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Review

From Hospital Information Systems to Health Information Systems - Problems, Challenges, Perspectives

1. Introduction and Scope

In his 1994 IMIA yearbook review paper, Hammond described how hospital information systems have developed since the 1970s, and how their functionality has evolved [1]. In 1995, the observations, conclusions and recommendations of the Durham IMIA Working Group 10 HIS working conference were published [2, 3]. These publications outlined the shift towards clinically oriented and patient-centered approaches, advocating health information systems without boundaries and seamless linkages connecting all individuals contributing to patient care. As a consequence, the scope and definition of "hospital information system" was seen as extending towards "health information system" [2, 1].

The IOM report of 1991 [4] has defined the terms "computer-based patient record" (CPR) and "patient record system". The IMIA working conference saw the CPR as a subset of the hospital information system within the boundaries of an institution, while from the perspective of cross-institutional data the CPR was seen as encompassing the hospital information system [2]. There seems to be some terminological confusion, e.g. with the terms "electronic medical record" (EMR) or "electronic health record" [5].

The term "information system" is often defined in a broad sense, e.g. "a system, whether automated or manual, that comprises people, machines, and/or methods organized to collect, process, transmit, and disseminate data that represent user information" (Inst. f. Telecomm. Sciences, U.S. Dept. of Commerce; [6]). The term "hospital information system" has been used similar to this definition [7], and the CPR has been described as part of, evolving from, or a byproduct of a hospital information system [8, 3, 9].

Without discussing definition questions, we will use the term health information system in a broad sense close to the above definitions. We will describe the development of health information systems since 1994, looking at it from the hospital perspective.

2. Major Trends in Healthcare and in Healthcare IT since 1994

Massive cost pressure has been a driving force for healthcare and healthcare IT during the last years. One consequence has been the development and introduction of coding systems and classifications, intended to make cases more comparable and allow for statistical analysis. Diagnosis Related Groups (DRG) and similar systems are used, or being introduced, in many countries [10]. Healthcare organizations are shifting towards integrated care. The merger of hospitals and individual practices into large integrated healthcare networks has been described as a dominant trend in U.S. healthcare [11], and the situation in Europe has been described as a decentralized network of health care delivery institutions that slowly replaces hospitals as centers of care delivery [12].

These organizational changes have had a major influence on hospitals, and they have added new challenges. While a trend towards open systems and object technologies has already been emerging during the '90s, institutional mergers and networks have made new concepts mandatory. The need for a master patient index has emerged in order to maintain a correct, non-duplicative list of patients [11], and matching algorithms to compare demographic information have been playing an important role [e.g. 13]; universal patient identifiers are being discussed in many countries [e.g. 14]. Clinical data repositories have been introduced to provide a single (real or virtual) shared record [11]. Open systems [s. 2, 3] remain a major challenge.

The functionality of clinical computing has developed in the direction foreseen in 1994 [1, 2]. The HIMSS 2000 survey has shown a high interest in clinical computing and in web technology [15]. Survey participants were asked to select the top five healthcare applications they considered most important over the next two years. Tabulation of the survey results (number of representatives of healthcare providers surveyed = 858) showed the following application categories as the most important:

Clinical information systems	71%
Web-based applications	70%
Clinical data repository	65%

The trend towards clinical computing and a patient-centered computer-based record can be seen worldwide [16]. As predicted, the hospital information system of earlier decades with its mainly administrative functionality has become much more focused on the clinical perspective and the patient record, while becoming more open in a technological as well as an organizational sense. It is now understood that data, not systems, is what counts [17, 18]. Moreover, the critical issue is people - not technology, and technology is the enabler, not the driver [16].

The technical infrastructure deployed in healthcare organizations has changed massively, and it has been a significant enabling factor. TCP/IP-based intra- and inter-institutional networks have spread. Hardware performance has grown, and prices have dropped further. Powerful networked PCs and PC-based servers are available in most health institutions. Government programs have contributed to the broad availability of computers in health care.

The success of the World Wide Web has added its own dynamics. Web access to clinical data repositories is used in a growing number of systems, and web interfaces to commercially available information systems exist or are under development. Most important, the web and its technology show the potential of supporting an advanced healthcare environment with secure health networks offering information to healthcare professionals and to patients, supporting logistics, and offering new kinds of application services. Having patient data available over secure intranets could improve coordination of care; linking healthcare institutions to trusted suppliers could improve the supply chain; and delivering care remotely where appropriate could offer new perspectives for both patients and caregivers.

A networked health environment raises questions of data security and confidentiality. The need for technology to support the secure exchange of confidential patient data is highlighted by legislation such as the United States' HIPAA (Health Insurance Portability and Accountability Act of 1996) [e.g. 19].

