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# Application of the Bow-Tie Model in Medication Safety Risk Analysis

## Consecutive Experience in Two Hospitals in the Netherlands

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## Abstract

**Background:** To improve medication safety effectively, one should systematically analyse and assess the risks for medication errors and determine the possible causes. So far, no risk-analysis instrument exists in healthcare that can be used to analyse and visualize risks, causes and consequences of potential adverse events in a prospective manner. In high-risk industries such as petrochemistry and aviation, the Bow-Tie model is frequently used. This model combines causes, errors, preventive and recovery measures, and consequences in one model and gives insight into the magnitude and causes of existing safety risks. The aim of our project was to study the usefulness of the Bow-Tie model in the hospital setting for prospective analysis of risks in the medication process in order to develop a practicable method.

**Methods:** The model was first adapted to the clinical setting. Thereafter, the risk-analysis model was applied in a large tertiary teaching hospital in multidisciplinary sessions. The sessions and risk-analysis method were evaluated on the following aspects: applicability, comprehensibility, creation of awareness in and motivation of participants, and the capability of the 'system approach' (the approach taken by the Bow-Tie model, which focuses on the conditions under which individuals work and tries to build defences to avert errors or mitigate their effects, in contrast to a 'person approach', which focuses on errors of individuals, blaming them for forgetfulness, inattention etc.). Based on this evaluation, the risk analysis method was adjusted and consecutively applied in a general teaching hospital. After evaluation of the sessions in the second hospital a recommended method for risk analysis with the Bow-Tie model was defined.

**Results:** The risk-analysis method with the Bow-Tie model in the first hospital gave insight into many medication safety-related risks. However, the method was insufficient on comprehensibility and on the creation of awareness and motivation owing to a great number of determined risks which made thorough analysis, drawing of Bow-Ties and prioritizing difficult. The adjusted method in the second hospital focused more on the in-depth analysis of a small number of important safety issues of a department with specific attention for underlying causes. This approach was considered better in applicability, comprehensibility and the creation of awareness. Furthermore, by analyzing underlying causes, more attention could be paid to latent conditions (which can translate into error-provoking conditions) within the system.
**Conclusion:** We found the Bow-Tie to be an appropriate model for prospective risk analysis of medication safety in a hospital. By applying the model in two hospitals consecutively we developed a feasible method for risk-analysis sessions. Key factors of this recommended method are a focus on the prioritized selection of safety issues and specific attention to latent conditions within the system by analysing these safety issues in depth to the root causes with the help of the Bow-Tie model.

## Background

Patient safety is an important issue in healthcare. Adverse drug events (ADEs) occur frequently.[1-7] Whereas some ADEs cannot be prevented (unintended adverse drug reactions), many ADEs are due to systematic medication errors and organizational failure and are therefore preventable,[8] Currently, many healthcare organizations are working to improve patient safety in general and medication safety in particular. In order to improve medication safety effectively, one should systematically analyse and assess the risks for medication errors, and determine the possible causes. However, experience with systematic risk analysis is still scarce in healthcare. So far, no risk-analysis instrument exists that can be used to analyse and visualize risks, causes and consequences of potential adverse events in a prospective manner. To develop useful methods for systematic risk analysis in healthcare, one can apply the knowledge of risk management in the petrochemical and other high-risk industries. In these industries, broad experience exists with the application of risk-analysis instruments within safety management systems.

One of the risk-analysis instruments frequently used in the petrochemical industry is the Bow-Tie model[9-12] (figure 1). This model combines causes, errors, preventive and recovery measures, and consequences in one model, and gives insight into the magnitude and causes of existing safety risks. Thereby, it helps to prospectively prioritize potential risk-reducing interventions. With this model it is possible to depict the relationship between causes and consequences of a specific unwanted event in an understandable manner. Weaknesses in processes (ineffective or missing safeguards and barriers) can be visualized.

The aim of our project was to study the usefulness of the Bow-Tie model in the hospital setting for prospective analysis of risks in the medication process in order to develop a practicable method.

