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A medicines terminology governance model for Thailand

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ABSTRACT

At present, Thailand does not have a national governance system for developing a health data standard and coding system, especially drug codes and medicine terminology. There is no single responsible organization and also no mechanism for cooperation among stakeholders to govern 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 proposed a medicines terminology governance model for Thailand by applying a participatory research design. This researcher reviewed the experience from other countries that are very advanced in health information technology and then included all stakeholders as participants for interviewing. The interviews were iteratively done until the authors acquired enough data and saturation was reached then synthesized the medicines terminology governance model. The model confirmation step was conducted among 45 stakeholders in a stakeholder consultation seminar followed by usability testing.

The governance model for medicines terminology was presented in three areas: Foundation, processes, and tools and services. The result demonstrated a responsible organization structure and functions, the collaborative network structure of stakeholders and cooperation process, and suggested tools and services facilitate users for medicines terminology governance. The usability of the proposed model was evaluated by six professional experts: The policy maker, medicines terminology administrator, drug manufacturer and distributor, health insurance scheme administrator, pharmacists or health-care professionals from the hospital and an expert in the national drug control section. In general, the professional experts agreed that the proposed model will suit the context and situation in Thailand.

INTRODUCTION

In Thailand, drug information in health-care system and drug system is rapidly growing and increasingly complex at both local and national level. Health service units, drug companies, government organization, used their own drug code for their own data processing.

Before 2002, Thailand does not have a national drug code for drug information exchange between health service units. Due to a lack of a national drug code, the health service units had difficulties to exchange patients' drug profiles between hospitals for continuing of care. In addition, compiling drug utilization for monitoring and evaluation at the national level was difficult and needed a lot of effort. These issues affect the efficiency and effectiveness of medical care and drug reimbursement in the national health insurance schemes.

In 2002, a 24-digit drug code was initiated as the first national drug code and used for national drug inventory management [1]. The 24-digit drug code has limitations when used for drug reimbursement and medical care. Therefore, Thai Medicines Terminology (TMT) has been developed by applying the international concepts of medicines terminology [2].

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 [3,4].

The 24-digit drug code and TMT implementation have not been successfully adopted by all stakeholders. One important factor is the lack of an effective governance system. The organizations which developed the 24-digit drug code and TMT were both assigned by governmental agencies and have no formal authority for cooperation 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.

Thailand has both registered drugs, which have to be registered with the Thai Food and Drug Administration (Thai FDA), and non-registered drugs. Drugs which are manufactured by the Government Pharmaceutical Organization, the Defense Pharmaceutical Factory, the Thai Red Cross Society and Hospitals for internal use are exempt from registration. The drug information that is used to generate drug codes and medicines terminology comes mainly from the Thai FDA and partly from the drug manufacturers, but the cooperation process is intermittent and inconsistent, this affects the updating of drug codes and user adoption. This is an example of the problems created by an ineffective governance system of medicines terminology in Thailand that affects implementation.

Medicines terminology governance has a lot of stakeholders and needs a well-designed governance system and mechanism for the cooperation of stakeholders. Therefore, this research aimed to demonstrate a medicines terminology governance model derived from all stakeholders' opinions.

METHODOLOGY

The study was conducted from October 2013 to September 2014. This research was a qualitative study and applied the method of participatory research design to develop a medicines terminology governance model. The participatory research design is a stakeholder-centered approach that allows the stakeholders to present their expectations, requirements, and involvement throughout the design process. Consequently, it can reduce stakeholder's resistance to new system implementation. The study was divided into five steps as follows:

Conceptual Framework Development

This research reviewed the WHO eHealth development model, and Office of the National Coordinator for Health Information Technology (HIT) Standards and Interoperability Framework (S and I framework) to formulate a conceptual framework as in Figure 1 [5,6]. The main components for health data standards' development to enable interoperability are foundation, processes, and services and tools. The components of the conceptual framework were used in the next steps for reviewing the experience of more advanced countries, reviewing the current situation in Thailand, and developing a governance model. The governance model was also developed and tested according to good governance principles. Eight major characteristics of the good governance principles which are participation, rules of law, transparency, responsiveness, consensus oriented, equity and inclusiveness, effectiveness and efficiency, and accountability are applied as the design consideration [7].

Review on the Experience of Six Advanced Countries

The researchers reviewed six countries: The United States, the United Kingdom, Australia, Canada, Hong Kong, China, and New Zealand. The researchers discovered the governance of health data standards and medicines terminology from relevant websites and documents. The information from these countries was analyzed and formed the foundation for Thailand governance model.

