engine Google[5] the starting point for finding good health information: Google ranks websites partly by the number of inbound links to a given site.

Perhaps here lies the answer to the question of how to get good health information on the internet: do what we do in the rest of our lives, and rely on reputation, sometimes.

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Education and debate

Regulating health information: a US perspective

Nicolas Terry

Technologically mediated health care raises problems of quality of information, cross border practice, and patient confidentiality. Nicolas Terry probes the legal aspects of these complexities, and Benedict Stanberry adds a European perspective

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Identifying the regulatory agenda for health information is not difficult. The quality of publicly available health information, cross border medical and pharmacy practice, and the privacy of medical records appear on the radar screens of most public health and consumer protection organisations. Left unregulated, any of these issues can cause considerable harm. Each issue also embodies difficult tensions: state versus federal rights, increased access to care versus quality assurance, and confidentiality versus professional discourse.

US state and federal legal systems have not achieved a coherent approach to regulating the dissemination of health information. Furthermore, the American experience will not always transfer directly to publicly funded medicine and government initiatives. Nevertheless the American experience with private sector ehealth is an instructive model, even if some areas have been neglected and others overregulated.

Summary points

- Quality of publicly available health information, cross border medical and pharmacy practice, and privacy of records will be key issues for European regulators
- Concerns about medical advice sites may be exaggerated
- US regulators have yet to find the appropriate balance between risk and benefits of cross border practice
- New US federal laws on health privacy appear cumbersome but may be instructive for other legal systems

Regulating the quality of online health information

Concerns about widespread inaccuracies in online health information are speculative and intuitive rather than based on robust research. Berland's quality assessments, at least for English language sites and well educated users, suggest the picture is not so gloomy as critics expected.[1]

Public law regulation of health information may conflict with US guarantees of free speech, and differences of opinion among medical professionals make the broad regulation of health advice difficult. Consequently, intervention through public law is reserved for obviously dangerous health content where government agencies can apply traditional consumer protection, drug regulation, and fraud powers, as with the Federal Trade Commission's "Operation Cure.All."[2]

Arguments about freedom of speech can be used to defend private legal actions against web sites offering medical advice, and precedents from actions against publishers of "advice" or "how to" books show that such claims are hard to win.[3] Case by case, retrospective, private law "regulation" may, however, be judicially more acceptable than blanket public law regulation.

Since regulation can do only so much to deter the web's snake oil salesmen, the focus inevitably shifts to strengthening the role of the market by reducing the costs of health information to the consumer. "Kitemark" or "trustmark" schemes seek to limit the need for consumers to assess the quality of information themselves by encouraging providers to rate their own contributions or to comply with codes of conduct. With compliance or rating in place, a technology layer can be added that leverages downstream filtering technology or upstream filtering through membership in a distinct top-level domain[4]; Medcertain is an example of downstream filtering technology,[5] whereas the World Health Organization

favours the upstream approach.[6] Filtering persuades content producers to participate in ratings systems because search engines and, increasingly, browsers may be set to ignore unrated sites.

One approach that is emerging in the United States is to combine the evaluation of online content—for example, kitemarking—with private accreditation, a quality assurance system widely adopted by bricks and mortar healthcare providers.[7] For this, a provider of online health information would subscribe to an accrediting agency's quality standards and pay the agency to check for compliance. Accreditation is a particularly interesting model because it uses a well respected method of quality assurance that is already recognised in private malpractice actions and brings traditional healthcare bodies and online providers under the same quality assessment umbrella. The use of such a model will also be of interest to litigators as US courts have held that failure to comply with applicable accreditation standards may constitute sufficient evidence of medical malpractice.

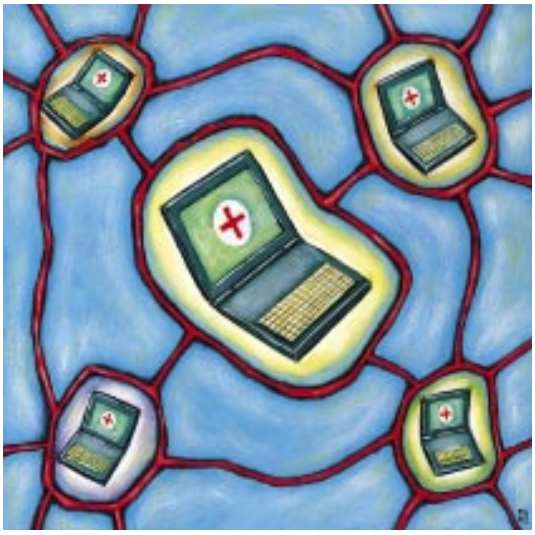
Whether simple or sophisticated, and whether relying on self regulation or rating by third parties, kitemarking systems are not without their difficulties,[8] critics,[9] or legal pitfalls, including the potential liability of rating organisations to private legal actions.[10] The voluntary adoption of codes of conduct in good faith by health websites should not be trivialised or discouraged. Equally, the potential for fraudulent self rating and the likelihood that kitemarking will reduce consumers' natural skepticism about health information continue to trouble US regulators; this may explain a lack of enthusiasm relative to that of their colleagues in Europe.

