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Editorial

A Question of Duty: Common Law Legal Issues Resulting from Physician Response to Unsolicited Patient Email Inquiries

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Patients have eagerly embraced the Internet and its email capacity to increase their knowledge and access to medical information. Along with access to countless patient support "chat rooms" and an ever-increasing volume of full text health and medical literature, the Internet also offers a virtually barrier-less opportunity to engage physicians in email dialogue. While this opportunity is seductive and cost-free to patients, physicians should exercise care and wariness in their email exchanges with patients - especially if the patient is unknown to them.

This issue of the *Journal of Medical Internet Research* features an interesting study illustrating the willingness of an astoundingly high percentage of anesthesiologists to enter into a dialogue with unknown patients [1]. The study, which looks at the quality and quantity of anesthesiologist responses to a patient problem presented through email communication, generated a 54% response rate. Of these, 83% of the responses were assessed as friendly in tone and 41% went so far as to suggest a diagnosis to the inquiring email patient. The study reproduces the results of an earlier study with similar methodology [2], demonstrating a surprising naiveté on the part of well-meaning physicians.

This brief commentary will summarize the common law legal risks of responding and offering advice or diagnostic suggestions to patients over the Internet. It will focus primarily on the concept of duty and how it has evolved in the United States. (Medical negligence cases in the United States are state law causes of action. Thus there are jurisdictional differences from state to state. However, the concept of duty as discussed in this article is well-settled law, and the consensus in virtually all U.S. jurisdictions.)

The risks in providing email medical advice flow from the inadvertent birth of a physician-patient relationship and a resulting duty and responsibility to the patient. Once there is a cognizable physician-patient relationship, the physician has a duty to provide care and advice that is consistent with the applicable standard of care. The standard of care varies somewhat from jurisdiction to jurisdiction. However, it generally requires that the physician conform to the standard of a reasonably prudent practitioner practicing under similar

circumstances. The standard typically does take into account specialty status. Medical negligence is defined as a breach of the standard of care resulting in the patient suffering a harm with quantifiable damages.

In order for a physician-patient relationship to be formed, there must be an assent by the physician to see or counsel the patient, although this may be indirect. In the common law, this agreement is referred to as an implicit contract. In order for a duty relationship to have been formed, the content of the interaction must include some evaluation, even if only a rudimentary one, by the physician as to the patient's complaint. Finally, the patient must rely upon the physician's determination, however preliminary that evaluation might have been.

Lessons learnt from cases related to telephone communication

Valuable lessons can be learned from the case law that has accumulated with respect to telephone communications between physicians and patients. Like the Internet, the telephone allows patients to access physicians directly and provides an instrument by which an implicit contract to provide care could be initiated. In the context of telephone communication, a patient call to a physician requesting and scheduling an appointment for the future does not necessarily result in the formation of a contract and the creation of a physician-patient relationship [see [Textbox 1](#)]. The physician may decline to accept the patient by refusing to schedule an appointment, or may condition acceptance on certain criteria or requirements [see [Textbox 2](#)]. One could argue that this situation approximates that in which a prospective patient seeks to consult or query the physician by email. In the email context, the physician could refuse to participate by simply not responding, issuing a reply declining to engage in an interaction, and/or suggesting the patient consult their own physician for medical advice and diagnosis.

However, if in the course of making an appointment, the patient is given some indication over the telephone that the physician has indeed agreed to provide care for the instant episode of illness, reasonably assumes that care is forthcoming, and relies upon that assumption by ceasing further efforts to obtain care for the condition, then a relationship giving rise to a duty will

have been formed. The content of the interaction must show that the physician has undertaken to provide care for the patient for this episode of illness. Once the physician has "undertaken"

to provide care, he is compelled to see the care through to its natural conclusion [3].

Textbox 1. A patient call to a physician requesting and scheduling an appointment for the future does not necessarily result in the formation of a contract and the creation of a physician-patient relationship

For example, in *Weaver v. University of Michigan Board of Regents*, 201 Mich. App. 239, 506 N.W. 2d 264 (1993) a medical center neurosurgeon had cared for a child with hydrocephalus during her infancy. Parent later received follow-up care from another neurosurgeon nearer their home. Several years later, when the child developed vision complications, the father sought a second opinion from the medical center neurosurgeon. In obtaining the appointment, he volunteered the information that the child had been seen by the local neurosurgeon who did not consider the condition to be emergent. An appointment was obtained one week hence. The medical center neurosurgeon correctly diagnosed increased intracranial pressure and recommended emergency surgery. Although the surgery was a success, the child had already suffered permanent damage to her vision. The father sued all the caregivers, including the medical center neurosurgeon. The latter successfully argued that at the time the child suffered the harm, there had been no physician-patient relationship with the medical center and its physicians.

Textbox 2. The physician may decline to accept the patient by refusing to schedule an appointment, or may condition acceptance on certain criteria or requirements

For example, in *Childers v. Frye*, 201 NC 41, 156 SE 744 (1931), the physician asked to see a victim from a motor vehicle accident observed that the patient appeared intoxicated and declined to provide care for the patient.

Even if the physician provides a tentative offer to provide care, the patient may fail to fulfill his role in forming the implicit contract. For example, in *Miller v. Sullivan*, 214 A.D. 2d 822, 625 N.Y.S. 2d 102 (1995), a dentist experiencing back pain, shortness of breath, and other symptoms called a physician friend and related his complaint. The physician urged the dentist to come to the physician's office immediately for evaluation. The dentist essentially disregarded this advice, finished seeing his scheduled patients and then proceeded to the physician's office, where moments after arrival, he suffered a cardiac arrest. Here, the court held that the physician-patient relationship had not been formed because the plaintiff had essentially disregarded the very preliminary advice offered over the telephone.

For example, in *Lyons v. Grether* [4], a patient requested an appointment with a specialist physician for care of a specific complaint related to the physician's particular area of practice. Relying upon the assurance that he would see her, she arrived at his office with her guide dog and child in tow. The physician refused to see her unless she left her dog outside. Concerned for the safety and security of the dog, she insisted the dog remain. Thereupon, the physician reneged on his agreement to see her and evicted her from the office. The court held that because the plaintiff's appointment had been granted for the care of a specific ailment within the specialty expertise of the physician, it indicated the formation of a physician-patient relationship and a duty for the physician to perform that service: "Whether a physician-patient relationship is created is a question of fact, turning upon a determination whether the patient entrusted his treatment to the physician and the physician accepted the case."

Similarly, in *Bienz v. Central Suffolk Hospital* [5], the court held that a telephone conversation in which a physician provided advice to the patient, which the patient relied upon, constituted a physician-patient relationship and gave rise to a duty on the part of the physician [6].

However, if the patient failed to rely upon the advice provided over the telephone, the mere fact that the physician conversed with the patient on the telephone and listened to a recital of symptoms is not sufficient to form a physician-patient relationship. For example, in *Clanton v. Von Haam* [7], a patient with severe back pain called a physician she had previously seen for other complaints. The physician listened to her complaints and refused to see her that evening but agreed to see her in the morning, if her pain persisted. The court held that although the patient might have relied upon this advice, in this case the plaintiff had not relied upon the defendant physician.

How does this apply to email?

Applying these principles to an email interaction such as that posed in Dr. Oyston's study, the fictional patient made a request - albeit somewhat veiled - for evaluation of the medical problem. The patient sought the physician's advice without any enticement or invitation from the physician. Several of the anesthesiologist respondents entered into an email dialogue, asked additional clinical questions, and 41% of them suggested a diagnosis. Providing a diagnosis could easily be assumed to be an undertaking to provide care to the patient. For example, if the physician has suggested a specific diagnosis and even discussed potential treatments, the patient may well rely upon this diagnosis and advice. If the diagnosis is in error or falsely reassuring and, as a result, the patient sustains harm, the patient would have a viable negligence action against the email physician. Assume, for instance, that the email anesthesiologist reassured the inquiring patient that her prior anesthesia complication was likely a one-in-a-million fluke and irrelevant to future care. The patient might well dismiss the concern from her mind and not even mention it to the next provider, who happens to be a surgeon, consulted to perform an elective surgery on the patient. The patient again responds abnormally to succinylcholine and, as a result, suffers a neurologic deficit. Having relied upon the email advice, the patient will almost certainly include the email anesthesiologist on the defendant list. The other defendants will welcome their email colleague as his negligent advice serves to decrease their potential liability.

Recommendations for physicians confronted with unsolicited email

Dr. Oyston's study provides substantial food for thought and reflection. First and foremost, physicians, whatever their specialty, should be wary about providing email advice, especially to unknown "new" patients. The physician can have

no way to accurately assess the patient under these circumstances. There will be no easily verifiable history and the physician will be completely dependent on the patient's story as it is related over the email. The physician will not have access to the many other senses and sources that support a legitimate differential diagnosis, such as a physical exam and the intuitive response to the patient's personal presentation of symptoms. As such, the physician is forming his opinion with information that is likely to be incomplete at best and inaccurate - or even untrue - at worst.

