Understanding and Reasoning About Early Signs of Sepsis: From Annotation Guideline to Ontology

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***Abstract*—In the clinical domain, patient states such as sepsis due to bloodstream infection (BSI) result in observable symptoms and signs used to determine diagnosis and treatment, all of which often is documented in electronic health records. However, clinical text is brief and implicit, making it challenging to infer patient conditions by reasoning tasks and supervised machine learning. To study sepsis-related BSIs we developed an ontology from an annotation guideline and annotated corpus that empirically captures BSIs from adverse event notes containing procedural deviations, guideline deviations, and unwanted incidents that can bring harm to patients. The resulting ontology represents (1) the physical patient state, clinical observations, and clinical documentation, and (2) background clinical knowledge for artificial intelligence, reasoning, and machine learning.**

***Index Terms*—Sepsis, Ontology development, Reasoning, Clinical knowledge representation, Adverse events**

I. Introduction

Sepsis contributes to approximately 30% to 50% of hospitalized deaths [1], [2]. It is a dysregulated host response to an infection, such as a bloodstream infection (BSI), which leads to organ failure and possibly death [3]. A gram-positive bacteria frequently found on the skin that commonly causes BSIs is *Staphylococcus aureus* (*S. aureus*) [4]. 7.6% to 35% of *S. aureus* BSIs are caused by peripheral intravenous catheters (PIVCs) [5]. PIVC is the most used medical device in hospitals [6] and is inserted into a peripheral vein to administer IV fluids, medications, and blood transfusions. Although PIVCs cause *S. aureus* BSIs only in ∼0.5 cases per 1.000 PIVC catheter days [7], the impact on BSI is important, as up to 80% of patients admitted to a hospital will be given at least one PIVC [8]. If PIVCs are improperly managed, mortality risk via BSI can increase. Possible gateways for PIVC-related BSIs include bacteria circulating the bloodstream from an existing infection attaching to the catheter or microbes migrating through the catheter tract, catheter hub, or contaminated infusate [9].

Although sepsis is the most common cause of death among hospitalized patients [10], it is poorly documented outside the intensive care unit [11]. Additionally, since PIVCs are frequently used, they are often not documented in clinical records [6]. This lack of documentation makes performing retrospective and real-time systematic quality surveillance for PIVC-related BSIs challenging and inhibits improvement and learning of PIVC care to lower BSI and adverse event (AE) incidents. To overcome this, a clinical knowledge representation is necessary to capture documented observable patient states and infer underlying knowledge for PIVC-related BSI from clinical text. The clinical text used in the project are from adverse event (AE) reports which more frequently report failures related to PIVCs.

II. Related Work

There are many studies focusing on the relationship between annotation, tagging, and ontologies for natural language processing (NLP) development. The Colorado Richly Annotated Full-Text (CRAFT) Corpus was annotated using the Uberon multi-species anatomical ontology to provide a resource for NLP development [12]. It has also been semantically annotated with concepts from eight Open Biomedical Ontologies (OBO) ontologies and terminologies. Through annotation with OBO ontologies, they discovered OBO are not developed for annotation and there are issues with overlapping terms within different OBOs, context-specific definitions, semantic ambiguities within the ontology, and linking annotated concepts [13]. An i2b2/VA challenge evaluating three tasks found relationship classification based on provided annotated concepts was the most difficult and suggested domain knowledge may help with the lack of explicit contextual information needed for relationship classification [14]. Conversely, assertion classifications based on annotated concepts was the easiest task, and concept extraction from the unannotated text was more difficult because of concept boundary detection. Additionally, methods are being developed for automatically extracting ontologies from documents [15].

Currently, there is no specific ontology for sepsis-related BSI, signs, locations, related devices, and procedures. However, there could be relevant concepts in existing ontologies such as the following: sepsis and hospital-acquired infection entities in the Infectious Disease Ontology (IDO) [16], sign and symptom entities from the Ontology for General Medical Science (OGMS) [17], vital sign entities from the Vital Sign Ontology (VSO) [18], [19], anatomical entities in the Foundational Model of Anatomy Ontology (FMA) [20], [21], anatomical spatial location descriptor entities from the Biological Spatial Ontology (BSPO) [22], adverse event entities in the Ontology of Adverse Events (OAE) [23], [24], and relationship object properties from the Open Biological and Biomedical Ontology (OBO) Relation Ontology [25]. Additionally, potential relevant standardized nursing practice language includes the International Classification for Nursing Practice (ICNP) terminology, Nursing Interventions Classification (NIC) taxonomy [26], and NANDA International Nursing Diagnoses Classification taxonomy [27]. Concepts or terms from these resources can be used to expand the ontology if deemed necessary by ontology users.

