IS RELIABILITY-CENTRED MAINTENANCE A VALID MAINTENANCE STRATEGY?

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INTRODUCTION

Healthcare is becoming increasingly reliant on technology to deliver healthcare services which meet the expectations of clinicians, patients and the community. Medical technology employed is becoming more complex and, generally speaking, more reliable. However, technical complexity while delivering greater functionality also brings an increase in the ways, or modes, in which a device or system can fail to fulfil its intended purpose. As a professional community, we have addressed the changes in technology and the ever increasing volume of technology we are asked to manage, with a diversity of responses. Some have continued with traditional methods, others by developing risk calculators, and still others by adopting a 'run to failure' approach for a select range of devices.

For a number of years we, the Biomedical Engineering Dept. (BME), at the Royal Adelaide Hospital (RAH), have been examining the response of other industries to these same challenges. Of particular interest to us was the approach of the airline industry and the development of what has become known as Reliability-centred Maintenance or simply RCM. Of all the methods adopted by biomedical engineering departments and medical device manufacturers, we have come to conclude that RCM is the only method that produces an adequate and effective management strategy for the maintenance of medical technology.

WHAT IS RCM?

In a nut shell, RCM is a structured method of examining the functions of a device, item of equipment or a system, in the context in which it is used, to determine how it can fail to meet its function(s), the root cause and consequence of each failure mode and what, if anything, can be done to prevent the failure.

RCM originated in the airline industry in the 1960's. The Federal Aviation Authority (FAA) in the US was concerned with the failure rates experienced in certain types of aircraft engine. All attempts to improve the reliability of the engine through feasible changes to either the content or frequency of scheduled overhauls had failed. The FAA convened a task force to investigate the true capability of preventative maintenance. The task force led to the establishment of the FAA Industry Reliability Program. The program made two significant discoveries [1]:

1. scheduled maintenance had little effect on the overall reliability of a complex device or system unless there was a dominant failure mode.
2. more effective maintenance programs can be developed through the use of logical decision processes.

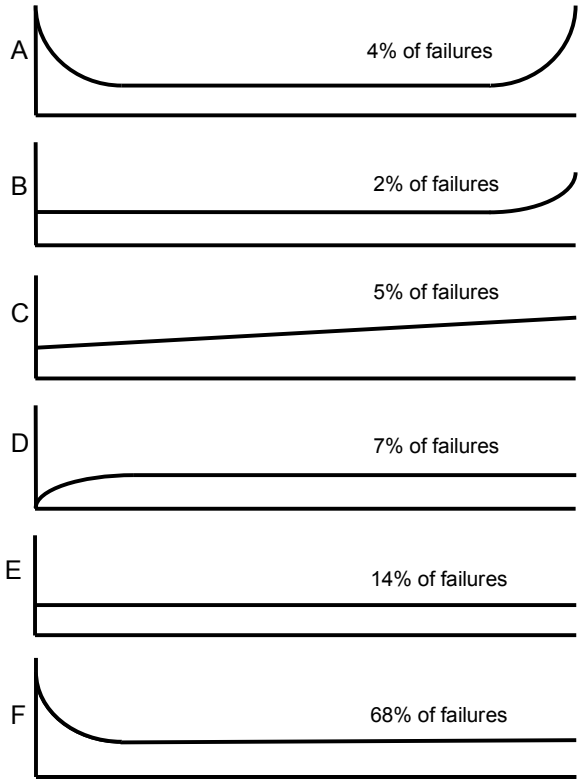

Fig 1: Age-reliability patterns [2, Exhibit 2-13]

