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A Digital Clinical Guideline Based on HL7 Arden Syntax for the Treatment of Children with Traumatic Brain Injury

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Abstract. Background: Intracranial hypertension is a serious complication accompanying the intensive care of children with traumatic brain injury. Intensive care of these patients is based on internationally accepted guidelines and their local editions. Objective: The goal was to develop a software system for digital implementation of the clinical protocol for the treatment of intracranial hypertension in children, based on HL7 Arden Syntax clinical decision support. Methods: Arden Syntax, an HL7 medical knowledge representation and processing standard, was used to develop a digital version of the local guideline. Results: Comparison of 37 patients given conventional treatment with a second group of 84 patients treated with the digital clinical guideline yielded statistically significant differences. Conclusion: The digital clinical guideline system undoubtedly improves the doctor's awareness of the patient's existing condition and potential complications of intracranial hypertension.

Keywords. clinical guideline, intracranial pressure (ICP), clinical decision support (CDS), Arden Syntax.

1. Introduction

Traumatic brain injury (TBI) remains one of the main causes of death and persistent disability among children involved in accidents [1]. These patients usually need intensive therapy and multimodal monitoring in intensive care units (ICUs). A typical complication is elevated intracranial pressure (ICP) and the development of intracranial hypertension (ICH), which frequently leads to cerebral ischemia and brain edema.

The treatment of ICH is based on internationally accepted guidelines [2] and their local adaptations. A local Russian guideline for the treatment of ICH in children was developed in 2015 at the Clinical Research Institute for Emergency Pediatric Surgery and Trauma (CRIEPST), Moscow, and is known as "Step therapy for treatment of intracranial hypertension in children" (step protocol) [3]. This clinical protocol is an

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algorithmic sequence of steps aimed at normalizing ICP and maintaining safe levels of cerebral perfusion pressure (CPP). It has been specially adapted for the intensive care of children with TBI.

The general trend in the digitalization of healthcare and particularly intensive care is based on the increasing use of clinical decision support (CDS) systems. One of the modern instruments for building CDS is Arden Syntax, which is a medical knowledge representation and processing standard for CDS systems, defined and supported by Health Level Seven International [4]. It defines the way clinical and scientific knowledge can be represented, computerized, and processed. Arden Syntax was first approved as a standard by the American Society for Testing and Materials in 1992 [5]. Several extensions followed. The current version (v2.10) was released in November 2014 [6].

The goal of this work was to develop a computer system based on Arden Syntax for digital implementation of the step protocol for the treatment of ICH in children with TBI.

2. Material and Methods

The digital clinical guideline (DCG) system was developed with the aid of ArdenSuite software, a commercial CDS authoring and processing platform based on Arden Syntax, created by Medexter Healthcare, Vienna, Austria [7]. The DCG system is an add-on module integrated into a hospital information landscape which includes, among other components, an ICU monitoring system (Philips IntelliVue [8]), a hospital information system (MediaLog [9]), and a monitoring database (MDB). All components are synchronized via HL7 standard protocol.

The clinical guideline (step protocol) for the treatment of ICH in children with TBI consists of seven clinical actions (steps) aimed at reducing ICP and maintaining a safe level of CPP. These clinical steps are: body position control, sedation, drainage of cerebral fluids, introduction of osmotic diuretics, controlled hyperventilation, barbiturate coma, and decompressive craniotomy. The steps are performed sequentially. However, the user has the option of repeating or deleting steps.

This clinical guideline is a “knowledge source” for programming so-called medical logic modules (MLMs), which are the basic elements of Arden Syntax. Each MLM contains enough clinical knowledge for at least one medical computation or decision.

The general architecture of the DCG system is presented in Figure 1. It includes three main blocks. The middle part known as “development and processing” is the ArdenSuite software which consists of two main modules: an IDE (integrated development environment) for writing, compiling, and testing MLMs, and the ArdenSuite server for executing the compiled MLMs. The “integration and sources” include patients’ medical documents, real-time monitoring data, and clinical knowledge guidelines. The web interface provides a device-independent graphical user interface and a message service for office and mobile applications.

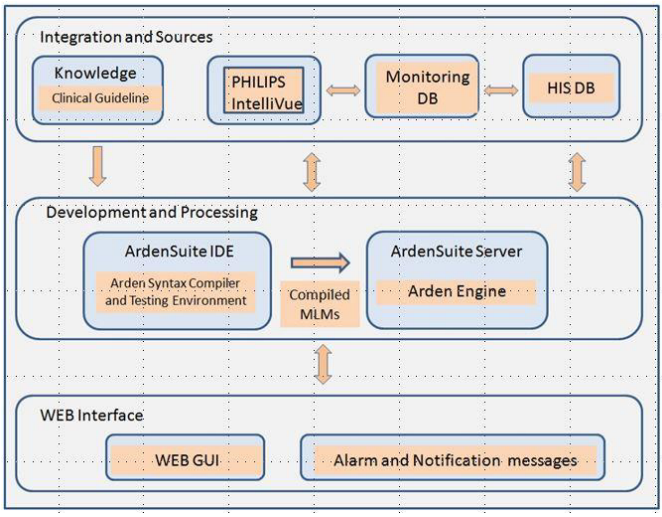

Figure 1. Architecture of the digital clinical guideline system.

The "step protocol" was introduced in the clinical setting in 2015. Since this time, all children with TBI have been treated according to this protocol. The DCG system was created in early 2017 and is being routinely used since. Between 2015 and 2019, 84 children with TBI underwent intensive care according to the protocol. The digital version of the protocol is being used since 2017. The reference group of 37 patients was created from historical data concerning conventional ICH therapy. The groups did not differ statistically in terms of the severity of trauma, clinical stage, age, gender, or the period of stay at the ICU. Each patient was rated on the Glasgow Outcome Scale (GOS) after six months [10,11]. According to the GOS, the outcomes were divided into three groups: moderate disability or good recovery, severe disability or vegetative state, and fatal outcome or death (Table 1). The STATISTICA 8 package was used for statistical analysis [12].

Table 1. Glasgow Outcome Scale in the protocol and the reference group.

GOS	Protocol group	Reference group
Moderate disability or good recovery	63 (75.00%)	18 (48.65%)
Severe disability or vegetative state	14 (16.67%)	7 (18.92%)
Death	7 (8.33%)	12 (32.43%)

3. Results

Statistical analysis of the combined frequencies revealed significant differences between groups in respect of the GOS. A significant fall of 24.1% in the number of deaths, and a rise of 26.35% in the number of favorable outcomes were noted in the protocol group compared to the reference group; Pearson's Chi-square was 12.24 with df=2, $p=0.0022$, thus $p<0.05$.

4. Discussion

Obviously, the software solution developed for the digital clinical protocol is not aimed to, and cannot replace, the clinical physician. It is not possible to single out the separate effect of the digital version of the clinical protocol on the outcome of treatment. Moreover, the digital protocol inherits all limitations of the step-by-step treatment strategy for ICH. The decision to perform surgery is made jointly by several doctors and is based on comprehensive clinical data. However, the DCG system undoubtedly improves the doctor's awareness of the patient's current condition and potential complications of intracranial hypertension. It is also a useful tool for logging clinical actions of medical personnel in regard of scientific, legal, and other aspects of intensive care. The use of Arden Syntax creates a unified platform for building compatible systems to support clinical decisions, and is expected to accelerate the process of their certification.

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