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A Framework for Big Data Governance to Advance RHINs: A Case Study of China

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ABSTRACT The emergence of big data presents a serious challenge to the fast growth of regional health information networks (RHINs) globally. In China, many constructors of RHINs have spontaneously and independently created governance measures, which may be valuable as a point of reference for other countries. This paper aimed to propose a big data governance framework for healthcare data based on the governance activities associated with the processing of RHINs in China. Typical methodology for RHIN case studies in China, including rich personal experience in nationwide consulting, literature review, expert consultation, and interpretative structural modeling methods, was adopted. Based on the analysis of ten typical RHIN case studies, healthcare big data governance practices in China were summarized. A framework with 3 domains and 12 elements was proposed, which include a drive domain (big data strategy planning, laws and regulations, open transaction, and industry support), capability domain (healthcare big data organization, collection, storage, process and analysis, and usage), and support domain (healthcare big data resource planning, standards system, and privacy and security protection). We obtained 12 guidelines for healthcare big data governance. A big data governance framework with 3 domains and 12 elements was presented based on Chinese practice, which might serve as valuable references for the cross-dimensional development of RHINs, provide overall guidance for the sustainable development of regional health informatization, and contribute to realizing the business value of healthcare big data.

INDEX TERMS Big data governance, framework, regional health information networks (RHINs).

I. BACKGROUND

Over the past 20 years, information technology (IT) has permeated a wide variety of industries. The use of IT applications in the medical field is considered rather conservative, but its informatization has undergone significant changes under the digital wave rush. In China, IT development in healthcare has undergone three phases: institutional informatization of individual healthcare institutions, industrial informatization of cross-institution healthcare information exchange (HIE), and social informatization of cross-industry creative development.

In the first phase, hospitals managed their informatization processes by themselves, and the state centrally established

and deployed business systems for public healthcare institutions using a top-down approach. Such systems served the needs of the institutions but accumulated massive amounts of internal business data that could not be shared. The second phase began in 2009, when a new medical reform required medical institutions to share data regionally, leading to a large-scale activation of Regional Health Information Networks (RHINs) throughout the country. For the first time, medical and public healthcare data that had been scattered among the various institutions became centralized in the form of electronic health records (EHRs). This phase was mainly characterized by an internal consolidation of the healthcare industry. The third phase began in 2015, when the explosion of social networks created massive amounts of personal healthcare-related raw data (emotional and behavioral) and various sets of personalized daily healthcare data (mostly

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machine-generated real-time individual physiological data), which were documented and linked to EHRs, resulting in the emergence of healthcare big data [1]–[6].

Big data has been drawing increasing attention globally, and researchers have high expectations regarding its strong potential to improve the quality of healthcare services and lower healthcare expenditures. Big data has ensured the future of RHINs because these systems can provide a different perspective for obtaining greater medical value from medical data. Unfortunately, the existing capability of traditional data can no longer satisfy the current needs. The effective utilization of big data and the maximization of the value of these data have become a global problem in the processing of RHINs. This study focuses on the practical activities related to big data utilization in China’s RHINs, a process denoted big data governance, and proposes a big data governance framework to help solve this problem globally.

II. METHODS

First, using our rich experience of consulting, planning, guidance and construction of RHINs, we selected 10 typical cases that covered three levels of national, provincial and municipal levels as the research samples from masses of RHINs cases in China. The selection criteria were no less than 5 years since construction, ownership over at least one big data governance activity, and willingness to participate in case analysis to gain practical activities about healthcare big data.

Second, through consulting the domestic and international key literature on RHINs, data governance, big data governance and healthcare big data, combined with the practices of the above 10 case studies, we further refined 17 initial elements that are associated with the success of healthcare big data governance.

