

HEALTH INFORMATION TECHNOLOGY AND PHYSICIANS' DUTY TO NOTIFY PATIENTS OF NEW MEDICAL DEVELOPMENTS[#]

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I. INTRODUCTION

Physicians' duties to their patients traditionally have been limited in time and scope to the specific episode of care or clinical encounter. Physicians generally have had no legal or ethical duty to notify patients about new, patient-specific medical information or general medical advances discovered after the patient's last episode of care.¹ Because of a perceived undue burden, notification after a

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¹ See Alasdair G.W. Hunter, Neil Sharpe, Michelle Mullen, & Wendy S. Meschino, *Ethical, Legal, and Practical Concerns About Recontacting Patients to Inform Them of New Information: The Case in Medical Genetics*, 103 AM. J. MED. GENETICS 265 (2001) (reviewing ethical and legal doctrines in light of genetics); B.E. Calfee, *Note, What You Don't Know Will Hurt You: Physicians' Duty to Warn Patients About Newly Discovered Dangers in Previously Initiated*

clinical encounter has been required only in extraordinary circumstances, such as to correct erroneously reported test results.²

New developments in health information technology (HIT) have drastically altered the ratio of benefits to burdens in patient notification.³ Several types of HIT have the potential to serve as efficient and effective, real-time links between physicians and patients.⁴ Based on current and projected developments in HIT, this article proposes that physicians should have a limited duty to notify patients about certain significant and relevant information discovered after a clinical encounter.⁵ The duty to notify patients advocated in this article is consistent with analogous statutory and common law obligations to share or divulge information. It is also consistent with modern principles of medical ethics, which emphasize shared decision-making by physicians and patients based on information disclosure.⁶

The terms “duty to report,” “duty to inform,” “duty to warn,” “duty to re-contact,” and “duty to notify” are often used interchangeably in every day parlance, the ethics literature, statutes, and common law.⁷ For clarity, “duty to report” refers to a report made to a governmental or professional body, such as a public health agency. “Duty to inform” refers to informed consent, where a physician has a duty to explain in understandable language the

Treatments, 31 CLEV. ST. L. REV. 649 (1982) (discussing possible tort liability for failure to follow up).

² See generally Thomas L. Hafemeister & Selina Spinos, *Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient*, 86 WASH. U. L. REV. 1167 (2009).

³ Hardeep Singh et al., *Reducing Diagnostic Errors Through Effective Communication: Harnessing the Power of Information Technology*, 23 J. INTERNAL MED. 489, 491–92 (2008).

⁴ *Id.* at 493.

⁵ This article does not specifically consider the legal or ethical obligations of non-physician health care providers to notify patients of new medical developments, but the analysis would follow along the same lines as the one used for physicians. The article also does not consider legal or ethical issues raised by governmental notification of individuals for public health purposes.

⁶ See AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS, 2010–2011 Edition, § 8.08(2010), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8082.page>.

⁷ For a discussion of the confusing state of the terminology, see Bartha Maria Knoppers & Amy Dam, *Return of Results: Toward a Lexicon?*, 39 J.L. MED. & ETHICS 577, 577 (2011).

patient's diagnosis, prognosis, and treatment options.⁸ "Duty to warn" refers to the duty of a health professional to warn identifiable victims of serious threats.⁹ "Duty to re-contact" refers to the obligation of a researcher to communicate with research subjects about after-acquired or incidental research findings.¹⁰ "Duty to notify," the primary focus of this article, refers to the duty of a physician to communicate with and disclose to patients new medical developments relevant to their ongoing medical care.

Part II of the article presents the medical justification for establishing a legal and ethical duty to notify patients of new medical developments. Part III describes and analyzes the HIT that enables patient notification without undue burden. Part IV traces how the ethical obligations of physicians to disclose information to patients have evolved and how a duty to notify is consistent with the ethical principles governing the modern physician-patient relationship. Part V discusses some recently enacted federal and state statutes requiring physicians to notify patients about adverse outcomes, including medical errors, and breaches of health information security. Part VI analyzes common law liability for failing to disclose information, including informed consent and the duty to warn intended victims of the violent threats of mental health patients. Part VII details key aspects of the proposed duty, including to whom it is owed, when it arises, and how it is satisfied. Finally, Part VIII concludes by assessing prospects for the adoption and implementation of the duty to notify patients of new medical developments.

⁸ For a further discussion, see *infra* Parts IV-B and VI-A.

⁹ For a further discussion, see *infra* Part VI-C.

¹⁰ See generally Susan M. Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219 (2008); Ma'n H. Zawati et al., *Incidental Findings in Genomic Research: A Review of International Norms*, 9 GENEDIT 1 (2011). The term "re-contact" also has been used to describe the obligation of clinicians to notify patients about new studies, see, e.g., Reed E. Pyeritz, *The Coming Explosion in Genetic Testing – Is There a Duty to Recontact?*, 365 NEW ENG. J. MED. 1367, 1367–69 (2011), but this article refers to "re-contact" by a clinician as notification.

II. THE MEDICAL BENEFITS OF NOTIFICATION

Medical benefit to the patient is the reason for recognizing a legal and ethical duty on the part of physicians to notify patients of new medical developments. The existence of the duty proposed in this article depends on the importance of notification to the patient's health. This section explores how notification can result in medical benefits in three illustrative cases: preventing potentially life-threatening adverse drug reactions, obtaining prompt information about medical device recalls, and modifying lifestyle.

A. Preventing Severe Adverse Drug Reactions: The Withdrawal of Rofecoxib

Since 1993, an average of 1.5 drugs per year have been withdrawn for safety reasons in the United States.¹¹ Although the rate of withdrawals has been relatively constant, more recent withdrawals have involved larger numbers of users.¹² The more users of withdrawn prescription drugs, the more important it becomes to provide timely and comprehensive patient notification.

In 2004, the Food and Drug Administration (FDA) issued a Public Health Advisory about the voluntary market withdrawal of rofecoxib (Vioxx®), a nonsteroidal anti-inflammatory drug, by its manufacturer, Merck & Co., Inc.¹³ A large study had indicated an increased risk for cardiovascular events in patients taking rofecoxib, especially those who had been taking the drug for longer than eighteen months.¹⁴ At the time of the withdrawal, approximately two million people in the United States were taking the drug.¹⁵ The

¹¹ A.M. Issa et al., *Drug Withdrawals in the United States: A Systematic Review of the Evidence and Analysis of the Trends*, 2 CURRENT DRUG SAFETY NO. 3, 177, 180 (2007).

¹² *Id.*

¹³ U.S. FOOD & DRUG ADMIN., *FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product*, FDA NEWS RELEASE (Sept. 30, 2004), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108361.htm> (last updated June 18, 2009).

¹⁴ Anil Jain et al., *Responding to the Rofecoxib Crisis: A New Model for Notifying Patients at Risk and Their Health Care Providers*, 142 ANNALS INTERNAL MED. 182, 182 (2005); see also U.S. FOOD & DRUG ADMIN., *supra* note 13.

¹⁵ Jain et al., *supra* note 14; Eric J. Topel, *Failing the Public Health – Rofecoxib, Merck, and the*

withdrawal occurred at the pharmacy level, meaning that new prescriptions for the drug would not be filled, but notification of the public was still necessary to urge patients to discontinue taking the drug immediately.¹⁶ Many people learned of the withdrawal via print, broadcast, or electronic media, but some undoubtedly did not learn of the withdrawal until they attempted to refill their prescription. The delay in notice placed these individuals at an avoidable risk.

Immediately after the notice of withdrawal, the Cleveland Clinic used its electronic health record (EHR) system to identify all of its patients with a prescription for rofecoxib, sent standard messages to all of these patients who were utilizing the clinic's Internet-based shared EHR system, sent an e-mail to all of the clinic's health care providers, and sent a computer-generated postal mailing to all patients with a rofecoxib prescription.¹⁷ Within twenty-four hours of the withdrawal, notices were sent to 842 prescribing providers and all 11,699 patients with a rofecoxib prescription.¹⁸ The success of the Cleveland Clinic's response to the medication withdrawal demonstrated the feasibility and desirability of using EHRs and HIT to provide important patient information in an expedited manner.¹⁹

B. Medical Device Recalls: Silicone Gel Breast Implants

High technology medicine requires the use of numerous medical devices, and sometimes the devices fail or prove dangerous.²⁰ The

FDA, 351 NEW ENG. J. MED. 1707 (2004).

¹⁶ Jain et al., *supra* note 14.

¹⁷ *Id.* at 183.

¹⁸ *Id.* at 184.

¹⁹ Consumer website updates are also effective in responding rapidly to drug withdrawals. Peter J. Embi et al., *Responding Rapidly to FDA Drug Withdrawals: Design and Application of a New Approach for a Consumer Health Website*, 8 J. MED. INTERNET RES. NO. 3, e16, doi:10.2196/jmir.8.3.e16 (2006).

²⁰ Each year, over 8,000 new medical devices are marketed in the United States, including 50-80 high-risk, or class III, devices. David W. Feigal et al., *Ensuring Safe and Effective Medical Devices*, 348 NEW ENG. J. MED. 191 (2003). Among the many types of devices recalled in recent years are artificial joints, breast implants, catheters, hemodialysis systems, implantable cardioverter defibrillators, infusion systems, pacemakers, stents, tracheostomy tubes, ventilators, and ventricular assist devices. See FOOD & DRUG ADMIN., *List of Device Recalls*, <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm> (last visited

FDA approval process for medical devices involves the following two alternative mechanisms: (1) premarket approval, which requires clinical testing and inspections; or (2) the so-called 510(k) clearance or notification process (named after section 510(k) of the Medical Device Amendments of 1976),²¹ which merely requires that the device be “substantially equivalent” to a device already on the market.²² The second method is intended for low or moderate risk devices, although many critics claim this lower scrutiny process is overused²³ or should be eliminated entirely.²⁴ According to one study, between 2005 and 2009, there were 113 medical device recalls involving devices the FDA determined could cause serious health problems or death.²⁵ Only twenty-one of the 113 devices had been approved through the more rigorous premarket approval process, eighty were cleared through the 510(k) process, eight were deemed exempt from FDA regulation, and four were determined to be counterfeit devices or classified as “other.”²⁶

Medical device recalls are usually conducted voluntarily by the manufacturer.²⁷ If the manufacturer fails to do so, and the FDA finds that “there is a reasonable probability that a device . . . would cause serious, adverse health consequences or death,” it may order the

Sept. 21, 2012).

²¹ Federal Food, Drug, and Cosmetic Act, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as amended at 21 U.S.C. §§ 301-399a (2006)).

²² 21 C.F.R. § 807.92 (2010).

²³ See, e.g., Alan M. Garber, *Modernizing Device Regulation*, 362 NEW ENG. J. MED. 1161 (2010). For a discussion of the FDA’s initiatives to improve the section 510(k) process, see Hearing, Before the S. Spec. Comm. on Aging, 112th Cong. 1 (April 13, 2011) (statement of William Maisel, M.D., Deputy Ctr. Dir. for Science, Ctr. for Devices & Radiological Health, FDA), available at <http://www.fda.gov/NewsEvents/Testimony/ucm250709.htm>.

²⁴ INST. OF MED., *Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years* (2011), available at <http://www.iom.edu/Reports/2011/Medical-Devices-and-the-Publics-Health-The-FDA-510k-Clearance-Process-at-35-Years.aspx>.

²⁵ Diana M. Zuckerman et al., *Medical Device Recalls and the FDA Approval Process*, 171 ARCHIVES INTERNAL MED. 1006 (2011).

²⁶ *Id.*

²⁷ U.S. FOOD & DRUG ADMIN., *Postmarket Requirements (Devices)*, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/> (last visited Oct. 17, 2011). See 21 C.F.R. § 7.40 (2010).

cessation of distribution or use of the device.²⁸ These orders, however, are rarely issued.²⁹ When a high risk medical device is recalled, the following three strategies are used to notify the public: (1) the FDA lists all recalls, withdrawals, and alerts on its website;³⁰ (2) the manufacturer is required to notify vendors, physicians, and hospitals of the recall, withdrawal, or alert; and (3) physicians and hospitals are responsible for notifying their patients.³¹

If the FDA finds that a device “presents an unreasonable risk of substantial harm to the public health,” that notification is “necessary to eliminate” this risk, and that “no more practicable means is available” to eliminate the risk, it may order manufacturers or health care providers to notify device users of the risk.³² This authority has been used quite rarely.³³ Because there is generally no legal obligation for the manufacturer to notify patients directly, sometimes patients receive untimely notification or none at all.³⁴ The FDA Amendments Act of 2007 established an Internet-based system for disseminating risk information to patients and providers.³⁵ The system allows for the accumulation of data from labeling, package

²⁸ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360h(e)(1) (2006).

