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標準的電子カルテのための施設間診療情報交換に関する研究

(H15-医療-028)

総括研究報告書

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I. 総括研究報告

厚生労働科学研究費補助金（医療技術評価総合研究事業）
総括研究報告書

標準的電子カルテのための施設間診療情報交換に関する研究
（ H15-医療-028 ）

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(五十音順)

研究要旨 日本の詳細な画像検査オーダに対応するべく JJ1017 コードは拡張され、外保連提案の検査分類にも 1 対多の写像として対応した。

JJ1017 コードは、DICOM 規格のボキャブラリーの一つとして登録されるだけでなく日本での標準的コードとして MEDIS-DC の標準化委員会に採択されようとしている。MERIT-9 紹介状は、ISO 規格となろうとしている HL7 CDA R2L2 に対応した。この紹介状形式は、静岡県をはじめ、施設間診療情報連携の形式として採用されようとしている。院外処方箋情報の 2 次元シンボル化印刷については、薬剤コードとして、H0T をデータ形式として、HL7 を用いるのが最適であることが判明しこれの実装実験をおこなった。

A. 研究目的

厚生労働省の示した保健医療分野の情報化に関するグランドデザインでは、電子カルテの普及は必須のものとされており、それに関連して各種の研究・開発が進められている。申請者はこれまで診療情報の連携に関しての研究を進めてきたが、電子カルテがもたらす施設間診療情報連携の推進のため以下の点について、研究・開発をおこなう。

* CD などによる電子的紹介状の情報多量化とその運用に関する検討

電子カルテ導入のメリットとして診療施設間紹介状の持つ情報が、紙による紹介状に比べ電子化により数段情報量が多くできるという点がある。これは患者、施設の双方にとって連携の充実と手間の削減のメリットをもたらす。そこで本研究では、送出側、受取側、両方においてこの機能のコンポーネント化をおこなう。また、情報多量化がなった際は、特に受取側での有意な情報の迅速な選択のための機能が必要となることが予想されるの

でこれについても機能の提案・開発をおこなう。

* 所見記述について、施設内・特定他施設間では構造化されたものとして検索可能であるが、不特定の外部には、自然な文章表記をおこなう機能ならびに自然文表記から特定所見を抽出する機能の研究・開発

電子カルテにおいて、テンプレートなどで記述が、構造化され用語が共通化されていれば統計処理も可能である。これは、構造や用語を共有する施設内・施設間では有効であるが、同時に他施設への情報提供がスムーズでなければならない。これは自然文による必要がある。また逆に自然文で記述された所見記述から特定所見を見つけ出すことができれば広域サーベイなどで有用である。これらの機能を自然言語処理の技術で実現することを目指す。

* 院外処方箋に処方内容を 2 次元バーコードで記載し、受取側である薬局で読み取る機能の研究・開発

院外処方箋が薬局を特定しないこ

とは重要であるが、それが故に紙運用のままであるのは、非効率であり事故防止の観点でも望ましくない。ネットワークでの配信も可能であるが、その設備の有無が、特定の薬局に有利にならないようになるまでにはまだ時間がかかる。以上の理由で標記の機能の研究・開発をおこなう。

電子カルテの機能を充実させるこういった個々の機能を実現することにより診療施設間の情報連携が促進され連携診療の向上につながり、また事故防止にも寄与し一方患者にとってはセカンドオピニオンを受けやすくなり、ひいては医療の透明性の向上が期待される。

B. 研究方法

まず、施設間診療情報連携の基礎となる各種項目コードであるが、以前より主任研究者が取り組んでいる画像検査項目コード JJ1017 について本邦における画像検査依頼の詳細レベルを含む必要性、および外保連の提唱する検査項目分類との対応の必要性について検討をおこなった。

また、以前より進めている MERIT-9 紹介状形式について、HL7CDA レベル 2 の正規リリースにともない、これへの対応を検討した。これによる XML 形式での情報のスタイルシートでの自然な表記による提供を検討した。

最後に、院外処方箋の情報の 2 次元シンボル化について HL7 形式化についての留意点、採用すべき薬剤コード、採用すべき 2 次元シンボルの種類に

ついて検討をおこなった。

(倫理面への配慮)