As more clinical data have become available in health information systems, multiple use of data has become more prevalent. Separate data warehouses are being added for analytical purposes to the operative (online transaction processing) databases [20]. Data originally collected for clinical purposes are being reused [21], and data mining techniques are being applied [22]. Legal issues have to be considered in this context, as well.

Further overviews can be found, for instance, in [16, 23, 24, 25, 26, 27, 28, 29].

3. Examples of Successful Systems

Success stories of advanced health information systems, often in academic sites, are not uncommon, and many important results have been obtained in this field. New technologies and expanding functionality have formed the basis for important evaluation results.

After the Harvard Medical Practice Study [30, 31] had shown that errors of omission play an important role in adverse events and that high complexity is a risk factor in clinical medicine, the great potential of information systems for preventing adverse events was demonstrated [32]. Leape has described system causes of errors in medicine and reported on measured effects of computer screening. He also reported that lack of information about the patient and lack of knowledge of drugs strongly influence serious adverse drug events [33]. The recent IOM publication on errors in medicine has provided an overview of errors and causes [34]. Among the IOM recommendations are to improve access to information and to implement physician order entry. It is important to conduct evaluations [35, 36] of health information systems, which have the potential to greatly affect the quality of care and its costs.

In this section, we will look at some of the systems mentioned in the 1994 yearbook article [1] in order to demonstrate that advanced functionality of health information systems did result in measurable effects on healthcare. More examples of successful systems could be added to the ones given below, e.g. [37, 38, 39, 40, 41].

In Europe, BAZIS has emerged from an experimental government-sponsored project to the commercial sector, becoming the leading hospital information system in the Netherlands. In order to offer users sufficient clinical content in the hospital database at an early stage, system development was not started with functions for finance and administration, which were added later. Focus was placed on patient information, and development began in medical departments in which a 'complete' work process could be supported. Extensive evaluations have confirmed the effects on quality of care and cost reductions [42].

The Diogene system in Geneva has evolved, and in 1999 a distributed architecture and a broad scope of functionality, including the use of Intranet technology for accessing and retrieving medical images, have been described [43]. In a European research project, a SynEx server (see below for more details) has been demonstrated.

In the U.S., the Regenstrief medical record system has been extended to store patient records at more than 30 clinics. The developers state “we believe that our success represents persistent efforts to build interfaces directly to multiple independent instruments and other data collection systems, using medical standards such as HL7, LOINC, and DICOM” [44]. The functional scope is broad and includes physician entry of orders, problems, visit notes, and discharge summaries. Physicians are provided with output forms, choice lists, templates, reminders, drug interaction information, on-line articles, and more. Rule-based reminders have been in use at Regenstrief since 1974, and significant effects on patient care have been shown [see 44 for references]. For example, reminders increased the use of preventative interventions up to four-fold. Also, the effects of physician order entry (POE) have been demonstrated [45]. From his experience, McDonald has identified major barriers [46] which we will discuss below.

The U.S. Department of Veterans Affairs (VA) has successfully worked on the online availability of images throughout hospitals. The Digital Imaging and Communications in Medicine (DICOM) standard [47] has been used to integrate image data objects from multiple systems for use across the healthcare enterprise. DICOM now forms the basis of most commercial Picture Archiving and Communication Systems (PACS), which are moving radiology departments towards a fully digital environment. The VA’s DICOM capabilities are used to interface different commercial PACS systems and numerous different radiology image acquisition modalities [48].

BICS, the Brigham Integrated Computing System, has demonstrated the effects of computerized order entry on improving quality of care [49]. Of the 15,000 orders written each day in 1999, about 400 were modified as a result of a computer reminder or warning. Alerts, structured ordering, checking for allergy and drug interaction , prompts for consequent orders, and adverse event detection are being used with good user satisfaction. Effects on outcomes, or at least direct effects of the intervention, have been demonstrated in a number of studies [see 49 for references]. Examples are the prevention of adverse events after safety interventions (warnings), and the display of laboratory charges resulting in massive savings through reduced lab utilization. An overall analysis of adverse drug events after implementation of order entry showed a dramatic reduction in events [50].

Evaluation of CCC [51](see also [8]) has shown a high intensity and extensiveness of use without coercion. Effects on quality of care and on financial factors have been shown. Similar to figures from other sites [e.g. 2], calculations show that information handling costs for CCC make up around 1.5-2% of the operating budget.

For the HELP system, highly important evaluations have been reported [52]. Besides showing good user acceptance of the system and its computerized decision support, studies have also documented the concrete impact of the information system on patient care. For example., in the field of antibiotics prescription, the use of reminders and an ‘antibiotic assistant’ produced, among others, a significant decrease in total hospital costs, length of stay, antibiotic costs, number of adverse drug events, and number of excess drug doses. Since 1991 [53], a series of studies has demonstrated the effects of the system in detecting potential adverse drug events and in detecting medication errors. The effects of other decision-support tools were reported in a 1994 summary [54].

