Mini Review

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The EFLM strategy for harmonization of the preanalytical phase

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Abstract: The Working Group for the Preanalytical Phase (WG-PRE) was officially established by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) in 2013, with the aim of improving harmonization in the preanalytical phase across European member societies. Since its early birth, the WG-PRE has already completed a number of projects, including harmonizing the definition of fasting status, patient and blood tubes identification, color coding of blood collection tubes, sequence of tubes during blood drawing and participation in the development of suitable preanalytical quality indicators. The WG-PRE has also provided guidance on local validation of blood collection tubes, has performed two European surveys on blood sampling procedures and has organized four European meetings to promote the importance of quality in the preanalytical phase. The future activities entail development and validation of an external quality assessment scheme focused on preanalytical variables, development and dissemination of a survey about the local management of unsuitable samples in clinical laboratories, as well as release of EFLM phlebotomy guidelines. This article summarizes all recent achievements of the WG-PRE and illustrates future projects to promote harmonization in the preanalytical phase.

Keywords: diagnostics; errors; laboratory testing; preanalytical phase; quality.

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Introduction

The total testing process is conventionally partitioned in many sequential parts, developing through the pre-preanalytical phase (i.e. test ordering), the preanalytical phase (i.e. patient preparation, sample collection, handling, transportation, storage and preparation for testing), the analytical phase (i.e. sample measurement), the postanalytical phase (i.e. results transmission) and the post-postanalytical phase (i.e. results interpretation) [1] (Figure 1). Throughout this multifaceted process, and like other medical disciplines [2], some mistakes may occur, leading to possible generation of diagnostic errors, which may detrimentally affect clinical decision making and managed care, thereby jeopardizing patient safety [3].

There is now solid evidence that diagnostic errors are mostly attributable to the lack of standardization or harmonization of many manually intensive activities belonging to the preanalytical phase [4–6]. Unlike mistake in other parts of the total testing cycle, the identification of preanalytical errors remains challenging because the vast majority of these activities are performed outside the physical boundaries of clinical laboratories, with insufficient guidance, or often without the direct supervision of laboratory professionals [7]. This may be due to the lack amongst healthcare professionals of both education and training on best practice in the preanalytical phase, such as in the collection of biological specimens [8–10], along with an insufficient dissemination and application of existing guidelines and recommendations [11].

In keeping with these important issues, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has endorsed the establishment of a Working Group for the Preanalytical Phase (WG-PRE) in 2013. The terms of reference of this WG are many and ambitious, encompassing (i) the promotion of importance of quality in the preanalytical phase; (ii) definition of the best practices and release of guidelines or recommendations pertaining the most vulnerable steps of the preanalytical phase; (iii) design, validation and dissemination of

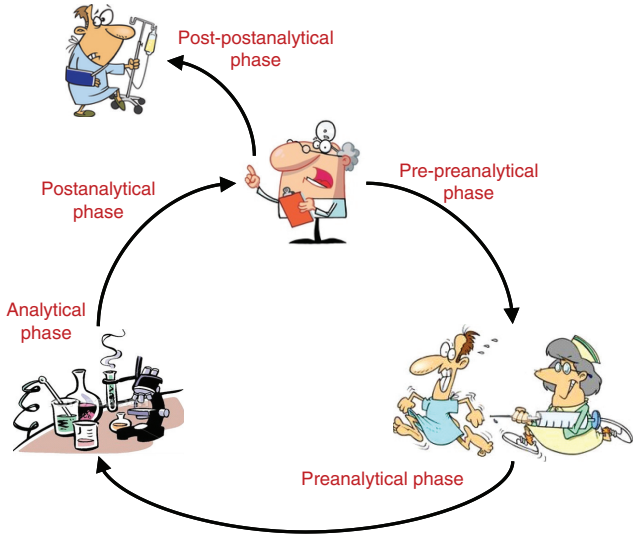

Figure 1: The total testing process.

surveys and questionnaires intended to assess the current preanalytical practices; (iv) organization of meetings, symposia, workshops, webinars or other forms of educational courses on preanalytical phase issues [12]. These objectives were originally established for improving quality in clinical and laboratory practice, but were then broadened to other domains of science and medicine such as clinical research trials, in which the quality of the preanalytical phase is at least as important as in routine diagnostics [13]. The actual composition of the group (including both laboratory professionals and representative of diagnostic companies), the aims, the published documents and recommendations, along with the ongoing and future projects of the WG-PRE, are available on a dedicated page of the EFLM website [14]. The following sections of this article are aimed at providing an overview of the current and future strategies of the WG-PRE for improving harmonization in the preanalytical phase, with a brief description of the completed and ongoing activities (Table 1).

