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# Laboratory Results defects and Its Relations with Patient Safety

**Mishari Muneer Alhudhali[1] Mohammed Abdalmohsen Aljuaed[2] Abdullah Hameed Almalki[3] Ghazwa Aedh Alotaibi[4] Faisal abdullah ali Alghamdi[5] Raya Mohsen Alhomaidi[6] Sulafa Ezzat Sharaf[7] Abdullah Faisal Halawani[8] Naif Nidhal Alshareef[9] Sakinah Nasser Almitwazi[10]**

*[1]Laboratory and blood bank King Faisal hospital- Makkah Saudi Arabia*
*[2]Technology Lab Specialist King Faisal Hospital-Makkah Saudi Arabia*
*[3]Laboratory technician King Faisal Hospital Makkah Saudi Arabia*
*[4]Medical Technologist /Laboratory specialist King Faisal Hospital -Makkah Saudi Arabia*
*[5]Technician laboratory and blood bank King Faisal hospital Makkah Saudi Arabia*
*[6]Specialist / laboratory Medicine King Abdulaziz Specialist Hospital Saudi Arabia*
*[7]Laboratory Medicine Specialist King Faisal Hospital Saudi Arabia*
*[8]Biochemistry Department, King Faisal Hospital, Ministry of Health, Makkah Saudi Arabia*
*[9]Medical laboratory specialists King Faisal Hospital Saudi Arabia*
*[10]Medical laboratory specialists Prince Mohammed Bn Fahad Hospital Alqatif Saudi Arabia*

**Abstract**
The purpose of this study is to analyse potential threats of medical laboratory activities at Strategic, operational (pre-preanalytical, preanalytical, analytical, postanalytical and post-postanalytical), and support process. Moreover, we appreciate the risk with these in patient safety. In this study, the Failure Model and Effects Analysis (FMEA) method was presented to identify and estimate the possible failure modes. The real failures were not registered in the same processes then in according to Failure Reporting Analysis and Corrective Action System (FRACAS) methodology [1, 2]. In addition, it was based on the quality system of the available information of the laboratory. The RPN was calculated with each one of the methodologies for each laboratory process, and a comparative of the results obtained with both methodologies was carried out. From these results we prepare the risk map in medical laboratory. These results permitted us to identify the critical points existent in all laboratory processes and thus above all to prioritize the control of which points. Additionally, it assisted in choosing preventive or corrective action that should be included in the laboratory quality improvement and risk management plans.

## 1. Introduction

Patient safety is defined as the absence of avoidable patient harm during theprocess of medical attention.

All medical attention brings inherent risk of adverse events (AE) that couldcause injury, disabilities and even death of the patient.

Based on studies conducted by Brennan [1], in 1999 Kohn published “To err is human: Building a Safer Health System” [2]. This paper told that at least 1,000,000 of AE happen in the United States yearly, and carry on the death of 44,000 to 98,000 people. This studies a real important revolution in health world,being aware of the error rate attributable to health system that has great impacton patients. At the beginning of the 2000s some initiatives appeared and some strategies were proposed to analyze and to see how you can reduce the rate of preventable errors.

Patient safety is a target for health systems and is a fundamental principle of healthcare, as well as an important component of quality management.

The main global health organizations have incorporated patient safety in their review of work practices. Among these, the World Alliance for Patient Safety, from the 55th Health Conference in October 2004 found that the professional services of health care play an important role in risk management and in creation of safer health systems [3]. The president of that alliance, L. Donaldson, re-fers to the role of medical laboratory in patient safety [4].

Several studies about risk management and patient safety analyze their in- volvement in it scope. We highlight the Spanish National Study on Hospitalisa- tion-Related Adverse Events (ENEAS) in 2005 [5], which was part of a quality program of the national health system and showed that 42.6% of the Adverse Events (AE) were preventable. In the laboratory, AE rate according to some re- ports by Plebani [6] fluctuates from 2.7% to 12%.

Nowadays, quality management systems are implemented in medical labora- tories. Their aims are reducing potential risks and improve patient safety [7] [8][9].

The information provided by the medical laboratory has a direct impact on patient safety and a fault in any of processes strategic, operational (preanalytical, analytical, postanalytical) and support, could affect patients. An improvement in the safety of the various processes brings to light the potential failure modes in the laboratory and try to solve them.

