

A Global Infectious Disease Surveillance and Case-Tracking Model for COVID-19: An Implementation that is Designed on the Block-chain and HL7 FHIR International Patient Summary

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A Global Infectious Disease Surveillance and Case-Tracking Model for COVID-19: An Implementation that is Designed on the Block-chain and HL7 FHIR International Patient Summary

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Abstract

Background: 2019 novel Coronavirus (COVID-19), which presumably originated in bats and transmitted to humans through unknown mechanisms in Wuhan, Hubei province, China in December 2019, has affected more than 180 countries and territories around the world. On March 11, 2020, World Health Organization (WHO) characterized the COVID-19 outbreak as a pandemic. This is the first pandemic known to be caused by a new coronavirus. While the complete clinical picture with regard to COVID-19 is not fully known, based on currently available information, older adults and people of any age who have serious underlying medical conditions might be at higher risk for severe illness from COVID-19. The emergence and rapid widespread of COVID-19 are not only becoming a new public health crisis, but also wreaking havoc on the global economy and industries. However, disease investigation, patient-tracking mechanisms and the transmission of case reports seem to both labor-intensive and slow.

Objective: The ongoing pandemic is putting healthcare systems under strain worldwide and forcing hospitals and other medical facilities to scramble to make sure data can be shared effectively. The primary aim of this study is to design a Global Infectious Disease Surveillance and Case Tracking system capable of facilitating detection and control of COVID-19 transmission. A blockchain-based architecture is built to protect the security and guarantee the correctness of International Patient Summary (IPS).

Methods: An International Patient Summary (IPS) which is an electronic health record extract containing essential healthcare

information about a subject of care be used in this study. IPS is designed for supporting the use case scenario for 'unplanned, cross border care'. It is intended to be international, i.e., to provide generic solutions for global application beyond a particular region or country.

The design, global scope, and utility of IPS towards unplanned cross border care, potential for re-use makes it suitable to be a situation like COVID-19. A Fast Healthcare Interoperability Resources (FHIR) confirmed IPS, including symptoms, therapies, medications, laboratory data, can be transferred and exchanged on the platform for ease of access by the physicians efficiently. Patient data are de-identified to protect privacy. All system be protected by blockchain architecture, including data encryption, validation, and exchange or transfer record. Members of the Centers for Disease Control and Prevention (CDC) around the countries will be able to carry out risk control and track high-risk groups using tracking module in the system.

Results: This study designs an international patient summary that complies with infectious disease surveillance and clinically meaningful data according to the IPS HL7-FHIR guideline.

In order to achieve the purpose of global COVID-19 surveillance and enhance health resilience, global infectious disease information exchange must be enacted. The COVID-19 surveillance system was built and designed based on the blockchain architecture. IPS is used to exchange case study information among physicians. When physicians pass system verification, they can upload the case IPS and get IPS data of other global cases from the system. The system includes daily IPS uploading and the enhancement plan, which covers real-time uploading through interoperations of the clinic system with the module based on the Open API architecture. The authenticated physician can use this system to share and exchange patient IPS to provide international references. Through the treatment of different cases, drug treatments, and exchange of patient treatment results, the disease spread can be controlled, and treatment methods can be funded. From the establishment of the infectious disease case tracking module, and according to the location information of IPS, we can track the moving paths of infectious disease cases. The location information recorded in the blockchain is for all users to check the location information for different cases. The case tracking module is established for CDC members to track cases and prevent the spread of a disease. Based on this module, CDC members can identify the cases' moving path and design a case tracking plan.

Conclusions: This study has created an IPS of infectious disease for physicians to access when treating COVID-19 patients. We also established a secure blockchain architecture for the protection of IPS and completed the application of patient moving path tracking. The results of this research can help health authorities quickly respond to the transmission and spread of any unknown disease and provide a good platform for information retrieval on disease transmission. Another benefits from this system is that it can help public health researchers to form a study trial and analysis data from different countries. One of the effective means in fighting an unknown virus could be by means of a common forum to facilitate mutual sharing of experiences, best practices, therapies for patients, possible useful medications and outcomes from clinical interventions being trailed in various countries in a secure, trustworthy manner. The platform suggested in our study can become an effective tool to facilitate global collaboration, cooperation and collective evidence-based efforts to address the unprecedented situation created by COVID-19.

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A Global Infectious Disease Surveillance and Case-Tracking Model for COVID-19: An Implementation that is Designed on the Block-chain and HL7 FHIR International Patient Summary

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Abstract

Background

The 2019 novel coronavirus (COVID-19) has affected more than 180 countries and territories around the world. On March 11, 2020, the World Health Organization (WHO) characterized the COVID-19 outbreak as a pandemic. This is the first pandemic known to be caused by a new virus. While the complete clinical picture regarding COVID-19 is not yet fully known, based on currently available information, older adults, and people of any age who have a serious underlying medical condition, might be at a higher risk of becoming severely ill with COVID-19. The emergence and rapid spread of COVID-19 is not only becoming a new public health crisis, but it is also wreaking havoc on the global economy and industries. However, investigations into the disease, patient-tracking mechanisms and the transmission of case reports seem to both labor-intensive and slow.

Objective

The ongoing pandemic is putting healthcare systems under strain worldwide and forcing hospitals and other medical facilities to scramble to make sure that data can be shared effectively. The primary aim of this study is to design a Global Infectious Disease Surveillance and Case-Tracking system that is capable of facilitating the detection and control of COVID-19 transmission. A block-chain-based architecture has been built to protect the security and guarantee the correctness of the International Patient Summary (IPS).

The primary aim of this study is to design a Global Infectious Disease Surveillance and Case-Tracking system that is capable of facilitating the detection and control of COVID-19 transmission. We have designed an International Patient Summary (IPS) that is based on the HL7/FHIR standard and have used block-chain architecture to build a platform for protecting the security and guaranteeing the correctness of IPS.

Methods

An International Patient Summary (IPS), which is an electronic health record that contains essential healthcare information about a patient, is used in this study. IPS is designed to support the used case scenario for 'unplanned, cross-border care'. It is intended to be international, i.e., to provide generic solutions for global application beyond a region or country.

The design, global scope, and utility of IPS for unplanned cross-border care, and its potential for re-use, make it suitable for a situation like COVID-19. The Fast Healthcare Interoperability Resources

(FHIR) confirmed that IPS, which includes symptoms, therapies, medications, and laboratory data, can be efficiently transferred and exchanged on the system for easy access by physicians. Patient data are de-identified to protect their privacy. All systems are protected by block-chain architecture, including data encryption, validation, and exchange or transfer records. Members of the Center for Disease Control and Prevention (CDC) in various countries will be able to carry out risk control and track high-risk groups by using a tracking module in the system.

Result

This study designs an International Patient Summary (IPS) that complies with infectious disease surveillance and clinically-meaningful data, according to the IPS HL7-FHIR guidelines.

In order to achieve the purpose of global COVID-19 surveillance and to enhance health resilience, a global infectious disease information exchange must be enacted. The COVID-19 surveillance system was built and designed, based on block-chain architecture. IPS is used to exchange case study information among physicians. When physicians pass the system verification, they can upload the case IPS and get the IPS data of other global cases from the system. The system includes a daily IPS uploading and enhancement plan, which covers real-time uploading through the interoperation of the clinic system with the module based on the Open API architecture. An authentic physician can use this system to share and exchange a patient's IPS, in order to provide international references. Through the treatment of different cases, drug treatments, and the exchange of patient treatment results, the disease spread can be controlled and treatment methods can be funded. From the establishment of the infectious disease case-tracking module, and according to the location information of the IPS, we can track the moving paths of infectious disease cases. The location information recorded in the block-chain is for all users to check the location information of different cases. The case-tracking module is established for CDC members to track cases and prevent the spread of a disease. Based on this module, CDC members can identify the moving paths of the cases and design a case-tracking plan.

Conclusion

This study has created an IPS of infectious diseases for physicians to access when treating COVID-19 patients. We have also established secure block-chain architecture for the protection of IPS and have completed the application of the moving path tracking of patients. The results of this research can help health authorities to respond quickly to the transmission and spread of any unknown disease and provide a good system for information retrieval on disease transmission. Another benefit of this system is that it can help public health researchers to form a study trial and analyze data from different countries. One of the effective means of fighting an unknown virus could be by means of a common forum to facilitate the mutual sharing of experiences, best practices, therapies for patients, possible useful medications and outcomes from clinical interventions being trailed in various countries in a secure, trustworthy manner. The system that is suggested by our study can become an effective tool for facilitating global collaboration, cooperation and collective evidence-based efforts to address the unprecedented situation created by COVID-19.

Introduction

The novel 2019 Coronavirus (COVID-19), which presumably originated in bats and was transmitted to humans by means of unknown mechanisms in Wuhan, in the Hubei Province of China in December 2019, has affected more than 180 countries and territories around the world. On March 11, 2020, the World Health Organization (WHO) characterized the COVID-19 outbreak as a pandemic. This is the first pandemic known to be caused by a new virus. While the complete clinical picture with regard to COVID-19 is not fully known, based on currently-available information, older adults, and people of any age who have serious underlying medical conditions, might be at a higher risk for the severe illness caused by COVID-19.

Ever since a total of 41 cases with an unknown etiology of pneumonia were confirmed in Wuhan city, in the Hubei Province of China on December 2019 [1], COVID-19 has spread rapidly across that country and around the world [2-8]. Thus far, it has affected more than 12,723,798 people in 188 countries/regions (data obtained through to July 12, 2020) [9]. COVID-19 is now the most serious infectious disease event after SARS, in 2003, and no effective vaccine, drug, or treatment has been found.

Many different infectious diseases still exist in the world, such as the Ebola hemorrhagic fever, the highly pathogenic avian influenza, the Severe Acute Respiratory Syndrome (SARS), the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), and seasonal influenza. When an infectious disease event occurs suddenly, it is crucial to find a quick treatment and control method. Normal patient treatment needs a corresponding treatment that is based on the medical history and symptoms of the different cases.

The rise of COVID-19 was sudden and was marked by the global information flow not being fast enough and the case reports being transmitted slowly. All this led to a sluggish treatment progress, patients not being cured in an efficient manner, and the infectious disease still not being effectively controlled. In today's age of information, our global connectivity gives us a strong advantage in the fight against infectious diseases. We can analyze masses of data to identify outbreaks across different parts of the world and we can use advanced machine-learning models to predict their future movement across different geographical territories. The challenge is that collating relevant data and standardizing it on a global level is a complicated task. In many parts of the world, data does not flow easily from hospitals into the public realm, or across borders. Global data standards have yet to be developed and this creates gaps in the datasets and delays in how the data can be used to shape global health efforts. One way of improving the speed at which data is standardized could be to encourage better interconnectivity across national data systems by using more homogenous data standards. This would require a great deal of collaboration between the various stakeholders and it could be challenging to promote it across borders [10].

The challenge of such a slow and insufficient global information flow could be tackled by a good framework, such as the Asia eHealth Information Network (AeHIN's) GAPS framework (which refers to Governance, Architecture, Program Management, Standards and Interoperability), as well as a good collaboration model.

