



# A Patient Safety Vocabulary

## Safety Improvement for Patients in Europe

### SimPatIE - Work Package 4

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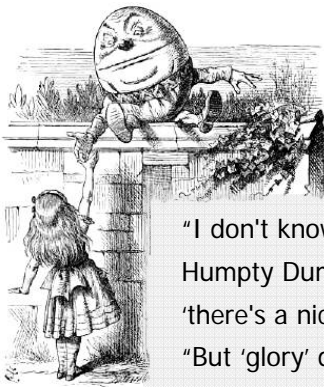
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"I don't know what you mean by 'glory'," Alice said.  
Humpty Dumpty smiled contemptuously. "Of course you don't - till I tell you. I meant 'there's a nice knock-down argument for you!' "  
"But 'glory' doesn't mean 'a nice knock-down argument'," Alice objected.  
"When I use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean - neither more nor less."  
"The question is," said Alice, "whether you can make words mean so many different things."  
"The question is," said Humpty Dumpty, "which is to be master - that's all."

From *Through the Looking-Glass*, Chapter 6 by Lewis Carroll.

## Summary

The objective of this work package (WP4) of the SimPatIE-project was the development of a vocabulary and an intern indicator set for patient safety. This report describes the work done to develop the vocabulary.

The ESQH-Office for Quality Indicators in Aarhus, Denmark, was the lead partner of WP4. An expert group with European representatives of project partners, stakeholders and external experts was established for the achievement of the aims of WP4.

A literature search was performed to identify nationwide and international definitions of terms related to patient safety. Selecting and defining terms, and clarifying the concepts was done in a formalised consensus process in a sub-group to the expert group, interacting with the expert group. The work was carried out using telephone conferences and mail correspondence, the sub-group met once in the developmental process to deepen the work. The final draft of the vocabulary was sent to the expert group and two patients' representatives for comments. Comments were discussed in a telephone conference of the subgroup, alterations were made accordingly and the vocabulary finalised.

A vocabulary of 24 definitions of patient safety terms covering the domains: 'Detection of Risks', 'Analysis of Risks', 'Resulting Actions' and 'Failure Mode' was developed and accompanied by an illustrating overview of the relation of the five core terms of the vocabulary. The terms are available in English on [www.simpatie.org](http://www.simpatie.org). The vocabulary is aimed at professionals, e.g. risk managers, administrators and others working with patient safety.

The vocabulary provides a basis for achieving greater unity of patient safety work in Europe - it serves particularly as a basis for applying the patient safety evaluation tools from the toolbox of SimPatIE. We strongly recommend that the vocabulary and the vocabulary framework (diagram 1) be made accessible in the European countries. It should be translated into the European languages using a standardised method, and we recommend the development of adequate local implementation strategies; healthcare organisations, professional and scientific bodies and educational institutions should be made aware of the existence of the vocabulary, be encouraged to use it in a way so that the key elements can be put into everyday practice.

## **Introduction to WP4**

Patient safety is an outcome of safe health care processes. While patient safety is the ultimate goal, it is a safer care environment in the course of the process of patient care which ultimately determines safety. Safety is one dimension of the broader construct of culture, which includes aspects of organisational and clinical culture, subcultures, e.g. related to specialities and professions, as well as cultures related to national, regional and local aspects.

Communication is vital to patient safety in many ways; thus supporting mutual understanding across cultures is essential in the general development of patient safety – a vocabulary with definitions of essential terms can facilitate communication between professionals in Europe.

The SImPatIE project was made possible by a grant from the European Commission on 'Public Health/Directorate General for Health and Consumer Affairs in 2004' (OJ 2004/C52, 27 February 2004). This report represents the views of its authors and the expert group of WP4. These views have not been approved by the European Commission and should not be relied upon as a statement of the European Commission.

## **Objectives**

The objective of this work package was the development of a vocabulary and an intern indicator set for patient safety, that is to be part of a final project toolbox for improving patient safety. This report describes the work done to develop the vocabulary.

