International Journal for Quality in Health Care 2009; **Volume 21, Number 6:** pp. 427–432
Advance Access Publication: 14 October 2009
10.1093/intqhc/mzp043

Integration of prospective and retrospective methods for risk analysis in hospitals

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Abstract

Objective. To explore how hospital management could gain a better picture of risks to support them in setting priorities for patient safety.

Methods and Setting. This study deals with the combined application of prospective and retrospective methods for risk analysis on two units of a Dutch general hospital. In the prospective analyses, employees identified and assessed possible risks in selected processes. In the retrospective analyses, incidents were reported by employees and subsequently investigated. The methods were integrated by using information from retrospective incident reports for prospective risk identification and assessment, and by matching their categorization schemes. Two evaluation forms provided insight into the perceived usefulness of the methods and their integration.

Results and Conclusions. For both units, the prospective and retrospective analyses resulted in divergent overviews of risks in terms of nature and magnitude, which suggests that one or both methods were subject to biases. Findings from the evaluation forms showed that both methods were perceived as useful and that triangulation provided additional insight into risks. Due to the convergent evidence, triangulation of prospective and retrospective methods can provide hospital management and frontline staff with a more complete and less biased picture of risks. An integrative approach might be advantageous in terms of efficiency of analysis, setting priorities for patient safety and improving the methods themselves.

Keywords: patient safety, prospective risk analysis, incident reporting, retrospective incident analysis

Introduction

Hospitals use retrospective methods to analyse errors and to prevent their recurrence. However, the objective of minimal patient harm [1] stresses the need to identify risks prospectively and to *foresee* errors [2]. This is endorsed by the requirement of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to conduct one prospective analysis every 18 months (The Joint Commission, 2009: Standard LD.04.04.05). Several methods for prospective analysis are available, such as (health-care) failure mode and effect analysis ((H)FMEA), hazard analysis and critical control points (HACCP) and probabilistic risk assessment (PRA). Despite differences between these methods, such as the consideration of combinatorial events in PRA and the use of a decision tree in HFMEA™ and HACCP, they all aim to identify, assess and eliminate or reduce risks *before* errors may occur [3–5].

Perfect prospective analyses would anticipate all errors and therefore make retrospective analyses redundant [6]. However, both methods are subject to biases (see Table 1). For instance, judgement variability could influence the reliability of risk identification in prospective analyses [7], and prospective risk assessments might be inaccurate due to a lack of insight into error rates [4, 8, 9]. Retrospective incident reporting and analysis is susceptible to problems such as underreporting [10–18], incomplete data [11, 19], hindsight and recall bias [20] and unreliable classifications [12, 14].

The question arises how to overcome those biases. Since a 'golden standard' is still lacking, triangulation could be the answer for now. By using prospective *and* retrospective methods, their strengths could be combined and their weaknesses minimized, which could yield a better picture of risks [1, 6, 21, 22]. Recently, the National Quality Forum recommended such a combined approach to improve patient safety [23]. But will the advantages outweigh the additional

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Table 1 Possible biases of prospective risk analysis and retrospective incident reporting and analysis

Prospective risk analysis	Retrospective incident reporting and analysis
Unreliable risk identification due to judgement variability during brainstorming [7]	Limited number of reported incidents [10–12], for instance due to a lack of error recognition, a tendency to keep errors in-house, feelings of fear or shame, time pressure and a lack of feedback [12, 14, 15, 17, 18]
Inaccurate risk assessment due to a lack of insight into error rates [4, 8, 9]	Limited spectrum of reported incidents, partly due to the lack of incident reports from doctors [12–17]
Failure to consider combinatorial events[a] [4, 8]	Incomplete data for instance due to anonymity, confidentiality, shame and fear [11, 19]
	Hindsight and recall bias [20]
	Poor quality of classifications [12, 14]

[a]PRA does explicitly consider combinatorial events.

resources required to conduct two analyses instead of just one? Probably yes, because the extra efforts could be limited if the methods are integrated in terms of matching categorizations for risk identification and assessment. Then, efficiency of analysis might be increased, for instance by making use of retrospective data for the development of prospective failure scenarios [10, 24]. Moreover, through integration the analysis results will be directly comparable, thereby facilitating the process of making sense of risks and determining interventions [3].

In only a few prior studies have researchers concentrated on integration of methods, for instance by using retrospective error rates for prospective analyses [9, 25], or by comparing prospectively and retrospectively identified causes of risks [26]. However, those studies did not consider the perceived usefulness of such integration. In the present study, we examined how integration of prospective and retrospective methods could be realized and whether it would be perceived as useful. We integrated the methods by using information from retrospective incident reports for prospective risk identification and assessment, and by matching their categorization schemes.