According to different research case reports in China [2, 5, 6] of the patients who are in the 18 year and older group, 61.9% were male ($n = 172$), and 2 of the 13 patients with COVID-19 were children, who ranged between 2 and 15 years old [11]. Conclusion of the symptoms and history disease of patient with COVID-19 from those researches is founded. Hypertension and cardiovascular disease were the two most common diseases in the adult patient group, followed by diabetes mellitus. With regard to the symptoms, fever was the most common (92.8%; $n = 258$), followed by a cough (69.8%; $n = 194$), dyspnea (34.5%; $n = 96$), myalgia (27.7%; $n = 77$), a headache (7.2%; $n = 20$), diarrhea (6.1%; $n = 17$), a sore throat (5.1% [6]), and pharyngeal (17.4% [2]). Wang et al. showed that the intensive care rate was significant in older patients [2]. Other research reports noted that patients who needed intensive care had a greater percentage of dyspnea than those not needing intensive care [2, 5]. From a report presented by a Beijing research team, among 13 patients with COVID-19, 12

(92.3%) had a fever, with a mean of 1.6 days before the patient went to a hospital, and they also had a cough (46.3%), myalgia (23.1%), upper airway congestion (61.5%), and a headache (23.1%) [11]. Although there are many reports and studies on COVID-19, the details of disease control and treatment are still being broadcast slowly, which may cause an out-of-control spread of the disease and make it difficult to share the experiences of successful case treatments. According to the control status and experience of COVID-19, all cases should be uploaded to the WHO website by different governments, but the route of transmission is still difficult to track, and treatment experiences in different countries cannot be effectively shared. A literature review of infectious disease surveillance, presented by Jajosky et al. [12], on the analysis of the timeliness of reporting by the National Notifiable Diseases Surveillance System, shows that longer reporting lags and the variability among the states limit its usefulness. Some systems have the function of being a static continuous spatial map of the risk of infectious diseases, while others have the function of continuously updating the reporting of infectious diseases, but there is still no system that combines these two functions [13]. After the rise of the COVID-19 infectious disease, the problem has developed into the pathogenic spread across, and among, nations by means of international travel, which has unfortunately enabled the pathogens to invade new countries and adapt to new environments and hosts faster [14, 15]. In many countries, where the public health infrastructure is poor, or where there is an insufficient budget to develop it, the ability of electronic disease surveillance, including data collection and an analysis capability, should be improved [16, 17]. Furthermore, the data exchange of international infectious disease reports and information has certain constraints, not only out of fear for the repercussions on trade and tourism, but also because of the delays in data transfer through the multiple levels of governments or organizations [18]. After experiencing epidemic infectious diseases caused by mutant viruses, such as SARS and MERS, we have found that when facing treatment for unknown diseases, related health organizations and authorities should conduct comprehensive tests, using different drugs and treatment methods, and they should then present the differences between each case and the analyzed treatment results, in order to find the best treatment. However, this process is very tedious and dangerous, and it creates uncertainties regarding the patient treatment. In the face of new infectious diseases, the exchange of treatment results and case experiences is critical.

When facing a new type of infectious disease, it is important not only to treat the disease, but also to prevent its contagion. For example, hundreds of COVID-19 cases in South Korea were found to have occurred at the same church. Hundreds of cases in Japan were found to have originated on a cruise ship. In Hong Kong, several cases were found to have been infected through a hot-pot meal. Iran's speedy and large-scale infection may be due to specific type of religious behavior. In Italy, the outbreak may have also been caused by the Italian culture, where hugs and kisses are a common way of greeting someone. During the SARS outbreak in 2003, it was found that infections were caused by the drainage designs of high-rise buildings [19]. Information on the correlation between the context of the event, the living, transportation or environmental design, the religion, and the cultural behavior is critical for the study of coronavirus transmission.

In order to understand the epidemiology and trends of COVID-19, the WHO has provided a template for a case-based reporting form and a data dictionary for that case-based reporting form, and it has requested member countries to report probable and confirmed cases of COVID-19 infection within 48 hours of their identification [20]. These reports are sent through to the National Focal Point and the Regional Contact Point for International Health Regulations at the appropriate WHO regional office. The WHO has asked the countries to provide aggregated data for surveillance when it is not feasible to report case-based data.

However, to the best of our knowledge, there has thus far been no functional collaborative global case exchange model that can co-create case data on COVID-19 and facilitate care coordination across countries. The aim of this research is to design an infectious disease surveillance module for the global exchange of infectious cases and the sharing of treatment experience. Information on the

movement and path-tracking of cases, including the linkage and correlation between each case, can also be included in infectious disease control in various countries. When an infectious disease outbreak occurs, it can therefore be quickly controlled.

In the initial stages of the COVID-19 outbreak, very little research was available on the data format of the disease and no-one knew what the best data format was; there had only been some discussions on the importance of clinical data exchange regarding the disease.

Currently, several places have created an FHIR-based COVID-19 data structure. A good example is provided by the National Coordinator for Health Information Technology (NCHIT) in its ISA section of Interoperability for the COVID-19 Novel Coronavirus Pandemic [21, 22], namely, the Logica COVID-19 (FHIR v4.0.1) Implementation Guide CI Build. The Logica used HL7 FHIR profiles for COVID-19 to create an implementation guide for a collection or library of data elements that relate to COVID-19. This can be used in many different situations where COVID-19 data are shared to support patient care, billing, research, or public reporting.

Another example can be found in the Dedalus COVID-19 Solution [23]. In their "COVID-19 Simplifier Project", they used FHIR resources in the Dedalus COVID-19 Solution software. The data elements cover a patient self-assessment, a remote clinical assessment, and telemedicine/self-monitoring. They claimed that their first activations will be in Italy and France. Our study used a similar method that started from the COVID-19-related clinical data and we used the International Patient Summary (IPS) as a basis for the data structure. The IPS document is an electronic health record extract that contains essential healthcare information for the necessary care of its subjects. Due to the rapid outbreak of the disease in the early weeks, no format had been designed for the exchange of COVID-19 data. Therefore, we designed a version of IPS that can be used for COVID-19.

An IPS document is an electronic health record extract that contains essential healthcare information about a subject of care [24]. It is designed to support the used-case scenario for 'unplanned, cross-border care', but it is not limited to it. It is intended to be international, i.e., to provide generic solutions for global application beyond a particular region or country, and the IPS dataset is minimal and non-exhaustive, specialty-agnostic and condition-independent, yet still clinically relevant. The design, global scope, and utility of IPS towards unplanned cross-border care, and its potential for re-use, makes it suitable for a situation like COVID-19. The Fast Healthcare Interoperability Resources (FHIR) confirmed that IPS, including the symptoms, therapies, medications and laboratory data, can be efficiently transferred and exchanged on the system, for easy access by physicians. Patient data are de-identified to protect their privacy. In addition, the blockchain-based architecture can be used to ensure the security and immutability of the case data.

Our goal is to provide an immediate reference for people to use in the current crisis, so the design is not focused on a single use case, and the IPS therefore has a more general data structure that focuses on the clinical data needed for COVID-10.

We understand that the data structure will not be perfect or comprehensive, but it can be modified in the future after more and more institutes use the data structure to exchange records. According to the research of Holmgren et al. [25], the inability of hospitals to receive electronic data is an obstacle for the effective monitoring of patient symptoms. Therefore, the aim of our study is to create a COVID-19 data structure and a system that can share the data among healthcare institutions. It is expected that the proposed system can contribute to the control of the COVID-19 situation.

Methodology

1. Architecture for the global infectious disease surveillance and case-tracking model

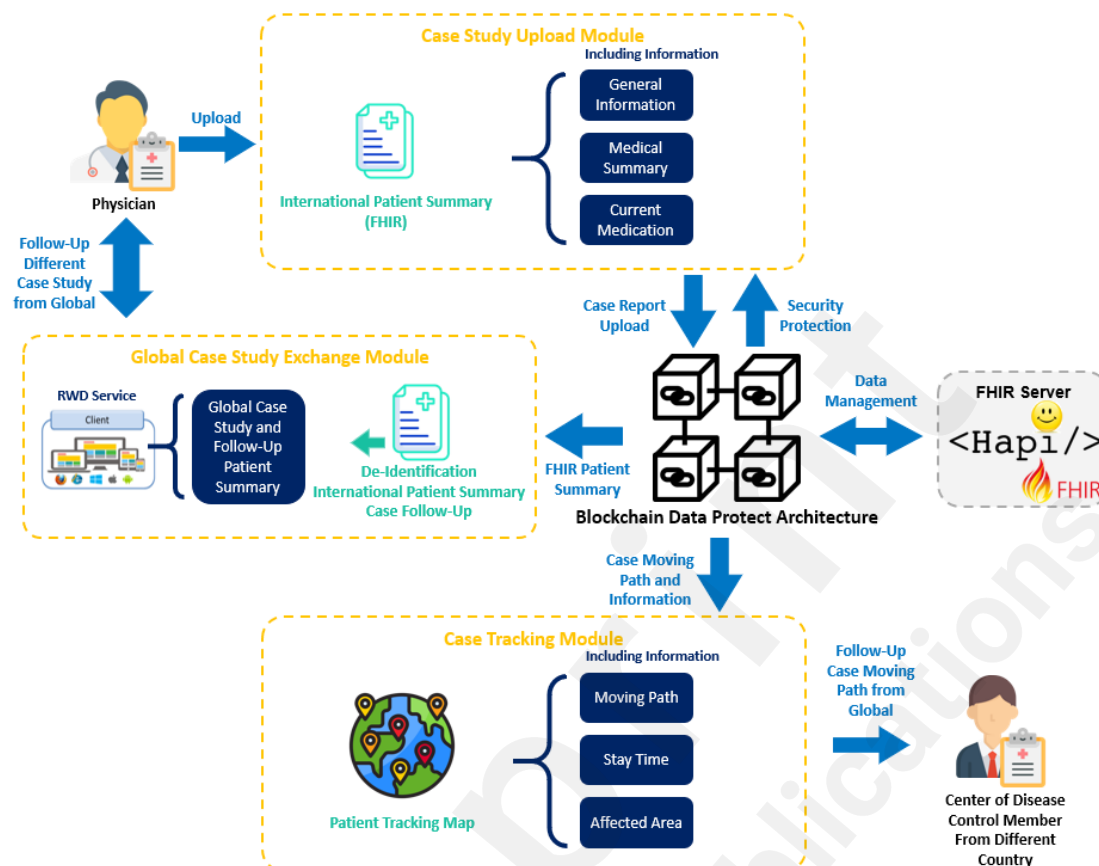


Fig. 1 Architecture of the global infectious disease surveillance and case-tracking module

This study designs a global infectious disease surveillance and case-tracking model, and it includes a "Case Study Upload Module", a "Global Case Study Exchange Module", and a "Case Tracking Module". Each module has different goals. The architecture of a global infectious disease surveillance and case-tracking model is shown in Figure 1.

The main goal of "Case Study Upload Module" is to allow physicians worldwide to continuously upload the International Patient Summary (IPS) and to include detailed information about the treatment of COVID-19 patients. Through experience sharing and sharing patient summaries with other physicians, they can find better essential treatment methods. This module has the ability to identify and verify the identity of physicians in different countries or regions. The "Global Case Study Exchange Module" allows physicians to brainstorm together on different patient summaries and to learn about, and find, possible potential treatments. A large amount of open and complete information is required for currently unsolved disease treatment issues. Under the condition of privacy protection and the provision of correct information with regard to the different case symptoms, treatment methods, drugs, etc., it may be possible to find the best antidote to solve the infectious disease crisis that is facing the world. The "Case Tracking Module" allows CDC members to track a patient's movement path before a diagnosis is made. The tracking map is shown in the module. According to different patients' statements about their own moving paths, a moving map can be established that contains international paths. CDC members will be able to carry out risk control and track high-risk groups, according to this map, thereby effectively controlling the scope of disease infection and completing it as soon as possible.

