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A Validity Review of the NBR

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Abstract

Objective—Health-related registries arose due from clinician desire to improve patient quality of care for a specific disorder. As such, disease registries differ from administrative registries in concept, organization, purpose, data recording, and results. Due to their voluntary nature, health-related disease registries are not regularly audited, have a narrow focus, and are designed for clinicians, not administrators. As part of a Department of Defense initiative we conducted an intensive qualitative review of the American Burn Association's National Burn Repository (NBR). Our objectives are to inform future users of the NBR of issues that could affect statistical analyses and inferences and assist efforts to improve data collection.

Methods—We obtained a deidentified copy of the 2009 release of the NBR containing 286,293 records. We reviewed this data set for 1) records lacking vital patient information (age, burn size, survival, gender), 2) inconsistencies between data in different fields of the database, and 3) duplicate values.

Results—Restricting our review to records with an admission year of 2000 or later, vital patient information was missing or invalid for about 60,000 records. Data inconsistencies were found in hospital admission status (initial admission or readmission) for about 12,000 records, survival for about 950 records, and burn injury for about 5,500 records. Depending on the criteria used to identify duplicate records, we found at least 4,000 duplicate records but as many as 14,000 in the

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database. Finally, significant data quality issues were found for facilities not using the TRACS software.

Conclusions—All health-related disease registries, unlike administrative databases, are voluntary. Anonymity of data is vital, and data auditing and reporting are challenging. The data contained in the NBR is disease-specific, and, as such, has the potential to provide valuable epidemiologic, treatment, and outcome data as reported by clinicians, not registrars. The NBR provides substantive data on burn injury; however, data review needs to precede data analysis. Revisions to NBR data collection have improved the quality of data submitted, yet data quality issues remain in the current database. Investigators are cautioned to thoroughly assess all fields prior to conducting analyses using the NBR.

Keywords

National Burn Repository; health registry; burns

Health-related registries provide a structure for the collection, storage, retrieval and dissemination of information about patients with a particular disease, condition or exposure, or who undergo specific procedures. National and state-level registries are maintained for a wide range of health concerns such as cancer, insulin-dependent diabetes mellitus, rare diseases, and cardiovascular disease to name a few. These databases compile enormous amounts of information on patient characteristics, treatments and outcomes. The expanse of data available in registries allow researchers to investigate questions that otherwise would be impossible to address because individual facilities often do not have sufficient numbers of patients to investigate certain questions while other questions are unethical or logistically impossible to prospectively evaluate. Thus, health-related registries fill a vital role in evaluating patient outcomes and improving care. Disease-specific registries differ from administrative registries in several key aspects. First, data provision is often voluntary and unfunded, making anonymity of data vital. Recording of clinical variables of interest is often difficult and subject to interpretation, and regular on site audits are virtually impossible. Disease-specific registries are also used for a different purpose than administrative databases: disease-specific registries are collected by and for clinicians who are trying to better understand a specific disease presentation, treatment, and outcomes.

The National Burn Repository (NBR) compiles information on patients seeking treatment at burn centers in the United States and some foreign institutions. With thousands of records spanning more than a decade, the NBR is an unparalleled resource for investigating burn care and outcomes. A recent search for “National Burn Repository” in The Journal of Burn Care and Research yielded 50 articles, but this represents only a portion of studies using the NBR. Investigators have used the NBR to investigate broad questions such as the relationship between mortality and burn size and inhalation injury¹, focused clinical questions (e.g., use of bronchoscopy for patients with inhalation injury and pneumonia²) to health care policy-related questions such as the prevalence and distribution of across-state care³. Clearly, these significant questions could not effectively be investigated without the breadth of information available in the NBR. However, while the NBR and other registries provide a tremendous resource, analyses and inferences derived from these registries are only as good as the data that they contain.

