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Editorial

An Ontology of Quality Initiatives and a Model for Decentralized, Collaborative Quality Management on the (Semantic) World Wide Web

Gunther Eysenbach, MD

Corresponding Author:
Gunther Eysenbach, MD
University of Heidelberg
Research Unit for Cybermedicine & E-health
Department of Clinical Social Medicine
Bergheimerstr. 58
D-69115 Heidelberg
Germany
Email: ey@yi.com

Abstract

This editorial provides a model of how quality initiatives concerned with health information on the World Wide Web may in the future interact with each other. This vision fits into the evolving "Semantic Web" architecture - ie, the prospective that the World Wide Web may evolve from a mess of unstructured, human-readable information sources into a global knowledge base with an additional layer providing richer and more meaningful relationships between resources. One first prerequisite for forming such a "Semantic Web" or "web of trust" among the players active in quality management of health information is that these initiatives make statements about themselves and about each other in a machine-processable language. I present a concrete model on how this collaboration could look, and provide some recommendations on what the role of the World Health Organization (WHO) and other policy makers in this framework could be.

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KEYWORDS

Semantic Web; Resource Description Framework; World Health Organization; Internet/standards; Ethics, Professional; Social Control, Formal; Health Care Quality; Quality Assurance; Health Care/standards; Commerce/standards; Information Management/standards; Medical Informatics/standards; Quality control

> *"An ontology is a specification of a conceptualization, i.e., a formal description of the concepts and their relations for a universe of discourse." [1]*

In this issue of the Journal of Medical Internet Research, Risk and Dzenowagis present a review of quality initiatives of health information on the Web [2]. This review will be a useful starting point for anybody interested in this field, with the limitation that it is not a systematic review meant to cover all relevant initiatives worldwide (see Textbox 1 for some additional initiatives not mentioned in the report)

The review raises a question about how the different initiatives relate to each other and how they could play out their potential for synergy to benefit consumers and users. The following article shall provide a framework and an abstract model of how these initiatives may in the near future interact with each other. While there have been many calls for collaboration between the existing initiatives, I will present a concrete schema on how this collaboration could look and also what the role of the World Health Organization (WHO) and other policy makers in this framework could be.

Textbox 1. Additional initiatives not mentioned in the review

The report of Risk and Dzenowagis [2] focuses on 13 selected initiatives that are most visible in the Western world (eg, through publications and participation in international meetings), namely:

- eHealth Code of Ethics
- Health Internet Ethics (Hi-Ethics)
- URAC Health Web Site Accreditation Program
- MedPICS Certification and Rating of Trustworthy and Assessed Health Information on the Net (MedCERTAIN)
- TNO Quality Medical Information and Communication (QMIC)
- Health on the Net Foundation Code (HON Code)
- EC (European Community) Quality Criteria for Health-related Websites
- Organizing Medical Networked Information (OMNI)
- DISCERN
- American Medical Association (AMA): Guidelines for Medical and Health Information Sites on the Internet: Principles Governing AMA Web Sites
- British Healthcare Internet Association (BHIA): Quality Standards for Medical Publishing on the Web
- The Health Summit Working Group-Criteria for Assessing the Quality of Health Information on the Internet: IQ Tool (HSWG IQ Tool)
- The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Code of Marketing

Some additional initiatives are worth mentioning, for example:

- Third-party certification programmes:
  - the Japanese "JIMA mark" [3],
  - the Verified Internet Pharmacy Practice Sites (VIPPS) certification mark of the US National Association of Boards of Pharmacy [4]
  - the Web Médica Acreditada initiative of the Medical College Barcelona
- Third-party annotators and gateways, such as HealthInSite or Healthfinder
- Groups and organizations active in promoting quality standards or codes of conduct, eg. national health-information-provider associations such as *Aktionsforum Gesundheitsinformationssytem*(AFGIS) [5] or AMIDI in Germany [6], the American Health Information Management Association (AHIMA) [7] or the European Federation of Pharmaceutical Industries and Associations (EFPIA) [8].

The Journal of Medical Internet Research encourages these and other initiatives and organizations not yet listed here to submit letters or articles to present themselves.

"Why bother at all? We don't care about the quality in other media either"

One frequent question asked is why we should look at quality issues on the Web at all: there is also misinformation in other media where we seem to do little to ascertain the quality. Risk and Dzenowagis also quote the argument that "Traditional media did not require quality standards; therefore neither should the new media." However, I can see at least 4 reasons why this is not a convincing argument:

- First, the fact that we have not done something in the past is hardly a sufficient argument for not doing something in the future. The quality of patient education and consumer health information has been a neglected field over the past decades, and this should not be an argument for continuing this negligence.
- Second, it is simply not true that nothing is being done in traditional media, as there are quality standards and codes of conduct for traditional media as well; there are also evaluators guiding us to high-quality information such as television guides, and book reviews; there are also organizations that for example certify printed patient-information leaflets.
- Thirdly, there are several characteristics of the Internet which make information and communication over this medium "special" and attention to quality issues necessary, in particular:
  - (1) lack of quality control (editorial boards) at the stage of production is more prevalent than in traditional media *;*
  - (2) the extremely cheap publishing process makes it easy to publish without the need to make revenue, thus without the need to stick to highest publishing standards;
  - (3) dubious and alternative medicine products are now primarily offered on the Internet;
  - (4) a " *context deficit*", leading to the situation that information does not necessarily have to be false to harm [9];
  - (5) enormous reach, with the potential to affect the health of large populations;

- (6) interactivity, leading to higher involvement of the users and perhaps a greater impact on individuals;
- (7) users retrieve information "just-in-time" and are more likely to apply it immediately. Unlike information in other media, which often is encountered by consumers only by chance, users on the Web mostly retrieve information "on demand"-when they need a piece of information, they type the respective search terms into a search engine, and are likely to act immediately upon the information they searched for.

- A fourth reason - and perhaps the most important - is that the Internet is not a static medium such as a patient leaflet, a newspaper, or a book, where once a person has obtained misinformation there is little health professionals can do to complement or rectify this information. On a decentralized, electronic medium, intelligent systems can automatically give additional information about the information from other sources to the consumer, or help in guiding consumers to the best-available evidence. In the future, people will use intelligent browser plug-ins for "knowledge based" Web-browsing, as well as intelligent software agents that retrieve information using metadata (data about data) harvested from the "semantic" web. It is this vision I am going to dwell on in the following.

The need for intelligent "next generation" tools

The common, overarching aim of any quality initiative is the desire to "help people, patients and professionals to identify health information useful to them" [10]. As the Risk and Dzenowagis review shows, there is a lack of reliable and valid tools that can be used by consumers or professionals to locate trustworthy health information. Neither questionnaire instruments such as DISCERN nor "kitemarks" (in the form of simple seals or logos) provide appropriate and sufficient ways for consumers to assess the trustworthiness of information (letting alone the problem that some consumers may ignore or not have the skills to look at and interpret the correct quality markers). Kitemarks and questionnaire instruments very much come from traditions outside of the Web and do not harness any of the advantages of the Web as a decentralized information system. There is a need for "next generation" tools, intelligent knowledge-based tools, allowing consumers to positively identify reliable health information suitable for their needs, such as intelligent agents or client-side advisory systems for people. These intelligent tools will be able to aggregate and process statements (descriptions, annotations and ratings) made by a variety of actors and integrate them with the individual preferences of the user, thereby harnessing the power of the Web as a decentralized medium. These statements (descriptions, annotations, and ratings) are essentially "data about data", or "metadata" (for an excellent introduction into metadata see [11]), and they are the prerequisite for forming the semantic web, which "will bring structure to the meaningful content of Web pages, creating an environment where software agents roaming from page to page can readily carry out sophisticated tasks for users." [12]

The actors

Many individuals and organizations ("actors") from the health care field have become interested in the topic of quality of health information on the Internet. This interest usually arises out of one or more of the following motivations or perspectives:

- An individual or organization is (or wants to become) a "health information provider" ("first party"). Health information providers are usually interested in providing health information or services on the Web according to the highest-possible quality standards, and want to know what quality criteria they should adhere to, eg, what information they should disclose, and whether or not they act in line with generally-accepted quality guidelines or codes of conduct. These individuals or organizations may also be interested in using quality as a marketing argument, eg, by displaying to the user that they adhere to these standards, especially if the health information provider hasn't yet established a brand name which the user associates with quality. Ideally, this quality mark is not self-awarded but indicates that an independent party (a "third party," see below) has confirmed adherence to predefined standards.
- An end user ("second party") wants to know whether or not to trust information, and wants to know what quality criteria or quality marker he or she should look at.
- An independent individual or organization ("third party") feels special responsibility or has special expertise and knowledge to endorse, evaluate, validate, certify, recommend, approve, peer-review, comment on, or annotate information or services provided by health information providers (or other actors). These third parties could be, for example, gateways, libraries, portal sites, or certifying institutions.
- An organization or association (*group*) of health information providers ("fourth party") wants to set up a code of conduct or guideline, eg. because it has responsibilities for its members and wants to set-up guidelines or codes of conduct for these members to comply to.

In practice, each of these actors can have one or more of these roles simultaneously, for example, an evaluating third party can be identical to the actor that sets up codes of conduct (fourth party).

The framework

I now describe some of the roles these actors can have in a decentralized "health information quality management framework." In Figure 1, this framework is depicted by illustrating the actors or other concepts as nodes (in the description below the nodes are in italics) and the relationships between the actors as arcs (underlined).

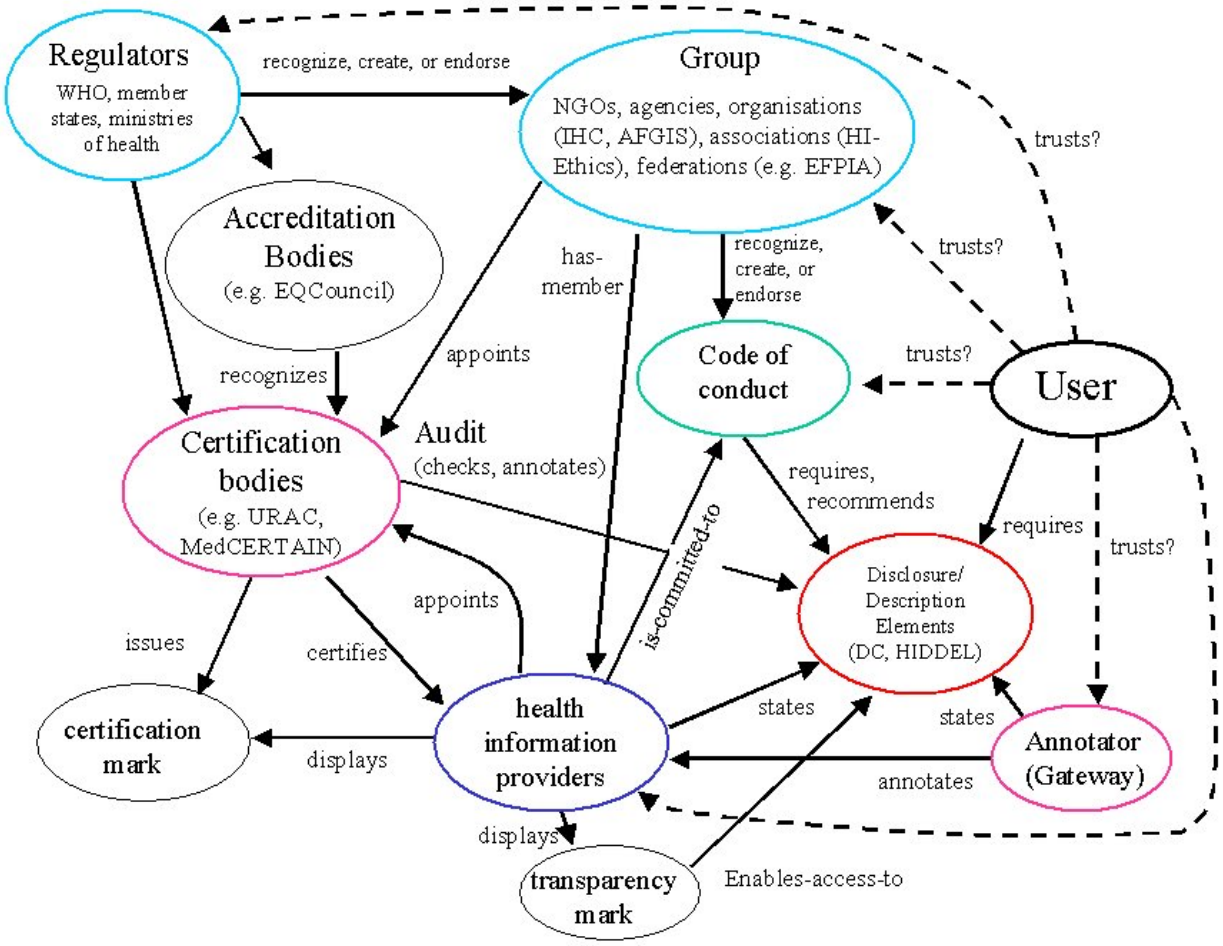
In this framework, there will be the following concepts and relationships:

- *health information providers*(blue) which are for example "committed-to" a set of *codes of conduct*, ie, to a standard, or guideline (green). For instance, a *health information*

provider could be committed-to the eHealth Code of Ethics [13]. At the same time, health information providers adhere to the disclosure and transparency recommendations in these codes of conduct by making certain *statements* about themselves. These statements (for instance, a disclosure statement about who the sponsor of the site is) can (and should) not only be expressed in "narrative" form, but in a standardized, machine-readable form.

- *groups*(light blue), ie, organizations or associations, which can "have-members." Groups are, for instance, associations, federations, or other organizations (eg, Hi-Ethics, AFGIS, IFMPA/EFPIA); their members usually are *health information providers*. The group as a whole may create or endorse *codes of conduct*(green), implying that their members are supposed to stick to this standard.
- these *codes of conduct*(created or endorsed by a group) in turn contain items that may, for example, prescribe the existence of certain d *isclosure and description elements* on a Web site (such as the disclosure on who the sponsors are), or meeting certain other requirements such as a maximum response time for email requests, the recognition of another body (eg. licensed cyberpharmacies) etc.
- *groups* or individual *health information providers* optionally may appoint external *certification organizations* that may give additional assurance to users, to the health information providers themselves, or to the groups representing health information providers, that their members actually stick to their self-prescribed standards. An audit by a third party may be a necessary "enforcement" mechanism to prevent users from getting a false sense of security when relying just on self-labelling or self-commitment. Some *members* claiming to be committed to *codes of conduct* may fall short of the principles prescribed therein and may damage both the reputation of the code and of the group promoting it. In more tightly-regulated areas, such as in the pharmaceutical industry, associations will have an intense interest in avoiding situations where individual members violate-willingly or unwillingly-their self-regulatory codes, as this may trigger regulators to step in and to replace self-regulation with legislation. The certification process can be seen as the solicitation of third-party statements which will complement, validate, or comment the statements made by the health information provider, empowering the consumer to compare what the health information provider claims with what an independent party says. Thus, a *group* or *health information provider* could appoint or hire a *certification body* to conduct an audit, which would involve the certification body in making statements about statements (eg, to check or annotate disclosure statements made by the health information provider), or simply confirming (certifying) that the health information provider complies with the prescribed guideline as a whole (if the health information provider does not pass the audit it is up to the *group* to decide on possible sanctions such as withdrawal of membership if the health information provider falls short of the *code of conduct*). Such an audit could be done by humans, or by software, or by a combination of both (in the Semantic Web scenario it would be easy to make certain checks automatically, eg, to check whether certain disclosure statements prescribed in the guideline are present, but it may be advisable to check the content by humans as well). It is important that the certifier is explicit about which aspects of the site have been checked, by whom, and when. Traditional "kitemark" approaches, simply relying on a logo or seal, often fall short of reaching this explicitness, which can however be reached again by making RDF statements (RDF=Resource Description Framework, an infrastructure for organizing and managing metadata [14]) about the RDF statements made by the health information provider.
- In addition, we may see the emergence of accreditation bodies, which "accredit" (ie, endorse or recognize) certifiers. (Note that we discriminate the terms certification and accreditation here - what a certifier like URAC presently calls "Web site accreditation" is, according to this terminology, actually certification). For example, a MedCERTAIN steering group may decide to "accredit" (recognize, endorse, support) other certifying organizations that act according to the MedCERTAIN model, ie, demand machine-readable level-1 descriptions from their members (disclosure and self-description labels) and perform level-2 and level-3 descriptions (provide computer-readable evaluative metadata from third parties).

Figure 1. A (simplified) model of decentralized quality management ("Collaboration Schema") or "web of trust". Actors in this collaboration use metadata (eg. expressed in XML/RDF) to describe their relations with other actors and to make statements about themselves or other actors using elements from standardized vocabularies (DC=Dublin Core, HIDDEL=Health Information Disclosure, Description and Evaluation Language). Users can set their own information preferences and requirements using the same vocabularies, and/or can tell their software that they trust certain actors a-priori (dashed lines). Intelligent browsing tools or agents may then assist users to locate trustworthy information



Statements made by actors

One key issue for interlinking these players on the Semantic Web is that they speak a common language. With this language, these actors may say certain things about themselves and each other, like:

- Health information provider A (first party): "I am a member of an organization called D. I am committed to answer all my e-mails within 3 days. I am funded by public money. My target audience is consumers, my information is provided in English, and my main internal quality-assurance mechanism is described on page URL."
- User B (second party): "I trust organization E, but I don't know whether or not I can trust health information provider A. I prefer to have health information providers that are located in Germany and I prefer health information providers that answer my e-mail questions within 3 days."
- Certifier C (third party): "I can certify that health information provider A complies with the standards set up by group D."
- Group D (fourth party): "I am an organization with the name D, I am sponsored by S, and we have adopted guideline Z. We have appointed an external certification agency C to audit our members and to make sure that they actually stick to these codes of conduct."
- Organization E (Accreditor): "I am recognizing certification body C."

These actors form a complex network in making statements about each other or about themselves. Transparency is one of the ethical tenets demanded by all ethical codes, but how transparent is this complex network in reality to the user, if the actors use only human-readable (not machine-processable) information? For a human user, it may be almost impossible to figure out the various relations between these players and to infer from the statements, eg, to conclude whether or not the user can trust a given health information provider (leaving aside the difficulty of obtaining these statements in a timely manner). In fact, some "intelligence" and "reasoning" (analyzing the relationships and their implications) is necessary. The multitude and complexity of the relations between the initiatives and the data they produce will soon be too complex to be interpreted and digested by consumers without intelligent systems helping them to infer from what the various initiatives say. The consumer will need intelligent systems (browser plug-ins or intelligent agents), which the user can feed with some information on the his/her information-quality needs, for

downstream filtering, eg, advising whether or not to trust a given site.

Towards a Health Information Disclosure, Description and Evaluation Language

It is the vision of the protagonists of the Semantic Web to form a consistent logical web of data on the World Wide Web. A prerequisite for the Semantic Web is the development of languages for expressing information in a machine-processable form. In line with this vision, one aspect of the MedCERTAIN project [15] aims to harness the power of networked information to achieve decentralized quality management and to weave a machine-processable web of trust. The first step was therefore the definition of a language to express self-descriptions and third-party annotations for health Web sites, formerly called medPICS [16], now called HIDDEL (Health Information Disclosure, Description and Evaluation Language) [17]. This language can be expressed in XML/RDF and can be used to "label" sites in a standardized format; similar to food labels [18,22]. Web sites could carry a machine-readable file (eg, hiddel.xml) which can be parsed and processed by software. For example, the statements by group D made above could be expressed using HIDDEL vocabulary elements and XML/RDF syntax as depicted in Textbox 2 (XML means eXtensible Markup Language).

Software designed to assist users in locating trustworthy information also needs some additional "knowledge", such as how the actors relate to each other and what these relations imply; for example, the fact that if a *health information provider* is a member of a *group*, this implies that the provider is committed to (and supposed to) stick to the guideline adopted by the group. Any such framework (or ontology) can be expressed as a "schema" in a Semantic Web language such as RDF or DAML/OIL (DARPA Agent Markup Language), and indeed Figure 1 is a simplified version of an RDF schema modelled in the MedCERTAIN project. Such a schema can serve as a template for each of the actors to make statements about themselves and other actors, and more importantly, it would allow "knowledge" to be given to intelligent client-side software or intelligent agents to query this semantic network and to make inferences, eg, about the trustworthiness of given actors based on what others say about them and what they say about themselves.

The Health Information Disclosure, Description and Evaluation Language therefore has 3 components:

- A HIDDEL core vocabulary: hierarchical metadata elements and subelements, providing the predicate in an RDF statement to describe properties of resources, eg, to indicate a sponsor. This metadata vocabulary is different from generic vocabularies such as the Dublin Core, as it uses atomic terms and concepts from ethical codes such as the eHealth Code of Ethics and includes concepts normally only used by third parties to describe or evaluate health Web sites. It also enables, for example, health information providers to make disclosure statements in a machine-readable form [17].
- A "collaboration schema" modelling a collaborative framework, giving names to the actors and defining their relationships (as, in a simplified form, depicted in Figure 1).
- An "annotations schema," providing a mechanism for making statements about statements [19].

The development of HIDDEL is an ongoing process requiring the continuous input of all organizations active in the field. We have previously attempted to draw together these players for an initial workshop in Heidelberg to agree on some building blocks for a core vocabulary and ontology that can be used on a Semantic Web [20], and a second workshop will be hosted in 2002. We formerly called this (informal and loosely organized) community "Collaboration for Critical Appraisal of Health Information on the Internet" [9] and now refer to it as the "Heidelberg Collaboration" [10,18]. There is no need for political wrangling and wrestling among organizations about under whose umbrella a collaboration should take place and who should take the lead in the hierarchy - a hierarchy doesn't exist on the Web. Or as Tim Berners-Lee put it: "That's the beauty of the Web: It's a web, not a hierarchy" [21].

Textbox 2. Example machine-readable site-label in XML/RDF and HIDDEL (also using a Dublin Core element), as it could be provided on a website of an association of health information providers . The label says the following: "I am an organization with the name D, I am sponsored by S, and we have adopted guideline Z. We have appointed an external certification agency C to audit our members A, B and C.". Similar labels can be used by other health information providers to make machine-readable disclosure or description statements. [Note: this is for illustration purposes only - the HIDDEL specification is still under development and elements may change].

```
<?xml version="1.0"?>
<RDF xmlns = "http://www.w3.org/1999/02/22-rdf-syntax-ns#"
xmlns:rdf="http://www.w3.org/1999/02/22-rdf-syntax-ns#"
xmlns:DC = "http://purl.org/dc/elements/1.1/"
xmlns:HIDDEL = "http://www.medcertain.org/metadata/2001/12/HIDDEL#">
<Description rdf:about=" D ">
<DC:title> Group D </DC:title>
<HIDDEL:sitespecific>
<HIDDEL:disclosure>
<HIDDEL:funding> Sponsor S </HIDDEL:funding>
</HIDDEL:disclosure>
</HIDDEL:sitespecific>
<HIDDEL:endorsed-guideline> Z </HIDDEL:endorsed-guideline>
<HIDDEL:appoints-certifier> C </HIDDEL:appoints-certifier>
<HIDDEL:has-member>
<Bag>
<li> A </li>
<li> B </li>
<li> C </li>
(...)
</Bag>
</HIDDEL:has-member>
</Description>
</RDF>
```

The role of the World Health Organization and policy makers

Only a few weeks after the first Heidelberg workshop, WHO brought forward the "dot-health" proposal [22]. A quote from a WHO representative reveals the level of confusion on Internet standards: "A top-level domain, as a recognized Internet label, is more valuable than a trustmark because of its enforceability. . .it can be suspended or canceled if the domain-name holder is in violation of the established standards. The .health top-level domain has the potential to become a reference model for how international organizations and other, non-technology focused groups can support and promote transparent, high-quality information on the Internet in their respective fields." [23]

This statement not only shows a certain degree of naivety on the difficulties of withdrawing a domain name (which would have disastrous effects on a health information provider and would inevitably lead to legal battles) as opposed to a trustmark, it also indicates that WHO was very much thinking in terms of hierarchies and failed to recognize fundamental design principles of the Web as a decentralized, non-hierarchical medium, and that top-level domains never were thought of as "quality labels." Instead, the W3C (World Wide Web Consortium) recommendation for endorsement data ("labels") was the PICS standard, which is now being replaced by XML/RDF [14].

