Abstract
This paper describes VSDB, a large-scale vascular screening database being constructed as part of an industry/university partnership between Life Line Screening, Inc. and the University of South Florida. Strokes are one of the leading causes of death and disability in the United States. The economic costs of caring for patients afflicted by stroke represents a significant portion of total Medicare expenditures. The fact that most strokes are preventable and occur often in asymptomatic patients indicates that a widely available screening program may be an excellent tool in our fight against strokes. Increasingly, such screening programs are cited as the means toward stroke prevention. Life Line Screening, Inc. is committed to providing such screening services and has recognized the potential value of historical screening data. In conjunction with the University of South Florida, a prototype vascular screening database is being designed and implemented. A pilot data collection effort is underway and will grow to several thousands of screens per month. Eventually, nationwide data from a wide variety of symptomatic and asymptomatic participants will be collected on an ongoing basis. This database will provide a unique resource for healthcare research into the causes and risk factors of strokes.

1. Introduction
Stroke and other cardiac ailments are among the most serious health risks facing the nation. There are more than 500,000 strokes each year in the United States, with over 400,000 due to cervical carotid artery disease. It has been estimated that nearly half of these strokes occur in asymptomatic patients and that the majority of these strokes are preventable. Strokes are the leading cause of disability in the United States and the reason for approximately half of the nursing home admissions. Strokes are also the third leading cause of death. From an economic perspective, the cost of strokes is equally staggering. Cost estimates place annual expenditures for the care of stroke patients at $40-80 billion (a significant percentage of the $190 billion Medicare budget). The fact that strokes are preventable and occur often in asymptomatic patients highlights the importance of cost-effective screening programs that can identify high-risk patients before strokes occur.

The editor of Vascular Ultrasound Today comments on the impact of strokes in the opening of Lavenson’s article, Carotid Screening: Preparing for the Future [3].

“Stroke remains our most devastating and costly national health care problem. Management of the stroke problem can be broken into three categories: stroke prevention, acute stroke management, and stroke rehabilitation.

Prevention is the most important of the three. New lytic techniques applied in acute stroke management have received much attention and have resulted in some lessening of overall stroke damage in some patients. Rehabilitation efforts are important to try to minimize the disability resulting from devastating strokes. However, significant reduction of strokes as a major health care problem at this point can only be accomplished by prevention of strokes in the first place.

The stroke statistics are drawn largely from Lavenson, 1997 [3].
The exciting realization is that the majority of strokes are caused by carotid artery disease, atrial fibrillation, or hypertension. Though often present silently, these causes are all discoverable by diagnostic screening and, when and if appropriately managed, these strokes can be prevented.”

Clearly, an important objective of stroke prevention is the ability to employ ultrasound and other screening techniques in a cost-effective manner on well patients, especially those in high-risk categories. In this paper, we describe the VSDB prototype, a large-scale vascular screening database. This database is being made possible through the efforts of Life Screening, Inc. in partnership with the University of South Florida. Life Line Screening is providing the type of screening services necessary for stroke prevention, while satisfying two important goals.

1. The company is committed to providing widespread access to a set of advanced screens, including ultrasound stroke screens, at very reasonable costs.

2. The size of the screening effort and the potential of longitudinal data make this an opportune time to develop a large-scale vascular screening database to support future healthcare research.

A prototype vascular screening database has been designed and implemented. A pilot data collection effort is under way and initial healthcare research initiatives are being planned.

2. The Company

Life Line Screening, Inc. is a privately held for-profit company started by individuals with backgrounds in the major medical equipment-imaging industry. It was founded in 1993 in Florida, but has grown to a presence in thirteen states as of 1998. Screening offerings have expanded to include: osteoporosis screening and cholesterol screening products. By performing high volume, short time frame screening exams, the cost to the screened population can be low while the technical expertise of operating personnel can be maintained at high levels due to economies of scale. The hope of the company is to provide a link between the underserved population and the high-technology, high-cost arena of diagnostic medicine by providing accessible and affordable healthcare screening services.

“This quote from Lavenson embodies one of the primary goals of Life Line Screening, Inc. [3]. Life Line Screening employs state-of-the-art mobile screening technology to bring stroke screens, as well as other screens, to the elderly and general asymptomatic population. Mobile screening technology provides convenient access and low cost, two critical ingredients necessary for making a comprehensive screening effort a reality.

The typical screening event is held at a known location, such as a senior citizen center, and advertised well in advance. The event is usually a half or full day in length depending on telephone registration demand. The equipment is transported by truck and set up for the event. The staffing consists mostly of screening technologists with some support personnel.

