Risk Identification Ontology (RIO): An ontology for specification and identification of perioperative risks

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ABSTRACT

Medical personnel in hospitals often works under great physical and mental strain. In medical decision making, errors can never be completely ruled out. Studies exposed that between 50 and 60 percent of adverse events could have been avoided through better organization, more attention or more effective security procedures. Critical situations especially arise during interdisciplinary collaboration and the use of complex medical technology, for example during surgical interventions and in perioperative settings. In this paper we present an ontology and an ontology-based software system which can identify risks across medical processes and which supports the avoidance of errors in the perioperative setting in particular.

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1 INTRODUCTION

Patient safety is a quality target and an important factor of the quality of treatment in hospitals in general ("Empfehlung Zur Einführung von CIRS Im Krankenhaus" 2007). Prevention of medical errors and risks is a significant method to improve patient safety. Medical personnel often works under great physical and mental strain. In medical decision making, errors can never be completely ruled out (Mahajan 2010). In 2000, the report "To Err is Human" (Kohn 2008) was published by the Institute of Medicine of the US National Academy of Sciences (IOM). This attracted great international attention and moved the topics of medical risks, errors and patient safety into the focus of the scientific interest. The IOM concluded in the report that from 2.9 to 3.7 percent of all patients admitted to hospitals in the USA suffer an adverse event. In 70 percent of these cases, the patient retains no or only minor damage, 7 percent lead to permanent damage and 14 percent cause the patient's death. The study also exposed that between 50 and 60 percent of these adverse events could have been avoided through better organization, more attention or more effective security procedures. Even for Germany, analyses show that the number of medical errors is not negligible. According to a report by the Robert Koch Institute (Hansis et al. 2007), the incidence of suspected medical errors is approximately 40,000 cases across Germany per year. The error recognition rate of about 30%, corresponds well to approximately 12,000 recognized medical errors.

Since the publication of "To Err Is Human", risk management and patient safety has consistently remained a topic of interest for scientific studies as well as for suggestions of goals for improvements (Bunting et al. 2016). Critical situations arise especially during interdisciplinary collaboration and the use of complex medical technology, for example during surgical interventions and in perioperative settings. Especially the oversight of medically relevant treatment data or an incomplete medical history may cause an incorrect treatment ("Aus Fehlern Lernen" 2008).

We present an ontology and a conception for an ontology-based software tool which can identify and analyze risks across medical processes. Furthermore, the tool supports the avoidance of errors in the perioperative setting. The results of the risk analysis are transmitted to the medical personnel in form of context sensitive hints and alerts. The software architecture is designed to respond not only to risks within a single treatment step, but it also takes into account the patient's entire stay in the hospital. For a practical implementation in the clinical environment, the cochlear implantation (CI) has been selected as a surgical use case at Jena University Hospital. Here, medical and technical treatment risks were analyzed, and medical guidelines and standards were taken into account. In addition, data and information sources have been defined on the basis of an anonymized CI patient record. Further sources of critical events were collected by undertaking of qualitative interviews with technical, nursing and medical personnel participating in a CI. On this basis, risk situations were defined and integrated into ontological models. This work is a part of the BMBF-supported project OntoMedRisk ("OntoMedRisk" 2016).

2 METHODS

2.1 Introduction in General Formal Ontology (GFO)

The development of the intended ontologies and of the needed ontological analyses are carried out within the top-level ontology GFO (Herre 2010; Herre et al. 2006). In GFO the entities of the world are classified into categories and individuals. Categories can be instantiated, individuals are not instantiable. GFO allows for categories of higher order, i.e., there are categories whose instances are themselves categories, for example the category "species". Spatio-temporal individuals are classified along of two axes, the first one explicates the individuals' relation to time and space, and the second one describes the individuals' degree of existential independence.

Spatio-temporal individuals are classified into continuants, presentials and processes. Continuants persist through time and have a lifetime; they correspond to ordinary objects, as cars, balls, trees etc.

