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Prospective risk analysis of health care processes: A systematic evaluation of the use of HFMEATM in Dutch health care

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The aim of this study was to evaluate the use of Healthcare Failure Mode and Effect Analysis (HFMEATM) in Dutch health care by means of user feedback. Thirteen HFMEATM analyses of various health care processes were successfully concluded and on average took 69 person-hours (excluding reporting). These results show that HFMEATM can successfully be applied in Dutch health care. However, the user feedback also uncovered several perceived drawbacks, such as the fact that HFMEATM is very time-consuming and that, particularly, the risk assessment part of HFMEATM is difficult to carry out. Moreover, a lack of guidance with regard to the identification of failure mode causes and effective actions might influence the quality of the outcomes of an HFMEATM analysis. Several suggestions are put forward to improve the perceived utility and acceptance of HFMEATM. Nevertheless, future research is necessary to evaluate the actual effects of these recommendations. Error modelling and risk analysis, and their contribution to explaining human performance in socio-technical systems, traditionally belong to the field of ergonomics. The user feedback on HFMEATM and the suggestions that are put forward may also be useful for (H)FMEA and hazard analysis and critical control point applications in sectors other than health care.

Keywords: patient safety; system failure modelling; risk assessment and management; human reliability; human error

1. Introduction

Safety management in health care is still in its infancy compared to other sectors such as the chemical and nuclear industries and civil aviation. Health care organisations so far have particularly concentrated on retrospective incident reporting and analysis, whereas prospective risk analysis has been applied less frequently. However, when one considers the objective of a safety management system, this retrospective focus does not seem to be sufficient. According to the definition of patient safety, the objective of a safety management system should be to prevent patient harm. Hence, one should foresee risks in health care processes instead of reactively taking action after incidents have occurred (Ternov and Akselsson 2004, Battles *et al.* 2006, Catchpole *et al.* 2006, Hollnagel 2008, Rath 2008).

Failure Mode and Effect Analysis (FMEA) is a systematic method for prospective risk analysis that can be used to identify and assess potential failure modes in products, processes and systems. FMEA has a long history in the technical design of work settings. In subsequent applications, the human and organisational components of work settings have also been taken into account. FMEA is mainly used in

manufacturing. However, it has also been applied in health care to improve patient safety in processes such as drug administration and blood transfusion (e.g. Burgmeier 2002, Dhillon 2003, Apkon *et al.* 2004, Adachi and Lodolce 2005, Kunac and Reith 2005, Wetterneck *et al.* 2006, Day *et al.* 2007, Jeon *et al.* 2007, Paparella 2007). In 2002, Healthcare Failure Mode and Effect Analysis (HFMEATM) was developed by the United States Department of Veterans Affairs' National Center for Patient Safety (NCPS) by combining concepts, components and definitions from FMEA, hazard analysis and critical control point (HACCP) and root cause analysis (DeRosier *et al.* 2002). This method was designed to enable health care organisations to evaluate and improve health care processes before actual incidents occur. In HFMEATM, a multidisciplinary team graphically describes a selected health care process and subsequently identifies all possible failure modes. Each failure mode is assessed with regard to its potential severity and frequency. After having identified the failure mode causes, the team determines actions, barriers and controls that either eliminate those failure mode causes or mitigate their

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effects. Since its introduction in 2002, HFMEATM has been applied on several health care processes, such as drug ordering and administration and the sterilisation and use of surgical instruments (e.g. Wetterneck *et al.* 2004, Esmail *et al.* 2005, Linkin *et al.* 2005, Van Tilburg *et al.* 2006). In the United States in 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) began requiring accredited health care organisations to conduct one prospective risk analysis every year (The Joint Commission: Standard PI.3.20).

Despite reported successful FMEA and HFMEATM applications in several health care settings, the use of those prospective risk analysis methods in health care still needs to be thoroughly evaluated and discussed. In some studies, a single FMEA or HFMEATM analysis has been conducted and critically evaluated (e.g. Wetterneck *et al.* 2004, 2006, Kunac and Reith 2005, Jeon *et al.* 2007). Unfortunately, a systematic evaluation of a larger set of HFMEATM analyses has, to the present authors' knowledge, not yet taken place. The need for a profound evaluation of HFMEATM applications is endorsed by the fact that The Joint Commission has found that health care organisations are not always conducting their prospective risk analyses consistently or well (N. Kupka, The Joint Commission, personal communication, 24 April 2008). This study carried out multiple HFMEATM analyses at MAASTRO clinic, a radiotherapy institute in Maastricht, and at University Medical Center Utrecht (UMC Utrecht) to systematically evaluate HFMEATM by means of user feedback. The clustered positive and negative comments resulted in several suggestions for change to improve the perceived utility and acceptance of HFMEATM.

