子化されていないことが主因と考えられるが、もし電子化されていたとしても、その情報を有効に取得できるかが疑問であり、さらに取得できたとしても同義語や症状概念の範疇的な処理を行うことは難しい（標準病名マスターに相当する症状のシソーラスが存在しない）と考えられる。

E．結論

診療ガイドラインの判断に必要なデータを診療情報システムからそのまま取得できる割合は1割以下と極めて少ないが、何らかの変換を施すことにより、8割程度の情報を取得できることが明らかとなった。

F．健康危険情報

G．研究発表

1．論文発表

Yu Zhang, Yuzo Onogi・Analysis of Information Conversions for Implementation of Computer-Interpretable Clinical Practice Guidelines. ・Methods of Information in Medicine・（投稿中）

2．学会発表

張宇、小野木雄三・電子化診療ガイドラインを実行するための診療情報システム上のデータ項目の比較分析・第26回医療情報学連合大会論文集・2006・530-532

H．知的財産権の出願・登録状況

1．特許取得

なし

2．実用新案登録

なし

3．その他

なし

Ⅲ　研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書　籍　名	出版社名	出版地	出版年	ページ

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
張宇、小野木雄三	電子化診療ガイドラインを実行するための診療情報システム上のデータ項目の比較分析	第26回医療情報学連合大会論文集	26(suppl.)	530	2006
Yu Zhang, Yuzo Onogi	Analysis of Information Conversions for Implementation of Computer-Interpretable Clinical Practice Guidelines	Methods of Information in Medicine	(posting)		

Ⅳ　研究成果の刊行物・別刷

電子化診療ガイドラインを実行するための診療情報システム上のデータ項目の比較分析

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Comparative Analysis of Information Requirement for Implementation of Computer-Interpretable Clinical Practice Guidelines

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In an effort to implement computer-interpretable clinical practice guidelines (CPGs) by capturing required patient data from Hospital Information Systems (HIS), we determined data items and their values necessary for decision-making coincided with CPGs and compared them with those existed in HIS of the University of Tokyo Hospital. There were 211 data items for executing the CPG of hypertension and we found that 200 (95%) of the CPG's data items could not be obtained directly from HIS. Then we tried to acquire these underived items through various transformations from existing data and medical knowledge.We categorized these transformations into 4 level of the difficulty: 0) no transformation, which means some data items and values can be used without any changes; 1) simple transformations, such as numerical calculations; 2) complicated transformations, such as those using medical knowledge; 3) impossible to transform, which means some data items can not be acquired through any transformation. And we found that 178 items (84%) could be derived from HIS as categorized in level 0~2.

Keywords: Data items, Guideline, Hospital Information System

1. 背景

診療ガイドラインに基づいた臨床意思決定支援システム(CDSS)を病院情報システム(HIS)と連携して適切なタイミングで医師に助言を提示することは、医療の質の向上に有用とされている[1-3)]。そのためにはHISから患者のデータを取得してガイドラインの判断材料とする必要がある。しかしこれら判断に必要なデータ項目は、どのくらいHIS上に存在するであろうか[4)]。HIS上にガイドラインのデータ項目が存在しても、その形式が一致しない場合もあるほか、存在しないデータ項目がどの程度既存のデータから変換できるのかについても明確ではない。そこで本研究では、診療ガイドラインの判断を実行するために必要な項目それぞれに対し、それらがHIS上に存在するか否か、存在しない場合には他の既存データ項目から変換可能であるかを明らかにすること、を目的とした。

2. 方法

2.1 材料

「高血圧治療ガイドライン2004」(Minds、財団法人日本医療機能評価機構)[5)]。

2.2 ガイドライン判断項目の抽出

高血圧治療ガイドラインの診療行為における判断・実施部分を意思決定ステップに分解し、各ステップにおける判断項目・値をルールの条件部、推奨される診療内容を実行部とした。ルールの正確性について、医師による確認を行った後に、この条件部の判断項目を以下で使用した。

2.3 病院情報システム(HIS)上での判断項目の存在調査

病院情報システムは東大病院の診療支援システムを使用した。抽出されたガイドラインの各判断項目に対し、それがHIS上に存在することを以下の3通りに分類して調査した:A) 判断項目とその値がHIS上に存在する;B) 判断項目がHIS上に存在するが、値が存在しない;C) 判断項目自体がHIS上に存在しない。各判断項目とHIS上の項目との比較は、その「表記」の存在ではなく、ガイドラインの文脈に依存して定まる概念レベルでの一致を見ることによって行った。

