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Data Sources (LLM) for a Clinical Decision Support Model (SSDC) using a Healthcare Interoperability Resources (HL7-FHIR) Platform for an ICU Ecosystem

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Summary

The increasing development of digital technologies in recent years has led to a concomitant increase in the availability of data in ICUs. For this vast amount of information to be useful, it must be processed and analyzed to extract meaningful information. However, its size and complexity often exceed the capabilities of traditional tools, motivating ongoing research efforts to develop new analytical techniques better able to address these challenges. This effort has resulted in the maturation of disciplines such as artificial intelligence, machine learning (ML), data mining (LLM), parallel computing, and many others. Despite these advances, countless challenges of modern computing remain unaddressed and strategies to extract knowledge from complex data will undoubtedly persist as an active area of research in the years to come.

Real-time risk estimation of isolated pathologies provides interpretable information to understand the different risks of patients with multiple pathologies using electronic health records (EHRs) in an ICU patient; However, in this case there are fundamental problems when formulating hypotheses such as sample selection bias, imprecise variable definitions, implementation limitations, frequency of variable measurement, subjective treatment assignment and model overfitting.

Decision-making and predictive models (CDSS), on the other hand, are not yet widely developed with the current known health systems. However, their potential based on massive data sources, allows with the structured data of data lakes, to perform artificial intelligence (AI) to improve training and control for algorithms according to the different requirements and security that we must carry out and that we will build for the different syndromes. Here we present an CDSS model that captures data from public ICUs and we show in our report the potential data mining, for later analysis with different predictive models.

We highlight that with the current results of a public ICU, through a Smart ICU there is 0.003% that corresponds to EHR data and only 3.97% is structured data in data lakes that are susceptible to useful algorithms -at the present time- for an CDSS system.

Keywords: Data sources; Intensive Care Units; CDSS; Artificial Intelligence; Interoperability; EHR

Abbreviations

ICU: Intensive Critical Care Units.
ML: machine learning.
LLM: large databases.
EHR: Electronic Health Record.
AI: Artificial Intelligence.
CDSS: clinical decision support system.
Smart: Intelligent.
UPC: Critical Care Patient Units.
FHIR: Fast Health Interoperability Resources.
HL7 v3: Health Level Seven version 3.
API: Application Programming Interface.
DNN: Deep Neural Network.
NPL: Natural Programing Language.
IoT: Internet of Things.
TI: Technology Informations.

Introduction

As the amount of data available in healthcare has increased significantly and only 20% of the data included in electronic health records (EHR) are in a structured format, databases have become a common solution to manage heterogeneous data in healthcare [1]. Today, these are used far below their capacities in medical research. As a result, there is a 15 times higher rate of semi-structured data generation (e.g. CSV, JSON and XML), as well as a much higher unstructured and undimensioned data production (in ECG, CT and MRI scans) compared to structured data [10]. When focusing on EHR data from an ICU, the analysis is more affected by the criteria for admission to the ICU, which vary from one unit to another, and even within the same hospital at different times [1, 4, 8].

Decision making in the critical care setting is complex, fraught with uncertainty, and stressful. An intensive care physician makes approximately 100 decisions when caring for 6 patients and up to 244 ad hoc decisions during a 24-h shift [1]. Most of these are complex, event- or data-driven combinations of diagnostic assessments and therapeutic interventions [3]. But, we must also take into account other considerations, such as sample selection biases, imprecise variable definitions, implementation limitations, frequency of variable measurement, subjective treatment assignment, and model overfitting [8]. Similarly, many other clinical decisions are subject to subjectivity, such as when a patient is ready to be discharged (selective censoring) [6] or when a patient is readmitted from the ward [7].

Technological advances have led to a "digitalization" of, among others, biomedical research and clinical care. Therefore, in any modern hospital, every patient encounter is documented in an EHR, which includes information such as: vital signs, laboratory values, images, and much more [3, 4].

Moreover, the large databases generated by decades of scientific research are now stored in vast, isolated databases [4]. Furthermore, the amount and complexity of this data is multiplying every day as more information is produced. In biomedicine, the ideal would be to use this information to better understand disease mechanisms, predict clinical outcomes, or design better, optimal treatments for patient care, i.e. "personalized" medicine. However, this is impossible without analytical tools capable of extracting meaningful knowledge from the vast amount of data available. This idea is intrinsic to what is known as the "big data" problem, i.e. data of a size or complexity beyond the capacity of traditional methods and software to store, process, and analyze, a type of Big Data models large database (LLM). The challenges of working with such information are summarized in the "Four Vs of Big Data." Over the years, LLMs have emerged as a breakthrough technology with immense potential to revolutionize various aspects of healthcare. Furthermore, with the exponential growth of EHRs, medical literature, and patient-generated data, LLMs could help healthcare professionals extract valuable insights and make informed decisions.