2. Methods

2.1. Setting

A total of 13 HFMEATM analyses were carried out to obtain insight into the perceived benefits and drawbacks of the application of HFMEATM in Dutch health care. MAASTRO clinic provided a single focus, a high volume health care environment, while UMC Utrecht represented the general and academic hospitals.

2.2. Selection of health care processes

At MAASTRO clinic, four HFMEATM analyses were conducted on topics that were selected by the management team and the patient safety manager. At MAASTRO clinic, actual accidents, near misses and process deviations are registered in a database and analysed in a systematic way. The processes that were selected for the HFMEATM analyses of this study were

high risk processes (according to the MAASTRO clinic incidents database) and/or new and innovative processes.

At UMC Utrecht, each of the 12 divisions was asked to define three high risk processes. Subsequently, the patient safety coordinator and the division management involved jointly selected one of these processes. Criteria for this decision were: a direct connection with patient care; high risk; availability of clear process boundaries; feasibility. Finally, nine health care processes were selected to be included in this study. In three cases, two divisions both identified identical high risk processes. In those cases, the divisions involved carried out a single HFMEATM analysis collectively.

The 13 selected processes were quite diverse. Both urgent and non-urgent care were included and scheduled as well as unscheduled tasks were considered. Moreover, technology played an important role in some selected processes, whereas it played a minor role in others. Finally, processes in both inpatient and outpatient settings were selected.

2.3. HFMEATM analysis

For each HFMEATM analysis, a multidisciplinary team was composed that consisted of at least two health care employees who were involved in the investigated health care process (e.g. nurses, physicians, technicians or clerical staff) and a facilitator. In three teams, a patient or a patient's relative participated in the analysis. At MAASTRO clinic, in two teams the patient safety manager (P.R.) was also present during the meetings; in one of those two teams a student (J.R.) was present to learn more about how to facilitate an HFMEATM analysis. In those two teams the patient safety manager and the student were only indirectly involved in the HFMEATM analysis. At MAASTRO clinic, the number of team members ranged from four to eight; on average a team consisted of 5.5 persons (SD 1.7). At UMC Utrecht, the number of team members ranged from six to 13; on average a team consisted of 7.9 persons (SD 2.1). This difference in average number of team members can be explained by the fact that, at UMC Utrecht, sometimes multiple departments were involved in a single HFMEATM analysis, whereas in all HFMEATM analyses at MAASTRO clinic only one department was involved.

In each team the facilitator concentrated on the correct use of HFMEATM and the progress of the analysis. In 12 of the 13 teams, the facilitator also took the minutes. In nine teams the facilitator was not involved in the selected process at all (M.H. and J.R.); in fact, those two facilitators are non-health care

workers. In four teams the facilitator was either employed at the organisation and familiar with the investigated health care process (P.R. and C.P.) or directly involved in the investigated health care process (D.Z.). All facilitators gathered specific knowledge about HFMEATM by means of the NCPS toolkit. One facilitator (P.R.) had conducted HFMEATM analyses before; two facilitators (M.H. and J.R.) had been taught FMEA at university. All facilitators had experience in conducting retrospective incident analyses and were familiar with the system approach (Reason 2000). The other team members received a concise draft manual about HFMEATM (translated into Dutch). Furthermore, at the start of the first meeting the facilitator gave a short presentation about the objective and the contents of HFMEATM.

Each multidisciplinary team met several times and each meeting took 1.5 h. The teams first reached an understanding about the exact definition of the selected process. Subsequently, the selected process was mapped. Then, the teams made a decision about the focus of the analysis. Sometimes, the complete process was analysed, whereas in other cases only a particular part of the selected process was analysed due to time constraints. Next, the teams determined all possible ways in which the process could fail (i.e. not produce the anticipated result). Those identified failure modes were all assessed on their potential severity (i.e. catastrophic, major, moderate or minor outcomes) and frequency (i.e. frequent, occasional, uncommon or remote). For each failure mode, a decision was made about the extent to which the risk was sufficiently covered in the health care system. In case that system did not take care of the failure mode effectively, the teams identified the causes of the failure mode. After the teams had assigned priorities to the failure mode causes, the teams described actions, barriers and controls to either reduce the chance of occurrence of the failure modes or to mitigate their effects. All information and decisions were (mostly) on site recorded in a worksheet. As an example, the results of a single HFMEATM analysis are summarised in Box 1.

2.4. User feedback on HFMEATM: Evaluation forms

At the end of an HFMEATM analysis all team members (apart from the facilitators) were asked to fill out an evaluation form about their experiences with HFMEATM. The evaluation forms consisted of both multiple choice questions and open-ended questions. At MAASTRO clinic, the patient safety manager (P.R.) and the student (J.R.) were not asked to fill out an evaluation form as they were only indirectly involved in the two HFMEATM analyses in question. Hence,

Box 1. Example of a Healthcare Failure Mode and Effect Analysis (HFMEATM).