## Methods

### Setting

The study was performed between January and December 2005 in a large tertiary teaching hospital (Academic Medical Center Amsterdam)

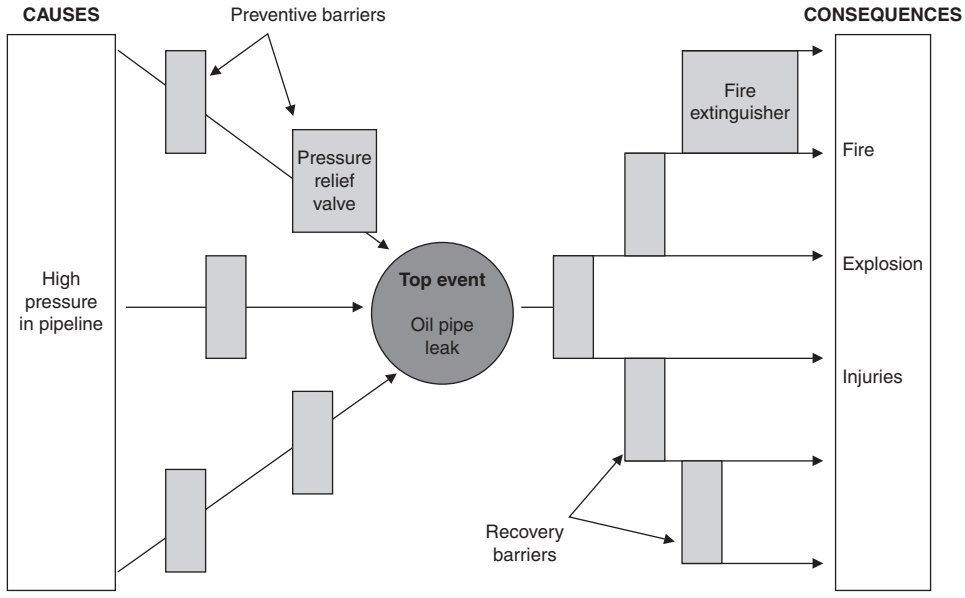


**Fig. 1.** The Bow-Tie model. The model combines the concepts of fault and event trees used in risk assessment and resembles the shape of the men's fashion accessory with the same name. It integrates the understanding of how accidents happen derived from Reason's Swiss Cheese Model.[13,14] 'Top events' are placed centrally in the Bow-Tie. Top events present an unwanted situation or event that has the potential to cause damage. In other words, a hazard is released, but has not yet caused any harm. An example of a top event at an oil-drilling platform would be an oil pipeline leak. This oil pipe leak can have various causes and consequences, which can be analysed with the Bow-Tie model. The left-hand side of the Bow-Tie describes how causes (for example high pressure in the pipeline), either in isolation or in combination, can release a hazard and lead to the undesirable top event. The right-hand side represents the various scenarios that might develop from the undesired top event (for example a fire or an explosion), dependent upon the effectiveness of systems and activities to stop progression to lasting harm and damage.[9] Barriers on the left side normally prevent a cause from releasing a hazard and becoming a top event, whereas recovery barriers on the right side of the model prevent a top event from causing actual harm. An example of a preventative barrier (left side) would be a pressure-relief valve or strengthened pipes on the platform. An example of a recovery barrier (right side) would be a fire-extinguishing system.

and consecutively in a large general hospital (Diakonessenhuis Utrecht-Zeist-Doorn) between March and May 2006. The tertiary teaching hospital (hospital A, 1002 beds) consists of a general and a children's hospital. There is a hospital-wide implemented Computerized Physician Order Entry (CPOE) system. The general teaching hospital (hospital B, 627 beds) started the implementation of a CPOE system in 2005–6. In both institutions, hospital pharmacists did not operate on the ward on a daily basis, but performed their tasks mainly in a centrally located hospital pharmacy department and could be consulted on demand by physicians and nurses.

### Trajectory Overview

The application of the Bow-Tie model was conducted as follows: the model was first adapted to the clinical setting by determining medication safety 'top events' (see the next section for further details). Thereafter the model was used and tested in hospital A. The performed risk analysis was evaluated and alterations were made in the method to improve the application of the Bow-Tie model in hospital B. Based on the experiences in both hospitals a recommended method for risk analysis was determined.

### Adaptation of the Bow-Tie Model for Medication Safety Risk Analysis

First the Bow-Tie model was translated to the medication use process by determining medication safety-specific 'top events' that would be placed centrally in the model. Top events in our model were described as an unwanted event or error that takes place (e.g. an incident,

a hazardous situation), but at that moment has not yet caused any harm or has not yet had any consequences. Interviews were held by an external safety expert, experienced in risk analysis in the oil and aviation industries, with representatives of five key professions (an internal medicine physician, a surgeon, a paediatrician, two nurses, two hospital pharmacists and a pharmacy technician) in order to get insight into the medication use process and its risks. In our definition, the medication use process encompassed prescribing, transcribing, dispensing, administering and monitoring. Based on risk safety theories, themes from the interviews were grouped by the external expert and three basic top events were determined for the medication use process.

