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Survey on stat tests in Catalan clinical laboratories

Ariadna Arbiol-Roca, Dolors Dot-Bach

Laboratori Clínic Territorial Metropolitana Sud, Hospital Universitari de Bellvitge, Hospitalet de Llobregat, Barcelona, Spain

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Corresponding author:
Ariadna Arbiol-Roca
Laboratori Clínic Territorial Metropolitana Sud
Hospital Universitari de Bellvitge
Hospitalet de Llobregat
Barcelona
Spain
Phone: +34932607500
E-mail: ariadna.arbiol@bellvitgehospital.com

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ABSTRACT

Introduction

The Catalan Association of Clinical Laboratory Sciences (ACCLC) conducted a survey on the vast majority of hospital clinical laboratories in Catalonia. In order to establish a debate on the emergency laboratories and aspects related to the stat tests.

Materials and methods

An online survey was distributed by ACCLC to 69 hospital laboratories in Catalonia. A 30-question survey was designed with 9 different issues. The questionnaire examined general information regarding the hospital and laboratory model, stat laboratory workload, laboratory information system, quality control, critical values results, authorization/validation of results, laboratory report and human resources, among others. The results were reported in number of laboratories and in percentage (%).

Results

The total survey response rate was 59 %. 68.3 % stat laboratories biochemistry, haematology and microbiology

departments were integrated. The majority (60.9%) of the stat tests were integrated in part with laboratory core. All laboratories employed laboratory information system and are using barcode system. In 75.6% of laboratories all requests were made electronically. 43.9% of laboratories did not give results in international system, only in conventional units. All laboratories participated in internal and external quality assessment programs. Internal quality controls are processed more than once a day in 80.5% of laboratories. The vast majority of laboratories reported critical results (97.6%). 75% of laboratories have a medical specialist (biochemistry or analysis). The average number of laboratory technicians was 4.

Conclusions

Our study highlighted the variation in how emergency laboratories and stat test are run across Catalonia.

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INTRODUCTION

The last few decades have seen a significant change in clinical laboratories. The laboratory management information system has allowed improvements with patient identification, turnaround times, manual transcription data, automated procedures for data validation, reporting on critical values, etc., reducing error and improving patient safety.

A great variability exists among different laboratories; each laboratory is a world of its own. There are different emergency laboratory models related to the size and type of hospital or institution in which they are employed. Ordinary and stat tests integrated or separated. Biochemistry, haematology and microbiology departments integrated or independent among them. There are different characteristics of each laboratory: the number of request and tests per day, laboratory information system (LIS), aspects of quality control, reporting and receiving critical values, validations of results, laboratory report, human resources... etc.

Within the scope of the IX European Symposium of Clinical Laboratory and *in vitro* Diagnostic Industry entitled "Stat Tests in Clinical laboratory", Catalan Association of Clinical Laboratory Sciences (ACCLC) [1] conducted a survey on the vast majority of hospital clinical laboratories in Catalonia. In order to establish a debate on the emergency laboratories and aspects related to the stat tests, to know the *state of the art* and new trends on stat tests. 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 [2-3]. Stat analytes were tests ordered when the results were in urgent need, typically for patients from emergency department, intensive care unit (ICU) patients whose condition change suddenly, and inpatients with serious diseases or whose condition change suddenly.

Using a national survey, ACCLC has collected information on the workload and roles of different clinical laboratories in Catalonia in order to present a picture of current practice across Catalonia.

MATERIALS AND METHODS

In 2017, an online survey was distributed by ACCLC using Google Surveys tool to 69 hospital laboratories from Catalonia. A 30-question survey was designed with 9 different issues. The questionnaire examined general information regarding the hospital and laboratory model, stat laboratory workload, laboratory information system, quality control, critical values results, authorization/validation of results, laboratory report and human resources, among others. The

questions and format of the survey are provided as supplementary data. The questionnaire was administered in an online format (https://www.google.com/forms/). A web link to the survey was distributed to the laboratory medical specialist responsible for each stat laboratory with an invitation to participate in the survey. The survey link was made available up till April 2017.

The collected information was analysed and the results were reported in number of laboratories and in percentage (%).

RESULTS

There were 49 responses to the online survey, of which 41 were included in analysis of the objective data (59%). Eight responses were excluded as they were duplicates from laboratories already represented in the data.

Twenty-nine respondents represented laboratories in Barcelona province, nine of which were situated in Barcelona. Four laboratories in Girona, three laboratories from Lleida, three from Tarragona, one in Balearic Islands and one in Andorra were also represented.

