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# Journal of Medical Internet Research

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## Editorial

# Challenges and changing roles for medical journals in the cyberspace age: Electronic pre-prints and e-papers

Gunther Eysenbach

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*"We are in the business of revealing, not suppressing information."*

*J. P. Kassirer, N. Eng. J. Med. 327, 1238 (1992).*

In May 1999, the Director of the US National Institutes of Health (NIH), Harold Verms, proposed a project, then dubbed "E-biomed" [1] (now called "PubMed Central" [2]). In this proposal, the National Institutes of Health - through the National Center for Biotechnology Information, a component of the National Library of Medicine - proposed to establish an Internet-accessible database of full electronic papers, which would be submitted directly by their authors. The original E-biomed plan [1] envisaged two sections in this system: one that allowed authors to submit papers which would only be electronically released after going through peer-review by editorial boards; and another one that allowed authors to publish electronic papers directly, without any peer-review, but with some minimal filtering in the form of requiring "approval by two individuals with appropriate credentials (...) to provide protection of the database from extraneous or outrageous material."

The proposal was embraced in numerous articles and editorials [3,4]; but several proponents of the traditional scientific publishing industry, especially the more conservative journals such as the New England Journal of Medicine (NEJM) uttered concerns, especially concerning the latter, non-peer-reviewed part of the system. Arnold S. Relman argued in a NEJM editorial that any "system that allowed immediate electronic publication of new clinical studies without the usual careful process of peer review and revision would be risky," [5] and argued that a "virtual community of experts and users could not provide practitioners with the kind of assistance they receive from the reports, reviews, and commentary found in high-quality peer-reviewed journals" [6].

Does this sound familiar? Indeed, the argument that peer-review is the only means of protecting the public from erroneous and thus potentially harmful research had been brought forward 30 years previous by former NEJM editor Franz Ingelfinger, who at that time announced the policy that a manuscript could not be accepted if it had previously been published elsewhere. Many journals have adopted this so-called Ingelfinger rule [1]; some of them, for example Science and the NEJM, have extended this rule into cyberspace, in that they will promptly reject manuscripts if they have been "published" on the World Wide Web: "posting a manuscript, including its figures and tables, on a host computer to which anyone on the Internet can gain access will constitute prior publication" [2]. This leads to the apparent paradox that articles which were published on the Web

for the very purpose of open peer-review and in an effort to improve the manuscript are routinely rejected by these journals, with the argument that the public shall in this manner be protected from non-peer-reviewed, low-quality information. It shows the paternalistic concern of these journals, their belief that the public cannot discriminate between the different levels of credibility of a manuscript. Another explanation for this unwillingness to embrace electronic advance publication could be that traditional paper journals attempt to preserve their priority, newsworthiness, and exclusive access to research papers (which has long been a guarantee for circulation, attention, and paid advertisements for their journals). However, this race of traditional journals against the Internet for priority and exclusivity of research reports cannot be won by the journals.

Scholarly journals were originally established to serve scientists as a tool for communication. The Internet has the potential to further improve the communication process and perhaps - by fostering a broad and immediate debate - the quality of manuscripts. Systems such as the British Medical Journal (BMJ) e-print server and the original E-biomed proposal have the potential to make an article visible to experts before it is published in traditional print journals. It seems that any non-peer-reviewed paper published on the Web should be seen as a "virtual conference", thus papers presented in such a context on the Internet should be treated as papers presented at scientific meetings, for which the Ingelfinger rule is waived as well.

The NEJM editorial predicted that there would be "probably disastrous effects of E-biomed on journals" and frankly admitted the commercial concern that "a flourishing E-biomed system would very likely reduce the submissions, paid circulation, and income of most clinical journals enough to threaten their survival" [5]. However, I would argue that *every medical journal which can be replaced by an e-print server deserves to be* (in analogy to Warner Slacks saying that "any physician who can be replaced by a computer deserves to be" [7]).

Communication technology has changed profoundly since the times of Ingelfinger. These days, information is often first published on the Web and sometimes read by millions of users before printed journals can cover the story, which has perhaps most impressively been demonstrated by events such as the publication of the Starr Report on the Web [8]. In these cases, readers don't buy newspapers and journals because of their newsworthiness, but because of their in-depth analyses and comments.

A similar development in science seems to be inevitable and desirable. Medical journals - at least general medical journals - should give up their aim of being the primary and sole source

of scientific information, but shift their aim toward acting as catalysts to get evidence-based medicine into practice. Their principal mission should not be newsworthiness, but putting "primary" information (which may have already been published on the Internet) into context and perspective, by evaluating, commenting, and weighting raw information. While the NEJM argues that the existence of non-peer-reviewed material on the Internet may confuse the public and pose a threat to traditional medical journals, we think that exactly the opposite will be true - that the more information is available, the more urgently traditional journals are needed to guide readers through this information jungle. The Internet will only make *bad* journals redundant - those journals which do little more than physically "publish" papers. The Internet will in the future become a huge library containing all the ingredients and information a researcher needs, but busy clinicians will still need journals such as the BMJ, Lancet, and even the NEJM to make the information digestible and to highlight the information which is relevant to clinical practice.

Perhaps even a new generation of journals will be established - journals which do not publish primary papers themselves, but which only evaluate, weight, comment, and put into context information that has been published elsewhere on the Web. Traditionally, the primary aim of journal publishers is to establish quality control mechanisms and to establish a reputation for the reliability of their information. In the near future, publishers - without putting any ink to paper or producing another medium - may get back to this fundamental truth of publishing - to be a credible source and to establish trust, to evaluate and describe information which perhaps is already published on the Internet. In fact, today we have two different meanings of "publishing" - one is the physical process of making a document public, the other is the process that implies establishing trust. While in traditional publishing, both of these processes were amalgamated into one single process, they are

now separated; manuscripts may first be "published" on the Internet, but "establishing trust" may be a separate process and may have many different faces (e.g. favorable comments of colleagues, or a printed comment of a peer-reviewed journal pointing to a Web-published piece).

It is true, however, that there must be exceptions - certain manuscripts may for ethical reasons not be suitable for release on the Internet without previously having been peer-reviewed, if for example their results would raise false hopes among patients. However, these decisions should be made on an individual basis (perhaps made by the Institutional Review Board which approves the study) and should not be a basis for dismissing a whole new way of publishing.

Journals which do not change their editorial policies along these lines, allowing print-publication of material previously published on the Web for the sole purpose of review, and which continue to oppose and lobby against NIH plans to allow non-peer-reviewed material to be published in "PubMed Central", demonstrate that their primary concern is not to discourage public announcement of research findings which bypassed peer-review, but attempting to preserve their circulation by publishing exclusive reports before a broader audience has had the ability to access them. In doing so, they would cease to serve the research community but serve only the commercial interests of publishing companies. They would also demonstrate that they do not understand the Internet and that they do not understand that they are not longer in the business of revealing new information, but in making existing information understandable and useful for a broader audience.

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Editor,

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## Short Paper

# Online Prescribing of Sildenafil (Viagra) on the World Wide Web

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## Abstract

**Background:** A growing number of prescription medicines such as Viagra® are offered and sold directly to consumers on the Internet. Little is known about the structure and "quality" of these "virtual pharmacies" in terms of how responsibly "online-prescriptions" are actually issued.

**Objective:** To determine to what extent Viagra is sold on the Internet despite clear contraindications.

**Methods:** The World Wide Web was searched for companies who offer to issue prescriptions for Viagra online or sell Viagra without prescription. We pretended to be a patient in which the ordered drug (Viagra) is clearly contraindicated, and tried to obtain an online prescription for this drug on the Internet. Our test case was as a 69-year-old woman giving a sexual history of having "no orgasm," with obesity (165cm/78kg), coronary artery disease, and hypertension, and taking captopril, pravachol, atenolol, and erythromycin.

**Results:** Twenty-two distinct companies were identified, consisting of three different types: 2 required a written prescription by a "real" physician, 9 dispensed the drug without any prescription at all, and 11 issued an "online prescription" after an alleged physician reviewed the online order form containing medical questions. We tested 10 of the latter type, among them 8 based in the USA. We ordered a total of 66 pills worth US\$ 1,802.84. Three companies, among them both European companies, delivered within 6, 10, and 34 days respectively, despite Viagra being clearly contraindicated. In 80% no complete history was taken, in 70% inappropriate medical terminology was used, and in only 2 cases was the order form reviewed by a physician who identified himself.

**Conclusions:** Although a surprisingly high number of Internet pharmacies declined delivery, the public should be alerted to the risks involved with prescription drug prescribing and dispensing via the Internet.

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## KEYWORDS

Internet; Referral and Consultation; Fees; Pharmaceutical; Prescriptions; Drug; Commerce; Physician's Practice Patterns; Impotence; Piperazines; Medical History Taking; Quality of Health Care

## Introduction

The World Wide Web has become a medium to advertise and dispense medicines directly to consumers. Since little is known about the structure and "quality" of these "virtual pharmacies" in terms of how responsibly "online-prescriptions" are actually issued, we created a fictitious patient for whom the ordered drug (sildenafil, known by the brand name Viagra®) was clearly contraindicated and tried to purchase this drug on the Internet.

## Methods

In March 1999, we searched for "cyberpharmacies" selling Viagra by entering the terms "+order +viagra" into a search engine (<http://www.altavista.com>). We reviewed the first 60 of the 60,000 pages found, and researched the company name and address behind the Internet addresses using InterNIC's "Whois" service [1]. Twenty-two distinct companies of three different types were identified: 2 required a written prescription by a "real" physician, 9 dispensed the drug without any prescription at all, and 11 issued an "online prescription" after an alleged physician reviewed the online order form containing medical

questions answered by the patient. We tested 10 pharmacies of the latter type, among them 8 companies based in the USA, by posing as a 69-year-old woman giving a sexual history of having "no orgasm," with obesity (165cm/78kg), coronary artery disease, and hypertension, and taking captopril, pravachol, atenolol, and erythromycin. In this case, prescription of sildanefil would clearly not be indicated, as Viagra is not approved for females, and special caution has to be taken with patients having a history of cardiovascular disease [2]; besides, the fictitious patient was taking multiple medicines which could interact with sildanefil. We ordered a total of 66 pills among the 10

companies. The average price was US\$ 17.00 per pill, ranging from US\$ 8.33 to 50.00. Eight companies charged a consultation fee, ranging from US\$ 65.00 to 89.00 (mean US\$ 74. 88). In all cases, the consultation fee was only charged if the doctor determined that Viagra was "appropriate." Including shipping fees (US\$ 34.00 on average), the total value of all orders was US\$ 1,802.84.

## Results

An overview of all cyberpharmacies contacted is given in [Table 1](#).

