GOVERNANCE MODEL DEVELOPMENT FOR HEALTH DATA STANDARD IN THAILAND: A CASE STUDY IN MEDICINES TERMINOLOGY

Miss Ratsapan Phuksaritanon

A Dissertation Submitted in Partial Fulfillment of the Requirements
for the Degree of Doctor of Philosophy Program in Social and Administrative Pharmacy
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คณะเภสัชศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
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By	Miss Ratsapan Phuksaritanon
Field of Study	Social and Administrative Pharmacy
Thesis Advisor	Assistant Professor Anuchai Theeraroungchaisri, Ph.D.
Thesis Co-Advisor	Boonchai Kijsanayothin, M.D., Ph.D.

Accepted by the Faculty of Pharmaceutical Sciences, Chulalongkorn University in Partial Fulfillment of the Requirements for the Doctoral Degree

.....Dean of the Faculty of Pharmaceutical Sciences
(Assistant Professor Rungpetch Sakulbumrungsil, Ph.D.)

THESIS COMMITTEE

.....Chairman
(Associate Professor Sathitpong Thanaviriyakul)

.....Thesis Advisor
(Assistant Professor Anuchai Theeraroungchaisri, Ph.D.)

.....Thesis Co-Advisor
(Boonchai Kijsanayothin, M.D., Ph.D.)

.....Examiner
(Assistant Professor Rungpetch Sakulbumrungsil, Ph.D.)

.....Examiner
(Suntaree Watcharadamrongkun, Ph.D.)

.....External Examiner
(Oraluck Pattanaprateep, Ph.D.)

รัศพรรณ พฤกษะริตานนท์ : การพัฒนาต้นแบบการอภิบาลมาตรฐานข้อมูลสุขภาพในประเทศไทย กรณีศึกษาบัญชีข้อมูลยาและรหัสยามาตรฐาน (GOVERNANCE MODEL DEVELOPMENT FOR HEALTH DATA STANDARD IN THAILAND: A CASE STUDY IN MEDICINES TERMINOLOGY) อ.ที่ปรึกษาวิทยานิพนธ์หลัก: ผศ. ภก. ดร.อนุชัย ธีระเรืองไชยศรี, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม: นพ. ดร.บุญชัย กิจสนาโยธิน, 189 หน้า.

ในปัจจุบันประเทศไทยยังไม่มีระบบการอภิบาลมาตรฐานข้อมูลสุขภาพและบัญชีข้อมูลยาและรหัสยามาตรฐานที่ได้รับการออกแบบอย่างดี โดยในการศึกษานี้ได้ศึกษาระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานเป็นกรณีศึกษา ในการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานพบว่ายังไม่มีหน่วยงานรับผิดชอบหลักที่เป็นหน่วยงานเพียงหน่วยงานเดียวที่ทำหน้าที่อภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานทั้งหมด รวมถึงยังขาดกลไกในการประสานงานระหว่างผู้มีส่วนเกี่ยวข้องในการพัฒนาและดูแลบัญชีข้อมูลยาและรหัสยามาตรฐาน ซึ่งทำให้การแลกเปลี่ยนข้อมูลยาระหว่างหน่วยบริการสุขภาพและการติดตามและประเมินผลการใช้ยาในระดับประเทศเป็นไปด้วยความยากลำบาก การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาและพัฒนาตัวแบบอภิบาลมาตรฐานข้อมูลสุขภาพสำหรับประเทศไทยโดยใช้บัญชีข้อมูลยาและรหัสยามาตรฐานเป็นกรณีศึกษา

การศึกษานี้นำเสนอตัวแบบการอภิบาลโดยประยุกต์หลักการการออกแบบอย่างมีส่วนร่วมของผู้ที่มีส่วนเกี่ยวข้อง โดยแบ่งขั้นตอนการวิจัยเป็น 3 ระยะ ได้แก่ 1) ผู้วิจัยศึกษาระบบการอภิบาลมาตรฐานข้อมูลสุขภาพและมาตรฐานข้อมูลยาของประเทศที่มีความก้าวหน้าด้านเวชสารสนเทศ 2) ศึกษาสถานการณ์ปัจจุบันของประเทศไทยในการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานโดยการสัมภาษณ์ผู้มีส่วนเกี่ยวข้อง 3) พัฒนาตัวแบบการอภิบาลแล้วนำไปปรึกษาหารือกับผู้มีส่วนเกี่ยวข้อง จากนั้นนำตัวแบบอภิบาลไปให้ผู้เชี่ยวชาญประเมินความสามารถในการใช้งานโดยใช้เทคนิคฮิวริสติกในการประเมิน

ตัวแบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานนำเสนอใน 3 ด้าน ได้แก่ องค์ประกอบพื้นฐาน กระบวนการ และเครื่องมือและบริการ ในด้านองค์ประกอบพื้นฐานประเทศไทยควรกำหนดนโยบายและแผนที่ชัดเจนในการพัฒนาและการใช้บัญชีข้อมูลยาและรหัสยามาตรฐานให้สอดคล้องกับนโยบายในการพัฒนาระบบสารสนเทศเพื่อสุขภาพ ควรมีการจัดตั้งหน่วยงานผู้รับผิดชอบหลักในการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานโดยเป็นหน่วยงานที่มีอำนาจทางกฎหมาย โครงสร้างการประสานงานประกอบด้วยผู้มีส่วนเกี่ยวข้องทุกภาคส่วนโดยมีทั้งโครงสร้างความร่วมมือที่เป็นทางการและไม่เป็นทางการ กระบวนการซึ่งประกอบด้วยกระบวนการพัฒนา กระบวนการนำไปใช้ กระบวนการบำรุงรักษา พร้อมทั้งบทบาทของผู้มีส่วนเกี่ยวข้องในแต่ละกระบวนการ เครื่องมือและบริการสนับสนุนการใช้งานของผู้ใช้ได้นำเสนอทั้งเครื่องมือสนับสนุนการใช้งาน การบริการความรู้แก่ผู้ใช้ และการบริการสาธารณะอื่นๆ

ภาควิชา	เภสัชศาสตร์สังคมและบริหาร	ลายมือชื่อนิสิต	.....
สาขาวิชา	เภสัชศาสตร์สังคมและบริหาร	ลายมือชื่อ อ.ที่ปรึกษาหลัก	.....
ปีการศึกษา	2559	ลายมือชื่อ อ.ที่ปรึกษาร่วม	.....

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RATSAPAN PHUKSARITANON: GOVERNANCE MODEL DEVELOPMENT FOR HEALTH DATA STANDARD IN THAILAND: A CASE STUDY IN MEDICINES TERMINOLOGY. ADVISOR: ASST. PROF. ANUCHAI THEERAROUNGCHAISRI, Ph.D., CO-ADVISOR: BOONCHAI KIJSANAYOTHIN, M.D., Ph.D., 189 pp.

Thailand does not have a well-designed governance system for health data standard and coding system. In this study, the governance of medicine terminology was selected as a case study. There is no single responsible organization to govern drug code and medicines terminology and also no mechanism for cooperation among stakeholders to develop and maintain medicines terminology. This leads to difficulties of drug information exchange between health service units and drug utilization monitoring and evaluation at the national level. This study aims to study and develop the governance model for health data standard in Thailand by using the medicines terminology as a case study

This study proposed a medicines terminology governance model for Thailand by applying a participatory research design concept for the research methodology. The methodology was divided into three main steps. 1) Review the experience of advanced countries focus on the governance of health data standards and medicines terminology. 2) Review the current situation of Thailand by using multi-techniques of qualitative research. 3) Develop the governance model for medicines terminology, consult with the stakeholders, and evaluate by the experts with heuristics evaluation technique.

This research proposed the governance model in three main areas, such as foundations, processes, tools and services. For the foundations, Thailand should set up the clear policy and set up the explicit plan for developing and using medicines terminology according to the health information technology development policy. The main organization should be legally established to be responsible for the governance of medicines terminology. The collaborative structure which comprises all stakeholders should be set up as both formal and informal structures. The processes including development, implementation, and maintenance, organization, roles and responsibility of all stakeholders for all processes are proposed in each process detail. Tools and services to support the user adoption are also proposed as supportive tools, knowledge services, and public services.

Department: Social and Administrative Pharmacy Student's Signature .....
Field of Study: Social and Administrative Pharmacy Advisor's Signature .....
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Introduction

1.1 Rational and statement of the problem

1.1.1 Important of governance for health data standards

Health information system plays the crucial role in the health system. The world health organization defines health information system as one of the six building blocks to strengthen health system [1]. Health information technology enhances to increase quality, efficiency, and safety of healthcare [2]. In addition, electronic health care information exchange and interoperability can reduce the cost of care [3]. Health data standards are important for health information exchange and interoperability. Health data standards help to support the medical diagnosis and treatment, reduce medical error and increase the efficient of the healthcare [4]. Successful information exchange through health data standards does not require only existence physical technical connection between system but also need the effective governance system for development and maintenance [5]. In the advanced countries for health data standard, the governance system for national health data standards includes medicines terminology was set and the mechanism of work which composing of the process of work and the role of stakeholders was identified in details. New Zealand, Canada, and the United States are the examples of the countries which establish the governance system for development and maintenance of national health data standards [4, 6, 7].

New Zealand has established Health Information Standards Organization to support and promote the development, understanding, and use for health data standards to improve the national health system [6]. In addition, the mechanism for development and maintenance of health data standards has been set to ensuring that the health data standards are developed with a coordinated and consistent approach. The mechanism for development and maintenance composes of five main stages. Stage 1, the standard requirement will be identified; then, proposal and plan will be set. Stage 2, drafted standard will be developed and will be evaluated

for adjustment. Stage 3, drafted standard will be passed the process of public consultation. Stage 4, full standard will be approved and implemented. Stage 5, the standard will be scheduled review and maintained. The processes of work and responsible organization have been clearly identified in all stage of mechanism for development and maintenance [8].

Canada and the United States have established the organization to integrate eHealth with national health systems. In order to develop health data standards for health information interoperability, the coordinated network and the committee composing of all stakeholders have been set within this organization. In Canada, Standard Collaborative was established within the Canadian Health Infoway to establish, and provide services to stakeholders for support and maintain health data standards. Role and responsibility of the relevant department for developing and maintaining health data standards have been identified. In addition, the processes for developing and maintaining health data standards are set and plan for reviewing standards are set to update these health data standards [4]. In the United States, National library of medicine (NLM) within Department of Health and Human Services is the central body responsible for supporting the development of health data standards and health data terminology standards, and accelerate adoption of health data standards in health information exchange. An important duty is coordination to develop mappings and promotes harmonization between health data standards and health data standard terminologies [7].

The countries advanced for health information system development give precedence to governance for development and maintenance of health data standards within their countries to facilitate the use of health data standards for interoperability. Successful governance of health data standards development and maintenance enhance and accelerate the adoption and implementation of health information exchange and interoperability.

1.1.2 Situation of governance for development and maintenance of medicines terminology in Thailand

Drug information is one of the important information for eHealth, and medicines terminology is needed for eHealth interoperability. According to the study of Kijsanayothin and his colleagues (2010), Thailand did not setup the governing body to provide the vision, policy, and develop the mechanism for development and maintenance health data standards [9, 10]. There are many standard drug coding systems have been developed in Thailand, such as Thai food and drug administration's drug registration coding system, twenty-four digits drug coding system, GS1 system, hospital working codes, and so forth. Each standard drug code has been used for the specific purpose but they cannot communicate between each other system[11].

At present, Thailand does not have a well-designed governance system for developing and maintenance national health data standards including medicines terminology. Organizations which facilitate and support the adoption of medicines terminology to be used within national health information systems is also not present. In addition, the mechanism for development and maintenance of national medicines terminology which is accepted from every stakeholder has not been setup as other countries advancing in health information technology system [12]. This leads to the problem in managing of national terminology standards and drug standard code which can be seen from the problem in the governance of maintaining the 24 digits drug coding system.

In 2010, Ministry of Public Health announced that the 24 digits drug codes would be used as the drug standard code for drug information exchange in health care system [12]. Several organizations within the Ministry of Public Health are responsible for generating standards drug code and the announcement of the codes. The process is supposed to be the standard drug codes maintaining system of the 24 digits drug codes. When there is a new registered drug, Thai Food and Drug Administration (Thai-FDA) will create drug registration code and sends drug information to Bureau of Health Administration to generate the 24 digits drug code.

These drug codes will be sent to Bureau of Policy and Strategy for announcement and sent to the relevant organizations for mapping codes to existing working codes in the organization information systems, such as hospital, Government Pharmaceutical Organization(GPO), the Comptroller General's department, and etc [13]. Although the processes and responsible organization were set, there is no main organization to defining policy and plan for development and maintenance, no process for review and improve standard code, and no coordination body for connection with other standard code systems. This leads to the problems in updating standard, mapping with other standard code, and not cover 5-10% of drug use in big hospitals [11].

In 2012, Thai government realized the problems of existing drug standard code and the governance system which cannot use for drug information exchange in medical care and reimbursement. The government launched the policy to develop new national medicines terminology for Thai healthcare systems especially for three health insurances schemes reimbursement system, and develop the governance mechanism for development and maintenance of national medicines terminology [11]. Although Thai medicines terminology has been developed in 2012, the governance system for development and maintenance of national medicines terminology has not been developed.

This study aims to develop the governance model for health data standard by using medicines terminology governance as a case study. The study aims to develop the governance model which is accountable for the needs of relevant stakeholders in Thailand. Participatory design methodology is used in this study. The study divides into 4 stages. Stage 1, the governance systems for standard and terminology in the countries advancing in health information system development are reviewed. Stage 2, current situation of the governance system for drug code and medicines terminology in Thailand is explored. Stage 3, the results from other countries and current situation of Thailand are analyzed and generated the prototype. The prototype is evaluated by the expert, and the final governance model for medicines terminology is concluded. This model will be useful for set up the governance system for medicines terminology in Thailand and can be applied for other clinical terminology and health data standard.

1.2. Research Questions

1) What is the governance model for national health data standards and medicines terminology in the countries advanced in health data standards?
2) What is the current situation of the governance for drug standard code and medicines terminology in Thailand?
3) What is the appropriate governance model for medicines terminology in Thailand?

1.3. Objectives of the study

1) To review the national health data standard and medicines terminology governance model in countries advanced in health data standard
2) To explore the current situation of governance for drug standard code and medicines terminology in Thailand
3) To develop the governance model for medicines terminology in Thailand

1.4. Scope of the study

Design the medicines terminology governance model for medication and reimbursement.

1.5. Conceptual framework

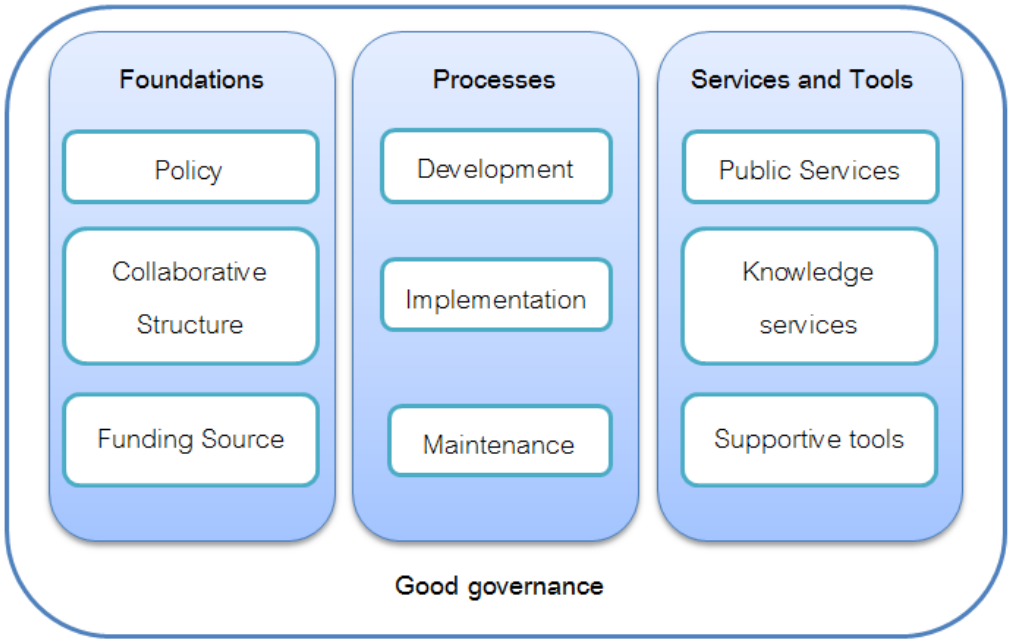

Figure 1 Conceptual framework [14-16]
(Applied from the concept of system design, S&I framework of ONC and WHO's eHealth development model)

The conceptual framework in figure 1 is applied from the concept of system design, S&I framework of ONC and WHO's eHealth development model (details are reviewed in chapter II). This research will develop the governance model showing the structure, role, and co-operate procedures of stakeholders which are necessary to develop, implement, maintain, and provide services and tools to enables the using of medicines terminology for drug information exchange.

The conceptual framework for developing the governance model will compose of three main components which applied from S&I framework, such as foundations, processes, and services and tools [14]. The medicines terminology governance requires the foundations including policy, collaborative structure, and funding resource which are applied from the foundation in WHO's eHealth development model. The processes for medicines terminology governance include development, implementation, and maintenance [15]. The model has to show the main responsible organization for providing necessary services and tools which are

applied from S&I framework [14]. Eight principles of good governance which are suggested by the United Nations will be the principles to set up the governance model including participation, rule of law, transparency, responsiveness, consensus oriented, equity and inclusiveness, effective and efficiency, and accountability [17]. The description of each principle is applied from the explanation of the United Nation, the Thai Chamber of Commerce, and the Office of the Public Sector Development Commission (details are reviewed in chapter II) [17-19].

1.6. Operational definitions

Health data standard are the set of rules, format, and definitions that provide the uniform meaning which is necessary to exchange the health information between different electronic systems [20, 21].

Drug code is the set of numbers that represent and uniquely identify the drug product.

Medicines terminology is a type of health data standard, which standardizes drug information attributes with a unique identifier and drug concept relationships, such as name, dosage form, strength, pack size, therapeutic use, and so forth [22, 23].

Governance model for medicines terminology is a model showing structure, role, and cooperate procedures of stakeholders which is necessary to develop, implementation, maintain, and supportive services and tools to enables the using of medicines terminology for drug information exchange.

Foundations refer to the base components that necessary to establish the governance mechanism for medicines terminology.

Processes refer to the series of operation that enables the effective development and using of medicines terminology for drug information exchange.

Services and tools are necessary services and tools that facilitate the implementation, adoption, and use of medicines terminology.

Policy refers to the decisions and plans which are set as the direction of action to achieve the goal within medicines terminology collaborative structure.

Funding sources refer to financial sources which are need for support the governance of medicines terminology.

Collaborative structure refers to the governing body and collaborative network for development, implementation, and maintenance medicines terminology.

Development processes refer to the activities for identifying the requirement, improve, and approval of medicines terminology.

Implementation processes refer to the activities for promoting and supporting the adoption of medicines terminology.

Maintenance processes refer to activities to maintain and support the use of medicines terminology.

Public services refer to the activities to facilitate the stakeholders for medicines terminology use and adoption.

Knowledge services refer to the activities to improve and serve the learning activities and the body of knowledge about medicines terminology

Supportive tools refer to important tools that facilitate the implementation, adoption, and use of medicines terminology.

Good governance refers to the guiding principles which are applied for governance of medicines terminology in all process for good policy making, development, implementation, and maintenance of medicines terminology.

1.7. Expected benefits

Results from the study will give the information of current situation and propose the governance model for medicines terminology in Thailand which is accountable to the need of involved stakeholders. The methodology and the proposed governance model can be applied to develop the governance model for other clinical terminology and other health data standard.

Chapter II

Literature review

This study is mainly focused on designing the governance model for health data standard, by using medicines terminology as a case study. This governance model should appropriate for Thailand context and should be accepted by the stakeholders. Related literature will be reviewed in five topics. First, health data standard and medicines terminology concept will be reviewed because it is important to understand that why health data standard and medicines terminology are required and what is relevant organization and main process for managing medicines terminology. Second, the concepts for design the medicines terminology governance model and the core components which should be the parts of medicines terminology governance model will be reviewed to create a conceptual framework and to design the governance model. Third, governance for health data standard and medicines terminology in health information technology advanced countries and Thailand will be reviewed. The fourth, the methodology of participatory design will be reviewed. The last, the heuristics evaluation technique will be presented

2.1. Health data standard and medicines terminology

The sharing and exchanging health information between different systems among health organization require health data standards. Standard is defined as a set of rule, condition, and definition of term which is need for data access, data exchange and data usage between system [21]. Terminology standard is a type of data standards [24]. A terminology standard is a set of structured term which represents the system of concepts and their descriptions and relationships [20, 25]. Without terminology standard, information in one system cannot understand by another system even both systems are developed by the same system developer [26]. A terminology standard is usually attached with identifier known as code to provide unambiguous means for the computational purposes, for example SNOMED identifier which each concept of terminology has unique identifier or code [27].

Drug information exchange also requires drug information standard, especially terminology standard. Various terminology standards were developed by public and industrial sector to represent the term used for drug prescribing, dispensing, and administering. For example, the U.S. Food and Drug Administration (FDA) produced the National Drug Codes based on drug manufacturers. Each manufacturer can define the code which the codes may be reused and it cannot provide sufficient therapeutic data. Therefore, the RxNorm was created for support the requirement for drug terminologies [20]. The U.K., Australia, New Zealand, and Thailand also faced the problems of various drug coding system and lack of the agreement of terminology standard using for drug information interoperability; therefore, national terminology standard for drug information was considered to developed. This research will call the terminology standard for drug information as medicines terminology as same as Australia, New Zealand, and Thailand [11, 22, 28, 29].

Medicines terminology was developed in many countries for sharing and exchanging drug information between electronic health system, such as Australia, New Zealand, Thailand, and so forth [11, 22, 28, 29].

This research defines Medicines terminology is a type of health data standard, which standardizes drug information attributes with a unique identifier and drug concept relationships, such as name, dosage form, strength, pack size, therapeutic use, and so forth [22, 23]

Medicines terminology structure consists of three main components including concepts, descriptions, and relationships. Concepts represent drug product perspectives and every concept has a unique numeric identifier code. Descriptions link the standard terms to concepts and a concept may have several descriptions. Relationships link a concept to the associated concepts which have a related meaning [30, 31]. A terminology of medicine provides a code of concepts and the relationships of concepts [22]. In general, the concepts consist of main product concept groups such as trade name, generic name, strength, unit of use, and pack size [11, 30]. The terminology structure is presented in figure 2 which is the example model of a trade product Parafen® in Thailand medicines terminology structure.

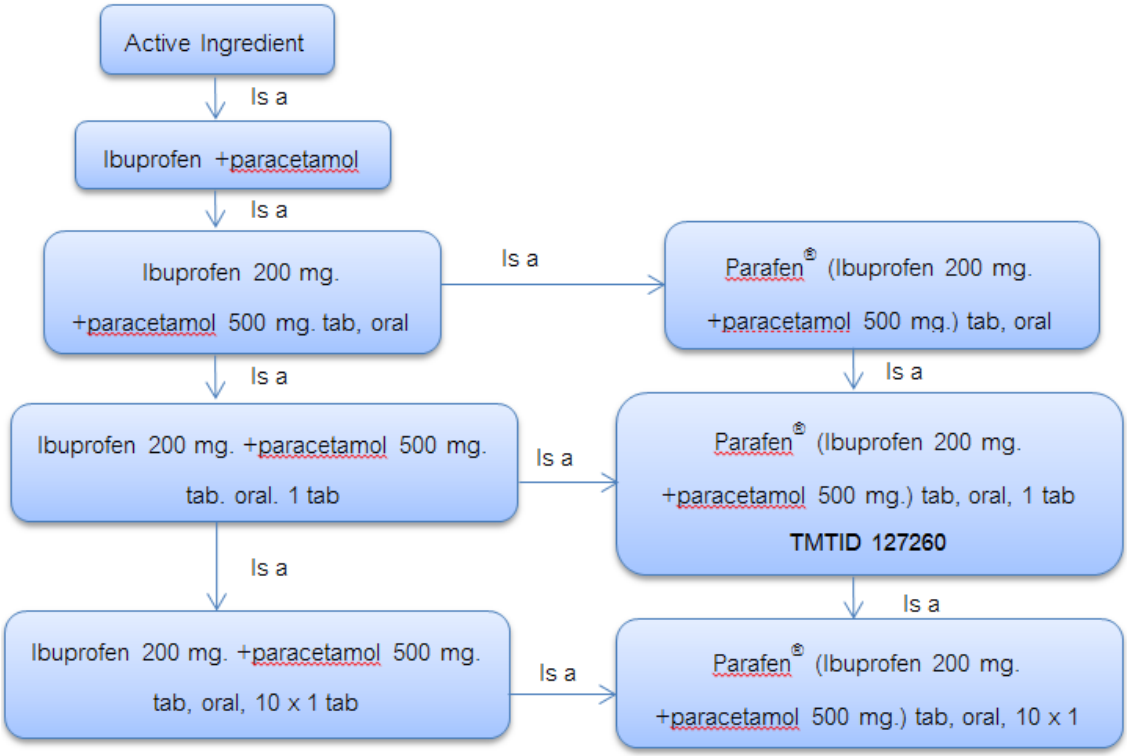

Figure 2 The example model of Parafen in Thailand medicines terminology [11]

In figure 2, the concepts and relationships for Parafen may be described as follows:

- Concepts:
  - Parafen®, tab, oral
  - Parafen®, tab, oral, 1 tab
  - Parafen®, tab, oral, 10x1 tab
- Relationships
  - Active ingredients of Parafen®: ibuprofen and paracetamol
  - Dose form of Parafen®: tablet
  - TMT code for Parafen® oral tablet, 1 tablet: 127260

Medicines terminology requires the organization and process for development, implementation, and maintenance as same as other health data standards. The development of data standard can be explained as follows [20]:

1. Ad hoc method: Standard will be developed from specific group of people to use for specific purpose, such as hospital system vendors.

2. De facto method: a single developer produces the standard and this standard is used as common, such as microsoft's windows.

3. Government-mandate method: the government develops a standard and mandate to use this standard.

4. Consensus method: the stakeholders work together to create standard. Most health data standards have been developed by the consensus method.

The processes for health data standard including medicines terminology compose of some main steps, such as identification, conceptualization, discussion, implementation, and maintenance. The need for a standard must be identified in the first step. In conceptualization step, the characteristics, format, and scope of the standard will be defined. The drafted standard should available for all stakeholders and the stakeholders can discuss and provide comment and recommendation in the discussion step. The implementation step is the important step for standard adoption which may be mandatory or voluntary. The consensus of stakeholders on standard agreement affect to the rapid adoption. The maintenance and promulgation step will enhance the standard availability and facilitate the use of standard. The conformance of standard should be test and the vendor product which conformed to the standard should be certified. These standard process associated with many stakeholders, such as standard development organizations (SDOs), approved standard body, government, system and software vendors, and users [20, 21]. The governance for medicines terminology plays the crucial role to ensure that the medicines terminologies are effectively developed, implemented, and maintenance by the well-organized stakeholders to serve the need for drug information exchange.

2.2 Concepts for model design and components of governance model for medicines terminology

Effective governance system is necessary to facilitate successful information exchange through terminology standard [5]. This research aims to design the governance system which will present in the format of governance model to facilitate the use of medicines terminology. To design the governance system, it is

important to know the components of the system, the concept of system design, and the related framework which can use to develop the framework for governance model. This section will review the related literatures to create the conceptual framework for developing the governance model for medicines terminology.

2.2.1 System design and organizational design concept

The organization design or system design creates the structures, functions, input resources, processes and the relationship of these components to accomplish the goal [16, 32]. From the concepts of system design, governance model for medicines terminology should present the structure, role, and co-operate procedure of stakeholders which is needed for medicines terminology governance.

The functional structure is simple and widely used for organization or system structure design. The functional structure designs the departments responsible for main functions or main tasks, and this design concept is suitable for the expert organization in specific task or service. This type of structural design by grouping the task that having the specific activity and using the same resource in a department which is simple for control and increase the effectiveness to accomplish the functional goals [33, 34].

The functional structure has the limitations in cross-functional processes and slow adaptive to change. The horizontal organizational linkages are important to decrease the limitation and increase the flexibility and effectiveness of the co-operation between the main departments. Gallbraith and others (2002) divided the horizontal organizational as informal group or network, lateral processes, formal group or team, integrator roles, and matrix structure [34].

- Informal group or network is the natural co-operation process between the department in organization or co-operation among groups or organizations. The informal group or network may coordinate by communities of practice, meeting, training programs, technology or electronic coordination [34].

- Lateral processes is the co-operation process between the different function which have to set the objective for the co-operation task and set the new process

map showing the participants for each task. The lateral process is as same as the reengineering process [34].

- Formal group or team co-operate for specific task and specific problem solving. The formal group is a group of representative from different business which is relate to the task or problem which has the same objective and coordinate to do the task or solve the problem. The formal group appoints the supervisor or co-operator to administer and support the team [34].

- Integrator roles co-operate and integrate the task from each department by assign a people in some position to do the specific job [34].

- Matrix structure is widely used for project management and the complex business organization, such as hospital, government organization, or insurance. The matrix structure has two chains of command as the regular function and specific project. The matrix structure can adapt to response for various purposes and flexible to environment change but the officers who receive the assignment from two chains of command may difficult to manage their job and may have conflict in the organization [34].

The functional structure is the basic organization design which has the advantage and disadvantage. The organizational linkages can reduce the disadvantage of the functional structure. Each type of organizational linkages is suitable for some task and have to carefully choose for the structure design [34].

2.2.2. S&I framework of ONC

The Office of the National Coordinator for Health Information Technology (ONC) of the United States has created the standards and interoperability (S&I) framework as an approach to developing a model of health information exchange [35]. The S&I framework composes of community, process, and specifications, tools, and services which is needed to support health outcomes and improve the health information exchange [36].

S&I framework presents the development cycle for harmonized standard and enables interoperability between community and different information systems. The development cycle is shown in figure 3.

From figure 3, the main functions for development of standard compose of use case development and functional requirements, harmonization of core concepts, implementation specifications, reference implementation, testing, and certification. The use case development and functional requirement is the activity which the requirement of all relevant stakeholders will be identified and create the documentation of the use cases and functional requirement. For harmonization of core concepts, the different concepts will be integrated into a consistent concept. For Implementation specification, the interoperability specification will be developed. The reference implementation will provide the code, source code, and the supporting guidance to the software provider for standard compliant. Testing and certification are the activity to test and qualify the electronic health record technology. Tools and services may compose of use case development, harmonization tools, vocabulary browser, repository, testing script, and etc. [36]. This research apply the S&I framework and the definitions for developing the conceptual framework and operational definitions.

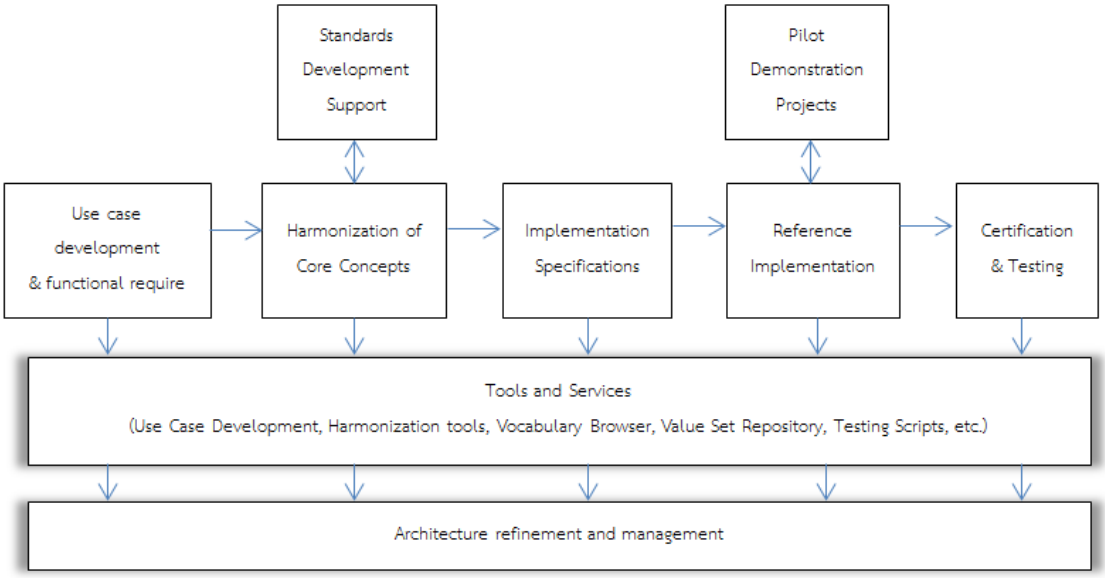

Figure 3 Development cycle of standard in S&I framework [36]

2.2.3 WHO's eHealth development model

World Health Organization also suggests eHealth development model as shown in figure 4. WHO's eHealth development model provides structural framework as a guide to strategic planning and implementation, monitoring and evaluation. WHO's eHealth development model suggests that the country should lay the foundations for development including governance governing body, policy, and funding. Creation of appropriate governing body to leading and providing the policy should compose of multi-stakeholders. Policy should be developed to providing the vision and action. Funding framework should be developed to support the vision, infrastructure and mechanisms eHealth services. WHO suggests four principles governance for eHealth consisting of accountability, participation, consistency, and transparency [15].

Second, enabling actions are required to serve eHealth interoperability policies to ensure that systems can exchange the information with another system. Building the ICT capacity of health professionals, protecting citizen, promoting access, and promoting equity for multilingual and cultural diversity, are functions of enabling action [15].

Finally, health applications including tools and services should be implemented to provide information service to citizen, training to health professionals [15].

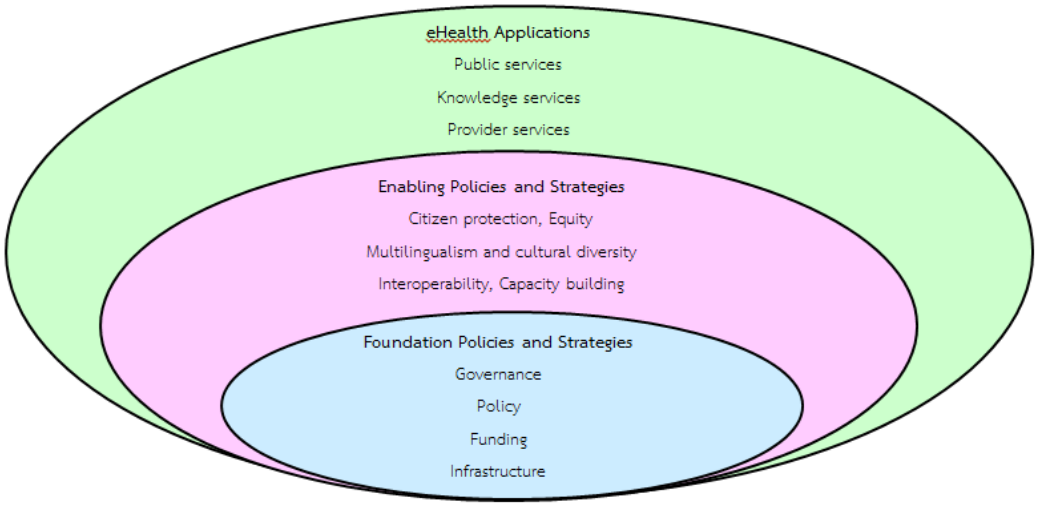

Figure 4 WHO's eHealth development model [15]

The foundation policies and strategies and the four principle of good governances of WHO's eHealth development model are applied to use in this research. Policy, funding, and structure will be the foundation of the collaborative structure in the conceptual framework.

2.2.4 Good governance principles

The concepts of the good governance principles were widely used and applied as the guiding principles in many areas. WHO also suggest the principles of good governances for eHealth governance [15]. The United Nations stated eight major characteristics of the good governance which are participation, rules of law, transparency, responsiveness, consensus oriented, equity and inclusiveness effectiveness and efficiency, and accountability. These principles were applied in Thailand for the public sector reform, good governance of public and private sector, business management, commerce and others. Eight principles of good governance and the description which are applied from the United Nation, the Office of the Public Sector Development Commission, and the Thai chamber of commerce are following [17-19]:

- Participation: The stakeholders have to get the chance to know, access, and understand the information, and participate in the process to discuss and make decision about the relevant issues and solving the problems. The stakeholders can participate in the process by themselves or participate through the institution, organization, or their representatives.

- Rules of law: Governance, management, or business control have to impartial enforcement of fair legal and protect the human rights.

- Transparency: The direct accessible channel or process of information should be set to making information freely available for the stakeholders in the form of easily understanding forms and media.

- Responsiveness: The responsible organization has to set the objective and process to response the requirement and expectation of the stakeholders within the suitable timeframe.

- Consensus oriented: The stakeholder requirement identification and condition conclusion process in the necessary issues should be set for finding and reducing the argument and making more understanding to reach a broad and long term consensus of stakeholders. The condition conclusion does not receive unanimous agreement from stakeholders.

- Equity and inclusiveness: All groups of stakeholder get equally opportunity to participate in the process as the relevant and receive the service.

- Effectiveness and efficiency: The organization and governance process are well-designed to response the need of stakeholders by using appropriate and cost-effectiveness resources in the acceptable timeframe. The clear objective, plan, and monitoring and evaluation system should be set for well and lasting development of the governance system.

- Accountability: The responsible organization and governance system have to set to answer the objective and expectation of the stakeholders and public society. The responsible organization have to realize and responsible for the effect of the decision and the administration to the stakeholders and public society.

2.3. Governance for health data standard and medicines terminology in advanced countries and Thailand

2.3.1 Case studies of health IT advanced countries

Health information technology enhances the quality and efficiency of health care, reduce medical error, increase patient safety, and reduce the cost of care [2, 3]. Many countries develop eHealth and integrate health IT into healthcare system to provide the scientific health information for clinical decision and policy decision [15]. To enable successful use of eHealth, the countries have developed health data standards for health information exchange between different systems and improve the governance system for standard and terminology. The countries which are the role models for medicines terminology development are the United States, the United Kingdom, Australia, New Zealand, and Hong Kong of China. The development of Thai Medicines Terminology (TMT) is based on the experiences and lesson learnt about terminology standard development from these countries [11]. According to

the research of Brendan Kernan (2011), the researcher selected the United States, the United Kingdom, Australia, and New Zealand as the case study. He reviewed and analyzed the development, implementation, and organization and governance to using the experiences of these countries to identify key components to create an organization framework for supporting drug catalogue in Ireland [37].