So what is the role of WHO and health policy makers in this framework? I would add the following recommendations to those already made in the Risk and Dzenowagis paper:

Recommendation 1: Take on the role as an actor in the Semantic Web

First, WHO can take on the roles of any of the actors described above, being part of a *web* rather than attempting to form the top of a hierarchy. As one player in the Semantic Web, WHO could, for example, endorse or appoint any other actor - and make these endorsements explicit on the Semantic Web using RDF metadata. For example, WHO could use metadata on its site to link to trusted government sites of member states or to Web sites of NGOs (nongovernmental organizations) which have official relations with WHO (in this scenario, WHO would act as the leader of a *group* according to the schema defined

above). As such, it may for example also create (or endorse) a guideline for Web sites of the organizations that have official relations with WHO, and could "enforce" this code of conduct by appointing an external certification organization. One of the certification criteria could be that these organizations use metadata to identify the sites they trust, and demand the use of metadata on the sites they trust, and so on. Consumers could then parse which organizations are trusted by the WHO, whom these organizations trust, and so on - thereby forming a web of trust.

Recommendation 2: Make health information on the Web a policy priority

Secondly, acknowledging that the quality of health information is a critically-important public health issue, as it could potentially affect health outcomes for millions [24], health information on the Web should be made a WHO program priority and - recognizing that research is urgently needed in this field - WHO should also consider designating one or several "Collaborating Centers for Consumer Health Informatics." In other fields, WHO has acknowledged that research in policy priority areas is best advanced by assisting, coordinating, and making use of the activities of existing institutions, and has appointed collaborating centers, eg, for the purpose of standardization of terminology, nomenclature, technologies, methods and procedures.

Recommendation 3: Promote best practices, including the use of metadata

Thirdly, perhaps the biggest role for WHO (and policy makers in member states) is the promotion of the appropriate standards (rather than promoting the wrong hierarchical models - see comments in this section about "dot-health"), and of best e-health practices. This includes that the provision of metadata (for disclosure and description) should be promoted as being one important quality criterion for Web sites *per se*, and that WHO should act as a role model in providing and using metadata itself (see recommendation 1).

Promotion and backing of this approach from the policy side is needed, as otherwise uptake of Semantic Web technologies in the health field could be delayed by a typical chicken and egg problem: If health information providers (and the other actors such as third-party gateways) do not start using RDF metadata, there will be no vendors developing semantic-web/web-of-trust applications. If there are no applications, health information providers will have no incentives to use RDF metadata. The medical community is currently wasting too much time and effort with debating anarchical quality-control mechanisms - such as seals of approval - and with politicized discussions on who should be in charge of quality control, without recognizing that the Web itself provides the answer. The first Heidelberg workshop [20] provided the best example: A workshop designed to debate a metadata vocabulary was quickly overturned by a general debate about who should be in charge and whether we should provide evaluative data at all.

Publicly-funded projects such as MedCERTAIN (MedPICS Certification and Rating of Trustful and Assessed Health Information on the Net, 2000-2001) and MedCIRCLE (Collaboration for Internet Rating, Certification, Labeling and Evaluation of Health Information, 2002-2003) aim to create awareness and a critical mass of metadata, so that industry jumps in and develops intelligent Web browsers and agents able to aggregate and interpret this data. Still, MedCERTAIN is often misunderstood as a third-party certification service or trustmark project, on par with, eg, URAC. However, although this is one aspect of the project, the main goal of the project is to demonstrate the overall framework depicted in Figure 1 and to demonstrate the use of metadata. In the follow-up project MedCIRCLE, 3 European gateways will implement HIDDEL on a broader scale, will demonstrate the synergy created through collaboration on the Semantic Web, and will invite and support other organizations to become part of the "Heidelberg Collaboration" by implementing the HIDDEL vocabulary.

Conclusion and outlook

The Semantic Web will greatly magnify the challenges, but also the opportunities, created by the human-readable World Wide Web. On the Semantic Web, people will use intelligent agents to find the cheapest airfares or the best used car in town, but inevitably they will also ask intelligent agents about the best physician or best treatments available. It is easy to imagine what will happen without quality assessment and quality-related metadata: "intelligent" agents will not deliver the best medical answers, but may provide answers given on quackery sites. Without quality related metadata, the impact of the Semantic Web on consumers could be detrimental. On the opportunity side, the Semantic Web will give even greater power to the consumer to determine the trustworthiness of a given health information provider or service than the Web in its current form, if quality-related metadata are used. The Semantic Web also opens up new ways for educating consumers and reaching less technology-savvy and health-literate consumers, because part of the intelligence and knowledge required to critically appraise and understand health information (and to put it into context with one's personal health data) could be built into search tools and client-side software.

While the biggest advantage of the Semantic Web is often discussed under the aspect of increasing the findability of information ("resource discovery"), and while this may remain to be an important aspect for health information on the Web, the perhaps bigger opportunity for e-health lies in the prospect of weaving a web of trust. The e-health community has the unique opportunity to lead this development, where much research and standardization work needs to be done.

With this perspective in mind, the time is ripe for the health information quality initiatives to start looking beyond their own horizon and to become active as a player in the Semantic Web.

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Conflicts of Interest

The author is coordinator of the MedCERTAIN and MedCIRCLE projects.

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Abbreviations

DAML/OIL: DARPA Agent Markup Language / Ontology Inference Layer
HIDDEL: Health Information Disclosure, Description and Evaluation Language
MedCERTAIN: MedPICS Certification and Rating of Trustful and Assessed Health Information on the Net
MedCIRCLE: Collaboration for Internet Rating, Certification, Labeling and Evaluation of Health Information
MedPICS: Platform for Medical Content Selection
NGO: Nongovernmental Organization
PICS: Platform for Content Selection
RDF: Resource Description Framework
WHO: World Health Organization
XML: eXtensible Markup Language

###Reviewer names will be inserted here### published 31.12.01.

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Review

Review Of Internet Health Information Quality Initiatives

Ahmad Risk[1]; Joan Dzenowagis[1]

World Health Organization, 20 Avenue Appia, Switzerland

Corresponding Author:
Ahmad Risk
World Health Organization
Department of Health Information Management and Dissemination
20 Avenue Appia
CH-1211 Geneva 27
Switzerland
Email: riska@who.ch

Abstract

Background: The massive growth of health information on the Internet; the global nature of the Internet; the seismic shift taking place in the relationships of various actors in this arena, and the absence of real protection from harm for citizens who use the Internet for health purposes are seen to be real problems. One response to many of these problems has been the burgeoning output of codes of conduct by numerous organizations trying to address quality of health information.

Objectives: Review the major self-regulatory initiatives in the English-speaking world to develop quality and ethical standards for health information on the Internet. Compare and analyze the approaches taken by the different initiatives. Clarify the issues around the development and enforcement of standards.

Methods: Quality initiatives selected meet one or more of the following criteria: Self-regulatory. A reasonable constituency. Diversity (eg, of philosophy, approach and process)-to achieve balance and wide representation, and to illustrate and compare different approaches. Historic value. A wider reach than a national audience, except when its reach is a significant sector of the Internet health information industry. The initiatives were compared in 3 ways: (1) Analysis and comparison of: key concepts, mechanism, or approach. Analysis of: the obligations that a provider has to meet to comply with the given initiative, the intended beneficiaries of that initiative, and the burdens imposed on different actors. These burdens are described in terms of their effect on the long-term sustainability and maintenance of the initiative by its developers. Analysis of the enforcement mechanisms. (2) Analysis and comparison by type of sponsoring organization, the reach of the initiative, and the sources of funding of the initiative or the sponsoring organization. (3) How the various initiatives fall under 1 of 3 key mechanisms and comparison of the advantages and disadvantages of these key mechanisms.

Results: The issues that affect the initiatives and future work on the quality of health information on the Internet are identified and analyzed. These issues are: (a) Three key mechanisms used in the quality initiatives (b) Sustainability issues that affect the initiatives: Burdens placed on health information providers, citizens and others. Currency and maintenance issues of the initiatives. Funding. Cost. Acceptance. Market conditions. User indifference or ambivalence. (c) Enforcement issues surrounding the initiatives (d) Adequacy of approach, scope, reach, and enforcement provisions of the various quality initiatives (e) Gaps that need to be addressed to achieve good quality of health information on the internet

Conclusions: Ten conclusions are presented. A framework of action to be undertaken by the World Health Organization in the field of quality of health information on the Internet is recommended.

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KEYWORDS

Internet/standards; Ethics, Professional; Social Control, Formal; Health Care Quality; Quality Assurance; Health Care/standards; Commerce/standards; Information Management/standards; Medical Informatics/standards; Quality control; Guidelines; Privacy; Informed Consent

Introduction

Current situation of health information on the Internet

A global medium and a seismic shift

There is an explosion in the amount of health information available on the Internet. This increase does not show signs of slowing down. For example, entering the word "health" in a generic search engine like Google (www.google.com) currently yields over 60 million pages.

The sources of that information are numerous and varied. For the first time in history, we have a global medium that transcends geography and operates across cultures and languages.

The Internet has been the catalyst for the seismic shift that is happening in the doctor-patient relationship. It continues to have a profound impact on other relationships among health care actors. This shift has been in access to knowledge, and consequently in access to power [1,2].

Numbers vary and none are very accurate, but it is estimated that there are over 100,000 health-related Web sites on the Internet today. These vary from highly-academic sites, online peer-reviewed journals, governmental sites, and health-provider-institutions' sites to countless individual contributions from citizens, patients, and health professionals.

There is also an unmeasured number of industry-related Web sites, ranging from large and small pharmaceutical company sites to a multitude of commercial sites disseminating information or selling products and services in a variety of bewildering ways.

Recent surveys estimate the number of Internet health-information seekers to be about 86% of the estimated 168 million American adults who have access to the Internet [3], and that 55% (Germany) to 90% (United States) of primary-care physicians had ever used the Internet (P/S/L Research [4] i-MD 2000 Survey. 2nd Quarter 2000; currently, survey is not available at the P/S/L Research Web site). These surveys indicate that the trend towards use of the Internet for health purposes is rising.

In addition, we are beginning to witness the large-scale entry of mainstream health care organizations into the field of the health Internet. There are an increasing number of purchaser organizations and health-care-funding governments that are exploring the use of the Internet as a tool for containing the spiraling cost of health care and improving the quality of care to citizens.

Numerous surveys and studies paint a picture of dubious information quality, widespread practice of fraud, potentially-dangerous claims, and the risk of exposure of citizens to harm. One good example of such surveys is the study conducted by RAND health [5].

Even when information appears to be of high quality it can cause unintentional harm to citizens [6]. This can happen for a number of reasons:

- Language and complexity barriers [7]
- Inappropriate audience or context
- Unavailability of certain services or products in different parts of the world
- Difficulty in interpreting scientific data
- Accuracy and currency of information
- Potential for source bias, source distortion, and self-serving information

No real protection

Amid all this disorder, there is a common concern among many individuals and institutions interested in the health Internet. This concern is for the prevention of physical, mental, and emotional harm-caused by wrong, misleading, inappropriate, false, fraudulent, or self-serving information-to people who use the Internet to seek or receive health information, products, and services.

Yet, in a large number of Web sites currently offering health information we cannot find credible and enforceable protection of citizens from potential harm.

While there is some degree of protection provided either by national regulatory mechanisms or through self-regulation, this modest protection is currently only afforded to a small number of people.

The response

One response to many of these problems has been the burgeoning output of codes of conduct from numerous organizations trying to address quality of health information. All of these codes have a primary goal of citizen protection, and some have a secondary goal of protecting the company's "good name," thus succeeding in competition based on quality. These initiatives derive from different philosophies and apply different approaches and processes.

This paper

This paper reviews and compares major self-regulatory initiatives for health information quality and ethics developed in the English-speaking world.

Scope

This paper analyzes the major quality initiatives for health information on the Internet. The criteria for inclusion in the review are discussed in "Methods, " below.

The focus of this study is health information, while being mindful of the inevitable overlaps between information and products and services. This study adopts the definition of health information of the eHealth code of Ethics in view of its accuracy and completeness. The eHealth Code of Ethics defines health information as:

> *Health information includes information for staying well, preventing and managing disease, and making other decisions related to health and health care. It includes information for making decisions about health products and health services. It may be in the form of data, text, audio, and/or video. It may involve enhancements through programming and interactivity.*

This paper does not address:

- Provision of organized health care services
- The practice of telemedicine
- Laws and regulatory instruments
- Quality initiatives developed or being developed by non-English speaking groups or organizations

The review does not perform a competitive analysis of the various initiatives.

This paper avoids the use of the neologism *eHealth* because of its ambiguity. Rather, it uses the terms *health Internet, health Internet information*, or *health information* referring broadly to the use of information and communication technologies to create, deliver, or receive health information with particular reference to Internet technologies.

Objectives

Provide a comprehensive review of the key efforts to develop quality and ethical standards for health information on the Internet.

Provide comparison and analysis of the approaches taken by the different initiatives.

Clarify the issues around the development and enforcement of standards for health information on the Internet.

Methods

The selection of quality initiatives for review and comparison in this paper is based on meeting one or more of the following criteria:

- The initiative is an expression of a self-regulatory mechanism. This study focuses on those initiatives that aim to provide models of self-regulation of the health Internet industry. Legal and regulatory mechanisms are the subject of a separate paper. Self-regulation of the health Internet remains a powerful driver of the pursuit of quality standards for health information on the Internet.
- The initiative has a reasonable constituency, that is, a body of developers and followers who are keen on sustaining and maintaining the initiative-or the initiative has been developed by a broad spectrum of people. Issues of sustainability and maintenance are important components of the comparisons that follow.
- Diversity of philosophy, approach and process, and other characteristics-to achieve balance and wide representation, and to illustrate and compare different approaches.
- The initiative has some historic value representing an early example of thinking on quality standards. This criterion resulted in the inclusion of two early examples from 1996 whose current utilization is unknown.
- The initiative has a wider reach than a national audience, except when its reach is a significant sector of the Internet health information industry, for example, pharmaceutical Web sites or large commercial consortia. Many initiatives did not reach beyond national constituencies. In some cases, the geographical reach is not easily defined or crosses 2 different boundaries. For example, the MedCERTAIN project is classified in this paper as having a regional reach (in view of its European base and funding) but it also has ambitions to develop the project into an international standard. Another example is the code of conduct of the American Medical Association (AMA). Although it is intended to cover those sites under the control of the AMA, it also states that it can be utilized by any medical website.

The process of identifying the initiatives reviewed was based on personal knowledge of, involvement with, and exposure to the field of quality-of-health-information on the Internet.

The initiatives were compared in 3 ways:

1. Analysis and comparison of the different key concepts, mechanisms, or approaches. The analysis also looks at the obligations that a provider has to meet in order to comply with the given initiative, the intended beneficiaries of that initiative, and the burdens imposed on different actors. These burdens are described in terms of their effect on the long-term sustainability and maintenance of the initiative by its developers. Finally, the enforcement mechanisms applicable to the initiatives are looked at. (Table 1)
2. Analysis and comparison by type of sponsoring organization, the reach of the initiative, and the sources of funding of the initiative or the sponsoring organization. (Table 2)
3. Finally, how the various initiatives fall under one of 3 key mechanisms are looked at (Table 3). The advantages and the disadvantages of these key mechanisms are compared in the "Discussion" section. Briefly, these key modes are:
    - Codes of conduct
    - Third-party certification
    - Tool-based evaluation (for example, questionnaires that are filled by hand or embedded software that automatically gives access to the quality attributes of the site)

Review of the initiatives

Much of the information about the initiatives has come from the published initiative; discussions with some of the key players in each initiative, and attendance at conferences on quality of health information on the Internet

For each initiative, the review is divided into the following areas (however, review of some initiatives did not involve discussion of all the areas):

- **Launch Date**
- **Responsible Organization**
- **Key players**
- **Intended target users**
- **Objectives**
- **Approach**
- **Process**
- **Implementation mechanisms**
- **Sustainability issues**

The actual text of the initiatives was used to describe the various aspects of the work on many occasions. On other occasions, the author provided descriptions and interpretations based on his own sources of information and his current understanding

Table 1. Characterization of quality initiatives

Initiative	Philosophy	Mechanism	Implementation Obligations	Intended Beneficiary	Sustainability	Burden Bearer	Enforcement
eHealth Code of Ethics	Code of conduct	Guidance	Interpret and specify guiding principles	• Citizens	• Currency • Funding	• Providers • Citizens	None
HI-Ethics	Third-party certification or Voluntary compliance with code of conduct	Quality seal	Comply with code of conduct	• Consumers • Member companies	• Currency • Market • Hi-E Inc	• Providers • Citizens	• Withdrawal of accreditation • Withdrawal of membership
URAC	Third-party certification	Accreditation process	Comply with accreditation process	• Companies	• Cost • Acceptance	• Providers • Citizens	Withdrawal of accreditation
MedCERTAIN	• Voluntary meta tags • Trust mark • Third-party certification	• Meta tagging by provider • Citizen assesses based on tags or rating or Sees trust mark	• Comply with vocabulary • Apply tags • Third-party certifiers use tags	• Citizens	• Currency • Acceptance • Human resources • Funding	• Providers • Raters • Citizens	• None • Withdrawal of accreditation (when site is rated by third party)
TNO QMIC	Third-party certification	Accreditation process	Comply with accreditation process	• Companies	• Cost • Acceptance • Other Trusted Independent Parties (TIPs)	• Providers • Citizens	Withdrawal of accreditation
HON	Code of conduct	Quality seal	Comply with code of conduct	• Citizens	• Currency • Market • Human resources • Funding	• Providers • Citizens	None
EC Quality Criteria	Quality criteria	Guidance	Comply with criteria	EU (European Union) member states	• Relevance • Interpretation • Political commitment	• Providers • Member states • Citizens	None
OMNI	Third-party evaluation based on quality criteria	Manual filtering	Comply with quality criteria	Academe	• Currency • Human resources • Funding • Raters	• Providers • Citizens	None
DISCERN	Tool-based assessment	Tool-based filtering	Comply with quality criteria	• Citizens	• Currency	• Providers • Citizens	None
AMA	Code of conduct	Self-regulation of own sites	Comply with code of conduct	AMA	• Currency	• Providers	Enforced by AMA
BHIA	Code of conduct	Guidance	Comply with code	• Citizens	• Currency	• Providers • Citizens	None
HSWG IQ Tool	Tool-based evaluation	Tool-based rating	Comply with quality criteria	• Citizens	• Currency • Funding	• Providers • Citizens	None

Initiative	Philosophy	Mechanism	Implementation Obligations	Intended Beneficiary	Sustainability	Burden Bearer	Enforcement
IFPMA	Code of conduct	Guidance	Comply with code	Member companies	• Currency • Specificity	• Providers • Citizens	None

This review looks at these initiatives:

1. eHealth Code of Ethics
2. Health Internet Ethics (Hi-Ethics)
3. URAC Health Web Site Accreditation Program
4. MedPICS Certification and Rating of Trustworthy and Assessed Health Information on the Net (MedCERTAIN)
5. TNO Quality Medical Information and Communication (QMIC)
6. HON Code
7. EC (European Community) Quality Criteria for Health-related Websites
8. Organizing Medical Networked Information (OMNI)
9. DISCERN
10. American Medical Association (AMA): Guidelines for Medical and Health Information Sites on the Internet: Principles Governing AMA Web Sites
11. British Healthcare Internet Association (BHIA): Quality Standards for Medical Publishing on the Web
12. The Health Summit Working Group-Criteria for Assessing the Quality of Health Information on the Internet: IQ Tool (HSWG IQ Tool)
13. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Code of Marketing

Table 2. Quality initiatives: Sponsors, Scope, and Funding

Name of initiative	Type of Organization		Reach			Funding				
	Voluntary	Commercial/ Corporate	National	Regional	International	Donations	Members	Fee for Service	Public Money
eHealth Code of Ethics	•				•	•	•		
Hi-Ethics	•		•				•		
URAC		•		•				•	
MedCERTAIN	•			•					•
TNO QMIC		•	•					•	•
HON Code	•				•	•			•
EC Quality Criteria	•			•					•
OMNI	•		•						•
DISCERN	•		•						•
AMA		•	•				•		
BHIA	•				•		•		
HSWG IQ	•	•			•				
IFPMA	•				•		•		

Table 3. Quality Initiatives: Key Mechanisms

Codes of Conduct/Ethics	Third-party Certification or Rating	Tool-based
1. eHealth Code of Ethics	1. URAC	1. DISCERN
2. Hi-Ethics	2. MedCERTAIN	2. IQ Tool
3. HON Code	3. TNO QMIC	
4. EC quality criteria	4. OMNI	
5. AMA		
6. BHIA		
7. IFPMA		

eHealth Code of Ethics [8-9]

Launch date

24 May 2000.

Responsible organization

The Internet Healthcare Coalition.

Key concept: the Code sets out ethical concepts that inform the processes of self-assessment and compliance based on interpretation and specification.

The Internet Healthcare Coalition is a not-for-profit organization whose mission is to enhance quality health care resources on the Internet. It aims to achieve its mission by consumer and provider education, self-regulation, and the nurturing of on-line communities that promote ethical, innovative, and high-quality sources of health care information and services.

Membership of the Coalition comprises publishers of professional and consumer health care information; academic institutions and other accredited educational providers; medical libraries and database providers; medical specialty and special-interest societies; patient advocacy and support groups; manufacturers of regulated drugs and medical devices; and commercial developers and providers of Internet-based health-related education, information, and services.

The Coalition is funded by membership fees, unrestricted educational grants and donations, and proceeds from conferences and educational activities.

Intended target users

The eHealth Code of Ethics is developed as a set of guiding principles aimed at health Internet stakeholders worldwide. These stakeholders include health-application developers; site sponsors; managers; Webmasters; clinicians; laypeople who seek health information, products or services via the Internet; policy makers; academics; and publishers.

Objectives

- Protect from harm
- Create ethical environment
- Ensure fairness and synergy amongst the various entities

The goal of the eHealth Code of Ethics is to ensure that "people worldwide can confidently and with full understanding of known risks realize the potential of the Internet in managing their own health and the health of those in their care."

Thus, the Code has the overarching goal of identifying the values that are important in creating conditions of trust. The Code defines the kinds of conduct that support those values in practice. This becomes the foundation for enabling people to use the health Internet with confidence.

Approach

The approach is geared towards producing a set of overarching ethical principles for the health Internet that can provide guidance to further interpretation, specification, and development of ethical codes of conduct.

Process

- Grass root participation in development
- Democratic broad stakeholder consensus
- Professional-ethicists input
- Prior identification of the issues of concern through an on-line questionnaire undertaken by the Internet Healthcare Coalition
- Supply-side and public education
- Preparation and collection of case studies and interpretative guidelines

Implementation mechanisms

The Code together with its case studies and interpretative materials components is used in a number of ways:

- As the basis for a number of operational implementation activities, for example, those being developed by URAC, Kaiser Permanente, and the USA National Mental Health Association.
- As the basis for the series of eHealth Ethics workshops organized by the Coalition to inform and educate organizations that provide health information on the Internet on the issues of ethics and quality.
- The process deployed in developing the eHealth Code of Ethics is being used in developing other initiatives. Examples include the MedCERTAIN project and the European Commission's workshop on quality criteria for health-related Web sites
- The cochairs of the Summit and its Steering group, in common with the key players of the other initiatives reviewed here, play key roles in dissemination of the guiding principles of the Code, encouraging the adoption and adaptation of the Code and facilitating the development of standards in many international arenas.

Sustainability issues:

The eHealth Code of Ethics places a burden on other organizations developing quality standards for Internet health information in terms of those organizations having to (a) interpret and specify the Code according to the constituency addressed, as these activities will have to be supported by commitment of time and resources; and (b) be in compliance with the Code in broad terms.

Sustainability of the Code itself and its further development is vulnerable to scarcity of resources and commitment.

The burden of codes of conduct in general is ultimately passed onto the citizen. In the absence of real enforcement citizens are required to be interested, knowledgeable, and caring, with the desire and commitment to apply critical appraisal of sites proclaiming to be in compliance of a particular code.

Health Internet Ethics (Hi-Ethics) [10]

Launch date

7 May 2000.

Responsible organization

Hi-Ethics Inc [11].

Key concept: third-party certification.

Hi-Ethics Inc is a not-for-profit consortium of US-based commercial health Internet companies. Current membership is 15 companies. Member companies provide the funding for the initiative through membership fees. Current membership fees are $6000.

Intended target users

US-based commercial Web sites: that offer or plan to offer health services, products, and information to consumers; that comply with the Hi-Ethics Principles; and that pay the applicable membership fee.

Objectives

The rules developed by Hi-Ethics are intended to assure that:

- Internet health services reflect high quality and ethical standards
- Health information is trustworthy and up-to-date
- Personal information is protected
- Consumers are able to distinguish on-line health services that follow the Hi-Ethics principles from those that do not
- Member companies' good names are maintained
- Self-regulation remains the primary mode of oversight
- Conformance with the applied principles serves as a means of legal defense and for verification procedures

Approach

The founding members of Hi-Ethics were motivated to approach the issue of health Internet ethics following media and consumer criticisms of commercial Web site practices, particularly in the areas of trust, privacy, and confidentiality. Other areas of concern that triggered the Hi-Ethics initiative were editorial integrity and advertising policies. Some argue that the founder of drkoop.com called for the initiative following specific criticism of his company.

