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Verifying a medical protocol with temporal graphs: The case of a nosocomial disease

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ABSTRACT

Objective: Our contribution focuses on the implementation of a formal verification approach for medical protocols with graphical temporal reasoning paths to facilitate the understanding of verification steps.
Materials and methods: Formal medical guideline specifications and background knowledge are represented through conceptual graphs, and reasoning is based on graph homomorphism. These materials explain the underlying principles or rationale that guide the functioning of verifications.
Results: An illustration of this proposal is made using a medical protocol defining guidelines for the monitoring and prevention of nosocomial infections. Such infections, which are acquired in the hospital, increase morbidity and mortality and add noticeably to economic burden. An evaluation of the use of the graphical verification found that this method aids in the improvement of both clinical knowledge and the quality of actions made.
Discussion: As conceptual graphs, representations based on diagrams can be translated into computational tree logic. However, diagrams are much more natural and explicitly human, emphasizing a theoretical and practical consistency.
Conclusion: The proposed approach allows for the visual modeling of temporal reasoning and a formalization of knowledge that can assist in the diagnosis and treatment of nosocomial infections and some clinical problems. This is the first time that one emphasizes the temporal situation modeling in conceptual graphs. It will also deliver a formal verification method for clinical guideline analyses.

1. Introduction

A medical protocol (also known as a clinical protocol, medical guideline, or clinical guideline) is a document attesting to a good practice of a medical or paramedical action (treatment or diagnosis) according to a bibliography, a shared clinical experience, or recommendations of a consensus among professionals.

Protocol development receives attention in the medical community to the extent that these tools can improve the quality of care and reduce health care costs. Medical protocols are usually in the form of a corpus of text describing the diagnostic steps and processes of care, written in natural language. Properties that have been used to verify (model check) protocols are derived from lists of indicators of good medical practice, the latter being systematically developed by medical experts.

Nosocomial infection is a recognized public health problem worldwide with a prevalence rate of 3.0% to 20.7% and an incidence rate of 5% to 10% [1]. In Europe, the Scandinavian countries and the Netherlands, with appropriate policy measures by developing a protocol known as Search and Destroy, have a low prevalence rate of nosocomial infections (<1%). Meanwhile, there are high prevalence rates (>10%) in France, the United Kingdom, Germany, Belgium, and Spain. Because of this fact, it is necessary to develop a way to fight against these nosocomial infections.

Here, we work on protocols defining guidelines for the monitoring and prevention of nosocomial infections. Nosocomial infections are those infections acquired in a hospital or other healthcare facility by a patient and first appear 48 hours or more after hospital admission or within 30 days after discharge following in-patient care. In addition, occupational infections also occur among facility staff [2]. These infections are unrelated to the original illnesses that bring patients to the hospital and neither present nor incubating at the time of admission [3]. Our contribution is the visual approach, and we illustrate this with the use case of nosocomial infection.

To develop a nosocomial infection, 4 elements must be present at the level of the disease:

- An infectious agent: A variety of microorganisms are likely to lead to nosocomial infections: bacteria, viruses, fungi, and parasites. Infections may be caused by a microorganism acquired from another person in the hospital (a cross infection) or may be caused by the patient's own flora (an endogenous infection). Some organisms may be acquired from an inanimate object or substances recently contaminated from another human source (an

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environmental infection). In some regions with poor basic hygienic practices, some nosocomial infections are due to pathogens of an external origin (foodborne and airborne diseases, gas gangrene, tetanus) or were caused by microorganisms not present in the normal flora of the patients (e.g., diphtheria, tuberculosis).

