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Medical Healthcare Network Platform and Big Data Analysis Based on Integrated ICT and Data Science with Regulatory Science

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SUMMARY This paper provides perspectives for future medical healthcare social services and businesses that integrate advanced information and communication technology (ICT) and data science. First, we propose a universal medical healthcare platform that consists of wireless body area network (BAN), cloud network and edge computer, big data mining server and repository with machine learning. Technical aspects of the platform are discussed, including the requirements of reliability, safety and security, i.e., so-called dependability. In addition, novel technologies for satisfying the requirements are introduced. Then primary uses of the platform for personalized medicine and regulatory compliance, and its secondary uses for commercial business and sustainable operation are discussed. We are aiming at operate the universal medical healthcare platform, which is based on the principle of regulatory science, regionally and globally. In this paper, trials carried out in Kanagawa, Japan and Oulu, Finland will be revealed to illustrate a future medical healthcare social infrastructure by expanding it to Asia-Pacific, Europe and the rest of the world. We are representing the activities of Kanagawa medical device regulatory science center and a joint proposal on security in the dependable medical healthcare platform. Novel schemes of ubiquitous rehabilitation based on analyses of the training effect by remote monitoring of activities and machine learning of patient's electrocardiography (ECG) with a neural network are proposed and briefly investigated.

key words: *medical ICT, body area network (BAN), medical healthcare, big data, machine learning, dependability, regulatory science*

1. Introduction

Due to the populations' fast aging, demands for applications providing better medical healthcare systems and services, so-called medical ICT, using advanced information and communication technology (ICT) are increasing drastically [1]. For personal healthcare use, wide variety of mobile health monitoring devices already exists. However, in professional medical diagnosis and therapy, novel advanced medical devices and services being compliant with medical regulations have just recently been invented. These devices and services

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have been studied and developed individually, not much targeting for comprehensive solution.

The authors and their collaborating colleagues have been working hard to establish a total medical healthcare network infrastructure, which is based on a concept of regulatory science. That is an interdisciplinary subject between technology and regulation guaranteeing safety, security, reliability, fault-tolerance, and robustness, i.e., dependability for life critical use cases in medicine. To sustainably serve dependable medicine, both regulatory compliance and global business promotion should be kept in stable by means of efficient regulatory compliance exam and international standardization. Current and future human centric medicine needs artificial intelligence (AI) and machine learning in data science to make diagnosis and therapy more efficient and dependable beyond limits of human manual operation.

In this paper, a universal medical healthcare platform of wireless medical body area network (BAN) [2], cloud network, edge computing, big data AI mining server and repository is discussed [3]. Figure 1 illustrates it in the case of rehabilitation in Yokohama, Kanagawa, Japan.

This paper has four major contributions. First in Sect. 2, architecture of a universal platform based on integrated ICT with data science is proposed. Section 3 describes a concept of regulatory science and introduces international collaboration between Japan and Finland for compliance exam and business promotion of medical devices. Section 4 focuses on

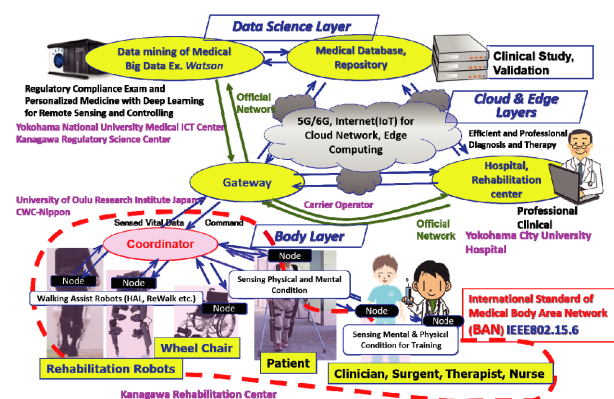


Fig. 1 Medical healthcare platform of wireless medical BAN, cloud network, edge computing, big data AI mining server and repository in the case of rehabilitation in Yokohama, Kanagawa, Japan.

security in the integrated medical platform. Finally, Sect. 5 presents a novel scheme for analysis of rehabilitation using BAN-based remote monitoring of vital signs and equipment motion, and analyzing electrocardiography (ECG) for patient's feeling using a neural network.

2. Universal Medical Healthcare Platform by Integration of Wireless BAN, Cloud Network and Big Data Mining Server

The present and near future will see an exponential increase of wearables, implants and Internet-of-things (IoT) devices in healthcare and medicine. E-health and tele-medicine, such as remote sensing of vital signs and controlling of health assisting actuators and robotics, on demand analysis and digitalized clinic records, will be part of the everyday life in few years. To make healthcare and medicine dependable and safe, reliability and security of a medical healthcare platform should be designed and investigated. This paper provides a solution to this challenge: to obtain sustainable dependable medical healthcare platform based on advanced ICT and data science, i.e., integrating BAN/Cloud/Edge/Data Science platforms.