2.4 判断項目の補完可能性分類

上記の方法で単純に比較するとほとんどの項目や値が存在しないことになるため、幾つかの変換レベルによって項目や値が補完可能であるか否かを調べた。判断項目や値がそのままで利用できる場合を「レベル0」、ごく簡単な操作によって変換可能ならば「レベル1」、知識を必要とする複雑な変換を「レベル2」、変換できない場合は「レベル3」とした。例えば項目の値が数値で、単位が同じなら「レベル0」、単位が同じでなくてもgとmgの変換、あるいは体表面積を身長と体重から計算するなどを「レベル1」、数値の範囲で異常と正常が決まるなど外部知識が必要なものを「レベル2」とした。「レベル3」はHIS上に存在せず変換による補完もできないので、必要度に応じて項目自体を新たに入力しなければならないことを意味する。

2.5 判断項目のカテゴリ分類

判断項目は診断名や薬物名などのカテゴリに分類することもできる。そこで以上の調査結果を個々に示すと同時に、「診断名」「薬物名」「その他」に分類して結

果を提示した。

3. 結果

高血圧診療ガイドラインから抽出した判断項目は合計211個であった。これをHIS上の項目と比較して分類した結果を表1に示す。このままでガイドラインに利用できるのは僅か11項目(5%)に過ぎない。

表1 ガイドラインの判断項目とHIS上の項目の存在分類

存在分類	判断項目数
A)項目と値が存在	11
B)項目存在、値が存在しない	77
C) 項目と値が存在しない	123
合計	211

次に、各判断項目を既存データや外部知識により変換することによって一致させた場合の分類結果を表2に示す。Bの77項目は1個を除きAに変換することができ、Cの123項目は10項目をBに、91項目をAに変換することができた。これにより、ガイドラインに利用できる項目数は178(84%)になった。いくつかの変換例をここに示す。

「mg/d」を「g/d」へ変換する(単位の変換)(B→A、レベル1)

「平均血圧」を「収縮期血圧」と「拡張期血圧」から計算する(C→A、レベル1)。

「喫煙の有無」というガイドライン上の項目をHISの「喫煙しない/喫煙中/不明」という文字列から変換し、不明の場合は喫煙しているものと仮定する(B→A、レベル2)。

「高コレステロール血症」というガイドライン上の項目を、HISの「血清総コレステロール値」から動脈硬化学会の基準による閾値処理により計算する(C→A、レベル2)。

臓器障害/心血管病という疾患カテゴリの展開:高血圧に基づく臓器障害や心血管病合併の有無が高血圧患者の予後に影響するので、これを疾患名、検査所見に展開する(C→A、レベル2)。

無症候性脳血管障害:無症候性なので存在を否定できないが、最近頭部MRI・CT検査が行われていて無症候性脳血管障害に同義な疾患名が存在しなければ、無しとする(C→A、レベル2)。

同義語の変換:「糖尿病・神経学的合併症あり」を「糖尿病性神経症」などの同義病名に変換。自然言語処理等ではなく、判断項目を設定する時点で統制用語に変換する(C→A、レベル1)。

下位概念から上位概念へ:「脳挫傷」を「脳外傷」へ変換する。(C→A、レベル1)

薬物の商品名から一般名・薬効分類名へ:「ラシックス」を「利尿薬」へ変換する。(C→A、レベル2)

表2 ガイドライン判断項目のHIS上での存在分類・レベルごとの項目数

	A)項目と値が存在	B)項目存在、値が存在しない	C)項目と値が存在しない	合計
レベル0	11	0	0	11
レベル1	99(B: 69; C: 30)	0	0	99
レベル2	68(B: 7; C: 61)	0	0	68
レベル3	0	11(C: 10)	22	33
合計	178	11	22	211

(括弧内は変換前のABC分類と項目数)

判断項目のカテゴリを表3に示す。診断名と薬物名が132項目であり、全判断項目の63%を占める。その中で76項目(58%)はレベル1の変換、46項目(35%)はレベル2の変換に出現した。また、これ以外のカテゴリには、検査(総コレステロールなど)、生理検査(収縮期血圧など)、生活習慣(喫煙など)、疾患状態(高血圧重症度など)、家族歴(若年発症の心血管病の家族歴)などがあった。特にレベル3の数を見ると、「その他の判断項目」が23を占めており、HIS上に存在しない項目の2/3が診断名・薬物名以外の「その他の判断項目」であった。

表3 判断項目のカテゴリ分類

	診断名	薬物名	他の判断項目	合計
レベル0	0	0	11	11
レベル1	76	0	23	99
レベル2	8	38	22	68
レベル3	10	0	23	33
合計	94	38	79	211