## **Organisation**

The ESQH-Office for Quality Indicators in Aarhus, Denmark, was the lead partner of this work package (WP4). The project was led by Prof. Jan Mainz, medical director of the Danish Institute for Quality and Accreditation in Healthcare, supported by Dr. Paul Bartels, medical director of the Danish Indicator Project. Overall project management and scientific work was executed by Master of Health Science Solvejg Kristensen.

The expert group consisted of representatives of project partners and external experts. Members of the expert group concerning the vocabulary were:

- MD, PhD. A. Bourek, University Center for Healthcare Quality, Masaryk University, Czech Republic
- Dr. I. Callanan, Vice President of the Irish Society for Quality and Safety in Healthcare
- Dr. K. Essinger, President, HOPE Subcommittee on Co-ordination (Appointed by HOPE)
- Dr. J. van Everdingen, chief medical officer of CBO (Appointed by CBO)
- Dr. M. Kallewaard of the Association of Medical Specialists (Appointed by CBO)
- Dr. J. Hansen, The Danish National Board of Health
- Dr. G. Maguerez (Appointed by HAS)
- MD, PhD R. Suñol, Director of Avedis Donabedian Foundation (FAD).
- Dr. B Lilja, Director of the Danish Society for Patient Safety, Denmark
- Prof. Dr. med. G. Ollenschläger, Guidelines International Network (G-I-N).

## **Results to be achieved**

The results to be achieved by the work package were:

- Defining a vocabulary related to patient safety, taking into account language, health care system organisation and economy as well as cultural issues across Europe
- Establishing a set of indicators/outcome measures that can be used in efforts to improve patient safety both at the system and organisation level (described in another report)
- Developing a brief rating assessment instrument for external application to provisional outputs (described in another report)

## **Deliverables fulfilled**

The work package delivers:

- A set of definitions of terms related to patient safety and a framework to illustrate the core terms of the vocabulary
- A set of indicators for use in efforts to improve patient safety (described in another report)
- A brief rating assessment instrument for external application to provisional outputs (described in another report)

## **Overall approach taken**

The work of WP4 was initiated and co-ordinated by the ESQH-Office for Quality Indicators in Aarhus.

The expert group met in February 2006 with the purpose of introducing SIMPatIE and WP4. SimPatIE project manager Benno van Beek, CBO, took part in the meeting. The following presentations were given:

- Overall SIMPatIE Project Plan and Organisation, by project manager Benno van Beek, CBO
- Related Work of Work Package 5, by Dr. Georges Marguerez
- Introduction to Indicators, Including Qualifications and Characterisation, by Prof. Jan Mainz
- Proposed Schemes for Classification and Evaluation of Indicators, by Prof. Jan Mainz
- Patient Safety Indicators, by Dr. Paul Bartels
- Specific Issues of Definition and Methodology and an Overview of Available Materials and Ongoing Work on Taxonomy/Vocabulary, by Dr. Paul Bartels

A detailed work plan for WP4 was established and tasks were assigned.

The overall working method in the expert group has been telephone conferences. Development has been initiated and decisions made in a formalised consensus process. The method of developing the indicators is described in detail later.

Prior to the meeting of the expert group, an extensive literature search was initiated using the search terms: 'patient safety', 'vocabulary', 'glossary', 'taxonomy' and 'indicator'. PubMed <http://scholar.google.dk/> were searched. The literature search was repeated and extended in the process of the work and finalised in August 2006. Details of the literature/background sources relating to the development of the vocabulary are given later.

## **Description of Work**

### **Objectives of a common European vocabulary on patient safety**

The patient safety terms are meant for use by professionals, e.g. risk managers, administrators, project managers and others working with patient safety. The purposes of the vocabulary are to:

- Define basic terms and concepts related to patient safety
- Ease communication and understanding across Europe
- Be easily understood by non-native English speaking people
- Take cross-cultural European aspects into account.

### **Organisation**

To develop the vocabulary a sub-group of the expert group was formed. Members of the sub-group were: Dr. Ian Callanan (chairman), Dr. Jannes van Everdingen, Dr. Joergen Hansen and Dr. Paul Bartels. The work in the vocabulary sub-group was managed by MHS Solvejg Kristensen from the ESQH-Office for Quality Indicators in Aarhus.

