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Synopsis



The term 'patient record' is intuitively understood, but does not have an agreed upon information model. The emerging and broader concept of Electronic Health Record (EHR) includes an attempt to suggest such a model but, as yet, has no formal agreement. Nevertheless, three of the four excellent papers in this section (Brandner et al., Branston et al., and Weir et al.) deal with clinical documents as an integral part of the patient record. This demonstrates the centrality of clinical documents as fundamental constituents in the current perception of medical informatics for patient records. I will start by exploring this common ground and then review the fourth paper, which deals with patient-access to medical records (Ross and Lin)-in itself a challenging aspect of EHR.

In their paper "Electronic Signature for Medical Document – Integration and Evaluation of a Public Key Infrastructure in Hospitals", Brandner et al. analyze medical documents that are signaturerelevant. They describe the incorporation of an electronic signature system into an operational clinical information system, in order to promote the use of electronic versions of medical docu-

ments and circumvent the need for paper versions. The study has shown that the use of the new system saved a great deal of work and resulted in a time savings of about seven days, on average, in the completion of discharge letters. The authors argue that the use of electronic signatures in medical documents is a further step towards the adoption of electronic patient records because (a) most of the medical documents in a hospital are signature-relevant, and (b) shared care, provided by the cooperation of various highly-specialized health care providers, requires electronic data exchange. This exchange, in turn, necessitates the data protection, security, and authentication offered by electronic signatures.

In their paper "The implementation of guidelines and computerized forms improves the completeness of cancer pathology reporting. The CROPS project: a randomized controlled trial in pathology", Branston et al. focus on pathology reports and argue that inconsistent pathology reporting (e.g., absence of essential data items of therapeutic or prognostic relevance) can lead to inconvenience for the patient and the clinician, delays in treatment, and inadequate or inappropriate postoperative therapy. There is evidence to show that the use of standardized pre-defined forms, as opposed to the use of free text, improves the quality and completeness of pathology reports. Indeed, this research showed that the use of pre-defined forms led to a 28.4% increase in complete reporting of the minimum dataset required for cancer registration and a 24.5% increase in complete reporting of the minimum data required for patient management.

In their paper "Direct Text Entry in Electronic Progress Notes - An Evaluation of Input Errors", Weir et al. focus on progress notes created in the US Veterans Administration **Computerized Patient Record System** (CPRS), which supports provider order entry. In this system, progress notes are entered directly by clinicians, primarily through keyboard input. The objective of this study was to examine the incidence of input errors related to direct text entry for progress notes, in order to identify efforts for preventing and reducing such errors. Because direct input of clinical documents is the least favored method for note generation, typing-assists have been developed to facilitate direct input.

These assists have created a new class of errors that emerge, for example, from copying portions of previous notes and blocks of information from repositories (e.g., vital signs), without updating them in the current note or checking for their relevance to the current progress note. Study results showed that "the percentage of all notes with at least one documentation error was 84% and the average number of documentation problems per patient was 7.8 (not including signature errors)."

Structuring Clinical Documents

The above three papers refer to different aspects of using computerized methods to improve the generation and structuring of clinical documents as part of the patient record. The computerized clinical document is similar to its paper counterpart and the clinician's narratives are a key component of both versions. Narratives are compositions based on the natural language of the writer, while computerized structuring of a document is limited to some computer language. The gap between these 'languages' poses a challenge to medical informatics and new standards of clinical documents strive to bridge this gap, e.g., HL7 CDA (Health Level Seven - Clinical Document Architecture). This challenge is even greater when it comes to the mixture of structured and unstructured data intertwined to describe the same phenomena, while addressing two important goals: human readability and machine-processability. The drive to structure medical narratives is also reflected in the thin line between art and craftsmanship in medicine. Evidence presented in the above three papers demonstrate this gap.

Branston et al. describe computerized and structured pathology reports, where interviewed pathologists expressed their attitudes towards using structured forms as opposed to creating free text reports. The authors concluded, "there should always be room for adding a free text component to the form, in order that pathologists can describe properly the complex specimen, the special situation that 'does not fit' and the truly unusual observation that may lead to new insights into the understanding of cancer and its treatment." Thus, the computerized forms for pathology reports were indeed more complete as shown in the study, but less rich and flexible in accommodating the complexity of medical reality.