4. 考察

高血圧治療ガイドラインの判断項目を東大病院のHIS上の項目と単純に比較した結果(表1)、病院情報システムの既存のデータをそのままガイドラインに適用することは難しいが、データの変換や知識の補完をすることにより(表2)、ある程度はガイドラインに基づいたDSSなどへの応用が可能であるとの結論が得られた。

なおこれらの変換とは、既存データや外部知識(日本語医学用語シソーラスや医薬品マスターなど、現時点で電子的に入手可能なリソース)を組み合わせることによって理論的に取得可能であることとし、変換操作の具体的な実装は本研究の範囲外である。さらに1つの判断項目を変換によって取得する際に、複数ルールの組み合わせを必要とするなど、複雑な操作も含むものもあるが、ここでは結果的に「変換可能か否か」を判定した。

米国の先行研究[4]では、ガイドラインの実行に必要なデータ項目と電子カルテに存在するデータ項目を比較する際に、UMLSの概念コードを利用しているが、本研究では統制用語集を利用していない。しかし単なる表記による比較ではなく、ガイドラインの文脈に依存した内容にまで踏み込み、場合により記述が省略

されている条件までも加えて「概念」として判断項目を抽出しているため、統制用語集を利用した場合と同等以上の正確さを持つと考える。結果は表4のように比較した。先行研究では2つのガイドライン(高血圧と高コレステロール血症)を利用しているが、抽出した項目総数は本研究より少ない。これはガイドラインの内容の違いであり、より簡潔に必要な項目が提示されているものと考えられる。また直接利用できる項目であるレベル0の項目割合は先行研究の方が多く、既存データから変換することができず、医師による入力を必要とするレベル3の項目割合は本研究の方が多い(表4)。この原因のひとつとして、先行研究の施設で導入されている電子カルテシステムと、本研究でのオーダーエントリーシステムとの差であると考えられる。

表4 先行研究と本研究の結果比較

	先行研究	本研究
ガイドライン数	2	1
項目総数	178	211
レベル0	42 (24%)	11 (5%)
レベル1と2	121 (68%)	167 (79%)
レベル3	15 (8%)	33 (16%)

ところでガイドラインに必要な判断項目でHIS上に存在しないものであるレベル3のカテゴリ分類を見ると「その他の判断項目」が多く、その内訳は生活習慣・家族歴・所見などが大半を占めている。ガイドラインに基づいたDSS等を稼働するためには、これらのデータを入力しなくてはならない。しかし将来DNAチップやプロテインチップによって容易に生活習慣や家族歴が明らかになるならば、こうした項目はHISから直接入手可能となる可能性がある。

HIS上で新たに入力する必要のある項目と値について、ガイドライン全体の判断ステップで出現する頻度を表5に示す。また、ある判断項目Aの値を決定する判断項目Bがあるとき、Bは二つの判断ステップの起点なので、Aよりも影響度が高く重要であると考えられる。そこで出現頻度が多いもの、および影響度の高いものは優先的にHISに実装すべき項目であると考えられる。

表5 最終的にBとCに分類された項目のガイドライン全体での出現頻度

出現頻度 (1判断にあたり)	1	2	合計
B)項目存在、値が存在しない	11	0	11
C)項目と値が存在しない	19	3	22
合計	30	3	33

今回は高血圧のガイドラインに関する解析を行ったが、他の診療ガイドラインに出現する判断項目に共通して出現するものもあると考えられる。上記のように頻度や影響度を計算してHISに実装する優先度を考えるためには、他の診療ガイドラインも解析した上で、その全体の出現頻度と影響度を総合的に算出することが有用と考えられる。そこで今後は他のガイドラインについても同様な解析を行っている予定である。

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Title:

Analysis of Information Conversions for Implementation of Computer-Interpretable Clinical Practice Guidelines

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clinical practice guidelines, computer-interpretable, hospital information system, data items, conversions

Abstract:

In an effort to increase usage of the best practice recommended by clinical practice guidelines, computer interpretable guidelines (CIGs), for providing reminders or alerts, are being integrated into institutional clinical information systems (CISs). In order to clarify to what extent clinical data items required to execute CIGs could be acquired from those CISs, 141 data items were extracted from the hypertension guideline and explicitly defined according to that guideline and other clinical knowledge. Then, they were conceptually compared to those that existed in the hospital information system (HIS) of the University of Tokyo Hospital. As a result, only eight of them could be captured directly from the HIS. We tried to obtain the underived data items through performing various conversions based on existing data, clinical knowledge and other useful information. All of the conversions were then classified into one of four levels: 0) no conversion, which means a data item can be used without any change, 1) simple conversions, such as numerical calculations or synonyms, which use clinical information inside of the HIS, 2) complex conversions, such as concept relationships or pharmaceutical information, which use clinical knowledge or other electronic sources complemented outside of the HIS, and 3) impossible to convert, which means a data item cannot be acquired through any conversion. Using conversions, we found that 115 data items could be derived from the HIS. Level 1 and level 2 conversions were analyzed for their authorities and logics. We conclude that, although only a minority of data items required to execute CIGs is covered by those from the HIS, it is possible to implement CIGs if level 1 and level 2 conversions work properly. Construction of a conceptual data model, whose functionality is expanded beyond controlled clinical vocabulary and is capable of automating these conversions, offers promise for improving CIG implementation.

