk categories (described below) in order to decrease the overregulation of low risk devices, including tongue depressors, while ensuring the safety of high-risk devices, such as pacemakers.[9]

The premarket application process includes submission of a premarket approval application (PMA) or premarket notification (510k).[12] The PMA will be described with class III devices. The 510k process is used to show substantial equivalence of a legally marketed medical device. There is no specific application for the 510k process; however, the guidelines and requirements for 510k submission can be found in the Code of Federal Regulations, 21 CFR 807 subpart E.[13] When the device passes the 510k submission process it will be cleared for market by the FDA. If the device does not pass it can be resubmitted with new information, a PMA can be filed, or a request for the device to be reclassified may be made through either a de novo process or a reclassification petition.[13] The application process will be determined by the medical device classification, indications, and risk level.

Class I devices are considered low risk devices. They are not used to support life and are considered to have a low likelihood of causing harm to the patient.[1] Typical examples of Class I devices are cotton balls, tongue depressors, canes, and surgical skin markers.[14] Class I devices must be registered with the FDA[5] and are subject to general controls that encompass good

manufacturing practices and appropriate labeling.[1] According to the FDA, only one-fourth of Class I devices are required to undergo the 510K process and the rest are exempt.[12]

Class II devices have a greater risk level than Class I devices. They are subject to the same general controls as in Class I, but also have special controls.[12] The increased risk of Class II devices make special controls necessary. These may include design controls, performance standards, or specifications published in FDA guidance documents.[4,14] Class II medical devices require the submission of 510k unless they are exempt. The 510k exemptions are a result of the Food and Drug Modernization act of 1997, which was enacted to reduce the premarket notification submissions by manufacturers. This also eased the FDA's burden by reducing the number of submissions requiring review.[13] Examples of Class II medical devices include absorbable gut suture, stethoscope, blood pressure cuff, and powered wheelchairs.[14]

Class III medical devices are considered to exhibit the highest risk. These devices may be used to support human life or have the potential to cause severe injury. Pacemakers and artificial knees are examples of Class III medical devices.[14] This class has the most regulatory hurdles to overcome for FDA approval. Most Class III devices have to undergo a premarket approval process, which may require data from clinical trials.[4] An investigational device exemption (IDE) must be approved by the FDA for a class III medical device to undergo clinical trials.[1] Data from clinical trials demonstrating safety and efficacy is used to file for premarket approval (PMA) with the FDA.[4] If the PMA is approved, then the medical device is cleared for market.

Although the 1976 Medical Device Amendments were landmarks in device regulation, they were not without fault. The Bjork-Shirley heart valve incident led the FDA to tighten regulations on medical devices.[11] The Bjork-Shirley heart valve was implanted in 86,000 patients

worldwide. The valve had a manufacturing defect that caused some of the valves to fracture, leading to death. This faulty valve is believed to have caused over 300 deaths.[11] At the same time the FDA sought to increase its safety regulations on breast implants due to the increased use of implants in breast augmentation and heightened safety concerns.[15] It became clear that high-risk devices should be more closely monitored. The response of the United States Congress to this problem was the enactment of the 1990 Safe Medical Devices Act, which requires the registration of and post-market reporting for medical devices.[1,16]

Increased regulatory obstacles by the FDA resulted in an increased time for the approval of medical devices. Public outcry about the time required to make new medical devices available for patient care led the FDA to review its own regulatory timeframe.[16] In 1997, the FDA Modernization Act was passed, which decreased the timeframe for medical device approval.[8] In 2002 the FDA passed the Medical Device User's Fee and Modernization Act, which instituted a fee for submission of medical device applications and added regulations for the reuse of single use devices. [8]

SPECIFIC AIMS

1. Summarize the process that devices must follow to transition from basic research into clinical trials.

2. Identify the common obstacles that hinder the progression of devices from basic research to clinical trials.

3. Assess clinicians' awareness of the process of medical device translation and its challenges.

SIGNIFICANCE

The first step in the process of medical device development, approval, and implementation is to identify the problem a new medical device will address. The NIH Roadmap acknowledges that clinicians are in the best position to recognize where research efforts must be concentrated.[17] Firsthand knowledge obtained by clinicians may guide them to specific ideas regarding how to correct a medical condition with a new or improved medical device. For clinicians to be able to implement their medical device ideas, they must know where to start, and what steps to take. It is also important for them to know to whom they must go for assistance in this process.

The examination of translational research of medical devices by this project addresses specific issues concerning the development of medical devices in their earliest stages. By addressing these issues we will be able to facilitate improved outcomes by clinicians in development of medical devices and their advancement to clinical application.

METHODS

To address Specific Aims I and II, a literature review was conducted to identify a common pathway that medical devices may follow. Discussions with professionals in the fields of intellectual property at UNT Health Science Center and medical devices industry were held to assess the resources available to researchers and clinicians and to gain an overall understanding of the device industry. These discussions also contributed to an understanding of some of the reasons why some devices fail to translate from bench to bedside.

A survey was developed to further address Specific Aims II and III (Appendix II). This survey was developed from information gleaned from the meetings with professionals and from a literature review on translational research of devices. The survey consists of questions to assess clinician awareness of medical device translational research, assess the support available for clinical researchers, and gain a general idea of the possible growth in medical device development at the UNT Health Science Center. The survey was made available as an online survey and a paper survey for ease of use with the clinicians. The online survey was developed at surveymonkey.com. This electronic survey tool was chosen because it was cost effective and easy to use.

The survey was submitted to the UNT Health Science Center Institutional Review Board (IRB) for approval. The submission received exempt approval from the IRB. Permission to use a cover letter with the survey in lieu of informed consent was granted because of the minimal risk that participation presented. Appendix III contains documents related to IRB submission.

The survey developed as a part of the practicum project targeted clinicians employed in the UNT health network. The survey was designed to target MD's, DO's, and PA's, but did not exclude other licensed medical professionals, such as podiatrists, physical therapists, and nurse practitioners. An email was disseminated to the clinicians asking them to complete the survey by following a link. There was also an announcement on the UNT Health Science Center's Daily News web publication that provided a link for the clinicians to access the online survey. In addition to this electronic form, paper copies of the survey were delivered to clinicians' offices. The print survey was returned to the student investigator and then manually entered into the online database. No information specifically identifying the individual was collected. The protocol targeted a response rate of at least 30 practicing clinicians and any other licensed professionals that responded to the survey.

The survey asked questions regarding the professional background of the clinicians. The next set of questions in the survey addressed the clinician's basic understanding of medical devices. This is important because a clinician must first understand what a medical device is. If clinicians do not understand what the term "medical device" encompasses, then clinician education will be focused on addressing this issue. The next sections of the survey were designed to assess clinician's awareness of intellectual property and patenting processes. It also addressed the second specific aim regarding where medical devices fail in the patenting process and why. The last section of the survey had additional questions regarding development duration and cost of medical devices. The complete survey is presented in Appendix II.

RESULTS

Device Pathways

For a novel medical device to be beneficial to the healthcare community it must fill an unmet need or improve upon existing strategies to address a need, as well as being safe. An opportunity for development of a new medical device occurs when a specific need is not being met by an existing medical device. In some instances a medical device may already exist, but could be improved to better meet patient needs. An example of an improvement to a medical device is the gastric banding port, which was remade into a low-profile port so that the port was less visible after weight loss.

The pathway for the introductory phase of device development is shown in Figure 1. This flowchart represents how to detect a patient need in the development of new medical devices. If a patient need is being met by an existing medical device, the clinician may work to improve this technology. If a device does not exist to meet a patient need, then an opportunity exists to develop a new device. Once a device idea is developed, then the clinician should proceed to the intellectual property phase.

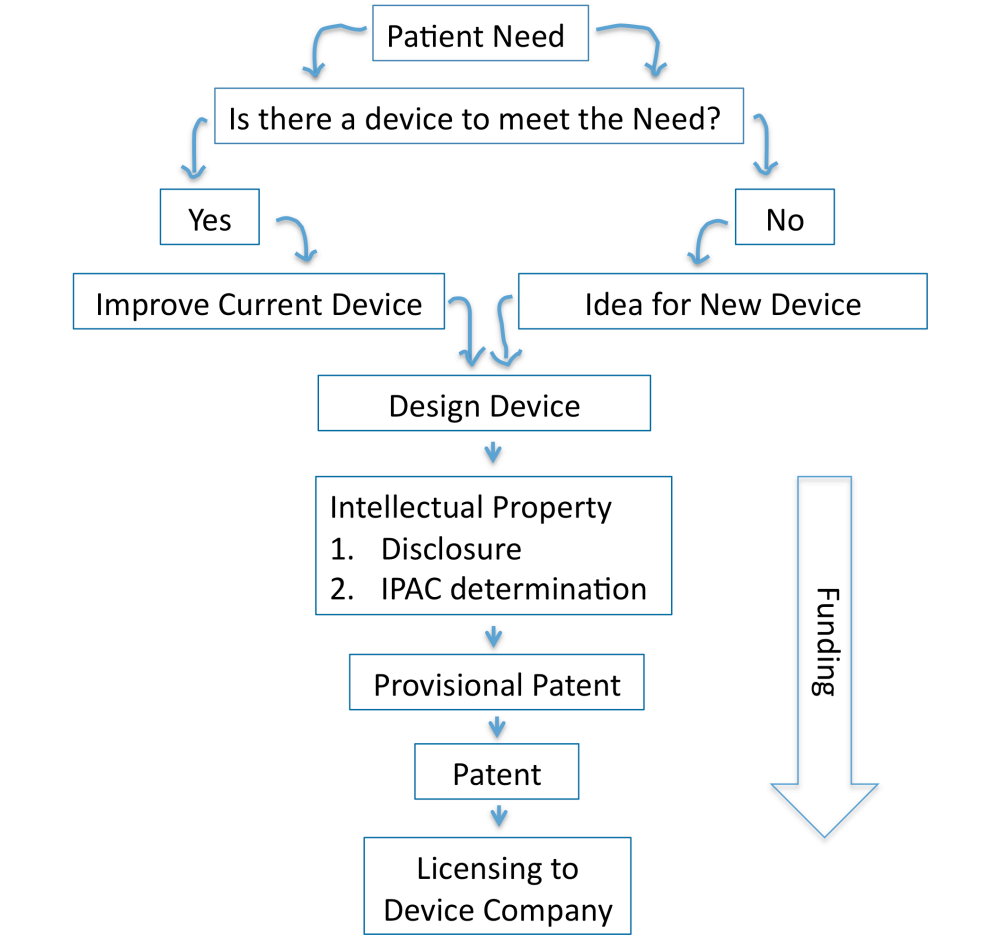
Most academic institutions will have an office responsible for coordinating intellectual property assets. At the UNT Health Science Center this is conducted through the Office of Technology Transfer and Commercialization (OTTC), which assists its faculty, students, and staff in the development and use of intellectual property. All faculty, students, and staff are required to submit their invention ideas to the OTTC through an invention disclosure form.[18] The invention disclosure will be forwarded by the OTTC to the Intellectual Property Advisory

Committee (IPAC).[18] This committee will make decisions regarding ownership of the intellectual property, sharing of revenues resulting from intellectual property, and the amount of time and resources the institution should allocate to developing the invention.[18]

Based on the determination of IPAC and OTTC the institution may provide some funding to file for additional intellectual property protection, which is the next step in the pathway. Government grants or private entities may provide funding to further develop the invention into a functioning prototype.[4] Funding may also come from personal acquaintances (angel investors) or in the form of equity financing through venture capital firms.[4]

The next sections of the pathway, provisional patents and patents, are used in the protection of intellectual property. A provisional patent application will protect an invention for one year and is not required to include claims.[19] If a full patent application is not submitted within one year of the provisional patent application, then the invention loses it's protection.[19] A full patent application must include claims, and lasts for 20 years.[19] Patents give the inventor exclusive rights to make, use, or sell an invention for the duration of the patent.[19] The patent may be licensed out to medical device companies. Proper disclosure agreements should be filed anytime an invention idea is disclosed before a patent is obtained. If the clinician obtains a patent before presenting the invention to a medical device company, the clinician will have greater authority over the medical device invention.