The lifetime of a continuant is presented by a time interval of non-zero duration; such time intervals are called chronoids in GFO (Baumann et al. 2014). Continuants are individuals which may change, for example, an individual cat *C* crossing the street. Then, at every time point *t* of crossing *C* exhibits a snapshot *C(t)*; these snapshots differ with respect to their properties. Further, the cat *C* may lose parts while crossing, though, remaining the same entity. The entities *C(t)* are individuals of their own, called presentials; they are wholly present at a particular time point, being a time boundary. Presentials cannot change, because any change needs an extended time interval or two coinciding time boundaries.

Processes are temporally extended entities that happen in time, for example a run; they can never be wholly present at a time point. Processes have temporal parts, being themselves processes. If a process *P* is temporally restricted to a time point then it yields a presential *M*, which is called a process boundary of *P*. Hence, presentials have two different origins, they may be snapshots of continuants or process boundaries. There is a duality between processes and presentials, the latter are wholly present at a time point whereas this is never true for processes. The corresponding classes/sets of individuals, denoted by the predicates *Cont(x)*, *Pres(x)*, and *Proc(x)*, are assumed to be pair-wise disjoint. Processes present the most important kind of entity, whereas presentials and continuants are derived from them. There are several basic relations which canonically connect processes, presentials, and continuants (Herre 2010; Herre et al. 2006).

Spatio-temporal individuals, according to the second axis, are classified with respect to their complexity and their degree of existential independency. Attributives depend on bearers which can be objects (continuants, presentials) and processes. Situations are parts of reality which can be comprehended as a coherent whole (Barwise et al. 1983). They are complex presentials and boundaries of situoids, being processes which satisfy certain principles of coherence, comprehensibility, and continuity. A surgical intervention is an example of a process or a situoid. A snapshot of this situoid at a certain time point is a surgical situation, which has spatial location and includes various entities such that a coherent whole is established.

There is a variety of types of attributives, among them, qualities, roles, functions, dispositions, and structural features. Categories the instances of which are attributives are called properties throughout this paper. According to the different types of attributives (relational roles, qualities, structural features, individual functions, dispositions, factual, etc.) we distinguish quality properties (or intrinsic properties) and role properties (extrinsic properties), and the role properties are classified into relational role properties (abr. relational properties) as well as social role properties (social properties).

2.2 Ontological Definition of the Risk Notion

The solution of all philosophical problems, related to the notion of risk, is out of scope of this paper. Instead, we focus on a practicable definition of the risk notion, which can be easily understood by the medical staff and is usable for the software tools. Based on this definition, it should be possible for the medical staff to specify the relevant risk types, and for the software to identify and to analyze the risk in a particular treatment situation.

There are various definitions of the notion of risk. One of the most known/popular definitions is that by (Kaplan et al. 1981). These authors divide the notion of risk into three components which are associated to the following questions:

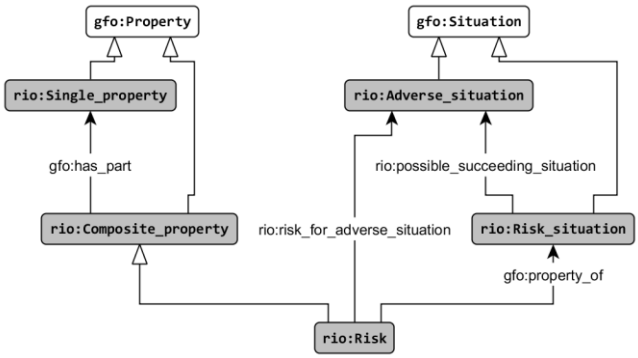

Fig. 1. Definition of the risk notion (the white arrows represent the is-a relation)

1. What can happen, i.e., what can go wrong? (scenario)
2. How likely is it that that will happen? (probability of the scenario)
3. If it does happen, what are the consequences? (consequence of the scenario)

A risk, then, is a triple which consists of a scenario, the probability of that scenario, and consequence of that scenario. Furthermore, there are several standards investigating the notion of risk. The ISO/IEC 27005 ("Information Technology -- Security Techniques -- Information Security Risk Management" 2008) defines the notion of risk as "a potential that a given treat will exploit vulnerabilities of an asset or group of assets and thereby cause harm to the organizations."; the OHSAS 18001 ("OHSAS 18001 (Occupation Health and Safety Assessment Series)" 2007) - as a "combination of the likelihood of an occurrence of a hazardous event or exposure(s) and the severity of injury or ill health that can be caused by the event or exposure(s)"; and the ISO 31000 (Risk management) (Purdy 2010) - as an "effect of uncertainty on objectives". The common ground of all these definitions is that all of them consider a risk as a possibility for the occurrence of a particular event or situation. Most of these definitions consider such events as adverse ones, whereas in the standard ISO 31000 both adverse and positive events are admitted.