This approach required: emphasis on high ethical standards, gaining the trust and confidence of the consumer, self-regulation, a framework for legal defense, and the establishment of a set of clear rules of conduct that sometimes go into great operational detail.

Hi-Ethics Inc also sees the need for governmental policy setting as well as the corporation's engagement in lobbying and educational activities.

Process

Establishing the Hi-Ethics Principles required the cooperation and collaboration of large commercial Web companies that were often in direct competition with one another, and whose business models and technology infrastructure were often very different from one another.

To ensure a level playing field and to address the issues of competition and the different business models of its members, Hi-Ethics Inc chose to have all decision-making processes require unanimous agreement. The law firm of Hogan and Hartson was retained to ensure that the Hi Ethics Principles could stand up to the rigor of any verification requirements either by regulatory authorities or through third-party certification.

It can be argued that the founding members of Hi-Ethics have acted with enlightened self-interest to obtain unanimous consent of the consortium in order to achieve the goal of setting the governing principles for the intended users.

Implementation mechanisms

Direct implementation by health Internet companies who meet membership criteria, and undergo a third-party certification process through the cooperative program between Hi-Ethics Inc and URAC for website accreditation.

The number of companies who have implemented the Hi-Ethics principles fully is not known.

Sustainability issues

Sustainability of the Hi-Ethics code of conduct is vulnerable to the burdens placed on citizens, member companies, prevailing market conditions, and the ability of Hi-Ethics Inc to maintain the currency of the principles.

This will be explored further in the "Discussion" section.

MedCERTAIN [12- 13]

MedPICS [14] Certification and Rating of Trustworthy and Assessed Health Information on the Net

MedPICS is now replaced with HIDDEL (Health Information Disclosure, Description and Evaluation Language) [15]

Launch date

2000.

Responsible organization

This is an EU (European Union)-funded demonstration project under the "Action Plan on Promoting Safer Use of the Internet by Combating Illegal and Harmful Content on Global Networks" [16].

MedCERTAIN is a system based on metadata tagging technology, standard quality vocabulary, and content filtering labels. It relies on the cooperation of individuals and organizations that evaluate, assess, accredit, or recommend health information on the Internet to apply these technologies to their production processes.

The project is managed by a Project Consortium, which comprises 3 core partners:

- The University of Heidelberg, Department of Clinical Social Medicine
- The University of Bristol, Institute for Learning and Research Technology at the University of Bristol (ILRT)
- Finnish National Research and Development Centre for Welfare and Health (STAKES) / The Finnish Office for Health Care Technology Assessment (FinOHTA)

In addition, the project draws on the resources of the "Heidelberg Collaboration,", a loose collaboration based on the "Collaboration for Critical Appraisal of Internet Health Information," proposed in 1997.

Intended target users

Information providers and rating organizations (which include every organization, portal, or subject gateway active in recommending, evaluating, or endorsing health information or health-information providers), and ultimately, the end user of health information.

Objectives

- Establish self and third-party rating systems that enable consumers to filter harmful health information and to identify and select high-quality information ("downstream filtering") through Web site content labels
- Creation of an enforcement infrastructure
- Consumer education
- Active encouragement of information providers to conform to ethical codes of conduct
- Information providers and rating facilities achieve this through the application of meta tags and labeling technologies

Approach

- Metadata self-labeling by information providers
- Third-party rating and the award of a trust mark
- Standard metadata vocabulary, which draws on other quality initiatives like the eHealth Code of Ethics and the DISCERN questionnaire

Process

- Standard European Commission project management routines
- Input from the Heidelberg Collaboration
- Feedback from medical Webmasters on the MedPICS draft metadata vocabulary and rating criteria

Implementation mechanisms

- Information providers describe their content using the standard quality vocabulary and meta data technologies, for example, XML (Extensible Markup Language)
- These descriptors would act as labels that allow users to filter content according to personal criteria
- The same labels would also feed through to labeling bureaus by third-party rating facilities (for example, URAC), search engines, and health Internet Web sites
- Trust mark: MedCERTAIN defines 4 levels for the award of a trust mark:
  Level I: Transparency Mark (self-certification)
  Level II: Verification of Level I claims and formal assessment of the Web site by professional volunteers based on the quality criteria
  Level III: Third-party assessment and rating of content
  Level IV: Outcome evaluation

Sustainability issues

Sustainability of MedCERTAIN is dependent on certain conditions that have to be met. These are:

- Sufficient acceptance and implementation of meta tags by providers
- Correct interpretation and specification of the extensive quality vocabulary by information providers
- The emergence of strong third-party description and annotating organizations
- Progress in browser technology (to allow user-specified quality preferences) and wide acceptance of XML and meta tags standards
- Citizens being aware of the quality labels, having an interest in using them, and being able to interpret them

MedCERTAIN places burdens on citizens, providers, and third-party certification bodies.

Update

MedCIRCLE (Collaboration for Internet Rating, Certification, Labeling and Evaluation of Health Information) will use HIDDEL to describe other Web sites as "inner circle" and a loose collaboration of other subcontractors or non-funded partners as "outer circle," all using HIDDEL. MedCIRCLE is a collaboration of 3 national gateways in: Germany (Ärztliche Zentralstelle Qualitätssicherung-German Medical Association), Spain (Medical College of Barcelona), and France (CISMeF) [17].

DAERI [18] (Database of Adverse Events Related to the Internet) project, which is not directly part of MedCERTAIN, is somewhat related to the subject of this study in terms of providing useful feedback to quality processes. This is achieved through the collection of case studies of situations where patients have been harmed by information on the Internet.

URAC Health Web Site Accreditation Programme [19- 20]

Launch date

August 2001.

Responsible organization

URAC (formerly known as the American Accreditation Healthcare Commission) [21].

URAC is a not-for-profit organization founded in 1990 to establish standards for the managed care industry. URAC's broad-based membership includes representation from all the constituencies affected by managed care: employers, consumers, regulators, health care providers, and the workers' compensation and managed care industries.

Member organizations of URAC participate in the development of standards, and are eligible to sit on the Board of Directors. URAC offers 10 different accreditation programs for managed care organizations.

More recently, URAC embarked on developing a program for the accreditation of health-related Web sites. The formulation of the program is now completed and it has been approved by the board of directors of URAC. It has undergone beta testing by selected health Internet organizations and is fully operational as of August 2001.

URAC primarily derives its funding from fees paid by applicants for accreditation,

Intended target users

Health-related Web sites, initially those organizations providing managed care services.

Objectives

- Address the concerns of consumers and other health care stakeholders
- Provide a tool to identify Web sites that meet high standards for quality and accountability

Approach

URAC approached the development for this accreditation program in the same way it approaches other non-Internet accreditation programs.

This approach involved appointing an advisory committee composed of expert representatives of all stakeholders. This committee follows standard URAC procedures in its work.

The approach relies on adaptation of existing quality initiatives; interpretation and specification for the target constituency; consensus; and public consultation and drafting, until a fully-operational program can be presented to the URAC Board of Directors for approval.

Process

URAC brings together experts in the field to debate and discuss what standards are appropriate for a particular aspect of health Internet information. The standards-development process is inclusive and broad-based-URAC membership itself includes a balance of organizations representing providers, regulators, businesses, consumers, and the health Internet information industry.

Implementation mechanisms

Health Web site organizations that wish to seek accreditation from URAC submit documentation of compliance with each standard. A member of URAC accreditation staff reviews this document, working closely with the applicant to resolve any issues that have been identified. URAC staff visits the applicant to ensure that its operations are consistent with the documentation submitted. Finally, the Accreditation Committee and the Executive Committee review the application. These committees are composed of representatives of URAC's member organizations.

An important requirement of the accreditation program is that the applicant demonstrates that it has established an organizational quality committee to oversee the ethical Internet operations of the organization.

URAC has set preliminary accreditation fees of $2000 to $5000, plus travel fees for URAC certifiers, for on-site inspections.

Sustainability issues

The success of the URAC program depends on:

- Sufficient acceptance by fee-paying customers to make the program viable
- Favorable market conditions in the health care industry in general and the health Internet sector in particular
- The ability of URAC to maintain the currency of its program of accreditation
- The value, if any, attached to accreditation by citizens

URAC places burdens on citizens through the need to understand and assess the quality criteria applied to the sites and the accreditation process behind it, and on its customers through financial and organizational burdens.

TNO Quality Medical Information and Communication (QMIC)-Quality for medical information communication and transactions

Launch date

January 2001.

Responsible organization

Health Trust, part of the Netherlands TNO Prevention and Health Institute [22].

TNO (Applied Scientific Research) Institutes are independent organizations that were set up by the Netherlands government to act as bridges between science and society. The institutes are partly funded by public funds and partly by fees for services.

QMIC aspires to be the Netherlands Trusted Independent Party (TIP), while it hopes to become an "international facilitator for domain specific trusted independent parties." The scope and functions of the latter role lack clarity.

This will be a fee-for-service system; such fees will be in line with conventional ISO (International Organization for Standardization) accreditation fees. TNO sees the need for accreditation aggregators that could offer services at much-reduced rates to small enterprises.

Intended target user

Trusted Independent Third Parties (TIPs) whether existing or yet to emerge.

Objectives

Perform a capability assessment of the information suppliers on their ability to verify conformity with the requirements ("self-certification with external reference").

Approach

The TNO approach is third-party certification.

The core team of TNO QMIC comprised 3 individuals whose backgrounds are from the certification and accreditation industries.

This core team was later expanded to 10 people to include IT specialists and other conformity, standards, and process-flow specialists. The team is advised by an unknown number of physicians and informatics specialists.

Process

Classic International Organization for Standardization (ISO) process routines based on consensus, industry-wide solution, and voluntary compliance [23].

The process involves 6 stages:

- Proposal

- Preparatory
- Committee
- Enquiry
- Approval
- Publication

Implementation mechanisms

QMIC is an instrument based on the ISO 9000 and ISO 2000 accreditation procedures and has its roots in the certification and accreditation culture within the framework of the European New Approach Directives.

The system relies on 2 types of bodies: an intra-organizational Notified Body Function (NBF) (a compliance committee) and an external Trusted Independent Third Party (TIP) that performs the audits and accreditation.

TNO QMIC accreditation involves the following procedures:

> *Initial audit of the organization applying for accreditation conducted by the TIP:*
>
> *The Notified Body Function is an independent intra-organizational body that deals with quality functions. The main functions of the NBF are the scrutiny of documents produced by the organization, confirmation of compliance with standards set, and ultimate release of documents for publishing onto the Web site. The TIP supervises all activities of the NBF.*
>
> *The organization would "'notify" the TIP, which in turns carries out the capability assessment and issues the necessary "certification.". Additionally, the NBF issues the organization with self-certificates for the day-to-day management of the organization.*
>
> *Organizations apply for reaccredidation on a yearly basis.*

According to TNO, QMIC "sets a low ceiling for quality standards that is balanced by robust feedback mechanisms that can access the provider as well as the TIP's databases," that is, although the quality standards themselves might not be too onerous for information providers, nonetheless, the standards will be validated through strong feedback mechanisms by citizens and third-party certifying companies.

Sustainability issues

See under "URAC," above.

HON Code [24- 25]

Launch Date

1996.

Responsible Organization

Health on the Net (HON) Foundation in Geneva Switzerland [26].

The HON Code is probably the earliest quality initiative on the health Internet. The HON Code logo can be found on more than 3000 health-related websites. Nevertheless, despite the profound changes taking place in the health Internet sector, the HON Code has not been updated since its creation.

The Foundation is a not-for-profit organization established in 1995, funded primarily by the State of Geneva and the Geneva Ministry of Health. HON receives additional support and donation and grant money from a variety of sources, including the Swiss Institute for Bioinformatics and Sun Microsystems.

More recently, the Foundation is seeking formal recognition by the United Nations as a Non-Governmental Organization.

Intended target users

Health information providers, consumers, and medical practitioners.

Objectives

Guide laypersons and medical practitioners to useful and reliable online medical and health information.

Approach

Self-regulatory quality seal displayed on sites that conform to the HON Code.

This is the approach definition used by HON: "The HONcode is not an award system, nor does it intend to rate the quality of the information provided by a Web site. It only defines a set of rules to:

- Hold Web site developers to basic ethical standards in the presentation of information;
- Help make sure readers always know the source and the purpose of the data they are reading

Process

The HON Code was developed as an internal process in consultation with Webmasters, information providers, patients, and citizens.

Implementation mechanisms

The HON Code sets 8 principles for basic ethical standards for the health Internet. Sites that conform to those 8 principles are allowed to display the active HON Code logo on their pages.

This is a self-certification system that has little control of how the logo is used. However, HON does try to police the use and abuse of its logo through the following mechanisms:

- An alert of breach is sent to the provider
- A warning is issued to the offending site
- Removal of the live link between the HON logo on the provider site and the HON site

HON also provides an online checklist questionnaire (Site-Checker) that can help consumers assess whether a given site conforms to the HON Code principles.

Sustainability issues

The HON Code places a burden on citizens through the need by those citizens to verify for themselves what is essentially a claim by the information provider. It is vulnerable to availability of funding for HON Foundation, which will be required to maintain the currency of the Code.

European Commission: Quality Criteria for Health Related Websites [27]

Launch Date

June 2001.

Responsible Organization

European Commission

DG Information Society: Information Society Technologies: Systems and Services for the Citizen

DG Health and Consumer Protection: Public Health

Intended target users

European Union member states.

Objectives

Produce a European Commission Communication on Good Practice Guidelines for the Health Internet. The scope of this Communication will be health-related information society services, and covers health information and services on the Internet. This scope does not extend to the category of products.

A European Commission Communication differs from a Directive in that it has no binding power on the member states to incorporate into domestic law. It is issued for guidance and to recommend a particular course of action. A Communication, however, can be used in legal arguments and a judge may cite it in cases of non-compliance.

Approach

EC "soft power" based on consensus building and guidance to member states on a voluntary code of conduct based on quality criteria.

Process

- Expert, stakeholder and EC civil servants workshop
- Drafting Group
- Online discussion
- Public consultation

Implementation mechanisms

Non-binding EC Communication guidance to member states.

Sustainability issues:

- Acceptance and implementation by member states will determine usefulness
- Like codes of conduct, it places a burden on citizens

OMNI [28- 29]

OMNI, Organizing Medical Networked Information, is part of the BIOME gateway hub.

Launch Date

1996.

Responsible Organization

UK (United Kingdom) Joint Information Services Committee (JISC), which also funds the program.

Intended target users

OMNI targets medical students, researchers, academics, and practitioners. OMNI is currently widening its appeal to consumers and is developing a set of quality-evaluation criteria for complementary and alternative medicine.

Objectives

Provide access to evaluated, quality Internet resources in the health and life sciences, aimed at students, researchers, academics, and practitioners.

Approach

Expert third party evaluation of networked medical information based on the OMNI "Evaluation Guidelines" created by the OMNI "Advisory Group on Evaluation Criteria."

Process

- OMNI Evaluation Guidelines created by the OMNI "Advisory Group on Evaluation Criteria
- Description and cataloging of resources based on the BIOME "Cataloguing Guidelines"
- Collection development policy

Implementation mechanisms

OMNI uses a standard web interface to search the catalogs of reviewed resources. It has catalogued approximately 4000 sites to date.

Sustainability issues

The OMNI team faces a Herculean task in keeping up with new sites, products, and services that are emerging all the time, let alone keeping the original evaluation up to date.

This places a burden on the team in terms of human and financial resources and at the same time, the OMNI program places a burden on citizens in terms of their need to understand and assess the quality criteria applied to the catalogs.

DISCERN [30- 31]

Launch Date

1999.

Responsible Organization

The DISCERN Project Team based at the Division of Public Health and Primary Care at the Institute of Health Sciences of the University of Oxford England. DISCERN is funded by UK National Health Service Executive Research and Development Programme.

Intended target users:

- Citizens seeking information on treatment choices for certain conditions
- Authors and publishers of information on treatment choices

Objectives

- Enable consumers to judge the quality of written information on treatment choices
- Facilitate the production of high quality evidence-based patient information

Approach

Citizen evaluation of Web sites carrying treatment information based on an aggregated assessment derived from a predefined questionnaire (the instrument).

Process

- Expert panel analysis. Panel composition: clinical specialists, self-help group representatives, general practitioners, consumer health information expert, lay medical publisher, health journalist, health consumer representative, Community Health Council representative, Plain English Campaign representative, and NHS Centre for Reviews and Dissemination representative
- Development of draft instrument
- Instrument testing
- Selected stakeholder testing
- National pilot
- Development of a standardized quality index derived from the questionnaire

Implementation mechanisms

Subjective rating system for decisions on treatment choices based on the questionnaire.

Sustainability issues

DISCERN places a burden on the citizens, as they would have to (a) understand the quality criteria behind the questionnaire, (b) have the commitment to fill in the questionnaire, and(c) have the ability to understand the meaning of the score value.

Guidelines for Medical and Health Information Sites on the Internet - Principles Governing AMA Web Sites [32- 33]

Launch Date

2000.

Responsible Organization

American Medical Association (AMA)

Intended target users

Web sites of the American Medical Association, Medem (http://www.medem.com) and other providers and users of medical information on the Web.

Objectives

Govern the Web sites of the AMA, AMA Publications, and Medem.

Approach

Rules of conduct that govern health information on the Web are based on those that govern medical journals, including rules of peer review, authorship, full disclosure of funding and sponsorship, editorial independence, separation of content and advertising, and the principles of privacy and confidentiality based on the principle of informed consent.

Process

The development of these guidelines began in 1999. An AMA staff committee, composed of the listed authors, was organized to review the existing individual guidelines and draft a single document that would provide principles to govern the presentation and functionality of the 4 major areas for which quality standards were needed: content, advertising and sponsorship, privacy and confidentiality, and e-commerce.

Committee members reviewed initial drafts and consensus was reached on the content of each of the 4 principles. The document was then reviewed internally and externally by experts in ethics, publishing, government regulations, law, and medical informatics, and by the AMA Online Oversight Panel. After subsequent revision, the document was reviewed by the Executive Committee of the AMA Board of Trustees and was approved on February 28, 2000. The guidelines underwent peer review and were published in JAMA on March 22, 2000.

Implementation mechanisms

These are governance tools intended for use by the developers of the AMA's Web sites and of the Medem Web site. Other organizations have adopted these guidelines or used them as the basis for their guidelines. The AMA does not ensure compliance with the guidelines for organizations other than itself and Medem.

Quality Standards for Medical Publishing on the Web [34]

Launch Date

1996.

Responsible Organization

British Healthcare Internet Association (BHIA).

This is a not-for-profit organization whose mission is better health care through the application of Internet technologies. It is funded by membership fees. The membership is open to anyone who supports the mission of the organization, and currently comprises clinicians, publishers, Web site developers, information providers, information technology professionals, health care managers, government officers, and academics. The BHIA has 120 members. The organization is currently not active.

Intended target users

Medical Webmasters and medical information providers.

Objectives

Better quality of medical information on the web.

Approach

A set of quality criteria for improving the quality of on-line medical information focusing on the content of Web sites.

Process

Paul Galloway authored the draft of the quality standards. That draft was submitted to the membership for comments and amendments. The final document was approved by the membership as a BHIA Recommendation in an online consensus process.

Implementation mechanisms

Guidance to medical Webmasters.

There has been no further development of the criteria and it is not known if they are used in practice and, if they are used, it is not known how they are used.

The Health Summit Working Group (HSWG) Criteria for Assessing the Quality of Health Information on the Internet: IQ Tool [35]

Launch Date

1997/1998.

Originally funded by Mitretek Systems Inc [36], the HSWG IQ Tool is one of the earliest tools-based scoring methods for assessing the quality of health websites.

Mitretek Systems Inc, although it morally supports the use of the tool, no longer funds the project. The project is no longer developed or maintained by any organization.

The tool was developed using an expert-group consensus process. The work resulted in a set of criteria that have a weighted scoring system.

Users deploy the tool when visiting a Web site they wish to evaluate and have to go through the process of completing the questionnaire in order to arrive at a quality score.

It is not know whether this tool is in use.

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Code of Marketing [37]

Launch Date

1981/1982.

Last major revision: 1994.

The IFPMA Code of Marketing sets out universal principles for ethical marketing conduct for use in countries where a more-demanding national code of conduct does not exist.

The Code applies to ethical pharmaceutical products and stresses the need to respect local and national laws; however, its scope also includes the controversial issue of direct-to-consumer marketing of ethical pharmaceutical products.

The IFPMA Code does not have specific clauses on Internet health information; however, it includes the addendum below addressing the issue of the Internet in a vague and general way:

> *Addendum 1:*
>
> *Use of the Internet*
>
> *The research based pharmaceutical industry, represented by the IFPMA, strongly supports the right to use the Internet as a means of providing accurate and scientifically reliable information on medicines in a responsible manner, for the benefit of patients, healthcare professionals and other appropriate parties. Recognizing patient safety is of paramount importance, IFPMA's goal is to encourage the appropriate use of the Internet.*
>
> *The IFPMA considers that there should be open access to all information put on the Internet by pharmaceutical companies. It accepts that there are national differences in the laws and regulations governing the promotion of medicines.*
>
> *Many pharmaceutical companies have established corporate sites on the Internet, which provide information about the company. Non-product related information is outside the scope of the IFPMA Code.*
>
> *The IFPMA recognizes that certain uses of the Internet may fall within the scope of the IFPMA Code of Pharmaceutical Marketing Practices. The following points concern product-related information:*
>
> *The identity of the pharmaceutical company and of the intended audience should be readily apparent. The content should be appropriate for the intended audience. Links should be appropriate and apparent to the intended audience. Country-specific information must comply with local requirements.*

The IFPMA Marketing Code, does not specify in detail what aspects of the Code apply to health information (on, for example, diseases and conditions) attached to products or produced and published by pharmaceutical companies on the Internet.

It would be interesting to determine the level of acceptance and implementation by member pharmaceutical companies. It is important to determine how this guidance from the IFPMA differs from any criteria set by pharmaceutical companies for their own internal processes in general.

Other pharmaceutical organizations that may have an impact on quality of Internet health information

Listed below are some of the organizations that may have an impact on quality of Internet health information of pharmaceutical companies in the relevant jurisdictions. Almost all of these organizations will have some sort of reference to quality standards of health information published by their constituencies on the Internet. The list below was adapted with permission from the InPharm Web site http://www.inpharm.com/db/ieindex.html.

All Web sites in this list: [accessed 2001 Oct 4].

- General Pharmaceutical Inspectorate (Belgium) URL: http://www.afigp.fgov.be/
- Medicines Evaluation Board (Netherlands) URL: http://www.cbg-meb.nl/uk/overcbg/index.htm
- European Agency for the Evaluation of Medicinal Products URL: http://www.emea.eu.int/
- European Department for the Quality of Medicines-European Pharmacopoeia on the Web URL: http://www.pheur.org/
- European Society of Regulatory Affairs URL: http://www.esra.org/Resource.phx/community/mainpage/mainpage.htx
- US Food and Drug Administration (FDA)-Center for Drug Evaluation and Research URL: http://www.fda.gov/cder/

- US Food and Drug Administration URL: http://www.fda.gov
- IDRAC, International Drug Registration URL: http://www.eu.imshealth.com/idrac/
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use URL: http://www.ifpma.org/ich1.html
- Irish Medicines Board URL: http://www.imb.ie
- UK Medicines Control Agency URL: http://www.mca.gov.uk/
- UK National Institute for Biological Standards and Control URL: http://www.nibsc.ac.uk/
- Pharmaceutical and Medical Devices Evaluation Center (Japan) URL: http://www.nihs.go.jp/pmdec/outline.htm
- Prescription Pricing Authority (UK) URL: http://www.ppa.org.uk/
- Regulatory Affairs Professionals Society (RAPS) URL: http://www.raps.org/
- Medical Products Agency (Sweden) URL: http://www3.mpa.se/ie_engindex.html
- The United States Pharmacopoeial Convention Inc URL: http://www.usp.org/

Discussion

The discussion is organized into:

- Key mechanisms of the health information quality initiatives
- **Sustainability issues**
- Enforcement issues
- Adequacy of approach and enforcement provisions
- Scope and reach
- Gaps that need to be addressed

Key mechanisms of the health information quality initiatives

The starting block of all the initiatives is a set of quality criteria. These sets of criteria range from the simple common-sense perspective of Paul Galloway and the peer-review journal approach of William Silberg et al [38], to the extensive and elaborate sets of quality criteria of URAC and MedCERTAIN.

