

Failure modes and effects

— a tool for evaluating packaging safety?

By Duncan Jenkins, PhD, MRPharmS, and Raj Gokani, MBA, MRPharmS

Failure modes and effects analysis is a tool that was developed outside of health care but has been used in the US to evaluate the safety of medicines packaging. This article describes how the approach, now being trialled on a small scale in the UK, may fit in with existing risk reduction processes



Error reporting data show that look-alike and sound-alike drugs are implicated in a third of dispensing errors made in NHS hospitals.¹ Recently, the National Patient Safety Agency reporting system drew attention to selection errors associated with two childhood vaccines which resulted in 93 children receiving the wrong product. A safer practice notice was issued by the NPSA and the Medicines and Healthcare products Regulatory Agency which highlighted this issue and provided action points for NHS staff to reduce the risk of further errors.² The bulletin also announced that manufacturers would be redesigning the packaging of one of the vaccines to aid differentiation.

This article discusses an approach to risk management using an analysis tool currently being trialled on a small scale in the UK, which may help to reduce the likelihood of such scenarios in the future.

Duncan Jenkins and Raj Gokani are directors of MORPh Consultancy Ltd.

Background

Despite the awareness of the influence of packaging and labelling on drug selection errors, dispensary shelves still contain similar looking products. The most common reason for this is the pharmaceutical industry's use of corporate livery. In some cases packaging is identical in all respects except for drug names and other product specifics. The view that if all health professionals read the label properly errors would be avoided is of course true. However, the role of human factors in risk management is now a well accepted phenomenon; vigilance alone is not always sufficient to reduce risk to an acceptable level.

Furthermore, human behaviour can introduce hazards to the medicines management process. Errors have occurred due to decanting of ampoules from containers, sometimes being carried from one clinical area to another in health professionals' pockets and then replaced into the wrong container. While the adoption of a "no decanting" policy may reduce this risk, it may not eliminate it to an acceptable level. As well as human

factors, the hospital environment can contribute to errors. For example, hospital theatres are often poorly lit which could make reading of small labels such as those on ampoules difficult.

In order to reduce the risk of selection error to an acceptable level, a multifaceted approach is required. This should involve a joined up approach by manufacturers, regulators, the NPSA, procurement professionals and clinical staff.

The MHRA has produced "Best practice guidance on the labelling and packaging of medicines".³ This makes recommendations for the positioning and presentation of information, the use of innovative design to aid identification and selection of the correct product and the use of user-testing to support packaging and labelling risk assessment. More recently, the NPSA has published a guide to the graphic design of medicines packaging.⁴ As well as providing clear guidance and an accompanying checklist on safe design of packaging and labelling, the document provides guidance for conducting user testing and thus complements the MHRA guidance. In a

previous article in this series, the procurement approach to risk assessment was discussed, the overall aim of which is to ensure that products with apparent inherent risk are not purchased.⁵ The assessment process, which forms part of tender evaluations, consists of three parts:

- The medicine's potential error in use
- The medicine's quality and fitness for purpose to ensure safe and secure handling
- The performance of the manufacturer

When errors are made in clinical practice, professionals are obliged to report the incident via local or national reporting systems. This surveillance process has proven useful in the identification of issues with packaging where there is a high risk of error, for example, in the case of the vaccine errors discussed above. A previous article in this series has also described how some manufacturers are considering safety in the design of packaging.⁶

The developing systems outlined above provide reassurance that the risk of selection errors is being tackled. However, some questions remain. First, how does a manufacturer go about ensuring safe design of products? Guidance from the MHRA and NPSA provides a good starting point and an awareness of the procurement risk assessment process is essential if tendering for contracts. Second, is there a standard formula for a safe design? We suspect that there is not and that safe design will be defined by the ability to reduce both general and product specific risks. Third, are pharmacists aware of the real risks of using new or even established products and do they know how medicines are really used in clinical practice?

