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Evaluation factors for testing and validation of Clinical Reporting System

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***Abstract* -** Automate Clinical decision support system(CRS) provide assistance to physician as well as to society to enhance quality of healthcare. Methodical and apposite testing a of automate reporting system prior to liberate to end-users is kind of critical aspect any automate expert system related to healthcare domain. Testing and validation, is one of the most vital and critical step of CRS because lack of well defined testing tools , oversight this step may lead to dangerous and severe outcome issues. Great efforts are required for testing of system as data collecting form number of resources and may be in different formats. Clinic data available in Electronic Health Records (EHR) form. Testing of such huge amount of clinical data by human became to tedious and risky because chances of mistakes are there. Adaption rate of clinical reporting system quite slow, as many of them not tested properly prior to liberate .Testing and Validation of CRS depends on various factors that considered in this paper. For testing technique, considered functional and structural techniques by receiving information for input from every level of progress.

Keywords -Testing, Clinical reporting System, Evaluation factors, EHR (Electronic Health Records)

I. INTRODUCTION

With the diversity of technology in domain of healthcare , has changed the way physician do practice in their daily routine. Pattern of diagnosis became automate, patient can directly and indirectly seeks assistance from physician without visiting hospitals at anytime from anywhere with support of mobile health technology. Both term clinical reporting system and clinical decision system are compatible. Clinical decision support system assist the physician to make diagnosis more quickly and correctly. Integrating medical knowledge with information technology with support of data mining techniques, artificial intelligence etc. provide immense impact to automate clinical system to enhance healthcare quality[1]. Various kind of clinical decision support system by using various kind of techniques adapted and implemented world widely [2] , many systems under developing phase. Major objective of CDSS to improve quality of healthcare and provide convenience to end users. Foremost phase of CRS to integrate with EHR(electronic health record), repository of patient clinical information for processing to diagnosis disease[3]. Many times information gathered online uploaded by patient, physician, clinic staff or lab staff. Testing and validation of CDSS depends on various factors that has considered in this paper. As per knowledge many of CDSS tested prior released to end users[4]. Methodical and apposite testing a of automate reporting system prior to liberate to end-users is kind of critical aspect any automate expert system related to healthcare domain. Testing and validation, is one of the most vital and critical step of CRS because lack of well defined testing tools , oversight this step may lead to dangerous and severe outcome issues. Great efforts are required for testing of system as data collecting form number of resources and may be in different formats. Testing technique is a barrier for proper adoption and implementation of clinical reporting system.

In development of any kind of software, appropriate test tools and systematic plans that can perform funtional and structural testing are prerequisite. As per perception of developer and testing debuggers real time along with daily basis scenario quite adequate to make testing of complex automate CDSS. Most of CDSS testing scenario gather clinical information from knowledge base EHR repository, process that information and validate outcomes with experts. If any unexpected outcome or wrong diagnosis produced during daily practice that signify testing has been not correctly done prior to its release. For example if any CDSS has total 15 input parameters, all of them further have 15

different levels then total number of combination 15^{15},quality of CDSS defines on basis of potential to testing all the combinations. Objective of this paper to provide various factors need to be considered for testing and validation of automate clinical decision support system.

II. MATERIAL AND METHODS

Clinical Decision Support System

Clinical decision support systems (CDSS) can be defined as computer based systems designed to impact clinician decision making about individual patients at right time when decisions are made[Berner and Tonya 2007]. Broadly, CDSS are divided into two broad categories:(i) Knowledge Based CDSS (ii) Non- knowledge Based CDSS. Every CDSS has four major components: (i) input component: through which the information supplied to CDSS .Many CDSS integrated to EHR or PHR[3] as per requirement.(ii) Knowledge Base: Can include compiled information in form of rules (e.g if-then rules) or probabilistic alliance of a disease in form of signs and symptoms(e.g. drug–food interactions).(iii) Inference Engine:: It associate the input patient data and knowledge base by using some algorithm(rules and schemes) to provide output.(iv) *Presented choices*: After the utilizing the functionality of CDSS the physician can provide the recommendation, alerts or diagnosis report.