All the sets of criteria derive from very similar roots and differ only in the language and expression of those roots. Briefly, these roots are the principles of honesty, privacy, confidentiality, accuracy, currency, provenance, consent, disclosure, and accountability.

The initiatives' developers chose different mechanisms to transform these sets of quality criteria into programs of Internet health information governance. On the surface, these key mechanisms seem to be many; however, a closer look reveals that these key mechanisms (or philosophies) belong to one of 3 underlying mechanisms.

These 3 key mechanisms can be summarized as follows:

Codes of conduct or ethics

These are based on principles of ethical behavior and sets of quality criteria. Almost all the quality criteria used by the initiatives converge at some point or another. It is only the language used to describe the criteria that is different. For example, the ehealth Code of Ethics states: "Disclose information that if known by consumers would likely affect consumers' understanding or use of the site or purchase or use of a product or service" in the "Candor and honesty," section, whereas we find Hi-Ethics Inc states: "We will inform consumers who use our Internet health services of the risks, responsibilities, and reasonable expectations associated with their use of our services" in the "Transparency of Interactions, Candor and Trustworthiness" section.

Codes of conduct rely on self-certification by participating Web sites, for example, those displaying the HON Code. This self-certification process is nothing more than a claim or a pledge that has little enforceability.

Third-party certification

This requires recurrent validation of compliance with a set of standards. These standards may or may not be based on some of the codes of conduct and ethics discussed here. In all cases, third-party certification requires payment of fees to the certifying company.

Special note on the metadata element of the MedCERTAIN initiative:

- The MedCERTAIN initiative is essentially a third-party certification program. However, the developers describe the program as third-party description and annotation rather than certification. Thus, it would seem that the MedCERTAIN process contains both elements of "self-description" and third-party evaluation.
- The program uses sets of detailed quality tags (quality vocabulary) embedded in the technical infrastructure of documents to describe the content on offer (similar in concept to food labels) [39].
- Users of health information would be able to filter the content they receive or view based on, initially, being aware of the metadata sheet, and later, automatically via the setting of personal preferences within the browser environment (downstream filtering).
- Third parties endorsing, describing, or evaluating other sites, for example, gateways and libraries (such as MedlinePlus or OMNI); professional associations; or certifying organizations (such as URAC), can use this metadata language to describe information content or information providers.

Tool-based evaluation

This is mostly based on a predefined questionnaire that would yield a certain "quality score" for the content under evaluation.

Tool-based evaluation is primarily intended for use by citizens, who would invoke the particular tool to assess the quality of a given site. This process differs from self-certification and logo-bearing sites, for example, under the HON or MedCERTAIN programs [Comment added by the editor: However, note that MedCERTAIN enables the development of intelligent "next generation" tools aggregating and interpreting metadata, see editorial]

Advantages and disadvantages of the three key mechanisms are listed in Table 4.

Sustainability issues

The following unresolved issues cast doubts over the ability of the various quality initiatives to survive what is largely an unregulated and often anarchic medium.

Burdens

All the quality initiatives under discussion place a number of burdens on producers and users of health information and on others. These burdens are seen as a serious threat to the sustainability and maintenance of the quality standards. The burdens fall on one or more of the following:

- Citizens: by having to care about, bother about, understand, and apply the methodology of any given initiative
- Providers of health information: by having to understand, interpret, and specify the program, and apply the program to their operations
- Third-party accreditation organizations: by having to acquire sufficient knowledge and a customer base to make their business viable
- Organizations that sponsor initiatives: by having to develop and maintain their programs, often under very adverse financial conditions, for example, many of these organizations rely on donations and grant money that might not always be forthcoming
- Clinicians and other health care workers: by having to care about, bother about, understand, and apply the methodology of any given initiative

Currency and maintenance

The ability of the organizations sponsoring the quality initiatives to maintain their initiatives up to date can be vulnerable to scarcity of funding (for voluntary and non-profit organizations and for-profit and fee-based organizations alike), and to low acceptance of quality programs. This is particularly acute at times of rapid change in the health Internet or market downturns that affect donor contribution or membership gains adversely.

Funding

Most of the initiatives rely on donation and grant money to maintain and develop their work. This makes them vulnerable to conditions outside the their control at best, and to potential undue influence at worst.

Table 4. Advantages and Disadvantages of the 3 Key Mechanisms of the Health Information Quality Initiatives

Mechanism	Advantages	Disadvantages
Codes of conduct	• Usually developed by broad-based participation • Create useful stakeholder consensus • Amenable to sector-specific interpretation • Can be updated as necessary with relative ease • Can be implemented by any organization, large or small • Create synergy between corporate objectives and ethical environments	• Implementation is by a nonbinding pledge • Open to abuse • Potential for misinterpretation of principles • Require non-specific organizational change that is difficult to measure • Difficult to measure utilization by Web sites and citizens • Difficult to measure effectiveness
Third-party certification	• Provides independent validation and revalidation • Can be objective • Forces organizational change in terms of ethical culture, audit, and accountability • Forces provider education • Clear criteria that are consistently applied; but, criteria can be quite clear, without being well-considered and defendable • Relatively easy to measure utilization (in the case of fee-for-service programs) • Can be used as a quality differentiator	• High cost to providers • Exclusion of smaller and other deserving providers due to cost or required organizational change • User indifference (don't know, don't care) • Provider ambivalence (don't care, can't do) • Enforcement relies on withdrawal of accreditation; this has a weak impact • Labor and resource intensive in the case of manual review and certification (eg, MedCERTAIN and OMNI)
Tool-based evaluation	• Consistency of process	• Semblance of objectivity • User indifference • Difficult to measure utilization by Web sites and citizens • Difficult to measure effectiveness • Narrow "expert"-only participation in developing the questionnaires that underlie the tool • False sense of security • Difficult to maintain currency • Difficult to establish validity

Cost

The initiatives most likely to command credibility are those in which there is independent third-party certification. Yet, third-party certification places a financial burden on the organization seeking certification, because of the high level of fees charged for accreditation or certification as well as the cost of the required organizational change. There are no credible means of offsetting that cost or ameliorating it for small yet useful providers.

Acceptance

Most of the initiatives rely on establishing a critical mass of acceptance. It remains difficult to assess the degree of current or future acceptance for any given initiative.

Market conditions

Prevailing market conditions play a crucial role in determining corporate policies. There is a real fear that market downturns would affect quality implementation adversely. Equally, in times of plenty, corporate sights might be set on other things. In market downturns, quality and ethics might be victims of cutbacks. In times of plenty, quality and ethics might be relegated behind profit making, unless they are seen to be a competitive advantage.

User indifference or ambivalence

Users need to care about, bother about, understand, and implement the requirements of the quality initiatives; but, users

- might not be aware of the issues of quality or the existence of quality initiatives and programs
- might care about and be aware of the quality initiatives, but not understand the initiatives and the requirements these initiatives place on them
- might not care too much about quality issues
- might be aware of and care about quality of health information, yet not bother too much about following what is required of them by the various initiatives

Enforcement issues

All except one of the quality initiatives discussed here are based on self-regulation systems that are applied voluntarily and which have enforcement mechanisms that rely on the unconvincing notions of self-declaration, self-certification, or withdrawal of accreditation. The exception is the initiative by the American Medical Association's program, which is enforced by the AMA corporate body.

Even when third-party certification and revalidation are the requirements, it seems that the only enforcement sanction is withdrawal of accreditation, which might not be a very effective enforcement sanction or might have a weak impact on the Web site in question.

Enforcement provisions of the voluntary initiatives discussed here do not seem to be adequate in view of the lack of credible sanctions for non-compliance and worthy rewards for compliance.

There are so many disparate constituencies within the domain of Internet health information that it is quite difficult to see how sector-specific self-regulation can be successful without further and deeper characterization, interpretation, and specification to identify the needs of specific sectors of information providers.

Enforcement mechanisms used are summarized as follows:

- None
- Self-certification or a pledge, without validation
- Third-party withdrawal of accreditation and revalidation by a third party

Adequacy of approach and enforcement provisions

The following inadequacies in the approach and enforcement provisions have been identified.

The potential high cost of implementing quality standards, particularly by small and voluntarily-funded entities.

The inability to formulate mechanisms that address the quality of the "pseudo-health" sector:

- The existence of the pseudo-health segment of information producers and users complicates efforts to introduce quality standards for health information on the Internet. This is the "gray market" of health information and it includes practices and remedies that have not yet been proven empirically or anecdotally; some unproven wellness products; misleading nutrition information; dubious mineral, plant and animal alternatives to pharmaceuticals; and the dissemination of untypical personal experiences.
- This pseudo-health sector presents the most challenges in ensuring the dissemination of good quality health information and practices. Whereas reputable producers of health information on the Internet would not have many problems complying with most of the quality criteria under discussion, the pseudo-health sector will probably remain outside the philosophy of applying quality standards in a self-regulatory manner. This is because much of the motivation for this sector is mainly financial gain through fraud and deception.
- It is important to distinguish this sector from the alternative and complementary health-care sector. Many of the disciplines in the latter sector have an important and legitimate role to play in the health and well-being of many people.

The lack of credible incentive and deterrence in implementing quality policies by information providers.

The size of the burden placed on the various players.

The absence of strategies for auditing utilization of the initiative's implementation.

The absence of adequate sector characterization and specification.

Lack of clarity of the language and terminology of quality [40].

Absence of any clear mechanisms for cooperating with regulatory authorities to implement programs of co-regulation.

Absence of clear strategies to extend the proposed protection measures on a global scale.

Inadequate response to liberal and conservative arguments against development of standards for health information on the Internet.

Scope and reach

Most of the initiatives target citizens as the ultimate beneficiaries without recognizing the scale and practical challenges of citizen-education issues and the diverse levels of critical appraisal skills among citizens.

That focus on citizens ignores the other participants in the matrix of health information: for example, clinical services providers, research communities, public health institutions, and policy makers worldwide. It also neglects the crucial role of doctors and other health-care workers as effective arbiters of quality of health information.

Many of the initiatives do not have a universal reach, for example, Hi-Ethics Principles and the AMA Guidelines.

All the initiatives stem from a Western orthodox view of health and health information. This is particularly noticeable whenever evidence is mentioned. Examination of quality initiatives originating from non-English speaking organizations might provide a different view.

None of the initiatives address the issues and needs of communities that are still catching up with, deprived of, or oblivious of the information revolution because of poverty, lack of access to content and connectivity, or the capacity to produce and disseminate health information.

With the exception of the eHealth Code of Ethics, MedCERTAIN, and the HON Code, the initiatives are published in the English language only. Not only does that limit the benefits accrued to non-English speaking citizens, but it also prohibits non-English speakers from contributing to the formulation of Internet health information standards.

Gaps that need to be addressed

Many of the gaps that need to be addressed in future quality initiatives are discussed above. In summary, these gaps are (in order of priority):

- Enforcement provision
- Burdens
- Sustainability
- Scope
- Reach
- Definition of quality
- Language and terminology
- Meaningful dialogue with regulatory authorities and entities outside the health Internet sphere
- Strategic and operational programs of co-regulation
- Audience characterization and specification
- Provider education
- Language and readability barriers
- Audit strategies for quality-program utilization
- The pseudo-health sector
- The needs of clinicians and other health-care workers
- The role of clinicians and other health care workers as effective intermediaries of health information quality

Conclusions

The complexity of the issues surrounding quality of health information in the context of the health Internet has been shown.

Some of the key self-regulation initiatives of Internet health information quality have been described and analyzed. The various initiatives have been compared in a number of ways.

The "Discussion" section, above, clarifies and discusses the issues and requirements for the further development of Internet health information quality.

Conclusion 1

Internet health quality initiatives discussed here have 1 of 3 mechanisms. It seems that 1 or more of 3 mechanisms would underpin future development of quality initiatives. These key mechanisms are:

- Codes of conduct or ethics
- Third-party certification of compliance (accreditation)
- Tool-based evaluation of quality

Conclusion 2

Based on the analysis of quality initiatives and the discussion above, it is proposed that a successful quality program has these 3 essential elements:

- A set of health information quality criteria
- An educated, interested, and active citizen
- Credible enforcement instrument(s)

None of the initiatives discussed in this paper comprise all 3 elements convincingly.

These 3 elements must be taken into account in any future developments and implementation of health information standards.

Conclusion 3

The current batch of quality initiatives for Internet health information reveals many gaps that need to be addressed. These gaps are discussed and listed in this paper. The most serious of these gaps are the excessive burdens placed upon citizens and the cost of implementing credible programs providing accreditation and enforcement.

Further examination and the addressing of these gaps is essential for any future development work on Internet health information governance.

Conclusion 4

More research is needed to further clarify the complexities of Internet health information. Of special interest are the governance mechanisms that need to address quality of information content and information value, the context and relevance of the content of information, the educated interested citizen, and the desired instruments that would strengthen any envisaged enforcement provision.

Conclusion 5

There is an urgent requirement to examine the needs of the developing world and the info-poor in relation to quality of Internet health information, products, and services. This is a reflection on how poorly the current batch of quality initiatives have addressed those needs.

This examination would include determining whether or how quality standards can help developing countries, especially where regulatory agencies are weak or nonexistent; or where there is excessive, uninformed, or onerous regulation.

Conclusion 6

There are no current mechanisms for ensuring the quality of Internet health information in relation to the pseudo-health sector. This sector will probably remain outside the efforts to implement governance of health information quality.

Conclusion 7

The quality initiatives discussed here have not addressed the thorny issue of alternative and complementary disciplines outside the orthodox view of health care.

These disciplines differ from those of the pseudo-health sector in that they have a legitimate place in health care, whereas the pseudo-health sector is essentially about fraud and quackery.

Conclusion 8

Language, whether in tongue or in syntax, remains a major obstacle to the dissemination of good practices and the education of citizens and information providers alike.

Conclusion 9

There is a need for coordination and harmonization of the efforts striving towards quality health information on the Internet. This extends to the key players in both the self-regulation and the mainstream and regulatory camps, and includes regional and international bodies, the health care products industry, foundations with an explicit interest in Internet health information, private and corporate interests, and citizen and country representation and participation.

Conclusion 10

There are concerns and criticisms directed against establishing models of governance for Internet health information quality. These arguments come from different perspectives and take different routes but arrive at the same destination. These concerns include:

- Users are ambivalent or indifferent about quality through ignorance, lack of caring, or low priority
- Quality programs that are not rigorously enforced and validated might produce a false sense of security
- Traditional media did not require quality standards; therefore neither should the new media
- Brand loyalty is more important than quality seals; the Internet has no center; therefore, it does not need central control; and, kitemarking (referring to the application of a kite-shaped mark granted for use on goods approved for use by the British Standards Institution) the Internet is like "kitemarking the west wind" [41].
- Freedom of speech
- Free market forces
- The enormous practical and logistical difficulties associated with implementing quality programs are a barrier to implementation

As arguments, they are in no way compelling or well thought out. Indeed, they seem more to be descriptions of behavior for which no rationale for taking them seriously is given by those who invoke them.

It is concluded that these arguments should be countered with a coherent strategy for health information quality governance that can unite the stakeholders in an effort to reduce the risk of harm to citizens throughout the world (see "Recommendations," below).

Recommendations

In any new field of human endeavor there emerges at the beginning a group of individual pioneers, visionaries, and entrepreneurs. These individuals, by their nature, kick-start the standards setting process for that new field. They tend to do this either as individuals or through forming into associations. These are mostly voluntary organizations that rely on the enthusiasm and energy of their members, and often struggle to meet the financial and management demands that are placed upon them.

The new field of and the early work in standards development eventually attract the attention of society's mainstream players or the gap between the pioneers and the mainstream players narrows enough for the mantle to pass onto the mainstream players.

The health Internet has been no different. We are probably at the cusp of that convergence to the extent that it has become imperative to bring together the 2 camps of active pioneers and mainstream players in a coherent and coordinated process to develop the next generation of quality standards.

The need for global leadership

Quality of Internet health information is important, because it has the potential to benefit or harm a large number of people. It has this potential because of the nature of the Internet and the Internet's rapid worldwide spread.

The quality of Internet health information is too important to be left to the anarchy of the Internet or the vagaries of the free market, or to be conducted in a haphazard uncoordinated way.

The absence of clear, credible, and trusted leadership in the sphere of Internet health information compounds the problems of quality and trust relationships among people who use the Internet for health purposes.

The author believes that there is a need for clear leadership on a global scale to achieve the yet-unfulfilled promise of information and communication technologies of better health for all.

This global leadership needs to take the following steps to assume that leadership role:

- Bring together the key players of both the pioneer and mainstream camps in a coherent effort that can benefit all citizens of the world
- Harmonize a global framework for Internet health information quality standards
- Act as intellectual and technical knowledge resource for the world
- Provide custody and good stewardship of the evolving standards
- Implement a program to ensure the prevention of harm to communities and nations yet to be exposed to powerful free-market-economy forces

- Safeguard the interests of the info-poor
- Provide impartial advice and guidance not constrained by politics or geography
- Facilitate the dialogue between the interested parties of self-regulation and the regulatory authorities towards the creation of programs of co-regulation
- Work towards "the global public good" and the benefit of all citizens of the world

The role of the World Health Organization (WHO)

In line with the WHO's global role in setting norms and standards and assisting member states to implement these norms and standards, the organization has a crucial role to play in developing norms and standards for Internet health information quality.

We recommend that the WHO's activity in this sphere should include the following terms of reference:

- The fulfillment of 3 crucial requirements:
  o Increase the understanding of Internet health information quality standards
  o Assess the impact of implementation of such standards at country level
  o Recommend a framework of action for Internet health information quality
- Bringing together key players from the stakeholder communities in a coherent and coordinated manner.
- Ensuring good stewardship of ethics and quality standards development.
- Consensus building among the various interested parties.
- Facilitating the steering of these programs towards the establishment of universally-agreed quality standards for Internet health information.
- Providing a world resource for Internet health information quality thinking and research.
- Coordinating educational and training activities relating to quality.
- Disseminating good practices throughout the world and assisting member states in the implementation of those good practices.
- Working with the private sector to help advance the cause of quality of Internet health information.

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Conflicts of Interest

This work was commissioned by the World Health Organization. AR and JD were engaged as a Consultant at the World Health Organization to carry out this and other research.
AR is a member of the Board of Directors of the Internet Healthcare Coalition and cochairs its eHealth Code of Ethics Initiative. AR also has taken part in a number of workshops and meetings organized by some of the organizations represented here. These organizations include MedCERTAIN, URAC, and the European Commission. This work was unpaid.
Tim Nater (external reviewer) was Executive Director of the Health on the Net Foundation (HON) until last year, and remains a member of the eHealth Code of Ethics Steering Group.
Bette Crigger (external reviewer) served as the Project Editor for the eHealth Code of Ethics, and had prepared a comparison of that code and those of the American Medical Association, HON, and Hi-Ethics, for the benefit of the eHealth Code of Ethics Steering Group.

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Abbreviations

AMA: American Medical Association
BHIA: British Healthcare Internet Association
EC: European Community
EU: European Union
HIDDEL: Health Information Disclosure, Description and Evaluation Language
HON: Health on the Net
HSWG: The Health Summit Working Group
HSWG IQ Tool: The Health Summit Working Group-Criteria for Assessing the Quality of Health Information on the Internet: IQ Tool
IFPMA: International Federation of Pharmaceutical Manufacturers Associations
ISO: International Organization for Standardization
IT: Information Technology
NBF: Notified Body Function
OMNI: Organizing Medical Networked Information
QMIC: TNO Quality Medical Information and Communication
TIP: Trusted Independent Party
UK: United Kingdom
US: United States
WHO: World Health Organization
XML: Extensible Markup Language

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Viewpoint

Commentary to "Review of Internet Health Information Quality Initiatives"

Cynthia Baur[1]; Mary Jo Deering[1]

Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, USA

Corresponding Author:
Cynthia BaurSenior Policy Advisor in e-Health
Office of Disease Prevention and Health Promotion
U.S. Department of Health and Human Services
200 Independence Ave SW Rm 738G
Washington DC 20201
USA
Phone: +1 202 205 2311
Fax: +1 202 205 0463
Email: cbaur@osophs.dhhs.gov

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The report of Ahmad Risk and Joan Dzenowagis for the World Health Organization [1] provides a useful compendium and commentary for those who are trying to get a handle on the proliferation of quality improvement mechanisms for the health Internet. The authors identify the prevention of harm and citizen protection as the main motivations for quality improvement efforts. We suggest that realizing the potential of the Internet for health improvements should be an equal if not more important reason to undertake quality improvement activities. This affirmative purpose is important because the current evidence suggests that actual harm has been negligible to date, and over time, benefits on a population basis could be substantial.

The report summarizes and comments on thirteen quality improvement initiatives that have been developed since the mid-1990s. Some are included mainly for historical purposes. Although the authors include a section on "implementation mechanisms," there is no clear means for someone who has not been following the progress of the initiatives to distinguish which initiatives are most substantial, furthest along and likely to be supported by health Internet Web sponsors. Readers would benefit from further categorization of initiatives in terms of potential for realization and likely support in the health Internet space.

The paper provides persuasive evidence that the commonalities of substance among the various approaches outweigh the differences of their specific implementation approaches. The authors observe that all the initiatives begin with quality criteria that derive from similar roots and have involved consensus-building, the scope of which depended on how the initiative's participants defined their interests and constituents. It is hard to avoid the conclusion that the time is ripe to bring the fundamental language of the different initiatives into harmony, and consolidate the agreement that has emerged to date. The author's equally persuasive discussion of the many remaining pitfalls in implementation and sustainability suggests that the individual initiatives might be interested in common solutions to share the burdens of operating and financing quality improvement activities on an on-going basis.

More consolidated implementation would also make it easier to think about how to deal with an issue that has been sidelined in much of the debate about quality standards: communication with end users about quality. Communication with users or the public broadly about the importance and nature of quality and quality standards has continuously been a missing but essential piece of the quality activities in the health Internet space. As the report acknowledges, the current crop of initiatives places a heavy burden on the end user to sort out what the criteria, seals, and tools mean and when to apply them. Consumer education about the importance of quality, the meaning of quality criteria and the different approaches merits a brief mention in the Recommendations, but it is clearly subordinated to the other activities listed in the section, despite the author's conclusion (#2) that an educated, interested and active citizenry is essential for the success of any quality program. Communicating with the public generally and end users of specific health Internet resources about quality must be a top priority for the field, no matter which initiatives survive and in what form.

The paper proposes that we need global leadership to move to the next generation of quality standards. Depending on the extent of Web site sponsors' participation, a global approach potentially decreases the proliferation of initiatives and consumer/citizen confusion about their different meanings and value. Global leadership could motivate a large number of Web sites to get behind the same set of criteria, or at least some core set. There is no question that being able to clearly communicate to users about a widely endorsed and recognizable set of quality standards, issues, and implementation would be a great public good. Although it would not be necessary that all public

education about quality be coordinated by a single entity, global leadership in promoting culturally appropriate communications about core criteria and approaches would be beneficial. WHO is experienced in the varieties of health-related attitudes and practices and could extend this experience to the field of health information. But, global leadership and global governance are not the same. Global governance requires at least a minimum set of shared values and understanding of the problem and appropriate remedies, including the appropriate actors to undertake such actions. It is not clear yet that we have this in the health Internet space on a national, let alone international, scale.

Two problems clearly challenge any quality initiative: how to sustain it, and how to influence those health Internet actors who will most likely remain outside the boundaries of quality initiatives, especially those the author calls "pseudo health" and quackery. The authors carefully avoid recommending that WHO become the single guarantor of global standards, although they come close. Further clarification would be needed about the exact "what" and "how," before WHO could propose such a role to its member states. WHO would most likely have to make a long-term commitment and undertake activities outside its traditional mandate. Even more troubling, though, is the nagging certainty that even if the best system in the world were developed and implemented, it would most likely have its strongest influence on the better, more responsible, and more easily traceable Internet health activities. Those activities that are most spurious and likely to cause actual harm are also most likely to ignore quality standards, although clearly fraudulent activities may be covered by the laws of individual countries. Enforcement efforts in a few countries to date-and efforts from other sectors-would be instructive. In the U.S., a governmental apparatus exists to deal with fraud and quackery, although there is nothing comparable to address activities that do not rise to the level of law-breaking.

The time has come for a global dialog on Internet health quality and concrete steps toward harmonization, coordination, and-most important-effective communication to our many publics. We may not reach a fixed "solution" to the dual challenges of risks and benefits, but we could at least consolidate the path taken to date into a firm foundation for next steps.

Conflicts of Interest

None declared.

