

Going Online With Quality

What You Need to Know

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June 25, 2000

E-Healthcare Connections

San Francisco, California

Why be Concerned?

Goal

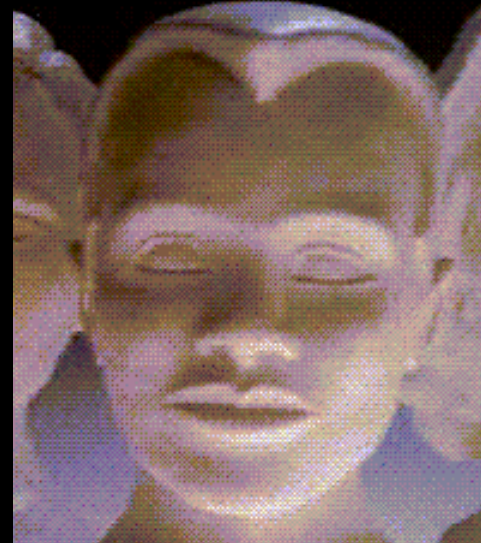
**To promote a quality
Internet health
experience...**

**...and protect against
a bad experience**

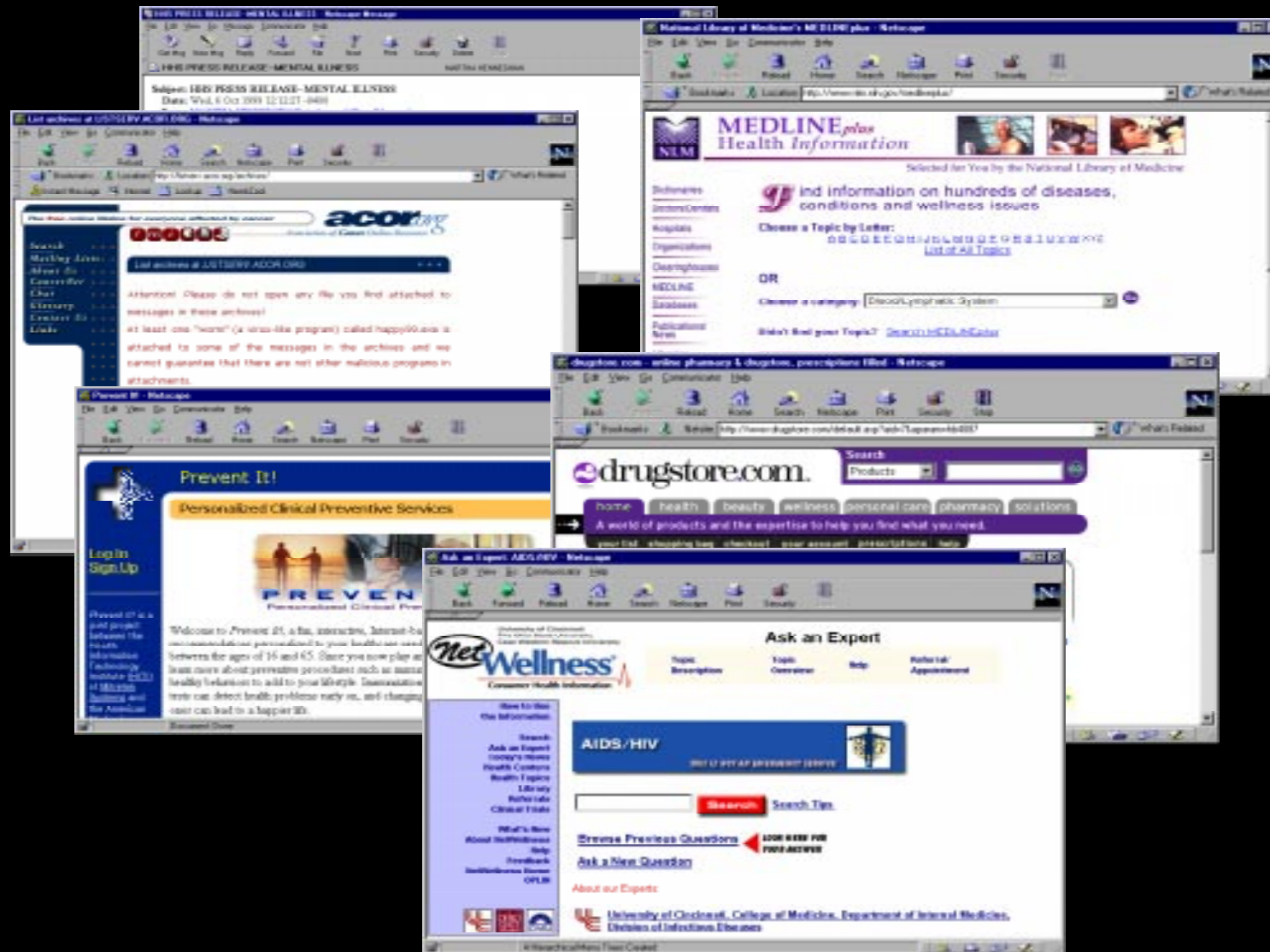
How Do We Reach This Goal?

