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Original Article

Acute Stroke Quality Registry System with Guideline Based Diagnosis for Intravenous Thrombolysis Monitoring

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Abstract

Background: Electronic registration systems, integrated with guideline-based clinical support tools, are one of the most powerful requirements to improveclinical care quality.This study aims to design and development of an electronic registration system for acute stroke with the guideline-based diagnosis and monitoring of intravenous thrombolysis.

Methods: In thedesign phase, Scram methodology, web-based platform, onionarchitecture and MVC design patternwere usedand system data model, database, user interface, rule base and inference engine were designed and developed with C# programming language and SQL Server DBMS.

Result: The study result is a web based electronic registration system for stroke, with all detail patient medical data elements in stroke acute phase that was adjusted in 11 tabs including initial assessment, past medical history, LAB data, imaging, Diagnosis, treatment, drugs, guide, accountand embedded guideline based clinical support tool to automatic diagnose and monitoring of the intravenous thrombolysis.

Discussion: The system is not only a source of useful data but also a structured electronic registration system that includes detail medical data of stroke patients (about 600 data elements). In addition to advantages of the web platform, more powerful architecture, structured format and multi purpose coverage, it has significant advantages like an embedded guideline-based clinical support tool and care quality measures, stroke dictionary, clinical guideline information and an accessible and flexible drug list.

Key words: Design, Development, Stroke, Thrombolysis, Registry, Web-based, Onion Architecture, MVC

INTRODUCTION

Stroke is an important health threat in the world.(1) It is one of the most important causes of disability and the second cause of death in the world and especially developing countries.(2-4) Despite its public health impact, many countries don't focus on stroke properly as a high priority. One of the causes is a lack of accessible and accurate data to analyze, compare statistics and develop health strategies.(5,6)so the basic and most important step is gathering and registering accurate and reliable data and mobilize health society with stroke registries as a powerful tool to reach diverse epidemiologic, care quality improvement and outcome evaluation purposes.(7) It is inevitable to adopt electronic registration in near future. It is simple, reliable and cost effective in long term.(8) In IRAN, most of data or information registrationsare paper based that is very time consuming and lead to many difficulties to real time. Electronic registration with much more accessibility,accuracy and usability, is very helpful and has much more benefits for physicians, managers, policy makers and of course patients.(9)So it is obvious that the first and most basic requirement is to develop electronic clinical information systems. In the other hand, although information registration systems are very necessary, their

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wide variety of abilities will be a waste if does not equip them with powerful clinical support tools. One of the most useful clinical support tools is clinical guideline-based decision support systems that can be used for wide variety of purposes and improve guideline adherence in point of care.(10) The most important and emergency clinical care in ischemic stroke acute phase is intravenous thrombolysis therapy that significantly improves ischemic stroke patients outcome, if This emergency therapy is used in a limited time window (at most 4.5 hours after ischemic stroke onset). So patient rapid admission, initial assessment and eligibility diagnosis are vital in this phase.(11-14)Patient eligibility criteria are available in stroke clinical guidelines, so a guideline-based clinical support tool for patient eligibility diagnosis and intravenous thrombolysis monitoring is very beneficial. Although clinical support tools can be designed to be used separately, it is clear that their integration with a complete and accurate registration system significantly adds to their value, due to excess data entry elimination and real-time, automatic accessibility to data.(15, 16)The firstaim of this research is to provide researchers and cliniciansquick access to the data of the first aim of this research is to assist researchers and clinicians to stroke patients data quick access. So an electronic registration system was developed. Another purpose was to monitor Intravenous Thrombolysis as the most important care quality measure in ischemic stroke acute phase with a guideline-based clinical support tool embedded in the registration system.

METHODS

Inorder to design and development phases, a developing method was used. As the first step in the design phase, Onion architecture with MVC design pattern wass elected, then each layer was designed and implemented.