What was known before this study:

- In clinical institutions of Western countries, while computer-interpretable clinical practice guidelines (CIGs) are integrated with institutional clinical information systems (CISs), clinical terms from both of them need to be mapped to controlled clinical vocabularies such as SNOMED-CT for explicit definitions.
- Controlled clinical vocabularies can provide explicit definitions of clinical variables or terms, most of which are used as representations of data items, and relationships between those variables or terms.
- Not all data items needed to execute CIGs exist in institutional CISs, and not all those that do exist are in the form required for execution of CIGs.

What this study has added to the body of knowledge:

- In order to acquire patient data necessary for implementation of CIGs from our hospital information system (HIS), clinical knowledge from guidelines and other approved sources were utilized to unambiguously define not only concepts corresponding to the necessary data items from both CIGs and the HIS, but also each conversion between them corresponding to an identical data item.
- Definitions of data items required for implementation of CIGs contain not only clinical variables, but also clinical values, which include data types and units. Relationships between data variables are more than those defined by controlled clinical vocabularies. For example, the relationship between *body surface area* from guidelines and *height* and *weight* from the host system is *the formula of DuBois*, which is not defined by any controlled clinical vocabulary as a concept relationship. However, conversions between data types and units for identical data items and additional relationships between data variables can be adequately defined by guidelines or other clinical knowledge.
- We clarified that although only a minority of data items needed to execute CIGs could be provided by the HIS directly, it is highly likely that a majority of them can be acquired from the HIS after various information conversions. Therefore, if the architecture for those information conversions was designed properly, without any change of the HIS, CIGs still could be integrated with the HIS and applied to clinical decision support.

Introduction

Clinical Practice Guidelines (referred to as *clinical guidelines* in this paper), defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances" [1], embody a rich source of knowledge designed to inform clinical decision-making and care planning, and consequently have gained support as vehicles for improving best practice in clinical medicine [2]. In spite of the considerable efforts of health care organizations over recent decades, clinical guidelines still have not being disseminated or implemented widely. McGlynn *et al.* carried out a telephone survey of a random sample of adults living in 12 metropolitan areas in the US and found that participants received the recommended care only in 54.9% of instances [3]. CIGs have the potential to address this problem, because computer-based clinical decision support systems could deliver the knowledge incorporated into them at the point of care. Shiffman *et al.* performed a systematic review of computer-based guideline implementation systems by analyzing 25 previous studies [4]. In the 18 studies that included evaluations of provider adherence to the guidelines, 14 of them described some level of adherence improvements. Therefore, application of CIGs has been proposed as a strategic means to promote guideline-recommended clinical practices.

There are a number of CIG representation models for formalizing the clinical knowledge contained in the clinical guidelines being developed as a prerequisite for the application of CIGs [5-10]. In order to be executed automatically with a CIS, these methodologies should encompass two structured formats, which are used to represent two sorts of information necessarily acquired from the CIS. The first one specifies clinical events and contexts, such as a patient's first visit to a doctor, in different clinical scenarios. They can be used to trigger suitable execution of guideline logic. The SAGE project [11] addressed this issue by modeling the healthcare organization in which a guideline is implemented. The current model contains an enumeration of clinical and information technology resources and an event model defining the structure of the events. Another practical solution, used typically in the GUIDE project [12], is to build a separate workflow system as external service for CIG and CIS. The second one, generally referred to as patient data model, defines patient data required to initiate the delivery of patient-specific decision support based on clinical guidelines, and needs to be mapped to that of institutional CISs such as electronic medical records (EMRs) and computerized physician order entries (CPOEs). Virtual Medical Record [13], which is built on the basis of HL7 Reference Information Model (RIM) [14] and currently adopted by the SAGE project [15], has provided a promising approach to facilitate mappings between different structured patient-data models of host CIS.