Life Line Screening also uses the screening event as an educational forum. Educational materials, videos, and seminar-style presentations are used to deliver important information regarding strokes and other cardiac diseases. The assessment data on these educational efforts will be included in future versions of the database.

3. The Database

In this section, we review the database design and data collection effort. One of the design objectives is to provide a flexible infrastructure for the support of future healthcare research projects. There has been a growing interest in building large-scale databases to support healthcare research, see for example [4]. Since most of the vascular research projects are yet to be proposed, there is considerable emphasis on the ad-hoc use of the database. With regard to data collection, the challenges are to automate the process as far as possible and enable the construction of a truly large-scale database without adding to the cost of the screening process. This must be accomplished in a mobile environment with many elderly participants. One of the first uses of the database will be to investigate drug therapies. For instance, while many new pharmacological treatments are coming into the market every day, with this database finding the incidence of disease in the population and tracking progression or lack thereof in the population with or without use of the new “statin” class of pharmaceuticals would be immensely important.

The prototype database design was initially based on the hardcopy forms in current use. These forms are completed by the participants, with screening results recorded by the technologists. The forms are “carbon copy” in nature and are used to mail results back to participants, as well as for archival purposes at Life Line Screening. After developing a preliminary design from these forms, the design was refined through interviews.
with experts from Life Line Screening. Lastly, the development of new scan forms for data collection (see the following section) provided additional requirements for the design.

Two of the major assumptions driving the design process were:

1. Participants will usually maintain an on-going relationship with Life Line Screening, resulting in a history of screening results (i.e., longitudinal data).
2. Participants will often have a group of screenings done during each visit, providing a rich set of data for each visit.

The development of a long-term relationship with participants is an important business goal of Life Line Screening and also provides the basis for a unique research database. The large, multi-state participant base and historical set of screens promises to make VSDB a unique research resource. In addition, the screens are being performed on both diagnosed and asymptomatic participants. This large-scale and varied participant population may provide the basis for significant new insights into the risk factors of stroke.

Figure 1 is a fragment of the database schema showing the PARTICIPANT entity with a one-to-many relationship to the VISIT entity (for general information regarding database design, consult an introductory database textbook or a more detailed reference such as [5]). In the actual database there are several supporting tables for more detailed information regarding each PARTICIPANT. Figure 1 also shows the support tables for recording the medications being used at the time of each visit. In addition, these tables form the basis for some of the reporting mechanisms. The historical nature of the drug information is critical for evaluating the efficacy of drug therapies over time. Additional tables are available for more specific drug information.

Figure 2 shows the STROKE_SCREEN entity. Supporting tables include the physician READER, screening TECHNOLOGIST, and MACHINE used for the screen. The STROKE_RESULT table provides information on important ranges used to report the results of the stroke screen. These ranges will most likely evolve over time and are useful for reporting purposes and for clinical decision making.
Figure 1. The participant/visit fragment
Figure 2. The stroke screen fragment
3.1. Data Collection

One of the most difficult challenges was to develop a cost-effective mechanism for collecting the large volumes of data necessary to build a successful database. While maintaining low cost was an important factor, the mobile nature of the business operations and more elderly clientele also played a role in the choice of scanning technology.

The use of simple scan forms is an appropriate choice for several reasons.

1. The cost of the forms and scanning tasks is very low, allowing Life Line Screening to maintain a low-cost approach to the screening procedures.
2. A cost-effective pilot project can be run in parallel with the normal business operations, minimizing disruptions to standard operating procedures.
3. The scan forms suit the mobile nature of the screening effort.
4. The elderly clients seem comfortable with the process.
5. Scanning technology can handle large volumes of data with minimal staff resources.

A pilot data collection effort is already under way and has shown that the use of scan forms is a suitable mechanism for automating a large part of the collection process. The screening participants have responded enthusiastically, even with the scan forms being administered in parallel with the original forms. Once the scan forms are filled out, they are bundled and shipped to a scanning facility. The electronic data files produced by the scanning process are then translated and loaded into the database using loader utilities.

Figure 3 is the form used to collect participant identification, attributes, and general risk factors independent of specific screens. In addition, there is optional information regarding cholesterol levels for use with simple screens that are selected by most participants. Figure 4 is an example of a pilot scan form used for both ankle/arm and aneurysm screens. The form includes participant identification and visit information, as well as data regarding specific risk factors. A test result area is completed by the responsible technologists. Figure 5 is the pilot form for stroke screens. Again, there is participant identification information, specific risk factors, and screen results. The results include a general result for the left and right carotid arteries, as well as specific velocity ranges. These pilot scan forms capture a rich set of data that will make VSDB an important research asset. The forms in Figures 3-5 will continue to be refined and several additional forms are under development.