本研究は、個人情報を含む保健医療福祉情報のプライバシー保護等を確保することも含めた情報伝達(情報交換)の方法を目的として行った。研究推進に当たって人や動物等を直接対象とすることは、無かったため、倫理面における新たな問題を発生することはなかった。

C. 研究結果

画像検査項目コードについては、実際にオーダ時に利用されるコードと情報連携時に用いられるコードとが異なる必要はなく、真に今求められているものは、実際にオーダできるコードであるという結論に達した。その結果、部位 3 4 7、手技 4 2 7 とかなり前年までと比して増加し、負荷や体位などの検査条件などについても従来「方向」としてまとめられていた中に収録した。JJ1017 コードは、部位、手技、方向の 3 軸を組み合わせて用いるため現在可能な組み合わせは 1 2 万を超えるが、このなかで実際行われている組み合わせは数千であろうかと思われる。また、この際、外保連コードとの対応を行った。

MERIT-9 紹介状形式の CDA L2R2 対応については、大本の規格の固定化を待っていたが、ISO 化という目標もあり比較的早期に固定化したため、作業は問題なく行われた。また、これにより記述される紹介状の自然表記は、XML のスタイルシートが簡単に適用でき

ることが判明した。

院外処方箋情報の2次元シンボル化については、用いるべきコードはH0Tコードであり、またHL7項目で保険情報、処方量情報などが十分でなく日本国内拡張として補う必要があることが判った。採用すべき2次元シンボルは、処方箋のスペースからしてQRとPFD417が適当であることがわかり、次年度は実際に多数印刷して優劣を判定する予定である。

D. 考察

JJ1017コードについては、当初は手技、部位、方向などの3軸を組み合わせて利用することを考えていたが、実際この組み合わせ形式のマスターに対応したRIS、HISはほとんどなく、診療施設がオーダ系を導入する際に頭を悩ませる一つが、検査マスターの入手であることもあり、実際行われている検査に絞り、リストの形で提供することが最も望まれていると考えられ次年度早期にそれを作成する予定である。

MERIT-9紹介状については、静岡県など自治体主導の診療施設連携の基盤形式として採用されようとしている。CDAそのものがISO化されつつあり今後はこれが、基盤となるであろう。

院外処方箋のHL7化に際して不足であった項目は、保険情報と一日処方量であった。前者は当然でもあるが、後者は、諸外国では「一回1錠、一日3回」と表記することが通常であるのに対して、本邦では、「1日3錠、一日

3回」と表記するためである。ただ、事故防止の観点からも、国際的通常表記を求める声も多いようである。

E. 結論

日本の詳細な画像検査オーダに対応するべくJJ1017コードは拡張された。また外保連提案の検査分類にも1対多の写像として対応した。JJ1017コードは、DICOM規格のボキャブラリーの一つとして登録されるだけでなく日本での標準的コードとしてMEDIS-DCの標準化委員会に採択されようとしている。

MERIT-9紹介状は、ISO規格となろうとしているHL7CDA R2L2に対応した。この紹介状形式は、静岡県をはじめ、施設間診療情報連携の形式として採用されようとしている。

院外処方箋情報の2次元シンボル化印刷については、薬剤コードとしてH0Tをデータ形式としてHL7を用いるのが最適であることが判明し、これの実装実験をおこなった。用いるべきシンボルとしては、QRシンボル、あるいはPFD417シンボルのどちらかが、院外処方箋の少ないスペースでは適当であろう。

F. 健康危険情報

本研究推進において、生命、健康に重大な影響を及ぼすと考えられる新たな問題及び情報はなかった。

G. 研究発表

1. 書籍発表

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-日本薬剤師会・保健医療福祉情報システム工業会標準規格を目指して-
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木村通男 医療情報分野の標準化の動向とHELICSの役割
第1回標準化推進協議会シンポジウム 基調講演 1月29日，2004

H. 知的財産権の出願・登録状況
(予定を含む。)

1. 特許取得
なし
2. 実用新案登録
なし
3. その他
なし

II . JAMI Viewpoint Concerning the Definition of the Electronic Medical Record

Japan Association of Medical Informatics

February, 2003

JAMI Viewpoint Concerning the Definition of the Electronic Medical Record

Japan Association of Medical Informatics

February 2003

A. Background

In recent years, clinical and related medical information is increasingly managed by information systems as so-called the electronic medical record (EMR). However, a common definition of the term "electronic medical record" has not yet been established, causing problems in business transactions as well.

