Telesonography Adoption and Use to Improve the Standard of Patient Care Within a Dominican Community

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(ABSTRACT)

Teleradiology has far-reaching implications for the health of remote and underserved populations. With coordination of radiographic evaluation and diagnosis from a distance, teleradiology has the potential to raise the standard of patient care throughout the world. Perhaps the safest and most cost-effective mode of teleradiology today is telesonography. The current research determined that telesonography improves the standard of care at a rural, government-run primary clinic within the Dominican Republic. The work reported herein is intended to compare the use of telesonography to the current standard of sonographic examination which is referral to government hospital 60km from the clinic. the following research questions were addressed: When compared to the standard of care, (1) To what extent does the use of asynchronous telesonography increase the percentage of received sonographic reports based on the total number of ultrasound referrals (sonographic reports / total number of referrals)? (2) To what extent does the use of asynchronous telesonography increase the rate of successful follow-up visits based on the total number of ultrasound referrals? (3) To what extent does the elapsed time between ultrasound referral and sonographic report delivery decrease with the use of asynchronous telesonography? (4) To what extent does the elapsed time between ultrasound referral and patient follow-up decrease with the use of asynchronous telesonography? Research methodology included randomly assigning 100 patients with clinical indications for sonographic examination into experimental and control groups during a 9-week implementation period. Findings from this study indicate that the implemented telesonography system, along with patient awareness of such a system, while not having an appreciable effect on the time to patient follow-up, provided a 4-fold increase in the proportion of patient follow-ups and a 6-fold increase in the proportion of returned radiological reports, and delivered those reports to the referring physician 6-times faster than in the control group. This study demonstrates the feasibility of utilizing a store-and forward telesonography system within this setting. Additional research focusing on the impact of telesonography on patient outcomes within this setting is recommended.

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Chapter 1

Introduction

Diagnostic Imaging in Developing Nations

According to the World Health Organization (WHO), diagnostic imaging is a requirement for the accurate treatment of at least 25% of all patients worldwide. There is currently a lack of safe and proper imaging services in vast portions of the developing world. Images are often of low quality resulting in non-diagnosis or misdiagnosis. Imaging facilities are often non-functional or too great a distance to be of practical use for large segments of the population. This is due in part to a lack of resources, insufficient training, and poor maintenance of facilities and equipment (WHO, 2007). In addition, while some remote areas have access to basic primary care services, including X-ray and ultrasound, they do not often have access to radiologists and their diagnostic expertise (Bassignani et al., 2004).

Diagnostic imaging should be utilized when a physician wishes to exclude a certain disease process, to identify a suspected pathology, to guide a physician in his or her treatment decisions, or to continue staging a previously-diagnosed disease. Reports from various countries indicate that a considerable portion of all abdominal surgical interventions, such as explorative laparoscopies, could have been avoided if simple diagnostic imaging services such as ultrasound had been available (Sinclair, 1998).

While diagnostic imaging technology has progressed at an astonishing rate and produced ever more innovative modalities such as multi-slice computed tomography

(CT), magnetic resonance imaging (MRI), and positron emission tomography (PET), over 90% of all imaging can be performed using basic X-ray equipment and/or simple ultrasound machines (WHO, 2007).

Diagnostic imaging services are a critical part of national and/or regional health care systems. Unlike North America and Europe, developing nations, such as Africa, Central America, the Caribbean, and portions of the Middle East, Asia and the South Pacific do not have widespread access to the resources required for high-quality diagnostic imaging, including necessary equipment and skilled technicians. Given the distance to tertiary care centers from many rural clinics, the local introduction and diffusion of lower-cost imaging such as X-ray and ultrasound has great potential to improve healthcare in these areas.

While it is clear that basic X-ray and ultrasound are the imaging technologies most easily adaptable for use in the developing world, the mere presence of such equipment does not routinely translate into improved healthcare for a given patient population. Without proper information management or access to skilled operators and interpreters, any benefit to the patient is dubious at best. Once the physical equipment necessary for basic imaging is made available, there should be logistical solutions in place to provide for long-term viability and to overcome any local shortages of qualified staff.

Among the efforts to overcome such shortages, the use of teleradiology is one technical strategy that continues to gain popularity. Teleradiology has been proven effective in several domestic and international projects aimed at providing basic imaging services to remote locations.

There are ongoing public and private efforts to increase the availability of health care, including vital services such as diagnostic imaging. Proponents of these efforts should be mindful of the prohibitive costs often associated with the expansion of health services. If the cost of expanding certain health services is too great, either the added services will not be sustainable in the long-term or the sponsoring organization may be forced to pass these costs along to the patient population they intend to reach, the latter option being unlikely given the socioeconomic status of many third-world communities. General approaches to reducing overall cost of health care include lowering the number of hospital admissions, shortening the length of hospital stays, and reducing the number of unnecessary procedures such as explorative surgery.

The judicious use of X-ray and ultrasound within the ambulatory care setting can contribute to long-term cost savings if its use in a particular setting is shown to prevent the aforementioned high-cost and inefficient medical decisions. It is also hopeful that with the expansion of health information technologies, including telemedicine and teleradiology, there will be an increase in the numbers of appropriate and expeditious patient triage. It is the opinion of several telemedicine experts, as well as certain U.S. government agencies, that the use and diffusion of telemedicine has the potential to play a vital role in improving the delivery of healthcare (Craig & Patterson, 2005; Fuentes 2003; Hersh, Hickam, & Erlichman, 2006). This is particularly true within medical subspecialties such as radiology, dermatology, pathology, and ophthalmology where visualization of a given ailment is imperative and direct patient contact is not a prerequisite for appropriate patient care.

As telecommunication networks, processing speed, and data storage capacity continue to expand in parallel, so too will the availability and efficiency of telemedicine. While there may be long-term benefits of utilizing telemedicine, it is often difficult to justify the short-term cost and sheer complexity of certain ventures. In regards to radiology, the first step is to make the equipment available to remote and underserved communities. The use of CT, MRI, and nuclear medicine requires immense equipment and maintenance cost, as well as proprietary imaging software. Indeed, these modalities have limited availability and long wait times in even the wealthiest of nations. Fortunately, the use of plain radiography and ultrasound is comparatively simple to use and certainly more affordable for leaders looking to invest in the healthcare of the developing world.

Dominican Republic

The Dominican Republic (DR) is located on the eastern two-thirds of the island of Hispaniola, with Haiti occupying the western one-third of the island. The island of Hispanola is located directly within the hurricane belt between the Caribbean Sea and North Atlantic Ocean immediately to the west of Puerto Rico. Foreign tourism and free trade have made the service sector the largest employer within the DR today (CIA, 2008). Because of the extreme poverty, high mortality rates, and political instability of neighboring Haiti, the DR has become home to over one-half million Haitians and Dominicans of Haitian decent (Corten, Duerte, 1995). While the DR may seem a desirable place to live by Haitian standards, international watchdog groups report mistreatment of workers within several sectors including agriculture and construction. In the past, many native Dominicans have legally (and illegally) immigrated to the U.S. or crossed the Mona Passage to Puerto Rico to search for better work (Metz, 1989).

The DR is the second most populous nation in the Caribbean with 9,025,000 inhabitants, half of which live in rural areas. About 30% of Dominicans live below the poverty line ($60 U.S. monthly) (USAID, 2002) and 225,000 live below the international poverty line (less than $1 U.S. per day). The DR has a striking income inequality with the poorest half of the nation's population receiving one-fifth of the GNP and the richest 10% gathering 40% of national income. As of 2004, the DR has a US dollar per capita income of $2100. The Dominican government spends only 1.4% of its GDP on health care for its citizens (CIA, 2008).

The DR ranks in the bottom half of all Caribbean nations for several health-related statistics. For instance, 10.8% of all newborns are underweight (<2500g) and average life expectancy is only 68.3 years. The DR ranks second to last in the Caribbean for rates of infant mortality (40/1000), under 5 mortality, and maternal mortality with Haiti holding the lowest ranking (PAHO, 2006). Between 2000 and 2004, the DR had the highest mortality rate due to land transport accidents in the Caribbean (25.1 per 100,000) making this nation a very dangerous place for long-distance travel (such in the case of traveling to distant tertiary medical centers). Lastly, when looking across all age categories, the most common health issues facing the general population within the DR are: perinatal illness, external causes, communicable diseases (most notably AIDS and Tuberculosis), cardiovascular disease, and neoplasm (PAHO, 2000).

The healthcare infrastructure of the DR is organized into three levels based on the intensity of care required (Virginia College of Osteopathic Medicine, 2007). These levels, in order of increasing subspecialty care and intensity of services, are: level 1 (ambulatory care centers), level 2 (district health centers and municipalities), and level 3 (district hospitals). Within the DR, this healthcare structure translates into 1,099 ambulatory clinics (474 of which are located in rural areas), 126 secondary care clinics providing five basic medical specialties, and 42 tertiary care hospitals.

There are 19 physicians and 3 nurses per 10,000 population (PAHO, 2000). The majority of domestic health research is carried out at the Maternal and Child Health Research Center (CENISMI) in the capital city of Santo Domingo. The Ministry of Health provides health care services for 75% of the population, many of who are uninsured. While health care is low-cost for this large segment of the population, there is no guarantee of access or quality. In rural areas, home remedies and traditional healers are a major source of healthcare. Many rural families will travel to urban hospitals only in extreme circumstances ("Dominican Republic," 2008). Given the high mortality rate associated with land transportation, this tendency for remote populations to avoid long distance travel is likely due to a combination of inability and pragmatism.

Even with these aforementioned socioeconomic and health disparities, the DR has a thriving and relatively modern national telecommunication network which boasts 105,000 Internet hosts with over 1.6 million Internet users (CIA, 2008). A modern telecommunication network is a prerequisite to terrestrial-based telemedicine projects. Furthermore, regions of the DR near resort destinations tend to have robust and reliable sources of electricity and communication. This is a providential benefit to local inhabitants and visitors who can afford such services.

The Veron Community

The confluence of poor health statistics, expanding rural population, established telecommunication infrastructure, and stable political environment makes the DR fertile ground to conduct telemedicine-based research. Over the last three decades, communities such as Veron have been established on the outskirts of major tourist destinations on the eastern coastline. Dominicans and Haitians alike have traveled to these transient worker-communities to seek out employment by the massive Dominican, U.S., and European-owned resorts scattered along the beachfront. The projected expansion of the service industry in this region will create a continuing population growth within such communities from both native Dominicans and Haitian immigrants.

The community of Veron (pop. ~8000[*]) consists of several scattered neighborhoods, stores, and restaurants along a stretch of rugged highway. This highway connects the region's largest city, Higuey (pop. 180,000), to the coastal resorts of Punta Cana and Playa Bavaro, which are located in the easternmost municipality of the country, La Altagracia. According to the Puntacana Resort and Club (PCRC), since the establishment of the Puntacana International Airport in 1984, the region has become the fastest growing tourist destination in the Caribbean and added 35,000 employees (Foundation, 2005). While several public work projects have been established since the start of this tourism boom, including an elementary school, ecological foundation, and polytechnic center, indigent members of the Veron community remain in great need of health care services.

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[*] source: http://www.vcom.vt.edu/resource/MM/missions-dr.html

In just the past two years, a collaborative effort between the Edward Via Virginia College of Osteopathic Medicine (VCOM), the Secretariat of State for Public Health and Social Welfare (SESPAS), and the PCRC has resulted in improvements to the community's only government-run ambulatory (level 1) clinic, including basic laboratory equipment, greater numbers and types of pharmaceuticals, increased staffing, and increased phone and Internet services. Such improvements to the clinic enable native and visiting health care workers to provide quality care to members of the Veron community. Improvements to the clinic have allowed health care workers to correlate patient symptoms with laboratory findings, communicate via phone or Internet, and provide U.S. medical student externs with an environment in which to expand their medical education. Most relevant to the current project, these specific improvements to the Veron clinic provide a greater opportunity for clinical, epidemiological, and educational research.

Organizations supporting the Veron Clinic expect it to become both a national model for primary care within the Dominican Republic and an international model for collaborative humanitarian medical relief around the world. The majority of the clinic's medical, financial, and human resources will continue to be provided by VCOM, SESPAS, and the PCRC. In addition, outside philanthropists directly and indirectly provide material and financial support to the clinic on occasion. This unsolicited generosity will contribute greatly to the health of the community and to the success of research projects based within the clinic.

In regards to the current research, the Veron clinic was chosen as the project site for the following specific reasons:

1. The medically-underserved status and impoverished nature of the patient population.

2.The community's distance from the nearest government-run tertiary (level 3) medical center (50km).

3. The high proportion of female patients who visit the clinic solely for obstetric and gynecological care.

4. The marked discontinuity of healthcare and delayed (or non-existent) follow-up that results from referrals to tertiary health centers.

5. The large patient volume of the community clinic (50-70 patients/day).

6. The relatively large-bandwidth DSL networking capability of the clinic.

7. The preliminary patient data and expert testimony which indicate a great need for point-of-care sonography within this particular setting (see appendix D).

Problem Statement

The combination of a growing population, sparse number of healthcare providers, and inadequate government resources in communities such as Veron will likely result in a worsening of regional health disparities in the coming years. Diagnostic imaging standards for indigent patients within the Veron community is inadequate and may contribute to countless delays in diagnosis, non-diagnoses and/or misdiagnoses leading to poor patient outcomes.

Purpose

To determine the feasibility of using a store-and-forward telesonography system within a remote clinic within the Dominican Republic and to quantify certain patient advantages provided by such a service as compared to the local standard of ultrasound care.

Research Objectives

As compared to the standard of care:

1. To what extent does the use of asynchronous telesonography increase the percentage of received sonographic reports based on the total number of ultrasound referrals (sonographic reports / total number of referrals)?
2. To what extent does the use of asynchronous telesonography increase the rate of successful follow-up visits based on the total number of ultrasound referrals?
3. To what extent does the elapsed time between ultrasound referral and sonographic report delivery decrease with the use of asynchronous telesonography?
4. To what extent does the elapsed time between ultrasound referral and patient follow-up decrease with the use of asynchronous telesonography?

Definition of Terms

1. *Bandwidth*: The data transfer capacity of a digital communication system such as the Internet; expressed in the number of bits transferred per second (bps) (Bassignani et al., 2004).
2. *Continuity of care*: Coherent patient care over time and place; often defined by three different components: relational (ongoing patient-provider relationships), management (co-ordination of care), and informational (information transfer) (Biem, Hadjistavropoulos, Morgan, Biem, & Pong, 2003).
3. *Digital Imaging and Communications in Medicine (DICOM)*: A comprehensive set of standards for handling, storing and transmitting information in medical imaging. It includes a file format definition and a network communication protocol.

4. *Digital Subscriber Line (DSL)*: Family of technologies that provide digital data transmission over the wires of a local telephone network. A typical DSL configuration will download information at 1.544 mbps and upload information at 128 kbps. This service is faster than standard ISDN BRI and less costly than ISDN PRI.
5. *Internet Protocol (IP)*: The standard that allows dissimilar hosts to connect to each other through the Internet.
6. *Local Area Network (LAN)*: A group of computers that share a common communication line or wireless link. This network is confined to a small geographic area, or within the same building, and usually relies on a central server for software applications and data storage.
7. *Medical Ultrasonography*: A medical imaging technique that utilizes ultrasound to visualize internal anatomy including soft tissues and body cavities, and is often used to monitor fetal development.
8. *Secure Socket Layers (SSL)*: Functions by using a private key to encrypt data that is being transmitted over the Internet.
9. *Standard of Care*: A diagnostic and treatment protocol that a clinician should adhere to for a given patient, illness, or clinical circumstance (Studdert, Mello, & Brennan, 2004).
10. *Store-and-Forward (SF)*: Telecommunications technique in which information is sent to an intermediate station, where it is kept and sent at a later time to the final destination or to another intermediate station. SF can be as simple as a question in an email or as complex as a multi-media file with images and/or streaming video

coupled with patient history and physical data. Software applications allow for the attachment of data that include digital pictures, radiographs, and ultrasound (Thelma McClosky Armstrong et al., 2004).

11. *Telemedicine*: Use of telecommunications technology for medical diagnosis and patient care when the provider and client are separated by distance.
12. *Teleradiology*: Refers to the electronic transmission of radiological images, such as X-rays, CTs, and MRIs, from one location to another for the purposes of interpretation and/or consultation.
13. *Teleultrasound*: A form of teleradiology that refers to the electronic transmission of sonographic images for the purpose of interpretation and/or consultation.
14. *Ultrasound*: Sound waves with a frequency greater than the upper limit of human hearing (>20,000 hertz).
15. *Virtual Private Network (VPN)*: A network connected together by encrypted tunneling protocols. VPNs can create a private point-to-point connection within an existing LAN or WAN.
16. *Wide Area Network (WAN)*: A long-range communication network that is usually accessible by the public. Large companies can operate their own private WAN to communicate with distant affiliated sites.

Limitations

The results are limited to the indigent patient population of Veron, Dominican Republic, which consists mainly of low-skill workers who rely on government-supported primary clinics for their health care. Although countless communities of similar socioeconomic status and remoteness exist throughout the world, it may be difficult to generalize the results of this project to other areas and demographics. This project is a pilot study limited to 9-weeks of data collection and may be limited in significance by its relatively short duration.

The principal investigator was responsible for the initial on-site ultrasound interpretations. Second-look diagnoses are limited to telediagnosis by U.S.-trained radiologists with no senior on-site physician contributing to sonographic diagnoses. While Spanish-English and Creole-English translators are available within the clinic, communication breakdowns between the provider and patient are possible. Inadequate communication between the health care provider and participant may have artificially increased or decreased the number of patients believed to require sonographic referral.

Adequate time was allowed for U.S. radiologists to transmit reports back to the target clinic. To ensure that final reports were received by the time participants returned for follow-up, the participants were instructed to return to the clinic two days after their initial scan. Strict research protocols were followed to maintain the internal validity of the study that could have been compromised due to unforeseen influences on the participants from the instrumentation and/or researcher. The health and safety of the patients was paramount throughout the duration of the project. Patients with urgent medical conditions were treated and/or referred to the closest tertiary center and were not included in the project statistics.

Significance of Study

The value of this project is comparable to the diagnostic imaging goals of the WHO including 1) make safe and reliable diagnostic imaging services available to as many as possible; 2) advise, guide and support those working in the field developing and maintaining diagnostic imaging services; 3) promote the importance of safe and appropriate diagnostic imaging services (WHO, 2007).

This project utilized a store-and-forward telesonography system to rapidly diagnose and rule-out abdominal, retroperitoneal, and pelvic pathologies within the jointly-operated primary clinic of Veron, Dominican Republic. Patient records and expert opinion of the clinic's physicians indicated a need for this diagnostic modality based on symptomologies suggestive of abdominal, retroperitoneal, and pelvic pathology including fever, abdominal pain, abdominal tenderness, and abnormal menses. In addition, there is a high prevalence of construction projects and transportation accidents in this area which result in blunt abdominal trauma. The myriad of clinical scenarios, patient indications, the clinic's remote location, and the difficulty and/or resistance of residents to undergo timely radiological evaluation demonstrate the utility of on-site telesonography.

This study is designed to determine to the feasibility of using a store-and-forward telesonography system to improve the standard of patient care at the Veron Clinic; additionally this study is designed to improve the efficiency of healthcare through increased diagnoses, decreased time to diagnoses, and increased continuity of care.