²⁹ U.S. FOOD & DRUG ADMIN., *FDA 101: Product Recalls—From First Alert to Effectiveness Checks* (May 2010), available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm>.

³⁰ See *id.* Each month there are over 300,000 visits to the FDA consumer information sections of the website. See U.S. FOOD & DRUG ADMIN., *Consumer Update Analytics*, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm215588.htm> (last visited Sept. 21, 2012)..

³¹ U.S. FOOD & DRUG ADMIN., *What Happens in a Medical Device Recall?*, <http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ucm243982.htm> (last visited Feb. 25, 2011).

³² 21 U.S.C. § 360h(a) (2006).

³³ It was used only once in 2010. INST. OF MED., *supra* note 24, at 58.

³⁴ See, e.g., JoNel Aleccia, *Torn Corneas, Vision Problems Follow “Stealth Recall” of Contact Lenses*, VITALS ON MSNBC.COM (Oct. 11, 2011, 8:42 AM), http://vitals.msnbc.msn.com/_news/2011/10/11/8259138-torn-corneas-vision-problems-follow-stealth-recall-of-contact-lenses; Susan Hogan, *Patients Left in Dark after Medical Recall: Thousands of Patients Affected*, WPRI.COM EYEWITNESS NEWS (Nov. 12, 2009, 10:42 PM), http://www.wpri.com/dpp/target_12/medical-device-hernia-recall-patients-not-told-.

³⁵ Food and Drug Administration Amendments Act of 2007, Pub L. No. 110-85, § 915(1)-(2), 121 Stat. 823, 957 (2007).

inserts, medication guides, and safety alerts.³⁶ It does not include patient notification.³⁷ Methods to notify patients more efficiently using HIT hold promise for preventing injuries and deaths from dangerous medical devices.³⁸

One of the best known medical device recalls occurred in 1992, when the FDA, responding to reports that some breast implants leaked and caused serious illness, announced a voluntary moratorium on silicone gel-filled breast implants.³⁹ The FDA requested that manufacturers stop supplying them and surgeons stop implanting them while the FDA reviewed studies on implant safety.⁴⁰ The ban did not apply to reconstruction or revision surgery.⁴¹ The moratorium continued until 2006, when the FDA approved silicone gel-filled breast implants sold by Allergan and Johnson & Johnson's Mentor unit on the condition that both companies follow 40,000 women for ten years to look at safety issues.⁴² The FDA indicated that a 65% enrollment rate was needed but, as of 2011, Allergan's two-year participation rate has been only 60% and Mentor's three-year rate has been only 21%.⁴³ In 2011, the FDA announced it was considering establishing a registry of all breast implant recipients to

³⁶ *Id.*

³⁷ *Id.*

³⁸ Because most lawsuits involving harms caused by medical devices have involved products liability actions against the manufacturers, there is little case law on the legal responsibility of physicians to provide notice. This may be changing, however, in light of the Supreme Court's holding in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), that FDA approval of a medical device operates to preempt common law tort actions for products liability. It is not clear whether physicians will be liable for failing to provide notice of recalled medical devices to their patients. Compare *Tresemmer v. Barke*, 150 Cal. Rptr. 384 (Cal. Ct. App. 1978) (holding physician had duty to contact patient when IUD recalled three years later), with *Doyle v. Planned Parenthood*, 639 P.2d 240 (Wash. Ct. App. 1982) (holding physician had no duty to warn patient of recalled IUD because episode of care had expired years earlier).

³⁹ U.S. FOOD & DRUG ADMIN., *Regulatory History of Breast Implants in the U.S.*, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics> (last visited Oct. 17, 2011).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Anna Yukhananov, *FDA Eyes Registry for Breast Implants Problems*, NRC (Aug. 31, 2011), <http://www.center4research.org/2011/09/fda-eyes-registry-for-breast-implants-problems/>.

⁴³ *Id.*

track adverse events.⁴⁴ Although there has been no mention of a more robust patient notification program, HIT could provide prompt notice of medical device recalls to patients, such as women with defective silicone-gel breast implants. Unfortunately, the importance of notifying women about defective silicone gel breast implants has been underscored by the 2011 recall of implants manufactured by the French company PIP.⁴⁵

C. Lifestyle Modification: Diverticular Disease and Diet

Until quite recently, physicians have generally recommended that patients with diverticular disease of the colon⁴⁶ avoid eating nuts, seeds, corn, popcorn, and certain fruits (e.g., blueberries, strawberries) because they were thought to cause colonic irritation and aggravate diverticular disease.⁴⁷ The recommendation was based on the reasonable assumption that, among other things, food with poorly digested particles could abrade the mucosa or lodge in small diverticula and cause inflammation, bleeding, and other complications.⁴⁸ Despite being based on seemingly good reasoning, there was no empirical evidence to support the recommendation. In 2008, a study appeared in the *Journal of the American Medical Association* that presented compelling evidence on the relationship between diet and diverticular disease.⁴⁹ An eighteen-year study of

⁴⁴ *Id.*

⁴⁵ See Atika Shubert, *UK Breast Implant Victims Want Answers*, CNN (Jan. 7, 2012, 2:42 AM), www.cnn.com/2012/01/07/world/europe/uk-breast-implant/index.html (discussing recall responses in European countries).

⁴⁶ Diverticular disease is caused by diverticula, “saclike mucosal outpouchings that protrude from a tubular structure. . . . Colonic diverticula “cause symptoms by trapping feces and becoming inflamed or infected, bleeding, or rupturing.” THE MERCK MANUAL OF DIAGNOSIS & THERAPY ch. 20 (19th ed. 2011). The term includes the less severe diverticulosis, “the presence of multiple diverticula in the colon,” as well as the more severe diverticulitis, an “inflammation of a diverticulum, which can result in phlegmon of the bowel wall, perforation, fistula, or abscess.” *Id.*

⁴⁷ Lisa L. Strate et al., *Nut, Corn, and Popcorn Consumption and the Incidence of Diverticular Disease*, 300 JAMA 907, 907 (2008). See Danny O. Jacobs, *Clinical Practice: Diverticulitis*, 357 NEW ENG. J. MED. 2057, 2064 (2007); see also S. Schechter et al., *Management of Uncomplicated Acute Diverticulitis: Results of a Survey*, 42 DISEASES OF COLON & RECTUM 470, 472 (1999).

⁴⁸ Schechter et al., *supra* note 47, at 2057.

⁴⁹ Strate, *supra* note 47 at 911-12.

47,228 male health professionals showed no correlation between consumption of these foods and increased symptoms of diverticular disease.⁵⁰ In fact, for unknown reasons, the foods exhibited a mild protective effect.⁵¹

Almost immediately, many (although not all) gastroenterologists and internists prospectively revised the dietary recommendation they gave to their patients with diverticular disease. It is not clear, however, whether or how many physicians made efforts to contact patients and former patients to update the earlier dietary recommendations. Undoubtedly, many thousands of patients have continued to be deprived of, among other things, popcorn at movies, chocolate bars with almonds, and a popular fast food double cheeseburger served on a sesame seed bun. Although the restricted diet might actually be beneficial to their health for other reasons, many patients undoubtedly would welcome the option to restore certain previously excluded foods to their diet.

One might be tempted to dismiss this example as involving only a minor lifestyle choice. Nevertheless, restricted ingredients may provide some protective effect or, in the case of nuts, serve as a source of protein and therefore could have a nutritional benefit.⁵² In addition, for many individuals, these dietary restrictions, perhaps when added to other restrictions for medical or nonmedical reasons, might have a significant effect on their quality of life. Furthermore, in other situations new dietary recommendations, rather than permitting consumption of previously banned foods, might warn patients to avoid certain foods to prevent severe adverse effects. In such a case, a change in diet becomes an important medical intervention and not merely a matter of personal choice or lifestyle. Other lifestyle factors with potentially serious health implications include consumption of alcohol or other substances, exposure to extreme environments, physical exertion, and sexual activity.

⁵⁰ *Id.*

⁵¹ *Id.* at 909.

⁵² Strate et al., *supra* note 47, at 907-08.

III. THE ROLE OF HEALTH INFORMATION TECHNOLOGY

The proposal in this article is based on the desirability of conveying actionable information to patients. The development and continuous progress of the computing and communication sciences and new applications provide a wide range of relevant tools to achieve this end. These include Internet (e-health), social networks, cellular phone communication availability (m-health), electronic health records (EHRs), decision-support systems, and medical databases. The possibilities and spin-offs of HIT in health care are virtually endless and constantly evolving. Legislative enactments, such as the American Recovery and Reinvestment Act (which included the Health Information Technology for Economic and Clinical Health (HITECH) Act), are intended to encourage a broader adoption and utilization of HIT in health care.⁵³

Three lines of communication with patients are especially relevant to the proposal in this article. First, EHRs allow 24/7 access to and sharing of patients' medical history, medication plan, and imaging studies. Some countries' health systems have reached a near-complete transformation to digital information systems,⁵⁴ whereas others (notably the United States) have lagged behind.⁵⁵ Data mining of EHRs through computing algorithms provides an easy way of identifying individuals who stand to benefit from new information about their medical past, present, or future.⁵⁶

⁵³ Frederick Turner, *Use HITECH as Directed*, 32 HEALTH MGMT. TECH. 24, 24 (2011). See generally Health Information Technology for Economic and Clinical Health (HITECH) Act [hereinafter, "HITECH Act"] Provisions of the American Recovery and Reinvestment Act of 2009, Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs, and Overview ERH Incentive Programs. See CMS.GOV, <https://www.cms.gov/ehrincentiveprograms> (last visited Feb. 24, 2012).

⁵⁴ See, e.g., WHO, *Belize Health Information Goes Digital*, 87 BULLETIN OF THE WHO NO. 2 81, 87-88 (Feb. 2009) available at <http://www.who.int/bulletin/volumes/87/2/09-020209.pdf>

⁵⁵ See Eric Jamoom et al., *Physician Adoption of Electronic Health Record Systems: United States, 2011*, NCHS DATA BRIEF No. 98 (July 2012), available at www.cdc.gov/nchs/data/databriefs/db98.pdf, (reporting that 55% of physicians were using an EHR); INST. OF MED., HEALTH IT AND PATIENT SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE 18 (2011); David Blumenthal, *Wiring the Health System—Origins and Provisions of a New Federal Paradigm*, 365 NEW ENG. J. MED. 2323 (2011); HITECH Act, *supra* note 53 (describing the new voluntary Medicare EHR Incentive Program Congress has passed to address the United States' EHR deficiencies).

⁵⁶ Naren Ramakrishnan et al., *Mining Electronic Health Records*, 43 COMPUTER 95, 99 (2010).

Second, social networks are proving to be highly effective in disseminating information on a large scale.⁵⁷ Providers can use this technology to create patient groups (based on common grounds such as diagnosis or affiliation with a specific provider), where information exchange is feasible without the need for many resources. Two main objections can be identified. First, Internet literacy and accessibility varies widely, and not all patients are computer savvy.⁵⁸ The “digital divide” mostly affects elderly, minority, and low-income populations, thereby raising concerns about increasing health disparities.⁵⁹ These concerns should dissipate in the long run with more universal access to computers.⁶⁰ In the short run, however, efforts are needed to provide notification through other reliable and secure means. The second objection pertains to the need for stringent security to prevent third parties from accessing personal information available in social networks.⁶¹ This latter concern can be resolved via coded or anonymous identities, or by designing rules for proper use of social medical networks.⁶² The willingness of individuals to share their personal health information is remarkable, and it can be harnessed for the benefit of many others, notwithstanding privacy and security concerns.⁶³

Finally, mobile health (m-health) is amplifying HIT potency with

⁵⁷ Nicolas P. Terry, *Physicians and Patients Who “Friend” or “Tweet”*: Constructing a Legal Framework for Social Networking in a Highly Regulated Domain, 43 IND. L. REV. 285, 286–89, 292–93 (2010).

