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RESEARCH ARTICLE

Responsibility Governance Framework for e-Health solution designing in Sri Lanka

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Abstract: Healthcare (HC) policies are complex and revised on situational basis, which requires flexibility in healthcare processes. However, most Healthcare Information System (HIS) deployments fail to align with governance directives. This misalignment creates challenges in delegating responsibilities among stakeholders and automating healthcare workflows. To address these challenges, it is essential to develop a structured approach that first classifies responsibilities and then designs e-Health solutions that comply with constantly evolving governance directives. The research is based on a comprehensive literature review and a case study conducted at a medical service centre. It follows the well-established design science research methodology and a case-based approach. The proposed solution consists of a three-dimensional framework with three sub-frameworks; (i) Healthcare Process (HCP) (ii) Healthcare Responsibility (HCR) (iii) Healthcare Rule Enforcement (HCRE). This Healthcare Governance Framework is designed to handle the complexity and dynamics of HC service processes. It helps identify and manage governance requirements through the HCR sub-framework, providing a complete solution. Additionally, the framework facilitates the design of HC solutions by using rule-based process patterns. This approach enables domain experts and software designers to better understand policy requirements and implement e-Health solutions that fully meet the needs of HC stakeholders. The derived rules and patterns were tested against existing governance procedures. The framework was further tested by comparing the performance of automated and manual systems at the Medical Centre of the University of Sri Jayewardenepura. Finally, the framework was evaluated with input from healthcare domain experts and strengthened based on their feedback.

***Keywords**: Healthcare Information System, Responsibility, Policies, Rules, eHealth*

Introduction

Healthcare domain is well established with the defined clinical pathways mostly practiced manually. These manual procedures are expected to adhere to policies, procedures, and guidelines that are adopted in manual workflows with the domain knowledge of involved personnel of health institutions (Department of Health Services Sri Lanka, 2014, Madhusanka et al., 2020). However, to guarantee the quality of treatment processes, real-time adherence to governing policies is necessary. Although there are several contributions in literature for responsibility management in general businesses (Melnic and Puiu, 2011, Cabanillas et al., 2018), in the healthcare domain, the lack of studies is evident (Feltus et al., 2014).

Healthcare policies and governance requirements have been studied based on a literature review together with investigations on existing local and global policy related documents and investigations on current eHealth solutions. Existing higher-level theoretical frameworks in HC are lacking with support in governance requirement identification and limitations have also been highlighted in this section. Further, the well-established standards in general business selected as the basis for designing the proposed system have also been summarized here.

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When investigating in policies and governing related documents in the HC industry, very many different forms could be located such as policies, health ministry acts & circulars, HC guidelines, SOPs etc. For instance, the policy repository recently published by the Sri Lankan health ministry indicates the national policies and strategies subjected to identify key disease areas and health problems (Nicholson, 2005, Department of Health Services Sri Lanka, 2014, Directorate of Non-Communicable Diseases Ministry of Health, 2021). According to these higher-level policy descriptions, HC service provisions are expected to adhere to these directives (Sabar et al., 2016). However, the difficulties of retrieving and adhering to these directives are in manual process. Further, there may be variations in local HC institutional adaptations of responsibilities and privileges against prescribed governance requirements by authorities. There could be several such reasons as situational (coping with situations such as pandemic, emergency, etc.) and personnel (Staff unavailability, workload).

However, these policy standards specify the procedures in higher-level statements that demand systematic and unambiguous translations into technical realization. Therefore, it is necessary to fill this gap between the HC authority level and the eHealth solution developer level by providing a complete and comprehensive approach to realizing governing perspectives. Limitations with designer assistance and the scarcity of such global initiatives addressing some of these requirements of HC governance were observed during the literature review.

Service Aware Interoperability Framework (SAIF) (Landgrebe and Smith, 2011) and refined eHealth European Interoperability Framework (ReEIF) (d'Hollosy et al., 2018) are two such interoperability frameworks that highlighted the importance of considering different interoperability levels in the integration of different eHealth solutions.