Though an ontology for sepsis PIVC-related BSIs is not available, there are relevant clinical guidelines, studies, and tools. For instance, there is a Norwegian PIVC care guideline for reducing infections [28]. This guideline is based on commercial evidence-based guideline publishers such as UpToDate[1] and BMJ Best Practice[2]; these publishers compile clinical guidelines based on publications. Additionally, the Guidelines International Network (GIN)[3] has a guideline repository[4] which contains guidelines for various infections and management of peripheral intravascular devices. Using clinical text, some studies have focused on creating sepsis alert systems to identify patients or notes with suspected infection [29], [30]. Furthermore, there are PIVC phlebitis assessments [31]–[33] and a Peripheral Intravenous Catheter mini Questionnaire (*PIVC-miniQ*) quality surveillance tool for scoring PIVC problems related to insertion site, equipment condition, documentation, and use [34].

III. Objective

This paper presents initial work on an ontology for early sepsis signs based on an annotation guideline and annotated corpus of adverse event (AE) notes. The annotation guideline and annotated corpus capture explicit observable items in documentation for PIVC-related BSIs such as signs, locations, related devices, and procedures. Based on the clinical research question "Is there a connection between BSIs and PIVCs at the hospital?", the following competency question requirements for an ontology representing and reasoning about PIVC-related BSIs were identified:

1) Does patientA have an infection?
2) Does patientA have a BSI?
3) How many patients have an infection or BSI?
4) Which patients have sepsis?
5) Does patientB have a catheter?
6) Does patientB have a PIVC?
7) How many catheters does patientB have, where are they, and why does patientB need them?
8) Does patientC have an infection and catheter? If so, was patientC's infection associated with a catheter?

The clinical goal is eventually to automate *PIVC-miniQ* for PIVC quality surveillance and create a reminder to notify clinicians which patients require additional monitoring or follow-up care to lower BSI incidents because they currently have or have had a PIVC.

IV. Datasets

A. Norwegian Adverse Event Dataset

18,555 AE reports between September 30, 2015 and December 31, 2019 were extracted from the electronic incident reporting system at St. Olavs hospital, Trondheim University Hospital in Trondheim, Norway. These AE reports describe various events such as procedural deviations, guideline deviations, near-miss events that could have harmed patients, misunderstandings, resource needs, and patients whose poor behavior posed a risk to others. Approval to use AE notes for this study has been approved by the Norwegian Regional Committees for Medical and Health Research Ethics (REK), approval no 2018/1201/REKmidt, 26814.

B. Synthetic Adverse Event Dataset

The original Norwegian AE dataset was used to manually create 100 unique synthetic free-text notes for annotation. These notes were created either by a nurse or by combining different parts of original notes together and having a nurse verify the content. Manually creating synthetic data ensures the content appears realistic and could be real. It also guarantees data are anonymized, provides additional data for downstream analyses, and allows scare clinical data to be reusable and accessible.

V. Annotation Guideline and Annotations

A. Synthetic Dataset Annotation Guideline

The preliminary annotation guideline was developed by simplifying the clinical research question "is there a connection between BSIs and PIVCs at the hospital?" into:

- How can sepsis or BSIs be identified when the symptoms are similar to other diseases?

[1] https://www.uptodate.com/
[2] https://bestpractice.bmj.com/
[3] https:/https://G-I-N.net/
[4] https://guidelines.ebmportal.com/

- How can PIVCs be identified when it's poorly documented?

Formulating questions and holding discussions with nurses led to insights about which catheters are documented distinctly and how catheters can be distinguished based on the anatomical insertion site or procedures. Based on the clinical perspectives of nurses, questions were modified into the following domain-specific *questions of interest*:

- What are the different signs of infections, specifically for BSIs, sepsis, or infected PIVCs?
- What are the signs for different types of catheters?
- Where are the anatomical insertion sites of catheters?
- What procedures, interventions, and activities can be related to catheter use?

The list of answers provided by nurses for domain-specific questions were sorted into four categories: **Sign**, **Location**, **Device**, and **Procedure**. These categories, technically known as entities in annotation and classes in ontologies, are used as annotation labels which can span a single word or phrase.