Methods

Setting

The study was conducted at two units of a Dutch general hospital. At the pharmacy a project called *RISC* (Risk analysis by Incident reporting and Scenario analysis in the Cytostatics dispensing process) concentrated on the process from ordering up to and including delivering chemotherapy drugs and archiving. A project at the nuclear medicine unit called *NUSAFE* (NUclear medicine SAFE) included the complete process from planning an examination or treatment up to and including archiving.

Study design

The projects comprised both prospective risk analyses and retrospective incident reporting and analysis. For both units, the quality coordinators constructed flowcharts of the selected processes by means of process mapping [27]; all process steps were sequential. In the prospective analyses, employees identified and assessed possible risks for each process step; in the retrospective analyses, all process steps that had contributed to the occurrence of reported incidents were registered. During feedback sessions, the employees were informed about preliminary results.

For a 4-month period, all 46 employees who were involved in the selected processes were asked to report any deviation from normal patient care. At the pharmacy, employees used a hardcopy reporting form, while an electronic form was used at the nuclear medicine unit. Moreover, clerical staff from the latter unit scored each occurrence of a predefined set of minor deviations in the subprocess of planning. For both units, the first author together with one or more

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employees analysed the reported incidents. Information about the incidents and the process steps involved was registered in special databases.

Two months after the start of the incident reporting, 22 of the 46 employees participated in the prospective analyses. For each unit, two teams were composed, which were comparable in terms of disciplines involved and participants' work experience. Each team conducted a condensed version of an HFMEA™ analysis [28]. We decided to use HFMEA™ because the suggested components of a prospective analysis as proposed by JCAHO are all part of HFMEA™ (The Joint Commission, 2009: Standard LD.04.04.05), because HFMEA™ has been applied in a diverse range of hospital settings, and because a manual and DVD are available. The analysis consisted of the identification of risks in the selected processes and the assessment of their frequencies. The estimated frequencies were corrected for the 4-month study period to enable direct comparison with the incident analyses. At each unit, one team was provided information from the incidents database, such as the type and frequency of reported incidents, while the other team had to rely completely on the expertise and judgement of its team members.

We used two self-developed evaluation forms to examine the perceived usefulness of the prospective and retrospective methods and their integration. After the prospective analyses had been finalized, the 22 participants received an evaluation form (Form 1); 19 (86.4%) were completed and returned. At the end of the project, all 46 employees received another evaluation form (Form 2); 34 (73.9%) were completed and returned.

Data analysis

To explore the benefit of the integration, we used chi-square tests to compare the prospective and retrospective evaluations of risks per process step. Since some expected cell counts did not exceed the minimum level [29], Pareto analyses were used to identify those process steps that accounted for the majority of the risks. The remaining process steps were combined into a single category, called 'other'. For setting priorities and determining interventions, exact frequencies might be not that important [7], as opposed to rankings of risks. Therefore, for each analysis we ranked the process steps in terms of the identified frequencies of risks. Next, Spearman's rank correlation coefficients (r_s) were calculated to explore differences between the analyses regarding the rankings of the 10 highest risk process steps. For all statistical analyses, an alpha level of 0.05 was used.

Results

We integrated prospective and retrospective methods by using similar categorization schemes. This enabled us to compare the analysis results directly. Tables 2 and 3 present the results of the analyses in terms of the identified frequencies of risks per process step and accompanying rankings. For both units, the results clearly showed a lack of congruence between prospective and retrospective analyses. For instance, Table 2 shows that the prospective analysis teams estimated that in a period of 4 months about 700 process deviations would occur in the process step 'check labels and dispensing protocol', while in the 4-month study period only 119 of such process deviations had been actually identified by the retrospective analysis of reported incidents.

At the hospital pharmacy (RISC), 503 incident reports were analysed, which revealed 1421 process deviations. When corrected for the study period, the prospective analysis teams predicted that risks would have resulted in 7062 and 12 654 process deviations, respectively. The frequencies of risks were significantly different ($P < 0.001$). At the nuclear medicine unit (NUSAFE), 552 incident reports were analysed, which showed 1169 process deviations. After correction for the study period, the prospective analysis teams estimated that risks would have caused 8677 and 4756 process deviations to occur, respectively. Assessment of differences in those overviews yielded a significant result ($P < 0.001$). The significant results for RISC and NUSAFE indicate that prospective and retrospective analyses can result in divergent overviews of the nature and magnitude of risks.