### **Method**

In order to find terms for patient safety, suitable for the vocabulary, web pages of organisations working with (patient) safety were identified and screened. The most frequently used terms were identified, and in the first place considered suitable for the vocabulary. A literature review was done by the ESQH-Office in Aarhus in order to identify all relevant sources for the description of concepts and terminology related to patient safety. Calls for terms to be contained in the vocabulary were made amongst the expert group.

A list of 18 terms was produced and discussed at the initial expert group meeting. In the course of the meeting different frameworks of understanding of the most vital terms of patient safety, e.g. ‘adverse event’, ‘complication’ and ‘near miss’ were presented, their connections illustrated and discussed. More terms were added, and some deleted from the vocabulary. Finally a list of 30 basic terms to be included in the vocabulary was proposed. It was decided that the vocabulary should contain 20-30 terms. Apart from the objectives of the vocabulary listed above, the following criteria for establishing the vocabulary were agreed on:

- 1) To include terms frequently used in the work with patient safety in Europe
- 2) To include terms needing a common European definition as a basis for mutual understanding
- 3) Not to include terms covering fixed notions or methods, e.g. ‘double loop learning’, ‘root cause analysis’
- 4) Definitions in the vocabulary should be consistent and their relations illustrated
- 5) The terms should be categorised

The list of the 30 terms was discussed in further detail in a telephone conference among the expert group. It was decided to categorise the terms according to the stage of patient safety work, to support the work of WP5. Following this expert group telephone conference, the list of 30 terms, the criteria agreed upon and three possible overviews of relations of terms were handed over to the elected vocabulary sub-group for further development.

For each of the 30 terms in the list definitions were identified from existing glossaries/vocabularies of organisations working with (patient) safety. A new list of the terms was produced, showing all the available alternative definitions of the terms. The list of terms and a suggestion of categorising the terms was sent to the full expert group with a call for input and comments. Suggestions for definitions were added, e.g. nationally used definitions, and the list was sent to the vocabulary sub-group. Each of the sub-group members commented in writing, comments were added to the list and circulated within the sub-group.

The vocabulary sub-group agreed on 24 definitions of terms, subdivided into four categories, and an overview of relations of the core terms of the vocabulary. The vocabulary sub-group held a telephone conference and met once for a one-day meeting.

The final suggestion for the vocabulary was sent to the full expert group for comments in writing and to two patient representatives. The sub-group held a telephone conference to discuss the comments made and finalise the vocabulary.

## **Background sources and literature**

Information provided by the organisations mentioned below was taken into account in developing the vocabulary. Either the web page was screened for identification of terms for the vocabulary, or definitions of terms considered. It was decided to take all available material/information, both European and international into account as a basis for the discussions in developing the vocabulary. We found this relevant in order to ensure that as many terms and concepts as possible, also such not yet dominant in Europe, were examined with a view to finding them suitable or not for the vocabulary.

Information from the following sources was reviewed:

- Australian Commission for Safety and Quality in Health Care (ACSQHC)
- Agency for Healthcare Research and Quality (AHRQ)
- Act on Patient Safety in the Danish Health Care System (APSDHCS)
- Council of Europe (CoE)
- Institute of Medicine (IOM)
- Information Security Group (ISG)
- International Organisation for Standardization (ISO)
- Dutch Consensus Group with participants of (semi)government and different professional groups (JPSG)
- Joint Commission on Accreditation in Health Care (JCAHC)
- Joint Commission International (JCI)
- National Patient Safety Agency (NPSA)
- The Danish Society for Patient Safety (DSPS)
- The Quality Interagency Coordination Task Force (QuIC)
- Socialstyrelsens Författningssamling, Sweden (SF)
- The National Board of Health, Denmark (SST)
- Veterans Affairs (VA)
- World Health Organisation (WHO)

## **Selecting terms for the vocabulary**

Altogether 24 patient safety terms are defined in a cross-cultural perspective. Please see table 1 for selected terms and definitions. In the process of choosing the terms suitable and necessary for a common European vocabulary, we emphasised terms which we found were ambiguous and/or interpreted differently in different European settings and clinical cultures. The definition of the terms and the mutual relations of the five core terms was tested by asking the question: “Do we understand the same thing by this term?”

