Journal of Medical Internet Research

Journal Impact Factor (JIF) (2023): 5.8
Volume 7 (2005), Issue 1 ISSN 1438-8871 Editor in Chief: Gunther Eysenbach, MD, MPH

Contents

Editorial

Electronic Health Records Should Support Clinical Research

John Powell[1], MA, MB, BChir, MSc, PhD, MRCPsych, MFPHM; Iain Buchan[2], BSc, MB, ChB, MD, MFPHM

[1]Division of Health in the Community, Warwick Medical School, University of Warwick, Coventry CV4 7AL, United Kingdom

[2]Northwest Institute for Bio-Health Informatics, Medical School, University of Manchester, Manchester M13 9PT, United Kingdom

Corresponding Author:
John Powell, MA, MB, BChir, MSc, PhD, MRCPsych, MFPHM
Warwick Medical School
University of Warwick
Gibbet Hill Road
Coventry CV4 7AL
United Kingdom
Phone: +44 2476 574883
Fax: +44 2476 574893
Email: john.powell@warwick.ac.uk

Abstract

One aspect of electronic care records which has received little attention is the potential benefit to clinical research. Electronic records could facilitate new interfaces between care and research environments, leading to great improvements in the scope and efficiency of research. Benefits range from systematically generating hypotheses for research to undertaking entire studies based only on electronic record data. Researchers and research managers must engage with electronic record initiatives to realize these benefits. Clinicians and patients must have confidence in the consent, confidentiality and security arrangements for the uses of secondary data. Provided that such initiatives establish adequate information governance arrangements, within a clear ethical framework, innovative clinical research should flourish. Major benefits to patient care could ensue given sufficient development of the care-research interface via electronic records.

(J Med Internet Res 2005;7(1):e4) doi:10.2196/jmir.7.1.e4

KEYWORDS

Medical records; medical records systems, computerized; health services research; epidemiologic research design

In the United Kingdom, the government has invested £6200 millionin establishing a National Programme for Information Technology (NPfIT) in the National Health Service (NHS), and further vast resources will be spent on its implementation [1]. This program promises to deliver electronic records, electronic prescribing and electronic booking of appointments underpinned by a modern NHS Information Technology (IT) infrastructure [2]. Of these initiatives, the one with the greatest potential to revolutionize patient care and the working practices of health professionals is the electronic record. This issue of the *Journal of Medical Internet Research* carries a "Viewpoint" article by Gunter and Terry which summarises the benefits of the Electronic Health Record (EHR) [3]. These include the following: medical-error reduction and time saving due to the e-record's availability and legibility; information sharing with patients; and support for clinical decision making. Drawing on the experience of Australia and the United States, Gunter and Terry provide a thorough overview of recent developments in the EHR, and a rigorous examination of the drivers of these developments and the challenges faced by providers.

One aspect of the EHR that is not addressed by Gunter and Terry, and which has received little attention elsewhere, is the great potential of electronic records to benefit clinical research. Research, service-development and public health uses of care records have been referred to as "secondary uses". In the United Kingdom, the NPfIT is preparing a Secondary Uses Service (SUS) that will become part of the new NHS Information Centre [4]. The confidentiality and security of patient records is an essential consideration [5], especially in the SUS context, where anonymization and pseudonymization of records is planned. Understandably both patients and professionals have raised concerns about the security of electronic records; and it is important that adequate information governance arrangements are established to ensure that confidentiality is protected. The accuracy of records and the quality of data coding must also be assured [6]. Given adequate safeguards, electronic care records could facilitate new interfaces between care and research environments, leading to great improvements in the scope and efficiency of clinical research.

Possible research benefits range from systematically generating hypotheses for research to undertaking entire studies based only

on electronic record data. Information for planning studies, such as prevalence and variance of conditions in local contexts could be collected with ease. The patient-owned section of the record could be used by individuals to indicate their general willingness or otherwise to participate in research, or by investigators to alert potential research participants to the existence of a trial. Electronic prompts could signal an attending clinician of a patient's eligibility for an ongoing trial. Simple links from the care electronic record to the trial website could be used to provide further information on the trial for both clinician and patient. Informed consent procedures could be handled systematically under full clinical information and research governances.

National registers of diseases and treatments could be established easily and economically, and with a coherent approach to security across agencies. Epidemiological research could be accelerated and expanded in scope via registers covering well-characterised populations. This would reduce the cost of setting up such studies and provide more timely data that could lead to findings that have greater external validity than the equivalent based on less contemporary data collected in the conventional way. In addition, electronic records which “follow” the patient are likely to provide an efficient method of capturing outcome data in clinical trials and longitudinal studies. This is not an exhaustive list, but it illustrates the enormous potential of electronic records to support clinical research. In the United Kingdom the NPfIT represents an opportunity to develop clinical research that should not be missed.

Researchers and research managers must engage with EHR initiatives to realize such benefits. Programs such as the NPfIT must ensure that clinicians and patients have confidence in the consent, confidentiality and security arrangements for the uses of secondary data. Trust is vital to the practitioner-patient relationship and should not be eroded. Debates around the ”opt-in” or ”opt-out” consent to the use of electronic record data must consider the issue of secondary data usage and clinical research as a population health need. Clinicians and patients must be reassured that no personally identifiable information will be used for research without the consent of the individual. Provided that such programs establish adequate information governance arrangements, within a clear locally-owned ethical framework, such concerns should be addressed and innovative clinical research should be able to flourish. Major benefits to patient care could ensue.

Conflicts of Interest

None declared.

References

1. Collins T. Final cost of NHS IT programme could rise to more than £18.6bn. Computer Weekly 2004 Oct 12 [FREE Full text]
2. Humber M. National programme for information technology. BMJ 2004 May 15;328(7449):1145-1146. [Medline: 15142891] [doi: 10.1136/bmj.328.7449.1145]
3. Gunter TD, Terry NP. The emergence of national electronic health record architectures in the United States and Australia: models, costs, and questions. J Med Internet Res 2005 Mar 14;7(1):e3 [FREE Full text] [Medline: 15829475] [doi: 10.2196/jmir.7.1.e3]
4. ; The United Kingdom Parliament, Lords Hansard. Patient Information and Advisory Group. 2004 Jul 6 (col 655).
5. Adams T, Budden M, Hoare C, Sanderson H. Lessons from the central Hampshire electronic health record pilot project: issues of data protection and consent. BMJ 2004 Apr 10;328(7444):871-874 [FREE Full text] [Medline: 15073070] [PMC: 15073070] [doi: 10.1136/bmj.328.7444.871]
6. Sanderson H, Adams T, Budden M, Hoare C. Lessons from the central Hampshire electronic health record pilot project: evaluation of the electronic health record for supporting patient care and secondary analysis. BMJ 2004 Apr 10;328(7444):875-878 [FREE Full text] [Medline: 15073071] [PMC: 15073071] [doi: 10.1136/bmj.328.7444.875]

Abbreviations

EHR: Electronic Health Record
IT: Information Technology
NHS: National Health Service (UK)
NPfIT: National Programme for Information Technology
SUS: Secondary Uses Service

Submitted 28.02.05; this is a non–peer-reviewed article;accepted 01.03.05; published 14.03.05.

Please cite as:
Powell J, Buchan I
Electronic Health Records Should Support Clinical Research
J Med Internet Res 2005;7(1):e4
URL: http://www.jmir.org/2005/1/e4/
doi:10.2196/jmir.7.1.e4
PMID:15829476

Review

What Is eHealth (3): A Systematic Review of Published Definitions

Hans Oh[1,2], BSc; Carlos Rizo[1,2], MD; Murray Enkin[1], MD; Alejandro Jadad[1,2], MD, DPhil

[1]Centre for Global eHealth Innovation, University Health Network, Toronto ON, Canada

[2]Department of Health Policy Management and Evaluation, University of Toronto, Toronto ON, Canada

Corresponding Author:
Alejandro Jadad, MD, DPhil
Centre for Global eHealth Innovation
University Health Network
R Fraser Elliott Building, 4th Floor
190 Elizabeth Street
Toronto, ON M5G 2C4
Canada
Phone: +1 416 340 4800 ext 6903
Fax: +1 416 340 3595
Email: ajadad@uhnres.utoronto.ca

Abstract

Context: The term eHealth is widely used by many individuals, academic institutions, professional bodies, and funding organizations. It has become an accepted neologism despite the lack of an agreed-upon clear or precise definition. We believe that communication among the many individuals and organizations that use the term could be improved by comprehensive data about the range of meanings encompassed by the term.

Objective: To report the results of a systematic review of published, suggested, or proposed definitions of eHealth.

Data Sources: Using the search query string "eHealth" OR "e-Health" OR "electronic health", we searched the following databases: Medline and Premedline (1966-June 2004), EMBASE (1980-May 2004), International Pharmaceutical Abstracts (1970-May 2004), Web of Science (all years), Information Sciences Abstracts (1966-May 2004), Library Information Sciences Abstracts (1969-May 2004), and Wilson Business Abstracts (1982-March 2004). In addition, we searched dictionaries and an Internet search engine.

Study Selection: We included any source published in either print format or on the Internet, available in English, and containing text that defines or attempts to define eHealth in explicit terms. Two of us independently reviewed titles and abstracts of citations identified in the bibliographic databases and Internet search, reaching consensus on relevance by discussion.

Data Extraction: We retrieved relevant reports, articles, references, letters, and websites containing definitions of eHealth. Two of us qualitatively analyzed the definitions and coded them for content, emerging themes, patterns, and novel ideas.

Data Synthesis: The 51 unique definitions that we retrieved showed a wide range of themes, but no clear consensus about the meaning of the term eHealth. We identified 2 universal themes (health and technology) and 6 less general (commerce, activities, stakeholders, outcomes, place, and perspectives).

Conclusions: The widespread use of the term eHealth suggests that it is an important concept, and that there is a tacit understanding of its meaning. This compendium of proposed definitions may improve communication among the many individuals and organizations that use the term.

(J Med Internet Res 2005;7(1):e1) doi:10.2196/jmir.7.1.e1

KEYWORDS

eHealth; Internet; medical informatics; systematic review; information services; telemedicine

Introduction

During the 1990s, as the Internet exploded into public consciousness, a number of e-terms began to appear and proliferate. The terms were useful: email brought new possibilities for people to communicate rapidly and share experiences; e-commerce proposed new ways to conduct business and financial transactions through the Internet. The introduction of *eHealth* represented the promise of information and communication technologies to improve health and the health care system [1]. It too has become an indispensable term.

As with most neologisms, the precise meaning of eHealth varied with the context in which the term was used. Nevertheless, it has been fairly well understood, and is now widely used by many academic institutions, professional bodies, and funding organizations. We recognized the impossibility of finding a universally acceptable, universally applicable formal definition, yet felt that a clearer understanding of the term could be achieved by reviewing the range of proposed meanings. What is this thing called eHealth? Two previous articles in this journal have dealt with the question of how eHealth can be or should be defined [2,3]. The aim of this paper is to systematically search the literature for definitions, which have been published to date, in an attempt to answer this unanswerable question and to determine the contexts or settings in which the term has been used.

To the best of our knowledge, no such search has previously been carried out or published. We believe that a better understanding of the meaning and perspectives of eHealth could improve communication among the many individuals and organizations that use the term. For this reason, we collected, examined, and qualitatively analyzed the published proposed definitions of the term eHealth.

Methods

Systematic Review

We first conducted a systematic review of the peer-reviewed literature to capture as many definitions of eHealth as possible. Our inclusion criteria required that a source be published in either print format or on the Internet, be available in English, and contain text that defines or attempts to define eHealth in explicit terms.

We searched the following electronic databases: Medline and Premedline (1966-June 2004), EMBASE (1980-May 2004), International Pharmaceutical Abstracts (1970-May 2004), Web of Science (all years), Information Sciences Abstracts (1966-May 2004), Library Information Sciences Abstracts (1969-May 2004), Wilson Business Abstracts (1982-March 2004).

For each database, we used the search query string *"eHealth"OR "e-Health" OR "electronic health"*. In addition, we then searched dictionaries [4,5] and the Google web search engine (June 2004) which ranks retrieval by importance and relevance [6]. Because the search of Google resulted in an overwhelming number of hits, we reviewed only the first 400 results. We also refined our search by including the additional term *definition* and again reviewed the first 400 hits. We then conducted a further search using the search query string *"what is eHealth" OR "what is e-Health"*, reviewing all 358 results. We conducted our searches between February 1, 2004, and June 30, 2004. A summary of our search strategy and results is presented in Tables 1 and 2.

Two of us (HO, CR) independently reviewed titles and abstracts of citations identified in the bibliographic databases. By viewing summaries and websites of the Internet search, we reached consensus on relevance by discussion. We retrieved the relevant reports, articles, references, letters, and websites. We also manually searched the reference lists of the articles reviewed for additional relevant sources. From the hard or electronic copy of each report, we obtained the following data: author name, publication year, source, and definition (listed in Table 3). We identified and excluded duplicate definitions.

Qualitative Analysis

Upon collection, we analyzed all the definitions and coded for content, emerging themes, patterns, and novel ideas. We used the constant comparative method described by Strauss and Corbin [7] involving open coding, axial coding, and selective coding. The constant comparative method is an iterative process of analyzing qualitative data (ie, text). Units of text (ie, words, phrases, sentences, or paragraphs) are labeled, compared, and grouped until no new categories emerge. Two of us (HO, CR) independently coded the definitions and compared results for consistency and reliability using a commercially available qualitative analytical software package (QSR NVivo v2.0).

Results

Systematic Review

In total, we scanned 1209 abstracts and reviewed 430 citations from the bibliographic databases. From these we collected 10 different definitions for the term eHealth (Table 1). From the Google search, we reviewed 1158 sites and identified 41 additional unique definitions (Table 2).

The definitions that we found were as short as 3 words [8] or as long as 74 words [9] (Table 3). We identified 2 universal themes (health and technology) and 6 less generally mentioned themes (commerce, activities, stakeholders, outcomes, place and perspectives) (Table 4).

Table 1. Summary of database searches

Database (time)	Citations	Articles Reviewed	Unique Definitions
MEDLINE (1966-June 2004)	493	157	10
EMBASE (1975-2003)	218	73	0
International Pharmaceutical Abstracts	16	3	0
Information Sciences & Library Sciences Abstracts	61	15	0
Web of Science	217	77	0
Wilson Business Abstracts	204	105	0
Total	**1209**	**430**	**10**

Table 2. Summary of Google searches

Search Query	Citations	Sources Reviewed	Unique Definitions
“eHealth” OR “e-Health” OR “electronic health”	960000	400	0
“eHealth” OR “e-Health” AND definition	77000	400	9
“what is eHealth” OR “what is e-Health”	358	358	32
Total	**1037358**	**1158**	**41**

Table 3. Definitions (verbatim quotations) of eHealth presented in chronological order

	Year	Source (M = Medline, W = Wilson Business Abstracts, G = Google)	Definition
1	1999	Mitchell [42] (G)	A new term needed to describe the combined use of electronic communication and information technology in the health sector. The use in the health sector of digital data – transmitted, stored and retrieved electronically – for clinical, educational and administrative purposes, both at the local site and at a distance.
2	1999	Loman - First Consulting Group [12] (G)	E-health – the application of e-commerce to healthcare and pharmaceuticals
3	2000	JHITA [13] (G)	Internet-related healthcare activities
4	2000	McLendon [14] (M)	Ehealth refers to all forms of electronic healthcare delivered over the Internet, ranging from informational, educational and commercial "products" to direct services offered by professionals, non-professionals, businesses or consumers themselves. Ehealth includes a wide variety of the clinical activities that have traditionally characterized telehealth, but delivered through the Internet. Simply stated, Ehealth is making healthcare more efficient, while allowing patients and professionals to do the previously impossible.
5	2000	Medical Business News [46] (G)	E-Health is a convergence between the Internet and the health care industry to provide consumers with a wide variety of information relating to the health care field
6	2000	GJW Government Relations [52](G)	A wide-ranging area of social policy that uses new media technologies to deliver both new and existing health outcomes
7	2000	Oracle Corporation [15] (G)	Healthcare transactions, encounters, messaging, or care provision occurring electronically.
8	2000	DeLuca, Enmark - Frontiers of Medicine [16] (W) (M)	E-health is the embryonic convergence of wide-reaching technologies like the Internet, computer telephony/interactive voice response, wireless communications, and direct access to healthcare providers, care management, education, and wellness.
9	2000	Pretlow [17] (G)	E-health is the process of providing health care via electronic means, in particular over the Internet. It can include teaching, monitoring (e.g. physiologic data), and interaction with health care providers, as well as interaction with other patients afflicted with the same conditions.
10	2001	Baur, Deering and Hsu [11] (G)	The most broad term is ehealth, with refers to the use of electronic technologies in health, health care and public health. (...) The various functions of ehealth [are]: (...) reference (electronic publishing, catalogues, databases); self-help/self-care (online health information, support groups, health risk assessment, personal health records), Plan/provider convenience services (online scheduling, test and lab results, benefit summaries), Consultation and referral (doctor-patient or doctor-doctor consultation via telemedicine systems, remote readings of digital image and pathology samples), E-health commerce (sales of health related product and services) [and] Public health services (automated data collection, data warehouses, online access to population survey data and registries, advance detection and warning systems for public health threats). (...) This chapter uses the term ehealth to refer to the broadest possible range of interactive technologies applied to health and health care.
11	2001	Orlikoff & Totten [18] (M)	The use of the Internet and related information systems and technology in all aspects of health care.
12	2001	Eysenbach [3] (M)	e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology
13	2001	Blake [43] (M)	The combined use of electronic communication and information technology in the health sector. It is important to note that e-health is much more than business transactions. It encompasses everything from digital data transmission to purchase orders, lab reports, patient histories and insurance claims.
14	2001	Strategic Health Innovations [19] (G)	The use of information technology in the delivery of health care.
15	2001	Robert J Wood Foundation [20] (G)	EHealth is the use of emerging information and communication technology, especially the Internet, to improve or enable health and health care.
16	2001	Wysocki [21] (G)	e-Health refers to all forms of electronic healthcare delivered over the Internet, ranging from informational, educational and commercial "products" to direct services offered by professionals, non-professionals, businesses or consumers themselves
17	2001	JP Morgan Partners [45] (G)	The health care industry's component of business over the Internet

	Year	Source (M = Medline, W = Wilson Business Abstracts, G = Google)	Definition
18	2001	Ontario Hospital eHealth Council [22] (G)	EHealth is a consumer-centred model of health care where stakeholders collaborate utilizing ICTs including Internet technologies to manage health, arrange, deliver, and account for care, and manage the health care system.
19	2001	Tieman [55] (M)	E-health is all that's digital or electronic in the healthcare industry
20	2001	DeLuca, Enmark [61] (M)	E-health is the electronic exchange of health-related data across organizations, although every health care constituent approaches e-health differently.
21	2001	Ball – HIMSS [47] (G)	Internet technologies applied to the healthcare industry
22	2002	Health e-Technologies Initiative [23] (G)	The use of emerging interactive technologies (i.e., Internet, interactive TV, interactive voice response systems, kiosks, personal digital assistants, CD-ROMs, DVD-ROMs) to enable health improvement and health care services.
23	2002	Grantmakers in Health [24] (G)	Use of ICT, especially (but not only) the Internet to enable health and health care.
24	2002	Kirshbaum [25] (G)	There are many different definitions of eHealth • Electronic connectivity vehicle for improving the efficiency and effectiveness of healthcare delivery • Enabling consumers/patients to be better informed about their healthcare • Enabling providers to deliver better care in more efficient ways
25	2002	Wyatt and Liu [51] (M)	The use of internet technology by the public, health workers, and others to access health and lifestyle information, services and support; it encompasses *telemedicine*, *telecare*, etc.
26	2003	Staudenmeir - Arthur Anderson [26] (G)	Any use of the Internet or related technology to improve: the health and wellness of the population; the quality of healthcare services and outcomes; efficiencies in healthcare services or administration
27	2003	COACH [39] (G)	The leveraging of the information and communication technology (ICT) to connect provider and patients and governments; to educate and inform health care professionals, managers and consumers; to stimulate innovation in care delivery and health system management; and, to improve our health care system.
28	2003	Rx2000 [9] (G)	eHealth signifies a concerted effort undertaken by some leaders in healthcare and hi-tech industries to harness the benefits available through convergence of the Internet and healthcare. Access, cost, quality and portability have been concerns in the health care arena. It's evident from many recent surveys that both health consumers and healthcare professionals are frustrated with the maze of health care delivery. Some, therefore, are turning to the Internet for answers and cost effective solutions.
29	2003	Beaulieu & Beinlich - First Consulting Group [27] (G)	eHealth (ē´helth), n. 1. The application of Internet principles, techniques and technologies to improve healthcare. 2. New way of conducting the business of healthcare enabling stronger and more effective connections among patients, doctors, hospitals, employers, brokers, payers, laboratories, pharmacies, and suppliers. 3. The “customer facing” e-revolution in healthcare. [1999]
30	2003	eEurope - eHealth2003 [53] (G)	The application of information and communication technologies (ICT) across the whole range of functions which one way or another, affect the health of citizens and patients.
31	2003	Decker – HealthVision [28] (G)	Corporate strategy and using the power of the Internet and emerging technology to redefine the delivery of health care.
32	2003	Miller - athealth.com [29] (G)	E-health means any form of healthcare information made available over the Internet.
33	2003	Telehealth Victoria [30] (G)	Term that is used to describe most aspects of healthcare delivery or management that is enabled by information technology or communications
34	2003	Ebrunel.com [31] (G)	The provision of healthcare services available through the Internet - and particularly to the rash of health related web sites.
35	2003	Regional Office for the Eastern Mediterranean - World Health Organization [44] (G)	E-health is a new term used to describe the combined use of electronic communication and information technology in the health sector OR is the use, in the health sector, of digital data-transmitted, stored and retrieved electronically-for clinical, educational and administrative purposes, both at the local site and at a distance
36	2003	www.avienda.co.uk [32] (G)	A generic field of information and communications technologies used in medicine and healthcare.
37	2003	Brommey [33]	The use of electronic information and communications technologies to provide and support health care wherever the participants are located

	Year	Source (M = Medline, W = Wilson Business Abstracts, G = Google)	Definition
38	2003	Southwest Medical Group [34] (G)	e-health is an emerging field focused on medical information and health care services delivered or enhanced through advanced Internet or related technologies. In a broader sense, the term extends the scope of health care beyond its conventional boundaries. Conceptually, e-health enables patients to easily obtain medical related services online from health care providers
39	2003	HMS Europe [40] (G)	The practice of leveraging the Internet to connect caregivers, healthcare systems and hospitals with consumers
40	2003	Nova Scotia Telehealth Network [62] (G)	E-health is a broad term to describe the accessing of information, products and services on "e-health" sites
41	2003	Strengthening Support for Women with Breast Cancer [35] (G)	The use of information and communication technology (ICT) to enhance health care.
42	2003	Vigneault [10] (G)	The development and evolution of technical tools to support program delivery
43	2003	Policy on ICT Security [50] (G)	Using the Internet and other electronic channels to access and delivery health and lifestyle information and services
44	2003	Health systems group [49] (G)	eHealth is health promotion delivered and managed over the Internet
45	2003	Marcus and Fabius [8] (G)	Ehealth is connectivity
46	2003	Silber [54] (G)	eHealth is the application of information and communications technologies (ICT) across the whole range of functions that affect health.
47	2003	Ehealth Technologies [36] (G)	The use of emerging information and communication technology, especially the Internet, to improve or enable health and healthcare thereby enabling stronger and more effective connections among patients, doctors, hospitals, payors, laboratories, pharmacies, and suppliers
48	2003	International Telecommunication Union [41] (G)	Encompasses all of the information and communication technologies (ICT) necessary to make the health system work
49	2003	Baker [48] Modified from Gott (1993) (G)	The promotion and facilitation of health and well-being with individuals and families and the enhancement of professional practice by the use of information and communication technology
50	2004	Sternberg [37] (M)	New business models using technology to assist healthcare providers in caring for patients and providing services.
51	2004	Watson [38] (M)	The integration of the internet into health care.

Table 4. Themes found in definitions of eHealth

	Year	Source(M = Medline, W = Wilson Business Abstracts, G = Google)	Health	Technology	Stakeholders	Activities	Attitudes	Place	Outcomes	Commerce
1	1999	Mitchell [42] (G)	X	X		X		X		
2	1999	Loman - First Consulting Group [12] (G)	X							X
3	2000	JHITA [13] (G)	X	X		X				
4	2000	McLendon [14] (M)	X	X	X	X	X		X	
5	2000	Medical Business News [46] (G)	X	X	X		X			X
6	2000	GJW Government Relations [52](G)	X	X		X	X		X	
7	2000	Oracle Corporation [15] (G)	X			X				
8	2000	DeLuca, Enmark - Frontiers of Medicine [16] (W) (M)	X	X	X					
9	2000	Pretlow [17] (G)	X	X	X	X				
10	2001	Baur, Deering and Hsu [11] (G)	X	X						
11	2001	Orlikoff & Totten [18] (M)	X	X						
12	2001	Eysenbach [3] (M)	X	X	X	X	X	X	X	X
13	2001	Blake [43] (M)	X	X		X				X
14	2001	Strategic Health Innovations [19] (G)	X	X		X				
15	2001	Robert J Wood Foundation [20] (G)	X	X					X	
16	2001	Wysocki [21] (G)	X	X	X	X				X
17	2001	JP Morgan Partners [45] (G)	X	X						X
18	2001	Ontario Hospital eHealth Council [22] (G)	X	X	X	X	X			
19	2001	Tieman [55] (M)	X	X						X
20	2001	DeLuca, Enmark [61] (M)	X	X	X					
21	2001	Ball – HIMSS [47] (G)	X	X						X
22	2002	Health e-Technologies Initiative [23] (G)	X	X		X			X	
23	2002	Grantmakers in Health [24] (G)	X	X		X				
24	2002	Kirshbaum [25] (G)	X		X	X			X	
25	2002	Wyatt and Liu [51] (M)	X	X	X	X				
26	2003	Staudenmeir - Arthur Anderson [26] (G)	X	X					X	
27	2003	COACH [39] (G)	X	X	X	X			X	
28	2003	Rx2000 [9] (G)	X	X	X	X			X	
29	2003	Beaulieu & Beinlich - First Consulting Group [27] (G)	X	X	X	X	X		X	X
30	2003	eEurope - eHealth2003 [53] (G)	X	X	X				X	
31	2003	Decker – HealthVision [28] (G)	X	X			X			X
32	2003	Miller - athealth.com [29] (G)	X	X						
33	2003	Telehealth Victoria [30] (G)	X	X		X				
34	2003	Ebrunel.com [31] (G)	X	X		X				
35	2003	Regional Office for the Eastern Mediterranean - World Health Organization [44] (G)	X	X		X		X		
36	2003	www.avienda.co.uk [32] (G)	X	X						
37	2003	Brommey [33]	X	X	X	X				
38	2003	Southwest Medical Group [34] (G)	X	X	X	X		X		
39	2003	HMS Europe [40] (G)	X	X	X					

	Year	Source(M = Medline, W = Wilson Business Abstracts, G = Google)	Health	Technology	Stakeholders	Activities	Attitudes	Place	Outcomes	Commerce
40	2003	Nova Scotia Telehealth Network [62] (G)	X			X				
41	2003	Strengthening Support for Women with Breast Cancer [35] (G)	X	X					X	
42	2003	Vigneault [10] (G)		X		X				
43	2003	Policy on ICT Security [50] (G)	X	X		X				
44	2003	Health systems group [49] (G)	X	X		X				
45	2003	Marcus and Fabius [8] (G)					X			
46	2003	Silber [54] (G)	X	X						
47	2003	Ehealth Technologies [36] (G)	X	X	X	X			X	
48	2003	International Telecommunication Union [41] (G)	X	X						
49	2003	Baker [48] Modified from Gott (1993) (G)	X	X	X	X			X	
50	2004	Sternberg [37] (M)	X	X	X	X				X
51	2004	Watson [38] (M)	X	X						

Qualitative Analysis

Not surprisingly, all the definitions included the theme of health. The word *health* per se was used in almost all 51 definitions collected (only two did not include it) [8,10]. Most commonly, the word *health* was used in relation to health services delivery (eg, health care [3,11-38], health system [39-41], health sector [16,22,42-44] or health industry [9,45-47]) which suggests that eHealth may refer more to services and systems rather than to the health of people. Wellness as a concept was used only 5 times (namely, wellness [3], public health [26], health and wellness [48], health and well-being [49], and health promotion [13]).

All the definitions also referred to technology, either explicitly or implicitly. The word *Internet* was explicitly mentioned in 27 of the 51 definitions [3, 9, 11, 13, 14, 16-18, 20-24, 26-29, 31, 34, 38, 40, 45-47, 49-51]; 4 of them used *Internet* as an adjective (Internet-related [13], Internet technologies [27, 51], or Internet principles [27]) rather than as a noun. Some authors listed specific technologies such as interactive television [23], personal digital assistants [23], CD-ROMs/DVD [23] or Internet telephony [16]. Others referred to technology in more general terms (eg, new media [52], information and communication technologies [19, 20, 22, 24, 30, 32, 33, 35, 36, 39, 41-44, 48, 53, 54], and Internet-related technologies [3,11,18,26,27,34]). Only 1 definition [38] used the term *integration*.

In 11 definitions, [3,12,21,27,28,37,43,45-47,55] eHealth was referred to in terms of commerce, suggesting that eHealth is "health care's component of business over the Internet" [45], the "application of e-commerce to health care and pharmaceuticals" [12], or as "new business models using technology" [37]. Others associated eHealth with activities such as managing [22], educating [39], arranging [22], connecting [39], obtaining [34], providing [33], redefining [28], supporting [33], using [42], assisting [37] and accessing [51]. The stakeholders most often mentioned were health care providers (doctors [27,36], health care providers [16,37], health care professionals [34,39], health workers [51], managers [39], and caregivers [40]). The public is mentioned as public [51], patients [17,25,27,34,39,53], consumers [14,21,25,39], non-professionals [14,21,46], and citizens [53]. Governments [39], employers [27], and payers [27] are also listed as potentially benefiting from eHealth.

While most of the definitions concentrated on the process of care, about one quarter of them focused on the outcomes to be expected. These definitions mentioned improving and increasing the cost-effectiveness of health care [9] and making processes more efficient [14,25,26]. Others suggested that eHealth could solve problems related to access to care, cost, quality, and portability of health care services [9].

While the actual word *place* was not used in any of the definitions, some authors referred to the concepts of distance, geography, and location. One definition describes the impact of eHealth as local, regional, and worldwide [3]. Another describes eHealth as taking place both at the local site and at a distance [42]. A third suggests that distance and place no longer remain barriers, as eHealth is "to provide and support health care wherever the participants are located" [33].

Finally, other definitions suggest that eHealth represents a new perspective on health care. One author describes eHealth as a "state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking" [3]. Another source describes eHealth as a "consumer-centered model of health where stakeholders collaborate" [22].

Discussion

The term eHealth encompasses a set of disparate concepts, including health, technology, and commerce. The 51 unique published definitions that we found included these concepts with varying degrees of emphasis. All specifically mentioned

health and the technology involved. Many noted the varying stakeholders, the attitudes encompassed, the role of place and distance, and the real or potential benefits to be expected from eHealth.

Health, as used in these definitions, usually referred explicitly to health care as a process, rather than to health as an outcome. This is as expected; there is no consensus on the meaning of the word *health* per se, the definitions of which range from a narrowly construed “converse of disease or infirmity or when disease or infirmity is absent” [56] to the all-encompassing World Health Organization's “health is a state of complete physical, mental, and social well being and not just the absence of disease or infirmity” [57].

In the definitions of eHealth we found, technology was viewed both as a tool to enable a process/function/service and as the embodiment of eHealth itself (eg, a health website on the Internet). We were pleased to note that technology was portrayed as a means to expand, to assist, or to enhance human activities, rather than as a substitute for them. Surprisingly few of the published definitions referred explicitly to the commercial aspects of eHealth (Table 4).

The overwhelming understanding of eHealth reflects an attitude of optimism. All definitions had positive connotations and included terms such as benefits [9], improvement [3,20,23,26,27], enhancing [34,35,48], efficiency [3,25], and enabling [20,23,25,27,36]. One definition suggests that eHealth allows patients and professionals to "do the previously impossible" [14]. None of the published definitions suggests that eHealth may have any adverse, negative, harmful, or disadvantageous effects.

In this review, we do not report the frequency with which certain definitions were used by others, or the impact of each definition. The most commonly cited definition on the Internet is Eysenbach's [3] which was adopted or referred to by at least 87 websites on the Internet. Mitchell's definition [42] was used by a handful of others. There were many variations on the definition that characterizes eHealth as the "use of information technology in the delivery of health care" [19]. Most definitions implied that theirs was “the” definition.

In a perfectly logical language, as envisioned by Ludwig Wittgenstein in his early years [58], each word would have a specific and clear meaning. The philosopher himself recognized that such an idealized language could not be achieved in real life; he concluded his classic book, *Tractatus Logico-Philosophicus*, with "My propositions serve as elucidations in the following way: anyone who understands me eventually recognizes them as nonsensical, when he has used them—as steps—to climb up beyond them. (He must, so to speak, throw away the ladder after he has climbed up it.)" [58]. In his later work, *Philosophical Investigations* [59], Wittgenstein compares words in a language to tools in a toolbox, saying that their functions are varied according to the needs of the speaker much like the tools in a toolbox are varied according to the needs of the repairman. Their functional differences are what make them practical, and in the case of words this difference is usage. The way in which a word is used is what makes it useful in the language; a particular usage of a word gives the word its special authority in that situation [60]. For this reason we have not yielded to the temptation (nor do we have the chutzpah) to attempt another “better” definition of eHealth. The widespread use of the term suggests that eHealth is an important concept, and the term is a useful “tool” to express that concept. It is generally understood despite the lack of a precise definition. The variations among the proposed definitions reflect the various perspectives, settings and contexts in which *eHealth* is used; they round and enhance our understanding of the concept.

In this systematic review and qualitative analysis of the definitions, we have completed only a first step in research on the evolving meaning of eHealth. It is an essential first step because it tells us how the current literature defines the term. We hope, and believe, that this compilation of existing definitions can be a useful resource to facilitate communication, discussion, and stimulate further research.

Questions remain about how the differing concepts and understandings of the term eHealth affect different stakeholders. What do people expect from eHealth? Do patients want eHealth? Do health care providers want eHealth? How does eHealth change the relationships, understandings, and interactions within the health care system? Time, patience, and further research will provide at least provisional answers to these questions, and to the myriad of questions still unasked.

Acknowledgments

We would like to acknowledge Ms. Rea Devakos (Gerstein Science Information Centre, University of Toronto) for her help in refining the strategy to search the many electronic databases. The Centre for Global eHealth Innovation provided funding for photocopying and library access fees. All of the authors were supported by funds from the Rose Family Chair in Supportive Care and the Canada Research Chair in eHealth Innovation (Canadian Institutes of Health Research).

Authors' Contributions

HO and CR conducted the search, extracted the data, and analyzed the content. All the authors participated in designing the search strategy, reviewing results, and preparing the final manuscript.

Conflicts of Interest

None declared.

References

1. Alvarez RC. The promise of e-Health - a Canadian perspective. eHealth Int 2002 Sep 17;1(1):4. [Medline: 12459044] [PMC: 12459044] [doi: 10.1186/1476-3591-1-4]
2. Della Mea V. What is e-health (2): the death of telemedicine? J Med Internet Res 2001 Jun 22;3(2):e22 [FREE Full text] [Medline: 21578029] [doi: 10.2196/jmir.3.2.e22]
3. Eysenbach G. What is e-health? J Med Internet Res 2001 Jun 18;3(2):e20 [FREE Full text] [Medline: 21578027] [doi: 10.2196/jmir.3.2.e20]
4. Stedman TL. Stedman's Medical Dictionary. Baltimore, Md: Lippincott Williams & Wilkins; Jan 15, 2000.
5. Soanes C, Stevenson A, editors. Oxford Dictionary of English, 2nd edition. Toronto, Ontario, Canada: Oxford University Press; Sep 1, 2004.
6. ; Google Inc. Google Technology Overview. URL: http://www.google.com/intl/en/corporate/tech.html [accessed 2004 December 12]
7. Strauss A, Corbin JM. Basics of Qualitative Research : Techniques and Procedures for Developing Grounded Theory. Thousand Oaks, Calif: Sage Publications; Sep 22, 1998.
8. Marcus E, Fabius R. What is E-health?. URL: http://www.acpenet.org/Forums/Topical/Ehealth/Primer.htm [accessed 2004 June 24]
9. ; Rx2000 Institute. eHealth FAQ. URL: http://www.rx2000.org/KnowledgeCenter/ehealth/ehfaq.htm#Whatis [accessed 2004 June 24]
10. Vigneault R. First Nations and Inuit Health Information Systems. URL: http://www.afoa.ca/conf2002/FNIHIS%20AFOA-R%20Vigneault.ppt [accessed 2004 June 24]
11. Baur C, Deering MJ, Hsu L. ehealth: Federal Issues and Approaches. In: Rice RE, Katz JE, editors. The Internet and Health Communication. Thousand Oaks, Calif: Sage Publications; Nov 17, 2000:355-384.
12. Loman P. E-Health: Putting health on the Net. An FCG White Paper. URL: http://www.fcg.com/webfiles/whitepaper/white_paper_files/wpEhealth.asp [accessed 2004 June 24]
13. ; Joint Healthcare Information Technology Alliance. e-Health. URL: http://www.jhita.org/ehealth.htm [accessed 2004 June 26]
14. Mclendon K. E-commerce and HIM: ready or not, here it comes. J AHIMA 2000 Jan;71(1):22-23. [Medline: 20352571]
15. ; Oracle Corporation. CEO Perspective: Health Care Information Technology. URL: http://www.hciv.com/profiles/oracle.pdf [accessed 2004 June 26]
16. Deluca JM, Enmark R. E-health: the changing model of healthcare. Front Health Serv Manage 2000;17(1):3-15. [Medline: 20470299]
17. Pretlow R. eHealth International: A Cutting Edge Company For A New Age In Health Care. URL: http://www.ehealthnurse.com/ehealthi.html [accessed 2004 June 24]
18. Orlikoff JE, Totten MK. Trustee workbook 3. E-health and the board: the brave new world of governance, Part 1. Trustee 2000;53(7):4 p following 14. [Medline: 21643374]
19. ; Strategic Health Innovations. FAQs. URL: http://www.shi.ca/ourcompany/faqs.html [accessed 2004 June 26]
20. ; The Robert Wood Johnson Foundation. The eHealth Landscape. URL: http://www.rwjf.org/ [accessed 2004 June 24]
21. Wysocki M. What is e-Health?. URL: http://www.suite101.com/article.cfm/9670/57010 [accessed 2004 June 26]
22. ; Ontario Hospital eHealth Council. An eHealth Blueprint. Setting the Course For Action. An Ontario Hospital Perspective. URL: http://www.oha.com
23. ; Health e-Technologies Initiative. 2002 Call for Proposals. URL: http://www.hetinitiative.org/sub-call_for_proposals/cfp-faqs.html [accessed 2004 June 24]
24. ; Grantmakers In Health, Washington, D.C., USA. Examining e-health. Issue brief (Grantmakers Health) 2002 Nov(14):1-28. [Medline: 22897117]
25. Kirshbaum D. eHealth: Past, present & future. URL: http://www.nehimss.org/pubs/Kirshenbaum.ppt [accessed 2004 June 26]
26. Staudenmeir S. Introduction to eHealth. URL: http://www.healthaction.net/esnets/web_bots/slide+presentationswebot.htm [accessed 2004 June 24]
27. Beaulieu D, Beinlich J. Current promises and challenges. URL: http://www.tricare.osd.mil/conferences/2001/downloads/breakout/W801_Beaulieu.ppt [accessed 2004 June 24]
28. Decker S. What is e-Health?. URL: http://12.42.224.48/ehealthresources/what_is_ehealth.pdf [accessed 2004 June 24]
29. Miller JL. The Internet as Therapist and Teacher. URL: http://www.athealth.com/Practitioner/particles/art_InternetAsTandT.html [accessed 2004 June 24]
30. ; Telehealth Victoria. Telehealth Victoria FAQs. URL: http://www.shi.ca/ourcompany/faqs.html [accessed 2004 June 26]
31. ; ebrunel.com. eHealth. URL: http://www.ebrunel.com/ehealth.php3#ehealth [accessed 2004 June 26]
32. Telehealth & EHealth. URL: http://www.avienda.co.uk/ [accessed 2004 June 24]
33. Brommey M. Challenges in e-health service delivery. 2nd annual online summit. URL: http://www.health.gov.au/healthonline/docs/summit2/brommeyer.pdf [accessed 2004 June 24]

34. ; Southwest Medical Group. Frequently Asked Questions. URL: http://www.southwestmedicalgroup.com/faq.asp [accessed 2004 June 26]
35. ; Breastcare Victoria. Strengthening Support for Women with Breast Cancer. E-health Information Package. URL: http://www.breastcarevic.org.au/sswbc/docs/infopak.pdf [accessed 2004 June 26]
36. ; eHealth Technologies. What is eHealth?. URL: http://www.ehealthtechnologies.com/what%20is%20ehealth.htm [accessed 2004 June 26]
37. Sternberg DJ. The new e-health. As technology matures, more sensible approaches to online healthcare are emerging. Mark Health Serv 2004;24(1):46-48. [Medline: 23181606]
38. Watson R. EU wants every member to develop a "roadmap" for ehealth. BMJ 2004 May 15;328(7449):1155 [FREE Full text] [Medline: 15142907] [doi: 10.1136/bmj.328.7449.1155-b]
39. ; Canada's Health Informatics Association (COACH). What is eHealth?. URL: http://www.e-healthconference.com/Default.asp?id=3& [accessed 2004 June 24]
40. What is eHealth?. URL: http://www.hmseurope.com/e_health.htm [accessed 2004 June 24]
41. ; International Telecommunication Union. Standardization in e-health. URL: http://www.itu.int/itunews/issue/2003/06/standardization.html [accessed 2004 June 26]
42. Mitchell J. From telehealth to e-health: The unstoppable rise of e-health. Canberra, Australia: Commonwealth Department of Communications, Information Technology and the Arts (DOCITA); 1999.
43. Blake G. Accelerating the E-health Connectivity Imperative: Implementing Short-term Value against Long-term Goals when Building Private-sector Relationships. Electronic Healthcare 2001;1:56-59 [FREE Full text]
44. ; World Health Organization - Regional Office for the Eastern Mediterranean. E-Health in the Eastern Mediterranean. URL: http://208.48.48.190/HIS/ehealth/AboutEhealth.htm [accessed 2004 June 27]
45. ; JP Morgan Partners. The Rise & Fall and ??? Of e-Health. URL: http://www.upenn.edu/ldi/healthpolicyseminarjan26_Jan.%2022%20'01.ppt [accessed 2004 June 26]
46. What is e-Health?. URL: http://www.tsmi.net/april12continued.html [accessed 2004 June 24]
47. Ball MJ. E-Health: Empowering clinicians and consumers. URL: http://www.himss.org/content/files/proceedings/2001/roundtab/rslides/rsl08.pdf [accessed 2004 June 26]
48. Baker B. Nursing in an e-healthy world? A vision of e-health as core to caring. URL: http://www.hlth.qut.edu.au/nrs/inc2003/post/ppts/2 [accessed 2004 June 26]
49. ; Health Systems Group. eHealth - Wellness in the 21st Century. URL: http://www.healthsystemsgroup.com/Resources/Articles/eHealth.htm [accessed 2004 June 26]
50. Policy on ICT Security. URL: http://www.qub.ac.uk/cm/gp/UG-Med-Informatics/ [accessed 2004 June 26]
51. Wyatt JC, Liu JLY. Basic concepts in medical informatics. J Epidemiol Community Health 2002 Nov;56(11):808-812 [FREE Full text] [Medline: 22276130] [doi: 10.1136/jech.56.11.808]
52. ; GJW Government Relations Ltd Health Affairs. Memorandum. URL: http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldeucom/95/95we29.htm [accessed 2004 June 26]
53. ; eEurope. What is eHealth. URL: http://europa.eu.int/information_society/eeurope/ehealth/whatisehealth/index_en.htm [accessed 2004 June 26]
54. Silber D. The case for eHealth. URL: http://europa.eu.int/information_society/eeurope/ehealth/conference/2003/doc/the_case_for_eHealth.pdf [accessed 2004 June 26]
55. Tieman J. On the trail of a computer cure-all ... eHealth Initiative. Mod Healthc 2001 Jun 18;31(25):36-37. [Medline: 21330505]
56. The Atlas of Canada - Health. URL: http://atlas.gc.ca/site/english/maps/health/1 [accessed 2004 December 12]
57. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. URL: http://www.who.int/about/definition/en/ [accessed 2004 July 5]
58. Wittgenstein L, Pears DF, McGuinness B, Russell B. Tractatus Logico Philosophicus, New Ed (Routledge Classics). New York, NY: Routledge; Sep 1, 2001.
59. Wittgenstein L, Anscombe E, Anscombe GEM. Philosophical Investigations: The German Text, With a Revised English Translation. Cambridge, Mass: Blackwell Publishers; Jan 1, 2002.
60. Beaver ET. Wittgenstein's Meaning and Use in Philosophical Investigations, Searle's Speech Act Theory in 'What is a Speech Act?': An Exposition and Comparison. URL: http://www3.baylor.edu/~Elijah_Beaver/witterm.htm [accessed 2004 August 25]
61. Deluca JM, Enmark R. The latest revolution. What solutions will technology offer? Health Forum J 2001;44(1):22-25. [Medline: 21118262]
62. ; Nova Scotia Telehealth Network. Frequently Asked Questions. URL: http://www.gov.ns.ca/health/telehealth/faq.htm [accessed 2004 June 25]

submitted 30.07.04; peer-reviewed by J Powell, C Pagliari; comments to author 16.08.04; revised version received 07.02.05; accepted 14.02.05; published 24.02.05.

Please cite as:
Oh H, Rizo C, Enkin M, Jadad A
What Is eHealth (3): A Systematic Review of Published Definitions
J Med Internet Res 2005;7(1):e1
URL: http://www.jmir.org/2005/1/e1/
doi:10.2196/jmir.7.1.e1
PMID:15829471

Review

What Is eHealth (4): A Scoping Exercise to Map the Field

Claudia Pagliari[1], PhD; David Sloan[2], MSc; Peter Gregor[2], PhD; Frank Sullivan[3], PhD; Don Detmer[4], MD; James P Kahan[5], PhD; Wija Oortwijn[5], PhD; Steve MacGillivray[3], MSc

[1]Division of Clinical and Community Health Sciences (General Practice Section), University of Edinburgh, Edinburgh, United Kingdom

[2]Division of Applied Computing, University of Dundee, Dundee, United Kingdom

[3]Tayside Centre for Health Informatics, University of Dundee, Dundee, United Kingdom

[4]Department of Health Evaluation Sciences, University of Virginia, Charlottesville VA, USA

[5]RAND Europe, Leiden, The Netherlands

Corresponding Author:
Claudia Pagliari, PhD
Division of Clinical and Community Health Sciences (General Practice Section)
University of Edinburgh
20 West Richmond Street
Edinburgh EH8 9DZ
United Kingdom
Phone: +44 (0)131 650 9464
Fax: +44 (0)131 650 9119
Email: claudia.pagliari@ed.ac.uk

Abstract

Background: Lack of consensus on the meaning of eHealth has led to uncertainty among academics, policymakers, providers and consumers. This project was commissioned in light of the rising profile of eHealth on the international policy agenda and the emerging UK National Programme for Information Technology (now called Connecting for Health) and related developments in the UK National Health Service.

Objectives: To map the emergence and scope of eHealth as a topic and to identify its place within the wider health informatics field, as part of a larger review of research and expert analysis pertaining to current evidence, best practice and future trends.

Methods: Multiple databases of scientific abstracts were explored in a nonsystematic fashion to assess the presence of eHealth or conceptually related terms within their taxonomies, to identify journals in which articles explicitly referring to eHealth are contained and the topics covered, and to identify published definitions of the concept. The databases were Medline (PubMed), the Cumulative Index of Nursing and Allied Health Literature (CINAHL), the Science Citation Index (SCI), the Social Science Citation Index (SSCI), the Cochrane Database (including Dare, Central, NHS Economic Evaluation Database [NHS EED], Health Technology Assessment [HTA] database, NHS EED bibliographic) and ISTP (now known as ISI proceedings).We used the search query, “Ehealth OR e-health OR e*health”. The timeframe searched was 1997-2003, although some analyses contain data emerging subsequent to this period. This was supplemented by iterative searches of Web-based sources, such as commercial and policy reports, research commissioning programmes and electronic news pages. Definitions extracted from both searches were thematically analyzed and compared in order to assess conceptual heterogeneity.

Results: The term eHealth only came into use in the year 2000, but has since become widely prevalent. The scope of the topic was not immediately discernable from that of the wider health informatics field, for which over 320000 publications are listed in Medline alone, and it is not explicitly represented within the existing Medical Subject Headings (MeSH) taxonomy. Applying eHealth as narrative search term to multiple databases yielded 387 relevant articles, distributed across 154 different journals, most commonly related to information technology and telemedicine, but extending to such areas as law. Most eHealth articles are represented on Medline. Definitions of eHealth vary with respect to the functions, stakeholders, contexts and theoretical issues targeted. Most encompass a broad range of medical informatics applications either specified (eg, decision support, consumer health information) or presented in more general terms (eg, to manage, arrange or deliver health care). However the majority emphasize the communicative functions of eHealth and specify the use of networked digital technologies, primarily the Internet, thus differentiating eHealth from the field of medical informatics. While some definitions explicitly target health professionals or patients, most encompass applications for all stakeholder groups. The nature of the scientific and broader literature pertaining to eHealth closely reflects these conceptualizations.

Conclusions: We surmise that the field – as it stands today – may be characterized by the global definitions suggested by Eysenbach and Eng.

(J Med Internet Res 2005;7(1):e9) doi:10.2196/jmir.7.1.e9

KEYWORDS

eHealth; Internet; telemedicine; medical informatics

Introduction

The application of information and communications technology (ICT) in health care has grown exponentially over the last 15 years and its potential to improve effectiveness and efficiency has been recognized by governments worldwide [1]. National strategies aimed at developing health information infrastructures and "infostructures" are emerging across North America, Australia, Europe and elsewhere [2-5]. These are united by a vision to improve the safety, quality and efficiency of patient care by enabling access to electronic health records and by supporting clinical practice, service management, research and policy though availability of appropriate evidence and data. In addition, these strategies emphasize the importance of standards and policies for ensuring interoperability and data security, and many incorporate a commitment to facilitate consumer empowerment and patient self-care through provision of electronic information and/or telemedicine facilities. In the United Kingdom, these principles are reflected in the National Information Strategy for Health and are being addressed via the UK National Programme for Information Technology (NPfIT, now called Connecting for Health) and related initiatives [6,7].

While such initiatives have been taking place, the focus of health care information technology (IT) has been changing, from an emphasis on hardware, systems architectures and databases, to innovative uses of technology for facilitating communication and decision making, coupled with a growing recognition of the importance of human and organizational factors. At the same time, Internet technologies have become increasingly pervasive. In parallel, the language of health care IT has been changing, and references to the concept of eHealth have proliferated in international health policy, management and research arenas. Despite the clear interest in and apparent marketability of eHealth, it was not evident, at the time this research was commissioned, what exactly was meant by the term. It had been variously used as a synonym for health informatics, telemedicine, consumer health informatics and e-business, as well as more specific technological applications, but no consensus existed on its conceptual scope and it was unclear whether it indeed represented a new concept, or simply a linguistic change. An international call for definitions of eHealth posted in 2001 failed to generate any published responses and the call was updated in June 2004, suggesting that this is still a grey area [8,9].

In view of these uncertainties, it was considered important by the UK National Health Service (NHS) Research and Development Programme to define eHealth and to assess its scope and value for the future of health care, in particular to synthesize the available evidence relating to its potential impact, likely trajectory, and implications for service development and organization. The current paper reports descriptive work to profile and define the field, which was conducted independently of, but complements, the systematic review of definitions of eHealth provided elsewhere in this volume [10]. This work produced a framework for locating evidence on the effectiveness, promise and challenges of eHealth, as well as recommendations for future research, which are reported elsewhere [11].

Potential areas of eHealth considered at the outset of the project are shown in Table 1. This was derived by group discussion among the research team, utilizing team members' a priori knowledge of topics and issues in medical informatics (drawing on backgrounds in health care research, practice, policy, and computing), key eHealth discussion papers, and the results of a preliminary Medline search suggesting that eHealth is closer to the emerging area of health informatics than to medical informatics as a whole. While it was established that eHealth is about the use of information technology to facilitate patient and citizen health care or service delivery, rather than technology per se, uncertainty remained about what specific topics or issues, among those shown, fall within the scope of, or have relevance to, the concept.

It was recognized that in order to fully explore the area, multiple sources of information would need to be examined. While identifying the scope of eHealth research was a crucial objective, the published research literature presents a filtered record of activity and thinking and, given the fast-moving pace of the field and its importance beyond academia, nonresearch sources are likely to yield rich information about the current status of eHealth and future trends. For this reason we conducted two parallel, large scale reviews—one focusing on the medical and related scientific literature and the other drawing on alternative sources available via the World Wide Web, including independent scoping exercises (of which there have been several), policy documents and technology reports. The results of these exercises were converged in order to derive a conceptual map and are considered together in this report.

Table 1. Potential eHealth areas and issues considered at the outset of the project

What issues currently dominate eHealth? **What is going on in eHealth?**			**What emerging technologies are likely to impact on health care?**	**How does research inform eHealth?**	**How do developments in eHealth inform research?**
Professional Clinical Informatics - Decision aids for practitioners (eg, prompts, reminders, care pathways, guidelines) - Clinical management tools (eg, electronic health records [EHRs/EPRs], audit tools) - Educational aids (guidelines, medical teaching) - Electronic clinical communications tools (eg, e-referral, e-booking, e-discharge correspondence, clinical email/second opinion, laboratory test requesting/results reporting, e-shared care) - Electronic networks (NHS-Net and disease-specific clinical networking systems) - Discipline/disease-specific tools (eg, diabetes informatics) - Telemedicine applications (for interprofessional communication, patient communication and remote consultation) - Subfields eg, nursing & primary care informatics)	**Electronic Patient/Health Records (EPR, EHR)** - Electronic medical records. Record linkage. The Universal Patient Indicator. Databases and population registers. - Achieving multiprofessional access. Technical and ethical issues. - Data protection/security issues - Patient access and control - Integration with other services (eg, social work, police) - Clinical coding issues (terminologies, etc) **Healthcare Business Management** - Billing and tracking systems - Audit & quality assessment systems	**Consumer Health Informatics** - Decision aids for patients facing difficult choices (eg, genetic screening) - Information on the web and/or digital TV (public information and educational tools for specific clinical groups) - Clinician-patient communication tools: 1. Remote: Clinical email and web-based messaging systems for consultation, disease monitoring, service-oriented tasks (eg, appointment booking, prescription reordering). 2. Proximal: Shared decision making tools, informed consent aids 3. Mixed: On-line screening tools (eg, for depression) and therapeutic interventions (eg, cognitive behaviour therapy) - Access and equity issues (data protection issues, the Digital Divide) - Quality issues for health information on the net - “virtual” health communities	**New Technologies** - Satellite communications (eg, for remote medicine) - Wireless networks (eg, within hospitals, across geographical areas) - Palmtop technologies (for information, for records) - New mobile telephones - Digital TV (for disseminating health information & communicating with patients) - The WWW and it's applications for health (issues: quality control, confidentiality, access) NHS-Direct etc. - Virtual reality (eg, remote/transcontinental surgery) - Nanotechnology - Intersection of bioinformatics and health informatics.	**Research Input** - Development - Need for user involvement in product conception, design and testing. Iterative development. Needs assessment, accessibility and usability research. Multi-faceted expertise required. - Implementation – Understanding people and organizational factors eg, system acceptability, resistance to change etc. Use of tailored implementation strategies. - Innovative methods for mapping functional and technology needs eg, place of systems in the organization - Knowledge management, systems approaches, communication networks models, organizational development to map pathways. - Evaluation Formative, as above, also: Outcome assessment to establish impact of new systems on clinical outcomes, processes and costs.)	**Research Outcomes** - Potential of electronic databases such as population registers for epidemiological research. - Research into the impact or use of informatics tools suggests appropriate and cost-effective priorities for policymakers. - Areas of cross-over (eg, bioinformatics)

Methods

Assessing the Taxonomic Structure of Research Databases and the Presence of eHealth

In the formative stage of the project, we explored the subject taxonomies, or thesauri, of multiple databases of abstracts in order to identify high-level subject headings which could be used to profile the volume and content of the medical informatics literature and to construct searches for pertinent evidence. In the case of Medline the thesaurus containing a hierarchical controlled vocabulary is referred to as Medical Subject Headings, or MeSH (see below). As part of this we sought to assess whether eHealth was explicitly represented within these thesauri. A further objective was to determine the ontological structure of the databases in relation to medical informatics and eHealth and the implied relationships between alternative subfields.

The databases examined were Medline (PubMed), the Cumulative Index of Nursing and Allied Health Literature (CINAHL), the Science Citation Index (SCI), the Social Science Citation Index (SSCI), the Cochrane Library Database (including Dare, Central, NHS Economic Evaluation Database [NHS EED], Health Technology Assessment [HTA] database, NHS EED bibliographic) and Index to Scientific and Technical Proceedings (ISTP, now known as ISI proceedings), all of which predate the targeted search period.

Exploring the Composition of the Medical Informatics Literature Using the Existing MeSH Thesaurus

MeSH has been developed (and is constantly updated by) the US National Library of Medicine. It consists of sets of terms

naming descriptors in a hierarchical structure that permits searching at various levels of specificity. At the most general level of the hierarchical structure are very broad headings such as *Anatomy* or *Information Science*. More specific headings are found at more narrow levels of the eleven-level hierarchy, such as *Ankle* or *Medical Informatics*. There are 22568 descriptors in MeSH.