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Original Paper

A Java-based Electronic Healthcare Record Software for Beta-thalassaemia

S Deftereos[1], MD, PhD; C Lambrinoudakis[2]; P Andriopoulos[3], MD; D Farmakis[1], MD; A Aessopos[1]

[1]First Department of Internal Medicine, University of Athens, Medical School, Laiko Hospital, Ag. Thoma 17, 11527, Athens, Greece

[2]Department of Information and Communication Systems, University of the Aegean, Karlovasi, 83200 Samos, Greece

[3]General Hospital of Sparti, Sparti, Greece

Corresponding Author:
S Deftereos, MD, PhD
Nikis 31 st, 13122
Ilion, Athens
Greece
Phone: +30977072366
Fax: +301 9314045
Email: deftereo@otenet.gr

Abstract

Background: Beta-thalassaemia is a hereditary disease, the prevalence of which is high in persons of Mediterranean, African, and Southeast Asian ancestry. In Greece it constitutes an important public health problem. Beta-thalassaemia necessitates continuous and complicated health care procedures such as daily chelation; biweekly transfusions; and periodic cardiology, endocrinology, and hepatology evaluations. Typically, different care items are offered in different, often-distant, health care units, which leads to increased patient mobility. This is especially true in rural areas. Medical records of patients suffering from beta-thalassaemia are inevitably complex and grow in size very fast. They are currently paper-based, scattered over all units involved in the care process. This hinders communication of information between health care professionals and makes processing of the medical records difficult, thus impeding medical research.

Objective: Our objective is to provide an electronic means for recording, communicating, and processing all data produced in the context of the care process of patients suffering from beta-thalassaemia.

Methods: We have developed - and we present in this paper - Java-based Electronic Healthcare Record (EHCR) software, called JAnaemia. JAnaemia is a general-purpose EHCR application, which can be customized for use in all medical specialties. Customization for beta-thalassaemia has been performed in collaboration with 4 Greek hospitals. To be capable of coping with patient record diversity, JAnaemia has been based on the EHCR architecture proposed in the ENV 13606:1999 standard, published by the CEN/TC251 committee. Compliance with the CEN architecture also ensures that several additional requirements are fulfilled in relation to clinical comprehensiveness; to record sharing and communication; and to ethical, medico-legal, and computational issues. Special care has been taken to provide a user-friendly, form-based interface for data entry and processing.

Results: The experience gained through the use of JAnaemia in 4 Greek hospitals reveals a significant contribution towards (1) improvement of the quality of the data being recorded, since data entry is guided by appropriate forms, (2) easier cooperation between physicians, who share a common information repository, and (3) increased processing capabilities, which facilitate medical research.

Conclusions: JAnaemia appears to be a useful tool, which can improve the quality of care offered to beta-thalassaemic patients in Greece.

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KEYWORDS

Medical records systems, computerized; computerized medical record; beta-thalassaemia; delivery of health care; automatic data processing

Introduction

Beta-thalassaemia is a hereditary disease, which results from a mutation in the genes that are responsible for the production of hemoglobin. The hemoglobin found in healthy persons is substituted by a nonfunctional protein, thus leading to severe anemia, the onset of which usually lies between the fourth and sixth month of life. Untreated severe beta-thalassaemia is uniformly fatal in childhood. Life can only be prolonged by periodic blood transfusions [1]. Unfortunately, transfusions overload patients with iron, which deposits on virtually all organs causing significant damage. Heart failure due to iron deposition on the heart, diabetes mellitus due to its deposition on the pancreas, and hepatic failure due to its deposition on the liver are only a few of the possible complications. As a result, patients suffering from beta-thalassaemia need to receive continuous chelation treatment, in order to remove the excess of iron from their body, as well as periodic hematology, cardiology, endocrinology, and hepatology evaluations. The content of these evaluations ranges from simple laboratory tests, such as complete blood count or oral glucose tolerance test, to complicated laboratory and imaging studies, such as heart and liver MRI (Magnetic Resonance Imaging) scans.

Evidently, the care process of patients suffering from beta-thalassaemia involves continuous and complex care procedures, which produce a large volume of diverse data. This makes the management of the current paper-based patient records cumbersome. The problem is further complicated by the fact that all required services are rarely offered by a single health care unit. Typically, different services are offered in different, often-distant, units, each of which maintains a separate record for each patient. Because there are currently no means of linking the individual records together, the most-common way of communication between health care professionals is through patients themselves. This often results in loss of data and in communication of inaccurate or erroneous information.

The prevalence of beta-thalassaemia is high in countries around the Mediterranean basin. It is also found in central Africa and Southeast Asia [2]. In Greece, it constitutes an important public health problem. We have therefore undertaken the development of an Electronic Healthcare Record (EHCR) software, called JAnaemia, to support the systematic collection of information related to beta-thalassaemic patients, to allow communication of patient records between the units participating in their care process, and to facilitate medical research. The software was developed in cooperation with 4 Greek hospitals and has been used in their everyday practice since late 2000. The software is based on Java [15,16] technology (see the Implementation section of Methods and in Discussion).

The complexity and diversity of the information recorded in patient records is one of the major issues with which contemporary research is concerned [3,4,5,6,7,8]. This is especially true in the domain of beta-thalassaemia, due to the inherent difficulties discussed above. JAnaemia builds upon the EHCR architecture proposed by the European Standardization Committee (CEN) in the ENV 13606:1999 standard [9,10,11,12]; in order to cope with the diversity of EHCR contents, the CEN architecture defines the building blocks from which patient records are constructed and the rules by which these can be put together, but imposes no restrictions upon the actual contents of individual records.

ENV 13606:1999 has already been implemented in a commercial product [29], which the authors have extensively used in the past, while a number of partial implementations have been produced by research groups [14]. The need for a new CEN-based EHCR application was dictated by 3 main facts:

1. Although ENV 13606:1999 defines a generic mechanism for specifying how patient record contents should be displayed, it does not further elaborate on presentation issues, allowing developers to customize them at will. Our previous experience, on the other hand, suggests that form-based data-entry Graphical User Interfaces make EHCR applications more user friendly and thus more attractive to physicians. It was therefore deemed necessary to produce a specialized version of the generic ENV 13606:1999 mechanism, in order to allow the contents of CEN-based patient records to be presented in a form-like manner.
2. Patient records, according to CEN, are composed of *Data Items*, the names of which may be specified in the form of codes retrieved from medical terminologies (see the Implementation section of Methods for a more-detailed description of *Data Items*). Existing CEN-based applications utilize the terminology produced by the Good European Health Record Project [4,7]. The authors have many times found this terminology limited, regarding the wealth of medical terms it contains and its capability of expressing the concepts pertaining to several clinical domains. This limitation is particularly important in the domain of beta-thalassaemia, due to the complexity of the health care items it involves and the number of medical terms that are necessary for recording and processing all relevant information. Such terminology limitations become critically dominant in the Greek language, where small variations in the syntax or grammar of a word may result in large variations in its meaning. The above-mentioned issues implied the need for a beta-thalassaemia-specific terminology and for an EHCR software capable of managing it. Our intention is to compare this custom terminology to currently-existing ones, in an attempt to draw conclusions on its suitability for beta-thalassaemia (see Discussion).
3. One of the user requirements for any EHCR software that would be utilized for maintaining the records of patients suffering from beta-thalassaemia was to support advanced data-processing capabilities, thus assisting health care professionals in their everyday work. Such functionality is not described in ENV 13606:1999; it was thus decided to define a generic data-processing mechanism for CEN-based EHCR applications (see the Implementation section of Methods).

Our initial goal was to develop a clinical system capable of supporting health care professionals in all data management tasks pertaining to beta-thalassaemia. However, given the

dependence of our work on ENV 13606:1999, we have been able to draw conclusions on the suitability of the standard for beta-thalassaemia and to propose possible enhancements (see Discussion).

In the Design Objectives section of Methods, we present the design objectives of JAnaemia. In the Implementation section of Methods, we describe the basics of the CEN architecture and we present in detail the JAnaemia software. In Results, we present the current status of the Project. In Discussion, we present our conclusions and provide pointers to further work.

Methods

Design Objectives

Laiko is one of the major Greek hospitals; it is located in the capital, Athens. Its First Department of Internal Medicine has been responsible since 1980 for the cardiology follow-up of approximately one thousand patients suffering from hemoglobinopathies, including beta-thalassaemia. Although most patients live in Athens, several originate from other parts of Greece. The Thalassaemia Unit of the Ag. Sophia Children's Hospital, which is also located in Athens, is responsible for providing transfusion and chelation services to the main bulk of beta-thalassaemic patients that live in the capital. These patients constitute the majority of the Greek patients suffering from the disease. Similar services are offered by the Thalassaemia Unit of the Hospital of Korinthos to patients living in the city of Korinthos, which is approximately 100 kilometers away from Athens, and in the rural areas nearby. The pediatric clinic of the Hospital of Sparti is responsible for the management of patients living in Southeastern Pelloponese, a region approximately 300 kilometers away from Athens.

Specialized services, such as MRI studies and stress tests, are offered by other independent health care units in Athens. While these are easily accessible by the citizens of Athens, this is not the case for patients living in Sparti or Korinthos.

To provide an efficient way to cope with the continuously-growing issues of information storage, retrieval, and processing, starting in early 1998 a pilot EHCR application was developed and introduced in the everyday practice of the First Department of Internal Medicine of the Laiko hospital. In the early releases of the software, medical information was entered via static forms, which contained predetermined cardiology data. It was not possible to modify the form contents according to the needs of individual patients or health care professionals. Although this pilot project has successfully met its initial goals, it soon became apparent that considerable problems would arise if we decided to enrich patient records with information originating from specialists other than cardiologists. More specifically, it would be extremely difficult to modify the application in a way suitable for accommodating any of the other data that are frequently produced during the care process of patients suffering from hemoglobinopathies. Communication of EHCRs between different specialists would be an equally-difficult problem.

It was therefore decided to redesign the application, taking into account the following issues:

1. The expected diversity of record contents; patient records should be allowed to contain information pertaining to any of the medical specialties and health care procedures relevant to beta-thalassaemia.
2. The diverse needs of health care units or health care professionals; different units offer varying ranges of services, while health care practices may also vary. The software should be customizable to the needs of individual users.
3. Ease of use and user friendliness; the form-based user interface, implemented in the pilot EHCR application, has been positively evaluated by physicians and it should therefore be utilized in the new application.
4. Automated data processing; the care process of patients suffering from beta-thalassaemia involves clinical decisions that are based on the results of laboratory tests, or on parameters derived as complicated functions of these results. All calculations required for the parameters are currently made by hand; they should be automated by the software.
5. Record sharing, within the context of a single unit or between units; contributions made to the record of each patient by various health care professionals should be communicable to all other professionals involved in the patient's care process. Since patient mobility has increased within the European Union, ethical, medicolegal, and automatic-translation issues should be taken into account. In this context, off-line methods for exchanging medical data between professionals should also be considered. An example is the support of personalized patient smart cards for storing a "minimal medical set" for the card owner.
6. Scalability; the software should be capable of running on different machines and operating systems, to allow different hardware and network configurations, according to the size of the units in which it operates.
7. Performance; the technology that will be employed for the development of the application must be appropriate for a hospital environment, where a significant number of users should be allowed to concurrently access the patient medical records and other supported functionality, without causing a deterioration of the application's performance or unavailability of the information.
8. Automatic integration of laboratory results into medical records; although this is a design objective for the new application, it has not been implemented in the current version since the participating hospitals do not have the necessary technical infrastructure for exporting laboratory data in electronic form.

Implementation

Electronic Healthcare Record Architecture

As mentioned in the Design Objectives section of Methods, the capability to manage diverse patient-record contents and the flexibility to customize the application to the needs of individual users are 2 major design objectives. Such features are provided by the Electronic Healthcare Record architecture proposed by CEN in the current European standard, ENV 13606:1999. In addition, the CEN architecture takes into account computational, educational, and medicolegal issues related to patient records, as well as issues of sharing, of clinical analysis, and of clinical

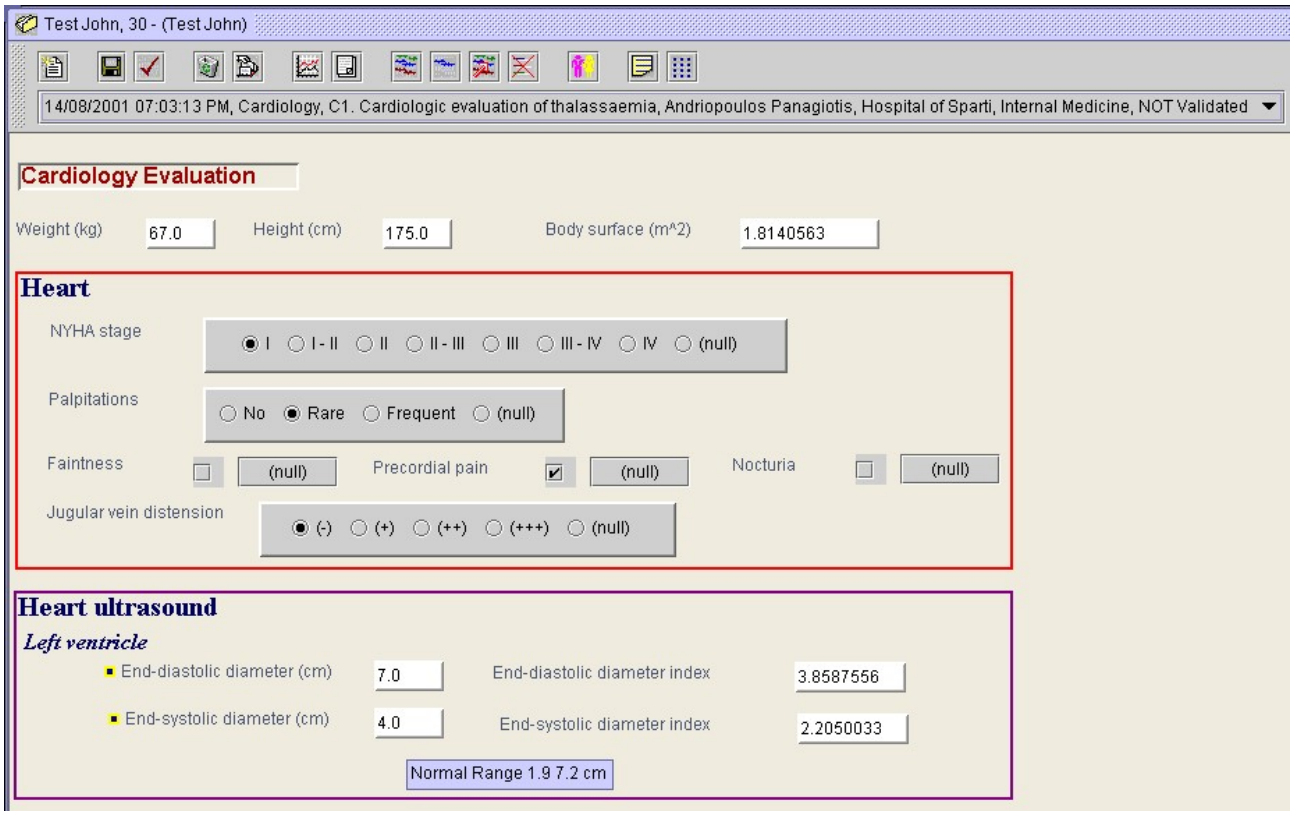
comprehensiveness [4,13]. JAnaemia is, therefore, based on this standard, an overview of which we provide in the current subsection.

ENV 13606:1999 defines that Electronic Healthcare Records consist of *Compositions* created during the various instances of health care service provision. Each *Composition* contains all data recorded at one place and time of care delivery, in a single session with a particular health care professional [9]. During a patient's lifetime, numerous *Compositions* may be created at different health care institutes, for different reasons. All these are uniquely identified and can be linked together to constitute the patient's lifelong EHCR. *Compositions* are the minimum groupings of patient-record data that can be safely transferred between different locations, without altering the meaning initially conveyed or violating any medicolegal rules that may apply to EHCR communication [9,17].

Compositions comprise *Data Items (DIs)*, either single or grouped together in *Clusters*. *DIs* are the smallest structural units into which the content of EHCRs can be broken without losing its meaning. *DI* clusters provide an aggregation mechanism for the representation of compound concepts. They consist of single *DIs*, linked together in a tree-like structure [9,17].

Figure 1 illustrates the above concepts. It presents an extract from the record of *Test John*, who is 30 years old. The details of the particular *Composition* are given in the combo box, directly under the toolbar; it was created on 14/08/2001, at 07:03:13 pm, by Dr Andriopoulos Panagiotis, at the department of Internal Medicine of the Hospital of Sparti and it contains a Cardiology evaluation. The combo box in Figure 1 contains a combination of different types of information, yet all this information is combined in a single string. The user can select from a drop-down list of such strings.

Figure 1. An extract from a Composition of a patient record



The reader can see that all the contents of the composition presented in Figure 1 lie under the heading "Cardiology Evaluation". *Headed Sections*, as defined in ENV 13606:1999, are subdivisions of compositions which are used to group entries with a common theme or which are derived through a common health care process [9]. *Headed Sections* often convey the situation in which the information was gathered (such as "cardiology evaluation") or the time relationship, place relationship, or person relationship the information has to the patient (such as patient history, management plan, or family history), without placing any constraints on the data they in turn contain [4,13,17].

Information on the patient weight, height, and body surface is recorded in the single *DIsWeight*, *Height*, and *Body surface* respectively, immediately below the heading. Although they are located under the *Headed Section* Cardiology Evaluation, there are no other constrains pertaining to those three *DIs*. Heart ultrasound results, on the contrary, are grouped under the item *Heart Ultrasound*, thus forming a *Cluster*. *DIsEnd-diastolic diameter*, *End-systolic diameter*, *End-diastolic diameter index*, and *End-systolic diameter index* are now perceived as conveying more-detailed information on the patient's *Heart ultrasound* and, more specifically, on its results pertaining to the *Left ventricle*. Although it is allowed to remove the *Weight*, *Height*, or *Body surface DIs* from the Headed Section, it is not allowed to remove any of the *DIs* that constitute the *Heart ultrasound* cluster; it is only allowed to remove the entire cluster.

The *Composition* in Figure 1 also includes selected information from the history and the clinical examination of the particular patient, grouped in the *Heart* cluster. The *Heart* and *Heart ultrasound* clusters and the *Weight*, *Height*, and *Body surface* single *Data Items* were all created at the same date and time, at the same place, by the same health care practitioner. They convey information on the health status of the patient at a particular point in time. For this reason, they are grouped together, thus forming a *Composition*.

Data Items are further qualified by their attributes, which convey all relevant information; the name of a *Data Item* is recorded in the *Component Name* attribute; its data type is recorded in the *Data Type Item Reference* attribute, and its actual content in the *Data Item Content* attribute. *Data Item* names may be specified in the form of codes retrieved from medical terminologies, such as SNOMED [18], UMLS [19] and the ones produced by the GEHR (Good European Health Record) [4] and GALEN Projects [20,21].

The *ComponentName* attribute of the *End-systolic diameter* item, presented in Figure 1, has the value *End-systolic diameter*(as one might expect), while its *Data Item Content* attribute has the value *4*. *DIs* can be further qualified by the *units* in which their contents are measured and their *range of normal values*. In our example, the units are *centimeters(cm)* and the normal range *1.9* to *7.2 cm*, as indicated by the tooltip in Figure 1. See Figure 1 for more examples and to the ENV 13606:1999 CEN standard for a complete account of the *Data Item* attributes.

JAnaemia implements all the above-mentioned concepts. CEN defines, in addition, a number of architectural sub-components, which are partially implemented in our work. They, too, are presented in detail in ENV 13606:1999.

Record Sharing and Communication

Efficient record sharing is of utmost importance in the domain of beta-thalassaemia, mainly because health care services are offered by multidisciplinary teams, usually scattered over several departments of even different units. It is, therefore, required that compositions created at the various places of care provision are communicated to all involved health care professionals.

The CEN architecture describes rules for distributing Electronic Healthcare Records, called *distribution rules*. *Distribution rules* are logical concepts or rules intended to convey intent for and govern the distribution of the EHCR components (the *Data Items*, *Clusters* and *Compositions* discussed in the Electronic Healthcare Record Architecture subsection of the Implementation section of Methods are examples of such components). *Distribution rules* constitute a controlling mechanism, enabling access to and/or further distribution of the components to which they are attributed. Distribution rules define, among other things, *who* should have access to a record component, *when* this access should be granted, *where*(ie, to which countries and/or health care units) and for *what purposes* the component may be distributed. CEN defines the general principles that govern EHCR distribution. Specific implementations are left to the developers of EHCR software [11].

CEN also describes a set of messages that implement the above-mentioned distribution rules and enable the electronic transfer of health care record information [12]. They have the form of XML documents and they are designed to allow the exchange of EHCR information between different types of clinical information systems.

The EHCR architecture presented in the Electronic Healthcare Record Architecture subsection of the Implementation section of Methods and elaborated on in ENV 13606:1999, together with its accompanying distribution rules and exchange messages, ensure that all pertinent ethical and legal issues are taken into consideration when EHCRs are transferred between health care professionals, working either in different units or in the same unit.

On the programming level, JAnaemia is based on the Java [15,16] technology. As mentioned in Introduction and the Design Objectives section of Methods, the software operates at departments of 4 different hospitals, of varying size and requirements. As the Project expands, smaller units (such as primary care centers) and bigger units (such as entire hospitals) may be involved. JAnaemia should be capable of running on a variety of operating systems, supporting different hardware and network configurations, according to the size of the involved units. While a single Intel-based PC [27] running Microsoft Windows 2000 [30] may be sufficient for a primary care center, a network of servers based on more-powerful processors, such as Sun's UltraSPARC [28], might be required for larger units. The portability features of Java make it an ideal choice for this purpose.

An additional reason for relying on Java is the rapidly-increasing use of Internet appliances. Several research groups have found the use of palmtop computers beneficial for data entry [31,32]. Java and the EmbeddedJava application environment [33] constitute one of the major operating environments for such devices. Since future work will focus on producing a version of JAnaemia for internet appliances, it was considered appropriate to develop it in Java from the very beginning.

EHCRs are stored in a central repository, currently implemented as a relational database maintained by Microsoft's SQL Server v7.0 [22]. SQL Server v7.0 was initially selected on the basis of its high performance [22]; yet the selection of the database engine may vary among health care units, depending on the their size, on the expected workload and, on the software and hardware configuration on which JAnaemia operates in each case.

Physician workstations run JAnaemia as a client that connects to the central repository via JDBC (informally, Java Database Connectivity) [23] - a method of interfacing Java software with SQL databases - and thus allows users to access the patient records. This architecture supports record sharing at the level of a single department or health care unit. In this context, individual workstations are linked to the database server via local intranets [24]; new compositions are stored in the EHCR repository, as parts of the patient records to which they pertain. In this manner, all members of the unit or department have direct access to the entire EHCR repository. It should be stressed that compositions are stored in the repository together with their

associated distribution rules. This ensures that appropriate access and transfer permissions are enforced, even in the context of a single health care unit or department. Thus, from the point of view of efficient and secure record sharing, accessing an EHCR from a common repository or over longer distances, via exchange messages, are equivalent.

Although the record sharing architecture (described in the paragraph directly above) method of sharing could be used over longer distances, via Internet for example, experience shows that it cannot reach the desired degree of efficiency. JAnaemia makes heavy use of JDBC and network resources and requires fast and reliable network connections. For this reason, a separate EHCR exchange mechanism is being developed, to allow communication of EHCRs between distant health care units. Complete patient records or record extracts are exported in the form of messages, implemented as XML documents, according to the Document Type Definitions (DTDs) provided by CEN [12]. They can then be transferred to remote sites over any available communication medium. Upon reception, they are imported to the local EHCR repository and from then on, they can be processed via JAnaemia. Work is under way to develop smart-card and Internet-based record-exchange solutions. In view of these future developments, the compatibility of Java with the JavaCard technology [34] was an additional reason for selecting Java as the basis for our work.

Currently, JAnaemia operates as a stand-alone application, since the participating hospitals do not feature an integrated Information System. However, compatibility with hospital information systems that may be installed in the future will be achieved via the above-mentioned message-based EHCR exchange mechanism, the design of which allows the communication of information between different types of systems [12].