This finding might make it difficult for management to determine interventions to improve patient safety. However, for priority setting the relative magnitude of risks might be more important than their exact frequencies [7]. Therefore, we calculated the correlations between the rankings of the 10 process steps that were provided with the highest frequencies of risks. For RISC, significant positive correlations were found between the retrospective incident analyses and the two prospective analyses ($r_s = 0.59$, $P = 0.04$; $r_s = 0.79$, $P = 0.001$). No significant correlation was found between the two prospective analyses ($r_s = 0.35$, $P = 0.24$). For NUSAFE, no significant correlations were found at all ($r_s = 0.16$, $P = 0.54$; $r_s = 0.18$; $P = 0.48$; $r_s = 0.22$, $P = 0.39$).

Although the prospective and retrospective analyses showed a lack of congruence regarding the frequencies of risks, the analysis of risk rankings yielded a different conclusion. For NUSAFE, management might still feel uncertain about resource allocation, due to the lack of substantial consensus on risk rankings. Conversely, for RISC, predictions were supported by actual data (as reflected by the two significant correlations). This might convince management to allocate resources to the process step of entering data and printing labels, which was identified as a high risk process step by all analyses.

Evaluation forms

The evaluation form of the entire project (Form 2) revealed that 33 respondents (97.1%) agreed that incident reporting and analysis was useful for improving patient safety and optimizing processes. Also, most respondents felt that prospective analysis was useful for improving patient safety ($n = 26$; 76.5%) and optimizing processes ($n = 27$; 79.4%). Furthermore, prospective and retrospective analyses provided insight into *new* risks according to 16 (47.1%) and 20 (58.8%) respondents, respectively.

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Table 2 RISC: identified frequencies (freq.) of risks per process step and accompanying rankings (rank) by analysis

Process step	Analysis					
	RIA		PRA RISC 1		PRA RISC 2	
	Freq.	Rank	Freq.	Rank	Freq.	Rank
Ordering						
Fill in prescription form[a]	207	2	600		1250	5
Pre-check prescription form	11		366		33	
Sending						
Fax prescription form to pharmacy	114	5	649	5	704	
Processing						
Fill in dispensing protocol	140	3	917	3	1758	4
Enter data and print labels	255	1	1109	1	2100	2
Check labels and dispensing protocol	119	4	675	4	700	
Add prescription form	77		350		1834	3
Sort prescription form by date	83		284		2516	1
Dispensing						
Put medication ready	74		944	2	433	
Dispense chemotherapy drugs	53		375		272	
Release chemotherapy drugs	56		8		333	
Delivering						
Transport chemotherapy drugs	66		176		167	
Other	166		609		554	
Total	1421		7062		12 654	

Note: Frequencies (freq.) have been corrected for the study period of 4 months. Rankings (rank) are only presented for the five highest risk process steps; all other cells are left empty. RIA, retrospective incident reporting and analysis. PRA RISC 1, prospective risk analysis *without* information from the retrospective incidents database. PRA RISC 2, prospective risk analysis *with* information from the retrospective incidents database. [a]Diagnosis errors have been excluded.

Form 2 also showed that 16 respondents (47.1%) thought it was the *combination* of the analyses that provided most insight into risks. Others felt it was either the prospective ($n = 3$; 8.8%) *or* retrospective ($n = 7$; 20.6%) analysis that yielded most insight. In those numbers, the participants in the prospective analyses are included, but they also answered this question in Form 1. Interestingly, in Form 1 a much higher percentage of the respondents ($n = 14$; 73.7%) thought it was the *combination* of the analyses that provided most insight into risks.

Regarding the integration of the methods, 10 participants in the prospective analyses (52.6%) felt that information about incidents and their frequencies was or would have been useful; information about causes of incidents was or would have been useful according to 11 participants (57.9%). Form 1 also revealed that seven participants (50%, excluding management) were more willing to report incidents after participation in the prospective analysis. This could imply that participation in a prospective analysis could enhance incident reporting behaviour. For both units, follow-up chi-square tests indicated that, after the start of the prospective analyses, participants reported other incident types than non-participants in terms of the subprocesses that contributed to the occurrence of the reported incidents ($P = 0.006$ and $P = 0.04$, respectively). This endorses the assumption that participation in a prospective analysis is positively associated with incident reporting behaviour.

