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METHODOLOGY FOR THE DETERMINATION OF THE RELIABILITY OF DATABASE DERIVED DATA

by

JUANITA M. LYONS

DISSERTATION

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Dedication

To my Lord Jesus Christ, and my family, immediate and extended.

Acknowledgments

Special thanks to Shlomo, Annetta, and the cardiovascular staff at Children's Hospital of Michigan for the help, support, and especially their patience.

Table of Contents

List of Tables

List of Figures

Chapter I

Introduction

In the medical sciences, patient information is often collected and stored in a computer which has been programmed to track and report on individual or aggregated cases and descriptors. This program for storing information is referred to as a database (DB) program.

With the increasing amount of clinically derived medical data available on databases, many researchers are investigating the possibility of using these same databases for additional medical research. Due to a variety of reasons, however, this is highly problematic. Issues of concern to researchers have included the accuracy and validity of information contained in existing databases. Researchers identified valid reasons to question the accuracy of database data, including patient base bias, conflicting nomenclature used by medical professionals, and complete and accurate entry of data. In addition, the original goals which dictated data base development may render them ill-suited for further research. Without thorough evaluation of the accuracy of data contained within a database and adequate investigation into the original intent and purpose of the design of the database, using this resource for medical research may generate disputable results. However, because these issues have been identified and discussed by research professionals, it may be possible to develop methodologies which will minimize the uncertainties inherent in using existing database information.

Research produced from a database accounts for a considerable portion of medical research and challenges the randomized clinical trial as the most important medical research standard used in deriving at valid conclusions (Byar, 1991, Frame, 1991, Hlatky et al., 1988, Langfitt, 1991, Little, 1991). Indeed, Hlatky et al. (1988) reported results produced from a myocardial infarction database at Duke University which were very similar to the outcomes of a set of randomized clinical trials that were not in the DB. Similarly, Gale and Horowitz (1991) demonstrated that their work with a large bone marrow transplant DB consisting of over half of the known bone marrow transplant cases also correlated with results from a set of clinical trials.

Characteristic of quasi experimental research, database research methodology lacks randomization and control. Thus, this form of research poses a major challenge towards efforts at reaching interpretable conclusions.

Safran (1991) suggested that most DB research problems center on selection bias and missing data. Because of inherent limitations, such as no randomization or control, selection bias is difficult to control. However, as with any form of quasi-experimental research, Pryor and Lee (1991) reasoned that the alternative to DB research, the physician's personal experience, poses an even greater hazard. In spite of these limitations, utilization of DB research continues.

The Problem

This study considers a methodology for estimating DB reliability. Estimating database research reliability is predicated on a conglomerate of

estimates which sum to the total reliability of the database. It is an integrated approach to estimating reliability.

Errors attributable to database research will impact on observed scores. Database error constitutes all of the aforementioned sources of variability and is attributed to the total database research process.

The job of ensuring DB derived data are clear (i.e., free of errors and accurately reflect its source) appears to be a direct function of the amount of time and resources allocated to minimizing error at each phase of the research process. Thus, the degree of DB reliability may be associated with the availability of resources, or merely the integrity of the investigator. Since many DB derived reports may have been based on unreliable data, it is a vital concern that DB reports reflect referenced populations as accurately as possible. Further, there is no established standard or guideline for reporting the reliability of DB derived data. To this end, the investigator proposes a methodology for assessing the reliability of a small medical database focusing on the following study questions.

Study Questions

1. How is the proposed methodology for estimating reliability applied to database derived data?
2. Where is the estimated source of errors in the DB research process?
3. How does the proposed methodology estimate the reliability of DB derived data?

4. What are the outcomes of the proposed DB reliability methodology after application?

Assumptions

Sources of measurement error, other than those identified and assessed by the study, are not considered significantly detrimental to observed outcomes. Selected measures for study are considered valid.

Limitations

Database research study conclusions are limited to sample populations used due to the absence of random sampling. Additionally, the lack of random assignment compromises any confidence in the adequacy of the control of independent variables and, thus, on the conclusions. More importantly, if a measurement instrument is only moderately reliable, a finding may be ambiguous and inconclusive.

Definition of Terms

Bias -- A systematic under- or over-representation of an individual or group's true score. Recorded data in a database program collected in such a way that aggregated descriptors are influenced or distorted from what may have been obtained under the conditions of pure chance.

Database or Database Program (DB) -- A collection of recorded information regarding individual cases and their descriptors systematically encoded into a computer application programmed to track and report on individual or aggregate cases and descriptors.

Database Administration (DBA) -- A method of collecting and entering records into a database program including order of collection, methodology, and data input. DBA also restricts personnel permitted to record, enter, and monitor quality assurance of overall database. The terms "data administration," "data management" and "database administration" were developed by the Guide International, Inc. (Guide, 1977). The Guide defined "data administration" as a group responsible for managing a firm's data as a valuable corporate resource. It is responsible for developing "data management" and administering "database administration" the procedures, practice and plans for the definition, organization, protection and efficient utilization of data within a corporate enterprise.

Data Communication Errors -- 1. Noise : white noise, impulse noise and interference in data transmissions. 2. Jitter: variations in phase or magnitude of

transmissions. 3. Attention: weakening of data signals over distance.

Database Derived Data -- Data which has been systematically extracted from a database.

Database Research -- A method of research involving a combination of the following processes:

1. Selection and organization of variables of interest by experts who: (a) Validate the selection criteria, (b) Issue a definition of terms, and (c) Retain the on going task of modifying, updating and clarifying variables and definitions as needed.
2. Creation of database: Descriptors of selected variables are systematically encoded into a database computer application designed to track and report prescribed individual or aggregated cases and descriptors.
3. Creation of a data collection form: This is the measurement instrument or tool for recording variables by selected personnel. Data collections forms may be either paper or electronic. An electronic form is a form that is created in the computer and is accessed by selected personnel for entering data.
4. Data Processing: Data may be entered into the database by keyboard or scanned by selected personnel.
5. Data communications/equipment and software: The type of equipment and software applications used, configuration and setup.

6. Data extraction: The rules of extraction according to prescribed criteria by a principle research investigator.

Data Processing Errors -- 1. Keyboard errors: errors in keying data into the database, e.g. typographical and spelling errors. 2. Recording errors: errors in recording into the database, e.g., transpositions, omissions or redundancies. 3. Raters' recording error. Errors same as above. Errors made while recording onto paper database forms i.e. typographical, spelling, transpositions, omissions and redundancies (rater errors).

Error -- A fluctuation or variation of measurements due to chance or bias (Kerlinger, 1986).

Randomized Clinical Trial (RCT)--A prospective experiment in which subjects are assigned by chance to receive different clinical treatments.

Reliability--The repeatability, stability, consistency, reproducibility, dependability, completeness and accuracy of a database. The degree to which variability due to error has been minimized. Domholdt (1993) presented and defined four primary components for reliability: *instrumental, intrarater, interater,* and *intrasubject*. *Instrumental reliability* estimates the degree to which an instrument is calibrated. *Human instruments* are performing the examinations with prescribed checklists for observation, and subsequently, measures subjects' performances based on the checklists. *Intrarater reliability* assesses the agreement of two or more ratings by the same examiner over a specified period of time. *Interater reliability* agreement assessed by two or more raters of the

same patient's performance. Domholdt agreed this form of reliability is "crucial" when physicians work as a team. *Intrasubject reliability* is an assessment of the degree of variability within the subject when measurements are acquired at different points in time.

Selection Bias -- An influence on measurements due to the manner in which cases were included, or "selected," into a database.

Validity --The soundness, truthfulness, legitimacy, correctness and veracity of the database derived data. Is the database derived data measuring what it is suppose to measure, providing assurance that the database derived data measured what was intended for measurement?

Chapter II

Review of Literature

Issues of Accuracy

Some of the most prevalent concerns regarding the use of clinical databases for research are inherent in the process of data capture. In order to be useful, the information incorporated into a clinical practice database must be highly accurate, data entry must be strictly controlled, and the study must be designed so that information pulled from the database will be appropriate.

Renwick (1991) identified that flaws in database design contribute to database errors. "Unfortunately, the resulting limitations in the usefulness of a database are often not recognized until long after the planning stages, that is, when its users attempt to draw on the information it incorporates" (p. 827). Renwick went on to state that "the ultimate success or usefulness of a database also depends on the making of appropriate technical decisions. These sorts of decisions pertain to both hardware . . . and software" (p. 827).

Although warned that using a database as an archive of research methodology invites bias and subsequent error, Moses (1991) argued it is more important to concentrate on having a good set of data rather than working on improving methods of analysis. Moses also identified bias and sampling error as the two most prevalent problems in database research since there is opportunity to examine several things, many times, and in many different ways. Moses (1991) further suggested that, as a result:

> p-values are often irrelevant, simply gauging sampling error and especially sample size. Contentment with a lot of small p-values tends to divert attention from real equations, which are questions of estimation. 'How large is this effect?' That is an important question. The p-value answers quite a different one. 'How small is the probability that if the effect is truly zero should we see so big a sample effect as the one we have here?' Not only is the question well off the track of substantive interest, the answer to it is very largely only a meter for measuring sample size, because the almost-fact that all null hypotheses are false (p. 630).

Connell, et al. (1987, p. 62) concurred by stating, "If the data set contains a large enough number of cases, even very weak relationships will be statistically significant . . . . it is important to concentrate on the size, or clinical importance of the effect, rather than simply its statistical significance." Maintaining and improving health standards are dependent upon high quality measurement of the course of medical treatment." Critics agree that there is not enough emphasis being placed on DB methodology, measurement, assessment, and rectification (Deane, 1993, Haug, 1991, Holzner, 1993, Jacso, 1993, Renwick, 1991, Spiegel, 1991, Tennis, 1993). Kerlinger (1986) stated, "If one does not know the reliability and validity of one's data, little faith can be put in the results obtained and the conclusions drawn from the results." Medical database research, to be considered an objective method of observation at the very minimum, needs to be valid and reliable in order to be considered plausible and

translate into effective decision making and improved outcomes.

Tierney and McDonald (1991) discussed prevalent problems with "practice databases" used in clinical research. They noted that despite "the advantages of practice databases and their use to date, important methodological issues need to be resolved if the research scope involving them is to grow" (p. 549). They identified three categories containing most of the problems: data, subjects and bias. Data problems included missing data and multiple measures of the same variable, as well as accuracy of gathered measurements. For example, Tierney and McDonald (1991) noted: Electrocardiograms from the coronary care unit may be of high quality, and therefore more readable and reliable, than those done in the emergency room. Quantifying these differences and controlling for them is difficult, and researchers using practice databases must constantly make hard decisions about which data to include in their analyzes (p. 550).

Gable (1990) also stressed the importance of the realization that "it is difficult to provide a comprehensive, accurate, and current summary of any data sources" (p. 389), especially when incorporating public health data sources into a study.

Bias in a database was also discussed by many professionals as an ongoing concern over the effectiveness of a clinical database as a research tool. Bias issues include patient sensitivity to clinical changes reflected in a clinical database. For example, claims databases were purported to be "more sensitive

to low frequency events by having more patients," whereas practice databases were found to be more sensitive to individual patient changes (Tierney & McDonald, 1991, p. 551).

The finding that the majority of practice databases were situated in academic settings was also considered a patient issue. Tierney and McDonald suggested that physicians who had databases were most often teachers with patients who were either indigent or were specialized care referrals (p. 553).

Hlatky (1991) also discussed the impact of biased patient data on a clinical database. He reported:

> The patients are generally less selected, however, and so the broad scope of an administrative database permits analyzing the effects of geography and institutions on outcome. The clinical and administrative databases are complementary, the former provides a detailed 'high power' view of outcome, and the latter provides a broad 'low power' view of outcome. With either type of database, researchers should follow a number of methodological principles in prognostic studies to assure reliable results. These include testing well-formed hypotheses (or using independent validation samples to confirm the results of exploratory data analyzes) and limiting the number of variables tested to avoid spurious results. (Hlatky, 1991, p. 650).

Edwards, Clark and Schwartz (1994) also identified a bias in multi institutional databases, stating that it "inevitably will be weighted toward those

groups having the largest number of patients in the registry" (p. 1842). The team also identified some clinical inconsistencies which would affect the data. They warned that important discrepancies due to the presence, or absence, of certain physical or chemical attributes needed to be identified in order to ensure that "the meaning of entered data is uniform for each participating institution" (p. 1842).

Sorensen (1992) expressed a concern that "only a few data sources have sufficiently high validity to be used in epidemiologic research in the primary health sector" (p. 325). Sorensen (1992) cited the registry of the National Health Service, observing that:

> This registry covers the whole country, including virtually the entire population and all the general practitioners, it has a high external validity. Therefore, since mistakes in registration, misclassification, and even fraud are probably very infrequent, the registry also has a high internal validity. This internal validity, however, is reduced by the inability to distinguish between individual general practitioners in a partnership practice, and between services, whether rendered to children or to their parents (p. 325).

After studying Medicaid claims data, Bright, Avorn and Everitt (1989) identified many limitations which pose major methodological difficulties. "Foremost among these is the uneven validity and completeness of the diagnoses appearing on claims" (p. 937). Bright et al. (1989) determined that, because of their wide scope, Medicaid databases are suitable for certain studies.

However, they cautioned that "very rare outcomes or exposures probably need medical chart verification, because the potential for bias due to random error is high" (p. 939). They further advised that "requiring the same data collection methods for exposure history or outcome follow-up for all subjects can prevent many kinds of information bias" (p. 940). Bright et al. did indicate that "in any study using Medicaid data, the investigator must judge whether the exposures under study could cause health care providers to differentially monitor their patients for certain outcomes" (p. 940). They further cautioned that:

> Certain potential confounders, such as medical history prior to Medicaid enrollment and personal lifestyle . . .are not available. Any study for which this is a problem is best avoided in this kind of research. In any case . . . Medicaid study results will require replication in other settings (Bright, et al. p. 940).

Another important question they raised concerned the fact that:

> Medicaid recipients do not truly reflect a typical cross-section of Americans, an important question is whether the associations found in populations of Medicaid patients, however strong, are good predictors of associations in the population as a whole. Because of eligibility requirements, Medicaid patients are much likelier than the population as a whole to be poor, chronically ill, or institutionalized (Bright, et al. p. 940).

It was further noted that incidents of "mental illness, drug abuse, and alcoholism are higher in the poor than in the population as a whole" (p. 940).

Because those who qualify for Medicaid status are to be assumed to have higher health risk factors, Bright et al. (1989) warned that the Medicaid databases may be precluded from generalizability.

Another factor affecting the quality of the information contained in Medicaid databases was also highlighted by Bright et al. (1989): "Some aspects of diagnosis coding in Medicaid pose major problems of reliability and completeness" (p. 942). They compared records for the same patient and discovered that diagnostic codes were in agreement only 40% of the time (p. 942).

Goldman (1992) also studied the "degree of agreement beyond chance" by comparing 12 studies, which were performed using medical databases. "Most of these studies found agreement corrected for chance to be in the range regarded as poor, indicating that physician agreement regarding quality of care is only slightly better than the level expected by chance" (p. 958). Goldman (1992) noted:

> Given the magnitude of the resources devoted to quality assurance and the centrality of peer assessment to these efforts, there is a need for a global reexamination of the peer review process including more objective assessment procedures, multiple reviewers, higher standards for reviewers, elimination of systemic reviewer bias, use of outcome judgements, and adoption of practice guidelines (p. 958).

Goldman (1992) further suggested that "modifying the peer review

process to improve its reliability is an alternative to attempting to replace it. A number of proposals for achieving this goal are available in the medical literature" (p. 959), which were further discussed in this article.

