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1.1 Clinical Informatics

CHAPTER OUTLINE

1.1.1 THE DISCIPLINE OF INFORMATICS

Clinical informatics is the discipline that results from the intersection between computers and medicine. According to the American Medical Informatics Association (AMIA), those who practice this art "transform health care by analyzing, designing, implementing, and evaluating information and communication systems that enhance individual and population health outcomes, improve patient care, and strengthen the clinician-patient relationship".[1]

1.1.1.1 Definitions of Informatics

Data are measurements taken in the real world, such as a patient's height or weight. Alone, data have limited value. Informatics, as a field of study, aims to transform data into usable, actionable **information**. Informatics includes knowledge acquisition, dissemination and implementation and everything in between, starting from basic science research and extending to clinical decision support systems. One way to understand informatics is by examining the kinds of questions that informaticists ask, such as:

- In research studies, how are the data are gathered?
  - How reliable is the recording mechanism? Is it susceptible to mechanical failure or human bias?
  - How often is it collected? Is that timeframe relevant to the question being asked?
  - How accurate is the measurement? Does it have the precision to show subtle changes? Is it reliable? (i.e. If you measure the same thing several times, do you get the same result?)

1 Gardner R., et al. J Am Med Inform Assoc. 2009;16:153–157.

- How are the data analyzed?
  - How are the data organized? Are the data from a single source or multiple sources? Can data from one source reasonably compare to data from another source? Should some form of correction be applied?
  - How do we account for missing data? Can we interpolate from adjacent measurements? How relevant are the missing data to our study? Do the missing data reflect a random failure or a systematic bias?
  - In what way are the findings tabulated? What statistical methods can be used? Is the data qualitative or quantitative? Is there enough data to properly conduct an analysis?
- Are my conclusions meaningful?
  - Is there a statistically significant finding in the data shown? Is this likely to make a real clinical difference, or just a laboratory difference? Are the data disease-oriented endpoints (DOEs) or are they patient-oriented endpoints that matter (POEMs)?
  - How can I tell if my findings are reproducible? Does my correlation imply causation? What other factors need to be controlled?
- How do I present the data?
  - Can I use standard methods, such as a line graph or bar chart, or do I need something more advanced like a bubble plot or a heatmap? Does the interpretation of the data change when I change the method of visualization?
  - What is the best way to publicize the information? Is it robust enough to be published in a peer-reviewed journal? If not, should it be reported locally to my group or my organization?
- Does the data demand a change in practice?
  - Are the findings compelling or are they ambiguous? Do they indicate a "better way" of doing things? Does the "old way" have any benefit that is not measured by my data? Do these findings apply to all populations or only to a specific population? How can I define the population most likely to benefit from my research?
  - Are there other sources of information that contradict mine? Are those studies comparable to what I am doing? Are they using similar methods? Can data from similar studies be comingled to produce more meaningful results?
- How do I bring this information to the forefront when the subject and decision maker (e.g. doctor and patient) are both present?
  - How do I identify patients for the intervention? Is the identification based on some simple, readily visible characteristics? Are the inclusion criteria rigorously algorithmic, or do they involve a "gut feeling" by one of the managers?
  - Once I identify the correct subject, how do I give the provider everything they need to know in order make the best decision possible? How do I know if providers are making good decisions? Are there cases when a machine should resist or even override a human decision?

1.1.1.2 History of Informatics

Until 1900, medicine was very much a cottage industry. Although doctors were formally educated, practice patterns varied widely and were based on dubious science. Medical recordkeeping was rare, and when it was done, it was almost always in the form of retrospective case reports of interesting or unusual patients.

The Flexner Report, released in 1910 chastised American medical education for having lax admission and graduation criteria and for not adhering to established principles of science. The report had a tremendous impact on medical education. Over the next decade, many smaller medical schools closed or merged. Clinical teaching in hospitals was now

under the control of medical schools. Requirements for medical licensure became much stricter.

As medical science began to mature, medical care was held to more rigorous standards. Doctors (and nurses) were expected to write notes on patient care at the point of contact, encouraging communication amongst the various caregivers. More and more, the resulting document was being used to explain, analyze or even critique the care received.

In 1910, the epidemiological study of disease began to gain traction with the publication of the International Classification of Causes of Sickness and Death. This compendium of illness sought to classify and tabulate all the different types of illness and causes of death in the United States. This document would later be shortened to the International Classification of Disease, or ICD. At the time of this writing, most hospitals are using the tenth revision of the ICD.

By 1960, mainframe computers were available in large research institutions, and many were used for the financial systems in hospitals. By 1970, a specialized health care programming language, called **MUMPS** (Massachusetts General Hospital Utility Multi-Programming System, also called **M**) became the dominant platform for hospital-based application development. Since a hospital generally had only one mainframe computer (with many terminals available for time-shared access), the Hospital Information System (**HIS**) was a huge, bespoke application, heavily customized for the host institution.

In 1966, the American Medical Association (AMA) released its first version of Current Procedural Technology (CPT), a set of procedural codes used to describe medical services. The initial version contained mostly surgical procedures, while subsequent versions included diagnostic and medical services. The CPT is updated every year and is copyrighted by the AMA. Entities who use CPT codes must pay licensing fees to the AMA.

In order to ensure accuracy, insurers developed standard formats for submission, processing and payment of claims. In most cases, this included CPT codes for services and ICD codes for diagnoses. This also represented the first time that an insurance claim could be rejected entirely by computer. If a claim didn't have a diagnosis appropriate to justify a procedure, the insurer's computer could identify the mistake and return it to the physician for clarification.

Simultaneously, and probably as a result of better reimbursement, the variety and quantity of medical services increased dramatically, resulting in significantly more information being generated for each patient encounter. In a private office, this information resided in large paper filing cabinets. In hospitals, much of it was stored in the HIS.

In the 1980s, computational power became exponentially cheaper with the arrival of the personal computer (PC). As a result, complex computing tasks shifted away from the monolithic HIS into smaller departmental applications. Although this allowed the purchase of commodity software and hardware, weaving these applications together required an intricate mesh of interfaces and protocols. Commonly, these interfaces failed to yield the tight integration that was present in the original HIS.