⁵⁸ Mollyann Brodie et al., *Health Information, the Internet, and the Digital Divide*, 19 HEALTH AFFAIRS 255, 257–59 (2000).

⁵⁹ See *id.*; Betty L. Chang et al., *Bridging the Digital Divide: Reaching Vulnerable Populations*, 11 J. AM. MED. INFORMATICS ASS’N 448, 449 (2004).

⁶⁰ But see Brodie et al., *supra* note 58, at 263 (questioning whether all social groups will attain more universal access to computers and thus whether access disparities and usage will decrease).

⁶¹ See Terry, *supra* note 57, at 285, 294–97.

⁶² See generally *id.*

⁶³ Mark A. Rothstein, *Health Privacy and the Facebook Generation*, BIOETHICS FORUM (Aug. 11, 2011), <http://www.thehastingscenter.org/BioethicsForum/post.aspx?id=3794>; Tom Ferguson, *E-Patients—How They Can Help Us Heal Healthcare*, E-PATIENTS.NET (Mar. 2007), http://e-patients.net/e-Patients_White_Paper.pdf (last visited Feb. 24, 2012); Terry, *supra* note 57, at 321–29.

the addition of mobile capacities.⁶⁴ Although HIT availability is still restricted in some geographic areas or in some subgroups of society, cellular services are widely available.⁶⁵ Several high-tech companies are engaged in software solutions to turn mobile phones into information portals (“smartphone-like”), allowing access to the Internet, social networks, and other electronic platforms.⁶⁶ As envisioned by the International Telecommunication Union (the leading United Nations agency for information and communication technology issues):

With mobile communication, populations can be treated in their homes and communities with access to expert care. Any healthcare personnel can get access to vital information anywhere and at any time. Wireless technologies increase real time access to accurate patient data, including clinical histories, treatment, medication, tests, laboratory results, etc. and result in overall improvement of patient care and the provision of personalized health services. Mobile technologies can also improve data accuracy and significantly reduce errors during data collection and disease surveillance. Mobile clinics and mobile portable e-Health terminals can take healthcare to distant locations to support prompt medical assistance at remote sites or during emergency responses.⁶⁷

It would be a small step to communicate health-related information to large groups of patients via mass text messages or automated voice messages.

Once the technology is in place, numerous questions will still remain, including what, when, how, and by whom health information should be distributed. Professional bodies (by codes of

⁶⁴ See generally Naveen Menon et al., *Asia Pacific Mobile Observatory 2011*, Global Sys. for Mobile Comm'n Ass'n (GSMA), www.gsma.com/go/download/?file=amoewebfinal.pdf (last visited Feb. 24, 2012); see also Vital Wave Consulting, *mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World* at 9, UN Foundation-Vodafone Foundation Partnership (2009) (describing the increase of mobile device usage in developing countries and mobile devices' greater potential as HIT tools).

⁶⁵ Vital Wave Consulting, *supra* note 64, at 7 (estimating by 2012 half of all people living in “remote areas of the world” will have mobile phones).

⁶⁶ Joshua J. Romero, *Top 11 Technologies of the Decade: No. 1 Smartphones: Is Your Phone Smarter than a Fifth Grader?*, IEEE SPECTRUM 28, 28–31 (Jan. 2011), available at <http://spectrum.ieee.org/telecom/wireless/smartphones-the-pocketable-pc>.

⁶⁷ INT'L TELECOMM. UNION, *Applications and Cybersecurity (CYB): Mobile e-Health*, ITU.INT, <http://www.itu.int/ITU-D/cyb/app/e-health/mhealth.html> (last visited Feb. 24, 2012) (citing INT'L TELECOMM. UNION, *MOBILE E-HEALTH SOLUTIONS FOR DEVELOPING COUNTRIES* (2010)).

ethics, clinical guidelines, and position statements), governmental authorities (by laws, regulations, and disciplinary measures), and litigation all will play a role in shaping notification policy and law.

IV. ETHICAL PRINCIPLES RELATED TO THE DUTY TO NOTIFY PATIENTS

Sections II and III indicated that notifying patients of new medical discoveries is often medically necessary and technologically feasible. This section demonstrates that an ethical duty on the part of physicians to notify patients is consistent with and compelled by modern conceptions of the physician-patient relationship as evidenced by several ethical principles addressing the disclosure of information and shared decision-making.

A. Veracity or Truth Telling

The history of medical practice is one of largely unchallenged paternalism, including a reluctance to share information with patients:

At least since Hippocratic days, patients have been asked to trust their physicians without question. But only in recent years have doctors been asked to trust patients by conversing with them about medical options and soliciting their views on how to proceed.⁶⁸

In 1961, 90% of physicians surveyed indicated that they avoided disclosing a diagnosis of cancer to their patients.⁶⁹ By 1979, 98% of physicians surveyed said they disclosed a diagnosis of cancer to their patients.⁷⁰ What accounts for such a dramatic shift in such a relatively short period of time?

Beginning in the 1960s and continuing through the 1970s, a substantial social upheaval took place in the United States.⁷¹ The civil

⁶⁸ JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT*, xli (rev. ed. 2002).

⁶⁹ Donald Oken, *What to Tell Cancer Patients: A Study of Medical Attitudes*, 175 JAMA 1120, 1120 (1961).

⁷⁰ Dennis H. Novack et al., *Changes in Physicians' Attitudes Toward Telling the Cancer Patient*, 241 JAMA 897, 898 (1979).

⁷¹ PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE*, 388–89 (1982).

rights movement, the anti-war movement, the women's rights movement, and other social forces challenged the status quo in relationships between individuals and social institutions.⁷² Medicine and health care also reflected these new societal values. Medicare and Medicaid expanded access to health care to individuals who were elderly, low income, or disabled.⁷³ The field of bioethics arose, prompted by legal developments and changing public attitudes toward medical care at the end of life, reproductive freedom, and research ethics.⁷⁴ Activists argued in favor of rights *in* health care as well as a right *to* health care:⁷⁵

The new health rights movements were also concerned with rights *in* health care, such as the right to informed consent, the right to refuse treatment, the right to see one's own medical records, the right to participate in therapeutic decisions, and the right to due process in any proceeding for involuntary commitment to a mental institution.⁷⁶

The days of the tight-lipped, directive physician and the docile, compliant patient were largely over. More educated, informed, and assertive patients demanded to know the details of their health, and physicians quickly acknowledged it was their professional responsibility to supply truthful and complete information. Truth telling, or veracity, joined the virtues of candor and honesty as core professional values and character traits.⁷⁷

The sharing of information was not always complete, however. One category, exempt from disclosure obligations, lasted for decades. The "therapeutic privilege" permitted physicians to withhold information deemed likely to cause such distress to the patient that it

⁷² See generally *id.*

⁷³ Richard G. Frank, *The Creation of Medicare and Medicaid: The Emergence of Insurance and Markets for Mental Health Services*, 51 *PSYCHIATRIC SERVS.* 465, 465 (2000).

⁷⁴ See generally Mark A. Rothstein, *The Role of Law in the Development of American Bioethics*, 20 *INT'L J. BIOETHICS* 73 (2010) (discussing events that led to the development of bioethics in the 1970s).

⁷⁵ See STARR, *supra* note 71, at 389.

⁷⁶ *Id.*

⁷⁷ TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 288 (6th ed. 2009).

would undermine the patient's physical or emotional health.⁷⁸ Although it is easy to discern a beneficent basis for the exception, the therapeutic privilege was not clearly limited and it undermined the concepts of autonomy and respect for persons that gave rise to the principle of veracity in the first place.⁷⁹ In 2006, with an amendment to its *Code of Medical Ethics*, the American Medical Association (AMA) ended its support for the therapeutic privilege.⁸⁰ Thus, the duty to supply patients (or those responsible for their care) with truthful and complete information about a patient's medical condition is now an absolute ethical precept, at least in the United States.⁸¹

B. Informed Consent

The doctrine of informed consent in clinical settings has two main elements. First, the physician discloses relevant health information to the patient.⁸² Second, the patient manifests informed consent or refusal to a treatment plan, procedure, or therapy.⁸³ As discussed in the previous section, the longstanding, accepted medical practice was not to disclose all medical information to patients.⁸⁴ "The informational part of what we call today 'informed consent'

⁷⁸ See AM. MED. ASS'N, *supra* note 6, at § 8.082 (adopted 2006, and announcing its intent to no longer support such a privilege's exemption from disclosure obligations).

⁷⁹ See generally Nathan A. Bostick et al., *Report of the American Medical Association Council on Ethical and Judicial Affairs: Withholding Information from Patients: Rethinking the Propriety of "Therapeutic Privilege"*, 17 J. CLIN. ETHICS 302 (2006).

⁸⁰ AM. MED. ASS'N, *supra* note 6, at 8.082:

Section 8.082 Withholding Information from Patients:

The practice of withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated is known as "therapeutic privilege." It creates a conflict between the physician's obligation to promote patients' welfare and respect for their autonomy by communicating truthfully. . . . Withholding medical information from patients without their knowledge or consent is ethically unacceptable. *Id.*

⁸¹ *E.g.*, Israel Patient Rights Act, 1996, § 13(D) (a healthcare provider may withhold information if such information will create "severe" physical or mental harm).

⁸² See 45 C.F.R. § 46.116 (2005).

⁸³ See *id.*; AM. MED. ASS'N, *supra* note 6, at § 8.08.

⁸⁴ See, *e.g.*, Oken, *supra* note 69, at 1120.

was, it appears, 'up to the doctor.'"⁸⁵

Although tort law applications of nascent elements of informed consent began to emerge in the early part of the twentieth century,⁸⁶ medical ethics did not begin to embrace informed consent until the late 1950s and early 1960s.⁸⁷ Again, legal developments, both common law and statutory, led the way:

The standards and the essential elements of informed consent were stated in legal fashion and incorporated into the statutory law of many states: physicians must inform their patients about the nature of their condition and its expected course, about the benefits and risks of any proposed treatment . . . or non-treatment. This new legal requirement was impressed upon physicians as a professional duty.⁸⁸

As with veracity, once a professional consensus developed favoring informed consent, it soon swept the medical profession. What many legal scholars consider the landmark informed consent case was not decided until 1972,⁸⁹ and by 1982, a survey of physicians suggested that informed consent had become routine, at least for invasive procedures:⁹⁰

Almost all of the physicians surveyed indicated they obtained either written consent (over 80%) or *both* written *and* oral consent (about 15%) from their patients before inpatient surgery or the administration of general anesthesia. . . . At least 85% [of physicians] said they usually obtain[ed informed consent]. . . for minor office surgery, setting of

⁸⁵ ALBERT R. JONSEN, *THE BIRTH OF BIOETHICS* 354 (1998).

⁸⁶ RUTH R. FADEN & TOM L. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 119-120 (1986). For a further discussion of the legal doctrine of informed consent, see *infra* Part VI-A.

⁸⁷ *Id.* at 86. The post-World War II period also was an important time for the development of informed consent to research, as the Nuremberg Code recognized informed consent as the first principle of ethical research. The issue of informed consent in the research context, however, is beyond the scope of this article.

⁸⁸ JONSEN, *supra* note 85, at 355. See generally Jaime S. King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 *AM. J. L. & MED.* 429 (2006); Sheldon F. Kurtz, *The Law of Informed Consent: From "Doctor Is Right" to "Patient Has Rights,"* 50 *SYRACUSE L. REV.* 1243, 1252 (2000); Annette M. O' Connor et al., *Toward the "Tipping Point": Decision Aids and Informed Patient Choice*, 26 *HEALTH AFFAIRS* 716, 723 (2007).

⁸⁹ *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972). See Marjorie M. Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 *YALE L. J.* 219, 237 (1985).