Step 1. Define the HFMEATM topic

Medication administration by means of infusion pumps at an Intensive Care Unit.

Step 2. Assemble the team

- Two nurses
- A member of the quality department
- An internal medicine specialist
- An external facilitator (M.H.)

Step 3. Graphically describe the process

The selected process was divided into the following process steps:

- Prescribing the medication
- Entering the prescription in the computer system
- Dispensing the medication
- Conducting a double check
- Adjusting the drip speed

Step 4. Conduct a hazard analysis

The team identified several potential failure modes such as:

- Wrong prescription or wrong entry of the medication or its concentration
- Making use of the wrong fluid when dispensing the medication
- Not conducting a double check
- Adjusting the drip speed wrongly

The causes underlying the failure modes were technical, organisational and human in nature. Examples of failure modes causes are:

- Wrong computation
- Lack of communication about a modified layout of the medication cupboard
- Incorrect or incomplete protocols
- Health care employees being unfamiliar with certain types of infusion pumps

Step 5. Identify actions and outcome measures

The team proposed several actions to eliminate or control the failure modes. The most important actions are:

- Use of generic drug names when prescribing medication
- Use of weighing beds
- Communication of modifications via e-mail and advice
- Revision of the double check protocol
- Computation as part of Intensive Care Unit education
- Specific instructions in case of new equipment

none of the facilitators and none of the members of the research group filled out an evaluation form. The evaluation form for patients or their relatives slightly differed from the evaluation form for health care employees. The evaluation forms were anonymous with regard to person, but not with regard to team.

2.5. Data coding

On the evaluation forms, the respondents were asked to write down comments in free text regarding

HFMEATM and its application. Subsequently, those comments were categorised. Two independent coders were involved in the coding process (M.H. and H.W.). The fact that one of the two coders (M.H.) was the facilitator of nine teams could have biased the results of the coding process. However, this potential bias was minimised because the second coder was an Industrial Engineering student (H.W.), who, apart from the coding process, was not involved in the study at all. H.W. had been taught (H)FMEA at university and as part of her master project she had used patient safety tools such as retrospective incident analysis techniques. Moreover, the potential bias was lessened because the two coders discussed until a consensus was reached. The two coders first independently classified the comments into four categories: positive (single, positive statements, e.g. 'a constructive attitude of the participants'); negative (single, negative statements, e.g. 'the analysis was time-consuming'); plural (multiple statements, e.g. 'a thorough approach, enthusiastic guidance, cooperation'); irrelevant (single statements without any relation to the contents of HFMEATM and/or its application, e.g. 'good luck!'). The percentage agreement between the two coders was 71.8%. The corresponding Cohen's kappa of 0.61 indicated substantial agreement (Landis and Koch 1977). For the comments that were classified as plural, the coders also determined which separate statements could be distinguished and to which category (i.e. positive, negative or irrelevant) those statements could be assigned. The percentage agreement between the two coders regarding the classification of the plural statements was 58.3%. During a consensus meeting the two coders reached an agreement about the categorisation of all statements.

Subsequently, the two coders jointly defined nine codes that referred to the separate steps and aspects of HFMEATM (such as the multidisciplinary team, the facilitator and the identification of failure modes and failure mode causes). In addition, the coders used open coding (Babbie 2005) to develop codes for the exact opinion the respondents had on the various steps and aspects of HFMEATM (e.g. 'difficult' or 'time-consuming'). While assigning the statements to the positive, negative and irrelevant categories, the coders gained a first understanding of the exact opinion of the respondents. Together, the two coders decided upon six codes for type of opinion. Those codes completely emerged from the data, which is in accordance with the open coding principle. Each of the six codes for type of opinion was formulated in both positive and negative terms (e.g. 'easy' and 'difficult' or 'clear' and 'unclear'). Both coders then independently assigned all positive and negative statements to one of the nine codes for the steps and aspects of HFMEATM and to one or

more of the six codes for type of opinion. The percentage agreement between the two coders on the classification of the statements into both steps/aspects of HFMEATM and type of opinion was 58.4%. Because the coders were allowed to classify one statement into multiple types of opinions, it was only possible to calculate kappa for the assignment of the statements to the nine steps/aspects of HFMEATM. The percentage agreement between the two coders on the assignment of the statements to the steps/aspects of HFMEATM was 77.3%. The corresponding Cohen's kappa of 0.72 again indicated substantial agreement. During a second meeting, the two coders reached a consensus about the classification of all statements. Moreover, the coders decided to accentuate the definitions of some types of opinions and to add an additional code referring to HFMEATM in general. The final classification scheme for positive and negative statements regarding HFMEATM therefore consisted of ten codes for steps/aspects of HFMEATM and six codes for type of opinion (see Table 1).