Onion Architecture

Jeffrey Palermo has introduced a new architecturalstyle called onion architecture (Figure 1).(17)Onion architecture is a result of bringing the dependency inversion principle(DIP) into the system architecture level. In onion architecture, the dependencies are reversed in opposed to traditional layered architecture. The result of this is when there is a change to components like UI, Database, Webservices, Messaging infrastructure etc., and as are the components changing most often, the changes are not reflected on core in any way. Onion Architecture uses the concept of layers, but they are a little different. The layers in this architecture areDomain Model Layer, Domain Services layer, Application Services layer, user interface.Palermo defines the key tenets of onion architecture as follows:

1. the application is built around an independent object model

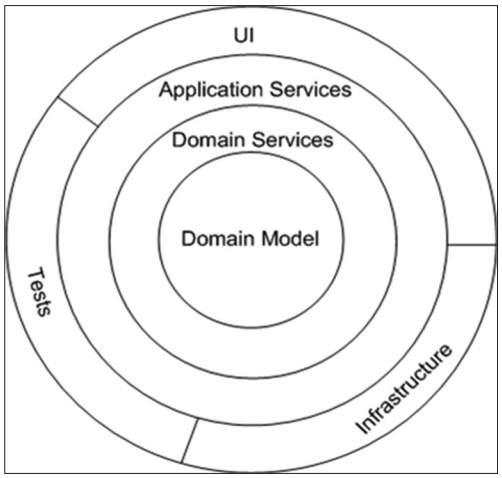

Figure 1: Onion architecture

2. Inner layers define interfaces, outer layers implement interfaces.
3. Direction of coupling is toward the center
4. All application core code can be compiled and run separately from infrastructure

Using onion architecture leads to more flexible and reusable codes and results in easier development and maintenance. (18) Below, we are going to describe development phase based on onion architecture:

Domain Model Layer Design

In this phase, after data elements identification, usecases Entities and their properties and behaviours were designed and implemented and then each entity transforms to one or more table of thedatabase and for each table, relative fields with their limitations were designed and implemented.

Domain Service Layer Design

In this phase all operations that are in relation with domain model layer and user interface layer were designed and implemented. These operations include, create, read, edit and delete (CRUD). And also data validation operations in server side were investigated and controlled.

View Model Layer Design

In this phase, views related with user interface were designed and implemented.

User Interface Design

The system appearance in user view and compatible with view model layer was designed and implemented and different levels of access and their appropriate permissions identified. In theuser interface implementation MVC design pattern was used.

Model–View–Controller (MVC)

An architectural pattern for user interfaces implementation (Figure 2). In this pattern an application divided in three

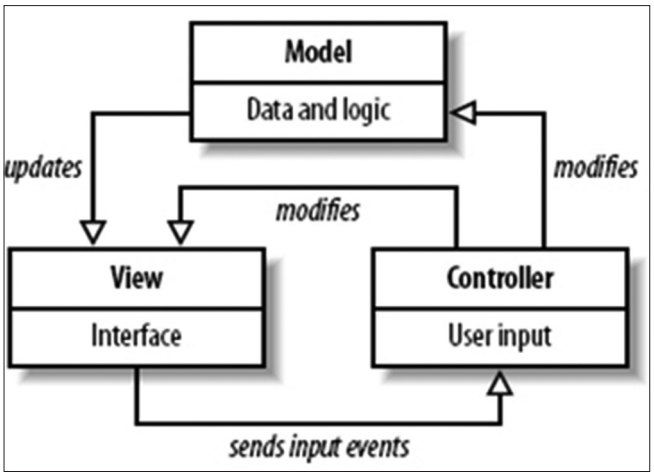

Figure 2: MVC design pattern

interconnected parts to separate internal representations of information from information that is viewed to the user. The MVC design pattern decouples these major components allowing for efficient code reuse and parallel development.(19-22)

Guideline-based Rule tablethat includes eligibility criteria (Figure 3)for the treatment of acute ischemic stroke with recombinant tissue plasminogen activator (alteplase) was designed and implemented in domain model layer and inference engine was designed and developed in theservice layer.net framework and SQL server softwarewere used for system development.

Data Quality, Access and Security Support

For more usability and prevent user typing errors, a structured format was designed for Data elements in the system. Most of the data element values designed to be selectable and just a few ones need to enter a limited number of digits. Some value ranges were determined in order to decrease data entry errors. Mandatory data elements were defined in each table withexpertspinion that users must fill them. In the first page of system Users Authentication and then users Authorization were controlled and were determined. Because of the limited number of system manager users in Authentication and Authorization ready to use components, a new component was developed to cope with this problem. According to general data exchanges, Sessions capability was used. To increase the system security against hackers, system interfaces were used instead of models direct use.