When analyzing or predicting outcomes of treatment decisions, using a clinical decision support system (CDSS), a greater number of data from different sources must be incorporated. But ultimately, we must know how we will make decisions and what these data sources are and their relative importance.

This was evident during the COVID-19 pandemic, when demand outstripped ICU capacity [7]. For this, we developed a robust solution that captures large volumes of anonymized data from different silos in a dynamic and high-stress environment and generates useful ML algorithms to support clinical decision making in a public adult service for a multipurpose and undifferentiated ICU [9, 21, 34].

Importance of methodological robustness

Although EHR data could offer enormous research opportunities, their analysis is challenging for several reasons. First, the large feature space introduces more opportunities for variation in data collection regarding the technology used and sampling frequency compared to other repositories and clinical trials. Second, the cohort, exposure, and outcome are defined post hoc and therefore provide an opportunity for data wrangling and p-hacking. Third, the type and quality of data are not necessarily the same as in other clinical trials.

The quality of the data, including the patients being captured, is highly dependent on the clinical practice patterns of the designed EHR model that introduce biases in sampling selection leading to spurious associations. It must be kept in mind that EHR data are not primarily collected for research purposes, but rather represent a digital escape from clinical care or, in some cases, better serve an administrative function such as billing a patient.

The accuracy and reliability of the information provided by language models can be a matter of life and death as it could impact healthcare decisions, diagnosis, and treatment plans. In recent years, with the increasing use of data from the EHR, we have observed that studies based on these are plagued with validity and semantic interoperability issues that affect their robustness or applicability in clinical practice and decision making using AI and we have to consider this as the transcendent importance of not discriminating in the use of data between the different data lakes.

While the practical application of LLMs in healthcare is still in its early stages, preliminary research has already revealed their tremendous potential in specialized medical research and potential clinical decision support, provided data ethics standards are respected. Especially in tasks involving the integration of multimodal medical data from pathology, radiology, and genomics.

LLMs have demonstrated their unique ability for in-depth interpretation and linkage. Of course, their practical effects and values in real medical settings still require further study and validation. With the introduction of these advanced data science tools, we not only anticipate efficient consolidation of medical data from multiple sources, but also expect AI agents to offer support in predictive analysis and patient management for physicians. For example, AI algorithms could help analyze patient histories, laboratory results, and radiology data, subsequently providing diagnostic suggestions based on more robust data. Furthermore, these tools can further assist physicians in choosing the optimal treatment plan from a plethora of options, ensuring that patients receive optimal and individualized therapeutic outcomes. Through this approach, we can expect a medical decision-making process that is not only more scientific but also more systematic, ensuring that patients receive the best personalized healthcare.

Clinical information exchange is not seamless due to several technical difficulties, with information interoperability being one of the main technical challenges, but still, it is the effective enforcement of interoperability standards that enable the transfer and exchange of health data mining; considering authentication, authorization, logging, and auditing mechanisms that must ensure the privacy, integrity, and confidentiality of personal data information.

The FHIR interoperability standard provides a framework for structuring health data and supporting data exchange between disparate systems and vendors. FHIR documentation is very detailed and available in open source form. Briefly, FHIR consists of a set of resources that describe the most common entities in healthcare. As local contexts are expected to deviate from the global standard, FHIR introduces a mechanism called "profiling." Profiles are modifications of the FHIR base resources intended for use in a local context, such as a hospital system or primary care clinic. These profiles allow the flexibility of capturing data as it is exchanged in the local system, while also allowing for standardization, as most fields present in each resource will be consistent with the global standard (the base resource). FHIR also provides significant detail on all aspects of information exchange and has a large ecosystem of tools, particularly around data exchange. The FHIR format was primarily designed to represent processes; therefore, it closely resembles the clinical data model and is more readily available in modern e-health systems. However, no common standardized data format is directly suitable for statistical analysis, and data must be pre-processed prior to such analysis.