2.6. Facilitator's feedback on HFMEATM:

Discussions

During the project, the research group (M.H., T.S., I.L. and P.R.) also consulted the facilitators (M.H., P.R., J.R., D.Z. and C.P.) to evaluate the application of HFMEATM. The research group and facilitators met several times and exchanged experiences. After all HFMEATM analyses had been finalised, but before the quantitative and qualitative data analysis of the

Table 1. Classification scheme for positive and negative statements regarding Healthcare Failure Mode and Effect Analysis (HFMEATM).

<i>Step/aspect of HFMEATM</i>	
Process selection and scope	
Multidisciplinary team	
Facilitator	
Process description	
Identification of failure modes and failure mode causes	
Risk assessment	
Identification of actions and outcome measures	
Implementation of actions	
HFMEA TM in general	
Other	
<i>Type of opinion (positively stated)</i>	<i>Type of opinion (negatively stated)</i>
Pleasant	Unpleasant
Easy	Difficult
Clear	Unclear
High output	Low output
Small time investment	Large time investment
Other	Other

evaluation forms, the research group and facilitators collectively drew conclusions regarding the application of HFMEATM in Dutch health care.

3. Results

3.1. Descriptive statistics

All 13 HFMEATM analyses were successfully concluded. Table 2 presents some important descriptive statistics for each selected health care process and the accompanying health care setting: the initials of the facilitator; the team size; the number of meetings; the total number of person-hours needed for the analysis; the number of identified failure modes; the number of proposed actions. Each meeting took 1.5 h, as scheduled beforehand. The number of meetings needed to carry out the analysis ranged from four to eight; on average the teams needed 6.3 meetings (SD 1.3). The average number of meetings at MAASTRO clinic was lower than that at UMC Utrecht (5.8 and 6.6, respectively). This difference can partly be attributed

to the fact that at MAASTRO clinic the process had already been mapped before the formal start of the HFMEATM analysis and the graphical process description only needed to be verified by the team members. The number of person-hours needed to conduct the analysis ranged from 30.0 to 136.5 (excluding reporting on the meetings and reporting on the results of the HFMEATM analysis); on average the HFMEATM analyses took 69.1 person-hours excluding reporting (SD 28.7) and 78.0 person-hours including reporting. The differences between the teams with regard to time investment can largely be attributed to differences in team size and scope. In earlier studies, HFMEATM analyses on vincristine prescription and administration and the sterilisation and use of surgical instruments took a total of 140 person-hours and 250 person-hours, respectively (Linkin *et al.* 2005, Van Tilburg *et al.* 2006). The average number of identified failure modes was 51.8 (SD 30.6) and the average number of proposed actions was 16.2 (SD 8.8). Again, differences in scope

Table 2. Selected health care processes, accompanying health care settings and descriptive statistics.

ID	Health care process	Health care setting	Facilitator ^a	Team size ^b	Number of meetings	Number of person-hours ^c	Number of failure modes	Number of actions
<i>MAASTRO clinic</i>								
1	Documentation of treatment	Radiotherapy	PR	5	4	30.0	32	17
2	Electronic Portal Imaging	Radiotherapy	MH	8	6	72.0	109	33
3	Treatment on linear accelerator	Radiotherapy	JR	5	8	60.0	70	30
4	Release of accelerator after maintenance	Radiotherapy	PR	4	5	30.0	50	22
<i>UMC Utrecht</i>								
5	Communication of unexpected findings	Radiology Cardiology	MH	7	5	52.5	19	7
6	Diet food process	Children's Hospital	MH	13	7	136.5	39	18
7	Physically restraining patients	Neurosurgery	MH	7	7	73.5	31	17
8	Ordering repeat prescriptions	Primary care	DZ	8	8	96.0	50	12
9	Patients with hip fractures	Emergency Room Radiology Ward Operating Room	MH	8	6	72.0	120	7
10	Medication administration (pumps)	Intensive Care Unit	MH	6	6	54.0	46	22
11	Admission of cardiac patients	Emergency Room Cardiac Cath Room Coronary Care Unit	CP	6	6	54.0	44	6
12	Use of a PICC line (catheter)	Neonatal Intensive Care Unit	MH	8	8	96.0	37	8
13	Administration of blood products	Laboratory Haematology ward	MH	8	6	72.0	27	11
			Mean	7.2	6.3	69.1	51.8	16.2
			SD	2.2	1.3	28.7	30.6	8.8

^aM.H. and J.R. Eindhoven University of Technology; P.R. MAASTRO clinic; D.Z. and C.P. UMC Utrecht.