The core terms are defined according to their relation to either process or outcome. An overview of the core terms and their relations is given in diagram 1. The five core terms of the vocabulary are:

- Adverse event
- Adverse outcome
- Actual event
- Near miss (sub-event)
- Harm

The terms of the vocabulary are ordered according to the four categories:

- Detection of risk
- Analysis of risk
- Resulting actions
- Failure mode

Table 2 shows the categorising of the terms.

In the process of deciding terms suitable for the vocabulary, a lot of terms were considered, but not chosen. Terms that were not chosen, were considered to be generally well-known terms, already well-defined across Europe. Yet another definition would not clarify nor add anything new. A list of such terms not chosen for the vocabulary is provided beneath.

The reader is referred to the wide range of international patient safety literature and to the reference list (1-14) for further definitions of these and other terms.

- |                              |                               |
|------------------------------|-------------------------------|
| – Accident                   | – Latent error                |
| – Active error               | – Non-harmful result          |
| – Active failure             | – Potential for harm          |
| – Blame                      | – Preventable adverse event   |
| – Clinical decision          | – Protection                  |
| – Clinical expectation       | – Reporting                   |
| – Clinical intended result   | – Root cause analysis         |
| – Clinical process           | – Situational awareness       |
| – Clinical result            | – System error                |
| – Clinical unintended result | – Unintended adverse event    |
| – Injury                     | – Unpreventable adverse event |
| – Latent failure             | – Voluntary reporting         |

## Definitions of the 24 terms of the vocabulary

Table 1. Definitions of the 24 terms of the vocabulary

| NO                       | TERM                         | DEFINITION  |
|--------------------------|------------------------------|---|
| <b>DETECTION OF RISK</b> |                              |   |
| 1                        | <b>Patient safety</b>        | The continuous identification, analysis and management of patient-related risks and incidents in order to make patient care safer and minimising harm to patients. Safety emerges from interaction of the components of the system. Improving safety depends on learning how safety emerges from such interactions.   |
| 2                        | <b>Adverse event</b>         | An unintended and undesired occurrence in the healthcare process because of the performance or lack of it of a healthcare provider and/or the healthcare system.<br><i>Please note: In this vocabulary adverse events are considered as preventable (cf. diagram 1) although the authors realise that the clinical distinction between preventable and non-preventable events is rather academic.</i>   |
| 3                        | <b>Actual event</b>          | An adverse event, which causes harm.  |
| 4                        | <b>Near miss (sub-event)</b> | An adverse event, with the capacity to cause harm but without adverse consequences, because of for instance timely and appropriate identification and prevention of potential consequences for the patient.   |
| 5                        | <b>Complication</b>          | An unintended and undesired outcome, which develops as a consequence of intervention of an already present illness. It may be non-preventable under the given circumstances.<br><i>Cf. the related definition of term number 12: 'adverse outcome'.</i>   |
| 6                        | <b>Sentinel event</b>        | Sentinel event reflects the seriousness of an injury and the likelihood that investigation of an event will reveal serious problems in current policies or procedures. Such occurrences signal the need for immediate investigation and response.   |
| 7                        | <b>Critical incident</b>     | Occurrences which are significant or pivotal in either a desirable or an undesirable way. Significant or pivotal means that there was significant potential for harm (or actual harm), but also that the event has the potential to reveal important hazards in the organisation. In other words, these incidents, whether near misses or events in which significant harm occurred, provide valuable opportunities to learn about individual and organisational factors that can be remedied to prevent similar incidents in the future. |
| 8                        | <b>Complaint</b>             | Each expression of resentment or discontent with the practice, operation or conduct of a healthcare provider, made by a potential user or a user of the health care services, or someone acting on their behalf.  |
| 9                        | <b>Reporting system</b>      | A system which is designed to contain reports on adverse events. On the basis of reports analysis and communication of known causes and risk situations is possible. The system can contain reports on human and technical errors as well as organisational circumstances which affect the occurrence of adverse events in the healthcare process. Reporting systems include input from all stakeholders – providers and service users.   |
| 10                       | <b>Professional standard</b> | The standard of performance in particular circumstances, taking into account recent insights, evidence-based norms and a standard of practice to be expected of a comparable, experienced, qualified and prudent practitioner in equal circumstances.<br><i>Cf. the related definition of term number 24: 'negligence'.</i>   |