To provide useful and reliable information to the clinician, it is important to emphasise the need to design risk and processes map in the laboratory [10], to- gether with quality indicators that allow monitoring and risk management [11].

Our study aims calculate the impact of the failure modes in a medical labora- tory and compare the risk with two risk management tools: Failure Mode and Effects Analysis (FMEA) versus the Failure Reporting Analysis and Corrective Action System (FRACAS). Use FMEA to estimate the potential risks and FRACAS to make real errors analysis.

## 2. Methodology

The scope of application is all processes in the medical laboratory (Catlab) at Consorcio Sanitario de Terrassa Hospital (CST). Medical laboratory was certi- fied with ISO 9001:2000 Quality Management since 2004 and nowadays has been accredited according to UNE-EN ISO 15,189:2013.

Makkah health care cluster hospital manages 340 beds for intensive care patients and 32 beds for penitentiary patients. In its hospital network provides services to 34 primary care centres and two specialized primary care centres. Itserves a population of almost 400,000 people.

The study was made about 90 possible modes of failure detected by the Failure Model and Effects Analysis (FMEA) model applied to laboratory processes [12] [13]. FMEA is a preventive and proactive tool. It analyzes the quality, safety and/or reliability of a system performance operation, identifying possible failure modes presented, and to apply preventive actions to avoid problems that couldbe manifested themselves in the future.

The failure modes were identified from the literature [14] [15] [16] and a brainstorming conducted among a working group of laboratory professionals.

FMEA allowed identify potential failure modes and estimate risk through a table of three variables (**Table 1**): severity, frequency and detection [12] [17]. The severity score variable is based on a scale from 1 to 10, being 1 the least se- vere value and 10 the worst. The variable frequency is based on a scale from 1 to 10, being 1 the least likely to appear and 10 the highest. Finally, the variable de- tection, it is also classified on a scale from 1 to 10, but in this case 10 means aminor probability to detect and 1 a higher one. With the product of these three variables the risk priority number (RPN), has a potential value between 1 and