Exploration the Current Situation and Requirements of Stakeholders

The current situation was studied by document reviews, in-depth interviews and focus group interview. Purposive sampling was used in this step. The Medicines Terminology Development Committees appointed by the Thai Ministry of Public Health (MOPH) were identified as the key informants and were asked for additional key informants from other groups of stakeholders, such as the drug codes and medicines terminology generators, pharmacists, or IT personnel who responsible for information processing in the hospitals, the agencies from health insurance schemes, the agencies from the manufacturer association, the agencies from the drug companies, and the agencies from software manufacturer. The inclusion criteria are key informants have to work around drug codes or medicines terminology for at least 2 years. The interview topics were developed according to the conceptual framework for in-depth interviews and focus group interview. Overall, the 32 key informants were interviewed for the current situation, the current governance problems, and suggestions for the governance model.

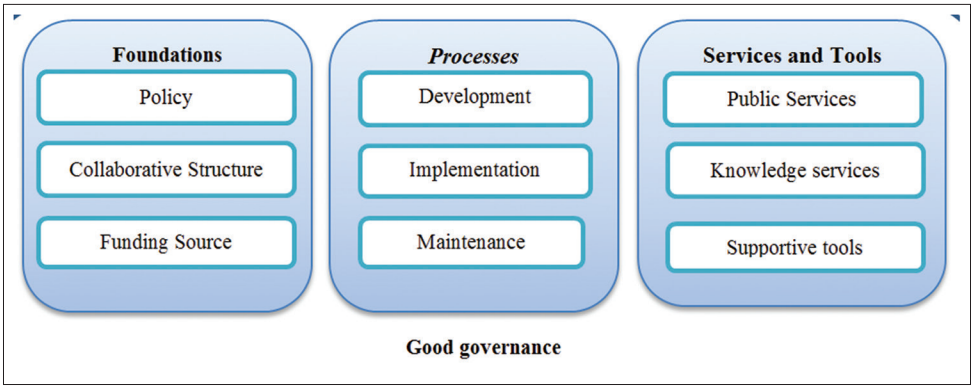

Figure 1: Conceptual framework for medicines terminology governance model (formulated from Standards and Interoperability framework of Office of the National Coordinator for Health Information Technology, and WHO eHealth Development Model) [5,6]

Medicines Terminology Governance Model Development

The review sought information from advanced countries. Thailand's current situation and requirements were analyzed by the researchers who synthesized the first drafted governance model. The current situation, problems, and recommendations for the medicines terminology governance model were confirmed and concluded by 45 stakeholders in a stakeholder consultation seminar. The first drafted prototype was improved according to the suggestions of the stakeholders and developed as the second drafted prototype.

Medicines Terminology Governance Model Usability Testing

Six professional experts: The policy maker, medicines terminology administrator, drug manufacturer and distributor, health insurance scheme administrator, a user in hospital, and an expert in the National Drug Control Section were invited to participate in model testing. All experts have at least 3 years' work experience around drug codes or medicines terminology and still work in this area.

In this study, heuristics evaluation was applied for model testing. Heuristics evaluation is a usability test method appropriate to identify the usability problems of the design prototype [8,9]. Good governance principles were applied as the heuristics to examine the design prototype. Four use case scenarios were created to describe the role of the stakeholders in each process of the medicines terminology governance. Four use case scenarios are medicines terminology development, medicines terminology implementation, medicines terminology maintenance, and drug information collection and medicines terminology usage for exchange.

The contents of the case demonstrate that who have the role in each process. For example, a hospital found that the strength of drug A in the medicines terminology is not correct; therefore, a hospital sends the request form to the medicines terminology development and maintenance department. An officer of medicines terminology development and maintenance department examine and correct the medicines terminology and inform to the users.

The researchers described each scenario to the experts and the experts explored and gave feedback about the problems or unsuitability of the model where it was not compliant with the design considerations. The suggestions for solving design problems or the unsuitability of the model from the experts were analyzed by the researchers and we synthesized the proposed medicines terminology governance model.

RESULTS AND DISCUSSION

Reviewed the Experience of Six Advanced 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 road map 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 HIT (ONC) to enforce the HIT and health data standard adoption [10].
2. Collaborative structure and funding resource: Most of the countries studied 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 [11]. Hong Kong established an eHealth Record Office within the Government of Hong Kong [12].
   - 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 [13,14]. The UK established the Health and Social Care Information Centre as an Executive Non-Departmental Public Body receiving a budget from the government and charging for services [15].

