臨床意思決定支援システム

Clinical Decision Support System

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要　旨

臨床意思決定支援システム（Clinical Decision Support System: CDSS）は，医療資源の不均衡という社会課題の解決に貢献するものであり，中国に巨大な市場がある．CDSSは，主要な病院の臨床の知見や信頼できる医学文献に基づき，人工知能により臨床経験を学習することで，外来および入院患者に対して医師の臨床現場での意思決定を支援することを目的としたデジタルサービスである．エビデンスに基づいた意思決定のためのナレッジベースとして，広範で信頼性の高い臨床ナレッジグラフとその自動構築のための技術を開発した．我々のCDSSサービスは，誤診や病気の見落としを減らすことで診断の精度を向上させ，医療行為の品質管理の人的労力の無駄を省いて診療効率を向上させる．さらに医師が実際に自分自身の医療技術を向上させ続ける仕組みを提供することで，総合的に医療サービスを改善することに貢献する．2019年以来，数十の医療機関，特に中国での医療資源提供の94%以上を占める一次医療機関向けに本サービスを提供している．

ABSTRACT

Clinical Decision Support Systems are a huge market in China, due to their potential as a solution to address the problem of unevenly distributed medical resources. In this digital service, AI decision-making models are trained by learning clinical experience from top grade hospitals and authoritative medical documents, and then provide decision supports to doctors in outpatient clinics and hospitals. We have developed a broad and reliable Clinical Knowledge Graph, which is automatically built, as the knowledge base for providing evidence-based decision-making. Our product can improve the accuracy of diagnoses by reducing misdiagnoses and missed diagnoses. It can also reduce mis-operations and human workloads, as well as provide opportunities for doctors to continue to improve themselves in practice, thereby improving efficiency and quality of medical service. Since 2019, we have been providing service to dozens of medical institutions, particularly Primary Healthcare Institutions which account for over 94% of medical resources in China.

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1. Background and Purpose

A Clinical Decision Support System (CDSS) is intended to improve healthcare delivery by enhancing medical decisions with targeted clinical knowledge, patient information, and other health information[1]. It is an intelligent information system that provide digital service to doctors, nurses, hospital managers and other medical practitioners at their workplaces. It works together with Hospital Information System (HIS), Electronic Medical Record (EMR), Laboratory Information System (LIS), Radiological Information System (RIS), Computerized Physician Order Entry (CPOE). The key features include the following, 1) employs a medical knowledge base, Clinical Knowledge Graph, to support evidence-based decision-making in CDSS; 2) helps to collect and analyze patient information by taking real-time data feed of EMR as input, 3) gives real-time evidence-based decision support prompts to practitioners. CDSS can help to improve the efficiency of diagnosis and treatment, and the quality of medical service.

CDSS originated in the United States in 1950s as an expert system, and soon became an urgent demand in the global market such as Europe and Asia Pacific, then entered the Chinese market in 2015. In China, there is a serious social issue of insufficient medical resources. China is a populous country, but the medical resources are unevenly distributed. There are around 1,000,000 healthcare institutions in China, of which only 3.5% are graded hospitals located in big cities, while 94.8% are primary medical institutions located in communities and remote areas, cannot provide high-quality medical service[2]. The difference of medical resources (doctors) per thousand population between Urban and Rural is very obvious, 4.10:1.96[2]. According to a misdiagnosed data from the Chinese Medical Association, across the country, the number of misdiagnosed cases per year in clinical care is about 57 million, and the total misdiagnosis rate is 27.8%. In primary healthcare institutions, it accounted for 44% of the doctors with bachelor's degree or above[2], and it takes about 5 to 10 years to train a general practitioner.