In the 1990s, insurers began demanding more structure in medical records. The medical record was also formalized so that Evaluation and Management services were reimbursed based on the thoroughness of the record with specific details required in sections of the chart, such as History of Present Illness, Review of Systems, Physical Exam and so on. Records that did not possess this level of detail were denied payment.

The need for robust and reliable documentation coupled with the rapidly increasing volume of data led to what we now know as the Electronic Health Record (EHR), or Electronic Medical Record (EMR).

The first EHR's were little more than word processors with privacy protection. Some offered spelling correction, but that was the limit of their interactivity. Today's EHR's not only record medical data but also analyze it and provide relevant clinical information and even suggest treatment options. The question of whether or not EHR's actually improve medical care is hotly debated.

EHR's got an enormous boost in popularity in 2009 with the Health Information Technology for Economic and Clinical Health Act (HITECH). This act established criteria for "meaningful use" of electronic medical records and listed a total of 25 capabilities that modern EHR's were expected to have. Most importantly, it also provided a large cash award to providers and institutions who implemented certified EHR technology. The cash awards

were divided into three stages. The first stage ran from 2011 to 2012 and involved data capture and sharing. The second stage, from 2012 to 2016, was intended to improve clinical processes. The third (and final) stage will measure improved outcomes.

1.1.1.3 Domains, Subspecialties of Informatics

There are many sub-fields of informatics, primarily defined by the type of information that is studied.

- **Clinical Informatics** is the application of informatics to delivery of healthcare services. It is also known as **applied informatics** and **operational informatics**.
- **Clinical Research Informatics** includes management of information related to clinical trials and also involves informatics related to secondary research use of clinical data, such as mining medical records for interesting information.
- **Consumer Health Informatics** analyzes information from the perspective of the health care consumer. It stresses health literacy, patient education and access to personal health records. The focus is on empowering consumers to manage their own health and make their own healthcare decisions.
- **Public Health Informatics** is focused on the health of communities rather than individuals. It includes surveillance, prevention, preparedness, and health promotion by identifying geographical, social or other environmental risks.
- **Translational Bioinformatics** involves the translation of large amounts of data into smaller chunks which can be used for proactive or predictive health. This includes harnessing very large data sources as well as new or innovative methods of collecting biological measurements (such as wearable computers)

1.1.1.4 Careers in Informatics

What can you do with a degree in informatics? Actually, quite a bit.

The majority of graduates will work in hospitals or larger medical practices to support clinical activities. A **physician champion** is a respected member of the medical staff who encourages his colleagues to embrace new technology. One common example is when a hospital switches from paper orders to Computer Provider Order Entry (CPOE). Many members of the medical staff will resist the change because they find the process time-consuming. The physician champion's responsibility is to demonstrate how the new process actually makes order entry more accurate and safer than it was before.

A **departmental information manager** collects and analyzes data for a particular department. He is involved in the selection, budgeting, implementation, integration and management of new technology. He helps make sure that the department's IT interests are aligned with those of the organization. An example is the manager of the Picture Archiving and Communication System (PACS) in the radiology department.

The **chief medical informatics officer** is responsible for supporting medical applications across the organization. This role varies greatly in responsibility. In some organizations, the CMIO reports directly to the Chief Executive officer (CEO) or the board. In others, the CMIO reports to the Chief Information Officer (CIO) or the Chief Medical Officer (CMO). The CMIO works with departmental information managers and quality officers to ensure that the organization's technology is powerful, reliable and useful. In many cases the CMIO recruits and trains physician champions in various specialties. When a non-physician occupies this role, the title is often **chief health informatics officer**.

Not all health care institutions can support permanent informatics officers, and instead rely on **health informatics consultants**, who work collaboratively with the organization's staff on a project-by-project basis. Their roles and responsibilities are very similar to permanent staff, but they have the advantage of bringing a perspective from many other organizations.

When technology vendors create new products, they require medical input in the development, implementation and training process. Some of the larger EHR companies maintain a staff

of physicians to advise and guide their development. This panel usually consists of doctors from many different specialties so as to provide as broad a spectrum of activity as possible.

Public sector clinical informaticists may be involved in epidemiology, health literacy, education, syndromic surveillance, prescription monitoring programs, health information exchanges (HIE's) and many other public health issues.

One can safely say that any time a doctor interacts with a computer, a clinical informaticist has been involved.

1.1.1.5 Professional Organizations

There are many fantastic organizations which aim to advance medical informatics. Some of the larger ones are listed here. In most cases, the information is taken from the respective organization's web site.

Departments of Health Information Management (formerly known as Medical Records) include professionals who organize, maintain, index, encode, categorize and store medical information. Two of the largest professional organizations are **American Health Information Management Association** (AHIMA) and **Healthcare Information and Management System Society** (HIMSS).

With over 100,000 members, AHIMA's primary goal is to provide the knowledge, resources and tools to advance health information professional practice and standards for the delivery of quality healthcare. AHIMA also provides certification pathways for health information managers, coders, and others.

HIMSS, with 52,000 members is a global, cause-based, not-for-profit organization focused on better health through information technology (IT). HIMSS leads efforts to optimize health engagements and care outcomes using information technology.

While HIMSS and AHIMA are geared towards management of medical records and Health IT, the **American Medical Informatics Association** (AMIA) and **American Nursing Informatics Association** (ANIA) represent healthcare providers and nurses.

AMIA, with about 5000 members, is probably the best known informatics association in the United States. The AMIA mission statement is: to lead the way in transforming healthcare through trusted science, education, and the practice of informatics. ANIA, with 3000 members is dedicated to advance the field of nursing informatics through communication, education, research and professional activities.

AMIA was the driving force in creating the Accreditation Council for Graduate Medical Education (ACGME)—certified fellowships and board examinations in Clinical Informatics. In the coming years AMIA will develop certification for non-physicians called Advanced Health Informatics Certification. The core curriculum for AHIC will likely mirror that of the Clinical Informatics board exam.

Health Level Seven International (HL7) is a not-for-profit, American National Standards Institute (ANSI)-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7 has more than 2300 members, including approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare. HL7 is most famous for endorsing an interoperability messaging standard, which we will learn more about in Sect. 3.4.4.