- ⇒ **Where are we today?**
- **What are the stumbling blocks?**
- **How can we ensure success?**

How Will We Define Healthcare?



Online Today



The Players

- **Healthcare sector**
 - Healthcare providers
 - Healthcare delivery systems
- **Healthcare related industry**
 - Pharmaceuticals
- **Health content providers/services**

Increased Role of Third Parties

- **Third party “involvement” in managing health**
 - **Not bound by health care provider - patient relationship**
 - **No “licensure” or validation requirements**
 - **Not covered by HIPAA, FDA, FTC**
 - **Revenue generation**
 - **selling of user information**
 - **advertising**
 - **sales**

How Do We Reach This Goal?

- Where are we today?
- ⇒ **What are the stumbling blocks?**
- How can we ensure success?

What are the Stumbling Blocks?

- Fraud and quality
- Confidentiality, privacy and security
- Medical practice

How Do We Reach This Goal?

- Where are we today?
- What are the stumbling blocks?
- ⇒ **How can we ensure success?**

How Can We Ensure Success?

- ➔ **Excellence**
- **Ethics**
- **Education**
- **Enforcement**



The Starting Point: Defining Excellence

- **Fraud and quality**
- **Confidentiality, privacy and security**
- **Medical practice**

Fraud is Legally Defined



What is Quality?

Quality Criteria

- **Basic criteria**
 - **Health Summit Working Group**
<http://hitiweb.mitretek.org/hswg>
Policy paper available
Internet based educational tool (beta) available
- **Additional criteria for risk assessments**

Quality Criteria: Health Summit Working Group

- Credibility
- Content
- Disclosure
- Links
- Design
- Interactivity
- Caveats

Health Summit Working Group

What makes this effort unique?

- **All stakeholders**

- Health care providers, international, pharmacists, consumers, librarians, academicians, government (FTC, NLM, NCI, ODPHP, OAM), IHC, AMIA, HON, Science Panel

- **International scope**

- White paper and policy paper translated into numerous languages

Health Summit Working Group

What makes this effort unique?

- **Developed through consensus**
- **Implemented**
 - **Policy Paper broad endorsements**
 - **IQ Tool**

Special Issues With Interactive Applications

| Health Age | Achievable Age | Life Expectancy |
|------------|----------------|-----------------|
| 36 | 34 | 83 |
| 37 * | 37 * | 83 |
| 38 * | 38 * | |
| 39 | 38 | |

* Same source

Quality Criteria: Criteria Specific to Health Assessments

- Source of algorithm
- Testing of algorithm
- Algorithm availability
- Privacy and security
- Appropriate questions
- Appropriate results



Quality Criteria: Formal Evaluation of Health Assessments

- **Successful studies**
 - **Controlled environment (can be Internet)**
 - **Outcome measures in design**
 - **Tracking features in design**