All respondents were laboratory medical specialists. All stat laboratories were in a hospital setting. There were 8 tertiary hospitals (19.5%) with more than 400 patients per day in the emergency department and there were 21 secondary hospitals (51.2%) with more than 170 patients per day. The majority of hospitals (68.3%, 28 hospitals) involved in this study were teaching hospitals with medical training for residents. 63.4% (26 hospitals) had an intensive care unit. 53.7% were public hospitals. In 28 stat laboratories (68.3%), biochemistry, haematology and microbiology units were integrated. In 10 laboratories (24.4%), biochemistry and haematology units were integrated with an independent microbiology unit. Only two laboratories (4.9%) had the three units unintegrated. In majority of the laboratories (25 laboratories, 60.9%), the stat tests were integrated in part with core laboratory.

The number of daily requests and the number of tests per day can be found in Table 1. The average number of tests per request in the stat laboratories was 8 (range: 4-14).

All laboratories employed laboratory information system. The LIS employed are: Eyra (Laboratori Referència Catalunya®) by 10 laboratories, Servolab (Siemens®) by 7 laboratories, Modulab (Werfen®) by 6 laboratories, Omega (RocheDiagnostics®) by 4 laboratories, Lumen Software® by 3 laboratories, Infinity (RocheDiagnostics®) by 2 laboratories, Link It (Cegeka®) by 2 laboratories, OpenLab (Nexus®) by 2 laboratories, and Indra (GestLab®) and LabSuite® by 1 laboratory each.

Table 1 Stat laboratory workload. Number of laboratories (n labs) and percentage (%)

Requests/day	n labs (%)	Tests/day	n labs (%)
<100	12 (29.3 %)	<1000	13 (31.7 %)
100-300	19 (46.3 %)	1000-3000	20 (48.8 %)
300-500	9 (22.0 %)	3000-5000	6 (14.6 %)
>500	1 (2.4 %)	>5000	2 (4.9 %)

All laboratories delivered the final reports to the hospital information system.

All participating laboratories used the barcode system to ensure accuracy and timeliness of the transmission of test reports of the results of biochemistry, blood gas, and haematology tests. In 31 laboratories (75.6%) all requests were made electronically and in 9 laboratories only part of them were electronical. Only one laboratory processed manual requests.

In the final test reports, 46.3% of laboratories were using international and conventional units and 43.9% of laboratories did not give results in international system, and were using conventional units only. Only 4 laboratories (9.8%) expressed their final test report in the international system units.

All laboratories participated in internal and external quality assessment programs. In stat laboratories, 80.5% internal quality controls are processed more than once a day. The vast majority of laboratories reported critical results (97.6%). Only one laboratory did not report critical values. Table 2 presents survey responses on dealing with critical values. The responses about the authorization or validation of results can be found in Table 3.

Human resources, i.e., stat laboratory staff are shown in Table 4. In majority of stat laboratories there was one medical specialist (biochemistry

Table 2 Critical values in stat laboratories. Number of laboratories (n labs)and percentage (%)

		n labs (%)
How were the critical value limits established?	By literature, laboratory and consensus with clinicians	24 (59.0 %)
	Only by literature	10 (24.4 %)
	By Laboratory and consensus with clinicians	5 (12.2 %)
	Only by laboratory	2 (4.9 %)
Notification procedure	By telephone	28 (68.2 %)
	By telephone & email	11 (26.8 %)
	By telephone & hospital information system	2 (4.9 %)
Responsible for receiving the critical value notification	Clinician or nurse	19 (46.3 %)
	Only clinician	15 (36.6 %)
	Only nurse	6 (14.6 %)
	Administrative staff	1 (2.4 %)

Table 3 Validation of stat laboratory results. Number of laboratories (n labs) and percentage (%)

		n labs (%)
Who performs the validation of patients' results?	Clinical validation by Laboratory medical specialists	1 (2.4 %)
	Technical validation	10 (24.4 %)
	Technical validation & Clinical validation	13 (31.7 %)
	Technical validation & Autovalidation	6 (14.6 %)
	Technical validation & Clinical validation & Autovalidation	8 (19.5 %)
	Other options	3 (7.3 %)
If the validation is not done by laboratory medical specialist, is there a pre-report or a final report of patient results?	Yes (pre-report)	8 (19.5 %)
	No (final report)	3 (7.3 %)

or analysis) (75%) and in some laboratories also there was additionally a microbiology or haematology specialist. The average number of laboratory technician staff was 4 (range: 5-8).

DISCUSSION

This is the first survey ever launched to know the state of the art in stat tests laboratories in Catalonia. The majority of responses were received from Barcelona, leaving other regions of Catalonia relatively under-represented. There are few publications in the literature about laboratory clinical survey results.

Several national surveys have been published on different aspects of the laboratory in other countries: clinical authorization [4], intra-laboratory turnaround time [5] and critical results reporting [6-7] but no survey was as complete as this study.