**Table 1.** Cyberpharmacies. Reasons for non-delivery: F=not indicated in females, I=import restrictions, M=medical reasons, X=no reason given

	<i>URL</i>	<i>Country of origin</i>	<i>Remarks</i>	<i>Total price</i>	<i>Delivered yes/no</i>
1.	<a href="http://kwikmed.com/">http://kwikmed.com/</a>	USA	Did not ask for concomitant medications. Affiliate program.	US\$ 216.00 (10x50mg)	No/F - "cannot prescribe to females at this time"
2.	<a href="http://www.viagragsuys.com/">http://www.viagragsuys.com/</a>	USA	Offers to ship cimetidine (Tagamet®) with sildanefil to enhance its effect.	US\$ 130.00 (3x50mg)	No/F - "even though there is no reason to believe that Viagra might be harmful to women ...in order to remain consistent with prescribing information...we are not filling prescriptions for women at this time."
3.	<a href="http://www.qualitymed.com/">http://www.qualitymed.com/</a> <a href="http://www.viagra-cafe.com/">http://www.viagra-cafe.com/</a>	USA	Affiliate program.	US\$ 196.00 (3x50mg)	No/F - "we know of its benefits in both sexes, however, we are unable to fulfill any orders for females at this time"
4.	<a href="http://www.viagra.nu/">http://www.viagra.nu/</a>	Gibraltar (delivered from USA)	Very short medical history questionnaire.	US\$ 59.80 (2 x 100mg)	Yes - (34 days)
5.	<a href="http://www.mdby-phone.com/">http://www.mdby-phone.com/</a>	USA	Charged credit card but did not deliver.	US\$ 149.00 (5 x 100mg)	No/I - "we are prohibited to deliver into Germany"
6.	<a href="http://thepillbox.com/">http://thepillbox.com/</a> <a href="http://www.medicalcenter.net/">http://www.medicalcenter.net/</a>	USA		US\$ 236.00 (10 x 100mg)	No/I - "due to your country's import restrictions, we are unable to ship into your country"
7.	<a href="http://cyber.globalrx.com/">http://cyber.globalrx.com/</a>	USA	Advertised as "miracle drug."	US\$ 228.00 (10 x 50mg)	No/X - "we must decline your order at this time."
8.	<a href="http://viagra.stiver-son.com/">http://viagra.stiver-son.com/</a>	USA	Charged credit card but did not deliver.	US\$ 194.00 (10 x 50mg)	No/M - "the doctor was concerned about your heart conditions and the medication you are on."
9.	<a href="http://www.net-dr.com">www.net-dr.com</a>	USA	German questionnaire, prescription by US doctor. Sent email warning to stop other drugs.	US\$ 219.00 (10 x 100mg)	Yes (10 days)
10.	<a href="http://swisspharma.com/">http://swisspharma.com/</a>	Switzerland (delivered from Spain)		US\$ 99.70 (3 x 100mg)	Yes (6 days)

All companies requested that customers waive the site's liability in the event that they experienced health problems. While all

sites asked whether customers were currently taking nitrates, only 4 specifically asked about recent "myocardial infarction,"

and only 2 of those used the lay term "heart attack." Seven asked about hypertension, but only 3 used the lay term "high blood pressure." Only 3 asked about retinitis pigmentosa, another important contraindication of sildenafil.

One site offered to ship, together with Viagra, tablets of cimetidine (Tagamet®), as it causes "56% increase in plasma sildenafil concentrations when coadministered with Viagra. This would indicate that increased effectiveness would be noted with the same dose of Viagra taken with 800mg of Cimetidine."

Three companies, among them both European companies, delivered within 6, 10, and 34 days respectively. One company sent an email warning to discontinue all other 5 medications when taking Viagra. A photocopy of the original Pfizer package insert was enclosed in 1 case, in all other cases incomplete package information was provided.

Two companies declined to deliver because of import restrictions, 1 declined to deliver without giving specific reasons, 3 declined to deliver because the drug is not approved for women (2 of them however claimed that they "know of the benefits for women"), and 1 did not deliver "because the doctor was concerned about your heart conditions and the medication you are on." Two of the companies which did not deliver nevertheless charged the credit card. The name of the consulting doctor was revealed in only 2 cases.

## Discussion

Although a surprisingly high number of Internet pharmacies declined delivery, the public should be alerted to the risks

involved with prescription drug prescribing and dispensing via the Internet. In 30% of our cases, "prescriptions" were issued although clear contraindications existed, in 80% no complete history was taken, in 70% inappropriate medical terminology was used, and in only two cases was the order form reviewed by a physician who identified himself. Pharmacies claiming to "consult" consumers may be harmful, as the clients may rely on a non-existent "physician." However, even if doctors appear to be employed at the pharmacies, this is no guarantee for a safe drug-shopping experience for patients; in 2 out of the 3 cases where Viagra was delivered, physicians appeared to have approved the prescription, recalling the problem of the questionable credentials of "cyberdocs" [3]. Consumers should also be aware that Viagra on the Internet costs on average twice as much as in regular pharmacies, and that in our test 20% of the pharmacies charged the credit card without delivering a product. We estimate that at least 4,500-15,000 web pages offer online ordering of Viagra. Many dispensing companies run "affiliate" programs offering a commission to individuals who advertise and link customers to them [4], which is one explanation for the immense number of doorway pages, and another reason for incomplete and misleading drug information on the Internet. Future legislative action may target this lay-advertising practice. Consumer education and an international modus operandi for managing drug sales on the Internet are further steps that should be taken by the World Health Organization (WHO) [5] and other organizations.

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Original Paper

# Evaluation of Internet-Based Clinical Decision Support Systems

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## Abstract

**Background:** Scientifically based clinical guidelines have become increasingly used to educate physicians and improve quality of care. While individual guidelines are potentially useful, repeated studies have shown that guidelines are ineffective in changing physician behavior. The Internet has evolved as a potentially useful tool for guideline education, dissemination, and implementation because of its open standards and its ability to provide concise, relevant clinical information at the location and time of need.

**Objective:** Our objective was to develop and test decision support systems (DSS) based on clinical guidelines which could be delivered over the Internet for two disease models: asthma and tuberculosis (TB) preventive therapy.

**Methods:** Using open standards of HTML and CGI, we developed an acute asthma severity assessment DSS and a preventative tuberculosis treatment DSS based on content from national guidelines that are recognized as standards of care. Both DSS's are published on the Internet and operate through a decision algorithm developed from the parent guidelines with clinical information provided by the user at the point of clinical care. We tested the effectiveness of each DSS in influencing physician decisions using clinical scenario testing.

**Results:** We first validated the asthma algorithm by comparing asthma experts' decisions with the decisions reached by nonpulmonary nurses using the computerized DSS. Using the DSS, nurses scored the same as experts (89% vs. 88%;  $p = \text{NS}$ ). Using the same scenario test instrument, we next compared internal medicine residents using the DSS with residents using a printed version of the National Asthma Education Program-2 guidelines. Residents using the computerized DSS scored significantly better than residents using the paper-based guidelines (92% vs. 84%;  $p < 0.002$ ). We similarly compared residents using the computerized TB DSS to residents using a printed reference card; the residents using the computerized DSS scored significantly better (95.8% vs. 56.6% correct;  $p < 0.001$ ).

**Conclusions:** Previous work has shown that guidelines disseminated through traditional educational interventions have minimal impact on physician behavior. Although computerized DSS have been effective in altering physician behavior, many of these systems are not widely available. We have developed two clinical DSS's based on national guidelines and published them on the Internet. Both systems improved physician compliance with national guidelines when tested in clinical scenarios. By providing information that is coupled to relevant activity, we expect that these widely available DSS's will serve as effective educational tools to positively impact physician behavior.

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## KEYWORDS

Asthma; Tuberculosis; Decision Support System; Clinical Guidelines

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## Introduction

In the last 30 years, we have seen an explosion in basic and clinical research on disease pathophysiology and treatment.

Coupled with increased demands on healthcare delivery systems, this rapid growth in scientific knowledge has made the practice of medicine increasingly complex. Local, national, and international organizations have responded to this growing

complexity by developing clinical practice guidelines to simplify and improve healthcare quality and delivery. Despite the widespread publication of clinical standards and practice guidelines, however, physicians have had difficulty understanding and applying these guidelines in the clinical care setting. As a result, their practice patterns often do not reflect these consensus-derived, evidence-based recommendations [1-3]. It is clear that in addition to the development and content of clinical practice guidelines, dissemination and implementation strategies are critical to the impact the guidelines will have on physician behavior [4]. Furthermore, the local environment, health care system variables, and patient-specific variables also influence physician acceptance of clinical guidelines [2-5].

Both paper- and computer-based decision support systems (DSS) have evolved to educate physicians about practice standards and to improve guideline impact on a case-specific basis. Computerized DSS's can enhance physicians' clinical performance and guideline compliance in a wide variety of settings [6,7]. When used at the point of clinical care, automated, computer-based DSS's improve physician compliance with specific treatment guidelines [8,9]. In contrast to static, paper-based DSS's, a well-designed, computerized DSS can provide patient-specific information to the user at the time and location of need, at the content level appropriate for the user, and at a pace individualized to the user. Given that adult education occurs most effectively when coupled to relevant activity [10], computerized DSS's incorporated into the workflow of clinical care have the potential to function as important medical education tools.

Many previously described computerized DSS's are proprietary, run on local networks, and are therefore not available to most physicians. While physicians have not yet widely embraced the Internet as a professional information source, they are nevertheless beginning to use it for clinical information and education [11,12]. Because of its open standards, the Internet can be used to deliver information easily to computer networks anywhere in the world. The Internet therefore has the immense potential to serve as an educational resource and dissemination tool for clinical guidelines and DSS's. This potential is contingent on developing tools that are openly and freely available, can be adapted to local conditions, and can be incorporated into the physician workflow.

In this study, we report our initial experiences in the development of two DSS's delivered over the Internet. We developed a DSS for the National Asthma Education Program-2 (NAEP-2) [13] Asthma Treatment Guidelines, and another for the American Thoracic Society/Centers for Disease Control (ATS/CDC) Tuberculosis Preventive Guidelines [14], using Hypertext Markup Language (HTML) and Common Gateway Interface (CGI) open standards. We then tested the effectiveness of the Internet-delivered guidelines compared to paper-based resources using clinical scenario testing.

## Methods

### General Design Considerations

During the development of both DSS's, we incorporated several design characteristics that have been identified as important for widespread acceptance and utilization [15]. These characteristics included telegraphic representations of the guidelines, navigation components commonly used on the World Wide Web (WWW), clear indexing, and forgiving interfaces. Furthermore, each DSS was designed to operate with input from clinicians entered with mouse clicks; neither requires free text or detailed data entry. Both DSS's were designed to function as supplements and additions to existing national guidelines. We provided these guidelines in their entirety within each system through HTML links.

### Development of the Acute Asthma Severity Evaluation and Treatment Decision Support System

The NAEP-2 clinical asthma guidelines form the knowledge base upon which we structured the asthma DSS. We created the acute asthma DSS to complement and expand the existing guidelines by providing specific guideline information tailored to a unique clinical situation. The asthma DSS provides the clinician with information on disease severity assessment, recommendations for objective functional patient testing, and recommendations for case-based treatment. Furthermore, the DSS serves as a portal for hypertext navigation through the entire NAEP-2 guidelines. We organized the operation of the DSS on a simple decision tree model for acute asthma exacerbations (Figure 1).

The DSS first estimates disease severity by calculating an arithmetic mean of up to 12 scores of clinical parameters provided by the user. The input parameters cover asthma symptoms, signs, and objective findings as assessed and interpreted by the clinician. The algorithm also identifies risk factors for acute respiratory failure and determines whether objective assessments, e.g. arterial blood gases or pulmonary function tests, are indicated based on disease severity. Using CGI, we scripted this algorithm for use on the Internet and published it on the WWW at the Virtual Hospital(tm) at the following URL:

<http://www.vh.org/Providers/ClinGuide/AsthmaIM/Default.html>

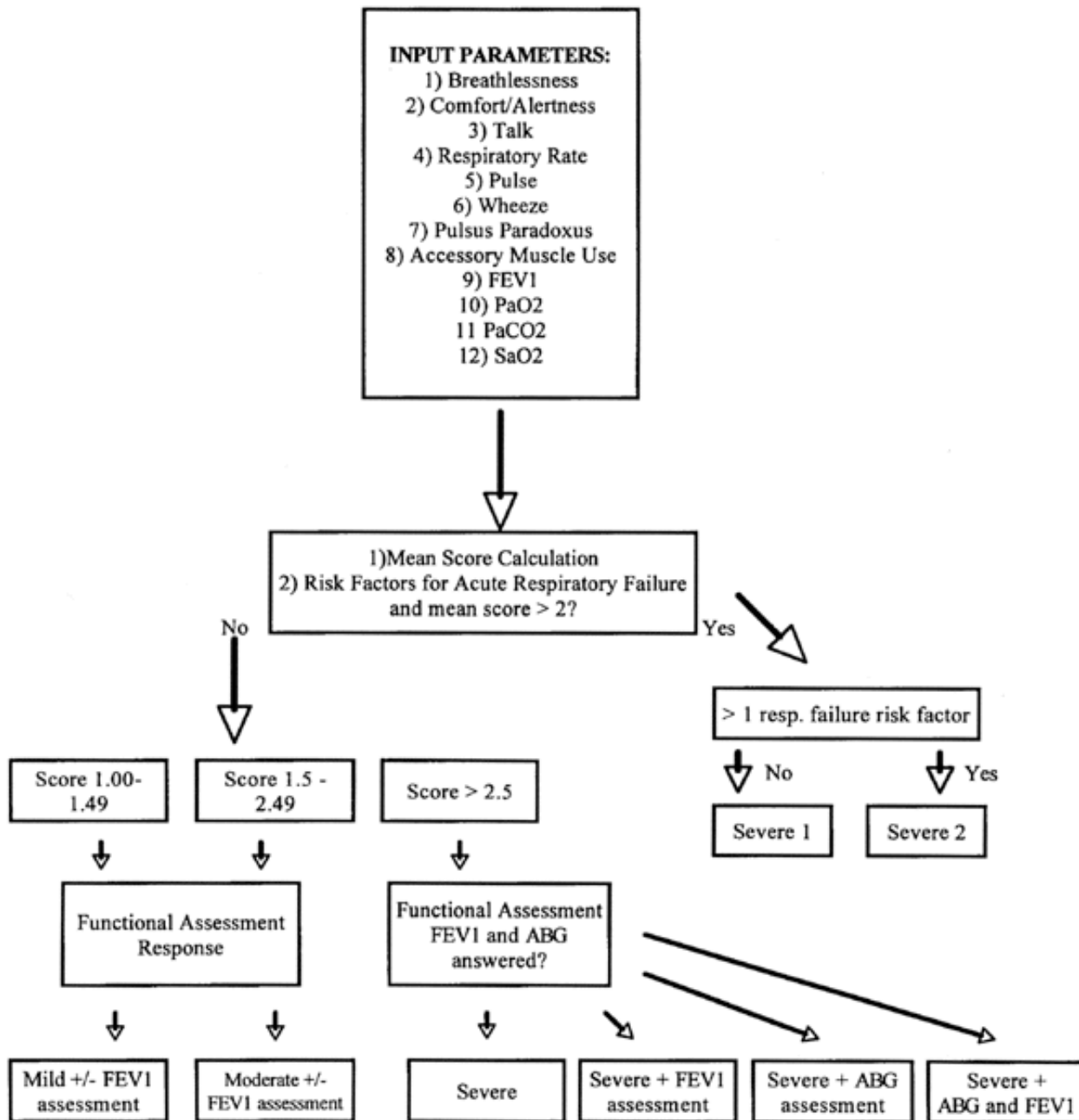
### Development of the ATS/CDC Preventive Tuberculosis Guidelines Decision Support System

Using a similar approach based on hypertext links, we developed a second DSS for treating positive tuberculosis skin reactions. We organized the ATS/CDC guidelines for preventive tuberculosis care into a series of hierarchical choices based first on the size of the reaction to purified protein derivative (PPD) and then on specific patient characteristics. Using these two sets of input parameters to drive the decision process, we created a series of individual information pages using HTML to be delivered on the WWW. We published this DSS along with the hypertext-linked pages containing background information and the ATS/CDC guidelines themselves on the Virtual Hospital(tm) at the following URL:

<http://www.vh.org/Providers/TeachingFiles/AssessmentPage1.html>  
[PulmonaryCoreCurric/TBCase/AssessmentTool/](http://www.vh.org/Providers/TeachingFiles/PulmonaryCoreCurric/TBCase/AssessmentTool/)

Figure 1. Algorithm For Acute Asthma Severity Decision Support System

### Algorithm for Acute Asthma Severity Decision Support System



#### Development and Scoring of Clinical Case Scenarios

We tested both the asthma and tuberculosis DSS's with case scenarios. Using the NAEP-2 guidelines as the primary resource, we developed and refined six acute asthma scenarios to reflect mild, moderate, and severe exacerbations. Each case scenario also included information on the response of the hypothetical patient to the proposed treatments. Five questions reflecting the main points of the NAEP-2 guidelines followed each scenario:

1) initial assessment choices, (mild, moderate, severe, or severe with life-threatening features); 2) diagnostic testing requirements (peak flow, arterial blood gas analysis); 3) initial treatment choices (b-agonists, corticosteroids, oxygen, cholinergic antagonists, methylxanthines, and antibiotics); 4) treatment response assessment (poor, incomplete, or good response); and 5) patient disposition (discharge to outpatient management, inpatient general ward, or inpatient ICU). The same questions followed each scenario. We scored the responses to the clinical

scenarios using the NAEP-2 guidelines as the standard for the most appropriate response. Responses generated the maximum possible score if they reflected the guidelines; partial credit was given for answers near the correct answers (e.g. moderate rather than severe assessment). The maximum possible score was the same for each question in each case scenario.

To test our second DSS, we developed eight wide-ranging patient scenarios of tuberculosis infection. Four local tuberculosis experts validated the DSS by assuring that the recommendation provided by the DSS was the same as the recommendation provided by the ATS/CDC guidelines. All four experts agreed that the DSS recommendation for the each of the eight scenarios accurately reflected the ATS/CDC guidelines. We scored the responses of the test groups on the basis of agreement with the ATS/CDC guidelines.

### Testing the Decision Support Systems

Four groups of healthcare practitioners completed the acute asthma case scenarios. The first group included board-certified pulmonologists (N=10), who were asked to complete the questions based on their practice patterns. This group was our positive control group to verify the system. The second group consisted of clinical oncology nurses who work with respiratory patients but have no special expertise in asthma (N=5). They answered the same scenario questions with the assistance of the acute asthma DSS. Medical residents (postgraduate training year 1 to 3) at the University of Iowa Hospital comprised the third and fourth test groups in the asthma DSS evaluation. We randomly assigned an unselected group of residents attending a teaching conference to complete the scenarios using either the DSS (N=11) or a printed copy of the Practical Guide for the Diagnosis and Management of Asthma [16] provided with the scenarios (N=16).

We developed this DSS using open standards to make it easier for physicians to use the program. We reasoned that physicians would be more likely to use the tools if they did not require additional training. For that reason, we did not provide instruction in the use of the DSS prior to the scenario testing. In this way, we could determine whether the system was intuitive and easy to use.

We similarly tested the tuberculosis DSS using a group of unselected general Internal Medicine Residents (postgraduate training year 1 to 3) at the University of Iowa Hospital. The

evaluation occurred during a regularly scheduled teaching conference with no prior selection of participating residents. We randomly assigned residents to answer the same eight clinical scenario questions using the computerized DSS (N=12) or using written resources (N=17). The written resource consisted of a guideline card developed at our institution, which was provided to all participants. For the same reason as above, we did not provide any specific training in the use of the tuberculosis DSS prior to the scenario testing.

### Statistical Analysis

After establishing normality, the mean total scores and individual components of the scores for the tuberculosis and acute asthma clinical scenarios were analyzed with two-sample t tests. Cronbach's coefficient alpha was calculated for the acute asthma clinical scenarios as a measure of internal consistency of the testing instrument. We used SPSS v. 9.0 software (SPSS Inc., Chicago IL, 1998) for all data analysis.

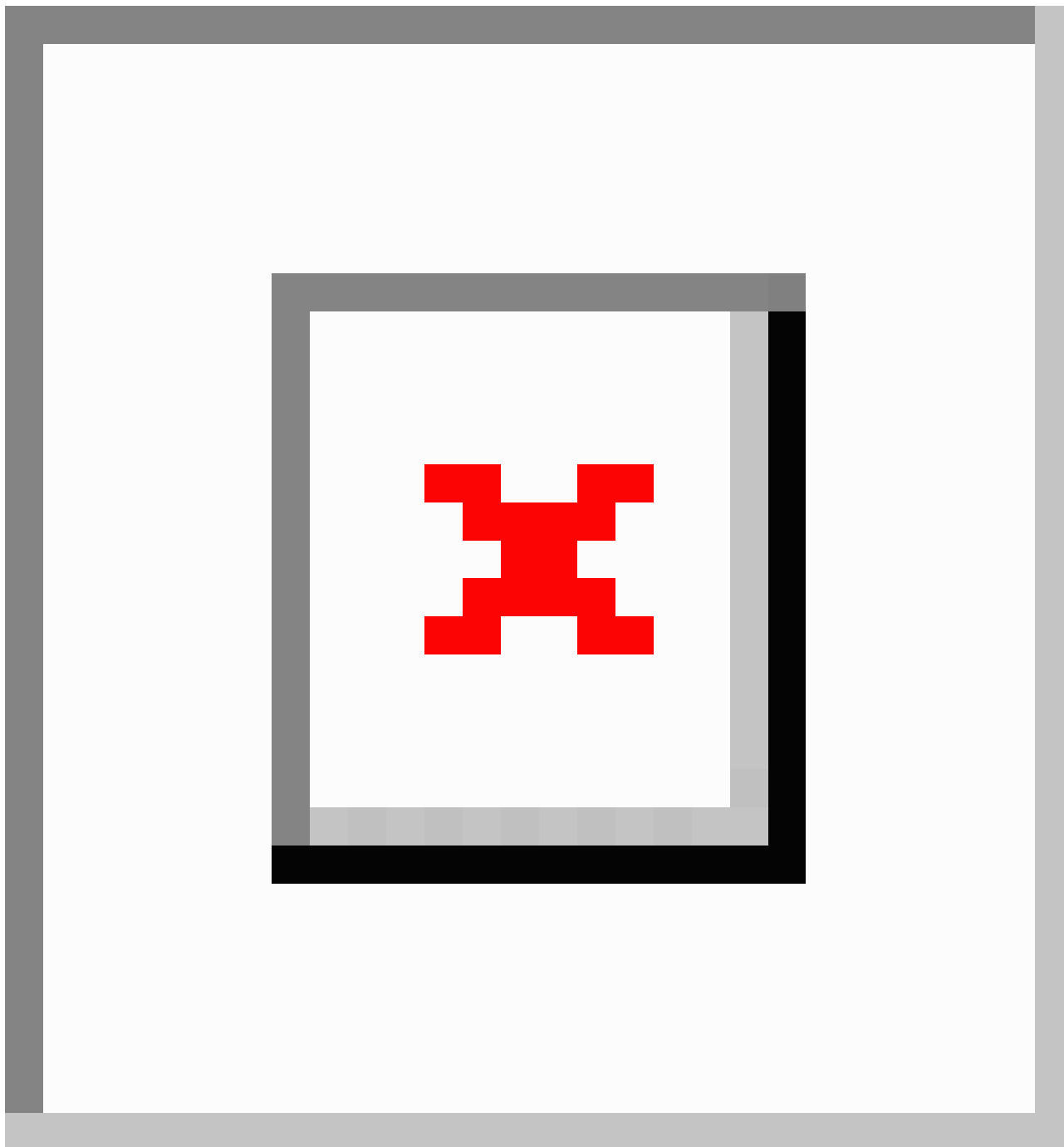
## Results

### Acute Asthma DSS

We first evaluated the validity of the asthma clinical scenarios by analyzing the consistency of the responses. Cronbach's standardized coefficient alpha calculated for all the asthma scenarios was 0.76, indicating good internal consistency of the scenario testing instrument. When we recalculated the intraclass correlation coefficient after deleting each item of the test instrument sequentially, we found good reliability with an alpha range 0.67 to 0.71.

As noted in the previous section, four groups of participants completed the acute asthma scenario test instrument as described in materials and methods. The expert panel (N=10), instructed to answer the questions based on their practice standards, had a mean score of 89.1% (95% CI 86.0-92.1%) in agreement with the guidelines. The group of clinical nurses (N=5) with no respiratory specialty training who used the acute asthma DSS reached a mean score of 88.3% (CI 80.9-95.8%). The nurses' performance was not statistically different from the experts at a  $p = 0.78$  (Figure 2). These data demonstrate that a group of health professionals without specific training in asthma can reach the same conclusions when using the Internet DSS as experts.