History of the National Burn Repository

Creation of a burn database has evolved over time. Dr. Irving Feller from the University of Michigan, one of the pioneers in burn database development, established the National Burn Information Exchange (NBIE), in 1964. The original NBIE, similar to today’s NBR, was a voluntary registry, which by 1986 had collected a total of 94,594 patient records from 130

hospitals. The goal of the NBIE project was to establish standards for burn patient care and survival. In addition, the NBIE sought to improve the quality of burn care by identifying centers with the lowest mortality rates and identifying best practices used to achieve survival⁴. The data were analyzed using the INQUIRE system, which was state of the art for that time. Unfortunately these initial efforts did not maintain sufficient individual center support to sustain the database due to its comparative nature. However, the NBIE provided the foundation for further burn database initiatives.

As computer technology advanced in the late 1980s the American Burn Association (ABA) began laying the foundation for an electronic burn registry software program that could be used by individual burn centers. As a result, a burn registry was made available to ABA members without charge in 1992⁵. By 1993 it became apparent that additional resources would be needed, and the ABA partnered with the American College of Surgeons (ACS), who had developed a robust trauma registry, to develop the NATIONAL TRACS®/ABA Burn Registry. The burn module was made available to all ABA members at no charge on two conditions. First, users had to complete a tutorial program on data entry and second, they must sign a licensing agreement to use the modules solely within their institutions⁵. This software combined features of the original ABA burn registry with the NATIONAL TRACS software being used by the ACS. The original data were collected in Foxpro™, based on DOS, which was the most appropriate software for a database at that time. The burn database retained data points specific to burn injury (such as inhalation injury) but was expanded to include E-codes, ICD-9 codes, customized data points, and report writing capabilities. The initial emphasis of the NBR was to obtain participation by as many burn centers as possible. As such, there was an emphasis on maintaining facility anonymity to improve compliance with data entry, assure compliance with patient privacy legislation, and avoid conflicts in data interpretation.

The early emphasis of the burn database was the collection of data by individual centers for individual center use. Multiple training sessions were offered to facilitate data entry training by individual centers. Subsequently the ABA began to issue national calls for data, which entailed compiling burn patient data from individual centers into a single cohesive data set. This endeavor grew from 28 centers contributing data on a total of 6,400 patients in 1994 to 54,000 patient admissions reported in 2002⁶. A number of burn centers had developed their own databases during the interim between the NBIE and NBR development, and the decision was made to accept data from these non-TRACS centers for a period of time. Data from these centers were converted to the NBR data format and added to the NBR data set. The NBR now contains over 300,000 records spanning more than a decade. Eighty-five facilities in the US and abroad have contributed data to the NBR.

Clearly, the NBR has been a successful endeavor and has the potential to improve the care of burn patients. During its history, due to advances in computer technology, it has undergone multiple “renovations”, each of which both improved the database and created new challenges in data analysis. Similar to putting an addition on an existing home, each change improved the overall database but has created other data integrity issues. As we discuss in detail below, these decisions have had data quality ramifications that need to be considered in using the NBR for research.

Prior to statistical analysis of any data set, auditing the data for inconsistent or out-of-range value is a standard practice and necessary to ensure valid results. Because our ultimate intent is to statistically analyze outcomes of burn patients using the NBR, we embarked on an intensive effort to create a clean, internally-validated data set from the NBR. Here we report the results of our review of the NBR. Our objectives are to inform future users of the NBR of issues that could affect statistical analyses and inferences and assist efforts to improve

data collection. The goal of this article is to provide the reader with an understanding of the strengths and potential pitfalls of analyzing the NBR to improve the accuracy of future NBR analysis research endeavors.

METHODS

We received a deidentified version of the NBR database inclusive of the 2009 call for data from the ABA. This database contained 286,293 records in the NBR Main data table which was the focus of our review. This project was approved by the Human Subjects Review Board at the University of California Davis.

