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Short communication

Risk analysis of analytical validations by probabilistic modification of FMEA

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ABSTRACT

Risk analysis is a valuable addition to validation of an analytical chemistry process, enabling not only detecting technical risks, but also risks related to human failures. Failure Mode and Effect Analysis (FMEA) can be applied, using a categorical risk scoring of the occurrence, detection and severity of failure modes, and calculating the Risk Priority Number (RPN) to select failure modes for correction. We propose a probabilistic modification of FMEA, replacing the categorical scoring of occurrence and detection by their estimated relative frequency and maintaining the categorical scoring of severity. In an example, the results of traditional FMEA of a Near Infrared (NIR) analytical procedure used for the screening of suspected counterfeited tablets are re-interpreted by this probabilistic modification of FMEA. Using this probabilistic modification of FMEA, the frequency of occurrence of undetected failure mode(s) can be estimated quantitatively, for each individual failure mode, for a set of failure modes, and the full analytical procedure.

1. Introduction

Failure Mode and Effects Analysis (FMEA) is "a systematic method of analyzing and ranking the risks associated with various product (or process) failure modes (both existing and potential), prioritizing them for remedial action, acting on the highest ranked items, re-evaluating those items and returning to the prioritization step in a continuous loop until marginal returns set in"[1]. In pharmacy, its application is increasing, for the development of production processes of pharmaceuticals [2], in health care risk management [3,4], and for the evaluation of methods for analytical validation [5,6]. In the quality assurance of the production of medicines its usefulness is apparent from Annex 1 of the ICH Q9 guideline, where FMEA is named as a possible risk management tool [7].

The first step in performing FMEA to analytical analysis is identification of potential failure modes. These failure modes are listed and then scored based on three aspects of the failure modes: occurrence (O), detection (D) and severity (S). Traditionally, this FMEA scoring is done by assigning discrete values to each of the items on a predefined scale, for example from 1 to 3, 1 to 5 or 1 to 10. Categorical scores are ranked, such that higher scores are associated with higher risks and the risk are calculated as a Risk Priority Number (RPN), which is the product of the scores of these three parameters. These RPN values allow a comparison of risks: the failures modes with the highest RPN-scores are the most urgent for improvements to reduce these risks.

We applied that traditional FMEA to the Near Infrared (NIR) spectroscopic analytical procedure, in use in our laboratory, for screening of suspected counterfeited tablets [8]. The consistency of the results of that traditional FMEA was also studied [9].

However, risk prioritization in traditional FMEA, which is based on the multiplication of these three categorical scores and expressed as RPN values, has been criticized. Zambrano et al. [10], Cox et al. [11] and Cox [12], showed serious limitations opposed to more quantitative risk analysis methods. Gilchrist [13], and also Kmenta and Ishii [14], suggested to evaluate risk using probabilities for occurrence and detection, and expected cost as a quantitative measure for severity. Harpster [15] indicated that RPN alone can be misleading and that the scores used to calculate RPN should be considered separately. FMECA (Failure Modes Effects and Criticality Analysis), is a method of criticality analysis by which each potential failure mode is ranked according to the combined influence of severity and probability of occurrence [16]. However, these alternative methods are remote from the traditional FMEA. Like Gilchrist [13] and Kmenta and Ishii [14], we modified the traditional FMEA by changing the categorical scoring of occurrence and detection, to probabilistic estimation of relative frequencies of occurrence ($P_{(O)}$) and detection ($P_{(D)}$). Our approach differs from that of these authors by the fact that the categorical scoring of severity, (S), could not be changed into another, meaningful, quantitative measure and therefore it was kept unchanged.

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Table 1
Process steps of a NIR analytical procedure for the screening of suspected counterfeited tablets, published earlier [8], and the failure modes per process step. *N.A.*: Not Applicable: no failure mode identified in the process step.

