Partners in error prevention

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In an exclusive acutecaretesting.org interview, Dr Mario Plebani, Head of the Department of Laboratory Medicine at the University Hospital of Padova, Italy and international patient safety advocate, talks about how laboratory, clinicians and manufacturers can work together to reduce errors in testing and diagnosing and increase patient safety.

acutecaretesting.org: Why is addressing errors in laboratory medicine so important?

Mario Plebani: Evidence has been collected to demonstrate that 60-70 % of the most important medical decisions are based on laboratory medicine. Thus, even small error rates in relationship with the billions of tests performed every day may result in poor clinical outcomes and negative economic outcomes for every healthcare system.

acutecaretesting.org : Have errors in laboratory medicine always been an issue?

Mario Plebani: Yes. In the modern age, starting with the famous study by Belk and Sunderman in 1946, the problem of errors in clinical laboratories has received an increasing amount of attention.

However, only in the last decade has it been possible to evaluate – using well-designed studies – the rates, frequency and distribution of errors.

In particular I would like to underline the importance of the publication by Ross and Boone in 1991 and successive papers by my group in Clinical Chemistry to demonstrate that pre- and postanalytical phases are much more vulnerable to errors than the analytical phase.

acutecaretesting.org: What are the most typical errors in lab medicine and how often do they occur?

Mario Plebani: According to the frequency of errors described in the literature, the most typical and serious errors are observed in the preanalytical steps. In

particular, misidentification of patients and samples is a dramatic and still frequent event.

Errors in blood collection are also common, as well as problems in transport and storage of biological samples. In the postanalytical phase, delays in reacting to laboratory information and problems due to poor or wrong interpretation of laboratory data are also common.

acutecaretesting.org: What is the total testing cycle and why is it a unique framework for identifying and reducing errors in the testing process?

Mario Plebani: The total testing cycle, formerly known as "brain-to-brain loop", describes all steps starting with ordering the right test to correctly reacting and interpreting laboratory results for an effective clinical decision-making process.

What really counts, from a patient point of view, is the use of laboratory information to improve clinical outcomes. From this point of view, it is not relevant where the possible error occurs; in test ordering, collecting blood, in the analytical phase or when interpreting results.

All these possible errors, because they can translate into adverse events or missed and delayed diagnoses, are *"laboratory errors"* and should thus be avoided.

acutecaretesting.org : What are the cited deficiencies in POCT laboratories?

Mario Plebani: The ten most cited deficiencies are as follows:

1. Failure to perform quality control testing
2. Failure to document QC activities
3. Failure to follow manufacturers' instructions explicitly
4. Failure to document personnel training and competency
5. Failure to document and take appropriate corrective action for control outliers
6. Failure to have a procedure manual for testing and result reporting
7. Failure to perform and document calibration verification at least every 6 months
8. Failure to verify accuracy for analytes not included in a PT program
9. Failure to provide continuing education for testing personnel
10. Failure to document POCT results in the patient record

Some of the previously reported errors are related to unsatisfactory quality procedures that affect the quality system of the institution. However, these do not have immediate consequences on patient safety. On the other hand, other failures are directly related to possible errors and adverse events.

This is the case for poor training and education, as well as failure to follow manufacturers' instructions, and to perform quality control testing.

In addition, the poor documentation of each and all POCT result(s) in the patient record may translate into inappropriate request of additional tests, and lack of information that can lead to changes in patient management and therapy.

acutecaretesting.org: What are the sources these errors?

Mario Plebani: According to the seminal paper published by Meier and Jones in 2005, the main sources of error are operator incompetence, non-adherence to procedures and use of uncontrolled reagent/equipment.

These are sources of analytical errors that cannot be immediately identified, also when some quality control programs are performed. It has been demonstrated that incompetence and poor training lead to a wrong utilization of medical devices, including POCT equipment, impacting result reliability.

The control of equipment and the use of reagents within the expiration dates are basic, yet fundamental issues in

providing valuable and clinically useful laboratory data.

acutecaretesting.org: Are there aspects that amplify these sources of error?

Mario Plebani: In my opinion, there are three: incoherent regulation, rapid result availability and immediate therapeutic implications.

Most POCT tests are designed to allow a rapid turnaround time for an effective management of critical situations. This, however, leaves no time for further considerations and perhaps repetition of tests due to the immediate need of clinical decisions and treatment.

Therefore, the availability of rapid results and the immediate clinical-therapeutic implications may amplify the risk of adverse events and negative clinical outcomes.

acutecaretesting.org: Where does this leave us?

