What are the standard functions of electronic clinical pathways?

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ABSTRACT

Purpose: The present study was performed to determine the standard functions of electronic clinical pathways (eCP) embedded in electronic medical records with regard to demand definition.

Methods: The standard functions of eCP were decided by the required functions determined from interviews with hospital staff, those derived from the implementation of paper-based clinical pathways (CPs), and additional functions generated through the shift from a paper-based to an electronic system. Moreover, the proposed standard functions and those of eCP embedded in electronic medical records for large hospitals were compared by interviews with five vendors.

Results: Seventeen functions were deemed necessary for eCP, and these were classified into six categories: displaying, recording, ordering, editing, variance, and statistics. Although most of these functions are already included in eCP products, their implementations differ between products.

Conclusions: We propose 17 standard functions required for eCP embedded in electronic medical records. The functions for editing patient checklists, checking the occurrence of variance, and statistics are especially important and should be implemented as standard functions. This study will aid in the future development of eCP embedded in electronic medical records.

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1. Introduction

The earliest critical pathways were introduced by Zander in the mid-1980s, who adopted a program evaluation and review technique in the management of clinical processes to improve the efficiency and quality of patient care [1]. In the late-1980s, critical pathways evolved into care maps by the introduction of outcomes [2], and these have since been implemented in plan–do–check–act (PDCA) cycles. These have become known as clinical pathways (CPs), and have been adopted for various diseases in many clinical departments around the world.

However, with the exception of advanced computerized institutions, CPs have mostly been implemented in paper-based systems.

On the other hand, electronic versions of paper-based CPs have also been developed. The linear sequential model of electronic clinical pathways (eCP) was designed in the early 1990s [3]. However, as its CP capability was severely limited, the state-transition model was designed in the late-1990s [4,5]. Since 2000, there have been a number of investigations of the structural design of eCP [6,7], cooperation with electronic medical records [8,9], and integration with the nursing process.
There have also been a number of reports regarding the effectiveness of eCP and the introduction of eCP at individual hospitals [12–16]. However, there have been few previous reports concerning the detailed functions of eCP with regard to demand definition, such as which eCP functions are necessary and desirable when implementing CPs. Hayward-Rowe and Whittle proposed several functional improvements of eCP, which were used in paper-based medical records in a Mother and Baby Unit, based on the results of a questionnaire study [17]. Blaser et al. developed an approach utilizing the infrastructure to implement a guideline-based clinical pathway for patients with proximal femoral fracture [18]. Lenz et al. presented several recommendations for developing well-adapted interaction mechanisms in eCP [19]. Takase and Abe reported that eCP embedded in electronic medical records require functions, such as those for editing CPs, choosing CPs, managing variance (defined as outcomes when coming off treatment; i.e., discrepancies between planned and actual events, as well as outcomes differing from those anticipated prior to treatment or deviations from the projected timeline), evaluating outcomes, collecting evidence, and managing the history of CPs [20]. The computerization of CPs is inevitable as computerization in the clinical field is already shifting from electronic medical records toward electronic health records. A number of vendors of products with eCP embedded in electronic medical records have begun to develop additional functionalities, such as the addition of specific professional datasets and special on-screen forms, which are powerful means of expanding the use of electronic medical records [21]. Hence, it is important to determine the minimal, standard, and desirable functions for eCP embedded in electronic medical records. In the present study, we examined the necessary functions of eCP and we propose a standard set of functions for eCP based on our observations. The necessary functions of CPs in electronic medical records are different from those of CPs in order entry systems because the former implements clinical processes in an electronic system, while the latter is paper-based. However, the former is less flexible than the latter. Moreover, it is necessary to distinguish between eCP designed specifically for supporting nursing standards, such as NANDA (North American Nursing Diagnosis Association), NIC (Nursing Interventions Classification), and NOC (Nursing Outcomes Classification) for nursing care, and those generalized for clinical processes because the former will be used exclusively by nurses, while the latter will be used by almost all clinical professionals. Here, we discuss eCP for all clinical professionals in electronic medical records.