Even if the information gap can be minimized, there is considerable room for diagnostic error and uncertainty. Assume for instance that the email patient agreed to fax over her chart, as was requested by one of the physician subjects in Dr. Oyston's study. What guarantee does the physician have that this chart is authentic, complete, or contemporaneous? Would any physician treat solely on the written chart without interviewing and examining the patient personally, or at least verifying the authenticity of the material? Moreover, had the email patient forwarded the chart to the email anesthesiologist, this act would serve to bolster the impression that the physician had indeed undertaken to provide care, thus demonstrating that the physician did indeed assume a duty to care for the patient. In such a case, the assiduousness of the physician in seeking to review the chart would actually increase his exposure to liability.

This is not to say that email communication between physicians and patients is always risk-laden. In the situation where email is used to apprise the physician of the patient's progress, response to treatment, and well-being during an episode of care, ongoing email communication will benefit both physician and patient. However, in this context, the physician will have met

and evaluated the patient, assuming the burden of care in the more traditional way. The physician will have a relationship with the patient, and be confident and knowledgeable about the patient's ability or limitations with respect to accurately describing signs and symptoms. Thus, the physician may proceed with greater assurance in advising the patient via email.

With respect to requests for advice and diagnosis over the Internet from "new" prospective patients, physicians would be well advised to proceed with the utmost caution. There is no duty to respond to an unsolicited message or plea for assistance. These email scenarios do not approximate "Good Samaritan" scenarios where a physician might reasonably believe there is a duty to provide assistance in an emergency. In fact, in the United States, "Good Samaritan" statutes provide qualified immunity for health care providers who have chosen to give unsolicited assistance at the scene of an accident. Generally the statute's definition of "scene of an accident" is narrow and would not include responding to a request for help through email. (One could argue that the duty relationship would be more substantiated if the patient has not independently solicited the physician's advice, but rather has responded to the physician's advertisement or offer of medical services extended to the general or a specific Internet audience, i.e. a disease-specific chat group.)

However, if the physician is unable to refrain from engaging in such a dialogue, he should be extremely circumspect in his responses, avoid engaging in differential diagnosis, and steer the patient to his or her own physician or an appropriate medical center [8]. In the final analysis, this is not just an issue of potential liability, but of the judicious practice of good medicine.

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Original Paper

Anesthesiologists' Responses to an Email Request for Advice from an Unknown Patient

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Abstract

Background: People are using the Internet as a method of getting medical advice. Some Web sites include the email addresses of physicians, and some people are contacting these physicians for advice. As many patients undergo surgery on a "day surgery" basis, they often have no opportunity to ask anesthesiologists for advice before surgery; these patients may be more likely than other groups to use Internet email to ask questions. It seemed that it would be useful to find out what, if any, advice anesthesiologists would give in response to email from an unknown patient.

Objective: To determine how anesthesiologists would respond to an email requesting advice about an anesthetic problem from an unknown patient.

Methods: In February 1998, an email message was sent from a fictitious patient, using an email address created for this study, to 115 anesthesiologists whose email addresses were found on publicly accessible web sites. The message described the patient's problem with a previously administered anesthetic and requested advice about anesthesia for upcoming surgery. Responses were entered in a database and analyzed to determine the percentage of anesthesiologists who responded, and how helpful, accurate, and complete their advice was.

Results: Fifty-eight responses were obtained from 108 valid email addresses (54% response rate). Of these, 78% were received within 48 hours. Eighty-three percent (83%) of respondents suggested contacting a local physician, 62% mentioned reviewing the old chart, and 41% suggested a specific diagnosis. None of the initial replies contained inaccurate advice, but only five responses were considered to be comprehensive. Ten percent (10%) included a disclaimer with the response. Eighty-three percent (83%) of replies were subjectively assessed as being friendly in tone.

Conclusions: At present, patients who email an unknown anesthesiologist can expect to get a reply from over half. The advice is likely to be prompt, friendly, and to provide accurate and appropriate - but probably incomplete - advice.

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KEYWORDS

Internet; Email; Electronic Mail; Referral and Consultation; Medical History Taking; Quality of Health Care; Physician's Practice Patterns; Remote Consultation; Physician-Patient Relations; Professional-Patient Relations; Medical History Taking

Introduction

Note: An accompanying editorial, "A Question of Duty: Legal Issues Resulting from Physician Response to Unsolicited Patient Email Inquiries," by P. Kuszler, MD, JD, has been published in this issue.

Many patients are using the Internet as a source of medical information. Mainstream publications, such as "Consumers Reports" are teaching the public how to use the Web, Internet

mailing lists, and email to get medical information and advice from the Internet [1].

New methods of communication between doctors and the public give rise to new practical, ethical, moral, and legal issues [2]. There are established guidelines for the use of email in established doctor-patient relationships [3]. Comparable guidelines in dealing with email from unknown members of the public are currently being proposed [4]. This issue was considered "a significant unresolved problem" by 62% of respondents to one survey [5].

One study published in the lay press [1] investigated eight web sites that invited medical questions. Only three sites (38%) responded, and two gave vague or unhelpful replies. Another study found that only ten of seventeen "cyberdocs" responded to a request for advice on a dermatological emergency, and that two gave questionable advice, suggesting that vitamins and herbal remedies would suffice [6]. These studies involved physicians who were setting themselves up to answer patient's questions, and yet they provided a very poor service.

This study involved sending email to physicians who have published an email address on a web site, but have not specifically requested email from patients. In a similar study, it was found that 18 out of 56 dermatologists were willing to offer a diagnosis for an unknown patient via email [5]. There has not been an equivalent study of anesthesiologists, or of any other medical specialty. As one Canadian anesthesiologist reports that he receives now about 50 email messages a week from unknown patients as the result of having his email address posted on a web site [7], it seemed appropriate to investigate how anesthesiologists respond to requests for medical advice from unknown patients, to determine if physicians in a different specialty were also willing and able to respond to patients' questions.

Methods

To determine the response a patient would get from sending an email request for advice to an anesthesiologist, a fictitious patient email address was set up using HotMail. An email

message asking for advice about an anesthetic problem was created, based on an actual email the author had received from a patient. In this message [see [Box 1](#)] the patient gave a history of requiring ventilation after a previous minor operation, and asked for advice about a future anesthetic. The history suggested that the patient had pseudocholinesterase deficiency, an inherited condition in which patients remain paralyzed for a prolonged period after the use of succinylcholine. This inheritable condition can be diagnosed by a simple blood test and treated by avoiding certain muscle relaxants.

The message was sent in February 1998 to 115 anesthesiologists whose email addresses were published on publicly accessible web sites. The addresses were found by searching English-language web pages listed at major anesthesia sites such as GASNet, the Anesthesiology section of The Mining Company(now About.com), and Anesthesia and Critical Care Resources on the Internet. Pages were searched for the "@" sign. Where the context made it clear that this was an anesthesiologist's email address, the address was used. Responses were read and analyzed for the presence or absence of certain types of statements, such as a disclaimer of responsibility, a diagnosis, specific points of advice, or suggested course of action. Data was entered into an EpiInfo 6.0 database [8] and analyzed using simple descriptive statistics.

A follow up message was sent to each responding anesthesiologist eight to ten days later, stating that the patient had been diagnosed with pseudocholinesterase deficiency and had had a successful anesthetic avoiding the use of succinylcholine [see [Box 2](#)].

Textbox 1. Fictitious patient request for help sent to 115 anesthesiologists

Dear Doctor:

I would appreciate your advice about an anesthesia problem.

When I had my appendix out, I had to be put on a breathing machine after surgery. I was told this was because of a problem with the way my body handles anesthetic drugs.

Now I need surgery on my gall bladder and I am worried about the anesthetic. Can you give me any advice?

Thank you,

John Wilkinson

Textbox 2. Follow up message

Dear Doctor:

Thanks for your reply to my request for anesthetic advice.

I thought you would like to know that a blood test showed I lacked an enzyme called "pseudocholinesterase" which makes me sensitive to "succinylcholine".

My anesthesiologist used a different drug and everything went fine.

Thanks again,

John Wilkinson

Results

The results are summarized in [Table 1](#). There were 65 replies to the 115 email requests for advice. Seven were messages saying the email address was invalid. These were excluded from

further analysis, leaving 58 responses from 108 valid addresses, for a 54% response rate. Seventy-eight percent (78%) of replies were received within 48 hours, and all replies were received within five days.

Six respondents declined to give an opinion without more information. Ten asked "Who are you?", and six asked "Where are you?". Ten asked specific clinical questions, and seven invited further correspondence, including one who gave a fax number to which the patient's physician could forward the old medical record.

Forty-eight respondents (83% of replies) suggested the need to consult a physician. Forty-seven suggested an anesthetic consult, and five suggested contacting the family doctor. Fifteen responses stressed the need to arrange an early preoperative consultation. Thirty-six responses (62% of replies) mentioned the need to review the old chart.

Twenty-four responses (41% of replies) suggested a specific diagnosis. Of these, 88% mentioned succinylcholine, 67% specifically suggested avoiding succinylcholine, 58% suggested a blood test, 50% suggested other possible diagnoses, and 33% suggested that this could be a genetic problem.

