Healthcare failure mode effect analysis of a miniaturized extracorporeal bypass circuit

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Objective: The introduction of new and more advanced technology in healthcare occurs with an increasing speed. Therefore more attention is needed for safety evaluation of new devices or techniques from an end-user perspective, especially when (inter-) national perfusion safety standards are lacking. Objective was to perform a prospective risk analysis of a miniaturized bypass system to prevent or reduce the severity or likelihood of failures.

Methods: To evaluate the safety of the Extra Corporeal Circulation Optimized (ECCO, Sorin Group, Mirandola, Italy) bypass circuit, healthcare Failure Mode and Effect Analysis (hFMEA) was used. A multi-disciplinary team that consisted of two clinical perfusionists, a clinical physicist, a clinical physicist trainee and a technician has performed this analysis.

Results: The hFMEA demonstrated that failure of the bubble sensor for the electric remote clamping system on the arterial line, activated by air passing the venous bubble trap, had the highest risk score of all failure modes. This has led to the implementation of an extra level sensor in the system to prevent air passing through into the centrifugal pump.

Conclusion: Early identification of possible technology failures in any process or device can avoid adverse patient outcomes. The technique of hFMEA is a valuable tool to evaluate the use of high-risk apparatus, such as an extra-corporeal bypass system, in patient treatment in order to increase patient safety.