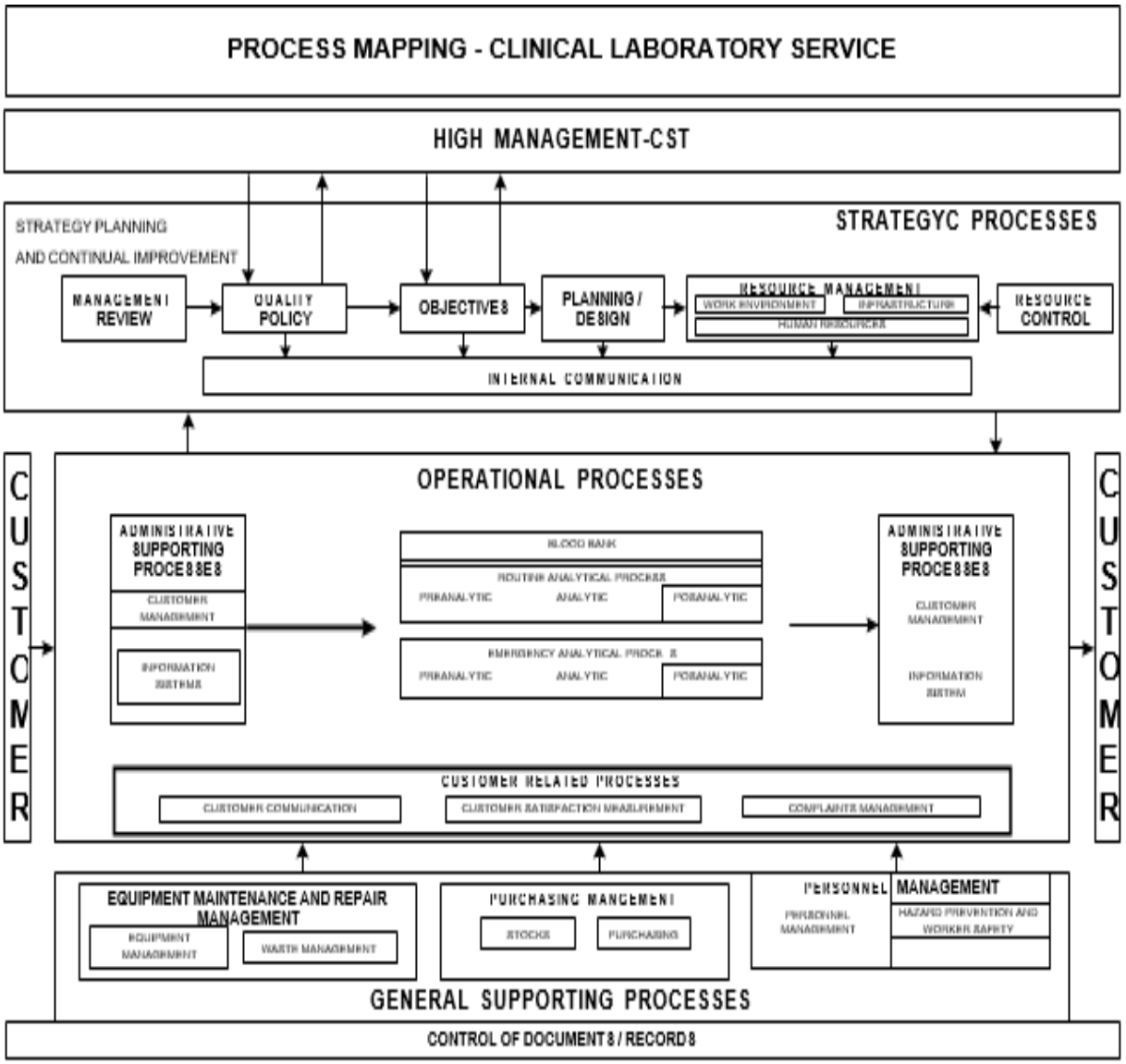


**Figure 1.** Processes map of medical laboratory.

**Table 1.** Risk assessment values.

| Scale | Severity | Detection | Frequency | | Frequency/Indicator |
|---|---|---|---|---|---|
| 10 | Highly hazardous | Non-detectable | 1 in 2 | Very high | 0.5 |
| 9 | Hazardous | Very improvable | 1 in 3 | Very high | 0.33 |
| 8 | Very high | Improvable | 1 in 8 | High | 0.125 |
| 7 | High | Very low | 1 in 20 | High | 0.05 |
| 6 | Moderate | Low | 1 in 80 | Moderate | 0.0125 |
| 5 | Low | Moderate | 1 in 400 | Moderate | 0.0025 |
| 4 | Very low | Moderately high | 1 in 2000 | Low | 0.0005 |
| 3 | Minor | High | 1 in 15,000 | Low | $6 \times 10^{-5}$ |
| 2 | Very minor | Very high | 1 in 150,000 | Very low | $6 \times 10^{-6}$ |

| | | | | | |
|---|---|---|---|---|---|
| 1 | None | Highly detectable | 1 in 1,500,000 | Remote | $6 \times 10^{-7}$ |

1000. From this way those risks were evaluated which could have direct or indi- rect impact on patient safety.

Then Failure Reporting Analysis and Corrective Action System (FRACAS) [15] was used. It is a corrective and reactive tool that allows analyzing variablesassociated with the damage and factors that explain it. FRACAS uses only two variables, severity and frequency with the same scale than FMEA for severity. For frequency, annual indicators were calculated and with the objective to harmonize with FMEA [17] the same scale was used **Table 1**, they were transformed to the same FMEA frequency scale used. With the product of these two variablesthe risk priority number (RPN), has a value between 1 and 100.

FRACAS allowed a real calculation of the frequency of detected faults and the severity of them. It is a dynamic tool that can identify and incorporate unantici- pated errors in the FMEA [18]. It was used information from the quality man- agement system of the laboratory (audits, management reviews, indicators, nonconformities, etc.) to do this calculation.

Risk and processes maps were made with a Visio program from the results ofFMEA and FRACAS [10].

This study allowed the calculation of the potential risk in the preanalytical, analytical and postanalytical processes, as well as strategic and support processes of medical laboratory.

## 3.Results

The processes map of medical laboratory shows the activities in each process and a general viewer of laboratory medicine (**Figure 1**).

The results show the priority risks identified by FMEA. These risks are classi- fied according to the risk priority number (RPN). The five failure modes with maximum NPR for each process are presented in **Table 2**.

Detected failure modes are classified by FRACAS according to risk priority number (RPN). Five failures with maximum RPN are presented for each process(**Table 3**).