Ten percent of respondents prefaced their remarks with a disclaimer, and one said that it was inappropriate to seek medical advice by email. None referred the patient to another resource,

such as a web page or a journal article. Twenty-six (45%) of respondents offered reassurance that the problem could be dealt with safely. None of the initial replies contained inaccurate or inappropriate medical advice.

Only five of the responses were comprehensive, including the probable diagnosis, a mention of familial involvement, the possibility of a blood test, the need for an anesthetic consult, and the recommendation to avoid succinylcholine. The overall tone of the messages was subjectively assessed as being unfriendly in 3%, neutral in 14%, friendly in 78% and very friendly in 5% of replies.

A second email was sent to the 58 respondents, reporting the successful outcome of the surgery. This generated 26 responses (45%). Responses included: "Glad to hear all went well" (15 responses); "Document problem/tell others" (9); "Consider a MedicAlert bracelet" (7); "Thanks for letting me know" (5); "Beware of Mivacurium as well as succinylcholine" (4); "Have family members tested" (4); "It is not a problem now that it is diagnosed" (4); and "Avoid Atracurium" (1). This last was the only false piece of advice in any response to the survey.

Table 1. Results Summary and comparison with an earlier study

	Current Study	Eysenbach et al [5]
Question	Requesting advice about an upcoming anesthetic after a previous problem	Requesting advice about a dermatological emergency
Study Group	115 anesthesiologists (108 valid email addresses) 58 responses	58 dermatologists (56 valid email addresses) 29 responses
Advised To See MD	48/58 (83%)	27/29 (93%)
Specific Diagnosis	24/58 (41%) All "correct"	18/29 (62%) One "incorrect"
Specific Treatment	18/24 (67%)	5/18 (28%)
Refused To Give Advice	6/58 (10%)	2/29 (7%)

Discussion

As the public becomes more aware of medical resources on the Internet, some patients are emailing unknown physicians to request medical advice. This produces an ethical and legal dilemma, as the recipient of the message has to balance a natural and desirable human response to offer help to someone who has a problem against the medical, legal, and ethical pitfalls of providing advice to an unknown person, without access to the past medical history, a physical examination, or laboratory data [4]. Usually the patient expects advice for free, but even giving free advice exposes the physician to the possibility of legal action for malpractice or for practicing in a jurisdiction in which he or she has no license. There is no consensus as to how best to deal with this issue.

A recent survey of dermatology web sites revealed that 24% attempted to answer patients' questions individually, 27% did not usually respond and 24% usually sent a form letter [6]. As part of the same study, the authors also sent a fictitious email request from an immunocompromised "patient" who required urgent treatment of herpes zoster to 58 dermatologists whose email address appeared in dermatology web sites. Their study

had results similar to this one [see Table 1]. Their response rate was 52% (compared to 54% in this study), "usually within 1 - 2 days" (compared to 78% in 48 hours). Ninety-three percent (93%) of their responses said, "See a local physician" (compared to 83% in this study). Sixty-two percent (62%) of dermatologists suggested a diagnosis, compared with 41% of anesthesiologists. As the scenarios are not comparable, it is not possible to determine if anesthesiologists and dermatologists differ in their propensity to provide medical advice based on information in an unsolicited email.

In the current study, just over half (54%) of anesthesiologists responded to the email request, and of these 41% suggested a specific diagnosis. Only a minority were concerned enough to add a disclaimer to their comments. They provided advice which was timely and appropriate, in a friendly manner, but which was rarely complete. From a patient's perspective, emailing an unknown anesthesiologist for advice about an anesthetic problem appears to be a useful way of acquiring information, even if the majority of responses included the suggestion of consulting a local anesthesiologist and having him/her review the old chart.

It is estimated that 28 million people undergo surgery each year in the USA alone [9]. Many of these patients will not meet an

anesthesiologist until the day of surgery, so it would not be surprising if more of them start to look for answers to their anesthesiology questions on the Internet.

Ideally, patients seeking advice about anesthesia should be able to contact a local anesthesiologist in person, so that the situation can be reviewed in conjunction with medical records and laboratory data. Email may be appropriate for follow up, for

example for the patient to provide extra details, or for the anesthesiologist to forward laboratory results. However, some patients are likely to want second opinions, or to ask advice of someone assumed to be an expert in a specific field (such as the author of a relevant web page). This survey suggests that if they do so, they stand a reasonable chance of getting a prompt, friendly reply, which is likely to be valid, but may be incomplete.

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Conflicts of Interest

None declared.

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Review

Some Benchmark Searches for Testing Search Capabilities and Medical Coverage of Internet Discovery Tools

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Abstract

The past few years have seen a proliferation of search engines for the World Wide Web (WWW), as well as a growing number of specialized subject directories geared to the needs of health care professionals. Yet documentation on scope, coverage, and search features is often uneven at best; and even documented search features may not perform as advertised. This paper will present a group of sample searches to assist users in gauging database size, determining default search operators, and testing for the presence of advanced search features such as case sensitivity, stemming, and concept mapping for medical topics on English-language web sites.

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KEYWORDS

Internet; Information Storage and Retrieval; Search Engines

Introduction

The software used by World Wide Web (WWW) search engines continues to evolve so rapidly that keeping abreast of search features is a never-ending task. Search engines, such as Northern Light, HotBot, and AltaVista, undergo constant overhauls. Search engine software changes so frequently that help screens, if they exist at all, are often inadequate. At worst, the help screens may even refer to a previous version of the software. Often, even a system with accurate and up-to-date documentation will present it in a Frequently Asked Question and answer format (FAQ), making it difficult to locate specific facts and features of a search engine.

To further add to the confusion, sometimes search engines do not perform as advertised. In other cases, search engines seem to be deliberately vague about the inner workings of their searching software or ranking algorithms because they consider that information to be proprietary.

Benchmarking Tests for Search Engine Features

Default Operator

Understanding how an engine combines search terms is essential to effective searching. Many of the search engines, especially in basic or novice mode, employ fuzzy logic, where all search

terms are linked with a Boolean OR. This is sometimes referred to as "Match any of the terms." This accounts for the large number of results returned from some search engines.

It is possible to determine the default operator by performing a few simple searches. First, enter a single search term and record the retrieval: a recent search for the word "ear" on Excite retrieved 129,711 pages. Then add a second word to the search: searching "ear infections" on Excite yielded 183,650 pages. Since the second search retrieved more than the first search, the default operator on Excite is OR.

If the second search retrieves a smaller number of results than the first one, the default operator may be AND. Searching "ear" on Northern Light retrieved 959,152 pages, while "ear infections" retrieved 55,560. The smaller results indicates that the default operator may be AND; however, it could also be doing an even narrower search, retrieving only pages with the exact phrase "ear infections." To determine whether the default operator is AND or ADJacency, do a third search with the two terms reversed: "infections ear." If the retrieval is the same as in the second search, as it is for Northern Light, the default operator is almost sure to be AND. If the search result is different, the default is probably an adjacency operator, or an exact phrase search.

Stopwords

Stopwords, or noise words, can also be problematic in searching. Some search engines index even the smallest words, including "a" and "the." Others have a list of stopwords that are not indexed; these lists are often unpublished. One way to test for the presence of stopwords is to do searches for "vitamin a deficiency" and "vitamin k deficiency" and compare retrieval. In Excite, both of these searches retrieve 96,794 items, indicating that single letters are indeed stopwords. Another test for stopwords is to enter the search term alone; and indeed a search for "a" in Excite returns no results.

Database Size

One area where the search engines seem especially prone to hyperbole is in their claims to database size. Here are some claims that have appeared on search engine web pages, either now or in the past:

"Excite Search, the Internet's most comprehensive search tool..."

"AltaVista gives you access to the largest Web index..."

From HotBot: "...the largest and most complete index of Internet documents in the world."

More than one search engine boasts that its database is the largest and most complete on the WWW. Even when actual

numbers on database size are provided, they can be misleading and difficult to compare. One search engine may claim that its database has the most URLs; but this number may be artificially inflated if the database contains many duplicates. And how many of these URLs represent pages which no longer exist? Another search engine may base its claim to be the largest on the size of its database in terabytes [1]. But this may reflect an inefficient file structure more than anything else. How, then, can one accurately gauge the size of a search engine database? Perhaps it is best to focus on estimating relative size based upon retrieval when compared to other search engines. This is easily done by performing benchmark searches for the same word on several different search engines, then comparing the results. A single, unambiguous word works best, one which adequately represents a single concept without a lot of synonyms or variant endings, such as "arthritis." Avoid words which are not specific to the medical domain, which convey a different meaning in a non-medical context; such as "labor," which is used to refer both to childbirth and work (in addition to having an alternative British spelling). As a first step toward gauging the amount of content geared toward health professionals as opposed to patients and health consumers, select a word which is more likely to be used by health practitioners, such as "splenomegaly," "diaphoresis," "dyspnea," "osteoarthritis," or "lymphadenopathy" [see Table 1].