First of all, even the term "medical record" has not been given a steady definition, and although it is difficult to provide a fixed and permanent definition for such a developing concept, we at the Japan Association of Medical Informatics publish our opinion on how the EMR should be defined under the present circumstances, to solve some of the aforementioned problems. It is evident that these opinions should be revised along with technological advances and environmental changes.

To present a meaningful opinion under the present circumstances, we should primarily evaluate the current situation, since various functions expected of the EMR and its current achievements need to be taken into consideration.

Also, since functions are to be focused, we defined the EMR in the manner we considered the most adequate at present, by grasping each individual function of various existing information systems (for example, systems such as hospital information system, clinic information system, order entry system, department-specific system) rather than treating them as given infrastructures (actor analysis).

Finally, we added brief technical explanations, implementation checkpoints, as well as our thoughts on the EMR's potential contributions to the medical reforms, described in the Grand Design.

B. Current Evaluation

Current goal attainment of the existing systems has been evaluated.

B-1. Clinical Information Sharing

A large percentage of information is successfully shared within each facility. However, information exchanges between outside institutions are few, and, if any, are limited to specific partners, and even in these cases they seldom occur routinely. Nonexclusive information exchanges are extremely rare, despite the importance of information sharing across medical institutions in improving transparency of medical practices.

B-2. Data Presentation at physician's terminal

The increased in-house information sharing enhanced the on-demand availability of medical data on physician's terminals, as compared to the individual order system. These systems are also helpful in providing patients with explanations.

B-3. Data Reuse

Data reuse for clinical support, management support, education, and research support has not been realized as much as we expected. However, there are some instances in hospital logistics where targeted investments have contributed to successful data reuse.

B-4. User Interface and Responses

Data entry, depending on the type of information, often requires more time than hand-writing on paper charts. This is particularly true for information generated by medical personnel, such as findings. A majority of the facilities prefers, depending on physicians' specialties, entering free-format text data by keyboard to entering data on document templates. Few facilities are effectively utilizing mouse or tablet for graphical data entry.

C. Electronic Medical Record – Its Position and Functions

The so-called "order entry systems" have two major functions: order transmission and result query. The EMR logically includes the latter. While prescriptions and instructions must be documented in medical records, the EMR functions do not necessarily include order transmissions through information systems. Results of laboratory tests for which orders are not transmitted through information systems may be referenced by the EMR. The EMR is not the same as order transmission systems and does not necessarily include full-featured ordering systems.

The term "hospital information systems" has a very broad concept. It can include tasks ranging from basic patient information management to order transmission, performed procedure information, result database, accounting, and appointment management. It may also include various department-specific systems. It is quite natural for the order entry system and the EMR, not to mention the various department-specific systems, to share functions such as basic patient information management.

According to this point of view based on actor analysis, the main function of the EMR is to store patients' medical documents such as clinical findings and examination results, while the main function of order entry systems is

to transmit hospital information such as physician's orders and test results. These two systems share some functions in common and constitute a part of the hospital information system or the clinic information system.

D. Definition

We defined the EMR, distinguishing the standard EMR (with the least functional requirements: Bottom-line) and the paperless EMR. In reality, EMRs at different degree of electronization exist between these two.