Testing consideration category

To perform testing on developed CDSS generally divided into three categories are: (i) to review about acceptability (ii) to review about quality (iii) to find out the problem. Testing related to the acceptability verifies all requirements related to the system should meet. Quality testing refers to enhance and retain confidence in the system. Finally, Problem testing supports to isolate discrepancies among specification of design and observed outcomes. Both Problem discovery and acceptability testing are most preferred kind of testing for systems[4,5] . By performing the testing on system can support the end users from Titanic principal. According to this principle: "Magnitude of a system's failure is directly proportional to the designer's belief that it can never fail"[5].

Commonly used paradigm for testing a system are: Clear box testing or white box testing also known as structural testing and Black box also known as functional testing. structural testing is a kind of approach where all test are derived from knowledge of software's structure or every individual component used for implementation. Whereas \Functional testing techniques those are used to test functionality of every features of system. It considered all the scenario like failure paths and boundary related cases. Major goal of testing is to reduce risks to end users, determine the capability of system, increase quality of upgrade(quality =confidence), to stabilize system and meet requirements of end users etc.

Pre-requisite to perform testing is to sketch a proper test plan. Idyllically, sketched plan based on documentation of validation and verification prepared during the development phase of system design. While testing of CDSS depends upon kind of expected standard required by developers. For effective design of CDSS to make clinical decision requires either medical evidence based knowledge or known clinical practice guidelines knowledge. Mostly efficiency and usefulness of CDSS depends upon kind of information gathering. So it is required, to sketch the plan properly and selection of right procedures before start the trial of testing.

Conventional Testing Paradigm

Generally, in testing paradigm of CDSS generate common scenario where developers feels that it's a scenario that CDSS encounter with real time. With these kind of testing foremost pathways can be tested, not have potential to properly checked all combination of possibility scenario. Such kind of system can leads towards hazardous results as being not tested methodically. If one of diagnosis outcome, diagnosed wrong by system among thousands of diagnosis then it will considered as unreliable CDSS. Whereas in new testing paradigm additional emphasis has given to the scope of consideration along with conclusion section other than measures metrics (like specificity, accuracy etc.). Author [6] had suggested standard for validation of numerous system. With these standard, investigators can provide the information regarding efficacy i.e promise of performance made during development phase and effectiveness (performance promises delivered) of system during testing phase.

Methods of Testing

Preliminary phase of testing is to prepares a verification and validation document that provide the detailed description about methods and standard to be used for testing. In our case divided the testing plan into several parts to perform the testing on knowledge base(KB) and implementation phase. During the implementation phase must ensure that knowledge base must be according to design phase[7].

Testing methods used for CDSS that mandatory are structural testing for module of KB and perform functional testing on every integrated module to other than knowledge base.