The success of the pilot project will allow us to redesign the scan forms and possibly pursue alternative data collection strategies. For instance, an early alternative was based on using portable computers to run on-site database applications that could transmit the data electronically to a central repository. In addition to standard portable computers, there are a host of handheld devices that are both small and capable of running the type of data collection applications required. While technologically elegant, the cost and complexity of such approaches make them ideas for the future.

3.2. A Prototype Interface

A simple interface has been built for the prototype VSDB project. The interface consists of a set of forms for navigation and queries, as well as some initial summary reports. There are also maintenance forms that support database administration functions. Besides direct database navigation, the extraction of data for statistical analysis will be a common activity. The database will also provide an important resource for developing and evaluating data mining techniques and other exploratory tools in the healthcare environment [1] [2].

The interface consists of a “main” screen that organizes the various database activities, such as maintenance functions, summary reporting, and participant-level navigation. The participant form includes address information and a list of visits. From this screen, a particular visit can be selected and any of the associated screening results displayed. Some standard summary reports are available, but custom reports and data extraction functions will certainly be required for individual research projects.
Figure 3. General information scan form
Figure 4. Aortic aneurysm and ankle/arm BPI form
Figure 5. Stroke screen scan form

Stroke Screen History
A. Have you ever had a Carotid Ultrasound?
☐ Yes  ☐ No

When? ___________________ Where? _________________________ Results? _________________________

Watch For Major Warning Signs
Adapted From The National Stroke Association

If you are experiencing any of the symptoms below, please advise your physician. This disease can be found in asymptomatic people who may not have warning signs for this disease.

B. Do you now or have you ever had:

Yes ☐  No ☐

☐ 4. A sudden temporary weakness or numbness of the face, arms, legs.
☐ 5. A sudden loss of speech or trouble understanding speech.
☐ 6. A sudden memory loss.
☐ 7. A sudden loss or "shading" of your vision.
☐ 8. Unexplained headache.
☐ 9. Severe dizziness.
☐ 10. Recent change in personality or mental ability.

Do Not Write In This Area - Test Result

Left Side
☐ None - essentially no calcium or cholesterol buildup is seen.
☐ Mild - some atherosclerotic plaques are seen. Within normal range.
☐ Moderate - moderate amount of atherosclerotic plaques are seen. Suggested re-evaluation in about two years.
☐ Moderate to Severe - Evaluation suggested. (Please see enclosed information.)
☐ Severe - large amounts of atherosclerotic plaques are seen and/or high Doppler velocity is obtained. Evaluation suggested. Please see enclosed information.

Physician ______________________ Reading Date ______________________

☐ Further Evaluation Suggested
☐ Note to the Physician

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Figure 5. Stroke screen scan form
4. Conclusions

Lavenson’s concluding remarks offer a succinct argument for the need for a widespread screening program [3].

“The evidence now is that stroke is largely a preventable disease. The three major immediate causes of stroke—carotid artery disease, atrial fibrillation, and hypertension—are all detectable and manageable. It is entirely possible that we can remove stroke as a major health care problem, just as polio, carcinoma of the cervix, tuberculosis, and ulcer disease have been brought under control during my professional lifetime. What is required is a low-cost screening effort to discover these silent causes of stroke in order to prevent strokes.”

In addition to the need for a low-cost screening effort, we would add an additional goal. There is a need for an organized collection of data resulting from such screening efforts. The large-scale vascular database described in this paper is a first step in that direction. For the first time, a large collection of data resulting from well patient screens will be available for research purposes. This database will allow the verification of previous research on much larger and broader populations, as well as new research on the effectiveness of drugs and the significance of patient attributes.

In conclusion, Life Line Screening, Inc. is providing the cost-effective screens that have been identified as an important weapon in our fight against strokes. In fulfilling the mission to provide widely available screens, one of the first large-scale vascular screening databases is being built through an industry/university partnership. The current status of the prototype is summarized below.

- The initial schema for the database has been designed, along with a prototype interface.
- Scan forms have been designed for data collection.
- The scan forms have been field tested.
- A pilot data collection effort is being conducted to begin populating the database.

Immediate tasks that require attention include redesigning the scan forms and refining the prototype interface and reports in response to feedback from ongoing efforts. In addition, preliminary healthcare research initiatives are being planned. The true research potential of the VSDB project must await the collection of historical or longitudinal data for a large population.

5. References