1.1.1.6 Current and Future Challenges for Informatics

Today is, perhaps, the golden age of medical informatics. There are several emerging trends that aim to make informatics much more relevant and valuable to health care.

1. Without a doubt, the US government's 20-billion dollar investment in health information technology through the Health Information Technology for Economic and Clinical Health Act (HITECH) has been the single greatest enticement for large and small medical practices

to convert their paper systems into electronic medical records. The reimbursement for a single provider is in the range of $40,000–$70,000, and for a large institution can run into the tens of millions of dollars. During the next decade, as the various phases of Meaningful Use criteria evolve, clinical informaticists are going to be intimately involved in creating, implementing, maintaining and certifying electronic medical records systems.

2. At the same time that money is being poured into health information technology, the cost of any unit of that technology is dropping precipitously. Widespread broadband internet access has allowed previously unimaginable access to data. In the coming years, wearable and implantable technology will provide a nearly continuous stream of measurements which will be stored safely and securely in ever-growing data warehouses. One of the great challenges for informaticists is to devise useful ways to sift through that data and provide meaningful displays through **data visualization**.
3. Quality measures and pay-for-performance (P4P) initiatives require providers to collect metrics on their provision of care. Payors are inviting hospital systems to share the risk of caring for patients, and the more quality metrics that are met, the greater the overall reimbursement. Future work includes creating fair and reliable metrics, aggregating relevant and meaningful data, and determining proper incentives.
4. Telemedicine is allowing people in remote areas access to specialists all over the world. Clinical informaticists will be highly involved in creating networks, defining scopes of practice and enabling these kinds of practices.
5. **Disease management** is a system of rules and supports designed to manage specific medical conditions, empowering individual patients to manage their own illness. This process has been used successfully in diabetes, hypertension, heart failure and many other conditions. In most cases, this requires patients to periodically record their own measurements. From time to time, these measurements are reviewed and management decisions are made according to a predefined algorithm. In some cases, algorithmic management actually produces outcomes superior to those actively managed by physicians. Clinical informaticists will play a pivotal role in transitioning patients into disease management programs.
6. While health information exchanges offer the promise of sharing patient data between institutions, true interoperability is far away. Although many standards for information exchange exist, vendors are reluctant to allow their products to be too similar for fear of losing market share. As a result, patients who are seen in different institutions are faced with significant difficulty when they try to transfer their medical records from one system to another. When the records are actually transferred, the receiving institution is usually unable to incorporate the new data in a meaningful way. During the coming years, informaticists will develop protocols and specifications to improve the sharing of data between different software vendors.
7. From a physician standpoint, very few electronic health record systems can be considered easy to use, and none are easier than the paper and pen they were trained on. One of the great challenges of the coming decade is to create more intuitive user interfaces and more responsive decision support systems. For example, one of the meaningful use stage 2 criteria was that at least 60% of orders are entered by a provider (Computer Provider Order Entry, (CPOE)). As a result, many physicians complain that their clinical workload has increased dramatically as they have now taken on the additional responsibility of being data-entry clerks. Finding ways to mitigate this workload while maintaining patient safety is a difficult task indeed.

1.1.2 KEY INFORMATICS CONCEPTS, MODELS, AND THEORIES

Key concepts in clinical informatics can be found throughout this book. Those that do not get specific treatment elsewhere can be found here.

The **Data-Knowledge-Information-Wisdom** (DKIW) framework expresses the way that medical facts and measurements become increasingly useful as they are collected,

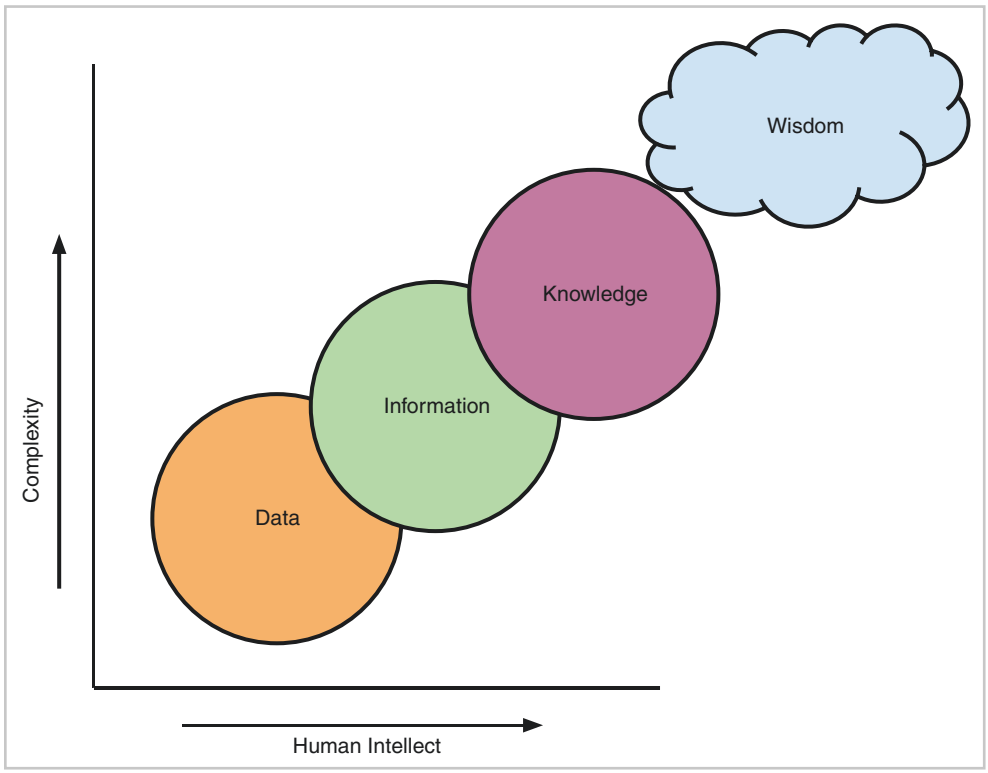


FIGURE 1-1

The Data-Information-Knowledge-Wisdom framework. Data are interpreted into information. Information is analyzed into Knowledge. Knowledge is applied and becomes wisdom

