WHEN TO REJECT SAMPLES IN HEMOSTASIS TESTING?

QUAND FAUT- IL REJETER LES PRÉLÈVEMENTS EN HÉMOSTASE ?

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Abstract

Pre-analytical errors account for nearly 70% of errors in clinical laboratories. Those errors can directly impact patients' care and influence clinicians' decision making.
Hemostasis samples collection are highly sensitive to pre-analytical conditions. Samples' rejections are often due to the disrespect of the pre-analytical requirements.
Identifying samples' non conformities guarantees reliable results. Nevertheless, samples' rejection can also cause delays in diagnosis and patients' discomfort. Identifying and preventing those causes of errors should then be a continuous task in hemostasis laboratories aiming at reducing testing costs and improving patients' care in general.

Key-Words: Pre-analytical phase; Blood coagulation tests; Total quality management.

Résumé

Les erreurs pré-analytiques comptent pour près de 70% des erreurs aux laboratoires de biologie médicale. Ces erreurs impactent significativement la prise en charge des patients.
La phase pré-analytique est particulièrement sensible en hémostase comparée aux autres types d'explorations biologiques. La non satisfaction de certaines exigences pré-analytiques ou non-conformité est à l'origine du rejet du prélèvement dans la plupart des cas.
La reconnaissance des non-conformités permet d'assurer la fiabilité des résultats rendus. Toutefois le rejet des prélèvements non conformes est aussi à l'origine d'un retard diagnostique, d'un inconfort pour le patient. Ainsi la prévention des causes de non-conformité, leurs identifications et la gestion de ces causes d'erreur doit intégrer un processus continu au sein du laboratoire d'hémostase, visant à améliorer la qualité et à réduire le coût des analyses pratiquées.

Mots – clés : Phase pré-analytique; Tests de coagulation sanguine; Management par la qualité.

ملخص

تمثل أخطاء ما قبل التحليل نحو 70٪ من الأخطاء في المختبرات السريرية. يمكن أن تؤثر هذه الأخطاء بشكل مباشر على رعاية المرضى وعلى اتخاذ القرارات الطبية.
تعتبر عينات تحليل التخثر شديدة الحساسية لظروف ما قبل التحليل و غالبًا ما يرجع رفض العينات إلى عدم احترام متطلبات ما قبل التحليل. يضمن تحديد عدم مطابقة العينات جودة النتائج. لكن ذلك قد يؤدي إلى تأخير التشخيص. لهذا يجب أن يكون تحديد أسباب الأخطاء ومنع وقوعها مهمة مستمرة في مختبر تحاليل التخثر في سبيل تقليل تكاليف الاختبار وتحسين رعاية المرضى بشكل عام.

الكلمات المفاتيح :مرحلة ما قبل التحليل التخثر ; اختبارات تخثر الدم ; إدارة الجودة الكلية.

1-Introduction

Analytical errors in hemostasis testing have been substantially reduced in the last decades thanks to technical improvements and to the implementation of quality control programs [1,2]. Pre-analytical phase remains however critical and deserves the biologist's attention.

2 - Pre-analytical phase in hemostasis testing

The pre-analytical phase is particularly susceptible to errors in hemostasis testing [3,4].This is partially due to the sensitivity of samples to pre-analytical variables and to the predominantly manual nature of this phase. Indeed, inadequate processing of samples can lead to hemolysis or platelet activation. An insufficiently homogenized tube can cause from a partial activation of coagulation to coagulated samples. Freezing of samples containing cellular materials may also cause hemolysis or the activation of the coagulation cascade. All of these variables can falsely shorten or prolong clotting times [5].
Adherence to pre-analytical requirements in hemostasis seems essential, as results obtained on non-compliant samples do not accurately reflect the patient's clinical condition [6].

