Health Information Technology Policy

27

Robert S. Rudin, Paul C. Tang, and David W. Bates

After reading this chapter, you should know the answers to these questions:

- Why have health care professionals in the U.S. been slow to adopt electronic health records and other forms of health IT?
- How can public policy promote the adoption and use of health IT?
- How does health IT support national agendas and priorities for health and health care?
- Why it is important to measure the value of health IT in terms of improvements in care quality and savings in costs?
- How can public policies safeguard patient privacy in an era of electronic health information?
- What are the main policy issues related to exchanging health information among health care organizations?
- What are the major tradeoffs for regulating electronic health records in the same way that other medical devices are regulated to ensure patient safety?
- What policies are needed to encourage clinicians to redesign their care practices to exploit better the capabilities of health IT?
- How does the U.S. approach to health IT policy compare with those of other countries?

27.1 Public Policy and Health Informatics

In the year 2000, an international survey in 20 of the world's most developed countries asked physicians about their use of electronic health records (EHRs; see Chap. 12). The survey found that in many of these countries, EHR penetration was high, especially for primary care physicians. Some countries such as Sweden and the Netherlands achieved near universal adoption with almost every physician using some form of EHR (Fig. 27.1). However, in other countries such as France and Portugal, only a few percent of physicians used them. The United States ranked 16th with only 17 % of physicians adopting EHRs.

Why would there be such variation in the levels of EHR adoption? And why would the U.S., which spends far more money per person on health care than any other country, be so far behind? The reason is not lack of interest among medical leaders. Since 1991, the U.S.-based Institute of Medicine (IOM)[1] has published

R.S. Rudin, BS, SM, PhD (✉)
Health Unit, Rand Corporation,
20 Park Plaza Suite 920, Boston 02116, MA, USA
e-mail: rrudin@rand.org

P.C. Tang, MD, MS
David Druker Center for Health Systems Innovation,
Palo Alto Medical Foundation, 2350 W. El Camino
Real, Mountain View 94040, CA, USA
e-mail: paultang@stanford.edu

D.W. Bates, MD, MSc
Division of General Internal Medicine and Primary
Care, Department of Medicine, Brigham and
Women's Hospital, 1620 Tremont St., Boston 02120,
MA, USA
e-mail: dbates@partners.org

---

[1] http://www.iom.edu (Accessed 12/9/2012)

E.H. Shortliffe, J.J. Cimino (eds.), *Biomedical Informatics*,
DOI 10.1007/978-1-4471-4474-8_27,

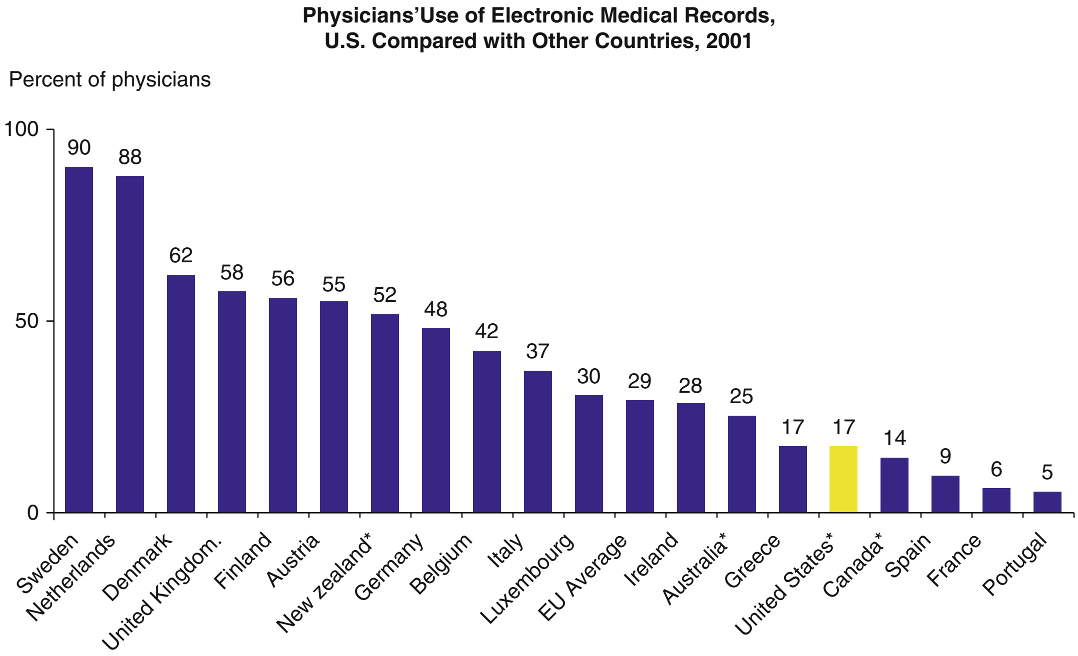


Fig. 27.1 Physicians Use of Electronic Medical Records in Developed Countries. Source: Commonwealth Fund National Scorecard on U.S. Health System Performance, 2006; European Union EuroBarometer (2001); Commonwealth Fund International Health Policy Survey of Physicians (Harris Interactive 2002); * data is from the year 2000

several widely cited reports extolling the potential benefits of health IT, calling for greater use of EHRs, and making the case that computers are critical for modernizing and improving health care systems. The reason for low adoption is likely not a lack of availability of EHR technology either. EHR vendor companies that have succeeded in Sweden or the Netherlands, for example, would undoubtedly try to expand into larger and more lucrative markets, especially in the U.S. Yet in 2013, many U.S. physicians still use paper charts.

To understand these low adoption rates of EHRs and how to accelerate adoption, one must look to public policy. The influence of policy can be found throughout a health care system. Policies shape the structure of health care delivery organizations and the markets for medical products. Directly or indirectly, policies influence the behaviors of all health care stakeholders including patients, providers, health plans and researchers. Much of the effectiveness or dysfunction in a health care system can be attributed to public policies.

In recent years, policymakers have taken a strong interest in fostering health IT. In 2004, U.S. President George W. Bush issued an executive order to establish the Office of the National Coordinator for Health IT.[2] In 2009, the U.S. Congress allocated approximately $30 billion to support providers' **meaningful use** of health IT. Governments of many other countries are also spending significant public funds on health IT and paying close attention to related policy issues.