**Table 2.** Classified failure modes by FMEA.

| PROCESSES | FAILURE MODES | NUMBER OF PRIORITY |
|---|---|---|
| Preanalytical | Incorrect temperature of sample transport | 252 |
| | Clotted sample | 180 |
| | Hemolysed sample | 180 |
| | Difficulty of obtaining a sample. Sample obtained is not correct | 162 |
| | Wrong container drawn | 126 |
| Analytical | Inappropriate use of equipment or incorrect maintenance | 210 |
| | Incorrect validation of previous analytical results | 180 |
| | Failure in relation sample-diagnostic reactive (interferences, prozone effects, viscosity…) | 126 |

| | | |
|---|---|---|
| Postanalytical | Wrong magnitude selected in the request | 108 |
| | Adverse environmental conditions | 108 |
| | Misinterpreted results | 280 |
| | Inadequate performance of the patient results | 280 |
| | Critical value not notified | 270 |
| | Alert value not recognized | 189 |
| | Entry error results | 180 |
| Strategic | Management error of the corrective and improvement actions | 80 |
| | Failures in the organization of the indicators in preanalytical processes | 40 |
| | Failures in the organization of the indicators in analytical processes | 40 |
| | Failures in the organization of the indicators in postanalytical processes | 40 |
| Support | Lines of responsibility are poorly-defined | 14 |
| | Error or failures of staff competence | 14 |
| | Failure of replacement of staff | 12 |
| | Failure of installation maintenance | 10 |
| | Failure of reagent delivery (outstanding stocks) | 7 |
| | Lack or inappropriate health training | 7 |

Compare the results obtained by FMEA and FRACAS according risk priority.It presents only 10 faults with major RPN according to FMEA (**Table 4**).

Compare the results obtained by FRACAS and FMEA according the risk pri-ority. It shows only the top10 failures with higher RPN, according to FRACAS (**Table 5**).

Percentage (%) distribution of failure modes identified according the affectedprocess shows in **Table 6**.

The results obtained are distributed in the risk map.

The risk map allows us to have a global view on each activity of risk estima- tion and detection of failure modes. The results show AMFE versus FRACAS ineach affected process.

**Table 3.** Classified failure modes by FRACAS.

| PROCESSES | FAILURES | NUMBER OF PRIORITY |
|---|---|---|
| Preanalytical | Not sample | 42 |
| | Hemolysed sample | 42 |
| | Clotted sample | 36 |
| | Insufficient sample amount | 36 |
| | Wrong container/incorrect sample | 30 |
| Analytical | Incorrect interpretation of internal control results | 42 |
| | Lack or inappropriate staff training | 36 |
| | Problems of method or analytical mode | 32 |
| | Wrong internal controls | 30 |
| | Validation patient results before internal controls | 30 |
| | Results not entered in the database | 30 |

| | | |
|---|---|---|
| Postanalytical | Misinterpreted results | 28 |
| | Misidentification among patients | 24 |
| | Error of decimal result | 18 |
| | Informed test with wrong results | 18 |
| Strategic | Wrong Management of the corrective and improvement actions | 10 |
| | Failures in the organization of the indicators in preanalytical processes | 3 |
| | Failures in the organization of the indicators in analytical processes | 3 |
| | Failures in the organization of the indicators in postanalytical processes | 3 |
| | Poorly-defined responsibility | - |
| Support | Failure of reagent delivery (outstanding stocks) | 7 |
| | Error of staff competence | 7 |
| | Lack or inappropriate health training | 7 |
| | Power blackouts not notified during working hours | 7 |
| | Failure of replacement of staff | 6 |

**Table 4.** Comparison of the top risk numbers FMEA versus FRACAS.

| FAILURES OF MODE | AMFE | FRACAS |
|---|---|---|
| Misinterpreted results | 280 | 28 |
| Calculation mistakes | 280 | 7 |
| Not notified critical/alert values | 270 | - |
| Inappropriate transport temperature | 252 | - |
| Improper use of equipment or maintenance | 210 | - |
| Warning/safety values not identified | 189 | - |
| Clotted sample | 180 | 36 |
| Hemolysed sample | 180 | 42 |
| Not correct validation of the results | 180 | - |
| Informed test with wrong results | 180 | - |