^bA patient was included in teams 1, 6 and 8.

^cReporting on the meetings and reporting on the results of the Healthcare Failure Mode and Effect Analysis (HFMEATM) are excluded.

contributed to team differences regarding the number of identified failure modes and the number of proposed actions.

3.2. User feedback on HFMEATM: Results from evaluation forms

All team members apart from the facilitators and team members (if any) who were only indirectly involved in the HFMEATM analysis, that is, 77 people, were asked to fill out the evaluation form. In total 62 evaluation forms were filled out and returned to the researchers; 59 by health care employees and three by patients or their relatives. The overall response rate was 80.5%. The response rates of MAASTRO clinic and UMC Utrecht were almost equal (80.0% and 80.6%, respectively). Table 3 presents the contents and results of the multiple choice questions of the evaluation forms.

About 90% of the health care employees and patients who filled out the evaluation form thought that the HFMEATM analysis was meaningful (90.3%). The majority of the respondents (87.1%) expected the investigated health care process to become more safe as a result of the HFMEATM analysis that had been carried out. Also about 90% of the respondents would recommend others to participate in an HFMEATM analysis (90.3%). The evaluation form for the health care employees also included some questions about patient involvement in the HFMEATM analysis. Of all respondents who participated in a HFMEATM analysis in which a patient was involved, over 90% (93.3%) thought that this patient involvement was useful. Interestingly, only a minority of all respondents who participated in an HFMEATM analysis in which no patient had been involved (9.1%) thought patient involvement would have been useful.

The classification of the comments of the respondents into steps/aspects of HFMEATM and types of opinions shows the perceived benefits and drawbacks of HFMEATM. In addition to the percentage of respondents that made a particular comment, the results show the number of teams in which that particular comment was made by at least one team member. In both section 3 and the tables, the percentage of respondents is directly followed by the number of teams, that is, presented in parentheses. Table 4 presents the resulting classification of the positive statements. As the respondents were allowed to write down multiple (positive) comments and because some respondents did not answer the open-ended questions, the totals do not equal 100%. According to 36.4% of the respondents (10 teams) the HFMEATM analysis resulted in high output in terms of the insight obtained into the health care

process in general, in other health care employees' tasks and in the possible risks (e.g. 'HFMEATM makes failure modes apparent' or 'by means of HFMEATM I gained a clear insight into processes and relations'). Positive remarks with regard to HFMEATM in general, such as the fact that HFMEATM is a systematic, stepwise approach, were made by 28.6% of the respondents (nine teams) (e.g. 'HFMEATM is a clear method' or 'it is a structural approach'). Furthermore, 22.1% of the respondents (eight teams) thought the multidisciplinary nature of the analysis was pleasant and useful (e.g. 'the multidisciplinary approach was useful').

Table 5 presents the resulting classification of the negative statements. As the respondents were allowed to write down multiple (negative) comments and because some respondents did not answer the open questions, the totals do not equal 100%. Negative remarks of 20.8% of the respondents (nine teams) concerned the notion that the time investment necessary to conduct the HFMEATM analysis was large (e.g. 'it takes a lot of time'). Although the positive remarks indicated that the HFMEATM analysis resulted in high output in terms of the (additional) insight into processes, tasks, and risks, 20.8% of the respondents (seven teams) felt that the analysis did not yield (significant) results, i.e. that the output was low (e.g. 'many aspects lead to useless discussions'). According to 13.0% of the respondents (six teams) the HFMEATM analysis was difficult to carry out. From the negative remarks of 7.8% of the respondents (five teams), it can be concluded that especially the risk assessment part of HFMEATM (i.e. determining the hazard score and using the decision tree) was perceived to be difficult (e.g. 'the decision tree was difficult for me' or 'it is difficult to score the risks'). In general, the risk assessment part of HFMEATM was the subject of the negative comments of 15.6% of the respondents (eight teams). Although the multidisciplinary nature of the team was perceived to be beneficial, 13.0% of the respondents (six teams) faced problems within the team, such as planning problems and problems regarding the frequent absence of certain team members (e.g. 'often people were absent').

As can be concluded from the positive and negative remarks, the facilitator's role is perceived to be crucial. Respondents from five teams mentioned that the facilitator's presence had been of great value (e.g. 'pleasant and clear guidance'), while respondents from four teams even claimed that the facilitator's role had been essential and that the analysis would not have been possible without the facilitator (e.g. 'a good facilitator is necessary' or 'we needed quite a lot of guidance').

Table 3. Contents and results of evaluation forms: multiple choice questions.