In this chapter, we review some of the key policy goals relevant to informatics and discuss how researchers and policymakers are trying to address them. Accelerating adoption of health IT is one policy goal. Others include fostering interoperability of health IT products, protecting privacy of patients' health information, ensuring health IT products are safe for patients, and improving medical practice workflows.

---

[2] http://www.healthit.gov/newsroom/about-onc (Accessed 12/9/2012)

While informatics research has been occurring for several decades, research in health IT policy is still in its infancy. As stakeholders look to health IT to solve the major cost and quality problems in national health care systems, we expect the issues discussed in this chapter to become more important to policymakers and researchers in the fields of health policy and informatics.

27.2 How Health IT Supports National Health Goals: Promise and Evidence

Health IT is not an end in itself. Like all technology, it is simply a tool for achieving larger clinical, social and policy goals, such as improving health outcomes, improving the quality of care, and reducing costs. Health IT promises to have a tremendous impact on these goals.

Policymakers, however, are interested not only in the promise of health IT but also the reality. Like most software products, early versions of health IT products tend to have many problems, such as bugs, poor usability, and difficulties integrating with other products. Only after the technology matures is it possible for a larger portion of the promised benefits to be realized. Policymakers are reluctant to invest public funds, which are raised primarily in the form of taxes, on technologies that have not been proven in empirical studies to produce benefits.

Indeed, many studies have been able to detect empirical benefits of health IT (Buntin et al. 2011). However, a large portion of these studies come from a handful of academic medical centers (Linder et al. 2007; Chaudhry et al. 2006). It is not clear how well the benefits from academic centers will generalize to other care settings. Why haven't researchers been able to demonstrate the benefits of health IT more broadly (Jones et al. 2012)? We have already mentioned one possible reason: the technology used by most clinicians may not be mature. Another reason might be that users are not taking advantage of the technology's potential. Finally, it may be that the technology is actually producing benefits but the benefits are inherently difficult to detect (see Chap. 11). It will be challenging to determine which of these reasons plays the greatest role.

Despite the limits of the empirical evidence, policymakers are currently investing substantial sums in health IT hoping that the technology will realize its promised benefits and support national health goals. However, they would potentially invest even more in technologies that are proven effective in empirical studies. This section presents an overview of both the promise and the evidence of how health IT supports policy goals.

27.2.1 Improving Care Quality and Health Outcomes

As informatics professionals understand intuitively, health IT has enormous potential to improve care quality and health outcomes, which is, of course, a central policy goal (Table 27.1). Just as computers have revolutionized many other industries, from banking to baseball, information technology has the potential to revolutionize health care through the creation of innovative applications. Policymakers in the U.S. appear to recognize this potential as demonstrated by the emphasis on health IT in the U.S. National Quality Strategy[3] and regulations related to **Accountable Care Organizations** (**ACOs**) (AHRQ 2011; Berwick 2011). Many other countries also specifically encourage adoption and use of health IT in order to improve health care quality.

Electronic health records (EHRs; Chap. 12) probably represent the form of health IT that has been evaluated most extensively. Several studies have demonstrated the benefits of EHRs in real clinical settings. For example, studies have found that EHRs with clinical decision support (Chap. 22) will reduce the number of adverse drug events from 30 to 84 % (Ammenwerth et al. 2008). In addition, physicians using EHRs with clinical decision support have been shown to make more appropriate medical decisions

---

[3] http://www.ahrq.gov/workingforquality/ (Accessed 12/9/2012).

Table 27.1 The promise of health IT (selected functionality)

Health IT functionality	Expected effect on care quality	Expected effect on cost
Electronic health record (EHR) with clinical decisions support (CDS)	Improved clinical decisions, fewer errors	Fewer unnecessary tests
Health information exchange (HIE)	Improved clinical decisions	Reduced burden of information gathering, reduced duplicate testing
Patient decision aids	More personalized treatment	Fewer procedures
Telehealth and personal health records (PHR)	More interaction with clinicians	Fewer office visits
E-prescribing	Fewer errors	Reduced costs from errors

(Tang et al. 1999a). One study that examines EHR use in several hospitals in Texas found that there are reduced rates of inpatient mortality, complications, and length of stay when EHRs are used (Amarasingham et al. 2009). Not all the benefits of EHRs have been demonstrated in empirical studies, but enough of the benefits have been proven so that policymakers are keenly interested in promoting widespread adoption.

Another component of health IT that may substantially improve quality of care is clinical data exchange, which is the ability to exchange health information among health care organizations and patients (see Chap. 13). There is a great need for this kind of capability. In the U.S., the typical Medicare beneficiary visits seven different physicians in four different offices per year on average, and many patients with chronic conditions see more than 16 physicians per year (Pham et al. 2007). Not surprisingly, in such a fragmented system, information is often missing. One study shows that primary care doctors reported missing information in more than 13 % of visits and other studies suggest much higher rates of missing data, affecting as much as 81 % of visits (Smith et al. 2005; van Walraven et al. 2008; Tang et al. 1994b). A study in one community found that there may be a need to exchange data among local medical groups in as many as 50 % of patient visits (Rudin et al. 2011). However, few empirical studies have been able to show that real-world implementations of electronic clinical data exchange systems result in improvements in care quality or health outcomes.

Researchers and policymakers agree that improving the quality of health care must involve making it more patient-centric, and health IT will likely be crucial to achieving that goal on a large scale (Kaelber and Pan 2008). For example, **personal health records** (**PHRs**) and patient portals would give patients access to their clinical data (see Chap. 17), facilitate communication between patients and providers, and provide relevant and customized educational materials so that patients could take a more active role in their care (Tang et al. 2006; Halamka et al. 2008). PHRs may also incorporate patient decision-aids to help them to make critical health care decisions, taking into account their personal preferences (Fowler et al. 2011). **Telehealth** technologies, which enable patients to interact with clinicians over the Internet (see Chap. 18), would make health care more patient-centric by allowing patients to receive some of their care without having to go physically to the doctor's office. Few empirical studies have shown that these technologies result in improvements in care quality or health outcomes. However, studies have reported high levels of patient satisfaction with PHRs and many patients use them extensively in certain hospitals and medical centers.