These conceptual frameworks suggest the applicability and appropriateness of many tools and methods of modeling each sub-framework or layer. However, most of these approaches are not complete and systematic in facilitating to capture and support of technical realizations of governing requirements.

It is important to analyze the applicability and adaptability of well-established theoretical contributions in the direction of realization of pragmatic and social level modeling and also to ensure the eHealth solution's success.

Responsibility is one of the main governing aspects in healthcare and it also varies with specific process categories. The responsibility of the actors associated with a particular process is diverse and perhaps changes due to dynamic behaviour in the care delivery process. Therefore, it is a challenging task to analyze the responsibility spectrum of an HC process. RAM (Responsibility Assignment Matrix) is a promising approach which can be used to analyze complex processes governed by different types of responsibilities (Cabanillas et al., 2018). As a method to analyze responsibility variations, RAM can also be applied in the HC context (Dantanarayana and Jayaweera, 2022). However, it is required to propose a specific RAM matrix since the HC actors are responsible in different ways for each activity in the HC domain.

In addition to various RAM models applied to project management in the business sector, a recent study has demonstrated RAM is a useful approach to model responsibility distributions in HC processes (Dantanarayana and Jayaweera, 2022). However, it is necessary to extend the work and analyses the applicability with selected service processes in care pathway.

The different responsibility types in service processes are to be realized and put into enforcement employing rules (Open Management Group, 2013) on eHealth platforms. These enforcement levels may vary depending on the concerned contextual conditions and Business Motivation Model (BMM) defines five such enforcement levels. For instance, it is required to receive consultancy from a physician when deciding on substitutes instead of prescribed medicine. In some situations, this rule must be strictly enforced when the

direction for no substitutes has clearly been indicated and there can be situations where the same rule can be overridden in case of the absence of the same directive. According to BMM, business rules are the practicable directives whereas business policies are higher-level directives and may not be atomic as a rule (Sharma et al., 2017). Therefore, a business policy can be implemented through accomplishing connected business rules. The severity of the action required to keep a business rule in force is identified with a set of enforcement levels and these enforcement levels range from a 'strictly enforced' level to a 'guideline' level.

The clinical pathway-centered service process and governing directives around pathway activities have been considered in our research (Aspland et al., 2021). Therefore, the appropriateness of the modeling standards in clinical pathways has also been analyzed. Business Process Modeling Notation (BPMN) was developed and maintained by the Object Management Group (Pufahl et al., 2022). BPMN provides a graphical notation for specifying business processes based on a process specification notation. Nowadays process modeling is mostly integrated into HC domain since it enables communication among different stakeholders and the potentiality of digital transformation which leads to enhanced care delivery (Zerbato et al., 2015).

Based on the literature review of existing e-Health systems, it was identified that addressing governance aspects is crucial, as emphasized by theoretical frameworks that highlight the importance of specifying governance components in eHealth systems. Additionally, it was found that there is a lack of handling emergency situations and managing responsibilities in ad-hoc circumstances. Therefore, it was concluded that a comprehensive healthcare (HC) governance realization approach is required.

The completed literature review revealed that a systematic and real-time adaptation approach for the realization of these governing requirements in eHealth solutions has not been adequately addressed. The proposed Healthcare Governance Framework (HCGF) is capable of capturing HC governing requirements in a complete and comprehensive manner. Further, HCGF could assist eHealth solution developers with the realization of ever-emerging and complex governing requirements in the health domain.

The main research question of the study is, how healthcare governance policy realization framework be developed to facilitate eHealth solution developers in the realization of HC governance? Further, the main research question is explained with the following three sub-questions; (i) How to specify HC processes with assigned different responsibilities on various actors? (ii) How to capture complex responsibility coordination in multi-party collaborations with various actor involvements? (iii) How to formulate HC governance rules for responsibility coordination? To answer the research questions the following objectives were used; (i) Development of Actor-Activity based HC process modeling sub-framework (ii) Development of HC responsibility coordination sub-framework (iii) Development of HC rules sub-framework. Finally, we formulate the HC Governance Framework (HCGF) by integrating the above three sub-frameworks, and then we validate the Framework.

