Integrated Digital X-Ray System for the WHIS-RAD

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Executive Summary

Our mission has been to design a digital X-ray capability as either a retrofit or a modification to existing WHIS-RAD (World Health Imaging System-Radiology) systems that meet the requirements of clinics and primary care hospitals in the developing world. To this end, our primary objectives are to eliminate film to lower recurring costs, develop a suitable viewing system to view images once they have been acquired, and design a storage, archival, and retrieval system in order to efficiently manage the digital images taken. In our project, we researched the work that has been done to improve the quality of X-ray services in the developing world by Rotary International and the World Health Organization in implementing the WHIS-RAD system. The cost of obtaining and processing film has been a major problem with WHIS-RAD operations and therefore the development of a digital retrofit was undertaken. Our project led us to consider numerous technologies to fulfill the requirements of such a device in the developing world with the most important being cost. Our final recommendation is to use computed radiography instead of film, to view images using high resolution, reasonably priced LCD monitors and to archive and view images using free, open source utilities such as Konquest and K-PACs and a local PC. Migration from this system from film would improve the quality of patient care since the time needed to view the image after exposure is shorter and patient records can be more easily maintained. In the future this technology can allow for additional improvements to the quality of diagnoses and healthcare in general, such as teleradiology.

1.0 Introduction

1.1 Current Situation

Vital health issues have long been a persistent issue in developing countries. The main focus of efforts by humanitarian groups is to supply essentials, such as food and shelter, to people with little or no ability to provide these goods for themselves. However, in recent years the need for diagnostic systems, such as X-ray, has become an important focus of WHO, and recently, Rotary International. Due to an extreme lack of funding for expensive X-ray machines in developing countries, such as those in sub-Saharan Africa, and a lack of trained radiologists or technicians to perform examinations and develop diagnoses, nearly two-thirds of the world's population does not have access to adequate X-ray services[1]. Coupled with the fact that sixty percent of all medical diagnoses and treatment require X-ray analysis, the effect of the lack of X-ray machines on developing countries is significant. Faced with growing health problems in Africa, such as tuberculosis facilitated by AIDS, the need for X-ray machinery was realized by the WHO and an initiative was begun nearly 30 years ago.

1.2 Current Solution – WHIS-RAD

1.2.1 Background

In 1975, a meeting on *A Primary Care Radiological System* was held at the Pan American Health Organization (PAHO) in Washington DC. From this conference arose a proposal to develop a basic radiological system (BRS) to attempt to meet the radiological needs of developing countries deprived of such technology. The guidelines outlined by

[1] Vanden Brink, J. "Rotary WHIS-RAD Project." 2006, from http://www.rotarywhis-rad.org/description.html.

the WHO were that a BRS system must posses excellent X-ray image quality; must be safe for patients and operators; must be easy to install and train; must be usable where electrical power is not stable; and must require minimal maintenance. It must also be able to fulfill 80-90% of the radiological needs of a community in order to be maximally effective. The WHO-BRS targeted rural hospitals, and 250 units were successfully deployed in over 40 countries in the mid 80s.

In 1985, the technical specifications for such a system were decided upon and development of World Health Imaging Systems for Radiology (WHIS-RAD) systems for deployment in developing countries was begun. Following further development, the *Report from the consultation meeting on the WHO Basic Radiological Systems* in Lund, Sweden was released in June 1993 and contained very detailed recommendations for technical specifications for WHIS-RAD systems.

1.2.2 Benefits

The WHIS-RAD is designed to provide the best radiological care possible for an accessibly low cost. Its benefits vastly outweigh its inherent drawbacks, and it can therefore deliver much of the radiological needs of a hospital or clinic. It is capable of producing images of very high quality, rivaling those of significantly more expensive systems. Due to the setting in which the WHIS-RAD will be used, there are numerous features intended to simplify installation and use of the system. If the technologist operating the system is insufficiently trained, poor quality results and safety issues may arise. In order to mitigate these problems, the WHIS-RAD features variables fixed at optimum settings, making it very safe and limiting operator error. It is powered by batteries, allowing the system to be used for up to three weeks without recharging. Lastly, the system is very reliable and requires little maintenance in order to reduce costs and provide optimal service. The many features of the WHIS-RAD system allow it to provide excellent radiological services for a low cost.

1.2.3 Limitations

A major limitation of the current screen-film (SF) WHIS-RAD system is the high cost of taking and processing an image. The film and chemicals required for a single exposure cost about $3.50. Multiple images or retakes are often needed, further increasing costs. In developing countries, where there is no medical insurance and incomes may be less than a $1 per day, this cost is an enormous burden for patients to bear. Attempting to reduce the financial burden of X-ray by sending donations to pay for film and developing chemicals is not a viable option in many areas. While equipment can potentially be donated, any money sent may not reach its destination due to disorganization, taxes, or corruption. Furthermore, film is difficult to obtain in most developing countries, which can result in shortages. To extend the usefulness of the WHIS-RAD system and improve access to X-ray, film and developing chemicals must be eliminated.

Another major limitation inherent to using a WHIS-RAD unit in a developing nation is that there is a shortage of medical professionals in the developing world, specifically of radiologists and specialists. For example, in Sub-Saharan Africa, there are fewer than 10 doctors for every 100,000 people and many countries do not have even one radiologist. If there are radiologists in a country, they are usually located in urban areas. As a result, remote areas of developing countries are left without adequate ability to interpret X-ray images even if a WHIS-RAD unit is available.

1.3 Mission Statement

Our mission has been to design a digital X-ray capability as either a retrofit or a modification to existing WHIS-RAD systems that meet the requirements of clinics and primary care hospitals in the developing world. To this end, our primary objectives are to eliminate film to lower recurring costs, develop a suitable viewing system to view images once they have been taken, design a storage, archival, and retrieval system in order to efficiently manage the digital images taken and pave the road to allow future teleradiology. This would allow for diagnoses in areas where a radiologist is not on staff (or in the country) and would improve the quality of diagnoses overall. Lastly, we aim to identify methods for implementing digital technology in our target markets, specifically in terms of assembly, \funding, purchasing, operator training, and on-site technical support.

1.4 Market Analysis

The market for a digital retrofit is developing nations who already have a WHIS-RAD system or any that need such a system. All developing countries can be taken as target markets, but in the case of specific interactions with hospitals in such a country, Zimbabwe will be a key case study due to our interaction with the South Bulawayo Rotary Club and its local private Mater Dei Hospital. Although Mater Dei is not representative of most low-income hospitals in Africa, it being relatively well-run and staffed, it would be a model pilot site since there is a functioning Rotary Club. A reliable

CR system with reasonably high resolution at the targeted price points would find a ready market in small hospital, clinics and doctors' offices in the developed countries.

Companies such as GE, IMS, and Philips have basic radiological systems in their line of products and are actively pursuing the WHIS-RAD market, although not directly in developing countries in the manner in which Rotary International is involved. These manufacturers may or may not possess the digital retrofit system, which we ultimately decide should be installed on their WHIS-RAD systems so the possibility of purchasing WHIS-RAD from one of these three and also purchasing a digital retrofit from another manufacturer must be considered when installing new, complete units.

It is estimated that about 1500 WHIS-RAD units have been installed with less than half in operation today. Potentially, there is a need for as many as 700 WHIS-RAD digital retrofits in addition to new units installed with the integral digital capability plus existing X-ray units other than WHIS-RAD. No data exists on this market but units which will be worth upgrading can be assumed to be at least as large and probably several times as large as the existing WHIS-RAD installed base. The demand for the technology will be driven by the benefits of lower operating and patient costs, simplified operations and expanded capabilities that will improve health care for the patient.