### 2. Methods

This investigation was performed at Hamamatsu Rosai Hospital, a hospital with 21 departments and 400 beds (currently 350 beds) founded for workers’ health by Labor Welfare Corporation under the control of the Ministry of Labor (currently the Ministry of Health, Labor, and Welfare) of Japan. Paper-based CPs were first implemented at Hamamatsu Rosai Hospital in 2000, and an electronic filing system for the management of the paper-based CPs using the existing network and terminals of the order entry system was introduced in 2002 [22]. The features of this CP management system are listed in Table 1. We interviewed the staff of Hamamatsu Rosai Hospital, mainly members of the CP committee, regarding the improvement of implementing CPs before and after the introduction of the paper-based CP management system. The CP committee was composed of four physicians, one pediatrician, two surgeons, one brain surgeon, one orthopedic specialist, one ophthalmologist, two ward nurses, one nurse for outpatients, one operating room nurse, one pharmacist, one dietitian, one laboratory technologist, one rehabilitation technologist, and one radiological technologist. Problems or staff requirements regarding the implementation of CPs were discussed at monthly committee meetings with representative of the various departments or divisions who summarized the opinions of their respective staff. From 2000 to 2005, during the period of this study, one of the authors (S. Wakamiya) worked for the hospital, served as the chairman of the committee, and discussed the problems or staff requirements. We considered the minutes book as the result of interviews. The standard functions of eCP were determined from the functions mentioned in the interviews, those derived from the implementation of paper-based CPs, and additional functions that were generated through the shift from the paper-based to the electronic system.

Moreover, interviews with five vendors, who were the market leaders in electronic medical record systems in Japan in 2006, regarding functions eCP embedded in electronic medical records for large hospitals were conducted in July 2007 at the International Modern Hospital Show in Tokyo, Japan [23].

### 3. Results

#### 3.1. Implementation of CPs before introduction of the paper-based CP management system

Copies of original paper of checklists were used where necessary. Checklists were regulated in the overview format, and

| Table 1 – Specification of the paper-based CP management system. |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| **Hardware**                  | **Software**                  | **Main functions**             | **Software for the new system was installed on client terminals of the order entry system.** |
| Order entry system (EGMAIN by Fujitsu) | (100BASE-T/10BASE-T Ethernet) | - Registration and deletion of patients | - Mainly developed with Visual C++ Ver.6 |
| Own server (Windows 2000 Professional) | 1. Registration and deletion of patients | - 5. Statistics of circulation of CPs and variance | - Order entry system. Excel VBA and FileMaker Pro were also used. |
| Order entry system (EGMAIN by Fujitsu) | - Printing of sheets for CPs | - 6. Support for checklist creation | - 7. Registration and deletion of Excel files of CPs |
| - Report of staff requests | | | |
| | | | | |
| Software for the new system was installed on client terminals of the order entry system. The new system had no data relations to the order entry system. Excel VBA and FileMaker Pro were also used. |
each day’s schedule after admission was described in them. CPs for cataract surgery were made with FileMaker Pro and schedules were arranged on demand. Staff in charge did not always report variance. Statistics regarding the number of CPs in use and variance were unknown and the hospital managers did not have data to allow evaluation of the implementation of CPs, despite their promotion of CP usage—the more CPs were made, the more difficult their management became.

3.2. **Staff requests for the improvement of CP implementation before introduction of the paper-based CP management system**

As CPs were in use to some extent, a number of concrete requests were mentioned in the interview as follows:

(A) managing checklists;
(B) not filling additional terms, such as patient’s name, in checklists;
(C) collecting variance without omission;
(D) statistics of circulation;
(E) statistics of variance.