1. A patient receiving the wrong drug; this top event includes therapeutic omissions – a patient not receiving an indicated drug because a doctor forgot to prescribe it. This top event was named 'wrong drug'.
2. A patient receiving a wrong dose, for example, because of an erroneous drug order. This top event was named 'wrong dose'.
3. A patient being given the drug incorrectly in both timing and manner. This top event was named 'wrong administration'. Choosing the incorrect route of administration is an example of a wrong manner of administration (e.g. intrathecally instead of intravenously). A patient receiving a drug 2 hours late is an example of incorrect timing. This top event also includes the omission of one or more administrations of a prescribed drug.

### Application of the Bow-Tie Model

Following adaptation, the Bow-Tie model was applied in two hospitals successively. Multidisciplinary sessions were organized. In hospital A the risk analysis was performed at the departments of surgery, internal medicine and intensive care, and in the paediatric hospital. The teams consisted of physicians, nurses and pharmacists (partly volunteers and partly individuals suggested by the head of the department). The team members were individuals other than those representatives who were interviewed for the top event determination. Group size varied between five and ten persons. During every 2-hour session there were one or two facilitators and a notetaker. The overall number of sessions was nine. In hospital B, sessions were held at the departments of internal medicine and surgery (four sessions in total, two per department). Team composition and group size, as well as the duration of the sessions, were comparable to the sessions in hospital A. Participants attended all of the sessions. Two of the authors participated in the sessions in both hospitals, one author as facilitator (PW), the other as an observer (SS).

Bow-Tie risk analysis in hospital A consisted of the following three stages:

- *Risk analysis (analysing the safety situation)*: For each of the three top events, all possible causes that could lead to this event were determined. For all causes that could lead to one of the top events, existing preventive barriers on the left side of the model were discussed, but also barriers that could be implemented in the future to improve the safety of the process. Potential consequences were discussed if a top event would progress to eventually cause harm or damage. Recovery barriers, both existing and future, on the right site of the model that mitigate or prevent the consequences were determined. Finally, situations that could make a defensive or recovery barrier less effective (degrading factors) were discussed.
- *Risk assessment*: Risks were assessed in terms of (i) the existence of barriers; (ii) the number of barriers; and (iii) the existence and effect of barrier-degrading factors.
- *Prioritization*: A risk-prioritization step was undertaken. In order to prioritize, estimations were made of the frequency of possible causes and the seriousness of possible consequences. Scales (table I) and a risk matrix (figure 2) were used for this purpose. In estimating the consequences team members had to consider the worst possible outcome.

Adjustments in the risk analysis strategy for hospital B involved the following. Instead of systematically working through the top events

**Table I.** Frequency and severity scales

| |
|---|
| **Frequency** |
| 0 Has never happened |
| 1 Has happened in a hospital somewhere in the world |
| 2 Has happened in a hospital somewhere in the Netherlands |
| 3 Has happened in this hospital (this year) |
| 4 Has happened in this department (this year) |
| 5 At least once per month in this department |
| 6 Happens daily in this department |
| **Severity of consequences** |
| 0 No effect |
| 1 Minimal effect, no harm |
| 2 Discomfort and minor harm, monitoring necessary |
| 3 Harm and severe complaints, intervention and prolonged hospital stay |
| 4 Fatal |

and determining as many risk factors as possible, team members first pointed out safety issues that were considered highly relevant problems at their department. Thereafter, before using the Bow-Tie, those safety issues were prioritized using the risk matrix to achieve a maximum of three top events. Top events were made department specific and were more specified: the type of (sub) process, type of drug (group) and type of patient were defined instead of only 'wrong drug' as in hospital A. The Bow-Tie analysis of these selected issues was conducted in greater depth. In-depth analysis would involve visualizing and analyzing all data in the Bow-Tie model and discussing the Bow-Tie diagrams until potential underlying causes were determined. The facilitators planned to create an open atmosphere for discussion and to motivate each member of the multidisciplinary team to speak up and give their point of view.

### Evaluation Methodology

In both hospitals, the risk-analysis approach was tested qualitatively. Evaluation took place by participatory observation and in discussions with the multidisciplinary panel at the start and ending of sessions. In particular, the method was evaluated for the following aspects by asking the multidisciplinary team:

- whether the model is applicable in the healthcare setting for risk analysis in medication safety (applicability);
- whether the model is able to give insight into the present safety situation and risks in a comprehensible manner (comprehensibility);
- whether the application of the model increases the awareness in the participants of medication risks and creates a sense of urgency to address these problems (awareness and motivation);
- whether the application of the model helps to reveal the underlying causes (latent conditions), which can translate into error-provoking conditions of medication safety problems (the 'system approach', which focuses on the conditions under which individuals work and tries to build defences to avert errors or mitigate their effects, in contrast to a 'person approach' which focuses on errors of individuals, blaming them for forgetfulness, inattention, etc.).[14]

Discussion notes were documented and evaluated with peers (MK, PB, PH). The findings were used to further improve the method.