The NBR is structured as a star-schema database with the NBR_MAIN table located at the center, surrounded by seven dimensional tables (COMORBIDITY, COMPLICATION, DIAGNOSES, DRUG SCREEN, INHALATION INJURY, OPERATIONS, RESOURCE UTILIZATION). To maintain patient anonymity, the tables are related by the RECORDNO field which contains a number randomly but uniquely assigned by the ABA to each new record during each annual call for data. Each record is associated with one patient visit. The NBR_MAIN table contains most of the patient data (e.g. age, gender, burn size, burn thickness, admission status, admission type, outcome, etiology, Lund and Browder results, ICU days, ventilator days, inhalation injury, hospital disposition, year of admission/injury/discharge, TRACS version, and visit number). Not all of the NBR_MAIN records have associated dimensional table record data available. Therefore, we focused our analyses on only the NBR_MAIN table.

We first identified records with sufficient data for analysis. We defined the minimum required information as 1) a discharge status of “Lived” or “Died”, 2) a gender, 3) an age, and 4) an indication of a burn or inhalation injury. We identified records lacking information for one or more of these fields. Per requirements of our Institutional Review Board, we restricted our review to the 210,683 records with an admission year of 2000 or later.

Records with “Unknown” or NULL (defined as a value of empty, no result, or blank) as entries in the DEAD field, which specifies survival to discharge, were dropped as were records with NULL values for the SEX field. For age, we considered both the AGE and the MAN_AGE fields. In TRACS, the AGE field is automatically calculated based on the patient’s birthday listed in the admission data while the age in the MAN_AGE field is manually entered. We dropped records if both AGE and MAN_AGE were NULL or unknown.

The presence of a burn or inhalation injury was identified by a non-NULL or non-zero entry in any of the three burn summary fields (AREATOT, AREAPART, and AREAFULL), the occurrence of the phrase “TBSA” in the text of the INJEVENT (injury event description) field, an indication of an inhalation injury (from either INHAL_YES or INJINHAL fields), an indication of an electrical injury (from ETIOCODE_CAT field), or an indication of a burn in any of the Lund and Browder chart fields. AREATOT, AREAPART and AREAFULL contain the total percentage burned, the percentage of partial thickness burn and the percentage of full thickness burn, respectively.

This screening removed 60,212 records, retaining 150,471 records with the minimal data necessary for analysis. We then conducted a rigorous internal validation of this pared down data set which consisted of 1) comparing related fields to identify inconsistencies, 2) investigating the prevalence of duplicate records and 3) identifying facility-specific data quality concerns.

RESULTS

Analysis of the NBR revealed several data integrity issues: inconsistent data within a record, the presence of duplicate records, and data from non-TRACS facilities. Each of these issues is discussed below.

Inconsistent Data

Our review of the NBR revealed some records with inconsistent entries in important fields such as burn size and survival. Survival to discharge is captured by three fields (HOSPDISP, HOSPDISP_CAT, and DEAD) and as noted by Pavlovich et al.⁷ these fields are not always in agreement. Because of a diversity of entries in the HOSPDISP field, the ABA derives the HOSPDISP_CAT field from HOSPDISP to provide standardized categories of hospital disposition. We compared the DEAD and HOSPDISP_CAT fields, and found discrepancies in mortality for 952 records. Considering that the total number of deaths (based on the DEAD field) is 4,792, an uncertain death status for 952 records represent a sizable proportion that could influence inferences on mortality.

The total burn surface area (TBSA) is fundamental information for burn patients, but this basic piece of information is lacking for many records in the NBR. We removed over 40,000 records with NULL entries or 0 values for burn size. While researchers using the NBR routinely exclude records with NULL values for TBSA, treatment of records with burns sizes of 0 varies. Some investigators presumably retain records with a TBSA of 0^{1,8} but others explicitly drop records with a burn size of 0.^{2,9,10} We found that for some records with a TBSA of 0, the etiology fields indicated that the person was burned and retaining such records could bias results. In this case, dropping records with a TBSA of 0 is justified. In contrast, in our screening, we kept records with a TBSA of 0 if the burn was an electrical burn or if the patient suffered an inhalation injury because these patients could reasonably have a TBSA of 0. Thus, treatment of records with a TBSA of 0 needs careful consideration in light of the research question of interest.