RESULTS

Design and Development

In this part, we describe the main results of system design amd development. After main data sets identification, in data base design, 14 table were created for each related data sets (Figure 4) and 5 tables created for users (Figure 5)

Patient medical information wereadjusted in 11 tabs including initial assessment, past medical history, LAB data, imaging, Diagnosis, medication, monitoring, drugs, guide user info, (Figure 6). Entered data can be saved or delete with theregister and delete bottoms in thebottom of each page in each tab. Patients list with select for view or edit, add, search, print and delete capabilities were implemented in the first tab, patient list.

Initial assessment tab includes patient demographic and initial administration information, final diagnosis, chief complaint (CC), present illness, vital signs, NIHSS items, admission and discharge NIHSS score(Figure 7).

In past medical history tab, all important disease(22 disease) with their type, duration,drug usages, more appropriate detail information and 10 more questions were considered Based on clinical guidelines, due to patient diagnosis for intravenous thrombolytic therapy as the most important and emergent treatment in theacute phase. Also, family history, patient habits,lifestyle and physical characteristics were considered (Figure 8).

LAB data tab includes, all detail information about appropriate test like, CBC, Electrolyte, Sugar Profile, Lipid profile, Coagulation test, Liver function test, Renal function test, Thyroid test, Anticoagulant markers, VBG test, CardiacEnzyme, Serologic test, Autoantibody test, Sugar Profile, Lipid profile, Anti phosphor lipid Ab, Renal function test, thyroid test, Anticoagulant markers, VBG test cardiac evaluation(Figure 9).

Imaging data tab includes all detail information in various imaging test like CXR findings, 1ST CT Scan Findings, 2nd CT Scan Findings, MRI findings, MRA findings, CTA findings, Carotid Doppler findings, TCD findings (Figure 10).

Diagnosis and treatment tabs include all information about stroke category and etiology, drug or intervention prescriptions and Rankin scale score (Figure 11 and Figure 12).

Discharge tab includes patient condition and required interventions.(Figure 13)

New drug name entry is available in drugs tab, in this tab the user can select a drug kind and then add one or more drug name to view in that drug kind. This drug information is available and automatically fetch in relative parts of information system (past medical history and diagnosis& treatment tabs)(Figure 14).

Guide tab includes some data definition and guideline information for users guide. (Figure 15)

Eligibility criteria for the treatment of acute ischemic stroke with recombinant tissue plasminogen activator (alteplase)
Inclusion criteria
Clinical diagnosis of ischemic stroke causing measurable neurologic deficit
Onset of symptoms <4.5 hours before beginning treatment; if the exact time of stroke onset is not known, it is defined as the last time the patient was known to be normal
Age ≥18 years
Exclusion criteria
Historical
Significant stroke or head trauma in the previous three months
Previous intracranial hemorrhage
Intracranial neoplasm, arteriovenous malformation, or aneurysm
Recent intracranial or intraspinal surgery
Arterial puncture at a noncompressible site in the previous seven days
Clinical
Symptoms suggestive of subarachnoid hemorrhage
Persistent blood pressure elevation (systolic ≥185 mmHg or diastolic ≥110 mmHg)
Serum glucose <50 mg/dL (<2.8 mmol/L)
Active internal bleeding
Acute bleeding diathesis, including but not limited to conditions defined in 'Hematologic'
Hematologic
Platelet count <100,000/mm^3*
Current anticoagulant use with an INR >1.7 or PT >15 seconds*
Heparin use within 48 hours and an abnormally elevated aPTT*
Current use of a direct thrombin inhibitor or direct factor Xa inhibitor with evidence of anticoagulant effect by laboratory tests such as aPTT, INR, ECT, TT, or appropriate factor Xa activity assays
Head CT scan
Evidence of hemorrhage
Extensive regions of obvious hypodensity consistent with irreversible injury
Relative exclusion criteria¶
Only minor and isolated neurologic signs
Rapidly improving stroke symptoms
Major surgery or serious trauma in the previous 14 days
Gastrointestinal or urinary tract bleeding in the previous 21 days
Myocardial infarction in the previous three months
Seizure at the onset of stroke with postictal neurologic impairments
Pregnancy
Additional relative exclusion criteria for treatment from 3 to 4.5 hours from symptom onset
Age >80 years
Oral anticoagulant use regardless of INR
Severe stroke (NIHSS score >25)
Combination of both previous ischemic stroke and diabetes mellitus

Figure 3:Guideline based Eligibility criteria for the tissue plasminogen treatment

Account tab includes some options related user information like user list, change thepassword, changeusers password, access group and system default.

