A FMEA Clinical Laboratory Case Study: How to Make Problems and Improvements Measurable

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The authors have experimented the application of the Failure Mode and Effect Analysis (FMEA) technique in a clinical laboratory. FMEA technique allows: a) to evaluate and measure the hazards of a process malfunction, b) to decide where to execute improvement actions, and c) to measure the outcome of those actions. A small sample of analytes has been studied: there have been determined the causes of the possible malfunctions of the analytical process, calculating the risk probability index (RPI), with a value between 1 and 1,000. Only for the cases of RPI > 400, improvement actions have been implemented that allowed a reduction of IPR values between 25% to 70% with a costs increment of <1%. FMEA technique can be applied to the processes of a clinical laboratory, even if of small dimensions, and offers a high potential of improvement. Nevertheless, such activity needs a thorough planning because it is complex, even if the laboratory already operates an ISO 9000 Quality Management System.

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BACKGROUND

Failure Mode and Effect Analysis (FMEA), together with other techniques, such as Fault Tree Analysis and Event Tree Analysis, is one of the process risk evaluation techniques that can be used to identify and measure the malfunction hazards of a process (1). FMEA is based on a preliminary study of safety and functionality of a component, part, product, or productive phase, developed taking into account its possible failure modes, the effects, the critical points, and the causes that have generated them.

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FMEA is based on a preliminary study of safety and functionality of a component, part, product, or productive phase, developed taking into account its possible failure modes, the effects, the critical points, and the causes that have generated them.

The FMEA target is to measure the risk probability of any possible failure or nonconformity (NC), by an index, called risk probability index (RPI), that is the product of:

- the "severity index" (SI), from 1 to 10
- the "probability index" (PI), from 1 to 10
- the "detectability index" from 1 to 10.

The RPI can go from a minimum of 1 ($1 \times 1 \times 1$) to a maximum of 1,000 ($10 \times 10 \times 10$). In general, the improvement interventions start from the NC/failures with RPI $>$ 400, and for each intervention it is possible to evaluate the RPI reduction, expected and actual, and the cost for RPI unit reduction.

We have evaluated an experimental application of the FMEA method to some analytical processes of a clinical laboratory.

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METHODS

The FMEA method has been implemented on three analytical processes of a clinical laboratory operating in Salerno, Italy. The laboratory operates a quality management system according to the ISO 9001:2000 standard, executes about 160,000 tests/year of clinical chemistry, immunoassay, microbiology, and hematology. The laboratory team consists of 13 people (three MDs, two biologists, three technologists, and five clerical/administrative and auxiliary personnel).

The study has been executed on a small sample, made by only three clinical chemistry analytes (glucose, total cholesterol, total bilirubin), from January to April 2002. The FMEA method has been implemented with reference to the *FMEA Manual* (2), adapting the activities and the documents to the clinical laboratory processes.

FMEA IMPLEMENTATION BY PHASES

As the results have been very similar for all of the three analytes, we present, as an example, the glucose (S-glucose) results. A part of the FMEA format of S-glucose is reported in Table 1. AQ3

Phase 1

The first phase was made by collecting all the available informations about the analytical activities for the three analytes. The analytical process only, and not the pre-analytical and the post-analytical phases, has been drawn, and, on its basis, have been reviewed and classified all the failures/NC observed for the analyte.

Phase 2

According to the process analysis, we have identified the function of each component of the analytical process, including reagent, sample, calibrator, and instrument (Table 1, column 1).

Phase 3

For each component of the analytical process, we have identified the effects of the component's failure on the final result of the process (Table 1, column 2).

Phase 4

We assigned an SI value (1–10) to each failure mode effect. The value has been assigned according to Table 2.

In our example (Table 1, column 4), to all the failure modes malfunction of reagent (MFR) the SI assigned was 9, as a malfunctioning reagent not discovered in time, can produce an analytical result useless or dangerous for the patient. For the case of malfunction of calibrator (MFC), the assigned SI value was 8, as the MFC makes impossible to execute the analytical run and usually alerts the operator to check the calibrator and/or repeat the calibration run. AQ4

