A Domain-Specific Modeling Language for Specification of Clinical Scores in Mobile Health

Allan Fábio de Aguiar Barbosa[1], Francisco José da Silva e Silva[1], Luciano Reis Coutinho[1], Davi Viana dos Santos[1] and Ariel Soares Teles[2]
[1]*Federal University of Maranhão, Brazil*
[2]*Federal Institute of Maranhão, Brazil*

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Abstract: Clinical scores are a widely discussed topic in health as part of modern clinical practice. In general, these tools predict clinical outcomes, perform risk stratification, aid in clinical decision making, assess disease severity or assist diagnosis. However, the problem is that clinical scores data are traditionally obtained manually, which can lead to incorrect data and result. In addition, by collecting biological/health data in real time from humans, the current mobile health (mHealth) solutions that computationally solve that problem are limited because those systems are developed considering the specificities of a single clinical score. This work is part of the MDD4ClinicalScores project that addresses the productivity in developing mHealth solutions for clinical scores through the use of Model Driven Development concepts. This paper focus in describing DSML4ClinicalScore, a high-level domain-specific modeling language that uses the Ecore metamodel to describe a clinical score specification. To propose the DSML4ClinicalScore we analysed 89 clinical scores to define the artifacts of this proposed Metamodel. In the end, a practical case study using this DSML is provided to validate the DSML4ClinicalScore Metamodel, and to show how to use the proposal in a clinical situation scenario.

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1 INTRODUCTION

Clinical scores have been discussed as part of modern clinical practice in recent decades. In general, these tools have been created to predict clinical outcomes, perform risk stratification, aid in clinical decision making, assess disease severity or assist diagnosis (Aakre et al., 2017b). In the medical literature, there are many formally defined clinical scores, in which each one of them deals with a specific type of disease, especially those considered as chronic. For example, there are clinical scores for heart diseases, infectious diseases, neurological diseases, and so on.

Recently, the importance of scores for clinical practice within the hospital environment has been investigated with greater emphasis. For example, Aakre et al. (Aakre et al., 2017a; Aakre et al., 2017b) examined the feasibility of including these scores within the patient's Electronic Health Record (EHR). In this context, clinical scores data are traditionally obtained in a manual way, which can lead to incorrect data and result, and they can also involve complex mathematical calculations. Initiatives in the mobile health (mHealth) field that currently arise to computationally solve the problem are limited because a software is developed considering the specificities of a particular clinical score.

In that scenario, the development process of mobile solutions for clinical scores using traditional approaches requires building a new software for each clinical score, even if they have similar characteristics, repeating all development steps, which limits productivity. To tackle this problem, we propose to use Model Driven Development (MDD) concepts that helps to simplify the process of developing mHealth applications for clinical scores. MDD offers an approach to address the inability of third-generation languages to reduce platform complexity and express domain concepts effectively. In particular, we propose a Domain-Specific Modeling Language (DSML) for specifying clinical scores in general. With a DSML, it is possible to develop a system using its elements captured by metamodels and express its project in a declarative and imperative way (Schmidt, 2006).

This work presents the `DSML4ClinicalScore`, a high-level DSML that uses an Ecore metamodel to de-

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scribe a clinical score specification. In general, a clinical score specification contains a section for defining its variables, a section for defining the rules for calculating its score, and a section for describing its evaluation models. Our `DSML4ClinicalScore` can cover all these particular features and generalizes specific details of different specifications.

This paper is structured as follows. In Section 2, we explain some basic concepts used in the whole paper. Section 3 discusses related work. Section 4 explains the proposed approach in which this work is part and describes the central concepts of the `DSML4ClinicalScore`. Section 5 validates the described language. Finally, Section 6 concludes the paper.

2 BACKGROUND

2.1 Clinical Scores

According to Thompson, clinical scores are based on clinical prediction rules (CPRs), which are tools that use specific criteria to establish probabilities of outcomes or assist in management decisions (Thompson, 2012). Falk and Fahey summarize the critical element of CPR as follows: "CPRs quantify the contribution of symptoms, clinical signs, and available diagnostic tests, and stratify patients according to the probability of having a target disorder. The outcome of interest can be diverse and be anywhere along the diagnostic, prognostic, and therapeutic spectrum" (Falk and Fahey, 2009).

In this context, some researchers have classified three types of CPRs and, consequently, three models of clinical scores: (1) Diagnostic CPRs that focuses on factors related to the clinical diagnosis; (2) Prognostic CPRs that predicts outcomes; (3) Prescriptive CPRs that provides recommendations for clinical intervention. The format of a CPR is variable and depends on the purpose for which it is intended, but it should include three or more variables obtained from patient history, physical examinations, or necessary diagnostic tests (Thompson, 2012). The combination of these CPRs forms the clinical score specification skeleton.

