Creation, Design and Implementation of Breast Reconstruction Surgical Database *Network* (::BRecSD*Net*)

by

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Performed at

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In partial fulfillment of the requirements of the Master of Health Informatics Program,
Dalhousie University

Report of Internship for the period May 3 – August 27, 2004

Date Submitted: September 30, 2004

Acknowledgements

I would like to thank all the workers at Dr. Leif Sigurdson Inc. for their support during the period in which this research project was conducted. My profound thanks go to my supervisor, Dr. Leif Sigurdson, for his sound advice, assistance, and guidance in the development of the entity relationships for the BRecSD database.

I would also like to thank the people who have clarified my thinking and my results via email and personal conversation, notably Dr. Mike Shepherd of the faculty of Computer Science, Dr. David Zitner, director of Medical Informatics, and Dr. John (Jack) Duffy of the faculty of Management at Dalhousie University. My apologies to those whose help or kindness I have forgotten to or did not mention.

Executive Summary

The Breast Reconstruction Surgical Database Network (BRecSDNet) was initially proposed by Dr. Leif Sigurdson because the division of plastic surgery at the Queen Elizabeth II Health Sciences centre does not have a central database to store patients' information related to breast reconstruction. Currently, all data captured are paper-based and require extensive work by the plastic surgeons to retrieve pertinent data as related to specific breast reconstruction.

The BRecSDNet is a newly developed relational database system to support plastic surgeons to capture, store and retrieve information related to patient's demographics, medical history, cancer history, pre-operative visits, reconstruction, operating room data and post operative follow-ups. With appropriate data mining techniques and statistical analysis of the data captured and stored in the system, the plastic surgeons will not only be able to determine the patient's health status: comfort, function, and likelihood of dying (severity) but also measure their health outcome.

The programming language used for the implementation of the BRecSD database is Visual Basic for Application (VBA). Microsoft Access is the relational database management system (RDBMS) used. The web interface required the use of MySQL Server and PHP. HyperText Markup Language (HTML), Cascading Style Sheets (CSS) and JavaScript were used in designing most of the web pages. MyODBC is also used to connect the BRecSD database with the MySQL Server.

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Organizational Profile

Dr. Leif Sigurdson Inc. is an independent company affiliated with the Capital District Health Authority of Nova Scotia. The company is located at the Queen Elizabeth II Health Science Centre in the new Halifax Infirmary Site. The core business of the company is not only to offer plastic and reconstructive surgery solutions to patients across the province and nationwide but also breast, hand, and aesthetic surgery. The company headed by Dr. Leif Sigurdson and affiliated with Dalhousie University is actively involved in research methodologies in the field of plastic surgery.

The Author

The author was employed as a Health Informatics Intern to:

- Create, design, and implement a breast reconstruction surgical database (BRecSD) using Microsoft Access as the relational database management system (RDBMS).
- Design and implement a web-based interface (BRecSDNet) to the BRecSD database.

The health informatics component of the BRecSDNet project was to identify the flow and use of information in plastic surgery settings that would help the plastic surgeon to evaluate the health status and outcome measurement of their patients. And like the saying goes, you can't manage what you don't measure; in other words, you can only manage what you measure. And the key to this project was to capture or acquire data and standardized them in a manner that would permit or facilitate easy evaluation.

1. Introduction

Society manifests its influence through ever-changing technology and in the health services marketplace. This manifestation has challenged researchers on a daily basis as to how best to implement technology of the time to serve the needs of patients. Advances in surgical techniques and changes in our understanding of the biology of breast cancer have made immediate or early breast reconstruction a viable option for the majority of women with breast cancer [1]. However, little is known about national, geographic or racial patterns of use of breast reconstruction procedures in hospitals across the country. This shortfall could be attributed to the fact that there is no standardized way in which data is captured and stored, and made available later to provide the necessary statistical analysis.

Moreover, the massive quantity of data collected from each patient in relation to breast cancer treatment coupled with lack of centralized and structured database often lead to increased redundancy and inconsistency. Lack of consistency might often result in medical errors [2] and thus call for the need of improved patient information in the form of brochures, and websites made available at cancer clinics and at oncological surgeons' offices to facilitate any discussion on the subject by the plastic surgeon [3].

This report deals with the creation, design and implementation of a relational database system, which is used to capture, store and retrieve patients information related to breast reconstruction. The first part deals with an overview of breast cancer and breast reconstructions using the National Cancer Institute's publication "General Information About Breast Cancer" [6] and Merck Manual Publication "Breast Cancer" [7]. In the second part the focus will be on the BRecSDNet design architecture. The third part discusses the implementation of the BRecSDNet.