D-1. Standard EMR (with the least functional requirements):

- (1) It does not cover all application areas, but it must support the order transmission system and the order result reference system in many of these areas, and in each of these, must form the basis for medical record information.
- (2) It does not cover all information types constituting the medical record, but for many of these types, it must allow prompt information retrieval simultaneously at different places. This must be possible even for sufficiently old information. Also, such information must be retrievable in various axes (such as in chronological order, in department-specific or clinical division-specific form, or in pathway format).
- (3) It must adopt standardized data formats and codes such as Health Level 7 (HL7) and Digital Imaging and Communications in Medicine (DICOM) wherever possible, taking into consideration the transition of these data into a new system after a future model update, as well as the information sharings with other medical institutions. Additionally, the mutuality between the information stored in traditional media, such as paper and films, and the electronic information must be preserved.
- (4) It must significantly improve information service for patients as compared to paper presentations, through direct viewing of a monitor screen, or utilizing a monitor screen.
- (5) It must be managed with the privacy protected. Concerning the information for which the original material in the form of traditional media such as paper and films is not preserved, the implementation must satisfy the three conditions of electronic storage (securing authenticity, securing readability, and securing storability).

D-2. Paperless EMR:

- (1) It must support the order transmission system and the order result reference system in all application areas, and in each of these, it must form the basis for medical record information.
- (2) It must allow electronic management of all types of information constituting the medical record, and must allow prompt information retrieval simultaneously at different places. This must be possible even for sufficiently old information. Also, such information must be retrievable in various axes (such as in chronological order, in department-specific or clinical division-specific form, or in pathway format).
- (3) It must satisfy D-1 (3), (4) and (5).

D-3. Additional Functions

- (1) The following two functions, although not required of the EMR at present, are quite important. Therefore, positive exploitation is desirable.
 - o Hospital logistics (these require too much hardware and software investments to be made an essential requirement at this point of time. The Grand Design also describes hospital logistics and the EMR as separate entities).
 - o Data Reuse (data contents such as terms and codes are not standardized enough to make data reuse a requirement at this point of time. However, positive implementations are encouraged for the well standardized items such as drug names, clinical examination names, and disease names).

D-4. Supplement

Concerning the following issue, in addition to satisfying the three conditions of electronic storage and the privacy protection requirements, continuous measures should be taken in accordance with technological advances.

- o Data security and privacy protection measures that should be taken when exchanging electronic clinical information within the facility as well as among institutions.

E. Technical Explanation

E-1. Paperless

Upon evaluating the current status, we considered that the key point in classifying EMRs was whether the management of such information as physicians' findings was paperless or not. Achieving paperless management is not easy, and it currently requires a large amount of investment and the facility's effort. However, even if paperless documentation of findings is implemented, effective data reuse cannot take place without data items such as disease names and finding description being standardized; in deed, the number of institutions effectively reusing data is limited. Efforts for such standardization are being made, but if a sufficient amount of reusable data cannot be generated, one of the benefits of going through the trouble of realizing paperless management in this area cannot be expected. On the other hand, other items such as images, examination results, prescriptions, and reports are relatively well standardized, and a variety of products for these is available and is relatively inexpensive. Although they do not constitute the entire clinical information, presenting such information in visually ingenious forms to health care personnel and patients is very meaningful. Therefore, it is not appropriate to exclude such benefits from the EMR just because it's not entirely paperless. Nevertheless, the situation differs considerably by whether the management is paperless or not, and we considered this to be the key point in classifying EMRs.

E-2. Relationship with Critical Pathway

Whether managed by paper or an information system, there are three types of Critical Pathway (CP) with different degrees of implementation: CP that is simply for informing patients before the treatment; CP in which various orders are initially generated but with the subsequent changes made individually; and CP in which orders as well as subsequent changes are generated. The most important point is that, when changes are made in response to the patient's conditions, the latest and the most reliable instructions be clearly indicated. In view of accident prevention, the third type appears to be desirable, but this requires the system to be something close to the "paperless EMR" defined above. In addition, all health care personnel must check the latest To-Do list before engaging in a medical practice. In other words, medical practice becomes too risky to perform in the case of system failure, thus requiring the hospital information system an extremely high degree of reliability. As a result, constructions of hospital information systems would require a significant amount of investment. Even then, because there may be several medical personnel who make changes to the CP, there must be a person responsible of the patient's treatment process. The same thing can be said to both CPs implemented through paper and information system. This is reflected by the fact that CPs are more effectively used in facilities where nursing staff is playing

more active roles, given the present circumstances in which nursing staff communicates information better than doctors.