Interactive Applications: Evaluation

[Http://www.scipich.org](http://www.scipich.org)

Evaluation Reporting Template For Interactive Health Communication Applications, Version 1.0, Science Panel On Interactive Communication And Health

This is an evaluation reporting template for developers and evaluators of interactive health communication (IHC) applications to help them report evaluation results to those who are considering purchasing or using their applications. Because the template is designed to apply to all types of applications and evaluations, some items may not apply to a particular application or evaluation. Complete only those items that apply. This and subsequent versions of the template and other resources on evaluation of IHC are available at: URL: www.scipich.org

I. Description of Application

1. Title of product/application:
2. Name(s) of developer(s):
3. Relevant qualifications of developer(s):
4. Contact(s) for additional information:
5. Funding sources for development of the application (e.g., commercial company, government, foundation/nonprofit organization, individual):
6. Category of application (e.g., clinical decision support, individual behavior change, peer support, risk assessment):
7. Specific goal(s)/objective(s) of the application (What is the application intended to do? List multiple if applicable):
8. Intended target audience(s) for the application (e.g., age group, gender, educational level, types of organizations and settings, disease groups, cultural/ethnic/population groups):
9. Available in languages other than English? No Yes (specify):
10. Technological/resource requirements of the application (e.g., hardware, Internet, on-site support available):
11. Describe how confidentiality or anonymity of users is protected:
12. Indicate who will potentially be able to get information about users:

II. Formative and Process Evaluation*

1. Indicate the processes and information source(s) used to ensure the validity of the content (e.g., peer-reviewed scientific literature, in-house "experts," recognized outside "experts," consensus panel of independent "experts," updating and review processes and timing):
2. Are the specific original sources of information cited within the application? Yes No
3. Describe the methods of instruction and/or communication used (e.g., drill and practice; modeling; simulations; reading generic online documents, interactive presentations of tailored information, specifying methods used):
4. Describe the media formats used (e.g., text, voice/sound, still graphics, animation/video, color):
5. For each applicable evaluation question below indicate (i) the characteristics of the sample(s) used and how they were selected, (ii) the method(s) of assessment (e.g., specific measures used), and (iii) the evaluation

Steps to a Quality Site

- **Develop a quality assurance procedure**
- **Follow guidelines**
 - **HSWG recommendations**
 - **SciPanel recommendations**
- **Link cautiously**
- **Disclose fully**

Privacy, Confidentiality & Security

- What will the data be used for?
- Most issues related to privacy, confidentiality and security are NOT technology dependent

HIPAA

- **Health insurance portability and accountability act of 1996 (HIPAA)**
- **Nov. 3 1999 - DHHS published a notice of proposed rule making - “standards for privacy of individually identifiable health information”**

HIPAA

- **Information protected:**
 - Information relating to individual's health...From transmission to maintenance in a computer system
- **Covered entities:**
 - Health care providers who transmit data electronically
 - Health plans
 - Healthcare clearinghouses

HIPAA

- **Individual rights**

- E.g.: Notice of information practices from providers, rights to access their information, amend, audit trail

- **Obligations of health care providers and plans**

- Develop and provide notice of information practices, training, provide safeguard, apply sanctions, document compliance...

HIPAA

- **Cost of compliance**
 - \$3.8 billion over 5 years
- **Enforcement**
 - Penalty of \$25,000/year
 - Criminal penalties up to \$50,000 or more
 - Patients can not sue entities for privacy violations

HIPAA

- **With respect to data security** (credit suisse first boston corp, 10/99)
 - **Compliance assessment (24%)**
 - **Document policies and procedures (22%)**
 - **Implement policies and procedures (18%)**
 - **Not yet planned (13%)**

Medical Practice

- E-mail use
- The provider-pt relationship





Patient-Provider Link is Important

- No disclaimer
- Personalization at its best
- Confidential
- Placebo effect
- Healthcare provider skepticism kills