Table 1. Results of Benchmark Searches for Medical Terms, Spring 1999

	Excite	HotBot	AltaVista	MedHunt	Medical World Search
Arthritis	40,191	138,080	311,810	1,992	3,261
Splenomegaly	751	185	194	123	471

One word of warning: determining the number of hits retrieved on a web search is not always easily done. In Excite, one must scroll down the page to reveal the number of hits. When searching a highly posted term in HotBot, the number of hits doesn't appear on the first page of results, only on subsequent pages. Sometime in 1998, Lycos removed the number of hits retrieved entirely from their screens, leaving no way to assess relative size using benchmark searches like these. It is also revealing to compare retrieval for medical terms in some of the larger medical directories with search engine results. Medical World Search, with its database of "nearly 100,000" pages [2], is only about 1/10 of a percent (.1%) the size of the largest search engines like HotBot and AltaVista, which are estimated to index between 100,000,000 - 150,000,000 pages. Yet, even though it is 1,000 times larger overall, AltaVista retrieves only four times as many pages containing "splenomegaly;" HotBot actually retrieves fewer pages than Medical World Search on this term.

Case Sensitivity

Often the presence of capital letters, or a combination of upper and lower case letters, conveys a specific meaning for a health sciences term. When searching for information on "AIDS," as in Acquired Immunodeficiency Syndrome, a searcher does not want to also retrieve information on hearing "aids." Typically

if a search engine recognizes case, it will retrieve both upper and lower case in response to a lower case query (e.g. aids or AIDS), but only upper case if the query is entered that way (e.g. only AIDS). To test for case sensitivity, search for the same word twice: once in upper and once in lower case, and compare the results. If the same number of items is retrieved on both searches, the search engine is not case sensitive.

Performing one additional search will test for the ability to search for terms which contain only a special combination of capital and small letters; this is sometimes referred to as "interesting case." An example of interesting case from the medical domain would be MeSH, referring to the Medical Subject Headings published by the National Library of Medicine. In HotBot, a search for "mesh" retrieves 175,950 items; "MESH" retrieves 7180; but "MeSH" retrieves 5480.

Stemming

With most search engines, what you type is what you get; nothing more, and nothing less. The engine does a literal search for exactly what is entered. There are two possible exceptions to this: stemming and concept searching.

A search engine which uses stemming will automatically retrieve some words with variant endings. In its simplest form, this operates as automatic right truncation, where a search for "germ"

also retrieves "germs," "germinate," and even "Germany." Yahoo uses this type of stemming. Other search engines stem more selectively, perhaps where searching a singular word also retrieves the plural form; e.g. searching "child" retrieves "children," but not "childhood." To test for the first type of stemming via automatic right truncation, search on a word stem such as "occlu" to see if "occlusion," "occluded," etc. are retrieved. The second type of stemming is more difficult to evaluate. Search for a simple plural with and without the "s," then perform the search using both terms linked with OR: first search "kidney," second "kidneys," then "kidney OR kidneys." If all three searches return the same number of hits, simple stemming of singular and plural word forms is in operation. To test for more sophisticated stemming, try an irregular plural: woman vs. women, child vs. children, person vs. people. If results are the same, the stemming is more sophisticated.

Concept Searching

Some of the search engines, notably Excite and Magellan, claim to be able to conduct concept searches. The user types in a single word, and the search engine purports to search not only that specific word, but also to automatically include synonyms in the search. Unfortunately, this feature is not always optimized for medical terms. One way to tell is by searching on a word such as "kidney," recording the result, and then searching a medical synonym such as "renal," recording that result, and

then pooling the two by searching "kidney OR renal." If the last search retrieves many more items than either the first or the second search, one can surmise that concept mapping is weak or perhaps nonexistent in the area of medical vocabulary. Table 2 shows the results of this test in Magellan and Excite, both of which purport to use mapping or ICE (Intelligent Concept Extraction). From these results, ICE apparently is not automatic for terms in the medical domain. However, along with the results, Excite returns a suggestion to add the following words to the search: kidneys, dialysis, nephrology, glomerular, polycystic, ureter, transplant, creatinine, tubule, and nephropathy. But it does not perform automatically as advertised in the help screens, which state:

Excite searches for documents containing the exact words that you enter into the Search box. But that's not all. Excite takes search technology one step further: Not just words, Excite also searches for ideas closely related to the words in your query.

For example, suppose you search on the terms "elderly people financial concerns." In addition to finding sites containing those exact words, the search engine will find sites mentioning the economic status of retired people and the financial concerns of senior citizens [3].

Table 2. Results of Tests for Concept Mapping in Magellan and Excite, Spring 1999

	Magellan	Excite
Renal	1,354	28,494
Kidney	2,349	49,424
Renal OR Kidney	2,509	67,223

One interesting footnote: Excite and Magellan use almost exactly the same wording and examples when explaining their concept search feature, although the results of these sample search illustrate that the two engines perform quite differently. The only way to account for this, although it doesn't really explain it, is that Excite now owns Magellan, even though the latter is still run as a separate search service with its own look, feel, and capabilities.

There is one specialized search engine targeted to a medical audience with relatively sophisticated concept mapping capabilities: Medical World Search (<http://www.mwsearch.com>). A search of its 100,000 item database of major medical sites retrieves 762 items regardless of whether "acetaminophen" or "tylenol" is searched, since queries are enhanced with terms from the National Library of Medicine's Unified Medical Language System Metathesaurus [4]. Indeed, the search also incorporates "Acetamidophenol," "Acetominophen," "Anacin-3," "Datril," "Hydroxyacetanilide," "N-Acetyl-p-aminophenol," "p-Acetamidophenol," "p-Hydroxyacetanilide," "Panadol," "Paracetamol," "Acamol," "Acetamide, N-(4-hydroxyphenyl)-," and "N-(4-Hydroxyphenyl)acetanilide."

Two words of caution apply when applying these benchmark searches. First, they are simply heuristics for determining search engine behavior, and will not provide definitive evidence of the

presence or absence of search features in all situations. Second, if these benchmark searches are run during a database update, results may differ by only one or two hits. For example, one evening, when testing AltaVista for case sensitivity, "aids or AIDS" retrieved only two more hits than a search for "aids" alone had only 5 minutes before. It turned out that these represented two new URLs just added to the database. This was confirmed by re-executing the original search for "aids" alone, which then retrieved two more items than it had just minutes before.

These same techniques can be used to evaluate the search capabilities of the free MEDLINE sites on the Web [5]. For example, while the HealthGate help screens clearly state that drug trade and generic names are mapped to one another [6], a search for the trade name "valium" retrieved 606 items, while a search for "diazepam," the generic name of the same drug, retrieved 6% more: 954 items.

These benchmark searches evolved partly as an byproduct of the Nothing But 'Net website [7], an internet search assistant developed at the J. Otto Lottes Health Sciences Library, University of Missouri - Columbia with the assistance of a grant from the National Network of Libraries of Medicine/Midcontinental Region [8]. The user completes a form selecting the capabilities needed for a given search, e.g.

case sensitivity, proximity search, nesting, etc. The request is translated into a query, which is sent to a SQL database that contains information on the features of 15 search engines, including HotBot, AltaVista, Yahoo, MedHunt, and Medical Matrix. The result is a listing of up to three search engines best suited to those types of queries, along with syntax examples. Both full and partial matches are included, with the best match(es) appearing first. For example if the user requested the

features "nesting," "within # of words," and "date searching," AltaVista, which supports all 3 search features, is listed first. HotBot and LycosPro are listed next, since they contain 2 out of the 3 search features requested. Help screens are available for each search feature, along with medically related search examples. Nothing But Net, which is updated semi-annually, can be found at: <http://hansel.mig.missouri.edu/engines>.

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Appendix 1

Default Operator:

a=ear

b=ear infections

c=infections ear

If $b > a$, default operator is OR.

If $b < a$ and $b = c$, default operator is AND.

If $b < a$ and $b \neq c$, default operator is ADJ.

Database Size:

Benchmark searches:

Arthritis, splenomegaly

Stopwords

a=vitamin a deficiency

b=vitamin k deficiency

If $a = b$, "a" is probably a stopword; if a search for "a" or "k" alone yields 0, they are stopwords.

Case Sensitivity:

a=AIDS

b=aids

If $a = b$, search engine is not case sensitive.

Interesting Case:

a=MeSH

b=mesh

c=MESH

If $a \neq b \neq c$, searches for interesting case are supported.

Stemming:

If a search for occlu retrieves occlusion, occlusive, occluded, etc, automatic right truncation is in use.

a=kidney

b=kidneys

If $a = b = (a \text{ OR } b)$, stemming is enabled for simple plurals.

a=women

b=woman

If a=b, more sophisticated plural stemming is in use.

Concept Searching:

a=kidney

b=renal

If a >= (a OR b), some concept mapping is taking place.

a=tylenol

b=acetaminophen

If a=b, some concept mapping is in place.