Controlling cross border practice

With the appearance of online medical advice sites, it is easy to overlook the proportion of cross border health information provided by physicians and pharmacists. In the United States, healthcare institutions are subject to national accreditation standards, and they educate their medical students according to a national curriculum with a view toward national testing. Medical professionals, however, are exclusively regulated by state authorities. Most state licensing and disciplinary systems assume that there will be some level of cross border medical practice by providers who consult with colleagues in other states or treat their travelling patients; these activities are not required to be licensed. Such exceptions aside, however, US states insist on local licensing.

Theoretically, increasing cross border services through technologically mediated health care should stimulate interest in an overall liberalisation of cross border practice. In reality, state authorities are strengthening their legislation to deter interstate ehealth services that either originate from or are received within their borders.[11] While some of the voices raised against ehealth may have protectionist accents, the reality is that states' disciplinary and quality assurance powers are tied to the licensing process and there is no political will for moving such functions to a federal body.

In the United States federal regulators have legal competence over drug approval and marketing.



MARK OLDROYD

Nevertheless, pharmacists, like doctors, face a state-by-state system of licensure and discipline. Licensing and quality issues, however, are not such a problem in pharmacy because it is easier for pharmacy chains to comply with multiple licensing requirements. The National Association of Boards of Pharmacy has facilitated compliance and consumer education by setting up a national system for trustmarking online pharmacies.[12] Additional state by state regulation of pharmacists may, however, be imminent. At least one state now believes it can achieve indirectly what it has failed to do directly: stopping internet doctors from writing prescriptions for its citizens by placing the responsibility on the pharmacist to make sure that the prescription was the product of a traditional doctor-patient interaction.[13] Such regulations will function as an indirect but effective method of controlling cross border medical practice.

This stringent regulation of ehealth exchanges across borders assumes too readily that indirect health care is inferior. Valid questions have been raised about the quality of email communications between doctor and patient,[14] particularly doctors' responses to unsolicited email from patients. Though they pose some marginally interesting legal questions, these are essentially transitional issues that call for better education of doctors more than for regulatory intervention. A more important issue is whether doctors must disclose the risks of remote consultations. The American Medical Informatics Association has cogently argued that an informed consent instrument should "provide instructions for when and how to escalate the contact from being via the internet to phone calls and office visits" and that it should "describe the security mechanisms that are in place."[15] Some US states already require specific consent for remote, technologically mediated care and professional organisations increasingly are recommending the use of encrypted systems for doctor-patient communications.[16] Such regulation is appropriate when motivated by concerns over quality or patient autonomy but less so if designed to discourage non-traditional care.

It may be time to review the marketing activities of pharmaceutical companies both on the internet and in more traditional media. Direct to the consumer adver-

tising is commonplace in the United States. The Federal Drug Agency's Center for Drug Evaluation and Research seeks valiantly to enforce advertising standards[17] through its general regulatory standards and processes.[18] In comparison with the constant barrage of pharmaceutical advertising aimed at US consumers, however, regulatory efforts tend to pale into insignificance. Against the background of the tightly controlled environment of doctors and patients under managed care, pharmaceutical companies are using direct to consumer advertising to try and persuade patients to pay for items not covered by their managed care plans, while simultaneously using both patients and doctors to coerce managers of health plans to add the company's products to their formularies. The importance to pharmaceutical manufacturers of direct advertising to consumers, however, may be illustrated by manufacturers' sanguine acceptance of increased exposure to liability for their products when they circumvent the traditional channel—doctor to patient—for drug information.[19]

Apart from suggesting the need for increased direct regulation (such as the American Medical Assoociation's demand that direct to consumer advertising should contain warnings that a doctor might actually recommend a different treatment[20]), the growth of direct advertising presents difficult issues of ethical and possibly legal conflicts of interest for health advice sites that seek click-stream revenue from their links to the sites of pharmaceutical manufacturers or pharmacies.[21]