Using E-Mail

- **AMIA Guidelines**
 - <http://www.amia.org/pubs/pospaper/positio2.htm>
- **Kane, B., Sands, D.Z for the AMIA Internet Working Group, Task Force on Guidelines for the Use of Clinic-Pt Electronic E-mail**

AMIA E-Mail Guidelines

- Establish turn-around time
- Inform patients on privacy issues
- Establish types of transactions and sensitivity allowed
- Instruct patients to provide a category to the transaction

AMIA E-Mail Guidelines

- Request patient name and identifiers in the body of the text
- Configure automatic reply
- Print all messages, with receipt, and place in pt's chart
- Send new message to inform pt re:task completion

AMIA E-Mail Guidelines

- Request pts use auto-reply to acknowledge receipt
- Maintain mailing list of pts, use blind copy features
- Avoid anger, sarcasm, harsh criticism, and libelous references to third parties in messages

How Can We Ensure Success?

- Excellence
- ⇒ Ethics
- Education
- Enforcement

Ethics

Four Reasons:

- Protect from harm
- Create ethical environment
- Pride, not embarrassment
- Fairness/Synergy



Source: Tom Murray

AMA - Principles of Medical Ethics - Netscape

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Bookmarks Netsite: <http://www.ama-assn.org/ethic/ceja/pome.htm> What's Related

Instant Message WebMail Contact People Yellow Pages Download Find Sites Channels

Relationship

- [CEJA Reports](#)
- [Reporting Ethical Violations](#)
- [CEJA Members](#)
- [CEJA Staff](#)
- [Contact Information](#)
- [Institute for Ethics](#)
- [EPEC](#)

• *Principles of Medical Ethics*

- I. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.
- II. A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.
- III. A physician shall respect the law and recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.
- V. A physician shall continue to study, apply, and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talent of other health professionals when indicated.
- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.
- VII. A physician shall recognize a responsibility to participate in activities contributing to an improved community.



Health On the Net Code of Conduct for medical and health Web sites (HONcode)

Principles

[[graphic](#)]

[[Introduction](#)]

[[Background](#)]

[[Method](#)]

[[Audience](#)]

[[Principles](#)]

- [English](#)

- [Finnish](#)

- [French](#)

- [German](#)

- [Italian](#)

- [Russian](#)

- [Spanish](#)

[[Membership](#)]

[[Policy](#)]

[[HONcode Check](#)]

[[Sample of sites](#)]

[[Feedback](#)]

Any medical/health advice provided and hosted on this site will only be given by

1. medically/health trained and qualified professionals unless a clear statement is made that a piece of advice offered is from a non-medically/health qualified individual/organisation.

2. The information provided on this site is designed to support, not replace, the relationship that exists between a patient/site visitor and his/her existing physician.

3. Confidentiality of data relating to individual patients and visitors to a medical/health Web site, including their identity, is respected by this Web site. The Web site owners undertake to honour or exceed the legal requirements of medical/health information privacy that apply in the country and state where the Web site and mirror sites are located.

4. Where appropriate, information contained on this site will be supported by clear references to source data and, where possible, have specific HTML links to that data. The date when a clinical page was last modified will be clearly displayed (e.g. at the bottom of the page).

5. Any claims relating to the benefits/performance of a specific treatment, commercial product or service will be supported by appropriate, balanced evidence in the manner outlined above in Principle 4..

The designers of this Web site will seek to provide information in the clearest possible



Hi-Ethics

- Hi-Ethics represents the efforts of major health web sites to develop “best practices”
- Lead: Don Kemper
- US commercial site focus
- A promise to users

eHealth Code of Ethics

- Sponsored by the Internet Healthcare Coalition
- January 31, February 1 & 2, 2000
- Host - Pan American Health Organization
- <http://www.ihealthcoalition.org>

Steering Group

● Summit members:

- Lynn Cates, drspock.com
- Murray Kopelow, ACCME
- Blackford Middleton, Medicallogic
- Beth Nash, Physicians Online, Hi-Ethics
- Tim Nater, HON
- Helga Rippen, Pfizer Health Solutions
- Ahmad Risk, British Healthcare Association
- Michael Samuelson, cancerfacts.com

● Facilitator:

- Kathy Alison, TRG

● Ethicists

- Tom Murray, Hastings Center
- Ruth Faden, Johns Hopkins

● Editor

- Bette Crigger

From the Statement of Vision

“...The goal of the "eHealth Code of Ethics" is to ensure that all people worldwide can confidently, and without risk, realize the full benefits of the Internet to improve their health.”

eHealth Code of Ethics

- **Eight Principles**

- **Candor**
- **Honesty**
- **Quality**
- **Informed Consent**
- **Privacy**
- **Professionalism in Online Health Care**
- **Responsible Partnering**
- **Accountability**

Health Code of Ethics

- **Unique**
 - **International**
 - **Inclusive**
 - **Comprehensive**
 - **Public commentary period**
 - **Focused on ethics, not law**

A Vision

Board of Trustees

HON

Hi Ethics

AMA

Ethicists

Universities

**Pharmaceutical
companies**

**Gov't agencies
(FDA, FTC, etc.)**

Lawyers

IHC

PAHO

Physicians

Nurses

Patients

Others

eHealth Code of Ethics

- International
- All stakeholders

**Abridged version
of code**

SPECIFICATION & INTERPRETATION

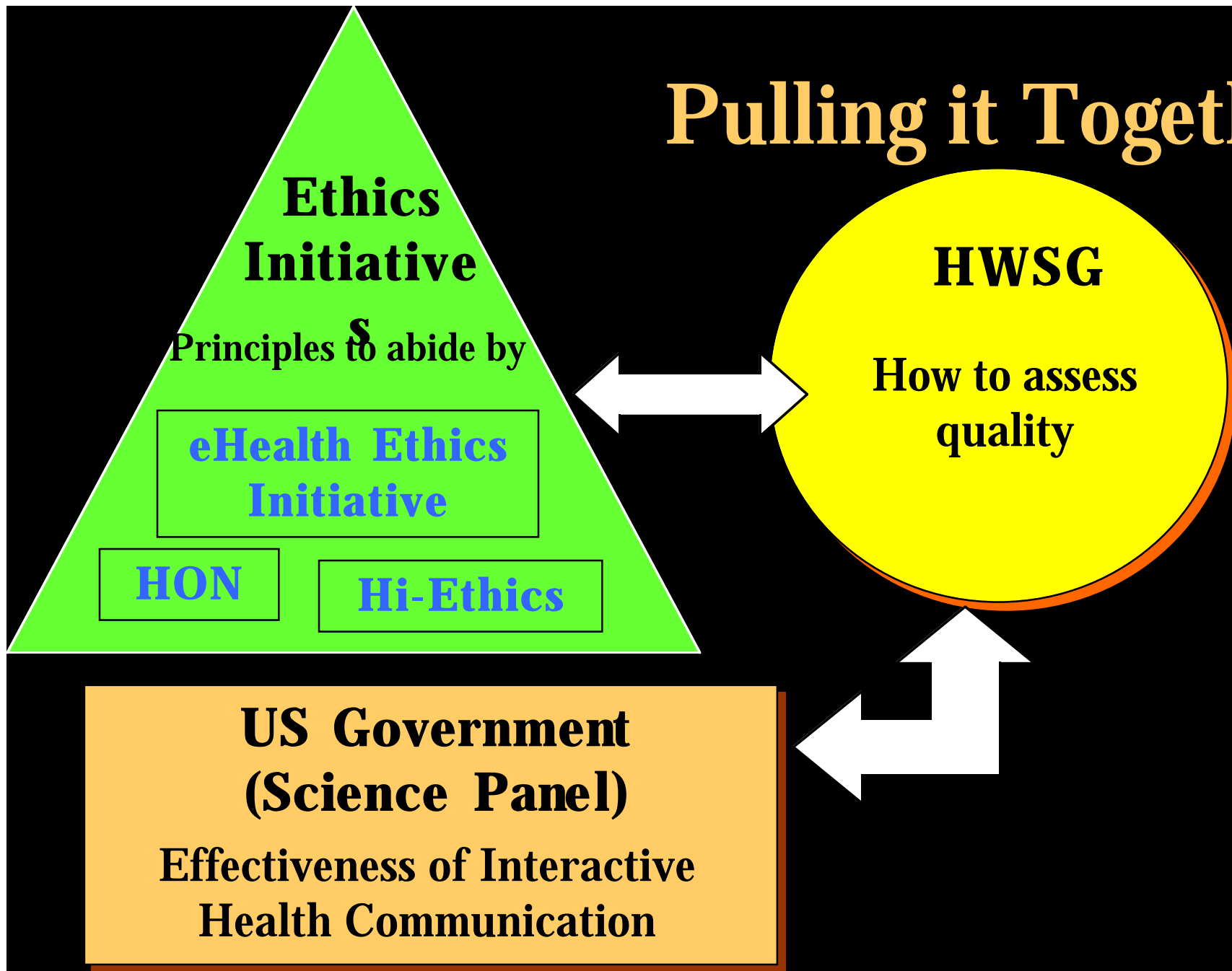
HON

Hi Ethics

AMA

**Others
accrediting o**

Pulling it Together



Approaches to Ensuring Excellence

Internal

- Established policies and procedures
 - Use quality assurance mechanisms (e.g., peer review)
 - Use appropriate criteria
- If applicable do outcomes research
- Abide by principles

Approaches to Ensuring Excellence

External

- Seal of approval
- Regulation
- Labeling technology
- Accreditation of developers
- Education

How Can We Ensure Success?

- Excellence
- Ethics
- ⇒ **Education**
- Enforcement

Education

- Educate Internet Website developers on what “quality and ethics” mean
- Educate site evaluators on what to look for
- Educate the consumer on what to look for

Interactive Education Online The Information Quality Tool (IQ)



HSWG - IQ Tool - Netscape

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Location: http://hitiweb.mitretek.org/iq/default.asp