3 - Pre-analytical requirements in hemostasis testing

Pre-analytical requirements in hemostasis remain poorly standardized internationally[7-9].A study including 662 hemostasis laboratories based in 28 European countries found a wide divergence in the acceptability requirements for hemostasis samples. Requirements for minimum blood volume, for example, varied from a tube filled to ≥80% for 15%-17% of participants to a tube filled to ≥70% for 5-8% of laboratories responding to the questionnaire, while 1%-4% of participants had no volume requirements [9].
The International Council for Standardization in Hematology and the French Hemostasis and Thrombosis Study Group (Le Groupe Français d'études sur l'Hémostase et la Thrombose) have recently issued recommendations regarding the pre-analytical phase in hemostasis [10,11].
Samples not meeting these requirements should be identified and rejected in most cases (Figure 1)[3,10-12].
"Coagulated samples" can be due to a lack of homogenization of the tubes or to a laborious blood collection [7]. This non-conformity seems to be One of the main causes of rejection of hemostasis and hematology samples in general [13-15].
« Insufficient volumes » constitute 2% to 88% of rejected samples in hemostasis testing [13,16,17]. Narang and al. noticed a preponderance of this cause of rejection in the pediatric population [18].
Hemolyzed specimens' treatment is not as consensual in the literature. Ellouze and al. recommend to process these samples, to report the hemolyzed nature of the sample and to check the result on another sample [3]. For Dikmen et al, a slightly hemolyzed sample could be analyzed, especially since the new instruments avoid this interference by detecting clot formation at a wavelength greater than 600 nm[8].However, these instruments do not compensate for the shortening of coagulation times secondary to the release of thrombotic substances after blood cells' lysis[19].
These pre-analytical errors appear to be rare [3]. They are serious because they can distort the diagnosis and have a substantial impact on patient's care. This is why the World Health Organization's "Alliance for Patient Safety" has defined "improving patient and sample identification" as the primary objective of medical laboratories. The introduction of barcodes is recommended as it has been shown to reduce this type of pre-analytical error [7]. The generalization of patients' ID bands could also minimize the risk of identification errors [7]. This avoidable cause of error should be reduced to a minimum [18].

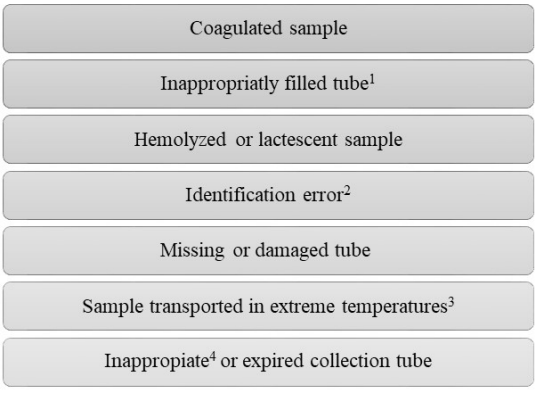

Figure 1: Samples' rejection criteria in hemostasis

[1] : insufficient volume or over-filled tube ;
[2] : no identification, illegible name or barcode, names' mismatch;
[3] : refrigerated, freezed, or transported in >37°c temperature ;
[4] : collected on tubes other than citrate or CTAD tubes;

4 - Other causes of samples' rejection in hemostasis

The rejection causes: "Missing or damaged tube", "Sample transported at extreme temperatures", and "Inappropriate tube or expired tube" have been less reported in the literature [7,13,16,17]. However, the low frequency of these rejection causes could be due to a lower awareness of the laboratory staff to these risks of pre-analytical errors and therefore a failure to identify them. This underlines the need to written procedures on hemostasis' samples requirements and sample rejection's procedure. Staff should be made aware of it and comply with these procedures.

5 - Samples' rejection rates in hemostasis

Few studies have been published on this subject despite the sensitivity of the hemostasis parameters to pre-analytical phase and the potential it offers in terms of improving the quality of analyses. Rejection rates in hemostasis laboratories vary from 8.18% to 25.25% depending on the study [13,16,17]. They are clearly higher than the rates of non-compliance in hematology laboratories, which range from 0.11% to 0.99% [14,18,20]. This underlines again the sensitivity of the pre-analytical phase in hemostasis and the potential it offers in terms of quality improvement.

6 - Importance of monitoring the rejection causes

Total quality management has evolved to focus not only on the quality of the result but also on the quality of the patient's care as a whole [13]. The pre-analytical phase offers more potential in terms of quality improvement [6,7,14]. The importance of this phase is further supported by the quality indicators proposed by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). Indeed, 16 of the 25 quality indicators developed by the IFCC Working Group on Laboratory Error and Patient Safety focused on the pre-analytical phase. The rate of rejected samples is one of these indicators [20].
The monitoring of the performance of the 3 phases "pre-analytical", "analytical" and "post-analytical" is encouraged [21].
Identifying difficulties helps to minimize the risk of errors and thus improve the quality of patient care [15,22,23]. Monitoring rejection causes allows corrective measures to be proposed and avoids diagnostic delays, iterative iatrogenic blood loss and the additional cost of rejecting these samples [12,18,22]. This should be achieved via a functional, simple and non-burdensome system [25]. The monitoring system should allow the follow-up of these parameters as well as the evaluation of the effectiveness of the different corrective measures [22,24]. Optimizing the existing information system is desirable [20,23].