2.0 Technologies

2.1 Direct Digital radiography

As discussed previously (see Appendix A), direct digital radiology (DR) is a viable technology for digital X-ray applications. Unfortunately, the target population in dire need of this technology cannot afford DR at this time. While it is expected that DR prices—like other digital technologies have—will fall, waiting is not an immediate solution to eliminate film. The price is kept high largely from the fabrication process. Most of the high quality DR technologies require crystals to be grown on a glass substrate, which has an inherently low yield. Moreover, the glass substrate also creates a disadvantage in making the device considerably fragile. This has counter-indications with our potentially rough operating environment. When attempting to retrofit, a digital flat-panel detector would also have difficulties, since the detector cannot necessarily be inserted into a cassette and slid into a cassette holder.

2.2 Computed radiography

Having seen over 20 years of clinical use, computed radiography (CR) is the current technology of choice for a WHIS-RAD retrofit. It has the immediate potential of being an affordable retrofit to the current WHIS-RAD system. The detector system requires image plates (usually BaFBr activated by Eu)--which are readily inserted into a cassette--and the image plate scanner. The scanner's output would be acquired by a capable PC and archived by an appropriate RIS/PACS package, discussed later in the report. As seen in Figure 1, CR plates are available in the standard six X-ray film sizes.

Figure 1 - CR Image Plates available in standard X-ray film sizes

2.3 Dose management

Digital modalities often allow reduction in X-ray dose, consistent with the radiological ALARA (As Low as Reasonably Achievable) principle when discussing ionizing radiation exposure. The higher Detected Quantum Efficiency (DQE) of digital over film is remarkable in that fewer X-rays are needed for an acceptable level of resolution.[2] This effect cannot be guaranteed with all types of CR, with older configurations sometimes having an inferior DQE. DR and double-sided CR consistently have superior DQE to screen/film. While overexposing a film leads to immediate rejection of an image and necessitates a retake, it is very difficult to overexpose a CR plate, because of the large dynamic range (see Figure 2[3]). The combination of decreased dose and difficulty in overexposure may lead to conflicts regarding the ALARA principle and thus patient-technician safety. Inherently, CR separates the acquisition from the display phase, leaving room for systematic overexposure.[7]

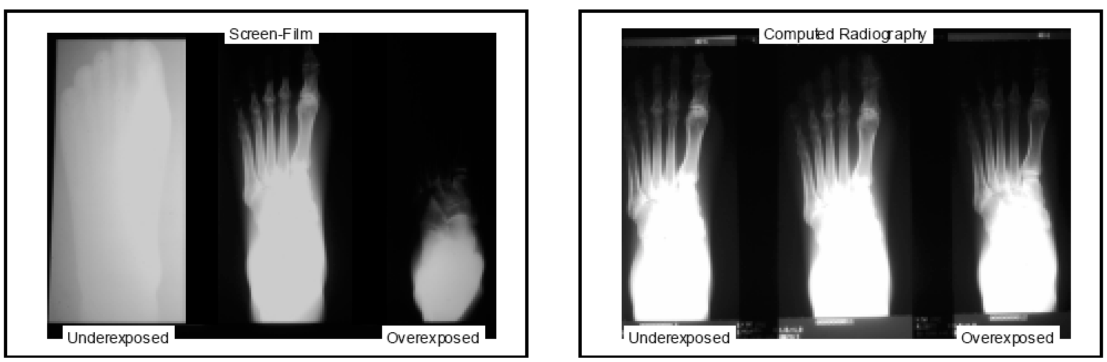

Figure 2 - Exposure levels: Film vs. CR

Standards for conventional film X-ray will typically require densities of a radiograph to be maintained between 1.8 to 4.0 H&D (Hurder and Drifield) for acceptable viewing.[4] Unfortunately, there are no standardized, systematic units for exposure on CR units, and digital X-rays do not have the density feedback mechanism, historically used by film X-

[2] Dainty JC, S. R. (1974). Image Science. London, Academic Press.

[3] Seibert, J. A. (1999). Physics of Computed Tomography. American Assn. of Physics in Medicine - Annual Meeting, Nashville, TN, UC Davis.

[4] Higashida, Y., Y. Murakami, et al. (1996). "Basic imaging properties of a new screen-film system for chest radiography." Med Phys **23**(8): 1351-7.

ray technicians. There is a great deal of variation in measuring CR exposure levels due to variations in calibration and equipment across manufacturers. Thus unless exposure measurements can be standardized by exploiting some of the fixed parameters of the WHIS-RAD setup, quantitative exposure measurements should not be used exclusively for dose management. A qualitative image quality selected by a radiologist for particular patient sizes should be included in the IFU (Instructions for Use) as X-ray generator settings.

2.3.1 Exposure Factor Creep

Because underexposed images appear grainy with considerable quantum mottle[5] and consequently are undesirable to radiologists, while over-exposed images appear crisp, CR operators tend to err toward over-exposure, lest the study be repeated due to poor images. Thus we have the well-documented "exposure factor creep" phenomenon for CR. As shown in Figure 3[3], CR mostly attributes its retakes to positioning problems rather than exposure level.

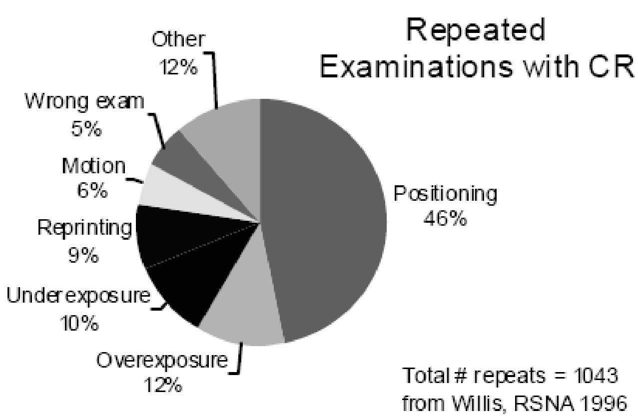

Figure 3 - Repeat examinations with CR

2.4 Limitations of CR

2.4.1 Physical abuse and product lifetime

Although CR plates are more rugged than DR detectors, they are not indestructible. Depending on the harshness of the environment and handling of the operator, the image plates are subject to

[5] Hillen, W., U. Schiebel, et al. (1987). "Imaging performance of a digital storage phosphor system." Ibid. **14**(5): 744-51.

scratches and have a finite lifetime from 5000 – 10000 exposures, at which point the resolution and image quality have been degraded to be substandard for accurate diagnoses. There is a model promising greater than 200,000 exposures. Nevertheless, there must be a backup supply of image plates.

2.4.2 Fixed parameters

The simplicity of the WHIS-RAD system lies in its set of fixed parameters. Due to X-rays' dependence on geometry, non-average-sized patients may have less than optimal results.

Corpulent patients

Overweight, large, obese, or otherwise more corpulent patients would cause excessive attenuation to the already reduced X-ray signal for CR. Dosage would need to be increased to allow acceptable resolution. Obesity is still quite prevalent in South Africa, and this variable would need to be incorporated into the revised product manual (IFU). It may be difficult to be vigilant of patient overexposure though, since higher exposure levels in CR tend to lead to more desirable images to radiologists. The heel effect[6] must also be considered so that the thickest parts of patients are placed in the proper orientation of highest beam intensity. This must be incorporated into the IFU appropriately.