Overall, the purpose of CDSS is to reduce the probability of medical accidents caused by improper medication or improper operation, reduce unnecessary harm to patients, and improve doctor's efficiency. The use of CDSS covers the whole process of pre-diagnosis decision-making, mid-diagnosis support and post-diagnosis evaluation. In the hospital, doctors use it as a digital service in their work, to improve efficiency and accuracy, at the meantime, it also improves the hospital's overall management and medical service. Individual patients can benefit from the reduction of misdiagnosis, missed diagnosis and mis-operation, more accurate insurance calculation, and improved efficiency of medical treatment.

2. Clinical Knowledge Graph

Knowledge Graph (KG)[3], is a knowledge base that uses a graph-structured data model to integrate data and represent knowledge. KGs are often used to store interlinked descriptions of real-world entities, such as a certain symptom is a manifestation of a certain disease, and certain medicines can treat a certain disease.

2-1 Schema Design

The Clinical KG served as the evidence base in CDSS, to provide entity descriptions, attributes, synonyms, relations between entities. That knowledge can be represented in different ways depending on the schema design. Some of them do not distinguish detailed treatment such as lab test, radiology examination, physical examination but consider all of them a same entity "treatment"; while some of them are missing of attributes such as days of symptom duration which is important in diagnosis. Our schema design was under the guidance from a team of professional medical experts, which is

disease-centered, consisting of 32 entities, 110 attributes, 133 relations, as Fig. 1 shows.

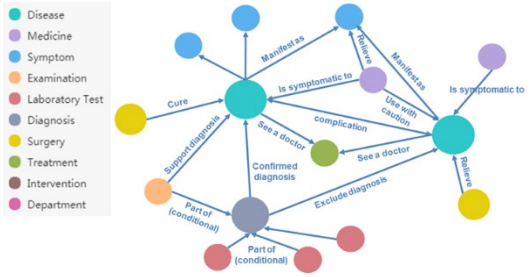

Fig. 1 Schema of our Clinical KG (partial).

2-2 KG Construction

Knowledge, i.e., entities, relations, attributes, are extracted from medical documents by utilizing Information Extraction technologies. Medical documents include textbook, guidelines, consensus, drug labels and instructions, and other authoritative medical articles, in total nearly 1 million pieces. In documents, knowledge exists mostly in plane texts, a few in tables and flowcharts. The difficulty lies in processing text, because the medical entities are complex, sometimes overlapped, nested and discontinuous. We employed BERT[4] and Graph Convolutional Network (GCN)[5] as the encoders to understand the context of sentence or paragraph, then ensembled them to achieve span-based recognition for entities and attributes.

As a result, our Clinical KG covers millions of entities/relations and tens of millions of relations. It is kept updating when there is newly released guidelines and consensus articles. A partial KG of lung cancer is shown in Fig. 2.

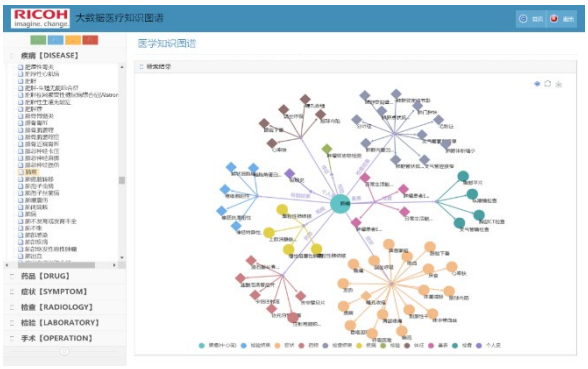

Fig. 2 Partial KG (lung cancer-centered).

3. Clinical Decision Support

3-1 Decision Support in Outpatient Clinic

The purpose of CDSS in outpatient clinic is to give real-time decision support to doctors, not only improving the efficiency but also helping to reduce the possibility of misdiagnosis, missed diagnosis, and mis-operation. At the meantime, doctors in Primary Healthcare Institutions can refer to the decisions in CDSS that are modeled based on experiences in top-grade hospitals, to improve themselves in practice.

