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'Optha': A Big Data based web tool for reusable data search in Ophthalmology

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K. Vinayakan* and M.V. Srinath

* Department of MCA, STET Women's College, Sundarakkottai, Mannargudi - 614 016, Thiruvarur Dt., Tamil Nadu, India.

Abstract

The proposed model of web application is to perform the cluster in the clinical data and clinical trials together in a big data programming model. Optha is a user-friendly Web application designed to manage, share and analyze clinical data from patients affected by degenerative and vascular diseases obtained from the eye care data centers. Clinical record scan also be extracted for statistical purposes and used for clinical decision support systems. Optha is based on an existing data centric technique of multi scale data mining process. The database structure has been specifically built to respect laterality, a key aspect in ophthalmology. Users can add and manage patient records, follow up visits, treatment, diagnoses and clinical history. There are two different modalities to extract records: one for the patient's own center, in which personal details are shown and the other for statistical purposes, where all center's anonymized data are visible. The big data web tool allows effective management, sharing and reuse of information within primary care and clinical research. Clear and precise clinical data will improve understanding of real-life management of degenerative and vascular diseases of the macula as well as increasing precise epidemiologic and statistical data. Furthermore, this Web-based application can be easilyemployed as an electronic clinical research file in clinical studies.

Keywords: EHR, Web based clinical data collection for reuse, multi-level and big data analytics.

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INTRODUCTION

Electronic Health Records (EHR) play an important role in the improvement in the collection of data and efficiency in the decision making of healthcare (Murdoch and Detsky, 2013). Obviously evidence based medicine recognize the value of a data set to guide clinical decision making (Murdoch and Detsky, 2013; McGinn *et al.*, 2000). EHRs offer significant advantages to patients by facilitating storage, retrieval and communication between different healthcare providers. Hence patients do not need to look after their own information. It also facilitates to avoid mistakes when receiving care from different physicians (Hwang *et al.*,2006).Since large amounts of heterogeneous information such as laboratory values, text-based documents, demographics and medications are stored in Big data, EHRs become difficult to search, and retrieve relevant patient information. Since it is difficult to obtain the right balance between easy access and the amount of information stored, finding a solution has become complex (Prados-Suarez, 2012).

In the eye care management of retina is one of the major issues of the physician. The major diseases of retina in the industrialised countries include Degenerative and vascular diseases. (Europe, US, Asia).

The incidence of retinal diseases has increased among the human beings in the recent years due to ageing and increased prevalence of systemic diseases such as diabetes and hypertension. It has been estimate that globally 20-25 million people currently have Age-related Macular Degeneration (AMD). It is expected that the number can increase as a result of age related problems and increase the life expectancy of human population (Kourlas and Abrams, 2014). Diabetes is most common disease in developed countries. It has been estimated that the prevalence is ranging between 2% to 5% of the global population (Wild*et al.*, 2004). Another important cause of visual acuity is Diabetic Macular Edema (DME). An estimate made in 2010 in the US state that about 740.000 had suffered due DME (Schmidt-Erfurth *et al.*, 2014). The legal blindness due to degenerative and vascular disease of the retina has significantly decreased because of the recent introduction of new treatment modalities, like anti-veg drugs (Bloch *et al.*, 2012). However due to the transient effect of these new drugs, patients need to be monitored on a monthly-basis and treated as needed through complex longitudinal follow-up programs.

*Corresponding Author :
email: *k.vinayakan@gmail.com*

It has been proved that the randomised trail didn't show the expected level of benefit of such treatment using either a monthly-based follow-up or a treat-and-extend strategy (Zarranz-Ventura *et al.*, 2014). In this context systems and software applications are needed to correctly store, manage and analyze the large amount of heterogeneous data. Moreover, routinely collected data regarding the treatments could provide new evidence about the efficiency of clinical trial results and real-life clinical outcomes. The application oriented systems and software should allow easy access of the complete patient information so as to help the ophthalmologist in the decision making process. They also help intuitively in performing complex tasks such as data extraction and statistical analysis through implementation of user friendly interface. The end-users should also be involved in all phases of the applications of the software life cycle; permit data sharing and integration between different levels of medical care as well as national and international institutions so as to stimulate collaborations and favour public health policies on macular diseases.

It has been proved that the integration between different levels of medical care and clinical research have many benefits (Giacomini, 2009) it has become the centre of attraction and attention has been focused on the strength towards achieving this objective (De La Toree *et al.*, 2007). Nevertheless the electronic medical/health care record systems are yet to prove their performance. Thus obviously a wide integration of administration and routine care information systems with those used for clinical research is yet to be developed. A perusal of literature on research in this aspects revealed that the more frequently used EHR tools in ophthalmology do not offer the possibility for a _ne-tuned interface and for smart data extraction in external statistical studies (Boland *et al.*, 2013).