Discussion

In this study, we examined how prospective and retrospective methods for risk analysis could be integrated and whether this integration is perceived to be useful. Our findings show that both methods are considered valuable in terms of improving patient safety and optimizing processes. Our study supports earlier findings that prospective and retrospective analyses are partly complementary because both can yield divergent overviews of risks in terms of nature and magnitude [6, 22]. Hence, our study empirically endorses the theoretical contention that due to the convergent evidence, triangulation of the methods can provide hospital management and frontline staff with a more complete and less biased picture of risks [1, 6, 21, 22].

Provided that risks are categorized similarly, integration of prospective and retrospective methods enables direct comparison of the analysis results. Then, follow-up research could reveal biases, whereby the methods could be further improved [10]. Moreover, integration might limit the additional resources that could be required due to the application of two methods instead of just one. As we proposed, information about incidents and their retrospectively reported frequencies could be used as a reference point in the prospective analyses, which might facilitate frontline staff in the risk assessment. Conversely, prospectively developed failure scenarios could be used as guideline for retrospective

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Table 3 NUSAFE: identified frequencies (freq.) of risks per process step and accompanying rankings (rank) by analysis

Process step	Analysis					
	RIA		PRA NUSAFE 1		PRA NUSAFE 2	
	Freq.	Rank	Freq.	Rank	Freq.	Rank
Planning						
Receive order	168	2	383		1202	1
Code order	69		291		217	
Plan examination or treatment	247	1	584	5	333	
Inform or instruct patient	61		180		184	
Execution						
Refer patient to waiting room	42		160		175	
Prepare examination or treatment	90	5	95		100	
Call patient and check patient data	69		2673	1	120	
Select protocol and equipment	71		48		171	
Carry out examination or treatment	121	3	861	4	348	3
Assess, edit and provide images	21		1814	2	50	
Execution—other process steps	99	4	0		258	
Reporting						
Type report	10		1012	3	350	2
Archiving						
Correct report	5		0		337	4.5
Send report and hardcopy	19		6		220	
Archiving—other process steps	4		0		337	4.5
Other	73		570		354	
Total	1169		8677		4756	

Note. Frequencies (freq.) have been corrected for the study period of 4 months. Rankings (rank) are only presented for the five highest risk process steps; all other cells are left empty. Ties have been assigned the average value of the associated ranks [29]. RIA, retrospective incident reporting and analysis. PRA NUSAFE 1, prospective risk analysis *without* information from the retrospective incidents database. PRA NUSAFE 2, prospective risk analysis *with* information from the retrospective incidents database.

incident analyses. Besides the probably consequential increase in efficiency of analysis, integration of the methods could also support hospital management in making sense of risks and justifying their decisions regarding interventions [3].

Our study has several limitations. We did not test all possibilities for integration. However, we purposely selected those possibilities that could be easily applied by hospitals themselves to gain a better picture of risks. In future studies, more possibilities could be tested and one could establish whether integration actually increases efficiency of analysis. The results of our retrospective analyses might have been affected by hindsight bias; that is, the tendency for people to overstate the extent to which they would have predicted events beforehand [20]. We have tried to limit this by analysing incidents as soon as possible after they had been reported and by interviewing the people involved [30].

The perceived usefulness of the integration of prospective and retrospective methods could be influenced by respondents logically tending to evaluate the triangulation better than the application of only one method; conversely, respondents could tend to evaluate the triangulation negatively because of the extra effort required. Since the former positively affects the perceived usefulness, while the latter negatively affects it, future studies could examine whether the perceived benefits of combining the methods actually outweigh the perceived drawbacks.

Similar studies should be carried out in other health-care settings to assess the external validity of our results. However, independent-samples *t*-tests and ANOVA did not reveal any significant differences between the two units or the four prospective analysis teams, which confirms our findings. Further, our results could suggest that participation in a prospective analysis positively influences health-care employees' willingness to report incidents. Therefore, future studies could focus on the effects of participation in and taking notice of a prospective analysis on incident reporting behaviour.

In conclusion, notwithstanding the fact that either prospective or retrospective methods can be used to improve patient safety, hospital management should seriously consider their integration. Such an integrative approach might increase efficiency of analysis and can yield a better picture of risks, which could support hospital management in setting priorities for patient safety and allocating resources to the most important problems. Moreover, integration of the methods could bring about advances in safety research by improving the methods themselves. Together, such progress in theory and practice could make health-care safer and reduce patient harm accordingly.

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Acknowledgements

We thank all employees from the two units for their cooperation. In particular, we would like to thank Gonda Nienhuis, Hanneke Stoffels and Adriaan van Sorge for their help in the study design, data collection and data analysis.

Funding

This study was funded by Alysis hospitals and Infoland.

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Accepted for publication 15 September 2009

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