Mario Plebani: Taking into consideration the main sources of error and amplifiers, the lesson we have learned is that POCT testing must be regulated and subjected to accurate controls. Without effective training, education of operators and adherence to procedures, POCT results cannot maintain the expected levels of reliability and quality.

Because of the immediate implications that laboratory results may have when produced by POCT technologies, the impact of errors can be dramatic and higher than for other types of laboratory tests.

However, the situation can be remedied in a strict cooperation between laboratory professionals, clinicians and other POCT operators. Manufacturers are also involved in this alliance for quality, because there is the need to design and produce robust technologies, which may avoid gross errors and assure quality, if appropriately utilized.

acutecaretesting.org: To what extent can or does automation minimize the main sources of error and amplifiers in POCT?

Mario Plebani: Automation, particularly if the term does not refer simply to analytical steps, is fundamental in reducing errors. Examples of the importance of *"automation"* in a broader sense are the unambiguous identification of patients and labeling of biological samples, the decrease of manual manipulation in the analytical phase, and the automation of results interpretation thanks to mathematical algorithms and expert systems.

acutecaretesting.org: During the last AACC meeting in July 08, you presented some interesting data on the effect of introducing interpretative reports as a way of reducing the number of errors and possible misdiagnosis. What are interpretative reports and how do they aid physicians in keeping up with an ever increasingly complex test panels?

Mario Plebani: The practice of adding comments to laboratory reports, particularly when the physician is not familiar with a test or with a panel of laboratory tests, is not new. However, some factors may favor the continuation, or even expansion, of the practice, such as:

- Introduction of new and complex tests
- Data on physician's satisfaction and impact on clinical outcomes
- Clinical and regulatory guidelines
- Increased communication of electronic data
- Competition between clinical laboratories
- Increasing use of expert systems and interpretative algorithms
- Need to provide an improvement in the quality of care

I would like to stress the point that new and complex tests have been and will be increasingly introduced into clinical practice, particularly in some diagnostic areas such as autoimmune disease, allergy testing, cancer diagnosis, etc.

In addition, a body of evidence has been collected to demonstrate the physician satisfaction and the improvement of clinical outcomes when interpretative services are available.

acutecaretesting.org: Does the introduction of interpretative reports pose QA challenges in terms of how and who ensures the quality of the comments and their upkeep? What about the regulatory and legal aspects? Can and should these comments be subject to inspection? And can the hospital be sued if an incorrect diagnosis is based on an incorrect comment?

Mario Plebani: There is the need to evaluate the quality of interpretative services and in some countries, such as the UK and Italy, some external quality assessment schemes (EQA) are already available.

The lesson we have learned is that interpretative comments may be entrusted to pathologists and scientists with the appropriate professional qualifications and who are accredited for being specifically trained in providing comments in specialized areas of laboratory medicine.

While top management of the individual laboratory is responsible for defining standards assuring the appropriate qualification and training for performing this activity, it must be borne in mind that interpretation provided by laboratory professionals with inadequate expertise can be clinically dangerous.

Finally, it should be underlined that interpretative comments do not represent "a diagnosis", but a suggestion for better interpretation of the laboratory information.

Diagnosing is a more complex issue and the knowledge of clinical history, symptoms and other diagnostic information are mandatory for achieving a diagnosis. From a legal point of view, there is no further implication for a laboratory service adding comments to the report than those related to the reliability of the analytical results.

acutecaretesting.org: What are the main challenges facing POCT when it comes to avoiding errors and ensuring patient safety?

Mario Plebani: POCT cannot be considered a substitute of common laboratory services, but as important and even essential technological support to deliver laboratory services. However, POCT technologies are not safe per se.

It should be underlined that operator education and training, appropriate choice and evaluation of technologies, quality control and quality assessment are fundamental issues to guarantee reliable results.

The role of laboratory professionals is to supervise these activities and educate operators. The main challenges are therefore to correctly understand the advantages and limitations of POCT technologies and counteract the vision of POCT as a commodity.

acutecaretesting.org: How do you see these challenges being solved?

Mario Plebani: First, there is the need to recognize the role of laboratory professionals in selecting the technologies, types of test and in educating other operators to perform POCT tests.

In particular, the key role of laboratory professionals must take into consideration the importance of quality control and assurance in everyday practice. Secondly, manufacturers should design and produce robust technologies to improve the safety of operators and procedures, thus allowing a reduction of current error rates.

Thirdly, clinicians have to better understand the value and reliability of laboratory results. Recent data demonstrate that less than 50 % of clinicians base clinical decisions on results of potassium obtained from the blood gas analyzers.

Most clinicians still await laboratory confirmation. This stresses the point that there is no rational request for and utilization of POCT tests.

Interviewee

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