FHIR is widely used by healthcare systems around the world, but there remains a shortage of dataderived from publicly available healthcare systems in FHIR. Therefore, a system based on HL7v3 FHIR provides unprecedented opportunities for broader dissemination and sharing in the logic of an SSDC, with innovative capabilities and instruments that facilitate the development of predictive algorithm models in the critical environment.

With the beginning of the 21st century marked by astonishing growth in artificial intelligence (AI) capabilities and data processing, we have witnessed breakthroughs and groundbreaking transformations in various industries. Especially in the healthcare industry, these transformations are even more pronounced. However, while AI has revealed countless new opportunities and possibilities to us, it also sheds light on the deep complexity inherent in medical decision-making processes. When considering key stages such as diagnosis, treatment and prognosis, the real-world medical data we are faced with is incredibly diverse and intricate. Intensive care physicians, when dealing with these data, not only refer to a vast and complicated set of standard baseline medical knowledge, but also need to develop individualized treatment plans based on the unique circumstances of each critically ill patient. Moreover, medical examinations are multimodal and span domains such as pathology, radiology, and genomics. In such a scenario, integrating this vast amount of data and information to form a coherent and comprehensive diagnostic and treatment strategy is undoubtedly a challenge. Most current tools are isolated to single tasks, implying that clinicians need to perform more holistic analysis and judgment during decision-making. Therefore, there is an urgent need for powerful intelligent assistance tools to assist these physicians. This is precisely what LLMs [10] generate. Their development and modeling can not only help physicians consolidate and interpret complex data, but also provide inputs based on extensive knowledge, thereby ensuring more efficient and accurate assistance at critical stages such as diagnosis, treatment, and prognosis of big data. With these smart tools we aim to gain insight into the real, personalized patient situation and make more accurate and precise medical decisions when used in an SSDC.

Not surprisingly, a recent study on clinical rationale models points out that most LLMs in the medical field are trained using "small and limited in scope" clinical data sets with limited annotation types (e.g., MIMIC) or "broad and public" biomedical literature (e.g., PubMed) that has limited insights into biased healthcare [11].

Objectives of this work

In this article we review the current set of SSDC standards that are based on HL7-FHIR in developing an interoperable solution for a public ICU of a healthcare ecosystem where LLMs can provide greater statistical power to perform subgroup analysis and reduce the risk of type II errors.

Our objective is to show LLMs of data from an ICU and which ones are derived from the different sources that could be effectively used in decision making. The solution captures and analyzes data, estimating the relative importance of the different data lakes [5, 6] in such a way that we can generate both machine learning (ML) and deep neural networks (DNN) algorithms that are used as an SSDC in different prevalent pathologies of a critical patient.

Materials and Methods

The bibliographic search was carried out in PubMed and Embase, we systematically searched for observational studies published between January 2019 and October 2023 and previous narrative reviews before January 2024. Abstracts without full text were excluded. The search terms used to find literature included: ("machine learning" or "deep learning" or "neural network" or "artificial intelligence" or "Big data Large Database (LLM)") and ("ICU", "Critical care", "Electronic Clinical Record", "Clinical Decision Support System"). A total of 74 articles were initially identified with these search terms, of which 15 non-full text abstracts were excluded, leading to a final count of 38. Given the narrative nature of this review, the final cohort of articles was selected to provide the reader with the best overview of the topic and is not intended to be rigorous or exhaustive. We selected a few other research manuscripts, systematic reviews, and doctoral dissertations, and referenced a number of narrative reviews. This article is based on previous studies and only contains a summary of the literature. has studies with human participants.

The original prediction system is based primarily on an CDSS, using data collected at the bedside in the ICU by the Smart UPC type system [9]. These massive and constant flows of data volumes include heart rate, respiratory rate, blood pressure (systolic, diastolic and mean, differential pressure), temperature, diuresis. In addition, information from the electronic health record (EHR), continuous monitoring of mechanical ventilators, visual image coverage from closed circuit video systems, laboratory test results, drug prescriptions, even environmental variables and management of safety and quality in medical care (hand washing; day/night rotation; number of nurses; professional/patient ratio; etc.). Added to this is data from visits by treating specialists and subspecialists, their interconsultations by means of digitalized forms or in language processed by NPL.