Both clinical scenario model and patient data model should use clinical concepts to record and

signify clinical data clearly. Either in CIG or in an institutional CIS, clinical concepts would be defined by mapping them to an identical terminology system. In the SAGE project, clinical guideline concepts are encoded in terms of standard reference terminologies, including SNOMED-CT and LOINC, and terminologies used in any host CIS must be mapped to those reference terminologies while they are integrated for application in clinical practice. Studies show that most of the clinical terms used in CISs can be conceptually matched to controlled clinical terminologies such as UMLS and SNOMED-CT [16-17]. However, explicit definitions obtained from such controlled clinical terminologies are, by themselves, not sufficient for representing concepts extracted from clinical guidelines, and which can only be defined by the guideline sources. For example, *asymptomatic hyperuricemia* is determined by the upper limit of normal range, which is stated definitely in the related clinical guideline; however, this concept cannot be defined by controlled clinical terminologies because the normal range differs in different countries.

In addition to standardizing patient data definitions for the concept mapping, we need to consider to what extent an existing CIS at a local institution is capable of capturing patient data in a manner suitable for CIG implementation if a CIG could be integrated into the local system. Since the statements of clinical guidelines not only contain diagnosis and treatments, but also include temporal conclusions and causal relationships derived by physicians individually and that might not be recorded as patient data, we argue that not all guideline data (referred to as *G data* in this paper) items, including data values required to implement guidelines, exist in CISs. Basically, the extent of patient data required for guideline execution existing in a particular CIS is mainly determined by the category of the system. For instance, the number, and the category, of data items used in EMRs are different from those used in CPOEs. Moreover, for data items that do not exist in a CIS, but are necessary for guideline execution, it might be possible to use either clinical knowledge or external electronic sources other than computerized guidelines to generate these non-existent, but necessary, data items from existent ones. In one study, Sonnenberg *et al.* [18] examined the existence of 178 unique data variables, required to implement two separate CPGs in the EMR in use at University of Medicine and Dentistry of New Jersey (UMDNJ), according to the vocabulary similarity between the EMR's observation terms and the guideline terms. They then evaluated the correspondence of the above guideline terms with the Unified Medical Language System (UMLS). As a result, they found a wide difference between the clinical vocabulary used in guidelines and that used in UMDNJ's EMR. Furthermore, they also found that, while each guideline term could be identified by matching it to a corresponding UMLS concept, many concepts important for guideline application lacked explicit definitions in their guideline sources. However, although they classified guideline terms according to whether they were simple or complex and whether they were clinical observations, health issues or treatment, the specific approaches used to convert observation terms of the EMR into guideline

terms were, in most cases, not analyzed or explained in detail, the exception being the simple ones, which could be directly acquired from the EMR. Performing a detailed analysis that would better clarify how such data conversions are achieved would be of great value.

In this paper, we aimed to clarify the nature of the different approaches to acquiring the data items needed to implement guidelines from the specific data items available in a certain HIS (which is CPOE in this paper) through comparing them via their explicit definitions and identifying their relations. We first drew up the terms and the definitions of G data items necessary to execute the decision rules narrated in the clinical guideline for hypertension, whose accuracy were previously confirmed by a health care professional. We next compared these G data items with the data items available at the HIS of the University of Tokyo Hospital (referred to as *H data items* in this paper) in order to examine whether or not they could be captured during routine clinical care. G data items and H data items were all considered to be determined by either the clinical guideline or other external sources selected according to the context of the clinical guideline. After that, we analyzed the possibility of generating those data items that did not exist in the HIS through various conversions of existing data items, using clinical knowledge or other electronic information sources such as HL7 Messages. Finally, two other clinical guidelines, asthma guideline and diabetes guideline, were analyzed in the same way to evaluate the influence of clinical guideline contents on the conclusions of our analysis.

Methods

1. Extraction of G data items

Since Hypertension is one of the most popular lifestyle-related diseases in Japan and the recent version of the Hypertension Guideline consists of many more detailed narratives than other disease guidelines, the clinical guideline of Hypertension in 2004, published by Minds (Medical Information Network Distribution Service in Japan) [19], was selected as one of the trial guidelines for the detailed analysis below. Moreover, although patient states, execution states, decisions, actions, etc. are elements common to all guidelines, only decisions perform the role of intersection whereby alternative results could change guideline execution. Therefore, we chose to use statements containing decisions as the subjects of this study.

No less than two choices are typically involved in all decisions and each of them can be considered as one logical rule, which is divided into a conditional side, containing data items that serve to trigger the rule, and an executive side, containing diagnostic and therapeutic practices that serve as recommendations of clinical guidelines. All logical rules were thus constructed and a health care professional confirmed not only their accuracy but also the explicit definitions of data items on the conditional side. If a certain data item was not defined unambiguously by the guideline, other

clinical knowledge was referenced based on the context of the guideline. As most hypertension patients do not have to be hospitalized, we selected outpatient clinic as the clinical scenario and filtered out rules that could not be applied in that setting. After that, G data items needed to perform the remaining rules were aggregated, exclusive of any duplication.