The process of establishing a clinical score within the clinical practice is complex and requires considerable time. According to Adams and Leveson, only to prove a CPR, the following steps are necessary: development, validation, impact analysis and implementation. Development is the stage in which it is identified the predictors from an observational study. Validation is the stage in which it is tested the rule on a separate population to see if it remains reliable. Impact analysis is the stage in which it is measured the usefulness of the rule in a clinical setting concerning cost-benefit, customer satisfaction and time/resource allocation. Implementation is the stage that there are universal acceptance and adoption of the rule in clinical practice (Adams and Leveson, 2012).

In general, a clinical score specification consists of variables, rules for calculation of the score and evaluation. Variables are precisely the predictors obtained in the development phase of the model. Rules define the punctuation of each variable in the specification according to the methodology used in the validation step of the model. Evaluation describes the interpretation of a clinical score according to the result obtained by applying the rules for calculating the score.

For example, the well-known **Modified Early Warning Score** (MEWS) (Subbe et al., 2001), which determines the degree of illness of a patient, has variables, rules for calculating score and evaluations as detailed in Table 1. It is possible to see in the Table 1 the declared variables, the set of rules associated with each specified variable and its respective score, and the two types of evaluation of this clinical score. We propose that mHeatlh applications can use a DSML to specify different clinical scores, in which transformation rules will be applied to generate executable code artifacts.

2.2 Domain-Specific Modeling Languages

Domain-Specific Modeling Languages are part of the MDD approach. According to Schmidt, MDD is an approach that deals with platform complexity by combining DSMLs with transformation engines and generators. DSMLs serve to formalize the structure, behavior, and requirements of an application and describe them using metamodels, which define the relationships between concepts in a domain and precisely specify critical semantic and constraints associated with these domain concepts (Schmidt, 2006).

Engineering models aim to reduce risk by helping to better understand both a complex problem and its potential solutions before undertaking the expense and effort of a full implementation. To be useful and effective, an engineering model must possess the following five key characteristics: abstraction, understandability, precision, predictiveness and inexpensive. Abstraction is a reduced rendering of the system that it represents by removing irrelevant details from a given viewpoint. Understandability is a direct function of the expressiveness of the modeling form

Table 1: MEWS score specification.

Variable	Value	Score
Systolic blood pressure	$\leq$ 70 mmHg	+3
	71–80 mmHg	+2
	81–100 mmHg	+1
	101–199 mmHg	0
	$\geq$ 200 mmHg	+2
Heart rate	$<$ 40 bpm	+2
	41–50 bpm	+1
	51–100 bpm	0
	101–110 bpm	+1
	111–129 bpm	+2
	$\geq$ 130 bpm	+3
Respiratory rate	$<$ 9 bpm	+2
	9–14 bpm	0
	15–20 bpm	+1
	21–29 bpm	+2
	$\geq$ 30 bpm	+3
Temperature	$< 35^oC$	+2
	35–38.4^oC	0
	$\geq 38.5^oC$	+2
AVPU Score	Alert	0
	Reacts to voice	+1
	Reacts to pain	+2
	Unresponsive	+3
Evaluation		**Result**
Not linked to death or an ICU admission		$\leq$ 4
Linked to death or an ICU admission		$\geq$ 5

used. Precision refers to a model that must provide a true-to-life representation of the modeled system's features of interest. Predictiveness is related to use a model to correctly predict the modeled system's but non-obvious properties, either through experimentation or some formal analysis. Inexpensive means that the process of a model construction and analysis must be significantly cheaper than other development process approaches (Selic, 2003).

The definition of a modeling language usually begins by capturing and identifying the main application domain. The result of this activity produces the abstract syntax of the modeling language, which corresponds to a metamodel with all the concepts identified at the meta-domain level. The concrete syntax of modeling language refers to how users learn and use it, whether by reading or writing and designing the models. Finally, a modeling language can be classified as General-Purpose Modeling Language (GPML) or DSML. Different from DSML, a GPML has broader and widespread use in several fields of application (Fowler, 2010; Mernik et al., 2005). We propose a DSML related to clinical scores domain in the health field.