Table 1: Activities of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE).

Finalized projects
– Harmonization of fasting status
– Harmonization of patient and blood tubes identification
– Harmonization of color-coding of blood collection tubes
– Harmonization of the sequence of blood tubes to be followed during blood drawing
– Harmonization of preanalytical quality indicators
– Guidance on local validation of blood collection tubes
– Performance and publication of two European surveys on blood sampling procedures
– Organization of four international meetings
– Walter Guder Preanalytical Award
Ongoing projects
– Development and validation of an external quality assessment (EQA) scheme on preanalytical variables
– Development and dissemination of a survey about local management of unsuitable samples
– Release of EFLM phlebotomy guidelines
– Organization of webinars for harmonizing preanalytical activities

Finalized projects and official recommendations

Patient preparation and fasting status

The standardization of patient preparation before testing is a critical issue, which embraces many potential sources of variability such as the circadian rhythm, physical activity, posture during sample collection and, last but not least, fasting status. Several lines of evidence showed that collecting blood after food (or beverage) intake may be an important cause of clinically relevant bias in tests results [15]. This may be attributable to a direct effect of hemodilution, to the increase of food components (e.g. glucose, triglycerides) or their metabolites in blood, or to indirect effects of foods on hormones and other endogenous compounds. In keeping with these findings, the WG-PRE has recently published a document containing some clear indications about the fasting status before collecting blood [16]. Briefly, according to the WG-PRE, blood for laboratory testing should be preferably drawn between 7:00 and 9:00 am, the patient should be fasting for not <12 h, alcohol should be avoided for not <24 h before blood collection, while cigarettes, coffee and tea should not be permitted immediately before drawing blood.

Harmonization of blood sampling procedures

At the dawn of the third millennium, with non-invasive blood testing still an unmet target [17], the collection of venous (or arterial) blood samples remains virtually unavoidable for obtaining biological materials (whole blood, serum or plasma) that can be reliably used for laboratory testing. Phlebotomy – and the synonyms of venipuncture, blood collection and blood draw – is probably the most frequently performed "modestly invasive" procedure in healthcare [18]. Despite this, there is objective evidence that the practice of collecting blood is poorly harmonized

across Europe and that training of healthcare professionals with blood collection responsibilities is dramatically insufficient. In 2013, the WG-PRE developed and disseminated a specific questionnaire about education and training on phlebotomy in European countries [19]. Some interesting findings emerged from this project, which can be briefly outlined as follows: (i) there is an urgent need to audit the quality of current practices and identifying the most vulnerable steps in phlebotomy; (ii) many European countries have not developed local phlebotomy guidelines, nor they have recommended the use of available international recommendations; (iii) the implementation of, and compliance to, phlebotomy guidelines in different healthcare settings is dramatically insufficient; (iv) the national EFLM societies should be more committed to development of educational programs and to establishing continuous education courses for healthcare phlebotomy personnel. After discussing the data obtained with this former survey, a second project was then developed by the WG-PRE. A structured, 29-item checklist was constructed and disseminated across Europe to investigate the level of adherence of national phlebotomy procedures with the Clinical and Laboratory Standards Institute (CLSI) H3-A6 document [20]. Interestingly, data collection from 12 European countries identified that compliance with CLSI H3-A6 was dramatically low. Moreover, accurate patient identification and tube labelling were identified as the most vulnerable steps, requiring immediate action.