The ontological analysis of risk is carried out within the framework of GFO and takes into account the available definitions of risk. The analysis is built upon the ontology of situations and situation types, which partly uses ideas presented in (Barwise et al. 1983; Stalnaker 1986). Situations which contain adverse events, being related to a risk, are called adverse situations. In this paper we use the notion of adverse event/situation not only in the sense of "*Any untoward occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relation to the treatment*" (Edwards et al. 2000), but we also include events/situations that are not related to medical interventions. A situation *S* is said to be a risk situation if it satisfies certain conditions which imply that one of the possible succeeding situations of *S* is an adverse situation.

The notion of possible situation is established within the framework of a particular actualist representationism, which postulates that possible objects are abstract entities, the existence of which is consistent with the currently available knowledge about the actual world. This view is partly influenced by (Adams 1974; Roper 1982; Zalta 1993).

We hold that a risk exists in a situation, that it depends on it, and, hence, that it can be considered as a situation's property. We distinguish between single (in sense of gfo:Property (Herre 2010)) and

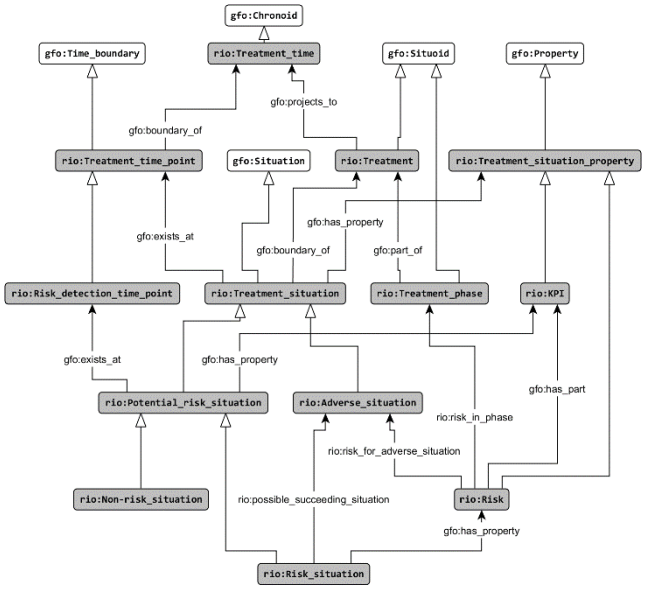

Fig. 2. Risk Identification Ontology (RIO)

composite properties, the latter being composed of single ones and which can be disassembled by the relation gfo:has_part.

Definition 1. A composite property *CP* is a property that has as parts several single properties *SP1*, ..., *SPn*.

Definition 2. A risk for an adverse situation of type *AST* is a composite property *CP* such that every situation *S* possessing the property *CP* has a possible succeeding situation of type *AST* which can be realized with a certain probability.

Definition 3. A risk is a composite property *CP* for which there exists an adverse situation *AST* such that *CP* is a risk for the adverse situation *AST* (as defined by 2).

Definition 4. A risk situation is a situation having at least one risk (Fig. 1).

Example 1. The risk of a bacterial infection during cochlear implantation in infants depends on various parameters, such as the infants' age, the corresponding bone thickness of the skull and the inner ear structure. If the child is younger than 5 months, the bone thickness mostly remains below 2 mm. Thus, the risk of penetrating the skull and injuring the dura mater during surgery increases so that the bacterial dura mater infection risk (meningitis) increases as well. The ground-truth probability for the adverse event of dura mater infection during CI is about 5-9% (Reefhuis et al. 2003). For meningitis prevention the patient has to be vaccinated against pneumococcus, meningococcus and haemophilus influenzae type b several weeks before the surgery (indication phase). In addition, an antibiotic prevention should be performed right before the surgery. According to our definition an increased risk for acquiring meningitis can be represented as a composite property, consisting of three single properties, namely, the young age (< 5 month), the absence of a meningitis vaccination, as well as of an antibiotic prevention. This example is used in this paper for further explanations.