RELATED WORK

The research so far on the application of big data included the fields of comparative-effectiveness (CER) and outcomes research and the research and development (R and D). The research on comparative-effectiveness (CER) is gaining momentum as the healthcare reform moves toward enhanced evaluation of providers with quality, efficiency and outcome measures for patient care, by utilizing large datasets containing patient information, cost and outcome data. Best practices of reduction of in appropriate treatment or care regimens can be best informed to providers through CRE. Proper utilization of big data in the research and development can have tremendous impact and benefit on healthcare. Personalized medicine is one of the emerging fields of medicine. This can be made effective by using and analyzing the big data tools such as predictive monitoring and algorithms and clinical trial data, disease patterns and genomic data sets. This can also reduce the expenditures of healthcare sector could by approximately $25 billion.

Representation of medical concepts has become one of the main issues in implementing an EHR system in ophthalmology (Hwang *et al.*, 2006). Beside inconsistent terminologies are for customized solutions. This not only makes it difficult to compare data obtained from different sites but also it difficult for the physician to interpret the stored data (Hwang *et al.*, 2006). Standardized terminologies are to be used to describe the different events as an essential component of efficient and coherent system.

Web based solutions are increasingly used as the means of delivering the system (Roy *et al.*, 2013; Grant *et al.*, 2006). Possession of the view rights and credentials of a particular web is essential. This makes easy access to information from anywhere with the help an internet connection and a computer, but only a web browser to good line (Giacomini *et al.*, 2009; Giacomini, et al., 2011).

'Optha' is a web-based platform. This is used to collect and manage data in a routine clinical practice and to integrate then with the data research in ophthalmology domain. This platform it focuses on patients affected by degenerative and vascular diseases of the macula. It also brings a novel perspective to ophthalmology by combining individual patients and population data relevant for degenerative and vascular diseases of the macula. Furthermore, stored data can be extracted for statistical purposes and used for clinical decision support systems. The platform is available for different simultaneous multicenter Clinical Trials. The proposed system takes into account personal medical data accumulated over time in order to develop a Clinical Decision Support System. Moreover, the inclusion of standardization procedures offers a stable quality of data over time.

PROPOSED MODEL

Most of the clinical data, comprised phenotypic characterization of the patients (signs and symptoms), such as records of *in vivo* images or data concerning administration of therapeutics and nutrition/exposure to environmental factors. Whichever include collected during ophthalmological visits Data were also linked to computer models of personalized algorithms for drug administration, physiology, functional disorders and other diseases. Numerical values are used to quantify visual acuity as well as the thickness of the retina. Early Treatment Diabetic Retinopathy Study (ETDRS) charts have been employed in many clinical trials. This has been is accepted worldwide as the gold Standard for accurate and standardized methodology to measure visual acuity (Kaiser, 2009). Optical Coherence Tomography (OCT) is used to obtain

detailed B-scan images and to quantify the thickness of the central part of the retina (macula). OCT is considered a mandatory step in the evaluation and follow-up of degenerative and vascular diseases of the macula. In addition to OCT, ophthalmic copy and retinal angiography can also be employed to obtain images of the retina, so that objective values could be observed and changes over time, evaluated.

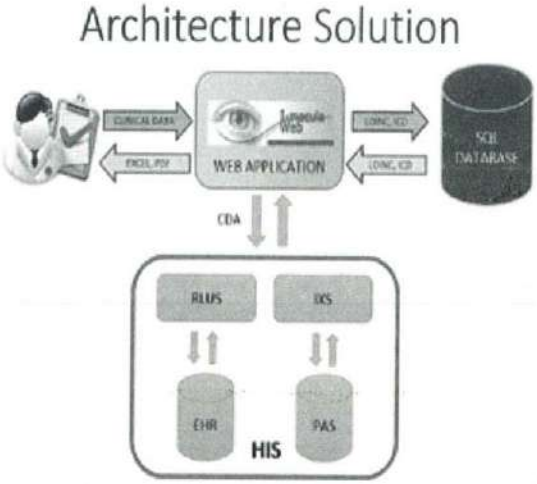

Fig. 1. Shows the architecture of the system

ARCHITECTURE SOLUTION

The architecture solution has been chosen based on the consideration of many aspects after continuous interaction with the users and considering the positive features described above (Giacomini *et al.*, 2009). A web based Database interaction system was used. The diagrammatic representation of the architecture solution shows web-application depends on a SQL database. In this data are stored and retrieved through standard terminologies. Users (i.e. ophthalmologist) can enter access and retrieve information on the web as well as saving reports in Microsoft Excel and PDF formats. The figure also shows the way in which the proposed solution integration of the proposed system with the Hospital Information System (HIS), in particular with the Electronic Health Record (EHR) and the Patient Administration System (PAS). It is further studies involvement in the design and implementation of a standardized infrastructure that was able to is clearly indicate the diagram (Fig.1) completely support interoperability for the HIS of the care facility involved in the proposed solution.