The United States is a country that has a clear policy about eHealth. The U.S. established the Office of the National Coordinator for Health Information Technology (ONC) to promote meaningful use of electronic health records and interoperability of health information since 2004 and enacted the Health Information Technology for Economic and Clinical Health Act. (HITECH ACT) in 2009 [38]. About drug information exchange, Food and Drug Administration created National Drug Codes (NDCs) which is the product identifiers identified by manufacturer and packager. The NDC code can be assigned by each manufacturer and the code may be reused. The NDC provide insufficient drug information for therapeutic use, such as therapeutic class, ingredient, and form. The standard for drug terminology is required; therefore, RxNorm was created in 2004 with standard names and identifier and it included NDC [20]. RxNorm was created by the cooperation of National library of Medicines with Food and Drug Adiministration and the Department of Veterans Affairs. At present, RxNorm is maintained by NLM [29]. In the U.S., many different healthcare applications have been used and they were supported by many different classifications and terminologies. The legacy systems are a major barrier for successful adoption of new standards because the stakeholders do not want to investment to change to use new terminology [37]. U.S. has created the coordination committee and community, and created many project to promote the harmonization of standard and accelerate new standard adoption [7].

The United Kingdom developed dm+d which is a dictionary of medicine and medical device standard for communication among health information system within the National Health Service (NHS) since 1999. dm+d composes of unique identifier code and text description for identify medicines and medical devices. It was approved by the Information Standards Board for Health and Social Care (ISBHaSC) and maintained by Health and Social Care Information Centre and the NHS Business

Services Authority [39]. dm+d has not standardized terminology which cannot interoperability with various clinical system. Therefore, UK adopted SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms) which is the international terminology standard with the principles of good terminology practice to support the information exchange in different system. SNOMED CT UK drug extension has the components of dm+d but it can provide the content of nine tables of dm+d in only three tables supporting the business requirement of NHS, and interoperability of reimbursement and clinincal information [40]. SNOMED CT UK drug extension has released since 2006 and updated every four week by the UK Terminology Centre (UKTC). The governance for development and maintenance for dm+d and SNOMED CT UK drug extension has developed and managed for many years. The terminologies is always update and the users can access easily on the website and can contacts to the helpdesk for the problem solving [39].

Australia is a country which is advance in development and implementation of medicines terminology. The Australian, State and Territory governments established the National E-Health Transition Authority (NEHTA) in 2005. Australian medicines terminology was developed in 2007 by the National Clinical Terminology and Information Service (NCTIS) within. Australian medicines terminology was developed by extended from the dm+d data model of UK and SNOMED CT for terminology. Australia has prepared the roadmap, implementation plan, and service and tool to support the adoption of stakeholders, such as prepare to map with GTIN [41].

New Zealand developed medicines terminology in 2009 by learning the experience from Australian medicines terminology, RxNorm, and GS1. New Zealand has established Health Information Standards Organization to support and promote the development, understanding, and use for health data standards to improve the national health system. New Zealand is a country that set up the system managing the development and maintenance of the medicines terminology. The National Health IT Plan was set up to enable sharing health care information for patient, care plan, and decision support in 2014. New Zealand has set up the mechanism for development of health data standards to ensuring that the standards are developed

with a coordinated and consistent approach. The maintenance schedule and process is set up to review the medicines terminology. The mechanism for development and maintenance composes of five main stages. Stage 1, standard requirement will be identified; then, proposal and plan will be set. Stage 2, drafted standard will be developed and will be evaluated for adjustment. Stage 3, drafted standard will be passed the process of public consultation. Stage 4, full standard will be approved and implemented. Stage 5, standard will be scheduled review and maintain. The organizations and stakeholders who associated with these processes are identified and invited to participate in these processes. The role of organizations, the roadmap for implementation, the services and tools are designed and set to harmonize and integrate the New Zealand medicines terminology in the eHealth system [22, 42].

Hong Kong has been developed EHR program since 2009 and established the policy to develop the health data standard for interoperability. The organization structure for eHR information standard was established for development, implementation, and maintenance of eHR information standard [43]. Hong Kong medication terminology has been developed for eHR interoperability. The development of Hong Kong medication terminology is divided into four phases: defining data sets, import to medication terminology table, mapping with Snomed-CT, and full co-production [44].

In Canada, Standard Collaborative was established within the Canadian Health Infoway to support and maintain health data standards. Role and responsibility of the stakeholders and the processes for developing and maintaining health data standards have been identified. [4].

The United States, the United Kingdom, Australia, New Zealand, Canada and Hong Kong have the experience in governance for development and maintenance of medicines terminology. These countries are interesting and are selected as the case study to review their health data standard and medicines terminology governance experiences. The experience of these countries will be useful for creating a governance model for Thailand standard medicines terminology. This research will review these countries and analyze the governance model for health data standard

and medicines terminology of these four countries to develop the governance model which is appropriate for Thailand.

2.3.2 Situation of Thailand

The situation of governance for health data standards, drug codes, and medicines terminology in Thailand is also important for developing the governance model. According to the study of Kijsanayothin and his colleague (2010), Thailand did not setup foundations and mechanism to develop and maintenance health data standards [10]. Therefore, many silo type information systems were developed and many standard drug codes have developed for specific purpose, such as drug registration code, twenty-four digits drug code, GS1 code, hospital working code, and so forth. Some standard drug coding system has own governance system. Moreover, these systems do not have mechanism to support the information exchange with other systems [11].

Thailand has many organizations involve with the standard drug code and medicines terminology such as Bureau of Health Administration, Thai Food and Drug Administration (Thai-FDA), Thai Health Information Standard Development Center (THIS), Cluster for Health Information Standard Development in Ministry of Public Health, and so forth. Bureau of Health Administration develops and maintains 24 digits drug code. Thai-FDA has the role to register new drugs and develops the drug registration number [13]. THIS has the role to develop the health data standard by coordinating with the stakeholders, such as THIS cooperate with Thai-FDA and the Comptroller General's Department (CGD) to develop Thai Medicine Terminology [13, 45, 46]. Cluster for Health Information Standard Development within Bureau of Policy and Strategy, Ministry of Public Health has the role to collect health data and information, develop health data standards and coding by assigning and disseminating to the relevant organization [47].

Although Thailand has many organizations involved with standard drug code but a well-designed governance system for develop, maintenance, and harmonization of national health data standards including medicines terminology has not been set up. Main organization which provide policy, develop, maintain,

harmonize the core concept of various drug codes and medicines terminology, facilitate, and support the adoption of medicines terminology to be used within national health information systems, is also not present. In addition, the mechanism for development and maintenance of medicines terminology which is accepted from every stakeholder has not been setup as other countries advancing in health information technology system [11]. This leads to the problem in managing of national terminology standards and drug standard code. An example of the problem in governance for development and maintenance of drug code can be found from the 24 digits drug code system. The 24 digits drug code was announced to be the standard drug code for drug information exchange in health care system [12].

Thai food and drug administration is responsible for create drug registration code and send drug information to Bureau of health administration to generating 24 digits drug code. These drug codes will be sent to Bureau of policy and strategy for announcement and sent to the relevant organization for mapping this code with existing working code, such as hospital, Government Pharmaceutical Organizations, the Comptroller general's department, and etc. These organizations are co-operate in the form of committee [13]. Because of no governing organization for providing policy, coordinating for maintaining the drug code, harmonizing with other standard code and reviewing and improving standard code, the 24 digit drug code system is facing the problems of updating standard, mapping with other standard code and the coverage of drug entity in Thailand (around 5-10% of drug items used in big hospitals and the hospital extemporaneous drugs are not in 24 digit drug code system database) [11].

According to the problems of various drug codes and the governance system, the government launched the policy to develop new national medicines terminology for healthcare systems especially for reimbursement system of three health insurances schemes, and develop the system for national medicines terminology for using in medical care and reimbursement especially in three health insurances schemes. Thai Medicines Terminology has been developed in 2012-2013 but the governance system of national medicines terminology has not been developed [11].

The 24-digit drug code and TMT were both assigned to develop by governmental agencies and the administrative organizations have no formal authority to co-operation and enforcement. The development of the 24-digit drug code and TMT were both assigned as the policy setting from the government agencies which the stakeholders did not participate and present their requirement in the policy setting and development process.

The national medicines terminology should be able to harmonize with other drug codes, schedule update, and integrate into health information system. The governance system is required to enable the effective use of national medicines terminology. This research will develop the governance model by learning the experience from the advanced countries and review the current situation of the governance of standard drug code and terminology in Thailand to design the governance model which is appropriate to Thailand context.

2.4. Participatory design

Participatory design (PD) originated in Scandinavia which enrolls the stakeholders in the process of design. PD process allows the stakeholders showing their real expectation and gives the right to participate in decision process. PD can improve the stakeholder' s knowledge when the stakeholders participate in design process, and it can reduce the resistance to change of stakeholders to the new system implementation. PD is different from other design approaches which emphasize on technology and system development but PD also realize to change and development of stakeholders, organization, and practice [48].

PD is widely used in many research areas, such as product innovation, software, communication, social innovation, governance, education, architecture, informatics, health information system, and etc. [49-55]. In informatics area, PD is used as a standard design for developing information systems, governance of information system, applications, infrastructures, practices, and related works [55]. New national standard development and maintenance affects many stakeholders, the stakeholder involvements in any process are important [56]. Therefore, this research selects the PD design which is a suitable method to design the governance

model for terminology standard.

The stakeholders have the important role in the participatory design process. From the research of Vink P., Imada A.S., and Zink K.J, the researchers questioned that which participants should be involved in which stage of work place or organizational improvement. They found that the designers had the important role in idea generation and prototyping. The involvement of top governance and middle governance depended on the type and scope of project. Top governance and middle governance should be involved to setting the goal and strategy of the organization. The workers should be involved in all steps, especially in the step of situation analysis, idea generation, and testing. They have known the work procedure and normally done their job. They have ideas for organization improvement and they can test that the new organization improvement suitable to the task or not. Defining stakeholders in participatory design is based on the scope of the project. The understanding of the stakeholders concern will help to identify that which stakeholders should participate in which step [57].

PD researcher has to be a facilitator and empowers the stakeholders to co-design and make the decision for design conclusion. The method of PD design is always tailored made to the project and use many research methods, such as observation, interviews, document analysis, prototyping and etc. [52, 57]. The basic steps of participatory design research include [52, 57, 58]:

1) Design planning: Main focus of design and planning for process of design will be set up in this step. The stakeholders should be identified and the identified stakeholders have to be informed to participate in this step [52, 57, 58].

2) Current situation analysis: The work flow, work procedure, teamwork, technology used, experienced problem, and others related to work should be explored in this step. The ethnography method should be used in this step, such as observation, interview, site visit, artifact examination, and etc. [52, 57, 58]

3) Idea generation and selection: This step will explore the possible design solutions, analyze the feasibility design, and conceptualize the design [52, 57, 58].

4) Prototyping: One or more model is designed. The various techniques can be used in this step, such as scenarios, mock-ups, case-based prototyping, paper

prototyping, and cooperative prototyping. Prototyping technique creates the tangible model representing the underdevelopment system which facilitates the stakeholders and the designer to providing feedback and thinking about the usability problems before concluding the final system [52, 57-60].

5) Testing and modification: The first prototypes cannot reflect the actual participant ideas; therefore, the first prototype has to be tested by the users. The designer will collect the feedback and problems for improving and concluding the model [52, 57, 58, 61].

These processes may be iterated many times. Current situation analysis, idea generation and selection, and prototyping process are the processes that are found in almost participatory design research [48, 57, 58]. In some researches, the processes of implementation, maintenance and evaluation are included in the design process [48].

2.5. Usability testing and heuristics evaluation

Usability testing is a cost-effective method to find the usability problem of the design for improvement before implementation. Usability testing is widely use in the software design. There are many methods for usability testing, such as heuristics evaluation, cognitive walkthroughs, formal usability inspections, pluralistics walkthroughs, feature inspection, consistency inspection, standards inspection, and think aloud [62, 63].

Heuristics evaluation is a most popular and common usability test method for testing health technology by identify the principles or heuristics which is relate to the design and experts examine the design prototype & assess the compliance with usability principles (heuristics). It is quick, cheap, and suitable for usability problem detection. Limitation of this method is the heuristic guideline often generally described which the evaluators may interpret in the different way. The results of the study affected by the expert skill [62, 63].

There are a few researches compare heuristic evaluation method with other method, such as cognitive walkthrough and found that heuristic method can identify more problem than cognitive walkthrough with less effort & time. But both methods

have limitation and should combine with other techniques. Heuristics evaluation method often combines with other techniques, such as use case scenario, think aloud, and etc. to reduce the limitation of this method. For testing the application, fourteen heuristics was used for testing, such as consistency, visibility, match, minimalist, memory, feedback, flexibility, message, error, closure, undo, language, control, and document [62-65].

Heuristics evaluation is applied to assess usability in health application and many areas. This method widely applied &modified to assess usability of the application design in health care area, such as electronic health record systems, infusion pumps implications for patient safety in intensive Care Unit, and patient safety of medical device. Heuristics evaluation is also applied to assess usability test in other arrears, such as the usability test of the architecture design which applied the architecture principles as the design consideration for usability testing [65-71].

Heuristic evaluation procedures include four main steps as follows [62, 65, 70, 72]:

1. Create heuristics with description tailored to the specific design
2. Choose the experts and train the experts on heuristic evaluation method
3. Experts review and identify usability problems of a design
4. Collect and analyze usability problems

For evaluation, the evaluators examine the design and evaluate according to its heuristics as severity rating or problem description [62, 65, 70, 72].

Use case scenario is a technique that uses to demonstrate the system and evaluate the user requirement for the system and the design problem in heuristic evaluation. Use case scenario consists of two important parts include use case and scenario. Scenario describes the interaction between the system and the actors that occur within the conditions to achieve the goal. Use case demonstrate possible system scenarios and the actors [73]. The use case scenario was applied to used for heuristics evaluation, such as the electronic health record usability test which create the use case scenarios to describe the role of the relevant and the situation of the electronic health record use for identifying the usability problem [72].

Chapter III

Methodology

This research aims to create the governance model for health data standard in Thailand by using medicines terminology as a case study which is appropriate to Thailand context and accepted from stakeholders. Participatory design method is suitable to use in this research. The concepts and processes of participatory design will be applied to develop the governance model and multi-technique of qualitative research will be used in each stage. The heuristics evaluation technique is applied to test the first prototype of the governance model.

The research is designed in three stages which are applied from the process of participatory design as figure 5. The three stages are designed to answer three research questions and objectives include review the experience of advance country, review current situation in Thailand, and develop the governance model for medicines terminology in Thailand. The details of research design in three stages are described as follows:

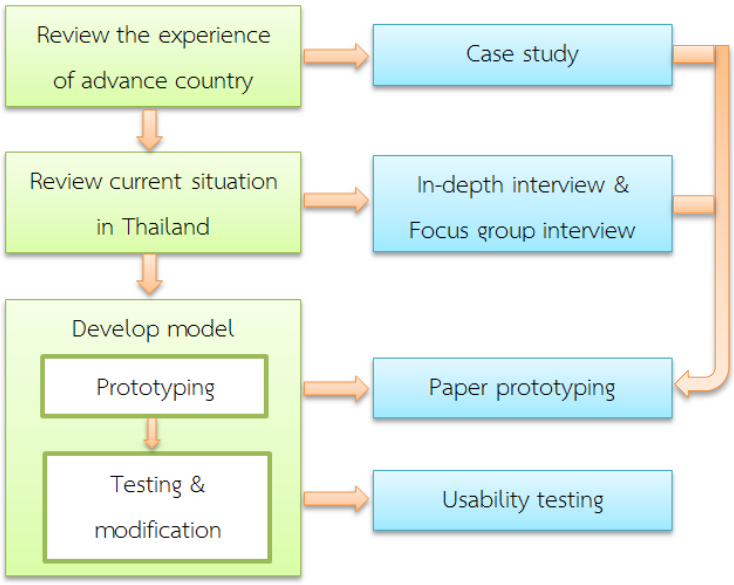

Figure 5 Research methodology

1) Review the experience of advance country: The governance system for health data standard and medicines terminology in other countries will be reviewed and used to generate design idea. In this stage, the case study is selected as an

appropriate method. Case study is widely used in organizational study, health service study, and various fields [74, 75]. Yin (2003) states that a case study is a suitable design to answer how and why question [76]. Case study can use to study the context and phenomena of the complexity system [75]. The procedures of case study design as following steps:

1.1) Selecting case study: Selecting case study is first step of case study method. Case study should be typical and fit the criteria of research. Literature review or expert interview are the suggested procedure to finding the certain case study [74]. In this study, case study is required to generate the design idea. The countries which advance in governance of standard and terminology are appropriate to choose as case study. According to literature review in chapter II, the US, the UK, Australia, New Zealand, Canada, and Hong Kong of China are the advanced countries which have the experience in governance for health data standard and medicines terminology. These countries are the role model and selected as case study in the previous researches [4, 11, 38, 77, 78]. These countries use English as national language which we can find and review the information about their governance for health standard and medicines terminology. The US, the UK, Australia, New Zealand, and Hong Kong of China are chosen as case study and each country is a unit of analysis.

1.2) Data collection: Data of each country was collected by searching from the websites, and documentation review. The case study method needs to explore in depth; therefore, some focus of case study should be set [74]. In this study, the conceptual framework in chapter I was used as the framework to collect the data. The data about collaborative network with the foundations, process, and services and tools for development and maintenance health data standard and medicines terminology within the country were collected.

1.3) Data analysis: Data was analyzed according to the conceptual framework. The governance model of each country was analyzed. The stakeholder collaborative networks and foundations, the necessary functions for health data standard and medicines terminology governance, and necessary services and tools was analyzed to generate the design idea.

2) Review current situation in Thailand: Multi-technique of qualitative research was used in this step, such as documentation review, in-depth interview, and informal focus group interview. This step collected the data in three issues as follows:

- Current situation of drug code and medicines terminology governance in Thailand
- The problems of current governance system
- Suggestion for governance model development will be collected.

The methods for review current situation in Thailand are described as follows:

2.1) Defining stakeholders and sampling method: Due to this step aims to review the current situation of governance system for drug codes and medicines terminology, the targets of analysis are divided into two groups. The group of developer and maintenance administrator to share the situation about the working for development and maintenance of drug code or medicines terminology, and the group of user to share the situation about using drug code or medicines terminology.

- Developer and maintenance administrator group includes the stakeholders who associate with the development and maintenance of drug registration code, 24 digit drug code, GS1 code, and Thai medicines terminology.

- The user group includes the stakeholders who use drug code and medicines terminology for interoperability. The user group divides into three subgroups:

  - The group of stakeholders who use drug code and medicines terminology to prepare drug information for medication and reimbursement, such as university hospital, regional hospital, community hospital, and provincial health data center.
  - The group of stakeholders who use drug code and medicines terminology for reimbursement administration, such as National Health Security Office, Social Security Office, and the Comptroller General's Department.

- The group of drug manufacturers and distributors who use drug code and medicines terminology for drug procurement in the hospital.

Sample size is 3-10 key informants of each group of stakeholders. First, the experts from the Committee for Medicines Terminology Development appointed by Ministry of Public Health will be selected as the key informants. The Committee for Medicines Terminology Development composes of the developers and maintenance administrators of 24digits drug code, GS1, drug registration code, and Thai medicines terminology. The representative from the university hospital, National Health Security Office, and the Comptroller General's Department were also appointed as the committees.

Second, the researcher asked the experts in the first steps to advice other key informants cover all group of stakeholders. The inclusion criteria: the key informants should have the experience about development, maintenance, or use drug code at least one year.

2.2) Data collection: In-depth interview and informal focus group interview were the main techniques for data collection in this step.

In-depth interview is the unstructured interview which is the researcher and interviewee naturally interaction. The researcher asks an open-end question and encourage the interviewee to freely describe [77]. This method helps to explore the complexity phenomena, and provides better detail about the interviewee understanding and experience [79].

Focus group interview is a method that encourages the group of participants to describing and discussing their perception, interpretation, and belief to gain the information in a specific interesting issue. Although the researcher does not have a deep knowledge in that topic and does not know much about the participants, the focus group interview can use to find out the knowledge and experience of the interesting population. Focus group can combine with other approach as multi-method studies, such as observation, in-depth interview, and so forth [79].

The use of more than one methods, data sources, theories, and researchers in a research enhances to ensure the research finding, increase validity of study, and eradicate personalistic biases that occurred from single theory, or single methodology called Triangulation [79, 80].

For data collection, documentation review and open ended in-depth interview were used to collect the data. The interview might be iteratively done until acquire enough data. The stakeholder consultation was arranged after finish the data collection to confirm and recheck as triangulation for ensure the validity and eradicate bias of the finding result.

Theme lists for in-depth interview and informal focus group interview are listed for each group of stakeholders as follows:

- Developer and maintenance administrator group:
    - What is the current policy to develop drug code or medicines terminology and the problems of the current policy?
    - What is the source of funding for development and maintenance drug code or medicines terminology?
    - What are the organizations that involve with development and maintenance drug code or medicines terminology?
    - How do these organizations working together?
    - How do the administrators develop and maintain the drug code or medicines terminology?
    - What are the functions that necessary to development and maintenance drug code or medicines terminology?
    - What are the necessary services and tools?
    - What are the organizations providing necessary services and tools?
    - How do the organizations provide necessary services and tools?
    - What are the problems in development and maintenance drug code or medicines terminology?

- What are the suggestion for develop the governance model for medicines terminology? (The idea from advance country may be added to increase the information)

- User group

- What are the objectives and useful of using drug code or medicines terminology?
- How do the users work with the organizations related to the governance for drug code or medicines terminology?
- Does the governance system for drug code or medicines terminology provide sufficient information and serve the user need? And How?
- What are the services and tools that users need to support the using of medicines terminology?
- What are the problems of using drug code or medicines terminology?
- If the users have to change current drug code or medicines terminology to new system, what are the problems of switching drug code or medicines terminology system?
- What are the suggestion for develop the governance model for medicines terminology? (The idea from advance country may be added to increase the information)
- What are the organizations that the users want to send the drug information to generate medicines terminology and inform the problem?

2.3) Data analysis: Data was coded and interpreted according to the conceptual framework. Data analysis was conducted along with data collection period, iterative process of data collection will occurred if the data is insufficient. Interpreting data was used to draw the whole picture of current situation of governance model for medicines terminology.

3) Develop the governance model for medicines terminology in Thailand: In this step, the idea from previous steps was used to develop the governance model for medicines terminology in Thailand. The procedures for the governance model development were described as follows:

3.1) Prototyping: The idea from reviewing the experience from advanced countries, the current situation of governance system for drug code and medicines terminology in Thailand, and the suggestion from stakeholders were used to create first prototype of governance model. Paper prototyping is a simple and fast method for prototyping. It is a widely use method for designing and testing the application or system [81]. In this step, the governance model was created by using paper prototyping technique. The model was created on paper presenting the structure of community for medicines terminology governance, role of the organization in the community, process flow, and services and tool which is required along with governance process and required for supporting users. The process flow was presented as the process for set up the policy, development, maintenance, and providing service for medicines terminology. The organizations responsible in each process and responsible to provide services and tools were designed and presented in this paper prototype.

The stakeholder consultation seminar was arranged for current situation conclusion and consulted the first prototype of the governance model to the stakeholders. The suggestion of the stakeholders was collected and concluded the second prototype.

3.2) Heuristics evaluation: Second prototype was tested by stakeholders and collected the feedback to modify and conclude the final model. In this research, heuristics evaluation will be modified for governance model testing. The use case scenarios of development, implementation, maintenance, and use of medicines terminology were created for model testing.

The good governance principles which are reviewed in chapter two were applied to create the model design consideration and the evaluation sheet for model evaluation and collect the feedback of the experts. The good governance principles, the model design consideration, and the evaluation sheet were verified by

an expert who was trained, work, and responsible about the good governance of the organization at least five years.

Inclusion criteria: six experts who have at least two years experienced and still operates related to drug codes and medicines terminology including policy maker, medicines terminology administrator, drug manufacturer, national health insurance reimbursement administrator, and hospital user were invited to the testing process. The researchers described the good governance principles which are applied to the model design consideration, and describe the role of the stakeholders and the process in each use case scenario. The experts were asked by the researcher to evaluate each process and model design consideration by rating the severity of the model design problem according to the severity rating scales, and discuss the problem and recommendation with the researcher. The researcher collected the recommendations from the experts and concluded the final model.

4) Ethics: The ethical issue was concerned in this study. The key informants and participants were invited as the voluntary participation. The researcher introduces the name and background of the researchers as a doctoral program student to the participants. The researcher explains the participants about the research topic, objective, methodology, data collection, and data analysis, the process and consequences of the study. The data of the participants has been confidentially kept. The participants were described that how they would be participated in this research, the researcher asked the permission from the participants, and the participants signed the consent form.

This study was approved by The Ethic Committee of The Pharmaceutical Sciences, Chulalongkorn University in 2013 (Protocol Review No. 13-33-027).

Chapter IV

Results and discussion

4.1. Introduction

This study aims to review the governance of health data standard and medicines terminology in the countries advanced in health information technology, explore the current situation of governance of drug standard codes and medicines terminology in Thailand, and develop the governance model for health data standard in Thailand by using medicines terminology as a case study. The data collection was conducted on September 2013-September 2014.

To review the governance of medicines terminology in the countries advanced in health information technology, six advanced countries were reviewed by documentary review and searching the information from the main responsible organization websites in each country, such as the United States, the United Kingdom, Australia, New Zealand, Canada, and Hong Kong of China. In this section, the governance of health data standard and health information technology which related to medicines terminology was also reviewed to better understand about the medicines terminology governance in these countries. The data of each country was reviewed in three main components according to the conceptual framework, foundations, processes, services and tools. For foundations, the researcher reviewed the policy about health information technology and health data standard including medicines terminology development, main responsible organization and related collaborative structure, and funding resources for the governance of health data standard and medicines terminology in each country. For processes, main processes for health data standard and medicines terminology development, implementation, and maintenance were reviewed. The services and tools, such as public services, knowledge services, and necessary tools enhancing the user adoption of health data standard and medicines terminology were reviewed.

To explore the current situation of governance of drug standard codes and medicines terminology in Thailand, the current situation was studied by multi-

technique of qualitative research, such as documentation review, in-depth interview, and focus group interview. Overall, thirty-two key informants and 16 hour and nine minutes were interviewed for the current situation of the governance of medicines terminology in Thailand. Sixteen key informants were individual in-depth interviewed. The informal focus group interviews were arranged two times. Five manufacturers participated in first informal focus group. Eleven key informants from the provincial public health office and the hospitals in the province participated in second informal focus group interview. Theme lists were used for in-depth interview and informal focus group interview to collect data about the current situation, the problems, and the suggestion for the governance model.

Table 1 Key informants interviewed for current situation in Thailand

Key informants	Amount
Drug code &medicines terminology administrator	3
Policy maker	1
Thai-FDA representative	1
Hospital officer	17
health insurance schemes administrator	2
Officer of provincial health data center	3
drug manufacturers &distributors	5

To develop the governance model for medicines terminology in Thailand, the idea from advanced countries review and current situation of Thailand was used to draft the first prototype. The first prototype model was shown in appendix 5. The first prototype model demonstrated three main components of governance model for medicines terminology according to conceptual framework, such as foundations, processes, and services and tools. Forty-five stakeholders participated in the Thailand current situation conclusion and fist drafted prototype consultation. The consultation seminar was arranged on March 28, 2014 from 9.30 am to 15.00 pm. The stakeholders include drug code and medicines terminology administrators, policy

makers, Thai-FDA representatives, hospital officers, health insurance scheme administrators, officers of the provincial health data center, drug manufacturers and distributors, and academicians. The suggestions of stakeholders were collected for second drafted prototype improvement.

The heuristics evaluation was applied for governance model usability testing and find out the usability problem of the second drafted model. The use case scenarios were developed to demonstrate and describe the governance model for medicines terminology. The use case scenarios were shown in appendix 1. The good governance principles were applied to create the model design consideration and the evaluation sheet for model evaluation. The evaluation sheet was verified by an expert before use for usability testing. The evaluation sheet was shown in appendix 2. Six experts including policy maker, medicines terminology administrator, drug manufacturer, national health insurance reimbursement administrator, and hospital user attended in the model testing. The experts evaluated the usability of the model in the evaluation sheet, then discussed and concluded the problem and recommendation for final model. The results of usability testing were analyzed and concluded the final governance model for medicines terminology.

The findings according to these objectives will be presented in this chapter. The findings are divided into three sections. The first section presents the analyzing results of the reviewing of the governance of health data standard and medicines terminology in the countries advanced in health information technology. The second section presents the current situation governance of drug standard codes and medicines terminology in Thailand. The last section presents the governance model for medicines terminology in Thailand.

4.2. Governance of health data standard and medicines terminology in countries advanced in health information technology

4.2.1. United States (U.S.)

4.2.1.1 Background and medicines terminology related policy

In 2003, U.S. launched the Medicare Prescription Drug Improvement and Modernisation Act (MMA) to accelerate e-Prescribing and eHealth policy. This policy requires health data standards for electronic prescribing interoperability and RxNorms was initiated as medicines terminology by the cooperation of National Library of Medicines, U.S. Food and Drug Administration, and Department of Verterans Affairs [37, 82].

Medicines terminology is one of the health data standards which the U.S. developed for electronic health information exchange. According to the MMA policy, health data standards and eHealth has been developing. The governance of HIT including health data standards and medicines terminology of the U.S. has also developed, the U.S. established the Office of the National Coordinator for Health Information Technology (ONC) within the U.S. Department of Health and Human Services (HHS) as the HIT administrator. The ONC is the national coordinator to support health data standards development for electronic health information exchange and legislative mandated according to Health Information Technology for Economic and Clinical Health Act (HITECH Act) in 2009. [38, 83].

HITECH Act is an important legal to promote the HIT adoption and electronic health record (EHR) development. The HITECH Act authorized the ONC to setup the program and promote the adoption of “the meaningful use of health IT policy” [78]. The meaningful use of health IT policy is an important policy to stimulate the adoption of health data standards and medicines terminology interoperability for electronic health record (EHR) [84, 85]. The goal for meaningful use of EHR was set to promote the use of electronic health record and provide the information for the health care professional and policy maker which enhance to improve quality of health care in the U.S. The meaningful use of EHR provide many benefits, such as more information about patient to the health care providers, easily access and share

the patient information between the hospital, and empower the patients to share medical information with their family [84, 85]. The meaningful use of health IT policy was set in three stages as follows [84]:

Stage 1 Data capture and sharing (2011-2012): This stage focus on standardized the health information and communicating the information for health care [84].

Stage 2 Advance clinical processes (2014): This stage focus on increasing health information exchange between the health care providers especially e-prescribing and laboratory results, and empower the patient to use and control their data [84].

Stage 3 Improved outcomes (2016): This stage focus on the using health IT and EHR to improve health outcomes of the citizen and use for decision support in national level [84].

4.2.1.2 Collaborative structure and funding resource

For policy setting, an HIT Policy Committee and an HIT Standards Committee were appointed according to the American Recovery and Reinvestment Act of 2009 (ARRA) and these committees work under the Federal Advisory Committee Act (FACA). HIT Policy Committee acts as a federal advisory committee providing recommendation and approve the health IT policy to the National Coordinator. The HIT Policy Committee also consist of the sub-committee which is the workgroup to provide the suggestion for HIT Policy Committee for specific area, such as certification/adoption, meaningful use, governance, and so forth [86]. For health data standard policy setting, HIT Standard Committee provides the recommendations about the standard for interoperability. The HIT Policy Committee also consist of the sub-committee which is the workgroup to provide the suggestion for HIT Policy Committee for specific area, such as certification/adoption, meaningful use, governance, and so forth [86]. The policy framework about health IT, standard, certification criteria may be proposed by ONC and these committees will provide comment, recommendation, or approve the policy framework [87].

As previously mentioned, ONC is the national coordinator to develop, support, and promote the use of health data standards and health IT. The budget of ONC derives from the Fiscal year congressional budget of Department of Health and Human Services (HHS). ONC organization structure is shown in figure 6 [38].

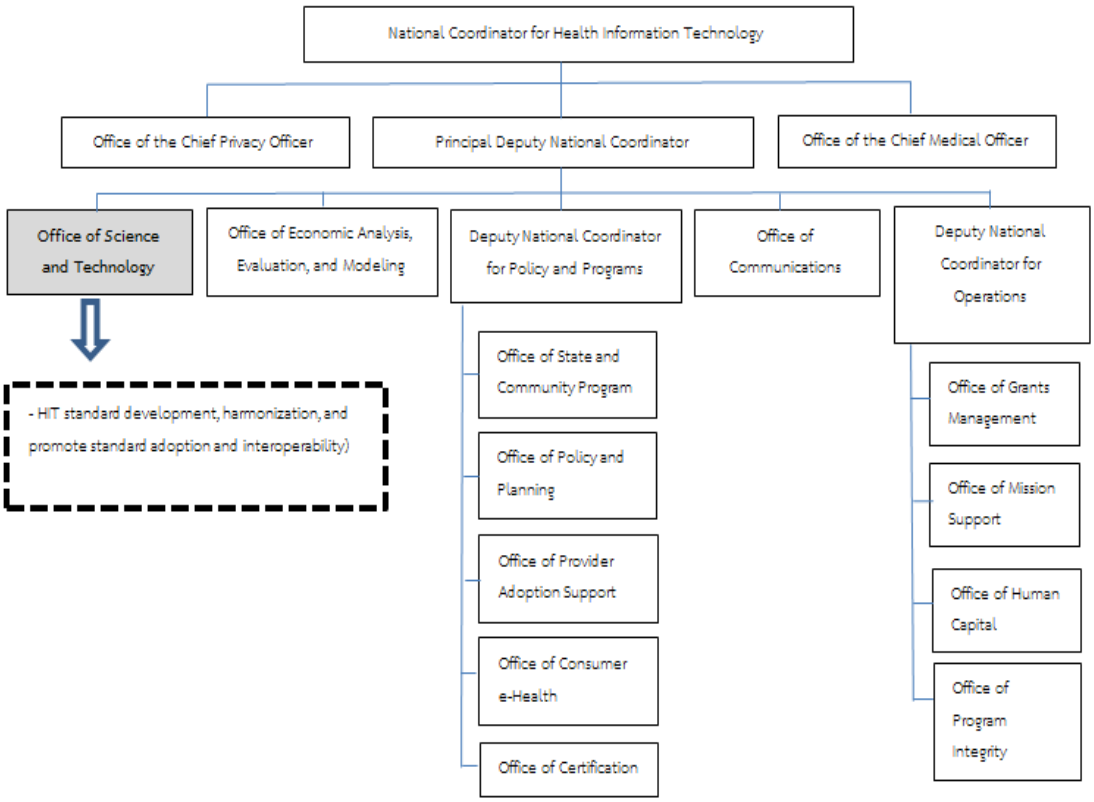

Figure 6 Organization structure of Office of the National Coordinator for Health Information Technology [85]

To facilitate the health data standard development and adoption, ONC set up the S&I Framework Community which allow the public and private sector to working together to create, harmonize, and solve the problem about the standard and interoperability in the U.S. S&I Framework Community have the important role to empower the stakeholders to establish health standard for interoperability. The community consists of individuals and organizations in both public and private sector, such as consumer/patients, health care providers, government organizations and agencies, standards development organizations, health IT vendors, payers, and other stakeholders [14].

For terminology development, National Library of Medicine (NLM) has the important role to develop and distribute the clinical vocabulary and support the interoperability through terminology. NLM is established within the National Institutes of Health, US Department of Health and Human Service. NLM is the main coordinating body for health data standard development and cooperate with ONC for health IT development. NLM developed and maintained RxNorm, develop other clinical vocabulary standards, and developed many tools for EHR certification and meaningful Use [88-90].

4.2.1.3. Process

Development process

ONC developed the development cycle for harmonized standard and enable interoperability between community and different information systems. The development cycle is shown in figure 7.

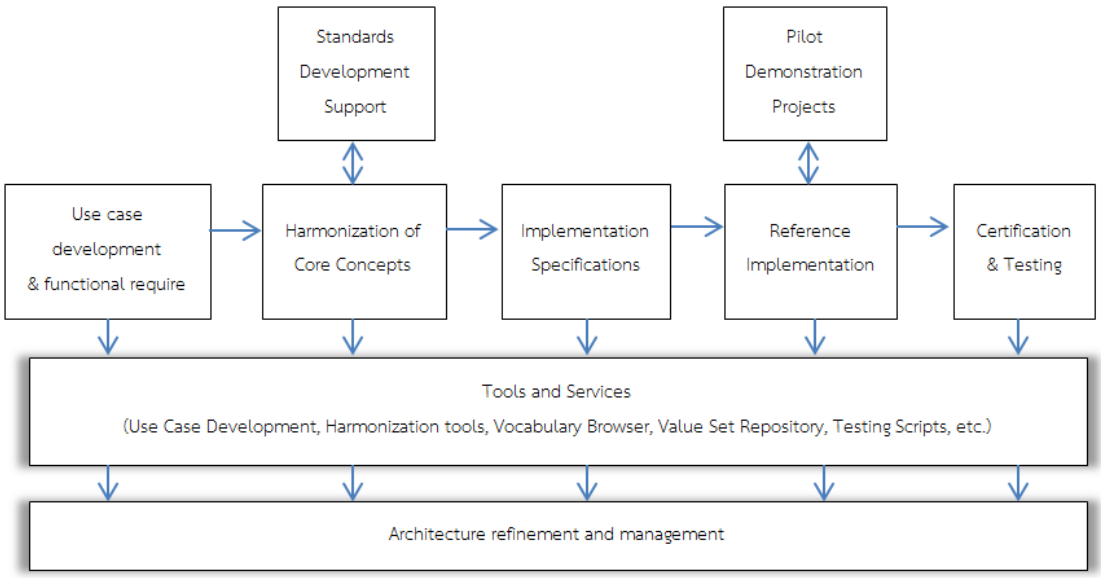

Figure 7 Development cycle of standard in S&I framework [36]

From figure 7, the main functions for development of standard compose of use case development and functional requirements, harmonization of core concepts, implementation specifications, reference implementation, testing, and certification. The use case development and functional requirement is the activity which the

requirement of all relevant stakeholders will be identified and create the documentation of the use cases and functional requirement. For harmonization of core concepts, the different concepts will be integrated into a consistent concept. For Implementation specification, the interoperability specification will be developed. The reference implementation will provide the code, source code, and the supporting guidance to the software provider for standard compliant. Testing and certification are the activity to test and qualify the electronic health record technology. Tools and services may compose of use case development, harmonization tools, vocabulary browser, repository, testing script, and etc. [36].