The benefits on medical quality management in outpatient clinic are reflected in, 1) Smart Inquiry (Pre-diagnosis) helps to collect medical history in standard terms, 2) AI Diagnosis and Treatment Plan Recommendation (In-diagnosis) help to reduce misdiagnosis and missed diagnosis, 3) Reminder in Medical Advices (Post-diagnosis) helps to reduce health risks in medication treatment according to patient individual conditions.

As Fig. 3 shows, the system takes EMRs as input, through Medical Information Extraction and Decision Model, real-time medical recommendations can be provided to doctors, including AI diagnosis, treatment plan recommendation, smart inquiry, reminder for taboos and precautions in medical advice, knowledge retrieval.

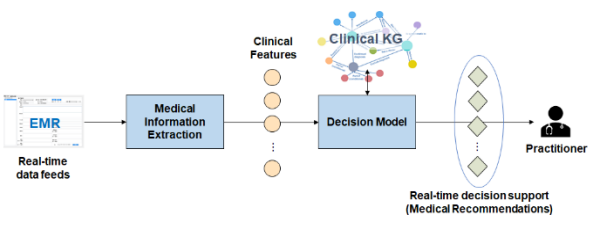

Fig. 3 Decision support flowchart.

Along with the input of EMR, CDSS accept the same information as the doctor. Firstly, the Medical Information Extraction module recognize the clinical features in the input content, such as symptoms and its attribute, vital signs, disease history, lab test results, allergy history, medicine history, and etc. The extraction performance on metrics F1 (weighted average of Precision and Recall) reached 95%, which is good enough for subsequent functions. Then, those features are fed into Decision Model, in which evidence-based knowledge came from Clinical KG and experience learned by Deep Learning or Machine Learning, are combined to give the final ranking list of medical recommendations.

3-1-1 AI Diagnosis

AI diagnosis is the core decision function in CDSS. Once the content in EMR is updated, AI diagnosis also update its recommendation of top 10 predicted diagnosis. Doctors can refer to the recommendations to confirm their inference, make differential diagnosis, diagnose complications, and give the final diagnosis.

Accuracy and interpretability are the criteria to evaluate the capability of this function, or even the entire CDSS. However, the two criteria are seldomly compatible, and for each, a specific approach is better fit, namely, evidence-based decision support and experience-based decision support.

- The former requires the construction of an accurate Knowledge Base for inference, the most typical example of which is an Expert System. This kind of system can provide explicit knowledge and decision rules with full interpretability but costs a lot of manual work to build. In practical cases, it is unable to cover all possible decision paths for inference.
- The latter learns from historical data and experiences by utilizing Machine Learning and Deep Learning. Compared to Expert System, it is not expensive to build and, in most cases, provide more accurate prediction. the more the pursuit of high accuracy, the more complex the model, and lacking interpretability of the results has become a major shortcoming of it.

As Fig. 4 shows, firstly we build a Clinical Knowledge Graph as CDSS's knowledge base which is covering a wide range of knowledge, reliable, but with lower cost. Then we combine the evidence-based method and experience-based method to achieve decision support which is accurate and interpretable at the meantime.

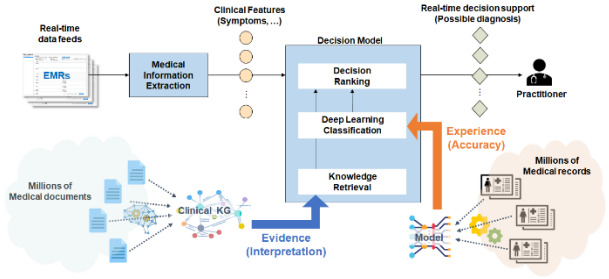

Fig. 4 AI diagnosis flowchart.