Process step		Failure modes per process step	
1	Meeting between NIR expert, technician and head of department on examination plan	1.1	Technical incompetence of NIR expert, and/or technician and/or head of department
		1.2	Failing discussion of planning between NIR expert, and/or technician and/or head of department project leader
2	Collecting of sample(s) by technician	*N.A.*	
3	Verification & validation of equipment by technician	3.1	Controls of NIR equipment forgotten
		3.2	Inadequate functioning of the printer
		3.3	Wrong measurement parameters of NIR equipment
		3.4	Incorrect interpretation of the results of the verification of the NIR equipment
		3.5	Incorrect action taken by the results of the validation of the NIR equipment
4	Preparing sample(s) by technician	4.1	Mistakenly switching of samples
		4.2	Sample incorrectly subjected to moisture
		4.3	Incorrect hight of sample for the NIR equipment
		4.4	Incorrect tamed down of sample for the NIR equipment
		4.5	Less than 5 tablets used for the NIR analyse
5	Performing measurements by technician	5.1	Wrong parameters NIR equipment for sample analyzed
		5.2	Incorrect labelling of sample to tablet holder of NIR equipment.
		5.3	Incorrect positioning of tablet holder
		5.4	Incorrect working process of PC and/or printer
		5.5	Not turning around the sample in the tablet holder
		5.6	Decripancy between sample number and sample number on produced NIR spectrum
		5.7	Resolution and number of scans not correct
6	Processing of measurement results by technician	6.1	Incorrect including the data of the reference taken.
		6.2	Changing the spectra produced by the NIR equipment.
		6.3	Mistake in selection of 2^{e} derivative of obtained spectrum
		6.4	Mistake in choice of wavelength range
		6.5	Mistake in selection of spectrum of the reference
		6.6	Mistake in interpretation of obtained spectrum
		6.7	By NIR expert to little competence in chemometrics
		6.8	By technical analyst to little competence in chemometrics
7	Interpretation of measurement results by technician	*N.A.*	
8	Reporting measurement results by technician to NIR expert	*N.A.*	
9	Review of the technicians report by NIR expert	9.1	Report insuffient
		9.2	Inadequate control of report by NIR expert
10	Conclusions of examination by NIR expert	*N.A.*	
11	Discussion of measurement results and conclusions of examination by NIR expert and head of the department	11.1	Incorrect additional measurement assignment by NIR expert and/or head of the department
12	Drafting of result of examination letter by NIR expert and discussion of letter with head of the department	12.1	No qualification of library in letter to commissioner

Table 2
Definitions and categorical rankings of failure modes for occurrence (O), detection (D), and severity (S), for traditional FMEA, applied to a NIR analytical procedure for the screening of suspected counterfeited tablets [8].

Definition of occurrence of failure mode	(*O*)	Definition of detection of failure mode	(*D*)	Definition of severity of failure mode	Consequence of failure mode with this severity	(*S*)
Negligible	1	Certainly	1	Dangerously high	People can get severely wounded	10
Very low	2	Very likely	2	Extremely high	Fail does no longer meet legal rules	9
Low	3	Likely	3	Very high	Customer end up with faulty report/product	8
Occasionally	4	More than average	4	High	Rejection of produced products	7
Now and then	5	Average	5	Moderate	Long delay in process due to carrying out repairs	6
Regularly	6	Low	6	Low	Moderate delay in process	5
Very regularly	7	Very low	7	Very low	Short delay in process	4
Often	8	Unlikely	8	Extremely low	Extra effort to produce, no delay	3
Very often	9	Very unlikely	9	Almost none	Failure not noticed; little effect	2
Extremely often	10	Excluded	10	None	Unnoticed; no relevant effect	1

The results of risk analysis of the Near Infrared (NIR) analytical procedure by traditional FMEA and the proposed probabilistic modification of FMEA are compared.

2. Methods

2.1. Traditional FMEA

A Near Infrared (NIR) analytical procedure for the screening of suspected counterfeited tablets was subjected to risk analysis by traditional FMEA and published earlier [8]. Summarizing: this NIR procedure was split up in 12 process steps to undergo risk analysis. These 12 process steps and 31 failure modes are shown in Table 1. The failures modes were subjected to traditional FMEA, using categorical rankings for (*O*), (*D*) and (*S*), each to a scale from 1 to 10. The definitions for each score are shown in Table 2.

For each of the failure modes, RPN values were calculated by:

$$RPN = (O) \times (D) \times (S)$$

The failure modes with the six highest RPN values, ranging from 150 to 320, were improved, to make these failure modes more robust. Thereafter the same traditional FMEA was applied to these six improved failure modes and their RPN-values again calculated, now being 30 to 160. The improvement index (II) for each improved failure mode was also calculated, by:

$$\text{II} = \frac{(\text{RPN}_{\text{before improvement}})}{(\text{RPN}_{\text{after improvement}})}$$

Note that this improvement index II has a value larger than 1 and that a higher value implies a larger improvement.