**Table 5.** Comparison of the top risk numbers FRACAS versus FMEA.

| FAILURES | FRACAS | AMFE |
|---|---|---|
| Hemolysed sample | 42 | 180 |
| Lack of sample | 42 | 126 |
| Misinterpreted internal controls | 42 | 72 |
| Clotted sample | 36 | 180 |
| Insufficient sample amount | 36 | 72 |
| Lack or inappropriate health training | 36 | 12 |
| Problems of method or analytical mode | 32 | 24 |
| Validation of the patient results without internal checking of the controls | 30 | 72 |
| Wrong sample container | 30 | 126 |
| Results not notified | 30 | 54 |

**Table 6.** Failure modes identified (%) by processes according to FMEA and detected faults (%) according to FRACAS.

| | PROCESSES | AMFE (%) | FRACAS (%) |
|---|---|---|---|
| Operational | Preanalytical | 34.2 | 48.4 |
| | Analytical | 26.5 | 28.2 |
| | Postanalytical | 35.1 | 17.2 |
| | Strategic | 2.9 | 2.0 |
| | Support | 1.3 | 4.2 |

## 3. Discussion

Any failure in the processes established into the laboratory can lead to conse- quences in patients, being a key component in relation to patient safety [19] [20]. That is why we have to manage these failures and implement improvement plans to reduce them [7]. Nowadays, it is seen a tendency to move from the cul-ture of error detection to the management of risk in all quality systems of clinical laboratories [21].

In the literature, authors believe that the study of the impact of risks must bemade in operational, strategic and support processes. There are studies showing these processes by designing indicators, such as related to the competence of professionals, customer service [22] or indicators associated with strategic sup- port processes [23] [24] or operational and support processes [11]. It must be stressed, however, that most publications are focused on the operational proc- esses (preanalytical, analytical and postanaytical) [25] [26] [27] [28] or preana-

lytical and postanalytical [29] [30] or exclusively preanalytical [31] [32].

This series of quality indicators described in those studies, as well as patient risk, come to meet the need to comply with the strategic lines that are being de- fined in the health sector, related to the dissemination of the culture of patient safety and the implementation of improvement plans to increase safe practices in this environment.

On the other hand, the two standards of broad application in laboratories (UNE-EN ISO 9001:2015 and UNE-EN ISO 15,189: 2013) are also involved in the risk management of the patient [8] [9], although the design of its indicators is not made from the use of tools such as FMEA and FRACAS. Therefore, we found it interesting to carry out this study in all laboratory processes using both FMEA and FRACAS tools because they are widely used in the clinical laborato- ries to highlight the need for implement risk management.

The application of these tools is not as widespread as indicators of quality of clinical laboratories. However, it is interesting the Astion and colleagues' study

[33] that analyzed the impact on the patient of incidents in the laboratory andcompares real potential adverse events. Another interesting study was done by A. Giménez and colleagues [34] which used FMEA only in preanalytical processes. In our study, results from FMEA were obtained with three variables andFRACAS with two variables. Detectability in FRACAS is real because the errorsare registered, while FMEA estimates detectability. This fact is reflected in the results presented in **Tables 2-5**.

**Table 6** shows the percentage of distribution of failures in laboratory proc- esses using the FMEA tool and the percentage of distribution of errors using the FRACAS tool. It is noticeable that there is a significant difference in the support processes between FRACAS and FMEA (4.2% FRACAS compared with 1.3% FMEA).

Discrepancies are observed between preanalytical (48.4% FRACAS versus 34.2 FMEA) and postanalytical (17.2% FRACAS versus 35.1% FMEA) processes. However, the results showed a good agreement in analytical processes (28.2% FRACAS versus 26.5% FMEA).

If we compare our results with those obtained by Plebani [35], we have similar results for the preanalytical processes (in FRACAS 48.4% versus 46% - 68.2% of Plebani) and the postanalytical processes (35.1% compared FMEA 18.5% - 47% of a Plebani). However, in analytical processes the results do not match the twostudies (26.5% FMEA and FRACAS 28.2%, versus 13% and 7% Plebani).

Strategic and support processes contribute to patient risk rate much lower than the operative processes. As

regards strategic by low estimated frequency and in support processes due to low gravity failure modes. The processes map adds information about the organization of processes and subprocesses in clinical laboratory. Together with the risk map, it gives us a global view of the distribution of failures in each of the processes.