3 RELATED WORK

In the literature, there are several works on mHealth applications for remote patient monitoring (Free et al., 2013; Silva et al., 2015). On the other hand, there have been some initiatives involving mHealth and clinical scores in recent years. For example, Altini et al. created and validated a mobile clinical score to estimate the relative risk of a woman having a premature birth. With a database of four million pregnancies, the authors created a model of risk estimation that involves demographic and gestational characteristics, as well as obstetric behavior and history (Altini et al., 2017). Aminian et al. developed a mobile application that provides quick and convenient access to evidence-based clinical scores, specifically in cases of bariatric surgery. The authors implemented three scoring systems: a vertical gastrectomy risk assessment score, a post-discharge thromboprophylaxis risk score, and a score-based selection of evidence-based metabolic surgery (Aminian et al., 2017). Andrew et al. proposed the incorporation of real-time data obtained through mobile devices for acute stroke code evaluation. The authors used, among other factors, the National Institutes of Health Stroke Scale (NIHSS) score as a criterion for assessing of stroke risk (Andrew et al., 2017). Furberg et al. developed a mobile system for clinical decision support to reduce pediatric cardiovascular risk. The authors used a multilayer framework to convert clinical evidence into specialized knowledge through integrated risk assessment with body mass index, blood pressure and lipid management (Furberg et al., 2017). Pereira-Azevedo et al. created a mobile application for the prostate cancer risk score of Rotterdam. With the application, the authors improved the risk stratification of prostate cancer, avoiding unnecessary biopsies and reducing the time for diagnosis and unnecessary treatment (Pereira-Azevedo et al., 2017).

Most of the works described above tackle the problem of clinical scores in a restricted way, developing a computational system for a specific clinical score. Their main focus is on solving the clinical score or using it as a mean to address a more significant problem. They do not apply MDD concepts to solve their clinical scores too. Different from those studies, this paper approaches the issue more generically and comprehensively, employing a solution not explored in the literature yet. By specifying different clinical scores using a DSML, we standardize the requirements of any application that fits within these same characteristics and can use the code artifacts resulting from our approach in other applications. In this way, we present a solution that allows increasing the productivity in the software development process in this context.

4 PROPOSED APPROACH

This work is part of the `MDD4ClinicalScores` research project that focuses on the development of software to allow real-time remote patient monitoring using the processing of data streams generated from people and biomedical sensors. Unlike most previous works, which develop a computational system for each specific clinical score, `MDD4ClinicalScores` stands out by allowing the specification of several clinical scores and the automatic generation of software components through the use of model transformation techniques. The generated software components allow real-time remote patient monitoring according to the provided clinical score specifications. Figure 1 illustrates the proposed approach.

The first part of Figure 1 (identified by the (1) label) corresponds to the clinical score specification. This step is based in a DSML (`DSML4ClinicalScore`) used to implement a high-level graphical authoring tool for supporting healthcare professionals in providing clinical score specifications. Based on the provided specification (concrete model), `MDD4ClinicalScores` applies transformation rules for the generation of OWL ontology classes that are based on **Deklaer's Declarative Modeling Language** (Pinheiro et al., 2018), an ontology used to describe IoT applications. The generated ontology describes the rules that will be used for patient monitoring according to the provided clinical score specification. The second part of Figure 1 corresponds to the execution environment step of the proposed approach. This step involves the submission of the generated Deklaer ontology to a middleware infrastructure called **Scalable Data Distribution Layer** (SDDL) (Endler et al., 2011) for the automatic generation of software components comprising the IoT mobile application. The process of an IoT application generation and the deployment of the its software components is described in (Pinheiro et al., 2018).

4.1 Domain Analysis

In order to propose a metamodel that allows to define a DSML to develop clinical score specifications, we needed to identify which concepts should be included as artifacts in that metamodel. Consequently, the first step was to identify data and functional requirements to specify a clinical score. As the quantity of clinical scores is undefined, in order to achieve this goal we adopted the work of (Aakre et al., 2017a) as an initial reference point, taking into account its relevance and contemporaneity with the proposal in that paper. In that work, the authors empirically surveyed 110 clinical scores and submitted them to the assessment of United States medical experts in relation to the importance of having their scores automatically entered into patient's EHR. That evaluation was based on subjective criteria, in which the clinical scores were classified as VERY IMPORTANT, NICE TO HAVE or NOT IMPORTANT.

Therefore, to define the requirements with a focus on the clinical scores, we analyzed those 110 clinical scores by two viewpoints: (1) to develop a classification in relation to how the variables of a clinical score are obtained computationally; (2) elaborate a conceptual map to extract relevant concepts about clinical scores from different specialties. The first step is related to the purpose of the `MDD4ClinicalScores` project proposal, and the second step is focused on the development of the `DSML4ClinicalScore` proposal.

4.2 Domain Conceptual Map

In order to facilitate the interpretation of the domain analysis and the elicitation activity, we developed a Conceptual Map (see Figure 2) for clinical score specifications to clarify the main concepts that must be included in the metamodel. This conceptual map was elaborated from 89 of those 110 clinical scores previously analyzed since we take into account only those evaluated as VERY IMPORTANT or NICE TO HAVE.

