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Contents

Viewpoints

<u>Original Paper</u>

Building and Growing a Hospital Intranet: A Case Study

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Abstract

Background: The Intranet is a rapidly evolving technology in large hospitals. In this paper, we describe the first phase of an Intranet project in a multi-hospital system in New York City.

Objectives: (1) To encourage the use of the Intranet among physicians, nurses, managers, and other associates in a multi-hospital system; and (2) to build the Intranet in a cost-effective manner using existing resources.

Methods: A WebTrends Log Analyzer assessed the Intranet use in terms of the number of accesses from each department.

Results: A broad range of features, including medical knowledge resources, clinical practice guidelines, directions, patient education, online forms, phone directory, and discussion forums were developed. Analysis of more than 890,000 hits revealed the departments with hits greater than 1,000 were the 'Library' (6,130), 'Physicians Gateway' (2,539), 'Marketing' (1,321), 'Information Systems' (1,241), and 'Nutrition' (1,221). Of 819 unique visitors, 74 per cent visited more than once.

Conclusions: It is possible to create and diffuse an Intranet in a multi-hospital system in a cost-effective manner. However, the key challenges were selling the potential of this new technology to opinion leaders and other stakeholders, and converting pre-existing printed content by obtaining word processed and image files from other departments or contracted print publishers.

Introduction

Hospitals are rapidly adopting Intranet technology. According to a survey by PriceWaterhouseCoopers and Zinn Enterprises, the proportion of large hospitals (number of acute care beds greater than 500) with an Intranet rose from less than half of the respondents in 1999 to nearly three-quarters in 2000 [1].

This paper describes the first phase of Intranet growth in a hospital system from October 1999 through July 2000. We describe the challenges encountered, solutions created, and resources brought to bear to develop a dynamic, enterprise-wide Intranet.

Background

Saint Vincent's Catholic Medical Centers of New York (SVCMCNY) is a newly merged enterprise of seven acute care hospitals with services that include a wide spectrum of health care. The system includes 2,600 acute medical/surgical beds, 61 primary care, behavioral health and ambulatory care sites, 800 long-term care beds, 1 million home care visits, approximately 2,000 physicians, and 15,000 associates. SVCMCNY serves communities in Brooklyn, Manhattan, Queens, Staten Island, and Westchester.

The first phase of the Intranet project was limited to the services and settings of care affiliated with four acute care hospitals in the boroughs of Brooklyn and Queens in New York City.

Methods

Resources, Infrastructure, and Software

The Intranet comprises a variety of resources, infrastructure, and software (Table 1).

The Intranet project team comprises a project manager, a webmaster, and a technical lead. At present, the webmaster also

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designs and develops the Intranet. Departments, with sites on the Intranet, have content providers that send digital content to the developer.

Internet Explorer 5 is the standard web browser and FrontPage 2000 the supported HTML (hypertext markup language) editor.

Each department with an Intranet site has a content provider, who must ensure that the relevant department chair has approved material before it is sent to the developer. Content is sent via e-mail. Hardcopy photography is accepted but paper-based text for optical character recognition is not.

Site statistics are monitored with WebTrends Log Analyzer [2] and FrontPage 2000's report function.

Site Map and Content

At the end of this first phase of the project, the Intranet has 267 MB of files. At the time of writing, 3,011 files have been posted in the last 30 days. The remaining 1,230 files have not been modified in over 72 days. Of the 5,447 hyperlinks, the majority (5,088) is internal and a minority (359) is external.

A frameset is used to facilitate navigation with links to the main department sites, such as the 'Administrative Manual', 'Library', 'Phone Book', and the 'Physician Gateway' (Figure 1).

Figure 1. Example Frameset

Links on home page

Links on navigation bar of the frame set

News

Physician Gateway

The Library

About the Intranet

Intranet Home Page

Administration Manual

Cancer Centers

Directions

Forms

Human Resources

Information Systems

The Library

Marketing

Nutrition

Phone Book

Physician Gateway

Quality Assurance

Radiology

Success Agenda

Training

The home page has links to a 'News' page with the latest corporate announcements. For example, the current version of 'News' has information and links to resources on Ambulatory

Payment Classification and a news release about a prostate cancer screening campaign.

Functions served by the Intranet include those shown in Textbox 1.

Table 1. Intranet Resources, Infrastructure, and Software

Category	Description		
Resources	*Position*	*Intranet Project Team Role*	*Time devoted to Intranet (full-time equivalent, FTE)*
	Director, Medical Informatics	Design, development, and webmaster	0.5
	Director, Data Administration and Security	Project manager	0.1
	Network Coordinator	Technical lead	0.1
Infrastructure	• Compaq Proliant 3000 Server with 256 MB RAM and 14 GB hard disk		
	Compaq Proliant 3000 Server with 256 MB RAM and 14 GB hard disk		
Software	• Windows NT 4 • Microsoft Internet Information Server • Internet Explorer 5 • FrontPage 2000 • Microsoft Office Suite • Image Composer • Adobe Photo Deluxe, Business Edition • WebTrends Log Analyzer • Hewlett Packard Precision Scan Pro		

Textbox 1. Functions served by the Intranet of the Saint Vincent's Catholic Medical Centers of New York

- Online administrative manual
- Internal marketing
- Directions to the hospitals
- Digital forms
  - Adult Medical Record Review Form
  - Inter-Library Loan Request
- Form repository (links to Microsoft Word files)
- Secure site for an enterprise-wide work group ('Success Agenda')
- Public and restricted information for Human Resources and Information Systems
- Web-based and Intranet-enabled medical knowledge resources
  - PubMed
  - Harrison's Online
  - PDR.net (the online version of the Physicians' Desk Reference)
  - Clinical Pharmacology 2000
  - Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Comprehensive Accreditation Manual for Hospitals 2000
  - 1999 Hospital Statistics from the Greater New York Hospital Association
  - STATRef
  - InfoTrak
  - Dialog@CARL
  - Centers for Disease Control and Prevention, including Travel Advisory
  - AIDS Treatment Information Service
  - New York City Department of Health, including West Nile Virus updates and restaurant inspection reports
- Nutrition information
- Searchable phone book, an Access database of the global address book from Outlook
- Physician resources ('Physician Gateway')
  - Order sets and clinical practice guidelines
  - Patient education
  - Pharmacy newsletter
  - Health care-related web links, such as MedCalc 3000
  - Highlighted links to resources of particular importance to New York City, for example, West Nile Virus, HIV/AIDS, Lyme Disease
  - Palm Pilot downloads, such as ePocrates.com
- Training
  - PowerPoint presentations converted to web pages
  - Self-instructional training on conscious sedation with an online post-test
- Discussion group for the Information Systems Help Desk
- Suggestion boxes

Results

Intranet Traffic Report

At the time of writing, the Intranet has had 890,253 hits with an average of 3,091 hits per day. The total number of visitor sessions was 24,251 with an average of 84 per day. The total number of unique visitors was 819, of which 74 per cent (608 of 819) had visited more than once. About a third of the visitors (276) visited 10 or more times. The greatest proportion of total visitors (45%) viewed three pages.

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Excluding hits to the home page, the departments receiving the most visitor sessions (defined as greater than 1,000 visitor sessions) were the 'Library' (6,130), 'Physicians Gateway' (2,539), 'Marketing' (1,321), 'Information Systems' (1,241), and 'Nutrition' (1,221) (see Table 2).

Table 2. Departments Receiving the Most Visitor Sessions

Department	Visitor Sessions
Library	6130
Physicians Gateway	2539
Marketing	1321
Information Systems	1241
Nutrition	1221
Administrative Manual	715
Help Desk	692
Human Resources	579
Phone Book	475
Training	462
Quality Assurance	450
Success Agenda	426

The average number of visitors per day was 105 on weekdays and 59 on Saturday and Sunday combined. The most active day of the week was Wednesday and the least Saturday. The most active hour of the day was from 2 PM to 3 PM and the least from 5 AM to 6 AM.

Discussion

The Intranet has succeeded in becoming a tool used on a daily basis throughout the enterprise. It serves both business critical and patient care functions. The Intranet garnered more than 800,000 hits in its first phase. More than 500 visitors have visited more than once. Content at the end of this first phase includes a gamut of resources from an administrative manual to online training.

This mirrors the success of Intranets elsewhere in healthcare. Intranets have been used to support clinical practice guidelines [3], radiology test results [4], disease management [5], paging services [6], and a link between emergency departments [7].

The project costs in resources, software, and hardware were modest in comparison with other similar Intranet projects [4]. An existing network, server, and Microsoft software license cut Intranet project costs. The 0.7 FTE resources, less than $70,000 total for the first year, were in-sourced. In contrast, one price advertised on the web for Intranet start-up design and development is $7 per user per month . At this price, an Intranet distributed to the 5,000 users in phase one of our project, could have cost $420,000 [8].

One limitation of our analysis was the inability to determine use by different segments of the audience. Intranet was designed to permit access by all staff and associates ('Anonymous browsing allowed' in Internet Information Server 4.0). Individual logon was not necessary for access. We were therefore unable to stratify use in terms of physicians, nurses, administrators, and others.

The Challenges and Solutions

> *"Build it, and they will come." It may have worked for Kevin Costner in the movie "Field of Dreams", but chances are this philosophy alone won't work for your company's Intranet. - P.G. Daly [9].*

As with any innovation, at the outset, the Intranet was not adopted immediately [10]. Early adopters provided content to the Intranet and promoted its early use by physicians. The medical library director asked that web-based and web-enabled resources be put online. The clinical chair of medicine requested that the physician order sets and clinical practice guidelines be made available online.

Content spurred use by other staff groups. The nursing coordinator for patient education worked to create material for the most common conditions and illnesses. The Nutrition department submitted training presentations.

The project team webmaster and leader actively sought content and marketed the Intranet in one-on-one meetings with department and corporate leadership. As influential early adopters made the Intranet their own, more stakeholders and departments showed interest in the Intranet.

Though adoption may have been the principal barrier, solutions for other challenges were no less critical to the Intranet's performance and survival. The Intranet project team faced a number of challenges.

- The imminent merger presented a barrier to some who were unclear what their own role or that of their department might be in the new organization. They were hesitant to commit time and resources to a venture they might not see complete. For others, creating an Intranet site for their department fostered collaboration between the regions and served as a means to advertise the products and services they offer to the enterprise.

- Timely receipt of content was particularly based on promoting existing or building new interpersonal relationships. Lack of familiarity with Intranet functionality and questions about how departmental content would be managed were two often voiced concerns. The webmaster developed a PowerPoint presentation that introduced Intranet technology and described its potential to enable the business and patient care missions of the enterprise. Communication skills were as critical as programming knowledge. A policy was developed that required that all content have the approval of the relevant departmental leadership.

- Converting corporate pamphlets, leaflets, and newsletters required obtaining ASCII or word processed text from the various contracted print publishers. Marketing was encouraged to send soft copies to the Intranet webmaster whenever new print media was created. To prevent delays in publication and to reduce development turnaround time, text was accepted only in digital format. Photographs were accepted in Graphic Interchange Format (GIF) or Joint Photographic Experts Group (JPEG) format but could also be sent in hardcopy and scanned.

- Collapsible guidelines, dynamic HTML, and other features at the time were only supported by Internet Explorer versions 4 and above. Internet Explorer 5 was made the standard web browser. Web browser standardization was accomplished with Microsoft Systems Management Server.

- To enable collaborative authoring and work team sites with restricted access, security permissions for directories (access control lists) and files were managed in the Windows NT file system (NTFS).

- Marketing the Intranet meant more than announcing its existence in corporate email broadcasts and newsletters. The Intranet team met with departmental leadership in locations and times convenient to them. Meeting preparation required a checklist of several items. We confirmed network connectivity and installation of Internet Explorer 5 on suitable workstations before each meeting. The Intranet was made the default home page on these workstations and a readily apparent shortcut placed on each desktop screen.

If a user did not have an account on the new enterprise-wide domain, a new account was made or an old account was moved.

- Success inherently generates problems of its own. As more departments adopt the Intranet, more content is created that must be re-formatted to web-browser friendly layout and incorporated into the web architecture. The increase in content may be temporary and related simply to the recent merger.

If the content submission and turnover continue to grow, several options will be considered. We are currently experimenting with a method that permits Marketing to publish content directly to the Intranet without the need of an intermediary, for example, form posting to an HTML file. Alternatively, content submission and development could be limited to once or twice a month rather than weekly. Finally, more resources may be needed in Intranet design and development.

Next Steps

With successful completion of the first phase of the Intranet project, the second phase will have three goals:

1. Re-engineer the Intranet content and format to serve the new enterprise in all regions. New sites will include the physicians-hospital organization, the nursing department, and JCAHO readiness.
2. Grow Intranet application development, for exempt, enterprise-wide job postings, podiatry procedure log, uniform formulary database.
3. Extend the web browser standard and validate network connectivity throughout the enterprise.

Conclusion

Intranet technology is readily available and is, if pre-existing resources are already in place, of modest cost. Adoption was the key barrier to diffusion in our project. By demonstrating how the Intranet can serve business critical and patient care needs, we were able to empower early adopters. The Intranet has succeeded in reaching the early majority and has evolved from a cutting edge technology to an everyday tool.

Conflicts of Interest

None declared.

Appendix 1

Downloadable Screenshots of the Intranet [PowerPoint ppt file, 2 MB - jmir_v3i1e10_app1.ppt]

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Commentary

Cyberpharmacies and the role of the US Food And Drug Administration

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Abstract

The sale of consumer products over the Internet has grown rapidly, including the sale of drugs. While the growth in online drug sales by reputable pharmacies is a trend that may provide benefits to consumers, online drug sales also present risks to purchasers and some unique challenges to regulators, law enforcement officials and policy makers. The Food and Drug Administration (FDA or the Agency) is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as part of our overall goal of developing and implementing risk-based strategies to protect public health and safety. Although other products regulated by the Agency, such as medical devices, medical test products, foods, dietary supplements and animal drugs also are sold online, this paper focuses on online drug sales. We discuss the advantages and risks of online drug sales, outline FDA's authority and enforcement activities in this area, and describe new initiatives we are taking to better respond to the regulatory challenges we face.

Benefits of Online Drug Sales

The use of the Internet by our nation's citizens, from school age children to seniors, has opened up vast new opportunities for the exchange of information and for enhancing commerce in all types of consumer products. Electronic mail and chat groups have dramatically facilitated communications. Information gathering that once took hours or days of research, whether for a student's homework assignment or to look up information on the medical condition of a family member, can now be accomplished in minutes.

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy. In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors in the nation's finest academic health centers. The Internet permits an increasing number of individuals to obtain a plethora of medical information that often helps them to understand health issues and treatment options. In fact, more than 22 million Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. According to Investor's Business Daily, 43 percent of web surfers access health care data online each year. Conducting research regarding

their health concerns is the sixth most common reason that people use the Internet, and according to the market research firm, Cyber Dialogue Inc., this number is growing by 70 percent a year.

The increasing recognition of the Internet as a legitimate and important vehicle for drug sales is evidenced by the recent activity of major drugstore companies and Internet retailers in financing, supporting, and sponsoring online pharmaceutical outlets. Last year, for example, CVS Corporation acquired the online pharmaceutical retailer Soma.com and merged the online retail sites of the two companies. We expect this expansion of the online drug sales industry to continue.

Prescription drug sales on the Internet can provide tremendous benefits to consumers. These benefits are many and include: access to drugs for the disabled or otherwise home-bound, for whom a trip to the pharmacy can be difficult; the convenience of shopping 24 hours a day; an almost unlimited number of products for customers; and privacy for those who don't want to discuss their medical condition in a public place. Hyperlinks and search programs provide online customers with written product information and references to other sources of information much more easily than the traditional storefront. Finally, as the use of computer technology to transmit

prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales will be important for some customers, it must be noted that the traditional "brick and mortar" pharmacy offers benefits or services that are often not available through the Internet, such as immediate access to prescription drugs needed for immediate treatment. These pharmacies will undoubtedly remain an essential component in the delivery of effective health care.

The challenge for government at both the state and federal level is to pursue policies that will allow legitimate electronic commerce to flourish but provide that safety is assured. Consumers will have confidence in the quality of the medical prescription and in the medicine delivered because the protection for online consumers is equivalent to the safeguards of the traditional local pharmacy and the practice of medicine and pharmacy.

Concerns About Online Sales

As beneficial as this new technology can be, the Internet also creates a new marketplace for activity that is already illegal, such as the sale of unapproved new drugs, prescription drugs dispensed without a valid prescription, and products marketed with fraudulent health claims. As FDA considers the issues related to online drug sales, we recognize that there are various types of these Web sites. Many sites focus on selling prescription drugs and have been referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. While the sales sites of legitimate, properly licensed pharmacies provide benefits to consumers, those that are unlicensed or otherwise engaged in the illegal dispensing of prescription drugs pose a serious threat to the health and safety of American citizens. Other drug sales sites do not sell prescription drugs, but may offer for sale unapproved drug products, products making fraudulent health claims, or drugs for recreational use. Examples of these sites are those that sell products containing gamma hydroxy butyrate (GHB), an unapproved drug used recreationally, for body building and for incapacitating the victims of sexual assaults, or sites that offer unproven cancer therapies. It should be noted that with regard to GHB, Congress recently passed legislation which the President signed in February to place GHB in Schedule 1 of the Controlled Substances Act. While the increase in "Internet pharmacy" sites engaged in illegal sales is seen by some as a particularly potent threat, FDA considers the non-pharmacy sites to be just as harmful, or in some cases more so, and we have moved aggressively against them.

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new Web sites or removing old ones, pose new challenges for the enforcement of existing laws. FDA has found that most drug sales websites are actually made up of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates particular problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies need to work closely with foreign governments to share information and to develop mechanisms for cooperative law enforcement.

FDA Authority

The establishment of FDA as it exists today grew out of a time early in the century when consumers were victimized by dishonest purveyors of fraudulent potions and compounds that were ineffective, dangerous, or both. A system of drug regulation was established in the United States that has served us well. Under this system, FDA reviews new drugs to assess their safety and efficacy. In addition, certain types of drugs must be prescribed and dispensed by only licensed health care professionals. The prescribing requirement is based on the principle that certain drugs have risks of such significance associated with them that they should be administered only under the supervision and recommendation of a "learned intermediary" - that is, a licensed practitioner with the education and training necessary to oversee the administration of potentially harmful drug products. Similarly, these products may only be dispensed by a licensed professional that can help to assure proper dosing and administration, and can provide important information on the drug's use to patients. These requirements are crucial components of the risk management system for drugs in the United States. The types of unlawful conduct involving online drug sales that FDA has identified are similar to unlawful activities that occur in other sales contexts. Under the Federal Food, Drug, and Cosmetic Act, FDA has the legal authority to take action against:

- the importation, sale, or distribution of an adulterated or misbranded drug;
- the importation, sale, or distribution of an unapproved new drug;
- illegal promotion of a drug;
- the sale or dispensing of a prescription drug without a valid prescription; and,
- counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice, must establish the same elements of a case, develop the same charges, and take the same actions as it would if another medium, such as a storefront or a magazine, had been used. FDA has investigated and referred cases for criminal prosecution and initiated civil enforcement actions against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency. As will be described later, FDA has significantly expanded its enforcement activities during this past year with regard to online drug sales.

State Regulation of Practice of Medicine, Pharmacy and Dispensing of Drugs

Similarly, the States have enacted laws regulating the practice of pharmacy and the practice of medicine in order to protect patients from harm resulting from the use of unsafe drugs, counterfeit drugs, and the improper practice of medicine and pharmacy. Under many of these laws, to receive a prescription drug for the first time, a patient generally must be physically

examined by a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state practice standards.

Use of the Internet to Bypass the Regulatory System

Even with these federal and state systems in place, there are those who try to circumvent established safeguards, and the Internet provides them with new opportunities for doing so. It is fair to say that the speed and ease of ordering products on the Internet that attracts consumers can likewise entice unscrupulous sellers to use the Internet as their new medium of choice. Individuals not licensed to sell prescription drugs can easily create Web sites that appear to represent legitimate pharmacies. The fact that operators can easily change the location and appearance of their Internet sites makes enforcement all the more difficult. Unlike other forms of electronic commerce, the unauthorized sale of prescription and unapproved drugs poses a potential threat to the health and safety of consumers.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life-threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or contaminated drugs, as well as the possible ill effects of impure or unknown ingredients found in drugs manufactured under substandard conditions. Further risk to patients is posed by their inability to know what they are really getting when they buy some of these drugs. Although some patients may be purchasing genuine product, some may unknowingly be buying counterfeit copies that contain inert ingredients, outdated legitimate drugs that have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent versions that were improperly manufactured. Moreover, consumers who are desperate for a cure to a serious medical problem may be more susceptible to purchasing an unapproved product.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, health care practitioners who offer a prescription for a patient they have never seen before, based solely on an online questionnaire, generally do not meet the appropriate medical standard of care. Additionally, the use of such questionnaires may jeopardize the availability of legal protections for privacy of medical records.

The Agency is equally concerned that in some Internet transactions, there is an apparent absence of any health professional/patient relationship. This is a particular concern where the prescription involves a first-time use by a patient or where the patient may be taking other medications. FDA believes that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient is essentially practicing self-diagnosis. Consequently, the risk of negative outcomes such as harmful

drug interactions, contraindications, allergic reactions or improper dosing is greatly magnified.

Jurisdictional Issues

Internet technology can obscure the source of the product as well provide some degree of anonymity to persons responsible for making and shipping the product. The participants in a transaction can be widely dispersed geographically (in different States or countries) and they may never meet. If one or more participants in the transaction are located outside of the United States, the task of regulating the activity is further complicated.

The sale of drugs to U.S. residents via foreign Web sites is an extremely challenging area. Some medications sold on the Internet may be legal in foreign countries but not approved for use in the United States, and some products may include addictive and dangerous substances. Products not approved for sale in the United States often do not conform to the good manufacturing practice and quality assurance procedures required by U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the United States. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries.

FDA efforts are mostly limited to requesting the foreign government to take action against the seller of the product, or asking the Customs Service to stop the imported drug at a U.S. port-of-entry.

Other governments are also struggling with how to address the problem of illegal drug sales over the Internet. For instance, pharmaceutical industry officials in Italy are recommending that the issue be addressed by the European Community as a whole.

Last month, the New Zealand Health Ministry began to look at options to prevent pharmaceuticals from being dispensed from New Zealand to overseas consumers without a prescription, after a court decision revealed a loophole that prevents regulators from preventing the practice.

FDA's Internet Drug Sales Action Plan

In July 1999, FDA adopted, and has since been implementing, an Internet Drug Sales Action Plan to expand and improve the activities of the Agency in addressing the unlawful sale of drugs over the Internet. This plan is based on internal deliberations, meetings with federal and state regulatory and law enforcement bodies, as well as organizations representing consumers, health care practitioners, and the pharmaceutical and pharmacy industries. Details of the action plan's elements and FDA's activities in implementing them are as follows.

Engage in Public Outreach

Consumers buy drugs on the Internet for different reasons, and some may be targets of unscrupulous business practices, such as the selling of unsafe, unapproved, expired, counterfeit, or otherwise illegal drugs. Public outreach offers one mechanism by which the Agency can help protect consumers from dangerous or inappropriate drugs. In the year 2000, FDA has launched a new media campaign about safe ways to purchase pharmaceutical products over the Internet. The campaign

includes placing advertisements on health related Web sites; taping public service announcements for distribution to television stations nationwide; and developing a "safety checklist" to be posted online and distributed through health care providers and consumer advocacy organizations.

Engage in Professional Outreach and Partnering

The National Association of Boards of Pharmacy (NABP) has implemented a new program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verified Internet Pharmacy Practice Sites, or VIPPS, provides a NABP "seal of approval" to sites meeting state licensure requirements and NABP's standards. Over time, this seal of approval may help to assure consumers that the designated sites are offering FDA approved pharmaceuticals. The VIPPS program is voluntary.

Cooperate Internationally

Because FDA and the other federal agencies possess limited investigatory jurisdiction over sellers in foreign countries, they must work with foreign governments to bring action against such individuals. Internet crime and the practice of online pharmacy are a growing concern throughout the international law enforcement community. FDA's Office of Criminal Investigations (OCI) maintains ongoing liaison with numerous government agencies in Canada, the United Kingdom, Spain, Germany, Belgium, the Netherlands, Ireland, Brazil, Singapore, and others.

An example of this cooperation involved OCI contact with authorities in a Pacific Rim country where a Web site operator alleged that he used the services of two legitimate doctors to review his online questionnaire. Through our foreign counterparts, we were able to have the doctors interviewed. Both denied any involvement in the scheme, thus exposing the operator to possible mail and wire fraud or other charges.

In another case, OCI made an undercover purchase of drugs from a site operating out of a European country. The site made no pretense of a medical review. OCI was looking for a domestic connection for charges in the United States. While none was found, our contacts with the health authorities in that country resulted in their initiation of a criminal investigation.

Finally, OCI is involved in two cases with U.S. Customs Service overseas offices regarding foreign Web sites selling prescription and controlled pharmaceuticals. Enforcement activity by Customs resulted in numerous arrests and the seizure of over 1.5 million pills and several computers.

Customize and Expand Enforcement Activity

FDA's emerging role in regulating online drug sales is consistent with its traditional regulatory role. Existing approaches to enforcement, including close cooperation with state agencies, are being adapted to focus more effectively on the problems posed by online drug sales. An effective Internet enforcement process requires establishing priorities, identifying and monitoring potentially violative Web sites, and making appropriate referrals for criminal prosecution and/or civil enforcement actions. FDA is enhancing its enforcement efforts by - amongst others - undertaking the following actions.

Establishing Priorities

FDA has initially focused its online drug sales-related enforcement activities to the following areas, particularly where there is a significant public health risk:

- Unapproved new drugs,
- Health fraud, and
- Prescription drugs sold without a valid prescription.

Improving Data Acquisition

FDA has increased its capability to monitor the Internet and identify potentially violative sites through the use of various search tools and by upgrading its data handling capabilities. This is helping the Agency to better understand the kind and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal Internet behavior.

In an attempt to better comprehend the universe of Web sites selling drugs, the Office of Criminal Investigations reviewed thousands of Web sites early this year and identified approximately 326 Web sites involved in the sale of drug products. This review was based on a search of Web sites performed by Internet search software, which was followed by a manual review of sites that appeared to involve the sale of drug products. Because new Web sites are put up everyday and old ones are taken down, the total number of these sites is subject to change and will not be consistent over time. Additionally, because OCI's technology and methodology probably differs from that used in studies by other organizations, the results of this study are not directly comparable to other studies.

Coordinating Case Assessment

In June 1999, FDA established a case assessment, or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of the Chief Counsel (OCC), and the Office of Policy. Under the triage process, FDA obtains leads on potentially violative sites from internal Internet monitoring activity, state, other federal or foreign law enforcement agencies, consumers, Congress, and the press. The triage team evaluates the leads and decides whether they should initially be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, prescription drugs sold without a valid prescription, and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, to FDA's civil and criminal enforcement units for follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process better ensures that decisions are made in a timely way, with an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated and will ensure that they are brought to appropriate

completion. In addition, the scope of this group is being broadened to include all FDA-regulated products.

Results to Date

Using information generated by Internet searches, as well as leads from all parts of the Agency, other state and federal law enforcement units, and the public, FDA has performed at least cursory reviews of thousands of Web sites related to drug sales. FDA has evaluated for possible regulatory or criminal action well over 400 sites and has taken enforcement action on many of those sites, as follows.

Civil or regulatory enforcement actions are pursued by ORA and CDER's Office of Compliance in cooperation with OCC. Currently, ORA and the Office of Compliance have at least 40 sites under active review for possible regulatory or civil action. Regulatory action has been taken on 49 sites as follows. Twenty-three warning letters have been sent by the Office of Compliance to domestic online sellers. A warning letter is a written communication from FDA notifying an individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the FD&C Act, or other relevant statutes, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future repeat of the violation may result in administrative and/or regulatory enforcement action without further notice.

Additionally, the Office of Compliance has sent 13 "cyber letters" to operators of foreign-based Internet sites offering to sell online prescription drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters, which are sent over the Internet to the suspect Web sites, warn these operators that they may be engaged in illegal activities, and informs them of the laws that govern prescription drug sales in the United States. Hard copies of each "cyber" letter are sent to the Web site operator, the U.S. Customs Service, and to regulatory officials in the country in which the operator is based. FDA already has received two responses from "cyber" letter recipients indicating that they will cease illegal activities. A third recipient has stated that it has ceased activities regarding Viagra, but it is still evaluating how it will handle other products.

Other civil and regulatory actions include the following. In cooperation with the Department of Justice (DOJ), an injunction has been imposed on the sale of a product marketed as a weight-loss aid that contains a potent thyroid hormone, which could cause heart attacks or strokes. FDA and DOJ are pursuing injunctions against the sale of other unapproved new drugs over the Internet, and unapproved cancer therapies. Additionally, eight product seizures, six product recalls, and the voluntary destruction of seven violative products have been achieved, generally pertaining to unapproved new drug products including gamma hydroxy butyrate (GHB), gamma butyrolactone (GBL), Triax, 1,4 butanediol, and laetrile. Fourteen import alerts have been issued targeting products offered by foreign online drug sellers.

The Office of Criminal Investigations, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The information collected by OCI headquarters is analyzed by the Investigative Analysis Branch. After the suspect sites are researched they are sent to the OCI field offices for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and looks at the relationship between the patient and doctor, and the doctor and pharmacy. OCI has ongoing cooperative relationships with the USCS, DEA, FBI, the Postal Inspection Service, and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

Currently, OCI has 134 Internet related investigations, including 88 open criminal investigations and 46 preliminary investigations. Of these 134 investigations, 54 cases are investigations of sites selling prescription drugs, while 80 cases are related to various types of health fraud, or unapproved drug products such as GHB or other illegal drug sales. Thirty-six arrests and 17 convictions have resulted from OCI investigations involving products being sold over the Internet.

Legislative Proposal

The Administration is currently completing the development of legislation to implement its Internet drug sales initiative. The underlying basis for the proposal is that online pharmacies should be licensed and operated under the same regulatory system that Congress and the States have put in place for traditional "brick and mortar" pharmacies. A key element of the initiative, therefore, is a requirement that online pharmacies post information on their Web sites about their ownership, state licensure, name of the pharmacist in charge, and a phone number where consumers can contact the pharmacist. This information mirrors what is available to the consumer at the corner pharmacy, where the license is on display and the pharmacist is available for consultation. Online pharmacies operating without the licensure required by States would be subject to both state and federal penalties.

Under this proposal, the traditional role of the States in regulating the practice of medicine and pharmacy would be maintained. It should be noted that the plan would establish only minimal new federal requirements that would not appreciably impact the day-to-day operations of legitimate pharmacies doing business online.

FDA is continuing to work with the Administration on putting this initiative into legislative language, and we look forward to working with you when legislation is forwarded to Congress.

Conclusions

Online shopping for pharmaceutical products clearly provides certain benefits for consumers, but it also has a number of significant risks. Additionally, the nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with the challenges posed by online drug sales and with our need to carefully balance consumer access to information and products with protecting

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the public health. We are adapting our compliance and enforcement techniques to the new electronic marketplace and we will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate. We want to ensure, as much as possible, that the protections afforded to consumers who purchase drugs from their corner drugstore are extended to consumers in the electronic marketplace.

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<u>Viewpoint</u>

Information Technologies, Health, and Globalization: Anyone Excluded?

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Abstract

Modern information technologies and worldwide communication through the Internet promise both universal access to information and the globalization of the medico-social network's modes of communication between doctors, laboratories, patients, and other players. The authors, specialists in public health and members of an association that aims to create opportunities for access to training in public health in developing countries, warn that the use of the term "globalization" ignores the reality of the "digital divide," that is, the fact that social inequalities may preclude the realization of this promise on a truly global scale.

Information Technology, Globalization, and Social and Geographic Inequality

Two initial observations come to mind upon noting the facility with which the term "globalization" is applied to virtually everything: Enormous socio-economic differences exist, and it is known that the Internet network is mainly spreading in countries with a high gross domestic product and an open and competitive market in telecommunications. These distinctions are ignored when the term "globalization" is used.

Disease, risk behaviors (addiction to smoking, diet, sedentary life), and access to care are all correlated with socio-economic indicators such as family income, household composition, and parents' level of education [1,2]. It is a fact that we are not equal when it comes to prevalence of disease. Policy-makers and politicians working in the health field should set up adequate strategies in favor of populations at risk. The answer to inequality is "positive discrimination," that is, the answer lies in giving more means where needs are greater and, by doing so, decreasing iniquities in health. It seems that the development of information technology and improvements in health may create new needs. By answering to the exclusive demands of populations that can enter the market, these developments may increase inequality as well as reinforce the digital divide between industrialized countries and the developing world [3].

Let us take an example. According to the results of a national study on health among Belgians, single women with one or more children are one of the most vulnerable target groups. It seems unlikely that this group would have easy access to the Internet and all the new technologies linked with improving health. Moreover, it would be interesting to study the possible correlation between real access to and acceptability of such high technology tools on the one hand, and socio-economic factors on the other, especially in well-defined target groups. Differences in income and educational levels are the leading factors contributing to the divide in the United States [4]. The same approach could be used in relation to the development of technological devices aimed at improving patient home care.

Thus, the erroneous use of the term "globalization" in the context of information technology must be seen at the country and regional levels, but also at the supranational level. An example would be how difficult it is for associations and companies in the Southern Hemisphere to obtain commercial sponsoring for quality online services such as medical databases. Clearly, it wouldn't be opportune for sponsors to fund the development of high technology tools in an environment where the number of consumers with purchasing power is insufficient.

At this stage, one may question the usefulness of developing information technology in countries with a weak computer network. For example, there are currently more Internet users in New York City than on the entire African continent [5,6]. This question also applies to areas where there is sufficient accessibility for developing information technology for individual health and for the community (in order to differentiate the essential from the accessory in benefit). However, this

question is even more pertinent for developing countries when resources are limited.

Information Technology and the Need for Contextual Analysis

When one takes into account the actual benefits of efficacy and efficiency obtained through introducing information technology in increasingly global health strategies, it is necessary to recognize that the role of information technology is directly dependent on the context (the country and the health system).

Information Technology and the Health Information System

In countries with a high gross domestic product, improving the health information system through an Internet network means mainly improving exchanges between doctors and patients in the field of individual medicine. In Central and Western Africa, this type of tool could be aimed at increasing the efficiency of health systems in terms of statistical and epidemiological data collection as well as the ongoing establishment of indicators for running the different levels in the health system. Direct feedback at a decentralized level, such as at the level of the health district, is also a good tool for supervision and continuous evaluation. In these countries, the aim is mainly the improvement of strategies at the organizational and community levels.

Information Technology and Training

Another important field of use for multimedia tools is education and training. Indeed, there is a tendency to believe that use of the Internet necessarily means opportunities for long-distance learning (lectures and distance training); at-home, ongoing training; use of databases for clinical decision-making; and so on. But in countries where accessibility to the Internet or even to a computer is poor, it might not seem appropriate to propose training methods using information technology. However, to take this stance would mean that these tools would only be used as a mode of communication and information between individuals, with their great pedagogical potential forgotten.

The use of new technologies is an important approach to teaching and learning [5] and, eventually, to quality training in countries where accessibility to such training is difficult.

The local context must be taken into account, and the development of this kind of tool at the central and regional levels as well as in training schools and universities must be promoted. It is mainly in these schools and institutions that computers are accessible and resources for computer maintenance are available. It is in these establishments, as well, that the training of trainers is most adequate and integrated into the national educational system. At this level, pilot projects can be undertaken and followed up in order to decentralize training and knowledge tools such as CD-ROMs. This mode of learning also gives students the opportunity to appropriate computer techniques included in the training.

In addition to the pedagogical benefits, the development of training projects with local schools reinforces their programs and their expertise and allows for the exchange of experiences and know-how between the Southern and the Northern Hemispheres. In the African context, for instance, the interest in using multimedia for training purposes lies more in the interactive potential and reinforcement of pedagogical means than in the setting up of a network. Of course, this use of information technology does not exclude, for instance, the development of Intranets or the Internet for telemedicine projects [6].

Conclusions

It is important and strategically necessary both to be aware of the erroneous "globalization" concept and to recognize the numerous possibilities offered by information technology and multimedia in relation to their different contexts. It is even more important to realize that, in areas where there is no real market for the economy, it is still necessary and possible to apply information technology according to the needs of people and to utilize multimedia with well-defined objectives, for instance in community health and training.

Conflicts of Interest

None declared.

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Viewpoint

Internet Medical Usage in Japan: Current Situation and Issues

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Abstract

Internet use by physicians and patients has become very popular in Japan. Fifty percent of physicians use the Internet to search for medical and other information. Over the past year, 22% of patients used the Internet to obtain medical information. Because there are no restrictions within Japan on using Web sites to advertise medical treatment, information can be freely sent out, and over the past two or three years this practice has increased dramatically. Internet medical information provides information about illnesses and medications, and it helps improve the quality of life of patients and families. Yet, depending on the content of the information provided and the way this information is used, there is a potential negative side as well. On principle, users are responsible for the way information is used, but there is a need for information providers to consider users' safety and to make the information effective for use. Because there is no absolute standard for evaluating the value of medical information, it is necessary to establish a system that opens a dialogue with society and that continuously accumulates high-quality information through the collection of various evaluations, rather than rely on an established authority. For industries and organizations related to commercial pursuits, in particular, it is most effective to establish their own codes for ethical conduct, rather than rely on governmental regulations. At the same time, it is important to have a confirmation function to evaluate how goals set by the outside are being implemented. Aiming at establishing a framework for the Internet medical usage, the Japan Internet Medical Association (JIMA) was founded in 1998 by medical professionals, lawyers, researchers, consumer representatives, patients and their families. We propose a system that would combine feedback from users, who would take on the role of evaluators of the implementation of an ethical code, with a displayed mark that verifies the identity of the Web site. Objective evaluation of information is needed to ensure that users have the power to make choices. Medical experts or patient and family groups would assist in this task. The development of medical care will be promoted through patients and physicians' working together in the accumulation of shared resources for good medical care information.

Introduction

As the population with Internet access increases in Japan, there is a notable trend toward the use of this new information communication medium in the fields of medicine and welfare. The words "e-commerce" and "e-business" may be taken as indications of a new human economic activity based on the latest information technology medium. "E-health" is now a commonly used word in Europe and America, but in Japan it still does not have a very familiar ring. One of the special features of the medical care environment in Japan is the health insurance system, which ensures that all citizens can receive basically equal medical treatment. Under this system, the medical care needs of a broad population are served by institutions that provide medical treatment, from regional medical clinics that provide primary care to highly specialized hospitals that provide comprehensive care. In the near future, however, there will be changes in the way people think about medical care for the nation's citizens.

Examples include litigation actions brought on by the treatment of AIDS and problems of recently increasing medical malpractice. In response to such incidents, patients and the

population in general are looking at medical care with a critical eye. Another example is the increased use of the term "informed consent," which represents the emphasis placed on patients' rights and trends in the release of information, as seen in the trend toward disclosing of patient charts. These changes have just begun, but in the future, as patients become aware of their rights, it is expected that these trends will become stronger. Another societal factor is the rapid aging of the population. The increase of the older population will increase the nation's financial burden of medical expenses. As a result, the foundations of the insurance system, which has provided low-cost medical care to citizens, will be increasingly threatened.

The Current Situation and Issues

Background

With these changes in the social environment taking place, medical policy is needed that both contains the nation's medical expenses and provides high-quality, high-efficiency healthcare. Efforts should be made to prevent illnesses so that people can live long, healthy lives, and efforts should be made to increase the quality of life through the appropriate control of illness. In the past, under the national insurance system, one could obtain medical treatment, with no great disparity in the quality of treatment, regardless of location. Patients would generally accept the provided treatment passively, without asserting themselves. Now, however, this passive attitude is changing as issues of protecting independence in medical care are being raised. Patients increasingly want to make their own decisions about methods of therapy and care.

One significant factor driving this change is the increased convenience of accessing medical treatment information through the Internet. In other words, as the Internet increases the demand for information about medical treatment and health that is needed by patients and families [1], the medical institutions and other providers supplying such information will provide an environment in which it is easier to send information, thereby accelerating the flow of released information [2].

Access to the Internet in Japan

According to a study supported by a research grant of Japan's Ministry of Health and Welfare, as of January 2000, 34% of 1021 medical institutions were providing some form of information about their work or the medical treatment they provide through a Web site [3] (see appendix for the full study). In addition, 50% of physicians were using the Internet. Of the physicians using the Internet, 65% were "searching for medical/treatment information," and 56% were "corresponding." Furthermore, with regard to making information about the physician's medical institution accessible, physicians were in favor of making basic information about hospitals and clinics available, 87% agreed to having physicians' names made available, and 80% or more thought information about physicians themselves, such as field of specialization, medical society certification, and university, should be made public.

As for what benefits for patients could be expected from the release of information about medical care institutions, 78% thought that it would be "useful to patients for the selection of medical care institutions," and 70% thought that it would make "going to medical care institutions easier." With regard to how the accessibility of information about their own illness would change the relationship between physicians and patients, 62% thought it would "bring into being the right of patients to make their own decisions." Finally, 59% thought that "as the amount of information that can be shared increases, relationships of trust will further increase." From these numbers, we see that medical care institutions and physicians will look favorably on future trends toward the release of general information.

Internet Use in Japan

What about the thinking of those who use medical information provided by medical care institutions and physicians? According to a study conducted in February 2000 supported by a grant of the Ministry of Health and Welfare (joint researcher, Sapporo Medical University professor, Haruyuki Tatsumi), the Japan Internet Medical Association (JIMA) found that, of the 1842 persons who were using the 29 institutions and were the object of the study, the proportion of patients/families using the medical institutions that were using the Internet was 645, or 35% [3]. At present, 13% of the Japanese population uses the Internet (Nielson NetRatings, December 1999). Compared to this figure, both patients and physicians have higher than average rates of Internet use.

As for use of Internet medical information by patients/families, 405 persons used medical information over the previous year. This figure was 63% of the Internet users and 22% of the total respondents. In their use of the Internet, 41% "obtained specialized information about an illness," 30% "obtained information about health control such as preventing illness," and 27% "obtained information about medications." With regard to future use of medical information, 67% said they would "like to obtain more specialized information concerning illness and health control," and 60% said they would "like to obtain more specialized information about effectiveness and side effects of medications." From these figures, we have concluded that patients and families have a strong desire to obtain specialized information about illnesses and medications.