Although HELP is a highly sophisticated, well-accepted system whose effects on the quality of care have been demonstrated, lack of a quick return on investment has been reported as one of the barriers to wider use. Because each clinical implementation step takes some time, and the more sophisticated applications depend on a robust and nominally complete integrated database, those applications cannot be implemented immediately. Further reported barriers to wider use of the HELP system are problems with culture and process changes, the need for vision and perseverance, and the need for high initial investment [52]. Such barriers are likely to prove a challenge to any implementation of health information systems. This leads us to the discussion of information processing problems, which are even more prevalent in the majority of hospitals that rely on less sophisticated systems.

4. Problems

Problems with health information systems exist, and we will present a number of them below.

4.1 Important questions of integration and data input are still unsolved

Several old and well-known problems remain relevant and, unfortunately, unsolved. The old discussion between “best of breed” solutions and “holistic” or “integrated” approaches is still very relevant [55]. Increased numbers of commercial special-purpose applications (pre-operative, respiratory care, departmental document management etc.) offer good solutions to niche problems but make enterprise-level integration difficult. More of these systems are actually being deployed, and often have strong departmental support and investment. This may complicate the integration problem, if the applications are not ready to interact with a (logically) unified data repository. As another consequence, single sign-on is still not generally available. The complexity of information systems in hospitals and health networks is still high. Users are exposed to different functionality and a different interface for each system. While solutions are being proposed that would hide these differences under a common interface [56, 57], the reality of clinical practice is still largely one of non-integrated applications. Finally, appropriate data input mechanisms and the adequate structure and representation of clinical data remain central issues. The critical mass of clinical data necessary for a system to be really useful is still one of the central problems.

4.2 The market remains volatile and few successful clinical systems have been deployed

Hammond listed commercially available hospital information systems in 1994. Newer market overviews have been published more recently [58]. Hammond already pointed out that the survivability of many systems was uncertain. It can be noted today that the market still shows volatility, and numerous mergers result in the need for combining products and adjusting strategies. For example, SMS was recently taken over by Siemens, which had been supporting a combination of SAP and Cerner until then. Eclipsys acquired TDS systems in 1997 and added them to previously acquired systems.

While the HIMSS 2000 survey [15] showed a high interest in clinical computing, responses to the question of whether a CPR is already operational painted a less optimistic picture. The following data show changes in response after one year (the numbers of healthcare providers surveyed in 1999/2000 were 769/858):
We have begun to install CPR hardware and software:
32% in 1999, 29% in 2000.
We have a fully operational CPR system in place:
11% in 1999, 12% in 2000

Slack and Bleich have stated that, to date, the computing in too many hospitals is of little use to the clinician [51]. For Europe, Iakovidis [12] has reported that few hospitals have integrated their administrative systems with clinical information systems. Dorenfest has come to a pessimistic view for the U.S. [60]. According to him, the massive CPR investments resulting from influencing factors such as the IOM study of 1991 [4], the integrated delivery model, managed care and community health information networks, have not accomplished their objectives: “While the vision of the CPR continues to be appropriate in 2000, faulty implementation in the ’90s caused the healthcare industry to further weaken its work processes by building in another layer of redundant systems”.

Physician Order Entry (POE) has been proven to be one of the leading functionalities of health information systems for improving health care and reducing costs. Nevertheless, a survey of a systematic sample of 1,000 U.S. hospitals showed a relatively low use of computerized POE systems [61]. Only 32% of responding hospitals had POE completely or partially available, and usage by physicians and percentage of orders entered through POE systems were low.

Haruki et al. [23] add to this picture that no more than approximately 20% of Japanese hospitals are using order entry, and that one of the major effects of hospital information systems was a reduction of office work.

A study conducted by the Kaiser Permanente health maintenance organization in 1998 did show positive attitudes of physicians towards both result reporting and order entry, but physicians attributed higher benefits to result reporting [38].

4.3 It is difficult to demonstrate return on investment; health IT suffers from lack of funding

Obviously, the benefits of IT in healthcare are still extremely difficult to quantify. Answers to the HIMSS 2000 survey [15] show that it is difficult to provide quantifiable benefits and return on investment, and that consequently, IT is suffering from a lack of adequate financial support. The following data show the top ranked answers to the question “What is the most significant barrier to successfully implementing IT in your department/ facility/enterprise today?” from the HIMSS survey in the year 2000 (n = 858 answers):
Difficulty in providing IT quantifiable benefits / return on investment: 22%
Lack of adequate financial support for IT: 19%
Difficulty recruiting and retaining high quality IT staff: 15%

Stead’s and Lorenzi’s [62] arguments point in exactly the same direction. While healthcare providers accept the need for an information system to a certain degree, they are not convinced of its strategic importance: “Health care does not appear to explicitly value information. The tie between information and improved financial outcomes has not been established. Where are the examples of health systems that have overwhelmed their competition through strategic application of information technology?"