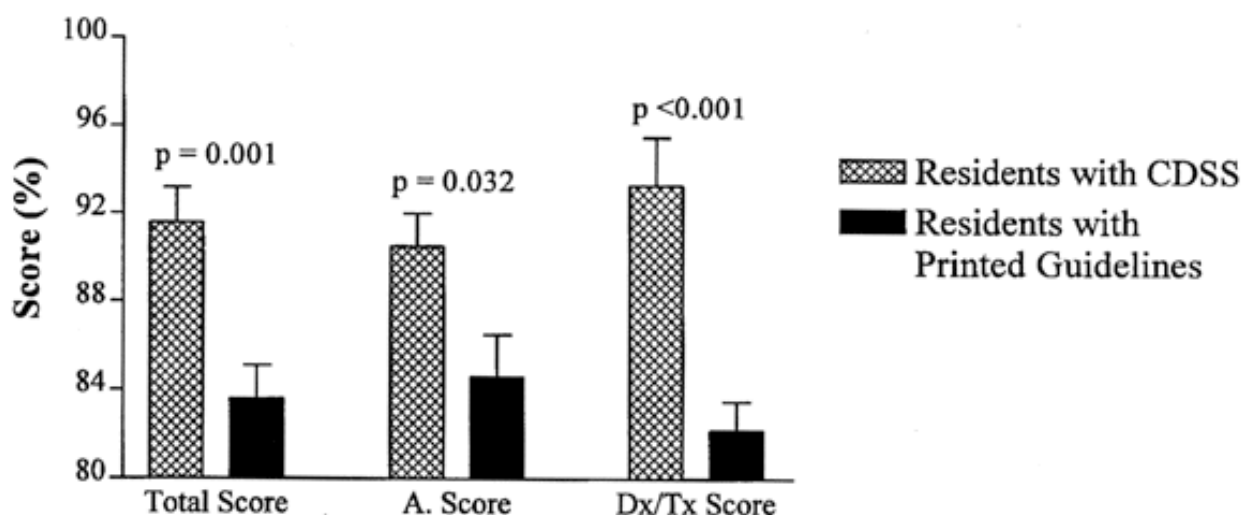
Figure 2.



We next examined the effect of the DSS on the decision-making process among similarly trained physicians. An unselected group of Internal Medicine residents was randomly divided and assigned to use either the DSS (N=11) or a printed copy of the Practical Guide for the Diagnosis and Management of Asthma [16]. The residents using the DSS performed much better than the residents using the printed guidelines (mean score 91.6%, CI 88.0-95.3% compared to 83.6%, CI 80.5-86.7%;  $p = 0.001$ )

(Figure 3). There was no statistical difference between the mean scores of the expert panel and the residents using the DSS ( $p = 0.26$ ). However, the residents using only the printed materials performed statistically worse than the experts ( $p = 0.017$ ). Both the resident group using the computer DSS and the resident group using the printed resources completed all patient scenarios in less than 30 minutes (% minutes per case).

Figure 3.



When we analyzed the specific components of the asthma scenario questions, we found that the expert panel performed better than the nurses on initial and repeat asthma severity assessment (93% vs. 86%,  $p = 0.025$ ). This difference was offset by the expert group's tendency to order more diagnostic tests, to hospitalize more frequently, and to treat some cases more aggressively than the nurses using the treatment guidelines delivered through the DSS (83% correct vs. 92%,  $p = 0.034$ ) (Figure 2). In a similar analysis of the resident groups, the cohort using the DSS performed better in all areas tested including severity assessment and diagnostic/therapeutic responses than did the residents using printed guidelines ( $p = 0.03$  and  $p < 0.005$  respectively) (Figure 3).

### ATS/CDC Preventive Tuberculosis DSS

We compared the effect of printed guideline reminders to the computerized DSS for preventative tuberculosis treatment in a separate session of scenario testing. Two randomly assigned groups of unselected Internal Medicine residents ranging from postgraduate years 1 to 3 participated in this assessment of responses to eight clinical scenarios. The computer-based group ( $N=12$ ) demonstrated better compliance with the ATS/CDC guidelines on each scenario than did the paper-based resource group ( $N=17$ ). Overall, the computer group reached the appropriate ATS/CDC recommendation in 92/96 scenarios or 95.8%, (8 scenarios x 12 subjects in the group). The medical resident group using the paper resource, however, reached the same conclusion as the ATS/CDC guidelines in only 77/136 or 56.6%, (8 scenarios x 17 subjects in the group). This difference was statistically significant at  $p < 0.001$ . The computer group required less than 2 minutes per case to reach their conclusions.

### Discussion

The profession of medicine has a long history of continuing education in an attempt to assure that all physicians are practicing the highest quality medicine [17]. In the last few decades, this pursuit has contributed to the development of evidence-based medicine and to a proliferation of practice guidelines [18]. Unfortunately, many studies have demonstrated

that traditional continuing education, including lectures and the publication of practice guidelines, does not significantly alter physician behavior. This ineffectiveness may result from the fact that these modalities fail to link the educational activity to the time and setting of the intended activity. DSS's are one method to overcome this shortfall. DSS's can act to remind physicians of certain behaviors at the most appropriate time and location. They are, therefore, more likely to serve as effective educational tools. Both paper-based and computer-based DSS's can change physician behavior and improve quality of care. In contrast to paper-based clinical support systems, computerized DSS's can easily accommodate broad content and knowledge bases that can be accessed using specific clinical information quickly and efficiently.

Many issues including physician reluctance, proprietary interests, technical limitations, and local practice environments limit the widespread application of many previously reported computer-based DSS's [19,20]. The growth and availability of the Internet provides a new model for sharing medical knowledge and DSS's across existing computer networks. The main limitations of the Internet include technical aspects imposed by the open standards and the challenge of controlling information quality [21,22]. These limitations, however, do not necessarily impose disadvantages. The open standards available on the Internet allowed us to simplify our user interface within existing standards and thus ensure widespread availability and ease of navigation. To target the largest possible audience, we used nationally developed and widely applied clinical guidelines. Therefore, we were able to restrict the focus of our data synthesis and delivery to peer-reviewed information of the highest quality.

We developed DSS's and published them on the Internet for two medical problems, asthma management and tuberculosis preventive therapy. We chose these problems to test for several reasons. First, high quality and well-accepted standards are available for both problems. Second, we identified both these subject areas as important for clinical improvement. We have previously found that physicians have difficulty applying the National Asthma Education Program's staging system and

treatment recommendations to patients [1]. Our results are not unique; other investigators have identified significant deviations in asthma care from the guidelines in many different settings [23,24]. Divergent clinical practice patterns with respect to published guidelines for tuberculosis treatment have been similarly described [25]. Finally, both of these problems are exceedingly common around the world and their increasing incidence presents a significant management challenge for clinicians.

Before widespread clinical application of our DSS's, we sought to test the effectiveness and accuracy of both computerized systems in relevant but controlled artificial clinical settings. We evaluated both systems using scenario testing, a technique which has been established and used successfully to test clinical decision-making [26]. When compared to the performance of experts, both DSS's produced accurate and reliable responses reflective of evidence-based standards of care. The acute asthma DSS assisted both medical residents and clinical nurses to perform at levels not statistically different from a group of experienced pulmonologists. Similarly, the Internet-based tuberculosis DSS delivered the same responses as a panel of experts, and improved medical resident compliance with ATS/CDC recommendations for treating PPD reactions.

One interesting finding with the asthma DSS was the fact that inexperienced nurses did not score as well as experienced pulmonologists in certain subcategories but performed better in others. We did not find similar differences in the two resident groups. This suggests that the computer DSS works most consistently and accurately when used by more experienced clinicians. The design of each DSS around national guidelines that provide generic information which must be interpreted for unique patients requires that the physician provide his or her

own judgment before clinical action is taken. Thus, the DSS supplements but does not replace human clinical judgment. Furthermore, by providing relevant information at the point of need, these DSS's can function to educate and encourage sustained improvements in clinical judgment.

Finally, we have developed the acute asthma and preventative tuberculosis DSS using open standards for information display, HTML and CGI, thus enabling them to be published on the WWW. These systems function independently of local patient data systems by using an interactive format, which requires the input of clinical parameters by the user. While this design characteristic does create some barriers to automatic DSS function through an interface with local computerized patient records, it also avoids numerous technical database management and non-uniform data exchange issues. By requiring only that the user have Internet access, these nonproprietary decision support tools are widely available with existing technology. Given the fact that increasing numbers of physicians are using computers and the Internet as a source of medical information [11], we expect that Internet accessibility will enhance DSS use and integration into physician workflow.

In summary, we have published two computerized decision support tools on the WWW and evaluated them using clinical scenario testing. We have shown that both guideline-based DSS's delivered over the Internet enabled the users to more accurately choose assessment or treatment plans in concordance with established guidelines. While patient outcomes with these systems have not yet been evaluated, we expect that the widespread availability and adaptability to local conditions of these systems will further guideline dissemination and implementation.

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## Conflicts of Interest

None declared.

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Original Paper

# Impact of the Internet on Primary Care Staff in Glasgow

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## Abstract

**Background:** The Government has invested £7 million (approx. \$11.5 million) to connect all Primary Care Practices in Scotland to the National Health Service Intranet (NHSnet). This provides General Practitioners (GPs) and Practice Nurses with access to the Internet and a wealth of healthcare information of varying quality.

**Objective:** This study examines Primary Care Staff's use of the Internet, their views on the reliability of healthcare information available via the Internet, and their interaction with patients who have presented them with information downloaded from the Internet.

**Methods:** A postal questionnaire was distributed to a random sample of 300 GPs and 130 Practice Nurses throughout Glasgow. There was a response rate of 60%.

**Results:** Time restraints (20%) and concerns that they lack the necessary skills (17%) were highlighted as the most common reasons for not accessing the Internet. Sixty-nine per cent of GPs and 70% of Practice Nurses had looked at the Internet for healthcare information. Forty-eight per cent of GPs and 41% of Practice Nurses were concerned about the reliability of Internet information. Fifty-eight per cent of GPs and 34% of Practice Nurses have been approached by patients with Internet healthcare information. Sixty-five per cent of the information presented by patients was new to GPs.

**Conclusions:** The majority of Primary Care Staff now have access to the Internet and use it to look up healthcare information. Almost half of GPs would consider referring their patients to the Internet for further information about their condition. Results highlight that the healthcare information downloaded from the Internet by patients is accurate, but patients have problems correctly interpreting this information. An increase in the use of home computers and free access to the Internet will see a continued increase in patients approaching GPs and Practice Nurses with healthcare information downloaded from the Internet.

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## KEYWORDS

Internet; Consultation; General Practice; Information Technology; Patient Education

## Introduction

The NHSnet was developed as part of a nationwide Information Management & Technology Strategy to create a National Health Service Intranet (NHSnet). The Government has now spent £7 million (approx. \$11.5 million) to link every Primary Care Practice in Scotland to a secure connection to this network. This has important benefits for primary care practitioners. The Scottish Health Minister recently stated, "The GP (General Practitioner) will have at his fingertips a wealth of up-to-date information, new procedures, and the best of current thinking in the NHS" [1]. The use of this new technology and the

knowledge of how to put it into practice are varied amongst Primary Care Staff [2,3].

A large number of good quality, credible healthcare resources are accessible using the Internet, allowing both patients and professionals to browse, download, and read endless reams of clinical information. This healthcare information exists in the form of online medical journals, Royal Colleges, national charities, pharmaceutical companies, disease support groups, etc. In addition to these high quality websites, there are many more less reputable websites, newsgroups, listservs, chat rooms, etc., containing medical information that has little or no scientific evidence. Although the Internet does not have a

monopoly on misinformation, health information can be posted by anyone with access to the net and an interest in doing so. Impicciatore et al examined 40 web sites providing advice on the management of a feverish child and found that only four adhered to published guidelines [4].