While checklists and best practice statements play an essential role, there is a danger that some risks may not be apparent until a product is in use. This may be compounded with an increasingly diverse range of clinical settings, including the patient's home, and the shift towards self administration of medicines in hospital and at home.

| Steps in the process | Failure mode | Failure causes | Failure effects | Likelihood of occurrence (1-10) | Likelihood of detection (1-10) | Severity (1-10) | Risk priority number | Actions to reduce occurrence |
|----------------------|--------------|----------------|-----------------|---------------------------------|--------------------------------|-----------------|----------------------|------------------------------|
| 1 | | | | | | | | |
| 2 | | | | | | | | |
| 3 | | | | | | | | |

Figure 1: The matrix used to document the FMEA process

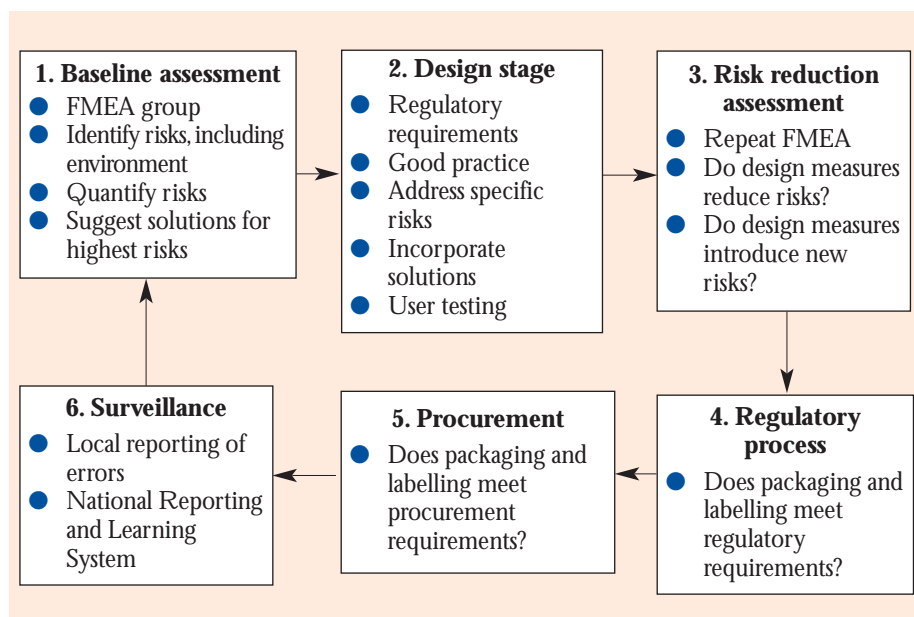


Figure 2: Relationship of FMEA to other risk management processes

We are proposing that a standard methodology should be adopted by the pharmaceutical industry, in collaboration with health professionals, which will allow the identification and quantification of practice-related risks with medicines. Although the focus here is on the role of packaging and labelling, this methodology could be used by both product manufacturers and health professionals to quantify risks associated with broader aspects of medicines use such as safe preparation, (self-) administration and monitoring. The methodology also lends itself to assessing the reduction in risks associated with a redesign in product packaging.

— FMEA

Failure modes and effects analysis (FMEA), a generic tool developed outside of health care, has been widely applied, including to manage risk associated with medicines. It is a systematic tool for evaluating a process and identifying where and how it might fail.⁷ It also assesses the relative impact of different

types of failure and so prioritises which areas need attention first. The FMEA process involves a review of:

- Steps in the process
- Failure modes (what could go wrong?)
- Failure causes (why should failure happen?)
- Failure effects (what would be the consequences of each failure?)

FMEA is multidisciplinary and should include everyone involved in the process being considered. The first step consists of mapping out the steps in the process through group discussion. The group then lists all possible failure modes by means of brainstorming. For each error type or failure mode identified, a cause and effect is attributed, together with scores for likelihood of occurrence, likelihood of detection and severity. The scores should be between one and 10, with 10 being the most likely or most severe. The risk priority number (RPN) is obtained by multiplying these three scores and so can be between one and 1,000. The matrix shown in Figure 1 is used for documenting the FMEA process.

It is possible to use FMEA to evaluate the potential impact of changes by discussing and re-evaluating the RPN. In effect this provides the opportunity to simulate the process and evaluate risk without actually making the change.