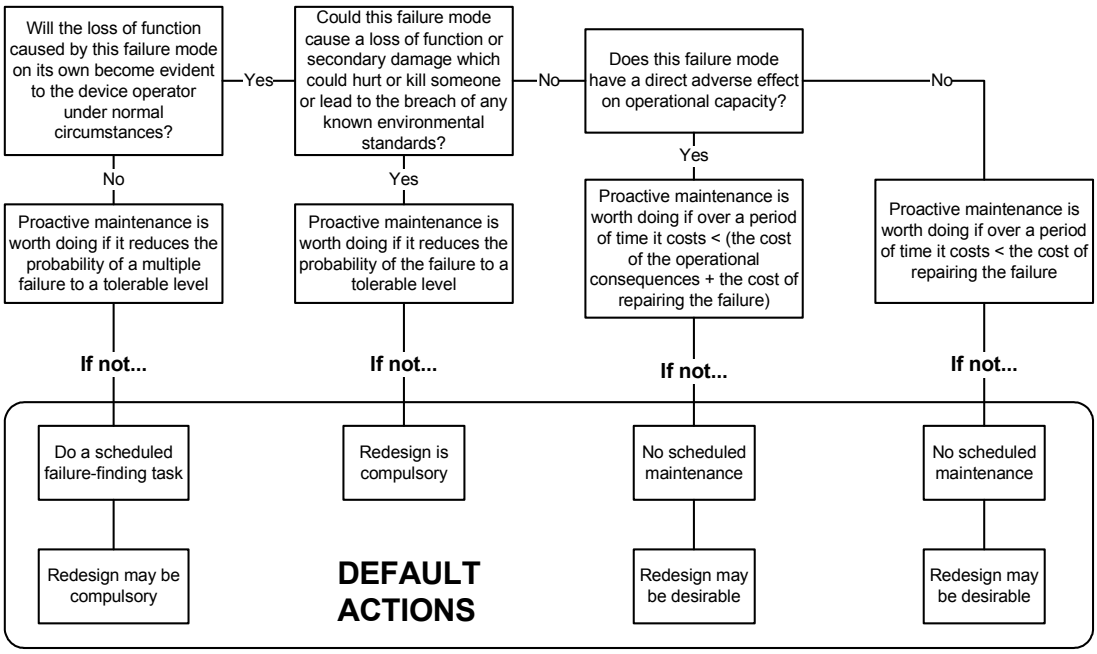

Fig 2: Simplified version of John Moubray's RCM II Decision Diagram [3, Fig. 5.16]

Nolan and Heap made a significant contribution to improving maintenance practices when they wrote what they described as *"the first full discussion of reliability-centered maintenance as a logical discipline for the development of scheduled maintenance programs."* They went on to say, *"the objective of such programs is to realize the inherent reliability capability of the equipment for which they are designed, and to do so at minimum cost"* and; *"The chief focus was on the identification of a set of tasks that would eliminate the cost of unnecessary maintenance without compromising safety or operating capability."* [2]

United Airlines found that there were 6 basic age-probability curves patterns (Fig 1). Curves A, B and C demonstrate age related failure patterns but these were found to only represent 11% of failures. The majority of failures at 89% were subject to a constant random probability of failure after an initial bedding in phase (Curves D, E, F). Therefore, 89% of failure cannot benefit from any scheduled preventative maintenance. We can further deduce that for the 68% of failures that are subject to age-reliability pattern F any scheduled maintenance will increase the average probability of failure.

John Moubray also made a significant contribution to our understanding of RCM. Moubray [3] developed seven questions to provide the structure to the RCM process:

1. What are the functions and associated performance standards of the asset in its present operating context?
2. In what way does it fail to fulfil its functions?
3. What causes each functional failure?
4. What happens when each failure occurs?
5. In what way does each failure matter?
6. What can be done to predict or prevent each failure?
7. What should be done if a suitable proactive task cannot be found?

The responses to the first four questions are recorded on a Failure Modes and Effects Analysis (FMEA) worksheet. They aid the analysis team to define:

1. the functions and performance standards the user expects of the device
2. the functional failures
3. the failure modes and
4. the effects or consequences of each failure.

The last three questions assist the evaluation team to determine:

1. the effect of the failure on safety, the environment and the operations of the organisation

2. the maintenance task(s), if any, that will effectively prevent the consequence of the failure
3. the interval at which the task should be undertaken to meet organisational objectives, and
4. who can most effectively carry out the task, and
5. what should be done if no effective maintenance task can be found that will be effective in preventing the consequence of the failure.

This information is then collated and used to develop a maintenance strategy for the device or system.

To assist in determining the most effective maintenance strategy a Decision Diagram is used. The two most credible that we have examined are:

1. the MGS-3 Decision Diagram and
2. John Mobray's RCM II Decision Diagram (Refer Fig 2).

While for BME the jury is still out on an appropriate decision diagram for application in biomedical engineering, we have concluded that the MSG-3 diagram is too complex and Moubray's does not adequately address patient safety aspects.

Moubray examines two types of proactive maintenance; on-condition maintenance tasks and scheduled maintenance tasks. For an on-condition task to be technically feasible it must be possible to detect the potential failure – an identifiable condition that indicates a functional failure is about to occur or is in the process of occurring – with sufficient lead time to enable action to be taken to prevent or avoid the consequences of the functional failure. For a scheduled maintenance task to be technically feasible the assembly or component subject to failure must have a consistent average life. Schedule maintenance is only applicable to assemblies or components that are subject to aging or normal wear.

THE EXPERIENCE TO DATE OF THE RAH

The Biomedical Engineering Dept. at the Royal Adelaide Hospital (RAH) has undertaken training in RCM II by a certified trainer who also facilitated RCM workshops on three devices; a Dræger Oxilog 2000 ventilator, a Baxter Colleague general purpose infusion pump and an Alaris Asena GH syringe infusion pump. A number of clinicians were invited to participate in the workshops and were provided with an abridged version of the training – one day versus the 3 days undertaken by BME staff. Dræger, Baxter, and Cardinal Health were invited to participate in their respective workshops and to attend the training together with members of BME. Dræger and Baxter accepted the invitation.

Very quickly our facilitator recognised that he had significantly under estimated the complexity of each device and therefore the time required to complete each analysis. Consequently we had insufficient time to complete the analyses.