Table 1. Definitions of the 24 terms of the vocabulary (cont.)

| NO                       | TERM                         | DEFINITION   |
|--------------------------|------------------------------|--|
| <b>ANALYSIS OF RISK</b>  |                              |  |
| 11                       | <b>Harm</b>                  | Negative consequence experienced by a patient leading to: death, a permanent or temporary impairment of physical, mental or social function or a more intense or prolonged treatment.  |
| 12                       | <b>Adverse outcome</b>       | An unintended and undesired occurrence in the healthcare process, which causes harm to the patient.<br><i>Cf. related definition of term number 5: 'complication'.</i>   |
| 13                       | <b>Risk</b>                  | The possibility or chance that something undesirable will happen. A measure of the probability and severity of potential harm.   |
| 14                       | <b>Calculated risk</b>       | A deliberately and consciously taken risk in which the benefits of a treatment are deemed to offset/countervail the possible burden of serious harm.   |
| 15                       | <b>Barrier</b>               | Barriers protect people and structures from adverse events.  |
| 16                       | <b>Situational awareness</b> | Refers to the degree to which one's perception of a situation matches reality.   |
| <b>RESULTING ACTIONS</b> |                              |  |
| 17                       | <b>Risk management</b>       | Identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance of risk, benefits and costs.   |
| 18                       | <b>Error management</b>      | An approach to managing the aftermath of an error with the goal of reducing future errors, avoiding negative consequences and dealing quickly with consequences once they occur.   |
| 19                       | <b>Action plan</b>           | An action plan can be the result of analysis of adverse events. The action plan addresses system and process deficiencies; improvement strategies are developed and implemented.   |
| 20                       | <b>Culture of safety</b>     | An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seek to minimise patient harm, which may result from the processes of care providing.   |
| 21                       | <b>Human factor</b>          | Refers to the study of human abilities, behaviour and characteristics as they affect the design and intended performance of equipment, systems, and jobs. The field concerns itself with considerations of the strengths and weaknesses of human behaviour, with physical and mental abilities, and how these affect the systems design. |
| <b>FAILURE MODE</b>      |                              |  |
| 22                       | <b>Error</b>                 | Preventable event, leading to an adverse outcome being either an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or has significant potential for such an outcome.  |
| 23                       | <b>Situational factor</b>    | The factor in a process which activates an error in the system.  |
| 24                       | <b>Negligence</b>            | Care provided that failed to meet the standard of care within reason to be expected of a prudent and careful practitioner, qualified to care for the patient in question. <i>Cf. the related definition of term number 10: 'professional standard'.</i>  |

Table 2. Overview of categorised terms of the vocabulary

| <b>DETECTION OF RISK</b> |                       | <b>ANALYSIS OF RISK</b> |                       | <b>RESULTING ACTIONS</b> |                   | <b>FAILURE MODE</b> |                    |
|--------------------------|-----------------------|-------------------------|-----------------------|--------------------------|-------------------|---------------------|--------------------|
| <b>No</b>                | <b>Term</b>           | <b>No</b>               | <b>Term</b>           | <b>No</b>                | <b>Term</b>       | <b>No</b>           | <b>Term</b>        |
| 1.                       | Patient safety        | 11.                     | Harm                  | 17.                      | Risk management   | 22.                 | Negligence         |
| 2.                       | Adverse event         | 12.                     | Adverse outcome       | 18.                      | Error management  | 23.                 | Situational factor |
| 3.                       | Actual event          | 13.                     | Risk                  | 19.                      | Action plan       | 24.                 | Error              |
| 4.                       | Near miss             | 14.                     | Calculated risk       | 20.                      | Culture of safety |                     |                    |
| 5.                       | Complication          | 15.                     | Barrier               | 21.                      | Human factor      |                     |                    |
| 6.                       | Sentinel event        | 16.                     | Situational awareness |                          |                   |                     |                    |
| 7.                       | Critical incident     |                         |                       |                          |                   |                     |                    |
| 8.                       | Complaint             |                         |                       |                          |                   |                     |                    |
| 9.                       | Reporting system      |                         |                       |                          |                   |                     |                    |
| 10.                      | Professional standard |                         |                       |                          |                   |                     |                    |

