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THE MOST SERIOUS CAUSES OF KIDNEY FAILURE AND THEIR PREVENTION

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ABSTRACT

Remarkable advances in instrument technology, automation and computer science have greatly simplified many aspects of previously tedious tasks in laboratory diagnostics, creating a greater volume of routine work, and significantly improving the quality of results of laboratory testing. Following the development and successful implementation of high-quality analytical standards, analytical errors are no longer the main factor influencing the reliability and clinical utilization of laboratory diagnostics. Therefore, additional sources of variation in the entire laboratory testing process should become the focus for further and necessary quality improvements. Errors occurring within the extra-analytical phases are still the prevailing source of concern. Accordingly, lack of standardized procedures for sample collection, including patient preparation, specimen acquisition, handling and storage, account for up to 93% of the errors currently encountered within the entire diagnostic process. The profound awareness that complete elimination of laboratory testing errors is unrealistic, especially those relating to extra-analytical phases that are harder to control, highlights the importance of good laboratory practice and compliance with the new accreditation standards, which encompass the adoption of suitable strategies for error prevention, tracking and reduction, including process redesign, the use of extra-analytical specifications and improved communication among caregivers.

KEYWORDS

Error; laboratory instrumentation; laboratory testing; preanalytical variability.

INTRODUCTION

The medical error Systems of medical and healthcare practices have existed among human societies since at least the dawn of recorded history. When medicine was basically characterized by the doctor's intellect, the nurse's empathy, simple surgical procedures and a limited number of drugs, there was little price to be paid for poor safety systems or disorganization, and adverse events were generally attributed to providence, fate, misfortune, or "God's will" (1). As

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medicine became more powerful and technologically sophisticated, highly specialized teams for care delivery emerged (2). In common with all other human activities, accidents go hand in hand with medicine and represent an unfavorable but inevitable circumstance. There is a long history of errors in medicine and the last century has seen a growing openness on the part of the medical profession regarding the part played by human error in patient mishaps. An evocative body of research describing this problem began to emerge in the early 1990s, supported by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality (AHRQ), when medical errors were identified as one of the four major challenges facing the USA in improving healthcare quality (3). In its report, "To Err Is Human: Building a Safer Health System", the United States Institute of Medicine (IOM) estimated that 44,000–98,000 Americans die each year not from the medical conditions they checked in with, but from preventable medical errors (4). IOM statistical analysis identifies medical errors as the eighth leading cause of death among Americans, with error-caused deaths each year in hospitals alone exceeding those from car, plane and other traumatic accidents and far ahead of those related to breast cancer or acquired immunodeficiency syndrome (AIDS). In practice, a US patient should be currently much more worried when falling within the net of the healthcare provider rather than deciding to take a plane. Nevertheless, such a significant figure, which is apparently attributable to professional malpractice or to lax compliance with quality requirements, should take into account some peculiar aspects of the care provided in the United States, such as the presence of highly specialized centers where complex procedures are performed (5). Therefore, comparison of error rates among different countries is hampered by substantial differences in design and development of national health systems, incidence of diseases and many other factors. For instance, analysis of the available data suggests that the United States performs the greatest or nearly thegreatest number of medical procedures per capita in several areas, including, for example, coronary bypass, dialysis and magnetic resonance imaging (6). A medical error, according to the IOM definition, could mean "a health-care provider chose an inappropriate method of care, or it could also mean the health provider chose the right course of care but carried it out incorrectly". Alternatively, a medical error is "the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim". An adverse event is defined as "an injury caused by medical management rather than by the underlying disease or condition of the patient" (4). The key point of the report is that "whether a person is sick or just trying to stay healthy, he or she should not have to worry about being harmed by the health system itself". Following the IOM declaration, the medical community has considerably increased awareness of this topic and several regulatory bodies and specialty organizations have incorporated the provision of increased patient safety as a core principle for accreditation. However, although great emphasis has been placed on medical errors alleged to have resulted in increased patient morbidity and mortality, less attention was paid to the tracking and prevention of diagnostic errors. In general, diagnostic errors are commonly multifactorial in origin and can be clustered within three categories: "system errors" typically play a role when diagnosis is delayed or missed because of latent imperfections in the healthcare system; "no-fault errors" occur when the disease is silent, presents atypically, or mimics something more common; and "cognitive errors" reflect misdiagnosis from faulty data collection or interpretation, flawed reasoning, or incomplete knowledge (7). Types and frequency of errors in laboratory medicine Most people, especially those less

