Present Status of Clinical Decision Support System (CDSS) and Proposal of Ethical Guideline for Artificial Intelligence Development in Medical Field

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Abstract: This paper is looking at the trends of future medicine focusing on IBM Watson, Microsoft Intelligent Network for Eye care (MINE), and Google’s AI Eye Doctor. Microsoft’s Mine, an artificial intelligence assistant program, and Google’s Eye Doctor, were created because of the two characteristics of eye disease. The disease of the eye significantly reduces the quality of human life, but it can be prevented if the illness is discovered in advance. Therefore, prevention of these diseases is important. Through the development of the Google eye Doctor Program shown in the article of “Retinopathy Algorithm”, we obtained the implications for the ethical guidelines that can be applied to other artificial intelligence development programs. At the heart of these guidelines is the efficient and safe treatment of patient illnesses for medical purposes.

Key words: Artificial intelligence physician, IBM Watson, MS Mine, Google Eye Doctor, artificial intelligence physician development, ethical guidelines.

1. Introduction

Artificial intelligence is divided into strong and weak. Stronger is the Terminator T-1000, which appears in the film “Ultron” in the movie “Avengers: Age of Ultron” or in the movie “Terminator Genisys”. And in the movie “Prometheus”, there are artificial intelligence robots such as David. Weakness is Jarvis in Iron Man. The recently developed IBM Watson is a weak artificial intelligence. This can be called the CDSS (Clinical Decision Support System) program. IBM Watson is especially well received in Korea. IBM Watson summarizes the papers that doctors should look at in relation to the patient’s illness, and it is equipped with the function to display the latest medical information. In addition, the most appropriate treatment for patients is presented using up-to-date latest medical information. In this way, CDSS is helping doctors. In this paper, I will examine IBM Watson, Microsoft Intelligent Network for Eye care (MINE), and Google’s AI Eye Doctor, which are currently developed artificial intelligence programs. IBM Watson is currently the most famous CDSS in the world. In particular, IBM Watson for oncology was introduced in Korea. In particular, we will look at the artificial intelligence assistant programs (CDSS for ophthalmology) created through strategic alliances with Indian hospitals. Microsoft has Mine, and Google has Eye Doctor. Ophthalmologists often use imaging to diagnose a specific disease rather than other diseases. And blindness significantly reduces the quality of human life, so prevention is more important than anything else. It seems that two characteristics of these ophthalmologic diseases have met and artificial intelligence ophthalmologist program has been made. In particular, the Google eye doctor has already published a paper entitled “Development and Validation of a Retrieval Algorithm for Detection of Diabetic Retinopathy in Diabetic Retinopathy
(Retinopathy Algorithm).” It is medically proven. I believe that through the development of the Google Eye Doctor program in the retinopathy algorithm, I can get implications for ethical guidelines that can be applied to other artificial intelligence development programs. Next, I propose ethical guidelines for artificial intelligence development and production through this process. At the heart of these guidelines is the efficient and safe treatment of patient illnesses for medical purposes. Next, we look at how artificial intelligence can help physicians in future medicine.

2. Status of International CDSS Development

2.1 IBM Watson [1]

In Korea, the cancer diagnosis “Watson for Oncology” was introduced at Gil Medical Center in Incheon [2]. In addition, seven hospitals including Daegu Catholic University Hospital, Keimyung University Dongsan Hospital, Gungyang University Hospital, Chosun University Hospital and Chonnam University Hospital introduced Watson [3]. In December 2017, a consensus rate of 56% was announced at the 1st anniversary symposium of the Gachon University Gil Hospital in Korea. The rate of agreement was 91%~100% in five cancers. Although it is described as a difference according to the racial characteristic, there is opinion that the performance is exaggerated such as using training data for verification from the beginning. The Food and Drug Administration classified Watson as a “non-medical device” at the end of 2017 when it released the guidelines for approval and examination of medical devices with big data and artificial intelligence technologies.

2.2 MS Mine (Microsoft Intelligent Network for Eye Care)

LVPEI (The L V Prasad Eye Institute) [4] was established in Hyderabad in 1987 as a non-profit, non-governmental, public mental health comprehensive eye care facility. LVPEI has the Hyderabad Eye Institute and the Hyderabad Eye Research Foundation. The Institute is a global resource center for the World Health Organization Collaborating Center and VISION 2020: Right to Sight initiatives to prevent blindness. In addition, LVPEI has six areas of activity: clinical services, education, research, rehabilitation and vision improvement services, eye banking, public health and rural activities. The LVPEI network includes Hyderabad’s Center of Excellence, the third center of Bhubaneswar, Visakhapatnam and Vijayawada, Antal Pradesh. It has 16 secondary and 141 primary care centers covering the most remote rural areas in the four provinces of Odyssey and Karnataka [4].