Historical trends in the literature indexed by the individual Medline MeSH terms subsumed within the broad *Medical Informatics* category were assessed for the period 1987 to 2003, and part way through 2004. Individual MeSH definitions were examined to assess the range and nature of the topics covered and to clarify which are most clearly related to common conceptions of eHealth (eg, specific applications of information technology (IT) to health care versus technical issues). The number of publications in Medline was profiled by year, as was the type of publication, subject to the limitations of the Medline categorization scheme (Randomized Controlled Trial/Controlled Trial/Meta-analysis/Review). In addition, the MesH tree was compared with an expert-derived taxonomy from the International Medical Informatics Association (IMIA) in order to assess its coverage of key areas and its merits as a means of identifying appropriate literature.

Using eHealth as a Search Term

Applying eHealth as free-text search term to multiple databases offered a "grounded" method of defining the field, as represented in the research literature. In order to identify publications specificially relating to eHealth and to place the concept within the wider medical informatics literature, all the databases described previously were searched for the presence of the word *eHealth* or its variants in the title or abstract for the period January 1, 1997 to December 31, 2003 (search string: *Ehealth OR e-health OR e*health*). Results were organized to show the number of articles arising each year, the journals in which they appeared, and the range of topics covered.

Profiling the Literature From Wider Web-Based Sources

Mixed methods were used to (*a*) identify current commentary and analysis relating to the emergence, nature, scope and potential of eHealth, and (*b*) locate evidence and opinions on general trends in technology and technology adoption with direct or indirect relevance to eHealth now or in the future. Relevant terms (including *e health, e-health, ehealth, healthcare information technology* and *healthcare computing*) were applied, singly and in combinations, to the Google search engine, which indexes over 8 billion URLs and ranks results by relevance and link popularity. In addition, websites previously identified as being likely to contain information relevant to eHealth were visited directly and scrutinized for pertinent information. In some cases, this was guided by the results of preliminary Google searches or by following up leads suggested in documents found earlier on, while in others it was guided by the existing knowledge of team members. As the searches were predominantly opportunistic and iterative in nature, it is inappropriate to try to document them exhaustively; however, the following types of information were targeted:

- previous exercises to map, scope or define eHealth;
- white papers, technical reports, predictions and early research reports on aspects of technology in health care, eHealth related policy, evaluation and trends, from the United Kingdom, Europe and beyond;
- funding programmes for eHealth- and/or health-and-technology - focused research and development;
- relevant articles from computing and information science-focused academic publications;
- eHealth and health technology-focused websites, web logs and online journals, online ehealth news feeds, email discussion groups and email newsletters;
- online sources with a focus on human-computer interaction, usability and accessibility, with specific attention on health care issues;
- technology-oriented news websites profiling general and health-related trends and developments;
- online studies, reports and statistical surveys relating to general technology take-up; consumer purchasing trends; attitudes and strategies of consumers and clinicians towards adoption of technology in general and for health care-focused tasks in particular; evaluation of the effectiveness of technological innovation, in the health care sector and beyond.

Given the increasing online availability of refereed academic literature there was inevitably some overlap between the information identified by the two searches.

Aggregating and Analyzing Definitions of eHealth

Scientific abstracts identified using the key word search were examined in order to assess the presence of definitions. While hand searching of full text articles was not a primary objective, this was done where easy Web-based access to this information was available. In the case of Web-based reports or commentary the definition was extracted from the page in which it appeared or was quoted. In both cases the initial extraction was performed by one research fellow and the results checked for inclusion eligibility by a second investigator. Our aim was not to perform an exhaustive and systematic review of definitions (because of time constraints) but to aggregate those appearing most easily and commonly in the research and wider arenas, as a means of supplementing our wider scoping study. The aggregated definitions were then analyzed thematically in order to assess the applications, stakeholders, contexts and theoretical perspectives targeted, so that the heterogeneity of conceptualizations could be determined. They were also considered with reference to the perspectives of the defining individual or organization and associated clarifications within the source document.

Results

Assessing the Taxonomic Structure of Research Databases and the Presence of eHealth

Of the databases of scientific abstracts consulted, only Medline has a comprehensive hierarchical taxonomy of descriptors for the broad field of medical informatics. This part of the MeSH tree is shown in Figure 1. Medical informatics is also represented

on CINAHL; however the subtree is relatively shallow and undifferentiated, forming only a small branch of the higher *Information Science* category, with many potentially relevant areas subsumed within other branches.

That eHealth has yet to be explicitly included among these thesauri, indicates the relative youth of the topic and the lack of an agreed conceptual definition. The literature relevant to eHealth is thus distributed among a range of existing MeSH fields.

The Medline MeSH structure for *Medical Informatics* contains 3 main subbranches: *Public Health Informatics*, *Medical Informatics Computing*, and *Medical Informatics Applications*. Examining the definitions of these and their lower order MeSH descriptors indicates that the *Medical Informatics Applications* tree encompasses the greatest number of component categories relevant to eHealth, taken broadly as the use of information and communication technologies to facilitate health care. For example, it subsumes the lower-order categories of *Decision Making, Computer Assisted* (which subsumes *Computer Assisted Therapy and Diagnosis*, among others); *Information Systems* (electronic information systems, networks, clinical decision support) and *Information Storage and Retrieval* (databases, laboratory information systems, etc). In contrast, *Medical Informatics Computing* is mainly characterized by an emphasis on systems and hardware, although it does contain MeSH descriptors relevant to eHealth — most importantly *Internet*, which may appear in eHealth publications as a specific technology or an application of technology. *Public Health Informatics* is concerned with the application of information and computer sciences to public health practice, research, and learning. Although this potentially encompasses eHealth-relevant research (for example, use of information and communications technologies for population health surveillance), the term was only recently introduced and has yet to contain any subcodes, limiting its usefulness at the present time. While the broader taxonomic categories each have their own character, there is clearly overlap between them. For example, decision support systems appear within both *Medical Informatics Applications* and *Medical Informatics Computing*, and electronic databases are a common feature in medical informatics applications, as well as representing a type of system.

Comparison of the MeSH tree with an expert-derived conceptual map endorsed by the International Medical Informatics Association (IMIA) revealed interesting differences in terms of the breadth of included concepts and their structural relationships (Table 2) [12]. For example, human and organizational factors appear to be underrepresented within Medline, while applications for consumers do not have a specific MeSH term (however, the IMIA taxonomy also appears to underrepresent consumer issues). This reflects the historical evolution of the MeSH hierarchy, which has been added to as the need arose by elaborating upon existing structures. Nonetheless, all the main areas apparently relevant to eHealth were encompassed by the MeSH tree and we are confident that using it as the basis of our search enabled the majority of pertinent literature to be identified.

Figure 1. Hierarchy of MeSH descriptors found below the Medical Informatics descriptor in the MeSH tree

Table 2. Medical informatics scientific content map endorsed by the International Medical Informatics Association (IMIA) [12]

Applied Technology	Information Technology Infrastructure	Data-Infrastructure Related	Applications and Products	Human-Organizational	Education and Knowledge
• Algorithms • Bioinformatics • Biosignal processing • Boolean logic • Cryptology • Human genome related • Human interfaces • Image processing • Mathematical models in medicine • Pattern recognition	• Archival-repository systems for medical records- EPR-CPR-EMR • Authentication • Chip cards in health care • Distributed systems • Health professional workstation • Interfaces • Knowledge based systems • Networks • Neural networks • Pen based • Security • Speech recognition • Standards • Systems architecture • Telehealth • User interfaces	• Classification • Coding systems • Concept representation-preservation • Data acquisition-data capture • Data analysis-extraction tools • Data entry • Data policies • Data protection • Database design • Indexing • Syntax • Language representation • Lexicons • Linguistics • Modeling • Nomenclatures • Standards • Terminology-vocabulary • Thesaurus tools	• Biostatistics • Clinical trials • Computer-supported surgery • Decision support • Diagnosis related • Disease management • EPR-CPR-EMR • Epidemiological research Hosp IS • Event-based systems • Evidence based guidelines • Expert systems • Health services research • Health Information Systems management • Knowledge-based systems • Laboratory data • Image processing • Operations/resource management • Outcomes research and measurement • Quality management • Patient identification • Patient monitoring • Minimum data sets • Supply chain • Telematics • Telemedicine	• Assessment • Compliance • Cognitive tasks • Collaboration • Communication • Economics of IT • Ethics • Implementation-deployment • Diffusion of IT • Evaluation • Human Factors • Legal issues, implementing national laws • Management • Managing change • Needs assessment • Organizational redesign processes • Organizational transformation • Planning • Policy issues • Privacy • Project management • Security • Strategic plans • Unique identifiers • User-computer interface	• Bibliographic • Cognitive learning • Computer aided instruction • Computer-supported training • Consumer education • Continuing education • Digital libraries • E-Business • Health/medical informatics education • Information management- dissemination • Knowledge bases • Knowledge management • Learning models • Online/distance education

Clinical Disciplines: Anesthesia, Behavioral, Cardio/Thoracic, Cardiovascular, Dentistry, Dermatology, Emergency Medicine, Environmental Health, Gastroenterology, Human Genetics, Internal Medicine, Neurosurgery, Nursing, Obstetrics & Gynecology, Ophthalmology, Orthopedics, Pathology, Pediatrics, Pharmacy, Primary Care, Psychiatry, Radiology, Surgery, Urology

Exploring the Composition of the Medical Informatics Literature Using Existing Taxonomic Systems

Figure 2 describes trends in the volume and nature of the literature indexed by the *Medical Informatics* MeSH descriptor (note that searching for MeSH terms in PubMed automatically includes the more specific MeSH terms in a search). There has been a steady growth in the volume of medical informatics research literature. The annual number of publications increased from 1987 to 2003 five-fold.

Figure 2. Number of publications over time indexed with the MeSH descriptor Medical Informatics

Publications indexed with MeSH keywords from each of the 3 main medical informatics MeSH subtrees (*medical informatics computing, medical informatics applications, public health informatics*) all follow this steady upwards trend, as do most narrower MeSH (eg, *Information Systems; Therapy, Computer Assisted*). However, the frequency of publications concerned with *Clinical Laboratory Information* Systems (Figure 3), appears to be decreasing, while research concerned with computer-assisted diagnosis increased rapidly in 2003 (Figure 4).

A breakdown of Medical Informatics MeSH, including definition, year of introduction, number and type of publications is supplied in Multimedia Appendix 1.

Figure 3. Number of publications over time indexed with the MeSH descriptor Clinical Laboratory Information Systems

Figure 4. Number of publications over time indexed with the MeSH descriptor Diagnosis, Computer Assisted

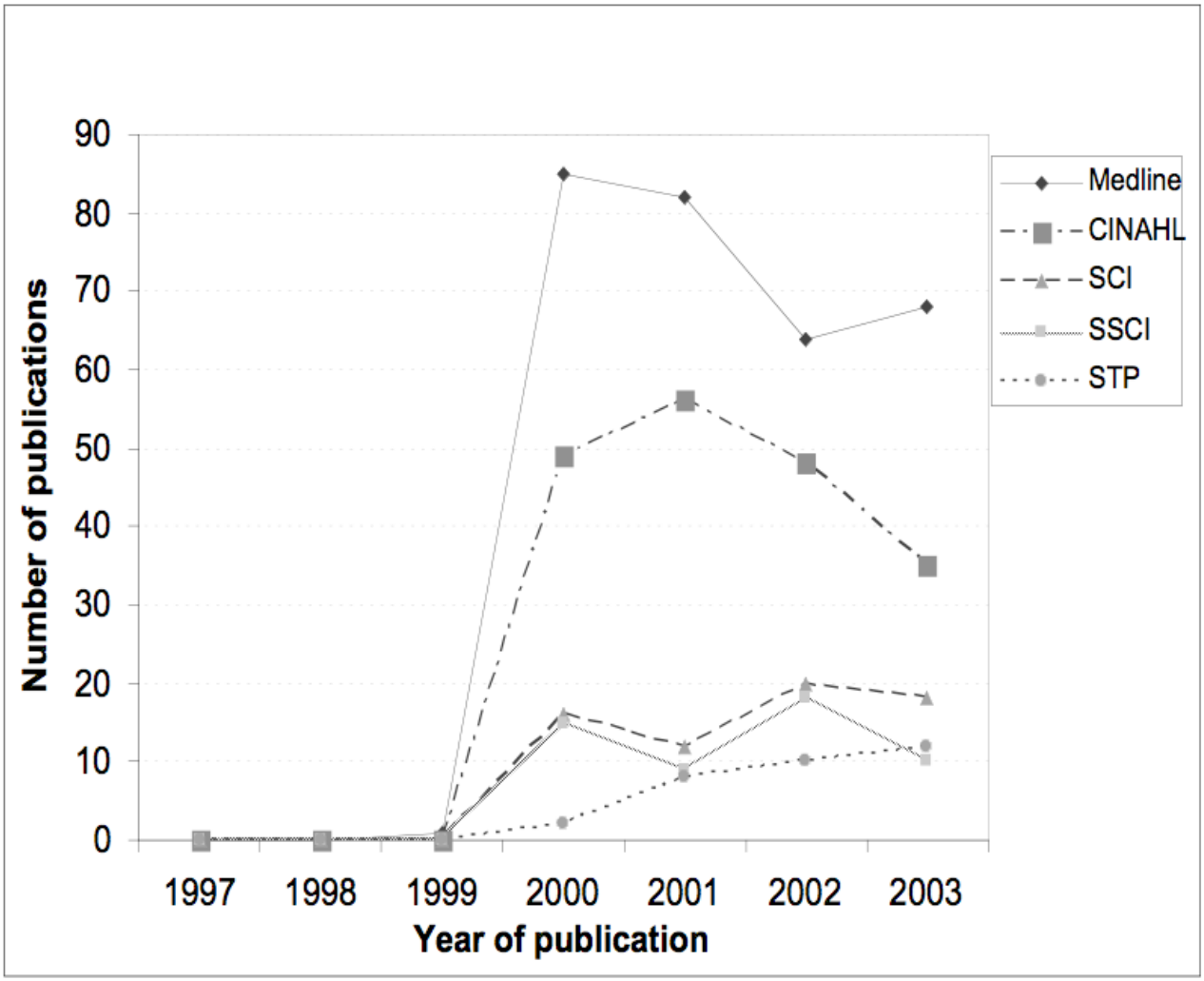
Using eHealth as a Search Term

As mentioned previously, there are currently no MeSH or equivalent coding categories in any of the databases searched which explicitly incorporate the term *eHealth* or its variants in their thesauri. This suggests that articles making reference to eHealth are being absorbed within existing classification schemes, such as Medline's *Medical Informatics* taxonomy.

When duplicates across databases were discarded we identified a total of 392 publications which explicitly referred to eHealth in the title, abstract, or journal title. Of these, most were represented in Medline. Appearing only in the Medline database were 283 (72%) articles, 54 (14%) only on the CINAHL database, and 55 (14%) only on the SCI, SSCI and ISTP databases.

Figure 5 illustrates trends in the volume of eHealth publications appearing across databases over time. This shows that the term did not start to be used in the research literature until 2000. References to eHealth showed a dramatic rise in 2000 to 2001 and, despite a small dip in 2002 a general upward trend persists. Note that we also retrieved publications from the *Journal of Telemedicine and E-health* which were picked up due to the journal name, not necessarily because they dealt with eHealth.

Figure 5. Number of publications found using the search term eHealth (or variants) in 5 research databases by year.



In Which Journals Do Publications Using the Term eHealth Appear?

In our study, publications containing the term *eHealth* were found in 154 different journals. A research fellow classified these by type, using a scheme agreed by the research team. The number of articles appearing within each journal were documented. Of the 387 publications found across multiple databases (after eliminating 5 that were clearly irrelevant), 77 appeared in clinical journals, 61 in health-services - related journals, 7 in finance-related journals, 4 in legal journals, 3 in journals related to medical education, and 28 in other journals not easily categorized. The journal titles with the most articles containing the term *eHealth* (n=9 for each journal) were the *Journal of Medical Internet Research*, *Managed Care Interface*, and *Journal of AHIMA / American Health Information Management Association*. The majority of publications were IT-related (207): however, among these, 116 articles were

published in the *Journal of Telemedicine and E-health*, which were mainly picked up due to the journal name: only 4 articles actually contained the term *eHealth*in the abstract or title. Further details are provided in Table 3 and a detailed breakdown of journal titles is given in Multimedia Appendix 2.

Table 3. Topical areas of journal titles containing articles using the term eHealth

Main Topic Area	More Specific Topics	Number of Publications (%)
Information Technology	Telemedicine	124* (32%)
	Medical Informatics	35 (9%)
	Internet	23 (6%)
	Medical Computing	6 (1.5%)
	Biotechnology	2 (0.5%)
	Others	17 (4 %)
	Sub total	**207 (53%)**
Clinical	Specialist Medical	30 (8%)
	Generalist Medical	16 (4%)
	Nursing	13 (3%)
	Others	18 (4%)
	Sub total	**77 (19%)**
Health Services	Management	30 (8%)
	Case Management	16 (4%)
	Others	15 (4%)
	Sub total	**61 (16%)**
Finance	**Sub total**	**7 (2%)**
Legal	**Sub total**	**4 (1.5%)**
Education	**Sub total**	**3 (1.5%)**
Others	**Sub total**	**28 (7%)**
Total		**387 (100%)**

* Of the 124 publications listed under telemedicine, 116 articles were published in the *Journal of Telemedicine and E-health*, of which only 4 articles actually contained the term *e-health*

What Topics are Covered in the Literature Using the Term eHealth?

In our study, in order to identify the topics dealt with in papers explicitly referring to eHealth, article titles and abstracts were examined by a research fellow and classified using narrative descriptors. This indicated that the most common topics are related to telemedicine (25% of publications) or the Internet (13%), while some (6%) are concerned with issues such as the scope of eHealth, future trends, or progress and challenges in the field. Note that this view is possibly biased towards the telemedicine field, as all articles published in the *Journal of Telemedicine and E-health* were retrieved, even if they did not mention eHealth specifically. Other topics are distributed across a range of diffuse areas such as antiterrorism and medical errors, none of which is represented by more than 4 papers (hence relevant percentages have not been calculated). A heuristic summary is provided in Figure 6, which highlights the key topics and subtopics identified. These results are based on preliminary analysis; further validation work is underway.

Figure 6. Map of topics in published articles using the term eHealth

Definitions of eHealth

We identified 36 definitions of eHealth [13-52] appearing in published scientific abstracts and Web-based information sources (Table 4). As stated previously, our aim was not to perform an exhaustive and systematic review of definitions (which would have necessitated hand searching of full-text articles and reference lists), but to aggregate the most salient and easily accessible examples. Since many research databases are Internet accessible, there was some overlap between the definitions obtained by the two methods; however, they did yield largely unique results. In total, 36 definitions were identified. Definitions 1 to 15 were accessed via the research literature and 16 to 36 via the independent online searches, while 1, 5, 6, 7, 15 and 28 emerged from both searches.

Definitions were analyzed thematically in order to highlight specific technologies, applications or stakeholders referred to, and other theoretical concepts addressed, as detailed in Table 4. Analysis was initially performed by one investigator and the results checked by two others, thereby establishing agreement.

Our analysis suggests that there is significant variability in the scope and focus of existing definitions of eHealth both within the research literature and relevant sources on the World Wide Web. In terms of its functional scope, most definitions conceptualize eHealth as a broad range of medical informatics applications for facilitating the management and delivery of health care. Purported applications include dissemination of health-related information, storage and exchange of clinical data, interprofessional communication, computer-based support, patient-provider interaction and service delivery, education, health service management, health communities, and telemedicine, among others. A few narrow the concept down to specific applications, such as telemedicine or e-business, but these are the exceptions. While the range of applications is broad, a general theme relates to communication. One example is "E-health is connectivity; it is transactional; it is clinical. It is informational, interactive and interventional."[43]

The majority of definitions (n=24) specify the use of networked information and communications technologies, primarily the Internet, and digital data, thus differentiating eHealth from the broader field of medical informatics, which incorporates "harder" technologies, such as scanning equipment, and bioinformatics research which tends to take place in isolation and is less directly applicable to health care service delivery. It is acknowledged that the Internet "…has the reach, the infrastructure, and the acceptance to achieve widespread change" [17] and it is envisaged that "Internet technology may rank with antibiotics, genetics and computers as among the most important changes for medical care delivery."[16] Only 1 definition makes specific reference to harder technologies such as nanotechnology, robotics and laboratory tools [27], although another refers to Internet-compatible ICTs such as digital TV [40]. Of the 36 definitions identified, a sizable proportion make reference to telemedicine or telecare, either explicitly (7 examples) or in terms commonly used to describe these areas, such as delivery of care over distances. In most cases this is presented as part of a wider sphere of applications, although the definition from NHS Wales clearly identifies eHealth with telemedicine and telecare [45]. We identified 6 definitions that make explicit reference to business or e-business, although others contain related ideas such as the online trading of goods and services. In the majority of cases, such commercial applications are presented as merely one expression of eHealth.

In terms of the stakeholders considered to be the users or targets of eHealth, many definitions emphasize applications for providers and organizations–particularly those stressing electronic data exchange for clinical and administrative purposes. Others emphasize provision of information, education and services to consumers, including patients and "citizens", with a small number clearly identifying eHealth with consumer health informatics [14, 46, 50]. Nevertheless the majority appear to encompass applications for *all stakeholder groups*, whether specified or implied by the breadth of the definition.

There is also variation in the degree to which alternative definitions consider wider theoretical issues, such as the influence of eHealth on society or on professional behaviour. Several highlight the changing cultural environment of health care; particularly growing patient empowerment (access to information and ability to use it), and point to the potential of eHealth to facilitate doctor-patient communication, partnership and shared decision making. Others emphasize the changes required to ensure that eHealth reaches its full potential, recognising that it requires new ways of working and attitudes and must take account of human and organizational influences affecting technology adoption and change. More broadly, eHealth is said to require a fundamental rethinking of health care processes and a commitment for networked global thinking to improve health care [22]. Overall, the definitions suggest a general excitement and optimism about the potential of this rapidly evolving field to improve health care processes and patient outcomes, and many clearly identify projected benefits such as improved clinical decision making, efficiency and safety.

Table 4. Definitions of eHealth identified from searching databases of scientific abstracts and wider Web-based information sources

Definition	Source	Date	Technologies Specified	Applications Specified	Stakeholder Focus (and Other Concepts)
1) “e-Health is a consumer-centred model of health care where stakeholders collaborate, utilizing ICTs, including Internet technologies to manage health, arrange, deliver and account for care, and manage the health care system”	Alvarez [13], based on Ontario Hospital e-health Council [14]	2002 (2002)	ICTs including Internet	General: manage health, arrange, deliver and account for care, and manage the health care system	Consumer centered but also emphasizes collaboration with providers
2) “Healthcare delivery is being transformed by advances in e-health and by the empowered, computer-literate public. Ready to become partners in their own health and to take advantage of online processes, health portals, and physician web pages and e-mail, this new breed of consumer is slowly redefining the physician/patient relationship. Such changes can effect positive results like improved clinical decision-making, increased efficiency, and strengthened communication between physicians and patients.”	Ball and Lillis [15]	2001	Internet online processes, health portals, physician en-pages, email.	General: healthcare delivery	Consumers (Change. Citizen empowerment. Physician/patient relationship/ communication. Improved clinical decision making, efficiency)
3) “The "e-health" era is nothing less than the digital transformation of the practice of medicine, as well as the business side of the health industry…. The Internet is the next frontier of health care. Health care consumers are flooding into cyberspace, and an Internet-based industry of health information providers is springing up to serve them. Internet technology may rank with antibiotics, genetics, and computers as among the most important changes for medical care delivery.”	Coile [16]	2000	Internet	The practice of medicine as well as the business side of the health industry	Consumers and providers (Change. New frontiers. Transformation of medical practice.)
4) “E-health—any electronic exchange of healthcare data or information across organizations—reflects an industry in transition…. The Internet clearly drives the development and adoption of e-health applications; standing alone, it has the reach, the infrastructure, and the acceptance to achieve widespread change.”	DeLuca and Enmark [17]	2000	Internet	Electronic exchange of healthcare data or information across organizations	Not specified. Implies focus on professional & organizational levels (Change)
5) "a new term needed to describe the combined use of electronic communication and information technology in the health sector... the use in the health sector of digital data - transmitted, stored and retrieved electronically - for clinical, educational and administrative purposes, both at the local site and at distance"	Della Mea [18], based on Mitchell [19]	2001 [1999]	Combined use of electronic communication in and IT in the health sector. Digital data transfer	Transmission of digital data locally and across distances, for clinical, educational and administrative purposes	Professionals and organizations
6) “e-health is the use of emerging information and communication technology, especially the Internet, to improve or enable health and healthcare.”	Eng [20], based on Eng [21]	2004 [2001]	Emerging ICTs, especially the Internet	General: To improve or enable health and health care	Not specified but implies consumers and providers
7) “e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.”	Eysenbach [22]	2001	Broad definition encompassing many aspects of health informatics but focusing on the Internet and related technologies	Delivery of health services and information	Not specified. Implies consumers and providers. (“a state of mind, a way of thinking, an attitude and commitment for networked, global thinking to improve healthcare…”)
8) “Many of the major forces of change impacting health care today have technological underpinnings, and many of the less desirable impacts may have technological solutions. Two related technological forces are transacting business, online (e-business) and delivering health care online (e-health).”	Ellis and Schonfeld [23]	2001	Internet	General: Delivering healthcare	“Delivering” implies focus on professionals (Change. Relationship between eHealth and eBusiness)

Definition	Source	Date	Technologies Specified	Applications Specified	Stakeholder Focus (and Other Concepts)
9) “ehealth includes use of the internet or other electronic media to disseminate health related information or services.”	Gustafson and Wyatt [24]	2004	Internet or other electronic media	Dissemination of health related information or services	Implies consumers
10) “As a special expression of e-business in the health service the sphere of e-health has developed in recent years which increasingly manifests itself in the internet via health portals. Next to the transmitting of medical contents, the offer of community functions and the trading with goods from the medical sector, these health portals now increasingly provide advisory services for citizens by medical experts.”	Khorrami [25]	2002	Increasingly manifests itself in the Internet via health portals.	e-business Heath advice. Information exchange. Community functions. Advisory services for citizens	Consumers Healthcare organizations
11) “e-Health (use of interactive communication and information technologies to engage in health-related activities) includes not only telehealth-related media and telecommunications but also a wide array of consumer and healthcare provider activities that use the Internet.”	Maddox [26]	2002	Interactive ICT, telehealth, internet etc	General: health-related activities	Consumer and healthcare provider
12) “ …technologies with practical applications that have the potential to improve both quality of and access to healthcare….Telemedicine, Health Information Systems, Databases, Genomics, Biotechnology, eLearning, Continuing Professional Development, Nanotechnology, Drug Treatment Technologies, Decision Making Tools, Diagnostic Aids, eLibraries, Laboratory tools, and Robotics are all innovative or 'disruptive' technologies that promise a better health for our children.”	McConnell [27]	2002	Wide range of digital technologies	Wide range of informatics applications that may contribute to improved quality of and access to healthcare	Providers and patients (Quality. Access. “Disruptive technologies”)
13) “e-Health offers the rich potential of supplementing traditional delivery of services and channels of communication in ways that extend the healthcare organization's ability to meet the needs of its patients. Benefits include enhanced access to information and resources, empowerment of patients to make informed healthcare decisions, streamlined organizational processes and transactions, and improved quality, value, and patient satisfaction.”	Nazi [28]	2003	Not specified	Delivery of services Communication. Access to information and resources.	Patients (empowerment, satisfaction) Organization (efficiency and quality)
14) “the use of the Internet for health purposes”	Provost et al [29]	2003	Internet	General: “Health purposes”	Any
15) "a means of applying new low cost electronic technologies, such as 'web enabled' transactions, advanced networks and new design approaches, to healthcare delivery. In practice, it implies not only the application of new technologies, but also a fundamental re-thinking of healthcare processes based on using electronic communication and computer-based support at all levels and for all functions both within the healthcare service itself and in its dealings with outside suppliers. eHealth is a term which implies a way of working rather than a specific technology or application".	Richardson [30], based on Silicon Bridge [31]	2003 [2001]	Internet New low-cost electronic technologies such as ”web enabled” transactions and advanced networks”	General: “Healthcare delivery” Electronic communication and computer-based support at all levels and for all functions	‘Healthcare delivery [and] processes' implies organizational/ professional level (“…a way of working”)
16) “The healthcare industry's component of business over the internet.”	Blutt [32]	2001	Internet	Business	Implies organizations
17) "The application of the Internet and other related technologies in the healthcare industry to improve the access, efficiency, effectiveness, and quality of clinical and business processes utilized by healthcare organizations, practitioners, patients, and consumers to improve the health status of patients."	Broderick and Smaltz [33]	2003	Internet and related technologies	Improvement of access, efficiency, effectiveness and quality of clinical and business processes	Organizations, practitioners, patients, consumers

Definition	Source	Date	Technologies Specified	Applications Specified	Stakeholder Focus (and Other Concepts)
18) “eHealth includes the development, application and implementation of technology to improve effectiveness in healthcare. But it also includes getting it out there wherever it's needed in the service and making it happen across the service. It includes the use of telemedicine and clinical systems used for diagnosis and care pathways. We also apply the term to the policies and protocols that assure the confidentiality and security of sensitive data. Most of all it includes those aspects that support major change of working practice - training, support and Organisational Development.”	Chisholm [34]	2003	Technology	Telemedicine Clinical systems for diagnosis and care pathways Policies and protocols	Not specified, but implies organizational/professional focus (Importance of organizational and professional behaviour change recognized. Also confidentiality and security issues.)
19) “…using Information and Communications Technologies to ensure the right treatment to each patient, specialised to each individual's context and situation, and to deliver healthcare where patients and providers need not be in the same place at the same time.	CSIRO [35]	Undated	ICTs	Delivery of personalized patient care. Telemedicine implied	Not specified. Implies provider focus but also interaction with patients
20) "Put simply, e-health is a wide-ranging area of social policy that uses new media technologies to deliver both new and existing health outcomes. In the UK, it incorporates everything from NHS Direct online to Internet pharmacies to webcast operations involving consultants in another country…At the moment, the main focus of e-health is on patient empowerment and self-care. As the area develops, e-health could expand to include online long-term disease management, personalised health checks, and more efficient primary care services due to informed patients accessing the healthcare system at the most appropriate point."	GJW Government Relations Ltd [36]	2000	New media technologies	On-line health information Long-term disease management and patient self-care Telemedicine	Patients and professionals (Patients emphasized)
21) “something to do with computers, people, and health”(Centre for Global e-Health Innovation, 2003)	Gustafson [37]	2003	Computers in general	Very broad – computers, people and health	Implies all stakeholders
22) “the application of information and communication technologies (ICT) across the whole range of functions which, one way or another, affect the health of citizens and patients.”	European Commission [38]	2003	ICTs	Broad – the whole range of functions which, in one way or another, affect the health of citizens and patients	All stakeholders. Providers, patients, citizens.
23) “the emerging world of e-health can be defined as the application of information, communication and video technologies to the delivery of timely, professional and safe healthcare.”	European Health Telematics Association [39]	2004	ICT and video technologies	Broad – delivery of timely, professional and safe care	Not specified. Implies professional perspective.
24) “the use of emerging interactive technologies (i.e., Internet, interactive TV, interactive voice response systems, kiosks, personal digital assistants, CD-ROMs, DVD-ROMs) to enable health improvement and health care services. For this Initiative, these technologies should focus primarily on health behavior change and chronic disease management for consumers/patients.”	Health e-Technologies Initiative [40]	2002	Emerging interactive technologies (Internet, interactive TV, interactive voice response systems, kiosks, personal digital assistants, CD-ROMs, DVD)	Enabling health improvement and health care services, chronic disease management, health behaviour change	Consumers, patients
25) “the use of ICT to support and improve healthcare”	Hoving et al [41]	2002	ICT	General: support and improve health care	Not specified.
26) "eHealth means taking the most recent developments in computer and networking technology, and applying it to the problems facing the healthcare community in all its forms - eHealth is the endeavour to produce reliable, easy-to-use, highly-automated, accurate systems, so that health care professionals can spend less time and resources on finalising the paperwork, and more time doing what they do best - taking care of people's health!"	IBA eHealth [42]	Undated	Recent developments in computer and networking technology	General: Applying it to the problems facing the healthcare community in all its forms Specific: administrative and clinical information to improve efficiency	Professionals (improved efficiency)

Definition	Source	Date	Technologies Specified	Applications Specified	Stakeholder Focus (and Other Concepts)
27) “The "e" is for electronic. Placed before the word health, it implies all things transmitted and technological in health care, which help improve the flow of information and the process of health care delivery. "E" networks integrate isolated towers of information and create new knowledge through the creation of relational databases. The spectrum of "E" is broad and goes beyond the use of a computer as a box on the desktop. It includes wireless communication using hand-held devices and the storage and function by the microchip which is revolutionizing health care, as it is inserted into everything we use to diagnose, treat, record, sort, analyze, and conclude. It also incorporates electronic forms of care delivery, such as telemedicine, providing health care over a distance, communicating by sound and image transmission. E-health is connectivity; it is transactional; it is clinical. It is informational, interactive and interventional.”	Marcus and Fabius [43]	Undated	Electronic networks, relational databases. Wireless communication.	All things transmitted and technological in health care, which help improve the flow of information and the process of health care delivery Electronic care delivery (telemedicine) Sound and image transmission	Not specified Connectivity; communication, interactivity, intervention
28) "the health services organisation and societal approach to health and health services which result from the introduction of, and increasing access to, new digital technologies: including the Internet, other computerised networks and tele- or distant health care facilitated by new digital technologies".	NHS SDO Programme [44]	2002	New digital technologies Internet Other computerized networks Telemedicine	Health service organization “Societal functions”	Organizations Society (citizens)
29) “More commonly known as “eHealth”, the headings of Telemedicine and Telecare are themselves subsumed under the framework category of "health informatics", which basically means the delivery of healthcare and medical knowledge through the application of advanced information and computer technologies.”	NHS Wales [45]	2003	Advanced information and computer technologies	Telemedicine and Telecare.	Not specified. (Identified eHealth with telemedicine)
30) “The big difference between yesterday's knowledge-based patient care and that of tomorrow is a fundamental premise that patients will explore the web world with a desire to learn more about their condition, including its treatment and prognosis. This has evolved into the concept of e-health”	Podichetty and Biscup [46]	2003	Internet	Patient information and decision support	Patients (Cultural shift to patient participation/ empowerment in health care)
31) “eHealth signifies a concerted effort undertaken by some leaders in healthcare and hi-tech industries to harness the benefits available through convergence of the internet and healthcare…”	Rx2000 Institute [47]	Undated	Internet	None specified	Not specified. Implies organizations (Harnessing benefits of converging internet and healthcare)
32) “eHealth describes the application of information and communications technologies (ICT) across the whole range of functions that help health. It is the means to deliver responsive healthcare tailored to the needs of the citizen.”	Silber [48]	2003	ICTs	Broad – the whole range of functions that help health	Citizens (consumers, patients, public)
33) “E-health is a new term used to describe the combined use of electronic communication and information technology in the health sector OR is the use, in the health sector, of digital data-transmitted, stored and retrieved electronically-for clinical, educational and administrative purposes, both at the local site and at a distance.”	WHO [49]	Undated	ICTs Digital data	Clinical, educational and administrative purposes, at the local site and at a distance	Organizations/professionals
34) “Using the internet and other electronic media to disseminate or provide access to health & lifestyle information or services”	Wyatt [50]	2003	Internet and other electronic media	Access to health and lifestyle information or services	Patients, public
35) “e-Health refers to all forms of electronic healthcare delivered over the Internet, ranging from informational, educational and commercial "products" to direct services offered by professionals, non-professionals, businesses or consumers themselves. e-Health includes a wide variety of the clinical activities that have traditionally characterized telehealth, but delivered through the Internet. Simply stated, e-Health is making health care more efficient, while allowing patients and professionals to do the previously impossible.”	Wysocki [51]	2001	Internet	Delivery of informational, educational and commercial "products" Direct delivery of services Clinical activities traditionally characterized telehealth	Professionals, consumers, businesses (Making health care more efficient, while allowing patients and professionals to do the previously impossible)

Definition	Source	Date	Technologies Specified	Applications Specified	Stakeholder Focus (and Other Concepts)
36) "E-health is a very broad term that encompasses many different activities related to the use of the Internet for healthcare. Many of these activities have focused on administrative functions such as claims processing or records storage. However, there is an increasing use of e-health related to patient and clinical care."	American Telemedicine Association [52]	2001	Internet	Administrative functions, patient and clinical care	Not specified. Implies organizational and professional focus (increasing use of eHealth for patient and clinical care)

Discussion

We have established that *eHealth* is a new term which has yet to be formally represented in bibliographic research taxonomies but is part of the wider field of medical or health informatics. The *Medical Informatics* MeSH tree encompasses most topics likely to be classed as eHealth and is broadly compatible with an expert-derived taxonomy endorsed by IMIA. Since eHealth cuts across a range of health informatics topics a new MeSH term may neither be necessary nor appropriate at the present time. Topics related to eHealth are distributed across all component MeSH trees within the broader field, although most are represented by the *Medical Informatics Applications* tree, which emphasizes functions of technologies, rather than technologies themselves, and prioritizes delivery of clinical information, care or services. The medical informatics literature has grown steadily over the last 15 years although research on some topics, such as clinical laboratory information systems, is becoming less prevalent, while that on others, such as computer-assisted diagnosis, has recently increased rapidly, reflecting a change in emphasis from systems and database architectures to supportive applications.

Research articles explicitly referring to eHealth or its variants begun to appear in 2000 and are accumulating rapidly. The majority of such articles are indexed by Medline, although others appear in alternative databases. Such articles are published in a wide range of journals, spanning information science to law, but they are most commonly represented in journals related to health care information technology and telemedicine. A vast array of topics is covered by research articles referring to eHealth, highlighting the diffuse nature of the field and the lack of an agreed conceptual definition.

Definitions of eHealth demonstrate variation in the breadth and focus of alternative conceptualizations. At the extremes these range from the highly vague and diffuse, eg, "something to do with computers, people and health" [37] to the highly specific, eg, "the healthcare industry's component of business over the internet." [32] Nevertheless, most conceptualize eHealth as a broad range of medical informatics applications for facilitating the management and delivery of health care, including dissemination of health-related information, storage and exchange of clinical data, interprofessional communication, computer-based support, patient-provider interaction, education, health service management, health communities and telemedicine, among other functions. A general theme relates to electronic communication, which is supported by the fact that most definitions specify the use of networked digital information and communications technologies, primarily the Internet. This differentiates eHealth from its parent field of medical informatics, which encompasses fixed technologies, such as X-Ray equipment, and pure bioinformatics research. While Internet technologies represent the prevailing theme, there is sufficient reference to applications that may be enabled by other interactive ICTs to suggest caution before identifying eHealth exclusively with this medium. This is supported by the high profile of decision support as a generic topic within the health informatics literature, which may, for example, take the form of clinical decision support systems or patient decision aids available via CD-ROM. Nevertheless, rapid increases in bandwidth and desktop computing capability make it likely that most such tools will soon be accessible using digital networked systems.

Many conceptualizations of eHealth incorporate telemedicine and although most do so as part of a wider sphere of applications, some authors use the terms synonymously [45]. We suggest that the latter is more likely due to a misuse of the term than, as some have speculated, "the death of telemedicine" in favour of eHealth [19] (cited in [18]). While telemedicine is certainly a theme in the eHealth literature, and the ICTs used in this area are common to many eHealth functions, it clearly represents only one domain of the broader field. Similarly, while several definitions extend to e-business, primarily meaning online transactions between suppliers and purchasers (2% of eHealth-related articles appear in journals of finance), most of these portray it as merely one application of eHealth for service management or care delivery.

Most definitions appear to encompass applications for all stakeholder groups, although many emphasize support for providers and organizations and a few see eHealth as an application of consumer health informatics or, even narrower, as the use of "internet and other electronic media to disseminate or provide access to health & lifestyle information or services."[50] Our review of eHealth topics in the research and Web-based literature also indicates that the concept extends across stakeholder groups, including providers, patients, citizens, organizations, managers, academics and policymakers. A tendency has been noted for an inclusive model to predominate in Europe and a narrower consumer-focused one in the USA, possibly reflecting top-down versus bottom-up health systems and cultures [53]. However our results indicate that there is currently more overlap than difference between conceptualizations emanating from either side of the Atlantic, with the inclusive view predominating (also the case for Australia). Even of those conceptualizations tending toward the consumer informatics model, most emphasize interaction with professionals rather than simply passive delivery or provision

of information to citizens or patients, thus drawing in the professional stakeholder. While there may be a valid argument for narrowing eHealth down to consumer health informatics in the future, namely to circumscribe the field and thereby make it more manageable, analysis of the existing eHealth landscape suggests that the concept is currently more inclusive.

Existing conceptualizations also vary in the extent to which they consider broader issues relating to the place, function or promise of eHealth in the modern world, such as its ability to promote patient self-care and communication, and the implications of this for the doctor-patient relationship. Many see eHealth as facilitating the transition of decision making control and responsibility from the professional to the empowered consumer, consistent with conceptions of the information age flipping over the "power pyramid" of health care [54]. The human and organizational changes required to effect new ways of working and attitudes also represent a strong theme. This is reflected in the relatively large number of publications, identified by the keyword search, that are concerned with issues such as challenges to implementation, as opposed to specific technologies or applications. We therefore agree that the concept incorporates "a state-of-mind, a way of thinking, an attitude." [22] Such human and organizational factors appear to be underrepresented in the MeSH *Medical Informatics* taxonomy at present, suggesting that a review may be warranted to bring it into line with expert-derived ontologies such as that endorsed by IMIA. More broadly, eHealth is said to require a fundamental rethinking of healthcare processes" [31] and a "commitment for networked global thinking to improve healthcare" [22], but there is clearly a general optimism surrounding the potential benefits of this rapidly evolving field for health care processes and patient outcomes.

Of course, definitions do not exist in isolation and the source documents for those reviewed provide further elaboration. For example, Eng provides a "5 C's model" of functions and capabilities of eHealth (content, connectivity, community, commerce, care) [21]; Eysenbach lists "10 essential E's" in eHealth (efficiency, enhancing quality of care, evidence-based, empowerment of consumers, etc) [22], and Richardson proposes a "4-pillar model" (under the headings of clinical applications, healthcare professional continuing education, public health information, and education and lifetime health plan) [30]. Yet others have attempted to define eHealth in terms of its potential role during a patient's care pathway [55] or with reference to the settings in which it may be useful [48]. Nonetheless, most authors have successfully distilled their concepts within the definitions they provide. Converging these with the other information sources documented in this report provides a fairly comprehensive overview of the concept and enables us to draw broad conclusions about its nature and scope.

In an editorial on the website, Health Informatics Europe, Ahmad Risk posed the question: "So, is this it? … Does 'eHealth' mean 'web health informatics'?"[9] Based on our results, our conclusion is largely "Yes", or "It soon will be", recognising that the parameters of the field currently extend to other interactive ICTs which, with increasing computing power, bandwidth and wireless capability, may rapidly be accommodated by Internet technologies. Based on our analysis of the place of eHealth within the wider informatics field and the nature of research activity and general commentary on the topic, we conclude that it is well represented by the global definitions suggested by Eng and Eysenbach early in the emergence of the field, with a minor change to the latter, as indicated below:

> *e-health is the use of emerging information and communications technology, especially the Internet, to improve or enable health and healthcare. [21]*
>
> *e-health is an emerging field of medical informatics, referring to the organization and delivery of health services and information using the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a new way of working, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology. (adapted from Eysenbach [22])*

Acknowledgments

The research was supported with funds from the NHS Service Delivery and Organisation Research and Development Programme. The project reference number is SDO/60/2003.

We thank Silvia Anton for contributing to the research proposal and for feedback on draft reports.

Contributorship

Claudia Pagliari drafted the paper, which was commented upon by all authors prior to submission. The project was designed and supervised by Claudia Pagliari and Peter Gregor, with input from Frank Sullivan, Don Detmer, Jim Kahan and Wija Oortwijn. Steve MacGillivray and David Sloan acted as the project research fellows – collecting and analysing the data with assistance from Claudia Pagliari, Peter Gregor and other authors. Editorial note: Figures 2-4 were redrawn by the editor, using Hubmed (http://www.hubmed.org).

Conflicts of Interest

None declared.

Multimedia Appendix 1

Medline MeSH descriptors potentially relevant to eHealth. [MS-Word file, 168 KB - jmir_v7i1e9_app1.doc]

Multimedia Appendix 2

Journals in which publications explicitly the terms *eHealth*, *e-health*, or *e health* appear. [MS-Word file, 192 KB - jmir_v7i1e9_app2.doc]

References

1. ; Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academies Press; Jun 1, 2001. URL: http://www.nap.edu/books/0309072808/html/
2. ; National Committee on Vital and Health Statistics. Information for Health: A Strategy for Building the National Health Information Infrastructure. Washington, DC: US Department of Health and Human Services; Nov 15, 2001. URL: http://aspe.hhs.gov/sp/nhii/Documents/NHIIReport2001/default.htm [accessed 2005 Feb 1]
3. ; Office of Health and the Information Highway. Canada Health Infoway: Paths to Better Health. Ottawa, Canada: Health Canada; Feb 1999. URL: http://www.hc-sc.gc.ca/ohih-bsi/pubs/1999_pathsvoies/info_e.html [accessed 2005 Feb 1]
4. ; Australian Health Information Council. Strategic Plan for Information Management and Information and Communication Technology (IM&ICT) in Health. Canberra: Australia; 2004. URL: http://www.ahic.org.au/strategy/index.html [accessed 2005 Feb 1]
5. ; Department of Health and Children. Health Information: A National Strategy. Dublin, Ireland URL: http://www.dohc.ie/publications/pdf/nhis.pdf?direct=1 [accessed 2005 Feb 1]
6. ; UK Department of Health. Information for Health Strategy Document. 1999. URL: http://www.dh.gov.uk/PolicyAndGuidance/InformationPolicy/InformationForHealth/ExecutiveSummaryArticle/fs/en?CONTENT_ID=4015309&chk=NBKLfo [accessed 2005 Feb 25]
7. ; UK Department of Health. National Programme for IT. URL: http://www.npfit.nhs.uk/ [accessed 2005 Feb 24]
8. Risk A. What is e-health? Email sent to the SIM mailing list. 2001. URL: http://www.venus.co.uk/hypermail/sim/0101/0001.html [accessed 2004 Jul 13]
9. Risk A. Editorial: What is e-health? Health Informatics Europe 2004 Jun 7 [FREE Full text]
10. Oh H, Rizo C, Enkin M, Jadad A. What is eHealth (3): a systematic review of published definitions. J Med Internet Res 2005 Feb 24;7(1):e1 [FREE Full text] [Medline: 15829471] [doi: 10.2196/jmir.7.1.e1]
11. Pagliari C, Gregor P, Sloan D, Mcgillivray S, Sullivan F, Kahan J, et al. Literature Review and Conceptual Map of the Field of eHealth. Final Report to the NHS Service Delivery and Organisation Programme. 2005. URL: http://www.sdo.lshtm.ac.uk/ehealth.htm#pagliari [accessed 2005 Feb 28]
12. Lorenzi NM. Working and Special Interest Groups: Connecting the world's medical informatics working groups. Yearbook of Medical Informatics 2002:71-72 [FREE Full text]
13. Alvarez RC. The promise of e-Health - a Canadian perspective. eHealth Int 2002 Sep 17;1(1):4. [Medline: 12459044] [PMC: 12459044] [doi: 10.1186/1476-3591-1-4]
14. ; Ontario Hospital e-health Council. An Ontario Health Blueprint and Strategic Agenda. 2002 Nov. URL: http://www.hctp.utoronto.ca/Pdf/Technology%20Course%20Readings/BlueprintandStrategicAgendaFINAv1_Nov2002.pdf [accessed 2005 Feb 15]
15. Ball MJ, Lillis J. E-health: transforming the physician/patient relationship. Int J Med Inform 2001 Apr;61(1):1-10. [Medline: 21145978] [doi: 10.1016/S1386-5056(00)00130-1]
16. Coile RC. The digital transformation of health care. Physician Exec 2000 Jan;26(1):8-15. [Medline: 20163258]
17. Deluca JM, Enmark R. E-health: the changing model of healthcare. Front Health Serv Manage 2000 Dec;17(1):3-15. [Medline: 20470299]
18. Della Mea V. What is e-health (2): the death of telemedicine? J Med Internet Res 2001 Jun 22;3(2):e22 [FREE Full text] [Medline: 21578029] [doi: 10.2196/jmir.3.2.e22]
19. Mitchell J. From telehealth to e-health: the unstoppable rise of e-health. Canberra, Australia: National Office for the Information Technology; 1999. URL: http://www.noie.gov.au/projects/ecommerce/ehealth/rise_of_ehealth/unstoppable_rise.htm [accessed 2005 Feb 1]
20. Eng TR. Population health technologies: emerging innovations for the health of the public. Am J Prev Med 2004 Apr;26(3):237-242. [Medline: 15026105] [doi: 10.1016/j.amepre.2003.12.004]
21. Eng T. The e-Health Landscape – a terrain map of emerging information and communication technologies in health and health care. Princeton NJ: The Robert Wood Johnson Foundation; 2001. URL: http://www.rwjf.org/global/404errorpage.jhtml?requestedDocument=/publications/publicationsPdfs/eHealth.pdf [accessed 2004 Jul]
22. Eysenbach G. What is e-health? J Med Internet Res 2001 Jun 18;3(2):e20 [FREE Full text] [Medline: 21578027] [doi: 10.2196/jmir.3.2.e20]
23. Ellis D, Schonfeld PJ. E-business, e-health, e-hospitals. Mich Health Hosp 2001 Jul;37(4):46-47. [Medline: 21360764]

24. Gustafson DH, Wyatt JC. Evaluation of ehealth systems and services. BMJ 2004 May 15;328(7449):1150. [Medline: 15142895] [doi: 10.1136/bmj.328.7449.1150]
25. Khorrami E. [E-health and Cyberdoc - "health portals" from a professional and quality assurance viewpoint]. Gesundheitswesen 2002 ;64(8-9):466-475. [doi: 10.1055/s-2002-33779] [Medline: 22209350]
26. Maddox P. Ethics and the Brave New World of E-Health. Online J Iss Nurs. 2002 Nov 21. URL: http://nursingworld.org/ojin/ethicol/ethics_10.htm
27. Mcconnell H. eHealth International. eHealth Int 2002 Sep 17;1(1):1. [Medline: 12459047] [PMC: 12459047] [doi: 10.1186/1476-3591-1-1]
28. Nazi KM. The journey to e-Health: VA Healthcare Network Upstate New York (VISN 2). J Med Syst 2003 Feb;27(1):35-45. [Medline: 22504060] [doi: 10.1023/A:1021005111996]
29. Provost M, Perri M, Baujard V, Boyer C. Opinions and e-health behaviours of patients and health professionals in the U.S.A. and Europe. Stud Health Technol Inform 2003;95:695-700. [Medline: 23026314]
30. Richardson R. eHealth for Europe. Stud Health Technol Inform 2003;96:151-156. [Medline: 23233466]
31. ; Silicon Bridge Research. Understanding the market for eHealth: study report. Basingstoke, UK: Silicon Bridge Research Ltd; 2001.
32. ; Blutt MP for JP Morgan Partners. The Rise & Fall and ??? Of e-Health. Seminar Series, Leonard Davis Institute of Health Economics, University of Pennsylvania. 2001 Jan 26. URL: http://www.upenn.edu/ldi/healthpolicyseminarjan26_Jan.%2022%20'01.ppt [accessed 2005 Feb 1]
33. Broderick M, Smaltz D. HIMSS E-Health White Paper: e-Health Defined. Chicago: Healthcare Information and Management Systems Society; May 5, 2003. URL: http://www.himss.org/content/files/ehealth_whitepaper.pdf [accessed 2005 Feb 1]
34. Chisholm M. Speech given by the Scottish Minister for Health at a meeting to discuss the national electronic clinical communications programme. 2003 Feb 28. URL: http://www.show.scot.nhs.uk/ecci/docs/conference/conference/spch-ECCIConf28feb2003.doc [accessed 2005 Feb 1]
35. Commonwealth Scientific & Industrial Research Organisation. Victoria, Australia: ICT Centre URL: http://www3.ict.csiro.au/ict/landing/channelandchildoverview/0,,a16254_b16406,00.html [accessed 2005 Feb 1]
36. ; GJW Government Relations Ltd. Memorandum to the UK Parliament Select Committee on European Union. 2000 Mar 29. URL: http://www.publications.parliament.uk/pa/ld199900/ldselect/ldeucom/95/95we29.htm [accessed 2005 Feb 1]
37. Gustafson D. Quoted on the website of the Centre for Global eHealth Innovation. URL: http://www.uhnresearch.ca/centres/ehealth/html/what/eh_what_faq_students.shtml [accessed 2005 Feb 1]
38. ; European Commission. What is E-health?. URL: http://europa.eu.int/information_society/eeurope/ehealth/whatisehealth/index_en.htm [accessed 2005 Feb 1]
39. ; European Health Telematics Association. e-health Information Systems: A High Level Position Paper. 2004 Apr 26. URL: http://www.ehtel.org/SHBlob.asp?WCI=ShowD&F=english%2Fdti56098%2Fti135.TF_Patients_%26_Citizens-Position_Paper-2004.04.26-v01.0.pdf [accessed 2005 Feb 1]
40. ; Health e-Technologies Initiative. Frequently Asked Questions from 2002 Call for Proposals: What is eHealth?. URL: http://www.hetinitiative.org/sub-call_for_proposals/cfp-faqs.html [accessed 2005 Feb 1]
41. Hoving D, De Koning N, Van De Pas R, Dries J; Netherlands Council for Public Health and HealthCare. ICT, Health and Living – an exploration of trends, players and services in the Netherlands. 2002. URL: https://doc.telin.nl/dscgi/ds.py/Get/File-31979/xhome_D1.1.pdf [accessed 2005 Feb 15]
42. IBA eHealth. Sydney, Australia URL: http://www.ibatech.com/ProductList.asp?iProductCategoryID=3 [accessed 2005 Feb 1]
43. Marcus E, Fabius R. Primer for American College of Physician Executives. Tampa, Fl, USA URL: http://www.acpenet.org/Forums/Topical/Ehealth/Primer.htm [accessed 2005 Feb 15]
44. ; NHS Service Delivery and Organisation Programme. Research Commissioning Brief. 2002. URL: http://www.sdo.lshtm.ac.uk/pdf/eh1_brief.pdf [accessed 2005 Feb 1]
45. ; NHS Wales UK. What Is Telemedicine?. URL: http://www.wales.nhs.uk/sites/page.cfm?orgid=351&pid=1925 [accessed 2005 Feb 1]
46. Podichetty VK, Biscup RS. The Internet Journal of Allied Health Sciences and Practice 2003;1(2) [FREE Full text]
47. ; Rx2000 Institute. e-health FAQ: Frequently Asked Questions. URL: http://www.rx2000.org/ehealth/ehfaq.htm [accessed Feb 1 2005]
48. Silber D. The Case for e-Health. European Commission's first high-level conference on e-Health. 2003 May 22. URL: http://europa.eu.int/information_society/eeurope/ehealth/conference/2003/doc/the_case_for_eHealth.pdf [accessed 2005 Feb 1]
49. ; World Health Organisation. E-health in the Eastern Mediterranean.: WHO Eastern Mediterranean Regional Office URL: http://www.emro.who.int/his/ehealth/AboutEhealth.htm [accessed 2005 Feb 1]
50. Wyatt J. eHealth: What are the likely impacts on patients, professionals and organisations?. Presented at: The Congress on ICT in Healthcare; June 11, 2003; Amersfoort, Netherlands URL: http://unimaas.exhem.nl/download/pres_wyatt.ppt [accessed Feb 1 2005]
51. Wysocki M. What is e-health? Suite101.com, Suite University. 2001 Jan 9. URL: http://www.suite101.com/article.cfm/9670/57010 [accessed 2005 Feb 1]

52. ; American Telemedicine Association. Telemedicine and E-Health. URL: http://www.atmeda.org/ehealth/ehealth.htm [accessed 2005 Feb 1]
53. Detmer D. Current Status on E-Health and Personal Health Records: European v. North American Perspectives. In: University of Edinburgh, Clinical and Community Health Sciences Seminar Series Jan 19, 2005. URL: http://www.chs.med.ed.ac.uk/gp/sempres/detmer.ppt [accessed 2005 Feb 1]
54. Ferguson T. Consumer health informatics. Healthc Forum J 1995 Jan;38(1):28-33. [Medline: 96167851]
55. Wilson P, Leitner CAMA. Mapping the Potential of eHealth: Empowering the Citizen through eHealth Tools and Services. Presented at: eHealth Conference; May 5-6 2004; Cork, Ireland URL: http://www.ehealthconference2004.ie/images/Mapping%20the%20Potential%20of%20eHealth.pdf [accessed 2004 Jun 21]

Abbreviations

ICT: Information and Communications Technology
IMIA: International Medical Informatics Association
IT: Information Technology
MeSH: Medical Subject Headings
NHS: National Health Service

submitted 07.03.05; peer-reviewed by F Griffiths; comments to author 10.03.05; revised version received 23.03.05; accepted 23.03.05; published 31.03.05.

Please cite as:
Pagliari C, Sloan D, Gregor P, Sullivan F, Detmer D, Kahan JP, Oortwijn W, MacGillivray S
What Is eHealth (4): A Scoping Exercise to Map the Field
J Med Internet Res 2005;7(1):e9
URL: http://www.jmir.org/2005/1/e9/
doi:10.2196/jmir.7.1.e9
PMID:15829481

Viewpoint

The Emergence of National Electronic Health Record Architectures in the United States and Australia: Models, Costs, and Questions

Tracy D Gunter[1], MD; Nicolas P Terry[2], LLM

[1]Department of Psychiatry, Roy J. and Lucille A. Carver College of Medicine, University of Iowa, Iowa City, IA, USA

[2]Center for Health Law Studies, School of Law, Saint Louis University, St. Louis, MO, USA

Corresponding Author:
Nicolas P Terry, LLM
Center for Health Law Studies
School of Law
Saint Louis University
3700 Lindell Boulevard
St. Louis, MO 63108
USA
Phone: +1 314 977 3998
Fax: +1 314 977 3332
Email: terry@slu.edu

Abstract

Emerging electronic health record models present numerous challenges to health care systems, physicians, and regulators. This article provides explanation of some of the reasons driving the development of the electronic health record, describes two national electronic health record models (currently developing in the United States and Australia) and one distributed, personal model. The US and Australian models are contrasted in their different architectures ("pull" versus "push") and their different approaches to patient autonomy, privacy, and confidentiality. The article also discusses some of the professional, practical, and legal challenges that health care providers potentially face both during and after electronic health record implementation.