MULTI-LEVEL AND MULTI-SCALE MODEL

The 'Optha' database is based on an existing multi level and multi-scale data management model. It is based on some general principles, which are suitable for several different clinical domains. Previous implementation of such a template originated from a specific tool for data reuse in Infective Diseases has been reputed (Fraccaro and Giacomini, 2012).

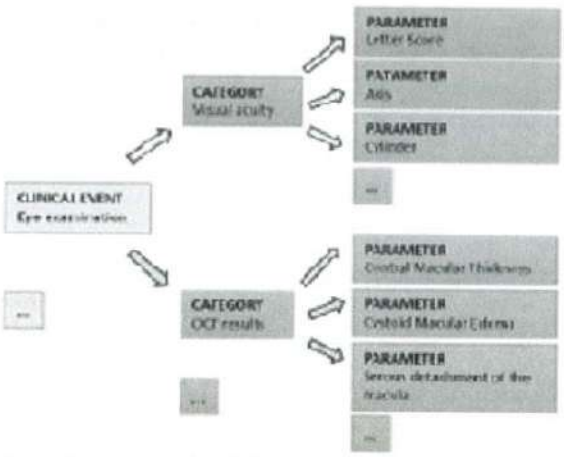

Fig.2. Example of multi level structure

The conceptual framework developed is presented in (Fig.2). It is structured on a three-level hierarchical structure it includes Clinical Events, Categories and parameters (with Unit of measure)..Results have been for the patient and the time of measurement. For example, information concerning the "Letters score" and "Axis" are parameters that are grouped into the "Visual acuity" Category that belongs to the "Eye examination" event. Clinical results, obtained during the visit, are automatically saved in several tables according to the type of parameter and format to save. Eye care centres often utilize different instruments such as OCT. If they provide numeric parameters, in particular the integer and float value, which may have different characteristics, like normal ranges or units. These differences are central to the data extraction phase. Hence relevant information is specifically recorded for each centre ("Unit-Conversion" and "Conversion-Coefficients" tables in the database). Thus all possible conversion coefficients between different units are stored. Finally, once the different units are converted to the uniform unit, data are harmonized using the z-score methodology. It allows the comparison of data collected with different normal ranges. Patients and operators are both saved on the table. "Person" where encrypted name, date of birth, address, telephone number and others which mainly in clinic general demographic information are saved. The patient's tax code is generated automatically, using the demographic information. They are compared with the actual code stated by the patient, in order to ensure reliable patient identification. The information on the operator role and affiliate centre is stored in a separate table. In this way, a physician can also assume different roles in different hospitals. Access to the database is strictly limited to authorized physicians with credentials checked for their security level and with a strict change policy. Furthermore, each user can be authorized, with different levels of permission to access various studies; this information

is stored in "Operator-Studies". All actions are recorded and linked to the specific operator, through the concept of sessions, which include the date and time of the user login.

LATERALITY

The database structure has to be designed specifically to respect laterality is a key aspect in ophthalmology. As the template used to develop this database was mainly focused on general clinical concepts, it does not consider the concept of laterality; it is because a new table was added to identify the eye responsible for a specific parameter. In such a way, each result is associated with the correct eye. Laterality was also added to the table of "Patients in Studies" because, in many cases, only one or both eyes could be enrolled in the study.

EXPERIMENT AND RESULTS

This was made possible with AGILE (Syed-Abdullah *et al.*, 2006) methodology was used to make the development of interface to be performed strict interaction with end users in order to get indications to obtain an extremely user friendly tool that would cover all their needs in this field. This received of the interface good acceptance and integration into a routine workflow. The main objective was to allow physicians to extract data for research and epidemiological purposes. Hence a specific extraction tool was developed. They instruments permit physicians to access normalized and comparable information according to their criteria and to extract these data in a portable format. Further the search rationale can be saved for future needs and integration