Microsoft started its business in India in 1990, and its current Microsoft subsidiary in India has 7,000 employees in sales, marketing, research and development and customer service and support in 10 cities, including Ahmedabad, Bangalore, Chennai, Delhi, Gurgaon and Hyderabad. Microsoft will work with the LVPEI (LV Prasad Eye Institute) to create a predictive model to help predict regression rates for eye operations so that physicians can pinpoint the procedures needed to prevent and treat blindness.

2.3 Google’s AI Eye Doctor

Diabetic retinopathy patients are approximately 28.5% in the US and 18% in India. In most guidelines, people without retinopathy or mild diabetic retinopathy should be repeatedly screened for diabetic retinopathy for 6 months. Clinically significant macular edema, known as severe or malignant diabetic retinopathy or diabetic macular edema, should be treated by an ophthalmologist for evaluation of treatment within weeks to months. And the target diabetic retinopathy should be screened annually and managed every four years when diabetic retinopathy is considered moderate or worsening. At this time, retinal imaging is a widely used test tool for diabetic retinopathy. India has a lack of ophthalmologists. These circumstances have led many Indians to receive
eye care abroad. In China, special rice varieties have been developed to prevent diabetes, but Aravind Hospital in India tried to prevent patients from losing sight by testing. Google’s AI Eye Doctor is the CDSS that can identify the initial signs of impairment that can lead to blindness due to diabetes developed jointly by India and the United States. This system scans the retina of a patient looking for damage to blood vessels that indicate diabetic retinopathy and tells the results. Particularly, this CDSS was needed because Aravind Hospital in India has a diabetic retinal telemedicine system in hospital for people without ophthalmologist. This is a field of telemedicine that provides eye care through digital medical equipment and communication technology. India’s Aravind Hospital has been using this system to screen low-income Indian and noninsured diabetic retinopathy patients in an ophthalmologic area. Patients residing in remote locations can be screened, diagnosed and monitored by an ophthalmologist through this system. The system is said to have started in 2002 with the support of ORBIS and the Acumen Fund for the Aravind tele-ophthalmology network. Through this system, Aravind Hospital in India regularly interacts with various units of Aravind Eye Hospitals as well as other renowned eye care centers around the world. The first telemedicine session and the first joint presentation by Madurai at Trichy’s State Ophthalmic Conference, held between John Hopkins and the Wilmer Eye Institute of Aravind-Madurai, were helpful on both sides. Ophthalmologist services for the poor provide primary eye care services at a very low cost with the help of ophthalmologists trained by the centers. Each center has a primary eye care service center in rural areas where 50,000 people cannot be treated. In this case, a well trained ophthalmologist manages it and is supported by the center coordinator. The ophthalmologist examines the slit lamp, performs refraction, and inputs all data into the EMR (electronic medical record). After consulting the hospital’s ophthalmologist via the internet, the ophthalmologist treats minor illnesses and prescribes glasses. Patients can be consulted and consulted by doctors. If additional treatment is needed, such as cataract surgery, the patient visits the hospital. There are currently 61 vision centers in India and about 1,500 patients are examined daily through the vision center. A surgeon at Aravind Hospital in India can manage 5-6 vision centers. In particular, DR (diabetic retinopathy) should be diagnosed early in the disease so as not to lose sight due to complications of diabetes. DR has no symptoms at an early stage. The retina image of a diabetic patient is captured from a diabetic clinic using a fundus camera and sent to the Aravind eye clinic. This retinal image is reviewed by an ophthalmologist and a report on the presence of DR is delivered within an hour. Aravind’s Online Virtual Ophthalmic Academy was launched on January 19, 2008 by former Indian President APJ Abdul Kalam. Aravind is working with ISRO (Indian Space Research Organization) to develop complete software and systems to facilitate the Virtual Academy’s functions. Because of the background of this India Aravind hospital, a Google Eye Doctor could be made. In order to develop the data set algorithm, retinal fundus photographs of the macula center were obtained in EyePACS of USA and Aravind Eye Hospital of India (Sankara Nethralaya, Narayana Nethralaya). The 54 graders who established the development plan were an American licensed ophthalmologist or ophthalmologist in the residency (grade 4 graduate) of the last few months.