It has been made the calculation of RPN, to assess the impact of potential risks. From these results, it could be developed an improvement plan to imple- ment corrective and preventive actions, in accordance with the standards ISO 15,189:2013 [8] and ISO 9001:2015 [9]. Keep in mind that prioritization must be made from the calculation of the failure modes and not from the subprocesses or processes because potentially serious risks (but less frequent) could be masked.

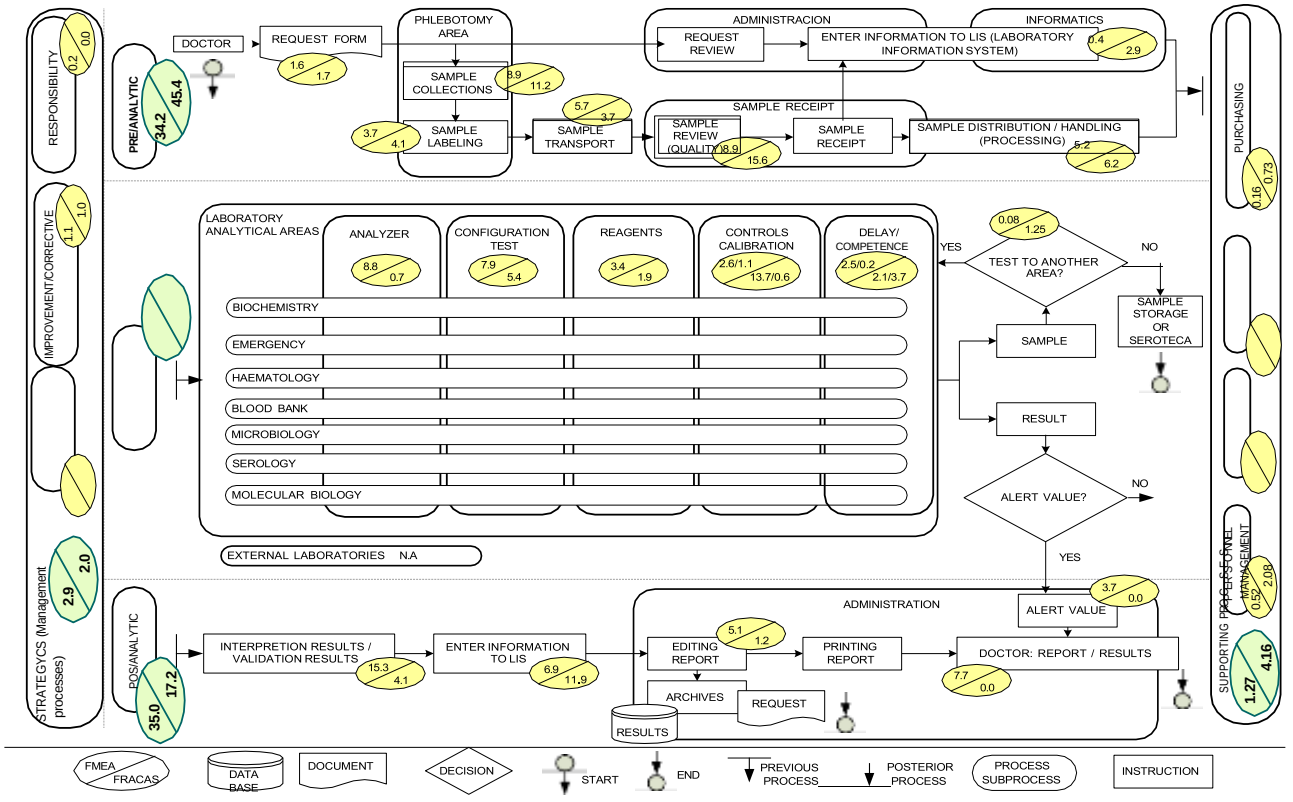


**Figure 2.** Risks map of medical laboratory.

## 4. Conclusions

The fact of identifying potential failure modes by FMEA tool makes to review meticulously the processes implemented to detect all possible faults in the vari- ous activities and stages involved in them. It was decided to make the study ofrisks in all laboratory processes (operational, strategic and support), since activi- ties performed in all processes can cause potential risks and can have an impacton patient safety as shown in

**Figure 2**.

FMEA allows detecting critical points in terms of the patient risk and FRACAS highlights the priorities to control these points and help to select pre-ventive or corrective actions that we should be incorporated in the laboratory improvement planning.