One concern of policymakers is that there may be an emerging digital divide in health IT. One study found that minority groups were less likely to access web-based PHRs and, in general, minorities and disadvantaged groups have less web access than other groups (Yamin et al. 2011). On the other hand, adoption rates of mobile platforms do not show as much of a divide and it is likely that PHRs will soon be accessible via these platforms. Policies may be necessary to fund special approaches targeting minorities to prevent disparities in health care from getting worse and to ensure that the improvements in care quality enabled by health IT are enjoyed by all.

Unfortunately, health IT also has the potential to facilitate harmful unintended side effects (Bloomrosen et al. 2011). In one study involving a pediatric intensive care unit in Pittsburgh, patient mortality actually increased after computerized physician order entry (CPOE) was installed (Han et al. 2005). The study found that certain aspects of the ordering system they implemented and some of the implementation decisions they made, restricted clinicians' ability to work efficiently, causing delays in treatment, which was especially deleterious because of the urgent nature of the children's conditions. Implementation decisions involving configuration of the system and changes in workflows appear to have been the major contributors to the increase in mortality– the same EHR product was installed in another hospital without such adverse impacts on mortality (Beccaro et al. 2006). Nonetheless, questions about the need to regulate the safety of EHRs are being debated. Balancing the need to protect patients from unintended harm is the concern, further discussed later in this chapter, that over-regulation may impede innovation. Most researchers tend to believe that if health IT systems are well-designed and implemented with close attention to the needs of the users, these kinds of unintended consequences can be avoided and health IT systems will result in tremendous improvements in quality of care (Berg 1999).

27.2.2 Reducing Costs

In addition to improving quality, health IT is expected to reduce costs of care substantially (Table 27.1). Projections based on models show huge potential savings for many forms of health IT. One study by the RAND Corporation estimated that EHRs could save more than $81 billion per year (Hillestad et al. 2005). Another study estimated that electronic clinical data exchange has the potential to save $77.8 billion per year (Walker et al. 2005). Many of these savings are expected to come from reductions in redundant tests and use of generic drugs, as well as reductions in adverse drug events and other errors that EHRs might prevent (Bates et al. 1998; Wang et al. 2003). Telehealth and PHRs have also been projected to result in billions of dollars in savings (Kaelber and Pan 2008; Cusack et al. 2008).

One weakness of these projections is that they relied on expert opinions for some point estimates because, other than a number of studies showing that EHRs reduce costs by reducing medical errors, few studies have tried to examine empirically the effect of health IT on costs. Also, some of the projections have been criticized because they estimate potential savings rather than actual measured savings (Congressional Budget Office 2008). However, the projections do not include a number of types of savings that may result from providing better preventive care and care coordination which would reduce the need for patients' use of high cost procedures in hospitals and emergency rooms. They also do not include potential reductions in costs that may result from decision aids for patients, which may, for example, reduce the number of unnecessary surgeries (O'Connor et al. 2009). The actual savings therefore may be much greater than the projections suggest.

27.2.3 Using Health IT to Measure Quality of Care

All health care stakeholders agree that a health care system should deliver high quality care. But how does one measure care quality? Current methods of quality measurement rely largely on administrative claims submitted by providers to insurers. These data may be useful for certain quality measurements such as for assessing a primary care physician's mammography screening rates, but they lack important clinical details, such as the results of laboratory tests. They also do not represent a comprehensive picture of the care that is delivered, assess the appropriateness of most medical procedures, or determine if a patient's quality of life has improved after treatment. Also, most patients in the U.S. switch insurance companies every few years, limiting the ability of any one insurer to measure quality improvements over longer periods of time, which is required to assess accurately the treatment of many medical conditions. Clinical data are much more comprehensive than administrative claims, but only a minority of existing quality measures uses clinical data from EHRs. The lack of robust methods for measuring clinical quality represents a major impediment to making substantial improvements in quality. More attention should be paid to developing clinical quality measures, especially now that payments systems are moving from fee-for-service payments to ones based on quality (Tang et al. 2007). We discuss some of the issues surrounding paying providers based on quality measures later in the next section.

Health IT has the potential to improve **quality measurements** greatly by allowing clinical data automatically to produce standardized quality measures. In the U.S., there is growing policy interest in creating such measures as shown in the National Quality Strategy and other reports (AHRQ 2011). This approach has been highly successful in the United Kingdom (U.K.) where nearly 200 quality measures have regularly been assessed, with up to 40 % of payment for general practitioners based on performance on these measures. In addition, there is growing support for developing patient-reported **outcome measurements** which may be integrated in PHRs, or obtained through other mechanisms and integrated with the patient's clinical data (Cella et al. 2010).

However, using electronic clinical data to generate quality measures is also associated with a number of problems. Studies have found that clinical data in EHRs are often incomplete, inaccurate and may not be comparable across different EHRs (Chan et al. 2010). More research is needed to develop and standardize meaningful quality measures that would be worth the burden of reporting them.

27.2.4 Holding Providers Accountable for Cost and Quality

Currently, in the U.S., most care is delivered using a fee-for-service payment system, in which providers are paid for every procedure or patient visit. Under this payment method, providers have incentives to provide more care rather than less, which may lead to overtreatment. It is therefore not surprising to find that in the U.S., costs are high and rising, nearly double those of many other industrial nations, and quality of care is mixed (Fuchs and Milstein 2011). As Fig. 27.2 shows, the U.S. spends more money per capita on health care than any other country by a wide margin. Yet, several studies suggest that the U.S. is far the from the world's leader in overall care quality (Nolte and McKee 2008). A seminal study by McGlynn et al. found that patients in the U.S. received recommended care only about half of the time across a broad array of quality measures (McGlynn et al. 2003).