For medicines terminology development, RxNorm was developed by NLM. Drug names and drug information are collected from 11 data sources, such as Gold Standard Drug Database, Medi-Span Master Drug Data Base, Medical Subject Headings (MeSH), Multum MediSource Lexicon, Micromedex RED BOOK, FDA National Drug Code Directory, FDA Structured Product Labels, FDB MedKnowledge (formerly NDDF Plus), Veterans Health Administration National Drug File - Reference Terminology, SNOMED Clinical Terms (drug information), Veterans Health Administration National Drug File. The drug information will be analyzed and processed to be the outputs into RxNorm files [88].

Maintenance process

RxNorm has maintained by NLM. New drug information from FDA Structured Product Labels source will be send to updated new RxNorm. RxNorm updates weekly and full monthly release. RxNorm users have to free register for UMLS terminology services and use the account to download RxNorm release files and release notes from website. Release notes will contain the information about vocabulary updates and changing data. The RxNorm technical documents are also provided by NLM on website. The users can send comments and ask questions about RxNorm by email [88].

4.2.1.4. Tools and services

Both ONC and NLM provide the EHR, interoperability, and health data standard information on the websites and the courses of training has arranged for the

stakeholders in both e-learning, in-class training, and in-house training [91, 92]. ONC and NLM also provide the grant and scholarship for projects and researches about EHR, health data standard, and interoperability development and promote adoption [89, 93, 94].

ONC provides the suggestion, guideline, and tools for EHR implementation which the users can find these resources and tools on the ONC website in the topic "How to implements EHR". In addition, ONC has set up many projects and training for health care professional and other stakeholders to stimulate the adoption of EHR [38, 95].

S&I framework community was set up by ONC to promote health data standard adoption and interoperability, and the stakeholders can register to the community to exchange knowledge and experience about health data standard implementation. ONC provides the information, toolkit, and shares the best practice of health data standard implementation on the website [96].

NLM provides the technical guidelines, and training about RxNorm and other terminologies to the health care professional, other users, and technology vendors [92].

4.2.2. United Kingdom

4.2.2.1. Background and medicines terminology related policy

The UK initiated health IT policy in 1998 to promote the use of health IT for health care decision support. From 1998-2002, there are many documents suggesting the UK to develop the health IT. The important document was developed in 2002 named "Delivering 21st century IT support for the NHS: national strategic programme", the vision and strategy about eHealth was set up in National Health Service(NHS) and the health IT plan was integrated in the NHS plan. The health IT policy from 1998-2002 was conclude in figure 8 [97].

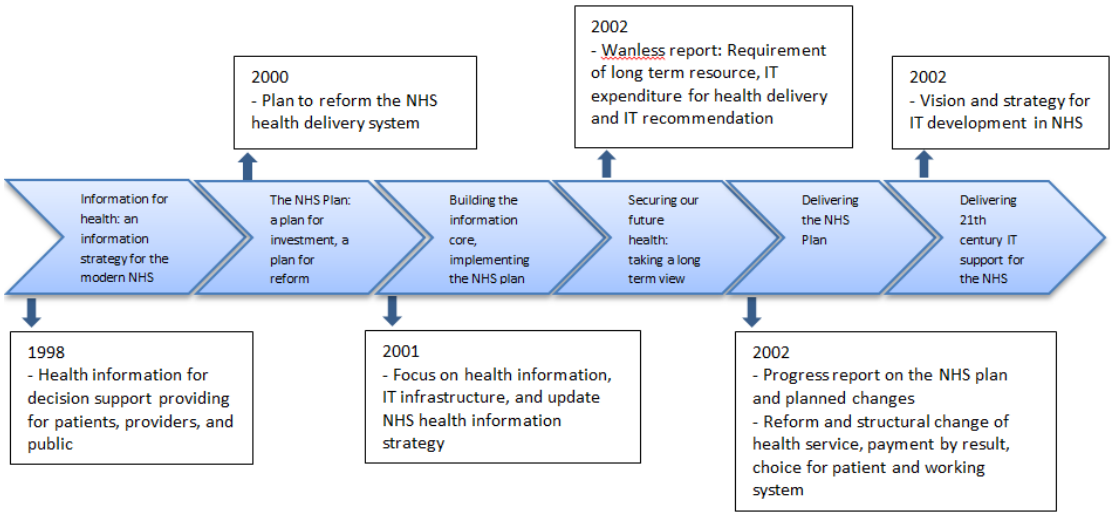

Figure 8 Policy documents for eHealth 1998-2002 [97]

In 2010-2012, the NHS has been reviewing the eHealth policy and set a new ten year strategy to support the using information and new technology to increase health care quality and outcomes. The new strategy named "The Power of Information – putting us all in control of the health and care information we need" focus on many issues, such as secure online access for personal GP record in 2015 (personal data which is record by general physician), online booking to GP in 2015, encourage adoption of health care providers, online prescription and label with barcode, online communication between health professional and patient, and online information support on trusted website. This new eHealth strategy has set according to the Health and Social Care Act 2012 and government information principles. The seven government information principles are shown in figure 9. The department of health has used these principles to set up the appropriate health information system to support the health care delivery of NHS and associated organizations [98].

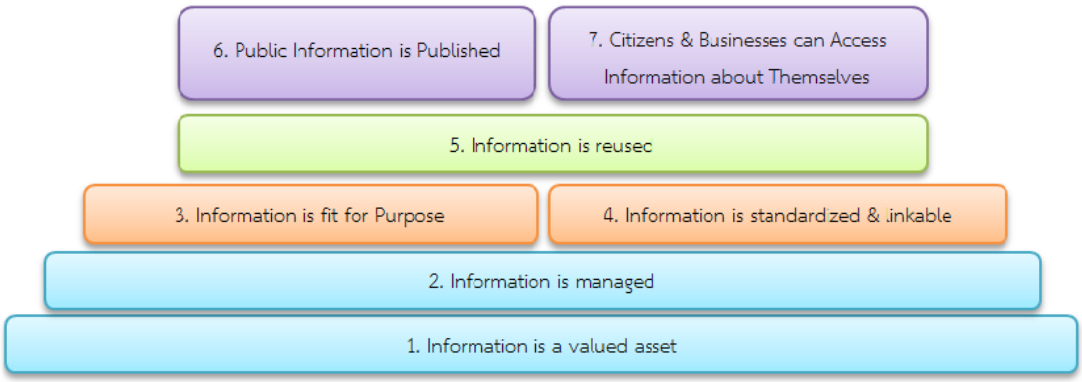

Figure 9 Government information principles [98]

Health and Social Care Act 2012 was legislative to reform and modernize the NHS service because the increasing demand for health service and highly increasing cost of treatment, and the limited budget of NHS [99]. The main context of this Act is to encourage the NHS, local government, and associated sectors to collaborate and integration the work and service to improve the quality of health care to accountable the need of patients [100]. According to the Act, some old organizations are abolished and new national organizational models were created, such as Executive Non-Departmental Public Body (NDPB), Special Health Authority (SpHA), Executive agency, Statutory Committee within another statutory body, and etc. [101]. The Act also concern about the eHealth and health data standards. The new organization named Health and Social Care Information Centre was established to setting the national health IT system for health information exchange, and collecting and analyzing the health data [102]. According to this Act, the health care organizations have to comply with the information standards which are set by the NHS England [103].

About the policy about medicines terminology, the United Kingdom developed dm+d which is a dictionary of medicine and medical device standard for communication among health information system within NHS since 1999. The dm+d composes of unique identifier code and text description for identify medicines and medical devices. dm+d has not standardized terminology which cannot

interoperability with various clinical system. Therefore, UK adopted SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms) which is the international terminology standard with the principles of good terminology practice to support the information exchange in different system. SNOMED CT UK drug extension has the components of dm+d but it can provide the content of nine tables of dm+d in only three tables supporting the business requirement of NHS, and interoperability of reimbursement and clinical information. SNOMED CT UK drug extension has released since 2006 [39, 40, 104].

4.2.2.2. Collaborative structure and funding resource

In the past, NHS Connecting for Health, the Department of Health Informatics Directorate within the NHS was the main division to develop and maintain the NHS national IT infrastructure since 2005. The Information Standards Board for Health and Social Care (ISB) had the role to approve the information standards [105-107]. After the legislation of Health and Social Care Act 2012, the organizations related to the health IT was changed to the new structure, and new roles and responsibilities in 2013.

Health and Social Care Information Centre (HSCIC) is established in 2013 and has the role to setting the health IT systems for health information exchange, and collect and analyze the national health data. The Health and Social Care Information Centre is established as an Executive Non-Departmental Public Body (ENDPBs)[102, 108]. ENDPB is a type of Non-Departmental Public Body (NDPB) which is the non-government organization working for the national government. ENDPBs has the special role about administrative, regulatory, or technical functions [102, 108, 109]. The information about health information system and service of NHS Connecting for Health which is has the role to develop and maintain NHS national IT infrastructure is transferred to the HSCIC website. The HSCIC has the role to update the information succeed to NHS Connecting for Health. Funding of HSCIC comes from the Department of Health and charge for their services [105-108].

UK terminology centre (UKTC) is a part of HSCIC which is responsible for management of health terminology standard including dm+d [104]. The structure for dm+d governance is shown in figure 10 [110].

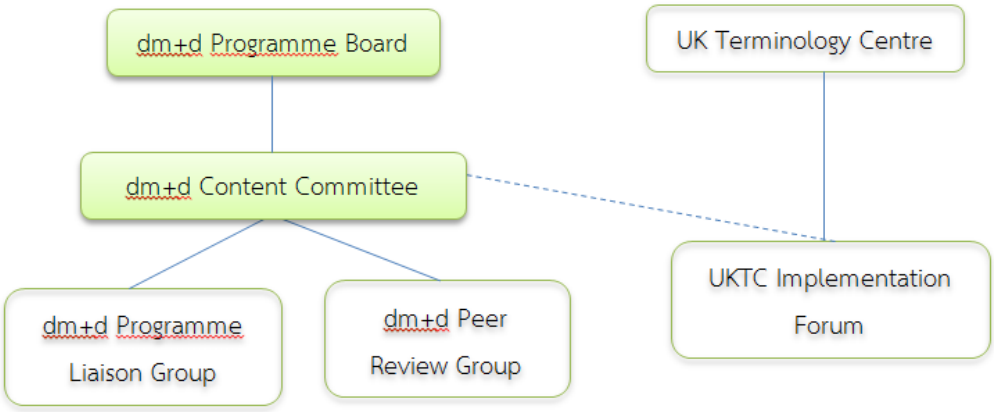

Figure 10 dm+d Governance [110]

dm+d Programme Board is responsible for all issues of dm+d and assigns the tasks to the dm+d Content Committee. dm+d Content Committee has the responsibilities to setup the editorial policy and ensure that the dm+d has been maintained consistent with the policy. The committees also approve the dm+d changes in major contents, structural, and technical [110].

Programme Liaison Group has the role to give an advice to the dm+d Content Committee and give the comments on the papers proposed to the dm+d Programme Board and Content Committee [110].

Peer Review Group is asked for review and comment on the papers proposed to the dm+d Programme Board and Content Committee [110].

UK terminology Centre Implementation Forum (UKTCIF) is the main forum for receiving and providing stakeholders feedback on proposals from the Content Committee and Programme Board [110].

4.2.2.3. Process

Development and maintenance process of health data standard

The development of health IT standards have to be consistent with national policy and the clinical practice. The developers may be the Department of Health,

NHS England, Public Health England, UK Terminology Centre, National Institute for Health and Care Excellence [111]. The ISB has suggested the information standards development methodology for health and social care standard development. Process for developing the standard has been done for 9-12 months. The seven stages of development methodology are shown in figure 11 [112, 113].

Figure 11 Development methodology suggested by Information Standards Board for Health and Social Care [112, 113].

Seven stages of development methodology are described as follows [113]**:**

- Need stage: In this stage the stakeholder need for health data standard will be assessed. The developer has to identify the key stakeholders and assess the need of stakeholders for health data standards. The impacts of information standard on the stakeholders have to be identified in this stage. The scope, purpose, and stakeholders need have to be clearly identified and the developer can consult with the ISMS for the need statement [113].

- Requirement stage: The requirements which meet the purpose of business need are identified and consult with stakeholders to receive the input information from the key stakeholders [113].

- Draft stage: Health data standards specification, implementation guidance, and implementation and maintenance plans will be drafted in this stage. Drafted standard will be passed the consultation with stakeholders. The drafted standard will be submitted to the ISMS for reviewing and checking before submitting to the ISB. The ISB will consider the standard and give the recommendation or approve for full stage [113].

- Full stage: In this stage, the scope of implementation testing which is include the implementation, communications, and operational guidance will be defined to demonstrate the practical use of health data standard. The implementation testing plan will be conducted and the results of the

implementation testing will be reported to demonstrate the issues which have to be solved. The results of all stage of standard development process and the standard specification have to be reviewed by the key stakeholders for the acceptance. The proposed standard will submit to ISMS to check before propose to the ISB for approval. ISB will consider the standard to give the recommendation or approve for implementation [113].

- Implementation Stage: This stage normally completes in 2-3 years. The approved health data standard will be published and communicate to the health and social care organization by email and website. The implementation manager has to support the relevant organization to implement the new health data standard, response to the issues during the implementation, and help to solve the problems. The measuring the acceptance according to the success criteria will be checked during this stage and reported to the ISMS. The development project will close when the implementation is complete and report to the ISMS [113].

- Maintenance stage: The standards have to be maintained for updating. For maintaining the standards, the legal, organization, knowledge and medical changes have to be monitored. In addition, standards have to be reviewed and update to the change environment. The standards have to be reviewed with the stakeholders to ensure that they are still response to the business. The information standards should be schedule review at least every three year. The standards may be changed and the standards which are not appropriate will be retired [113].

- Retirement stage: The maintenance manager will report the results of the maintenance review to the ISB. The ISB will agree to reject the standard and the maintenance manager will communicate to stakeholders for the time for retirement of that health data standard [113].

Development and maintenance process of dm+d and UK SNOMED CT extension

dm+d has been developed and delivered by the Health and Social Care Information Centre and the NHS Business Services Authority. dm+d was approved from the ISB to use as the standard for drug information exchange. dm+d is governed by the dm+d Programme board and the committees [39]. The users can

accept the license term and register for free account to download the dm+d files from the website. UKTC has the role to maintain the dm+d in collaborate with the NHS Business Service Authority [114]. dm+d data is weekly released and SNOMED CT UK Drug Extension is monthly released through the website of UK terminology centre [115]. The implementation guidance is developed for the health care organization in the format of pdf files which can download from the website [116]. Help desk team is set for information and technical support which can contact by email and the telephone [117].

4.2.2.4. Services and tools

dm+d browser is provided on the website [118]. HSCIC also provides many services to the public especially the information and statistic about health and medical care and support the guidance about health IT and health data standard. Some service is charged from HSCIC. HSCIC provides the health IT and health data standard article on the website which is the public can free access [119-121].

4.2.3. Hong Kong

4.2.3.1. Background and policy

In 2005, the Food and Health Bureau has the vision to develop the eHR Sharing system which aimed to share the patients' record for better quality of patient transfer between the all levels of public or private healthcare delivery units. In 2007, the Secretary for Food and Health appointed the Steering Committee on eHR Sharing and the working groups to setting the eHR development strategy. In 2008, Hong Kong was set up the healthcare reform consultation and the Food and Health Bureau proposed the eHR Program as one of the healthcare reform issues. The eHR sharing system development was planned for over ten years since 2009 to 2019, and the Legislative Council approved the budget for first stage from 2009 to 2014 [43, 122-124].

In 2009, the eHealth Record Office (eHR Office) was established by the Food and Health Bureau to co-ordinate for the eHR sharing system development. The eHR sharing system development has been planned to develop in three important

components according to the key consensus issues of the stakeholders. First component is eHR sharing infrastructure for interoperability between the different provider systems such as data storage, data exchange system, eHR data access including patient and provider identification and consent for access, and so forth. Second component is the adoption of Hospital Authority (HA)'s Clinical Management System (CMS) of private hospitals and clinics which the eHR sharing system development program will facilitate these providers to adopt and use the HA systems and eHR systems. The last is the technical standard development for interoperability between different systems [123, 125].

The clinical data standard development was an important issue for eHR sharing system development program. The development of clinical data standards in Hong Kong was still in the initial stage including medicines terminology development. In the past, Hong Kong never had a drug standard code; therefore, the Department of Health, known as the manufacturer of Drug Compendium and the Hospital Authority (HA) proposed to use the International Nonproprietary Names (INN) code to indicate the medicines' names. However, the INN code was just a set of data indicating the medicine information at the treatment level only. Hong Kong had approved the registration of all product types with serial numbers, known as de facto displayed on products. De facto was considered as a code used to indicate a certain product up to a trade name of a product. Due to lack of the national medicines terminology, the Steering Committee on eHR Sharing System develop the Hong Kong Medication Terminology Table (HK MTT) developed from SNOMED – CT [126-129].

4.2.3.2. Collaborative structure and Funding Sources

The information technology management structure of Hong Kong's electronic health record was shown in figure 12. The Food and Health Bureau is responsible for setting policies and support the information service. Hong Kong appointed the Program Steering committee and the Steering Committee on eHR Sharing System for the eHR program. The Program Steering Committee is responsible for co-ordination to setting and proceeding the strategies, objectives, approved budget and action plans for the eHR Program The committee consisted of representatives from the Food and

Health Bureau, the Department of Health, the Hospital Authority, the Office of the Government Chief Information Officer and the evaluation department within the organization [44].

The Steering Committee on eHR Sharing System is responsible for give and advice on the strategy and management to facilitating the eHR development. The Steering Committee on eHR Sharing System consisted of representatives from the Food and Health Bureau, the Department of Health, the Hospital Authority, the Office of the Government Chief Information Officer and other related departments within the organization. The Steering Committee on eHR Sharing System is comprised of 4 working groups. Working Group on eHealth Record Partnership supports the exchange information system in the private sector. Working Group on eHealth Record and Information Standards develops the information standard for the electronic information exchange. Working Group on Legal, Privacy and Security Issues develop the laws facilitating the exchange of information. Working Group on Institutional Arrangements is responsible for the study of the possibility of implementation, organizational structure and department by considering the organizational management, implementation management and monitoring of eHR Sharing Infrastructure [44].

Hong Kong set up the eHR office within the Food and Health Bureau to take forward the eHR program development. The eHR office consisted of 3 divisions. Policy and Planning Unit is responsible for the policies and the plan development for health information technology system. Infrastructure and Development Unit is responsible for the development of health information structure and system, monitoring the implementation of information standards and the requirements and guidelines for the health information exchange from the stakeholders. Finance and Project Management Unit is responsible for the management of resources used in the development of health record exchange system and risk management for the project achievement [44].

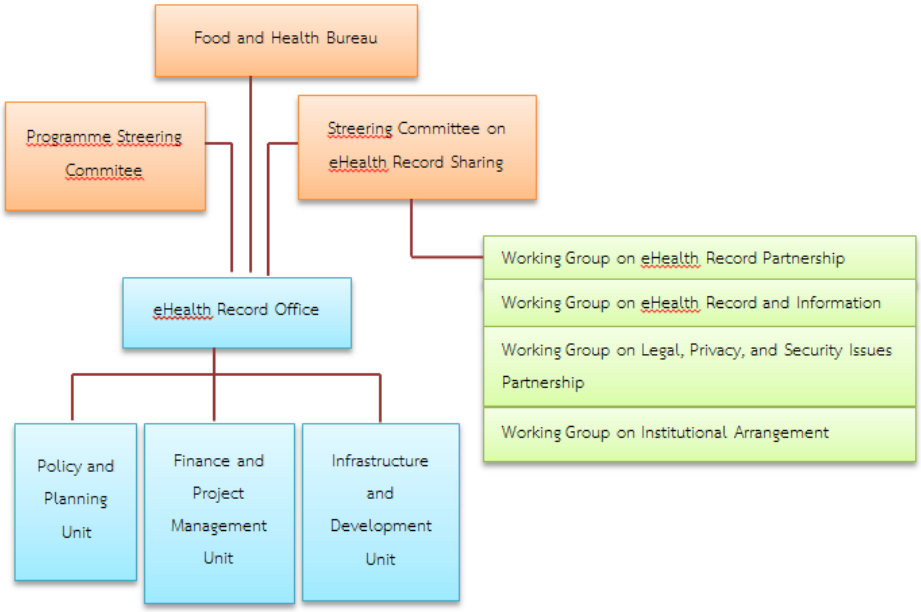

Figure 12 Management structure of Hong Kong's electronic health information program[44]

The eHR office set up the eHR Information Standards which is responsible for the establishment of stakeholder network for the information standards development as the structure shown in figure 13. The eHR Information Standards Office is responsible for supporting and co-operating with the working group for developing, enforcing, facilitating adoption, and monitoring the health data standards. The organization work with working group on the eHealth Record & Information Standards, the Coordinating Group on eHR Content & Information Standards and the Domain Group on eHealth Content & Information Standards [44, 130].

Working Group on eHealth Record & Information Standards is responsible for setting the roadmap to support the development of health information system and health data standards, approve the standard and set the policy for adoption. The working group is comprise of the representatives from the HKSAR Government, the Food and Health Bureau, the Office of the Government Chief Information Officer, the Efficiency Unit, the Hong Kong Academy of Medicine, the Hong Kong College of Pathologists, the Hong Kong College of Radiologists, the Hong Kong Society of Medical Informatics, the Hong Kong Medical Association, the Hong Kong Private

Hospitals Association, the Hospital Authority, the Department of Health, the Internet Professional Association and the GS-1 and HL-7 Hong Kong Developer [44, 130].

Coordinating Group on eHealth Content & Information Standards (e HR IS CG) initiates the new health data standards, co-operate for all standard life cycle, and harmonize the different information standards, approve information standards, monitor and review the health data standard. The working group includes the representatives from the HKSAR Government, the Food and Health Bureau, the Office of the Government Chief Information Officer, the Efficiency Unit, academic sector, private health care sector, public health care sector, information technology sector, Standards body (such as, GS1, HL7, and etc.) [44, 130].

Domain Group on eHealth Content & Information Standards (eHR IS DGs) draft and recommend health data standards in the standards lifecycle as approved by the eHR IS CG [130].

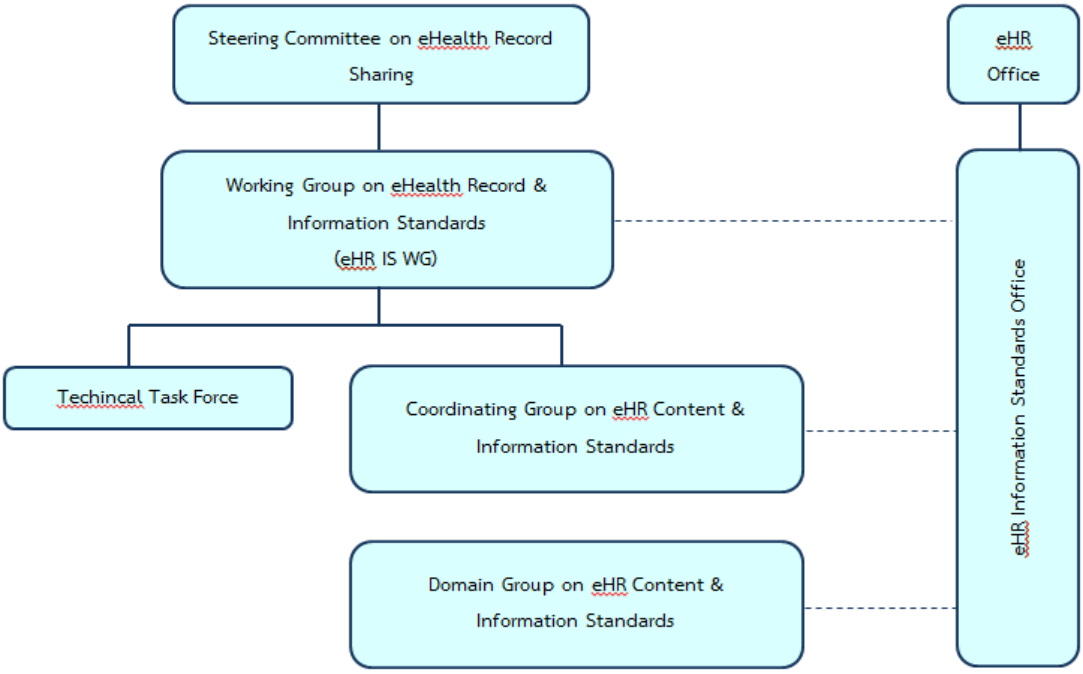

Figure 13 Organization Structure of Hong Kong's Health Information Developer [44]

4.2.3.3. Process of medication terminology development

Hong Kong initiated to develop the medication terminology for eHR sharing by setting the roadmap for medication terminology development. Hong Kong searched for the international standards and selected the SNOMED-CT system to be the core concept of medication terminology development. The drug information which is used for medication terminology development was derived from the Hospital authority database which contains all drug used and Department of Health which contain all registered pharmaceutical products [78, 126-129].

eHR Information Standard Office collects the drug information and synchronize the information to the core concept of the SNOMED-CT system. The eHR Information Standard Office is responsible to announce and updated the medication terminology [78, 126-129, 131].

4.2.4. New Zealand

4.2.4.1. Background and policies

In 2005, New Zealand set the Health Information Strategy for New Zealand and appointed the Health Information Strategy Action Committee (HISAC) which is responsible for the strategic implementation of health information. Health data standard development is one of the most important strategies for health information system development and New Zealand appointed the Health Information Standards Organization (HISO) in the form of committee and established the HISO office [132, 133].

In 2008, the Minister of Health announced the restructuring of health information management and established the National Health Board, the National Health IT Board and the Health Information Standards Organization (HISO) in 2010. New HISO has the obvious infrastructure and role for the health standard [132-135].

New Zealand set the National Health IT plan which was published in 2010. The National Health IT plan was divided into 2 stages [135]:

Stage 1 (July 2010-June 2012) is the period for building a strong foundation and encourage the health care organization to use health IT. In this stage, New

Zealand focused on health information transfer between the organization and foundation construction to encourage the organizations applying the information technology system for patient managing and improvement of health care system [135].

Stage 2 (July 2010-December 2014) focused on the health information exchange. This included the exchange of patient information, medical history and information to support the decision making for treatments [135].

The Privacy Act of New Zealand is the important law which its content aimed to protect the personal privacy. In 1994, the Health Information Privacy Code comply with the Privacy Act 1993 was legislated which focused on the protection of health information. The Health Information Privacy Code was revised in 2008 which aimed to provide greater understanding on collection guidelines for health service personnel and disclose health information by health organizations [136-139].

The New Zealand Medicine Terminology (NZMT) was developed in 2009 in accordance with the e-Pharmacy strategy. New Zealand Medicine Terminology is a medicine standard code which applied the international standard: SNOMED-CT and Australian Medicines Terminology. In addition, New Zealand had developed the New Zealand Universal List of Medicine (NZULM) in 2011, which was a dictionary showing the medicine data that were used in New Zealand [133-136].

4.2.4.2. Collaborative structure and funding resources

For budget planning, National Health Board is responsible for budget planning and prioritization of investment in information technology. The National Health Board (NHB) had allocated a budget from the Ministry of Health [133-136]. In addition, the health information technology project had been funded by the District Health Board project funding, National Health Board project funding, Primary Care IT Grant Fund [135, 140].

National Health IT Board is responsible for setting the national health information policy and responsible for the implementation of national health information. The board also supported the development of health data standards [135, 140].

Health Information Standard Organization (HISO) Committee is responsible for providing the technical advices about the health data standards to the National Health IT Board and responsible for the development, maintenance, and implementation for the use of the health data standard in accordance with the health information technology plan. The HISO committee is comprised of representatives from various organizations including the Accident Compensation Corporation (ACC), the Chief Medical Officer's Forum, the DHB Chief Information Officer's Forum, the Health Informatics New Zealand Executive, the Ministry of Health, the Medical Council (Medical Council of New Zealand), the Nursing Council. (Nursing Council of New Zealand), the NZ Health IT Cluster, the Primary Care Information Management Group (PCIM) and the Representation for Maori Interests [133, 136, 141].

Health Information Standard Organization (HISO) Office is a department within the Ministry of Health which supported the HISO committee. The HISO office provided the instructions and responsible for all health data standard life cycle including development, maintenance, announcement, implementation, and maximization of understanding for the use of information standard [133, 136].

4.2.4.3. Process

Development and Maintenance of Health data standards

The development and maintenance processes of health data standards conducted by the HISO committee and HISO office were divided in 5 steps as follows [8, 134]:

1. Identification and planning: In this step, the requirements were analyzed, and the purpose and plan of health data standards development were setting. The HISO office would study the requirements of stakeholder involved. Later on, the HISO office set the objectives and development and implementation plan for health data standards. The HISO committee will provide the recommendation for the proposal.

2. Development and evaluation: The HISO office drafts the specification of health data standards.

3. Consultation: In this step, the HISO office hold a public meeting to hear comments from stakeholder involved. The draft of information standards would be proposed to receiving the comments for better improvement.

4. Approval and implementation: The draft of information standards would be approved by the HISO committee. After approval, the HISO Office is responsible for announcement and support the implementation.

5 Review and maintenance: The health data standards require maintenance and review for up-to-date and appropriateness. For the maintenance of health data standards, the HISO Office set the schedule of maintenance and review. In the case of emergency problem, the HISO Office would consider the improvement of health data standards or ad-hoc maintenance in accordance with the specified guidelines. The HISO Office set the schedule review and established a working group for consideration to make the appropriate change or reject the health data standard, then the HISO committee considered for a final approval.

Development Process of New Zealand Medicine Terminology (NZMT)

New Zealand Medicine Terminology (NZMT) is a national drug information standard used for drug identification, and providing drug information and relationship of drug information. In the development step, New Zealand studied the options for medicine terminology development by searching the international standard and medicines terminology from other countries. New Zealand selected to design the medicines terminology by using SNOMED-CT concept and applied the Australian Medicines Terminology for NZMT design [37, 106, 132].

In addition, New Zealand had developed the New Zealand Universal List of Medicine (NZULM), which is a dictionary collecting the drug information that were used in New Zealand and used the NZMT for drug information exchange [142].

The data sources for NZMT and NZULM derived from many sources, such as Medsafe (an organization which is responsible for the quality of medical products in New Zealand), The Pharmaceutical Management Agency (an organization which is responsible for the essential drug list and promote the appropriate use of medicine in the hospital). Pharmacy Guide of New Zealand (an organization providing supports

to community pharmacy and responsible for Pharmacode® which is the drug code using for drug inventory management) [142-145].

The NZMT is updated monthly and the users can download the NZULM with free of charge. In addition, guidelines and help desk service are provide to facilitate the users for NZMT adoption [142].

4.2.4.4. Services and tools

The NZULM information, technical information, knowledge, and training media are provided for free download by in the websites [142, 146, 147].

The help desk service and technical support are provided to facilitate the users which can ask for help by email or telephone call [146].

NZULM and NZMT browser is available on website which the users can search the information [147].

4.2.5. Australia

4.2.5.1. Background and medicines terminology related policy

In 2005, Australian State and Territory governments have established a National E-Health Transition Authority (NEHTA) to develop the electronic health information system. In 2006, NEHTA had developed the National eHealth standard catalogue and health data standards for the health information exchange. In the same year, NEHTA had developed Australian Medicines Terminology by applying the SNOMED CT concepts [148, 149].

In 2008, Australian Health Ministers' Advisory Council, commissioned Deloitte has developed National E-Health Strategy by defining the basic principles of electronic health information system development in four areas as follows (as shown in figure14) [150, 151]:

- Foundations for the health information exchange between health care units
- Processes and tools to support the health information system development and facilitate the use of electronic health information systems
- Change management and promote the acceptance and adoption of the stakeholders

- Governance for establishing the structure and mechanism of management to achieve effective coordination in the development, maintenance and use of electronic health information systems

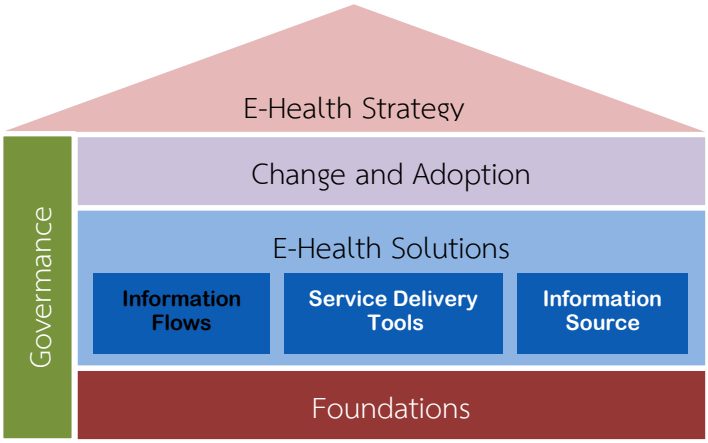

Figure 14 Principles of electronic health information system development of Australian National E-Health Strategy [150]

4.2.5.2. Collaborative structure and funding resources

National E-Health Transition Authority (NEHTA) is the main organization which is responsible to develop electronic health information systems, health data standards for health information exchange, and the Personally Controlled eHealth Record (PCEHR). NEHTA received funding from the Council of Austraian government (COAG), all State, and Territory Governments. The governance structure consists of [149, 152-155]:

- NEHTA Members are representatives from the Australian state, territory, and Federal health departments.

- The NEHTA Board of Directors

- Board Committees is responsible for setting the strategy and project plans which consists of the Audit Committee, Risk Committee, Finance Committee, and Remuneration Committee

- The Chief Executive Officer is responsible for the strategic direction and implementation of the assignment.

- The Company Secretary

- The NEHTA organization consists of four main groups, such as national infrastructure services, solutions and development, strategy and architecture, and governance and support [149, 152-155].

National Clinical Terminology and Information Service (NCTIS) was a department within NEHTA which is responsible for the development of health data standards including medicines terminology. For the Australian Medicines Terminology (AMT), the working groups had established for the stakeholders cooperation for [152, 156].

In 2013, the Australian government reviewed the implementation status of the PCEHR and set the policy and budget to strengthen the governance in accordance with the review. According to the governance transition in 2015, NEHTA was changed to the new entity called the Australian Digital Health Agency [157].

4.2.5.3 Process

Development, implementation, and maintenance process of Australian Medicines Terminology (AMT)

Data sources for AMT development derived from three data sources as bellows [152].

- The Australian medicines industry

- The Therapeutic Goods Administration (TGA) was a department under the Australian Government Department of Health and Ageing which is responsible for quality of medical products including pharmaceuticals, medical devices, and blood and blood-related products [158].

- Pharmaceutical Benefits Scheme (PBS) is a list of essential medicines [159].

For AMT development, the preliminary model and the use case diagram were developed and discussed with the stakeholders for improvement, including the software developer, the health care professionals, the representatives from PBS, the representatives from TGA, the representatives from the Australian medicines industry, and other stakeholders. After approval, the AMT was announced and communicate for the stakeholder adoption [30].

The AMT implementation was an interesting process. AMT implementation plan was divided in three formats and three phases as bellows [160].

Phase 1 mapping (preliminary AMT coverage) with local medicine list which the health care unit must always match and updated AMT with the local drug use in their health care unit.

Phase 2 mapping (full AMT coverage) with local medicine list which the software application in the hospital was developed to use AMT to exchange data.

Phase 3 Native implementation which the hospital software applications could use the AMT to exchange information.

AMT update monthly and release for the users to download the AMT. In addition, guidelines and help desk service are provide to facilitate the users [152].

4.2.5.3. Services and tools

The AMT and mapping guideline, technical information, knowledge resources, training media, are provided for download from the websites [152].

Australian Medicines Terminology Browser is available on website which the users can search and easier to find the names and relationships of the concepts of drugs which is available through the AMT website [161].

4.2.6. Canada

4.2.6.1. Background and related policies.

Canada recognizes the importance of health information and established the Canadian Institute for Health Information (CIHI) in 1993. CIHI established the CIHI Partnership for Health Informatics/Telematics, which consists of representatives of relevant government agencies, representatives of health service unit, representative from private sector and representatives from non-profit agencies. The partnership had a role in developing a national agenda on health information technology [162, 163].

In 1997, Canada had made the health care reform. The development of health information technology was the key issue. In 2001, Canada established the Canada Health Infoway which had a role and responsibility in electronic health

information system and health data standard development for the information exchange [162, 164]. Infoway worked with many sectors for the development of electronic information systems in both central and regional. The important policy was described as follows [165]:

- Investing and co-operate with the provinces and territories to encourage the use of health information technology in all regions of Canada.

- To encourage and support the adoption and use of health information technology for health care professionals

- Prepare the blueprint for the development of electronic health record in hospitals and health sectors in both central and regional to develop the system for the electronic health information exchange.

- Support the development of health information technology and sustain communications and technology standards to achieve the patient health information exchange securely and correctly.

- Providing tools and services for technology venders to encourage software manufacturers to accelerate technology development

For health data standard development, CIHI and Infoway established Standards Collaborative to develop health data standard, such as laboratory standards, diagnostic imaging standards, drug standards, and etc. [4]

4.2.6.2. Collaborative structure and funding resources

CIHI and Infoway were two important organizations in Canada which co-operate for health data standard development. Canadian Institute for Health Information (CIHI) is an independent and not-for-profit-organization received funding from the Federal and Provicinal / Territorial Ministries of Health. CIHI is responsible for gathering and analyzing health information, increase the understanding and adoption of health information. CIHI also had a role in the development of health information exchange in order to use and compare health information effectively [154][155].