The issue of correct data entry has also been addressed by many of the field's professionals. Database research is "generally 'hampered' by issues of data quality more so than 'analytical difficulties'" (Moses, 1991, p. 630). As an example, when situations are dealing with missing or proxy data, Moses decided it was preferable to seek solutions to the pitfalls of database research from "innovative methodologies" (p. 630).

Moses (1991) also reasoned that database research is "difficult to do" and is "full of traps," but, nevertheless, recognizes that it is becoming more and more prevalent as a basis for research. He stressed the urgency for researchers to concentrate on innovative methods for getting the data into the database and better methods of analyzing extracted data (p. 633). Moses further noted that the quality of database research is a direct function of its participants. Therefore, it is posited that the choice of personnel, their education and training, and management skills are essential components of a reliable database (p. 632).

Safran (1991) supported the use of coded information, suggesting that it is "widely available and simpler to analyze than abstracting it from clinical source documents" (p.562). Safran referred to clinical database derived data as representing a "largely untapped resource." However, the problems associated with the use of database derived clinical data were recognized as including "high

error rates, coding bias for reimbursement, inadequacy of the coding rules, and subjectivity." The reported error rate was as high as 44% (Safran, 1991, p. 562).

Additionally, Safran (1991, p. 563) pointed out that the most important clinical database problems were missing data, inconsistencies in data collection, and selection bias, since sicker patients were found to have the most database entries. Cahn's (1994) report on a progression of tests designed to test the quality of information in a database, observed that there was no direct correlation between size of database and error rate or the database type to error rate (p. 26).

From an application development standpoint, the question of data requirements has been identified as a critical component. According to Arinze and Banerjee (1992):

> Data collection is often performed haphazardly and unsystematically, resulting in unacceptable and inaccurate DSS (Decision Support System) output. One reason is that few frameworks have been developed to enable the DSS developer understand and analyze the sources of errors in DSS data . . ... Validating and checking the quality of data for DSS in data requirement analysis has not received a great deal of attention in the DSS literature (p. 261).

They warned that the "robustness of a DSS and its reliability depend centrally upon the prevention, detection and correction of errors in collected data" (p. 261).

In the Annals of Emergency Medicine, Spaite et al. (1990) noted that "all three levels of supervisory personnel (paramedic supervisors, research coordinator, and medical director) are involved in evaluation of data validity" (p. 1271). They detailed three steps used in a quality assurance program to evaluate data validity. The first step is a supervisory review of each first-care form. In this phase, the supervisor verifies with the emergency response staff that any recorded unusual occurrences did in fact happen. For the second step, the medical director and the research coordinator supervise the ongoing data evaluations, constantly comparing the prehospital information with ED assessments. At this point, any discrepancies in the patient's condition or the recorded data can be evaluated. The third step consists of collecting and recording time-related data e.g. response time, scene time, transport time, etc.

The authors also reviewed the frequency of failure in an effort to evaluate the completeness of data entry. In order to perform this evaluation, they focused on cardiac arrest records. They examined the rate of failure to enter data during the first month, against the rate of failure of data entry during the subsequent two months, followed up by an additional two-month block after a three-month interim. This time line was developed to identify long-term alterations in data entry compliance. "During the first month of the study, 40% of patient records were lacking procedural data, and nearly 25% were missing all medical data points" (Spaite et al. 1990, p. 1271).

Because of the large amount of missing information, any attempt to

modify the emergency room treatment system would be based on faulty data. The authors admitted that the faults with data entry during the first month may have been due to unfamiliarity with the new form. They postulated that what was experienced was a "learning curve" which can be expected at the rollout of any new form or procedure.

However, they also acknowledged that:

> If an extensive quality assurance program is not in place, it appears that at least an accurate knowledge of the data entry compliance rate is essential. Failure to enter data is a relatively easy information error to identify and should be considered a bare minimum for data quality assurance in all EMS systems . . . . Although a high rate of compliance is important, even 100% compliance does not imply 100% accuracy. Thus, other means of checking information validity should be added to enhance the "baseline" compliance checks that should occur frequently in each system Spaite et al. (p. 1271).

Their investigation revealed that future study into accurate data collection is still needed. Also needed are mechanisms which allow large volumes of data to be checked for accuracy. In conclusion, "only when such mechanisms are in place can valid conclusions be made that will result in proper system changes" (p. 1272).

Pisanelli, Ricci, and Tarantino (1991) further warned that a database is limited by the computer literacy level of the data entry operators. Thoughtful development of a database can promote "a high degree of user-friendliness in

diverse user groups" (p. S56). By this method, a carefully developed system will allow "better documentation of the aggregated data and for easing their sharing in multi-group cooperative environments" (p. S56). Simpson (1991) also identified problems with the data which include "a general deficiency in clinical content, lack of ability to estimate the accuracy of diagnostic and procedural information, and little information on the appropriateness of quality care provided" (p. S56).

Castleden et al. (1992), in their study on the accuracy of database information when data is collected by resident medical staff members, found that, out of 50 occasions, there was complete agreement between the data entry technician and the medical records department's fully trained coder on 33 occasions. Further, they found that all of the studied systems depended "on the enthusiasm of the surgeon in charge" (p. 566). However, they warned that there was a risk of data loss as junior staff members were introduced into the system. According to their study, the quality of the surgical audit was to be less than satisfactory. They noted that 21% of in-hospital wound infections were not recorded, and "up to 33% of other hospital acquired infections were not recognized as complications" (p. 566). These findings lead the research team to conclude that there was a "need for surgeons and microbiologists to better define clinically relevant HAI [hospital acquired infection] in surgical patients" (p. 567).

In an article published by Biddle et al. (1993), the issue of establishment of parameters and measurement instruments are critical in order to collect and incorporate accurate, valid and pertinent data. Additionally, they identified four

major barriers to an accurate database. First was "the lack of training of personnel involved in data collection" (p. 116). Secondly, they questioned the "impact of data collection on patient care" (p. 116). They said that, from experience, data collection takes away from patient care. However, careful development of data recording forms will expedite data recording. The third barrier was "the burden of multiple data collection requests on the health care team" (p. 116). One of the study team's concerns was the frequency of duplicate requests they witnessed. Finally, "the fourth was the lack of consensus on what should be collected to generate a prospectively useful database" (p. 116). They concluded that it would "be impractical to collect everything on every patient, but . . . priorities for data collection parameters could be established by experts in the community to create a useful database" (p. 116). The study team identified a common theme in the last three barriers: "collecting data in the most efficient, expeditious, and thorough manner" (p. 116).

Roos et al. (1982) had previously raised issues with health care data banks, voicing concerns over "their reliability and validity for a wide spectrum of possible research questions" (p. 266). They concentrated their 1982 study on "information concerning diagnostic and surgical procedures, identifying those areas in which problems exist and those in which the data can be relied upon" (p. 266). The team illustrated that "positive results tend to be reported more frequently than negative results" (p. 266). They also identified that "maximum reliability might be expected when the information being sought is unambiguous

and not subject to professional disagreement" (p. 268). Another concern they voiced was the reliability of both the procedure and the diagnosis. In conclusion, they "adopted a practical outlook to problems of reliability, emphasizing the sorts of checks that can be done with minimal resources" (p. 275). They indicated that duplicate fields within patient records, such as date of birth and home address, can be used as a check to weigh the overall reliability of the medical database being used.

In 1994, a study based on the Basignstoke Orthopaedic Database (Barlow, Flynn and Britton, 1994) revealed that "only 2.5% missed entries; of the recorded entries regarding the nature of the operation was found to be 92.5% complete and 98% accurate. The high percentage accuracy reflects the high degree of medical input in operation of the system" (p. 285). Barlow et al. (1994) found that shortcomings in other data systems could be traced to data being handled by non-medical staff. They felt their database had such a high degree of accuracy because "only demographic information is collected by the administrative staff; the remainder of data entry is the responsibility of the doctors, thereby ensuring greater accuracy of information through better motivation and understanding." They went on to say that their "system is operated by the interns, supervised by more senior members of the team. 'Quality Control' is facilitated by weekly checks on incomplete files within the system" (p. 286). In summary, Barlow et al. (1994) determined that previous studies "have shown accuracy of collected data of between 63% and 96%; one

using a custom produced system and the other a commercial system" (p. 286). They cited problems with "data collection and compliance of staff with data entry" to be the prime reasons for poor results (p. 286).

Frequently, there is a hesitancy among clinical professionals to trust the hardware which houses databases systems. In a study by Brower, ten Katen and Meester (1984), it was discovered that "catastrophic failures at the central computer occurred twice over a period of 6 years [sic], destroying large portions of the data bank. As nightly backup was performed on magnetic tape, data loss was effectively limited to less than one working day" (p. 14).

Although a full scale analysis of commercially available packages may appear to be intimidating, the assistance of a statistician can be invaluable when seeking a data storage system which allows for accurate data handling, as well as efficient retrieval of data.

When using a clinical database for research, another area generating much discussion is the medical nomenclature physicians use to identify patient status. For example, in a study performed by Tennis, Bombardier, Malcolm and Downey (1993), it was observed that "the validity of the diagnoses being coded and the resulting validity of disease classification must be quantified for each condition studied and, if possible, for specific subgroups of subjects" (p. 682). Further, they went on to say "it is clear that validity of classification by discharge diagnosis can vary substantially; and most studies undertaken in these databases need an assessment of validity and misclassification" (p. 682).

Conrick and Foster (1994) also called for a national (Australian) standardization of data. They warned, "fragmentation of data collection must be contained. This can only be achieved by education, collaboration and information sharing" (p. 2).

In a study of the Utstein Style for Uniform Reporting of Data, Cummins (1993) also encountered the problems of nomenclature: "we cannot compare results from different systems if these systems use inconsistent terminology to describe imprecisely define results" (p. 38). Additionally, Cummins (1993) warned:

> Multicenter research never will proceed without this nomenclature problem being solved . . . .The era has ended in which each emergency medical services (EMS) system develops interesting data to collect, designs their incident report forms, collects their data, and then writes up and publishes their results. Such information will be invalid, inaccurate, unscientific, and editorially uninteresting. (p. 38). Harris, DeRose and Jamieson (1991) also identified problems with various nomenclature coding systems. "The alphabet or character coding systems are subject to spelling errors and misunderstandings due to different nomenclatures and abbreviations" (p. S50). Additionally, the team identified that "the inflow/outflow/operation model is cumbersome when more than one operation is being performed on a single patient" (p. S50).

Edward, Clark and Schwartz (1994) suggested that by "using a standard set of clinical definitions," most problems of this type can be effectively addressed.

They went on to say that:

> If all user institutions adhere to the same set of definitions, then clinical inconsistencies within the database should be minimal. Presently there is no single set of such definitions that has gained universal acceptance, although the Veterans Administration has definitions that are well accepted. (p. 1842)

However, they warned that, although the use of accepted clinical definitions may reduce inconsistencies within each record, there will inevitably remain some contradictory information.

An additional nomenclature issue identified by Edwards, Clark and Schwartz (1994) identified that:

> There may be conflicts in terminology, and there may be significant administrative impositions associated with gathering data. The possibility of electronically converting previously accumulated data to conform to the proposed new format is almost always feasible, but actually performing this task may be difficult and time-consuming (p.1842).

Hedges (1993) studied factors contributing to system models which will enhance database design and planning. In the study, it was noted that establishment of a consensus was critical to the development of an accurate multiresource database. The study also noted that other factors included "verifying the accuracy of the data collected; coordinating data storage and analysis; and obtaining fiscal support for such a project" (p. 41). Hedges also

stressed the importance of nomenclature standardization in order to reduce the confusion of physician's reports. "The greater the standardization of terminology and definitions, the better will be the communication" (p. 42) between the various systems incorporated into the database.

Methods of Analysis

Early database research conducted by Goldberg, Gelfand and Levy (1980) acknowledged that quality was a major problem with data registries. Their examination confirmed that the quality of the information collected needed to be questioned. Goldberg et al. indicated there were two fundamental concerns which should govern registry data evaluation: completeness and validity (p. 212). They noted that the completeness of a database seriously compromises any research performed with such data:

> For example, if a registry is 60 per cent [sic] complete and the data which are missing come from a random group of cases, the extent of disease will be underestimated, but the underestimation will be he same for all patient subgroups. However, if the missing data are concentrated on one case characteristic . . . the error in the calculation of rates would be compounded; the extent of the disease would be underestimated as before, but, in addition, the relative frequency of severe cases would be overestimated (Goldberg, Gelfand and Levy, 1980, p. 212).

They further suggested that independent case ascertainment may be the "most definitive method for determining registry completeness . . .the subsequent

examination of case selection bias is then easily accomplished." However (p. 213), they warned that this approach is often precluded due to the expense generated by the intensity and care with which the information is further researched.

Further, Goldberg et al. (1980) noted: "The problems of registry completeness and validity are ubiquitous and are not limited to specific diseases or conditions. The parochial development of disease-specific registries may actually hinder their successful operation" (p. 218). Through their article, they presented a methodology which purported to optimally allocate resources, while addressing the problem of inadequate integrity of the data resource. The goal was to determine the most efficacious manner in which those resources would be utilized. They formulated a model to "maximize the savings that arise from enhanced data integrity, subject to the constraints that available resources cannot exceed and that, at most, one procedure can be applied to a given data set" (p. 215).

Goldberg et al. (1980, p. 213) also presented the "Historic Data Method," in which a comparison is made with the registry being researched by applying a known prevalence rate derived from a similar population. However, this method does not allow for examination of the biasing factors. They also discussed the "Simulation Method," which does not directly measure completeness (p. 214). Goldberg et al. (1980) warned that although the Simulation Method is a powerful tool to determine the affect of case selection bias, it does not give any indication

of the actual completeness of reporting.

Goldberg et al. (1980) also discussed and developed a variety of methodologies to test for database accuracy and validity. They stated:

In this context validity may be defined as the percentage of cases in the registry with a given characteristic . . . . which 'truly' has this attribute. In practice, it is the percentage of agreement between registry data and independent sources objectively measuring the same variable. The need for registry data with a high degree of validity is obvious; case ascertainment may be nearly completed, but the registry may contain a high percentage of information which is incorrect. Once again, the importance of differentiating between random errors and systematic errors must be stressed (p. 213).

Goldberg et al. (1980) discussed three methods which have been utilized to assess the validity of registry data. The Diagnostic Criteria Method "determines the proportion of registry cases which meet strict diagnostic criteria" (p. 214). However, they warned of two main difficulties: first being that the instrument used in determining diagnostic validity may be open to differing interpretations, and secondly that there is a limited focus. Even after stating these warnings, Goldberg et al concluded that "the principal advantage of this method is that independent data collection is not required; the type of diagnostic test used to confirm the final diagnosis is often routinely recorded during case ascertainment" (p. 214).

Another method Goldberg et al. (1980) introduced to assess registry data

validity is the Reabstracted Record Method (p. 214). They described this method as "an excellent means to appraise the validity of registry data." Since the same variables were contained in both the registry and the reabstracted date, validity checks of particular case characteristics can be conducted. However, they warned that the expense of this method must be considered a limiting factor.

The third method discussed was the "Internal Consistency Method" (Goldberg, et al. 1980, p. 215). This simple method examines specific fields to verify that only legitimate codes have been entered. However, Goldberg et al. (1980) warned that the "usefulness of the internal consistency method for assessing registry validity is limited" because only those cases which fall outside the prescribed logic boundaries are considered invalid" (p. 218). They acknowledged that the "most attractive aspect of this method is its low cost" (p. 218).

In their 1991 study, Pryor and Lee argued that "appropriately analyzed clinical databases derived data depict a more broader experience than that of a clinician, and therefore could potentially enhance information used by clinicians for decision making" (p. 617). They stated that "methods required to study the agreement between two observers for the interpretation of a test are different from methods used to describe the natural history of a disease or to study alternative treatments" (p. 617), pointing out that patients' therapies are usually not randomized. However, they admitted that the "challenge in analyzing DB derived data involve the improvement of biostatistical methods" (p. 618).