Additionally, with regard to obtaining information about medical institutions, the items of interest relating to medical institutions that concerned the content of medical treatment and systems for providing such treatment were "information about examinations, diagnosis, and therapy." For these items, interest was high at 65%. Interest for an item relating to patient care, "explanation of an illness to the patient and family," was high at 75%. And, with regard to information about physicians, 71% wanted information about "particular fields of specialization" released.

From the perspective of a country such as the United States, where information about medical institutions and physicians was released early on, the meaning of such data may be hard to understand. According to the provisions of Japanese law (Medical Law No. 69), when medical institutions provide information about the content of treatment administered and their work to an unspecified, large number of people, it is considered advertising, and restrictions have been established

for what information can be released. Medical law is currently being reexamined for the relaxation of advertising restrictions, but many restrictions will probably remain. The Internet, however, is exempt from these restrictions. Information provided through a Web site is not considered advertising and is allowed. This circumstance is one reason for the rapid establishment of Web sites by medical institutions over the last two or three years [4].

In this way, the increase in medical information provided over the Internet is a favorable development for patients and the population in general: it allows them to obtain information about their own health or illness, deepen their knowledge, and independently manage their own illness or health. By increasing the sources of information, and broadening the range of choices, it will be possible to find the most appropriate therapy or care [5]. In a questionnaire study conducted by JIMA in March 1999, of 502 persons among patients/families and citizens who use the Internet to obtain medical information, 83% said that medical information provided over the Internet was useful in improving daily life. There were various forms of use, such as homepage browsing, bulletin boards (electronic meeting rooms), mailing lists, and e-mail medical consultation. Of these respondents, 37% said that, as a result of using this information, they were "able to have a good understanding of medical treatment they were presently receiving," and 11% said that they were "prompted to go to the medical institution." Thus, the trend was one of positive evaluation.

Quality of Health Information

With regard to opinions about the quality of the medical information provided, 68% said that the content of the information "was reliable," and a combined total of 32% said that it "was unreliable" or that they were "undecided." Reasons given for the unreliability of the information were that "there was no one to guarantee the information's reliability," "the content is for advertising," "sometimes it is not clear who is issuing it," "the information is slanted," and so on. When asked whether or not using medical information in the past had actually led to problems or trouble, 6% said that it had. Concrete examples included "advertising mail about related products were continually sent" and "the actual treatment by the physician was different from my expectations."

Although no serious example has been set up to now, there is concern about the use of medical information. Fifty-seven percent said that "the use of bad information or the misuse of information could endanger the user," 45% said that "the issuance of information being used for commercialism or for profit-making competition was a concern," 43% said that "it was hard to question the issuer's responsibility with regard to the content of information," and 24% said that "when the patients have too much information, many will actually have more trouble making decisions."

Perhaps because of these concerns, in response to an item on the current state of rapid developments in the use of Internet medicine, 42% believed that "some form of regulation is needed to ensure the safety of users," and 22% believed that "no regulation beyond current law is needed if users thoroughly follow the principle of accepting personal responsibility." From

these results it can be seen that users of Internet medical information have a strong desire for specialized medical information pertaining to illnesses and health, but that the level of trust regarding the content of various information is not always high and that users have various concerns about the use of information.

With regard to the quality of Internet medical and health information, problems have appeared in Europe and America [6,7], and the same is true for Japan. Such information is issued either by individuals or organizations, for profit or not for profit, and from various standpoints and for various objectives. The control of quality is in various hands, and the level of control also varies. Information on medical treatment and health may affect the lives of people, and there is a need for high quality, yet there is no system in place for objectively evaluating it and providing users with helpful information. With the lack of such a system in place, a Web site was established in Japan that sent a hydrocyanic acid chemical compound over the Internet to a person who wanted to commit suicide, and in December 1998, an unfortunate incident occurred in which a young woman who used this substance died. Reacting to reports of such incidents, the general public has come to adopt a critical view.

To what extent can information from the Internet be trusted? With regard to this question, in the study mentioned above [3], JIMA selected 516 Web sites from the medical institute directory of the medical page of "YAHOO!JAPAN," a large search site, drawing from five categories: internal medicine, pediatrics, dermatology, behavioral health, and neurological surgery. Numerous specialist physicians from each discipline conducted evaluations of the medical information being provided. Judging the content of information provided, these physicians found that 7% of the sites "have problems." The reasons given included "there is a concern that ordinary people will use bad information," "information with inadequate verification is included," "it diverges from current standard medicine," "the content is slanted," and "there are errors in the article items." The category that was found to have the most problems was dermatology, and the one with the fewest problems was internal medicine. Whether 7% is considered to be many or few, the reality is that if a specialist in the same field finds problems in a medical institution's Web site, which ought to be reliable, it is due reason for exercising caution.

Ethical Codes

As medicine progresses, the techniques and content of medical treatment change. And as information concerning medical treatment and health becomes more diversified, the volume of information provided via diverse media increases dramatically. Although these changes greatly benefit the user, the information becomes more diverse and voluminous; hence, it becomes difficult for the user to correctly understand the content and confirm authenticity [6,8]. To enable users to reap an even greater benefit from the accessibility and use of information from the Internet, a societal arrangement is needed to properly conduct the flow and use of information [7,9]. In the development of e-health, which first arrived in Europe and America, a code of ethics was created to define standards for conduct. This code of conduct is based on self-regulation by

the companies and organizations that provide information and services, and it was developed so that users could safely use information. The e-Health Code of Ethics, Health on the Net Foundation (HON), Hi-Ethics, Health Insurance Portability and Accountability Act (HIPAA) were all created as the Internet was developing. In addition, the American Medical Association has adopted the "Guidelines for Medical and Health Information Sites on the Internet."

By observing such self-imposed ethics codes, and not relying on legal regulations, the role played by this system, which guarantees the independent conduct of these parties, is surely very great. However, these ethical norms do not govern independent entities. In each of the various areas efficiency can be heightened by mutually achieving the defined norms, and a course can be set to finally ensure benefit to users.

With the aim of creating an environment for the safe and effective use of the Internet in the medical field, medical specialists, attorneys, and patient representatives in Japan assembled in 1998 to form a nonprofit citizen's organization, the Japan Internet Medical Association (JIMA) [10]. JIMA first proposed the "Information Source Guideline," which set down the following three items as minimal conditions for information providers: (1) The party providing information is to be identified. (2) A contact method for questions, such as telephone or e-mail, is to be provided. (3) Notice is to be given that the user takes personal responsibility for his or her use of the information, with the premise that the information provided is not always correct or valid.

These conditions were intended to promote the provision of the basic information minimally necessary for users and to recommend prudent use of medical information. Members who agreed to conform to this guideline and provide information would be issued an emblem and would be entitled to display the emblem on their Web site. Even though information providers must take these three basic requirements into consideration whether or not they are members, the above-mentioned study found that, of the 1147 medical-related Web sites in the directory of "YAHOO!JAPAN," 13% gave no phone number, and 24% gave no e-mail address [3].

It was expected that the ethical norms which information providers must observe would be added to the above-mentioned "Information Source Guideline" and that principles of conduct for information sources in the medical and health fields would eventually be compiled. The content would include privacy protection, preservation of dignity, responsible issuance of

information, notice of the principle that users take personal responsibility for use of information, and some way of addressing problems. However, new problems were foreseen in areas where such provisions could not be applied, and it would have been difficult to adopt an all-inclusive ethical standard. The e-Health Code of Ethics [11] was similar to ethical standards being considered by JIMA, and the spirit of the code was in agreement with JIMA's basic ideas. Even if there were differences in language, law, and social environment, the problems encountered in the medical use of a worldwide information network were broadly common, and problems in the same arena were shared. Hence, participation in discussions seeking solutions to such issues was considered necessary. In December 2000, JIMA created the Japanese version of the e-Health Code of Ethics [see Appendix or http://www.jima.or.jp/trust/eHealthEthics_jp1.pdf].

This ethical code, which deals with the assured safety and benefit of users when medical and health-related information and services are provided by companies or individuals, is a rational guideline for taking ethical and just actions. It is believed that information and service providers will respect this guideline and, by achieving required conduct goals, will maintain a high-quality standard for activities within e-health. This compliance will, in turn, deliver reliability to users. The important points here are the propriety and reasonableness of goals and, at the same time, the evaluation and monitoring of whether actual conduct is in line with the goals and whether goals are actually being met [12,13].

The JIMA mark (Figure 1) displayed on the Web sites of JIMA members not only indicates the site operators' agreement with JIMA's principles of conduct, it also means that if users are dissatisfied or have opinions about the information or service provided, there is a feedback function to convey complaints or opinions to the administrators of the Web site. Information providers, by constantly receiving evaluations of their work from outside sources through such feedback, will increase the level of users' trust. This process is called the "trust program," and the JIMA mark indicates participation in this program. In the beginning, the real purpose of the JIMA mark was as a tool to increase the effectiveness of the trust program. However, there was concern that, contrary to our aim, the display of the mark would convey a high evaluation of the Web site. We now believe that by presenting the code of ethics and by making the meaning of the trust program clear, the danger inherent in this mistaken interpretation can be reduced.

Figure 1. JIMA Mark

Third-party Certification

As of January 2001, a new JIMA certification function is being added to this mark. Although the identity of the entity that operates the Web site is important information, objectively guaranteeing the actual correctness of that information is difficult. Here, the issue involves ascertaining who is to guarantee the correctness of information. For each server on

which a Web site is placed, an identification is issued, and a third-party certification system is being provided. One requirement is that it be a corporation, and certification is by each server. Even if a single server has multiple Web sites, each one cannot always be certified. There is also the issue of cost. At JIMA, by providing a certification function for the mark, the identity of the party is verified; to prevent misuse of the mark,

certification has been made possible, not at the server level, but for each Web site.

Efforts are being made to ensure observance of this ethical code. When a conflict with this standard is perceived, opinions are graciously accepted and efforts are made toward revision. It is believed that this trust mark systematically supports the trust program. For example, JIMA members mutually conducted evaluations, and, through the presentation of their opinions, improvements were made in content in terms of more appropriate methods of expression. In such experiments, not only are member sites individually improved, but examples can also be found where application is possible for the improvement of general medical-related sites on the Internet.

Security and Confidentiality

At present, problems of security and personal information have been the biggest issue when individuals obtain medical or health-related services from the Internet or purchase medications or health-related products. Public concern has increased with the development of e-commerce. In particular, when intangibles such as services or information are provided, personal information is obtained from users (unlike in the case of purchasing physical products). Most likely, too little caution is paid in cases where such information is used. In Japan, concern about the use of personal information is low among company employees and consumers, and it has been pointed out that measures to address this issue have been slow.

Of all the kinds of personal information, it is particularly necessary to make known the importance of protecting information related to highly confidential personal medical treatment. In the questionnaire for patients used by JIMA in the above-mentioned study [3], of 645 respondents who have used the Internet, 72% said that they "believe problems occur when personal medical treatment information leaks." Similarly, to the question, "when personal medical information is transferred over the Internet, what kind of measures do you think are needed to prevent leaks, falsification, or misuse?" 50% said that "information such as names that are specific to an individual are better not sent," 41% said that "the use of personal medical information must be regulated by law," and 34% said that "data or information should be sent encrypted."

When a study was conducted on the disclosure status of proprietor information in the 1147 aforementioned medical-related Web sites, it was found that regardless of whether or not personal information had been obtained from the other party (e.g. in an online medical consultation), none of the sites explicitly stated their policy for handling personal information in the form of a privacy statement [3]. Furthermore, with regard to "measures such as the encryption of information" for the transmission of content relating to personal illness or health in the same medical consultations, it could not be confirmed that any of the Web sites used countermeasures such as encryption. So far, there are not many opportunities for medical-related Web sites to collect personal information, but this fact shows the low level of awareness among the people involved.

A basic law on individual information protection that will establish a comprehensive framework for the protection of personal information is currently being prepared in Japan. Based on this basic law, further individual laws are being studied for each field with respect to transmission, confidence, and medical treatment. In future, with the development of electronic chart proliferation and online access, the categories that will require protection and surveillance in the medical field are expected to expand in scope. Finally, yet another security problem surfaces: As we move from the closed systems of the past to open systems connected to networks, the potential risk of security being breached is increasing. In this area, as well, a multifaceted approach in pace with the progress of technology must be devised.

The "Medical Information Usage Guidebook"

Creating and implementing a self-imposed ethical standard for providers of information and services is like purifying water (the information) that is poured into an ocean (the Internet). After the harmful and valueless information has been removed, one can expect to find something of value. But on the user side, one must be able to distinguish between the contents of information and selectively use useful information for one's own health and benefit [14]. It is necessary for users to develop the habit of critically appraising information at all times through education and mutual learning. At times, a medical expert may be a source of support in this process. At other times, support may be found in patient and family groups [15]. Guidebooks are being provided overseas for the correct and effective use of medical and health information [16], and in December 1999, JIMA created and is now publicizing its own "Medical Information Usage Guidebook." We have compiled 10 recommendations in this guidebook, with points that are easy to understand, regarding the kinds of information a user needs and the way it should be used (see Textbox 1). A user should not believe all information relating to medical treatment or health, but should make a sober comparison and analysis and use the information prudently, under the principle of taking personal responsibility for information use.

Textbox 1. Guideline to the Use of Medical Information on the Internet

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* Developed by the Japan Internet Medical Association.

Use information from sites where the information provider is clearly identified.

If the information provider is not clearly identified, responsibility that accompanies the supply of information becomes ambiguous, and the accuracy of information provided tends to be diminished. In addition, if the information is used, no adequate support can be expected, even if trouble occurs. It is important that the name, address, and contact method for the information provider be clearly provided, and that it is possible to confirm its existence.

Use information that is not-for-profit.

Even if the information is supposed to represent the latest science, there is sometimes a hidden profit motive. There may be product sales or special services behind the information provided. It is very important to look with a discriminating eye for some mechanism through which someone is making profit.

Use information that has an objectively scientific basis.

At first glance, even if information appears to be specialized, it is necessary to exercise caution with information having arbitrary content or questionable information that seems to exceed scientific understanding. One should consider whether related medical papers or articles and test data are properly quoted and whether the information has a proper scientific basis.

Mainly use medical information provided by public medical institutions or official research institutions.

At public medical institutions and official research institutions, such as organizations, responsibility is taken seriously, and information provided is carefully investigated and verified by committees and numerous specialists. As a result, they are sources of information with a high level of objectivity and minimal slant. However, because individual contributions are also included, it is necessary to confirm to what extent information is official. In addition, even the private sector provides information that is known to have been objectively well investigated may be said to have high levels of reliability.

Always use recent information.

Advances are constant and rapid in information related to health and medicine. Even the latest information, if it is not revised, at some point becomes old information, and its use value also changes. One should always check the dates of posted information as well as their revision dates.

Compare and study multiple information sources.

Information on the Internet is issued by people with various positions and various ways of thinking. Even if the theme is the same, viewpoints will differ depending on the information provider's position. Rather than just use one type of specific information, it is important to read and compare different information and to select the information needed for one's own purpose.

Recognize the principle of taking personal responsibility for the use of information.

In using information that is provided to large numbers of unspecified persons, if by chance the user suffers some misfortune, it is difficult to charge the information provider with responsibility. Basically, "information is to be used at one's own risk." Information should be used in a sober and prudent fashion.

When in doubt, consult with a specialist.

Some of the medical information provided in places such as the Internet does not agree with current standard medicine, and some information is ambiguous in its scientific foundations. One might enjoy early access to the latest fruits of medicine, but there is also a danger of mishaps and damage to one's own health. Do not accept all information that is provided. Always consider risks, consult with an attending family physician or medical specialist about any doubts, and obtain appropriate advice.

Make a sober evaluation of the results from using information.

When information is used, the value of its content should be evaluated. In order to assess the information's content and the results of its use, it is necessary to have the composure to make a calm and fair evaluation.

If trouble is encountered, consult a specialist.

If some trouble or damage to health is encountered when such information is actually used, do not remain silent. Consult with a medical specialist, public consultation center, or neutral third party institution. By promptly providing information, the next incident of injury or trouble may be prevented.

Conclusion

In the past, medical treatment was structured like a pyramid, with the physician at the top, the co-medics and paramedics supporting at the periphery, and the patient buried inside, not to be seen. In the future, the patient is expected to move to the center, while the physician (professional) and support members will surround the patient at the periphery, making up a network to jointly support the health of the patient. In the development of the Internet, medical information is not the property of specific individuals; it is, rather, for the common use of all concerned parties. Information related to medical treatment and health affects the quality of life of patients and the therapy provided by physicians to patients.

This may be the era in which decisions encompass the medical treatment and welfare standards for society. According to the "Guidelines for Medical and Health Information Sites on the Internet," access to medical information through use of the Internet can change the relationship between patient and physician, and the process of medical treatment is being changed

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from one of the physician authority ministering advice and treatment to one of shared decision-making between patient and physician [17]. The development of information networks in medical treatment goes beyond the restrictions of time and space, systematically connects various types of information, and spawns new communication between parties with differing vantage points. This development has the potential to change the state of medical treatment, which had become rigid because of various restrictions and lack of communication, and to dramatically heighten the quality of medicine. With respect to information, it is also expected to support patients and families who have been placed in a weak position and to convey power never before enjoyed on the receiving side of medical treatment. The empowerment of patients will, at the same time, be linked to the empowerment of those providing medical care and will result in progress in medicine as a whole. This is the very direction of e-health's development.

Acknowledgments

Conflicts of Interest

None declared

Appendix 1

Note: To read these documents you may need to install Japanese fonts, see [http://www.adobe.com/products/acrobat/acrrasianfontpack.html]

Report "Research on the Analysis of the Current State of the Provision and Use of Health Information Provided Through a New Technology Medium [in Japanese]" [3] as [PDF-file -] [82 kB]

Appendix 2

Japanese translation of the Washington e-health Code of Ethics [11] as [PDF-file -] [34 kB]

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<u>Viewpoint</u>

Electronic Medical Consultation: A New Zealand Perspective

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Abstract

Electronic medical consultation is available worldwide through access to the World Wide Web (WWW). This article outlines a research study on the adoption of electronic medical consultation as a means of health delivery. It focuses on the delivery of healthcare specifically for New Zealanders, by New Zealanders. It is acknowledged that the WWW is a global marketplace and that it is therefore difficult to identify New Zealanders' use of such a global market; nevertheless, we attempt to provide a New Zealand perspective on electronic medical consultation.

Introduction

Electronic medical consultation as a means of health delivery is available worldwide. Although only in its infancy in New Zealand, it is likely to gain momentum and acceptance and will have an impact on both the health deliverer and the consumer. The adoption of electronic consultation could radically change the environment of healthcare. The emergence of new business models and social impacts are just two of the areas where there could be significant change.

As technology is embraced by commercial, health, and other interests, law and governance are left struggling to keep up with the changes. Will the gap between the "haves" and "have-nots" widen or close? Has a beast been unleashed, or are we embarking into a brave new world where anyone can access the health information they need, regardless of socio-economic status, race, or geographic situation? We discuss these questions with an emphasis on the New Zealand scene.

Discussion

Background

Traditionally, patients and health providers have interacted face to face. The arrival of the telephone revolutionized communication, yet it did not significantly alter the way health providers and patients interact. The introduction of the Internet into the public arena throughout the 1990s has paved the way for significant advances in communication and information exchange in the health industry. The facility of e-mail, via the Internet, allows for the quick and efficient transmission of a written message to a targeted receiver. This article predicts profound alterations in the healthcare infrastructure, changes that will provide exciting opportunities at all levels of healthcare, from individual providers to large multinational corporation initiatives.

E-mail consultation offers patients numerous opportunities, including convenience, the ability to access second opinions, and the ability to choose from a wide range of specialists who might otherwise have been inaccessible. Jones suggested that

although there are many concerns about the rise of "Web doctors," the number of them is likely to increase [1].

A study analyzing requests for consultations at a free pediatric e-mail consultation service for parents gave rise to the following conclusions: (1) Parents would rather use e-mail than face a "harassed" doctor for further explanations. (2) Parents were not overly concerned about posting personal details that may not be secure. The authors concluded that e-mail was a legitimate way for patients to receive disease-specific information in a timely manner [2]. In addition, many patients apparently find it difficult to discuss embarrassing or taboo subjects with their doctors. Howe reported that this anonymous, faceless form of consultation can be at once personalized and anonymous [3].

Dr Mulholland, a general practitioner based in Taranaki, New Zealand, operates a commercial e-health service called "doctorglobal," which is reported to be outstandingly successful [4]. This type of enterprise is gaining the attention of professional medical associations, which believe that some standards and protocols should be set [5]. Conversely, commenting on the launch of "doctorglobal," Dr Wiles, chairman of the New Zealand College of General Practitioners, described e-mail consultation as "dangerous nonsense" [4]. However, there are publicly funded initiatives in New Zealand that are taking advantage of the possibilities offered by e-health. These initiatives include the Waikato Tele-dermatology, the Waitemata Tele-psychiatry, the South Island Tele-medicine Project, the Christchurch Tele-medicine Service, and the New Zealand Tele-paediatric Service [6].

In researching this article we found that positions on the future impact and appropriateness of telemedicine seem to be polarized. At one pole are the "tele-evangelists," who believe that telemedicine will lead to a more patient-focused model. At the other pole are the "tele-Luddites," who think that telemedicine introduces technology that complicates an already complex healthcare environment and that will always come second to face-to-face interactions [7].

Social Implications

The arrival of e-commerce has caught the health sector unprepared and without existing conventions. Innovators have adopted electronic medical consultation at a pace that has surpassed the formalization of any frameworks or guidelines. This situation has engendered a developmental environment that is relatively unfettered by any of the standards usually applied to a new form of treatment or service.

It is likely that protocols and guidelines will evolve as emerging trends and patterns become more obvious or pressing. However, because of a significant gap in the literature related to social impacts (particularly empirical work), predictions put forward continue to be speculation. There are several relevant potential social effects of e-health, including issues related to equity, consumerism, and altered relationships.

Equity

Most national health systems should develop equity policies for electronic medical consultation. Although Internet connections are very accessible in New Zealand, computing resources should be made available to the consumer to ensure equity. The profile of the Internet-enabled consumer is significantly skewed to higher socio-economic and better educated segments [8,9]. Therefore, patient-initiated e-mail consultation may have entry barriers. As well as access to resources, the user must have adequate language abilities, literacy, and technical knowledge. These requisites give several groups, such as ethnic minorities, older persons, the poor, and people with literacy problems, a potential equity disadvantage with regard to electronic healthcare options. Some of these may be within. Eysenbach highlighted this point in his discussion of a potential widening gap between privileged "Internet-able" populations and underprivileged populations that will not be able to participate in Internet-distributed healthcare [10]. However, electronic consultation can also offer significant benefits to some groups that are arguably disadvantaged in traditional models of healthcare. Telemedicine supplied to rural areas, for example, could dramatically reduce costs incurred in transfer to specialist care and improve speed of access [10].

Health reforms have resulted in the closure of many regions' hospitals. Consequently, patients may be faced with increasing difficulties in accessing healthcare. Along with this trend, rural New Zealand faces the loss of medical personnel. The Ministry of Health telephone pilot, which serves parts of the East Coast District of the North Island, is a pioneering service that aims to address some of these issues. If successful, it may well pave the way for the formation of services utilizing more sophisticated technology.

Public policy will eventually need to address these issues in the longer term, particularly as public health systems move toward greater use of e-health initiatives. This task may require the eventual supply of resources to selected individuals or groups, such as the provision of community Internet kiosks or centers. Or, as Mulholland has suggested, provision might be made through a contact person, such as a community nurse, who has access to the Internet [4].

Consumerism

Information technology gives patients access to a wealth of knowledge and information [11]. An informed patient can participate more actively in healthcare decisions. This circumstance may, however, lead to a situation in which providers find themselves faced with more aggressive and demanding patients, who require more time and explanation [5,12]. It may be difficult to meet these needs within the usual length of commentary supplied in e-mailed responses. It may also be time-consuming to compile and find additional information to attach as an accompanying file or document.

E-mail consultation services may be designed for patients who have an established relationship with a provider or, alternatively, may be offered as a means of attracting business. Egger suggested that when patients indicated that access to their doctor by e-mail was important to them, then doctors would consider introducing e-mail into their practices [13]. Hence, it is feasible that offering this service could give future competitive advantage to a health practice.

The Internet has opened up new opportunities for financial gain. In the space of only a few years there has been a burgeoning number of both small and large e-health providers responding to the demands of a new wave of consumer-driven healthcare seekers. It is now possible for healthcare suppliers to create revenue regardless of physical location and even to offer niche services on a global basis.

Provider-Patient Relationships

The extent to which consultation over the Internet will change the patient-provider relationship is unclear. Stevens compared the social impact of the Industrial Revolution with that of information technology [14]. Just as the Industrial Revolution ultimately re-ordered traditional relationships, such as how children related to parents or men related to women, the Internet may likewise radically redefine traditional models. It seems likely that the evolution of styles and frameworks will be one response to the many aspects that communication technology brings to the context.

Historically, a patient base comprised those who lived or worked near a health practice. The Internet now provides the healthcare seeker with the opportunity to decide where to get information. This information may be from a provider far from the patient's locality. A patient may even approach a provider from a different country who is considered to be a leading expert within a particular field [15].

The adoption of e-mail consultation is by no means the only factor that will influence how patients and practitioners interact in the future. Other forces that will have an impact on this interaction include the vast array of information available through Web sites; the increasing financial imperatives to contain costs; and the new generations of software and hardware that enable increasingly sophisticated systems of interaction, for example, SendTalk, PowerTalk, and video-streaming through NetMeeting.

When entering into an e-mail consultation with an unknown online provider, patients will need to take on more responsibility for their treatment. Without the usual tangible evidence that bricks and mortar supply, patients will potentially be exposed to more risk and will have to invest extra time and effort into researching questions to ask providers, assessing quality of responses, and coordinating their own healthcare [16]. "Surfing" providers and the use of advice in a piecemeal fashion also pose significant risks to patients. Currently, it seems unlikely that a provider would happily become involved in cases where multiple consultation and treatment trial are being undertaken, but in the future this practice might be normal.

Legal and Ethical Issues

At present there is no special legislation in New Zealand that covers electronic consultation. E-commerce laws are currently being finalized. These laws will be of a general nature and will need to be adapted to cover e-health [17].

The Health Act (1996) and Privacy Act (1993) are deemed to cover this area . The Privacy Act is intended to promote and protect individual privacy in accordance with the Organisation for Economic Co-operation and Development (OECD)

Guidelines (1980). Legislation relevant to the health sector is the Health Information Privacy Code (1994; http://www. privacy.org.nz/comply/hinfopc.html), which contains 12 rules regarding the use and disclosure of health information. The code addresses patient empowerment and informed consent. Four rules relevant to electronic consultation are Rules 3, 5, 10, and 11.

Rule 3 requires that the consumer be fully informed about the fact that personal information is being collected. It seems that adherence to this rule is quite poor. Although no survey has been conducted to ascertain the level of compliance with the Privacy Act by New Zealand-based Web sites, an examination by the US Federal Trade Commission of over 1400 Web sites found that although more than 85% of sites collected personal information from consumers, only 2% provided a comprehensive privacy policy [20]. Privacy Commissioner Bruce Sloan has warned that he is prepared to act on any breach of privacy under this code [21], although he would seem to prefer the introduction of self-regulation [22], despite the US Federal Trade Commission's conclusion that "industry's efforts to encourage voluntary adoption of the most basic fair information practice . . . have fallen far short of what is needed to protect consumers" [20].

Rule 5 deals with security and storage and therefore has particular relevance for electronic information. Some of the areas covered are password protection, screensavers, access control, and secure Intranets. Rules 10 and 11 limit health information use and disclosure. There would be interesting implications if browsing were considered "use" of information. The privacy commissioner has deemed that to constitute "use," data must be retrieved and some action must be taken.

On an international level, several non-profit organizations that aim to ensure ethical use of medical information on the Internet have been established. These organizations include the Internet Healthcare Coalition (http://www.ihc.net/) and the Health On the Net Foundation (http://www.hon.ch/). The former has drafted, via the e-Health Ethics Summit, the International e-Health Code of Ethics, and the latter has elaborated a code of conduct for medical and health Web sites. These codes cover issues of quality, privacy, informed consent, and confidentiality, as well as advertising, editorial policy, sponsorship, and authorship. The vehicle for implementing the code has yet to be decided, although various labeling techniques are under development using both cybermetrics and human ratings systems [23,24] .

Conclusions

The speed of technological development and the eventual public acceptance of it are difficult to wage. In general, development and acceptance are increasing daily. Some people will embrace the advances, others will be hesitant, and still others will disapprove of them. Electronic consultation and e-health are no different in this respect. It seems the global reach of the electronic arm will always ensure a market. What remains variable, for e-health as for healthcare in general, are the issues of quality, accessibility, and confidentiality. In recent years these issues have been addressed in depth by health and legal

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organizations. The results provide a good existing framework on which to build, and it is in this area that the challenges lie for the next decade.

E-health has its own specific and special aspects related to the doctor-patient relationship and confidentiality. Some we are aware of, others we will encounter as we go. This dynamism characterizes the Internet. Control needs to be flexible and manageable; otherwise, it is open to problems.

New Zealand is known for its early acceptance of new technologies, and our research reflects this tendency. "Dr Global" (http://www.doctorglobal.com/) is here-we expect that more will follow. Yet this change does not signal the demise of face-to-face consultations. There is a place for both services. The challenge is to help make it work for the benefit of all.

Conflicts of Interest

None declared.

Appendix 1

URLs Accessed

New Zealand perspectives:

[http://www.doctorglobal.com/]

[http://www.enigma.co.nz/hcro_articles/9810/vol2no12_001.htm]

[http://www.nzhealth.co.nz/nzdoc/archives.html]

[http://www.cnn.com/2000/TECH/computing/04/25/nz.doctor.idg/index.html]

[http://www.xtra.co.nz/homepage/health/main/0,1439,Health%3AAsk+the+Expert%3A,00.html]

Other perspectives:

[http://www.telemedtoday.com/]

[http://www.telehealthmag.com/]

[http://www.yi.com/mednet99/index.htm]

[http://www.askyourdoctoronthenet.com/]

[http://www.healthfile.co.uk/]

[http://www.hon.ch/Conduct.html]

[http://www.mdweb.com/]

[http://www.la-doctor.com/main-directory.htm]

[http://www.marketadoctor.com/index.html]

[http://www.retina-doctor.com/namequery.htm]

[http://207.198.253.192/default.htm]

[http://www.ppdnet.com/content/netdisc/doctorcom.htm]

[http://www.1-800-doctors.com/index.cfm]

[http://www.e-med.co.uk/home.html]

[http://www.dis.port.ac.uk/ndtm/]

[http://www.ihealthcoalition.org/community/join.html]

[http://www.atmeda.org/news/testimony04112000.htm]

[http://www.cyberdialogue.com/resource/press/releases/1999/11-03-cch-ehealth.html]

[http://www.dc.com/deloitte_research/featured/e-health/e-health.pdf]

[http://tie.telemed.org/legal/]

[http://telehealth.net/]

[http://www.doctorgeorge.com/consultation_room/index.htm]

[http://www.doctors.net.uk/]

[http://www.nap.edu/html/networking_health/ch2.html]

[http://intel.com/intel/e-health/whatisehealth.htm]

[http://intel.com/intel/e-health/tips.htm]

[http://intel.com/pressroom/kits/events/9810ihd.htm]

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Original Paper

Internet-based Prescription of Sildenafil: A 2104-Patient Series

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Abstract

Background: The Internet is becoming increasingly important as a way for patients to acquire medical information and as a means for patient-physician communication. Questions about appropriate use of this new technology have been brought to the fore by the many patients using the Internet to seek sildenafil prescriptions.

Objective: To present the first description of a physician designed and directed Internet-based prescribing system of sildenafil, together with data covering more than 2,100 patient encounters.

Methods: Retrospective analysis of a large case series from a medical practice that prescribes sildenafil based on medical and sexual histories obtained through a physician designed and directed World Wide Web (WWW) site, compared against patients from clinics at a Midwestern inner city medical center. We compared all 2,104 Internet patients seeking sildenafil prescriptions online between June 14, 1998, and March 1, 1999, with all 36 medical center patients obtaining sildenafil prescriptions during the same period. The outcome measures compared were: completeness of medical record; patient safety as noted by the follow up responses of all patients requesting refills, any comments received by the internet site (webmaster), and patient or physician comments noted in the clinic medical record; satisfaction as noted by the follow up responses of all patients requesting refills, any comments received by the internet site (webmaster), and patient or physician comments noted in the clinic medical record; examinations and laboratory tests.

Results: Fifty-six percent of Internet requests came from 46 states, and 44% from eight foreign countries. Of 2,104 requests, 2,100 were granted. Three hundred ten patients have requested medication refills: all reported erections sufficient for intercourse and 69% said their satisfaction exceeded all expectations; none were at all dissatisfied. Side effect rates were comparable to those in the literature. Comparison of the medical history obtained from Internet patients with that recorded in clinic patients' charts revealed that the former was far more complete. No clinic patient received any examination or laboratory test specific for erectile dysfunction or its causes. There were no reported deaths or serious complications in either group.

Conclusions: Internet-based prescription of sildenafil provides the physician with a complete and very detailed medical and sexual history for 100% of patients without denying any information routinely obtained in a direct patient contact setting. Internet-based practice, which may be expected to require far fewer healthcare resources than traditional settings, rates very high in patient satisfaction among patients requesting a refill; no negative comments were received from all other patients. Overall, these data support the safety and effectiveness of Internet prescribing of selected medications.

Introduction

Erectile dysfunction is an extremely common condition: according to the Massachusetts Male Aging Study, 52% of surveyed men aged 40 to 70 had some degree of erectile dysfunction, with dysfunction being moderate to complete in approximately half of the 70-year-old men [1]. Similarly, the National Health and Social Life Survey found erectile dysfunction reported by 18% of men aged 50 to 59 (the oldest group surveyed) [2]. Until recently, the condition was often

ignored. This reflected both the mistaken perception that nothing practical could be done, and the understandable discomfort of many patients and healthcare providers in openly and frankly discussing sexual matters.

This changed dramatically with the March 1998 approval of sildenafil (Viagra, Pfizer), the first effective oral medication for treatment of erectile dysfunction. Within two weeks, newspapers reported physicians were writing 15,000 to 20,000 prescriptions a day for the medication [3]. Erectile dysfunction had graduated from secret shame to headline news.

Even with erectile dysfunction on the front pages, many men continue to feel uncomfortable discussing their own conditions face-to-face with a health-care provider [4]. At the same time, many patients are turning to the Internet for medical information and advice on a wide variety of conditions, often because they find the relative anonymity of the Internet less intimidating than a traditional office-based consultation [5]. Their Internet usage may take the form of formal physician consultation [6,7]; informal physician-originated information and advice [8,9]; or information, advice, and support from others with similar conditions [10].

This combination of circumstances suggests the Internet as a natural resource for addressing the needs of men with erectile dysfunction who may be reluctant to seek help from their regular physicians. To meet this need, the NET Doctor Group (an association of physicians, pharmacists, and information specialists) established an Internet-based system to provide information on erectile dysfunction and its treatment with sildenafil; to obtain the medical histories of patients with this condition, when appropriate and desired by the patient; and to prescribe sildenafil and, if requested, dispense it through an independent licensed pharmacy. We report on the first 2,104 patients to request sildenafil prescriptions, together with a comparison group of patients who received sildenafil prescriptions in a traditional medical practice (inner city teaching hospital clinic) setting, during the same 10.5 month period.

Methods

Setting

The NET Doctor Group is a private company that uses a physician-designed World Wide Web (WWW) site (http://www. net-dr.com) to collect patient information and medical history relevant to prescription of sildenafil. This form is shown in

Textbox 1. Physicians associated with but not employed by the NET Doctor Group review the provided medical history, on a fee-for-service basis (the fee is waived if the requested prescription is refused). All physicians are United States educated and trained, hold active license in multiple states, have current DEA registrations, practice independently of the NET Doctor Group, provide full licensure and identification information to dispensing pharmacies, and maintain individual professional liability insurance. The physicians also attempt to make telephone contact with all patients requesting sildenafil prescriptions; such contact is required when the submitted information appears contradictory or otherwise inadequate to support a decision. Requests are typically approved or refused within 24 hours of submission.

U.S. patients who are approved for sildenafil prescription have a choice of receiving the medication directly from the NET Doctor Group's independent pharmacy (not owned or operated by the NET Doctor Group), or of having the prescription faxed to their usual pharmacy. Non-U.S. patients receive the medication directly from the NET Doctor Group. All prescriptions are written for 100-mg tablets of sildenafil as follows:

> *Use 1/2 tab po at least 30 min. before anticipated intercourse (may need to take up to 2 hours before intercourse for maximal effect). If effect inadequate try 1 tab po as above. Warning: Do not take more than 1 tab/day. If unusual pain or symptoms occur consult physician. If chest pain occurs report immediately to nearest ER.*

For unusual pain or symptoms, patients are advised to consult a physician. Patients are free to contact any physician, including the NET Doctor Group associated physicians, at any time. The patient insert (see Textbox 2) advises the patient to consult his or her personal physician. For the most severe and life threatening reactions associated with vigorous or infrequent sexual activity, patients are unequivocally advised to report immediately to the nearest ER.

The patient informational insert developed specifically for the NET Doctor Group's patients and included with directly dispensed medication is shown in Textbox 2. The patient information sheet used by the private pharmacy for its non-NET Doctor Group clients is shown in Textbox 3. The typical prescription written for non-NET Doctor Group patients is for 25 mg sildenafil and reads as follows: Take as directed.

Textbox 1. Online Medical Consultation Form

Please take the necessary time to carefully and truthfully complete all applicable questions on the form. Incomplete forms will not be submitted to our physicians for a consultation, as failure to provide the medical information required to render a professional opinion is prima facie grounds to deny a prescription. If you want to ask us any questions before submitting your form, see our Frequently Asked Questions or email us at inquiries@Net-Dr.com.

It would help us a lot to expedite the consultation process if you provide us your correct email address.

Name:

Address:

City: State: Zip Code:

Country :

Phone: Fax:

Email address:

If my responses indicate that my impotence may be treatable with medication, I understand that Net Doctor physicians have found Viagra to be effective in many cases. If my sexual and medical history suggests that I may benefit from Viagra therapy, please: mail the Viagra tablets immediately.

Please send me a pill cutter. I understand my credit card will be billed.

Click here for refill information

Section A. (To be completed by All patients)

date of birth: (mm/dd/yy) height weight lbs.

Sex: male female

Have you been diagnosed with:

atherosclerosis yes no

heart attack yes no

low testosterone yes no

endocrine disorders yes no

diabetes yes no

stroke yes no

prostate cancer yes no

kidney disease/renal failure yes no

hypertension yes no

spinal cord injury yes no

cirrhosis of the liver yes no

thyroid disease yes no

enlarged prostate yes no

liver disease/other yes no

hepatitis yes no

anxiety yes no

Are you on dialysis? yes no

Have you had an organ transplant? yes no

Please list all medications you are now taking:

Please respond to these questions regarding specific contraindicated medications:

Are you taking nitroglycerine? no yes

Are you taking erythromycin? no yes

Are you taking ketoconazole? no yes

Are you taking cimetidine? no yes

Are you taking itraconazole? no yes

Are you taking mibefradil? no yes

List of Contraindicated Medications

Please list all known allergies:

Are you being treated for other medical conditions at this time? no yes (please specify)

What is your past surgical history?

Do any diseases/disorders run in your family? no yes (please specify)

Describe your alcoholic beverage consumption:

Have you ever been treated for substance abuse? no yes

If you answered "yes", please describe:

Do you smoke? no yes packs per day

Do you consider anything else in your medical history to be relevant? no yes (please specify)

Section B (To be completed by patients seeking Viagra)

If you are a woman, describe why you are interested in taking Viagra: (you must have a qualifying medical reason, Viagra is not a recreational drug). Women may obviously leave blank all impotence-related questions which follow, please answer all other questions.

How would you describe your sex life?

Impotence occurred: Suddenly Gradually

Impotence involves: inability to maintain an erection inability to get an erection

Which best describes your impotence:

penis not at all firm

penis not self-supporting but slightly firm

hardness sufficient for sex but firmness is decreased

Are there ever times when you are not impotent? no yes (please specify)

Have you consulted any other physicians about erectile dysfunction? no yes

If you answered 'yes', please indicate the type of treatment you received:

medical surgical injectable psychological

If you have been treated, were you satisfied with the results? Please explain:

Are you interested in trying Viagra for your erectile dysfunction? yes no

Do you suffer from depression? no yes (please specify frequency and severity)

Do you have any of the following conditions:

Multiple Myeloma no yes

Sickle cell anemia no yes

Curvature of the penis (Peyronie's disease) no yes

Leukemia no yes

Bleeding disorders no yes

Active peptic ulcer no yes

Retinitis pigmentosa no yes

Viagra should be taken with caution and only under the direct supervision of your local physician if you suffer from heart complications or have a family history of heart problems. The following questions are designed to determine that risk:

Do you have a pacemaker? no yes

Have you been diagnosed with angina pectoris? no yes

Do you or have you suffered from chest pains? no yes

Do you suffer from shortness of breath? no yes

Do you exercise regularly? no yes

If you answered "yes", please describe the nature/duration of your exercise:

Are your natural mother and father alive? no yes

If you answered "no", please provide any health reasons that contributed to the death of your mother/father:

How long has it been since you were last sexually active?

I have read and understand the side effects of Viagra true false

By submitting this form, I certify that:

I understand that my credit card will be billed for a physician's consultation if I am approved for Viagra therapy. (If you are not approved, there is no charge.) true false

I have read and agree to the Net Doctor's waiver of liability true false

I am permitted to receive Viagra in the state/region/country indicated as the shipping address: true false

Note to US patients: In many cases, a Net Doctor physician shall prefer to speak on the telephone briefly with patients prior to reaching a final decision. Please provide a telephone number (if different than above) where you may be reached and a convenient time in the 24 hours following the submission of your form. If you are not available at the time that the physician phones you, no message will be left, and if someone other than the patient answers the phone no details about the nature of the call or the caller will be disclosed. The physician will try to phone you on the following day at the same time, and if you still cannot be reached, we will contact you via e-mail.

Phone number (if different than above): (US patients only)

Convenient time to call:

Where did you find us?

Net Doctor Home || FAQs || Privacy & Security || Contact Us

Revised: April 24, 1999.

