Analysis of Bias Criteria Checklist for Wound Care Registries & EHRs

Presented by U.S. WOUND REGISTRY™

Introduction

Chronic wounds affect nearly 15% of Medicare patients (8.2 million people) and may cost as much as $96.8 billion per year. The most common are not venous or diabetic, even though they are the most often studied in prospective trials. The most common chronic wounds are surgical incisions that dehisce and the “wounds with no name” due to the patients’ underlying medical conditions. That is because wounds are not a disease – they are a symptom.

The US Wound Registry (USWR), a 501 (c)(3) non-profit organization, has been a patient registry since 2005. Since 2014, the USWR has been recognized by the Centers for Medicare and Medicaid Services (CMS) as a Qualified Clinical Data Registry (QCDR) that collects medical and/or clinical data for the purpose of improving the quality of patient care. While we understand that randomized, controlled trials are needed to demonstrate efficacy in a perfect world, real-world patients have an average of 6 serious co-morbid conditions and take 10 medications. These complicated patients are invariably excluded from clinical research studies, which makes it impossible to know what treatments work best. We believe the way to demonstrate effectiveness in the real world is by using real-world data.

Since 2005, the USWR has set the standard for wound care registries derived from electronic health record (EHR) data. We hope this document will raise the bar on the quality and usefulness of registries derived from electronic clinical data so that real-world data can be used to help real patients. Our goal is to “Find What Works for Chronic Wounds.”

The Checklist

The below ABCs (Analysis of Bias Criteria) checklist of items should be followed in observational reports of wound care registry data obtained from EHRs[1] and is based on a modified STROBE Statement.[2]

Beginning	Guideline
Title and Abstract	(a) Indicate the study's design with a commonly used term in the title or the abstract.
	(b) Provide in the abstract an informative and balanced summary of what was done and what was found.

Introduction	
Background and Rationale	Explain the scientific background and rationale for the investigation being reported.
Objectives	State specific objectives, including any prespecified hypotheses.

Methods	
Study Design	Present key elements of study design early in the paper. If applicable, explain why emulating a specific controlled trial is necessary in the context of available data.

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Methods (continued)	
Setting	(a) Describe the clinical setting(s) in which the wound data were acquired (e.g., hospital outpatient clinic, doctor's office, hospital, etc.), locations (number of facilities, number of states), and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.
	(b) Describe how specific sites were selected (e.g., if data were not contributed by all possible sites, explain how specific sites were chosen to contribute data and clearly state the percentage of total facilities or sites contributing to a dataset).
	(c) If more than one type or version of electronic medical record (EHR) contributed, describe each one and their key differences, including their level of certification (e.g., "2015 Certified" is the most current, effective in 2019).
	(d) State whether the registry data derived from the EHR contains identified or deidentified patient data.
Participants and Study Size: to limit selection bias	(a) Explain the method used to determine the total number of patients or wounds.
	(b) Identify whether data from all patients were obtained at each site. If the dataset is less than all possible patients from any site, state what percent of the patient population was included at each site and the criteria for inclusion.
	(c) Describe the key aspects of the patient EHR that were not included. The Methods must specifically state whether comorbid conditions, medications, laboratory results, and quality reporting data were included since these can be critical to matching cohorts.
	(d) Describe how the above were obtained (e.g., interoperable data exchange with other clinical data sources or a list of specific comorbid conditions and medications were identified at the outset for which patients were screened).
	(e) Define the specific wound/ulcer types included.
	(f) Specify which ICD-9 or ICD-10 codes or pairs of codes were used to create each "type" of wound or ulcer. This is important, because (for example) there is no code for diabetic foot ulcer but several for venous ulcers.

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Methods (continued)	
Participants and Study Size: to limit selection bias (continued)	(g) State whether the wound diagnosis was selected by the provider from a menu of predefined options or whether by ICD-9 or ICD-10 diagnosis code. (If by ICD-9 or ICD-10 code, state whether a "look-up" tool was used or some other method for identifying the diagnosis).[3]
	(h) Identify whether the dataset contains all wounds on every patient or only certain wounds, and how these were chosen. Describe the diagnostic algorithms used. Estimate the percentage of total wounds on each patient that were included.
	(i) Identify the individual(s) who determine patient and/or wound outcome. Specifically state whether wound outcome was determined at the point of care, or was calculated using other EHR data, imputed or assessed by photographs, etc.
Variables	(a) Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable. If relevant, include definitions of micro- or macroischemia, of a closed/healed wound, and how amputations are classified.
	(b) Define the time frame for each outcome (example: 1-year healing rate).[3]
	(c) Define standard of care variables, their limitations, and express these variables in the context of duration of treatment time.
	(d) Identify whether data are available that make it possible to control for variations in "usual and customary care" such as frequency of offloading, arterial screening, or compression. If data are not available to determine whether variations in usual and customary care might have occurred, specifically state this.[3]
	(e) Describe when the intervention(s) under evaluation started and stopped, their duration, and their relationship to the entire episode of care.