Figure I: Medical Device Development Pathway



For a medical device to have commercial success, Medical Device companies must carefully coordinate development of the medical device through the regulatory pathways and cost hurdles. The Institute for Health Technology and Studies (In Health) funded research by Stanford University's Program in Biodesign to develop a comprehensive model on how medical devices are brought to market. The research developed a five phase approach to medical device design and development.[20]

- Phase 0: Predevelopment
- Phase I: Initiation, Opportunity, and Risk Analysis
- Phase II: Formulation, Concept, and Feasibility

- Phase III: Design Development, Verification, and Validation
- Phase IV: Final Validation and Product Launch Preparation
- Phase V: Product Launch and Post-Launch Assessment

The Predevelopment phase of device development involves assessing the patient need that must be met.[20] This may occur by a clinician developing an idea and collaborating with a medical device company, as shown in Figure 1. Medical device companies may seek out clinicians via discussions and surveys to find where a need exists.

Phase I includes developing a financial plan for device development, and includes conducting a market analysis to identify what share of the market the new device might capture. An analysis of existing intellectual property is conducted to determine if there are existing patents for similar devices. The regulatory path is assessed in this phase in order to determine how the new medical device will be categorized, as well as what kind of clinical trials must be conducted.[20]

Phase II could be referred to as the strategy phase because it takes the results of Phase I and strategically plans the pathway for developing the medical device. The company determines feasibility of the device based on market analysis from Phase I. Development costs, development time, and resources available for the project are taken into account. A timeline is constructed for device development, as well as a computer model of the device that will be used to develop physical prototypes.[20]

Phase III is the physical development phase. At this point, the invention has been refined and is ready for prototype production. Quality standards are evaluated ensuring that general controls, such as labeling, are met. This information will be submitted to the FDA. If the new

device must undergo clinical trials an Investigational Device Exemption application is submitted during this phase of product development.[20]

Phase IV is a regulatory intensive phase. This is the phase during which final approval is obtained from the FDA. Also, business strategies, including marketing and reimbursement, are finalized as the device is prepared to launch.[20] Phase IV is expected to take longer for Class III medical devices because of the increased regulatory requirements.

Phase V is product launch and post-launch assessment.[20] Marketing strategies are employed which educate both physicians and patients on the medical device.[20] Education of the physician is focused on the indications and proper technical use of the medical device.[21] The device will continue to be monitored for safety as required from the 1990 Safe Medical Devices Act.[1]

Industry Obstacles

Recognizing the common industry obstacles is the first step in improving development outcomes. Recent publications have reviewed the major obstacles that medical device industries face when trying to bring medical devices to market. At the top of the list are concerns resulting from increasing FDA regulatory requirements to pass devices through evaluation.[21] Knowing that regulatory concerns are a top issue motivates medical device companies to focus their efforts on streamlining this process when developing medical devices. Second on the list is the length of time and high cost of clinical trials.[21] A close third is the concerns over Medicare requirements and decreasing reimbursements.[21] When the FDA approves the use of a medical device, Centers for Medicare and Medicaid Services (CMS) and insurance companies are not required to

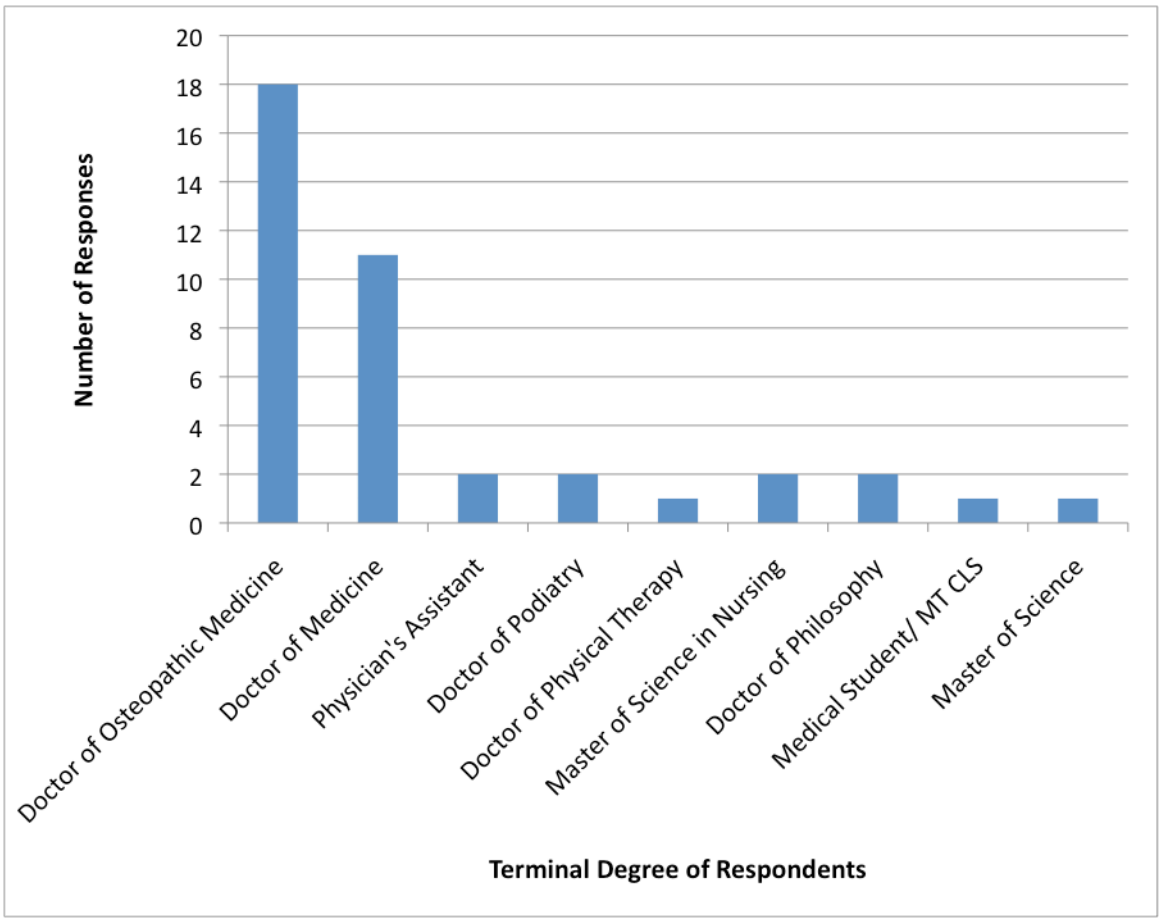
reimburse patients for the approved indications. CMS requires that a therapeutic treatment be "reasonable and necessary." [1]

Clinician Awareness and Obstacles

Clinicians use medical devices every day in their diagnosis and treatment of patients. A survey was distributed to clinicians to assess their awareness of medical device development and their experiences in the translation of medical devices. Approximately 50 surveys in print form were delivered to clinicians at the UNT Health Science Center. The survey was also provided to clinicians in an electronic format. Twenty-four of the print surveys were returned, and 16 electronic surveys were completed.

The survey targeted clinicians affiliated with the UNT Health Science Center. The percentage of responses from Doctors of Osteopathic Medicine (DO's) was 45% and Doctors of Medicine (MD's), 28 %. The graph in Figure 2 depicts terminal degrees of individuals responding to the survey. The distribution of those who responded shows the diversity of the clinicians at the UNT Health Science Center who took the survey. Ninety percent (90%) of responses are from board certified clinicians in their respective fields. Half of the clinicians surveyed had over 15 years of clinical experience.