analyzed and displayed. **Data** are the smallest components of the DIKW framework. They are usually self explanatory and refer to a single measurement in time (such as blood pressure). When a series of data points are connected, making a meaningful picture, the result is **Information.** Information can be thought of as "data with context". For example, a series of blood pressure measurements showing a steady decline is much more meaningful than a single, isolated measurement. Information answers the questions of "who", "what", "when" and "where". **Knowledge** is information that has been analyzed so that relationships and meanings are visible. Knowledge answers the questions of "why" or "how". For example, a downward trending blood pressure may be associated with sepsis in a sick person or possibly with better control of an otherwise healthy hypertensive patient. **Wisdom** refers to the appropriate use of knowledge to manage and solve human problems. Wisdom also implies ethical considerations, such as examining the patient's needs and desires and consolidating them into sound clinical judgment. Wisdom is knowing when to initiate emergency treatment for septic shock and when to continue observation. (See Fig. 1-1).

Informatics Competencies

The Technology Informatics Guiding Education Reform (TIGER)[2] Summit listed three competencies in informatics:

Computer Competency is a set of skills that allow individuals to use computer technology to accomplish tasks, such as using a word processor or spreadsheet.

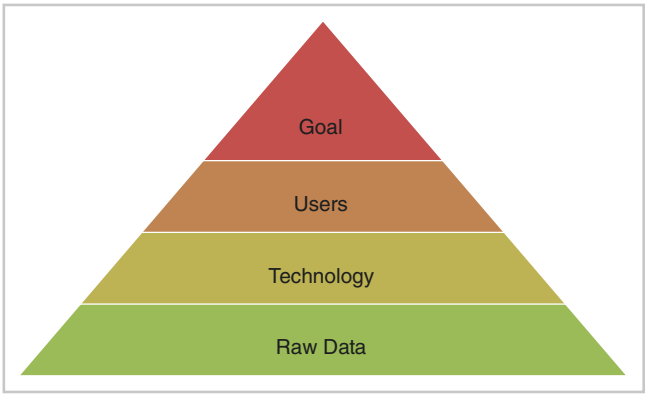
Information Literacy is a set of cognitive processes that allows an individual to recognize what, when and where information is needed and how to obtain it.

Informatics Management is a process consisting of (1) collecting data, (2) processing the data, and (3) presenting and communicating the processed data as information or knowledge.

2 http://www.thetigerinitiative.org/docs/tigerreport_informaticscompetencies.pdf

FIGURE 1- 2

The Nursing Informatics Pyramid, after Schwirian. Raw data forms the base, which is consumed by technology and presented to the user in order to achieve a goal



Nursing Informatics Pyramid

According to the Schwirian model, nursing informatics begins with **raw data**, such as patient observations, progresses through **technology**, which might be some form of data processor, then is presented to the **users** (in her case, nurses) and then finally reaches a predefined **goal**. (See Fig. 1-2).

For example, a patient in the intensive care unit (ICU) has low blood pressure. He is attached to a monitor which measures his central venous pressure (CVP). The physician consults the CVP readings and decides to increase or decrease the rate of IV hydration. In this case, the CVP measurements are the raw data. The monitor represents the technology. The physician is the user and the goal is appropriate fluid management for the patient.

1.1.3 CLINICAL INFORMATICS LITERATURE

1.1.3.1 Core Literature

Amazon.com sells about 5000 books on different kinds of informatics and there are over 100 peer-reviewed journals related to the study of information. With this much literature, what is the best way to identify the most relevant and trustworthy sources?

The following recommendations apply to all academic literature, not just clinical informatics:

1. Look at the author and his scholarly reputation. Some authors have a reputation for producing excellent science, while others do not. Alone, this may not have much relevance. Remember that even famous scientists like Galileo, Mendel, Kepler and others were rejected at their time.[3]
2. Look at the author's institution. Nearly all medical journals require the author to be a representative of an institution, such as a hospital or university. The larger the institution, the more zealously they protect their scholarly reputation. Most big institutions have academic integrity boards and will sanction or fire their members for academic violations. For example, if a professor at a prestigious university publishes bogus research, he will quickly be terminated in order to preserve the reputation of the institution. Therefore, both the institution as well as the author have great incentive to produce high-quality work.
3. Look at the publication and consider its scholarly reputation. Reliable journals are **peer-reviewed**, which means that every article is reviewed by other experts in the field of study to make sure that the research is reasonable and logical. In some cases, reviewers will ask to see raw data or original specimens before they are willing to render judgement. Articles that don't pass this test are never published.

3 Similarly, consider the science proffered by Dr. Mehmet Oz.

4. Check the publication date. A maxim in medicine is that you should never be the first person or the last person to adopt a new teaching. If an article is too new, it has not had a chance for the community to assess its value. If an article is too old, it may refer to ideas that have been supplanted by newer, better or safer practices.
5. Be careful with websites. Educational (.edu) and governmental (.gov) websites tend to have large institutions which govern their contents and make efforts to preserve accuracy. For example, the Centers for Disease control (www.cdc.gov) is an excellent source of up-to-date information on emerging infectious diseases. Emedicine (www.emedicine.com) hosts many scholarly monographs on a variety of medical subjects. On the other end of the spectrum, it takes only a few dollars to set up a commercial website and there is absolutely nothing preventing a person from widely disseminating false information.[4] Somewhere between these extremes lies sites like Wikipedia (www.wikipedia.org) which has hundreds of thousands of articles which are continuously reviewed by millions of people. While the site is anonymous and continuously edited (i.e. unstable), it is generally considered useful, but not reliable.

Suppose you limit yourself to the highest quality publications and only read current, peer-reviewed scholarly journals with good reputations. How can we separate the good journals from the great ones? One way is to look at absolute circulation. If a journal is valuable, people will spend money to buy it. For example, the *New England Journal of Medicine* is the world's most popular printed medical journal with over 200,000 subscribers. Does that make it the most reliable?