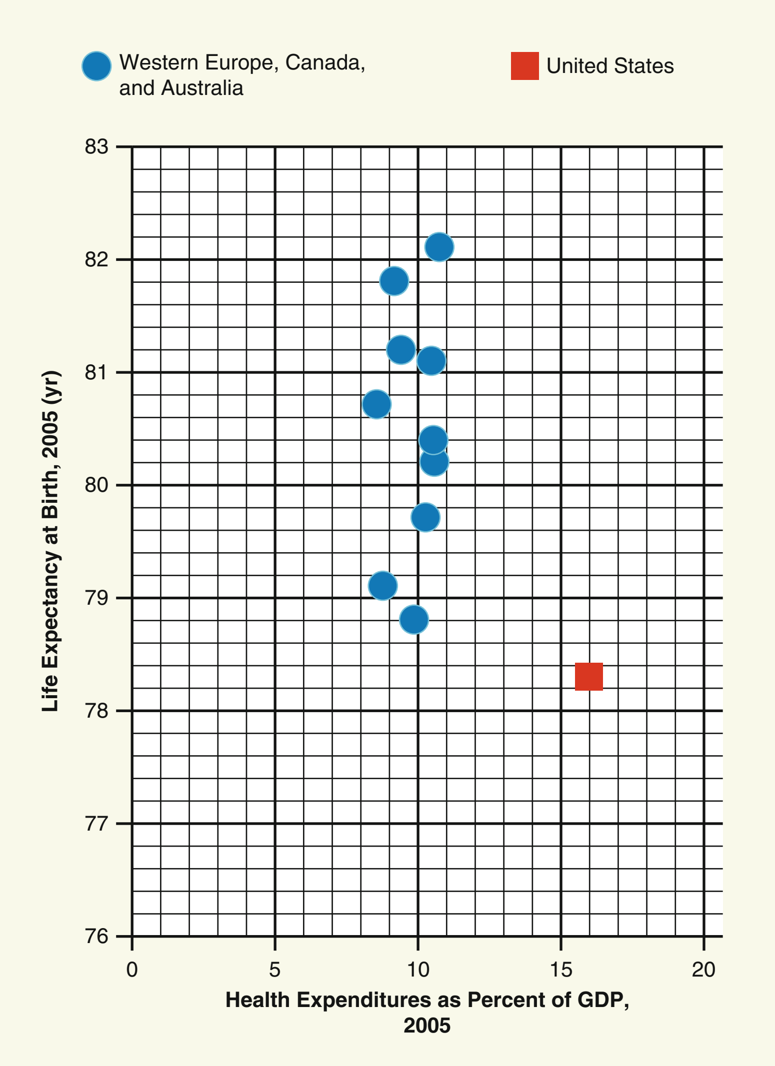
Policymakers are trying to replace the fee-for-service payment method with other methods that would hold providers accountable for the care they deliver. For these attempts, health IT systems are essential. In the U.S., one of the proposed mechanisms for accomplishing this is through Accountable Care Organizations (ACOs). As specified in the Affordable Care Act of 2010,[4] an ACO is a group of providers who are held accountable, to some extent, for both the cost and the quality of a designated group of patients (Berwick 2011; McClellan et al. 2010). Only a few pilot ACOs currently exist, but early indications suggest that they may be effective, and there is strong interest among medical professionals to form them. The concept of ACOs depends on having an electronic health information infrastructure in place, including widespread use of EHRs, because health IT would enable ACOs to improve quality, reduce costs, and measure their performance.

Many other countries have experimented with paying providers for quality and outcomes, or holding providers responsible for costs, although few have done both at the same time to a high degree. Health IT systems are critical for many of these efforts. For example, in the U.K. 40 % of general practitioner funding has been based on more than 170 quality measures for which the

---

[4] http://www.healthcare.gov/law/index.html (Accessed 12/9/2012)

Fig. 27.2 Health care expenditures and life expectancy in the United States and ten other developed countries (Fuchs and Milstein 2011, with permission)



data are extracted directly from clinicians' computing systems. Few policymakers or researchers believe providers can be held accountable to a substantial degree for the care they delivery without a robust health IT infrastructure.

27.2.5 Informatics Research

As we mention above, many health IT capabilities are still emerging, or standards have not yet been defined. With health data just beginning to become widely accessible, new applications will still require additional research and development. For example, we are still in the early stages of understanding how to design applications for team care (Chap. 15), remote patient monitoring (Chaps. 18 and 19), online disease management (Chaps. 17 and 18), clinical decision-making (Chap. 22), alerts and reminders (Chap. 22), public health and disease surveillance (Chap. 16), clinical trial recruiting (Chap. 26), and evaluations of the impact of technologies on care and costs (Chap. 11). One concern is that most provider organizations, and increasingly even academic medical centers, are now using software applications made by private vendors, and innovating with them has been challenging. Private vendors are not investing enough resources in research to produce transformational innovations (Shortliffe 2012). It will be essential to identify "sandboxes" in which new and innovative IT approaches can be developed and tested. More interactions between industry and academia may be a good way to accelerate progress.

Federal funding plays a major role in supporting this kind of upstream informatics research to help to incubate these new technologies. Because the benefits of such research will be enjoyed by everyone who uses the health care system, the investment of public funds is justified. Few private companies have taken the risk of doing this kind of experimental research to date because most health IT companies have been relatively small, and they are currently focused on adding the functionality that is needed to meet **meaningful use**. Much of the innovation in health informatics has occurred at universities and other government-funded research organizations affiliated with academic medical centers and that will likely continue.

27.3 Policy for Accelerating the Adoption of Health IT Infrastructure

Many governments around the world are actively developing and implementing policies to accelerate the adoption of health IT. Some countries have had more success than others. As we describe in the opening of this chapter, the U.S. has had a much lower adoption rate of EHRs compared with most other developed countries, although the current CMS meaningful use incentive program is starting to improve the statistics. It is likely that the new payment models, such as ACOs, and increased payment for practices involved in patient-centered medical home pilots, will accelerate health IT adoption even further because providers will see EHRs and other health IT, as necessary tools for achieving their cost and quality goals. However, there is no guarantee these new payment models will succeed. Also, they may take many years to become widespread, and they may require that health IT be adopted first because health IT will allow the creation of the improved quality measures that new payment approaches will need in order to hold providers accountable. To overcome this chicken-or-the-egg problem, the U.S. is attempting to accelerate the adoption of health IT through direct incentives mentioned above. Other counties have taken different approaches. This section describes some of these efforts.