Canada Health Infoway is an independent and not-for-profit-organization funded by the federal government. Infoway is the main responsible organization for

development of electronic health information systems, encourages the adoption and use of health information systems, and develop health data standards for exchange [156].

CIHI and Infoway established the Standard Collaborative as the cooperation network in 2006. Standard Collaborative was responsible for the development and maintenance of health data standards, and provides services to support the implementation of the health information technology for electronic data exchange Standards Collaborative was a part of Infoway in 2007. The Standard Collaborative structure was shown in Figure 15 [4].

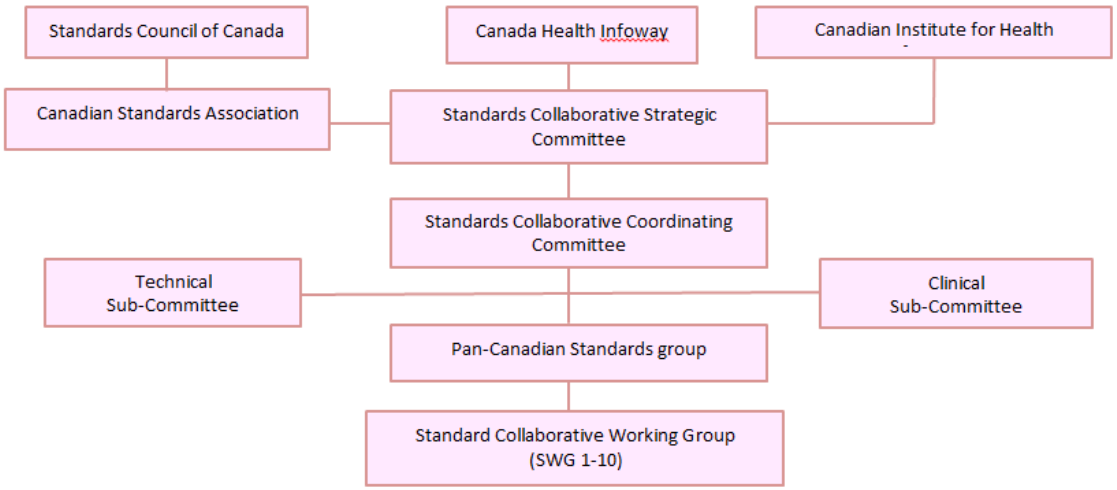

Figure 15 Standard Collaborative structure [4]

The structure of the Standard Collaborative Committees and working groups consisted of [4]:

- Standard Collaborative Strategic Committee (SCSG) is responsible for policy setting.

- Standard Collaborative Coordinating Committee (SCCC) is responsible for the coordination, prepare guidelines for implementation.

- Standard Collaborative Working Group (SCWG) has the role for providing guidance in the selection of health data standards, develop and maintain standards, and review the content of health data standards. SCWG had more than 10 working groups with expertise in various aspects.

4.2.6.3. Process

The development and maintenance process of health data standards

The development and maintenance process of health data standards in Canada is divided into four stages as shown in Figure 16 [166].

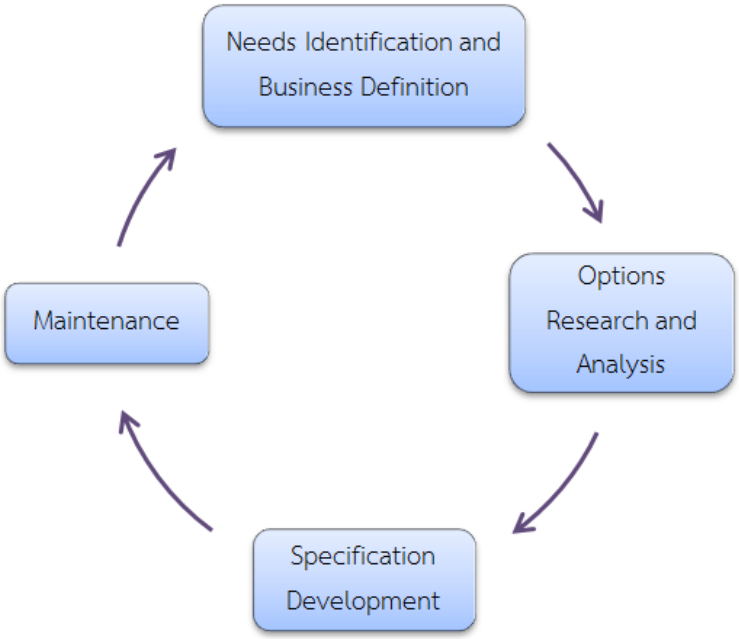

Figure 16 The cycle of the health data standard development process [166]

1. Needs Identification and Business Definition: Explore the need of all stakeholders to develop the standard specification of health information [166].

2. Options Research and Analysis: Study the international standards to select the option that the features and specifications which meet the requirements, then analyze costs such as licensing fees, maintenance costs, etc. [166]

3. Specification Development: If the international standard was appropriate to use and the working group decided to choose the international standard, the working group would set the implementation and user guidelines. If the international standard did not meet the needs of stakeholders, the working group would develop new standard specification. Drafted specification had to consult with the stakeholders and presented to the SCCC to review and make recommendations before submitted to the SCSC for approval [166].

4. Maintenance: Health data standard need the schedule updated and reviewed that it still meet the requirements of the stakeholders to use or not. If SCWG reviewed and agreed that the standard was unsuitable for current use, SCWG would propose to be changed or canceled health data standards [166].

4.2.6.4. Tools and services

- Knowledge service and user guidance for health data standards can download from the website of Infoway [167].

- Mapping guidance and tool to match old health data standard with new health data standard [168].

- Certification Services which is the service that Infoway provided the certification services for the software application that could use new health data standard for exchange. The Infoway certified the software products to encourage the development of technology to produce products that are cost effective and can be used to exchange data securely. In addition, this could encourage the private sectors and health care professional increasing to use information technology products [168].

4.2.7. Summarize of the review of the experience of six countries

From the review of the experience of six countries, it could be seen the countries advanced in HIT have similar governance systems for health data standards and medicines terminology as follows.

1. Policy and legal: All countries launched the policies and set up a prominent roadmap for medicines terminology development consistent with the HIT policy. In addition, some countries announced the legal facilitation of HIT development and promoted the adoption, For example, the US announced HITECHACT in 2009 authorized by the Office of the National Coordinator for Health Information Technology (ONC) to enforce the HIT and health data standard adoption [84].

2. Collaborative structure and funding resource: Most of the countries established an organization responsible for HIT governance and has a department

responsible for health data standard governance including medicines terminology governance.

The HIT organization forms in the countries advanced in HIT are government organizations and independent organizations.

- Government organization: Some countries established a HIT organization as a government organization receiving a fiscal budget from the government. The US established the ONC within the Department of Health and Human Services [38]. Hong Kong established an eHealth Record Office within the Government of Hong Kong [169].

- Independent organizations: Some countries have established a HIT organization as an independent body, which is more flexible than a government organization. Australia established the National E-Health Transition Authority *(*NEHTA*)* and Canada established Health Infoway as independent and not-for-profit organizations receiving a fiscal budget from their governments [148, 164]. The UK established the Health and Social Care Information Centre (HSCIC) as an Executive Non-Departmental Public Body (ENDPB) receiving a budget from the government and charging for services [70].

In these countries, the HIT organization coordinates with related agencies for medicines terminology governance in the form of a committee for policy setting and a working committee for medicines terminology development. Some countries have established a stakeholder coordinate network for promoting health data standard development and adoption, such as Canada who set up the Standard Collaborative, the US set up the Standard & Interoperability framework to empower, facilitate use, and accelerate adoption of the stakeholders [4, 96].

3. Process: All countries studied set up a similar process for health data standards and medicines terminology as follows:

- Policy setting process: This process allows the stakeholders to participate in the policy setting process in the form of committees

- Development process: This process consists of user requirement identification, standard specification, and public consultation

- Approval process: The UK, Canada, and New Zealand appointed committees of experts for specification approval and review [112, 141, 166].

- Maintenance process: All countries studied have a regular schedule to release and update the medicines terminology.

- Implementation process: This process consists of implementation plan setting, integrating health data standards to the eHealth system, and facilitating user adoption.

4. Tools and services: All countries developed tools and services to facilitate the users to use medicines terminology, such as medicines terminology browsers, mapping guidance and tools for mapping the medicines terminology and other drug codes, toolkit, helpdesk, training services, and a certification service for software suitable for medicines terminology.

Table 2 Summarize of the review of the experience of six countries

Countries/ governance system	**US**	**UK**	**Canada**	**New Zealand**	**Australia**	**Hong Kong**
1. Foundations						
1.1 Policy and plan: • Setting the prominent HIT and health data standard policy, roadmap and plan. • Setting the roadmap and plan for health data standard development in accordance with HIT development plan • Announce the legal to facilitate enforcement and adoption						
Important national HIT & health data standard policy &legal	✓ Meaningful use of EHR &HITECH ACT	✓ Information for health, The power of information, and Health and Social Care Act 2012	✓ EHR sharing system	✓ Health information strategy for New Zealand	✓ National vision for eHealth and National eHealth strategy	✓ EHR vision
Collaborative structure & funding resource: • Established main responsible organization for HIT and health data standard • Collaborative structure in the form of committee and informal user community • Main funding resource for HIT development according to the HIT roadmap from the government						
HIT & health data standard organization	ONC	HSCIC & NHS	Infoway	National Health IT Board and HISO	NEHTA	EHR office
0rganization form * Gov = government organization	Gov	Non-Departmental Public Body	Ind	Gov	Ind	Gov

Countries/ governance system	US	UK	Canada	New Zealand	Australia	Hong Kong
** Ind = Independent organization						
Funding resources * Gov = fiscal budget from government	Gov	Gov and charge for service	Gov	Gov	Gov	Gov
Health data standard process • The stakeholders participate for policy setting in the form of committees • Development process: user requirement identification, standard specification, and public consultation • Maintenance process: regular schedule to release and update the medicines terminology, and the stakeholders can request for urgent update • Implementation process: implementation plan setting, communicate to stakeholders and facilitating user adoption.						
Policy setting	✓	✓	✓	✓	✓	✓
Development	✓	✓	✓	✓	✓	✓
Approval	NA	✓	✓	✓	✓	NA
Maintenance	✓	✓	✓	✓	✓	✓
Implementation	✓	✓	✓	✓	✓	✓
Tools and services • All countries developed tools and services to facilitate the users • Necessary tools and services : medicines terminology browsers, mapping guidance and tools for mapping the medicines terminology and other drug codes, toolkit, helpdesk, training services, and a certification service for software suitable for medicines terminology						

4.3. Current situation of drug code and medicines terminology governance in Thailand

4.3.1. Background and related policy

In 2000, Ministry of Public Health (MOPH) appointed the committee to develop drug code and drug information standard, and the 24 digits drug code was developed and use for drug inventory management within both central and region hospitals since 2002. Later on, the National Health Assembly set the strategic plan for health information system (HIS) to develop the HIS and mechanism to support the health information exchange for health care use. An important strategy is health data standard development for interoperability between the health care unit and organizations. According to the national drug information standard requirements, the 24 digits drug codes was announced as first national drug information standard and use for drug reimbursement in Thailand since 2010 [45, 170].

Although the health information technology strategy just launched in 2010, the ICT application is pervasive in health system for many years. Various drug codes were developed to use as local code in each health service unit and some drug codes was developed for specific purpose before announce to use 24 digits drug code as national drug information standard. Due to, the 24 digits drug code was initiated for only inventory management purpose not for health care and reimbursement purpose; therefore, the code does not contain some necessary information and not standardize some drug information before generating code such as dosage unit, dosage form, and etc. In addition, the governance of 24 digits drug code were not well-prepared and improved for using as national drug information standard; therefore, many problems were occurs in implementation. Due to insufficient foundations for maintenance, lack of regular mechanism for updated drug code, no data source transferring system to generate and update drug code, and no necessary tools and services for user support; therefore, 24 digits drug code is not cover all medicines, not up to date, and not cover all non-registered drug and hospital formulary which are used in all health service units. The 24 digits drug code

implementation is not successful because the governance system cannot serve the requirement of the users for health care and reimbursement purpose [11].

According to the high expenditure of drug reimbursement in three health insurance schemes such as the universal coverage scheme (UCS), the social security scheme (SSS), and the Civil Servant Medical Benefit Scheme (CSMBS) and the problems of 24 digits drug code, Thai government launched the policy to develop medicines terminology which can really use for multi-purpose, such as reimbursement and cost containment, inventory management, and health care. Although the policy to develop the HIS and mechanism was set since 2010, Thailand still has no governing body for health information technology including no main organization for health data standard governance [11].

After the policy was announced, the MOPH appointed the Committees for Medicines Terminology Development and the Thai Health data standard Development Center (THIS) has been assigned to develop Thai Medicines Terminology (TMT) in 2012. TMT was developed by applied SNOMED-CT and the drug information from 24 digits drug code to generated TMT code which is more flexible and easier to use for reimbursement and health care [11]. At present, TMT was used for drug reimbursement in CSMBS and UCS.

The slowly implementation of TMT was from many causes, such as lack of authority and efficient co-operation for enforcement, lack of national roadmap and governing body for implementation, lack of efficient drug information collection and transferring system, and lack of health informatician and pharmacy informatician. The lack of authority and efficient co-operation for enforcement and lack of national road map and governing body for implementation affects to the adoption of the health insurance schemes and the health care professionals. The lack of efficient drug information collection and transferring system is the cause of slowly TMT code generation and uncover of drugs used within health service.

4.3.2. Governance of drug codes and medicines terminology

4.3.2.1. Policy and plan setting

In 2010, the national health assembly concluded that the lack of foundations and effective management system are the main important problems of the Thailand health information system. At present, Thailand still has no main responsible organization to health information technology. The Bureau of policy and plan, Ministry of Public Health (MOPH) responsible to develop the policy and plan about health information technology including health data standard and present to the health assembly to set up the strategic plan for health information development. The national health assembly is the public participatory process to develop and push the health policy. After the strategic plan was set, the Bureau of policy and plan responsible to co-ordinate with the stakeholders and the National health information committee to manage the strategic plan, monitor and report the progression [171, 172].

4.3.2.2. Governance of 24 digits drug codes

Due to the lack of main responsible organization to govern health data standard; therefore, the Bureau of health administration was assigned to develop and maintain 24 digits drug codes and received the fiscal budget from MOPH [12, 45, 170, 173]. The governance for the 24 digits drug code is shown in figure 17.

According to figure 17, Bureau of health administration has been collecting drug information to generating 24 digits drug code from many sources, such as Thai-Food and Drug Administration (TH-FDA), the Government Pharmaceutical Organization (GPO) and the Defence Pharmaceutical Factory, hospitals, manufacturers, and Institute of Thai Traditional Medicines.

Due to Thailand has both registered drugs which have to register by Thai-Food and Drug Administration (TH-FDA) and non-registered drugs, such as hospital formulary, and drugs manufactured from the Government Pharmaceutical Organization (GPO) and the Defence Pharmaceutical Factory which are omitted to register by TH-FDA. For the registered drugs, drug information was mainly derived

from TH-FDA but the manufacturers can request the drug code in the case of urgent use. For the non-registered drug except hospital formulary, the manufacturers have directly sent drug information to the Bureau of health administration. After collecting drug information, Bureau of health administration has examined and cleaned drug information, then generated 24 digits drug codes. For the hospital formulary, the hospital could generate 24 digits drug code from the software program and sent to the Bureau of health administration for examination and announcement.

Thai traditional medicines were widely used in hospitals and reimbursement in health insurance schemes. Due to the dosage form and strength of Thai traditional medicines are various and different from the modern medicines. The Institute of Thai Traditional Medicines has generated 24 digits drug code and sent to the Bureau of health administration for examination and announcement.

The 24 digits drug codes has been sent to Bureau of policy and strategy for announcement and posted the updated drug code on the websites for download. The users can download the 24 digits drug code updated file from websites and use the mapping tool to map 24 digits drug code with the local code. The hospitals use 24 digits drug code to report drug information to MOPH, NHS, CGDs, SSO, and so forth.

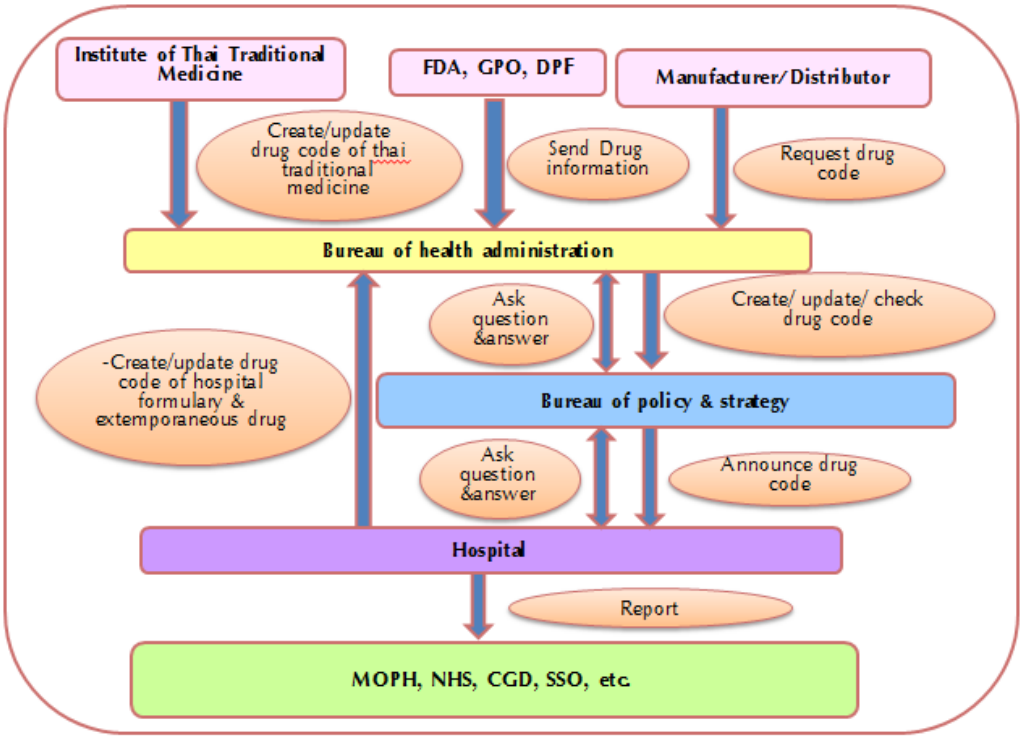

Figure 17 Governance model of the 24 digits drug code

Problems of 24 digits drug code governance

1. Lack of main responsible organization and effective governing system. Because of no governing organization for providing policy, coordinating for maintaining the drug code, harmonizing with other standard code, and reviewing and improving standard code, the 24 digit drug code system is facing the problems of updating standard, mapping with other standard code, and the coverage of drug entity in Thailand (around 5-10% of drug items used in big hospitals and the hospital extemporaneous drugs are not in 24 digit drug code system database) [11]. These affect to the manufacturers which cannot sell the products to the hospitals, the hospitals cannot reimburse drugs which do not have 24 digits drug code from the health insurance schemes, the health insurance schemes cannot analyze the drug use information for policy setting.

2. Lack of the effective drug information transferring system and agreement of format of drug information for updating drug code. TH-FDA database and other database did not standardize drug information and the co-operation to send the drug

information for updating drug code did not set up the time schedule for data transferring and agreement of the format of drug information.

3. Lack of the effective tools and service to support the users. There is no timeline for user problem solving service when the users has the problems about 24 digits drug code and ask to the administrator. The 24 digits drug code updated file was presented in the excel file which is hard to search for specific drug and map with other drug codes. The users suggested the administrator to develop the searching tool.

4.3.2.3. Governance of Thai Medicines Terminology

TMT was developed and maintained by Thai Health Information Standard Development Center (THIS) which is a health data standard research unit in Health systems Research Institute (HSRI) [11, 174]. The governance for TMT is shown in figure 18.

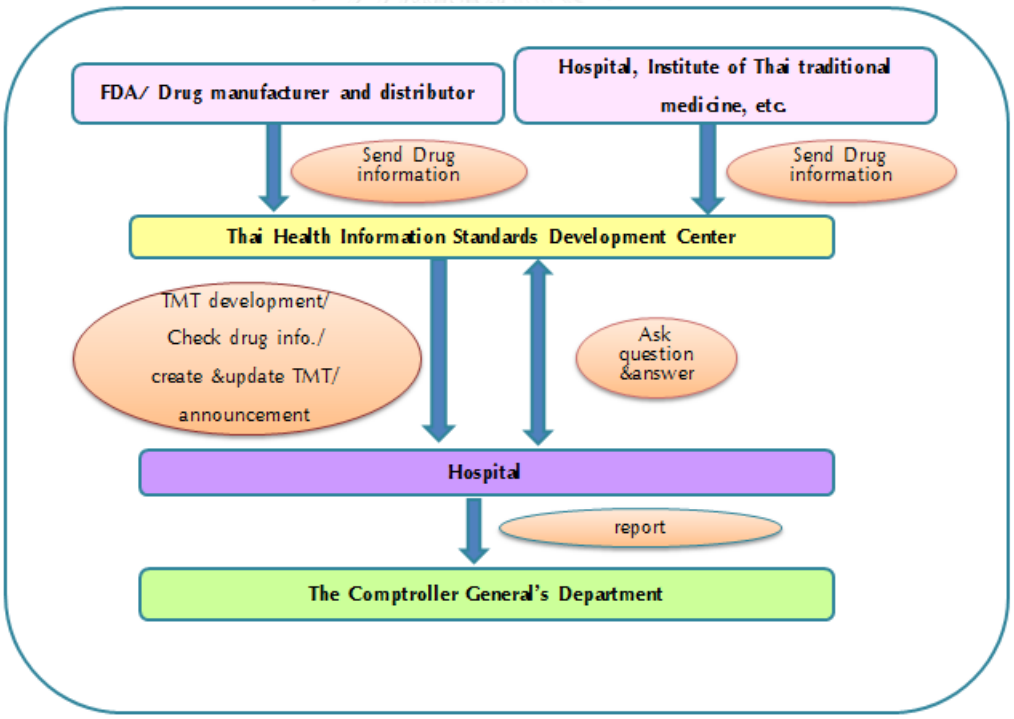

Figure 18 Governance model of Thai Medicines Terminology

In the initiation phase, drug information has been gathering from many sources, such as TH-FDA database, 24 digits drug code database, hospital drug use information from the Central Office for Healthcare Information. Later on, THIS has

been collected drug information from TH-FDA, manufacturers, hospital, and Institute of Thai Traditional Medicines. Data has been cleaned, standardized, examined, and added more details from the references. For TMT drug code generating, THIS developed the software application for generating TMT drug code. TMT updating file releases at first and third Monday in every month which the users will receive the inform letter and can download from the websites.

THIS provides mapping tool for search the TMT code and map with the 24 digits drug code and TH-FDA drug registered code. The mapping tool also facilitates the users to map these drug codes with the local code which is the users use in their organizations.

THIS provides helpdesk for the users which the users can ask the questions by telephone, email, and social media. If the users want to ask question, they can download the form from website and send the question via email. The administrator will answer the question within 3 days. If the administrator cannot answer the question, the user will receive the email to postpone for 10 days [11].

Problems of TMT governance

1. Problems in drug information collection to generate and update TMT. Drug information is mainly derived from TH-FDA database, but TH-FDA database does not set timeline for updating new drug information and does not clear the old drug information. This leads to the problems for updating TMT from TH-FDA database. THIS has to gather the drug information from other sources. The drug information which is sent to THIS does not set the standard format of drug information; therefore, It is wastes of time to cleaned and examined drug information before generate TMT.

2. Lack of authority to enforce the medicines terminology and coordinate development and maintenance. THIS is a health data standard research unit which is assigned to develop TMT but THIS does not have authority to enforcement which affects to the implementation process.

3. Users concern about the continuous and sufficient funding resource for maintenance. Due to the TMT development is funding as project, the users concerns about the continuous of policy and sufficient funding resource. The users complain that the implementation in manufacturer companies and hospitals has to invest for

software program changing and change the working processes. The continuous of policy is required from users.

4. Lack of main responsible organization and effective governing system. THIS has the mission to develop health data standard but do not have the mission to maintain health data standard. In Thailand, there are many organizations responsible to governance health data standard including drug code and medicines terminology. These organizations may have the redundant role in drug code and medicines terminology governance. Various health data standard has been developing in Thailand, and require the main responsible organization and effective governing system.

5. Lack of specialist and human resource. The specialists for develop and maintain medicines terminology are insufficient and the hospitals require the health informatics health informatician.

4.3.2.4. Conclusion of the current situation of medicines terminology governance, problems, and the recommendations

In the stakeholder consultation seminar, the stakeholders was concluded the problems of current governance, and the recommendations for governance model development as table 3.

Table 3 Results from key informant interviews about the problems and the suggestion of the drug code and medicines terminology governance

Interview topics	Problems	Recommendations
Policy	- No clear roadmap and plan - National body for HIS policy setting is not clear. - Lack of stakeholder participation in the policy setting process.	- Establishing a national body for HIS policy setting comprising of stakeholder representatives from both government and private sectors - Creating the standard procedure for setting a national policy for health data standards and medicines terminology

Interview topics	Problems	Recommendations
		development
Collaborative structure	- No main organization responsible for medicines terminology governance - The assigned organizations do not have a mission for medicines terminology governance. - Lack of authority to enforce the medicines terminology and coordinate development and maintenance	Develop the collaborative structure as follows: 1) Establish a main organization responsible for HIT governance including health data standards and medicines terminology governance. The organization needs to have the legislative authority to govern and enforce and be flexible for effective management. 2) Create the organization as an independent or government organization or develop from the present organizations (such as the HIT department of MOPH) or establish a new organization 3) Develop the stakeholder network for medicines terminology development and empower stakeholders to use medicine terminology for drug information sharing
Funding resource	- Funding as a project - Concerns about the continuous and sufficient funding resource for maintenance	- Set the funding plan to conform to the policy and long term planning - Other funding resources from other organizations as the co-

Interview topics	Problems	Recommendations
	- Lack of other sources of funding	project
Development process	- Lack of participatory process for other stakeholders - Lack of stakeholder requirement assessment process	- Set up a process that allows the stakeholder to explain their requirements
Implementation process	- Lack of efficient communication process before and after enforcement - There are problems of user adoption after enforcement	- Set an implementation plan and communicate to the stakeholders - Set the preparation phase before enforcement for better user understanding and adoption
Maintenance process	- The problems of drug information collection and transferring system and process for updating - Lack of an efficient monitoring and evaluation process to explore governance and user problems	- Improve the drug information collection system by consulting with the Thai FDA to collect both registered and non-registered drug information, or develop channels or automatic application and setting the schedule for the Thai FDA, hospitals, and manufacturers to send drug information directly to the responsible organization - Setting monitoring and evaluation plans and processes to review the problems for better adoption
Tools and	- Insufficient tools and	- Develop the tools to respond to

Interview topics	Problems	Recommendations
services	inefficient services - Inconvenient and inactive problem solving service of the medicines terminology administrative organization - Lack of human resources in hospitals and the medicines terminology administrative organization to provide the knowledge and services for users	stakeholder needs - Training the users for initial problem solving - Improve the problem solving service - Set up a service for human resource development

4.3.2.5 Summarize the review of the experience of six countries and current situation of Thailand

The researcher summarizes the information of the review of the experience of six countries and current situation of Thailand in table 4. The information from the review of the experience of six countries and current situation of Thailand were used to design the governance model.

Table 4 Summarize the review of the experience of six countries and current situation of Thailand

Topic	Review from advanced countries	Thailand current situation
Policy	- Setting the prominent HIT and health data standard policy, roadmap and plan. - Setting the roadmap and plan for health data standard development in accordance with HIT development plan - Announce the legal to facilitate enforcement and adoption	- No clear roadmap and plan - No legal announcement to facilitate enforcement and adoption - The assigned organizations for medicines terminology development are lack of authority to enforce the medicines terminology and coordinate development and maintenance
Collaborative structure	- Established main responsible organization for HIT and health data standard - Collaborative structure in the form of committee and informal user community	- No main responsible organization responsible for HIT, health data standard, and medicines terminology governance

Topic	Review from advanced countries	Thailand current situation
Funding resource	- Main funding resource for HIT development according to the HIT roadmap from the government	- Funding as a project - Stakeholders concern about the continuous and sufficient funding resource for maintenance
Process	- The stakeholders participate for policy setting in the form of committees - Development process: user requirement identification, standard specification, and public consultation - Implementation process: implementation plan setting, communicate to stakeholders and facilitating user adoption. - Maintenance process: regular schedule to release and update the medicines terminology, and the stakeholders can request for urgent update	- Lack of participatory process for other stakeholders - Lack of stakeholder requirement assessment and consultation in development process - Lack of efficient communication process before and after enforcement
Tools and services	- All countries developed tools and services to facilitate the users - Necessary tools and services : medicines	- Insufficient tools and inefficient services - Inconvenient and inactive problem solving service of the medicines terminology

Topic	Review from advanced countries	Thailand current situation
	terminology browsers, mapping guidance and tools for mapping the medicines terminology and other drug codes, toolkit, helpdesk, training services, and a certification service for software suitable for medicines terminology	administrative organization

4.4. Proposed governance model

The proposed governance model was developed from the information collected from the review of the experience of six countries and current situation of Thailand. The researcher compares the governance system of the advanced countries and Thailand and synthesizes the model from this information. The first drafted model was developed and consulted with the stakeholders in consultation seminar and improved as second drafted model. The first drafted model and second drafted model was shown in appendix 5. The second drafted model was tested for usability testing from the experts and the result of the heuristics evaluation was shown in appendix 5. The second drafted model was improved as the proposed governance model. The proposed governance model is presented in three main areas, foundations, process, and tools and services.

4.4.1. Foundations

1) Policy: In the stakeholder consultation process, the participants concluded that the important policies for all national HIS system development and implementation should be set and the medicines terminology policy should be important, which conforms with the national HIS. The legal support medicines

terminology development should be carried out and enforced to accelerate adoption of health data standards and health information exchange. The committee for policy setting should comprise of the representatives of all the groups of stakeholders, such as the drug codes and medicines terminology administrators, the users in the hospital, the users in health insurance schemes, the users who are drug manufacturers and distributors, and the users in software manufacturing. At present, the medicines terminology development and implementation policy emphasizes the reimbursement use in health insurance schemes and not medical care. A policy to promote development and adoption for medical care, public health information exchange, and patient information exchange that the patients and caregivers should access their drug information should be emphasized.

2) Collaborative network and funding resource: In the stakeholder consultation process, the participants proposed to set up a HIT governance organization (HITGO) to coordinate and support HIS development including medicines terminology development, implementation, and maintenance. They proposed the HITGO be legally established as an independent organization authorized by MOPH receiving a budget from MOPH. The structure and functions of HITGO is proposed in figure 19. The HITGO has to co-operate with the stakeholders in the form of the collaborative structure seen in figure 20. The HITGO should co-operate with the ministry of public health, health insurance schemes, other government sectors, and the private sector in the form of a policy committee and medicines terminology working committee. The HITGO should support the user community as the informal collaborative network to accelerate user adoption.

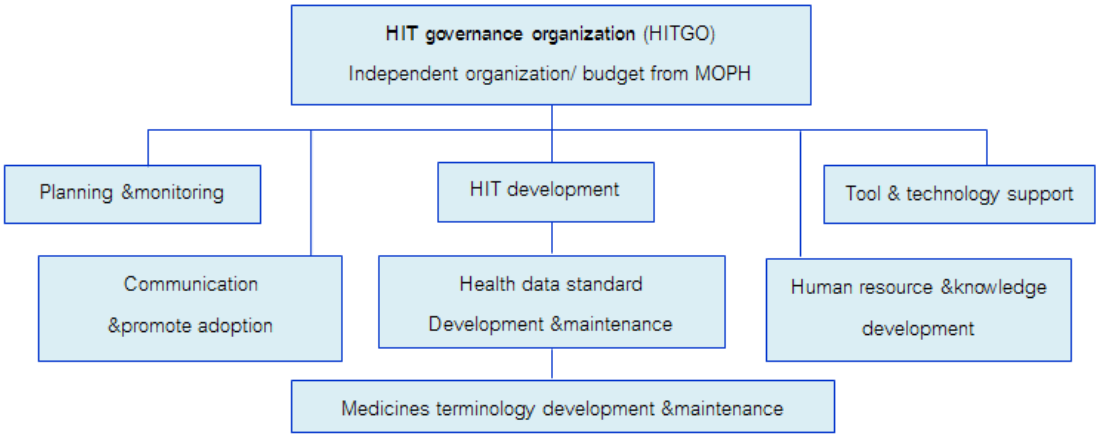

Figure 19 HIT governance organization and the functions related to medicines terminology governance

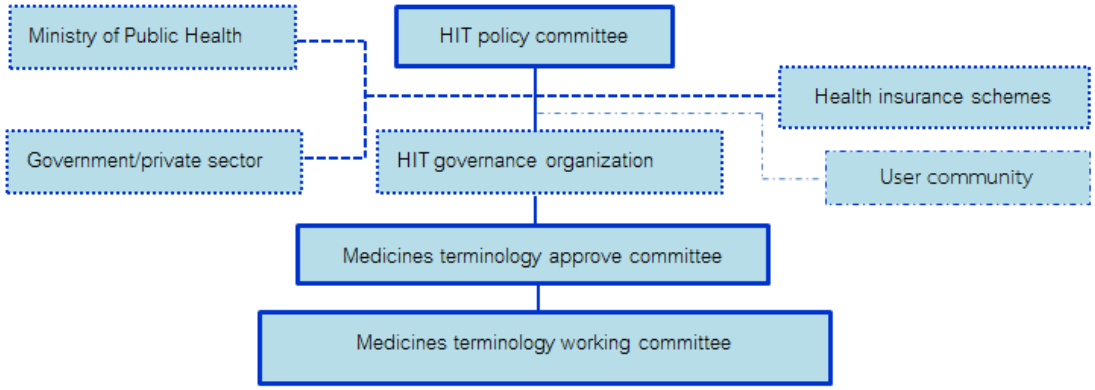

Figure 20 Collaborative structure for medicines terminology governance

Main collaborative structure
Formal collaborative network
Informal collaborative network

In the stakeholder consultation process, the participants proposed an independent organization similar to the National E-Health Transitional Authority of Australia (NEHTA) and proposed a collaborative network structure to coordinate for health data standards and medicines terminology governance similar to the Standard Collaborative of Canada. The functions of the main responsible organization was set by applying the functional structure theory suitable for the organization that has a unique or special expertise in business, non-competitive business, and necessitates high standards However, the organization design theory has limitations in co-operation among the departments in the organization and other relevant

organizations. The horizontal organizational linkage structure as the working committee and informal practitioner community will help to decrease this limitation [34].

In this study, usability testing applies the good governance principle for testing. All experts were concerned about the effectiveness and efficiency of the organization because the HIT governance organization should be flexible and adaptable to innovation and a changing environment.

The authority for regulation enforcement of the main responsible organization is a key issue, which all key informants and experts expressed concern because the organizations have to enforce consistent use of national health data standards for health information sharing in the government sector, private sector, and health insurance schemes. In Thailand, the body which has the regulation authority must be a government organization. In Thailand, the government organizations were established in various forms for more flexible management, such as privatization, service delivery units, and public organizations. These organizations must be established according to the law or regulations. The public organization is similar to the non-departmental public body of the UK.

The funding resource of public organizations in Thailand is sponsored by the government as the ministry's fiscal budget. The researchers found that some HIT organizations in other countries receive project funding support, research grants from other government departments and the private sector, and charge for services [18,19]. In the researchers view co-operation and co-funding with other government departments or the private sector for specific projects or research will accelerate development and adoption. In addition, charges for some services should be done to facilitate the users with more convenience and more efficiciency. The funding resources should not be limited only from the government budget.

4.4.2. Process

This study proposed the medicines terminology development process, implementation process, and maintenance process as shown in figures 21.

1) Development process: The requirement of user identification is the first step in development. A suitable option for development, such as adopting international medicines terminology or creating new medicines terminology will be selected by the medicines terminology working committee. Then, the medicines terminology specification will be developed and approved by the medicines terminology approval committee.

2) Implementation process: The implementation plan, the user manuals, services and supportive tools to be developed by the HITGO and medicines terminology working committee before a new medicines terminology announcement and enforcement. The user communication, training, and problem solving will be arranged after the new medicines terminology announcement. The HITGO will co-operate with the software manufacturers to develop software programs, which can use new medicines terminology for drug information exchange and certification of the software.

3) Maintenance: The plan for maintenance and the schedule for updating medicines terminology will be set and announced by HITGO. If the users cannot find the medicines terminology or find mistakes in medicines terminology, they can send a request for an urgent medicines terminology update. After an implementation period, the medicines terminology specification should be set. If the medicines terminology specification is not appropriate to the requirement of the users, it should be rejected and a new medicines terminology specification developed.

HITGO will co-operate with the stakeholders for medicines terminology development, implementation, and maintenance as in figure 22. The HITGO will collect new or updated drug information from Thai FDA database, hospitals and the manufacturers to create or update the medicines terminology and schedule announced to the users. In the stakeholder consultation process, the participants proposed two options for drug information collection to create and update medicines terminology. Option 1 proposes that the Thai FDA should be a center to collect both registered and non-registered drug information to be sent to HITGO to create or update medicines terminology. Option 2 proposes that the process may be

made shorter and faster if the manufacturers send their drug information to HITGO to create or update medicines terminology.