## Results

### Applying the Model and Evaluation of the Approach

#### *Hospital A*

The chosen approach in the sessions of hospital A gave insight into many medication

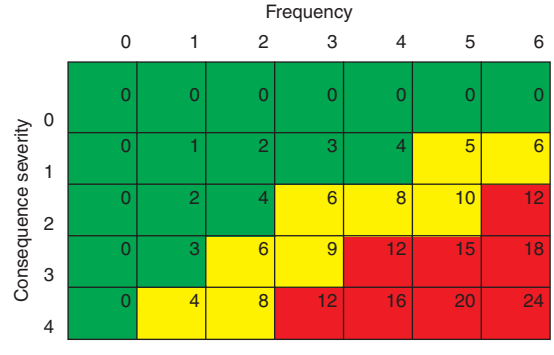


**Fig. 2.** Risk matrix. The red area in the risk matrix corresponds with risks that are unacceptable, the yellow area with risks that should be reduced and managed, and the green area with risks that are acceptable.

safety-related risks, but made in-depth discussion and analysis of specific risks difficult. In more detail, the four aspects were evaluated as follows.

### Applicability

The systematic manner of discussing the three top events (wrong drug, wrong dose and wrong administration), and thinking of as many risk factors as possible during the sessions gave insight into a number of local medication-related problems at the participating departments, but, most of all, into many general hospital-wide risks. Some examples of hospital-wide risks are shown in table II. The nonspecific formulation of the three top events hampered the analysis. Sometimes it was impossible to determine specific barriers because some were drug-dependent (e.g. the antidote acetylcysteine for paracetamol [acetaminophen] as a recovery barrier). Furthermore, because of drug dependency, the determination of possible consequences was considered difficult.

### Comprehensibility

Group members found it difficult to interpret the large amount of collected information during the sessions. Because of the nonspecific top events, drawing of Bow-Ties and prioritizing the necessary medication safety improvements were considered to be complicated.

### 'System Approach'

Analysis with the Bow-Tie was considered time consuming. Participants had no possibilities to go into an in-depth analysis of their local medication safety problems with specific attention to latent conditions in the system.

### Creation of Awareness and Motivation

Session leaders pointed out that participants felt little ownership of the analysed risks as a

**Table II.** Examples of hospital-wide risks, current barriers and proposed future barriers in hospital A

| Risk factors (causes) | Current barriers | Future barriers | Top event[a] |
|---|---|---|---|
| Administration errors with injectable drugs | *Prevention:*<br>only check by second nurse at some wards;<br>only second check with high-risk drugs (e.g. antineoplastics) | *Prevention:*<br>general second check;<br>barcode-assisted electronic administration check;<br>handbook consisting of protocols with evidence-based information on drug administration | Wrong administration |
| Prescribing the wrong dose owing to:<br>not taking co-morbidities into account;<br>insufficient drug knowledge | *Prevention:*<br>dosage check during drug ordering by CPOE<br>*Recovery and mitigation:*<br>pharmacist checks overruled dosage alerts generated by CPOE within 48 h | *Prevention and recovery:*<br>decision support and a more intelligent CPOE (using laboratory values in dosage advising);<br>proactive pharmacist participation in direct patient care, medication review<br>*Recovery:*<br>therapeutic drug monitoring | Wrong dose |
| Transfers and medication information exchange:<br>between wards;<br>between hospitals;<br>at admission and discharge | *Prevention:*<br>pharmacy service point: responsible for correct medication history information at admission by contacting patient's pharmacist and responsible for checking and faxing discharge prescriptions to patient's pharmacist | *Prevention:*<br>electronic data exchange between healthcare professionals;<br>a national medication or medical record | Wrong drug<br>Wrong dose<br>Wrong administration |
| Drug order stickers attached in paper medication record of the wrong patient | No structural barriers;<br>coincidental discovery by nurse | *Prevention:*<br>barcode-assisted electronic administration check;<br>electronic patient record, abandoning paper records | Wrong drug |

a Top events are an unwanted situation or event that has the potential to cause damage.