2.1 Architecture of Dependable Medical Healthcare Platform

Figure 1 illustrates the integrated BAN/Cloud/Edge/Data Science platform in the case of rehabilitation. However, the architecture is universal making it suitable for most of the diagnosis and treatment departments in terms of three ICT layers and a layer of data science. Thus, the platform is applicable even for non-medical use cases [3].

The Body-layer includes all the wearables and implantable devices for healthcare and medicine. It consists of BAN coordinating wireless links between sensors used for diagnosis of patient's vital signs or equipment's, robot's, and environmental statuses, and also actuators for therapy. BAN is connected with cloud networks, offering ubiquitous access to therapists and clinicians.

The Edge-layer including all the IoT devices that are surrounding the user, is a new layer for edge computing. It consists of distributed embedded processors of IoT devices used in medical healthcare. Its security and dependability must be addressed together with higher layers consisting of ad-hoc networks, e.g., WiFi, WiMAX, and infrastructure networks, such as 4G, 5G and 6G.

The Cloud-layer consists of wider area network technologies, including wide area networks (WAN) and network cloud. This layer connects multiple edge-layers, artificial intelligence and data mining systems remotely, and provides big data analysis and feedback/control services based on data science.

These three ICT layers are closely interoperable with the Data Science layer, which analyzes medical big data based on vital signs, equipment statuses, etc. in mining server and repositories. These four layers have various characteristics

and vulnerabilities, which have to be investigated. A comprehensive solutions for dependable medical healthcare by combining BAN, cloud networking, edge computing and data mining must be jointly provided and kept updating in cognitive fashion.

In the case of rehabilitation, as shown in Fig. 1, patients' activities in and outside a hospital with various real-time vital signs' data and equipment statuses are sensed at the Body layer and processed locally in the embedded processors and edge computers at the Edge Layer. The uplink network at the Cloud Layer is used to analyze human's physical and mental conditions, as well as machine conditions utilizing sensed and stored big data for diagnosis and safety with legacy algorithms and deep learning at the Data Science Layer. Interactive and recursive processes together with downlink for therapy and safety control are keen for emergent response and long-term investigation by data mining with fresh high quality data, as well as quantity of data for dependable medical healthcare.

2.2 Security for Dependable Medical Healthcare Platform

Medical big data gathering and its analysis are the key enablers that enable the utilization of dependable medical healthcare platform.

There are several requirements set for the integrated BAN/Cloud/Edge/Data Science platform from dependable and secure healthcare and medicine viewpoints.

- (1) Since healthcare and medical related data must be the most important data to protect human life against cyber attacks and other enforcement, the data should be secure.
- (2) Even machine centric communications, i.e. IoT, must be designed and maintained for safe and secure human centric living with sophisticated ICT and cyber security technologies in medical and even non-medical use cases.
- (3) Collecting and maintaining reliably and securely patients' vitals big data with associating environmental information must be the most important issue, primarily for research and development of innovative medicine and secondarily for various new social services and businesses. Privacy and security of pure vital data should be protected in the highest priority order among all big data.
- (4) Outcome of the research and development for reliable and secure integrated BAN/Cloud/Edge/Data Science platform for collection, analysis and utilization of medical big data must also be applicable for other use cases.

Once efficient data gathering from human end-users and their environment are deployed in a large-scale globally, there will be a countless amount of applications that can take advantage of developed big data analysis methods and database management systems or repositories. For further data utilization, the most critical issue is that the collected data is highly reliable.

Our solution is in the provision of a scalable approach, which can be easily adopted in different application fields. The selected test case consists of the collection of personal data alongside various other data sources. This is done us-

ing multiple sensors, actuators and IoT devices, which are forming heterogeneous wireless networks, such as BAN, to create interconnection between numerous correlating data measured from the same conditions. Collected data handling can be carried out through transregional federated clouds, such as local, national, and global clouds, thus distributing data storage to several places - benefitting large global distribution.

The solution provides dependable interoperability between heterogeneous networks and device structures although IoT devices based on different standards can provide different types and amount of data. All these variations need to be handled by generic data analysis algorithms. That requires commensurable data formats. In addition, throughout the data transmission, storing and analysis processes, data security and constancy need to be assured. Moreover, the system complexity will be increased due to the number of connected cloud services, which could also be globally distributed.

The use of shared cloud services in various medical applications requests not only highly reliable and secure communications but also efficient methods for maintaining databases and cloud services. In addition, the constancy of data needs to be guaranteed in every point of the communications, data storage and analysis chain. The main part of our proposing secure technical schemes will be described in Sect. 4.3.

3. Dependable ICT and Data Science Based on Regulatory Science

To ensure dependability in design and operation of the integrated BAN/Cloud/Edge/Data Science platform for healthcare and medicine, regulatory science could be applied as a core concept for design and performance evaluation. International collaboration between Japan and Finland for research, development, regulatory compliance exam, and business promotion of medical devices based on regulatory science is introduced in this chapter.

3.1 Regulatory Science

The concept and philosophy of regulatory science is simply: any regulation should be established under consensus of all stakeholders in logical manner using scientific analyses and evaluation of risks and benefits of applied technologies, services, and the uses of a numerical criteria under mandatory or constraint conditions and deployment requirements [4], [5]. Procedure of regulatory science is presented in Fig. 2 and described below.