Infants

Pediatric radiology proves to be another challenge for digital imaging. Because infants present small body sizes, it becomes more difficult to resolve subtle defects such as

[6] Geiger, J. (1960). "The heel effect." Xray Tech **32**: 55-6.

fractures. Film radiology has been successfully imaging infants, but a standard CR unit is not successful at imaging infants adequately. Increasing the dose on CR would not be consistent with the ALARA concept. After all, “Research indicates an increased risk of childhood acute lymphocytic leukemia from plain film studies and an increased risk of fatal breast cancer from scoliosis series.” Children are also an order of magnitude more sensitive to radiation than middle-aged adults.[7] Thus increasing the dose must not be done haphazardly. However, repeat exposures due to rejected images have potential for danger for small patients, so a necessary and sufficient exposure must be ensured the first time. It has been shown that CR exposure must be increased at least by a factor of 2 to achieve similar noise (mottle) levels as with film-screen methods.[8] This exposure-level parameter should be fixed in the WHIS-RAD based on infant size and weight in permanent chart form and/or on the included electronic guide discussed elsewhere in this report.

4.0 Processing & Transmission

4.1 Viewing

With conventional X-ray, viewing the image consists of putting the processed film up to a light box and reading the image directly. In digital X-ray the film has been eliminated and so alternative options for looking at the image are available. We recommend displaying the images directly onto a computer monitor. Specifically recommended to us

[7] Willis, C. E. and T. L. Slovis (2005). "The ALARA Concept in Pediatric CR and DR: Dose Reduction in Pediatric Radiographic Exams--a White Paper Conference Executive Summary." Radiology **234**(2): 343-344.

[8] Huda, W., R. M. Slone, et al. (1996). "Mottle on computed radiographs of the chest in pediatric patients." Ibid. **199**(1): 249-252.

by Fred Behlen PhD and an article in the Journal of Imaging Technology Management[9], is the Dell 2405. This model can be found, in its widescreen version, on Dell's website for under $1000. It is a 24-inch, medium-range LCD with a brightness of up to 120 foot-lamberts. The brightness and color will require calibration. This can be done using a simple USB light meter.

4.1.5 Teleradiology

Digital radiology and the need to send images over distances necessitates teleradiology. The fact that 14 countries in Africa do not have a single radiologist also illustrates the need. In today's globalized society, outsourcing and offshoring are a reality for success. Teleradiology for our purposes is possible with a simple internet connection. For very rural areas without this access, we have obtained support from a satellite company. Chaparral Communications from San Jose, CA has offered to donate the necessary receiver/transmitter for a pilot test site. Chaparral is highly experienced in satellite technology especially in developing areas. They supply educational TV programming to 30,000 satellite dishes in rural Mexico and also have customers in Africa.

4.2 Storage

As in viewing, conventional X-ray is straightforward in storage. The processed film is stored with the patient's records or at an offsite location. Digital X-ray, on the other hand, can be stored in its digital format. We recommend the use of a local PC with a large hard disk. Putting images on a local machine allows for sizeable amounts of storage space in a

[9] Hirschorn, David, MD; Dreyer, Keith, DO, PhD, "Do I Still Need a Grayscale Monitor?," The Journal of Imaging Technology Management (Feb 2006)

small area. It also enables users to immediately retrieve the images instead of searching for a physical disk, as you would with CD storage. The local disk is also simpler and more cost effective than a web server. With the entire setup on-site, maintenance and upgrades can be done gradually with the cooperation of personnel at the specific location.

To reduce file size on the local machine, we suggest that the images be compressed using 10:1 JPEG2000 wavelet compression. It has been shown that this level of compression does not interfere with diagnosis.[10] This compression would need to be tested in the field though to verify and depend on application. For example, TB-screening facilities require lossless compression due to the subtleties in chest X-rays.

We also recommend the use of DVD-R disks to archive and backup the original images. DVD-R is an affordable archive option for long-term storage. In order to archive all of the images taken at a site it would only take three DVD-Rs each year[11]. DVDs would only be acceptable to the small clinic doing volumes of 30-50 patients per day needing to archive for up to ten years. The Bureau of Mines in South Africa requires 40 years of archival past a patient's retirement for legal purposes. For this application, tape drives are recommended to protect against obsolescence, but this will not be a concern for WHIS-RAD's primary target market.

[10] Bak, Peter, PhD, "Will the Use of Irreversible Compression become a Standard of Practice?," SCARNews 18:1 (Winter 2006)
[11] See Appendix

When considering digital storage of images, one must also have a program to store, organize, and retrieve the images when necessary. One group of programs that does this is a Picture Archival Communication System (PACS)[12]. We are recommending the use of the open-source DICOM server ConQuest and the free version of the K-PACS viewer. These programs are easy to set-up and simple to use. Also, these programs are free for noncommercial use and both support JPEG format.

4.3 Analysis

Currently, under the WHIS-RAD protocol, the majority of images are read by a technologist or local physician. This works for many of the obvious acute diagnoses, but for more specific cases a trained radiologist or specialist's opinion is needed. This is currently not available in many WHIS-RAD locations. Teleradiology offers the ability to transfer medical images over the internet to trained radiologists who make reports on them and send them back to the local physician.

Teleradiology could be a positive addition to the WHIS-RAD system, but it will cost significant money. The retail price for a teleradiology read in Australia for US customers is approximately $50 per read. Teleradiology requires not only internet access, but also a dedicated amount of bandwidth. This means that a specific amount of a hospitals' internet will have to be kept open for the transfer of images. It has been shown that

[12] Johnson, D. (2004). "Digital Imaging Goes Regional." Wodonga Regional Health Service, from http://www.wrhs.org.au/news/20044263146.htm.

teleradiology can be done at speeds as low as 128kbs[13]. Therefore, it should be possible to do teleradiology over virtually any modern internet connection.

The largest cost of teleradiology will be the service itself. In order for the WHIS-RAD sites to use the service it must either be free or greatly reduced in cost. The service could be shared between sites or over a large network or sent by individual or small clusters of sites. The advantage of having a smaller scale teleradiology system is that it would be cheaper to implement and simpler in scope. This could lead to the possibility of having existing teleradiology companies provide the service free of charge or for a small fee that could be covered by donations.

The large scale option would allow for a more centralized and coordinated system. Multiple WHIS-RAD sites could send images to the same location. This could decrease the cost per image. This might also allow for a large network of volunteers, including technical support and radiologists. This type of system would also be highly scalable, allowing new WHIS-RAD sites to join as needed. A large organized system would moreover, give a single face to the issue. This one entity could handle logistics and be able to accept donations on a larger scale. The main problem with such a large system is its size. Such a system would have a large startup cost and would have several issues that would need to be dealt with, such as international law, physical location, and who would organize it. In our conversations with a lobbying agency in Washington, DC, Boeing has

[13] Kalyanpur, A., J. Weinberg, et al. (2003). "Emergency radiology coverage: technical and clinical feasibility of an international teleradiology model." Emerg Radiol **10**(3): 115-8.

expressed interest in making some of its bandwidth available specifically for telemedicine and teleradiology.

Chaparral Communications (San Jose, CA) has offered to supply free pilot equipment to test the teleradiology aspects of our design. The CEO of Chaparral recommends the Broadband Global Area Network (BGAN) supplied by Inmarsat. This terminal allows broadband connection via satellite, anywhere on the planet and plugs directly into a PC. Once we select a unit, we will test it in the US before piloting it abroad.

5.0 Ethics

Rotary International and the World Health Organization have undertaken the task of pursuing a digital retrofit for the existing WHIS-RAD system in order to develop a solution to help alleviate an ethical problem: the lack of access to X-ray services in the developing world. Because there is little apparent financial gain or reason to pursue this project other than to help improve the quality of life for people in developing countries, the primary principle in this work is beneficence. However, neither our team nor Rotary and WHO wish to do harm in the process of implementing digital X-ray technology. Our aims are nonmaleficent and are not intended to expose anyone to additional danger inadvertently—however dosage must be properly researched and managed in the final design. Lastly, we are aware that we must pursue justice and deliver greater benefits than negatives by employing digital technology. The major objective is to improve the quality of healthcare and we must not let other interests interfere with this aim.