2. Investigation of the existence of G data items

All the H data items existing in the HIS of the University of Tokyo Hospital and that could be used in outpatient settings were adopted for comparison to those extracted from the hypertension guideline. Each G data item contains one G data variable and more than one G data value. A G data item was judged to exist in the HIS only if its concept was represented by one H data item, irrespective of the identity of the terms both sides used respectively as their names. According to the principle of the above judgment criterion, we divided all the G data items into the following three classes by determining how G data variables or G data values exist in the HIS: A) both one G data variable and its values exist; B) one G data variable exists, but its values are not in the same form as those of the identical H data item; C) neither one G data variable nor its values exists.

3. Levels of conversions for complementing G data items

Since there are G data items that could not be acquired directly from the HIS, it is indispensable to determine how H data items could be converted into G data items. Herein we classified all conversions for complementing G data items into four levels, based on the extent of difficulty of the conversions: 0) no conversion, which means some data items and values can be used without any change; 1) simple conversions, such as numerical calculations or synonyms, which use information inside HIS; 2) complex conversions, such as concept relationships or pharmaceutical information, which use clinical knowledge or other electronic sources outside of HIS; 3) impossible to convert, which means some data cannot be acquired through any conversion. After conversion, all the G data items were once more classified into ABC classes (see the previous section). We also enumerated the authorities of level 1 and 2 conversions to confirm their validity.

4. Categories of logic for conversions

The logics of Level 1 and level 2 conversions for program design were analyzed in detail. We categorized these two conversion levels into logic of conversion for class B and logic of conversion for class C. The former contains logic of conversion for number and string because the data types of H data values are either numbers or strings. The latter contains logic of conversion for synonym and concept. Moreover, conversions for concept were further divided into two groups according to whether or not the logic uses is-a relationship.

5. Categories of G data items

In order to clarify to what extent G data items could be acquired from diverse categories after the above conversions, we categorized them into general information, examination, treatment, diagnosis, family history, disease condition, and causal relationship. General information, examination, treatment and family history are objective data, and diagnosis, disease condition and causal relationship belong to subjective data.

6. Comparison of G data items from three clinical guidelines

Finally, two other widely accepted clinical guidelines, Asthma guideline and Diabetes guideline, were analyzed in the same way to determine whether a great difference among the results of the three guidelines occurred. The results here refer to data coverage of HIS for executing guideline-based decisions and the extent of conversion of H data items into G data items.

Results

The result of data extraction showed that 141 G data items were collected from the Hypertension Guideline. These data items were classified into ABC classes. As a result, we found that only eight G data items could be directly utilized for execution of guideline decisions. After all conversions, G data items were again classified in the same way. The numbers of classified G data items before and after conversions are comparatively tabulated (Table I), and the levels of difficulty of data conversions are categorized (Table II). As the result shows, an additional 107 G data items could be acquired through a variety of conversions.

53 data items were converted from class B into class A through level 1 conversions. For example, whether or not total cholesterol concentration in the blood is *abnormally high* can be converted using the *digital values* of the serum test of total cholesterol concentration; whether or not diabetic nephropathy is being *diagnosed* can be converted using the *string values* of the current disease names. Eight data items were converted from class C into class A through conversions at the same level. For example, the *value of Body Surface Area* can be acquired using the Formula of DuBois, which requires *values of Height and Weight*. Conversions at this level do not use electronic clinical knowledge or other sources outside of HIS.

Five data items were converted from class B into class A through level 2 conversions. For example, *hypercholesterolemia* is converted using the diagnostic criteria of hypercholesterolemia as determined by the Japan Atherosclerosis Society and *the value of total cholesterol* from HIS. 41 data items were converted from class C into class A through conversions at the same level. For example, *complications of the aged with hypertension* are determined by this Hypertension Guideline and *the*

values of diagnosed diseased names from HIS.

The authorities of level 1 and level 2 conversions were categorized to ensure their validity (Table III). Only six of the conversions are unambiguously defined by the hypertension guideline, but all of the conversions have been approved and are currently being applied in clinical practices. For example, the conversion "junior high school students mean children are from 12 to 15 years old" is common knowledge; the conversion "extraction of the value of IMT from carotid sonography report" belongs to data processing as a sonography report is recorded in a narrative form. Although ICD-10 is one sort of controlled clinical vocabulary, because it is only adopted in diagnosis for accounts, we still regard it as information inside HIS instead of being defined by an institutional terminology system.