(J Med Internet Res 2005;7(1):e3) doi:10.2196/jmir.7.1.e3

KEYWORDS

Medical records systems, computerized; delivery of health care; patient care; information management; medical record linkage; confidentiality; policy making; United States; Australia; Internet

Introduction

The electronic health record (EHR) is an evolving concept defined as a longitudinal collection of electronic health information about individual patients and populations. Primarily, it will be a mechanism for integrating health care information currently collected in both paper and electronic medical records (EMR) for the purpose of improving quality of care. Although the paradigmatic EHR is a wide-area, cross-institutional, even national construct, the electronic records landscape also includes some distributed, personal, non-institutional models.

Emerging EHR models present numerous challenges to health care systems, physicians, and regulators. This article provides explanation of some of the reasons driving the development of the EHR, describes three different EHR models, and discusses some of the practical and legal challenges that health care providers potentially face both during and after EHR implementation.

Stakeholders and Drivers

Information technology (IT) has become the principal vehicle that some believe will reduce medical error. In the United States, the non-governmental and highly influential Institute of Medicine (IOM) has committed to technology-led system reform [1] and urged "a renewed national commitment to building an information infrastructure to support health care delivery, consumer health, quality measurement and improvement, public accountability, clinical and health services research, and clinical education." [2] As is well known, this IT-led system reform involves several intersecting technologies, including the following: tracking systems (barcodes and Radio Frequency Identification [RFID]); computerized physician order entry (CPOE) systems; clinical decision support systems (CDSSs) that complement order entry devices operating with server-side systems that reference drug interaction information or treatment models (such as clinical practice guidelines); and enhanced reporting systems that provide for adverse event and medical

error disclosure, and facilitate population-based health care models and more extensive outcomes research.

The electronic record is at the center of the IOM's goal of eliminating most handwritten clinical data by the end of this decade [2]. Electronic records are superior to paper records because they decrease error due to handwriting problems and ease physical storage requirements [3]. Additionally, electronic records simultaneously leverage other error-reducing technologies and render them coherent. EHR models present significant additional advantages because of their potential to deliver a longitudinal record that tracks all medical interactions by a particular patient and provide comprehensive data across populations. Thus, the IOM envisions a longitudinal collection of electronic health information for and about individuals and populations as feeding data into error-reducing "knowledge and decision support systems." [4,5]

Error reduction aside, business concerns and structural changes in health care delivery are driving EHR implementation. Although some of these phenomena are unique to the US model of health care financing and delivery, mature systems in other countries must also accommodate stresses from similar developments. First, the shift from in-patient to ambulatory care (and other episodic models) has accelerated the need for accurate and efficient flow of patient medical and billing information between organizationally and geographically distinct providers. Second, the operational aspects of managed care, such as the data needs of "gate keeping" physicians, demands by payers for performance "report cards," and system administrators' increasing needs for sophisticated utilization review and risk management tools, have increased the need for data transparency [6]. Third, the growth of "shared care", whereby the patient both shares responsibility with the provider for care and is likely to have increasingly fragmented or episodic relationships with multiple providers, requires that patients must have access to health data generally and, more controversially, to information in their record [7,8]. Furthermore, it requires that providers have transparent access to other occasions of treatment, particularly pharmacotherapy. Finally, both patients and regulators are demanding increasing amounts of data regarding errors or near misses and outcomes in populations [9]—data that is difficult to generate without sophisticated data coding and nearly impossible to analyze without complex, comprehensive database systems.

In addition to safe, high-quality care, patients expect privacy, rights of access and correction [7], and the opportunity to give consent for research uses of their health information [10]. As patient care moves from an in-patient to ambulatory or other fragmented models of service delivery utilizing multiple providers, the portability of and timely access to data become increasingly important to patients as well as providers. In the words of one patient,

> *I don't want much - just for my medical records to be seen only by those whom I authorize, and for the record to be readily accessible to them wherever they are. . . . I would like a bigger say in what goes into my notes, and if I don't like something I would like it taken out. [11]*

Providers continue to embrace confidentiality to foster an environment in which patients will disclose information related to their health. However, in the realm of health information, the needs of those delivering, regulating, and paying for health care may be at odds with the principles of privacy and confidentiality [12,13]. Technological acquisition, storage, access to, and distribution of patient health data exacerbates that tension.

In addition to maintaining confidentiality, providers are subject to legal and ethical obligations to evaluate and document the encounter. Providers engage in narrative with the patient and form opinions throughout and across interviews [14]. Therefore it follows that the available EHR vocabulary must accommodate symptoms and modifiers in addition to diagnoses and summary statements [14]. Data entry systems must be seamless and unobtrusive, and should include handwriting or voice recognition in addition to standardized checklists and templates. Otherwise, provider time will be lost as physicians attempt to code findings during the encounter [14]. Since medical care itself is not standardized, it remains difficult to envision a "one size fits all" approach to medical record computing [8,15].

Although there has been debate among providers about the feasibility and safety of having all patient information computerized and available across institutions, the authors accept the premise that EHR implementation is inevitable because of the support for the idea from health care regulators, third-party payers, hospital administrators, and physician advocacy groups such as the American Medical Association [16].

Progress and Models

As EHR models have struggled towards maturity, some key questions have arisen. Debatable issues include the following: whether the originating record should supply complete data or a summary; whether the data subsequently generated is episodic or longitudinal; and whether patients and providers will either control which information is "pushed" to the central record or be spectators as comprehensive data is "pulled" by remote systems. The EHR models that are developing in Australia and the United States suggest some divergent answers to these questions. Although less visible than institutional (provider or governmental) models, a third EHR model focuses on a web-based, distributed "personal" longitudinal record. This model raises discrete quality and confidentiality issues.

Australia

Australia's proposed national health information network is called Health*Connect* [17]. The basic Health*Connect* model is to extract a summary record from locally collected patient data which is then aggregated to create a centralized Health*Connect* record that may then be shared among participating and authorized providers [18].

A Health*Connect* "event summary" consists of the "critical information considered to be useful to other health care providers involved in the future care of the consumer." [19] Thus, Health*Connect* does not create a comprehensive longitudinal record. Rather, patients, with their providers, will choose which elements may be extracted from an existing health

record and transmitted to the Health*Connect* record. Providers, with the consent of their patients, may subsequently add data to the Health*Connect* record. It follows, therefore, that *HealthConnect* is a "push" system, selectively sending data to a centralized record [20].

The patient controls which elements of the centralized record may be used for which purposes or displayed in which "views" [21]. For example, a patient might elect to include details of his psychotropic prescriptions in an event summary and consent to all his prescribing doctors viewing that data, but only consent to other mental health professionals viewing his psychiatrist's discharge order. The system's dedication to voluntary participation is desirable based on demonstrated patient interest in confidentiality. However, the summary data that is centralized may not fully support the system's secondary goals of disseminating professional education, supporting research, furthering utilization, increasing access, and improving quality [20]. Health*Connect* has completed 2 years of pilot testing. It is estimated that the system will save AUD $300 million per year by reducing errors and duplication of effort [20].

United States

The IOM has been critical of the rate of technology adoption by US hospitals [22]. Notwithstanding, and representing the public sector, the Department of Veterans Affairs is committed to process reform and technologically mediated delivery of services [23]. More broadly, the Consolidated Health Informatics (CHI) initiative is accelerating the use of common clinical vocabularies and messaging standards across federal agencies that process health data [24]. In addition to projects of national scope, some state governments have EHR launch initiatives; for example, Massachusetts has recently announced a statewide initiative, partially funded by the health insurer Blue Cross Blue Shield, with the goal of having a statewide electronic records system in place within five years [25]. Similar initiatives are being undertaken by some of the largest private providers; for example, Kaiser Permanente, the largest nonprofit health management organization (HMO) in the United States, with some 8.4 million members in 9 states and 12000 participating physicians, has recently adopted a 3-year, $1.8 billion electronic records program [26].Providing additional direction in developing EHR models have been the Connecting for Health initiative funded by the Markle Foundation [27], and the work of the EHR Collaborative [28], which consists of the major professional stakeholders such as the American Medical Association, and the Healthcare Information and Management Systems Society.

In the United States, as is the case in Australia and the UK [29], the purer EHR model is evolving at the national level. To date, the IOM [30] and the National Committee on Vital and Health Statistics (NCVHS) [31,32] have focused primarily on the *technical* aspects of EHR implementation in the United States. Both have identified two core components in the project: first, building a national health information infrastructure and, second, establishing data interoperability and comparability for patient safety data. In order to achieve data interoperability and comparability, NCVHS and IOM have recommended the adoption of core standardized EHR terminologies (eg, ICD-9 for diseases or symptoms [33], CPT-4 to code medical procedures, and services [34], and RxNorm for drug names and doses [35]). Considerable development is also underway to standardize event taxonomy (eg, adverse event or near-miss reporting using the College of American Pathologists' SNOMED CT taxonomy [36]) and to express knowledge representation such as clinical practice guidelines.

At this stage in the development of the US national model, its architects are concentrating on the interoperability and comparability of *all* patient safety-related data [37], designing a full "pull" architecture such that centralized and local records can import semantically similar data. Currently it is unclear which data consumers will choose to extract from remote systems or what limitations will be imposed, or by whom.

The Internet Alternative—the Personal EHR

Most EHR initiatives are national in scope and frequently government initiated or funded. EMR initiatives are typically hospital- or system-wide, yet are being designed with an eye to broader push or pull systems that will make wide-area use of such institutional data. A personal EHR model is quite different in concept. It assumes that individual patients will aggregate their diverse records and then make them selectively available to new or emergency providers. There are several subscription, web-based personal EHR systems such as PersonalMD.com [38] and Vital Vault [39] that provide secure web space in which patients can aggregate their medical data. Some of these systems also offer automated updating from select providers. Thus, the emerging model emulates popular personal finance applications (such as Microsoft Money or Intuit's Quicken) that allow for both end-user input and importation of data from institutional records to allow management of accounts. As with many emerging Internet-based health-related services, personal EHRs are immature, tend to exhibit limited functionality, and lack permanence [40,41].

Challenges

While Australia's Health*Connect* respects patient and provider choices and generates only limited data sets, the US system seems to be moving towards interoperability and comparability of *all* patient data, maximizing patient data flow into local and national systems but, arguably, at the cost of patient autonomy. The Australian system may pay too much attention to patient consent and jeopardize broader outcomes and reporting goals. Both institutional systems require careful scrutiny with regard to their costs, confidentiality, and liability risks. The nascent Personal EHR model generates additional concerns, which are similar to those experienced with other web-based products such as medical advice sites.

Cost

Considerable uncertainty exists regarding the costs associated with electronically mediated health initiatives and their allocation [42]. During transitional periods, costs rise as both traditional and technologically mediated models work in parallel. Most immediately, the health care industry will have to adjust to costs associated with evolving technologies and short system-lives. There has been recent controversy in the United

States over Congressional rejection of President Bush's initiative to expand funding for the Office for National Health Information Technology coordination (ONCHIT) of the Department of Health and Human Services; this will likely jeopardize public-sector EHR demonstration projects that were to have been funded out of that office [43].

Equally, there are practical, economic, political, and professional barriers that impede the acceptance of electronic records systems. Individual physicians or small practice groups have particular concerns about the costs and learning curves associated with electronic records systems [44]. Additionally, there are questions about whether to convert records retrospectively or whether electronic records systems should be prospective. Predictably, the medical community is concerned about costly dependence on proprietary technology companies, which could potentially monopolize the hardware and software required for interoperability. One possible solution would be for the mechanism of implementation of the EHR to be a public service built to public standards and/or under patient control [45].

Privacy and Confidentiality

An EHR system must satisfy its users regarding privacy, confidentiality, and security [46]. In the United States, the Health Insurance Portability and Accountability Act (HIPAA), passed in 1996 [47], committed the federal government to a process of "Administrative Simplification" to reduce health care costs. That mandate included regulatory authority to promulgate national Standards for Privacy of Individually Identifiable Health Information (PIHI) [48]. The PIHI regulations only regulate the disclosure of health data; they place no limitations on its the collection. Although the regulations limit use and disclosure with a "minimum necessary" rule [49], that limitation is inapplicable in cases of treatment or when disclosure is required by law [50]. Further, PIHI permits disclosure to a very broad range of public health, law enforcement, and judicial authorities [51], and provides for less than robust control of disclosures for secondary uses, such as marketing by providers [52]. Confusingly the PIHI regulations only supplement more rigorous state privacy laws. More recently, the HIPAA legislation has given rise to comprehensive federal security rules that govern health care transactions [53].Their limitations, notwithstanding the regulations made under HIPAA, apply to existing health records kept by most providers and are equally applicable to forthcoming EMR and EHR data. It appears unlikely, however, that US EHR developments will be accompanied by any additional protections, either by providing enhanced collection (privacy) or disclosure (confidentiality) rules or by derogating from a pure "pull" model of data aggregation.

Australian state [54] and federal (Commonwealth) governments aggressively protect patient information [55]. The Commonwealth National Privacy Principles [56] are broadly sensitive to the needs of the health information domain and protect patients with collection-centric (by placing limits on collection and granting consumers anonymity rights) and disclosure-centric rules as well as addressing data quality, data security, and access rights. In 2001, the Australian Federal Privacy Commissioner issued his nonbinding but influential initial Guidelines on Privacy in the Private Health Sector [57] that map the National Privacy Principles to the health context and provide for a robust collection-centric approach. In most cases, consent is required prior to collecting patient health information. This consent should include disclosure of the purposes for which the information is being collected. Further, the "[i]nformation collected should be limited to what is necessary for the health service provider's functions and activities." [58] The Guidelines state that a provider should "only use or disclose personal information for the primary purpose for which it was collected, or for directly related secondary purposes if these fall within the reasonable expectations of the individual" [59]. As a result, the Guidelines provide a satisfactory framework for emerging EHR models, while the Health*Connect* patient-controlled "push" model is intrinsically protective of patient interests.

The US PIHI rules regulating the disclosure of health data have less certain application outside traditional bricks-and-mortar providers, such as those engaged in Internet prescribing and web-based medical advice [60]. As a result, considerable attention needs to be paid to the confidentiality and security of data stored by Personal EHR businesses. In many cases the patient's protection will be limited to that granted by a privacy policy published by the personal EHR provider.

Litigation Risks

Privacy and confidentiality aside, providers already face legal costs with regard to their records. For example, a US provider's failure to maintain timely, legible, accurate and complete records will likely breach state licensure standards [61,62], with severe disciplinary implications [63,64], and may also jeopardize Medicare participation [65]. Improper record keeping may also give rise to medical malpractice liability [66]. In this context, at least one US court has expressed doubt as to the adequacy of a summary rather than comprehensive record [67].

EHR systems inevitably will contribute other costs for users because of interactions with the legal system. Emerging EHR systems, particularly those linked to CDSSs, will be vulnerable to actions focusing on design or other operational flaws [68]. Providers who adopt immature systems may face liability risks because of system deficiencies or insufficient training; those who wait for mature systems are likely to face actions for their failure to implement new but plaintiff-labeled "state-of-the-art" records and CDSSs [69]. Adoption of electronic records systems may also create more indirect legal costs. Litigants may attempt to leverage the new systems to promote their recovery in clinical negligence cases. For example, plaintiffs' attorneys may attempt to use data-mining tools to identify related occurrences to bolster evidence or use their clients' rights of access and modification to manipulate the patient record [70].

Conclusion

On April 26, 2004, President Bush announced the goal of assuring that most Americans have EHRs within the next 10 years [71]. To this end, the President appointed a National Health Information Technology Coordinator to guide the

"nationwide implementation of interoperable health information technology." [72]

If properly funded and nationally implemented, the US EHR model has the following potentials: to interconnect with and enhance other error-reducing and cost-saving technologies such as decision support systems; to streamline health care dataflow using an interoperable and standardized nomenclature; to improve quality by encouraging accurate and legible communication among providers; to automate adverse event and medical error disclosure; and to facilitate reliable and reproducible outcomes research and reporting [73].

As EHR progress continues, several important questions remain unanswered. Which is the preferable EHR model—a shared summary system or a full interpretational longitudinal record? How much say will or should patients and providers have regarding which health information is shared across systems? Would an interactive EHR increase patient interest and involvement in their own care? And, of course, will electronic records conquer the technical problems they pose, avoid the security and privacy costs their critics identify, and deliver lower costs and higher quality; or will they be responsible for still more costs and errors, while promoting the continued industrialization of health care delivery and subordinating patient autonomy and professional ideals to soulless systems?

It has never been more important for providers to be aware of emerging technology, to comprehend the tension between improved care and the preservation of patient privacy and autonomy, and to offer feedback to the American Medical Association and other professional bodies as these entities move to influence the development of the EHR.

Conflicts of Interest

None disclosed.

References

1. ; Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academies Press; Jun 1, 2001:15 URL: http://books.nap.edu/books/0309072808/html/index.html
2. ; Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academies Press; Jun 1, 2001:166 URL: http://books.nap.edu/books/0309072808/html/index.html
3. Hippisley-cox J, Pringle M, Cater R, Wynn A, Hammersley V, Coupland C, et al. The electronic patient record in primary care - regression or progression? A cross sectional study. BMJ 2003 Jun 28;326(7404):1439-1443 [FREE Full text] [PMC: 12829558] [doi: 10.1136/bmj.326.7404.1439] [Medline: 22712601]
4. . In: Aspden P, Corrigan JM, Wolcott J, Erickson SM, editors; Committee on Data Standards for Patient Safety, Board on Health Care Services, Institute of Medicine. Patient Safety: Achieving a New Standard for Care. Washington, DC: The National Academies Press; 2004:4 URL: http://www.nap.edu/catalog/10863.html
5. Kaushal R, Bates DW. Computerized Physician Order Entry (CPOE) with Clinical Decision Support Systems (CDSSs). In: Shojania KG, Duncan BW, McDonald KM, Wachter RM, editors. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment, No. 43, Chap 6. AHRQ Publication No - 01-E058 (Prepared by the University of California at San Francisco - Stanford University Evidence-based Practice Centre). Rockville, MD: Agency for Healthcare Research and Quality; 2001. URL: http://www.ahrq.gov/clinic/ptsafety/ [accessed 2004 Dec 16]
6. Tang PC, Hammond WE. A Progress Report on Computer-Based Patient Records in the United States. In: Dick RS, Steen EB, Detmer DE, editors; Committee on Improving the Patient Record, Institute of Medicine. The Computer-Based Patient Record: An Essential Technology for Health Care. Rev ed. Washington, DC: National Academies Press; 1997. URL: http://books.nap.edu/html/computer/commentary.html [accessed 2004 Dec 16]
7. Tsai CC, Starren J. Patient participation in electronic medical records. JAMA 2001 Apr 4;285(13):1765. [Medline: 21176198] [doi: 10.1001/jama.285.13.1765]
8. Rashbass J. msJAMA. The patient-owned, population-based electronic medical record: a revolutionary resource for clinical medicine. JAMA 2001 Apr 4;285(13):1769. [Medline: 21176203] [doi: 10.1001/jama.285.13.1769-a]
9. Landro L. The informed patient: consumers need health-care data. In: Wall Street Journal Jan 29, 2004:D3.
10. Willison DJ, Keshavjee K, Nair K, Goldsmith C, Holbrook AM; Computerization of Medical Practices for the Enhancement of Therapeutic Effectiveness investigators. Patients' consent preferences for research uses of information in electronic medical records: interview and survey data. BMJ 2003 Feb 15;326(7385):373 [FREE Full text] [PMC: 12586673] [Medline: 22473881] [doi: 10.1136/bmj.326.7385.373]
11. Macdonald R. Commentary: A patient's viewpoint. BMJ 2001;322(7281):287 [FREE Full text] [doi: 10.1136/bmj.322.7281.287]
12. Mandl KD, Szolovits P, Kohane IS. Public standards and patients' control: how to keep electronic medical records accessible but private. BMJ 2001 Feb 3;322(7281):283-287 [FREE Full text] [Medline: 21096638] [doi: 10.1136/bmj.322.7281.283]
13. Markwell D. Commentary: Open approaches to electronic patient records. BMJ 2001;322:286 [FREE Full text]
14. Walsh SH. The clinician's perspective on electronic health records and how they can affect patient care. BMJ 2004 May 15;328(7449):1184-1187 [FREE Full text] [Medline: 15142929] [doi: 10.1136/bmj.328.7449.1184]

15. Safran C. msJAMA. Electronic medical records: a decade of experience. JAMA 2001 Apr 4;285(13):1766. [Medline: 21176199] [doi: 10.1001/jama.285.13.1766]
16. AMA throws support behind health IT coordinator. Modern Physician 2004 Dec 9.
17. ; Australian Government Department of Health and Ageing. HealthConnect. 2004 Nov 11. URL: http://www.healthconnect.gov.au/ [accessed 2004 Dec 16]
18. ; Australian Government Department of Health and Ageing. HealthConnect - an overiew. 2004 May. URL: http://www.healthconnect.gov.au/pdf/HealthConnect_overview_May2004.pdf [accessed 2004 Dec 16]
19. ; Australian Government Department of Health and Ageing. HealthConnect Business Architecture version 1.0. 2003 Apr. p. 20, sect 4.3 URL: http://www.healthconnect.gov.au/pdf/bav1.pdf [accessed 2004 Dec 17]
20. ; Australian Government Department of Health and Ageing. HealthConnect Business Architecture version 1.0. 2003 Apr. p. 30-31 URL: http://www.healthconnect.gov.au/pdf/bav1.pdf [accessed 2004 Dec 17]
21. ; Australian Government Department of Health and Ageing. HealthConnect Business Architecture version 1.0. 2003 Apr. p. 23, sect 4.5 URL: http://www.healthconnect.gov.au/pdf/bav1.pdf [accessed 2004 Dec 17]
22. . In: Aspden P, Corrigan JM, Wolcott J, Erickson SM, editors; Committee on Data Standards for Patient Safety, Board on Health Care Services, Institute of Medicine. Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academies Press; May 10, 2004:436 URL: http://www.nap.edu/catalog/10863.html
23. ; VA National Center for Patient Safety (NCPS). Creating a Culture of Safety. URL: http://www.patientsafety.gov/vision.html [accessed 2004 Dec 16]
24. ; Consolidated Health Informatics. Home page. URL: http://www.whitehouse.gov/omb/egov/gtob/health_informatics.htm [accessed 2004 Dec 16]
25. Peter J. Mass. launches computerized medical files. Washington Post/Associated Press. 2004 Dec 6. URL: http://www.washingtonpost.com/wp-dyn/articles/A41136-2004Dec6.html [accessed 2004 Dec 16]
26. Rundle RL. Big HMO plans to put medical records online. In: Wall Street Journal Feb 4, 2003:D4.
27. ; Markle Foundation, Data Standards Working Group. Connecting for Health - A Public-Private Collaborative, Report and Recommendations. 2003 Jun 5. URL: http://www.connectingforhealth.org/resources/dswg_report_6.5.03.pdf [accessed 2004 Dec 16]
28. ; EHR Collaborative. Home page. URL: http://www.ehrcollaborative.org/ [accessed 2004 Dec 16]
29. ; National Health Service, United Kingdom. National Programme for IT in the NHS. URL: http://www.npfit.nhs.uk/ [accessed 2004 Dec 16]
30. . In: Aspden P, Corrigan JM, Wolcott J, Erickson SM, editors; Committee on Data Standards for Patient Safety, Board on Health Care Services, Institute of Medicine. Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academies Press; May 10, 2004:1-28 URL: http://www.nap.edu/catalog/10863.html
31. ; National Committee on Vital and Health Statistics. Report to the Secretary of the US Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information. 2000 Jul 6. URL: http://www.ncvhs.hhs.gov/hipaa000706.pdf [accessed 2004 Dec 16]
32. ; National Committee on Vital and Health Statistics. Recommendations for PMRI terminology standards. 2003 Nov 5. URL: http://www.ncvhs.hhs.gov/031105lt3.pdf [accessed 2004 Dec 16]
33. ; National Center for Health Statistics, Centers for Disease Control and Prevention. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). URL: http://www.cdc.gov/nchs/about/otheract/icd9/abticd9.htm [accessed 2004 Dec 16]
34. ; American Medical Association. CPT Process - How a Code Becomes a Code. 2004 Nov 4. URL: http://www.ama-assn.org/ama/pub/category/3882.html [accessed 2004 Dec 16]
35. ; National Library of Medicine. Unified Medical Language System, RxNorm. 2004 Nov 2. URL: http://www.nlm.nih.gov/research/umls/rxnorm_main.html [accessed 2004 Dec 16]
36. ; SNOWMED International. SNOMED CT. URL: http://www.snomed.org/snomedct/index.html [accessed 2004 Dec 16]
37. . In: Aspden P, Corrigan JM, Wolcott J, Erickson SM, editors; Committee on Data Standards for Patient Safety, Board on Health Care Services, Institute of Medicine. Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academies Press; May 10, 2004:438 URL: http://www.nap.edu/catalog/10863.html
38. ; PersonalMD. Home page. URL: http://www.personalmd.com/ [accessed 2004 Dec 16]
39. ; VIMSystems. Vital Vault. URL: http://www.vimsystems.com/prod_vault.htm [accessed 2002 Dec 16]
40. Schneider JH. Online personal medical records: are they reliable for acute/critical care? Crit Care Med 2001 Aug;29(8 Suppl):N196-N201. [Medline: 21387190] [doi: 10.1097/00003246-200108001-00009]
41. Kim MI, Johnson KB. Personal health records: evaluation of functionality and utility. J Am Med Inform Assoc 2002;9(2):171-180. [PMC: 11861632] [Medline: 21850602] [doi: 10.1197/jamia.M0978]
42. Hawryluk M. Push continues for electronic health records. Bills set the foundation for action in the next Congress. American Medical News. 2004 Jun 14. URL: http://www.ama-assn.org/amednews/2004/06/14/gvsc0614.htm [accessed 2004 Dec 16]
43. Lohr S. Health Care Technology Is a Promise Unfinanced. New York Times. 2004 Dec 3 p. C5.
44. Richmond R. Small Business: Doctors See Healthy Returns in Digital Records. Wall Street Journal 2004 Dec 7:B1.

45. Mandl KD, Szolovits P, Kohane IS. Public standards and patients' control: how to keep electronic medical records accessible but private. BMJ 2001 Feb 3;322(7281):283-287 [FREE Full text] [Medline: 21096638] [doi: 10.1136/bmj.322.7281.283]
46. Terry NP. Privacy and the health information domain: properties, models and unintended results. Eur J Health Law 2003 Sep;10(3):223-237. [Medline: 23094590] [doi: 10.1163/157180903770847517]
47. Health Insurance Portability and Accountability Act of 1996 (HIPAA). (Pub.L. 104-191, Aug. 21, 1996, 110 Stat. 1936).
48. Standards for Privacy of Individually Identifiable Health Information (PIHI), Federal Register. (codified at 45 CFR §160, §164).
49. 45 CFR. §164.502(b)(1).
50. 45 CFR. §164.502(b)(2).
51. 45 CFR. §164.512.
52. 45 CFR. §164.508.
53. Health Insurance Reform: Security Standards, 68 Federal Register 8334. 2003. (codified at 45 CFR §160, §162, §164) URL: http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2003/03-3877.htm [accessed 2004 Dec 16]
54. ; Office of the Health Services Commissioner, Commonwealth of Australia. Victorian Health Privacy Principles extracted from the Health Records Act. 2001. URL: http://www.health.vic.gov.au/hsc/hppextract.pdf [accessed 2004 Dec 16]
55. ; Office of the Federal Privacy Commissioner, Commonwealth of Australia. The Commonwealth Privacy Amendment (Private Sector) Act 2000 extended the operation of the Privacy Act of 1988 to cover the private sector, including healthcare. Effective from December 21, 2001 URL: http://www.privacy.gov.au/act/privacyact/index.html [accessed 2004 Dec 16]
56. ; Office of the Federal Privacy Commissioner, Commonwealth of Australia. National Privacy Principles (Extracted from the Privacy Amendment (Private Sector) Act. 2000. URL: http://www.privacy.gov.au/publications/npps01.html [accessed 2004 Dec 16]
57. ; Office of the Federal Privacy Commissioner, Commonwealth of Australia. Guidelines on Privacy in the Private Health Sector. 2001 Nov 9. URL: http://www.privacy.gov.au/publications/hg_01.html [accessed 2004 Dec 17]
58. ; Office of the Federal Privacy Commissioner, Commonwealth of Australia. Guidelines on Privacy in the Private Health Sector (November 9, 2001). 2001 Nov 9. Sect 1.2: Collect only necessary information URL: http://www.privacy.gov.au/publications/hg_01.html [accessed 2004 Dec 17]
59. ; Office of the Federal Privacy Commissioner, Commonwealth of Australia. Guidelines on Privacy in the Private Health Sector (November 9, 2001). 2001 Nov 9. Sect 2: Use and disclosure URL: http://www.privacy.gov.au/publications/hg_01.html [accessed 2004 Dec 17]
60. Terry NP. Prescriptions sans frontières (or how I stopped worrying about Viagra on the Web but grew concerned about the future of healthcare delivery). Yale J Health Policy Law Ethics 2004;4(2):183-272. [Medline: 101785425]
61. NRS. §630.3062(1) (Nevada).
62. Wyo. Stat. §33-26-402 (Wyoming).
63. Schwarz v. Board of Regents, 89 AD2d 711, 453 NYS2d 836. (NY App Div 3d Dep't 1982).
64. Nieves v. Chassin, 214 AD2d 843, 625 NYS2d 344. (NY App Div 3d Dep't 1995).
65. 42 CFR. §482.24(b)-(c).
66. Brown v. Hamid, 856 SW2d 51. (MO 1993).
67. Thomas v. United States, 660 F Supp 216, 218. (DDC 1987).
68. Fernando B, Savelyich BSP, Avery AJ, Sheikh A, Bainbridge M, Horsfield P, et al. Prescribing safety features of general practice computer systems: evaluation using simulated test cases. BMJ 2004 May 15;328(7449):1171-1172 [FREE Full text] [Medline: 15142922] [PMC: 15142922] [doi: 10.1136/bmj.328.7449.1171]
69. Terry NP. When the “machine that goes ‘ping’” causes harm: default torts rules and technologically-mediated health care injuries. St Louis Univ Law J 2002;46:37-59.
70. Terry NP. An eHealth diptych: the impact of privacy regulation on medical error and malpractice litigation. Am J Law Med 2001;27(4):361-419. [Medline: 21825759]
71. ; The White House. Transforming Health Care: The President's Health Information Technology Plan. URL: http://www.whitehouse.gov/infocus/technology/economic_policy200404/chap3.html [accessed 2004 Dec 16]
72. Executive Order 13335 of April 27, 2004, Incentives for the Use of Health Information Technology and Establishing the Position of the National Health Information Technology Coordinator, 69 Federal Register 24059, Sect. 3. 2004 Apr 30. URL: http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-10024.pdf [accessed 2004 Dec 16]
73. ; Australian Council for Safety and Quality in Health Care. Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals, Following an Adverse Event in Health Care. 2003 Jul. URL: http://www.safetyandquality.org/articles/publications/OpenDisclosure_web.pdf [accessed 2004 Dec 16]

Abbreviations

CDSS: computerized decision support system

CHI: Consolidated Health Informatics
CPOE: computerized physician order entry
EHR: electronic health record
EMR: electronic medical record
HIPAA: Health Insurance Portability and Accountability Act
HMO: health management organization
IOM: Institute of Medicine
IT: information technology
NCVHS: National Committee on Vital and Health Statistics
PIHI: Standards for Privacy of Individually Identifiable Health Information
RFID: Radio Frequency Identification

submitted 17.02.05; peer-reviewed by J Powell; accepted 25.02.05; published 14.03.05.

Please cite as:
Gunter TD, Terry NP
The Emergence of National Electronic Health Record Architectures in the United States and Australia: Models, Costs, and Questions
J Med Internet Res 2005;7(1):e3
URL: http://www.jmir.org/2005/1/e3/
doi:10.2196/jmir.7.1.e3
PMID:15829475

Viewpoint

The Law of Attrition

Gunther Eysenbach[1], MD, MPH

Centre for Global eHealth Innovation, University Health Network, Toronto ON, Canada

Corresponding Author:
Gunther Eysenbach, MD, MPH
Centre for Global eHealth Innovation
University of Toronto & University Health Network
190 Elizabeth Street
Toronto ON M5G 2C4
Canada
Phone: +1 416 340 4800 ext 6427
Fax: +1 416 340 3595
Email: geysenba@uhnres.utoronto.ca

Abstract

In an ongoing effort of this Journal to develop and further the theories, models, and best practices around eHealth research, this paper argues for the need for a "science of attrition", that is, a need to develop models for discontinuation of eHealth applications and the related phenomenon of participants dropping out of eHealth trials. What I call "law of attrition" here is the observation that in any eHealth trial a substantial proportion of users drop out before completion or stop using the appplication. This feature of eHealth trials is a distinct characteristic compared to, for example, drug trials. The traditional clinical trial and evidence-based medicine paradigm stipulates that high dropout rates make trials less believable. Consequently eHealth researchers tend to gloss over high dropout rates, or not to publish their study results at all, as they see their studies as failures. However, for many eHealth trials, in particular those conducted on the Internet and in particular with self-help applications, high dropout rates may be a natural and typical feature. Usage metrics and determinants of attrition should be highlighted, measured, analyzed, and discussed. This also includes analyzing and reporting the characteristics of the subpopulation for which the application eventually "works", ie, those who stay in the trial and use it. For the question of what works and what does not, such attrition measures are as important to report as pure efficacy measures from intention-to-treat (ITT) analyses. In cases of high dropout rates efficacy measures underestimate the impact of an application on a population which continues to use it. Methods of analyzing attrition curves can be drawn from survival analysis methods, eg, the Kaplan-Meier analysis and proportional hazards regression analysis (Cox model). Measures to be reported include the relative risk of dropping out or of stopping the use of an application, as well as a "usage half-life", and models reporting demographic and other factors predicting usage discontinuation in a population. Differential dropout or usage rates between two interventions could be a standard metric for the "usability efficacy" of a system. A "run-in and withdrawal" trial design is suggested as a methodological innovation for Internet-based trials with a high number of initial dropouts/nonusers and a stable group of hardcore users.

(J Med Internet Res 2005;7(1):e11) doi:10.2196/jmir.7.1.e11

KEYWORDS

Internet; clinical trials; longitudinal studies; patient dropouts; survival analysis

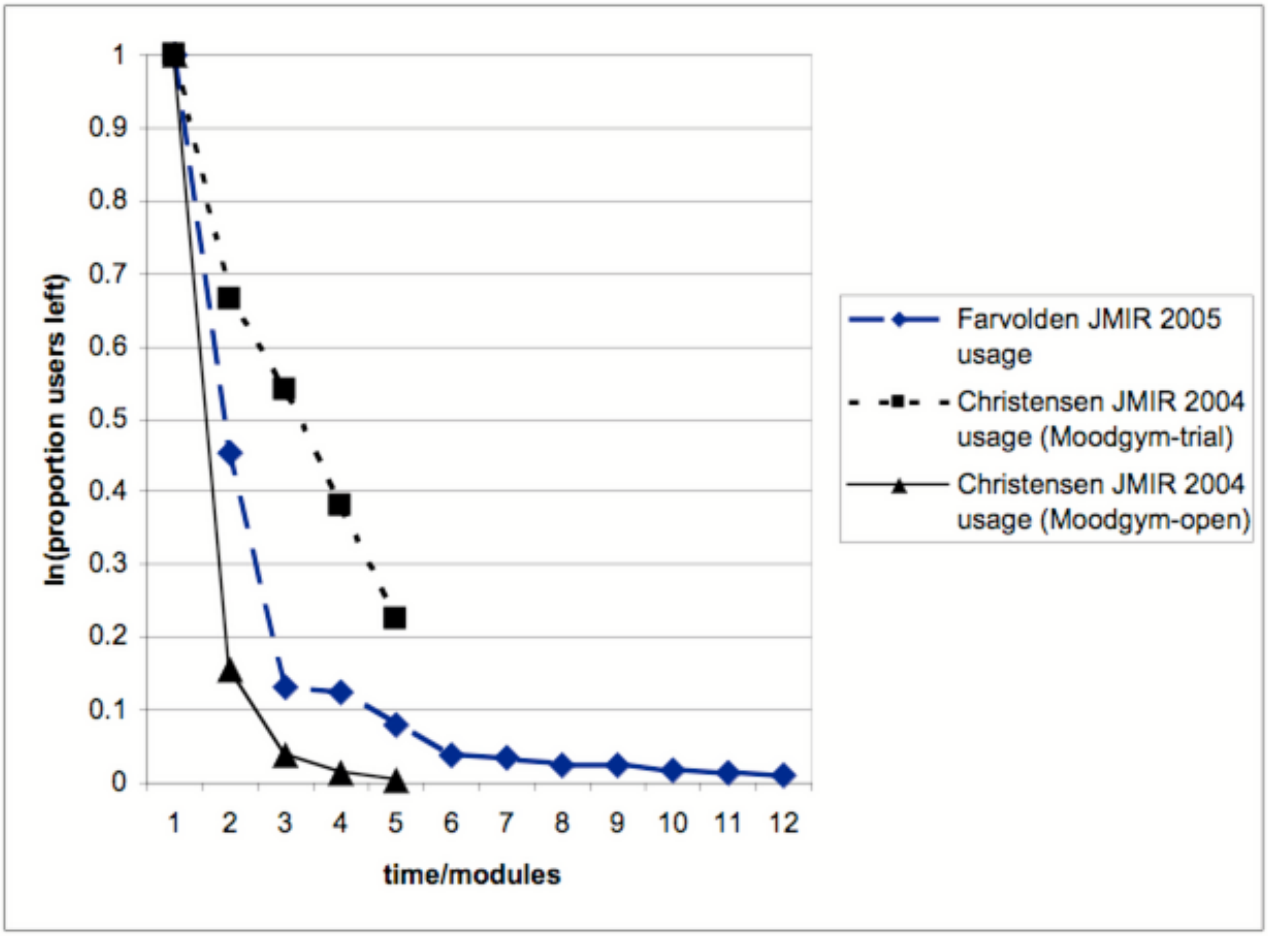
The Law of Attrition (Or: Why Do eHealth Users Discontinue Usage?)

In this issue of the Journal, several excellent papers deal with the methodology of conducting Internet-based trials. Peter Farvolden and colleagues present an Internet-based evaluation of a panic disorder self-help Web program, struggling with a huge proportion of users discontinuing usage: only 12 out of 1161 (about 1%) completed the entire 12-week program [1]. A similar observation has been made previously by Christensen et al in her evaluation of Moodgym, a depression program with 5 modules, where only 97 out of 19607 (0.5%) participants completed all 5 modules in an "open " setting, and 41 out of 182 (22.5%) completed all of them in a trial setting (Figure 1) [2,3]. Also in this issue, Wu et al report results from an exemplary study evaluating whether people would actually use (and continue to use) an innovative Internet-based communication and disease management platform requiring patients to enter different parameters and enabling them to exchange messages with clinicians online. He found that 26 out of 58 used it over a period of 3 months, only 16 patients continued to use the system after 12 months, 8 continued to use

the system at 2 years, and 4 continued to used the system after 3 years [4]. Among the users, there also seemed to be a decline in the intensity of use, with a decrease in the number of messages entered by both patients and clinicians over time. These data are reminiscent of the experiences of Anhoj in a previous issue of the *Journal of Medical Internet Research*. Anhoj observed the contrast between users' positive perception of LinkMedica and their unwillingness to use the website for more than short periods. The primary reason for this was that LinkMedica "did not fit into their everyday lives." [5] Finally, in this issue, is Jean-François Etter's landmark paper reporting results from one of the largest and perhaps best conducted Internet-based trials ever published to date [6]. He as well reports a considerable proportion of dropouts, with only 35% of the 11969 enrolled participants replying to the follow-up questionnaire. Amazingly, despite this huge loss-to-follow-up rate, the study still had enough statistical power to detect significant differences between the two interventions.

All these papers allude to a common problem: the law of attrition, as I call it, ie. the phenomenon of participants stopping usage and/or being lost to follow-up, as one of the fundamental characteristics and methodological challenges in the evaluation of eHealth applications.

Figure 1. Nonusage attrition curves for two studies [1,2] published in this issue of the Journal of Medical Internet Research. Plotted are the number of completed modules from two Web-based interventions against the proportion of participants completing them. From the two Christensen/Moodgym curves, the upper one refers to a trial setting, while the other (lower one) refers to an "open" situation with casual Internet visitors.



While in most drug trials the intervention is "prescribed", in studies involving information and communication technology usage of the intervention is mostly at the discretion of the participant and the participant has the option to discontinue usage very easily. In any longitudinal study where the intervention is neither mandatory nor critical to the participants' well-being, trial participants will be lost. Lack of compliance is usually not a major problem in drug trials, as participants are more closely supervised and sometimes experience observable and immediate health benefits in taking a drug. Thus, in drug trials, almost everyone in the intervention group will actually be getting the intervention (and receiving the same dose). In contrast, one of the fundamental methodological problems in eHealth trials is that in the intervention group a (sometimes substantial) proportion of people will not be using the intervention or using it sparingly [7]. It is difficult to measure an effect of an intervention if participants in the intervention group do not use the application.

In this paper I argue that a "science of attrition" is needed. Nonusage data *per se* should be of great interest to researchers, and attrition curves may be underreported and underanalyzed. Some theoretical models of attrition are proposed and I argue that by understanding and describing patterns and predictors for attrition and empirically verifying the proposed models, eHealth researchers may not only advance our understanding of the impact and uptake of eHealth interventions, but also

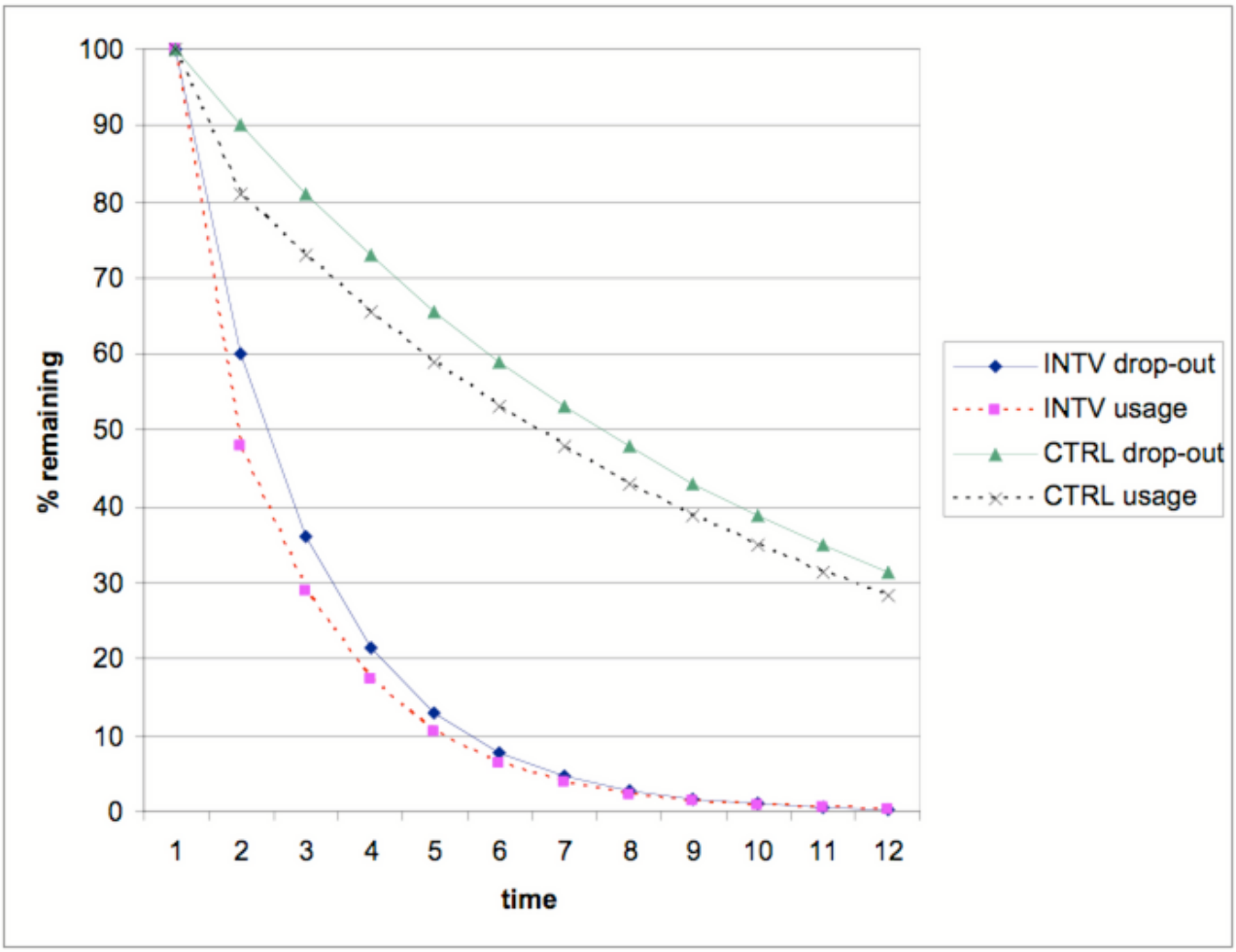
contribute to the interdisciplinary field of diffusion research at large.

Attrition Curves

When talking about attrition in longitudinal studies, we may actually refer to two different processes: the phenomenon of losing participants to follow-up (eg, participants do not return to fill in follow-up questionnaires), which I call *dropout attrition* here, and the phenomenon of nonusage, which I call *nonusage attrition*. Both may be closely related: often, high loss-to-follow-up rates indicate that a considerable proportion of participants have lost interest in the application and stopped using it. On the other hand, it may also be possible to have a low loss-to-follow-up rate, and still have participants not using (or infrequently using) the intervention (eg, in [2, 3]).

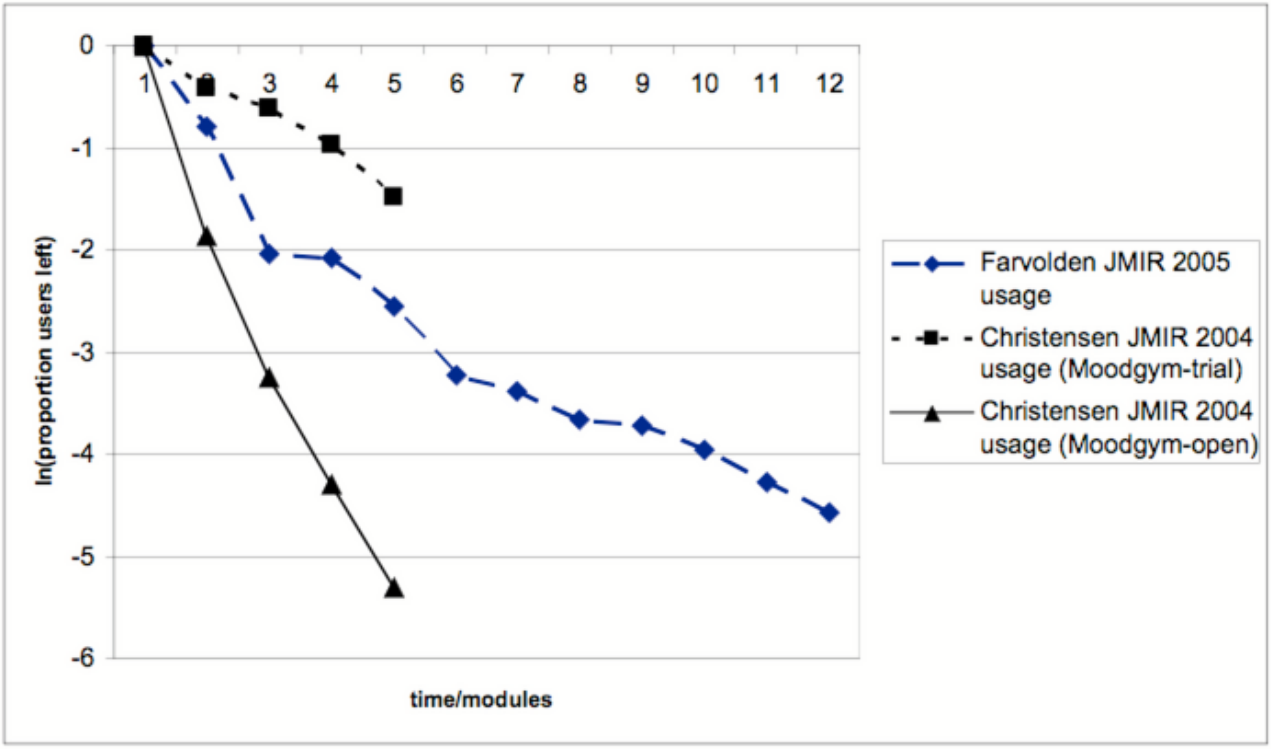
Thus, in any longitudinal eHealth study, we can draw two kinds of attrition curves: (1) proportion of users who are lost to follow-up over time, and (2) proportion of users who do not drop out (eg, who are still filling in questionnaires), but who are no longer using the application, plotted over time. My hypothesis is that the loss-to-follow-up attrition curve usually follows the nonusage attrition curve because a high proportion of loss to follow-up is a result of nonusage ("losing interest" is the underlying variable which explains both curves). In longitudinal studies with control groups, for example randomized trials, a third curve can be drawn to illustrate loss-to-follow-up rate in the comparison group. If the comparison group consists of providing another technological innovation, a fourth curve can be drawn to characterize nonusage of the control intervention (Figure 2).

Figure 2. An example for logarithmic "attrition curves" in a hypothetical eHealth trial. In the intervention group (INTV), a proportion of participants will be lost to follow-up (INTV dropout), as will be in the control group (CTRL dropout). In addition, even within those not lost to follow up, there might be a proportion of nonusers



The hypothetical attrition curves in Figure 2 are logarithmic curves, and they are very similar to the actually observed attrition curves in the trials of Farvolden et al [1], Christensen et al [2], and Wu et al [4] (compare with Figure 1). In fact, when plotted on a logarithmic scale, the attrition curves from Figure 1 form almost straight lines (Figure 3).

Figure 3. Attrition curves from Figure 1 on a logarithmic scale (y-axis is the natural logarithm of the proportion of users completing a module)



Nonusage Attrition: Diffusion of Innovation Reversed

The "science of attrition" can be seen as an application of (and contribution to) the theoretical framework of diffusion research. An eHealth intervention trial usually brings an innovation to participants. Everett M. Rogers defines innovation as "an idea perceived as new by the individual" and diffusion is "the process by which an innovation spreads." [8] The model of diffusion of innovation proposed by Rogers was originally used by rural sociologists to study the diffusion of agricultural technologies in social systems. After its conception, an innovation spreads slowly at first — usually through the work of *change agents*, who actively promote it — then picks up speed as more and more people adopt it. Eventually it reaches a saturation level, where virtually everyone who is going to adopt the innovation has done so.

In trials of efficacy of eHealth interventions we are usually starting with an enrolled population of 100% "intent-to-use" participants, who have already gone through a recruitment, selection and informed consent process, ie, all of them have, in principle, already agreed to use and "adopted" the intervention. However, as shown above, in many trials a considerable number of users may discontinue the intervention or (worse) drop out of the trial altogether — a reversal of the adoption process.

In his 550-page book about how new ideas spread and are adopted, Rogers spends a mere 5 pages on *reversal* of decisions to adopt an innovation, illustrating how little research has been done in this area. Empirical evidence in eHealth (and perhaps in other areas in health care, for example, the self-help and self-support area in general, as noted by Farvolden [1]) suggests that abandoning an innovation is a significant phenomenon, perhaps deserving more attention and research. The fact that reversals of decisions are frequent is acknowledged by diffusion scholars. Rogers cites a study among Wisconsin farmers showing that the rate of discontinuance was just as important as the rate of adoption in determining the level of adoption at any particular time, for in any given year there were as many discontinuers as there were first-time adopters.

Rogers calls the innovation adoption stage where people may reverse their decision the *confirmation stage*. In this stage, according to Rogers, "The individual … seeks reinforcement for the innovation-decision already made, and may reverse this decision if exposed to conflicting messages about the innovation." If a dissonance is created, ie, a state of internal disequilibrium or uncomfortable state of mind evolves, the innovation may be abandoned.

Rogers distinguishes *disenchantment* from *replacement* discontinuance. *Replacement discontinuance* is a "decision to reject an idea in order to adopt a better idea that supersedes it", eg, MP3 and iPod players replacing walkmans, email replacing postal mail. In the context of Internet-based medical studies, the next website with (perhaps better) content competing for the attention of the participant is only a few mouseclicks away [8], making replacement discontinuance a not unlikely event. *Disenchantment discontinuance* leads to a rejection because the individuals are dissatisfied. In health care, disenchantment and replacement often go hand in hand, as it is often not possible to simply drop an intervention without using a replacement. In an Web-based communication tool intervention such as the one described by Wu et al [4], electronic messaging can, for example, be replaced by phone calls or office visits.

Factors Influencing Attrition

In the classical model of Rogers, the rate of adoption is positively related to several characteristics of the innovation as

they are perceived by the members of the system in which the innovation is diffusing. These are

1. relative advantage, the degree to which the innovation is perceived to be superior to the idea that it replaces;
2. compatibility, the degree to which an innovation is perceived as being consistent with the existing values, past experiences, and needs of potential adopters;
3. complexity, the degree to which an innovation is perceived as difficult to understand and use;
4. trialability, the degree to which an innovation may be experimented with on a limited basis; and
5. observability, the degree to which the results of an innovation are visible to others.

These characteristics of the innovation also play a role in the decision to stop using an eHealth innovation and/or to drop out of an eHealth trial. For example, the innovation will be rejected if it is not perceived as creating any benefit (relative advantage) or if it has usability problems (complexity). However, there are further factors involved which are not related to the innovation itself but more to the environment and the trial setting. These factors, for example, expectation management before the trial or "push factors" such as reminders by the study team, influence the shape and slope (steepness) of the attrition curve. In Figure 1 (and Figure 3) it is interesting to see how "push" factors involved in conducting a randomized trial of MoodGym (eg, research assistants contacting participants) lead to a flatter attrition curve, compared to a less "pushy" environment with casual users in an "open trial" of MoodGym (compare top and bottom curves).

A more formal analysis of such curves, eg, with methods of survival curve analysis, may elicit metrics for different attrition rates and identify factors affecting the shape and slope of these curves. Some of these proposed (hypothetical) factors have been compiled in Table 1.

There will also be additional participant factors, for example, demographics, which influence attrition rates. Users with less formal education, lower socioeconomic status, and less change agent contact are more likely to discontinue innovations [8]. Rogers also claims that later adopters (laggards) are more likely to discontinue innovations than earlier adopters ([8], generalization 5-11, p. 191). In the eHealth trial context, this perhaps means that if a participant hesitates to participate this may be an early indicator for a potential dropout. The predictive value of such factors for discontinuing a trial with a specific eHealth intervention could be identified by statistical models such as proportional hazards regression analysis (Cox model), comparing for example the dropout curve of the control group against the dropout curve of the intervention group.