To ensure the four categories related to catheters and infections could be found and occurred frequently enough for downstream analysis, 700 randomly selected AE notes from the original Norwegian dataset were manually screened. Following screening, three additional categories (**Sensitivity**, **Person**, and **Whole**) were included to ensure correct anonymization, allow categories to be linked to an individual, and incorporate a label representing the span of the whole text. This resulted in the following seven categories:

1) **Sign**: infection signs
2) **Location**: anatomical insertion sites
3) **Device**: signs of catheter types
4) **Procedure**: procedures, interventions, or activities related to catheters
5) **Sensitivity**: protected health information
6) **Person**: individuals mentioned, such as patient, clinician, or relative.
7) **Whole**: label representing the span of whole text and given to indicate if the note contains information about infection, BSI, sepsis, faulty device malfunctioning, catheter, PIVC, or is sensitive.

Additionally, categories 1-6 each form an hierarchy with more specific subcategories to capture different detailed granularity in text (e.g., in Fig. 1, the **Device** category has a general "catheter" subcategory which contains a more specific "PIVC" subcategory). Furthermore, four relationships were added to link categories 1-4:

1) **Person** $\xrightarrow{\text{Person has}}$ **Sign**, **Location**, **Device**, or **Procedure**
2) **Procedure** $\xrightarrow{\text{Procedure uses}}$ **Device**
3) **Sign** $\xrightarrow{\text{Caused by}}$ **Device** or **Procedure**
4) **Sign**, **Device**, or **Procedure** $\xrightarrow{\text{Located nearby/on/in}}$ **Location**

These relationships ensure information is not lost in downstream analysis (e.g., infection sign at a specific location). From these seven categories and four relationships, a preliminary guideline describing how each category and relationship

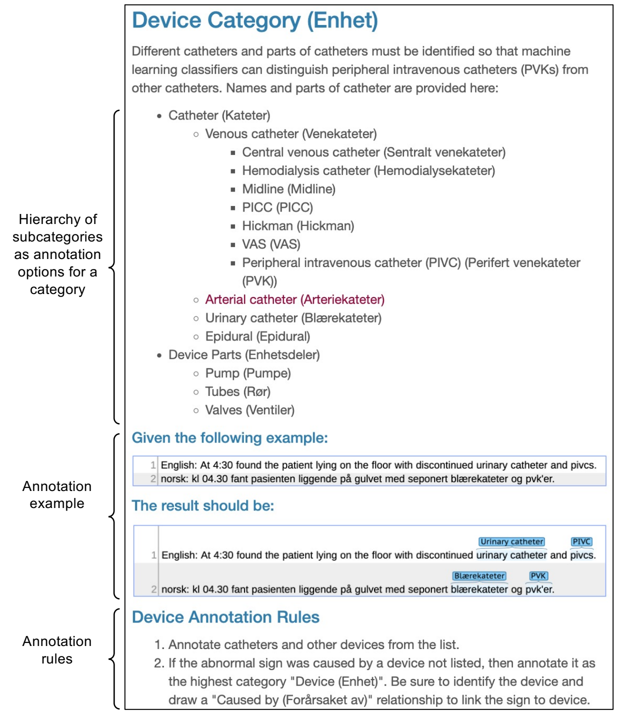

Fig. 1. The **Device** category in the annotation guideline which contains subcategories, examples, and rules. Red font indicates changes made to the guideline after a revision.

was created (Fig. 1). Fig. 2 shows the importance of an annotation guideline for consistent annotations and differences in how text can be annotated: either without relationships and detailed granularity (Fig. 2(a)) or with relationships and detailed granularity by utilizing subcategories and attributes (Fig. 2(b)).

B. Synthetic Dataset Annotation

The 100 unique synthetic notes were divided into 10 distinct sets with 10 notes each. These 10 sets were sorted such that four sets were annotated by each group once and the remaining six sets were annotated at least twice by separate groups. Sets were sorted to evaluate guideline revision improvements using the same data on a different group. This resulted in four annotation sessions and four groups with two annotators each. Additionally, each annotator annotates 70 notes total (i.e., 10 notes in session one and 20 notes in the remaining three sessions).

These synthetic notes were annotated by eight annotators comprised of four nurses, one nursing student, two medical students, and one computer scientist with experience working with clinical text. During annotation, annotators followed the annotation guideline and annotated using the Brat rapid annotation tool (BRAT) [35]. Then annotations are evaluated using the inter-annotator agreement (IAA) F_1-score for each group and assessed to determine if items related to the clinical question are captured. Ambiguities and comments from annotators were discussed with nurses and used to refine the annotation guideline. The process was repeated for four sessions (Fig. 3).

