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Review

Extra-analytical quality indicators and laboratory performances

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ABSTRACT

In the last few years much progress has been made in raising the awareness of laboratory medicine professionals about the effectiveness of quality indicators (QIs) in monitoring, and improving upon, performances in the extra-analytical phases of the Total Testing Process (TTP).

An effective system for management of QIs includes the implementation of an internal assessment system and participation in inter-laboratory comparison. A well-designed internal assessment system allows the identification of critical activities and their systematic monitoring. Active participation in inter-laboratory comparison provides information on the performance level of one laboratory with respect to that of other participating laboratories.

In order to guarantee the use of appropriate QIs and facilitate their implementation, many laboratories have adopted the Model of Quality Indicators (MQI) proposed by Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of IFCC, since 2008, which is the result of international consensus and continuous experimentation, and updating to meet new, constantly emerging needs.

Data from participating laboratories are collected monthly and reports describing the statistical results and evaluating laboratory data, utilizing the Six Sigma metric, issued regularly.

Although the results demonstrate that the processes need to be improved upon, overall the comparison with data collected in 2014 shows a general stability of quality levels and that an improvement has been achieved over time for some activities. The continuous monitoring of QI data allows identification all possible improvements, thus highlighting the value of participation in the inter-laboratory program proposed by WG-LEPS.

The active participation of numerous laboratories will guarantee an ever more significant State-of-the-Art, promote the reduction of errors and improve quality of the TTP, thus guaranteeing patient safety.

1. Introduction

Since the extra-analytical phases of the Total Testing Process (TTP) are known to be more error-prone than intra-analytical phase, it has become a priority for laboratory professionals to use adequate procedures that reduce the risk of errors in these phases, as well as a system ensuring continuous improvement, and enhancement of patient safety [1–5].

Laboratory performance in its entirety hinges on quality of pre-analytical activities, which has a direct impact on intra-analytical procedures and post-analytical activities. The performance characteristics of intra-analytical procedures, long monitored by internationally recognised tools, such as internal quality control (IQC) procedures and External Quality Assessment (EQA)/Proficiency Testing (PT), have stimulated continuous improvement [6–8].

In the last few years, awareness of laboratory medicine professionals has been raised concerning the effectiveness of quality indicators (QIs) in monitoring and improving performance in the extra-analytical phases [9–11]. Of course, their efficacy as a tool depends on their correct utilization, calling for: adequate identification and definition of each and every indicator; definition of a standardized and systematic data collection procedure; integration of QIs in a coherent strategy of quality improvement; use of QI data to identify appropriate improvement actions. A strong commitment of laboratory professionals in using this tool is prerequisite to promoting improvement projects since data on quality indicators do not per se improve quality. Only the correct interpretation of, and reaction to, data can clarify the nature of errors (root cause analysis) thus leading to corrective and preventive actions.

The use of QIs covering the entire TTP, required by the International Standard for Accreditation of laboratories ISO 15189:2012, is widely accepted as a process and strategy assisting risk identification and management [12–15].