If FMEA is compared versus FRACAS, the difference is that indices of risk priority are higher in FMEA in postanalytical processes, while comparing FRACASversus FMEA the rates of risk priority are higher in preanalytical processes.

The greatest impact of potential real errors in patients appear in activities re-lated to operational processes, which are more related to the actions of health professionals on patients.

It is important to note that FMEA is a subjective tool and that to be able tomake a real study of failures FRACAS has to be performed.

On the basis of the results obtained of FMEA and FRACAS a strategic risk management plan should be implemented.

It is conclusive the need for risk management in clinical laboratories and monitoring them within the quality plan, a fact that would lead to an increase on patient safety.

## References


1. Brennan, T.A., Leape, L.L., Laird, N.M., *et al*. (1991) Incidence of Adverse Eventsand Negligence in Hospitalized Patients Results of the Harvard Medical PracticeStudy I. *The New England Journal of Medicine*, **324**, 370-376. https://doi.org/10.1056/NEJM199102073240604
2. Kohn, L.T., Corrigan, J.M. and Donaldson, M.S. (1999) To Err Is Human. Buildinga Safer Heath System. National Academy Press, Washington DC.
3. World Health Organization (2002) The World Health Report 2002. Reducing Risks,
4. Promoting Healthy Life. WHO, Geneva. http://www.who.int/whr/2002/en/
5. Donaldson, L. (2007) Laboratory Medicine and Patient Safety. Foreword. *ClinicalChemistry and Laboratory Medicine*, **45**, 697-699.
6. Aranaz Andrés, J.M., Aibar Ramón, C., Vitaller Burillo, J., *et al*. (2006) Spanish Na-tional Study on Hospitalisation-Related Adverse Events (ENEAS).
7. Plebani, M. (2010) The Detection and Prevention of Errors in Laboratory Medicine.*Annals of Clinical Biochemistry*, **47**, 101-110. https://doi.org/10.1258/acb.2009.009222
8. International Organization of Standardization (2010) Medical Laboratories—Re- duction of Error through Risk Management and Continual Improvement. CEN ISO/TS 22367, Geneva.
9. International Organization of Standardization (2012) Medical Laboratories. Re- quirements for Quality and Competence. ISO 15189, Geneva.
10. International Organization of Standardization (2015) Quality Management Systems. Requirements. ISO 9001, Geneva.
11. García Gómez, M.M. (1994) Risk Maps. Concept and Methodology for Its Elabora-tion. *Revista de Sanidad e Higiene Pública*, **68**, 443-453.
12. Plebani, M., Astion, M., Barth, J., *et al*. (2014) Harmonization of Quality Indicators in Laboratory Medicine. A Preliminary Consensus. *Clinical Chemistry and Labora-tory Medicine*, **52**, 951-958. https://doi.org/10.1515/cclm-2014-0142