We describe the process of developing an algorithm for the diagnosis of macular edema and its application. In this paper, the authors used a computerized multiple convolutional neural network to train AI with diabetic retinopathy using 12,875 retinas, and the results are presented to 54 American licensors from May to December 2015. The algorithm was verified using two datasets for each of January and February 2014. As a result, the sensitivity and specificity of the
algorithm for detecting RDR (referable diabetic retinopathy) defined as moderate and diabetic retinopathy, were similar to those of ophthalmologist. The algorithm was evaluated through two selected operating points in the development set. One point is selected for high specificity and the other is selected for high sensitivity. The results of this paper are as follows.

The EyePACS-1 data set consisted of 9,963 images from 4,997 patients (mean age: 54.4 years; 62.2% women; prevalence of RDR, 683/8,878 fully gradable images [7.8%]); the Messidor-2 data set had 1,748 images from 874 patients (mean age: 57.6 years; 42.6% women; prevalence of RDR, 254/1,745 fully gradable images [14.6%]). For detecting RDR, the algorithm had an area under the receiver operating curve of 0.991 (95% CI, 0.988-0.993) for EyePACS-1 and 0.990 (95% CI, 0.986-0.995) for Messidor-2. Using the first operating cut point with high specificity, for EyePACS-1, the sensitivity was 90.3% (95% CI, 87.5%-92.7%) and the specificity was 98.1% (95% CI, 97.8%-98.5%). For Messidor-2, the sensitivity was 87.0% (95% CI, 81.1%-91.0%) and the specificity was 98.5% (95% CI, 97.7%-99.1%). Using a second operating point with high sensitivity in the development set, for EyePACS-1 the sensitivity was 97.5% and specificity was 93.4% and for Messidor-2 the sensitivity was 96.1% and specificity was 93.9% [7].

As noted above, the authors of this paper finds that algorithms based on deep-learning learning show high sensitivity and specificity for detecting diabetic retinopathy. However, the authors suggest that further study is needed to determine the feasibility of applying this algorithm in clinical settings and to determine whether the use of algorithms can lead to improved therapies and outcomes compared to current ophthalmic assessments do. However, in the current situation, the authors suggest that Google Eye Doctor can reduce the access barriers of patients who have difficulty accessing medical care, and can protect patients’ health through early detection and treatment of disease.

3. Proposal of Ethical Guidelines for the Development and Production of International CDSS

I think the development of Google’s Ophthalmic CDSS through the alliance between Aravind Hospital in India and the US IBM is very exemplary. I emphasis on “Artificial Intelligence and Healthcare Resource Allocation” [8] the distribution of surplus resources and medical resources from artificial intelligence in the thesis of emphasizes the priority distribution of environment and irrational practices in labor-intensive medical field, and the priority distribution of patient-centered medical environment. The paper “The Retinopathy Algorithm” shows how advanced country skills and data from underdeveloped countries can be combined to work for patients who are the least beneficiaries of inadequate medical care in India. The development of CDSS due to this technical cooperation is expected to continue. I would like to elaborate the ethical guidelines for the development of future artificial intelligence program CDSS, as shown in the paper “Retinopathy Algorithm”.

3.1 Ethical Guidelines for the Purpose of International CDSS Development and Production: Minimum Beneficiary Priority Supply—Priority to Where There Is No or Insufficient Doctors and Doctors Do Not Work

I believe that the development of Ophthalmic CDSS in India’s Aravind Hospital and Google has been justified as a special medical environment in India. Aravind Hospital in India seems to have planned this project for patients who are in blindness but do not receive ophthalmologic care. Due to the development of Ophthalmic CDSS, patients without blindness who live in areas without ophthalmologist have relatively easy access to ophthalmology. Because of this project, the benefits of developing Ophthalmic CDSS are the
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first to return to those who receive the least benefit. Google’s Ophthalmic CDSS is a very good example of how to improve patient health through early detection and treatment of disease. In the future, we should continue to work together for the least beneficiaries by meeting the knowledge of advanced countries and the information of the developed countries for those who have no doctors or do not have money in very few places and have diseases.

