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Major article

Failure analysis in the identification of synergies between cleaning monitoring methods

Greg S. Whiteley MSafetySci [a,b,*], Chris Derry MSc(Med) [a], Trevor Glasbey PhD [b]

[a] University of Western Sydney, Richmond, New South Wales, Australia
[b] Whiteley Corporation, North Sydney, New South Wales, Australia

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Background: The 4 monitoring methods used to manage the quality assurance of cleaning outcomes within health care settings are visual inspection, microbial recovery, fluorescent marker assessment, and rapid ATP bioluminometry. These methods each generate different types of information, presenting a challenge to the successful integration of monitoring results. A systematic approach to safety and quality control can be used to interrogate the known qualities of cleaning monitoring methods and provide a prospective management tool for infection control professionals. We investigated the use of failure mode and effects analysis (FMEA) for measuring failure risk arising through each cleaning monitoring method.
Methods: FMEA uses existing data in a structured risk assessment tool that identifies weaknesses in products or processes. Our FMEA approach used the literature and a small experienced team to construct a series of analyses to investigate the cleaning monitoring methods in a way that minimized identified failure risks.
Results: FMEA applied to each of the cleaning monitoring methods revealed failure modes for each. The combined use of cleaning monitoring methods in sequence is preferable to their use in isolation.
Conclusions: When these 4 cleaning monitoring methods are used in combination in a logical sequence, the failure modes noted for any 1 can be complemented by the strengths of the alternatives, thereby circumventing the risk of failure of any individual cleaning monitoring method.

Cleaning in health care settings is a manageable activity that can be audited for consistency and quality.[1] The processes of cleaning environment surfaces within hospitals can be monitored by 4 distinct methods: visual inspection, microbial recovery, rapid ATP bioluminometry detection, and use of fluorescent marker (FM) technologies.[2] Each of these monitoring methods generates a distinct type of information that is difficult to integrate into a single monitoring result.[3,4]

Although cleaning has the goal of removing soils and pathogens, the monitoring methods used for management and supervision of cleaning have a distinct quality assurance role.[5] The goal of any monitoring method is to provide feedback on cleaning failure to assist in the management and improvement of environment cleaning within health care settings.[6-9]

The sampling approach taken for the monitoring of environment surfaces within health care settings is a constant problem.[10,11] The apparently random distribution of soils, including dry surface biofilms and pathogens, presents a challenge for any sampling plan investigating the nature of environment contamination, and is complicated by the presence high-touch objects.[12-14] Health care environment cleaning protocols are management tools that set out the practical steps to achieving the goal of removing soils and improving the quality of environment surface hygiene.[15,16]

Health care cleaning processes are designed on a risk-based format with the highest risk areas requiring the most frequent or highest-intensity cleaning.[17] The secondary process of cleaning monitoring is intended to ensure that soil removal goals are met with optimal efficiency and efficacy.[18]

If the cleaning monitoring method is flawed due to uncontrolled or unrecognized failure, then the data on cleaning outcomes will also be flawed and unreliable. This compromises the management goal of ensuring that the primary process of cleaning has been achieved.

We focused on the failure of cleaning monitoring methods and not on the actual processes of cleaning. Failure mode and effects analysis (FMEA) is a reliable safety and quality management risk-assessment tool that identifies potential failure conditions or errors that may cause failure for products or processes.[19] The FMEA

* Address correspondence to Greg S. Whiteley, MSafetySci, PO Box 1076, North Sydney, NSW, Australia 2059.
E-mail address: gregswhiteley@aol.com (G.S. Whiteley).
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applied here investigated if current cleaning monitoring methods could be optimized to reduce cleaning failures as a type of medical error.[20,21]

Within this management context, FMEA as a risk tool can add value by systematically examining failures to mitigate or minimize their influence on the cleaning process being undertaken.[22] An ultimate aim is the identification of failure modes within cleaning monitoring systems as a quality improvement process in health service provision.[23]

FMEA is typically conducted on products or processes, through the application of existing information on identified failures or failure modes to anticipate failure events. A failure mode is defined as a "loss of intended function" under normal operating conditions. FMEA was selected as a suitable method for prospective risk assessment of the 4 monitoring methods due to its applicability as a forecast model and as a risk-assessment tool that is frequently used in the context of medical devices.[24]

A risk-assessment team of 3 individuals with collective skills in FMEA and cleaning monitoring using each of the 4 methods was formed, with the following aims:

- To identify a modified approach for the application of FMEA in failure analysis relating to the 4 commonly used cleaning monitoring methods,
- To test the feasibility of the approach by carrying out a preliminary assessment of the 4 monitoring methods using the modified FMEA approach and to identify areas of commonality and work toward a monitoring model that could include the 4 methods in an integrated monitoring approach, and
- To identify strategies for the development of potential synergies during an integrated application of the 4 cleaning monitoring methods.