The results of this traditional FMEA risk analysis of the NIR analytical procedure are shown in Table 3.

Table 3
Results of the traditional FMEA of the NIR analytical procedure before and after the improvements of six failures modes. Also shown: the Improvement Index (II) of the failure modes.

Failure mode	Traditional FMEA before improvements				Traditional FMEA after improvements				Improvement Index
	(*O*)	(*D*)	(*S*)	RPN	(*O*)	(*D*)	(*S*)	RPN	
1.1	5	3	8	120					1.0
1.2	4	3	5	60	NIM				1.0
3.1	5	3	8	120					1.0
3.2	4	3	3	36					1.0
3.3	4	7	8	224	4	3	8	96	2.3
3.4	5	3	8	120	NIM				1.0
3.5	5	3	8	120					1.0
4.1	4	10	8	320	2	10	8	160	2.0
4.2	2	4	5	40					1.0
4.3	4	3	8	96					1.0
4.4	4	3	8	96					1.0
4.5	7	3	2	42					1.0
5.1	5	3	8	120	NIM				1.0
5.2	2	3	8	48					1.0
5.3	5	10	1	50					1.0
5.4	3	1	4	12					1.0
5.5	4	10	3	120					1.0
5.6	5	10	1	50					1.0
5.7	3	10	5	150	3	2	5	30	5.0
6.1	4	3	8	96					1.0
6.2	2	3	8	48					1.0
6.3	3	3	5	45	NIM				1.0
6.4	3	3	5	45					1.0
6.5	3	3	8	72					1.0
6.6	4	3	8	96					1.0
6.7	3	10	8	240	3	4	8	96	2.5
6.8	5	3	8	120	NIM				1.0
9.1	7	3	5	105					1.0
9.2	4	10	8	320	4	3	8	96	3.3
11.1	2	3	8	48	NIM				1.0
12.1	3	10	8	240	3	2	8	48	5.0

NIM: No improvements made.

Table 4
Definitions of the categorical scoring, (O), and associated estimated relative frequency, $P_{(O)}$, for *occurrence* of failure modes; and the categorical scoring, (D), and associated estimated relative frequency, $P_{(D)}$, for *detection* of failure modes. The corresponding estimated relative frequency of non-detection of the failure modes, $(1 - P_{(D)})$, is given as well.

Occurrence of failure modes			Detection of failure modes			
Definition	(O)	$P_{(O)}$	Definition	(D)	$P_{(D)}$	$(1 - P_{(D)})$
Negligible	1	5×10^{-10}	Certainly	1	1	0
Very low	2	2×10^{-9}	Very likely	2	0.99	0.01
Low	3	6×10^{-7}	Likely	3	0.96	0.04
Occasionally	4	6×10^{-6}	More than average	4	0.93	0.07
Now and then	5	1×10^{-4}	Average	5	0.90	0.1
Regularly	6	3×10^{-3}	Low	6	0.75	0.25
Very regularly	7	1×10^{-2}	Very low	7	0.50	0.5
Often	8	5×10^{-2}	Unlikely	8	0.30	0.7
Very often	9	3×10^{-1}	Very unlikely	9	0.10	0.9
Extremely often	10	6×10^{-1}	Excluded	10	0	1

2.2. Probabilistic modification of FMEA

In the probabilistic modification of FMEA, we estimated the relative frequency of occurrence and detection of failure modes, $P_{(O)}$ and $P_{(D)}$. No change was made in the categorical ranking of severity, (S). $P_{(O)}$ and $P_{(D)}$ represent probabilities with values between 0 and 1. $P_{(O)}$ values for the (O) definitions were taken from literature [17], see Table 4. The values of $P_{(D)}$ for the definitions of (P) were assigned by the FMEA team, specifically for the purpose of the probabilistic modification, see also Table 4. Also, the associated estimates for non-detection of failure modes, $(1 - P_{(D)})$, are shown in Table 4.