Step 1 “Test and data collection”: To investigate the risks and benefits of targeted medicine, medical device or system including hardware and software. The survey data are collected by field and clinical tests and mined to make sure they are fitting critical use cases due to their architecture, composition, program, etc.

Step 2 “Scientific analysis and evaluation”: All implicit and

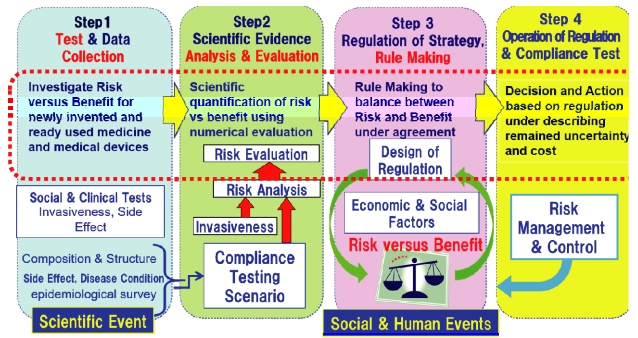


Fig. 2 Concept of regulatory science for social services and systems (e.g. medicine and medical devices).

explicit risks and benefits should be numerically analyzed and evaluated with the balance of the risks versus benefits using predefined numerical parameters.

Step 3 “Strategic regulation making”: According to fair balance between risks and benefits, technical requirements and conditions for regulation are logically derived in such a way that permissible range of parameters with mandatory constraints by consensus or agreement of all stakeholders are met.

Step 4 “Operation of regulation and compliance test”: To examine the medicine and medical devices and their compliant use with the regulation, feedback procedures should be designed. It is important to educate appropriate examiners who can strictly approve such medicine and device, and its use, using predefined procedures and openly describe its remaining uncertainty and necessary cost. A strict manner of measuring and evaluating parameters under clearly defined conditions and environment should be regulated.

3.2 Kanagawa Medical Device Regulatory Science Center

Regulatory science has been applied for regulatory compliance testing of innovatively developed drugs to solve a problem called as a drug lag by PMDA (Pharmaceuticals and Medical Devices Agency) in Japan. However, cutting-edge medical devices, robotics and systems including software are used to be developed using newly invented high technologies. Since compliance testing of medical devices and systems could take longer time and being more complex, we have now focused on healthcare devices and systems.

In order to promote “medical device regulatory science for advancing the innovation of medical healthcare”, Kanagawa Medical Device Regulatory Science Center (MDRS Center) was established by the future medical social infrastructure based on information communications technology, so-called medical ICT Center, Yokohama National University (YNU) in Keihin waterfront Life Innovation International Strategic Comprehensive Special Zone in September 2014 by co-sponsorship of Kanagawa prefecture government. MDRS Center organized MDRS consortium for industry, academia and government collaboration. In April 2018 it consists of 59 companies and institutions. MDRS

Center advances the research of regulatory compliance of integrated medical devices and medical programs and international standardization and business along with MDRS consortium.

MDRS Center aims to promote the followings,

- (1) Research on medical device regulatory science
- MDRS Center quantitatively estimates the possible risks caused by medical devices to human health and environment, confirms scientifically the technologies by analyzing and evaluating the benefits, safety, and quality. It also develops the indices for clinical trials and approval reviews.
- (2) Human resources development by medical device regulatory science

MDRS Center fosters human resources who are capable of taking the lead in medical device regulatory science related projects with the knowledge of development, evaluation, and examination medical devices' standards.

- (3) Evaluation of medical devices and their support
- MDRS Center implements the evaluation of the related medical devices based on the indices confirmed in the research described in (1). In special, the benefits and risks of the state-of-the-art medical devices with ICT, such as BAN, are evaluated.

In the research (1) and the evaluation (3), we examined "Class 0.5 device," which is defined as a healthcare device with lower risk than Class 1 medical device. Class 0.5 device includes the ones for "Me-Byo" concept [6]. Me-Byo, which is literally defined as neither healthy nor sick, is a state that continuously changes between health and illness. To address Me-Byo, individuals need support to maintain health and prevent the onset or further progression of disease. Kanagawa prefecture implements the Me-Byo strategy to achieve health through curing Me-Byo undertaking measures that complement medical approaches. The compliance testing of Class 0.5 devices protects the quality of uncertified healthcare devices and promote their use.

3.3 Kanagawa-Oulu Collaboration for Medical Device Research and Development

Kanagawa prefecture officially concluded partnership agreements with City of Oulu, Finland for promoting medical device research and development. MDRS Center has promoted Kanagawa-Oulu collaboration strongly and coordinated activities for collaborative researches and businesses.

MDRS Center also performed experiments to evaluate the usability of medical devices developed by the MDRS consortium member companies with medical doctors, clinical nurses, and physical therapists. The experiments were conducted at OYS TestLab at Oulu University Hospital (<http://ouluhealth.fi/labs/>) in June 2017. Then after, MDRS Center supported these companies to obtain CE marking in Finland and Europe for tested devices.