Instant Message Internet Lookup New&Cool

MITRETEK SYSTEMS Innovative Technology in the Public Interest [Site Guide / Search](#)

home

IQ Tool

HSWG HEALTH SUMMIT WORKING GROUP

- [About IQ Tool](#)
- [Beginner's Guide](#)
- [What the Scores Mean](#)
- [Funding](#)
- [Disclaimer](#)

Welcome to the IQ, the Health Information Quality Assessment Tool!

The IQ Tool helps you become and educated consumer by helping you ask the right questions. Based on your answers IQ will evaluate the site's strengths and weaknesses. All you have to do is enter the site's URL to begin! Then it is up to you to find the answers.

Begin using IQ!

We'd like to hear what you have to

ABOUT US
PARTICIPANTS
CONTACT US
DOCUMENTS
SUMMIT MEETINGS
MEMBERS ONLY
IQ TOOL

Document: Done

IQ Assessment Tool - Netscape

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Bookmarks Location: <http://hitiweb.mitretek.org/iq/iqframes.asp> What's Related

Instant Message Internet Lookup New&Cool

HSWG
HEALTH SUMMIT
WORKING GROUP

HSWG Information Quality

General Questions

Address:

If this is promotional site selling a product, [click here](#).
 If this is promotional site selling a service, [click here](#).

Note: Scroll down to see more questions. If a question is not applicable question, click on the button beside the question. To comment on

1. Is the author identified in the article?
 Yes No
2. When the author refers to another source, are appropriate references
 Yes No
3. If the author is not referring to a source, does he/she clearly state th
 Yes No
4. Are the site author's credentials listed?
 Yes No
5. Does the site author's credentials relate to the knowledge of the field
 Yes No

Burning Up: Facts About Your Child's Fever - Netscape

File Edit View Go Communicator Help

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Bookmarks Location: t/healthy/fever.html What's Related

Instant Message Internet Lookup New&Cool

Expert Information from The Nemours Foundati

Burning Up: Facts About Your Ch

Are fevers dangerous? What should you do when your child has a fever? [duPont Hospital for Children](#) pediatrician [David West, M.D.](#), explains the basics.