Textbox 2. Internet Viagra Patient Information Sheet

Viagra 100mg Tablets

Take 1/2 tablet by mouth at least 30 min. before anticipated intercourse(may need to take up to 2 hours before intercourse for maximal effect). If effect inadequate try 1 tablet by mouth as above. Warning: Do not take more than 1 tab/day. If unusual pain or symptoms occur consult physician. If chest pain occurs report immediately to nearest emergency room.

IMPORTANT!!! Please read all of the following information concerning the medication, including the list of medications that should not be taken with Viagra.

What is Viagra used for?

Viagra is used to treat impotence in men. Viagra increases the body's ability to achieve and maintain an erection during sexual stimulation. Viagra does not protect you from getting sexually transmitted diseases, including HIV.

Who should not take Viagra?

Men who are currently using medicines that contain nitrates (see complete list below) should not use Viagra because taken together they can lower the blood pressure too much. Other medications may also interact with Viagra. Please review the list below. Viagra should not be used by women or children.

General Precautions with Viagra:

Men who have medical conditions that may cause a sustained erection such as sickle cell anemia, leukemia or multiple myeloma or who have an abnormally shaped penis may not be able to take Viagra. There are several medications that are known to interact with Viagra, so be sure to tell your doctor and pharmacist about all medications you are taking including those you can get without a prescription. In addition, please review the list below of medications that should not be taken with Viagra.

How should I take Viagra?

Your physician has prescribed Viagra as one tablet about 1 hour before sexual activity. However, Viagra may be taken anywhere from 30 minutes to 4 hours before sexual activity. Do not take more than one tablet in a 24 hour period.

What are some possible side effects of Viagra?

Viagra is generally well tolerated. If any side effects are experienced, they are usually mild and temporary. The following is a listing of the most common side effects(This list is NOT a complete list of side effects reported with Viagra. Your personnal pharmacist or physician can discuss with you a more complete list of side effects.): Headache Flushing Upset stomach Diarrhea Stuffy nose Urinary tract infection Visual changes such as mild and temporary changes in blue/green colors or increased sensitivity to light.

IMPORTANT!!! Medications to Avoid when taking Viagra:

Amyl Nitrate Cardilate (Erythrityl tetranitrate)

Cartrax (Pentaerythritol tetranitrate)

Dilatrate & Dilatrate SR (Isosorbide dinitrate)

Diflucan (Fluconazole)

Duotrate (Pentaerythritol tetranitrate)

Erythromycin Imdur (Isosorbide mononitrate)

Ismo (Isosorbide mononitrate)

Iso-Bid (Isosorbide dinitrate)

Iso-D (Isosorbide dinitrate)

Isordil (Isosorbide dinitrate)

Isotrate (Isosorbide dinitrate)

Miltrate & Miltrate 10 (Pentaerythritol tetranitrate)

Minitran Transdermal System (Nitroglycerin Patches)

Monoket (Isosorbide monnitrate)

Nitro-Bid (Nitroglycerin)

Nitro-Dur (Nitroglycerin)

Nitro-Time (Nitroglycerin)

Nitrong (Nitroglycerin)

Nitroguard (Nitroglycerin)

Nitrol Ointment (Nitroglycerin)

Nitrocine (Nitroglycerin)

Nitroglyn (Nitroglycerin)

Nitrolingual Spray (Nitroglycerin)

Nitropress (Sodium nitroprusside)

Nitrostat (Nitroglycerin)

Nizoral (Ketoconazole)

Onset-5 (Isosorbide dinitrate)

Papavatral (pentaerythritol tetranitrate)

Pennate (pentaerythritol tetranitrate)

Penta Cap#1 (pentaerythritol tetranitrate)

Pentrate (pentaerythritol tetranitrate)

Pentritol (pentaerythritol tetranitrate)

Peritrate (pentaerythritol tetranitrate)

Sorbide-10 (isosorbide dinitrate)

Sorbitrate & Sorbitrate SR (isosorbide dinitrate)

Tagamet (Cimetidine)

Tetrate-30 (Pentaerythritol tetranitrate)

Transderm Nitro (Nitroglycerin)

Transerm-NTG (Nitroglycerin)

Tridil (Nitroglycerin)

Textbox 3. Walk-in Patient Sildenafil Information Sheet

USES: This medication is used to treat male sexual function problems (erection problems).

HOW TO USE THIS MEDICATION: This drug is taken by mouth as needed between four hours and one-half hour before sexual activity (about one hour before is most effective). Take only as directed, usually once daily as needed. Sildenafil works along with sexual stimulation to help achieve an erection.

SIDE EFFECTS: Headache, flushing, stomach upset, nasal stuffiness, diarrhea and dizziness might occur. If these effects persist or worsen, notify your doctor promptly. Unlikely but report promptly any pain or other urination problems, vision problems or skin rash. Very unlikely but report promptly any chest pain, fainting or foot/ankle swelling.

PRECAUTIONS: Before using this drug, tell your doctor your medical history, including any allergies (especially drug allergies), any penis conditions such as fibrosis/scarring, history of painful/prolonged erection (priapism), sickle cell anemia, blood system cancers (such as leukemia or myeloma), or Peyronie's disease, eye problems (retinitis pigmentosa), kidney or liver disease, bleeding disorders or active stomach ulcers. Limit alcohol intake, as it may aggravate side effects or this drug. Since this drug may cause dizziness, caution is advised when performing tasks requiring alertness (e.g. driving). To avoid dizziness and lightheadedness when rising from a seated or lying position, get up slowly. This drug is not to be used in women or children. The elderly may be more sensitive to the side effects of this drug, therefore caution is advised in this group.

NOTES: Do not share this medication with others, since they may have a problem that is not effectively treated by this drug. Use of this drug does not protect against sexually transmitted disease.

MISSED DOSE: Not applicable.

STORAGE: Store at room temperature between 59 and 86 degrees F (15 - 30 degrees C) away from light and moisture.

Patients

This study includes all patients of the NET Doctor Group who requested prescriptions for sildenafil during the period from the opening of the Web site on June 14, 1998, to March 1, 1999. All patients acknowledged a waiver of liability and agreed to specific terms of comprehension and truthfulness before submitting their request for physician consultation. The wavier applies to the NET Doctor Group, and not the independent physicians associated with the NET Doctor Group, as they are not employees of the NET Doctor Group. Each physician may rely on the patient's understanding of sildenafil and its potential complications, and the veracity of the patient's answers to the data collection device, as implied by the wavier.

We informally compare these Internet patients to patients receiving sildenafil prescriptions at clinics of an inner city teaching hospital during the same period. We reviewed charts of these patients, most of whom had been seen on several occasions prior to prescription of sildenafil, for a period of up to one year prior to the prescribing visit and for all subsequent visits. This report covers information obtained from the medical records of all patients who received sildenafil prescriptions as a result of in-person clinic consultations. It should be noted that

the clinics are part of an inner city teaching hospital that is a publicly owned and operated facility. Thus, most clinic patients are members of a lower socioeconomic group. Most patients of the hospital do not have the financial means to afford treatment for erectile dysfunction. The small number of patients (36) in the office-based comparison group is a reflection of the group's socioeconomic status.

Results

Characteristics of patients receiving sildenafil prescriptions are reported in Table 1. During the period covered by this report, 2,104 patients requested sildenafil prescriptions at the NET-Doctor Web site. These patients were somewhat younger than typical for men with erectile dysfunction (mean age 49.4 + 5.3 years, median age 45.9 years), possibly reflecting a lower rate of computer usage among the elderly. Diagnoses of hypertension were reported by 18%, of diabetes by 13%, and of atherosclerosis by 7%. Ten patients had been treated for prostate cancer and one had experienced a spinal cord injury. Approximately 33% of the patients said they smoked; very few reported more than social drinking, while an unusually high 86% reported exercising regularly.

About 95% of the patients said that their impotence had occurred gradually, and 97% that it involved an inability to maintain, rather than to achieve, an erection. Most said their penises were slightly firm but not self-supporting, although a significant minority reported hardness sufficient for sex despite decreased firmness. Eighty seven percent indicated that there were times they were not impotent.

Significantly, almost 66% of the patients reported previously seeking treatment from other physicians for their erectile dysfunction. At least 75% of these men received only psychological counseling or reassurance, and almost none were satisfied with their previous treatment.

Of the 2,104 requests for sildenafil, 2,100 were granted. The small number of refused requests may appear unusual. It must be remembered that patients requested sildenafil only after reading information on the drug and its contraindications and completing an extensive medical history form. Individuals with contraindications to sildenafil presumably did not complete and submit the form, and therefore do not appear in the database of patients requesting sildenafil.

Three of the requests that were refused came from the same address, provided the same demographic information, and requested the maximum number of tablets (30) for a single prescription. Attempts to reach the requester or requesters by telephone were unavailing. The other patient whose request was refused reported having been diagnosed with stroke, hypertension, and angina, yet denied chest pain. Attempts to reach him by telephone were likewise unavailing. Attempts were made to contact all patients by telephone. Less than 10% of all patients had conversations with the consulting physician. Less than one dozen questions required a physician's response; all questions were answered by email within 24 hours. The questioning patients submitted no follow-up questions.

Table 1. Characteristics of Internet Patients Receiving Sildenafil Prescriptions

Category	Number	Percent	Clinic Chart Documentation
All Patients	2100	100	X
Male	2097	99.90	
Female	3	0.10	
Place of Residence:			
U. S. (46 states)	1167	76	X
Non-U.S. (8 countries)	933	24.0	
Age (mean +/- SD)	49.4 +/- 5.3		X
Height (mean +/- SD)	177.8 +/- 11.2		X
Weight (mean +/- SD)	82.4 +/- 15.6		X
Diagnosed with:			
Atherosclerosis	157	7.50	
Endocrine disorders	51	2.40	
Diabetes	268	12.80	
Stroke	1	0.04	X
Prostate cancer	18	0.50	
Enlarged prostate	152	7.20	
Kidney disease/renal failure	8	0.40	
On renal dialysis	1	0.04	
Hypertension	384	18.30	X
Spinal cord injury	1	0.04	
Cirrhosis of liver	2	0.10	
Hepatitis	1	0.04	
Thyroid disease	1	0.04	
Anxiety	10	0.50	
Depression	1	0.04	
Currently taking:			
Nitroglycerine	0		
Erythromycin	0		
Ketoconazole	0		
Itraconazole	0		
Cimetidine	0		
Mibefradil	0		
Being treated for other medical conditions	46	2.20	
Allergies (various)	61	2.90	
Past surgical history (various)	179	8.50	
Regular exercise	1806	86.00	
Both mother and father alive	884	42.10	
Alcoholic beverage consumption:			
Never	968	45.70	
Rarely	352	16.80	
Social	652	31.00	
Moderate	124	5.90	

Category	Number	Percent	Clinic Chart Documentation
Heavy	12	.060	
Smoking reported	673	32.10	
Packs/Day	1.5 +/-0.7		
Sex life described as:			
Good	149	7.10	
Poor	1951	92.40	
Time since last sexual activity	37 +/-9.4 days		
Impotence occurred:			
Suddenly	117	5.60	
Gradually	1983	94.40	
Ever not impotent	1827	87.00	
Impotence involves inability to:			
Maintain an erection	2037	97.00	
Get an erection	63	3.00	
Impotence described as:			
Penis not at all firm	63	3.00	
Penis slightly firm, not self supporting	1267	60.30	
Firmness decreased but sufficient for sex	770	36.70	
Previous treatment for erectile dysfunction:			
Medical	26	1.20	
Surgical	25	1.20	
Injectable	34	1.60	
Psychological	1009	48.00	
Not specified	286	13.60	
Satisfied with previous treatment	15	0.70	
Have following conditions:			
Multiple myeloma	0		
Sickle cell anemia	0		
Peyronie's disease	0		
Leukemia	0		
Bleeding disorders	0		
Active peptic ulcer	0		
Retinitis pigmentosa	0		
Pacemaker in use	0		
Angina pectoris	0		
Chest pain (past or present)	0		
Shortness of breath	0		

There were 2,101 male patients and 3 female patients in the group. One of the female patients reported a complete absence of libido, which had been relieved by taking sildenafil. The second had experienced sexual dysfunction since her complete hysterectomy three years previously. The physician managing her case had recommended that she try sildenafil in addition to the estrogen-testosterone combination with which she was currently being treated. The third reported problems of sexual performance. She was prescribed 10 sildenafil tablets.

Table 2. Measurements and Conditions Noted in Medical Records of Clinic Patients Receiving Sildenafil Prescriptions

Category	Number	Percent	Noted by Net-Dr.com Documentation
All Patients	36	100	X
Male	36	100	X
Female	0	0	X
U.S. Residence	36	100	X
Blood pressure	34	94.40	
Pulse	30	83.30	
Respiration	10	27.80	
Age	36	100	X
Height	6	16.70	X
Weight	6	16.70	X
General examination	20	55.6	
Rectal examination	0	0	
Referral to specialist	0	0	X
Testosterone concentration	0	0	
Diagnosed with:			
Atherosclerosis	0	0	X
Diabetes	0	0	X
Stroke	1	2.70	X
Prostate cancer	0	0	X
Enlarged prostate	0	0	X
Hypertension	4	11.10	X
Currently taking:			
Nitroglycerine	0	0	X
Erythromycin	0	0	X
Ketoconazole	0	0	X
Itraconazole	0	0	X
Cimetidine	0	0	X
Mibefradil	0	0	X
Other medications	16	44.40	X
Being treated for other medical conditions	36	100	X
Allergies (various)	7	19.40	X
Past surgical history (various)	5	13.90	X
Smoking reported	14	38.90	X
Sex life described as:			
Good	0	0	X
Poor	8	22.20	X
Ever not impotent	4	11.10	X

Table 3. Information Reported by Patients Requesting Sildenafil Refills

Category	Number	Percent
Total seeking refill	310	100
Improvement sufficient for sexual activity	310	100
Improvement sufficient for penetration /intercourse	310	100
Successful sexual performance:		
Always	16	5.20
Almost always	287	92.60
Occasionally	7	2.30
Seldom	0	0
Never	0	0
Overall satisfaction:		
Exceeds all expectations	215	69.40
Meets most expectations	76	24.60
Satisfied	19	6.10
Somewhat dissatisfied	0	0.00
Dissatisfied	0	0.00
Side effects:		
Headache	5	1.60
Diarrhea	0	0.00
Nausea	0	0.00
Dizziness	0	0.00
Nasal congestion	15	4.80
Rash	0	0.00
Urinary tract infection	0	0.00
UTI in partner	2	0.60
Chest pain	0	0.00
Blurred vision	3	1.00
Shortness of breath	0	0.00
Vision - blue/green tinge	9	2.90
Heartburn	9	2.90
Light sensitivity	0	0.00
Skin flushing	17	5.50

Three hundred ten (14.76%) of the 2,100 patients requested refills during the study period and have filled out forms reporting their experiences with the drug (see Table 3). The number of patients granted refills at their pharmacies is unrecorded. All 310 reported improvement sufficient for them to resume sexual activity and to achieve penetration. Two hundred eighty seven reported that they almost always enjoyed successful sexual performance, with 16 claiming that their sexual performance was always successful and 7 stating that successful performance occurred occasionally. Two hundred fifteen said that their overall satisfaction exceeded all expectations, 76 that it met most expectations, and 19 that they were satisfied; none said that they were dissatisfied or somewhat dissatisfied. Reports of side effects listed in Table 3 were comparable to those from sildenafil clinical trials [11]. Since data could be obtained only from patients requesting refills, however, the sample may not be fully representative. No patient has complained directly to the NET Doctor Group via its web site. All prescriptions list the name, address, and telephone number of the dispensing pharmacy. The name of the prescribing physician is included on each prescription and the dispensing pharmacy has the physician's DEA number, state license, office address, and telephone numbers. No pharmacy has contacted the NET Doctor Group or its associated physicians concerning patient complaints.

During this same period, 36 patients obtained sildenafil prescriptions from the hospital clinics. The type of medical information contained in the office-based group's charts is summarized in Table 2. These patients' medical records generally showed that blood pressure and pulse rate had been recorded at least once during the previous six months (including the index visit). Twenty of the 36 patients had received a general physical examination during that period, but only 6 had had their height and weight recorded and there was no record that any had received a rectal examination.

Eight clinic patients were recorded as stating that their sex lives were poor and 4 as saying that there were times they were not impotent; these items were not recorded on any of the other reviewed charts. No chart contained any statement as to the quality of the patient's erection or whether the onset of erectile dysfunction was gradual or sudden. Likewise, no chart recorded either a blood lipid profile or any laboratory test relevant to diabetes. The only medical conditions of note recorded in these patients' charts were 4 instances of hypertension and 1 cerebrovascular accident. Just 16 of the 36 charts included a complete list of medications being taken by the patient. Since the primary contraindications to sildenafil use are certain concurrent medications, this is a significant omission. No deaths or serious complications among patients using sildenafil have been reported to the NET Doctor Group, its associated private physicians or independent pharmacies by any patient; patient family member; attorneys representing the patient or their estate; or any local, state, or federal governmental agency. The medical records of the clinic patients had no indication of any adverse effects or death related to sildenafil usage. Lastly, FDA and Pfizer surveillance systems have not reported any deaths directly attributed to sildenafil. The possibility of unreported deaths or complications cannot be completely ruled out.

Discussion

The explosive popularity of sildenafil, and the demonstrated desire of many patients to obtain this medication without a face-to-face discussion of what they regard as intimate personal matters, has brought to the fore the simmering question of Internet-based medical advice and consultation [12]. Concern has been expressed by the Food and Drug Administration, members of the American Medical Association's Council on Ethical and Judicial Affairs, and the vice president of the Federation of State Medical Boards [13].

Yet sildenafil is only a small part of the changes currently in progress. At least two groups are offering fee-for-service Internet-based medical consultations on a wide variety of conditions [6,7] and many other physicians find themselves responding to on-line requests for medical information and advice even when that is not their officially stated policy [9]. Indeed, medical information on the Internet is proliferating so rapidly that it has been the subject of an official report from a panel convened by the U.S. Department of Health and Human Services [14]. While this panel did not specifically address one-to-one communication between physicians and patients, it did note many of the benefits, such as greater willingness to engage in frank discussions about health status, behavioral risks, and fears and uncertainties.

Advantages and problems

Advantages of Internet-based patient-physician communication when real-time contact is not required include convenience for the patient and savings in both time and office resources for the physician. Perhaps most importantly, the computer interface greatly facilitates both obtaining and recording a complete medical history. This conclusion is supported by our comparison of medical history data from the Internet consultation form with that from the charts of clinic patients. Due to the limited number of patients and the limited clinical setting, our findings indicate the need for funding further study and comparisons of physician directed Internet prescribing versus traditional prescribing practice.

One objection that has been raised to Internet-based consultation and prescribing is that, as with the NET Doctor Group, there is generally no mechanism for providing a consultation report to the patient's primary care physician. Several points need to be made. One is that, even in the U.S., it cannot be assumed that all patients have a primary care physician. A second is that many patients - almost half of those seeking sildenafil prescriptions - are from outside the U.S.; they and their physicians may have very different expectations regarding consultation reports. Third and most significantly, a considerable fraction of the patients may have sought Internet-based consultation because they did not want their usual physician to know of their condition or of a specific sildenafil order. For example, they may not wish their wife to know of the order and may not fully trust the discretion of a physician who treats both family members. Although this is regrettable, respect for patient autonomy requires that there should be no attempt to contact the patient's primary care physician without the patient's explicit permission.

This latter point is also relevant to the frequently expressed opinion that it is easier to assess a patient's truthfulness in a face-to-face encounter [15,16]. We are dealing here with patients who have specifically chosen to seek a prescription from someone other than their usual physician. In the absence of an established relationship, mere physical propinquity would do little to assure a complete and truthful medical and sexual history. Indeed, the relative anonymity of the Internet may, in our opinion, well increase patient truthfulness and openness. Another objection sometimes raised is that Internet-based practices, including the one described here, may not specifically list the credentials of the associated physicians [15,17]. However, while physicians reviewing the site might find such information reassuring, its usefulness to patients appears remote. With rare exceptions, very few patients either understand or utilize the data on physician credentials that are available to them. Rather, they typically base their initial choice of physician on friends' recommendations and on convenience. Those factors remain valid in the context of Internet-based prescribing.

Can erectile dysfunction be managed online?

Clearly, not every medical condition is appropriately managed by Internet encounters alone. Erectile dysfunction may be particularly prominent among the appropriate conditions.

Although objective means exist for establishing the existence of erectile dysfunction and for distinguishing between organic and psychogenic causes [18], these tests are cumbersome and often omitted even from specialists' most comprehensive recommendations. Indeed, there appears to be little in the way of consensus as to what, if anything, beyond the medical history might be appropriate in the diagnostic work-up of erectile dysfunction [19]. Recommendations that the physical examination focus on signs of vascular [20] and neurologic [21] disease, together with palpation of the penis for Peyronie's disease [22] and tests for atrophy are common [23]. Except for detection of Peyronie's disease, which can usually be elicited by a thorough medical history, these observations are directed primarily toward determining a cause for the dysfunction. Prior to advent of sildenafil, the etiology of erectile dysfunction rarely affected the choice of treatment [24]. Consequently, Hakim and Goldstein limit their recommended physical examination to abnormal penile curvature and palpable corporal fibrosis [25].

Vinik has noted that erectile dysfunction is often the presenting symptom of diabetes and is also a marker for development of generalized vascular disease and for myocardial infarction [26]. Godschalk et al [23] recommend inclusion of a hemoglobin A1c and a lipid profile in all work-ups for erectile dysfunction. Similarly, Mobley and Baum recommend assessment of sacral root function by means of a rectal examination that includes evaluation of the bulbocavernosus reflex and of sphincter tone [27]. All three tests are absent from the recommended diagnostic work-ups of other experts. Significantly, we found no mention of them in the charts of any of the teaching hospital clinic patients who received a sildenafil prescription.

One can conclude that there is an almost total absence of expert consensus as to the essential components of an erectile dysfunction work-up. The only area of agreement is the importance of a complete medical and sexual history. Our observations of practice in a Midwestern inner city teaching hospital clinic suggest that physicians in this setting rely primarily on the history in deciding whether a sildenafil prescription is appropriate. Yet we also find that the medical and sexual history they obtain is less complete than that obtained by the NET Doctor Group.

Once the physician has concluded that a sildenafil prescription is appropriate, the next step is to instruct the patient in the medication's proper and safe use. Although it is extremely difficult to assess how well different physicians communicate such instructions to their patients, many observations suggest that physician-patient communication is often less than optimal [28]. It would presumably follow that many patients do not understand the instructions they receive.

When oral information is poorly expressed or poorly understood, the patient information sheet becomes critical. As a comparison of Textbox 2 and Textbox 3 shows, the information sheet provided by the NET Doctor Group to its Internet patients is far more thorough and complete, and perhaps more comprehensible as well. Further, it is not the standard for pharmacists to provide a specific patient instruction sheet when dispensing sildenafil. Greater thoroughness may be particularly important given the intuitively plausible assumption that Internet users as a group are likely to grasp information more easily when it is presented in written rather than oral form.

Are current ethical codes and legislation too restrictive?

The American Medical Association has noted that:

> *Telecommunications advisory services, by way of phone, fax, or computer, can be a helpful source of medical information for the public. Often people are not sure where to turn for information of a general medical nature or do not have easy access to other sources of information. Individuals may also be embarrassed about directly bringing up certain questions with their physicians [29].*

The statement goes on to say: "Under no circumstances should medications be prescribed." This dictum, which is currently being revised [13], appears unduly restrictive. It may derive from the belief that, without physical examination and laboratory tests, the etiologic basis of a patient's complaint cannot be identified. The point overlooked by this assumption is that sildenafil is only one of many medications intended, not to cure an etiology, but to relieve a symptom; symptoms are normally diagnosed solely on the basis of patient histories.

The ease with which the appropriateness of certain medications may be assessed underlies the prescriptive authority sometimes granted pharmacists, who are highly expert in medications and their uses but have little or no diagnostic training. As of 1996, 16 states plus the Indian Health Service and the Department of Veterans Affairs allowed pharmacists to initiate or modify drug therapy under certain conditions; similar legislation was pending in 15 additional states [30]. In almost all instances, this authority was gained with the acquiescence of organized physician groups [31].

Support for pharmacists initiating drug therapy is greatest when the condition being treated is diagnostically obvious. A 1993 survey of New York State internists and family practitioners found that 64% of the physicians questioned supported pharmacists providing a butoconazole vaginal cream for candidiasis and 61% supported pharmacists providing a steroid-containing rectal suppository for hemorrhoid sufferers [32]. Washington State allows certain pharmacists to directly dispense emergency contraceptives [33]. And although Florida pharmacists are authorized to prescribe approximately 30 types of medication, 82% of their prescriptions fall into just three categories: topical pediculicides (lindane shampoos), oral analgesics, and otic analgesics [34].

Neither physicians nor the Food and Drug Administration, which in recent years has approved the transfer of large numbers of formerly prescription-only drugs to nonprescription status [35], believe that every prescription drug calls for elaborate physician physical examination and history. The clinic records from the inner city teaching hospital we examined indicate that some believe sildenafil may belong in this category. It might well be argued that the only reason sildenafil requires a prescription is the need for monitoring of contradictions and potential drug interactions, plus the mistaken ideas many patients hold about its indications and proper usage. This study provides evidence

that both monitoring and the provision of patient information can be performed via the Internet at least as well as, and perhaps better than, through a traditional face-to-face physician-patient interview.

Cross-border issues

Concerns have been expressed about the potential availability to patients of drugs not yet approved in their countries of residence [12]. That this is a very real possibility is shown by the experience of the NET Doctor Group: 44.4% of the sildenafil prescriptions were issued to patients in 8 different non-U.S. countries. The concern is not truly limited to Internet-based prescribing: many Canadians crossed the border to obtain sildenafil from U.S. pharmacies prior to the medication's availability in their own country [36].

A large number of countries allow patients to import small amounts of nationally unapproved medications for their personal use. The question is whether individuals' increased ability to obtain nationally unapproved drugs without physically traveling outside their country of residence calls for changes in the law.

Conclusions

Our results support Internet-based prescription (IBP) of sildenafil utilizing a physician designed and controlled information and decision system. The Internet-based prescribing physician consistently has more, not less, clinically relevant and useful information than was typically obtained and utilized in a specific hospital clinic setting. The data suggest that contrary too conventional thought, there is no evidence of compromise to patient safety. This statement is made with the important limitation that our study utilized only passive means to document patient adverse reactions or complaints. Our web site is available for comments 24 hours a day every day of the year. No negative feedback from patients using sildenafil was noted. Established monitoring systems operated by the FDA, Pfizer, local and state governments are actively gathering data. As of the current date we have served over 5100 patients and have received only one complaint from a patient (the patient had a history of asthma and was distressed that he was granted a prescription, he had been advised by a physician "acquaintance" it was unsafe for him to use sildenafil). While our patients represent a minute proportion of all patients using sildenafil, we expect the aforementioned external event tracking systems would detect any significant variation in the expected outcomes of our patients. Based on the significant lack of spontaneous and voluntarily recorded complaints and the overwhelmingly positive comments of patients seeking refills, patients appear to be satisfied with our approach. IBP is associated with extremely low demands on health care resources and maximum responsiveness to patient needs. Health care standards and governmental regulatory efforts to date have not been based on objective or experimental evidence. They have significantly lagged behind the capabilities and implementation of Internet prescribing systems. We hope that data from this first large, objective scientific study can serve as a starting point for development of fact based, meaningful standards and regulations. We encourage further and broader evaluation of physician-designed and controlled Internet prescribing systems.

Conflicts of Interest

Miles Jones, MD serves as the medical director for Net Doctor International and owner of Consultative & Diagnostic Pathology, Inc. Consultative & Diagnostic Pathology receives compensation from Net Doctor International for each medical review provided by Dr. Jones. Dr. Jones personally owns 180 shares of Pfizer stock.

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<u>Original Paper</u>

Access Control based on Attribute Certificates for Medical Intranet Applications

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Abstract

Background: Clinical information systems frequently use intranet and Internet technologies. However these technologies have emphasized sharing and not security, despite the sensitive and private nature of much health information. Digital certificates (electronic documents which recognize an entity or its attributes) can be used to control access in clinical intranet applications.

Objectives: To outline the need for access control in distributed clinical database systems, to describe the use of digital certificates and security policies, and to propose the architecture for a system using digital certificates, cryptography and security policy to control access to clinical intranet applications.

Methods: We have previously developed a security policy, DIMEDAC (Distributed Medical Database Access Control), which is compatible with emerging public key and privilege management infrastructure. In our implementation approach we propose the use of digital certificates, to be used in conjunction with DIMEDAC.

Results: Our proposed access control system consists of two phases: the ways users gain their security credentials; and how these credentials are used to access medical data. Three types of digital certificates are used: identity certificates for authentication; attribute certificates for authorization; and access-rule certificates for propagation of access control policy. Once a user is identified and authenticated, subsequent access decisions are based on a combination of identity and attribute certificates, with access-rule certificates providing the policy framework.

Conclusions: Access control in clinical intranet applications can be successfully and securely managed through the use of digital certificates and the DIMEDAC security policy.

Introduction

Today's healthcare environments use clinical electronic records that are shared between computer systems and which may be distributed over many locations and between organizations, in order to provide information to internal users, to payers and to respond to external requests. With increasing mobility of populations, patient data is accumulating in different places, but it needs to be accessible in an organized manner on a national and even global scale. Large amounts of information may be accessed via remote workstations and complex networks supporting one or more organizations, and potentially this may happen within a national information infrastructure [1].

Security is therefore a major concern for managing the electronic healthcare record (EHR).

According to a recent report, more than 1000 accidental deaths have been attributed to computer system failure [2]. No patient's life should be endangered because of information system error or illegal modification of medical information. Equally important is the need to protect patients' privacy by allowing only authorized users to gain access medical records (especially

sensitive information). Robust encryption algorithms can be used to protect information as it moves through distributed networks, but the risk of security breaches are now coming from the huge numbers of people needing access, difficulties in evaluating their clearances as well as the challenge of maintaining the integrity and trustworthiness of their sites.

Internet technologies were designed to optimize information sharing not security. Recent efforts to preserve a satisfactory level of Internet security rely on public-key cryptography and digital certificates. A Public-Key Infrastructure (PKI) supports the issuing and management of digital certificates which identify and authenticate authorized users.The emerging complementary Privilege Management Infrastructure (PMI) can provide another type of certificate particularly suitable for authorization purposes. We have already developed the DIMEDAC (DIstributed Medical Database Access Control) security policy, which has been well accepted in healthcare environments. This paper gives an overview of digital certificates for controlling access in distributed medical database systems and proposes a method of access control using digital certificates and DIMEDAC.

Access management methods

There is a need to change from the specialized case-by-case access management systems in use today and move towards a small number of general approaches that can be operated by individual access management infrastructures [3].

Use of a networked resource is generally controlled by authenticating and authorizing particular users and uses. Authentication is the process where a networked user establishes a right to an identity. A large number of techniques may be used to authenticate a user: passwords, biometric techniques, smart cards, and digital certificates. Authorization is the process of determining whether an identity is permitted to access a resource. An identity has associated attributes, such as permission to access particular resources, or they may be demographically based, and these attributes may change. Authentication and authorization decisions can be made at different points, by different organizations.

A well-known major access management approach to establishing identity is the credential-based approach, with users needing to present some form of evidence that they are indeed the identity claimed. Traditionally the collection of the credential and its validation have been packaged into the application itself, in the familiar 'userid - password' form. However in a network environment, credentials, which are built into protocol mechanisms, such as the use of certificates with HyperText Transfer Protocol (HTTP) and Secure Socket Layer (SSL) Internet protocols are more suitable.

Certificate-based credentials offer a number of advantages. From the user's perspective, this approach facilitates access, minimizes redundant authentication interactions and provides a single sign-on and a user-friendly view of the available resources. From the administrator's viewpoint, it does not require a vast amount of ongoing maintenance. Certificate-based access management provides strong authentication and gives

confidence that systems are secure. It is suitable for fine-grained access control and it guarantees user privacy and confidentiality. It also addresses user accountability, with administrators able to investigate if improper use is discovered.

Access management over the Internet

The benefits of the Internet as a communication medium for sensitive medical information must be tempered with a significantly greater risk to the confidentiality and integrity of information. Security risks cannot be entirely removed when transmitting information over the Internet [4], since the TCP/IP (Transmission Control Protocol/Internet Protocol) allows information to pass through intermediate computers. This makes it possible for a third party to interfere with communications in the following ways:

- *Tampering*: Information in transit is changed or replaced and then sent on to the recipient.
- *Eavesdropping*: Information remains intact, but its privacy is compromised.
- *Impersonation*: Information passes to a person who poses as the intended recipient. The term spoofing is also used to describe the case in which an entity pretends to be someone else.

Fortunately, some well-established techniques and standards collectively known as public-key cryptography (PKC) make it reasonably simple to take precautions. PKC uses a pair of keys, a public key and a private key. Each public key is published, and the corresponding private key is kept secret. Data encrypted with the public key can be decrypted only with the private key and vice versa. PKC and related techniques provide the additional capabilities:

- *Encryption* and *decryption* allows two communicating sides to transform information they send to each other. The sender encrypts, or scrambles, information before sending it. The receiver decrypts, or unscrambles, the information after receiving it. While in transit, the encrypted information is incomprehensible to an intruder.
- *Tamper detection* allows the recipient of information to verify that it has not been altered in transit. Any attempt to modify data or to substitute a false message for a legitimate one will be detected.
- *Source authentication* allows the receiver of information to confirm its origin. That is to verify the sender's identity.
- *Non-repudiation* establishes proof that the sender sent the data and the receiver received it.

By themselves, encryption and decryption do not address the problems of tampering and impersonation. Tamper detection relies on a mathematical function called a one-way hash (also called a message digest). The encrypted hash of the data, along with other information, such as the name of the hashing algorithm, is known as a digital signature. The importance of a digital signature is comparable to the significance of a hand-written signature. Once someone has 'digitally' signed some data, it provides a high degree of non-repudiation. Confirming the identity of the signer, however, also requires some way of confirming that the public key really belongs to a particular person or entity. Digital identification documents

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called certificates, which are described below, address the issue of impersonation.

Types of digital certificates

Identity Certificates

Until recently, the only widely adopted digital certificate has been the identity certificate. An identity certificate (IC) is an electronic document used to recognize an individual, a server, or some other entity, and to connect that identity with a public key. Like a credit card, a passport, or other personal IDs, a certificate provides generally recognized proof of identity. Identity certificates are issued by certificate authorities (CAs) in much the same way as government agencies issue passports after verifying an individual's identity. Certificate authorities can be either independent third parties or organizations running their own certificate-issuing server software. The certificate authority generally uses published verification procedures to ensure that an entity requesting a certificate is in fact who it claims to be.

When a certificate authority issues an identity certificate, it binds a particular public key to the name of the entity identified in the certificate (such as the name of a doctor). Public-key cryptography uses certificates to help avoid the use of impersonation through forged public keys. Access will only work when the certificate's public key matches with the corresponding private key of the entity identified in the certificate. In addition to a public key, a certificate always includes the name of the entity it identifies, an expiration date, the name of the certificate authority that issued the certificate and other information. Most importantly, a certificate always includes the digital signature of the issuing certificate authority. The certificate authority's digital signature allows the certificate to be used as a 'letter of introduction' for users who trust the certificate authority, but who are not familiar with the entity identified by the certificate.

Attribute certificates

More recent research and development efforts have resulted in a second kind of digital certificate, the attribute certificate [5,6,7]. An attribute certificate (AC) has a data structure comparable to an identity certificate. However, a major difference is that an attribute certificate does not contain a public key. It contains attributes that specify access control information associated with the AC holder (such as group membership, role, security clearance). Attribute certificates are able to support and implement a significant part of the authorization process. The basic idea is that not all access control decisions are identity-based. Role-based, rule-based and rank-based access control decisions require additional information. For example, information about a user's current role (e.g. physician) or a client's ability to pay for a resource access may be more important than the client's identity.

Although this kind of authorization information can be placed in extension fields of identity certificates, there are two fundamental reasons against doing this. Firstly, the certificate authorities who issue the identity certificates are not usually responsible for this sort of authorization information. As a result,

certificate authorities must take additional steps to obtain access control information from the source. Secondly, the authorization information may give different lifetimes for the binding of the identity and the public key. Placing access control information in an IC extension shortens the lifetime of an identity certificate, while time/validity requirements for attribute certificates allow both long-lived and short-lived ACs. Typical validity periods might be measured in hours, as opposed to months and years for ICs [5]. Short validity periods also allow ACs to be used without a revocation mechanism which means access permissions can be changed in a relatively flexible way. Longer-lived ACs may be particularly relevant for authorizations that are relatively static [6]. In this case, if a common authority is responsible for identity and attribute certification, the attributes can be included within IC extension fields, but in most cases it is better to keep the authorization attributes separate from ICs.

In an AC, attributes also need to be protected in a similar way to an IC. Since they are simply digitally signed sets of attributes, ACs provide this protection. Attribute authorities are the entities authorized by one or more users to create and sign attribute certificates [7]. Just like certificate authorities, attribute authorities are responsible for their certificates during their whole lifetime, as well as issuing them.

The attribute certificate format allows any non identity-based authorization information to be bound to an identity certificate by including, in a digitally signed data structure, a reference (linkage) back to a specific identity certificate.

The proposed access-rule certificates

Traditionally, authorization policies have been expressed and managed in a relatively centralized manner: one person or organization administers and enforces the access control requirements. In many cases however, policy control has to be decentralized. In distributed computing environments, there may be multiple, independent and geographically spread entities (individuals, organizations, institutes, notaries etc.) with authority to control access to their local resources. Each of these parties is responsible for defining access-rules to protect resources and each brings its own set of concerns. In order to address those problems in our approach we propose the use of another kind of digital certificate, the access-rule certificate (RC).

An access-rule certificate has a data structure comparable to an IC and AC. It enables parties responsible for policy to create and distribute access control mechanisms remotely and securely and to create rules authorizing access to their resources. RCs are digitally signed sets of rules. Similar to attribute and certificate authorities, a rule authority (RA) is the entity authorized by one or more users to create and sign access-rule certificates. Rule authorities may be both physically and organizationally remote from the information resource.

A suitable security policy is needed to fully exploit digital certificates in protecting clinical intranet applications. Our DIMEDAC (DIstributed Medical Database Access Control) security policy has the required structure and is PKI and PMI compatible.

The DIMEDAC security policy

The DIMEDAC security policy provides a role-based authorization mechanism for accessing medical records. Authorization depends on the particular values of the identity-based context parameters of users that form the user location. Furthermore, it provides mandatory security features [8]. The following are some major characteristics of DIMEDAC, which are particularly useful for distributed access control through digital certificates.

Location control

In distributed medical database systems it is often critical to control the location where users' access requests originate.

A *user location* can be viewed as depending on the following parameters:

- *Site*, which could be a workstation (including the hardware, software and network connection) from where a user logs in the system. It can be of any size or computational power and connected either by cable or wireless.
- *Administrative domain*, which is a part of an organization where a unique administration policy is in effect [9]. Possible types of administrative domains in medical applications might be: clinic, department, hospital, national, international (e.g. European Union).
- *Context parameter*, which differentiates between the need-to-know requirements of users. For example, the identities of particular patients, who have been admitted and charged to particular users with corresponding medical or ward user roles, may be considered as user locations.

Location control is used for two main reasons. Firstly the trustworthiness of the user location (site/workstation or administrative domain) and the user's profile determine the set of roles that a particular user can activate. Secondly, knowledge of the user location (administrative domain or context) also contributes to the decision of the type of access allowed. Control determined by context is highly relevant in the healthcare environment, where there are often temporary increased need-to-know requirements for special cases [10].

As a general rule, the privileges of users are reduced as they are 'located' further from the data.

The distributed access control mechanisms

The access control mechanisms of the DIMEDAC security policy consist of hyper node hierarchies for user roles, data sets and user locations respectively, as well as sets of user location-dependent authorization rules.

Hyper node hierarchies

Hyper node hierarchies (HNHs) are used as normal role hierarchies [11] for permission inheritance, as well as to derive security labels. These labels consist of a security level and a set of categories, due to the two types of connections used between nodes [12]. The mechanism of HNH is used to construct the appropriate user role, data set and user location hierarchies.

The user role hierarchy (URH) consists of nodes, which represent the user roles of a specific application, placed at their corresponding classification levels. The number of levels in URH is predefined depending on the granularity of the control needed.

The data set hierarchy (DSH) consists of nodes, which represent the data sets of the application, placed at their corresponding sensitivity levels. The number of levels in DSH is also predefined.

The user location hierarchy (ULH) is a means for representing the organizational structure of the health care establishments involved in the application.

Location-dependent authorization rules

For access control in wide distributed information systems with multilevel administrative domains, we propose the use of global and local user roles, data sets and user locations. The activation of a global user role determines the ability of the user to access a number of data sets in another remote site. This means that every local security administrator may be able to decide about the authorization of subjects (users) of its administrative domain on objects of other domains. It is clear that access control for other administrators must be limited when they are in other administrative domains [13] and it follows that the privileges of a given user role must be reduced for remote access. This can be accomplished on the basis of user locations, by eliminating the global user role permissions set to access the database remotely. To achieve this a third dimension, concerning the user location, is introduced in the classical access matrix. The resulting access matrix is called Three-Dimension Access Matrix (3DAM) and can be implemented as multiple access matrices, one for each possible user location. A user role (UR) in a user location (UL) has the authority to access a data set (DS) with an access-mode (AM). An authorization rule of this kind can be expressed with a quadruple: {UR, UL, DS, AM}. Data sets in a 3DAM can be defined as data views (e.g. by using the SELECT statement of the Structured Query Language - SQL). Using views of the relational model results in a view-based protection [14]. A significant advantage is a flexible granularity for the definition of objects to be protected. So, it is easy to introduce detailed specifications for specific items (e.g. fields) as well as more general declarations for groups of data sets (e.g. tables) in order to save storage space. The need-to-know requirements of users like doctors are highly dependent on their specific patients. As a consequence, there is a need for increased temporary access privileges for accessing the medical records of their patients. However, there is no way to express this functionality by using static entries in a conventional access matrix. So, we propose, in the context of a view-based protection, the use of dynamic entries that are defined including parameters (e.g. by using ORACLE Dynamic SQL [15]). Such an entry for the table of patients could have the following form:

```
SELECT patient_fielda, patient_fieldb
FROM patient_table
WHERE patient_id IN ':set_of_user_locations'
```

The value of the parameter ':set_of_user_locations' represents the set of locations of the user that requests to access the database. The patient identification code (patient_id) could be used as a global location (e.g. the patient charged to the doctor

who is trying to access the database remotely) given that a unique code identification system is in effect.

