Editorial

Linoj Samuel and Mario Plebani

Targeting errors in microbiology: the case of the Gram stain

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In the last decades a body of information has been accumulated to characterize the nature and incidence of errors in clinical laboratories. These studies led to further efforts to identify the steps of the testing process that are at high risk of errors and errors related to patient harm [1, 2]. This, in turn, paved the way for projects aiming to develop quality indicators specifically for the reduction of errors in clinical laboratories [3]. However, most of available data have been generated in clinical laboratories performing clinical chemistry, coagulation and hematology tests. The basic question is therefore "are collected data transferable to other types of clinical laboratories including microbiology, cytology and surgical pathology"?

Recently, Nakhleh and colleagues suggested that "the test cycle in surgical pathology and cytology is similar to the test cycle of other laboratory tests" [4]. In fact, the testing process is always composed of the pre-analytic, analytic and post-analytic phases and although the brain-to-brain loop model was developed specifically for laboratory medicine, it is useful for describing the general process of diagnostic testing [5].

More recently, a careful exploration at the beginning and the end of the cycle prompted the proposal to split the pre-analytical steps into a "pre-pre-analytical" and a "true" pre-analytical phase, being the former the initial steps of the cycle performed before the biological sample enters into the clinical laboratory, while the "true" pre-analytical phase includes all steps occurring within the laboratory in order to prepare the samples and ending when the analytical procedure begins. Analogously, the post-analytical steps are grouped into a "true" post-analytical phase consisting in procedures performed within the laboratory to validate the results, transforming the data into a report and finally communicate the report to the users. The "post-post-analytical phase" is represented by the steps that follows the report communication and takes into consideration the acknowledgment by the physician, the interpretation and utilization of the laboratory information [5]. Unlike the extra-analytical steps, the analytical phase is substantially different in some areas of laboratory medicine such as surgical pathology and microbiology in that it involves the inherent judgment of the professional at the time of the test interpretation. It is therefore more subjective than most clinical chemistry tests. This subjective nature makes it challenging to define errors in each phase and accurately document their incidence. Anatomic pathologists have documented the difficulty of establishing agreement on cause of errors in cancer diagnosis [6]. The Gram stain is an example of a microbiology test that requires interpretation by the medical laboratory technologist. The process of performing Gram stains may be manual or automated and the methods involved vary between laboratories but ultimately the challenge remains in accurately reading and reporting Gram stains. This can complicated by a number of variables such as quality of the specimen, method of fixation, organism viability and inherent variations in staining of the organisms present in the specimen as documented by Samuel et al. in their multicenter study on the incidence of Gram stain errors [7]. The growing trend of consolidation of microbiology laboratories mean that many hospitals are left without dedicated microbiology staff [8]. The majority of Gram stains continue to be performed by microbiologists at centralized laboratories, however, the need for stat Gram stains at satellite facilities when the information is needed for immediate intervention such as suspected cases of bacterial meningitis or intraoperative biopsies mean that this burden now falls on local laboratory staff. The limited volume of specimens for Gram stains processed by laboratory staff at these sites makes it challenging to develop proficiency in Gram stain interpretation. Errors in Gram stain interpretation are more likely to occur at such satellite laboratories and the clinical consequences can be significant [9, 10]. While regulatory bodies use proficiency specimens to gauge laboratory performance on Gram stains, these do not adequately measure performance nor do they serve to address gaps in proficiency [10, 11].

In an attempt to improve Gram stain performance, Guarner and colleagues describe in this issue of *Clinical Chemistry and Laboratory Medicine* the development of an alternative bimonthly Gram stain proficiency

challenge to complement the existing regimen [12]. This included staining and review of multiple slides from the central laboratory by technologists followed by both individual and group review of challenge results. Over the course of the study, they were able to demonstrate significantly improved performance in reporting of both Gram stain tinctorial characteristics as well as bacterial morphology. While other studies have advocated routine review by the central laboratory of Gram stains performed by the satellite laboratories [11], Guarner et al. were able to improve technologist performance to the point where routine review could be limited to once daily. This in turn reduces the burden on core laboratories to monitor performance of the satellites. The use of visual aids for Gram stain education is fairly common. By coupling these with regular individual and group review of commonly occurring Gram stain errors, Guarner and colleagues appear to have addressed the problems caused by low frequency of Gram stain performance. This also includes ensuring that technologists have the opportunity to participate in staining and smear interpretation as part of the proficiency testing process. The use of digital images or prestained slides alone for Gram stain proficiency limits the ability of the process to address gaps in the technologist ability to correctly fix and stain slides prior to interpretation. Each step add its own challenges to the process and failure to correctly follow protocol at any stage makes accurate interpretation of smears even more difficult. Quality improvement efforts need to address errors at all stages of the process. Targeting errors in the analytical phase of both surgical pathology and microbiology can be challenging due to the subjective nature of the work and the number of variables involved. The limited number of Gram stains performed by satellite laboratories and the failure of proficiency regimens to mimic actual patient specimens means that the responsibility falls on central laboratories to adequately train satellite laboratory staff. The effectiveness of the Gram stain as a diagnostic tool is incumbent on clinicians confidence in the quality of the result and willingness to act on the result rather than wait for a culture report. Guarner et al. used a multipronged approach combining proficiency challenges with educational huddles and visual tools to effectively reduce the error rates in a sustainable manner. The collaboration of central and satellite laboratories in this combined effort was crucial to this process. In the era of laboratory consolidation, the lessons learned here can prove to be invaluable for other laboratories that struggle to maintain Gram stain proficiency.

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Corresponding author: Linoj Samuel, PhD, D(ABMM), Division Head, Clinical Microbiology, Henry Ford Health System, Detroit, MI 48202, USA, Phone: +313-916-2341, E-mail: lsamuel2@hfhs.org
Mario Plebani: Department of Laboratory Medicine, University-Hospital, Padova, Italy. http://orcid.org/0000-0002-0270-1711