The issues of misleading or inaccurate information are especially important in health care, as a little knowledge can be dangerous and very distressing for the less adept patient faced with the bare facts about his disease [6]. Therefore, it is important to know how patients use the Internet healthcare information available to them and the response of the GPs and Practice Nurses in Glasgow to caring for people with such information. Increasingly more patients are attending Primary Care Practices with health care information from the Internet in hand; this article looks at the impact on Primary Care Staff within Greater Glasgow.

## Methods

An anonymous postal questionnaire was sent to a randomly selected sample of 300 General Practitioners and 130 General Practice Nurses throughout Greater Glasgow. The names and addresses of Primary Care Staff were identified using data from Greater Glasgow Health Board Department of Public Health. A covering letter was included with the questionnaire outlining the aims of the study. Staff were questioned on their use of the Internet and its potential as a source of healthcare information. Respondents were asked if they were concerned about the reliability of Internet healthcare information, and on a scale of positive to uncomfortable were asked to rate their opinion on patients obtaining information from the Internet. A section was included asking Primary Care Staff about their interactions with patients holding Internet healthcare information. Finally, staff

were asked if they would consider referring a patient to the Internet for further information, and if they would recommend any particular websites.

## Data Analysis

Data from completed questionnaires were entered into a Microsoft Access database and SPSS data analysis software (Version 9.0) was used to apply statistical tests to the data. A  $p$  value of  $< 0.05$  was used to indicate statistical significance. General Practitioner and Practice Nurse groups were compared using the chi-squared ( $\chi^2$ ) test for nominal data, and the two sample  $t$ -test and Mann Whitney U tests for ordinal data. When differences between the two staff groups were demonstrated to be statistically significant, analysis of variance tests (ANOVA) were used to explore relationships.

## Results

A total of 160 of 300 completed questionnaires were returned by GPs, a response rate of 54%. There were 96 of 130 completed forms returned by Practice Nurses, providing a response rate of 74%. The overall response rate for the total population was 60% ( $N=256$ ).

No evidence of a difference in age was found between the two staff groups. While the GPs were reasonably evenly distributed between the sexes (Male 55%:Female 45%), Practice Nurses were overwhelmingly female (Male 1%:Female 99%). The Internet is accessed by 79% of GPs and 73% of Practice Nurses. Primary Care Staff were asked from where they accessed the Internet (Table 1). Results show that significantly more GPs access the Internet from home ( $p=0.003$ ). Overall, significantly more male Primary Care Staff access the Internet ( $p=0.001$ ).

**Table 1.** Where do Primary Care Staff Access the Internet?

	Practice (No. of Staff)	Home (No. of Staff)
General Practitioner	108 (67.5%)	90 (56.3%)
Practice Nurse	60 (62.5%)	34 (35.4%)

**Table 2.** What Information Have You Found Useful as a Primary Care Clinician?

	General Practitioner (No. of Staff)	Practice Nurse (No. of Staff)
Disease Information	79 (49.7%)	44 (48.2%)
Online Journals	67 (42.1%)	34 (35.4%)
New Medical Information	47 (29.6%)	27 (29.0%)
Drug Information	37 (23.3%)	20 (20.8%)
Research Information	19 (11.9%)	19 (19.8%)
Other Information	8 (5.0%)	19 (10.6%)
Email with Other Clinicians	26 (16.4%)	4 (4.2%)
Complimentary Medicine	9 (5.7%)	3 (3.1%)
Healthcare Newsgroups	6 (3.8%)	3 (3.1%)
Notice of Meetings	10 (6.3%)	3 (3.1%)

Time (20%) and lack of skills (17%) were the most common reasons cited for not accessing the Internet (Table 2). Of those

staff with Internet access, 69% of GPs and 70% of Practice Nurses had used it to access healthcare information. Table 2

shows which categories of information they found useful as Primary Care Clinicians. Significantly more GPs used the Internet for email with other clinicians ( $p=0.004$ ). Primary Care Staff aged under 40 are more likely to refer to the Internet for drug information ( $p=0.03$ ).

Staff were asked their opinion about the quality/accuracy of Internet healthcare information; 48% (74) of GPs and 41% (37) of Practice Nurses expressed concern over the reliability of information available via the Internet (Table 3).

Results show that 58% (91) of GPs and 34% (32) of Nurses have, at some time, been approached by patients with information about their condition obtained from the Internet.

This showed a significant statistical difference between the 2 staff groups ( $p<0.001$ ). On average, GPs have seen 2.9 patients holding Internet healthcare information in the past six months (min.=1, max.=20) and Practice Nurses 1.9 patients in the same period (min.=1, max.=6).

Table 3 outlines how Primary Care Staff interact with these patients. Surprisingly, 65% of the information presented by these patients was new to GPs, and only 45% of the patients had correctly interpreted the information in the GPs opinion. Both Staff Groups reported that the consultation time was increased, and significantly more Practice Nurses felt that they were able to use the consultation time more effectively ( $p=0.03$ ).

**Table 3.** Consultation with Patients Holding Internet Healthcare Information

	General Practitioner (No. of Staff)	Practice Nurse (No. of Staff)
The patient participates more actively in his treatment	65 (78.3%)	26 (83.9%)
The patient has higher expectations	75 (85.2%)	26 (78.8%)
The information is accurate	59 (73.8%)	24 (75%)
The length of consultation is increased	68 (77.3%)	24 (72.7%)
This type of patient is a welcome challenge	46 (55.4%)	24 (72.7%)
The consultation is more interactive than usual	43 (50.6%)	22 (68.8%)
The patient correctly interpreted information	38 (44.7%)	19 (59.4%)
The patient is more demanding	50 (58.8%)	14 (42.4%)
The information is new to the clinician	55 (64.7%)	13 (40.6%)
The clinician was able to use the time more effectively	16 (19.0%)	12 (38.7%)

Primary Care Staff were asked to rate how they felt about patients obtaining information from the Internet (Table 4). Results highlight that significantly more GPs were indifferent

to patients retrieving healthcare information from the Internet ( $\chi^2=5.42$  DF=1  $p=0.002$ ), and significantly more Practice Nurses felt unsure about this issue ( $\chi^2=11.52$  DF=1  $p=0.001$ ).

**Table 4.** How Do You Feel about Patients Obtaining Information from the Internet?

	General Practitioner (No. of Staff)	Practice Nurse (No. of Staff)
Positive	61 (39.1%)	29 (30.9%)
Indifferent	53 (34.0%)	19 (20.0%)
Uncomfortable	19 (12.2%)	15 (16.0%)
Not Sure	23 (14.7%)	31 (33.0%)

Almost half of the GPs, 45% (69), said they would consider referring a patient to the Internet for further information compared to only 29% (27) of the Practice Nurses. This was a statistically significant difference ( $p=0.01$ ).

## Discussion

A recent study in Australia by Young and Ward [7] reported that 43% of GPs in New South Wales have access to the Internet at home or work. A survey of GPs in the United Kingdom in 1997 by Roscoe [3] showed that around 50% had Internet access. It is encouraging to note that in Glasgow, with recent government funding, this figure has now reached 79%. Lack of time is most commonly cited as a barrier to accessing the

Internet; one GP commented: "Most days having lunch is a luxury, if a patient has the time let them use it". The other most commonly cited barrier was the lack of appropriate skills, which may point towards a need for education and continued professional development in this area. The following comment is typical of those Primary Care Staff who said they were of unsure of the technology: "Tend to get lost in it and it wastes a lot of time."

Approximately half of all the Primary Care Staff questioned have seen patients who supplemented their consultation with information obtained from the Internet. Results from this survey show that these patients have overwhelmingly higher expectations than average and more actively participate in their treatment (Table 3). With the continued proliferation of health

sites on the Internet and more patients empowered by new personal computers and free Internet access, this type of patient consultation will increase [8]. The role of the clinician as patient advisor/interpreter of medical Internet information is a new and time-consuming task. This study does not address the actual time invested by clinicians in Internet related activities; but as Table 3 shows, 74% of clinicians identified that the length of consultation with patients holding Internet healthcare information was increased.

A large amount of the information collated from the Internet and presented by patients at their consultation is new to the clinician and, in some cases, it seems that practitioners do not view this as a welcome challenge. Results from this survey show that patients are having problems correctly interpreting the medical information they have downloaded. Comments from participants highlight the difficulty in assessing the quality of this information, its source, evidence-base, and date posted. One General Practitioner likened Internet healthcare sites to the Curate's egg - "good in parts." This would seem to reinforce the idea that healthcare sites should be given a "seal of approval," confirming they have been reviewed and deemed suitable for

the general public. Indeed, many frameworks now exist to allow professionals to assess the credibility, accuracy, and relevance of healthcare information on the Internet [9], but clear, understandable rating criteria to assist the public in evaluating health related Internet sites are difficult to find.

As one may expect, those Primary Care Staff that have themselves accessed the Internet for healthcare information are significantly more likely to refer patients to the Internet for similar information. Primary Care Staff presented with new and accurate Internet healthcare information are also statistically more likely to refer a patient to the Internet.

In summary, if Primary Care Staff have a positive approach to the Internet themselves and have had good interactions with this type of patient, they appear far more open to the concept of this new technology and happier to refer their patients for more healthcare information.

This information will provide a basis for determining the current scope of these activities in Glasgow, and assist in determining future directions for preparing staff to deal more effectively with more knowledgeable patients.

## Conflicts of Interest

None declared.

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Original Paper

# Borderless Teleradiology with CHILI

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## Abstract

Teleradiology is one of the most evolved areas of telemedicine, but one of the basic problems which remains unsolved concerns system compatibility. The DICOM (Digital Imaging and Communications in Medicine) standard is a prerequisite, but it is not sufficient in all aspects. Examples of other currently open issues are security and cooperative work in synchronous teleconferences. Users without a DICOM radiological workstation would benefit from the ability to join a teleradiology network without any special tools. Drawbacks of many teleradiology systems are that they are monolithic in their software design and cannot be adapted to the actual user's environment. Existing radiological systems currently cannot be extended with additional software components. Consequently, every new application usually needs a new workstation with a different look and feel, which must be connected and integrated into the existing infrastructure. This paper introduces the second generation teleradiology system CHILI. The system has been designed to match both the teleradiology requirements of the American College of Radiology (ACR), and the functionality and usability needs of the users. The experiences of software developers and teleradiology users who participated in the first years of the clinical use of CHILI's predecessor MEDICUS have been integrated into a new design. The system has been designed as a component-based architecture. The most powerful communication protocol for data exchange and teleconferencing is the CHILI protocol, which includes a strong data security concept. The system offers, in addition to its own secure protocol, several different communication methods: DICOM, classic e-mail, Remote Copy functions (RCP), File Transfer Protocol (FTP), the internet protocols HTTP (HyperText Transfer Protocol) and HTTPS (HyperText Transfer Protocol Secure), and CD-ROMs for off-line communication. These transfer methods allow the user to send images to nearly anyone with a computer and a network. The drawbacks of the non-CHILI protocols are that teleconferences are not possible, and that the user must take reasonable precautions for data privacy and security. The CHILI PlugIn mechanism enables the users or third parties to extend the system capabilities by adding powerful image postprocessing functions or interfaces to other information systems. Suitable PlugIns can be either existing programs, or dedicated applications programmed with interfaces to the CHILI components. The developer may freely choose programming languages and interface toolkits. The CHILI architecture is a powerful and flexible environment for Picture Archiving and Communications Systems (PACS) and teleradiology. More than 40 systems are currently running in clinical routine in Germany. More than 300,000 images have been distributed among the communication partners in the last two years. Feedback and suggestions from the users influenced the system architecture by a great extent. The proposed and implemented system has been optimized to be as platform independent, open, and secure as possible.