⁹⁰ FADEN & BEAUCHAMP, *supra* note 86, at 98-99.

fractures, local anesthesia, invasive diagnostic procedures, and radiation therapy. [Although] blood tests and prescriptions appear to proceed . . . without patient consent, . . . even here about half of the physicians reported obtaining oral consent.⁹¹

The requirement of informed consent has become an important element of the codes of medical ethics of both the American Medical Association and numerous medical specialty colleges and societies.⁹² The AMA's code of ethics also addresses other issues raised by the broad principle of informed consent, including determining competency to consent, consent in emergencies, and consent of minors.⁹³ All of these variations build on a central, now unassailable principle that the physician's role is to explain the medical facts and assist patients in reaching informed healthcare decisions consistent with their own values and interests.

As the doctrine has been developed and applied, informed consent has become increasingly complicated. The facts to be disclosed to the patient include the diagnosis, nature and purpose of treatment, risks and outcomes, disclosure of the physician's skill or status risks (e.g., health), alternatives, prognosis if treatment is declined, prognosis with treatment, and any conflicts of interest.⁹⁴ Among the reasons why there has been an ongoing critique of the doctrine of informed consent are the complexity of the information to be disclosed, the pro forma nature of many written and oral

⁹¹ *Id.*

⁹² AM. MED. ASS'N, *supra* note 6, at 8.08:

8.08 Informed Consent:

The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. *Id.*;

see also See BARUCH A. BRODY, MARK A. ROTHSTEIN, LAURENCE B. MCCULLOUGH, & MARY ANNE BOBINSKI, MEDICAL ETHICS: ANALYSIS OF THE ISSUES RAISED BY THE CODES, OPINIONS, AND STATEMENTS 425-66 (2001) (reviewing informed consent provisions of leading medical associations, societies, and colleges).

⁹³ *See* AM. MED. ASS'N, *supra* note 6.

⁹⁴ BARRY R. FURROW ET AL., HEALTH LAW 270-279 (2000); FADEN & BEAUCHAMP, *supra* note 86, at 30-32.

disclosures by physicians or other health care providers, the inability of a substantial number of patients to comprehend the information, the reluctance of some patients to ask questions, and concerns about whether patients actually want the responsibility to make difficult health care decisions.⁹⁵ Nevertheless, virtually no one is suggesting a return to the age of silent paternalism. According to Jay Katz, “[t]he legal vision of informed consent, based on *self-determination*, is still largely a mirage. Yet a mirage, since it not only deceives but can also sustain hope, is better than no vision at all.”⁹⁶

C. Patient Information

Section 8.12 of the American Medical Association’s *Code of Medical Ethics* seems to have direct relevance to a physician’s duty to notify patients of new medical developments. It reads in part: “Ethical responsibility includes informing patients of changes in their diagnosis resulting from retrospective review of test results or any other information.”⁹⁷ This provision and other parts of the section are

⁹⁵ See, e.g., Jay Katz, *Informed Consent – Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL’Y 69, 74 (1994); William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1721 (1999); Carl E. Schneider, *Bioethics with a Human Face*, 69 IND. L.J. 1075, 1094 (1994); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 921 (1994); Gil Siegal, Richard J. Bonnie, & Paul S. Appelbaum, *Personalized Disclosure by Information-on-Demand: Attending Patients’ Needs in the Informed Consent Process* 40 J. LAW MED. & ETHICS 359 (2012).

⁹⁶ KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* *supra* note 68, at 84 (italics in original).

⁹⁷ AM. MED. ASS’N, *supra* note 6, at 8.12:

8.12 Patient Information

It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which the patient suffers significant medical complications that may have resulted from the physician’s mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care.

Ethical responsibility includes informing patients of changes in their diagnoses resulting from retrospective review of test results or any other information. This obligation holds even though the patient’s medical treatment or therapeutic options may not be altered by the new information.

broad enough to incorporate the duty to notify patients about new medical developments, but they have never been construed to do so.⁹⁸

The section was intended to discourage physicians from failing to disclose a patient's complete medical information, including possible mistakes, based on a concern for legal liability.⁹⁹ It is not clear the extent to which the section also seeks to establish additional disclosure obligations. There is no reason to suspect that such an application was even considered, let alone intended, by the drafters of this section of the code. Indeed, all of the literature references to this section of the code address the issue of medical malpractice.¹⁰⁰

Regardless of the specific intent of this section of the code, it generally supports the obligation of physicians to apprise patients of all relevant medical information, including information discovered after the episode of care.¹⁰¹ It is additional support for the proposition that even if a duty to notify patients is considered a new obligation, such an obligation is consistent with established principles of medical ethics.

D. Non-abandonment

A fundamental element of the physician-patient relationship is that "[t]he patient has the right to continuity of health care."¹⁰² Continuity of care refers to coordination of care among members of a health care team, including not having a physician withdraw from a case without giving sufficient notice to the patient or caregivers so that another physician may be secured.¹⁰³

Concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with the patient. *Id.*

⁹⁸ See e.g., AM. MED. ASS'N, *supra* note 6, at § 8.08.

⁹⁹ John D. Banja, *Does Medical Error Disclosure Violate the Medical Malpractice Insurance Cooperation Clause?*, in 3 ADVANCES IN PATIENT SAFETY: FROM RESEARCH TO IMPLEMENTATION 371, 372 (Kerm Hendriksen et al. eds., 2005), available at <http://www.ahrq.gov/downloads/pub/advances/vol3/Banja.pdf>.

¹⁰⁰ See e.g., AM. MED. ASS'N, *supra* note 6, at § 8.12..

¹⁰¹ *Id.* at 280.

¹⁰² *Id.*, § 10.01(5) Fundamental Elements of the Physician-Patient Relationship, at 367.

¹⁰³ *Id.*, § 8.115 Termination of Physician-Patient Relationship, at 278. See Allan S. Detsky, *What*

Continuity of care also refers to professional obligations over time within the context of an ongoing physician-patient relationship:

The obligation of non-abandonment emphasizes the longitudinal nature of a caring and problem-solving commitment between physician and patient. Ethical analyses of clinical actions sometimes focus on one moment in time and seek generalizable rules or answers, but patients and their physicians do not have the luxury of existing in such isolation. Clinical decisions involve a series of choices over time, and the consequences of one decision may immediately lead to new choices.¹⁰⁴

The ethical obligation of physicians rejects the “one moment in time” approach to physician-patient relationships.¹⁰⁵ When there is a change in circumstances, either because of the health status of the patient or the state of the art in medicine, continuity of care and non-abandonment require that the physician share the new information with the patient so they can work collaboratively in developing a new patient-centered treatment plan.¹⁰⁶

E. Fiduciary Loyalty

The ethical principles discussed thus far include a physician’s duty to tell patients the truth, to obtain informed consent, to provide relevant information to patients, and to ensure continuity of care. Overarching all of these – and many other – professional obligations is the physician’s duty of loyalty. “The relationship between patient and physician is based on trust and gives rise to physicians’ ethical obligations to place patients’ welfare above their own self-interest and above obligations to other groups, and to advocate for their patients’ welfare.”¹⁰⁷

The physician-patient relationship is one of several legally

Patients Really Want from Health Care, 306 JAMA 2500, 2500 (2011) (mentioning importance to patients of continuity, choice, and coordination of care).

¹⁰⁴ Timothy E. Quill & Christine K. Cassel, *Nonabandonment: A Central Obligation for Physicians*, 122 ANNALS INTERNAL MED. 368, 370 (1995).

¹⁰⁵ *Id.* at 370.

¹⁰⁶ *Id.* at 371.

¹⁰⁷ AM. MED. ASS’N, *supra* note 6, at § 10.015 (The Patient-Physician Relationship).

recognized fiduciary relationships.¹⁰⁸ All fiduciary relationships are characterized by the fiduciary having special knowledge and the other party reasonably expecting the fiduciary to act in the best interests of the individual.¹⁰⁹ Fiduciaries have a duty to disclose information relevant to fulfilling their fiduciary duties.¹¹⁰ In the physician-patient context, the fiduciary duty means more than nonmaleficence; it establishes that the physician has an affirmative obligation to act for the benefit of the patient, including the duty to disclose information relevant to the patient's health.¹¹¹ The duty also has been held to extend beyond the discrete episode of care, even beyond the termination of the physician-patient relationship:

It is also worth noting that a physician's fiduciary duty to disclose emergent adverse medical risks¹¹² may extend beyond the termination of the physician-patient relationship. Courts have recognized that the timing of the emergent adverse medical condition does not mitigate the duty to disclose when the physician learns of information indicating that the patient's medical well-being is at significant risk.¹¹³

It can be fairly asserted that the ethical duty at the center of this article, the physician's duty to notify patients of new medical developments, is consistent with the language and intent of several important ethical principles and further serves to advance the modern conception of the physician-patient relationship.

¹⁰⁸ Other examples include attorney-client, guardian-ward, financial advisor-client, and corporate officer-shareholder. Hafemeister & Spinos, *supra* note 2 at 1187; *see also* Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 466 (2002) (arguing that trust is the unifying theme of health law). *See generally* David Orentlicher, *Health Care Reform and the Patient-Physician Relationship*, 5 HEALTH MATRIX 141, 147 (1995); Marc A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 AM. J.L. & MED. 241, 241 (1995).

¹⁰⁹ *See* Hafemeister & Spinos, *supra* note 2, at 1195.

¹¹⁰ *Id.* at 1188.

¹¹¹ *Id.* at 1184.

¹¹² "Emergent medical risks" as used in the quoted article refers to medical errors and incidental clinical findings. *See id.* at 1167.

¹¹³ *Id.* at 1191 (citing *Mink v. Univ. of Chicago*, 460 F. Supp. 713, 720 (N.D. Ill. 1978); *Schwartz v. United States*, 230 F. Supp. 536, 540 (E.D. Pa. 1964)).

V. STATUTORY DUTIES TO NOTIFY PATIENTS

Until the 1980s, there was no legal, regulatory, or ethical obligation for physicians to notify patients about certain important matters related to their care, such as medical errors and adverse events.¹¹⁴ Traditionally, many physicians have been concerned about potential malpractice liability and therefore have refrained from disclosing explanatory health information to their patients.¹¹⁵ Indeed, standard risk management advice to physicians has been to not admit any wrongdoing or even to express any regret at an unfavorable treatment outcome, because such expressions could be admitted into evidence in a subsequent malpractice case.¹¹⁶ Beginning in 1981, the AMA specifically mandated disclosures to patients of adverse events.¹¹⁷ The Joint Commission for the Accreditation of Health Care Organizations (now simply The Joint Commission) also adopted a rule requiring the notification of patients about outcomes of their care, including unanticipated outcomes.¹¹⁸

Despite ethical rules and institutional accreditation standards, most physicians still do not provide full disclosure about medical errors.¹¹⁹ According to a 2006 mail survey of 2,637 physicians, only 42% of responding physicians said they would make a full disclosure, including an explicit statement that an error occurred; 56% said they would make a partial disclosure, mentioning the adverse event but not the error; and 3% said they would make no reference to the adverse event or error.¹²⁰ Because the survey involved self-reports

¹¹⁴ It is beyond the scope of this article to address the duties of physicians to report health-related matters to parties other than the patient, such as public health authorities, law enforcement agencies, or professional accrediting bodies.

¹¹⁵ David M. Studdert et al., *Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy*, 26 HEALTH AFFAIRS 215, 215 (2007).

¹¹⁶ See *id.* (reviewing traditional risk management strategies and asserting that disclosure will reduce liability).

¹¹⁷ See discussion, *supra* Part IV-C.

¹¹⁸ JOINT COMMISSION, HOSPITAL ACCREDITATION STANDARDS (2007).

¹¹⁹ Thomas H. Gallagher et al., *Choosing Your Words Carefully: How Physicians Would Disclose Harmful Medical Errors to Patients*, 166 ARCHIVES INTERNAL MED. 1585, 1589–90 (2006).

¹²⁰ *Id.*

about how much information the physicians would disclose in the future in a hypothetical case, it is arguable that in a real-life situation, actual disclosure rates would be lower.