This study contributes to the body of knowledge on telesonography by determining to what extent this technology can improve the standard of patient care within this setting. The results of this study have implications to the practice of medicine within Veron and similar settings throughout the developing world. The further development of telesonography within this setting is important, given its potential to improve the efficiency of healthcare through increased diagnoses, decreased time to diagnoses, and increased continuity of care.

This pilot study focuses mainly on transabdominal evaluation of abdominal, retroperitoneal, and pelvic structures. Long-term use of telesonography at the clinic could expand to include regular fetal monitoring, vascular studies, and perhaps interventional procedures granted the clinic physicians are provided with the appropriate training and equipment. Given that the majority of health disparities within the DR are related to maternal, pre/perinatal, and circulatory pathologies, using telesonography to target these specific abnormalities will be the ultimate goal of a continuing telemedical presence.

Chapter 2

Review of Literature

Telemedicine and the Standard of Patient Care

In many remote and medically-underserved areas of the world, the standard of patient care leaves much room for improvement. While access to primary medical care exists in many remote areas, regular access to tertiary medical centers remains difficult. The low socioeconomic status of many people living in remote areas makes long-distance travel to tertiary centers most demanding. With little or no health insurance coverage, consultation fees associated with tertiary care are often unaffordable except in nations with universal health care systems. This combination of factors often translates into a discontinuity of patient care between the primary care physician and medical sub-specialist.

It is important to note that developed nations are not immune to matters regarding access to care, shortages of medical subspecialties, and rapidly changing patient needs. For this reason, developed nations with expansive and rugged landscapes, such the U.S., Canada, and Australia, have been pioneers of telemedicine research and pilot studies. In the U.S., the incorporation of telemedicine into the existing system of health care has the potential to further the goals of the federally-mandated Healthy People 2010 initiative (Rheuban, 2006).

Early research in telemedicine has shown its utility in providing subspecialty expertise to medically-underserved and remote patient populations (Balestri et al., 1999). As commercial telecommunication networks continue to expand into most inhabited regions of the globe so too will the potential for furthering telemedicine-based research and establishing new pilot programs. As of 2001, meta-analysis of the research has found the most clinically and fiscally-effective forms of telemedicine to be teleradiology, teleneurosurgery, telepsychiatry, transmission of echocardiographic images, and the use of electronic referrals enabling email (store-and-forward) consultations and video conferencing between primary and secondary health care providers (Roine, Ohinmaa, & Hailey, 2001).

Of the aforementioned forms of telemedicine, it is teleradiology that has attracted the most international attention (Lagalla, 2001). Radiology is well adapted to the practice of telemedicine. Unlike medical specialties that require direct patient interaction and observation, the large majority of radiological examinations do not require the physician to meet face-to-face with the patient. A technician completes the scan and this information is passed along to the radiologist who makes the final diagnosis. Teleradiology, however useful, is often prohibitive in nature due to its dependence on ionizing radiation, the use of expensive and bulky equipment, and the need for constant maintenance. Of all radiological modalities, ultrasound is the most appealing candidate for use in remote settings. The high birth rates and young maternal ages that are widespread within much of the developing world indicate a great need for obstetric sonography in these settings. Ultrasound equipment is portable, requires little maintenance, is relatively inexpensive, and uses high-frequency sound waves rather than hazardous ionizing radiation. However, the diagnostic quality of ultrasound images is very user-dependant and requires extensive training to become competent in all modalities (Ma, Mateer, & Blaivas, 2008).

Telesonography

Telesonography-based research can be divided into those studies using synchronous (real-time) and those using asynchronous (store-and-forward) data transmission. Within these two categories of research are three recurrent themes relevant to the successful implementation of any telesonography system. These themes include:

1. Quality of transmitted images.
2. Clinical applications.
3. Technical and non-technical barriers to implementation.

Some of the earliest research projects using clinical telesonography were applied to subspecialties such as cardiology and obstetrics (Fuentes, 2003). While early projects were limited by transmission bandwidth and signal degradation, early successes with transmitted echocardiograms and fetal scans have spurred continued interest and research in counties such as Canada, Britain, Europe, and Australia (Burgul, Gilbert, & Undrill, 2000; Chan, Soong, Watson, & Whitehall, 2000; Johnson et al., 1998; Macedonia et al., 1998; Zocco et al., 2001). In recent years, telesonography has also demonstrated its value in the field of veterinary medicine (Papageorges et al., 2001). Regardless of the setting or application, the progress made in the field of telesonography, and indeed all of telemedicine, has mirrored the accelerating development and proliferation of telecommunications worldwide. From two-way microwave transmissions such as those used by the National Aeronautical and Space Administration (NASA) during the 1970s, to current-day IP-based fiberoptic communication with terabyte-sized bandwidth capabilities (Bashshur & Indian Health Service, 1980; Tyrer, Wiedemeier, & Cattlet, 2001), much progress has been made in a relatively short time period.

Research focusing on the clarity of transmitted images has attempted to determine the minimal acceptable bandwidth (Brebner et al., 1999; Brebner et al., 2000), as well as the most efficient signal processing (Li, Hu, & Gao, 1999) and codec to use (Bassignani et al., 2004) in order to maintain an image of high diagnostic value. While some researchers have rated image clarity through surveys of interpreting radiologists, others have measured actual image degradation through careful analysis of Fourier spectra and contrast measurements before and after transmission (Burgul et al., 2000). Image clarity was elusive in the early days of telesonography (Landwehr, Zador, Wolfe, Dombrowski, & Treadwell, 1997), but modern-day telecommunications and image compression technology have made the transmission of both high-quality asynchronous and synchronous imaging data a reality (Brebner et al., 2000; Fuentes, 2003; Landwehr et al., 1997; Popov, Popov, Kacar, & Harris, 2007; Yoo et al., 2004).

Researchers interested in the various clinical applications of teleultrasound have continued to focus on obstetrics (Landwehr et al., 1997; Lockwood, Bahado-Singh, D'Alton, & Platt, 2001; Soong, Chan, Bloomfield, Smith, & Watson, 2002) as well as infectious disease (Moro et al., 1999; Moro et al., 2005), transabdominal (Blaivas, Kuhn, Reynolds, & Brannam, 2005), and even the use of a robotic-arm to perform scans (Arbeille et al., 2007). The aforementioned advances in telecommunications and signal processing, and the relatively high resolution available with today's portable ultrasound units, make the clinical application of telesonography relatively limitless. In regards to the use of telesonography in remote areas, the remaining technical and logistical barriers include the availability and speed of telecommunication within the target area, as well as the availability and skill-level of both on-site and off-site medical providers (Fuentes, 2003).

The majority of telesonography research focuses on its use within an ambulatory care setting. No studies were found that explored the application of telesonography in the emergency setting. Perhaps the most well-known emergency use of ultrasound is the Focused Assessment with Sonography for Trauma, or FAST Scan. This scan protocol can provide immediate insight into the severity of internal injuries sustained during trauma. A study using 331 patients at a level I trauma center found the use of ultrasound in evaluation of blunt abdominal trauma to be more timely and cost-effective than magnetic resonance imaging or diagnostic peritoneal lavage (Arrillaga, Graham, York, & Miller, 1999). Given the time-sensitive nature of injuries sustained during blunt force trauma, any future application of telesonography in this setting would likely consist of an immediate real-time interaction between sonographer and radiologist, which lies outside the scope of the current study. However, if the email delivery of diagnostic reports can be achieved in less than 48 hours, store-and-forward telesonography can have practical applications with certain urgent medical conditions. For example, a retrospective study that looked at 40 post-surgical cholecystectomy patients discovered that those whose intervention occurred more than 48 hours after initial diagnosis had a 40% higher rate of gall bladder perforation while those with an intervention occurring fewer than 48 hours had only a 9% rate of the same life-threatening complication (Johnson, 1987).

Training Strategies. Telesonography systems have been successfully tested in both Canada (Johnson et al., 1998) and Australia (Soong et al., 2002); proving the technical feasibility and usability of such a system (O'Neill, Allen, & Brockway, 2000).

However, the diagnostic quality of ultrasound images is very user-dependant and requires a certain level of expertise to attain all necessary views, as well as to interpret their significance (Fuentes, 2003; Popov et al., 2007). One study from Italy found that, with regards to the use of telesonography, at least one month of training should be required of operators in the field in order to ensure the necessary user skills, technical knowledge, and anatomical orientation. (Cavina, Goletti, Lippolis, & Zocco, 2001). A different study from Bosnia concluded that three-dimensional sonographic data sets could be obtained in the field by operators with less than 30 minutes of training (Macedonia et al., 1998). In one veterinary study, researchers state that the appropriate knowledge and skills to use telesonography could be acquired through 2 or 3 short courses plus 2 days on-site training (Papageorges et al., 2001). Other researchers have addressed this issue by enabling a real-time collaboration between the on-site sonographers and interpreting radiologists, especially with regards to fetal monitoring and primary care settings (Chan et al., 2000; Chan, Soong, Watson, & Whitehall, 2001; Chan et al., 1999; Hussain, Deshpande, Shridhar, Saini, & Kay, 2004; Johnson et al., 1998; Landwehr et al., 1997; O'Neill et al., 2000; Smith & Brebner, 2002).

Currently, there are no standard training protocols for ad hoc sonographers in remote settings. The ideal situation would be to recruit sonographers certified by a respected governing body within their country of origin, such as the American Registry for Diagnostic Medical Sonography (ARDMS). But in situations where certified sonographers are in limited supply, as is often the case in remote settings (Fuentes, 2003), a minimum of one month didactic and hands-on ultrasound training should be completed by on-site operators as suggested by Cavina et al. (2001). The investigators of the current project strongly advise for any sonographer in the field to have previous medical or paramedical training in addition to this one-month didactic and hands-on ultrasound training. To provide an added level of quality control, images produced by the on-site sonographers should be continually scrutinized via telecommunication with board-certified radiologists to ensure appropriate scanning protocols are followed and images contain sufficient diagnostic value.

As the use of telesonography or any form of telemedicine to underserved areas continues to grow, it is important that high quality standards are maintained or its use may have detrimental health consequences. Researchers have already proposed the establishment of a framework to address and examine telemedical errors to ensure high-levels of quality and safety (Demiris, Patrick, Mitchell, & Waldren, 2004). Failures in quality control with regards to telesonography include, among others: inappropriate scan protocol, inappropriate scanning technique, inappropriate image labeling, misdiagnosis, and non-diagnosis.

Influences on Patient Management. Two studies were identified in which researchers address the general influence of ultrasound on patient management in remote areas. Researchers in the first study attempted to quantify the impact of portable ultrasound on patient disposition and course of treatment (Blaivas et al., 2005). This study compared pre-ultrasound with post-ultrasound differential diagnoses and discovered that of the 25 patients scanned, 7 had their treatment course dramatically altered and “4 were able to avoid potentially dangerous evacuations”. The second study found that the use of telesonography made transfer unnecessary in 42% of cases and influenced patient management in 59% of cases (Johnson et al., 1998).

While the clinical and patient advantages of using portable ultrasound in remote settings (rapid diagnosing, accurate treatment and/or referral, and time saved) are mentioned in the literature, there is little cumulative data representative of these advantages. Furthermore, this literature review found no studies that utilized a case-study approach with randomization of participants into treatment versus control groups to quantify and compare certain advantages of telesonography over a previous standard of ultrasound care. Such a research methodology would better demonstrate the advantages of telesonography by comparing the experimental group with a group assigned to the particular region's existing standard of care. As Hersh et al. (2006) has already pointed out, in order for telemedicine to become widely accepted, there needs to be more evidence demonstrating its advantages over current standard of care protocols. Furthermore, since "telemedicine is a technique and not a specific test or treatment", other research methodologies should be explored in an attempt to collect such evidence. On the other hand, a lack of evidence for telemedicine's efficacy should not bar its preliminary use in areas where certain types of health care delivery would otherwise be impossible.

Barriers to Implementation. Although the technical barriers to telesonography implementation are continually dissolving, non-technical barriers to the implementation of any form of telemedicine persist. Such barriers include the relative lack of training and operational protocols, prohibitive cost of hardware / software, complexity of use, and concerns over the confidentiality of electronically-transmitted patient information (Anderson, 2007). While early telemedicine projects utilized private closed-system networks, today the use of Internet protocol (IP) transmission has proved its feasibility

(Gemmill, 2005). Many studies have proven the effectiveness of store-and-forward telemedicine including such fields as dermatology (Klaz et al., 2005), dentistry (Mandall, O'Brien, Brady, Worthington, & Harvey, 2005), and neurology (Patterson, Humphreys, & Chua, 2003), including several projects based within developing nations (Heinzelmann, Jacques, & Kvedar, 2005; Vassallo, Hoque et al., 2001; Vassallo, Swinfen, Swinfen, & Wootton, 2001). Researchers from Australia have focused on improving efficiency and lowering the cost of existing Picture Archiving and Communication Systems (PACS) by utilizing email notification systems and developing software applications using free-license products (Caffery & Manthey, 2004). However, even with the past successes of store-and-forward telemedicine projects, as of 2004 only 2% of clinicians use email for the purpose of medical consultations (Struber, 2004).

Data Transmission. All medical practice within the U.S., including the practice of telemedicine, is bound by federal law to comply with the Health Information Privacy and Portability Act (HIPPA) standards to protect patient confidentiality (HIPPA, 1996). Therefore, certain data standards and encryption methods have been established to ensure the confidentiality of transmitted patient data. PACS may utilize a central server connected to a local area network (LAN) or wide area network (WAN) in order to securely transmit images between several regional hospitals or clinics. On the other hand, web-based PACS can utilize the Internet and transmit data securely via a virtual private network (VPN) or a secure socket layer (SSL). Digital Image Communications in Medicine (DICOM) data-standard currently allows HIPAA-compliant transmission of patent data and images between PACS workstations anywhere in the world. In general, PACS systems are integrated with the preexisting hospital information system. Patient data can be retrieved using a computer search of the patient's name, accession number, or other identifier. Radiologists can then easily view imaging studies of any patient entered into this integrated system. Patient information is placed into this system through official channels established by hospitals. Such stringent control of patient information is quite sensible within and between closed-system health care organizations. However, radiologists cannot use such a system to view patient information that has not first been authenticated by a given hospital. Radiologists with an interest in performing pro bono work outside their respective hospital systems may wish to utilize a more simplified yet equally confidential system of teleradiology.

Fortunately, web-based email providers, coupled with the appropriate open-license software, can form the electronic backbone of a simple and free way to transmit patient images between any two points on earth with IP access (Della Mea, 1999). In just the past 3 to 4 years, several email providers (Gmail, Hotmail, etc.) have increased their clients' transmission and storage capacity to several hundred megabytes. With such large transmission, reception, and storage capacities, there is no need for image compression or the resulting lossy effects on data that were encountered with earlier studies. In regards to confidentiality, the current project adheres to the highest standard of patient privacy. All images and documents related to patient telediagnosis will be transmitted using SSL encryption and will not include personally-identifying information. Imaging reports transmitted in this fashion can, in theory, be intercepted by a third-party, but the images and/or reports will remain untraceable to the individual patient.

Diffusion of Innovation. Advances in technology are often made in response to specific needs of individuals, groups, or entire populations. As new health care challenges have arisen, so too have innovative methodological and technological solutions to meet these challenges. Telemedicine has developed over the years in hopes of addressing the need for access to care, lower costs, and increased efficiency of health care delivery throughout the globe.

Many innovations cannot be viewed as a single idea or technology emerging into the world at a single point in time. Today's innovations are often a convergence of previous innovations developed over many decades. Telemedicine is no exception. A few broad examples of innovations preceding Telemedicine include: the controlled flow of electricity along a conductive material from point A to point B, which serves as the basis for telecommunications; the innovation of telecommunications, which serves as the core for telemedicine; and the untold hundreds of individual innovations which were integrated over time to give us today's portable lightweight ultrasound technology.

Of all forms of telemedicine, teleradiology has made the most progress in terms of widespread diffusion and utilization (Dimmick & Ignatova, 2006). While in previous sections we touched on technical and logistical barriers to the implementation of teleradiology, there remain persistent and less-conventional barriers to its current and future acceptance. As with any relatively new innovation or novel use of a preexisting innovation, teleradiology presents knowledge, economic, organizational, and behavioral barriers to its adoption. As Tanriverdi and Iacono (1999) suggest, overcoming these barriers will require intensive efforts by champions within their adopter organizations.

Tanriverdi and Iacono point out that by applying Rodgers' organizational diffusion of innovation model, we can illustrate how and why teleradiology has flourished at home and abroad. This model consists of two general activities: (1)

Initiation, which addresses organizational problems and matching these problems with innovations; and (2) *Implementation,* which addresses the modification, clarification, and normalization of the innovation (Rodgers, 2003). For the health care industry, it was soon discovered that several persistent problems could be solved through the use of teleradiology, which increases access to care, timeliness of service, cost-savings, and productivity of a limited number of radiologists. During its ongoing implementation phase, teleradiology has undergone several transformations and adaptations in the past 20 years. These include 24-7 coverage using international centers, and novel uses of computer hardware and software to reduce equipment and transmission costs for health centers with smaller operating budgets.

In his theory of diffusion of innovation, Rodgers points out that the acceptance and diffusion of a particular innovation is a multi-factorial process. It will likely take many years before telesonography is normalized within remote settings like Veron. Knowledge to use such a system, economic efficiency of the technology, organizational consensus, and cultural acceptance will be required before this particular innovation becomes routine. It is hoped that the current research can further the case for telesonography in remote settings and illustrate a successful modification of its continuing global implementation.

Chapter 3

Methodology

Research Design

This study implemented a telesonography system based on the use of a portable ultrasound coupled with store-and-forward data transmission (i.e. email with attached jpeg images). The on-site investigator, a physician with prior clinical experience within both Central America and the Caribbean, received didactic and hands-on sonographic training over a two-month period by ARDMS-accredited hospital sonographers and ACR board-certified radiologists (the PI participated in >100 hands-on ultrasound scans prior to project implementation). IRB approval was obtained.

Two groups were included in the study during the 9-week implementation period, an experimental group and control group. The experimental group received the telesonography service and the control group received traditional ultrasound consults (i.e. travel to nearest tertiary center for sonographic evaluation and return with radiologist's report). An ultrasound examination was offered if, based on initial clinical evaluation, the patient was found to have symptoms consistent with any the following abnormalities: ascites, pleural effusion, blunt abdominal trauma, cholelithiasis, cholecystitis, cholangitis, pancreatitis, hydronephrosis, abdominal aortic aneurysm, hepatitis, portal hypertension, urolithiasis, abnormal uterine bleeding, pelvic inflammatory disease, ovarian mass or torsion. Each patient that agreed to be a research participant was randomly assigned using a coin-flip to either the experimental group (telesonography) or control group (traditional ultrasound consult). Non-emergent participants who required a pelvic ultrasound were asked to drink between 16 and 32 ounces of water before beginning the exam to ensure a full bladder. Patients with emergent symptomology (severe right upper quadrant pain with tenderness, rebound tenderness, history of blunt trauma) were not recruited as participants but would receive a brief scan to pinpoint / rule out abnormalities before being referred to the nearest tertiary center. All patients (participants and non-participants) presenting with the appropriate symptoms were clinically evaluated, diagnosed, and treated by a local Dominican physician in conjunction with the final radiological report.