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**KEYWORDS**

Teleradiology; Telemedicine; Remote Consultation; Diagnostic Imaging; Computer-Assisted Image Interpretation; PACS; Middleware; TLS; Security; Plugin; Visualization

## Introduction

The American College of Radiology (ACR) defined teleradiology in *ACR Standard for Teleradiology* [1] as the following:

*Teleradiology is the electronic transmission of radiological images from one location to another for the purposes of interpretation and/or consultation. Teleradiology may allow even more timely interpretation of radiological images and give greater access to secondary consultations and to improved continuing education. Users in different locations may simultaneously view images. Appropriately utilized, teleradiology can improve access to quality radiological interpretations and thus significantly improve patient care.*

In this paper we want to introduce the current state of our development in teleradiology. CHILI (tm) is a general purpose radiology workstation with additional functions for teleradiology. The task of the system is the transmission of radiological images to different locations for interpretation and consultation. The transmitted images can be simultaneously viewed at different locations and examined cooperatively. The development of the system was based on experience with the successful teleradiology project MEDICUS-2, which was a dedicated teleradiology system [2]. The second generation teleradiology system CHILI has been designed to match the teleradiology requirements of the ACR and the needs of MEDICUS users [3]. The experiences of software developers and teleradiology users who participated in the first years of clinical use have been integrated into the architecture [4,5]. This paper describes the general system design and application areas.

## Methods

### Principal Functionality

The principal functions of the system are the following:

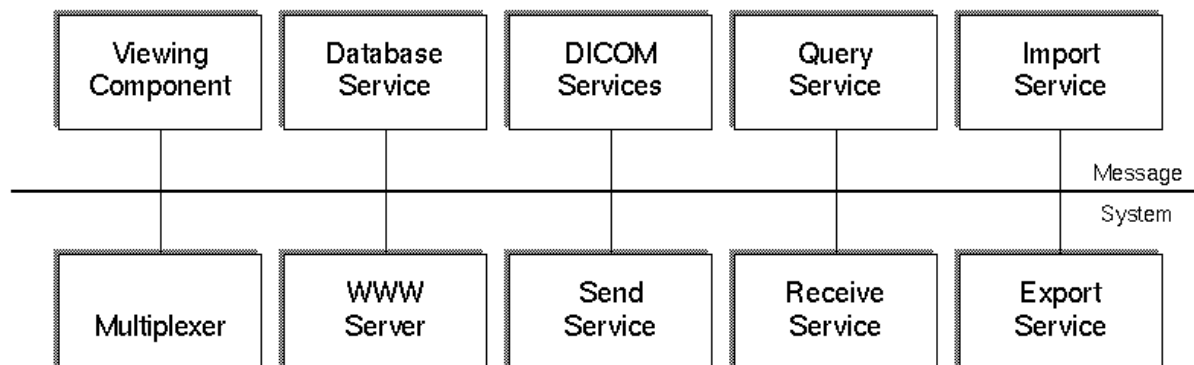
- The system receives images from different sources, such as imaging modalities, radiological viewing stations, digital archives, video cameras, etc., and stores them in a local database management system.
- The image viewing functionality allows the user to display and analyze the images in several ways (e.g. level/windowing, measurements, ROI analysis).
- Images can be transmitted to other sites with a number of (vendor-independent) protocols. Security measures are taken into account. The network protocol is TCP/IP and independent of the physical network layer. Different protocols are available.
- Images can be compressed using wavelet-based algorithms.
- Users at remote locations can work on the images simultaneously in teleconferences with synchronized images, functions, and mouse pointers.
- Exporting images to hard disk, floppy, or CD-ROM is possible, and hardcopies of the images can be printed on inexpensive, ordinary PostScript printers. Also, the DICOM protocol can be used to perform printing management in combination with DICOM compliant print servers.

### Component Architecture

The software architecture of CHILI is based on the results of the European Project HELIOS, in which concepts for distributed, object-oriented software systems were developed [6]. The core of the HELIOS software engineering environment is the HELIOS Unification Bus (HUB), a middleware technology. Independent and distributed software components communicate by means of the HUB. The middleware of CHILI is based on the same concepts as HELIOS, but has been redesigned in several aspects to match the specific requirements of an image communication environment that has parts which are linked by low bandwidth networks and are not permanently reachable. Security enhancements have been added to fulfill the legal requirements for data security and privacy. The middleware supports the security standards SSL/TLS (Secure Sockets Layer/Transport Layer Security) for authentication and secure communication [7].

Figure 1 shows the main components of the architecture:

Figure 1. shows the main components of the architecture





- The *Viewer* is the graphical interface for the user. Nearly all functions are controlled by the viewer, including viewing images, transmission of images, teleconferences, and system configuration.
- The *Message System* is used as the communication channel (middleware) between the software components.
- The *Database Service* component stores the data for the system and delivers it to other software components. It provides an abstract interface which hides the specific SQL database management system (DBMS). Thus, it is independent of a specific DBMS implementation. DICOM (Digital Imaging and Communications in Medicine) archives can be accessed through this interface as well. This is a great advantage both for users and programmers.
- *Send and Receive Services* are used to exchange data between the CHILI systems via the CHILI protocol. Other protocols are available as well and allow data exchange with non-CHILI systems (see Cross-Platform Communication). An optional wavelet module (MT-Wice, MeVis Technology, Bremen, Germany) can be employed to compress the image by a factor of 10-100 to speed up the transmission process.
- The *Import and Export Services* are needed to get the data into the system and to export data to the local disk or an archive medium. DICOM is the most relevant image format for this purpose. The older ACR/NEMA 1.0 and 2.0 standards; industry standards; and public domain formats such as GIF, TIFF, PostScript, PPM, JPEG, M-JPEG are supported as well. Vendor specific formats, like SOMATOM, MAGNETOM, and GENESIS, can also be processed.
- The *DICOM Server* receives image data via the DICOM protocol as a Storage Class Provider from other DICOM devices, such as CT or MRI scanners.
- The *Query Service* is based on the DICOM protocol to retrieve image data from Picture Archiving and Communications Systems (PACS) archive systems.
- The *Multiplexer* manages connection requests between the different components and starts modules when necessary.
- The *World Wide Web (WWW) Server* is the gateway between the CHILI database and internet technology (see WWW: Independent of Hardware and Operating System).

This overall design allows a very flexible configuration of the system which can easily be adapted to any specific environment. The different services and modules can be combined in different ways to provide custom solutions. Examples of typical configurations (in clinical use) are:

- *CHILI Classic*, with full functionality ranging from DICOM image database to printing and teleconferencing.
- *CHILI Video* is a package without connections to modalities or databases but with on-line communications using digital images which are grabbed from a video source.
- *Send and Receive systems* can be used to perform one-way communications setups.
- *Client/Server* configurations use a central PACS archive or CHILI database and allow the transmission of data to remote sites as well as teleconferences. The server can either be a CHILI Classic (with or without viewer) or a database

server (SQL and/or DICOM). The clients can either be viewers or complete systems which share a central database. All clients have the complete functionality of a CHILI Classic configuration in connection with a server. Other dedicated systems can be realized depending on the actual user needs.

### Security Concept

The most powerful communication protocol for data exchange (and the only protocol that allows teleconferencing) is the CHILI protocol, which includes a strong data security concept [8]. This includes all measures which are necessary to comply with German and European requirements and laws. As a result of the data security concept, it is possible to restrict the rights of the receiver on the image data. The following restrictions are possible:

1. Only viewable in a teleconference with the sender.
2. Not exportable.
3. Not printable.
4. Automatic removal after the teleconference.

All data packets to be transmitted are encrypted with the PGP (Pretty Good Privacy) public key encryption system [9]. The public key of the receiver is used for the encryption. A checksum of the data is calculated and signed with the digital signature of the sender. This protects data integrity, and allows for authentication of the sender and privacy. Furthermore, all local data are encrypted with a symmetric key encryption method. Transmitted and received images are logged in special log files which are protected with a checksum.

The communication between the CHILI components via the middleware can optionally be protected using the TLS standard [7]. This ensures authentication and privacy.

### Cross-Platform Communication

It cannot be expected that all communication partners have the same teleradiology system. Thus, CHILI offers additional communication methods (Figure 2):

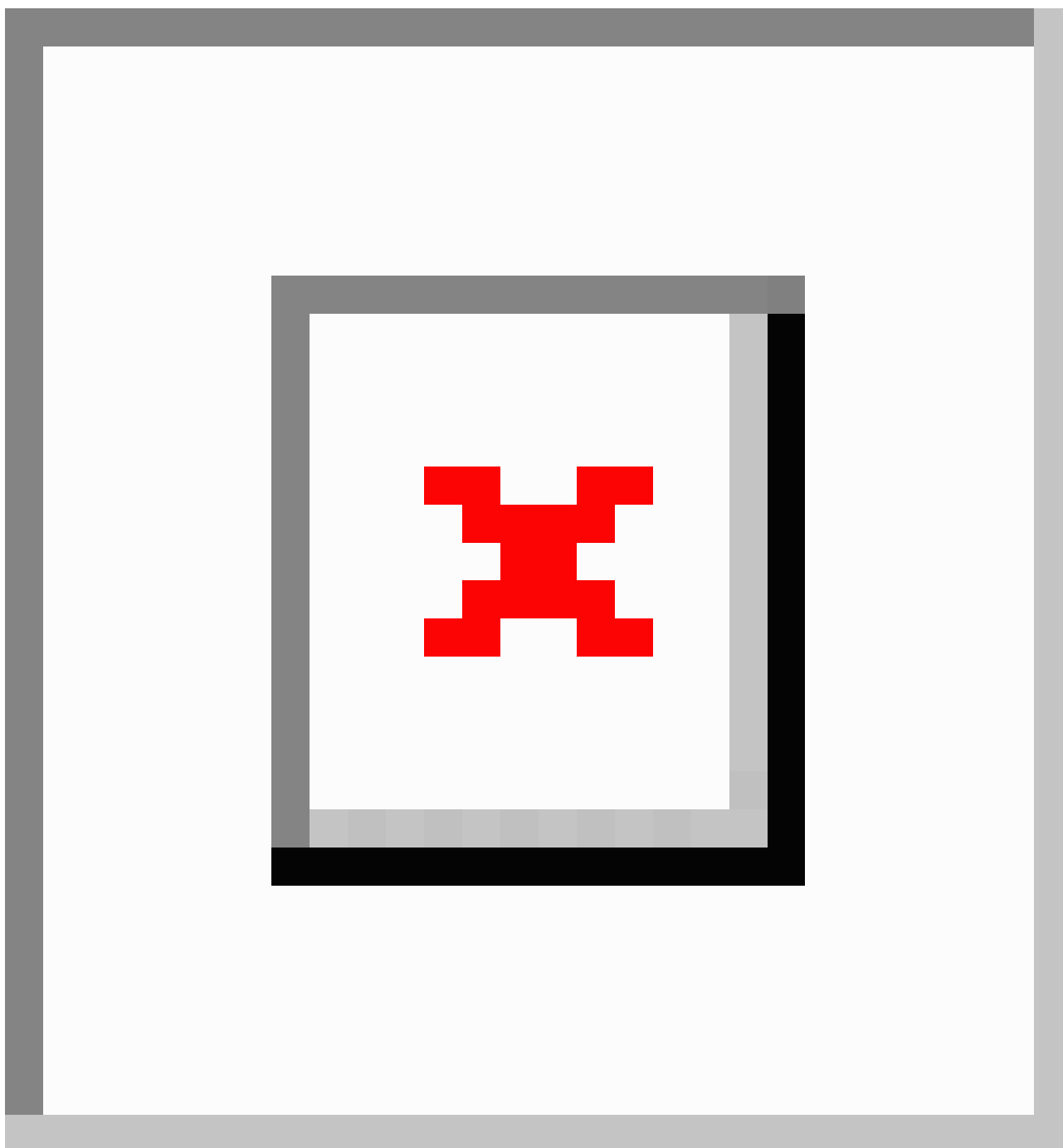
- The *DICOM protocol* allows the exchange of images with all other DICOM compliant systems. The following service classes are supported: storage class user, storage class provider, and print management classes for both user and provider. Find and Move are also supported.
- Classic *e-mail* (SMTP protocol) can be used to send images encoded in either DICOM or JPEG formats.
- *File Transfer Protocol* (FTP) and *Remote Copy functions* (RCP) are available to transmit image data to other hosts where the data is processed with other software tools.
- Data can be transferred to *portable media*, such as CD-ROMs (DICOMDIR). The CD-ROMs are suitable for archiving purposes as well. The database stores a reference to the CD-ROM where the data are actually stored. The media can be handled manually or automatically with a jukebox. Non-archive CD-ROMs can be given to other medical institutions, referring physicians, or even the patient. The standardized DICOMDIR format ensures that the data can be viewed with different programs which are compliant to the standard.