Pryor and Lee (1991) offered methods to help the analyst meet this challenge. They reported that the most common goal of analyzing data from a clinical database is "to predict an outcome." In order to reach that goal, they felt that the analyst's approach to the database must contain three related issues, a predictive method, a quality assessment, and a validation strategy. They warned that the "when analytic methods are applied, assumptions about the distribution of dependent and independent variables or their relationship to each other are required" (p. 618). They discussed internal and external methods to use information contained in dependent or independent variables, along with appropriate warnings and other considerations.

Internal methods were all characterized by strategies that use the same population on whom the model was developed in the validation approach. Although better than no attempt at validation, the methods are inherently limited in their ability to describe the applicability of the findings to new patients (Pryor and Lee, 1991, p. 623).

The authors also discussed the viability of external models. External methods are all characterized by the assessment of the performance of a model in a different population of patients from that in which the model was developed. The rigor of the validation process can be judged by how different the population is and how the model will be used (p. 623).

They also expressed concern that outcomes may be combined to satisfy statistical requirements in order to gather a large enough number of outcome

events. Their concern is the researcher will not consider whether it is pathophysiologically reasonable to expect that different outcomes can be predicted from the same set of characteristics (p. 625).

Pryor and Lee (1991) admitted that when pertaining to evaluating databases, "it is extremely important that such evaluations be performed and that innovative methods that communicate the advantages of the use of clinical databases compared with other technologies be developed" (p. 623). They stressed:

> The importance of recognizing the three methodologic components of the analytic approach couples the intent of the analysis with its potential clinical application. Innovation in a predictive method in the assessment of the quality of the prediction and in the validation strategy also result from coupling the clinical and analytic insight into the problem (p. 624).

Pryor and Lee (1991) continued on to state that:

> Virtually all therapeutic studies that have been described (in the article) fail to incorporate the complex transitions in patient status over time. Randomized clinical trials and observational studies have traditionally relied on a baseline characterization and subsequent response to therapy" (p. 625).

In an effort to validate a database's accuracy, Ballou and Tayi (1989) developed a methodology based on the supposition that the data set has been so "identified that the errors in its data elements have fairly uniform impact" (p.

323). Their report identified statistical sampling as a procedure that is often employed to obtain parameter estimates.

Ricketts et al. (1993) performed an extensive study of two hospitals with these stated aims: (a) determining the completeness, accuracy and quality of data, (b) determining the reasons for any discrepancies between the two hospitals; and (c) to identify an index of data quality in the system. As part of their sampling technique, they chose a percentage of notes taken by each provider reflecting the portion of those patients under that provider's care during the preceding year. They also identified the use of keywords used by the system. This ratio was used to determine the quality of the data. Additionally:

> The completeness and accuracy data were analyzed [sic—UK] by logistic regression, using the presence or absence of keywords as the dependent variable, with department and senior/junior status as the independent variables. The quality data were analyzed [sic—UK] by repeated measures analysis of variance, pairing junior and senior scores within each firm. (Ricketts et al. 1993, p. 394).

As a result of this study, they discovered that many of the computer audit systems failed to capture 30% of data (p. 395). However, Ricketts et al. (1993) found that the presence of a systems coordinator significantly affected the results. They drew the conclusion that a systems coordinator can assure a properly organized and motivated team, as well as prevent unrealistic expectations, which results in disillusionment and poor data collection. However,

the team admitted "recording complications is the hardest thing to do, and is a good index of the quality of record collection" (p. 396). According to Rickets et al. (1993) this observation was confirmed by an audit conducted by the Royal College of Surgeons of England during the team's study. That audit revealed that a lack of standard definitions made comparison of data quality difficult, and that only completeness could be assessed (Ricketts et al. 1993, p. 396).

Errors in databases can generate widely inaccurate data. Posner et al. (1994, p. 129) had concerns over the false-positive rate, reportedly as high as 95%, exhibited through database research. Due to problematic issues inherent in self-reporting checklist systems, including possible inconsistencies in reporting by practitioners, the physician's perception that these checklists have a low-priority, inherent inflexibility which limit the amount of clinically useful information, and lack of context-sensitive information, the team developed a continuous quality improvement program designed to abate these concerns. They redesigned the program to make reporting by the practicing physician easier, with committee review process designed to classify problems, which lead to classification standardization. This standardization further allowed a higher degree of consistency in data collection, thus reducing the probability of inadequate data collection. Additionally, there was a high rate of physician compliance with the redesigned data collection methodology. Standardized analysis of clinical data also provides identification of problem areas through trend analysis.

In a letter to the Lancet on DB derived data and meta analysis, Eastbrook (1993) wrote:

> The notion of routine archiving of clinical trials' data is still fairly new. The only existing national archive of clinical trials' data known to us is the National Technical information Service (NTIS) which has maintained a computer data file on selected US federally funded research since 1975. The process of MAP [meta-analyses with individual patient data] would be greatly facilitated by standardization [sic—U.K.] of procedures for archiving data, and rules governing access to the data for legitimate purposes. A standard format for storage of data (on tape or disc), procedures for maintaining confidentiality and incentives for individual investigators to contribute data would also be needed (p. 965).

Methodology developed by Haug et al. (1991) for scrutinizing DB quality, identified three parts incorporated in a process to automatically audit documentation produced by the professional staff:

> 1) capturing the data contained in these reports in a form suitable for computerized manipulation, 2) evaluating the quality through reference to a standard, and 3) delivering the results of this audit procedure to the medical practitioners responsible (p. S57).

The team further cautioned that the "factual content of a report is largely inaccessible unless it is encoded and placed in a structured database." The team recommended a formal approach which draws from the quality

management techniques developed in Japanese and American industries, which would include statistical control charts depicting the variances in information content, as well as diagnosis (p. S58).

Ferguson (1991) identified methods "that key components in the evaluation of a database system are, financial costs and savings, recruitment, retention, and satisfaction of staff, and quality assurance needs" (p. 17). Ferguson went on to note that, for one of the studied projects, the critical care nursing staff controlled the computerized system for their unit. This aspect was interesting because it "was entirely driven by the critical care nursing staff, rather than by doctors or management information systems staff in hospitals" (p. 17). At that hospital, "they have been able to demonstrate a reduction in medication errors and incidents adversely affecting patients and staff" (p. 17).

Another key method for evaluating a clinical database for research involves the original intent and design of the database itself. Hannan et al. (1992) studied the relative merits of two clinical databases in order to predict a patient's risk of in-hospital mortality and "for assessing hospital performance in terms of risk-adjusted mortality" (p. 901). They discovered that, for patient mortality, one of the two models proved to be a better fit due to the data incorporated in that database. They also found that the same database proved an effective tool to assess hospital performance. They stated:

> Our cautious guess based on the results of this study is that a good portion of the clinical database advantage comes form the use of clinical

> data elements with no comparable diagnosis code, superior variable definitions that are unconstrained, and the ability to distinguish between complications and co-morbidities (Hannan et al. 1992, p. 901).

In their analyses of large databases for healthcare studies, Connell et al. (1987) indicated that there are two general reasons for flaws inherent in those same databases "both related to the fact that the individuals who design and compile databases cannot consider the particular needs of every person who eventually might use them" (p. 73). Specifically, the following flaws were identified:

> First, many data bases [sic], particularly those used primarily for administrative functions, are simply not designed or maintained to maximize data quality or consistency. Usually more data are collected than are used for the primary (administrative) purpose; infrequently used data elements are often incompletely and unreliably coded . . . . Second, even in well-maintained data bases [sic], the original goals that dictated how data were collected will invariably not coincide with those of subsequent users. Consequently, the original study, design, data collection strategy, and coding practices may make secondary analysis difficult or impossible (Connell et al, 1987, p. 73).

The study team issued several caveats that a researcher should keep in mind when using large health care databases as a study tool. They suggested that each user should investigate the following questions:

1) What are the inclusion criteria for cases, events or variables?. 2) What is the record structure of the data base?. 3) Are required data elements present and are they adequately coded?..4) Will more than one data set be used? (Connell et al., 1987, p. 73).

As part of the users' investigation into a health care database, Connell et al. strongly suggested that a careful review of database materials be conducted to "assess the design and quality of the data collection process and the appropriateness of the data base for the proposed study" (p. 73). When conducting this review, the study team reminds the researcher that the "best informed individuals are generally those closest to the that data base itself: programmers, research analysts, and data specialists" (p. 60). Other analytical and statistical issues identified by Connell et al. included "screening the data for outliers and missing data, looking at the distribution of the data, and pilot testing all analyses on a subset of the data" (p. 61). However, (Connell et al. 1987, p. 62), cautioned that: . . . "With a large number of variables, the potential to generate misleading conclusions is great. Careful specification of an analytic model, plan, or hypothesis is essential to determine which variables should be used" (p. 62).

The study team concluded that an "awareness of the potential pitfalls inherent in the use of large health data bases can help prevent many problems and disappointments, as well as improve the validity and efficiency of statistical analysis" (p. 73).

Safran (1991) reported on the development and implementation of a clinical computing system for Boston's Beth Israel hospital that assists health providers in delivery of patient care. This study raised some valid concerns regarding the original intent of the database. Of the data collected by Boston's Beth Israel hospital, 38% was used for clinical research, 16% was used for patient care information searches, while the remainder was used for education, exploration, and administration (p. 562). Safran employed a stepwise multiple regression analysis to predict resource utilization to reveal the power of clinical databases and assist in monitoring costs. This procedure was used to identify data coding failures in resource utilization predictions. Safran concluded that the use of diagnosis or laboratory data alone was inferior to using clinical data with coded discharge diagnoses in making predictions (p. 562).

Thus, the researcher must take certain realities into consideration when determining the effectiveness of using an existing clinical database for research purposes. Hettinger and Brazile (1992) issued a reminder that "a database system is a model of some bounded aspect of the real world . . . .The purpose of this database system is to store, maintain, and retrieve data necessary to perform nursing duties efficiently and effectively" (p. 110). They warned that any future database development must not interfere with the day-to-day care of the patient.

Many of the researchers previously cited have outlined some guidelines future database developers and researchers need to keep in mind. Tierney and

McDonald (1991) stated that: "It falls on our shoulders to establish standards for quality data and research so these databases can yield good results that help efficiently deliver health care" (p. 553).

Horii (1994) believed that "organized data management increases the reliability of statistical analysis" (p. 71). Careful preparation of the database assures the integrity and the quality of data. Which, in turn, leads to reliable statistical analysis.

Although there are myriad difficulties in using clinical databases for research, there are methods that can be employed to effectively use this data. As early as 1980 Goldberg et al. stated:

> If we had accepted prima facie that the ITS (Illinois Trauma System) was correct, our conclusions would have been disastrously incorrect. Our experience with the ITS indicates that researchers using registry databases should not rely solely on a single validity or completeness assessment, but must subject their data to a more thorough examination (p. 218).

Goldberg et al. (1980) reported that there are a wide variety of techniques that can be used to verify the completeness and validity of registry data.

Finally, Cahn (1994) stated that there are "no benchmarks to compare, no consistent test repeated over time to consider when choosing a database" (p. 26). Cahn went on to state that "a measure of reliability is suggested when the ranking of error rates is compared. If standard database tests were published, we'd have to be wary that producers wouldn't try to bias the result, by cleaning

up only those errors that the tests look for" (p. 26).

Examination of the literature underscores a myriad of problems in database research. Standard methods for evaluating the reliability of databases have been, to this point, only speculative. Prescribed criteria for establishing reliability before DB research is reported clearly needs to be established. Because utilization of database derived data, as the source of medical research reports, is increasing in prevalence, methods for determining the reliability of these data should be developed, scrutinized, refined, and a standard method placed into practice.

Chapter III

Methodology

Data Administration

In April 1993, the Society of Thoracic Surgeons (STS) produced a national congenital heart surgery database with the stated primary goal of establishing a national resource and standard for comparison by state associations, regulatory agencies and third-party payers. The STS Congenital database subcommittee was delegated the responsibility of developing "a database that would (1) provide a reliable count of congenital heart surgical procedures and (2) provide outcome data with the potential for risk factor analysis" (The Society of Thoracic Surgeons, 1995).

The STS commissioned Summit Medical Systems, Inc. to design the database program according specifications which included entire or subset population listing capabilities, a biostatistical component, and the Harvard Graphics program for transformation of raw data into slides and graphs. The database also included some preprogrammed summary reports. These reports included length of stay, mortality by age, complications, diagnostic, procedural field tallies, and a referring physicians report.

As a part of this concerted effort, Children's Hospital of Michigan's Department of Cardiovascular Surgery purchased a version of this national database program, which not only included the aforementioned standard features, but also features which allowed customization. The customized version

of the database was purchased to accommodate the academic hospital-based operations and interests.

On April 7, 1993, department's research team, including staff surgeons, clinical nurse practitioners and research personnel, convened to examine and discuss modifications of the DB program and data collection form (Appendix A). Routinely scheduled departmental research meetings subsequently became the standard forum for discussing the DB research process. Discussions were focused on issues regarding selection and addition of new variables, clarification of variable definitions, institution of protocol for recording and entering data, and assignment of DB related tasks to selected personnel. On the basis of these efforts, as well as those of the Society of Thoracic Surgeons, the DB collection form is assumed valid.

The DB program was implemented July 1, 1993. In an effort to keep data processing errors at a minimum, all DB forms were completed in red. It was decided that the contrast of red against black text on the white paper forms would provide additional clarity and would help reduce possible errors by data entry personnel. Upon each patient's discharge, the attending surgeon recorded patient history, diagnoses and all surgically related data. The secretarial staff supplied demographic information, while the research staff recorded the preoperative laboratory values, admission and discharge dates and times. Afterwards, each form was double checked for accuracy by the nurses and research personnel. After all data had been recorded, the DB forms were passed

on for data entry. Each DB research team member was cautioned to be vigilant for errors in an effort to correct them as discovered.

Sampling Procedure

Patient records will be sampled from the total database. The study population will consist of all database archived congenital heart surgery cases. Manly (1993), in concurrence with Crothers (1977), suggested that where it has not been possible to define the effect size, a sample size of at least 150 cases is probably adequate. Therefore, a simple random sample of 150 cases will be extracted for analysis.

Methodology

Intrarater and interater reliability will be estimated for surgeon rated ordinal scaled DB variables. These variables include "Status", (Table 1), and the "New York Heart Association (NYHA)" (Table 2). Since these variables encompass rating criteria, they are not primarily susceptible to data processing errors, as in the case of the remaining DB variables, but are also susceptible to intrarater and interater bias as well.

Estimates of intrarater reliability are acquired by employing test retest reliability methodology described as follows.

Interater reliability will be estimated from data available in each patient's medical record. For the purpose of this study, these records will be considered as source documentation. Information extracted from the medical records will be recorded on a duplicate copy of the National Congenital Surgery Database Data

Table 1

Status (Operative Categories)

Term	Definition
Elective	An elective operation is one that is performed on a patient with cardiac function that has been stable in the days or weeks prior to operation. Elective cases are usually scheduled at least one day prior to surgical procedure.
Urgent	An urgent operation is one that is required within the present hospitalization in order to minimize the chance of further clinical deterioration. Delay in operation is necessitated only by attempts to improve the patient's condition, availability of a parent or spouse for informed consent, availability of blood products, or the availability of results of essential laboratory procedures or tests. An urgent status is not merited by purely administrative considerations.
Emergent	Patients requiring emergency operations will have ongoing, refractory, unrelenting, cardiac compromise, with or without hemodynamic instability, and will not be responsive to any form of therapy except cardiac surgery. An emergency operation is one in which there should be minimal delay in providing operative intervention.