1.1. Introduction to Breast Cancer

Cancer is a term for diseases in which abnormal cells divide without control [4]. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body [4] [5]. There are several main types of cancer. However, for the purpose of this report, the concentration would be on breast cancer.

Breast cancer may be defined as a disease in which malignant (cancer) cells form in the tissues of the breast [6]. It is the second most common cancer in women after skin cancer and, of cancers, is the second most common cause of death among women after lung cancer [7] [8].

The most common type of breast cancer is ductal carcinoma, which begins in the cells of the ducts of the breast [6]. Cancer that begins in the lobes or lobules of the breast is called lobular carcinoma and is more often found in both breasts than are other types of breast cancer. Figure 1 shows a normal breast with lobular carcinoma in situ (LCIS) in an enlarged cross section of the lobule [9]. Inflammatory breast cancer is an uncommon type of breast cancer in which the breast is warm, red, and swollen [6].

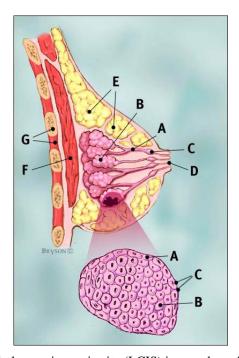


Figure 1: Normal breast with lobular carcinoma in situ (LCIS) in an enlarged cross–section of the lobule. **Breast profile:** A ducts, B lobules, C dilated section of duct to hold milk, D nipple, E fat, F pectoralis major muscle, G chest wall/rib cage. **Enlargement:** A normal lobular cells, B lobular cancer cells, C basement membrane

Despite the high prevalence of the disease among women, the origin and cause, like many other cancers, still remain unknown [5]. However, scientists and researchers have identified several risk factors to be the likely cause of the disease. Risk factors such as age, race, early and late menarche, delayed childbirth, hormone replacement therapy (estrogen, and progesterone), radiation therapy, obesity, personal and family history of breast cancer, and inherited gene mutations are known to affect the risk of developing breast cancer [6] [7] [10].

1.2. Diagnosis & Treatment

Various diagnostic tests are available today for patients who suspect breast cancer development. Although controversial, diagnostic tests such as self-examination, screening mammogram, biopsy, and estrogen and progesterone receptor tests have found their place in the early detection of breast cancer [6] [7]. The prognosis and treatment options depend on the developmental stage of the cancer and several other factors [6].

There are four types of standard treatment of breast cancer [11] [7]; these are *Surgery*, *Radiation therapy*, *Chemotherapy* and *Hormone Therapy*.

1.2.1. *Surgery*

Surgery is the most common type of breast cancer treatment. It includes:

• Lumpectomy: This is a breast-conserving surgery procedure, which involves the removal of tumor (lump) and a small amount of normal tissue around the breast.

- Partial/Segmental Mastectomy: This is a breast-conserving surgery procedure, which involves the removal of the part of the breast that contains cancer and some normal tissue around it.
- Total Mastectomy: A surgical procedure to remove the whole breast that contains cancer.
- Radical Mastectomy: A surgical procedure to remove the breast that contains cancer, chest walls under the breast, and all of the lymph nodes under the arm.

1.2.2. Radiation Therapy

Radiation therapy is a cancer treatment that uses high-energy X-rays or other types of radiation to kill cancer cells. There are two types of radiation therapy. External radiation therapy uses a machine outside the body to send radiation toward the cancer. Internal radiation therapy (brachytherapy), on the other hand, uses a radioactive substance sealed in needles, seeds, wires, or catheters that are placed directly into or near the cancer. The way the radiation therapy is given depends on the type and stage of the cancer being treated.

1.2.3. Chemotherapy

Chemotherapy is a cancer treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping the cells from dividing.

1.2.4. Hormone Therapy

Hormone therapy is a cancer treatment that removes hormones or blocks their action and stops cancer cells from growing. Hormone therapy with tamoxifen is often given to patients with early stages of breast cancer and those with metastatic breast cancer.