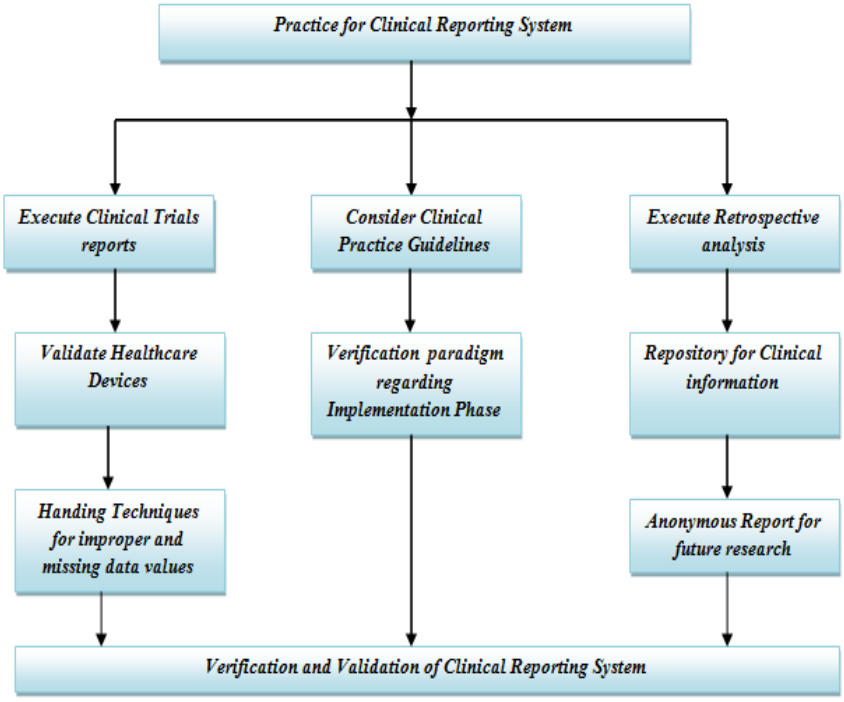

Fig. 1 Validation and Verification of Clinical reporting System.

Structural Testing: Structural testing performed on every module of the system. Basically paradigm of automate finite state implies testing on every module by considering methodology of implementation. It necessitates the detail knowledge and specification of structure of clinical reporting system. To perform the testing of every modules of CDSS, verification of each state at coding level and functional level along with automation phase performed by considering worst case robust testing[7].

Functional Testing: In case of functional testing considered the testing of functionality of system irrespective to the implementation methodology of system[8].During the design phase, development of test cases module and specification can be performed exclusively for testing various phase of implementation of KB.

Selection and Design of Test Case*:* To perform functional and structural testing, various kind of test cases has been considered. The performance of the clinical reporting system can not only measured alone on the basis of structural and functional testing. A flowchart shown in fig. 2 that describe various steps make use of for the development of various test cases and associated test plans.

Error handling:During testing of individual component of CDSS[9], major four category kind of errors can be found:
Inaccuracy in Knowledge Source : Let us considered, USA based clinical guidelines related to hypertension describe that," If any diabetic patient at the stage of microalbuminuria, recommendation of angiotesion that converts to enzyme inhibitors. At same time if any patient suffering from Type-II diabetic included other factors also , same recommendation of angiotensin converting enzyme inhibitors are recommended. In this scenario, statements of recommendations are ambiguous for both the cases for diabetic patient and patient suffering from microalbuminuria. Such kind of ambiguity leads towards interpretation errors.
Inaccuracy in Knowledge Base: Repository of patient information stored in Knowledge base(KB) in structured form, where exactly translation of knowledge source to KB not feasible. For example as considered scenario of above

mentioned guidelines doesn't able to correspond the guidelines that will stored in KB like " if a patient suffering from diabetics along with microalbuminuria, then recommended of angiotesion at that stage which converts to enzyme inhibitors. While in above statement consider stage whereas it consider the earlier stages also while not scenario in case of rule.

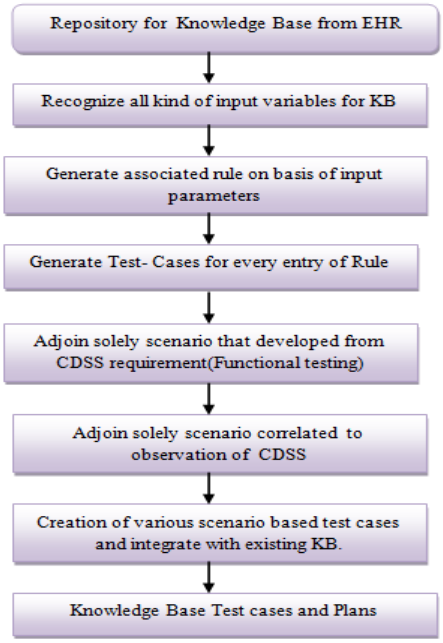

Fig. 2 Testing Development Plan Phases

Inaccuracy inference engine: It associate the input patient data and knowledge base by using some algorithm(rules and schemes) to provide output. During testing it as been noticed in many cases where does not apply rules in preferred order and may be bugs arises in software of inference engine.