Table 2

New York Heart Association (NYHA)

Level	Description
I	Patients with cardiac disease, but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable as rest. Ordinary physical activity results in fatigue, palpitations, dyspnea, or anginal pain.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest, but less than ordinary physical activity results in fatigue, palpitations, dyspnea, or anginal pain.
IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Collection Form. This duplicate form will be designated for manual extraction of all pertinent anomaly related research data from the medical records.

Discrepancies between database records and source documentation will be identified and recorded. Physicians will be queried to determine possible reasons for each occurrence of error. The source of these errors will either be classified as human instrument or DB form recording errors (Essentially, these errors are the same as DB keyboard and recording errors except they are caused by raters recording errors onto the DB form as opposed to data entry personnel processing erroneous data into the DB program).

Data processing reliability estimates on keyboarding and recording errors by data entry personnel and raters will count as each discrepancy between the completed DB form and the DB program entry is revealed. This estimate will be obtained for all DB variables.

Although data communication and intrasubject variability are considered probable contributors to the reduction in overall DB reliability, it would be quite difficult, in retrospect, to identify and subsequently measure these types of errors. Therefore, since there were no known or documented data communication issues which may have affected the DB, there will be no attempt measure these forms of error. Nevertheless, both sources of error merited mention as possible sources of error having some influence on reliability measurements. Likewise, estimates of intrasubject reliability are precluded by ethical considerations since surgical procedures would have to be duplicated.

These sources of error will be subsumed by the other sources of DB error identified for examination.

Data Analysis

As previously stated, the information provided by this report will estimate the amount of impact DB errors have on the reliability of DB derived data and then examine the source of these errors in the DB research process. To estimate the impact of intrarater errors on DB reliability, the reliability coefficient of stability will be obtained. This coefficient will be generated by computing Spearman correlation between the physicians original and re-rated scores.

Interater agreement will be estimated by application of generalizability. This approach will be applied to separate the extent of variation among physicians. To analyze this type of problem as posited by generalizability theory, analysis of variance is employed to estimate reliability coefficients and errors. Generation of generalizability coefficients is "a way of thinking about reliability, which leads to procedures for choosing the reliability coefficients and or error variance most appropriate for the situation at hand" (Crocker, 1986).

Within this context, interater agreement will be treated as a "single-facet" design. Each rated case will constitute the single-facet on the DB form. Ratings will be considered as replicated measurements on the cases. A generalizability coefficient will be estimated by using results generated from a single factor, ANOVA. The results will be presented in an ANOVA table in the following chapter. The degree to which obtained measurements generalize to the "universe" ratings of sampled DB forms will be quantified by the generalizability

coefficient.

The impact of Data processing errors on DB reliability will be estimated by examining the correlation between DB collection and electronic forms. A reliability coefficient referred to as the coefficient of equivalence will be determined. Statistical treatment will proceed with the generation of the Pearson Product moment coefficient. Employing the Pearson Product moment coefficient is contingent on the underlying assumption of linear relationships between variables. These conditions between associated measures will be assessed by initially obtaining a scatter diagram. Relationships between variables will be plotted to establish linearity, unimodal distributions and symmetry. Sources of data processing error will be tabulated per form. A preliminary examination of the data will be performed to determine normality and homogeneity of variance. The Levene Test will be employed to assess homogeneity of variance and a Lilliefors significance level will be obtained for testing normality. Subsequently, a one-way ANOVA will be performed to analyze the data and determine the sources of error. The null hypothesis is H_o: $:_1=:_2=:_3$ where $:_1$= mean errors due to keyboarding; $:_2$= mean errors due to data entry recording, and $:_3$ = mean errors due to rater recording. If the omnibus F is significant, post hoc comparisons will be made using Hochberg's GT2 for equal comparisons and Tamhane's T2 with unequal comparisons to further examine categorical differences.

Nominal alpha will be set at .05. Resulting data will be sorted in Microsoft Excel version 5.0, and subsequently downloaded in SPSS version 7.5 for

statistical analysis. Results will be presented in Chapter 4 with tables and figures.

Chapter IV

Results

Profile of Analyzed Variables

The database was profiled for accuracy or correctness, and overall reliability in reporting and recording results for each respective variable. Factors for classified errors were analyzed by type and group to determine the sources of error for reliability estimates. Averages computed for quantitative variables for the entire sample population were reported as the mean plus or minus the standard error of the mean, with the median. Other quantitative variables were reported as mean, standard deviation of the mean.

Data collection forms had a total of 593 possible variable categories that could be coded per form and where errors could originate (Table 3). There were a total of 10,759 variables coded in the 150 sampled database collection forms yield, which averaged to 71.73 (mean) ± 1.2 (standard error), 72 (median) variables coded per form. The 593 variables were subdivided into 13 sections according to the 13 subdivided sections on the paper data collection form (Appendix A). Each section was analyzed as a group for errors. Errors effecting reliability estimates were classified according to three primary types including two types of rater error, recording and omission; two types of keyboard errors, typographical and spelling; and three types of recording errors, transposition, omission, and redundant.

The rating and entering of data from database collection forms primarily

Table 3

Analyzed Variables for Reliability Estimates

Variable Name	Value	Value Label
	1- 593	Collection Form Variable Categories
		(see Appendix B for a detailed listing)
Demo	1-52	Demographics
PtHist	53-104	Patient History
DiagOR	105-130	Diagnostic and Operative Data
Trtmnt	131-151	Treatment Categories
Diag	152-288	Diagnosis
Diagcur	289-351	Diagnosis for Current Procedure
Compnt	352-435	Component
Diaglst	436-447	Diagnostic Listing
Proclst	448-459	Procedural Listing
Valve	460-487	Valve and Valved Conduit Surgery Data
Shunts	488-490	Shunts
CPBP	491-522	Cardiopulmonary Bypass and Support Data
PstOp	523-593	Post-Operative Data
	1-7	*Coded Error Types*
typo	1	Keyboard error: Error keying data into database;

Table 3 continued

sp	2	Keyboard error: Spelling error keying data into database
trans	3	Recording error: Transposition error in recording into the database
omit	4	Recording error: Omission error from recording into the database
redun	5	Recording error: Redundant error in recording into the database
raterec	6	Rater recording: Error in recording onto the database form
rateomt	7	Rater omission: Omission error from recording onto the database form
		Personnel
Rater	1-3	Heart Surgeon who rated the DB form
	1	MH
	2	HW
	3	KL

Table 3 continued

Enter	1-9	Person who entered the rated form into the database
	1	BP
	2	JL
	3	SS
	4	CP
	5	MB
	6	NH
	7	PC
	8	AM
	9	PN
		Measurement
Total		Total variables recorded on form
Errors		Total errors (rater and data entry personnel)
Dataprc		Data entry personnel errors: keyboard and recording errors
Keyerr		Keyboard errors
Recrderr		Data entry recording errors
Raterr		Rater recording errors

involved fourteen individuals. Two of the fourteen were only responsible for completing the demographic section of each form, then passing it on to one of three attending surgeons who subsequently rated and completed the remaining form. The three surgeons were held accountable to the entire database collection form as primary raters. Rater number one completed 53 (35.3%) forms, rater two, 74 (49.3%) forms, and rater three, 24 (15.3%) forms. The responsibility of entering data from the paper collection forms onto the electronic forms was divided among a total of nine individuals. Four of the nine entered the majority of the 150 sampled forms (Table 4).

Accuracy Profile

There were a total of 10,609 correct answers for all sampled forms. The average amount of correct answers per form was 70.73 ± 1.20, 72. There were a total of 150 errors for the sample, an average of 1 ± .137, 0 per form. The ratio of errors to total number of entries was .014. The total amount of errors per form ranged from a minimum of 0 to a maximum of 12. Half (n=76, 50%) of the sampled errors were from recording errors, 40 (27%) from rater errors and 34 (23%) from keyboard errors (Table 5).

Error types were not necessarily mutually exclusive per case. There were 84 (56%) cases with no errors, 22 (14.7%) with only recording errors, 13 (8.7%) withonly keyboard errors, and 9 (6%) with only rater errors. The remaining 22 (14.7%) cases had a combination of error types including 12 (8%) of the cases with both keyboard and recording errors, 3 (2%) with keyboard and rater errors,

Table 4

Number of Collection Forms Entered by Designated Data Entry Personnel

Personnel ID	Frequency	Percent
1	17	11.30%
2	76	50.67%
3	34	22.67%
4	10	6.67%
5	3	2.00%
6	4	2.67%
7	1	0.67%
8	4	2.70%
9	1	0.67%
Total	150	100.00%

Table 5

Summary of Error by Type

Error Type	N	Percent
Recording		
Transposition	14	9%
Omission	60	40%
Redundancy	2	1%
Subtotal	76	50%
Rater		
Recording	3	2%
Omission	37	25%
Subtotal	40	27%
Keyboard		
Typographical	28	19%
Spelling	6	4%
Subtotal	34	23%
Total	150	100%

6 (4%) with recorder and rater errors, and 1 (.7%) with the combination of the three, rater, keyboard, and recorder error types.

Raters made no errors on 125 (83.3%) of the sampled cases, one on 21 (14%), three on 2 (1.3%), five on 1 (.7%) and eight on 1 (.7%). The KW test was employed and failed to reject the hypothesis that there were no differences among raters' recording error (Table 6).

Table 7 shows the data processing errors among data entry personnel. The KW was also employed due to non supported assumptions for normality and homogeneity of variance as tested using the Lilliefors' and Levene's tests respectively. Results from the KW test supported that there were significant differences among errors generated by entry personnel ($p=.022$). Further examination revealed that there was also a significant difference between recording errors produced by both entry personnel two and three and the remaining entry personnel (Mann Whitney U-Wilcoxon Rank Sum W Test, $p<.01$).

The majority of the errors found in the database were data entry personnel and rater errors located in the Demographic section (n=40 [26.6%]) of the database (Table 8). Diagnostic, Patient History, Diagnostic and Preoperative Data, Cardiopulmonary Bypass and Support Data, and the Post-Operative Data sections of the data forms were other sections where concentrations of errors were found.

Table 6

Summary of Rater Errors

Rater	No. of Errors	Total Rated	Mean	Std Dev
1	13	53	0.25	0.55
2	14	74	0.19	0.66
3	13	23	0.57	1.75
For Entire Sample				
Population	40	150	0.27	0.89

Table 7

Summary of Data Processing Errors by Data Entry Personnel

Data Entry Person	No. of Errors	Total Processed	Mean	Std Dev
1	1	17	0.06	0.24
2	37	76	1.05	1.77
3	13	34	0.5	0.75
4	3	10	0.8	1.55
5	0	3	0	0
6	1	4	0.25	0.5
7	0	1	0	*
8	0	4	0	0
9	0	1	0	*
For Entire Sample Population	55	150	0.71	1.42

Database Reliability

It was not possible to estimate either intrarater or interrater error since physicians found it difficult to recreate the time of the original ratings prior to surgery. Additionally, the New York Heart Association (NYHA) scores were interpreted primarily for the adult patient population. Further, the NYHA scale was considered by the surgeons to be an inappropriate measurement for the pediatric cardiac population.

The two variables NYHA and Status were to contribute to reliability estimates for interrater and intrarater agreement respectively. Since these estimates were not possible to obtain, data reliability estimates were assessed upon data processing errors exclusively. Data processing errors were estimated by examining the correlation between tabulated errors on collection and electronic forms. A scatterplot was generated and satisfied assumptions of linearity, unimodal distributions and symmetry (Figure 1).

The coefficient of equivalence was obtained by employing the Pearson Product moment coefficient. Calculated results from the Pearson Product produced a reliability coefficient of equivalence of .99 (p=.000).

Table 8

Location of Errors by Type

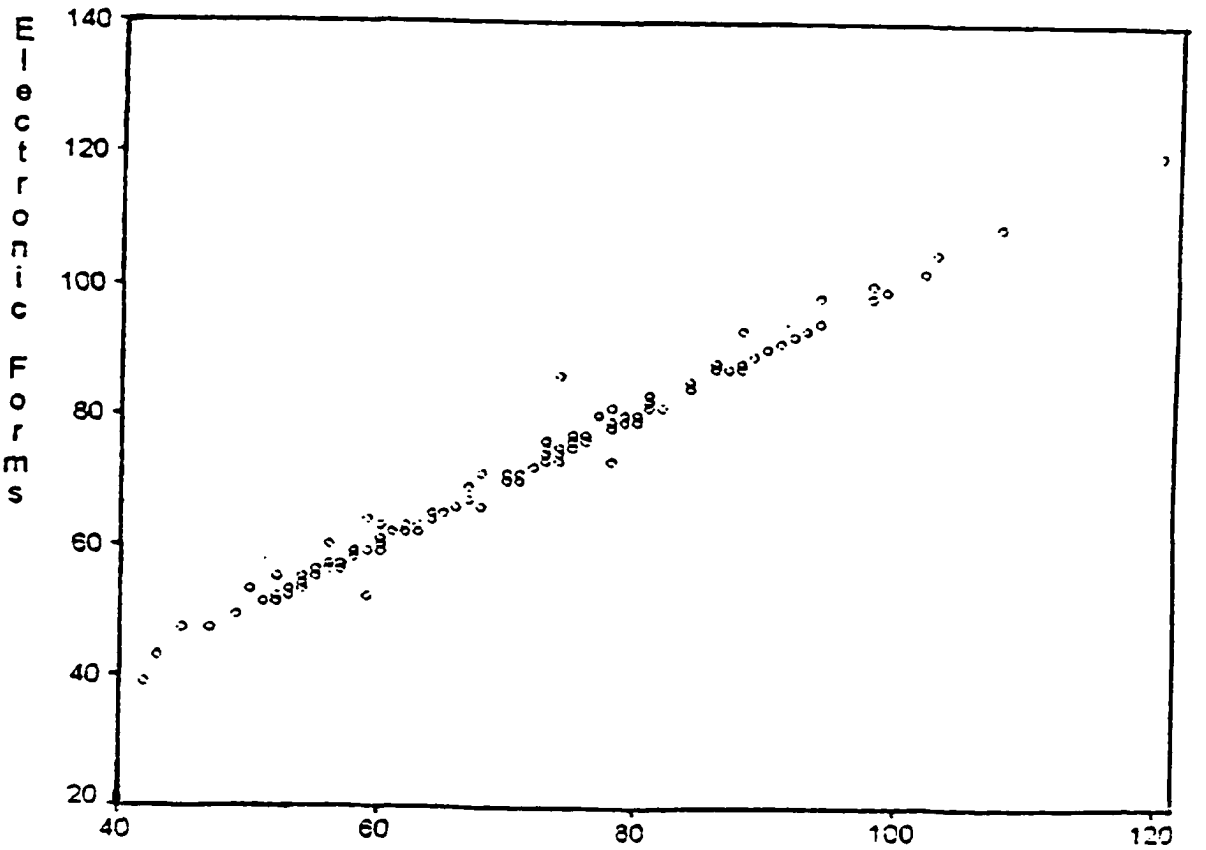
	Data Entry Personnel Errors		Rater Errors		Total Errors	
Section	n	Percent of Total	n	Percent of Total	n	Percent of Total
Demo	21	14.00%	19	12.67%	40	26.67%
PtHist	14	9.33%	2	1.33%	16	10.67%
DiagOR	14	9.33%	2	1.33%	16	10.67%
Trtmnt	2	1.33%	8	5.33%	10	6.67%
Diag	15	10.00%	1	0.67%	16	10.67%
Diagcur	5	3.33%	0	0.00%	5	3.33%
Compnt	7	4.67%	1	0.67%	8	5.33%
Diaglst	2	1.33%	0	0.00%	2	1.33%
Proclst	2	1.33%	0	0.00%	2	1.33%
Valve	0	0.00%	0	0.00%	0	0.00%

Table 8 continued

Shunts	0	0.00%	0	0.00%	0	0.00%
CPBP	14	9.33%	2	1.33%	16	10.67%
PstOp	11	7.33%	8	5.33%	19	12.67%
Total	**107**	**71.33%**	**43**	**28.67%**	**150**	**100.00%**

Figure 1

Accuracy of Electronic vs Collection forms



Collection Forms

Methodology for the Determination of DB Derived Data

Chapter V

Discussion

Although fourteen individuals were responsible for the data in the database, the personnel responsible for the preponderance of error were the three surgeons who rated the DB forms and two DB entry personnel (ID numbers 2 and 3) who entered the bulk of the data into the database. The surgeons (raters) made very few data processing errors. Most of the data processing errors in the database were associated with the two data entry personnel above and not the remaining data entry personnel. A possible reason for the disparity between these data entry personnel and the remaining seven data entry personnel is all of the work of the seven had been double-checked. Because of limited time and resources, it was not possible to double-check all of the data entered by the two. Thus, it is important to the reliability of the database that all data entry personnel work be double-checked. This information should be useful to database managers developing data processing procedures.

