

Critical issues and new trends on stat tests in clinical laboratory

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ABSTRACT

Meeting Report on the IX European Symposium on Clinical Laboratory and In Vitro Diagnostics Industry (Barcelona)

The IX European Symposium of the Clinical Laboratory and In Vitro Diagnostics Industry, entitled “Stat Tests in Clinical laboratory”, took place in Barcelona, Catalonia (Spain), between May 17–18, 2017.

The scientific program was structured in several roundtables that dealt with the following topics: emergency laboratory models, accreditation of stat tests by ISO 15189, critical issues of stat tests and the new proposals of the in vitro diagnostics industry for emergency laboratories. The aim of the Symposium was the discussion of the transformation that stat tests have generated on clinical laboratories in terms of organization, turnaround time, accreditation, and probable evolution of these laboratories coming years.

INTRODUCTION

The IX European Symposium of the Clinical Laboratory and In Vitro Diagnostics Industry, entitled “Stat Tests in Clinical laboratory”, was held in a most welcoming yet modern environment at the old gothic Hospital de la Santa Creu. The event was co-organized between the Catalan Association of Clinical Laboratory Sciences (ACCLC) and the Catalan Society of Biology (SCB). The symposium was sponsored by the International Union of Pure and Applied Chemistry (IUPAC) and under the auspices of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).

The topic of stat testing in clinical laboratories was chosen as an opportunity to discuss the current state of emergency laboratories and also analyse the probable evolution of these laboratories in the coming years. Stat (from the Latin *statim*, immediately, but also considered as an acronym for “short turnaround time”) identifies laboratory tests that should be made available within a defined, as short as possible time, according to clinical necessity (1,2).

There are several reasons that make stat testing an interesting topic for a Symposium. Mainly, organizational and economic aspects: collecting blood outside scheduled activity, the need of quick sample transportation to the laboratory in some cases with pneumatic tube systems, activation of specific paths for managing specimens with priority over routine samples, in many of laboratories entails exclusive staff, specific instrumentation and the need to maintaining back-up instrumentation (3).

EMERGENCY LABORATORY MODELS

Currently, three laboratory models are adopted for the management and performance of stat tests. Each of these solutions is related to the

size and type of hospital or institution in which they are employed (2).

Generally, in small- and medium-size laboratories, ordinary and stat tests are integrated, and their analysis is performed in the same place using the same instrumentation. The situation in large laboratories is rather more heterogeneous, with the majority of organisations continuing to separate stat from ordinary tests, using different instrumentation, personnel and locations. An intermediate option also exists, in which stat test analyses are semi-integrated in an automated core chain with routine samples, all of which are processed at the same time. However, each approach requires specific workflow processes, leading to different timeliness to produce a validated result. Generally speaking, the stat testing process should be structured to fit the context of care in which the testing services are required.

There was a strong discussion regarding how to prioritise these stat analyses in order to provide an adequate turnaround time (TAT), such as for samples in a specific emergency chain and branches of the chain for the highest-priority samples. It was concluded that large laboratories tend to incorporate stat tests in central automation areas (core), prioritising and adapting circuits to obtain response times appropriate to the needs of each situation.

For decades, stat tests have been performed in dedicated laboratories, either at stand-alone satellite locations or aggregated with central laboratories. However, considering that today all first-line tests can be managed rapidly via total laboratory automation (TLA) (24-hour laboratories), the traditional model appears outmoded for several reasons.

Firstly, a dedicated emergency laboratory represents a source of duplication of analytical platforms that perform the same assay in both emergency and ordinary situations, as well as the

duplication of operating staff and, sometimes, the duplication of orders for the same test.

Secondly, from an analytical perspective, parallel processing of tests across more than one laboratory location within a healthcare setting requires that the analyser alignment be checked continuously to assure comparability of patient results. Although ensuring that the difference between results produced for the same test in stat and central laboratories does not exceed a clinically acceptable difference is often a challenge, it is mandatory for patient monitoring during hospitalisation. All this complexity represents a significant drain on laboratory resources and makes the dedicated emergency laboratory/section model outdated and more expensive than TLA, especially when the latter can manage modern testing processes effectively and with a short TAT (2).