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Short Paper

Rating the Raters: Legal Exposure of Trustmark Authorities in the Context of Consumer Health Informatics

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Abstract

There are three areas of potential legal exposure for an organization such as a trustmark authority involved in e-health quality rating. First, an e-health provider may make a complaint about negative or impliedly negative ratings rendered by the ratings body (false negative). Typically, a negative ratings complaint would rely on defamation or product disparagement causes of action. In some cases such complaints could be defended on the basis of absence of malice (US). Second, the rating body might render a positive rating on e-health data that a third party allegedly relied upon and suffered injury (false positive). While the primary cause of action would be against the e-health data provider, questions may arise as to the possible liability of the trustmark authority. For example, some US liability exposure is possible based on cases involving the potential liability of product warrantors, trade associations, and certifiers or endorers. Third, a ratings body may face public law liability for its own web misfeasance. Several risk management approaches are possible and would not necessarily be mutually exclusive. These approaches will require careful investigation to assess their risk reduction potential and, in some cases, the introduction of legislation.

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KEYWORDS

Internet; Medical Informatics Applications/legislation and jurisprudence; Rating; Consumer Health Informatics; Risk management; Liability, Legal

Introduction

The avowed, logical, and admirable purpose of a trustmark system such as MedCERTAIN is to "establish a fully functional self- and third-party rating system enabling patients and consumers to filter harmful health information and to positively identify and select high quality information" [1]. A ratings system inserts itself into the meta-information structure surrounding consumer choice. The motivation of a trustmark authority may be totally altruistic, specifically: to reduce informational asymmetry between patients and providers of health care, drugs, or advice. However, any such rating authority joins the ranks of infomediaries that increasingly will be exposed to legal liability for the occurrence of risks associated with e-health services.

It may seem that there is something intrinsically negative, even self-defeatist in injecting notions of legal liability at this stage in the development of health informatics trustmark authorities. Any such caustic view will no doubt be compounded when the source of such notions is US law, a system not renowned in the

rest of the world for any exercise of self-restraint when it comes to the imposition of liability. As a famous US jurist once put it "[as] a litigant I should dread a lawsuit beyond almost anything else short of sickness and death" [2]. However, any partisan reaction should be resisted - the whole process of rating is premised on a desire for improved quality; and those who rate must be subject to the same high standards, while at the same time protected from overt or exaggerated disincentives to perform their evaluative tasks.

This paper primarily examines potential liability under US law. The choice of US law is deliberate and should not be dismissed as parochial, the product of regional bias or, worse, some clumsy attempt at legal colonialism. US tort law (delictual) liability for inaccurate information is more mature than that found in other countries (a fact that should not necessarily be equated with optimal results). Further, until the Internet and (and hence e-commerce and e-health business models) take on more of a Eurocentric focus (itself unlikely until the second half of the decade), the majority of e-health sites will be US (or US-centric), while the majority of those who rely on trustmarks

promotes inspection and trustmark qualifying activities much like a franchisor or intellectual property holder. Poor quality performance of these functions could negatively impact the reputation and economic health of the medical site evaluated (false negative cases) or the economic or physical well being of a consumer or patient (false positive cases). Finally, the authority itself generates and provides information about its own or rating systems generally, and may perform standard web functions such as user data collection or profiling and cookie generation (issues primarily of interest to public authorities) (see [Figure 1](#)).

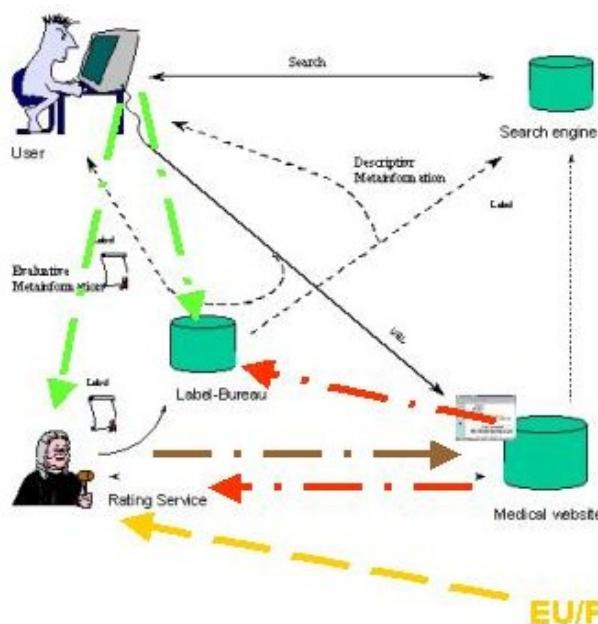
A trustmark authority likely would perform several functions. First, it facilitates self-rating by, say, consumer health sites (providing criteria, link pages, or "tokens" to symbolize compliance). Second, it provides independent external evaluation of the content on sites, a process that can involve either "whitelisting" or "blacklisting." Third, and assuming a decentralized model, the central trustmark authority itself

False Negative: Medical Site vs. Trustmark

False Positive: Patient vs. Trustmark

Regulatory Authority vs. Trustmark

Trustmark vs. Medical Site



Negative ratings (or "blacklisting") could dramatically affect the level of traffic to a medical advice web site (or its "stickiness" in the case of metadata-supplied rating information), and hence its ability to attract advertising or financing. Sites that complain of an allegedly incorrect low rating likely would argue that the trustmark authority is liable for damages on some type of product disparagement (probably the most famous US case of this type is *Bose Corp. v. Consumers Union*, 466 U.S. 485, 80 L. Ed. 2d 502, 104 S. Ct. 1949 (1984) in which a product manufacturer that complained about a review in a well-known consumer magazine was held to have to prove malice or reckless disregard of the truth) or defamation theory [4]. There are several, far more tenuous theories that may be raised by rated sites. These might include arguments as varied as:

- (*New Kids on the Block v. New America Pub., Inc.*, 971 F.2d 302 (9th Cir. 1992) which ruled that fair use applied when newspaper used trademark to identify pop group and not to imply the group's endorsement. Court further noted that a competitor could use a rival's trademark in advertising for profit if the use was not false or misleading and did not implicate the source-identification function of the trademark. Also applied to web linking and searching in *Playboy Enterprises, Inc. v. Netscape Communications*, 2000 U.S. Dist. LEXIS 13418 (C.D. Cal. September 12, 2000))

- anti-competitive activity
(an antitrust claim would be extremely difficult to sustain absent evidence that, for example, the trustmark authority became dominated by whitelisted sites and such created a barrier of entry to the e-health market)

Not surprisingly "truth" remains the best defense to the most likely type of action - that for defamation. However, it is not always the most cost-effective defensive approach. Under US law it is generally the case that "in a suit by a private plaintiff involving a matter of public concern... allegedly defamatory statements must be provably false, and the plaintiff must bear the burden of proving falsity, at least in cases where the statements were directed towards a public audience with an

interest in that concern" [5]. Yet, burden of proof of falsity aside, US law offers some powerful defensive arguments. As is well known, the United States Supreme Court in *New York Times Co. v. Sullivan* [6], held that a public official could not recover for libel absent a showing of "actual malice" by the newspaper publisher. While that principle does not fit the trustmark authority scenario exactly, later cases have made clear that "[i]t is speech on matters of public concern that is at the heart of the First Amendment's protection" [7].

As a result, there seems general agreement that what is known as a "qualified privilege" will be extended to non-profit organizations such as trustmark authorities that undertake to rate services supplied by others [8]. This is particularly the case where it is public figures or organizations that are being rated (e.g., *National Foundation for Cancer Research v. Council of Better Business Bureaus*, 705 F.2d 98 (4th Cir. 1983), which held that a non-profit that engaged in mass solicitation efforts and declared a goal of making itself a "household name" was a "public figure" thereby erecting the Sullivan obstacles to defamation liability). In general terms such defensive categorizations would compel a plaintiff under US law to prove *actual malice*- that the trustmark authority gave an inaccurate rating based on knowledge of the true facts or reckless disregard of the accuracy of the rating (e.g., *Elite Funding Corp. v. Mid-Hudson Better Business Bureau*, 165 Misc.2d 497, 629 N.Y.S.2d 611 (N.Y. Sup. Ct. 1995), in which the brokerage claimed BBB's "unsatisfactory" rating was defamatory, held: (1) statement that brokerage had "unsatisfactory" record based on pattern of not responding to customer complaints was true and therefore not defamatory, and (2) even assuming challenged statements were not true, brokerage failed to produce evidence of express malice). This would not be an easy burden for the e-health site protagonist. However, narrow windows of vulnerability would open up if, for example, the trustmark authority lacked internal quality control procedures or had a record of inconsistent criteria or results (an issue that might well arise given a decentralized ratings system).

False Positive Ratings

Whitelisting cases typically will involve actions brought by patients alleging injury because of reliance on data or treatment extracted from a medical advice web site previously rated by the trustmark authority. The authority becomes involved if the patient alleges that reliance on the trustmark influenced the choice of advice site and so, albeit indirectly, caused the injury complained of.