The above mentioned Japanese study by Haruki et al. [23] found that, in general, the effect on improvement of costs and benefits had not met the expectations of the hospitals surveyed.

For Europe, Iakovidis reported that health IT suffers from a lack of financial support. This is shown by the low percentage of the budget spent on information and telecommunication technologies in different sectors [12]: $5,000 per employee in the financial sector, $1,500 per employee in manufacturing, and only $400 per employee in the healthcare sector.

4.4 There seem to be more failures and concrete difficulties than the success stories suggest

While the majority of reports have focussed on successes, there is evidence of surprisingly frequent failures. Berg [63] speaks of "the fact ... that most applications to date have failed", and Anderson reported on high numbers of failures [64, 65].

In a remarkable article, Tonnesen et al. [66] report on problems from an academic hospital when an EMR system was introduced. They identified organizational problems, e.g. "Finding time in a business for training ... was very difficult", "Weaknesses in training magnified the load on the help desk", and "Clinical users do not complain or use the help desk...". Interestingly, the authors reported technical problems such as insufficient level of software development despite extensive pre-negotiation evaluation, and insufficient performance despite the vendor's contractual commitment to response time.

Although this is a single report, the question arises of whether the problems it describes might be typical. Iakovidis has described similar user complaints concerning slow response time, time-consuming login-procedures, and non-intuitive data input [12].

After decades of development, experiences, and successes, we have to face the fact that health information systems at a majority of institutions are far from the stated goals of supporting healthcare through advanced clinical computing and an electronic health record.

5. Core Challenges and Possible Solutions

In this section, we identify core aspects underlying the above problems and summarize possible solutions.

5.1 Integration and standardization

Integration is still central for health information systems. Healthcare institutions need timely patient information from various sources at the point-of-care, and they would like to buy a comprehensive, complete and fully functional system fulfilling all their needs from one vendor. At the same time, however, domain-specific "best of breed" solutions show advantages such as a better adaptation to users' terminology and processes. Consequently, specialized systems are being used broadly and the resulting heterogeneity remains a key problem. McDonald [46] described lack of integration as one of the core problems: "the sources of electronic patient information that do exist … reside on many isolated islands".

Integrating heterogeneous system components requires consensus on different levels. Available software products differ in functionality, presentation, and terminology. The data processed differ in representation and semantics. Thus, application integration covers different aspects, such as ubiquitous data access, consistency, and a single system image [67]. In order to clarify integration challenges, at least the presentation, functional, and data layer need to be considered separately [68]. System autonomy is at the roots of heterogeneity. It is useful to distinguish between design autonomy and execution autonomy. Design autonomy stems from the independent design of applications, and produces incompatible data models, query languages, semantic interpretation of data, and functions. Execution autonomy indicates that the execution order of local operations is not controlled by a foreign system, which makes synchronization of related data in different systems difficult.

Today, different autonomous systems typically communicate by exchanging messages. If the systems to be interconnected use standard interfaces such as HL7, the problems with semantic interpretation of data can be reduced to some degree. Management of large-scale interfaced systems is difficult, because the number of interfaces grows with the square of the number of systems to be interconnected. Using an interface engine (also called communication server or mediator service) to handle messaging between different systems is a common approach to simplify management of interfaces. Instead of directly interconnecting different systems among each other, each system is connected to the interface engine, leading to linear growth in the number of interfaces as the number of connected systems increases. Commercial products such as Cloverleaf (Healthcare.com, Marietta, GA) or Datagate (Software Technologies Corp., Arcadia, CA) offer graphical tools that support mapping of different interfaces (e.g., by defining translation rules), routing of messages, and some monitoring functionality. However, interface engines alone cannot solve the problems of semantic incompatibility and limited synchronization of related data in different systems.

Typical examples of co-existing systems are a central administrative/

billing application (sometimes still incorrectly called the “hospital information system”) communicating with other systems such as the laboratory system, the radiology system, and systems in clinical departments. Unique patient identification is mostly provided by a “leading” system.

A common approach to integration is to collect and replicate data in a physical data repository. This repository may belong to the “leading” system or to a dedicated system. Often, so called “computerized patient record” systems provide a physical data repository. In any case, this approach requires translation of data from different sources into one common database schema. The prevalent implementation method is to use existing HL7 interfaces. Results of an HL7 message are delivered to the repository database, where they can be retrieved by different systems for different purposes. Adding a new system into this environment requires implementation of functionality to handle the replicated data (e.g. to display the results delivered and replicated from a clinical subsystem).