An on-site physician / project director trained with the aforementioned method and having >100 cases of experience with ultrasound observation and hands-on operation performed the sonographic exams on patients within the study group. A “first-look” diagnosis, correlated with patient symptomology and laboratory analysis, was made at the point of care. Using a store-and-forward framework, properly formatted sonographic images and “Request for Interpretation” (RFI) forms were transmitted to participating radiologists[1]. RFI forms were used to record diagnostic findings and rate the quality of the images and/or diagnostic value using a five-point Likert scale. RFI forms also included a five-digit patient number, age, sex, and symptomology / reason for sonographic exam. No personally-identifying information was included within the transmitted images or RFI forms. Completed RFI forms were transmitted back to the clinic at the radiologist’s earliest convenience. Diagnostic findings, or lack thereof, were correlated with “first look” on-site diagnoses.

Sample. A convenience sample of 108 low-income Dominican and Haitian patients 13 years old or greater who utilize the primary care clinic of Veron, Dominican

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[1] Appendix B

Republic was selected to participate based on clinical indication. Patients' participation in this study was voluntary. IRB-approved protocols were used throughout the study. Objectives, risks, and benefits of the study were communicated to participants in their native language (Spanish or Creole) before signing a written consent[2]. Patients were then randomly assigned to each group through the use of a random number generator (coin-flip). 53 patients were assigned to the telesonography group and 52 were assigned to the control group.

Instrumentation

Instruments included medical and telecommunication equipment, as well as questionnaires related to the study objectives. These included:

1. Portable ultrasound with 5.2 MHz transducer (SonoSite Titan©)
2. Personal computers (Dell©, Apple©)
3. Wireless router (2Wire© 2700HG)
4. Request for Interpretation (RFI) form with 5-point Likert-scale questionnaire for qualitative measure of image quality.
5. Adult Consent Form (Spanish and English versions)

Questionnaire content validity was determined by a panel of six ACR board-certified radiologists, who assured that the questions were sufficient to meet the study objectives. This panel of radiologists completed a short evaluation form addressing the RFI form's ability to achieve project objectives (Appendix C).

Medical instrument reliability was ensured through manufacturer-recommended calibration standards and guidelines for appropriate use. In addition, the researcher

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[2] Appendix D1, D2

completed extensive training with board-certified U.S. sonographers and radiologists using the same make and model of ultrasound unit prior to departing for the Dominican Republic to conduct the study.

Procedure

Participant Flow Chart[3]

ACR Practice Guidelines, 2006

1. Liver

Examinations included long axis and transverse views. Liver parenchyma was evaluated for focal and/or diffuse abnormalities. The echogenicity of the liver was compared with the echogenicity of the right kidney. An attempt was made to visualize the right hemidiaphragm and pleural space. Attempts to image the following structures were made with each participant:

a. The major vessels in the region of the liver, including the inferior vena cava (IVC), the hepatic veins, the main portal vein, and, if possible, the right and left branches of the portal vein.
b. The hepatic lobes (right, left, and caudate) and, if possible, the right hemidiaphragm and the adjacent pleural space.
c. Doppler was used to document blood flow characteristics and direction in hepatic artery, hepatic veins, portal veins, and intrahepatic portion of the IVC. (*ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum*, Revised 2006 (Res. 39, 35))

[3] See appendix E for protocol flow chart.

2. Gallbladder/Biliary

Evaluation included long-axis and transverse views obtained in the supine position. Other positions, such as left lateral decubitus, erect, or prone, were used to evaluate the gallbladder and its surrounding structures, especially when stones or sludge were detected. The gall bladder wall was measured in transverse view if the patient indicated pain or tenderness to transducer compression.

Intrahepatic ducts were evaluated by obtaining views of the liver with right and left branches of the portal vein. Doppler was used to differentiate hepatic vasculature from bile ducts. The intrahepatic and extrahepatic bile ducts were evaluated for dilatation, wall thickening, and intraluminal findings. The size of the common bile duct (normal = 5mm plus 1mm per decade over 60 years of age) and porta hepatis were documented. When able to be visualized, the distal portion of the common bile duct entering the pancreatic head was evaluated.

An attempt was made to ensure examinations occurred with the gallbladder sufficiently distended. While fasting for 8 hours prior to exam facilitates adequate distension of the gall bladder, the "walk-in" nature of the Veron clinic meant such a fasting time was rarely met. (*ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum*, Revised 2006 (Res. 39, 35))

3. Pancreas

When possible, all portions of the pancreas were visualized (head, unciate process, body, and tail). The patient was often asked to drink several cups of water to assist better visualization of the pancreas. The following was assessed:

a. Parenchymal abnormalities

b. The distal common bile duct near the pancreatic head

c. The pancreatic duct was evaluated for dilation (confirmed with measurement or other abnormalities)

d. The peripancreatic regions for adenopathy and/or fluid *(ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum*, Revised 2006 (Res. 39, 35))

4. Spleen

Views of the spleen in long-axis and transverse projections were obtained. Doppler was used to evaluate for the presence and direction of flow in the splenic vein and artery. Measurements were obtained, especially if enlargement was suspected. The echogenicity of the spleen was compared to the echogenicity of the left kidney. An attempt was made to visualize the left hemidiaphragm and the adjacent pleural space was made (*ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum*, Revised 2006 (Res. 39, 35)).

5. Peritoneal fluid

The location and extent of free peritoneal fluid or loculated peritoneal fluid was documented if present (*ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum*, Revised 2006 (Res. 39, 35)).

6. Renal

Examination of kidneys included long-axis and transverse views of the upper poles, mid portions, and lower poles of the kidneys. The cortex and renal pelves were assessed. Renal length was recorded for both kidneys. A variety of patient positions were used to best visualize the kidneys, including decubitus, prone, and upright. When possible, renal Echogenicity was compared to neighboring liver and spleen. The perirenal regions were assessed for abnormalities.

For vascular examination of the kidneys, Doppler was used to:

a. Assess renal arterial and venous patency
b. Assess for renal artery stenosis. This process involved angle-adjusted measurements of the peak systolic velocity at the proximal, central, and distally extrarenal portion of the main renal arteries if possible. Peak systolic velocity of the adjacent aorta was documented for calculating the ratio of renal to aortic peak systolic. Spectral Doppler evaluation of the intrarenal arteries from the upper and lower portions of the kidneys, obtained to evaluate the early systolic peak, could provide indirect evidence of proximal stenosis in the main renal artery (*ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum* , Revised 2006 (Res. 39, 35)).

7. Urinary Bladder and adjacent structures

Transverse and longitudinal images of the distended urinary bladder and its wall were included when possible. Bladder wall or lumen abnormalities were noted. Dilation or other distal uteteral abnormalities were documented if present. Pre and post-void residual volumes were obtained when investigating obstructive or neurogenic bladders *(ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum*, Revised 2006 (Res. 39, 35)).

8. Aorta

Transverse images of the proximal, mid, and distal aorta were obtained. Longitudinal images with anteroposterior measurements of the proximal, mid, and distal aorta were obtained. Transverse imaging of the proximal common iliac arteries at the bifurcation were obtained. Longitudinal images with AP measurements of the proximal right and left common iliac arteries at the bifurcation were obtained. Color Doppler imaging and spectral Doppler with waveform analysis were acquired when indicated. Documentation of mural thrombus or other abnormalities were made if present. All measurements were made from outer wall to outer wall perpendicular to the long axis. If aneurysm was present, the maximal AP and transverse diameter was recorded in addition to the relationship of aneurysm position to renal arteries (*ACR Practice Guidelines for the Performance of Diagnostic and Screening Ultrasound of the Abdominal Aorta*, Amended 2006 (Res.35)).

9. Inferior vena cava

Transverse and longitudinal images of the inferior vena cava (IVC) were obtained. Patency and abnormalities were evaluated with Doppler. When present, vena cava filters or other implanted devices were localized with respect to the hepatic and/or renal veins (*ACR Practice Guidelines for the Performance of an*

Ultrasound Examination of the Abdomen and/or Retroperitoneum, Revised 2006 (Res. 39, 35)).

10. Pelvic

For transabdominal exam, the bladder was distended in order to displace the regional small bowel from view. The following was documented when possible:

a. Uterine size, shape, and orientation
b. Endometrium
c. Myometrium
d. Cervix
e. Vagina

Uterine length was evaluated by measuring in long axis from the fundus to the external os of the cervix. The AP dimension of the uterus was measured in the same long-axis view perpendicular to uterine length. Uterine width was measured in the axial view. If volume measurements of the uterine corpus were necessary, cervical component was excluded. Abnormalities will be documented. Endometrium was evaluated for thickness, focal abnormality, and presence of fluid or mass in the endometrial cavity. Endometrial evaluation took into consideration the menstrual phase and/or hormone supplementation. Difficulty imaging the endometrial strip was noted. Myometrium was evaluated for contour changes, echogenicity, and/or masses. Masses, if present, were measured in at least two dimensions and their locations recorded.

When possible, the adnexa were identified and measured (length, width, and depth), and any abnormalities noted. Views in two orthogonal planes were obtained. Some adnexa were not identifiable, due to any number of reasons including menopause or large leiomyomatous uterus. The region of the fallopian tubes was evaluated for presence of dilated tubular structure. Any adnexal mass was documented and its relationship to the ovaries and uterus made clear. Size, echogenicity, and internal characteristics (cystic, solid, or complex) were determined. Doppler or color Doppler ultrasound was used to identify vascular nature of pelvic structures.

The area corresponding to the cul-de-sac was evaluated for presence of free fluid or mass. If a mass was present, documentation of size, position, shape, echogenicity, internal characteristics, and relationship to the ovaries and uterus was made (*ACR Practice Guideline for the Performance of Pelvic Ultrasound in Females*, Amended 2006 (Res. 35)).

Internal Validity

A minimum of 3 radiologists independently interpreted and graded each set of sonographic images based on technical and procedural quality using a 5-point Likert-type scale. Although patient age, sex, and symptomology was included in the RFI form, the radiologists were blinded from “first look” diagnoses and from one another’s study interpretations to reduce potential interrater bias.

Forms rating image quality (RFI forms) were designed through collaboration between the project leader and up to six U.S. board-certified radiologists. Multiple iterations of this form were created through this process. The internal validity of the finalized RFI form was assessed using an Internet-based questionnaire delivered to six U.S. board-certified radiologists[4].

Data Analysis

Using frequency distribution graphs, the time to final diagnosis, time to follow-up appointments, number of successful follow-ups, and number of delivered reports were compared between the experimental and control groups. Measures of variability were obtained using the standard deviation. Measures of central tendency were assessed using the mean. The highest and lowest elapsed times within each comparison were excluded from the final analysis. For significance testing of quantitative data such as the average time of patient follow-up between groups and the average time of report delivery between groups, bivariable parametric and nonparametric analyses were performed using one-sided *t*-test, two-sided *t*-test, and Mann-Whitney test. For significance testing of categorical variables such as the number of patient follow-ups between groups and the number of delivered sonographic reports between groups, Chi-squared testing of independence was utilized.

[4] Appendix B

Chapter 4

Findings

Introduction

The purpose of this research was to determine the feasibility of using a store-and-forward telesonography system within a remote Dominican primary-care clinic and to quantify certain patient advantages of using such a system as compared to the standard of care. The research objectives were to determine:

1. To what extent does the use of asynchronous telesonography increase the percentage of received sonographic reports based on the total number of ultrasound referrals (sonographic reports / total number of referrals)?
2. To what extent does the use of asynchronous telesonography increase the rate of successful follow-up visits based on the total number of ultrasound referrals?
3. To what extent does the elapsed time between ultrasound referral and sonographic report delivery decrease with the use of asynchronous telesonography?
4. To what extent does the elapsed time between ultrasound referral and patient follow-up decrease with the use of asynchronous telesonography?

The project was implemented within the government-run primary care clinic of Veron, Dominican Republic (pop. 8000). A convenience sample of 108 low-income Dominican and Haitian patients 13 years old or greater who utilize the primary care clinic of Veron were selected to participate based on clinical indication. Participants were randomized to either the experimental or control group.

Participants

During the project implementation period, there were between 40 and 70 patient visits per day. This translated to an average of 2,310 (55 patients x 43 total office days) general medical consults provided by clinic personnel during the project run time (9-weeks minus weekends and local holidays [43 days]). There were a total of 108 ultrasound referrals during this time period. Of these 108 referrals, two patients randomized to the experimental group agreed to participate in the study but left the office before having their ultrasound exam. One person randomized to the experimental group did not wish to participate and was given the standard-of-care ultrasound consult. This translated to 2.51 ultrasound referrals per office day during the project run time with an average of 50.2 ultrasound referrals per month.

Of the 108 ultrasound referrals, 105 voluntarily consented to participate in the project and were assigned to either the experimental (telesonography) or control (standard-of-care) groups. There were 53 participants randomized to the experimental group (90.3% F, 9.7% M, mean age = 26.8) and 52 participants randomized to the control group (94.2% F, 5.8% M, mean age = 28.5).

The ultrasound scans conducted within the experimental group consisted of 44 (83.0%) transabdominal pelvic scans, 8 (15.1%) right upper quadrant scans, and 1 (1.8%) transabdominal prostate scan. Of the known ultrasound scans conducted within the control group, 9 (100%) were transvaginal pelvic scans.

Post-Sonography Follow-Up

Of the 53 participants within the experimental (telesonography) group, 35 (66%) had a successful follow-up appointment with the referring physician in order to discuss relevant findings within the radiological report and decide the best treatment or referral plan. Of the 52 participants within the control group, 9 (17.3%) had a successful follow-up appointment to discuss relevant findings within the radiological report and decide the best treatment or referral plan.

Diagnostic Report / Patient Return Times

Within the telesonography group, the average referral to outbound transmission time was +3:59:38 (SD = 4:49:23). The average outbound transmission to return time (inbound transmission) using data from the three fastest volunteer radiologists was +13:47:18 (SD = 10:22:18). Total average return time was +16:58:20 (±11:07:30) per report received within the telesonography group. The average time to patient follow-up within the telesonography group was +92:02:16 (SD = 3.219).

The total follow-up time for each member of the control group was recorded. Reports from this group provided time stamps which made it possible to calculate the time required for control group participants to arrive to an outside sonographer in addition to the time required for their post-sonography return to the Veron clinic. These participants had an average referral to scan time of +63:17:53 (SD = 38:26:33) and an average scan to return time of +36:31:32 (SD = 28:13:35). This provided a total average return time of +99:49:26 (SD = 44:20:12). These results are summarized in Table 1.

Data Analysis

Analyses of distributions were performed to inspect basic descriptive statistics, such as the mean and standard deviation of certain project variables (e.g. “elapsed time of report” and “elapsed time of patient follow-up”). The highest and lowest elapsed times within each group were excluded from data analysis. The means and standard deviations of telesonography quality rankings from RFI reports were calculated as well. Bivariable parametric and nonparametric analyses of “elapsed time of patient follow-up” and “elapsed time of report” between groups were performed, including one-sided *t*-test, two-sided *t*-test, and Mann-Whitney test. Due to the low number of patient returns within the control group versus the telesonography group, bivariable analyses did not result in a statistical significance ($p < 0.05$) for quantitative data. However, Chi-squared analysis of categorical data such as the number of successful patient follow-ups between groups (36 vs 9) and the number of successful sonographic report deliveries between groups (53 vs 9) provided for a statistical significance of $p < 0.001$ in both cases. In addition, descriptive statistics from both groups indicate an overwhelming difference between the average time to report delivery (+16:58:20 vs +99:49:26). There was no appreciable difference between groups in regards to the average time of patient return (+99:49:26 vs +92:02:16). In Figures 1 through 3 below, participants with successful follow-ups, as well as reports that were successfully returned, are listed sequentially from left to right on the horizontal axis, with elapsed times represented on the vertical.

Study Groups	*Report Received*	*Successful Follow-Up*	*Average Time of Report Delivery (hours)*	*Average Time of Patient Follow-Up (hours)*
Telesonography	100% (n=53)	66% (n=35)	16.9 (±11.0)	92.0 (±77.3)
Control	17.3% (n=9)	17.3% (n=9)	99.8 (±44.3)	99.8 (±44.3)

Table 1. Telesonography group vs. control group.

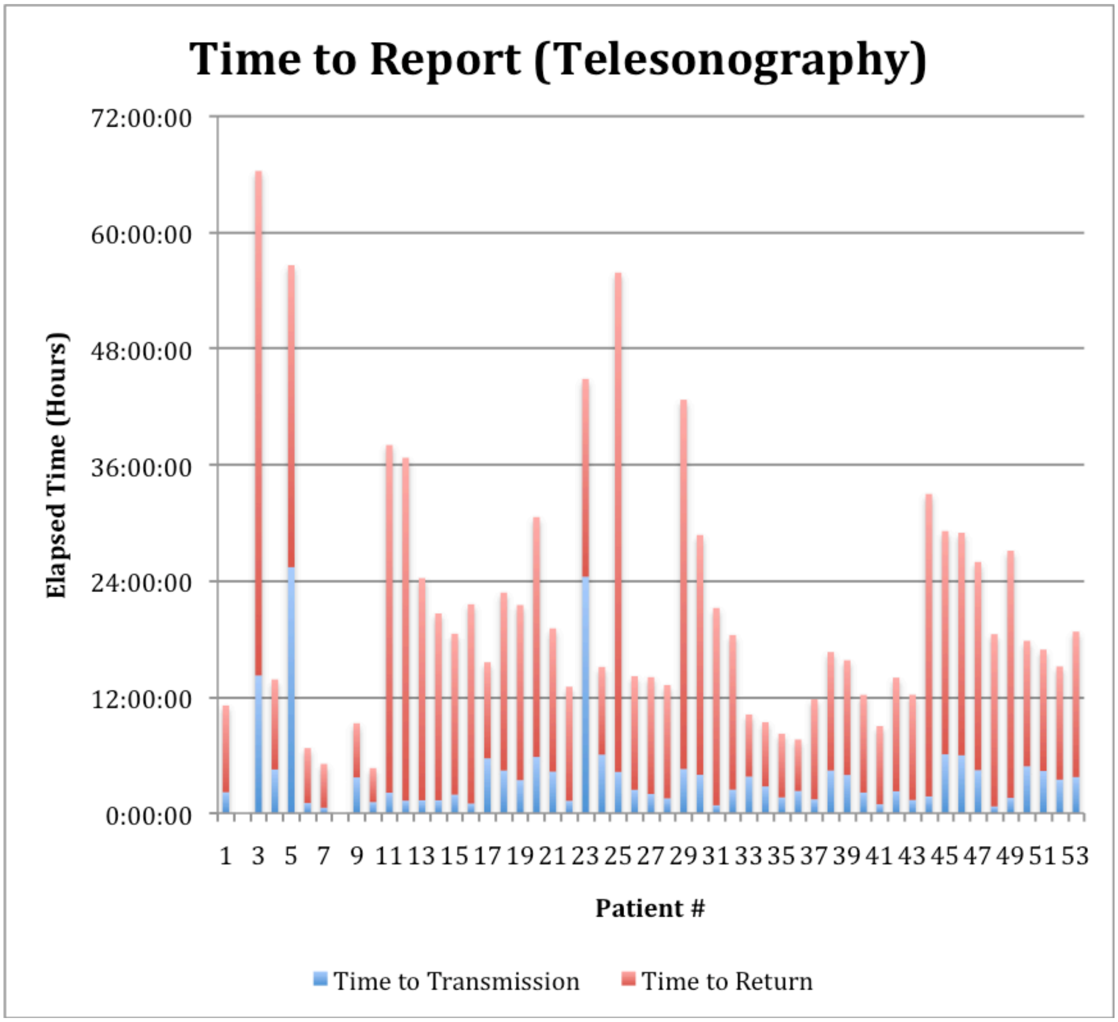

Figure 1. "Time to Transmission" (blue) is dependant upon the on-site sonographer while "Time to Return" (red) is dependant on the off-site radiologist.