- Images or image sequences can be acquired from *Video* sources, such as video camera, video recorder, and ultrasound devices. The system converts the analog video signal into DICOM compliant image files. Demographic data is acquired as well to facilitate data-handling in the patient-oriented database and long-term PACS archives.
- Data from document or film scanners can be imported in different formats and converted to the DICOM standard for further processing.
- The WWW server (see Component Architecture) translates the internal SQL or DICOM representation of the data to the HTTP protocol. Thus, the data can be accessed with

any web browser in the network. The advantage of this solution is that the clients do not need any special hardware or software. Authenticity of users and privacy are ensured by different measures, such as user accounts, passwords, restricted group access, and the secure protocol TLS.

The user of the CHILI system is not confronted with the various protocols directly. The definition of the protocol to be used is configured for each communication partner. It has to be defined if the partner is connected via LAN, Internet, or ISDN lines. The ISDN zone is defined as well to be able to estimate the transfer costs depending of the transmission time, duration, distance, and compression rates.

**Figure 2.** CHILI offers additional communication methods



The broad set of transfer methods enables the CHILI user to send images to nearly anyone with access to a computer and a network. The limitations are that teleconferences are possible with the CHILI protocol only, and that the user has to take reasonable precautions for data privacy and security when he does not use the secure CHILI protocol.

**Explicit Transmission and Auto-routing**

Image data can be transmitted manually by the user or automatically by the auto-routing component which is activated by the import service. Certain data fields of the image header are used to determine if and to whom the incoming data should be transmitted automatically.

**Functional Openness**

A typical problem in radiology is that nearly every application needs its own computer. Console computers are necessary to operate the imaging modalities. Viewing stations are used for reporting or further analysis of the image data. Radiology Information System (RIS) terminals are used to manage and organize the patient information flow. Additional Personal Computers (PCs) are used for word processing (e.g. reports, publications). New computers for teleradiology are now entering the radiology department.

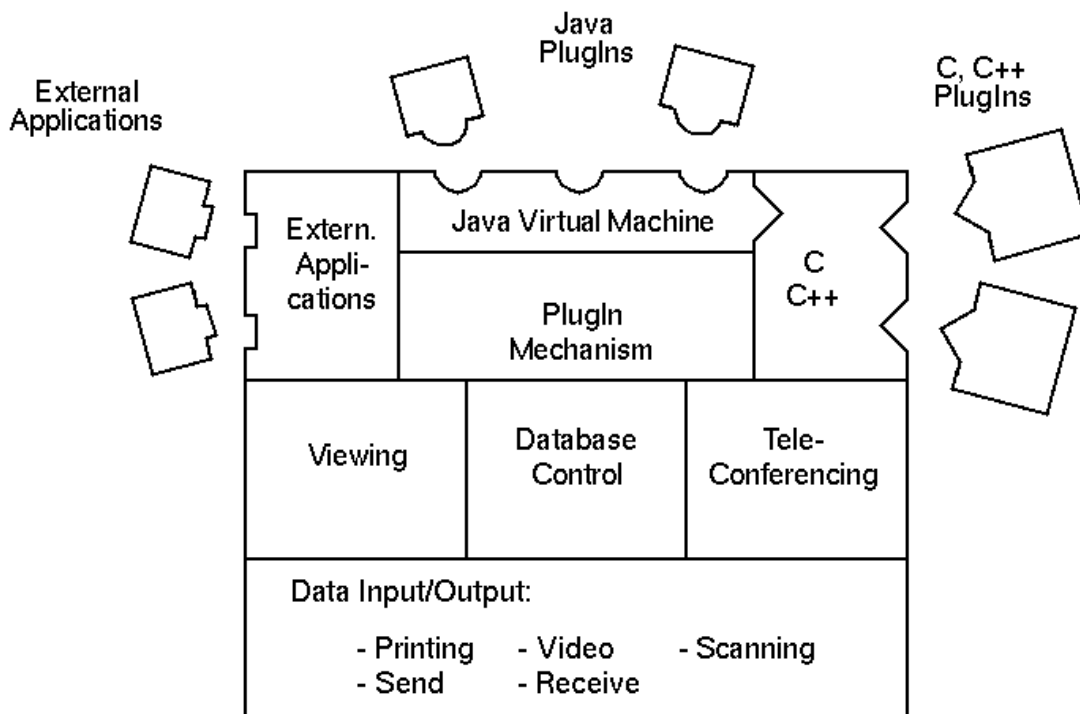
Developers of new medical image analysis applications face the problem that the current computer applications (e.g. viewing stations) are not open enough. Every developer must consider

the connection to the modality or viewing station, file formats, data storage of files on the disk or in a data base system, and the display of 12-bit images on 8-bit screens. For the radiologist, the development a new method means the invention of many wheels a second or third time before the real problems can be addressed. Most of the manufacturers of the existing viewing stations do not allow the installation of additional software. Usually the customers do not get the root password of the systems. An additional computer with different user interfaces and additional interfaces to the rest of the world has to be introduced, therefore, to get the new functionality to the users.

The result of the depicted problem is that it takes a lot of effort for developers to implement and introduce new methods; this is most of the time very costly for the end user. Therefore, we designed the CHILI PlugIn mechanism [10]. Users can extend the system by adding powerful image postprocessing functions [11] or interfaces to other information systems. PlugIns can be either existing applications or new modules with interfaces to the existing CHILI components (Figure 3).

The PlugIn developers' Application Programming Interface (API) includes interfaces to all software components and the message system [10]. The developer is free to choose programming languages and interface toolkits (e.g. C, C++, Tcl/Tk). The Java Virtual Machine [12] is a PlugIn itself; thus, Java programs can easily be integrated to communicate with CHILI.

**Figure 3.** PlugIns can be either existing applications or new modules with interfaces to the existing CHILI components

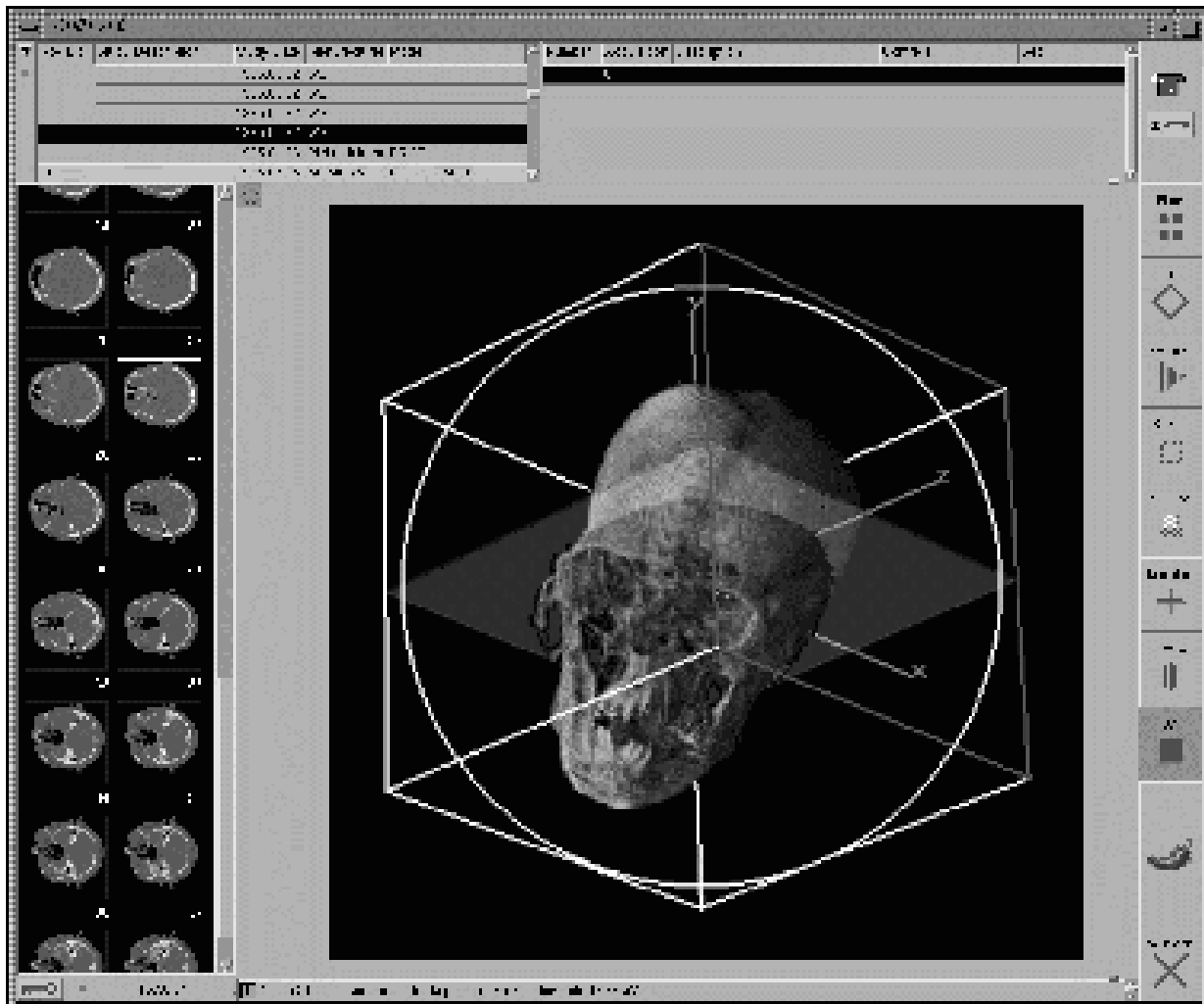


Several existing applications have successfully been integrated into CHILI as useful additions to the main system. One example is a terminal window (xterm) which is connected to a RADOS-M RIS. This enables the user to see both the image data and RIS information on the same screen (Figure 4). Another

example of such a simple PlugIn is a WWW browser, which allows the user to explore, for example, reference cases on the intra- or internet. The user manual of the system is integrated with the same mechanism.



**Figure 5.** Examples for ongoing PlugIn development projects are a general purpose 3D volume segmentation and visualization project



## Hardware and Operating Systems

### *Unix-Workstations and Personal Computers with Linux*

CHILI has been developed under the UNIX operating system in ANSI C. The most important reasons were portability, reliability, and data security. The realized system is not dependent on vendor-specific UNIX dialects or hardware features. It is available on workstations running IRIX, Solaris, Ultrix, and Linux. The most economically priced and powerful system is a PC running the Linux operating system [16].

### *Personal Computers with Microsoft Windows*

CHILI clients are running under Microsoft Windows under the eXceed system (Hummingbird). The latter allows the original code to run and provides a X Window-based user interface. It offers the same functionality as the Unix client, including teleconferences.

A complete CHILI Classic configuration has been realized using Interix (formerly known as OpenNT, by Softway Systems, Inc.) on Windows NT systems, with all components for data exchange and teleconferencing operational.

### *WWW: Independent of Hardware and Operating System*

The Web Interface is the most hardware and operating system independent solution. The CHILI WWW Server is a frontend to the CHILI database. Users can access it with any web browser. The user interface is nearly the same as the standard CHILI Viewer. Data can be retrieved from CHILI databases, or DICOM archives which are accessed through the CHILI database interface. The images can be displayed with 8-bit screens in GIF or JPEG format, and DICOM encoded for the Java/DICOM viewer. The compression rate of the JPEG images can be defined in different quality steps.