An initial analytical step is to examine the potential liability of web-based information and advice sites. In general terms these have little liability exposure under US law [9]. Decided cases suggest that courts are unwilling to impose duties on either authors or publishers. For example, in *Birmingham v. Fodor's Travel Publications, Inc.* [10], the court considered the potential liability of the publisher of a travel guide that failed to mention the dangerous ocean surf conditions at a beach resort. The publisher was held to be under no duty to warn a reader because "absent guaranteeing or authoring the contents of the publication, a publisher has no duty to investigate and warn its readers of the accuracy of the contents of its publications" [11]. (See also

Smith v. Linn, 563 A.2d 123, 126 (1989), in which a reader died of complications arising from the liquid protein diet featured in a book; and *Walters v. Seventeen Magazine*, 241 Cal. Rptr. 101 (Ct. App. 1987) in which plaintiff contracted toxic shock syndrome allegedly as a result of using a tampon advertised in the defendant's magazine). In cases where the defendant is more closely tied to the origination of the flawed content, courts have been swayed by constitutional (freedom of speech) arguments. For example, in *Herceg v. Hustler* [12], the plaintiffs' 14-year old son took his own life attempting the practice of autoerotic asphyxia, having read about the practice in a magazine article. Citing well-known First Amendment case law, the court found the speech was protected. At first sight it would seem that many medical advice and treatment sites are commercial in nature and so-called "commercial speech" is given only limited protection by the First Amendment. However, even dangerous content will not qualify as "commercial" just because a web site accepts advertising or even is paid to serve the content [13].

At common law, therefore, it is clear that even US courts have circumscribed a relatively narrow window of private law liability for print "advice" content, and there are no indications that cyberspace content will attract any more stringent liability. Ironically, however, the trustmark authority could be under greater threat of legal liability than the underlying medical data sites that it rates. This is certainly the case from a purely practical perspective. High visibility, "brand-name" advice sites are more likely to put considerable resources into their own quality assurance programs. They are also likely to be highly protective of their brand and settle all but the most frivolous or speculative lawsuits. In contrast, the low-resource, high-risk site likely will "fold" at the first sign of litigation, leaving the trustmark authority as the most exposed potential defendant.

Beyond purely practical considerations, US torts doctrine suggests that the relative safety with which at least non-reckless advice sites operate might not extend to a trustmark authority. This distinction primarily is based on a recognition that the trustmark authority has voluntarily undertaken a role that it knows and intends the third-party consumer to rely upon. Of greatest potential concern is the cause of action summarized in §324A of the RESTATEMENT (SECOND) OF TORTS:

One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if

- (a) his failure to exercise reasonable care increases the risk of such harm, or*
- (b) he has undertaken to perform a duty owed by the other to the third person, or*
- (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.*

In cases involving certifiers or endorsers of defective products, this theory has been held sufficient to base an action against the certifier. For example, in *Hempstead v. General Fire Extinguisher Corporation* [14], Underwriter's Laboratories, a

well-known non-profit testing laboratory, was held potentially liable after a whitelisted fire extinguisher exploded. The court noted: "The alleged failure of Underwriters to exercise reasonable care in approving the design of the extinguisher has obviously increased the risk of harm to plaintiff over that which would have existed if reasonable care had been exercised" (approved of by the court in *Arnstein v. Manufacturing Chemists Association, Inc.*, 414 F. Supp. 12 (E.D. Pa. 1976), also positing potential liability based on the closely related RESTATEMENT (SECOND) OF TORTS § 323).

In a case where the trustmark authority does "passive" rating by, for example, making its trustmark available to an e-health site for self-rating, then a liability argument likely would track the case of *Hanberry v. Hearst Corp.* [15], in which a shoe manufacturer utilized a magazine's "Good Housekeeping Consumers' Guaranty Seal" (cf. *Yanase v. Automobile Club of So. Cal.*, 212 Cal.App.3d 468, 260 Cal.Rptr. 513 (1989) which held that the family of an auto club member killed in motel parking lot was not owed a duty of care with respect to neighborhood safety or security measures at motels listed and rated in guide). More recent cases are consistent, continuing to enlarge the pool of potential defendants to include intellectual property licensors and trade associations that become involved in certifying or endorsing the activities or representations of others (e.g., *Torres v. Goodyear Tire*, 786 P.2d 939 (Ariz. 1990); *King v. National Spa*, 570 So.2d 612 (Ala. 1990)). Obviously, a proposal for a trustmark authority such as MedCERTAIN posits several different approaches for the delivery of evaluative metainformation [3]. At least as a working hypothesis it could be argued that the closer the trustmark authority integrates itself at a commercial or technological level with the underlying medical data suppliers, the greater will be its liability exposure.

It must be emphasized that even under US law a trustmark authority's exposure under such theories is somewhat limited. While the plaintiff may be able to point to a recognized cause of action, it does not follow that the trustmark authority ultimately would be held liable. Generally, data is not considered a "product" for the purposes of applying products liability doctrine (although if data were considered a "product," a trustmark authority might be exposed under Article 3, 1. of the products liability directive, where a "producer" means the manufacturer of a finished product, the producer of any raw material, or the manufacturer of a component part and any person who, by putting his name, trade mark, or other distinguishing feature on the product presents himself as its producer [17]). As a result, the plaintiff would still have to prove that the authority failed to exercise reasonable care and that such negligence caused plaintiff's injury. Specific acts of negligence that might be alleged by consumer plaintiffs could include failure by the authority to follow its own internal ratings criteria or, somewhat less convincingly, a trustmark authority's failure to enforce its intellectual property claims against sites fraudulently using the trustmark.

Public Law Liability

Public law liability probably is the least of the concerns of a non-profit trustmark authority. Nevertheless, such an authority by its nature will generate and publish information about its

own functions and practices. Particular care would be needed if the authority accepted any form of advertising or engaged in any for-profit activities. In particular, there could be public law exposure if rated sites could in any way "buy" disproportionate visibility, and such practices are not clearly disclosed to users (a practice that would also increase civil liability exposure).

It should also be assumed that a trustmark authority would perform standard web functions such as data collection and cookie generation. Such functions may be performed within its non-profit mandate, for example, to establish traffic patterns to justify its continued funding by public or other entities. Nevertheless, any such activities must be consistent with the authority's published privacy and other policies so as to avoid scrutiny from bodies such as the US Federal Trade Commission (FTC) for unfair or misleading marketing. (FTC actions potentially would be brought under 15 USCS § 45 (2000) § 45(a), 15 USCS § 52 (2000)). For an overview of the FTC's investigative and law enforcement powers see <http://www.ftc.gov/ogc/brfovrw.htm>. The FTC has been highly active in scrutinizing site compliance with privacy policies. See *FTC v. Rennert*, in which operators of a group of Online pharmacies that promoted themselves touting medical and pharmaceutical facilities they didn't actually have and making privacy and confidentiality assurances they didn't keep, have agreed to settle FTC charges that their promotional claims were false and violated federal laws [17].) Such policies and practices must also be consistent with applicable state and transnational privacy laws. It should also be noted that the FTC already closely regulates marketing based on endorsements and testimonials that could impact the utilization of a trustmark authority rating by an e-health site [18].

Risk Management

This purpose of this paper is not to deter those apparently prepared to perform as trustmark authorities. Indeed, the contrary is the case - the potential upside of quality rating for medical sites is too great, and the overall risk-reduction that will be accomplished by a comprehensive, professional trustmark authority is simply too important for such a defeat to be tolerated. Rather, the preceding analysis is offered as a first step in managing the risks attendant with the endeavor.

There are many approaches to such risk management that may be appropriate and require further investigation and possible pilot projects. First, the trustmark authority must have its own quality assurance features that apply to both the centralized and decentralized aspects of the endeavor, and bring consistency to the latter. Another possible internal approach is to incorporate a formal dispute resolution process into the trustmark authority's structure.

As follows from the analysis above, trustmark authorities face a serious yet - at least compared to many businesses - a relatively discrete and, in some regards, even controllable window of liability. However, even assuming a positive result in any litigation, the trustmark authority would still incur considerable defense costs. As such, the utilization of an indemnity strategy such as a third-party liability (errors and omissions) insurance policy that includes a robust duty to defend would be necessary.

In this regard, attention should be paid to mandating the scope of coverage taken out by any decentralized bodies, while trustmark authorities will also require financial reserves to handle internal costs associated with defense of suits. Various other risk management techniques will require study. These range from disclosure statements and exculpatory clauses incorporated into the "rating report," to limiting delivery of any report to regional "zones" that feature less aggressive liability rules and related strategies designed to deliver advantageous jurisdictional and choice of law decisions.

Almost inevitably, however, effective risk management likely will require some type of statutory immunity for "Good Samaritan" trustmark authority activities. Regional or transnational in nature, such immunities will also have to deal with the potential extraterritorial reach of the disparate legal systems liability laws. This could require the negotiation of reciprocal safe harbor provisions between major trading groups such as the EU and USA or, with less regard to comity, national or regional provisions denying cross-border enforcement of judgments against trustmark authorities. (An example of such "remedial zoning" is to be found in the UK's "Protection of Trading Interests Act 1980" that limits the UK enforceability of damage awards involving multiple damages - a provision clearly aimed at US antitrust and related laws providing for treble damages (e.g., section 4 of the Clayton Act, 15 USCS § 15).)