27.3.1 The U.S. Approach: Paying for 'Meaningful Use' of Health IT

The first published interest in promoting health IT directly through public policy and leadership in the U.S. dates back to at least 1989. For the next 15 years several informatics leaders published reports calling for the federal involvement and oversight. However, serious government activity in health IT promotion did not begin until the establishment of the Office of the National Coordinator for Health IT (ONC) in 2004. This office, which was later made permanent by an act of Congress, is located within the U.S. Department of Health and Human Services and tasked with "promoting development of a nationwide Health IT infrastructure that allows for electronic use and exchange of information."

The importance of this office grew considerably in 2009 when Congress passed legislation that is considered a major landmark in the history of health IT policy: the Health Information Technology for Economic and Clinical Health (HITECH) Act.[5] This legislation authorized $27 billion in stimulus funds to be paid to health care providers who demonstrate meaningful use of electronic health records. These incentive funds were made available to individual physicians and hospitals to help them implement and become meaningful users of health information technology to improve health outcomes of patients and

---

[5] http://en.wikipedia.org/wiki/Health_Information_Technology_for_Economic_and_Clinical_Health_Act (Accessed 12/9/2012)

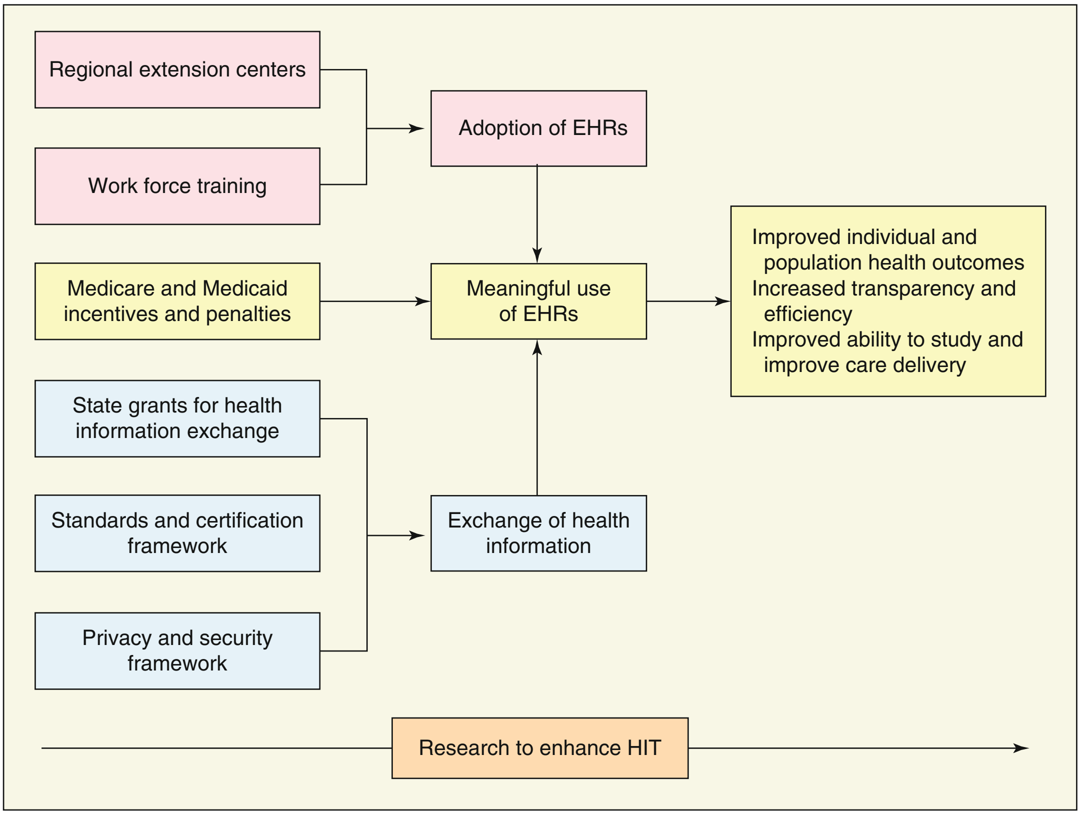


Fig. 27.3 The HITECH act's framework for meaningful use of Electronic Health Records (EHRs) (Blumenthal 2010, with permission)

populations. The criteria for qualifying for the incentive payments are based on demonstrated use of health IT to achieve health and efficiency benefits, and these criteria are to become more stringent over time. In addition to the incentive payments to providers to accelerate adoption of health IT, an additional $2 billion was allocated to provide workforce and infrastructure support needed to deploy the health IT systems nationwide and to facilitate clinical data exchange (Fig. 27.3). (Blumenthal 2010). The HITECH legislation also created two federal advisory committees, the Health IT Policy Committee,[6] which makes health IT-related policy recommendations to the U.S. Department of Health and Human Services, and the Health IT Standards Committee,[7]which identifies or recommends standards to be used for certification of health IT products.

These incentives payments and related HITECH programs are important enablers for broader health systems reforms. As we describe earlier, policymakers in the U.S. hope to hold health care providers accountable for improvements in care quality, such as via ACOs, rather than for use of technology. The current policy approach of paying for use and then gradually raising the bar so that the government is paying for quality, with the eventual aim of moving to pay for actual outcomes, is probably wise because it will take time to realize quality benefits and it is important to get providers started on

---

[6] http://www.healthit.gov/policy-researchers-implementers/health-it-policy-committee (Accessed 12/9/2012)

[7] http://www.healthit.gov/policy-researchers-implementers/health-it-standards-committee (Accessed 12/9/2012)

the right path before expecting too much of them (Bates 2009). In the long run, it is likely that payments for both use of health IT and health outcomes may be necessary to ensure providers are fully realizing the potential of their health IT systems.

27.3.2 Electronic Health Records

Dr. David Blumenthal, the first national coordinator appointed after HITECH was enacted, described the purpose of HITECH as "creating a market." A market involves both buyers and sellers. Therefore, ONC has intended to influence both the buyers (physicians and hospitals) and the sellers (health IT product vendors). On the seller side, ONC has established a certification program for EHRs. Only EHR products that include specific features and adhere to standards can be certified, and only certified EHRs will allow providers to be eligible to receive meaningful use incentive payments. The intention of the certification program is to improve transparency in the marketplace for EHR products and ensure that physicians and hospitals will be able to use a minimum set of critical functionalities, such as clinician decision support and **e-prescribing**.

