

Failure to Communicate Clinical Test Results- A Legal Analysis for Pennsylvania

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Issue Summary

A clinician's failure to communicate medical diagnostic testing results is a serious medical error that can endanger patient life and well-being. Two legal responses to this issue exist, first laws addressing the specific contours of the clinician-patient relationship, and second laws requiring direct patient notification of diagnostic test results.

While almost every state has adopted some form of a "Patient's Bill of Rights" these laws do not enumerate the clinician's duty to inform patients of test results. Further, these laws often target treating physicians and not diagnostic centers or third party medical providers.

Alternatively, patient notification laws are occasionally used in federal and state regulatory frameworks. The Mammography Quality Standards Act passed by Congress in 1999 required that all radiology testing facilities communicate test results directly to patients on whom mammographies were performed. Further, a variety of state statutes require that diagnostic test results are directly communicated to patients. However, these state laws are not comprehensive in their scope. For example, they may be limited to specific conditions or tests, such as those for HIV/AIDS. Additionally, a number of these laws require direct notice of results only with a patient's request or consent of a treating clinician.

Pennsylvania currently has a number of laws addressing patient safety, standards of care and the clinician-patient relationship. However, these laws do not address failure to inform. In light of this, the Patient Test Result Information Act (HB 1358) was introduced to the Pennsylvania State Legislature in 2009. This law would require diagnostic testing facilities to send test results directly to patients, after they have been sent to prescribing clinicians.

Even without a clear legal mandate, many diagnostic testing centers in Pennsylvania already send results directly to patients as a component of risk management protocols. Consequently, it is unclear what impact direct notification laws would have in reducing medical error resulting from a failure to inform. If any notification laws are enacted in the Commonwealth, they should operate on patient consent and should work to standardize patient notification procedures in clinical settings.

**I. Introduction:
The Causes of
Failure to Inform**

A treating clinician's failure to inform an individual of diagnostic test results presents a significant risk to the patient. According to a study published by the Weil Cornell Medical College "Failure to report abnormal test results can lead to serious, even lethal consequences for the patient."¹

There are a variety of explanations for why this happens. First there are issues related to widespread use of electronic medical test tracking systems. Often triggers are built into these systems to identify abnormal results. Yet, because multiple care providers may define abnormal testing results differently, when patient test results are transferred between electronic systems, certain results may be omitted as a consequence of different diagnostic thresholds.² Further, many medical test results are conveyed through textual notes that are not codified as normal or abnormal. Accordingly, the nuanced form of these diagnostics prevents automated computer reviews and notifications.

Beyond electronic patient management systems, organizational and human resource issues affect patient outcomes in clinical settings. Varying levels of experience in attending clinicians pose challenges. For example, a radiology test may first be read as normal by a resident but later deemed abnormal by a more experienced attending radiologist.³ Further, failure to inform can arise from delays in the transmission of test results to treating clinicians. Outpatient diagnostic tests vary dramatically in times required for completion and availability. Results may be communicated from hours to weeks after the tests are initially requested. This gap in time, coupled with the volume of patient information may contribute to a clinician's failure to inform a patient of abnormal results.

1 Casalino et al. *Frequency of Failure to Inform Patients of Clinically Significant Outpatient Test Results*. *Archives of Internal Medicine*. 169(12):1123-1129 (2009). Available at <http://archinte.ama-assn.org/cgi/reprint/169/12/1123>

2 Tejal K. Gandhi, *Fumbled Handoffs: One Dropped Ball after Another*, *Annals of Intern Medicine*. 142:352-358 (2005). Available at <http://www.annals.org/content/142/5/352.full>

3 Gandhi, *supra* note 2, at 5.

Moreover, the cumbersome nature of paper-based test reporting systems can cause delivery delays and misfilings.⁴

Finally, the sheer volume of data treating clinicians are responsible for reviewing creates obstacles for positive patient outcomes. Studies have shown that a typical primary care provider may review up to 800 results from chemistry and hematology reports, 40 radiology reports, and 12 pathology reports per week.⁵ Given this vast amount of information, inevitably some test results are overlooked or neglected.