Table 1
FMEA format for S-glucose chemicals, reagent, and calibrator

LOGO		**FMEA Format**			**Project leader**				**Date**
FMEA name: S-Glucose		Description: S-Glucose on ILAB 500				Component group: chemicals			
FMEA N.		Component code: 01/02				Component description: reagent/calibrator			
1	2	3	4	5	6	7	8	9	10
REF. N.	FAILURE MODE	FAILURE MODE EFFECT	SI	FAILURE MODE CAUSE	PI	CONTROL MEASURE	DI	RPI	PROPOSED ACTION
01.01	Malfunction of reagent MFR	Useless result	9	Expired	3	Check expiration date	1	27	None
01.02	Malfunction of reagent MFR	Useless result	9	NC storage temperature	6	Visual check of reagent	10	540	Add temperature monitoring system
01.03	Malfunction of reagent MFR	Useless result	9	Contaminated	8	QC before run	10	720	Add QC after run
02.01	Malfunction of calibrator MFC	Calibration failure	8	Expired	3	Check expiration date	2	48	None
02.02	Malfunction of calibrator MFC	Calibration failure	8	NC storage temperature	6	Visual check of calibrator	2	96	None
02.03	Malfunction of calibrator MFC	Calibration failure	8	Contaminated	8	Visual check of calibrator	2	128	Freeze sigle doses and use once

Table 2
Severity index

Severity level	Value	Description
Minimal	**1**	User is not able to know the effect, it does not affect the product performances
Low	**2–3**	Slight disturbance to the user, which can identify a reduction in performance
Mild	**4–6**	Disturbance to the user, with clear evidence of reduction in performance
High	**7–8**	High level of unsatisfaction due to high reduction of performance
Very high	**9**	Defect can damage safety and makes the product useless
Catastrophic	**10**	Defect causes damage to people and/or properties

Phase 5

In this phase, to each failure mode an effect has been linked to its possible causes. In our example, to MFR and MFC have been coupled the causes (Table 1, column 5), to obtain the couples "failure-cause."

Phase 6

The PI (1–10) has been assigned to each couple. The criteria to assign PI are reported in Table 3.

The PI has been determined on the basis of the frequency of each failure/NC as reviewed in Phase 1. In our example (Table 1), the PI of expiration of the reagent or the calibrator was 3 because the internal procedure was to eliminate the reagent/calibrator the week before its expiration, so there was a very low likelihood to find an expired reagent or calibrator on board an analyzer, whereas the PI of contamination of the reagent was 8 because its frequency in failure/NC review was approximately 1%.

Phase 7

In this phase, the control measures actually used were reported, for each couple "cause-failure." In our example (Table 1, column 7), for the item 02.03, corresponding to the MFC due to contamination of the calibrator, there was only a visual inspection measure activated at the moment of the FMEA.

Phase 8

In this phase, each couple "failure-cause," with reference to its actual control measure, has been assigned a value of detectability index (1–10). This index is assigned according to:

a) the capability to keep the user from receiving a nonconforming product
b) the perception of the defect from the user.

The values range from 1 (the user does not receive a nonconforming product or does not notice the effect) to 10 (the failure/NC is not detectable, so the user will suffer all its consequences).

Phase 9

In this phase, the RPI (1–1,000) has been calculated, by multiplying SI × PI × RI and obtaining a value between 1 (1 × 1 × 1) and 1,000 (10 × 10 × 10). In our example, the RPI values (Table 1, column 9) ranged between 27 and 720. The improvement actions have been designed and implemented as preventive actions, according to the QMS applicable procedure, but their impact has been analyzed in terms of RPI point reduction, and the relative cost has been analyzed in terms of cost for RPI point reduction. AQ5

In our example, improvement actions have been designed for the following items:

a) 01.02–MFR/nonconforming storage temperature (RPI = 540), by adopting a continuous temperature monitor for the reagents/calibrators refrigerator
b) 01.03–MFR/contaminated reagent (RPI = 720), by changing the frequency of quality control execution, introducing a second quality control test after the end of the execution of unknown samples and before their approval
c) 02.03–MFC/contaminated calibrator (RPI = 128), by changing the procedure of preparation, storage and use of the calibrator, by reconstituting the calibrator, dividing it in aliquots, freezing them, and chilling and using one aliquot for each calibration run.

Phase 10

The improvement actions have been implemented and the results have been analyzed (see *Results*).

RESULTS

The improvement action carried out on item 01.02 showed an RPI = 180. The reduction of RPI was 360 (540 − 180), with a percentage value of 66% (360/540). This result was obtained by the FMEA reassessment shown in Table 4.

Table 3
Probability index

Probability index	Value	Description/explanation
Remote	**1**	It's not reasonable to expect that the cause will show itself
Low	**2–3**	The rate of failure/NC for that cause goes from 1/20,000 to 1/10,000
Mild	**4–6**	Rate of failure/NC in parts/1,000
High	**7–8**	Rate of failure/NC in parts/100
Very high	**9–10**	Rate of failure/NC worse than 10%

Table 4
Improvement actions effects for malfunctioning reagent/nonconforming storage temperature

Index	Before	After	Comment
SI	9	9	No possible modification of severity: if a malfunctioning reagent enters the process, the possible damage remains high.
PI	6	4	The probability, even if in the same group (mild, see Table 3), is reasonably reduced to the minimum of the group.
DI	10	5	The adoption of a monitoring system makes the detectability much better: estimated DI lowers 50% (from 10 to 5).