Patient and blood tubes identification

The critical data that emerged from the two WG-PRE surveys have clearly demonstrated that both patient and blood tube identification remains vital issues for the quality of the total testing process. The many errors still attributable to inaccurate patient identification and inappropriate labelling of blood tubes are well known to everybody working in clinical laboratories, but are somehow underestimated, or overlooked, by a large proportion of healthcare staff with blood collection responsibilities [21, 22]. This evidence persuaded the WG-PRE to develop *ad hoc* recommendations to help increase the standardization of these two crucial preanalytical steps [23]. Essentially, the WG-PRE currently recommends that (i) zero tolerance should be established by the healthcare institutions for patient identification errors; (ii) no fewer than two (preferably three) unique patient identifiers are needed for accurate patient identification, one of which may be the full name of the patient; (iii) the verification of patient identity with specimen labels should be performed in the presence of the patient; (iv) a set of standard operating procedures for patient and blood tubes identification should be made available by healthcare institutions to the phlebotomy staff; (v) a policy of systematic detection and recording of identification errors should be locally established by each healthcare institution; (vi) supplementary education and training of phlebotomy staff should be planned; (vii) the member societies of the EFLM have a duty to implement and audit compliance with these recommendations at both a national and local level; (viii) these recommendations should be considered by supranational quality and standardization organizations such as the CLSI or the International Organization for Standardization when drafting or revising their documents.

Validation of blood collection tubes

The evacuated blood collection tube is a sterile plastic container with a closure and is designed to collect a well-defined volume of blood. Since the quality of these devices is vital for both laboratory testing and for ensuring operators' and patients' safety, the WG-PRE has recently drafted a document defining precise criteria for local validation of blood collection tubes in clinical laboratories, so that their quality can be objectively established as for reagents and laboratory instrumentation [24]. Briefly, the most important criteria that should be verified encompass (i) demonstration that the combination of all the different components of the system have been validated by accredited bodies; (ii) checking the existence of studies performed by the manufacturers to demonstrate the performance, ease of use, sample quality and potential risks of their products; (iii) the manufacturers' capacity to manufacture and supply an adequate number of blood tubes to all the facilities that are planned; (iv) performance of local studies aimed at verifying the consistency of declared performance (i.e. failure rates, underfilling, blood spilling, inappropriate positioning of blood separators, failure of additives to obtain the desired effects); (v) inclusion of laboratory professionals in tenders for purchasing blood collection devices.

Color coding of blood collection tubes

The different types of evacuated blood tubes are usually identified by the phlebotomy staff from the color of the closure (i.e. the cap). An arbitrary order of color-coded plastic cap, along with the sequence of the blood drawing was defined by one manufacturer many years

ago, entailing that a yellow-colored cap was to be used for tubes containing sodium polyanethole sulfonate (for blood culture), light blue for those containing sodium citrate (plasma, for coagulation testing), red or orange for those containing no additives or clot activators (serum, for clinical chemistry and immunochemistry testing), green for those containing lithium-heparin (lithium-heparin plasma, for clinical chemistry and immunochemistry testing), lavender for those containing ethylenediaminetetraacetic acid (EDTA) salts (whole blood or EDTA plasma, for hematological, genetic or immunochemistry testing) [25] and gray for those containing sodium fluoride and potassium oxalate (plasma, for glucose testing). Unlike this arbitrary but functional scheme, other manufacturers have designed blood tubes with different colors caps, so generating a substantial confusion for the phlebotomy staff, especially when the personnel moves from one facility to another. As a paradigmatic example, some manufacturers use light blue-colored caps to identify citrate tubes, whereas this color is used to identify serum tubes by other companies. Since this lack of agreement may be a source of tangible errors (i.e. collecting blood in unsuitable containers or with the wrong additive), the WG-PRE has endorsed an official recommendation that major efforts should be made to reach major harmonization of colour coding for blood collection tube closures and labels across Europe [26].

Order of draw

The "order of draw" is the term conventionally used to describe the specific sequence that blood tubes should be drawn, as described in the previous paragraph about color coding (e.g. blood culture tube should be collected first and sodium fluoride/potassium oxalate blood tube for last). This sequence was proposed many years ago, after the publication of a limited number of anecdotal case reports describing cross contamination of additives from one tube to another, and since then has been endorsed by both the CLSI and the World Health Organization phlebotomy guidelines. In recent years, after development of high quality evacuated blood collection tubes, the risk of cross contamination of additives during a well-conducted venipuncture using straight needles has been convincingly ruled out when manufacturers recommendations are followed [27]. Nevertheless, in the belief that an ideal blood collection is sometimes unattainable, and also considering that following the order of draw is not a challenge for phlebotomists [28–30], the WG-PRE currently recommends that the order of draw should preferably be followed when drawing venous blood [31].