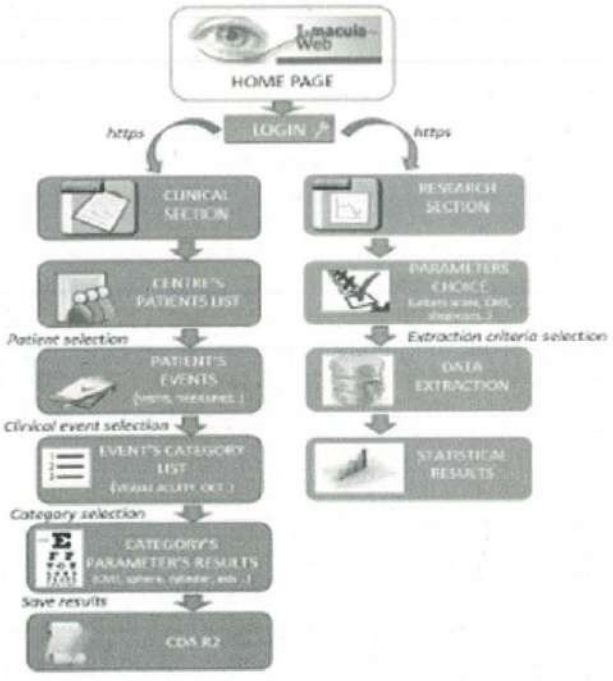

Fig. 3. Web interface of Optha

with the same modularity philosophy present in the whole tool.

The Web Platform architecture (Fig.3) is structured in two different sections: (i) they include Clinical section, physician and Research section. (ii) The Clinical section is with a user friendly and intuitive interface this can be to record, modify and view patients' results by the physician. The research section is used to extract and export information depending on the requirements. The process is structured in a few passages and almost all web page contents are dynamically loaded, with reference to the first activity Physicians are able to access the Centre's Patients list. This helps to select a patient to display further details. The main menu of the Clinical section shows patient details. It is organized as follows: unique identification number of the patient, last and first name, date of birth, gender, date of the last visit, center Id and three buttons linked to demographic data, clinical chart and delete function pages.

The web page "Patient's Clinical chart homepage "shows a summary of specified patient activity (visits, diagnoses, Intravitreal/laser/surgery treatments, clinical studies). The system automatically loads from the list of the Clinical Events associated with the selected patient. As soon as there are more than two visits, ETDRS score letters and mean Central Macular Thickness (CMT) are plotted onto two separate graphs in the clinical home page. In the case of specification studies the participation patients the relative information is highlighted in an ad hoc panel. For example, indications for Intravitreal treatments, are inserted in a red rectangle based on the "Two Eyes" study. If the patient is not yet enrolled in a study, but he/she has the feature to be inserted, an study-specific alert button is visible on the page.

In a study where patient is yet to be enrolled the specific feature is to be in served, for which a study specific buttons visible on the page.

After choosing the particular Clinical Event, the platform shows the related list of available categories. Now the physician has to ultimately selecting a specific Category, Then he/she can access a Parameter list and record or view results; the web page is dynamically loaded in relation to the Parameters format, Centre's units and ranges. The physician can save the results in a report regarding the web application. The visualization and contextualization of the data can be improved by enlarged each graph to full-screen.

In this case, temporary sequences of ETDRS score letters and CMT values are automatically put in relation to the patient's recorded therapies and divided in four sections, which include (i) virus and symptoms, (ii) anterior and posterior segment, topical therapies ongoing and report. The main characteristic of the virus and symptoms section is the automatic

calculation of the ETDRS score letter and Snellen equivalent. This operation is simplified by an electronic image of the ETDRS chart pops out. The operator has to digit the number of letters correctly read at each line. The system automatically calculates the ETDRS score and Snellen equivalent (Ferris and Bailey, 1996). The posterior and anterior segment section; there are four different menus regarding OCT, ophthalmoscopic, angiographic and anterior segment signs. It is possible to compare the signs with the same signs record data in some cases, such as sub retinal fluid or cystoid macular edema of the previous visit, specifying when it has increased, decreased, disappeared or remained unchanged, besides the ETDRS letter score, it is possible to digit the thickness values for the nine ETDRS thickness field maps available in every OCT machine. The precision of the system needs the automation of data input from clinical instruments to the database. A web service allows the export of OCT results to the web application by it thus data will be automatically stored in the database. The system will automatically calculate the mean value of the CMT (Fig. 4). Direct recording of patient's demographics will also be possible by using the same application.