Inaccuracy presence in Decision Support System: Many times users of DSS not familiar with the proper execution way, so chances to make errors during uploading patient data and many times in appropriate understanding the output provide by the DSS. Most commonly errors can be made during data entry of CPG(Clinical Practice Guidelines) , medications ,recomendation etc[10].. Not properly tested DSS can lead towards serious medication conclusion.

Generally, testing and validation of KB should be done vigilantly. As errors[10] arises in Knowledge Base arises more challenging, but during testing these errors can be fixed by referencing other knowledge source like expert committee of physicians. While errors arises in inference engine presume to be less challenging as these can be domain independent which could be tested with any available software. During testing extra focus be on errors in KB, numerous kind of errors found in KB like:

Syntax Anomaly *:* Theses kind of errors occurred when doesn't follow appropriate rules, grammar suppose to be expected like mismatching in parenthesis, not putting semicolon etc..

Logical Anomaly: Mostly anomaly leads towards errors, in case of DSS logical anomaly when ever rules get duplicated, wrong diagnosis of disease etc.. Logical anomalies indication of presence of inaccuracy in KB and need to be considered. Major kind of anomalies considered for logical are inconsistency, deficiency, regularity and circularity. Category of anomalies varies according application domain.

Semantic Anomaly: Mostly these kind of errors occurred whenever modules are accurate from logic point of view but conflicts arises due to issue related to the knowledge domain . For example, a male patient suffering from Gestational diabetes a kind of semantic error because a pregnant women suffer from these diabetes only or temperature of human body 90°C.

Knowledge Base Anomaly: This kind of error arises when knowledge base not properly able to associate with knowledge source, though semantically, logically and syntactically its correct. A error is considered to be knowledge base if found in KB. For example, " If a patient type-2 diabetic then recommendation to control its diet for start phase", while associated a rule-based KB make statement that " If a patient type-2 diabetic then recommendation of medication for initial phase".

III. Results and Discussion

During testing , clinical data of patient of Medical Hospital Amritsar and Medical Centre had and been collected and perform diagnosis to evaluate validation of CDSS. Proposed system has potential to diagnosis numerous diseases but for this study considered chronic decease diabetics. Make classification either patients is diabetic or non-diabetic. Multiple runs had been evaluated to perform results. For study, data of more than 100 subjects has been collected in between the age of 18-80 years. Classification techniques applied for diagnosis and classification accuracy of SVM obtained 94%, for K-NN 92.3% obtained and for NB it was 87%[11,12]. Another measure metrics like Specificity and

Sensitivity performance better of SVM as compared to K-NN and NB[13]. To elucidate the Medical Reporting System framework using existing standards , our testing methodology compared with other outlined system[2,13].Other major deliberation not addressed of evaluating procedure for expert system like impact of CDSS[14] on patient care, medical outcomes etc.. Although limitation which considered for system are that system relies basically on rules which designed by human being, formation of test cases and make entry of these cases into computer. Only efficiency of CDSS can be checked through this way. Although dependence on human being is inconvenience so scope for future improvement that can be considered as weakness of the system.

IV. Conclusion

Prediction and diagnosis of chronic diseases at early stage with support of physician and technology required to expanded in domain of healthcare. with the integration of automate CDSS with healthcare offered a harmonizing service to society for diagnosis of chronic diseases. To provide better performance for diagnosis of chronic disease 25 novel rules apply to 20 metrics as per Clinical Practice Guidelines. To perform the efficient testing we recommend that make the combination of static and dynamic methods , integrate methods that generate automatically along with method suggested by experts. Selection of the test cases should have similitude with real world cases. Its suggestion that verification and static scheme must to performed before dynamic and validation processes. Another suggestion is to formulate appropriate guidelines and rules with experts before automate the system, as in future during enhancement of system, provide convince in making automate testing rather to associate mapping with experts.

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