Third, we used the expert consultation method for 17 elements. 1) We selected 12 experts in China, covering universities, enterprises, associations, government departments, hospitals, etc. The professional fields of the 12 experts focus on regional healthcare informatization or big data, indicating a high level of expertise for those selected. The formula for determining the expert authority coefficient is:

$$Cr = \frac{Ca + Cb + Cc}{3}$$

where Cr represents the degree of expert authority, Ca represents the cultural title coefficient, Cb represents the judging coefficient, and Cc indicates the familiarity degree coefficient; Cb is derived from the experts’ theoretical analysis, practical experience, peer understanding, and personal intuition. All experts’ authority coefficients were higher than 0.8, with high authority for experts. 2) All experts agreed on the selection of 17 initial elements, without additions and deletions. The importance of the 17 initial elements is calculated as:

$$P = \frac{\sum_{r=1}^{12} (Cr * Pr a)}{\sum_{r=1}^{12} Cr}$$

where Cr is the expert authority coefficient, Pr a is the r-th expert to score the importance of the a-th initial element, and a range from 1 to 17,

$$\sum_{r=1}^{12} Cr$$

representing the sum of the expert authority coefficients. We calculated the weighted score of each initial element. 3) We determined the ordering of the 17 elements according to the final score and only retained the main elements (top 70%).

Fourth, we applied the interpretive structural model [7]. As a qualitative analysis method, it can effectively clarify the level of the problem and the overall structure, and can transform the complex relationship into an intuitive structural relationship model. The main elements (12) were recorded as S₁-S₁₂, and the reason for the success of healthcare big data governance was S₀. Through in-depth analysis and joint discussion with the expert group and the elements of S₀-S₁₂ compared in pairs, we established the adjacency matrix A. The reachable matrix M was calculated according to the Boolean matrix algorithm. The interpretative structure model was obtained through multiple hierarchical decomposition. Finally, our healthcare big data governance framework was derived after further reference to IBM’s data governance model (IBM’s data governance model had 11 elements that divided into 4 domains, and we referred to its domain division and the presentation).

III. RESULTS

We gained the human data capability chain, which proved the necessity and value of healthcare big data governance (Figure 1). We summarized big data governance activities for 10 typical RHIN samples in China (Table 1), which were valuable based on the interpretive structural model (Figure 2).

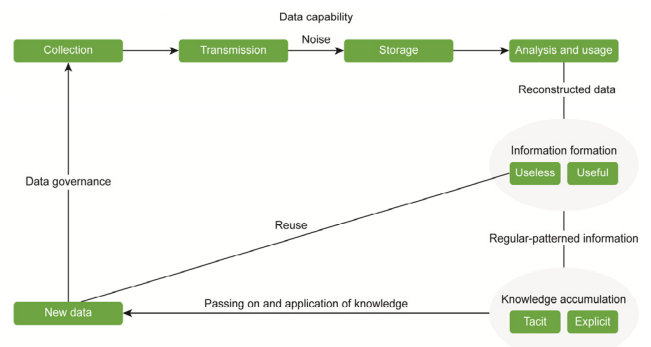


FIGURE 1. The human data capability chain.

A healthcare big data governance framework (Figure 3) was obtained by interpreting the structural model. The framework consists of 3 domains and 12 elements. If we imagine the ability of big data governance as the ability of people to run, then the “Drive domain” determines whether it can run, the “Support domain” determines how fast it can run, and

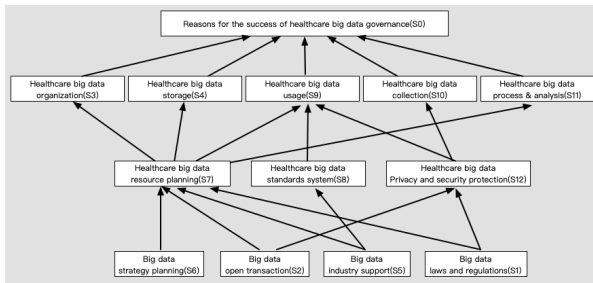


FIGURE 2. Interpretive structural model.

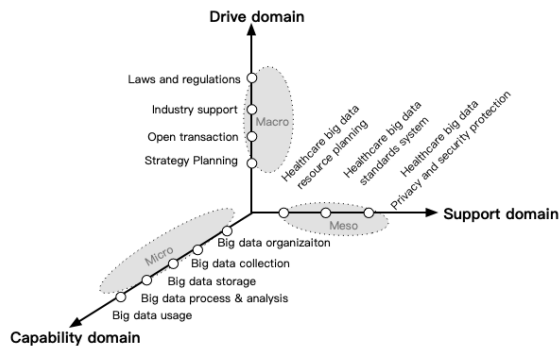


FIGURE 3. A healthcare big data governance framework.

the “Capability domain” determines how far it can run. To better implement and apply the framework, we engaged in further discussion and analysis to match the 12 governance guidelines.