   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 S and I framework to empower, facilitate use, and accelerate adoption of the stakeholders [6,16].
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 [17-19].
   - 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.

Current Situation of Drug Code and Medicines Terminology Governance in Thailand

The 24-digit drug code and TMT are two drug codes used as the national standard code for interoperability at present. Both are mostly used for drug reimbursement in health insurance schemes more than used for supporting health care or policy decision-making. The results from key informant interviews about the current situation of medicines terminology governance, problems, and recommendations were concluded and are shown in Table 1.

The 24-digit drug code

The 24-digit drug code was developed by MOPH for drug inventory management in both central and region hospitals by the Bureau of Health Administration. The MOPH announced the 24-digit drug code as the national drug code for drug information exchange between health service units, health insurance schemes, and government organizations in 2010 [1,20].

The 24-digit drug code was initiated for only inventory management purposes, not for health care and reimbursement. Therefore, the code does not contain some necessary information and not standardized drug information attributes with identifier and drug concept relationships before generating code such as dosage unit and dosage form. In addition, the governance of the 24-digit drug code was not well-prepared and improved for using as the national drug information standard; therefore, many problems occurred in implementation. The 24-digit drug code is not generated for all medicines, is not frequently updated, and does not cover all non-registered drug and hospital formulary which are used in all health service units. Therefore, the 24-digit drug code cannot serve the requirements of users for health care and reimbursement purposes.

TMT

The Thai government launched a policy to develop new medicines terminology, which can really be used for multi-purposes, such as reimbursement and cost containment, inventory management, and health care. After the policy was announced, the MOPH appointed the Committees for Medicines Terminology Development and the Thai Health Information Standard Development Center, which is a health data standard research unit in the Health Systems Research Institute. It was assigned to develop the TMT in 2012. TMT was developed by applying Systematized Nomenclature of Medicine Clinical Terms and the drug information from the 24-digit drug code to generate TMT code, which is more flexible and easier to use for reimbursement and health care [2]. TMT was announced as the national drug information standard for electronic transactions for medical care and public health by the Office of the Electronic Transactions Commission, Ministry of Information and Communication Technology, and it has been used for drug reimbursement in the Civil Servant Medical Benefit Scheme and was planned for implementation in the Universal Coverage Scheme in 2015.

The slow implementation of TMT arose from many causes, such as a lack of authority and efficient cooperation for enforcement, lack of a national roadmap and governing body for implementation, lack of efficient drug information collection and transferring system, and lack of health informaticians and pharmacy informaticians. The lack of authority and efficient cooperation for enforcement and lack of a national road map and governing body for implementation has affected the adoption of health insurance schemes and health-care professionals. The lack of efficient drug product information collection and a transferring system is the cause of slow TMT code generation and the revealing of drugs used within the health service.

Proposed medicines terminology governance model

The proposed medicines terminology governance model is presented in three main areas, foundations, process, and tools and services.

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 be 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 2. The HITGO has to cooperate with the stakeholders in the form of the collaborative structure seen in Figure 3. The HITGO should cooperate 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

Table 1: Results from key informant interviews about the current situation of medicines terminology governance, problems, and the recommendations

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	• Setting a national body for HIS policy setting comprising of stakeholder representatives from both government and private sectors • Setting the standard procedure for setting a national policy for health data standards and medicines terminology development
Collaborative structure	• No main organization responsible for medicines terminology governance • The assigned organizations, such as the THIS which is the research unit do not have a mission for medicines terminology governance • Lack of authority to enforce the medicines terminology and coordinate development and maintenance	• 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 • Create the organization as an independent or government organization • Develop from the present organizations (such as the HIT department of MOPH) or establish a new organization • 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 • Lack of other sources of funding	• Set the funding plan to conform to the policy and long-term planning • Other funding resources from other organizations as the co-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 services	• Insufficient tools and 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	• Develop the tools to respond to stakeholder needs • Training the users for initial problem solving • Improve the problem solving service • Set up a service for human resource development