13. Cuatrecasas, L. (2005) Comprehensive Quality Management. 3rd Edition, Gestion 2000, Barcelona.
14. Kenneth Crow DRM Associates. http://www.npd-solutions.com/fmea.html
15. Clinical and Laboratory Standards Institute (2007) Management of NonconformingLaboratory Events; Approved Guideline. GP32-A. CLSI, Wayne.
16. Clinical and Laboratory Standards Institute (2009) Risk Management Techniques toIdentify and Control Laboratory Error Sources; Approved Guideline-Second Edi- tion. EP18-A2. CLSI, Wayne.
17. Clinical and Laboratory Standards Institute (2011) Laboratory Quality Control onRisk Management; Approved Guideline. EP23-A. CLSI, Wayne.
18. Govindarajan, R. (2009) Health Disorder Has a Cure. ICG Marge Médica Books,Barcelona.
19. Krouwer, J. (2006) Dynamic Rather than Static Performance Measures Are Neededto Improve Patient Safety. *Accreditation and Quality Assurance*, **11**, 644-646. https://doi.org/10.1007/s00769-006-0199-4
20. Stankovic, A. (2004) The Laboratory Is a Key Partner in Assuring Patient Safety.
21. *Clinics in Laboratory Medicine*, **24**, 1023-1035.
22. Wagar, E. and Tuan, S. (2007) The Laboratory and Patient Safety. *Clinics in Labo-ratory Medicine*, **27**, 909-930.
23. Plebani, M. (2007) Errors in Laboratory Medicine and Patient Safety: The RoadAhead. *Clinical Chemistry and Laboratory Medicine*, **45**, 700-707. https://doi.org/10.1515/CCLM.2007.170
24. Plebani, M., Ceriotti, F., Messeri, G., *et al*. (2006) Laboratory Network of Excellence:Enhancing Patient Safety and Service Effectiveness. *Clinical Chemistry and Labora-tory Medicine*, **44**, 150-160. https://doi.org/10.1515/CCLM.2006.028
25. Ricos, C., Biosca, C., Ibarz, M., *et al*. (2008) Quality Indicators and Specifications for Strategic and Support Processes in Laboratory Medicine. *Clinical Chemistry and Laboratory Medicine*, **46**, 1189-1194. https://doi.org/10.1515/CCLM.2008.225
26. Ruiz, R., Llopis, M., Biosca, C., *et al*. (2010) Indicators and Quality Specifications forStrategic and Support Processes Related to the Clinical Laboratory. Four Years' Ex-perience. *Clinical Chemistry and Laboratory Medicine*, **48**, 1015-1019. https://doi.org/10.1515/CCLM.2010.229
27. Carraro, P. and Plebani, M. (2007) Errors in a Stat Laboratory: Types and Frequen-cies 10 Years Later. *Clinical Chemistry*, **53**, 1338-1342. https://doi.org/10.1373/clinchem.2007.088344
28. Alsina, M., Alvarez, V., Biosca, C., *et al*. (2007) Quality Indicators and Specificationsfor Key Processes in Clinical Laboratories; A Preliminary Experience. *Clinical Chemistry and Laboratory Medicine*, **45**, 672-677.
29. Szecsi, P. and Odum, L. (2009) Error Tracking in a Clinical Biochemistry Labora-tory. *Clinical Chemistry and Laboratory Medicine*, **47**, 1253-1257. https://doi.org/10.1515/CCLM.2009.272
30. Angüiano-Sánchez, N., Perales-Quintana, M., Díaz-Olachea, C., *et al*. (2011) Errorsin Clinical Laboratory: Evaluation of Types and Frequencies. *Medicina Universi- taria*, **13**, 133-138. (In Spanish)
31. Laposata, M. and Dighe, A. (2007) Pre-Pre and Post-Post Analytical Error: High-Incidence

Patient Safety Hazards Involving the Clinical Laboratory. *Clinical Chem-istry and Laboratory Medicine*, **45**, 712-719. https://doi.org/10.1515/CCLM.2007.173

32. Hawkins, R. (2012) Managing the Pre- and Post-Analytical Phases of the TotalTesting Process. *Annals of Laboratory Medicine*, **32**, 5-16. https://doi.org/10.3343/alm.2012.32.1.5
33. Lippi, G. and Guidi, G. (2007) Risk Management in Pre-Analytical Phase of Labo-ratory Testing. *Clinical Chemistry and Laboratory Medicine*, **45**, 720-727. https://doi.org/10.1515/CCLM.2007.167
34. Plebani, M. (2012) Quality Indicators to Detect Pre-Analytical Errors in LaboratoryTesting. *The Clinical Biochemist Reviews*, **33**, 85-88.
35. Astion, M., Shojania, K., Hamill, T., *et al*. (2003) Classifying Laboratory Incident Reports to Identify Problems That Jeopardize Patient Safety. *American Journal of Clinical Pathology*, **120**, 18-26. https://doi.org/10.1309/8U5D0MA6MFH2FG19
36. Giménez, A., Molina, P., Ruiz, J., *et al*. (2010) Application of Failure Mode and Ef- fects Analysis of the Pre-Analytical Phase in a Clinical Laboratory. *Revista del La- boratorio Clínico*, **3**, 161-170. (In Spanish)
37. Plebani, M. (2006) Errors in Clinical Laboratories or Errors in Laboratory Medi-cine? *Clinical Chemistry and Laboratory Medicine*, **44**, 750-759. https://doi.org/10.1515/CCLM.2006.123

Mishari Muneer Alhudhali[1] Mohammed Abdalmohsen Aljuaed[2] Abdullah Hameed Almalki[3] Ghazwa Aedh Alotaibi[4] Faisal abdullah ali Alghamdi[5] Raya Mohsen Alhomaidi[6] Sulafa Ezzat Sharaf[7] Abdullah Faisal Halawani[8] Nai Nidhal Alshareef[9] Sakinah Nasser Almitwazi[10]