work before they can be widely or routinely used in quality assessment across the UK, and the context in which they are used will be crucial.

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FMEA and RCA

FMEA and RCA: the mantras* of modern risk management

J W Senders

FMEA and RCA really do work to improve patient safety

For a number of years root cause analysis (RCA) has been used when an adverse event has occurred. It is generally accepted that adverse events do have causes, and that a careful analysis of the actions of persons and the states of the system in which the event occurred will reveal the causal agents. It remains only to select the most reasonable cause from the myriad of competing causes to bring the RCA to completion. RCA is obviously a reactive process taking place after the harm has been done.

Failure mode and effects analysis (FMEA) is less familiar to the medical world. It has little history in medicine although its military and industrial origins go back almost to World War II.[1] FMEA is a proactive process aimed at predicting the adverse outcomes of various human and machine failures, and system states.

FMEA and RCA cannot be separated. FMEA seeks to know the effects of each of all possible causal sets. RCA seeks to know the causal set of each of all possible effects. The underlying assumptions are that for every effect there must exist a set of causes (excluding the null set); and for every set of causes there must be some effect (including the null set). FMEA is the temporal mirror of RCA reflected in the ''now'' moment. FMEA looks forward in time; RCA looks backwards.

It is important to examine the underlying assumptions and logic of both processes. In its most primitive form, FMEA asks for the effect of a component failure. ''If the shaft of this pump failed, what malfunction would follow?'' Then, if the malfunction was unacceptable, the shaft might be redesigned or a duplicate pump might be installed to take over when the first failed. RCA, confronted with an unacceptable malfunction, asks: ''What component caused this malfunction?'' and discovers that the pump shaft had failed. A thorough RCA would examine every antecedent action and state in identifying the set of causes of the event. A thorough FMEA should ask its question about every component. If FMEA could do exactly what it is claimed to be, there would be no need for RCA. A complete proactive analysis would have identified all the causal sets and the outcomes that would have occurred. Unfortunately, things do not work out that way. Neither analysis is able adequately to deal with human failures—the inevitable errors that occur in any system involving people.

When the failure in question—whether hypothetical (FMEA) or actual (RCA)—is a human error, the analysis techniques become complicated, particularly in FMEA. There is no component failure but rather a probabilistic deviation from intention and expectation. An error may have a general form—a substitution, for example—but how that form is expressed in the environment depends on what there is that *can* be done wrong and the number of ways there are of doing it wrong. The analyst must be able to imagine the unthinkable. A mere tabulation of all those errors that have so far occurred is not adequate.

FMEA has been around for a long time in engineering practice and its use in engineering has become common and sophisticated. In medicine, however, there are relatively few reports of actual use of FMEA. When it has been used it appears to have been beneficial, and there has been little objection to its use. It is a non-threatening technique. RCA is more common in medicine, driven by the large number of adverse events that must be explained. It also generates more argument because of the legal and ethical implications of causal assignment (usually to human error). Medicine can learn much from engineering usage of FMEA.[2–4]

FMEA today is very big business. A Google search on FMEA yielded 150 000 hits; a combined search with ''engineering'' yielded 40 000 hits while a combined search with ''medicine'' yielded only 3000. Many hits are offers of manuals, forms, software, and training programs on FMEA. It is easy to spend large sums of money but it is not easy to assess the quality of the products. The use of FMEA in medicine is growing and it is in medicine to stay: JCAHO Standard LD.5.2 requires facilities to select at least one high risk process for proactive risk assessment each year.

The Institute for Safe Medication Practices (ISMP) became interested in FMEA around 1990[5 6] and uses it in the analysis of potential medication errors. Its website presents a straightforward description of FMEA and shows how it can be applied to problems in medication safety:

''*These pitfalls can be avoided by using a process known as Failure Mode and Effects Analysis (FMEA) to examine the use of new*

*Mantra: Sacred words or sounds invested with the power to transform and protect the one who repeats them.

products and the design of new services and processes to determine points of potential failure and what their effect would be—before any error actually happens.''

''*FMEA is a proactive process used to look more carefully and systematically at vulnerable areas or processes. FMEA can be employed before purchase and implementation of new services, processes or products to identify potential failure modes so that steps can be taken to avoid errors before they occur*.''[7]

Like RCA, FMEA induces thoughtful consideration of the causal complexities of classes of medical adverse events. If used with care and intelligence it can reveal potential hazards and instruct ways to mitigate them. The paper by Apkon *et al*[8] in this issue of *QSHC* is an encouraging example of what can be done. What neither process can do is to reveal the complete consequential and causal sets of any singular error or adverse outcome. Thus, an RCA may appear to show that a physician's error was the cause of a patient injury. However, if one subscribes to the notion that *all* manifested behavior is caused, then one must push the RCA deeper into the central nervous system and so ad infinitum. Similarly, one might attribute the singular patient injury to the fact that the physician's alarm woke him/her in time to get to the operating room. The wake up call and the error are equipotent in ''causing'' the injury. If either had not occurred, that physician could not have caused that injury.

Similarly, an FMEA may appear to show that a specific error could cause a specific injury, but whether it would actually do so requires an analysis of the actions of all other persons and of all states of all systems and devices that might possibly be involved. In fortunate truth, most human errors do not lead to adverse outcomes.

FMEA and RCA really do work to improve the safety of patients, and they really are mantras. When the names are repeated in court along with records showing that the procedures they stand for were performed, they may protect you against ruinous litigation costs and losses by showing that you did everything you could think of to avoid preventable injury to a patient.

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ECHO

Guidelines based on presenting problems cut invasive procedures in children with diarrhoea or seizures

Please visit the *Quality and Safety in Health Care* website [www.qshc.com] for a link to the full text of this article.

Unnecessary invasive tests and treatment could be avoided for many children presenting as emergencies with diarrhoea or seizures if evidence based care guidelines were widely adopted, according to a UK hospital study.

Better management and significantly fuller clinical records resulted after guidelines for diarrhoea (with or without vomiting) and seizures (with or without fever) in children aged 0–15 years were implemented in the accident and emergency department. More children with diarrhoea had optimum rehydration according to their needs. Unnecessary intravenous infusions fell from 11 to one, as did the proportion of children undergoing invasive tests—for full blood count (4% *v* 11%) and urea and electrolytes (5% *v* 12%). Similarly, in children with seizures tests were significantly lower for urea and electrolytes (17% *v* 29%) and calcium concentration (10% *v* 23%).

The guidelines significantly speeded up assessments, though they raised the relative risk of admission—an outcome measure—for children with diarrhoea. These admissions were for observation and shorter stays than previously. Relative risk of admission for seizures was unchanged.

The prospective study was performed in 502 children with diarrhoea and 398 with seizure attending directly or referred by their general practitioner. Process and outcome measures were assessed for four months in early 1997 and a further four months two years later, after guidelines had been introduced.

Care pathways providing a clinical management ''map'' for doctors should improve management but have always been based before on diagnosis, not presenting problems.

▲ *Archives of Disease in Childhood* 2004;**89**:159–164.