II. Failure to Inform: Data & Challenges

General error within the U.S Medical care system is a serious issue which based upon a report issued by the Institute of Medicine may cause up to 98,000 deaths and cost upwards of \$38 billion per year.⁶

The most frequent basis for medical malpractice litigation in the United States is “failure to diagnose.” However, information provided by medical malpractice insurance companies suggests that the second most common cause is failure to communicate results of radiologic examinations.⁷ Further, insurance company data suggests that “communication problems” are at least a causative factor in up to 80% of medical malpractice cases.⁸

Despite these claims, specific statistical information showing adverse patient outcomes as the result of a clinician’s

4 Eric G. Poon, et al., “I wish I had seen this test result earlier!”: Dissatisfaction With Test Result Management Systems in Primary Care, *Arch Intern Med.*;164:2223-2228, (2004). Available at <http://archinte.ama-assn.org/cgi/reprint/164/20/2223.pdf>

5 Poon EG, Wang SJ, Gandhi TK, Bates DW, Kuperman GJ. *Design and implementation of a comprehensive outpatient Results Manager*, *Journal of Biomedical Information.* 36:80-91 (2003).

6 Joan S. Ash et al., *Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-related Errors*, *Journal of the American Medical Information Association.* 11:104–112 (2004).

7 Leonard M. Berlin, *Failure of radiologic communication: An increasing cause of malpractice litigation and harm to patients*, *Applied Radiology.* 39: 1-2 (2010).

8 Berlin, *supra* note 7.

failure to inform is minimal. Much evidence is largely anecdotal. There have been no national studies addressing this issue to date. What information there is comes from studies that are limited in scope to individual hospitals or treatment networks.

In 1996, the Archive of Internal Medicine published a study on the topic of patient notification and clinical follow-ups of abnormal test results. The study was conducted among 161 attending physicians and 101 residents in family and internal medicine practices at a “large urban teaching hospital” and 21 suburban primary care practices in Southeastern Michigan.⁹ The study demonstrated not only did 17%-32% of physicians report that they maintained no standardized reliable method of ensuring that all laboratory tests are received, but one-third of physicians reported that they did not always notify patients of abnormal results.¹⁰ Typically, physicians cited an expectation that patients would return to the clinic soon as a reason for not following up with them directly.¹¹

Additionally in 2009, the Department of Public Health at Weill Cornell Medical College published a report that examined the failure to inform from the patient’s perspective. The study involved a retrospective medical record review of 5343 randomly selected patients from 19 community based and 4 academic medical center primary care practices.¹² This study found that failure to inform or to document informing the patient occurred in 7.1% of treatment relationships, and most commonly happened where medical records were maintained in mixed paper and electronic formats.¹³

This study further suggested several clinical risk management protocols. First, all test results must be routed to the responsible physician who must sign off on all results. Second, patients must be informed of all results, normal and abnormal, at least in general terms, with accompanying clinical

9 Emily A. Boohaker, et al., *Patient Notification and Follow-up of Abnormal Test Results*, *Archive of Internal Medicine*. 156; 327-331 (1996). Available at <http://archinte.ama-assn.org/cgi/content/abstract/156/3/327>

10 Boohaker, *supra* note 9.

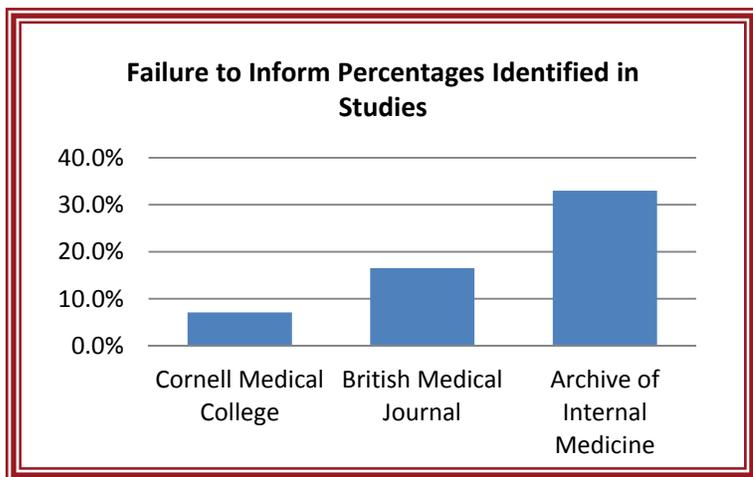
11 Boohaker, *supra* note 9.