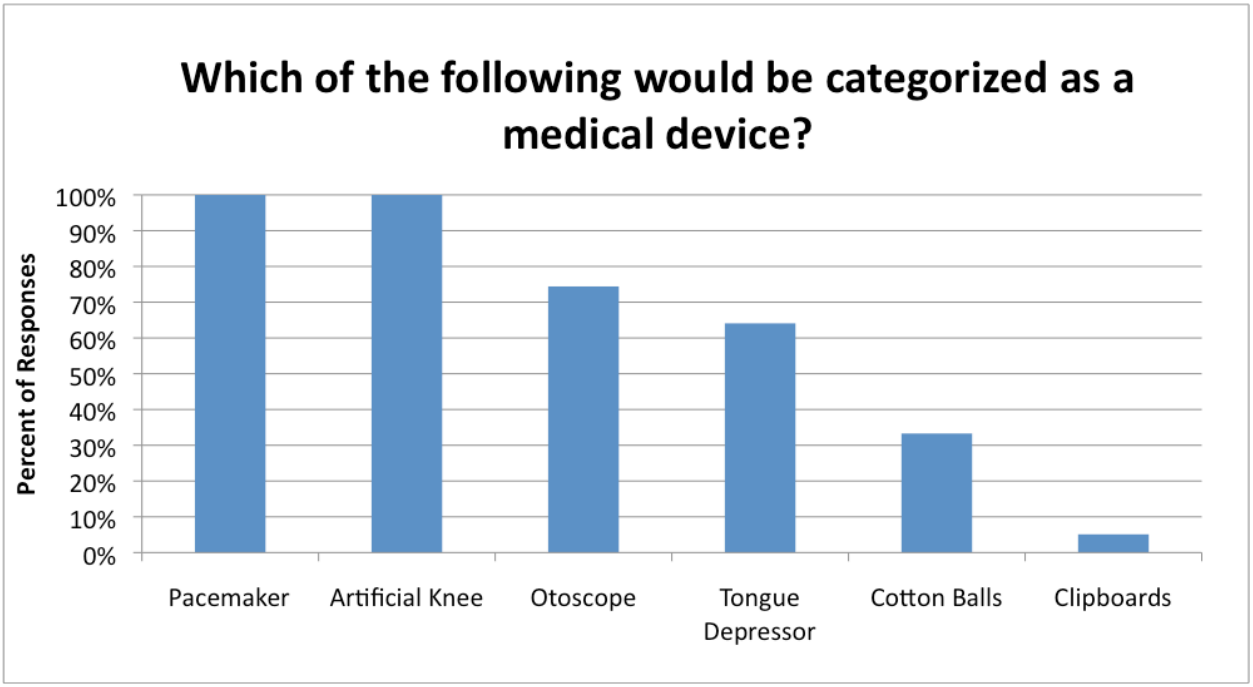
Figure 2



The survey gave the definition of a medical device according to the FDA (see Appendix II) and asked the clinician, "Based on the definition above, do you feel you have a good understanding of what a medical device is?" This question was skipped by one respondent, and 100% of given responses were "yes," they understood the definition. This question was followed by a question allowing the respondent to indicate what would be categorized as a medical device. Six items were listed: pacemaker, artificial knee, otoscope, tongue depressor, cotton balls, and clipboards. All of these are medical devices except the clipboards. As shown in Figure 3, of the 39 respondents who answered "yes" to the previous question, 100% of them correctly identified a pacemaker and artificial knee as a medical device. Seventy-four percent (74%) of respondents

correctly identified the otoscope as a medical device while 64% of respondents correctly identified tongue depressors as a medical device. Cotton Balls had the lowest response rate which only 33% correctly identified them as medical devices. Clipboards were incorrectly identified as medical devices by 5 % of respondents.

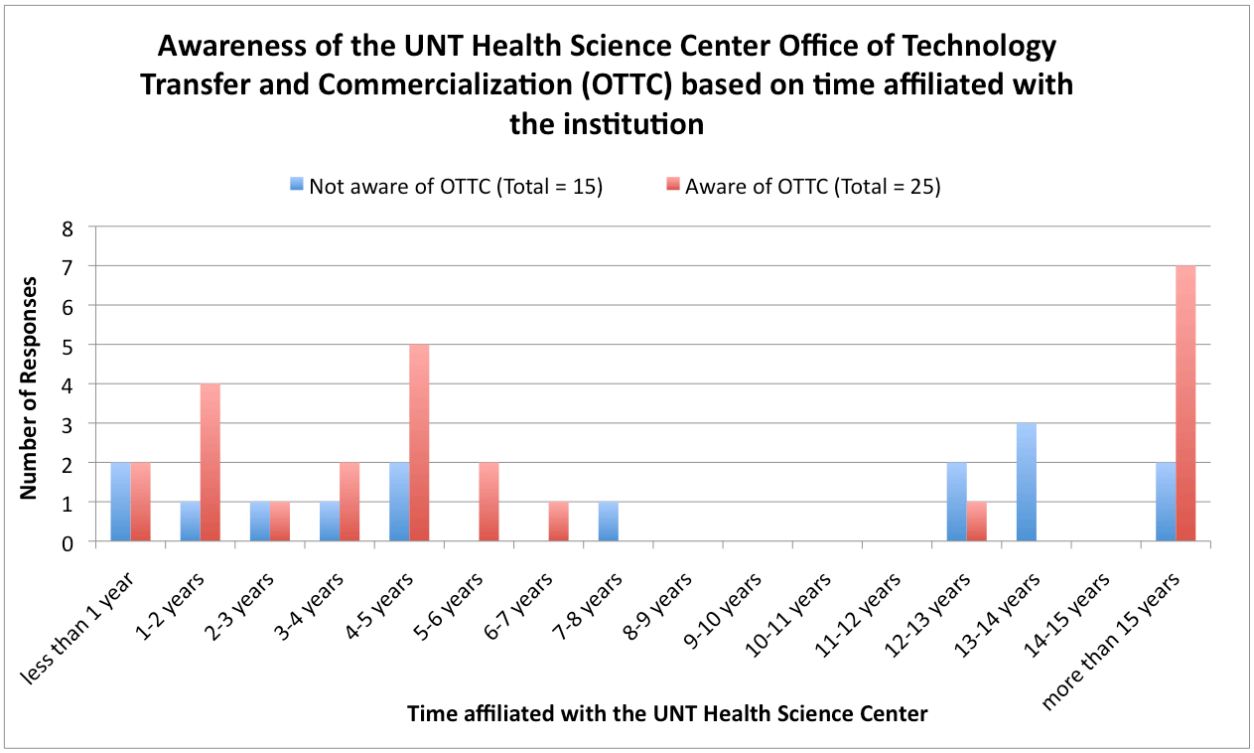
Figure 3



Clinicians who participated in the survey reported that they either did not understand or did not have time to follow through with the intellectual property process. One resource for clinicians at the UNT Health Science Center is the Office of Technology Transfer and Commercialization (OTTC). The OTTC specifically helps with intellectual property, patenting, and biotechnology based business development processes. This office assumes part of the workload associated with the legal and business aspects of the development process in order to encourage the continued development of new technology. Thirty-eight percent (38%) of respondents were not aware of the assistance available to them from the OTTC. Data in Figure 4

suggests that years affiliated with the UNT Health Science Center did not correlate with awareness of the OTTC.

Figure 4

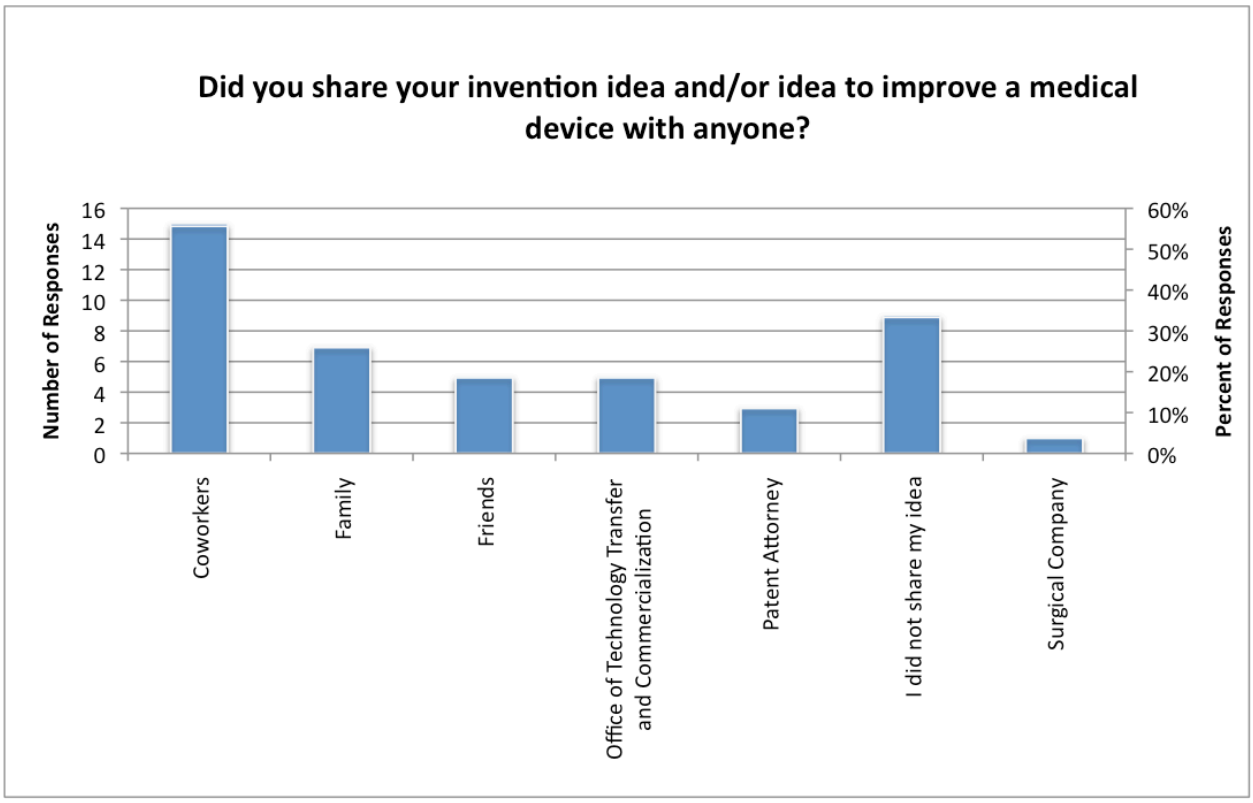


The NIH Roadmap acknowledges that clinicians are in the best position to make observations leading to medical research.[17] In medical device research this takes form in practicing clinicians becoming the quintessential inventor of new medical devices.[1] The following results pertain to the survey questions about clinicians' ideas, inventions, and actions pertinent to medical device inventions.

When asked if a problem had been encountered which could be addressed with a new medical device 80% of respondents answered "yes." Further inquiry revealed that 70% of respondents have had ideas to either invent a new medical device or make improvements on a current medical device. The survey directed these individuals to answer questions on the subject of invention disclosure. Figure 5 presents the responses to this question. Fifty- five percent

(55%) of respondents disclosed their invention to coworkers, and 33% of respondents chose not to disclose their invention. 19 % of respondents submitted their idea to the OTTC.

Figure 5



Five respondents reported that they have applied for patents. Thus, only 22% of the individuals with a new device idea/improvement pursued a patent. Respondents who did not pursue a patent indicated that the process was too time consuming, involved to much work, they did not understand the process, or that the idea remains in the planning and development phase. Of the individuals who applied for patents, 2 received a patent, 2 applied for a provisional patent, and 1 did not receive the patent due to an existing patent on a substantially similar device.

Development of pharmaceuticals and medical devices can be an arduous task. Pharmaceuticals and medical devices follow different regulatory and developmental pathways, resulting in differences in the cost and duration of development. The final two questions in the

survey dealt with clinician awareness of these differences. Data presented in Figure 6 indicates that 52% of respondents correctly answered that it takes less time to develop a medical device compared to a pharmaceutical. Of the remaining responses, 29% did not know the differences, while 19% answered that it requires the same or more time. As shown in Figure 7, similar responses were generated when asked about the cost of medical device development compared to pharmaceuticals. In general, it costs less to develop a medical device, as correctly indicated by 43% of the respondents (shown in Figure 7). An equal number of respondents answered that they did not know the cost differences. Fifteen percent (15%) of respondents answered that it cost more or the same to develop a medical device compared to a pharmaceutical.