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Methods (continued)	
Data Source: to ensure limitation of systematic error from data documentation/ accrual	(a) Identify the individual(s) who collected data at each facility (e.g., clinician, manager, etc.).
	(b) Identify the temporal association between the care provided and the entry of data into the EHR or database (e.g., was data entry in the EHR performed at the point of care or after some delay?).
	(c) State the purpose of the electronic medical record from which the registry data was derived (e.g., the legal medical record, the record from which facility and/or physician billing is performed, a record used primarily for internal reporting, etc.).
Data Reporting: Information and recall bias	(a) Describe whether electronic data were entered using structured language or whether by natural language processing (NLP) and the source of NLP programming.
	(b) Identify the multiple data dictionaries used that comprise the common definitional framework that implements the structured language.
	(c) Confirm that an IRB provided oversight and ensured patient privacy and research ethics were upheld[3] (Although retrospective analysis of data collected in the context of usual care are exempt from the requirement of informed consent, an IRB should make this determination).
	(d) State the point at which deidentification occurred for purposes of analysis.
	(e) State whether it was possible for non-clinicians to modify EHR data after-the-fact and, if yes, identify who performed this function and why.
	(f) Describe the method by which EHR data were conveyed to the registry. Were data transmitted electronically, directly from the clinical facility to the registry, or were clinical data provided to the registry via a pathway separate from the EHR vendor? What methods are in place to ensure that there is no loss of data or bias in the aggregation of data into the registry?

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Methods (continued)	
Statistical Methods: To limit analytical and channeling biases	(a) Describe all statistical methods.
	(b) Describe the wound and/or patient risk stratification model that enables fair comparisons of wound outcome and patient outcome.
	(c) Explain deidentification protocols or the way in which protected health information (PHI) was protected.
	(d) Describe any methods used to examine subgroups and interactions.
	(e) Describe any methods used to remove outliers, invalid data, or excluded populations.
	(f) If applicable, explain how "lost to follow-up" was addressed, how matching of cohorts was addressed (including, and/or describe analytical methods taking account sampling strategy. As applicable, report methods used with standardized differences of key variables to match cohorts specifically for comparative effectiveness/safety research and/or benchmarking.
	(g) Describe any sensitivity analyses.

Results	
Participants	(a) Report numbers of individuals/wounds at each stage of study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed.
	(b) Give reasons for non-participation at each stage.
	(c) Include a flow diagram.
	(d) Specifically state the percent of ulcers for which the primary outcome (e.g., healing) was assigned contemporaneously by a clinician vs determined using other patient-specific clinical data (e.g., wound measurements) vs post hoc analysis, such as by imputation.

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Results (continued)	
Descriptive Data	(a) Give characteristics of study participants (patient age, sex, mobility, renal impairment, diabetes, peripheral vascular/arterial disease, other relevant comorbidities, adverse events) and their wounds (type, number of concurrent/prior wounds, number of prior amputations, duration, wound area, wound depth, wound severity, presence of ischemia) and information on exposures and potential confounders.
	(b) Indicate number of participants/wounds with missing data for each variable of interest.
	(c) Summarize follow-up time (e.g., average and total amount).
Outcome Data	(a) Report numbers of outcome events or summary measures.
	(b) Report each outcome based on the point along the patient's entire episode of care.[3]
Main Results	(a) Give unadjusted estimates and risk-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included.
	(b) Report category boundaries when continuous variables were categorized.
	(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.
Other analyses	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses.

Discussion

Key results	Summarize key results with reference to study objectives.
Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.
Interpretation	(a) Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.
	(b) Discuss the reliability of the conclusion(s).

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Discussion (continued)	
Generalizability	Discuss the generalizability (external validity) of the study results.

Other information	
Funding	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.

Conclusion

As medical professionals and scientists, we are committed to maintaining ethical standards in patient care and research. The USWR strives to maintain high standards by analyzing data fairly and reporting results honestly. We believe all registries should so the same, so that together we can facilitate better patient care and more informed public policy. Let us find what works for chronic wounds.

Notes

[1] Based on reporting standards and analytic guidelines proposed to minimize bias in wound care registries published by: Fife CE, Eckert KA. Harnessing electronic healthcare data for wound care research: standards for reporting observational registry data obtained directly from electronic health records. Wound Repair Regen. 2017;25:192-209. Carter MJ. Harnessing electronic healthcare data for wound care research: Wound registry analytic guidelines for less-biased analyses. Wound Repair Regen. 2017;25:564-73.

[2] STROBE Statement. Version 4. October/November 2007. https://www.strobe-statement.org/index.php?id=available-checklists. Accessed March 1, 2019.

[3] Additional criteria on how to report wound outcomes by:
Fife CE, Eckert KA, Carter MJ. Publicly reported wound healing rates: the fantasy and the reality. Adv Wound Care (New Rochelle). 2018;7(3):77-94.