The Conceptual Map shows all the concepts identified. To classify these concepts we have answered the following questions: (1) why do we want to develop mHealth applications for clinical score?; (2) how do we obtain inputs to develop these applications?; (3) what results do we want to obtain?

- **Variables:** this core concept identifies and represents the necessary clinical predictors that influence the final score of the clinical score. All possible electronic and manual variables provide the specific classification of the variables.
- **Rules:** this core concept identifies and represents the necessary rules for computing the score of each previously defined clinical predictor. All possible atomic and composed expressions provide the specific classification of the rules.
- **Evaluations:** this core concept identifies and represents the necessary assessments for interpretation of the clinical score. The result and assessment information provide the specific classification of the evaluations.

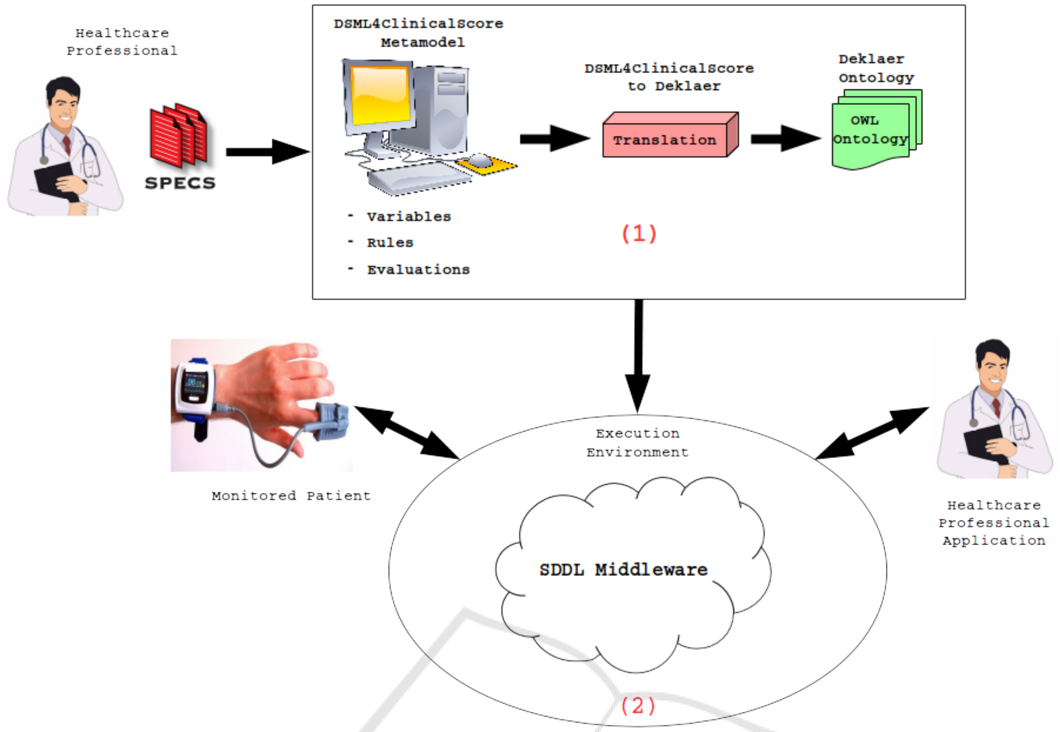

Figure 1: The proposed approach of which DSML4ClinicalScore is part.

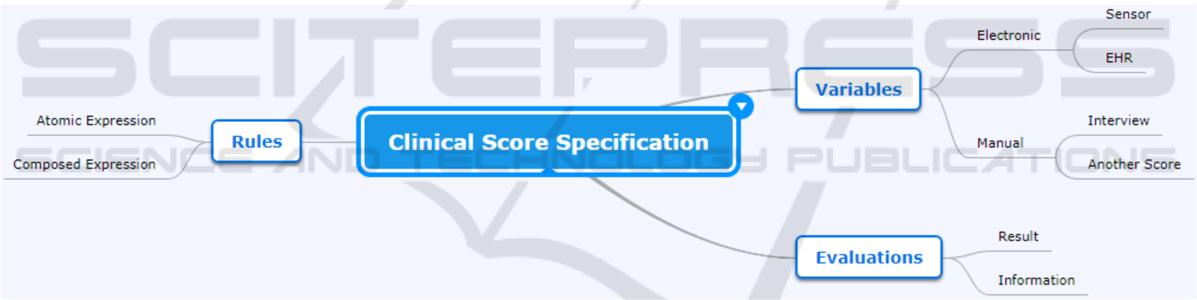

Figure 2: Conceptual Map of a clinical score specification.

