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# Evaluating Interoperability in German Critical Incident Reporting Systems

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**Abstract. Introduction:** In industrialised countries, one in ten patients suffers harm during hospitalization. Critical Incident Reporting Systems (CIRS) aim to minimize this by learning from errors and identifying potential risks. However, a lack of interoperability among the 16 CIRS in Germany hampers their effectiveness. **Methods:** This study investigates reports' syntactic and semantic interoperability across seven different reporting systems. Syntactic interoperability was examined using WHO's Minimal Information Models (MIM), while semantic interoperability was evaluated with SNOMED concepts. **Results:** The findings reveal a low structural overlap, with only two terms correctly represented in the SNOMED CT terminology. In addition, most systems showed no syntactic interoperability. **Conclusion:** Improving interoperability is essential for increasing the effectiveness and usability of CIRS. The study suggests a unified data model such as MIM or using Health Level 7 Fast Healthcare Interoperability Resources (HL7 FHIR) resources and expanding SNOMED CT with patient safety-relevant terms for semantic interoperability. Given the current lack of both syntactic and semantic interoperability in CIRS, developing a patient safety ontology is recommended for efficient critical incident analysis too.

**Keywords.** Interoperability, semantic, syntactic, CIRS, SNOMED CT

## 1. Introduction

In industrialised countries, one in ten patients is harmed during a hospital visit. Studies in the USA have shown significant costs resulting from errors during medical care. In one study with about 400,000 patients, the damage caused by medical errors per year cost amounted to 20 billion dollars [1]. Adverse events occur in between 400,000 and 800,000 hospital patients in Germany every year, with avoidable mortality affecting to 20,000 patients per year [2].

In the context of patient safety, Critical Incident Reporting Systems (CIRS) play a central role [3,4]. CIRS and mortality conferences are referred to as generating

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procedures because the reports are intended to draw attention to unknown factors [5]. The implementation of CIRS is based on the idea of learning from mistakes, identifying potential risks and problems early through systematic analysis, and eliminating them [6,7].

The "Aktionsbündnis Patientensicherheit e.V." (German Coalition for Patient Safety - APS) describes the organizational requirements and processes of operating reporting systems in detail. However, one aspect remains unconsidered: the exchangeability and evaluability of CIRS reports [6]. The World Health Organization (WHO) Patient Safety Action Plan 2021-2030 highlights that the aggregation of error reports offers important opportunities to better understand the causes of medical errors [8]. A prerequisite for this is the interoperability and high quality of the data. An analysis of the publicly available reporting system CIRSmedical.de shows different data structures within the reporting system, reducing accessibility dramatically [9]. In Germany, various CIRS have been developed over time for both inpatient (e.g. CIRSmedical.de [10], CIRS-NRW[11]) and outpatient settings (e.g. "Jeder Fehler zählt" [12]). There are also CIRS for specific topics, such as cirs.bayern specifically for emergency. This diversity of systems contrasts with the approach of collecting and evaluating all information centrally, as in the UK with the National Reporting and Learning System (NRLS [13]), which contains over 20 million reports. A current project of APS, "Erfahrungen teilen" refers to the importance of information exchange across system boundaries but overlooks a discussion of the problem of exchangeability and interoperability. Another result of this project is that a central CIRS in Germany is not desired by the various operators [14].

The issue of interoperability has been present at least since the COVID-19 pandemic, where a unified data structure for medical data related to the COVID-19 pandemic was developed within a brief period as part of the COCOS (Corona Component Standards) initiative. In this context, the German Corona Consensus Dataset (GECCO) includes data elements and medical terminology from SNOMED CT, LOINC, ICD-10, ATC, and FHIR [15].