An alternative to the physical repository is the virtual data repository approach, which is characterized by implementing an additional layer on top of existing operational systems that enables transparent access to these systems. The original data are still generated and stored within the operational systems, but can be accessed via a unique user interface capable of displaying data from different sources. While the physical data repository is still predominant, the virtual repository approach is seen more often recently; but again, the use of a repository does not solve the problems resulting from semantically conflicting data from different sources.

The introduction of web technology has resulted in a somewhat modified picture. The use of web browsers for clinical workstations is attractive, as browsers offer a simple and intuitive user front end. The feasibility of building web interfaces to clinical information systems has been shown in 1996 [69], and reports of successful projects followed. WebCIS is an example of implementing a web server atop a clinical information system architecture with a central data repository [70]. The W3-EMRS project has explored web technology as a framework for integrating heterogeneous information systems, and a web-based virtual repository approach has been successfully implemented. [71, 72].

Web technology does not solve all the problems, however. The limitations of HTML, such as limited data types, simple interaction model, no representation of the data model, and resulting consequences like need of high computer power and network speed were summarized by Wang et al. [71]. Kohane et al. have also described the problems resulting from heterogeneous schemas [72]. Similarly, Teich [11] found that browsers had been effectively used for display applications such as results review, but had been less effective for highly interactive applications. Many of the same limitations in web-based user interfaces still exist today; Nadkarni et al. [73] describe the complex solutions required to support functionality that could be implemented easily in conventional thick-client environments. Java is used to supply the necessary application functionality, but performance and security concerns are limiting factors. To date, unfortunately, the approach has typically resulted in a “least common denominator” feel for most web applications in the field of health information systems.

While HTML as a presentation language lacks the ability to capture semantics, XML offers a syntactic framework to describe the semantic structuring of documents through user definable tags. The Document Type Definition (DTD) can be used to specify which tags may be included into an XML-document and the valid arrangements of these tags. XML seems to be becoming a dominant format for data interchange, but the task to be solved for systems integration will be to find a common basis for medical concepts described by standardized tags and DTDs. As an example, the EU project “Intranet Health Clinic” has created web-accessible patient-specific documents using XML, where the approach has been based on a common information structure, and component databases have to adhere to this structure [74].

Internet technology with HTML and XML has improved consensus on technical and syntactical questions. Web technology provides ways for building a user-interface layer. Central issues, however, are to achieve consensus at the data and at the application level. The challenges of open systems and of interoperability have been discussed in the IMIA WG 10 conference [3, 2]. Interoperability means the ability to exchange both data and services [75].

“Classical” database terms are commonly used to characterize data and their structure: the schema describing entities and their relationships has to be viewed separately from the data instances, which may be medical terms. From a more generalized viewpoint, ontologies capture domain models by describing classes of concepts and an organizing framework among these concepts formally. Conventional controlled vocabularies concentrated on describing the instances of classes [76].

Ontologies allow software developers to formally describe the underlying concepts of an application domain. Stead et al. [77] present a perspective of future systems using formal ontologies that can be interpreted by generic plug-in components. Falasconi et al. describe a concept of distributed agent based systems with a central ontology server that supports interoperability among systems with possibly different ontological foundations [78]. A formal description of concepts helps translating between different ontologies, but will not consistently merge incompatible ontologies. Thus, consensus on ontologies will be a key element to integration [67].

Object-based middleware architectures such as OMG/CORBA and COM/OLE have been introduced to provide a generic infrastructure for interoperation [79, 80, 81]. In the object-oriented paradigm, objects, the behavior of which is determined through methods, interact by sending messages, and implementation details are hidden. An object request broker mediates requests between clients and object implementations, which includes identifying objects, delivering requests, and finding the required methods. Developers can rely on application objects and concentrate on their functions regardless of the implementation [79, 80]. Spahni et al. characterized these architectures as “second generation” middleware [81]. Increasingly, domain-specific generic services are being provided as a “third generation”, which may be built on top of second generation middleware. CORBAmed, HL7 and HISA [82, see below] make use of these middleware approaches.

The CORBAmed initiative [83, 84, 85] is working on domain-specific services for the medical environment; a Patient Identification Service (PIDS), a Lexicon Query Service (LQS) and the Clinical Observations Access Service (COAS) have been specified: the Clinical Images Access Service (CIAS) is being finalized. The latter is intended to also provide the basic services of DICOM.

HL7 has started to use the XML syntax for embedding HL7 messages [86]. An important step towards standardization of semantics, however, could be the HL7 Document Patient Record Architecture [87]. The idea is to create a common data architecture for the interoperability of healthcare documents which is specified in XML. The semantics are drawn from the HL7 Reference Information Model, and the document specifications form an architecture that, in aggregate, defines the semantics and structural constraints necessary for the exchange of clinical documents. HL7 is also working on object brokering technologies (now called component based messaging) in order to implement HL7 over CORBA and OLE. [88]. HL7 version 3 will include both the Patient Record Architecture for clinical documents based on XML, and support of component technologies [89].