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involved in the healthcare system, tend to believe that medical errors usually occur from misuse of drugs or mishandled surgery. Nevertheless, there are many other types of medical errors, including misinterpretation of medical orders and prescriptions, nosocomial and post-surgical wound infections, equipment failure and, last but not least, diagnostic errors, such as misdiagnosis leading to an incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results, and failure to act on abnormal results. Although there are several and heterogeneous characterizations for "laboratory error", a reasonable definition, recently acknowledged by the International Organization for Standardization, could be "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these" (8, 9). Although there is extensive literature dealing with the prevalence and types of mistakes, there is varying information on the total (preanalytical, analytical and postanalytical) error rates for laboratory testing, the relative burden of which traditionally spans a wide range (0.1–9.3%). The main reasons for such a broad difference are underreporting and impaired error detection techniques, the lack of a definite and universally accepted definition of laboratory testing error before 2002, different study designs and heterogeneous methodological approaches (10). Using data from the current literature, the error probability spans from 1 in 8300 laboratory results (or 2000 patients) (11) to 1 in 33–50 laboratory results (12). As these two limits probably do not reflect the real situation, a more probable error rate might range from 1 in 164 to 1 in 330 events or laboratory results (13–16). However, even very low rates, because of the large number of laboratory tests available, may reflect significant patient numbers (17). Whatever the type (random or systematic), there are several occasions for laboratory testing errors. Substantial advancements in automation and computer applications, particularly during the last two decades, have raised the awareness that analytical errors are no longer the main factor influencing the quality of laboratory testing, allowing a major sense of security regarding the analytical phase and focusing attention on alternative sources of errors, such as preanalytical and postanalytical factors. The process of laboratory medicine is typically divided into three main phases (preanalytical, analytical and postanalytical), with each of them variably affected by uncertainties and errors (18). Despite heterogeneity in study design, methodology of process analysis and error tracking or classification, the error distribution across the different phases of the entire testing process appears similar. In particular, it has been demonstrated that most laboratory errors occur in the preanalytical phase, primarily because of a lack of standardized protocols. The main reason for the high prevalence of errors in this crucial step of the testing process is that it is currently difficult to monitor all preanalytical variables and to implement any improvement processes necessary, particularly when most of the variables (such as phlebotomy) are not under direct laboratory control or supervision (19). The relative percentage of errors in this phase, suggested to be as high as 84.5% (8, 20), is frightening. There is a considerable difference between in- and outpatients, as reflected by the rather different error rates (0.60% vs. 0.039% for the two categories, respectively), which has been attributed to human factors related to skill in drawing blood and the sheer volume of laboratory tests carried out for inpatients (8, 10). Therefore, patient care involving non-laboratory personnel seems to account for the majority of errors, representing 95.2% of these mistakes (21). The typology of preanalytical errors encountered in laboratory practice is rather heterogeneous (Figure 1). Data from the most representative studies on this topic show that problems directly related to specimen collection are the main cause of preanalytical errors or variability,

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including hemolyzed (54%), insufficient (21%), incorrect (13%) and clotted (5%) samples (8). In vitro hemolysis, reflecting a more generalized process of blood and vascular cell damage that occurs during phlebotomy, is the most frequent reason forspecimen rejection, five-fold more frequent than the next reason (insufficient specimen quantity), as indicated by the College of American Pathologists (CAP) Chemistry Specimen Acceptance Q-Probes study (22). In hematology, a clotted specimen is the most frequent reason for rejection and the container type with the highest frequency of rejection is a pediatric tube (17). Overall, inappropriate specimen quality and quantity account for over 60% of preanalytical errors. Additional problems, such as incorrect sample identification or handling, might occur beyond the blood drawing process, although their prevalence is reportedly much lower (22).

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