3.3. **Implementation of CPs after introduction of the paper-based CP management system**

The format of CPs was not changed but those structured by the phases of diseases (e.g., gastroenteritis), those used together with other CPs at the same time (e.g., CPs for treatment or prevention of bed sores), and those adopted as part of clinical care or examinations (e.g., CPs for the acute abdomen used at the emergency department to observe a patient only on the first day of admission), were added as CPs of various designs. These latter CPs mean that patients do not leave the hospital and other forms of care are continued when these CPs are completed. Thus, two additional functions are required for eCP: one is the use of more than two CPs at the same time and the other is the use of CPs adopted in parts of clinical treatment, care, or examinations (#1).

Three types of files for checklists—i.e., those for staff, for nurses, and for patients—were produced automatically with the system in Excel format. Checklists for staff were made by doctors and the others were made by nurses. Variance was reported by staff using one of the menus on the paper-based CP management system. As the list of CPs, statistics of circulation of CPs, reports of variance, statistics of variance (sum of variance in each CP, each code, each action plan, and each day), and reports of staff comments could be inspected in the paper-based CP management system, the CP committee could examine the implementation of CPs using these data. Thus, two additional functions are required for eCP: one for calculating statistics of variance and viewing reports of variance and another for calculating statistics of variance and viewing reports of variance (#2).

Rough costs could be estimated in some CPs as part of the informed consent procedure.

3.4. **Staff requests for the improvement of CP implementation after introduction of the paper-based CP management system**

CPs were implemented more efficiently after the introduction of the paper-based CP management system. However, there were a number of additional staff requests, as follows:

(G) no use of printed matter;
(H) automatic input of patient’s basic information;
(I) registration of CPs from the order entry system;
(J) linking orders, such as medicine, examination, or injection, between the paper-based CP management system and the order entry system;
(K) separating the start day of CPs from the day of admission;
(L) recording clinical treatment or care in the order entry system;
(M) means of easily calculating rough costs in each CP.

(J) was intended because the paper-based CP management system had no data relations with the order entry system. (K) was intended because some CPs for abdominal surgery required a few days for physical examinations after admission, which could not be predicted, while the day of admission was registered into the paper-based CP management system as the start day of CPs.

3.5. **Necessary functions of eCP derived from the paper-based implementation**

Staff requests (A), (B), (G), (H), and (I) in the paper-based implementation are peculiar to paper-based CPs and will be dealt with naturally in eCP. With the exception of these staff requests, necessary functions of eCP derived from the implementation of CPs before and after the paper-based CP management system were as follows:

(1) editing checklists for staff, nurses, and patients (from C);
(2) reporting variance (from D);
(3) checking the occurrence of variance (from D);
(4) calculating statistics of circulation of CP and viewing the list of CPs (from E and #2);
(5) calculating statistics of variance and viewing reports of variance (from F and #2);
(6) automated ordering of medications, examinations, or injections included in CPs (from J);
(7) separating the start day of CPs from the day of admission (from K);
(8) computerizing records (from L);
(9) calculation of rough costs of each CP.

3.6. **Additional functions that should be considered when implementing eCP**

The following were added to the eCP functions that should be considered from the viewpoint of usage of the order entry system and the implementation of paper-based CPs. They need not be taken into account in paper-based CPs but failure to include these functions in the systems will result in problems...
or reduced efficiency in eCP:

10) improving visibility of checklists;
11) switching views alternately between electronic medical or care records and eCP;
12) entering orders including medicine guidance, nourishment guidance, and rehabilitation directly from the checklists;
13) adding or canceling some orders while CPs are implemented;
14) canceling remaining scheduled orders for CPs in a batch when variance occurs;
15) using more than two CPs at the same time (from #1);
16) using CPs adopted in part of clinical treatment, care, or physical examinations (from #1);
17) preparing templates of items within the cells of checklists;
18) recording the history of both addition and revision of CPs.