4.3 Language Design

The `DSML4ClinicalScore` metamodel design was implemented on top of the Ecore metamodel and we used the Eclipse Modeling Framework[1] (EMF), a distribution of the Eclipse community, to edit and create case studies of clinical scores. EMF is a modeling framework and code generation facility for building tools and other applications based on a structured data model, in addition to providing an API for the Ecore dialect to UML. Ecore describes models and runtime support for the models, including change notification, persistence support with default XMI serialization, and a very efficient reflective API for manipulating EMF objects generically (Irawan, 2010).

Therefore, the `DSML4ClinicalScore` metamodel is defined from the concepts identified in the domain analysis and from the resulting Conceptual Map. It is organized into four main classes (see Figure 3) in order to separate the element needed for identifying a clinical score specification (`Specification`) from those related to each section model definition (`VariableSection`, `RuleSection` and `EvaluationSection`).

The `Specification` class of the Figure 3 represents a single clinical score specification, including an identifier, a description and a type from the `SpecificationTypes` class (Diagnostic, Prognostic or Prescriptive). A `Specification` is composed by one `VariableSection`, by one `RuleSection`, and by at least one or by many `EvaluationSection`.

[1] `https://www.eclipse.org/sirius/overview.html`.

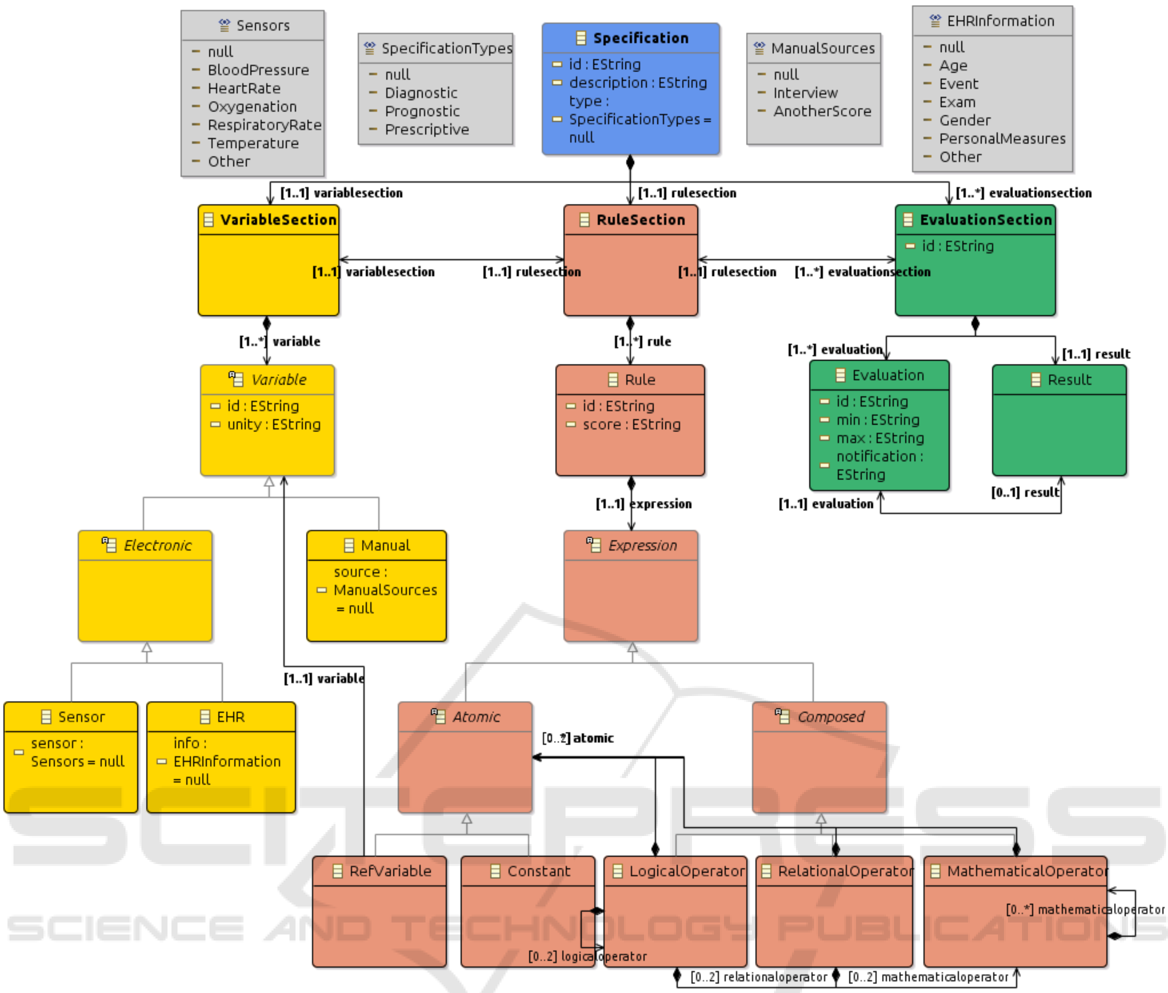

Figure 3: DSML4ClinicalScore Metamodel.