There are several EU projects contributing to standard architectures. The Synapses project [90] has specified an object model and an object dictionary, as well as access methods for a federated health care record, and it has led to a European Health Record Architecture standard (prENV12665, now prENV 13606-1) for sharing healthcare data.

The HISA project [82] has worked on the definition of generic medical services, building on predecessor work such as RICHE which introduced act management [91] and Helios which introduced a software bus [80, 81]. The DHE, the distributed healthcare environment, is an implementation of the HISA standard ENV 12967-1 (CEN/TC251) “Healthcare Information System Architecture”. The idea is to provide an open infrastructure to federate and thus integrate heterogeneous multi-vendor applications which interact through a set of common healthcare-specific components. The intermediate DHE layer of generic services is positioned between a more specific application layer and a basic technological platform layer. The SynEx project [92, 93, 94] is set out to combine the results of HISA, Synapses and also GALEN [95], which provides a generic terminology server. The use of XML in SynEx has been reported [96].

Altogether, there is overwhelming consensus that standards are essential for solving the integration problem [46, 2, 12, 97]. IMIA WG 10 has identified problems with the standards-making process such as lack of funding, lack of qualified people, poorly defined objectives, limited recognition and awards for people developing standards, and poorly defined processes. The development of a strategic plan has been proposed to remedy these problems [2].

Patterson and Huff have recently commented on standardization efforts: “The key for standard committees is to find the narrow line between developing superior but difficult-to-implement standards and exploiting imperfect but functional strategies that build upon existing systems” [98]. Berg has argued in the same direction: “powerful technical systems comprise ... artful integrations between working practices and new and old devices ... Such integrations should be allowed to emerge rather than be brought about through enforced revolution ... This is even true for such seemingly technical and elementary issues such as standards” [63].

5.2 Human-computer interaction and the structure of data/information/knowledge

Iakovidis noted that users complain about unfriendly systems, and about non-intuitive data input [12]. McDonald considered problems with data input as one of the major barriers to EMR systems [46]. Anderson added the important observation that the content, sequence and format of information entered reflects the individual's practice style [65]. This leads to a two-fold underlying problem: interface design and structure of data.

To optimize the design of human-computer interaction, concepts are needed, and they should be based on further formal studies. Among the important results available are the studies of Poon et al. [99] who evaluated how interface designs were accepted, and of Sittig et al. [100] who formally studied physician satisfaction regarding user interactions. The HELIOS project has suggested a style-guide for designing interfaces [101].

Human-computer interaction also depends on technology. There is a broad consensus that response time is extremely important, whereas real world systems do not seem to have solved the problems [12, 66]. Flexibility and adaptability of applications is another major remaining challenge. Work on new modalities and technologies such as wireless, hand-held, and speech recognition is important and looks promising, [99, 102, 103, 104, 105, 106], but there is no real breakthrough yet.

Much important work has been performed in the fields of terminologies, vocabularies, and ontologies [107]. When structured data are to be entered into a computer, the chosen terminology is influential on data input.

In his description of work on GALEN, Rector stated that "the claims of this paper are that clinical terminologies bridge the gap between language, medicine and software" [95], and he also [108] gave reasons why developing terminologies is hard, stating that problems stem from underestimating the change entailed in using terminology in software for 'patient centered' systems. Rossi-Mori et al. summarized standards to support development of terminological systems for healthcare telematics (e.g. prENV 12264), and described three generations of terminological systems: traditional terminological, compositional, and formal [109]. Different nomenclatures, classifications and coding systems are coexisting in health information systems (e.g. ICD9-CM, ICD10, MeSH, READ Codes, SNOMED international, and UMLS [80]). Moreover, institutional and/or application-specific controlled vocabularies are in use. This leads to the problem of matching ontologies outlined above [67, 77, 78, 80]. But also, structured data entry and structured presentation depend on the underlying terminology/ontology: GALEN-IN-USE is building a structured clinical user interface, thus exploiting new technology for model-based interface applications and making use of the GALEN technologies [110].

The Medical Entities Dictionary (MED) is an example of successful use of a pragmatically constructed ontology. The MED defines all coded data stored in the database, translates between application coding systems, and provides a classification hierarchy and semantic relationships that simplify coding and vocabulary maintenance [111]. In WebCIS, spreadsheets are available as part of the user interface. Users may define and request new spreadsheets. These are not hard coded, but are defined in the MED, and a knowledge engineer can quickly incorporate changes on requests [70].