Some experts contend that the reluctance of physicians to disclose information related to adverse events and medical errors is a leading cause of malpractice claims, because lawsuits often are filed when patients feel deceived or abandoned.¹²¹ Regardless of its effectiveness as a risk management strategy,¹²² disclosure is an ethical obligation, and complete health information may advance the health of the patient. To give effect to these considerations, in the 1990s, state legislatures began enacting “apology” and “disclosure” laws.¹²³ This section discusses these state laws as well as recent federal legislation mandating the notification of patients in the event of a health information security breach. Taken together, these laws indicate a major change in the regulation of physician-patient relations to require more transparency and comprehensive information sharing. Greater disclosure obligations are consistent with the proposal in this article to establish a duty to notify patients of new medical developments.

¹²¹ See Howard H. Hiatt et al., *A Study of Medical Injury and Medical Malpractice*, 321 *NEW ENG. J. MED.* 480 (1989); Gerald B. Hickson et al., *Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries*, 267 *JAMA* 1359, 1359 (1992); Wendy Levinson et al., *Physician-Patient Communication: The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons*, 277 *JAMA* 553, 553 (1997); Tamara Relis, “It’s Not About the Money!”: A Theory on Misconceptions of Plaintiffs’ Litigation Aims, 68 *U. PITT. L. REV.* 341, 352 (2007). Cf. Allen Kachalia et al., *Does Full Disclosure of Medical Errors Affect Malpractice Liability? The Jury Is Still Out*, 29 *JT. COMM’N J. QUALITY & SAFETY* 503 (2003) (meta-analysis of studies did not allow for an estimate of the number of additional lawsuits prevented by disclosure).

¹²² See Studdert et al., *supra* note 115.

¹²³ See generally Allen Kachalia et al., *Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program*, 153 *ANNALS INTERNAL MED.* 213 (2010); Steve S. Kraman & Ginny Hamm, *Risk Management: Extreme Honesty May Be the Best Policy*, 131 *ANNALS INTERNAL MED.* 963, 963–966 (1999); Carol B. Liebman & Chris S. Hyman, *A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients*, 23 *HEALTH AFFAIRS* No. 4, at 22–32 (2004); Anna C. Mastroianni et al., *The Flaws in State ‘Apology’ and ‘Disclosure’ Laws Dilute Their Intended Impact on Malpractice Suits*, 29 *HEALTH AFFAIRS* 1611, 1612 (2010); Michelle M. Mello & Thomas H. Gallagher, *Malpractice Reform – Opportunities for Leadership by Health Care Institutions and Liability Insurers*, 362 *NEW ENG. J. MED.* 1353, 1354 (2010).

A. Medical Errors and Adverse Events

To promote openness in physician-patient communications, thirty-four states and the District of Columbia have enacted “apology” laws.¹²⁴ The laws differ, but they generally provide that a health care provider’s oral or written communications of apology, regret, sympathy, compassion, mistake, or similar expressions regarding a patient’s unanticipated outcome may not be admitted into evidence in a malpractice case and do not constitute an admission of liability or a statement against interest.¹²⁵ Significantly, these statements of apology are not legally required.¹²⁶ By contrast, nine states have enacted laws requiring the disclosure of unanticipated outcomes.¹²⁷ These laws, however, are usually applicable only to institutional health care providers.¹²⁸ Moreover, they “require only a bare-bones statement that an unanticipated outcome occurred,” without requiring an acknowledgement of error.¹²⁹ Whereas apology laws attempt to promote openness and to

¹²⁴ ARIZ. REV. STAT. § 12-2605; CAL. EVID. CODE § 1160; CAL. GOV’T CODE § 11440.45; COLO. REV. STAT. § 13-25-135; CONN. GEN. STAT. ANN. § 52-184D; DEL. CODE ANN. tit. 10, § 4318; D.C. CODE § 16-2841; FLA. STAT. § 90.4026; GA. CODE ANN. § 24-3-37.1; HAW. R. EVID. 409.5; IDAHO CODE § 9-207, IDAHO R. EVID. 414; IND. CODE § 34-43.5-1; IOWA CODE § 622.31; LA. REV. STAT. ANN. § 13:3715.5; ME. REV. STAT. ANN. tit. 24, § 2907; MD. CTS. & JUD. PROC. CODE ANN. § 10-920; MASS. GEN. LAWS ch. 233, § 23D; MO. ANN. STAT. § 538.229; MONT. CODE ANN. § 26-1-814; NEB. REV. STAT. § 27-1201; N.H. REV. STAT. ANN. § 507-E:4; N.C. GEN. STAT. ANN. §8C-1, RULE 413; N.D. CENT. CODE § 31-04-12; OHIO REV. CODE ANN. § 2317.43; OKLA. STAT. tit. 63, § 1-1708.1H; OR. REV. STAT. ANN. § 677.082; S.C. CODE ANN. § 19-1-190; S.D. CODIFIED LAWS § 19-12-14; TENN. R. EVID. 409.1; TEX. CIV. PRAC. & REM. CODE § 18.061; UTAH CODE ANN. § 78B-3-422, UTAH R. EVID. 409; VT. STAT. ANN. tit. 12, § 1912; VA. CODE ANN. § 8.01-52.1; VA. CODE ANN. § 8.01-581.20.1; WASH. REV. CODE § 5.64.010; W. VA. CODE § 55-7-11A; WYO. STAT. ANN. § 1-1-130.

¹²⁵ See sources cited *supra* note 124.

¹²⁶ See sources cited *supra* note 124.

¹²⁷ CAL. HEALTH & SAFETY CODE § 1279.1 (West 2011); FLA. STAT. ANN. §§ 395.0197, 395.1051, 456.0575 (West 2011); FLA. ADMIN. CODE ANN. 64B8-8.001, 64B8-8.011 (2011); NEV. REV. STAT. §§ 439.855, 439.860 (West 2011); N.J. STAT. ANN. § 26:2H-12.25D (West 2011); N.J. ADMIN. CODE § 8:43E-10.7 (2011); OR. REV. STAT. ANN. § 442.837 (West 2011); 40 PA. CONS. STAT. ANN. § 1303.308 (West 2011); TENN. CODE ANN. § 68-11-211 (West 2011); VT. CODE ANN. tit. 18, § 1915 (West 2011); VT. CODE R. § 12-5-16:2 (West 2011); WASH. REV. CODE § 70.41.380 (West 2011).

¹²⁸ See sources cited *supra* note 127.

¹²⁹ Mastroianni et al., *supra* note 123, at 1615.

protect physicians from malpractice liability, disclosure laws attempt to promote the interests of patients in learning the existence and cause of adverse outcomes. Although these statutes must be regarded as extremely limited or tentative steps, at least they are steps in the right direction. They further support the need to encourage or even compel additional communications by physicians to patients.

B. Health Information Security Breaches

The Health Information Technology for Economic and Clinical Health (HITECH) Act,¹³⁰ Title XIII of the American Recovery and Reinvestment Act of 2009,¹³¹ contains a provision directing the Secretary of Health and Human Services (HHS) to issue regulations setting forth the breach notification obligations of entities subject to the Health Information Portability and Accountability Act (HIPAA) Privacy Rule.¹³² The HITECH Act requires HIPAA covered entities to provide notification to affected individuals and to the Secretary of HHS following the discovery of a breach of unsecured protected health information.¹³³ In addition to the federal requirement, laws in forty-six states and the District of Columbia mandate the notification of health information security breaches, although the details vary among the states.¹³⁴

¹³⁰ Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 115, 226, 263 (2009).

¹³¹ Title XIII of the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

¹³² Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of titles 18, 26, 29, and 42 U.S.C.). The HIPAA Privacy Rule is codified as follows: Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. pt. 164 subpart E (2010); *see also* 45 C.F.R. §160.103 (defining “individually identifiable health information”). The covered entities are health care providers, health plans, health clearinghouses, and business associates of the first three entities. 45 C.F.R. § 160.102 (2010).

¹³³ 42 U.S.C.A. § 17932 (West 2011).

¹³⁴ ALASKA STAT. § 45.48.010(a), (b) (2011); ARIZ. REV. STAT. ANN. § 44-7501(a) (2010); ARK. CODE ANN. §§ 4-110-101, 4-110-105 to -108 (West 2011); CAL. CIV. CODE §§ 56.06, 1785.11.2, 1798.29, 1798.82 (West 2011); COLO. REV. STAT. ANN. § 6-1-716(1)(a), 2(a) (West 2012); CONN. GEN. STAT. ANN. § 36a-701b(a-b) (2011); DEL. CODE ANN. tit. 6, § 12B-101 (West 2011); D.C. CODE § 28-3851 to -3852 (2012); FLA. STAT. § 817.5681(1)(a) (2011); GA. CODE §§ 10-1-910 to -912 (2011); HAW. REV. STAT. § 487N-2 (2011); IDAHO CODE ANN. §§ 28-51-104 to -107 (2012); 815 ILL. COMP. STAT. ANN. § 530/1, 530/10, 530/15 (2011); IND. CODE §§ 24-4-9-1-1, 24-4-9-2-2, 4-

According to the federal regulations, except when law enforcement requests a delay, a covered entity is required to send a notice within sixty calendar days of discovering the breach.¹³⁵ The notice must include the following: (1) a brief description of what happened, the date of breach, and the date of discovery; (2) a brief description of the types of health information involved; (3) any steps individuals should take to protect themselves from harm due to the breach; (4) a brief description of what steps the covered entity is taking to investigate the breach, minimize resulting injury, and prevent a breach from recurring; and (5) contact information.¹³⁶ The notice must be written in plain language¹³⁷ and sent by first-class mail or, according to prior agreement with the recipient, by electronic mail.¹³⁸ In urgent situations, where there is possible imminent misuse of the information, the covered entity may provide notice by telephone or other suitable means.¹³⁹ Notification also must be provided to the media, and the Secretary is required to post on the

1-11-1 to -10 (2011); IOWA CODE ANN. §715C.1-715C.2 (West 2011); KAN. STAT. §§ 50-7a01, 50-7a02 (2011); LA. REV. STAT. ANN. § 51:3071, 51:3074 (2011); ME. REV. STAT. tit. 10, § 1347, 1347-A (2011); MD. CODE ANN., COM. LAW § 14-3501, 14-3504(2011); MASS. GEN. LAWS ANN. ch. 93H, §§1-3 (2011); MICH. COMP. LAWS ANN. § 445.72 (West 2011); MINN. STAT. ANN. §§ 325E.61, 325E.64 (West 2011); H.B. 583, 2010 Leg. (Miss. 2010); MO. REV. STAT. ANN. § 407.1500 (2011); MONT. CODE §§ 30-14-1704, 2-6-504 (2011); NEB. REV. STAT. ANN. §§ 87-801 to -807 (2011); NEV. REV. STAT. ANN. §§ 603A.010, 603.220 (West 2010); N.H. REV. STAT. §§ 359-C:19 to -C:21 (2011); N.J. STAT. ANN. § 56:8-163 (West 2011); N.Y. BUS. LAW § 899-aa(1)(a, c), (8)(a) (2011); N.C. GEN. STAT. § 75-65 (2011); N.D. CENT. CODE ANN. § 51-30-01 to -07 (West 2011); OHIO REV. CODE ANN. §§ 1347.12, 1349.19, 1349.191, 1349.192 (West 2011); OKLA. STAT. §§ TIT. 74, § 3113.1, tit. 24 §§ 161 to 166 (2011); OR. REV. STAT. ANN. § 646A.600-.604 (West 2011); 73 PA. CONS. STAT. ANN. §2303 (2011); R.I. GEN. LAWS § 11-49.2-1 to -4 (2011); S.C. CODE ANN. § 39-1-90 (2011); TENN. CODE ANN. § 47-18-2107 (2011); TEX. BUS. & COM. CODE § 521.053 (West2011); UTAH CODE ANN. §§ 13-44-101, -102, -201, -202, -301(West 2011); VT. STAT. ANN. tit. 9, §§ 2430, 2435 (West 2011); VA. CODE ANN. §§ 18.2-186.6, 32.1-127.1:05 (West 2011); WASH. REV. CODE ANN. §§ 19.255.010, 42.56.590 (West 2012); W. VA. CODE ANN. § 46A-2A-101 to -105 (West 2011); WIS. STAT. ANN. § 134.98 (West 2011); WYO. STAT. §§ 40-12-501 to -502 (2011).

¹³⁵ See 45 C.F.R. §§ 164.404(b), 164.412 (2012); Breach Notification for Unsecured Protected Health Information, 74 Fed. Reg. 42,768-69 (Aug. 24, 2009).