1.3. Breast Reconstruction

Breast reconstruction is a surgical procedure designed to rebuild the shape of the breast after a successful mastectomy, segmental resection or aggressive lumpectomy [11] [12]. Breast reconstruction can strengthen the self-image of women who feel less feminine after the loss of the breast; hence it is an excellent treatment option for those who have had a mastectomy [8]. It is therefore not surprising that seventy-five percent of women who have mastectomies go on to have surgical reconstruction of one or both breasts [13]. Many reconstructive plastic surgeons also regard breast reconstruction as one of the most important procedures that they perform [3]. The missing breast can be reconstructed with an implant, autogenous (their own) tissue or by combining the two methods [8]. Basically there are two types of breast reconstruction. These are *Autogenous Tissue Flap*, and *Implant Procedures*.

1.3.1. Autogenous Tissue Flap Procedures

The tissue flap procedures use tissue from the patient's abdomen, back, hip or buttocks to reconstruct the breast [14]. The three most common types of tissue flap are the TRAM (Transverse Rectus Abdominus Myocutaneous flap), which uses tissue from the tummy; Latissimus Dorsi flap, which uses tissue from the upper back; and the DIEP (Deep Inferior Epigastric Perforator flap), which uses tissue from the same area as the TRAM flap but does not use the muscle to form the breast mound [14][17]. Figure 2 shows a schematic view of TRAM flap procedure.

Breast reconstructions using autogenous tissue alone have been shown to result in the best quality reconstruction both in the short and long-term [15]. These procedures leave scars both from where the tissue was taken and on the reconstructed breast [14] and require 4-5 hours for a single reconstruction in the case of the perforator flap [17].

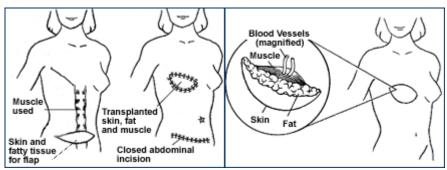


Figure 2: Schematic view of TRAM Flap procedure [14].

1.3.2. Implant Procedures

This is a type of breast reconstruction, which involves the least amount of surgery of all the reconstruction options. Slim, small-breasted women tend to do best with breast implants, because they often do not have enough excess abdominal tissue to form a satisfactory tissue transplant [16]. The most common implant is a saline filled implant that has an external silicone shell and is filled with sterile saline [14].

Even though the implant procedures are typically shorter operations (1-2 hours) and do not prolong hospitalization, they tend to require multiple operations prior to achieving the final result. The implants often require replacement, as the implant manufacturers do not consider them "lifetime devices". Their life expectancy is less than ten years per manufacturer documentation [17]. Figure 3 shows a side view of the breast area with a filled tissue expander in place.

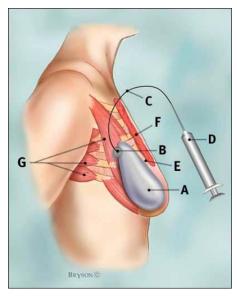


Figure 3: Side view of breast area with filled tissue expander in place labels. A tissue expander-filled, B port, C catheter, D syringe, E ribs, F pectoralis major muscle, G Other muscles of the chest wall (3 lines to one letter) [16]

Based on the description above on breast cancer and reconstruction, it is clear that there are vast quantities of data to be captured in order to effectively carry out the reconstruction procedure. Also patients need to be informed on exactly what is require of them to achieve a successful reconstructive surgery procedure. In addition, the digitized collection of breast reconstruction data would allow more efficient long-term follow-up, enhance quality assurance and provide information essential for epidemiologic research. It is in this regard that the BRecSDNet project was proposed.

2. Overview of BRecSDNet Architecture

The BRecSDNet architecture involves a confluence of databases (BRecSD and MySQL) and web technologies as shown lucidly in figure 3.

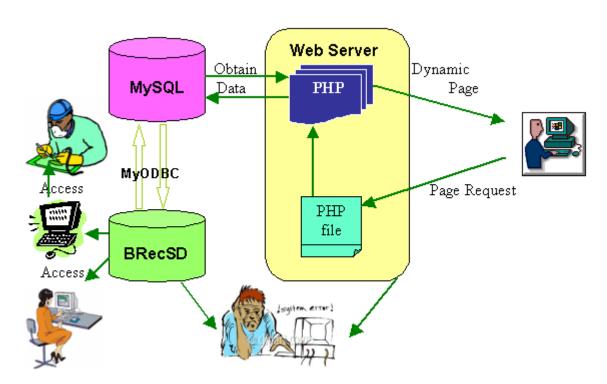


Figure 4: Overview of BRecSDNet architecture

2.1. BRecSD

Information collection, analysis and dissemination inform and monitor the actions of health service providers and identify the most successful procedures, diagnoses and treatments [18]. A database is designed to provide meaningful information to someone within a business or organization. This information can be provided only if the appropriate data exists in the database and the database is structured in such a way to support that information [19]. The technical goal of the BRecSDNet project is to develop a database that will increase the plastic surgeon productivity, facilitate medical decision-making, and improve quality of health care, quality assurance and research.