A. HEALTHCARE BIG DATA GOVERNANCE GUIDELINES

Guideline 1: Upgrade the lead department of the original RHINs, or establish a new full-time big data governance department to oversee the entire governance and fully absorb the healthcare big data stakeholders, thus achieving the objectives of governance through the department, the aim of which is to adjust and optimize rather than overthrow or completely rebuild the RHINs.

Guideline 2: Expand the scope of data collection around the healthcare business goal, such that increasing the data supply capacity does not significantly increase the difficulty of data use.

Guideline 3: Based on the open hardware resource cloud service established by the IT architecture, adjust the traditional storage mode to a distributed cloud storage mode under the premise of ensuring autonomy and control.

Guideline 4: Continue to carry out quality management of healthcare big data, and implement big data asset management and control from the two dimensions of system and informatization. Prioritize the construction of a general big data analysis model and universal algorithm.

Guideline 5: Differentiate application objects, and emphasize effective use and data interpretation.

TABLE 1. Big data governance activities based on typical cases of RHINs in china.

Activity	Motive	Category	Measures	Cases
Make regional health information resources planning	Guide the sustainable development of RHINs from top to bottom	Data resources planning	Entrust for consulting program; Health information state assessment ; Functional domain and main business analysis; Metadata analysis; Setup data standards and criteria	Guangzhou
Conduct RHINs state assessment and classification	Define RHINs process	Data resources planning	Health information state assessment ; Establish maturity assessment indexes for RHINs	Xiamen
Set up a provincial medical health big data center	To guide the development of regional health and health big data	optimize organizational structure	Adjust the functions of the original information management department	Sichuan
Set up information office or big data office	To guide the development of regional health and health big data	optimize organizational structure	Virtual establishment of internal departments	Shanghai
Technology upgrade of RHINs	Reply to big data challenge	Optimize technology architectures	Upgrade traditional IT architectures to big data distributed architectures	Wuhan
Improve data quality	Promote RHINs to apply and value	Data life cycle management	Build data quality assessment index system; Build data quality improvement management mechanism	Shanghai

TABLE 1. (Continued.) Big data governance activities based on typical cases of RHINs in china.

Conduct performance assessment based on RHINs	Promote RHINs to apply and value	Data life cycle management	Performance assessment indexes; Conduct hospital performance assessment based on RHINs	Wuhan
Setup national health data standards and criteria system	Guild RHINs construction from the top down	Standards and criteria	Found standard committee; Specialized research fund; Initialize standards and criteria and enrich; Standard conformity assessment	National
Setup provincial health data standards and criteria system	Localization of standards and criteria system	Standards and criteria	Special scientific research project; Training practitioners of RHINs; Make standards and criteria system as the acceptance basis of RHINs project	Hubei
Lay down residents' health cards nationwide	Unify Personal Identification Number in the field of health	Standards and criteria	Release card's standards and criteria; Promote card distribution and application by cooperation with commercial banks	National
Release National Regulations for Population Healthcare Information Management	Normalize and guild data behavior in RHINs	Security and privacy protection	Publish certain regulations; Training practitioners of RHINs	National

TABLE 1. (Continued.) Big data governance activities based on typical cases of RHINs in china.

Release Regulations for Electronic Health Records Management	Normalize and guild EHR	Security and privacy protection	Publish certain regulations; Training practitioners of RHINs	Ningbo
Improve data collection efficiency	Data collection real-time in RHINs	Data life cycle management	Apply an active fetching strategy	Yantai
Real-time data interaction and services for chronic diseases	Real-time services for chronic diseases in RHINs	Data life cycle management	Invest home health monitoring equipment; Collect personal vital signs data in real time; Government buys basic public health services from businesses	Shanghai
Optimize mass data storage	Adapt to the development of RHINs	Data life cycle management	Unified construction of government affairs cloud and big data center; Establishment big data assets for the organization	Chengdu

Guideline 6: Integrate national big data planning, and implement big data resource planning into the healthcare industry as the first link in overall governance activities.

Guideline 7: Applicability evaluation and optimization supplement based on the original data standard, following the construction process of standard formation, standard implementation, and standard maintenance, and continuously promote compliance testing of healthcare big data standards.