Definition of distributed access control mechanisms

The DIMEDAC security policy permits the enforcement of access control policies in large scale distributed systems that are spread over different organizations. It provides a satisfactory level of security of global objects that are accessed by global subjects in a predefined manner.

In the context of a multi-level hierarchy of administrative domains, the following actions should be accomplished for the definition of the access control mechanisms of DIMEDAC (URH, DSH, ULH and 3DAM) in every administrative domain:

- Inheritance of mechanisms from the ancestor (upper level) administrative domain,
- Refinement of those mechanisms in order to meet the specific local needs of the particular administrative domain.

A specific method for the definition of the DIMEDAC access control mechanisms has already been proposed in [8]. This method results in a combination of local and global access control policies, which remain compatible between different organizations without sacrificing the flexibility to further define inner components and to assign more specific authorization rules. The defined access control mechanisms could be stored in special security servers that provide directory and certification services. The process of inheriting the access control mechanisms between different levels of administrative domains could also be accomplished by using access-rule certificates (RCs). As shown in Fig. 2, a security server is proposed to update the inherited URH, DSH, ULH and 3DAM by acquiring specific RCs from the corresponding security server of its upper level, which acts as an access rule authority (RA).

The proposed operational architecture

The proposed operational architecture consists of two phases. Initially, every user obtains an identity certificate. When users initiate a new session, they must first identify and authenticate themselves by using their identity certificates. Then they activate a subset of user roles and locations, which form a session-dependent user profile that is recorded in a set of short-lived attribute certificates. In subsequent user access requests, an access decision-making process takes place based on the combination of identity and attribute certificates of the user. The proposed operational architecture is described in more detail below.

### Phase 1: Gain Security Credentials

As shown in Figure 1, the first phase consists of five steps:

Step 1: Users place their identity certificate request to the local certificate authority (CA) along with their personal data needed for authentication purposes.

Step 2: The local CA authenticates users against their presented personal data, generates the identity certificate and issues it to the user. Conditions for steps 1 and 2 are rarely met.

Step 3: When users initiate a new session, they must first identify and authenticate themselves, during a SSL session with the local application server, by using their IC and password. The validated IC of the user is then used for subsequent remote identification and authentication processes. Then the user activates a subset of user roles (URs), from a set of initially assigned roles, which are needed to accomplish specific tasks. The site of the user is assigned as the initial set of user locations (ULs). The set of user locations is enriched depending on the responsibility/authority of the roles activated by the user. During the upgrade process of the user location set, all the relative administrative domains are included, as well as the context parameters (e.g. the IDs of the patients of the user) of the user task. The user identity, as well as the sets of activated user roles and assigned user locations, forms a session-dependent user profile.

Figure 1. Security credentials acquisition (Phase 1)
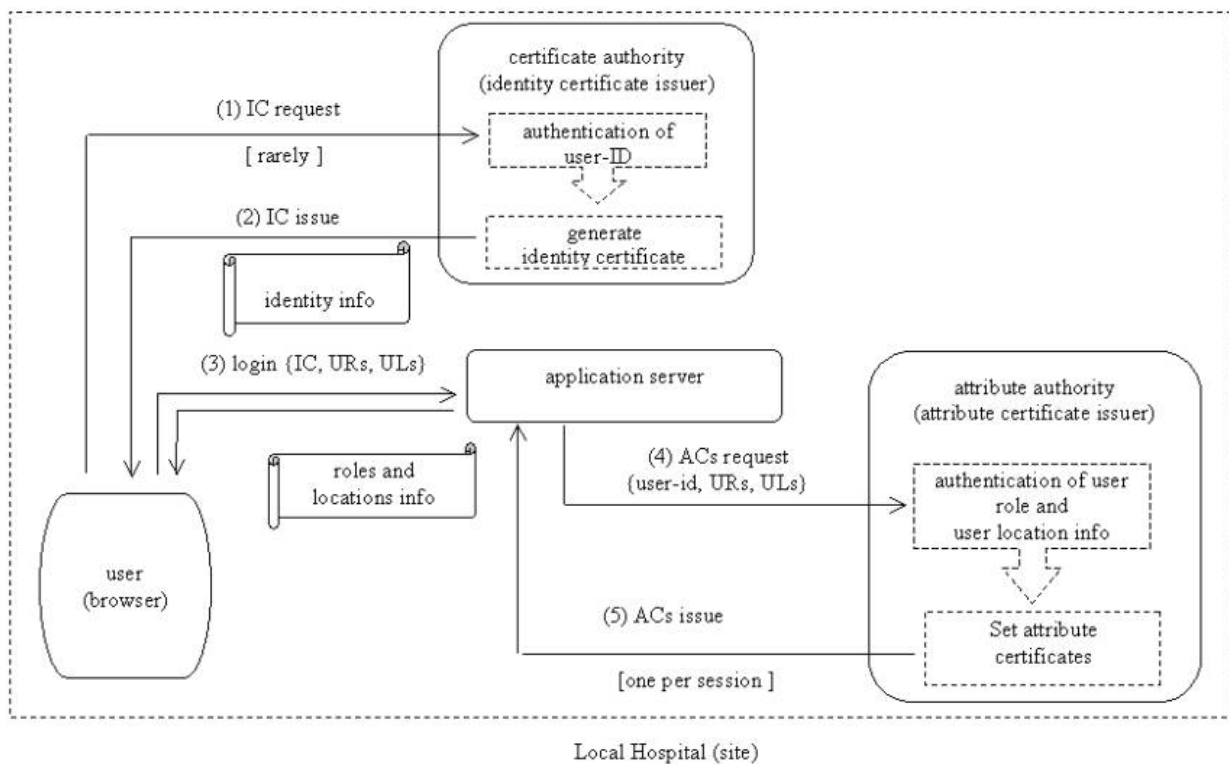
Step 4: The result of the previous step is the preparation of an attribute certificate (AC) request, which is then submitted to the local attribute authority (AA).

Step 5: The AA authenticates the information included in the user profile, sets the attribute certificate and issues it to the user. The issued AC is then used in subsequent access requests during the same session. An attribute certificate is session-dependent and is valid only during the current session. This can be achieved by issuing certificates with a lifetime only a few hours.

Phase 2: Access Medical Data

Subsequently users request access to medical data at any particular site in the whole Intranet. The proposed steps are performed in the following order (Fig. 2).

Step 1: Using the browser, users send their access requests and their accompanying identity and attribute certificates to the application server of a different (remote) site.

Step 2: Using the identity certificate, the remote application server identifies and authenticates the user. Then, it extracts the role (URs) and location (ULs) information from the set of attribute certificates of the user. After a filtering process a new user profile to be used in the remote site is specified containing the final sets of activated roles (URs) and assigned locations (ULs). This user profile is stored in the remote application server and is updated in subsequent user access requests, with new insertions in the presence of new attribute certificates and deletions when the activated user roles and the assigned locations are expired. The new profile and the access request of the user are forwarded (pushed) to the security server of the remote site.

Step 3: The remote security server contains the access control mechanisms as well as the policy engine for the implementation of the DIMEDAC security policy at the remote site. Based on them, a decision making process is performed. The final decision on accessing global data sets at the remote site has the form of a simple 'permitted' or 'denied'.

Step 4: The access decision is returned to the remote application server. Then, the permitted access request of the user is forwarded to the remote database server.

Step 5: The database engine performs the user access request and the data results are returned to the application server.

Step 6: The application server forms the data results in HTML format and sends them back to the user in the form of Web pages.

Figure 2. Access medical data (Phase 2)
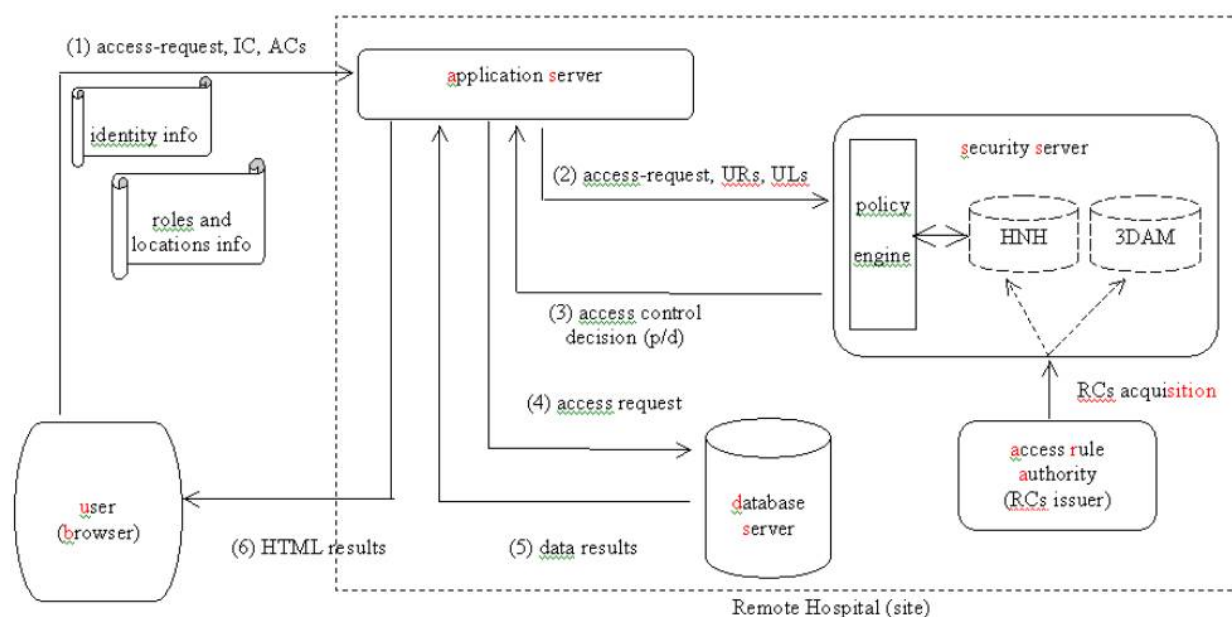
Conclusions

This paper contributes to the discussion of an important, and as yet not fully solved, challenge for healthcare: how to exploit Internet technologies to improve quality of care, while protecting patient privacy and the confidentiality and integrity of sensitive medical data. The focus here is on authentication mechanisms using digital certificates not only for user identification, but also for access control decisions and authorizations.

Access control in clinical intranet applications can be successfully achieved by the proposed use of the PKI and PMI infrastructures together with our DIMEDAC security policy. In our implementation approach we use three types of digital certificates: identity certificates (identity-based, long-lived digital certificates with revocation mechanisms) for authentication as well as attribute (role and location-based, short-lived certificates without revocation mechanisms) and access-rule (access rule-based, long-lived certificates with revocation mechanisms) certificates for authorization purposes. The use of identity certificates offers strong authentication, giving all parties confidence in the security and functionality of the system. It is also suitable for fine-grained access control, it guarantees user privacy and confidentiality and it is capable of ensuring user accountability. Attribute certificates also provide a means for exchanging user profiles between different healthcare institutions in a secure way. The access control policy can be securely and effectively propagated with the proposed access rule certificates.

Conflicts of Interest

None declared.

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Abbreviations

3DAM: three-dimension access matrix

A: attribute authority

AC: attribute certificate

AM: access-mode

CA: certificate authority

DIMEDAC: Distributed Medical Database Access Control

DS: data set

DSH: data set hierarchy

EHR: electronic healthcare record

HNH: hyper node hierarchy

HTTP: HyperText Transfer Protocol

IC: identity certificate

ID: identification/identity

PKC: public-key cryptography

PKI: public-key infrastructure

PMI: privilege management infrastructure

RA: rule authority

RC: access-rule certificate

SQL: Structured Query Language

SSL: Secure Socket Layer

TCP/IP: Transmission Control Protocol/InternetProtocol

UL: user location

ULH: user location hierarchy

UR: user role

URH: user role hierarchy

Original Paper

Building and Growing a Hospital Intranet: A Case Study

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Abstract

Background: The Intranet is a rapidly evolving technology in large hospitals. In this paper, we describe the first phase of an Intranet project in a multi-hospital system in New York City.

Objectives: (1) To encourage the use of the Intranet among physicians, nurses, managers, and other associates in a multi-hospital system; and (2) to build the Intranet in a cost-effective manner using existing resources.

Methods: A WebTrends Log Analyzer assessed the Intranet use in terms of the number of accesses from each department.

Results: A broad range of features, including medical knowledge resources, clinical practice guidelines, directions, patient education, online forms, phone directory, and discussion forums were developed. Analysis of more than 890,000 hits revealed the departments with hits greater than 1,000 were the 'Library' (6,130), 'Physicians Gateway' (2,539), 'Marketing' (1,321), 'Information Systems' (1,241), and 'Nutrition' (1,221). Of 819 unique visitors, 74 per cent visited more than once.

Conclusions: It is possible to create and diffuse an Intranet in a multi-hospital system in a cost-effective manner. However, the key challenges were selling the potential of this new technology to opinion leaders and other stakeholders, and converting pre-existing printed content by obtaining word processed and image files from other departments or contracted print publishers.

Introduction

Hospitals are rapidly adopting Intranet technology. According to a survey by PriceWaterhouseCoopers and Zinn Enterprises, the proportion of large hospitals (number of acute care beds greater than 500) with an Intranet rose from less than half of the respondents in 1999 to nearly three-quarters in 2000 [1].

This paper describes the first phase of Intranet growth in a hospital system from October 1999 through July 2000. We describe the challenges encountered, solutions created, and resources brought to bear to develop a dynamic, enterprise-wide Intranet.

Background

Saint Vincent's Catholic Medical Centers of New York (SVCMCNY) is a newly merged enterprise of seven acute care hospitals with services that include a wide spectrum of health care. The system includes 2,600 acute medical/surgical beds, 61 primary care, behavioral health and ambulatory care sites, 800 long-term care beds, 1 million home care visits, approximately 2,000 physicians, and 15,000 associates. SVCMCNY serves communities in Brooklyn, Manhattan, Queens, Staten Island, and Westchester.

The first phase of the Intranet project was limited to the services and settings of care affiliated with four acute care hospitals in the boroughs of Brooklyn and Queens in New York City.

Methods

Resources, Infrastructure, and Software

The Intranet comprises a variety of resources, infrastructure, and software (Table 1).

The Intranet project team comprises a project manager, a webmaster, and a technical lead. At present, the webmaster also

designs and develops the Intranet. Departments, with sites on the Intranet, have content providers that send digital content to the developer.

Internet Explorer 5 is the standard web browser and FrontPage 2000 the supported HTML (hypertext markup language) editor.

Each department with an Intranet site has a content provider, who must ensure that the relevant department chair has approved material before it is sent to the developer. Content is sent via e-mail. Hardcopy photography is accepted but paper-based text for optical character recognition is not.
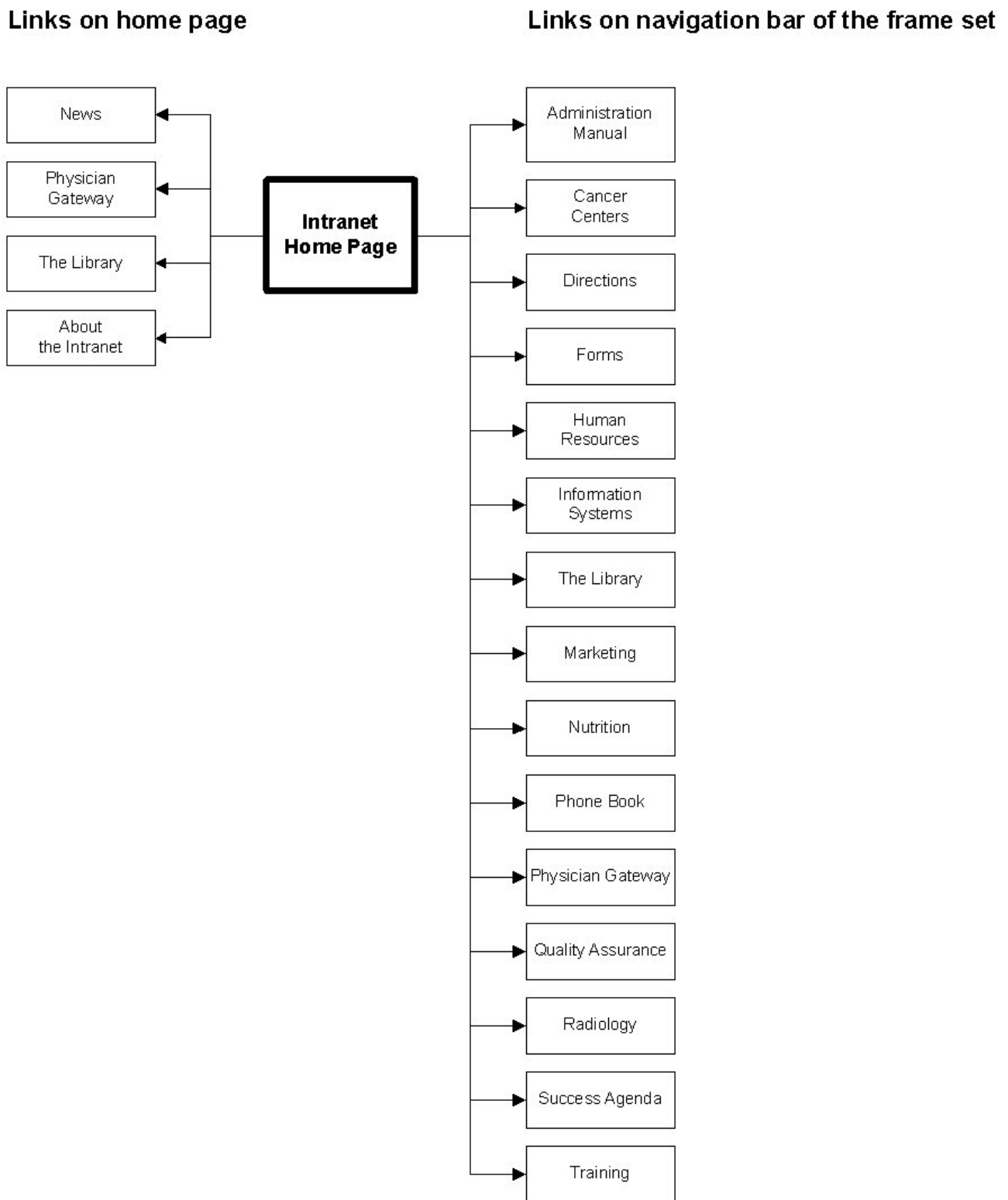
Site statistics are monitored with WebTrends Log Analyzer [2] and FrontPage 2000's report function.

Site Map and Content

At the end of this first phase of the project, the Intranet has 267 MB of files. At the time of writing, 3,011 files have been posted in the last 30 days. The remaining 1,230 files have not been modified in over 72 days. Of the 5,447 hyperlinks, the majority (5,088) is internal and a minority (359) is external.

A frameset is used to facilitate navigation with links to the main department sites, such as the 'Administrative Manual', 'Library', 'Phone Book', and the 'Physician Gateway' (Figure 1).

Figure 1. Example Frameset

The home page has links to a 'News' page with the latest corporate announcements. For example, the current version of 'News' has information and links to resources on Ambulatory Payment Classification and a news release about a prostate cancer screening campaign.

Functions served by the Intranet include those shown in Textbox 1.

Table 1. Intranet Resources, Infrastructure, and Software

Category	Description		
Resources	*Position*	*Intranet Project Team Role*	*Time devoted to Intranet (full-time equivalent, FTE)*
	Director, Medical Informatics	Design, development, and webmaster	0.5
	Director, Data Administration and Security	Project manager	0.1
	Network Coordinator	Technical lead	0.1
Infrastructure	• Compaq Proliant 3000 Server with 256 MB RAM and 14 GB hard disk		
	Compaq Proliant 3000 Server with 256 MB RAM and 14 GB hard disk		
Software	• Windows NT 4 • Microsoft Internet Information Server • Internet Explorer 5 • FrontPage 2000 • Microsoft Office Suite • Image Composer • Adobe Photo Deluxe, Business Edition • WebTrends Log Analyzer • Hewlett Packard Precision Scan Pro		

Textbox 1. Functions served by the Intranet of the Saint Vincent's Catholic Medical Centers of New York

- Online administrative manual
- Internal marketing
- Directions to the hospitals
- Digital forms
  - Adult Medical Record Review Form
  - Inter-Library Loan Request

- Form repository (links to Microsoft Word files)
- Secure site for an enterprise-wide work group ('Success Agenda')
- Public and restricted information for Human Resources and Information Systems
- Web-based and Intranet-enabled medical knowledge resources
  - PubMed
  - Harrison's Online
  - PDR.net (the online version of the Physicians' Desk Reference)
  - Clinical Pharmacology 2000
  - Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Comprehensive Accreditation Manual for Hospitals 2000
  - 1999 Hospital Statistics from the Greater New York Hospital Association
  - STATRef
  - InfoTrak
  - Dialog@CARL
  - Centers for Disease Control and Prevention, including Travel Advisory
  - AIDS Treatment Information Service
  - New York City Department of Health, including West Nile Virus updates and restaurant inspection reports

- Nutrition information
- Searchable phone book, an Access database of the global address book from Outlook
- Physician resources ('Physician Gateway')
  - Order sets and clinical practice guidelines
  - Patient education
  - Pharmacy newsletter
  - Health care-related web links, such as MedCalc 3000
  - Highlighted links to resources of particular importance to New York City, for example, West Nile Virus, HIV/AIDS, Lyme Disease
  - Palm Pilot downloads, such as ePocrates.com

- Training
  - PowerPoint presentations converted to web pages
  - Self-instructional training on conscious sedation with an online post-test

- Discussion group for the Information Systems Help Desk
- Suggestion boxes

Results

Intranet Traffic Report

At the time of writing, the Intranet has had 890,253 hits with an average of 3,091 hits per day. The total number of visitor sessions was 24,251 with an average of 84 per day. The total number of unique visitors was 819, of which 74 per cent (608 of 819) had visited more than once. About a third of the visitors (276) visited 10 or more times. The greatest proportion of total visitors (45%) viewed three pages.

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Excluding hits to the home page, the departments receiving the most visitor sessions (defined as greater than 1,000 visitor sessions) were the 'Library' (6,130), 'Physicians Gateway' (2,539), 'Marketing' (1,321), 'Information Systems' (1,241), and 'Nutrition' (1,221) (see Table 2).

Table 2. Departments Receiving the Most Visitor Sessions

Department	Visitor Sessions
Library	6130
Physicians Gateway	2539
Marketing	1321
Information Systems	1241
Nutrition	1221
Administrative Manual	715
Help Desk	692
Human Resources	579
Phone Book	475
Training	462
Quality Assurance	450
Success Agenda	426

The average number of visitors per day was 105 on weekdays and 59 on Saturday and Sunday combined. The most active day of the week was Wednesday and the least Saturday. The most active hour of the day was from 2 PM to 3 PM and the least from 5 AM to 6 AM.

Discussion

The Intranet has succeeded in becoming a tool used on a daily basis throughout the enterprise. It serves both business critical and patient care functions. The Intranet garnered more than 800,000 hits in its first phase. More than 500 visitors have visited more than once. Content at the end of this first phase includes a gamut of resources from an administrative manual to online training.

This mirrors the success of Intranets elsewhere in healthcare. Intranets have been used to support clinical practice guidelines [3], radiology test results [4], disease management [5], paging services [6], and a link between emergency departments [7].

The project costs in resources, software, and hardware were modest in comparison with other similar Intranet projects [4]. An existing network, server, and Microsoft software license cut Intranet project costs. The 0.7 FTE resources, less than $70,000 total for the first year, were in-sourced. In contrast, one price advertised on the web for Intranet start-up design and development is $7 per user per month . At this price, an Intranet distributed to the 5,000 users in phase one of our project, could have cost $420,000 [8].

One limitation of our analysis was the inability to determine use by different segments of the audience. Intranet was designed to permit access by all staff and associates ('Anonymous browsing allowed' in Internet Information Server 4.0). Individual logon was not necessary for access. We were therefore unable to stratify use in terms of physicians, nurses, administrators, and others.

The Challenges and Solutions

"Build it, and they will come." It may have worked for Kevin Costner in the movie "Field of Dreams", but chances are this philosophy alone won't work for your company's Intranet. - P.G. Daly [9].

As with any innovation, at the outset, the Intranet was not adopted immediately [10]. Early adopters provided content to the Intranet and promoted its early use by physicians. The medical library director asked that web-based and web-enabled resources be put online. The clinical chair of medicine requested that the physician order sets and clinical practice guidelines be made available online.

Content spurred use by other staff groups. The nursing coordinator for patient education worked to create material for the most common conditions and illnesses. The Nutrition department submitted training presentations.

The project team webmaster and leader actively sought content and marketed the Intranet in one-on-one meetings with department and corporate leadership. As influential early adopters made the Intranet their own, more stakeholders and departments showed interest in the Intranet.

Though adoption may have been the principal barrier, solutions for other challenges were no less critical to the Intranet's performance and survival. The Intranet project team faced a number of challenges.

- The imminent merger presented a barrier to some who were unclear what their own role or that of their department might be in the new organization. They were hesitant to commit time and resources to a venture they might not see complete. For others, creating an Intranet site for their department fostered collaboration between the regions and served as a means to advertise the products and services they offer to the enterprise.

- Timely receipt of content was particularly based on promoting existing or building new interpersonal relationships. Lack of familiarity with Intranet functionality and questions about how departmental content would be managed were two often voiced concerns. The webmaster developed a PowerPoint presentation that introduced Intranet technology and described its potential to enable the business and patient care missions of the enterprise. Communication skills were as critical as programming knowledge. A policy was developed that required that all content have the approval of the relevant departmental leadership.
- Converting corporate pamphlets, leaflets, and newsletters required obtaining ASCII or word processed text from the various contracted print publishers. Marketing was encouraged to send soft copies to the Intranet webmaster whenever new print media was created. To prevent delays in publication and to reduce development turnaround time, text was accepted only in digital format. Photographs were accepted in Graphic Interchange Format (GIF) or Joint Photographic Experts Group (JPEG) format but could also be sent in hardcopy and scanned.
- Collapsible guidelines, dynamic HTML, and other features at the time were only supported by Internet Explorer versions 4 and above. Internet Explorer 5 was made the standard web browser. Web browser standardization was accomplished with Microsoft Systems Management Server.
- To enable collaborative authoring and work team sites with restricted access, security permissions for directories (access control lists) and files were managed in the Windows NT file system (NTFS).
- Marketing the Intranet meant more than announcing its existence in corporate email broadcasts and newsletters. The Intranet team met with departmental leadership in locations and times convenient to them. Meeting preparation required a checklist of several items. We confirmed network connectivity and installation of Internet Explorer 5 on suitable workstations before each meeting. The Intranet was made the default home page on these workstations and a readily apparent shortcut placed on each desktop screen.

If a user did not have an account on the new enterprise-wide domain, a new account was made or an old account was moved.

- Success inherently generates problems of its own. As more departments adopt the Intranet, more content is created that must be re-formatted to web-browser friendly layout and incorporated into the web architecture. The increase in content may be temporary and related simply to the recent merger.

If the content submission and turnover continue to grow, several options will be considered. We are currently experimenting with a method that permits Marketing to publish content directly to the Intranet without the need of an intermediary, for example, form posting to an HTML file. Alternatively, content submission and development could be limited to once or twice a month rather than weekly. Finally, more resources may be needed in Intranet design and development.

Next Steps

With successful completion of the first phase of the Intranet project, the second phase will have three goals:

1. Re-engineer the Intranet content and format to serve the new enterprise in all regions. New sites will include the physicians-hospital organization, the nursing department, and JCAHO readiness.
2. Grow Intranet application development, for exempt, enterprise-wide job postings, podiatry procedure log, uniform formulary database.
3. Extend the web browser standard and validate network connectivity throughout the enterprise.

Conclusion

Intranet technology is readily available and is, if pre-existing resources are already in place, of modest cost. Adoption was the key barrier to diffusion in our project. By demonstrating how the Intranet can serve business critical and patient care needs, we were able to empower early adopters. The Intranet has succeeded in reaching the early majority and has evolved from a cutting edge technology to an everyday tool.

Conflicts of Interest

None declared.

Appendix 1

Downloadable Screenshots of the Intranet [PowerPoint ppt file, 2 MB - jmir_v3i1e10_app1.ppt]

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Original Paper

An Infrastructure for Integrated Electronic Health Record Services: The Role of XML (Extensible Markup Language)

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Abstract

Background: The sharing of information resources is generally accepted as the key to substantial improvements in productivity and better quality of care. In addition, due to the greater mobility of the population, national and international healthcare networks are increasingly used to facilitate the sharing of healthcare-related information among the various actors of the field. In the context of HYGEIAnet, the regional health telematics network of Crete, an Integrated Electronic Health Record environment has been developed to provide integrated access to online clinical information, accessible throughout the island.

Objectives: To make available comprehensive medical information about a patient by means of incorporating all the distributed and heterogeneous health record segments into an Integrated Electronic Health Record that can be viewed on-line through a unified user interface and visualization environment.

Methods: The technological approach for implementing this Integrated Electronic Health Record environment is based on the HYGEIAnet Reference Architecture, which provides the necessary framework for the reuse of services, components, and interfaces. Seamless presentation of information is achieved by means of the Extensible Markup Language (XML), while its underlying capabilities allow for dynamic navigation according to personalized end-user preferences and authorities.

Results: The Integrated Electronic Health Record environment developed in HYGEIAnet provides the basis for consistent and authenticated access to primary information over the Internet in order to support decision-making. Primary information is always kept at the place where it has been produced, and is maintained by the most appropriate clinical information system, contrasting traditional store and forward techniques, or centralized clinical data repositories.

Conclusions: Since documents are much more easily accessible rather than data inside a database, Extensible Markup Language has the potential of becoming a very cheap technology provided, of course, that the underlying Healthcare Information Infrastructure exists. XML can be introduced incrementally and its implementation is completely transparent to the end user.

Introduction

Parts of patients' medical records are located in all the places where they have received clinical services (eg, community doctors, primary care, and secondary care). All of these segments, which are related to personal healthcare delivery and well being, reside in places that are disparate and, in most cases, not directly accessible. Moreover, a number of restrictive policies do not allow personal, sensitive clinical information to be carried outside the corresponding organization's boundaries,

while the healthcare providers continue to maintain detailed and confidential notes about their cases. This is true even when healthcare providers use electronic clinical record systems and communication between them is by electronic means. Although the World Wide Web (WWW) provides the means for global access to all kinds of information, personal health information still remains fragmented and not directly accessible in a unified way.

Any Integrated Electronic Healthcare Record (I-EHR) environment should be capable of handling these issues and provide uniform ways for accessing authentic, physician-generated, patient record information that is physically located in different clinical information systems. Furthermore, it needs to provide fast and authorized on-line access to longitudinal views of each patient's personal health record, in order to allow for the timely delivery of health care. Such an environment is expected to allow patients to become more actively involved in the monitoring and assessment of their own wellness. At this point, the main reason driving the need for integrated access to clinical information is information sharing. Issues that need to be resolved on the way towards providing integrated solutions are mainly focused around patient identification, interoperability among cooperating software components and the involved clinical information systems, and all the security related medico-legal issues.

Methods

The technological approach for implementing the I-EHR environment is based on the HYGEIAnet Reference Architecture (HRA), which provides the necessary framework for the reuse of services, components, and interfaces [1]. At the middleware level, these services include: authorization, naming, messaging, terminology, semantic mapping, and other metadata services, as well as services for the management of medical acts, patient identification, and clinical data location [2].

The HRA applications and services model that was used provides a logical paradigm of the relationships between applications, end-user services and the underlying middleware enabling services. At the bottom layer, generic services and tools (eg, data bases and directories), the Internet and software component infrastructures (eg, Common Object Request Broker Architecture [CORBA], Distributed Common Object Model [DCOM], or Common Object Model Plus [COM+]) form the technological infrastructure for storing and managing information. Autonomous clinical information systems are the information sources to be integrated. These information sources can be accessed by means of a number of alternative interfaces (eg, Web/ Open Data Base Connectivity [ODBC] and CORBA). On top, the presentation layer provides the end-user with the means for accessing advanced I-EHR services and supporting activities in the various areas of the organization. Visualization can be delivered by means of, for example, the Web or Wireless Access Protocol (WAP) over a number of different possible devices (Personal Computers [PCs], handheld computers, mobile phones, etc.). The heart of the whole I-EHR environment, and core of the underlying Healthcare Information Infrastructure (HII), consists of middleware services that provide the mechanisms for information provision, filtering, and fusion. Figure 1 depicts how the required components for building the I-EHR are structured.

Figure 1. A two-dimension view of the multi-level architectural framework for the I-EHR environment of HYGEIAnet
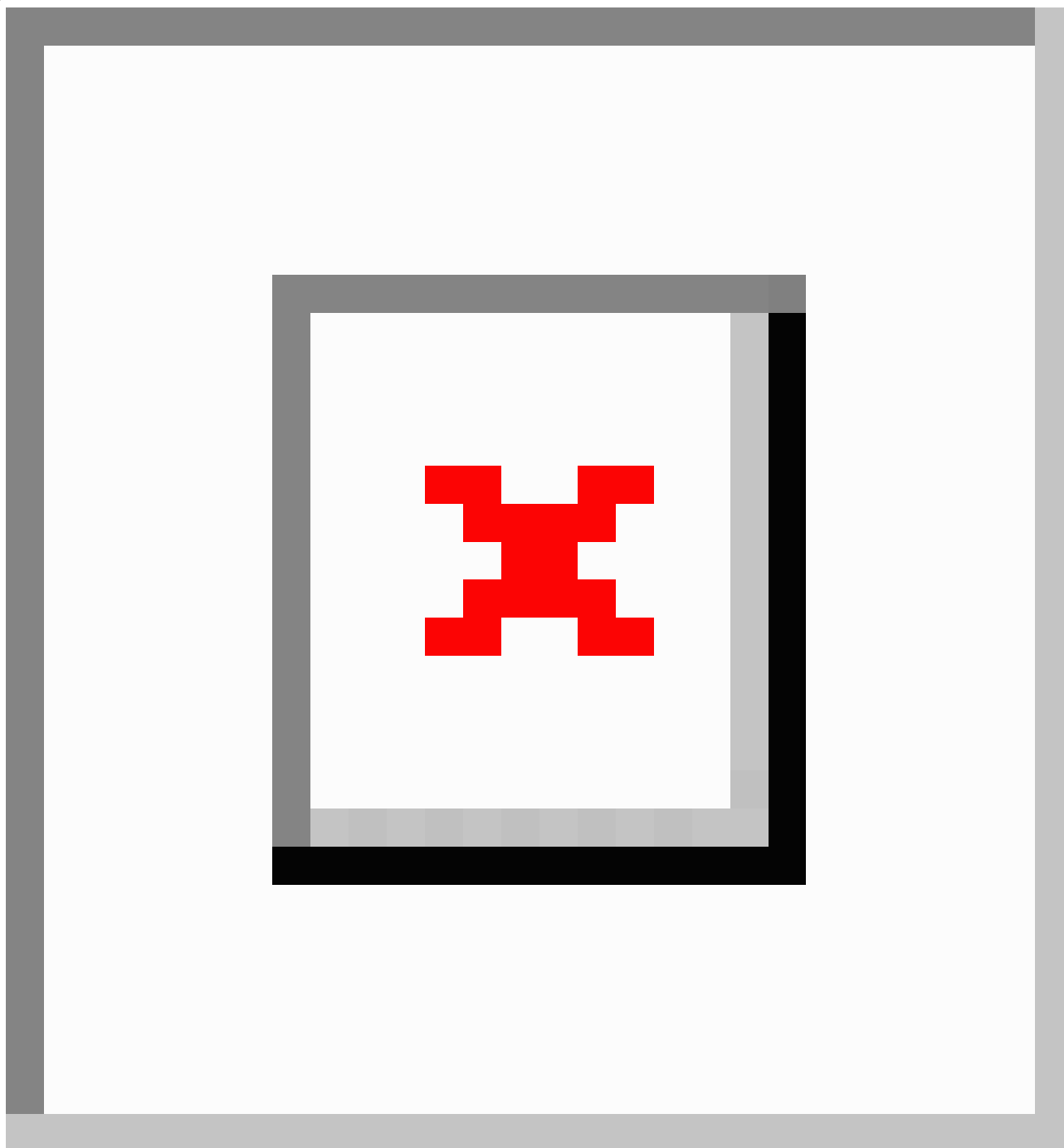
The currently available execution architecture is based on CORBA interfaces (for data acquisition, patient identification, semantic mapping and messaging), X.500/ Light Directory Access Protocol (LDAP) (for security services, user profiles, patient clinical information, and healthcare resources), dedicated Structured Query Language (SQL)/ODBC-LDAP gateways (for accessing primary information and maintaining up-to-date indexing), and the Extensible Markup Language (XML) (to sustain the collected clinical information in a consistent way). Primary information is usually kept on commercial data base management systems, and this is expected to continue in the years to come. A key strength of existing databases is their ability to allow complex queries about clinical information that is kept in single data repositories. On the other hand, the

emerging directory technology promises enhanced integrity offering personalized user environments, simplified service and application configurations, security service integration, and improved bandwidth allocation. Key strengths of the emerging directory technology are its distribution provisions and fast lookup based on name. The International Telecommunication Union's (ITU) X.500 and LDAP are the most promising approaches for building global directories [3]. Well-documented interfaces. expressed in the Interface Definition Language (IDL) associated with the integration framework of CORBAmed [4], provide basic support for interoperability among computer systems. This is essential, particularly in large hospitals, where many different kinds of computers have been installed and cannot be changed. The results of the CORBAmed efforts in

standardizing IDLs has been to influence the design of interfaces developed worldwide due to its strong industrial support. Adopted models and architectures can be easily used by any alternative implementation (eg, DCOM, or COM+) or combinations.

Recently, the Extensible Markup Language (XML) has gained great attention and is becoming the preferred language for data interchange over the WWW. Its origins are in the Standard Generalized Markup Language (SGML), but in comparison, XML is simpler [5]. It looks like the HyperText Markup Language (HTML), but it's stricter and more generic since anyone can define the vocabulary intended for use. It is well defined, and there is emerging technology and tools for authoring, validating and presenting. XML offers freedom in using user-defined vocabularies, while the content is forced to conform to strict grammars (Document Type Descriptions [DTDs], XML schemas) that define how the tags can be mixed. The only thing that needs be described inside an XML document is the content, together with the component parts of the document, and not its presentation. Since its raw format is plain text, any XML document can easily be exchanged over well-known protocols such as the HyperText Transfer Protocol (HTTP) or the File Transfer Protocol (FTP), making it a very flexible platform for structuring and exchanging information.

Results

The I-EHR is a front-end to an EHR indexing service, managed by the Patient Clinical Data Directory (PCDD) [2] which indices both structured and unstructured information that is provided by cooperating information systems, without imposing any constraint on their internal operation or their interface beyond the medical encounter level. At its current implementation, the main objective of the I-EHR environment is to deliver an encounter-centered view of the patient's EHR. It utilizes the available CORBA interfaces to provide a consistent way to locate, access and transmit secure information about a patient's EHR segments. Throughout any regional setting, these segments are maintained by a wide diversity of existing, autonomous, networked clinical information sources having different internal structures (database schemata) and different vocabularies to describe the notions they use.

References to recorded data are obtained and used to retrieve actual information by means of the Object Management Group's (OMG) Clinical Observation Access Service (COAS) implementations. COAS seems to be generic and simple, yet powerful, expressing the clinical observations and the relationship between them, composition being the most common. On the other hand, the terms used to describe and identify these observations may come from different coding schemes, and so a terminology service implementation is also necessary. This terminology service is responsible for concept mapping and translation between coding schemes. OMG's Terminology (or Lexicon) Query Service (TQS) is used at this point to provide both conceptual mappings among the different clinical information systems available and the coding schemes they use for recording clinical findings. This is a requirement in order for the existing information to be capable of providing comparable patient data among different institutions.

In this context, a generic mapping between observations and attributes of database tables has been deployed. Composite observations have been mapped to database views while atomic observations have been mapped to attributes. The composite observations contain other observations, and this composition in the database is implemented through links and references from one table to another (Figure 2). Observations that are contained or related to another observation are, in turn, views that reference other tables and so forth. This recursion ends when an atomic observation is found and, if this is the case, the value of an attribute is retrieved. There is a specific mapping for each type of clinical information source, and each mapping follows a coding scheme accessible through a terminology server so that a client can "understand" the semantics of the information returned to it. The actual COAS implementation is the same for all information systems as long as they store their information in a relational database system. When moving from an information source to another, the actual implementation remains the same and the only thing that changes is the mapping from internal database relations to observations, provided that these information sources store their data in relational databases.

Figure 2. Example of database schema mapping to the COAS observation structure
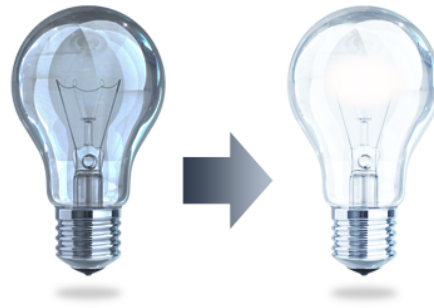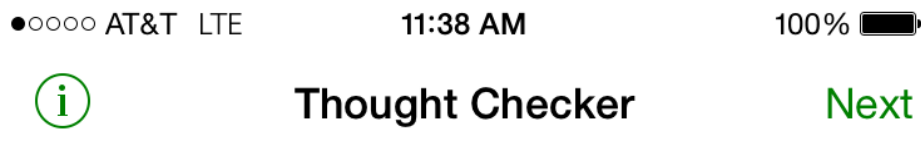
As far as the Graphical User Interface (GUI) for accessing the I-EHR environment is concerned, apart from the lifeline view of all the available encounters of the patient, a number of alternative views are currently supported: a per-clinical system view of the encounter's history, as well as the traditional tabular view of old generation GUIs. When requested, primary information is collected and presented to the end user by initiating remote COAS servers. The COAS data returned need further transformation in order to be properly presented to the user. The underlying data model supported by the Patient

Clinical Data Directory (PCDD) is based on the Subjective Objective Assessment Plan (SOAP) model that originates from the primary healthcare domain [6].

In this context, XML has not only been used to describe the COAS observation data in a human readable format but also to be the central point of the transformation process. The composition and recursion concepts that are an integral part of the COAS representation of clinical observations are inherently supported in XML. An XML tag represents each COAS observation. If this is a composite observation, then this tag contains other tags that represent the component observations, and so on, until an atomic observation is reached. An atomic observation is a different tag that can have a "value" attribute or "parsed character data" as its content.