3.2 Ethical Guidelines for Acquisition and Management of International CDSS Data

3.2.1 Obtaining Legitimate Data—Securing Consent through Safe Harbor and Legitimacy through IRB (Institutional Review Board) Passing

The data used in the Retinopathy Algorithm retrospectively retrieved the macular center retina from the EyePACS of the United States and the Aravind Eye Hospital of India (Sankara Nethralaya, Narayana Nethralaya) to develop a data set algorithm. At this time, all images were not identified according to the Safe Harbor before transferring to the investigators. And this project has passed the IRB of each institution. Obtaining such legitimate data require the anonymization of the information to be secured and the approval of the Institutional Bioethics Committee. In the securing of data, the identification, management and supervision of the Institutional Bioethics Committee on the non-identification and anonymization measures of personal information and its research process and research results are required.

3.2.2 Ensure Financial Verification of Data—Provide Reasonable Labor Costs for Labor Verification for Algorithm Verification

Fifty-four US-licensed resident ophthalmologists and 54 ophthalmologists who participated in Google’s Ophthalmic CDSS graded 20 to 62,508 images (mean: 9,774; median: 2,021) for each individual. Three of these trainees scored over 1,000 images. However, these three trainees did not lag behind in the evaluation of licensed ophthalmologists. The reliability of the mediator was measured for each physician using a pair of comparisons, and the number of classes matched the other graders that exceeded the total number of pairs I believe that in the development of any kind of CDSS, professional labor must be put in place for data validation. In some authoritarian cultures, medical practitioners, such as interns and residents, may put CDSS-validated labor under the name “education” and not pay for labor. Therefore, when submitting the CDSS research plan to the Institutional Bioethics Committee, an item of labor cost for algorithm verification labor should be submitted.

3.2.3 Establishing a Data Sharing Plan—Sharing Secured Medical Data

Google’s Ophthalmic CDSS algorithm was trained to identify only diabetic retinopathy and diabetic macular edema, and there was no training to identify it in the presence of non-diabetic retinopathy. Therefore, this case can be missed. In the paper Retinopathy Algorithm, the authors believe that Google’s Ophthalmic CDSS algorithm does not replace a comprehensive visual acuity test with many factors such as visual acuity, refractive, slit lamp, and intraocular pressure measurements. The authors of this paper propose two preconditions for developing a similar high performance algorithm for medical imaging using computer deep learning based on this study. First, there should be more data. In other words, there must be a large development kit with tens of thousands of unusual cases. Second, more diverse data must be secured so that various diseases can be diagnosed. Thus, securing of data is the key to any CDSS. Therefore, for future medical care, sharing of data and in-depth management of medical data secured for such sharing is required.

3.3 International CDSS Ethical Guidelines for Supplementing Research: Establishment of Future Research Plans and Securing of Resources—Planning and Financing for Algorithm Supplementation
As we have seen, Google’s Ophthalmic CDSS should be upgraded in the future. Data on the clinical adaptation of Ophthalmic CDSS to this Google should be obtained and the Ophthalmic CDSS should be expanded for other diseases. Planning and financing for these algorithms are the key to this expansion. The artificial intelligence program, CDSS developer, should keep this in mind from the research planning stage.

4. Conclusion

In this paper, I propose the following ethical guidelines for the development and production of artificial intelligence: (1) establish standards for data standardization, (2) formulate data, (3) secure legitimate data, (4) provide reasonable labor cost for labor verification for algorithm verification; (5) provide minimum beneficiary priority supply; (6) provide priority to places where physicians are not available and doctors are not able to do; (7) provide data sharing plans; (8) secure shared medical data; (9) the establishment of research plans and the securing of resources; (10) planning and financing for algorithm refinements. Artificial intelligence programs already developed should be supplemented and modified. In addition to ophthalmology, artificial intelligence will be developed for a number of other diseases. I emphasized that it is important that the six propositions proposed in this paper are more important than the development of assistive programs for patients and physicians. I can think of the criticism that the technology of developed countries exploits the information of the backward countries about this proposal of the writer.

I think trust is the most important thing in medicine. I believe that as for trust between individuals and society, the development of any artificial intelligence program that does not presuppose such a culture of trust will lead to many misunderstandings and end up in a form of misfortune in which the least beneficiaries do not receive the appropriate benefits. At this time, people without money and ignorance will not know that they will not benefit even though they can benefit. All of this will happen because of the culture of trust. Instead of this invisible tragedy, I hope that we can unfold the courage to do what our civilization can do based on a culture of trust.

References

[1] Wikipedia. See https://www.wikipedia.org/wiki/%EC%99%93%EC%8A%A8_%EC%BB%B4%ED%93%A8%ED%84%%B0 #% EC% 9D% 98% ED% 95% 99%.