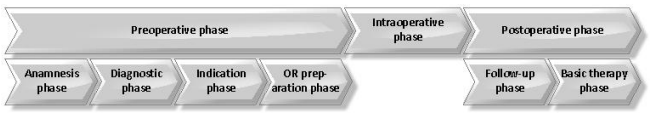

Fig. 3. Treatment phases

3 RESULTS

3.1 Risk Identification Ontology (RIO)

We developed a risk identification ontology (RIO, Fig. 2) which is built upon the ontological model of the notion of risk. This ontology is used for the specification and the identification of perioperative risks. The ontology RIO is embedded into the GFO. As starting point we consider the treatment process, which may possess various treatment phases (gfo:has_part). The complete treatment as well as the phases are complex processes (gfo:Situoid). The treatment has a particular temporal extension, called the treatment time (gfo:Chronoid). According to GFO processes are projected (gfo:projects_to) onto its time intervals. For every time point (gfo:Time_boundary) of the treatment exists (gfo:exists_at) exactly one treatment situation (gfo:Situation). A treatment time point is according to GFO a boundary of the treatment time (gfo:boundary_of), whereas the corresponding treatment situation is a boundary of the treatment itself.

For each treatment phase particular time points, called risk detection time points (RDTP), can be defined. The treatment situations, existing at these time points, are analyzed with respect to the existence of risks. Such situations are called potential risk situations (PRS), because they do not necessarily contain risks. Situations and in particular treatment situations possess various properties (gfo:Property). These properties may belong to the situation, but also to the participants, as, for example physicians (doctors), medical instruments, and, most important, to the patients. We consider these properties also as properties of the current treatment situation (gfo:has_property). Properties of the potential risk situations that are relevant for the estimation of the risk are called in this paper KPIs (Key Performance Indicators). According to **Definitions 1-4** a particular combination of a subset of the KPIs of a PRS (for example, age of patient = 3 months, menginitis vaccination = false) represents a risk if the PRS may lead to a later time point to an adverse situation (rio:possible_succeeding_situation).

A PRS may contain various risks, and risks of the same type may occur in distinct PRS and may lead to distinct adverse situations (rio:risk_for_adverse_situation). Each KPI is associated with potential risk situations, whereas the risk situations additionally possess the composite risk properties. Furthermore, the risks can be related to those treatment phases for which they are relevant (rio:risk_in_phase). Adverse situations may exhibit various degrees of severity and risks may possess various probabilities for the occurrence of adverse situations.

With help of the RIO the risks in a current potential risk situation are identified by the software component OntoRiDe, and, hence the situation can be classified either as a risk or as a non-risk situation.

3.2 Risk Specification

3.2.1 Perioperative risk assessment

For the development of a perioperative risk identification ontology the recognition and assessment of potential medical, technical, organizational and human risk factors are an essential prerequisite. Therefore, an extensive risk assessment has been performed for an otorhinolaryngological use case. The insertion of cochlear implants (CI) was chosen in order to demonstrate the features and benefits of the ontology-based risk identification system. The perioperative medical and technical risk factors, procedure related complications and their complication rates as well as prevention strategies were

Risk	*Infection_Risk_001*					
Risk Specification Rule	(c1 OR c2 OR c3) AND (c4 OR c5) AND c6					
Message	Risk of **Dura Mater Bacteria Infection (Meningitis)**. Please check antibiotic administration and vaccination status (pneumococcus, meningococcus and haemophilus influenzae type b).					
Condition Nr	KPI	Operator	Values	Adverse Situation	Probability	Treatment Phase
c1	Age_in_months	IN	[0; 5)	Dura_Mater_Bacteria_Infection	[0.05; 0.09]	Indication
c2	Skull_bone_thickness	IN	[0; 2]			
c3	Ear_structure	==	"abnormal"			
c4	Vaccination_status	==	"no"			
c5	Vaccination_status	==	"unknown"			
c6	Antibiotic_prevention	==	false			

Fig. 4. Risk specification

extracted from peer-reviewed publications and evidence-based best-practice guidelines of the German Society of Oto-Rhino-Laryngology, Head and Neck Surgery (Lenarz et al. 2012). In addition, entries of the Critical Incident Reporting System (CIRS) of the University Hospital Jena (Germany) and an example of an anonymized patient record have been analyzed for organization and human-related risk assessment. The derived risk characteristics, potential following adverse situations and their causes were used to describe relevant perioperative and cross-process risks factors.