Figure 3. XML to HTML transformation by means of XSL
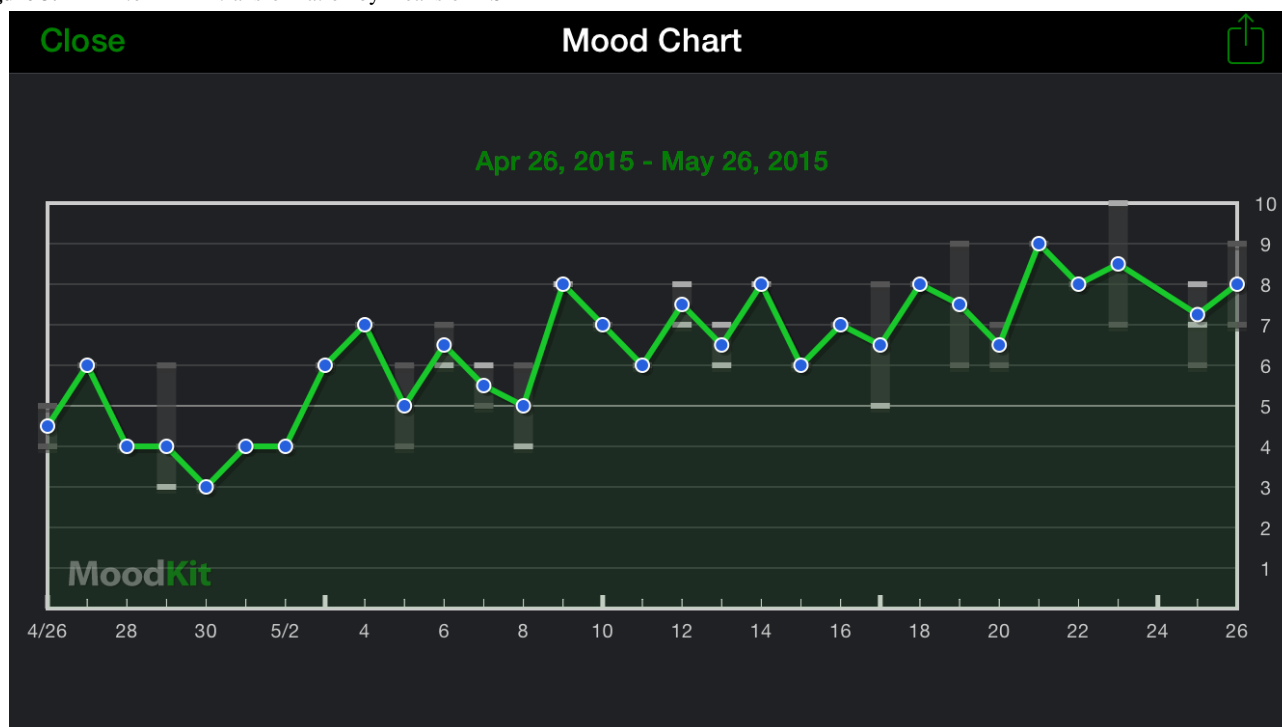
The COAS results are represented in XML through a DTD that has been developed (available in Appendix 1). Having been represented in XML, the clinical information can be transformed to many other formats, such as HTML and the Portable Data Format (PDF), using the Extensible Stylesheet Language (XSL). Such an example is depicted in Figure 3.

In a potential use scenario, the end user needs to locate and access clinical information about a specific patient. The system forwards this request to all known or existing COAS servers and collects their responses. These clinical observations are transformed to XML and then transformed again to a number of HTML pages. These pages can be presented to the user sorted chronologically, and the user can browse going back and forth in time. Alternatively, XML clinical data can be grouped by type and then transformed to HTML pages where the user can view a patient's clinical information categorized according to personal preferences (eg, all biochemical exams together).

Currently a COAS server and a COAS client have been implemented using the Java Programming Language [7] with CORBA as the communication infrastructure. Java is a Web application accessible through the WWW. The client side, which is responsible for collecting the COAS results of a user's query, saves them in XML format and transforms the XML data to HTML. The implementation has been developed using Java Servlet technology [8] and the Jakarta Tomcat 3.2 servlet container [9]. The system is stable enough for practical use.

However, the deployment of such a system also requires other fully implemented components, such as the OMG's Person Identification Service (PIDS) to ensure unique identification of patients, TQS to manage different nomenclatures, and the Resource Access Decision (RAD) service to impose security policies. These components are required not only as far as COAS is concerned, but also in the general context of HYGEIAnet and are work-in-progress, partly implemented today.

Discussion

HYGEIAnet builds on a regional healthcare information infrastructure to improve the quality and accessibility of health care and to enable the delivery of integrated health care services. It provides the information and services that are the foundation for accountability, continuous improvement to health care, and better understanding of the determinants of the population's health. The design of HYGEIAnet is based on the existing regional healthcare system in Greece. Its goal is to serve local the local population, regardless of whether they are patients, healthcare professionals, researchers, or managers. The I-EHR environment, as it has been developed and set up, provides a decentralized view of the patient's medical record, by dynamically composing information that resides in a variety of heterogeneous clinical information systems. Under a secure Internet/ Intranet environment, the full personal health history can be rapidly collected and composed totally transparently and

sent to the authorized health professional (the Internet/ Intranet is not limited in capacity). In addition, maintaining electronic health record information is extremely economical to the very end users and consumers of the system (the citizens themselves), since the cost is transferred to the healthcare practitioners keeping primary information and to telecom operators and ISPs maintaining regional or national networks. The I-EHR, as used in the current context, is "virtual" in that it provides a uniform view of data (metadata) possibly configured to work differently at different locations.

Users seek selective information following specific paths, depending on their personal preferences, so it is expected that the I-EHR concept will eventually lead to a uniform applications and services environment. Since electronic records can provide much easier navigational facilities, navigational issues are expected to become even more important in the future, mainly because end-users require interfaces which are similar in look and feel.

The lack of a standardized interface for accessing clinical objects has forced the current implementation to follow an open architecture approach that utilizes the best available technologies for accessing clinical multimedia data. It is indeed a fact that information systems use different technologies and terms for accessing the same clinical objects. CORBAmed currently leads the definition of the interoperable specification effort that can support activities related to directly accessing a greater variety of healthcare information. XML provides the appropriate technology and makes up the most convenient vehicle towards

a common format for delivering and presenting information content. Elaboration of the standard DTD logical structure and related XML infrastructure will make information personalization flexible and generic enough to adapt to various types of users and client devices. Since documents (accompanied of course by the physician's signature) are much more easily accessible than data inside a database, XML has the potential of becoming a very cheap technology, provided of course, that the underlying HII exists. XML can be introduced incrementally, and its implementation is completely transparent to the end user. One of the main advantages of this approach is the support of context searching capabilities.

Currently, major organizations like Health Level Seven (HL7) [10], the Comité Européen de Normalisation Technical Committee 251 [11], and the American Society for Testing and Materials [12] work in modeling the electronic health record and are expected to provide useful DTDs for the healthcare domain. In the case of HL7 Clinical Document Architecture (previously known as 'Patient Record Architecture'), defined as "a document markup standard for the structure and semantics of exchanged clinical documents," documents are encoded in XML and can be put in a hierarchy of increasing strictness and detail. At the HL7 level, the only HL7 DTD currently available is one DTD, which uses only blocks of free text and coded entries to represent the patient's record. Unfortunately, very few results about the standardization of DTDs currently exist worldwide for the medical domain; no need mentioning best practice examples, and significant effort ought to be paid towards that direction.

Acknowledgments

Conflicts of Interest

None declared.

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Appendix 1

```
<!ELEMENT Query (Observation)*>
<!ATTLIST Query TimeofQuery CDATA #REQUIRED
                WhoAsk CDATA #REQUIRED
                SelectedQuery CDATA #REQUIRED
                GeographicRegion CDATA #REQUIRED
                TimeRange CDATA #REQUIRED
                Gender CDATA #REQUIRED
                Age CDATA #REQUIRED
<!ELEMENT Observation (AtomicObservation | CompositeObservation)>
<!ATTLIST Observation Patient_ID CDATA #REQUIRED
                Information_System CDATA #REQUIRED
                Visit_ID CDATA #REQUIRED>
<!ELEMENT CompositeObservation ((AtomicObservation | CompositeObservation)*
                    ,ObservationReference *, ObservationQualifier *)>
<!ATTLIST CompositeObservation   ObservationType CDATA #REQUIRED
                              ObservationTime CDATA #IMPLIED>
<!ELEMENT AtomicObservation (ObservationValue,ObservationReference*, ObservationQualifier *)>
<!ATTLIST AtomicObservation    ObservationType CDATA #REQUIRED
                              ObservationTime CDATA #IMPLIED>
<!ELEMENT ObservationValue ((PlainText | NoInformation | CodeElement | LooselyCodeElement | Curve
                   MultiMedia | DateTime | Measurement | TechnologyInstanceLocator),
                   ObservationQualifier *)>
<!ELEMENT Plaintext EMPTY>
<!ATTLIST PlainText  Value CDATA #REQUIRED
                   language CDATA #IMPLIED>
<!ELEMENT NoInformation EMPTY>
<!ATTLIST NoInformation reason CDATA #REQUIRED>
<!ELEMENT CodeElement EMPTY>
<!ATTLIST CodeElement value CDATA #REQUIRED
                    printName CDATA #IMPLIED>
<!ELEMENT LooselyCodeElement EMPTY>
<!ATTLIST LooselyCodeElement text CDATA #REQUIRED
                   codingSchemeID CDATA #REQUIRED
                   versionID CDATA #REQUIRED>


<!ELEMENT Curve EMPTY>
<!ATTLIST Curve values CDATA #REQUIRED
               xUnits CDATA #IMPLIED
               yUnits CDATA #IMPLIED
<!ELEMENT Multimedia EMPTY>
<!ATTLIST Multimedia header CDATA #REQUIRED>
<!ELEMENT DateTime EMPTY>
<!ATTLIST DateTime value CDATA #REQUIRED
                  relationalOperator CDATA #IMPLIED
                  accuracy CDATA #IMPLIED
                  accuracycontext CDATA #IMPLIED
                  accuracyUnit CDATA #IMPLIED>
<!ELEMENT Measurement EMPTY>
<!ATTLIST Measurement NumericValue CDATA #REQUIRED
                   units CDATA #IMPLIED>
<!ELEMENT TechnologyInstanceLocator EMPTY>
<!ATTLIST TechnologyInstanceLocator protocol CDATA #REQUIRED
                                 address CDATA #REQUIRED>
<!ELEMENT ObservationQualifier (QualifiedBy)*>
<!ATTLIST ObservationQualifier ObservationQualifierType CDATA #REQUIRED>
<!ELEMENT QualifiedBy (ObservationQualifier)+>
<!ELEMENT ObservationReference EMPTY>
<!ATTLIST ObservationReference ObservationReferenceType CDATA #REQUIRED
                   ObservationReferenceName CDATA #REQUIRED
                   Patient_Id CDATA #REQUIRED
                   Information_System CDATA #REQUIRED
                   Visit_Id CDATA #REQUIRED
                   ObservationTime CDATA #IMPLIED>
```

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Abbreviations

CMI-HTA: Centerfor Medical Informatics and Health TelematicsApplications
COAS: ClinicalObservation Access Service
CORBA: CommonObject Request Broker Architecture
COM+: CommonObject Model Plus
DCOM: Distributed Common Object Model
DTD: Document Type Description
EHR: Electronic Health Record
FORTH: Foundation for Research and Technology - Hellas
FTP: FileTransfer Protocol
GUI: Graphical User Interface
HII: Healthcare Information Infrastructure
HRA: HYGEIAnet Reference Architecture
HTML: HyperText Markup Language
HTTP: HyperText Transfer Protocol
I-HER: Integrated Electronic Health Record
IDL: Interface Definition Language
ITU: International Telecommunication Union
LDAP: LightDirectory Access Protocol
ODBC: OpenData Base Connectivity
OMG: ObjectManagement Group
PC: PersonalComputer
PCDD: PatientClinical Data Directory
PDF: PortableData Format
PIDS: PersonIdentification Service
RAD: ResourceAccess Decision
SGML: StandardGeneralized Markup Language
SQL: Structured Query Language
SOAP: Subjective Objective Assessment Plan
TQS: Terminology Query Service
WAP: WirelessAccess Protocol
WWW: WorldWide Web
XML: Extensible Markup Language
XSL: Extensible Stylesheet Language

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Original Paper

Developing a European internet and kiosk-based health information system

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Abstract

A consortium of partner organisations (universities, health care organisations and information technology companies) from Northern Ireland, Germany, Portugal and Italy have collaborated to develop a multi-lingual, multi-media Internet and kiosk-based health information system in cardiology and skin cancer. The project, CATCH II (Citizens Advisory System based on Telematics for Communication and Health), has been funded by the European Commission under the Fourth Framework Research and Development TELEMATICS Applications Program (TAP), Health Care Sector. In this paper we provide an overview of the system and the methodological approach adopted. Key characteristics with respect to the technical architecture and flexible customisation of different web and kiosk-based versions will be presented. In particular, the development of dedicated software for the procurement, structuring and management of the information knowledge-base is illustrated. Some of the most interesting findings from a cross-national study of 'health information needs on the internet' are presented along with information on the validation of the system by the general public, content providers and health care authorities.

Introduction

In recent years, the number of people accessing the World Wide Web (WWW) has increased beyond expectation. All manner of users, from the casual surfer to the professional can avail themselves of this vast information resource, with health information and health promotion resources being prominent [1]. The Internet is seen as a new medium for the dissemination of health related information having the potential to reach a global audience. It is with this potential in mind that the idea of the European CATCH II (Citizens Advisory System based on Telematics for Communication and Health) project came about.

Funded by the European Commission under the Fourth Framework Research & Development TELEMATICS Applications Program (TAP) in the area of Health Care, the system is being developed by a consortium of partner organisations (universities, health care organisations and IT (Information Technology) companies) from Northern Ireland, Germany, Portugal and Italy. The aim of CATCH II, which has been in existence since January 1998, was to develop, evaluate, and disseminate a methodology and framework for the creation, maintenance, update, and configuration of multilingual, multimedia, medical information systems for the European citizen. The final objective is to provide a system that facilitates the collation, management and dissemination of a comprehensive health information knowledge-base that can be accessed easily via the Internet or stand alone kiosks. CATCH II is an extension of its predecessor CATCH I (an EU (European Union) project funded under the same program) to develop a touch-screen kiosk-based health information system. The key objective of CATCH II was the redesign and migration of the system from a stand alone kiosk version to a multi-functional kiosk and internet system.

Previous studies have demonstrated that much of the health information on the web is of variable and inconsistent quality,

difficult to understand [2,3,4] and difficult for medical professionals to make direct contributions [5,6]. While the Internet has the capability of transforming the future of online health information systems, "...the potential for misinformation and confusion is there on the web" [7]. A significant pitfall with many systems is that they lack the endorsement of medical professionals and verification of the medical information provided. CATCH II attempts to address such problems by only offering material that has been created, proofed and certified by professionally recognised medical organisations, public health institutions and university faculties of medicine in several European countries. A user needs study clearly established the requirement to create easy to use tools for professional medical content providers, to give them direct interactive control of how information is input, managed and presented. This aspect is discussed further in the CATCH II methodology section.

User needs study and technical/functional specification

Prior to the development of the system, a user needs study was conducted in the four participating countries. The study included two independent surveys - the first consisted of a survey of a stratified random sample of the *general public* and the second was a set of semi-structured interviews with a variety of *health care professionals* with a particular remit for health promotion. For the general public survey, respondents were asked for their opinions and attitudes towards a range of important issues such as health behaviour and lifestyle, attitudes to health promotion, familiarity with computing, the Internet and kiosk technologies and their use for health related information. Consumers involved were surveyed using a questionnaire based study in Germany (n = 300), Italy (100), Portugal (101) and Northern Ireland (122). A response rate of circa 90% was achieved in all countries. The objective was to identify any content and technical issues, including cross-cultural differences, which should be accommodated for in the development of a multi-lingual, multi-national health information system. It was also important to examine attitudes of the public about the future potential of kiosk and Internet-based health information systems. The semi-structured qualitative interviews with health care professionals were conducted among representatives from various organisations in Germany and Northern Ireland e.g. Federal Central for Health Education (BzgA) in Germany and the Western Area Health and Social Services Board in Northern Ireland. These organisations and their representatives were selected as key organisations within their respective national health care structures and the fact that 'health promotion' plays a large role in their day to day activities. In all, eighteen interviews were carried out in Germany and fourteen in Northern Ireland. All of the organisations asked to participate in the study did so willingly. The interviews were designed to elicit information on the various ways health promotion activities are managed and delivered within different European health care systems. Also, current methods of best practice in the creation, management and presentation of health promotion information were investigated. Respondents were asked their opinions about the use of the Internet and kiosks as modes for the delivery of health information and for ways in which our system methodology in particular could facilitate new and better ways for the creation, management and delivery of health promotion materials.

The results, summarised very briefly here, yielded some interesting findings with implications for the design of the functional and technical specifications of the system. From the general public survey, differences in health behaviour between countries were clearly evident. For example, people in the southern European countries are more likely to smoke while the northern Europeans are more likely to drink alcoholic beverages (especially beer and spirits rather than wine and in greater quantities). The implication is that a European health information system might require various languages and a different emphasis or approach to particular issues for particular countries. Other significant issues related to a general lack of satisfaction with current Internet and kiosk-based health information systems. In particular, respondents were less than complimentary about the volume and complicated (medical) nature of many texts and images, ease of navigation and general usability of some systems. Many were of the opinion that navigational tools should be made more intuitive to enhance the concept of a user-friendly system. Textual information and images were generally viewed as being too convoluted in terms of the medical language used. It was therefore in the remit of CATCH II to provide legitimate information in a format that is easy to interrogate and understand.

From the health care authority survey it was evident that the Internet and information communications technologies (ICT) in general have great potential for health promotion activities. To date though very few agencies were making use of such technologies, the Northern Ireland Health Promotion Agency (http://www.healthpromotionagency.org.uk/) and the German AOK health Insurance Company (http://www.aok-info.de/) being notable exceptions. It was also clear from the perspective of content creation, that the development of a simple user-friendly system for the transfer of existing materials and the creation and management of new materials into a suitable format for web and kiosk media would be extremely valuable. The point was regularly made that the owners and creators of health promotion information, being medical professionals and not computer scientists, would benefit greatly from such a method and that their needs should be taken into consideration.

From a user needs study (of potential end users and content creators) and previous experience of the consortium team, the functional and technical specifications were identified to facilitate the successful implementation of the CATCH II system. The functional specification defined the performance requirements of the CATCH II system; the technical specification defined the technology that is required to meet the functional specification (Figure 1). Failure to meet the users' needs would result in the system failing to gain widespread support and acceptance. Both the user needs study and previous work on the prototype system provided input to these specifications to ensure the system was properly constructed.

**Figure 1.** Iterative process of functional & technical specification
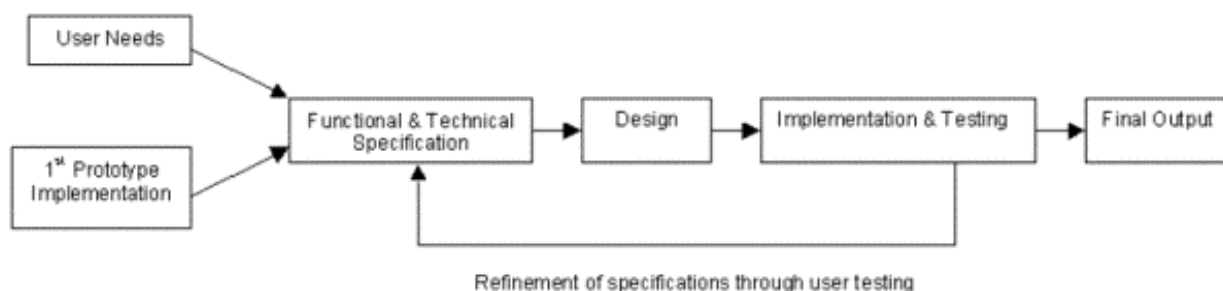
The CATCH II methodology

Taking into account the functional and technical specifications and the key findings of the user needs study, the CATCH II team developed a unique methodology that would act as the framework to carry our project through to implementation. The methodology itself is comprised of five main sections; content creation, data preparation, data management, verification and presentation and dissemination (Figure 2). The process begins with a content creator (e.g. a medical specialist) who has materials on a particular subject and wishes to incorporate them into the CATCH II system. The medical professional is core to this methodology; they are responsible for the provision of appropriate structured information and are placed at the beginning of the process in an attempt to provide freedom from excessive restrictions and regulations that may be imposed by technological factors [8,9,10]. All relevant materials for inclusion are 'storyboarded' to include all relevant links and

associations between components (be they text, graphics, audio or video). The individual components are then incorporated into the system using one of two specially developed editing tools and an associated CATCH II medical domain ontology (as described later).

The texts created by the medical professionals are then structured and have metadata added in an XML (eXtensible Markup Language)-like format. With these tagged texts, the value added information allows alternative databases to be prepared for presentation use. The medical professional is responsible for the accurate content of the system along with the page authoring. As the system of tagging using the editing tools is very intuitive and easy to put into practice, the medical professional would have little problem in carrying out this procedure. Few computer skills are necessary to use the editors. As the system was a prototype methodology, medical experts involved in the project were eager to perform their role as content creators.

Figure 2. The CATCH II methodology
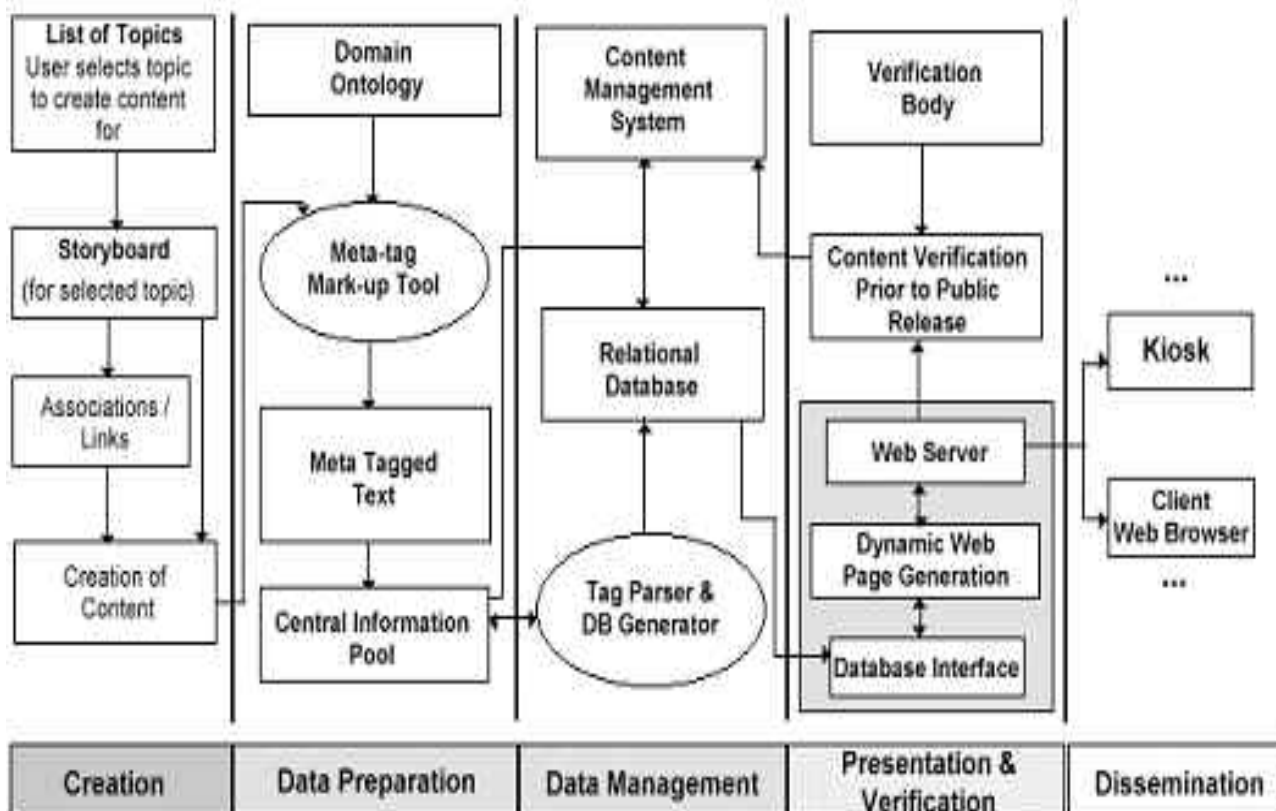
CATCH II authoring environments

A key requirement identified from the user needs of the medical professional was the provision of an easy to use content authoring tool that would assist in the realisation of the domain ontology for the human body. The CATCH II team developed two individual tools, *ConteXt* and *CEdit* [11]. Both satisfied the methodology as outlined above but used different modes of delivery, i.e. ConteXt can be downloaded, installed on the client machine and be run locally whilst CEdit is a Java applet designed to run over the web. For the purposes of this paper the ConteXt editor is demonstrated.

The authoring environment is made up of two key components - an editor and a domain ontology, upon which the editors are built. An ontology defines the basic terms and relations comprising the vocabulary of a topic area, as well as the rules for combining terms and relationships to define extensions to that vocabulary. They are ' *explicit specifications of conceptualisations*'. The CATCH II ontology is not designed to become a scientific domain ontology like SNOMED [12] or MESH. What authors need to fulfil their task is a practical tool

that allows them to characterise the nature and the intention of a text element.

ConteXt is a tool that we designed for the structuring and management of reusable multimedia content. It grew out the need to help the medical professionals creating the content for websites [13,14,15,16]. *ConteXt* has the ability to structure, tag texts and then to store these texts in a central information pool. From this pool, the information can be extracted and displayed in a browser. Effectively, *ConteXt* is a text and graphic management tool with specialised functionality that is heavily based upon the domain ontology. The current ontology is comprised of medical terms specifically relating to the human body (cardiology and skin cancer). The tool allows editing of texts, addition of meta-tags and placement of texts into appropriate sections using the domain ontology. The author, or content creator, begins by creating a piece of text by directly typing new content or importing text for mark-up. This text must also have metadata added. Metadata is *data about data*. Its inclusion extends content reusability because it defines structural units and individual elements of the texts that can be manipulated and used in a variety of different contexts. Additional video and audio files can also be associated with the section of domain content.

Figure 3. Example of using ConteXt to add metatags
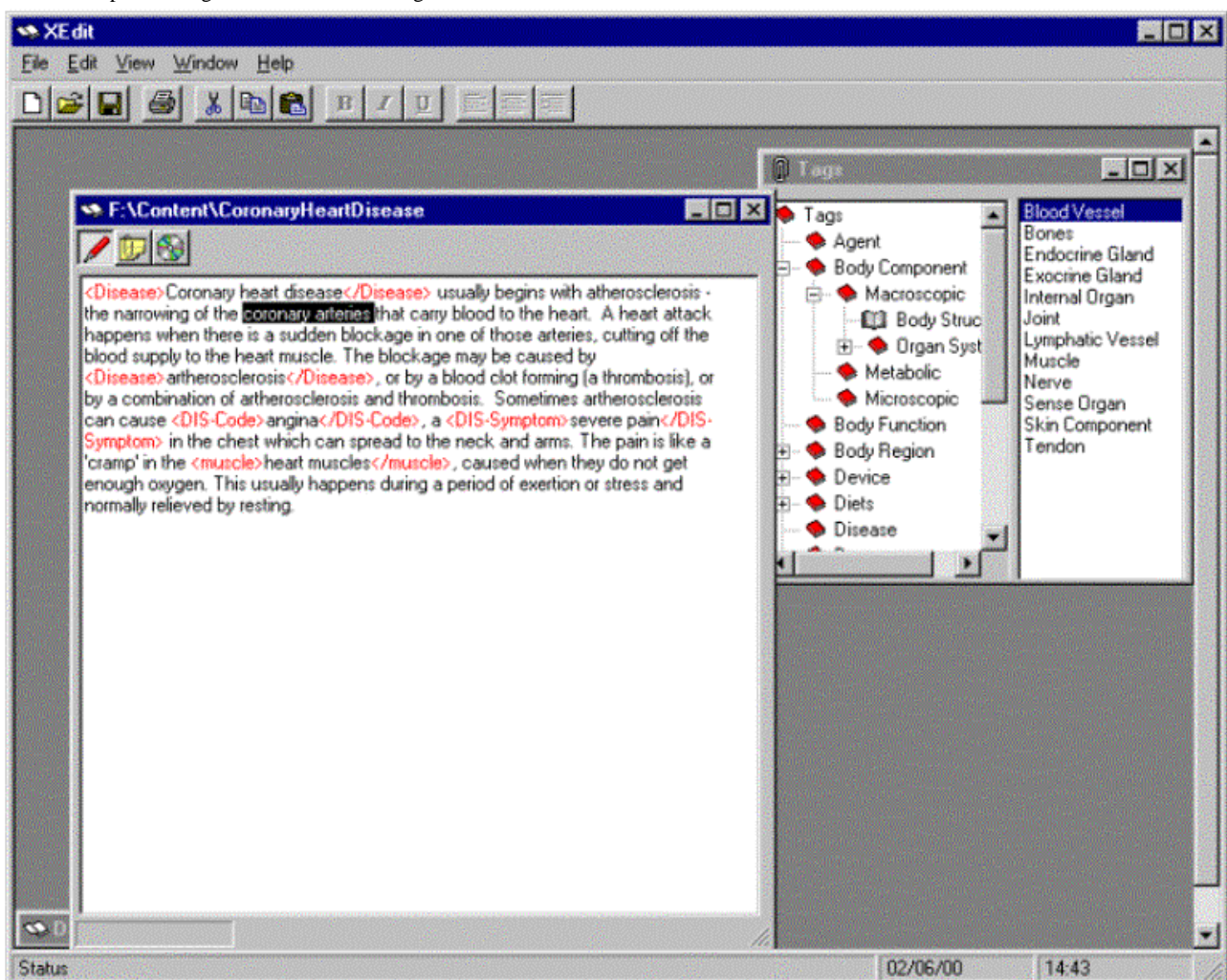
One of the primary functions of ConteXt is to add metadata to created texts. The metadata is physically incorporated using XML(eXtensible Markup Language)-like tags [17,18]. These tags are defined by the domain ontology. To tag a piece of text, the user highlights the desired piece of text and then selects the appropriate tag from a menu. This process is similar, for example, to making a piece of text bold in a word-processor (see figure 3 above). A description of the ontology is dynamically loaded at runtime; this defines the tags available for selection by the content creator. Figure 3 shows how the tags can be selected from the 'Tags' window, which contains the entire ontology. Tagging texts in this manner is key to making the texts reusable. The tagging function maps directly to the underlying tables that warehouse the data.

The tagging process is particularly valuable when addressing the topic of information presentation. The tags allow the texts to be easily categorised and searched with a view to creating customised databases specifically for presentation purposes. For example, we can extract all texts which are connected with sunburn. These can then be placed in a simple database to be read for display by a kiosk or web application under that medical theme.

The current CATCH II Web site uses these procedures to dynamically produce HTML pages from the database. The web server accepts a request, queries the database, extracts the results and prepares a formatted web page that is then sent to the requesting client. The CATCH II web site was initially produced in English and German.

Kiosk-based systems have different technical considerations because of additional functional requirements [19,20,21,22]. In the case of CATCH II, the kiosk-based system should be functionally similar to the web-based system, and therefore should use similar underlying structures in an off-line fashion. That is, the server-side for the web-based system should be used as the framework to provide the requested information to the kiosk. This information can then be structured and presented in a format appropriate for touch screen kiosks. The CATCH II kiosk system deployed only a German translation. However, a direct translation of the skin cancer topics were replicated in the English website version. Figure 4 below shows a multimedia example of both the current CATCH web site and kiosk system.
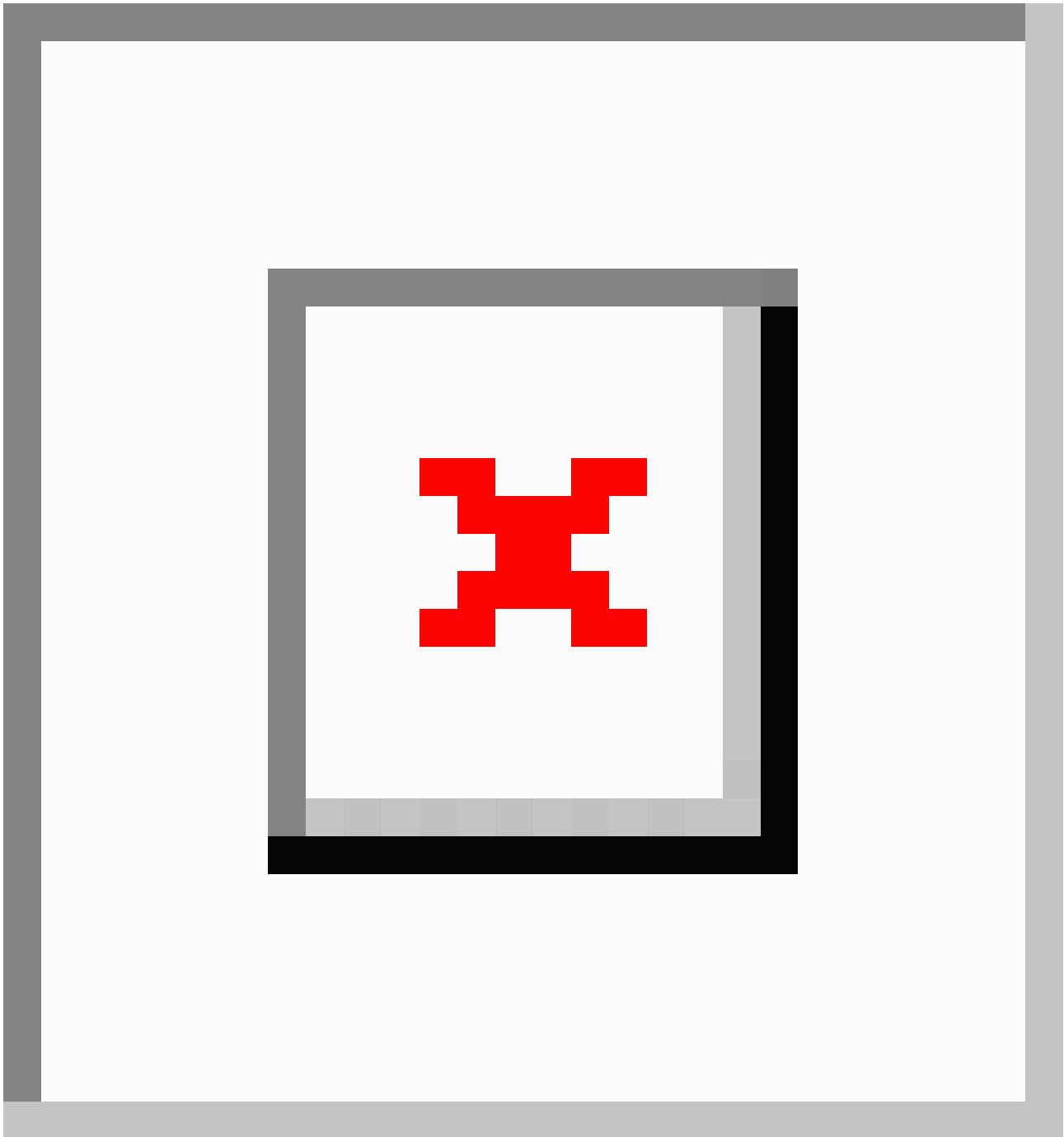
Figure 4. The web-based system

Figure 5. The kiosk-based system

Validation

Throughout the validation phase of the project various procedures and de facto standard instruments were used to assess the value of key components within the overall project. In addition, workshops were set up to evaluate the responses of medical content providers and health promotion professionals. Validation was carried out from three very different perspectives; technological, end-user and health care authorities.

A standard industry tool, WAMMI (Web Site Analysis and MeasureMent Inventory), produced by the Human Factors Research Group in Cork, Ireland was adopted to evaluate the usefulness of the web system. It proved to be a convenient and cost-effective method of assessing the value and usefulness of the Internet system. WAMMI uses a scoring program with six categories: attractiveness, controllability, efficiency, helpfulness, learnability and global usability. Results showed that the web site scored above average on four of the five single measurement scales (except controllability). In particular, the two best scores were obtained for the attractiveness of the web site and the efficiency of the web site. The composite score measuring global usability revealed that overall the web site had been rated above average, indicating that users were generally happy with the function, style and feel of the site. A separate questionnaire was developed for the evaluation of the kiosk-based system. Respondents were confronted with different statements about

the content, the presentation and the quality of use. Additionally, suggestions and opinions, which would help to design the kiosk system in a more interesting and informative way, were sought. On the whole, the participants of the validation assessed the kiosk version positively.

Validation of the editing software was performed with SUMI (Software Usability Measurement Inventory) developed by Nomos, Sweden. It is a rigorously tested and proven questionnaire-based method of measuring software quality from the end user's point of view. It is also considered as a consistent method for assessing the quality of use of a software product or prototype and can assist with the detection of usability flaws before a product is launched. Medical professionals, and other potential content creators, from the UK, Germany, Italy and Portugal were selected to use and experiment with the software and then complete a SUMI questionnaire.

The results indicated that respondents in general had very little difficulty learning to operate the software. They felt that it was efficient and they could perform data entry functions e.g. tagging of text and graphics easily. An interesting endorsement of the software was that many of the users would have recommended it to their colleagues, suggesting that it is a quality product.

Health care authority validation workshops were conducted in participating countries. The objective was to try and establish if those people directly involved in health promotion activities thought that the CATCH II system (its methodology and

component parts) could play a realistic and practical role in the promotion of health within their respective domains and for the European citizen. From the feedback, it was very clear that all of the participants were impressed with the system and viewed it as a very innovative approach to providing health promotion information. It was also encouraging that many could see ways in which they could adapt CATCH II or components of the system into the practices of their own organizations.

A number of issues were consistently raised and discussed by participants. In general, they centered around the content of the system - for example, verification, certification, ownership and control of the information, quality assurance and consistency and the form in which information was presented to the public (i.e. the type of language used). This was an important finding as it highlighted some of the issues that the project was already trying to address directly. For example, the development of the remote editing tools was a deliberate attempt to give control of the creation, management and presentation of information to the content creators and health care specialists as opposed to technical professionals.

Conclusions

The CATCH II project demonstrated the importance of engaging the user community of the intended target system in order to evolve a flexible methodology for its eventual realisation. This has been made possible by devoting the time to take into consideration the drawbacks of existing Internet-based health information systems, to consider comments from citizens in each country, and to engage the health authorities and medical professionals who could benefit from our approach. The methodology and tools we have developed under CATCH II can be easily customised to include other health modules, or indeed address other information-rich applications that require a presence on the Internet.

The development of the methods and processes described above will continue and attempt to embrace the advanced technologies of the Internet. We see our approach as having applications beyond the health domain and welcome the opportunity for further discussion and collaboration with colleagues and interested parties.

Conflicts of Interest

None declared

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<u>Original Paper</u>

Wireless access to a pharmaceutical database: A demonstrator for data driven Wireless Application Protocol applications in medical information processing

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Abstract

Background: The Wireless Application Protocol technology implemented in newer mobile phones has built-in facilities for handling much of the information processing needed in clinical work.

Objectives: To test a practical approach we ported a relational database of the Danish pharmaceutical catalogue to Wireless Application Protocol using open source freeware at all steps.

Methods: We used Apache 1.3 web software on a Linux server. Data containing the Danish pharmaceutical catalogue were imported from an ASCII file into a MySQL 3.22.32 database using a Practical Extraction and Report Language script for easy update of the database. Data were distributed in 35 interrelated tables. Each pharmaceutical brand name was given its own card with links to general information about the drug, active substances, contraindications etc. Access was available through 1) browsing therapeutic groups and 2) searching for a brand name. The database interface was programmed in the server-side scripting language PHP3.

Results: A free, open source Wireless Application Protocol gateway to a pharmaceutical catalogue was established to allow dial-in access independent of commercial Wireless Application Protocol service providers. The application was tested on the Nokia 7110 and Ericsson R320s cellular phones.

Conclusions: We have demonstrated that Wireless Application Protocol-based access to a dynamic clinical database can be established using open source freeware. The project opens perspectives for a further integration of Wireless Application Protocol phone functions in clinical information processing: Global System for Mobile communication telephony for bilateral communication, asynchronous unilateral communication via e-mail and Short Message Service, built-in calculator, calendar, personal organizer, phone number catalogue and Dictaphone function via answering machine technology. An independent Wireless Application Protocol gateway may be placed within hospital firewalls, which may be an advantage with respect to security. However, if Wireless Application Protocol phones are to become effective tools for physicians, special attention must be paid to the limitations of the devices. Input tools of Wireless Application Protocol phones should be improved, for instance by increased use of speech control.

KEYWORDS

Medical Informatics Applications; Database Management Systems; Dictionaries, Pharmaceutical; Wireless Application Protocol; Open source software

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Introduction

The Global System for Mobile communication (GSM) digital wireless network that is used to transmit audio communication in cellular phones may also be used to transmit data at rates that are typically limited to 9600 bits/s. However, for access to the Internet a mobile phone needs connection to a computing device, i.e. either a portable or stationary computer or a Personal Digital Assistant (PDA) with an appropriate interface connection. The Wireless Application Protocol (WAP) is a specification for a communication protocol used to standardize the way wireless devices, such as cellular telephones and radio transceivers, can be used for Internet access, including e-mail and the World Wide Web. The aim of using a standard protocol is to enable devices and service systems that use WAP to operate together. The advantage of WAP phones is that connection to the Internet can be obtained using a modem, a small computer, and a dedicated browser all of which are built into the WAP device. On the other hand, the small screen size, keyboard size, lack of pointing device and especially the low bandwidth made it necessary to develop a standard for design of web pages aimed at WAP devices and a modified markup language, the Wireless Markup Language (WML), had to be developed, taking the limitations of the device into consideration. Cellular phones using the WAP for access to the Internet comprise potentials for assisting in handling many clinical information needs [1].