Table 1. Proposed (hypothetical) factors influencing nonusage attrition and dropout attrition in eHealth trials

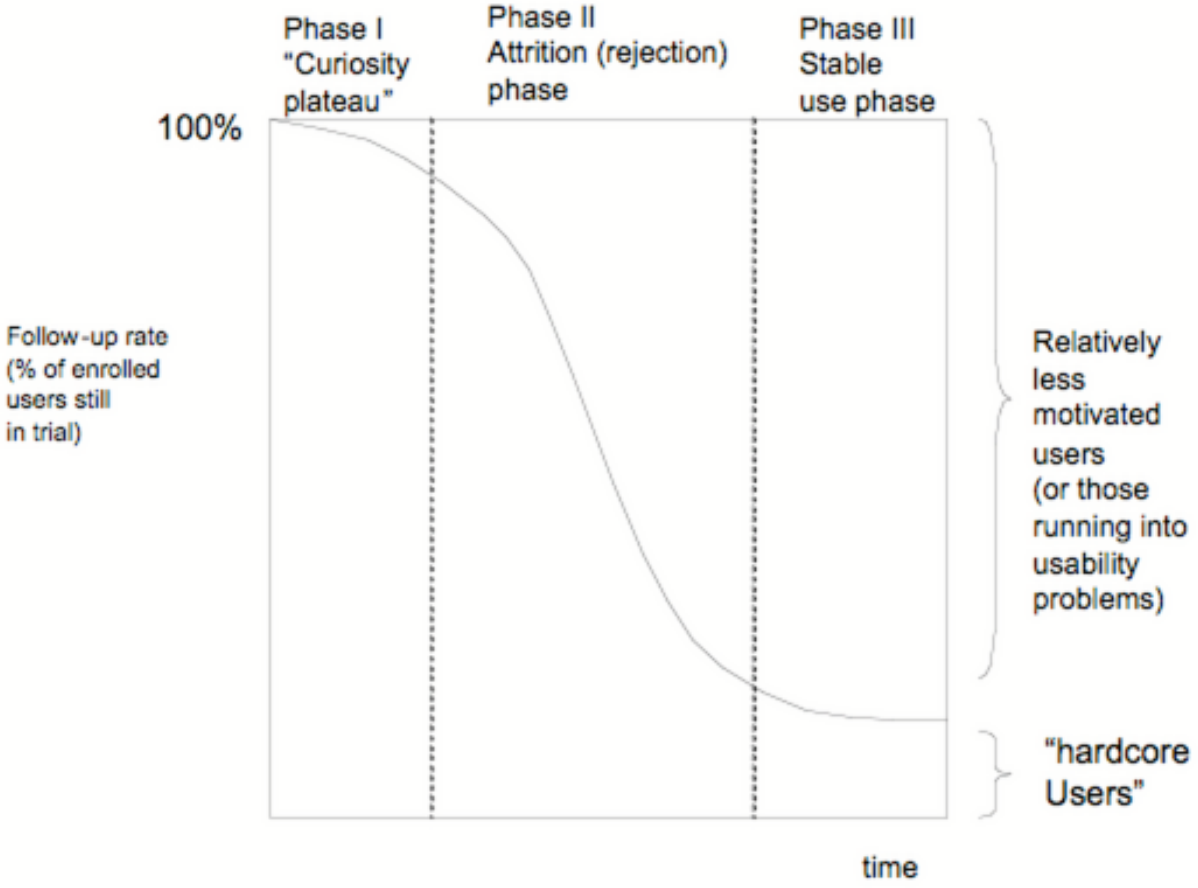
Factor	Impact on Nonusage Attrition Rate	Impact on Dropout Attrition Rate
Quantity and appropriateness of information given before the trial, expectation management	Inappropriate information leads to unrealistic expectations which in turn leads to disenchantment discontinuance	Indirectly through nonusage (usage discontinuance leads to drop out)
Ease of enrolment (eg, with a simple mouseclick as opposed to personal contact, physical examination etc), recruiting the "right" users, degree of pre-enrolment screening	If the "wrong" participants are enrolled, ie, those who are less likely to use it, and willing to invest time, and for whom the intervention does not "fit"	The easier it is to enroll, the more users will later drop out if they realize that filling in questionnaires, etc creates more work than they thought. Also indirect via nonusage.
Ease of drop out / stop using it	The easier it is to stop using the application, the higher the nonusage attrition rate will be (and indirectly through dropouts)	The easier it is to leave the trial, the higher the attrition rate will be (and indirectly through nonusage)
Usability and interface issues	Usability issues obviously affect usage	Indirectly through nonusage (usage discontinuance leads to drop out)
"Push" factors (reminders, research assistants chasing participants)	Participants may feel obliged to continue usage if reminded (cave external validity)	Participants may feel obliged to stay in trial
Personal contact (on enrolment, and continuous contact) via face-to-face or phone, as opposed to virtual contact	Mainly indirectly via dropout	The more "virtual" the contact with the research team is, the more likely participants will drop out
Positive feedback, buy-in and encouragement from change agents and (for consumer health informatics applications) from health professionals / care providers	Participants may discontinue usage without buy-in from change agents. In particular, patients may stop using eHealth applications if discouraged (or no actively encouraged) by health professionals	Indirectly through nonusage (usage discontinuance leads to drop out)
Tangible and intangible observable advantages in completing the trial or continuing to use it (external pressures such as financial disadvantages, clinical/medical/quality of life/pain)	Yes	Yes
Intervention has been fully paid for (out-of-pocket expense)	If individuals have paid for an innovation upfront they are less likely to abandon it (as opposed to interventions paid on a fee-per-usage basis)	Indirectly through nonusage (usage discontinuance leads to drop out)
Workload and time required	Yes	eg, to fill in the follow-up questionnaires may create such a burden that participants drop out
Competing interventions	For example similar interventions on the web or offline can lead to replacement discontinuance	Indirectly through nonusage (usage discontinuance leads to drop out)
External events (9/11 etc)	These may lead to distractions and discontinuance, especially if the intervention is not essential	Indirectly through nonusage (usage discontinuance leads to drop out)
Networking effects/peer pressure, peer-to-peer communication, and community building (open interactions between participants)	Communities may increase or slow the speed with which an innovation is abandoned.	Communities may increase or slow dropout attrition.
Experience of the user (or being able to obtain help)	As most eHealth applications require an initial learning curve and organizational change, users have to overcome initial hurdles to make an application work. Experience/external help can contribute to overcoming these initial hurdles and help to see the "light at the end of the tunnel"	Indirectly through nonusage (usage discontinuance leads to dropout)

Measuring and Reporting Attrition

When reporting the results of eHealth studies, a number of usage and dropout attrition metrics can (and should) be provided in addition to efficacy measures. Raw attrition proportions at different points in time should be reported and can be illustrated as attrition curves. The shape of the curve may indicate the underlying causes for attrition. A logarithmic curve, such as

those in Figures 1 to 3, indicates a steady attrition with a constant proportion of users discontinuing use (or dropping out), similar to a probabilistic event. A sigmoid curve, such as the one illustrated in Figure 4, suggests a 3-phase process: an initial phase (Phase I) where participants out of curiosity initially stay in the trial (and use the eHealth application); Phase II where rejection and attrition set in, for example, because participants realize that the application does not meet their expectations; and Phase III where a stable user group ("hardcore users") remains, who continue to use the application over extended periods of time. In contrast, an L-shaped curve (not shown, but similar to Phase II+III in Figure 4) reflects an initial rapid decline of participants and then a more steady group of "hardcore" users and/or trial participants who remain in the trial. This indicates an initial rapid weed-out process without preceding "curiosity plateau", possibly because many of the enrolled participants were the wrong user group who lose interest quickly.

Figure 4. A (hypothetical) sigmoid attrition curve



In addition to providing attrition curves, some summary metrics can be calculated. In biology, physics and economics the term "half-life" is used to measure "the time required for half of something to undergo a process" (Merriam-Webster Medical Dictionary). "Usage half-life" might be an useful measure to report for eHealth trials, indicating after how much time t50 (t10, t25…) will 50% (10%, 25% ….) of a volunteer user group have stopped using the application (As many applications hopefully have a slow attrition it might be more practical to report t10 or t25, where 10% or 25%, respectively, have been lost).

It is also interesting to formally compare different attrition curves, for example, a dropout attrition curve of intervention A against a dropout attrition curve of intervention B, evaluated in the same trial. For example, Christensen et al [3] report that after 6 weeks 89.3% remained in the control group, while only 74.7% in the Moodgym trial could be followed up, while the group using another intervention, Bluepages, had a follow-up rate of 84.9%, perhaps indicating more usability problems in the Moodgym application. If the attrition curve is logarithmic, it may be of advantage to report the logarithmic ratio $\ln(P_A[tx]) / \ln(P_B[tx])$ of two curves A and B (P[tx] being the proportions of users in group A or B still in trial and/or using the application after a certain time tx), because this ratio is constant across different points in time if the curve is logarithmic.

Further statistical comparisons across attrition curves can be done using Kaplan-Meier (survival curve) analysis and using Cox regression models.

Dealing With Attrition: ITT and "Run-In and Withdrawal Design"

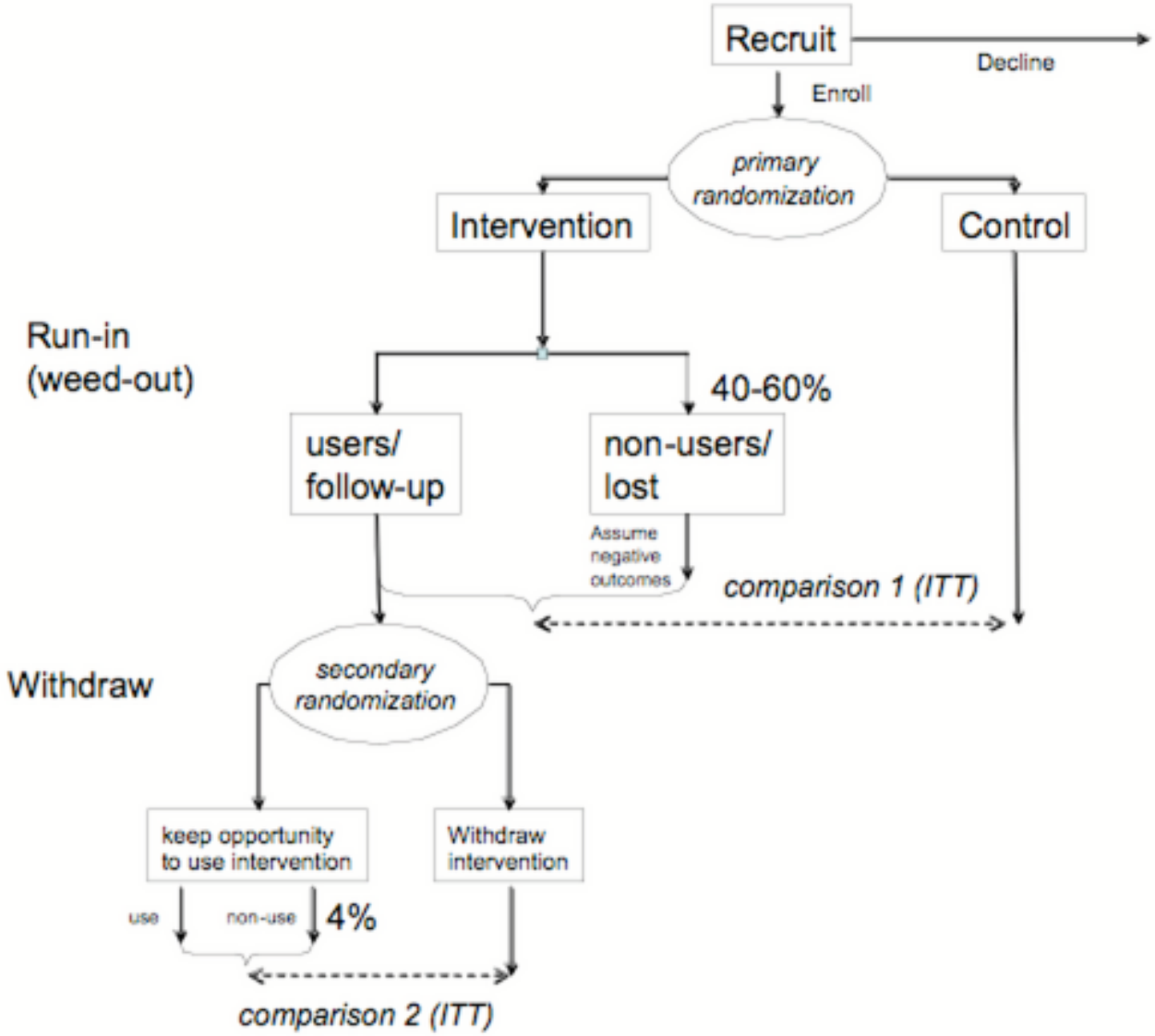
Dropout attrition is a threat to validity, because it may introduce a selection bias. For example, the intervention group may selectively lose more unmotivated people (who may have different outcomes due to the fact of being unmotivated) than the control group, and this differential dropout may lead to differences in outcomes measured among the remaining participants. An intention-to-treat (ITT) analysis, where all

dropouts are assumed to have negative or neutral outcomes, is the only chance to avoid this bias. However, a high attrition rate and an intent-to-treat analysis greatly diminish the power to detect differences between groups (increasing the beta, ie, the chance that true differences are not measured).

ITT analysis could be combined with a method which I would call a "run-in and withdrawal design." Here, the first phase of the trial (corresponding to Phase I and Phase II in Figure 4) is a "run-in and weed-out" period, where participants who will not want to use the application for an extended period of time are "weeded out" from the intervention group. This is followed (at the beginning of Phase III from Figure 4) by another randomization among the remaining actual users in the intervention group, which will be randomly split into those who can continue to use the application, and those from whom the application is withdrawn (Figure 5). The first evaluation after the run-in period will determine how many of the participants who originally intended to use the system actually used it, will determine the characteristics of the user group, and will give a conservative efficacy estimate based on a ITT comparison. For the second, the withdrawal phase, the intervention will be removed from half the users of the original intervention group. Comparing the withdrawal group with the nonwithdrawal group will then give a less conservative estimate for the effectiveness of the intervention – with the caveat of reduced generalizability, since this estimate is valid only for a subgroup of the population who actually end up using it.

Sadly, this design is only feasible if there is indeed a "hardcore" user group (ie, attrition virtually stops if the right users are found), if the outcomes are fully reversible, and if there are no learning or other carryover effects, such as in educational interventions. However, the proposed design is feasible for evaluating eHealth interventions which have a transient effect only for the duration in which they are used, such as evaluating email versus telephone communication with physicians, or evaluating access to electronic clinical guidelines, and so on.

Figure 5. A proposed "run-in and withdrawal" design



Conclusion: Overcoming Pro-Innovation Bias

The law of attrition may be a cause for publication bias, as authors with eHealth trials and high attrition rates may have difficulties in getting their work published. Journal editors and reviewers usually frown if they see substantial dropout rates. At the *Journal of Medical Internet Research*, studies with high dropout rates are welcome, because we know that in many cases discontinuance of eHealth innovations in a trial situation is a fact of life and worth reporting. Attrition data may give clues for real-life adoption problems.

The other reason that we see attrition rates so rarely analyzed in depth is that many investigators (in particular if they were involved in the development of an application) have an implicit pro-innovation bias, not expecting that an innovation will be rejected [8]. This leads to overlooking or underemphasizing discontinuance. As a consequence, Rogers notes that "We know too much about innovation successes and not enough about innovation failures." For diffusion scholars, eHealth in particular presents a particularly rich field for studying rejected or discontinued innovations, and eHealth scholars might want to start directing their attention to attrition, uptake and diffusion measures with the same interest as they used to emphasize outcome efficacy.

References

1. Farvolden P, Denisoff E, Selby P, Bagby RM, Rudy L. Usage and longitudinal effectiveness of a Web-based self-help cognitive behavioral therapy program for panic disorder. J Med Internet Res 2005 Mar 26;7(1):e7 [FREE Full text] [Medline: 15829479] [doi: 10.2196/jmir.7.1.e7]
2. Christensen H, Griffiths KM, Korten AE, Brittliffe K, Groves C. A comparison of changes in anxiety and depression symptoms of spontaneous users and trial participants of a cognitive behavior therapy website. J Med Internet Res 2004 Dec 22;6(4):e46 [FREE Full text] [Medline: 15631970] [doi: 10.2196/jmir.6.4.e46]
3. Christensen H, Griffiths KM, Jorm AF. Delivering interventions for depression by using the internet: randomised controlled trial. BMJ 2004 Jan 31;328(7434):265 [FREE Full text] [Medline: 14742346] [PMC: 14742346] [doi: 10.1136/bmj.37945.566632.EE]
4. Wu RC, Delgado D, Costigan J, Maciver J, Ross H. Pilot study of an Internet patient-physician communication tool for heart failure disease management. J Med Internet Res 2005 Mar 26;7(1):e8 [FREE Full text] [Medline: 15829480] [doi: 10.2196/jmir.7.1.e8]
5. Anhøj J, Jensen AH. Using the Internet for Life Style Changes in Diet and Physical Activity: A Feasibility Study. J Med Internet Res 2004;6(3):e28 [FREE Full text] [doi: 10.2196/jmir.6.3.e28]
6. Etter JF. Comparing the efficacy of two Internet-based, computer-tailored smoking cessation programs: a randomized trial. J Med Internet Res 2005 Mar 8;7(1):e2 [FREE Full text] [Medline: 15829474] [doi: 10.2196/jmir.7.1.e2]
7. Eysenbach G. Issues in evaluating health websites in an Internet-based randomized controlled trial. J Med Internet Res 2002 Dec 23;4(3):e17 [FREE Full text] [Medline: 22442449] [doi: 10.2196/jmir.4.3.e17]
8. Rogers EM. Diffusion of Innovations, 5th edition. New York, NY: Free Press; Aug 16, 2003.

submitted 31.03.05; peer-reviewed by H Christensen; accepted 31.03.05; published 31.03.05.

Please cite as:
Eysenbach G
The Law of Attrition
J Med Internet Res 2005;7(1):e11
URL: http://www.jmir.org/2005/1/e11/
doi:10.2196/jmir.7.1.e11
PMID:15829473

Tutorial

The Internet and Clinical Trials: Background, Online Resources, Examples and Issues

James Paul[1,2], MSc, MD; Rachael Seib[1,2], MA; Todd Prescott[1,2], BSc

[1]Department of Anesthesia, Hamilton Health Sciences, Hamilton, ON, Canada

[2]Department of Anesthesia, Faculty of Health Sciences, McMaster University, Hamilton, ON, Canada

Corresponding Author:
James Paul, MSc, MD
Department of Anesthesia
Hamilton Health Sciences
Hamilton General Site
237 Barton St East
Hamilton, ON L8L 2X2
Canada
Phone: +1 905 527 4322 ext 46698
Fax: +1 905 577 8023
Email: james_paul@sympatico.ca

Abstract

Both the Internet and clinical trials were significant developments in the latter half of the twentieth century: the Internet revolutionized global communications and the randomized controlled trial provided a means to conduct an unbiased comparison of two or more treatments. Large multicenter trials are often burdened with an extensive development time and considerable expense, as well as significant challenges in obtaining, backing up and analyzing large amounts of data. Alongside the increasing complexities of the modern clinical trial has grown the power of the Internet to improve communications, centralize and secure data as well as to distribute information. As more and more clinical trials are required to coordinate multiple trial processes in real time, centers are turning to the Internet for the tools to manage the components of a clinical trial, either in whole or in part, to produce lower costs and faster results. This paper reviews the historical development of the Internet and the randomized controlled trial, describes the Internet resources available that can be used in a clinical trial, reviews some examples of online trials and describes the advantages and disadvantages of using the Internet to conduct a clinical trial. We also extract the characteristics of the 5 largest clinical trials conducted using the Internet to date, which together enrolled over 26000 patients.

(J Med Internet Res 2005;7(1):e5) doi:10.2196/jmir.7.1.e5

KEYWORDS

Clinical trials; randomized controlled trial; Internet

Introduction

Both the Internet and clinical trials were significant developments in the latter half of the 20th century: the Internet revolutionized global communications and the randomized controlled trial (RCT) provided a means to conduct an unbiased comparison of two or more treatments. This paper reviews the historical development of the Internet and the randomized controlled trial, describes the Internet resources available that can be used in a clinical trial, reviews some examples of online trials and describes the advantages and disadvantages of using the Internet to conduct a clinical trial.

Historical Aspects of the Internet and Clinical Trials

Origins of the Internet

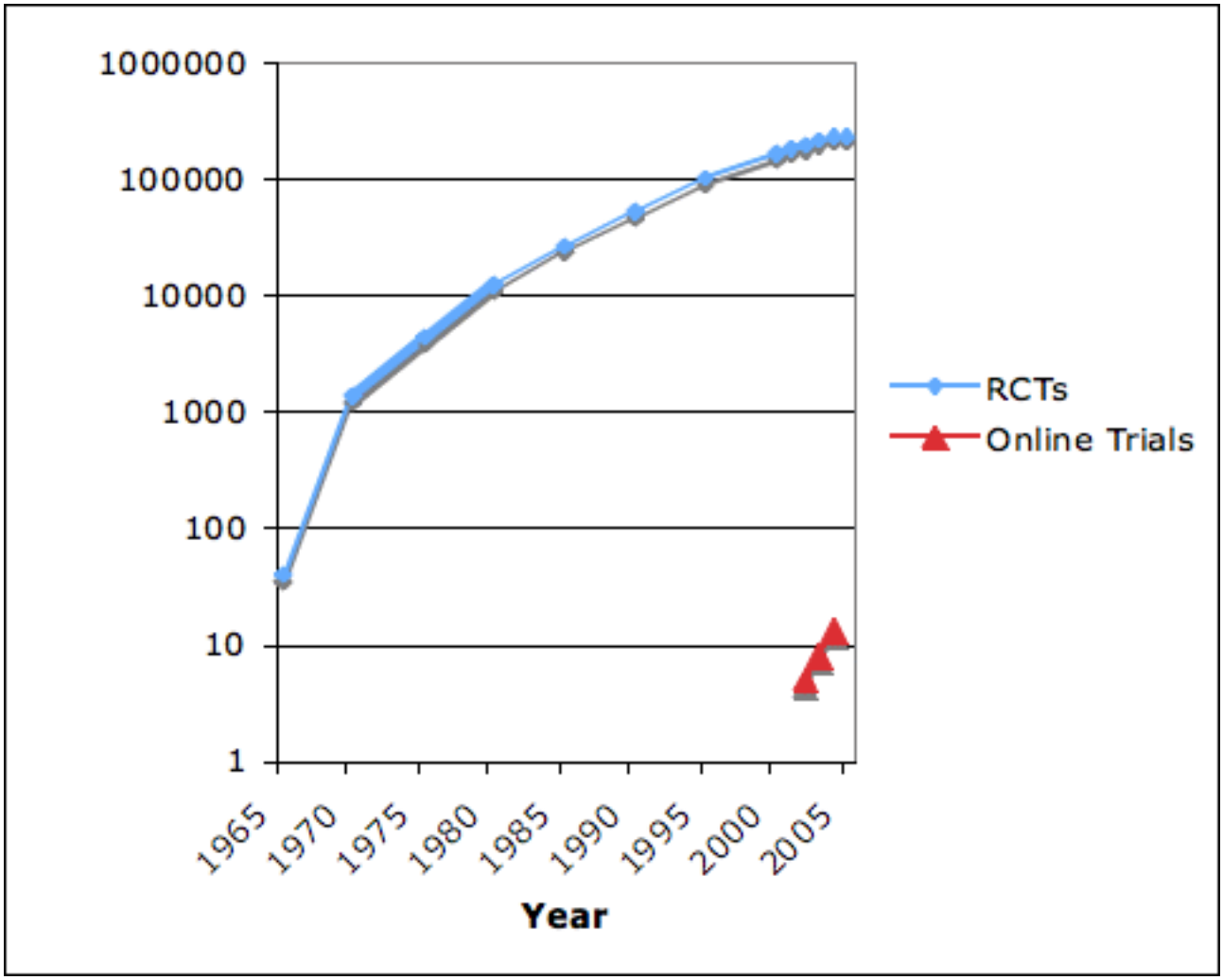
The Internet was born in the 1960s and its applications were initially limited by the military uses for which it was originally conceived. The original “Internet” consisted of a cooperative network of four university computers in the United States (Stanford Research Institute; University of California, Los Angeles [UCLA]; University of California, Santa Barbara; and University of Utah) [1]. The development of a protocol for information distribution in 1990 by Tim Berners-Lee paved the way for the emergence on the Internet of applications with broader public appeal [2]. Fifteen years after its inception, the World Wide Web has become a nearly indispensable tool in education, government, business, news media and, most

important for the purposes of this paper, medicine and research [3]. Originally designed as an emergency communications network, the medium evolved from a communications tool for academics and the military to a medium used for education, government, business, news media, entertainment, medicine, and research. The Internet has grown at a phenomenal rate; with over 100 thousand domains or hosts in 1993 it currently has over 250 million [4]. It is the first unrestricted uncensored broadcast medium, and under ideal circumstances (namely, the right location, low traffic volumes and the right service provider), it can be very cost-effective, because unlike the telephone system, there is no charge for long-distance service.

Origins of the Randomized Controlled Trial

A clinical trial can be defined as any form of planned experiment involving patients [5]. The goal of a trial is to discover or verify the safety and effectiveness of interventions designed to promote wellness and prevent, diagnose, treat and provide prognosis information about disease [6]. The essence of a trial is comparison [7]. The comparison is between a group of patients who receivedtreatment with the intervention in question and a group of patients who receivedplacebo or another standard treatment. The modern clinical trial has evolved to include several features in order to provide reliable and valid results. A good trial addresses a specific clinical question for which there is equipoise (an uncertainty as to whether any of the treatments is to be preferred over the others). It uses a predefined patient population, a well-defined intervention in comparison with an appropriate control, predefined outcomes, and a methodology that involves getting informed consent from participants. Further, a trial involves appropriate blinding, randomization, and analysis. The inclusion of a control group, as opposed to historical data, is to ensure that any observed differences are due to the treatment under investigation and not another prognostic factor [5]. The purpose of randomization is to balance the treatment groups for both known and unknown prognostic factors such that any observed differences in outcome are more likely to be due to differences between the treatments in question [8]. Hence, randomization helps to prevent patient selection bias. The purpose of blinding (patients, investigators, and analysts) is to prevent outcome assessment bias.

Figure 1. Cumulative number of randomized control trials (RCTs) versus online RCTs (based on Medline and Old Medline searches from 1950) on a logarithmic scale over time



Although many examples of clinical investigation can be found throughout the history of medicine, the RCT emerged in the mid-20th century as the most powerful and scientifically sound way to establish the efficacy and safety of medications [9]. Statistician Ronald Fisher introduced the practice of randomization (randomly assigning study participants to one

or more treatment groups) in horticultural research in 1926 [6]. An epidemiologist, Austin Bradford Hill, is generally given credit for the first randomized trial involving humans in 1948 [7]. This trial, conducted by the Medical Research Council in the United Kingdom, addressed the question of whether streptomycintherapy and bed rest was more effective than bed rest alone in treating patients with pulmonary tuberculosis. In the past few decades the RCT has been increasingly used as a method to evaluate medical interventions. The Cochrane Controlled Trials Register (CCTR) is a bibliography of controlled trials generated from hand searching the world's medical journals and as of the year 2004 it identified over 415 thousand trials [10]. A recent search of the PubMed database of the National Library of Medicine in the United States yielded 65886 controlled clinical trials and 32760 of these were randomized controlled trials. This represents published trials since the mid-1960s [11]. Figure 1 illustrates the growth of RCTs. The increasing pace of RCT research is reflected by the fact that it took 21 years (1948-1969) for the first 1000 trials to be conducted yet thousands of trials were conducted in 2004 alone.

The Complexity of Modern Clinical Trials

An RCT is conceptually simple, but to plan a protocol for a study, obtain funding, recruit patients, conduct the trial, and analyze the data collected require considerable resources. The initial clinical trials evaluating antibiotic therapy for communicable diseases had the advantage of large treatment effects–Hill's trial on streptomycin therapy demonstrated a 74% risk reduction for mortality [12]. Today, most interventions investigated in superiority trials are expected to have a more modest benefit, perhaps a 10% to 20% risk reduction for an important outcome [6]. In order to investigate these more modest treatment effects it is necessary for modern trials to be carefully designed so that both systematic and random error are minimized, as differences of this magnitude cannot be detected reliably against a background noise of chance or other influences. Systematic error is minimized with a well-designed protocol that avoids bias, and random error is avoided by studying a large enough sample size [13]. Sample size is of particular importance in the conduct of equivalence trials. Equivalence trials, in contrast to superiority trials, are designed to establish no difference in efficacy between two interventions. However, in order to show equal efficacy, equivalence trials usually will require a 10% larger sample size in comparison with conventional superiority trials [14]. In order to achieve a sufficient sample size in a reasonable time, many trials recruit patients from multiple centers across several geographical entities (eg, cities, countries) [6]. These multicenter trials require infrastructure which is accomplished with a central coordinating center that usually handles the recruitment of study centers, the randomization of patients, any necessary laboratory analysis of patient samples, data collection, data analysis, and quality control [15].

Internet Resources Applied to the Clinical Trial

Although the complexity of modern clinical trials is unlikely to change in the future, using Internet resources may reduce the expense and development time of a clinical trial. The Internet has many features that are useful in the conduct of a clinical trial. For instance, funding information and tools for developing a trial protocol are available online; and the processes of patient registration, randomization, data collection, analysis, and publication can all be accomplished with online resources. The Internet is also an ideal vehicle for the dissemination of information, and in this respect may facilitate the ease and rapidity with which the findings of a trial are translated into clinical practice. Table 1 summarizes a selection of Internet resources for conducting a clinical trial.

Online Resources for Developing a Trial Protocol

A well-designed RCT begins with the identification of a medically important question [16]. Before undertaking a new trial it is important to know what research has been done on the question in the past. To identify previous trials and systematic reviews, the Internet can be used to search online databases. Medline, EMBASE, and the Cochrane Library are online resources that can be used to quickly identify both systematic reviews and clinical trials [17]. Medline can be accessed free of charge using PubMed, but both EMBASE and the Cochrane Library require registration and an access fee [10-12]. Once relevant citations are found, most of the full text articles can be obtained by accessing the journal's home page. Members of academic institutions can often access electronic journals free of charge from their homes or offices by accessing websites via a proxy server, most often the institution's library home page [18]. Ongoing and some completed trials can be located from online trial registries in both the United States and Europe [19,20]. Online searches are useful in identifying published studies but researchers interested in exhaustive searches on a subject will have to supplement them with conventional hand searching of relevant article reference lists and by contacting experts in the area [21].

Once a research question is formulated and the literature in the field is reviewed, the Internet has tools to aid with the task of protocol development. The US National Cancer Institute maintains a website that has suggested templates for phase I – III studies, guidelines for dealing with various patient groups, as well as guidelines for formulating informed consent documents [22]. The University of California, San Francisco, School of Medicine maintains a website devoted to clinical research tools [23]. The site includes templates for study subject screening and data collection, data and safety monitoring, financial tracking, study budget, and checklists for protocol feasibility and study management. If the local expertise is not available to help with the development of the trial protocol, companies advertising online offer experienced teams of medical experts, biostatisticians, and clinical research specialists to help clients design clinical trials [24]. One of the key steps in the generation of a trial protocol is calculating the required sample size; online tools exist to perform this calculation [25].

Online Funding Information

A difficult hurdle is obtaining funding to conducta clinical trial. The Canadian Institute for Health Research, the National Institutes of Health in the United States, and the Medical Research Council in the United Kingdom maintain websites

that contain advice to applicants and online submission forms for specific grants [26-28].

Study Website and Communication Amongst Trial Personnel

There are many reasons for a multicenter clinical trial to have a website [29]. A study website can be used for the following tasks: providing information to potential participants, study subjects, and investigators; listing contact information; and centralizing data handling for patient registration, randomization and data collection. Detailed information about the trial can be displayed, and the entire protocol (apart from any confidential aspects) can be made available. A secure (password protected) section of the website can be used as a powerful means of communication for trial personnel (investigators, monitors, sponsors and committee members). Today electronic mail is the standard for communication amongst members of a trial group; it is faster than conventional mail, cheaper than using long-distance telephone service, and provides an archive record of the communications. A directory on the website of the investigators, committees, sponsors, and monitors with their email addresses can help improve communications. A directory of participating centers and regional coordinators would also be helpful. A news section of the website can provide a progress report concerning the trial status and advertise upcoming meetings. A ”Frequently Asked Questions” section can provide investigators with answers to common questions regarding the study protocol, and a download page can be a means of distributing study materials (protocol, case report forms, informed consent forms) to participating study centers.

Table 1. Summary of Internet resources for clinical trials

Organization	Universal Resource Locator (URL)
Funding Information	
Canadian Institutes of Health Research	http://www.cihr.gc.ca
US National Institutes of Health	http://grants1.nih.gov/grants/index.cfm
UK Medical Research Council	http://www.mrc.ac.uk/index/funding.htm
Bibliographic Databases	
National Library of Medicine - Medline	http://www.ncbi.nlm.nih.gov/entrez/query.fcgi
The Cochrane Collaboration – The Cochrane Library	http://www.cochranelibrary.com
Elsevier Science – Bibliographic Databases	http://www.embase.com
Clinical Trial Registries	
National Institutes of Health – ClinicalTrials.gov	http://www.clinicaltrials.gov
Current Controlled Trials - *meta*Register of Controlled Trials	http://www.controlled-trials.com
Veritas Medicine Inc.	http://www.veritasmedicine.com
Centerwatch Clinical Trials Listing Service	http://www.centerwatch.com
Internet Randomization Services	
Directory of Randomization Services	http://www.sghms.ac.uk/depts/phs/guide/randser.htm
Randomization.com	http://www.randomization.com
Paradigm	http://telescan.nki.nl/paradigm.html
Online Analysis and Sample Size Calculation	
Simple Interactive Statistical Analysis – SISA	http://home.clara.net/sisa/index.htm
Statpages.net	http://members.aol.com/johnp71/javastat.html
Online Publications	
Free Medical Journals	http://www.freemedicaljournals.com/
Directory of Open Access Journals	http://www.doaj.org

Online Recruitment of Patients

The Internet also plays an increasing role for informing the general public about ongoing trials that are recruiting patients. Prior to the emergence of the Internet most patients were recruited for clinical trials through their physicians or perhaps through mass media advertising [30]. This system depends on individual physicians keeping up-to-date with a large range of clinical trials--an impossible task. The US Food and Drug Modernization Act of 1997 required the Department of Health and Human Services to establish a registry of clinical trials for both the government and the private sector [31]. As a result a new trial registry was launched and the home page banner reads “linking patients to medical research.”[19] The site was launched in February 2000 and currently contains approximately 11300 clinical studies sponsored by the National Institutes of Health, other US government agencies, and the pharmaceutical industry in over 90 countries. People who access the site can find trials

by searching by disease condition or funding source. The website also provides information for people considering participating in a trial, including basic information on clinical trials. Several other commercial websites have been launched with the business idea of linking patients with clinical trials [32-34]. It is important for potential participants to be cautious because financial incentives used to recruit patients may interfere with ethical informed consent [30].

Online Patient Registration and Informed Consent

Once a patient indicates interest in participating in a particular trial, he is then screened for eligibility, and provided with the information necessary for informed consent and a consent form for signature. The necessary data for enrollment into the study is then collected. A study website can provide detailed information about the clinical trial presented in terms which the general public can understand. An online questionnaire canscreen for potential participants, and eligible patients, who elect to participate, canbe directed to the enrollment page and consent forms, made available for downloading from the website. This paradigm necessitates that potential participants have access to the Internet and that they be reasonably familiar with computers. To access the Internet, potential participants would require a personal computer, a Web browser, and access to the Internet via an Internet service provider [35]. Given these requirements, this method of patient recruitment could lead to selection bias. Surveys conducted on the demographics of Internet users show that the average user is young, white, employed, well-educated, with a higher social-economic status, and suburban [36]. Those who lack the resources for online access (for example, those with a disability that prevents access, or those who are socially disconnected or lack knowledge about Internet access points in the community) would be less likely to use the Internet and would therefore be underrepresented; whereas professionals working in the computer or telecommunications industries would likely be overrepresented.

Traditionally, study participants have signed consent documents by hand, but new legislation in both the United States and Canada has given legal weight to digital signatures for the purpose of facilitating electronic commerce [37,38]. A digital signature is a unique string that special software creates by applying a mathematical function and an encryption key to a message or file [39]. The unique string confirms both the file author's identity and the maintenance of the integrity of the file during its transmission. If accepted as ethical and legal for clinical trials, digital signatures would save the step of mailing hand-signed consent forms to the coordinating center. Regardless of the method used to obtain consent, it is important that the study participants are appropriately informed of the potential risks and benefits of the trial intervention, and of their rights regarding their electronic information. It is necessary to offer patients the option of not having their information handled electronically (for those that refuse)and to give them the option to request removal of their electronic information from the electronic environment [40]. In terms of informed consent, an argument couldbe made that all eligible patients should speak to a study representative (in person or on the phone) in order to ensure that the complexity of the study and confidentiality issues are clearly communicated and understood prior to proceeding with registration into the clinical trial. In-person contact with all trial participants wouldhelp with verification of the baseline data collection and help guard against people who might attempt to pose as a patient for mischievous reasons.

Online Randomization

The method of dividing subjects into groups is called random allocation or randomization and is necessary to ensure that any baseline differences between groups are due to chance alone [41]. This prevents selection bias and ensures validity of certain statistical tests. Several methods of randomizing have been used over the years, including coins, dice, cards, lots, spinning wheels, random number tables, and random number generators on computers. For multicenter trials a central coordinating center often serves as the randomization center and participating centers access the randomization allocation by a 24-hour phone service. As an alternative to this service, which can be expensive, there are several online randomization programs (some free of charge and some commercial) that can generate random allocations [42]. Randomization.com is a cost-free online randomization program that generates simple lists of allocations that can then be printed [43]. Paradigm is a Web-based randomization package developed by the Netherlands Cancer Institute and the UK Medical Research Council; it is free of charge and guides through studies interactively [44].

Online Data Collection

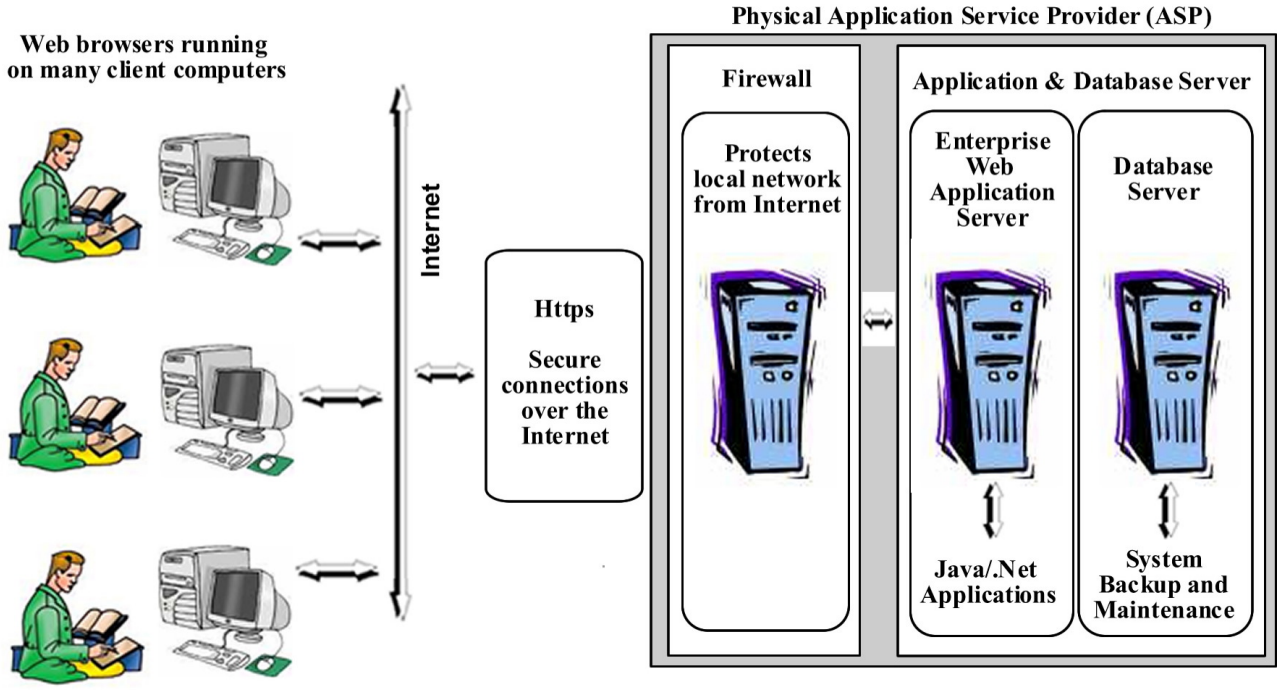
Remote data entry to a central database is one of the more useful promises of conducting a clinical trial using the Internet. A single-center clinical trial can have data entry decentralized by having a two-tier (client-server) network system that involvesindividual application instances (thick clients) running on remote computers connected to a central database server [45].

In a multicenter trial, participating centers can be geographically separated by great distances across several cities and countries, making the traditional local area network unfeasible. A thin-client (less bandwidth intensive) Internet-based solution canbe used to connect study centers from all over the world. An Internet data entry solution has Web-browsers - thin clients running on remote computers with the application itself running in a central Web enterprise application server. The three tiers (client/investigator, Web application server, and database server) of an online trial system are illustrated in Figure 2. With this system the following processes occur: browser requests/submits data from/to the Web application server; the Web application server in turn executes incoming business logic and submits/requests data to/from the database server; the database server saves the submitted data and sends the requested data to the Web application server; and the Web application server then executes the outgoing business logic in the application, formats the resulting data into HTML,and sends it back to the browser as a Web page. With this Web system the traditional case report forms are translated into electronic forms in HTML [46].

HTML Web pages by themselves are static text documents that cannot accept data input [47]. It is necessary to incorporate an additional enterprise application between the Web server and

the database server in order to facilitate data collection, increase the efficiency of database requests and offer additional functionality for interactive real-time data validation [46]. Real-time data validation (see below) can reduce transcription errors and avoids missing data; the data thus collected should be of higher quality. The step of double keying the data for quality assurance becomes redundant [48]. This additional functionality can be incorporated by running Java or .Net code in the application server, which allows for interactive behavior with each data field [46,49]. Java is a computer programming language developed by Sun Microsystems that allows small-application programs to be downloaded from a server to a client along with the data that each program processes [50]. More commonly Java writes server-side enterprise applications that interact with Web browsers and other enterprise applications through pure HTML and Extensible Markup Language (XML) over the Internet and corporate intranet, and XML Web services (small, discrete, building-block applications that connect to each other). Microsoft .NET is a set of Microsoft software technologies for software integration through the use of XML Web services as well as to other larger applications—via the Internet [51].

Figure 2. Example of a 3-tier architecture in an online clinical trial system



XML is designed to improve the functionality of the Web by providing more flexible and adaptable information identification. It is called extensible because it is not a fixed format as is HTML (a single, predefined markup language). Instead XML is actually a metalanguage (a language for describing other languages) for designing customized markup languages for limitless types of documents [52].

Online Data Validation

Clinical data comes directly from the patient, the medical record, or a laboratory test. In traditional paper-based clinical trials, data is recorded on paper case report formsand then transcribed into a computer. Electronic data collection through the Internet has a number of advantages including real-time data validation, time savings due to fewer steps in data collection, and reduced handling and storage costs due to the near-elimination of paper source documents. Real-time validation could alert a researcher to an invalid entry even as he is viewing the original data source. For example, a researcher recording systolic blood pressure (in mmHg) and entering a value of 1400 couldbe prompted immediately of an invalid entry, allowing for immediate correction. The disadvantage of this electronic approach is that the US Food and Drug Administration requires validation of clinical data from each trail and it is not clear how this can be done with electronic systems. In the past the computer hardware for mobile data collection was insufficient, and study data monitors have been reluctant to embrace a fully electronic data collection model [53].

Online Data Analysis

After collection, data can be analyzed using online statistical tools. Simple Interactive Statistical Analysis (SISA) is one example of such Web service [25]. This Java program allows users to do statistical analysis directly on the Internet. Users select one of the procedure names, fill in a form, and click a button for immediate data analysis. Another website contains hundreds of links to free-of-charge online statistics books, tutorials, downloadable software, and related resources; immediate analysis of the results is available to the investigator [54].

Security Issues

Security is a central issue when considering the Internet for sensitive information exchange. Both patients and study investigators need to be confident that the data entered on electronic forms and in email communications will not be intercepted by a sniffer. A sniffer is software that monitors network traffic and it is analogous to a telephone tap [48]. The

database server itself needs to be protected from intrusion from unauthorized Internet users and from unauthorized intranet users (clients connected to the local area network) [39]. Lastly, the system needs to guard against spoofing (the practice of someone pretending to be someone else) [48]. Malicious Internet users could enter fictitious patient information and invalidate the trial results. Essentially, a secure Internet clinical trial system should ensure confidentiality (information is only disclosed to users authorized to access it), integrity (information is only entered or modified by users authorized to do so), and availability (information and other resources can be accessed only by authorized users) [55].

The underlying network protocol (TCP/IP) on the Internet contains no security layer [49]. To address the issue of secure Internet transmissions, Netscape designed a nonproprietary protocol for providing data security between application protocols (such as http, telnet, NNTP, or FTP) and TCP/IP [39]. The Secure Socket Layer (SSL) provides data encryption, server authentication, and optional client authentication for a TCP/IP connection. Encrypting a file changes it from readable text to a series of numbers that only parties that have the decryption key can interpret. The latest versions of Web browsers support 128-bit encryption, translating to a code that is almost impossible to break. A computer capable of 225 million instructions per second would take a dedicated year of processor time to break such an encryption code. Documents from secure servers can be identified from the location (URL) field. The letter “s” is added to the protocol (http:// becomes https://). Encryption is also available for email communications, and this is usually (depending on the software used) can be selected as an option in the preferences menu of the email application.

After secure transmissionand storage, the data needs protection from unauthorized access once it is stored on the central database server. For this purpose firewalls – hardware and/or software that sits between the database server and the Internet – are used [39]. Further, the database server needs to be placed in a secure location so that unauthorized users cannot access it.

With the confidentiality of the clinical data maintained by encrypted transmissions and firewalls, the integrity of the data can be maintained by user logins and passwords for data entry and editing [56]. More sophisticated user authentication is possible using digital signatures. Potential spoofers have to be screened out by the enrollment procedure. This can be accomplished by communicating with the primary caregivers of potential study participants.

Online Publication

Currently, most major medical journals are published online and individual articles, including the title and abstract, can be browsed; full text versions are often available for download. Freemedicaljournals.com is a website that contains links to over 900 medical journals with full text articles free of charge [57]. Several mainstream journals are included but some journals limit access to articles that have been published for greater than six months to a year. Open Access journals such as those listed in the Directory of Open Access Journals (eg. BioMed Central [58] or the Journal of Medical Internet Research) offer speedy peer review and rapid publication. Article Processing Fees need to be paid from the authors' research institution or grant to cover the expenses for the peer review process and the preparation for online publication. It is the main source of income to recover publication costs for Open Access journals since the articles can be viewed free of charge and no pay-per-view charges can be imposed.

Examples of Online Trials

Prior to the wide availability of the Internet, the The Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarcto micocarico acuto (GISSI-3) Trial used telecommunications technology in the administration of the trial, [3,29]. Of the 200 participating Italian centers, 100 were provided with a computer and a modem to allow direct telephone connection to the GISSI-3coordinating center's main computer. Custom software allowed for patient enrollment, randomization, and reminder notices to the participating centers.

A Medline search of the with the search query “Internet and Clinical Trials” reveals that the Internet is increasingly being used, in whole or in part, to conduct clinical trials [40,59-73]. The 5 largest trials are summarized in Table 2. As of today, all results, except those of the ophthalmology trial which began in 2001, have been released. A large number of patients participated in Internet-based clinical trials. In these 5 trials alone over 26000 patients have been enrolled and randomized [74]. The largest Internet trial is the INVEST cardiology trial which investigated the adverse outcomes from different antihypertensive therapies. This trial alone randomized over 22000 patients. Each trial used different components of Internet technology in the administration of the studies. All 5 trials used a trial website, 4 published the protocol online, 4 allowed for online registration, 5 allowed for online data collection, and 4 used email to communicate amongst investigators. Security was approached differently as well. Two trials described using a data server firewall, 4 trials used confidential website addresses to shield their sites from spammers, 4 trials used user IDs and passwords, 3 trials described using encrypted transmissions, 2 trials did not send any patient identifying data online, and 1 trial required a 6-digit numerical code to access the website which was assigned by an RSASecurID key fob (RSA is a cryptosystem named after its inventors Rivest, Shamir and Adleman). The trials may have used other Internet technologies and security features but the preceding details are those described in their methods.

Table 2. Examples of clinical trials conducted using the Internet

Number	Title	Specialty	Year*	References
1	Lower Pole Renal Calculi	Urology	2004	[65]
2	Growth Restriction Intervention Trial (GRIT)	Obstetrics	1996	[48, 62]
3	International Verapamil SR/Trandolapril Study (INVEST)	Cardiology	1997	[59,74,75]
4	Osteoarthritis of the Knee: Trial of Glucosamine	Orthopedics	2000	[40]
5	Intraoperative Anti-infective Prophylaxis	Ophthalmology	2001	[60]

Trial	1	2	3	4	5
Study centers	21 centers in North America	69 centers in 13 European countries	862 centers in 14 countries	Single center	Various centers in Germany
Methodology	Multicenter randomized controlled trial	Multicenter randomized controlled trial	Multicenter randomized controlled trial	Double blind randomized controlled trial	Multicenter controlled trial
Population	Adults with lower pole renal calculi	Primary physician uncertain whether a growth restricted baby should be delivered or not	Adults with coronary artery disease and hypertension	Adult patients with osteoarthritis of the knee.	Adult patients undergoing elective cataract surgery
Sample size	112	548	22576	205	4000 to date
Intervention	Shock wave lithotripsy, percutaneous nephrolithotomy and retrograde ureteroscopic stone manipulation	Early delivery versus delayed delivery	Antihypertensive therapy with verapamil versus atenolol/hydrocholorothiazide	Glucosamine versus placebo	Irrigation with gentamicin versus regular irrigation
Outcomes	Stone removal	Perinatal mortality and developmental quotient at 2 years	Adverse outcomes: all-cause mortality, nonfatal MI, or nonfatal stroke	WOMAC pain scores	Postoperative endopthalmitis
Internet Technologies					
Online protocol	•†	•	•	•	
Online registration	•	•	•	•	
Online randomization	•	•	•	•	
Online data collection	•	•	•	•	•
Email communication	•		•	•	•
Data server Fifrewall	•			•	
Confidential website	•	•	•	•	•
User IDs / passwords	•	•	•	•	
Encrypted transmission	•		•		
Other	Website requires a 6-digit code assigned by an RSA SecurID key fob	No patient identifying data sent online, but by more secure means	Online ordering of study medications	Automated reminder emails and personalized schedules	No patient identifying data sent online

* The year that the trial was started.

† "•" Denotes that the feature was present in the trial. If the "•" is absent, the feature was not present or was not documented in the protocol.

Advantages and Disadvantages of Online Trials

The numerous issues with online clinical trials are summarized in Table 3. Some advantages and disadvantages mentioned there are highlighted below.

Advantages

The main advantage of online clinical trials is the ability to centralize study information and coordinate multiple trial processes in real time at a lower cost [75]. Multicentered trials are more manageable because a system can be scaled easily to many study centers around the world without special requirements for hardware or software. The only requirement

for each participating center is a computer with a Web browser and Internet access. Site training, patient recruitment, randomization, data collection, site monitoring and patient safety can all be enhanced and simplified using a clinical trial system. Further advantages include fewer personnel for trial administration, reduced or neglible paper reporting, security and backup of the entire trial at a single location, optional updating and distribution of trial protocol and data collection forms from a single location, and simplified dissemination of results.

Disadvantages

The key disadvantages of online trials are the real and perceived security threats that may inhibit both patients and study centers from participating. It is difficult to convince the average person of the efficiency of the abstract security measures used in Internet trials (firewalls, encrypted transmissions, password protection) compared with the conventional security measures used in traditional trials (locked file drawers). If participants are recruited through the Internet, this may lead to selection bias. Given the anonymous and transient nature of the Internet, it can be difficult for trial coordinators to assess the suitability of Internet resources that are not directly associated with well-known academic institutions. The transient and anonymous nature of the Internet is illustrated by the practice of citing the date of access for electronic resources and by the fact that many documents on the Internet do not have a documented author. If a trial relies on a third-party Internet resource, there is always the possibility that the third-party website ceases to exist prior to the completion of the study, leaving the coordinators to find an alternative resource to complete the trial. For example, finding another randomization site in the midst of a trial, which takesinto account previously allocated patients, would be problematic.

Table 3. Advantages and disadvantages of using the Internet to conduct clinical trials

Topic	Advantages	Disadvantages
Communication	• Email and website notices make exchange of information less expensive, faster and easier	• Online communications are not as secure as more traditional means (telephone, fax and mail)
Feasibility	• No need for special hardware or software at participating centers • An online clinical trial system is easier and less expensive to scale to multiple sites across multiple countries	• Risk of selection bias if all study centers are required to have Internet access
Training	• Online training resources allow for easily accessible and flexible programs for investigators	• Online training may not be as effective as a live educator
Patient recruitment	• Cost-effective broadcast medium to advertise a study to potential participants and study centers • Maintenance of a real-time view of newly registered patients	• Some patients and study centers may decline involvement because of concerns over the security of online data • May miss enrolling patients if study centers have technical difficulty with the system and do not have a study coordinator available to help them troubleshoot one-on-one
Randomization	• Eliminates the need and expense of a 24-hour call-in center for registration and randomization. • Concealment of allocation would be easier without the presence of pre-prepared randomization envelopes that have the potential to be defeated	•It is harder to locate a computer terminal than a telephone at the point of patient contact
Data collection	• Enables real-time data validation • Increased speed of data acquisition, and quality of data • Eliminates need for double-keyed data entry	• Data input could be slowed down during times of peak Internet use when access to the Web server is slowed
Monitoring	• Study monitors have real-time access to all aspects of the trial activity	• With less frequent in-person site monitoring some problems may take much longer to be identified
Safety	• Internal Review Board (IRB) has real-time access to adverse events	
Security	• Sensitive patient data is centralized in one location which simplifies security management	• Online data can be intercepted during transmission or accessed from the database server if security measures are not sufficient
Study personnel	• Fewer data entry personnel required • Fewer trial coordinators required given the centralized administration	• Requires experienced computer professionals to set up and maintain an online clinical trial system
Administration	• Reduction or elimination of paper reporting • Study protocol and data collection forms can be updated centrally and distributed to the participating centers easily • Patient data can be backed up from one location • Audit trail functionality can allow a clinical trial to be reconstructed from any point • Once a research coordinating center develops or acquires an online clinical trial system the same system could be used for multiple trials	• Because of the expense of developing an online trial system it may not be feasible for smaller trials • Would have to duplicate Internet pages in multiple languages to accommodate international trials • If a trial relies on third party Internet resources there is no guarantee that the service will remain available for the duration of the trial • Internet resources are often anonymous and transient

Other disadvantages of an online system includes system performance, lack of live support personnel, and the setup cost. The speed of the online system can be slowed significantly during peak Internet traffic and this can prolong every step of a study, from registration to data entry. The lack of a 24-hour call-in center can lead to the loss of some patients because some study centers may not be able to use online help to solve their difficulties with the study protocol or the registration and randomization steps. To set up and maintain an online clinical trial system requires experienced computer professionals. This might be too expensive for smaller trials where the administration budget is modest.

Conclusions

Clinical trials often involve investigations of interventions of modest benefit that require multiple study centers in order to recruit a sufficient sample size in a reasonable time. The Internet can be used to administer these multicenter trials. Online resources are available to aid with each step of the study, including protocol development, identification of funding opportunities, recruitment, registration, randomization, data

collection, analysis, publication and communications. The Internet has the potential to enhance clinical trials such that multicentered trials are more manageable, less expensive, easier to administer, and less time-consuming. The biggest threats to online trials are the security risks of electronic data collection, transmission, and storage. Online security measures exist but it is not clear that these are sufficient to reassure most potential study participants. We can look forward to evolving Internet technology which will bring enhanced security measures, thereby adding to the general public's comfort with electronic data.

Conflicts of Interest

None declared.