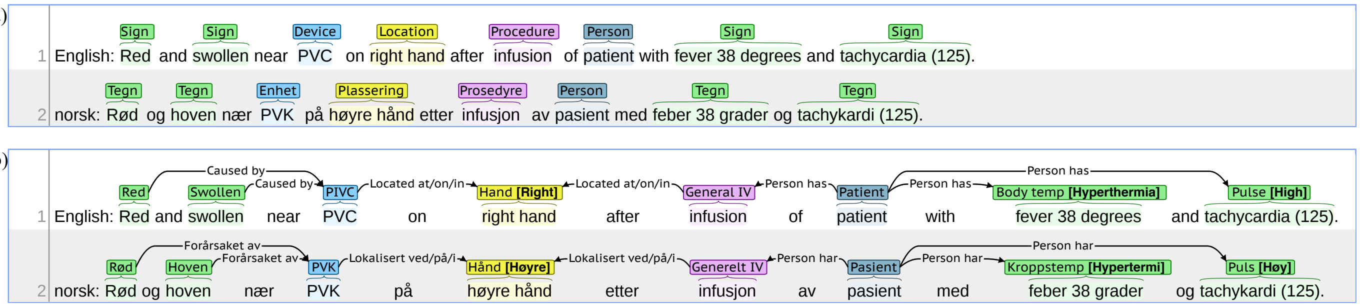

Fig. 2. Annotation granularity. (a) Using the Brat rapid annotation tool, it is possible to annotate text using only the categories (i.e., **Sign**, **Location**, **Device**, **Procedure**, **Person**). (b) However, it is preferable to annotate text more detailedly to ensure information is not lost downstream by using relationships, subcategories, and attributes. For instance, relationships are used to link one label to another (e.g., "Red" is linked to "PIVC" using the $\xrightarrow{\text{Caused by}}$ relationship). Additionally, "right hand" which was previously labeled **Location** in (a) is now labeled using **Location**'s subcategory "Hand" and given the attribute [Right].

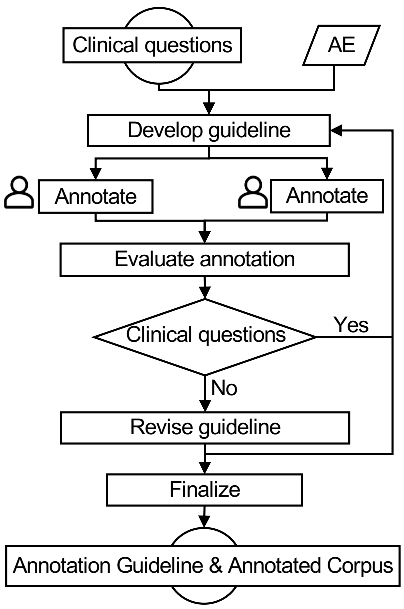

Fig. 3. Annotation process.

This generated an annotated dataset of 560 notes stored in the BRAT standoff format and a refined annotation guideline (guidelines for each session are available online[5]).

VI. Experiment

The development process of the annotation guideline and ontology are intertwined and occurred in parallel, but were separated into individual sections within the paper for readability.

A. Annotation Guideline to Ontology

The annotation guideline for PIVC-related BSIs describes how information in the text should be annotated to capture the necessary information. From the last annotation session, the resulting annotation guideline contains seven categories, various attributes for some categories, and four relationships. An category describes a concept or thing. Attributes provide additional entity information, and relations map relationships between entities. In this project, the annotation guideline was built using a combination of the top-down and bottom-up approaches. It was developed with an ontology in mind and with feedback from clinicians through a systematic, iterative annotation process. From the annotation guideline, each hierarchy of entities is converted into a class hierarchy within the ontology. Data properties are added to classes using attribute information for each entity, and object properties are generated based on relations. The conversion from annotation guideline to ontology framework was done using Protégé version 5.5.0 [36].

B. Design Decisions

Based on clinician needs, the focus is on identifying and inferring signs and observations documented in annotated text related to PIVC-related BSI for automating quality surveillance. Hence, causality, such as the reason for chemical and mechanical reactions resulting in infection-like signs, is not within the scope of this ontology. As clinician needs change, it will be possible to extend this ontology and incorporate other well-founded ontologies, as previously mentioned in Section II.

C. Ontology Development

After developing an ontology based on the annotation guideline as a framework, modifications were made to remove ambiguity. For example, an **Observation** class was introduced to remove ambiguity between symptoms, infection signs, and device malfunction signs. Additionally class names were changed for clarification (i.e., **Whole** was changed to "Note" and **Sensitive** was changed to "Identifier"). Following modifications, assumptions and inferences linking documented signs and patient conditions were incorporated to ensure competency questions could be answered.