For each of the identified failure modes, literature support was required as part of the process of identification and consideration of mitigation for each major failure mode.

METHODS

The initial step in the FMEA process was for the FMEA team members to identify all possible causes of failure (loss of intended function) for each of the 4 cleaning monitoring methods.[24] Each identified failure mode was substantiated by relevant material in the literature. Where similar, multiple, or overlapping causes of failure were identified, these were gathered under a common failure mode. A comprehensive list of failure modes was noted for each cleaning monitoring method.

The risk associated with each of the failure modes was then assessed individually by each of the FMEA team members. Each of the failure modes was graded against 3 distinct categories with associated risk criteria. These categories were first graded for the likely frequency of occurrence of that failure mode during normal use, second for the severity of the effect of this failure mode on the validity of the information produced, and finally the assessment was also graded for whether the failure mode had any detectability in the normal course of its use. The grading system applied for this study is shown in Table 1. It uses a 3-tiered scoring approach similar to the 3-tiered risk criteria that are used in Australian Infection Prevention.[23] In the FMEA method used in our study, each category was assigned a score of 1-3 (low to high).

After the grading of each failure mode against each of the 3 categories (frequency, severity, and detectability), the grades for each failure mode were multiplied to produce a single score known as the risk priority number (RPN). The RPN is an overall indicator as to whether the failure mode requires further consideration or mitigation to minimize the identified failure risks. Whereas some authors have suggested use of weighting to accentuate critical failures, for the purposes of simplicity no weighting of the RPN was used in our study.[25] Using the 3-point grading system outlined in Table 1, there are only 10 possible RPN scores, with a minimum score of 1, a median of 7, and a maximum score of 27. The RPN for each failure mode was noted and ranked from high risk to low risk of the nominated failure occurrence.

Table 1
Ordinal conversion table for assigning values to identified failure risk cofactors

Failure risk cofactor and criteria	Descriptor	Value
Frequency		
The failure mode is unlikely to occur, or cannot occur, during normal monitoring operations	Low risk	1
The failure mode is fairly likely to occur during normal monitoring operations	Medium risk	2
The failure mode is highly lightly to occur, or always occurs, during normal monitoring operations	High risk	3
Severity		
Occurrence of the failure mode will have minimal or no effect on the monitoring results, or on the associated cleaning outcome	Low risk	1
Occurrence of the failure mode will have some effect on the monitoring results, or on the associated cleaning outcome	Medium risk	2
Occurrence of the failure mode will have considerable or extreme effect on the monitoring results, or on the associated cleaning outcome	High risk	3
Detectability		
Occurrence of the failure mode is easy to detect. Feedback is likely to inform immediate monitoring-failure mitigation	Low risk	1
Occurrence of the failure has a possibility of being detected. Feedback may inform early monitoring-failure mitigation	Medium risk	2
Occurrence of the failure mode is difficult or impossible to detect. Feedback is unlikely to inform monitoring-failure mitigation	High risk	3

Following the establishment of each RPN a structured dialogue was conducted to arrive at a common view on the RPN score using a modified Delphi approach.[26] The FMEA team members then reconfirmed each identified failure mode through the published literature and where no published evidence in support of the failure mode was available then that failure mode was discarded.

The RPN scores were finally ranked and divided into 3 classes based on a low, medium or high risk classification.[23] For ease of interpretation, the failure modes with RPN scores less than the median of 7 were accepted as low risk. Scores >7 and <13 were set as medium risk. Scores >13 were accepted as high risk.

The combined FMEA results were then considered to investigate whether combinations of the cleaning monitoring methods would provide mitigation of the effects of failure modes. This allowed for the FMEA team members to identify any novel approaches that could provide an enhanced approach to cleaning monitoring. This step allows for mitigation to be used as a form of redundancy whereby a reduction of the overall risks arising from cleaning failure is practically achieved by reducing the risks of failure of the cleaning monitoring methods. Thus the risk assessment approach is used as predictive tool to improve practice in advance of failure. This will lead to further research opportunities.

RESULTS

For the 4 cleaning monitoring methods 32 failure modes were identified and risk-assessed. Table 2 shows the 15 failure modes