4. Security of Medical Healthcare by Integrated BAN/Cloud/Edge/Data Science Platform

In this chapter, the collaboration of the authors in Japan and Finland is overviewed focusing on security in medical healthcare using the above-mentioned platform.

The regulatory compliant medical healthcare platform can be applied to carry out extensive research to develop novel advanced technologies, which are combining security, BAN, IoT, cloud and big data aspects. The final goal is to improve the overall dependability of the platform. This includes security and efficiency of the network chain, data storage, analysis and utilization of big data. An integrated platform between ICT and data science is established to guarantee high reliability and security with interactive loop between dynamic sensing of human vitals and environmental data, and feedback controlling medical healthcare and maintenance commands in multiple layers beyond ordinary medical healthcare services.

The integrated platform between ICT and data science can provide secure and trustworthy smart society a scalable platform, which is usable in all social infrastructures, such as finance, energy and transportation, extending the scope from medical healthcare to cyber terrorism and natural disasters.

Biometrics authentication and encryption using biometric information ensure high security during dataflow among Body, Edge and Cloud layers. Figure 3 shows an example of such a dataflow. Biometrics authentication is used for sending sensor data from Body layer to Edge and Cloud layers and also for feedback by sending data analysis results from Edge and Cloud layers to Body layer. The sensor data is encrypted using biometric features and is then combined by using composite code that depends on the applications stored in Edge and Cloud layers and biometric feature codes, such as composite codes.

This integrated platform provides the following benefits compared to the existing systems:

- Reduce home visits for general practitioners and family doctors: Clinicians can access and review all data and vitals, which were sent remotely using the platform.
- Safer care for house bound patients and those that can-

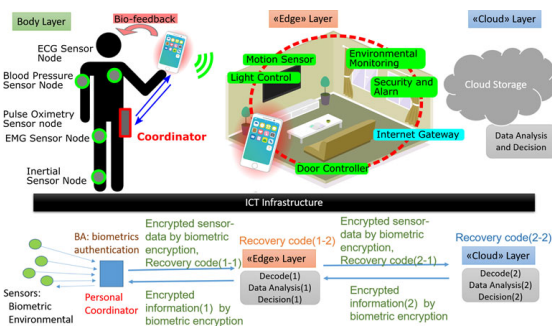


Fig. 3 Security process in BAN, edge, and cloud layers of medical healthcare platform.

not use technology.

- Reduced accident and emergency attendance.
- Can be used as a part of a supported discharge model.
- Empower community teams and district nurses to access patients dynamically.

Integrated platform is used as a mobile remote monitoring platform for patients living independently or used by care/nursing homes for patients in care.

4.1 Dependability and Security in BAN Layer

The objective is two-fold: 1) mitigate jamming attacks and 2) protect against critical data interception. To fulfil the first objective, our aim was to develop an intelligent monitoring system for wireless operation environment of BANs in order to detect intentional and unintentional jamming attacks, which would decrease the performance of medical data delivery.

The second objective was addressed by proposing novel physical layer security solutions that enabled critical data to be delivered reliably.

(1) Spectrum sensing method is the most suitable solution to collect information about the wireless traffic at the BAN environment. Such solutions already exist [7], [8]. One example is an energy detection method called the localization algorithm based on double-thresholding (LAD), which is based on the forward consecutive mean excision (FCME) algorithm. FCME is an automated method for setting a threshold in order to separate the samples into signal and noise sets. The LAD method uses two thresholds and outperforms the original FCME algorithm in the sense of detecting signals more precisely.

(2) Cross-Technology Machine (CTMac) collects data from different types of radio systems and spectrum sensing components taking advantage of analyses made by edge and cloud servers using collected radio data (Fig. 4). Based on the collected information, CTMac is able to make intelligent decisions about jamming attacks and to give control commands for radios to recover from jamming. The possibility to use machine learning methods and/or deep learning algorithms were also investigated, since they were promising methods for new generation radio systems [9], [10]. CTMac can also be used to improve communications performance and energy efficiency. It will improve the coexistence of different technologies by controlling them intelligently based on sensing and big data analysis information.

(3) Physical layer security solutions propose appropriate countermeasures to the security threats. Computer simulation models are used to address the efficiency and performance of the proposed solutions. Higher layer security complements the solutions of the physical layer security in order to guarantee the desired level of network security and reliability. Data encryption based on biological fingerprinting and physical layer security measures, such as spread spectrum, time-frequency hopping, wavelet, noise modulation, etc., can be combined in order to maintain security of

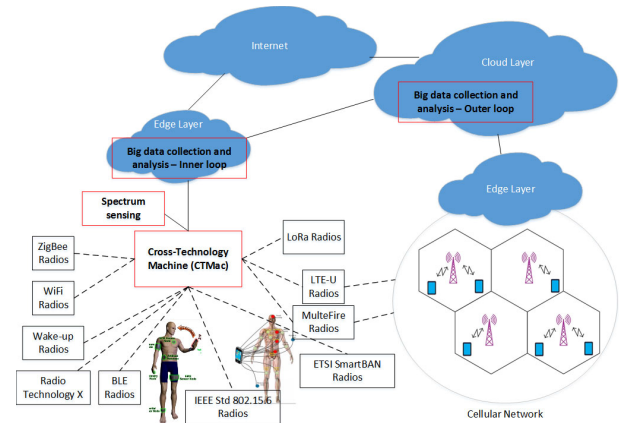


Fig. 4 High-level illustration of the CTMac for Security in heterogeneous environment.

data exchange and authentication.