Finally, the chairman enquired as to the role of point-of-care testing (POCT) in emergency laboratories. Bedside testing through implementation of point-of-care devices in the emergency department, intensive care unit or any other ward that more often would require urgent test results for patient management.

The experts explained that POCT at satellite locations may represent a new laboratory model. Stat tests may sometimes be performed near an intensive care department as part of critical analyses used in the evaluation of vital functions. POCT is typically evaluated positively by clinicians because it allows a reduction in TAT and a reduced length of stay in the emergency department (4).

All the experts agreed that POCT should depend on laboratory staff because it is a stat test activity. The involvement of laboratory staff in the management of POCT should therefore be total, from the choice of measurement system, staff training, and quality control assurance to the integration of the results into the clinical history of the patient.

ACCREDITATION OF STAT TESTS BY ISO 15189

The second roundtable discussion addressed issues regarding the accreditation of stat tests by the International Standard ISO 15189. All experts work at emergency laboratories, accredited by UNE-EN ISO 15189, and which perform a high percentage of accredited stat tests. Accreditation is a procedure by which an authoritative body gives formal recognition that an organisation is competent to carry out specific tasks according to certain standards. The National Accreditation and Certification Authority (ENAC) is the agency appointed by the Spanish government to operate as the only national accreditation body. Accreditation of stat test laboratories according to ISO 15189 is becoming more and more a matter of course in Catalonia. However, there are currently only accredited stat tests laboratories in the province of Barcelona, with those in Girona, Lleida and Tarragona certified by ISO 9001:2008 or ISO 9001:2015. The essential difference between certification and accreditation is that the latter, as well as management requirements, also refers to technical competence (5).

To accredit or not to accredit, that is the question. All speakers agreed that the process of accreditation would improve the quality of lab services due to the better documentation of processes and the increased responsibilities or interest of management. The first step prior to accreditation is building an enthusiastic team that is educated regarding the development of quality management systems.

There was an interesting debate as to whether the accreditation of stat tests is more difficult than the accreditation of routine analyses. The former is certainly more laborious because emergency laboratories contain many members of staff and accreditation requires an increase in staff competence. Frustration of evaluated

staff must be avoided, and they must be shown that accreditation is a continuous process of improvement. Laboratory leaders must ensure that staff technical competence is highly praised, as this can provide a great boost to team spirit, as well as instil a sense of achievement and pride in their accreditation.

It was agreed that quality standards for stat tests should be just as rigorous as those for routine tests. Moreover, internal and external quality controls must be available for all parameter devices and must fulfil the same quality requirements specified for non-stat test analysis (5).

In addition, interchangeability studies must be carried out when emergency laboratories are separated from routine laboratories using different instrumentation. ISO 15189 requires that results obtained using different devices are interchangeable in order to assess non-different clinically relevant discrepancies (5).

It was deemed necessary to be proactive in risk management and to make good use of brands listed by ENAC in the final laboratory reports, although the experts outlined the potential difficulties of their use following the regulations.

During the roundtable, it was also emphasised that laboratories should evaluate the impact of work processes and potential failures on examination results, as they can affect patient safety. Laboratories should therefore modify these processes to reduce or eliminate the identified risks, as well as document decisions and actions taken.

It was noted that the presence of the ENAC mark on reports provides an assurance that the laboratory will be able to rely on this endorsement; only laboratories that are actually accredited can make use of the ENAC mark to indicate accredited status (5). However, the experts explained there can be difficulties in using the ENAC mark in final reports, with improper use potentially leading ENAC to bring legal action against the laboratory.

Finally, the speakers encouraged the attendees to consider and initiate actions that will lead them to accreditation, arguing that they themselves had perceived internal improvements in their processes and that they were very satisfied to have achieved this. Accreditation is a process that involves the whole laboratory and requires both good support from management and the positive assessment of clients (clinicians and patients).