Miscellaneous Functionality

As suggested by the authors' experience, form-based data-entry Graphical User Interfaces make EHCR applications more user-friendly and thus more attractive to physicians. Yet, ENV 13606:1999, as mentioned in Introduction, is not specific on how presentation issues should be handled. Previous implementations of the standard do not provide form-based data-entry interfaces. It was therefore deemed necessary to implement such an interface in JAnaemia. For this purpose, it should be possible to use the standard controls supported by the various operating systems, such as check boxes, text boxes, combo boxes, and groups of radio buttons, for entering data in *Data Items*(see the Electronic Healthcare Record Architecture subsection of the Implementation section of Methods for a description of *Data Items*). To provide this functionality, we have defined 3 *Data-Item* attributes in addition to the ones already defined by CEN:

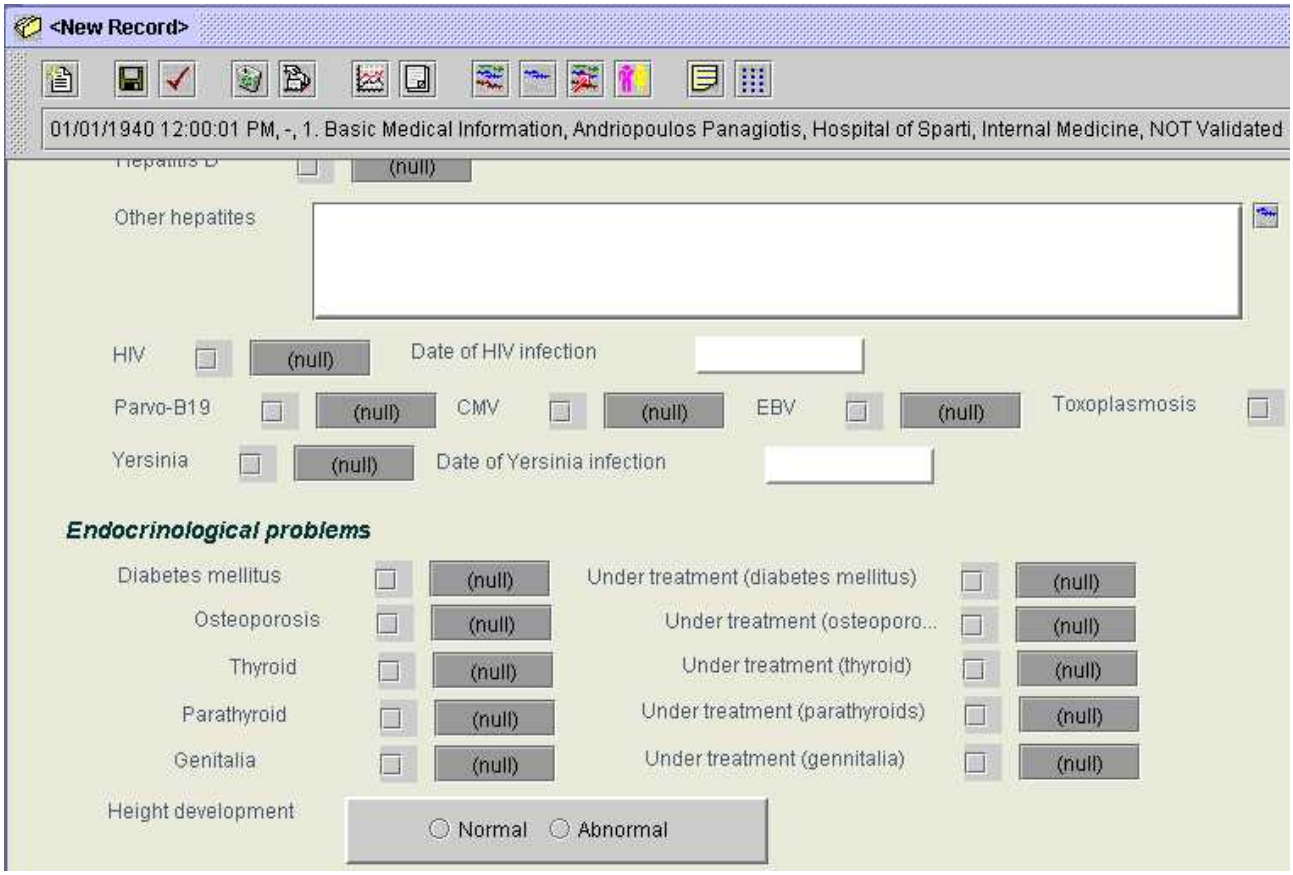
(1) The *Display Type Item Reference* attribute conveys information on the way *Data Items* should be displayed. It is complementary to *Data Type Item Reference*.

JAnaemia supports simple and compound data types. Simple data types are used to store plain numeric, text, date, and time values. Compound data types are used to store coded terms, originating from medical terminologies, as well as combinations of the latter with any of the simple data types. A separate data type is used to store multimedia objects. Basic type checking is performed on the contents of *Data Item* s to ensure their compatibility with their associated data types. This includes the validation of date-time values.

Each data type may be associated with certain display types: numeric *Data Item* s may be presented as text boxes, check boxes, toggle buttons, groups of radio buttons, or combo boxes; date-time *Data Items* may be presented as text boxes or combo boxes, while text and compound data types may be presented as combo boxes or specialized data entry windows.

Figure 2 presents examples of *Data Items* displayed in different ways. The *Height developmentData Item* is displayed as a group of radio buttons, from which the user can make a selection. *Date of HIV infection* and *Date of Yersinia infection* items are expected to receive a date value and are displayed as plain text boxes. *Other hepatites* may receive a string value and is therefore presented as a large edit window. *Diabetes mellitus*, *Osteoporosis* and *Thyroid* may be true or false and are presented as checkboxes.

Figure 2. An extract from a Basic Medical Information Composition



(2). the *X Position* and (3) the *Y Position* attributes define the location on the data-entry window where a given item should appear. The data-entry window is the one in which *Composition* contents are displayed. It is an inner, scrollable window, thus allowing the system to automatically adjust to different screen sizes; *Composition* contents that lie outside the visible screen area can easily be scrolled in the window.

This absolute positioning of *Data Items* allows users to combine them in complex arrangements, thus creating custom data-entry forms according to the users' own needs and tastes. It is more flexible than relative positioning, as it provides additional freedom in defining item locations.

It was a user requirement that JAnaemia provides a mechanism for automatically assigning values to *Data Items*, by processing related items of the patient record, referring either to the same or to different *Compositions*. This would both facilitate data entry and serve as an elementary decision-support tool. It should be possible, for example, to calculate the patient *Body Surface* as a function of the patient's *Weight* and *Height*. Such functionality has been supported through a fourth *Data Item* attribute, called *Macro-directive*. The *Macro-directive* attribute contains macro-directives which specify the automatic-processing behavior *Data Items* should exhibit (*Macro-directives* are defined, in the context of our work, as statements capable of retrieving and processing the contents of *Data Items*, and of assigning values to them). See Discussion for further explanations and more examples.

Results

Status Report

JAnaemia is generic-purpose EHCR software that can be used in all medical domains. New *Compositions* added to patient records are completely empty. Their contents need to be defined by users and can vary according to individual needs. *Compositions* referring to the Cardiology evaluation of patients, for example, should contain all *Data Items* required for recording the information produced by the patient's history and physical examination, by the patient's ECG and cardiac ultrasound examination, etc. *Compositions* referring to the patient's Endocrinology evaluation, on the other hand, should contain *Data Items* concerning the patient's thyroid and sex hormones, bone density measurements, etc. To facilitate data entry, JAnaemia allows the definition of sets of *Data Items*(henceforth called *data item sets*) that refer to a common item of care and can be utilized as a single entity. The contents of the *Composition* in Figure 1 are part of the Cardiology Evaluation *data item set*, while those of the *Composition* in Figure 2 are part of the Basic Medical Information *data item set*. *Data item sets* are equivalent to data entry forms, which makes their role in facilitating data entry crucial.

Ten *data item sets* have been created, in cooperation with the above-mentioned hospitals, to cover the information-recording and information-processing needs of beta-thalassaemia, namely: (1) a set for entering administrative information (patient name, sex, age, date and place of birth, etc.), (2) a Basic Medical Information set, (3) a Chelationset, (4) a Transfusion set, (5) an

Endocrinology evaluation set, (6) a Cardiology evaluation set, (7) a Hepatology evaluation set, (8) an Annual transfusion summary set, (9) an Annual chelation summary set, and (10) an Annual report on the L1 oral chelation treatment.

These sets have been used in the everyday practice of the participating hospitals since late 2000. Although the sets are roughly the same in all installations, small differences among them reflect the slightly different health care practices followed in each hospital. For example, the contents of the Hepatology Evaluation set in the Ag. Sophia Children's Hospital is different from the contents of the Hepatology Evaluation set in the hospitals of Korinthos and Sparti. The former is a tertiary hospital, with access to a broad range of laboratory tests that physicians routinely perform and store in patient records. Some of these tests are not readily available at Korinthos and Sparti; physicians at these hospitals therefore use a simpler Hepatology Evaluation *data item set* than the one used at Ag. Sophia Children's Hospital. The same goes for the other sets. In addition, Ag. Sophia Children's Hospital participates in a clinical trial on the new L1 oral chelation treatment. In the context of this trial, physicians routinely check for side effects of the L1 pill and perform additional tests that are part of a predetermined research protocol. Two additional *data item sets* have been created to cope with the increased recording and processing needs: (1) a Side effects of the L1 pill set and (2) an Additional Laboratory Investigations set.

The number of *data item sets* and their contents can vary among health care units, departments, or even health care professionals. Users may customize them according to their own needs. Customization is performed through the GUI (Graphical User Interface) of JAnaemia and does not involve modifying the software or the structure of the underlying database. As soon as they are created, custom *data item sets* may be used to define the contents of the new *Compositions* that are added to patient records. No matter how diverse these contents are, JAnaemia can process them and store them in the EHCR repository, in the uniform way defined in ENV 13606:1999. *Compositions* are stored together with their *distribution rules*(described in the Record Sharing and Communication subsection of the Implementation section of Methods) and can be directly shared with users accessing the same repository or with remote users, via exchange messages.

The current use of JAnaemia involves recording and processing of all care items related to the beta-thalassaemic patients treated at the 4 participating hospitals. For example, the software is used by the 6 physicians serving at the Thalassaemia Unit of the Ag. Sophia Children's Hospital. The unit is responsible for the follow up of about 500 patients, 30 of whom are part of the L1 clinical trial. Each patient receives transfusions approximately 2 times every month and undergoes laboratory examinations at regular intervals. During a normal day, the unit treats approximately 80 patients.

At the Laiko hospital, JAnaemia is used by 6 physicians of the First Department of Internal Medicine. The department is responsible for the cardiology evaluation of approximately 1000 patients suffering from various hemoglobinopathies, including beta-thalassaemia. Patients are typically examined once or twice a year.

The Thalassaemia Unit of the hospital of Korinthos provides transfusion, chelation, and other follow-up services to 50 patients, which on average visit the department twice a month. JAnaemia is used by 3 of the physicians serving there, as well as by 4 nurses. Efforts are under way to engage the nursing stuff of the other hospitals in the use of the software.

The hospital of Sparti is responsible for 10 patients, which are treated by 2 physicians of the Pediatric department.

Discussion

Electronic Healthcare Record architecture and clinical functionality

JAnaemia was found to facilitate clinical work by allowing patients' records to be well organized and easily accessible as well as by offering advanced processing functionality. The latter includes the macro-directive mechanism, presented in the Miscellaneous Functionality subsection of the Implementation section of Methods, which assists users in entering data and provides elementary decision support, as well as statistical functions.

The macro-directive mechanism was found to be particularly useful in clinical practice, as it facilitates data entry and it provides elementary decision-support functionality. The Cardiology *data item set*, for example, includes approximately 150 automated calculations; physicians enter a number of basic parameters, produced by the cardiac ultrasound equipment, and are automatically provided with many other parameters, which are functions of the basic parameters. The cardiac mass and the left ventricular volume are calculated from the end-systolic and the end-diastolic diameters of the left ventricle, the total cardiac diameter is calculated by adding the diameters of the individual cavities, etc. The calculated parameters are valuable to cardiologists, who use them as a basis for their clinical decisions. The interpretation of an Oral Glucose Tolerance Test (OGTT) is another example. OGTT is used to diagnose diabetes mellitus. After orally administering to the patient a predefined quantity of glucose, the patient's blood glucose levels are measured every 30 minutes, for 3 hours. If blood glucose before the test starts is >= 140 mg/dl, then diabetes mellitus is diagnosed. If it is < 140 mg/dl and blood glucose measured 2 hours after the initiation of the test is >= 200 mg/dl, then again diabetes mellitus is diagnosed. If blood glucose before the test starts is < 140 mg/dl, and if at 2 hours it is >= 140 mg/dl but < 200 mg/dl, then impaired glucose tolerance is diagnosed [2]. JAnaemia allows recording the blood glucose levels during an OGTT. After data is entered, an appropriate macro is executed, to check the above-mentioned conditions. It then checks or unchecks the *OGTT indicative of glucose intolerance* and *OGTT indicative of diabetes mellitusData Items* as appropriate, thus indicating to the user the results of the test.

The macro-directive mechanism is also useful for maintaining a Basic Medical Information *Composition*, which is automatically updated as new data are added to the patient record. Basic Medical Information contains a minimal set of

data summarizing the patient's health status. Physicians consult it whenever they need to quickly get an overall view of the patient's problems.

The advanced data-processing functionality provided by the macro-directive mechanism was the main reason for developing JAnaemia as a thick client written in Java, an object-oriented programming language, rather than as a thin client or as a Web-based application. A thick client is software that does most of the processing required for a task, leaving little or no processing to be done on the server. A thin client is simple software that performs very little processing, leaving most of it to be done on the server. Java provides greater flexibility and ease of implementation than a Web-based application in relation to the handling of the complicated data structures and of the logic involved in such a mechanism. Furthermore, Java offers developers the opportunity to perform a substantial part of the necessary tasks in the memory of the client, thus improving the overall performance of the application, as opposed to continuously accessing the database server. In large health care units, where several users may concurrently request such processing, the performance gain is even bigger. In a thin client or Web-based alternative, most of the operations would need to be performed directly on the database server and/or in the server memory, thus quickly leading to the exhaustion of server resources and deterioration of the performance.

The CEN architecture, as suggested by the experience accumulated so far, is capable of modeling all the basic information structures pertinent to beta-thalassaemia. It also allows customization to the particularities of individual health care units (see Results).

Our proposed enhancements to the CEN architecture, described in the Miscellaneous Functionality subsection of the Implementation section of Methods, were found to be useful for clinical practice. CEN defines a *Presentation Information Data Item* attribute, which, among other things, dictates the way in which items should be displayed [9]. However, ENV 13606:1999 is not specific about how the presentation issues are to be specified. We found that our method of specifying presentation information is useful for clinical practice, as it provides a user-friendly, form-based interface that greatly facilitates data entry. Our aim is to get the method evaluated by the responsible CEN workgroup, for possible inclusion in future versions of the standard. The macro-directive mechanism for processing patient record contents, previously discussed, was also found to be a useful feature. As it is much easier to implement such mechanisms than other, more-sophisticated, data-processing and decision-support techniques, we will also investigate the possibility of having such mechanisms incorporated in future versions of ENV 13606:1999.

Other proposals on the EHCR architecture do exist. The Synapses Project [5] and the HL7 group [6] are some of the research teams working in this area. Their architectures are flexible and comprehensive as well; the CEN architecture, however, is the current European standard. The authors have been convinced of its value and believe that it should be endorsed, in order to gain wide acceptance. On the other hand, joint efforts are made by the various research groups to bridge the differences of their proposals and to converge to a common standard [35,36]. It is the authors' intent to follow these future developments of ENV 13606:1999 and to adjust JAnaemia as appropriate.

As mentioned in the Electronic Healthcare Record Architecture subsection of the Implementation section of Methods, the names of the *Data Items* comprising an EHCR may be specified in the form of codes retrieved from medical terminologies. Health care professionals, on the other hand, pose very strict requirements on the wording of patient record contents. The problem is more intense in the Greek language, in which small variations in the syntax or grammar of a word may result in large variations in its meaning. The authors have many times had difficulties in modeling various clinical domains, using the GEHR terminology, on which existing CEN-based EHCR applications rely. We have therefore decided to initially create a proprietary medical terminology for beta-thalassaemia, which would be shared by the participating units and would be capable of expressing all concepts related to the disease in the exact way demanded by the participating health care professionals. Work is under way to compare the resulting terminology to other existing ones, such as GALEN, SNOMED, GEHR, and UMLS. If any of these terminologies proves sufficient for beta-thalassaemia, it will be adopted, replacing our proprietary one. In the opposite case, the authors shall either propose amendments to existing terminologies, or investigate alternative exchange methods that are capable of communicating records based on proprietary terminologies.

An important feature that was found to facilitate medical research is the capability to export database search results in a format directly readable from widely-used statistical packages, such as SPSS [37] or SAS [38]. JAnaemia supports database searches defined by combining any number of simple criteria, as many other EHCR applications do. Users can, for example, search the EHCR repository for patients that have *total cholesterol* over 250 mg/dl and *blood pressure* over 160/100 mmHg. However, the parameters sought each time, such as *total cholesterol*, may occur more than once in each record. Statistical tests that are used to compare population parameters, on the other hand, require that only one of their values is associated with each patient. Researchers should decide whether they want to extract, for example, the last or the biggest cholesterol value. JAnaemia provides users with appropriate data-extraction options, thus automating the described task, which would otherwise have to be performed by hand.

Technical issues

From a technological point of view, Java was found to be powerful enough for handling all storage/retrieval, processing, and user-interface related issues in an acceptable way. After several stages of optimization, today JAnaemia provides a responsive user interface and performs all basic operations, including loading, saving, and analyzing EHCRs, in a few seconds. More specifically, the following performance figures were obtained for the main application tasks, for all the user configurations described in Results:

- Data entry is performed in real time. This includes the time required to execute the macro directives relevant to the

Data Items being edited. In some cases dozens of calculations may be performed.
- New compositions are saved in less than a second. A large composition, in our customization for beta-thalassaemia, typically contains approximately 250 *Data Items*.
- The time required to load patient records is proportional to the number of *Data Items* they contain. One of the largest EHCRs in our databases contains information on 120 transfusions, on 10 cardiology evaluations, and on 20 evaluations of other types. These were accumulated during the 10-year follow up of the particular patient. The EHCR contains a total of 10000 *Data Items* and is loaded in 25 seconds. It is important to note that a separate control is created for each loaded *Data Item*. Most EHCRs, however, are loaded in less than 10 seconds
- The time consumed during database searches exhibits large variations depending on factors such as the size of the database and the number of matching records. In the database of the Ag. Sophia Children's Hospital, which contains 500 records, a typical search takes approximately 60 seconds. This is an acceptable delay, taking into account the diversity of patient record contents, which necessitates specially-designed searching strategies, as opposed to the plain SQL [25] queries that can be utilized in EHCR applications that rely on static data entry forms

The above measurements were obtained on computers based on Intel Pentium III [27] processors, operating at 733 MHz (megahertz). According to our observations, the time consumed by the above-mentioned tasks is inversely proportional to the CPU (central processing unit) clock speed. We therefore expect that on the 2 GHz (gigahertz) Pentium IV processors that are now available, the reported times will decrease by a factor of 2.7.

Despite the large number of windows and controls it creates, JAnaemia never occupied more than 80 MB (megabyte) of memory even after long (6 hour) continuous operation. As a result, it runs smoothly on the 256 MB RAM computers that are now widely available.

Based on our monitoring, one of the most time-consuming processes in EHCR software is communication with the database server, via JDBC. The delay increases as the patient database grows larger. In CEN-based EHCR software, the problem becomes even worse; as described in the Electronic Healthcare Record Architecture subsection of the Implementation section of Methods, patient records consist of *Compositions*, which contain *Data Items*, which are in turn qualified by attributes. In early versions of JAnaemia, information on patients, *Compositions*, *Data Items* and attributes were stored in separate tables. An average sized record for beta-thalassaemia contains approximately 2500 *Data Items*, each of which is qualified by 15 attributes. It therefore corresponds to 2500 x 15 = 37 500 entries in the attributes table. We very soon realized that the latter would grow beyond bounds very fast; that fact alone would make performance suffer and would exhaust the available database space. As a result, we were forced to store *Data Item* attributes in separate fields of the *items* table, thus making it possible to store all information on an item in a single table row. Although the new database schema resulted in some redundancy, since not all attributes are required for every *Data Item*, it also led to a 10-fold increase in application performance and substantially reduced the database size.

Optimizing the design of the database schema to reduce the number of SQL statements required to retrieve EHCRs, therefore, results in immense performance gains. Keeping all frequently-accessed data in memory and performing as much processing as possible there, rather than continuously accessing the database, also increases performance. JAnaemia relies heavily on strings and string arrays for temporarily storing data; A comparison of the current version of JAnaemia with a new one, in which string handling will be implemented in C++, is planned, so that we can assess the improvement in performance, due to the enhanced string-handling capabilities of C++.

The performance of JAnaemia increased by up to 300% with the aid of the JOVE optimizing native compiler [26].

Despite the extensive arguments of software engineers against the speed and efficiency of the Java programming language, we found it to be sufficient for the needs of EHCR applications. Careful programming and appropriate database design, as described above, aided by optimizing native compilers, makes its performance acceptable for clinical use. Furthermore, it provides scalability features that are important in the diverse health care environment.

Platform independence is a Java feature that makes possible scalable designs, suitable for the needs of health care units differing in size. Currently, JAnaemia operates on stand-alone Pentium-based computers. Both JAnaemia and the database server run on the same machine. As the Greek University Network (GU-Net) and other health-care-related networks expand, all hospitals in Athens will be linked together. It will then be possible to link individual units to a common EHCR repository. This will require more-powerful database servers and, in certain cases, more-powerful workstations. Java makes it possible to directly port JAnaemia to computers based on more-powerful processors, such as Sun's UltraSPARC series. It also facilitates its porting to Internet appliances, which can provide mobile solutions to health care professionals.

Conclusions

Participating health care professionals quickly accustomed themselves to the software and now find it superior to their initial, paper-based records, in terms of both efficiency and time consumption. The form-based GUI, the macro-directive data-processing mechanism and the direct link to statistical packages, described in the Electronic Healthcare Record architecture and clinical functionality section of Discussion, were the main factors that contributed to its acceptance. These conclusions are currently based on personal communication with the involved health care professionals; formal user-satisfaction surveys are planned during the next phases of the Project.

To conclude, JAnaemia appears to be a useful tool for health care professionals involved in the care process of patients suffering from beta-thalassaemia. It is based on the European Standard Electronic Healthcare Record architecture and it has several features that render it user-friendly and provide it with

advanced data-processing functionality. It possesses all the prerequisites for EHCR exchange while specific communication solutions are currently under development. We believe that JAnaemia can improve the quality of care offered to beta-thalassaemic patients in Greece.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix

Downloadable presentation " A Java-based Electronic Healthcare Record for beta-Thalassaemia "

[jmir_v3i4e33_app1.ppt - jmir_v3i4e33_app1.ppt]

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Abbreviations

CEN: European Committee for Standardization
DI: Data Item, as defined in the ENV 13606:1999 CEN standard
DTD: Document Type Definition
EHCR: Electronic Healthcare Record
GEHR: Good European Health Record
GU-Net: Greek University Network
GUI: Graphical User Interface
JDBC: Java Database Connectivity (informal; JavaSoft, the maker of JDBC, does not consider it to be an abbreviation)
MB: Megabyte
MRI: Magnetic Resonance Imaging
OGTT: Oral Glucose Tolerance Test
XML: Extensible Markup Language

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Original Paper

Use of the Internet as a Resource for Consumer Health Information: Results of the Second Osteopathic Survey of Health Care in America (OSTEOSURV-II)

John C Licciardone[1], DO; Peggy Smith-Barbaro[1], PhD; Samuel T Coleridge[1], DO

Department of Family Medicine, Texas College of Osteopathic Medicine, University of North Texas Health Science Center, Fort Worth TX, USA

Corresponding Author:
John C Licciardone, DO
University of North Texas Health Science Center
3500 Camp Bowie Boulevard
Fort Worth TX 76107
USA
Phone: +1 817 735 2028
Fax: +1 817 735 0157
Email: jlicciar@hsc.unt.edu

Abstract

Background: The Internet offers consumers unparalleled opportunities to acquire health information. The emergence of the Internet, rather than more-traditional sources, for obtaining health information is worthy of ongoing surveillance, including identification of the factors associated with using the Internet for this purpose.

Objectives: To measure the prevalence of Internet use as a mechanism for obtaining health information in the United States; to compare such Internet use with newspapers or magazines, radio, and television; and to identify sociodemographic factors associated with using the Internet for acquiring health information.

Methods: Data were acquired from the Second Osteopathic Survey of Health Care in America (OSTEOSURV-II), a national telephone survey using random-digit dialing within the United States during 2000. The target population consisted of adult, noninstitutionalized, household members. As part of the survey, data were collected on: facility with the Internet, sources of health information, and sociodemographic characteristics. Multivariate analysis was used to identify factors associated with acquiring health information on the Internet.