Therefore, the systematic approach for healthcare responsibility governance based on HCGF has been proposed in this work. The remaining structure of the paper is organised into the sections; methodology of the proposed approach, Healthcare Governance Framework (HCGF), results with the application of proposed study & discussion, evaluation and future directions.

Methodology

This study was designed with five phases: (i). awareness of HC processes and governance, (ii). suggestions of governing perspectives, (iii). designing and development of HGCF, (iv). Application of HCGF, and (v). evaluation of HCGF and designing the proposed approach mapped with the design science methodology (Fig. 1).

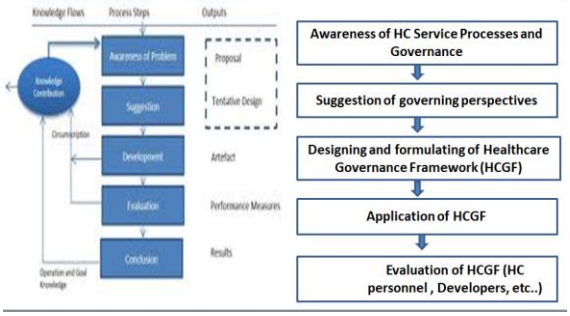

Figure 1: Design Architecture of the proposed Healthcare Governance Framework (HCGF)

The research method adopted in this study is based on a design science research approach (Hevner et al., 2004, vom Brocke et al., 2020) combined with a case-based study (Dresch et al., 2015). The case-based approach is mainly subjected to the focused areas of this research as on deployed Hospital Health Information Management Systems (HHMIS) solution at the Medical Center at the University of Sri Jayewardenepura (MC@USJ). Adaptation of major phases (awareness of HC processes and governance, suggestions of governing perspectives, designing and development of HCGF, evaluation of HCGF) of design science in this work are summarized below.

Phase 1: Awareness of the HC process has been mainly carried out with literature study, and process observation at MC@USJ. The completed literature review could be considered as secondary information sources for awareness while process observation carried out could be considered as primary information source.

Phase 2: Suggestions for accommodating governing aspects have been conducted through three main perspectives; HC Process Modeling Perspectives, HC Responsibility Assignment Perspectives, and HC Rules and Enforcement Perspectives.

Phase 3: Designing and development of the Healthcare Governance Framework (HCGF) has been carried out based on the three perspectives and the HC governance framework has been formulated.

Phase 4: Application of Healthcare Governance Framework (HCGF). In this phase, the framework was applied in the University of Sri Jayewardenepura Medical Center in both manual procedures and the HHIMS system (having only limited features) provided by the ICTA.

When applying the proposed system, we identify the improvement possibilities and additional features available in our proposed approach. For this identification, we use a structured questionnaire to gather relevant information from different-level HC personnel (E.g., doctors, nurses, and pharmacists). We obtained the model in several iterations to strengthen it.

Phase 5: With consultation of the HC personnel (doctors, nurses, and pharmacists) several questionnaires were designed with appropriate validation, and conduct the survey. The survey outcomes were analyzed using qualitative methods. Subsequently, the evaluation of the proposed approach has been completed with the feedback received through the questionnaires from domain experts such as doctors, nurses, and pharmacists. Feedback from the stakeholders has been accommodated to the system and enhanced accordingly.

Healthcare Governance Framework (HCGF)

This section introduces the proposed systematic approach for HC governance as a framework consisting of three sub-frameworks. Suggested three sub frameworks are:

- Healthcare Process (HCP) sub-framework
- Healthcare Responsibility (HCR) sub-framework
- Healthcare Rules Enforcement ((HCRE) sub-framework

Each sub-framework is explained with relevant examples from the case study, the current deployed HHIMS at medical center USJ with treatment process at OPD as referred in methodology.