BRecSD is the name of the database system developed. The BRecSD serves as an Electronic Health Records (EHR) of patients registered to undergo breast reconstructive surgery. The key to the development of the database was to identify the flow and use of information in plastic surgery settings that would help plastic surgeons to evaluate the health status and outcome measurement of their patients. Due to the complexity of information required for breast reconstruction, the database is designed and structured in a way that accommodates all the attributes that support the different types of the reconstructive procedures.

2.1.1. Design

The BRecSD conceptual design utilizes a relational database management system in client-server architecture. The increased flexibility of the use of relational database and client-server allows for growth and change [20]. The BRecSD conceptual model consists of 28 core entities or tables, including Demographics, Medical History, Cancer History, Physical Examination, Allergies, Medications, Risk Factors, Diagnostic Tests, Preoperative Visits, Reconstructions, Operating Room Data and Post Operative Follow-ups. Appendix A shows a complete list of all tables and queries used in the BRecSD design. Forms and sub-forms are shown in Appendix B.

The design outlines a system with the following [20] characteristics:

- State of the art technology
- Interactive and easy to use
- Flexible reporting capabilities
- Reliable data
- Good performance, and
- Confidentiality

It is very important to note here that the data captured and stored in the BRecSD database system is independent and with few modifications could be implemented in any hospital that offer breast reconstructive surgery to patients.

The database allows for quicker and more efficient patient care since all necessary information is contained within one system rather than using hardcopies of patient files where things are hard to find and can easily be misplaced [21].

By storing the information in the BRecSD database, redundancy is controlled by allowing the surgeon or the secretary to enter data only once, and allowing the different users to access it for their specific needs. Moreover, data stored in the system require minimum data preprocessing techniques [22] to facilitate the use of data mining algorithms to extract patterns of interest. The relational structure is inherently flexible and as information needs increase or change, new data elements are easily added, without requiring a restructuring of existing tables [20].

2.1.2. Graphical User Interfaces (GUIs)

The BRecSD graphical user interfaces are designed to facilitate navigations, data entry as well as reporting and data retrieval. Heuristic analysis approach is used to design the interfaces to match the users' tasks [23]. The main GUI after login is shown in Figure 5. The database provides three different data entry interfaces: *Secretarial*, *Physician*, and *Patient Interfaces*.

- Secretarial Interface: This part of the database is the demographic part of the database. The secretarial interface enables the secretary to enter the demographic information of patients at registration. The demographic interface is shown in Figure 6.
- Physician Interface: This interface forms the major part of the database, as the surgeon is the main person required to enter most of the data into the database. Various entry interfaces are made available to the surgeon to collect data from the patients during physical examination, pre-operative visits, operating room data, etc. Figure 7 shows the medical history interface of the BRecSD.
- *Patient Interface:* The patient entry interface is mainly the web interface as the only data currently accepted from patients are the online questionnaires.