- Conventional GSM telephony for synchronous, two-way voice telephony
- Asynchronous unilateral communication via e-mail and Short Message Service (SMS)
- Dictaphone function using answering machine technology or built-in speech message facilities
- Built-in calendar and personal organizer functions
- Phone number catalogue and other smaller databases built into the device
- Calculator and other dedicated built-in applications

In addition WAP technology allows access to databases on Internet servers - e.g. pharmaceutical information, laboratory data, educational materials, and access can be gained to Internet based Electronic Patient Records [2]. Reference materials (pocket manuals) are often used by physicians in the daily work, but printed reference books are rarely updated and may thus become outdated. Many doctors carry some sort of paging or communications device like a PDA with varying capacity to store clinical databases. There are a number of advantages to be gained by incorporating references manuals and other clinical information into handheld devices through the WAP standard [3]. This would allow easy access to several reference manuals through a single device. Manuals would be updated centrally and dynamically. Although many of the functions mentioned are already available in today's cellular phones, they have only been exploited only to a limited extent. This paper describes our first experiences with porting a pharmaceutical database to a WAP accessible database, involving the following steps:

a. a) A pharmaceutical relational database was interfaced with server side scripting and deployed to a WAP device
b. b) The information should be formatted in a way suited for small handheld devices
c. c) The project was implemented using a standard personal computer without purchase of any new software

Methods

Web Server

Establishing a data-driven online resource available to WAP devices requires a modified web server, with a database engine and a programming interface to the database. If the server needs to work as a dial-in interface for the WAP device, a WAP gateway must also be established. All of these features were implemented using free, open source software. Documents served from a web server are associated with a Multi-Purpose Internet Mail Extension (MIME) type. The MIME type is needed by the browser to determine how the file should be processed (e.g. rendered like a normal hypertext markup language (HTML) file or handled by a helper application). The file types used for WAP devices have a new set of MIME types (Table 1) unknown to most web servers and the web server must have these types added.

Table 1. WAP MIME types

MIME type	File extension	Content
Text/vnd.wap.wml	.wml	WML source code
Application/vnd.wap.wmlc	.wmlc	Compiled WML
Text/vnd.wap.wmlscript	.wmls	WML script source code
Application/vnd.wap.wmlscriptc	.wmlsc	Compiled WML script
image/vnd.wap.wbmp	.wbmp	Wireless bitmap

We used an *Apache 1.3* web server installed on a Linux server. The MIME types were registered by adding the lines shown in (Table 1) to the configuration file "httpd.conf":

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```
AddType text/vnd.wap.wml .wml
AddType application/vnd.wap.wmlc .wmlc
AddType text/vnd.wap.wmlscript .wmls
AddType application/vnd.wap.wmlcscriptc .wmlsc
AddType image/vnd.wap.wbmp .wbmp
```

Database

Data containing the Danish pharmaceutical catalogue was imported from an ASCII file received every two weeks from the Danish Medical Association. Data was distributed in 35 interrelated tables with easy access to the hierarchy in the pharmaceutical directory, facilitating browsing through the pharmaceutical classes. The database structure also facilitated search for specific brand names or active substances. Import into a MySQL 3.22.32 database was done using a dedicated Practical Extraction and Report Language (Perl) script designed for easy update of the database. The program structure was designed around the brand names. Each brand name was given its own WML page (card) with links to general information about the drug, active substances, contraindications etc. Access to these cards was available through browsing the therapeutic groups or searching for a specific brand name. The text entry was made as simple as possible. Typically only the first three characters of the brand name need to be entered before activating the search.

Programming

A server-side scripting layer was used to interface the database. The scripting layer is used to a) send SQL queries to the database and b) format the data from the database as WML for interpretation by the WAP gateway. The database interface was programmed in the server-side scripting language PHP3. PHP is designed as a scripting language embedded in HTML and it is designed to generate HTML. To ensure that the content returned by the script was WML the document MIME type was sent explicitly with the "header" function. An example of a PHP script that returns a WML page is shown in Figure 1.

Figure 1. An example of the code to be entered in the header of the WML document for the web

```php
<?php
header("Content-type: text/vnd.wap.wml");