Finally The system uploaded in thehost with domain www.Iranstroke.ir in order to use and evaluate by clinical neurology experts.

DISCUSSION

According to a demand from the center of neurologic diseases in Imam Khomeini hospital of tehran university of medical sciense, we started to design and development of an electronic registration system for acute stroke. Acording to our perivious studies most of stroke

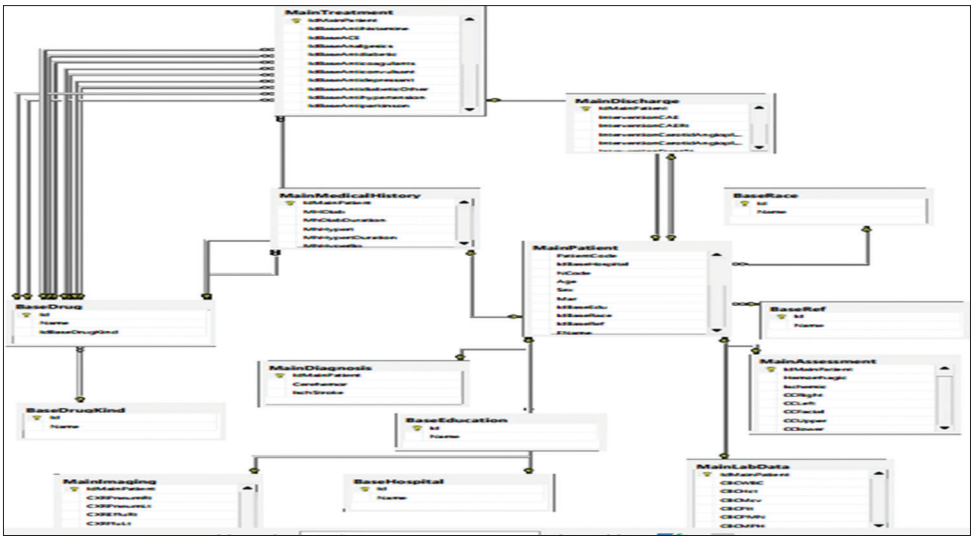

Figure 4: Data table relation diagram

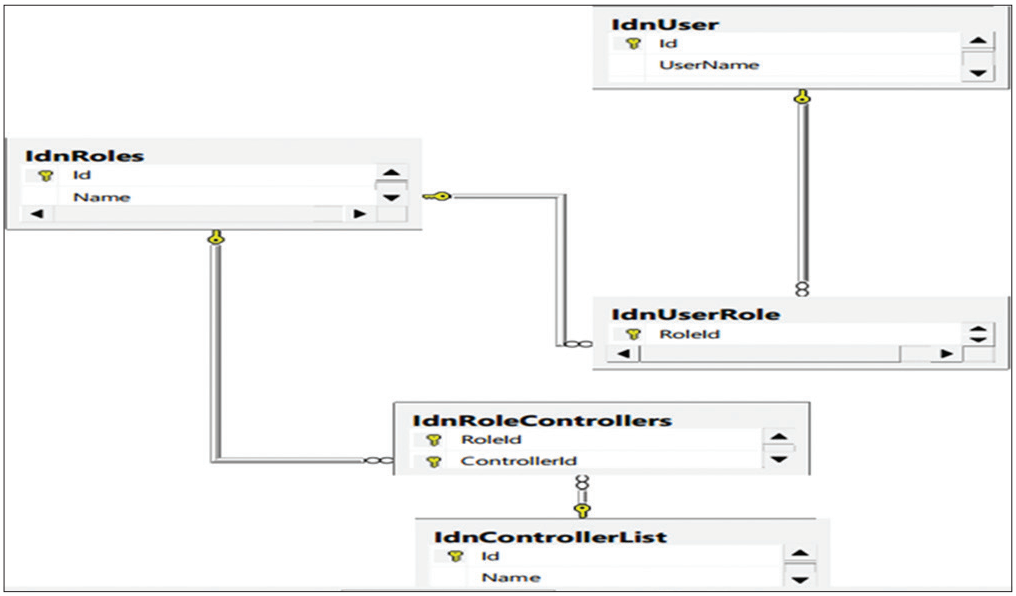