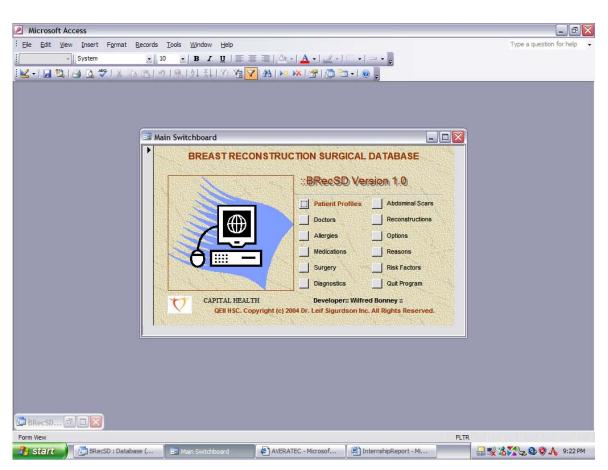


Figure 5: Main switchboard of the BRecSD database

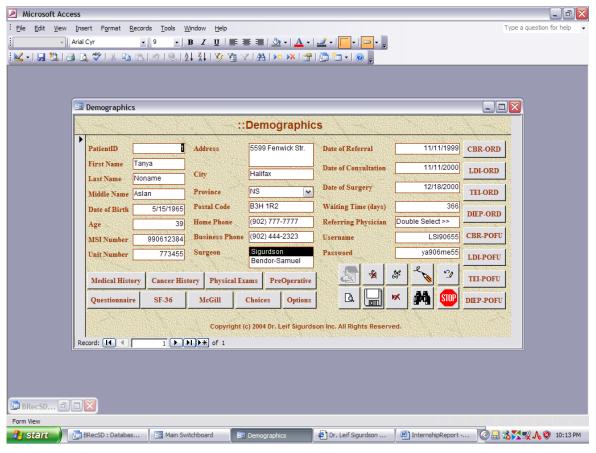


Figure 6: Snapshot of the Demographic Interface

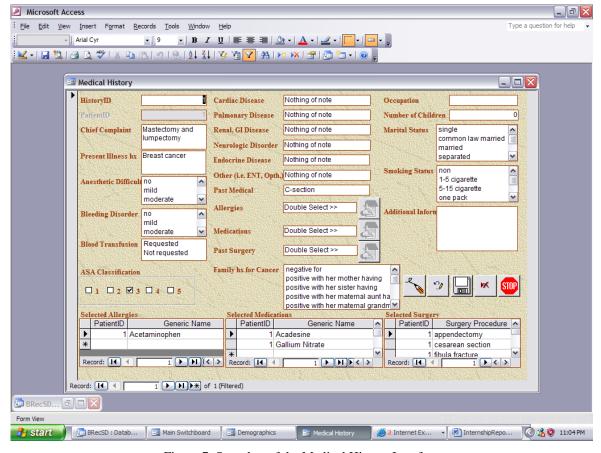


Figure 7: Snapshot of the Medical History Interface

In general, the database performs the following functions:

- Capture and store patient information
- Assign patients to different breast reconstruction procedures
- Analyze and generate four different reports based on the information captured and stored into the database. The reports include consent form, patient health history questionnaire form, pre-operative and physical examination form, and final report. Figure 8 shows a generated pre-operative and physical examination report.

The entity relationship (ER) diagram is shown in Appendix C. For security and confidentiality reasons, the data definitions of the entities and their attributes used in the database is not included in this report.

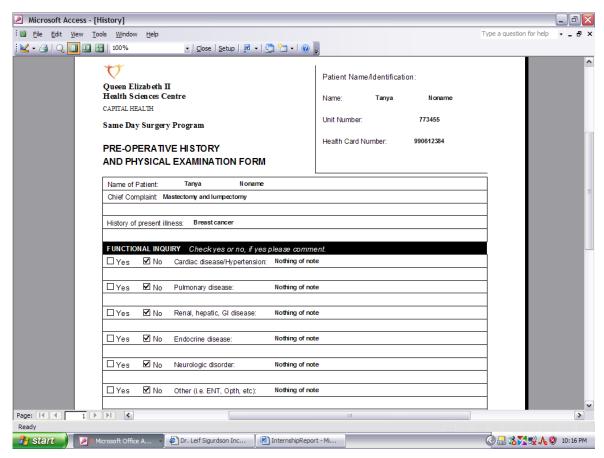


Figure 8: A generated pre-operative history and physical examination report

2.2. MyODBC

Open Database Connectivity (ODBC) is a widely accepted application-programming interface (API) for database access and is based on the Call-Level Interface (CLI) specifications from X/Open and ISO/IEC for database APIs and uses Structured Query Language (SQL) as its database access language [24]. The BRecSD database uses myODBC 3.51 (also known as MySQL ODBC 3.51 driver), which is a 32-bit ODBC driver, to access the MySQL functionality. MyODBC makes it possible to incorporate mySQL into other applications, including Microsoft Access [25].

Through the MyODBC connection, the BRecSD database is linked to three online questionnaire tables on the mysql database server. Thus any information updated using the Access interface, will automatically update the MySQL database and vice versa, making the information immediately available from any application using that data. In the BRecSD database design, the data collected from the online questionnaires are use to generate the reports in the Access interface.

2.3. MySQL Database Server

The MySQL software delivers a very fast, multi-threaded, multi-user, and robust Structured Query Language (SQL) database server. The MySQL database server is intended for mission-critical, heavy-load production systems as well as for embedding into mass-deployed software [26]. In the BRecSDNet design, the mysql database server is made up four tables: Login, Questionnaire, SF-36 Health Survey and the McGill Pain Questionnaire. Figure 9 shows the tables in the mysql control center.