The VariableSection class of the Figure 3 defines all variables in a clinical score specification. These variables can be obtained through sensors, information of the patient's EHR, interviews with the health professional or patient, or information from other clinical scores. A VariableSection is composed by at least one or by many Variable, and it is associated with a single RuleSection. The Variable class signs an identifier and an unity of measurement for each variable created within the specification, and it can be a type of Electronic or Manual. The Electronic class encompasses the variables of the specification obtained electronically, and it can be a type of Sensor or EHR. The Manual class includes the variables of the specification obtained manually, assigning to each one of them its generating source from the ManualSources class (Interview or Another Score). The Sensor class identifies which type of sensor data is feeding the specification, as described by the Sensors class (Blood Pressure, Heart Rate, Oxygenation, Respiratory Rate, Temperature or Other). Finally, the EHR class identifies which type of information from patient's EHR is feeding the specification, as described by the EHRInformation class (Age, Event, Exam, Gender, Personal Measures or Other).

The RuleSection class of the Figure 3 defines all rules for calculating the score of the clinical score, associated with each variable in the specification. Here a rule can be represented by any possible expression (logical, relational or mathematical). A RuleSection is composed by at least one or by many Rule, and it is associated with a single VariableSection, and with at least one or with many EvaluationSection. The Rule class describes how the rules for calculating the clinical score are defined, assigning to each one of them an identifier and a score, and it is composed by a single Expression. The Expression class creates an atomic or composed expression for a specific rule within the specification, and it can be a type of Atomic or Composed. The Atomic class creates an atomic expression within the Rule, and it can be a type of RefVariable or Constant. The Composed class creates a composed expression within the Rule, and it can be a type of LogicalOperator, RelationalOperator or MathematicalOperator. The RefVariable class represents an atomic expression associated with a predefined variable in the VariableSection, and it is associated with a single Variable. The Constant class represents an atomic expression associated with a constant. The LogicalOperator class describes which logical operator (And, Or, Not, Not And, Not Or, Or Exclusive or Not Or Exclusive) is used in a composed expression, and it is composed by up to two Atomic, by up to two RelationalOperator, and by up to two LogicalOperator. The RelationalOperator class describes which relational operator (Equal To, Different From, Greater Than, Less Than, Greater Or Equal Than, or Less Or Equal Than) is used in a composed expression, and it is composed by up to two Atomic, and by up to two MathematicalOperator. The MathematicalOperator class describes which mathematical operator (Addition, Subtraction, Multiplication, Division, Exponentiation, Square Root, Factorial, Logarithm or Other) is used in a composed expression, and it is composed by up to two Atomic, and by up to many MathematicalOperator.

The EvaluationSection class of the Figure 3 defines all possible evaluation models for a clinical score specification, and it can have more than one model, identifying each one of them. A EvaluationSection is composed by at least one or by many Evaluation and by a single Result, and it is associated with a single RuleSection. The Evaluation class describes an evaluation of a clinical score specification according to a range of possible values for its result, assigning an identifier, notification, and minimum and maximum score values, and it is associated or not with a Result. The Result class obtains the final result of a clinical score specification, and it is associated with a single Evaluation.

5 VALIDATION

According to Yin (Yin, 2014), a case study can be a single case to evaluate a research theory in order to obtain results that can generalize or improve this theory. To demonstrate the robustness and expressiveness of DSML4ClinicalScore, from those list of 89 clinical scores analyzed in the subsection 4.1, we developed eight concrete case studies based on clinical scores that exploit different characteristics regarding variables, calculation rules and evaluations. The list of selected clinical scores is described in Table 2 and all specifications are available on the MD+Calc platform (Mdc, 2005).

Table 2: List of clinical scores used in the case studies.

Clinical Score	Disease
4T Score	Thrombocytopenia
$CHADS_2$ Score	Stroke
CPIS Score	Pneumonia
CURB-65 Score	Pneumonia
HAS-BLED Score	Bleeding risk
MEWS Score	Degree of illness
TIMI Index	Acute coronary
Well's Criteria for PE	Pulmonary Embolism

Considering the available space in this section we will illustrated the clinical score shown in Subsection 2.1 as our case study. To create the model of the chosen clinical score, we used EMF metamodel validation tool.