Another way to rank journals is to see how often other scientists cite the work they publish. The simplest method is known as the **impact factor**. Journal impact factors are calculated based on the number of articles published during the past 2 years and cited during this year. For example, to calculate the 2015 impact factor for a journal, we tabulate the total number articles published in 2013–2014. Next, we count the total number of citations for those articles in 2015. The ratio of citations to articles is the impact factor. An impact factor of 1.00 means that, on average, each article is cited once during the following year. In general, editorials and letters to the editor are excluded from the calculation. Table 1-1 shows the top 10 informatics journals as ranked by Journal Impact factor. However, since the methodology of journal ranking is well-known, there will always be attempts to game the system. See box 1–1 for some examples.

TABLE 1-1

JOURNAL IMPACT FACTORS FOR THE MOST POPULAR INFORMATICS PERIODICALS

RANK	JOURNAL	IMPACT FACTOR
1	Journal of Medical Internet Research	4.669
2	Journal of the American Medical Informatics Association	3.932
3	Implementation Science	3.47
4	International Journal of Medical Informatics	2.716
5	Journal of Biomedical Informatics	2.482
6	Journal of Telemedicine and Telecare	1.736
7	Telemedicine Journal and E-Health	1.544
8	Biomedical Signal Processing and Control	1.532
9	BMC Medical Informatics and Decision Making	1.496
10	Computers in Biology and Medicine	1.475

4 Although I don't have an example of a bad website handy, numerous examples exist. Try searching for "male enhancement" on your favorite search engine.

Box 1-1: Methods to Increase Impact Factor

As you can imagine, many things determine how often a journal is cited, some more obvious than others. For example, with the New England Journal of Medicine's vast circulation, it is no surprise that it is widely cited. However, with a little creativity, there are ways that smaller journals can enhance their impact factor.

1. *Make the journal free.* Most citations come from journals published and indexed in PubMed or one of its commercial derivatives. When the full text of the paper is available online for free, it is much more likely to be cited.[5] PubMed Central® (PMC) is a free full-text archive of biomedical and life sciences journal literature at the U.S. National Institutes of Health's National Library of Medicine (NIH/NLM). There are over 2000 fully participating journals and over four million free full-text articles.
2. *Articles should be appropriately titled.* Articles with short titles describing the results are cited more often.[6]
3. *Review papers* and *method papers.* Review papers are reviews of other papers and tend to be cited more frequently than original research. This effect becomes even more pronounced when an editor encourages authors to review only papers published in the same journal. Method papers (i.e. those that describe a method for a particular procedure) are cited often because anyone who wants to use that procedure in a study has to cite the original paper.
4. *Publish the best articles in January*. Since writing a paper usually takes a few months, articles written in December are much less likely to be cited in papers published during the following year, which is how the impact factor is calculated.

TABLE 1-2

SCIMAGO JOURNAL RANK FOR THE MOST POPULAR INFORMATICS PERIODICALS

RANK	TITLE	SJR
1	Journal of the American Medical Informatics Association : JAMIA	2.594
2	Implementation Science	1.988
3	Medical Image Analysis	1.977
4	Journal of Medical Internet Research	1.685
5	International Journal of Medical Informatics	1.507
6	BMC Medical Research Methodology	1.392
7	Journal of Biomedical Informatics	1.097
8	Journal of NeuroEngineering and Rehabilitation	1.053
9	Journal of Telemedicine and Telecare	0.955
10	Journal of Clinical Bioinformatics	0.802

Another common method to rank journals is using the SCImago Journal Rank, a system modelled after Google's PageRank algorithm. This algorithm also measures the relative frequency that a journal is referenced. It gives greater weight to prestigious journals and gives lesser weight to journals that cite themselves. (see http://www.scimagojr.com/journalrank.php?category=2718) (Table 1-2).

5 For example, BMJ, the British Medical Journal has an impact factor 17. BMJ makes every research article freely available as soon as it is published.

6 Paiva CE, Lima JP da SN, Paiva BSR. Articles with short titles describing the results are cited more often. Clinics. 2012;67(5):509–513.

1.1.3.2 Critical Analysis of Informatics Literature

Statistical analysis is an essential component of all medical research including informatics. Since much of informatics research revolves about describing new techniques and demonstrating their efficacy, the informaticist must be familiar with basic statistical methods, such as sensitivity, specificity, precision, recall, p-values, confidence intervals and others. (These will be reviewed in Sect. 2.1.2).

In addition to being statistically significant, the results must be clinically significant. For example, a study may show a particular therapy is associated with a statistically significant improvement from 33% cure rate to 33.1% cure rate. Although numerically advantageous, this therapy offers only trivial benefit to the patient and should be considered in the context of expense, side-effects, stewardship and other factors.

Similarly, a study may examine a very limited population and attempt to extrapolate to a more general population, or there may be other methodological flaws that weaken the author's conclusions. Bias may have tainted the results, or sponsorship by a pharmaceutical company may have cast a shadow of doubt upon the study authors. These will be reviewed in Sect. 2.1.1.

1.1.4 INTERNATIONAL CLINICAL INFORMATICS PRACTICES

Kyle Marshall

Until recently, countries such as the United Kingdom (UK) and Denmark led others, like the United States, in regards to informatics research, development, and adoption (Collen 1994). The term *informatics* originated in the 1960s. In 1962, Philippe Dreyfus of France coined the term "informatique" as the application of computers to the storage and processing of information (Fourman 2002). The Soviet engineer and scientist Alexander Mikhailov used the term "informatika" to refer to the field concerning the properties and structure of information (Kabene 2010). Around the same time, the German computer scientist Karl Steinbuch published a paper describing "informatik," or the automatic processing of information (Steinbuch 1957). Prior to this, and even now in some countries, informatics is incorrectly synonymous with computer science.

Early on, members of health professions with interests in informatics were thinly scattered across their respective countries. Learning what was being discussed or done in other locations was difficult. Professional organizations were created as a way for individuals to come together and share their work, research, and ideas.

In the UK, the British Computer Society (BCS), founded in 1957, was conceived to provide a national body representing all aspects and activities of the emerging computing profession (Hayes and Barnett 2008). Initially, there were five health specialist groups which served as a forum for discussing medical computing possibilities as a specialty. Over time, the number of groups has increased as has their focus on health informatics (Hayes and Barnett 2008). In 2005, the BCS Health Informatics Forum (BCS HIF) was formed to provide leadership in all aspects of health informatics.