3.2.2 Perioperative process modeling

The information of risk factors and of potentially adverse events has to be provided to the responsible medical personnel in the right time by offering appropriate context-sensitive hints and alerts. Therefore, the medical and organizational processes have to be taken into account. The general perioperative workflow of the CI treatment was modeled and visualized in a process diagram, as event-driven process chain (EPC). In the following, both generalized and use-case specific treatment phases have been defined in the formal process model. The generalized treatment phases are depicted in Fig. 3. Besides the CI treatment process, the defined phases are suitable for representing various elective surgeries and interventions.

The treatment process was modeled by representing the sequence of clinical activities, treatment decisions, parallel processes and possible events, the involved persons as well as resources, like data and documents, medical devices or IT systems. In addition, the identified risk factors, complications and prevention activities were integrated in the process model.

By mapping the identified risk factors to the dedicated activities and treatment phases, the process model has then been used subsequently for further risk assessment and perioperative risk modeling. This enabled over 120 potential perioperative risks to be identified and also mapped to their related process step in the process model.

3.2.3 Perioperative risks modeling

In the next step the identified potential risk factors, adverse situations and critical incidents, which are related to cochlear implantation interventions, were examined in an extensive risk analysis. Thereof, a risk classification for formal risk specification was derived. The identified risk factors were subsequently classified into different categories of medical, organizational, technical or human-related risks. Thus, the treatment phases were categorized into risk detection phases, in which the corresponding risk is relevant and could potentially lead to an adverse situation. Additionally, there is a category for cross-process risks, which could lead anytime to an adverse situation, e.g. the risk of dizziness and falls or the high bleeding risk during surgery due to anticoagulant medication.

For each treatment phase different KPIs have been defined, which allow the identification of specific perioperative risks. The KPIs are linked with operators and a certain data type value to a conditional expression of a possible risk factor (e.g., c1: Age_in_months IN [0, 5), c4: Vaccination_status == “no”, Fig. 4, Example 1). The KPI data type values could be for instance a Boolean value, text, date or number. A combination of these conditional expressions is formalized as a risk specification rule. If the risk specification rule becomes true, due to the values of their conditions and KPIs, there is a high occurrence probability of adverse situations, which have to be also specified for each risk. In addition, for each adverse situation an occurrence probability and a severity (on a separate sheet) have been defined. In the risk specification, the KPIs were described along with their possible acquisition sources. Therefore, the risk specification defines both the required measurement phases and the measurement sources, like patient-related data and sensor data, e.g. data from the digital patient record, the hospital information system, checklists or situations in actual process execution. In Fig. 4 a risk specification based on Example 1 is presented.

Age_in_months_ge_0_to_5_l	has_data_value some xsd:double[>= "0.0"^^xsd:double , < "5.0"^^xsd:double]
Skull_bone_thickness_ge_0_to_2_le	has_data_value some xsd:double[>= "0.0"^^xsd:double , <= "2.0"^^xsd:double]
Ear_structure_e_abnormal	has_data_value value "abnormal"^^xsd:string
Vaccination_status_e_no	has_data_value value "no"^^xsd:string
Vaccination_status_e_unknown	has_data_value value "unknown"^^xsd:string
Antibiotic_prevention_e_false	has_data_value value false

Fig. 5. Risk conditions

The tool RIOGen, developed within the project, generates ontological entities from the risk specification and inserts it into RIO. For every risk condition, for example, a subclass of the corresponding KPI is inserted. Here the class names are automatically generated according to certain rules. For every condition class an anonymous equivalent class is created as property restriction, based on the property has_data_value (Fig. 5). Then, for the risk a subclass of rio:Risk is defined, which is named as the risk. For the risk subclass also an equivalent anonymous class is defined which is based on the has_part property and on the corresponding condition classes; this anonymous class represents the risk specification rule (Fig. 6). Furthermore the treatment phases are created and connected with those KPIs and risks which are relevant for them. Finally, we define the connection between risks and those adverse situations, which possibly evolve from them (incl. probability and severity as data property restrictions).