The analysis of the completed questionnaires reveals a heterogeneous laboratory situation. The tendency is that stat laboratory serves all three units: biochemistry, haematology and microbiology. In general, in small- and medium-sized laboratories, ordinary and stat tests are integrated, and their analysis are performed in the same place using the same instrumentation. The situation in large laboratories is rather more heterogeneous, with the majority of organizations 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 [1]. In the vast majority of laboratories, the number of stat laboratory orders is 100-300 requests per day and 1000-3000 tests per day, as in most

Table 4 **Human resources. Number of laboratories (n labs) and percentage (%)**

		n labs (%)
Are there laboratory medical specialists only for Stat laboratory? *(If yes: how many?)*	Yes	13 (31.7 %)
	1	7
	2	4
	≥3	2
	No	28 (68.3 %)
Is there a laboratory medical specialist on call 24 hours/day?	Yes	31 (75.6 %)
	Physically on duty	4
	In-house Call	13
	Physically on duty / In-house duty	14
	No	10 (24.4 %)
Are there clinical residents on call 24 hours/day?	Yes	24 (58.5 %)
	With In-house call support	15
	With physically on duty support	3
	Physically on duty / In-house duty support	6
	No	17 (41.5 %)
Laboratory staff constituted by	Laboratory technicians	41 (100 %)
	Laboratory nurses	12 (29.3 %)
	Administrative staff	5 (12.2 %)
Average laboratory staff	Morning: 3-4 people Afternoon: 2-3 people Night: 1-2 people	

emergency laboratories in other countries [5]. Also it revealed that the average stat ordering is 8 tests per request.

All stat laboratories are working with LIS. The most commonly used laboratory information management system was Eyra, implemented in 10 of the laboratories that answered (n=41). Laboratory information system receives, processes and stores information generated by the laboratory workflow. It automates the workflow of all information related to total testing process [2]. It facilitates communication between laboratory and clinicians and ideally, enables faster delivery of patient reports [3].

All stat laboratories surveyed were participating in quality assessment programs. Adequate internal quality and external control assessment are parameters which enhances laboratory quality testing [8]. Despite the recommendations of the IUPAC [9], the international units system is not the most commonly used in clinical laboratories.

The definition and reporting of critical values is an important phase of the clinical laboratory testing process, and laboratories are responsible for detecting life-threatening results, for reporting them to health care providers, and also for tracking and improving the timeliness of reporting and the receipt of results. All participants indicated that they communicate critical values. The criteria for considering test results critical are still controversial, with lack of harmonization both in defining the analytes as well as low and high critical value cut-offs [10]. There is no consensus on the most reliable source of information regarding the list of critical values and clinical laboratories may follow recommendations of scientific societies, clinician' opinions in their institutions with consensus of medical laboratory specialist (59 %).

The reporting of critical values from the laboratory to caregivers is still made mainly by telephone (68.2 %). Less commonly used means of communication included email, SMS or hospital information system. A great variability exists among the professionals involved in critical values communication: in reporting and receiving the data. The vast majority of laboratories notified to physicians or nurses (97.6 %). In Italy [10] the notification is similar but in United States the notification is directed to patients in some cases [11-12]. Guidance from NHS England and the British Medical Association (BMA) acknowledge that the ordering clinician is traditionally responsible for acting upon abnormal results and life-threatening results must be communicated to him [13-14]. Finally, few laboratories have yet adopted a read-back verification of the complete test result by the person receiving the information [7].

The analysis of the validation of results reveals a heterogeneous situation. Currently, each laboratory has different approaches to the challenge of authorization as there is no comprehensive guidance available. The validation process may include a combination of technical, clinical and autovalidation. The best practice guidelines issued by the Association for Clinical Biochemistry and Laboratory Medicine (ACB) [15] acknowledges the impossibility of clinically authorizing every result generated (web). It is impractical and time consuming to clinically authorize every result, but equally the use of technical and auto-validation alone may be over-sensitive to abnormal results. The focus of clinical attention must be on the neediest of patients [16]. Only one laboratory clinically authorized normal results.

24.4 % of laboratories did not have a formal duty specialist on call 24 hours/day. A national survey of practice in the UK shows only one laboratory (1/49) that did not have a formal duty specialist [4]. In vast majority of the laboratories laboratory technicians are non-medical staff. There are fewer nurses in laboratory. Nurses have been replaced by technicians in clinical laboratories.

In daytime rotas there are more laboratory staff than on the night-time rota.

The major limitation of this study is the veracity of the data. Nonetheless, there were a large number of hospitals and laboratories from Catalonia involved in this survey and the database can provide support with suitable information. The survey can be really meaningful and conductive. We expect to expand the scope of our survey to pre-analytical, analytical and post-analytical areas and conduct a more comprehensive survey in the future.