Healthcare Process (HCP) sub-framework

The healthcare process sub-framework can serve two major purposes in eHealth solution development: process analysis (As-is) and process design (To be). In this sub-framework, specific actor and activity

perspectives are proposed for process analysis and design. This process modeling is analogous to the behavioural sub-framework in SAIF (Landgrebe and Smith, 2011), as described in the literature review.

The treatment process of HHIMS deployment at MC@USJ has been illustrated below using BPMN (Fig. 2).

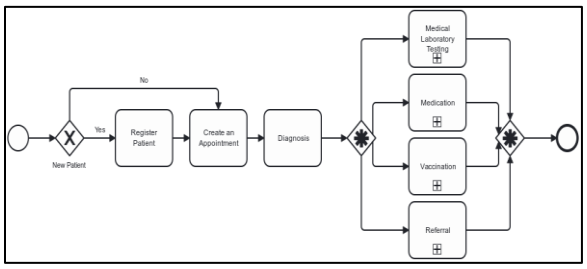

Figure 2: Treatment Process

The treatment process on HHIMS begins with patient registration where the new patient must register with demographic information. an appointment activity is the giving the time slot for patient to meet doctor by the system. The physician mainly responsible for the diagnosis step where it undergoes through several steps which may involve a set of parallel or sequential activities and more often these activities are performed with the help of nursing staff and other peripheral services such as medical laboratory service, radiology service, physiotherapy service etc. Therefore, as depicted in Figure 2, based on diagnosis, the subsequent activity could be ordering medical laboratory test or prescribing medicine or giving vaccination order or referring to or get consultation from HC consultant.

Healthcare Responsibility (HCR) sub-framework

As per the literature review, we have selected only four major relevant responsibility types for HCR. Most of the deployed eHealth platforms have facilitated and captured the performance responsibility of respective HC personnel leaving execution of other responsibility types often out of those platforms. In addition to performance responsibility, there are other types of auxiliary responsibilities. For simplicity, only four selected responsibility types have been explained below.

Perform (P): Perform is a key factor defined regarding the performance of a certain HC activity. The responsible actor for performing a particular activity must be explicitly defined in the care process. Defining performing actors is essential in some situations where it is necessary to record accountable actors in addition to performing actors. Nurses perform some tasks such as vaccinating the patient where the accountability of the task is with a doctor who recommends the vaccination for the patient.

Consult (C): Expert opinions should be consulted in many complex situations in the healthcare treatment process. It is important to specify whom to be consulted for relevant tasks. Often, inter-actor hierarchies are followed in consultancy or in making referrals to the next expertise level. In the clinical wards, usually follow the hierarchy of Consultant, Senior House Officer, and House Officer in requesting consultancy process during in-patient care.

Accountable (A): The person ultimately answerable for the correction and completion of the task, and capturing accountable responsibility is important in case of a delegation of performance responsibility. In HC it is important to record accountability information for certain problematic situations or emergencies for auditing purposes. In the HC treatment process, the pharmacist has the responsibility to inform the senior pharmacist while the senior pharmacist is accountable for the issued medicine. The senior pharmacist delegates the performing task of issuing medicine to the junior pharmacist, however, the accountability for the task is with the senior pharmacist.

Informed (I): An informed actor is a person who necessarily is informed when the task is performed. For instance, the physician would be the informed actor when the initial medical history is recorded by the nurse. Also, sub-tasks of the diagnosis process can have several informed actors. The pharmacist has the responsibility to inform the physician while the physician has the responsibility to be informed about the issued medicine.

The consideration of auxiliary responsibility types in eHealth solutions is important concerning assurance of compliance with governance requirements as well as to facilitate post-process auditing purposes.

Healthcare Rules Enforcement sub-framework (HCRE)

Governance requirements and policies can be realized in terms of rules (Milanovic and Gasevic, 2009). Further, these rules are enforced under different situational contexts at different levels of enforcement as also explained in literature review section. Therefore, we formulated the following rules in realization of governing responsibilities with different enforcement levels.