Nevertheless, Critical Pathway is a very effective tool for informing patients, and should be adopted positively. However, CP is basically built upon order entry, transmission, and change implementation functions. These are not required of the EMR nor premise the use of paperless EMR. Also, changes do not have to be made electronically. On the other hand, even in the case of paperless management, the person in charge of the treatment process must not be disregarded.

E-3. Number of Information Types to be Handled

According to the definition described above, even in-hospital Picture Archiving & Communication System (PACS) alone can be referred to as EMR if the display at physicians' terminal is well thought-out. It is desirable that not only images but as much information as possible be comprehensively displayed. However, the scope of information to be handled changes with the time. For example, even a simple system allowing only prescription and examination orders within a hospital ward was called an order entry system at the time of its initial introduction, but such a system is no longer sufficient even for business transactions. It is expected that the EMR would go through a similar process. In the present circumstances, the appropriate scope of information to be handled would be most of the information for which the data is generated from machines (clinical examinations, images), and for which the order entry is implemented (prescriptions and injection). In other words, at this point of time, systems that only allow examination result reference inside the hospital would be insufficient, while systems that allow reference of information encompassing examination results, prescriptions, and images would satisfy the requirements (provided that other conditions such as an improved information service are satisfied. Particularly, the requirements such as prompt retrieval and retrieval of sufficiently old information are often not adequately satisfied even at the present time). However, concerning the latter type of information (information for which the order entry is implemented), the system must mainly handle not only order information but also implementation information. In the case of drug prescriptions, for example, the order information would be the drug name and the implementation information would be the preparation instruction. Although prescriptions in generic names and query processing should be considered, instances of such achievement are rare. It is because of these reasons that in this definition, we did not lightly regard this type of information as a necessary requirement, and that the conditions concerning on information types are not set strict.

E-4. Information Storage

Long-term storage of important information must not be interfered with by system replacement or vendor change. Although this has been accomplished in areas well standardized by such systems as HL7 or DICOM, if information is stored in proprietary formats, measures to be taken at the time of future system upgrade must be carefully considered. Also, in the case where physicians' findings are documented electronically, if all the information subject to authenticity is to be stored in the database, in the worst case, the existing equipment may have to be maintained for as long as 5 years after the system replacement. This is an extreme view, since such information as under which circumstances and from what options the user entered the data is for usability purposes; therefore, it is not appropriate to document the user's each and every action and make it subject to authenticity. In information system management, the documented information needs to be confirmed by the user him/herself, and it is this confirmed information that should be subject to the authenticity.

E-5. Component-Based Approach, Multi-Vendor System, and Internationalization

EMR component products are already available for some applications such as image management solutions. Good examples of such are the component products using DICOM to receive images and Web to reference them within the hospital, or those storing images in the DICOM format. Standardization allowed the use of these products which are supplied by vendors different from that of the EMR. Naturally, in these limited vertical segments, new entries into the market are promoted, giving the possibility for users to purchase better quality products inexpensively. As the standardization progresses, component-based approach will probably be possible in wider application areas. Until now, Japanese hospital information systems and order entry systems have been rarely sold abroad, and, in the same manner, foreign systems have been rarely sold in Japan. However, EMR component businesses are expected to spread into imaging modalities and bed-side monitors, and many of these are supplied by foreign vendors; some Japanese vendors also sell to overseas markets. Therefore, international procurement is inevitable, and we must say that procurement based on some proprietary standard, which doesn't measure up to the international standard, is somewhat of a problem. On the other hand, Japan has the world highest diffusion rate of order entry systems, and given the hectic environment of hospital administration in Asian countries as compared to the Western countries, the technology which has been tested under such conditions must be of high-level. The Japanese vendors must have a vision to spread their high-level technologies through international standards.

F. Introduction Checkpoints

F-1. Paperless or Not?

The benefits (for example, information retrievable simultaneously at different places, safety improved by reduced handwritten documentations, availability of administrative, clinical, research, and educational support data) and the cost (for example, equipment (both software and hardware), purchase, maintenance, time and effort for data entry) must be weighed before decision-making.

F-2. To What Extent Should Data Be Reused?

To obtain meaningful data, certain preparation work is required (for example, master data preparation, code standardization, methods and efforts to obtain material data).

F-3. Should Hospital Logistics and Workflow Management be Included?