Figure 5: User table diagram

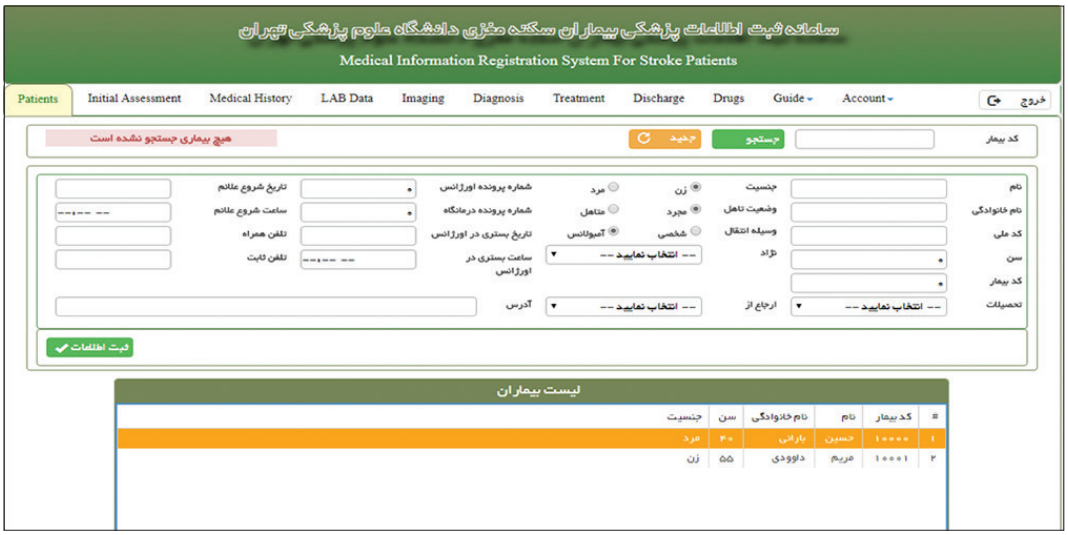

Figure 6: Patient tab

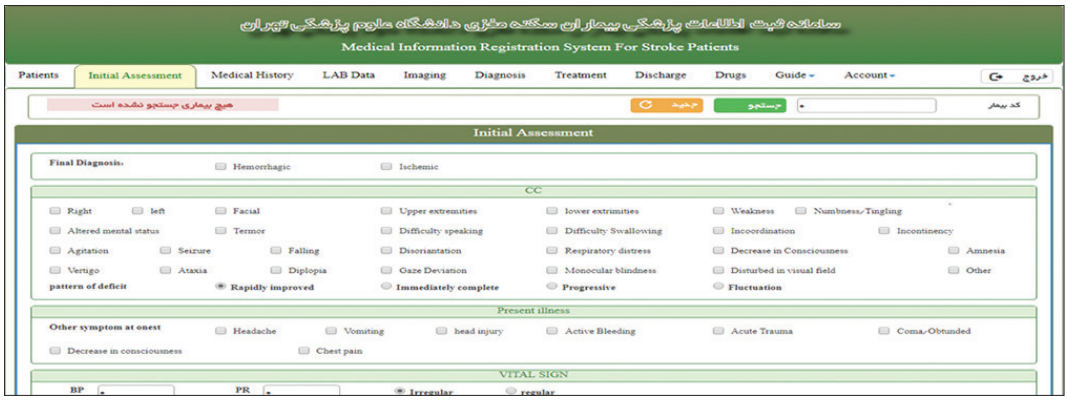

Figure 7: Initial assessment tab

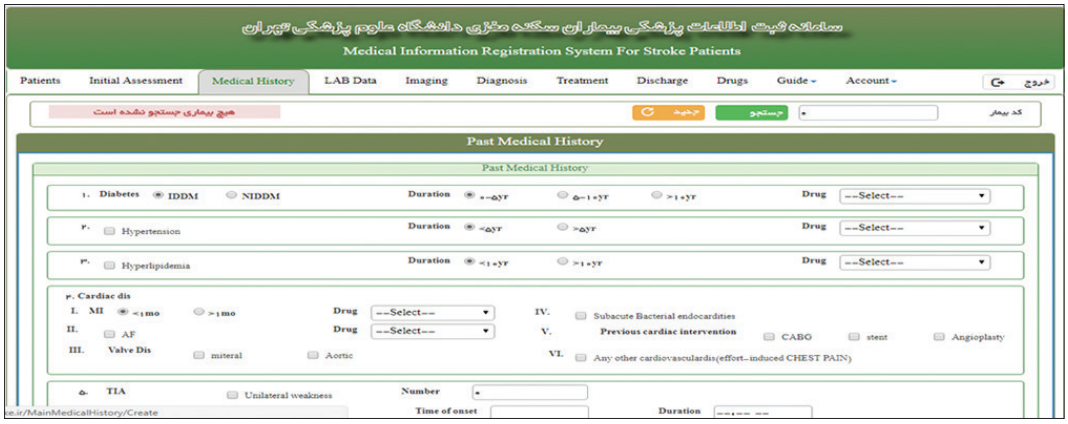

Figure 8: Medical history tab

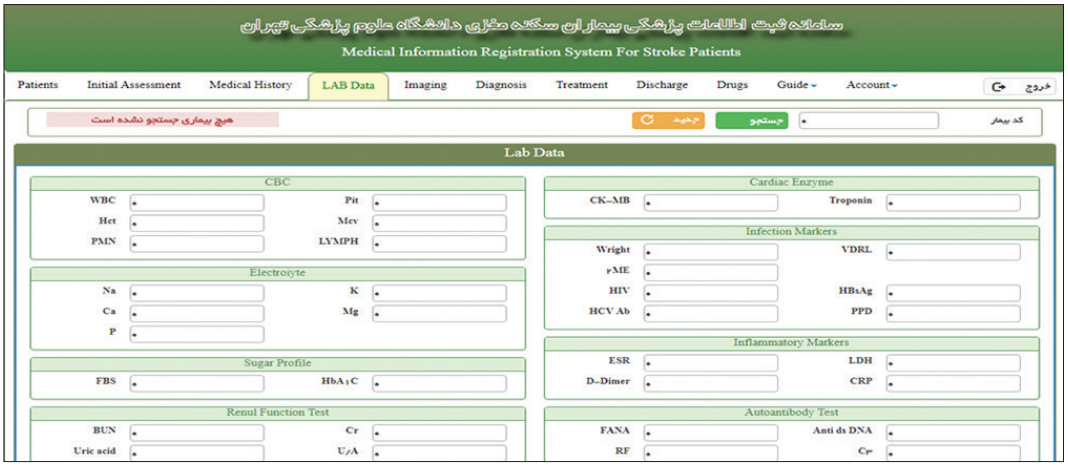

Figure 9: LAB data tab

electronic registration systems in the world, were developed in web platform, so the web based platform was choosed because of its accessibility advantages.(23) Onion architecture and MVC design pattern were used as new and more beneficial architecture instead of traditional 3 layer architectures that result more flexible and reusable codes and easier development and maintenance.(22)

Unlike most of stroke registration systems that follow only one purpose,(24-27) All detail data elements in the stroke patients medical record were identified based on paper medical record, clinical guidelines and care quality measures, after experts consultation and confirmation. The identified data elements cover multiple purposes like epidemiologic and statistics, care quality, clinical experts

