FMEA-FMECA: a risk management's strument for critical processes

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Introduction

The clinical risk unit of ASL Napoli1 Center takes care about the implementation of procedures to enforce ministerial recommendations, concerning sentinel events reduction and prevention.

Great attention has been paid to recommendation N. 5: "prevention of transfusional reaction by AB0 incompatibility". Thanks to both procedures adopted by "Immunohaematology and Transfusion Medicine Service" to services and patient safety and law criterias application, new improvement procedures were developed by using "clinical governance" tools and methodologies, such as the FMEA and FMECA (Risk management).

Methods

The selected strategy turned out by the use of different methods.

In order to satisfy the aim to prevent rather than to react, it has been chosen to adopt an approach through proactive analysis and a step by step process as follows:

– different management systems integration and its recording tools: Quality management system in accordance with ISO 9001:2008 regulation and Risk management;
– analysis about processes related to transfusion risk and detection of critical process that has to be analyzed through FMEA/FMECA;
– checking and recording of nonconformity, in acceptance sector of SIMT;
– multidisciplinary group identification to FMEA/FMECA analysis execution;
– identification of critical process (unique identification sample/patient)
– FMEA/FMECA Analysis;
– processes validation;
– monitoring.

Results

The analysis showed that the rules established by SIMT allow to block the greatest parts of beginning process mistakes, but many troubles still exist in patient identification during the blood sampling.

If the evaluation of analytic determinations referred to the two samples of the same person show a difference, so SIMT can reveal the patient exchange, but if an error occurs on both samples, then it will be impossible to note it.

By the evaluation of priority risk index carried out after the FMEA/FMECA analysis, middle and long terms corrective actions have been selected intervention priority-corrective actions selected:

– introduced a three new procedures conforming to Recommendation No. 5 of Ministry of Health and (AB0 Incompatibility) the DM of 3 March 2005 (transfusional safety);
– introduced registration forms for non-conformity and monitoring of indicators;
– the personnel has been formed about the right procedure to follow;
– measurament and monitoring.

Conclusions

The application of the methodology FMEA / FMECA was a aggregation multi-professionality that allowed the assessment of various issues in a broader vision.The barrier posed by the procedures selected, allows to prevent the error.

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