Structured Model for Clinical Processes: PCAPS-CPC

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Summary
One of the main parts of the healthcare social technology is a structured model for clinical processes. This process model will be commonly shared in a healthcare society, and clinical knowledge behind the model will play an important role in upgrading the level of healthcare clinical processes in each medical institution. In fact, clinical knowledge is a basis for quality and safety of healthcare in a country.

Several years ago, we developed Patient Condition Adaptive Path System (PCAPS). PCAPS describes an overall flow of possible clinical pathways that a patient's disease state may trace and detailed medical judgment and treatments for each disease state. The application of PCAPS makes it possible to implement proper healthcare interventions according to disease state. Medical records kept in the PCAPS will give useful information on the patient's state, the interventions at the state and the effects of the interventions. Through the analysis of these records, it is possible to improve the standard treatment plan. This presentation discusses the effectiveness and significance of the structured model for clinical processes in a view of healthcare social technology.

Keywords
clinical process, structured model, standardization, healthcare social technology

1. Background

Healthcare needs to be designed as a “condition-adaptive” service coping with disease specificity, patient individuality and patient condition change. Medical interventions may trigger temporary deterioration of independence and treatment-induced complications since medical treatment is a high-risk practice accompanying human body invasion. To assure patient safety, therefore, strong medical intervention needs to be followed by around-the-clock patient condition monitoring and immediate intervention when necessary.

In the field of highly complex and demanding healthcare, it is difficult to rely totally on each individual medical staff member in realizing patient safety and quality assurance. Healthcare needs to be recognized as a critical social technology and established as a social system. It is important to evolve knowledge to provide healthcare ensuring patient safety and quality assurance from “personal knowledge” to “organizational knowledge.”

Among the knowledge necessary to refine healthcare into a social system, clinical knowledge, which is medical-specific technology (expertise), serves as a core to materialize patient safety, quality assurance and quality management. This clinical knowledge lies in clinical process. The clinical knowledge can be identified by visualizing clinical process. In addition, by incorporating the identified clinical knowledge into clinical process in a structured way, it may become possible to enhance applicability of the clinical knowledge and extract new knowledge.

Authors have developed a model for clinical process structuration. This model enables us to identify “clinical knowledge to achieve patient safety and quality assurance” lying in clinical process. By incorporating the identified clinical knowledge into clinical process, it becomes possible to enhance applicability of the clinical knowledge, which leads to identification of new knowledge which is different from the existing knowledge. It is necessary to establish a mechanism, as a part of healthcare social technology, to keep repeating a cycle of “Identification – Application – Improvement & Enhancement” of clinical knowledge. This model has potential to contribute to development of such social technology.

This article reports a) development steps of PCAPS-CPC (Patient Condition Adaptive Path System – Clinical Process Chart) which is a model for clinical process structuration, b) structure of the developed PCAPS-CPC, c) development state of PCAPS-CPCs designed for different target healthcare domains, d) classification of PCAPS-CPCs by purpose of use, structure type, e) development of standardization technique, f) various potential applications of PCAPS-CPC and the like. The article also presents benefits and significance of clinical process structuration from the standpoint of healthcare social technology.

In 2003, basic concept of PCAPS-CPC (a model for clinical process structuration) was developed. Receiving a general research grant from Ministry of Health, Labor and Welfare in 2004~2007, authors initiated research and development of PCAPS-CPC. In 2007~2009, authors received a cancer research grant from Ministry of Health, Labor and Welfare to develop a model to structure clinical process for cancer. PCAPS Study Group was established as a research and development organization. The Study Group was composed of healthcare researchers and diverse healthcare professions including doctors, nurses, pharmacists, medical technologists, radiological technologists, physical therapists, occupational therapists, nationally certified nutritionists and hospital clerical staff (about 150 members as of 2007). A total of 117 hospitals were registered to help the Study Group verify PCAPS-CPC developed for each disease, including 65 hospitals for which the Study Group members work and 52 hospitals which belong to All Japan Federation of Social Insurance Associations. There are three steps to develop PCAPS-CPC: 1) concept development, 2) design and 3) verification.

<Step 1: PCAPS-CPC Concept Development (in 2003)>
It is not easy to visualize clinical process for each individual disease. In addition, people tend to believe clinical process is significantly varied among hospitals and doctors. Consequently hospitals have established their own in-house standardization of care pathway, but no hospitals have attempted an across-the-board care pathway standardization covering multiple hospitals. Standardization, however, is essential for quality assurance in healthcare. To establish healthcare as a social technology, it is absolutely necessary to develop a standard to be shared among different hospitals or across the country.