The importance of interoperability in medicine has been discussed for more than 15 years and includes syntactic and semantic aspects [16–19]. Syntactic interoperability requires a similar structure of documents based on standards such as HL7, currently HL7 FHIR and DICOM. To fulfil the minimum requirement of syntactic interoperability for error reports, the WHO has published the Minimal Information Model (MIM) for Patient Safety Incident Reporting and Learning Systems, which also presents an extended and a complete data model [20]. The Directorate-General for Health & Consumers (DG-SANCO) of the EU Commission evaluated this data model in 2014 [21]. The final statement addressed the necessity of similar data elements but did not reflect consistent terminology. It refers only to the International Classification for Patient Safety (ICPS) from the WHO [22]. The ICPS in its current version is a framework and therefore not a classification in the classical sense. The ICPS does not define specific rules for coding [23]. Semantic interoperability is the ability to exchange data with unique meaning between systems. The absence of standardized terms in CIRS can have several significant consequences for patient safety and data analysis. Without standardized terms, the same incident might be described in many different ways across different reports. This can lead to confusion and misinterpretation of the data, making it more difficult to learn from these incidents and implement effective preventative measures. The process of analyzing the reports becomes much more time-consuming and error-prone, as it requires manual translation and interpretation of the terms used in different reports. Identifying error patterns becomes much more challenging. Standardized terms facilitate communication and shared learning across different healthcare providers and institutions. When these standards are missing, it can prevent the effective sharing of knowledge and best practices [24]. Semantic interoperability is the prerequisite for enabling machine-computable logic between systems [25]. In healthcare, semantic interoperability allows understanding the meaning of words in the context of other medical terms. The Standardized Nomenclature in Medicine (SNOMED CT) is the cornerstone for semantic interoperability, providing a unique code for terms based on the same concept (e.g., Myocardial Infarction vs. Infarction of heart both map to the code "2229800"). The ICPS provides many terms and definitions usable for incident reporting. These terms should be integrated into the standardized medical nomenclature SNOMED. The SNOMED standard terminology should contain related patient safety for coding texts and improving computer readability. The codes allow transferring terms to another language or classifying them hierarchically. Currently, no German translation of medical terminology is maintained in SNOMED CT [26,27].

Due to Germany's distributed reporting and notification systems structure, national interoperability on a syntactic and semantic level plays a crucial role in learning from different error reporting systems. This work aims to examine report structures from different publicly accessible systems for their syntactic and semantic interoperability to answer whether these reports can be exchanged to foster cross-system learning. Only through interoperability can a common understanding of errors be achieved. As a result of interoperability, information in the different systems can be searched for and analysed using a search strategy.

## 2. Methods

In Germany, 16 cross-institutional error reporting systems could be identified [28]. For the interoperability study, only systems that are publicly accessible were considered (Table 1). The data from the CIRS-AINS [29] are completely contained in CIRSmedical.de and were therefore not requested separately. The data from CIRS Health Care [30] were not made available for the analysis. Table 1 shows the structures of the public CIRSs used for the study. The CIRSmedical.de network serves as the upper system and has interfaces for the CIRS-NRW and Krankenhaus-CIRS-Netz Deutschland 2.0 (KH-CIRS-Netz-D 2.0). This means that reports can exist redundantly in both systems.

**Table 1.** Public systems, which have been included in the study.

| System | Date | Medical speciality | Interface |
|---|---|---|---|
| CIRSmedical.de [10] | December 2019 | Inpatient | No |
| Netzwerk CIRS Berlin [31] | December 2019 | Inpatient | No |
| CIRS-NRW [11] | May 2020 | Inpatient | CIRSmedical.de |
| KH-CIRS-Netz-D 2.0 [32] | December 2019 | Inpatient | CIRSmedical.de |
| Jeder Fehler zählt [12] | January 2020 | Outpatient | No |
| CIRS.bayern [33] | December 2019 | Emergency | No |

Data from the mentioned systems, which total 11,534 reports, were exported and made available in formats such as Microsoft Excel or CSV. For these systems to achieve syntactic interoperability, they must exhibit similar structures. The evaluation of syntactic interoperability is primarily concerned with the architecture of data, particularly focusing on the fields within data tables. The WHO MIM was utilized as a benchmark to compare the data elements from the different CIRS [20]. In five CIRSs, the error reports were given a classification term by the operators based on the WHO ICPS [22]. The following classification terms were used: 1. Clinical Administration, 2. Clinical Process/Procedure, 3. Documentation, 4. Healthcare Associated Infection, 5. Medication/IV Fluids, 6. Blood/Blood Products, 7. Nutrition, 8. Oxygen/Gas/Vapour, 9. Medical Device/Equipment, 10. Behaviour, 11. Patient Accidents, 12. Infrastructure/Building/Fixtures, 13. Resources/Organizational Management

In this specific study, semantic analysis was applied to the classification terms from the ICPS and the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) to identify potential gaps of standardized terms. The process of determining whether a SNOMED concept exists for classification terms from the ICPS was undertaken. If a term was missing, an effort was made to align it with a similar term. Post-coordination is a process where, if a complex term doesn't have an equivalent in SNOMED CT, it is replaced by using IDs from similar terms within SNOMED CT. Each term in SNOMED CT has a semantic meaning, such as 'procedure' or 'finding,' which is written in brackets.

## 3. Results

### *3.1. Syntactic Interoperability*

The reporting systems CIRSmedical.de and KH-CIRS-Netz-D 2.0 differ minimally in their input forms (see Figure 1 in yellow). The corresponding terms from the MIM are shown in green.