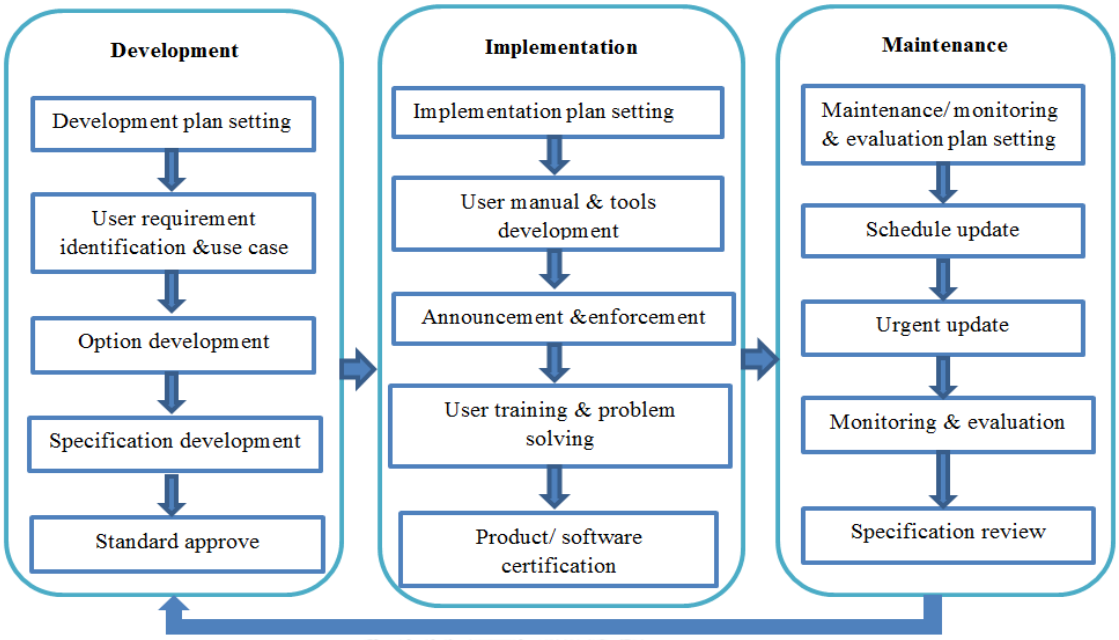

Figure 21 Process for health data standard and medicines terminology governance

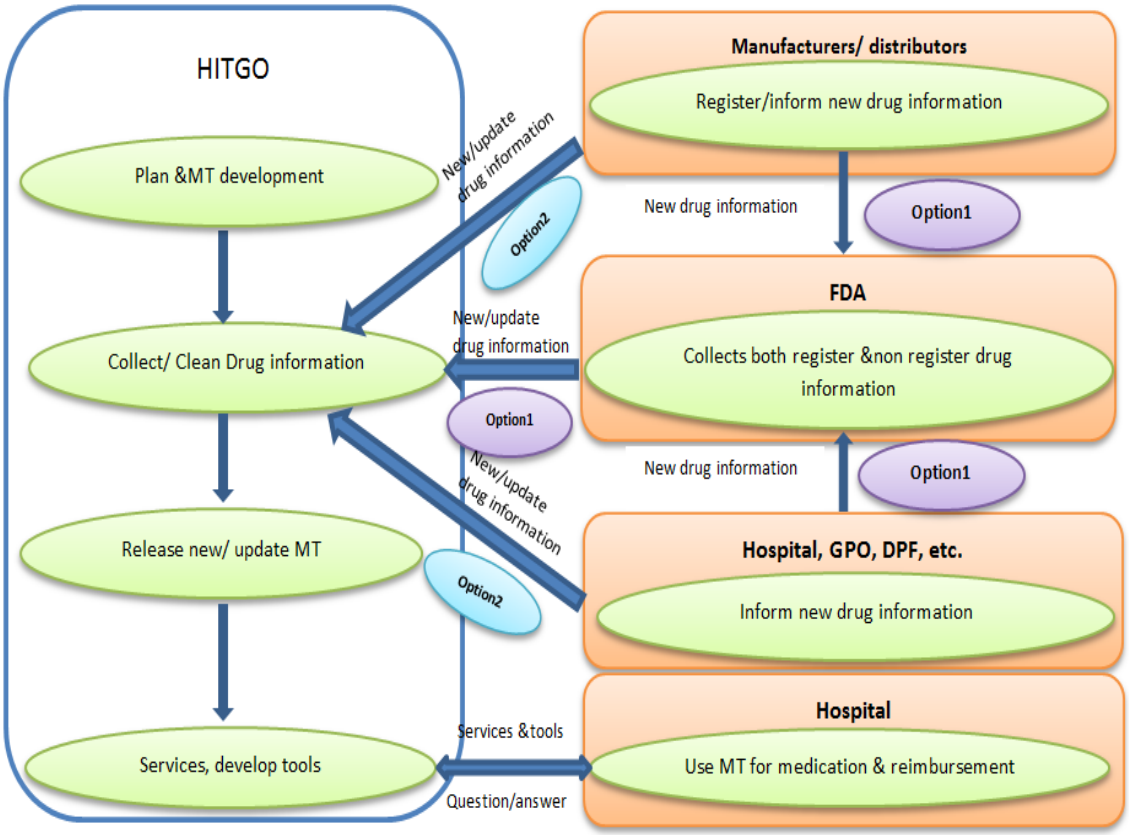

Figure 22 Collaborative structure and process for medicines terminology

4.4.3. Tools and service

1) Supportive tools: The important supportive tools, which should be developed for the users are as following:

- An electronic drug information collecting system enhanced to automatically transfer new or updated drug information from the Thai FDA, manufacturers, and hospitals.

- A repository tool to collect, search, and dowload documents, user manuals, or supportive tools about medicines terminology.

- The online medicines terminology database can help users to easily find the medicines terminology and download the updated medicines terminology.

- Mapping tools will be developed for mapping the new medicines terminology with other drug codes.

2) Public services: Necessary public service should be provided, such as user technical support and problem solving service, updated medicines terminology warnings and downloads

3) Knowledge service: A knowledge media, which health professionals can easily access and understand, trainning seminars, in-house training, and online training should be arranged for the users.

Chapter V
Conclusion and Recommendation

5.1 Conclusion

The research finding revealed that Thailand still lack of foundations and governance for health data standard including drug code and medicines terminology. A Lot of HIT applications have been pervasive used in Thailand and have no single standard for identified health information especially drug code. Various drug codes were initiated for drug information exchange and used for specific purpose in each health care unit and specific group of organizations as the local code. According to the national drug information requirements, the 24 digits drug codes and TMT are developed and used among health care institutions and health related organization.

The health data standard is an important component to enable national health information exchange among HIT application and was processed to be the meaningful information for management and decision making in every level of the healthcare system in the country. For example, the national medicine terminology should be used in all healthcare institues for drug information exchange. The drug information exchange in e-prescription system among healthcare institutes using the same standard code will enabling the consolidated patient profile and medicines used of individual patient that result in a complete profile of patient that will be benefit for health professional to do continuing of care. In addition, there are active movement of health data standard development and use in most country that have stable information technology infrastructure. Adopt or align international health data standard will be minimized the investment cost and can possible exchange the consolidated data among healthcare institutes or health related organization in the international level.

This study proposes the governance model for health data standard development by using medicines terminology as a case study for exploring the situation and developing governnance model. The governance model proposed the main responsible organization and collaborative structure for co-operating among

stakeholders in the process of governing health data standard and medicines terminology.

From the usability testing step which was the step to test the governance model, all experts concerned about the effectiveness and efficiency of the organization because the governance organization should be flexible and easily adapt to the rapid changing of health system context and information technology. In addition, the present application of health data standard and medicines terminolgy development in Thailand was focus on reimbursement purpose only which caused the limited scope of consideration when developing health data standard. To include more stakeholders and extend the scope of health data standard used will be strengthen the health data standard development and adoption.

The study proposed the organization type of health data standard as the public organization under Thai government. The public organization have authority to enforce regulation and more flexibility to perform their functions according to their missions. The flexibility nature of public organization also benefit for the organization to adapt to the innovation and changing environment.

The functions of the organization was set by applying the functional structure theory which is suitable for the organization which has the unique or special expertise business, non-competitive business, and require high standard. The organization design theory also has limitation in co-operation among the departments in the organization and other organizations. The horizontal organizational linkage stucture as the working committee and informal practitioner community will help to decrease this limitation [34].

The regulation to enforce all healthcare institutes and health related organizations to change to use the single national health data standard is very important. There are many barriers to block the stakeholders to change the health data standard in especially those who have already implemented their own health data identifiers. This study suggested that the health data standard organization should have authority and mechanism to collaborate, support, and manage the changing process.

The process of health data standard and the role of stakeholders in each process is important to the efficiency of the governance system. The key informants concerned that the long process may decrease the efficacy of governance system. The proposed governance model include the main important process for health data standard and medicines terminology governance, the details of each process should be setted by concerning to the efficiency and align with the good governance principle.

This study also suggested that tools and services are necessary to support the implementation of standard and facilitate stakeholders' adoption of the national health data standard. The researcher suggested that user requirement about tools and services should be studied and designed before implement each individual standard.

Normally, The public organization in Thailand is funded by the government as the original and only source of budget. The reserchers suggested that the co-operation and co-funding with other government sector or private sector for the specific projects or researches will accelerate the development and adoption of standard. In addition, additional fee charged for some services should be setted to decrease government investment and also enable good services to large group of customers.

5.2 Research recommendation

5.2.1 Recommendation for further study

This study proposed governance model for medicines terminology in Thailand which can apply to be a governance model of health data standard. The main components of the governance model are collaborative structure, process, tools and services, and role and responsibility of stakeholders were proposed based on the case study of medicines terminology. Future researchers should further study about the effective and appropriate of each components in the governance model, such as foundations, processes, and services and tools. In addtition, the details of mechanism to support and sustain the govenance model of health data standard is also important to study.

5.2.2 Recommendation for policy maker

From this study, the researchers would like to make recommendations to policy maker as follows:

1) Health data standard is very important to Thailand health information system. Its support the interoperability and health information exchange to improve the efficiency and effective of health system. The governance model of health data standard will enabling and sustain health data standard used among all stakeholders in Thailand.

The government should have national policy on health data standard and consider to issue the regulation of health data standard and establish the health data standard organization that have authority, structure and functions according to the governance model suggested by this study.

2) Health data standard evolve from time to time and have strong linkage with health information technology. In addition, implementing health data standard needed a lot of investment.

The government should encourage and support to sustain the development, implement, utilization and maintenance of health data standard with all mechanism.

5.3 Limitation of the study

There are several limitations of this study. First, the key informants were selected by purposive sampling with the expertise and working experience which the information from the interview may bias according to their expertise and working experience. The researchers attempt to decrease the respondents bias by include more stakeholders to be key informants in the interview process. The key informants cover the medicines terminology adminitrator group, health information's users in hospital, drug manufacturrers and distributor, and the health information system software producer. Using multi-techniques of qualitative research in this study allowed the reserachers to idenfify the dominant current situation issues and reach saturation of the requirements for governance model design.

Second, the consultation process should be done in wide range of stakesholders because the governance of health data standard affect to the wide

range of stakeholders. In this study, forty-five stakeholders participated in the stakeholders consultation process to identify the requirement and give suggestion for model design. Although the researchers cannot consult with the large group of stakeholders, the researchers realized the important of the usability of the model and designed to decrease the limitation by conducted usability testing with the experts. However, public hearing should be done to find the practical way for implementing the governance model.

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APPENDIX

Appendix 1

Use cases for governance model for medicines terminology

Use cases diagrams and scenarios in this document were designed for heuristic evaluation of the medicines terminology governance model. The use cases demonstrate the interaction of the system and the stakeholders in according to the medicines terminology governance model. The use cases comprise the following component.

1) The main stakeholders involved in the medicines terminology governance

2) Diagram and description of the scenario that shows the interaction of the main stakeholders to the system including four systems.

a. The development system of medicines terminology

b. The implementation system of medicines terminology

c. The maintenance of medicines terminology.

d. The code generation and usage of medicines terminology

The main stakeholders

1. The main responsibility stakeholder for the medicines terminology administration

1.1 Health information technology governance organization (HITGO) is the main responsibility organization. This organization has the legal authority to develop, implement, and facilitate adoption of the medicines terminology. This organization is responsible for administration of all health information system. This organization has the departments/ committee/ working group to support the work-related to the health data standard as follows:

- Policy, plan, and monitoring department is responsible for develop (draft) policy and plans about health information system and health data standards including budget allocation. The department is responsible for facilitate the policy committee for develop and review the drafted health information and health data standard policy and plan before proposed to the National Health Assembly. This

department also has a duty to regulate and monitor the work comply with the action plan.

- Health data standard development and maintenance department is responsible for develop and maintain health data standards including medicines terminology. This department also has a role in supporting the work of the working group, which consists of all relevant sectors to develop health data standards to propose to the medicines terminology approve committee which consisting of the expert about health data standards for approval and promulgation.

- Communications and promote adoption department is responsible for communicate to the users for the better understanding about the benefits of medicines terminology and promote the adoption for health information exchange.

- Tools and technology support is responsible for the development of tools and technologies to support the use of medicines terminology, and certificate the products and technologies that can use for support the use of medicines terminology.

- Human resource &knowledge development is responsible for support the health professional and health informatician development. In addition, this department supports the projects and research to develop the knowledge related to the health data standard and medicines terminology for information exchange.

- Medicines terminology policy approve committee comprises the experts. The committees have a duty to consider and approve the drafted policy according to the HIT policy.

- Medicines terminology policy working committee composes of the representatives from all sectors, such as Ministry of Public Health, hospitals, health insurance schemes. The working committees have a duty to develop and draft policy and plan.

- Medicines terminology working committee including the representative from all groups of stakeholder is responsible for medicines terminology development and the medicines terminology specification review according to the stakeholder requirement.

- Medicines terminology approved committee including the experts in health data standards and medicines terminology is responsible for consider the medicines terminology specification, give the comments and recommendation for improvement, and approve medicines terminology.

1.2 The organizations which sending drug information for medicines terminology update such as the Food and Drug Administration, the Government Pharmaceutical Organization (GPO) and the Defence Pharmaceutical Factory, hospitals, manufacturers, and Institute of Thai Traditional Medicine, and others are responsible for sending information to HITGO to create or update medicines terminology .

2. Medicines terminology users

- The users who use medicines terminology to prepare drug information for medication and reimbursement report including hospitals and health care units are responsible for preparing drug information by using medicines terminology for exchange, such as the information about drug use for medical treatment, drug reimbursement information to report to the Ministry of Public Health and health insurance scheme reimbursement administrators.

- The users who use medicines terminology for reimbursement administration including the National Health Security Office, Social Security Office, Ministry of Finance which use the drug information exchanged in health information systems to manage the reimbursement.

- The user who use drug information for medical treatment and the development of health systems including healthcare providers, hospitals, provincial public health office, and the Ministry of Public Health which use the drug for medical treatment, policy decisions, and the development of the public health system.

- A group of drug manufacturers and distributors who use medicines terminology for drug procurement in the hospital including drug manufacturers, importers, distributors hospitals which formulate and manufacture the medicine, and etc.

- Product and software manufacturers include product/ software manufacturer develop the product or software to support the use of medicines terminology for drug information exchange.

Medicines terminology development systems

Use case in this section covers the development process of medicines terminology since identifying the needs of the stakeholders, use case development to show the relationship between the user and medicines terminology, option development, select the available international medicines terminology or develop new medicines terminology specification that suitable to the need of stakeholders, and medicines terminology approval. The use case diagram shows the interaction of the stakeholders involved with the development system as shown in figure 23 and the description of the system is described as the scenarios. These consist of the main event and the exceptional events.

The role of stakeholders to the medicines terminology development system

Planning and monitoring department has the role in drafting the medicines terminology development policies and plans. The medicines terminology development policies and plan must be consistent with the health data standard development policy and health information technology development policy.

Medicines terminology policy approve committee comprises the experts. The committees have a duty to consider and approve the drafted policy according to the HIT policy. If the committee does not agree with the drafted policies and plans, the committee will give the suggestions for improvement. On the contrary, if the committee agrees with the drafted policies and plans, they will approve the policy and plan.

Medicines terminology policy working committee composes of the representatives from all sectors, such as Ministry of Public Health, hospitals, health insurance schemes. The working committees have a duty to develop and draft policy and plan.

Health data standard development and maintenance department has the role to support the working group/ committee involved in all drug development process. This department plays an important role in identifying the needs of the stakeholders, developing use case, searching for the current international medicines terminology and developing the options, and developing the medicines terminology specification.

Medicines terminology working committee has the role in choosing the options for development. If the current international medicines terminology is suitable to the need of stakeholders, the working committee will select the international medicines terminology and adapt for suitable. If there are no options which are suitable to the need of stakeholders, the working committee will develop new medicines terminology and its specification.

Medicines terminology approve committee play the role in considering the medicines terminology specification, make recommendations for improvement and approval.

Main event

An organization requires medicines terminology to exchange the drug information in medication and reimbursement purpose. The organization informs to the health data standard development and maintenance department. The health data standard development and maintenance department studies and identifies the need of stakeholders. The health data standard development and maintenance department co-operates with the planning and monitoring department and medicines terminology policy working committee to draft policy and plan for medicines terminology development. The drafted medicines terminology development policy and plans will be consulted with the stakeholders to receive comments and suggestions. The drafted medicines terminology development policy and plans will be improved based on stakeholders recommendations and propose to the medicines terminology policy approve committee for approval and announcement. The policy and plan will be monitored and reviewed as schedule for the effective development (Process 1).

The health data standard development and maintenance department will develop the medicines terminology according to the policies and plans for development by identifying the needs of stakeholders and studying the impact that may arise from the announcement and enforcement of medicines terminology. The use case of medicines terminology will be developed and consult to receive comment and suggestion from the stakeholders to improve more appropriate use case (process 2).

The health data standard development and maintenance department will search for the current international medicines terminology and develop the options. The options will be propose to the medicines terminology working committee. The committee will choose the best options by taking into account to the impacts such the fee of the international medicines terminology (Process 3).

The medicines terminology working committee adapts the international medicines terminology and develops the specifications to meet the needs of the user. The medicines terminology specification will be consulted with the stakeholders to receive the comments and suggestions for improvement (process 4) and proposed to the medicines terminology approve committee (process 5). After approval, the health data standard development and maintenance department will publish the specification through many channals.

Exceptional event 1

The health data standard development and maintenance department and medicines terminology working committee and found that the current international medicines terminologies are not suitable (process 3). The health data standard development and maintenance department and medicines terminology working committee will develop new medicines terminology specification according to the requirement of the users (process 4) and propose to the medicines terminology approve committee for approval (process 5).

Exceptional event 2

The medicines terminology approve committee consider that the medicines terminology specification is not appropriate and not cover the needs of the users. The medicines terminology approve committee will provide the recommendation to health data standard development and maintenance department for improvement. The medicines terminology working committee considers the recommendation and improves the specification. If the medicines terminology working committee does not agree with the recommendations, the committee will argue and give the reason to the medicines terminology approve committee for consideration (Process 5.2).

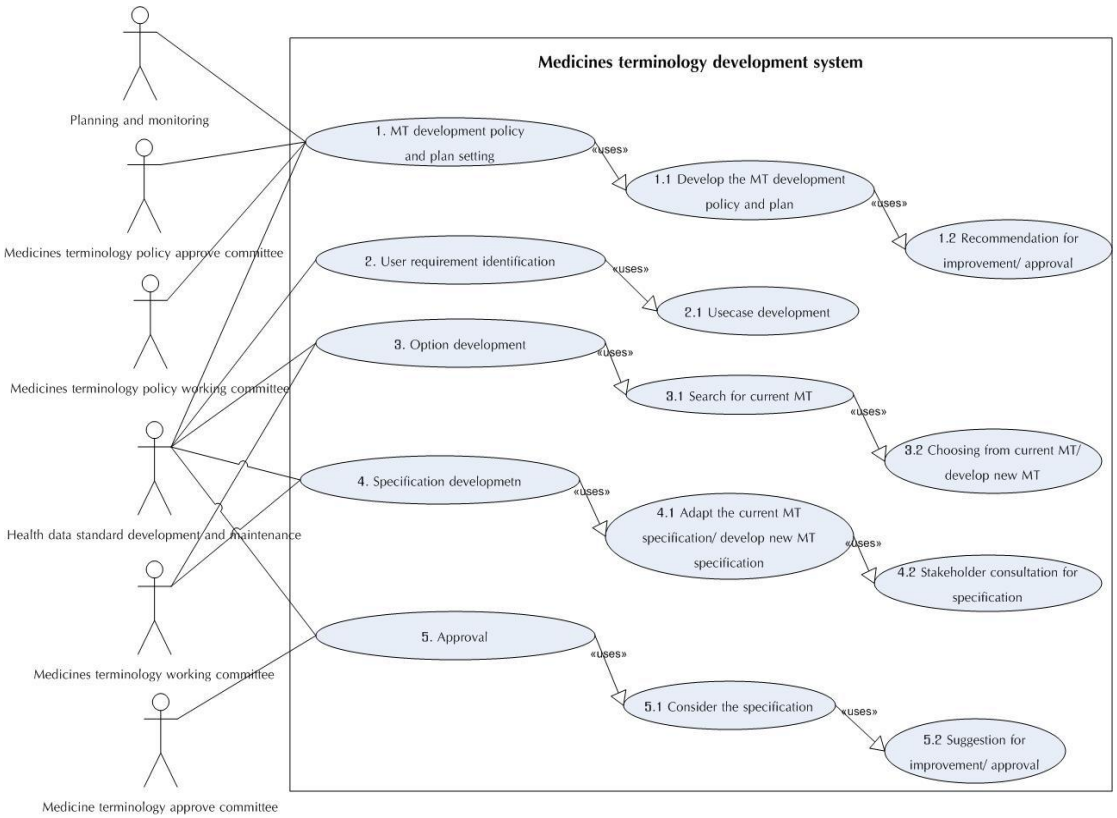


Figure 23 The use case diagram of medicines terminology development system

Medicines terminology implementation system

This use case scenario covers the implementation process of medicines terminology. The implementation processes are plan setting, user manual and supportive tool development, announcement and enforcement, publicity to promote the user adoption, user training and problem solving, products and software certification. The use case diagram shows the interaction of the stakeholders involved with the development system as shown in figure 24 and the description of the system is described as the scenarios. These consist of the main event and the exceptional events.

The role of stakeholders to the medicines terminology implementation system

Health data standard development and maintenance department co-operate with the communication and promote adoption department to set the plan, announcement and enforcement, and publicity to promote the user adoption. This department co-operate with the tool and technology support department to develop the user manual and supportive tool, problem solving service, and support products and software certification. This department also co-operate with human resource and knowledge development department for the knowledge development and user training.

Communication and promote adoption department has a role in determining an implementation plan, announcement and enforcement, and publicity to promote the user adoption.

Tool and technology support department has a role in the development of user manual and supportive tool, problem solving service, and products and software certification.

Human resource and knowledge development department has a role in user training and supports the knowledge development, such as support for research.

Main event

After the medicines terminology approve committee approved the medicines terminology specification, health data standard development and maintenance department co-operate with the communication and promote adoption department to study the current situation of the use of medicines terminology for drug

information exchange, the user requirement about service and tool to support the use of medicines terminology, the impact that may arise from the medicines terminology announcement, and offer the guidance and timing of implementation. The drafted of implementation plan will be set. The plan may be divided into two stages to minimize the impacts, including phase 1: using the medicines terminology with local drug code, and phase 2: after products / software supporting the use of medicines terminology were developed, a new medicines terminology was enforced to use for drug information exchange in the healthcare system and reimbursement system. The draft implementation plan will be consulted with stakeholders through various channels and improve according to the stakeholder recommendation, publish the final implementation plan, and implement the plan (Process 1).

Health data standard development and maintenance department co-operate with the tool and technology support department to develop the user manual and supportive tool, such as mapping tool, online medicines terminology database, repository tool, and etc. (process 2)

Then, the health data standard development and maintenance department announce to implement the medicines terminology (Process 3). The communication and promote adoption department publish the medicines terminology and promote the adoption to the health professional, health policy maker, health insurance scheme personal, and etc. The health data standard development and maintenance department co-operate with human resource and knowledge development department develops knowledge and publishes through various media to educate all stakeholders, such as online training media, visual training applications, training classes, and providing the channels for the users to interact and ask questions. In addition, they support the research funding and knowledge development to the interested researchers (Process 4). If the users have a technical problem, the users can contact and ask the health data standard development and maintenance department via phone and email. The health data standard development and maintenance department will answer questions within three business days (Process 5).

The tool and technology support department will develop products/ software specification which can use the medicines terminology for health information exchange. This department will encourage the products/ software manufacturers to develop the products/ software and certify products / software (Process 6).

Exceptional event

Hospital A cannot input new medicines terminology into the hospital electronic health record programs. The hospital officer asks the technical problem via e-mail to the Health data standard development and maintenance department. The health data standard development and maintenance department cannot answer the technical question. The health data standard development and maintenance department co-operates with the tool and technology support department for the problem solving. The tool and technology support department recognizes that this program is widely used in many hospitals throughout the country. The department co-operates with the software manufacturer for the problem but the manufacturer cannot solve the problems within three days. Therefore, health data standard development and maintenance department replies e-mail back to the hospital that the administrator is coordinating to the software manufacturer in order to solve the problem and postpone the question answering for 10 days. If they cannot solve the problem within 10 days which they inform to the hospital, they will inform the progression every 10 days until the problem was solved (Process 5).

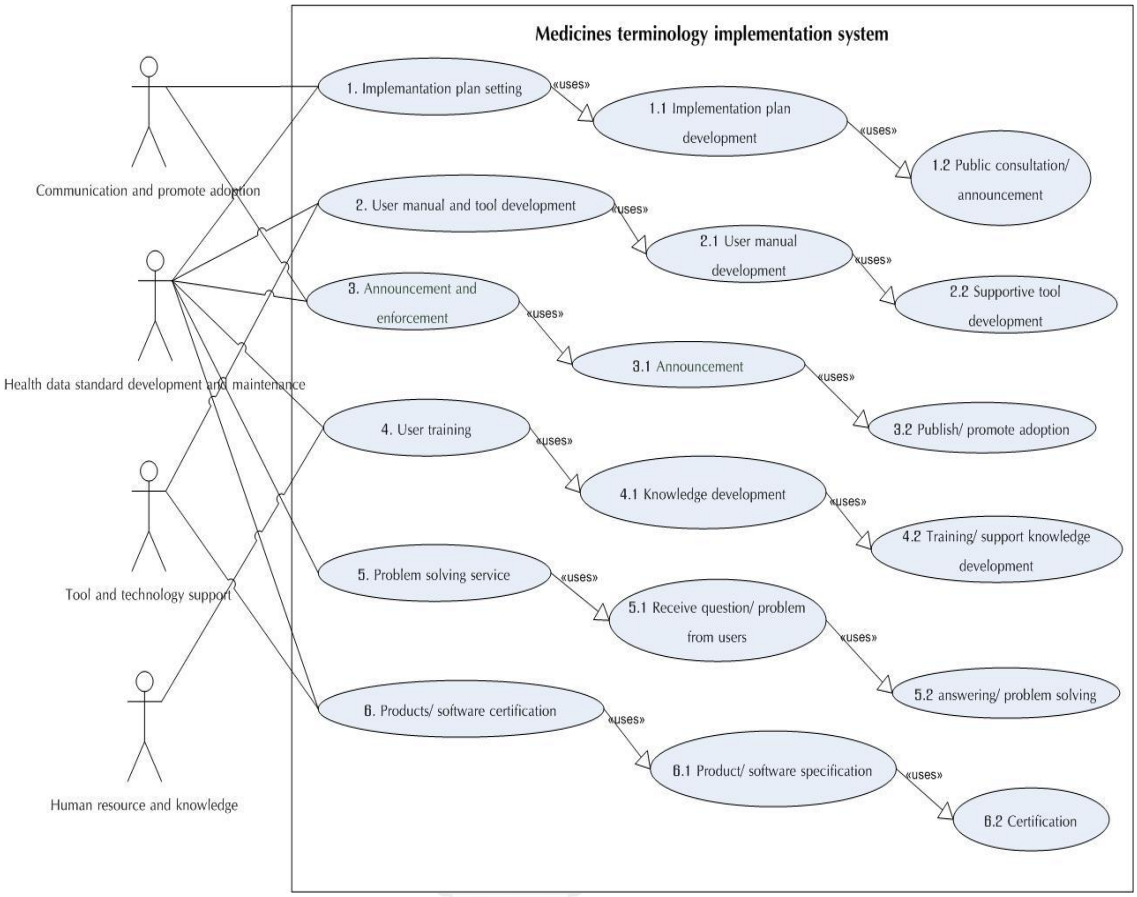


Figure 24 The use case diagram of medicines terminology implementation system

Medicines terminology maintenance system

This use case scenario covers the maintenance process of medicines terminology. The maintenance processes are maintenance/ monitoring and evaluation plan setting, schedule update by updating medicines terminology from the new drug information or update drug information, urgent update when the users have the urgent problem of medicines terminology using, and the monitoring and evaluation for the system improvement. After implementation, the medicines terminology specification will be reviewed for the appropriation according to the schedule. Use case diagram shows the interaction of the stakeholders involved with the development system as shown in figure 25 and the description of the system is described as the scenarios. These consist of the main event and the exceptional events.

The role of stakeholders to the medicines terminology implementation system

Health data standard development and maintenance department has an important role in maintenance/ monitoring and evaluation plan setting, schedule update and urgent update, monitoring and evaluation for the system improvement, and facilitate the medicines terminology working committee to review the medicines terminology specification.

Medicines terminology working committee has a role in review the medicines terminology specification for the appropriation.

Main event

After medicines terminology announcement and enforcement, health data standard development and maintenance department will co-operate with the relevant and the medicines terminology working committee to set the maintenance/ monitoring and evaluation plan setting and implement the plan. The maintenance/ monitoring and evaluation plan setting includes the schedule updating plan, monitoring and evaluation plan, and the medicines terminology specification review plan (Process 1).

Health data standard development and maintenance department will update the medicines terminology according to the plan. When the department receiving new or changed drug information, the department will verify and summarize the drug

information in the medicines terminology specification form. Then, the department will create the medicines terminology and publish according to the update schedule, such as every 2nd and 4th Wednesday of the month. The hospital and other users can subscribe to download updated medicines terminology through website and members will receive an email notification when medicines terminology was updated (Process 2).

Health data standard development and maintenance department is responsible for monitoring and evaluating the medicines terminology according to the plan. The monitoring and evaluation result will be presented to the medicines terminology working committee to give the recommendation for improvement. The health data standard development and maintenance department present the recommendation to HIT policy committee for policy and plan setting (Process 4).

After medicines terminology was implemented for a while (eg. four years), the user requirement situation may change, and the medicines terminology specifications may not meet the needs of the user. Health data standard development and maintenance department will co-operate with the medicines terminology working committee to review the medicines terminology specification. If the medicines terminology specification is still appropriate to the current working situation, the current medicines terminology specification will be continued to use. If the requirements do not meet the current needs of the users, the medicines terminology specification will be rejected and develop new medicines terminology. The review result will be informed to the stakeholders (Process 5).

Exceptional event

Hospital A inputs the medicines terminology into the hospital electronic system. The officer founds that a drug contains 60 cc but the drug information in the medicines terminology performs 600 cc which is not correct. The hospital has the reimbursement problem, then the officer informs to the health data standard development and maintenance department for urgent update. The health data standard development and maintenance department receives this problem from other hospitals and the health insurance scheme administrators, and request for

urgent update. The department corrects this problem and notices to the members by email (Process 3).

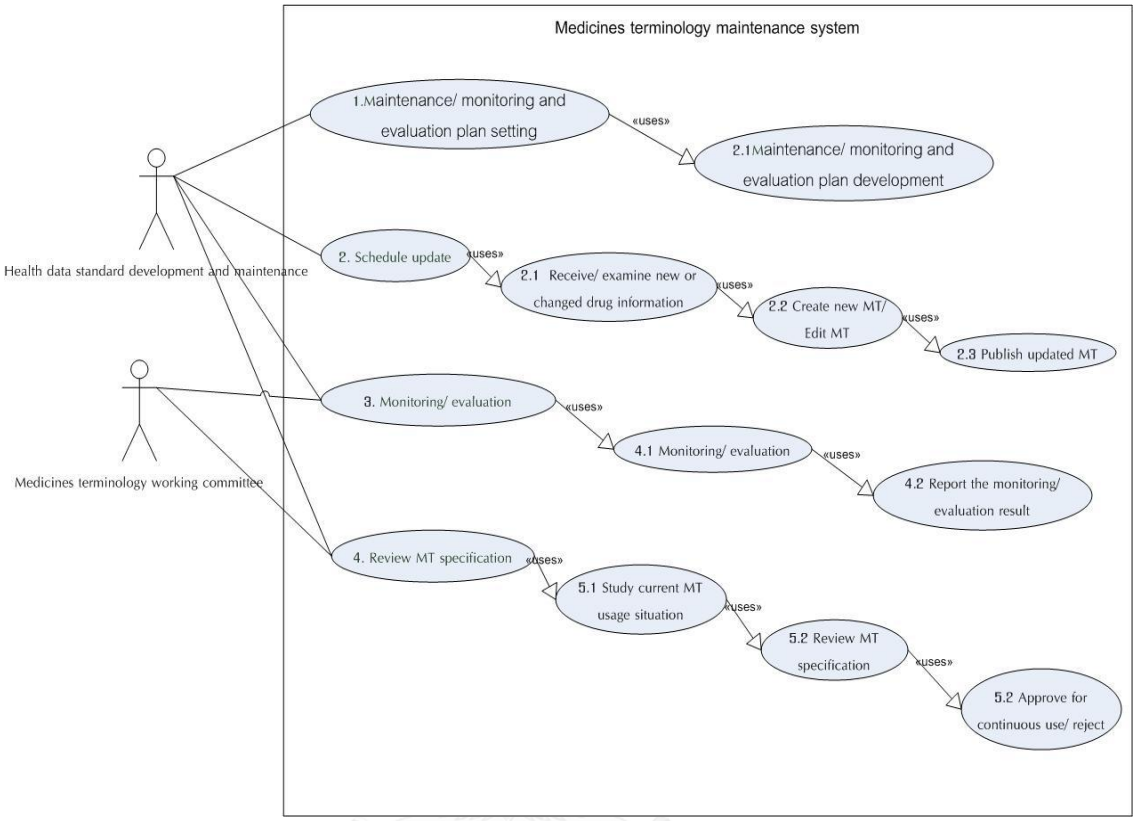


Figure 25 The use case diagram of medicines terminology maintenance system

System for collecting drug information, creating, and using medicines terminology

This use case scenario covers the process for collecting drug information, creating, and using medicines terminology. This use case diagram shows the interaction of the stakeholders involved with the drug information transferring and collecting process to create medicines terminology, and the medicines terminology usage as shown in figure 26 and the description of the system is described as the scenarios. These consist of the main event and the exceptional events.

The role of stakeholders to the medicines terminology implementation system

Health IT governance organization (HITGO) The health data standard development and maintenance department in this organization is the main responsible department in developing guidelines for collecting drug information, creating, and supporting medicines terminology adoption. This department is also responsible for collecting and verifying the drug information, creating, and publishing the medicines terminology. This department co-operate with other internal departments to promote the development of software products supporting the use of medicines terminology and promote user adoption for drug information exchange through the electronic systems.

Medicines terminology working committee has a role in establishing guidelines for collecting drug information, creating, and supporting medicines terminology adoption.

Food and drug administration (FDA) has a role in collecting and verifying drug information which registered with the Food and drug administration. The organization will send the drug information to the HITGO to create the medicines terminology.

Drug entrepreneurs This includes the Government pharmaceutical organization (GPO) and the Defence pharmaceutical factory, manufacturers, and drug importers which play a role in the transmission of drug information to the HITGO to create / update the medicines terminology.

Hospitals play a role in the transmission of hospital formulary drug information to the HITGO to create / update the medicines terminology. The hospital

is a medicines terminology user in the delivery of drug use information for medical treatment and reimbursement.

Health insurance schemes includes the universal coverage scheme (UCS), the social security scheme (SSS), and the Civil Servant Medical Benefit Scheme (CSMBS). These organizations use medicines terminology for the drug reimbursement information exchange, and use the information for policy decision.

Health care professionals and the public health developers are the medicines terminology users for drug information exchange and use the information for health care decision and public health development.

Main event

HITGO and medicines terminology working committee set the guidelines for collecting drug information, creating, and supporting medicines terminology adoption (Process 1).

FDA collects and transfers drug registration information to the HITGO. In most of the drug that does not require registration. In the case of non-registration drug, the manufacturers including GPO, the Defence pharmaceutical factory, hospitals, etc. will be sent the drug information to the HITGO. HITGO collects the drug information as schedule (such as every two weeks) and set the convenient channel for transferring drug information (such as developing the automatic transferring application for drug information delivery from FDA database, and developing the application/ form/ channel for online drug information delivery from other manufacturers (Process 2).

The HITGO verifies the drug information and formats according to the medicines terminology specification. If the FDA or other relevant organizations can collect and verify the non-registered drug information in the database, the organization will be able to participate in the collecting and verifying the non-registered drug information. The verified drug information will be published (Process 3).

The verified and formatted drug information will be created the medicines terminology according to the specification. The HITGO may develop the software to verify and create the medicines terminology. The HITGO will publish the updated medicines terminology as schedule through the various channels. The HITGO will

provide updating notification and the users can download the updated medicines terminology. Users can send the drug information or opinions if the users find the error or incomplete of information via the website or email (process 4).

For medicines terminology usage, drug information (such as, drug name, drug volume, dosage, drug price, and etc.) will be record in the application which support the medicines terminology. If hospital A needs to refer the patient to the hospital B, the hospital A can send the drug use information by using the medicines terminology to exchange. The hospital A can use the medicines terminology to sending drug reimbursement information to the health insurance schemes and exchange the drug information to the relevant organizations for collecting/ analyzing drug information. The organizations must to do the agreement about the exchanged and accessible drug information description (Process 5).

Exceptional event

Pharmaceutical company A will sell new drug to the hospitals which the company must inform the drug code to the hospital. But the company A cannot find the drug code in the online medicines terminology database. In addition, the company A also found that the drug information manufactured by company A in online medicines terminology database is incorrect. The company A sends the new drug information and corrected drug information to the HITGO. The HITGO will create/update drug information and inform to the company A and publishes to the users (Process 2).