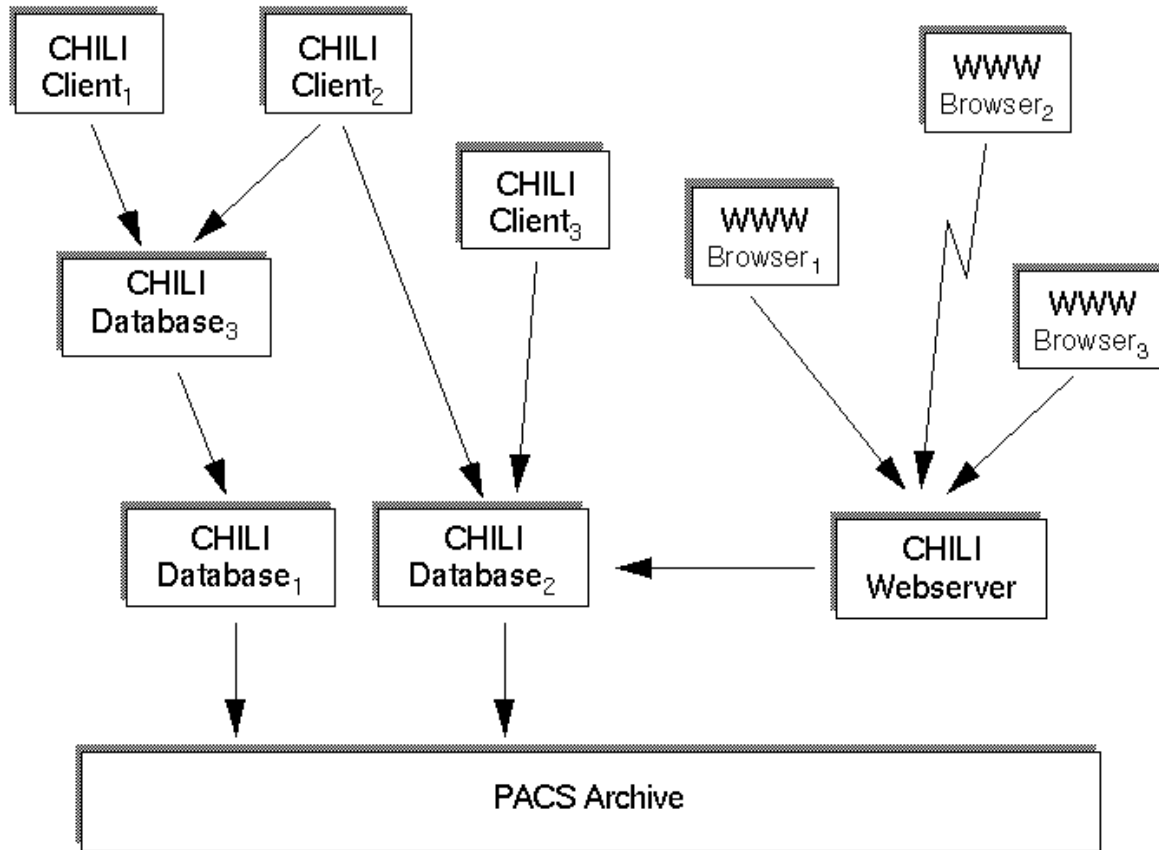
### *From Teleradiology to PACS*

Over time, the system has become a PACS component which can be used as an interface to DICOM compliant archives, and also for DICOM printing and reporting. Images can be distributed in-house, and light-weight clients running on PCs can be used to view or process the images in teleconferences. Clients for MS Windows are available, in addition to web-based interfaces which can be accessed from any hardware or operating system with a web browser. The CHILI database can be configured to act as a cache for the PACS archive (Figure 6).

A storage hierarchy can be configured to reduce the traffic on the archive and to optimize image transfers on the network. The user is released from the load of knowing where the data are actually stored.

The CHILI Viewer with the multi-head option and diagnostic monitors is suited for image reporting. Filmless radiology can be realized with this technology.

**Figure 6.** The CHILI database can be configured to act as a cache for the PACS archive



## Results

The CHILI project is a cooperation between the German Cancer Research Center and a technology transfer company Steinbeis-Transferzentrum Medizinische Informatik (STZ-MI), both located in Heidelberg, Germany. The STZ-MI is an outgrowth of the cancer center where scientific results are converted into products for market. Concepts and research are done by the research group at the cancer center, and the technology transfer company implements the research into

products and brings the results to the market. Marketing and sales is also done by OEM partners, system integrators, and consulting firms.

More than 40 systems are running in daily routine in private practices, small hospitals, university clinics, and research institutes. The system is in use in research projects, in medical image analysis, and even surgery planning systems. It is the basic platform of the German research project Sonderforschungsbereich 414 *Information Technology in Medicine: Computer and Sensor Supported Surgery* [17].

Figure 7. shows the current network (July 1999)

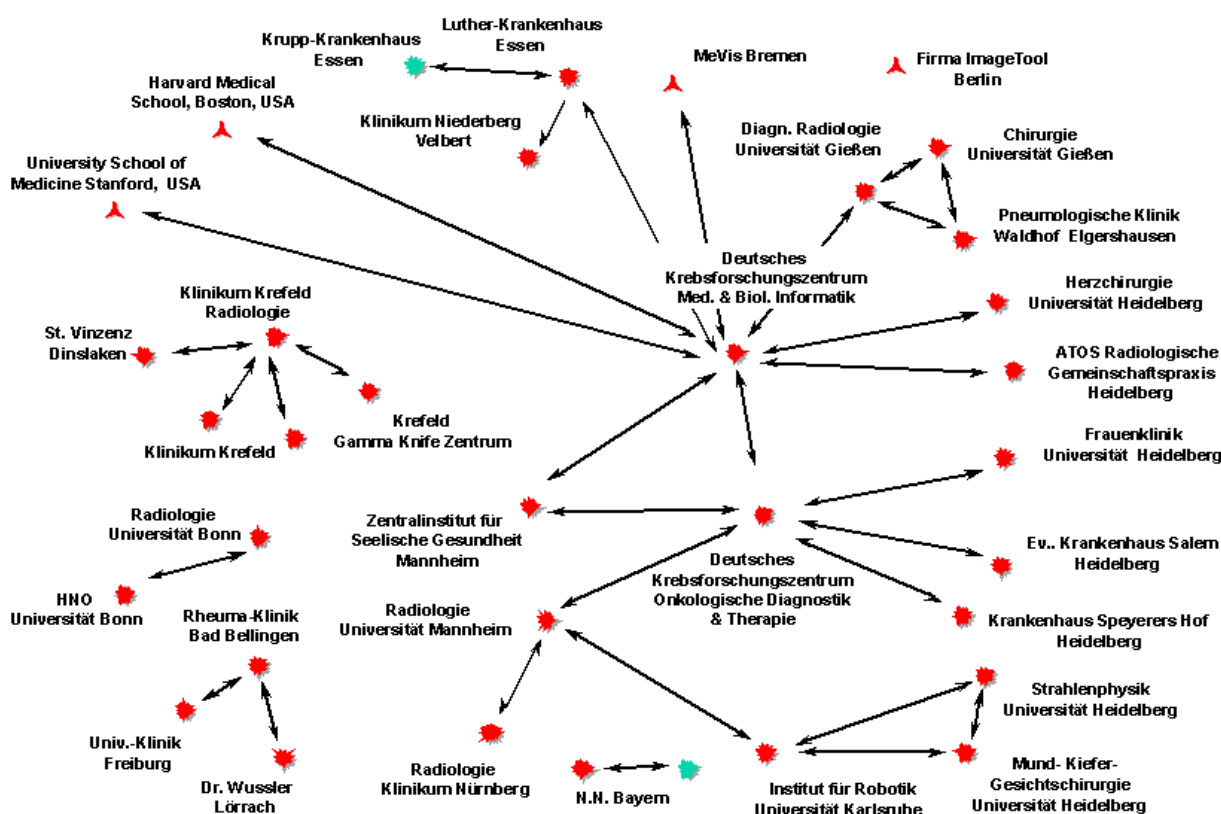


Figure 7 shows the current network (July 1999). More than 300,000 images have been processed by the network, and the program has been invoked nearly 20,000 times in the last 3 years. More than twenty modalities from different vendors are connected via DICOM or proprietary solutions [18].

The system is in use in different application scenarios, such as image delivery to referring physicians, interdisciplinary discussions, remote reporting, de-centralized radiology departments, resource sharing, data transfer for radiotherapy planning, scientific cooperation, quality control, and research.

## Discussion

### Comparison with Work of Others

An overview about the state of teleradiology in the United States has been published by Grigsby in 1994 [19]. Regular telephone lines and modems were normally used at that time in the US. Most of the systems developed were based on PCs using video cameras with PC frame grabber cards or scanners to capture the images, e.g [19,20]. Oft-discussed topics in the field of teleradiology were spatial resolution and grayvalue depth of the video images or scanners. However, these problems do not exist when the original digital images are processed; the receiver gets the images in original quality. Such advanced teleradiology systems based on digital data and digital telephone lines (ISDN) have been developed and used in Europe since 1994, e.g [20-24].

A prototype of a dedicated teleradiology system has been developed by Gomez and co-workers in a research project funded by the EU AIM Programme [21]. The system has been evaluated in two hospitals in Spain. One imaging modality was connected to one of two teleradiology workstations. Handels describes another German teleradiology system, called KAMEDIN, which has been used in a field test for several months but has never gone to clinical routine [22].

All major image modality vendors in the field of radiology have been talking about teleradiology since 1994 or 1995. The main difference of the industrial solutions is that they simply extend the local area network of the radiology department by an ISDN link to another location. Images are then sent with proprietary protocols (sometimes with DICOM) to a remote machine. Teleconferences with two users at different locations who work together on the same images are not possible. Security aspects are missing as well.

CHILI (and its predecessor MEDICUS) seems to be the only system which has a complete data security concept [8]. A great advantage of the system, compared to others, is the direct connection with the imaging modalities of different vendors. The DICOM protocol can be used to receive the images, or proprietary solutions can be enabled for older modalities without DICOM interfaces.

A major feature of CHILI is that it is not a dedicated teleradiology system, such as its prototype MEDICUS or the KAMEDIN system [22]. Instead, it is a general purpose

multimodality workstation with strong teleradiology and security features. Cross-platform communication, vendor independence, and extensibility are major distinctive features in comparisons. The system is also used for advanced image analysis functions and image reporting.

New teleradiology systems are currently under development in the programming language Java [12]. This makes the systems independent of the operating system and hardware used. Examples are the CYPRIS system which is under development by Klaiber [25] or the Jive system by Kleber [26]. Both systems are not yet mature enough to be compared with the CHILI environment. They lack basic image analysis functions, cooperative teleconferences, strong security features, and the full spectrum of vendor and system independent communications. The performance drawback of Java is another aspect which has to be taken into account; but independence from the operating system and the hardware are fascinating features.

### Conclusion and Outlook

CHILI is not just a research project where the system has been used for some test cases. It is integrated in the clinical routine

in many different locations and institutions. The accounting numbers and the feedback of the users are proving that the CHILI architecture provides a powerful and flexible environment for PACS and teleradiology. PlugIn modules will also extend the multimodality workstation for teleradiology by providing advanced image analysis and therapy planning functionality.

In the future, development will continue on the Java implementation of the complete CHILI architecture to offer the most flexible and hardware/software independent environment for PACS and teleradiology. The feedback and suggestions of the users has influenced the system architecture by a great extent. Our own experience is that the differences between PACS and teleradiology components will vanish. This observation is supported by a recent market investigation by Frost&Sullivan [27]. The "tele" aspect will become a natural feature of radiological workstations. Radiologists will profit from better performance; and as a consequence, the patients will receive better treatment.

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CHILI is a registered trademark of Steinbeis-Transferzentrum Medizinische Informatik, Heidelberg, Germany.

<http://www.chili-radiology.com/>

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### Conflicts of Interest

The concepts of the CHILI system have been developed at the German Cancer Research Center in cooperation with the technology transfer company Steinbeis Transferzentrum Medizinische Informatik (STZ-MI) Heidelberg, Germany, which develops and markets the CHILI Software. Some of the authors are working as employees or consultants for that company.

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