Figure 6

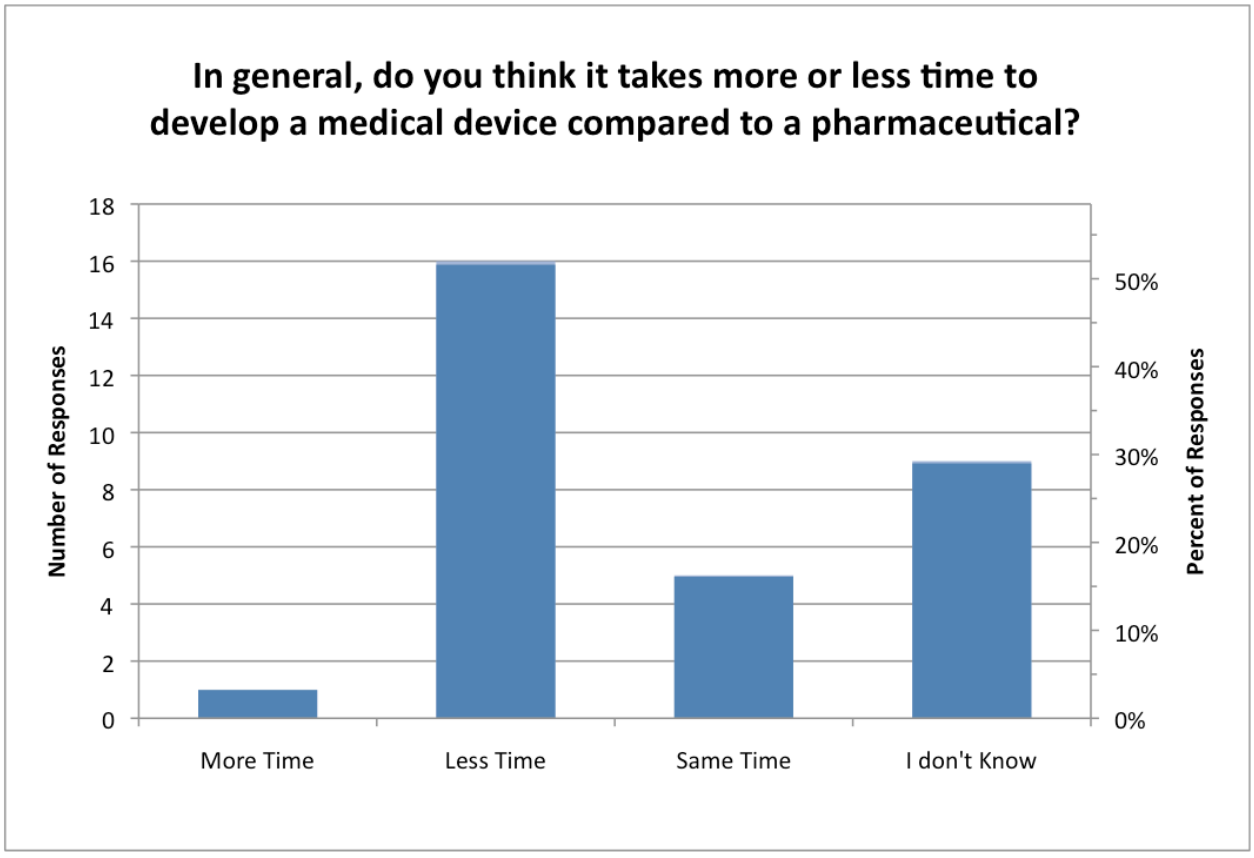
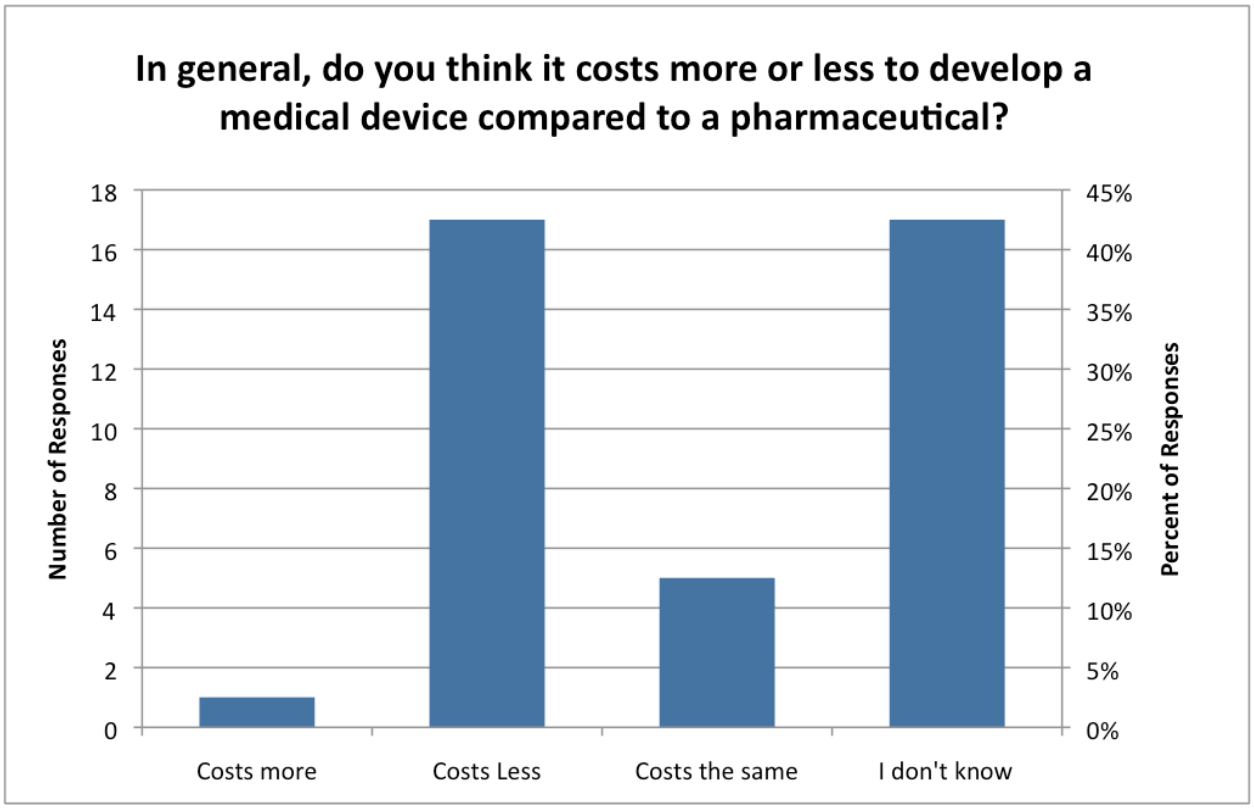


Figure 7


In general, do you think it costs more or less to develop a medical device compared to a pharmaceutical?
Number of Responses
Percent of Responses
18
16
14
12
10
8
6
4
2
0
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
Costs more
Costs Less
Costs the same
I don't know

DISCUSSION

Clinicians experienced difficulty when attempting to distinguish which items were medical devices. Class III medical devices were easily recognized by respondents. The Class I medical devices, such as otoscopes, tongue depressors, and cotton balls, were not as easily identified as medical devices by the respondents. Based on these results clinicians may be unaware that their ideas could be turned into marketable medical devices. To improve physician understanding, the UNT Health Science Center could give their physicians opportunities to learn about medical devices during the weekly scheduled Grand Rounds or other educational seminars. Improving understanding of medical devices is the first step to fostering the development of new medical devices.

An important step in the development of medical devices is the protection of intellectual property. Many academic institutions have a system set up to help their faculty, students, and staff with the difficult process of protecting intellectual property. Once a medical device has been designed, the invention should be submitted to the intellectual property office at the institution. At the UNT Health Science Center all faculty, students, and staff are required to submit an invention disclosure form to the OTTC. This is mandatory and violation of this policy may result in disciplinary action by the institution. The results from the survey showed that many of the clinicians were unaware of this office, and few of them submitted their ideas to the OTTC. This is a problem that should be corrected by educating clinicians on the policies of the institution and the purpose of the OTTC.

A medical device company will invest resources in developing an invention only if it is potentially profitable. Profitability is aided by the temporary monopoly ensured by the patent. During the design and development of a medical device, an inventor should be cautious in disclosing the invention. The results indicated that many of the clinicians shared their ideas with coworkers, family, and friends. These individuals may consider themselves co-inventors; particularly if they gave the inventor an idea on how to further improve the invention. Co-inventors must be listed on patents.[19] If a co-inventor of the invention is not mentioned, the patent may be invalidated if that individual comes forward. When an individual is listed on a patent, no matter what percent of the work they did, they have the same rights to use the device as the original inventor.[19] This can lead to issues regarding rights to market and sale the device, and how revenues are distributed. These points show that clinicians should be guarded in sharing their medical device idea before a patent is obtained, and stresses the importance of intellectual property disclosure.

The last 2 questions in the survey dealt with clinicians' awareness of the overall process of device development compared to pharmaceuticals. The mean time it takes to develop a medical device is less than pharmaceutical devices. It has been reported to take 2-7 years for a new medical device idea to become commercially available, verses 12-15 years to develop a new pharmaceutical drug.[22,23] Medical devices have the ability to reach patients faster than pharmaceuticals. It is important for physicians to anticipate the impact that medical devices may have on patients because of their shorter development time. For example, Americans are still awaiting a pharmaceutical that has a major impact on weight loss and type 2 diabetes. Meanwhile, gastric banding, using devices such as the Lap-Band®, is being used to promote weight loss and promote the recession of type 2 diabetes in morbidly obese patients.[2]

The cost to develop medical devices also appears to be less than that of pharmaceuticals. It has been reported to cost between $800 million and $1.7 billion to bring a new pharmaceutical to market.[23] This cost includes the many phases of clinical trials necessary to move pharmaceuticals through the FDA regulatory requirements. The shortened development duration of medical devices compared to pharmaceuticals also contribute to a decreased cost of development. Class I/II medical devices are not typically required to undergo clinical trials thus, having a lower investment, which was reported at approximately $400,000.[24] Class III medical devices are more risky and require clinical trials. The estimated cost of development for a Class III device has been reported at $1.5 million.[24] More than 50% of respondents were unaware of the decreased cost to develop medical devices. An objective in healthcare is to improve patient outcomes while decreasing cost. Innovations in medical devices can contribute to this.