Two critical factors in the care and outcomes of burn patients are the extent and severity of burns. Multiple fields in the NBR provide information on these factors but are not always consistent. For over 5,000 records, the diagnosis related group description (DRG_DESCR) indicated the presence of a full thickness burn but AREAFULL was missing or 0. For most of these records a burn size was recorded in AREAPART instead. Because mortality and other outcomes of interest can vary dramatically depending on whether a burn is full or partial thickness, the inconsistency among the burn fields (AREAPART, AREAFULL) and the DRG_DESCR is concerning. In addition, we found inconsistencies among AREAPART, AREAFULL and the Lund and Browder chart values but only a few hundred records were involved.

Accurate classification of a patient's admission status is fundamental for subsequent analyses of burn care and outcomes. Often researchers are interested in initial admissions and seek to limit the data to records of a patient's initial hospital admission.^{1,10} Several fields (ADMSTAT, ADMSTAT_CAT, ADMTYPE, and VISITNUMBER) in the NBR capture information on whether a particular visit is an initial admission or a subsequent visit. We found discrepancies among these fields in whether a visit was an initial admission or a readmission for over 12,000 records. Inclusion of readmissions in an analysis intended to focus on initial admission could impact results by 1) potentially including the same patient more than once (the patient's initial admission plus incorrectly classified readmissions) and 2) increasing survival estimates since readmissions usually survive to discharge. Clearly, in using the existing database, researchers need to be aware of the inconsistencies among admission status fields and carefully consider and document their inclusion criteria.

Some inconsistencies between fields were minor, affecting only a small number of records and/or fields of little consequence to downstream analyses. Such discrepancies included inconsistencies among the injury year, admission year and discharge year; inconsistency among number of hospital days, intensive care unit days, and ventilator days; negative hospital charges; and burn percentages less than 0 or greater than 100. While disconcerting that such clearly erroneous data are in a database, these errors are easy to find and exclude from analysis as necessary. Even if these records are retained in an analysis, given the small number of records, analytical results would not be substantially affected.

Duplicate Records

Potentially unknown to researchers, the NBR contains duplicate records, i.e., multiple records of the same admission of the same person. Duplicate records have entered the NBR through two processes. First, individual facilities sometimes update previously submitted records and resubmit updated records in a subsequent year's data call. Although these updates improve provide better and more complete information about a patient's admission, updated records do not replace previously submitted records. Rather, they are assigned a new record number and enter the NBR as new records. Second, data from a facility has been uploaded multiple times and assigned new record numbers. Without a unique patient identifier, identifying duplicate records is a laborious and imperfect process based on matching multiple fields and then *inferring* that records matched on the selected multiple fields refer to the same person and admission.

The algorithm used to identify duplicate records can greatly influence the number of records identified as duplicates. We first considered stringent criteria, matching records on 17 fields (facility, patient age, admission year, sex, race, admission status, discharge year, E-code, total surface area burned, the number of operative procedures, number of hospital days, number of ventilator days, number of days in intensive care, the injury event description, hospital charges, total operating room visits and visit number). This matching procedure identified about 4,000 records. While many of these records represent duplicates, this algorithm did not capture all duplicates. In particular, updated records often have missing values for some fields that were subsequently revised; these types of records were not identified as a match. Therefore, we also considered less stringent criteria. Matching on the first nine fields, as the ABA does in preparing its annual report¹¹, we identified over three times as many matching records. While some of these records are duplicates missed by our stringent matching, we observed that a portion of the matched records reflected readmissions of the same patient or multiple patients with a common burn and hence are not duplicates.