Results: A total of 499 (64% response rate) respondents participated in the survey. With the exception of an overrepresentation of women (66%), respondents were generally similar to national referents. Fifty percent of respondents either strongly agreed or agreed that they felt comfortable using the Internet as a health information resource. The prevalence rates of using the health information sources were: newspapers or magazines, 69%; radio, 30%; television, 56%; and the Internet, 32%. After adjusting for potential confounders, older respondents were more likely than younger respondents to use newspapers or magazines and television to acquire health information, but less likely to use the Internet. Higher education was associated with greater use of newspapers or magazines and the Internet as health information sources. Internet use was lower in rural than urban or suburban areas.

Conclusions: The Internet has already surpassed radio as a source of health information but still lags substantially behind print media and television. Significant barriers to acquiring health information on the Internet remain among persons 60 years of age or older, those with 12 or fewer years of education, and those residing in rural areas. Stronger efforts are needed to ensure access to and facility with the Internet among all segments of the population. This includes user-friendly access for older persons with visual or other functional impairments, providing low-literacy Web sites, and expanding Internet infrastructure to reach all areas of the United States.

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KEYWORDS

Internet, health care surveys, socioeconomic factors, age factors, family practice

Introduction

The explosion of health information on the Internet is shifting the focus of traditional medical informatics (medical information science) from health professionals to consumers [1]. Consumer informatics is the branch of medical informatics that is concerned with studying consumers' needs for information, providing them with access to health information, and integrating their preferences into medical information systems [1]. This shifting paradigm will have profound effects on the delivery of health care [2,3]. Nevertheless, questions remain about access to the Internet and proclivity to use this medium in health matters [4]. For example, a study of family-practice-clinic patients' intention of using a health information Web site found that those greater than 65 years of age were less likely to do so, even after adjusting for the presence of a home computer and Internet access [5]. The present study was undertaken to measure the prevalence of Internet use in acquiring health information in the United States as compared with other more traditional sources of health information and to identify sociodemographic factors associated with using the Internet for this purpose.

Methods

We used data from the Second Osteopathic Survey of Health Care in America (OSTEOSURV-II) to measure and determine the factors associated with the use of newspapers or magazines, radio, television, and the Internet as health information sources. The Osteopathic Survey of Health Care in America is a biannual longitudinal survey primarily intended to assess use of osteopathic physicians and public perceptions of osteopathic medicine in the United States. Methodologic details and results of the First Osteopathic Survey of Health Care in America (OSTEOSURV-I) have been published elsewhere [6]. Data from both OSTEOSURV-I and OSTEOSURV-II support the validity and reliability of this research instrument [7] (also J.C.L., unpublished data, 2001)

OSTEOSURV-II was a national telephone survey conducted in 2000 using random-digit dialing. The target population consisted of adult, non-institutionalized, household members. The survey sought to interview 500 respondents, including about 50% who were aware of osteopathic physicians and 25% who had used an osteopathic physician at least once (thus, about one half of those aware of osteopathic physicians would also have used an osteopathic physician at least once). After 361 interviews were completed, awareness and use of osteopathic physicians were 46% and 16%, respectively. Subsequently, random-digit dialing was followed by 2 survey screening items, concerning awareness and use of osteopathic physicians, to increase the percentages of respondents who were aware of or had ever used osteopathic physicians. At the conclusion of the survey, these percentages were 49% and 24%, respectively, thus approaching the initial survey objectives. Also, to increase response during the latter part of the survey, 43 initial nonresponders were subsequently converted into responders by offering a US $20 incentive for participation. All survey procedures were approved by the Institutional Review Board of the University of North Texas Health Science Center.

One section of OSTEOSURV-II was allocated to topics of emerging interest within the American health care environment, including use of the Internet to acquire health information. One survey item stated, "I am comfortable with using the Internet as a health information resource," and was followed by the potential response options: "strongly agree," "agree," "neutral," "disagree," and "strongly disagree." Another item asked, "Do you receive health care information from the following sources?" Responses were solicited for newspapers or magazines, radio, television, and the Internet. All respondents provided sociodemographic information, including age, sex, race or ethnicity, years of education, annual household income, residence (urban or suburban vs. rural), geographic region, health insurance coverage, and general health status as measured by the Medical Outcomes Study Short Form - 36 Health Survey (SF-36) [8].

Descriptive statistics were used to summarize the sociodemographic characteristics of respondents and their sources of health information. Contingency tables and the χ^2 test were used to identify statistical associations between sociodemographic characteristics and use of the various sources of health information. Multiple logistic regression was then used to compute the odds ratios (ORs) and 95% confidence intervals (CIs) for each source of health information while simultaneously adjusting for age, sex, race or ethnicity, education, residence, and geographic region. Statistical analyses were performed using the SYSTAT software package (SPSS Inc, Chicago, IL) and all hypotheses were tested at the .05 level of statistical significance.

Results

A total of 499 (64% response rate) respondents participated in the survey. Of these, 329 (66%) respondents were women. Otherwise, as shown in Table 1, respondents were generally similar to national referents based on information from the US Census Bureau [9] and normative standards for the SF-36 [8].

Fifty percent of respondents either strongly agreed or agreed that they felt comfortable using the Internet as a health information resource. Persons 60 years of age or older (χ^2_2=28.3; P<.001) and those with 12 or fewer years of education (χ^2_2=22.1; P<.001) reported less comfort with the Internet. The prevalence rates of using the health information sources were: newspapers or magazines, 69%; radio, 30%; television, 56%; and the Internet, 32%.

Table 1. Sociodemographic Characteristics of OSTEOSURV-II Respondents*

	Survey Respondents (n=499)		National Referents †
Characteristic	No.	%	%
Age (years), mean (SD)	46.3 (16.5)		44.9 (16.1)
18-29	90	18	
30-39	100	20	
40-49	115	23	
50-59	72	14	
60-69	64	13	
> 70	57	11	
Sex			
Men	170	34	48
Women	329	66	52
Race ‡			
White	405	86	84
Black	40	8	12
Asian/Pacific Islander	18	4	4
American Indian/ Native American	9	2	1
Geographic region			
Northeast	88	18	19
Midwest	132	27	24
South	179	36	36
West	96	19	21
Education, years			
<12	57	11	17
12	121	24	33
13-15	172	35	25
16	86	17	17
> 17 >17	62	12	8
Residence §			
Urban/suburban	310	63	75
Rural	179	37	25
Annual household income, median, $	38,318		38,885
<15,000	58	13	
15,001-25,000	75	16	
25,001-40,000	107	24	
40,001-60,000	83	18	
> 60,001 >60,001	132	29	
Health insurance coverage			
No	49	10	13
Yes	449	90	87
General health perceptions #			
MOS SF-36 score, mean (SD)	71.6 (21.1)		72.0 (20.3)

* Data are presented as number or percentage unless otherwise indicated. Totals may not equal 499 because of item nonresponse and may differ from

100% because of rounding. OSTEOSURV-II denotes the Second Osteopathic Survey of Health Care in America; MOS SF-36, Medical Outcomes Study Short - Form-36 Health Survey.

† Referent characteristics were based on information derived from the US Bureau of the Census [9] except for general health perceptions. For variables that were categorized differently by the Bureau of the Census and OSTEOSURV-II, only the mean (SD) or median were compared using methods for grouped data.

‡ A total of 13 (3%) respondents who described themselves as Hispanic are not included in the table because persons of Hispanic origin may be of any race.

§ Referents are categorized as urban or rural.

Referents for this characteristic were selected from the general United States population [8]. SD = standard deviation

Table 2. Prevalence Rates of and Multivariate Factors Associated with Use of Health Information Sources*

	Newspapers/Magazines				Radio				Television				Internet			
Characteristic †	**PR**	**OR**	**95% CI**	**P**	**PR**	**OR**	**95% CI**	**P**	**PR**	**OR**	**95% CI**	**P**	**PR**	**OR**	**95% CI**	**P**
Age, years																
18-39	60	1.00			31	1.00			48	1.00			36	1.00		
40-59	78	1.98	1.22 - 3.22	.01	34	1.16	0.74 - 1.83	.52	61	1.65	1.07 - 2.54	.02	39	0.93	0.59 - 1.46	.76
>60	70	1.94	1.11 - 3.39	.02	23	0.81	0.46 - 1.41	.45	58	1.71	1.03 - 2.83	.04	14	0.30	0.16 - 0.58	<.001
Sex																
Men	63	1.00			29	1.00			51	1.00			33	1.00		
Women	73	1.57	1.01 - 2.44	.04	30	1.05	0.68 - 1.60	.83	58	1.27	0.85 - 1.88	.24	31	1.01	0.65 - 1.57	.95
Race/ethnicity ‡																
White	71	1.00			30	1.00			55	1.00			32	1.00		
Non-White	64	0.79	0.44 - 1.39	.41	30	1.01	0.58 - 1.77	.96	61	1.45	0.85 - 2.47	.17	33	0.73	0.41 - 1.28	.27
Education, years																
<12	54	1.00			26	1.00			51	1.00			16	1.00		
13-15	75	2.70	1.64 - 4.43	<.001	35	1.47	0.91 - 2.39	.12	56	1.32	0.84 - 2.07	.23	36	2.48	1.45 - 4.24	.001
>16	81	3.19	1.84 - 5.50	<.001	29	1.08	0.64 - 1.82	.78	61	1.49	0.92 - 2.41	.10	45	3.25	1.87 - 5.65	<.001
Residence																
Urban/suburban	73	1.00			29	1.00			59	1.00			36	1.00		
Rural	63	0.66	0.43 - 1.03	.07	33	1.18	0.77 - 1.80	.44	52	0.81	0.54 - 1.21	.30	26	0.59	0.38 - 0.93	.02
Geographic region																
Northeast	80	1.00			36	1.00			60	1.00			38	1.00		
Midwest	70	0.66	0.34 - 1.30	.23	33	0.83	0.46 - 1.49	.52	53	0.81	0.46 - 1.44	.48	25	0.63	0.33 - 1.19	.15
South	67	0.64	0.34 - 1.22	.17	29	0.64	0.36 - 1.13	.12	58	1.05	0.61 - 1.82	.86	32	1.00	0.56 - 1.81	.99
West	65	0.44	0.22 - 0.89	.02	24	0.54	0.28 - 1.04	.06	52	0.71	0.38 - 1.31	.27	34	0.92	0.48 - 1.78	.81

* The various analyses included 470 (94%) to 473 (95%) respondents who provided complete data. Prevalence rate is reported as a percentage.

† PR = prevalence rate, OR = odds ratio, CI = confidence interval.

‡ Hispanics were included in the non-White category for these analyses.

Specific prevalence rates and multivariate ORs and CIs for each health information source are presented in Table 2. After adjusting for potential confounders, older respondents were more likely than younger respondents to use newspapers or magazines and television to acquire health information, but less likely to use the Internet. Women were more likely than men to acquire health information from newspapers or magazines. Higher education was associated with greater use of newspapers or magazines and the Internet as health information sources. Internet use was lower in rural than urban or suburban areas and newspaper or magazine use was lower in the West than in the Northeast.

Discussion

Our survey indicates that one half of the American adult population are comfortable using the Internet as a health information resource and that about one third actually use the Internet to acquire health information. These findings regarding overall Internet use are generally consistent with other studies in this area. The Pew Internet & American Life Project conducted a large national telephone survey using random-digit dialing during the same time period as our survey and estimated that 52 million American adults (55% of those with Internet access) have used the Internet to acquire health information [10]. Based on an estimated 205 million adults in the United States in 2000 [9], this indicates that 25% of American adults used the Internet to obtain health information. A random telephone survey of California households in 1998 found that 19% had used the Internet to acquire health information within the past year, compared with 31% who used newspapers or magazines [11]. Parenthetically, that Californians also identified newspapers and magazines as the most distrusted sources of health information [11], also supports our finding of a decreased use of newspapers or magazines for obtaining health information in the western United States. A study of patients who had undergone coronary artery bypass grafting found that 22% had used the Internet to acquire health information [12]. It has been recently reported that 22% of patients in Japan use the Internet to obtain health information [13].

The Pew Internet & American Life Project concluded that health information seekers on the Internet are proportionately more middle-aged than very young or old and more likely to be women than men, but that there are no major racial, ethnic, or income effects [10]. The only notable discrepancy between these results and our findings involves health information seeking on the Internet among men and women. We found no sex differences in this regard. The overrepresentation of women in our survey may be a potential explanation for this discrepancy. It is reasonable to speculate that the overrepresentation of women was attributable to respondents who were unemployed outside the home. Such unemployment would have precluded Internet use at the workplace, which is known to be a common site for Internet access [11].

The Internet has already surpassed radio as a source of health information but still lags substantially behind print media and television. Significant barriers to acquiring health information on the Internet remain among persons 60 years of age or older, those with 12 or fewer years of education, and those residing in rural areas.

There are 3 potential limitations of our survey that should be mentioned. First, the survey was conducted over one year ago and it is possible that Internet access and use may have increased since then. Second, as noted above, the survey included a disproportionately large representation of women (66%). This is a common finding in many surveys despite special techniques to minimize this problem [14,15]. Third, we used 2 screening items during the latter part of the survey to select a greater percentage of respondents who were either patients or aware of osteopathic physicians. This screening may have also selected respondents with somewhat better education than referents, as evidenced by the greater percentage of respondents with at least some college education (64% vs. 50%). Although these 3 factors may have biased our prevalence estimates to some degree, it is unlikely that they materially affected the survey findings. The use of multivariate modeling to adjust for potential confounders, such as sex and education, further attenuated any biases that may have been introduced by the large percentage of women who responded and by screening for use or awareness of osteopathic physicians.

Our findings have important implications, because consumer informatics is rapidly evolving with a public health focus that seeks to provide a greater emphasis on prevention and self care [1]. Stronger efforts are needed to ensure access to and facility with the Internet among all segments of the population. This includes user-friendly access for older persons with visual or other functional impairments, providing low-literacy Web sites, and expanding Internet infrastructure to reach all areas of the United States.

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Conflicts of Interest

None declared.

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Abbreviations

CI: Confidence Interval
OR: Odds Ratio
PR: Prevalence Rate
SD: Standard Deviation

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Original Paper

Design and Implementation of a Portal for the Medical Equipment Market: MEDICOM

Stergios Palamas[1]; Dimitris Kalivas[2]; Ourania Panou-Diamandi[1]; Cees Zeelenberg[3]; Chris van Nimwegen[3]

[1]National Technical University of Athens, Biomedical Engineering Laboratory, 9 Iroon Polytechniou Str., Computer Building, 15773 Athens, Greece

[2]Technological Education Institute of Piraeus, Department of Electronics, 250 Thivon Str., 12244 Athens, Greece

[3]Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek (TNO)-Prevention and Health, Department of Technology in Healthcare, Zernikedreef 9, P.O. Box 2215, 2301 ce Leiden, Netherlands

Corresponding Author:
Stergios Palamas
National Technical University of Athens
Biomedical Engineering Laboratory
9 Iroon Polytechniou Str
Computer Building
15773 Athens
Greece
Email: spalam@biomed.ntua.gr

Abstract

Background: The MEDICOM (Medical Products Electronic Commerce) Portal provides the electronic means for medical-equipment manufacturers to communicate online with their customers while supporting the Purchasing Process and Post Market Surveillance. The Portal offers a powerful Internet-based search tool for finding medical products and manufacturers. Its main advantage is the fast, reliable and up-to-date retrieval of information while eliminating all unrelated content that a general-purpose search engine would retrieve. The Universal Medical Device Nomenclature System (UMDNS) registers all products. The Portal accepts end-user requests and generates a list of results containing text descriptions of devices, UMDNS attribute values, and links to manufacturer Web pages and online catalogues for access to more-detailed information. Device short descriptions are provided by the corresponding manufacturer. The Portal offers technical support for integration of the manufacturers' Web sites with itself. The network of the Portal and the connected manufacturers' sites is called the MEDICOM system.

Objective: To establish an environment hosting all the interactions of consumers (health care organizations and professionals) and providers (manufacturers, distributors, and resellers of medical devices).

Methods: The Portal provides the end-user interface, implements system management, and supports database compatibility. The Portal hosts information about the whole MEDICOM system (Common Database) and summarized descriptions of medical devices (Short Description Database); the manufacturers' servers present extended descriptions. The Portal provides end-user profiling and registration, an efficient product-searching mechanism, bulletin boards, links to on-line libraries and standards, on-line information for the MEDICOM system, and special messages or advertisements from manufacturers. Platform independence and interoperability characterize the system design. Relational Database Management Systems are used for the system's databases. The end-user interface is implemented using HTML, Javascript, Java applets, and XML documents. Communication between the Portal and the manufacturers' servers is implemented using a CORBA interface. Remote administration of the Portal is enabled by dynamically-generated HTML interfaces based on XML documents. A representative group of users evaluated the system. The aim of the evaluation was validation of the usability of all of MEDICOM's functionality. The evaluation procedure was based on ISO/IEC 9126 Information technology - Software product evaluation - Quality characteristics and guidelines for their use.

Results: The overall user evaluation of the MEDICOM system was very positive. The MEDICOM system was characterized as an innovative concept that brings significant added value to medical-equipment commerce.

Conclusions: The eventual benefits of the MEDICOM system are (a) establishment of a worldwide-accessible marketplace between manufacturers and health care professionals that provides up-to-date and high-quality product information in an easy and friendly way and (b) enhancement of the efficiency of marketing procedures and after-sales support.

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KEYWORDS

Electronic commerce, medical devices, equipment and supplies, Internet, CORBA, XML, RDBMS

Introduction

The main objective for a European electronic marketplace for medical devices is to establish an environment hosting all the interactions of consumers (health care organizations and professionals) and providers (manufacturers, distributors, and resellers of medical devices). This objective is to be accomplished by concentrating the forces of organizations that are interested in globalization of the medical-products market. This has become necessary because the growth of the medical market requires introducing modern technologies for developing products and for establishing marketing policies. Our objective was to build a service that relies on seamless information exchange on the Internet to facilitate business relations (marketing, sales, and after-sales processes).

The MEDICOM (Medical Products Electronic Commerce) system is an Internet-based system that includes a unique Portal, which more or less acts as the yellow pages (a list of business and professional firms alphabetically by category; typically part of a telephone directory) for finding both products and providers. Its main advantage is fast, reliable, up-to-date information retrieval that eliminates all unrelated content that a general-purpose search engine would retrieve. The Portal accepts the end-user requests and generates a list of results containing text descriptions of devices, UMDNS (Universal Medical Device Nomenclature System) Attribute Values, and links to the providers' servers (for Web pages, online catalogues, and post-market surveillance systems) for access to more-detailed information in a way that is transparent to end-user customers. The post-market surveillance system collects information about adverse incidents; information on these incidents needs to be exchanged among competent authorities, health care institutions, and manufacturers, to deal with the consequences of the incidents and prevent reappearance of the same incidents.

The requirements of the medical-devices electronic-commerce community along with the technical requirements of the MEDICOM system have been analyzed within the framework of the MEDICOM project [1]. The European Commission, under the ESPRIT program, supported the project.

The end users of the MEDICOM system are clinicians; doctors; hospital administrative staff; clinical engineers; and in general everyone who uses medical devices, is involved in purchasing medical devices, or technically supports medical devices. The end-user requirements are, in summary:

- Advanced search and retrieval of structured and up-to-date information on medical devices of multiple manufacturers
- Friendly-and-informative multimedia presentations of medical products
- Presentation of complex equipment using virtual reality techniques
- Efficient after-sales support (for example, reporting incidents and technical assistance).

The medical equipment providers (manufacturers, distributors, and resellers) form the second user group of the system. Their main requirements are:

- Internet presence with Hypermedia Product Catalogues
- A secure communication channel with their customers for Post Market Surveillance (PMS)
- Access to user profiling and user-related statistical information
- Modularized service architecture which enables distribution of manufacturers' servers
- Capability of hosting a manufacturer's server at an Internet Service Provider's site
- Cost effectiveness.

Technical requirements are:

- Interoperability and easy integration of the MEDICOM platform with existing manufacturer infrastructure
- Consideration of all security issues about data integrity, confidentiality, and authentication
- Conformity of the technical implementation to existing standards.

In addition to the user requirements and technical requirements, some MEDICOM system-design issues have been considered:

- Even though on-line sales transactions and payment systems are not a usual practice in the current medical-device procurement process, it is anticipated that this will change. Therefore, incorporation of sales transactions and payment systems should be foreseen.
- An agreed and widely-used nomenclature system for the identification and description of medical devices in general terms is needed, to allow collation and data exchange across Europe.

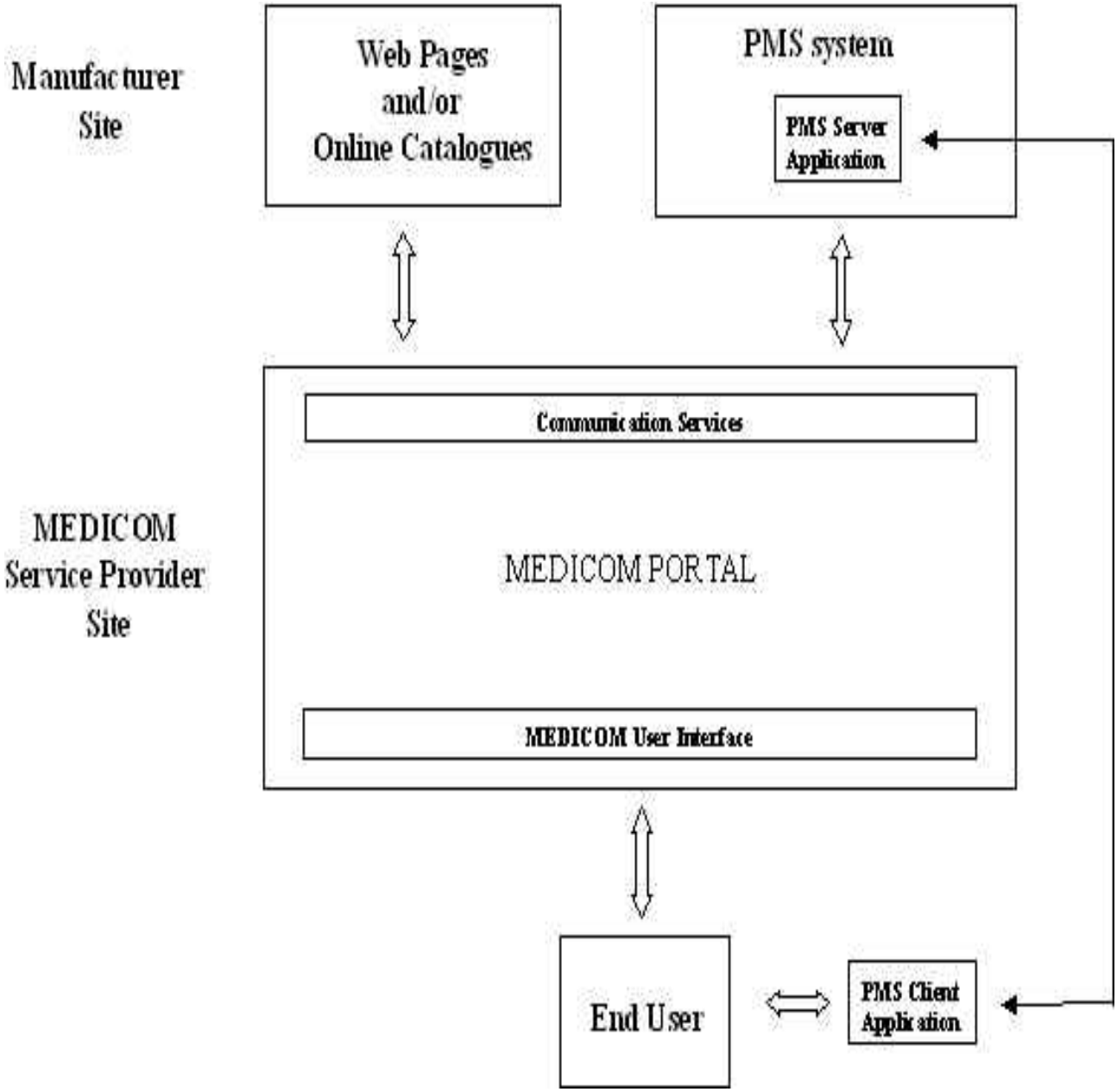
Since UMDNS was already widely used in Europe and the European Commission had adopted UMDNS as an interim standard, it was decided to use UMDNS as the classification basis throughout the MEDICOM system [2].

Methods

System design.

The MEDICOM system has been implemented using a modularized and distributed architecture. The main components of the system are shown in Figure 1. The Portal provides the end-user interface, handles system management, and ensures database compatibility throughout the system. It also provides necessary communication services, technical support for MEDICOM integrators, and additional services for the end users.

Figure 1. The MEDICOM system architecture



The MEDICOM Portal provides access to the whole system and coordinates the operation of the servers (catalogue and PMS servers) hosted by the manufacturers. The Portal hosts a database composed of 2 parts: (a) the Common Database, which stores a set of encoded parameters that will be included on all servers and (b) the Short Description Database, which contains the short descriptions of all medical products registered to the system.