**CPOE** = Computerized Physician Order Entry.

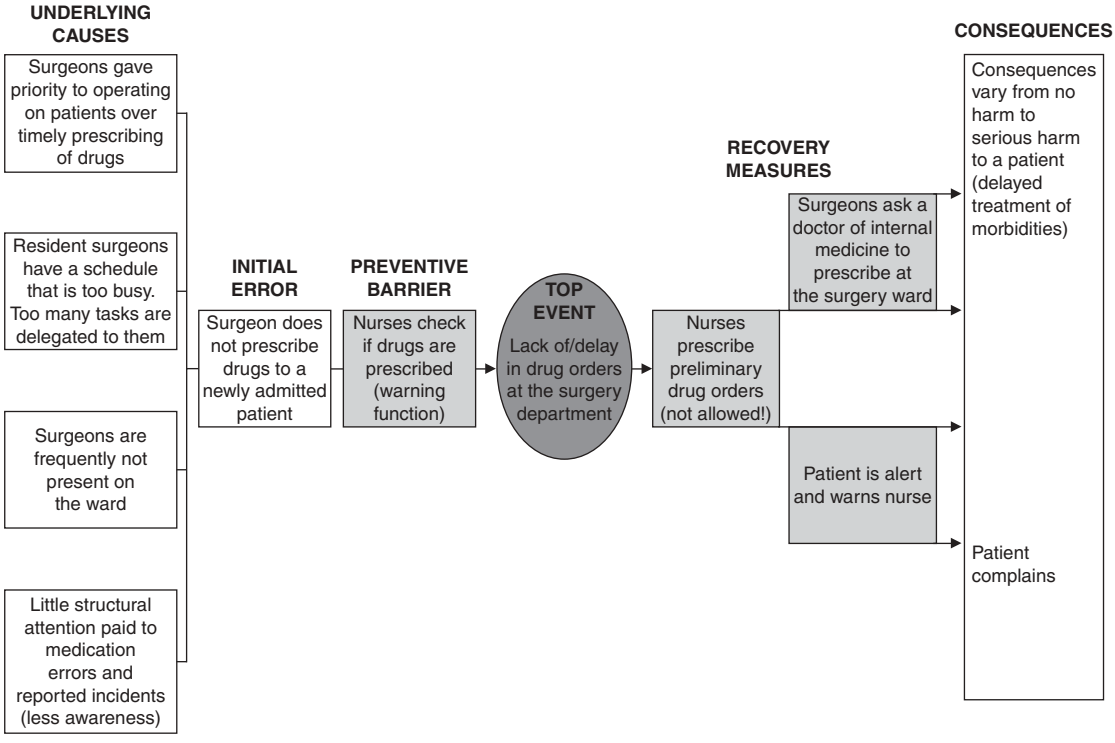


**Fig. 3.** Visualization of a Bow-Tie diagram for hospital B.

result of too much information and the impossibility of thoroughly analysing ward-specific risks, which participants often considered to be most urgent.

### *Hospital B*

The altered strategy in hospital B made in-depth discussion and analysis of ward-specific risks possible and increased the safety awareness of participants. In more detail, the four aspects were evaluated as follows.

#### Applicability

Session leaders pointed out that the approach was effective and created motivation in the teams. Letting participants select and prioritize specific safety issues before drawing Bow-Ties allowed a more efficient risk-analysis process. In-depth analysis of the safety issues with the Bow-Tie diagram and the systematic determination of the underlying causes made it easier to define possible improvements.

#### Comprehensibility

Drawing a Bow-Tie was considered easier if a more specific top event was being analysed more thoroughly. Furthermore, it stimulated the discussion during the sessions.

#### 'System Approach'

Ward-specific safety issues were analysed with regard to the underlying causes. Determining these causes gave insight into the latent conditions and directed the participants to the most suitable and possibly effective improvements.

#### Creation of Awareness and Motivation

The fact that participants prioritized and selected a set of local safety issues that they considered most urgent stimulated them to analyse these issues and to think of possible improvement

projects. Moreover, the analysis process was an eye-opener for the team members. Many aspects that were discussed created understanding for the difficulties of one another's professions.

Figure 3 gives a visualization of one of the specific top events and causes that were analysed in depth with the Bow-Tie (lack of and delay in drug orders at the surgery department).

### *Recommended Method for Risk Analysis with the Bow-Tie Model*

Based on the experiences in both hospitals, a recommended method for risk-analysis sessions with the Bow-Tie model in healthcare was made (table III). The basic structure of the Bow-Tie model for medication safety risk analysis should have the feature to depict underlying causes and is shown in figure 4. Errors that directly lead to a top event can be defined as 'initial errors' (e.g. errors that can be directly linked in a causal relationship to the top event, for example a nurse selecting the wrong drug in the storage room), which themselves can have multiple underlying, less obvious causes that can also be analysed during the risk-analysis process (e.g. a disorganized drug storage room). These 'root causes' or latent conditions are drawn in the event trees preceding the initial errors.