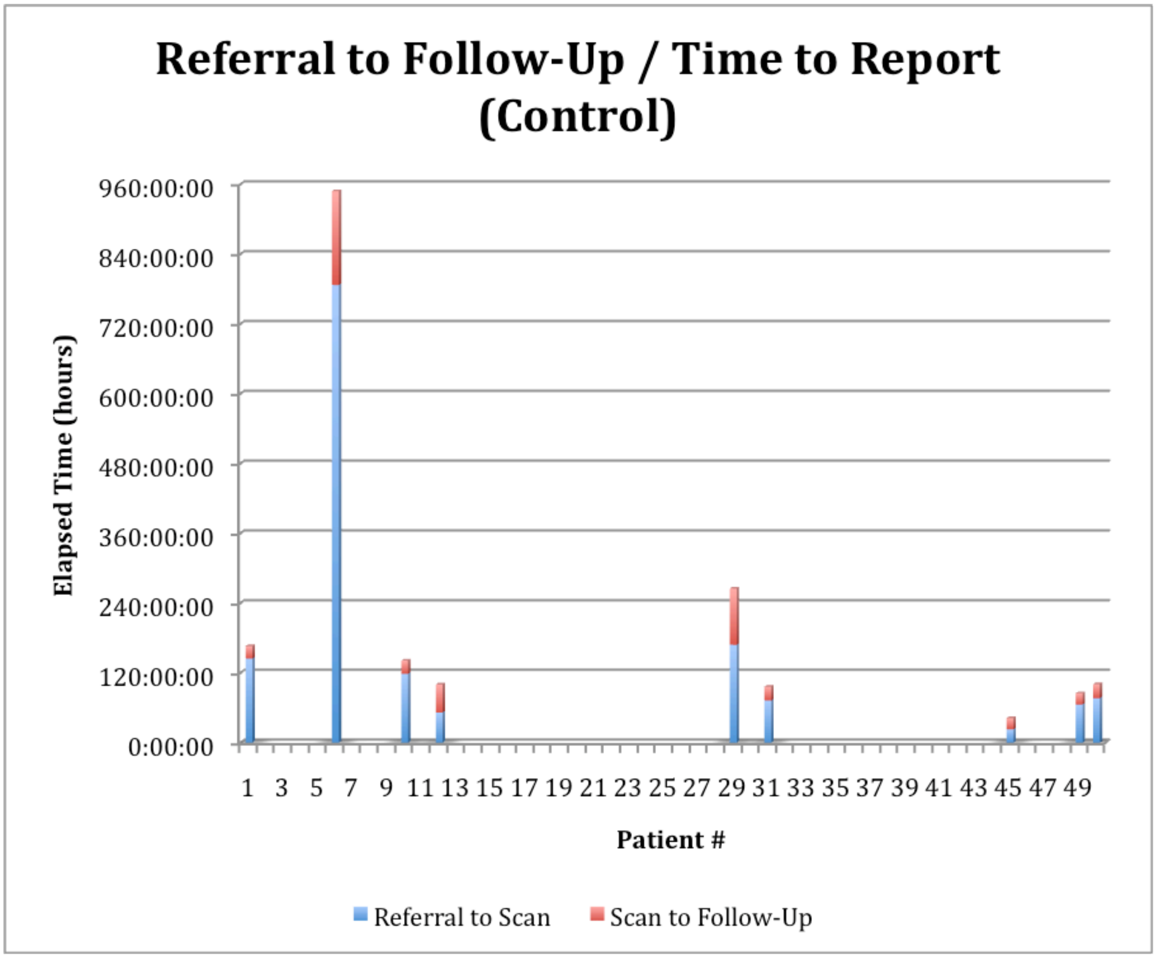

Figure 2. "Referral to Scan" (blue) and "Scan to Follow-Up" (red) are both dependant on the patient.

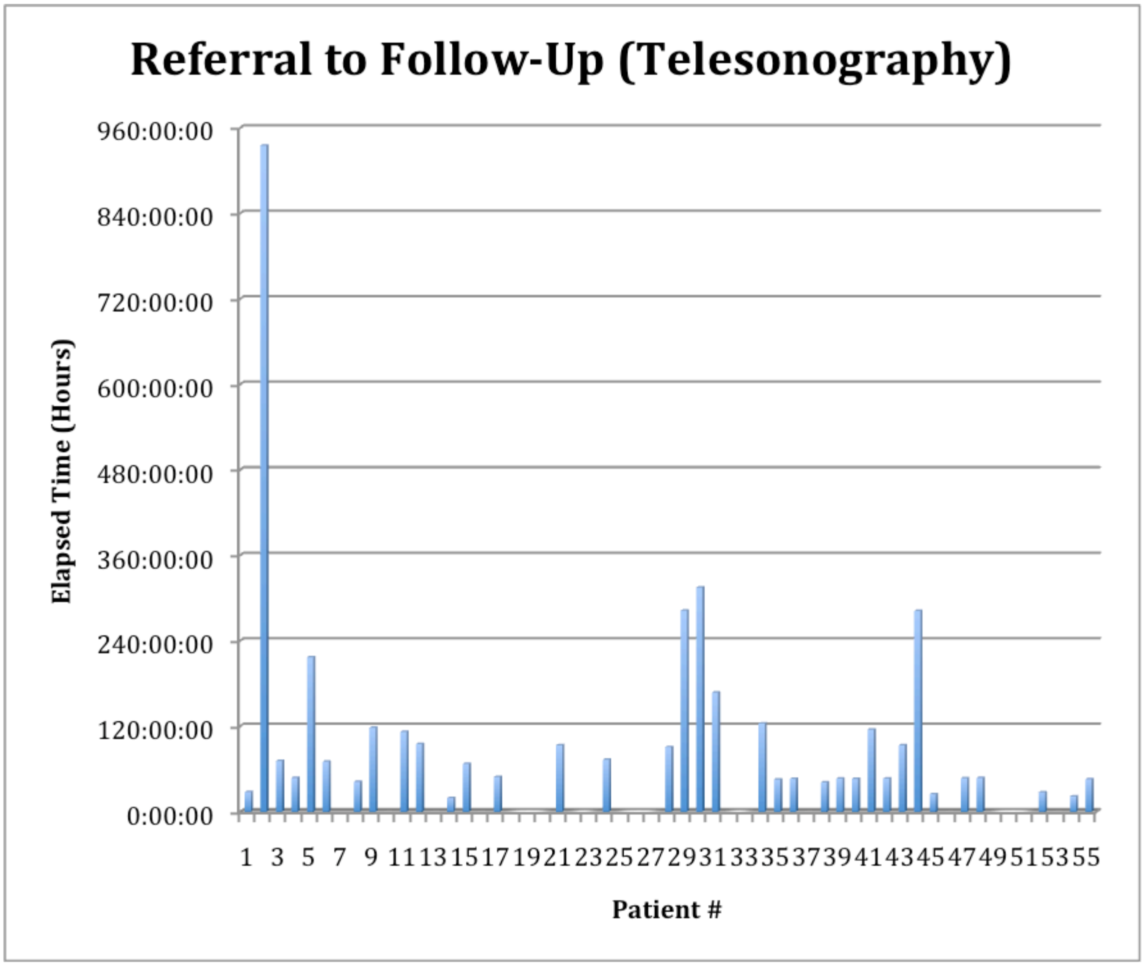

Figure 3. *"Referral to follow-up" time within the telesonography group.*

Symptom Frequency

The most common symptoms among all participants were hypogastric pain (control 34.9%, telesonography 27.3%), vaginal discharge (control 12.8%, telesonography 13.1%), and dysuria (control 12.8%, telesonography 11.1%).

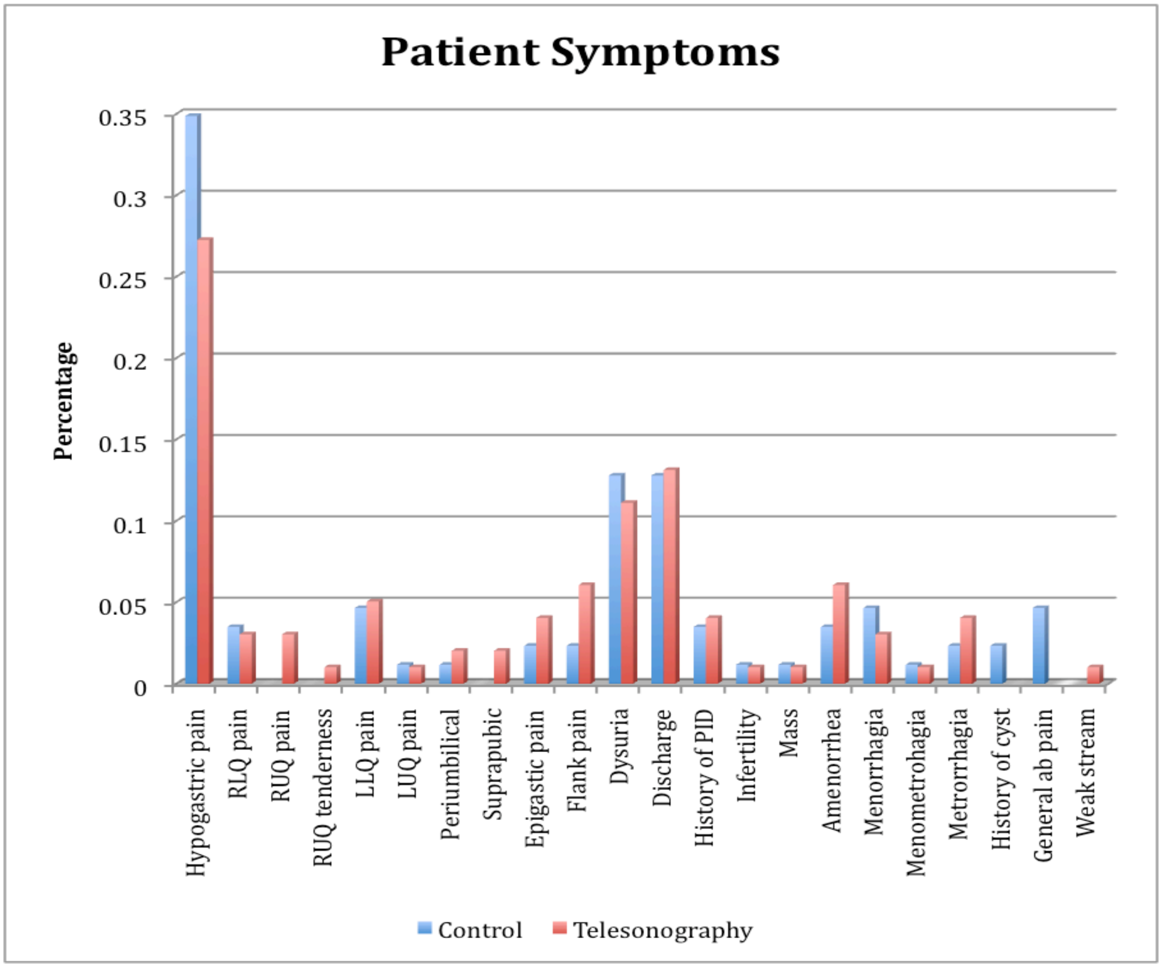

Figure 4. Patient symptoms.

Post-Sonography Referral Frequency

Within the telesonography group, information from patient history, exams, and sonographic report resulted in 11 referrals (31.4%) and 24 non-referrals (68.6%). Within the control group, information from patient history, exams, and sonographic report resulted in 4 referrals (44%) and 5 non-referrals (55%). No second follow-ups resulted from these additional referrals during the project run time.

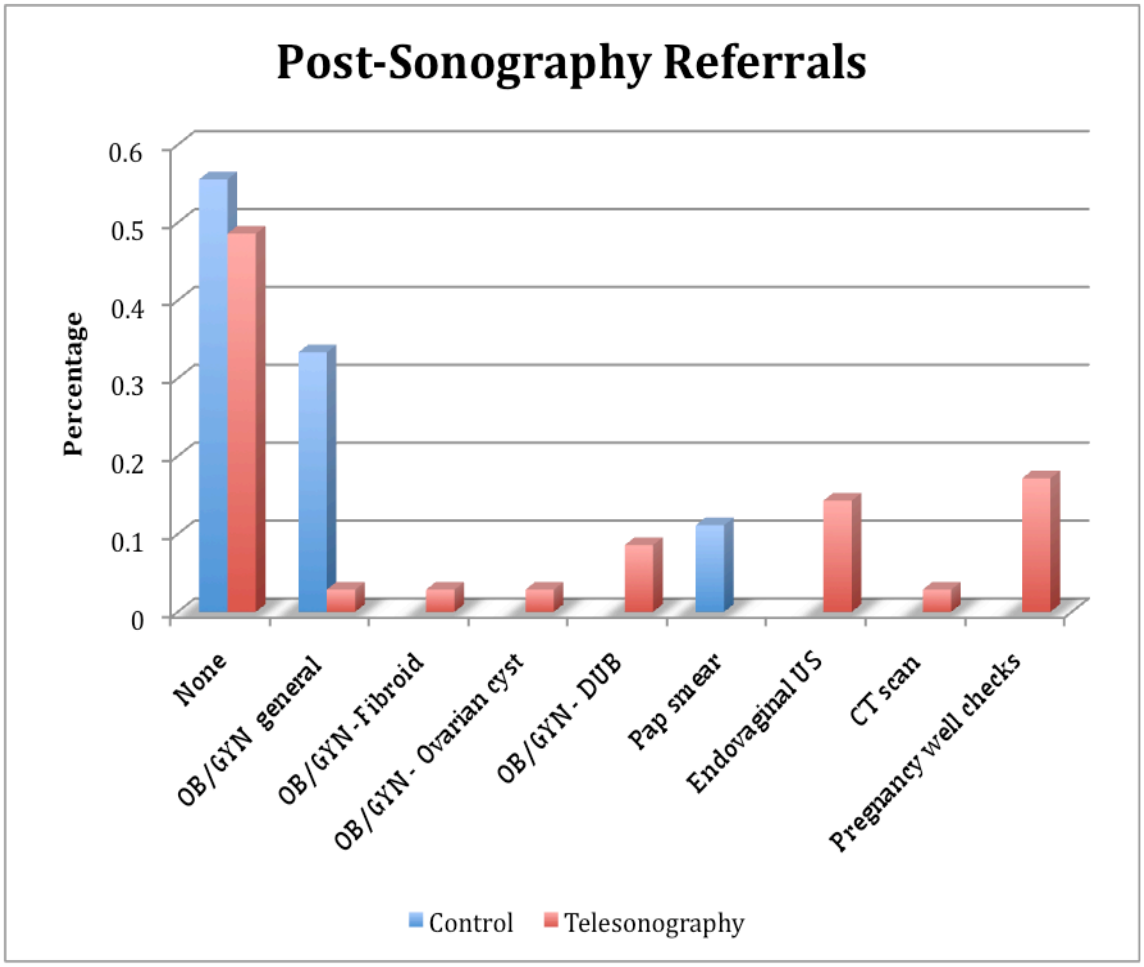

Figure 5. Post-sonography referral patterns.

Diagnosis Frequency

The most common final diagnoses based on patient history, exam, and sonographic report from all participants included ovarian cyst(s) (control 33.3%, telesonography 10.4%), first-trimester interuterine pregnancy (control 18.2%, telesonography 14.6%), and uterine fibroid(s) (control 11%, telesonography 5.1%).

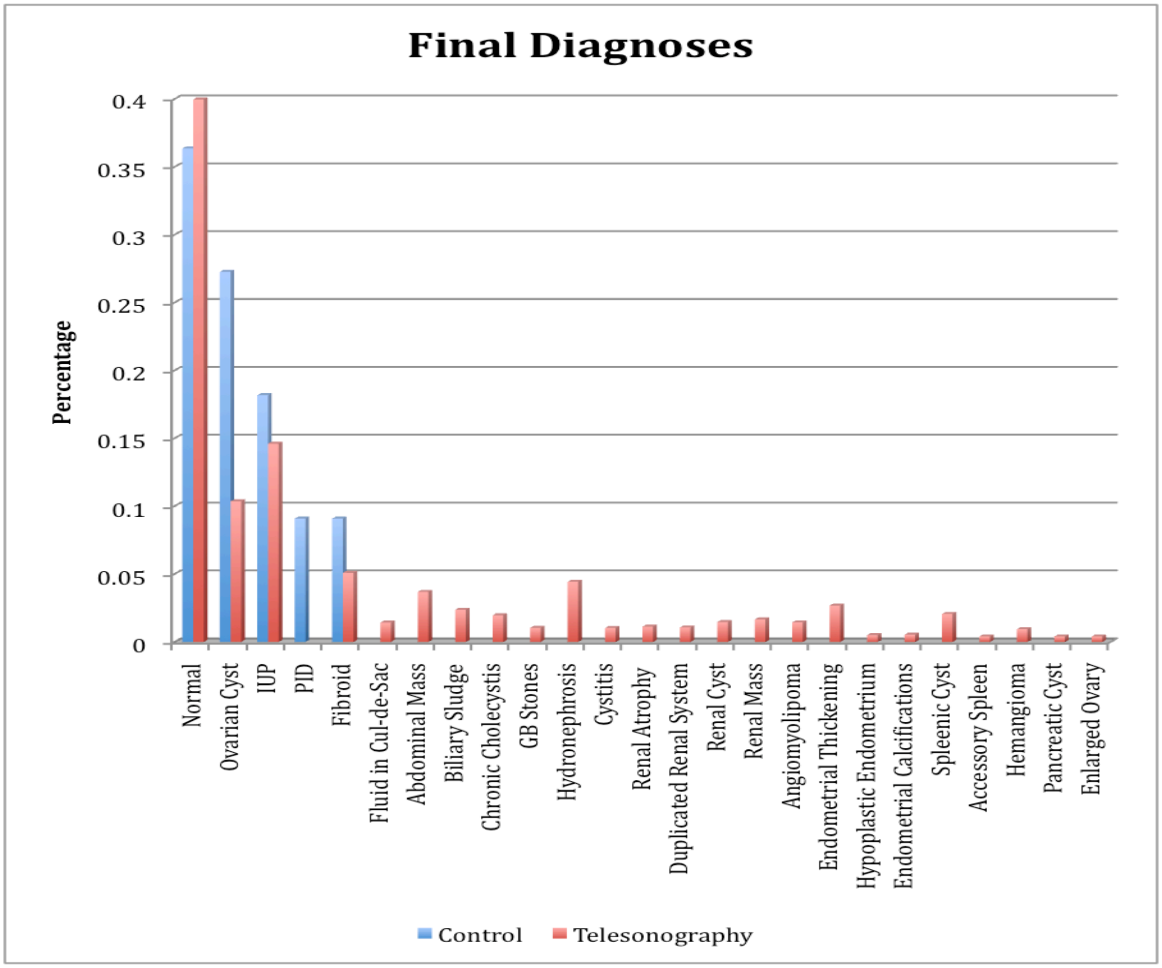

Figure 6. Final diagnoses between both groups.