3.3 Ontology-based Risk Detector (OntoRiDe)

We developed an ontology-based software module, called Ontology-based Risk Detector (OntoRiDe), which allows the identification of the ontologically specified risks. This tool receives the KPIs of the current potential risk situation as input parameter, and carries out the risk specification rule, which is contained in the ontology; then it classifies the current situation as risk or non-risk situation and returns the results. If the current KPIs satisfy one of the rules (i.e., at least one risk is recognized) then the considered situation is a risk situation, otherwise it is a non-risk situation.

Further information, which the tool returns to the user, includes the description of the existing risks, the treatment phases, in which the risks are relevant, but also the adverse situations which may evolve from them (with probability of occurrence and degree of severity). A particular position is the possibility to recognize the risks, but, furthermore, to determine and provide for every recognized risk all possible combinations of current KPIs which are responsible for every recognized risk. Using this information the user is able to eliminate all of the risks‘ causes.

In the following we briefly sketch the functionalities of the OntoRiDe. For every risk class the corresponding risk specification rule, which is specified as an anonymous equivalent class (Fig. 6), is in-

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((has_part some Age_in_months_ge_0_to_5_l) or
(has_part some Skull_bone_thickness_ge_0_to_2_le) or
(has_part some Ear_structure_e_abnormal)) and
((has_part some Vaccination_status_e_no) or
(has_part some Vaccination_status_e_unknown)) and
(has_part some Antibiotic_prevention_e_false)
```

Fig. 6. Risk specification rule

terpreted and transformed into a disjunctive normal form (by stepwise execution of the de Morgan rules and of the law of distributivity). Any of the conjunctions presents a possible explanation for the risk (e.g., c1 AND c4 AND c6, Fig. 4). Then, the single conditions (Fig. 5) are checked, i.e., it is determined whether the current KPI value is included in the specified value range. If all conditions of the conjunction are satisfied, then the corresponding KPIs and further information are provided for the user as explanation.

We decided not to use a standard reasoner. Firstly, we want to apply rules of types which cannot be easily interpreted by standard reasoners, especially rules which contain mathematical expressions or predefined constants. Such special types of rules are implemented by the OntoRiDe. Secondly, standard reasoners carry out various tasks (checking consistency, classification, and realization), not all of them are relevant for risk identification, but which reduce the efficiency of the overall system. Finally, OntoRiDe must provide the user with all possible explanations about the existence of a risk in the current situation in an understandable way. The problem of detection and exploration of all possible explanations and justifications of an entailment is a well-known task, for the solution of which there exists several methods and tools, (Kalyanpur et al. 2007; Horridge et al. 2012; Riguzzi et al. 2013). Furthermore, there are various investigations about the cognitive complexity and the understanding of the considered justifications (Horridge et al. 2013; Horridge et al. 2011). In this context a justification of an entailment is understood to be "the minimal set of axioms sufficient to produce an entailment" (Kalyanpur et al. 2007). In the case of RIO and OntoRiDe the solution is rather simple. The OntoRiDe translates the risk specification rules into a disjunctive normal form and checks all conditions of the respective conjunctions. By this procedure all KPI-combinations, verified by the rule as true, and the corresponding conditions (value ranges), can be provided for the user in form of understandable explanations (e.g., age < 5 month and vaccination = "no" and antibiotic prevention = false).

3.4 Agent System

An agent system was developed to get access to the distributed data in various systems in hospital needed to derive elementary information for the risk detection. The KPIs mainly determine the data which has to be captured by the agent system, respectively the parameters which have to be monitored. Throughout the entire perioperative treatment process the agent-based system retrieves risk-relevant data from different data sources and provides these data for further risk analyses in a centralized fashion. The results of such an analysis will be transferred to medical experts as context-sensitive hints and alerts. In doing so, continuous patient-specific risk monitoring is facilitated for each treatment phase of the perioperative treatment process. The OntoRiDe is an important component of the agent system, because it determines the KPIs which have to be monitored and it identifies the risks which have to be analyzed. This reduces the risk of adverse situations and complications through early and adequate interventions. The software-based agent system has been implemented using the Java Agent Development Framework

