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Harm in Nephrology: Its Systematization

Confident in the classical biophysical knowledge that governs vectorial translocation of molecules in solution, most nephrologists are unmistakably shaken when things go awry for their patients undergoing hemodialysis or other renal replacement therapies. The calculations and formulas were without error, but errors occurred anyway, with harm as the extant corollary. The reason is simple, what happens to ideal gases and solvents is not ideal when one deals with the variability of reality in man, where "to err is human."

In this issue of *Advances in Chronic Kidney Disease*, Guest Editor Kellerman has selected a never-beforechosen topic—"harm" within the realm of our nephrological practices. Yes, we are implicated and culpable. There are plenty practice points where harm can occur too. Among these are hemodialysis units; interventional nephrology, cardiology, and radiology suites; and medication administration, particularly in kidney allograft recipients and renally susceptible inpatients with CKD and/or acute kidney injury (AKI). Naturally, the point of the exposition of the multiple methods of harm in this issue is to educate this readership on avoidance strategies.

Harm, in medicine, is frequently iatrogenic and generally stems from errors. Errors can be typified as personal, systematic, and random. The first often relates to one's inexperience, arrogance, or lack of knowledge. An example of the former may result from slavishly attempting to balance the inputs and outputs in a patient with AKI via ultrafiltration. This often results in a period of hypotension in a vulnerable patient. The latter is chained to a mini episode of additional AKI that subtends any last vestiges of recovery. Arrogance and lack of knowledge errors similarly derive from ignorance of the best knowledge available and an impatience to locate it. With today's electronically interconnected knowledge portals and information sources, a lack of evidence primarily represents a lack of effort. Even a lack of evidence may represent the best evidence available. In these cases, we rely on experience and hope that we have enough of it, or know a colleague with sufficient know-how. There still is room for this, and such individuals are to be imbued with the humility and thought that their primary task is to do no harm.

Systematic medical errors are rarely detected before "it's too late." When systematic errors are suspected, conducting a root cause analysis is a fundamental step in the elucidation of the critical process(es) that produce an error/harm. Systematic errors can be avoided by repeated practice and testing. Running an "error" scenario, particularly when using a medical device, may expose intrinsic device errors or extrinsic protocol errors. One such error may be the ability to disable an alarming system. This has been possible in dialytic equipment, thus allowing an operator to repeatedly ignore a potentially dangerous and ongoing event. Another extraordinary systematic error occurred in the manufacture of heparin, with consequent oversulfation of the anticoagulant, which led to anaphylactoid reactions on systemic exposure to hemodialysis patients. This systematic error abrogated multiple components of the Six Sigma methodology: define, measure, analyze, improve, and control. No checklist would have averted these disasters, but the lack of a measurement device to detect this systematic mistake brought to life an unseen error in protocol, with vicious repercussions. The assumption that the maintenance of quality production was unfailing was the penultimate error, and the nonproduction of a surveillance device was the ultimate error.

Random errors occur during unanticipated changes in personnel, devices, and environment. However, an adherence to schedules, checklists, and protocols may reduce random errors by controlling situational entropy. Mere adherence to timeliness reduces the stochastic probability of error (and harm) production.

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Checklists enforce safety. When thoughtfully constructed, they provide for efficient safety. Moreover, adding a layer of automation can provide forcing functions that only permit further processing after successful serial passage through various checkpoints, that is, no shortcuts. Compliance with protocols can also reduce harm. For example, a hemodialysis unit that protocolizes its approach to new arteriovenous fistulas may substantially reduce infiltrations and fistula losses. Protocols that initially permit only the best cannulators of a hemodialysis unit to "needle" virginal arteriovenous and set forth principles that nurture vascular access maturation will probabilistically enhance the maturation and life span of vascular accesses. Likewise, rules to be obeyed and that strategically navigate personnel traffic in hemodialysis units may reduce the number of falls of this vulnerable patient contingent. Simply establishing a metric that represents the dialysis unit's fall rate is not enough. Finally, the application of LEAN principles (LEAN refers to the acculturation and implementation of non-wasteful production practice that drives customer value) in hemodialysis units can reduce harm, reduce costs, and increase efficiency. The staff engagement in these workplace transformations of practical process improvement engenders an esprit de corps of inestimable value.

Errors have also been categorized as those of omission and commission. Omission errors are startling still, but the advent of computerized, automated order sets should preclude the vast majority of them. Yet, they still occur. The design of all-inclusive order sets provides a brutish failsafe approach to medicine, but can be tempered by judicious health care workers. Knowing when to exclude wasteful "add-ons" to medical care is a by-product of experience that we hope becomes evidence-based and aligns itself to a LEAN approach. Errors of commission often are the consequence of flawed judgment or an incomplete knowledge base regarding a given situation. Emotional, social, cultural, financial, and administrative pressures may further confound such circumstances. In these cases, making the "null" decision harms no one.

Errors must be discussed in order to be avoided. Morbidity and mortality conferences provide safe harbor for such discussions and must be scheduled and attended. Inculcating Six Sigma principles and LEAN principles in healthcare has proven successful, and the discipline of nephrology arguably may benefit in a disproportionate way. A demand for process improvement is realized easily if continuous quality improvement projects are embedded within the curricula of fellows-in-training. The use of multidisciplinary teams that are tasked to acknowledge, appreciate, and evaluate risks must be constructed in order to mitigate harmful circumstances, in a meaningfully strategic fashion. Simple assignations such as designating a person to maintain a log of the prevalent number of "catheter patients" or follow the white cell counts in transplanted and oncology patients potentially reap large returns on patient outcomes with small investments of time.

In each of the articles that follow, some form of harm will be featured. Each type of harm can be categorized and factored as indicated previously. Attempt to derive a protection or avoidance scheme for each form of harm, and if you can't, just say "no."

> Jerry Yee, MD Editor-in-Chief