FDA: Food and Drug Administration, HIT: Health Information Technology

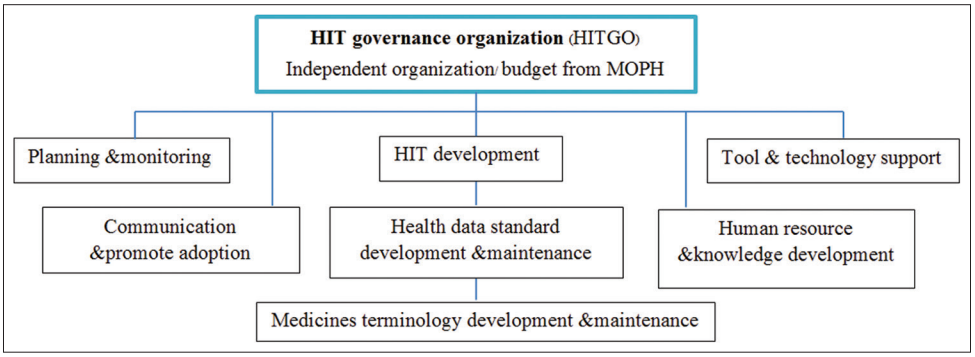

Figure 2: Health information technology governance organization and the functions related to medicines terminology governance

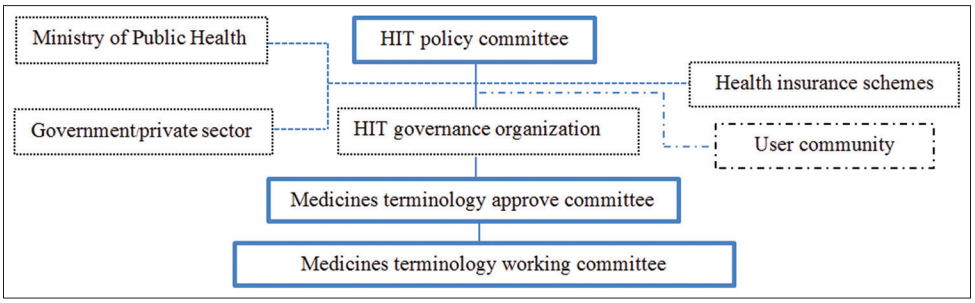

Figure 3: Collaborative structure for medicines terminology governance. —— Main collaborative structure, - - - Formal collaborative network, ... Informal collaborative network

should support the user community as the informal collaborative network to accelerate user adoption.

In the stakeholder consultation process, the participants proposed an independent organization similar to the NEHTA of Australia 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 were 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, this organization design theory has limitations in cooperation 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 [21].

Usability testing applies the good governance principle for testing. All the 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 nondepartmental public body of the UK. The public organization is the independent organization authorizing by the law and receiving budget from the government.

The strong partnership of the collaborative network is a most important successful factor. In the researchers view, the collaborative structure as the working committee and informal practitioner community is benefits. The agencies of all groups of stakeholders can participate and working together as the working committee to give their opinions and their requirements about policy and medicines terminology development which are benefit to the stakeholders. This can reduce the resistance of medicines terminology implementation and enhance the cooperation for medicines terminology development and maintenance. The informal practitioner community enhances the cooperation of stakeholders and promotes the strong partnership of stakeholders in each process of medicines terminology governance.

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 [22,23]. In the researchers view, cooperation and cofunding 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 efficiency. The funding resources should not be limited only from the government budget.

Process

This study proposed the medicines terminology development process, implementation process, and maintenance process as shown in Figure 4.

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 cooperate 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 cooperate with the stakeholders for medicines terminology development, implementation, and maintenance as collaborative structure and process in Figure 5. 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.

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 download documents, user manuals, or supportive tools about medicines terminology