On the buyer side of the market, policies are trying to encourage clinicians to adopt EHRs by offering them direct payments if they can meet the meaningful use criteria. Many clinicians are reluctant to purchase EHRs, with good reason. The barriers to adoption include: initial capital costs, operating costs, downtime during installation and training, limited availability of knowledgeable trainers, limited number of proven EHR vendors, lack of technical standards, and privacy and security concerns. In the U.S. the lack of a solid business case is probably the most important barrier and the meaningful use payments may help with that considerably (Kleinke 2005). Initial signs suggest that the meaningful use program is working to enhance the functionality of commercial EHRs and accelerating their adoption. In fact, recent surveys (2012) report that more than 55 % of physicians are now using EHRs.

Other countries have taken very different approaches to encourage or require health IT use by providers. For example, the U.K. has been able to achieve near universal adoption of EHRs because it devoted substantial resources to the effort early on, and has a national health care system which directly manages most of the health care providers in the country (Cresswell and Sheikh 2009; Ashworth and Millett 2008). Most other industrialized nations have achieved fairly high levels of adoption in primary care (Jha et al. 2008). Levels of adoption in secondary care such as hospitals, however, lag behind. Countries that have particularly high levels of adoption in non-hospital settings include Denmark, the Netherlands, Sweden, Hong Kong, Singapore, Australia, and New Zealand.

27.3.3 Clinical Data Exchange

The U.S. is trying several approaches to promote clinical data exchange (See Chap. 13). ONC is working with state governments to establish regional health information exchanges (HIEs) around the country. These organizations integrate the EHRs of local health care providers to create aggregate longitudinal patient records. Many HIEs will also provide services for automating the delivery of laboratory results, integrating with pharmacies to facilitate e-prescribing, and facilitating public health and quality reporting.

As was discussed in Chap. 13, every state in the U.S. is actively building at least one HIE and the latest survey counts more than 150 of them (Adler-Milstein et al. 2011). However, the same survey found that only 13 HIEs were operational and supported basic data exchange functionality and none of them supported the kinds of HIE that would be needed to realize their potential value as estimated by projections. Most HIEs rely on public grants for support and few are financially sustainable. In the long term, it is not clear if HIEs will need to be supported as a public utility or if they will be able to find sustainable business models.

Why is it so difficult to establish an HIE? Part of the problem is that current EHR products are not using the same technical standards and are not interoperable. To address this problem, ONC is actively developing technical and semantic standards (See Chap. 7). However, many of the available standards may not be specific enough to make the integration much easier (Halamka 2010). Standards may require many more years of development before EHRs and HIEs become "plug and play."

Even if the technical aspects of integrating health IT systems were easier, vendors have few incentives to develop functionality that allows easy export of patient data into their competitors' systems. They may be "locking-in" patients and providers with their proprietary systems by not creating functionality that allows clinical data to be exported easily. ONC has indicated that, in subsequent stages of the meaningful use program, providers will be required have their EHRs integrated with HIEs. This policy effort might change the vendors' incentives considerably so that they may begin to compete for customers based on how effectively their products integrate with other products (Rudin 2010). Vendors may then also become more interested in agreeing to standards to ease their integration issues.

HIEs may have many other challenges including: recruiting providers who are reluctant to share data with competing medical groups, privacy and security concerns, legal issues, HIE-related fees, training clinicians to use the HIE, and the lack of a business case (Chap. 13). ONC as well as state government programs are trying to address every one of these issues. Creating the business case for providers may be the most difficult. Who will pay for the HIEs? The meaningful use payments may help in the short term by requiring providers to exchange data electronically with other providers who treat the same patients. Patients may also begin to demand that providers join HIEs to better coordinate their care, which may make providers more willing to pay for HIE services (Rudin 2010). Payers may be willing to subsidize HIEs if HIEs reduced their costs by reducing the number of redundant laboratory tests for example, but projections of these savings are not based on the experience of real-world HIEs and there has been little empirical proof that HIEs save costs. In the long run, policymakers believe that other programs such as ACOs will motivate providers to engage in HIEs to improve their quality metrics and to reduce their costs.

In a separate project, the U.S. is also trying to develop protocols that would allow secure point-to-point data exchange of medical information, essentially a system for secure email among medical professionals and health care organizations. Called the Direct Project,[8] these protocols may be useful for many situations in which data exchange is important, but they cannot support an aggregate longitudinal record of a patient's data, so they will not replace HIEs.

Some have proposed a different approach to data exchange in which an independent organization provides a secure electronic repository for storing and maintaining an individual's lifetime health records and allows the individual to have control of who accesses their data.[9] The history and details of this model are explained in Chap. 13. There has been an increase in interest in this approach recently. However, it is too early to tell if it will become widely adopted.

No country in the world has solved the problem of clinical data exchange, although some have made considerable progress. In every country that attempts to foster data exchange, the hardest issues appear to be political rather than technical, and there is clear agreement that health IT policy is particularly important to address these problems, especially in establishing standards. The U.K. has set up a "spine" which allows summary care documents to be widely exchanged (Greenhalgh et al. 2010). However, the overall program has encountered major political difficulties, and has been largely dismantled. Canada has established a program called Canada Health Infoway, which has emphasized setting up an infrastructure for data exchange (Rozenblum et al. 2011). While that effort has been somewhat successful, relatively little in the way of clinical data is being exchanged to date, in part because

---

[8] http://directproject.org/content.php?key=overview (Accessed 12/9/2012)

[9] http://www.healthbanking.org/ (Accessed 12/12/2012)

the adoption rate of electronic health records remains low. In Scandinavia, there has been substantial concern about the privacy aspects of data exchange, especially in Sweden, though data exchange is taking place in Denmark and its use is growing.

27.3.4 Personal Health Records and Telehealth

To encourage more patient-centric care, many countries are trying to foster the adoption of PHRs and Telehealth (see Chaps. 17 and 18), although adoption rates are modest. In the U.S., the meaningful use requirements strongly encourage deployment of patient portals in support of PHRs. However, policymakers have not yet decided what criteria will be used to determine that clinicians are indeed "meaningful" users of them. Federal efforts are also developing standards for improving PHR-EHR interoperability. To promote telehealth, policymakers are exploring the possibility of reimbursing for telehealth care, which would probably improve adoption of this technology considerably (Tang et al. 2007).