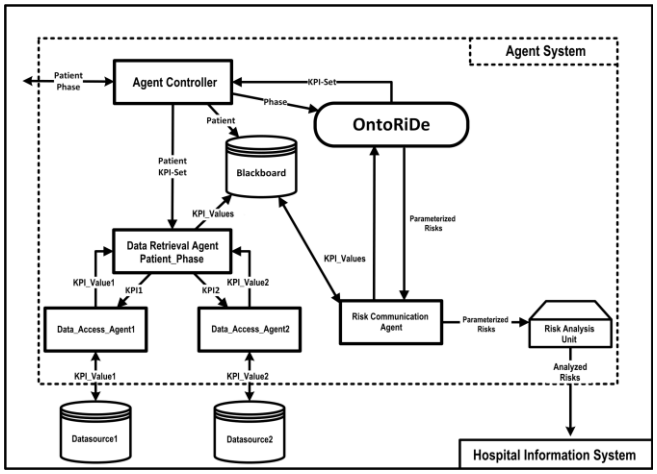

Fig. 7. Architecture of the agent system

(JADE), which embodies a framework, a platform and the middleware for a FIPA-standardized development of multiagent systems (MAS). The main functions of a JADE-based agent system can be categorized into agent behavior and agent communication. The agents communicate in an asynchronous, message-based fashion, using the Agent Communication Language (ACL) ("Jade: Java Agent DEvelopment Framework" 2016; "The Foundation for Intelligent Physical Agents" 2016). The architecture of the agent system consists of the OntoRiDe, a Blackboard, a Risk Analysis Unit and various agents. The functionality of the agent system can be separated into data acquisition and risk communication (Fig. 7). The internal data storage of the agent system is based upon the HL7-FHIR-Spezification. Therefore, the data is represented as FHIR-Resources ("FHIR: Fast Healthcare Interoperability Resources" 2016).

4 RELATED WORK

Several approaches towards the formal representation of risks and adverse events through ontologies are described in the literature. We analyzed these existing ontologies for their potential to detect perioperative risks in hospitals, but we concluded that none of these ontologies and tools could be applied to our project.

Bouamrane et al. (Bouamrane et al. 2010; Bouamrane et al. 2009a; Bouamrane et al. 2009b) report on the development of an ontology-based system to support clinical decision making. The support is provided in a two-step process. First, the developed system calculates risk scores using numerical formulas. In this step, the system does not use the developed ontology but computes numeric values using an open-source Java-based rule engine (JBoss Rules). After calculating the relevant risk scores, the DL reasoner (Pellet) classifies the patient into a number of predefined categories for risks, recommended tests and precaution protocols, using the OWL-DL representation of the patient medical history profile and the decision support ontology. The decision support ontology is divided into three domains: a risk assessment ontology, a recommended test ontology and a precaution protocol ontology. The aim of the risk assessment ontology is to detect potential risks of intra-operative and post-operative complications in a given formal representation of a patient medical profile.

Similar to the Bouamrane system, our approach also provides two components of decision support namely OntoRiDe and Risk Analysis Unit (Fig. 7). They can perform similar tasks as those of

Bouamrane's system. In addition, OntoRiDe will also use the self-developed RIO for risk identification similarly to the usage of the risk assessment ontology. However, there are also important differences between the two ontologies and systems. The risk assessment ontology focuses only on the patients risk related to intra-operative and post-operative complications such as cardio-vascular and respiratory risks, whereas RIO covers various risk types such as special and general treatment risks, technical risks, organizational risks etc. The second significant difference is that our approach integrates the treatment process, its steps and situations in the risk conceptualization. In this way, it is possible to analyze and identify cross process risks or risk situations so that errors especially in the perioperative field could be avoided.

In (Third et al. 2015) the authors describe a model for representing scientific knowledge of risk factors in medicine. This model enables the clinical experts to encode the risk associations between biological, demographic, lifestyle and environmental elements and clinical outcomes in accordance with evidence from the clinical literature. The major advantage of our approach in comparison with the model developed by Third is the formal representation of cross process risks that can lead to potential adverse situations during different treatment phases. Another added value of our approach is that it can also cover risks related to human and environmental factors such as technical or organizational risks. These types of risks are not considered in Third's model.