7 - Identifying repeat-offenders

Hospitalization wards appear to be the most common source of rejected samples in hemostasis testing [4,18]. In centralized laboratories, rejection rates for samples from decentralized collection rooms were higher than for those collected within the laboratory [23]. Thus, the departments with the highest number of rejected samples or "repeat offenders" would be those where the staff is the least aware of the importance of the pre-analytical phase in hemostasis, wards where the workload is important and where the phlebotomists turnover is higher[13,14].

8 - Implementing corrective measures

Monitoring samples rejection causes and the wards most responsible of them enables us to propose the appropriate corrective measures and to monitor their effectiveness in reducing rejection rates and improving the quality of patients care, following the processes' improvement model: Find-Organize-Clarify-Understand-Select (FOCUS) Plan-Do-Check-Act (PDCA) cycle[13,25].
This model is structured as follows : **Find :** find an opportunity for process improvement (reduction of rejection rates in hemostasis); **Organize**: organize a team with the necessary knowledge (biologists and laboratory staff); **Clarify**: current knowledge of the process (identify the frequency and main causes of samples' rejection); **Understand**: identify the problems in the process (identify the origin of samples' rejection and the different stakeholders); **Select**: select the actions to be taken to improve the process (propose corrective measures). The FOCUS model is realized through PDCA cycles (Figure 2).

9 - Involving the different stakeholders in the quality improvement process

A multidisciplinary approach involving laboratory staff, clinicians, phlebotomists and administrative staff is recommended [25]. This team will focus primarily on those laboratory activities that are most amenable to improvement and offering the

greatest benefits in patients' quality of care betterment. Involving the various stakeholders in the establishment of quality improvement programs identifies opportunities based on common experiences of the whole team and ensures their adherence to corrective actions [21,25].

10 - Educating phlebotomists on the importance of the pre-analytical phase in hemostasis

Several studies have looked at the contribution of educating nurses and phlebotomists on pre-analytical requirements in reducing rejection rates for hemostasis samples. Bostic and al. were able to reduce their rejection rate by informing the nursing staff through a bulletin entitled "Correct blood sampling for hemostasis investigations" and also by repeatedly communicating these recommendations to the wards that were most likely to be "repeat offenders"[4]. Salinas and al. were also able to reduce the sample rejection rates by addressing monthly bulletins to the collecting departments reporting their rejection rates as well as the main causes of samples' rejection compared to the previous month's results [23].

Via training in sampling techniques, Abbas and al. were able to improve the knowledge of samplers[22].The phlebotomists' knowledge assessment by Banković Radovanović et al has besides revealed a lack of information regarding the duration of venous stasis, the order of filling tubes, homogenization of tubes, and the procedures to be undertaken in case of difficult samples[13].
This deficiency was subsequently corrected by communicating the study results and by training the phlebotomists in proper sampling techniques.
The evaluation of the knowledge of the different teams allows offering a personalized training according to the knowledge of the target population and the different causes of non-conformities noted[12,13].

11 - Conclusion

Hemostasis investigations are particularly sensitive to pre-analytical conditions. The recognition of non-compliant samples is required to ensure the results reliability. The improvement of results quality depends on a continuous process of monitoring and prevention of these rejection causes.

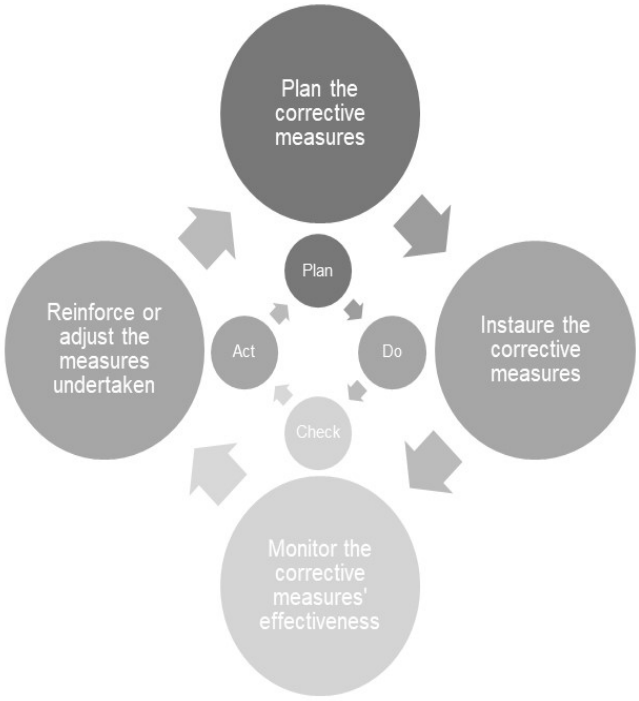

Figure 2: Implementing corrective measures using PDCA cycles

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