An important factor to be considered is that data obtained from medical sensors stems from analog signals that contain redundancy. In the process of digitizing and encrypting analog signals, a trade-off between security and fidelity is unavoidable. It is advantageous to remove redundancy from both a transmission and security perspectives. However, the algorithm that leads to the best compression does not necessarily be the most secure one. These trade-off mechanisms have to be quantified in order to determine the best possible system design requirements on the level of security and fidelity. Advanced techniques for secret key agreement, key extraction and key exchange with randomization source based on physiological parameters are improving the data protection performance.

(4) Cognitive radio to counter unknown malicious devices Cognitive radio technology is a wireless communication technology that recognizes the environment surrounding a node itself and the other nodes as well. As a key technology, collaborative sensing can be applicable to mitigate any malicious attacks against wireless communications, even if data source node cannot detect existing malicious devices. For example, if data transmission node cannot detect jamming signal coming from malicious devices, the source node cannot recognize a cause of communications fault. In such a case, the source node generally tries to send information using automatic repeat-request (ARQ) or transmission power control. These technologies may increase the possibility of information leakage and network system fault when getting malicious attack. On the other hand, collaborative sensing shares the environment information with the whole or part of the network nodes. Collaborative sensing can detect the malicious attack by using environment information from the other node in the same network system, even if the source node cannot detect the malicious attack. By using environmental information, which is shared by collaborative sensing, AI system can analyze environment information coming from lots of nodes and recognize a type of malicious attack analytically. Based on the result of recognition, Body and

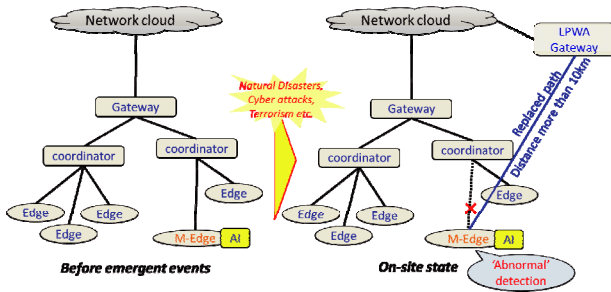


Fig. 5 Software reconfigurable network architecture according to emergent events, such as cyber attacks.

Edge layer networks can be reconfigured in order to mitigate the malicious attack autonomously, utilizing the software reconfigurable network (Fig. 5).

4.2 Security in Cloud and Edge Layers

(1) Communications chain security will take care of the confidentiality, integrity and authenticity of the data from WBAN to local devices in the Edge layer, such as gateway or hub, and then to the cloud. The task will identify the security risks associated with the patient monitoring and the security mechanisms to counter these risks. Due to the limited processing power on the WBAN, light-weight cryptographic methods should be identified and employed. This ensures that data flowing from the sensors to the edge layer, and then to the cloud, is always protected and trustworthy.

(2) Intelligent monitoring and adaptive re-configurability focuses on the intelligent monitoring of the activity of each IoT device in the edge layer. If unexpected activity is revealed, countermeasures are adopted. In particular, the cloud layer can change the kernel functions of each device, thus giving more or less intelligence in relating to the probability of infection of that device.

(3) Vulnerability discovering and patching Security risks emerge at different stages of the vulnerability lifecycle between vulnerability and patching:

- Vulnerability is discovered but no patch exists yet.
 - Identify affected devices
 - Filter attack flows to IoT devices
 - Improve authentication
 - Mitigate cross-site request forgery vulnerabilities
 - Secure vulnerable Secure Sockets Layer (SSL) connections
 - Inform user
- Quarantine affected application programming interfaces (APIs)
 - During the application of a patch
 - User consent for IoT device updates
 - Update device at convenient time by using awareness of the IoT state
 - Deal with update failure
- If a vulnerable device has been compromised

- Detect anomalies
- Traffic rate limit from device

From the security management point of view this procedure will take into account the following issues:

- Intercept Communications. The hub should interpose on all communications between devices and other parties
- Be Aware of All Edge layer Devices. Since the security manager sees all devices' network activities, it can keep track on which devices are on the network and keep a log of each device's status.
- Pre-Fetch and Install Updates. A core trusted feature of the security manager is its ability to assist with updating home devices. The availability and integrity of updates is critical to secure device's functionality.

4.3 Security in Data Science Layer for AI Data Mining Server and Repository

Big data analysis for automatic vulnerability detection and correction

The use of machine learning techniques for security applications dates back to several decades. Nowadays, advancements and capabilities of machine learning and data mining techniques and their success stories in addressing many difficult application problems have motivated researchers to more thoroughly investigate the effective utilization of these techniques for problems in the domain of computer security and privacy.