Question	Health care employees (n = 59)			Patients (n = 3)			Health care employees + patients (n = 62)			
	Yes	No	No answer	Yes	No	No answer	Yes	No	No answer	
Did the manual provide you with sufficient information about conducting an HFMEA TM ?	94.9%	1.7%	3.4%	100.0%	0.0%	0.0%	95.2%	1.6%	3.2%	
Were all relevant disciplines represented in the team?	88.1%	11.9%	0.0%	66.7%	33.3%	0.0%	87.1%	12.9%	0.0%	
Was a patient represented in the team?	25.4%	74.6%	0.0%	–	–	–	–	–	–	
– If yes, do you think this was useful?	93.3%	6.7%	0.0%	–	–	–	–	–	–	
– If no, do you think this would have been useful?	9.1%	72.7%	18.2%	–	–	–	–	–	–	
Were all meetings useful for you?	74.6%	20.3%	5.1%	100.0%	0.0%	0.0%	75.8%	19.4%	4.8%	
Do you think the HFMEA TM was meaningful?	91.5%	1.7%	6.8%	66.7%	0.0%	33.3%	90.3%	1.6%	8.1%	
Do you think the investigated process will be safer thanks to the HFMEA TM ?	88.1%	1.7%	10.2%	66.7%	33.3%	0.0%	87.1%	3.2%	9.7%	
Did you obtain another insight into your own work process thanks to the HFMEA TM ?	45.8%	45.8%	8.5%	–	–	–	–	–	–	
Would you recommend others to participate in an HFMEA TM ?	93.2%	1.7%	5.1%	33.3%	33.3%	33.3%	90.3%	3.2%	6.5%	
Are you more willing to report incidents since you have conducted the HFMEA TM ?	23.7%	62.7%	13.6%	–	–	–	–	–	–	
Are you more assured about safety in the institution since you have conducted the HFMEA TM ?	–	–	–	33.3%	0.0%	66.7%	–	–	–	
What did you think of the duration of the meetings?	Fine 83.1%	Too long 10.2%	Too short 6.8%	Fine 66.7%	Too long 0.0%	Too short 0.0%	Fine 82.3%	Too long 9.7%	Too short 6.5%	No answer 1.6%

– Indicates that the particular question is not applicable for the particular group of respondents.

HFMEA = Healthcare Failure Mode and Effect Analysis.

Table 4. Positive user feedback on Healthcare Failure Mode and Effect Analysis (HFMEATM): Percentage of respondents (and number of teams) per combination of step/aspect of HFMEATM and type of opinion.

	<i>Type of opinion</i>													
	Pleasant		Easy		Clear		High output		Small time investment		Other		Total	
<i>Step/aspect of HFMEATM</i>														
Process selection and scope											1.3%	(1)	1.3%	(1)
Multidisciplinary team Facilitator	2.6%	(1)					3.9%	(2)			16.9%	(8)	22.1%	(8)
Process description	5.2%	(3)			2.6%	(2)	1.3%	(1)			6.5%	(4)	13.0%	(5)
Identification of failure mode (causes)							10.4%	(5)			1.3%	(1)	11.7%	(6)
Risk assessment							7.8%	(5)					7.8%	(5)
Identification of actions							2.6%	(2)			1.3%	(1)	3.9%	(3)
Implementation of actions							2.6%	(2)			1.3%	(1)	3.9%	(2)
HFMEA TM in general	1.3%	(1)	1.3%	(1)	2.6%	(2)	13.0%	(7)	2.6%	(2)	15.6%	(6)	28.6%	(9)
Other											1.3%	(1)	1.3%	(1)
Total	9.1%	(4)	1.3%	(1)	5.2%	(4)	36.4%	(10)	2.6%	(2)	37.7%	(11)		

Note: As the respondents were allowed to write down multiple (positive) comments and because some respondents did not answer the open questions, the totals do not equal 100%. An empty cell indicates that no comment referred to that particular combination of step/aspect of HFMEATM and type of opinion.

Table 5. Negative user feedback on Healthcare Failure Mode and Effect Analysis (HFMEATM): Percentage of respondents (and number of teams) per combination of step/aspect of HFMEATM and type of opinion.