The Deep Learning based classification model is a multi-class classification to predict the likelihood of all thousands of diagnoses because it is very common for multiple diagnoses (with important priorities) to appear in one medical record. Classification models consider each diagnosis independent to each other, but in actual cases, diagnoses are not independent to each other. Usually the first diagnosis is the major diagnosis, accompanied by complications as second/third diagnosis. However, complication relationship cannot be described by rules simply, because it depends on the patient's conditions. To solve this problem, as Fig. 5 shows, we utilized expertise

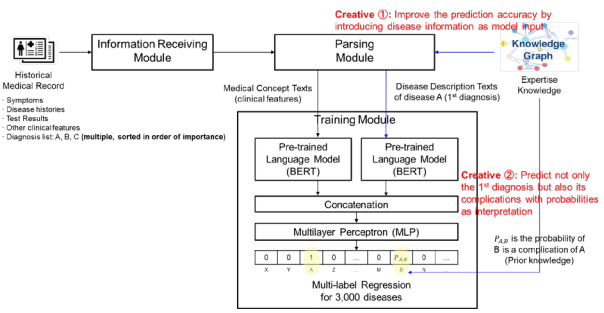

Fig. 5 Deep Learning based classification.

knowledge in KG, to predict not only the first diagnosis but also its complications with probabilities as interpretation.

We compare our system with the major competitor "灵医智惠"[6] supported by Baidu (百度), which is the biggest Search Engine provider and one of the strongest AI technology provider in China. Firstly, we outperform competitor on the accuracy. We achieve 90% accuracy at top 3 diagnosis, while competitor achieves 89%, based on a 15,000 historical record dataset of common diseases. Winning this 1 percentage point means that for every 100 cases, on average our system will give a completely correct diagnosis recommendation for 90 cases, while competitor gives completely correct recommendations for 89 cases. This means our system may help to avoid one more misdiagnosis per 100 cases, which is a significant outcome to the patients, especially in Primary Healthcare Institutions. Secondly, we can provide interpretable arguments for predicted results, such as which clinical features in the EMR are supporting current diagnosis and where the evidence comes from, while competitor cannot provide interpretable arguments because they do not integrate the evidence-based approach into their service. Interpretation is important to help doctor identify the cause and the rational.

3-1-2 Treatment Plan Recommendation

Given a diagnosis or a combination of multiple diagnosis, the system can recommend treatment plans, including medicine, surgery, radiology examinations, lab test, clinical scales, with corresponding reasons and expected effects. All that knowledge come from the Clinical KG.

3-1-3 Smart Inquiry

Smart Inquiry function helps to standardize medical inquiry to avoid missed diagnosis and misdiagnosis. The system presents common symptoms of Chief Complaint (also termed Presenting Complaint, which is a concise statement describing the symptom, problem, condition, or other reason for a medical encounter) in standard medical terms for doctor to select, and also gives hint to collect symptom attributes, patient histories, and accompany symptoms. It ensures not only the correctness of terms entered by doctors, but also help to avoid logical errors.

3-1-4 Reminder in Medical Advices

To avoid outpatient mis-operations, CDSS also standardize the medical advices given by the doctors. The patient conditions such as vital signs, symptoms, natural properties (age/gender/pregnancy), allergy history, disease history, medicine history are recognized from natural language text in EMR, then the possible conflicts between patient's condition and doctor's advice will be identified and warned as taboos or precautions in the system. Sometimes doctors may overlook the possibility of contradictions, or sometimes they decide to ignore the conflicts such as adverse reactions to ensure better treatment results. The system will provide decision support, and doctor will make the final decision.

3-1-5 Knowledge Retrieval

To help doctors to improve them in practice, CDSS provides retrieval service for general clinical knowledge of diagnosis and treatment, including diseases, medicines, lab tests, examinations, surgeries, and clinical scales. It supports keyword search and Pinyin query with typo tolerance.

3-2 Quality Management in Hospitalization

In healthcare, quality refers to the extent to which healthcare services are provided to patient individuals and populations to improve health outcomes. Medical error[7] in the delivery of healthcare services (diagnosis and treatment) is a major source of avoidable mortality and morbidity.