Privacy of medical information

Health websites on both sides of the Atlantic have failed to establish acceptable standards of data protection.[22] Somewhat ironically, the European Union's green paper exploring the development of a community-wide approach to consumer protection was published within days of the Federal Trade Commission's announcement that it was abandoning plans to introduce any new online privacy legislation.[23] Without such legislation, the commission's ability to protect consumer privacy on the internet is limited to cases where websites breach their own published privacy policies.[24] Websites need not have privacy policies, however, and if they do, the content goes unregulated. The United States' trading partners are justifiably concerned by this neglect for consumer privacy, and the Federal Trade Commission's recent backtracking on guarantees for online privacy for children will increase discomfort.[25]

Although US regulators have been derelict in protecting the general privacy of citizens, concerns regarding the privacy of health information in the United States are not necessarily warranted. The new federal standards for privacy of individually identifiable health information[26] (and related draft security regulations) issued under the Health Information Portability and Accountability Act (HIPAA) provide the world's most robust protection for medical information, although recent developments in Australia threaten that status.[27]

Most modern privacy regimes, including the EU data protection directive,[28] are collection-centric. That is, they limit the collection of consumer information, frequently by reference to a concept such as proportionality. Serious questions arise, however, as to whether health privacy regimes should place any limits on the collection of patient data, at least for purposes related to treatment. Thus HIPPA is a disclosure-centric confidentiality scheme. It protects patient information by prohibiting most disclosures unless they are preceded by highly regulated processes of consent for treatment or payment purposes. Even more stringent provisions, together with a "minimum necessary" rule, limit disclosures for other purposes, such as marketing or fundraising.

These privacy and security rules were not developed in a vacuum. US regulators are introducing a vastly more efficient system for health transactions, based on electronic data interchange. Unfortunately, this origin exposes the fundamental flaw in the HIPAA privacy and security schemes: they apply only to healthcare entities that use the electronic data interchange system. As a result, hospitals, doctors, and health insurers are likely to find their internet activities regulated, while the more typical ecommerce sites offering health advice or medical products, which collect and resell customer information, are far less likely to fall within the regulatory scope. State statutory and common law systems that provide higher levels of privacy protection are not, however, pre-empted by the federal HIPAA scheme. These unharmonised state law protections will become increasingly important as health websites sell their visitor data to research companies[29] and if healthcare organisations continue their unfortunate accidental postings of confidential patient information on the web.[30]

Conclusion

Industry consolidation around a few well known brands and the dot.com implosion have taken their toll on health advice sites. In the near term the major ehealth players will be drawn from basic health organisations looking to technology to improve the quality and efficiency of their services[31] and government agencies seeking to improve healthcare delivery to underserved populations.

It is both appropriate and practical to shift regulatory emphasis away from advice sites. Outdated, inaccurate, fraudulent, or even dangerous information on the web is notoriously difficult to regulate. Our regulatory energies are better devoted to pressing health information problems that are soluble, such as Balkanised approaches to regulating cross border health interactions and the security and privacy of personal medical information.

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Commentary: Legal aspects of health on the internet: a European perspective

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For many European citizens, online doctors and pharmacies offer the opportunity to acquire medical advice and treatment from abroad more cheaply or swiftly than they could in their own country. Yet, in common with the individual states in the United States, regional and national authorities of the member states of the European Union seem to be resisting online medical practice. Indeed, they are actively entrenching legal barriers to such practice rather than liberalising regulations.

On 10 January 2002, for instance, a doctor from Staffordshire who sold the "sex pill" Viagra and a slimming drug, Xenical, through the MEDClinic website (www.medclinic.co.uk) was found guilty of serious professional misconduct by the United Kingdom's General Medical Council and suspended for three months.[1] During his suspension the GMC will decide whether or not to take further action. The case clearly shows that the practice, common on websites, of requiring an online questionnaire to be completed by the patient and reviewed by the prescribing doctor is not considered anywhere near adequate to avoid a gross breach of the standards of patient care expected of doctors by the GMC. It remains to be seen whether or not, in light of this ruling, similar services throughout Europe will modify their practices.