Conclusions

It is naïve to believe that the trustmark authority will exist independently, aloof from the world's legal systems. In seeking to "combat illegal and fraudulent health information on the

Internet" [1], a trustmark authority will benefit from public law liability visited on those who misuse its ratings. Such an authority also will be forced to delineate and protect the uses of its certifying marks and other intellectual property from wrongful, misleading, or fraudulent display by health-related web sites. Such issues already are familiar to consumer protection infomediaries in the US (e.g., *Council of Better Business Bureaus, Inc. v. Better Business Bureau, Inc.*, 1999 WL 288669 (N.D.N.Y. Mar 30, 1999); *Better Business Bureau, Inc. v. Medical Directors, Inc.*, 681 F.2d 397 (5th Cir. 1982) which granted a preliminary injunction restraining a weight reduction clinic from representing that their program was approved by rating agency).

If a trustmark authority accused of providing poor advice to a consumer (false positive cases) can pass muster under US law, it should fare at least as well under other systems, be they common or civil law based. In contrast, blacklisting actions brought by the site or content owner being rated against the trustmark authority (false negative cases) are least likely to succeed in the United States because of First Amendment protections for certain types of speech. Thus, a trustmark authority may have greater exposure for defamation-like actions before European courts. (E.g., *Berezovsky v Michaels* [2000] 1 WLR 1004 (HL), facilitating grant of English jurisdiction and service of process in "international" defamation cases. Compare with the US position, the relatively narrow defenses permitted under the UK Defamation Act 1996.)

Working from this baseline of exposure, it will be incumbent on trustmark authorities and the legislative bodies that would endorse them to engineer effective risk management strategies so as not to jeopardize the ameliorative effects of such ratings bodies.

Conflicts of Interest

None declared.

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Commentary

Practical problems may preclude realization of this proposal

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Commentary

The topic discussed in the paper of James Till [1] is very interesting and urgent, now that medicine has also joined the preprint era with other scientific fields.

The author suggests that journals may use the preprints archives as a source for finding papers to be published, going into competition to obtain the best papers available, in the manner already outlined a year ago by other authors [2]. At a first glance, it is an intriguing proposal mainly from the author's point of view; the author could wait for some journal to offer publication instead of actively submitting his or her paper.

However, there is an issue that is not very clear in light of the current discussions about preprints and their relationship to the financial issues of publishing.

First of all, if preprints become successful, it can be supposed that there will be a very large number of them, comparable to the numbers of the physics archive ArXiv [3] which are distributed onto many different servers. Thus, it is arguable that the task of discovering interesting preprints will add significantly to the workload to be carried out on the editor/publisher side. Furthermore, this additional filtering work might be, in principle, harder on editors than traditional peer review, because the latter is based on some form of auto-filtering by the authors themselves who already send papers to the "right" journals. Although usually referees work for free, preprint selection from a large document base may incur some additional costs for publishers, who already fear income shortenings from the birth of publicly accessible archives.

Author fees have been proposed as a solution to financially sustain traditional journals, representing the added value they provide (i.e., the sort of "quality stamp" given by peer review, editing, and diffusion) [4] [5] in the new model of free scientific communication. This approach will shift costs from readers to authors, opening research results to a wider audience, and at the same time letting traditional publishers survive. However, the author fees issue leads to another unclear question not answered in the paper. The author mentions the competition among editors for publishing interesting preprints. How will this competition evolve in an model in which authors are paying for the right to be published? I suppose that the competition

could include the reduction of author fees for exceptional articles, but perhaps only journals with other funding resources could manage to afford that cost. In addition, some form of author payment might be introduced, as already proposed by the BMJ [6], to increase the journal's attractiveness.

Just to summarize, I suspect that journals would need to adopt different organization models to react to the author's proposal (e.g., employ new article seekers in addition to referees, and so on) with associated higher costs, and competition for articles may include economic aspects in conflict with the expected page charge that will likely be used to cover publication expenses when papers will be freely available online. So, although the idea is interesting, I'm not sure how it can practically be adopted, and I simply would like to see some discussion about this.

Another point worthy of discussion concerns comments and responses to Netprints. Why so few?

Nobody works for free: comments and responses, to be useful, should be as accurate as the usual (good) referee comments, which are work in exchange for prestige. In the same way, letters provide useful comments to authors (although after publication), but are usually regarded as small publications useful for the letter writer's resume, above all when appearing in prestigious journals.

Once it is recognized that comments and responses to preprints (and generally to online documents) are useful for improving science, it might be possible to solicit comments by providing the senders of responses that enhance the quality of the paper with an acknowledgement as an incentive, similar to a junior authorship. The mechanisms to enable such an incentive would be very difficult to evaluate and implement; however, there exists a germinal proposal [7] that links the comment activity to a specific, automatically calculated personal value to be added to something similar to a personal impact factor (which would derive from the comments).

Finally, I completely agree on the need for evaluative studies of preprints. Since the ClinMed NetPrints archive are still in the early stages, I wonder if there is a study already in existence on the effect of preprints in physics and their relationship to the publication process. Such an analysis could give very effective

advice on how medical preprints can be used to improve medical science.

Conflicts of Interest

None declared.

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Viewpoint

Peer Review in a Post-Eprints World: A Proposal

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Abstract

Recently, a number of electronic biomedical preprints servers, which allow the archiving of electronic papers without prior peer review, have been established, most notably the Clinical Medicine & Health Research NetPrints website and the The Lancet's Electronic Research Archive. These mark an extension to clinical medicine and health research of a novel experiment in the provision of public access to electronic versions of preprints. However, until now the biomedical community has been slow to adopt this new form of communication. This paper discusses how the value and attractiveness of eprint servers can be improved, and how electronic preprints (eprints, NetPrints) can be evaluated. Previous studies of variations in rejection rates after conventional peer review have indicated that the extent of scholarly consensus is an important variable for acceptance. This variable seems likely also to be important in readers' and editors' evaluations of eprints. A combination of unsolicited comments together with commissioned review might yield articles of higher quality than either could accomplish alone. However, if systematically applied to all eprints, such a process would be time-consuming and labor-intensive. A sequential review process is proposed, beginning with the acceptance of a preprint by an eprint server, followed by revision on the basis of comments received publicly or privately, and by the solicitation of selected eprints for commissioned review. This sequential process could have advantages, both for the authors of articles, and for journal editors. For example, the eprint would, in effect, have been submitted simultaneously to a large number of relevant journals. Some issues about evaluative studies of the outcomes of eprint submissions are also considered briefly. It would be particularly valuable if every eprint server included access to comparative statistics on visits by readers to individual eprints.

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KEYWORDS

Internet; Computer Communication; Electronic publishing; Cybermetrics

Background

The establishment of BMJ's Clinical Medicine NetPrints [1] and The Lancet's Electronic Research Archive [2] websites marks an extension to clinical medicine of a novel experiment in scientific publishing. The experiment involves public access to electronic preprints, without prior peer review. The arXiv archives [3], now involving preprints in physics, mathematics, nonlinear sciences and computer science, are probably the best-known, but other archives are participating (for example) in the Open Archives Initiative [4]. Although the term "eprints" is a generic one that could be applied either to electronic preprints ("e-preprints") or to electronic reprints ("e-reprints," or "e-postprints"), this article will be mainly about electronic preprints. These are referred to as "NetPrints" at the BMJ's website [1], and as "Eprints" at The Lancet's website [2].

Facilities for the storage and dissemination of electronic preprints will be referred to here as "eprint servers" or "eprint archives."

There has been much controversy about proposals to extend to the biomedical sciences a concept first adopted by a sub-group of physical scientists. To what extent is it appropriate to apply, more widely, experience "drawn from a well-defined and highly interactive community of voracious readers with a pre-existing hard-copy preprint habit ..." [5]?

A proposal designed to foster electronic publications in the biomedical sciences (originally called "E-Biomed," but subsequently modified and renamed "PubMed Central" [6]), was strongly criticized, especially by editors of The Lancet [7], and the New England Journal of Medicine [8]. It was pointed out that, in basic research, scientists are communicating primarily with one another, and (in comparison with clinical

research) the immediate practical consequences of a mistake are not as great and are easily corrected [8].

On the other hand, a major issue addressed by these websites is the information and communication needs of researchers and health professionals in resource-poor countries [2]. The concern that inadequately-evaluated eprints with significant public-health implications might cause unnecessary harm is addressed via editorial checks prior to posting at The Lancet's website [2], and via an explicit warning at the ClinMed NetPrints website [1] that the eprint has not yet been peer-reviewed. The latter website, which more closely resembles the arXiv archives [3], will be the main focus of the present article.

Stated purposes of the ClinMed NetPrints website include provision of access to electronic preprints of articles, and access to facilities for direct reader feedback prior to eventual publication in a paper journal [9]. In an editorial announcing the BMJ's website [9], it is stated that: "We have always regarded publication in the paper journal as not the end but rather only part of the peer review process. Every editor has seen published studies destroyed in the correspondence columns."

It is increasingly widely accepted that the conventional peer review of manuscripts is "expensive, slow, prone to bias, open to abuse, possibly anti-innovatory, and unable to detect fraud," and can yield published papers that "are often grossly deficient" [10]. A publication process in which correspondence columns are used to "sort out the good from the bad and point out the strengths and weaknesses of studies" [10] has not been compared with conventional peer review. And, "most studies have compared one method of peer review with another and used the quality of the review as an outcome measure rather than the quality of the paper" [10].