The Portal is responsible for maintaining, altering on demand, distributing across the subsystems, and ensuring the consistency of the information in the Common Database. The structure of the Common Database includes the following data (see the next 2 paragraphs for explanations of some of the terms): Supported Languages, Geographic Regions, UMDNS Codes, UMDNS Attributes, Predefined UMDNS Attribute Values, Manufacturers, Authorized Representatives and Distributors, Incident Reports Classification Codes, Healthcare Institutions with PMS Client Systems, Quality Certificates of Medical Devices, Organizations Classification Codes, Specialism Codes of End Users, Producers Mailing Lists, End-users Job Titles, and Authorities.

The UMDNS Code is a unique identifier for each product category. Each product category (that is, each UMDNS code) is characterized by a set of features (for example, the operational voltage and the resolution). In the UMDNS, these features are called UMDNS Attributes. The set of values of each attribute are the attribute values. An example is the Device Category *Scanners, Ultrasonic, General Purpose*, which is assigned the unique UMDNS code 15976. For this device category there are 5 attributes (features) defined in the UMDNS coding system: System, Doppler/C.V.I., Transducers (arrays), Application, and Accessories. These attributes are intended to be the most important features of this device category. Each of the attributes has one or more values. The values can be restricted to a predefined set of values or can be unrestricted. For example, the attribute Transducers has a set of predefined values (Phased, Linear, and Curved Linear); the attribute Application can take

any value. Using the attribute and attribute values, the UMDNS codification ensures that for each device category a common set of important feature characteristics will be supplied.

Authorities (Competent Authorities and Notified Bodies) receive reports on serious incidents involving medical devices. The reports are submitted by the manufacturers or the health care institutions. Generally, the authorities have to monitor the manufacturer's investigation and intervene when necessary.

The Short Description Database contains summarized descriptions of medical devices, whose extended descriptions are presented by the manufacturer's servers. The Short Description includes a text description, the manufacturer and/or authorized representatives and/or distributors, the UMDNS code, important product features, and links to the corresponding HTML pages of the manufacturers' servers (where extended information exists). The contents of the Short Description Database will be updated as a result of a manufacturer's-server request.

To satisfy the end-user requirements the Portal provides the end-user with the following services:

- **Profiling and registration:** The Portal maintains user profiles and handles user-authentication and security issues. In addition, it provides user-related information to the manufacturers on request.
- **Product Searching mechanism:** Perhaps the most useful service. Searching can use one or more of the following criteria:

- - Manufacturer: useful when searching for the whole range of products of one manufacturer.
  - Distributor: useful when searching for products distributed by a specific distributor.
  - Product Category (based on the UMDNS classification): used when searching for a specific product category.
  - Product Name: used when searching for a specific product.

  While searching, the user can define some parameters that narrow the resulting set of devices, such as the language of the provided information or the region where the requested products are available. The Portal, based on the searching parameters, performs a query in the local Short Description Database, and generates a list of matching products along with all the data that are stored in the Portal for each one of these products. The resulting set contains links to remote manufacturers' servers where the user can access more information about the specific product. Depending on the specific manufacturer, this information may include multimedia presentations and virtual exhibitions of complex equipment.
- **Free-Text Searching:** A search engine will allow the users to perform free-text queries on a selected set of Web sites (eg, the Web sites of the participating manufacturers). Restricting the user's query to a small number of sites that are highly related to the MEDICOM end-user's interests increases the relevance of the links that result from the user's query. This service is implemented with the Netscape Compass server (Version 3). Compass can index HTML, ASCII, Microsoft Word, Microsoft PowerPoint, Adobe PDF (Portable Document Format), and various other document formats on local or remote WWW (World Wide Web) and FTP (File Transfer Protocol) sites.
- **Bulletin Board:** The Portal hosts a bulletin board covering a wide range of topics relative to the end-users' interests. The end user will have the option to search through the posted articles, contact the authors, and initiate a new discussion thread.
- **Literature and Standards:** Literature and standards about specific products or product categories is stored in the Portal and end users can search though it.
- **On-line information for the MEDICOM system and Special Messages or Advertisements from Manufacturers.**

In addition to providing services to the end users, the Portal provides the following services to the manufacturers:

- **Technical Specifications for the MEDICOM Integrators:** The Portal will provide specifications and technical support, if necessary, for integration of proprietary subsystems with the MEDICOM system. There is a strong possibility that a manufacturer has already-developed Web pages and online catalogues, which the MEDICOM system should be able to incorporate.
- **Browsing and Updating of the Common Database:** The updates on this information affect the whole system, thus the Portal administrator moderates them.
- **Browsing and Updating of the Short Description Database:** Each manufacturer has access only to the data related to its products.
- **Access to system statistics and user profiling.**

Modularity, platform independence, and interoperability characterize the design of the Portal. Internet-standard technologies have been utilized wherever possible. The first version was developed for Windows NT and it is currently ported to HP-UNIX (Hewlett-Packard UNIX). All the data across the MEDICOM system are structured and maintained in databases. The Oracle 8 RDBMS has been used to develop the Portal databases. The end-user interface is a combination of static and dynamic HTML pages. Javascript code, which is executed by the user's browser, parses the XML (eXtensible Markup Language) data and displays the data on the browser [3]. Separation of formatting information and data through the use of XML has a strong benefit. The code, which formats the data, is transferred only once to the user's browser. From that point on, the browser receives only XML documents, which are parsed and presented. Communication and data exchange between (a) the Portal and (b) the remote Web sites and on-line catalogues of the medical equipment manufacturers and suppliers are based on CORBA (Common Object Request Broker Architecture) [4]. Java has been used for application development, enhancing the portability of code to different platforms [5,6].

System evaluation.

The objective of the evaluation was to validate the usability of the complete MEDICOM functionality. To evaluate the system

effectiveness and efficiency, representative users were asked to complete typical tasks. The evaluation procedure was based on ISO/IEC (International Organization for Standardization/International Electrotechnical Commission) 9126, Information technology - Software product evaluation - Quality characteristics and guidelines for their use [7].. Additionally, simple questionnaires were used to assess user satisfaction.

The users of the system were divided into 3 groups:

- End Users (hospital managers, clinicians, clinical engineers, and procurement office administrators)
- Manufacturers (IT [Information Technology] specialists)
- Service Provider (operator of the Portal)
  We intend to provide worldwide service through one organization - TNO (Toegepast Natuurwetenschappelijk Onderzoek [Netherlands Organization for Applied Scientific Research]), so there Service Provider, rather than Service Providers, is listed. However, there is the possibility of, for example, different portals in each country with each portal operated by a different service provider.

End-user functionality was evaluated by AUSL (Azienda Unita' Santaria Locale Di Modena) of Modena, which is the health care organization responsible for public service in the province of Modena, Italy. Manufacturer functionality was evaluated by Esaote S.p.A. (a medical-device company). Service-provider functionality was evaluated by the Prevention and Health Division of TNO.

Results

The overall user evaluation of the MEDICOM system was very positive. The MEDICOM system was characterized as an innovative concept that brings significant added value to the process of medical-equipment commerce.

Searching for a product in a specific product category resulted in a list of matching products that was highly representative of the actual market. The amount of information in the short description of each product was considered well chosen. The searching procedure was easy to use, even by persons without specific computer experience. The on-line help was often used and the information returned was adequate. The resulting list of matching products never contained products that should not be included (that is, that did not match the searching criteria). In comparison to the searching procedures that were used up to then the MEDICOM system proved to be more effective, more efficient and more user friendly.

Discussion

Researching the overall competition to MEDICOM showed that no company offers the complete set of MEDICOM services. Some companies only present basic company information or list their products, with neither search nor ordering options. Some companies present only part of the possible product mix, or they supply products from only one manufacturer or from a few manufacturers. Most companies offer only basic customer service or give their telephone number and/or e-mail address. Although there are Web sites where it is possible to order products made by many manufacturers, these Web sites are not strong potential competitors to MEDICOM, since they are not portals and their product mix is not as wide as MEDICOM's product mix.

The MEDICOM Portal targets the manufacturers of medical devices by stressing the importance of the Internet as a mean of providing information and promoting their products. The Internet is a new and cost-effective way of diffusing product information, offering technical and after sales support, providing information about new products and services, evaluating the competition, finding new distributors and suppliers, and reaching global customers.

For health-care professionals, MEDICOM provides a wide range of accurate information about new medical products and services. It will increase health-care professionals' knowledge about the market and it will improve communication between them and the manufacturers for after-sales and technical support. Most importantly, it will facilitate the involvement of all actors in the purchasing process for new medical equipment by providing a wide range of accurate information, by giving access to detailed technical features and commercial conditions on-line, and by offering an overview of the products' competition.

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Conflicts of Interest

None declared.

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Abbreviations

AUSL: Azienda Unita' Santaria Locale Di Modena
CORBA: Common Object Request Broker Architecture
ISO/IEC: International Organization for Standardization/International Electrotechnical Commission
IT: Information Technology
MEDICOM: Medical Products Electronic Commerce
PMS: Post Market Surveillance
RDBMS: Relational Database Management Systems
TNO: Toegepast Natuurwetenschappelijk Onderzoek (Netherlands Organization for Applied Scientific Research)
UMDNS: Universal Medical Devices Nomenclature System
XML: eXtensible Markup Language

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Original Paper

Evaluation of Norwegian cancer hospitals' Web sites and explorative survey among cancer patients on their use of the Internet

Jan Norum[1], MD, PhD

Norwegian Centre for Telemedicine, University Hospital of Tromsø, Norway

Corresponding Author:
Jan Norum, MD, PhD
Norwegian Centre for Telemedicine
University Hospital of Tromsø
P.O.B. 35
N-9038 Tromsø
Norway
Phone: ++ 47 777 54103
Fax: ++ 47 777 54098
Email: jan.norum@telemed.no

Abstract

Background: Hospital homepages should provide comprehensive information on the hospital's services, such as departments and treatments available, prices, waiting time, leisure facilities, and other information important for patients and their relatives. Norway, with its population of approximately 4.3 million, ranks among the top countries globally for its ability to absorb and use technology. It is unclear to what degree Norwegian hospitals and patients use the Internet for information about health services.

Objectives: This study was undertaken to evaluate the quality of the biggest Norwegian cancer hospitals' Web sites and to gather some preliminary data on patients' use of the Internet.

Methods: In January 2001, we analyzed Web sites of 5 of the 7 biggest Norwegian hospitals treating cancer patients using a scoring system. The scoring instrument was based on recommendations developed by the Norwegian Central Information Service for Web sites and reflects the scope and depth of service information offered on hospital Web pages. In addition, 31 cancer patients visiting one hospital-based medical oncologist were surveyed about their use of the Internet.

Results: Of the 7 hospitals, 5 had a Web site. The Web sites differed markedly in quality. Types of information included - and number of Web sites that included each type of information - were, for example: search option, 1; interpreter service, 2; date of last update, 2; postal address, phone number, and e-mail service, 3; information in English, 2. None of the Web sites included information on waiting time or prices. Of the 31 patients surveyed, 12 had personal experience using the Internet and 4 had searched for medical information. The Internet users were significantly younger (mean age 47.8 years, range 28.4-66.8 years) than the nonusers (mean age 61.8 years, range 33.1-90.0 years) (P= 0.007).

Conclusions: The hospitals' Web sites offer cancer patients and relatives useful information, but the Web sites were not impressive.

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KEYWORDS

Internet, information, consumer information, Web site, World Wide Web, cancer care facilities, cancer hospitals, hospitals

Introduction

Several investigators have shown that cancer patients consider information to be of great importance; further, informing patients and relatives is now an important part of cancer treatment [1,2]. During the last decade, information requests to health care workers in the Western world have steadily increased. Patients want to know more about the diagnosis, treatment, and follow-up of cancer. Questions about clinical results and hospitals' expertise are especially common. Many people have access to the Internet; in a Norwegian study [3], 63% had access to the Internet and 42% had their own PC with Internet access. The Internet has opened a new area to patients and their relatives.

Much medical information is available directly at their homes at any time. But, even using the Internet, patients and relatives have difficulty finding the information they need. Excellent medical information exists, but it is scattered across dozens of different Web sites. The World Wide Web is the "wild wild Web." There is no comprehensive Web site that provides links to all the best online information for the patient's disease - this may be one of the major causes of the demand for more information and help from health professionals.

On January 1, 2001, the Norwegian National Health Administration introduced a new system named "free hospital selection" [4]. Until then, Norwegian patients had to be admitted to their local hospital according to geographic regulations. Based on the new legislation, cancer patients are now free to select among the different national public cancer hospitals. Only the increased travelling costs, if any, have to be paid by the individual patient. However, the National Insurance Scheme has decided to cover all travelling costs above a limit of US $44 (approximately Euro 50). As a result, patients can act as customers, buying the most attractive treatment. The different cancer institutions are put in competition to be attractive to the cancer patients. In this situation the hospital Web sites may be crucial because they may perform the same function that display windows do for stores.

To clarify whether the World Wide Web is likely to be an important platform for hospitals to advertise their services, one week after the introduction of "free hospital selection" a study on hospital Web sites was performed and a selected group of cancer patients were asked about their use of the Internet.

Methods

Web site evaluation

In January 2001, we looked for Web sites for the biggest Norwegian cancer hospitals. We found Web sites for these hospitals: The Norwegian Radium Hospital (NRH), Ullevål hospital, Haukeland University Hospital (HUH), Central Hospital of Rogaland (CHR), University Hospital of Trondheim (UHT), University Hospital of Tromsø and the Rikshospitalet University Hospital (RUH). These hospitals (except RUH) offered cancer patients radiotherapy, chemotherapy, hormonal therapy, and palliative therapy. When we could not find a Web site, we made a phone call to the hospital to confirm that there was no Web site. We found Web sites for the following hospitals: NRH (http://www.dnr.uio.no, now available at http://www.dnr.org), HUH (http://www.haukeland.no), CHR (http://www.sir.no), UHT (http://www.rit.no), and RUH (http://www.rikshospitalet.no). We analyzed the Web sites according to the scheme shown in Table 1. The scheme was based on Norwegian recommendations for Web sites developed by the Norwegian Central Information Service [5]. We gave a 0 to 3 score (0 = no information, 1 = a little information, 2 = some information, 3 = much information) to 7 items (items 1-4, 8-10). We gave a 0 to 1 score (0 = no information, 1 = information is given) to 6 items (items 5-7, 11-13). The maximum total score was 27 points. One rater employing a checklist performed all the ratings. The rater had no connection to any of the rated hospitals.

Table 1. Scheme Employed to Score the Information on the Hospital Web Pages

1. General information	(0-3 score)	Maps (of the area and the hospital), general description (location, taxi, bus, train) and information about car-parking
2. Addresses	(0-3 score)	Postal address, phone number, and e-mail address
3. Cancer department(s)	(0-3 score)	etc.)
4. Treatment available	(0-3 score)	institution
5. Price list	(0-1 score)	No price list = 0, any price list = 1
6. Search option	(0-1 score)	No search option = 0, any search option = 1
7. Interpreter service	(0-1 score)	No service offered = 0, any interpreter service = 1
8. Leisure facilities	(0-3 score)	For example: physical activities, library, bedside phone, Internet access, sightseeing, hairdresser
9. Links to databases	(0-3 score)	For example: The Norwegian Cancer Union, different medical journals
10. Relatives	(0-3 score)	and associated costs. Restaurant availability
11. Waiting time	(0-1 score)	No information = 0, any information = 1
12. Date of update	(0-1 score)	No date = 0, any date of update = 1
13. English version	(0-1 score)	No English version = 0, any English version = 1

Patient survey

To get an idea of the use of the Internet by Norwegian cancer patients, 31 consecutive patients visiting one medical oncologist were interviewed. There were 21 women and 10 men; the majority of the patients suffered from breast cancer (15 patients), lymphoma (6 patients), or colorectal cancer (3 patients). Mean age was 56.3 years (range, 28.4-90.0 years). The interview was performed by the oncologist that the patients were visiting and took place at the outpatient clinic at the Department of Oncology, University Hospital of Tromsø (Tromsoe, Tromsö). During the outpatient visit, each patient was asked about any personal experience with the use of the Internet. If the patient

responded positively, the interviewer asked whether the patient had used the Internet to gain access to medical information.

Statistics

We used Microsoft Excel 97 for the final database and the Statistical Package for Social Science (SPSS) version 9.0 for statistical calculations. We used 1-way analysis of variance (ANOVA) to analyze for significant correlations. All *P* values are 2-tailed and considered statistically significant when $P< 0.05$.

Results

Web site evaluation

Of the 7 hospitals, 5 had a Web site on the Internet; the other 2 hospitals had plans for a running Web site within 2 months. We easily accessed the 5 Web sites using Microsoft Internet Explorer 3.0. The point scores for the Web sites were: Norwegian Radium Hospital, 15; Haukeland University Hospital, 10; Central Hospital of Rogaland, 6; University Hospital of Trondheim, 14; and the Rikshospitalet University Hospital, 13. Details on point scores are shown in Table 2.

Table 2. Scores of Hospital Web Sites

Item	NRH [a]	HUH [b]	CHR [c]	UHT [d]	RUH [e]	Maximum score
1. General information	2	2	1	3	2	3
2. Addresses	3	3	1	3	2	3
3. Cancer departments	1	1	0	1	1	3
4. Treatments available	2	2	0	2	2	3
5. Prices	0	0	0	0	0	1
6. Search option	0	0	0	1	0	1
7. Interpreter service	1	0	0	0	1	13
8. Leisure activities	3	1	1	0	2	3
9. Links	2	0	1	1	1	3
10. Relatives	0	1	1	2	1	3
11. Waiting	0	0	0	0	0	1
12. Date of update	1	0	1	0	0	1
13. English version	0	0	0	1	1	1
Sum	**15**	**10**	**6**	**14**	**13**	**27**

[a] NRH = Norwegian Radium Hospital

[b] HUH = Haukeland University Hospital

[c] CHR = Central Hospital of Rogaland

[d] UHT = University Hospital of Trondheim

[e] RUH = National Hospital of Norway

Information about price lists or waiting time was not included on any of the Web sites. A search option was included on 1 Web site (UHT). Information on an interpreter service was included on 2 Web sites (NRH and RUH). The date of last update was included on 2 Web sites (NRH, CHR); the time since last update was 3.8 and 19.5 months, respectively.

The best general information was on the UHT Web site (this Web site received 3 points). This Web site included: a map of the area, an overview of the institution, details about car parking, and written information about how to reach the hospital by plane, train, bus and/or taxi.

Information - e-mail address, phone numbers, and postal address - on contacting the hospital was easily available on 3 Web sites., None of the 3 included e-mail addresses for either the departments or the oncologists, although all 3 had a central e-mail system. However, it was possible to find some direct e-mail addresses for the oncologists at the UHT by using the link - on the UHT Web site - to the University of Trondheim (http://www.ntnu.no). Information about the e-mail system - and about laws, regulations and risks related to mailing sensitive information - was included on the NRH Web site. The capability to search the hospital phone book by name, position, and department was included on the RUH Web site.

Information about hospital departments was very limited and was usually written; there were few pictures and no maps. Information on the treatments offered included only high-level summaries such as "radiotherapy, chemotherapy and hormonal therapy is offered." There were neither pictures nor illustrations. There were no details about the different treatments. The written information about hyperthermia at the HUH may act as a model for hospitals that want to improve the way they include treatment information on their Web sites.

The best leisure facilities information was on the NRH Web site (this Web site received 3 points). This Web site included information about such services as: cafeteria, kiosk, post office, bank, pharmacy, hairdresser, wig maker, makeup course,

pedicure, hospital school, library, video, personal computers with games installed, bedside phone, television in all rooms, living room with a piano and a CD player, swimming pool, sauna, and exercise rooms. Information was included about possibilities for painting, carpentering, and sewing. The clergy offered devotions and services. Sightseeing tours and visits to museums, theaters, cinemas and football games as well as bicycles and cars were offered free of charge. Billiards, tennis and golf were also mentioned.

There was very limited information to help relatives on the Web sites. The best information to help relatives was on the UHT Web site (this Web site received 2 points). The UHT had made arrangements with 9 local hotels; hotel information included names, addresses and prices (590-829 Norwegian kroner/night, approximately 74-103 Euro/night). Some information about the cafeteria was included on the CHR and RUH Web sites. Some information about the possibility of staying at the hospital hotel was included on the HUH Web site.

Information in other language(s) was only on the UHT and the RUH Web sites. The UHT Web site included a summary in English and some information in German. The RUH Web site included information in English on treatment, teaching, staff, research, and development

Patient survey

Only 12 out of 31 patients reported that they had any personal experience using the Internet. Of the 12, 4 (13% of the 31 patients surveyed) had searched for medical information on the Internet. The Internet users were significantly younger (mean age 47.8 years, range 28.4-66.8 years) than the nonusers (mean age 61.8 years, range 33.1-90.0 years) (P= 0.007). We did not observe any difference in Internet use based on gender, type of cancer, or stage of disease (localized versus metastatic disease). However, the statistical power to detect differences in this pilot study was too low to make any reliable statements on lack of association between these variables and Internet use.

Discussion

Web site evaluation

This study has documented that only 5 of 7 major Norwegian hospitals had a running Internet Web site in January 2001. The quality of these Web sites differed markedly; score range was from 6 to 15 points. There was no information about price lists or waiting time, only limited information related to the departments and search options, and limited English summaries. However, some hospitals had very nice presentations about general information, ways to contact the hospital, and leisure facilities.

Price lists for treatment may have been omitted because all costs resulting from hospitalization are covered by the national public insurance, National Insurance Scheme (NIS). However, when patients are treated as outpatients, the patients and the NIS share the costs. Patients pay the same amount in all public hospitals and the hospitals are not allowed to make special offers.

Since the 5 institutions are research centers taking part in national and international research projects, it is disappointing that only 2 institutions offered an English summary. Factors that may require English information on the hospitals' Web sites include tourism, immigration, and patients from foreign countries seeking medical treatment or advice in Norway.

In this study, 3 of the 5 Web sites provided e-mail interactivity. This percentage (60%) is somewhat lower than the finding of Hoffman-Goetz and Clarke that 88% of the breast cancer sites on the World Wide Web provided this service [6]. It is generally recommended that Web sites provide a method for users to correct wrong information and report failures. There are reasons to believe that in the future patients will want to communicate with doctors directly instead of through a hospital's central e-mail system. This statement is based on the experience that Norwegian cancer patients consider their oncologist to be the most important source of information about the disease (Norwegian Centre for Telemedicine, oral communication, December 2001) and on individual patient-doctor relations created during visits at the outpatient clinics. Although this direct communication is technically possible in Norway, there are several security concerns that have to be solved, because connecting PCs both to the Internet and to a hospital intranet containing patient and hospital data may make it possible to manipulate that data from the Internet.

Patient survey

We found a significant correlation between patients' age and the use of Internet. This is in accordance with a Norwegian survey [3] that documented a correlation between age below 60 years and experience with the Internet. The Norwegian survey also observed a difference based on gender, as males were more frequently Internet users. Level of education may be another factor in Internet use. Other investigators have documented that patients with longer formal education have a more active information-seeking strategy than those with a more limited formal education [7-9].

Conclusions

Knowing that there will be increased competition between the hospitals, since Norwegian patients are now offered the possibility of selecting their hospital for treatment, and assuming that hospital Web sites may perform the function for patients selecting their hospital that display windows perform for stores, the Web sites were not impressive.

Our finding that few cancer patients (13%) had sought medical information on the Internet is comparable to other surveys. The results have to be interpreted with caution because this study lacks statistical power and does not use a large cross section of patients. However, the figures are in accordance with the results from a Swedish study done by Carlsson in Uppsala finding that only 6% of adult patients visiting the Department of Oncology had sought information from the Internet [2]. Another study performed by the Norwegian Centre for Telemedicine (NCT) documented that 19% of the Norwegian population had employed the Internet to gain access to medical information [10]. These results are surprising, particularly because Scandinavian countries have one of the highest Internet penetrations in the world.

It could be argued that there is no need to allocate resources to the development of Web sites, because only a few patients search for medical information on the Internet. However, there are several reasons to believe that this will change as more and more people gain access to the Internet. It has been estimated that about 500 million computers were linked to the Internet at the end of the year 2000 [11]. There are reasons to believe that in the future Intranets and the Internet will be more important in informing and communicating with cancer patients and their relatives.

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Conflicts of Interest

None declared.

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Abbreviations

CHR: Central Hospital of Rogaland
HUH: Haukeland University Hospital
NIS: National Insurance Scheme
NRH: Norwegian Radium Hospital
RUH: National Hospital of Norway
UHT: University Hospital of Trondheim

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Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org