Existing systems did not aim to detect bugs and identify their location, but to assess the quality of the digital services in terms of the prevalence of defects and vulnerabilities. This explores an approach for automatically protecting applications. The approach consists of analyzing the application's source code by searching for input validation vulnerabilities, and inserting fixes in the same code to correct these flaws. The programmer is kept in the loop by being allowed to understand where the vulnerabilities were found, and how they were corrected. This approach contributes directly to the application's security by removing vulnerabilities, and indirectly by letting the programmers learn from their mistakes. This last aspect is enabled by inserting fixes that follow common security coding practices, so programmers can learn these practices by seeing the vulnerabilities, and how they were removed.

4.4 Block Chain and Secret Sharing in Cross Layer

From the service point of view, the federated cloud can be seen as a virtual unique cloud, which collects data and then analyze it. Physically the cloud can be distributed in several countries e.g., in EU and Japan. This architecture will also help the use of block chain technology to validate and track each transit of sensitive data. On the other hand, there are lack of solutions providing efficient tools to fight against

hostile attacks and data manipulation. Secret key sharing technology can be a solution for this issue. The level of secrecy can be different in the defined three layers: BAN, Edge and Cloud layers. Novel biometrical authentication methods, which utilize human’s vital signs to produce secret key are one of those. A good possible solution to generate a biometrical key is to use, e.g., ECG, which is different between each individual. This key needs to be shared between different services in a reliable way. This forms one of the most important research topics for future security related research.

4.5 Analysis of DOS Attacks by Deep Learning

Data from the edge nodes (uplink) and data to the edge nodes (downlink) are transmitted via coordinators, gateways and network cloud and/or private network. Such information can be analyzed by artificial intelligence system, which is possible to be integrated into the multiple layered network (Fig. 6). It can realize big data analysis and data mining by AI system and utilizing, e.g., deep learning. AI data mining can be used to detect unwanted events even before they happen. For example, AI system could detect terrorists from image data, damage of the buildings from the acceleration data (e.g., unusual vibration) and unusual data traffic based on cyberattacks by the information collected from the coordinators and gateways.

When AI system detects a fault on both physical and cyber spaces (CPS), it can generate alert, control signal or some other approach in order to keep safety in that CPS. On the other hand, each coordinator and gateway can have small-scale and medium-scale AI system. These AI systems can realize real-time feedback in emergency conditions. AI system should renew their own model by using current information. However, large-scale AI, such as deep learning, requires huge computation power and takes time. In our proposal, large scale AI in “data mining & analysis layer” generates current model, and analyze current data. Middle scale AI also keeps learning and renew its own model although not focused on big data due to the small computation power at the middle scale AI, which is integrated on the gateway. A coordinator can also have a small scale AI without

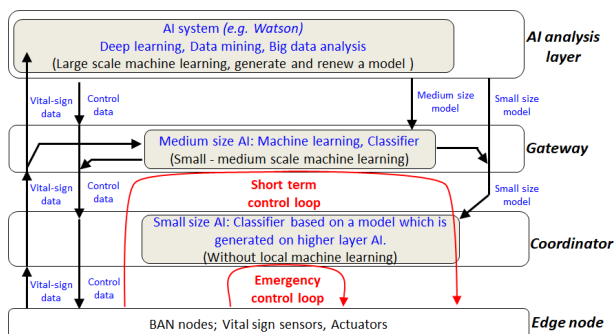


Fig. 6 Layered architecture of networking and computing for sensing & controlling BAN, cloud, and analyzing & learning malicious attacks.

learning function.

Although the edge AI cannot generate a threat model, larger scale AI (middle or large scales of AI) can provide a model via network connection. As a result, if accidents happened, emergency, alert signal or automatic control feedback can be generated within a BAN with ultra-low latency. Because edge AI does not need to have complex learning functionality, it can cost less and a larger number of coordinators can be accommodated in the system, which suggests further post-disaster/attack resilience.

5. Novel Schemes of Remote Rehabilitation Monitoring and Analysis

This chapter proposes a scheme to analyze patient’s activity and another scheme to study patient’s feelings in rehabilitation using the integrated platform.

5.1 Monitoring and Analysis of Rehabilitation Outside Hospital

In rehabilitation, it has been pointed out that the decrease of the patients’ physical activity level with lower limb paralysis may cause systemic symptoms [11]–[14]. However, the measurements and numerical analyses of physical activity are quite difficult to be performed in daily life, such as in homes and work places. In our research collaborated with rehabilitation hospitals, we developed a physical activity monitoring system using multiple accelerometers used by both the patient and a wheelchair. The acceleration data is transmitted by dependable WBAN, which is designed to be used for medical purposes and is also standardized. This chapter describes our prototype implementation presented in Fig. 7 and experiments of the proposed medical healthcare network platform.