The treatment process to be enacted after registration can be formalized as below:

If <Registered> Then <Enact Treatment Process> - R1

Situation 1: Normal Treatment -R1 Strictly Enforced (No treatment possible for not registered patient)

Situation 2: Emergency Treatment -R1 Differed Enforcement (Treatment can be started for patients in emergency conditions even before registration)

Policies can be implemented by rules; however, it is equally important to identify a variety of possible enforcement levels and facilitating the required situational flexibility for eHealth solution success.

Results and Discussion

Application of HC Governance

The proposed systematic approach for HC governance requirement realization based on the proposed framework has been explained in this section. The case considered to illustrate the application of the proposed approach is the medication phase with find substitution for a prescription. As illustrated in Figure 2, the analyzed HHIMS process contains only the medication sub-process of the patient treatment only with performance responsibility. However, our careful investigation revealed the necessity for considering other auxiliary responsibility types such as consultation of the prescriber (physician) by pharmacist in situations to decide for a substitute.

According to the HCR sub-framework, in addition to performance responsibility, the following auxiliary responsibility types (Table 1) have been identified for the aforementioned medication sub-process referred to the patient treatment scenario at the medical center.

Table 1: Responsibility Assignment Matrix for Issue Medicine

	Performance	Informed	Consulted
Issue Medicine	Pharmacist	Physician	-
Find Substitute	Pharmacist	-	Physician

According to the application of sub framework HCRE, the following rule enforcements can be identified referred to the service process activity "substitute medicine".

If <no substitute is mentioned in prescription> Then <consult prescriber for substitute> → strictly enforced

If <no substitute is not mentioned in prescription> Then <Issue Substitute instead what prescribed> → Post Justified

If the Substitute is not available, however, the pharmacist can issue the same drug with a different brand only with post justification.

With the application of the three sub frameworks HCP, HCR, and HCRE the rule enforcements for the 'find substitute' have been identified. As explained in HCP, the designed process can be obtained by accommodating rules and rule enforcement levels as depicted (Fig. 3). The initial process model illustrated in Figure 2 captures the medication process only with performance activity for issue medicine task. However, after accommodating with set of auxiliary responsibility types attached to 'issue medicine' activity has been captured and demonstrated with the process models in Figure 3 and Figure 4.

Evaluation of the HCGF

Since the resulting artifacts have been proposed according to the guidelines of design science methodology as a case-based research study, a few interviews consisting of open-ended questions were used out to get the feedback. Both, the whole framework and the concepts resulted from three

dimensions are evaluated against HC practitioners and eHealth solution developers.

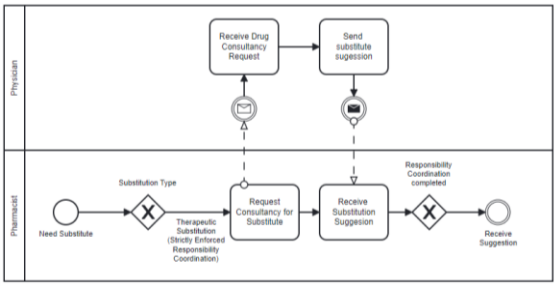

Figure 3: Consultancy Process Model –Find Substitute (No Substitution –Strictly enforces)

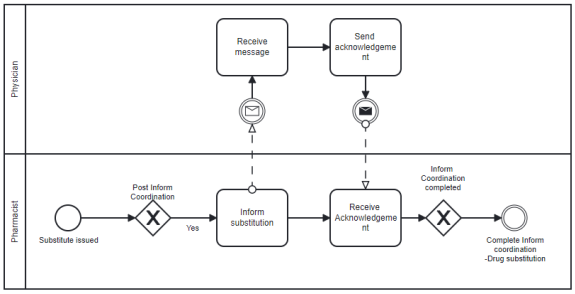

Figure 4: Inform Process Model – Find Substitute (Substitute - post justified)

Doctors, nurses, and pharmacists in the University medical center have been interviewed and received their feedback on the proposed solution. Structured questions prepared considering sub sections to evaluate different functional areas of HC treatment process such as HC actor classification and HC roles. HC treatment process and activities, HC responsibility types, HC responsibility coordination, HC governing rules, HC enforcement levels of governing rules.