This practicum study reinforces that the successful development of medical devices depends on the cooperation of clinicians and device companies in the coordination of device invention, intellectual property acquisition, regulatory approval, and marketing efforts, as seen in previous literature. The data obtained in the survey indicates that for medical device research and development to increase, clinicians need to be educated about medical device research and the impact it can have on patient outcomes. This can be accomplished at UNT Health Science Center Grand Rounds and other educational seminars.

Limitations of this practicum research include the small sample size of clinicians, and that it was only conducted at one institution. A larger study including multiple institutions would present data with a greater scientific value.

INTERNSHIP REVIEW

My internship was conducted at UNT Health Science Center in the Department of Surgery. My internship mentor, Dr. Albert O-Yurvati is currently involved in medical device research, and this led to the topic of interest, "Translational Research of Medical Devices." I also worked closely with the Department of Clinical Trials. During my internship I participated in the conduct of multiple clinical trials. The largest percentage of my time was occupied by a phase 3 clinical trial for recent acute coronary syndrome (ACS) patients. The intended effect of the study drug is to raise HDL levels, and thereby, reduce cardiovascular morbidity and mortality. The University of North Texas (UNT) Health Science Center of Fort Worth is one of many sites involved in this phase 3 trial. In total, the study projects to have 15,600 subjects. UNT Health Science Center currently has 17 subjects in various stages of this clinical trial. Working with the study provided me the opportunity to learn the regulatory and subject care aspects of a clinical trial. I also worked with regulatory and study management data on many other trials.

While working with the ACS trial, I was able to participate in subject recruitment, screening, enrollment, and randomization. This can be a long process that requires an immense amount of attention to detail. The Principal Investigator (PI) would give the name and contact information of potential subjects to the Clinical Research Coordinator (CRC). The CRC would then contact the potential subject and ask if he/she was interested in participating in the clinical trial. If the potential subject was interested, the CRC would pre-screen him/her by telephone and schedule an appointment for the screening visit. The screening visit would consist of completing

an informed consent with the subject, filling out source documents, and performing a blood draw. After receipt of the lab results, it was determined whether or not to randomize the subject based on his/her medical history and lab results.

Subsequent visits of this protocol involved a blood draw, electrocardiogram (ECG), vital signs, and questions regarding lifestyle and concurrent medications. The subject would return the medication dispensed at the previous visit, and new medication boxes would be dispensed. The medication had to be counted and compliance measured during the subject's visit. If compliance was low, the subject would be educated on the importance of compliance. During the subject's visit, adverse events would be recorded and reported as necessary. After the subject completed his/her visit, the blood samples would be processed and shipped. Information obtained during the subject's visit would be entered into the electronic source document system. The ECG would be faxed to the company and reviewed by the Principal Investigator or Sub-Investigator. A subject stipend request would also be completed by the CRC after each subject visit.

Clinical trials are closely monitored by the pharmaceutical company or clinical research organization that is responsible for conducting the trial. Clinical Research Associates are often sent to the study site to monitor study documents and verify adherence to the protocol. Any missing or incorrect information must be corrected at the monitor visit. If a protocol deviation has occurred, it is recorded and proper instruction and additional training is given to key personnel to ensure the mistake does not occur again. If a protocol violation has occurred it must be reported to the Institutional Review Board (IRB) in detail.

The IRB is responsible for ensuring the safety and protection of human subjects involved in clinical trials. The submission process to the IRB can be difficult without proper guidance or

training. During my internship, I learned how to submit documents to the IRB for exempt, expedited, and full board review. We had to submit documents for protocol amendments, continuing review, study closures, and serious adverse events (SAE).

The experiences in this internship have been invaluable, and will allow me to transition into a career in clinical research. One of the most important lessons I learned is that while the PI makes the study possible, the coordinator makes the study successful.

For a more detailed list of internship activities please see Appendix I: Daily Journal.

APPENDIX I: DAILY JOURNAL

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, December 7, 2009

- Started Internship.
- Della showed me around the surgery floor of PCC.
- Spent the day organizing and cleaning my office.
- Turned in key request.

Tuesday, December 8, 2009

- Read the Acute Coronary Syndrome protocol (ACS).
- Filed papers.
- Organized office
- Meeting with Della and Srishti

Wednesday, December 9, 2009

- Filed research documents, and began to familiarize myself with regulatory binders and subject binders.
- Went to property control to find new bookshelf and chair.

Thursday, December 10, 2009

- Continued to study ACS Protocol.
- Studied Informed Consent for ACS protocol.
- Turned in equipment transfer notification.

Friday, December 11, 2009

- Began researching background information for research proposal.

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, December 14, 2009

- Read Skin Infection Study
- Familiarized myself with Skin Infection Study Documents

Wednesday, December 16, 2009

- Office of Clinical Trails Coordinator Meeting
  - Discussed upcoming protocol Submissions
  - Discussed ongoing Clinical trails
  - Discussed ways to utilize and improve use of Study Manager
- Subject Follow-Up Visit
  - Learned about follow up visit procedures.
  - Learned how to update subject binder
  - Learned how to dispense new study drug
  - Drug Accountability
  - Obtain & Process Blood samples (Observed)
  - Obtain ECG (Observed)
  - Ship Specimens
  - Complete Source Documents
- ASC Monitor at Site
  - Assisted monitor by finding needed documents
- Attended Grand Rounds
  - Cooks Children's: Community-wide Children's Health Assessment and Planning Survey
  - www.cchaps.org

Thursday, December 17, 2009

- ACS Monitor at Site
  - Assisted Monitor with drug accountability
  - Read ARQIVE study

Friday, December 18, 2009

- Reviewed skin infection protocol
  - Specifically studied Inclusion/Exclusion criteria for our potential subject
  - Studied Timeline and subject visits

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, December 21, 2009

- The screening visit for our potential skin infection subject was today. She did not match criteria and was excluded.

Tuesday, December 22, 2009

- Jim came to begin my training in Study Manager
    - Input subjects in Study manager

Wednesday, December 23, 2009

- Data Entry in Study Manager

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, January 4, 2010

- Subject follow-up visit (With Della)
  - Updated subject binders.
  - Entered information in ECRF.
  - Entered information in study manager.
  - Drug Accountability
  - Ship Subject Specimens
  - Dispensed new study drug
  - Obtain & Process Blood samples (Observed)
  - Obtain ECG (Observed)
  - Fax ECG to company
  - Complete Source Documents
- Learned how to use ECRF for ACS
- Technician came to help fix my computer.
- Learned how to submit ECG to company
- Learned how to ship biological samples

Tuesday, January 5, 2010

- Updated patients ECRF
- Started working on CHD risk source document
- Started working on Healthy Heart diet counseling packet
- Filed Documents for ACS and another protocol

Wednesday, January 6, 2010

- Finished CHD source document
- 2 Subject follow-up visits
  - Updated subject binders.
  - Entered information in ECRF.
  - Entered information in study manager.
  - Drug Accountability
  - Ship Subject Specimens
- Wrote Healthy Heart counseling letter for subject.

Thursday, January 7, 2010

- Worked on research proposal.
- Worked on internship journal.

Friday, January 8, 2010

- Worked on research proposal.

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, January 11, 2010
- Filed documents for study.
- Worked on research proposal.
- Worked on internship journal.

Tuesday, January 12, 2010
- Patient Education Materials
- Literature Review for Research proposal
- Meeting with Della and Srishti

Wednesday, January 13, 2010
- Worked on Research Proposal
- Subject Follow-Up visit (With Della)
    - Updated subject binders.
    - Entered information in ECRF.
    - Entered information in study manager.
    - Drug Accountability
    - Ship Subject Specimens
- OCT Staff Meeting
    - Discussed upcoming protocol Submissions
    - Discussed ongoing Clinical trails
    - Discussed ways to utilize and improve use of Study Manager
    - Discussed revisions to SOP's

Thursday, January 14, 2010
- Worked on Research Proposal
- Met with Dr. O-Yurvati about Research Proposal

Friday, January 15, 2010
- Worked on Research Proposal

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Tuesday, January 19, 2010

- Worked on Research Proposal
- Completed ACS Conflict of Interest form
- Meeting with Della

Wednesday, January 20, 2010

- Completed Citi Training
- Sent Citi Training Certificate to Tina
- OCT Staff Meeting
    - Discussed upcoming protocol submissions
    - Discussed ongoing clinical trails
    - Update study manager studies
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Thursday, January 21, 2010

- Revisions on Research Proposal
- Source documents for ACS
- Meeting with Srishti

Friday, January 22, 2010

- Submit Subject education materials to IRB
- Worked on Research Proposal

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, January 25, 2010

- Study Manager
- Source documents for ACS
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, January 26, 2010

- Study Manager
- Revised Research proposal
- Sent Research proposal to Dr. O-Yurvati
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Wednesday, January 27, 2010

- OCT Staff Meeting
    - New SOP's
    - Data Management in Study Manager
    - Current and upcoming Studies
- Meeting with Della
- Grand Rounds
    - Educating Adult Learners: As Clinical Educators

Thursday, January 28, 2010

- Discussed research proposal with Dr. Gwirtz
- Meeting with Srishti
- Worked on Research Proposal

Friday, January 29, 2010

- Signatures for Continuing review forms for MRSA study
- Study Manager
- Filed documents for ACS

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, February 1, 2010

- Filed documents for B in Regulatory Binders
- Meeting with Srishti
- Ordered Lab Supplies

Wednesday, February 2, 2010

- Grand Rounds
- OCT Staff Meeting
    - New SOP's
    - Data Management in Study Manager
    - Current and upcoming Studies
- Meeting with Della and Srishti

Thursday, February 3, 2010

- Literature review for research
- Filed documents for ASC
- Met with Dr. O-Yurvati about Research

Friday, February 4, 2010

- Worked on Research
- Obtained Signatures for Research Proposal
- Filed documents for ACS

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, February 8, 2010
- Study Manager
- Source documents for ACS
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, February 9, 2010
- Study Manager
- Worked on Research
- Obtained study related signatures from Dr. Weiss

Wednesday, February 10, 2010
- OCT Staff Meeting
    - New SOP's
    - Data Management in Study Manager
    - Current and upcoming Studies
- Meeting with Della

Thursday, February 11, 2010
- Meeting with Della
- Worked on Proposal
- Filed regulatory documents for ACS

Friday, February 12, 2010
- Study Manager
- Filed documents for ACS
- Worked on Research

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Tuesday, February 16, 2010

- Study Manager
- Worked on Research
- Obtained study related signatures from Dr. Weiss