Non-Tracs Facilities

Most of the 85 facilities that have contributed data on their burn admissions to the ABA use the TRACS software developed for this purpose. However, eight facilities did not use the TRACS software for one or more years and submitted data to the ABA using individually-developed platforms. We found the completeness and quality of data to vary across the non-TRACS facilities. For some of the non-TRACS facilities, data in one or more fields is unusable or of questionable validity. Concerns regarding data from non-TRACS facilities include 1) missing information on the type of admission (initial vs. readmission), length of hospital stay (listed as 0 for all records), ventilator days (listed as 0 for all records), and age (listed as 0 for all records); 2) potentially erroneous survival data (listed as "Lived" for all records), and 3) missing information about the percentage of partial and full thickness burn areas. Of the approximate 13,000 records from non-TRACS facilities, most are affected by one or more of these data quality issues. Even if all facilities use the TRACS software in the future, these issues will remain for data already submitted from non-TRACS facilities.

DISCUSSION

Validation before Calculation

Health-related registries and administrative databases are an unparalleled resource for outcomes research and quality control monitoring. However, conclusions based on these data sets are only as good as the quality of the data they contain. Data quality issues and limitations are not unique to the NBR and have been documented for other health registries. Missing values are a common short-coming. For example, Phillips et al.¹² reported the percentage of missing values in the National Trauma Data Bank to be 6.8% for age, 2.9% for length stay and 30.5% for hospital charges. Roudsari et al.¹³ showed that blood alcohol content was missing for more than 60% of the patients in the National Trauma Data Bank and that statistical results were substantially altered depending on how missing values were handled. In cancer registries, certain conditions, treatments or patient characteristics are known to be under-reported^{14,15} or inaccurately reported.^{16,17} Given the large amount of data in these data bases and that contributions are voluntarily, some data quality issues are to be expected. It is incumbent on researchers to review the data prior to its use and to understand the limitations associated with any particular data set.

Despite the shortcomings of the NBR identified above, it is important to recognize that many records in the NBR are comprehensive and internally consistent. With more than 10 years of data, the NBR provides an extremely valuable resource for research. Nevertheless, for valid inferences based on data from the NBR, a critical review of the data prior to analysis is essential. In this paper we presented some of the issues to consider prior to data analysis. These points represent issues in the main table of the NBR. Investigators using data from the other tables are advised to critically review the data relevant to their research question to ensure, to the extent possible, the validity of the data.

In our review of the NBR, we found an interdisciplinary team consisting of an informatician, biostatistician and clinicians to be essential for data validation. The informatician was critical for querying data tables, revising and maintaining the database. The statistician was instrumental in the internal validation process through which we identified inconsistent or erroneous values. Clinicians played a vital role in interpreting the patient data and guiding decisions on revising or dropping records. Thus, each discipline brought essential skills and knowledge to the process.

Track Patients Rather than Visits

When the NBR was started, the database was structured to track hospital admissions rather than individual patients. This approach was logical as most burn patients admitted to the hospital remained there through completion of their care. Since then, pressure of increasing hospital costs has resulted in shifts in delivery of care. Now patients are discharged to other care settings (e.g., skilled nursing facilities or home with home-based care provided) when possible, but return to the hospital for subsequent procedures.¹⁸ Thus, a burn patient's hospitalization and care history are no longer captured by a single hospital admission. As a result, one patient can have multiple records.

Having multiple records for one patient is not inherently problematic, but does require a unique patient identifier for proper use. The TRACS software collects patient identifiable information and according to the manual¹⁹ each patient is given a "Registry Number" which is the "patient's unique number forever in the system". However, this number is not retained in the database given to the ABA by the database coordinator contracted to collect and collate records from all the facilities. Thus, it is also not available to investigators using the NBR.