Figure 4 illustrates the modeling of the MEWS clinical score using the DSML4ClinicalScore language in an UML class diagram. To start modeling a clinical score the user declares a set of attributes (id, description and type) which are part of the Specification object. After that, the user can define the clinical score variables, rules for calculating the score and evaluations.

Concerning to the declaration of the MEWS clinical score variables, Figure 4 illustrates how its variables and attributes can be modeled according to the DSML4ClinicalScore metamodel. This specification contains five objects of the type Variable related to systolic blood pressure, heart rate, respiratory rate, temperature, and AVPU score.

About the definition of the score calculation rules, Figure 4 demonstrates how rules of the MEWS specification are defined according to the proposed metamodel. This specification has a total of twenty three scoring rules, with five objects of the type Rule associated with systolic blood pressure, six associated with heart rate, five associated with respiratory rate, three associated with temperature, and four associated with AVPU score. Figure 4 shows in detail only the rules related to systolic blood pressure and AVPU score variables of this clinical score. For example, to compose the rule with **"id = SBP=[71-80]"**, we performed the following:

1. We first created a LogicalOperator of the type And;
2. From that logical operator, we created two RelationalOperator, one of the GreaterThan

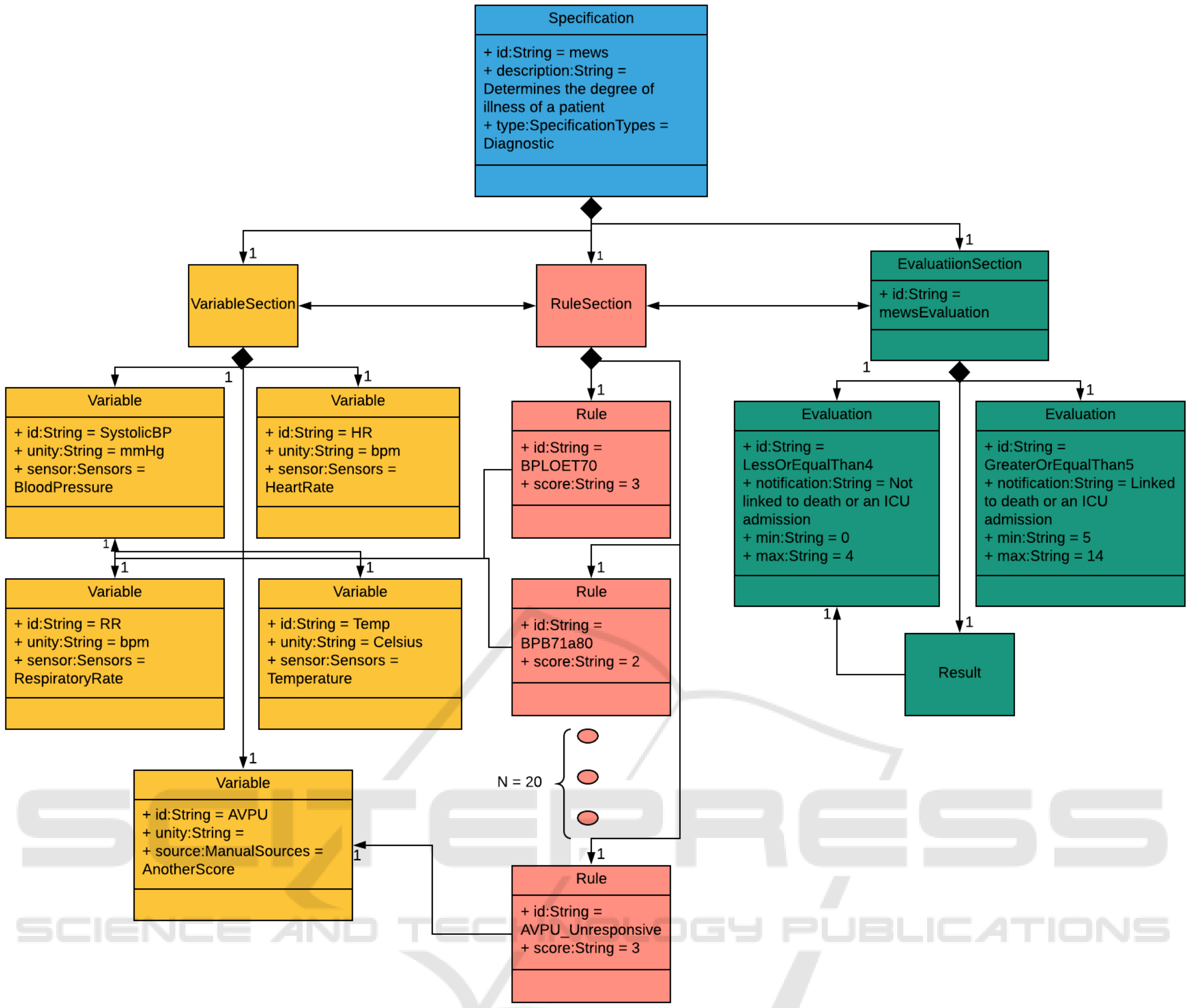

Figure 4: MEWS specification according to DSML4ClinicalScore metamodel.