In hospitalization, quality management become more important to both hospital managing and patients, because

hospitalization takes longer time for treatment (2 days to 100 days), there are many treatment operations that may need decisions, and many costs involved. It includes, 1) Treatment Process Decision (Pre-treatment) helps to reduce foreseeable health risks, 2) Reminder for Treatment Stage (In-treatment) helps to reduce mis-operations by giving real-time instructions and warnings, 3) Review the Entire Process (Post-treatment) helps to continuously improve hospital management and disease management by correcting errors in medical records and reporting important condition index. In CDSS, there are two functions (in 3-2-1 and 3-2-2) to achieve above quality management over medical records and treatment process.

3-2-1 Quality Management of Medical Records

Medical records are the carrier of the entire medical process. In hospitalization, there are more than 30 kinds of medical records are involved: admission record, discharge record and brief, daily progress notes, lab test reports, examination reports, surgery records (anesthesia records, pre-operation discussions, operation summary), nursing operation records, general therapy/treatment record, and others. Most important one is the Front Page of Medical Records (病案首页) which is drafted by practitioner as the summary of all medical records during hospitalization. It covers 192 items in standard codes, and is important as, 1) accounting basis for medical insurance and commercial insurance, 2) data basis for life-long health record of patient individuals, 3) evaluation basis for hospital's services and management, 4) data source for national healthcare statistics and disease prevention forecasts. Errors, omissions, and inconsistences always happen, which requires human inspectors put a lot of effort on correcting them. The inspecting is exhausting and requiring professional knowledge as much as doctor, but there are still omissions after reviewing hundreds of inspection items among dozens of records.

CDSS can help to reduce human effort by utilizing medical term extraction and linking technology, give a comprehensive inspecting over more than 400 inspection items of completeness, compliance, logical, rationality, then prompt by real-time during record drafting rather than reviewing afterwards.

3-2-2 Quality Management of Treatment Process

The in-process quality management is a step towards AI based Plan-Do-Check-Act (PDCA) Management. CDSS automatically check whether the treatment behavior meets clinical pathways and giving reminders in real time to human omissions and negligence. After patient discharge, the important condition indicators are reported to National Healthcare Office to continuously improve the quality of healthcare service.

Standardize treatment program should be stick to Clinical Pathways, including the inclusion and exclusion of specific diseases, the operations in treatment stages, the report of important indicators. In China, hospitalization treatment focus on 51 specific diseases in 10 categories (disease, surgery, chemotherapy, dialysis, and other treatments)[8]. The management starts from the moment of admission, monitors medical behavior every minute until discharge. In general, there are four stages as following.

Stage I: Admission

The specific disease quality control started. After the inclusion, a list of quality items is created based on clinical pathway. Then the check of admission quality items is completed.

Stage II: First day treatment (Day 1)

Check and prompt treatment steps on the first day, including the doctor's medical advices to see whether it meets the standard, the patient's medical history to see if there are contraindications. The patient's current condition to see if it is necessary to transfer or exit.

Stage III: Everyday treatment (Day 2 to Day N)

Check and prompt treatment steps that have not yet been performed, including those items in Stage II.

Stage IV: Discharge (Day N)

Extract each quality control item index in the whole treatment process and submit report for statistical purposes.

4. CDSS Products

Fig. 6 shows three kinds of CDSS products we are providing, including Hospital CDSS (in 4-1), Elderly Care CDSS (in 4-2), and Primary Healthcare Institution CDSS (in 4-3).

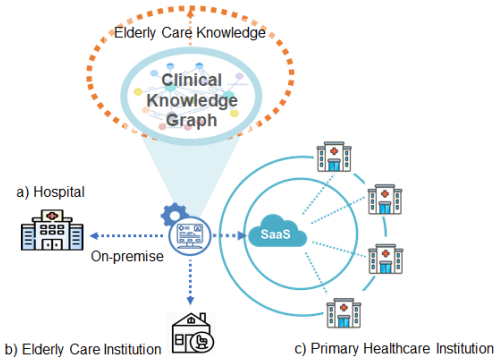

Fig. 6 CDSS products.