Hence, higher quality laboratory testing associated with accreditation is expected to improve patient care by aiding the timeliness and accuracy of medical decision making.

Accreditation programs can help drive improvements in the management of individual laboratories and laboratory networks and may also have positive spill over effects on performance in other sectors of the health care system. In summary, laboratory accreditation can be achieved through leadership, vision and hard work.

CRITICAL ISSUES OF STAT TESTS

The third debate was attended by a clinician who shared their vision of the laboratory from an outside perspective. Critical issues discussed included the non-conformities that laboratories detect in samples and the impact that they may have on result interpretation. All speakers agreed that a strict stance should be taken when dealing with stat test non-conformities such as haemolytic, poorly spotted or insufficient samples. Greater awareness should be promoted among clinicians, as should the continued training of nursing staff involved in sample extraction. It became clear during the debate that in special situations, such as with newborns, it would be necessary to consider a differentiated treatment.

Currently, serum index measurement (haemolysis, icterus and lipaemia) is automated and determination of the interfering substances is

objective (6). This approach provides benefits compared with subjective visual interpretation, such as increasing the traceability, efficiency and effectiveness of the work process.

In any case, internal and external serum index quality assurances are available for the vast majority of laboratories.

In summary, non-conformities must be dealt with and minimised systematically, as they can influence the reliability of test results, affect patient safety, delay result acquisition and, ultimately, are a drain on resources.

There was an interesting debate regarding the definition of turnaround time. Laboratories most commonly define turnaround time as the time taken from specimen receipt in the laboratory to the moment that test results are reported. However, clinicians may also define turnaround

time as the period from test ordering to reporting (7).

Speakers and assistants agreed that laboratory staff must be involved from the moment of sample arrival in the laboratory with the aim of optimising hospital circuits. Laboratory staff can help to achieve optimum turnaround time in a variety of ways, for example by introducing a pneumatic tube system. Many studies have proven the efficiency of this mechanism in reducing delays arising from human couriers (8).

The causes of poor satisfaction in laboratory users include stat test turnaround times; this parameter was considered by the majority as the most important indicator of laboratory functioning. Hospital computerisation, including the recording of time from test request, sample collection, report generation and report receipt by the clinician would help in generating

Table 1 Turnaround times in stat laboratories

Parameters	TAT (min)				TAT goals (min)
Literature	S. Angeletti (Ref. 9)	A. Dolci (Ref. 10)	AH. Lou (Ref. 11)	TL. Ellison (Ref. 12)	Wu, Nichols, Hawkins (Refs. 13-15)
Blood gas	-	-	-	-	<15
Blood count cell	21	11-20	22	-	<20
P – Potassium	41	28-49	40	-	<30
P – Troponin	45	29-34	-	52	<60
Prothrombin time	42	36-44	34	-	<45
P – Creatinine or P – Urea	41	36-58	39	-	<45
P – glucose	40	-	-	55	<45
Urinalysis	-	-	-	-	<30

turnaround time data. Analysis of any outliers in turnaround times in a lab would then provide an insight into potential causes of delays and the areas that need improvement.

Table 1 shows summarizing data from previous publications on turnaround times for stat test results. Differences among laboratories have been shown. TAT goals for stat samples were established by different recommendations from clinical practice guidelines.

There are situations that these TAT have to be improved, for example: sepsis code, stroke code and myocardial infarction code. Emergency departments, primary care physicians, divisions of cardiology, hospital administrations, and laboratory staff should work collectively to develop an accelerated protocol for the use of biochemical markers in the evaluation of these patients.

Another topic discussed was the catalogue of a stat test laboratory. It was argued that several aspects should be considered before a stat test is included in a catalogue, with the following underlined: cost, knowledge of the property, technological availability, human resources, and characteristics of the test in terms of positive and negative predictive value, sensitivity and specificity, and above all clinical utility.

The catalogue should be adapted to the laboratory needs of each hospital and it is essential to reach agreement with clinicians. The control of demand must be based on scientific evidence and not guided by economic criteria alone.