In the late 1990s and early 2000s, the United Kingdom's single-payer, tax-supported health system called the National Health Service (NHS), along with other companies, began a large and ambitious project to create and deploy a single electronic health record system for the entire country. Unfortunately, the idealistic goals were too lofty. The project took longer than expected and costs quickly ballooned, wasting more than $24 billion (12 billion GBP) of taxpayer money (Stone 2014). Lessons learned from this informatics failure include the importance of a competitive model that encourages electronic health record (EHR) innovation and the value of continuous improvement. Also, EHRs need to be able to accommodate large populations with significant diversity (Stone 2014). Despite this failure, the UK is still seen as a leader in the field of health IT. More recently, their GP2GP program facilitates the electronic transfer of health records when a patient moves from one general practitioner to another.

In France, an annual International Medical Informatics Conference was started in 1969 by the Institut de Recherche en Informatique et en Automatique (IRIA). This organization, along with the BCS, and leaders in other countries such as Denmark, Belgium, Finland, and Italy, laid the foundation for the European Federation for Medical Informatics (EFMI) at a meeting held under the auspices of the World Health Organization (WHO) in 1976. Over the next few decades, initial work of the EFMI focused on decision support, image processing, multimedia patient records, cooperative working, telemedical applications, and signal handling (Hayes and Barnett 2008).

In Denmark, MedCom's Health Data Network has been cited as an excellent model of health informatics implementation. While not an EHR, the Health Data Network acts as a data integrator and supports interoperability by facilitating communication and health information exchange. All hospitals, pharmacies, and emergency medicine physicians use this system, as well as 90% of general practitioners. More than 80,000 messages are sent through this system daily (Kuhn et al. 2007).

In Singapore, key drivers for change, as it relates to health information technology, include a shift in national demographics and burden of disease, threats of emerging infectious disease, and the globalization of healthcare services (Lim 2006). By 2030, it is estimated that 1 in 5 Singaporeans will be over the age of 65. This, along with other factors, has motivated the country toward an integrated healthcare delivery system with better allocation of resources (Liew 2015). This movement was spearheaded by the Ministry of Health (MOH) and the associated holding company (MOHH) which owns all public hospitals. In 2008, a national health informatics strategy was formed, along with clinical advisory groups, task forces, and the Integrated Health Information Systems (IHiS) entity, which acts as the de-facto Chief Information Officer and centralized IT office for all public healthcare groups. This work has led to the development of a national electronic health record with the vision of "one patient, one record." Key to this implementation were stakeholder input, support of the government, rich technology foundations, and collaboration (Liew 2015). An example of Singapore's success is the Ng Teng Fong General Hospital (NTFGH), which achieved Healthcare Information and Management Systems Society's (HIMSS) prestigious Electronic Medical Record Adoption Model (ERAM) Stage 7 only 16 months after opening (JurongHealth 2016). ERAM is an eight stage model that measures the adoption and utilization of EHR functions. NTFGH is only the fifth hospital in all of Asia Pacific to reach Stage 7 (JurongHealth 2016).

In Australia, the Electronic Health Records Act of 2012 laid the foundation for a national EHR system. Integral to their approach was the importance of focusing on the public's interest as well as privacy and data protection. The act requires personal health data to be encrypted prior to transmission, judicial penalties for privacy breaches, allowing patients to opt-out from the national EHR at any time, and creating the Access Control Center which provides participants full control over their data (OECD 2013). The health informatics network in Australia is made up of a number of discipline, focus, or geographically based health informatics groups which are members of the Health Informatics Society of Australia (HISA). HISA is the country's official representative to international informatics associations (Hovenga 1996).

In developing countries, challenges to health informatics are numerous, including structural deficits in physical networks, high costs, geographic dispersion, and high percentage of patients living in rural areas (Luna et al. 2014). Mobile health or telemedicine is proving to be useful, when there is lack of infrastructure, but not without its own difficulties, such as fragmented information and issues with scalability. Software can also be a challenge and expense. Open-source solutions are a viable alternative in resource-limited countries. For example, PostgreSQL is a powerful open-source object-relational database system that has been shown to be reliable and scalable (Luna et al. 2014). Open Medical Record System (OpenMRS), built with an enterprise-quality data repository modeled on the Regenstrief Medical Record system, enables the customized design of EHRs with no programming experience (Mamlin et al. 2006). It has been successfully implemented in Africa, Asia, and Central America (Luna et al. 2014). Other challenges facing health informatics in developing countries include the lack of developed health IT agendas, cultural barriers, lack of interoperability standards, and a limited qualified workforce.

In order to support the field and profession, the International Medical Informatics Association (IMIA), began as a special interest group and technical committee in the late 1960s under the International Federation for Information Processing (IFIP) (Kabene 2010). The organization developed into a world body linking medical informatics across the globe and allowed leaders to meet other experts in every aspect of health informatics (Hayes and Barnett 2008). International conferences are held every 3 years and recent locations include Brisbane, San Francisco, London, and Seoul.

Even though the countries and organizations above have made tremendous strides in developing and improving the field of informatics, the full impact falls short of expectations. As is true in other fields, the future success of clinical informatics on an international stage requires the knowledge of past challenges and of those yet to be faced (Luna et al. 2014).

1.1.5 ETHICS AND PROFESSIONALISM

Texts on medical ethics usually begin with ***Primum non nocere,*** a Latin phrase that means "**first, do no harm**." The cardinal sin in clinical informatics is inappropriate disclosure of personal information. Since informaticists are often in control of large amounts of data, privacy tends to be the primary context of ethics discussions. Ethics concerns itself with finding balance between harms and benefits.

HARMS	BENEFITS
Disclosure of private information can harm a person by causing shame or embarrassment, or can affect insurability, employability and other social opportunities.	Physicians can review records to diagnose disease, avoid duplicative tests, design and share treatment plans. Researchers can secondarily analyze records to improve public health.