- A susceptible subject: Important patient factors influencing the acquisition of an infectious agent include age, immune status, underlying disease, and diagnosis and therapeutic interventions (e.g., chemotherapy). Hospitalized patients with impaired immune systems due to chronic diseases or cancers (e.g., diabetes mellitus, respirator insufficiency, renal failure, immune disorders, burns, malignant tumors, leukemia, or acquired immunodeficiency syndrome (AIDS)) or because of their general condition (malnourished or at extreme ages of life (infancy and old age)) have an increased susceptibility to infections with opportunistic pathogens. The latter are infections with organism (s) that are normally innocuous, e.g., part of the normal human bacterial flora, but may become pathogenic when the body's immunological defenses are compromised. Immunosuppressive drugs or irradiation may lower resistance to infection. Injuries to skin or mucous membranes bypass natural defense mechanisms. Many modern diagnostic and therapeutic procedures, such as biopsies, endoscopic examinations, catheterization, intubation/ventilation, suction and surgical procedures, increase the risk of infection. Contaminated objects or substances may be introduced directly into tissues or normally sterile sites such as the urinary tract and the lower respiratory tract.
- Environmental factors: Patients with infections or carriers of pathogenic microorganisms admitted to hospitals are potential sources of infection for patients and staff. Crowded conditions within the hospital, frequent transfers of patients from one unit to another, and concentrations of patients highly susceptible to infection in one area (eg, newborn infants, burn patients, and intensive care) all contribute to the development of nosocomial infections. Microbial flora may contaminate objects, devices, and materials, which subsequently contact susceptible body sites of patients. In addition, new infections associated with bacteria such as waterborne bacteria (atypical mycobacteria) and/or viruses and parasites continue to be identified. World Health Organization studies and others have also shown that the highest prevalence of nosocomial infections occurs in intensive care units and in acute surgical and orthopedic wards [4].
- Bacterial resistance: Many patients receive antimicrobial drugs. Through selection and the exchange of genetic resistance elements, antibiotics promote the emergence of multidrug-resistant strains of bacteria and microorganisms in the normal human flora that are sensitive to the given drug and are suppressed while resistant strains persist and may become endemic in the hospital. The widespread use of antimicrobials for therapy or prophylaxis (including topical) is the major determinant of resistance. Antimicrobial agents are, in some cases, becoming less effective because of resistance. Many strains of pneumococci, staphylococci, enterococci, and tuberculosis are currently resistant to most or all antimicrobials that were once effective. Multidrug-resistant *Klebsiella* and *Pseudomonas aeruginosa* are prevalent in many hospitals. This problem is particularly critical in developing countries where more expensive second-line antibiotics may not be available or affordable.

We first present the setting of our context to provide some background. We will then review requirement specifications and finish with the verification of medical protocols. The approach presented in this article is inspired by a part of a larger research project aimed at improving the daily application of medical protocols, including a particular illustration of a medical protocol to reduce rates of nosocomial infections. The verification of a protocol can improve the quality of care and also patient safety. The protocol is the model, and the specifications are the properties. The model has to satisfy those properties.

2. Background and context setting

2.1. Monitoring of nosocomial catheter-related infections

Here, we review protocols to establish guidelines for the monitoring and prevention of nosocomial diseases that are transmitted by medical devices, such as urinary catheters, intubation probes, or catheters. The work performed in this article is based on a former study from a Spanish hospital that illustrates the application of a protocol for the management and prevention of intravenous catheter–related infections (CRIs) [5]. It was found that these infections are the most common cause of those nosocomial infections acquired in the hospital that affect morbidity and mortality and that also have economic implications (a prolonged duration of hospitalization, increased cost of health care, the emergence of multiple antibiotic resistance microorganisms, and reducing the incidence of treatment for other infections).

Taking care of and preventing nosocomial infections are the responsibility of all individuals and services providing health care (managers; physicians; and other health care workers, such as clinical microbiology, pharmacy, central supply, maintainers, housekeeping, and training services). It is recommended that transparent and appropriate evaluation criteria be used to evaluate the surveillance of nosocomial infections such as the catheter-related infections (CRI) or infections related to intravenous catheters (IRC) (Table 1). In some establishments, there are specialists in infection control, epidemiology, and infectious disease, including infection control physicians and infection control practitioners [6]. These individuals have a scientific and technical support role, for example, surveillance and research, developing and assessing policies and practical supervision, evaluating materials and products, controlling sterilization and disinfection procedures, and implementing training programs. These individuals should also support and participate in research and assessment programs at the national and international levels. A nosocomial infection prevention manual, compiling recommended instructions and practices for patient care, is an important tool [4]. The manual should be developed and updated by the infection control team with review and approval by a committee.

2.2. Model checking

The primary goal of model checking [7] is to check the conformity of the model with the requirements defined in the specification, with an important issue being: does the model provide an interpretation as to whether it meets or does not meet the system's requirements?

- The principle is to compare a model with a property of the system and to automatically check whether the model satisfies the property.
- Its issues: why verify the status of a model and check its outcome? There is a need to provide regulatory amendments that allow for the establishment of a new approach to safety oversight and for the certification of heath care operations. Indeed, for complex medical organizations and systems, it is necessary to have sufficient confidence in their functioning at all times.

Table 1
Simplified criteria for the surveillance of nosocomial catheter-related infections (CRI)

Vascular catheter infection	Inflammation, lymphangitis, or purulent discharge at the insertion site of the catheter, abscess, or spreading cellulitis at the insertion site of the catheter during the days or weeks after the intervention
Septicemia	Fever or rigors, and at least rigors, and at least 1 positive blood culture

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