**Table III.** Recommended method for risk analysis with the Bow-Tie model

| |
|---|
| 1. Select multidisciplinary groups and inform participants about the principles of the method |
| 2. Arrange a brainstorm session leader and one to two note-takers for each session |
| 3. During the session explain the principle of the model by using simple examples |
| 4. Brainstorm over possible (local) top events and safety issues |
| 5. Prioritize safety issues |
| 6. Specify the top events and analyse the highest priority risk in depth with the Bow-Tie model |
| 7. Brainstorm about root causes, initial errors, present barriers (preventive and recovery) and consequences. Draw Bow-Ties |
| 8. Brainstorm about risk factors that negatively influence barriers |
| 9. Assess if safety is sufficiently managed |
| 10. Brainstorm about new or improved barriers. Draw these in a Bow-Tie for the new situation |
| 11. Categorize all the data in tables |
| 12. Draw up an improvement plan with follow-up actions (multidisciplinary) |

## Discussion

We found the Bow-Tie to be an appropriate model for prospective risk analysis of medication safety in a hospital. By applying the method in two hospitals consecutively we developed a feasible method for risk-analysis sessions.

For this study we chose the Bow-Tie model, frequently used by the petrochemical industry, and applied it in two hospitals for prospective risk analysis on medication safety. The initial strategy followed during the risk-analysis sessions in the first hospital gave insight into many risks but was time consuming and unsatisfactory on aspects of creating awareness, the system approach and comprehensibility. The strategy resulted in too much information about general risks throughout the hospital, which made the risk analysis confusing and difficult to manage. The nonspecific formulation of the three basic top events made the determination of some barriers and consequences impossible because many are drug dependent. Focus on and thorough analysis of ward-specific risks was impossible, hampering the feeling of ownership in the participants. Therefore adjustments were made to the risk-analysis method before application in the second hospital. This adjusted method encompassed a prioritizing step before drawing Bow-Ties, a focus on the most important (local) risks, specifying the top events, and a thorough analysis of the risks with attention to underlying causes in the specific department. This adjusted method was found to be easily applicable. Although participants had little experience with safety management, they understood the concept of the system approach (identifying latent conditions in contrast to focusing on the person making the error) and were able to determine root causes of specific top events with help of the facilitators. Furthermore, the sessions increased safety awareness and motivated the participants to brainstorm about and prioritize potential safety improvements. Hence, the Bow-Tie was shown to be an appropriate method to start