(Sigwarth et al. 2015) present an ontology of the Open Process Task Model (OPT-Model). This ontology is primary intended as a generic knowledge base, which implements the various influences of processes and their relations in medical environments, for a prospective risk analysis. The advantage of RIO over the OPT-model-ontology is that it provides an accurate risk analysis. By using RIO, OntoRiDe is able to perform risks classification according to the risk occurrence time. This process allows us to identify the time point and treatment phase on which a risk arise. Another further benefit of RIO is the implicitly embedded risk specification, which meets the spirit of evidence-based medicine. This implicit domain knowledge is encoded in OWL rules and can be inferred automatically using ontological reasoning to assess current perioperative risk situations.

(Bau et al. 2014) report a clinical decision support system (CDSS) for undergoing surgery based on domain ontology and rules reasoning in the setting of hospitalized diabetic patients. Similar to our approach this system uses logical rules to complement the domain knowledge with implicitly embedded risk specification and clinical domain knowledge. The important upside of our approach is that it does not make restrictions based on certain diseases such as diabetes mellitus, whereas CDSD focuses only on glycemic management of diabetic patients undergoing surgery.

The Ontology of Adverse Events (OAE) (He et al. 2014) and the Ontology of Vaccine Adverse Events (OVAE) (Marcos et al. 2013) (Marcos, Zhao, and He 2013), which was developed based on OAE, describe data relating to adverse events. The OAE was designed to standardize and integrate data relating to adverse events that occur after medical intervention. The OVAE is used for representing and analyzing adverse events associated with US-licensed human vaccines. In OAE the notion adverse event is defined as a pathological bodily process that occurs after a medical intervention (e.g., following a vaccination), while a risk is represented by a factor associated with the occurrence of an adverse event. The work presented here focuses instead on the risk situations and proposes a generic model for the risk specification in the perioperative area. Thus, we don't restrict ourselves to risks that are causally and exclusively related to medical interventions. Contrary to OAE, our approach also considers other risk types such as technical and organizational risks. Moreover, we use the term "adverse situation" in order to avoid excluding situations that are not related to medical interventions.

None of the presented approaches can answer competency questions such as "Which treatment situation could be a potential risk situation?", "Which properties or KPIs are responsible for an actual risk situation?" and "Which risk situation belongs to which treatment phase?". The aim of RIO and OntoRiDe is to solve this issue.

5 CONCLUSION AND FUTURE WORK

We elaborated an ontological foundation of the notion of risk, upon which we developed a risk identification ontology (RIO). With help of RIO perioperative risks can be specified, whereas OntoRiDe can be used to identify risks in a current treatment situation. This allows the recognition of risk situations and supports the avoidance of possible adverse situations. Furthermore, we conceptualized an agent system which is currently implemented. This agent system gathers during the whole perioperative treatment process risk-relevant data from various sources and provides it for the risk identification resp. the risk analysis in a centralized fashion. The results of such an analysis are transmitted to the medical personnel in form of context sensitive hints and alerts.

We are currently working on the specification of risks. About 20 risks relating to cochlear implantation have already been specified, and on this basis the functionality of RIO, RIOGen and OntoRiDe successfully tested.

Future work includes the conception of mathematical evaluation methods and algorithms for the assignment of a risk to the current process status and determination of the probability of occurrence. The agent system will include risk communication features. In particular, a Risk Analysis Unit for risk assessment (based on probability and severity) and Cockpit component should be developed. These components implement a role-based visualization of risk information and of context-sensitive hints for the medical experts. In the further development, this visualization should also be displayed role-based on mobile devices. Furthermore, it is intended to expand and to optimize the application of this agent system to other use cases.

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