A major benefit of RCM is identifying when inspections are valid and beneficial, and the frequency at which inspections should be undertaken. Inspections are only valid for detecting 'hidden' failures, failures that are not evident to the operator, or for detecting potential failures associated with on-condition tasks. While Boeing advised us that there are very few failures for which on-condition inspections are not technically possible, we were not able to identify any failure modes during the workshops where it was feasible to implement an on-condition inspection, and the manufacturer had not included an on-condition inspection in the device's self diagnostics.

We did find a number of hidden failures for which the manufacturers had not included a recommended inspection task and interval. Also, where inspection tasks and frequencies are recommended by the manufacturer or Australian Standard AS3551, the recommended interval (eg 12 months recommended by AS3551) are arbitrary. They do not take into account the mean time between failures of the component/assembly that causes the functional failure or the consequence to the organisation of the failure.

It should be noted that inspections for hidden failures are not designed to prevent the failure, but to detect a failure and manage the consequence of the failure. The inspection interval determines the average time the function is unavailable using the formula:

$$U = 0.5 \times \left(\frac{FFI}{M} \right) \quad \text{OR} \tag{1}$$

$$FFI = 2 \times U \times M \tag{2}$$

Where:

U is the Unavailability of function

FFI is the Failure Finding Interval

M is the Mean Time Between Failures (MTBF) of the protective device

The acceptable unavailability of the function should be determined by the operating organisation and therefore the organisation should be establishing FFIs in order to meet their organisational objective.

The FFI should not be defined by the manufacturer. To impose an arbitrarily determined FFI on all healthcare facilities irrespective of their function or purpose does not make sense. The manufacturers should be required to provide the MTBF data for each hidden functional failure in each device they offer to the market. Likewise, accreditation agencies should be examining a hospital's strategies for managing the functionality of the medical devices it operates, not whether each device is inspected every 12 months.

Obtaining realistic mean time between failures (MTBF) data proved difficult. Our data was very limited and the manufacturers' representatives were not able to provide us with the required data, which made determining an appropriate failure finding interval (FFI) difficult. However, the 12 month interval commonly recommended did not figure in our analyses. In most cases the intervals we arrived at were factors smaller or larger than the recommended.

Electronic components exhibit age-reliability pattern F (Refer Fig 1). They are subject to an infant mortality period followed by a very slowly increasing failure probability. On-condition inspection is not technically feasible nor is scheduled preventative maintenance beneficial. Therefore the only maintenance option is 'no scheduled maintenance' or 'run to failure'.

With the exception of a few devices such as anaesthesia units, ventilators and O_2 analysers which contain components that are subject to age related failures, there are no preventative maintenance tasks that are effective in preventing device failures. Maintenance tasks, for the majority of biomedical devices, are limited to remedial or repair tasks and failure finding tasks.

It is worth noting that the more you 'black box' a device (treat it as a single component with inputs and outputs) the more it will conform to age-reliability pattern E. The only effective maintenance strategy for pattern E is run-to-failure.

Other findings that flowed from our experiences are:

1. the clinicians add a great deal to the analysis particularly in defining the effects of each failure and the clinical consequences
2. the technical information provided by the manufacturers both to in-house biomedical engineering departments and to their own service personnel is inadequate for the intended purpose
3. the maintenance strategies that flow from our analysis (even though they remain incomplete) differ significantly from the recommendations of the manufacturers and Australian Standard AS/NZA 3551 – Technical management program for medical devices.
4. RCM is a good tool for identifying design deficiencies in a device or item of equipment, and policies and procedures governing its operation and maintenance
5. the overhead for a hospital to implement RCM in isolation is prohibitive
6. RCM II is a rigorous process. However, it does not address patient safety in a manner that we believe is acceptable to health (this is not to imply that it does not address patient safety failures)
7. a run to failure strategy is inappropriate for the three devices analysed
8. it is tempting, but risky, to fast track the analysis
9. while RCM is 'common sense' and appears simple, a successful analysis is unlikely to be achieved without the facilitation of a skilled and experienced RCM facilitator.

CONCLUSION

Our initial conclusion is that we still have a lot to learn about applying RCM. However, we have great hope for improving our practices through the application of RCM principles not just to the maintenance of biomedical devices but in the technology management of biomedical devices through their complete life cycle. We have concluded that RCM offers the best opportunity for improving biomedical engineering practice and the function and safety of medical devices.

There is a significant cost in implementing RCM which places it out of reach for most hospital biomedical engineering departments. However, if as an international community we can develop a co-operative model based on that developed by the FAA, airline manufacturers and airline operators we can deliver significant improvements at an affordable cost.

REFERENCES

[1] A McCormick. *Required maintenance program*, Boeing Production Planning Seminar, Section 1.

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[3] J Moubray, *Reliability-centred Maintenance*, Second Edition, Elesevier Butterworth-Heinemann, Jordan Hill Oxford OX

[4] *Technical management program for medical devices Standards Australia, AS/NZA 3551:2004;*