The calculated costs for RPI point are as follows:

- cost of the temperature monitor: 500 Euro, duration 5 years = 100 Euro/year
- cost of the emergency batteries for the monitor + 12 paper recorder discs/year: 10 Euro/year
- working time to change discs, review data: 20 hours/year, value 240 Euro/year (at 2002 working time costs).

Total cost for year was 340 Euro, reduction 360 RPI points, cost for point 0.94 (340/360) Euro/point (about 0.95 $U.S. at end-2002 change rate). The cost increment estimated for the clinical chemistry laboratory and for the workstation on which the S-glucose is executed was about 0.3% per year.

The improvement action carried out on item 01.03 showed an RPI of 189. The reduction of RPI was 531 (720 − 189) RPI points, with a percentage value of 73% (531/720). This result was obtained by the FMEA reassessment shown in Table 5.

The calculated costs for RPI points are only the costs of the additional dose of quality control serum, the additional dose of reagent plus instrument time, and the additional working time to evaluate the result.

We estimated the full cost in about 300 Euro/year, and, with a reduction of 531 RPI points, cost for point = 0.56 (300/531) Euro/point (about 0.57 $U.S. at end-2002 change rate). The cost increment estimated for the clinical chemistry laboratory and for the workstation on which the S-glucose is executed was about 0.5% per year. The improvement action carried out on item 02.03 showed an RPI of 96. The reduction of RPI was 32 (128 − 96 =), with a percentage value of 25% (32/128).

In this case, the only item that changed with the improvement action was the PI, that changed from 8 before to 6 after the action, because freezing single doses of the calibrator and thawing one dose for each calibration, to be used once, reduces probability index from high (level 8, Table 3) to mild (level 6, Table 3).

The 25% reduction in RPI was obtained at a cost per year of <100 Euro, with an increase of costs for single analyte practically not measurable because the frozen single dose calibrator is used to calibrate all the analytes executed on the same instrument, and so the cost of the operation of preparation of doses and freezing is divided by the 38 analytes executed together. AQ6

DISCUSSION

FMEA is a preventive technique already experimented with and applied in some areas of health organizations. The first applications have been made in the field of clinical engineering (3), but the FMEA also has been recognized as a valuable instrument to forecast and risk assessment for health products and processes, to correlate them also to legal liability (4). More generally, FMEA has been used as an instrument of risk assessment in the cases in which the human intervention is involved, considering that the phases in which the human intervention is involved are the riskiest points of a process (5). AQ7

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The technique also has been evaluated as capable of identifying and preventing the potential problems in therapeutical systems, with reference to the patient safety (6, 7). FMEA also has been used in the transfusion laboratory/blood bank, in which it allowed to eliminate the process errors (8); in the transfusion/blood bank area, the concept of the error frequency measurement

Table 5
Improvement actions effects for malfunctioning reagent/contaminated reagent

Index	Before	After	Comment
SI	9	9	No possible modification of severity: if a malfunctioning reagent enters the process the possible damage remains high.
PI	8	7	The probability, even if in the same group (high, see Table 3), is reasonably reduced to the minimum of the group.
DI	10	2	The adoption of a more pressing QC plan makes malfunctions revelation much easier: DI lowers 70% (from 10 to 3).

already has been used, reducing error frequencies from 20–30 to 6–21 per 10,000 procedures (9), even if there has been identified a certain difficulty to compare the error frequency results between different institutions (10). Perhaps FMEA could become a common standard to measure and compare.

Other applications of FMEA have occurred in bioethics, as a support instrument to improve the accuracy of information to patients who participated in clinical trials (11) and as an instrument to improve a drug distribution system in a large teaching hospital (12).

In our experience, FMEA showed some problems in its application. These have been related to:

a) the necessity of a detailed analysis of the processes and of the failure/NC data
b) the lack of preceding experiences, that made more complex the attribution of the indexes
AQ8 c) the difficulty in making all the work manually, with a large consumption of time.

The above difficulties have been, however, overcome, and we can draw the following conclusions that must be considered only a suggestion for future research. FMEA is a technique that can be applied to a clinical laboratory, even if of small dimensions. Problems in its implementation are resoluble by a thorough planning and, if necessary, using a FMEA management software. The improvement potentially obtainable by FMEA in a clinical laboratory is high, and this fact should suggest further experiences in this field.

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