¹³⁶ 45 C.F.R. § 164.404(c)(1); Breach Notification for Unsecured Protected Health Information, 74 Fed. Reg. 42, 768 (Aug. 24, 2009).

¹³⁷ *Id.* at (c)(2).

¹³⁸ *Id.* at (d)(1).

¹³⁹ *Id.* at (d)(3).

HHS website a list of covered entities that experience breaches involving more than 500 individuals.¹⁴⁰

Neither federal nor state laws establish comprehensive notification obligations in the event of a health information security breach.¹⁴¹ As with the limited protections of state “apology” and “disclosure” laws, these provisions establish growing support for the public policy of health care providers and institutions sharing important information with patients.¹⁴²

VI. COMMON LAW LIABILITY FOR FAILING TO INFORM, WARN, OR NOTIFY

A. Informed Consent

Informed consent has become the centerpiece of the physician-patient relationship in medical ethics¹⁴³ as well as in health care law.¹⁴⁴ It establishes the duty of a physician to inform patients about their diagnosis, the nature of the proposed treatment, its benefits and possible risks, and available alternatives (including refraining from treatment) – all in an understandable fashion.¹⁴⁵ Two standards have

¹⁴⁰ See Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 115, 261–62 (2009); Breach Notification for Unsecured Protected Health Information, Interim Final Rule, 74 Fed. Reg. 42, 740 (2009).

¹⁴¹ See generally GINA STEVENS, CONG. RESEARCH SERV., RL 34120, FEDERAL INFORMATION SECURITY AND DATA BREACH NOTIFICATION LAWS 1–2 (2010); Paul M. Schwartz & Edward J. Janger, *Notification of Data Security Breaches*, 105 MICH. L. REV. 913, 913 (2007); Jane K. Winn, *Are “Better” Security Breach Notification Laws Possible?*, 24 BERKELEY TECH. L.J. 1133, 1133, 1135 (2009).

¹⁴² Thomas H. Gallagher & Mary Hardy Lucas, *Should We Disclose Harmful Medical Errors to Patients? If so, How?*, 12 NEW ENG. J. MED. 253, 253, 257 (2005); Agency for Healthcare Research and Quality, *In Conversation with...Thomas H. Gallagher, MD*, AHRQ WEBM&M: MORBIDITY & MORTALITY ROUNDS ON THE WEB – PERSPECTIVES ON SAFETY (Jan. 2009), <http://webmm.ahrq.gov/perspective.aspx?perspectiveID=69>.

¹⁴³ See *supra* Part IV-B.

¹⁴⁴ See *Canterbury v. Spence*, 464 F.2d 772, 781 (D.C. Cir. 1972). See generally Susan M. Wolf, *Toward a Systemic Theory of Informed Consent in Managed Care*, 35 HOUS. L. REV. 1631 (1999); Jay Katz, *Informed Consent – Must It Remain a Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL'Y 69 (1994); Alan J. Weisbard, *Informed Consent: The Law's Uneasy Compromise with Ethical Theory*, 65 NEB. L. REV. 749 (1986).

¹⁴⁵ See generally JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL

been used in state courts to evaluate the disclosure performance – the “reasonable physician” standard (what reasonable physicians tell their patients before rendering care) and the “reasonable patient” standard (what reasonable patients need to know in order to make an informed decision).¹⁴⁶ Failure to meet the standard of disclosure results in the medical treatment being nonconsensual care with the following legal liabilities: (1) nonconsensual physical interaction amounts to battery;¹⁴⁷ and (2) failure to provide adequate information is a breach of the duty owed to patients – i.e., malpractice.¹⁴⁸ In recent years, because most informed consent cases involved only *inadequate* information (as opposed to no information at all), malpractice has become the dominant liability theory, leaving battery to more severe cases such as in fraudulent concealment or unwanted forced care.¹⁴⁹ Pertinent to this article, failure to provide timely information can have a major impact on a patient’s life and health, and it is easy to see why patients would expect to be informed.¹⁵⁰ However, the duty of informed consent has been applied mostly for prospective or ongoing treatment.¹⁵¹ Thus, it is questionable whether it can be applied to the duty to notify patients of new medical discoveries after an episode of

PRACTICE 45–46 (2nd ed. 2001); FADEN & BEAUCHAMP, *supra* note 86, at 30–34 (discussing three different legal standards for determining the scope of informed consent).

¹⁴⁶ For a tabulation of states’ informed consent laws, see Jamie Staples King & Benjamin Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 493–501 (2006).

¹⁴⁷ Tortious battery requires intent to make physical contact with another person’s body without consent. See RESTATEMENT (SECOND) OF TORTS § 13 (1965). The individual need not intend to cause a particular harm or even to do wrong. See *id.* & cmt. c.

¹⁴⁸ See *Canterbury*, 464 F.2d at 781 (D.C. Cir. 1972).

¹⁴⁹ See, e.g., *Nathanson v. Kline*, 350 P.2d 1093 (Kan. 1960); *Tisdale v. Pruitt*, 394 S.E.2d 857 (S.C. Ct. App. 1990) (holding that unauthorized dilation and curettage was actionable under the informed consent doctrine); See *Mills v. Rogers*, 457 U.S. 291 (1982) (remanding for consideration of whether state law grants involuntarily committed mental patients a right to refuse antipsychotropic drugs). See also Jay Katz, *Informed Consent-- A Fairy Tale? -- Law’s Vision*, 39 U. PITT. L. REV. 137, 151-53 (1977); E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL’Y 1, 52-63 (2003).

¹⁵⁰ Joan H. Krause, *Can Health Law Truly Become Patient Centered?*, 45 WAKE FOREST L. REV. 1489, 1491–92 (2010).

¹⁵¹ See Morreim, *supra* note 149, at 63.

care.¹⁵²

B. Medical Malpractice

To prevail in a malpractice action a plaintiff must establish that the physician has breached the duty of care owed to the patient (based on a legally binding physician-patient relationship) by performing below the standard of care expected from a reasonable physician under the same circumstances and that the breach directly brought about the complained-of injuries (causation).¹⁵³ In this regard, assuming a duty of care (which is questionable in some notification scenarios, as mentioned earlier¹⁵⁴), failure to notify a patient about material risks can be construed as a failure to meet the duty of a reasonable physician, resulting in malpractice liability.

There have been relatively few malpractice cases involving a health care provider's alleged failure to apprise patients of new information of direct relevance to their health. In *Pisano v. Ferrara*,¹⁵⁵ a dentist was held liable for failing to inform a patient of the need to remove a dental implant later determined to be linked to tumors. On the other hand, in *Melton v. Medtronic, Inc.*,¹⁵⁶ although the duty to inform was acknowledged, a cardiologist was not liable for failing to inform a patient of defects in an implanted cardiac defibrillator because there was insufficient evidence of harm proximately caused by the delay in notification.

Because the standard of care is based on the generally recognized and accepted practices of physicians, it is essential to identify and delineate the situations where physicians should notify their current or past patients. To this end, professional associations should respond to the advancements in HIT and create workable guidelines for their members, an effort that could instruct the courts and

¹⁵² See *id.* at 63-86 and accompanying notes.

¹⁵³ Edward B. Hirshfeld, *Practice Parameters and the Malpractice Liability of Physicians*, 263 JAMA 1556, 1556 (1990).

¹⁵⁴ See *supra* note 129 and accompanying text.

¹⁵⁵ *Pisano v. Ferrara*, A-6663-06T3, 2008 WL 4392216 (N.J. Super. Ct. App. Div. 2008).

¹⁵⁶ *Melton v. Medtronic, Inc.*, 698 S.E.2d 886 (S.C. Ct. App. 2010).

regulators.¹⁵⁷

Opponents of this recommendation might argue that recognizing a duty to notify in position papers and guidelines will result in a clearer obligation, from which a deviation might be regarded as a compensable breach of duty.¹⁵⁸ Nevertheless, courts are likely to recognize a duty to notify patients even without professional recognition, and the lack of input by professional groups will merely cede development of the field to others.

A physician's duties arising from informed consent generally differ from those actionable as malpractice. As for the latter, the standard used by all jurisdictions is the reasonable physician.¹⁵⁹ For informed consent, however, some jurisdictions use the reasonable physician standard, whereas others use the reasonable patient standard.¹⁶⁰ This in turn might imply that failure to meet a *patient's* expectation to be notified might result in a breach of duty on the part of the physician. Consequently, in such jurisdictions, the shield of clinical guidelines and common practices loses its might, and courts will reconstruct the patient's informational needs in a way that is harder to anticipate. Accordingly, HIT allows physicians in such circumstances to address this difficulty up front, by requesting their patients to indicate if they want to be notified and, if so, their preferred method, such as e-mails or social networks.

Some analogies can be drawn to the legal scholarship on re-

¹⁵⁷ See KY. REV. STAT. ANN. § 342.035(8)(b) ("Any provider . . . who has followed the practice parameters or guidelines developed or adopted pursuant to this subsection shall be presumed to have met the appropriate legal standard of care in medical malpractice cases...."); *Hinlicky v. Dreyfuss* 848 N.E.2d 1285 (N.Y. 2006) (holding professional guidelines are admissible as evidence of the standard of care). See generally Ronen Avraham, *Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System*, 37 AM. J. L. & MED. 7, 7, 16-23, 26-27 (2011); Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 647 (2001); Scott B. Ransom et al., *Reduced Medicolegal Risk by Compliance With Obstetric Clinical Pathways: A Case-Control Study*, 101 OBSTETRICS & GYNECOLOGY 751, 754-55 (2003); Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POLITICS POL'Y & L. 327, 352-53 (2001).

¹⁵⁸ See Ransom, *supra* note 157, at 754.

¹⁵⁹ See generally 61 Am. Jur. 2d Physicians, Surgeons, Etc. § 287 (2012).

¹⁶⁰ See, e.g., *Canterbury v. Spence* 464 F.2d 772, 781 (D.C. Cir. 1972) (using reasonable patient standard).

contacting for “incidentaloma” – the discussion on the appropriate action expected from a physician or a researcher in light of incidental findings (e.g., a tumor identified during a CT scan ordered for another purpose, an experimental fMRI study, or a mutated gene discovered during a whole genome study).¹⁶¹ The issue is whether there is a legal duty to notify patients when information did not accrue during or as a result of rendering health care. Scholars generally have recommended a proactive approach, in which both parties discuss the possibility of incidental findings and the way to deal with them in advance.¹⁶² Courts have been reluctant to establish a legal duty absent a recognized relationship,¹⁶³ but some scholars believe that such a stance fails to protect the legal rights of research subjects.¹⁶⁴

Israel, a common law jurisdiction, had a unique case involving

¹⁶¹ For a detailed symposium, see Symposium, *Incidental Findings in Human Subjects Research: From Imaging to Genomics*, 36 J. L. MED. & ETHICS 216-383 (2008). See also L.L. Berland et al., *Managing Incidental Findings on Abdominal CT: White Paper of the ACR Incidental Findings Committee*, 7 J. AM. COLL. RADIOL. 754 (2011); Matthew P. Gordon, *A Legal Duty to Disclose Individual Research Findings to Research Subjects?*, 64 FOOD & DRUG L.J. 225 (2009); Erica K. Rangel, *The Management of Incidental Findings in Neuro-Imaging Research: Framework and Recommendations*, 38 J.L. MED. & ETHICS 117 (2010).

¹⁶² Susan M. Wolf et al., *The Law of Incidental Findings in Human Subjects Research – Establishing Researchers’ Duties*, 36 J. L. MED & ETHICS 361 (2008); NATIONAL RESEARCH COUNCIL AND INSTITUTE OF MEDICINE, *ETHICAL CONSIDERATIONS FOR RESEARCH ON HOUSING-RELATED HAZARDS INVOLVING CHILDREN* (2005).

¹⁶³ See *Ande v. Rock*, 647 N.W.2d 265 (Wis. Ct. App.), cert. denied, 650 N.W.2d 840 (Wis. 2002), cert. denied, 537 U.S. 1107 (2003) (malpractice claims dismissed on grounds that investigators did not have a physician-patient relationship with the research subject). *But see Blaz v. Michael Reese Hosp. Fdn.*, 74 F. Supp. 2d 803 (N.D. Ill. 1999) (holding a researcher had a duty under Illinois law to disclose the risks to individuals exposed to radiation therapy of the sort received by the plaintiff).