The evaluation with solution developers is mainly categorized into a few sections such as HC actor identification, Activity identification of treatment process, Responsibility coordination in multiparty collaboration, Governance rules, and enforcement levels management. The presence of the information regarding these sections has been questioned and eHealth solution developers accepted the proposed governance requirement approach is mostly applicable in governance requirement identification in terms of process modeling aligned with rule enforcement modeling.

According to the literature review, it was revealed that the Service-Aware Interoperability Framework (SAIF) (Landgrebe and Smith, 2011) and the refined eHealth European Interoperability Framework (ReEIF) (d'Hollosy et al., 2018) emphasize the importance of addressing governance aspects. However, there is no evidence to suggest that these approaches have been applied in practice. When applying these approaches to realize HC governance aspects, it was identified that it only gives guidance when designing the HC governance framework.

Although there is a lack of governance realization approaches in the healthcare (HC) context, well-established approaches exist in the business sector. In this study, these approaches were adopted with appropriate modifications. As a result of these modifications, a healthcare framework can be designed to address governance aspects in eHealth system development.

Similarly, the literature review revealed that the Responsibility Assignment Matrix (RAM) has been utilized across various disciplines. In this study, the RAM approach was extended and applied while designing the HCR sub-framework to capture different responsibility coordination aspects within healthcare.

The outcome of the study is the creation of rules and the generation of design patterns, which are not immediately visible in the normal context. Based on the generated rules of the HCGF, design patterns were derived. These rules and design patterns were thoroughly validated through several iterations with relevant healthcare domain experts. Finally, the required design framework is ready to be provided to the developers.

Conclusion

If one implements the proposed framework, it facilitates the complete visualization of HC rule categorization based on enforcement levels. This systematic approach enhances the framework's applicability. It is concluded that the complete visualization of HC rules will make them transparent and beneficial to stakeholders in the decision-making process.

This research guarantees bi-directional traceability between process modeling layers, which is achieved

through the connectivity among the proposed three sub-frameworks. It is concluded that the bi-directional traceability between process modeling layers enables inter-process (sub-process) communication and provides a clear pathway for implementing, tracing, and auditing decisions.

HCP initially captures performance responsibilities as the foundation for treatment processes. The HCR sub-framework suggests adapting the RAM in the HC sector. However, only four main responsibility types: perform, accountability, inform, and consult, are defined for HC, as most multi-party collaboration activities are connected to these four types of responsibility. Based on these factors, it is concluded that multi-party collaboration activities in HC will be effectively captured, which will facilitate handling complex situational requirements.

The ultimate result of the study is the generation of a set of rules and the creation of process patterns accordingly. These results will help automate governance procedures in the HC domain. It is concluded that by using rules and process patterns, the entire eHealth system can be developed to address the existing issues in realizing governance requirements.

This study was tested with HC domain experts and eHealth developers, and their feedback was incorporated to strengthen the framework through several iterations. It is concluded that this framework is suitable for implementation in countries like Sri Lanka.

Recommendations and Future Directions

This study is limited to proposing a supportive framework for responsibility driven healthcare service process modeling by focusing on the service process of generic clinical pathways. However, it should consider the holistic approach encompassing all the domain areas such as surgery, non-communicable disease treatment process etc. Therefore, future studies need to explore other contexts and expand the application of the framework to other domains as well.

The proposed HCR sub-framework of this study is mainly focused on the responsibility assignment of the OPD treatment process considering specific workflow in MC@USJ. However, responsibility assignments at different HC institutions must be different and there can be different responsibility types other than the defined types with the HCR sub-framework in this study. Therefore, the new matrix can be defined accordingly, or it can be extended without much difficulty as required.

The process mining approach can be used for further validation of the proposed approach with the process patterns derived and the degree of current realization of them can also be identified.

Further, a complete rule repository considering required enforcement levels, a Proof-of-Concept implementation and a real-world validation are among some of the potential future directions of these contributions. This framework can be implemented in real time considering all aspects of HC governance.

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