Wednesday, February 17, 2010

- OCT Staff Meeting
    - Data Management in Study Manager
    - Current and upcoming Studies
- Meeting with Della
- Meeting with Dr. O-Yurvati about research
- Grand Rounds

Thursday, February 18, 2010

- Meeting with Della
- Worked on Proposal
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Friday, February 19, 2010

- Study Manager
- Filed documents for ACS
- Worked on Research

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, February 22, 2010

- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, February 23, 2010

- Protocol For Masters Project
- Filed documents for ACS
- Meeting with Della

Wednesday, February 24, 2010

- OCT Coordinator meeting
    - Data Management in Study Manager
    - Current and upcoming Studies
    - OCT improvement Strategies
- Grand Rounds

Thursday, February 25, 2010

- Protocol for Masters Project
- Meeting with Della and Srishti
- Filed documents for ACS
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Friday, February 26, 2010

- Research for Masters

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, March 1, 2010

- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, March 4, 2010

- Reviewed literature for research proposal
- Made revisions on research proposal

Wednesday, March 3, 2010

- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents
- Grand Rounds
- OCT Staff Meeting
    - New SOP's
    - Data Management in Study Manager
    - Current and upcoming Studies
    - Plan for Risk Reduction

Thursday, March 4, 2010

- MRSA Study Closeout Visit
    - Worked with Monitor from GSK to complete study close-out documentation. (All Day)

Friday, March 5, 2010

- Worked on Research
- Obtained Signatures for Research Proposal

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, March 8, 2010

- Searched for new studies on clinicaltrails.gov
- Research for Internship Project
    - Talked to Mrs. McDermott for industry perspective on new medical devices.
- Site Selection Visit
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, March 9, 2010

- Filed ASC documents in reg binder
- Created new Subject Binder
    - Assembled Source
    - Copied IC & PS
- Faxed closeout documents
- Study Manager

Wednesday, March 10, 2010

- OCT Staff Meeting
    - New SOP's
    - Data Management in Study Manager
    - Current and upcoming Studies
- Reviewed Source Documents
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Thursday, March 11, 2010

- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Friday, March 12, 2010

- Continuing review paperwork for ACS

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, March 22, 2010

- Study Manager: T05
  - Met with Sandra for Questions
  - Emailed Jim- studies up to date
- Study Manager: T11
  - Met with Sandra for Questions
  - Emailed Jim- studies up to date
- Study Manager: Serene
  - Need Documents from Cynthia
    - Went by her office in AM and in PM, and she was not there.
- Research- Questionnaire
  - Waiver of Informed Consent for Survey

Tuesday, March 23, 2010

- Study Manager
- Meeting with Cynthia
- Meeting with Della

Wednesday, March 24, 2010

- Subject Follow-up Visit (With Della)
  - Dispensed new study drug
  - Drug Accountability
  - Obtain & Process Blood samples (Observed)
  - Obtain ECG (Observed)
  - Ship Specimens
  - Fax ECG to company
  - Complete Source Documents
- Grand Rounds
- OCT Staff Meeting
  - Review modifications to SOP's
  - Data Management in Study Manager
  - Current and upcoming Studies

Thursday, March 25, 2010

- Masters Research Project
- Meeting with Della
- Obtained study related signatures from Dr. Weiss

Friday, March 26, 2010

- Worked on Survey questions

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, March 29, 2010
- Study Manager
- Research for Masters
- Meeting with Cynthia
- Filed documents for ACS
- Requested medical records for subject in ACS

Tuesday, March 30, 2010
- Study Manager
- Meeting with Della
- Filed medical records for subject in ACS

Wednesday March 31, 2010
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents
- Grand Rounds
- OCT Staff Meeting
    - Review modifications to SOP's
    - Data Management in Study Manager
    - Current and upcoming Studies

Thursday April 1, 2010
- Masters Research Project
- Organize supplies in Lab
- Throw out expired supplies in Lab

Friday, April 2, 2010
- Research for Masters
- File source documents for patients
- Meeting with Srishti

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, April 5, 2010

- Meeting with Dr. O-Yurvati
- Meeting with Srishti
- File documents for ACS
- Study Manager

Tuesday, April 6, 2010

- Protocol For Masters Project
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Wednesday, April 7, 2010

- OCT Coordinator meeting
- 2 Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents
- Grand Rounds
    - Physician Quality Reporting (PRQI) e-Prescribing

Thursday, April 8, 2010

- Protocol for Masters Project
- Filed documents for ACS
- Obtained Study related signatures from Dr. Weiss

Friday, April 9, 2010

- Research for Masters
- Meeting with Della

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, April 12, 2010
- File documents for ACS
- Study Manager
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, April 13, 2010
- Protocol For Masters Project
- Meeting with Della
- Obtained study related signatures from Dr. Weiss
- Filed source documents
- Monitor Visit ACS (All Day)

Wednesday, April 14, 2010
- OCT Coordinator meeting
    - Discussed upcoming studies
    - Discussed improvements OCT can make
    - Discussed budgets of studies
- Monitor Visit ACS (All Day)
- Grand Rounds

Thursday, April 15, 2010
- Protocol for Masters Project
- Filed documents for ACS
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Friday, April 16, 2010
- Protocol for Masters
- Completed ACS documents
- Ordered Lab Supplies
- Meeting with Della

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, April 19, 2010

- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, April 20, 2010

- IRB documents for Research Survey
- Protocol For Masters Project
- Filed documents for ACS

Wednesday, April 21, 2010

- Ramona's Farewell Party
- OCT Coordinator meeting
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents
- Grand Rounds
    - Smoking out the evidence- shaping clean air policy with 21st century evidence and technology.

Thursday, April 22, 2010

- IRB documents for Research Survey
- Filed documents for ACS
- Made copies of ECG's for ACS

Friday, April 23, 2010

- IRB documents for Research Survey
- Made copies of ECG's for ACS

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, April 26, 2010

- Faxed ***Hospital for medical records for 2 Subjects
- Faxed ***Hospital for medical records for 1 Subject
- Called *** Hospital Regarding subject medical records
- Fixed fax machine
- Filed medical records for subjects
- Filed Source Documents

Tuesday, April 27, 2010

- Filed medical records for subjects
- Filled out IRB paperwork for survey
- Filled out conflict of interest forms for survey
- Wrote recruitment materials for survey
- Reviewed IRB paperwork with Dr. O-Yurvati
- Submitted project to IRB
- Discussed project with Dr. Gladue

Wednesday, April 28, 2010

- Grand Rounds
    - New Insights into the Benefits and Limitations of Energy Restriction as an Anti-aging Intervention
- OCT Staff Meeting
    - Data Management in Study Manager
    - Current and upcoming Studies
- Received revisions for research survey from IRB

Thursday, April 29, 2010

- Della back from ACRP- Meeting with Della
- Filed SAE's for ACS
- Filed regulatory docs for ACS
- Filled out Waiver of consent form.
- Revised Cover Letters for Research
- Submitted revisions for research to IRB

Friday, April 30, 2010

- Received Approval from IRB
- Filled out Daily News ad for Research
- Started recruitment for Research

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, May 3, 2010
- Continued recruitment for Survey
- Reviewed literature for Practicum Report

Tuesday, May 4, 2010
- Worked on Practicum Report
- Worked on Internship Journal
- Continued recruitment for survey

Wednesday, May 5, 2010
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents
- OCT Staff Meeting

Thursday, May 6, 2010
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Friday, May 7, 2010
- Worked on Practicum Report

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, May 10, 2010
- Worked on Practicum Report
- Collected surveys
- Input survey data in SurveyMonkey online database
- Study Manager

Tuesday, May 11, 2010
- Worked on Practicum Report
- Collected surveys
- Input survey data in SurveyMonkey online database
- Filed documents for ACS

Wednesday, May 12, 2010
- Grand Rounds
    - Hot topics in Pediatric Infectious Diseases
- Worked on Practicum Report
- Collected surveys
- Input survey data in SurveyMonkey online database

Thursday, May 13, 2010
- Worked on Practicum Report
- Collected surveys
- Input survey data in SurveyMonkey online database

Friday, May 14, 2010
- Found error in Printed Survey. Began working on IRB amendment
- Created new recruitment materials

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, May 17, 2010

- 2 Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Tuesday, May 18, 2010

- Dr. O-Yurvati out of town. Cannot get signatures for amendment until next Monday.
- Worked on Practicum Report
- Collected surveys
- Input survey data in SurveyMonkey online database

Wednesday, May 19, 2010

- Worked on Practicum Report
- Collected surveys
- Input survey data in SurveyMonkey online database

Thursday, May 20, 2010

- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Friday, May 21, 2010

- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Monday, May 24, 2010
- Dr. O-Yurvati's Signature on Protocol Amendment
- Submitted Protocol Amendment to IRB
- Reserved room for Defense
- Filled out form for Defense
- Signatures for Defense
- Picked up Approved protocol amendment from IRB
- Entered Surveys into online database

Tuesday, May 25, 2010
- Entered surveys into online database
- Worked on Practicum Report

Wednesday, May 26, 2010
- Entered surveys into online database
- Subject Follow-up Visit (With Della)
    - Dispensed new study drug
    - Drug Accountability
    - Obtain & Process Blood samples (Observed)
    - Obtain ECG (Observed)
    - Ship Specimens
    - Fax ECG to company
    - Complete Source Documents
- OCT Staff Meeting
    - Data Management in Study Manager
    - Current and upcoming Studies
    - Ways to obtain new clinical trails
- Meeting with Della and Srishti

Thursday, May 27, 2010
- Filed documents
- Edited Daily News Ad
- Internship Practicum Report
- Medical Records for SAE

Friday, May 28, 2010
- Worked on Practicum Report

Internship Journal for Jessica P Blaylock
Dept. of Surgery

Tuesday, June 1, 2010

- Revisions on Internship Journal
- Worked on Practicum Report
- Complete Study Manager tasks
- Cleaned Office.
- Meeting with Jim
- Meeting with Della and Srishti
- Discussed survey with Dr. O-Yurvati

Wednesday, June 2, 2010

- OCT Staff Meeting
    - Discuss upcoming clinical trails
    - Discuss data management in Study Manager
- Worked on Internship Practicum Report
- Finished Cleaning out office
- Wrapped up all projects at Internship Site.

APPENDIX II: SURVEY

Translational Research of Devices:

An Assessment of the Common Obstacles Encountered by Clinical Researchers

Principal Investigator: Dr. Albert O-Yurvati

Co-Investigator: Jessica Blaylock

Institution: University of North Texas Health Science Center

Introduction:
We are conducting a research project to determine clinical researchers' awareness of translational research of medical devices.