Post-Sonography Treatments

Based on the aforementioned patient symptomologies and diagnoses, patients not requiring an additional referral to outside subspecialists were treated mostly for bacterial and fungal genitourinary infections, as well as mild to moderate genitourinary inflammation and menstrual-related pain. The most common regimens consisted of a single oral dose of azithromycin 10 mg/kg + single intramuscular injection of ceftriaxone 125-250 mg for both patient and partner treatment of gonorrhea / chlamydia co-infection (control 22.2%, telesonography 8.6%); intravaginal clotrimizole 100mg (2 tabs / day, 3 days) for vaginal candidiasis (control 11.1%, telesonography 5.7%); and oral acetaminophen 500mg (3-5 tabs per day) for associated fever, pain, and inflammation.

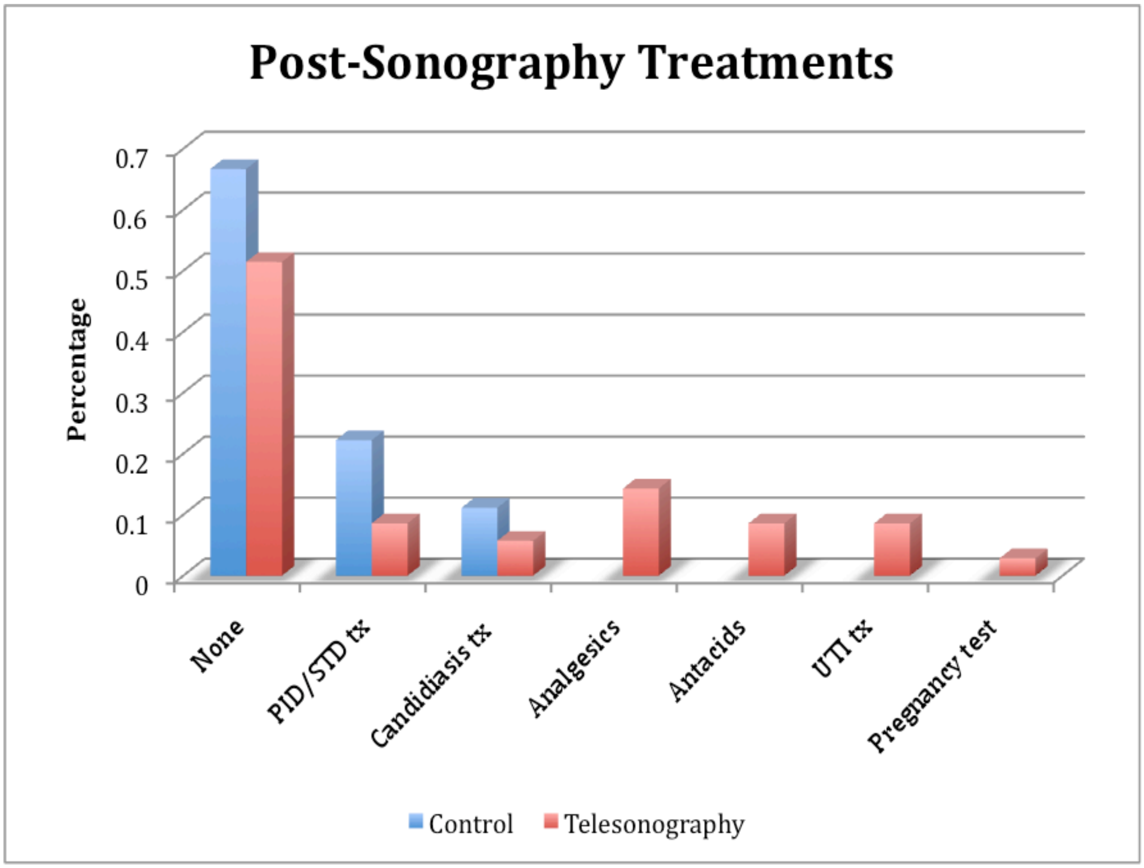

Figure 7. While "pregnancy test" is not a treatment per se, it was included in this data set as another course of action taken based upon clinical and sonographic findings.

Diagnostic Report Quality Rankings

Four volunteer radiologists using a 5-point Likert scale rated the technical and procedural quality of the ultrasound exams (with a rank of 1 meaning "no diagnostic value" and a rank of 5 meaning "excellent diagnostic value"). Volunteer radiologists returned a total of 179 RFI reports on 53 patients (3.4 reports per patient) to the referring physician. In terms of *interrater* rankings, radiologist #1 recorded an average technical rating of 3.95 (SD = 0.388) and average procedural rating of 4.01 (SD = 0.366). Radiologist #2 recorded an average technical rating of 4.33 (SD = 0.423) and average procedural rating of 4.32 (SD = 0.402). Radiologist #3 recorded an average technical rating of 4.32 (SD = 0.843) and average procedural rating of 4.66 (SD = 0.592). Radiologist #4 recorded an average technical rating of 4.56 (SD = 0.502) and average procedural rating of 4.69 (SD = 0.569). When combining the average ratings from each of the four radiologists we obtain an overall average technical rating of 4.29 (SD = 0.539) and overall average procedural rating of 4.42 (SD = 0.482). When viewing *intrarater* rankings of all 179 reports, the average standard deviation of both technical and procedural ratings between volunteer radiologists was 0.497.

This study also compared first-look or "wet read" sonographic diagnoses by the on-site physician with the final diagnoses provided by the volunteer radiologists. Of the 179 returned RFI reports, 121 (67.3%) were in agreement with the initial first-look diagnosis provided by the on-site physician. In addition, volunteer radiologists provided matching primary diagnoses 166 out of 179 times giving an *intrarater* diagnostic agreement of 92.7%.

Chapter 5

Discussion, Conclusions, and Recommendations

Study Objectives

As compared to the standard of care, asynchronous telesonography increased the percentage of sonographic diagnoses based on the total number of referrals. To discover this, we compared the proportion of reports received to the total number of referrals between the control and telesonography groups. Participants within the control group served as couriers of their own diagnostic report therefore, the number of returned diagnostic reports was dependent on the success of patient follow-up. Within the control group, 17.3% of all sonographic referrals resulted in a diagnostic report being received by the Veron clinic, whereas 100% of sonographic referrals within the telesonography group resulted in at least one diagnostic report ($p<0.05$). Also, while the current standard of care has the potential to generate 1 diagnostic report per patient, the preliminary use of the current telesonography system produced an average of 3.4 diagnostic reports per referral.

As compared to the standard of care, asynchronous telesonography increased the continuity of care for patients. To discover this, we compared the number of successful post-sonography follow-ups between the telesonography and control groups. 17.3% of referrals within the control group resulted in a successful post-sonography follow-up, compared to 66% within the telesonography group. The follow-up patterns between both groups are illustrated in figures 2 and 3.

As compared to the standard of care, the elapsed time between referral and final radiological interpretation decreased with the use of asynchronous telesonography. To discover this we compared the average elapsed time to report between both groups.

Within the control group, the delivery of this report had an average elapsed time of +99:49:26 while reports from the telesonography group averaged +16:58:20.

As compared to the standard of care, the elapsed time between referral and patient follow-up did not decrease substantially with the use of asynchronous telesonography. To discover this we compared the average elapsed time to follow-up between both groups. Given the inseparable nature of patient follow-up and delivery of the diagnostic report within the control group, the elapsed time to follow-up was the same as the elapsed time to patient report (+99:49:26). Within the telesonography group, patient follow-up and delivery of diagnostic report are two independent occurrences. The average follow-up time within the telesonography group was +92:02:16.

Post-Sonography Follow-Up

Based on the difference in follow-up rates between the telesonography and control groups ($p < 0.05$), our attention is immediately drawn to the uncertain processes that are delaying or, more often, preventing the patient from traveling to the closest government-run tertiary center and returning to the referring clinic for follow-up. Given the demographics of the Veron community along with expert opinion from Veron clinic physicians, there are several likely contributors to this pattern of patient non-compliance: (1) lack of immediate transportation, (2) time demands from occupation or family, (3) waning or termination of presenting symptoms, (4) seeking alternative diagnostic and treatment options, and (5) stoicism. The much higher return rate within the telesonography group gives further credence to the notion that long-distance travel is a significant barrier to patient follow-through. This is not to say that the presence and application of telesonography has an effect on post-sonography time to follow-up. While it was not necessary for patients within the telesonography group to travel outside of the Veron community, post-sonography follow-up times within both control and telesonography groups were very similar, averaging nearly 4 days. In spite of these similar follow-up times between groups, the results from this study indicate that the applied system of telesonography within this setting enabled a greater number of patients to complete post-sonography returns.

Off-Site Practices

It is entirely possible that, upon referral, several patients within the control group were traveling to tertiary centers, successfully completing their ultrasound exam, and then not returning to the Veron clinic with sonographic reports. In fact, given the low rate of return within the control group, there was some trepidation by the principal investigator that sonographers at tertiary centers were referring patients on to other subspecialists without instructing the patient to return to the referring primary care physician first. Upon discussing this issue in-person with sonographers at the closest and most well-known tertiary center in the region, it was confirmed that it is their policy to return the patient to the referring primary care physician with sonographic report in hand.

Diagnoses, Referrals, and Treatment Decisions.

Differences between groups in the type and proportions of post-sonography diagnoses, referrals, and treatments are illustrated in figures 5 through 7. Within the telesonography group, there were 24 different diagnoses recorded over the course of the project. Within the control group, there were only 4 different diagnoses recorded. Patient gender, age, and symptomology were similar between control and telesonography groups and correlate well with archival patient data. While the larger number of successfully-returned reports within the telesonography group can partially account for this discrepancy, this difference is too great to be explained by differences in the number of returned reports alone. Possible explanations for the disproportionate number of individual diagnoses between groups include the following: (1) Greater ranges of diagnostic experience among the volunteer US radiologists versus local Dominican radiologists. (2) Patient scans transmitted to US radiologists contained greater numbers of images with more reliance on multi-planar views, Doppler flow, and volumetric measurement techniques. (3) Within the experimental group, use of additional transabdominal scanning protocols to search for renal, ureter, and bladder etiologies of pelvic discomfort. (4) Within the control group, patients with pelvic discomfort were given a transvaginal scan protocol only. (5) Reports generated from the control group describing scan modalities other than transvaginal did not return to the Veron clinic during the course of this project.

While the use of ultrasound within this setting can provide important information leading to quick diagnostic conclusions, of equal importance is its role in preventing unnecessary referrals and treatments. As seen in figures 5 through 7, patients who utilize either the standard of care ultrasound referral or telesonography within this setting have benefited from a large number of “non-findings”. The ability to rule-out certain diagnoses and prevent unnecessary referrals to subspecialists is of great clinical, fiscal, and psychological benefit to the patient. Based on the current study, the applied telesonography system can provide “non-findings” to a greater number of patients and deliver this information to the referring physician at a much faster rate.

Volunteer Radiologists

Based on the number of returned RFI forms, four of the six radiologists were able to utilize this particular telesonography system regularly and balance their time between pro-bono telesonography readings and regular duties. Of these four radiologists, three were able to transmit completed RFI reports to the referring physician an average of 14 hours after receiving patient information and images. Of the two radiologists who did not consistently participate in the project, one ceased communications and another notified the PI that his / her other duties had made it difficult to review the project scans within a timely manner.

While the patients randomized to the experimental arm of the project were instructed to return in 48 hours for final results (or on the following Monday if scanned on the previous Thursday or Friday), the average final report was transmitted to the clinic within 24 hours. Given these initial results, future telesonography projects in this environment may be able to provide results as soon as the following day. While this quick diagnostic reporting provides a clinical advantage over the standard of care, if the patient follow-up time continues to be upwards of 100 hours, any benefit of this increased diagnostic speed may remain largely unrealized in terms of patient outcomes.

Information Management

The system of downloading and emailing images to volunteer radiologists was successful but somewhat inefficient. The principal investigators used no specific protocol when modifying, uploading, and transmitting images and RFI reports to volunteer radiologists. While proprietary software exists to seamlessly upload and transmit patient information for the purpose of telemedicine, the principal investigators adhered to more laborious non-proprietary transmission methods. Images were delivered to volunteer radiologists in the following manner:

1. Images were downloaded from the Sonosite memory card(s) to a PC laptop computer using SiteLink Image Manager 2.2 software.
2. All images were converted into jpeg format using Irfanview 3.31 software.
3. Jpeg images were transferred to a Mac-based laptop using an external hard drive.
4. Jpeg images were uploaded to an outgoing email along with the appropriate RFI form using Apple Mail 2.1.2 software.
5. The finalized email was sent using the PI’s personal Gmail© account.

Ideally, the images would have been downloaded directly to the Mac-based laptop, but this particular Sonosite model was not compatible with the Mac-based operating system. Apple Mail was the preferred method of uploading images to outgoing emails due to the principal investigator’s familiarity with the software and its ability to seamlessly display attached images within the body of the email. This allowed volunteer radiologists to simply open the email and begin viewing images rather than needing to open each attached image in a separate window.

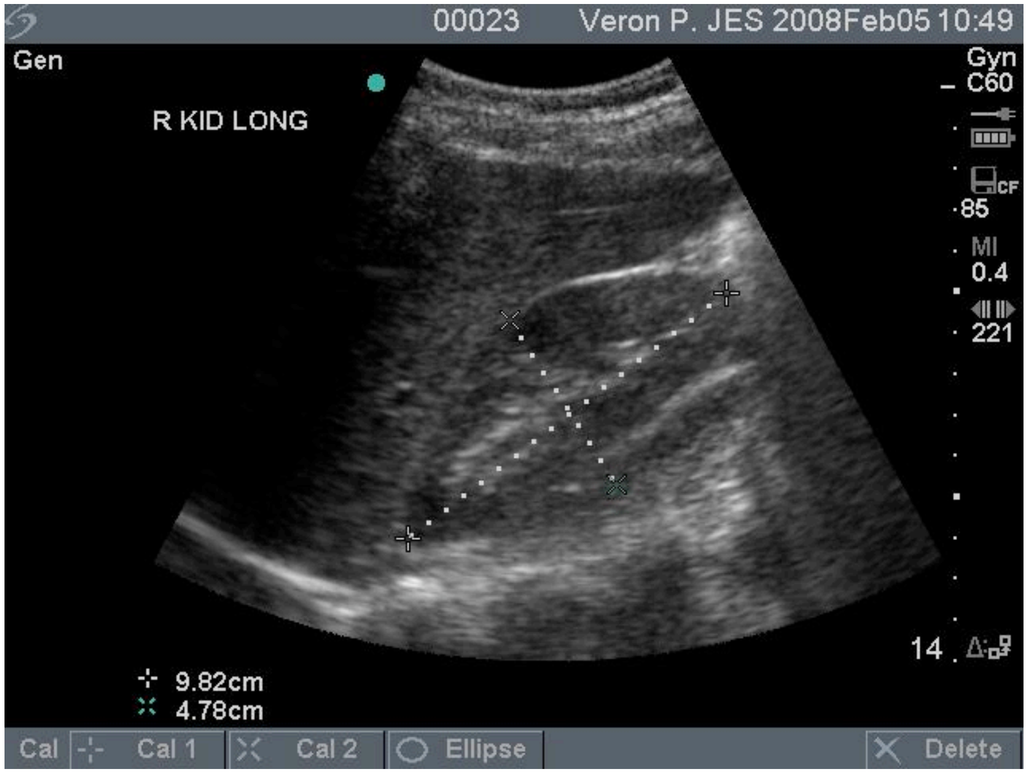

Figure 8. Transabdominal longitudinal view of right kidney with measurement calipers. Volunteer radiologists read hundreds of images such as this over the course of the study.

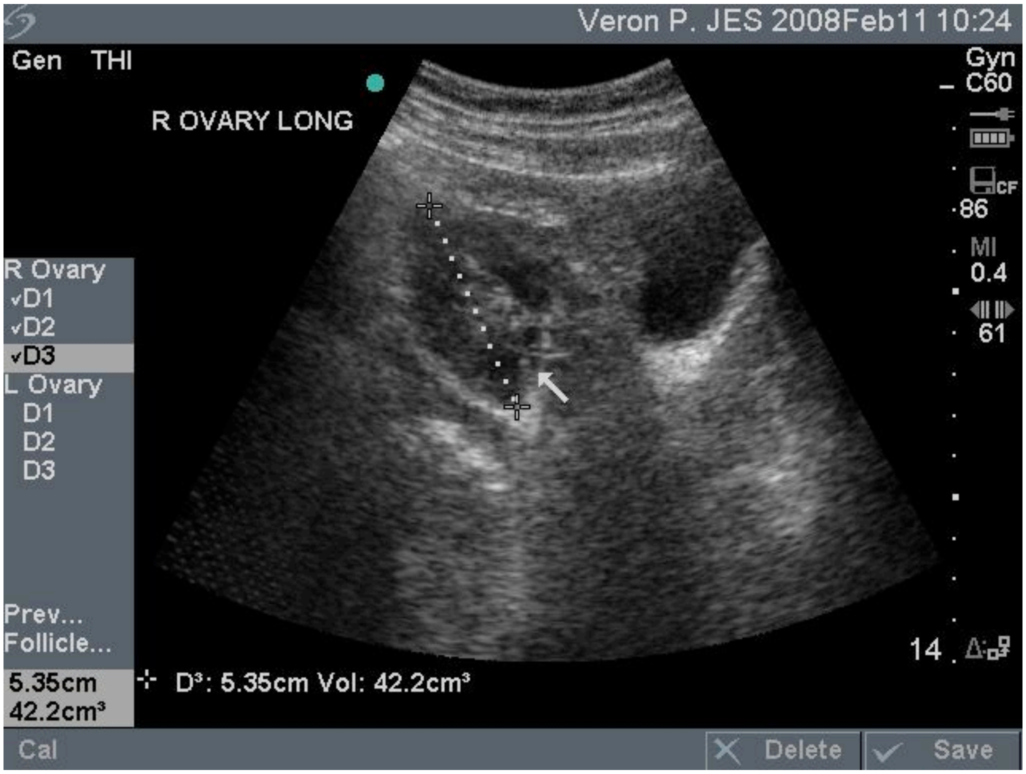

Figure 9. Transabdominal longitudinal view of right ovary with multiple internal hypoechoic cysts.