CONCLUSIONS

Our study highlighted the variation in how emergency laboratories and stat test are run across Catalonia. This survey was helpful in order to know the state of the art in emergency laboratories in Catalonia and debate about new trends on stat tests.

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SUPPLEMENTAL DATA: STAT LABORATORY SURVEY

Thank you for participating in this survey. Please complete the following questions about your Stat Laboratory:

I. Type of your center

1. Skills of your center?
   (You can mark more than one option)
   a) Hospital
      a. Teaching
      b. No-teaching
      c. With Intensive Unit Care
      d. Tertiary hospital
      e. Secondary hospital
   b) Non-Hospital
   c) Primary Health Care
2. Number of patients in the Emergency Department for day:
3. Type of center
   a. Public
   b. Private

II. Laboratory model

4. Type of laboratory
   a. Public
   b. Private
5. Stat Laboratory
   a. Biochemistry, Hematology and Microbiology joined
   b. Biochemistry and hematology joined and microbiology independently
   c. Biochemistry, hematology and microbiology independently
6. Stat Laboratory is
   a. Independently from the rest of laboratory
   b. Semi-integrated with routine laboratory
   c. Integrated Core laboratory
   d. Point of care testing

III. Stat Laboratory Workload

7. Number of requests per day
   a. < 100
   b. 100-300

c. 300-500
d. > 500

8. Number of tests per day in Stat Laboratory:
   a. < 1000
   b. 1000-3000
   c. 3000-5000
   d. > 5000
9. Average of tests per request
   a. < 5
   b. 5-8
   c. 8-10
   d. > 10

IV. Laboratory Information System (LIS)

10. The analytical request is:
    a. Electronically
    b. Manual
11. Laboratory information system
    a. Type (Commercial or own laboratory system)
    b. Name of LIS:
12. Connections:
    a. All devices online
    b. Partially devices online
    c. Manual transcription of results
13. Is barcode system used in your laboratory?
    a. Yes
       i. Printed in extraction department
       ii. Printed in the request
       iii. Printed in the laboratory
    b. No

V. Quality control

14. Internal quality control assessment
    a. Once a day
    b. > once a day
15. Does the laboratory participate in external quality control programs?
    a. Yes
    b. No

VI. Critical values

16. Has the laboratory defined critical values?
    a. Yes
       i. By bibliography
       ii. Own laboratory
       iii. Laboratory with consensus with clinicians
       iv. Bibliography, laboratory and consensus with clinicians
    b. No
17. How laboratory report critical values?
    a. By telephone
    b. By email
    c. By SMS
    d. Writing in clinical history of patient
18. Who should receive the critical values results?
    a. Physician who requested the test
    b. Nurse
    c. Administrative staff

VII. Validation of results

19. Who perform the validation of patients' measured values?
    a. Laboratory medical specialist
    b. Laboratory technician
    c. Laboratory specialist + technician
    d. Autovalidation + laboratory medical specialist
    e. Autovalidation + laboratory technician
    f. Autovalidation + laboratory specialist + technician
20. If the validation is not by laboratory medical specialist, does exist a pre-report

of patients results or there is a final report?

a. Yes (pre-report)
b. No (final report)

VIII. Laboratory report

21. Units
    a. International system units (IS)
    b. Conventional units
    c. International system and conventional units
22. Is laboratory report recorded in patient's clinical history?
    a. Yes
    b. No

IX. Human resources

23. Are in stat laboratory medical specialists full dedicated to stat tests?
    a. Yes
        i. How many?
            1. 1
            2. 2
            3. 3
            4. >3
24. What is the specialization of laboratory medical staff?
        i. Clinical chemistry
        ii. Clinical analysis
        iii. Hematology
        iv. Microbiology
    b. No
25. Is there a laboratory medical specialist on call 24 hours/day?
    a. Physically on duty
    b. In-house call
    c. Physically on duty/ In-house duty
26. Are there laboratory clinical residents on call 24 hours/day?
    a. Yes
        i. With in-house call support
        ii. With physically on duty support
        iii. Physically on duty/ In-house duty support
    b. No
27. Laboratory staff constituted by
    a. Laboratory technicians
    b. Laboratory nurses
    c. Administrative staff
28. How many people (no medical specialist) are working in the morning rota?
    a. 1
    b. 2
    c. 3
    d. 4
    e. >5
29. How many people (no medical specialist) are working in the afternoon rota?
    a. 1
    b. 2
    c. 3
    d. 4
    e. >5
30. How many people (no medical specialist) are working in the night rota?
    a. 1
    b. 2
    c. 3
    d. 4
    e. >5

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