Guideline 8: Promote healthcare big data privacy security protection and governance from the four dimensions of privacy and security laws and regulations, technical means, management mechanism and security awareness. Clarify the

main body of responsibility for the ownership, management and use rights, protection principle and segmentation rights for healthcare big data, combining superior law, special law and industry self-discipline. Actively optimize and upgrade traditional data privacy protection technology, covering the entire life cycle of healthcare big data and matching legal regulations and management mechanism requirements. Improve the management mechanism around the licensing mechanism, reporting mechanism and traceability mechanism. Enhance the concept of cognition: owners' participation and awareness of rights, simultaneous with managers' supervision and cautious attitude and users' responsibility and self-discipline awareness.

Guideline 9: Implement national big data strategic planning and design, and clarify the overall development goal positioning, main content, business development focus and priorities. Provide safeguards to ensure that strategic planning can be implemented along with guidance to serve as the basis for all industries, including medical health.

Guideline 10: Introduce incentive policies and improve the big data trading system.

Guideline 11: Promote the development of big data industry through key projects.

Guideline 12: Clarify the legislative strategy, and improve the legal and regulatory system with regard to three aspects: personal privacy protection, open access to government data, and market-based transactions and industrial development.

IV. DISCUSSION

To achieve satisfactory application performance, different managers of RHINs (at the national, provincial and city levels) have taken some positive actions, and these spontaneous, isolated, unsystematic actions, which are shown in Table 1, can be generalized to the behavior of big data governance. *The China Action Program for Promoting Big Data Development* upgraded big data development to a national-level strategy, which in particular illustrates the priority of the medical industry. The state health authority released a series of specialized policies to promote healthcare big data applications. To ensure the consistency of the technical architecture of various provinces and cities, China even released technical guidance for RHINs in 2009: "Construction scheme of RHINs based on EHR". To obtain greater access to high-quality data, a national special committee was established to initialize and regularly update medical informatization standards and criteria systems through compulsory standard conformity testing and necessary localization for the promotion of their execution. In the absence of a national privacy law, some provinces and cities launched *Management Regulations for EHR* based on the *National Regulations for Population Healthcare Information Management*, and full-featured technical measures were created for medical privacy protection. For example, the RHINs of Guangzhou (owning EHR for more than 10 million local residents) stored personal basic information and medical treatment information separately, and only the owner of the EHR, namely the patient, could

decide which content, what type of issue and which role could be authorized to access the EHR online with real-time short-message reminders or password control. To ensure that the EHR data are accurate and timely, it is mandatory that residents' health cards are top-down used to identify individuals at a national level, which is different from European and American countries, and different identity cards are issued in different industries in China. For example, the Ministry of Human Resources and Social Resources and Social Security issued a social security card, and the Ministry of Public Security issued an identity card, but the cards of various industries are not compatible and universal. Many managers took specific measures to improve the data quality of RHINs. For example, Wuhan established strict data quality assessment indexes, and their results further influenced the management performance of the data's source institution. Some local governments incorporated social health data services into government public health services and paid for them, which promoted the widespread institution of mobile medical equipment at the residents' homes and the real-time input of an individual's daily physiological data into the EHR, which is a popular activity of family practitioners [8]–[12].

A. GOVERNANCE FOR DRIVE DOMAIN

1) STRATEGY PLANNING GOVERNANCE

Big data capability is becoming one of the core issues contributing to competition among countries. Its governance requires national dominance and advancement to make big data benefit all industries. As early as 2012, the US government released the "Big Data Research and Development Plan" and correspondingly introduced a number of policies. The European Union, the United Kingdom, Australia, Japan, South Korea, etc. have also developed national big data strategies. The big data strategy planning of developed countries is similar in terms of strategic objectives, clear action plans and key support projects, clear management institutions and implementing agencies, but there are differences in the direction of strategic promotion and the direction of technological capabilities. Relying on the national big data strategic plan, the introduction of an industry-specific big data strategic plan will be more reasonable and effective. In establishing their national big data strategy plans, an increasing number of countries verified the belief that the medical industry should have first priority due to the high value of its application. For example, the United States introduced strategic planning for health information technology covering five years (2015-2020). Developing countries can also refer to the above path [13]–[15].