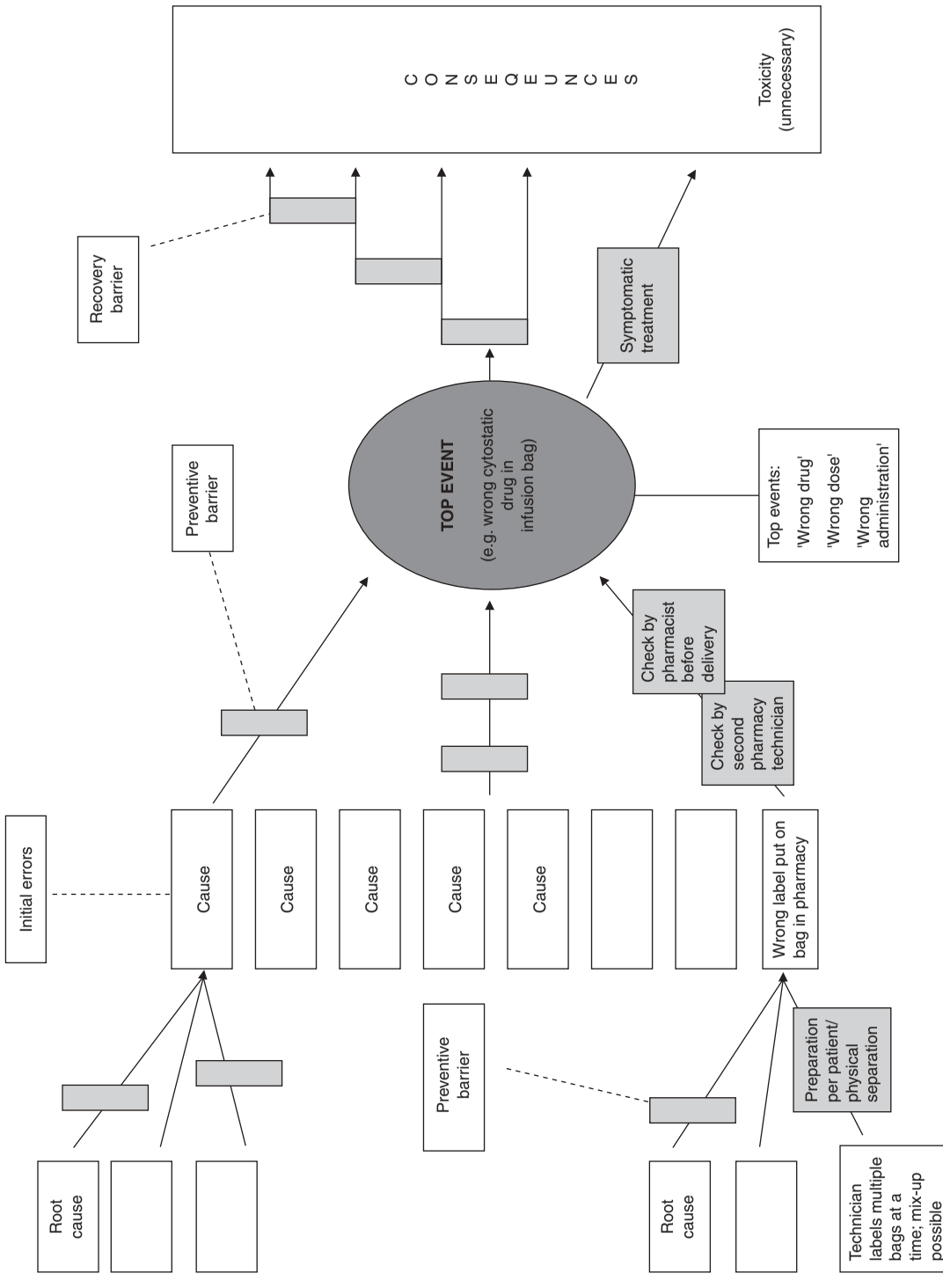


**Fig. 4.** Basic Bow-Tie model for medication safety-risk analysis with an example of a specified top event to illustrate the principle.

medication safety initiatives, even in departments without specific expertise in this field.

In recent years, some other risk-analysis methods have been translated to the healthcare setting. Examples of methods that are used for analyses of adverse events or incidents are Root Cause Analysis (RCA)[15-17] and incident report classification with the Eindhoven Classification Model (PRISMA).[18,19] Because of the important information that root causes can give, we incorporated this principle into the Bow-Tie model for medication safety-risk analysis (figure 4). Thus, without the need for incident reports, aspects of RCA can be used prospectively in our Bow-Tie model. Several other studies have described the application of Failure Mode and Effect Analysis (FMEA) as a prospective risk-analysis instrument in healthcare.[20-23] In contrast to FMEA, where a specific process is the subject of analysis, the Bow-Tie method centralizes top events of a specific safety item (in our study 'the hazard' medication) and helps to analyse their causes and consequences. It can depict the relationship between causes, top events, barriers and consequences in a comprehensible manner for every discipline. Therefore, the Bow-Tie model is primarily useful for an initial multidisciplinary risk analysis of a broader safety topic, whereas the FMEA seems more suitable to analyse a specific high-risk process in more detail.[24-28] Because of these different purposes, both risk-analysis instruments are complementary rather than competitive.

This study has some limitations. It was set up as an explorative study on the application of the Bow-Tie model in clinical practice. The focus was on the determination of a recommended method for using the Bow-Tie. We did not study the possible post-analysis effects of our risk analysis on front-line staff and daily practice. Therefore, no conclusions can be drawn on induced change. The risk-analysis approach was qualitatively evaluated by participatory evaluation and by asking participants about specific aspects of the method. Thereafter the findings were discussed with peers. Therefore some bias in the evaluation could have been introduced owing to the specific experience of or professional relationships between the participants. As for participatory evaluation, the problem applies that the results could be biased in their favour by participating stakeholders, but we tried to manage this by selecting several different medical professions in the study team. Moreover, we tested the model in only two Dutch hospitals. Consequently, our findings could have limited generalizability. First and foremost, however, we think that the safety culture in a specific hospital, the motivation and attitude of the participants and the question of whether the risk analysis is part of a well supported improvement plan with follow-up actions, will influence the success of the method and its results. If a hospital has no intention to take action upon the findings of the risk analysis, the effort will be in vain.

In future research, we will further expand the use of the Bow-Tie model for risk analyses in other fields of patient safety than medication. Although not examined in this study, the structure of the Bow-Tie model makes it possible to define standard practices of safety management.[11] Responsibilities and tasks can be appointed to every barrier, making the Bow-Tie model also a management tool. In that way, auditing with aid of the model can take place, as opposed to unstructured investigations or mere counting. This aspect of the model will be explored in future research.