Weir et al. describe the direct input of progress notes in the VA CPRS system, where over-automation in the form of 'typing-assists' appears to have added a new class of errors to the direct-text-entry notes. These errors were not prevalent when progress notes were written by hand or dictated. When three consecutive daily progress notes include the phrase "today the patient walked for the first time...", this points to adverse effects in the automation of narrative composition and sheds light on another aspect of the unstructured-structured gap.

Brandner et al. who deal with the computerization of the human signature, also touch on this gap. A signature is not only about the graphical scribble that each clinician imprints on documents, but also serves to attest to the authenticity and wholeness of a record's medical content as completed by the responsible party. When using electronic signatures, this content should be verifiable at any time in the future and "clearly indicate to which data the electronic signature applies, that these have been unaltered, by whom the signature was generated, if the corresponding certificates are available at the time of verification, and that the certificates have not been revoked." Other issues raised by the authors included the limited lifespan of electronic signatures due to the use of cryptographic algorithms that require renewal mechanisms, and conversion of documents to different formats. which poses a challenge in maintaining the above verification requirements. In this regard, preserving the same presentation seen by the attesting provider is medico-legally important. Overall, the electronic signature system was shown to offer a significant savings in time, but poses challenges that are not present when we deal with a signed piece of paper. These challenges mainly refer to the coherency, acceptability, and sustainability of the signed contents.

Terms and Templates

The structuring process of clinical documents should be facilitated by templates and medical terms. These lower-layer artifacts are fundamental to the success of computerized documents in the sense that their existence can advance the documents to be machine-processable and consequently enable semantic interoperability between dispersed software applications. As described in the papers on pathology reports and progress notes, templates are common domain-specific constructs that facilitate the creation of a document. Templates are also used to validate certain business logic imposed by health care enterprises and can be presented as computerized forms that clinicians fill in. To assist in utilizing templates, medical terms are often used; these represent the lowest level of granularity of clinical data. For example, in the pathology report paper, Branston et al. also utilized SNOMED (Systemized Nomenclature of Medicine) in their cancer reporting screens. SNOMED, as well as other controlled coding schemes (e.g., ICD - International Classification of Diseases; LOINC-Logical Observation Identifiers Names and Codes) represent a source for the essential atomic units of the clinical document. When the use of codes from international coding schemes constrain the utilization of templates in the creation of a clinical document, the resultant document's structure is much more effective, especially in the context of information exchange between disparate health care providers.

While the standardization of medical terms is quite advanced, templates are still in their infancy. HL7 recently established the Templates SIG, and the OpenEHR foundation, in collaboration with CEN (the European standardization body), are developing the somewhat similar concept of archetypes while suggesting methods for harmonizing both concepts. In addition, there are discussions on how templates/archetypes will be developed and made available to the public. To this end, it is recommended that new public registries will allow the contribution of standardized templates that could be used by health care providers. The registries could also support the evolution of templates by continuing improvement of the current ones, based on the input from professional societies such as those mentioned by Branston et al. (e.g., Minimum Dataset for Colorectal Cancer Histopathology Reports defined by the Royal College of Pathologists in 1998).

Records

Templates and terminologies are the base of 'well-formed' clinical documents. On the other side of the medical informatics continuum we find the concept of a record. The relationship between a document and a record is an on-going controversy. A large collection of lengthy and redundant clinical documents could serve as a substrate for a patient record, but make it difficult to present a succinct summary of the patient's medical

status to the busy clinician at the current point of care. Weir et al. refer to this question in their paper on progress notes and suggest, for example, a problem-oriented display of the data. However, the paper indicates that the method for selecting important and relevant data represents a grand challenge for medical informatics and decision support tools. I would add to this the challenge of identifying redundancy and possible contradictions. At present, a special EHR project is underway by various standardization organizations concerning the functionality of EHR systems and aimed at an "EHR Functional Model" (see http://www.hl7.org/ehr/). The function of intelligently summarizing the patient's clinical documents should be part of this model.