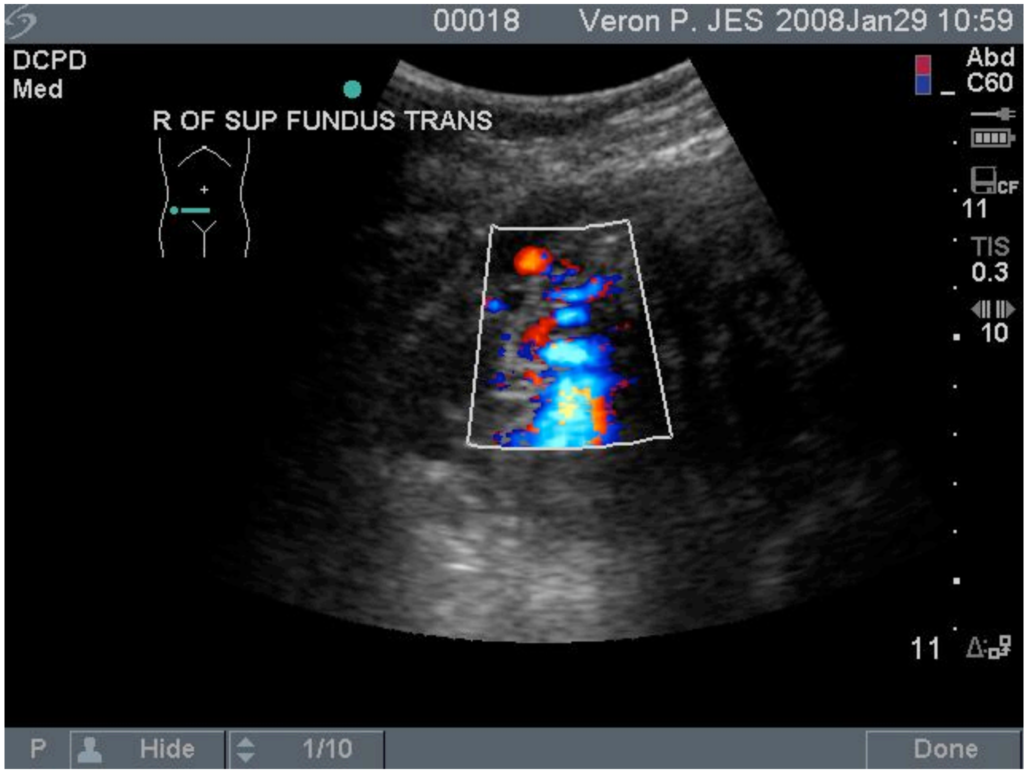

Figure 10. Transabdominal transverse view of a vascular malformation associated with a large abdominal mass.

Clinic Environment

There was no loss of electricity or telecommunications during regular clinic hours over the course of the project. The Veron Clinic physicians, students, and staff were receptive to the telesonography project and the principal investigator experienced no opposition from clinic members, patients, or surrounding medical institutions. Indeed, many of the physicians and students enjoyed observing salient findings and reviewing their knowledge of abdominal, retroperitoneal, and pelvic anatomy in real-time. While the major thrust of this research was to discover how telesonography might improve the patient standard of care within the Veron Clinic, the educational benefits of using telesonography within this particular learning environment were evident during the course of this project.

Conclusions

This pilot study demonstrates that in-house ultrasound, coupled with redundant store-and-forward telediagnosis, reduces time to diagnosis and increases continuity of care compared to the current ultrasound referral system. Also, the high degree of discontinuity of care that results from referral to the closest government-run center for ultrasound examination is made evident through this study.

Findings from this study indicate that the implemented telesonography system, along with patient awareness of such a system, while not having an appreciable effect on the time to patient follow-up, provided a 4-fold increase in the proportion of patient follow-ups and a 6-fold increase in the proportion of returned radiological reports, and delivered those reports to the referring physician 6-times faster than in the control group. Based on the high average rankings of technical and procedural quality by the volunteer radiologists, the pre-implementation ultrasound-training regimen appeared adequate for the principal investigator to provide high quality scans to patients within the telesonography group. There was also a moderately high correlation between "first-look" diagnoses and the final diagnoses within the radiological report.

The increased speed of received radiological reports and improved continuity of care facilitated by telesonography systems such as this is only the first step in a broader effort to provide high-quality health care to Veron and similar underserved communities around the globe.

Recommendations

Based on the findings and conclusions of this study, the following recommendations were developed for future study, public health sector model development, and related areas:

1. To measure the true effectiveness of telesonography and other forms of telemedicine, there needs to be more comprehensive research devoted to its effect on patient outcomes.
2. The future use of telesonography in this setting may wish to incorporate transvaginal sonography in order to ensure optimum visualization of pelvic structures, most notably the uterus, fallopian tubes, and ovaries, as well as first-trimester fetal development.
3. Future projects should continue to refine low-cost data manipulation and transmission methods pertinent to this form of teleradiology.
4. A larger sample size and / or longer implementation time should be utilized in future studies in order to avoid low return rates among traditional referrals. Greater numbers of patient follow-ups within the control group will improve significance testing between the groups under observation.
5. Given the findings of this study and the reliability of telecommunications at the Veron Clinic, telesonography may be considered as a routine standard of care for patients with symptoms that could benefit from this technology.

6. Health officials in the Dominican Ministry of Health should consider telecommunications technology deployment in rural clinics to enhance the standard of health care in the region.
7. This research model may be considered for implementation in other countries with similar conditions of underserved populations and limited access to radiological equipment and expertise within their respective primary care clinics.

References

Anderson, J. G. (2007). Social, ethical and legal barriers to e-health. *International Journal Of Medical Informatics, 76*(5-6), 480-483. doi:10.1016/j.ijmedinf.2006.09.016

Arbeille, P., Capri, A., Ayoub, J., Kieffer, V., Georgescu, M., & Poisson, G. (2007). Use of a robotic arm to perform remote abdominal telesonography. *AJR. American Journal Of Roentgenology, 188*(4), W317-322. doi:10.2214/AJR.05.0469

Arrillaga, A., Graham, R., York, J. W., & Miller, R. S. (1999). Increased efficiency and cost-effectiveness in the evaluation of the blunt abdominal trauma patient with the use of ultrasound. *The American Surgeon, 65*(1), 31-35. Retrieved from http://www.sesc.org/TAS/Journal.htm

Balestri, R., Cavina, E., Aliferis, A., Goletti, O., Rocci, R., Lippolis, P. V., et al. (1999). Telemedicine on a small island. *Journal Of Telemedicine And Telecare, 5 Suppl 1*, S50-52. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Bashshur, R., & Indian Health Service, T. A. Z. O. o. R. a. D. (1980). Technology Serves the People: The Story of a Co-operative Telemedicine Project by NASA, the Indian Health Service and the Papago People. STARPAHC. Retrieved from http://eric.ed.gov/ERICWebPortal/custom/portlets/recordDetails/detailmini.jsp?_nfpb=true&_&ERICExtSearch_SearchValue_0=ED225794&ERICExtSearch_SearchType_0=no&accno=ED225794

Bassignani, M. J., Dwyer, S. J., III, Ciambotti, J. M., Olazagasti, J. M., Moran, R., Moynihan, S., et al. (2004). Review of technology: planning for the development of telesonography. *Journal Of Digital Imaging: The Official Journal Of The*

Society For Computer Applications In Radiology, 17(1), 18-27. doi: 10.1007/s10278-003-1721-4

Biem, H. J., Hadjistavropoulos, H., Morgan, D., Biem, H. B., & Pong, R. W. (2003). Breaks in continuity of care and the rural senior transferred for medical care under regionalisation. *International Journal Of Integrated Care, 3*, e03-e03. Retrieved from http://www.ijic.org/

Blaivas, M., Kuhn, W., Reynolds, B., & Brannam, L. (2005). Change in differential diagnosis and patient management with the use of portable ultrasound in a remote setting. *Wilderness & Environmental Medicine, 16*(1), 38-41. doi: 10.1580/1080-6032(2005)16[38:CIDDAP]2.0.CO;2

Brebner, J. A., Ruddick-Bracken, H., Brebner, E. M., Gilbert, F. J., Maclean, J. R., Ritchie, L. D., et al. (1999). Low-bandwidth tele-ultrasound. *Journal Of Telemedicine And Telecare, 5 (Suppl 1)*, S75-76. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Brebner, J. A., Ruddick-Bracken, H., Brebner, E. M., Smith, A. P., Duncan, K. A., McLeod, A. J., et al. (2000). The diagnostic acceptability of low-bandwidth transmission for tele-ultrasound. *Journal Of Telemedicine And Telecare, 6*(6), 335-338. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Burgul, R., Gilbert, F. J., & Undrill, P. E. (2000). Methods of measurement of image quality in telesonography. *The British Journal Of Radiology, 73*(876), 1306-1312. Retrieved from http://bjr.birjournals.org/cgi/reprint/73/876/1306

Caffery, L., Manthey, K. (2004). Implementation of a Web-based teleradiology management system. *Journal Of Telemedicine And Telecare*, 10(suppl. 1), 22-5. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Cavina, E., Goletti, O., Lippolis, P. V., & Zocco, G. (2001). Telesonography: technical problems, solutions and results in the routine utilization from remote areas. *Studies In Health Technology And Informatics, 81*, 88-89. Retrieved from http://books.google.com/books?hl=en&lr=&id=34xRCE516ggC&oi=fnd&pg=PA88&ots=dKv7dYbTX5&sig=P-coTnDKKsh_t_L49TKqyuFNcaI#PPA87,M1

CIA. CIA-The World Factbook--Dominican Republic. Retrieved April 20, 2008, from https://www.cia.gov/library/publications/the-world-factbook/geos/dr.html.

Chan, F. Y., Soong, B., Lessing, K., Watson, D., Cincotta, R., Baker, S., et al. (2000). Clinical value of real-time tertiary fetal ultrasound consultation by telemedicine: preliminary evaluation. *Telemedicine Journal: The Official Journal Of The American Telemedicine Association, 6*(2), 237-242. doi:10.1089/107830200415171

Chan, F. Y., Soong, B., Watson, D., & Whitehall, J. (2001). Realtime fetal ultrasound by telemedicine in Queensland. A successful venture? *Journal Of Telemedicine And Telecare, 7 (Suppl 2)*, 7-11. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Chan, F. Y., Whitehall, J., Hayes, L., Taylor, A., Soong, B., Lessing, K., et al. (1999). Minimum requirements for remote realtime fetal tele-ultrasound consultation. *Journal Of Telemedicine And Telecare, 5*(3), 171-176. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Corten, A., Duerte, I. (1995). The Dominican Republic: Social Change and Political Stagnation. Five Hundred Thousand Haitians in the Dominican Republic. *Latin American Perspectives, 22*(3), 94-110. doi:10.1177/0094582X9502200306

Craig, J., & Patterson, V. (2005). Introduction to the practice of telemedicine. *Journal Of Telemedicine And Telecare*, 11(1), 3-9. Retrieved from http://books.google.com/books?hl=en&lr=&id=CUoi5nNCVaYC&oi=fnd&pg=PA3&ots=wcSDrONQut&sig=B1KUudsqKQ0sW94pfY_hjhvV5MU

Della Mea, V. (1999). Internet electronic mail: a tool for low-cost telemedicine. *Journal Of Telemedicine And Telecare*, 5(2), 84-89. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Demiris, G., Patrick, T. B., Mitchell, J. A., & Waldren, S. E. (2004). To telemedically err is human. *Joint Commission Journal On Quality And Safety, 30*(9), 521-527. Retrieved from http://www.jcrinc.com/26813/newsletters/33/

Dimmick, S. L., & Ignatova, K. D. (2006). The diffusion of a medical innovation: where teleradiology is and where it is going, *Journal of Telemedicine & Telecare, 12*, 51-58): Royal Society of Medicine Press Limited. doi: 10.1258/135763306778393090

Dominican Republic. (2008). *Britannica Book of the Year*, 2007. Retrieved Febuary 8, 2008, from http://www.britannica.com/eb/article-9433181

Foundation, P. E. (2005). Commitment Statement: Clinton Global initiative. Retrieved November 12, 2007, from http://www.puntacana.org/news31.htm

Fuentes, A. (2003). Remote interpretation of ultrasound images. *Clinical Obstetrics & Gynecology, 46*(4), 878-881. Retrieved from http://www.clinicalobgyn.com/pt/re/clnobgyn/abstract.00003081-200312000-00019.htm;jsessionid=Lv0dQPX0Znk6VzmhPzJJHsWgv5ZmtT11ln7nzTmf9wyLPP91jhkL!-1412394389!181195629!8091!-1

Gemmill, J. (2005). Network basics for telemedicine. *Journal Of Telemedicine And Telecare, 11*(2), 71-76. doi: 10.1258/1357633053499822

Health Insurance Portability and Accountability Act of 1996. Retrieved March 7, 2008, from http://www.hhs.gov/ocr/hipaa/

Heinzelmann, P. J., Jacques, G., & Kvedar, J. C. (2005). Telemedicine by email in remote Cambodia. *Journal Of Telemedicine And Telecare, 11 (Suppl 2)*, S44-47. doi:10.1258/135763305775124858

Hersh, W. R., Hickam, D. H., & Erlichman, M. (2006). The evidence base of telemedicine: Overview of the supplement. *Journal Of Telemedicine And Telecare*, 12 (Suppl 2), S1-2. doi:10.1258/135763306778393081

Hussain, P., Deshpande, A., Shridhar, P., Saini, G., & Kay, D. (2004). The feasibility of telemedicine for the training and supervision of general practitioners performing ultrasound examinations of patients with urinary tract symptoms. *Journal Of Telemedicine And Telecare, 10*(3), 180-182. doi:10.1258/135763304323070850

Johnson, L. B. (1987). The importance of early diagnosis of acute acalculus cholecystitis. *Surgery, Gynecology & Obstetrics, 164*(3), 197-203. Retrieved from http://journalseek.net/cgi-bin/journalseek/journalsearch.cgi?field=issn&query=0039-6087

Johnson, M. A., Davis, P., McEwan, A. J., Jhangri, G. S., Warshawski, R., Gargum, A., et al. (1998). Preliminary findings from a telesonography study in Alberta.

Telemedicine Journal: The Official Journal Of The American Telemedicine Association, 4(3), 267-276. Retrieved from http://www.liebertpub.com/publication.aspx?pub_id=54

Klaz, I., Wohl, Y., Nathansohn, N., Yerushalmi, N., Sharvit, S., Kochba, I., et al. (2005). Teledermatology: quality assessment by user satisfaction and clinical efficiency. *The Israel Medical Association Journal: IMAJ, 7*(8), 487-490. Retrieved from http://www.ima.org.il/imaj/

Lagalla R (2001). Telecommunications, health and radiology: potential synergies for the new millennium. *La Radiologia Medica*, *102*(1-2),14-9. Retrieved from http://www.sirm.org/pubblicazioni/radiologia_medica/

Landwehr, J. B., Jr., Zador, I. E., Wolfe, H. M., Dombrowski, M. P., & Treadwell, M. C. (1997). Telemedicine and fetal ultrasonography: assessment of technical performance and clinical feasibility. *American Journal Of Obstetrics And Gynecology, 177*(4), 846-848. Retrieved from http://journals.elsevierhealth.com/periodicals/ymob

Li, X., Hu, G., & Gao, S. (1999). Design and implementation of a novel compression method in a tele-ultrasound system. *IEEE Transactions On Information Technology In Biomedicine: A Publication Of The IEEE Engineering In Medicine And Biology Society, 3*(3), 205-213. doi:10.1109/4233.788582

Lockwood, C. J., Bahado-Singh, R., D'Alton, M. E., & Platt, L. D. (2001). Applying new advances in OB ultrasound. *Contemporary OB/GYN, 46*(6), 51. Retrieved from http://ieeexplore.ieee.org/xpl/RecentIssue.jsp?punumber=4233

Ma, John O., Mateer, James R., Blaivas, Michael (2008). *Emergency Ultrasound* (2nd ed.). China: McGraw-Hill.

Macedonia, C. R., Littlefield, R. J., Coleman, J., Satava, R. M., Cramer, T., Mogel, G., et al. (1998). Three-dimensional ultrasonographic telepresence. *Journal Of Telemedicine And Telecare, 4*(4), 224-230. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Mandall, N. A., O'Brien, K. D., Brady, J., Worthington, H. V., & Harvey, L. (2005). Teledentistry for screening new patient orthodontic referrals. Part 1: A randomised controlled trial. *British Dental Journal, 199*(10), 659. doi:10.1038/sj.bdj.4812930

Metz, H. C. (1989). Dominican Republic and Haiti: country studies / Federal Research Division, Library of Congress. Retrieved November 12, 2007, from http://lcweb2.loc.gov/frd/cs/dotoc.html

Moro, P. L., Bonifacio, N., Gilman, R. H., Lopera, L., Silva, B., Takumoto, R., et al. (1999). Field diagnosis of Echinococcus granulosus infection among intermediate and definitive hosts in an endemic focus of human cystic echinococcosis. *Transactions Of The Royal Society Of Tropical Medicine And Hygiene, 93*(6), 611-615. doi:10.1016/S0035-9203(99)90068-8

Moro, P. L., Garcia, H. H., Gonzales, A. E., Bonilla, J. J., Verastegui, M., & Gilman, R. H. (2005). Screening for cystic echinococcosis in an endemic region of Peru using portable ultrasonography and the enzyme-linked immunoelectrotransfer blot (EITB) assay. *Parasitology Research, 96*(4), 242-246. doi:10.1007/s00436-005-1350-6

O'Neill, S. K., Allen, D., & Brockway, P. D. (2000). The design and implementation of an off-the-shelf, standards-based tele-ultrasound system. *Journal Of Telemedicine And Telecare, 6 (Suppl 2)*, S52-53. Retrieved from http://www.rsmpress.co.uk/jtt.htm

PAHO, H. A. a. S. U. H. (2000). Dominican Republic: Health Situation Analysis and Trends. Retrieved October 10, 2007, from http://www.paho.org/English/DD/AIS/cp_214.htm

PAHO, H. A. a. S. U. H. (2006). Health Situation in the Americas: Basic Indicators. Retrieved October 10, 2007, http://www.paho.org/english/dd/ais/coredata.htm

Papageorges, M., Hebert, P., Hanson, J., Girard, E., Leveille, R., & Feleciano, J. (2001). Telesonography. *Clinical Techniques In Small Animal Practice*, 16(2), 117-121. Retrieved from http://www.sciencedirect.com/science/journal/10962867

Patterson, V., Humphreys, J., & Chua, R. (2003). Teleneurology by email. *Journal Of Telemedicine And Telecare, 9 (Suppl 2)*, S42-43. doi:10.1053/svms.2001.26234

Popov, V., Popov, D., Kacar, I., & Harris, R. D. (2007). The feasibility of real-time transmission of sonographic images from a remote location over low-bandwidth Internet links: a pilot study. *AJR. American Journal Of Roentgenology, 188*(3), W219-222. doi:10.2214/AJR.05.2148

Radiology, A. C. o. (Amended 2006 (Res.35)). *ACR Practice Guidelines for the Performance of Diagnostic and Screening Ultrasound of the Abdominal Aorta.* Retrieved August 15, 2007 from http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/us.aspx

Radiology, A. C. o. (Amended 2006 (Res. 35)). *ACR Practice Guidline for the Performance of Pelvic Ultrasound in Females.* Retrieved August 15, 2007 from http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/us.aspx

Radiology, A. C. o. (Revised 2006 (Res. 39, 35)). *ACR Practice Guidelines for the Performance of an Ultrasound Examination of the Abdomen and/or Retroperitoneum.* Retrieved August 15, 2007 from http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/us.aspx

Rheuban, K. S. (2006). The role of telemedicine in fostering health-care innovations to address problems of access, specialty shortages and changing patient care needs. *Journal Of Telemedicine And Telecare*, 12 Suppl 2, S45-50. doi: 10.1258/135763306778393171

Rogers, E (2003). Diffusion of Innovation. New York, New York: Free Press.