2) OPEN TRANSACTION GOVERNANCE

The opening of data was originally derived from the American folk movement, and follow-up activities in the United States and the United Kingdom has initiated an international trend to reform the government. Since 2009, the United States, Britain, Australia, France, Canada and other countries

have established an open sharing policy for government data. Big data open transaction is an important prerequisite for the development of the national big data industry. Building an open trading mechanism for big data can promote the exchange and integration of big data among different industries. Approximately 80% of China's information resources are in the hands of government departments. State domination is the fundamental driving force for public (government) big data development [16]. The government is more concerned about its own big data opening, and companies are more focused on big data transactions.

3) INDUSTRY SUPPORT GOVERNANCE

The big data industry system needs to cover the upstream, midstream and downstream of the industry [17], consisting of infrastructure, core technologies, services and industry applications, talent development, government regulation and guidance, industry associations, enterprises and other elements [18]. In the early stages of big data development, European and American countries usually carried out the construction of several key projects in key industries and gradually formed key technologies, management and business models, etc., with a view of promoting the rapid development of big data. When countries are planning big data, most of the healthcare sectors are at the forefront of industry choices, and the potential for big data to be applied and prioritized in the health sector is high.

4) GOVERNANCE OF LAWS AND REGULATIONS

It is safe to say that robust laws do not so much lead to the satisfactory development of big data; rather, they lead to the absence of unsatisfactory results. Big data has legal attributes and should be promoted and regulated by legislation. Big data legislation should balance three aspects: achieving full and effective personal information protection; promoting the open sharing of government data; and promoting the development of the big data industry around commercial data transactions. In specific legislation, a conservative government-led strategy or an active market-led strategy can be adopted based on national conditions and balance the interests of the big data industry with national security. For example, the EU adopts a conservative strategy for personal information protection and emphasizes personal rights, such that "private life is not disturbed." It adopts a comprehensive national legislative model and emphasizes privacy protection in cross-border data circulation. By contrast, the United States is relatively more market-oriented, emphasizing the economic value of personal data, adopting a decentralized legislative model, and emphasizing the combination of industry self-discipline. China has been a "net exporting country" for a period of time now and will remain so in the future. Whether based on the private law perspective of national conditions or on national security considerations for cross-border data circulation, it is more suitable to adopt a conservative strategy before developing into a big data industry power.

B. GOVERNANCE FOR CAPABILITY DOMAIN

The healthcare big data life cycle includes healthcare big data organization, collection, storage, process and analysis, and usage.

1) HEALTHCARE BIG DATA ORGANIZATION

The focus is on organizational structure and IT architecture governance. The design and construction of the information organization structure is one of the most important components of traditional data governance. Globally, medical and health institutions are becoming more and more data driven [19]. IT architecture governance is optimal for fully protecting and utilizing existing investments, and it does not have a major impact or on the original healthcare business.

2) HEALTHCARE BIG DATA COLLECTION

In China, data collection mainly focuses on EHR in RHIN construction, and more uncollected data are still buried in the original unit of data generation. The value of the full amount of healthcare big data in the region cannot be tapped. The construction goals of RHINs in different countries are not the same, and the requirements for data collection and sharing are very different. The unified access data specification should be designed in advance to ensure the standardization and ease of use of the collected big data. This point is more applicable to developed countries, especially those countries where medical insurance purchases such equipment services. But developing countries should also pay attention to this point if they want to form a latecomer advantage.

3) HEALTHCARE BIG DATA STORAGE

A centralized data storage model has been popular in RHINs, but as the volume of data increases, it is becoming infeasible to purchase storage space for storage needs. Such a model should be transformed into a distributed cloud storage model (pay for open hardware cloud resource services). Of course, the above cloud storage service should be built by a domestic enterprise or a government-funded private cloud for government service, which can ensure that cloud storage for healthcare big data is not interfered upon by other countries from beginning to end. Cloud storage for healthcare big data should provide more stringent security protection and backup measures.

4) HEALTHCARE BIG DATA PROCESS AND ANALYSIS

This governance involves big data quality management, big data asset management, big data analysis and algorithms. A review of an early EHR system in the United States found that there were one or more input-related errors in 60% of patients' data [20]. Based on near-total samples, big data technologies have increased the fault tolerance of the original data, but there is currently a very low tolerance for deviation and error correction in RHINs in consideration of health and life. Big data analysis technology can aggregate and analyze multiple sets or different types of data. It focuses

more attention on the fusion and correlation analysis between different data. It is an analytical method that attends to global features. For RHINs, priority should be given to building general-purpose, high-speed and flexible big data analyses and mining models and developing pervasive algorithms. Specialized personality models and algorithms are developed by individual hospitals and public health agencies.