27.4 Policies to Support Medical Practice Redesign

Clinical workflows are inherently complex. Clinicians must manage huge amounts of medical information that may originate from patients, other clinicians, laboratories, imaging centers, and insurers. Well-designed EHRs and other forms of health IT have the potential to make their workflows easier. However, health IT systems themselves may also introduce new forms of complexity. For example, clinicians may find that actions that they could have carried out by simply scribbling a note on a slip of paper will demand several mouse clicks in their EHR. Health IT will also offer many capabilities that were not available to them in a paper world, such as medication management, reminders, and alerts that indicate when they are about to prescribe medications that could have adverse reactions. If these software tools are going to improve care, clinicians will need to know how to use them and how to integrate them effectively into their workflows.

Even after the typical 1–3 months of training, clinicians often do not use EHRs to their fullest potential (Torda et al. 2010). Studies have shown that even experienced clinicians working with well-established health IT systems, such as those in the Veterans Affairs, will use "workarounds" for many clinical tasks which will involve ad hoc paper processes (Saleem et al. 2009a, 2011).

To address this problem, policies are funding efforts to train clinicians to integrate EHRs into their practice workflows. Regional health IT extension centers are being established around the U.S. that are responsible for training and educating clinicians to use health IT.

Another policy effort for improving clinical workflows is called the **patient-centered medical home** (**PCMH**) (American Academy of Family Physicians 2008). This effort focuses on the primary care clinician as coordinator of patients' medical care and will entail extensive use of health IT including telehealth, clinical data exchange, and clinical decision support (Bates and Bitton 2010; Kilo and Wasson 2010).

In the future, medical practices may have to change even more to exploit all the capabilities of health IT including: monitoring patient health status remotely, preventive health, and use of patient decision aids (Fowler et al. 2011). Clinical workflows will increasingly rely on health IT.

27.4.1 Informatics Workforce

Training and redesigning hundreds of thousands of medical practices in the U.S. will require a new pool of skilled workers. These workers will need expertise in both software and clinical workflows, which is rare to find in one person. In addition, to realize the full potential of the new health IT systems, these workers will need training in quality improvement, performance measurement, team dynamics, and medical practice culture (Torda et al. 2010). Policies have begun funding new training programs to build up this new professional workforce. Initial efforts have focused mostly on increasing training in community colleges. These efforts will need to be expanded to address the growing need for health IT and workflow expertise, and new policies may be needed to make sure clinical workflows continue improving.[10]

27.5 Policies to Ensure Safety of Health IT

As adoption of health IT accelerates, it is important to be vigilant about, and to reduce, the risk of unintended harmful side effects related to health IT use (Bloomrosen et al. 2011). Harm could arise from deficiencies in a number of areas when designing and deploying complex systems, including poor system design, inadequate testing and quality assurance, software flaws, poor implementation decisions, inattention to workflow design, or inadequate training. Policymakers are exploring various options to improve the safety of health IT design, deployment, and use, including direct regulations of products and dissemination of best practices.

27.5.1 Should Health IT be Regulated as Medical Devices?

One policy option for reducing the likelihood of health IT-related medical errors is to create regulations that require health IT product to adhere to strict principles of safe design, and be tested and certified (see also Chap. 10). This is how many medical devices are regulated by the U.S. Food and Drug Administration.[11] While this approach may ensure some degree of patient safety, the regulatory burden will increase the price of health IT systems, raise barriers of entry for new companies, and could stifle innovation. Also, even with regulations, health IT products might still have safety issues because software products can be used in many different ways, unlike other medical devices that have more limited utility. Also, principles of safe design are not well developed in health IT and it is not clear how they would be applied by regulatory bodies. Thus, intensive regulation by the Food and Drug Administration is probably not the most effective approach, although some oversight of vendors may be appropriate (Miller et al. 2005a).

27.5.2 Alternative Ways to Improve Patient Safety

There are many other policy options to support patient safety. Policies may fund training programs to educate clinicians in how to use health IT safely and alert them to common mistakes. Policies might encourage providers to report problems with software, including usability issues and bugs, so that vendors can fix them quickly. Policies might also help to establish programs in which users can rate health IT products, an approach that vendors have so far resisted. Finally, funding research into the science of patient safety would improve our knowledge of how to design better products and identify risks of errors (Shekelle et al. 2011).

27.6 Policies to Ensure Privacy of Electronic Health Information

It is almost impossible to have a conversation about digital medical records without discussing issues of privacy. Although this topic arose in the discussion of ethics in Chap. 10, it also has policy implications and warrants mention here. In some ways, health IT offers the ability to have greater privacy protection compared to paper records because electronic accesses can be tracked and audited, whereas if someone inappropriately views a paper record, there is no audit trail. However, if an electronic record system is breached, the scale of the privacy violation may be enormous. If patient data are not kept private, patients may not trust their health care providers and they may forgo necessary treatment. Protecting privacy is clearly an important policy goal.

---

[10] http://www.healthit.gov/policy-researchers-implementers/workforce-development-program (Accessed 12/9/2012)

[11] http://www.fda.gov/ (Accessed 12/10/12)

27.6.1 Regulating Privacy

The Health Insurance Portability and Accountability Act (HIPAA) of 1996[12] and subsequent regulations created a legal category of "protected health information" which was defined to encompass most forms of clinical data. **Covered entities** which include providers and insurers are legally required under this law to safeguard electronic health information and would face fines if they did not.

Many states have additional privacy laws regarding data exchange (e.g., mental health and HIV status). The effectiveness of these privacy-protective laws has not been rigorously evaluated. They can inadvertently reduce privacy protection, particularly when exchanging data across state lines, and have been showed to slow the adoption of EHRs (Miller and Tucker 2009; Harmonizing State Privacy Law Collaborative 2009).