The security and correctness of IPS are protected by block-chain architecture. When IPS data are uploaded, the details of the data will be de-identified, the block will store the data update log,

and the IPS hash value is calculated by SHA-256. The IPS data are stored in the HAPI FHIR database, which is an open source, and is an implementation of the interoperability of HL7-FHIR for healthcare systems in Java. It was developed as an open community by a global team [26]. The IPS continuity of each patient will be connected through the information of the block-chain. User identities are divided into two types, namely, physicians and CDC members. Physicians need to be authenticated through their medical ID certificate in their countries, and CDC members are registered and managed by the CDC units in various countries.

2. International Patient Summary Tailored for COVID-19 Case Data

An "International Patient Summary Implementation Guide" has been published by the Health Level 7 Fast Healthcare Interoperability Resource (HL7 FHIR). The goal is to provide a universal international solution for global healthcare service applications. This research used IPS (STU 1-FHIR R4, launched on 2019-08-06) as a case study, as it provides treatment and healthcare information records for global cases of unknown infectious diseases. IPS is a minimal and non-exhaustive patient summary, which means that it is not intended to copy the full content of an EHR. IPS is usable by clinicians for the unscheduled cross-border care of a patient and focuses on a patient's current condition, instead of anything specific to a particular condition. Furthermore, IPS is applied on a global scale to address the international feasibility of usage as much as possible.

To provide a reference for global cases, the IPS is designed to include information on the following: "Medication Summary", "Allergies and Intolerances", "Problem List", "Immunizations", "History of Procedures", "Diagnostic Results", "Vital Signs", "Past History of Illness", "Plan of Care", "History of Location and Moving Path before Diagnosis", and "Location". The structure of the IPS is shown in Figure 2.

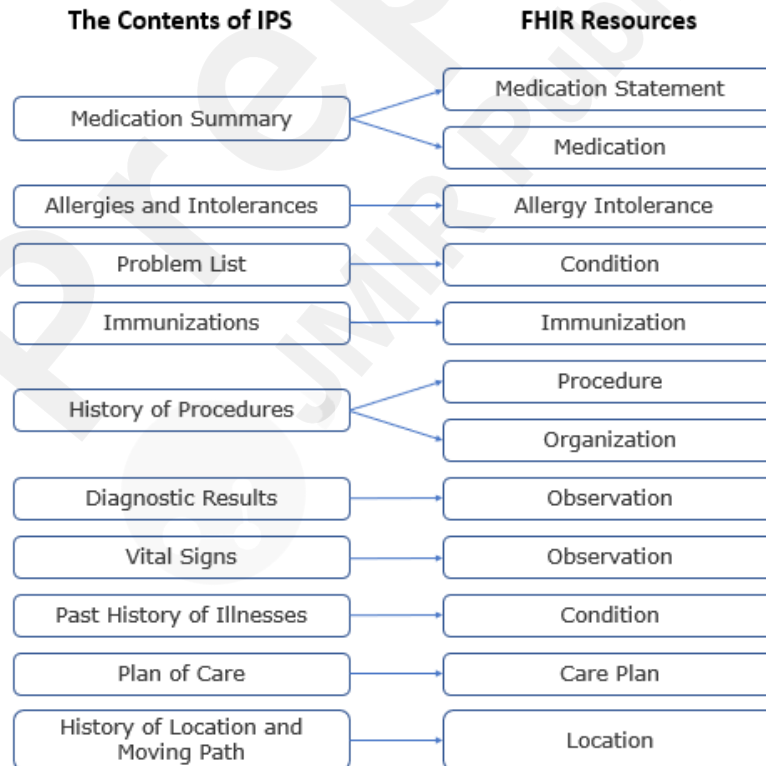


Fig. 2 IPS structure for case study

3. Case Study Upload Module for IPS Protection and Validation

The physician uploads the patient's IPS to the system's HAPI server, and the HAPI server corresponds to the IPS index with the block-chain architecture. The IPS index information is designed to connect the data from the HAPI server, including the IPS hash value and the

encrypted IPS index value. The de-identified and simplified case data include the gender, age, symptoms, country, and location index value of the HAPI server. After the physician has been authenticated, he/she has permission to upload the IPS and view its study cases. The encryption and decryption for the data upload process and architecture is shown in Figure 3.

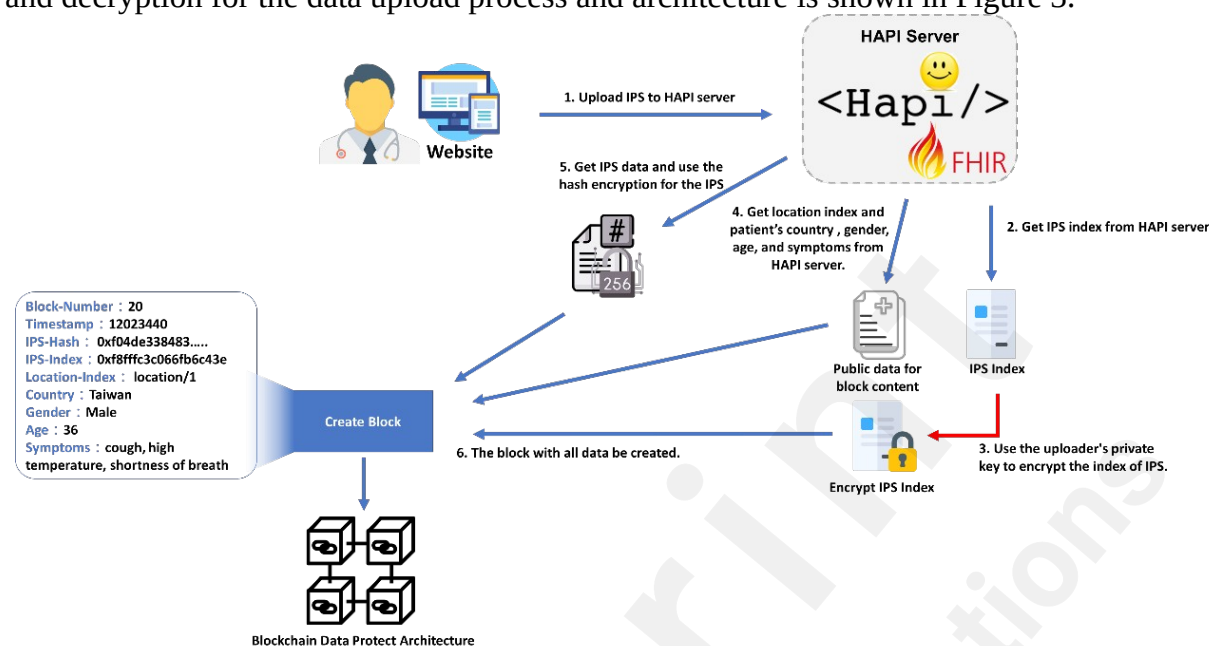


Fig. 3 The encryption and decryption for the data upload process and architecture

Step 1. The certified physician uploads the patient's IPS file to the system, and the IPS will be stored in the HAPI server. Patient identification will be replaced by a Globally Unique Identifier (GUID), which is a 128-bit number that is used to identify the information in the system.

Step 2. The data index position of the IPS is obtained from the HAPI server.

Step 3. The private key of the uploaded physician is used to encrypt the IPS index of the data, which is stored in the HAPI server.

Step 4. The anonymous IPS public information is obtained from the HAPI server, including the mobile path index position, the gender, age, country, and symptoms.

Step 5. The hash value of the IPS is calculated by the SHA-256 encryption function.

Step 6. The content of this block is transferred to the block-chain architecture, and a new block is established by the block-chain architecture.

4. Global Case Study Exchange Module for the Global Case Study Exchange

In a state of globalization, new diseases or clinical pathways that are not treated correctly are likely to rage around the world. COVID-19 has spread throughout the world, and therapeutic vaccines and drugs have not yet been developed to treat it. This study constructed a Global Patient Summary Exchange model and shared the global research progress through case analyses, so that physicians in different regions of the world can refer to the results of the acquisition and test cases, while at the same time obtaining and learning more about the unknown disease and finding the best treatment process together.

Our study is designed for IPS sharing, which can help clinical physicians to find successful treatments and clinical pathways to improve the patients' survival and reduce sequelae. Because we have designed the model, physicians need to register first and provide proof of their identity. The system provides each physician with a privacy key for IPS decryption. This system allows physicians to view the summary of the patient cases that have been uploaded all over the world and it provides a filter function of the cases. Specific cases can be tracked by using this module. The process of how physicians get the IPS of global study cases is shown in Figure 4.

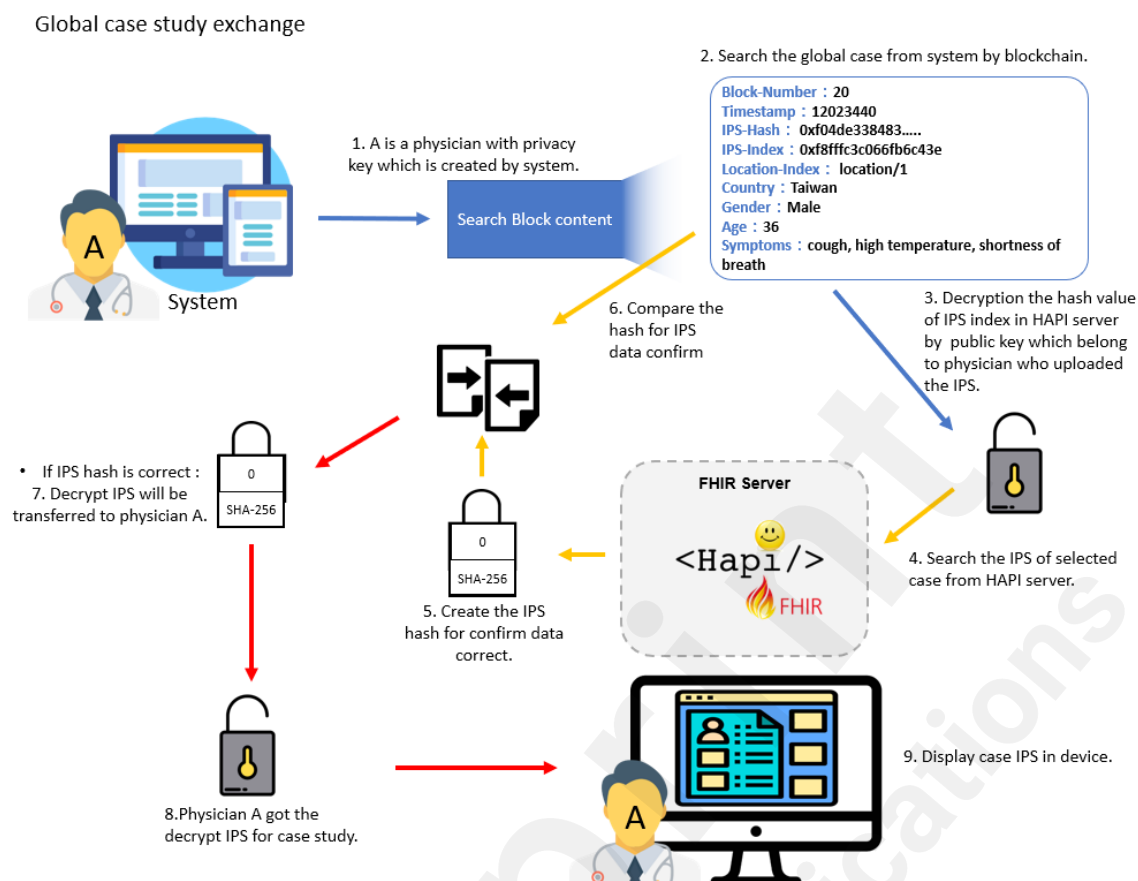


Fig. 4 Process flow of physicians getting the IPS of global study cases

We designed a nine-step process for completing the SEIPS access to international cases, which includes a data search, decryption, verification, and transmission.

