

FAILURE MODE AND EFFECTS CRITICALITY ANALYSIS: MULTICENTRIC APPLICATION ON CANCER CHEMOTHERAPY PROCESS

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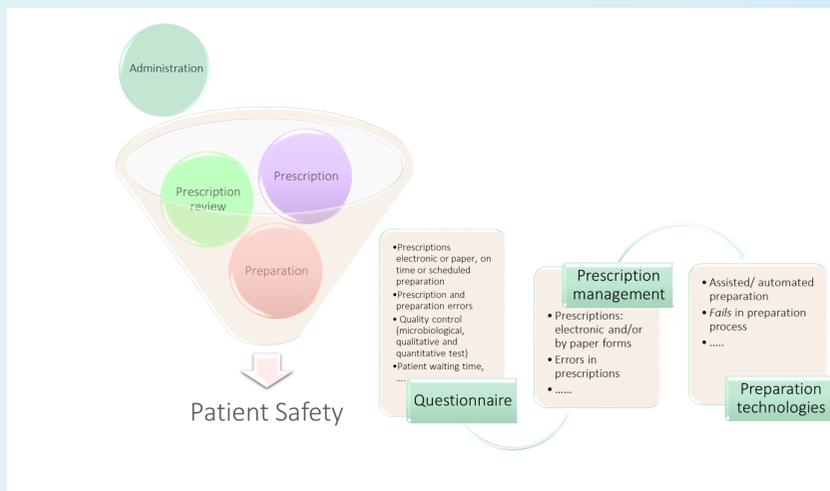
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Background

Risk reduction in cancer chemotherapy process should be a major objective for all healthcare workers due to severe consequences. One of the most effective method of minimizing errors and improve safety in this high risk process is the failure modes, effects and criticality analysis (FMECA).

Purpose

The present study attempted to perform a prospective risk analysis associated to chemotherapy process focused on prescription and preparation steps in three hospitals.

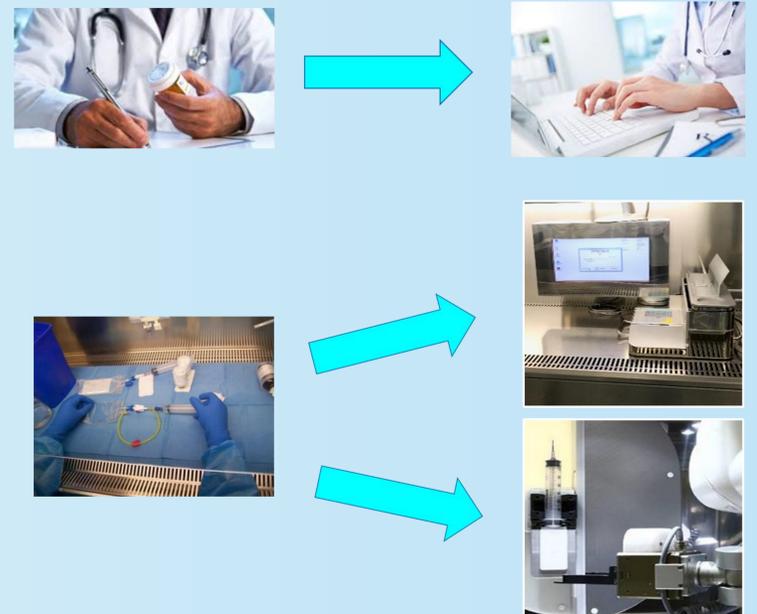


Material and methods

The FMEA analysis allowed us to perform chemotherapy process mapping, identification and prioritization of possible risks for each phase of prescription and compounding. The decomposition of the whole process into steps characterized with specific failure modes was carried out by a multidisciplinary team made up of three different hospital to limit subjectivity. The failure modes were defined and their criticality indices calculated on the basis of the likelihood of occurrence, potential severity and detection probability. Repeatability, severity and identification probability received a score between 1 to 10 and a Risk Priority Number (RPN), which is equal to their multiplication, was determined.

Results

Five areas of greatest concern and 318 failure modes were identified, of which those evaluable by each hospital were 98.1%, 57.9% and 50.3% respectively, due to different organization (electronic prescription and automatic compounding of chemotherapy agents; handwritten process and manual production; electronic prescription and manual production). Sixty-three criticality indices (RPN > 100) were calculated and the most high risk area was “Chemotherapy treatment schemes and scheduling” (50% of total RPN), followed by “Check and delivery” (23.3%), “Medical prescription” (20.8%), “Compounding” (15.1%) and “Validation and Transcription” (13.6%). Informatic software and automated or assisted preparation systems led to a reduction of 50% and 41% of RPN respectively compared to handwritten process and manual compounding.



Conclusion

Technology and electronic devices at the prescription and production steps led to a decrease in criticality indices number detected but also led to the appearance of new specific criticality indices. A more systematic use of FMECA may guide and help to focus priorities in continuous security improvement of high-risk medical activities in which hospital pharmacist is involved.

References and/or Acknowledgements

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