3.7. Results of standard functions of eCP

Standard functions of eCP were determined by adding the functions from Sections 3.5 and 3.6 (Table 2). The function for separating the start day of CPs from the day of admission (7) was substituted by a function using CPs adopted in part of clinical treatment, care or examinations (16) because the CPs implemented between admission and the start day of CPs fulfilled this role. Therefore, necessary functions are from (1) to (18) excluding (7). Each function is classified according to six categories: displaying, recording, ordering, editing, variance, and statistics.

3.8. Results of comparison between the proposed standard functions and the functions of recent eCP products

The results of comparison between the functions of eCP proposed in this study and the functions of eCP embedded in actual products are shown in Table 3. Implementation of the functions proposed in this study differed between these products.

With regard to display, only one product could increase or decrease the categories of care in each CP for improving visibility of checklists and two products could do so for each user. Such changes were not possible in the other products.

With regard to recording, all products could input records.

With regard to ordering, one product could not cancel remaining scheduled orders for CPs in a batch when variance occurs.

With regard to display, one product could not switch views alternately between medical or care records and eCP. None of the products included a function to allow rough estimation of costs for each CP.

With regard to editing, one product did not have templates of items within the cells of checklists. Two products could record the history of both addition and revision of CPs, and one product could do only the former. All of the products could edit checklists for staff, but only two products could do so for patient checklists.

<table>
<thead>
<tr>
<th>Table 2 – Proposed standard functions of eCP.</th>
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<tbody>
<tr>
<td>Functions</td>
</tr>
<tr>
<td>Displaying</td>
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<tr>
<td>Recording</td>
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<tr>
<td>Order</td>
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<tr>
<td>Automated ordering of medications, examinations, or injections included in CPs (6)</td>
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<tr>
<td>Entering orders including medicine guidance, nourishment guidance, and rehabilitation directly from the checklists (12)</td>
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<tr>
<td>Canceling remaining scheduled orders for CPs in a batch when variance occurs (14)</td>
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<tr>
<td>Adding or canceling some orders while CPs are implemented (13)</td>
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<tr>
<td>Using more than two CPs at the same time (15)</td>
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<tr>
<td>Using CPs adopted in part of medical care or examinations (16)</td>
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<tr>
<td>Calculation of rough costs of each CP (9)</td>
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<tr>
<td>Editing</td>
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<tr>
<td>Recording the history of both addition and revision of CPs (18)</td>
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<tr>
<td>Editing checklists for staff and nurses (1)</td>
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<tr>
<td>Editing checklists for patients (1)</td>
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<tr>
<td>Variance</td>
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<tr>
<td>Checking the occurrence of variance (3)</td>
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<tr>
<td>Statistics</td>
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<tr>
<td>Calculating statistics of variance in each CP (5)</td>
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<td>Calculating statistics of variance in each variance code (5)</td>
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<td>Calculating statistics of variance for each day that variance occurred (5)</td>
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<tr>
<td>Calculating statistics of variance for each action plan (5)</td>
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</tbody>
</table>

With regard to variance, two products could check the occurrence of variance automatically judging from the change of remaining scheduled orders for CPs or the dropout of CPs.

With regard to statistics, no product had all proposed functions and each product had different functions.

4. Discussion

Prior to this investigation, we had intended to determine the standard functions of eCP by comparing the functions mentioned among a number of reports. However, as the amount of data available was quite small, we explored the standard functions of eCP through the actual implementation of paper-based CPs at a hospital. With regard to the relationship between eCP and paper-based CP, Chu suggested that redesigning the current clinical pathway concepts for
Table 3 – Comparison between the proposed standard functions and the functions included in current eCP products.