Errors of omission were the most prevalent type of data processing error found among both raters and data entry personnel. Omission errors by raters constituted failure to record data onto DB forms. Most of the rater errors were found in the demographic section of the database. Although held responsible, raters did not complete this section of the form. The two individuals who completed this section of the DB form were actually responsible for these data processing errors.

Errors of omission by data entry personnel were failures to enter data recorded on the DB forms into the database. These were the most common errors made by the two principal data entry personnel referred to above. It was interesting that most of the data entry errors were also found in the demographic section of the database. Other prevalent areas with data entry errors were the Diagnosis, Patient History, and Diagnostic and Operative data sections of the DB form. It is extremely important to be able to maintain a high level of accuracy in these areas of the database, since diagnoses and prognoses are dependent on these data. Double-checking the work would have most likely greatly reduced the prevalence of these errors.

The methodology for the assessment of DB reliability proposed in this report contends that reliability is "predicated on a conglomerate of estimates which sum to the total reliability of the database" (p. 3). And further, "is an integrated approach to estimating reliability" (p. 3). In order to do this assessments should be made considering every possible source of error that could hypothetically influence observed scores. Careful scrutiny of a database would necessarily include assessment of all possible forms of error or at least assess what was available for measurement. This report suggests that if possible and appropriate, researchers consider examining at minimum the following five sources of variability estimated by the appropriate measurement coefficient and generated by the appropriate test of measurement as follows:

Source of Variability	Estimator	Measurement test
1. Interrater	Generalizability coefficient	ANOVA
2. Intrarater	Coefficient of stability	Pearson/Spearman
3. Intrasubject	Coefficient of stability	Pearson/Spearman
4. Data processing	Coefficient of equivalence	Pearson/Spearman
5. Data communication	Coefficient of equivalence	Pearson/Spearman

Ideally, there would be a coefficient generated for each source of variability. In the case of this report, available variability for measurement included data processing errors. Data communication and intrasubject variability as previously sited (p. 54) could not be obtained due to logistics and ethics respectively. Obtaining estimates for intrarater and interrater variability was impeded also. Since raters served as observational instruments, determining factors of intrarater and interater error, and estimating reliability based upon these types of error was contingent upon raters abilities to recreate or recall rating conditions. In this case, regeneration posed a logistical problem. Due to the loss of surgical staff and an increase in their caseloads, available surgeons were precluded from having time to recall and recreate conditions. Re-quirements for rerating NYHA and Status would have involved spending time already allocated to patient care, on surveying charts for background information.

Domholdt (1993) noted that observational measurements such as the NYHA, only require human observation and systematic knowledge of what to observe. Further, human observers as required for NYHA rating, play a passive, unobtrusive role in the rating of the subjects. Additionally the NYHA scale was

considered by the surgeons (raters), to be inappropriate as a measurement tool for the pediatric cardiac population and should only be interpreted for the adult population which is hardly representative of the usual pediatric patient population. Further these scores can only be interpreted very cautiously for the adult population. It would be inappropriate to use the scores to guide medical treatment for a predominately pediatric environment.

Since reproduction of NYHA and Status ratings were impossible to obtain, intrarater and interrater reliability coefficients could not be assessed. Errors generated from these variables would be linked to the overall reliability estimate. However, any error produced by these variables could not be measured. Thus, possible influences of error were subsumed by the data processing errors and that were identified for examination.

Researchers should be aware of other possible contributors of error such as interrater or intrarater error when attempting to draw conclusions since the reliability assessment of the database was based on rater and data entry personnel data processing errors exclusively. New York Heart Association and Status represented only two out of an average of 71.73 coded variables. Errors from these two variables may only have had a minor impact upon the total reliability of the database. Nevertheless, in matters of health assessments, being able to determine the level of accuracy on all database-derived data before decisions are made, may be critical.

This report aimed to bring to researchers' attention the importance of checking databases or performing quality evaluations. The reliability estimates

based on data processing accuracy only, can be quite useful. Even though all methodology could not be employed, this report brought investigators to a greater level of confidence about the condition of the stored data. Further, because of this investigation, it is brought forward that we should not rely or be completely confident about the NYHA ratings or Status variables. Investigators should especially proceed with caution when analyzing NYHA for two major reasons 1. Ratings for the pediatric patient may not be appropriately applied 2. Assessment of overall reliability was not possible. However, estimates reflected the accuracy of the data from the point of recording it on to the paper form to the point it was entered into the database. Additionally, this evaluation provided specific information on the strength of the correlation of equivalence of the data from paper to the database. The investigator was also able to identify 1. who was making the errors among raters and data entry personnel 2. the location of these errors, and 3. the types of errors made.

This information provided an opportunity for managers to make adjustments on data processing operations in order to refine and subsequently improve the reliability status of the database. This methodology presented a snapshot of the general condition of the database. Possession of this information is the basis of the confidence inquirers would be able to place in database derived data at that point in time. It is therefore highly recommended that the proposed methodology for database assessment be applied as often as possible at regular intervals, especially prior to publication of research or making decisions.

At this juncture, the investigator is able to offer a concise statement on the state of the Children's Hospital of Michigan, Department of Cardiovascular Surgery database. The database is highly reliable for data processing (coefficient of equivalence =.99 {p=.000}). However, caution is advised when examining recorded information based on scaled ratings, since the reliability of these data is undetermined.

The above statement notably offers inquirers a concise statement on the state of a medical database currently operating as a basis for medical research and decision making. It would be a valuable practice to have at the very least, all medical databases be required to report on database reliability status in a concise, standardized manner.

Appendix A

Customized version of the Society of Thoracic Surgeons National Congenital Heart Surgery Database Form (c. 1995)

THE SOCIETY OF THORACIC SURGEONS

NATIONAL CONGENITAL SURGERY DATABASE

DATA COLLECTION FORM

Demographics

Form Complete ☐ Yes ☐ No

Patient Name (Last,First,M.) _____

Member Number: ☐☐☐☐☐ (5 Digit Number) Country: _____

Address: _____ City: _____ State: _____

ZIP: _____ Telephone: (_____) - _____ - _____ Social Security Number: _____ - _____ - _____

Hospital: _____ Hospital Number: _____

Insurer: ☐ BCBS ☐ Medicaid ☐ CHAMPUS ☐ Private/Corporate/Self Pay ☐ HMO/PPO ☐ Uninsured

Planned Same Day Admission: ☐ Yes Billing Account #: _____

Dates (time): Admission: __/__/__ (__:__) Surgery: 1. __/__/__ (__:__) 2. __/__/__ (__:__) 3. __/__/__ (__:__)

Discharge: __/__/__ (__:__) #of Operations During This Admission: ☐ 1 ☐ 2 ☐ 3 or More

Date of Birth: ___ - ___ - ___ Age _____ Sex: ☐ Male ☐ Female #Open: _____ #Closed: _____

Race: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other _____

Ref. Cardiologist: _____ Address: _____ Phone: (___) - ___ - _____

Ref. Physician: _____ Address: _____ Phone: (___) - ___ - _____

Staff Surgeon: _____ Assistant Staff Surgeon: _____ Resident Surgeon: _____

Primary Resident Surgeon: _____ Second Resident Surgeon: _____

Patient History

Weight: ____ kg Height: ____ cm BSA: ____ m^2

Non-Cardiac Abnormalities:
☐ Asplenia/Polysplenia
☐ Down's
☐ Other Chromosome
☐ DiGeorge
☐ Other _____

Signs and Symptoms:
☐ Cyanosis (O_2 sat <85%)
☐ Polycythemia (Hct >60)
☐ CHF
☐ Hypoxic Spells
☐ Neurologic Deficit
☐ Pre-Op ECMO
☐ Fatigue, Exercise Intolerance

Labs:
☐ Hct: ____ %
☐ O_2 Sat: ____ %

Pre-op Medications:
☐ Digoxin ☐ Diuretics ☐ Antiarrhythmic ☐ Other

☐ Yes ☐ Prematurity
☐ Bleeding Disorder
☐ Ventilatory Support
☐ Renal Failure (Creat >2)
☐ Marfan's Syndrome
☐ Shone's ☐ Tumors

☐ Yes
☐ Infective Endocarditis
☐ Shock
☐ Asymptomatic
☐ Acidosis
☐ Pre-Op Mech Support
☐ Failure To Thrive
☐ Other

☐ Yes
☐ BUN: ____ mg/dl
☐ Creat: ____ mg/dl

☐ Yes
☐ Prostaglandins ☐ Vasodilators ☐ Antiplatelet ☐ $NaHCO_3$
☐ IV Inotropes ☐ Inderal ☐ Anticoagulant ☐ Antibiotic

DIAGNOSTIC AND OPERATIVE DATA

Imaging Diagnostic Procedures: ☐ Yes
☐ Echocardiography ☐ Cardiac Catheterization
☐ MRI ☐ CT Scan
☐ Angiography ☐ PET
☐ Electrophysiologic Study ☐ Other ☐ ECG

Pre-Op Catheterization Data: ☐ Yes Date: ___ - ___ - ___
☐ Pulmonary Hypertension (50% Systemic Pressure)
☐ Pulmonary Vascular Disease (>3 Wood Units)
Systemic Ventricular Function
☐ Normal ☐ Depressed ☐ Severely Depressed
Pulmonary-to-Systemic Flow Ratio _____ : 1
☐ Balloon Septostomy
☐ Significant PA Distortion
☐ Other: _____
☐ PVR: _____ Woods·m^2 ☐ SVR: _____ Woods·m^2
☐ Cardiac Index: _____ L/min/m^2

Status:
☐ Elective ☐ Urgent ☐ Emergent for Salvage

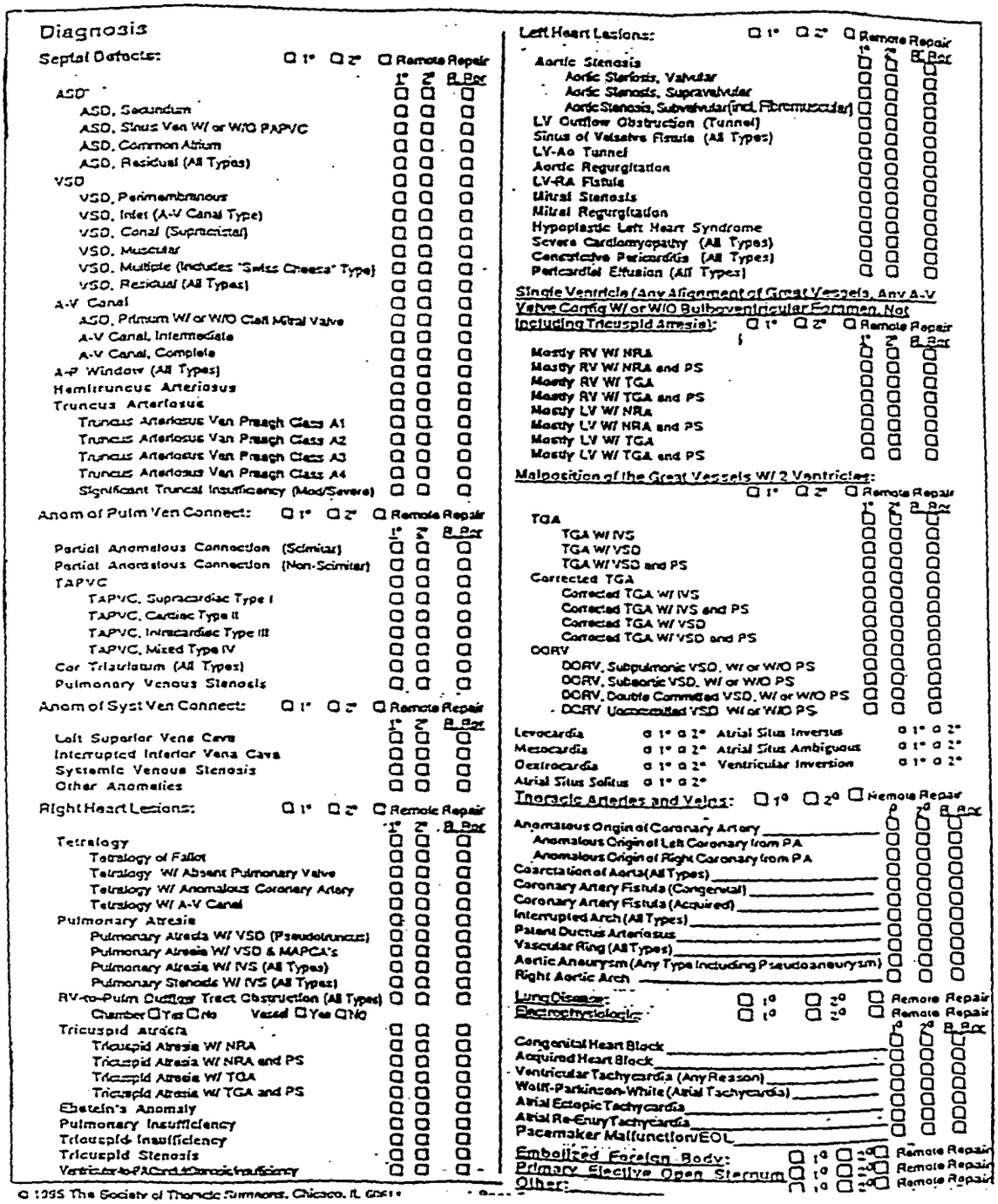
ASA Class (1-5): _____ NYHA Funct. Class (1-4): _____

Treatment Categories (For This Entry)

Is this a re-sternotomy: ☐ Yes
Is this procedure: ☐ Palliative ☐ Corrective (Anatomic/Physiologic)
What Number open or closed operative heart surgery procedure is this:
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 or more

Previous Vascular/Cath Interventions: ☐ Yes
☐ Balloon Dilatation ☐ Stents
☐ Septal/PDA Closure ☐ Coil Embolization
☐ Catheter Ablation ☐ Other

Previous Palliative Procedures:
☐ Increase effective pulmonary artery flow
☐ Pulmonary artery band
☐ Atrial septectomy
☐ Stage I Norwood operation or Damus-Stansel-Kaye
☐ Other _____
☐ Systemic to Pulmonary artery shunt
☐ Cavopulmonary shunt