References

1. Zakon R. Hobbes' Internet timeline. 2004. URL: http://www.zakon.org/robert/internet/timeline/ [accessed 2004 Aug 16]
2. Howe W. A brief history of the Internet. 2004. URL: http://www.walthowe.com/navnet/history.html [accessed 2004 Aug 16]
3. ; Gruppo Italiano per lo Studio della Sopravvivenza nell'infarto Miocardico. GISSI-3: effects of lisinopril and transdermal glyceryl trinitrate singly and together on 6-week mortality and ventricular function after acute myocardial infarction. Lancet 1994 May 7;343(8906):1115-1122. [Medline: 94239026]
4. ; Internet Systems Consortium. ISC Internet domain survey. URL: http://www.isc.org/index.pl?/ops/ds/ [accessed 2004 Aug 18]
5. Pocock SJ. The historical development of clinical trials. In: Clinical Trials: A Practical Approach. Toronto, Ont: John Wiley & Sons; Jan 20, 1984.
6. . In: Aaron HJ, Gelband H, editors; Institute of Medicine Staff. Extending Medicare Reimbursement in Clinical Trials. Washington, DC: National Academy Press; Apr 15, 2000.
7. Hill AB. The clinical trial. N Engl J Med 1952 Jul 24;247(4):113-119. [Medline: 52071838]
8. Jadad AR. Randomised Controlled Trials: A User's Guide. London, UK: BMJ Publishing Group; Oct 1, 1998.
9. Scolnick EM, Slater EE, Williams GW. "Natural history" clinical trials: an enduring contribution to modern medical practice. Adv Protein Chem 2001;56:1-12. [Medline: 21228605]
10. ; The Cochrane Collaboration. The Cochrane Library. 2004. URL: http://www.cochrane.org/ [accessed 2004 Aug 16]
11. ; US National Library of Medicine. PubMed. 2004. URL: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi [accessed 2004 Aug 16]
12. Fahey T. Randomized controlled trials. Br J Gen Pract 1997 Jun;47(419):401-402. [Medline: 97375130]
13. Peto R. Why do we need systematic overviews of randomized trials? Stat Med 1987;6(3):233-244. [Medline: 87291418]
14. Senn S. Statistical Issues in Drug Development. New York, NY: John Wiley & Sons; 1997.
15. Friedman LM, Furbert CD, Demets DL. Multicenter Trials. In: Fundamentals of Clinical Trials, 2nd edition. Littleton: Year Book Medical Pub; Aug 1, 1985:285-297.
16. Pogue J, Yusuf S. Overcoming the limitations of current meta-analysis of randomised controlled trials. Lancet 1998 Jan 3;351(9095):47-52. [Medline: 98095021] [doi: 10.1016/S0140-6736(97)08461-4]
17. Hunt DL, Mckibbon KA. Locating and appraising systematic reviews. Ann Intern Med 1997 Apr 1;126(7):532-538 [FREE Full text] [Medline: 97230750]
18. ; McMaster University Libraries. Electronic resources. 2002. URL: http://www.mcmaster.ca/library/research/research.htm [accessed 2002 May 4]
19. ; US National Institutes of Health. ClinicalTrials.gov. 2004. URL: http://www.clinicaltrials.gov/ [accessed 2004 Aug 16]
20. Godlee F. Current clinical trials. 2002. URL: http://www.controlled-trials.com/ [accessed 2002 May 4]
21. Oxman AD, Cook DJ, Guyatt GH. Users' guides to the medical literature. VI. How to use an overview. Evidence-Based Medicine Working Group. JAMA 1994 Nov 2;272(17):1367-1371. [Medline: 95018983] [doi: 10.1001/jama.272.17.1367]
22. ; US National Cancer Institute, Cancer Therapy Evaluation Program. Protocol templates, applications and guidelines. 2004. URL: http://ctep.cancer.gov/guidelines/templates.html [accessed 2004 Aug 16]
23. ; University of California, San Francisco, School of Medicine. UCSF clinical research manuals and guidelines. 2004. URL: http://medschool.ucsf.edu/research_forms/ [accessed 2004 Aug 16]
24. Research Triangle Institute 2002 [FREE Full text]
25. Uitenbroek D. SISA-Binomial. 1997. URL: http://home.clara.net/sisa/index.htm [accessed 2004 Aug 16]
26. ; Canadian Institutes of Health Research. Funding. 2004. URL: http://www.cihr.gc.ca/ [accessed 2004 Aug 16]
27. ; National Institutes of Health, US Department of Health and Human Services. Grants & funding opportunities. 2004. URL: http://grants1.nih.gov/grants/index.cfm [accessed 2004 Aug 16]
28. ; UK Medical Research Council. Funding. 2004. URL: http://www.mrc.ac.uk/index/funding.htm [accessed 2004 Aug 16]
29. Santoro E, Nicolis E, Franzosi MG, Tognoni G. Internet for clinical trials: past, present, and future. Control Clin Trials 1999 Apr;20(2):194-201. [Medline: 99241957] [doi: 10.1016/S0197-2456(98)00060-9]

30. Lutz S, Henkind SJ. Recruiting for clinical trials on the Web. Healthplan 2000;41(5):36-43. [Medline: 21021516]
31. Charatan F. US launches new clinical trials database. BMJ 2000 Mar 11;320(7236):668 [FREE Full text] [Medline: 20177567] [doi: 10.1136/bmj.320.7236.668]
32. Condon G. Web firms match patients with drug companies, government studies. Hartford Courant. 2000 Dec 26. URL: http://www.detnews.com/2000/health/1226/internet/internet.htm [accessed 2004 Aug 16]
33. ; Veritas Medicine Inc. Veritas Medicine. 2004. URL: http://www.veritasmedicine.com/ [accessed 2004 Aug 16]
34. ; Thompson Centerwatch. Centerwatch clinical trials listing service. 2004. URL: http://www.centerwatch.com/ [accessed 2004 Aug 16]
35. Comer D. Internet. 2001. URL: http://encarta.msn.com/ [accessed 2002 May 2]
36. Greenspan R. Internet not for everyone 2003 [FREE Full text]
37. Costello S. Clinton signs digital signature bill. 2000. URL: http://www.fcw.com/civic/articles/2000/0703/web-1esign-07-03-00.asp [accessed 2004 Aug 16]
38. ; The House of Commons, Parliament of Canada. Bill C-6, An Act to support and promote electronic commerce by protecting personal information that is collected, used or disclosed in certain circumstances, by providing for the use of electronic means to communicate or record information or transactions and by amending the Canada Evidence Act, the Statutory Instruments Act and the Statute Revision Act, Part 2, Electronic Documents. 1999. URL: http://www.parl.gc.ca/36/2/parlbus/chambus/house/bills/government/C-6/C-6_3/90052b-3E.html [accessed 2004 Aug 16]
39. Jamsa K. Hacker Proof. Albany, New York: Thomson Delmar Learning; Feb 1, 2002.
40. Dorman K, Saade GR, Smith H, Moise KJ. Use of the World Wide Web in research: randomization in a multicenter clinical trial of treatment for twin-twin transfusion syndrome. Obstet Gynecol 2000 Oct;96(4):636-639. [Medline: 20494434] [doi: 10.1016/S0029-7844(00)00978-9]
41. Bland M. An Introduction to Medical Statistics (Oxford Medical Publications). New York, NY: Oxford University Press; Sep 15, 2000.
42. Bland M. Directory of randomisation software and services. 2004. URL: http://www.sghms.ac.uk/depts/phs/guide/randser.htm [accessed 2004 Aug 16]
43. Dallal G. Randomization.com. 2004. URL: http://www.randomization.com/ [accessed 2004 Aug 16]
44. Jenkin L. Paradigm. 2002. URL: http://telescan.nki.nl/paradigm.html [accessed 2002 May 11]
45. Brandt CA, Nadkarni P, Marenco L, Karras BT, Lu C, Schacter L, et al. Reengineering a database for clinical trials management: lessons for system architects. Control Clin Trials 2000 Oct;21(5):440-461. [Medline: 20472497] [doi: 10.1016/S0197-2456(00)00070-2]
46. Wübbelt P, Fernandez G, Heymer J. Clinical trial management and remote data entry on the Internet based on XML case report forms. Stud Health Technol Inform 2000;77:333-337. [Medline: 21035838]
47. Francisco M. Internet. Clinical trials. Nat Biotechnol 1999 Feb;17(2):202. [Medline: 99159726] [doi: 10.1038/6211]
48. Kelly MA, Oldham J. The Internet and randomised controlled trials. Int J Med Inform 1997 Nov;47(1-2):91-99. [Medline: 98165224] [doi: 10.1016/S1386-5056(97)00091-9]
49. Sippel H, Ohmann C. A web-based data collection system for clinical studies using Java. Med Inform (Lond) 1998;23(3):223-229. [Medline: 99001503]
50. Niemeyer P, Peck J. Exploring Java. Bonn, Germany: O'Reilly; May 1, 1996.
51. Platt DS. Introducing Microsoft .NET. Redmond, Washington: Microsoft Press; May 16, 2001.
52. Flynn P. The XML FAQ. 2004. URL: http://www.ucc.ie/xml [accessed Aug 16]
53. Marks RG. Validating electronic source data in clinical trials. Control Clin Trials 2004 Oct;25(5):437-446. [Medline: 15465614] [doi: 10.1016/j.cct.2004.07.001]
54. Pezzullo J. Statpages.net - web pages that perform statistical calculations!. 2004. URL: http://members.aol.com/johnp71/javastat.html [accessed Aug 16]
55. Edworthy SM. World wide web: opportunities, challenges, and threats. Lupus 1999;8(8):596-605. [Medline: 20038220] [doi: 10.1191/096120399680411434]
56. Mcfadden ET, Lopresti F, Bailey LR, Clarke E, Wilkins PC. Approaches to data management. Control Clin Trials 1995 Apr;16(2 Suppl):30S-65S. [Medline: 95308991] [doi: 10.1016/0197-2456(94)00093-I]
57. ; Amedeo Group. FreeMedicalJournals.com. 2002. URL: http://www.freemedicaljournals.com/ [accessed 2002 June 2]
58. ; BioMed Central. BioMed Central Journals. 2002. URL: http://www.biomedcentral.com/ [accessed 2002 May 14]
59. Pepine CJ, Handberg-thurmond E, Marks RG, Conlon M, Cooper-dehoff R, Volkers P, et al. Rationale and design of the International Verapamil SR/Trandolapril Study (INVEST): an Internet-based randomized trial in coronary artery disease patients with hypertension. J Am Coll Cardiol 1998 Nov;32(5):1228-1237. [Medline: 99025802] [doi: 10.1016/S0735-1097(98)00423-9]
60. Kuchenbecker J, Dick HB, Schmitz K, Behrens-baumann W. Use of internet technologies for data acquisition in large clinical trials. Telemed J E Health 2001;7(1):73-76. [Medline: 21220147] [doi: 10.1089/153056201300093976]
61. Kiuchi T, Ohashi Y, Konishi M, Bandai Y, Kosuge T, Kakizoe T. A World Wide Web-based user interface for a data management system for use in multi-institutional clinical trials--development and experimental operation of an automated

patient registration and random allocation system. Control Clin Trials 1996 Dec;17(6):476-493. [Medline: 97129700] [doi: 10.1016/S0197-2456(96)00104-3]
62. ; The GRIT Study Group. When do obstetricians recommend delivery for a high-risk preterm growth-retarded fetus? Growth Restriction Intervention Trial. Eur J Obstet Gynecol 1996;67(2):121-126. [Medline: 8841799] [doi: 10.1016/0301-2115(96)02448-7]
63. Mezzana P, Madonna Terracina FS, Valeriani M. Use of a web site in a multicenter plastic surgery trial: a new option for data acquisition. Plast Reconstr Surg 2002 Apr 15;109(5):1658-1661 discussion 1662. [Medline: 21930658] [doi: 10.1097/00006534-200204150-00027]
64. Rangel SJ, Narasimhan B, Geraghty N, Moss RL. Development of an internet-based protocol to facilitate randomized clinical trials in pediatric surgery. J Pediatr Surg 2002 Jul;37(7):990-994 discussion 990-4. [Medline: 22072393] [doi: 10.1053/jpsu.2002.33826]
65. Lallas CD, Preminger GM, Pearle MS, Leveillee RJ, Lingeman JE, Schwope JP, et al. Internet based multi-institutional clinical research: a convenient and secure option. J Urol 2004 May;171(5):1880-1885. [Medline: 15076298] [doi: 10.1097/01.ju.0000120221.39184.3c]
66. Formica M, Kabbara K, Clark R, Mcalindon T. Can clinical trials requiring frequent participant contact be conducted over the Internet? Results from an online randomized controlled trial evaluating a topical ointment for herpes labialis. J Med Internet Res 2004 Feb 17;6(1):e6 [FREE Full text] [Medline: 15111272] [doi: 10.2196/jmir.6.1.e6]
67. Mcalindon T, Formica M, Kabbara K, Lavalley M, Lehmer M. Conducting clinical trials over the internet: feasibility study. BMJ 2003 Aug 30;327(7413):484-487 [FREE Full text] [doi: 10.1136/bmj.327.7413.484] [Medline: 22827257]
68. Thornton JG, Hornbuckle J, Vail A, Spiegelhalter DJ, Levene M; GRIT study group. Infant wellbeing at 2 years of age in the Growth Restriction Intervention Trial (GRIT): multicentred randomised controlled trial. Lancet 2004 Aug 7;364(9433):513-520. [Medline: 15302194] [doi: 10.1016/S0140-6736(04)16809-8]
69. Pepine CJ, Handberg EM, Cooper-dehoff RM, Marks RG, Kowey P, Messerli FH, et al; INVEST Investigators. A calcium antagonist vs a non-calcium antagonist hypertension treatment strategy for patients with coronary artery disease. The International Verapamil-Trandolapril Study (INVEST): a randomized controlled trial. JAMA 2003 Dec 3;290(21):2805-2816. [Medline: 14657064] [doi: 10.1001/jama.290.21.2805]
70. Miravitlles M, Llor C, Naberan K, Cots JM; Estudio EFEMAP. [Use of the Internet in a multicenter study of chronic obstructive pulmonary disease in primary care. Pilot phase of the EFEMAP study]. Arch Bronconeumol 2002 Sep;38(9):427-430 [FREE Full text] [Medline: 22222093]
71. Weber G, Kassai M, Csontos Z, Czuczor C, Horváth PO. First Hungarian, internet-based prospective, multicenter study: the hernia-project. Acta Chir Hung 1999;38(2):219-220. [Medline: 20064131]
72. Hollingsworth RA, Hay C, Richards B. An Internet implementation of an international clinical study. Stud Health Technol Inform 1999;68:528-531. [Medline: 20109672]
73. Farup PG. [Treatment of Helicobacter pylori infection--results and experiences with an Internet-based collaboration trial]. Tidsskr Nor Laegeforen 2003 Nov 20;123(22):3214-3217 [FREE Full text] [Medline: 14714012]
74. Pepine CJ. Introduction: the European INVESTigators meeting. Clin Cardiol 2001 Nov;24(11 Suppl):A6. [Medline: 21569186]
75. Marks R, Bristol H, Conlon M, Pepine CJ. Enhancing clinical trials on the internet: lessons from INVEST. Clin Cardiol 2001 Nov;24(11 Suppl):V17-V23. [Medline: 21569192]

Abbreviations

CCTR: Cochrane Controlled Trials Register
FDA: Food and Drug Administration
HTML: Hypertext Markup Language
RCT: Randomized Controlled Trial
SISA: Simple Interactive Statistical Analysis
SSL: Secure Socket Layer
XML: Extensible Markup Language

submitted 17.01.05; peer-reviewed by R Marks; comments to author 16.02.05; revised version received 07.03.05; accepted 09.03.05; published 16.03.05.

Please cite as:
Paul J, Seib R, Prescott T
The Internet and Clinical Trials: Background, Online Resources, Examples and Issues
J Med Internet Res 2005;7(1):e5
URL: http://www.jmir.org/2005/1/e5/
doi:10.2196/jmir.7.1.e5
PMID:15829477

Original Paper

Comparing the Efficacy of Two Internet-Based, Computer-Tailored Smoking Cessation Programs: A Randomized Trial

Jean-François Etter[1], PhD, MPH

Institute of Social and Preventive Medicine, University of Geneva, Geneva, Switzerland

Corresponding Author:
Jean-François Etter, PhD, MPH
University of Geneva, CMU
Institute of Social and Preventive Medicine
1 rue Michel-Servet
CH-1211 Geneva 4
Switzerland
Phone: +41 22 379 59 19
Fax: +41 22 379 59 12
Email: jean-francois.etter@imsp.unige.ch

Abstract

Background: Online computer-tailored smoking cessation programs have not yet been compared directly.

Objective: To compare the efficacy of two Internet-based, computer-tailored smoking cessation programs.

Methods: Randomized controlled trial conducted in 2003-2004. Visitors to a smoking cessation website were randomly assigned to either an original online, interactive smoking cessation program or to a modified program. Both programs consisted of tailored, personalized counseling letters based on participants' characteristics, followed by monthly email reminders. The original program was based on psychological and addiction theory, and on preliminary research conducted in the same population. The modified program was shorter and contained more information on nicotine replacement therapy and nicotine dependence, and less information on health risks and coping strategies. In both programs, 1 month and 2 months after entering the study, participants were invited by email to answer the same tailoring questionnaire again in order to receive a second counseling letter. Participants in both programs obtained, on average, 1.2 feedback counseling letters over 2.5 months, and 84% received only 1 feedback letter. The outcome was self-reported smoking abstinence (no puff of tobacco in the previous 7 days), assessed 2.5 months after entry in the program. We report results from intention-to-treat (ITT) analyses, where all non-respondents at follow-up were counted as smokers.

Results: The baseline questionnaire was answered by a total of 11969 current (74%) and former (26%) smokers, and the follow-up survey by 4237 people (35%). In an ITT analysis, abstinence rates in baseline current smokers were respectively 10.9% and 8.9% (odds ratio [OR]=1.24, 95% confidence interval [CI]1.08-1.43, *P*=.003) in the original and modified programs, and 25.2% and 15.7% (OR=1.81, CI 1.51-2.16, *P*<.001) in baseline former smokers. While we found statistically significant differences in quit rates in smokers in the contemplation stage favoring the original program (OR=1.54, CI 1.18-2.02, *P*=.002), no between-group differences in quit rates were observed in smokers in the precontemplation (OR=1.07, CI 0.36-3.14, *P*=.91) and preparation (OR=1.15, CI 0.97-1.37, *P*=.10) stages of change.

Conclusions: In smokers in the contemplation stage of change and in former smokers, the original program produced higher smoking abstinence rates than the modified program.

(J Med Internet Res 2005;7(1):e2) doi:10.2196/jmir.7.1.e2

KEYWORDS

Tobacco dependence; Internet; randomized controlled trials; smoking cessation; behaviour change

Introduction

Self-help smoking cessation booklets and leaflets can reach large numbers of smokers, but they may not be very effective [1]. Computer technology and psychological theory can be combined to produce effective individualized self-help smoking cessation materials and to disseminate them at the population level, in particular on the Internet [2]. Because individually tailored materials take into account the relevant characteristics of each participant, smokers may be more interested in reading these materials than untailored booklets, and may be more likely

to apply the advice included therein [3,4]. Consequently, tailored materials may be more effective than those intended for all smokers [1,5]. Several studies have tested the effectiveness of computer-tailored smoking cessation programs, with positive and negative results [1,6]. These programs were evaluated either on personal computers or when feedback materials were printed and sent by mail. Few studies tested the effect of smoking cessation programs administered on the Internet [7,8,9]. An early randomized trial conducted in 1998 on CompuServe showed that after 3 months smoking abstinence rates were higher in smokers who took part in an online discussion group and received e-mail messages compared to a control group, but this effect was not maintained at 6-month follow-up [7]. More recently, the only other randomized trial on this topic showed that in nicotine patch users, an online computer-tailored program was more effective in the short-term (10 weeks) than a non-tailored program [9]. A non-randomized trial showed that the effect of an online interactive program could be improved by tailored follow-up by email [8]. We know of no randomized trial comparing two online, computer-tailored smoking cessation programs. Such comparisons are nevertheless necessary, given the large variability in the effect of these programs [1].

In a previous study, we tested a paper version of a computer-tailored program [10,11]. In this version, questionnaires, computer-tailored counseling letters and stage-matched booklets were sent by mail to smokers. This study showed that 7 months after entry into the program, 7-day smoking abstinence rates were 2.4 times greater (8.0% vs 3.3%, $P<.001$) in the intervention group than in a control group that received no treatment. The same program is also available online, but the efficacy of the online version is unknown. We compared the online version of this program with another online smoking cessation program intended for users of nicotine replacement products.

Several websites offer interactive, computer-tailored smoking cessation programs, but these programs have never been compared directly in a randomized trial. Our aim was to compare the efficacy of two online, computer-tailored smoking cessation programs.

Methods

Setting and Participants

Participants were visitors of Stop-tabac.ch, a French-language website that provides information, advice, and support to smokers and ex-smokers. This website was listed among the 5 best websites on smoking cessation in a recent study [12], and it is listed first in Google.fr when searching with the words *arrêter de fumer*, *fumer*, or *tabac* (quit smoking, smoke, or tobacco) (tested February 21, 2005).

Interventions

Various services are available to visitors of Stop-tabac.ch, including fact sheets, booklets, answers to frequently asked questions, personal stories written by current and former smokers, discussion forums and chat rooms, tests, games, and two interactive, computer-tailored smoking cessation programs [10,11]. Each month, about 2% of the 50000 monthly visitors of the website take part in these interactive computer-tailored programs [13]. After reading an information page that briefly describes the programs, participants are informed that they will have to answer a questionnaire, that their answers will be retained on file, and that the data will be used only to organize a follow-up and for statistical analyses conducted in an anonymous format. They have the option of refusing to have their answers retained on file. The next step consists of answering the tailoring questionnaire. Enrollment of participants in this study took place between April 2003 and July 2004. In this period, two different questionnaire forms, referring participants either to the original or the modified program, appeared alternatively in random order. Thus participants were randomly assigned to either program.

Both programs consisted of tailored personal counseling letters compiled by a computer according to the answers made by participants. The counseling letters appeared on the screen immediately (<5 seconds) after the answers were submitted. Participants were advised to print their counseling letter and to read it again later. Participants in the original program were also advised to print stage-matched booklets available on the website.

The Original Program

The original program was based on the Transtheoretical Model of Change [14,15], on the Theory of Planned Behavior [16], on theories of relapse prevention [17] and tobacco dependence [18], on the Agency for Health Care Policy and Research recommendations [19], and on relevant literature [20,21]. The questionnaire, counseling letters, and brochures were also based on extensive research conducted on Swiss smokers and ex-smokers [22,23,24]. The tailoring questionnaire (Figure 1) assessed demographic characteristics, smoking status, stage of change (*precontemplation*, no intention of quitting smoking in the next 6 months; *contemplation*, seriously considering quitting in the next 6 months; *preparation*, has decided to quit in the next 30 days; *action*, has quit smoking for 6 months or less; and *maintenance*, has quit smoking for more than 6 months)[15], level of tobacco dependence, attitudes towards smoking, self-efficacy, use of self-change strategies and coping methods, and intention to use nicotine replacement therapy (NRT). We used validated multi-item scales to measure these variables [22,23,24,25]. Former smokers indicated the date that they had quit smoking. After answering the 62-item questionnaire, participants received a personal counseling letter of 6 to 9 pages (3000-4000 words) illustrated with cartoons and graphs that were also tailored to each participant's answers (Figure 2). The counseling letters consisted of about 20 paragraphs of text, chosen by the computer in a library of 350 paragraphs according to pre-established decision rules. This program was launched online in French in 1997 and was later expanded to include English, Danish, Italian and Chinese versions [13]. The interactive program was updated to include innovations (eg, new NRT products and bupropion), pictures, and a few additional questions and feedback paragraphs. Overall, the online version of the program tested in the present study is nevertheless largely similar to the paper version tested in our previous studies [10,11].

Figure 1. Screenshot of the tailoring questionnaire for the original program

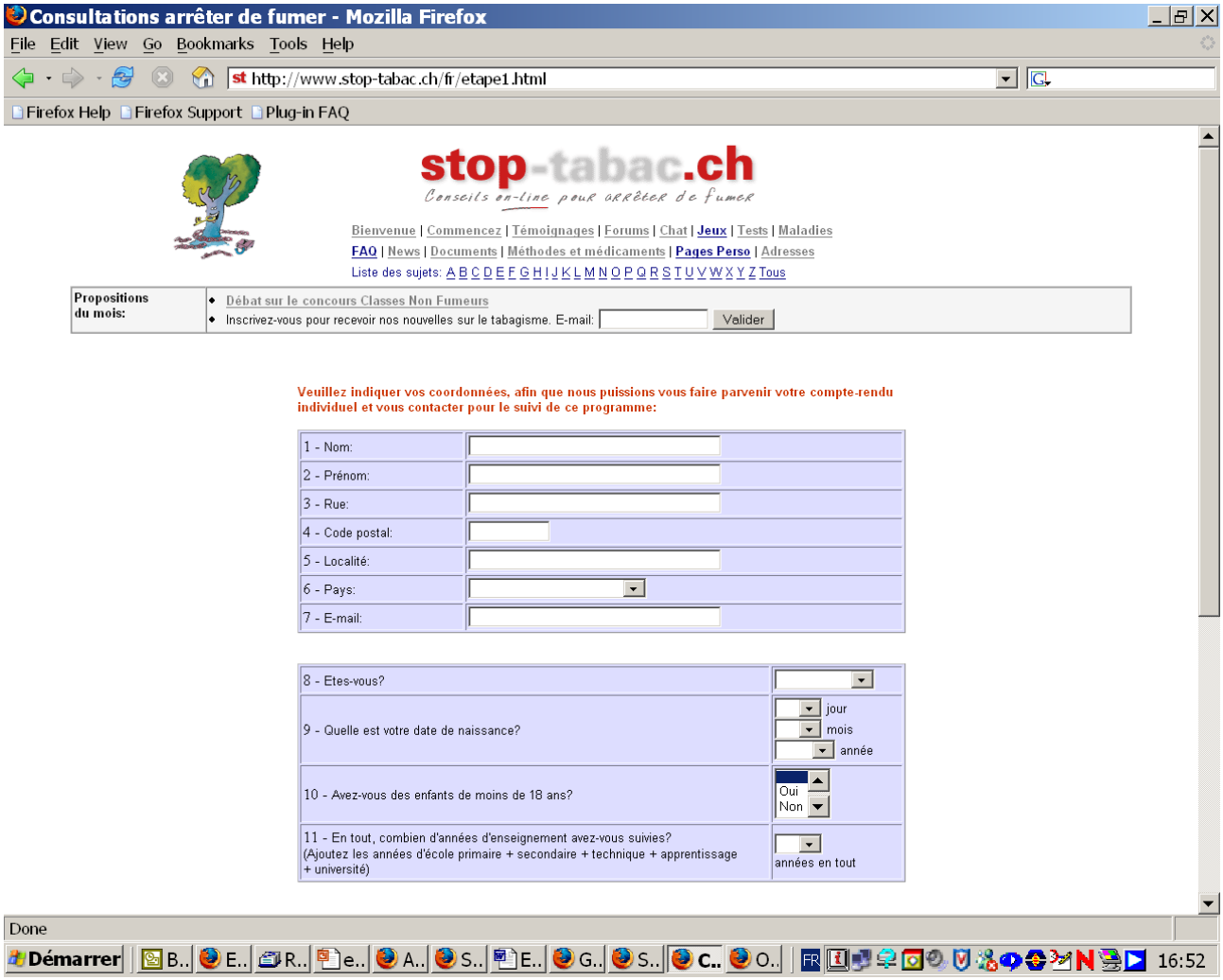
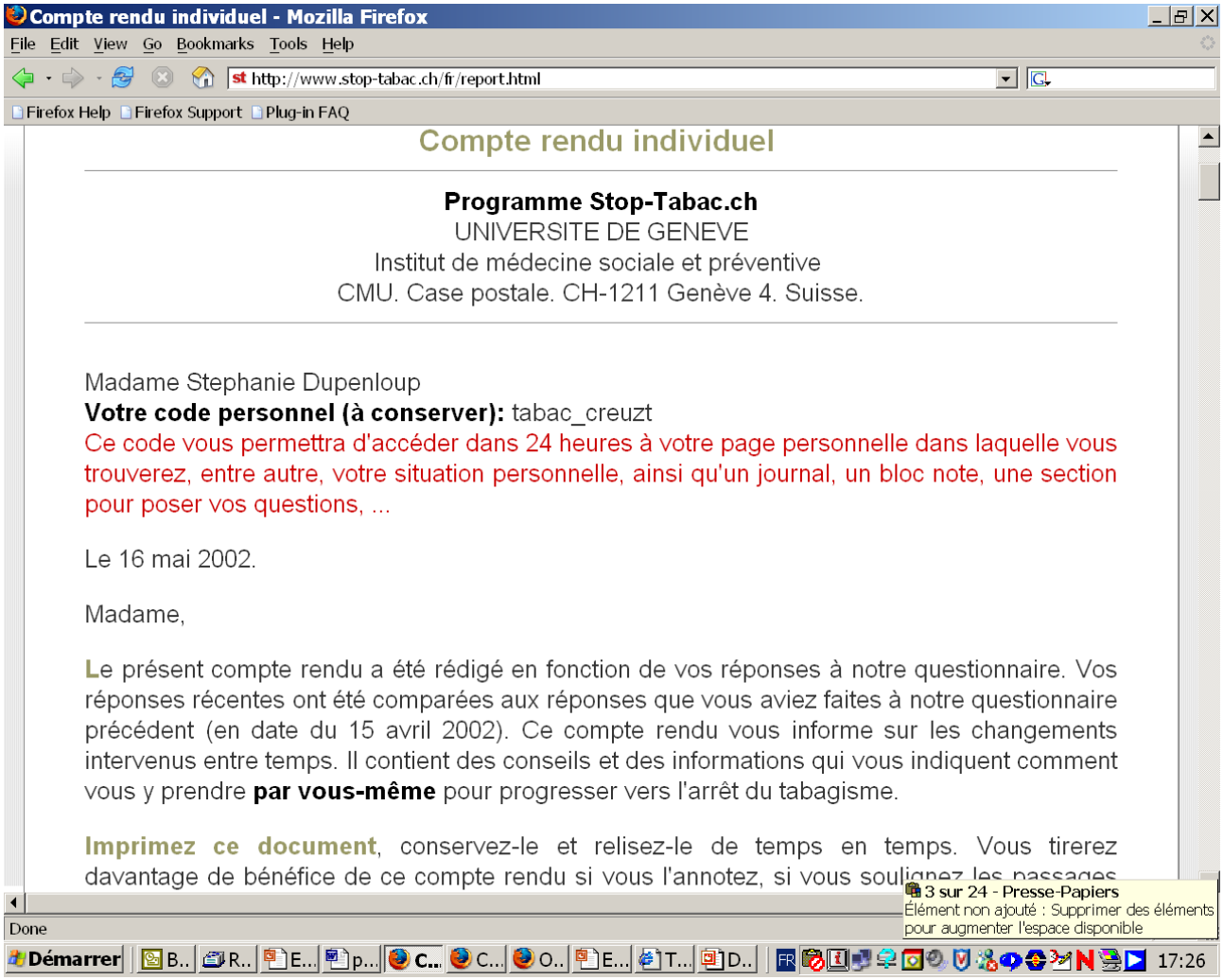


Figure 2. Personal counseling letter of the original program



The Modified Program

The modified program was developed by us for Novartis, a producer of nicotine replacement products, when these products became available over-the-counter (OTC, ie, without a medical prescription) in Switzerland in 2000. This program was intended to provide some smoking cessation counseling to smokers who bought OTC NRT products and thus did not receive medical supervision. Compared with the original program, the modified program used a shorter questionnaire (38 questions) that included ad hoc questions instead of validated multi-item scales (Figure 3). The counseling letter was of similar length (3000-4000 words), but contained more information on NRT and nicotine dependence, and less information on health risks and coping strategies (Figure 4).

Figure 3. Screenshot of the tailoring questionnaire for the modified program

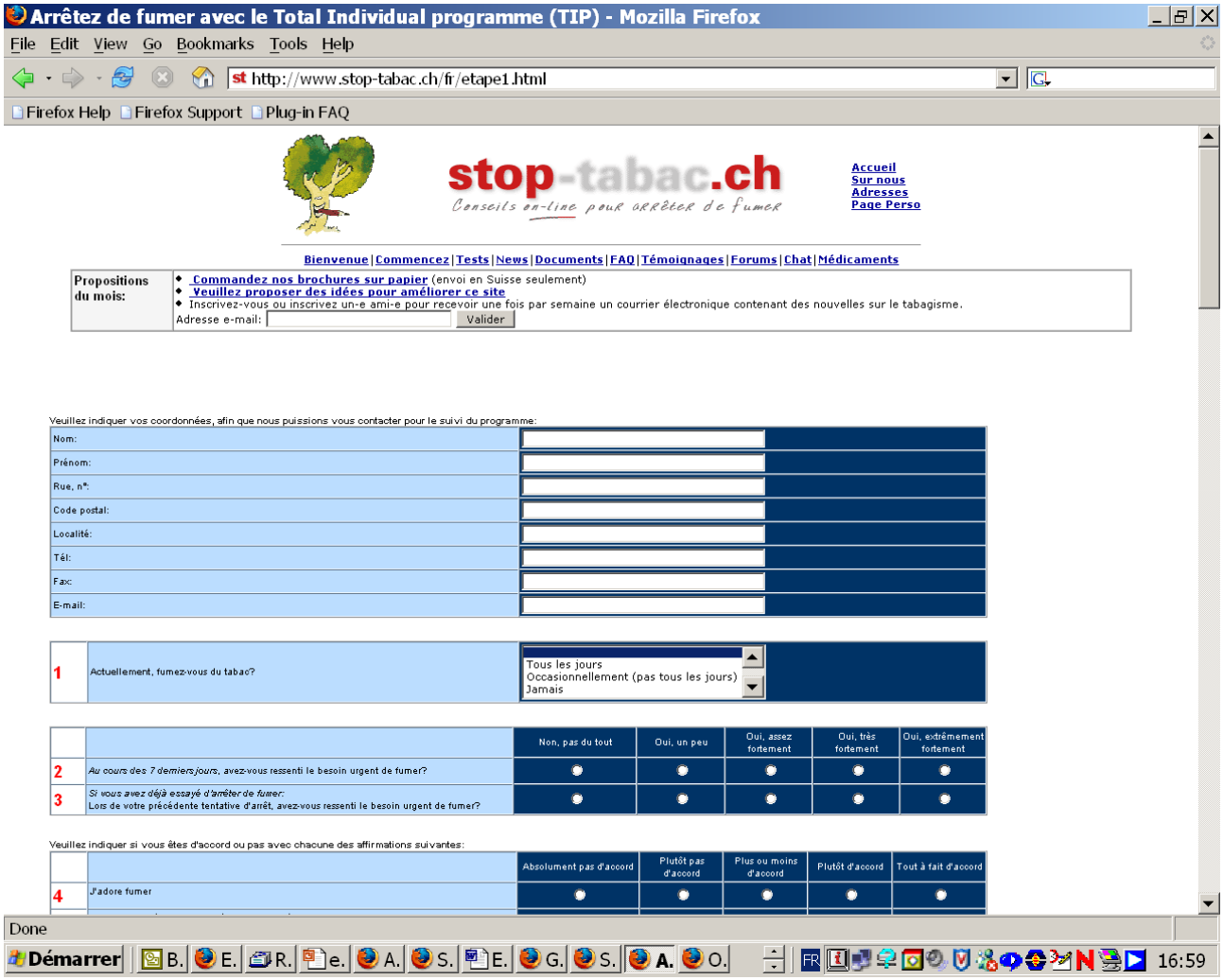
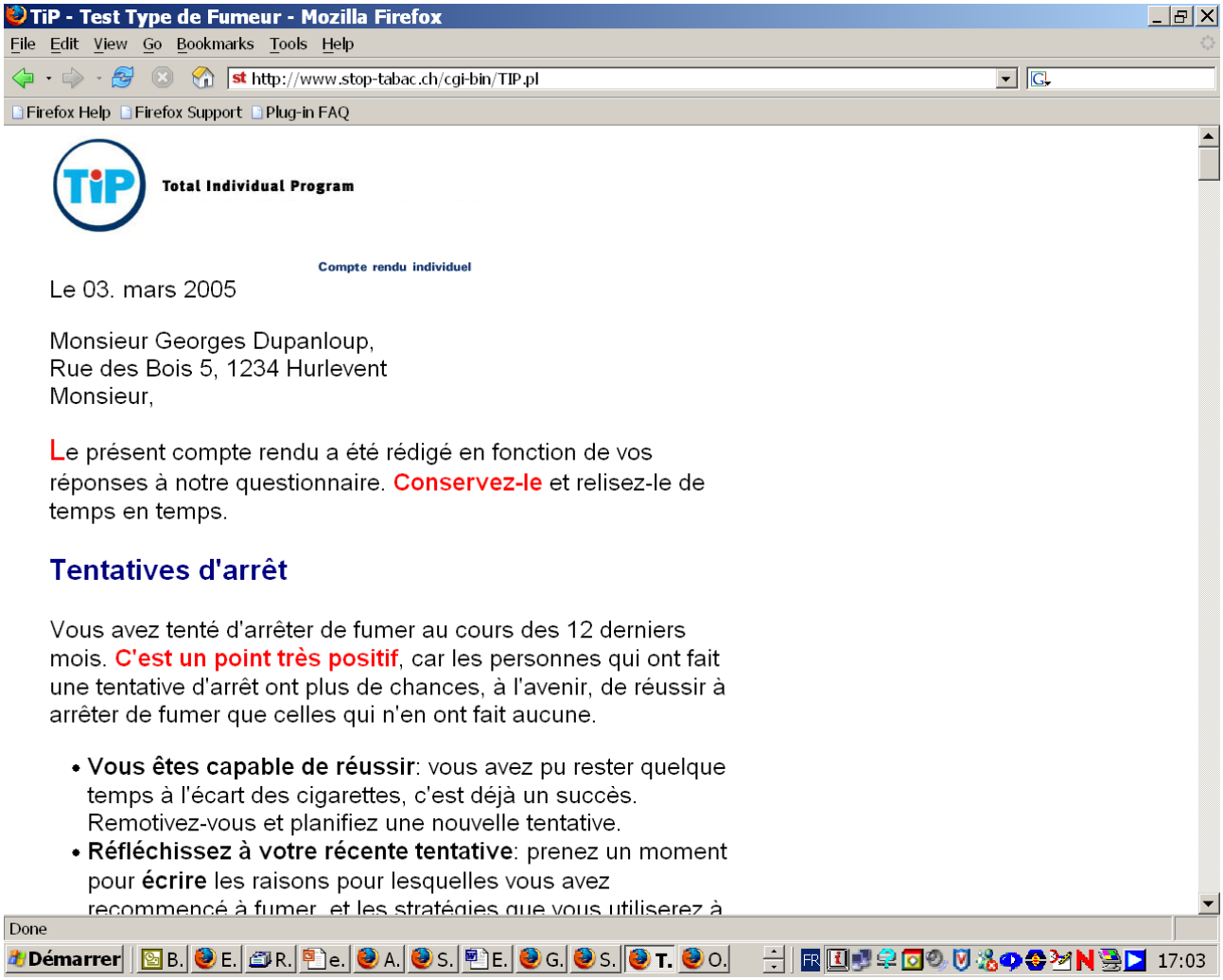


Figure 4. Personal counseling letter of the modified program



Additional Program Interactions

In both programs, 1 month and 2 months after entering the study, participants were invited by email to answer the same tailoring questionnaire again in order to receive a second counseling letter. To write the second letter, the computer compared each participant's new answers with the answers given on their previous visit. Participants were congratulated for any progress they had made since their last visit or encouraged, if they had relapsed. In both groups, participants received on average 1.2 counseling letters; 84% of participants received only 1 counseling letter and 16% 2 or more letters.

Outcome Measures

To assess smoking abstinence, an email message was sent out 11 weeks after receipt of the baseline questionnaire; those who failed to respond received up to 3 email reminders. Participants answered the following question by clicking on *Yes* or *No* directly in the email message: "Did you smoke any tobacco in the past 7 days (even one puff of cigarette, cigar, pipe, etc)?" The criterion of 7 days' abstinence was used in a recent guideline to assess smoking cessation in randomized trials [26]. We used an intention-to-treat analysis in which all non-respondents were counted as smokers.

Sample Size Calculations

Sample size calculations indicated that a sample of 5300 was necessary to detect a between-program difference of 2 percentage points in abstinence rates in current smokers (8% vs 6%, confidence level 95%, power 80%). The expected difference of 2 percentage points was estimated on a basis of a synthesis of previous studies of computer-tailored programs [1], and taking into account an expected follow-up rate of about one third [28] and an intention-to-treat analysis. With its final sample size of 11969 participants, the study was powered to detect differences in subgroups of participants, in particular current and former smokers.

Statistical Analyses

We used chi-square tests to compare proportions (eg. abstinence rates) and *t* tests to compare means. We used odds ratios (OR's) with 95% confidence intervals (CI's) to express the proportion of non-smokers (abstinence rate) in the original program compared to the proportion of non-smokers in the modified program. We tested the effectiveness of the program in subgroups, stratifying by age, sex, number of cigarettes per day, and stage of change.

Because participation rates in the follow-up survey differed in the two groups, we report both intention-to-treat data, where

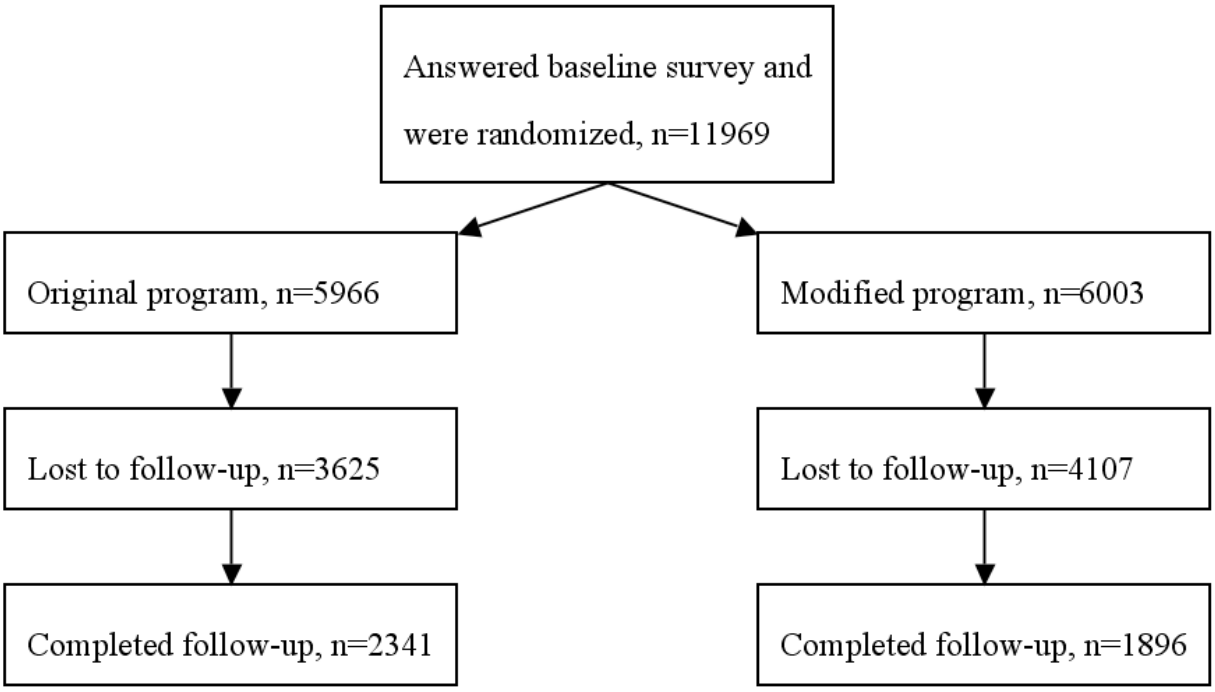
all baseline participants were included in the denominator and non-respondents were counted as smokers, and an analysis including only those who took part in the follow-up survey. We also conducted a sensitivity analysis, extrapolating results under a hypothetical situation where response rates to the follow-up survey were assumed to be the same in the two study arms.

Results

Participation

The raw database included 12434 records. We excluded 245 participants who had taken part in both programs and deleted 220 entries of people registered twice in the same program. Thus 11969 participants were included in the study. Figure 5 illustrates the flow of participants through the trial.

Figure 5. Flow chart of participants in the randomized controlled trial



At baseline, the two study groups were similar in terms of age and sex distributions, smoking status (current or former smokers), stage of change, cigarette consumption, and, among former smokers, the number of days since smoking cessation (Table 1). As in a previous study [13], the sample included a substantial proportion of former smokers (n=3095, 26%), and relatively few smokers in the precontemplation stage of change (n=385, 3%). Smokers in this study were more motivated to quit smoking than a representative sample of smokers in Geneva (distribution of smokers by stage of change in Geneva: 74%, precontemplation; 22%, contemplation; 4%, preparation) [27].

Table 1. Baseline characteristics of study participants

	Original Program	Modified Program	P
Number of participants	5966	6003	
Age (mean, SD)	34.1	33.8	.13
Men (n, %)	2308 (39.0)	2181 (38.2)	
Smoking status			.73
Current smokers (n, %)	4346 (73.9)	4336 (73.6)	
Former smokers (n, %)	1538 (26.1)	1557 (26.4)	
Among current smokers			
Cigarettes per day (mean)	19.6	19.3	.06
Minutes to first cigarette of the day (mean)	50.5	51.3	.64
Made a quit attempt in the previous year (n, %)	2079 (47.9)	2104 (49.4)	.15
Stage of change (n, %)			.13
Precontemplation	214 (4.9)	171 (4.0)	
Contemplation	1497 (34.5)	1480 (34.9)	
Preparation	2623 (60.5)	2584 (61.0)	
Among former smokers			
Interval since quit date (days, mean)	101	91	.73
Stage of change			.06
Action (n, %)	1349 (93.7)	1082 (91.9)	
Maintenance (n, %)	90 (6.3)	96 (8.1)	

The response rate to the follow-up survey was 35.4% (4237 of 11969). However, more participants in the original program (n=2341, 39.2%) than in the modified program (n=1896, 31.6%) answered the follow-up survey (χ^2=76.7, *P*<.001). In both groups, the median interval between the baseline and follow-up surveys was 2.5 months (25th, 50th, and 75th percentiles in both groups; 75, 77 and 80 days respectively).

Smoking Abstinence Rates

At follow-up, when all baseline participants were included in the denominator and non-respondents were counted as smokers, the 7-day abstinence rate was higher for the original program than for the modified program (14.6% vs 10.7%, *P*<.001, OR=1.43, 95% CI 1.28 - 1.59) (Table 2). Thus compared with the modified program, the original program produced 1 additional quitter for every 26 participants. The original program was more effective than the modified program in baseline current smokers (abstinence rates: 10.9% vs 8.9%, OR=1.24, CI 1.08-1.63, *P*=.003) and in baseline former smokers (25.2% vs 15.7%, OR=1.81, CI 1.51-2.17, *P*<.001).

Among smokers in the precontemplation and preparation stages of change, there was no statistically significant difference in quit rates between programs; but the original program produced more quitters than the modified program among smokers in the contemplation stage (Table 2). Among light smokers (1-10 cigarettes/day), there was no difference in quit rates between programs; but the original program was more effective than the modified program in smokers of 11 to 24 cigarettes/day (OR=1.28) and in heavy smokers (25 or more cigarettes/day) (OR=1.54). The relative effect of the two programs was the same in men and women and across age groups. Interestingly, younger smokers (≤19 years old) were the least likely to quit smoking.

Secondary Analysis

When we included only the 4237 participants who answered the follow-up survey, abstinence rates were significantly (χ^2=5.0, *P*=.03) higher in the original program (873 out of 2341, 37.3%) than in the modified program (644 out of 1896, 34.0%).

Sensitivity Analysis

In a sensitivity analysis, we extrapolated data assuming a hypothetical situation where the same proportion of participants in both groups (39.2%) answered the follow-up survey. Under this assumption, 2356 out of 6003 (39.2%) participants in the modified program (instead of 1896) would have answered the follow-up survey, and 800 out of 2356 (34.0%) would have quit smoking. Under this assumption, and including all baseline participants in the denominator, 13.3% (800 out of 6003) would have been abstinent in the modified program versus 14.6% (873 out of 5966) in the original program (χ^2=4.3, *P*=.04). Thus the original program was still more effective than the modified program, even after taking into account the difference between groups in response rates.

Table 2. Smoking abstinence rates (no puff of tobacco smoke in the past 7 days), intention-to-treat analysis, 2.5 months after entry into two computer-tailored smoking cessation programs on a French-language smoking cessation website, 2003-2004

	n in Analysis	Original Program	Modified Program	Odds Ratio	95% confidence interval	P
All participants (N, %)	11969	873 (14.6)	644 (10.7)	1.43	1.27-1.59	<.001
Men	4489	339 (14.7)	235 (10.8)	1.43	1.19-1.70	<.001
Women	7145	534 (14.8)	406 (11.5)	1.34	1.17-1.54	<.001
Age						
<19 years	492	11 (4.5)	6 (2.4)	1.92	0.70-5.28	.20
20-29	3936	226 (11.5)	186 (9.4)	1.25	1.02-1.53	.03
30-39	3920	357 (17.5)	238 (12.7)	1.46	1.22-1.74	<.001
40-49	2259	207 (17.7)	156 (14.3)	1.29	1.03-1.62	.03
50-77	940	72 (14.9)	46 (10.1)	1.57	1.05-2.31	.03
All current smokers	8682	472 (10.9)	388 (8.9)	1.24	1.08-1.43	.003
Stage of change at baseline						
Precontemplation	385	8 (3.7)	6 (3.5)	1.07	0.36-3.14	.91
Contemplation	2977	143 (9.6)	95 (6.4)	1.54	1.18-2.02	.002
Preparation	5207	321 (12.2)	279 (10.8)	1.15	0.97-1.37	.10
Smoking rate						
Very light smokers (1 to 5 cig./day)	308	11 (7.6)	13 (7.9)	0.96	0.42-2.22	.93
Light smokers (6-10 cig./day)	1385	63 (9.1)	76 (11.0)	0.81	0.57-1.15	.23
Average smokers (11-24 cig./day)	4520	242 (10.7)	192 (8.5)	1.28	1.05-1.56	.015
Heavy smokers (> 25 cig./day)	2347	154 (12.9)	101 (8.8)	1.54	1.18-2.01	.001
All former smokers	3095	387 (25.2)	244 (15.7)	1.81	1.51-2.17	<.001
Action stage of change	2305	340 (26.2)	198 (19.6)	1.46	1.19-1.78	<.001
Maintenance stage of change	175	23 (27.4)	19 (20.9)	1.43	0.71-2.87	.31

Discussion

Efficacy

We compared two Internet-based computer-tailored smoking cessation programs: a program based on theory and preliminary research conducted in the study population; and a modified and simplified version of the same program designed for NRT users. The original program was more effective than the modified program in helping current smokers in the contemplation stage of change quit smoking and in helping former smokers avoid relapse. In a previous study, we showed that when implemented on paper (ie, when counseling letters and booklets were sent by mail), the original program was more effective than no intervention [10,11]. This study showed that the efficacy of this program was apparently maintained when it was implemented over the Internet. Among baseline smokers, 7-day abstinence rates were quite comparable in the Internet version (10.9%) and in the paper version of the original program (8%) [10]. In this previous study, we tested the original program on current smokers only. The present study suggests that this program was also effective in preventing relapse in former smokers.

Because the present study did not include a no-treatment control group, we are unable to say whether both programs were more effective than no intervention. However, quit rates in smokers in the modified program (8.9%) were higher than quit rates in smokers in the no-treatment control group in our previous study (3.3%) [10], which suggests that even the modified program might be more effective than no intervention. Tests of the Internet versions of both programs against a no-treatment control group are nevertheless warranted, but such tests are made difficult by the risk of selective drop-out in the no-treatment group, and by the potential for contamination from external programs, as disappointed participants in the no-treatment group could obtain counseling from other websites able to be found in just a few clicks.

The follow-up in both programs consisted of short, monthly email messages inviting participants to answer the same questionnaire again, in order to receive a second counseling letter that was largely similar to the first one. This follow-up procedure may not have been intensive enough, which may explain why so few participants obtained additional counseling letters. The follow-up in the program could be improved by using individually tailored email messages, sent more frequently just before and after the quit date, as was done by Lenert and colleagues [10].

Cost

The total cost of implementing the website where the two programs are available is currently 70000 Swiss francs a year (US$ 60000), for a reach of over 8000 participants per year in the computer-tailored programs, and for 600000 visitors per year to the website (where other features, such as discussion forums and personal stories, are more popular than the computer-tailored program). The average duration of a visit to the website is 7 minutes, with an average of 8 pages viewed per visit. This is comparable to the cost of running a small smoking cessation clinic which would treat about 50 smokers a month.

Strengths and Limitations of This Study

A strength of this study is that it was powered to detect small differences in quit rates in subgroups of participants (eg, current and former smokers). The response rate at follow-up was low (35%), but it was close to the average response rate of 39.6% reported in a meta-analysis of 68 Internet-based surveys [28], and it was in the range of 30-40% in response rates obtained in follow-up surveys of the three other efficacy trials of online smoking cessation programs [7,8,9]. Follow-up rates in Internet studies are lower than those usually found in smoking cessation studies. Several steps could be taken to increase follow-up rates in Internet surveys such as: asking participants to indicate a second email address or the email address of a relative; asking them to keep their email address active for the duration of the study; requiring participants to commit to taking part in the follow-up survey; and asking for a phone or fax number, or a postal address. Paying participants could introduce bias and is not a very cost-effective option, given the large samples obtained in Internet studies.

There were more non-respondents in the modified program group than in the original program. This could produce an artificial advantage for the original program in intention-to-treat analyses where non-respondents are counted as smokers. However, even when data were analyzed in respondents only, quit rates were higher in the original program. In addition, a sensitivity analysis showed that if participation rates had been similar in both study arms, the original program would still have been more effective than the modified program. Under this assumption however, the between-group difference would have been smaller.

Fewer participants in the modified program than in the original program took part in the follow-up. The modified program was developed in collaboration with a pharmaceutical company and emphasized NRT use. Participants were informed of this collaboration and may have been less keen to take part in the follow-up of a program associated with the industry than in the original program, which was university based.

Because the study did not include a no-treatment control group, it remains possible that the natural quit rates in this sample (ie, the quit rate outside any intervention) lies somewhere between the quit rates measured in the 2 study arms. In this case, the programs would have no effect. However, the original program produced similar quit rates whether it was implemented on the Internet or on paper, and these quit rates were higher that in the no-treatment control group in our previous study [10]. This suggests that the original program is more effective than no intervention. Nevertheless tests of the online versions of both programs against no-intervention control groups are warranted.

The difference in program efficacy between the original and modified versions was observed only in smokers in the contemplation stage of change, but not in those in the precontemplation and preparation stages. Similarly, the paper version of the original program had no effect in smokers in the preparation stage [10]. The paper version had however a significant impact in smokers in the precontemplation (3 percentage points) and contemplation stages (4 percentage points) [10]. These results suggest that this program may be effective mainly in motivating contemplators to make a quit attempt. A new version of the program should be developed in order to better take into account the needs of smokers in the preparation stage.

We measured point prevalence of abstinence after 2.5 months, but this approach may not reflect long-term continuous abstinence rates. In our previous study of the paper version of the original program, we showed that the effect measured 7 months after entry into the program was not maintained, one-and-a-half years after the intervention was stopped [11]. Previous research showed that one half of the people who succeed in abstaining from smoking for 6 months will relapse within 5 years [29]. Thus long-term follow-up studies are needed to assess whether Internet-based programs have sustained effects. The only existing studies are short-term (<=6 months) [7, 8,9]. Long-term studies are however limited by the difficulty of obtaining high response rates in Internet surveys [28].

We conducted no biochemical verification of smoking status for several reasons. First, collecting saliva samples for the determination of cotinine (a metabolite of nicotine) or collecting expired carbon monoxide would have decreased participation rates [30]. Second, biochemical verification will not change the results of most smoking cessation studies because self-report is generally accurate in adults, and because large between-group differences in misreporting are unlikely [31]. Third, biochemical verification is not recommended in large scale population-based studies with limited face-to-face contact, and in studies where data collection is done over the Internet [32]. In a study conducted in a similar population, we showed that for the association between saliva cotinine and self-report of smoking, the area under the receiver operating characteristic curve was 0.95, and that most cases of disagreement were due to occasional smokers rather than to misreporting [33]. Furthermore, at least two studies indicated that in intervention trials, self-report of smoking was not, or only minimally, biased in intervention groups, compared with controls [34,35]; therefore, such bias would not explain away our results.

Conclusion

The original program was more effective than a modified version of the same program intended for NRT users. Given the already documented large variability in the effect of computer-tailored programs [1], other available online smoking cessation programs should be compared directly, in randomized trials [36].

Acknowledgments

The Health on the Net (HON) Foundation, Geneva, Switzerland, provided the services of Vincent Baujard (informatics engineer), who developed the software that produces the counseling letters and who managed the data collection and storage. Development and implementation of the Stop-tabac program was funded by the Health Department of the Canton of Geneva; the Swiss Cancer League [Berne]; and the Swiss Federal Office of Public Health[Berne], all of Switzerland. Development and implementation of the modified program (called TIP) was funded by Novartis (Berne, Switzerland), a producer of nicotine replacement products. Data collection and storage were supported by all the preceding sponsors. The salary of the author was paid by the University of Geneva.

Conflicts of Interest

The author developed the two programs presented in this study as part of his work at the University of Geneva, Switzerland. Both programs are available at no charge to smokers. The author has no financial or commercial interest in these programs. The Institute of Social and Preventive Medicine, University of Geneva, Switzerland, receives support from the sponsors mentioned above to run these programs.

References

1. Lancaster T, Stead LF. Self-help interventions for smoking cessation. Cochrane Database Syst Rev 2002(3):CD001118. [Medline: 12137618]
2. Etter JF. Using new information technology to treat tobacco dependence. Respiration 2002;69(2):111-114. [Medline: 21959558] [doi: 10.1159/000056311]
3. Brug J, Steenhuis I, Van Assema P, De Vries H. The impact of a computer-tailored nutrition intervention. Prev Med 1996;25(3):236-242. [Medline: 96374773] [doi: 10.1006/pmed.1996.0052]
4. Dijkstra A, De Vries H, Roijackers J, Van Breukelen G. Tailoring information to enhance quitting in smokers with low motivation to quit: three basic efficacy questions. Health Psychol 1998 Nov;17(6):513-519. [Medline: 99063547] [doi: 10.1037//0278-6133.17.6.513]
5. Lancaster T, Stead L, Silagy C, Sowden A. Effectiveness of interventions to help people stop smoking: findings from the Cochrane Library. BMJ 2000 Aug 5;321(7257):355-358 [FREE Full text] [Medline: 20384441] [doi: 10.1136/bmj.321.7257.355]
6. Aveyard P, Cheng KK, Almond J, Sherratt E, Lancashire R, Lawrence T, et al. Cluster randomised controlled trial of expert system based on the transtheoretical ("stages of change") model for smoking prevention and cessation in schools. BMJ 1999 Oct 9;319(7215):948-953 [FREE Full text] [PMC: 10514156] [Medline: 99443824]
7. Schneider SJ, Walter R, O'donnell R. Computerized communication as a medium for behavioral smoking cessation treatment: controlled evaluation. Comp Hum Behav 1990;6(2):141-151. [doi: 10.1016/0747-5632(90)90002-X]
8. Lenert L, Muñoz RF, Perez JE, Bansod A. Automated e-mail messaging as a tool for improving quit rates in an internet smoking cessation intervention. J Am Med Inform Assoc 2004;11(4):235-240. [Medline: 15064291] [PMC: 15064291] [doi: 10.1197/jamia.M1464]
9. Strecher V, Shiffman S, West R. Process and outcome evaluation of a web-based computer-tailored smoking cessation program among nicotine patch users. Presented at: 6th Annual Conference of the Society for Research on Nicotine and Tobacco-Europe; October 6-9, 2004; Tuebingen, Germany p. 66.
10. Etter JF, Perneger TV. Effectiveness of a computer-tailored smoking cessation program: a randomized trial. Arch Intern Med 2001 Nov 26;161(21):2596-2601. [Medline: 21575573] [doi: 10.1001/archinte.161.21.2596]
11. Etter JF, Perneger TV. Post-intervention effect of a computer tailored smoking cessation programme. J Epidemiol Community Health 2004 Oct;58(10):849-851. [Medline: 15365111] [doi: 10.1136/jech.2003.017103]
12. Bock B, Graham A, Sciamanna C, Krishnamoorthy J, Whiteley J, Carmona-barros R, et al. Smoking cessation treatment on the Internet: content, quality, and usability. Nicotine Tob Res 2004 Apr;6(2):207-219. [Medline: 15203794] [doi: 10.1080/14622200410001676332]
13. Wang J, Etter JF. Administering an effective health intervention for smoking cessation online: the international users of Stop-Tabac. Prev Med 2004 Nov;39(5):962-968. [Medline: 15475030] [doi: 10.1016/j.ypmed.2004.03.038]
14. Prochaska JO, Diclemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. Health Psychol 1993 Sep;12(5):399-405. [Medline: 94038821] [doi: 10.1037//0278-6133.12.5.399]
15. Prochaska JO, Diclemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. Am Psychol 1992 Sep;47(9):1102-1114. [Medline: 93036742] [doi: 10.1037//0003-066X.47.9.1102]
16. Ajzen I, Fishbein M. Understanding Attitudes and Predicting Social Behavior. Englewood Cliffs, NJ: Prentice Hall; 1980.
17. Marlatt GA, Gordon JR, editors. Relapse Prevention: Maintenance Strategies in the Treatment of Addictive Behaviors. New York, NY: The Guilford Press; Feb 20, 1985.