<table>
<thead>
<tr>
<th>Functions</th>
<th>Details</th>
<th>Vendors</th>
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<tbody>
<tr>
<td>Displaying</td>
<td>Improving visibility of checklists</td>
<td>F</td>
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<tr>
<td></td>
<td>Switching views alternately between electronic medical or care records and eCP</td>
<td>N</td>
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<tr>
<td>Recording</td>
<td>Computerizing records</td>
<td>I</td>
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<tr>
<td></td>
<td>Ordering medicine, examination, or injection included in CPs automatically</td>
<td>H</td>
</tr>
<tr>
<td>Ordering</td>
<td>Entering orders including medication guidance, nourishment guidance, and rehabilitation directly from the views of checklists</td>
<td>T</td>
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<td></td>
<td>Canceling remaining scheduled orders for CPs in a batch when variance occurs</td>
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<td></td>
<td>Adding or canceling some orders while CPs are implemented</td>
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<td></td>
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<tr>
<td>Variance</td>
<td>Reporting variance</td>
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<td></td>
<td>Checking occurrence of variance</td>
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<td></td>
<td>Calculating statistics of circulation of CPs and viewing the list of CPs</td>
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<tr>
<td>Statistics</td>
<td>Viewing reports of variance</td>
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<td></td>
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<tr>
<td></td>
<td>Calculating statistics of variance in each action plan</td>
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</tr>
</tbody>
</table>

“O” indicates complete correspondence to the functions; “o” indicates incomplete correspondence; Blank indicates no correspondence; “dev” indicates under development.

Implementation as computerized CPs represents one possible solution to overcome the problems related to paper-based systems [5]. This is appropriate in the technological design of eCP but not the functions of eCP with regard to demand definition because the requirements for implementing CPs are essentially the same in both eCP and paper-based CPs.

The results of the present study indicated that at least 17 functions were necessary for eCP. These were classified into six categories: displaying, recording, ordering, editing, variance, and statistics. Here, we discuss the significance of each category.

4.1. Significance of the proposed standard eCP functions

4.1.1. Display function
There are many items in the cells of checklists. In paper-based CPs, checklists are rearranged to allow printing within regular paper sizes. However, in eCP, all views of a checklist cannot be obtained without scrolling if it is larger than the size of the display. Therefore, some changes are necessary to improve visibility. Specifications regarding human interfaces, such as direct switching between electronic medical or care records and checklists, or entering orders, including medication guidance, nourishment guidance, and rehabilitation from the views of checklists (this function is classified as belonging to the ordering category in Section 3.7), are very important for working efficiency.

4.1.2. Recording function
The function for recording medical treatment or care must be implemented in eCP.

4.1.3. Ordering function
The function for ordering of medications, examinations, or injections included in CPs must also be implemented in eCP. It
is also necessary to be able to enter orders without specifying a day because it is not always possible to determine the expected day of orders, such as medicine guidance, nourishment guidance, or rehabilitation, on admission. When variance occurs, either canceling the remaining scheduled orders for CPs in a batch or continuing them should be chosen according to whether the type of variance is change, deviation, or dropout.

A function to allow the simultaneous use of more than two CPs is necessary for CPs, such as treatment or prevention of bed sores. Separation of the start day of CPs from the day of admission is necessary for CPs, such as those of abdominal surgery where the schedule of clinical treatments is decided according to the results of examination after admission. There is no problem if a function for using CPs between admission and the start day of CPs is available.

Modification of processes within CPs prior to their use in patients is required, especially in the field of ophthalmology, because it is desirable that the days of admission, discharge from hospital, or of surgery should be different according to the needs of each patient. Such functions have been achieved using FileMaker Pro in Japan. It may be possible to include this function in that using CPs adopted in part of the clinical treatment or examination schedule, but further studies will be required.

Rough estimation of cost in each CP is necessary not only for patients’ informed consent but also to address economic requirements, such as the Diagnosis Related Group—Prospective Payment System (Diagnosis Procedure Combination in Japan).

4.1.4. Editing function
Each hospital uses its own items within the cells of checklists. As their preparation is a labor-intensive process, templates should be prepared. As they are also related to the function of editing checklists for patients from those for staff, standardization is necessary, at least within a country.