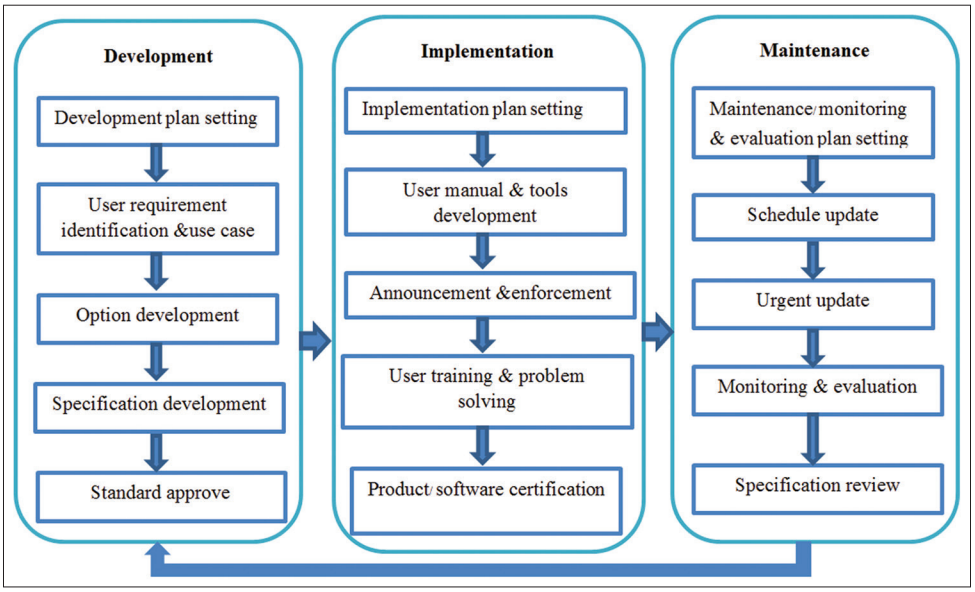

Figure 4: Process for health data standard and medicines terminology governance

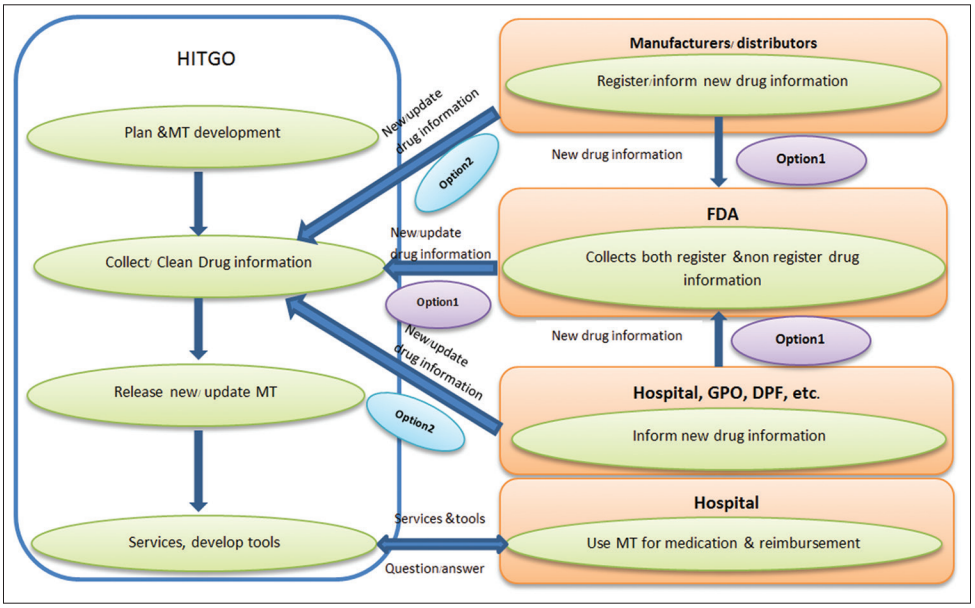

Figure 5: Collaborative structure and process for medicines terminology

- 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, training seminars, in-house training, and online training should be arranged for the users.

CONCLUSIONS

This study proposes the main responsible organization and collaborative structure for cooperation among stakeholders in each step of the process for developing a drug code and medicines terminology, which will solve the current problems that exist in Thailand. The main responsible organization will facilitate the stakeholders.

The development of a medicines terminology governance model will be a case study for health data standard governance in Thailand. The proposed model in this study can be used as a prototype and applied to be used with other health data standards, which will be the foundation for health information systems in other developing countries.

There are several limitations of this study. 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 respondent bias by a wide range of key informants interview cover the medicines terminology administrator group and users in hospital, drug manufacturers and distributors, and the software producer group. We believe that multi-technique of qualitative research using in this study allowed the researchers to identify the dominant current situation issues and reach saturation of the requirements for governance model design.

Due to the governance of medicines terminology affecting a wide range of stakeholders in Thailand, the consultation process should be done with a wide variety of stakeholders. In this study, forty-five stakeholders participated in the stakeholder consultation process to identify the requirements and give suggestions for model design. Although the research could not consult with all stakeholders, the researchers realized the importance of the usability of the model and attempted to decrease the limitation by conducted usability testing by experts. However, the researchers recommend to put the proposed governance model out for wider public consultation before setting up the real national governance system.

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