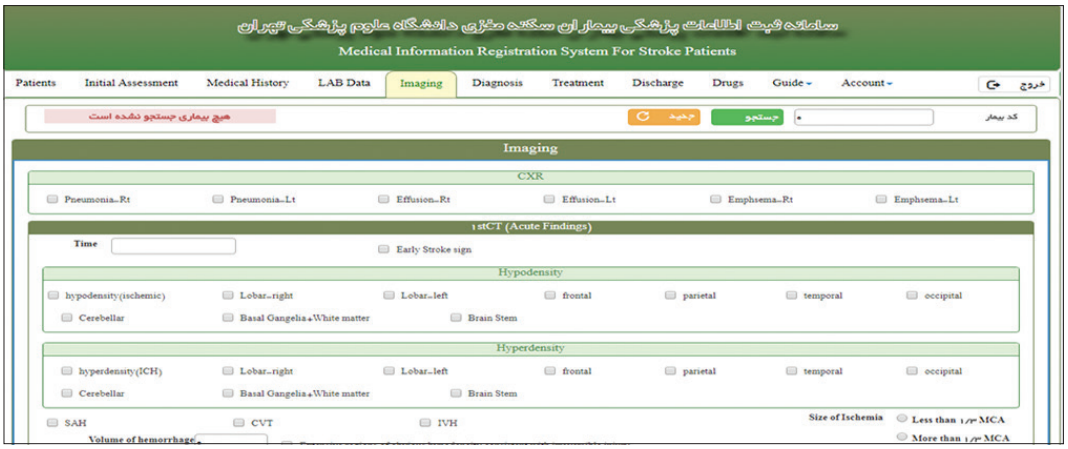

Figure 10: Imaging tab

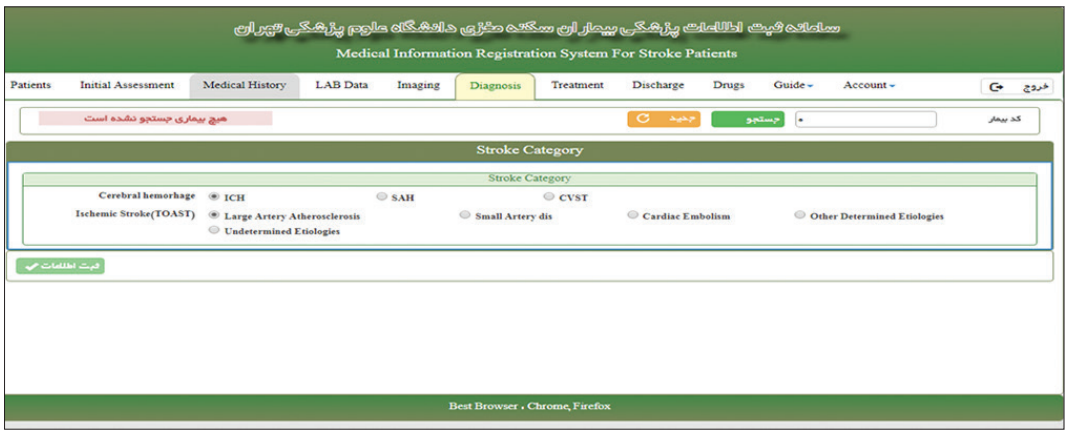

Figure 11: Diagnosis tab

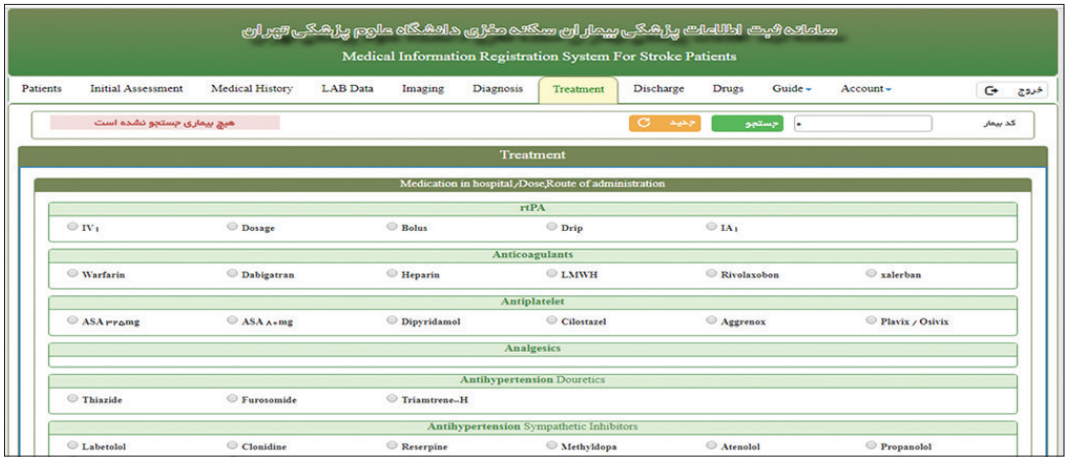

Figure 12: Treatment tab

accessability to patients information and ease of future reasearches. so, This system is not only a source of useful data but also an structured medical record registration system that includes all detail medical data of acute stroke patients. In addition to advantages of web platform, more powerful architecture, its structured formatand multi purpose coverage, it has significant advantages includes an embeded guideline-based clinical support tool that's a rare capability in other registration systems, includsion of the most important care quality measures in stroke acute phase like time of arrival in ED, time of CT Scan, patient eligibility for tPA treatment, Early tPA treatment in the time window, Early tPA treatment time Reasons for no early tPA treatment in the time window,

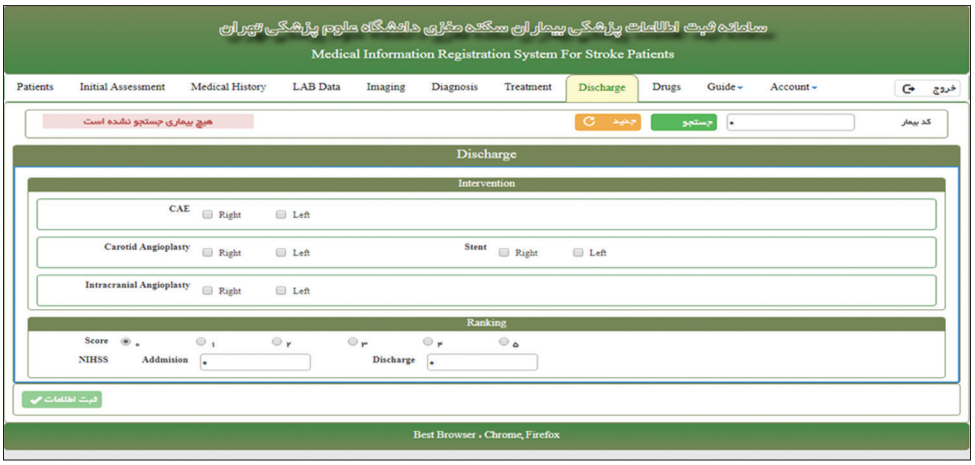

Figure 13: Discharge tab

Figure 14: Drug tab