18. Benowitz NL. Cigarette smoking and nicotine addiction. Med Clin North Am 1992 Mar;76(2):415-437. [Medline: 92194874]
19. The Agency for Health Care Policy and Research Smoking Cessation Clinical Practice Guideline. JAMA 1996;275(16):1270-1280. [Medline: 8601960] [doi: 10.1001/jama.275.16.1270]
20. De Vries H, Brug J. Computer-tailored interventions motivating people to adopt health promoting behaviours: introduction to a new approach. Patient Educ Couns 1999 Feb;36(2):99-105. [Medline: 22891265] [doi: 10.1016/S0738-3991(98)00127-X]
21. Strecher VJ. Computer-tailored smoking cessation materials: a review and discussion. Patient Educ Couns 1999 Feb;36(2):107-117 [FREE Full text] [Medline: 22891266] [doi: 10.1016/S0738-3991(98)00128-1]
22. Etter JF, Bergman MM, Humair JP, Perneger TV. Development and validation of a scale measuring self-efficacy of current and former smokers. Addiction 2000 Jun;95(6):901-913 [FREE Full text] [Medline: 20402901] [doi: 10.1046/j.1360-0443.2000.9569017.x]
23. Etter JF, Humair JP, Bergman MM, Perneger TV. Development and validation of the Attitudes Towards Smoking Scale (ATS-18). Addiction 2000 Apr;95(4):613-625. [Medline: 20288145] [doi: 10.1046/j.1360-0443.2000.95461312.x]
24. Etter JF, Bergman MM, Perneger TV. On quitting smoking: development of two scales measuring the use of self-change strategies in current and former smokers (SCS-CS and SCS-FS). Addict Behav 2000;25(4):523-538. [Medline: 20426260] [doi: 10.1016/S0306-4603(00)00068-X]
25. Etter JF, Duc TV, Perneger TV. Validity of the Fagerström test for nicotine dependence and of the Heaviness of Smoking Index among relatively light smokers. Addiction 1999 Feb;94(2):269-281 [FREE Full text] [Medline: 99325116] [doi: 10.1046/j.1360-0443.1999.94226910.x]
26. Anderson JE, Jorenby DE, Scott WJ, Fiore MC. Treating tobacco use and dependence: an evidence-based clinical practice guideline for tobacco cessation. Chest 2002 Mar;121(3):932-941 [FREE Full text] [Medline: 21886031] [doi: 10.1378/chest.121.3.932]
27. Etter JF, Perneger TV, Ronchi A. Distributions of smokers by stage: international comparison and association with smoking prevalence. Prev Med 1997;26(4):580-585. [Medline: 97394863] [doi: 10.1006/pmed.1997.0179]
28. Cook C, Heath F, Thompson RL. A meta-analysis of response rates in web- or internet-based surveys. Educ Psychol Meas 2000;60(6):821-836 [FREE Full text] [doi: 10.1177/00131640021970934]
29. Blondal T, Gudmundsson LJ, Olafsdottir I, Gustavsson G, Westin A. Nicotine nasal spray with nicotine patch for smoking cessation: randomised trial with six year follow up. BMJ 1999 Jan 30;318(7179):285-288 [FREE Full text] [PMC: 9924052] [Medline: 99122875]
30. Etter JF, Perneger TV, Ronchi A. Collecting saliva samples by mail. Am J Epidemiol 1998 Jan 15;147(2):141-146. [Medline: 98118119]
31. Velicer WF, Prochaska JO, Rossi JS, Snow MG. Assessing outcome in smoking cessation studies. Psychol Bull 1992 Jan;111(1):23-41. [Medline: 92169086] [doi: 10.1037//0033-2909.111.1.23]
32. ; SRNT Subcommittee on Biochemical Verification. Biochemical verification of tobacco use and cessation. Nicotine Tob Res 2002 May;4(2):149-159. [doi: 10.1080/14622200210123581] [Medline: 22025335]
33. Etter JF, Vu Duc T, Perneger TV. Saliva cotinine levels in smokers and nonsmokers. Am J Epidemiol 2000 Feb 1;151(3):251-258. [Medline: 20134009]
34. Glasgow RE, Mullooly JP, Vogt TM, Stevens VJ, Lichtenstein E, Hollis JF, et al. Biochemical validation of smoking status: pros, cons, and data from four low-intensity intervention trials. Addict Behav 1993;18(5):511-527. [Medline: 94144412] [doi: 10.1016/0306-4603(93)90068-K]
35. Murray RP, Connett JE, Lauger GG, Voelker HT. Error in smoking measures: effects of intervention on relations of cotinine and carbon monoxide to self-reported smoking. The Lung Health Study Research Group. Am J Public Health 1993 Sep;83(9):1251-1257. [Medline: 93370587]
36. ; No Author. Testing online smoking cessation programs. CA Cancer J Clin 2005;55:6 [FREE Full text]

Abbreviations

CI: Confidence Interval
ITT: Intention-To-Treat
NRT: Nicotine Replacement Therapy
OR: Odds Ratio
OTC: Over-the-Counter

submitted 02.02.05; peer-reviewed by C Norman; comments to author 18.02.05; revised version received 22.02.05; accepted 22.02.05; published 08.03.05.

Please cite as:
Etter JF
Comparing the Efficacy of Two Internet-Based, Computer-Tailored Smoking Cessation Programs: A Randomized Trial
J Med Internet Res 2005;7(1):e2
URL: http://www.jmir.org/2005/1/e2/
doi:10.2196/jmir.7.1.e2
PMID:15829474

Original Paper

Usage and Longitudinal Effectiveness of a Web-Based Self-Help Cognitive Behavioral Therapy Program for Panic Disorder

Peter Farvolden[1], PhD, CPsych; Eilenna Denisoff[1], PhD, CPsych; Peter Selby[1], MD, FRCPC; R Michael Bagby[1], PhD, CPsych; Laura Rudy[1], BA

Centre for Addiction and Mental Health, Toronto ON, Canada

Corresponding Author:
Peter Farvolden, PhD, CPsych
Clinical Research Department
Section on Personality and Psychopathology
Centre for Addiction and Mental Health
250 College Street
Toronto ON M5T 1R8
Canada
Phone: +1 416 535 8501 ext 6181
Fax: 416 979 6821
Email: peter_farvolden@camh.net

Abstract

Background: Anxiety disorders are common problems that result in enormous suffering and economic costs. The efficacy of Web-based self-help approaches for anxiety disorders has been demonstrated in a number of controlled trials. However, there is little data regarding the patterns of use and effectiveness of freely available Web-based interventions outside the context of controlled trials.

Objective: To examine the use and longitudinal effectiveness of a freely available, 12-session, Web-based, cognitive behavioral therapy (CBT) program for panic disorder and agoraphobia.

Methods: Cumulative anonymous data were analyzed from 99695 users of the Panic Center. Usage statistics for the website were examined and a longitudinal survey of self-reported symptoms for people who registered for the CBT program was conducted. The primary outcome measures were self-reported panic-attack frequency and severity at the beginning of each session (sessions 2-12).

Results: Between September 1, 2002 and February 1, 2004, there were 484695 visits and 1148097 page views from 99695 users to the Panic Center. In that same time period, 1161 users registered for the CBT program. There was an extremely high attrition rate with only 12 (1.03%) out of 1161 of registered users completing the 12-week program. However, even for those who remained in the program less than 12 weeks we found statistically significant reductions (P<.002) in self-reported panic attack frequency and severity, comparing 2 weeks of data against data after 3, 6, or 8 weeks. For example, the 152 users completing only 3 sessions of the program reduced their average number of attacks per day from 1.03 (week 2) to 0.63 (week 3) (P<.001).

Conclusions: Freely available Web-based self-help will likely be associated with high attrition. However, for the highly self-selected group who stayed in the program, significant improvements were observed.

(J Med Internet Res 2005;7(1):e7) doi:10.2196/jmir.7.1.e7

KEYWORDS

Anxiety; depression; disorders; cognitive behavioural therapy; CBT; self-help; Web-based; treatment; primary care; collaborative; management; access; mental health

Introduction

Anxiety disorders are common problems that result in enormous suffering and economic costs [1]. Unfortunately, a large proportion of people who suffer from anxiety disorder remain either untreated or inadequately treated [2,3]. Effective treatments for anxiety disorders include pharmacological as well as psychotherapeutic approaches and the majority of patients with anxiety disorders respond to appropriate treatment. However, limited access to evidence-based psychotherapy outside of specialized clinics and research settings often renders

pharmacotherapy the most practical first-line treatment option in primary care [4-7].

Self-help therapy for anxiety disorders has been found to be effective, especially when the interventions are tailored to the individual's specific symptoms and situation and administered with a minimal amount of professional guidance and support [6-10]. Web-based self-help is likely to be more effective than traditional bibliotherapy, insofar as it has the potential to be interactive, tailored to an individual's specific needs, able to monitor progress and offer peer support, and augment the traditional physician-patient relationship [7,10-12].

There has been some research on Web-based programs designed to provide relatively generic CBT interventions for depression and anxiety [13], programs designed specifically to provide self-guided CBT for depression [14-16], and programs for anxiety disorders [17-20] and especially panic disorder [21-26]. Most recently, Carlbring and colleagues [27] have reported that Web-based self-help plus minimal therapist contact can be equally as effective as traditional therapist administered CBT in the treatment of panic disorder.

Although the evidence for the efficacy of Web-based self-help for mood and anxiety disorders from controlled trials is encouraging, it is important to determine how such programs are utilized and to estimate their effectiveness when accessed by diverse, less well-selected groups of users under less controlled conditions. To this end, Christensen et al [28] recently reported the results of study in which they compared changes in anxiety and depression symptoms of spontaneous users and trial participants of a CBT website. Christensen et al [28] reported that public registrants did not differ from trial participants in baseline measures including gender, age, and initial level of depression. Most importantly, both groups improved across the training program, although only 15.6% of public registrants completed the program. While such data suggest that public registrants to a cognitive behavior therapy website can experience as much improvement in symptoms as participants in a controlled trial, there is very little data on the patterns of use and effectiveness of Web-based interventions specifically for panic disorder outside of the context of controlled trials.

In contrast to previous reports of the efficacy of computer-assisted and Web-based interventions for anxiety in well-controlled research settings, in the present study we examined the use and effectiveness in an uncontrolled visitor population of a freely available Web-based CBT program for panic disorder.

Method

Description of the Intervention

The Panic Center [29] is an interactive website dedicated to helping those who suffer from panic disorder and agoraphobia. The goal is to promote interaction between people who suffer from panic disorder and their health care professionals. People who visit the Panic Center are a self-selected sample of people who choose to use the Internet to access information and to seek self-help for panic disorder and agoraphobia. Features (tools) of the Panic Center include educational content, a moderated support group, a validated screening test for mood and anxiety disorders [30], a panic symptom diary, and a 12-session self-help CBT program (the Panic Program). Visitors to the Panic Center can use any one of the individual tools either on their own or in collaboration with a health care professional. However, the components of the Panic Program include a combination of the tools described above designed to provide a comprehensive program for the assessment, treatment and maintenance of improvement of the symptoms of panic disorder and agoraphobia.

Figure 1. Panic program process

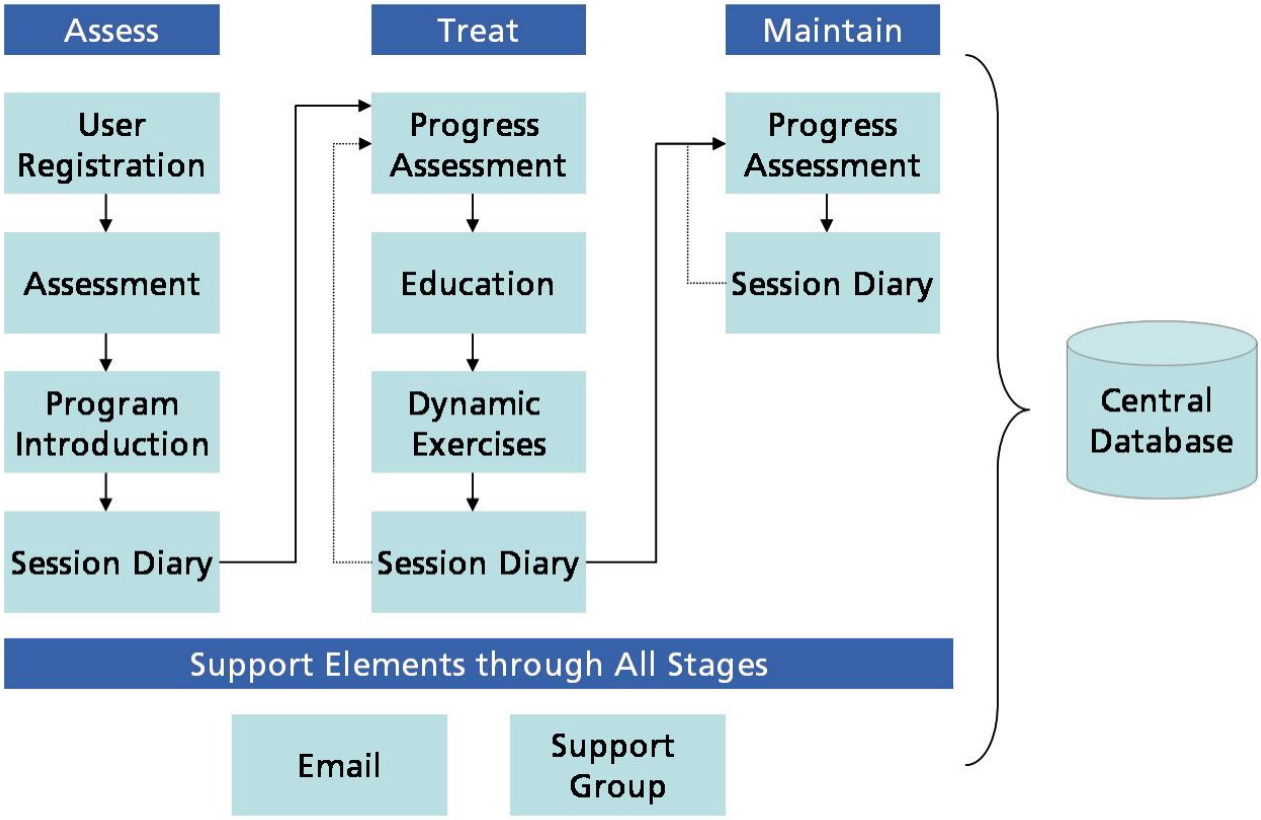
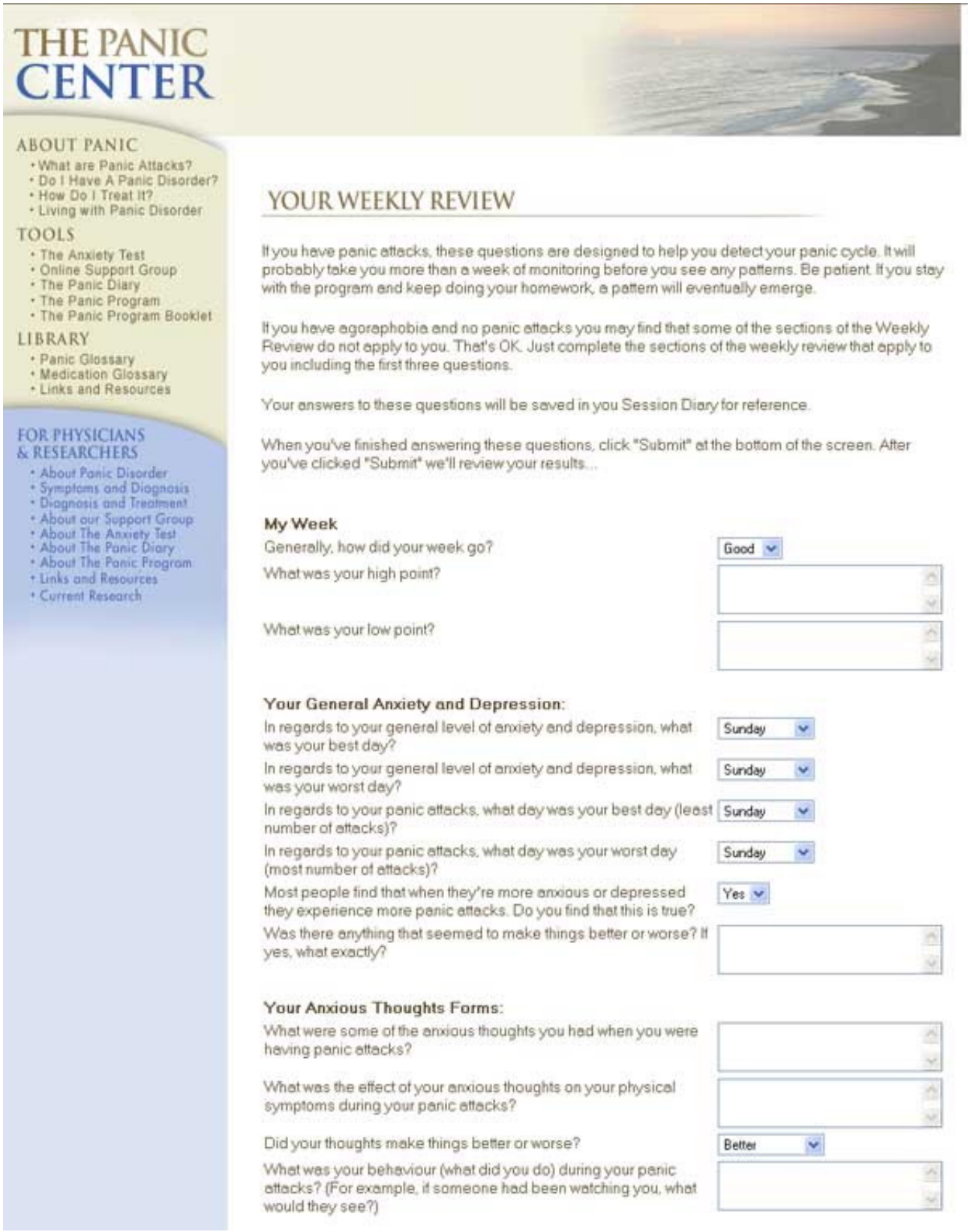


Figure 2. Sample weekly review at session 2



As illustrated in Figure 1, following registration for the Panic Program, users complete an assessment of their current symptoms of anxiety and depression using a screening questionnaire (Web-Based Depression and Anxiety Test, WB-DAT, see below). Following the initial assessment, users are free to proceed through the Web-based 12-session CBT program at their own pace. The sessions are designed to be completed in weekly intervals, hence completion of the entire program normally takes 12 weeks. In order to register for the program users are asked to provide an anonymous email address, select a screen name that is different from their own, provide basic demographic data (age, gender and country of residence)

and provide preliminary information on their panic symptoms (Multimedia Appendix Slide 2). Users who register for the Panic Program are automatically registered to use the panic symptom diary. At the beginning of each session users complete a Weekly Review (Progress Assessment) Figure 2 in which they respond to a variety of questions about their current symptoms and assigned homework. The results of these assessments, as well as the results of dynamic exercises completed during each session, are saved to the user's Session Diary (Multimedia Appendix Slide 4). As part of the CBT, each session provides educational text and suggests exercises (Multimedia Appendix Slide 5). Finally, following the completion of session 12, users are asked to respond to a number of specific questions about their current symptoms and symptom improvement as well as a second screening assessment of their symptoms of anxiety and depression (Multimedia Appendix Slides 6 and 7). Following completion of the 12-session program, users can continue to use the Session Diary and panic symptom diary indefinitely to continue to improve and maintain their gains. Users of the CBT program have indefinite access to the moderated support group (Multimedia Appendix Slide 8) as well as individualized email support and advice.

As an alternative to using the Web-based treatment program, users can download an Adobe version of the 12-session program and use the hard copy as a traditional self-help book. Although this option reduces the number of people using the Web-based program and options for collecting data about the use and effectiveness of the program, it is offered in the interest in maximizing the dissemination and use of the program.

The following describes some of the components in more detail.

Support Group and Email

The support group format consists of asynchronous communication (bulletin board format) between members of the support community and the moderators. Users of the support group also have access to individualized email support and advice from the moderators, who are Registered Nurses (Multimedia Appendix Slide 8).

Screening Assessment (WB-DAT)

The Web-Based Depression and Anxiety Test (WB-DAT) is a self-report screening tool for mood and anxiety disorders compatible with the DSM-IV [31] and the *International Classification of Diseases and Related Health Problems*, tenth revision (ICD-10) [32] diagnostic systems. Preliminary data suggest that the WB-DAT is reliable for identifying patients with and without major depressive disorder (MDD) and the anxiety disorders (Figure 3).

Figure 3. WB-DAT panic disorder screener

Symptom Diary

The panic symptom diary (Panic Diary) allows users to record and track the frequency and severity of their panic attacks, their overall daily level of anxiety and depression, and their medication(s) and dose(s) Figure 4. A graphics interface allows users to track their symptoms over time.

Figure 4. Panic diary recording form

CBT Program

The CBT program was designed based on current evidence for the effective components of CBT interventions for panic disorder and agoraphobia. The essential components of the CBT program include orientation to the cognitive behavioural model of panic disorder and agoraphobia, goal setting, exposure work exercises, cognitive restructuring, interoceptive exposure work, relaxation training, and information about lifestyle change and stress management (Multimedia Appendix Slide 5). Users are assigned homework to complete each week. As mentioned previously, users are at the beginning of each session asked to respond to a number of questions about their symptoms, homework and progress to date (Weekly Review, see Figure 2. These results as well as the results from the dynamic exercises completed during each session are stored in the user's Session Diary and can be viewed by the user at any time.

Data Collection

In order to determine the overall usage of the individual Panic Center tools, we examined log statistics regarding website usage and traffic, including overall statistics regarding the number of visitors to the website, page views, and usage of the screening test, symptom diary and support group. With respect to evaluating the effectiveness of the CBT program, we conducted a longitudinal survey examining data from the Weekly Review questions as well as the screening assessments conducted at registration and at the end of session 12.

Ethics and Privacy

This study was approved by the Research Ethics Board at the Centre for Addiction and Mental Health in Toronto, Ontario, in accordance with all applicable regulations. With respect to the log statistics, the number of unique visitors was determined based on IP addresses. WebTrends was used to analyze log files. No techniques were employed to analyze the log file for identification of multiple entries. With respect to the informed consent process for evaluating the use of the panic symptom diary and the WB-DAT, and effectiveness of the CBT program, users were informed of the approximate length of time of the surveys, which data are stored and where and for how long. Users were neither informed of the specific name of the investigators nor the specific purpose of the study. They were informed that ". . . anydata that is collected is cumulative. That means we compile your data with the results of others. We do not keep individual statistics and we are unable to find out who you are." The policy also informed users that "Your information will be grouped with other peoples' information so that independent researchers can conduct research to improve the system for other people with panic disorder and agoraphobia. We will not sell e-mail identification, names or addresses to third parties."

No personal identifying information was collected or stored. A number of specific measures were taken to protect the privacy of the participants and unauthorized access including the following:

1. Users do not have to provide any identifying information when they access the website or register to use any of the tools. Therefore, these are essentially cumulative and anonymous survey data.
2. Users are not required to provide any identifying information when they register for the WB-DAT, support group, symptom diary, or CBT program. In order to ensure anonymity, they are in fact discouraged from using their real names or email addresses. Users are explicitly asked to use a pseudonym when they use the program and are asked to create a hotmail or Yahoo account using a pseudonym so that they cannot be identified by their email address.
3. The design of the Panic Center strictly adheres to international laws that protect privacy. The data collection methodologies follow guidelines set forth by the Personal Information Protection and Electronic Documents Act (PIPEDA) [33], the Health Insurance Portability and Accountability Act of 1996 (HIPPA) [34] and Directive on Privacy and Electronic Communications – European Union (Directive 2002/58/EC) [35].
4. Security of the database is assured by a robust firewall setup that sits at the edge of their Web network to secure the flow of data. The network operations are manned 24 hours a day, 7 days a week, and a security officer is present round-the-clock. Closed Circuit Television (CCTV) monitors all access points at the server co-location facility, Peer1 Networks [36].

Electronic Surveys

The usability and technical functionality of the electronic data collection was rigorously tested and subjected to quality assurance (tested on multiple browsers, error checking code implemented, unit testing) before data collection began. The format of data collection was a "closed survey" posted on a website and initial contact was made on the Internet. No incentives were offered. Items were not randomized. The maximum number of items per page was 32. A completeness check was performed using JAVAscripterror checking. All questions were static and mandatory. Adaptive questioning was not used. Most questions did not allow for a not applicable response. Respondents were not able to review and change their responses. The "view rate" (as defined by Eysenbach [37]) for the first session of the CBT program was 1161 out of 99695 or 1.16%. The "completion rate" [37] for the CBT program was 12 out of 1161 or 1.03%. Duplicate entries were prevented by ensuring that the survey was only displayed once to each user. No cookies or time stamps were used. Each user who registered had a unique email address as the "primary key" to identify them as a unique user. Data from all users who registered for the program were analyzed. No statistical methods were used to adjust for a nonrepresentative sample. Data were stored in a SQL database and analyzed using SPSS.

Participants

The sample was a self-selected convenience sample. Cumulative anonymous logfile data were analyzed from 99695 users of the Panic Center from September 1, 2002 to February 1, 2004. In addition, we examined self-reported outcome data from 1161 people who registered for the CBT program (the Panic Program) within the same time frame.

Measures

Log Statistics Regarding Website Usage and Traffic

We examined cumulative data regarding website usage (traffic) including number of visits, number of page views, number of unique visitors, and average viewing time (length of visit).

Usage of the Screening Measure, Panic Symptom Diary, and Support Group

We examined cumulative data regarding usage of the WB-DAT including number of tests completed, number of males and females completing the test, average number of diagnoses per user and the relative frequency for users meeting screening criteria for the anxiety disorders, major depressive disorder (MDD), and dysthymia. In addition, we asked users what they intended to do with their screening test results. We examined cumulative data regarding use of the symptom diary including number of registered users and their gender. We examined cumulative data regarding usage of the support group including number of visitors, number of registered members, and number of posts.

Usage and Longitudinal Survey of Effectiveness of the CBT Program

When individuals registered for the Panic Program, they were asked a number of questions about their current symptoms, including questions about the frequency and intensity of their panic attacks, as well as the degree to which their symptoms interfered with their daily lives. In addition, users were asked to indicate whether they were using the program on their own or in collaboration with a health care professional. At the beginning of each session, users were asked a number of questions regarding their symptoms, homework and progress to date (Weekly Review). At the end of session 12 users were asked to respond to a number of questions regarding the frequency and severity of their panic attacks as well as the degree to which their symptoms interfered with their daily lives. Finally, users are asked to complete the WB-DAT at the time they register for the program as well as at the end of session 12.

We evaluated the effectiveness of the Panic Program in three ways. First we used the Weekly Review data to compare the reported frequency and severity of panic attacks at the beginning of sessions 2, 4, 6, 8, 10, and 12. Second, we compared data on the degree to which users' panic attacks interfered with their daily lives at the time they registered for the program and at the end of session 12. Third, we compared users' WB-DAT data at registration and at the end of session 12 to determine the number of users who met screening criteria for DSM-IV Axis I diagnoses at the time they registered for the program compared to the end of session 12. Dimensional data regarding frequency and severity of panic attacks and interference in daily life were analyzed using paired-samples *t* tests.

Results

Log Statistics Regarding Website Use and Traffic

Between September 1, 2002 and February 1, 2004, there were 484695 visits and 1148097 page views from 99695 unique visitors to the Panic Center. The average length of a visit was 13 minutes and 11 seconds (SD [standard deviation] 4 minutes, 21 seconds). There were 28123 unique visitors to the Panic Program, WB-DAT, and Panic Diary and 356134 page views of those features.

Use of the Screening Test, Panic Symptom Diary, and Support Group

Between September 1, 2002 and February 1, 2004, 15269 users completed the WB-DAT. Table 1 describes the number of tests completed (male/female), as well as the number of users who met screening criteria for 0-8 disorders. Table 2 describes the number of users who met screening criteria for each of the DSM-IV disorders screened for by the WB-DAT.

Table 1. Number of screening diagnoses criteria met by users of the WB-DAT

Users	Total	% (N=15269)
Total males	5075	33.24
Total females	10194	66.76
Total tests with no diagnosis	1933	12.66
Total tests with 1 diagnosis	3691	24.17
Total tests with 2 diagnoses	2731	17.89
Total tests with 3 diagnoses	2237	14.65
Total tests with 4 diagnoses	1890	12.38
Total tests with 5 diagnoses	1474	9.65
Total tests with 6 diagnoses	1056	6.92
Total tests with 7 diagnoses	257	1.68
Total tests with 8 diagnoses	0	0

Table 2. Number of users meeting screening criteria on the WB-DAT

Screening Diagnosis	Total	% (N=15269)
No diagnosis	1933	12.66
Major depressive disorder	2021	13.24
Dysthymic disorder	4107	26.90
Generalized anxiety disorder	5891	38.38
Obsessive compulsive disorder	2504	16.40
Panic disorder with agoraphobia	4360	28.55
Panic disorder without agoraphobia	254	1.66
Agoraphobia without a history of panic disorder	2971	19.46
Social phobia (generalized subtype)	3643	23.86
Social phobia (nongeneralized subtype: public speaking)	3525	23.09
Specific phobia	40	00.26
Post-traumatic stress disorder	3707	24.28
Acute stress disorder	44	00.29

Out of 15229 users, 6687 (43.79%) responded to the survey. Of these 1388 (20.76%) reported that they intended to share the results with their doctor; 2517 (37.64%) reported that they were going to think about sharing the results with their doctor; 777 (11.62%) reported that they were not going to share the results with their doctor; 229 (3.42%) reported that they were health care professionals reviewing the test; and 1776 (26.56%) had "no comment." Of the total number of users who completed the screening test, 4003 (26.21%) printed their results (Final Report), 1676 (10.97%) emailed their results to themselves, and 198 (1.29%) emailed their results to a health care professional.

Between September 1, 2002 and February 1, 2004, 493 (357 [72.41%] female and 136 [27.59%] male) users registered to use the panic symptom diary (Panic Diary) without also registering for the CBT program. During the same time period, 1451 users registered for the online support group and there were a total of 6664 posts and 75622 visitors. On average, each post was viewed by 8.81 (SD 2.34) visitors.

Use and Longitudinal Survey of Effectiveness of the CBT Program

Between September 1, 2002 and February 1, 2004, 856 (73.90%) females and 305 (26.1%) males registered for the Panic Program. Out of 1161, 126 (11%) reported that they were using the program "with a health care professional" and 1065 (92%) reported that they were using it "on their own." In addition, 190 users reported that they were "a health care professional reviewing the program." Their data were excluded from further analyses. The Panic Program in booklet form was downloaded by 1059 users. Table 3 presents the number of users who completed each session of the 12-session CBT Program, showing a substantial degree of attrition from session to session, with only 12 out of 1161 original users remaining at the end of the program.

Table 3. Number of users who completed each session of the 12-session CBT program

Session	Completers	% Users from Previous Session
Session 1	1161	N/A
Session 2	525	45.22
Session 3	152	28.95
Session 4	145	95.39
Session 5	91	62.76
Session 6	46	50.55
Session 7	39	84.78
Session 8	30	76.92
Session 9	28	93.33
Session 10	22	78.57
Session 11	16	72.72
Session 12	12	75.00

The primary outcome measure for the effectiveness of the Panic Program was user's self-report of panic attack frequency and severity at the beginning of each session (sessions 2-12). At the beginning of each session users were asked to report the number of panic attacks they had experienced per day for the previous week and the average intensity of those panic attacks on a scale from 0 to 10 with 0 being “no panic” and 10 being as intense as the “worst attack ever” Figure 2. Results of paired-sample *t* tests for these variables are presented in Tables 4 and 5. There were statistically significant reductions in panic attack frequency and severity across treatment, including significant reductions between sessions 2 and 3 (*P*<.001).

Table 4. Average number of panic attacks per day in the past week

Interval	Average # of Attacks/Day (SD)	*df*	t	*P* (2-tailed)
Week 2 Week 3 (n=152)	1.03 (1.47) 0.63 (1.04)	1.151	3.983	<.001
Week 2 Week 6 (n=46)	1.04 (1.38) 0.30 (0.76)	1.45	3.995	<.001
Week 2 Week 8 (n=30)	1.07 (1.41) 0.37 (0.85)	1.29	3.427	.002
Week 2 Week 12 (n=12)	1.00 (1.60) 0.08 (0.29)	1.11	2.303	.042

Table 5. Average intensity of panic attacks in the past week

Interval	Average Intensity of Attacks (SD)	*df*	t	*P* (2-tailed)
Week 2 Week 3 (n=152)	3.63 (3.17) 2.50 (2.34)	1.151	4.512	< .001
Week 2 Week 6 (n=46)	3.30 (3.16) 0.96 (2.39)	1.45	5.580	< .001
Week 2 Week 8 (n=30)	3.10 (3.19) 1.07 (2.48)	1.29	4.210	< .001
Week 2 Week 12 (n=12)	2.08 (2.81) 0.33 (1.16)	1.11	2.303	.044

Only 12 users completed all outcome measures, including the WB-DAT. At session 1, those 12 individuals met criteria for an average of 1.42 (SD 0.90) DSM-IV Axis 1 Disorders according to the screener. At session 12, they met criteria for an average of 0.42 (SD 0.79) disorders ($t[1.11] = 3.633$, $P=.004$). At session 1, 8 out of these 12 users met screening criteria for panic disorder with agoraphobia; at session 12, only 2 continued to meet screening criteria for the disorder. In addition, 3 out of these 12 users met screening criteria for social anxiety at session 1, whereas only one met screening criteria at session 12.

At registration and at the end of session 12, users were asked a number of questions, including a question about the degree to which their panic attacks interfered with their normal daily lives on a 0 to 4 scale with 0 being *none/no interference* and 4 being *extreme/severe interference*. At registration, the average interference rating was 2.58 (SD 1.08), as compared to 0.42 (SD 0.77) at the end of treatment ($df=1,11$, $t = 5.348$, $P<.001$). At the end of session 12 users were also asked to rate the degree to which their fear/and or avoidance interfered with their normal daily life, with 0 being *none/no interference* and 4 meaning

extreme/severe interference. On average, the 12 users who completed the survey rated this question as 0.42 (SD = 0.90).

In response to the survey at the end of session 12, 12 out of 12 (100.00%) users reported that since challenging the Panic Program they were challenging their anxious thoughts, 11 out of 12 (91.67%) reported that they were getting better at setting goals and designing exposure plans, 12 out of 12 (100.00%) reported that since starting the Panic Program they had gained confidence in their ability to challenge their fears and win, and 12 out of 12 (100.00%) reported that they believed that their hard work was paying off. Out of 12 users, 10 (83.33%) reported that they used the Support Group and 10 out of 10 (100%) rated the Support Group as "extremely helpful."

Discussion

Principal Findings

This study evaluated the patterns of use and effectiveness of a Web-based self-help program for panic disorder and agoraphobia. We found that the website is popular and well utilized. Users tend to visit the website several times and spend considerable time on the website. With respect to the goal of increasing collaborative disease management and promoting communication between consumers and health care professionals, it would appear that the website is being used for that purpose. For example, approximately 50% of users who complete the WB-DAT report that they either intend to share the results with a health care professional or are considering doing so, and approximately 10% of users reported that they were using the CBT program in collaboration with a health care professional. A small but noteworthy percentage of people who registered to use the WB-DAT and CBT program, and those who downloaded the print version of the CBT program identified themselves as health care professionals.

Among the interesting findings from this study is the fact that a fairly high proportion of users who completed the WB-DAT met criteria for one or more anxiety disorders. It appears that users of the website are likely people who are self-selected because they are suffering from some type of anxiety disorder and perhaps especially panic disorder or agoraphobia. It is also interesting that most support group users were passive visitors and viewers as opposed to users who post information.

The data regarding the usage and effectiveness of the CBT program are also interesting. Although many people used the program for a few weeks, only a few used it for the entire 12 sessions. However, consistent with the literature [7-11,27,28] it appears that the CBT program can be effective in reducing panic attack frequency and severity. At the end of session 12 the remaining users reported a significant reduction in the number and severity of panic attacks and interference in daily life due to panic attacks. More importantly, the CBT program appears to have been of benefit to many users even if they used it only for a few weeks. Psychoeducation and information about anxiety, panic and avoidance may be all that many people need to feel "better enough." In addition, there appears to be a dose-response effect between treatment duration and the degree of reduction in number and severity of panic attacks (Tables 4 and 5).

Limitations

It is important to note that these data were collected in an uncontrolled fashion. In contrast to previous reports of controlled trials of computer and Web-based interventions, we analyzed cumulative anonymous data from a freely available program. In addition, the sample was not demographically well characterized. In order to ensure anonymity, only minimal demographic data were collected. Because this was a longitudinal design with no control group we do not know whether the highly self-selected group of users who stayed in the program would have become better also without the intervention.

The most notable problem is the high attrition rate, which is consistent with other research on self-help interventions [9,10]. For most people it is difficult to do exposure-based treatment without professional assistance [11,12].

The high attrition rate may also be caused by the option of downloading a PDF file of the entire Panic Program. Given that 1161 users registered for the program and 1159 users downloaded the PDF version, it seems likely that many users preferred to read from the hard copy. They may have stopped using the Web-based program and their data regarding their usage of the program was therefore lost. However, they may have continued to use the hard copy to some effect. It also may be that many people choose to use self-help resources in a nonlinear manner.

Comparisons with Other Studies

The results of this study are consistent with the results of recent research demonstrating the efficacy of Web-based self-help for panic disorder [27], the efficacy of freely available Web-based self-help programs for mood and anxiety problems [28], and the high attrition rates reported in other studies of self-help interventions [9,10].

Summary and Questions to be Addressed by Further Research

In summary, despite the high attrition rate, these data suggest that freely available Web-based self-help for panic disorder can be effective for self-selected individuals. Such a result is interesting given the cost-effectiveness of Web-based treatments compared to conventional psychotherapeutic treatment and the potential for Web-based interventions to reach people in need [12, 38,39]. It seems likely that attrition rates can be reduced by making Web-based self-help interventions a part of a stepped model of care that includes the option of some minimal amount of therapist contact and guidance. An important focus of future research will be to conduct "dose finding" studies to determine the optimal level of professional guidance and support that will facilitate treatment adherence and effectiveness for users of free Web-based programs.

Conflicts of Interest

Dr. Farvolden has acted as a paid consultant to Van Mierlo Communications Consulting Inc., Toronto, ON, Canada, the owner of the Panic Center content and software.

Multimedia Appendix

Additional Screenshots [PowerPoint ppt file, 616 KB - jmir_v7i1e7_app1.ppt]

References

1. Murray CJ, Lopez AD. Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. Lancet 1997 May 24;349(9064):1498-1504. [Medline: 97310291] [doi: 10.1016/S0140-6736(96)07492-2]
2. Nisenson LG, Pepper CM, Schwenk TL, Coyne JC. The nature and prevalence of anxiety disorders in primary care. Gen Hosp Psychiatry 1998 Jan;20(1):21-28. [Medline: 98167152] [doi: 10.1016/S0163-8343(97)00096-0]
3. Harman JS, Rollman BL, Hanusa BH, Lenze EJ, Shear MK. Physician office visits of adults for anxiety disorders in the United States, 1985-1998. J Gen Intern Med 2002 Mar;17(3):165-172. [Medline: 21927187] [doi: 10.1046/j.1525-1497.2002.10409.x]
4. Gega L, Marks I, Mataix-cols D. Computer-aided CBT self-help for anxiety and depressive disorders: experience of a London clinic and future directions. J Clin Psychol 2004 Feb;60(2):147-157. [Medline: 14724922] [doi: 10.1002/jclp.10241]
5. Dinos S, Stevens S, Serfaty M, Weich S, King M. Stigma: the feelings and experiences of 46 people with mental illness. Qualitative study. Br J Psychiatry 2004 Feb;184(2):176-181 [FREE Full text] [Medline: 14754832] [doi: 10.1192/bjp.184.2.176]
6. Kenardy JA, Mccafferty K, Rosa V. Internet-delivered indicated prevention for anxiety disorders: A randomized controlled trial. Behav Cog Psychother 2003;31(3):279-289. [doi: 10.1017/S1352465803003047]
7. Newman MG. Recommendations for a cost-offset model of psychotherapy allocation using generalized anxiety disorder as an example. J Consult Clin Psychol 2000 Aug;68(4):549-555. [Medline: 20421134] [doi: 10.1037//0022-006X.68.4.549]
8. Richards A, Barkham M, Cahill J, Richards D, Williams C, Heywood P. PHASE: a randomised, controlled trial of supervised self-help cognitive behavioural therapy in primary care. Br J Gen Pract 2003 Oct;53(495):764-770. [Medline: 22963945]
9. Marrs RW. A meta-analysis of bibliotherapy studies. Am J Community Psychol 1995 Dec;23(6):843-870. [Medline: 96258177]
10. Gould RA, Clum GA. A meta-analysis of self-help treatment approaches. Clin Psychol Rev 1993;13(2):169-186. [doi: 10.1016/0272-7358(93)90039-O]
11. Marks IM, Mataix-cols D, Kenwright M, Cameron R, Hirsch S, Gega L. Pragmatic evaluation of computer-aided self-help for anxiety and depression. Br J Psychiatry 2003 Jul;183(1):57-65 [FREE Full text] [Medline: 22718773] [doi: 10.1192/bjp.183.1.57]
12. Newman MG, Erickson T, Przeworski A, Dzus E. Self-help and minimal-contact therapies for anxiety disorders: Is human contact necessary for therapeutic efficacy? J Clin Psychol 2003 Mar;59(3):251-274. [doi: 10.1002/jclp.10128] [Medline: 22466904]
13. Proudfoot J, Goldberg D, Mann A, Everitt B, Marks I, Gray JA. Computerized, interactive, multimedia cognitive-behavioural program for anxiety and depression in general practice. Psychol Med 2003 Feb;33(2):217-227. [Medline: 22509227] [doi: 10.1017/S0033291702007225]
14. Selmi PM, Klein MH, Greist JH, Sorrell SP, Erdman HP. Computer-administered cognitive-behavioral therapy for depression. Am J Psychiatry 1990 Jan;147(1):51-56. [Medline: 90087136]
15. Clarke G, Reid E, Eubanks D, O'connor E, Debar LL, Kelleher C, et al. Overcoming depression on the Internet (ODIN): a randomized controlled trial of an Internet depression skills intervention program. J Med Internet Res 2002 Dec 17;4(3):e14 [FREE Full text] [Medline: 22442446]
16. Bowers W, Stuart S, MacFarlane R, Gorman L. Use of computer-administered cognitive-behavior therapy with depressed inpatients. Depression 1993;1:294-299.
17. Smith KL, Kirkby KC, Montgomery IM, Daniels BA. Computer-delivered modeling of exposure for spider phobia: relevant versus irrelevant exposure. J Anxiety Disord 1997 Sep;11(5):489-497. [Medline: 98071159] [doi: 10.1016/S0887-6185(97)00025-X]
18. Greist JH, Marks IM, Baer L, Kobak KA, Wenzel KW, Hirsch MJ, et al. Behavior therapy for obsessive-compulsive disorder guided by a computer or by a clinician compared with relaxation as a control. J Clin Psychiatry 2002 Feb;63(2):138-145. [Medline: 21862922]
19. Lange A, Rietdijk D, Hudcovicova M, Van De Ven JP, Schrieken B, Emmelkamp PMG. Interapy: a controlled randomized trial of the standardized treatment of posttraumatic stress through the internet. J Consult Clin Psychol 2003 Oct;71(5):901-909. [doi: 10.1037/0022-006X.71.5.901] [Medline: 22879528]
20. Przeworski A, Newman MG. Palmtop computer-assisted group therapy for social phobia. J Clin Psychol 2004 Feb;60(2):179-188. [Medline: 14724925] [doi: 10.1002/jclp.10246]

21. Newman MG, Kenardy JA, Herman S, Taylor CB. The use of hand-held computers as an adjunct to cognitive-behavioural therapy. Comput Human Behav 1996;12(1):135-143. [doi: 10.1016/0747-5632(95)00024-0]
22. Klein B, Richards J. A brief Internet-based treatment for panic disorder. Behav Cog Psychother 2001;29(1):113-117. [doi: 10.1017/S1352465801001138]
23. Richards JC, Alvarenga ME. Extension and replication of an Internet-Based treatment program for panic disorder. Cognitive Behaviour Therapy 2002;31(1):41-47. [doi: 10.1080/16506070252823652]
24. Kenardy JA, Dow MGT, Johnston DW, Newman MG, Thomson A, Taylor CB. A comparison of delivery methods of cognitive-behavioral therapy for panic disorder: an international multicenter trial. J Consult Clin Psychol 2003 Dec;71(6):1068-1075. [doi: 10.1037/0022-006X.71.6.1068] [Medline: 22986333]
25. Carling P, Westling BE, Ljungstrand P, Ekselius L, Andersson G. Treatment of panic disorder via the Internet: A randomized trial of a self-help program. Behav Ther 2001;32:751-764.
26. Carlbring P, Ekselius L, Andersson G. Treatment of panic disorder via the Internet: a randomized trial of CBT vs. applied relaxation. J Behav Ther Exp Psychiatry 2003 Jun;34(2):129-140. [Medline: 22782210] [doi: 10.1016/S0005-7916(03)00026-0]
27. Carlbring, Nilsson-Ihrfelt, Wasrs, Kollenstam, Buhrman, Kaldo, et al. Treatment of panic disorder: Live therapy vs. self-help via the Internet. Behav Res Ther [in press].
28. Christensen H, Griffiths KM, Korten AE, Brittliffe K, Groves C. A comparison of changes in anxiety and depression symptoms of spontaneous users and trial participants of a cognitive behavior therapy website. J Med Internet Res 2004 Dec 22;6(4):e46 [FREE Full text] [Medline: 15631970] [doi: 10.2196/jmir.6.4.e46]
29. ; The Panic Centre. Welcome to the Panic Center. URL: http://www.paniccentre.net/ [accessed 2004 July 21]
30. Farvolden P, Mcbride C, Bagby RM, Ravitz P. A Web-based screening instrument for depression and anxiety disorders in primary care. J Med Internet Res 2003 Sep 29;5(3):e23 [FREE Full text] [Medline: 22879622] [doi: 10.2196/jmir.5.3.e23]
31. ; American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders DSM-IV. Washington DC: American Psychiatric Association; Jan 15, 1994.
32. ; World Health Organization. International Statistical Classification of Diseases and Related Health Problems (ICD-10), 10th edition. Geneva, Switzerland: World Health Organization; 1992, Vol. 1.
33. Personal Information Protection and Electronic Documents Act (Canada) (amended 2004). 2000. URL: http://www.privcom.gc.ca/legislation/02_06_01_e.asp [accessed 2004 July 21]
34. Health Insurance Portability and Accountability Act of 1996 (United States of America; Pub L No. 104-191). URL: http://www.hhs.gov/ocr/hipaa [accessed 2004 July 21] URL: http://aspe.hhs.gov/admnsimp/pl104191.htm [accessed 2004 July 21]
35. ; European Parliament and the Council. Directive on Privacy and Electronic Communications (Directive 2002/58/EC). URL: http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_201/l_20120020731en00370047.pdf [accessed 2004 July 21]
36. Peer 1 Network. URL: http://www.peer1.com/en/index.asp [accessed 2004 September 14]
37. Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004 Sep 29;6(3):e34 [FREE Full text] [Medline: 15471760] [doi: 10.2196/jmir.6.3.e34]
38. Merrill KA, Tolbert VE, Wade WA. Effectiveness of cognitive therapy for depression in a community mental health center: a benchmarking study. J Consult Clin Psychol 2003 Apr;71(2):404-409. [Medline: 22584777] [doi: 10.1037/0022-006X.71.2.404]
39. Warsi A, Wang PS, Lavalley MP, Avorn J, Solomon DH. Self-management education programs in chronic disease: a systematic review and methodological critique of the literature. Arch Intern Med 2004 Aug 9;164(15):1641-1649. [Medline: 15302634] [doi: 10.1001/archinte.164.15.1641]

Abbreviations

CBT: Cognitive behaviour therapy
MDD: Major Depressive Disorder
WB-DAT: Web-based depression and anxiety test

submitted 22.09.04; peer-reviewed by P Carlbring; comments to author 22.11.04; revised version received 04.03.05; accepted 10.03.05; published 26.03.05.

Please cite as:
Farvolden P, Denisoff E, Selby P, Bagby RM, Rudy L
Usage and Longitudinal Effectiveness of a Web-Based Self-Help Cognitive Behavioral Therapy Program for Panic Disorder
J Med Internet Res 2005;7(1):e7
URL: http://www.jmir.org/2005/1/e7/
doi:10.2196/jmir.7.1.e7
PMID:15829479

Original Paper

Pilot Study of an Internet Patient-Physician Communication Tool for Heart Failure Disease Management

Robert C Wu[1], MD, MSc; Diego Delgado[2], MD; Jeannine Costigan[3], RN, MScN; Jane MacIver[2], RN, MScN; Heather Ross[2], MD, MHSc

[1]Division of General Internal Medicine, University Health Network, Toronto ON, Canada

[2]Division of Cardiology, University Health Network, Toronto ON, Canada

[3]Cardiology and Heart Function Clinic, St. Mary's Regional Cardiac Care Centre, Kitchener ON, Canada

Corresponding Author:
Robert C Wu, MD, MSc
Division of General Internal Medicine
Toronto General Hospital
9ES-424
200 Elizabeth Street
Toronto ON M5G 2C4
Canada
Phone: +1 416 340 4567
Fax: +1 416 340 3391
Email: robert.wu@uhn.on.ca

Abstract

Background: Internet disease management has the promise of improving care in patients with heart failure but evidence supporting its use is limited. We have designed a Heart Failure Internet Communication Tool (HFICT), allowing patients to enter messages for clinicians, as well as their daily symptoms, weight, blood pressure and heart rate. Clinicians review the information on the same day and provide feedback.

Objective: This pilot study evaluated the feasibility and patients' acceptability of using the Internet to communicate with patients with symptomatic heart failure.

Methods: Patients with symptomatic heart failure were instructed how to use the Internet communication tool. The primary outcome measure was the proportion of patients who used the system regularly by entering information on average at least once per week for at least 3 months. Secondary outcomes measures included safety and maintainability of the tool. We also conducted a content analysis of a subset of the patient and clinician messages entered into the comments field.

Results: Between May 3, 1999 and November 1, 2002, 62 patients (mean age 48.7 years) were enrolled.. At 3 months 58 patients were alive and without a heart transplant. Of those, 26 patients (45%; 95% Confidence Interval, 0.33-0.58) continued using the system at 3 months. In 97% of all entries by participants weight was included; 68% of entries included blood pressure; and 71% of entries included heart rate. In 3386 entries out of all 5098 patient entries (66%), comments were entered. Functions that were not used included the tracking of diuretics, medications and treatment goals. The tool appeared to be safe and maintainable. Workload estimates for clinicians for entering a response to each patient's entry ranged from less than a minute to 5 minutes or longer for a detailed response. Patients sent 3386 comments to the Heart Function Clinic. Based on the content analysis of 100 patient entries, the following major categories of communication were identified: patient information; patient symptoms; patient questions regarding their condition; patient coordinating own care; social responses. The number of comments decreased over time for both patients and clinicians.

Conclusion: While the majority of patients discontinued use, 45% of the patients used the system and continued to use it on average for 1.5 years. An Internet tool is a feasible method of communication in a substantial proportion of patients with heart failure. Further study is required to determine whether clinical outcomes, such as quality of life or frequency of hospitalization, are improved.

(J Med Internet Res 2005;7(1):e8) doi:10.2196/jmir.7.1.e8

KEYWORDS

Internet; disease management; congestive heart failure; physician-patient relations; communication

Introduction

Intensive management of patients with heart failure improves the quality of care, has a positive impact on quality of life, and reduces readmissions [1-3] through frequent monitoring, detailed assessment, optimization of medications, and education. Nevertheless, even with current optimal management, quality of life is still poor in patients with symptomatic heart failure. Thus improving quality of life remains a major goal in the treatment of heart failure [4].

The Internet has shown promise in the care of chronic disease particularly in obesity. Patients who received Internet behavioural counselling lost more weight after 1 year than patients randomized to receive only Internet educational information [5,6]. There have also been pilot studies of Internet interventions in cardiac care including cardiac transplantation [7] and heart failure [8]. A randomized controlled trial in heart failure, which focused primarily on providing patients with Internet access to their medical record, failed to show a difference in quality of life [8]. It was, however, well received by patients, and the patients believed the Internet could in theory deliver benefits including improved education, coordination of care, and self-care [9].

Similar to Internet management of diabetes [10], an Internet disease management tool could improve the care of patients with a chronic disease such as heart failure in the following ways: improve monitoring of patients, provide a method for clinicians to educate patients about their condition, provide individualized feedback and reassurance, and provide a framework for patients to self-manage their disease.

We have designed a tool to achieve these goals. The Heart Failure Internet Communication Tool (HFICT) was developed to enable electronic communication between clinicians and patients with heart failure to help manage their disease. Patients can enter parameters that are important to monitor in heart failure: symptoms, weight, blood pressure and heart rate. Patients would enter this information usually on a daily basis to allow the clinicians to monitor them closely. A clinician reviews the information on the same day and provides feedback, including educational messages, reassurance or suggesting a change in therapy. Our overall goal was to improve care by improving communication and better educating patients on how to manage their condition. Preliminary findings with 16 patients who used the tool showed a trend towards improved quality of life as well as high satisfaction levels [11].

A randomized controlled trial of Internet communication is needed to determine whether such an Internet disease management tool can improve care delivery and outcomes in individuals with congestive heart failure. In preparation for such a trial, we conducted a pilot study to determine whether patients would use such a tool over a sustained period of time, and to evaluate the safety and maintainability of such a tool.

Methods

This study was a prospective observational cohort study. The study was conducted in the Heart Function Clinic, Toronto General Hospital, University Health Network, Toronto, Ontario, Canada. The Heart Function Clinic is a multidisciplinary clinic receiving referrals for patients with complex heart failure.

Participants

As this was a pilot study, a convenience sample was used consisting of patients enrolled through the clinic over a period of 3 years (May 3, 1999 and November 1, 2002).

Eligibility criteria included new referral to the clinic with a diagnosis of heart failure, New York Heart Association (NYHA) functional class III or IV, and a left ventricular ejection fraction less than or equal to 30%. Exclusion criteria were lack of Internet access, inability to obtain their own body weights at home, and expected survival less than 3 months. Internet access was defined as having personal access or access through a trusted family member or friend.

Design

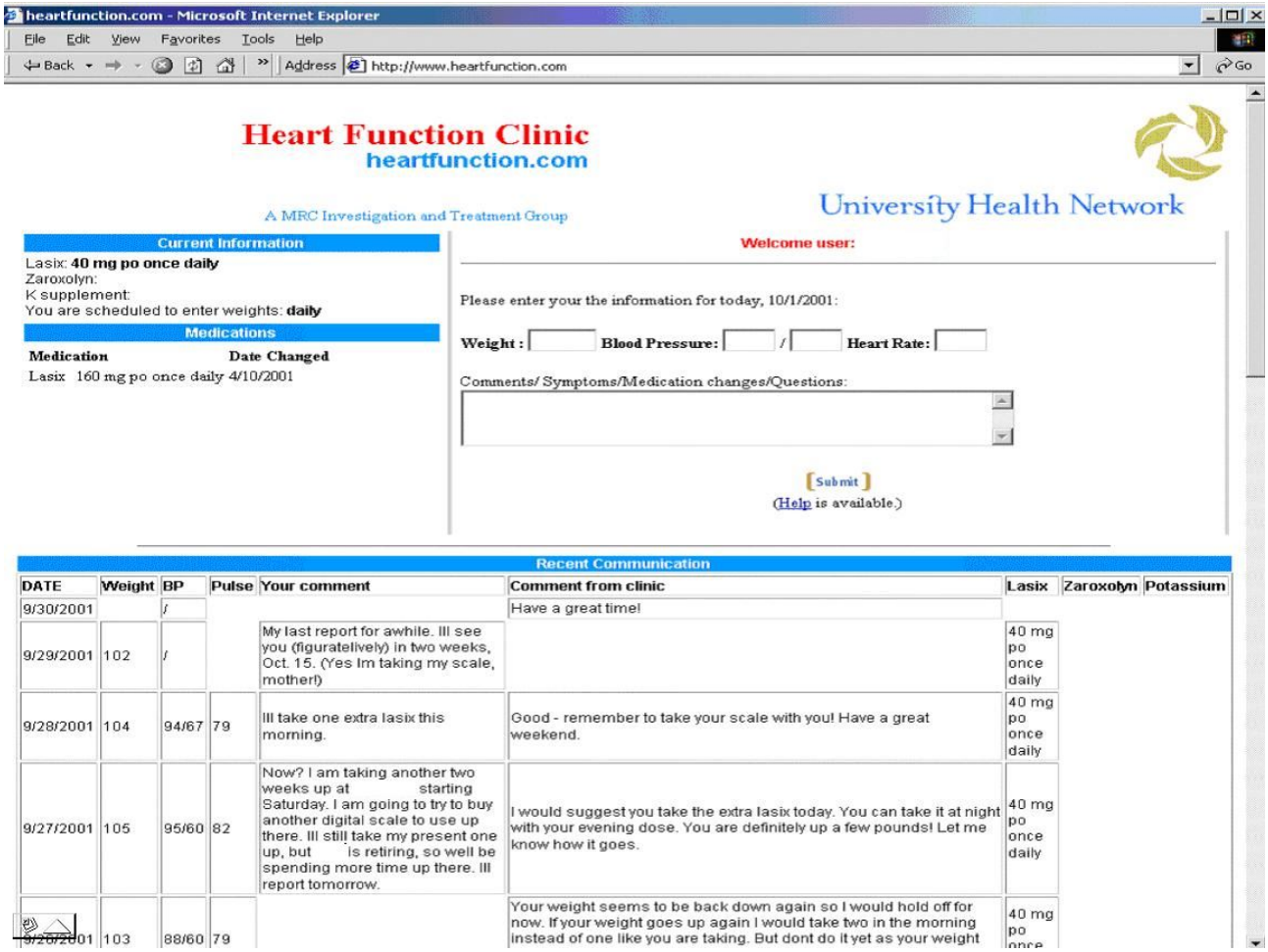
The Institutional Review Board at the University Health Network approved the protocol. Patients who were eligible based on the inclusion and exclusion criteria were given the option of using the Heart Failure Internet Communication Tool. Patients were instructed that if they declined to participate, they would still receive the usual standard of care provided by the Heart Function Clinic. Written informed consent was obtained from all participants. Following completion of baseline measurements, all consenting participants were instructed in the use of the HFICT. Measures were taken to protect confidentiality according to guidelines in effect at the time [12].