Changes were incorporated into TRACS version 5 to 1) track the number of visits by a patient and 2) to avoid conflicting information in the ADMSTAT and ADMTYPE fields. While an improvement over previous versions, these changes do not entirely compensate for the lack of a patient identifier. With no patient identifier, multiple records cannot be definitively assigned to a single patient. The only possible way to assign multiple visits to one patient is to painstakingly match on several fields such as gender, TBSA, facility and others and to *infer*, perhaps erroneously, that all records matching on these characteristics but with different visit numbers or admission status values represent multiple admissions of the same patient. Of course, this inference could be wrong. Thus, longitudinal analyses are effectively precluded. Further, because of the difficulty of matching readmissions to initial patient admissions, it is not possible to estimate the total care requirements and resource use of burn patients. We recommend retaining the registry number that is assigned to each patient through TRACS and provided in the deidentified data set, as part of the NBR.

Challenges of Duplicate Records

The presence of duplicate records in the NBR is problematic for researchers. First, the presence of duplicates can impact statistical analyses. By inflating the sample size, the degrees of freedom will be increased making it more likely to find statistically significant results. More importantly, if the NBR is used to develop and evaluate a predictive model, with duplicate records in the database, the same records could occur in both training and test sets. This occurrence would inflate the estimated accuracy of the model. Second, researchers that know the NBR contains duplicates may seek to remove the duplicates prior to analysis using their own method for identifying and removing duplicate records. As we showed, the specific process used to identify duplicates can identify widely varying numbers of records. Comparing results across studies then is complicated as investigators will not have the same analytical data set even if starting with the same data call.

Duplicates in the database could be addressed in two ways. First, duplicate records could be removed prior to distributing the NBR to investigators. This approach would avoid 1) researchers analyzing the data set without realizing it contains duplicate records and 2) standardize the analytical data sets. Alternatively or additionally, providing a unique patient identifier would greatly simplify identification and removal of duplicate records. While certainly an option in the future, it is unclear whether patient identifiers could be added to data already in the NBR.

Recommendations for Improving the TRACS Software and the NBR

During our review we identified several areas where both the TRACS software and the database itself could be improved in order to increase data quality in the future. While the focus of our review was the data in the database, we also conducted a cursory review of the TRACS user interface functionality. We were able to enter duplicate data, bypass data validation checks and generate inconsistencies in the data through the user interface. Inconsistencies between fields containing related information could be easily identified at the data entry stage. For example, an automatic check would be easy to perform to verify that AREAFULL plus AREAPART equals AREATOT (i.e., TBSA). These types of checks should be integrated to the extent possible in future versions of TRACS. Our review of the user interface was prompted by questions raised during our internal validation process and was not a thorough review of the functionality or integrity of the software. We recommend conducting a thorough review of the software to inform further improvements to the TRACS software.

Although this analysis addresses issues that must be addressed when analyzing the NBR, it should be noted that the NBR is the richest source of data on burn injury and treatment in

the world, and the problems encountered in the database are not unique to the NBR. The National Trauma Data Base has undergone revision similar to what we are proposing for the NBR. The NBR provides burn researchers with the most comprehensive database on burns and allows analysis of factors that cannot be done by any single center or group of centers alone. In addition, the NBR data are more generalizable than any single center study. The value of the NBR in burn research is unparalleled.

Health-related registries differ from administrative databases in their intent, data collection, analysis, and utilization. Administrative databases cover a broad range of diagnoses, rely on billing data, and are used to evaluate and compare hospital systems. The NBR, as a disease-specific database, is generated by clinicians voluntarily to better inform them on disease characteristics, the definition of which can be varied across centers. As such, the information collected is more specific for a given disease. In addition, anonymity of the individual center becomes important in order to assure continued compliance with accurate data collection. These differences impose limitations on disease-specific databases that do not exist in administrative databases. Updates to the TRACS software have already improved data quality of the NBR and in general, we identified fewer issues for data collected with Version 5 than for Versions 3/4 and non-TRACs facilities. While future revisions are expected to continue to improve the quality of the data in the NBR, the data quality issues we identified for the current NBR will remain. Certainly, the existing NBR encompassing over a decade of data is an exceptional resource that will continue to be valuable for researchers. To ensure the validity of results based on the NBR, we urge investigators to appropriately review and validate the data prior to analyses.

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