IQ Assessment Tool - Netscape

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Bookmarks Location: <http://hlweb.nih.gov/iq/iqframes.asp> What's Related

Instant Message Internet Lookup NewCool

HSWG Information Quality

<http://KidsHealth.org/parent/healthy/fever.html> Assessment

Summary of responses: ([jump to score](#))

| Positive | Negative |
|-------------------------------|--|
| Author was identified | |
| | LEFT BLANK: No source references given |
| | LEFT BLANK: Did not state that non-reference information was opinion |
| Author's credentials listed | |
| Credentials are related | |
| Experiences relevant to topic | |
| Contact information provided | |
| Sponsorship identified | |
| Conflict or bias explained | |
| | LEFT BLANK: Sponsors have cont |

Document Done

Score & Explanations

IQ Assessment Tool - Netscape

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Bookmarks Location: <http://hlweb.nih.gov/iq/iqframes.asp> What's Related

Instant Message Internet Lookup NewCool

HSWG Information Quality

Final Score: 76.80%

[Return to the IQ Working Area](#)

Your assessment of the site has been saved. The computed score does not necessarily reflect the overall assessment outcome of a particular site.

Details of negative or missing criteria:

- If a source is not cited, then it should clearly state that the information is only based on opinion and not necessarily based on sound research.
- If a site is honest about where it gets its money or why it is biased, it helps you to determine how to use the information given. It is difficult to believe information found on a site if these conflicts or biases are not explained.
- If a contributors or sponsors have control over the content of a website, the information is more than likely biased.
- An explanation of what will be done with your information is very important. If you do not know what information and being gathered and what it will be used for, BE CAREFUL!

[Return to the IQ Working Area](#)

Document Done

IQ - One Tool for Education

- **Reminder - Internet presence does not give automatic credibility**
- **Introduce and reinforce attributes of quality**
- **Foster common vocabulary**

Internet Healthcare Coalition

- **Education**

- Disseminating principles to all stakeholders
- www.ihealthcoalition.org

How Can We Ensure Success?

- Excellence
- Ethics
- Education
- ⇒ **Enforcement**

Enforcement

- **Already established law**



- [Vision, Mission & Goals](#)
- [Where to Go](#)
- [Procurement Ops](#)
- [Offices and Bureaus](#)
- [Budget History Tables](#)
- [GPRA](#)
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About Privacy

Current News Releases

Media Advisory

New Internet Scam Targeted by FTC

Millions of Legitimate Web Pages and Innocent Web Surfers, Including Children, Affected; Agency To Announce New High-Tech Internet Lab

FTC Reports on Industry Efforts to Avoid Promoting Alcohol to Underage Consumers

Self-Regulation Can Be Effective,



[Text Version](#)



U.S. Food and Drug Administration

WHAT'S NEW

Year 2000

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INTERNATIONAL

Welcome to Internet FDA

The Nation's Foremost Consumer Protection Agency

FDA MODERNIZATION ACT

FDA Modernization Act



Foods



Human Drugs



Biologics



Animal Drugs



Cosmetics



Medical Devices/
Radiological Health



Freedom of
Information



Field
Operations



CHILDREN
& TOBACCO
Regulations
& Information



Toxicology
Research



MEDWATCH
Medical Products
Rebottling

Internet Healthcare Coalition “Anti-Fraud” Initiative

- **Education and Enforcement**
 - **International collection of regulations and contacts**
 - **International “fraud” reporting site**
 - **Complaints forwarded to appropriate government agencies**

Excellence, Ethics, Education and Enforcement:

Ensuring a
safe and
rewarding
experience
for the
Internet in
health