Step 1. The system verifies the identity of the user, confirming that the user is a physician with registration data.

Step 2. A list of global patients and simple case information is provided to the physicians, including the patient's region, country, age, and gender.

Step 3. The index of the selected SEIPS is decrypted by the privacy key of the physician who is uploading the IPS.

Step 4. The selected patient IPS is retrieved from the decentralized database.

Step 5. The decrypted IPS data are hashed again by SHA-256.

Step 6. The hash value that is decrypted by Step 5 is compared to the hash value in the blockchain.

Step 7. If two hash values are equal, it means the data are correct, and the decrypted data are transmitted to the physician.

Step 8. The system confirms that the physician has obtained the decrypted case study data.

Step 9. All the IPSs of the selected cases are presented on the physician's display.

The module is designed as a web-based application, and it includes the Open API architecture. The module provides various APIs to let the public and private physicians' clinic management system operate easily with the module and to conduct the case exchange.

5. Case-Tracking Module for Infectious Disease Prevention Breach

The prevalence of international tourism and the rapid movement of populations, in an era of globalization, have increased the spread of COVID-19. In just three months, it has spread from a limited area (one city in Asia) to become a source of infection throughout the world, and the number of infected people continues to increase.

In order to effectively control the scope of infection and prevent continued expansion, the movement path of infected patients needs to be tracked. The FHIR "Location" resource is included in the patient's IPS, and it helps CDC members to effectively track the patients and prevent the continued spread of the disease, based on the record of moving paths and time stamps. The workflow of case tracking is shown in Figure 5.

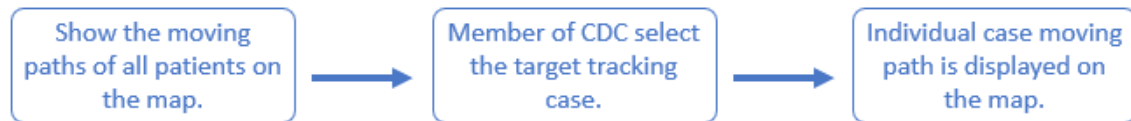


Fig. 5 Workflow of case tracking

6. Structure of Block-chain Security

The block-chain architecture is established for the security protection mechanism of IPS data, and the HAPI server is used as a data server for the FHIR IPS. The block in the block-chain is public data for all users and includes IPS index information and de-identified simple case data, which includes gender, age, symptoms, country, and the HAPI server data index.

Block-chains have many different authority mechanisms. In this study, considering the privacy of a patient's medical data and the need to process a large amount of medical information, the blockchain is built in a private chain, and a Proof of Authority (PoA), with a fast transaction speed and high privacy, is adopted as the consensus on the block-chain. In 2015, PoA was proposed by the Ethereum co-founder, Gavin Wood [27]. This consensus algorithm is used to set up trusted nodes as block validators. It is a centralized consensus mechanism that ensures data security and data verification through authorization mechanisms. The blocks on the chain are generated by trusted nodes, which can improve the efficiency of the generating blocks and ensure consistent data. At the mean times, the system runs well. The ownership of the nodes depends on the policy of the healthcare authority in different areas. For example, it can be a hospital center or the CDC of a state.

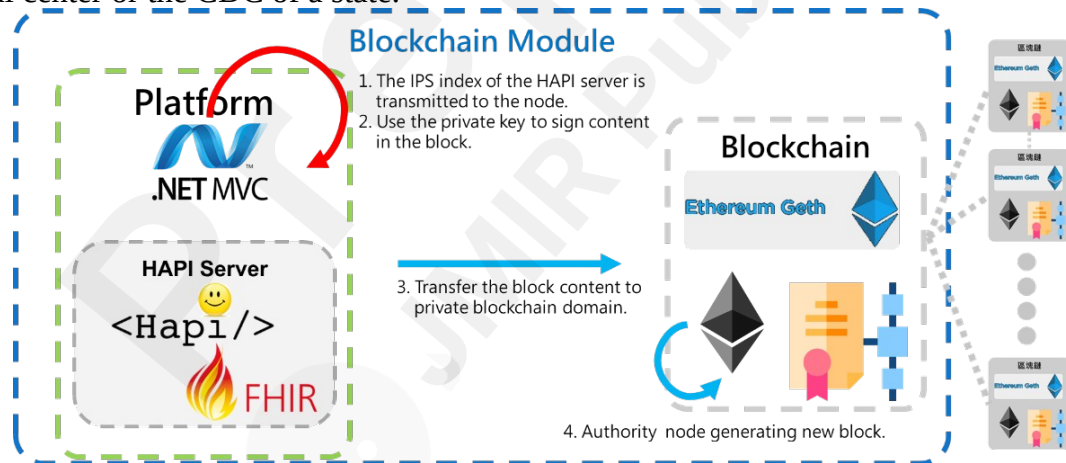


Fig. 6 The Process of Generating a New Block

The process of generating a new block includes four steps, as shown in Figure 6.

Step 1. The IPS index of the HAPI server is transmitted to the node.

Step 2. The private key is used to sign the content in the block.

Step 3. The block content is transferred to the private block-chain domain.

Step 4. The authority node generates a new block.

Blockchain architecture will automatically copy the new block data to other nodes, in order to complete the goal of block-chain decentralization.

Results

1. Global infectious disease surveillance of IPS for the case study

When facing the spread of an unknown disease around the world, such as COVID-19, global case studies must be shared and exchanged quickly. Clinical data must be allowed to be transmitted efficiently and safely, in order to jointly find the most appropriate control and treatment methods, through international cooperation. Because different patients have different disease histories, family disease histories, and life environments, their symptoms and disease progression will be different.

An example of this is the SARS outbreak in 2003. After the outbreak, Hong Kong found numerous problems in the surveillance systems of communicable diseases, and the 2003 Contact-tracking System was inadequate for dealing with the scale of the SARS epidemic. The public health surveillance systems were not well-developed in the private sector and in community clinics, there was no comprehensive laboratory surveillance system, and the Hospital Authority's laboratory database was not linked to the Department of Health in the early stages of the epidemic.

This study thus designs an international patient summary that complies with infectious disease surveillance and clinically meaningful data, according to the IPS HL7-FHIR guidelines. The IPS that is designed by us includes the following: a "Medication Summary", "Allergies and Intolerances", a "Problem List", "Immunizations", a "History of Procedures", "Diagnostic Results", "Vital Signs", a "Past History of Illness", a "Plan of Care", and a "History of Location and Moving Path before Diagnosis". The IPS content with the structures of FHIR resources is shown in Figure 7.

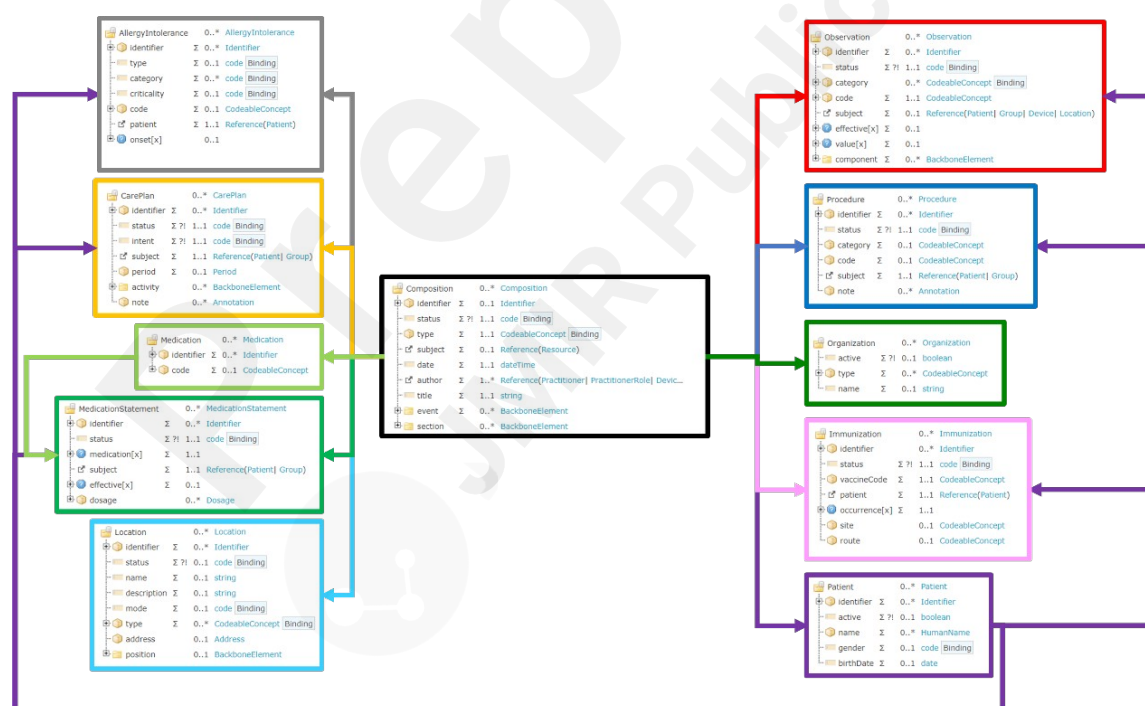


Fig. 7 IPS contents are mapped to the structures of the FHIR resources

The Medication Summary section includes a description of the current and past medications that a patient takes. The Allergies or Intolerances of a patient includes a description of the kind of reaction, the agents that cause it, as well as the criticality and the certainty of the allergy. The Problem List includes clinical problems, and the conditions of the patient that are currently being monitored. The Immunizations section includes a patient's current immunization status and pertinent immunization history. The History of Procedures section includes a description of the patient procedures that are within the scope of the IPS. The Diagnostic Results include the relevant observations and in-vitro biological specimens that are collected from the patient. In this

section, the laboratory, imaging and pathology reports may be included. The Vital Signs section includes the data collected when the patient received a medical service or was under surveillance in the hospital, such as the body temperature, blood pressure, heart rate, respiratory rate, height, weight, and BMI. The History of Illnesses includes the patient's disease history. This section can help physicians to make clinical decisions and get more information from the data. The Plan of Care includes a description of the clinical care, such as a plan of the proposals, goals, monitoring, tracking, and ordering of requirements to improve the patient's condition. The History of Location and Moving Path section includes where the patient has moved from and to during the incubation period of the infectious disease, as well as the location where the patient was infected, e.g., a hospital, hotel, restaurant, bus, plane, cruise ship, etc. This section is important for controlling the spread of the disease, for identifying potential patients, and for completing prevention.

After the data of the FHIR IPS is uploaded, the system accepts the input by using the JSON format. The FHIR IPS integrates each different resource into the same file as a “bundle” resource, and finally, it is uploaded into the HAPI Server.