In many laboratories, it is obvious that some tests are ordered as stat not for clinical needs but rather for other organisational reasons, such as quick retesting due to previously unsuitable samples, requests for previously forgotten tests, or a desire to receive routine results more rapidly (16).

Sometimes, users may simply be unaware of the difference between stat and ordinary tests.

However, logistical issues can never be considered a good reason for ordering stat tests, as inappropriately ordered tests may degrade the ability of the laboratory to deliver clinically urgent information in a timely fashion. Clinicians not receiving results in the expected timeframe typically order more urgent tests, further reducing laboratory effectiveness and increasing costs (17).

Finally, a discussion took place regarding critical results, i.e. those results that must be immediately sent, either by phone or electronically, to the patient care provider by laboratory staff. The question arose as to who should define a result as being of critical value; responses included the requirement for consensus with clinicians, published recommendations and laboratories' professional experience.

An expert outlined a project involving the Catalan Institute of Health (ICS) and other centres. As part of the project, a descriptive cross-sectional study was undertaken by laboratory professionals and clinicians from hospitals and primary care centres, with biological parameters reviewed whose values - are likely to be considered as possibly critical - and therefore must be reported. In addition, the critical limits considered and actions carried out after obtaining a critical result were also reviewed. From this approach an agreement between the participating laboratories was reached that subsequently formed the basis for the construction of an initial model, based on consensus with clinical practitioners.

To achieve consensus with clinicians, a Delphi model was applied in real time according to the "Health Consensus" methodology.

The model used data from a questionnaire that was sent to clinicians to value and identify, according to their criteria, when a result should be considered critical. The document prepared will be available soon.

PROPOSALS OF THE IN VITRO DIAGNOSTICS INDUSTRY FOR EMERGENCY LABORATORIES

The final debate was performed with the collaboration of the in vitro diagnostics industry, who outlined potential technological solutions for emergency laboratories.

Initially, each representative of the in vitro diagnostics industry explained their technological proposal for stat test laboratories. All speakers agreed that each laboratory and hospital is different and that flexible solutions should be sought for each model.

Currently, three laboratory models are available: ordinary and stat tests fully integrated into automated chains; stat test laboratories independent from ordinary test laboratories; and an intermediate option in which stat test analyses are semi-integrated in an automated core chain with routine samples, all of which are processed at the same time.

Many laboratories are currently considering the installation of total laboratory automation systems for routine clinical chemistry and laboratory haematology testing. The advantages of total laboratory automation include cost reduction and improved turnaround time. Such automated pipelines integrate pre-analytics (check-in, sorting, centrifugation and aliquoting) and post-analytics (storage and disposition), offering the possibility of bulk input, volume detection, aliquoting and storage. All speakers stated that their companies are attempting to find solutions with which to prioritise the processing of stat test samples within automated chains.

The moderator and attendees asked the industry representatives to promote the development of computer-based tools that would allow the calculation of turnaround time and allow users to determine exactly how long each process lasts, including centrifugation, aliquoting,

processing and report global delivery time. They also advised that the industry focus their efforts on achieving improvements in pre-analytical processes. Computer enhancements should also be made available for communicating critical results either through mobile telephony or messaging via tablets and other devices. All speakers agreed that they encounter many problems regarding the protection of data when installing such systems in hospitals. Finally, they were asked to work to offer technological and other solutions so that stat test laboratories can obtain accreditation, according to UNE-EN ISO 15189, for the analyses carried out.

Finally, the in vitro diagnostics industry representatives acknowledged that it is necessary to work together to solve both current needs and those that may arise in the future.

CONCLUSIONS

We are moving towards a new model of health-care system, in which every patient has a critical pathology and treatment is “emergent” for all. In this scenario, laboratories must consider every test a stat test, so that the separation between routine and stat processes is abolished. Automation, and particularly total laboratory automation, represents a formidable tool with which to both meet increasingly demanding critical needs and, even more importantly, improve patient outcomes.

In conclusion, in laboratory medicine, although technology can be used to improve clinical effectiveness and patient outcomes, it must be managed by qualified laboratory professionals.

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