— FMEA to evaluate packaging

In the US, the Institute of Safe Medicines Practice has used FMEA to examine recognised risks associated with specific products. A landmark in the work of the institute was the application of the method to redesign the packaging of a commercial

brand of cisplatin in 1996.⁸ The work was in response to a number of accidental overdoses associated with confusion between daily and total doses and confusion with carboplatin, which is normally used in higher doses. A multidisciplinary advisory panel was convened by the manufacturer in conjunction with the institute to consider the risks and provide solutions. Using FMEA, the group recommended changes to the packaging of the cisplatin, including daily dose warnings on packaging and vial closures, greater prominence of the generic name, with "cis" in red letters and a "stop sign" to warn professionals to check the drug name and dose.

— FMEA in the UK?

The NPSA management of the risks associated with methotrexate involved analysis of error reports and event audits, an expert working group, patient testing of packaging and labelling designs and working with manufacturers and regulators to provide solutions.⁹ The programme of work was in response to a number of deaths and was proportional to the level of risk. However, it is almost certain that techniques such as FMEA, had they been used when methotrexate was introduced, would have identified the risks and might have prevented a proportion of these deaths. With the cultural shift that has taken place over the past five to 10 years it is unlikely that such a high risk medicine would be licensed without explicit assessment of the risks, either voluntarily by manufacturers or as a regulatory requirement. However, the routine assessment of practice-based risks associated with medicines has yet to be adopted by manufacturers in the UK.

MORPh Consultancy is working with an industry partner to test FMEA methodology in the UK. The trial is being carried out to further assess the impact of the redesign of Hameln's packaging (reported in a previous article in this series⁶). The company's generic injections portfolio was redesigned in consultation with users and the new packaging was tested by the company using a picking test method involving pharmacy staff. The impact in terms of risk reduction is now

being assessed further by a multidisciplinary group of professionals using FMEA. The injections portfolio contains some products considered to be high risk; potassium chloride, lidocaine, adrenaline and atropine. Furthermore, these products are often used in an emergency or in environments where lighting is poor, eg, in hospital theatres.

We hope that the approach will complement other processes that are being developed and implemented. Figure 2 (p174) provides an illustration of how the different processes may work together. Although the processes are pictured in chronological order from pre-launch to practice, some elements may be a continuous consideration (such as the regulatory process). A baseline assessment of risks should ideally be carried out before product licensing and should involve an initial risk assessment with a multidisciplinary FMEA panel. This will identify any risks, quantify them and propose some solutions. For established products, this process could address known risks, perhaps identified by the National Reporting and Learning System. The FMEA process could then inform the design process with specific issues relating to use of the medicine in practice. Good design practice should be incorporated and user testing can validate the design. A second FMEA step could be carried out at this stage to assess the reduction in risk and rule out any design factors which might introduce new risks into practice.

The next step in our suggested scheme is involved with the regulatory process. Currently manufacturers are obliged to meet basic standards and are encouraged to adopt good practice in packaging design.³ However, given the recent emphasis on risk management plans for new products, there may be an opportunity for regulators to encourage consideration of risks associated with or reduced by good packaging design.

Procurement and purchasing for safety has been discussed previously. It would be useful however, to examine how FMEA might add further, product-specific insight into this process. The procurement framework could then provide a strong commercial incentive for manufacturers to undertake FMEA. However, additional requirements imposed on manufacturers will further add to product costs which may be passed on to the NHS. Key questions are whether risk assessments such as FMEA need to be carried out for all products, whether they could focus on portfolios as well as individual products, and how the NHS is willing to pay for robust risk assessments by manufacturers. Will the procurement process penalise unsafe products only or will it go as far as rewarding safer products?

The final stage is one of surveillance, which consists of both local systems and the NRLS. There should be a feedback system which can be used to update baseline risks,

where necessary, in the light of reported errors. This provides a further mechanism for identifying and managing risks, and could where needed, initiate the FMEA process again.

— Conclusion

FMEA is an established risk assessment tool which is used widely in the US and recommended by the Food and Drug Administration. In the UK, adoption of this approach by manufacturers in collaboration with health professionals could help to prevent drug errors, including those where packaging and labelling have an influence. It is not dissimilar to tools used in many NHS organisations which categorise risk using a traffic light system based on severity and likelihood. The application of FMEA could complement existing tools and guidance around packaging and labelling design, though key questions pivot around which products should be assessed and whether the method complements or duplicates other efforts. The methodology is currently being trialled on a small scale and findings will be reported in due course.

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