	<i>Type of opinion</i>													
	Unpleasant		Difficult		Unclear		Low output		Large time investment		Other		Total	
<i>Step/aspect of HFMEATM</i>														
Process selection and scope			1.3%	(1)									1.3%	(1)
Multidisciplinary team Facilitator									5.2%	(4)	7.8%	(5)	13.0%	(6)
Process description							5.2%	(2)			6.5%	(4)	6.5%	(4)
Identification of failure mode (causes)			1.3%	(1)							5.2%	(4)	11.7%	(6)
Risk assessment			2.6%	(2)							1.3%	(1)	3.9%	(2)
Identification of actions			7.8%	(5)	1.3%	(1)	2.6%	(1)	1.3%	(1)	5.2%	(4)	15.6%	(8)
Implementation of actions			1.3%	(1)			1.3%	(1)					2.6%	(2)
HFMEA TM in general			1.3%	(1)	2.6%	(2)	6.5%	(3)	16.9%	(8)	9.1%	(5)	27.3%	(10)
Other													0.0%	(0)
Total	0.0%	(0)	13.0%	(6)	3.9%	(3)	20.8%	(7)	20.8%	(9)	37.7%	(11)		

Note: As the respondents were allowed to write down multiple (negative) comments and because some respondents did not answer the open questions, the totals do not equal 100%. An empty cell indicates that no comment referred to that particular combination of step/aspect of HFMEATM and type of opinion.

3.3. Facilitators' feedback on HFMEATM: Results from discussions

In addition to the above-mentioned problems, the facilitators and the research group identified two possible threats to the quality of the outcomes of an HFMEATM analysis. First, HFMEATM itself provides no guidelines for the identification of failure mode causes. This might result in a biased analysis if the

team members would use a person approach instead of a system approach. If one applies a system approach during the causal analysis part of HFMEATM, one concentrates on the conditions under which health care employees work. On the other hand, if one applies a person approach, one especially blames individuals for their errors, inattention or forgetfulness (Reason 2000). The second problem that the research group and the facilitators recognised is the fact that HFMEATM

itself does not include guidelines for the translation of any identified failure mode cause into an appropriate countermeasure. Therefore, the countermeasures that team members come up with might not be the most effective ones; for instance, because again a person approach might be predominant.

4. Discussion

Although all 13 HFMEATM analyses were successfully concluded, the user feedback revealed both positive and negative comments with regard to HFMEATM. Interestingly, most positive comments of the participants are not exclusively related to HFMEATM. For example, the multidisciplinary nature of the team seems to be an important strength, which was also concluded in the evaluation of other, single (H)FMEA analyses (Wetterneck *et al.* 2004, 2006, Esmail *et al.* 2005). However, this is not an aspect of the method that is unique for HFMEATM. On the other hand, many negative comments that were put forward by the participants are indeed related to the aspects of HFMEATM that distinguish it from some other prospective risk analysis methods, such as the rating scales and the use of the decision tree. As concluded in earlier studies, one of the most important problems regarding (H)FMEA is the fact that the analysis is very resource intensive (Wetterneck *et al.* 2004, 2006, Kunac and Reith 2005, Linkin *et al.* 2005, Carstens 2006).

From the user feedback it can be concluded that the role of the facilitator is crucial for the successful application of HFMEATM (Rath 2008). The conclusions of the research group and the facilitators also stress the importance of team guidance. Besides the facilitator's task to explain the HFMEATM steps and to control the progress of the analysis, the facilitator should assist the team in applying a system approach when identifying failure mode causes and describing appropriate actions (Wetterneck *et al.* 2004, 2006, Kunac and Reith 2005). This system approach is important because only when one concentrates on the work settings and the conditions under which people have to work, the system failures can be revealed and effective interventions to improve patient safety can be determined (Reason 2000, Carayon *et al.* 2007). Therefore, the facilitators should be selected carefully and, if necessary, they should be trained in using a system and human factors approach. When applying FMEA on the medication use process of a neonatal intensive care unit, Kunac and Reith (2005) have already successfully combined FMEA with a system approach.

Based on the comments of the team members and the experiences of the facilitators, several suggestions

were put forward to improve the perceived utility and acceptance of HFMEATM. First, it is recommended to change the categories for probability of occurrence into more defined and reliable categories to prevent team members from placing their own interpretation on the categories. For instance, one could use categories such as 'weekly', 'monthly', 'yearly' and 'less than yearly' instead of the current HFMEATM categories (i.e. frequent, occasional, uncommon and remote, respectively). In accordance with recommendations that resulted from earlier single case studies, health care organisations are advised to verify whether the HFMEATM rating scales are applicable to the process under investigation. If necessary, one could customise the rating scales (Wetterneck *et al.* 2004, Jeon *et al.* 2007). Such a modification will probably prevent lengthy discussions about the exact meaning of the categories for severity and probability (Israelski and Muto 2007). Second, it is suggested that the numbers in the HFMEATM hazard scoring matrix are replaced. According to the facilitators, some participants (wrongly) assumed that the numbers in the hazard scoring matrix represented a ratio scale. Therefore, it is proposed that those numbers are replaced by ordinal scale categories, such as 'very high risk', 'high risk', 'low risk' and 'very low risk' with accompanying red or green shades of colour.