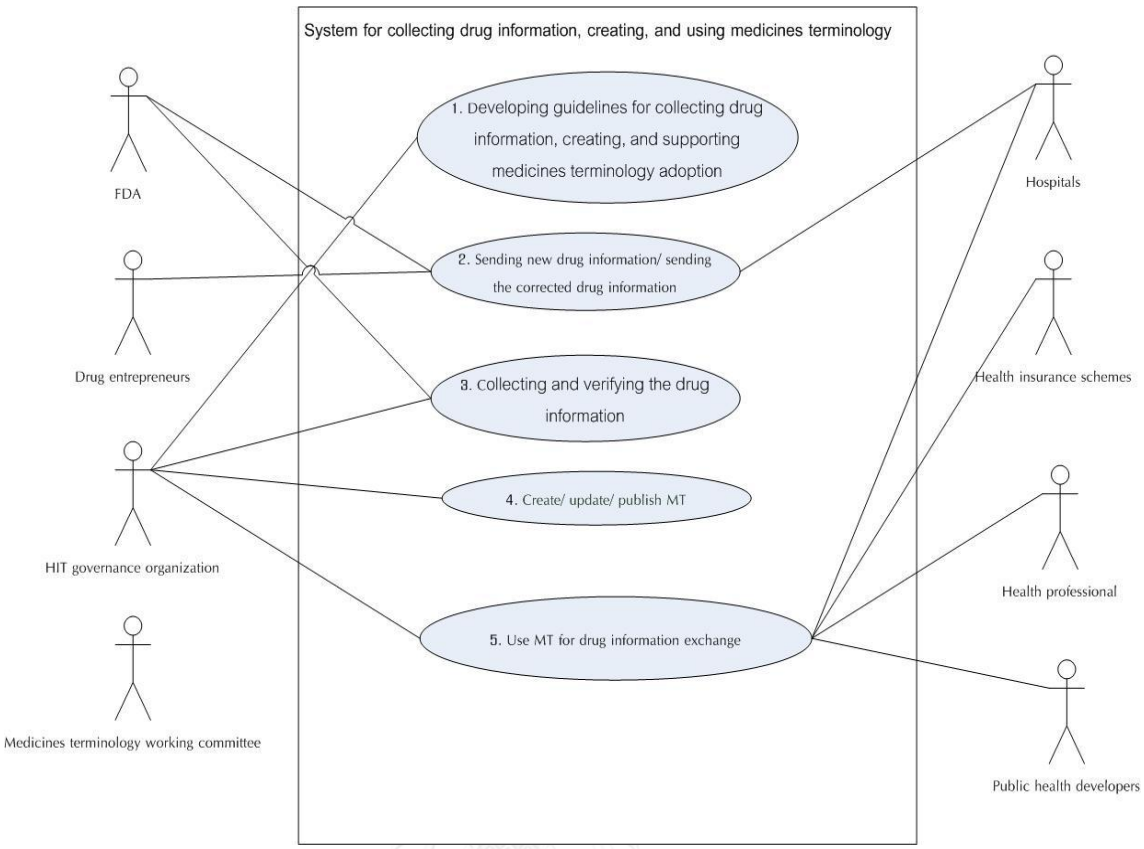


Figure 26 The use case diagram of System for collecting drug information, creating, and using medicines terminology

Appendix 2

Use cases for governance model for medicines terminology (Thai language)

แผนภาพและสถานการณ์แสดงปฏิสัมพันธ์ของระบบและผู้เกี่ยวข้องในการอภิบาล
บัญชีข้อมูลยาและรหัสยามาตรฐานที่สัมพันธ์กับการทำงานของผู้ใช้ระบบ
(Use cases for governance model for medicines terminology)

แผนภาพและสถานการณ์แสดงปฏิสัมพันธ์ของระบบและผู้ใช้ (Use cases) ในเอกสารฉบับนี้สร้างขึ้นเพื่อใช้ประกอบการประเมินด้วยวิธีฮิวริสติกเพื่อประเมินตัวแบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานที่ผู้วิจัยได้พัฒนาขึ้น แผนภาพและสถานการณ์แสดงปฏิสัมพันธ์ของระบบและผู้ใช้นี้จะจำลองปฏิสัมพันธ์ของผู้เกี่ยวข้องต่อระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานตามตัวแบบที่ผู้วิจัยได้พัฒนาขึ้นในการวิจัยเพื่อพัฒนาตัวแบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐาน (Governance model for medicines terminology) ประกอบด้วย

1) กลุ่มผู้เกี่ยวข้องหลักที่เกี่ยวข้องกับการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐาน

2) แผนภาพ และคำอธิบายสถานการณ์จำลองที่แสดงถึงความสัมพันธ์ของระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานหลักที่สัมพันธ์กับผู้เกี่ยวข้อง ใน 4 ระบบ ได้แก่

ก. ระบบการพัฒนาบัญชีข้อมูลยาและรหัสยามาตรฐาน

ข. ระบบการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้

ค. ระบบการดูแลและบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐาน

ง. ระบบการสร้างและการใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน

หมายเหตุ: *ต่อจากนี้จะใช้คำว่า Use case แทนแผนภาพและสถานการณ์แสดงปฏิสัมพันธ์ของระบบและผู้ใช้ และในแผนภาพจะใช้ตัวย่อ MT แทนคำว่าบัญชีข้อมูลยาและรหัสยามาตรฐาน*

กลุ่มผู้เกี่ยวข้องหลัก

1.กลุ่มผู้รับผิดชอบหลักในการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐาน

1.1หน่วยงานอภิบาลระบบสารสนเทศสุขภาพเป็นผู้รับผิดชอบหลักในการอภิบาลฯ เป็นหน่วยงานที่มีอำนาจตามกฎหมายในการพัฒนา และประกาศใช้มาตรฐานข้อมูลสุขภาพและบัญชีข้อมูลยาและรหัสยามาตรฐาน โดยหน่วยงานดังกล่าวมีหน้าที่รับผิดชอบในการพัฒนาและดูแลระบบสารสนเทศสุขภาพทั้งระบบ ซึ่งจะมีหน่วยงานภายใน/คณะกรรมการ/คณะทำงานสนับสนุนการทำงานที่เกี่ยวข้องกับมาตรฐานข้อมูลสุขภาพ ดังนี้

- ฝ่ายนโยบายและแผน และกำกับติดตาม ทำหน้าที่พัฒนา(ร่าง)นโยบายและแผนพัฒนาระบบสารสนเทศสุขภาพและมาตรฐานข้อมูลสุขภาพ พิจารณาจัดสรรงบประมาณภายในหน่วยงาน

ในส่วนที่เกี่ยวข้องกับมาตรฐานข้อมูลสุขภาพมีหน้าที่ร่างนโยบายและแผนมาตรฐานข้อมูลสุขภาพ สนับสนุนการทำงานการพัฒนาร่างฯและทบทวนนโยบายฯของคณะทำงานพัฒนานโยบายและแผนมาตรฐานข้อมูลสุขภาพใน เพื่อเสนอต่อคณะกรรมการพิจาณานโยบายมาตรฐานข้อมูลสุขภาพพิจารณาหรือเสนอเข้าสู่กระบวนการของสมัชชาสุขภาพแห่งชาติ รวมถึงมีหน้าที่กำกับดูแลให้เป็นไปตามแผนการดำเนินงานที่กำหนด

- ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ รับผิดชอบในการพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ รวมถึงการพัฒนาและดูแลบัญชีข้อมูลยาและรหัสยามาตรฐาน ในการพัฒนามาตรฐานในการพัฒนามาตรฐานข้อมูลสุขภาพฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจะมีบทบาทในการสนับสนุนการทำงานของคณะทำงานซึ่งประกอบด้วยผู้เกี่ยวข้องทุกภาคส่วนเพื่อพัฒนามาตรฐานข้อมูลสุขภาพ เสนอต่อคณะกรรมการที่ประกอบด้วยผู้เชี่ยวชาญมาตรฐานข้อมูลสุขภาพพิจารณาเพื่ออนุมัติและประกาศใช้

- ฝ่ายสื่อสารและสนับสนุนการนำไปใช้ รับผิดชอบในการสื่อสารให้ผู้ใช้ทราบถึงประโยชน์ของมาตรฐานข้อมูลสุขภาพและบัญชีข้อมูลยาและรหัสยามาตรฐาน สนับสนุนให้นำมาตรฐานสุขภาพไปใช้เพื่อแลกเปลี่ยนข้อมูล

- ฝ่ายสนับสนุนเครื่องมือและเทคโนโลยี รับผิดชอบในการพัฒนาเครื่องมือและเทคโนโลยีเพื่อสนับสนุนการใช้งานมาตรฐานข้อมูลสุขภาพและบัญชีข้อมูลยาและรหัสยามาตรฐาน และรับรองผลิตภัณฑ์และเทคโนโลยีที่รองรับการใช้งานมาตรฐานข้อมูลสุขภาพ

- ฝ่ายพัฒนาบุคลากรและส่งเสริมการพัฒนาความรู้ รับผิดชอบในการส่งเสริมบุคลาการทางการแพทย์และเวชสารสนเทศ และจัดทำโครงการและให้การสนับสนุนการวิจัยเพื่อพัฒนาองค์ความรู้ที่เกี่ยวข้องกับการนำมาตรฐานข้อมูลสุขภาพและบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้ในการแลกเปลี่ยนข้อมูล

- คณะกรรมการพิจารณานโยบายบัญชีข้อมูลยาและรหัสยามาตรฐานประกอบด้วยผู้เชี่ยวชาญ มีหน้าที่พิจารณา ให้ข้อเสนอแนะ หรืออนุมัติร่างนโยบายพัฒนามาตรฐานข้อมูลสุขภาพที่สอดคล้องกับนโยบายและแผนการพัฒนาระบบสารสนเทศ

- คณะทำงานพัฒนาและทบทวนนโยบายบัญชีข้อมูลยาและรหัสยามาตรฐาน ประกอบด้วยตัวแทนผู้เกี่ยวข้องทุกภาคส่วน เช่น โรงพยาบาล กองทุนสุขภาพ กระทรวงสาธารณสุข เป็นต้น ทำหน้าที่พัฒนาร่างนโยบาย และทบทวนนโยบายและแผนพัฒนามาตรฐานข้อมูลสุขภาพ

- คณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาและรหัสยามาตรฐานประกอบด้วยตัวแทนผู้เกี่ยวข้องจากทุกภาคส่วน ทำหน้าที่พัฒนาบัญชีข้อมูลยาและรหัสมาตรฐานยา และทบทวนข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยาให้ตรงกับความต้องการของผู้ใช้อยู่เสมอ

- คณะกรรมการอนุมัติบัญชีข้อมูลยาและรหัสยามาตรฐานประกอบด้วยผู้เชี่ยวชาญด้านมาตรฐานข้อมูลสุขภาพ มีหน้าที่พิจารณาให้ข้อคิดเห็นในการปรับปรุงข้อกำหนด และอนุมัติใช้

1.2 หน่วยงานส่งข้อมูลยา ได้แก่ สำนักงานคณะกรรมการอาหารและยา ผู้ประกอบการยา องค์การเภสัชกรรม โรงงานเภสัชกรรมทหาร โรงพยาบาล และอื่นๆ รับผิดชอบในการส่งข้อมูลให้กับหน่วยงานอภิบาลระบบสารสนเทศสุขภาพเพื่อนำไปสร้างหรือปรับปรุงรหัสยามาตรฐาน

2. กลุ่มผู้ใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน ประกอบด้วย

- ผู้เตรียมข้อมูลรายงาน ได้แก่ โรงพยาบาล และหน่วยบริการข้อมูลสุขภาพ ทำหน้าที่เตรียมข้อมูลเพื่อการแลกเปลี่ยนข้อมูลในระบบสารสนเทศสุขภาพผ่านบัญชีข้อมูลยาและรหัสยามาตรฐาน เช่น ข้อมูลการใช้ยาเพื่อการรักษาพยาบาล ข้อมูลการเบิกจ่ายยาตามสิทธิ เพื่อรายงานต่อกระทรวงสาธารณสุขและหน่วยงานบริหารการเบิกจ่าย

- กลุ่มผู้ใช้ข้อมูลเพื่อการบริหารการเบิกจ่าย ในประเทศไทยหน่วยงานการบริหารการเบิกจ่าย คือ กองทุนสุขภาพทั้ง 3 กองทุน ได้แก่ สำนักงานหลักประกันสุขภาพแห่งชาติ สำนักงานประกันสังคม กระทรวงการคลัง นำข้อมูลที่แลกเปลี่ยนด้วยมาตรฐานข้อมูลสุขภาพในระบบเวชสารสนเทศมาใช้เพื่อบริหารการเบิกจ่าย

- กลุ่มผู้ใช้ข้อมูลเพื่อการรักษาพยาบาลและการพัฒนาระบบสาธารณสุข ได้แก่ บุคลากรทางการแพทย์ โรงพยาบาล ศูนย์ข้อมูลสำนักงานสาธารณสุขจังหวัด และกระทรวงสาธารณสุข ใช้ข้อมูลที่โรงพยาบาลส่งให้เพื่อการตัดสินใจในการรักษาพยาบาล การตัดสินใจเชิงนโยบายและการพัฒนาระบบสาธารณสุข

- กลุ่มผู้ประกอบการยา ได้แก่ ผู้ผลิต ผู้นำเข้ายา และผู้จัดจำหน่ายยา ใช้รหัสยามาตรฐานในการจำหน่ายยา ซึ่งรวมถึงโรงพยาบาลที่ผลิตยาเอง องค์การเภสัชกรรม โรงงานเภสัชกรรมทหาร ฯลฯ

- กลุ่มผู้พัฒนาผลิตภัณฑ์/ซอฟแวร์ ได้แก่ ผู้ผลิตผลิตภัณฑ์/ซอฟท์แวร์ โปรแกรมเมอร์ นำบัญชีข้อมูลยาและรหัสยามาตรฐานที่ประกาศใช้ไปพัฒนาผลิตภัณฑ์/ซอฟแวร์ให้รองรับการใช้บัญชีข้อมูลยาและรหัสยามาตรฐานในการแลกเปลี่ยนข้อมูลสุขภาพ

ระบบการพัฒนาบัญชีข้อมูลยาและรหัสยามาตรฐาน

Use case ในส่วนนี้จะครอบคลุมกระบวนการพัฒนาบัญชีข้อมูลยาและรหัสยามาตรฐาน ตั้งแต่ระบุความต้องการของผู้ที่มีส่วนเกี่ยวข้องและพัฒนา Use case เพื่อแสดงความสัมพันธ์ของผู้ใช้กับบัญชีข้อมูลยาและรหัสยามาตรฐานที่จะพัฒนาขึ้น พัฒนาทางเลือกว่าในปัจจุบันมีบัญชีข้อมูลยาและรหัสยามาตรฐานสากลหรือมาตรฐานใดที่มีอยู่และตอบสนองต่อความต้องการในการใช้งานได้บ้าง จากนั้นอาจเลือกบัญชีข้อมูลยาและรหัสยามาตรฐานที่มีอยู่มาปรับใช้ หรือพัฒนามาตรฐานขึ้นใหม่โดยพัฒนาข้อกำหนดมาตรฐานข้อมูลสุขภาพที่เหมาะสมกับการใช้งาน และขออนุมัติใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน แผนภาพจะแสดงปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องกับระบบการพัฒนาฯ

ดังแสดงในแผนภาพที่ 1 และคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องกับระบบจะอธิบายผ่านสถานการณ์จำลอง โดยจะประกอบด้วยสถานการณ์หลัก(main event) และสถานการณ์ยกเว้น (exceptional events)

บทบาทผู้เกี่ยวข้องต่อระบบการพัฒนาบัญชีข้อมูลยาและรหัสมาตรฐานยา

ฝ่ายนโยบายและแผน และกำกับติดตาม มีบทบาทในการร่างนโยบายและแผนการพัฒนาบัญชีข้อมูลยาและรหัสมาตรฐานยา โดยนโยบายและแผนที่พัฒนาขึ้นต้องสอดคล้องกับนโยบายการพัฒนามาตรฐานข้อมูลสุขภาพและนโยบายการพัฒนาระบบสารสนเทศสุขภาพ

คณะกรรมการพิจารณานโยบายบัญชีข้อมูลยาและรหัสยามาตรฐาน ประกอบด้วยผู้เชี่ยวชาญ มีหน้าที่พิจารณา ให้ข้อเสนอแนะ หรืออนุมัติร่างนโยบายพัฒนามาตรฐานข้อมูลสุขภาพที่สอดคล้องกับนโยบายและแผนการพัฒนาระบบสารสนเท ศหากไม่เห็นชอบจะให้ข้อเสนอแนะเพื่อปรับปรุงร่าง และหากเห็นชอบจะอนุมัติให้ประกาศนโยบายฯ

คณะทำงานพัฒนาและทบทวนนโยบายบัญชีข้อมูลยาและรหัสยามาตรฐาน ประกอบด้วยตัวแทนผู้เกี่ยวข้องทุกภาคส่วน เช่น โรงพยาบาล กองทุนสุขภาพ กระทรวงสาธารณสุข เป็นต้น ทำหน้าที่พัฒนาร่างนโยบาย และทบทวนนโยบายและแผนพัฒนามาตรฐานข้อมูลสุขภาพ

ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ มีบทบาทสนับสนุนการทำงานของคณะทำงาน/คณะกรรมการที่เกี่ยวข้องในทุกกระบวนการพัฒนาบัญชีข้อมูลยาและรหัสมาตรฐานยา มีบทบาทสำคัญในการระบุความต้องการของผู้เกี่ยวข้อง พัฒนา use case การใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน ค้นหาบัญชีข้อมูลยาและรหัสมาตรฐานยาที่มีใช้อยู่ในปัจจุบันและพัฒนาทางเลือก และมีบทบาทในการพัฒนาข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยา

คณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาและรหัสมาตรฐานยา มีบทบาทในการเลือกว่าจะนำบัญชีข้อมูลยาและรหัสมาตรฐานยาที่มีอยู่มาปรับใช้ หรือจะพัฒนาขึ้นใหม่ มีบทบาทในการพัฒนาข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยา

คณะกรรมการพิจารณาอนุมัติมาตรฐานข้อมูลสุขภาพ มีบทบาทในการพิจารณาข้อกำหนดมาตรฐานข้อมูลสุขภาพและบัญชีข้อมูลยาและรหัสมาตรฐานยา ให้ข้อเสนอแนะในการปรับปรุงและอนุมัติใช้

สถานการณ์หลัก

หน่วยงานก.มีความต้องการบัญชีข้อมูลยาและรหัสยามาตรฐานเพื่อแลกเปลี่ยนข้อมูลยาที่ใช้ในการรักษาและเพื่อเบิกจ่ายค่ายา จึงแจ้งความต้องการกับฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพศึกษาวัตถุประสงค์ในการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้งานของผู้เกี่ยวข้อง ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพร่วมกับฝ่ายนโยบายและแผนและกำกับติดตาม และคณะทำงานพัฒนาและทบทวนนโยบายบัญชีข้อมูลยาและ

รหัสยามาตรฐาน ร่างนโยบายและแผนการพัฒนาฯ จากนั้นนำ(ร่าง)นโยบายและแผนการพัฒนารับฟังความคิดเห็นและข้อเสนอแนะจากผู้เกี่ยวข้อง ดำเนินการปรับปรุงแก้ไขตามข้อเสนอแนะแล้วนำเสนอต่อคณะกรรมการพิจารณานโยบายบัญชีข้อมูลยาและรหัสยามาตรฐานอนุมัติและประกาศนโยบายแผน เมื่อมีการดำเนินการตามนโยบายและแผนการพัฒนาบัญชีข้อมูลยาและรหัสยามาตรฐานไปตามระยะเวลาที่กำหนดจะมีการกำกับติดตามและทบทวนเพื่อให้การพัฒนาบัญชีข้อมูลยาและรหัสยามาตรฐานดำเนินไปอย่างมีประสิทธิภาพ (กระบวนการที่ 1)

ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจะดำเนินการตามนโยบายและแผนการพัฒนาฯ โดยระบุความต้องการของผู้เกี่ยวข้อง รวมถึงผลกระทบที่อาจจะเกิดขึ้นจากการประกาศและบังคับใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน และพัฒนาuse case การใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานขึ้น และรับฟังความคิดเห็นจากผู้แทนกลุ่มผู้เกี่ยวข้องเพื่อปรับปรุง use case ให้เหมาะสม (กระบวนการที่ 2)

จากนั้นจะค้นหาบัญชีข้อมูลยาและรหัสยามาตรฐานสากลที่มีอยู่ในปัจจุบัน และนำเสนอข้อมูลที่ครบถ้วน เพื่อให้คณะทำงานพิจารณาเลือกบัญชีข้อมูลยาและรหัสยามาตรฐานสากลที่เหมาะสมกับการใช้งานของผู้เกี่ยวข้อง โดยคำนึงถึงผลกระทบที่อาจจะเกิดขึ้น เช่น ค่าใช้จ่ายในการนำรหัสมาตรฐานสากลนั้นมาใช้ (กระบวนการที่3)

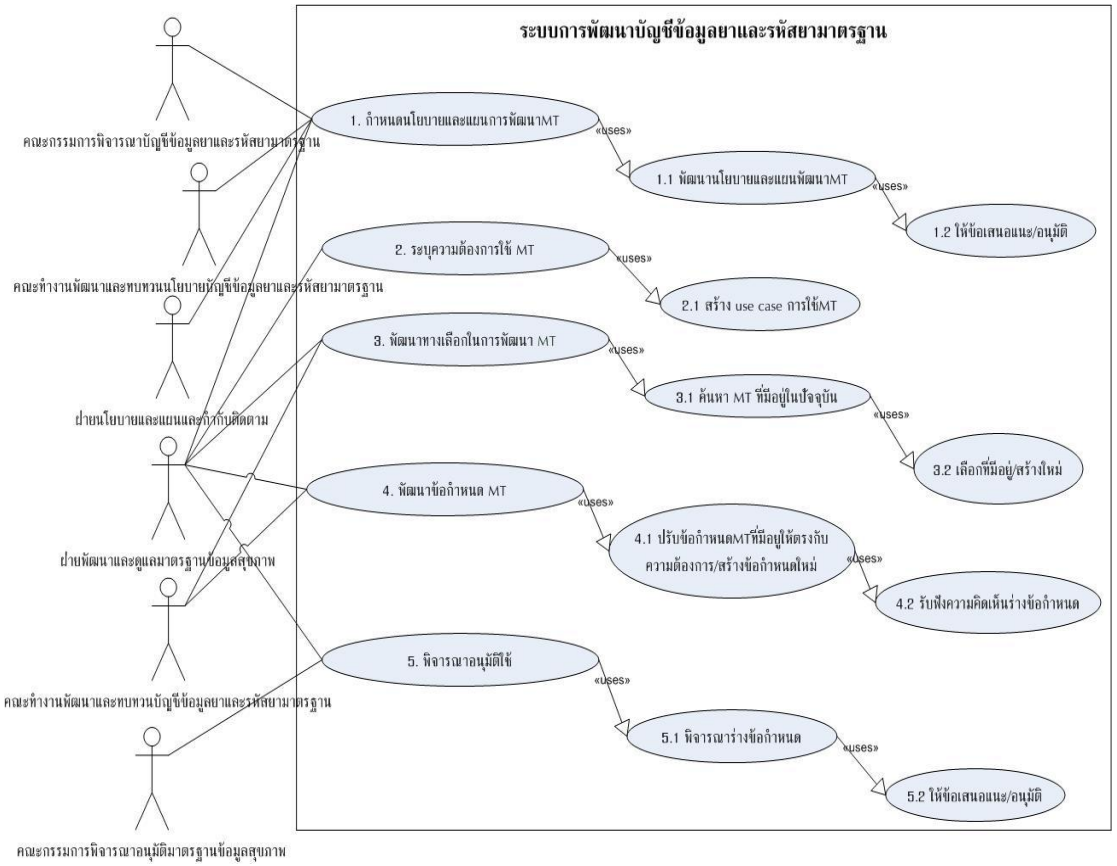
คณะทำงานฯนำบัญชีข้อมูลยาและรหัสยามาตรฐานสากลที่พิจารณาเลือกแล้วไปปรับและพัฒนาข้อกำหนดให้ตรงกับความต้องการในการใช้งาน จากนั้นนำเสนอข้อกำหนดฯต่อผู้เกี่ยวข้องเพื่อรับฟังความคิดเห็นและข้อเสนอแนะในการปรับปรุง(กระบวนการที่ 4) และเสนอให้คณะกรรมการอนุมัติมาตรฐานข้อมูลสุขภาพพิจารณาอนุมัติใช้ข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยา (กระบวนการที่ 5) เมื่อมีการอนุมัติใช้ข้อกำหนดฯแล้วฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจะเผยแพร่ข้อกำหนดฯผ่านช่องทางต่างๆ

สถานการณ์ยกเว้นที่ 1

คณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาและรหัสมาตรฐานยาและฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพพบว่าไม่มีบัญชีข้อมูลยาและรหัสยามาตรฐานสากลที่มีอยู่ในปัจจุบันเหมาะสม (กระบวนการที่ 3) ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพและคณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาและรหัสมาตรฐานยาจะพัฒนาข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยา (medicines terminology specification) ขึ้นใหม่ให้ตรงกับความต้องการในการใช้งาน (กระบวนการที่ 4) เสนอให้คณะกรรมการอนุมัติมาตรฐานข้อมูลสุขภาพพิจารณาอนุมัติใช้ข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยา(กระบวนการที่ 5)

สถานการณ์ยกเว้นที่ 2

คณะกรรมการอนุมัติมาตรฐานข้อมูลสุขภาพพิจารณาข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยาแล้วพบว่า ข้อกำหนดฯยังไม่เหมาะสมและครอบคลุมความต้องการในการใช้งาน จะให้ข้อเสนอแนะกับฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพและคณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาและรหัสมาตรฐานยาแก้ไข คณะทำงานจะร่วมกันพิจารณาข้อเสนอแนะ และปรับแก้ไขตามข้อเสนอแนะ หากไม่เห็นด้วยกับข้อเสนอแนะนั้นจะทักท้วงและให้เหตุผลประกอบการพิจารณา (กระบวนการที่ 5.2)



แผนภาพที่1 แผนภาพและคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องในระบบการพัฒนาบัญชีข้อมูลยาและรหัสมาตรฐานยา

ระบบการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้

Use case นี้จะครอบคลุมกระบวนการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้ โดยเริ่มจากกระบวนการกำหนดแผนการนำไปใช้ จากนั้นพัฒนาคู่มือและเครื่องมือสนับสนุนการใช้งาน ประกาศใช้บัญชีข้อมูลยาและรหัสยามาตรฐานและประชาสัมพันธ์ส่งเสริมให้นำไปใช้ในการแลกเปลี่ยนข้อมูลยา ฝึกอบรมการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้ ให้บริการตอบคำถามและแก้ปัญหาการใช้งานและปัญหาทางเทคนิค รับรองผลิตภัณฑ์และซอฟท์แวร์ที่รองรับบัญชีข้อมูลยาและรหัสยามาตรฐาน แผนภาพจะแสดงปฏิสัมพันธ์ของระบบกับผู้รับผิดชอบหลัก ดังแสดงในแผนภาพที่ 2 และคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องกับระบบจะอธิบายผ่านสถานการณ์จำลอง โดยจะประกอบด้วยสถานการณ์หลัก(main event) และสถานการณ์ยกเว้น (exceptional events)

บทบาทผู้รับผิดชอบหลักต่อระบบการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้

ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ มีบทบาทร่วมกับฝ่ายสื่อสารและสนับสนุนการนำไปใช้ในการกำหนดแผนการนำไปใช้ ประกาศใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน และประชาสัมพันธ์ส่งเสริมการนำไปใช้ รวมทั้งร่วมกับฝ่ายครื่องมือและเทคโนโลยีในการพัฒนาคู่มือการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานและพัฒนาเครื่องมือสนับสนุนการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน บริการตอบคำถามและแก้ปัญหาให้แก่ผู้ใช้ และรับรองผลิตภัณฑ์และซอฟท์แวร์สนับสนุนฝ่ายพัฒนาบุคลากรและส่งเสริมการพัฒนาความรู้ในการฝึกอบรมการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้

ฝ่ายสื่อสารและสนับสนุนการนำไปใช้ มีบทบาทในการกำหนดแผนการนำไปใช้ และประชาสัมพันธ์ให้ทราบถึงประโยชน์และส่งเสริมการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้งาน

ฝ่ายสนับสนุนเครื่องมือและเทคโนโลยี มีบทบาทในการพัฒนาคู่มือและเครื่องมือสนับสนุนการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน บริการแก้ปัญหาจากการใช้งาน และรับรองผลิตภัณฑ์และซอฟท์แวร์

ฝ่ายพัฒนาบุคลากรและส่งเสริมการพัฒนาความรู้ มีบทบาทในการฝึกอบรมการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้ และส่งเสริมให้พัฒนาองค์ความรู้ที่เกี่ยวข้องกับบัญชีข้อมูลยาและรหัสยามาตรฐาน เช่น สนับสนุนการวิจัย

สถานการณ์หลัก

หลังจากที่คณะกรรมการอนุมัติมาตรฐานข้อมูลสุขภาพอนุมัติใช้ข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยา ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพร่วมกับฝ่ายสื่อสารและสนับสนุนการนำไปใช้จะศึกษาสถานการณ์การใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานเพื่อการแลกเปลี่ยนข้อมูลยาในปัจจุบัน ความต้องการในบริการ/เครื่องมือสนับสนุนการนำไปใช้ และผลกระทบที่อาจจะเกิดขึ้นจากการประกาศใช้บัญชีข้อมูลยาและรหัสยามาตรฐานในผู้เกี่ยวข้องทุกกลุ่ม และเสนอแนวทางและกำหนดระยะเวลาในการนำไปใช้ จากนั้นร่างแผนการนำบัญชีข้อมูลยาและรหัสมาตรฐานยาไปใช้งาน โดยแผนอาจแบ่งเป็น 2 ระยะเพื่อให้เกิดผลกระทบน้อย ได้แก่ ระยะที่1 ใช้บัญชีข้อมูลยาและรหัสมาตรฐานยาควบคู่กับรหัสยามาตรฐานเดิมที่ใช้อยู่ ระยะที่ 2 เมื่อผลิตภัณฑ์/ซอฟแวร์รองรับการใช้งานบัญชีข้อมูลยาและรหัสมาตรฐานยาที่พัฒนาขึ้นใหม่แล้ว ให้ใช้บัญชีข้อมูลยาและรหัสมาตรฐานยาในระบบการรักษาพยาบาลและการเบิกจ่ายทั้งระบบ เมื่อร่างแผนการนำไปใช้แล้วจะนำแผนที่ร่างขึ้นรับฟังความคิดเห็นจากผู้เกี่ยวข้องผ่านช่องทางต่างๆ เพื่อนำความคิดเห็นมาปรับปรุงแผน เผยแพร่แผน และดำเนินการตามแผนต่อไป (กระบวนการที่ 1)

ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพร่วมกับฝ่ายสนับสนุนเครื่องมือและเทคโนโลยีดำเนินการพัฒนาคู่มือและเครื่องมือสนับสนุนการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน เช่น เครื่องมือจับคู่บัญชีข้อมูลยาและรหัสยามาตรฐานที่สร้างขึ้นใหม่กับรหัสยามาตรฐานเดิม เครื่องมือค้นหาบัญชีข้อมูลยาและรหัสยามาตรฐาน เครื่องมือรวบรวมและค้นหาเอกสาร/คู่มือ เป็นต้น (กระบวนการที่ 2)

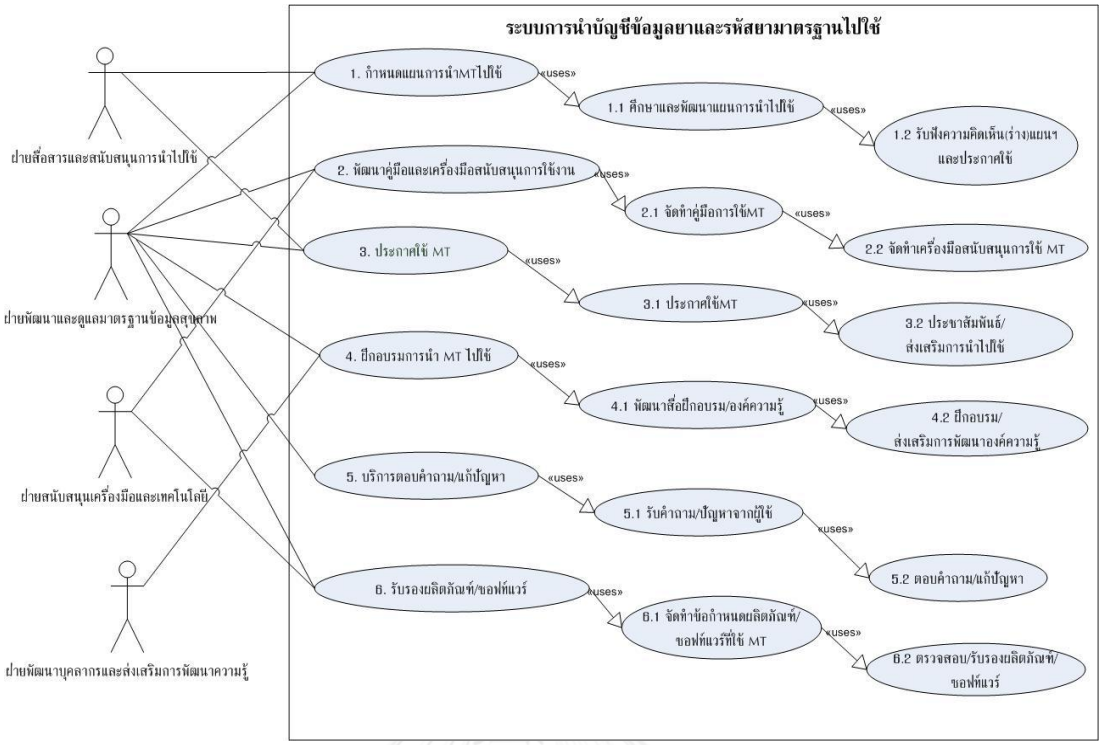
หลังจากพัฒนาคู่มือและเครื่องมือเรียบร้อยแล้ว ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจะประกาศใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน (กระบวนการที่ 3) และฝ่ายสื่อสารและสนับสนุนการนำไปใช้จะประชาสัมพันธ์ให้ผู้ที่เกี่ยวข้อง เช่นบุคลากรทางการแพทย์ กองทุนสุขภาพ ผู้จัดทำนโยบายสาธารณสุข ฯลฯ ทราบถึงประโยชน์และส่งเสริมให้นำไปใช้ ฝ่ายพัฒนาบุคลากรและส่งเสริมการพัฒนาความรู้จะร่วมกับฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ จัดทำสื่อให้ความรู้ผ่านช่องทางต่างๆเพื่อให้ผู้เกี่ยวข้องทุกกลุ่มสามารถเข้าถึงได้ง่าย เช่น สื่ออบรมผ่านระบบออนไลน์ วิดิทัศน์ฝึกอบรมการใช้งาน สื่อฝึกอบรมในชั้นเรียน และมีช่องทางให้ผู้ใช้โต้ตอบและถามคำถาม (กระบวนการที่ 4) หากผู้ใช้มีปัญหาในการใช้งานและปัญหาทางเทคนิคสามารถสอบถามมาที่ฝ่าย

พัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ ผ่านทางโทรศัพท์ และอีเมล์ โดยฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจะตอบคำถามภายใน 3 วันทำการ (กระบวนการที่ 5)

ฝ่ายสนับสนุนเครื่องมือและเทคโนโลยีจะจัดทำข้อกำหนดของซอฟแวร์ที่สามารถใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน โดยประสานงานกับผู้ผลิตผลิตภัณฑ์/ซอฟท์แวร์ที่ใช้ในการแลกเปลี่ยนข้อมูลสารสนเทศสุขภาพ ส่งเสริมการพัฒนาผลิตภัณฑ์/ซอฟท์แวร์ให้สามารถใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานได้ตามข้อกำหนด และให้การรับรองผลิตภัณฑ์/ซอฟท์แวร์ (กระบวนการที่ 6)

สถานการณ์ยกเว้น

โรงพยาบาล ก ไม่สามารถนำบัญชีข้อมูลยาและรหัสมาตรฐานที่ประกาศใช้ใหม่เข้าสู่โปรแกรมบันทึกข้อมูลสุขภาพของโรงพยาบาลได้ เจ้าหน้าที่จึงอีเมล์สอบถามปัญหาทางเทคนิคมายังฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพไม่สามารถตอบคำถามทางเทคนิคได้ จึงประสานงานเพื่อสอบถามไปยังฝ่ายสนับสนุนเครื่องมือและเทคโนโลยีเพื่อให้แนะนำวิธีแก้ปัญหานี้ ฝ่ายสนับสนุนเครื่องมือและเทคโนโลยีเห็นว่าโปรแกรมนี้เป็นโปรแกรมที่ใช้อย่างแพร่หลายในโรงพยาบาลต่างๆทั่วประเทศ จึงประสานงานกับผู้ผลิตผลิตภัณฑ์/ซอฟท์แวร์เพื่อให้ช่วยแก้ไขปัญหานี้ได้ แต่ใช้เวลาในการแก้ปัญหาของโรงพยาบาลเกิน 3 วัน ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจึงตอบกลับไปยังโรงพยาบาลว่าอยู่ระหว่างประสานงานกับผู้ผลิตผลิตภัณฑ์/ซอฟท์แวร์เพื่อให้ช่วยแก้ไขปัญหา และขอเลื่อนการตอบคำถามที่ทางโรงพยาบาลได้ถามมาไป 10 วัน และหากยังไม่สามารถแก้ปัญหาได้ภายใน 10 วันที่เลื่อนการตอบคำถามโรงพยาบาลจะแจ้งความคืบหน้าการแก้ปัญหาให้ทุก 10 วันจนกว่าจะแก้ปัญหาได้แล้วเสร็จ(กระบวนการที่ 5)



แผนภาพที่2 แผนภาพและคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องในระบบการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้

ระบบการบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐาน

Use case นี้จะครอบคลุมกระบวนการและผู้รับผิดชอบในการบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐาน โดยเริ่มจากกระบวนการกำหนดแผนการบำรุงรักษาและติดตามประเมินผลปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานตามระยะเวลาที่กำหนดโดยรับข้อมูลยาใหม่หรือข้อมูลยาที่มีการเปลี่ยนแปลงนำมาปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐาน ในกรณีที่ผู้ใช้มีปัญหาการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานซึ่งไม่สามารถรอการปรับปรุงตามระยะเวลาที่กำหนดได้จะมีกระบวนการปรับปรุงแบบเร่งด่วน กระบวนการติดตามและประเมินผลการใช้บัญชีข้อมูลยาและรหัสยามาตรฐานเพื่อนำไปปรับปรุงหรือพัฒนาการทำงานของระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานทั้งระบบ หลังจากมีการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานตามระยะเวลาที่ได้กำหนดไว้ในแผนจะต้องทบทวนข้อกำหนดมาตรฐานบัญชีข้อมูลยาและรหัสยามาตรฐานว่ายังมีความเหมาะสมหรือไม่ ในส่วนแผนภาพที่ 3 จะแสดงปฏิสัมพันธ์ของระบบกับผู้รับผิดชอบหลัก และคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องกับระบบจะอธิบายผ่านสถานการณ์จำลองที่แสดงสถานการณ์การบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐานในทุกกระบวนการและผู้รับผิดชอบหลัก โดยจะประกอบด้วยสถานการณ์หลัก(main event) และสถานการณ์ยกเว้น(exceptional events)

บทบาทผู้รับผิดชอบหลักต่อระบบการบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐาน

ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพ มีบทบาทในการกำหนดแผนการบำรุงรักษาและแผนการติดตามประเมินผล ปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานตามระยะเวลาที่กำหนดและกรณีเร่งด่วน ติดตามและประเมินผลการใช้บัญชีข้อมูลยาและรหัสยามาตรฐานเพื่อนำผลมาปรับปรุงและพัฒนาระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐาน และสนับสนุนการทำงานของคณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาและรหัสมาตรฐานยาในการทบทวนข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐานให้เหมาะสมกับการใช้งานในปัจจุบัน

คณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยา มีบทบาทในการทบทวนข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐานให้เหมาะสมกับการใช้งานในปัจจุบัน

สถานการณ์หลัก

ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจะกำหนดแผนการบำรุงรักษาและแผนการติดตามประเมินผลแล้ว ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจะทำหน้าที่ประสานงานกับผู้ที่

เกี่ยวข้อง และคณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาเพื่อกำหนดและดำเนินการตามแผนฯ แผนการบำรุงรักษาและติดตามประเมินผลประกอบด้วย แผนการปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานตามกำหนดระยะเวลา แผนการติดตามประเมินผลการใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน แผนการทบทวนข้อกำหนดมาตรฐาน (กระบวนการที่ 1)

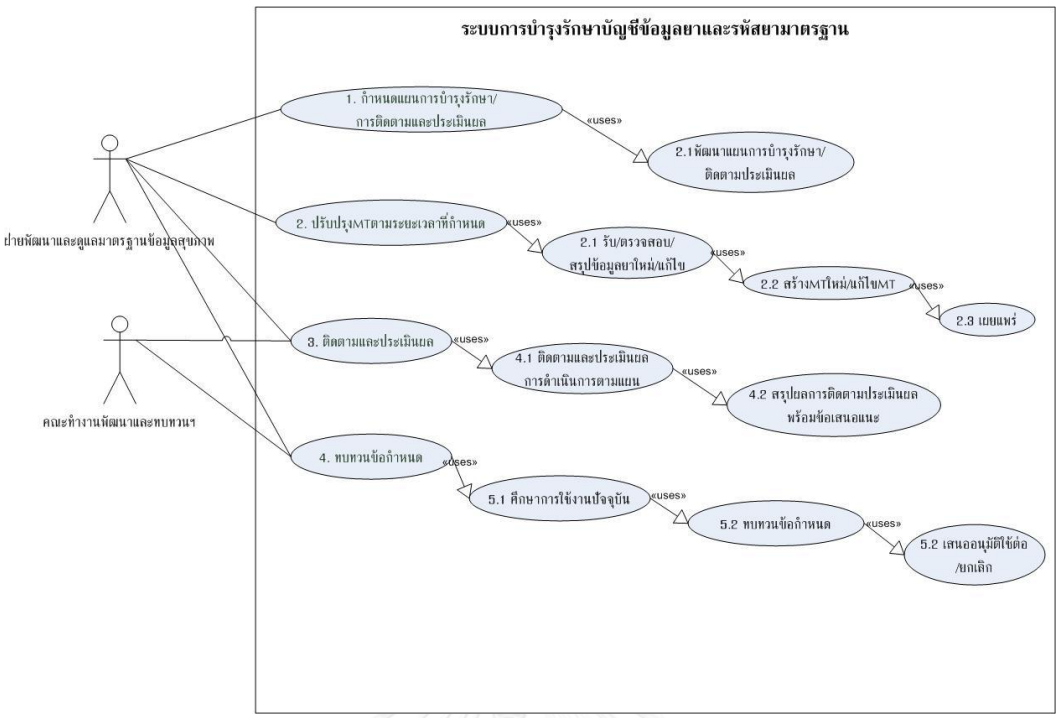
ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานตามกำหนดระยะเวลาที่กำหนดไว้ตามแผน เมื่อได้รับข้อมูลยาใหม่หรือข้อมูลยาที่มีการเปลี่ยนแปลงแล้วจะตรวจสอบและสรุปข้อมูลในตัวแบบที่พร้อมจะนำไปสร้างบัญชีข้อมูลยาและรหัสยามาตรฐานที่ชี้เฉพาะสำหรับยารายการนั้นขึ้น จากนั้นจึงสร้างบัญชีข้อมูลยาและรหัสยามาตรฐานและเผยแพร่ตามระยะเวลาที่กำหนด โดยประกาศบัญชีข้อมูลยาและรหัสยาใหม่ที่ปรับปรุงใหม่ตามกำหนดระยะเวลา เช่น ทุกวันพุธที่ 2 และ 4 ของเดือน โรงพยาบาลและผู้ใช้อื่นๆสามารถสมัครสมาชิกเพื่อดาวน์โหลดบัญชีข้อมูลยาและรหัสยาใหม่ที่ปรับปรุงใหม่ผ่านทางเว็บไซต์และสมาชิกจะได้รับอีเมล์แจ้งเตือนเมื่อมีการปรับปรุงใหม่ (กระบวนการที่ 2)

ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพทำหน้าที่ติดตามและประเมินผลการพัฒนาการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้ตามแผนการติดตามและประเมินผลที่กำหนด ข้อมูลจากการติดตามและประเมินผลนั้นจะนำเสนอให้กับคณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยา เพื่อนำข้อมูลไปพัฒนาข้อเสนอแนะเพื่อปรับปรุงและพัฒนาการดำเนินงานและบริการ ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพนำข้อเสนอแนะฯดังกล่าวเสนอต่อคณะกรรมการพัฒนานโยบายและแผนเพื่อนำไปกำหนดนโยบายฯตามระบบการพัฒนานโยบายต่อไป (กระบวนการที่ 4)

เมื่อมีการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้ได้ระยะหนึ่ง(เช่น 4 ปี) สถานการณ์ความต้องการของผู้ใช้อาจเปลี่ยนแปลงไป ข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐานอาจไม่ตอบสนองต่อความต้องการในการใช้งาน ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพร่วมกับคณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาจะต้องร่วมกันทบทวนข้อกำหนดฯ หากข้อกำหนดฯยังเหมาะสมกับการใช้งานปัจจุบัน ก็ใช้ข้อกำหนดฯเดิมต่อไป หากข้อกำหนดฯไม่ตอบสนองความต้องการต้องเสนอข้อมูลต่อคณะกรรมการพิจารณาอนุมัติมาตรฐานข้อมูลสุขภาพยกเลิกข้อกำหนดดังกล่าว และพัฒนาข้อกำหนดขึ้นใหม่ตามระบบการพัฒนาบัญชีข้อมูลยาและรหัสยามาตรฐาน ผลการทบทวนข้อกำหนดจะแจ้งให้ผู้เกี่ยวข้องทราบ (กระบวนการที่ 5)

สถานการณ์ยกเว้น

โรงพยาบาล ก นำข้อมูลบัญชีข้อมูลยาและรหัสยาเข้าสู่ระบบสารสนเทศเพื่อใช้แลกเปลี่ยนข้อมูลยา พบว่ามียารายการหนึ่ง มีขนาดบรรจุที่ใช้จริงขนาด 60 cc. ไม่ตรงกับขนาดบรรจุในบัญชีข้อมูลยาและรหัสยาซึ่งกำหนดไว้ 600 cc. ทำให้เกิดปัญหาในการเบิกจ่าย จึงแจ้งไปยังฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพเพื่อให้ปรับปรุงอย่างเร่งด่วน ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพได้รับแจ้งปัญหาดังกล่าวจากโรงพยาบาลอื่นๆและกองทุนสุขภาพต่างๆ และขอให้รีบดำเนินการแก้ไขอย่างเร่งด่วน ฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพจึงต้องดำเนินการปรับปรุงแก้ไขอย่างเร่งด่วนและส่งemailแจ้งเตือนไปยังสมาชิก (กระบวนการที่ 3)



แผนภาพที่3 แผนภาพและคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องในระบบการบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐาน

ระบบการรวบรวมข้อมูล การสร้าง และใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน

Use case นี้จะแสดงรายละเอียดของกระบวนการสร้างและใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน การสร้างบัญชีข้อมูลยาและรหัสยามาตรฐาน Use case นี้จะแสดงถึงบทบาทของผู้ที่เกี่ยวข้องต่อกระบวนการในการรวบรวมข้อมูล เพื่อนำไปสร้างบัญชีข้อมูลยาและรหัสยามาตรฐาน และการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้งาน แผนภาพจะแสดงปฏิสัมพันธ์ของระบบกับผู้รับผิดชอบหลัก ดังแสดงในแผนภาพที่ 4 และคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องกับระบบจะอธิบายผ่านสถานการณ์จำลอง โดยจะประกอบด้วยสถานการณ์หลัก(main event) และสถานการณ์ยกเว้น(exceptional events)

บทบาทผู้รับผิดชอบหลักต่อระบบการรวบรวมข้อมูล การสร้าง และใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน

หน่วยงานอภิบาลระบบสารสนเทศสุขภาพ มีฝ่ายพัฒนาและดูแลมาตรฐานข้อมูลสุขภาพเป็นหน่วยงานภายในหลักที่มีบทบาทในการพัฒนาแนวทางการรวบรวมข้อมูลยา การสร้าง และการนำไปใช้ และเป็นหน่วยงานหลักในการรวบรวมและตรวจสอบข้อมูลยา สร้างและเผยแพร่บัญชีข้อมูลยาและรหัสยามาตรฐาน นอกจากนี้ยังมีหน่วยงานภายในอื่นๆ ที่ร่วมกันทำหน้าที่ส่งเสริมการพัฒนาผลิตภัณฑ์ซอฟแวร์รองรับการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน และทำหน้าที่ส่งเสริมการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้ในการแลกเปลี่ยนข้อมูลผ่านระบบสารสนเทศสุขภาพ

คณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยา มีบทบาทในการกำหนดแนวทางการรวบรวมข้อมูลยา การสร้าง และการนำไปใช้

สำนักงานคณะกรรมการอาหารและยา(อย.) มีบทบาทในการรวบรวมและตรวจสอบข้อมูลยาที่ขึ้นทะเบียนกับสำนักงานคณะกรรมการอาหารและยา ส่งให้กับหน่วยงานอภิบาลระบบสารสนเทศสุขภาพเพื่อนำไปสร้างบัญชีข้อมูลยาและรหัสยามาตรฐาน

ผู้ประกอบการยา รวมถึงองค์การเภสัชกรรม โรงงานเภสัชกรรมทหาร บริษัทผู้ผลิตและนำเข้ายา ฯลฯ ซึ่งมีบทบาทในการส่งข้อมูลยาที่ตนผลิตให้กับหน่วยงานอภิบาลระบบสารสนเทศเพื่อนำไปสร้าง/ปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐาน

โรงพยาบาล มีบทบาทในการส่งข้อมูลยาที่ผลิตในโรงพยาบาลให้กับหน่วยงานอภิบาลระบบสารสนเทศสุขภาพเพื่อนำไปสร้าง/ปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐาน และโรงพยาบาลยังเป็นผู้ใช้บัญชีข้อมูลยาและรหัสยามาตรฐานในการส่งข้อมูลการใช้ยาในโรงพยาบาลเพื่อการรักษาพยาบาลและการเบิกจ่าย

กองทุนสุขภาพ หน่วยงานที่บริหารอภิบาลกองทุนสุขภาพ ได้แก่ สำนักงานประกันสังคม กรมบัญชีกลาง และสำนักงานหลักประกันสุขภาพแห่งชาติ เป็นผู้ใช้บัญชีข้อมูลยาและรหัสยามาตรฐานในการแลกเปลี่ยนข้อมูลยาเพื่อการเบิกจ่าย และนำข้อมูลการใช้ยามาวิเคราะห์เพื่อการตัดสินใจเชิงนโยบายต่อไป

บุคลากรทางการแพทย์ และผู้ใช้ข้อมูลเพื่อการพัฒนาระบบสาธารณสุข เป็นผู้ใช้บัญชีข้อมูลยาและรหัสยามาตรฐานแลกเปลี่ยนข้อมูลและใช้ข้อมูลจากการแลกเปลี่ยนเพื่อตัดสินใจในการรักษาพยาบาล และพัฒนาระบบสาธารณสุข

สถานการณ์หลัก

หน่วยงานอภิบาลระบบสารสนเทศสุขภาพและคณะทำงานพัฒนาและทบทวนบัญชีข้อมูลยาร่วมกันกำหนดแนวทางในการรวบรวมข้อมูลยา การสร้าง และการนำไปใช้ และดำเนินการรวบรวมข้อมูลยา สร้าง และส่งเสริมการนำไปใช้ตามแนวทางที่ได้กำหนด (กระบวนการที่ 1)

อย.รวบรวมและส่งข้อมูลยาที่ขึ้นทะเบียนให้กับหน่วยงานอภิบาลระบบสารสนเทศสุขภาพในส่วนของข้อมูลยาที่ไม่ต้องขึ้นทะเบียน หน่วยงานที่ได้รับการยกเว้นให้ผลิตยาโดยไม่ต้องขึ้นทะเบียน ได้แก่ องค์การเภสัชกรรม โรงงานเภสัชกรรมทหาร โรงพยาบาล ฯลฯ จะเป็นผู้ส่งข้อมูล หน่วยงานอภิบาลระบบสารสนเทศสุขภาพจะรวบรวมข้อมูลตามกำหนด เช่น ทุก 2 สัปดาห์ และกำหนดช่องทางในการส่งข้อมูลที่สะดวก เช่น พัฒนาระบบการส่งข้อมูลอัตโนมัติจากฐานข้อมูลของอย. มีโปรแกรม/แบบฟอร์มในการส่งข้อมูลยาผลิตจากผู้ผลิตอื่นและมีช่องทางส่งข้อมูลยาออนไลน์ (กระบวนการที่ 2)

หน่วยงานอภิบาลระบบสารสนเทศสุขภาพจะทำการตรวจสอบข้อมูลยาและจัดรูปแบบตามข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐานที่กำหรด หากสำนักงานคณะกรรมการอาหารและยาหรือหน่วยงานที่เกี่ยวข้องอื่นๆสามารถรวบรวมและตรวจสอบข้อมูลยาที่ไม่ต้องขึ้นทะเบียนไว้ในฐานข้อมูลก็จะสามารถมีส่วนร่วมในการรวบรวม ตรวจสอบและส่งข้อมูลยาที่ไม่ต้องขึ้นทะเบียนให้กับหน่วยงานอภิบาลระบบสารสนเทศสุขภาพอีกทางหนึ่ง ข้อมูลยาที่ผ่านการตรวจสอบแล้วจะได้รับการเผยแพร่ (กระบวนการที่ 3)

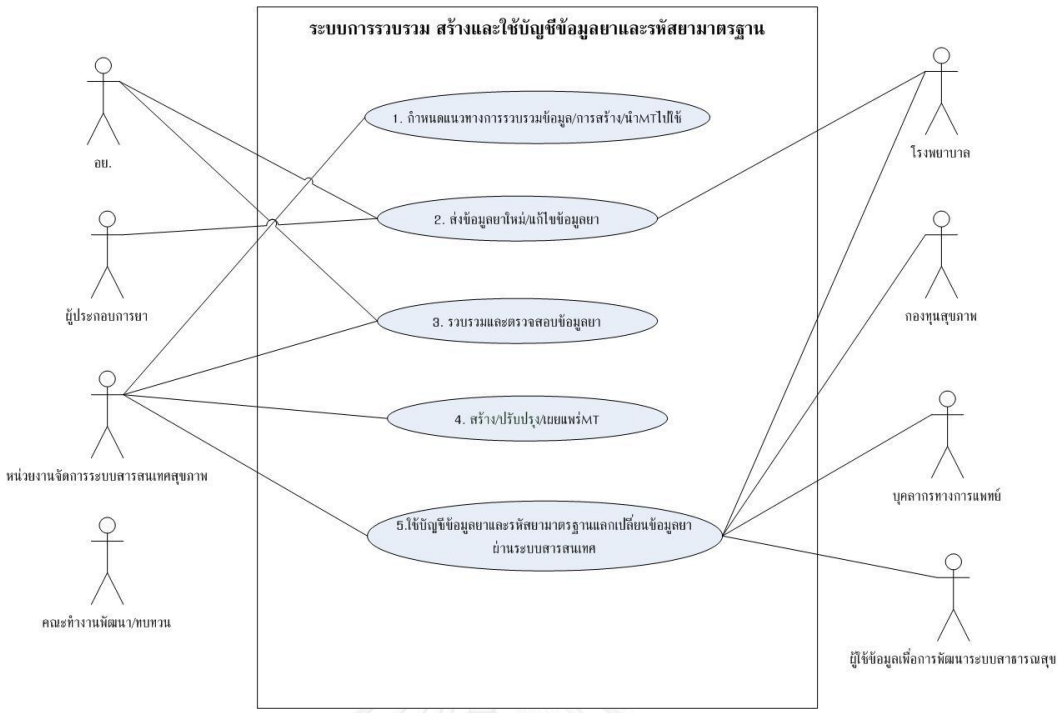
ข้อมูลยาที่ผ่านการตรวจสอบและจัดรูปแบบให้เป็นมาตรฐานแล้วจะถูกนำไปสร้าง/ปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานตามข้อกำหนดฯ อาจพัฒนาซอฟท์แวร์ช่วยในการตรวจสอบ

ข้อมูลยาและสร้างรหัสยามาตรฐาน บัญชีข้อมูลยาและรหัสยามาตรฐานที่สร้างใหม่/ปรับปรุงจะนำไปเผยแพร่ผ่านช่องทางต่างๆตามระยะเวลาที่กำหนด มีบริการแจ้งเตือน/ดาวน์โหลดเมื่อมีการสร้าง/ปรับปรุงรหัสแก่ผู้ใช้ ผู้ใช้สามารถส่งข้อมูลหรือความคิดเห็นในกรณีที่พบความผิดพลาดหรือความไม่ครบถ้วนของข้อมูลผ่านเว็บไซต์ หรืออีเมล์ (กระบวนการที่ 4)

ในการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน ข้อมูลยา เช่น ชื่อยา ปริมาณยา ขนาดยา ราคายา จะถูกบันทึกในระบบซึ่งรองรับการใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐาน เมื่อโรงพยาบาล ก. ต้องการส่งต่อผู้ป่วยไปยังรพ. ข จะสามารถส่งข้อมูลการใช้ยาโดยใช้บัญชีข้อมูลยาและรหัสยามาตรฐานในการแลกเปลี่ยนข้อมูลได้ รพ.กสามารถส่งข้อมูลให้กองทุนสุขภาพเพื่อเบิกค่ายา หรือส่งให้หน่วยงานที่เกี่ยวข้องอื่นๆเพื่อรวบรวม/วิเคราะห์ข้อมูลโดยใช้บัญชีข้อมูลยาและรหัสยามาตรฐานในการแลกเปลี่ยนข้อมูล ทั้งนี้ หน่วยงานที่จะแลกเปลี่ยนข้อมูลระหว่างกันจะต้องมีการตกลงร่วมกันในเรื่องของรายละเอียดข้อมูลที่จะสามารถเข้าถึงได้ (กระบวนการที่ 5)

สถานการณ์ยกเว้น

บริษัทยา ก จะนำยาใหม่ไปจำหน่ายให้กับโรงพยาบาลซึ่งมีข้อกำหนดว่าจะต้องแจ้งรหัสยามาตรฐานกับโรงพยาบาลด้วย แต่บริษัทA ไม่พบรหัสยามาตรฐานของยาในฐานข้อมูลบัญชีข้อมูลยาและรหัสยามาตรฐานที่เผยแพร่ออนไลน์ นอกจากนี้ยังพบว่าข้อมูลยาที่ผลิตโดยบริษัทในฐานข้อมูลที่เผยแพร่อยู่นั้นมีความคลาดเคลื่อนจึงส่งข้อมูลยาใหม่และข้อมูลยาที่ต้องปรับปรุงให้กับหน่วยงานอภิบาลระบบสารสนเทศไว้ หน่วยงานอภิบาลระบบสารสนเทศสุขภาพนำข้อมูลไปสร้าง/ปรับปรุงรหัสยาและแจ้งกลับให้บริษัททราบพร้อมทั้งเผยแพร่ให้กับผู้ใช้ทราบ (กระบวนการที่ 2)



แผนภาพที่ 4 แผนภาพและคำอธิบายปฏิสัมพันธ์ของระบบกับผู้ที่เกี่ยวข้องในระบบการบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐาน

Appendix 3

Evaluation sheet for usability testing of the medicines terminology governance model

Table 5 Principles, descriptions, and design considerations

(** Eight principles of good governance and the description which are applied from the United Nation, the Office of the Public Sector Development Commission, and the Thai chamber of commerce [17-19])

Principle	Descriptions	Design considerations
Participation	All groups of stakeholders get chance to receive the information, try to understand, give the opinion, participate in the decision and solving problem. The stakeholders has the freedom to participate by themselves or participate through the organization, or the stakeholder representative	- Medicines terminology governance model has the process or channel for the stakeholder representative to present their requirements, opinion, problems, and get chance to participate in the decision process.
Rule of Law	Governance, management, or business control have to enforcement in accordance with the law, treat the stakeholders with fairness, and consider the rights and freedoms of the relevant.	- The medicines terminology governance must work in accordance with the relative law. - The system must allow all stakeholders to free discussion and comment.
Transparency	The disclosure processes of information to the stakeholders should be set. The stakeholders must be able to freely access to the information. The enough	- Medicines terminology governance has the hearing process, the disclosure processes of information to the stakeholders. The channel to

Principle	Descriptions	Design considerations
	information must be provided to the stakeholders for decision making in the form or media that is easy to understand.	give suggestion, complaint, and ask question must be provided for the stakeholders.
Responsiveness	The responsible organization must set the process to response the needs and expectation of the stakeholders and can be implemented within the specified period.	- Medicines terminology governance has the processes to identify the needs of stakeholders. The process of policy and plan development must be set to respond to the needs of stakeholders.
Consensus Oriented	There are the processes of stakeholder requirement identification and agreement conclusion in the important issues to making more understanding and reducing the conflict. The consensus of stakeholders does not receive unanimous agreement from everyone.	- The medicines terminology governance has the process for requirement identification and agreement conclusion. In addition, the processes to prevent and reduce conflicts have to be set.
Equity and Inclusiveness	All the stakeholders must be given the opportunity to participate in the process and must be equally treated and serviced.	- In medicines terminology governance system, the representatives of all stakeholder groups equally participate in the process.
Effectiveness and Efficiency	The system must be designed to response the requirement of stakeholders by using	- Medicines terminology governance system has the processes covering the

Principle	Descriptions	Design considerations
	appropriate and cost-effectiveness resources in the acceptable timeframe. The system need to set clear objectives, monitoring and evaluation system to provide continuous improvement and sustainability.	development, implementation, and maintenance that respond to the users. The system has clear process, monitoring and evaluation, and processes for review and continuous improvement.
Accountability	The governance system has to set to take into account the objective and expectation of the stakeholders and public society. The responsible organization must realize and take into account for the consequences of decisions or actions that will take place with stakeholders and the public.	- The medicines terminology governance has the process for setting the objectives and the processes to respond to the needs of the stakeholders. The system has the processes to study the impact and minimize the impact that may occur.

Please evaluate the usability of the medicines terminology governance from the use case diagram and scenarios show the interaction of stakeholders and systems.

1. Please examine and rate the severity level of the usability problem that is not in accordance with the good governance as follows [162] [163]:

    0 = no usability problem

    1 = minor issues, do not require revision.

    2 = minor issues, the priority for improvement is low

    3 = major problems, the design problem should be revised

    4 = major problems, the design problem causes damage and need to be resolved before actual use

2. If you find a usability problem, please provide the recommendation.

Table 6 Medicines terminology development systems

Principles	Design consideration	Severity rating	Problem identification and suggestion
1. Participation	- The stakeholders proposed the requirements for medicines terminology. - The representatives of all stakeholder groups participate in the development and review of policies and plans, and consider the options for development and develop the medicines terminology specification as the working committee.		
2. Rule of Law	- The working committees are the representatives from all stakeholder groups.		

Principles	Design consideration	Severity rating	Problem identification and suggestion
	- Consideration / approval / announcement of policies and plans were operated by the committee or the organization with legal authority.		
3. Transparency	- There are the processes for information dissemination and public consultation on the (draft) medicines terminology specifications before promulgation.		
4. Responsiveness	- There are the processes for the requirement identification and use case development to develop the medicines terminology which respond to the needs of the user. - Search for international medicines terminology, select, and develop the medicines terminology specification in accordance with the use case		
5. Consensus Oriented	- The medicines terminology specification was edited and concluded as the stakeholders' recommendation. - The medicines terminology		

Principles	Design consideration	Severity rating	Problem identification and suggestion
	approve committee approve the medicines terminology specification.		
6. Equity and Inclusiveness	- There are the processes to identify the medicines terminology requirement from every user groups. - The Working Group comprises all stakeholder groups.		
7. Effectiveness and Efficiency	- There are the well-designed system for medicines terminology development including, main responsible organization and the processes for user requirement identification, the option consideration for development, the development of medicines terminology specification, and medicines terminology approval.		
8. Accountability	- There are the processes to study the stakeholder requirement before setting the policies and plans, and developing the medicines terminology.		

Table 7 Medicines terminology implementation system

Design principle	Design consideration	Severity rating	Problem identification and suggestion
1. Participation	- There is the process or channel for stakeholders to give the opinion about the implementation plan. - There is the process or channel for product/ software manufacturers to participate in product/ software certification criteria.		
2. Rule of Law	- The responsible organization has the legal authority for planning the implementation and announcing to use medicines terminology as the national standard. - The responsible organization has the legal authority for products/ software certification.		
3. Transparency	- There are the processes for publishing an implementation plan and public hearing before adoption of an implementation plan. - Publishing the guideline and supporting the information for medicines terminology adoption		

Design principle	Design consideration	Severity rating	Problem identification and suggestion
	via the media that users can easily access - Publishing the certified specification of the product/ software that can use medicines terminology for drug information exchange, and verifying/ certificating the software in accordance with the published specification.		
4. Responsiveness	- Studying the current situation in order to set an implementation plan to ensure that the plan will comply with the medicines terminology use of the stakeholders. - Publish the information, service, and support tools to promote and facilitate the user adoption. - Verify and certify the products and software that can facilitate the users to use the medicines terminology for drug information exchange.		
5. Consensus Oriented	- Promote the user adoption / help desk service in order to solutions to making more		

Design principle	Design consideration	Severity rating	Problem identification and suggestion
	understanding of the users and reducing the conflict.		
6. Equity and Inclusiveness	- There are the processes to promote the user adoption, support service and tools for all groups of users. The users must be equally serviced. - The process, help desk service, and timeline were systematical set for technical problem solving.		
7. Effectiveness and Efficiency	- There are the responsible organization, processes, and timeline for implementation/ service and supportive tool development/ promoting adoption/ products / software certification. - Process, channel, and timeline were systematically set for providing answers to user's question and technical problem solving.		
8. Accountability	- There are the processes for setting the implementation plan which realized to the user's expectations and the impact that		

Design principle	Design consideration	Severity rating	Problem identification and suggestion
	may occur. - Develop the guideline/ supportive tool to reduce the impact that may occur - There are the processes to promote the user adoption for all stakeholders group and communicate to minimize the impact and reduce resistance from stakeholders. - Certified products/ software to provide the option to users that can be reduce the impact and facilitate the user adoption of medicines terminology		

Table 8 Medicines terminology maintenance system

Principles	Design consideration	Severity rating	Problem identification and suggestion
1. Participation	- The representatives of stakeholders participate as the working committee for the maintenance planning, monitoring and evaluation conclusion, and making the recommendations to improve the system. - Stakeholders participate to providing the recommendation for review the medicines terminology specification.		
2. Rule of Law	- The organization which responsible to update the medicines terminology has the legal authority to announce the updated medicines terminology. - The medicines terminology working committee and the medicines terminology approve committee has the legal authority to continue or reject the medicines terminology.		
3. Transparency	- There are the process to publish the maintenance plans and conclude the monitoring and		

Principles	Design consideration	Severity rating	Problem identification and suggestion
	evaluation. - There are the easily access channel to the stakeholders for updated medicines terminology download. - Publish the result of the medicines terminology specification review		
4. Responsiveness	- Update the medicines terminology as schedule in order to serve the user requirement - Study the current situation and review the medicines terminology specification as the schedule to make sure that the medicines terminology specification still serve the user requirement.		
5. Consensus Oriented	- There are the processes to verify and standardize the drug information from various sources according to the medicines terminology specification before creating/ updating medicines terminology. - The stakeholders participate to conclude the monitoring and evaluation result, and the		

Principles	Design consideration	Severity rating	Problem identification and suggestion
	medicines terminology specification review result.		
6. Equity and Inclusiveness	- Users can equally download the created/ updated medicines terminology.		
7. Effectiveness and Efficiency	- The responsible organization, medicines terminology working committee, and processes were systematically work. - The processes and schedule for updating and publishing the medicines terminology were systematically set. - The responsible organization, medicines terminology working committee, and the approve committee were systematically set for review the medicines terminology specification.		
8. Accountability	- Monitoring and evaluation to ensure that the implementation was accomplished the objectives, and understand that how the implementation affect to the users. - There are the processes for the		

Principles	Design consideration	Severity rating	Problem identification and suggestion
	user to ask for urgently update medicines terminology that cannot wait for the scheduled update to reduce the problem of users. - There are the processes to review the medicines terminology specification to respond to the current user requirement and reduce the impact to the users.		

Table 9 System for collecting drug information, creating, and using medicines terminology

Principles	Design consideration	Severity rating	Problem identification and suggestion
1. Participation	- Manufacturers and stakeholders engage to send the drug information for additional and correction to update the drug information if the information in the medicines terminology is incorrect.		
2. Rule of Law	- The main responsible organization has the legal authority to collect drug information, create, update, and release medicines terminology. - FDA, manufacturers, and the hospital is responsible for transmission of new drugs, updated drug information to the main responsible organization for drug information collection. - Drug manufacturers can send their drug information to request the medicines terminology and drug code if they did not find their drug information in the medicines terminology list.		
3. Transparency	- Publish the guideline for		

Principles	Design consideration	Severity rating	Problem identification and suggestion
	request to add / edit medicines terminology to the stakeholders. - The clear processes for drug information collection/ verification were published to the stakeholders. - The verified drug information and medicines terminology were published to the stakeholders.		
4. Responsiveness	- The process for drug information collection covers all medicines used in the country, and there is the drug information verification process to response to the user requirement. - There are the process and schedule to create/ update the medicines terminology to respond to the current user requirement.		
5. Consensus Oriented	- Drug information transfer follows the guidelines that the medicines terminology working committee was developed and concluded. - There is a process to verified and finalized the medicines		

Principles	Design consideration	Severity rating	Problem identification and suggestion
	terminology from various sources in a format according to the medicines terminology specification.		
6. Equity and Inclusiveness	- All stakeholder groups can equally access to the published information and submit/ comment. - All stakeholder groups can equally use medicines terminology for drug information exchange.		
7. Effectiveness and Efficiency	- The processes and timeline for transfer and collecting drug information, verifying, creating, publishing, and implementing medicines terminology were systematically set.		