5) HEALTHCARE BIG DATA USAGE

At present, healthcare big data usage at home and abroad are mainly concentrated in five directions: accurate medical care in a clinical setting, self-health management in a market environment, research applications in an academic environment, lean management applications in healthcare, and emerging smart healthcare applications [21]–[23]. It is necessary to introduce data visualization technology to improve data interpretation and display capabilities, and the effective application of data, especially scene-driven applications, should be highly valued.

C. GOVERNANCE FOR SUPPORT DOMAIN

The internal governance of the healthcare industry includes healthcare big data resource planning, standard system, and privacy security protection.

1) HEALTHCARE BIG DATA RESOURCE PLANNING

At present, both developed and developing countries, regardless of the type of medical system and the level of economic development, regional medical and health information construction projects tend to be unified in their planning [24]. The medical industry data resource planning and governance needs are significantly higher than those of most other industries [25].

2) HEALTHCARE BIG DATA STANDARD SYSTEM

An important challenge for big data is to integrate data from different sources, and standard applications have been proven to promote interoperability between systems [26]. China's medical and health informatization standards were established late and reference the HL7, IHE, DICOM, SNOMED and LOINC standards. The resulting medical and health information standards are accelerating, while also self-optimizing and upgrading, the RHIN process in China. The experience of constructing China's medical and health informatization standards from scratch has had a high reference value for other developing countries without such standards. Globally, the construction of a big data standard system is still in its infancy, and a set of recognized, complete and universal big data standard systems has not yet been formed. Moreover, the small number of studies related to healthcare big data standards has mostly been based on demand analysis.

3) HEALTHCARE BIG DATA PRIVACY SECURITY PROTECTION

The degree of data recognition and the risk of being re-identified are different in various countries [27], [28]. Different countries have different perceptions of personal

privacy boundaries, control and awareness. For example, Indians are four times more likely to share personal data online to obtain better personalized services than are the Swiss [29]. Chinese privacy awareness and privacy laws and the construction of the regulatory system lag behind many European and American countries [30]. With the initiation of the big data era, other personal data, including income level, education and work experience, location information, eating habits, and fitness records, are automatically linked [31]. Privacy security issues exist throughout the lifecycle of big data [32]. The statistics are incomplete – so far there are approximately 90 countries and regions in the world that have introduced data privacy laws – but privacy laws have made very few adjustments and improvements in time for the new challenges of big data. In addition, the introduction of new law tends to take a long time. Prior to this, as a transitional initiative in which measures are coordinated after the implementation of laws and regulations, industry self-regulatory organizations can be established to guide and regulate market-oriented behavior, which is more mature in the United States.

This study also has limitations. This study requires further verification and optimization of the empirical research, referencing different countries combined with national conditions.

V. CONCLUSION

The appearance of big data governance is inevitable in the process of RHINs based on the human data capability chain. Our review of the process underlying the development of RHINs in China revealed many cases of successful and failed big data governance activities. Based on this practice and personal experience, we used a combination of qualitative methods, such as a literature review, expert consultation and interpretive structural modeling. Then, we designed a satisfactory big data governance framework, which is also useful for industries outside of healthcare. A big data governance framework with 3 domains and 12 elements was presented based on Chinese practice, which might serve as a valuable reference and provide late-comers an opportunity for the cross-dimensional development of RHINs. Discussions surrounding the 12 governance guidelines that accompany the framework show that understanding and adhering to the applicability and limitations of each element can help other countries throughout the world learn more effectively. The framework and governance guidelines are expected to provide overall guidance for the sustainable development of RHINs and may contribute to realization of the business value of healthcare big data. Of course, the journey to the achievement of governance is definitely expected to include some unforeseen challenges, and critical adjustment and localization will aid the implementation of this framework.

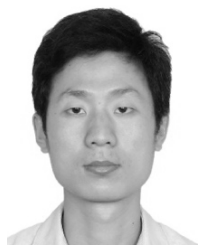
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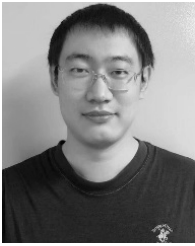


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