During the informed consent process, patients were told that a possible benefit was that the system could improve patient-clinician communication, which in turn could improve their care and possibly their quality of life. They were also told that risks included possible compromised confidentiality of health information when transmitted over the Internet, as well as possible delays in obtaining care if the Internet was used for urgent communication.

Internet Intervention

Participants were instructed on how to enter their weight, blood pressure, heart rate as well as any symptoms into the HFICT. Regular clinic practice is to prescribe blood pressure monitors for patients for whom it is important to monitor blood pressure. Based on the severity of their heart failure, participants were told how often to enter their information (from daily to once a week) Figure 1. Clinicians (nurse-practitioner or cardiologists) reviewed and responded to patients' entries using the online messaging tool each weekday. Clinicians answered questions, educated, provided reassurance, and changed medications when necessary.

Figure 1. Screenshot of patient's data entry screen, with recent communication displayed



As this was a method of nonurgent communication, patients were instructed at enrollment not to use the website for urgent communication. For urgent contact, patients were instructed to telephone the clinic, telephone their family physician or go to the Emergency Room as appropriate. These instructions were also displayed on the website. If patients tried to use the website for urgent communication, they would be instructed to seek medical attention promptly and were reminded that the Internet communication tool was not a method of urgent communication.

Baseline Patient Measures

The following baseline characteristics were obtained from the patient at enrollment: age, gender, medications, NYHA class, etiology of heart failure, left ventricular function and co-morbid conditions.

Primary Outcome

The primary outcome was the usage of the HFICT. Usage of the HFICT was defined as regular interaction (at least once per week on average) with the HFICT for a minimum of 3 months. While regular contact (daily or weekly) was desired, participants could miss a week for valid reasons such as vacation or hospitalization. In order to be considered users, patients did not need to log in every week, but they did need to enter information into the HFICT on average once per week. Patients were also required to continue entering information for at least 3 months to be considered users. The follow-up period of 3 months is that used in previous studies of telephone-based interventions [13] and home-based interventions [14]. Regular interaction (at least once per week on average) is assumed to be necessary to derive benefits, such as improved knowledge, monitoring and self-care skills, from the tool. Patients who died or required transplantation within 3 months were excluded from this outcome analysis.

Secondary Outcomes

A number of secondary endpoints assessing safety, effectiveness, security and maintainability further determined the feasibility of the HFICT. While we hope that this tool will improve quality of care, we recognize that this new intervention could be unsafe. If patients or clinicians rely on this tool too much and do not get appropriate follow-up, an increase in hospitalizations or deaths could occur. In order to evaluate the safety of the system, the following outcomes were monitored:

- unplanned hospitalizations
- unplanned hospitalizations due to heart failure
- planned hospitalizations (admissions that were scheduled in advance, such as pacemaker insertion or tailored inotropic therapy)
- mortality
- cardiac transplantation
- security breaches including incorrect logins and reported breaches as reported by participants, health care providers and administrators of the site

Since participants had the option of continuing to use the system beyond 3 months, we followed all enrolled participants (users and nonusers) for the mortality, hospitalization and transplantation endpoints until the study end date.

Maintainability was assessed by estimating workload on the clinicians as well as the training requirements of clinicians.

Qualitative Message Content Analysis

In order to better understand the nature of communication with the HFICT, a qualitative content analysis of patient messages and clinician responses was performed. A random 100 entries from the participants and 100 entries from the clinicians were reviewed to look for common themes. This coding structure was then applied to all remaining comments to quantify the content of communication. As this was a pilot study, there was only one coder, the primary investigator (RW).

Statistical Analysis

Descriptive statistics were expressed as mean ± standard deviation. Patients who used the HFICT were compared to patients who did not use the system. Associations were tested using the chi-square statistic for categorical variables and unpaired *t* tests for continuous variables. For all analyses, an alpha error of ± .05 was considered significant.

As the primary outcome was a proportion, a confidence interval was calculated for this proportion.

For the analysis of the safety data, patients who used the intervention were grouped and were compared to the patients who were enrolled but who did not use the HFICT. The endpoints such as mortality and transplant were calculated as proportions and were compared by chi-square analyses. For the end points of hospitalizations, mean hospitalizations per patient were calculated. For these continuous variables, an unpaired *t* test for association was performed.

Results

Between May 3, 1999 and November 1, 2002, 62 patients were enrolled. All patients were followed until March 2003, with a total patient follow-up of 109 patient-years. During the total follow up period, 11 patients died , giving an annualized mortality rate of 10.1%.

The baseline characteristics for the 62 patients are listed in Table 1. Those who used the HFICT were older, and more likely to be female, to have idiopathic dilated cardiomyopathy, to have a worse functional class, and to be on proven medications for heart failure such as Angiotensin Converting Enzyme (ACE) inhibitors and beta-blockers. These trends were not statistically significant.

Table 1. Baseline characteristics

Variable	All (N=62)	Users* (n=26)	Nonusers (n=36)	*P* value
Age	48.7 ± 13.0	52.4 ± 12.1	46.1 ± 13.2	.06
Men (%)	69%	61.5%	75%	.26
Co-morbidities	19.4%	19.2%	19.4%	.99
Diabetes	21.0%	19.2%	22.2%	.77
Coronary disease	1.7±1.5	1.8±1.5	1.6±1.4	.60
Number of co-morbidities (mean)				
NYHA class IV	4 (6%)	3 (12%)	1 (3%)	.20
Left ventricular grade	3.4±0.6	3.4±0.6	3.5±0.5	.56
Etiology of heart failure	43.5%	46.2%	41.7%	.72
Idiopathic dilated	25.8%	23.1%	27.8%	.68
Ischemic	30.6%	30.8%	30.6%	.99
Other				
Medications	80.6%	84.6%	77.8%	.50
ACE inhibitor	14.5%	15.4%	13.9%	.87
ARB†	77.4%	84.6%	72.2%	.25
Beta blocker	75.8%	69.2%	80.6%	.30
Loop diuretic	43.5%	42.3%	44.4%	.87
Spironolactone	69.4%	73.1%	66.7%	.59
Digoxin				
Baseline LHFQ‡ (n)§	57.5 (43)	62.2 (22)	52.5 (21)	.10

* Defined as a participant who used the system for at least 3 months, on average once per week

† ARBAngiotensin II receptor blocker

‡ Minnesota Living with Heart Failure Questionnaire [15]

§ Baseline LHFQ collection was incomplete. The number of subjects who completed the baseline questionnaire is listed in parenthesis.

Primary Outcome: Use of the HFICT

Of the 62 patients who were enrolled, 3 out of the 11 patients who died during the follow-up period passed away within 3 months after enrollment and 1 had a heart transplant, thus at 3 months we collected usage data from 58 patients. Of these 58 patients, 26 used the system for at least 3 months on average once per week (45%; 95% Confidence Interval [CI], 0.33-0.58). Of the nonusers, 23 patients were enrolled but never logged in; 14 patients logged on at least once but did not continue for 3 months. There were 3 patients who died within 3 months of enrollment, and 1 patient who underwent heart transplantation 1 month after enrollment. After 12 months, only 16 patients continued to use the system, all others stopped using the system. Of these, 8 continued to use the system at 2 years and 4 continued to used the system after 3 years.

With respect to the participants' use of individual components of the system, certain information was entered more frequently than others. In 97% of all entries by participants weight was included; 68% of entries included blood pressure; and 71% of entries included heart rate. In 3386 entries out of all 5098 patient entries (66%), comments were entered. Functions that were not used included the tracking of diuretics, medications and treatment goals. Diuretic changes were instead documented in the “Comments” section. Medications were initially entered at enrollment but were not kept up to date for the majority of patients (79%). Patient-specific goals such as the target weight and beta-blocker titration were not entered at all by clinicians. Usage data are shown in Table 2.

Table 2. HFICT usage data for those defined as ‘users'

	Mean (SD)	Range
Number of entries per user	191 (175.0)	27-636
Number of months of Internet follow-up	18.8 (12.0)	5.8-42.0

Secondary Outcomes

Safety

Table 3 lists the different safety endpoints in the HFICT, comparing users to nonusers. There was no excess of death or transplants in the user group. Mortality in the nonuser group was higher but not statistically significant (user 11.5%, nonuser 22.2%, *P*= .28). Transplantation was higher in the user group but again not statistically significant (user 15.4%, nonuser 5.6%, *P*=.20).

Table 3. Comparison of two groups for safety endpoints (during total follow-up period until March 2003)

	Users (n=26)	Nonusers (n=36)	*P* Value
Deaths – n (%)	3 (11.5%)	8 (22.2%)	.28
Transplant – n (%)	4 (15.4%)	2 (5.6%)	.20
Hospitalizations			
Total – n (mean per pt)	28 (1.08)	18 (0.50)	.10
Planned – n (mean per pt)	8 (0.31)	3 (0.08)	.04
Unplanned – n (mean per pt)	20 (0.77)	15 (0.42)	.26
Unplanned due to heart failure – n (mean per pt)	15 (0.58)	13 (0.36)	.40

There were more hospitalizations in the user group (mean hospitalizations: per user 1.08, per nonuser 0.50, *P*=.10).This was predominantly due to the statistically significant difference (*P*=.04) in the planned hospitalizations for procedures such as pacemakers, implantable cardiac defibrillators or tailored inotropic therapy.

The HFICT communications and the charts were reviewed and no errors attributable to the communication process were detected. Rather, the recurrent admissions were felt to be appropriate for the severity of heart failure.

Of the 11 patients who died, 4 died within 1 month of entering information. To determine whether the use of HFICT contributed to these deaths, the characteristics of these patients were examined further. As Table 3 shows, none of the 4 patients appeared unstable by weight change, vital signs or comments at the time of their last entry. Only 1 of these patients was defined as a user and had been using the HFICT for almost 1 year before a death that was not heart failure-related.

There were no reports or indications of lapses in security or confidentiality.

Table 4. Characteristics of patients who died within 1 month of having recently used the HFICT

User	Time on HFICT	Number of Entries	Recent Weight Trend	Recent Symptoms	Heart Failure Related Cause of Death
Yes	310 days	112	Stable	None	No
No	3 days	1	*	None	Yes
No	29 days	9	Stable	None	Presumed
No	70 days	33	Stable	None	Presumed

* Unable to determine due to only one entry on the system

Maintainability

Workload estimates for clinicians for entering a response to each patient's entry ranged from less than a minute to 5 minutes or longer for a detailed response. If further information was required, such as determining the side effects of a new medication or verifying details with a cardiologist, a response could take up to a half hour. Clinician monitoring and entries were done predominately by nurse-practitioners (98.3% of entries) with the remainder by cardiologists.

Website training was given to 3 cardiologists and 3 nurse-practitioners. All were able to use the website without problems after a half-hour training session.

Technical costs of the system included development time (approximately 200 hours) and system support (2 hours per month). Hardware and software costs were minimal as shared resources were used.

There were 5 occurrence when the system was not available, and these happened in the first 2 years of the pilot. Of these 3 occurred in the first 6 months of the study, resulting in 3 downtimes of several days each. The causes of these problems were corrected and no further downtimes were experienced in the final 2 years. After any downtime, many participants communicated the importance of keeping the website always available.

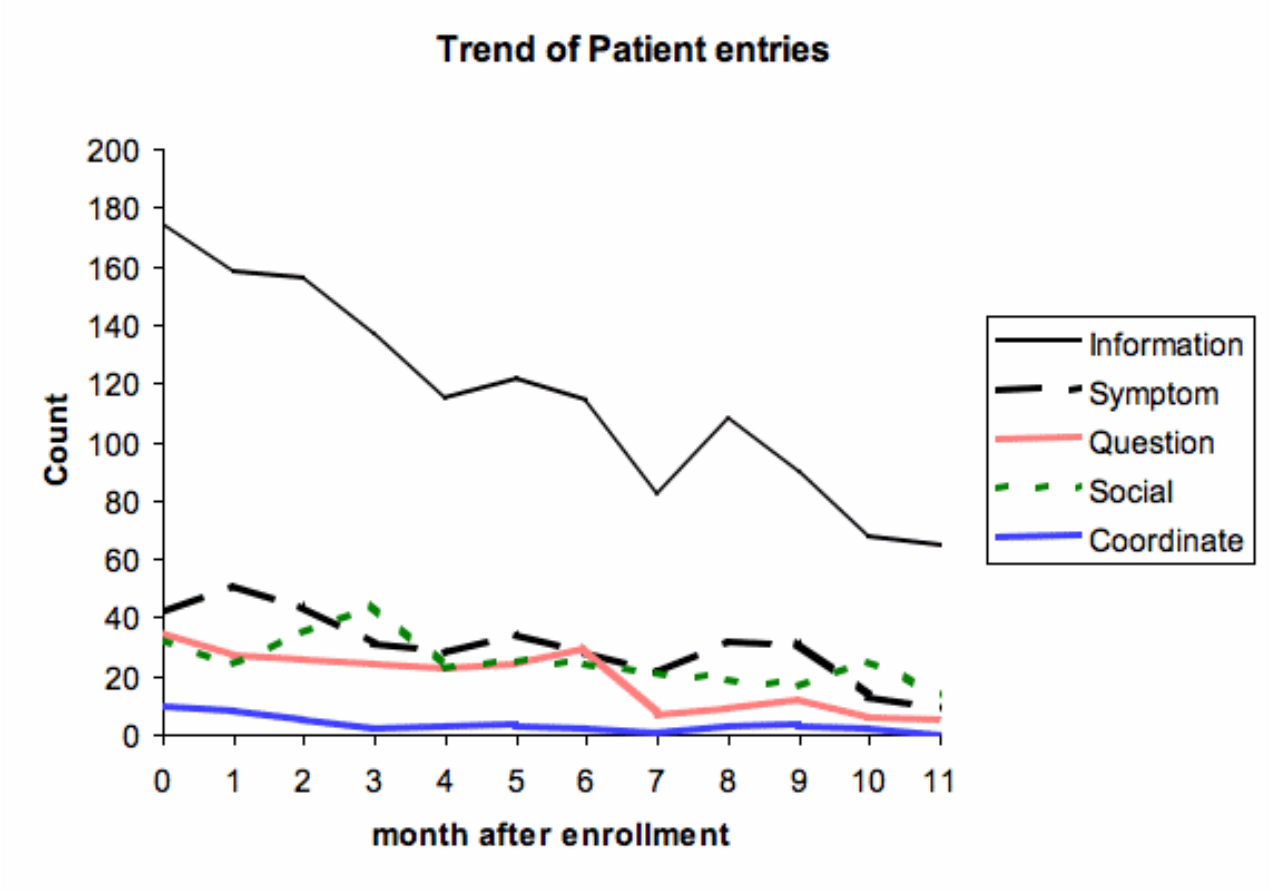
Analysis of Communication Content

Over the entire study period, patients sent 3386 comments to the Heart Function Clinic. Based on the qualitative review of 100 entries, the following major categories of communication were identified:

- patient information (eg, blood glucose, outside laboratory values, description of visits with family physician)
- patient symptoms (eg, shortness of breath, dizziness, ankle swelling, chest pain)
- patient questions regarding their condition (eg, how much diuretic to take, whether symptoms are side effects of medications)
- patient coordinating own care (eg, organizing next clinic appointment, arranging other tests such as angiogram)
- social responses (eg, statements regarding weather)

Figure 2 shows the trend of patient communication over time after enrollment. The number of comments decreased over time. Most communication consisted of patients providing information. Symptoms, questions, and social communications were all entered with similar frequency, declining over time. A small proportion of comments were used to coordinate care.

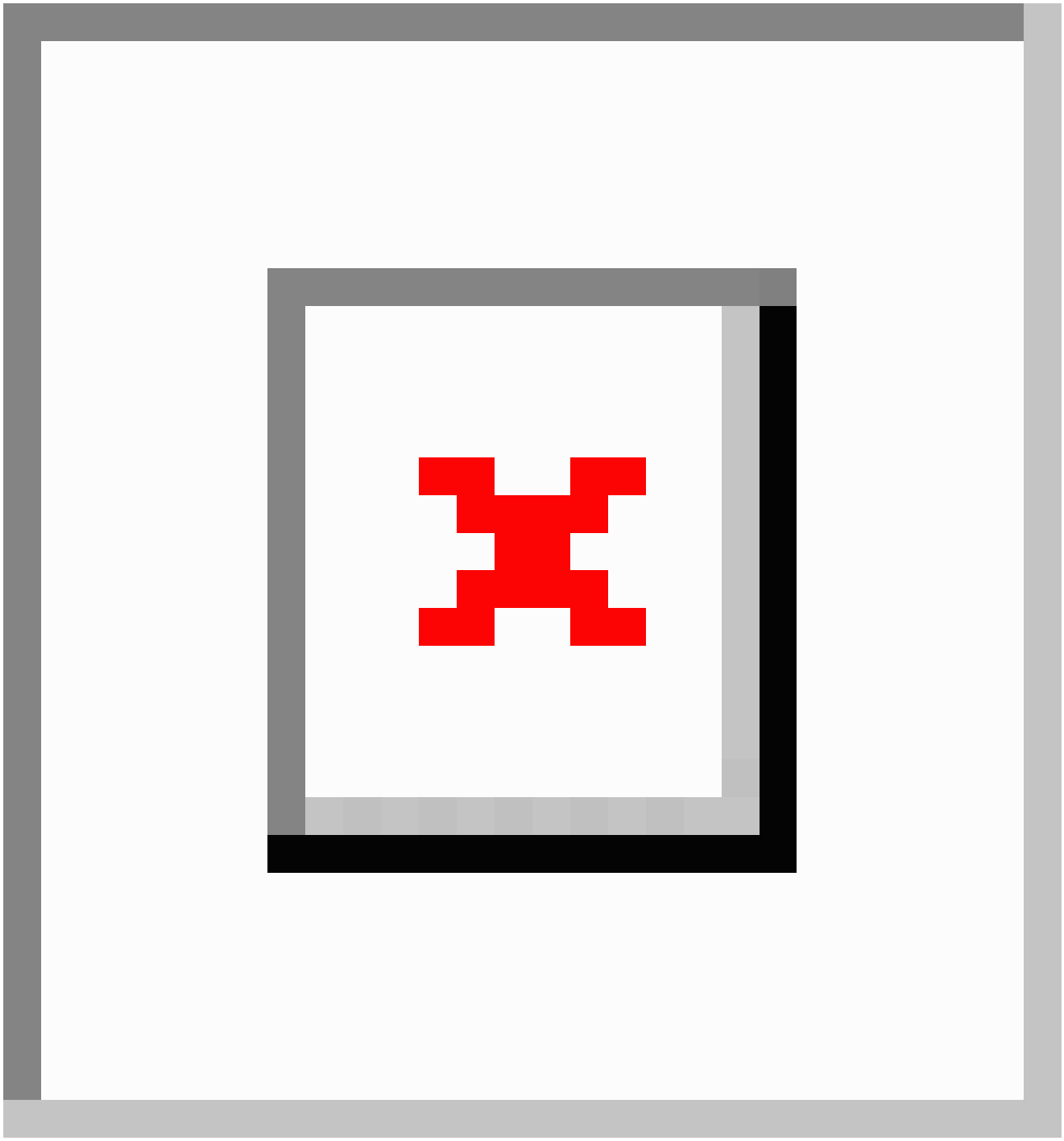
Figure 2. Trend of patient entries into the comments field over 12 months, adjusted for patient drop-out



In order to reduce the effect of participant dropout, the count of entries per month were normalized to 16 patients enrolled (the number of patients enrolled at 12 months). Figure 3 shows that for an average participant who continues to use the system, most of the categories are stable except for questions regarding their condition.

Over the entire study period, there were 3219 responses from the clinicians. From the qualitative review of 100 entries, the following categories of communication were identified:

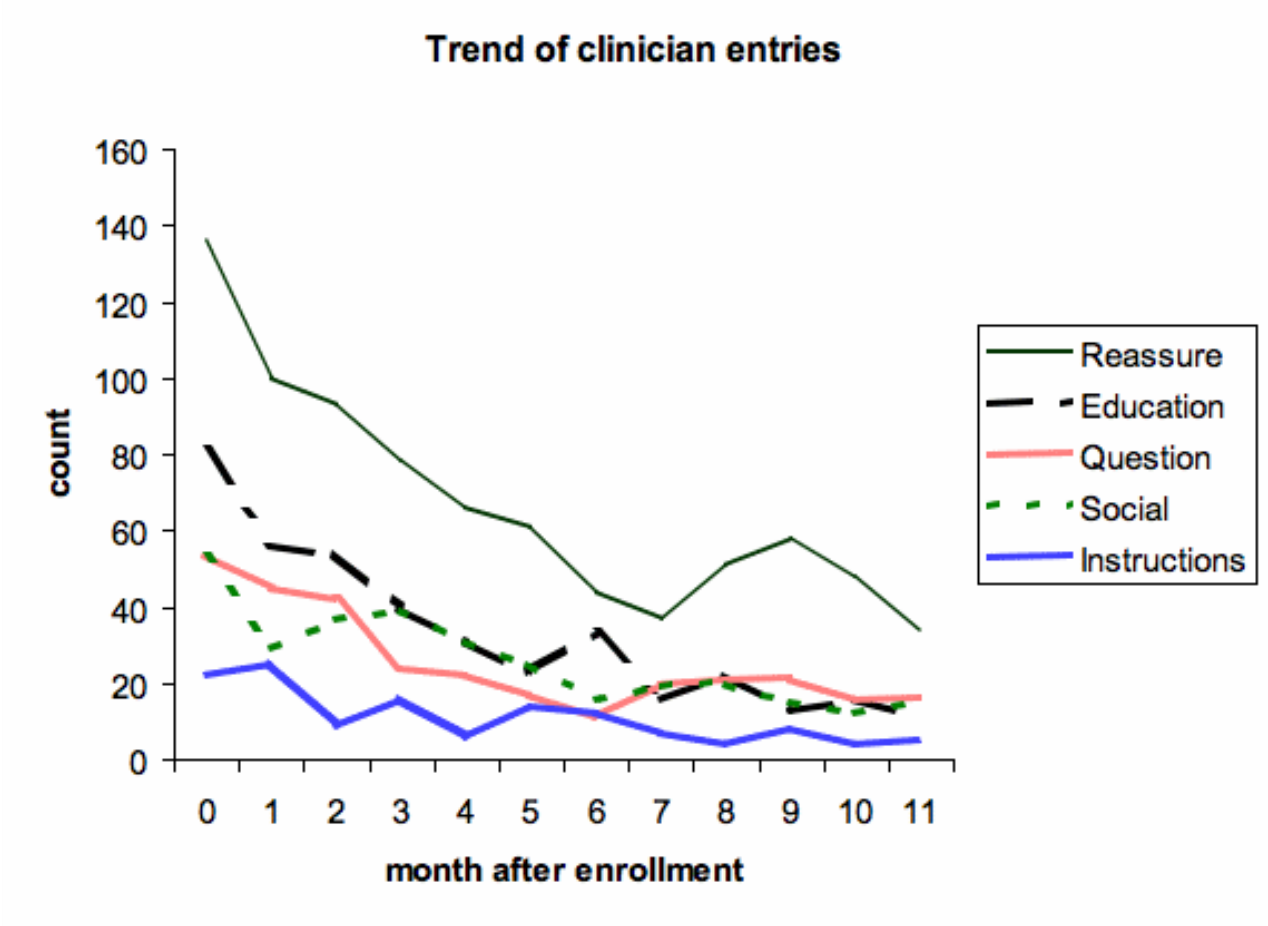
Figure 3. Trend of patient entries over 12 months, adjusted for patient drop-out



- education about heart failure (eg, explaining weight gain and salt intake)
- reassurance regarding their heart failure management (eg, encouraging that they are doing well managing their heart failure)
- questions on their symptoms (eg, asking if they have increased their salty food intake, or the nature of their chest pain)
- instructions to change their management (eg, increase diuretic, seek medical attention)
- social responses

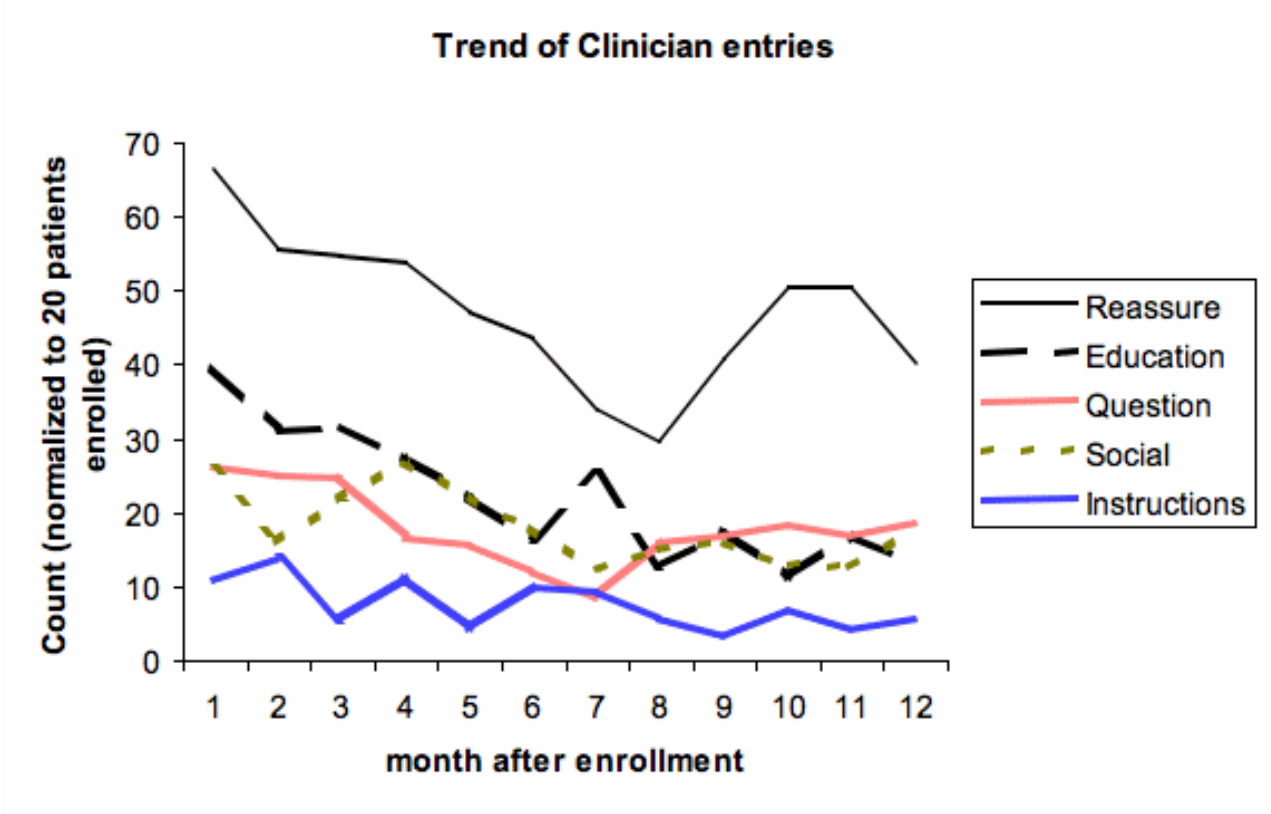
Similar to patient comments, the rest of the clinician responses were coded to these categories. Figure 4 shows the trend of clinician responses over time after enrollment. Predominantly, most communication dealt with reassurance. Initially, education was second in frequency but declined over 6 months. Questions, social communications, and instructions were all entered with about the same frequency, declining over time.

Figure 4. Trend of clinician responses over 12 months, adjusted for patient drop-out



Again, the effect of dropout was taken into account by normalizing the entries to 16 patients enrolled. As can be seen in Figure 5, educational messages and reassurance decreased whereas other categories like social interactions and instructions regarding care remained about the same level over the 12 months.

Figure 5. Trend of clinician responses over 12 months, adjusted for patient drop-out



Discussion

In this pilot study of a Heart Failure Internet Communication Tool, we evaluated whether patients with significant morbidity would communicate using the Internet with their clinicians. Our study population consisted of outpatients with heart failure who had significant symptoms and left ventricular dysfunction. We found that 45% of patients used the system for at least 3 months.

While it is encouraging that almost half of the enrolled patients used the system, it is important to determine why more patients did not use the system. This is crucial for the success of this system as well as other Internet communication tools for chronic disease management. Likely reasons for not using the system include lack of perceived benefit, and system usability issues. Patients might not use the system if there is a lack of interest in their condition or if they are already satisfied with their knowledge level regarding self-care. Although we enrolled only patients who had access to the Internet, this does not mean that they were sufficiently familiar with it or that they are comfortable using it to communicate about their condition. Finally, there is a significant time commitment even for those who are interested, likely up to 10 minutes per day to collect and enter information.

Patients decide to use the system because they expect that they would feel they would derive some benefit. Those patients most likely to benefit are those with significant morbidity from heart failure. Our data suggests that those who did use the system had more symptoms since the group that used the system had a worse NYHA functional class and a worse quality-of-life at baseline.

Finally, there were system issues that may have decreased compliance. System-specific issues, which were encountered, included several server crashes and software problems. The system underwent gradual improvements, and early problems were eventually resolved. However, system issues are unlikely to be a major factor in nonusage, as the majority of nonusers (64%) did not even login once.

The usage rate of 45% is comparable to other Internet communication tools. In a study of patients who registered for electronic messaging with their primary care physician, 47% used the system 3 or more times [16], while a previous study of heart failure patients found that approximately 35% continued to access their electronic record through the Internet [8].

The HFICT appeared safe to use, but there was a trend towards more hospitalizations in the user group. While it is hoped that the HFICT would decrease resource utilization, in fact, an increase in hospitalizations may be medically appropriate and indicate high quality care. In several instances, there were instructions by the clinicians via the HFICT to the patients to go to the Emergency Room for symptoms such as ”dizzy” spells that patients did not feel were significant or did not attribute to their heart failure. It is likely that if they had not been using the system they would not have sought medical attention. Interestingly, a recent study which provided heart failure patients access to their medical records was also associated with an increase in Emergency Room visits [8]. Further study is necessary to determine if there is an increase in unwarranted, unplanned hospitalizations.

Our study found that a low-cost solution was acceptable in a substantial proportion of patients who had significant morbidity.

System usage has been defined as a measure of success for nonmandatory information systems [17]. With our system, approximately half of the patients used the system and continued to use it on average for 1.5 years, entering information on average 191 times per person.

We found that patients used the tool primarily to communicate general information but also used the tool for asking specific questions and for social interaction. Reassurance and education were the important parts of the communication from the clinicians. This may support the hypothesis that patients are learning to manage their heart failure through this tool.

The limitations to this study include small sample size, lack of a control group and possible selection bias. Enrollment was low and not tracked. Qualitative studies, such as surveys and focus groups of nonusers would also clarify reasons for not using the tool. Selection bias and limited power make it impossible to draw definitive conclusions about the effects of HFICT on morbidity and mortality. Finally, the study population was a select group of heart failure patients, those referred to a specialized clinic including a substantial proportion of pre-transplant patients. Thus, our results may not be generalizable to patients seen in internal medicine clinics, general cardiology clinics, or possibly even other heart failure clinics. Nevertheless, patients attending tertiary heart failure clinics have significant morbidity and mortality, and interventions that improve quality of life and are cost-effective are still worthwhile even in this ”select” population. Further study would be required in other populations including those seen in other settings to see if the use of a HFICT is generalizable to the majority of patients with heart failure.

In conclusion, we found that 45% of patients with heart failure in our clinic would use an Internet disease management tool. Furthermore, we found it to be safe and maintainable. The HFICT appears to be a feasible method of helping to manage patients with a chronic disease such as heart failure. Further study is required to determine if it improves care and outcomes.

Acknowledgments

We would like to acknowledge Dr. Allan Detsky and Dr. Moira Kapral for their input and assistance in the writing of this manuscript.

Conflicts of Interest

None declared

References

1. Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. N Engl J Med 1995 Nov 2;333(18):1190-1195 [FREE Full text] [Medline: 96006334] [doi: 10.1056/NEJM199511023331806]
2. Rich MW, Vinson JM, Sperry JC, Shah AS, Spinner LR, Chung MK, et al. Prevention of readmission in elderly patients with congestive heart failure: results of a prospective, randomized pilot study. J Gen Intern Med 1993 Nov;8(11):585-590. [Medline: 94118076]
3. Mcalister FA, Lawson FM, Teo KK, Armstrong PW. A systematic review of randomized trials of disease management programs in heart failure. Am J Med 2001 Apr 1;110(5):378-384. [Medline: 21183885] [doi: 10.1016/S0002-9343(00)00743-9]
4. Liu P, Arnold JM, Belenkie I, Demers C, Dorian P, Gianetti N, et al; Canadian Cardiovascular Society. The 2002/3 Canadian Cardiovascular Society consensus guideline update for the diagnosis and management of heart failure. Can J Cardiol 2003 Mar 31;19(4):347-356. [Medline: 22590085]
5. Tate DF, Jackvony EH, Wing RR. Effects of Internet behavioral counseling on weight loss in adults at risk for type 2 diabetes: a randomized trial. JAMA 2003 Apr 9;289(14):1833-1836. [doi: 10.1001/jama.289.14.1833] [Medline: 22571311]
6. Tate DF, Wing RR, Winett RA. Using Internet technology to deliver a behavioral weight loss program. JAMA 2001 Mar 7;285(9):1172-1177. [Medline: 21154341] [doi: 10.1001/jama.285.9.1172]
7. Dew MA, Goycoolea JM, Harris RC, Lee A, Zomak R, Dunbar-jacob J, et al. An internet-based intervention to improve psychosocial outcomes in heart transplant recipients and family caregivers: development and evaluation. J Heart Lung Transplant 2004 Jun;23(6):745-758. [Medline: 23539024] [doi: 10.1016/j.healun.2003.07.002]
8. Ross SE, Moore LA, Earnest MA, Wittevrongel L, Lin CT. Providing a web-based online medical record with electronic communication capabilities to patients with congestive heart failure: randomized trial. J Med Internet Res 2004 May 14;6(2):e12 [FREE Full text] [Medline: 15249261] [doi: 10.2196/jmir.6.2.e12]
9. Earnest MA, Ross SE, Wittevrongel L, Moore LA, Lin CT. Use of a patient-accessible electronic medical record in a practice for congestive heart failure: patient and physician experiences. J Am Med Inform Assoc 2004;11(5):410-417. [Medline: 15187074] [PMC: 15187074] [doi: 10.1197/jamia.M1479]
10. Mazzi CP, Kidd M. A framework for the evaluation of Internet-based diabetes management. J Med Internet Res 2002 Jan 10;4(1):e1 [FREE Full text] [Medline: 21953329] [doi: 10.2196/jmir.4.1.e1]
11. Delgado DH, Costigan J, Wu R, Ross HJ. An interactive Internet site for the management of patients with congestive heart failure. Can J Cardiol 2003 Nov;19(12):1381-1385. [Medline: 14631472]

12. ; Committee on Maintaining Privacy and Security in Health Care applicati, Computer Science and Telecommincations Board Commission on Physical sc. For the Record: Protecting Electronic Health Information. Washington DC: National Academies Press; Jul 1, 1997.
13. Riegel B, Carlson B, Kopp Z, Lepetri B, Glaser D, Unger A. Effect of a standardized nurse case-management telephone intervention on resource use in patients with chronic heart failure. Arch Intern Med 2002 Mar 25;162(6):705-712. [Medline: 21909187] [doi: 10.1001/archinte.162.6.705]
14. Stewart S, Pearson S, Horowitz JD. Effects of a home-based intervention among patients with congestive heart failure discharged from acute hospital care. Arch Intern Med 1998 May 25;158(10):1067-1072. [Medline: 98266814] [doi: 10.1001/archinte.158.10.1067]
15. Rector TS, Kubo SH, Cohn JN. Patients' self-assessment of their congestive heart failure. II. Content, reliability, and validity of a new measure - the Minnesota Living with Heart Failure questionnaire. Heart Failure 1987;3:198-209.
16. Liederman EM, Morefield CS. Web messaging: a new tool for patient-physician communication. J Am Med Inform Assoc 2003;10(3):260-270. [PMC: 12626378] [doi: 10.1197/jamia.M1259] [Medline: 22615808]
17. DeLone WD, McLean ER. The DeLone and McLean model of information systems success: a ten-year update. Journal of Management Information Systems 2003;19(4):9-30.

Abbreviations

HFICT: Heart Failure Internet Communication Tool
HYHA: New York Heart Association

submitted 04.02.05; peer-reviewed by S Ross; comments to author 23.02.05; revised version received 26.03.05; accepted 23.02.05; published 26.03.05.

Please cite as:
Wu RC, Delgado D, Costigan J, MacIver J, Ross H
Pilot Study of an Internet Patient-Physician Communication Tool for Heart Failure Disease Management
J Med Internet Res 2005;7(1):e8
URL: http://www.jmir.org/2005/1/e8/
doi:10.2196/jmir.7.1.e8
PMID:15829480

Original Paper

The Role of an Online Community for People With a Rare Disease: Content Analysis of Messages Posted on a Primary Biliary Cirrhosis Mailinglist

Judith N Lasker[1], PhD; Ellen D Sogolow[1], PhD; Rebecca R Sharim[1],

Department of Sociology and Anthropology, Lehigh University, Bethlehem, PA, USA

Corresponding Author:
Judith N Lasker, PhD
Department of Sociology and Anthropology
Lehigh University
681 Taylor Street
Bethlehem, PA 18015
USA
Phone: +1 610 758 3811
Fax: +1 610 758 6552
Email: judith.lasker@lehigh.edu

Abstract

Background: This study focuses on the role of an Internet-based group for people who have an autoimmune liver disease, primary biliary cirrhosis. Primary biliary cirrhosis is a relatively rare disease, affects primarily women in their 40's and older, and is not well understood. The PBCers Organization (PBC stands for primary biliary cirrhosis) provides electronic mailinglists (listservs) and informational resources for those with primary biliary cirrhosis.

Objectives: (1) to identify the issues of greatest importance to those posting to the listserv, specifically the relative importance of biomedical, socioemotional, and organizational/systems messages; (2) to compare frequency and content of posts by people at different stages of disease; (3) to identify how people with primary biliary cirrhosis represent the psychosocial challenges and dilemmas (role and identity change, uncertainty, and stigma) identified in the social-scientific literature as key elements of the experience of chronic disease.

Methods: The paper is based on content analysis of messages posted during two months to the Daily Digest listserv for people who have primary biliary cirrhosis. To analyze the posts, we developed a coding system with three major categories--biomedical, socioemotional, and systems/organizations--and 12 codes in each category.

Results: A total of 275 people posted 710 messages. Of the 250 people for whom information on gender was available, 239 (95.6%) were women and 11 (4.4%) were men. Analysis of 710 messages posted to the listserv revealed a predominance of requests for and reports of biomedical information, such as health care providers (32.7%), medications (30.9%), tests and procedures (25.8%), and symptoms (25.7%), combined with very frequent expressions of emotional support. The most frequent single topics were peer support (included in 40.6% of all posts) and positive emotions (25.3%). Posters who reported fewer years since diagnosis were more likely to be seeking biomedical information than those who were further in time from their diagnosis ($r = -.241$, $P<.001$, $n=313$). Those in later stages posted an average of 3.87 messages, compared to an average of 2.64 for people in earlier stages ($t = 1.786$, $P=.08$, $n=90$), which is different from what we expected. No relation between years since diagnosis or age and number of messages was found. Contrary to our expectations, the topics reflecting issues of role change/identity (2.9%), stigma (0.7%), and thoughts about the future (3.9%), all identified in social-scientific literature as key concerns for people with chronic illness, appeared infrequently in this set of messages.

Conclusions: Messages exchanged on this particular mailing list have a biomedical, rather than socioemotional or organizational, emphasis. The Internet offers a highly valued opportunity for those with rare diseases to connect with, learn from, and provide support to others having similar experiences. Research that compares those with primary biliary cirrhosis, who are involved in an Internet support group and those who are not, would be an important next step to better understanding the role of the Internet among patients with chronic liver disease and the implications of it in the course of their illness.

(J Med Internet Res 2005;7(1):e10) doi:10.2196/jmir.7.1.e10

KEYWORDS

Internet support; chronic liver disease; primary biliary cirrhosis

Introduction

Primary Biliary Cirrhosis

Primary biliary cirrhosis is not a well-known disease, yet it is emblematic of two growing phenomena in modern medicine—the increasing prevalence of autoimmune disorders among women, and the increasing demand for and survival following organ transplantation. Primary biliary cirrhosis is one of the autoimmune disorders that areestimated to affect between 14 and 22 million Americans. Nearly all these disorders affect women at several times the rate at which they affect men; 90% of people with primary biliary cirrhosis are women. In fact, autoimmune diseases rank in the top ten causes of death of American women in every age group under 65. A 2002 report of the US National Institutes of Health (NIH) asserts that "autoimmune diseases . . . represent a significant physical, emotional, social, and fiscal burden to the country's health care system." [1] Just as importantly, they represent significant physical, emotional, social, and fiscal challenges to the families of these patients. Yet they are often poorly understood, misdiagnosed, and constructed as psychological, ie, not "real", with accompanying stigma and lack of validation of the women's physical and psychological experiences. Primary biliary cirrhosis is further stigmatized due to the assumption that any liver disease must be caused by substance abuse.

In the last ten years, over 30000 women have received liver transplants in the United States, and primary biliary cirrhosis is the second leading diagnosis in this group. Current data shows that liver disease is the seventh leading cause of death in the United States among Americans 25 to 64 years of age [2]. Primary biliary cirrhosis is one type of liver disease that is often debilitating and may be fatal. With primary biliary cirrhosis, the body attacks the cells lining the liver's bile ducts, causing inflammation and destruction. In advanced stages, it may lead to the possibility of a liver transplant for those who have adequate resources. The most common symptoms of primary biliary cirrhosis are debilitating fatigue and itching, affecting respectively, 65% to 85% and 25% to 70% of people with primary biliary cirrhosis. People with primary biliary cirrhosis usually also suffer from hyperlipidemia and osteoporosis. Potentially life-threatening symptoms that may occur in advanced stages of the disease are encephalopathy (inflammation of the brain, causing confusion and cognitive dysfunction), ascites (fluid in the abdomen that can become infected) and varices (swollen vessels in the esophagus that can rupture) (JNL, EDS and LM Short, unpublished data, 2005) [3].

Globally, an estimatedfive out of 100000 people have primary biliary cirrhosis [4]. Using this rate, one can estimate that primary biliary cirrhosis probably affects around 15000 people in the United States. The National Institute of Health's Office of Rare Diseases includes primary biliary cirrhosis in its list of 6000 diseases currently recognized as rare because they affect fewer than 200000 people in the United States.

With primary biliary cirrhosis, as with many other health concerns, women seek to empower each other to cope better with the challenges they face. Many women have organized to share information and support with each other and have become activists demanding greater funding and access to care [5]. The Internet is one major tool in the transformation of the experience of illness that is taking place, as well as offering a major source of information and support for people with health concerns [6].

A study of primary biliary cirrhosis offers an opportunity to focus on how women with a rare disease use the Internet and what issues are of greatest concern to them. Our purpose is to gain a better understanding of the needs and concerns of people with primary biliary cirrhosis who are participating in a computer-mediated support group. This paper is based on the results of a content analysis of 2 months of messages posted in 2003 to a listserv for people with primary biliary cirrhosis.

The Value of the Internet for People With Chronic Disease

As computers become more accessible to the general population, health-related searches have become one of the top 3 most common reasons for using the Internet [7]. About 4.5% of all searches on the Web are health-related [8], and it is estimated that as many as 93 million Americans have utilized the Internet for health related information [9].

One of the leading sources of health information online is from support communities that link people who have common problems with each other; a major reason for the growth of these networks is convenience of access [9]. Studies of people using such virtual networks [10-12] report the advantages of 24-hour availability of information and support from others who may be far away. Even with strong networks of support from family and friends, patients maybenefit from having an outlet of people who can relate to what they are going through on a personal level. Traditional face-to-face support groups can offer this support, but issues such as transportation, distance, privacy, and time restrictions typicallyreduce participation and attendance [12]. Thus, online support groups provide a particularly valuable alternative for people suffering from a relatively rare disease. It is often difficult for them to find medical specialists near their local communities; it is also more difficult for them to find others with the same or similar conditions with whom to share their experiences.

Two major reasons that people use the Internet for health-related concerns repeatedly emerge from reviews: first,to find biomedical information, and second, to interact with others who have similar conditions for the purpose of sharing experiences and emotional support. Online groups generally provide some combination of both information and emotional support [10]. White and Dorman [13] concluded from their study of an Internet mailgroup for caregivers of people with Alzheimer's disease that the leading type of message posted by users involved seeking or giving information. In contrast, in Finn's [14] study of an online group for disabled individuals, the

majority of messages were coded as being primarily socioemotional in orientation, such as expressing feelings and providing support and empathy, rather than biomedical (task-oriented).

Klemm et al [15] consider that differences in the relative frequency of biomedical vs socioemotional issues may be related to gender differences in communication about health online. In their study of posts to 3 online cancer support groups (one for breast cancer, one for prostate cancer, and one mixed-sex group for cancer in general), they found that women were more likely to communicate support and encouragement, while men were more likely to communicate information. It may be, however, that in the case of a rare disease that is poorly understood and misdiagnosed, the need for specific biomedical information would take precedence.

Prior studies [9] indicate that younger and/or more educated people are most likely to rely on the Internet for health information; thus characteristics other than gender are potentially important predictors of Internet use in the case of a support network for chronic disease.

Psychosocial Challenges of Chronic Illness

Social scientists who study the experience of chronic illness have identified psychological and social challenges that are caused by such illness. In particular, they focus on 3 issues: (1) the need to create a new identity, a new sense of self that corresponds to the illness experience, including changes in social roles related to family, work, and social relationships; (2) the need to manage stigma related to the illness itself and to the limitations it creates; and (3) a pervasive sense of uncertainty with regard to the future [16-18]. Charmaz [18] suggests that, as a result of these challenges, chronic illness poses the major problems of making sense of bewildering symptoms, reconstructing order, and maintaining control over life.

Very few studies focus on the psychosocial consequences of chronic liver disease specifically. An exception is Wainwright's [19] interviews of 10 posttransplant patients about their lives prior to transplant. He identified 4 key concerns: uncertainty arising from becoming ill; the desire to maintain independence despite debilitating symptoms; acceptance of oneself as disabled once symptoms became more severe; and the feeling of being judged by others as alcoholic, regardless of disease etiology. These are consistent with the emphasis on identity and role change, stigma, and uncertainty found in the literature on chronic illness in general.

Liver disease differs from other chronic diseases in several important ways. First, there are major symptoms such as fatigue, ascites (fluid in abdomen), pruritus (itching), and encephalopathy (brain dysfunction) that do not have the same prominence in other diseases. Consequently these symptoms are not well understood by others. We know, for example, that diseases that have fatigue as a major symptom (particularly if they mostly affect women, the case with primary biliary cirrhosis) are often discounted as psychiatric in etiology [20]. Second, liver disease is frequently stigmatized due to its association with substance abuse. There may be stigma associated with inability to function normally and a presumption of hypochondria when the person has no visible signs of the disease.

Additionally, when liver disease is progressive, it may be fatal except for the possibility of a liver transplant. The lack of recognition for chronic liver disease symptoms, the unpredictability of chronic liver disease prognosis, the scarce resources, uncertainty, and long waits associated with transplantation combine to present unique challenges for people with liver diseases with regard to negotiating role changes, reconstructing identity, and managing uncertainty and stigma. The experience of people with primary biliary cirrhosis gives us a unique opportunity for insight into this range of issues.

The PBCers Organization

The PBCers Organization is the largest and only US-based Internet support website for people with primary biliary cirrhosis. It provides informational and emotional support for people with primary biliary cirrhosis as well as fund-raising, advocacy, and educational programs. The organization provides services to people with primary biliary cirrhosis and to their family members and friends through a variety of mechanisms, including listservs, chatrooms, message boards, and other informational resources. An online daily digest, compiled by a team of moderators, is mailed Monday through Friday and some weekends. The PBCers Organization also offers separate listservs for specialized groups or interests: Family and Friends, Spiritual Side, Weight Loss, and Post-Transplant. The organization has local chapters and convenes conferences at which it hosts medical experts and raises money for research.

The PBCers Organization offers an opportunity to examine how people with one type of rare chronic disease utilize the Internet to enhance their health and quality of life. The organization was established in 1996 by a few people with primary biliary cirrhosis who lived far apart and began corresponding with each other by email. There are currently over 2400 members (persons with primary biliary cirrhosis, family members, friends, and health professionals) worldwide [21].

Hypotheses

At the outset, we raised 3 questions. The following hypotheses emerged from these questions:

1. Why do people with primary biliary cirrhosis turn to an Internet-based support group? Is it primarily for medical information that will help them manage their disease, or is it mostly for emotional support from peers? There is very little research on this question. The study by Klemm et al [15] could lead us to expect that because primary biliary cirrhosis is a disease primarily affecting women, the messages would be dominated by *socioemotional* expressions of support. On the other hand, due to having a rare disease, we might expect people with primary biliary cirrhosis to be seeking *biomedical* information that most nonspecialist physicians would be unfamiliar with and that is not easily accessible otherwise. While there are reasons to support either possibility, our preliminary research on the organization led us to hypothesize that there would be greater attention to biomedical information. We based this

in part on the PBCers Organization's emphasis on education, and their practice of establishing separate lists for conversations about spiritual and political issues. For instance, in a separate study of the PBCers Organization listserv for Family and Friends, we found that socioemotional topics dominated [22]. Thus, some of the socioemotional expression is potentially directed away from the Daily Digest.

We also expected that people who are more recently diagnosed would be experiencing the most uncertainty about their situation and would therefore post more frequently in order to gain new information and support to help them make sense of their situation. Concurrently, we also expected that there would be people who are many years postdiagnosis who would post often to provide the benefits of their hard-won understanding to others.

2. Do the posts differ among people in different stages of the disease? If indeed diagnosis with a rare disease prompts a search for biomedical information, we expected that soon after diagnosis or in the early stages of the illness, people would be most likely to post *biomedical* questions, eg, about tests, symptoms, and medications, to help in managing their health, and that they would also be concerned with *organizational* issues such as finding a good treatment center and having the financial means or insurance coverage to pay for care. As time goes on and as the disease progresses, we expected that messages would be more concerned with seeking *socioemotional* support from others and reflecting on the impact of an increasingly disruptive illness on family relationships and emotional state.
3. To what extent do the messages on a support group's listserv reflect the psychosocial challenges and dilemmas identified in the social-scientific literature on the experience of chronic disease? The following themes are identified: uncertainty, role change and identity reconstruction, and stigma. We anticipated that these themes would be explored in many of the messages posted to the PBCers' Daily Digest.

Method

Permission for the study was obtained from two sources: the Institutional Review Board of Lehigh University, Bethlehem, Pa, and the Board of Directors of the PBCers Organization.

Studies of computer-mediated support groups have generally used two approaches to understanding the role of such groups: content analysis of posts to listservs or websites, and surveys of users of Internet support websites to ask about their participation [12-14]. For the present study, we focus on 2 months of posts from the online Daily Digest, in March and September 2003.

Coding System

Two different time periods, spring and fall of 2003, were selected to avoid possible seasonal bias. To analyze the posts, we created a codebook that expanded on Bales' [23,24] theoretical framework of human interactions that emphasized the dynamic tension between task and socioemotional activities in an environmental or organizational context. Bales' framework has also formed the basis for coding of online messages by other researchers [14,25].

For the PBCers Organization listserv, the primary *task* involves educating persons with primary biliary cirrhosis about the many aspect of the disease, its diagnosis and treatment. *Socioemotional* aspects are critical as well, especially for members providing peer support to one another. As Bales and others have articulated, the challenge is for an organization (or small group, or society) to maintain a functional equilibrium or balance between achieving its task goals and maintaining an acceptable level of cohesion. In this case, some members have met face-to-face, but for most, the interactions are via the listserv.

Bales' research showed that groups can become more formalized over time, develop norms for more or less emphasis on task or emotions, and achieve more or less problem solving. Following Bales' framework, we developed a coding schema to understand how this Web-based group met members' needs. We developed a coding system with three main categories—*biomedical* (corresponding to task), *socioemotional*, and *organizational/systems*.

We specified the *biomedical* category to include a set of subcategories designed to represent the range of biomedical topics that was relevant to this group, such as references to medications, symptoms, tests, and treatments as well as issues related to self-care and transplant, as well as the subcategory "*other biomedical*".

The *socioemotional* category captured members interactions that had emotional content, such as fear and anxiety, hope, anger, frustration, the presence or absence of support from people in their lives, and support for others on the list. Included in the socioemotional categories are several codes designed to capture the psychosocial challenges of living with liver disease. These are “role change/identity”, “stigma”, and “thoughts about the future” (to capture expression of uncertainty about the future).

The *organizational* category was added as a special adaptation of the framework, recognizing that the listserv was also occasionally the place for discussions of broader topics, such as comments about the PBCers Organization, meetings, and fund-raising, or references to hospitals and financial issues.

We identified 12 topics in each category, based on our preliminary analysis of the Daily Digest during other months and informed by the coding systems employed by other researchers. Following Bales' Interaction Process Analysis coding system, we developed an equivalent number of subcategories in each category to facilitate analysis across categories.

Consistent with the Balesian approach, in each of these categories we included a code for ”seeking” either information or response, to distinguish those messages that involved asking about tests, insurance, etc from those that either reported information about the poster or provided information in response to questions.

Coding Process

For this content analysis we used the act, defined as the simple sentence (or thought), as the coding unit. As with face-to-face conversation, there were multiple acts in each exchange or post. For the 2 months of posts, we quantified the online interactions according to the 36 topics and 3 categories. Each topic was operationally defined in a detailed codebook, enabling coders to attach specific labels to manifest content.

Each post was independently reviewed and coded by 2 coders, assigning relevant codes only once to each complete message (post), regardless of how many times a particular topic might be expressed in that message. The coding supervisor resolved questions, and the coders achieved over 95% interrater reliability.

We also recorded demographic information about the poster — gender, age, and time since diagnosis — when available. Gender was inferred from the poster's name unless it was ambiguous or from message content (eg, references to “my husband”). The information about age and date of diagnosis was most often included in the signature that many gave after all of their posts (a typical format for signature is name, age, state of residence, and year of diagnosis); thus it is unlikely that much more complete information on these variables could have been obtained from Daily Digests outside the time period under review.

Validity

By using content analysis methods, we intrinsically had two key supports for validity. First, at the category level, we emphasized construct validity. We trained coders to understand the meaning of each (biomedical, socioemotional, and health systems). Further, we used only these 3 nonoverlapping categories so that no or little interpretation would be needed to determine the category. Second, at the topic (subcategory) level, in many instances the content itself provided face validity. For instance, a comment about a particular laboratory test is manifestly isomorphic with the item "tests/procedures." Coding for the topic was potentially more difficult, with 36 items. Coders were instructed, however, to determine the category first and then identify the topic. Thus, the task was quickly narrowed to selection from among only the 12 topics within the category.

In this analysis, the focus was on how individuals perceive their experience. We were not seeking concurrent validity, for example, with a physician's interpretation of the same data. Rather, our goal was to characterize the interactions in a way that was consistent with the intended meanings. Thus, if a person with primary biliary cirrhosis expressed worry when a laboratory report showed increased alkaline phosphatase, there would be socioemotional content even though that person's physician may view the same data as a normal fluctuation.

Statistical Analysis

Data from the posts were analyzed in SPSS. Descriptive statistics were used; correlation (Pearson *r*) and tests of difference (*t* test) were applied to determine statistical significance of results.

Results

The People who Post

Table 1 presents available demographic data on the posters, as well as the mean number of messages posted. A total of 275 people posted 710 messages (posts) to the PBCers' Daily Digest in 2 months during the spring and fall of 2003. There was a range of 1 to 28 different messages per person, an average of 2.58 posts per person. The number of topics per post ranged from 1 to16 out of a total potential 36; the mean number of topics per post is 4.24.

Of the 250 people for whom information on sex was available, 239 (95.6%) were women and eleven (4.4%) were men. They ranged in age at the time of posting from 28 to 78 (mean= 54.8); almost three fifths (37 out of 63, 58.7%) were in their 40s or 50s, and most of the remainder were 60 or older. Almost a third (34 out of 105, 32.4%) had been diagnosed one year or less prior to their post, while almost one fifth (21 out of 105, 19.1%) had known about having primary biliary cirrhosis for 10 years or more (mean number of years since diagnosis is 5.1).

Of the 90 people who cited their stage of disease, exactly half were in the earlier (1-2) stages, and half in the later (3-4) stages. Of all those who posted, 22 people (8%) mentioned that they had had a transplant.

Table 1. Data on people who posted to Daily Digest, N=275

	N (posters)	Minimum	Maximum	Mean	Standard Deviation
Messages posted per poster	275	1	28	2.58	3.01
Age	63	28	78	54.8	11.1
Stage	90	1	4	2.6	1.1
Years since Diagnosis	105	0	26	5.1	5.1

Emphasis of Posts

Consistent with our first hypothesis that a focus on biomedical information would dominate the listserv, topics in the biomedical category were almost twice as prevalent. Posts averaged 2.2 biomedical topics, 1.2 socioemotional topics, and 0.8 organizational/systems topics. See Table 2 for the proportion of posts that contain each of the 36 topics.