Diagnosis

Septal Defects: ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
ASD	☐	☐	☐
ASD, Secundum	☐	☐	☐
ASD, Sinus Ven W/ or W/O PAPVC	☐	☐	☐
ASD, Common Atrium	☐	☐	☐
ASD, Residual (All Types)	☐	☐	☐
VSD	☐	☐	☐
VSD, Perimembranous	☐	☐	☐
VSD, Inlet (A-V Canal Type)	☐	☐	☐
VSD, Conal (Supracristal)	☐	☐	☐
VSD, Muscular	☐	☐	☐
VSD, Multiple (Includes "Swiss Cheese" Type)	☐	☐	☐
VSD, Residual (All Types)	☐	☐	☐
A-V Canal	☐	☐	☐
ASD, Primum W/ or W/O Cleft Mitral Valve	☐	☐	☐
A-V Canal, Intermediate	☐	☐	☐
A-V Canal, Complete	☐	☐	☐
A-P Window (All Types)	☐	☐	☐
Hemitruncus Arteriosus	☐	☐	☐
Truncus Arteriosus	☐	☐	☐
Truncus Arteriosus Van Praagh Class A1	☐	☐	☐
Truncus Arteriosus Van Praagh Class A2	☐	☐	☐
Truncus Arteriosus Van Praagh Class A3	☐	☐	☐
Truncus Arteriosus Van Praagh Class A4	☐	☐	☐
Significant Truncal Insufficiency (Mod/Severe)	☐	☐	☐

Anom of Pulm Ven Connect: ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
Partial Anomalous Connection (Scimitar)	☐	☐	☐
Partial Anomalous Connection (Non-Scimitar)	☐	☐	☐
TAPVC	☐	☐	☐
TAPVC, Supracardiac Type I	☐	☐	☐
TAPVC, Cardiac Type II	☐	☐	☐
TAPVC, Intracardiac Type III	☐	☐	☐
TAPVC, Mixed Type IV	☐	☐	☐
Cor Triatriatum (All Types)	☐	☐	☐
Pulmonary Venous Stenosis	☐	☐	☐

Anom of Syst Ven Connect: ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
Left Superior Vena Cava	☐	☐	☐
Interrupted Inferior Vena Cava	☐	☐	☐
Systemic Venous Stenosis	☐	☐	☐
Other Anomalies	☐	☐	☐

Right Heart Lesions: ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
Tetralogy	☐	☐	☐
Tetralogy of Fallot	☐	☐	☐
Tetralogy W/ Absent Pulmonary Valve	☐	☐	☐
Tetralogy W/ Anomalous Coronary Artery	☐	☐	☐
Tetralogy W/ A-V Canal	☐	☐	☐
Pulmonary Atresia	☐	☐	☐
Pulmonary Atresia W/ VSD (Pseudotruncus)	☐	☐	☐
Pulmonary Atresia W/ VSD & MAPCA's	☐	☐	☐
Pulmonary Atresia W/ IVS (All Types)	☐	☐	☐
Pulmonary Stenosis W/ IVS (All Types)	☐	☐	☐
RV-to-Pulm Outflow Tract Obstruction (All Types)	☐	☐	☐
Chamber ☐ Yes ☐ No Valved ☐ Yes ☐ No			
Tricuspid Atresia	☐	☐	☐
Tricuspid Atresia W/ NRA	☐	☐	☐
Tricuspid Atresia W/ NRA and PS	☐	☐	☐
Tricuspid Atresia W/ TGA	☐	☐	☐
Tricuspid Atresia W/ TGA and PS	☐	☐	☐
Ebstein's Anomaly	☐	☐	☐
Pulmonary Insufficiency	☐	☐	☐
Tricuspid Insufficiency	☐	☐	☐
Tricuspid Stenosis	☐	☐	☐
Ventricle-to-PA Conduit Stenosis/Insufficiency	☐	☐	☐

Left Heart Lesions: ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
Aortic Stenosis	☐	☐	☐
Aortic Stenosis, Valvular	☐	☐	☐
Aortic Stenosis, Supravalvular	☐	☐	☐
Aortic Stenosis, Subvalvular (incl. Fibromuscular)	☐	☐	☐
LV Outflow Obstruction (Tunnel)	☐	☐	☐
Sinus of Valsalva Fistula (All Types)	☐	☐	☐
LV-Ao Tunnel	☐	☐	☐
Aortic Regurgitation	☐	☐	☐
LV-RA Fistula	☐	☐	☐
Mitral Stenosis	☐	☐	☐
Mitral Regurgitation	☐	☐	☐
Hypoplastic Left Heart Syndrome	☐	☐	☐
Severe Cardiomyopathy (All Types)	☐	☐	☐
Constrictive Pericarditis (All Types)	☐	☐	☐
Pericardial Effusion (All Types)	☐	☐	☐

Single Ventricle (Any Alignment of Great Vessels, Any A-V Valve Config W/ or W/O Bulboventricular Foramen, Not Including Tricuspid Atresia): ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
Mostly RV W/ NRA	☐	☐	☐
Mostly RV W/ NRA and PS	☐	☐	☐
Mostly RV W/ TGA	☐	☐	☐
Mostly RV W/ TGA and PS	☐	☐	☐
Mostly LV W/ NRA	☐	☐	☐
Mostly LV W/ NRA and PS	☐	☐	☐
Mostly LV W/ TGA	☐	☐	☐
Mostly LV W/ TGA and PS	☐	☐	☐

Malposition of the Great Vessels W/ 2 Ventricles: ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
TGA	☐	☐	☐
TGA W/ IVS	☐	☐	☐
TGA W/ VSD	☐	☐	☐
TGA W/ VSD and PS	☐	☐	☐
Corrected TGA	☐	☐	☐
Corrected TGA W/ IVS	☐	☐	☐
Corrected TGA W/ IVS and PS	☐	☐	☐
Corrected TGA W/ VSD	☐	☐	☐
Corrected TGA W/ VSD and PS	☐	☐	☐
DORV	☐	☐	☐
DORV, Subpulmonic VSD, W/ or W/O PS	☐	☐	☐
DORV, Subaortic VSD, W/ or W/O PS	☐	☐	☐
DORV, Double Committed VSD, W/ or W/O PS	☐	☐	☐
DORV Uncommitted VSD W/ or W/O PS	☐	☐	☐

Levocardia ☐ 1° ☐ 2° Atrial Situs Inversus ☐ 1° ☐ 2°
Mesocardia ☐ 1° ☐ 2° Atrial Situs Ambiguous ☐ 1° ☐ 2°
Dextrocardia ☐ 1° ☐ 2° Ventricular Inversion ☐ 1° ☐ 2°
Atrial Situs Solitus ☐ 1° ☐ 2°

Thoracic Arteries and Veins: ☐ 1° ☐ 2° ☐ Remote Repair

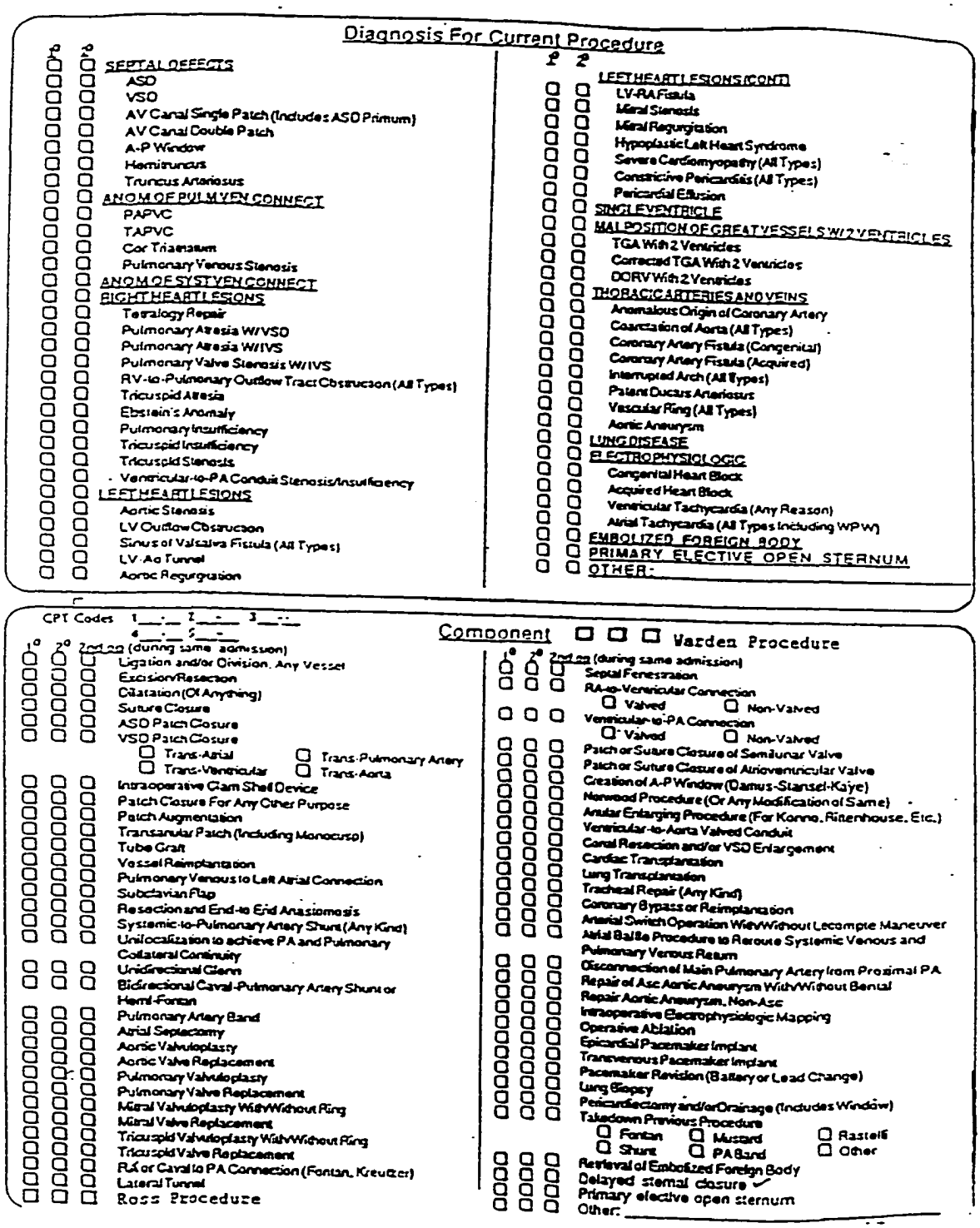
	1°	2°	R. Rpr
Anomalous Origin of Coronary Artery _____	☐	☐	☐
Anomalous Origin of Left Coronary from PA	☐	☐	☐
Anomalous Origin of Right Coronary from PA	☐	☐	☐
Coarctation of Aorta (All Types) _____	☐	☐	☐
Coronary Artery Fistula (Congenital) _____	☐	☐	☐
Coronary Artery Fistula (Acquired) _____	☐	☐	☐
Interrupted Arch (All Types) _____	☐	☐	☐
Patent Ductus Arteriosus _____	☐	☐	☐
Vascular Ring (All Types) _____	☐	☐	☐
Aortic Aneurysm (Any Type Including Pseudoaneurysm)	☐	☐	☐
Right Aortic Arch _____	☐	☐	☐

Lung Disease: ☐ 1° ☐ 2° ☐ Remote Repair

Electrophysiologic: ☐ 1° ☐ 2° ☐ Remote Repair

	1°	2°	R. Rpr
Congenital Heart Block _____	☐	☐	☐
Acquired Heart Block _____	☐	☐	☐
Ventricular Tachycardia (Any Reason) _____	☐	☐	☐
Wolff-Parkinson-White (Atrial Tachycardia) _____	☐	☐	☐
Atrial Ectopic Tachycardia _____	☐	☐	☐
Atrial Re-Entry Tachycardia _____	☐	☐	☐
Pacemaker Malfunction/EOL _____	☐	☐	☐

Embolized Foreign Body: ☐ 1° ☐ 2° ☐ Remote Repair
Primary Elective Open Sternum ☐ 1° ☐ 2° ☐ Remote Repair
Other: _____ ☐ 1° ☐ 2° ☐ Remote Repair



Diagnosis For Current Procedure

1°	2°	
		SEPTAL DEFECTS
		ASD
		VSD
		AV Canal Single Patch (Includes ASD Primum)
		AV Canal Double Patch
		A-P Window
		Hemitruncus
		Truncus Arteriosus
		ANOM OF PULM VEN CONNECT
		PAPVC
		TAPVC
		Cor Triatriatum
		Pulmonary Venous Stenosis
		ANOM OF SYST VEN CONNECT
		RIGHT HEART LESIONS
		Tetralogy Repair
		Pulmonary Atresia W/VSD
		Pulmonary Atresia W/IVS
		Pulmonary Valve Stenosis W/IVS
		RV-to-Pulmonary Outflow Tract Obstruction (All Types)
		Tricuspid Atresia
		Ebstein's Anomaly
		Pulmonary Insufficiency
		Tricuspid Insufficiency
		Tricuspid Stenosis
		Ventricular-to-PA Conduit Stenosis/Insufficiency
		LEFT HEART LESIONS
		Aortic Stenosis
		LV Outflow Obstruction
		Sinus of Valsalva Fistula (All Types)
		LV-Ao Tunnel
		Aortic Regurgitation

1°	2°	
		LEFT HEART LESIONS (CONT)
		LV-RA Fistula
		Mitral Stenosis
		Mitral Regurgitation
		Hypoplastic Left Heart Syndrome
		Severe Cardiomyopathy (All Types)
		Constrictive Pericarditis (All Types)
		Pericardial Effusion
		SINGLE VENTRICLE
		MALPOSITION OF GREAT VESSELS W/2 VENTRICLES
		TGA With 2 Ventricles
		Corrected TGA With 2 Ventricles
		DORV With 2 Ventricles
		THORACIC ARTERIES AND VEINS
		Anomalous Origin of Coronary Artery
		Coarctation of Aorta (All Types)
		Coronary Artery Fistula (Congenital)
		Coronary Artery Fistula (Acquired)
		Interrupted Arch (All Types)
		Patent Ductus Arteriosus
		Vascular Ring (All Types)
		Aortic Aneurysm
		LUNG DISEASE
		ELECTROPHYSIOLOGIC
		Congenital Heart Block
		Acquired Heart Block
		Ventricular Tachycardia (Any Reason)
		Atrial Tachycardia (All Types Including WPW)
		EMBOLIZED FOREIGN BODY
		PRIMARY ELECTIVE OPEN STERNUM
		OTHER:

CPT Codes 1____ 2____ 3____
4____ 5____

Component ☐☐☐ Warden Procedure

1°	2°	2nd on (during same admission)	
			Ligation and/or Division, Any Vessel
			Excision/Resection
			Dilatation (Of Anything)
			Suture Closure
			ASD Patch Closure
			VSD Patch Closure
			☐ Trans-Atrial ☐ Trans-Pulmonary Artery ☐ Trans-Ventricular ☐ Trans-Aorta
			Intraoperative Clam Shell Device
			Patch Closure For Any Other Purpose
			Patch Augmentation
			Transannular Patch (Including Monocusp)
			Tube Graft
			Vessel Reimplantation
			Pulmonary Venous to Left Atrial Connection
			Subclavian Flap
			Resection and End-to End Anastomosis
			Systemic-to-Pulmonary Artery Shunt (Any Kind)
			Unilocalization to achieve PA and Pulmonary Collateral Continuity
			Unidirectional Glenn
			Bidirectional Caval-Pulmonary Artery Shunt or Hemi-Fontan
			Pulmonary Artery Band
			Atrial Septectomy
			Aortic Valvuloplasty
			Aortic Valve Replacement
			Pulmonary Valvuloplasty
			Pulmonary Valve Replacement
			Mitral Valvuloplasty With/Without Ring
			Mitral Valve Replacement
			Tricuspid Valvuloplasty With/Without Ring
			Tricuspid Valve Replacement
			RA or Caval to PA Connection (Fontan, Kreutzer)
			Lateral Tunnel
			Ross Procedure