The ethical problem before our intervention was that people in developing countries were not enjoying the benefits of access to X-ray services, even if they were able to access a WHIS-RAD system. The cost of obtaining and developing film lessened the benefits that the WHIS-RAD system can offer, or even prohibited use of the system altogether in the poorest regions of the world. By eliminating film, our design reduces costs inherent to the use of the WHIS-RAD. This allows funds previously allocated for purchasing and developing film to be used in other ways, which improves the general quality of healthcare that can be provided. Migrating to a digital medium also allows for simple digital archival of images, improving patient care by allowing access to patient records for interpretation and comparison.

Although our work is intended to be beneficent and nonmaleficent, other ethical issues may exist that we have not taken into consideration. For example, if manufacturers decide to donate used CR systems or plates in order to receive tax deductions, an ethical issue may exist concerning whether the donated goods are as useful as the manufacturer claims; in other words, the ethical problem is to determine if a manufacturer is donating useful goods just for a tax refund. Further investigation is necessary to determine other risks, some of which can be assessed in a visit to hospitals in a developing nation.

6.0 Field research

One of our first goals was finding a potential pilot site for the digital WHIS-RAD.

Western Cape Community Health Centers

Our research in South Africa began with the observation of 12 Community Health Centers (CHC) in the Western Cape of South Africa. Administered by the Provincial

Authority (PAWC), these health clinics have functioning X-ray suites at varying levels of efficiency, quality and expertise. It was found that most of the clinics have 30 X-ray patients on average. Two radiographers usually staff the suite and the X-ray is film based. Most clinics have a daylight film processor. The primary doctor reads the images for the most part, but he may indicate an over read by the radiologist. In this case, the images are couriered to the central CHC where they are read by radiologists at Groote Schuur Hospital. Reports are picked up daily, returned to Woodstock and then distributed to the proper CHC—all by courier.

Field Research Meeting Reports:

Groote Schuur Hospital Radiology

One of our first formalized meetings was with Dr. Stephen Benningfield, the Head of Radiology at Groote Schuur Hospital. He explained to us the basic workings of the radiology department at GSH and insight into how computed radiography (CR) might fit in at certain hospitals. We learned that Red Cross Children's Hospital employed CR which accounted for, according to his estimate, 30,000-40,000 procedures per year, or about 60% of all x-rays taken. These came in the form of mainly chest and extremity x-rays. According to his estimate, trauma imaging accounts for about 20% of all x-rays taken at GSH with chest x-rays being the most common. He also estimated the cost of a single x-ray film to be about R10 (~$1.34 USD) and identified another type of film that worked with a dry laser printer. This type of developing requires no fixer or developer however costs more per film (about R20, or $2.68 USD per film). He also identified the main hurdles of going digital as the computer system that must be set up to support it along with the integration of old and new files (i.e. those that already exist on film and those that will be digital). Currently, x-ray films taken at GSH are stored on site for an extended period of time before they are transferred to a warehouse dedicated to exclusively storing films. Dr. Benningfield identified regional and secondary hospitals as prime candidates for digital x-ray technology and predicted that the GSH radiology department would be completely digital in 2-10 years time.

Clinical Engineering Input

We met with Rob Dickinson, a clinical engineer, following a lecture he gave at UCT concerning healthcare technology assessment. Although he didn’t have much specific experience with digital x-ray systems, he provided us with some useful information and more contacts. He suggested that when trying to “sell” groups on our system, to cater to the specific needs of that group which follows closely to the user centered design concepts we’ve seen previously. For buyers, it would be best to show the cost savings that CR would provide. For doctors and radiographers on the other hand, different strong points should be highlighted. Advantages such as lower dosage of ionizing radiation, faster image processing, decreased storage space and the potential for teleradiography would be more suited to actual users like radiographers as opposed to those actually spending the money. From his experience, he confirmed that hospitals were ready for digital x-ray and desired the new technology. One challenge that he identified which was based more on intuition that actual research was the mistrust of electronics and technology that seems too advanced by those providing healthcare in resource poor environments such as Zimbabwe where he is from. We were, however, unable to validate this statement during our subsequent field research. He gave us the contact information for Ivan Castillo, a fellow clinical engineer who has extensive x-ray experience as well as Leon Du Toit, an administrator at the Radiation Health Directorate.

Field Research: Michael Mapongwuana Hospital

The field research we were able to perform at community healthcare clinics (CHCs) such as Michael Mapongwuana CHC in conjunction with another project allowed us to investigate the x-ray particulars in a setting in which our system would likely be the most beneficial. In a later meeting with Carol Mehl, Head of the X-Ray Department for CHCs at the Provincial Administration of the Western Cape, she would suggest that a pilot site be set up at Michael Mapongwuana CHC to test the CR technology and possibly teleradiography. Michael Mapongwuana CHC uses one Toshiba x-ray unit and employs two radiographers, Claudia and Enook. Their patient throughput averages 417 patients per month working out to about 21 patients per day. Films are developed on an automatic processor and interpreted by doctors or radiographers on site. Many patients, however, are referred to either Tygerberg or Karl Bremmer Hospitals in the case that the case is to complex. The radiographers explained that they handle basic procedures but “nothing specialized.” Chest x-rays make up the majority of procedures along with extremities. If sputum samples return negative for a suspected patient, for example, they will perform a chest x-ray for verification. Their rejection ratio is about 6% of x-rays taken per month due to mostly to overexposure and incorrect positioning. A major problem at Michael Mapongwuana CHC was the lack of storage space for x-ray films. Although all hospitals are required to keep x-ray films for at least five years, they only have room to keep films for three. Overall, the x-ray department was one of the few well run areas of the CHC.

Field Research: Vanguard Hospital

Being an average sized hospital, the Vanguard x-ray department sees about 450-500 patients per month. Although many patients are seen at Vanguard, about half are sent away to a radiologist, and many films alone are sent away to be read at Woodstock Hospital. Staffed by two radiographers, one was extremely interested in CR and actually worked with the technology during her residency at the Red Cross Children's Hospital whereas the other was hesitant about digital technology due to the increased complexity mainly in the computer component. Both radiographers, however, were interested in the benefits of CR technology including the speed, potential for teleradiology and especially the savings of storage space. Like the x-ray department at Michael Mapongwuana CHC, Vanguard was lacking in space to store films and was unable to keep the full five years worth of film records. Teleradiography was also an intriguing and promising advantage in light of the current system in which x-ray films needing a radiologist's reading are couriered to Woodstock Hospital and back. The time for the reading, including transportation time is at least week and a half.

Field Research: Delft Hospital

As a larger hospital, Delft's x-ray department sees nearly 1000 patients per month (about 50 patients per day totaling about 70 examinations). Even at this high patient throughput, half of all x-rays are sent out to be read by a specialist at either Tygerberg or Karl

Bremmer Hospitals. When questioned about digital x-ray systems, specifically ones capable of teleradiology, staff were very enthusiastic, most specifically because of the ease of sending images via email instead of through a courier. Their developer is serviced quarterly and their generator calibrated yearly. Compared to other clinics, their rejection ratio of 3% per month is quite low.