2. Global COVID-19 Surveillance System for Case Studies

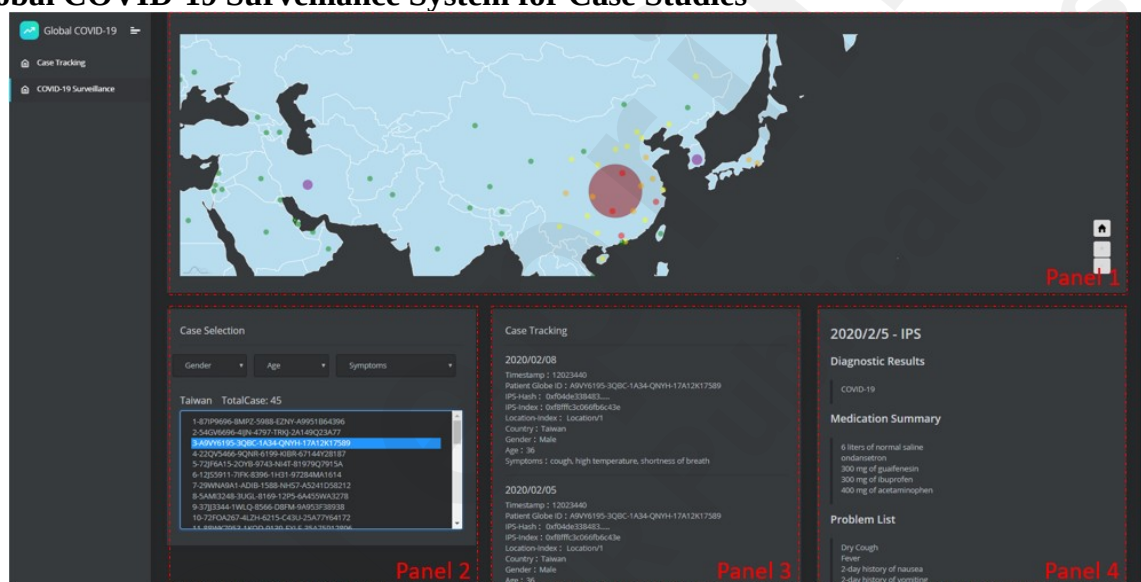


Fig. 8 The COVID-19 surveillance system

In order to achieve the purpose of global COVID-19 surveillance and to enhance health resilience, the exchange of global infectious disease information must be enacted. The COVID-19 surveillance system was built and designed based on the block-chain architecture. The IPS is used to exchange case study information among physicians. When physicians pass the system verification, they can upload the case IPS and get the IPS data of other global cases from the system. The IPS should be uploaded daily by the physician. The system includes daily IPS uploading and an enhancement plan, which covers real-time uploading through the interoperation of the clinic system with the module, based on the Open API architecture.

All physician users have access to the case IPSs in the case study system, in order to support clinical decision-making. The system's User Interface (UI) is shown in the Figure 9, and it is divided into four panels that achieve different functions. The case diagram is displayed in Panel 1, where users can obtain the number of cases and international case distribution information. Cases from different places can be selected in Panel 2, as well as the system UI, as shown in Figure 8. The screening conditions are gender, age, and symptoms, which are used to screen-reference the cases that are similar to their own case. The case IPS information can be viewed in Panel 3, which includes all the uploaded IPSs, the basic information of the patient summary, and the IPS information on the block-chain. The detailed IPS content is viewed in Panel 4. The authenticated physician can use this system to share and exchange the patient IPSs, in order to

provide international references. Through the treatment of different cases, the drug treatments, and the exchange of the patient treatment results, the spread of the disease can be controlled, and treatment methods can be funded.

In our design, the user selects the country to track the case in Panel 1, and the country circle represents the number of cases. After selecting the country, Panel 2 will display the total number of case data that have been uploaded, as well as the GUID that each case represents in the system. Panel 2 gives the option to filter cases. After selecting a case, Panels 3 and panel 4 will display the IPS information of the selected case. The case selection (Panel 2) is shown in Figure 9. It is a Taiwanese example and the patient GUID is represented as “5AIF63A5-9KWE-1653-AR1I-49682N29A22”.

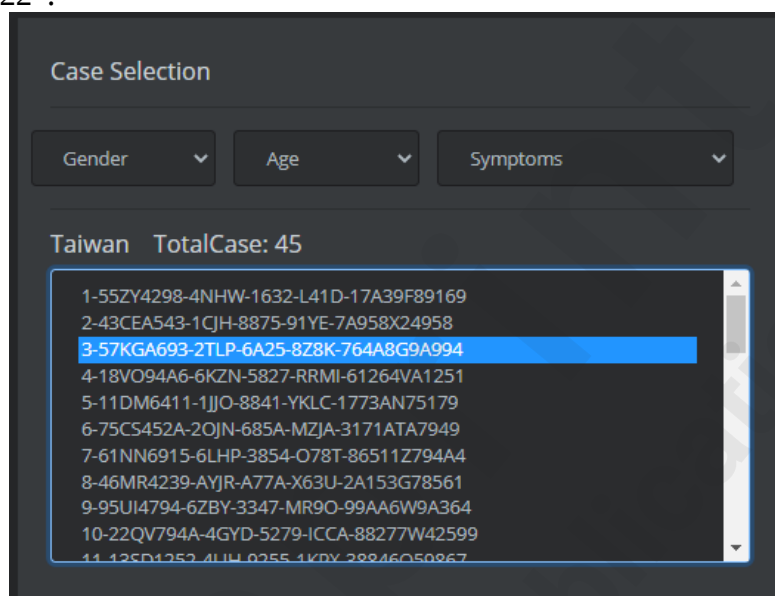
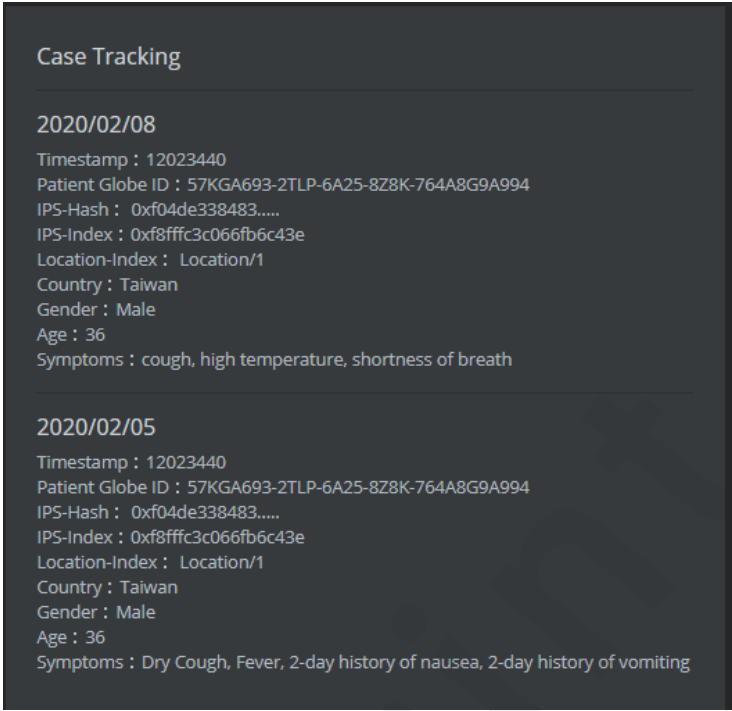


Fig. 9 UI of Case Selection (Panel 2)

3. Block-chain information of IPS data

In this study, all uploaded IPS information will be verified and stored in the uploading record by using the block-chain. Panel 3 is mainly the block information of the selected case. Figure 10 shows the block information of a patient whose GUID is "57KGA693-2TLP-6A25-8Z8K-764A8G9A994". In the example, two blocks mean that the case has two uploaded IPSs, and the block information includes a time-stamp, the GUID, the IPS-Hash and -Index, as well as the moving location, country, gender, age, and symptoms.



Case Tracking

2020/02/08
 Timestamp : 12023440
 Patient Globe ID : 57KGA693-2TLP-6A25-8Z8K-764A8G9A994
 IPS-Hash : 0xf04de338483.....
 IPS-Index : 0xf8fffc3c066fb6c43e
 Location-Index : Location/1
 Country : Taiwan
 Gender : Male
 Age : 36
 Symptoms : cough, high temperature, shortness of breath

2020/02/05
 Timestamp : 12023440
 Patient Globe ID : 57KGA693-2TLP-6A25-8Z8K-764A8G9A994
 IPS-Hash : 0xf04de338483.....
 IPS-Index : 0xf8fffc3c066fb6c43e
 Location-Index : Location/1
 Country : Taiwan
 Gender : Male
 Age : 36
 Symptoms : Dry Cough, Fever, 2-day history of nausea, 2-day history of vomiting

Fig. 10 UI of case-tracking by block information

4. IPS of COVID-19 Case

A COVID-19 case report is to be used as an example in this study. On February 5, 2020, a 52-year-old female patient presented with a fever and went to a hospital ED [28]. The patient had Type-2 diabetes, and had visited Wuhan on January 20. She developed a fever and myalgia five days after her return to Taiwan. She self-reported that she did not have dyspnea, a cough, chest pain, or diarrhea. The diagnosis of COVID-19 was made by a real-time Reverse-Transcription–Polymerase-Chain-Reaction (RT-PCR). The treatment for this patient was supportive care. The patient received the antipyretic therapy, which consisted of 300 mg of Ibuprofen every 6 hours and 400 mg of acetaminophen every 6 hours for symptom management. The patient also received approximately 6 liters of normal saline and 300 mg of Guaifenesin for her continued cough. An example of COVID-19 IPS is shown in Figure 11.

Other information about the patient can be found below:

- Medication Summary

6 liters of normal saline Ondansetron

300 mg of Guaifenesin

300 mg of Ibuprofen

400 mg of Acetaminophen

- Problem List

Dry Cough

Fever

2-day history of nausea

2-day history of vomiting

- Immunizations

-

- History of Procedures

Patient received 300 mg of Guaifenesin for her cough and approximately 8 liters of normal saline during the first 6 days of hospitalization.

- Vital Signs

Body temperature of 37.5°C

Blood pressure of 138/82 mm Hg

Pulse of 105 beats per minute

Respiratory rate of 15 breaths per minute

Oxygen saturation of 95%, while the patient was breathing ambient air.

● History of Illness

Hypertriglyceridemia

Hypertension

Based on the IPS of other patients, international physicians can refer to the care plans of other patient, as well as their disease history, medication, and therapy, and give their own patients the appropriate therapy. Our system provides a new architecture for the international patient exchange summary.

2020/2/5 - IPS
Diagnostic Results
COVID-19
Medication Summary
6 liters of normal saline
ondansetron
300 mg of guaifenesin
300 mg of ibuprofen
400 mg of acetaminophen
Problem List
Dry Cough
Fever
2-day history of nausea
2-day history of vomiting
Immunizations
-
History of Procedures
Patient received 300 mg of guaifenesin for his cough and approximately 8 liters of normal saline during the first 6 days of hospitalization.
Vital Signs
body temperature of 37.5°C,
blood pressure of 138/82 mm Hg,
pulse of 105 beats per minute,
respiratory rate of 15 breaths per minute
oxygen saturation of 95% while the patient was breathing ambient air.
Past History of Illness
hypertriglyceridemia
hypertension
Plan of Care
Treatment for this patient was almost supportive care. The patient received the antipyretic therapy consisting of 300 mg of ibuprofen every 6 hours and 400 mg of acetaminophen every 6 hours for symptom management. Patient also received approximately 6 liters of normal saline and 300 mg of guaifenesin for his continued cough.
Allergies and Intolerances
-
History of Location and Moving Path before Diagnosis
-

Fig. 11 An example of a COVID-19 IPS

5. Case-Tracking of COVID-19 Epidemic Prevention Breach



Fig. 12 The COVID-19 Case-tracking System. Panel 1 shows the distributions of the moving paths of all the cases. Panel 2 shows the detailed moving path information and history record with the locations, time stamps, and possible activities.

