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From the Editor

Data, data, data…

Julie Wegner

I have been thinking much about data over the last year, in part because of the potential of "big data" to provide new insights, and in part because of its bigness and the challenges that come with analyzing and interpreting large data sets. Although I do acknowledge the great potential for "big data" to impact health care and decision-making in the future, I have also developed some skepticism for what analysis of big data sets will actually achieve in improving patient outcomes. One of the main reasons for my skepticism is that analysis of big data sets are by their nature retrospective and observational in design, and thus carry all of the limitations of these types of studies. Increasing the number of subjects analyzed will not necessarily remove these limitations and may actually exacerbate biases if data collection and analysis are not carried out properly (1,2). At this time, the big perfusion/cardiac surgery–related databases do not fully represent the entire population, and increasing the number of patients analyzed may or may not improve generalizability to all patients. Testing the clinical validity of results from analysis from big data sets will be necessary to demonstrate the clinical utility of study findings (2,3).

Big databases are typically multi-institutional. Despite attempts at standardization of care, there are still variations in the conduct and practice of cardiopulmonary bypass (CPB) within and across institutions. This point is highlighted in this issue of *JECT* by Likosky et al. (4). In this study, two large databases were used to examine the equipment and conduct of CPB for isolated CABG surgery. The results of the study suggest that there is sufficient variation both within and between the databases to question whether or not "conventional bypass" truly exists. This study points out that the impact of "conventional" equipment and conduct of CPB in isolated CABG surgery on patient outcome is unknown, partly because "conventional bypass" is not 100% defined. The conclusion of the article is that there is a need for future studies to adequately describe the equipment and conduct of CPB so appropriate comparisons can be made. The study also calls for the development of reporting guidelines for CPB studies (4).

A second reason fueling my skepticism is the type of data collected, specifically, routinely collected data and the assumption that these collected data will provide answers to questions asked. Routinely collected data do not necessarily mean that the right measurements were collected to answer a study question or fully describe a physiological event. For instance, hematocrit and blood gases (arterial and venous) provide important information about the oxygen-carrying capacity of blood, but do not provide information about the delivery of oxygen to specific tissues such as the nephrons. Granted, the use of the routine measurements are the reality in health care, but it is still important to understand the limitation of the macro-physiological measurements to define what is happening at the tissue or cellular level, or the limitation of a point-in-time measurement. Perhaps analysis of big databases will reveal the inadequacies of currently used measurement techniques and inspire the development of better measurement devices that will help to better explain patient outcomes. Improved measurements of physiological processes may also lead to asking better questions about the physiological and pathological factors influencing patient outcomes.

A final reason for my skepticism related to big data analysis is based on the fact that the human body is a dynamic complex system. One of the hallmarks of a dynamic complex system is that the response of the system to an intervention is determined by initial conditions. Currently, most databases do not adequately measure the initial condition of the patient because of the use of routine measurements at one or maybe two points in time. The information from patient histories and preoperative tests are used to put patients into broad categories based on their general comorbidities (i.e. body mass index, diabetes, hypertension, and vascular disease). These broad categories do not provide the nuances that may be important to adequately explain how a patient will respond to CPB. Although there is potential for big data analytics to improve healthcare for all, getting there will require collection of the right information that adequately defines the patient's initial conditions. In other

areas of medicine, genomics is providing some of the initial condition information. Perhaps, one day, similar measurements will be available for cardiac surgery patients.

Along with the recommendation of guidelines for reporting equipment and conduct of CPB (4), the reporting of the methods used to collect and analyze big data sets is often inadequate. There is a need for transparent reporting so readers and reviewers can critically assess the strengths and weaknesses of the study design, the conduct of the study, and the analysis of the data. There are currently two reporting guidelines that address observational studies (STROBE), and more recently observational studies using routinely collected data (5,6). With the expansion of big data studies, there is a need to include these guidelines to allow authors, reviewers, and readers to assess the strengths and weaknesses of a study and the generalizability of the results (5). Look for these guidelines at the *Journal of ExtraCorporeal Technology* in the near future.

Announcement: As of January 1, 2019, I will be stepping down as Editor of the *Journal of ExtraCorporeal Technology*. Your new editor will be Raymond Wong, PhD, CCP. Ray is currently a practicing clinical perfusionist and the head of the perfusion education program at the University of Arizona. It has been an interesting experience being Editor of *JECT* and I want to thank all the reviewers, readers, board members, support staff, and *American Society of ExtraCorporeal Technology* community for their support over the last 3 years. Improvement in your community requires understanding of what is currently known and curiosity of the still unknown. Both will require engagement in the perfusion community beyond your daily clinical work. Thank you.

Julie Wegner
Editor-in-Chief

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