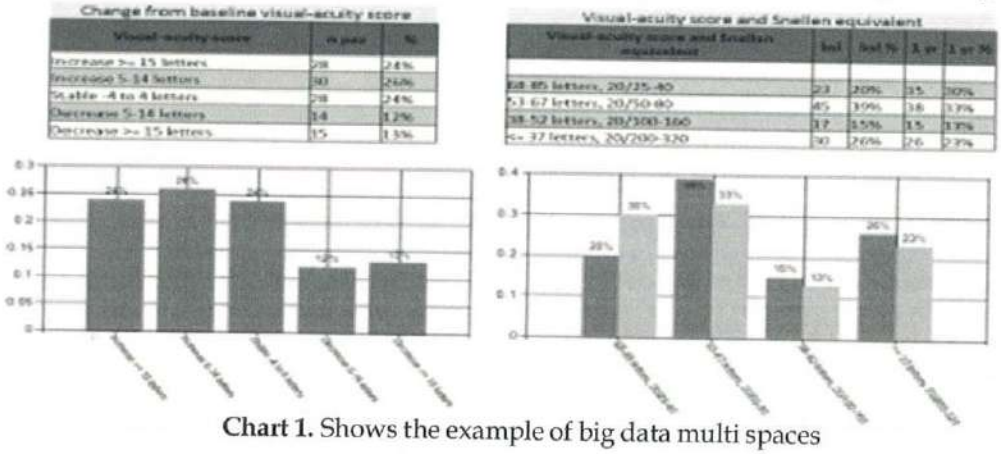

Chart 1. Shows the example of big data multi spaces

There is a list of Intravitreal drugs they can be selected for each eye with the corresponding injection data. In case of can be saved and patient as pdf document. There is the possibility to select the available retinal laser treatments, pan retinal or scatter photocoagulation, grid/focal laser, micro pulse or sub threshold laser and photo dynamic therapy. A visit report containing all relevant information collected during the examination as well as free text comments added by the physicians.

Optha can be further implemented with automatic algorithms to assist ophthalmologists in the decision-making process. These algorithms can be developed in order to help physicians to follow, the Diabetic Retinopathy Clinical Research Network retreatment guidelines (Fan *et al.*, 2011). Other international protocols can also be expressed in an informal graphic design. Specifically, using patient diagnoses, visual acuity, CMT and follow-up data, the system could display a hint to start or stop the treatment.

The treatment menu is divided in to injection, laser and surgical treatments. The injection treatment automatically notifies physicians whether a particular patient has the main inclusion criteria to be eligible for the study. The system was also implemented with the retreatment criteria based on visual acuity stability. Therefore, once the patient was recruited, the system suggested regarding the continuation or discontinuation on the basis of the protocol study. Thanks to previous study results produced using the described solutio, the involved hospital has been selected to participate in a randomized multicenter double-blind phase III study of *Lampalizumab*, using Optha, to evaluate its safety in patients with geographic atrophy secondary to AMD. Another objective was to allow physicians to extract data according to their needs, independently from technical administration of the tool. We two different modalities to be planned extract records. They included one for the patient's own center, in which personal details are shown and the other one they are obtained, used for statistical purposes, where the entire center's anonymised data are visible.

Physicians can enter specific extraction criteria to obtain information; by selecting the specific parameters are required. The specific parameter value can be made visible in the results table by selecting and setting criteria results. Records can be used for possibility of defining particular also provide an inclusive and exclusive, there should for numeric parameters. It also provides an opportunity to indicate specific requirements: for example positivity or negativity for Boolean and equality or inequality to a certain value for categorical parameters. Thus the criteria can be added, modified or deleted depending requirements. It is also the possible to save extractions and reuse thereafter; queries can be built dynamically

by interpreting the operators' demands. It is also possible to view and save score normalized data in an Excel format. T is important to avoid patients being individually recognizable, when the number of patients involved in the results obtained is less than five, the system will not show the search outcome. Statistical extraction that may be useful for evaluating treatment efficiency in patients affected by selected diagnosis is shows in Chart 1.

CONCLUSION

The application described in this paper fulfils the requirements specified by Chiang *et al., 2011* for Electronic Health Record Systems based on big data techniques in Ophthalmology. The web platform allows effective management, sharing and reuse of information within primary care and clinical research. The system results are made highly user-friendly by operators. It can be effectively integrated into the physician workflow. Clear and precise clinical data will improve the understanding of the real-life management of degenerative and vascular diseases of the macula and also increasing the precise epidemiologic and statistical data. Furthermore, this web-based application can be easily employed as an electronic clinical research file in clinical studies. The achievement of this web tool proves that it can be considered a valuable tool for ophthalmology EHRs and clinical studies as it overcomes the problems of other available HER systems.

FUTURE WORK

It is planned, in the near future, to share the system with other hospitals not only for clinical research but also for use in routine clinical practice. To encourage international collaborations, the application will also be translated into a multilingual website.

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