From the establishment of the infectious disease case-tracking module, and by using the location information in the IPS of the patient, we can track the moving paths of infectious disease cases. The location information of the patient is recorded in the block contents on the block-chain and is not protected as personal clinical data. Therefore, the location information can be retrieved and used by the system for the purpose of tracking the moving paths for different cases. The case-tracking module has been established for CDC members to track cases and prevent the spread of a disease. Based on this module, CDC members can identify the moving paths of cases and design a case tracking plan for the Epidemic investigation. The UI of COVID-19 case-tracking system is shown in Figure 12. The UI is divided into two panels. Nine cases who were diagnosed as COVID-19 in Taiwan were sampled as an example to show the case-tracking function of the system. Their data are uploaded onto block-chain and the distributions of the moving paths of all the cases is shown in Panel 1, where we can see all of the globally cases, as well as their moving paths in different colors on the map. The detailed case moving path information and history record is shown in Panel 2, with the locations, time stamps, and possible activities. In Figure 12, Panel 2, we show the detailed information of one case. We can see that from 3/15 to 3/21 the case has been travelled in UK. The case came back to Taiwan on 3/21 and showed some symptoms and went to emergency. The case was confirmed as COVID-19 on 3/23 and start to use respirator on 3/27. From these nine samples we can see that all of the cases were imported from outside of Taiwan.

Discussion and Conclusion

After the outbreak of infectious diseases such as SARS, MERS, and COVID-19, it is well-known that international cooperation for disease treatment is critical, especially due to the current high frequency of travel between countries around the world. Diseases, such as SARS and MERS, not only affect people's health, but also seriously affect the world economy [29]. Although the deterioration of a disease condition depends on many variables, when facing unknown diseases, experience sharing and the exchange of advice are still key points. The control and treatment of any disease needs to be found as soon as possible. To control and treat the disease, a global case study sharing system must be established, not only for clinical data sharing, but also for the development of treatment methods.

Through the system designed by this present research, minimal and useful patient summary data can be shared. Physicians only need to focus on essential clinical data that can be followed up on, and they can try a specific treatment or medicine when facing unknown diseases, such as COVID-19. Data from other countries or other patients can be taken as a reference for patient care and treatment. According to published studies, having a fever and a cough are the dominant

symptoms of COVID-19, while gastrointestinal symptoms are uncommon [5, 30, 31]. One report presents the first confirmed case of COVID-19 in the United States, including the process of identification, diagnosis, clinical course, management, and the patient's symptoms [3]. Overall, there is an important need for coordination between clinicians and public health authorities, as well as for the rapid transfer of clinical information relating to the care of COVID-19 patients.

One case study of the first-known imported case of COVID-19 infection in Taiwan describes how the doctor gave the patient supporting treatment for all her symptoms. However, there is still a lack of details and the clinical information about the patient [32]. Another study of numerous cases was conducted by Yuen et al. [33] at the Hong Kong University. They found that the outbreak of COVID-19 in Wuhan, China, was similar to the 2003 SARS outbreak in Guangzhou, China. Both outbreaks initially happened in the animal-to-people transmission model, and not by person-to-person transmission in the community. The case study exchange from the model and the subsequent knowledge exchange, analysis, conclusion, planning, and evaluation will provide a basis for understanding the experiences of previous epidemics, like SARS and MERS, and help to streamline the disease prevention and control measures, for example, regulations for animal and wet markets, patient isolation and tracking, contact quarantine, public health, and hygiene education, in order to prevent any rapid spreading. In view of it being helpless against SARS, Hong Kong later developed a Communicable Disease Information System to provide real-time and intelligent syndromic and communicable disease surveillance, in order to enable rapid intervention and quicker outbreak and emergency responses via field investigations, outbreak control, responsive risk communication, ongoing analysis, alert generation, predictive capability, and early outbreak detection, and to offer a framework for strategic planning and program evaluation. We can rapidly gather information for COVID-19 through international channels, but the information is still not clear enough for us to use as a reference for treating patients. Lipsitch et al. show that viral testing should not be used just for clinical care, but that public health efforts should use it to target the trajectory and severity of the disease [34]. Guan et al. from the State Key Laboratory of Respiratory Diseases note the limitations of COVID-19 research, due to the collection of data from different structures of electronic databases and the urgent timeline for data extraction. Some cases, therefore, have incomplete clinical data of the patients' exposure history and laboratory testing [35].

The main challenge of COVID-19 is that we do not have enough knowledge of the therapy, control methods and completed spread route of the virus, which can only be obtained from the patient. Based on the terrible experience of rapid virus transmission and the heavy burden on the healthcare system, a global information system is essential. When analyzing the development of COVID-19, it seems that an effective Global Communicable Disease Surveillance System has not yet been developed. The disease data are not timely or effectively linked. Physicians and scientists around the world are unable to obtain sufficient disease information in a thorough and timely manner, in order to control the epidemic. Currently, the exchange of case data for clinical research on COVID-19 is incomplete and not quick enough, which limits the development of a treatment design. Even if many case reports were to be submitted, the goals of real-time tracking, data exchange, and referencing could not be achieved. Therefore, in order to reduce the restrictions on COVID-19 research, an electronic health records-based information communication system is necessary, as it can quickly achieve such goals for the public.

This study has created an International Patient Summary (IPS) of infectious diseases that physicians can access when treating COVID-19 patients. We have also established a secure block-chain architecture for the protection of the IPS, and we have completed the application of patient moving-path tracking. IPS case studies can be exchanged through our system and verified through the block-chain architecture. Over the past few years, block-chain has been used in many different fields, not only with regard to medical records /EHR/PHR, but also to medical data exchange issues. Benil et al. [36] introduced block-chain architecture for managing EHR. In its

design, the EHR will be stored in the Cloud, and its integrity in the Cloud will be checked through the block-chain. This is a similar architecture to our research and proves that the block-chain can protect and verify the EHR. Fan et al. [37] proposed a block-chain-based consensus mechanism for medical information data security and privacy in the medical system. Sun et al. [38] presented a distributed signature scheme for medical systems with a record-sharing protocol that is based on block-chain. Yang and Li [39] designed an architecture for securing the EHR system, which is based on distributed ledger technology, to improve the interoperability of health record exchanges between different organizations. Chen et al. [40] introduced a searchable encryption scheme for EHR by using block-chain. Block-chain architecture can ensure data security and verify that the information is correct, and it is therefore a very suitable architecture for global IPS exchange.

The results of this research can help health authorities to respond quickly to the transmission and spread of any unknown disease and it can provide a good system for information retrieval on disease transmission. Another benefit of this system is that it can help public health researchers to form a study trial and to analyze data from different countries. A trial on medication treatment in COVID-19 patients found that the Lopinavir–Ritonavir treatment added to the standard supportive care, but that it was not significant for clinical improvement or mortality in COVID-19 patients [41]. Other research on the use of chloroquine and hydroxychloroquine in Covid-19, shows that the use of these drugs is premature and potentially harmful [42].

However, the clinical observation details of patients are not described by the authors. It is hard to identify which supportive care works best for patients in different situations. Another effective means for fighting an unknown virus could be by using a common forum to facilitate the mutual sharing of experiences, best practices, therapies for patients, and the possible useful medications and outcomes from clinical interventions being trialed in various countries in a secure, trustworthy manner. The system suggested by our study can become an effective tool for facilitating global collaboration and cooperation, and for promoting collective evidence-based efforts to address the unprecedented situation created by COVID-19. However, this study has some limitations. At present, there is no optimal treatment, and complete information about this disease has not yet been found. Governments, medical institutions and physicians from all over the world should cooperate in the study of this virus. Without international cooperation, global interests will suffer significant losses. This research has completed the design and development of the system, and found that it has a stable foundation and is a balanced system. However, there is still a need to test the effectiveness of a large number of users being uploaded and data being exchanged simultaneously. In the future, our team will have discussions with the government, international medical service providers and medical institutions, in order to activate this system, so that they can help to promote international cooperation and development during the COVID-19 outbreak.

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Authors' Contributions

The work presented in this research was carried out in collaboration among all the authors. Hsiu-An Lee and Chien-Yeh Hsu conceptualized the research and designed the architecture of the system. Yuarn-Jang Lee and Jane C-J Chao provide IPS of use case to testing and demo. Jai Ganesh Udayasankaran and Kwok-Keung Ng contributed to the conceptualization efforts. Hsiu-An Lee, Hsin-Hua Kung, Jai Ganesh Udayasankaran, Hueng-Chuen Fan, and Kwok-Keung Ng

carried out literature review. Hsiu-An Lee, Hsin-Hua Kung, and Yu-Kang Chang were instrumental in the implementation of the system. Hsiu-An Lee drafted the manuscript, and Chien-Yeh Hsu and Jai Ganesh Udayasankaran made significant revisions. Chien-Yeh Hsu, Yuarn-Jang Lee, Jane C-J Chao, Jai Ganesh Udayasankaran, Yu-Kang Chang, Boonchai Kijsanayotin, Alvin B. Marcelo, and Louis R. Chao supervised the methodology of implementing a global COVID-19 infectious disease surveillance and case tracking system and suggested valuable improvements. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