Authors recognize a clinical process standard as what is called “best practice” in the current medical technology, i.e. “a standard to be recommended.” To standardize clinical process, this study highlights “clinical process to fulfill appropriateness and comprehensiveness.”

In order to visualize clinical process in a structured manner, authors initially built PCAPS-CPC by connecting various units, each of which is composed of two elements: 1) “Execution Element” to execute a means to move from current patient condition to target condition and 2) “Decision Element” to decide whether target condition is achieved.

Working with doctors of cardiovascular internal medicine, authors applied PCAPS-CPC to illustrate clinical process for ischemic heart disease (IHD) in a structured way and came up with Clinical Process Chart (CPC) for IHD which was composed of 106 units. Various structural characteristics were also identified in CPC for IHD, e.g. “connection/branching/converging,” “serial flow/parallel flow,” “jump to a remote unit” and “embracing two units, which are independent by their nature, into a unit by internal actions.”

![Fig. 1. A part of Clinical Process Chart for IHD which was composed of 106 units](image)

<Step 2: PCAPS-CPC Design (in 2004)>
A basic PCAPS-CPC was developed by studying structuration of medical treatment process of six diseases. Eleven meetings were held to build this basic PCAPS-CPC, joined by 37 initial members of the Study Group (including 25 doctors, hospital directors and administrative directors). The six diseases are ischemic heart disease, total prostatectomy, cerebral infarction, infant bronchial asthma, diabetic insulin introduction and fracture of heck of femur.
Medical staff intends to grasp patient condition at a particular point of time and accordingly to provide healthcare services adapted to the condition. Along with change in patient condition, healthcare services will be changed adaptively. This adaption procedure is repeated until a patient arrives at state of recovery. Healthcare services, therefore, should be expressed as “Patient Condition Adaptive Healthcare Process,” which is designed as a process to move a patient through units adapted to his/her conditions one after another in a safe and effective way.

In the process of medical treatments, several target conditions are set. Once a target condition is achieved, a next target condition will be selected and patient condition will gradually get closer to the final target condition (recovery). Through structuration of and discussion about medical treatment processes of the six diseases, the basic PCAPS-CPC was designed as a logical connection (route) of multiple patient condition phases (units) which terminates at target condition.

<Step 3: Verification and Refinement of PCAPS-CPC (2005~2009)> Sub-groups were formed within the PCAPS Study Group. Each sub-group addressed a specific healthcare domain and developed a disease-specific PCAPS-CPC by applying the basic PCAPS-CPC. Multiple hospitals helped the PCAPS Study Group verify appropriateness and comprehensiveness of the developed disease-specific PCAPS-CPCs by applying the PCAPS-CPCs to their medical treatment records. Specifically the hospitals picked up hospitalization cases of a previous year and checked whether corresponding PCAPS-CPCs were applicable to the cases. Four verification projects were conducted in 2005~2009. In the four projects, 92 disease-specific PCAPS-CPCs were verified, a total of 172 hospitals participated in the verifications, and 11073 patient cases were examined.

At present, the PCAPS Study Group addresses 20 different healthcare domains. The Study Group develops several disease-specific PCAPS-CPCs for about ten healthcare domains every year. The basic PCAPS-CPC is found effective enough to develop all of these disease-specific PCAPS-CPCs. By being verified, the disease-specific PCAPS-CPCs were successfully improved and refined to become standard disease-specific PCAPS-CPCs applicable to multiple hospitals. It has been demonstrated that the disease-specific PCAPS-CPCs are clinically applicable to structure various clinical processes.

### Table 1. Outline of verification survey

<table>
<thead>
<tr>
<th>Item/Year</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of hospitals</td>
<td>55</td>
<td>51</td>
<td>35</td>
<td>31</td>
</tr>
<tr>
<td>No. of Patient’s cases</td>
<td>4279</td>
<td>2292</td>
<td>3078</td>
<td>1424</td>
</tr>
<tr>
<td>No. of PCAPS contents(CPC)</td>
<td>26</td>
<td>19</td>
<td>32</td>
<td>15</td>
</tr>
</tbody>
</table>

3. The Developed PCAPS-CPC

The developed PCAPS-CPC is a model to illustrate patient condition adaptive healthcare services in a structured manner. The basic specifications of the PCAPS-CPC are described below.

<Component>
- The components of PCAPS-CPC are “unit” and “route” connecting units. “Unit” represents a phase of patient condition while “route” represents a condition for unit-to-unit connection.
- Route is defined by “transfer logic.”
- Unit is composed of “execution element” and “decision element.”
- Decision element makes a decision about “achievement of target condition” and “transfer.”