Western Cape Radiology Administrator

Our meeting with Carol Mehl was extremely productive with the best outcome being the real possibility of a pilot site for our digital x-ray system implemented at Michael Mapongwuana CHC in the foreseeable future. Carol oversees the 17 of 47 total CHCs in the Western Cape with x-ray machines as well as the remote readings that take place across the province. This includes the 200 x-ray referral readings that are performed every day at Woodstock hospital. Clinics are asked just to send emergency cases, however, films cannot be turned away which forces the outsourcing of readings to either Groote Schuur Hospital or to private practices. This comes at a cost of approximately R270,000 ($42,000 USD) per year which includes the courier service that transports the actual films between Woodstock and the CHCs. The major problem that Carol saw with the current healthcare system, which is common given her position as a higher level administrator, is the lack of qualified staff which was also quite evident from our previous field research done at CHCs of the Western Cape. The salary and the working conditions are just not good enough to retain professionals and keeping them from finding work abroad, mainly in the United Kingdom or Saudi Arabia. For radiographers, however, the situation is more positive. According to Carol, most clinics and hospitals are well staffed, an observation which was confirmed by our research. In addition to the real possibility of a pilot site in the near future, Carol also provided us we many contacts, most of whom are on the manufacturing and/or sales side of x-ray technology.

Field Research: Mater Dei Hospital (Bulawayo, Zimbabwe)

The visit to Mater Dei was our main reason for traveling to Zimbabwe. Along with an advanced x-ray machine with fluoroscopy capibility installed in 2001, Mater Dei employs a WHIS-RAD unit donated in part from the Park Ridge Rotary Club in 2003 and is a prime candidate for computed radiography. Mater Dei is a private hospital of 145 beds (normally there are 175, but due to a fire in August, an entire floor was decommissioned) and usually runs at 63-78% occupancy. Their x-ray department sees about 300-600 patients per month, of which anywhere from 10 to 40 patients per day are imaged using the WHIS-RAD machine. The department is currently staffed by two radiographers working 12 hour shifts and will soon add a third to alleviate work loads along with an assistant to aid in the darkroom. The entire hospital, including the x-ray suites, are powered from the standard main and are also backed up with a universal power source that intervenes with no delay which is necessary given that “power goes out frequently.”

Because of the current economic situation in Zimbabwe, Mater Dei’s first priority is just to recoup expenses and collect payment. At current prices (24 May 2006) the admission fee to the hospital alone is Z$5 million ($50 USD at official bank exchange rate or $25 USD at the readily available black market exchange rate). Compared to the minimum wage of approximately Z$2.6 million per month, this fee is nearly impossible to pay. Also considering that any procedures cost extra (even the hospital meals are COD), quality medical care is nearly unattainable for the average Zimbabwe resident. The cost of film and chemical, not surprisingly, is equally as high and described as "horrible" by Sr. Maureen Jamieson, the head sister and administrator. In addition to being extremely expensive, film and chemical can be particularly difficult to obtain requiring the hospital to either shut down the radiology department or buy film from "runners" who buy supplies in South Africa (most likely Johannesburg) and bring them to Zimbabwe. Because of the low volume of film tendered and the added risks of extensive travel, these films come at an inflated price. Along with film, service, if available at all, is quite expensive. Although the WHIS-RAD system is exceptionally reliable (the machine has not needed service since installation in 2003) other equipment such as the automatic developer must be serviced either by Techmed who does not manufacture the equipment or Phillips who has stopped responding to requests for service. In addition, because no parts are manufactured in Zimbabwe, foreign currency is needed to purchase parts and service. The government, however, has shut down all foreign exchange accounts held by Zimbabwean businesses and citizens thus making acquiring spare parts nearly impossible.

Overall, the staff is extremely pleased with the WHIS-RAD system. It is quick, simple to use, more convenient for chest x-rays (about 80% of all x-rays taken with the WHIS-RAD unit) and closer to their trauma unit enabling less patient transfer for imaging. The quality is also superb. According to Dr. Mlotshwa, a general practitioner at Mater Dei, the WHIS-RAD produces images of "excellent quality" and he has "never had to send one [an x-ray image] back." Although mostly used for trauma, both radiographers and Dr. Mlotshwa asserted that the WHIS-RAD can do everything and is also good for case studies and quality control. Unfortunately, however, no matter how clear an image, if a complex reading is to be made, the film must be sent to Dr. Gandanhamo, the only radiologist in Bulawayo costing extra. This occurs in about 20% of all x-ray cases and turn around is about one week.

Although everyone we interviewed was quite happy with the WHIS-RAD system, there was one issue raised that could be improved upon. Because standard hospital beds are much taller than the standard WHIS-RAD examining table, patients requiring an x-ray that are currently in a standard bed must be transferred from bed to table. As most patients being imaged using this machine are trauma patients, this can cause unneeded aggravation and potential harm. The radiologist suggested that the system be ceiling so that patients could remain in the standard hospital bed, however, this would necessitate significant infrastructure modification and would negate the simplicity in operation that fixed parameters provide.

Field Research: Chegutu District Hospital (Chegutu, Zimbabwe)

Chegutu District Hopspital, located about 100 km outside the capital city of Harare was the first healthcare center we saw on our tour of Zimbabwe. In their radiology department, we were a bit surprised to see a fully functional Phillips-made WHIS-RAD unit along with a Phillips automatic developer. Staffing the unit was one radiographer and her assistant. Upon speaking to them, we learned that their x-ray machine was in perfect working order and had been since its installation in 1996 outside of one year when it needed a replacement tube that could not be found in Zimbabwe. This dependability is due in large part to the quick and reliable service from Phillips based in Harare. According to the radiographer, they are able to obtain service in only 2-3 hours and the maintenance personnel "always have spare parts." Unfortunately, there is no radiologist on site and films are therefore read by doctors and radiographers. If a more specialized reading is required, the patient must travel with their x-ray to Harare. At minimum, this adds cost, time and risk of injury to patient if transportation is available at all. The roads surrounding the hospital are poorly maintained, full of pot holes and ambulance transportation is rare. While visiting, for example, a 23 year old male patient was x-rayed for a bottle cap that was stuck in is throat. The specific reading could not be made at Chegutu and he was required to travel to Harare. Although not an extremely severe injury, a patient with something more life threatening would be at much greater risk to further injury upon transport.

Field Research: Mpilo Hospital (Bulawayo, Zimbabwe)

Mpilo is the second largest state hospital in Zimbabwe seeing between 150 and 200 patients per day in their x-ray department alone. Even in such a large hospital, however, there are problems obtaining film. In most circumstances, film is purchased by the government on monthly tenders. Due to the extremely high inflation rate (over 1000% per year) contracts negotiated for longer periods of time are not realistic as prices change almost daily. Because of this, many months the hospital runs out of film and has to shut down the x-ray department. It is possible to purchase x-ray films from "traveling salesmen", however this method is never a guarantee and is often accompanied by large markups due to the importation and transportation costs associated with obtaining the films in South Africa. Also, there is only one radiologist in the entire Bulawayo area and thus any x-rays that cannot be read by doctors or radiographers on site must be sent to him via courier requiring time for transportation there, reading, reporting and transportation back to Mpilo.

Field Research: National Rehabilitation Center of Zimbabwe (Ruwa)

The National Rehabilitation Center of Zimbabwe was a large facility drawing patients from all over Zimbabwe and even surrounding countries. Surprisingly, however, the center had no working x-ray units. The only x-ray unit on site was a Phillips MRS WHIS-RAD unit that has been dysfunctional for over three years. Installed in 1994, it had been working well until their radiographer left the facility and the machine went unused for an unknown period of time. Later, when the faculty went to turn on the machine, the batteries had died rendering the machine unusable with batteries unable to be recharged. A possible cause for this is the lack of a "Battery Low" light on the unit. There exists a light to show that the unit is fully charged, but nothing to notify staff that the battery was in danger of dying or a reminder of some kind to charge it. Documentation was plentiful though the extent to which they it was read and guidelines followed was unclear.

6.1 Questions for current radiology staff

We needed to find out more about the environment of these current or future WHIS-RAD sites. Some questions for current radiological staff were:

- How is film currently being processed? What processors/chemicals are used?