The remainder of the present article is divided into four sections. In the first, a problem (variable rejection rates) that might be expected to differ for eprints in comparison with conventional peer review is considered. In the second, a case study of a "gold standard" for electronic journals, involving a combination of online peer review with a second appraisal process (online comments from readers) is reviewed. In the third, a proposal about ClinMed NetPrints, involving a sequential process, initially providing an opportunity for readers to comment, followed by an invitation for selected NetPrints to be submitted for conventional peer review, is outlined. Finally, in a concluding section, some issues about evaluative studies of eprints are outlined briefly.

Variable Rejection Rates after Peer Review: Role of "Scholarly Consensus"

In 1971, Zuckerman and Merton [11] published an article about variation in rejection rates across journals in different disciplines. They reported substantial variation, with rejection rates of 20 to 40 percent in the physical sciences, and 70 to 90 percent in the social sciences and humanities. Cole, Simon, and Cole [12] subsequently suggested that: "Some fields, such as physics, have a norm that submitted articles should be published unless they are wrong. They prefer to make 'Type I' errors of

accepting unimportant work rather than 'Type II' errors of rejecting potentially important work." This suggestion might also account, at least in part, for the popularity of the arXiv eprint archives [3].

Hargens [13] reviewed previous explanations of the variation in rejection rates, which he found to be focused on two possible sources: space shortages and variation in consensus. He regarded variation in consensus as the more important determinant of rejection rates. Interdisciplinary variation in scholarly consensus involves the extent to which scholars share conceptions of appropriate research problems, theoretical approaches, or research techniques. When scholars do not share such conceptions, "they tend to view each other's work as deficient and unworthy of publication" [13].

Scholarly consensus seems likely to continue to be an important variable in the evaluation of eprints, even when acceptance for inclusion on an eprint server only depends on a favorable decision by the editorial staff of the server. Cole [14] has pointed out that: "Even at the research frontier ... minimal levels of consensus are a necessary condition for the accumulation of knowledge." Hargens [15] suggested that: "Perhaps a future study should examine the probability that a published paper will provoke a critical comment as a possible measure of scholarly consensus." From this perspective, perhaps rapid online responses to an eprint might provide a very convenient basis for efforts to assess the extent of scholarly consensus about the topics addressed in the eprint.

The establishment of some form of trust might be regarded as a crucial aspect of scholarly consensus. As Eysenbach has noted, "manuscripts may first be 'published' on the Internet, but 'establishing trust' may be a separate process and may have many different faces" [16].

One Proposed Reform: Online Peer Review

The current consensus seems to be that, although there are problems with peer review, it is unlikely to be abandoned [17], but may be opened up [10]. Ideally, peer review should be reformed in ways that encourage innovation without a sacrifice of quality control [18]. One way to reform peer review is to develop new ways to undertake it online.

A case study of a journal that appears only in electronic form, and uses only online review, is provided by the Journal of Interactive Media in Education (JIME) [19]. JIME uses a three-stage review process. In the first stage, an article submitted (electronically) by its author(s) is assigned to three reviewers selected by the editor. The reviewers' comments, and the authors' responses, are posted on a private website, accessible only to the editors, reviewers, and authors for each submission.

In the second stage, revised articles that have been approved by the editors are posted, and identified as preprints, at the publicly-accessible JIME website [19]. Reviewers, readers, and editors (all of whom are publicly identified) may post comments. For example, editors may post summaries of comments, if the comments about a particular article become numerous.

In the third stage, the authors prepare a final version, which takes into account the comments that have been received, and submit it for final publication in the archives of the journal.

This process might be regarded as a "gold standard" for online peer review. However, it takes time, and requires a lot of effort by all of those who are involved. It seems unlikely to be practical unless the number of articles is quite small (JIME published 12 articles in 1998, and 2 in 1999 [19]).

Another example of an online review process is the one used by Sleep Research Online (SRO), where authors can monitor the progress of the review of their article using a private web page [20], but comments from readers (other than the selected review editors) are not sought.

Might the comments from self-selected readers be considered as a substitute for comments from referees selected by the editors? Bingham and colleagues [21] have addressed this question, and concluded that: "Postpublication review by readers on the internet is no substitute for commissioned prepublication review, but can provide editors with valuable input from individuals who would not otherwise be consulted." In the next section, a proposal about ClinMed NetPrints will be based on this conclusion.

A Proposal about ClinMed NetPrints

In an editorial about the launch of ClinMed NetPrints [9], it was not clearly stated to what extent the editors of BMJ plan to take proactive steps to solicit the revision of NetPrints and their submission for conventional peer review. Unless otherwise negotiated, authors of preprints posted at the ClinMed NetPrints website retain copyright, and could submit revised versions to any journal willing to accept them for conventional peer review.

The editors of BMJ (and of other journals) might be well advised to consider the NetPrints posted at the ClinMed NetPrints website as equivalent to articles that have been submitted directly to their journal. After screening the NetPrints using their usual editorial screening criteria, they could decide to invite selected authors to submit their NetPrints (or revised versions of them) for conventional peer review.

Thus, a posted NetPrint would, in effect, have been submitted, simultaneously, to a (potentially) large number of relevant journals. Editors of different journals might soon discover that they are in competition with each other for the solicitation of NetPrints that they found to be interesting! Authors might then find that they must choose among journals, and decide to which one they would prefer to submit to first for conventional peer review.

Such a process should have advantages for authors, especially those at an early stage in their research careers. Authors of articles deemed to be of interest could quickly find an appropriate publisher. Competition among journals (and among authors) might be expected to enhance both the quality of manuscripts and the efficiency of the publication process. It seems much less likely that editors of well-established, high-impact journals would find such a proposal appealing. However, editors of newly-established journals might welcome

an opportunity to rely on an existing large pool of preprints into which they could dip in order to solicit submissions, especially preprints that clearly provide an excellent fit with their journal's particular "niche." Because of the advantages of such a process for a rising generation of researchers, editors of journals that refuse to participate in such a sequential publication process might, as time passes, find that they have lost some reputation, and hence, some impact.

Might comments about preprints, received from readers, provide valuable critical appraisal prior to subsequent revision and submission for formal publication? In theory, the answer should be "yes." In practice, for the preprints posted at the ClinMed NetPrints site, only a very limited number of responses have been received. For example, a search of the website on July 31, 2000 revealed only two publicly-accessible responses to the 20 NetPrints posted between December 1999 and July 2000. It appears that, in the absence of an appropriate incentive (such as a request from a well-respected editor for a peer-review commentary), responses may not be frequent, unless the topic of the preprint is an especially controversial one.

Of course, public access to these NetPrints provides an opportunity for their authors to solicit, from respected colleagues, constructive criticisms via private messages, or via one or more of the many online discussion groups and forums. An example of such a forum is provided by the archives of the September 1998 American Scientist Forum, moderated by Stevan Harnad [22].

It should be noted that, no matter which journal publishes an article, it seems likely that it will, at some point in time, become publicly accessible in a major electronic archive. Examples are JSTOR [23], and PubMed Central [6].

Conclusion: More Evaluative Studies Are Needed

The major proposal presented here is based on the view that eprint servers such as the ClinMed NetPrints website provide a novel opportunity for the establishment of what Peter A. Singer has called "free market in knowledge" [24].

Preprints archived at the server could be regarded as having been submitted, simultaneously, to all interested and relevant journals [24], a model for publishing similar to Gunther Eysenbach's "paper auction" model, which suggests that in the future researchers will not submit their papers to journals, but first to preprint servers for discussion and peer-review, and journal editors and publishers pick and bid for the best papers they want to publish in their journal - the best journals would be able to pay the highest prices for the best papers, and the number of bidders or the sum bid for each paper determines its value [25]. This process has obvious advantages for authors, and may benefit scientific publishing in general. For example, the editors and publishers who adapt best to such a "free market" may be those able to demonstrate most clearly that they provide added value, via their editorial and peer-review processes, to the published articles (in comparison with the initial preprints).

Evaluative studies of eprints are needed. For example, might articles published initially as preprints, and subsequently revised on the basis of comments received (publicly or privately) from readers, be of higher quality than articles submitted directly to a journal?

When making such a comparison, what criteria should be used to evaluate the quality of articles? As noted above, most studies have "used the quality of the review as an outcome measure rather than the quality of the paper" [10]. This important issue will not be addressed further here, except to make two points. The first is that it would be helpful to researchers interested in the evaluation of eprints if every eprint archive included a (preferably, standardized, and publicly-accessible) set of

statistics on usage. Such statistics might include data about the relative popularity of individual eprints, using measures such as the number of times a particular preprint is visited, the number of times it is downloaded, and the median duration of visits to it. For example, a collection of electronic theses and dissertations (ETDs) currently provides statistics about the ten most accessed ETDs [26]. The usefulness of such statistics as possible indicators of quality needs to be assessed, in comparison with more conventional criteria (see, for example, [27-29]). The second point about measures is to reiterate Tukey's warning: "when the right thing can only be measured poorly, it tends to cause the wrong thing to be measured, only because it can be measured well" [30].

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Conflicts of Interest

None declared.

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