4-1 Hospital CDSS

Hospital CDSS provide services to graded hospitals in China, helping to standardize the diagnosis and treatment, and to ensure quality management over the whole process. It consists a full set of functions and cover the knowledge of nearly 10 thousand diseases. Equipping with CDSS functions, is one of the conditions of passing "Evaluation of application level of electronic medical record system" (电子病历系统应用水平分级评价)[9] and "Standardized maturity evaluation of hospital information interconnection" (医院信息互联互通标准化成熟度测评)[10]. For the sake of information security, CDSS, like other information systems, needs to be deployed on-premise and interfacing with HIS and EMR at least.

4-2 Elderly Care CDSS

Elderly care means not only medical service but also health care related to elderly. The Clinical Knowledge Graph was expanded to cover elderly care knowledge, including chronic diseases, patient education and special precautions for elderly.

4-3 Primary Healthcare Institution CDSS

Primary Healthcare Institutions CDSS acts as General Practice (GP) doctor, since there are no subdivided departments but only internal medicine and surgery, which brings more difficulties to doctors who are not experienced. The AI Diagnosis function is further tuned to improve the diagnosis accuracy on the diagnosis of most common 623 diseases. On the other hand, in remote areas, the primary healthcare institutions are very small and do not even have EMR, which requires CDSS can provide additional service for EMR management and interconnection. Therefore, the SaaS version provides regional service to Primary Healthcare Institutions.

5. Conclusion

5-1 Conclusion

From the first launch in 2019, under the cooperation and promotion of local partners, our CDSS products are now serving dozens of medical institutions, including Grade III/II hospitals (top levels), provincial hospitals, specialized hospitals, traditional Chinese medicine hospitals, primary healthcare institutions, and elderly care institutions. The future expansion direction will focus on primary healthcare institutions, aiming to solve China's current issues of uneven distribution of medical resources and poorer medical services in remote areas.

CDSS is a tool for professionals and experts (doctors), which means it should not only meet the general needs of improving work efficiency and optimizing work processes,

but also meet the advanced needs of improving the quality of diagnosis and treatment services. Quality here means the higher accuracy, as well as the rationality and comprehensiveness of various details. We expect CDSS can not only provide assistance to doctors, but also provide instructive help to make up for the shortcomings in the doctor's own decision-making and solve the problems that the doctors themselves cannot solve. It is only a short-term goal for AI algorithms to learn the knowledge in literatures and doctor's clinical experience, which can assist or even complete the work of the doctor. How to make AI have decision-making capabilities beyond humans and overcome difficult and complicated diseases will be a long-term research topic.

5-2 Future Challenges

Medical Information Extraction in CDSS can be extended to help Real World Study (RWS) in medical schools and pharmaceutical manufacturers for scientific research, such as analyzing the results of clinical trials of drugs and instruments.

On the basis of processing EMR, interfacing with Picture Archiving and Communication System (PACS), further introduce imaging diagnosis is another challenge. IBM Watson has tried to solve cancer treatment but failed many times. We will start with the diagnosis of ultrasound images by remote ultrasound diagnosis product. Experts or experienced doctors in top-level hospitals can directly operate ultrasound probes through robotic arms to diagnosis patients in remote areas. Not only a one-time improvement of efficiency, but also the operation details, images, and conclusion diagnosis will become knowledge in CDSS to guide the operation of remote area doctors.

Due to the emergence of COVID-19 epidemic, the market of Internet + Health services in China is expanding. But current services can only provide limited knowledge base and expensive medical consultation by human doctors. CDSS is expected to extend from a system used by medical professionals to a system that can support patients' self-service consultations, to relieve some workload on hospitals, and to enable patients to receive timely advice and guidance.

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