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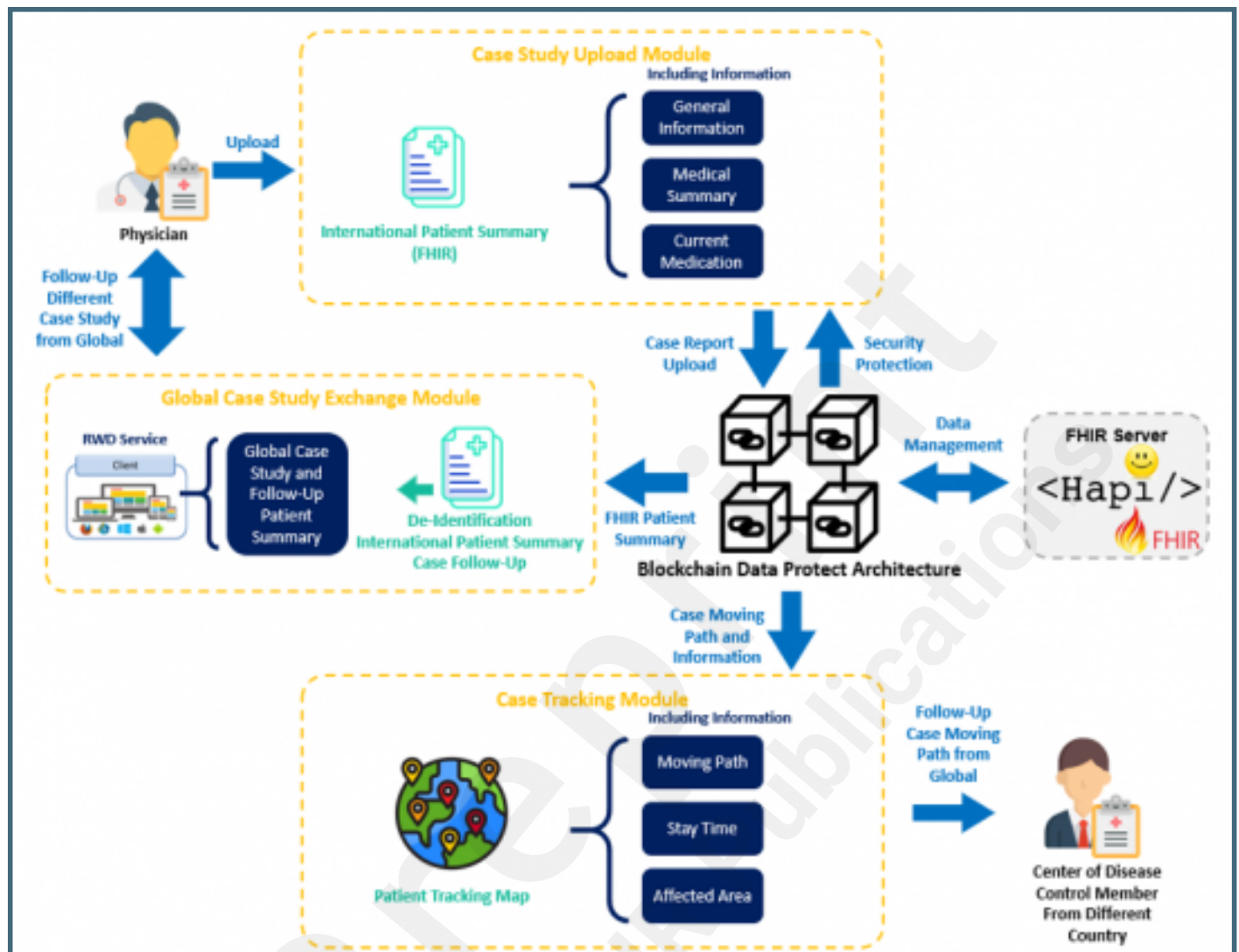
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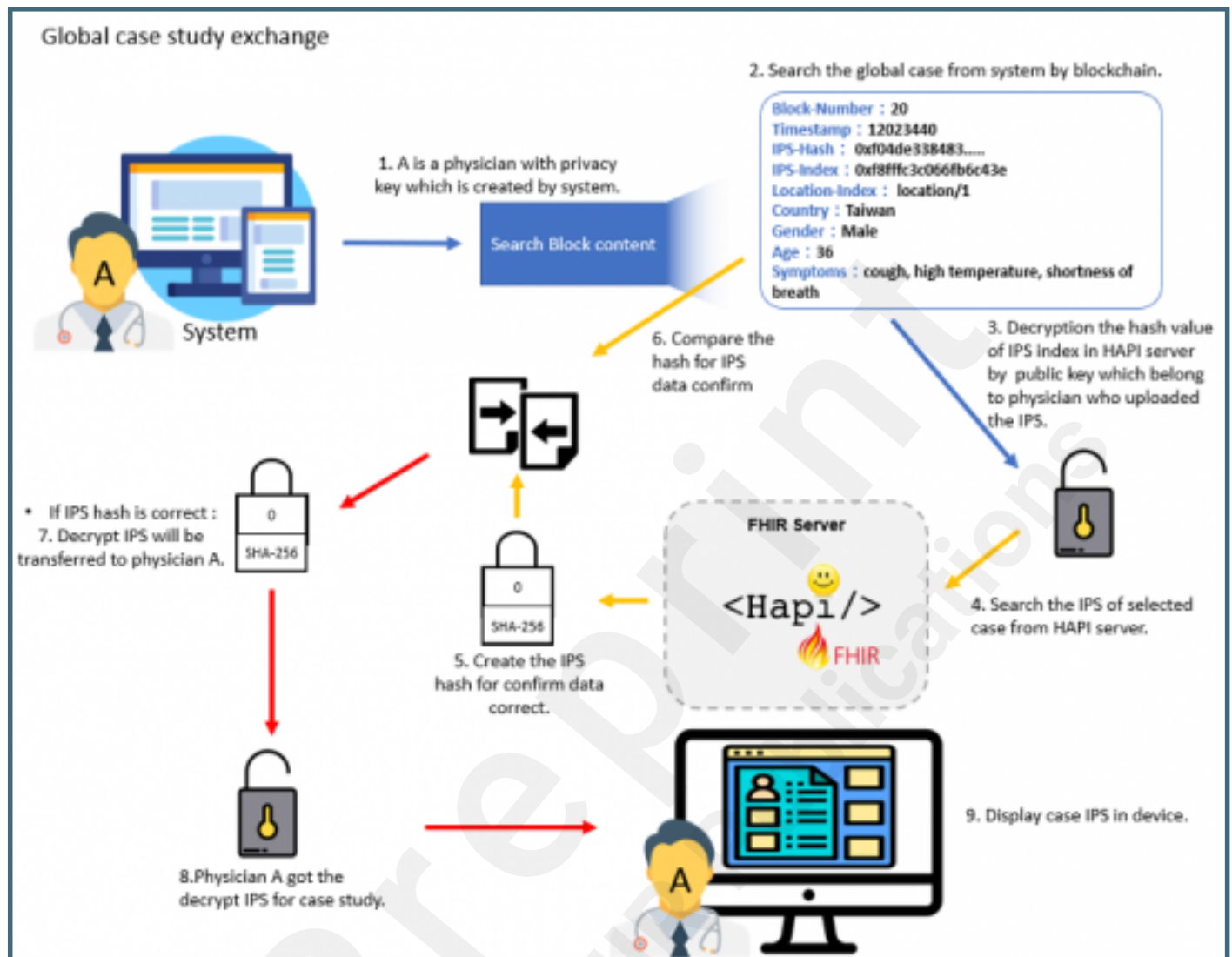
Supplementary Files

Figures

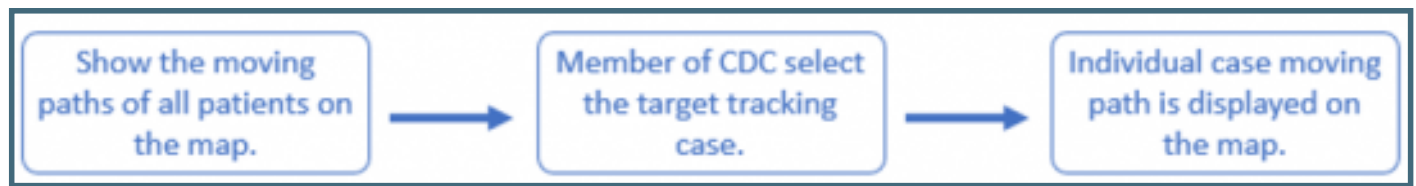
Architecture for global infectious disease surveillance and case tracking module.



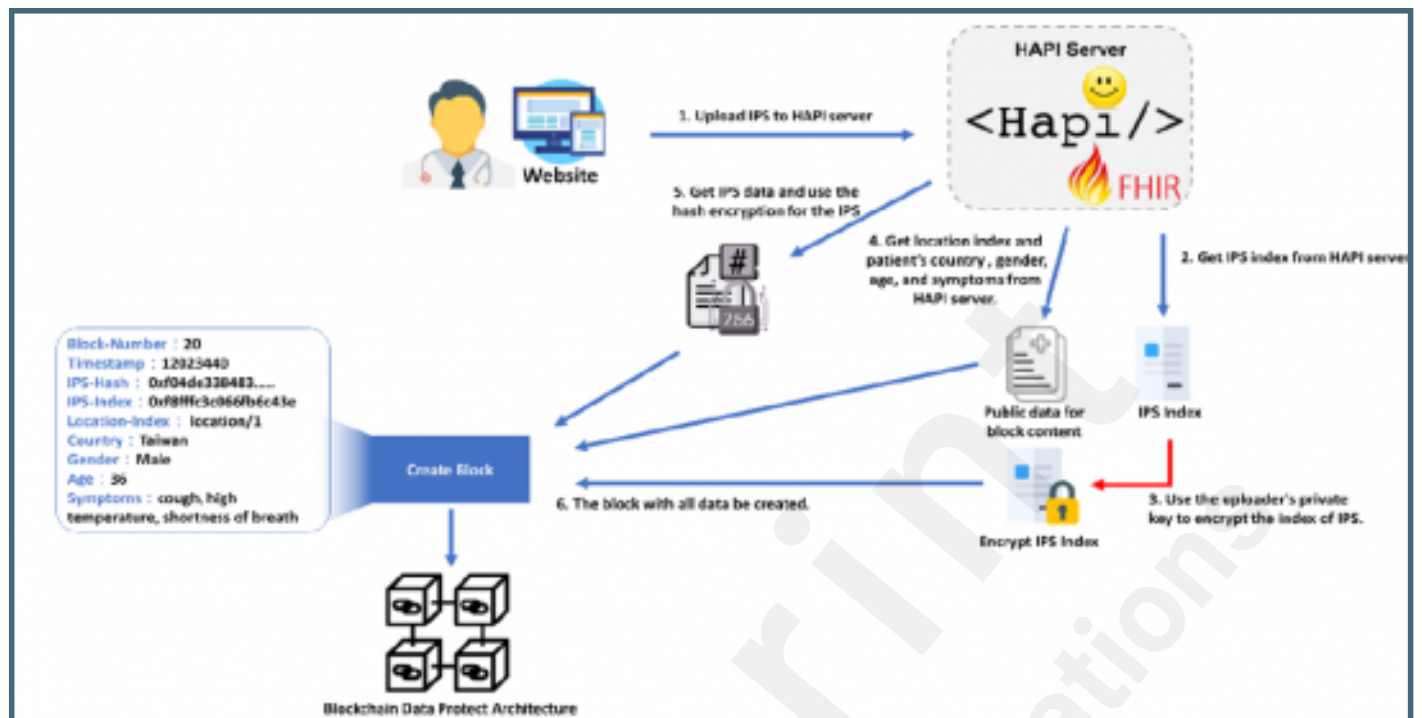
Process of physicians getting the IPS of global study cases.



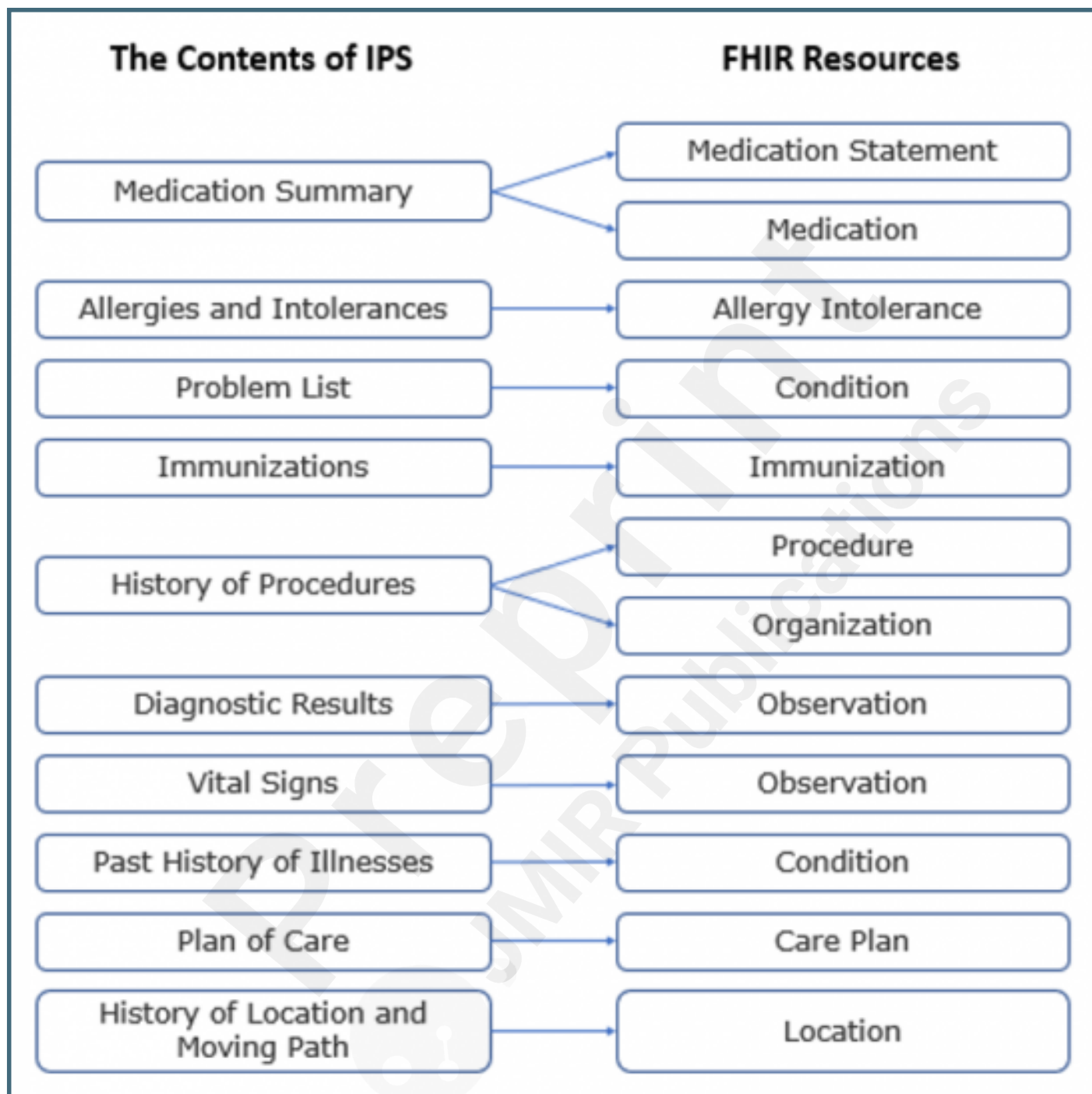
Workflow of case tracking.