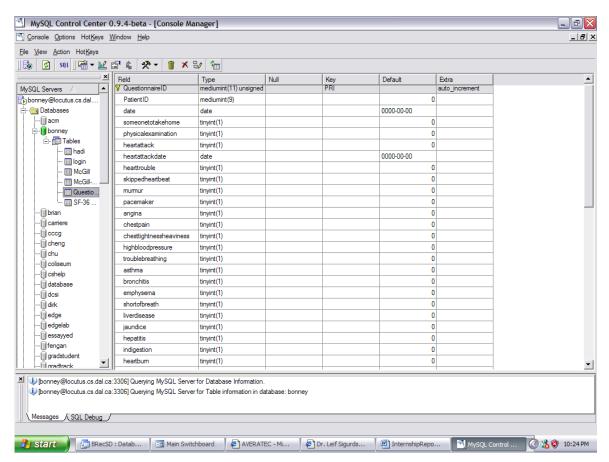


Figure 9: Snapshot of MySQL Control Center showing the attributes of the Questionnaire table

2.4. Web Interface

Capturing sensitive patient's profile through the Internet is essential in providing healthcare in a distributed environment [27]. This goal is best achieved by setting up a web portal that would serve as a gateway to other resources on the Internet. The web interface, as shown in figure 10, is not only implemented to provide access for patients to fill out questionnaires (Surgery Questionnaire, SF-36 Health Survey, and McGill Pain Questionnaire), but also to educate and empower themselves about various options of breast reconstruction available to them. Both the SF-36 Health Survey and McGill Pain Questionnaire are designed to evaluate and measure health outcome of the patients after each successful breast reconstruction.

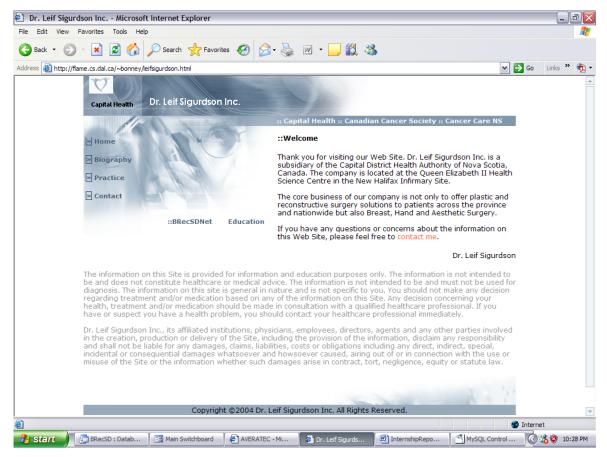


Figure 10: Main index page of the BRecSDNet

The web interface (BRecSDNet) provides a database-driven website for the patient. The whole idea of a database-driven website is to allow the content of the site to reside in a database, and for that content to be dynamically pulled from the database to create web pages for the patients to view with a regular web browser [28]. The web interface is made up of two modules: (1) User Authentication, and (2) Menu of services.

2.4.1 User Authentication

The user authentication module consists of a login page for the registered patients to interact with the BRecSDNet. Figure 11 shows the login page of the BRecSDNet.

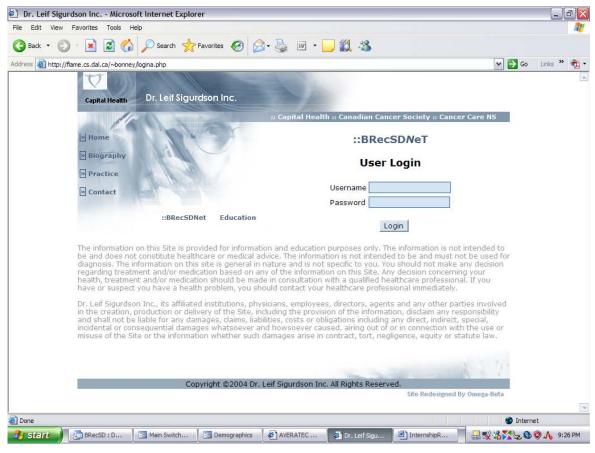


Figure 11: Login page of the BRecSDNet

The authentication process involves the use of unique usernames and passwords, which are hashed and stored in the MySQL database server. Each user is assigned with a unique *username* and *password*.

- *Username*: To ensure security to the system, users are assigned with usernames that cannot be traced back to their MSI numbers by hackers. Special algorithm is applied on the patient's name, MSI and Unit numbers to generate an 8- digit alphanumeric character including a prefix "LSI" preceding each username.
- *Password:* The password consists of 9-digit alphanumeric characters and uses similar algorithm like the username but does not include the prefix "LSI".