All this information is extracted through the different application programming integration interfaces (API) in real time; the image data is used through DICOM-type imaging data interoperability protocols; or through gateways, from the same suppliers for various clinical devices or devices used by professionals. Likewise, we collect and analyze more and more data via Wi-Fi from different sensors in critical units, through biosurveillance monitors and other Internet of Things (IoT) data sources in transmission to a capture solution based on different layers. This timed information is displayed on a dashboard for the decision-making work of doctors and paramedical staff in the command and control rooms that are incorporated into the ICU [9] or through mobile devices.

Demographic data, comorbidities, vital signs, infused drugs, and laboratory test results are included in the training dataset in the different algorithmic models of future utility in an ICU [14] in the analysis and work layers of this solution. Thus, for example, for a model based on machine learning to advance in the prediction of ventilatory asynchronies or sepsis [11], it will have to improve its performance by increasing the training data not only from the mechanical ventilator, but also from visual analytic monitoring. In addition to the deep learning mentioned above, other studies have developed new AI models for the prediction of cardiovascular, neurological, sepsis, etc. pathologies [25-30] in different ICU environments and are the conceptual basis for the structural design of a Smart UPC.

With sufficient data, we are in a position to perform normative artificial intelligence (AI) with training and control data for algorithms according to the different requirements that we have pointed out and that we will build for the different syndromes or pathologies [8].

With the models developed based on open source data for different ICUs [24], we can correlate results with our system. The explainable AI model extracts features for variable time and is able to predict different pathologies in real time according to clinical requirements.

This solution not only has a superior performance in estimating the risk of isolated pathologies in real time, but also provides interpretable information to understand the different risks of patients with multiple pathologies [8]. In our work proposal, to evaluate this function, the performance of deep learning was compared with other methods in the early prediction of different pathologies and we will make this explicit in new reports.

Decision-making and predictive models (SSDC) are not yet widely developed with current known healthcare systems and many improvements will be necessary for them to serve as tools in our healthcare centers.

It is the physician who interprets the data, he or she must reason about the most important content at different stages of a disease. For example, physicians may choose to ignore highly abnormal test results, which may be due to sampling, assay, or recording errors. Thus, definitions are prone to error and are not fixed. In addition, if reported, the model's performance must be compared with existing algorithms, whether based on expert opinion or linear programming.

With machine learning-based algorithms used for comparison, the differences must be made with structured data. In recent years, this analysis is performed using structured data records from EHRs.

However, EHRs often fail to capture the relevant clinical determinants of health in such a short time as well as the multiple clinical parameters that are being generated in continuous real-time monitoring in an ICU.

The scope of functions provided by SSDC is broad, including alarm systems, disease management, prescription (Rx), drug interaction, and much more. They can manifest as computerized alerts and reminders, computerized guidelines, order sets, patient data reports, documentation templates, and clinical workflow tools [10]. However, the requirements of all clinical environments shown in a computational model are difficult to achieve at a technical design stage, since - as we pointed out previously - they are incorporated into the structured data record in an EHR. Therefore, the behavior of our solution (Smart UPC) was to exclude it and make it independent of the EHR as a support and security support [12].

On the other hand, there are other problems in the different AI models used by an SSDC; For example, many studies have only trained and validated the model on the same patient cohort with static databases, but have not yet tested its generality in other populations in dynamic times. These models need to undergo further prospective testing to demonstrate their clinical benefits or other outcomes (the reason for our upcoming publications).

AI applied by an DCSS model will also face many implementation difficulties when used in the clinical practice of an ICU. Currently, many organizations do not have sufficient conditions to implement AI in clinical practice, which requires considerable AI expertise and mature information technology or IT capabilities, such as AI evaluation, fusion, continuous monitoring, and recalibration. The security and reliability of digital data collection and use must also be addressed.

Results

It took more than 3800 hours of work between medical teams and engineering professionals, with data scientists specialized in medicine, to obtain a scalable hybrid data management platform to easily collect, process, protect and analyze all these data models to evaluate ways to improve predictive patient outcomes [36].

With data visualization and processing capabilities for medical decision making and also in nursing, pharmacology and kinesiology clinics. We integrated these different systems in standard HL7v3 FHIR formats into our platform [36, 37].

In Figure 1, we see the amount of data (LLM) captured for 1 patient on average 8 ICU days. With the data from the different data sources and their total data load/hour; total data/day; structured and unstructured data and for an undifferentiated public ICU.