Roine, R., Ohinmaa, A., & Hailey, D. (2001). Assessing telemedicine: a systematic review of the literature. *CMAJ, 165*(6), 765-771. Retrieved from http://www.cmaj.ca/cgi/reprint/165/6/765

Sinclair, A. (1998). Medical Imaging: Discussion Paper For Industry Canada. Retrieved from http://md1.csa.com/partners/viewrecord.php?requester=gs&collection=TRD&recid=2007020179AN&q=&uid=792798065&setcookie=yes

Smith, P., & Brebner, E. (2002). Tele-ultrasound for remote areas. *Journal Of Telemedicine And Telecare, 8 (Suppl 2)*, 80-81. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/12217148

Soong, B., Chan, F. Y., Bloomfield, S., Smith, M., & Watson, D. (2002). The fetal tele-ultrasound project in Queensland. *Australian Health Review: A Publication Of The Australian Hospital Association, 25*(3), 67-73. Retrieved from http://www.aushealthcare.com.au/publications/articles/

Struber, J. C. (2004). An introduction to telemedicine and email consultations. *Internet Journal of Allied Health Sciences & Practice, 2*(3), 8p. Retrieved from http://ijahsp.nova.edu/articles/Vol2number3/telemedicine_Struber.htm

Studdert, D. M., Mello, M. M., & Brennan, T. A. (2004). Medical Malpractice. *New England Journal of Medicine, 350*(3), 283-292. Retrieved from http://content.nejm.org/cgi/content/extract/350/3/283

Tanriverdi, H., & Iacono, C. S. (1999). Diffusion of telemedicine: a knowledge barrier perspective. Telemedicine Journal: *The Official Journal Of The American Telemedicine Association*, 5(3), 223-244. doi:10.1089/107830299311989

Thelma McClosky Armstrong, S. B., Dimmick, S., Edison, K., Ricci, M., Rheuban, K., Scheideman-Miller, C., Settimo,R.J., Sprang, R. (2004). A Guide to Getting Started in Telemedicine. Retrieved from http://telehealth.muhealth.org/general%20information/TAD.html

Tyrer, H. W., Wiedemeier, P. D., & Cattlet, R. W. (2001). Rural telemedicine: satellites and fiber optics. Biomedical Sciences Instrumentation, 37, 417-422. Retrieved from http://journalseek.net/cgi-bin/journalseek/journalsearch.cgi?field=issn&query=0067-8856

USAID. (2002). Dominican Republic. Retrieved July 25, 2007 from http://www.usaid.gov/dr/

Virginia College of Osteopathic Medicine (2007). Personnel and Human Resource Descriptions, Veron Clinic - Dominican Republic

Vassallo, D. J., Hoque, F., Roberts, M. F., Patterson, V., Swinfen, P., & Swinfen, R. (2001). An evaluation of the first year's experience with a low-cost telemedicine link in Bangladesh. *Journal Of Telemedicine And Telecare, 7*(3), 125-138. Retrieved from http://www.rsmpress.co.uk/jtt.htm

Vassallo, D. J., Swinfen, P., Swinfen, R., & Wootton, R. (2001). Experience with a low-cost telemedicine system in three developing countries. *Journal Of Telemedicine And Telecare, 7 (Suppl 1)*, 56-58. Retrieved from http://www.rsmpress.co.uk/jtt.htm

WHO. (2007). Diagnostic Imaging. Retrieved October 12, 2007, from http://www.who.int/diagnostic_imaging/en/

Yoo, S. K., Kim, D. K., Jung, S. M., Kim, E. K., Lim, J. S., & Kim, J. H. (2004). Performance of a Web-based, realtime, tele-ultrasound consultation system over high-speed commercial telecommunication lines. *Journal of Telemedicine and Telecare, 10*(3), 175-179. doi:10.1258/135763304323070841

Zocco, G., Goletti, O., Lippolis, P.V., Lorenzetti, L., Musco, Cavina, E., Tsolakidis, K. (2003). *Telemedicine Journal and e-Health*. 9(1): 117-121. doi:10.1089/153056203763317747.

Appendix A

Request for Interpretation Form

Patient #:
Sex:
Age:
Reason for ultrasound:
Type of study:

Please rank both the technical and procedural quality of the overall ultrasound study on a scale of 1 to 5 in the spaces provided below.

1 = very poor / lacks most appropriate views / no diagnostic value
2 = poor / contains few appropriate views / little diagnostic value
3 = barely acceptable / contains some appropriate views / marginal diagnostic value
4 = good / contains most appropriate views / high diagnostic value
5 =very good / contains all appropriate views / excellent diagnostic value

---

Very Poor – Data from study provides for diagnostic certainty <10% (area of interest is not visualized; too grainy, dark, bright, improper gain settings, poor penetration, etc.)

Poor – Data from study provides for diagnostic certainty <30% (area of interest is visualized with many deficiencies with regard to image-size, field of view, focal zone, grey-scale, Doppler, or text information)

Barely Acceptable – Data from study provides for diagnostic certainty >50% (area of interest is visualized but still lacks in some aspect(s) of image-size, field of view, focal zone, grey-scale, Doppler, or text information)

Good – Data from study provides for diagnostic certainty >70% (area of interest is visualized with few deficiencies with regard to image-size, field of view, focal zone, grey-scale, Doppler, or text information)

Very Good – Data from the image provides for diagnostic certainty >90% (area of interest is well visualized with no deficiencies with regard to image-size, field of view, focal zone, grey-scale, Doppler, and text information)

Specific comments or critiques of images are welcome. Individual time stamps can be used to identify images Example: "Image 14:32 - adjust gain settings" or "Image 10:22 - rib shadowing obscures area of interest").

Technical quality of images (gain, penetration, grey-scale, color, Doppler, artifacts, resolution) [1-5]:

Procedural quality of exam (followed appropriate ACR scanning protocols based on patient symptoms and history) [1-5]:

Findings:

Diagnosis:

Comments / suggestions:

Appendix B

Request for Interpretation Form Evaluation

1) The form's ability to communicate appropriate patient information.

 1 strongly unfavorable to the concept
 2 somewhat unfavorable to the concept
 3 undecided
 4 somewhat favorable to the concept
 5 strongly favorable to the concept

2) The ranking system of technical and procedural quality.

 1 strongly unfavorable to the concept
 2 somewhat unfavorable to the concept
 3 undecided
 4 somewhat favorable to the concept
 5 strongly favorable to the concept

3) The clarity of the form.

 1 strongly unfavorable to the concept
 2 somewhat unfavorable to the concept
 3 undecided
 4 somewhat favorable to the concept
 5 strongly favorable to the concept

4) The criteria used to describe the ranking system itself.

 1 strongly unfavorable to the concept
 2 somewhat unfavorable to the concept
 3 undecided
 4 somewhat favorable to the concept
 5 strongly favorable to the concept

5) The criteria used to describe technical and procedural quality.

 1 strongly unfavorable to the concept
 2 somewhat unfavorable to the concept
 3 undecided
 4 somewhat favorable to the concept
 5 strongly favorable to the concept

6) The form's ability to assess key aspects of ultrasound technique.

1 strongly unfavorable to the concept
2 somewhat unfavorable to the concept
3 undecided
4 somewhat favorable to the concept
5 strongly favorable to the concept

7) The overall ability of this form to provide educational feedback to the sonographer regarding his or her technique and scanning protocol.

1 strongly unfavorable to the concept
2 somewhat unfavorable to the concept
3 undecided
4 somewhat favorable to the concept
5 strongly favorable to the concept

In the space provided below please make any additional comments or observations regarding the Request for Interpretation (RFI) form and its educational value:

Appendix C1

Consent Form (English)

INFORMED CONSENT

EDWARD VIA VIRGINIA COLLEGE OF OSTEOPATHIC MEDICINE

Informed Consent Form for Participants in Research Projects Involving Human Subjects

Telesonography Adoption and Use to Improve the Standard of Patient Care Within a Dominican Community

Investigator(s)

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I. Investigators' Statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, the possible risks and benefits, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

II. Purpose of this Research/Project

This project is being directed by a student physician working towards a D.O. / Ph.D. in Global Health Leadership at a major American university. This project will help doctors know if ultrasound is needed here at the Veron clinic. You have been chosen for this project because you or your child feels bad. Doctors use ultrasound to help them choose the right treatment for sick patients. This project will compare two different ways of providing ultrasound services to patients of the Veron clinic.

Procedures

If you choose to participate, you or your child will have an ultrasound exam at the Veron clinic **or** at the closest government-run hospital. Your medical records will also be used to help the doctors understand why you feel bad.

If the ultrasound exam is here at the Veron clinic, please return to the clinic in 2 days for the results. All ultrasound exams at the Veron clinic will be completed by an American physician.

If you are selected to have an ultrasound exam outside the Veron clinic, you will travel to the closest government-run hospital, complete your ultrasound exam there, and bring the final results of this exam with you to the Veron clinic as soon as possible.

III. Risks, Stress or Discomfort

Ultrasound is a safe and painless way to look inside the belly. The exam will take about 20 minutes. The exam may not find the reason why you or your child feels bad.

IV. Alternatives to Taking Part in this Study

If you or your child needs an ultrasound exam but you do not want to participate in this project, you or your child will have an ultrasound exam at the closest government-run hospital.

V. Benefits of the Study

No promise or guarantee of benefits has been made to encourage you to participate in this study.

VI. Extent of Anonymity and Confidentiality

Only you and your doctors will know the results. Your identity and other personal information will be kept confidential and will be stored in a locked room within the Veron clinic. Personal information regarding this project will be destroyed before May 15th, 2008.

VII. Compensation

You are not being offered compensation by the investigators for participation in this study.

If you think you have an injury or illness related to this study, contact the study staff right away. The study staff will treat you or refer you for treatment. You will be responsible for the cost of such treatment.

VIII. Freedom to Withdraw

Your participation is completely voluntary. If you want to stop your participation in this research project at a later date, you will still receive appropriate medical attention.

IX. Subject's Responsibilities

I voluntarily agree to participate in this study. I have the following responsibilities:

1. If selected to have an ultrasound exam at the Veron clinic, I will return to the clinic in two days for the results.

2. If selected to have an ultrasound exam at the closest government-run clinic, I will return to the Veron clinic with the final report as soon as possible.

X. Subject's Statement

I have read and understand the Informed Consent and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

"I have read this consent form and I wish to participate in this research study. I have had all of my questions answered. I realize that I will receive a copy of this form. I hereby acknowledge the above and give my voluntary consent. I realize that my consent does not take away any legal rights. I give permission to the researchers to use my medical records as described in this consent form."

By signing below you agree and realize that you will be participating in this study at your own risk. Further, by signing below you hereby consent to participating in this study as described above.

____________________________	____________________________
Printed name of participant	Signature of participant
	__________
	Date

When participant is a minor:

____________________________	____________________________
Printed name of parent	Signature of parent
	__________
	Date

When subject is not able to provide consent:

____________________________	____________________________
Printed name of representative	Signature of representative
	__________
	Date

____
Relationship of representative to participant

Should I have more questions about this research or its conduct, research subjects' rights, or research-related injury, I may contact:

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Higuey, La Altagracia
Republica Dominicana
1 809 455-1528
norbertorojas79@yahoo.com

For questions I may have about this study.

VCOM IRB Chairman
Hara P. Misra, D.V.M., Ph.D.
(540) 231-3693, misra@vt.edu

For questions I may have about my rights as a research subject.

This Informed Consent is valid from 1/9/08 to 3/7/08 .

Appendix C2

Consent Form (Spanish)

Forma del Consentimiento

LA UNIVERSIDAD VIRGINIA DE MEDICINA OSTEOPATICA

Forma del consentimiento para los participantes en los proyectos de investigación que implican temas humanos

Adopción y Uso de Telesonografia para Mejorar el Estándar de Cuidado a Pacientes Dentro de una Comunidad Dominicana

Investigadores

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1+540 449-1894

XI. Declaración de los Investigadores

Estamos pidiendo que participe en un estudio de investigación. El propósito de esta forma de consentimiento es darle la información que usted necesitará para ayudarle a decidir si participará o no. Lea por favor la forma cuidadosamente. Usted puede hacer preguntas acerca del propósito de la investigación, los riesgos y las ventajas posibles, y cualquier cosa sobre la investigación o esta forma que no esté clara. Cuando hayamos contestado todas sus preguntas, usted puede decidir si desea ser parte del estudio o no. Este proceso se llama "consentimiento informado." Le daremos una copia de esta forma para sus expedientes.

XII. Propósito de este Proyecto

Este proyecto está siendo dirigido por un Estudiante de Medicina Americano, que trabaja hacia un D.O./ Ph.D. en la dirección global de salud en una Universidad Americana importante. Este proyecto ayudará a doctores a saber si el ultrasonido se necesita aquí en la clínica de Veron.

Usted o su niño han sido elegidos para este proyecto porque posiblemente estan enfermos. Los médicos usan el Ultrasonido para ayudarles a elegir el tratamiento correcto para los pacientes enfermos. Este proyecto comparará dos distintas maneras de proporcionar servicios de ultrasonido a los pacientes de la clínica de Veron.

Procedimientos

Si usted elige participar, usted o su niño tendrán un examen del ultrasonido en la clínica de Veron o en el hospital estatal más cercano que este en funcionamiento. Sus informes médicos también serán utilizados para ayudar a los doctores a entender porqué usted se siente mal.

Si el examen del ultrasonido es realizado aquí en la clínica de Veron, vuelva por favor a la clínica en 2 días para los resultados. Todos los exámenes del ultrasonido en la clínica de Veron serán terminados por un estudiante médico Americano.

Si es seleccionado para tener un examen de ultrasonido fuera de la clínica de Veron, usted viajará al hospital más cercano perteneciente al gobierno. Al terminar su examen de ultrasonido allí, traiga los resultados finales de este examen a la clínica de Veron cuanto antes.

XIII. Riesgos, Tensión o Malestar

El ultrasonido es una manera segura y sin dolor de mirar dentro del vientre. El examen tardará cerca de 20 minutos. El examen puede no encontrar la razón por la que usted o su niño se sienten mal.

XIV. Alternativas a Participar en este Estudio

Si usted o su niño necesitan un examen de ultrasonido pero usted no quiere participar en este proyecto, usted o su niño tendrán un examen de ultrasonido en el hospital estatal más cercano.

XV. Ventajas del Estudio

No se ha hecho ninguna promesa o garantía de ventajas para animarle a que participe en este estudio.

XVI. Anonimato y Secreto

Solamente usted y sus doctores sabrán los resultados. Su identidad y la otra información personal serán mantenidas confidenciales y serán guardados en un cuarto cerrado con llaves dentro de la clínica de Veron. La información personal con respecto a este proyecto será destruida antes de mayo del 15 de 2008.

XVII. Remuneración

Los investigadores no le ofrecen remuneracion por su participacion en este estudio.

Si usted piensa que ha sufrido alguna lesión o una enfermedad relacionada con este estudio, entre en contacto con los encargados del estudio inmediatamente. El personal del estudio le tratará o le referirá para el tratamiento. Usted será responsable del costo de dicho tratamiento.

XVIII. Libertad de retirarse

Su participación es totalmente voluntaria. Si usted quiere parar su participación en este proyecto de investigación más adelante, usted todavía recibirá la atención médica apropiada.

XIX. Responsabilidades del participante

Acuerdo voluntariamente participar en este estudio. Tengo las responsabilidades siguientes:

1. Si soy seleccionado para tener un examen de ultrasonido en la clínica de Veron, volveré a la clínica en dos días para procurar los resultados.
2. Si soy seleccionado para tener un examen de ultrasonido en el hospital estatal más cercano volveré a la clínica de Veron con el informe final cuanto antes.

XX. Declaración del participante

He leído y entendido el consentimiento y las condiciones informados en este proyecto.Todas mis preguntas han sido contestadas. Reconozco por este medio lo anteriormente escrito y doy mi consentimiento voluntario:

"He leído esta forma del consentimiento y deseo participar en este estudio de investigación. Todas mis preguntas han sido contestadas. Entiendo que recibiré una copia de esta forma. Reconozco por este medio lo anteriormente escrito y doy mi consentimiento voluntario. Entiendo que mi consentimiento no quita ningún derecho legal. Doy el permiso a los investigadores para utilizar mis informes médicos según lo descrito en esta forma del consentimiento."

Firmando en la linea de abajo acepto que estoy participando en este estudio bajo mi propio riesgo. Además, con dicha firma acuerdo participar en este estudio según lo descrito arriba.

___________________________	________________________	__________
Nombre impreso del participante	Firma del participante	Fecha

Cuando el participante es un menor de edad:

___________________________	________________________	__________
Nombre impreso del padre	Firma del padre	Fecha

Cuando la persona no puede dar el consentimiento por si mismo:

___________________________	________________________	__________
Nombre impreso del representante	Firma del representante	Fecha

____

Relacion entre el representante y el participante

Si tengo más preguntas sobre esta investigación, sobre los derechos del participante en esta, o alguna lesion relacionada a la investigacion, puedo entrar en contacto con:

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Norberto Rojas, MD
Director de la Clinica
Clinica Rural Veron
Carretera Veron-Punta Cana (a 600 metros del cruce).
Higuey, La Altagracia
Republica Dominicana
1 809 455-1528
norbertorojas79@yahoo.com

Para las preguntas que pueda tener sobre este estudio.

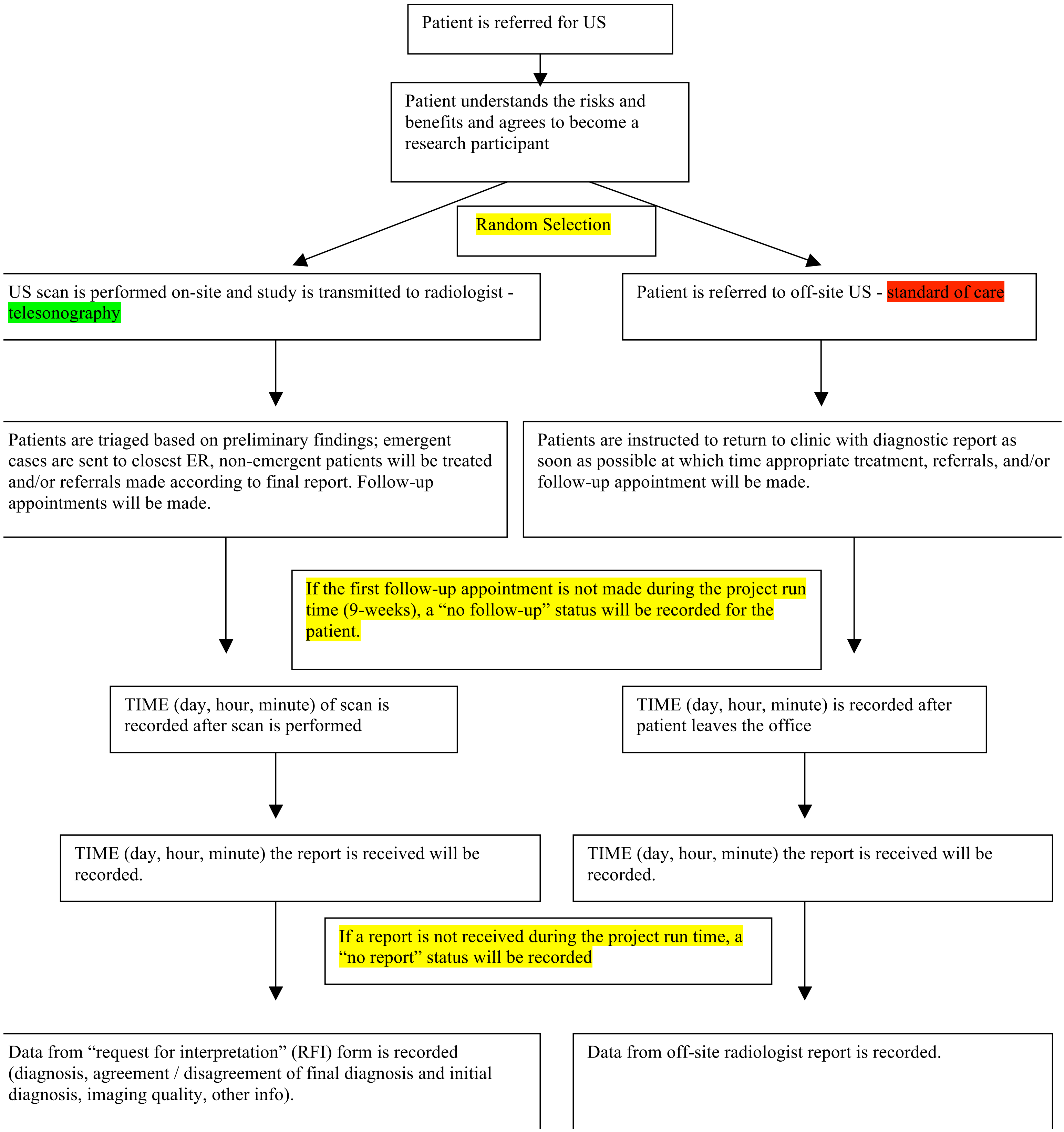
VCOM IRB Chairman
Hara P. Misra, D.V.M., Ph.D.
(540) 231-3693, misra@vt.edu

Para las preguntas que pueda tener sobre mis derechos como participante de este estudio.

