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EDITORIAL

Reviewing the Record: Medical Record Reviews for Medical Toxicology Research

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Medical records are a treasure trove of data with tantalizing prospects for scientific advancement. In medical toxicology, medical records can provide detailed narratives of the clinical course and treatment of poisoned patients. These narratives identify nuances about exposures, provide insights into novel treatments, and stimulate ideas for future research. On the other hand, medical records often contain errors, omissions, and inconsistencies. Therefore, medical record review studies, also known as chart review studies, should be well-designed to contribute meaningfully to the medical literature.

The randomized, double-blind, placebo-controlled study represents a high methodological standard for medical research [1, 2]. There are several reasons why this study design is not always practical or feasible, especially in medical toxicology. First, it is unethical to poison human subjects prospectively and simply describe the clinical course or provide therapy to only a subset of the cohort. Second, many poisonings are rare, and performing a sufficiently powered prospective study cannot be done in a reasonable timeframe. New knowledge in the field of medical toxicology usually occurs from novel exposures, unplanned events, and natural experiments. For these reasons, case reports, surveys, and medical record reviews each play an important role in advancing patient care. These each have limitations that can be mitigated through rigor in design and manuscript preparation.

Methodological rigor, regardless of study type, can minimize bias while performing the investigation and improve the published product [3]. Here at the *Journal of Medical Toxicology (JMT)*, we have previously published guidelines and best practices to help authors improve their case reports and survey studies [4, 5]. We believe the quality of case reports and surveys have improved since we published those guidelines. Since the majority of the research submitted to and published in our journal are retrospective medical chart reviews, our editors deliberated for several years how best to guide the authors of these submissions. Many experienced members of our editorial board frequently cite the 1996 guidelines proposed by Gilbert and the subsequent article in 2005 by Worster, both in the field of emergency medicine, when evaluating submitted manuscripts that rely on medical record reviews [6, 7].

Although many of the retrospective studies submitted to *JMT* include cases that originated in the emergency department, we recognize differences in the field of medical toxicology from that of emergency medicine. For these reasons we describe here the important elements of a medical chart review study that should be considered by investigators when planning their studies and by authors when drafting a submission to *JMT*.

It is most important for all stakeholders to remember that the primary purpose of the medical record is not for research: instead, it is a document containing patient-focused medical information [6]. A medical record serves many roles—a communication tool between clinicians about patient care, an archive of a patient's clinical course, a source for medical coders and insurance billing, and even as evidence in legal proceedings. Historically, William Osler and other pivotal physicians used patient care records for retrospective research studies [8]. Today's medical chart would be unrecognizable to Osler; we also have a better understanding of the limitations of using a medical chart for research. The modern medical record includes multiple authors with different levels of training and different perspectives on patient care. The authors may be paramedics, nurses, pharmacists, medical students, and varying levels of physicians—residents, fellows, and attendings. What is asked of patients and what is examined varies by provider, and how that information is documented by the many different people involved in a single patient encounter

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can be distorted and contradictory. This ambiguity has been characterized by some epidemiologists as "noise" [9]. Studies have demonstrated variation in clinician-to-clinician understanding of patient history, perceptions of physical exam findings, and accuracy of recording information in the medical record [7]. The now widespread use of electronic health records (EHR) provides additional challenges to the use of the medical record for research purposes. Templating errors occur when preformulated text is inserted into a medical record or the copy-and-paste tool is carelessly used. Timestamps may be inaccurate because they are automatically generated when events are recorded rather than when events occur and may not have been manually corrected. Additionally, the sheer volume of data in the EHR increases the opportunity for conflicting data to be present [10]. Despite all of these challenges in the modern medical record, meaningful research is possible from the chart when investigators recognize these issues and plan appropriately.

Several steps should be followed when planning a medical record review study. First, a clear case definition needs to be specified by the investigators. Often an unexpected event—such as the recent US outbreak of synthetic cannabinoids containing long-acting anticoagulant rodenticides [11] or implementation of extra-corporeal membrane oxygenation as a novel treatment modality for severe multi-organ poisoning [12]—warrants deliberate study and dissemination of findings. Investigators must start with an easily understandable case definition.

Second, the medical records used in a chart review study should be described completely and concisely. Sampling methods and why cases were included or excluded should be clearly detailed. Each study variable should be clearly and precisely defined to ensure consistency throughout the study.

Third, how the study data (i.e., the medical charts) are handled by all members of the study team should also be carefully planned ahead of time and then described in the manuscript. Ideally, abstractors of the medical charts should be blinded to the study hypothesis to reduce bias and improve accuracy [9]. When more than one person performs the data abstraction, consistency in the abstraction process should be measured and reported as a calculation of inter-rater reliability. How the abstractors were trained and monitored during the course of the study, and what was done in cases of missing data or discrepancies of how data are interpreted should also be described in the manuscript.

Attention to these details allows the reader to understand the study context, better interpret the study results, recognize inevitable biases, and appraise the conclusions presented by the authors. The most informative manuscripts provide enough detail to allow a reader to recreate the same study independently at her own institution. And the best manuscripts acknowledge limitations honestly and transparently.

The guidelines summarized here are adapted from Gilbert [6] and Worster [7]. These guidelines do not address institutional review board oversight. This is an important standard that is already required for submissions to the *JMT* and most other journals. These guidelines also do not address issues involved when research involves database queries of EHRs designed specifically for research purposes. This topic is addressed elsewhere [13].

Guidelines for *JMT* medical record review studies:

1. *Case definition*. The case selection criteria and sampling method should be clearly stated.
2. *Data source*. The medical records used in the study should be described completely and concisely.
3. *Variables*. Each variable used in the study should be defined precisely.
4. *Abstractors*. Those involved in data abstraction and how they were trained and monitored should be disclosed.
5. *Inter-rater reliability*. Authors should discuss inter-rater reliability and if possible provide a statistical measure.
6. *Missing data*. What was done in cases of missing or incomplete data should be explained.

We understand that adherence to each of these guidelines is not always feasible. When that is the case, openly disclosing such details within the limitations section of the manuscript is appropriate and may provide incentive for better studies in the future. The perfect study does not exist, neither does the perfect manuscript. Even the best prospective, randomized studies have limitations. We offer these guidelines as a roadmap for authors, reviewers, and readers. Rather than lowering the bar on medical chart reviews, we are confident that having an appropriate bar with achievable standards will benefit the body of medical literature and ultimately the patients we treat.

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Compliance with Ethical Standards

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