You are invited to participate in this research survey because you are a licensed clinician associated with the UNT Health Science Center. This survey will gauge your idea and understanding of translational research of medical devices. The survey will take no more than 10 minutes to complete.

This study exists in two forms, a hard-copy form and an online form. Please do not complete the online form if you submit this hardcopy form. If you would prefer to complete this survey online please go to **http://www.surveymonkey.com/s/TranslationalResearchOfMedicalDevices** or follow the link on the Daily News.

Risk/Benefit:
There are no foreseeable risks associated with participating in this survey. You may receive no direct benefit from participating in this study. The benefits of this survey will allow us to evaluate where we should concentrate our efforts in educating clinical researchers regarding medical devices. It will also allow us to understand where medical devices fail in translational research so that we may overcome these obstacles in the future.

Agreement to Participate:
Participation in the study is completely voluntary. If you decide to participate, you can complete and return the survey in the attached pre-addressed return envelope via intercampus mail.

Confidentiality:
You will not be asked for your name or any other identifying information on the survey.

Leaving the Study:
Since the survey is not identifiable, there will be no way to withdraw from the study once you complete and return the survey in the mail.

Questions/Concerns:
If you have any questions regarding this research project, please feel free to contact:

- Principal Investigator: Dr. Albert O-Yurvati Albert.Yurvati@unthsc.edu
- Co-Investigator: Jessica Blaylock jblaylock@live.unthsc.edu 817-735-0512

If you have any questions about your rights as a research subject, please contact the UNT Health Science Center Institutional Review Board at (817) 735-0409.

Thank you for participating in the study.

Survey: Translational Research of Devices

Profession

This section of the survey will ask questions about your academic background and your current profession.

1. Which of the following degrees do you hold? (Check all that apply)

- ☐ BS
- ☐ BA
- ☐ BSN
- ☐ BMSc
- ☐ MS
- ☐ MPH
- ☐ MPAS
- ☐ MSN
- ☐ PhD
- ☐ DO
- ☐ MD
- ☐ Other (please specify)

2. How long have you been affiliated with The University of North Texas Health Science Center?

- ◯ less than 1 year
- ◯ 1-2 years
- ◯ 2-3 years
- ◯ 3-4 years
- ◯ 4-5 years
- ◯ 5-6 years
- ◯ 6-7 years
- ◯ 7-8 years
- ◯ 8-9 years
- ◯ 9-10 years
- ◯ 10-11 years
- ◯ 11-12 years
- ◯ 12-13 years
- ◯ 13-14 years
- ◯ 14-15 years
- ◯ more than 15 years

3. What is your academic rank (title)?

- ◯ Assistant Professor
- ◯ Associate Professor
- ◯ Professor
- ◯ Other (please specify)

4. Have you acquired tenure?

- ◯ Yes
- ◯ No

5. Are you a board certified clinician?

- ◯ Yes
- ◯ No

6. How many years have you been in clinical practice?

- ◯ none
- ◯ 0-1 year
- ◯ 1-2 years
- ◯ 2-3 years
- ◯ 3-4 years
- ◯ 4-5 years
- ◯ 5-6 years
- ◯ 6-7 years
- ◯ 7-8 years
- ◯ 8-9 years
- ◯ 9-10 years
- ◯ 10-11 years
- ◯ 11-12 years
- ◯ 12-13 years
- ◯ 13-14 years
- ◯ 14-15 years
- ◯ more than 15 years

Survey: Translational Research of Devices

Medical Devices

According to the FDA a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

*recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

*intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

*intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes"

7. Based on the definition above, do you feel you have a good understanding of what a medical device is?

- ◯ Yes
- ◯ No

8. Which of the following would be categorized as a medical device? (Check all that apply)

- ☐ Clipboards
- ☐ Pace Maker
- ☐ Artificial Knee
- ☐ Otoscope
- ☐ Cotton Balls
- ☐ Tongue Depressor

Survey: Translational Research of Devices

Office of Technology Transfer and Commercialization

9. Are you aware that the UNT Health Science Center Office of Technology Transfer and Commercialization help faculty, staff, and students with Intellectual Property services, such as filing for patents?

- ◯ Yes
- ◯ No

Survey: Translational Research of Devices

Novel Medical Devices

10. In your medical practice, have you ever encountered a problem which you believe could be addressed with a new medical device?

- ◯ Yes
- ◯ No

11. Have you ever had an idea to

- ☐ Invent a new medical device
- ☐ Make improvements on a current medical device
- ☐ Neither.

If neither, please skip to question 16.

Survey: Translational Research of Devices

Intellectual Property

12. Did you share any information about your medical device invention and/or idea with anyone? (Check all that apply)

- [ ] Coworkers
- [ ] Family
- [ ] Friends
- [ ] Office of Technology Transfer and Commercialization
- [ ] Patent Attorney
- [ ] I did not share my idea
- [ ] Other (please specify)

13. Did you submit your idea to UNTHSC Office of Technology Transfer and Commercialization?

- ◯ Yes
- ◯ No

Survey: Translational Research of Devices

Intellectual Property cont.

14. Did you apply for a patent?

◯ Yes

◯ No (please explain why not)

If no, please skip to question 16.

Survey: Translational Research of Devices

Intellectual Property cont.

15. Did you receive the patent?

◯ Yes

◯ No (please explain why not)

Survey: Translational Research of Devices

Medical Device General Information

16. In general, do you think it takes more or less time to develop a medical device compared to a pharmaceutical?

- ◯ More Time
- ◯ Less Time
- ◯ It takes the same amount of time
- ◯ I don't know

17. In general, do you think it costs more or less to develop a medical device compared to a pharmaceutical?

- ◯ Costs more
- ◯ Costs Less
- ◯ Costs the same
- ◯ I don't know

Survey: Translational Research of Devices

End of Survey

Thank you for participating in this research survey!

Please put completed survey in attached envelope and return via intercampus mail to box # 636.

APPENDIX III: IRB FORMS

UNIVERSITY of NORTH TEXAS
HEALTH SCIENCE CENTER at Fort Worth
★
Education, Research,
Patient Care and Service

DATE: 30 April 2010

Office for the Protection of Human Subjects
3500 Camp Bowie Boulevard
Fort Worth, Texas 76107-2699

TO: Albert O-Yurvati, DO
(with student Jessica Blaylock, BS)
Clinical Research Management Program

PROTOCOL: #2010-066

"Translational Research of Devices: An Assessment of the Common Obstacles Encountered by Clinical Researchers"

IRB BOARD ACTION AND NOTICE OF APPROVAL

The Institutional Review Board (IRB) of the University of North Texas Health Science Center (UNTHSC) has reviewed your protocol and has granted approval for **EXEMPT** status as specified in Federal Regulations 45 CFR 46.101(b), category (2).

Note that you are responsible for complying with all UNTHSC IRB and OPHS policies, decisions, conditions and requirements regarding projects involving human subjects. You are responsible for insuring that the research is implemented as specified in the approved protocol. Unless otherwise authorized by the UNTHSC-IRB, you are responsible for notifying subjects that their participation and information will be used for research purposes. In addition, you are required to use ONLY the IRB approved documents, materials and/or process designated for this protocol.

You must report to the Chair of the IRB any changes affecting the protocol upon which this certification is based. **No changes may be made without prior approval by the IRB** except those necessary to eliminate immediate hazards.

If you have any questions, please contact Ms. Heather Cline, Human Subject Protection Coordinator, at phone (817) 735-5457 in the Office for the Protection of Human Subjects, or send email to her at hcline@hsc.unt.edu

Sincerely,

Brian Gladue, PhD
Chair, UNTHSC Institutional Review Board

cc: H. Cline, OPHS

UNIVERSITY *of* NORTH TEXAS HEALTH SCIENCE CENTER
OFFICE *for the* PROTECTION *of* HUMAN SUBJECTS
INSTITUTIONAL REVIEW BOARD

Request for Waiver of Documentation of Informed Consent
Form A

IRB #

Investigator's Name: Albert O-Yurvati, D.O.

Title of Project: Translational Research of Devices: An Assessment of the Common Obstacles Encountered by Clinical Researchers

Documentation of consent means that participants are required to sign a consent form, thereby documenting their consent. A waiver of documentation means that the UNTHSC IRB is waiving the requirement to obtain the participant's signature. Even if this waiver is granted, a consent process must still be in place. The consent process must contain all the required elements of consent and usually consists of a consent form/verbal script that is read aloud to them.

For the UNTHSC IRB to grant this waiver, your research project must meet one of the following conditions. ***Please initial the line next to the appropriate condition and explain why your research meets the condition in the space provided*.**

_____ *(initial)* **Condition 1-** The only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from the breach of confidentiality. This refers to instances where participants could be seriously harmed if it became known that they were participants in the research.

Explanation:

OR

MM *(initial)* **Condition 2-** The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Explanation: This project consists of a survey that will not elicit sensitive information. This survey will present no more than minimal risk of harm to participants.

Investigator's Signature _____ **Date** 4/28/10

IRB Chair's Signature _____ **Date** 4/30/10

TRANSLATIONAL RESEARCH OF MEDICAL DEVICES: AN ASSESSMENT OF THE COMMON OBSTACLES ENCOUNTERED BY CLINICAL RESEARCHERS

Principal Investigator:
Albert O-Yurvati, D.O.
UNT Health Science Center
3500 Camp Bowie Blvd
Fort Worth TX 76107
Email: Albert.Yurvati@unthsc.edu

Student Investigator:
Jessica Blaylock
UNT Health Science Center
855 Montgomery St
Fort Worth TX 76107
Telephone: 817-735-0512
Email: jblayloc@live.unthsc.edu

Specific Aims:

- Identify the prevalence of novel medical device ideas and inventions among clinical researchers at UNT Health Science Center.
- Identify common obstacles that hinder the progression of devices from basic research into clinical trails.

Background and Significance:

Advances in medical device technology help many fields of medicine. In cardiology medical devices have helped decrease deaths and increase overall life expectancy.[1] Medical devices are used in physical and occupational therapy to help improve the quality of life of patients. The potential advances in medical devices are endless, but there are many obstacles that must be overcome to have a successful medical device. The first step in the medical device process is to Identify the need for medical devices. For this we turn to clinicians.

The NIH Roadmap recognizes that clinicians are in the best position to recognize the areas where we need to concentrate our research efforts[2]. The firsthand knowledge obtained by clinicians may guide them to specific ideas as to how to fix a medical condition with a new or improved medical device. The examination of translational research of medical device research by this survey will address specific issues concerning the development of medical devices in their earliest stages. By addressing these issues we may be made more aware of the assistance we can provide clinical researchers at the UNT Health Science Center regarding the development of new medical devices.