The encryption and decryption for the data upload process and architecture.



IPS contents are mapping to the structures of FHIR resources.



The COVID-19 surveillance system.



UI of Case Selection (Panel 2).

Case Selection

Gender

Age

Symptoms

Taiwan TotalCase: 45

1-55ZY4298-4NHW-1632-L41D-17A39F89169

2-43CEA543-1CJH-8875-91YE-7A958X24958

3-57KGA693-2TLP-6A25-8Z8K-764A8G9A994

4-18VO94A6-6KZN-5827-RRMI-61264VA1251

5-11DM6411-1JJO-8841-YKLC-1773AN75179

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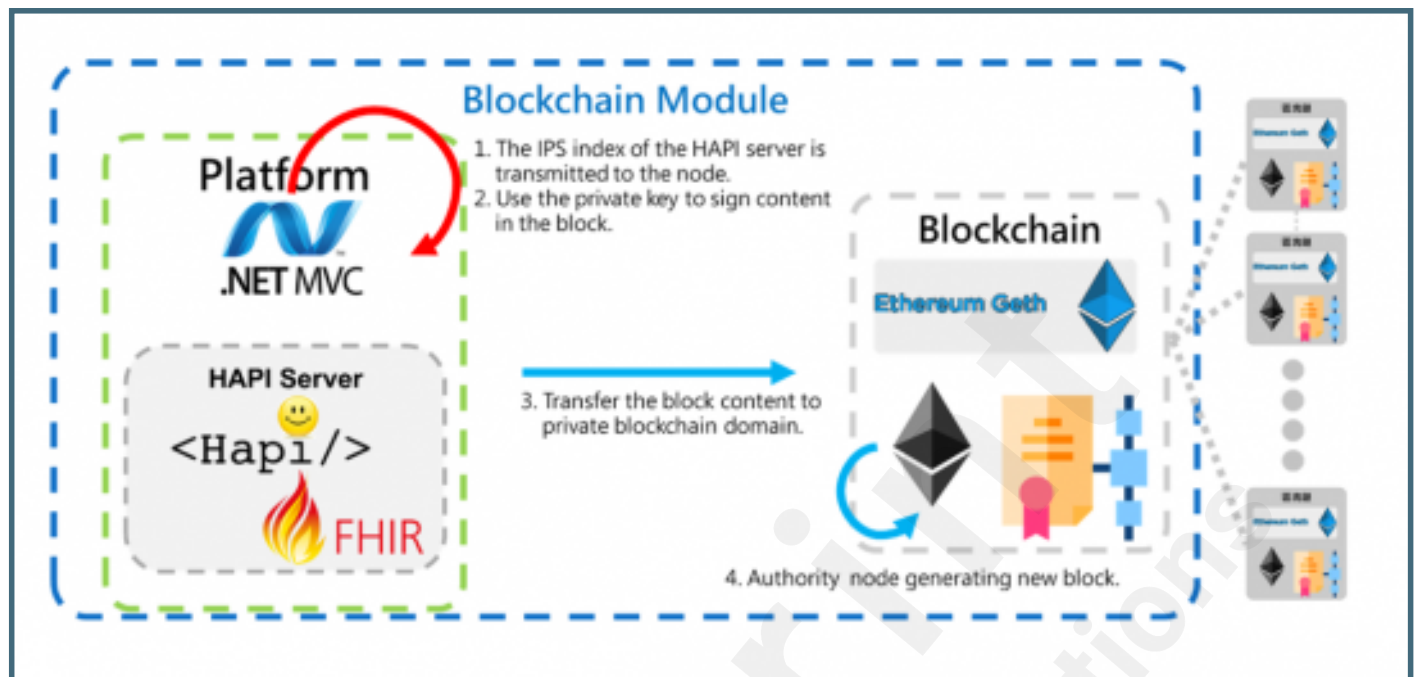
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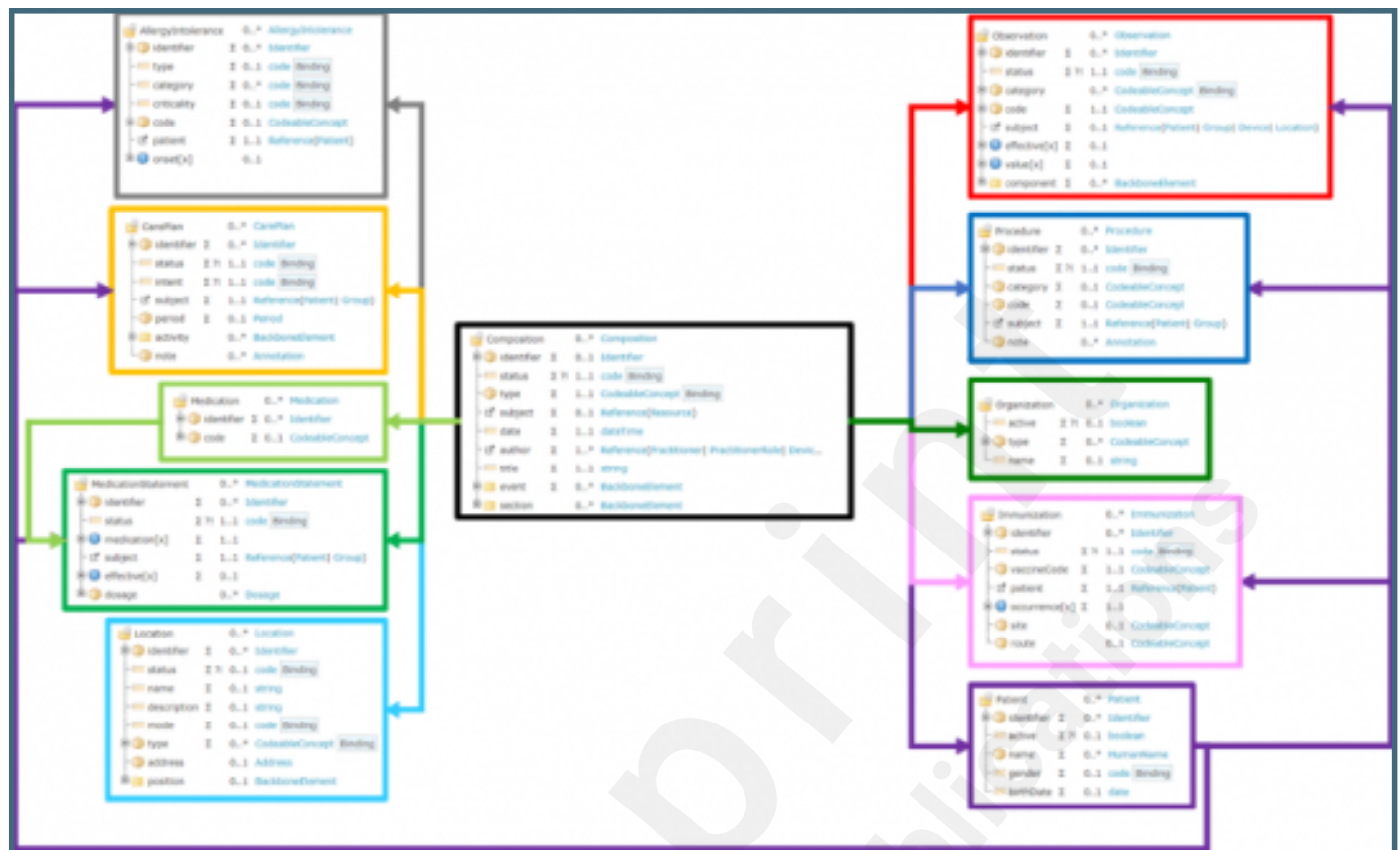
10-22QV794A-4GYD-5279-ICCA-88277W42599

11-12SD1252-4UJH-0255-1KDY-28946Q50867

The Process of Generating a New Block.



IPS contents are mapped to the structures of the FHIR resources.



UI of case-tracking by block information.

Case Tracking

2020/02/08

Timestamp : 12023440

Patient Globe ID : 57KGA693-2TLP-6A25-8Z8K-764A8G9A994

IPS-Hash : 0xf04de338483.....

IPS-Index : 0xf8fffc3c066fb6c43e

Location-Index : Location/1

Country : Taiwan

Gender : Male

Age : 36

Symptoms : cough, high temperature, shortness of breath

2020/02/05

Timestamp : 12023440

Patient Globe ID : 57KGA693-2TLP-6A25-8Z8K-764A8G9A994

IPS-Hash : 0xf04de338483.....

IPS-Index : 0xf8fffc3c066fb6c43e

Location-Index : Location/1

Country : Taiwan

Gender : Male

Age : 36

Symptoms : Dry Cough, Fever, 2-day history of nausea, 2-day history of vomiting

An example of a COVID-19 IPS.

2020/2/5 - IPS

Diagnostic Results

COVID-19

Medication Summary

6 liters of normal saline
ondansetron
300 mg of guaifenesin
300 mg of ibuprofen
400 mg of acetaminophen

Problem List

Dry Cough
Fever
2-day history of nausea
2-day history of vomiting

Immunizations

-

History of Procedures

Patient received 300 mg of guaifenesin for his cough and approximately 8 liters of normal saline during the first 6 days of hospitalization.

Vital Signs

body temperature of 37.5°C,
blood pressure of 138/82 mm Hg,
pulse of 105 beats per minute,
respiratory rate of 15 breaths per minute
oxygen saturation of 95% while the patient was breathing ambient air.

Past History of Illness

hypertriglyceridemia
hypertension

Plan of Care

Treatment for this patient was almost supportive care. The patient received the antipyretic therapy consisting of 300 mg of ibuprofen every 6 hours and 400 mg of acetaminophen every 6 hours for symptom management. Patient also received approximately 6 liters of normal saline and 300 mg of guaifenesin for his continued cough.

Allergies and Intolerances

-

History of Location and Moving Path before Diagnosis

-

The COVID-19 Case-tracking System. Panel 1 shows the distributions of the moving paths of all the cases. Panel 2 shows the detailed moving path information and history record with the locations, time stamps, and possible activities.



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