Although hospital logistics and workflow management are not part of the EMR functions, these are important in improving hospital services. However, in either application, gathering the basic data entails significant costs. Therefore, the amount of reduction in billing errors and dead stock, and the optimal personnel placement that would be possible by such applications need to be considered.

F-4. Is the Data Format Standardized?

At the time of system replacement, will important data migrate to the new system? Even if physicians' findings are preserved in structured documents, will they be reproduced in the new system? In other words, if a different vendor offers a better and less expensive system at the time of next replacement, would not the format be an obstacle to data migration? Furthermore, would not the data be lost if the current vendor pulls out of the market in the first place? These issues must be taken into consideration.

F-5. Can the System Handle Increased Data Volume?

The response must be sufficient to handle the data volume not only at the time of the installation but also near the end of the system's life span. Also, the storage capacity does not have to be excessive from the beginning, but in that case it must be expandable from both system design and cost planning points of view.

F-6. To What Extent Should User Authentication and the Three Conditions of Electronic Storage Be Implemented?

These are all too expensive to be covered by the information system alone, and must be implemented along with operational procedures.

G. Towards the Medical Reform

The Grand Design cites four issues for which EMR should contribute to the resolution.

G-1. Information Provision

o Accumulation of comparable data

A standardized data format must be used when accumulating important data. Also, accumulating sufficiently old data in a user-friendly format improves availability and enables meaningful comparisons.

o Clear presentation of information

Clearly presenting information to medical personnel is important for work efficiency, accident prevention, and for better medical service. Understandability is also essential in assuring transparency of health care.

o Information sharing among medical workers

Information exchange facilitates consultation of a second opinion. This also is important in gaining patients' trust in the health care system, and it contributes to efficiency and priority improvements by increasing the options available to patients of medical institutions.

These three points are also emphasized in this definition of the EMR.

G-2. Quality Improvement

As data accumulation and sharing bring about more effective data analysis, establishments of new medical treatments and new evidences are expected. However, such issues as terminology standardization still need improvement and information sharing is insufficient as well. Although these goals are not to be achieved by information systems alone, continuing efforts need to be made in order to resolve these problems and to provide as much material as possible. For example, when we think of the potential contributions to genome information-related researches, gathering comprehensive, multi-center epidemiological data is essential. However, the categories of clinical data that will be required cannot be predicted at this

stage. As it is impossible to be prepared in advance for each of these particular domains, we should at least be poised to promptly provide prescriptions and clinical examination results.

Neither data accumulation nor sharing is sufficient to evaluate medical service, but even if these problems are solved, the criteria (indicators) for such evaluation remain to be properly defined. In order to assist the establishment of such criteria, data accumulation and sharing must nonetheless be made possible in an accessible manner. Yet, the information sharing promotion results in increased opportunities to disclose medical activities among physicians, and this alone can contribute to the quality improvement of health care and description.

G-3. Efficiency Improvement

Utilization of medical practice implementation information which constitutes the infrastructure of the EMR can contribute to cost reduction. However, cost reduction cannot be achieved by the EMR alone since this is made possible under cooperation in the hospital logistics system and the work and human resource management system; it also needs sufficient amount of equipment investments and data entry/registration efforts.

G-4. Safety Measures

The Grand Design describes that the safety measures concern the order entry system. It is a fact that electronic order entry can reduce errors inherent in handwritten documentations. However, these measures must not be based on the assumption that the information system can be relied upon, since data can be originated from various sources, and software developers are also humans. For the EMR to contribute to data safety, a function which utilizes various information stored in EMR to validate integrity of instructions will be necessary.

H. For the Public to Understand -- Reduction of medical cost is not the purpose

Is health care quality in Japan inferior to those in other countries? Although the ratio of medical expenditure to GDP is the lowest among industrialized nations, life expectancy and other indicators in Japan rank at or near the top, and we, along with France, have been highly evaluated by the WHO. Many advanced clinical institutions have already begun reporting information such as department-specific, disease-specific, medical worker-specific revenues and expenditures. These data should of course be used to further improve efficiency and to reduce wastefulness, but at the same time, if current health care practice is properly run, they should also