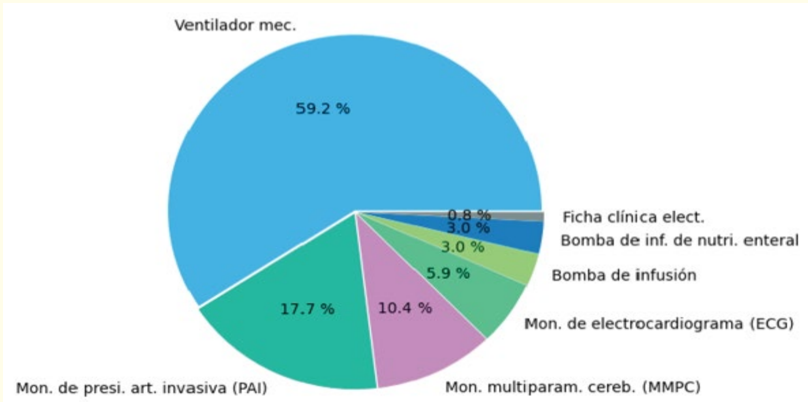

Figure 1: LLM data load graph, used in a Smart UPC system without video control (our own authorship in this project).

We show that in general, the data available through a Smart UPC solution reaches a value of 2244 MB/hr, that is, an average of 53.34 GB/day, which are available as data lakes through the decision support system (CDSS).

Of the total available data, the EHR only reaches 0.8% of the data used. For 1 patient, during 8 days of ICU with visual analytics (average) we can gather data according to the graph in Figure 2.

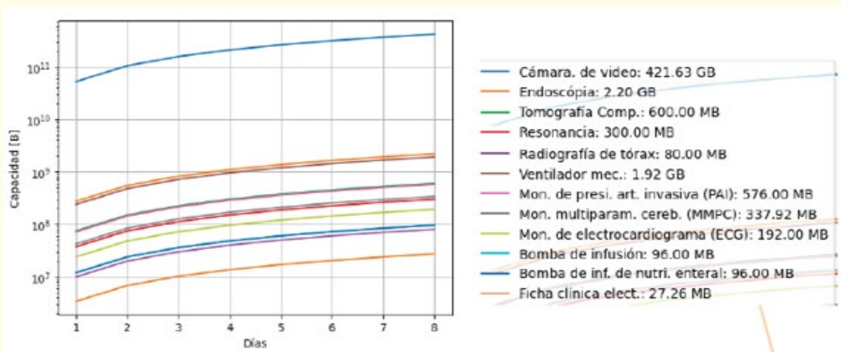

Figure 2: Shows a logarithmic graph of the LLM data in 1 patient in 8 days of ICU with visual analytics. (our own authorship in this project).

Unstructured data is 99.2%. There is a percentage of data that corresponds to different variable sources of unstructured data use, not daily in ICU (dialysis machines, ultrasounds, echocardiograms, plasmapheresis equipment, multiparametric neurological monitoring equipment, interconsultant evaluations, etc.).

The integrated situational analysis in real time, through the visualization layer in a dashboard of each patient is compiled in an Integrated Command Center and deployable on any mobile device. Figure 3 [40].

The structured data of the EHRs represent 0.8% as structured data susceptible to use for predictive algorithmic models. The amount of data of 1 patient in 8 days averages 492 GB.

Figure 3: Dashboard of (our own authorship in this project).

Conclusions

The LLMs are essential for innovative and disruptive solutions. Any clinical process for decision making supported by Artificial Intelligence requires a robust volume of structured data to carry out validly effective algorithms. To fully utilize.

The power of LLMs in healthcare, it is essential to develop and compare models using a configuration designed specifically for the medical field. This configuration must take into account the unique characteristics and requirements of healthcare data and applications.

A CDSS system, such as Smart UPC, relies on structured data from multiple data lakes, which is evident in a highly demanding unit such as ICUs. The development of methods to evaluate Medical-LLMs is not only of academic interest but of practical importance, given the real-life risks they pose in the healthcare sector.

It has been demonstrated that EHR data is not enough; it is now necessary to process LLMs, as we show in this report.

Conflict of interest

The authors (Bernardo Chávez P. and Rodrigo Covarrubias G.) have no conflict of interest.

(Luis Chicuy Godoy; Mario Cuellar Martínez; Jaime Briggs) partners and data scientists from technology companies (smart cities and cybersecurity).

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Informed consent: This study corresponds to a bibliographic review and does not require explicit consent from patients.

Ethical approval: Approval from the Institutional Review Board was obtained exclusively for the project.

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