The authentication also uses sessions, so the user does not have to re-authenticate on every page that requires authentication [29]. The session expires when the user logout or closes the browser. To protect the security of the patients' profile, the BRecSD database is designed in a way that all information collected online remains anonymous to whoever might try to hack the system. No demographic information is made available online. After login, the user can fill out any of the three online questionnaires.

2.4.2. Menu of Services

This module precedes the user authentication module and is made up of different menu of services targeted to registered patients. Forms are designed to support the required information that is required to be entered into the database. These forms are available to patients after successful login and allow them to query the database for specific documentations as well as fill online questionnaires. Currently, there are three online questionnaires:

- Patient Health History Questionnaire
- SF-36 Health Survey and
- McGill Pain Questionnaire

Figure 12 shows a snapshot of the online patient health history questionnaire form after successful login by a patient.

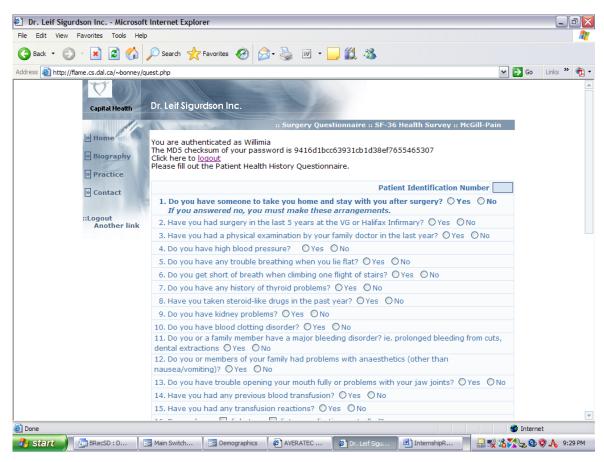


Figure 12: Questionnaire page of the BRecSDNet

3. Discussion

The BRecSD database has been tested with patient's data, implemented and is currently in use at the Queen Elizabeth Health Sciences Centre (Division of Plastic Surgery) by Dr. Leif Sigurdson Inc. For most purposes, an ordinary PC connected to the Internet with Microsoft Access is sufficient for running the program. The file size of the database without any patient record is only 12MB, which makes it very fast and robust. The client-

server architecture combines the benefits of centralized data storage and management with the ease of use found in a PC environment [20].

The programming language used for the implementation of the BRecSD database is Visual Basic for Application (VBA). Microsoft Access is the RDBMS used. The web interface required the use of MySQL Server and PHP. HyperText Markup Language (HTML), Cascading Style Sheet (CSS) and JavaScript were used in designing most of the web pages. MyODBC is used to connect the BRecSD database with the MySQL server.

4. Conclusion

With an information system failure rate of over 50 percent -- due to staff non-acceptance or technical problems-- cultural consideration cannot be ignored [30]. The cultural practice and the belief that medicine is an art that relies on individual clinical judgment make the use of information systems less attractive to physicians. It is also interesting to know that programmers and application developers have goals and values that may not match those of either practicing physicians or administrators [30].

Even though heuristic evaluation techniques [23] are employed in the design of the BRecSDNet, the entire success of its use depends solely on how effectively the plastic surgeons will embrace or adopt the use of the new system. It is also anticipated that the use of BRecSDNet would help reduce medical errors [2] that might occur with a paper-based scenario. The prompted entry interfaces ensure that information is not left out.

5. Recommendations

The implementation of the BRecSDNet in the client-server architecture provides great and enormous potential that would support various functions in the near feature. These functions include:

- *Scheduling of appointments*: To allow patient to schedule and book appointments online
- Integrate other surgical procedures to the BRecSDNet
- *Incorporate personalized delivery of patient information*: To allow patients to view their health status information online
- Patient education and empowerment: To provide educational materials on specific topic of interest for the patient to make informed decisions
- Discussion Forum: To allow patients to contact domain experts about their specific health needs and questions
- Online patient data entry in the form of questionnaires and surveys
- Extract patterns of interest using data mining algorithms