## Conclusion

The structure of the Bow-Tie model allows professionals in the clinical setting to identify the routes to and from medication safety top events. Barriers can be identified that either aim to prevent top events from occurring or aim to mitigate consequences. The structure of the model allows risks to be assessed by the identification of strong and weak points and these relationships can be visualized comprehensibly. Because the model can give an impression of the manner in which the medication and patient safety is managed (sufficiently or insufficiently), a risk analysis with the Bow-Tie model can be a suitable starting project in a larger safety improvement plan.

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## Reference

1. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med 1991; 324 (6): 370-6
2. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med 1991; 324 (6): 377-84
3. Wilson RM, Runciman WB, Gibberd RW, et al. The Quality in Australian Health Care Study. Med J Aust 1995; 163 (9): 458-71
4. Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ 2004; 170 (11): 1678-86
5. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ 2001; 322 (7285): 517-9
6. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995; 274 (1): 29-34
7. Hardmeier B, Braunschweig S, Cavallaro M, et al. Adverse drug events caused by medication errors in medical inpatients. Swiss Med Wkly 2004; 134 (45-46): 664-70
8. Nebeker JR, Barach P, Samore MH. Clarifying adverse drug events: a clinician's guide to terminology, documentation, and reporting. Ann Intern Med 2004 May 18; 140 (10): 795-801
9. Van de Graaf G, Milne P. HSE cases-some lessons learned. Exploration and production newsletter. The Hague: Shell International, 1996
10. Safety Risk Management Guidance for System Acquisitions. Federal Aviation Administration. Version 1.4a [online]. Available from URL: http://fast.faa.gov/toolsets/SafMgmt/docs/SRMGSA_1.4a.pdf [Accessed 2007 Aug]
11. Hudson PT, Guchelaar HJ. Risk assessment in clinical pharmacy. Pharm World Sci 2003; 25 (3): 98-103
12. Guchelaar HJ, Colen HB, Kalmeijer MD, et al. Medication errors: hospital pharmacist perspective. Drugs 2005; 65 (13): 1735-46
13. Reason JT. Managing the risks of organisational accidents. Aldershot: Ashgate, 2006
14. Reason J. Human error: models and management. BMJ 2000; 320 (7237): 768-70
15. Sweitzer SC, Silver MP. Learning from unexpected events: a root cause analysis training program. J Healthc Qual 2005; 27 (5): 11-9
16. Friedman AL, Geoghegan SR, Sowers NM, et al. Medication errors in the outpatient setting: classification and root cause analysis. Arch Surg 2007; 142 (3): 278-83
17. Braithwaite J, Westbrook MT, Mallock NA, et al. Experiences of health professionals who conducted root cause analyses after undergoing a safety improvement programme. Qual Saf Health Care 2006; 15 (6): 393-9
18. Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. Acad Med 2001; 76 (2): 125-33
19. Usin MF, Ramesh P, Lopez CG. Implementation of an event reporting system in a transfusion medicine unit: a local experience. Malays J Pathol 2004; 26 (1): 43-8
20. Kozakiewicz JM, Benis LJ, Fisher SM, et al. Safe chemotherapy administration: using failure mode and effects analysis in computerized prescriber order entry. Am J Health Syst Pharm 2005; 62 (17): 1813-6
21. Adachi W, Lodolce AE. Use of failure mode and effects analysis in improving the safety of i.v. drug administration. Am J Health Syst Pharm 2005; 62 (9): 917-20
22. Coles G, Fuller B, Nordquist K, et al. Using failure mode effects and criticality analysis for high-risk processes at three community hospitals. Jt Comm J Qual Patient Saf 2005; 31 (3): 132-40
23. Duwe B, Fuchs BD, Hansen-Flaschen J. Failure mode and effects analysis application to critical care medicine. Crit Care Clin 2005; 21 (1): 21-30, vii
24. van Tilburg CM, Leistikow IP, Rademaker CM, et al. Health care failure mode and effect analysis: a useful proactive risk analysis in a pediatric oncology ward. Qual Saf Health Care 2006; 15 (1): 58-63
25. Day S, Dalto J, Fox J, et al. Failure mode and effects analysis as a performance improvement tool in trauma. J Trauma Nurs 2006; 13 (3): 111-7
26. Wetterneck TB, Skibinski KA, Roberts TL, et al. Using failure mode and effects analysis to plan implementation of smart i.v. pump technology. Am J Health Syst Pharm 2006; 63 (16): 1528-38
27. Robinson DL, Heigham M, Clark J. Using failure mode and effects analysis for safe administration of chemotherapy to hospitalized children with cancer. Jt Comm J Qual Patient Saf 2006; 32 (3): 161-6
28. Bonnabry P, Cingria L, Sadeghipour F, et al. Use of a systematic risk analysis method to improve safety in the production of paediatric parenteral nutrition solutions. Qual Saf Health Care 2005; 14 (2): 93-8

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