Diagram 1. Overview of relations between the core terms of the vocabulary

| PROCESS   | Actual event*  |   | Near miss* (sub-event)   |  |   |
|---|--|---|--|--|---|
|   | Non-preventable event  | Preventable event<br>(adverse event*)   |  |  |   |
| OUTCOME   | Harm: adverse outcome*   |   | No harm*   |  |   |
| Examples of events as illuminated in the analysis |  |   |  |  |   |
|   | <p>Example 1.<br/>A patient does not report any intolerance of penicillin. The penicillin is administered, and the patient develops an anaphylactic shock. In the analysis the reaction was found to be related to the disease of the patient.</p> | <p>Example 2.<br/>A patient reports <i>not</i> to tolerate penicillin. The patient receives the penicillin and develops an anaphylactic shock.</p>  | <p>Example 3.<br/>A patient reports <i>not</i> to tolerate penicillin. The patient receives the penicillin. The patient does not develop any allergic reaction worth mentioning.</p> | <p>Example 4.<br/>A patient, who is allergic, does not report any intolerance of penicillin. Before the penicillin is injected, a relative arrives and points out that the patient does not tolerate penicillin. The event is prevented.</p> | <p>Example 5.<br/>A patient reports <i>not</i> to tolerate penicillin, and it is documented in the electronic patient file. As the doctor is about to prescribe penicillin in the electronic patient file, a pop-up alert warns him about the allergy. The prescription is altered accordingly.</p> |
|   |  | <p>Example 6.<br/>A patient is not clear in reporting tolerance to penicillin. The doctor calculates the risk according to the available information. Some patients in this situation will get the penicillin. Some of these patients may react to the penicillin, while others will tolerate it.</p> |  |  |   |

\* Terms in bold are defined in the vocabulary

## **Patient Perspectives**

Patient perspectives are represented in the work of WP4 in different ways, firstly the organisation Action against Medical Accidents (AvMA), an independent English charity, promoting better patient safety and justice for people who have been adversely affected by a medical accident, was represented in the overall project meetings; secondly two patient representatives were asked to review and comment on the vocabulary and a draft of this report; thirdly a range of international and national patient interest groups and organisation representatives participated in the SImpatIE Consensus Conference in Luxembourg.

## **Main Conclusions and Recommendations**

A set of 24 definitions of patient safety terms and a framework illustrating the connection of the five core terms of the vocabulary are available for use in Europe. The vocabulary is aimed at professionals, e.g. risk managers, administrators, project managers and others working with patient safety. The vocabulary covers the domains: 'Detection of Risks', 'Analysis of Risks', 'Resulting Actions' and 'Failure Mode'. The vocabulary is available in English via [simpatie.org](http://simpatie.org).

Cultural differences in the field of patient safety in Europe were revealed in discussions about definitions of the terms, their relations and usability. This underlines the need for common definitions of terms as a basis for mutual understanding in the cross-cultural European work on patient safety.

One aim of the Council of Europe is to achieve a greater unity among its members. This aim may be pursued in promoting the use of the vocabulary. The vocabulary serves particularly as a basis for applying the evaluation tools from the toolbox of WP4 and WP5, but it also supports the efforts to make European patient-safety programmes use the same language, a consistent terminology, and be focused around similar concepts.

The vocabulary is explicitly neither a taxonomy nor a classification of adverse events. For such publications we refer to the International Patient Safety Event Classification by the World Health Organisation (15).

In this context we strongly recommend that the vocabulary and the vocabulary framework (diagram 1) be made accessible in the European countries. It should be translated into the European languages, using a standardised method, and adequate local implementation strategies should be developed; healthcare organisations, professional and scientific bodies and educational institutions should be made aware of the existence of the vocabulary, be encouraged to use it as suggested so that the key elements can be put into everyday practice

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