<Unit Transfer>
- Unit transfer takes place “when target condition is achieved” or “when an ongoing unit becomes no longer suitable as patient condition changes.”
- Unit transfer logic defines a condition to move from a unit to another unit.
- Transfer logic without branching
  - When Condition X stands valid
    - Move from ongoing Unit A1 to Unit A2
  - Transfer logic with branching
    - When Condition X stands valid
      - And when Condition Y stands valid
        - Move from ongoing Unit A1 to Unit B1
      - And when Condition Y does not stand valid
        - Move from ongoing Unit A1 to Unit C1
4. Application of PCAPS-CPC for Different Healthcare Domains/Disease Groups

Development of PCAPS-CPC contents for different healthcare domains/disease groups
PCAPS-CPC developed for a healthcare domain or for a disease group by using the basic PCAPS-CPC is referred to as “PCAPS-CPC content.” Problems found in PCAPS-CPC verification can be solved. This means that PCAPS-CPC will be enhanced, after going through verification, to become clinically applicable to structure clinical process. As of March 2010, there are more than 130 PCAPS-CPC contents for different healthcare domains and disease groups. Majority of PCAPS-CPC contents is developed for target disease groups. Only a few PCAPS-CPC contents have been developed for target healthcare domains, and the existing PCAPS-CPC contents cover major diseases.

Classification of PCAPS-CPC contents by purpose of use
The PCAPS-CPC contents can be classified by purpose of use into categories such as content for clinical operation, content for clinical analysis, content for clinical epidemiological research and content for clinical development. Branching structure of PCAPS-CPC content is determined by purpose of use. In other words, granularity of PCAPS-CPC content or the number of units required in PCAPS-CPC content is varied, depending on purpose of its use. For example, PCAPS-CPC content for clinical operation is designed in a way to feature relatively coarse granularity so as to cope with varied clinical operation. On the other hand, PCAPS-CPC contents for other purposes of use feature relatively fine granularity, having a number of units, as they need to have multiple branches to achieve the purposes of use.

Structure type of PCAPS-CPC contents for different disease groups
Clinical process structures of PCAPS-CPC contents for different disease groups can be classified as well. Authors analyzed a number of PCAPS-CPC contents developed for different disease groups. It was found, for example, that clinical process structure of hospitalization following surgery is composed of a series of units: admission → preparation for surgery → surgery → postoperative hyperacute phase → postoperative acute phase → postoperative recovery phase → preparation for discharge → coordination of residence after discharge → discharge. It was also learned that various complication units are connected to those units after surgery. In the case of medication, its clinical process structure often starts with a first unit selected based on combination of patient condition severity and applicable medication and the following units are selected in a way to represent different patient conditions brought about by drug treatment.
5. Application of PCAPS-CPC

PCAPS-CPC contents for different disease groups have been developed by using the basic PCAPS-CPC. These PCAPS-CPC contents can be used in the applications shown below. The PCAPS-CPC Study Group has started using PCAPS-CPC contents in these applications on the trial basis.

- To prepare a standard healthcare service plan (to draft and share a plan)
- To support implementation of the plan and to support recording
- To establish and use a structured summarizing system (to extract, refer to and summarize cases)
- To identify and analyze potential problems, by comparing medical treatment history records of different hospitals, for continual improvement
- To create clinical knowledge by analyzing relation among patient condition assessment, medical intervention and effects of the intervention
- To improve analyzability of existing accumulated healthcare data
- To improve clinical process
- To train residents (doctors-in-training) and new comers

6. Benefit and Significance of Clinical Process Structuration from the Standpoint of Healthcare Social Technology

In clinical practices and management of medical staff and hospitals, PCAPS-CPC (Model for Structuration of Clinical Processes) features the following benefits and significance:

- To support patients’ decision-making process by providing them with visualized clinical process
- To promote informed choice
- To enhance quality assurance through standardization of clinical process
- To reduce differences in clinical process among different doctors and hospitals
- To establish a mechanism to bring hospitals’ clinical processes close to best practices
- To design an individual healthcare service plan which is effective in preventing medical errors, excessive healthcare services and too little healthcare services
- To identify and solve problems for improvement by benchmarking hospitals, i.e. comparing practices of different hospitals for the same patient condition
- To acquire new clinical knowledge

By promoting visualization, structuration and standardization among medical staff and hospitals, it will become possible to acquire and accumulate data, information and knowledge necessary for developing healthcare policies at local and national levels. The healthcare-related industries will be also able to acquire valuable knowledge.

An important element of medical social technology is “a model for clinical process structuration.” We will be able to enhance the foundation of quality and safety in healthcare services by sharing the model in community and improving clinical knowledge embedded in the model.