Preliminary Studies:
None

Investigator Experience:

AH O-Yurvati DO ,FACOS ,FICS, FAHA is a 1986 graduate of the UNTHSC Texas College of Osteopathic Medicine. He completed his Internship and General Surgery residency at Tulsa Regional Medical Center, Tulsa Oklahoma. He then completed a residency in Cardiothoracic and Vascular Surgery at the Deborah Heart and Lung Center, Robert Wood Johnson Medical School, Browns Mills New Jersey.

Currently Dr. O-Yurvati is Professor of Surgery and Interim-Chair in the department of Surgery, adjunct faculty in the Department of Integrative Physiology, and the school of Biomedical Sciences at the University of North Texas Health Science Center at Fort Worth.

He has served on many committees on the local, state and national level. He is immediate Past President of the Metro Fort Worth American Heart Association and is a past Board member of the Texas Affiliate of the AHA. On a national level Dr. O-Yurvati is the Cardiovascular and Thoracic board representative to the American Osteopathic Board of Surgery, as well as the Vice-Chair of the board. He is on the editorial board of the ***JAOA*** and ***Filtration***. He is a reviewer for many peered journals to include ***Cardiovascular Research ,Experimental Biology and Medicine ,Perfusion and the Annals of Thoracic and Cardiovascular Surgery***

He has published many peer reviewed articles, and has lectured nationally and internationally. He has presented and co-chaired previously at the Therapeutic Filtration and Extracorporeal Circulation meeting at the prestigious Hammersmith hospital in London, England.

Dr. Yurvati's research interests include the inflammatory effects of cardiopulmonary bypass, cardiac metabolism and post cardiac surgery adhesions. He has also participated as a co-investigator on grants from the NIH, NOF and NASA, and currently has a funded research grant from the Osteopathic Heritage Foundation.

Experimental Design and Methods:

This research will consist of a survey to assess clinician's awareness of medical device translational research and gain a general idea of the possible growth in medical device development at the UNT Health Science Center. The survey that has been developed has been made as both, an online survey and a paper survey for ease of use with the clinicians. The online survey is at surveymonkey.com.

The survey asks questions regarding the professional background of the clinicians. These questions will be used to assess if different educational backgrounds lead the clinicians to be more or less likely to engage in medical device research. It may be possible that some physicians who have had research backgrounds would be more likely to develop a new medical device.

The next set of questions addresses the clinician's basic understanding of medical devices. This is important because a clinician must first understand what a medical device is. If clinicians do not understand what a medical device is then this will allow us to focus clinician education in this area.

The next sections are designed to assess clinician's awareness of intellectual property and patenting processes. It will also address the second specific aim regarding where medical devices fail in the patenting process and why.

The last section has more questions regarding medical devices. These questions will be used to assess their awareness on the profitability and time to market of medical devices.

Data Storage:

Pre-addressed envelopes will be provided with the paper surveys. Investigators will be asked to place the survey into the provided envelope and mail to box #636 (Jessica Blaylock's UNTHSC Student Box) using intercampus mail. Paper copies will be stored in PCC 597 until they have been entered into the online database. Once the paper surveys have been entered and saved in the online database they will be shredded. .

Data collected from online survey will be stored at surveymonkey.com. The only users that will have access to this information are the Principal Investigator and Student Investigator. The online storage of survey information will not contain identifiers such as IP addresses or emails

The survey is expected to take approximately 10 minutes to complete. The survey will be made available as early as May 1st, and will stay open until a minimum of 30 responses have been submitted. There is no maximum number of responses.

Human Subjects:

The survey will be targeting clinicians that work in the UNT health network. The survey is set up to target MD's, DO's, and PA's, but will not exclude other licensed medical professionals. An email will be sent out to the clinicians asking them to complete the survey by following a link. There will also be an announcement on the Daily news that will provide a link for the clinicians to follow. In addition to this electronic form, there is a print form of the survey that has been developed. This will be hand delivered to clinician's offices. The print survey will then be mailed back and entered into the online database. No information specifically identifying the individual will be collected. This protocol is aiming at a response rate of at least 30 practicing physicians and any other licensed professionals that chose to answer the survey.

A cover letter will be used in lie of an informed consent. This survey will present no more than minimal risk. It will not adversely affect the rights and welfare of the subjects. The processes of obtaining an informed consent will identify the subjects whereas the cover letter will allow the subjects to remain anonymous. Participants will not be contacted with additional study information because no identifiers will be kept.

Payment and Costs:
There will be no payment for participating in this study. The cost to the subject will be the time spent on the study. This time will not be reimbursed.

Study Risks:
There are no known risks for participating in this study.

Study Benefits:
There may be no direct benefit to the subject. The information gathered in this study will be presented to faculty at the UNT Health Science Center and will contribute to general knowledge and understanding about the development of Medical Devices.

Key Personnel:
Principal Investigator: Albert O-Yurvati, D.O.
Student Investigator: Jessica Blaylock

References:

1. Kaplan AV, Baim DS, Smith JJ, et al. Medical device development: From prototype to regulatory approval. Circulation. 2004;109(25):3068-3072. Available from: 10.1161/01.CIR.0000134695.65733.64; http://circ.ahajournals.org/cgi/content/full/109/25/3068.
2. Translational Research - Overview Available at: http://nihroadmap.nih.gov/clinicalresearch/overview-translational.asp. Accessed 12/10/2009, 2009.

Attachments:

I. Recruitment Materials
   a. Email Flyer
   b. Add for Daily News
II. Survey
   a. Print Survey with Cover Letter
   b. Screen Shots of Electronic Survey
III. Conflict of Interest Form

Daily News Add/Email

Title: Participation needed for Survey

Description: We are recruiting licensed clinicians at the UNT Health Science Center to participate in a research project titled "Translational Research of Devices: An Assessment of the Common Obstacles Encountered by Clinical Researchers." This short survey asks a series of questions about your knowledge of medical device research. This survey should take you approximately 10 minutes to complete.

If you are interested in this survey please follow the link below to the survey. If you have any questions or concerns about completing the survey or participating with this research project, you may contact me at 817-735-0512 or jblayloc@live.unthsc.edu.

Http://www.surveymonkey.com/s/TranslationalResearchOfMedicalDevices

UNIVERSITY of NORTH TEXAS HEALTH SCIENCE CENTER at Fort Worth
TEXAS COLLEGE OF OSTEOPATHIC MEDICINE
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

BOARD ACTION

IRB PROJECT #: 2010-066 DATE SUBMITTED: May 24, 2010

PRINCIPAL INVESTIGATOR: Albert O-Yurvati, DO (with student Jessica P. Blaylock)

PROJECT TITLE: Translational Research of Devices: An Assessment of the Common Obstacles Encountered by Clinical Researchers

PROTOCOL #: n/a

DEPARTMENT: CRM Program TELEPHONE EXTENSION: _____

In accordance with UNT Health Science Center policy on the protection of human subjects, the following action has been taken on the above referenced project:

Approval, when given, is **only** for the project as submitted. **No changes** may be implemented without first receiving IRB review and approval.

_____ Project has received approval through _____.

_____ Informed Consent approved as submitted on _____. You **MUST** use this version (attached) rather than previously approved versions. In addition, only consent documents which bear the official UNTHSC IRB approval stamp can be used with subjects.

_____ Study Protocol dated _____ approved as submitted.

_____ Protocol Synopsis approved as submitted on _____.

✓ Amendment May 24, 2010 to the protocol approved as submitted.

_____ Based upon the recently completed Continuing Review (IRB Form 4), project has received continued approval through _____.

_____ Project has been reviewed. In order to receive approval, you must incorporate the attached modifications. You must submit one "highlighted" copy and one "clean" copy of the revised protocol synopsis, informed consent and advertisements to the IRB for review. YOU MAY NOT BEGIN YOUR PROJECT UNTIL NOTIFIED BY THE IRB.

_____ Consideration of the project has been tabled pending resolution of the issue(s) outlined below.

_____ Project is disapproved for the reason(s) outlined below.

_____ Completion of project is acknowledged and all required paperwork has been received.

_____ Special Findings:

Please see attached

_____ May 24, 2010
Chairman, Institutional Review Board Date

The PI requested approval for the following modifications to the protocol: 1) correction of typo on page 6 and 8 of the printed survey; 2) new recruitment email; and 3) changes to the UNTHSC Daily News recruitment announcement.

This project continues to qualify as Exempt category research. Modifications approved under the provisions of 45 CFR 46.101 (b) (1) category (2) research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior on May 24, 2010.

Translational Research of Devices:

An Assessment of the Common Obstacles Encountered by Clinical Researchers

Principal Investigator: Dr. Albert O-Yurvati

Co-Investigator: Jessica Blaylock

Institution: University of North Texas Health Science Center

Email Add

Subject:

LICENSED CLINICIANS NEEDED TO PARTICIPATE IN A RESEARCH SURVEY

Email Body:

Thank you to all the individuals who have completed the survey so far!

If you have not completed the survey, there is still time! We are still recruiting licensed clinicians at the UNT Health Science Center to complete a research survey titled "Translational Research of Devices: An Assessment of the Common Obstacles Encountered by Clinical Researchers". This survey about medical devices should take you less than 10 minutes to complete. Please do not complete the online survey if you have already completed the paper version of the survey.

If you are interested in participating please follow the link below to the survey. If you have any questions or concerns about completing the survey or participating with this research project, you may contact me at jblayloc@live.unthsc.edu.

Http://www.surveymonkey.com/s/TranslationalResearchOfMedicalDevices

Translational Research of Devices:

An Assessment of the Common Obstacles Encountered by Clinical Researchers

Principal Investigator: Dr. Albert O-Yurvati

Co-Investigator: Jessica Blaylock

Institution: University of North Texas Health Science Center

Daily News Add

Title:

LICENSED CLINICIANS NEEDED TO PARTICIPATE IN RESEARCH SURVEY

Description:

We are recruiting licensed clinicians at the UNT Health Science Center to complete a research survey titled "Translational Research of Devices: An Assessment of the Common Obstacles Encountered by Clinical Researchers." This survey about medical devices should take you less than 10 minutes to complete. Please do not complete the online survey if you have already completed the paper version of the survey.

If you are interested in participating please follow the link below to the survey. If you have any questions or concerns about completing the survey or participating with this research project, you may contact me at jblayloc@live.unthsc.edu.

Http://www.surveymonkey.com/s/TranslationalResearchOfMedicalDevices

APPENDIX IV: REFERENCES

1. Maisel WH. Medical device regulation: An introduction for the practicing physician. *Ann Intern Med*. 2004;140(4):296-302.

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