echo "<?xml version=\"1.0\" ?>\n";
echo "<!DOCTYPE wml PUBLIC \"-//WAPFORUM//DTD WML 1.1//EN\"
\"http://www.wapforum.org/DTD/wml_1.1.xml\"> \n\n";
echo "<wml> \n";
echo "<p>Example WML/PHP script</p> \n";
echo "</wml>";
?>
```

This example does not send any queries to the database, but it illustrates how http headers can be formed with the correct MIME type using PHP. Database queries were handled through the structured query language (SQL) access to the database and the contents of the database were sent to the WAP enabled device. The choice of scripting language is somewhat arbitrary. Other popular scripting languages like Active Server Pages (ASP) or Perl could also have been used. The communication between cellular phone and database could also have been implemented through an executable application on the web server (e.g. C/C++ programming). However, the overhead involved in starting a process for each database request, makes such a solution less feasible. Regardless of the implementation strategy, special care should be taken to ensure that the content-type header field is formed correctly.

Dataflow

The communication between a handheld device and a database passes through several different layers and different communication protocols are used (Figure 2). The individual layers have restrictions some of which are crucial to the implementation of the WAP application.

The handheld device connects to an Internet Service Provider (ISP) with a standard Point to Point protocol (like connecting to the Internet with a standard modem)w. The ISP is in contact with a WAP gateway; the ISP often provides both the Internet access and WAP gateway. The gateway may be public and provided by one of the mobile telecommunication companies. (See a list of public gateways at 4. www.wapdrive.com. WAP Gateways around the world. www.wapdrive.com/DOCS/wap_gateway/index.html) [4] or it may be private (see below). The role of the ISP is to transmit data between the handheld device and the gateway. The gateway sends requests from the phone to web-servers on the Internet and it encodes the results received from the web-servers to a more compact form to facilitate the communication across the low bandwidth connection. The encoded data is sent to the handheld device using the WAP. The amount of data that can be sent to the handheld device depends on the device. The Nokia 7110 has a limitation of 1397 bytes in the compressed form sent by the

gateway [5]. An uncompressed WML document should be kept below 1500 bytes to ensure that handheld devices can receive it. When the handheld device sends a request for a Uniform Resource Locator (URL), the gateway passes the request to the web-server using the standard http-protocol. The web-server handles the requests as it would a normal request for a web page. However, if the requested URL is a WML document the request is returned to the gateway for further processing. If the URL refers to a script (in this case a PHP script), the PHP interpreter will process the script (handle database queries, format the output and return it to the gateway). The gateway will subsequently encode and compress the data for transmission with the WAP protocol.

Figure 2. The flow of data during a request from the WAP device
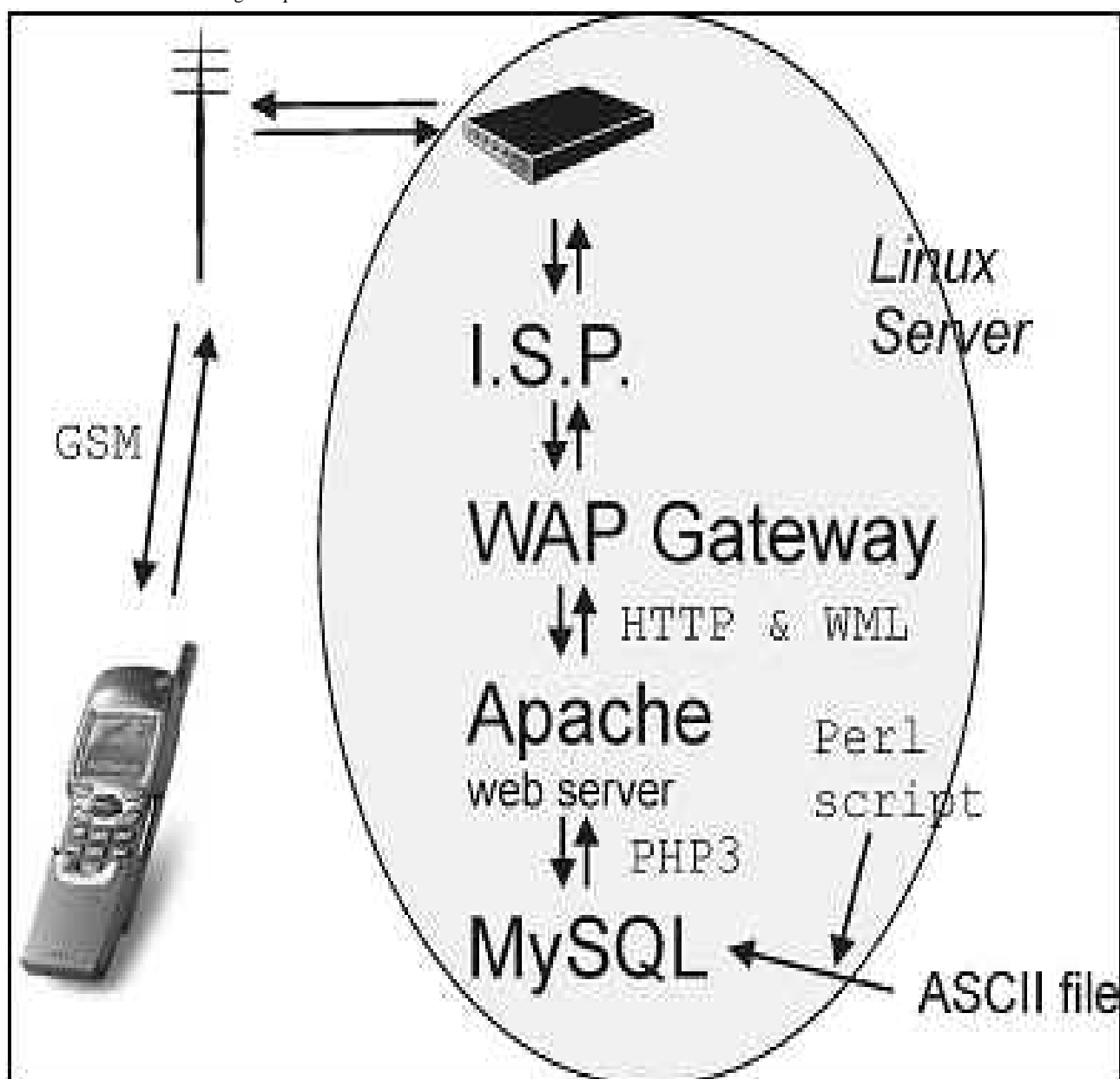
Figure 2. The flow of data during a request from the WAP device.
The mobile phone and the gateway communicate through the Wireless Application Protocol and the Gateway talks to the web server using HTTP. Requests for URLs containing scripts are first interpreted by the server (any SQL queries are sent to the database) and the output is returned to the gateway. The database gets its input from an ASCII file.

WAP Gateway

A WAP Gateway was established for direct dial-in access to the pharmaceutical catalogue. A free, and open source gateway was downloaded from www.kannel.org [6] and installed on a Linux server. The gateway is still being developed and the latest stable version is 0.11.2 (September 29th 2000). The gateway relies on an Extensible Markup Language (XML) parser to interpret the WML pages and the Linux server should have the library: libxml-1.8.7 or higher installed to compile the gateway.

For dial-in, a modem (ISDN or analogue) was connected and controlled by dial-in software on the server.

Phone set-up

The WAP enabled phone must be configured to access the appropriate gateway. Phone number, username and password (for the dial-in connection) and IP-address of the gateway (the IP-address of the server running the gateway) must be entered in the phone.

Figure 3. Sequence of screen dumps illustrating the search for of the dosage of Ibumetin on a Nokia 7110

Figure 3. Sequence of screen dumps illustrating the search for of the dosage of Ibumetin on a Nokia 7110. (Søg=search; præparat=brand name; Dosis=dosage; voksne=adults)

Results

A data driven interactive WAP-based pharmaceutical catalogue was established. Access to the individual brand names was available through free text search or by browsing the therapeutic groups. The application can be tested at http://hilist.au.dk/wap.php by using a public gateway or by using a WAP emulator on the www (Figure 3). Response time for accessing a new level in the catalogue hierarchy or completing a search was usually less than three seconds. Searching a brand name, which could be completed in only a few steps (Figure 3) in most cases was found to be faster than browsing the content hierarchy. The application was tested on Nokia 7110 and Ericsson R320s WAP phones. Several device-specific limitations were revealed. The display resolution is 95 x 45 pixels for the Nokia 7110 and 101 x 52 pixels for Ericsson R320s allowing four (Nokia) or five (Ericsson) lines of text to be displayed. The maximum amount of data per card (the maximum card size) was 1397 bytes for the Nokia and 3000 bytes for the Ericsson. These limitations must be considered when designing the WML pages (split data in a sequence of cards).

Discussion

With the present project we have demonstrated that an open source freeware WAP gateway to a complex database can be established with information of clinical relevance. However, a number of practical and technological problems still have to be solved before WAP devices can effectively substitute or supplement other devices for processing clinical information. Because of the high energy transmitted while communicating with GSM phones, their use is still prohibited within many hospital wards and the security is under debate [7,8]. Yet there seem to be several solutions to this problem. Handheld WAP devices, using a comparable communication technology, but transmitting significantly less energy may be used. The development of medical electronic devices for use on hospital wards is towards protection of individual devices that allows use of regular GSM communication without interference. The small screen and relatively ineffective input tools of the WAP phone should be improved. The first steps towards speech control have been taken on some newer WAP phones. Further development in this direction will significantly improve usability [9]. Doctors may connect to databases and even call for data on a specific patient by use of speech control. Further, the present speech message technology found in, for instance, the Ericsson R320s could be further developed to allow functions that are traditionally found in dictaphones. This would allow the physician to edit and finish a full dictation before sending the note for entry into the patient record. This technology will offer many advantages compared with present technologies; for example the secretary will have the dictated note directly available without a risk of audiotapes being mislaid and possibly the speech message could be stored on a central server for temporary access by others before it has been entered into the patient record. Testing the use of WAP phones for information processing in a clinical ward was not part of the present project. However, this project has shown that even with the small screen and scrolling text, once connection to the server is established, it is possible to fetch text from the database with a speed that comes close to normal reading speed. Entering larger amounts of text, however, is time-consuming on a cellular phone keyboard so we conclude that for text input is a bigger problem than output. New technologies are constantly being developed in an extremely dynamic market for handheld communication devices. Bandwidth is increased using i.e. the GPRS or UTMS services in conjunction with Bluetooth and other local wireless communication technologies. Functions found in PDA devices are being incorporated into cellular phones. Technology however, needs to be adapted to the clinical reality before we can expect a widespread use by physicians.

Conflicts of Interest

None declared.

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Abbreviations

Apache: is a freely available Web server that is distributed under an "open source" license. It runs on most UNIX-based operating systems

ASCII: American Standard Code for Information Interchange is the most common format for text files in computers and on the Internet. Bluetooth is a specification that describes how mobile phones, computers, and personal digital assistants can easily interconnect with each other and with home and business phones and computers using a short-range wireless connection Gateway is a network point that acts as an entrance to another network

GPRS: General Packet Radio Service is a packet-based wireless communication service that promises data rates from 56 up to 114 Kbps and continuous connection to the Internet for mobile phone and computer users

GSM: Global System for Mobile communication is the most widely used of the three digital wireless telephone technologies (TDMA, GSM, and CDMA). GSM digitizes and compresses data, then sends it down a channel with two other streams of user data, each in its own time slot. It operates at either the 900 MHz or 1800 MHz frequency band.

Http: Hypertext Transfer Protocol is the set of rules for exchanging files (text, graphic images, sound, video, and other multimedia files) on the World Wide Web

HTML: Hypertext Markup Language is the set of mark-up symbols or codes inserted in a file intended for display on a World Wide Web browser page.

ISP: An Internet Service Provider is a company that provides access to the Internet and other related services

IP: The Internet Protocol is the method or protocol by which data is sent from one computer to another on the Internet Linux is a UNIX-like operating system that was designed to provide personal computer users a free or very low-cost operating system comparable to traditional and usually more expensive UNIX systems

MIME: Multi-Purpose Internet Mail Extensions is an extension of the original Internet e-mail protocol that lets people use the protocol to exchange different kinds of data files on the Internet.

MySQL: is an open source relational database management system that uses Structured Query Language (SQL), for adding, accessing, and processing data in a database.

Perl: Practical Extraction and Reporting Language is a script programming language that is similar in syntax to the C language. It was invented by Larry Wall.

PDA: Personal Digital Assistant is a term for any small mobile hand-held device that provides computing and information storage and retrieval capabilities

PHP: is a script language and interpreter that is freely available and used primarily on Linux Web servers. The initials come from the earliest version of the program, which was called "Personal Home Page Tools"

SMS: Short Message Service is a service for sending messages of up to 160 characters to mobile phones that use Global System for Mobile (GSM) communication

UMTS: Universal Mobile Telecommunications System is a broadband, packet-based transmission of text, digitized voice, video, and multimedia at data rates up to and possibly higher than 2 megabits per second (Mbps)

URL: Uniform Resource Locator is the address of a file (resource) accessible on the Internet

WML: Wireless Markup Language, allows the text portions of Web pages to be presented on cellular telephone and personal digital assistants (PDA) via wireless access.

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Original Paper

The Use of Quality Benchmarking in Assessing Web Resources for the Dermatology Virtual Branch Library of the National electronic Library for Health (NeLH)

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Abstract

Background: In 1998, the U.K. National Health Service Information for Health Strategy proposed the implementation of a National electronic Library for Health to provide clinicians, healthcare managers and planners, patients and the public with easy, round the clock access to high quality, up-to-date electronic information on health and healthcare. The Virtual Branch Libraries are among the most important components of the National electronic Library for Health . They aim at creating online knowledge based communities, each concerned with some specific clinical and other health-related topics.

Objectives: This study is about the envisaged Dermatology Virtual Branch Libraries of the National electronic Library for Health . It aims at selecting suitable dermatology Web resources for inclusion in the forthcoming Virtual Branch Libraries after establishing preliminary quality benchmarking rules for this task. Psoriasis, being a common dermatological condition, has been chosen as a starting point.

Methods: Because quality is a principal concern of the National electronic Library for Health, the study includes a review of the major quality benchmarking systems available today for assessing health-related Web sites. The methodology of developing a quality benchmarking system has been also reviewed. Aided by metasearch Web tools, candidate resources were hand-selected in light of the reviewed benchmarking systems and specific criteria set by the authors.

Results: Over 90 professional and patient-oriented Web resources on psoriasis and dermatology in general are suggested for inclusion in the forthcoming Dermatology Virtual Branch Libraries. The idea of an all-in knowledge-hallmarking instrument for the National electronic Library for Health is also proposed based on the reviewed quality benchmarking systems.

Conclusions: Skilled, methodical, organized human reviewing, selection and filtering based on well-defined quality appraisal criteria seems likely to be the key ingredient in the envisaged National electronic Library for Health service. Furthermore, by promoting the application of agreed quality guidelines and codes of ethics by all health information providers and not just within the National electronic Library for Health, the overall quality of the Web will improve with time and the Web will ultimately become a reliable and integral part of the care space.

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Introduction

The U.K. National electronic Library for Health (NeLH) [1] is a Web-based, "library without walls" project announced in 1998 as part of the National Health Service (NHS) "Information for Health" strategy of the U.K. Department of Health [2]. It will be one of the cornerstones of the new NHS health information system, with the ultimate goal of giving the people of the United Kingdom the best healthcare service in the world.

Backed by specialized and supporting services like the National Institute for Clinical Excellence (NICE) and other evidence and quality benchmarking and assurance systems, the NeLH will provide easy, 24-hour access to the best current knowledge and consequently help improve health and healthcare, clinical practice and patient choice [3].

The NeLH will also reduce the variations in healthcare delivery and quality from one part of the United Kingdom to another and empower the public and patients, reducing inequalities and ending "knowledge poverty" (in access and quality). Furthermore, the NeLH will help its users cope with the "knowledge overload", often of poor or uncertain quality, coming from raw sources like the World Wide Web and even from specialized services like MEDLINE.

The NeLH will include vortals known as Virtual Branch Libraries (VBLs). A VBL is a special collection of resources relevant to a specific community (or more than one community) of users and related to their particular interests and needs [4]. A Dermatology VBL is among the planned VBLs and will be based on the same high quality principles as the rest of the NeLH. Psoriasis, a common dermatological condition, has been chosen as a starting point.

Quality Benchmarking of Health-Related Web Resources

The Internet has become a major source of health information. No wonder the American Medical Informatics Association has a special Internet Working Group and a new peer-reviewed Journal of Medical Internet Research (JMIR) [5] was launched in 1999.

The importance of the Internet for healthcare professionals cannot be overlooked. Eysenbach et al [6] redefine cybermedicine as a new academic specialty at the crossroads of medical informatics and public health (medicine in cyberspace where cyberspace denotes the Internet). Compared with telemedicine (which is primarily curative medicine), cybermedicine is primarily preventive medicine and has changed the traditional model of preventive medicine and patient/community health promotion. Cybermedicine features mass patient education and patient-to-patient exchanges of information for patient education and self-support.

There is however a growing concern about the quality of health information on the Internet, which is frequently inaccurate or biased and sometimes even misleading and dangerous (Figure 1). Anyone can be a publisher on the Web, which is good for a democratic society but potentially problematic in professions such as medicine [7].

Figure 1. Royal Rife Research Society Web site, a blatant example of quackery on the Web [39]. The site offers a "miraculous" universal electronic cure for arthritis, diabetes, tumours and other afflictions (the end to all disease), and claims that the University of Southern California has sponsored research into this electronic therapy on the terminally ill, with astounding results
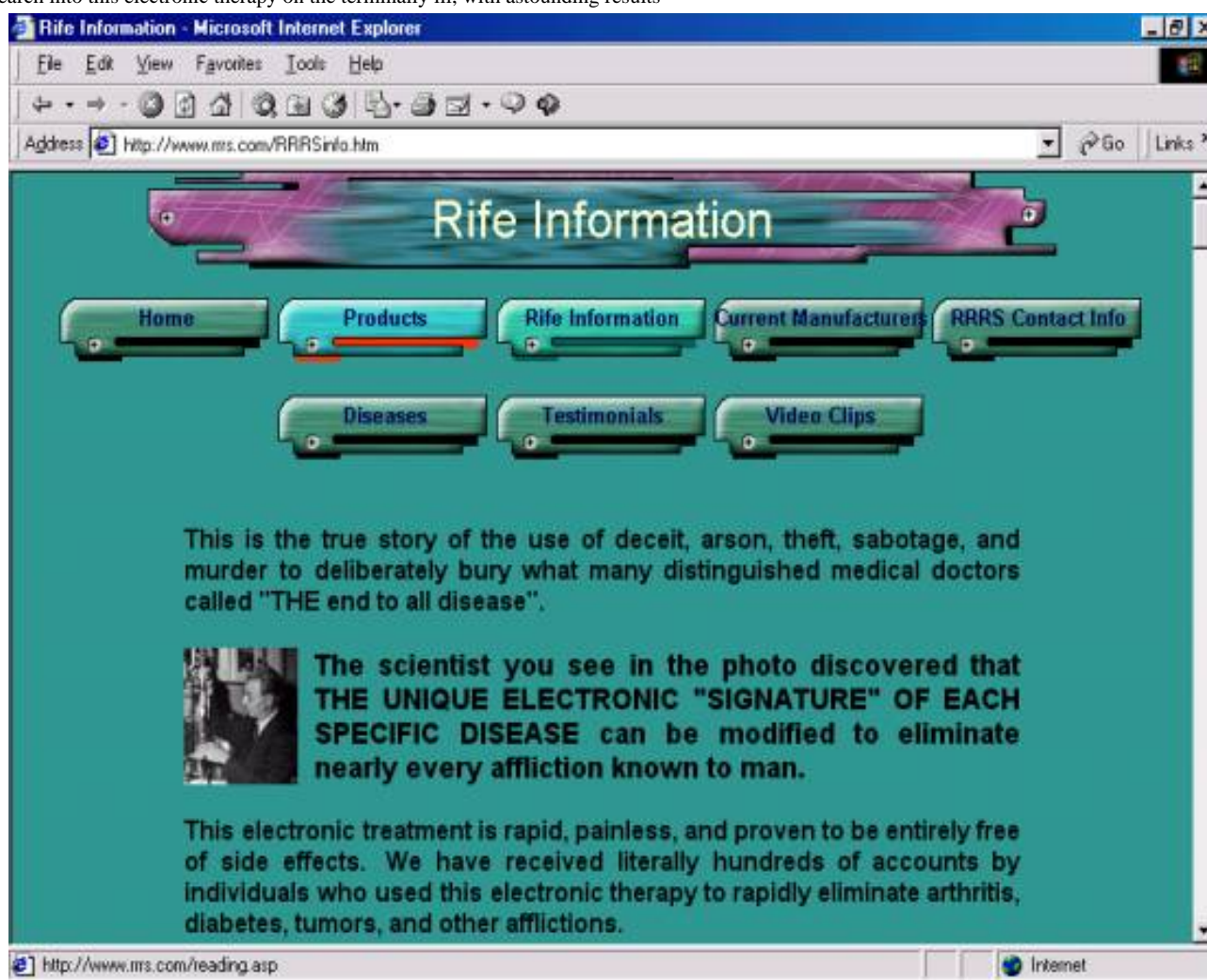
The NeLH will not act as a censor, but rather as a quality filter powered by an explicit quality measurement system. This role is analogous to that of the renowned Goldsmith's Company (founded in London in 1327), which never traded gold, but was able through its independent hallmark stamping system to set the standards for the quality and purity of gold being traded. Knowledge hallmarks are needed to perform the function of gold hallmarks. The Cochrane logo for example has become a knowledge hallmark for systematic reviews and readers can always refer to the Cochrane Collaboration Handbook [8] to see the methods used to appraise and produce the Cochrane Reviews [9].

Methods

A Review of the Major Quality Benchmarking Systems Available Today

Some of the systems discussed below are mainly codes of ethics for resource providers, e.g. HONcode [10], while others are true quality-rating tools, e.g. the Oxford Centre for Evidence-Based Medicine Levels of Evidence [11]. Both approaches are important and there have been few attempts to combine a code of best practice with true quality rating under a single umbrella.

Furthermore, two of the systems reviewed below, namely HONcode and med-PICS/MedCERTAIN [12,13], require target resource modification if they are to function optimally, e.g. adding the HONcode "active seal" logo and code or adding some PICS-labels or metatags to the section of Web pages in case of med-PICS. To use med-PICS consumers must also load the med-PICS rating description (a '.rat' file) into their Web browsers. The other systems described below provide quality evaluation schemes or checklists, sometimes very sophisticated, for selection of quality resources (they do not impose any modifications on target resources), e.g. OMNI [14], DISCERN [15] and QUICK [16]. Some systems also offer a directory service for quality resources, e.g. HON, OMNI and Medical Matrix [17].

Oxford Centre for Evidence-Based Medicine Levels of Evidence

Ball et al [11] from the Centre for Evidence-Based Medicine at Oxford define ten levels of evidence (1a, 1b, 1c, 2a, 2b, 2c, 3a, 3b, 4, 5) and map them to four grades of recommendation (A, B, C, D). A systematic review (with homogeneity) of randomized controlled trials is considered to be the most reliable source of evidence (top level), while an expert opinion (without

explicit critical appraisal) is graded as the least trustworthy piece of evidence (level 5, Grade D). Systematic reviews act like a quality filter by purifying the findings of primary (raw) research, detecting bias and poor quality research and distilling the findings (the good reliable ones) into a single report.

The Health on the Net Foundation Code of Conduct (HONcode)

An international initiative launched in early 1996, Health On the Net Foundation (HON) is a not-for-profit organization headquartered in Geneva, Switzerland. The major HON sponsors are Sun Microsystems, the Swiss Institute of Bioinformatics and the State of Geneva.

Figure 2. Health on the Net Foundation logo and HONcode blue and red seals

HON Code of Conduct (HONcode) [10] is a self-regulatory, voluntary certification system. HONcode does not rate the medical accuracy, validity or appropriateness of the information itself. It only defines a set of rules to hold Web site developers to basic ethical standards in the presentation of information and ensure readers always know the source and the purpose of the information they are reading. Compliant sites identify themselves by the blue-and-red HONcode hyperlink or "active" seal displayed usually at the bottom of their homepage (Figure 2).

HONcode addresses eight points: authority of the information provided, complementarity, confidentiality and privacy, proper attribution of sources, justifiability, transparency of authorship, transparency of financial sponsorship and honesty in advertising and editorial policy with emphasis on the importance of clearly separating advertising from editorial content. Dishonest operators may cut and paste the HONcode seal onto their Web sites. To check whether a given site featuring the HONcode seal is a bona fide HONcode subscriber, users can place their mouse cursor over the displayed HONcode seal and if the seal is authentic, they should see a special HONcode ID number appearing along the status bar of their browser. Clicking the seal should link them directly to a page on HON's site that summarizes the site's HONcode registration status. HON also has its own policing system and conducts random checks on subscribers.

Internet Healthcare Coalition e-Health Code of Ethics

The Internet Healthcare Coalition (IHC) (Figure 3) [18] is a not-for-profit organization with four major Internet health information providers, including Medscape, drkoop.com and Mediconsult, in addition to GlaxoSmithKline, the British pharmaceutical company, among its sponsors. (These sponsors should not pose any conflict of interest according to the Coalition's Statement of Independence).

Figure 3. Internet Healthcare Coalition logo

In May 2000, the IHC e-Health Ethics Initiative introduced the Washington e-Health Code of Ethics which sets forth some important guiding principles for Internet healthcare sites and services grouped under eight main headings: candor; honesty; quality; informed consent; privacy; professionalism in online healthcare; responsible partnering; and accountability [19]. The full code can be downloaded from http://www.ihealthcoalition.org/ethics/code0524.pdf [accessed 27 August 2000].

Health Internet Ethics Consortium

In May 2000 the Hi-Ethics Consortium (Figure 4) [20], a coalition that brings together some of the most widely used health Internet sites, published their thoughts on what constitutes good Internet ethics. The Hi Ethics Consortium summarizes the

key ethical principles of electronic health information publishing on the Web into a 14-point list. The complete list of Principles and a useful glossary is available [20].

Figure 4. Hi-Ethics Consortium Logo

MedCERTAIN (med-PICS Certification and Rating of Trustful and Assessed Health Information on the Net)

One way to ensure that only quality medical Web sites are delivered to the consumers is to configure their Web browsers to filter out information that does not meet a defined standard [21].

MedCERTAIN (Figure 5) and the closely related metadata vocabulary med-PICS are initiatives for assessing, rating, labeling and filtering health information on the Web [12,13].

MedCERTAIN, an international not-for-profit project, was launched in 2000. Backed by the European Union under the "EU Action Plan for Safer Use of the Internet," it aims at improving health information quality on the Web through raising consumer awareness and industry self-governance. The underlying idea, proposed by G. Eysenbach, is to label medical Web pages with meta-information (information about information) using a standard computer-readable vocabulary based on the PICS (Platform for Internet Content Selection) labeling scheme [22].

Figure 5. med-PICS and MedCERTAIN logos

These meta-information labels may be descriptive or evaluative. For example, a book review or critique is considered evaluative meta-information, while the table of contents is descriptive meta-information. Under the MedCERTAIN/med-PICS scheme, authors of medical Web pages are encouraged to include Unified Medical Language System (UMLS) codes in the header of their pages, as this can greatly enhance the quality of Web queries and increase the relevancy of search results. The proposed med-PICS vocabulary also includes definitions of target audience and country, type of information, contents rating, source assessment and advertising policy.

MedCERTAIN [13] will be a self- and third-party rating system. The project will develop and apply the necessary technologies to label health information on the Web, including exploring the next generation of PICS, which will apply Resource Description Framework (RDF), and eXtensible Markup Language (XML). A technical and organizational infrastructure will allow associations (e.g. medical societies) and individuals (e.g. medical domain experts) to rate (i.e. to assign meta-information to) health information on the Internet, in a collaborative, distributed and decentralized way.

Consumers will be able to use their browsers or additional software or search engines to retrieve this meta-information

automatically in the background whenever they access a Web site. Based on this meta-information, access can be limited to quality assessed content on the Web and a disclaimer may be displayed if the consumer leaves the rated subset of the Web. The MedCERTAIN consortium will create different levels of certification for publishers of health information on the Web, ranging from simple quality seals indicating a "good standing" of the site (level 1) to quality seals indicating that the site has been peer-reviewed externally. Web sites that want to get a MedCERTAIN certification will have to commit themselves to the Washington Code of e-Health Ethics or other ethical codes (see above). A community of trusted assessors will rate information as they surf the Web, flagging fraudulent information and evaluating (peer-reviewing) information if authors apply for a "level-3" quality seal.

To make use of med-PICS (Figure 6) [12], a rating description must be loaded into the Web browser. Microsoft Internet Explorer simply needs a text file, with the file extension '.rat.' Once loaded, the user is presented with a simple interface through which quality requirements and personal preferences can be defined (Figure 6). Users then need to define which labeling bureau(x) they wish to check with before accessing any Web site.

Figure 6. Defining the target audience in Microsoft Internet Explorer Content Advisor using med-PICS after loading the proposed med-PICS rating file (current version as of May 2000 is named 'medv0-3.rat'). In this screenshot, the target audience has been defined as a doctor/GP
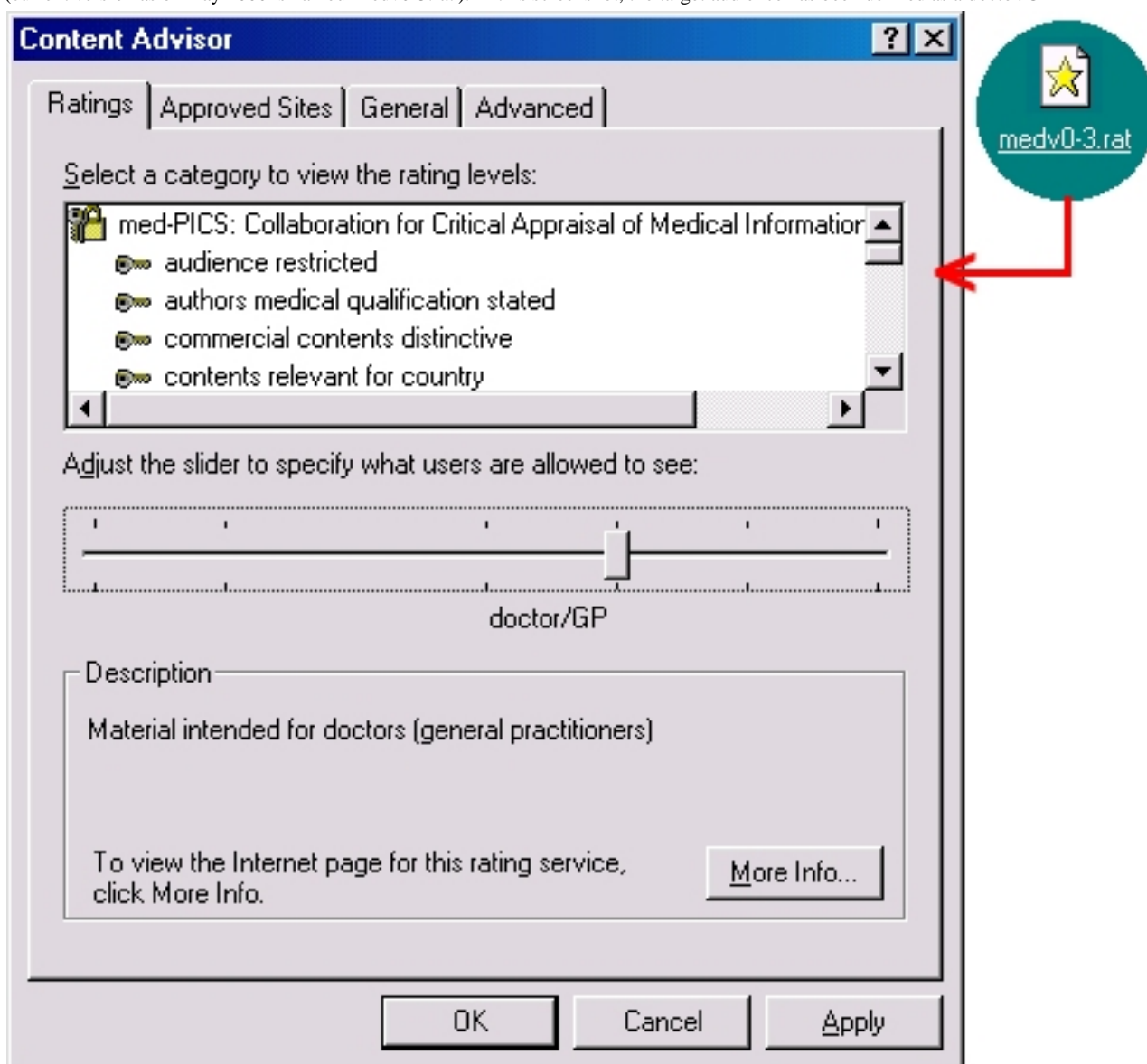
Subsequently, when a user requests, through the browser, any Web page, the software filter not only fetches the document but also makes an inquiry to the label bureau requesting any labels that have been assigned to that site. Depending on what the labels say, the filter may display an alert or disclaimer [21].

OMNI (Organising Medical Networked Information)

Based at the University of Nottingham and backed by people from a wide array of backgrounds and institutions, including several other universities, the Department of Health, the Wellcome Trust and the British Library, OMNI (Figure 7), which started in 1994, is now a much-respected UK point of access to quality biomedical Internet resources [14]. OMNI has recently become one of BIOME's health and life sciences gateways [23].

OMNI's Advisory Group on Evaluation Criteria (AGEC) started by examining a number of different services available via the Internet that seek to provide access to selected and evaluated medical networked information resources. The group compared the criteria these services use for evaluating resources before producing their own OMNI Guidelines for Resource Evaluation which constitute one of the most comprehensive quality benchmarking checklists available today [24].

Resources are included that are either accessible directly as Web pages or can be downloaded across the network, e.g. downloadable tutoring software. As a rule, OMNI does not point to sites as a whole but to specific resources, so resources are identified and indexed at the level of individual Web pages and downloadable files (i.e., cataloguing on a per-page as opposed to per-site basis). This rule is clearly unsustainable in the case of databases, electronic journals and similar resources with a huge content base, where, unless an individual article or posting is particularly valuable in its own right and offers unique insights, OMNI will normally only point to the homepages of such resources.

Figure 7. OMNI logo

OMNI's selection process starts by establishing the context of the candidate resource and examining its scope, target audiences, authority and provenance. The evaluation criteria can be grouped into two main sets: content evaluation criteria and access evaluation criteria.

Content evaluation criteria include coverage, accuracy of information content, currency/frequency and regularity of updating and uniqueness/comparison with other sources. Access evaluation criteria include accessibility, usability and charging policy (if there are access restrictions), any special requirements, software reliability (for software resources), copyright and redistribution issues, language, design and layout/user interface and finally user support/documentation. Each criterion consists

of a series of questions (checklist) to which the assessors are supposed to find answers.

The resource evaluation process considers all the criteria listed above, some of which might not be fully satisfied (or might not be applicable to the type of resource in question). In the final analysis, it is the overall impression about the value of a resource to the OMNI user community that guides the assessors to recommend it for inclusion in the OMNI database.

DISCERN

The DISCERN Project (Figure 8) [15] was funded by The British Library and the NHS Research & Development Program at the University of Oxford.

Figure 8. DISCERN logo

DISCERN is an instrument designed to help users of consumer health information judge the quality of written information about treatment choices. DISCERN is suitable for anyone who uses or produces information about treatment choices. To pass the DISCERN benchmark, a good quality publication about treatment choices must:

- have explicit aims;
- achieve its aims;
- be relevant to consumers;
- make sources of information explicit;
- make date of information explicit;
- be balanced and unbiased;
- list additional sources of information;
- refer to areas of uncertainty;
- describe how treatment works;
- describe the benefits of treatment;
- describe the risks of treatment;

- describe what would happen without treatment;
- describe the effects of treatment choices on overall quality of life;
- make it clear there may be more than one possible treatment choice;
- provide support for shared decision-making.

C-H-i-Q (Centre for Health Information Quality - UK)

The Centre for Health Information Quality (C-H-i-Q) (Figure 9) was established in 1997 as part of the Patient Partnership Strategy, an NHS initiative acknowledging the need to "put patients first." C-H-i-Q has an international reputation, in particular in the area of appraisal of consumer health information and promoting good quality patient information [25]. C-H-i-Q has developed close ties with NICE to provide patients in the future with clear, concise "consumer-friendly" versions of NICE clinical guidelines.

Figure 9. C-H-i-Q logo

Another major responsibility of the Center is to provide an appraisal service for NHS Direct Online, the NHS patient information service [26]. The following themes are on C-H-i-Q's checklist for resource evaluation:

- accessibility (the information is in an appropriate format for the target audience);
- accuracy (the information is based on the best available evidence);
- appropriateness (the information communicates relevant messages);
- availability (the information is available to the widest possible audience);

- currency (the information is up-to-date);
- legibility (written information is clearly presented);
- originality (information has not already been produced for the same audience and in the same format);
- patient involvement (the information is specifically designed to meet the needs of the patient);
- readability (words and sentences are kept short where possible and jargon is minimized);
- reliability (the information addresses all essential issues).

QUICK (The QUality Information ChecKlist)

Figure 10. Screenshot from the QUality Information ChecKlist Web site showing the eight points consumers have to consider when assessing the quality of information on Web sites
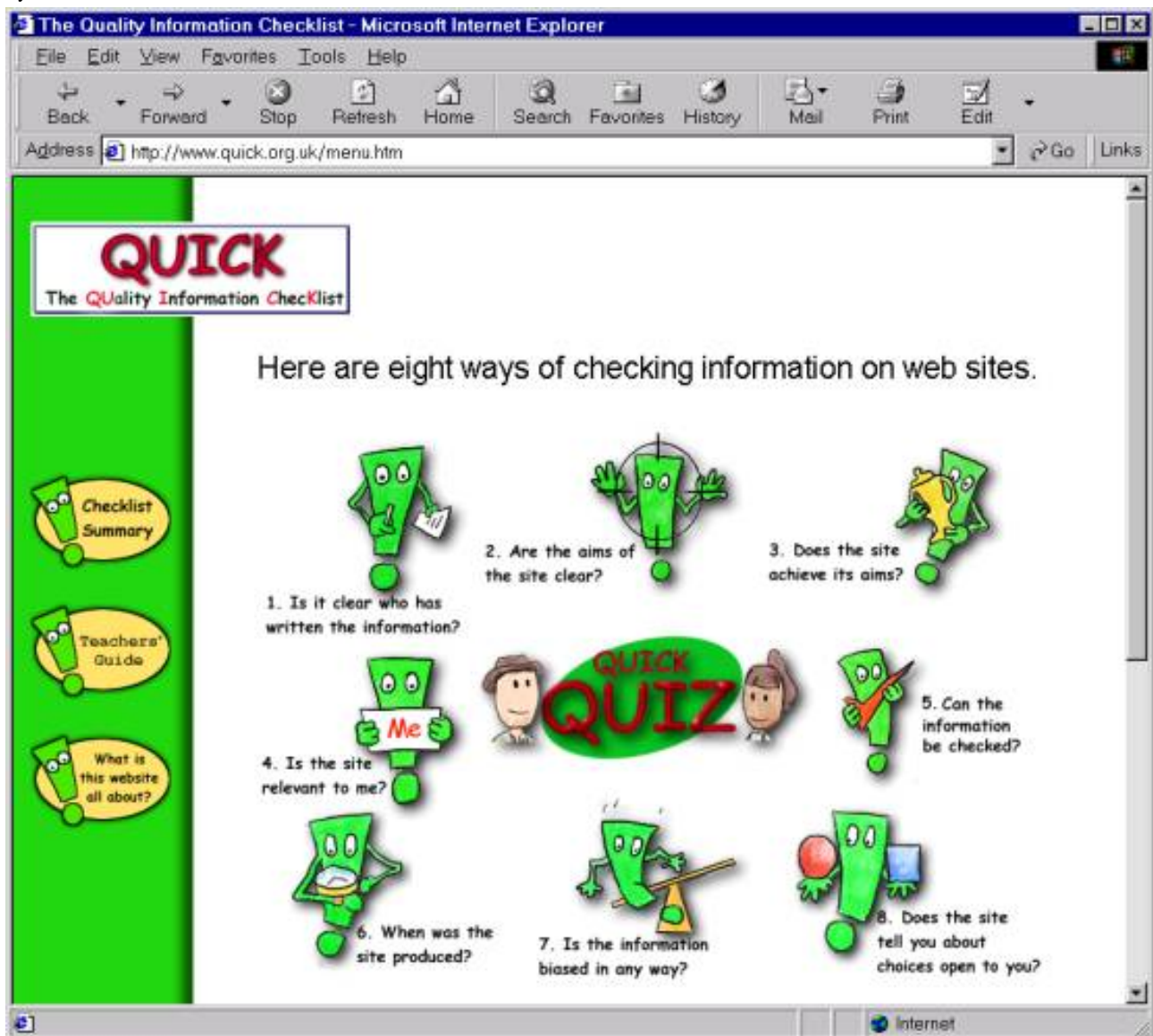
The QUICK (QUality Information ChecKlist) Web site (Figure 10) [16] was developed by C-H-i-Q (Centre for Health Information Quality) in collaboration with HEA (the Health Education Authority (now replaced by the Health Development Agency, HDA). QUICK is a resource to help young people evaluate the information they find on the Internet. QUICK checklist includes the following eight questions:

1. Is it clear who has written the information? Who is the author? Is it an organization or an individual person? Is there a way to contact them? An e-mail address on its own is not a proof that the author is a genuine expert on a subject or even who they claim to be as anyone can get an e-mail address especially with free services like Hotmail.

2.   Are the aims of the site clear? What are the aims of the site? What is it for? Who is it for?

3.   Does the site achieve its aims? Does the site do what it says it will?

4.   Is the site relevant to me?

5.   Can the information be checked? Is the author qualified to write the site? Has anyone else said the same things anywhere else? Is there any way of checking this out? If the information is new, is there any proof?

6.   When was the site produced? Is it up to date? Can you check to see if the information is up to date and not just the site?

7.   Is the information biased in any way? Has the site got a particular reason for wanting you to think in a particular way? Is it a balanced view or does it only give one opinion?

8.   Does the site tell you about choices open to you? Does the site give you advice? Does it tell you about other ideas?

Net Scoring: Criteria to Assess the Quality of Health Internet Information

Net Scoring (Figure 11) is a French quality benchmarking system in use by many prominent French institutions, including the Centre Hospitalier Universitaire de Rouen, which developed CISMeF (Catalogue et Index des Sites Médicaux Francophones), the French equivalent of OMNI [27]. Net Scoring [28] provides a set of criteria for assessing the quality of health information on the Internet. To ensure objectivity in the development of these criteria, a diverse group of individuals, including representatives of professional organizations, medical doctors, engineers and lawyers, was gathered. Net Scoring comprises 49 criteria grouped into eight categories: credibility, content, links, design, interactivity, quantitative aspects, ethics and accessibility. Each criterion is assigned a weight according to its importance. An essential criterion is rated from 0 to 10. An important criterion is rated from 0 to 5, while a minor criterion is rated from 0 to 2. It is noteworthy that Net Scoring considers the "use of metadata" an essential criterion. The total of these weighted criteria gives the overall score of a site (the maximum score a resource can achieve is 297 points). Net Scoring criteria are presented in Appendix 1.

Figure 11. Net Scoring logo

Medical Matrix

Medical Matrix (Figure 12) is a medical Web directory service that aims to improve the global medical community's access to useful digital clinical medicine resources [17] (registration is required but is free).

The Medical Matrix Project assigns star ranks to Internet resources based on their clinical utility as follows (Table 1):

Table 1. Medical Matrix Star Ranking System

*	Suitable, well-authored clinical content but lacking in substance, or currency. (1-10 points)
**	Clinical content is generally reliable and up-to-date. Site design is logical and easy to use. Limited usefulness as a regular clinical resource. (11-20 points)
***	Well-authored, accurate, current clinical content. Good site design, well-maintained and extensive functionality. Easily accessed and navigated by the routine user. An overall valuable clinical resource. (21-30 points)
****	Outstanding site across all categories and a premier web page for the discipline. (31-40 points)
*****	An award winning site for Medical Internet. (41-50 points)

Four main criteria are checked by the Medical Matrix Editorial Board when evaluating a resource:

- Dimension/usefulness for clinical applications: The resource enhances the knowledge base of the target clinician. Resource documents have current clinical relevance and importance, intellectual and scientific strength, and clarity of presentation. (1-20 points)
- Verifiability, clarity, and integrity: Resource document content is verifiable, endorsed, dated, current, and referenced. The material is original; the writing is clear; there is a minimization of bias; conclusions are reasonable and supported by evidence presented. The effort is ethical. The documents offer a comparison with relevant findings from other publications. Any conflict of interest is disclosed. (1-10 points)
- Evidence-based criteria: Conclusions are based on studies that are methodologically sound, meet statistical validity criteria and are clinically relevant. Conclusions are rated against a "gold standard" in that they are founded upon randomized trials with appropriate follow-up and are based on studies that make an independent, blind comparison of tests. (1-10 points)
- Media: Text, hypertext, or use of multimedia in the context of the resource. (1-10 points)
- Feel/ease of access: Easy to follow in terms of composition, presentation on the Web and integration within a larger database. (1-5 points)

Figure 12. Medical Matrix logo

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Principles Governing American Medical Association (AMA) Web Sites

A standing committee composed of AMA staff members from the Scientific Publications and Multimedia, Publishing and Business Development, Ethical Standards, and Internet and Database Services areas (Figure 13) developed these guidelines, which were released in March 2000 [29]. The guidelines cover four areas, namely content, advertising and sponsorship, privacy and confidentiality, and e-commerce [29].

Figure 13. AMA logo

The principles for advertising and sponsorship cover many issues including guidance on the placement of digital advertisements. Just as a print advertisement would never be placed next to an editorial page on the same topic, a digital advertisement should never be adjacent to editorial content on the same topic. Readers should not be sent to a commercial site unless they choose to do so by clicking on an advertisement.

The principles for privacy and confidentiality aim at maintaining Web site visitors' rights to privacy and the confidentiality of personal information. Tracking of personal medical and health information, i.e., medical conditions, health-seeking behaviors and questions, and requests about drug therapies or medical devices or information pertaining to them, could breach an individual's personal privacy and reveal an individual's health data. Identifying details should be omitted if they are not essential, but patient data should never be altered or falsified in an attempt to attain anonymity. Information about individual medical conditions must not be collected without the express permission of the site visitor.

The principles for privacy and confidentiality also state that e-mail alerts and newsletters should only be sent upon a visitor's explicit request and should always contain an "unsubscribe" option.

HSWG Criteria for Assessing the Quality of Health Information on the Internet

The Health Summit Working Group (HSWG), funded by the United States' Agency for Healthcare Research and Quality and the Health Information Technology Institute, selected, defined, ranked and evaluated seven major criteria for assessing the quality of Internet health information [30]. The credibility criterion covers the source, currency, relevance/utility, and editorial review process for the information. Resource content must be accurate (Table 2) and complete, and an appropriate disclaimer should be provided.

Disclosure includes informing the user of the purpose of the site, as well as any profiling or collection of information associated with using the site. Links are evaluated according to selection, architecture, content, and back linkages. Back linkages (also mentioned among Net Scoring criteria above) are links to one Web site from another. Many Web sites track and publish back linkages for the purpose of enhancing their credibility and marketability. The best way to evaluate back linkages is to examine the context in which they are used, that is, their purpose, relevance, credibility, and authority, as well as any associated bias. Design encompasses accessibility, logical organization (navigability), and internal search capability. Interactivity includes feedback mechanisms and means for exchange of information among users. The last criterion, caveats, involves clarification of whether the site function is to market products and services or is a primary information content provider.

Table 2. HSWG Hierarchy of Evidence

Validity of Evidence	What to Look For
++++ (Best Evidence)	Randomized controlled trials
+++	Non-randomized controlled trials
++	Well designed cohort or case-control analysis
+	Opinions of respected authorities, case reports, descriptive studies, reports of expert committees
No Evidence	Misrepresentation, fraud

Silberg's Core Criteria for Measuring Quality (Caveat lector and viewor)

Silberg [31] suggested the following four core criteria for measuring the quality of medical Web sites:

- Authorship: The author(s) of a Web page, along with their affiliations and credentials, should be clearly stated. Ideally, there should be the facility to contact the author(s) by e-mail.

- Attribution: If a Web site is quoting research or evidence then the source of this data must be explicitly stated.
- Disclosure: The owner of the Web site must be prominently displayed, along with any sponsorship or advertising deals that could constitute a potential conflict of interest.
- Currency: Web pages should indicate when the page was created, and when it was last updated.

The authors have noted that some webmasters use JavaScript within their pages to pick up the client machine's current date and display it after a "last updated" or similar string, fooling the reader into thinking that these pages were updated on the same day (i.e., a false impression of currency).

Price's PILOT Method for Evaluating Medical Web Sites

The PILOT method for evaluating medical Web sites consists of five criteria (Table 3) [32]:

Table 3. Price's Pilot Method

Purpose:	If the site has a mission statement, read it. If not, read the home page and analyse the site's purpose. Does it inform and educate? Or is designed to persuade, sell, outrage or entertain?
Information:	Truly useful medical Web sites offer valuable information and emphasise facts rather than opinion and testimonials. If the site is selling anything, ask yourself if that influences the content.
Links:	The best sites want to inform you and are happy to recommend additional Web sites to further your knowledge in that topic or related topics. The best links are rated or reviewed.
Originator:	Who is responsible for the information? Best bets for sound medical information are medical societies, consumer-advocacy groups, well-known hospitals, and government- and university-sponsored sites.
Timeliness:	Medical information is only useful if it is current. Look for sites that update frequently.

Developing a Quality Benchmarking System for the NeLH

According to the Centre for Health Information Quality (C-H-i-Q) [25], a new discipline will probably emerge in the near future, with the development of an academic qualification in health information appraisal. Healthcare professionals trained in this domain will be the ideal NeLH "knowledge miners" or "quality assurance officers." We believe that a quality evaluation software wizard should be developed, possibly by pooling the best criteria and methods from all the quality benchmarking systems that are available today to produce an all-in knowledge-hallmarking instrument. The aim of this wizard will be to assist (not to replace) NeLH knowledge miners in their work and ensure that they consistently and explicitly follow all the required evaluation steps. This wizard should be also able to write evaluation results and details of the resource being evaluated (e.g. URL, score or rating, currency information, etc.) and any other relevant meta-information to the appropriate NeLH page or to the record pointing to this resource in the NeLH resource catalogue or database. To develop a good quality benchmarking system, a standard statement must first be defined. The standard statement is the hub on which the other elements of the standard revolve. It describes an agreed level of quality appropriate to the organizational and target readers needs. It specifies a desirable, acceptable and achievable quality level. The next step is to develop criteria that clearly and precisely specify the quality level that must be present in order to satisfy the standard. For any given quality standard, it is possible to write a great many criteria. The quality assurance team responsible for the development of the quality benchmarking system, therefore, has to choose criteria on the basis of a sound principle like AMOUR [33]. AMOUR defines a set of five clear questions/goals that each of the candidate criteria must answer:

- is the criterion Achievable? The development group must choose between idealism (unattainable standards) and realism.
- is it Measurable? A standard statement might not be worded in measurable terms but a criterion must be. When writing a criterion it is helpful to consider "how can a check be made that a given resource fulfils the criterion?" and find a clear and practical answer to this question.
- is it Observable? For a phenomenon to be observable it must be detectable through the senses. If a criterion refers to unobservable (very abstract) objective, it will be almost impossible to determine whether or not this objective has been satisfied by any given resource under examination. A criterion which uses vague terms such as "appropriate content" or "information should not be biased" is very difficult to use (and very subjective).
- is it Understandable? The development team should unambiguously and explicitly define the meanings of linguistic variables like "appropriate" or "suitable." The rule is always to be clear, objective and specific.
- is it Reasonable? All involved or targeted "players" (information providers, patients and professionals) must be represented within the development group formulating the benchmarking system to ensure that all pertinent players find the final criteria reasonable.

Selection and Evaluation of Candidate Web Resources for the Dermatology VBL

The authors used Web Inspector, an offline metasearch tool [34], some specialized medical search engines and directories, e.g. HON MedHunt and HONselect [9], plus the personal knowledge of the first author (who is a dermatologist) about good dermatology Web resources to locate candidate sites.

Six major Internet search engines (Euroseek, Excite, Infoseek, Yahoo, All the Web and Google) were queried at the same time by Web Inspector (on 13 May 2000) using the keyword

'psoriasis'. The maximum number of results per search engine was set to 300. After the automatic removal by Web Inspector of all duplicate and dead links, 413 documents (containing the word 'psoriasis') remained for manual exploration by the authors.

We tried to include a balanced mix of resources that can be used to answer a variety of information queries and needs. The selected resources (Appendix 2) include sites intended mainly for patients, as well as sites targeting healthcare professionals. In addition to psoriasis-specific resources, the authors have also compiled a list of some of the very useful general dermatology resources on the Web for patients and healthcare professionals. These "general" resources can support continuing professional education and also provide different types of information on the rest of skin diseases.

Sites that are purely textual, searchable databases, atlases (dermatology image banks), sites that mix text, graphics and interactive elements (e.g. educational simulations) were all considered for inclusion, as long as they did not rely on sophisticated browser plug-ins and/or non-standard Web technologies to display their information. JavaScript (when properly implemented), Adobe Acrobat Reader and RealNetworks RealPlayer are examples of respectable, mainstream Web technologies and browser plug-ins or extensions. They are freely available, very stable, lightweight and supported on a wide variety of platforms, and therefore pages using them were not excluded. Web directories that are just link lists (pointers to other resources) were excluded unless they constituted a real resource guide offering additional evaluative or descriptive information. Information providers whose contributions to the knowledge base of dermatology have long been recognized as authoritative, e.g. the British Association of Dermatologists (http://www.bad.org.uk/[accessed 27 August 2000], were preferred.

Sites displaying advertisements or sponsored by commercial bodies, e.g. sites endorsed by pharmaceutical companies, were typically excluded for obvious reasons, unless the author felt there were no real conflicts of interest, possibility of bias or any other hidden or malicious motives. For example, the author has included the New Zealand DermNet (http://www.dermnet.org.nz [accessed 27 August 2000], which remains a very good and unbiased resource, despite the fact that it displays pharmaceutical advertisements.

Sites that are not regularly updated were excluded, based on the concept that every piece of information should have an "expiry date" after which it should be revised and, if necessary, updated. But again exceptions to this rule had to be made to include some sites with inadequate currency information, but providing very good basic information that is less likely to change over time.

Deleting the right hand side of a resource URL in steps has proved very helpful in providing additional insight and information concerning the credibility of the authors and publishers of some resources, e.g. http://www.ee.oulu.fi/~juko/psoriasis.html (the resource), http://www.ee.oulu.fi/~juko/(the author) and http://www.ee.oulu.fi/(the author's the academic institution).

Results