12 Casalino, *supra* note 1.

13 Casalino, *supra* note 1.

documentation that results have been communicated. Finally, clinicians should promote procedures where patients are told to call after a certain time interval if they have not been notified.¹⁴

While these studies establish that the failure to inform patients of test results does occur in a statistically significant percentage of cases, they did not examine the consequences of these omissions. In 2010, a study published in the British Medical Journal attempted to better assess the results of these errors.



Examining a roster of previously published studies, the British Medical Journal found that in an inpatient hospital context the extent of failure to follow-up ranged from 1.0% to 22.9% of inpatients.¹⁵

Subsequently, the British Medical Journal attempted to assess the results of these omissions. They reviewed one study from four liability insurers for injuries featuring 122 closed malpractice claims, which emergency room patients sustained between 1979 and 2001. The study found that 79 of the 122 claims (64.8%) involved

missed ER diagnoses that caused patient harm, and 13 of these 79 claims (16.5%) identified harm that arose from failures at the stage of treatment where “test results (are) transmitted to and received by the provider.”¹⁶

However, attempting to draw broader conclusions from the existing literature, the British Medical Journal review stated it was unclear in what percentage of failure to inform cases resulting in harm had actually occurred. The study reasoned that this was a consequence of the fact that the literature on this topic frequently uses medical record review, which relies upon documentary evidence rather than concrete statistical

14 Casalino, *supra* note 1.

15 Joanne Callen, et al., *The Safety Implications of Missed Test Results for Hospitalized Patients: A Systematic Review*, *British Medical Journal of Quality and Safety*. 20: 194-199 (2011). Available at <http://qualitysafety.bmj.com/content/20/2/194.abstract>

16 Callen, *supra* note 15.

information by way of follow-up.¹⁷ Accordingly, evidence of failure to inform often is reported by way of anecdotes.

The British Medical Journal study concluded that this practice “may lead to an overestimation of the problem, since, in some cases, results may have been seen and acted upon but not documented.”¹⁸ The study further confirmed that missed results often arose as an effect of the systems and practices used, procedures for reporting critical results, and test results for patients moving across care settings.

**III. Strategies for
Action: Clinical
Practices &
Legal Mandates**

In assessing what measures could be taken to rectify this problem the United States Department for Health and Human Services Agency for Healthcare Research and Quality published a study on improving patient safety practices in 2001. This study examined the rates which physicians failed to follow-up on diagnostic test results with patients, and focused particularly on instances where a patient was not notified of abnormal results.¹⁹ The report likewise sought to examine mechanisms and policies to reduce these occurrences.²⁰

The report featured a study designed to determine the specific consequences of a physician’s failure to follow up with patients. The examination focused on failure to inform patients of abnormal cervical cancer screening results. Two groups of patients were established. In the test group, a medical testing consent form allowed individuals to request direct notification of test results. By contrast, the physicians in the control group determined which patients would be offered direct notification. Patients of physicians in the control group were informed of test results through the standard procedures the provider typically employed.²¹

17 Callen, *supra* note 15.

18 Callen, *supra* note 15.

19 U.S Dept. of Health and Human Services: Agency for Healthcare Quality and Research, AHRQ Publication 01-E058, A Critical Analysis of Patient Safety Practices (2001)[hereafter *Analysis*]. Available at <http://psnet.ahrq.gov/resource.aspx?resourceID=1599>

20 *Analysis*, *supra* note 19.

21 *Analysis*, *supra* note 19.

The study examined the outcomes in these respective groups of individuals diagnosed with two abnormal cell conditions, cervical intraepithelial neoplasia and atypia. The primary treatment requirement of these abnormalities was follow-up visits, evidenced in laboratory records featuring subsequent testing one year after the initial notification.²²

The study found significantly fewer individuals with positive cervical intraepithelial neoplasia test results placed in the test group were lost to follow-ups. When individuals were allowed to opt into direct notification of test results, the study found 0% of these individuals neglected a follow up visit with their treating physician. By contrast, 23% of individuals in the control group with abnormal results (where there was no option of direct notification) failed to schedule a follow up visit.²³ Further, in the group of patients with atypia, 13% failed to follow up in the control group, while 10% were lost to follow-ups in the test group.²⁴