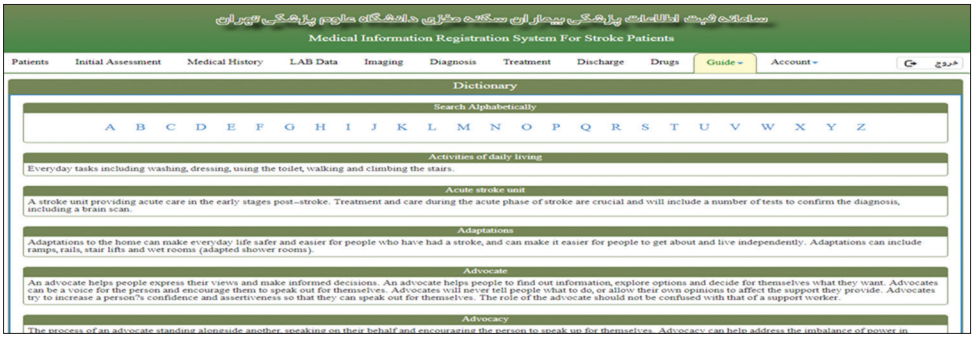

Figure 15: Guide tab

a guide tab that includes stroke dictionary and useful clinical guideline information of stroke, the capability of flexible drug list to add or remove new drug kinds and drug names and drug list accessability any where in the. The system identifies the eligible patients for Intravenous thrombolysis and if treatment is not done for them, The system wants the physician to explain the cause. According to our previous studies, compared to similar registry systems, many of thesystem features are unique. These characteristics distinguished the system from similar systems. Additionaly, all registered data can be import to Excel and SPSS softwares for more analysis and SQL business intelligencewide variety powerful facilities can be used in the system. However, it is just a start.Acording to health and clinical experts requirements, the system can beexpandedto have much more advantages like various guideline based or data based clinical support tools in near future.

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