VII. Results

A. Sepsis Ontology

To make the Ontology for Sepsis Peripheral intravenous catheter-related Bloodstream infections (OSPB) more acces-

[5]https://folk.ntnu.no/melissay/ae-guidelines/

sible, this is a bilingual ontology for Norwegian and English. The OSPB hierarchy has seven main classes (Fig. 4):

1) **Identifier**: protected health information
2) **Location**: anatomical location
3) **Medical Device**: treatment equipment or part
4) **Note**: representation of a note's contents
5) **Observation**: documented clinical observations
6) **Person**: an individual
7) **Procedure**: procedures, interventions, or activities for distinguishing catheter-related vs non-catheter-related

Object properties used to link classes with one another are the same as the annotation guideline relationships:

1) **Person** $\xrightarrow{\text{Person has}}$ **Observation**, **Location**, **Medical Device**, or **Procedure**
2) **Procedure** $\xrightarrow{\text{Procedure uses}}$ **Medical Device**
3) **Observation** $\xrightarrow{\text{Caused by}}$ **Medical Device** or **Procedure**
4) **Observation**, **Medical Device**, or **Procedure** $\xrightarrow{\text{Located nearby/on/in}}$ **Location**

VIII. Discussion

A. Dependency Issues

Competency questions determine an ontology's scope and provide requirements for evaluation [37]. In this study however, an ontology's success is interdependent on the competency questions, annotation guideline, and data. Certain competency questions cannot be answered because they are not documented within the data. The annotation guideline is based on the assumption that an iterative developed annotation guideline is adequate for developing an ontology. This annotation guideline is also dependent on documented data. Data might not be documented because of varying hospital practices and communicative behaviors among different clinicians within different departments [38]. Hence, evaluating the success of OSPB must include considerations for what type of data is documented, whether competency questions are answerable based on documented data, and if underlying implicit knowledge is captured based on explicit annotated items generated using an annotation guideline.

B. Future Work

Work presented here is the first step towards automating *PIVC-miniQ* and eventually implementing it within the AE and electronic health record (EHR) systems. The synthetic AE dataset used for annotations is a placeholder for the real Norwegian AE dataset and clinical records from the EHR. Future work includes using supervised machine learning to identify PIVC-related BSIs and classify patients requiring additional monitoring. This should be done utilizing AE reports for retrospective quality surveillance and EHR records for retrospective and real-time quality surveillance.

IX. Conclusion

The Ontology for Sepsis Peripheral intravenous catheter-related Bloodstream infections (OSPB) is a bilingual ontology in English and Norwegian for identifying PIVC-related BSI to facilitate systematic quality surveillance and reduce sepsis rates within hospitals. It was made for inferring patient conditions within a annotated corpus by capturing underlying knowledge in text as a representation for artificial intelligence, reasoning, and supervised machine learning.

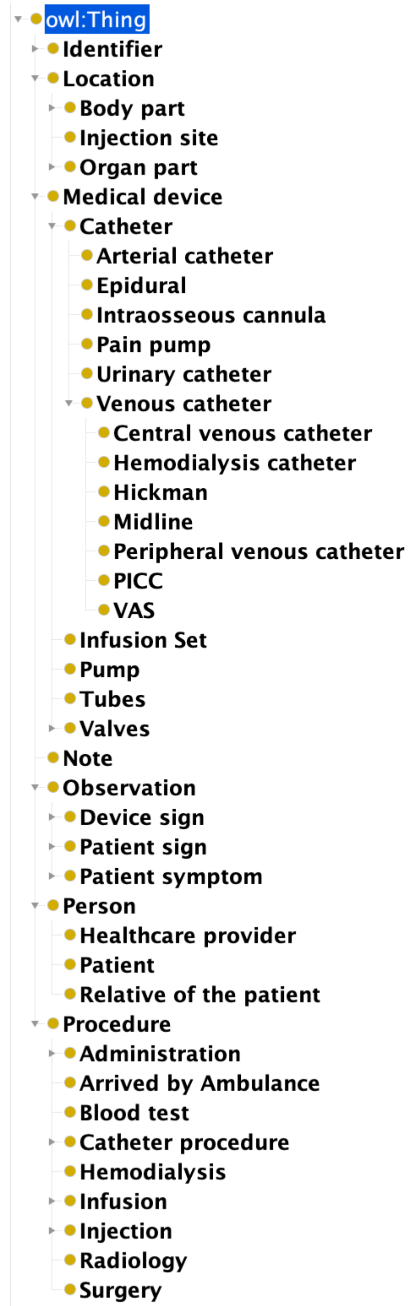

Fig. 4. Class hierarchy for the Ontology for Sepsis Peripheral intravenous catheter-related Bloodstream infections (OSPB)

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