Most important is the probability of occurrence of a non-detected failure mode, $P_{(UF)}$:

$$P_{(UF)} = P_{(O)} \times (1 - P_{(D)})$$

The data of (O) and (D) of the traditional FMEA of the NIR analytical procedure were re-calculated in $P_{(UF)\ \text{before improvement}}$ and $P_{(UF)\ \text{after improvement}}$, see Table 5. The impact of an improvement of the failure mode can be calculated as Relative Risk Reduction (RRR):

$$\text{RRR} = 1 - \left\{ \frac{P_{(UF)\,\text{after improvement}}}{P_{(UF)\,\text{before improvement}}} \right\}$$

Note that this RRR will have a value between 0 and 1, with 1 representing the best possible improvement.

These RRR data are also shown in Table 5.

An interesting observation is that the six improved failure modes, that is those with highest RPN values, are not those with the highest $P_{(UF)}$ values. For example, according to Tables 3 and 5, failure modes 6.7 and 12.1 have RPN 240 and $P_{(UF)}$ 6×10^{-7}, and failure modes 1.1; 3.1; 3.4; 3.5; 5.1 and 6.8 have RPN 120 and $P_{(UF)}$

Table 5
Results of the probabilistic modification of FMEA of the NIR analytical procedure before and after the improvements of six failure modes. Also shown: the Relative Risk Reduction (RRR) of the improvements.

Failure modes	Probabilistic FMEA before improvement				Probabilistic FMEA after improvement				RRR
	$P_{(O)}$	$1 - P_{(D)}$	$P_{(UF)}$	S	$P_{(O)}$	$1 - P_{(D)}$	$P_{(UF)}$	S	
1.1	1×10^{-4}	0.04	4×10^{-6}	8					0
1.2	6×10^{-6}	0.04	2.4×10^{-7}	5	NIM				0
3.1	1×10^{-4}	0.04	4×10^{-6}	8					0
3.2	6×10^{-6}	0.04	2.4×10^{-7}	3					0
3.3	6×10^{-6}	0.5	3×10^{-6}	8	6×10^{-6}	0.04	2.4×10^{-7}	8	0.9200
3.4	1×10^{-4}	0.04	4×10^{-6}	8	NIM				0
3.5	1×10^{-4}	0.04	4×10^{-6}	8					0
4.1	6×10^{-6}	1	6×10^{-6}	8	2×10^{-9}	1	2×10^{-9}	8	0.9997
4.2	2×10^{-9}	0.07	1.4×10^{-10}	5					0
4.3	6×10^{-6}	0.04	2.4×10^{-7}	8					0
4.4	6×10^{-6}	0.04	2.4×10^{-7}	8					0
4.5	1×10^{-2}	0.04	4×10^{-4}	2					0
5.1	1×10^{-4}	0.04	4×10^{-6}	8					0
5.2	2×10^{-9}	0.04	8×10^{-11}	8	NIM				0
5.3	1×10^{-4}	1	1×10^{-4}	1					0
5.4	6×10^{-7}	0	0	4					0
5.5	6×10^{-6}	1	6×10^{-6}	3					0
5.6	1×10^{-4}	1	1×10^{-4}	1					0
5.7	6×10^{-7}	1	6×10^{-7}	5	6×10^{-7}	0.01	6×10^{-9}	5	0.9900
6.1	6×10^{-6}	0.04	2.4×10^{-7}	8					0
6.2	2×10^{-9}	0.04	8×10^{-11}	8					0
6.3	6×10^{-7}	0.04	2.4×10^{-8}	5	NIM				0
6.4	6×10^{-7}	0.04	2.4×10^{-8}	5					0
6.5	6×10^{-7}	0.04	2.4×10^{-8}	8					0
6.6	6×10^{-6}	0.04	2.4×10^{-7}	8					0
6.7	6×10^{-7}	1	6×10^{-7}	8	6×10^{-7}	0.07	4.2×10^{-8}	8	0.9300
6.8	1×10^{-4}	0.04	4×10^{-6}	8	NIM				0
9.1	1×10^{-2}	0.04	4×10^{-4}	5					0
9.2	6×10^{-6}	1	6×10^{-6}	8	6×10^{-6}	0.04	2.4×10^{-7}	8	0.9600
11.1	2×10^{-9}	0.04	8×10^{-11}	8	NIM				0
12.1	6×10^{-7}	1	6×10^{-7}	8	6×10^{-7}	0.01	6×10^{-9}	8	0.9900

NIM: No improvements made.