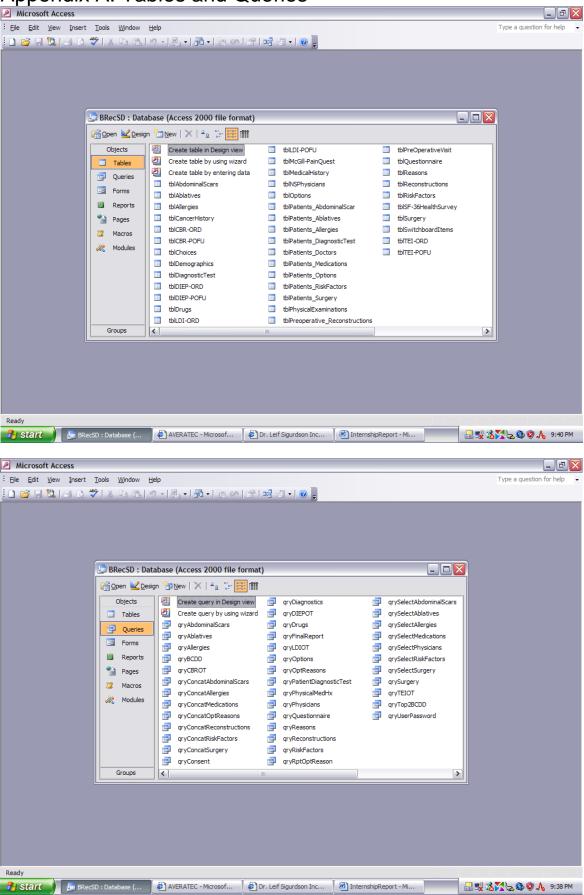
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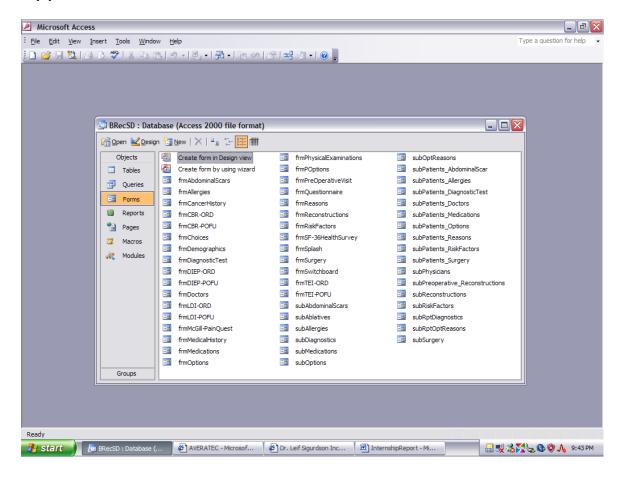
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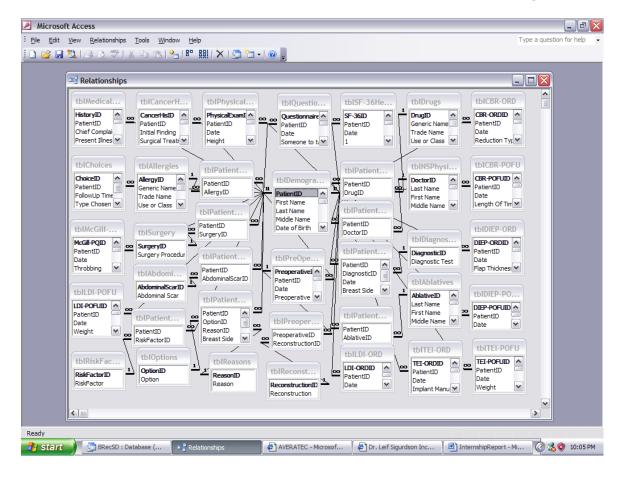
Appendix A: Tables and Queries



Appendix B: Forms and Sub-forms



Appendix C: Snapshot of Entity Relationship (ER) Diagram



Glossary & Nomenclature

Lumpectomy. Removal of lumps from the breast

Mastectomy. Removal of the breast

Metastatic. Cancer that has spread to other parts of the body

Prognosis. Chance of recovery

PC. Personal Computer

CBR-ORD. Contralateral Balancing Reduction Operating Room Data

CBR-POFU. Contralateral Balancing Reduction PostOperative Follow-Up

DIEP-ORD. Latissimus Dorsi Implant Operating Room Data

DIEP-POFU. Latissimus Dorsi Implant PostOperative Follow-Up

LDI-ORD. Latissimus Dorsi Implant Operating Room Data

LDI-POFU. Latissimus Dorsi Implant PostOperative Follow-Up

TEI-ORD. Tissue Expander and Implant Operating Room Data

TEI-POFU. Tissue Expander and Implant PostOperative Follow-Up

Declaration

I, the undersigned, hereby declare that the work contained in this report is my own orig work and has not previously in its entirety or in part been submitted at any university fedgree.	
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