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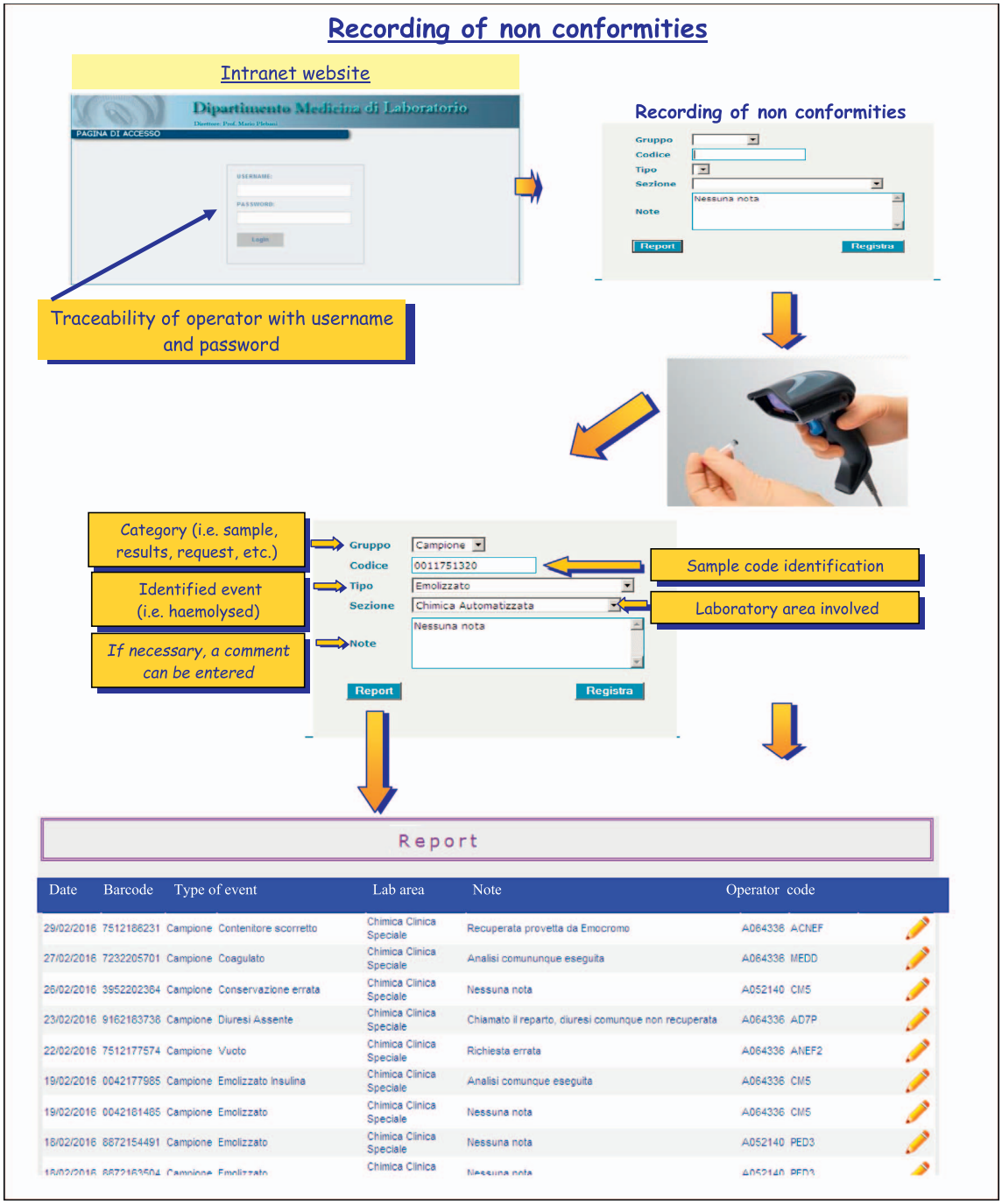

Fig. 1. Recording of non-conformities by a computerized application used in the Department of Laboratory Medicine of Padova (Italy).

In order to comply with the requirements of International Standard ISO 15189 and to improve the performance of extra-analytical phases, many laboratories have implemented QIs on the basis of their own health care context, purpose and goals, and number and typology of patients [16–18]. However, it is difficult to establish the current error rate because QIs from different laboratories yield incomparable data. The scientific community is now striving to identify the best possible procedure for managing and harmonizing the use of QIs in laboratory medicine [19–21].

In order to guarantee an effective QI management system, implementation of an internal assessment system and participation in inter-laboratory comparison have to be included. A well-designed internal assessment system allows the identification of critical activities and their systematic monitoring, and active participation in inter-laboratory comparison provides information on the performance level of one laboratory compared with that of other participating laboratories.

2. Internal assessment system

Aim of internal assessment system is to design an operative flow that guarantees appropriate definition and utilization of QIs that successfully keep critical lab activities under control and raise awareness in the laboratory staff concerning the need to adequately manage QIs data. The final purpose is to reduce the error rate and improve laboratory performance [22]. The system comprises the following.

a) Definition of a list of QIs that includes the following steps.