ORCA is an ongoing project supporting structured data entry through a dynamic interface based on a knowledge graph [112]. Melles et al. [113] have implemented a point-of-care data system with structured data entry, and tried to design the interface from the clinician's perspective. After a one-year period of routine use with more than 18,000 encounters and over 40,000 entries, they found positive results concerning use and acceptance. Interestingly, they found that in their limited subset of visit information, structured data entry took less time than entry of free-text [113].

In his description of barriers to electronic medical records [46], McDonald stated that entering structured data requires more user time than entry of free-text information, as the user has to map his concepts into the computer's concepts and spend time on searching for the "right" computer code. This corresponds to Anderson's [65] somewhat more global perspective of medical records reflecting the clinical reasoning process and also an individual's practice style, whereas computerized record systems tend to bring a loss of these individual characteristics.

Both observations can be put into the perspective of Coiera's use of the "common ground" notion [114]. As long as there is insufficient "common ground" between the physicians' thought processes and the knowledge structure underlying the human-computer interaction processes, computerized systems tend to be perceived as counter-intuitive, and data entry can be very time-consuming. On the other hand, intensive involvement of physicians in creating "their own" structured terms, and adaptation of a system to the clinical work practice, could explain why structured data entry may be well-accepted and not necessarily slow [113, 115].

5.3 Socio-technical and organizational issues

Socio-technical and organizational issues are of central importance for information systems. Anderson found that several decades of experience with computer-based information systems have made it clear that the critical issues in the implementation of these systems are social and organizational, not solely technical [65]. Lorenzi and Riley presented a list of different reasons for failure related to various organizational issues [116]. They cited Reed Gardner's estimate that the success of a project is perhaps 80 percent dependent on the development of the social and political interaction skills of the developer and 20 percent or less on the implementation of the hardware and software technology.

Lauer et al. [117] suggested (1) analyzing possible benefits and stresses from the perspective of the user, (2) considering fairness in relation to the employer in sharing gains or losses, and (3) comparing perceived changes by individual users with the effects on other users or user groups. The second point is especially important when the perception is that data collection only serves administrative or management purposes (e.g., DRG-related coding). McDonald has added the observation that much of the data needed by managers and outcome analysts are not provided in the current physicians notes [46].

Lauer et al. make the important assumption that there is no fundamental or irrational resistance to change [117]. While some irrational reluctance of physicians (especially of senior physicians with little computer experience) seems to be commonly used as an explanation for problems or failures, there is evidence that Lauer's assumption is reasonable. It is confirmed by Anderson's results who stated that "three decades of experience provide evidence that physicians generally accept applications that enhance their ability to manage patient care, but tend to oppose applications that automate clinical activities they perceive as primarily benefiting the organization" [65]. Anderson also identified the users' perceptions of usefulness and of the effects on their professional work as influencing factors [65]. In a highly interesting investigation, Gremy et al. have shown [118] that resistance to change was not a systematic or fundamental behavior: "as long as innovation is brought in and promoted by colleagues, identified as an internal process belonging to the profession, it is felt as a bonus for personal values and as a support for professional interests ... on the other hand, when change occurs from an external origin ... it is felt as a coercion ..."

Adaptation to the work practice, the workflow, and to the users' terminology is important. Berg [63] warns of replacing a "seemingly messy work culture" by the "rationality" of computer-based systems, and points out that health care professionals' work is highly skilled and pragmatical.

Coiera's [114] use of the psychological notion of common ground appears to be helpful. While common ground originally refers to the knowledge shared by two communicating agents, Coiera has extended it from (modeling) human interactions to human-computer interaction, and he has called for communication research to better understand basic principles of this interaction. The system designer and the user have to move towards common ground, when an information system is being designed and deployed. Typically, the system designer creates "his" model of how the application interacts with and fits into the user's domain, while users coming from a completely different background have to develop an interaction model based on the designer's decisions. As building common ground takes time for the involved agents, it has to be decided when and how to optimally build it. For the design of information systems, the conventional approach has been to model a system completely before implementing it; this is now changing towards interactive approaches that involve rapid prototyping. An evolving conceptual challenge is to increase the system's flexibility in order to allow personalization of the interaction [114].

Well-adapted systems, however, need not necessarily be complex: simpler systems fitted well into the clinical work process may be successful, as reports from departmental solutions have shown [e.g. 119]. Berg [120] has warned of overestimating the self-sufficient powers of IT, and of overlooking the skills already present in the work practice. He argues that sometimes a more 'dumb' solution could be cheaper and easier. This is important; it might, however, lead us back to the question of how to integrate locally optimal "best of breed" solutions. Therefore, in the design of systems, the overall perspective still has to be considered.

The "paradox of expertise" described by Friedman and Wyatt should be mentioned in this context: "Users typically cannot articulate which information they use to perform day-to-day tasks ... and are unable to imagine how computer-based techniques might improve its quality or availability" [121, p. 46]. This "paradox" describes one of the major difficulties in gaining common ground in the field of health information systems, and it clearly illustrates the massive need of extensive user participation in system analyses and in deployment as advocated by many authors, e.g. Anderson [65] and Berg [120].