Because of the fact that the time investment for an HFMEATM analysis might be too large, several suggestions were also put forward to decrease the amount of time necessary to carry out the analysis. One could, for instance, ask a subgroup of the team to map the selected process in advance. During the first meeting with the entire team, the other team members could then be asked to verify the graphical process description. However, as a result, team members might obtain less insight into each other's tasks because the team might discuss the graphical process description in less detail. Another possible way to save time is to conduct HFMEATM step 4 and step 5 in direct succession for each process step. In other words, one could first carry out both a hazard analysis and determine appropriate actions for one process step before investigating the next one. By doing so, the team members will master the different steps of HFMEATM more quickly, allowing a faster handling of the other process steps. Moreover, if time constraints force the team to stop the analysis, a complete HFMEATM analysis has been conducted for at least one or more entire process steps. A possible downside of this linear approach is the fact that the actions that the team comes up with might only optimise a particular process step, whereas the solutions are suboptimal for the entire process.

Therefore, the facilitator should assist the team in applying a comprehensive system view during and after the HFMEATM analysis. For some teams, it might be tempting to omit the decision tree for the failure mode causes. In that case, the team determines the risk scores for a set of failure mode causes and subsequently the team decides directly which failure mode causes warrant further action, that is, without using the decision tree. Because answering the detailed questions in the decision tree is omitted, the analysis will probably take less time. However, as the assessment of the detectability of the failure mode causes is an important aspect of prospective risk analysis, those teams should actually consider to use FMEA and the original risk priority numbers of FMEA (in which detectability is built into) instead of omitting the HFMEATM decision tree. But, still, this approach should only be considered by teams with sufficient analytical capabilities, as it might be too difficult for the majority of the health care employees to take into account detectability without using the predefined questions of the decision tree. Again, the facilitator should determine the best approach for the team without compromising the quality of the (H)FMEA analysis.

Irrespective of the type of modification, the importance of applying the basic principles of HFMEATM is emphasised as well as of other (similar) prospective risk analysis methods. One should first describe the process, then identify the risks within this process (and their causes) and, finally, determine actions to either eliminate or control the risks or to mitigate their effects, instead of the observed tendency to directly jump from identified problems to counteractions. This structural approach seems to be effective and highly appreciated by the users.

Although the above-mentioned recommendations seem to be plausible, the present study did not systematically test those recommendations, let alone measure the effects. Therefore, additional research is necessary to find out whether or not those recommendations really improve the perceived utility and acceptance of HFMEATM. Moreover, similar studies should be carried out in other health care settings and other countries to verify if the conclusions and recommendations are also valid for those settings. It should be noted that this study concentrated on the perceived utility and acceptance of HFMEATM. Therefore, future research should also focus on the effectiveness of HFMEATM and similar prospective risk analysis methods. By means of longitudinal research designs, one could, for instance, examine if proposed actions are indeed implemented and whether those actions do actually improve (patient) safety or not.

In contrast with the user feedback, the experiences of the facilitators have not been studied in a very systematic way. In future studies, the facilitators could be asked to provide feedback on each HFMEATM session. Structured evaluation forms might, for example, consist of questions regarding the steps of HFMEATM that have been dealt with in a particular meeting, the duration of the steps, the problems that occurred during the session and the impression the facilitator got from the meeting. Such studies might provide a more detailed insight into both the opportunities and problems with regard to the application of HFMEATM in health care.

An interesting finding of the current study is the fact that the respondents had differing views on the benefits of patient involvement. The respondents of teams in which a patient participated nearly all experienced the involvement of the patient as useful. On the other hand, only a few respondents who participated in an HFMEATM analysis without patient involvement thought that patient participation would have been valuable. The usefulness of patient involvement probably depends on the type of process to be analysed. However, the present results might also indicate that health care employees do not recognise the merits of patient involvement in (prospective) risk analysis until they actually see it happen. As patient involvement in health care, and safety management in particular, is becoming increasingly important, future studies should focus on the benefits and drawbacks of patient participation in (prospective) risk analysis (Coulter 2006, Entwistle 2007, Lyons 2007).

The results of the present study may also be useful for other sectors in which prospective risk analysis methods are used that are similar to HFMEATM, such as FMEA and HACCP. For instance, the engineering and manufacturing industries and the food industry may consider the user feedback and the suggestions that have been put forward in their FMEA and HACCP applications, respectively. Future research will probably result in modifications to existing prospective risk analysis methods such as HFMEATM or even in new methods. Such developments might improve the perceived utility and acceptance or even the effectiveness of those methods. Nevertheless, health care organisations should not wait for a perfect method, but continue or start conducting prospective risk analyses in their current form to improve patient safety proactively, that is, to really prevent patient harm.

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