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type and one of the `LessOrEqualThan` type;

3. From the `GreaterThan` relational operator, we created an instance of `RefVariable` associated with the variable with **SystolicBP** identifier, and a `Constant` with value **70**;
4. From the *LessOrEqualThan* relational operator, we also created an instance of `RefVariable` associated with the variable with **SystolicBP** identifier, and a `Constant` with value **80**.

Figure 4 also represents the evaluation model attributes of MEWS specification according to `DSML4ClinicalScore` metamodel concepts. For simplicity, Figure 4 describes only two possible objects of the type `Evaluation`, which are part of the MEWS specification, including their scoring range and respective interpretation, and one object of the type `Result`, which represents the final result of this clinical score.

5.1 Discussion

The provided case studies illustrates the expressiveness of the `DSML4ClinicalScore` language to describe different clinical score specifications. In the developed case studies, `DSML4ClinicalScore` allowed the user to correctly model any variable that serves as input for a clinical score specification, regardless of whether it is obtained manually or electronically. For example, we can express patient's age and gender, heart rate or blood pressure measurements, test results, history of several diseases, among others. In addition, the language also can express the attributes needed to identify a variable within any clinical score, regardless of how this variable is represented (numeric or textual).

Moreover, `DSML4ClinicalScore` allowed the user to correctly model several mathematical, relational and logical rule formats. For example, we can express the mathematical formula that calculates the TIMI risk index represented in the formula 1, which uses three variables related to heart rate, age, and systolic blood pressure to compose its calculation rule. We can also express a logic rule of the CURB-65 Score, described in the formula 2, which is composed of two relational expressions involving systolic blood pressure and diastolic blood pressure variables of this clinical score. Finally, one can express a rule that contains multiple choice options as the example shown in the formula 3 which is part of the 4Ts Score for Thrombocytopenia. In this way, `DSML4ClinicalScore` can express any Boolean rule.

$$TIMI = Heart\,rate * (Age/10)^2 / Blood\,pressure \tag{1}$$

$$IF\ SystolicBP < 90\ OR\ DiastolicBP \leq 60\ THEN\ +1 \tag{2}$$

$$\begin{bmatrix} Other\,causes & = & None\,apparent & +2 \\ & = & Possible & +1 \\ & = & Definite & 0 \end{bmatrix} \tag{3}$$

Finally, `DSML4ClinicalScore` allowed the user to correctly model several evaluation models. From those simpler ones such as the TIMI Risk Index assessment that defines only a probability as result, to more complex assessment models such as the Well's Criteria for Pulmonary Embolism, which presents a three-tier and two-tier evaluation model. Thereby, `DSML4ClinicalScore` can express any information associated with an evaluation of a clinical score specification considering the 89 clinical scores that served as reference for the `DSML4ClinicalScore` metamodel specification. One can obtain the plugins containing the proposed metamodel and the modeling of these mentioned case studies by following the URL `https://bit.ly/2zXwhkd`.

6 CONCLUSION

This paper presented a novel approach for the development of mHealth applications targeting the evaluation of clinical scores based on the use of Model Driven Development concepts. It is based on providing a DSML, called `DSML4ClinicalScore`, that allows end users to specify relevant clinical scores and on a transformation process that automate the generation of the software components that comprise the mHealth application.

This paper focus in describing `DSML4ClinicalScore` that was developed from the analysis of a set of 89 clinical scores selected by criteria of relevance and contemporaneity. From that set, we chose eight clinical scores to validate the proposed language by modeling the specifications. These specifications have been selected because they have different characteristics regarding the formatting of variables, scoring rules and evaluations, which allowed us to illustrate `DSML4ClinicalScore` expressiveness. In addition, we took one of those selected specifications as our case study to describe how its characteristics are modeled according to `DSML4ClinicalScore` metamodel.

The future steps of our work include the development of a graphical authoring tool for assisting end users (health care professionals) in the task of modeling clinical score specifications using `DSML4ClinicalScore` and the development of the transformation rules for partially automating the development process of generating mHealth applications targeting the monitoring of clinical scores.

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