4×10^{-6}, all with severity score (S) = 8. This implies that the failure modes selected for improvement in the traditional FMEA are not necessarily those that pose the highest risks.

3. Discussion

The use of a probabilistic modification of FMEA is illustrated in a case study. It shows that this modification is an improvement in understanding the outcome of the risk analysis.

First, by this probabilistic modification of FMEA, the actions to be taken for improvements of failure modes can be selected by considering two factors instead of one: not only RPN, but considering both categorical scorings of severity, (S), and the estimated frequencies of undetected failure modes, $P_{(UF)}$. This adds relevant information for the comparison of failure modes. By its nature, severity represents a different dimension of risk than occurrence and detection. For example, in our case study the highest severity class, (S) = 8, includes all failure modes that may lead to customers ending up with a faulty product and it is worthwhile to treat these important failure modes as a separate category. Also, improvements of failure modes will rarely, if ever, reduce their severity.

Second, the probabilistic modification of FMEA opens the possibility to estimate the yearly rate of occurrence of an undetected failure mode, if the number of samples that can be analyzed per year is known. This yearly rate is

$$P_{(UF)} \times \left\{\text{samples analyzed per year}\right\}$$

so it is expected that, with a constant number of analyses per year, an undetected failure mode will occur once in year

$$\frac{1}{P_{(UF)} \times \{\text{samples analyzed per year}\}}$$

For instance, in our laboratory about 100 samples per year are analyzed. For the non-detected occurrence of failure mode 3.3 *Wrong measurement parameters of NIR equipment*, with $P_{(UF)\ \text{before improvement}}$ being 3×10^{-6}, it can be calculated that this failure mode would occur once every 3333 year; after the improvement of that failure mode, with $P_{(UF)\ \text{after improvement}}$ becoming 2.4×10^{-7}, that failure mode would occur once in approximately 40,000 year. With this quantitative knowledge, the decision whether improvements of a failure mode are worth the costs to be made, will be better informed than with the traditional FMEA.

Last, the probabilistic modification of FMEA opens the possibility to estimate the effect of the improvements, for the full process, and parts of the full process in terms of changes in probabilities.

For a set of k failure modes i ($i = 1..k$), with associated values $P_{(UF),i}$, the probability of at least one undetected failure mode ($P_{(UF),\text{set}}$) is:

$$P_{UF,\text{set}} = 1 - \prod\nolimits_{i=1..k} (1 - P_{(UF),i})$$

For instance, most important is the set of all failure modes with the highest severity, (S) = 8, before improvements. For that set, including 19 failure modes, $P_{(UF),S=8}$ can be calculated to be 4.1×10^{-5} before improvements, whereas after the improvements of the five selected failure modes $P_{(UF),S=8}$ becomes 2.6×10^{-5}.

Applying:

$$\frac{1/P_{(UF),s=8}}{\{\text{samples analyzed per year}\}}$$

for the about 100 samples per year analyzed in our laboratory, at least one failure mode with (S) = 8 could be expected to occur once every 240 year, and after the improvements of these five failure modes it could be expected that at least one failure mode occurred once every 390 year. For that set, RRR can also be calculated using:

$$\text{RRR}_{(UF),S=8} = 1 - \left\{\frac{P_{(UF),S=8\ \text{after improvements}}}{P_{(UF),S=8\ \text{before improvements}}}\right\}$$

$\text{RRR}_{(UF),S=8}$ is 0.38.

This value implies that, after improvement of the NIR procedure, the likelihood of the undetected occurrence of a failure leading to customers ending up with a faulty product is 38% of the likelihood before improvement. Such information cannot be retrieved from the Improvement Index (II). The equivalent II for the failure modes in severity class (S) = 8 would be 189.75, a number that, other than RRR, cannot be interpreted in terms of residual risk.

The probabilistic modification of FMEA does not take more time than the traditional FMEA. The only potential disadvantage of this modification is the apparent precision of the resulting $P_{(UF)}$ values, with potentially a large number of digits, which may suggest a false feeling of accuracy, whilst they are based on the same subjective estimation of the traditional FMEA. That probabilistic modification of FMEA may therefore demand some additional experience and training of the FMEA team.

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