Privacy is the right of an individual to control disclosure of his personal information, while **confidentiality** refers to responsibility to protect information that has been received and to use it only in ways that benefit the patient. **Security** is the set of policies and procedures which safeguard the integrity of the information systems.

Broad categories of inappropriate disclosure include: (in decreasing order of occurrence)

1. **Insider accidental disclosure**. For example, two physicians discuss a patient while standing in an elevator; a nurse forgets to log out of a computer whose screen displays a patient's lab results.
2. **Insider Curiosity**. A medical professional is concerned about a co-workers adherence to medical recommendations and looks through her chart to see how she is doing.
3. **Insider Criminality**. A medical professional deliberately copies medical records with the intent to sell. For example, a celebrity comes to the hospital and an unreputable newspaper pays a filing clerk for inside information.
4. **Outsider Criminality**. Hackers use a combination of social engineering and technical vulnerabilities to break into a system to steal data. A complete medical record can fetch $10 on the black market (as compared to a stolen credit card which is worth $1 or less).[7] One increasingly common tactic is for the hackers to disable a network or encrypt data and demand money in exchange for return of normal functioning. (e.g. ransomware)

In addition to doing no harm (referred to as the principle of **non-malfeasance**), some other general medical ethical principles as applied to informatics include:

7 Humer C, Finkel J. Your medical record is worth more to hackers than your credit card. Reuters 2014. http://www.reuters.com/article/us-cybersecurity-hospitals-idUSKCN0HJ21I20140924 (accessed November 26, 2016).

1. **Autonomy**—the patient's right to make his own decisions. In the context of informatics, one of the most pressing questions relates to ownership of medical records. If records belong to a patient, should she be able to modify them at will, even if she may be misleading her doctors? If the records belong to the EMR vendor, may they sell the data to third parties? (Spoiler alert: they have.[8])
2. **Beneficence**—a provider should act only in the best interest of the patient; computer systems should be implemented for the benefit of the patient and society, not strictly for the insurer, provider or institution.
3. **Justice/equality**—fair distribution of limited resources. It is well known that poorer patients are less likely to have broadband internet access, which may limit their access to their medical records compared to patients with greater resources.
4. **Dignity**—patients have a right to be treated respectfully; while computers treat everyone with the same degree of dispassion, it could be considered embarrassing to have to check a computer for lab results.
5. **Honesty**—providers must be completely truthful with their patients at all times; again, this is a human foible. Computers are unable to lie, although improper programming can yield results that are deceptive or misleading.
6. **Integrity**—a person should fulfill their obligations to the best of their ability.[9] EMRs have the potential to boost integrity because of their advanced auditing functions and non-repudiation.

A Clinical Decision Support (CDS) system has its own set of ethical issues.

1. CDS should only be implemented after thorough evaluation of safety and efficacy, just like pharmaceuticals or medical devices.
2. All systems can provide misleading information if misused or misconfigured. All users of tools should be provided adequate training and availability of help should they need it.
3. The system should only provide *support* for decisions. Actual decisions must be made by professionals on the basis of their licensure, training and experience.

The Code of Ethics published by the International Medical Informatics Association[10] is summarized below.

1. **Information Privacy:** patients have a right to keep their information private.
2. **Openness**: when personal information is stored, the subject must be made aware of how the information is used.
3. **Security**: when data are collected, they must be protected from loss or corruption with all reasonable methods available
4. **Access**: the subject of an electronic record has a right to view, modify and correct his own information.
5. **Legitimate Infringement**: when the data must be used by other persons, it is done in a way that is most beneficial to society.
6. **Least Intrusive Alternative**: when personal data is used, only the minimum necessary should be accessed and it should be used in a way that is least intrusive to the subject.
7. **Accountability**: whenever personal data are used, it must be justified and explained to the affected person.

8 Sittig, DF, Singh H. Legal, Ethical, and Financial Dilemmas in Electronic Health Record Adoption and Use. Pediatrics. 2011 Apr; 127(4): e1042–e1047. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3065078/
9 Mercuri, JJ. The Ethics of Electronic Health Records. Clinical Correlations. January 15, 2010. http://www.clinicalcorrelations.org/?p=2211
10 See http://www.imia-medinfo.org/new2/pubdocs/Ethics_Eng.pdf

In addition, health information professionals (HIPs) have particular responsibilities to the patients, doctors, institutions, society at large, the informatics profession and to themselves.

Some examples include:

1. **Patient**: When a medical record is created, the HIP has the obligation to inform the patient that the record exists. In addition, the patient should know who created the record and for what purpose, where the information came from and who verifies it, who maintains it, who has access to it, and under what circumstances it may be communicated to other parties, and what rights the patient has regarding his record. In addition, the HIP should ensure the security, reliability and integrity of the record using reliable mechanisms. When these safeguards fail, the HIP has a duty to inform the patient about the data breach.
2. **Providers**: The HIP must assist providers by providing them with the best quality information possible and keep them informed when data may be unreliable.
3. **Institutions**: HIPs must exemplify loyalty and integrity to their employers by implementing the highest quality standards for data collection, storage, retrieval, processing, accessing, communication and utilization. They must notify their institutions of any possible impairments in quality or security of the data.
4. **Society**: When data are collected from a community, the HIP should ensure that only data relevant to providing healthcare are actually collected. When community data are acquired, they are de-identified as much as possible.
5. **Self**: HIP's should recognize the limits of their competence and be willing to ask for help. They should take responsibility for their actions and avoid conflict of interest.
6. **Profession**: In order to maintain the reputation of the profession, HIP's must act ethically in all circumstances. They should develop standards of professional competence and ensure that these standards are applied impartially and transparently.

1.1.6 LEGAL AND REGULATORY ISSUES

Federal Law

The Patient Protection and Affordable Care Act of 2010 (PPACA, also known as Obamacare) intended to decrease the number of Americans without health insurance by creating statewide insurance exchanges and by increasing eligibility for Medicaid, free health insurance for the poor. The act sought to level the costs of insurance by forcing insurers to grant policies to people regardless of pre-existing conditions and prohibited cancellation of policies when patients became too sick (a process known as rescission). The act also encouraged the formation of **Accountable Care Organizations** (ACO's) which would be reimbursed based on achieving certain benchmarks in patient care.