For this purpose, we designed a remote monitoring and analyzing system for rehabilitation inside and outside hospital (Fig. 7). Transmitted acceleration information from multiple wireless sensor nodes are collected by the coordinator. Then, the information reaches the host device. In this experiment, the host system is implemented on laptop computer and tablet PC. However, larger scale storage server and

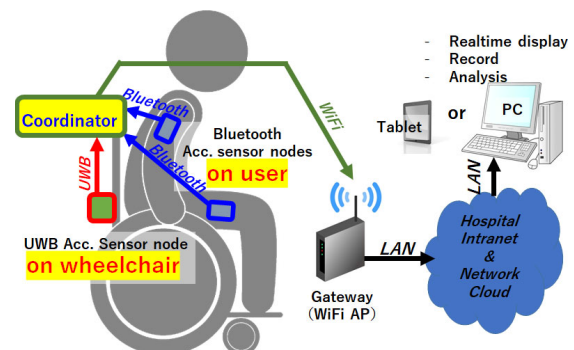


Fig. 7 Remote rehabilitation monitoring and analysis platform.

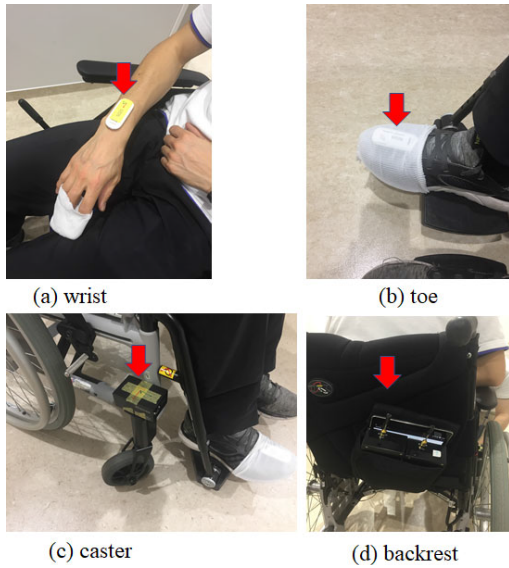


Fig. 8 Setup of the four 3-axis acceleration sensors.

Table 1 Experiment condition and analysis result of the propelled number counting experiment.

Trial No.	Condition	Result		
	Number of propelling	Estimated result	Error	Error rate [%]
1	27	24	-3	-11.1
2	25	22	-3	-12.0
3	17	18	+1	5.8
4	28	26	-2	7.1

data analysis system can also be connected through the network cloud. In the experiment, coordinator, gateway (WiFi access point), and host devices are connected via wireless and wired LANs provided by the hospital intra-network.

Experiment has been performed using four 3-axis acceleration sensors that are connected via BAN. Sensors are attached on user’s wrist, toe and wheelchair’s caster and backrest, respectively (Fig. 8). As a physical activity analysis, we tried to estimate the number of propelling of the wheelchair by using acceleration data. Raw acceleration information is filtered on the frequency domain. Then each acceleration data of X, Y and Z axes are weighted and combined. This combined acceleration data is compared to a template, which is generated from the acceleration data of wheelchair under propelling.

Experiment and analysis results are shown in Table 1. These results show that the proposed system can transmit and analyze the activity data of the wheelchair users in rehabilitation. The maximum error rate of the current results is 12.0%.

5.2 Machine Learning of Monitored ECG for Analysis of Patient’s Stress due to Rehabilitation

In order to estimate patient’s stress strength under rehabilitation, we propose a novel analysis scheme using machine

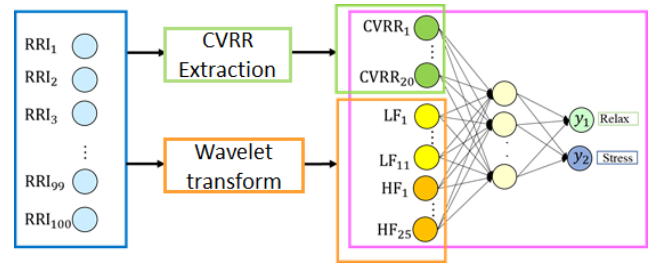


Fig. 9 Proposed system model.

learning with a neural network (NN) combined with a feature extracting preprocessing.

In our proposal, ECG is used to estimate a patient’s stress. As well known, RRI (R-R interval), CVRR (Coefficient of Variation of R-R intervals [15]) and the ratio of low frequency to high frequency power (LF/HF) can be measured from ECG. These parameters can be used as stress indicator. However, if raw ECG data is an input to machine learning algorithm, such as NN, its learning speed is low and the computational complexity becomes large.

In order to achieve faster and accurate learning and reduce calculation complexity, we propose to extract ECG features before inputting them to NN. To define the criteria of individual approach in rehabilitation by judging patient’s stress strength numerically using machine learning approach is shown in Fig. 9. We use patient’s RRI data from WBAN for NN. Pre-processing is performed to extract some features before machine learning with NN. We extract features of stress efficiently with less complexity and improve learning speed and accuracy with multilayered NN with preprocessing (Fig. 9).

Comparison of the following performances of NN, depending on presence or absence of preprocessing and the type of preprocessing (only CVRR, only wavelet transform, CVRR and wavelet transform), is shown.