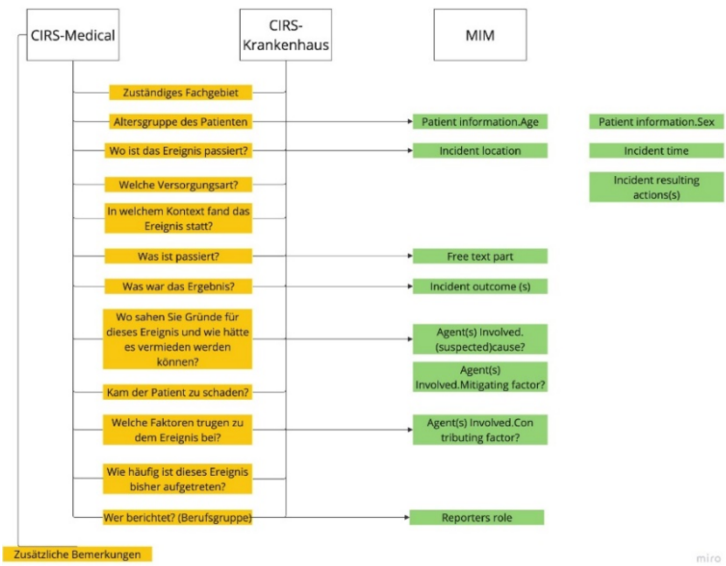


**Figure 1.** Form structure of CIRSmedical.de and KH-CIRS-Netz-D2.0 and their relation to the MIM

CIRSmedical.de has 13 input items, and KH-CIRS-Netz-D 2.0 has 12, eight of which can be transferred to the model. For the question, "Where do you see reasons for this event and how could it have been avoided?" no clear conceptual reference is necessary. Three items from the MIM cannot be assigned (far right in the figure).

CIRS.bayern uses 16 questions in its case report form. Six questions can be assigned to the items of the MIM. The MIM “agent(s)” items cannot be assigned, as CIRS.bayern asks about different factors (organization/working environment, team/communication, personal/individual). In CIRS.bayern, the patient is assigned to a contributing factor (as free text) in which patient age and gender could be included. The “event” field allows free text input in all systems. Since there is no event field in the MIM, an assignment to the free text part was made. The MIM item Incident type is missing in CIRS.bayern.

The CIRS "Jeder Fehler zählt" is designed for the outpatient sector and uses eleven items to complete the report form. Seven items map to the structure of MIM. Age and gender of the patients is not queried, nor are the timing and type of adverse event.

The CIRS-NRW is a reporting system regionally focused on the German state of North Rhine-Westphalia and can include both outpatient and inpatient reports. Eight of ten input questions map to the MIM. Four information items of the MIM are left out.

The Netzwerk-CIRS Berlin is a regionally-organized network for reports from the area served by the Berlin Medical Association. It uses a reduced question set of CIRSmedical.de with nine questions for case entry, six of which can be mapped to the WHO MIM.

### *3.2. Semantic Interoperability*

The analysis of semantic interoperability based on the classification terms from the ICPS shows that only one term, namely "Documentation", has a correct semantic representation in SNOMED CT. The term "Patient Accident" is a similar semantic expression, but SNOMED CT does not contain this exact term in the synonym list. In the post-coordination, only comparable expressions could be found, which, however, had a different semantic meaning. Table 2 shows the results of the SNOMED CT analysis.

## 4. Discussion

Error reporting systems are crucial for learning from past mistakes, with the WHO encouraging their use for prospective learning [34]. The ability to pool data offers opportunities to employ AI and machine learning in identifying new patterns and relationships; however, this requires quality data in large volumes. None of the studied systems can fully transfer information based on the WHO's Minimal Information Model for patient safety [20]. CIRSmedical.de stands out as it receives cases from other systems, but its information structure significantly limits systematic analysis [9]. The common structural intersection among all systems consists of only two MIM elements: “What happened?” and the Reporter’s Role.