It is necessary to record the histories of both addition and revision of CPs to allow calculation of the increase in CPs or presentation of data to determine improvements required in the action phase of the PDCA cycle.

The eCP must include a function for editing checklists by staff. If there is no function for editing checklists for patients, paper-based checklists for patients will be used after they are registered in the system. Therefore, a function for editing checklists for patients is necessary, and if possible a function for making checklists for patients from those for staff automatically is desirable because the schedules of both checklists are same.

4.1.5. Variance function
The implementation of CPs requires the recording of any variance that may occur. If both the occurrence and reporting of variance are not checked automatically, there is no guarantee that all of the variance will recorded. In fact, such problems have even been reported in eCP [24]. In our experience at Hamamatsu Rosai Hospital, reports of variance increased on its registration in the system. However, we cannot depend solely on staff reports, and automated methods for checking the occurrence of variance are required.

4.1.6. Statistics function
Statistics provide fundamental data for the implementation of CPs. Especially, it is important to collect regarding variance for the PDCA cycle in the management of CPs. There is as yet no consensus regarding what statistics of variance should be chosen, but monthly statistics according to variance codes, types of CP, day of occurrence, and action plans should be included. Action plans outline the courses of clinical treatment and care to be applied according to whether the variance is change, deviation, or dropout.

Some examples of the application of statistics are as follows. The collection of statistics regarding the monthly circulation number of CPs provides data on the transition of CPs used. Both circulation number of CPs and number of new inpatients provide data to allow calculation of the rate of adoption of CPs in patients. The statistics of circulation number of CPs in each department provide information regarding which department(s) the CP committee should encourage the use of CPs. Data regarding when variance can occur easily in each CP provide information regarding which process(es) should be changed, and the statistics of variance in each code can be used to determine why variance occurs.

4.2. Comparison between the proposed standard functions and the functions of recently developed eCP products
Two vendors whose products included functions for automatically checking the occurrence of variance considered changes in the remaining scheduled orders for CPs or dropout of CPs as variance. However, this method is not accurate because administering irrelevant medicine to CPs may cause excessive evaluation of variance and trivial changes of CPs may not be reported despite being valid incidences of variance.

Although most of the proposed functions have already been included in currently available eCP products, each product implements these functions in a different manner. It is necessary to implement all of these functions in all such products in future. A function to allow editing of checklists for patients, automatically if possible, a function to check the occurrence of variance, and a statistics function are especially important and must be implemented as standard functions in these products.

5. Conclusions
In the present study, we proposed 17 standard functions for eCP embedded in electronic medical records through exploration of the management of paper-based CPs. Functions for editing checklists for patients, for checking the occurrence of variance, and for gathering of statistics are especially important and should be utilized as standard functions. Almost all of these functions are already included in current eCP products, but their implementations differ between each product. The results presented here will aid in the future development of eCP.
Summary points
What was known before the study?

- It has been shown that IT applications can increase clinical pathway compliance.
- Some structural designs of eCP or cooperation with electronic medical records have been reported.
- Some specific models of eCP, such as proximal femoral fracture, have been reported.
- There was no consensus regarding which generic functions of eCP embedded in electronic medical records are necessary and desirable.

What the study has added to our knowledge?

- The dispensable, minimal, desirable, and standard generic functions of eCP embedded in electronic medical records were clarified.
- Seventeen standard functions for eCP embedded in electronic medical records were proposed and classified into six categories.
- Functions for editing checklists for patients, for checking the occurrence of variance, and for gathering of statistics are especially important and should be utilized as standard functions.

Acknowledgments

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The company and product names in this paper are registered trademarks of the respective companies.

Author contributions: S. Wakamiya contributed to the concept and design of the study, and data acquisition. Both S. Wakamiya and K. Yamauchi performed the analysis and interpretation of data. S. Wakamiya drafted the article and K. Yamauchi performed critical revisions for important intellectual content. S. Wakamiya gave final approval for the version submitted for publication.

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