Appendix 4

Evaluation sheet for usability testing of the medicines terminology governance model (Thai language)

<u>แบบประเมินความสามารถในการใช้ตัวแบบอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐาน</u>

<u>ตารางที่ 1</u> หลักการและคำอธิบายที่ใช้ในแบบประเมินความสามารถในการใช้ตัวแบบ (****พัฒนาจากหลักการกำกับดูแลที่ดีของสหประชาชาติ โดยประยุกต์คำอธิบายในภาษาไทยของหอการค้าไทย และหลักธรรมาภิบาลของสำนักงานคณะกรรมการพัฒนาระบบราชการ [17-19])

หลักการ	คำอธิบายหลักการ	ข้อพิจารณาในการออกแบบ
หลักการมีส่วนร่วม (Participation)	ผู้มีส่วนได้ส่วนเสียทุกกลุ่มมีโอกาสในการรับรู้ ทำความเข้าใจ แสดงความคิดเห็น เสนอประเด็นที่เกี่ยวข้อง ร่วมตัดสินใจ และร่วมแก้ปัญหา การมีส่วนร่วมสามารถทำได้โดยอิสระไม่มีการบังคับ ผู้มีส่วนได้ส่วนเสียให้ความร่วมมือด้วยตนเอง หรือมีส่วนร่วมผ่านหน่วยงาน สถาบันหรือผู้แทน	- ในระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานจะต้องมีเปิดโอกาส/มีกระบวนการ และช่องทางให้ผู้แทนของผู้มีส่วนได้ส่วนเสียในแต่ละกลุ่มมีส่วนร่วมเสนอความต้องการ แสดงความคิดเห็น เสนอปัญหา และมีส่วนร่วมในการตัดสินใจ
หลักนิติธรรม (Rule of Law)	การปกครอง การบริหารจัดการ ควบคุมดูแลกิจการต่างๆ ต้องเป็นไปตามกรอบของกฎหมาย ปฏิบัติกับผู้มีส่วนเกี่ยวข้องด้วยความเป็นธรรม และคำนึงถึงสิทธิและเสรีภาพของผู้มีส่วนเกี่ยวข้อง	- ระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานต้องดำเนินการตามกรอบของกฎหมาย - ระบบต้องเปิดโอกาสให้ผู้มีส่วนเกี่ยวข้องทุกกลุ่มแสดงความคิดเห็น ให้ข้อเสนอแนะอย่างเสรี
หลักความโปร่งใส (Transparency)	มีกระบวนการเปิดเผยข้อมูลข่าวสารแก่ผู้มีส่วนเกี่ยวข้อง เพื่อให้ผู้มีส่วนเกี่ยวข้องสามารถเข้าถึงข้อมูลข่าวสารนั้นได้อย่างเสรี และต้องให้ข้อมูลแก่ผู้มี	- ระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานมีกระบวนการรับฟังความคิดเห็น เปิดเผยข้อมูลให้ผู้มีส่วน

หลักการ	คำอธิบายหลักการ	ข้อพิจารณาในการออกแบบ
	ส่วนเกี่ยวข้องที่เพียงพอต่อการตัดสินใจในภาษา รูปแบบหรือสื่อที่เข้าใจง่าย	เกี่ยวข้องทราบ มีช่องทางในการให้ข้อเสนอแนะ ร้องเรียน สอบถามปัญหา
หลักการตอบสนอง (Responsiveness)	หน่วยงานผู้รับผิดชอบและกระบวนการดำเนินการต้องตอบสนองต่อความคาดหวัง/ความต้องการของผู้มีส่วนเกี่ยวข้อง และสามารถดำเนินการได้ภายในระยะเวลาที่กำหนด	- ระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานมีกระบวนการระบุความต้องการของผู้มีส่วนเกี่ยวข้อง และมีกระบวนการในการพัฒนานโยบายและแผนในการดำเนินการที่ตอบสนองต่อความต้องการของผู้มีส่วนเกี่ยวข้อง
การมุ่งเน้นฉันทามติ (Consensus Oriented)	มีกระบวนการค้นหา สรุปความต้องการและข้อตกลงร่วมกันของผู้มีส่วนเกี่ยวข้องในประเด็นสำคัญ เพื่อทำความเข้าใจและลดปัญหาความขัดแย้ง ฉันทามตินั้นไม่จำเป็นต้องได้รับความเห็นชอบจากทุกคนอย่างเอกฉันท์	- ระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานมีกระบวนการในการค้นหาสรุปความต้องการและข้อตกลงร่วมกัน รวมทั้งมีกระบวนการที่ป้องกันและลดปัญหาความขัดแย้ง
ความเสมอภาคและครอบคลุมกลุ่มผู้มีส่วนเกี่ยวข้อง(Equity and Inclusiveness)	ผู้มีส่วนเกี่ยวข้องทุกกลุ่มจะต้องได้รับโอกาสในการเข้าร่วมกระบวนการ และต้องได้รับการปฏิบัติและการบริการอย่างเท่าเทียมกัน	- ในระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานผู้แทนผู้มีส่วนเกี่ยวข้องทุกกลุ่มมีส่วนร่วมในกระบวนการอย่างเท่าเทียมกัน
ประสิทธิภาพและประสิทธิผล (Effectiveness and Efficiency)	มีการออกแบบกระบวนการโดยใช้ทรัพยากรและเวลาที่เหมาะสม คุ้มค่า และเกิดประโยชน์สูงสุดเพื่อตอบสนองความต้องการของผู้มีส่วนเกี่ยวข้อง	- ระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานมีกระบวนการที่ครอบคลุมการพัฒนา การนำไปใช้ และการ

หลักการ	คำอธิบายหลักการ	ข้อพิจารณาในการออกแบบ
	การบริหารจัดการจะต้องมีการกำหนดวัตถุประสงค์ที่ชัดเจน มีระบบการติดตาม ประเมินผล เพื่อให้มีการพัฒนาอย่างต่อเนื่องและยั่งยืน	ดูแลและบำรุงรักษา ที่ตอบสนองต่อผู้ใช้ มีกระบวนการในการดำเนินงานที่ชัดเจนเป็นระบบ มีระบบการติดตาม ประเมินผล และมีกระบวนการทบทวนและพัฒนาอย่างต่อเนื่อง
หลักภาระรับผิดชอบ (Accountability)	การบริหารจัดการ กำกับดูแล ต้องรับผิดชอบต่อเป้าหมายและความคาดหวังของผู้มีส่วนเกี่ยวข้องและสาธารณะ รวมถึงตระหนักและรับผิดชอบถึงผลกระทบจากการตัดสินใจหรือการดำเนินการที่จะเกิดกับผู้มีส่วนเกี่ยวข้องและสาธารณะด้วย	- ระบบการอภิบาลบัญชีข้อมูลยาและรหัสยามีกระบวนการกำหนดเป้าหมายและการดำเนินการให้ตรงตามความต้องการของผู้มีส่วนเกี่ยวข้อง มีกระบวนการศึกษาถึงผลกระทบและดำเนินการเพื่อลดผลกระทบที่อาจจะเกิดขึ้น

กรุณาประเมินการใช้ตัวแบบการอภิบาลบัญชีข้อมูลยาและรหัสยามาตรฐานจากแผนภาพและสถานการณ์แสดงปฏิสัมพันธ์ของระบบและผู้เกี่ยวข้อง

ในการประเมินกรุณาให้คะแนนระดับปัญหาในการใช้งานที่ไม่เป็นไปตามหลักธรรมาภิบาล ดังนี้

0 = ไม่พบปัญหาในการใช้งาน

1 = ปัญหาเล็กน้อยไม่จำเป็นต้องปรับปรุงแก้ไข

2 = ปัญหาเล็กน้อย มีความจำเป็นในการปรับปรุงแก้ไขน้อย

3 = ปัญหาหลัก ต้องได้รับการปรับปรุงแก้ไข

4 = ปัญหาหลักในการใช้งานที่ก่อให้เกิดความเสียหาย จำเป็นที่จะต้องได้รับการแก้ไขก่อนการใช้งานจริง

ในกรณีที่ท่านเห็นว่ามีปัญหาในการใช้งาน กรุณาระบุข้อเสนอแนะ

ระบบการพัฒนาบัญชีข้อมูลยาและรหัสมาตรฐานยา

หลักการ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
หลักการมีส่วนร่วม	- ผู้เกี่ยวข้องมีส่วนร่วมเสนอความต้องการใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน - ผู้แทนจากผู้เกี่ยวข้องทุกกลุ่มมีส่วนร่วมในการกำหนดและทบทวนนโยบายและแผนฯ พิจารณาทางเลือกในการพัฒนา และพัฒนาข้อกำหนดฯ ในรูปแบบคณะทำงานฯ		
หลักนิติธรรม	- คณะทำงานฯเป็นผู้แทนจากผู้เกี่ยวข้องทุกกลุ่ม - การพิจารณา/อนุมัติ/ประกาศใช้นโยบายและแผน และข้อกำหนดดำเนินการโดยคณะกรรมการฯ/หน่วยงานที่มีอำนาจตามกฎหมาย		
หลักความโปร่งใส	- เผยแพร่ข้อมูลและรับฟังความคิดเห็นต่อข้อกำหนดบัญชีข้อมูลยาและ(ร่าง)		

หลักการ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
	รับปรุงก่อนรหัสยามาตรฐานเพื่อปประกาศใช้		
หลักการตอบสนอง	- ศึกษา/ระบุความต้องการและพัฒนา Use case ในการนำรหัสยาไปใช้ของผู้เกี่ยวข้อง เพื่อให้บัญชีข้อมูลยาและและรหัสยามาตรฐานที่จะพัฒนาขึ้นตอบสนองความต้องการในการใช้งานของผู้ใช้ - ค้นหาและคัดเลือกบัญชีข้อมูลยาและรหัสยามาตรฐานสากล และพัฒนาข้อกำหนดฯตาม use case		
หลักการมุ่งเน้นฉันทามติ	- ข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐานปรับแก้ และสรุปตามที่ได้รับฟังความคิดเห็นจากผู้มีส่วนได้ส่วนเสีย - คณะกรรมการพิจารณาอนุมัติข้อกำหนดบัญชีข้อมูลยาและรหัสยา		
หลักความเสมอภาคและครอบคลุมผู้เกี่ยวข้อง	- มีกระบวนการศึกษาความต้องการการใช้บัญชีข้อมูลยาและรหัสยามาตรฐานของผู้ใช้ทุกกลุ่ม -คณะทำงานฯประกอบด้วยผู้เกี่ยวข้องทุกกลุ่ม		
หลักประสิทธิภาพและประสิทธิผล	- มีหน่วยงานผู้รับผิดชอบ และมีกระบวนการค้นหา ศึกษาความต้องการพิจารณาทางเลือก พัฒนาข้อกำหนดและอนุมัติใช้อย่างเป็นระบบ		
หลักภาระรับผิดชอบ	- มีกระบวนการศึกษาความต้องการของผู้เกี่ยวข้องก่อนกำหนดนโยบายและแผน และพัฒนาข้อกำหนดบัญชีข้อมูล		

หลักการ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
	ยาและรหัสยามาตรฐาน		

ระบบการนำบัญชีข้อมูลยาและรหัสยามาตรฐานไปใช้

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
หลักการมีส่วนร่วม	- ผู้เกี่ยวข้องมีส่วนร่วมในการเสนอความคิดเห็นต่อแผนการนำไปใช้ - ผู้ผลิตผลิตภัณฑ์/ซอฟแวร์มีส่วนร่วมในการจัดทำข้อกำหนดของซอฟแวร์ที่สามารถใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานได้		
หลักนิติธรรม	- หน่วยงานผู้รับผิดชอบหลักในการกำหนดแผนการนำไปใช้และประกาศใช้บัญชีข้อมูลยาและและรหัสยามาตรฐานมีอำนาจตามกฎหมาย - หน่วยงานที่ทำหน้าที่ตรวจสอบและให้การรับรองผลิตภัณฑ์/ซอฟท์แวร์เป็นหน่วยงานที่มีอำนาจตามกฎหมายกำหนด		
หลักความโปร่งใส	- มีกระบวนการเผยแพร่แผนการนำไปใช้ และรับฟังความคิดเห็นก่อนการประกาศใช้แผนการนำไปใช้ - เผยแพร่คู่มือ และข้อมูลสนับสนุนการนำไปใช้ผ่านช่องทางที่ผู้ใช้สามารถเข้าถึงได้ง่าย - เผยแพร่ข้อกำหนดของซอฟท์แวร์ที่สามารถขอรับรองว่าสามารถใช้บัญชีข้อมูลยาและรหัสยามาตรฐานในการแลกเปลี่ยนข้อมูลได้ และตรวจสอบ/รับรองตามข้อกำหนด		
หลักการตอบสนอง	- ศึกษาสถานการณ์ปัจจุบันเพื่อกำหนดแผนการนำไปใช้ให้สอดคล้องกับการใช้		

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
	งานของผู้เกี่ยวข้อง - ประชาสัมพันธ์ให้บริการและสนับสนุนเครื่องมือเพื่อเสริมการยอมรับของผู้ใช้และตอบสนองต่อการใช้งานของผู้ใช้ - ตรวจสอบและรับรองผลิตภัณฑ์ซอฟท์แวร์ที่สามารถใช้งานบัญชีข้อมูลยาและรหัสยามาตรฐานเพื่อแลกเปลี่ยนข้อมูล		
หลักการมุ่งเน้นฉันทามติ	- ส่งเสริมการนำไปใช้/บริการตอบคำถาม/แก้ปัญหาเพื่อทำความเข้าใจและลดปัญหาความขัดแย้งในการนำไปใช้		
หลักความเสมอภาคและครอบคลุมผู้เกี่ยวข้อง	- มีกระบวนการส่งเสริมการนำไปใช้บริการ/เครื่องมือสนับสนุนการนำไปใช้ครอบคลุมผู้ใช้ทุกกลุ่ม และผู้ใช้ทุกกลุ่มสามารถเข้าถึงบริการได้อย่างเท่าเทียมกัน - ผู้ผลิตผลิตภัณฑ์/ซอฟท์แวร์ทุกคนสามารถขอเข้ารับการตรวจสอบและรับรองการผลิตภัณฑ์/ซอฟท์แวร์ได้		
หลักประสิทธิภาพและประสิทธิผล	- มีหน่วยงานรับผิดชอบ กระบวนการและกำหนดระยะเวลาในการดำเนินการประกาศใช้/ พัฒนาบริการและเครื่องมือสนับสนุน/ ส่งเสริมการนำไปใช้/ และให้การรับรองผลิตภัณฑ์/ซอฟท์แวร์ - มีกระบวนการ/ช่องทางในการให้บริการตอบคำถามและแก้ปัญหาการ		

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
	นำไปใช้และมีการกำหนดระยะเวลาในการดำเนินการอย่างเป็นระบบ		
หลักภาระรับผิดชอบ	- มีกระบวนการในการกำหนดแผนการนำไปใช้ให้สอดคล้องกับความคาดหวังและผลกระทบที่อาจจะเกิดขึ้นกับผู้เกี่ยวข้อง - พัฒนาคู่มือ/เครื่องมือสนับสนุนการนำไปใช้เพื่อลดผลกระทบที่อาจจะเกิดขึ้น - มีกระบวนการส่งเสริมให้ผู้เกี่ยวข้องทุกกลุ่มเห็นประโยชน์ของการนำไปใช้และสื่อสารเพื่อลดผลกระทบและลดการต่อต้านจากผู้เกี่ยวข้อง - รับรองผลิตภัณฑ์/ซอฟท์แวร์เพื่อให้ผู้ใช้มีทางเลือกในการเลือกผลิตภัณฑ์/ซอฟท์แวร์ที่สามารถใช้งานได้เพื่อลดผลกระทบและสนับสนุนการใช้บัญชีข้อมูลยาและรหัสยามาตรฐานได้		

ระบบการบำรุงรักษาบัญชีข้อมูลยาและรหัสยามาตรฐาน

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
หลักการมีส่วนร่วม	- ผู้แทนจากผู้เกี่ยวข้องมีส่วนร่วมในการกำหนดแผนบำรุงรักษา/ติดตามประเมินผล สรุปผลการติดตามและประเมินผล และจัดทำข้อเสนอแนะเพื่อการพัฒนาระบบในรูปแบบคณะทำงานฯ - ผู้มีส่วนเกี่ยวข้องมีส่วนร่วมแสดงความคิดเห็นเพื่อทบทวนข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐาน		
หลักนิติธรรม	- หน่วยงานที่ทำหน้าที่ปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานเป็นหน่วยงานที่มีอำนาจตามกฎหมายในการประกาศใช้บัญชีข้อมูลยาและรหัสยามาตรฐานที่ปรับปรุง - คณะทำงานฯและคณะกรรมการฯพิจารณาผลการทบทวนบัญชีข้อมูลยาและรหัสยามาตรฐานว่าจะใช้ต่อหรือยกเลิกต้องมีหน้าที่ตามคำสั่งแต่งตั้งตามกฎหมาย		
หลักความโปร่งใส	- มีกระบวนการเผยแพร่แผนฯและสรุปข้อมูลการบำรุงรักษาและติดตามประเมินผล - มีช่องทางที่ผู้มีส่วนได้ส่วนเสียสามารถดาวน์โหลด บัญชีข้อมูลยาและรหัสยามาตรฐานที่ปรับปรุงแล้วได้สะดวก - เผยแพร่ผลการทบทวนข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐาน		

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
หลักการตอบสนอง	- มีการปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานตามระยะเวลาที่กำหนดเพื่อตอบสนองความต้องการใช้งานของผู้ใช้ - ศึกษาสถานการณ์การใช้งานปัจจุบันและทบทวนข้อกำหนดตามระยะเวลาเพื่อให้ข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐานยาตอบสนองต่อการใช้งานอยู่เสมอ		
หลักการมุ่งเน้นฉันทามติ	- มีกระบวนการในการตรวจสอบและมีการสรุปข้อมูลยาจากแหล่งข้อมูลต่างๆ ตามข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐาน ก่อนนำไปสร้าง/ปรับปรุงเพื่อให้ข้อมูลเป็นมาตรฐานเดียวกัน - ผู้มีส่วนได้ส่วนเสียร่วมสรุปผลการติดตามประเมินผล และผลการทบทวนข้อกำหนดบัญชีข้อมูลยาและรหัสมาตรฐาน		
หลักความเสมอภาคและครอบคลุมผู้เกี่ยวข้อง	- ผู้เกี่ยวข้องสามารถดาวน์โหลดบัญชีข้อมูลยาและรหัสยามาตรฐานที่สร้าง/ปรับปรุงอย่างเท่าเทียมกัน		
หลักประสิทธิภาพและประสิทธิผล	- หน่วยงานผู้รับผิดชอบ คณะทำงานและกระบวนการติดตามและประเมินผลทำงานอย่างเป็นระบบ - มีการกำหนดกระบวนการและระยะเวลาในการปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐาน และมีการเผยแพร่ตามระยะเวลาที่กำหนด		

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
	- มีหน่วยงานผู้รับผิดชอบ คณะทำงาน คณะกรรมการและมีกระบวนการในทบทวนข้อกำหนดที่ชัดเจน		
หลักภาระรับผิดชอบ	- ติดตามและประเมินผลเพื่อให้ทราบว่าการดำเนินการเป็นไปตามวัตถุประสงค์และเข้าใจว่าการดำเนินการส่งผลกระทบต่อผู้ใช้อย่างไร - มีกระบวนการให้ผู้ใช้ขอปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานในกรณีเร่งด่วนที่ไม่สามารถรอการปรับปรุงตามกำหนดระยะเวลาได้ เพื่อลดปัญหาในการใช้งาน - มีกระบวนการทบทวนข้อกำหนดเพื่อให้ข้อกำหนดตอบสนองต่อความต้องการในปัจจุบันของผู้ใช้และลดผลกระทบที่อาจจะเกิดขึ้นกับผู้เกี่ยวข้อง		

ระบบรวบรวมข้อมูล การสร้าง และใช้บัญชีข้อมูลยาและรหัสยามาตรฐาน

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
หลักการมีส่วนร่วม	- ผู้ผลิตและผู้เกี่ยวข้องมีส่วนร่วมส่งข้อมูลเพื่อขอเพิ่มเติม/แก้ไขเพื่อปรับปรุงข้อมูลหากพบว่าข้อมูลในบัญชีข้อมูลยาและรหัสยามาตรฐานไม่ถูกต้อง		
หลักนิติธรรม	- หน่วยงานผู้รับผิดชอบหลักเป็นหน่วยงานที่มีอำนาจตามกฎหมายในการรวบรวมข้อมูลยา/สร้าง/ปรับปรุง/เผยแพร่บัญชีข้อมูลยาและรหัสยามาตรฐาน - อยผู้ผลิต และโรงพยาบาลมีหน้าที่ . รับผิดชอบในการส่งข้อมูลยาใหม่/แก้ไขให้แก่หน่วยงานหลักที่มีหน้าที่รวบรวมข้อมูลยาตามที่กำหนด - ผู้ผลิตสามารถส่งข้อมูลยาของตนเพื่อขอรหัสยาได้อย่างเสรี ในกรณีไม่พบรายการยาของตนในบัญชีข้อมูลยาและรหัสยามาตรฐาน		
หลักความโปร่งใส	- เผยแพร่แนวทางในการขอเพิ่ม/แก้ไขบัญชีข้อมูลยาและรหัสยามาตรฐานให้ผู้เกี่ยวข้องรับทราบ - กำหนดกระบวนการในการรวบรวม/ตรวจสอบข้อมูลที่ชัดเจนและเผยแพร่ให้ผู้มีส่วนเกี่ยวข้องทราบ - เผยแพร่ข้อมูลยาที่ผ่านการตรวจสอบและบัญชีข้อมูลยาและรหัสยามาตรฐาน		
หลักการตอบสนอง	- กระบวนการรวบรวมครอบคลุมข้อมูลยาทั้งหมดที่ใช้ในประเทศ และมีการ		

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
	ตรวจสอบข้อมูลเพื่อให้บัญชีข้อมูลยาและรหัสยามาตรฐานตอบสนองต่อการใช้งานของผู้ใช้ - มีการสร้าง/ปรับปรุงบัญชีข้อมูลยาและรหัสยามาตรฐานตามระยะเวลาที่กำหนดเพื่อให้ทันต่อการใช้งาน		
หลักการมุ่งเน้นฉันทามติ	- การส่งข้อมูลยาดำเนินตามแนวทางที่ได้สรุปร่วมกันของคณะทำงานฯ - มีกระบวนการในการตรวจสอบและมีการสรุปข้อมูลยาจากแหล่งข้อมูลต่างๆ ในรูปแบบที่เป็นมาตรฐานตามข้อกำหนดบัญชีข้อมูลยาและรหัสยามาตรฐาน		
หลักความเสมอภาคและครอบคลุมผู้เกี่ยวข้อง	- ผู้เกี่ยวข้องทุกกลุ่มสามารถเข้าถึงข้อมูลที่เผยแพร่ และส่งข้อมูล/ข้อคิดเห็น อย่างเสมอภาค - ผู้เกี่ยวข้องทุกกลุ่มสามารถใช้บัญชีข้อมูลยาและรหัสยามาตรฐานแลกเปลี่ยนข้อมูลยาผ่านระบบสารสนเทศได้อย่างเสมอภาค		
หลักประสิทธิภาพและประสิทธิผล	- กระบวนการและระยะเวลาส่งข้อมูลยา รวบรวม ตรวจสอบข้อมูล สร้างและเผยแพร่บัญชีข้อมูลยาและรหัสยามาตรฐาน และนำไปใช้กำหนดไว้อย่างเป็นระบบ		
หลักภาระรับผิดชอบ	- กระบวนการรวบรวมข้อมูลและตรวจสอบข้อมูลต้องดำเนินการให้ครอบคลุมยาที่ใช้ในประเทศ มีแนวทาง		

หลักการในการออกแบบ	ข้อพิจารณาในการออกแบบ	ระดับปัญหา	ข้อเสนอแนะในการปรับปรุง
	ในการขอเพิ่มเติม/แก้ไขข้อมูลยาเพื่อให้บัญชีข้อมูลยาและรหัสยามาตรฐานมีข้อมูลยาครบถ้วนตามที่ผู้เกี่ยวข้องคาดหวัง และลดผลกระทบที่อาจจะเกิดขึ้น		

Appendix 5

Drafted model

First drafted model

The researcher synthesized the first drafted model from the information derived from the review of the experience of six countries and the suggestion from the key informant interview. The first drafted model was shown in figure 27-30.

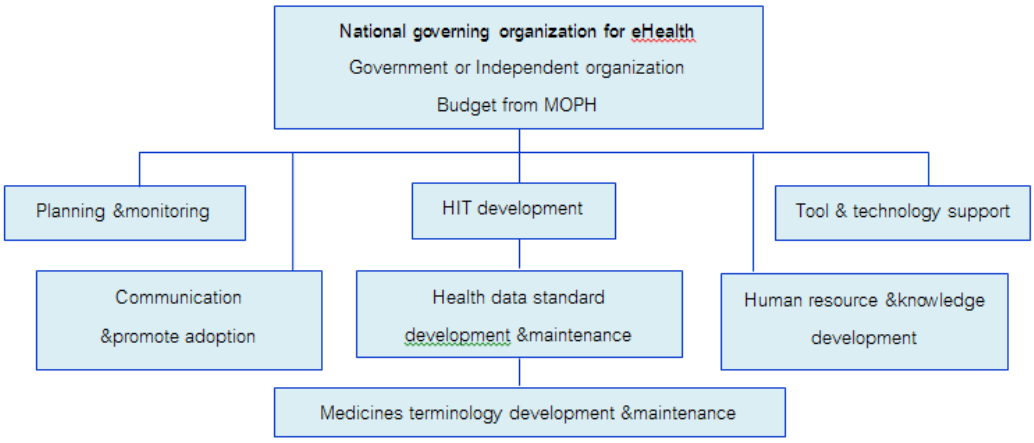


Figure 27 First drafted model - HIT governance organization and the functions related to medicines terminology governance

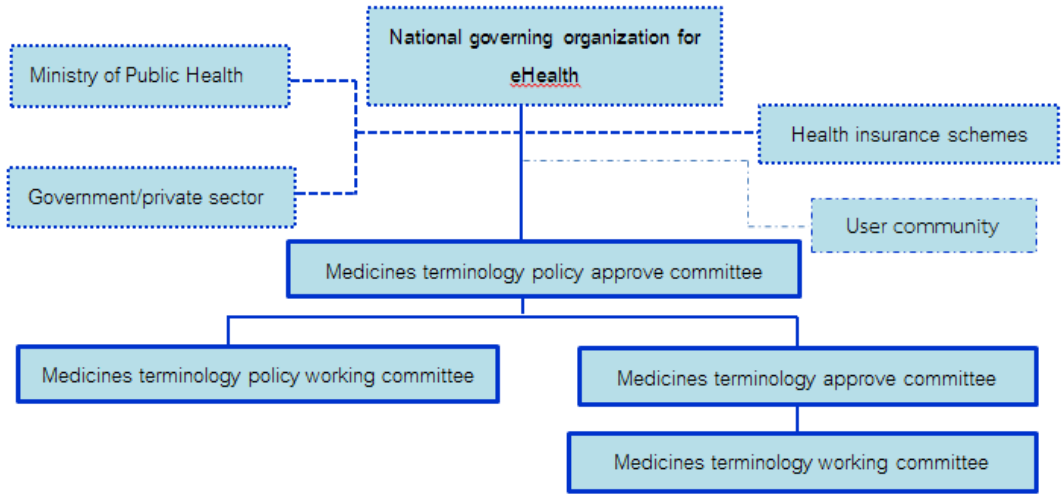


Figure 28 First drafted model - collaborative structure for medicines terminology governance

Main collaborative structure
Formal collaborative network
Informal collaborative network

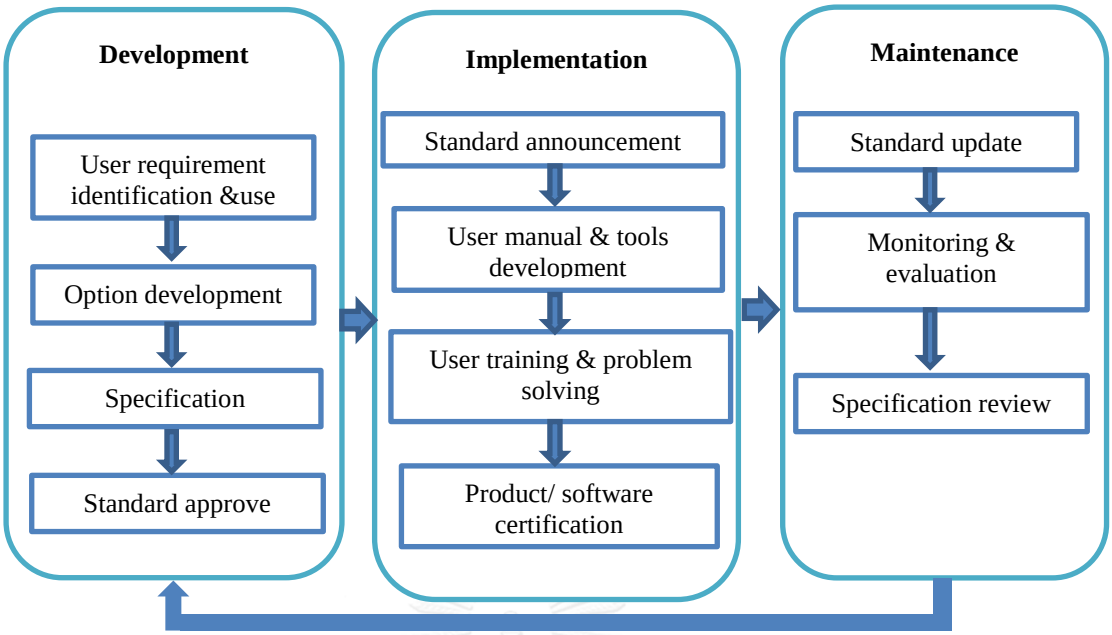


Figure 29 First drafted model - process for health data standard and medicines terminology governance

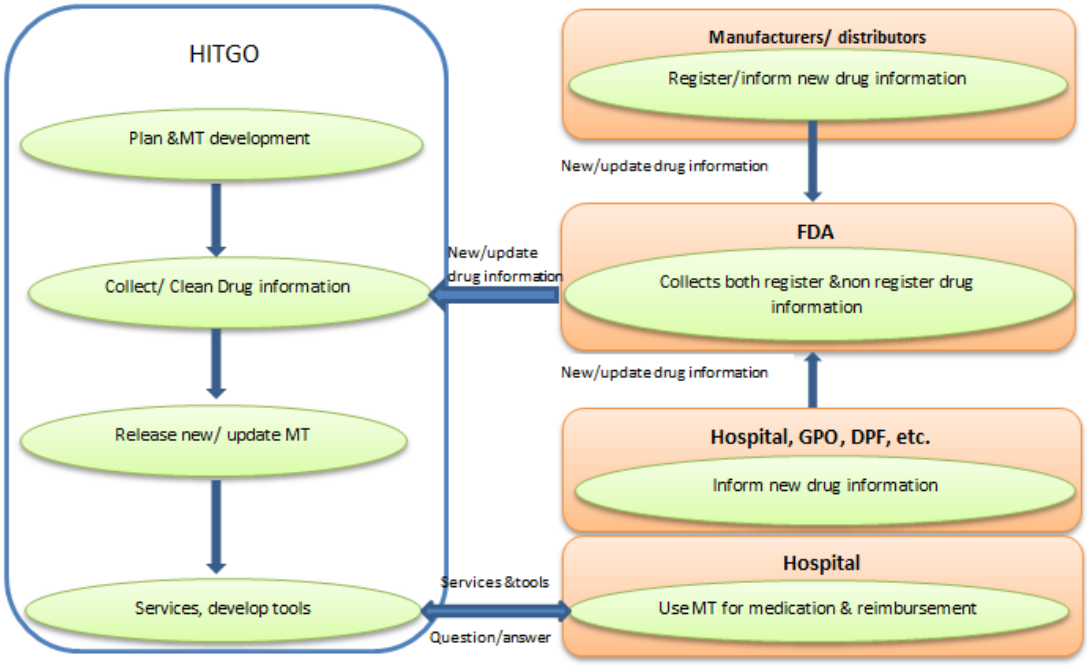


Figure 30 First drafted model - collaborative structure and process for medicines terminology

The first drafted model was consulted with the stakeholders in the consultation seminar which arranged on March 28, 2014. The recommendations of the participants for the model improvement concluded as follows:

1) Name of the governing organization: The participants suggested changing the name of the organization because the name was too long and many stakeholders do not understand the word “eHealth” in the name of the governing organization.

2) Type of the governing organization: The participants suggested that the individual organization was more suitable than the government organization because the individual organization was more flexible, effective, and adaptive. In addition, the participants suggested that this organization must have the authority from the regulation for enforcement.

3) Process: The participants suggested adding the plan setting process in development, implementation, and maintenance process. For standard update, the participants suggested to separate the standard update to the schedule update and urgent update as same as the review from New Zealand.

The user manual and tool development should be done before implementation.

4) Drug information collection: The participants widely discussed about the drug information collection which the model suggested Thai-FDA to collect both register and non-registered drug information because the information from interview suggested that Thai-FDA should have all drug information in Thailand for more effective of drug control. The participants discussed that Thai-FDA did not have the responsibility and authority according to the regulation to collect the non-registered drug information and the review from other countries revealed that the governing organization was responsible to gather all drug information. In addition, the manufactures should have the option to send new or update drug information to the governing organization. The participants suggested to developing two options for drug information collection.

Second drafted model

The suggestions from the consultation seminar were analyzed and synthesized the second drafted model as shown in figure 31-34

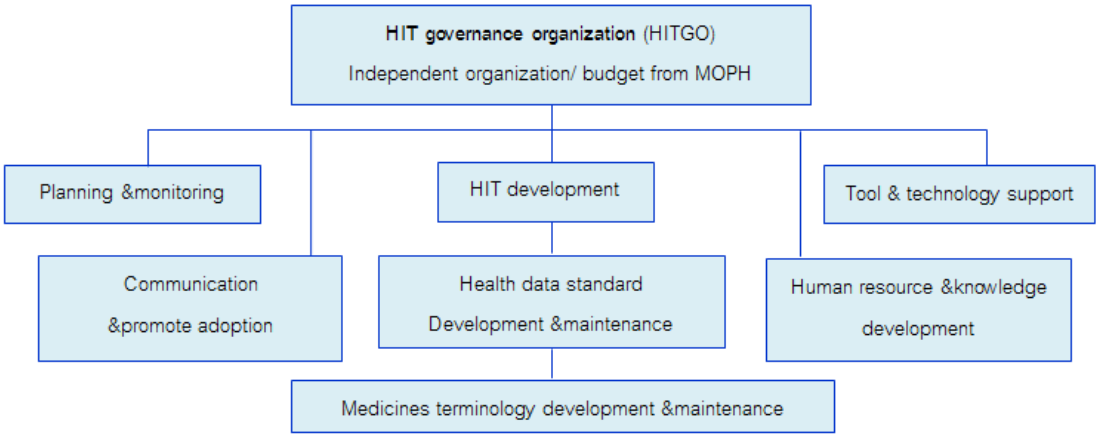


Figure 31 Second drafted model - HIT governance organization and the functions related to medicines terminology governance

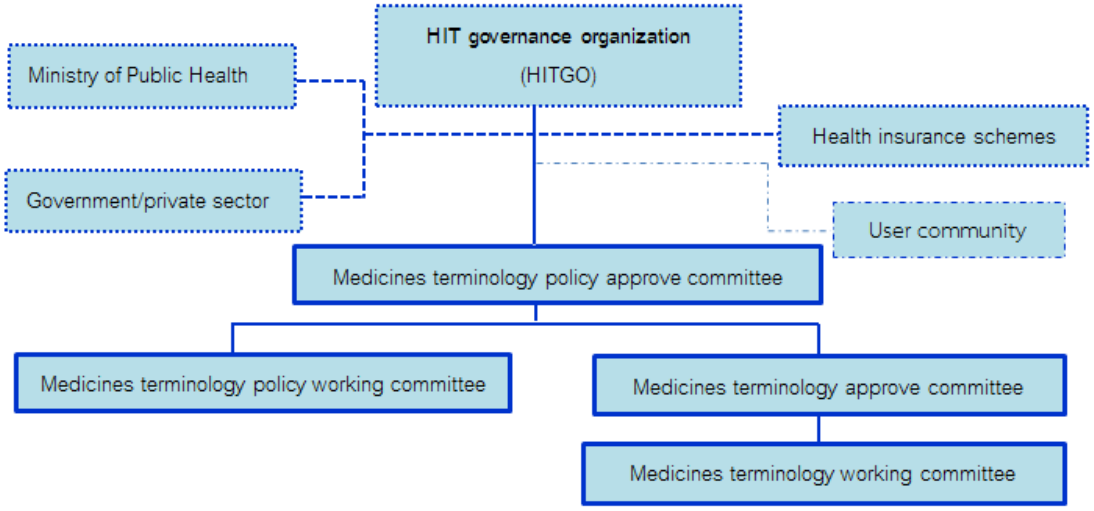


Figure 32 Second drafted model - collaborative structure for medicines terminology governanceSecond drafted model - collaborative structure for medicines terminology governance

Main collaborative structure
Formal collaborative network
Informal collaborative network

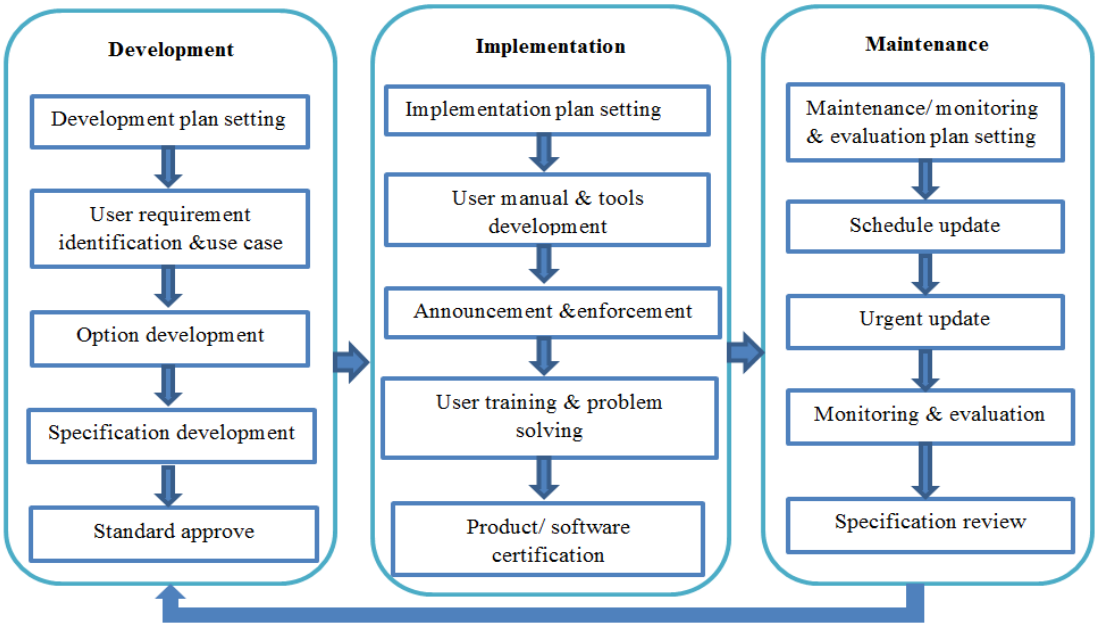


Figure 33 Second drafted model - process for health data standard and medicines terminology governance

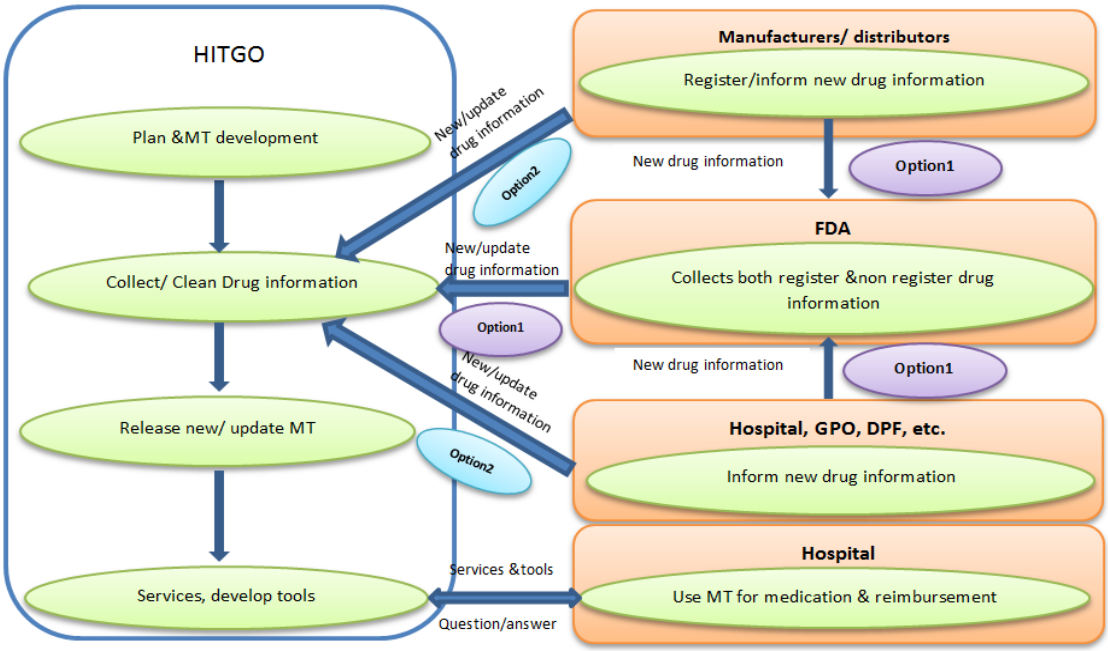


Figure 34 Second drafted model - collaborative structure and process for medicines terminology

The second drafted model was tested for usability from the experts by applying the heuristics evaluation. The results from heuristic evaluation concluded as table 10.

Table 10 usability problem and recommendation from heuristics evaluation

Severity and usability problem identification	**Recommendation for model improvement**
1. Major problems	
1.1 Development system	
- The policy setting process was not effective.	- The policy setting process should integrate with the HIT policy setting process. The medicines terminology policy approve committee should be change to HIT policy committee
2.2 Implementation system	
- Many processes of the technical question answer might affect to the efficacy and effectiveness.	- The responsible organization should set up the team for urgent problem solving and decrease the processes of the technical question answer.
2. Minor problems	
2.1 Development system	
- The stakeholders may not understand the option selection of the medicines terminology and the medicines terminology specification which may affect to the consensus oriented.	- Set up the criteria for option selection and communicate to the stakeholders before specification consultation.

Severity and usability problem identification	**Recommendation for model improvement**
2.2 Implementation system	
- The announcement and enforcement process in the scenario was not clear and could not responsible to the stakeholders need.	- The responsible organization should set up the technical support team in each province or sector to communicate for user adoption and help the users to solve problem before enforcement.
2.3 Maintenance system	
- The channel for medicines terminology update might not cover all stakeholders and might affect to the equity and inclusiveness.	- The responsible organization should set up many channels for medicines terminology update, such as email, formal letter, etc.
- The urgent update process was not clear.	- The criteria for urgent update should be set and announce to the stakeholders.

VITA

Name: Miss Ratsapan Phuksaritanon

Date of Birth: August 17, 1978

Place of Birth: Nakornsawan

Current work position: Pharmacist of Food and Drug Administration, Thailand

Educational credentials:

2005 Bachelor of pharmacy, Huachiew Chalermprakiet University

2009 Master of art (English for Business Communication), Chandrakasem Rajabhat University

2011 Ph.D. candidate in Social and Administrative Pharmacy, Chulalongkorn University