In the case of DocMorris (www.docmorris.com), an internet pharmacy based in the Netherlands, a Berlin court ruled in May 2001 that their sale of pharmaceuticals through the internet (at an average discount of 20% compared with German competitors' prices) was illegal. A second DocMorris case was brought before court in Frankfurt in August 2001. It has been referred to the European Court of Justice for a ruling as to whether Germany is infringing the principle of the free movement of goods by outlawing cross border trade in medicines.[2] A further question is whether internet pharmacies are effectively prevented from describing prescription medicines on their websites by a European directive which prohibits direct to consumer advertising of medicines (a practice permitted in the United States).[3]

Even if the case goes well for DocMorris, truly cross border medical practice remains a distant dream. Professional medical qualifications awarded by one EU state are valid in all the other members states, but this does not grant a right to automatic registration: clinicians must apply to the national or regional authority that supervises medical practice in the member state in which they wish to practise.[4]

This system can scarcely deal with the physical movement of clinicians within the European Union: there is no system by which the striking-off of a clinician in one member state can be brought to the attention of the authorities in other states in which that clinician may be practising. Supervising medical practice in the internet age therefore presents great challenges. It may become impossible to prevent foreign healthcare providers from delivering healthcare related goods and services into another member state. Logically, the emphasis of European policy in this area ought now to switch from resisting online health services to finding ways to properly supervise and accredit them.

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The quality and reliability of health information on the internet remains of paramount concern in Europe, as elsewhere. Self regulatory codes of ethics for health websites abound, yet the quality and practices of many are highly questionable.

Little progress seems to have been made, moreover, in assuring consumers that the information they share with health websites will not be misused. Several US studies have already concluded that websites' privacy practices do not match their proclaimed policies.[5] In an attempt to counter this erosion of trust in Europe, the European Commission's guidelines for quality criteria for health related websites have recognised that there is no shortage of legislation in the field of privacy and security.[6] They have drawn specific attention to a new recommendation regarding online data collection adopted in May 2001 that explains how European directives on issues such as data protection should be applied to the most common processing tasks carried out via the internet.[7]

The challenge facing Europe's health professionals and policymakers is to carefully craft the development of new approaches to the supervision of medical and pharmaceutical practice. Their ultimate goal is to raise consumers' confidence in online healthcare. They must ensure that the mechanisms are put in place whereby health professionals themselves can benefit from using the internet, while still ensuring the highest standards of medical practice.

Avienda was formerly known as the Centre for Law Ethics and Risk in Telemedicine.

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Statistics Notes

Validating scales and indexes

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An index of quality is a measurement like any other, whether it is assessing a website, as in today's *BMJ*,[1] a clinical trial used in a meta-analysis,[2] or the quality of a life experienced by a patient.[3] As with all measurements, we have to decide whether it measures what we want it to measure, and how well.

The simplest measurements, such as length and distance, can be validated by an objective criterion. The earliest criteria must have been biological: the length of a pace, a foot, a thumb. The obvious problem, that the criterion varies from person to person, was eventually solved by establishing a fundamental unit and defining all others in terms of it. Other measurements can then be defined in terms of a fundamental unit. To define a unit of weight we find a handy substance which appears the same everywhere, such as water. The unit of weight is then the weight of a volume of water specified in the basic unit of length, such as 100 cubic centimetres. Such measurements have *criterion validity*, meaning that we can take some known quantity and compare our measurement with it.

For some measurements no such standard is possible. Cardiac stroke volume, for example, can be measured only indirectly. Direct measurement, by collecting all the blood pumped out of the heart over a series of beats, would involve rather drastic interference with the system. Our criterion becomes agreement with another indirect measurement. Indeed, we sometimes have to use as a standard a method which we know produces inaccurate measurements.

Some quantities are even more difficult to measure and evaluate. Cardiac stroke volume does at least have an objective reality; a physical quantity of blood is pumped out of the heart when it beats. Anxiety and depression do not have a physical reality but are useful artificial constructs. They are measured by questionnaire scales, where answers to a series of questions related to the concept we want to measure are combined to give a numerical score. Website quality is similar. We are measuring a quantity which is not precisely defined, and there is no instrument with which we can compare any measure we might devise. How are we to assess the validity of such a scale?

The relevant theory was developed in the social sciences in the context of questionnaire scales.[4] First we might ask whether the scale looks right, whether it asks about the sorts of thing which we think of as being related to anxiety or website quality. If it appears to be correct, we call this *face validity*. Next we might ask whether it covers all the aspects which we want to measure. A phobia scale which asked about fear of dogs, spiders, snakes, and cats but ignored height, confined spaces, and crowds would not do this. We call appropriate coverage of the subject matter *content validity*.

Our scale may look right and cover the right things, but what other evidence can we bring to the question of validity? One question we can ask is whether our score has the relationships with other variables that we would expect. For example, does an anxiety measure