In order to ensure reproducibility, we used our own generated RRI data with the labels ‘relax’ or ‘stress’. In the simulation, Python 3.6 language with Keras library is used for implementation of NN. Table 2 shows NN specifications used in this simulation. In this research, we extract frequency components by performing wavelet transform using Morlet wavelet [16].

Figure 10 shows learning speed performance of the proposed scheme, which uses CVRR extraction and wavelet transformation. Loss function is defined as a cross-entropy loss which is expressed as

$$L = -\frac{1}{B} \sum_{n=1}^B \sum_{k=1}^O t_{nk} \log y_{nk}, \tag{1}$$

where, L , B , O , t_{nk} and y_{nk} are loss function output, mini-batch size, number of classes, label ($\in \{1, 0\}$) of training data and output of NN, respectively. Figure 10 shows that the proposed method can learn faster than the other methods, which are using only wavelet transformation (labeled as “Frequency”), CVRR (labeled as “CVRR”), and without any pre-processing (labeled as “w/o pre-processing”).

Table 2 Simulation specification.

Unit number of input layer	100
Unit number of middle layer	30
Number of middle layer	1
Unit number of output layer	2
Activation function (middle layer)	ReLU
Activation function (output layer)	Softmax function
Loss function	Cross-entropy loss
Learning rate	0.01
Optimizer	Stochastic Gradient Descent
Minibatch size	20
Max. epoch	1200
Number of teacher data	200
Number of test data	5000

Table 3 Comparison of accuracy (1200 epochs).

	RRI	CVRR	Frequency	Proposal
Accuracy [%]	81.131	89.664	68.58	93.41

Table 4 Comparison of number of multiplication.

	RRI	CVRR	Frequency	Proposal
Pre-processing	0	0.036×10^6	180×10^6	180×10^6
Learning	2595×10^6	232.32×10^6	197×10^6	892×10^6
Total	2595×10^6	232.35×10^6	377×10^6	1072×10^6

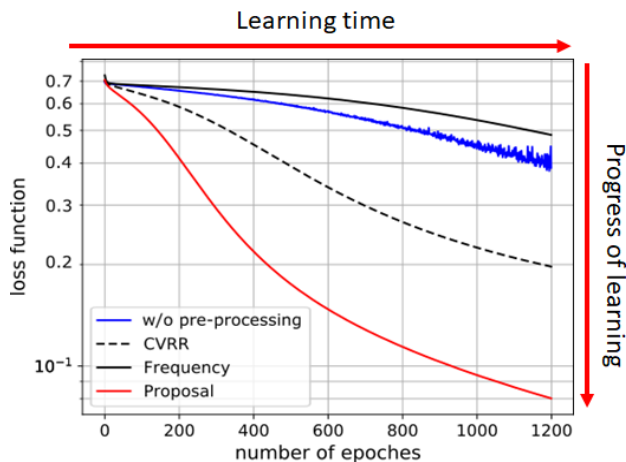


Fig. 10 Learning speed characteristics.

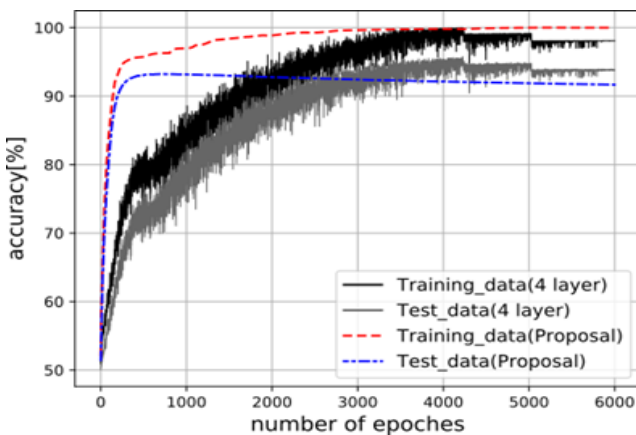


Fig. 11 Accuracy of classification of proposed and conventional method.

Figure 11 and Table 3 show classification accuracies of the proposed scheme and the conventional 4-layer NN without preprocessing. The proposed scheme using pre-processing can achieve faster learning and higher classification accuracy than the conventional scheme in the limited number of epoch condition. On the other hand, if the system

can use enough epoch numbers and computation time, conventional scheme achieves higher classification accuracy for test data classification than the proposed one.

From the computation complexity point of view, the number of multiplications used in each conventional and proposed methods are shown in Table 4. Pre-processing needs some calculation complexity. However, it reduces calculation complexity of learning of NN.

6. Conclusions

This paper introduced our comprehensive solution for truly dependable medical healthcare. Research and development in the medical ICT field is shifting to a new paradigm, which is integrated with data science in the sense of real-time data analysis and feedback for personalized medicine at edge computing in cloud network and secure repository of medical big data with machine learning for primary validation and genomics, and secondary commercial uses. Universal integrated BAN/Cloud/Edge/Data Science platform was proposed with its design concept to ensure dependability based on regulatory science. The security provided by the integrated platform is described in details. As a specific use case, a novel scheme of ubiquitous rehabilitation using machine learning was proposed and reported.

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