- Are they presently happy with their processing method?
- Who receives training? How are they trained? What is their background?
- What are the typical parameter settings? Focal spot?
- What is the largest cassette needed? Most frequent body parts imaged?
- What type of magnification (if any) is required?
- Would they be able to keep up with calibration requirements of the scanner (~ every 9 months)?
- How important is safety to the operators and patients?

6.3 Selected Technologies

We selected CR as our imaging modality in the first phase of the project. After two months of research in the field and further technology browsing, we have zeroed in on a particular CR technology and manufacturer. iCR (www.icrcompany.com) is a Torrance, CA-based CR company specializing in their patented true "flat path" scanning technology. Instead of the usual rollers that most large CR scanners use to move the CR image plate past the scan head, the iCR1000 involves no touching of the image plate.

Why a flat scan path?

- Prevents any stressing of the plates (rack and pinion instead of rollers)
- Significantly reduces Total cost of ownership (TCO)
- Image plates guaranteed for 250,000 scans

The image plates themselves are also innovative. They have a patented design with only one moving part, weigh 30% less than conventional cassettes and are shock proof.[14] In our more rough environment in the developing world, having durable equipment is

[14] iCR1000 product literature, 2006

critical. Image plates that do not often need to be replaced cut down on TCO. With a flat scan path on the scanner, maintenance costs can be reduced due to the simplicity of the unit.

Orex CR – TECH

The Orex CR-Tech is a product in the same price range as the iCR. We are convinced that iCR would be a better company to work with in the same endeavor. In addition to product superiority, Orex was just bought by Kodak and now Kodak may be sold. From a corporate stability standpoint, iCR is also superior.

Product spec comparison

Spec	**iCR2600**	**Orex RT**
Scan Rate	**55 cassettes/hr**	
Different Cassettes	**6**	**5**
Software included	**Yes**	**No**
Resolution	**15 line pairs/mm**	**6 pixel/mm & 3.5/mm**
Grayscale capture mode	**16 bits**	**12 bits**
Weight	**75 lbs**	**88 lbs**

Source: iCR Competitive Comparison Sheet

7.0 Implementation

While the technology to retrofit the WHIS-RAD system is available, the major challenge is implementation, the specifics of which will be different at each implementation site. The CR reader (detector system) is by far the most costly component and requires the most consideration.

7.1 Initiation

The implementation of digital X-ray in developing countries will need to be initiated by a donor organization. Rotary clubs that have sponsored WHIS-RAD systems are likely to be interested in updating the units they have helped to install. Specifically, John Vanden Brink of the Park Ridge Rotary Club has expressed current interest.

The current way Rotary clubs sponsor WHIS-RAD systems is a partnership with a beneficiary Rotary club in the destination area. The same beneficiary clubs would help to install digital retrofits as they installed the WHIS-RAD systems.

In addition to Rotary clubs, the WHO is interested in implementing WHIS-RAD systems. Some for of collaboration between all groups implementing digital retrofits would be beneficial. A larger program of teleradiology could be established through collaboration.

7.2 Funding

Currently, Rotary clubs raise money to donate WHIS-RAD systems. They are assisted by the Rotary Foundation Matching Grants program. This is likely arrangement for the funding of digital retrofits.

Depending on the nature of the retrofitting project, it may be eligible for other grants from the Rotary Foundation or certain institutes or centers of the NIH. Our recent call with the NIH showed several opportunities for funding and underscored the current need for the project. Drs. Fontelo, Francis and Haller described a number of funding opportunities from NIH. There was a Request for Applications (RFA) in 2003 about the very topic of this report. Unfortunately, that RFA has expired, but the text is available online NIH. They also expressed interest in the project and recognized its importance. Dr. Francis from the Fogarty Institute reflected on his experiences in Africa where patients in the field presented with tumors needing X-ray as well as many trauma cases involving auto accidents from the many people traveling on the expressway by foot. There has been a program announcement about research into trauma identified in the NIH by PAR04083. Specific funding to apply for included:

- R21 Exploratory Bioengineering grant
- R01 ($300,000) NIH Grant
- EB03006 Training Grant

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) would be interested in funding the project if it involved improving imaging technology. So, if the project's aim is to reduce the cost of imaging for low-income countries using technology, applying a grant would be worthwhile. The Fogarty International Center (FIC) is interested in improving global health. If the digital X-ray was proven to improve heath in developing countries, the FIC might support the project. The National Library of Medicine (NLM) would be most interested in the telemedicine applications of digital X-ray. If the project incorporated implementing low-cost telemedicine in developing countries, the NLM might support it. Our contact at the NLM is Dr. Paul Fontelo. Also, the project may be eligible for Health, Hunger, and Humanity (3-H) Grants through the Rotary Foundation if it is a more integrative approach to healthcare rather than just purchasing equipment, as is currently the case for WHIS-RAD. The requirements of 3-H

Grants could be met, especially since a requirement of 3-H grants is that the host and sponsor Rotary clubs worked together in the last five years.

A 3-H Grant or an NIH Grant through the NIBIB, FIC, or NLM could be possible. The project may or may not meet the requirements depending on the mission, leaders, size, and other specifics. Possible NIH Grants include the Small Grant Program (R03), Small Business Innovation Research (SBIR) Grants, Small Business Technology Transfer (SBTT) Grants, Training Grants, and Mentored Scientist Awards.

Rather than buying the equipment first, then pursuing teleradiology separately, incorporating teleradiology into the project from the beginning of the project could enhance the project's eligibility for grants. Not only would this greatly enhance the value of the equipment donated, but it also could help cover some of the costs of the equipment, since it is the most substantial investment required to allow teleradiology. Collaboration with anyone else pursing low-cost teleradiology including the WHO should be considered to expand the scope of the project and maximize its value.

7.3 Pricing

Because the purchaser will be a donor organization assisting a low-income population, the cost of a digital retrofit solution is a crucial factor to its success. The computer and monitor needed to function as a viewing station and mini-PACS will be a few thousand dollars at most – a fraction of the cost of a CR reader.

Figure 4 - Example of Portable CR Reader (iCR1000 by iCR)

Figure 5 - Example of Table Top CR Reader (ACR-2000 by Kodak)

Since specification require that all the components of a digital retrofit system cost less than $15,000-$25,000, the CR reader ideally would have a maximum price of $23,000 to even be considered. However, it seems that the most retail CR readers are currently not priced within this range. There are two design related reasons for this. First, many CR readers accommodate multiple image plates (IPs). Second, the CR readers often come with a PACS system intended to accommodate larger organizations. These productivity features are useful for busy hospitals and clinics, but, they increase the cost of production. Furthermore, the importance of these features in cutting costs by saving labor increase their purchase price since improvements in productivity dramatically increase the product's value in developed countries. In developing countries, productivity gains are unnecessary due to the low price of labor, so only the most basic CR readers without bundled PACS systems should be considered.

The type of CR scanner selected is the iCR1000, which is a flat scan path table top scanner. Based on conversation with the company, these units cost $47,000 which is well-above the maximum specified price. Nevertheless, it is still feasible to obtain a new CR reader for a number of reasons. First, we have a growing relationship with Xeikona, the future African representative for iCR company. Xeikona represents mostly the Swissray dDR line of products, and we have discovered that Swissray is the manufacturer of the Philips version of the WHIS-RAD, the MRS. This indicates there is potential to lower the cost of the WHIS-RAD, if we can have Swissray sell it under its own brand name. Further, with high potential volumes for the WHIS-RAD retrofits (due to 1400 units being in the field), we could negotiate reduced costs from volumes. Swissray also informally reports 50-200 orders per year for the Philips MRS system. We do know that the iCR1000 came down in price to $27,000 for a volume of 36 units for a set of Tuberculosis (TB) screening sites in South Africa. Also, Xeikona looks forward to the possibility of setting up assembly plants throughout Africa to lower costs and create jobs.