1°	2°	2nd on (during same admission)	
			Septal Fenestration
			RA-to-Ventricular Connection ☐ Valved ☐ Non-Valved
			Ventricular-to-PA Connection ☐ Valved ☐ Non-Valved
			Patch or Suture Closure of Semilunar Valve
			Patch or Suture Closure of Atrioventricular Valve
			Creation of A-P Window (Damus-Stansel-Kaye)
			Norwood Procedure (Or Any Modification of Same)
			Annular Enlarging Procedure (For Konno, Rittenhouse, Etc.)
			Ventricular-to-Aorta Valved Conduit
			Canal Resection and/or VSD Enlargement
			Cardiac Transplantation
			Lung Transplantation
			Tracheal Repair (Any Kind)
			Coronary Bypass or Reimplantation
			Arterial Switch Operation With/Without Lecompte Maneuver
			Atrial Baffle Procedure to Reroute Systemic Venous and Pulmonary Venous Return
			Disconnection of Main Pulmonary Artery from Proximal PA
			Repair of Asc Aortic Aneurysm With/Without Bental
			Repair Aortic Aneurysm, Non-Asc
			Intraoperative Electrophysiologic Mapping
			Operative Ablation
			Epicardial Pacemaker Implant
			Transvenous Pacemaker Implant
			Pacemaker Revision (Battery or Lead Change)
			Lung Biopsy
			Pericardiectomy and/or Drainage (Includes Window)
			Takedown Previous Procedure ☐ Fontan ☐ Mustard ☐ Rastelli ☐ Shunt ☐ PA Band ☐ Other
			Retrieval of Embolized Foreign Body
			Delayed sternal closure ✓
			Primary elective open sternum
			Other:

Valve and Valved Conduit Surgery Data

Procedure	Prosthesis			
Aortic: _____	Implant: _____	Size: ____ mm	Type: ____
	Explant: _____	Size: ____ mm	Type: ____
Mitral: _____	Implant: _____	Size: ____ mm	Type: ____
	Explant: _____	Size: ____ mm	Type: ____
Tricuspid: _____	Implant: _____	Size: ____ mm	Type: ____
	Explant: _____	Size: ____ mm	Type: ____
Pulmonic: _____	Implant: _____	Size: ____ mm	Type: ____
	Explant: _____	Size: ____ mm	Type: ____

Key For Table

Procedure
1 = Replacement
2 = Annuloplasty Ring
3 = Annuloplasty-No Ring
4 = Commissurotomy Ring
5 = Commissurotomy-No Ring
6 = Chordal Rupture Repair
7 = Papillary Muscle Repair
8 = Aortic Root Reconstruction
9 = Vent to PA Valved Conduit
10 = LV to Ao Conduit
11 = Konno

MECHANICAL
1 = Medtronic Hall
2 = Bjork-Shiley Conv/Conc
3 = Shiley Monostrut
4 = Starr-Edwards
5 = Omniscience
6 = Carbomedics
7 = St. Jude Medical
8 = Omnicarbon

BIOPROSTHAMOMOCRAFT
9 = Medtronic Intact
10 = Hancock Mod II
11 = Hancock II
12 = St. Jude Biocompliant
13 = Ionescu-Low Profile
14 = Meadox
15 = Carpentier-High
16 = Carpentier-Low
17 = Carpentier-SAV
18 = Carpentier-Pericardial
19 = Carpentier-Porcine
20 = Duromedics
21 = Cryopreserved
22 = Fresh
23 = Pulmonary Autograft

Size
Valve Size in mm

Type
M = Mechanical
B = Bioprosthesis
H = Homograft
A = Autograft

Shunts

Type: _____ Material: _____ Size: ___ mm

Type
1 = Blalock-Taussig Classic
2 = Modified Blalock Taussig
3 = Central
4 = All Others

Material
1 = PTFE
2 = Dacron
3 = All Others

Cardiopulmonary Bypass and Support Data

Cross Clamp Time: ____ min. Perfusion Time: ____ min.
Circ. Arrest Time: ____ min. Inflow Occlusion Time: ____ min.
Lowest Core Temp.: ____ (C°) 10% Flow: ____ min.
Cardioplegia: ☐ Yes
☐ Blood ☐ Induced Fib ☐ Crystalloid
☐ O2 Crystalloid ☐ Other
Flow: ☐ Retrograde ☐ Antegrade
Temperature: ☐ Warm ☐ Cold
Topical Hypothermia ☐ Yes ☐ No
Warm Reperfusate ☐ Yes ☐ No

Pacing Usage Leaving O.R.: ☐ Yes
☐ Atrial ☐ Ventricular ☐ Dual Chamber

Intra/Post-Op VAD: ☐ Yes
☐ LVAD ☐ RVAD
☐ BVAD ☐ TAH
☐ IABP ☐ ECMO
☐ Open Sternum
☐ Cell Saver Used
☐ Ultra Filtration Used

Post-Operative Data

Blood Bank Products Used: ☐ Yes
☐ RBC ☐ FFP ☐ Cryo ☐ Platelets
☐ Fresh Blood < 48 Hrs ☐ Whole Blood ≥ 48 hrs
☐ Fibrin Glue ☐ Aprotinin

Complications: ☐ Yes ☐ No
Interval: ☐ In Hospital <30 days
☐ In Hospital >30 days
☐ Out of Hospital <30 days

Operative: ☐ Yes
☐ Re-op/Bleeding
☐ Re-op/Valve Dysfunction
☐ Re-op for Residual Defect (During Same Admission)
☐ Re-op/Other Cardiac
☐ Re-op/Other Non-Cardiac
☐ Re-op/Sternal Closure

Infection: ☐ Yes ☐ Minor ☐ Major
☐ UTI ☐ Sepsis
☐ Wound

Neurologic: ☐ Yes ☐ Minor ☐ Major
☐ Seizures

Pulmonary: ☐ Yes ☐ Ventilator >5 days
☐ Respiratory Arrest

Renal: ☐ Yes ☐ Post-Op Dialysis/ Hemofiltration

Pressures: RV: _____ Sys: _____ RV/Sys Ratio: _____

Other: ☐ Yes
☐ Peri-Op Heart Block (Temp Pacing, Resolved)
☐ Peri-Op Heart Block (Temp Pacing, Perm Pace)
☐ Arrhythmia (No PM Required)
☐ Cardiac Arrest
☐ Anticoagulant Complication
☐ Tamponade
☐ GI Complications
☐ Multi-system Failure.
☐ Low Cardiac Output
☐ Pleural Effusion or Chylothorax
☐ Phrenic Nerve Injury
☐ Transplant Rejection
☐ Nutritional Support
☐ Recurrent Laryngeal Nerve Injury
☐ Pneumothorax
☐ Other: _____

Mortality: ☐ Yes Date ____/____/____
Operative Death: ☐ Yes
Interval:
☐ In Hospital <30 days
☐ In Hospital >30 days
☐ Out of Hospital <30 days
☐ Out of Hospital >30 days
Cause of Death:
☐ Cardiac ☐ Infection
☐ Neurologic ☐ Pulmonary
☐ Renal ☐ Valvular
☐ Vascular ☐ Other
☐ Sudden

Appendix B

Congenital Heart Surgery Database Variable Dictionary

Database Dictionary For Module: Congenital Heart Surgery Module

Childrens Hospital of Michigan
The Society of Thoracic Surgeons
National Congenital Heart Surgery Database
DEMOGRAPHICS

Form Complete: 1
Patient Name: 2 Member #: 3
Address: 4 City: 5
State: 6 Zip: 7 Country: 8
Telephone: 9 Social Security Number: 10
Hospital: 11 Hospital #: 12
Insurer : 13 Planned Same Day Admission: 14
Billing Account#: 15
Dates: Admission: 16 Surgery: 1. 17 Discharge: 18
2. 19
3. 20
Time: 21 hr 22 hr 23 hr
LOS: Admit-Surg: 24 Surg-Disch: 25 Admit-Disch: 26
# of Operations During This Admission: 27 #Open: 28 #Closed: 29

Date Of Birth: 30 Age: 31 Years Sex: 32
Race: 33
Referring Cardiologist: 34
Address: 35
36
City: 37
State: 38 Zip: 39
Telephone: 40

Referring Physician: 41
Address: 42
43
City: 44
State: 45 Zip: 46
Telephone: 47

Staff Surgeon: 48
Asst Staff Surgeon: 49
Resident Surgeon: 50

Database Dictionary For Module: Congenital Heart Surgery Module

Primary Resident Surgeon: 51
Second Resident Surgeon: 52

PATIENT HISTORY

Weight: 53 kg Height: 54 cm BSA: 55 meter(s) squared

Non-Cardiac Abnormalities: 56
- Asplenia/Polysplenia: 58
- Down's: 60
- Other Chromosome: 62
- DiGeorge: 64
- Other: 66

68

Premature: 57
Bleeding Disorder: 59
Ventilatory Support: 61
Renal Failure (Creat>2): 63
Marfan's Syndrome: 65
Shone's Syndrome: 67
Turner's Syndrome: 69

Signs and Symptoms: 70
- Cyanosis (O2 sat<85%): 71
- Polycythemia (Hct>60): 73
- CHF: 75
- Hypoxic Spells: 77
- Neurologic Deficit: 79
- Pre-Op ECMO: 81
- Fatigue, Excercise Intolerance: 83

Infectious Endocarditis: 72
Shock: 74
Asymptomatic: 76
Acidosis: 78
Pre-Op Mech Support: 80
Failure to Thrive: 82
Other: 84

85

PATIENT HISTORY (cont'd)

Labs: 86
- Hct: 87 %
- O2 Sat: 89 %

BUN: 88 mg/dl
Creat: 90 mg/dl

Pre-Op Medications: 91
- Digoxin: 92
- Diuretics: 95
- Antiarrhythmic: 98
- Other: 101

104

Prostaglandins: 93
Vasodilators: 96
Antiplatelet: 99
NaHCO3: 102

IV Inotropes: 94
Inderal: 97
Anticoagulant: 100
Antibiotic: 103

Database Dictionary For Module: Congenital Heart Surgery Module

DIAGNOSTIC AND OPERATIVE DATA

Imaging Diagnostic Procedures: 105

Echocardiography:	106	Cardiac Catheterization:	107
MRI:	108	CT Scan:	109
Angiography:	110	PET:	111
Electrophys Study:	112	ECG:	113
		Other: 114	115

DIAGNOSTIC AND OPERATIVE DATA (cont'd)

Pre-Op Catheterization Date: 116

Pre-Op Catheterization Data: 117

Pulmonary Hypertension (50% Systemic Pressure): 118

Pulmonary Vascular Disease (>3 Wood Units): 119

Systemic Ventricular Function: 120

Pulmonary-to-Systemic Flow Ratio: 121 :1

Balloon Septostomy: 122

Significant PA Distortion: 123

Other: 124

PVR: 125 Woods *meter(s) squared SVR: 126 Woods *meter(s) squared

Cardiac Index: 127 L/m/meter(s) squared

Status: 128 ASA Classification(1-5): 129

NYHA Functional Class(1-4): 130

TREATMENT CATEGORIES

Is this a Re-Sternotomy: 131

Is this Procedure: Palliative: 132 Corrective (Anatomic/Physiologic): 133

What Number Open or Closed Operative Heart Surgery Proc is this : 134

Previous Vascular/Cath Interventions: 135

Database Dictionary For Module: Congenital Heart Surgery Module

Balloon Dilatation: 136
Stents: 137
Septal/PDA Closure: 138
Coil Embolization: 139
Catheter Ablation: 140
Other: 141

142

Previous Palliative Procedures: 143
Increased Effective Pulmonary Artery Flow: 144
Pulmonary Artery Band: 145
Atrial Septectomy: 146
Stage 1 Norwood Operation or Damus-Stansel-Kaye: 147
Other: 148 149
Systemic to Pulmonary artery shunt 150
Cavopulmonary shunt 151

DIAGNOSIS - SEPTAL DEFECTS

Septal Defects: 152

ASD: 153
ASD, Secundum: 154
ASD, Sinus Ven With or Without PAPVC: 155
ASD, Common Atrium: 156
ASD, Residual (All Types): 157

VSD: 158
VSD, Perimembranous: 159
VSD, Inlet (A-V Canal Type): 160
VSD, Conal (Supracristal): 161
VSD, Muscular: 162
VSD, Multiple (Incl Swiss Cheese Type): 163
VSD, Residual (All Types): 164

DIAGNOSIS - SEPTAL DEFECTS (cont'd)

A-V Canal: 165
ASD, Primum W/ or W/O Cleft Mitral Valve: 166

Database Dictionary For Module: Congenital Heart Surgery Module

A-V Canal, Intermediate: 167
A-V Canal, Complete: 168

A-P Window (All Types): 169

Hemitruncus Arteriosus: 170

Truncus Arteriosus: 171
Truncus Arteriosus Van Praagh Class A1: 172
Truncus Arteriosus Van Praagh Class A2: 173
Truncus Arteriosus Van Praagh Class A3: 174
Truncus Arteriosus Van Praagh Class A4: 175
Significant Truncal Insuff (Mod/Sev): 176

DIAGNOSIS - ANOM OF PULM VEN CONNECT

Anom of Pulm Ven Connect: 177

Partial Anom Connect(Scimitar): 178

Partial Anom Connect(Non-Scim): 179

TAPVC: 180
TAPVC, Supracardiac Type I: 181
TAPVC, Cardiac Type II: 182
TAPVC, Infracardiac Type III: 183
TAPVC, Mixed Type IV: 184

Cor Triatriatum (All Types): 185

Pulmonary Venous Stenosis: 186

DIAGNOSIS - ANOM OF SYST VEN CONNECT

Database Dictionary For Module: Congenital Heart Surgery Module

Anom of Syst Ven Connect: 187

Left Superior Vena Cava: 188

Interrupted Inferior Vena Cava: 189

Systemic Venous Stenosis: 190

Other Anomalies: 191

192

DIAGNOSIS - RIGHT HEART LESIONS

Right Heart Lesions: 193

Tetralogy: 194

- Tetralogy of Fallot: 195
- Tetralogy With Absent Pulmonary Valve: 196
- Tetralogy With Anomalous Coronary Artery: 197
- Tetralogy With A-V Canal: 198

Pulmonary Atresia: 199

- Pulmonary Atresia W/VSD (Pseudotruncus): 200
- Pulmonary Atresia W/VSD & MAPCA's: 201
- Pulmonary Atresia W/IVS (All Types): 202
- Pulmonary Stenosis W/IVS (All Types): 203

Database Dictionary For Module: Congenital Heart Surgery Module

RV-Pulm Outflow Tract Obstruct: 204
Chamber: 205 Vessel: 206

DIAGNOSIS - RIGHT HEART LESIONS (cont'd)

Tricuspid Atresia: 207
Tricuspid Atresia W/NRA: 208
Tricuspid Atresia W/NRA and PS: 209
Tricuspid Atresia W/TGA: 210
Tricuspid Atresia W/TGA and PS: 211

Ebstein's Anomaly: 212

Pulmonary Insufficiency: 213

Tricuspid Insufficiency: 214

Tricuspid Stenosis: 215

Ventric-PA Conduit Sten/Insuff: 216

DIAGNOSIS - LEFT HEART LESIONS

Left Heart Lesions: 217

Aortic Stenosis: 218
Aortic Stenosis, Valvular: 219
Aortic Stenosis, Supravalvular: 220
Aortic Stenosis, Subvlv (incl Fibromusc): 221

LV Outflow Obstruct (Tunnel): 222

Sinus Valsalva Fist(All Types): 223

Database Dictionary For Module: Congenital Heart Surgery Module

LV-Ao Tunnel: 224

Aortic Regurgitation: 225

LV-RA Fistula: 226

DIAGNOSIS - LEFT HEART LESIONS (cont'd)