Logic for level 1 and level 2 conversions were categorized in detail as follows, and all of the typical examples are listed in Table IV:

I. Logic of conversion for number: numbers of H data values are either converted into a Boolean G data value or a string G data value. Example 1 and example 2 show their typical conversion logic, respectively.

II. Logic of conversion for string: strings of H data values are either converted into a string G data value or a Boolean G data value. Example 3 and example 4 show their typical conversion logic, respectively.

III. Logic of conversion for synonym: as synonyms of a G data variable exist in text on many occasions, text processing is naturally needed for conversions. Example 5 shows the typical conversion logic.

IV. Logic of conversion for concept using is-a relationship: sub-concepts of G data variable are required if the concept itself did not exist in the HIS. Is-a relationship is necessary to convert sub-concepts into their super-concepts. Example 6 shows the typical conversion logic.

V. Logic of conversion for concept without using is-a relationship: G data values sometimes are acquired from H data values through numerical calculation. Such relationships between G data variables and H data variables are other than is-a relationship. Example 7 shows the typical conversion logic.

Furthermore, G data items were categorized, and in each category the data items were divided according to whether they are obtainable after the conversions (Table V). 87% (67/77) of the objective data items could be acquired. However, exclusive of diagnosis data items, only 50% (11/22) of the subjective data items could be acquired. Among those that were unobtainable, some simple but important exams, such as blood pressure and pulse, could not be recorded in outpatient

settings.

Two other clinical guidelines, diabetes and asthma, were analyzed in the same way. Numbers of data items covered by the HIS before and after conversions, respectively, were obtained. All the results from the three clinical guidelines were compared against each other (Table VI). For each of three clinical guidelines, the coverage of G data items was remarkably improved by the use of conversions. Although the number of data items of the diabetes and asthma guidelines is much less than those of the hypertension guideline, their coverage rates are similar, both before and after conversions.

Discussion

The data items for application of decisions of the hypertension guideline published by Minds were analyzed in detail. A total of 141 data items were extracted and confirmed, among which only 6% in the HIS under study were in the form required for execution of the guideline. However, for the rest of the data items, most (80%) turned out to be obtainable using a variety of conversions of G data items from H data items. Sonnenberg *et al.* [18] analyzed the vocabulary requirements for implementing high blood pressure and high blood cholesterol guidelines. Because their research is similar to the first half of ours, both results are comparatively enumerated (Table VII).

Though we only identified data items partially, *i.e.*, only those applied in the outpatient clinic and only those used to execute decisions of the hypertension guideline, the total number is still larger than that of the hypertension guideline studied by Sonnenberg *et al.*, as they collected 133 data items from the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC7) [20]. One possible reason for the difference is the content difference between the hypertension guidelines used in Japan and in the US, respectively. For example, the clinical guideline of hypertension in 2004 in Japan includes the management of patients suffering from both hypertension and several liver diseases; this is not included in JNC7 because this condition is rare in the US. Among the different conversion levels of data items, the observed difference in the number of level 0 data items is much greater than the other three. A major reason for this might be that our research used CPOE applied in outpatient settings whereas theirs employed Logician's EMR. For example, their EMR contains a lot of data items for blood pressure, but there does not exist even one in the CPOE we adopted in our outpatient clinic. Furthermore, as their research did not separate JNC7's data variables from the other's, we could not determine what percentage of level 0 data items was extracted from JNC7.

Unlike Sonnenberg's methods, we did not employ controlled clinical vocabularies such as UMLS to determine definitions of data items, either from clinical guidelines or from HIS. Even if a Japanese

version of UMLS or SNOMED-CT had been developed, we would still argue that they could not provide adequate definitions to data items that work as conditions of guideline logical rules. Instead, knowledge supplied by clinical guidelines and other external sources approved by official clinical societies of Japan can be used to identify the concepts of those data items. However, as clinical guidelines and other knowledge sources are being updated separately, there might be different definitions of a certain data item between guideline developers and clinical societies. Therefore, during editing of clinical guidelines, it is better to distinctly reference the external knowledge in the clinical guidelines if any data item concept was not specifically interpreted by those clinical guidelines.

The distinction between level 1 and level 2 conversions is mainly focused on the relative difficulty in the extent of their programming, which is important for the actual system architecture. Most of the programs for level 2 conversions require building a database containing medical knowledge or other clinical information outside of the HIS, whereas the programs for level 1 conversions do not require this. A typical example of a level 2-conversion database is that of pharmaceutical information composed of drugs' trade names, generic names, subclass names, class names and the relationships among them.