**Table 2.** SNOMED CT analysis

| Classification | SNOMED CT | Post-coordination Possibility |
|---|---|---|
| Clinical Administration | None | Administration (navigational concept) - SCTID: 413454004 |
| Clinical Process/Procedure | None | Two concepts exist with a different semantic meaning: *Process (qualifier value)* SCTID: 719982003 *Process (observable entity)* SCTID: 415178003 |
| Documentation | *Documentation (procedure)* SCTID: 23745001 (not part of the synonym list) | |
| Healthcare Associated Infection | *Healthcare associated infectious disease (disorder)* SCTID: 408678008 (not part of synonym list) | |
| Medication/IV Fluids | None (for this term combination) | *Procedure related to the management of drug administration (procedure)* SCTID: 182832007 (synonyms are: medication action, medication management) *Fluid for intravenous administration (substance)* SCTID: 118431008 |
| Blood/Blood Products | None (for this term combination) | *Blood (substance)* SCTID: 87612001 *Blood (product)* SCTID: 410652009 |
| Nutrition | *Nutrition, function (observable entity)* SCTID: 384759009 ("nutrition" is in the synonym list) *Nutrition (regime/therapy)* SCTID: 386373004 | |
| Oxygen/Gas/Vapour | None (for this term combination) | *Oxygen (substance)* SCTID: 24099007 *Gaseous (substance*) SCTID: 74947009 (the term "gas" is in the synonym list) *Vapour (substance)* SCTID: 768005008 |
| Medical Device/Equipment | None (for this term combination) | Biomedical device (physical object) SCTID: 63653004 (term is in the synonym list) Equipment (attribute) SCTID: 246137000 |
| Behaviour | None | None |
| Patient Accidents | Medical accidents to patients during surgical and medical care (event) SCTID: 269691005 - but "patient accident" is not in the synonym list. | |
| Infrastructure/Building/Fixtures | None (for this term combination) | No term for infrastructure Room of building (environment) SCTID: 223398003 No term for the fixture |
| Resources/Organizational Management | None | None |

Syntactic interoperability of public CIRS is limited, with issues such as unclean data, evidenced by HTML code present in free text fields. A potential solution could be adopting HL7 FHIR, the efficacy of which is proven by the GECCO Dataset [15]. Semantic interoperability is also an issue. Only two ICPS terms correspond to SNOMED with correct semantic meanings. Some terms lack equivalent expressions and codes in SNOMED CT. Consequently, SNOMED can't currently solve the semantic interoperability problem. Interoperability's essential elements were demonstrated in the development of common data sets for Corona data, i.e., a standard syntactic structure of data with well-defined semantic meanings [15] . Yet, the WHO's Global Action Plan for Patient Safety 2021-2030 identifies shortcomings in pattern recognition essential for knowledge management [34]. Hence, systems that can manage high data diversity are still significant. One approach to ensure interoperability in CIRS systems could be employing a uniform structure or agreeing on data mapping between systems.

This study has two limitations: first, not all German reporting systems could be analysed; second, the semantic analysis only covers report classification, not the terms used within reports. Despite these, the study reveals that patient safety-related concepts and terms are not embedded in SNOMED CT. This necessitates developing a patient safety terminology and integrating it into SNOMED CT.

## 5. Conclusion

In conclusion, the task of harmonizing CIRS presents a significant challenge yet a substantial opportunity to enhance patient safety. Unfortunately, the existing fragmented and disparate data sources limit the potential of a comprehensive, integrated, systemic analysis vital for patient safety. Our study highlights significant limitations in both syntactic and semantic interoperability of current CIRS, with a significant lack of essential interoperability and data quality. The following recommended actions could aid in achieving harmonization of CIRS nationally and internationally:

1. Unification of a data exchange structure based on, for example HL7 FHIR: This will facilitate better communication, promote consistency, and lead to more accurate comparisons and analytics.
2. Expansion of SNOMED CT: This currently does not include all terms pertinent to patient safety. Expanding this standard medical nomenclature to encompass patient safety-relevant terms will improve semantic interoperability.
3. Development of a Patient Safety Ontology: Due to the limitations in SNOMED CT, there's a need for a ontology for patient safety. This would involve identifying and defining a set of concepts and categories specific to patient safety and establishing the relationships between these concepts. A comprehensive patient safety ontology would address gaps in existing systems, promoting greater understanding and focus on patient safety.
4. Collaboration and Communication: Promoting open communication and collaboration among different CIRS operators, both within and across countries, is pivotal. This shared understanding will not only facilitate the harmonization of systems but also provide a platform to share best practices and discuss shared challenges.
5. Continuous Training and Education: Human factors play a significant role in the effectiveness of CIRS. Hence, continuous training for healthcare staff is needed.With a better understanding of the systems, users can provide high-

quality data, enabling more efficient analyses and ultimately improving patient safety.

Each of these recommended actions has the potential to support CIRS interoperability, leading to more effective use of these systems for enhancing patient safety.

## Declarations

*Conflict of Interest:* The authors declare no conflict of interest.

*Author contributions:* Thomas Schrader: conception of the work, data aquisition and interpretation; Laura Tetzlaff: writing the manuscript, data aquisition and interpretation; Anne-Maria Purohit, Christine Holmberg, Jacob Spallek: substantial revising of the manuscript. All authors approved the manuscript in the submitted version and take responsibility for the scientific integrity of the work

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