Mitral Stenosis: 227

Mitral Regurgitation: 228

Hypoplastic Left Heart Syn: 229

Severe Cardiomyopathy (All): 230

Constrict Pericard (All Types): 231

Pericard Effusion (All Types): 232

DIAGNOSIS - SINGLE VENTRICLE

Single Ventricle: 233

- Mostly RV W/NRA: 234
- Mostly RV W/NRA and PS: 235
- Mostly RV W/TGA: 236
- Mostly RV W/TGA and PS: 237
- Mostly LV W/NRA: 238
- Mostly LV W/NRA and PS: 239

Database Dictionary For Module: Congenital Heart Surgery Module

Mostly LV W/TGA: 240
Mostly LV W/TGA and PS: 241

DIAGNOSIS - MALPOSITION OF THE GREAT VESSELS W/2 VETRICLES

Malposition of Grt Vess W/2 Vent: 242

TGA: 243
- TGA With IVS: 244
- TGA With VSD: 245
- TGA With VSD and PS: 246

Corrected TGA: 247
- Corrected TGA With IVS: 248
- Corrected TGA With IVS and PS: 249
- Corrected TGA With VSD: 250
- Corrected TGA with VSD and PS: 251

DORV: 252
- DORV, Subpulmonic VSD W/ or W/O PS: 253
- DORV, Subaortic VSD W/ or W/O PS: 254
- DORV, Double Committed VSD W/ or W/O PS: 255
- DORV, Uncommitted VSD W/ or W/O PS: 256

DIAGNOSIS - MALPOSITION OF THE GREAT VESSELS W/2 VENT. (cont'd)

Levocardia: 257

Database Dictionary For Module: Congenital Heart Surgery Module

Mesocardia: 258

Dextrocardia: 259

Atrial Situs Solitus: 260

Atrial Situs Inversus: 261

Atrial Situs Ambiguous: 262

Ventricular Inversion: 263

DIAGNOSIS - THORACIC ARTERIES AND VEINS

Thoracic Arteries and Veins: 264

Anomalous Origin of Cor Art: 265
Anomalous Origin of Left Cor from PA: 266
Anomalous Origin of Right Cor from PA: 267

Coarctation of Aorta(All Types): 268

Coronary Artery Fistula (Cong): 269

Coronary Artery Fistula (Acq): 270

Interrupted Arch (All Types): 271

Patent Ductus Arteriosus: 272

Vascular Ring (All Types): 273

Aortic Aneurysm (Any Type): 274

Right Aortic Arch: 275

DIAGNOSIS - LUNG DISEASE - ELECTROPHYSIOLOGIC

Database Dictionary For Module: Congenital Heart Surgery Module

Lung Disease: 276

Electrophysiologic: 277

Congenital Heart Block: 278

Acquired Heart Block: 279

Vent Tachycardia (Any Reason): 280

Wolff-Parkinson-White (A Tach): 281

Atrial Ectopic Tachycardia: 282

Atrial Re-Entry Tachycardia: 283

Pacemaker Malfunction/EOL: 284

DIAGNOSIS - EMBOLIZED FOREIGN BODY

Embolized Foreign Body: 285

Primary Elec Open Sternum: 286

Other:
287 288

DIAGNOSIS FOR CURRENT PROCEDURE

Septal Defects: 289

ASD: 290

VSD: 291

AV Canal Single Patch: 292

AV Canal Double Patch: 293

A-P Window: 294

Database Dictionary For Module: Congenital Heart Surgery Module

Hemitruncus: 295
Truncus Arteriosus: . 296

DIAGNOSIS FOR CURRENT PROCEDURE (cont'd)

Anom of Pulm Ven Connect: 297
PAPVC: 298
TAPVC: 299
Cor Triatriatum: 300
Pulmonary Venous Stenosis: 301

Anom of Syst Ven Connect: 302

Right Heart Lesions: 303
Tetralogy Repair: 304
Pulm Atresia W/VSD: 305
Pulm Atresia W/IVS: 306
Pulm Valve Stenosis W/IVS: 307
RV-Pulm Outflow Tract Obstruct: 308
Tricuspid Atresia: 309
Ebstein's Anomaly: 310
Pulmonary Insufficiency: 311

DIAGNOSIS FOR CURRENT PROCEDURE (cont'd)

Right Heart Lesions Cont'd:
Tricuspid Insufficiency: 312
Tricuspid Stenosis: 313
Ventricular-PA Cond Sten/Insuff: 314

Left Heart Lesions 315
Aortic Stenosis: 316
LV Outflow Obstruction: 317
Sinus of Valsalva Fistula (All): 318
LV-Ao Tunnel: 319
Aortic Regurgitation: 320
LV-RA Fistula: 321
Mitral Stenosis: 322

Database Dictionary For Module: Congenital Heart Surgery Module

Mitral Regurgitation:	323
Hypoplastic Left Heart Syndrome:	324
Severe Cardiomyopathy (All):	325
Constrictive Pericarditis (All):	326
Pericardial Effusion:	327

DIAGNOSIS FOR CURRENT PROCEDURE (cont'd)

Single Ventricle:	328
Malpos of Grt Vess W/2 Vent:	329
TGA With 2 Ventricles:	330
Corrected TGA With 2 Ventricles:	331
DORV With 2 Ventricles	332
Thoracic Arteries and Veins:	333
Anomalous Origin of Cor Artery:	334
Coarctation of Aorta (All Types):	335
Coronary Artery Fistula (Cong):	336
Coronary Artery Fistula (Acq):	337
Interrupted Arch (All Types):	338
Patent Ductus Arteriosus:	339
Vascular Ring (All Types):	340
Aortic Aneurysm:	341
Lung Disease:	342

DIAGNOSIS FOR CURRENT PROCEDURE (cont'd)

Electrophysiologic:	343
Congenital Heart Block:	344
Acquired Heart Block:	345
Vent Tachycardia (Any Reason):	346
Atrial Tachycardia (incl WPW):	347
Embolized Foreign Body:	348

Database Dictionary For Module: Congenital Heart Surgery Module

Primary Elec Open Sternum: 349

Other:
350 _____ 351 _____

COMPONENT
CPT Codes: 1. 352 2. 353 3. 354 4. 355 5. 356

Ligation and/or Division, Any Vessel: 357

Excision/Resection 358

Dilatation (Of Anything): 359

Suture Closure: 360

ASD Patch Closure: 361

VSD Patch Closure: 362
Trans-Atrial: 363 Trans-Pulm Artery: 364
Trans-Ventricular: 365 Trans-Aorta: 366

Intraoperative Clam Shell Device: 367

Patch Closure For Any Other Purpose: 368

COMPONENT (cont'd)

Patch Augmentation: 369

Transanular Patch (Including Monocusp): 370

Tube Graft: 371

Database Dictionary For Module: Congenital Heart Surgery Module

Vessel Reimplantation:	372
Pulmonary Venous to Left Atrial Connection:	373
Subclavian Flap:	374
Resection and End-to-End Anastomosis:	375
Systemic-to-Pulmonary Artery Shunt (Any Kind):	376
Unifocalization to Achieve PA & Pulmon Collat Continuity:	377

COMPONENT (cont'd)

Unidirectional Glenn:	378
Bidirectional Caval-Pulm Artery Shunt or Hemi-Fontan:	379
Pulmonary Artery Band:	380
Atrial Septectomy:	381
Aortic Valvuloplasty:	382
Aortic Valve Replacement:	383
Pulmonary Valvuloplasty:	384
Pulmonary Valve Replacement:	385
Mitral Valvuloplasty With/Without Ring:	386

COMPONENT (cont'd)

Mitral Valve Replacement:	387

Database Dictionary For Module: Congenital Heart Surgery Module

Tricuspid Valvuloplasty With/Without Ring: 388

Tricuspid Valve Replacement: 389

RA or Caval to PA Connection (Fontan, Kreutzer): 390

Lateral Tunnel: 391
Ross Procedure: 392
Septal Fenestration: 393

RA-to-Ventricular Connection: 394
Valved: 395 Non-Valved: 396

Ventricular-to-PA Connection: 397
Valved: 398 Non-Valved: 399

COMPONENT (cont'd)

Patch or Suture Closure of Semilunar Valve: 400

Patch or Suture Closure of Atrioventricular Valve: 401

Creation of A-P Window (Damus-Stansel-Kaye): 402

Norwood Procedure (Or Any Modification of Same): 403

Annular Enlarging Procedure (For Kinno,Rittenhouse,Etc): 404

Ventricular-to-Aorta Valved Conduit: 405

Conal Resection and/or VSD Enlargement: 406

Cardiac Transplantation: 407

Lung Transplantation: 408

Database Dictionary For Module: Congenital Heart Surgery Module

COMPONENT (cont'd)

Tracheal Repair (Any Kind): 409

Coronary Bypass or Reimplantation: 410

Arterial Switch Operation W/Without Lecompte Maneuver: 411

Atrial Baffle Proc to Reroute Syst Ven & Pulm Ven Return: 412

Disconnection of Main Pulmonary Artery from Proximal PA: 413

Repair of Asc Aortic Aneurysm With/Without Bental: 414

Repair of Aortic Aneurysm, Non-Asc: 415

Intraoperative Electrophysiologic Mapping: 416

Operative Ablation: 417

COMPONENT (cont'd)

Epicardial Pacemaker Implant: 418

Transvenous Pacemaker Implant: 419

Pacemaker Revision (Battery or Lead Change): 420

Lung Biopsy: 421

Pericardiectomy and/or Drainage (Includes Window): 422

Takedown Previous Procedure: 423

Fontan: 424 Mustard: 425 Rastelli: 426

Shunt: 427 PA Band: 428 Other: 429

430

Retrieval of Embolized Foreign Body: 431

Database Dictionary For Module: Congenital Heart Surgery Module

Delayed Sternal Closure: 432
Primary Elective Open Sternum: 433
Other: 434 435

DIAGNOSTIC ALPHA LISTING-LINK UP TO PATIENT FILES

	Diagnosis	Status
1.	436	437
2.	438	439
3.	440	441
4.	442	443
5.	444	445
6.	446	447

PROCEDURAL ALPHA LISTING-LINK UP TO PATIENT FILE

	Procedure	Status
1.	448	449
2.	450	451
3.	452	453
4.	454	455

Database Dictionary For Module: Congenital Heart Surgery Module

5. 456 457

6. 458 459

VALVE AND VALVED CONDUIT SURGERY DATA

	Procedure				
A - 460	Implant 461	Size 462	Type 46
	Explant 464	Size 465	Type 46
M - 467	Implant 468	Size 469	Type 47
	Explant 471	Size 472	Type 47
T - 474	Implant 475	Size 476	Type 47
	Explant 478	Size 479	Type 48
P - 481	Implant 482	Size 483	Type 48
	Explant 485	Size 486	Type 48

SHUNTS

Type: 488 Material: 489 Size: 490 mm

CARDIOPULMONARY BYPASS AND SUPPORT DATA

Cross Clamp Time (Min): 491 Perfusion Time (Min): 492

Database Dictionary For Module: Congenital Heart Surgery Module

Circ Arrest Time (Min): 493 Inflow Occlusion Time (Min): 494
Lowest Core Temp.(c): 495 10% Flow (Min): 496

Cardioplegia: 497
Blood: 498 Induced Fib: 499 Crystalloid: 500
O2 Crystalloid: 501 Other: 502

Flow: Retrograde: 503 Antegrade: 504

Temperature: Warm: 505 Cold: 506

Topical Hypothermia: 507 Warm Reperfusate: 508

CARDIOPULMONARY BYPASS AND SUPPORT DATA (cont'd)

Pacing Usage Leaving OR: 509

Atrial: 510 Ventricular: 511 Dual Chamber: 512

Intra/Post-Op VAD: 513

LVAD: 514 RVAD: 515

BVAD: 516 TAH: 517

IABP: 518 ECMO: 519

Open Sternum: 520
Cell Saver Used: 521
Ultra Filtration Used: 522

POST-OPERATIVE DATA

Blood Products Used: 523
RBC: 524 FFP: 525 Cryo: 526 Plate: 527 Fresh Blood <48 Hrs: 528
Whole Blood => 48 hrs 529

Database Dictionary For Module: Congenital Heart Surgery Module

Fibrin Glue: 530 Aprotinin: 531

Complications: 532 In Hosp <30 Days: 533
In Hosp >30 Days: 534
Out Hosp <30 Days: 535

Operative: 536 Re-Op/Bleeding: 537
Re-Op/Valve Dysfunction: 538
Re-Op for Residual Defect (During Same Admit): 539
Re-Op/Other Cardiac: 540
Re-Op/Other Non-Cardiac: 541
Re-Op/Sternal Closure: 542

Infection: 543 Minor: 544 Major: 545 Wound: 546
UTI: 547 Sepsis: 548

Neurologic: 549 Minor: 550 Major: 551 Seizures: 552

Pulmonary: 553 Ventilator >5 Days: 554 Respiratory Arrest: 555

POST-OPERATIVE DATA (cont'd)

Renal: 556 Post-Op Dialysis/Hemofiltration: 557

Pressures: RV: 558 Sys: 559 RV/Sys Ratio: 560 :1

Other: 561 Peri-Op Heart Block (Temp Pacing, Resolved): 562
Peri-Op Heart Block (Temp Pacing, Perm Pacing): 563
Arrhythmia (No PM Required): 564
Cardiac Arrest: 565
Anticoagulant Complication: 566
Tamponade: 567
GI Complications: 568
Multi-System Failure: 569
Low Cardiac Output: 570
Pleural Effusion or Chylothorax: 571
Phrenic Nerve Injury: 572
Transplant Rejection: 573
Nutritional Support: 574
Recurrent Laryngeal Nerve Injury: 575
Pneumothorax 576
Other: 577 _____ 578

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Abstract

METHODOLOGY FOR THE DETERMINATION
OF THE RELIABILITY OF DATABASE DERIVED DATA

by

JUANITA M. LYONS

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Advisor: Dr. Shlomo Sawilowsky

Major: Evaluation and Research (Education)

Degree: Doctor of Philosophy

Methodology to access the reliability of databases was presented. As an illustration of the proposed methodology, a simple random sample of 150 cases was extracted from a medical database at Children's Hospital of Michigan, Department of Cardiovascular Surgery in Detroit, Michigan. The database was reviewed for errors to determine overall reliability. Precluded by logistical limitations, the investigator was able to assess reliability as related to data processing errors. Data processing errors were defined as errors made when 1. recording data onto paper database forms, 2. recording errors into the database (referred to as keyboard errors) e.g. typographical and spelling errors and 3. recording errors, which are errors made when recording into the database, e.g., transpositions, omissions, or redundancies.

The methodology employed was the Pearson Product moment coefficient to determine the coefficient of equivalence between collection forms and

electronic forms. The reliability coefficient generated was .99 (p=.00). The investigator was also able to identify who was making errors, the location of those errors, and the type of errors made. The methodology offers inquirers a snapshot method to report on database reliability status in a manner in which a concise evaluative statement could be made regarding the database reliability status. Researchers are encouraged to ascertain reliability information on databases prior to publication of research or making decisions based on database derived data.

Autobiographical Statement

JUANITA MARIE JOHNSON LYONS

I am currently coordinating data as a part of a clinical research team at the Parke-Davis Corporation, Ann Arbor, Michigan. Over the past twenty years, I conducted medical research in pediatric medicine, including cardiovascular surgery and sickle cell disease. I managed and supervised research endeavors, designed and statistically analyzed studies, and managed a database system. I also implemented and monitored a local area network.

I have teaching experience at the graduate level and have co-authored publications in several peer-reviewed journals. I hold a Bachelor of Science degree in Psychology from Michigan State University and a Master of Science degree in Community Health Services from Wayne State University School of Medicine. My course work concentration was in research methodology, design and statistics. Currently I am a member of the American Educational Research Association.

I have been active in the church and community as a Drama Director, a parent advisor to Children's Hospital of Michigan and as vice president of a community business district in Detroit, Michigan. Pastime includes spending time with my family and working in theater.