Compared to subjective data items, a higher percentage of objective data items can be acquired after various conversions. Therefore, subjective data items might be the main reason for the higher percentage of level 3 conversions in our research than in Sonnenberg's. On the other hand, although EMR contains more subjective data items than CPOE, data items available from CPOE should be given priority in conversions because the scenario of our research is the outpatient clinic. When EMR and CPOE co-exist in one clinical institution, it is necessary to classify the resources of data items in advance of integrating CIG into an institutional CIS, thereby insuring a robust implementation of CIG. At this level, our analysis differentiated data items obtainable from CPOE from those that were not existent in CPOE but might be available in EMR.

Conversion logic categories point the way to concrete prototypes of program designs. Consequently, each category of conversion logic could be executable as components of a guideline-based decision support system. While one G data item could be acquired using more than one conversion logic, we select the one that is converted from an original H data item value. For example, *hyperpotassemia* could either be diagnosed by the value of *serum potassium* or acquired directly from *disease names*. Both *serum potassium* and *disease names* are available in the HIS and both conversion logics are feasible based on our analysis. In this case, we use the original value of serum potassium to decide whether hyperpotassemia exists. That is, if it is possible to construct multiple logics for the same G

data item, the most convincible conversion logic will be chosen.

Diabetes guideline and asthma guideline were analyzed in detail as well. However, the data items exacted in both cases were much fewer than that of the hypertension guideline. The different management contents between these chronic diseases may be the main reason for the difference. Asthma patients do not have many complications; diabetes patients do have some complications, but most of them are due to one reason, that is, a long history of diabetes. However, not only are patients with essential hypertension prone to cardiovascular, renal and other diseases, but also patients with cardiovascular, renal or other diseases have a high possibility of suffering from hypertension. Another reason might be related to the specific guideline versions. While asthma and hypertension guidelines were both published in 2004, the diabetes guideline was published six years ago (2000). Generally speaking, each guideline should be updated yearly, corresponding to the rapid development of clinical medicine.

The limited variation between the three coverage rates of data items, either before or after conversions, suggests that irrespective of disease, most guideline data items can be acquired from the HIS if the conversions are put into action consequently. According to Sonnenberg's variable dependency maps, this is because the HIS captures most of the data items that are independent of others routinely. In addition, some data items are required for execution of multiple clinical guidelines. 11 of 46 (24%) G data items from diabetes guideline also exist in those from hypertension guideline. Examples include *microalbuminuria* and *proteinuria*. 8 of 38 (21%) G data items from asthma guideline also exist in those from hypertension guideline as well. Examples include *pulse* and *age*.

Some clinical guideline modeling methodologies already have being applied in routine practice. The typical example is SAGE [21]. It uses SNOMED-CT, LOINC and NDF-RT [22] as its standard reference terminologies. Certain attributes of clinical concepts representing patient data, like *boundary value of hypercholesterolemia*, are not unambiguously defined in those reference terminologies, but VMR services can afford the value, and even the value's data type and unit, to complement its definition based on the patient data model of CIS. As we have demonstrated that there is a wide gap between clinical concepts used in clinical guidelines and CIS, all of the conversions between the two sides' clinical concepts that were clarified by us might have been completed manually before encoding a guideline knowledge base. Therefore, it is useful to separate the conceptual data model from CIG and CIS. Expanding the functionality of controlled clinical terminology, the conceptual data model would be designed to represent data items adequately defined by clinical guidelines or other reference resources and required for guideline execution, and

to support conversions of G and H data items.

In the future, after additional clinical guidelines are analyzed, a minimized group of data items from CPOE could be determined that could be used to execute most guideline decision rules. Meanwhile, conversions of H data items into the above minimized group of data items would be analyzed in detail and categorized into a series of conversion logics. After that, it is possible to develop a conceptual data model for both representing G data items and executing conversions to acquire their values. Finally, concerning the question of how to complement data items still at level 3 after conversions, additional interfaces between CIGs and the HIS need to be developed to request physicians to input data values necessary to execute the decision rule they show interest in. And concerning the question of how to complement data values missed because of unknown clinical incidents or errors, interfaces used to input data values whose data variables exist in the HIS need to be considered as well.

Conclusion

In this study G data items were compared with H data items, and our results showed that only a minority of G data items could be directly provided by the HIS in the form suitable for execution of CIGs. Comparatively, a majority of them could be acquired when conversions of H data items were put into action. Therefore, it is clearly possible that CIGs integrated with HIS can be executed for clinical decision support. Moreover, in order to automate these diverse conversions of data items, construction of a conceptual data model, by which controlled clinical terminologies are extended, for supporting CIGs to be applied with HIS, is a promising approach.

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