5.4 Processes in healthcare

From the above, the need for optimally adapting information systems to workflow in healthcare institutions has become evident. We will now summarize this point briefly.

Leape has pointed out that most errors in medicine result from defects in the systems in which we work, and that these are failures in the design of processes, tasks, training, and conditions of work. Specifically, wrongly designed workflow may increase workload and time pressure for users [33].

Health information systems have the potential of increasing or decreasing workload. The challenge is two-fold: to adapt information systems to work practice and workflow, and, furthermore, to reduce workload and ideally to simplify workflow. Exactly in this sense, Sittig et al. [100] have stressed the need of tailoring a system to optimize the clinician's workflow. Similarly, Teich et al. have advocated enhancing the workflow for the physician's benefit [122], and Dorenfest predicted that growing emphasis will be placed on improving work processes, simplifying workflow, and reducing redundancy [60]. Berg [63] has warned of a common mistake: looking at workflow in a mainly rationalist and technology-centered way, and obstructing work tasks by too much pre-fixed structure. He emphasizes the need to address cooperative work processes instead of discrete tasks.

As shortly described, there are conceptual and technological difficulties in providing integrated information systems that are intuitive to use. Workflow management systems are intended to specifically address the problem of modeling and supporting workflow. Unfortunately, they are far from really offering sufficient solutions for healthcare [123, 124].

Distribution adds to the complexity. One of the key difficulties in today's healthcare systems is the fact that important relationships among the participants are only implicitly represented, if at all. For example, information about individual episodes of care is usually spread among multiple systems. It is particularly difficult to establish the relationship among the care providers who participate in an episode of care, the patient, and other providers who may have a legitimate need to access the records resulting from the episode. This complicates any reporting, alerting, and access audit activities. The inter-personal relationships mentioned above are essential components of an organization's knowledge, but are almost universally only available as "collective memory".

The internet with its promises to support logistics and "e-health" might be a key component towards better availability of information in the care process. Open systems based on powerful standards might improve integration, while flexible and generic software architectures might allow for better adaptation to medical workflow. But it is clear from the problems and challenges summarized above, that adaptation of information systems to intra- and inter-institutional processes is still a major problem with both a socio-technical and a technological dimension. Thus, new concepts for health information systems suitable to the (distributed) health care process are needed.

6. Concluding Remarks

For health information systems, there are successes, failures, and major challenges.

Integration is still a central task, resulting in the need for standards. During the past few years, standardization efforts have made important steps forward. HL7 is a promising example of a well-accepted pragmatic approach, which is further developing towards standardization of semantics and towards implementation of object-based technologies. CORBAmed and HISA are examples of powerful generic solutions on the way to interoperability. The broad acceptance of web standards such as XML has led to their integration into the ongoing standardization process. Approaches may be either primarily "bottom up" such as HL7 (which started on a pragmatic consensus level) or more "top down" (starting from concepts) such as the EU standards. Fortunately, approaches and understanding have begun to converge, and "open" health information systems have come somewhat closer to reality. Distributed health care and the Internet have added opportunities and challenges, but there is no comprehensive concept yet of how distributed health information systems will effectively support health processes on a large scale.

Human-computer interaction is often perceived as unsatisfactory, and it is important to note that underlying problems related to health care have been better understood in the last few years. Consequently, a major focus of research has shifted towards socio-technical and organizational issues. Reasons for contemporary system failures have been identified [116], and Coiera has called for exploration of the communication space [114]. A better adaptation of computer systems to the work practice and terminology of the health care environment is needed; this issue still poses major conceptual and technological questions.

Many important results have become available, but their translation into working every-day applications still requires much closer partnerships between healthcare professionals and industry. R. Miller states that "Informatics is not a spectator sport" [125]. To be successful, crucial components such as POE require a huge political investment within each health care institution. HIS champions must be able to work with all levels of the organization, collect and provide constant feedback to the different constituencies, and (importantly) document the experience – both positive and negative – as collective organizational memory. Otherwise, the next unit to be implemented runs the risk of being as big a battle as the unit just finished. Unfortunately, vendors sometime do not understand this, and think they are in the shrink-wrapped software business.

Stead and Lorenzi [62] have proposed a list of “wins” that might best support further investment. They suggest developing tools that can be generalized and scaled, increasing research on the utility of Internet health resources, and investing in existing resources. One of their central points is the use of logistics to improve quality. “The goal for any enterprise can be stated as getting the right thing done, the right way, at the right time, by the right person.”

Health information systems must face the challenges outlined above, and joint efforts of all parties involved in the health care process are needed to improve, implement, and evaluate those concepts.

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