An alternative to purchasing new is encouraging the manufacturers to donate used systems. Currently, when hospitals purchase new digital systems, they trade in the current system. As the price for DR technology declines, many hospitals will trade in their CR readers. Rather than sell these trade-in CR readers in the developed world, the manufacturers could refurbish them then donate them to nonprofit organizations. These donations would be tax-deductible for the value of the CR reader, which may be full retail value.

A major concern with donated equipment is that it is not cost effective because it is usually unreliable. One reason the WHIS-RAD specifications were developed is to provide an alternative to used equipment. To avoid such problems, used CR readers could be effective if they can be supported by manufacturers or distributors in their destination country. Based on this need, any manufacturer would not only need access to many trade-in CR readers, but it would need adequate support presence in the destination country. Only through a partnership between a nonprofit organization and manufacturers with a strong presence in the developing world will the use of used CR readers be possible.

8.0 Maintaining Usability

An essential element to the success of the WHIS-RAD system is its high level of usability. Since it is expected that technicians in some developing countries receive less training than a fully qualified medical radiology technician (MRT), the WHIS-RAD system must be operated with little training. For this reason, the WHO has published the manuals covering the following topics:

- Radiographic Technique and Projections
- Darkroom Technique
- Radiographic Anatomy and Interpretation of the Musculoskeletal System
- Radiographic Anatomy and Interpretation of Abdomen
- Radiographic Anatomy and Interpretation of Chest
- Pediatric Examinations

They provide instruction on operation, film processing, and image interpretation, allowing WHIS-RAD systems to be operated from the manuals. Training a technician takes 3 weeks to several months. So, until a radiographer is available to train a technician and training is completed, someone else, like a nurse, should be able to take X-rays by using the manuals. Therefore, simply following the instructions in the manuals should yield images of acceptable quality.

8.1 Manuals/IFU

The change to digital X-ray must not detract from the usability from the usability of the WHIS-RAD system. For this reason, the manuals must be modified. New editions of the manuals will be needed to replace film instructions with the proper CR cassette instructions. In addition, CR may not require as high an X-ray does to achieve a high quality image. If this is the case, the settings in the manuals should be changed so that patients are exposed to less radiation.

Besides modifying WHIS-RAD manuals, separate manuals will be needed to deal with the operation of the software. Another manual should instruct users on good archiving and backup processes, since it is unlikely the users have experience with archiving digital data.

8.2 Guide

Since the use of digital X-ray requires the use of a PC, a PC will now be available for other applications. One relatively simple enhancement to usability would be the use of electronic manuals. These could be available online, allowing them to be updated regularly. Besides convenience, these manuals could be enhanced if they functioned as onscreen guides. They could help train the technicians and help guide inexperienced operators through the procedures. This could help to reduce errors; helping to avoid retakes which expose patients to additional X-ray radiation unnecessarily.

8.3 Healthcare Technology Management Considerations

When considering the implementation of a digital x-ray system, particularly in resource-poor environments, one must take into consideration issues that may not be immediately apparent in Western regions. In addition to these concerns, traditional matters of planning and management must not be forgotten. To ensure the successful implementation and sustained usability of a digital x-ray system on must consider basic needs assessment, acquisition, maintenance and most importantly sustainability.

Before the determination can be made that a particular technology belongs in a particular region or even healthcare center, it must first be demonstrated that the technology is needed and wanted. Because x-ray capability is a basic necessity to almost location of healthcare delivery, the need for x-ray technology is quite common. It is still necessary, however, to assess the locale in which the x-ray is "needed." Although a standard WHIS-RAD unit is quite capable, it still has limitations and may not be suitable for a place that sees a high throughput of complex cases, especially in corpulent patients and/or infants. On the other hand, in an area that is lacking the technology completely, without concerns of 100% applicability, the WHIS-RAD is well suited. Also, although the system is quite simple to operate and may be used extensively through solely instruction via the included manual, many countries and regions have regulations on staff that is able to operate an x-ray device. A place in which a qualified radiographer is required to image patients but that is lacking radiographers, for example, is a poor place to install any x-ray equipment, let alone a digital x-ray system. Overall, however, because of the common, basic need for x-ray service and the improvements in cost savings and sustainability that come with a digital system, a WHIS-RAD machine including digital retrofit is a versatile system capable of being utilized in a variety of environs.

Once it is decided that a particular location is suitable for a WHIS-RAD with CR capability, the system must be acquired. This can be done traditionally via purchase or possibly even donated in conjunction with Rotary International. In both cases, however, it is vital that a proper contract is negotiated including a proper maintenance and spare parts allowance. If purchased, this can be discussed in the tendering phase making quite sure it is included in the overall contract. If donated, this is more difficult to do, however, no less important. For a detailed look at exactly what should be done throughout the donation process, for all parties involved, the WHO has developed a set of guidelines to examine every step in the donation process making provisions for such things as maintenance and service.

Once implemented, the system must be sustainable which encompasses scheduled and corrective maintenance along with proper budgeting for all expenses associated with the full cost of ownership. These costs include costs for staff, operation, maintenance (both preventative and corrective), training (especially if staff must be trained in basic PC usage), transportation, supporting information systems (e.g. the internet connection supporting teleradiography if employed) and the cost of removal from service. In many cases, especially in resource-poor countries, the experience base to cost out all of these "extra" expenses does not exist, though they still must be accounted for. To aid with this there are many cost guidelines and predictions available from the Healthcare Technology Management sphere of knowledge which is readily accessible. Assuming proper costing is performed, proper funding should be allocated to this to ensure the sustained operation of the digital x-ray system.

Conclusion

Our field research in both South Africa and Zimbabwe proved fruitful. We have solidified a number of contacts in the community and industry locally, and have garnered enough support to begin pilot testing. With a loaner unit from iCR and donated teleradiology equipment, we can set up a pilot test site to test feasibility. The next steps would be to revise the product manuals to include the new digital technology and revise the training program. We also intend to move forward with discussions regarding implementation of CR assembly plants locally. Negotiations with iCR and Xeikona are ongoing as is collaboration with WHO. A grant application via Rotary International is pending. With this project we intend to bring radiology to all parts of the world, which surely will lead to better quality are in parts of the world never before possible.

Appendix A

3.0 Technical Constraints

Much of the strength of the WHIS-RAD system comes from its ease of use (before image processing). In retrofitting our design though, one parameter that must not be changed is the anode-detector distance of 140cm. This distance was standardized by WHIS-RAD designers and though not standard in the developed world, must be maintained. Although the WHIS anode-film distance of 140 cm is less than the usual distance used for a chest examination (180-200 cm), all the normal standard measurements on an image used by radiologists to diagnose remain unchanged. For example, the cardiac transverse diameter and the size of the pulmonary arteries measured on a WHIS-RAD image are exactly the same as they would be seen on a conventional chest radiograph taken at the longer (180-200 cm) anode-film distance. This is because the film in the cassette is much closer to the front surface of the cassette holder, and thus nearer to the front of the patient's chest than with ordinary X-ray equipment. Another difference is that the WHIS anode-film distance cannot be altered by the user, unlike on most other X-ray equipment. There are no instructions in the current WHIS-RAD instruction manual on changing this parameter. In current radiology systems, skeletal, abdominal, and all other non-chest radiographs are obtained at a much longer distance than the usual 100 cm. This is an advantage, because with the small focal spot size specified for the WHIS-RAD system, the quality of the images is better than usual.[15]

[15] Palmer, P. E. (2006). WHIS Research. J. V. Brink. Davis, CA.