Over 90 professional and patient-oriented Web resources on psoriasis and dermatology in general have been hand-selected for possible inclusion in the forthcoming Dermatology VBL (Appendix 2). Among the selected electronic Web-based atlases is Dermatology Online Atlas (DOIA) at the University of Erlangen, Germany (Figure 14) [35]. The history of this Atlas of Dermatology goes back to 1994, the early days of the World Wide Web. In these days, a German research project was launched to use this new technology for the benefit of medical education and teaching, especially in dermatology.

Figure 14.
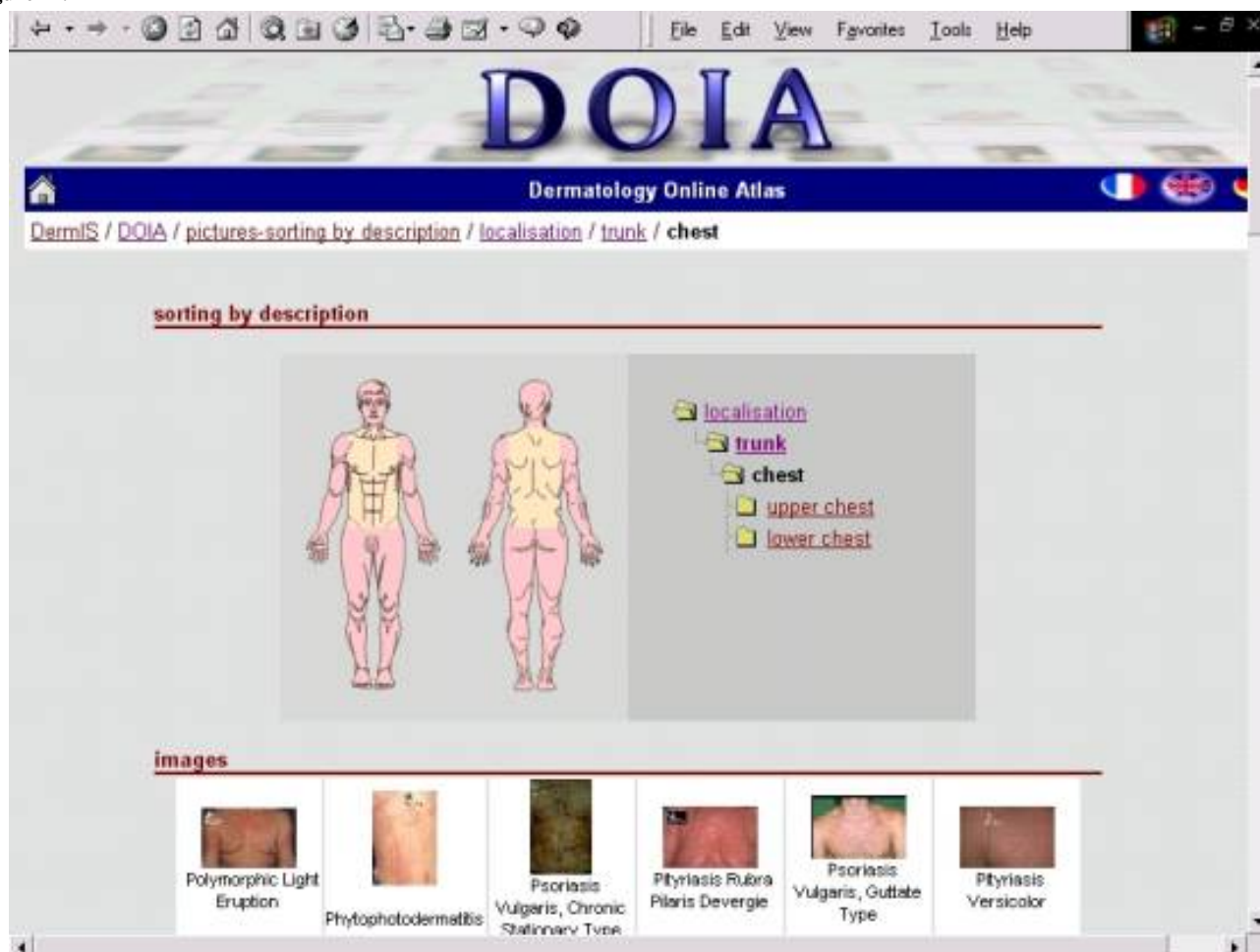
This online atlas of dermatology surpasses any printed image atlas and integrates both interactive and dynamic components, with more than 3000 high quality images of more than 600 dermatological diagnoses and differential diagnoses. Morphological features of the images have been described by dermatologists. The site offers a database query interface for advanced image selection by different criteria, including localization, morphological features, age and gender. With each image or set of images covering the same diagnosis, direct links are provided to other images of suitable differential diagnoses within the atlas. Also provided are commented and rated links to external Web sites offering further information on the respective dermatological disease. Special links allow direct, fast and easy access to disease-related information in databases like MEDLINE and OMIM (Online Mendelian Inheritance in Man). The atlas can be also browsed in 'quizmode' for training [36]. While the authors did their best to observe the essence and spirit of all the quality benchmarking systems described above during the selection and evaluation process, the list of candidate resources (Appendix 2) should not be considered an exhaustive and final selection, but rather a first-pass filtering. The identified candidate sites should be subjected to more scrutiny to determine their final status, whether suitable or not for inclusion in the NeLH. Quality benchmarking of health-related resources will always depend on a human assessor, and as such, it will always have attached to it an inevitable element of subjectivity that cannot be corrected by simply providing numerical scales for

rating a resource. These numerical scales can only offer apparent, but not true objectivity. According to Delamothe [37], rating the quality of medical Web sites may be impossible. One option he presents is to rate the process by which the content was produced rather than the content itself, i.e., rate the assessor or information provider rather than individual resources. Thus a medical journal's Web site containing peer-reviewed material would rate higher than a commercial site selling miracle cures for cancer.

Discussion

Online (e.g. http://www.metacrawler.com/[accessed 27 August 2000] and offline (e.g. Web Inspector [34]) metasearch Web tools can greatly assist human NeLH knowledge miners by performing an automatic preliminary mining and filtering of Web pages on a given topic, thus facilitating the final filtering task of the human knowledge miner. By querying multiple search engines at the same time the potential for finding information is much greater. Moreover, users are spared the time spent manually visiting a number of search engines and re-keying their query or in following dead or duplicate links. However, the NeLH should always remain a human-maintained catalogue with value added contents. Skilled, methodical, organized human reviewing, selection and filtering based on well-defined quality appraisal criteria seems likely to be the key ingredient in the envisaged NeLH service. Proper training

of human assessors to develop good discernment skills is as important as the quality benchmarking checklists themselves. The authors recommend that assessors take the "Internet Detective" interactive tutorial on evaluating the quality of Internet resources [38]. This tutorial is provided by the Social Science Information Gateway (SOSIG), which is part of the UK Resource Discovery Network. In the near future, MedCERTAIN [13] might become an international (or at least European) standard for rating health-related Web sites if it succeeds in setting the norm for quality benchmarking criteria and labeling infrastructure. By promoting the application of agreed quality guidelines and codes of ethics by all health information providers and not just within the NeLH, the overall quality of the Web should improve with time. This improvement in quality will always be the result of a collaborative world-wide effort based on the goodwill of "informed net citizens" and "professional obligation" of healthcare professionals and information providers, rather than on any enforced laws (i.e., self-regulation). Ultimately, the Web will become a reliable and integral part of the care space.

Conflicts of Interest

None declared.

Appendix 1

Net Scoring Criteria to Assess the Quality of Health Information

Table 4. Net Scoring Criteria to Assess the Quality of Health Information

1 Credibility (100 points)	1.1 Source
	1.1a Name, logo and references of the institution on each document of the site (essential criterion)
	1.1b Name and title of author on each document of the site (essential criterion)
	1.2 Disclosure 1.2a Context: source of financing, independence of the author(s) (essential criterion)
	1.2b Conflict of interest (important criterion) 1.2c Influence, bias (important criterion)
	1.3 Updating: currency information of the site including date of creation, date of last update and eventually date of last version (essential criterion)
	1.4 Relevance/utility (essential criterion)
	1.5 Editorial review process (essential criterion)
	1.5a Webmastering process (important criterion)
	1.5b Scientific review process (important criterion)
	1.6. Target/purpose of the web site; access to the site (free or not, reserved or not) (important criterion)
	1.7. Quality of the language and/or translation (important criterion)
	1.8 Use of metadata (essential criterion)
2 Content (79 points)	2.1 Accuracy (essential criterion)
	2.2 Hierarchy of evidence (important criterion)
	2.3 Original Source Stated (essential criterion)
	2.4 Disclaimer (important criterion)
	2.5 Logic organization (navigability) (essential criterion)
	2.5a Quality of the internal search engine (important criterion)
	2.5b General index (important criterion)
	2.5c What's new page (important criterion)
	2.5d Help page (minor criterion)
	2.5e Map of the site (minor criterion)
	2.7 Omissions noted (essential criterion)
	2.8 Fast load of the site and its different pages (important criterion)
	2.9 Clear display of available information categories (factual data, abstracts, full-text documents, catalogue, databases) (important criterion)
3 Hyperlinks (52 points)	3.1 Selection (essential criterion)
	3.2 Architecture (important criterion)
	3.3 Content (essential criterion)
	3.4 Back-links or number of hyperlinks to the resource in question (Web Impact Factor) (important criterion)
	3.5 Regular verification that hyper-links are functioning, i.e., no broken links (important criterion)
	3.6 In case of modification of the site structure, link between old and new HTML documents (important criterion)
	3.7 Distinction between internal and external hyper-links (minor criterion)
4 Design (20 points)	4.1 Design of the site (essential criterion)
	4.2 Readability of the text, images, or video (important criterion)
	4.3 Quality of the print (important criterion)
5 Interactivity (17 points)	5.1 Mechanism for feedback: Email of the author on every document (essential criterion)
	5.2 Forums, chat (minor criterion)
	5.3 Users must be clearly informed if the site is using cookies or any similar technologies to trace their logging into the site and to retrieve information about their machines (even if the tracing is done in anonymous form). Users must be able to opt in or opt out of functions that track personal or machine information at any time (important criterion)
6 Quantitative aspects (9 points)	6.1 Number of machines (IP addresses) visiting the site and number of visualised documents (important criterion)
	6.2 Number of press releases (minor criterion)
	6.3 Number of scientific production from the site, including bibliometric criteria (minor criterion)
7 Ethics (20 points)	7.1 Liability of the reader (essential criterion)
	7.2 Medical privacy (essential criterion)
8 Accessibility (10 points)	8.1 Accessibility from the main search engines and catalogues (important criterion)
	8.2 Intuitive address of a site (important criterion)
	297 points maximum

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Appendix 2

Patient Information

Table 5. List of candidate general dermatology and psoriasis Web resources for inclusion in the NeLH Dermatology VBL. Please note that URLs do not contain white spaces or line breaks

General Resources	
Site	**URL** (all URLs have been accessed 27 August 2000)
NHS Direct (U.K.) [26]	http://www.nhsdirect.nhs.uk/
U.K. Dermatology Patient Support Groups (U.K.)	http://www.kcl.ac.uk/depsta/medicine/dermatology/other/ukgroup.html
New Zealand DermNet for Patients	http://www.dermnet.org.nz/contents.a.html
American Academy of Dermatology Patient Information	http://www.aad.org/pamphlets/index.html
American Academy of Family Physicians - Patient Information (Skin and Hair)	http://www.aafp.org/patientinfo/body13.html
American Academy of Family Physicians - Patient Information (Skin Disorders)	http://www.aafp.org/patientinfo/common9.html
Educational Information on Common Skin Diseases for Patients - National Skin Centre, Singapore	http://www.nsc.gov.sg/commskin/skin.html
Psoriasis: Online Patient Information and Pamphlets	
NHS Direct Audio clip on psoriasis from the College of Health Healthline Tapes service (requires RealPlayer - www.real.com)	http://www.nhsdirect.nhs.uk/audio_cache/53.ram
PPP healthcare International-Health Info-psoriasis (U.K.)	http://www.ppphealthcare.co.uk/html/health/psors.htm
NIH - Questions and Answers About Psoriasis (U.S.A.)	http://www.nih.gov/niams/healthinfo/psoriasis.htm
MEDLINEplus - Psoriasis (U.S.A.)	http://www.nlm.nih.gov/medlineplus/psoriasis.html
AAD Psoriasis Pamphlet (U.S.A.)	http://www.aad.org/pamphlets/Psoriasis.html
American Academy of Family Physicians: What Can Be Done for Psoriasis (U.S.A.)	http://www.aafp.org/patientinfo/psoriasi.html
Psoriasis at Medinfo (U.K.)	http://www.medinfo.co.uk/conditions/psoriasis.html
MCW HealthLink: Psoriasis (U.S.A.)	http://healthlink.mcw.edu/article/926054522.html
Psoriasis Research Institute: Facts about Psoriasis (U.S.A.)	http://www.psoriasis-help.org/facts.html
Psoriatic Arthritis at the University of Washington (U.S.A.)	http://www.orthop.washington.edu/bonejoint/wzzzzzzz1_2.html
Psoriasis: Online Patient Information and Pamphlets	
Site	**URL** (all URLs have been accessed 27 August 2000)
DermWeb Handout: Psoriasis: What is it and How is it Treated? (Canada)	http://www.derm.ubc.ca/skincare/psoriasis/psorhand.html
National Skin Centre: Psoriasis (Singapore)	http://www.nsc.gov.sg/commskin/Psoriasi/psoriasi.html
Beware of Web quackery and the so-called miraculous cures: Psoriasis Hall of PShame (U.S.A.)	http://www.pinch.com/skin/pshame.html
Psoriasis: Online Organizations	
The Psoriatic Arthropathy Alliance (U.K.)	http://www.paalliance.org/
National Psoriasis Foundation (U.S.A.)	http://www.psoriasis.org/
Canadian Psoriasis Foundation	http://www.psoriasis.ca/
Psoriasis Society of Canada	http://www.psoriasissociety.org/
Health Care Professionals	
General Resources/Research Tools	
Cochrane Skin Group	http://www.nottingham.ac.uk/~muzd/
The British Association of Dermatologists	http://www.bad.org.uk/
New Zealand DermNet for Dermatologists	http://www.dermnet.org.nz/contents.b.html
New Zealand DermNet for General Practitioners	http://www.dermnet.org.nz/contents.c.html
Skindex - Dynamic Dermatology (Dr. Thomas B. Fitzpatrick - U.S.A.)	http://www.skindex.com/
Skin Diseases - Primary Care Clinical Practice Guidelines, University of California, San Francisco (U.S.A.)	http://medicine.ucsf.edu/resources/guidelines/guide12.html

General Resources

Site	URL (all URLs have been accessed 27 August 2000)
Archives of Dermatology (Full text Journal - U.S.A.)	http://archderm.ama-assn.org/
myMedline.com Dermatology Medline Engine	http://www.medplaza.com/medline/derm.php3
Hardin Library for the Health Sciences, University of Iowa - PubMed Medline search Dermatology & Skin Diseases (U.S.A.)	http://www.lib.uiowa.edu/hardin/pm/derm.html
Health On the Net Foundation: HONselect - Skin and Connective Tissue Diseases (Switzerland)	http://www.hon.ch/cgi-bin/HONselect?browse+C17
NIH Library - Skin Diseases Sites (U.S.A.)	http://libwww.ncrr.nih.gov/internet/Biomedicine_Science/bsskincon.htm

General Resources/Research Tools

Site	URL (all URLs have been accessed 27 August 2000)
Department of Dermatology Links Page at the University of Wales College of Medicine, Cardiff (U.K.)	http://www.uwcm.ac.uk/uwcm/dm/dermlink.html
Matrix Dermatology Resources (U.S.A.)	http://matrix.ucdavis.edu/
DermWeb, the Home Page for the Division of Dermatology at the University of British Columbia (Canada)	http://www.dermatology.org/
Dermatology Medical Journals - WebMedLit	http://webmedlit.silverplatter.com/topics/derm.html
Medical Matrix: Dermatology (Requires registration; registration is free)	http://www.medmatrix.org/_SPages/Dermatology.asp
Skin and Connective Tissue Diseases - MeSH classified index, Karolinska Institute (Sweden)	http://www.mic.ki.se/Diseases/c17.html
Dermatonet for Professionals (France)	http://www.dermatonet.com/mede.htm

Psoriasis: Comprehensive Reviews

eMedicine Online Text: Psoriasis (U.S.A.)	http://emedicine.com/cgi-bin/foxweb.exe/showsection@d:/em/ga?book=emerg&topicid=489
The Merck Manual of Diagnosis and Therapy: Psoriasis (U.S.A.)	http://www.merck.com/pubs/mmanual/section10/chapter117/117b.htm
Psoriasis in Handbook of Dermatology & Venereology, 2nd Edition, Social Hygiene Service, Department of Health, Hong Kong	http://www.hkmj.org.hk/skin/psoriasi.htm

Psoriasis: Genetics

Psoriasis Genetics Laboratory, University of Michigan (U.S.A.)	http://www.psoriasis.umich.edu/index.html
OMIM Psoriasis Inheritance and Genetics Research (U.S.A.)	http://www.ncbi.nlm.nih.gov/htbin-post/Omim/getmim?search=psoriasis

Psoriasis: Photographs

Dermatology Online Atlas (DOIA) Erlangen: Psoriasis (Germany)	http://www.dermis.net/cgi-bin/dbquery/frames.asp?diag=psoriasis&lokalisation=&zusatz=&eff1=&eff2=&farbe=&weitere=&age1=&age2=&lang=e&nr=0
Psoriasis of the nails	http://www.nh.ultranet.com/~mhabif/html/psoriasis.html

Psoriasis: Research/Online Pre-formulated Queries

eBMJ - Psoriasis Articles (U.K.)	http://www.bmj.com/cgi/search?hits=100&fulltext=psoriasis
Honselect - Psoriasis (Switzerland)	http://www.hon.ch/cgi-bin/HONselect?browse+C17.800.859.675

Psoriasis: Research/Online Pre-formulated Queries

Site	URL (all URLs have been accessed 27 August 2000)
CliniWeb Search Results for Psoriasis (U.S.A.)	http://www.ohsu.edu/cliniweb/C17/C17.800.859.html#C17.800.859.675
Medical World Search Results for Psoriasis (U.S.A.)	http://www.mwsearch.com/cgi-bin/new_search.pl?search_target=Major+Sites&initial_query=psoriasis&start_docid=1&which_form=initial_search

General Resources

Site	URL (all URLs have been accessed 27 August 2000)
Archives of Dermatology Search Results for Psoriasis (free full text articles available) (U.S.A.)	http://pubsearch.ama-assn.org/search?action=filtersearch&QueryZip=psoriasis&ResultMaxDocs=100000&Filter=search%5Ffilter%2Ehts&ResultTemplate=search%5Fresults%2Ehts&Collection=DERM&SortSpec=collPriority+desc&ResultStart=1&ResultCount=10&SF=Score&SO=desc&FreeText=psoriasis&volume_query=&title_query=&author_query=&startpage_query=&affil_query=&f_date=&f_fmonth=&f_fyear=&f_tmonth=&f_tyear=
NIH MEDLINE abstracts on psoriasis (All) (U.S.A.)	http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/query?db=m&form=4&term=Psoriasis[MAJR]+AND+Human[MESH]+AND+English[LANG]&dopt=d&relpubdate=1+Year&dispmax=20
NIH MEDLINE abstracts on psoriasis (Review) (U.S.A.)	http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/query?db=m&form=4&term=Psoriasis[MAJR]+AND+Human[MESH]+AND+English[LANG]+AND+review[PTYP]&dopt=d&relpubdate=1+Year&dispmax=20
NIH MEDLINE abstracts on psoriasis (Diagnosis) (U.S.A.)	http://www.ncbi.nlm.nih.gov/htbin-post/Entrez/query?db=m&form=4&term=Psoriasis[MAJR]+AND+Human[MESH]+AND+English[LANG]+AND+(sensitivity+and+specificity[MESH]+OR+sensitivity[WORD]OR+diagnosis[SH]+OR+diagnostic+use[SH]+OR+specificity[WORD])&dopt=d&relpubdate=1+Year&dispmax=20
NIH - Psoriasis info (U.S.A.)	http://search.info.nih.gov/s97is.vts?Collection=NIH&Summary=1&ResultTemplate=NIH.hts&queryText=psoriasis
Computer Image Analysing (CIA) System for Psoriasis Area Assessment (Research - Medical Informatics/Machine Vision - Finland)	http://www.ee.oulu.fi/~juko/psoriasis.html

Psoriasis: Treatment

Psoriasis treatments [Bandolier - May 1998; 51-5] (U.K.)	http://www.jr2.ox.ac.uk/bandolier/band51/b51-5.html
Topical capsaicin in Psoriasis [Bandolier - Jul 1996; 29-6] (U.K.)	http://www.jr2.ox.ac.uk/bandolier/band29/b29-6.html
Cochrane - Interventions for guttate psoriasis (U.K.)	http://www.update-software.com/ccweb/cochrane/revabstr/ab001213.htm
Cochrane - Antistreptococcal interventions for guttate and chronic plaque psoriasis (U.K.)	http://www.update-software.com/ccweb/cochrane/revabstr/ab001976.htm
Cochrane - Interventions for psoriatic arthritis (U.K.)	http://www.update-software.com/ccweb/cochrane/revabstr/ab000212.htm
American Academy of dermatology Guidelines of Care for Psoriasis (U.S.A.)	http://www.aad.org/Guidelines/psoriasis.html
American Academy of Family Physicians: Topical Psoriasis Therapy (U.S.A.)	http://www.aafp.org/afp/990215ap/957.html
Dermatology Times - Psoriasis Treatments (U.S.A.)	http://www.dermatologytimes.com/psorias.html
For Nurses: Psoriasis: what to tell your patients (NurseWeek, U.S.A.)	http://www.nurseweek.com/ce/ce804a.html
NIH MEDLINE abstracts on psoriasis (Treatment Research - U.S.A.)	http://www.pinch.com/hit?medline=psoriasis+%5Bti%5D+AND+(treat*+OR+therap*)

Professional Education

Online Textbooks, Lectures and Clinical Case Simulations

eMedicine Online Text - Dermatology (U.S.A.)	http://www.emedicine.com/derm/index.shtml
Handbook of Dermatology & Venereology, 2nd Edition, Social Hygiene Service, Department of Health, Hong Kong	http://www.hkmj.org.hk/skin/
The Electronic Textbook of Dermatology (U.S.A.)	http://telemedicine.org/stamford.htm
Interactive Dermatology Cases, UCLA Medical School (U.S.A.)	http://idtu.medsch.ucla.edu/scripts/Tangocgi.exe/Brian/derm4.qry
Simulated Dermatology Patient (Taiwan)	http://ades.tmc.edu.tw/english/pcare/simulation/default.htm
Multimedia Dermatology Course (Taiwan)	http://ades.tmc.edu.tw/english/pcare/course/default.htm
Dermatology and Dermatopathology Online Lectures, University of Rochester Medical Centre (U.S.A.)	http://www.urmc.rochester.edu/derm/lectures.html

General Resources

Site	URL (all URLs have been accessed 27 August 2000)
Dermatology for Students (Skin Tumours and Other Skin Diseases), University of California Davis (U.S.A.)	http://matrix.ucdavis.edu/tumors.html
Developmental Biology of the Skin: An Interactive Tutorial, University of Washington (U.S.A.)	http://www.hslib.washington.edu/courses/hubio567/

Online Atlases/Image Banks

DermIS - DOIA Dermatology Online Atlas - English version. (Germany)	http://dermis.net/bilddb/index_e.htm
Dermatology Atlas - Loyola University Dermatology Medical Education Website (U.S.A.)	http://www.meddean.luc.edu/lumen/meded/medicine/dermatology/melton/atlas.htm
Dermatology Images, University of Kansas Medical Center (U.S.A.)	http://www.kumc.edu/instruction/medicine/cont-ed/infotech/der-main.htm
Skin Images, Harvard Medical School (U.S.A.)	http://hms.medweb.harvard.edu/nmw/qry/imgpages/imgcollection.cfm?set=HS_Skin
Dermatology Images, University of Iowa (U.S.A.)	http://tray.dermatology.uiowa.edu/DermImag.htm (accessed 12 June 2000)
Dermatology Image Bank at the University of Utah School of Medicine (U.S.A.)	http://www-medlib.med.utah.edu/kw/derm/
Dermatopathology Atlas, Indiana University (U.S.A.)	http://www.pathology.iupui.edu/derm.html
Dermatology and Rheumatology Online Atlas (Italy)	http://www.archrheumatol.net/atlas/index-page.htm
Anatomy of the skin (Electron Microscopy), Department of Dermatology, Mie University School Of Medicine (Japan)	http://www.medic.mie-u.ac.jp/derma/anatomy.html

Evidence-based Practice

Bigby M. Welcome to evidence-based medicine. Arch Dermatol 1998; 134:1516	http://archderm.ama-assn.org/issues/v134n12/full/ded8023.html
Sharon E. Straus SE and Sackett DL. Bringing evidence to the clinic. Arch Dermatol 1998; 134:1519	http://archderm.ama-assn.org/issues/v134n12/full/ded8017.html
Bigby M. Evidence-based medicine in a nutshell: a guide to finding and using the best evidence in caring for patients. Arch Dermatol 1998; 134:1609	http://archderm.ama-assn.org/issues/v134n12/full/dre8017.html
Williams H. Adetugbo K, Li Wan Po A, Naldi L, Diepgen T and Murrell D. The Cochrane Skin Group: preparing, maintaining, and disseminating systematic reviews of clinical interventions in dermatology. Arch Dermatol 1998; 134:1620	http://archderm.ama-assn.org/issues/v134n12/full/dre8023.html
Adetugbo K and Williams H. How well are randomized controlled trials reported in the dermatology literature? Arch Dermatol 2000; 136:381	http://archderm.ama-assn.org/issues/v136n3/full/doc9010.html
The Outputs database of the R&D Programme (DoH - U.K.)	http://www.doh.gov.uk/research/index.htm
Primary Care Clinical Practice Guideline, University of California, San Francisco (U.S.A.)	http://medicine.ucsf.edu/resources/guidelines/intro.html

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Abbreviations

AGEC: Advisory Group on Evaluation Criteria

C-H-i-Q: Centre for Health Information Quality

NeLH: National electronic Library for Health

NHS: National Health Service

NICE: National Institute for Clinical Excellence

RDF: Resource Description Framework

UMLS: Unified Medical Language System

VBL: Virtual Branch Libraries

vortals: Vertical portal targets a specific topic

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XML: eXtensible Markup Language

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<u>Original Paper</u>

Internet Patient Records: new techniques

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Abstract

Background: The ease by which the Internet is able to distribute information to geographically-distant users on a wide variety of computers makes it an obvious candidate for a technological solution for electronic patient record systems. Indeed, second-generation Internet technologies such as the ones described in this article - XML (eXtensible Markup Language), XSL (eXtensible Style Language), DOM (Document Object Model), CSS (Cascading Style Sheet), JavaScript, and JavaBeans - may significantly reduce the complexity of the development of distributed healthcare systems.

Objective: The demonstration of an experimental Electronic Patient Record (EPR) system built from those technologies that can support viewing of medical imaging exams and graphically-rich clinical reporting tools, while conforming to the newly emerging XML standard for digital documents. In particular, we aim to promote rapid prototyping of new reports by clinical specialists.

Methods: We have built a prototype EPR client, InfoDOM, that runs in both the popular web browsers. In this second version it receives each EPR as an XML record served via the secure SSL (Secure Socket Layer) protocol. JavaBean software components manipulate the XML to store it and then to transform it into a variety of useful clinical views. First a web page summary for the patient is produced. From that web page other JavaBeans can be launched. In particular, we have developed a medical imaging exam Viewer and a clinical Reporter bean parameterized appropriately for the particular patient and exam in question. Both present particular views of the XML data. The Viewer reads image sequences from a patient-specified network URL on a PACS (Picture Archiving and Communications System) server and presents them in a user-controllable animated sequence, while the Reporter provides a configurable anatomical map of the site of the pathology, from which individual "reportlets" can be launched. The specification of these reportlets is achieved using standard HTML forms and thus may conceivably be authored by clinical specialists. A generic JavaScript library has been written that allows the seamless incorporation of such contributions into the InfoDOM client. In conjunction with another JavaBean, that library renders graphically-enhanced reporting tools that read and write content to and from the XML data-structure, ready for resubmission to the EPR server.

Results: We demonstrate the InfoDOM experimental EPR system that is currently being adapted for test-bed use in three hospitals in Cagliari, Italy. For this we are working with specialists in neurology, radiology, and epilepsy.

Conclusions: Early indications are that the rapid prototyping of reports afforded by our EPR system can assist communication between clinical specialists and our system developers. We are now experimenting with new technologies that may provide services to the kind of XML EPR client described here.

Introduction

Many European countries aim to introduce Electronic Patient Records (EPRs) as part of the modernization of their public health services. Indeed, the UK NHS (United Kingdom National Health Service) Executive [1] reported that:

> *2.7 The arguments for a move towards an electronic record are compelling. Such records are more likely*

to be legible, accurate, safe, secure, and available when required, and they can be more readily and rapidly retrieved and communicated. They better integrate the latest information about a patient's care, for example from different "departmental" clinical systems in a hospital. In addition, they can be more readily analyzed for audit, research and quality assurance purposes.

Two key benefits that they list are the *integration of care* between general practitioners (GPs) and hospitals, and *improving efficiency* by reducing the time spent by health professionals collecting existing data. Hospitals are often critical about the inadequate and incomplete information to support referrals. GPs in turn consistently complain about the quality and timeliness of test results and information following outpatient or inpatient care. In sum, the quality of clinical communication between hospitals and GPs presents a fundamental challenge to the quality and safety of patient care.

The ease by which the Internet is able to distribute information to geographically-distant users on a wide variety of computers makes it an obvious candidate for a technological solution for an electronic patient record system. Indeed, our previous project, WMED [2] illustrated how first-generation Internet technology could provide a useful infrastructure for secure EPR retrieval.

Yet, providing a nationwide healthcare information infrastructure based on Internet protocols, such as the UK's NHSnet, addresses only part of the electronic solution [3]. Confidentiality of communications and data storage must be guaranteed [4,5,6]. Furthermore, interoperable clinical applications should also be provided. Ensuring effective interoperation between heterogeneous applications generally requires adopting standard protocols and/or data formats. In the healthcare domain, such standards are usually issued by committee: HL7 (Health Level Seven), EDI/EDIFACT (Electronic Data Interchange/Electronic Data Interchange For Administration, Commerce and Transport), DICOM (Digital Imaging and Communications in Medicine), CEN (European Normalization Committee) [7], or imposed by proprietary software vendors. This has tended to inhibit the development of clinical applications that require network transactions. However, this may now change with the advent of a global open-standard for representing documents, XML (eXtensible Markup Language) [8]. In this article, we harness XML along with other second-generation Internet technologies to demonstrate new techniques for building highly interactive EPR web-clients.

XML, with its inherent facility to impose application-specific constraints on the hierarchy and data content of documents, appears well suited for specifying EPRs. XML is, in fact, a distilled version of SGML (Standard Generalized Markup Language), a more general standard by which rather more complex constraints can be applied. SGML's great complexity meant that it was not widely adopted for healthcare applications, a notable exception being a medical markup language project in Japan [9]. XML's greater accessibility has subsequently led to the wide availability of tools for its development. Indeed, major standards committees are now incorporating XML within their existing standards (eg, Structured Reporting in DICOM [10], Patient Record Architecture in HL7 [11], and the XML-EDI initiative). Independent pilot projects, like the Scottish Immediate Discharge Document system [12], are also deploying XML.

Containment of system complexity has been a primary motivation throughout the evolution of second-generation Internet technologies. For example, XML specifies the content of a document independently of how it should be presented and independently of the logic associated with its interactions. This can help simplify the design of an EPR system. Document content delivered as XML can be presented on the web through the application of stylesheets that conform to well-defined open standards: XSL (eXtensible Style Language) [13], to lay out the format; and CSS (Cascading Style Sheets) [14], for page-color and typographical styling.

Specifying the ways users can interact with the document presented to them (eg, to update or add to it) is intrinsically coupled to the way the content itself has been specified. Here, two different approaches have emerged to keep this specification reasonably simple. One has been to embed so-called event handling in the XML technology (as we largely adopt here), while the other has been to follow a comprehensive object-oriented (OO) paradigm in which data-content and the methods to manipulate it both become wrapped into true program objects. In theory an object can be strongly decoupled from other objects within a system and consequently overall complexity ought to be kept low. Ideally a web of objects [15] would communicate to achieve a joint purpose (eg, the maintenance of the EPR). In practice, complexity inevitably re-emerges when programs distribute their constituent objects over different nodes of a heterogeneous network even when standard interfacing and protocols - eg, CORBA/IDL/IIOP (Common Object Request Broker Architecture/Interface Definition Language/Internet Inter-ORB Protocol), Java/RMI (Java/Remote Method Invocation), or MS/DCOM (Microsoft/Distributed Component Object Model) - are adopted. In particular, tolerating temporary network failure can have significant impact on the complexity of object-to-object collaboration. Nevertheless, distributed object-oriented approaches do exist in the healthcare domain, notably the CORBAmed initiative and the HANSA (Healthcare Advanced Network System Architecture) system [16].

The DOM (Document Object Model) [17] provides the standard way to interact with XML documents. Web browsers have contained a primitive DOM (retrospectively named level-0) that applied to HTML form and link elements. Specifying user interaction on a web page was achieved by providing scripts, written in JavaScript, to specify how events such as clicking and selecting items were to be handled. The latest versions of the Internet Explorer and Netscape (Mozilla) web-browsers now embed more comprehensive, standards-based DOMs that are automatically populated whenever they receive an XML document. In effect, a mini-database (eg, a tree hierarchy representing patient data) resides for the duration of the web page on the client computer ready to be presented to, and manipulated by, the clinician. Again, the event handlers can be scripted to achieve programmatic interactivity. However, a

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barrier to principled approach here is the lack of explicit data-typing in XML delivered to the DOM. Until recently a Document Type Declaration (DTD) was all that was available to specify the rules governing document content, and those rules treated all data as character strings. However, this deficiency may soon be overcome by an emerging standard XML-Schema [18].

In anticipation of the arrival of web browsers that furnish access to a data-typed DOM, we have built a system that emulates some of the effects in today's (version 4 and 5) browsers. To do this we employ a combination of JavaScript and Java applets. Java allows us to incorporate a public-domain DOM/XML parser and XSL transformation methods [19]. It also provides a sophisticated OO programming environment when the need arises (eg, to implement clinical image viewing or decision support). Java applets have the benefits of being portable, transparently downloadable, and able to interface with JavaScript event handlers on the web page. Furthermore, by adopting the JavaBean [20] methodology each of our applets is made into an independent software component. This helps keep complexity under control, as does formalizing inter-component communication to use the Java InfoBus [21] class-library. Communication between components running in the same Java Virtual Machine is supported. We do not ask our JavaBeans to communicate directly with others across the network, but instead rely on the browser's innate asynchronous connectivity to download/upload resources according to standard Internet protocols. That way our system can remain fairly tolerant to transitory network disconnectivity.

Methods

We have built a prototype EPR client, named InfoDOM, that runs in both the popular web browsers: Internet Explorer 4 & 5, and Netscape 4. Figure 1 illustrates the basic mechanisms involved in this system. Here, version 2 of our prototype is described; we presented the first version at the PA Java 2000 conference [22]. The process begins by an IO (Input/Output) Manager bean (not shown) requesting an XML record over the web from the EPR server. For this we have used the Apache web server running SSL (Secure Socket Layer). The downloaded document is then stored in the client-side DOM.

An XSL file is also downloaded and then applied to the DOM content by the XSL Processor bean (not shown) to produce HTML. A pop-up web page (the EPR Browser) defined by that HTML is then generated. From that page users can begin to work on the patient data, simply by clicking on the appropriate contextual links. For example, users may choose to modify the textual data as shown in Figure 2, or else they may launch further pop-up windows containing the Image Viewer or Reporter beans parameterized appropriately for the particular patient and exam in question.

Figure 1. The electronic patient record is delivered over the Web via secure SSL as an XML document. On the client it is stored in the Document Object Model and thus its contents become available for presentation in a variety of ways. The basic patient details can be viewed as an interactive web page (by the application of XSL and CSS stylesheets). From the EPR Browser other views of the same record can be launched; the image Viewer and the clinical Reporter JavaBeans are shown. These tools have been used to modify the record so that it can be uploaded back to the server. Communication among JavaBeans is mediated by the InfoBus, while the launch of new windows is achieved using JavaScript libraries
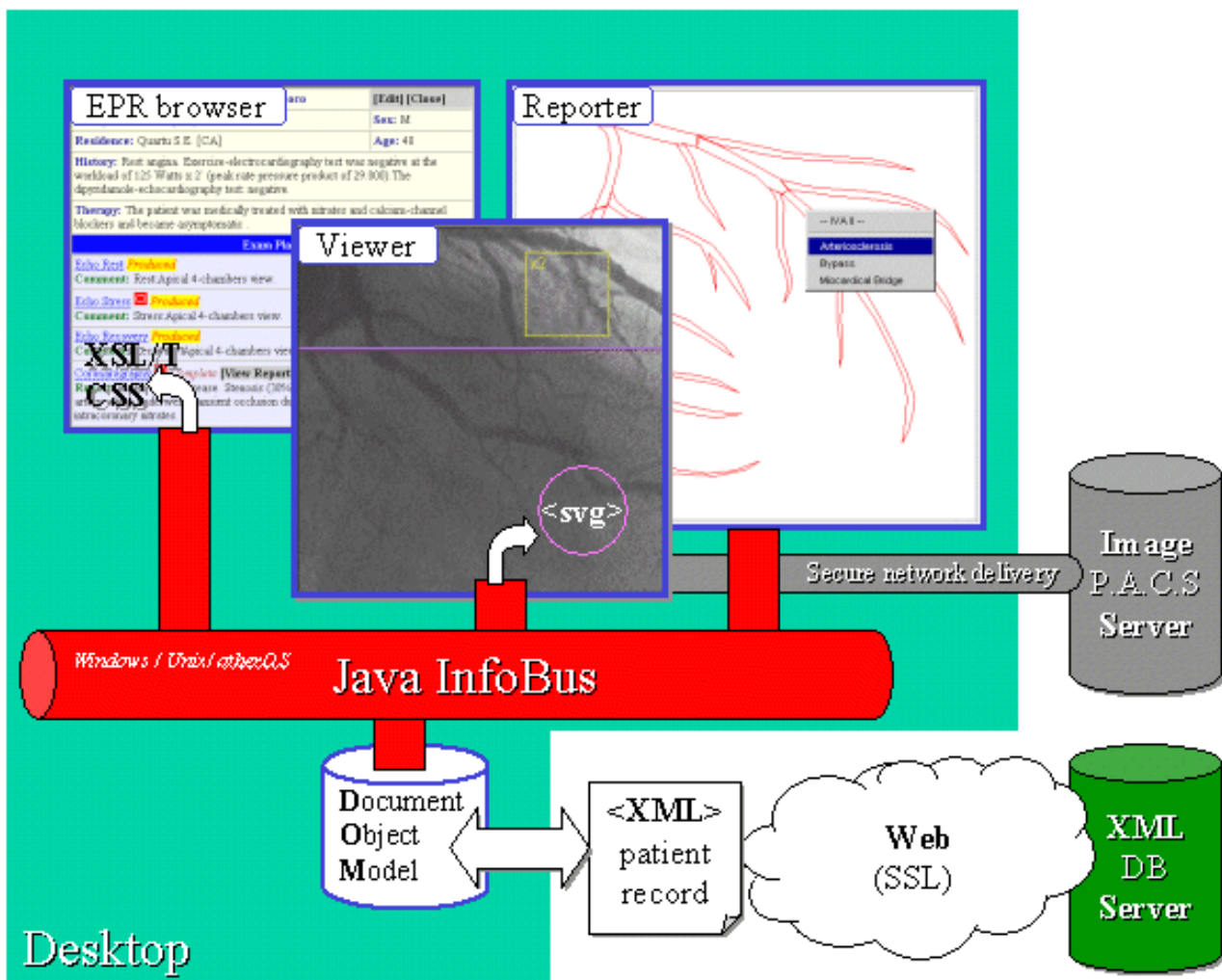
The Image Viewer reads image sequences from a patient-specified network URL on a PACS (Picture Archiving and Communications System) server and presents them in a user-controllable animated sequence. The animation can be halted to examine any particular image frame in detail. For example a 2-, 3-, or 4-times magnifier window can be made to track the mouse cursor. Image regions of interest can be annotated using line graphic overlays as illustrated in Figure 3. These overlays are read and written to the DOM and form parts of the report section. We leave the original image data as a read-only resource. This is because synchronizing updates to large image sequences across networked clients would inevitably be prone to delays and would require complex back-end integration with the PACS servers. The Scalable Vector Graphics (SVG) standard [23] is used to represent the overlays. As SVG is simply a dialect of XML, it is possible to store annotations in the DOM and transport them as XML fields. Our prototype client currently reads GIF images from a web directory; however it is not difficult to extend the system to read images from a PACS. We have carried out preliminary tests [24,25] using a DICOM 3 compliant PACS [26]. As such, we are in line with other researchers [27,28].

Figure 2. Parts of the XML patient record are rendered as a web page, the EPR Browser, in a pop-up browser window (shown). In addition to text summary items such as History, Therapy, and Report, this page contains several interactive items: form fields, such as Date of Birth (shown here as it is being modified); links to viewable imaging exams that are shown as underlined (eg, Coronography); and links to the graphical Reporter tool, to view and edit a report of the exam in question
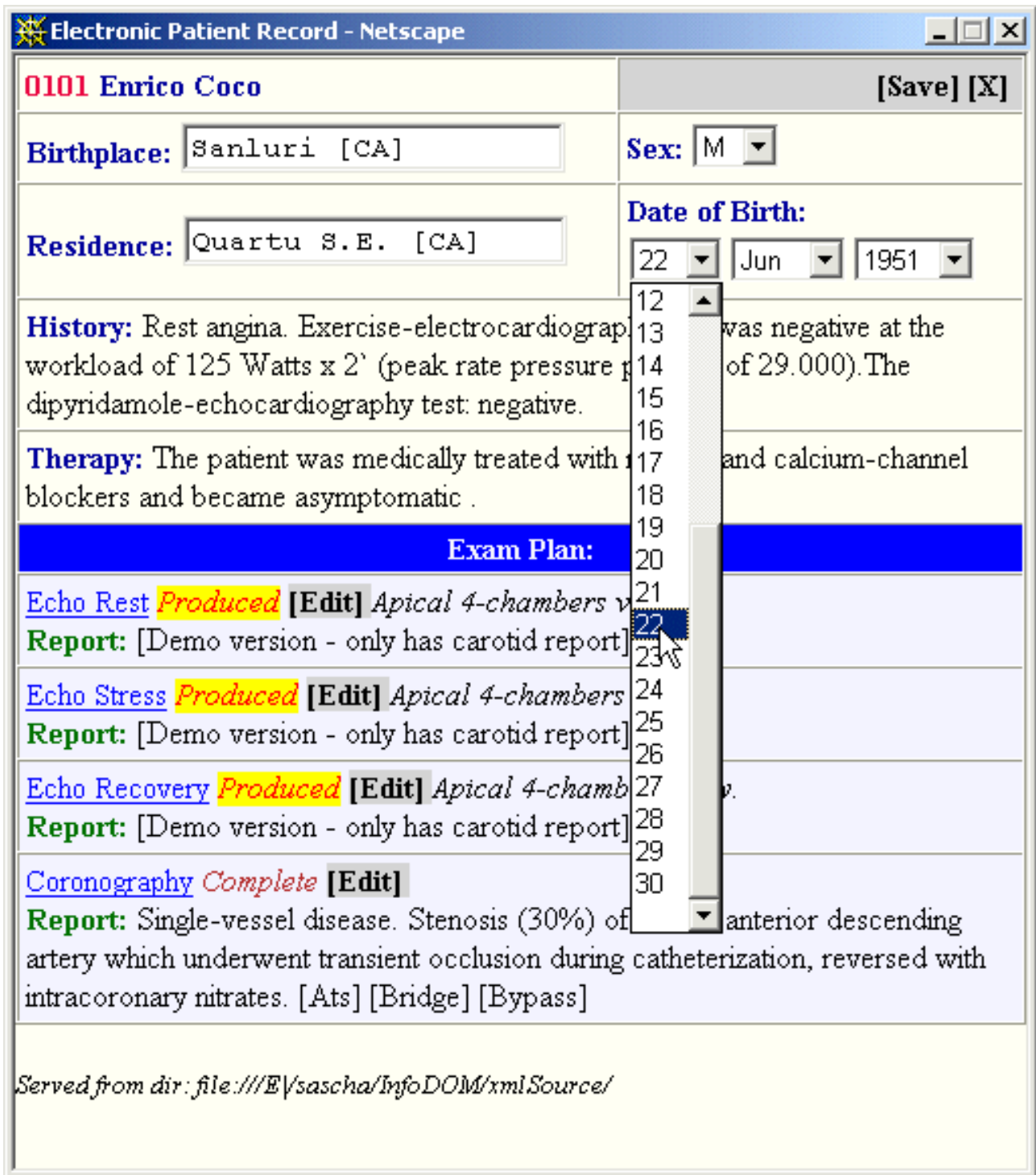
Clicking on the [Edit] link in theEPR Browser launches a context-specific Reporter tool. Figure 4 (top) illustrates the configuration for reporting on coronary arteries. The design follows an anatomical image map paradigm. The image map structure is read as SVG and its context-sensitive pop-up menu is specified in XML. For example the figure shows the IVA-II artery and a pop-up menu that can launch three different types of report: Arteriosclerosis, Bypass, or Myocardial Bridge. Selecting a menu item launches a pop-up reportlet window; the Arteriosclerosis reportlet window is illustrated in Figure 4 (bottom).

Figure 3. The JavaBean Image Viewer is capable of: showing an animated sequence; creating and modifying annotated graphical overlays; and then saving them in Scalable Vector Graphic format inside the DOM. In addition, parts of the image can be magnified and gray-level sections graphed (not shown)
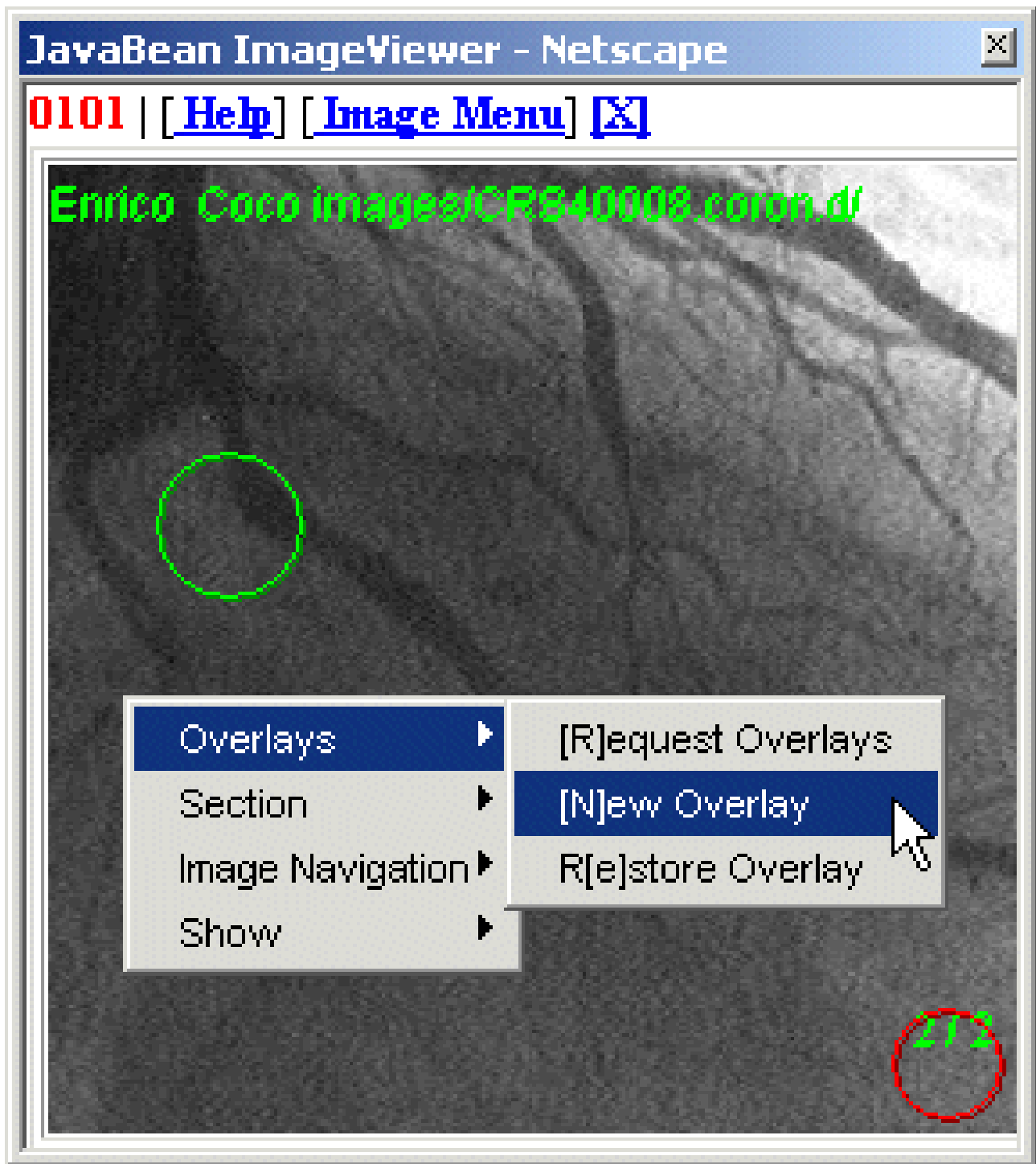

The Arteriosclerosis reportlet allows the medics to graphically specify the clinical signs appropriate for their patient's coronary vessel IVA II. The interface is constructed from sliders, pull-down text menus, and pop-up image menus, all of which are implemented via JavaScript library calls. Wherever feasible the user is presented with a limited range of items or numerical values to select from, thus minimizing difficulties in handling hand-typed text. The menu-bar at the top of every reportlet is, in fact, an embedded JavaBean that serves two functions: the reading and writing of data content to and from the DOM via the InfoBus; and the provision (when appropriate) of decision support information. For example, in Figure 4 the colored part on the right of the menu-bar adjusts dynamically to suggest the type of lesion, based on the evidence accumulated in the report. We have initially implemented a simple voting system. The medic may author each form element in such a way as to specify how its possible values can influence the probable diagnosis. For example, in the figure the choice being made, "Moderate tortuosity of proximal segment," will produce one vote for the diagnosis of a type B lesion.

An early version of this Arteriosclerosis tool [29] was included in the WMED system, but there it was not integrated into the EPR content. With InfoDOM the data content is now written and read from the DOM and transferred as XML. The current prototype provides five other such reportlets. All graphical assets, such as image-menus and SVG maps, follow a web directory style hierarchical organization and so are instantly transportable between websites or to hard disk.

Figure 4. The Reporter Bean (top-left) is launched from the EPR Browser. Each report is configured to the particular exam in question, here the left coronary artery. The user clicks on the resultant image map (SVG encoded) to initiate a reportlet page from a menu of context-sensitive reportlets. Here, the user chose to report on Arteriosclerosis for the vessel labeled IVA II. A reportlet (bottom) for Arteriosclerosis then appears and allows the medics to graphically specify the clinical signs appropriate for their patient. As is shown, the interface is constructed from sliders, pull-down text menus and pop-up image menus; there is no way to hand type information. The colored part of the menu-bar is a decision support aid that dynamically indicates the type of lesion, based on the evidence accumulated in the report. In this case the simple voting heuristic implemented indicates that a type B lesion is the most likely interpretation. The next figure illustrates the mechanism underlying each reportlet
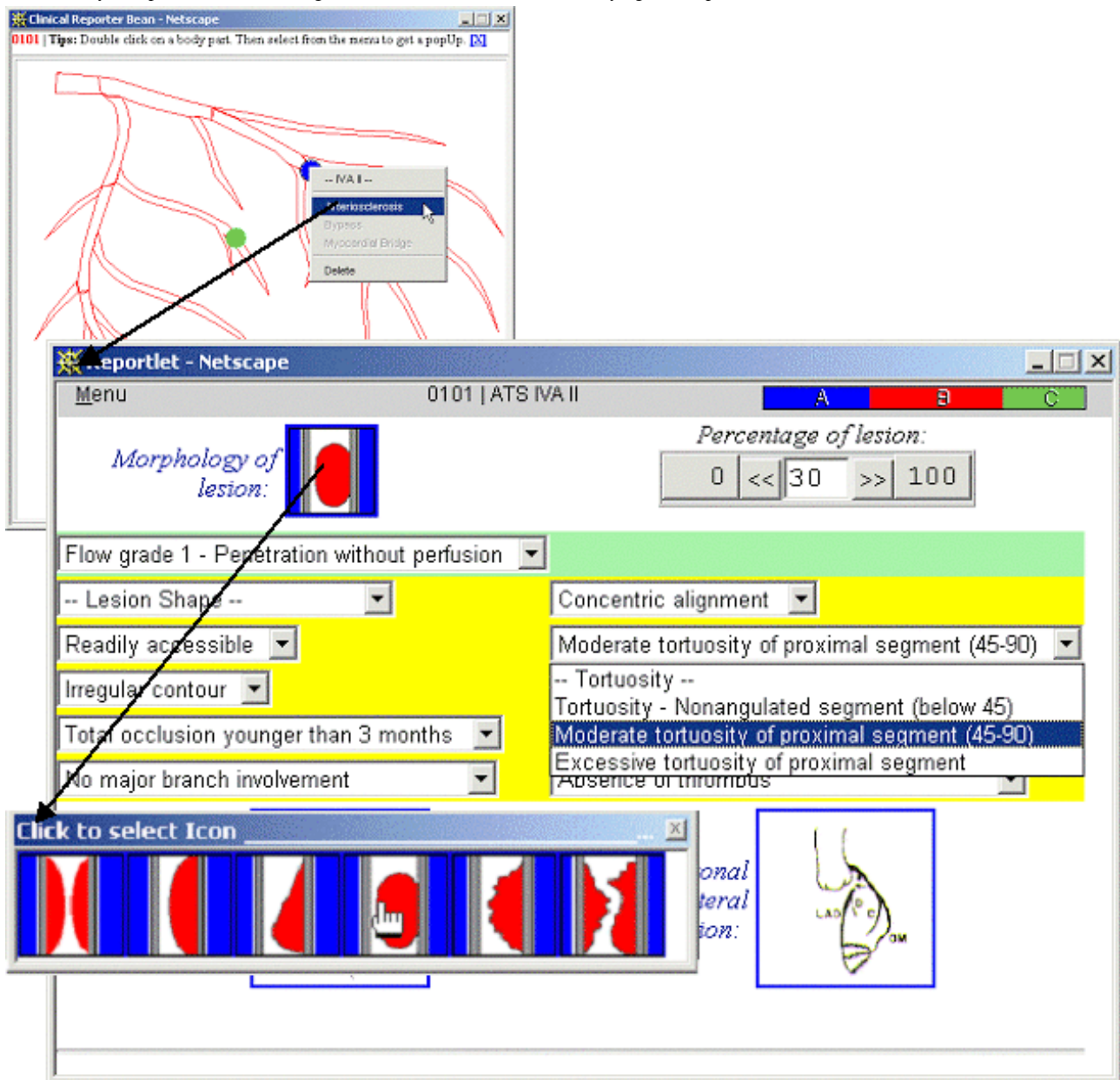
Version 2 of InfoDOM has rationalized and generalized the implementation of reportlets. JavaScript libraries have been written to generate arbitrarily specified reportlets. This approach provides an improvement in speed, stability, and configurability over our previous version that employed the Java AWT (Abstract Window Toolkit) to do this task. In particular, the gamut of interactions and choices available within a given reportlet is now specified by writing individual HTML forms following a small set of simple rules. These forms get automatically enhanced when placed inside the InfoDOM environment. Away from the InfoDOM environment they can be created using any HTML editor and viewed (unenhanced) in any browser. This makes it possible for a specialist in a particular field to specify a detailed set of reporting parameters and constraints on the parameters, without the need to interact with our system developers. The browser on a specialist's desktop is sufficient for the specialist to explore the interactive functionality of the part of the system that is being designed.

Once the specialist is satisfied with the content of the HTML form, it is incorporated into the InfoDOM system (a) by selecting a CSS style for its element, and (b) by ensuring it calls the appropriate JavaScript library. Figure 5 illustrates the mechanisms involved in generating an enhanced form:

1. The reportlet HTML form coded by the medic is loaded as a web page.
2. As soon as the page is loaded, a JavaScript routine examines the contents of each element of the HTML form (ie, it interrogates the level-0 DOM).
3. The script then identifies those elements that have been marked up for enhancement - eg,
   - A select box to transform into an icon menu (eg, the small pop-up in Figure 4 (bottom) marked "Click to select Icon"). Here, a set of GIF-icons that correspond to each select option has been prespecified by the medic.
   - A numerical text field to transform into a slider-bar (eg, the field in Figure 4 (bottom) marked "Percentage of lesion"). Here, a fixed range of values has been requested.
   - A date text field to transform into a day-month-year 3-way selection combo (eg, the field shown in Figure 2). Here, the combo is dynamically constrained by an algorithm to allow only legal dates (eg, leap days).

4. The script then generates a new page that re-represents each form element, substituting those that it can with enhanced versions and spatially formatting them in cells of a regular table.
5. Colors are assigned to each table cell according to the name of its element, using a custom-built CSS stylesheet. That name is the one which the medic specified in the original form using the standard attribute assignment: NAME="yourNameInHere".
6. That name, more importantly, identifies the DOM data-item to which that form element is to read and write its contents. In fact, each element in the new page can be updated with the correspondingly named DOM data-item as soon that page has been loaded into a browser window. A JavaBean, that manifests as the menu-bar of that page, carries out this task by communicating with the DOM and appropriately adjusting the value of the elements of the form in the enhanced page.

To achieve a stable synchronization of the above operations, we use a multi-frame web page (a frameset) so that the original form loads into an unseen frame, then the enhanced page loads into the main frame, and finally the JavaBean menu-bar loads into its own strip-like frame at the top.

Figure 5. The enhancement mechanism for reportlets: a reportlet HTML form (top) prototyped by the medic is loaded. Next, a JavaScript routine examines the contents of each element of the form, to identify the elements marked up for enhancement (eg, icon-menus and slider-bars). This generates a new page (bottom) in which elements are tabulated and colored according to a CSS stylesheet. The menu-bar inserted at the top of the new page is, in fact, a Java Applet that communicates with the DOM to read (and later write) the stored contents of the reportlet. Thus, once the new page has loaded, the menu-bar automatically populates the form elements (including the enhanced elements) of the page. Key to each step of this mechanism is the names of the elements in the original form. Indeed, those names identify the content of the XML fields that will be used in the EPR
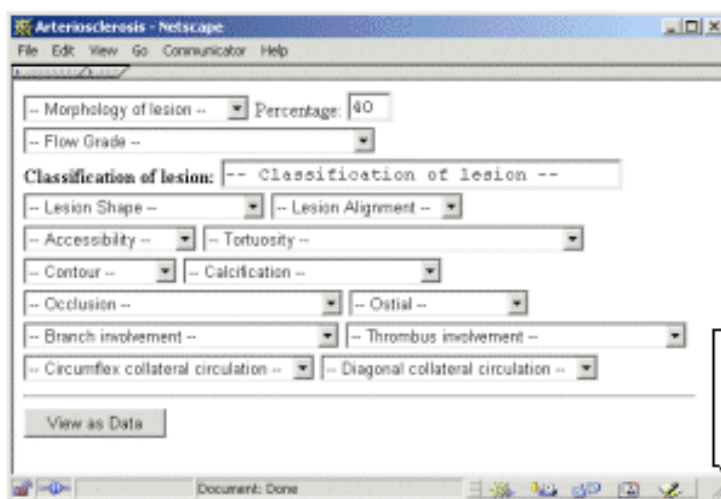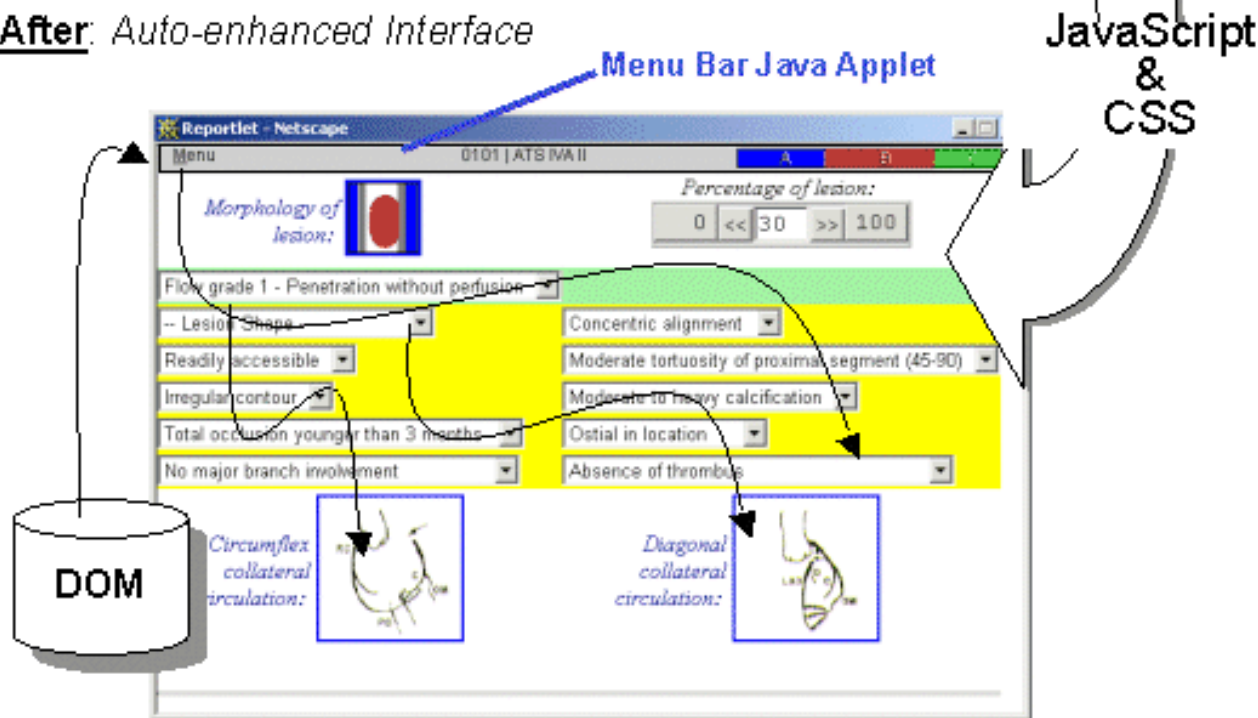
The XML specification of each clinical section of the EPR is *produced by example* when one follows the above methodology. Although this may be rather unconventional, it does promote a rapid prototyping style of development. In fact, each particular reportlet specifies a particular branch of the XML tree structure. Part of the specialist's skill is to comprehensively specify the options needed to make a particular report, while another part is to know where to cut each branch so as to best differentiate between distinct pathologies. The spatial image-map interface of the Reporter component can help guide the latter decision. In any case, once a reporting regime has been established by

example it is a minor task for an XML developer to convert the medic's original form into a formal XML specification.

Results

The experimental system illustrated above is currently being adapted for use in three hospitals in Cagliari, Sardinia. Each site constitutes a test-bed system [30] in which medics are participating as both users (that provide feedback) and designers (that provide clinical reports), according to their particular medical specialties. The test-beds include:

1. The support for clinical reporting between radiologists and neurologists. Here, DICOM-compliant MRI (Magnetic Resonance Imaging) and CT (Computed Tomography) devices are used by radiologists to acquire imaging exams of the brain. These are stored on a PACS archive and thus made available to networked neurologists in different parts of the same hospital. The electronic patient record acts, here, as a skeleton upon which to collate information on individual exams for each participating patient.

2. The support for reporting visits by outpatients to epilepsy centers. Here, we aggregate details gathered over visits made at different times. These details include seizure descriptions, EEG and MRI exam reports, and responses to drug therapies. Here, the electronic patient record acts as a dynamic repository that accumulates over time. By visualizing how the patient's conditions evolve over time, the medic ought to be better able to make diagnoses and more accurately prescribe treatments.

3. The support for reporting visits by patients to an oncology hospital. Here, the time evolution of the size of tumors in response to various cancer treatments is to be visualized

It is during the design phase that our system's rapid prototyping methods should be of great benefit because they afford integration of additional networked resources, without significant increase in overall system complexity. This ought to give a particular advantage over similar test-bed systems that are not built in quite such a flexible manner [31,32,33]. In practice, it has proved very difficult to persuade medics to code HTML forms to describe their own specialist reports. Nevertheless, we are still able to use such forms through a process of consultation and refinement, whereby medics check the forms that are being compiled by our developers. It seems that most medics are so fully occupied with their traditional work that they are not able to devote time to coding how they do it.

Discussion

As presented here, our InfoDOM prototype implements a rich, but entirely client-side, EPR system. On the server side, we have been satisfied to transmit and receive XML documents that get stored on the server file-system, just as a typical website deals with plain HTML files. Any practical EPR services, however, must consider more sophisticated server-side solutions that provide: confidentiality on the server, full auditing of the changes made to patient data over time, and the management of transactions when two or more users work simultaneously on the same patient. Some of these features are now becoming available as major database vendors, such as Oracle and Microsoft, incorporate XML processing into their products.

In theory, the tree structure of XML ought to afford an even more finely-grained control over the life of a document than traditional file-locking or database table-locking can do. In particular, problems arising due to the asynchronous nature of web connectivity ought to be ameliorated. For example, conflict resolution done at a tree-branch level would mean that medics working on different parts of the same document ought not to unduly hamper each other's access. We are currently developing a server-side version-control system based on these ideas.

Once an EPR server has established that two medics want to access the same part of the same patient's document, it might be appropriate to establish a peer-to-peer connection between them so that they become aware of each other's work and resolve conflicts before submission to the database. This would constitute a form of instant-messaging - cf, ICQ (I Seek You), AIM (AOL Instant Messenger) - whereby sections of the XML document are exchanged between participating clients. A network-aware JavaBean component connected on the existing InfoBus could be developed to fulfill this purpose.

It is also important that any new EPR server integrates well with existing information systems within the target healthcare institution. An immediate example is that our EPR server ought to able to appropriately handle notification from the PACS of new arrivals of imaging exams. Anagraphic databases and exam-booking systems provide other examples. We plan to use the SOAP (Simple Object Access Protocol) protocol [34] to specify server-to-server calls for information. SOAP protocol has the benefit that it works entirely in XML and runs on top of the standard web protocol. This means that it suffers none of the network accessibility problems that adversely affect CORBA/IIOP, Java/RMI and DCOM approaches. We are currently modeling an existing radiological workflow process using distributed servers that communicate by SOAP.

A problem we have not addressed here is that of the sheer volume of data that image exams contain. What can be done to serve image exams to users that do not have a broadband connection? For example, a consultant might save time by being able to see a particular aspect of an exam while off-site, or working from home. To this end, we are considering possible means for caching on the PACS server a variety of reduced representations of imaging exams, in such a way that the client could prioritize at a distance the order of arrival of the information, so that the medic can see the images in the order that they are needed. Such smart image-delivery mechanisms could be based on image-segmentation algorithms, wavelet compression, or simple tessellation techniques. A key issue here is to understand the human perceptual interface needed to support the medic at a distance.

Conflicts of Interest

None declared

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Abbreviations

CORBA: Common Object Request Broker Architecture
CSS: Cascading Style Sheet
DCOM: Distributed Component Object Model
DICOM: Digital Imaging and Communications in Medicine
DOM: Document Object Model
EDI: Electronic Data Interchange
EPR: Electronic Patient Record
GP: General Practioner
HTML: HyperText Markup Language
IIOP: Internet Inter-ORB Protocol
OO: Object Oriented
PACS: Picture Archiving and Communications System
RMI: Remote Method Invocation
SGML: Standard Generalized Markup Language
SOAP: Simple Object Access Protocol
SSL: Secure Socket Layer
SVG: Scalable Vector Graphics
XML: eXtensible Markup Language
XSL: eXtensible Style Language

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