Letter to the Editor

Giuseppe Lippi*, Laura Sciacovelli, Ana-Maria Simundic and Mario Plebani

Innovative software for recording preanalytical errors in accord with the IFCC quality indicators

DOI 10.1515/cclm-2016-1138
Received for publication December 14, 2016; previously published online January 26, 2017

Keywords: errors; laboratory medicine; preanalytical variability; software.

To the Editor,

The preanalytical phase, encompassing at large all those activities necessary to obtain a suitable biological specimen, is an essential part of the total testing process [1]. Several lines of evidence attest that uncertainties, poorly standardized and even misleading preanalytical procedures produce the vast majority of problems in diagnostic testing, wherein up to 60%–70% of laboratory errors can be brought back to the preanalytical phase [2, 3].

The definition, implementation and monitoring of reliable quality indicators (QIs) is an essential solution for reducing vulnerability in the various phases of testing, including the preanalytical phase. Nearly 10 years ago, the Education and Management Division (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) established a Working Group on "Laboratory Errors and Patient Safety" (WG-LEPS) [4], aimed at stimulating studies on the topic of errors in laboratory medicine, collecting data and recommending strategies and procedures to improve patient safety. Soon afterwards, a Working Group for the Preanalytical Phase (WG-PRE) was established by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) [5]. The activities of the latter WG are devoted to reducing the vulnerability of the preanalytical phase by producing official recommendations, guidelines and education material for laboratory professionals and healthcare operators.

The development of the project of QIs in Laboratory Medicine has been one of the most important and productive initiatives of the WG-LEPS [6], based on the assumption that the use of standardized QIs to assess and monitor the quality system of the laboratory may be valuable in maintaining control of the total testing process by means of a systematic and transparent approach. A first set of QIs was established during a Consensus Conference organized in Padua (Italy), in 2013 [7]. The preliminary list of QIs embraced 45 performance measures in 22 key processes, 12 of which belong to the preanalytical phase. During a second Consensus Conference, organized in the same town 3 years later, the panel of experts decided to introduce a refinement and simplification of the former list of QIs, which may become available later in the 2017.

Despite the general consensus that has been reached for using this standardized set of QIs in different laboratories worldwide, a gap remains to be filled. More specifically, the process of recording information about sample quality in different laboratories remains challenging. The many preanalytical errors can be manually registered in paper sheets or forms, directly entered in the laboratory information system (LIS) or elsewhere. Some years ago, a preanalytical errors recording software was developed for easing and standardizing the activity of recording preanalytical errors [8]. This software has been quite successful, as confirmed by the many laboratories requesting

***Corresponding author: Prof. Giuseppe Lippi,** Section of Clinical Biochemistry, University Hospital of Verona, P.le LA Scuro 10, 37134 Verona, Italy, E-mail: giuseppe.lippi@univr.it. http://orcid.org/0000-0001-9523-9054; Working Group for Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), Italy; and Working Group for Preanalytical Phase (WG-PRE) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Croatia
Laura Sciacovelli: Working Group for Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), Italy; and Department of Laboratory Medicine, University-Hospital of Padova, Padova, Italy
Ana-Maria Simundic: Working Group for Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), Italy; Working Group for Preanalytical Phase (WG-PRE) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Croatia; and Department of Medical Laboratory Diagnostics, University Hospital Sveti Duh, Zagreb, Croatia
Mario Plebani: Working Group for Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), Italy; Working Group for Preanalytical Phase (WG-PRE) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), Croatia; and Department of Laboratory Medicine, University-Hospital of Padova, Padova, Italy