Patient Access to Medical Records

The paper "The Effects of Promoting Patient Access to Medical Records: A Review" by Ross and Lin does not deal directly with clinical documents, but rather with patient access to medical records that also include documents. This extremely important paper presents both the benefits and the risks involved in allowing patients to access their records. The paper reviews many papers published on the subject and concludes that "overall, studies of patient-accessible medical records suggest modest improvements in doctor-patient communication, adherence, patient empowerment, and patient education. Although patients find parts of the medical record difficult to understand, patients who are offered a chance to review their medical record are generally satisfied with the experience."

In particular, the effects on the patient include benefits such as patient interest and acceptance; patient

education; providing reassurance; patient empowerment: improving autonomy and self-efficacy; promoting adherence; and risks such as confusion and misunderstanding; creating anxiety; and concerns about sensitive items and confidentiality. The effects on the doctor-patient relationship are less obvious, but include an improvement in doctor-patient communication (e.g., "numerous individual instances in which access to the medical record prompted doctor and patient to have useful discussions") and demystification of the record for those patients who are concerned about what might be hidden in the chart. The effects on medical practice include the correction of errors encountered by the patient, as well as the introduction of errors when patients make unauthorized additions or deletions in the record.

Doctor-Patient Relationship

The issue of patient-access to medical records is indeed very sensitive. In my mind, it is tightly coupled with the type of doctor-patient relationship, which should set the context for the access. In a 'paternalistic' type of relationship, there is not much point in offering access; it might even conflict with the authority the doctor is trying to establish. However, in 'informative', or 'deliberative' types of relationship, access to the medical record can be part of such a relationship. I believe that patient access to medical records should be facilitated by an informative/deliberative type of relationship with the doctor; otherwise. the risks encountered in this review paper will be difficult to eliminate. A deliberative attitude can lead to a teambased relationship where it is easier to cope with risks such as anxiety and confusion. Nevertheless, another important parameter is the attitude and the competency of the patient. If the patient chooses not to be informed or if the patient is not capable of being

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informed, the doctor has to adjust the nature of the relationship accordingly. This should also influence the patient access to the records and the type of presentation an EHR might provide. In summary, the doctor and the patient bring their attitudes and competencies into the relationship and only if a more deliberative type of relationship is established, should the patient have access to the medical record.

An interesting study in this regard, described by Ross and Lin, is a randomized controlled study of patientheld obstetric records. This obstetric study suggested that the resultant improvement in doctor-patient communication led to an adverse clinical outcome-a statistically significant increase in assisted deliveries. The study speculated, "patients who held their records became more vocal about their concerns and thus altered clinical practice in ways that were ultimately detrimental." This study shows, in my view, the common perception of causality in this regard: the doctor-patient communication is perceived as the result, whereas it should be perceived more as the context in which the clinical decisions are made. Indeed, in today's 'information society', we see patients arriving at their doctor's appointment well informed from other sources, such as the Internet, and expect the doctor to pay attention to the knowledge they have already gained. However, if the doctor still holds paternalistic attitudes, or attributes healing power to his authority, it will be difficult to gain benefits from having the patients access their records. The benefits will be modest if any and the risks will still exist, with no appropriate environment to minimize them.

In addition, some of the risks indicated by Ross and Lin have to do with the legibility of the data in the record (e.g., illegible handwriting of the clinicians in the clinical notes). This obstacle relates to the issue of computerized patient records and the level of standardization of the data included in the record. As long as clinicians write illegible notes in the patient record or describe the patient condition in ambiguous and vague ways, without the use of standard terminology embedded in common templates and guidelines, it will be difficult for anyone (including the clinicians' peers, not to mention the patients themselves) to make effective use of the medical records.

EHR

I would like to argue that even if the medical records are computerized and standardized, they may be still confusing for the lay reader, since the medical records are essentially raw data. What could be of great help is a longitudinal EHR framework where all the raw medical records are consolidated. harmonized, and summarized. For patients, the EHR will be the ultimate representation of their medical status; they would only dig into the raw medical records if they needed to see the evidence and facts. This is also important for clinicians, as we learn from the insights that Weir et al. provide in their paper on the VA CPRS system, when they advocated for more problemoriented display of data in the patient record. Thus, the papers in this section show how two major interests are converging in favor of having patient records in the EHR orientation, with standardized medical records summarized in useful ways for the benefit of clinicians as well as patients.

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