In other countries, privacy also has received a good deal of debate. In 2007, medical data on approximately 160,000 children in the U.K. were put on a compact disc that was lost in transit. Fortunately, the data were encrypted (EHI Primary Care 2007). There has also been substantial debate about privacy in Sweden, which has slowed down the development of data exchange. Governments are still trying to find the best policies to protect privacy of medical records without slowing the adoption of health IT.

27.6.2 Unique Health Identifiers

Many countries have adopted a **unique health identifier** (**UHI**). The advantage of such an identifier is to simplify the matching of health data to an individual. Without a unique identifier, organizations have to expend substantial resources disambiguating individuals. Although there are very good algorithms for doing this using data such as names and dates of birth, they sometimes results in incorrect matches or fail to find patient record that should be linked. Having a UHI could reduce the frequency these errors and save the costs of purchasing the patient matching software.

Many privacy advocates in the U.S. vehemently oppose UHIs. Although some states are experimenting with voluntary health identifiers, Congress defunded any use of federal dollars to support development of a UHI. Despite these concerns, there is little evidence that suggest UHIs pose an increased a risk of privacy violations and, in fact, not having a UHI may be even more risky because other kinds of personal data such as social security numbers may be used instead (Greenberg et al. 2009).

27.7 The Growing Importance of Public Policy in Informatics

Public policy is becoming increasingly important to the field of informatics. Policies have an effect on everything from what research projects receive funding to whether a physician in a solo practice adopts an electronic health record. Many of the health IT policy issues we discuss in this chapter are just beginning to attract attention from policymakers, and further research is needed just to frame the issues.

Traditionally, most informatics research has focused on the development of new technologies and how they integrate into clinical practice. Relatively few studies provide advice to policymakers on health IT policy issues, even though policies have enormous consequences for informatics research and practice. We hope that researchers and policymakers will recognize that technology and policy issues affect each other, and it is necessary to use both perspectives to understand how information technology can be used to improve health care.

Suggested Readings

Bates, D. W., & Bitton, A. (2010). The future of health information technology in the patient-centered medical home. *Health Affairs* (*Project Hope*), *29*(4), 614–621. This visionary paper supplies a comprehensive distillation of IT needs for the patient-centered medical home. It provides a reference for anyone wishing

---

[12] http://www.hhs.gov/ocr/privacy/index.html (Accessed 12/9/2012)

to implement a medical home and for anyone interested in the next phase of health IT innovation.

Chan, K. S., Fowles, J. B., & Weiner, J. P. (2010). Review: electronic health records and the reliability and validity of quality measures: a review of the literature. *Medical Care Research and Review*, *67*(5), 503–527. This comprehensive review should be required reading for anyone thinking about using electronic data for quality measurement. It shows that making accurate, reliable, and comparable quality measures from disparate electronic sources may not be easy.

Institute of Medicine. (2001). *Crossing the quality chasm*. Washington, DC: National Academy Press. This classic report makes an urgent call for a fundamental redesign of the U.S. health care system and 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." Optimistically, it opined that "this commitment should lead to the elimination of most handwritten clinical data by the end of the decade."

Hillestad, R., Bigelow, J., Bower, A., Girosi, F., Meili, R., Scoville, R., et al. (2005). Can electronic medical record systems transform health care? Potential health benefits, savings, and costs. *Health Affairs* (*Project Hope*), *24*(5), 1103–1117. etc. One of the most widely read studies in health policy, this paper by the RAND Corporation estimated a potential cost savings of $81 billion per year due to health IT. It was often cited by politicians as justification for investing in health IT, and likely helped persuade the U.S. Congress to pass the HITECH law, which committed more than $27 billion in meaningful use incentive payments for providers to purchase electronic health records.

Jones, S. S., Heaton, P. S., Rudin, R. S., & Schneider, E. C. (2012). Unraveling the IT productivity paradox — Lessons for health care. *New England Journal of Medicine*, *366*(24), 2243–2245. This brief perspective addresses the contentious issue of why few studies have been able to show that health IT produces an improvement in economic productivity. It makes its case by pointing out that the IT industry had the same problem in the 1980s and 1990s but managed to overcome these difficulties through better measurement of productivity, improved management of technology, and better usability.

Kleinke, J. D. (2005). Dot-gov: Market failure and the creation of a national health information technology system. *Health Affairs* (*Project Hope*), *24*(5), 1246–1262. This widely read perspective piece rails against the market inefficiencies in the current health care system and the lack of health IT adoption. It makes the case for "aggressive government intervention."

Agency for Healthcare Research and Quality. (2011). *National strategy for quality improvement in health care*.http://www.healthcare.gov/law/resources/reports/quality03212011a.html (Accessed 12/10/12). This document provides a blueprint for improving quality in the U.S. health care systems, and includes discussion of the role of health IT in that effort.

Institute of Medicine. (1997). *The computer-based patient record: An essential technology for health care,* revised edition. Washington, DC: *National Academy Press*; This landmark report brought many health IT policy issues to public attention, including the importance of assessing the value of health IT products, development of standards, legal constraints of health IT adoption, and the nettlesome question that has always plagued health IT: who will pay for it?

Walker, J., Pan, E., Johnston, D., Adler-Milstein, J., Bates, D. W., & Middleton, B. (2005). The value of health care information exchange and interoperability. *Health Affairs* (*Project Hope*), Suppl Web Exclusives: W5–10–W5–18. This interesting study by the Center for Information Technology Leadership at Partners Healthcare in Boston provides a point of comparison with the RAND study regarding the value of electronic health records. This study focused only on clinical data exchange and estimated its potential value to be $77.8 billion per year.

Questions for Discussion

1. What are the key barriers to widespread implementation of EHRs and effective exchange of health information? Which of these challenges are amenable to public policy decisions?
2. What might be some of the tradeoffs of using administrative claims data compared with using clinical data from health IT systems for care quality analysis?
3. What might be some of tradeoffs of promoting health IT by paying for use compared with paying for quality?
4. Should health IT be regulated the same way as devices are regulated to protect patient safety? Why or why not?
5. If research finds strong evidence of a digital divide in health IT, what policy actions should be taken?
6. What kinds of health IT functionality are needed to support accountable care organizations and patient-centered medical homes?
7. Compare the U.K.'s approach to clinical data exchange with the U.S.'s approach. What are the advantages, disadvantages and risks of each?