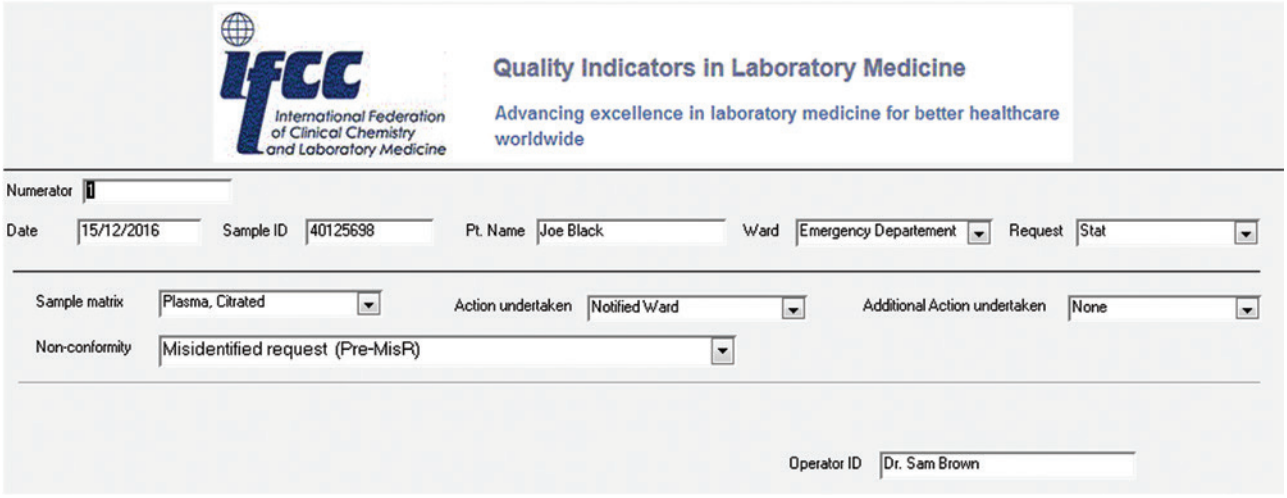

Figure 1: Layout of the preanalytical errors recording software developed in accord with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) quality indicators.
The full program is available as Supplementary Material.

to receive a copy and by the significant number of article citations. Nevertheless, some years after its development, we were finally persuaded to update the program, which has now been standardized according to the last panel of IFCC QIs.

Briefly, the program has been developed using the software Microsoft Access® (Microsoft, Redmond, WA, USA), and includes the most important fields for recording preanalytical non-conformities, namely date of sample receipt, sample number or identification (ID), name of the patient, origin of the specimen, type of request, sample matrix, main and secondary actions undertaken, type of non-conformity classified according to the list of IFCC QIs, and the name of the laboratory professional who has identified and managed the problem (Figure 1). Notably, although the different fields of the software can be easily customized in the menu "structure" of Microsoft Access® (e.g. including more hospital wards, listing the wards as a number instead of a name, modifying the actions undertaken, etc.), we strongly suggest that the field "type of non-conformity" should be left unaltered, so allowing (i) to directly exporting standardized data in the IFCC QIs program, and (ii) allowing comparison and benchmarking with other facilities around the globe, to permit participation to the IFCC QIs program. The software, which runs under the menu "Objects" → "Mask" → double click on "Table 1", may be especially useful for those laboratories which have difficulties in entering directly the preanalytical errors in their LIS, for those not having a LIS, or for those in which the LIS does not allow to extract data and generate statistics.

In addition to a means of standardized and homogenous reporting across different laboratories worldwide, there are other notable advantages of this software. First, the program can be stored in a mainframe or in the LIS server, and then used by many laboratory operators on "client" personal computers, so that the information can be finally archived from different clients to the single centralized database. Then, the data can be easily extracted and exported in Microsoft Excel® (Microsoft) worksheets, allowing rapid and efficient generation of local statistics to be used for tracking preanalytical errors and establishing proactive strategies for their prevention or reduction.

We really hope that this preanalytical errors recording software, available as a supplementary file to this letter, may help the ongoing process of standardizing errors reporting in the preanalytical phase and increasing participation in the IFCC QIs program [9]. The software will be maintained and continuously updated according to the ongoing revision of the QIs.

Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.
Research funding: None.
Employment or leadership: None declared.
Honorarium: None declared.
Competing interests: The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

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Supplemental Material: This article (DOI: 10.1515/cclm-2016-1138) contains supplementary material, available to authorized users.