Table 2. The proportion of all posts that include the category/topic (N=710 posts)*

Category/Topic	N of Posts	% of Posts
Biomedical (Mean 2.2 topics per post)	**531**	**74.6%**
Liver disease	57	8.0
Diagnosis/prognosis	126	17.7
Symptoms	183	25.7
Medications	220	30.9
Health care provider	233	32.7
Tests/procedures	184	25.8
Self-care behaviors	99	13.9
Other non-liver diseases	109	15.3
Transplant	63	8.8
Research	97	13.6
Other biomedical	36	5.1
Seeking biomedical information	142	19.9
Socioemotional (mean 1.2 topics per post)	**439**	**61.7%**
Spiritual/prayer	54	7.6
Negative emotions	136	19.1
Positive emotions	180	25.3
Thoughts about the future	28	3.9
Relationship to health care provider	49	6.9
Role change/identity	21	2.9
Stigma	5	0.7
Relationships with family and friends	44	6.2
Support to peers (e.g. others on the list)	289	40.6
Coping strategies	47	6.6
Other socioemotional	9	1.3
Seeking socioemotional response	14	2.0
Organizational/Systems (mean 0.8 topics per post)	**371**	**52.1%**
PBCers national organization (including Internet website)	125	17.6
PBCers/ALF fund-raising	57	8.0
Local PBCers activities	70	9.8
Hospitals/treatment organizations	62	8.7
Health care providers in general	46	6.5
Medical insurance	42	5.9
Social security/disability insurance	11	1.5
Pharmaceuticals	27	3.8
Financial issues	41	5.8
Employment issues	2	0.3
Other organizational/systems	33	4.6
Seeking organizational/systems response	64	9.0

* For example, 8.0% of all posts included a comment about liver disease. Since the majority of posts included more than one topic, the percentages do not add up to 100%.

Of the 6 topics that appeared in 25% or more of all posts, 4 were biomedical: health care provider (32.7%), medications (30.9%), tests and procedures (25.8%), and symptoms (25.7%). Selections from posts that illustrate the most frequent biomedical topics follow. (Please note that to present meaningful examples, we gave quotes longer than the coding unit--the single thought, sometimes meaning that multiple topics are included.)

> *I went to my doctor's appointment this morning and after blood work was told that the reason I am jaundiced is because of the two units of blood I had transfused last Thursday. (health care provider)*
>
> *My question is concerning the two different medications for PBC; my GI doctor insists that both medications are exactly the same and the only difference is in the company that manufactures the drugs. I talked to the pharmacy and was told that one of them is not on their formulary and that is why I cannot get a prescription for it. (medications)*
>
> *We had an appointment this morning and he has agreed to run a battery of liver tests as well as an ultrasound of her liver and another possible liver biopsy.(tests and procedures)*
>
> *Regarding your email about . . . nosebleeds, here is my one cent.. . . I have constant trouble with nosebleeds and they drive me bananas! . . . I don't know what to relate it to. (symptoms)*

In light of the dominance of the biomedical category, it is noteworthy that the first and sixth most frequently used topics were in the socioemotional category. While the 2 major categories, *biomedical*and *socioemotional*, are analytically distinct, they are commonly joined together in the messages; biomedical topics are significantly correlated with socioemotional topics (r= .326, P<.001, n=710). The most frequent single topics were peer support (included in 40.6% of all posts) and positive emotions (25.3%).

Examples of these two topics follow:

> *Congratulations to you for taking that pre-transplant evaluation step. It is an enormous step--and you did it! (peer support)*
>
> *Being a new member here at PBCers, it was a delight to hear from everyone . . . especially with all the wonderful information that was passed along to me. It is incredibly comforting to know that, even though our disease can be awful, we are all connected by this bond. (positive emotions)*

The peer support example illustrates how support is often combined with a biomedical topic. Very often posts reflected a number of socioemotional topics together as well. The following post illustrates how these topics often appear in combination:

> *I am so thankful for all of you, for even though I have not participated on the chat line, silently you have all been helping me cope. I find not many of my wonderful family or friends can understand the roller coaster of emotions you face when dealing with a chronic illness.. . . I have two young children. . . . My only prayer is to live to see my grandchildren. . . . Here is what has helped me. . . . Positive thinking, fill your life with positive people, live like it is your last day.*

Differences in Frequency and Content of Posts by Age, Disease Stage, and Time Since Diagnosis

Posters who reported fewer years since diagnosis were more likely to be seeking biomedical information than those who are further in time from their diagnosis (r= -.241, P<.001, n=313). However, a poster's time since diagnosis is unrelated to seeking either socioemotional or organizational/systems responses, although it must be noted that the topic, “seeking socioemotional response,” occurs infrequently for the entire sample.

We also hypothesized that newly diagnosed people or those in the early stages of the disease would post more often, but the results of correlational analysis show no relationship between the number of messages posted and years since diagnosis or stage of disease. Only when stage is divided into early (1 and 2) and late (3 and 4) is there a nonsignificant trend towards a difference, but in the opposite direction from expected; those in later stages posted an average of 3.87 messages, compared to an average of 2.64 for people in earlier stages (t= 1.786, P=.08, n=90).

We also found no evidence for the expectation that there would be more messages from a group of people who had known about their primary biliary cirrhosis the longest time and were thus sharing the knowledge they had acquired. Table 3 shows that those who were more than 10 years since diagnosis did post more often, an average of 3.45 messages, compared to those with less than a year since diagnosis, who posted an average of 2.44 times. Yet the largest number was 3.59 messages from people who were 2 to 4 years post-diagnosis, and these differences are not statistically significant.

In contrast to our expectation that younger people would use the Internet more, within this sample, age was unrelated to either frequency of posts or to the content of the messages. There were not enough men to be able to make meaningful comparisons by gender.

Table 3. Year since diagnosis and number of messages posted

Years Since Diagnosis	N	Number of Messages
1 year or less	34	2.44
2-4 years	27	3.59
5-9 years	23	2.83
10 or more years	20	3.45
Total	104	3.02

Psychosocial Themes.

Contrary to the expectations in our third hypothesis, the topics reflecting issues of role change/identity, stigma, and uncertainty (all identified in social-scientific literature as key concerns for people with chronic illness) appeared infrequently in this set of messages. “Role change/identity” appeared in 2.9% of messages. One example follows:

> *I am a grandmother and was the most active of women, a superwoman three years ago. Now I can hardly get out of bed sometimes.. . . I am mad most of the time, depressed, miss my family, feel guilty toward my husband. This PBC stinks.. . . I feel isolated.*

References to “stigma” were almost non-existent (0.7% of messages). When comments about stigma did appear, they often focused on proposals to change the name of the disease in order to try to disassociate it from alcoholism. As one person wrote,

> *If a new name has not been “officially” adopted, can the patients vote to do it? It looks like the single thing we could all do to improve understanding and treatment of the disease, and our own “life chances”. . . Cirrhosis means only one thing to most people—alcohol abuse. Doctors label us as alcoholic, knowing nothing about PBC. How many people were asked how much they drank as soon as the AMA antibody showed up on their blood test?*

“Thoughts about the future” appeared in only 3.9% of the posts. One example gives an indication that reading the Daily Digest can enhance as well as alleviate uncertainty about the future:

> *I have been reading some members' stories and am concerned about what's in store for me. I realize that it may be many years before I get to the final stages of this disease, but it may very well be sooner rather than later.. . . I am totally in the dark here and would feel a lot better if I knew more. Is there anyone else out there at the same stage of this disease, who shares the same concerns as I?*

Discussion

Reasons for Using the Internet

We identified 3 major issues regarding the reasons that people with rare diseases use the Internet, in particular the PBCers' Daily Digest: balancing biomedical and socioemotional needs, validation via the Internet, and online group development.

Balancing Biomedical and Socioemotional Needs

The primary finding is that the PBCers' Daily Digest has a biomedical, rather than socioemotional or organizational, emphasis. The Daily Digest acts as an informational resource, with participants sharing the empirical information they have gained from their own experiences and the research they have found. Additionally, the fact that individuals struggle with symptoms that are not understood or acknowledged by others as “real” motivates them to use the listserv as a resource for discussing their medical conditions with peers.

The PBCers Organization offers information in the context of support that is invaluable to individuals dealing with the emotional effects of primary biliary cirrhosis. Over 40% of the messages involve individuals giving or receiving peer support, indicating that people were likely to turn to a website that provides a supportive environment for obtaining biomedical information.

Validation via the Internet

The PCBers Organization is valued in part because it serves a population with a rare disease. Personal posts testify that primary biliary cirrhosis is a disease not well understood by physicians and other medical professionals, and that the ability to correspond with others in the same situation is greatly appreciated. As expressed in one post, “Even though PBC is rare and doctors don't know much about PBC, my doctor is going to learn. We will learn together.” Both factors—the lack of medical validation and the rarity of the illness--may help to explain why a group that is mostly women does not follow the findings of Klemm et al [15] regarding women's emphasis on socioemotional communication in cancer lists but rather emphasizes the biomedical aspects.

As with some other autoimmune disorders affecting women, people with primary biliary cirrhosis experience significant fatigue, but it is hard for others to appreciate or understand because it is an invisible symptom. Studies of primary biliary cirrhosis, including our own, show that fatigue is not linked to age or years since diagnosis, and it is not appreciated by others as an objective or “real” symptom [26]. It is not surprising, therefore, that many people who have primary biliary cirrhosis feel that their experiences are not well understood or appreciated, and that the PBCers' Internetwebsite offers necessary validation as well as information and support. As one person wrote, not atypically,

> *I too believe these PBCers are angels. They have calmed my fears so many times. They have answered any questions I have asked. . . . They have done*

anything I have asked of them and they don't even know what I look like. Isn't that amazing? . . . It just astonished me that there are so many people who will take the time to do this service for us out here who aren't frightened about a disease even our doctors don't understand. I can't imagine life without our angels and I love each and every one of you.

Online Group Development

The biomedical focus in the context of social support appears to reflect, in part, the organizers' priority. The leaders of the PBCers Organization have established alternative listservs for other topics, and posts from more ”senior” peer experts may provide role models for newer members. As with other self-help organizations, an emergent leadership may be important to the ongoing group culture. Research is needed to look explicitly at organizational leadership and emerging norms on the Internet.

Differences Within the Primary Biliary Cirrhosis Population in Posting to the Daily Digest

More recently diagnosed people post more messages seeking biomedical information, as predicted. The Daily Digest gives people an opportunity to find out more about ambiguous symptoms, the relative merits of different medications and their possible side effects, as well as the meaning of different diagnostic tests. For example, many times new members have questions about what they might expect from a liver biopsy that has been recommended.

Newly diagnosed people, contrary to our hypothesis, do not post more messages overall. At different points in the illness, people with primary biliary cirrhosis have different concerns to communicate. Those who are more experienced with the disease do often provide answers and encouragement in response to the posts of others, but they do not dominate the discussion. There were no differences by age in the frequency of posting.

Psychosocial Challenges and the Internet

We found few mentions of the key issues raised in the literature on chronic disease—uncertainty, role and identity change, and stigma. There are several possible explanations: these are not really salient issues to the people who post to the Daily Digest; our coding system is not sufficiently sensitive to capture these themes; or the Daily Digest, with its emphasis on exchanging biomedical information and encouragement, is not the forum for discussion of these problems. Supporting the last possibility, in-depth interviews have given us some insight into the importance of these challenges in the lives of people with primary biliary cirrhosis (EDS and JNL, unpublished data, 2005).

With regard to stigma specifically, it is possible that this is not much of an issue in the case of primary biliary cirrhosis because the major symptoms (fatigue and itching) are invisible. Yet some studies indicate that people with nonvisible symptoms do fear being stigmatized for complaining about their condition or not being able to fulfill their social roles [27,28]. As Wainwright [19] and others have found, the association of liver disease with substance abuse is problematic for many. Our current research looks more closely at the role of stigma with primary biliary cirrhosis.

The Use of the Internet for Health-Related Purposes

Many concerns have been raised about disadvantages of relying on the Internet for information and for support. For example, more than 79 studies have evaluated the accuracy, completeness, and comprehensibility of health-related websites, mostly coming to negative conclusion [29]. Han and Belcher's survey of parents using Internet support groups [12] revealed dissatisfaction with the lack of physical contact, the large volume of mail, including its use for unrelated topics, and the impact of receiving bad news about children who died. In contrast, Potts and Wyatt's [30] study of doctors' experiences of Internet-using patients found that despite concerns about misinformation, the doctors still praised the benefits of information, advice, and social support.

Online groups are not only easier to access for people who are geographically remote from face-to-face support groups, but they also have the potential to involve those who might not attend a group even if it were available nearby. Klemm and Hardie [31] discovered this when they compared cancer patients participating in online support to those in a face-to-face group; the online participants were significantly more depressed than those in the face-to-face group, suggesting that the Internet may provide an important outlet for people who might otherwise not attend the more traditional type of support group. It is noteworthy that 14.8% of the people we surveyed at the national PBCers Organization conference (EDS and JNL, unpublished data, 2005) reported being in stage 4 of the disease, the most advanced, while twice as many (28.9%) of people posting to the Daily Digest, who gave their disease stage, are in stage 4. As was found with depression, one might conclude that people with severe disease are more likely to connect with others online rather than in person.

Limitations of the Study

People who use the Internet for health and other purposes have been found to be younger, and more educated and affluent than those who do not [9,32]. A possible limitation of this study is that people who read and post to the PBCers' Daily Digest are more educated than the general population of people with primary biliary cirrhosis, a population for whom demographic characteristics are not known. Yet it is also likely that they are not younger on average than all people with primary biliary cirrhosis, who tend to be mostly in their 40s and 50s.

A further limitation of the Daily Digest data is that information on age, stage of disease, and time since diagnosis is not available for many of those who posted. Thus conclusions about differences in messages related to these factors must be considered with caution. It is also the case that we only have information from those who post, and studies of “lurkers” suggest that the majority of people who connect to online message boards do not post for a variety of reasons [33, 34].

On the other hand, posters represent a much larger group of people with primary biliary cirrhosis who are located all over the United States and in several other countries. Data from our survey (EDS and JNL, unpublished data, 2005) show that even

among those who are sufficiently connected to the PBCers Organization to attend a national conference, only about one fourth (25.7 %) post to the Daily Digest on any regular basis, while more than 3 times as many (82.3 %) read it very regularly. There were no demographic differences between those who posted regularly and those who did not (ie, the lurkers on this list).

Table 1 indicates a wide range of messages posted per person, from 1 to 28. Over 99% of the people in this sample posted less than 20 messages. To see if the outliers (2 people who posted 20 or more messages) influenced the overall results, we eliminated all of their messages and redid all the analyses, with no significant change in results. Findings in Table 2 for individual topics changed less than 1%, except for the total socioemotional category, which rose from 61.7% of total messages to 63.1%, and the total organizational/systems category, which increased from 52.1% to 54.1% of all messages.

In conclusion, these data suggest that the Internet provides a highly valued outlet for people who have a rare disease, primary biliary cirrhosis. It appears to be particularly valuable for those who are newly diagnosed and in need of health information, but it is an important resource for people at all stages of the disease. The focus on biomedical issues, often framed in the context of offering support to others, makes this Internet-based organization an important tool in helping people with chronic illness address the problems raised by Charmaz [18] of making sense of bewildering symptoms, reconstructing order, and maintaining control over life. People with primary biliary cirrhosis help each other through the Daily Digest to understand the disease process and its impact on their lives in an environment of encouragement and reassurance.

Research that compares those with primary biliary cirrhosis who are involved in an Internet support group and those who are not would be an important next step to better understanding the role of the Internet in patients with chronic liver disease and the implications of it on the course of the disease.

Acknowledgments

We are grateful to the leadership of PBCers.org for allowing us to carry out this research and to its members who participated in the survey referred to in this paper. We are grateful to Lehigh University, Bethlehem, Pa, and to the Dorothy Rider Pool Trust for financial support. Thanks as well to Sarah Kaye and Misty Currelli for their assistance with data analysis, to Ariella Siegel for assistance with coding, and to the JMIR reviewers for their helpful feedback.

References

1. ; National Institutes of Health, Autoimmune Diseases Coordinating Committee. Autoimmune Diseases Research Plan. URL: http://www.niaid.nih.gov/dait/pdf/ADCC_Report.pdf [accessed 2004 Aug 1]
2. ; University of Maryland Medicine. Chronic Liver Disease. URL: http://www.umm.edu/liver/chronic.htm [accessed 2004 Aug 12]
3. Talwalkar JA, Lindor KD. Primary biliary cirrhosis. Lancet 2003 Jul 5;362(9377):53-61. [Medline: 22737904] [doi: 10.1016/S0140-6736(03)13808-1]
4. Worman HJ. What is Primary Biliary Cirrhosis?. URL: http://cpmcnet.columbia.edu/dept/gi/PBC.html [accessed 2004 Mar 12]
5. Morgen S. Into Our Own Hands: The Women's Health Movement in the United States, 1969-1990. New Brunswick, NJ: Rutgers University Press; Jun 1, 2002.
6. Wood MS, Coggan JM, editors. Women's Health on the Internet. New York: Haworth Press; Feb 1, 2001.
7. Brann M, Anderson JG. E-medicine and health care consumers: recognizing current problems and possible resolutions for a safer environment. Health Care Anal 2002;10(4):403-415. [Medline: 22698133] [doi: 10.1023/A:1023483327756]
8. Eysenbach G, Köhler C. Health-related searches on the Internet. JAMA 2004 Jun 23;291(24):2946. [Medline: 15213205] [doi: 10.1001/jama.291.24.2946]
9. Cotten SR, Gupta SS. Characteristics of online and offline health information seekers and factors that discriminate between them. Soc Sci Med 2004 Nov;59(9):1795-1806. [Medline: 15312915] [doi: 10.1016/j.socscimed.2004.02.020]
10. Dickerson SS, Flaig DM, Kennedy MC. Therapeutic connection: help seeking on the Internet for persons with implantable cardioverter defibrillators. Heart Lung 2000 Jul;29(4):248-255. [Medline: 20359309] [doi: 10.1067/mhl.2000.108326]
11. Finn J. Computer-Based Self-Help Groups: On-Line Recovery for Addictions. Computers in Human Services 1996;13:21-41.
12. Han HR, Belcher AE. Computer-mediated support group use among parents of children with cancer--an exploratory study. Comput Nurs 2001 Jan;19(1):27-33. [Medline: 21078955]
13. White MH, Dorman SM. Online support for caregivers. Analysis of an Internet Alzheimer mailgroup. Comput Nurs 2000 Jul;18(4):168-76; quiz 177-9. [Medline: 20395099]
14. Finn J. An exploration of helping processes in an online self-help group focusing on issues of disability. Health Soc Work 1999 Aug;24(3):220-231. [Medline: 99434908]
15. Klemm P, Hurst M, Dearholt SL, Trone SR. Gender differences on Internet cancer support groups. Comput Nurs 1999 Mar;17(2):65-72. [Medline: 99210787]

16. Bury M. On chronic illness and disability. In: Bird C, Conrad P, Fremont A, editors. Handbook of Medical Sociology, 5th edition. NY: Prentice Hall; 2000:173-183.
17. Charmaz K. Good Days, Bad Days: The Self in Chronic Illness and Time. New Brunswick, NJ: Rutgers Univ Press; Nov 1, 1991.
18. Charmaz K. Experiencing Chronic Illness. In: Albrecht G, Fitzpatrick R, Srimshaw S, editors. Handbook of Social Studies in Health and Medicine. London, UK: Sage; 2000:272-292.
19. Wainwright SP. Transcending chronic liver disease: a qualitative study. J Clin Nurs 1997 Jan;6(1):43-45. [Medline: 97204597]
20. Richman JA, Jason LA, Taylor RR, Jahn SC. Feminist perspectives on the social construction of chronic fatigue syndrome. Health Care Women Int 2000 Apr;21(3):173-185. [Medline: 20563313] [doi: 10.1080/073993300245249]
21. PBCers Organization. Primary Biliary Cirrhosis. URL: http://www.pbcers.org/ [accessed 2004 Mar 10]
22. Lasker JN, Sogolow ED, Short LS, Sharim R. For better and for worse: family and friends - responses to chronic liver disease. Illness Crisis and Loss [in press].
23. Bales RF. Interaction Process Analysis: A Method for the Study of Small Groups. Chicago, Ill: University Microfilms; 1976.
24. Bales RF, Cohen SP, Williamson SA. SYMLOG; A System for the Multiple Level Observation of Groups. New York, NY: Free Press; Oct 1, 1979.
25. Bjornsdottir G. Online social support for individuals concerned with heart disease: observing gender differences. Proc AMIA Symp 1999:681-685 [FREE Full text] [Medline: 20032956]
26. Goldblatt J, Taylor PJS, Lipman T, Prince MI, Baragiotta A, Bassendine MF, et al. The true impact of fatigue in primary biliary cirrhosis: a population study. Gastroenterology 2002 May;122(5):1235-1241. [Medline: 21979323]
27. Gralnek IM, Hays RD, Kilbourne A, Rosen HR, Keeffe EB, Artinian L, et al. Development and evaluation of the Liver Disease Quality of Life instrument in persons with advanced, chronic liver disease - the LDQOL 1.0. Am J Gastroenterol 2000 Dec;95(12):3552-3565. [Medline: 21025210]
28. Werner A, Isaksen LW, Malterud K. 'I am not the kind of woman who complains of everything': illness stories on self and shame in women with chronic pain. Soc Sci Med 2004 Sep;59(5):1035-1045. [Medline: 15186903] [doi: 10.1016/j.socscimed.2003.12.001]
29. Eysenbach G, Powell J, Kuss O, Sa ER. Empirical studies assessing the quality of health information for consumers on the world wide web: a systematic review. JAMA 2002 May 22;287(20):2691-2700. [Medline: 12020305]
30. Potts HWW, Wyatt JC. Survey of doctors' experience of patients using the Internet. J Med Internet Res 2002 Mar 31;4(1):e5 [FREE Full text] [Medline: 21953333] [doi: 10.2196/jmir.4.1.e5]
31. Klemm P, Hardie T. Depression in Internet and face-to-face cancer support groups: a pilot study. Oncol Nurs Forum 2002 May;29(4):e45-e51. [doi: 10.1188/02.ONF.E45-E51] [Medline: 22007920]
32. Fogel J, Albert SM, Schnabel F, Ditkoff BA, Neugut AI. Use of the Internet by women with breast cancer. J Med Internet Res 2002 Nov 22;4(2):e9 [FREE Full text] [Medline: 22442441] [doi: 10.2196/jmir.4.2.e9]
33. Preece J, Nonnecke B, Andrews D. The top five reasons for lurking; improving community experiences for everyone. Computers in Human Behavior 2004;20(2):201-223. [doi: 10.1016/j.chb.2003.10.015]
34. Stegbaujer C, Rausch A. The silent majority-'lurkers' in Internet-based forums. Zeitschrift fur Soziologie 2001;30:48-64.

submitted 04.10.04; peer-reviewed by S Cotten; comments to author 02.12.04; revised version received 21.03.05; accepted 25.03.05; published 31.03.05.

Please cite as:
Lasker JN, Sogolow ED, Sharim RR
The Role of an Online Community for People With a Rare Disease: Content Analysis of Messages Posted on a Primary Biliary Cirrhosis Mailinglist
J Med Internet Res 2005;7(1):e10
URL: http://www.jmir.org/2005/1/e10/
doi:10.2196/jmir.7.1.e10
PMID:15829472

Original Paper

Challenges of Internet Recruitment: A Case Study with Disappointing Results

Malcolm Koo[1], PhD; Harvey Skinner[1], PhD

University of Toronto, Department of Public Health Sciences, Faculty of Medicine, Toronto, ON, Canada

Corresponding Author:
Malcolm Koo, PhD
Department of Public Health Sciences
Faculty of Medicine
McMurrich Building
University of Toronto
Toronto, ON M5S 1A8
Canada
Phone: +1 416 978 6206
Fax: +1 416 978 8299
Email: m.koo@utoronto.ca

Abstract

Background: The Internet provides tremendous opportunities for innovative research, but few publications on the use of the Internet for recruiting study participants exist. This paper summarizes our experiences from 2 studies in which we attempted to recruit teenagers on the Internet for a questionnaire study to evaluate a smoking-cessation website.

Objective: To evaluate strategies of recruiting teenagers for the evaluation of a smoking-cessation website through the Internet.

Methods: In Study 1 (Defined Community Recruitment), we sent invitation emails to registered members of a youth health website, CyberIsle. A total of 3801 email addresses were randomly divided into 2 groups. In the first group, emails indicated that the first 30 respondents would receive a Can $20 electronic gift certificate for use at an online bookstore if they would go to the Smoking Zine website and respond to a short survey. For the second group, the email also indicated that respondents would receive an additional Can $10 gift certificate if they referred their friends to the study. Reminder emails were sent 10 days after the sending of the initial invitation email. In Study 2 (Open Recruitment), we posted invitation messages on Web discussion boards, Usenet forums, and one specialized recruitment website, and attempted a snowball recruiting strategy. When potential participants arrived at the study site, they were automatically randomized into either the higher incentives group (Can $15 electronic gift certificate) or lower incentive group (Can $5 gift certificate).

Results: In Study 1 (defined community recruitment), 2109 emails were successfully delivered. Only 5 subjects (0.24%), including 1 referred by a friend, passed the recruitment process and completed the questionnaire; a further 6 individuals visited the information page of the study but did not complete the study. In Study 2 (open recruitment), the number of users seeing the advertisement is unknown. A total of 35 users arrived at the website, of whom 14 participants were recruited (8 from the Can $15 gift certificate group and 6 from the Can $5 gift certificate group). Another 5 were recruited from the general Internet community (3 from discussion boards and 2 from the Research Volunteers website). The remaining 9 participants were recruited through friend referrals with the snowball strategy.

Conclusions: Overall, the recruitment rate was disappointingly low. In our case, recruitment using Internet technologies including email, electronic discussion boards, Usenet forums, and websites did not prove to be an effective approach for soliciting young subjects to participate in our research. Possible reasons are discussed, including the participants' perspective. A major challenge is to differentiate trustable and legitimate messages from spam and fraudulent misinformation on the Internet. From the researchers' perspective, approaches are needed to engage larger samples, to verify participants' attributes, and to evaluate and adjust for potential biases associated with Internet recruitment.

(J Med Internet Res 2005;7(1):e6) doi:10.2196/jmir.7.1.e6

KEYWORDS

Internet; data collection; World Wide Web; research subjects

Introduction

The advent of the Internet has radically changed communication and information dissemination patterns among individuals and in society at large. Internet services such as websites, email, newsgroups, and blogs are providing new and powerful ways of disseminating and collecting information. Researchers have long been aware of the potential of the Internet [1,2]. The Internet has been considered a promising media for teaching and learning [3], research communications [1], and dissemination of medical information [4]. More recently, advancement in Web technology and its widespread adoption have further fostered the innovative use of the Internet in the areas of data collection [5-7] and online intervention programs and experimental research [8,9].

However, few published reports on the experiences of using the Internet for recruiting study participants are available [10-12]. Some authors have expressed concerns on the unrepresentativeness of Internet samples. Etter and Perneger [13] compared study participants who were recruited through a French-language smoking-cessation website with those recruited by mail. They found that smokers recruited through the Internet were younger, more educated, and more motivated to quit smoking; they also smoked more cigarettes per day than smokers in the other group. Despite the difference in smokers' characteristics, the authors concluded that Internet recruitment is a potentially useful method for analytical studies, which focus on associations between variables, but not for descriptive studies. Another study [14] evaluated whether the Internet could help to shorten the patient recruitment process in clinical trials. The authors concluded that the Internet is unlikely to become the core recruitment medium in the near future, but may be used as a part of an integrated approach to recruitment, mainly to inform potential participants of recruitment opportunities. The lack of representativeness of self-referred volunteers (they tend to be better educated, younger, and non-immigrants) threatens external validity--a major concern for an Internet-based recruitment approach for clinical trials.

Since young people are generally the early adopters of new technologies, the Internet holds great promise as an innovative medium for health research with this population [15].

In this paper, we first present results from two studies on the effectiveness of using the Internet to recruit young participants and then discuss some of the main challenges for Internet recruitment. The aim is to report our experiences on using the Internet for recruiting participants in studies. To present results from the Web-based studies themselves is not within the scope of this paper.

Methods

Study 1: Defined Community Recruitment

We sent invitation email messages to a subset of registered members of the CyberIsle youth website [16,17] during March 2003. The CyberIsle website [18] is a comprehensive Web-based health resource developed by the TeenNet Research Program [19], a youth health promotion initiative based at the University of Toronto. Subjects were selected from the registered member database if they were between 12 and 24 years old at the time of our study, resided in Canada, had provided their email addresses, and agreed to be researched for their activities on the CyberIsle website. Smoking status was not a selection criterion in the study.

The resulting 3801 email addresses were randomly divided into 2 groups. In the first group, emails indicated that the first 30 respondents would receive a Can $20 electronic gift certificate for use at an online bookstore if they went to the Smoking Zine website and responded to a short online survey (Figure 1). We decided to offer incentives only to the first 30 respondents to minimize the reaction time of the participants to the invitation. The Smoking Zine [20] is a Web-based smoking prevention and cessation intervention for youth that is embedded in the CyberIsle. In the second group, the invitation email also indicated that respondents would receive an additional Can $10 gift certificate if they referred at least one friend to the study. Thus, respondents could receive as a maximum gift certificates in the amount of Can $30 if they were able to refer a friend (or multiple friends) to the study.

In both groups, the invitation email was written in hypertext markup language (HTML) and contained images including a prominent banner depicting a Can $20 gift certificate, a logo of the University of Toronto, and screen images of the front page of the Smoking Zine and the CyberIsle websites (Figure 1). In addition, hyperlinks leading to the study website, contact information including telephone number and email address, and instructions for opting out of further email contact were provided. Bounced emails as a result of invalid email addresses were removed from the study email database.

Reminder emails were sent 10 days after the initial invitation email. The reminder email messages were fully text-based (not HTML-based) and no graphical images were used (Figure 2). The study was terminated 10 days after the reminder email.

When potential participants clicked the hyperlink on the invitation email, they connected to a Web page containing information about the study and a consent form. To proceed with the study, participants were required to click a button to indicate their consent to the online study. After going through the stage-based Smoking Zine website, participants were automatically presented with a short online 18-item questionnaire with 17 closed-ended multiple-choice questions on their Internet behavior and experience with the Smoking Zine. One open-ended question was placed at the end of the survey for participants to provide general comments. No sociodemographic data were collected from the participants. Once participants completed the questionnaire, they were sent an email indicating that they would receive the electronic gift certificates by email. During the study, participants who tried to exit the website without completing all 5 stages of the Smoking Zine would automatically be presented with a short 5-item questionnaire.

Figure 1. Invitation email written in hypertext markup language used in Study 1

From: CyberIsle <communityi@cyberisle.org>

Subject: Check out our Smoking Zine website and get a $20 Amazon.ca e-gift certificate!

Check out our Smoking Zine website and get a $20 Amazon.ca e-gift certificate!

amazon.ca GIFT CERTIFICATES

You receive this invitation email because you are a member of the CyberIsle Website Community.

The TeenNet Research Project at University of Toronto will give the first 30 teens who participate in this fun study a $20 Amazon.ca e-gift certificate.

So, if you are between the ages of 12 and 24 & you live in Ontario, Canada, you can participate. All you need to do is to go through the Smoking Zine website in one sitting to receive your e-gift certificate. You will be helping us learn more about youth and health.

Click here for more info on participation.

We try to keep our email list as current as possible.
If we have contact you by mistake. We apologize for this email.
Please reply to this email with "UNSUBSCRIBE" in the subject line.

CyberIsle (http://www.cyberisle.org) is a research initiative of the TeenNet Project at the University of Toronto

TeenNet

CyberIsle http://www.cyberisle.org
TeenNet http://www.teennetproject.org
Voice: 416-978-7543
FAX: 416-978-2087
Email: community@cyberisle.org

CyberIsle...created by teens for teens
A new way to learn the things
you want and need to know

cyberISLE
your youth health site

Figure 2. Reminder email written in plain text used in Study 1

From: CyberIsle <communityi@cyberisle.org>
To:
Subject: CyberIsle, University of Toronto needs your participation

Dear CyberIsle member,

You've received this invitation email because you are a member of the CyberIsle Youth Health Website Community.

We sent you an email a few days ago to invite you to check out our new Smoking Zine website.

If you go through our Smoking Zine in one sitting before March 31, you will receive a $20(CDN) Amazon.ca e-gift certificate.

Also, we'll give you an extra $10(CDN) in e-gift certificates if you refer some friends after you're done.

If you are between the ages of 12 and 24 & live in Canada, you can participate.

Please click here for more information on participation:

http://www.cyberisle.org/vr/welcome.php?dua=vahrui

Thank you in advance for your participation!

If you have forgotten your Cyberisle password, please send an email to nopassi@cyberisle.org.

==========
We try to keep our email list as current as possible.
If we have contact you by mistake, we apologize for this email.
Please reply to this email with "UNSUBSCRIBE" in the subject line.

==========
CyberIsle (http://www.cyberisle.org)
A research initiative of the TeenNet Project at the University of Toronto
Voice: 416-978-7543
FAX: 416-978-2087
Email: community@cyberisle.org

Study 2: Open Recruitment

Subject recruitment from the general Internet population was evaluated during March 2004. Invitations to participate were posted on Web discussion boards that were relevant to youth and smoking. The posting indicated that individuals must be between 15 to 24 years of age at the time of our study and residing in Canada to be eligible for the electronic gift certificate for participation. We selected 2 Canadian websites designed for youth (TakingITGlobal and Spank!) that had discussion boards with topics related to health and smoking [21,22]. In addition, Usenet forums were identified through Google Groups [23] where users were likely to have some ties with the University of Toronto community. The intention was to improve the credibility of our posting by choosing an audience that was local to our research project. The forums included were ut.general and ut.chinese. Also, we posted in a general smoking-related Usenet forum (alt.quit.smoking.support) that is not geographically restricted to Canada, as well as at the discussion board from the website of a local University of Toronto student group [24]. Finally, our posting was submitted to a new website, Research Volunteers [25], designed specifically for recruiting study participants through the Web. At the time of our study, the Research Volunteers website had been open to the public for one month and there were 9 studies in the database (8 from Ontario and 1 from British Columbia).

The message posted on the boards and forums was text-based and contained a link to our study website. There is no way of knowing how many people saw the advertisement. On all of the boards and forums except one, the message was posted for up to 24 days. However, on one board (Spank!) [22] our message was removed by the board administrator within a few minutes of being posted because it was perceived as spam [26] and had violated their discussion board rules.

When potential participants entered the study site, they were automatically randomized into either the higher incentives group (Can $15 electronic gift certificate for completing the Smoking Zine and a Web-based survey) or the lower incentives group (Can $5 gift certificate for completing the Smoking Zine). In both groups, participants had the opportunity to get additional $10 gift certificates for providing email addresses for up to 5 friends in respective fields presented after they filled in the survey.

Snowball sampling through referral by friends was also evaluated in this study. We asked 1 young subject who had been involved with other TeenNet evaluations as the initial recruiter to send personal emails to 8 of her friends with a message

indicating that an invitation email from our study would be sent to them soon. To remind the recipients that our email was the one mentioned by their friend, the initial referrer's email address was indicated in the message. We hoped that the 8 participants would each suggest up to 5 friends after filling in the survey, that these 5 would suggest 5 other friends, and so on.

The research protocol was approved by the University of Toronto's Human Subjects Review Committee. In both studies, participants were only required to provide their email addresses in order to receive the electronic gift certificate. In order to ensure anonymity of the participants' identity, no other contact information such as names, mailing addresses, or phone numbers was collected.

Results

Study 1: Defined Community Recruitment

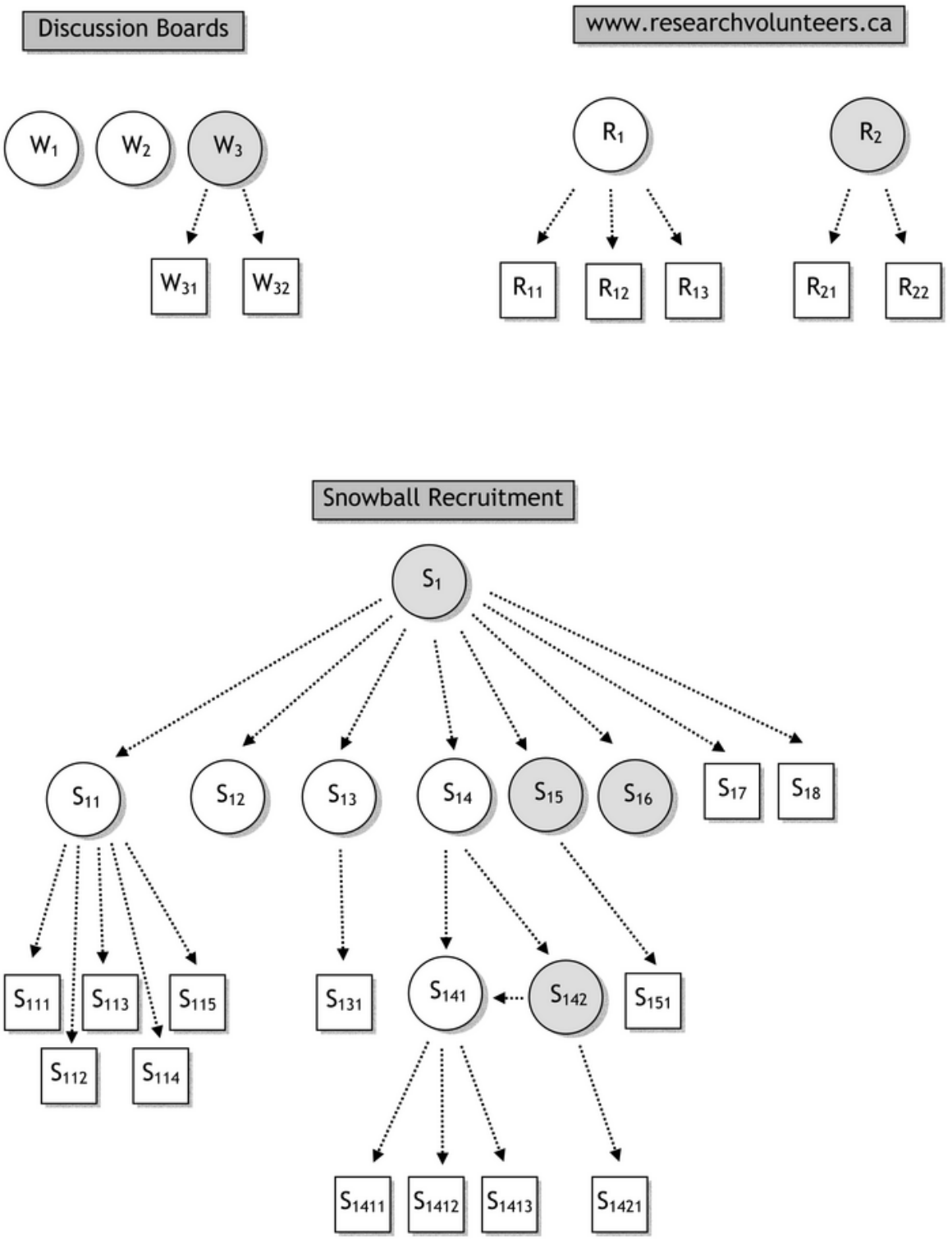
In the first study, 3801 recruitment emails were sent to members of the health website, CyberIsle. Of those, 1692 emails were undeliverable and the maximum number of youth who had possibly received our email was 2109. A total of 5 subjects (0.24%) satisfied recruitment criteria and completed the questionnaire; a further 6 individuals visited the information page of the study but did not proceed to the recruitment stage.

Initially, no response was received in response to the first email. After the reminder email was sent out, 4 participants (0.2%) completed the study (1 was from the first group and 3 were from the second group, in which participants received an additional Can $10 gift certificate for referring a friend). In the second group 1 participant referred 5 friends to the study, of whom 1 completed the study.

Study 2: Open Recruitment

In the second study, several routes of recruitment were attempted including Web discussion boards, Usenet forums, and a specialized recruitment website. A total of 14 participants were recruited of whom 5 were from the general Internet community (3 from discussion boards [subjects labeled with W] and 2 from the Research Volunteers [R] website). The remaining 9 participants were recruited through friend referrals using the snowball strategy [S]. Figure 3 shows the referral patterns with the levels of incentives. Eight participants received Can $15 gift certificates (unshaded circles), and 6 participants received Can $5 gift certificates (shaded circles). Those who were referred by their friends but did not participate in the study are indicated with unshaded squares.

Figure 3. The referral patterns of the three recruitment sources in Study 2



Participants who received Can $15 gift certificates are indicated with unshaded circles; those who received Can $5 gift certificates are indicated with shaded circle; and those who were referred by their friends but did not participate in the study are indicated with unshaded squares.

Despite the potential of receiving an additional Can $10 gift certificate, 4 participants (W_1, W_2, S_{12}, S_{16}) did not provide any email addresses (see Figure 3). Although 3 of the participants from the discussion board and Research Volunteers website (W_3, R_1, R_2) provided referrals (W_{31}, W_{32}, R_{11}, R_{12}, R_{13}, R_{21},

R_{22}), none of these 7 individuals responded to our invitation message to participate.

In the snowball recruitment (see Figure 2), 6 out of 8 (75%) individuals from the first level of referral responded and joined the study. Of these, 4 out of 6 (67%) provided email addresses for a total of 9 friends. At the second level of referral, only 2 out of these 9 (22%) participated and provided email addresses for a total of 5 friends, of whom one was a participant who had already enrolled (S_{141}). At the third level, 0 out of 4 were recruited and none provided further email addresses. The good response at the first level of referrals was the result of the initial referrer (S_1) sending personal emails to each of the 8 individuals to indicate the coming of our study email. If the email from the initial referrer had not been received, 2 participants would not have received the initiation email because their Web-based email accounts, Hotmail [27], were set so that unless the sender's email addresses already existed in the participant's personal address list, the email would be sent to the junk mail box.

Over the entire open recruitment study, 35 visitors arrived at the study website. Since the total number of visitors was 35 and the number of actual participants in our study was 14, the overall participation rate was 14 out of 35 or 40%. However, it must be noted that 10 participants arrived at the study page through referrals. These were more likely to participate than those who visited the site because of seeing our posting on discussion boards. Therefore, assuming all participants that came from referrals joined the study, a more conservative estimate of the actual participation for those who had reached the study website should be 4 out of 25 (16%).

Regarding the characteristics of the 14 participants, 12 (86%) used email everyday, 11 (79%) used the Web everyday, and 9 (64%) used instant messaging everyday. As expected, youth often actively maintained more than one email account [28]. The majority of participants (8/14, or 57%) used 3 or more email accounts.

Discussion

In our studies we experienced very low participation rates, despite the provision of monetary incentives. Since potential participants in the first study were members of our research website, CyberIsle, we did not expect such a low participation rate (0.2%) to our email invitation. This figure is close to the lower bound of response rates from email marketing of 0.1% [29] rather than the average rate of 1%. Several possible explanations for the low participation are discussed below followed by a description of some of the challenges of Internet recruitment.

Authenticity and Legitimacy of Information on the Internet

With the large number of websites youth encounter, it is plausible that the email recipients did not remember their previous involvement with CyberIsle. They may have considered the recruitment message as unsolicited commercial mass email (spam). Our initial recruitment email, which had a response rate of 0%, was formatted in HTML with colors and embedded images (Figure 1). The graphical layout along with several hyperlinks might have been mistaken for spam by the recipients or by the built-in spam filter in email programs resulting in automatic deletion from the incoming mailbox. However, the response was still low even when the reminder email was formatted as plain text (Figure 2). The recipients may not have received our second email because of spam filters or because they did not regularly check the email account of the address they provided during the CyberIsle registration (youth often set up separate email accounts used specifically for registration purposes).

Given the low response rate from the first study, where the potential participants were members of our health website, it is not surprising to see a similar low response rate when we extended the recruitment to the general Internet community where there had been no previous connection with our research project.

The level of spam and deceptive email on the Internet has exploded exponentially in the past few years [30]. The spam to non-spam ratio as of March 2004 was estimated to be 63%. About 12% of spam was estimated to be scams or fraud and many were infected with viruses or worms [31] that pose a serious threat to online privacy. Since online privacy is one of the major concerns for youth online, it is not surprising that postings or email messages that bear even slight resemblance to spam are ignored.

The context of a message may influence the decision of potential participants to join a study. We expected that postings on University of Toronto-related Usenet forums and discussion boards would enhance the credibility and relevancy of our study. However, only 3 participants were from the University of Toronto discussion boards. It is possible that more individuals would have participated in the study if we had kept the postings online for a longer period of time. However, older messages on discussion boards are rarely browsed once they are not shown on the first page (pushed to later pages by newer postings).

Incentives

The incentives level might not have been sufficient or gift certificates for an online bookstore may not have been attractive enough for our young potential participants. One of the limitations of electronic gift certificates is that the price of purchase must be lower than the value of the gift certificate. Otherwise, one would need to have access to a credit card in order to purchase online, which is an issue for trials with teenagers. After allowing for taxes and shipping charges, a Can $20-dollar certificate is worth only about Can $14 thereby limiting what can be bought. Despite this limitation with electronic gift certificates, it was chosen as the incentive in the study because of the anonymity it provided. Only a valid email address is required to deliver a certificate to a participant, as opposed to requiring the postal address if other coupons usable in stores are used as incentives. Until electronic cash payments such as PayPal become widely accepted, there are limited options for compensating respondents for their participation in an anonymous way.

Snowball Sampling and Personalization

The explosion of spam on the Internet may explain why our snowball recruitment through email referrals was ineffective. Despite the potential of receiving an additional Can $10 of gift certificate, 4 of the 14 participants in the second study did not provide their friends' email addresses. This is not surprising since they might have wished to preserve their friends' privacy.

Recruitment emails sent to the referrals in both studies were addressed from our study email account. In the body of the email, we indicated that how and from whom (email address of the referrer provided) we had obtained the referrals' email addresses. In the same email, we also sent a copy to the referrer as a way of indicating the legitimacy of the email. Additional personalization to the email was not introduced since we had only the email addresses of the referrals.

A recent study on online shoppers found that compared to basic site improvements such as ease of navigation, the effect of personalization provided little incentive for users to buy from an e-commerce website [32]. This is in contrast to the general recommendation given to improve response rates in mail surveys [33]. Again, the weak effect of personalization in email could be the result of widespread personalization in most electronic marketing materials encountered on a daily basis. Better response might be achieved if recruitment emails were sent directly under the referrers' email addresses rather than from the study email address. Instead of sending the referral's email to the study coordinator, the study website could be programmed so that the referrers could send invitation emails using their own email addresses directly to their friends. Spammers have exploited various deceptive techniques such as employing fake sender email addresses from legitimate domains, embedding real logos from legitimate websites onto messages, and using misleading or enticing (such as money or free prizes) subject lines. Therefore it is almost impossible to create a recruitment email message or a Web posting that can easily be distinguished from spam by a casual Internet user. For email to be a viable recruitment medium, more research is needed to explore the factors contributing to a trustable message.

Challenges and Practical Advice

Verification of Participants' Attributes

Because of the anonymous nature of our study design, it was impossible to verify the age of the participants. The eligible age range for our second study was 15 to 24 years. There is no simple online solution for verifying an Internet user's true age. A 2001 study on youth Internet behavior found that 15% of online teens and 25% of older boys when online have lied about their age to gain access to websites which often are pornographic in nature [28]. On the other hand, in studies where adult participants are required, it is possible to use commercial online age verification services using credit card information as the verifying identifier. However, privacy issues will become a major concern as individually identifiable information is collected by age verification companies.

The information page of our study specified that enrolment was limited to individuals currently living in Canada. There is no simple way to check or enforce the geographical location of a participant, although it is possible, with various free reverse lookup Internet websites, to identify the country of a participant's computer using the Internet Protocol (IP) address. However, it is both difficult and costly to implement this as a real-time check feature on the site. The solution we adopted in this study was to target our postings only to Canadian discussion boards and Usenet forums.

Preventing Multiple Participation

Preventing multiple entries from the same participant is another challenge for Internet recruitment, particularly in studies with monetary incentives [5,34]. Since it is simple for anyone to apply for new email accounts from free email service providers such as the Hotmail and the Yahoo Mail, the same individual can create multiple identities and participate in a study more than once. This issue is particularly difficult in studies using discussion boards or Usenet forums where unique login information (username/password) or URL cannot be assigned to each participant. The use of cookies is only effective to detect multiple participations if the participants access the study website twice from the same computer. This detection method can easily be circumvented by using a different computer or by deleting the cookies from the computer.

One step which can identify multiple participation is the examination of the survey results submitted from same IP addresses for the presence of other indications for multiple participation, such as the lack of internal consistency between items in the survey, and unrealistically short response time to survey questions [5].

Simply deleting all entries with duplicate IP addresses is not recommended, because the recent popularity of proxy servers or network address translation (NAT) servers, have made it not uncommon for one public IP address to be shared across many computers within a private local area network [35]. In addition, for computers connecting to the Internet through dynamic IP addresses (dial-up or broadband), new IP address can be obtained simply by logging in again. Thus, duplicate IP addresses do not necessarily indicate multiple entries from the same person and to delete all such entries would eliminate legitimate data.

Reips [9] estimates that repeat participations were below 3% in most studies and should not be a threat to the data quality of Internet-based research.

Coverage

Participation in Internet recruitment may be increased by broadening the dissemination of the recruitment information. For example, one can post the study invitation on those discussion boards or Usenet forums that have higher posting traffic, such as those related to computers. However, it is bad “netiquette” to cross-post in forums with out-of-context messages, such as study recruitment of a health behavior study in a computer-related forum. Such messages will either be ignored or removed. In some cases, the sender will be “flamed” (responded to by overly harsh and often hostile terms). Another possibility is to purchase advertisement space such as in the form of page banner on websites that are popular among target users.

Conclusion

This study is one of the first attempts to investigate the feasibility of Internet recruitment in the "age of spam." In our specific case our recruitment strategies were not efficient. However, we caution against generalizing our negative results. Internet recruitment may prove viable if studies are conducted on a larger scale, if the right newsgroups are targeted, the right incentives chosen, and the right wording is used. Recruitment announcements in the form of Web page banners can potentially be viewed by tens of thousands, if not more, of online users on high traffic Web portals.

From the researchers' perspective, the validity of study results can be compromised by limitations in verifying participants' attributes such as age. For motivated participants, it is not clear how to differentiate trustable and legitimate messages on the Internet. Researchers using Internet recruitment in their studies should focus on ways to improve the perceived legitimacy of the invitation message. For example, participants should be able to easily identify the study website as belonging to a legitimate organization such as a university.

Success in recruiting participants online depends on many factors, which are similar to those for getting responses in traditional mail and telephone surveys. Studies have investigated various strategies to maximize response rates in offline surveys [36]. It is clear that there is no single strategy that can guarantee good response rates in all situations, due to variations in study characteristics, target populations, type and amount of incentives, sponsorships, length of questionnaires, text used for recruitment, and follow-up strategies. Future studies on Internet recruitment should focus on investigating ways to convey trust online to Internet users and to find attractive incentive structures for Internet users.

Acknowledgments

This research was supported by grants from the Government of Ontario, Toronto, Ontario, Canada (grant #416632) and from the Canadian Institutes of Health Research (CIHR), Ottawa, Ontario, Canada (grant #452037). The authors thank their TeenNet colleagues (Department of Public Health Sciences, Faculty of Medicine, University of Toronto) for their feedback on this study.

Conflicts of Interest

None declared.

References

1. Laporte RE. Global public health and the information superhighway. BMJ 1994 Jun 25;308(6945):1651-1652. [Medline: 94297440]
2. Skinner H. Promoting Health through Organizational Change. San Francisco, Calif: Benjamin Cummings; Sep 14, 2001.
3. Vanzyl AJ, Cesnik B. The Internet and its role in teaching medical informatics to undergraduates. Medinfo 1995;8 Pt 2(pt 2):1154-1157. [Medline: 96174213]
4. Buhle EL, Goldwein JW, Benjamin I. OncoLink: a multimedia oncology information resource on the Internet. Proc Annu Symp Comput Appl Med Care 1994:103-107. [Medline: 95037187]
5. Eysenbach G, Wyatt J. Using the Internet for surveys and health research. J Med Internet Res 2002 Nov 22;4(2):e13 [FREE Full text] [Medline: 22442445] [doi: 10.2196/jmir.4.2.e13]
6. Robinson KM. Unsolicited narratives from the Internet: a rich source of qualitative data. Qual Health Res 2001 Sep;11(5):706-714. [Medline: 21438727] [doi: 10.1177/104973201129119398]
7. Tingling P, Parent M, Wade M. Extending the capabilities of Internet-based research: lessons from the field. Internet Res 2003;13(3):223-235. [doi: 10.1108/10662240310478231]
8. Norman CD. The web of influence: Evaluating the impact of the Internet on adolescent smoking cessation and eHealth literacy [dissertation]. Toronto, Ont, Canada: University of Toronto; 2004.
9. Reips UD. Standards for Internet-based experimenting. Exp Psychol 2002;49(4):243-256. [Medline: 22343759] [doi: 10.1026//1618-3169.49.4.243]
10. Smith MA, Leigh B. Virtual subjects: Using the Internet as an alternative source of subjects and research environment. Behav Res Methods Instrum Comput 1997;29:496-505.
11. Fernández MI, Varga LM, Perrino T, Collazo JB, Subiaul F, Rehbein A, et al. The Internet as recruitment tool for HIV studies: viable strategy for reaching at-risk Hispanic MSM in Miami? AIDS Care 2004 Nov;16(8):953-963. [Medline: 15511727] [doi: 10.1080/09540120412331292480]
12. Im EO, Chee W. Recruitment of research participants through the Internet. Comput Inform Nurs 2004;22(5):289-297. [Medline: 15520599]
13. Etter JF, Perneger TV. A comparison of cigarette smokers recruited through the Internet or by mail. Int J Epidemiol 2001 Jun;30(3):521-525 [FREE Full text] [Medline: 21309107] [doi: 10.1093/ije/30.3.521]
14. Marks L, Power E. Using technology to address recruitment issues in the clinical trial process. Trends Biotechnol 2002 Mar;20(3):105-109. [Medline: 21831313] [doi: 10.1016/S0167-7799(02)01881-4]

15. Skinner H, Biscope S, Poland B, Goldberg E. How adolescents use technology for health information: implications for health professionals from focus group studies. J Med Internet Res 2003 Dec 18;5(4):e32 [FREE Full text] [Medline: 14713660] [doi: 10.2196/jmir.5.4.e32]
16. Skinner HA, Morrison M, Bercovitz K, et al. Using the Internet to engage youth in health promotion. Promot Edu 1997;4:23-25.
17. Skinner HA, Maley O, Norman CD. Developing eHealth promotion Internet-based programs: The Spiral Technology Action Research (STAR) model. Health Promot Pract [in press].
18. ; Department of Public Health Sciences, University of Toronto, Ontario, Canada. CyberIsle. URL: http://www.cyberisle.org/ [accessed 2005 Mar 6]
19. ; TeenNet Research Program, Department of Public Health Sciences, University of Toronto, Ontario, Canada. TeenNet Project. URL: http://www.teennetproject.org/ [accessed 2005 Mar 6]
20. ; Department of Public Health Sciences, University of Toronto, Ontario, Canada. The Smoking Zine. URL: http://www.smokingzine.org/ [accessed 2005 Mar 6]
21. ; TakingITGlobal, Toronto, Ontario, Canada. Home page. URL: http://www.takingitglobal.org/ [accessed 2005 Mar 6]
22. ; SpankMag.com (Lopedia), Calgary, Canada. Home page. URL: http://www.spankmag.com/ [accessed 2005 Mar 6]
23. ; Google Incoporated, Mountain View, California, USA. Google Groups. URL: http://groups.google.com/ [accessed 2005 Mar 6]
24. University of Toronto Chinese Students' Association, Canada. URL: http://utcsa.sa.utoronto.ca/ [accessed 2004 Sept 14]
25. ; Research Volunteers, London, Canada. Research Volunteers. URL: http://www.researchvolunteers.ca/ [accessed 2005 Mar 6]
26. Fallows D. Spam: How is it Hurting Email and Degrading Life on the Internet. Washington, DC: Pew Internet & American Life Project; 2003. URL: http://www.pewinternet.org/pdfs/PIP_Spam_Report.pdf
27. ; Microsoft Corporation, Redmond, Washington, USA. MSN Hotmail. URL: http://www.hotmail.com/ [accessed 2005 Mar 6]
28. Lenhart A. Teenage life online: The rise of the instant-message generation and the Internet's impact on friendships and family relationships. Washington, DC: Pew Internet & American Life Project; 2001. URL: http://www.pewinternet.org/pdfs/PIP_Teens_Report.pdf
29. Wussler R; CRM Media LLC. How can we increase our email marketing response rates? CRM.com. 2002 Dec 9. URL: http://www.destinationcrm.com/articles/default.asp?ArticleID=2714 [accessed 2005 Mar 6]
30. Biever C. Spam-busters sport out the fakes. New Scientist 2004 Feb 7:26.
31. Greenspan R. The Deadly Duo: Spam and Viruses. 2004 Jun 7. URL: http://www.clickz.com/stats/big_picture/applications/print.php/3364421 [accessed 2005 Mar 6]
32. Gaudin S; Clickz Stats staff. Personalization not the secret to e-commerce. 2003 Nov 14. URL: http://www.clickz.com/stats/markets/retailing/print.php/6061_3092341 [accessed 2004 Dec 3]
33. Dillman DA. Mail and Internet Surveys: The Tailored Design Method, 2nd edition. New York, NY: Wiley; 1999.
34. Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004 Sep 29;6(3):e34 [FREE Full text] [Medline: 15471760] [doi: 10.2196/jmir.6.3.e34]
35. Rekhter Y, Moskowitz B, Karrenberg D, de Groot GJ. Request for Comments: 1918. Address Allocation for Private Internets. 1996 Feb. URL: http://www.ietf.org/rfc/rfc1918.txt [accessed 2005 Mar 6]
36. Edwards P, Roberts I, Clarke M, Diguiseppi C, Pratap S, Wentz R, et al. Increasing response rates to postal questionnaires: systematic review. BMJ 2002 May 18;324(7347):1183 [FREE Full text] [PMC: 12016181] [Medline: 22011649] [doi: 10.1136/bmj.324.7347.1183]

submitted 15.09.04; peer-reviewed by EO Im, L Marks, S Wang, A Alghamdi; comments to author 01.03.05; revised version received 07.03.05; accepted 09.03.05; published 19.03.05.

Please cite as:
Koo M, Skinner H
Challenges of Internet Recruitment: A Case Study with Disappointing Results
J Med Internet Res 2005;7(1):e6
URL: http://www.jmir.org/2005/1/e6/
doi:10.2196/jmir.7.1.e6
PMID:15829478

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org