Standardization of preanalytical quality indicators

The quality indicators (QIs) are conventionally defined as performance expectations of healthcare quality. They are typically used for assessing or monitoring whether or not a certain healthcare intervention is performed according to the best practice, and also whether changes in practices are really effective in reaching the expected outcomes. The history of QIs in laboratory medicine began many years ago, but a general consensus has only recently been reached about the number and type of QIs that should be used throughout the total testing process, which includes that of the preanalytical phase [32, 33]. In a recent consensus conference, a joint meeting of several members of both the Working Group on "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and of the EFLM WG-PRE has further revised the original scheme of QIs, thus proposing a new set of measures which contains 28 indicators of preanalytical quality including inappropriate requests, identification errors and measures of sample quality [34]. In order to harmonize data collection and facilitate benchmarking, a coordinated effort of the WG-LEPS and WG-PRE has then led to the design of a specific preanalytical error recording software, which can be used by different laboratories around the globe as a simple and reliable tool for homogenous and standardized reporting [35].

Ongoing projects

In addition to the many achievements of the WG-PRE since its inception, there are also several ongoing projects aimed to harmonize preanalytical practices. Recognizing the pivotal role of external quality assessment (EQA) in global harmonization [36], the WG-PRE has recently signed a Memorandum of Understanding (MoU) with EQALM (European Organisation for External Quality Assurance Providers in Laboratory Medicine), which represents European EQA providers in laboratory medicine [36, 37]. As a result of this MoU, the WG membership was expanded to include two EQALM representatives. The aim of the MoU is to develop a means of improving the coordination and collaboration between the EFLM and EQALM

on mutually important issues to improve the quality of laboratory medicine in Europe.

Future projects in this respect are aiming to develop a pilot European Type 2 EQA scheme based on preanalytical case scenarios (i.e. circulation of samples simulating errors) [38, 39] and a Type 1 preanalytical EQA survey to examine the way clinical laboratories throughout Europe detect and manage unsuitable samples in laboratories (i.e. registration of procedures).

WG-PRE is also working on the development of the EFLM phlebotomy guidelines along with some useful tools (checklist for performing audits, knowledge test to assess the competence of phlebotomy staff and a presentation to be used for the education of staff involved in phlebotomy), which will be then translated into various European languages to facilitate the implementation of the recommended procedures. Finally, the EFLM has also submitted a Horizon 2020 project entitled "Standardization of Preanalytical Procedures for in vitro diagnostic studies in Personalized Medicine" (PREPMED). The project has received a positive feedback by the European Community, but was not found to be eligible for funding. The aim of the WG-PRE is to resubmit this project for a future Horizon 2020 call.

Educational meetings and other activities

Education is one of the leading objectives of the WG-PRE. This has been developed through the participation of WG-PRE members in many national and international meetings about harmonization and standardization in laboratory medicine, and also through the organization of an international, joint EFLM-Becton Dickinson meeting every 2 years. The first meeting was organized in Parma (Italy) in 2011 (~300 participants) [40], the second in Zagreb (Croatia) in 2013 (~500 participants) [41], the third in Porto (Portugal) in 2015 (~600 participants) [42], the fourth (as yet) being organized in Amsterdam (The Netherlands) in 2017 (over 600 participants) [43] and the next one scheduled in Munich (Germany), in Spring 2019. The full programs of these meetings are available in a dedicated website [44].

The WG-PRE is also planning to develop a series of webinars, entailing short lessons aligned with the various guidelines and recommendations of the WG. Finally, to promote the importance of preanalytical phase and encourage the research in that area of laboratory medicine, the WG-PRE has established the Walter Guder Preanalytical Award, which is granted to young scientists for their significant contributions to improvement of the preanalytical phase. Two awards have already been made: the first one in 2014 during the 3rd EFLM-UEMS European Joint Congress in Liverpool to Dr. Johannes Zander from Germany for a study entitled "Effect of biobanking conditions on short-term stability of biomarkers in human serum and plasma" [45] and the second one in 2016 during the 4th EFLM-UEMS European Joint Congress in Warsaw to Niamh Daly from Ireland for the study entitled "Impact of implementing preanalytical laboratory standards on the diagnosis of gestational diabetes mellitus: a prospective observational study" [46].

Conclusions

On the awareness that the preanalytical phase is the leading source of problems in laboratory diagnostics, the WG-PRE has already made many efforts to disseminate a culture of quality in the extra-analytical phases of the testing process, and is also aiming to continue this educational activity in the future, with the aim of increasing standardization and harmonization of additional preanalytical activities.

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