4.0 Technology alternatives

Compared to imagery that was acquired and stored on film, digitization provides orders of magnitude improvement in processing, fidelity, resolution, optimization, re-transmission, and substantial reduction in time and costs—not to mention radiation dose for patient and operator. Two main paths to digital are Computed Radiography and Digital Radiography.

As focused on in the previous report, Computed Radiography (CR) promises to be an effective way to eliminate film. A CR image plate (IP) inside a cassette replaces the conventional film cassette. It stores the image in a continuous fashion, latently, on the plate in the form of excited, metastable electrons. The IP is then removed and inserted into a stand-alone scanning unit where a HeNe laser releases the energy in the form of visible light from the excited electrons. This in turn leads to our digital image via currents generated from photomultipliers or photodiodes.

4.1 Digital radiography

Although originally dismissed by our team as completely out of the question due to pricing, (direct) digital radiography (DR) deserves an adequate consideration regardless. While complete DR "rooms" can cost upwards of $400,000, we intend to obtain pricing on simple DR detectors. The scanner in CR is a considerable up-front capital cost, so we aim to find DR detector prices no more than the cost of a CR scanner. We will briefly discuss some of the common technologies used in DR detectors.

4.1.1 CCD Detector Technology:

Charged-coupled devices (CCDs) are small area detectors well-suited for small fields of view (FOV) such as in digital cameras. In digital X-ray they must be bonded together to span the required imaging area. CCD chips are coupled with a scintillation layer since they are not sensitive to X-ray photons and require visible light. Scattering is a notorious problem with CCD, so optics such as light guides have been developed to circumvent scattering.[16] Still, it is well-suited for spot imaging such as biopsy mammography. Swissray (OTC: SRYI) has been the major incorporator of CCD technology in its DR systems through its OEM, Fairchild Imaging. The Swissray system uses four CCDs tiled together in a proprietary optical configuration. It uses a scintillator material that is bonded to each CCD in the array. There are advantages to this approach. For one, CCD detectors are a tried and proven technology that has been used in digital medical and consumer imaging for years. Furthermore, data can be read from each of the modules simultaneously.[19]

4.1.2 CMOS Detector Technology

CMOS (complementary metal oxide semiconductor) chips are widely used type of semiconductor, most commonly incorporated into desktop and laptop computers. Cares Built, however, pioneered the use of CMOS chips as detector components for use in direct digital radiography. Cares Built has since folded, following a federal investigation. CMOS chips provide a type of digital memory that can hold data for long periods, using very little power, thus CMOS chips have been found to have

[16] Zhang, Q., Y. Li, et al. (2005). "Comparison of a CMOS-based and a CCD-based digital x-ray imaging system: Observer studies." Journal of Electronic Imaging **14**(2): 023002-6.

characteristics favorable to imaging applications. CMOS image sensors are built in to an array of photosensitive diodes with on-chip image processing capabilities.[19] However, the fill factor is usually reduced on CMOS models because three transistors are required per pixel, thus blocking some of the X-ray sensitive regions. CMOS enjoy a lower cost because they can be fabricated by standard CMOS Integrated Circuit (IC) techniques, whereas CCDs require special foundries.[17] Finally, CMOS is extremely temperature stable and physically robust. Even in a wide range from 32°F to 110°F, little or no re-calibration would be required. They can also withstand a moderately high amount of shock.[18]

4.1.3 Amorphous Silicon

In this detector material design approach, an amorphous silicon (a-Si) photodiode array is deposited onto a thin film transistor (TFT). This detects visible light from an overlying scintillation layer, which responds directly to ionizing radiation. The a-Si converts this light into electrical charge directly, but since there is an intermediate light step, there is room for some light scatter and loss of signal. This scatter could, as a result, increase the effective pixel size and decrease spatial resolution. The diodes are connected to a field effect transistor (FET) that controls the charge read-out. GE Medical Systems (NYSE: GE) is the principle developer of this technology, although Siemens Medical (NYSE: SI) and Philips Medical (through the amorphous silicon technology developed by Trixell in

[17] Smith, S. T., D. R. Bednarek, et al. (1999). Evaluation of a CMOS image detector for low-cost and power medical x-ray imaging applications. Medical Imaging 1999: Physics of Medical Imaging, San Diego, CA, USA, SPIE.

[18] (2006, 16 Feb 2006). "FAQ." Envision Product Design LLC FAQ, from http://cmosxray.com/Documents/faq.shtml.

France) also base their DR models on amorphous silicon. These “big 3” are parent companies of Trixell. GE Medical Systems’ technology is based on amorphous silicon and the usual scintillator coating of CsI. These components are the result of research and development efforts that have cost over $100M.[19] The arrays can be manufactured in large, unitary sheets that do not have to be tiled. As evidenced with some CCD solutions, tiling leads to seams on our images when tiles are “stitched” together. Though opponents of TFT technologies argue its fill factor is inferior, GE’s proprietary DR panel has a high fill-factor of over 80%. This means that the area of the photodiode occupies over 80% of the entire area of the pixel. This allows the detector to capture a greater number of the emitted X-ray photons, which in turn leads to better detected quantum efficiency (DQE). A drawback of a-Si is that it is very sensitive to temperature. Our design requirements and implementation may involve wide temperature shifts. Recalibration is required with as little as a 10°F shift.

4.1.4 Amorphous Selenium

Another option for a DR detector is amorphous selenium (a-Se) technology. The development was pioneered by DirectRay, which has been acquired by Hologic. Fischer Imaging reportedly also incorporates this approach to digital radiography. To fabricate, a-Se is deposited on the TFT. However, unlike the a-Si option, a-Se can directly absorb X-ray energy and convert it to charge. This makes the scintillating layer unnecessary (to provide conversion to visible light), and therefore a-Se is a true direct DR solution. The primary advantage of this approach is that the direct conversion to electronic charge

[19] Makrinos, S. T. (2004). White Paper: Digital X-Ray Sensors for Military, Commercial, and Homeland Defense Applications. Eatontown, NJ, CACI Technologies Incorporated.

limits the problem of light scatter. Sheets can be fabricated in large unitary arrays in the same manner as with amorphous silicon. However, selenium arrays have the disadvantages of high toxicity during manufacturing, and persistent latent images. This makes real-time display and "retakes" less efficient than a-Si. There is also a tendency for this technology to be particularly susceptible to noise.[19] The detector begins by creating an electric field before capture. As X-rays strike the a-Se, charge is released and carried away by the E-field to the recording array.

5.0 Decision Matrix

In the following Pugh Matrix, we show our decision progress between the main technology categories. We have begun to assign weights to the important criteria in this project.

Factors	Importance	CR	Double Sided CR	DR	Film
Initial Cost	10	1	-1	-5	4
Recurring Cost	5	1	-1	6	-2
Image Quality	6	1	6	7	8
Image Capture Time	3	1	1	7	-2
Simplicity of Operation	2	1	1	1	-1
Ease of Capturing High Quality Image	4	1	1	0	-1
X-Ray Dose	2	1	1	3	0
Retrofit Feasibility	10	1	1	-1	1
Teleradiology Potential	5	1	1	0	-1
Productivity	1	1	1	1	-2
Weighted Total		**42**	**47**	**41**	**31**

Table 1 - Pugh Decision Matrix

Appendix B

With a high-end estimate of 1MB per image using JPEG compression and the conservatively large estimate of 40 images per day given to us by our client, the yearly storage amount required by one location would be:

1MB * 40images/day * 365days/year = 14.26GB/year

Using the common single layer DVD-R archival would require:

14.26GB/year / 4.7GB/disk = 3.03disks/year

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