Este consentimiento informado es válido a partir de la 1/9/08 a 3/7/08.

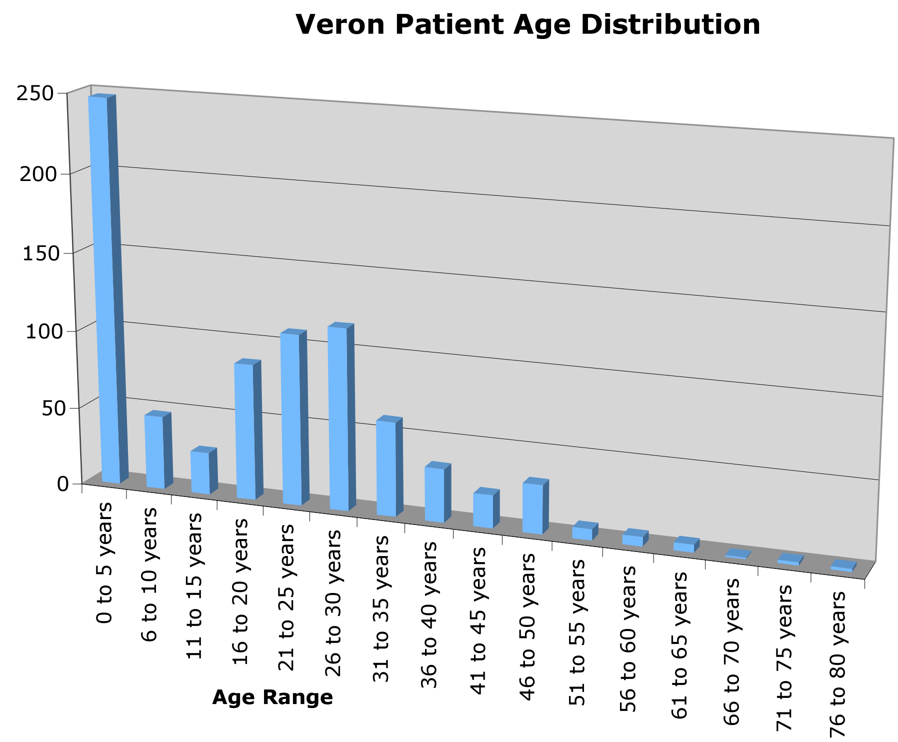
Appendix D

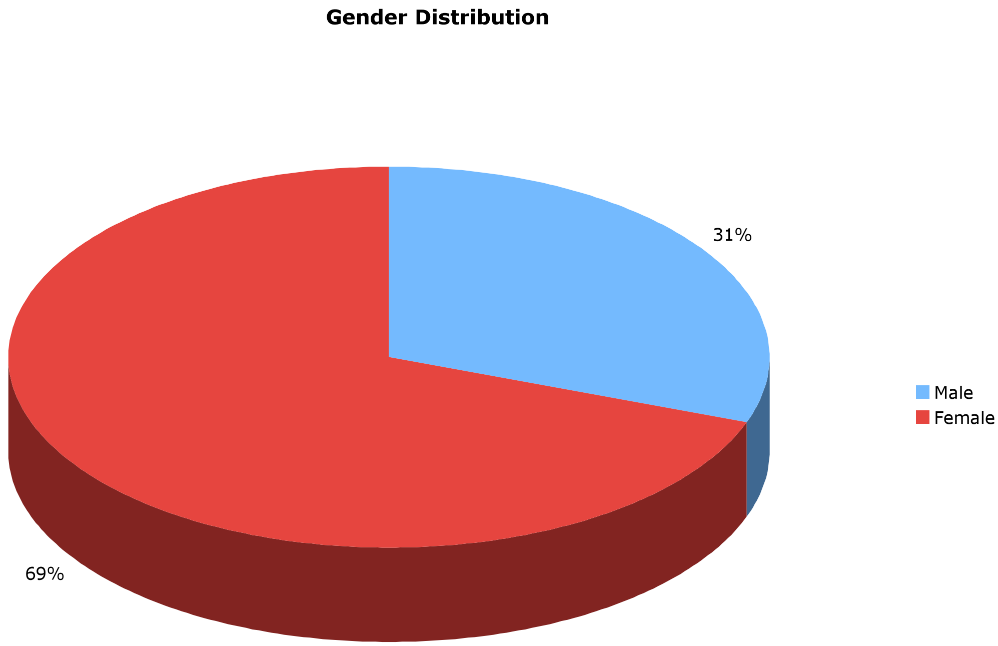
Patient Flowchart

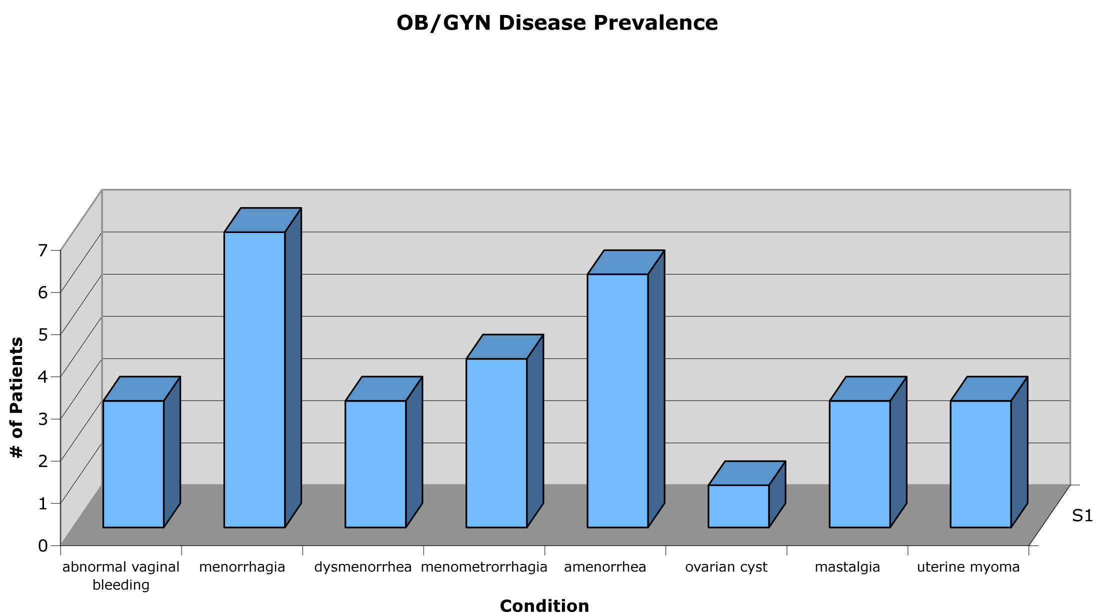


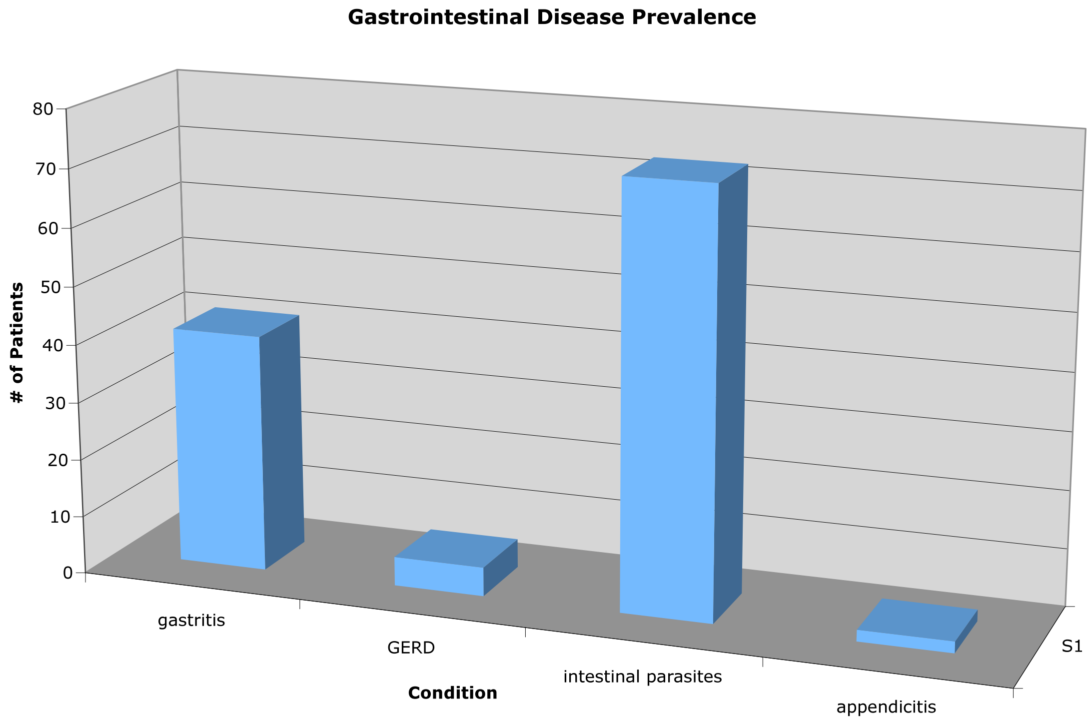
Appendix E

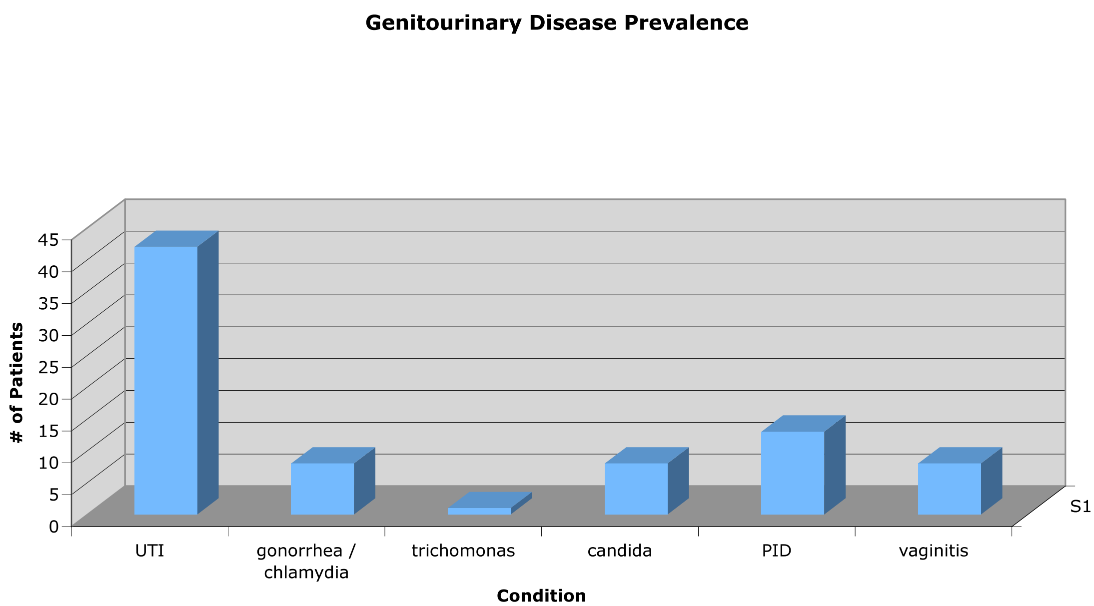
Preliminary findings and diagnoses taken from Veron clinic patient records (n = 830)

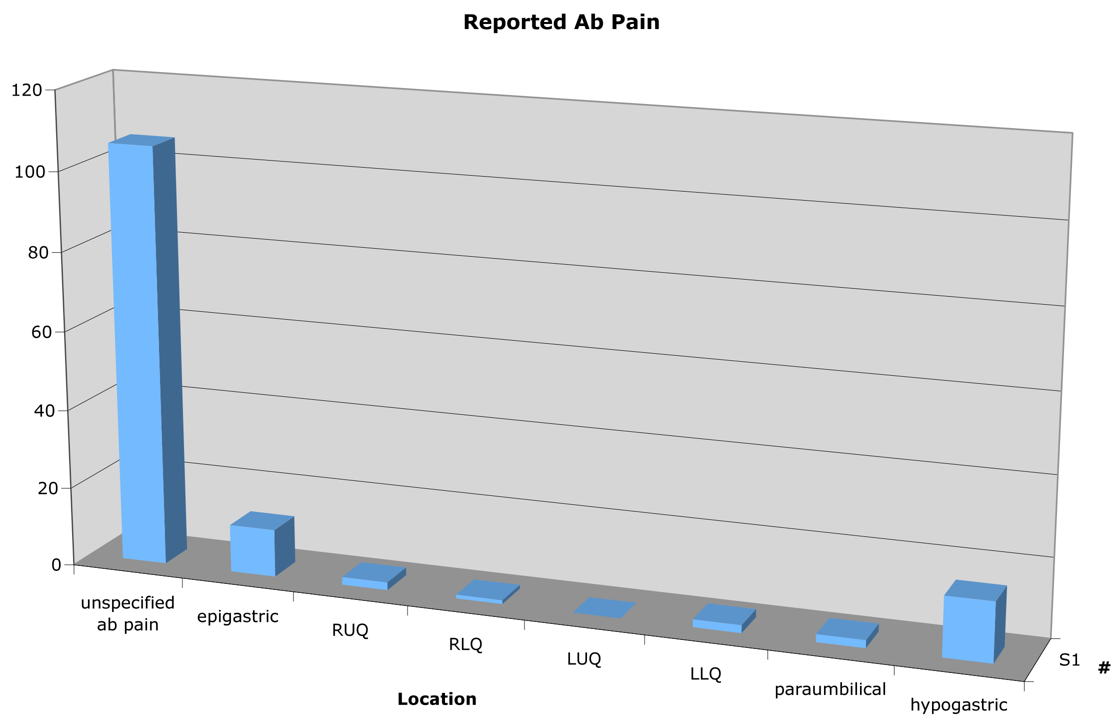


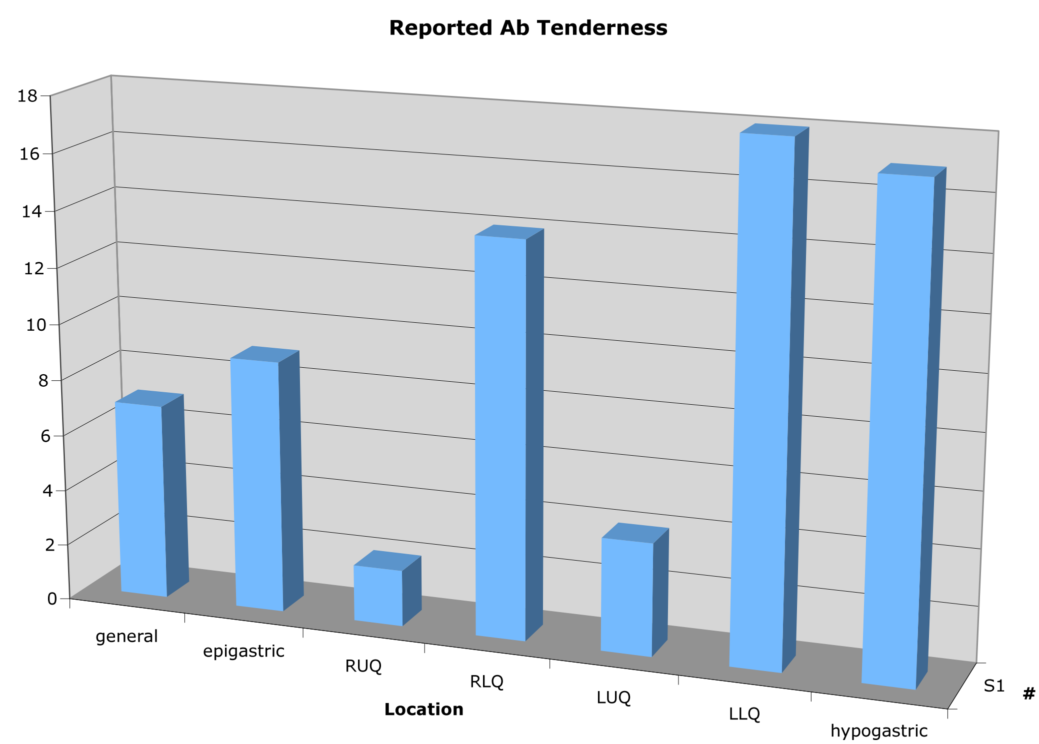

Gender Distribution
31%
69%
Male
Female


OB/GYN Disease Prevalence
7
6
5
4
3
2
1
0
# of Patients
S1
abnormal vaginal bleeding
menorrhagia
dysmenorrhea
menometrorrhagia
amenorrhea
ovarian cyst
mastalgia
uterine myoma
Condition


Gastrointestinal Disease Prevalence
80
70
60
50
40
30
20
10
0
# of Patients
gastritis
GERD
intestinal parasites
appendicitis
Condition
S1


Genitourinary Disease Prevalence
45
40
35
30
25
20
15
10
5
0
# of Patients
UTI
gonorrhea / chlamydia
trichomonas
candida
PID
vaginitis
Condition
S1


Reported Ab Pain
120
100
80
60
40
20
0
unspecified ab pain
epigastric
RUQ
RLQ
LUQ
LLQ
paraumbilical
hypogastric
Location
S1
#


Reported Ab Tenderness
18
16
14
12
10
8
6
4
2
0
general
epigastric
RUQ
RLQ
LUQ
LLQ
hypogastric
Location
S1
#