ARRA and Meaningful Use

The American Recovery and Reinvestment Act of 2009 (ARRA) provided a government bailout to many failing companies. A section of that act, the Health Information Technology for Economic and Clinical Health (HITECH) act set aside approximately $18 billion to fund the implementation of electronic health records. Eligible Providers (EPs) who were able to demonstrate **meaningful use** of healthcare technology were given awards of up to $70,000. Critical Access Hospitals (CAHs) received grants of $1 million or more.

The Meaningful Use program was managed by the Center for Medicare and Medicaid Services (CMS) and was divided into three stages. Stage 1, data capture and sharing, ran

11 https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Hosp_CAH_MU-TOC.pdf

from 2011 to 2012.[11] Requirements were divided into two categories: (1) core requirements which must be met completely; and (2) menu options, where individuals could select 5 of 9 options to satisfy the requirement. When the entity could attest to meeting the requirements, it was eligible to receive money from the government. Some of the Stage 1 requirements included Computerized Provider Order Entry (CPOE); medication lists; drug-drug, drug-allergy interaction checks; clinical decision support; and providing patients with electronic copies of their medical record and discharge instructions. Most of the requirements maintained certain threshold values for success. For example, the measure was considered a success when 10% of patients were offered electronic copies of their record or 30% of laboratory orders were entered through CPOE.

EHR Systems that were capable of these tasks had to be certified by the Office of the National Coordinator (ONC), or by one of its approved testing labs. As you can imagine, this was an incredible market opportunity for firms that created or certified EHRs. One of the drawbacks to this process was that the goals of the EHR were defined externally by CMS instead of by actual providers. Predictably, hospitals and providers purchased many systems that were difficult to use but met all the CMS criteria. This resulted in mistrust and frustration with EHRs.

Meaningful use stage 2, advance clinical processes, ran from 2012 to 2014 (although certain providers may attest with modified criteria as late as 2017). In addition to upgrading the threshold for success of various items in stage 1, it included provisions to track medications from order to administration using assistive technologies (such as bedside barcode scanning) and electronic transmission of the medical record in a structured format known as the **Consolidated Clinical Document Architecture** (CCDA). Some of the menu options included electronic prescribing (eRx) and recording progress notes in the EHR.

Meaningful use stage 3 started in 2016, however it will be replaced by the Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act, known as MACRA. There are eight requirements for stage 3.

1. PHI: Entities must conduct a risk analysis to find vulnerabilities which might lead to data breaches and disclosure of protected health information (PHI).
2. eRx: At least 80% of prescriptions must be electronic.
3. CDS: Clinical decision support must be used for at least five interventions; drug-drug and drug-allergy checking must be in place.
4. CPOE: Orders for laboratory, radiology and medication must be entered electronically by the provider.
5. Patient Portal: More than 80% of patients must be given personal access to the EHR, and 35% must have the option to receive educational information.
6. Patient Engagement: More than 25% of patients must access their EHR; 35% must receive a secure digital message from their provider; 15% must provide patient-generated health information (such as from a fitness tracker).
7. HIE: More than 50% of care transitions or referrals include transmission of electronic records; providers who are seeing a patient for the first time must acquire medical records from a secondary source at least 40% of the time; at least 80% of new patients must have their medication list reconciled with an online source.
8. Public Health: Providers must report data to three of the following: immunization registry; syndromic surveillance; public health registry; clinical data registry; case reports of reportable conditions.

After Meaningful Use Stage 3, what is the incentive for providers and hospitals to continue using EHRs? The Merit-Based Incentive Payment System (MIPS) is a new payment

mechanism that starts in 2019, based on performance in four categories: quality, resource use, clinical practice improvement and meaningful use. Providers will receive grades in each of these areas and a total composite score will be used to determine reimbursement. As with most of these program, it begins as an incentive for high achievement but becomes a penalty for low achievers after a few years.

Other Federal Laws

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides data privacy and security provisions for safeguarding medical information. See Sect. 3.1.4 for more information. The executive branch of the federal government is discussed more in Sect. 1.2.4.

State and Local Government

While the federal government enacts national laws, states are responsible for much of the day-to-day governing of healthcare. Licensing of physicians, nurses, other health professionals, hospitals and insurers is all controlled at the state level. Different states have different regulatory requirements and licenses are not transferrable from state to state.[12]

Most public health programs, such as sanitation, investigation of epidemics and food inspections, are the responsibility of state or municipal authorities. However, in each case, the federal Centers for Disease Control and Prevention provides national oversight.

Private Regulators

In the mid 1900s, the American Medical Association (AMA) helped create a number of organizations which provide regulatory support to healthcare. The Association of American Medical Colleges (AAMC) helps accredit medical schools and coordinate the application process. The Accreditation Council for Graduate Medical Education (ACGME) monitors and accredits residency programs. The American Board of Medical Specialties (ABMS) and its member boards (such as the American Board of Preventive Medicine) make pronouncements about standards of care and certify individuals as having expertise in their specialty.

In order to receive payment from the Centers for Medicare and Medicaid Services (CMS), hospitals must be **deemed** compliant. Deeming authority is granted to state health agencies as well as private companies, such as The Joint Commission, Det Norske Veritas Healthcare, Inc. (DNV) and Healthcare Facilities Accreditation Program (HFAP).

A Complex Partnership

It turns out that regulation is achieved by a meshwork of federal, state and private regulators. For example, in order to market a new drug, a manufacturer has to file with the United States Patent and Trademark Office (USPTO) and get permission to begin testing from the Food and Drug Administration (FDA). It must then try to get the drug included on formularies of various insurers and hospitals, which are private companies regulated by state authorities. Finally, it must persuade pharmacists to stock the drug and physicians to prescribe the drug. Pharmacists and physicians are state-licensed.

12 In the past, most states would grant licenses to doctors who had licenses in other states as part of a process called reciprocity. At this point, the only state that still has reciprocity is Michigan. Some states, such as New Mexico will grant short term Endorsements which allow physicians to practice in the state, but only under certain circumstances.

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