¹⁶⁴ See, e.g., E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOU. J. HEALTH L. & POL'Y 1, 86 (2003) (“Research litigation differs importantly from ordinary medical malpractice litigation. Familiar tort doctrines such as negligence, battery, and informed consent simply do not fit the realities of research and, if they are applied thoughtlessly in this emerging body of cases, the danger is great that research participants will be left without appropriate compensation for very real injuries, and reciprocally that investigators may be subjected to unfair standards of liability. Courts need to recognize clinical research as a distinct area of medical activity and to attune tort doctrines specifically to its nuances.”); see also T.C. Booth et al., *Incidental Findings Found in “Healthy” Volunteers During Imaging Performed for Research: Current Legal and Ethical Implications*, 83 BRIT. J. RADIOL. 456 (2010).

the duty to notify and malpractice on a large scale. In the early 1950s, tens of thousands of new immigrants from Asian and North African countries were treated with low-dose radiation for tinea capitis.¹⁶⁵ After forty years, it became known that the treatment created a significant risk of developing various head and neck tumors (such as tumors of the thyroid and brain).¹⁶⁶ As a result, the Ministry of Health issued a warning to general practitioners and family doctors to pay special attention in this population to complaints or symptoms that might indicate the progression of such a tumor.¹⁶⁷ Unsurprisingly, litigation resulted from the alleged failure to identify the manifestations of head and neck tumors. In 2006, a lower court in Israel found a physician in breach of his duty for failure to notify a patient of his high-risk situation, even though the patient had no complaints or symptoms.¹⁶⁸ The court reasoned that even though a national standard of follow-up (i.e., waiting for complaints or symptoms, or performing an annual MRI on such a large population) is ineffective or prohibitively expensive, the patient could have chosen another strategy of risk assessment other than waiting for symptoms, which usually appear at a more advanced stage.¹⁶⁹ The patient convinced the court that he would have opted for an annual MRI scan, even at his own expense (his HMO stated in court that it would not have covered these high expenses).¹⁷⁰ Thus, notification can be regarded as the impetus for a patient's opportunity to prevent harm, and the lack of notice prevented him from beneficial action.

¹⁶⁵ Tinea capitis, also known as ringworm of the scalp, is a fungal infection mainly affecting children that is contagious and may become epidemic. THE MERCK MANUAL OF DIAGNOSIS & THERAPY 706 (19th ed. 2011); NAT'L ACAD. OF SCIENCES, HEALTH RISKS FROM EXPOSURE TO LOW LEVELS OF IONIZING RADIATION: BEIR VII (2005); Ron E. Modan et al., *Tumors of the Brain and Nervous System after Radiotherapy in Childhood*, 319 N. ENG. J. MED. 1033 (1988); S. Sadetzki et al., *Long-Term Follow-up for Brain Tumor Development after Childhood Exposure to Ionizing Radiation for Tinea Capitis*, 163 RADIAT. RES. 424 (2005).

¹⁶⁶ *Id.*

¹⁶⁷ Directive 17/09, Israeli Ministry of Health [in Hebrew, on file with authors]

¹⁶⁸ DC (Jer) 6347/05 Sima Rheuben v. State of Israel [2006] (Isr.). (decision in Hebrew on file with the authors).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

This is another application of the doctrine of "loss of a chance."¹⁷¹

The analogy between the duty to notify and managing incidental findings in research is imperfect. On the one hand, research subjects often act out of a strong sense of altruism, and this fact might suggest a greater responsibility on the part of researchers.¹⁷² On the other hand, incidental findings often involve information that is not clinically actionable, whereas the essence of patient notification in clinical settings involves information that has clinical utility and arises out of the special fiduciary obligation of the physician-patient relationship.

C. A Duty to Warn

The duty to warn, although arising from the physician-patient relationship, involves duties owed by physicians to non-patient third parties. In the famous *Tarasoff* case,¹⁷³ a psychotherapist (clinical psychologist) was liable for failure to warn an identified third party about the imminent danger of violence likely to be perpetrated by the therapist's patient. The court offered the following criteria to determine the existence of the therapist's duty to warn: (1) foreseeability of the harm, probably the most important component in establishing a duty, and usually based on a special relationship; (2) degree of certainty; (3) the closeness of the connection between the professional's action or omission and the injury; (4) moral blame of the professional's action; (5) policy of preventing further harm; (6) extent of burden on the professional and his or her community; and (7) availability, cost, and prevalence of insurance for the risk

¹⁷¹ In the typical "loss of chance" case, the plaintiff asserts that the defendant's malpractice (e.g., failure to make a timely diagnosis) prevented the plaintiff from obtaining treatment, even though the treatment was likely to be unsuccessful. See Robert S. Bruer, *Loss of a Chance as a Cause of Action in Medical Malpractice*, 59 MO. L. REV. 969 (1994); David W. Feeder II, *When Your Doctor Says, "You Have Nothing to Worry About," Don't Be So Sure: The Effect of Fabio v. Bellomo on Medical Malpractice Actions in Minnesota*, 78 MINN. L. REV. 943 (1994).

¹⁷² See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001) (holding researchers have duties to research subjects). See also Wolf et al., *supra* note 162.

¹⁷³ *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 334 (Cal. 1976). See generally Alan A. Stone, *The Tarasoff Decisions: Suing Psychotherapists to Safeguard Society*, 90 HARV. L. REV. 358 (1976).

involved.¹⁷⁴

Following *Tarasoff*, other cases of duty to warn and third-party rights emerged, especially with respect to communicable diseases,¹⁷⁵ impairments in daily functions such as operating an automobile,¹⁷⁶ and genetics.¹⁷⁷ One particular type of professional duty to warn case, involving HIV/AIDS, has been the subject of a few tort cases and several scholarly articles.¹⁷⁸ In *Reisner v. Regents of the University of California*, the plaintiff Daniel Reisner alleged that Jennifer Lawson, a

¹⁷⁴ *Tarasoff*, 551 P.2d at 342.

¹⁷⁵ See *Bradshaw v. Daniel*, 854 S.W.2d 865, 866 (Tenn. 1993) (finding liability based on failure to warn a spouse about the risk of environmental exposure to Rocky Mountain Spotted Fever, which caused the death of the patient); *C. W. v. Cooper Health Sys.*, 906 A.2d 440, 452 (N.J. 2006) (finding liability for a third party contracting AIDS); *DiMarco v. Lynch Homes-Chester Cnty., Inc.*, 583 A.2d 422, 424 (Pa. 1990) (finding liability where a third party contracted hepatitis B). See generally Allison L. Almason, *Personal Liability Implications of the Duty to Warn Are Hard Pills to Swallow: From Tarasoff to Hutchinson v. Patel and Beyond*, 13 J. CONTEMP. HEALTH L. & POL'Y 471 (1997).

¹⁷⁶ See *Taylor v. Smith*, 892 So. 2d 887, 888 (Ala. 2004) (holding physician liable for administering methadone on an outpatient basis to patient who later caused auto accident); *Coombes v. Florio*, 877 N.E.2d 567, 574–75 (Mass. 2007) (holding physician may be liable to third-party for failing to warn patient of side-effect of treatment); *Hardee v. Bio-Med. Applications of S.C., Inc.*, 636 S.E.2d 629, 631–32 (S.C. 2006) (holding dialysis center liable for harms caused by failing to perform post-treatment test or warn patient who later was involved in auto accident). See generally Kathryn J. Schwartz, *Coombes v. Florio: The Negative Consequences of Leaving Massachusetts Physicians Open to Endless Third-Party Liability*, 45 NEW ENG. L. REV. 777 (2011).

¹⁷⁷ Compare *Pate v. Threlkel*, 661 So. 2d 278, 279 (Fla. 1995) (holding physician satisfied any duty to patient's children by informing patient of genetic basis of her medullary thyroid carcinoma), with *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. 1996) (holding physician had a duty to warn those known to be at risk of a genetically transmissible condition), cert. denied, 683 A.2d 1163 (N.J. 1996). *Safer* was legislatively overruled. N.J. STAT. ANN. § 10:5-47 (West 2001). See also Mary L. Kovalesky, *To Disclose or Not to Disclose: Determining the Scope and Exercise of a Physician's Duty to Warn Third Parties of Genetically Transmissible Conditions*, 76 U. CIN. L. REV. 1019, 1020 (2007-2008); Am. Soc'y of Human Genetics Soc. Issues Subcomm. on Familial Disclosure, *Professional Disclosure of Familial Genetic Information*, 62 AM. J. HUM. GENETICS 474 (1998); Kenneth Offit et al., *The "Duty to Warn" a Patient's Family Members About Hereditary Disease Risks*, 292 JAMA 1469, 1470 (2004); Sonia M. Suter, *Whose Genes Are These Anyway? Familial Conflicts Over Access To Genetic Information*, 91 MICH. L. REV. 1854, 1883 (1993).

¹⁷⁸ See, e.g., Troyen A. Brennan, *AIDS and the Limits of Confidentiality: The Physician's Duty to Warn Contacts of Seropositive Individuals*, 4 J. GEN. INTERNAL MED. 242, 244 (1989); Bernard M. Dickens, *Legal Limits of AIDS Confidentiality*, 259 JAMA 3449, 3449 (1988); Kenneth E. Labowitz, *Beyond Tarasoff: AIDS and the Obligation to Breach Confidentiality*, 9 ST. LOUIS U. PUB. L. REV. 495, 495 (1990).

twelve year-old girl, received a blood transfusion in 1985 at the UCLA Medical Center.¹⁷⁹ Her physician, Dr. Eric Fonklesrud, and the hospital became aware the day after the transfusion that the blood was contaminated with HIV, but they did not inform Jennifer Lawson or her parents.¹⁸⁰ In 1988, when Jennifer Lawson was fifteen, she had sexual relations with Daniel Reisner.¹⁸¹ In 1990, Dr. Fonklesrud diagnosed Jennifer as having AIDS and she died one month later.¹⁸² When Jennifer's parents notified Daniel, he was tested and found to be HIV-positive.¹⁸³ He sued Jennifer's physician and hospital based on a failure to warn.¹⁸⁴ The California Court of Appeals, relying on *Tarasoff*, held that the physician and hospital had a duty to apprise Jennifer or her parents of her HIV risk, and the breach of the duty led to Daniel's harm.¹⁸⁵

Reisner did not involve the issue of whether a physician has a duty to notify directly the foreseeable contacts of a patient with a sexually transmitted infection, such as a spouse or known sexual partner.¹⁸⁶ The HIPAA Privacy Rule, effective in 2003, prohibits a health care provider's direct notification of non-patient, at-risk individuals, thereby limiting the physician's duty to notify their

¹⁷⁹ *Reisner v. Regents of the Univ. of Cal.*, 37 Cal. Rptr. 2d 518, 519 (Ct. App. 1995) (settled after the court's decision).

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Reisner*, 37 Cal. Rptr. 2d at 519.

¹⁸⁵ *Id.* at 524; *see also* *DiMarco v. Lynch Homes – Chester Cnty., Inc.*, 583 A.2d 422, 425 (Pa. 1990) (physician's patient-nurse received a needle stick injury from a patient with hepatitis; physician incorrectly told her she could resume sexual activity if she was symptom free after six weeks; court held physician owed a duty to the nurse's boyfriend who became infected after sexual relations).

¹⁸⁶ The American Medical Association has taken the position that "a physician [should] attempt to persuade an HIV-infected patient to cease all activities that endanger unsuspecting others and to inform those whom he/she might have infected. If such persuasion fails, the physician should pursue notification through means other than by reliance on the patient, such as by the Public Health Department or by the physician directly." AM. MED. ASS'N, *HIV/AIDS Reporting, Confidentiality, and Notification*, Policy No. H-20.915 (2009).

patient and, where mandated by law, public health officials.¹⁸⁷ The Privacy Rule¹⁸⁸ prohibits warnings beyond the narrow facts of the *Tarasoff* decision, and generally prohibits the disclosure of personally identifiable health information without the authorization of the patient. There are several exceptions, and one of them permits disclosures to prevent an imminent harm.¹⁸⁹

Thus, it would appear that actions to avert a serious and imminent threat are permitted, but warnings about less immediate harms, such as those caused by a genetic predisposition or infectious disease, are not permitted by the Privacy Rule.¹⁹⁰ It should be noted that these provisions apply to warnings by a physician to third persons, and they do not relieve a physician's duty to provide health information to a patient, including a recommendation to inform other at-risk individuals. Indeed, the prohibition of physicians contacting at-risk individuals without patient consent makes patient notification even more important. The preceding discussion also does not affect the legal and ethical duties of a patient to inform at-risk family members (in the case of genetic disorders) or close contacts (in the case of infectious diseases). The development of a physician's limited duty to warn, however, is consistent with the proposal for a physician's limited duty to notify.

¹⁸⁷ For coverage of the HIPAA Privacy Rule, see FADEN & BEAUCHAMP, *supra* note 86 at 98–99.

¹⁸⁸ *Id.*

¹⁸⁹ 45 C.F.R. § 164.512(j)(1) (2010):

(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat . . .

¹⁹⁰ The HIPAA Privacy Rule generally preempts state laws. "A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. . . ." 45 C.F.R. § 160.203 (2010). Another provision permits state laws to operate without federal preemption if they serve a compelling need related to public health, safety, or welfare. *Id.* § 160.203(a)(1)(iv). A determination by the Secretary is required. *Id.*

VII. THE DIMENSIONS OF THE PROPOSED DUTY TO NOTIFY

The physician's duty to notify patients advocated in this article should be limited in order to be effective for patients; to be minimally burdensome for physicians; and to have a realistic chance of adoption by physicians, codes of ethics, and the courts. An unlimited duty would be unreasonable, impractical, and could be extended without limits, such as by requiring pediatricians to follow up with their patients for the rest of their patients' lives. Although limits are obviously needed, it is less obvious what the limits should be or how they should be set. This section presents a framework for analyzing some of the specifics regarding the duty to notify patients, including what patients should be notified, when the duty to notify arises, and what physicians should do to satisfy the duty.

A. Selecting the Patients to Be Notified

There are two main ways in which the potential patient population for notification can be limited to the patients most likely to benefit from notice with the least burden on physicians. First, notification duties could extend only to "current" or "active" patients. An advantage of this approach is that it eliminates duplicate notification of former patients who have a new physician. On the other hand, it is not always clear who is a "current" patient. A patient last seen two months ago may have no intent to return, whereas a patient last seen two years ago may be a continuing patient. In addition, a patient seeing a specialist for a single consultation may rely on the treatment recommendation of that specialist for a substantial length of time.

The second possible method of limiting the class of patients to be notified is to use a time limit. In other words, patients last seen within a certain period of time would be subject to notification, but patients not seen within that period need not be notified. This approach would be easier to implement. The duty to notify patients last seen within a certain period of time should be the minimum ethical and legal requirement; nothing would prevent physicians from providing notification to additional patients depending on the situation. Complicating questions are whether the same rule should apply to both generalists and specialists and whether its applicability

should be affected by the number of times a patient has been seen. Although the nature of the physician-patient relationship is relevant in determining the duty to notify, the significance and clinical utility of the information are the determinative factors. Thus, the duty to notify patients of potentially life-saving information, such as a serious drug interaction, would apply more broadly than a less serious or less imminent risk.

As to the question of what time period should be used, it would be appropriate to adopt the Medicare billing rule that deems a patient who has been seen within the past three years as “established,” whereas a patient who has not been seen within the past three years would be considered “new” if he or she made a return visit to that physician.¹⁹¹ Thus, all patients seen within the last three years (or their legally designated representatives) should be provided with notice about new medical developments. The date of last visit is an easily aggregated data element in an EHR.

Another important issue is what party should be responsible for providing the notice. Many patients obtain their health care from institutional providers, such as a multi-specialty group practice, health maintenance organization, or public health clinic. In these situations, the institution, rather than the individual physician, that provided the last episode of care should have the obligation to provide notification. Because of the evolving nature of practice arrangements and relationships, physicians and institutions should clearly establish the appropriate party for notification. Institutions also should establish protocols for allocating notification responsibilities, and they should undertake continuous quality assessment and improvement to ensure that the notification obligations are being met efficiently and effectively.

¹⁹¹ See Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates, 73 Fed. Reg. 68502, 68679 (Nov. 18, 2008) (to be codified at 42 C.F.R. pts. 410, 416, & 419) ; see also Medicare Program Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18434, 18451 (Apr. 7, 2000) (to be codified at 42 C.F.R. pts. 409, et al.).

B. Determining When There is a Duty to Notify Patients

The most difficult technical issue is deciding when the medical science has evolved sufficiently that the benefits of notification outweigh the burdens. As emphasized in this article, because of HIT, the burdens on physician notification will be sharply curtailed, thereby suggesting that notification will be appropriate in more situations. Nevertheless, notification is not without its own risks, including patient confusion, and therefore should be undertaken only on the basis of compelling scientific evidence. Preliminary, ambiguous, inconclusive, or minor findings should not be the basis for patient notification.

The following is a non-exclusive list of potential reasons for issuing patient notifications: (1) drug interactions, adverse events, and market withdrawals; (2) medical device recalls and warnings; (3) new treatment modalities with substantially enhanced efficacy; (4) changes in important lifestyle recommendations; and (5) significant new monitoring and imaging guidelines of preventive medicine. Each case requires a separate analysis of the burdens, benefits, and risks of notification.

The overriding purpose of notification is to provide substantial benefit to the patient. The concept of benefit includes clinical utility, but it is broader. The clinical utility aspect of benefit involves an analysis of objective factors, such as the severity of the condition and the likelihood that care will be altered based on the notification. In contrast, psychosocial aspects of benefits and harms are patient-specific and require a patient-centered approach. Patients with similar medical conditions may have very different views on the desirability of receiving information about new medical discoveries.¹⁹² One approach would be for physicians to ask each new patient and all patients periodically whether they want to be informed of new developments with the potential to affect their health significantly. Patient notification preferences should be a standard data element in EHRs.

¹⁹² There is robust literature on this issue in genetics. See, e.g., Constance A. Griffin et al., *Patient Preferences Regarding Recontact by Cancer Genetics Clinicians*, 6 FAMILIAL CANCER 265, 266-68 (2007); Martin Letendre & Béatrice Godard, *Expanding the Physician's Duty of Care: A Duty to Recontact?*, 23 MED. L. 531, 532, 534 (2004).

As electronic patient notification becomes an accepted practice, standard messages are likely to be produced by trusted entities, such as professional associations and experts charged with updating the clinical decision support features of EHRs used by physicians. The actual process could involve an expedited consensus meeting of experts and the drafting of the message by experts in health communication, with input from patient advocates on language and follow-up strategies. Using standard electronic messages will relieve individual physicians of much of the responsibility in analyzing new discoveries and writing messages for patients.

C. Practical Concerns

Electronic patient notification must strive to avoid causing needless fear, confusion, or information overload.¹⁹³ Although information overload is related to a lack of health literacy,¹⁹⁴ it is more complicated and also may affect individuals considered to possess a high level of health literacy. The ability to understand health information also varies widely based on such demographic factors as age, education, language proficiency, and health status.¹⁹⁵ An important concern is that too frequent notification or incomprehensible messages will cause patients to experience

¹⁹³ See Kyunghye Kim, et al., *Predictors of Cancer Information Overload: Findings from a National Survey*, 12 INFO. RES. Paper 326 (Oct. 2007), http://students.lti.cs.cmu.edu/11899/files/cp3a_readingw1_cancerarticle.pdf (citing NATIONAL CANCER INSTITUTE, HEALTH INFORMATION NATIONAL TRENDS SURVEY FINAL REPORT (2003), http://hints.cancer.gov/docs/hints_report.pdf (finding that 37.7% of the 6,369 persons surveyed found the cancer information in their last search as hard to understand)); see also Thomas D. Wilson, *Information Overload: Implications for Health Care Services*, 7 HEALTH INFORMATICS J. 112, 113 (2001) (finding technological advances have increased the amount of information available, which decreases the natural selection process of publishing only the most important information).

¹⁹⁴ Health literacy is defined as “[t]he degree to which individuals have the capacity to obtain, process, and understand, basic health information and services needed to make appropriate health decisions.” U.S. DEP’T OF HEALTH & HUMAN SERV., OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION, NATIONAL ACTION PLAN TO IMPROVE HEALTH LITERACY iii (2010), available at http://health.gov/communication/hlactionplan/pdf/health_literacy_action_plan.pdf (last visited Feb 24, 2012).

¹⁹⁵ See COMM. ON HEALTH LITERACY, INSTITUTE OF MEDICINE, HEALTH LITERACY: A PRESCRIPTION TO END CONFUSION 23, 24 (2004); see also NAT’L CENTER FOR EDUC. STATISTICS, U.S. DEP’T OF EDUC., THE HEALTH LITERACY OF AMERICA’S ADULTS: RESULTS FROM THE 2003 NATIONAL ASSESSMENT OF ADULT LITERACY v (2006).

needless anxiety or to regard the notice as unimportant and therefore to ignore the information. Consequently, discretion is needed in sending notices only when demonstrably necessary, in making it standard practice to follow-up with patients about the notice at their next scheduled appointment, and in ensuring that notices not be combined with any other information. Patients should not view exceptional, crucial, medical update notices as spam, advertising, or routine health promotion communications. Finally, it is essential to incorporate quality control measures in notification systems and to undertake ongoing studies on the efficacy and outcomes associated with notification.

Another concern involves privacy. Many individuals use employer-provided e-mail or shared accounts, and thus their notification might be sent to a computer or mobile device without adequate security or expressly viewable by other individuals. When physicians ask patients about their notification preferences and instructions, patients should be reminded of the potentially sensitive nature of physician-generated e-mail and other electronic communications. Encrypting the messages could help protect security, but it would be feasible only if patients had the ability to receive and decipher encrypted messages.

VIII. CONCLUSION

The development, adoption, and utilization of HIT are works in progress – and will remain so for the foreseeable future. The challenges for HIT policy makers and health care leaders go beyond resolving technological glitches and maximizing return on investment; they involve formulating a vision of the role of health information in the health care system of the future. With stringent protections for privacy, confidentiality, and security, an increased flow of health information can facilitate coordinated, safe, and effective health care as well as support outcomes, public health, and other research.

Many optimistic and positive terms have been used to describe the EHRs and EHR networks of the future, including “accurate,” “timely,” “comprehensive,” “longitudinal,” and “interoperable.” The

term “bi-directional” should be added to this list. Valuable health information needs to flow not only *from* the patient, but also *to* the patient. Additional medical information developed after the patient’s episode of care and shared with the patient will enable patients and their caregivers to play a more informed and meaningful role in health management. HIT makes this vision of information dissemination a realistic goal and an essential component of the emerging health care system.

The bi-directional flow of information has important implications for the physician-patient relationship,¹⁹⁶ and these issues ought to be addressed concurrently with the technological challenges. In the extraordinary situations described in this article, physicians should have a legal and ethical duty to notify patients of significant new medical developments of demonstrable utility to patient health. This duty should become an explicit element of medical codes of ethics and, where the duty is breached and harm results, there should be a common law cause of action.

The duty proposed in this article is intended to promote the well being of patients. Compliance with the duty is technically feasible with existing and developing HIT, and increasing consolidation of physician practices and hospitals will make it easier to send necessary updates to patients from a central source. Patient notification obligations are compatible with the coordination of care objectives of accountable care organizations, medical homes, and other elements of the emerging health care system. Patient notification is also consistent with already-recognized ethical principles. It parallels statutory duties of health care providers to share important information with patients, and it is consonant with recognized common law doctrines. Some practical issues remain to be resolved, such as deciding which patients should be notified and how notification should take place, but these problems are surmountable and should be addressed promptly. The substantial benefits of patient notification of new medical discoveries provide an important rationale for the expeditious adoption of HIT by health

¹⁹⁶ See Mark A. Rothstein, *The Hippocratic Bargain and Health Information Technology*, 38 J.L. MED. & ETHICS 7, 11 (2010) (discussing the effect of health information technology on the physician-patient relationship).

care providers.