These results suggest direct opt-in notification could improve the percentage of individuals who follow up on adverse results with a treating physician. However, the study recognized the assessment was limited in that providers decided who among the control group actually received direct notification of results after randomization. Accordingly, only 41% of patients in the control group were actually mailed their results.²⁵

Currently studies demonstrating rates of physician failure to inform, coupled with the difficulty assessing the consequences of these omissions has limited examination of the problem to small scale review. None of the current studies were performed in Pennsylvania. Therefore, no data exists on rates of failure to inform or its consequences in the Commonwealth. Because the absence of extensive data on this issue, it is difficult to evaluate the true extent of this problem on both a national and state level.

²² *Analysis, supra* note 19.

²³ *Analysis, supra* note 19.

²⁴ *Analysis, supra* note 19.

²⁵ *Analysis, supra* note 19.

A. Legal Strategies in Pennsylvania

Strategies for action in Pennsylvania take two principal forms. First, laws mandating specific standards of care in clinical settings, and second, laws requiring some form of patient notification.

Standard of care legislation is exemplified in several Pennsylvania statutes. First, the Medical Care Availability and Reduction of Error (Mcare) Act was signed into law in 2002. The law was targeted at reforming insurance, medical professional liability and healthcare administration in the Commonwealth. It contains a section on patient protection, designed to "reduce and eliminate medical errors by identifying problems and implementing solutions that promote patient safety."²⁶

The patient safety section mandates protective requirements for medical facilities. It also creates the Patient Safety Authority, a state agency funded by surcharges paid by medical facilities. The agency is tasked with specific duties in the area of patient safety, involving the collection and analysis of data on serious events and incidents, "including the identification of performance indicators and patterns in frequency or severity at certain medical facilities or in certain regions of the Commonwealth."²⁷The Authority is empowered, contingent upon Department of Health consent, to make operational recommendations to medical facilities.

Mcare likewise requires medical facilities to develop patient safety plans, and mandates reporting of incidents to the Patient Safety Authority. However, the patient safety elements of the act are exclusively focused on "serious events" and "incidents" in clinical facilities. These are understood to be acute occurrences. These definitions do not include harm caused as the result of omission or failure to inform.

The Pennsylvania State Legislature also enacted the Medical Practice Act. This set of laws creates mechanisms to

26 Medical Care Availability and Reduction of Error Act, 40 P. S. § 1303 (2002)[hereafter *Code*].

27 Lawrence J. Beaser & Howard A. Burde, *Patient Safety Under the Mcare Act - Will New Duties Lead to Greater Patient Safety?* POMA Newsletter (Pennsylvania Osteopathic Medical Association, Harrisburg, PA), 2007.

enforce standards of care between a doctor and patient.²⁸ The Medical Practice Act recognizes the authority of the Pennsylvania State Medical Licensing Board in establishing and enforcing physician standards of care. Specifically, the PA Medical Practice Act grants the state medical licensing board the authority to impose disciplinary or corrective measures on a board-regulated practitioner for any or all of the following reasons:

“Being guilty of immoral or unprofessional conduct. Unprofessional conduct shall include departure from or failing to conform to an ethical or quality standard of the profession. In proceedings based on this paragraph, actual injury to a patient need not be established.”²⁹

In *Koscielniak v. Bureau of Professional and Occupational Affairs*, the Pennsylvania Commonwealth Court heard a case on appeal from the Board, where a patient alleged injury resulting from her physician’s failure to inform of abnormal test results.³⁰ Specifically, the plaintiff claimed that the physician had not informed her of abnormal mammography results in a timely manner which eventually resulted in harm. The court affirmed the Boards findings, and held that “failure to inform a patient constituted a deviation from accepted standards of care to warrant corrective measures.”³¹

Alternatively, recently proposed legislation would require clinical facilities to directly notify patients of medical test results. During the 2009 legislative session the Patient Test Result and Information Act (HB1358) was introduced.³² The sponsor of the bill Rep. Marguerite Quinn stated in a press release that “This legislation is about saving lives. The communication of a diagnosis may be as important as the diagnosis itself. The absence of this communication can cause death. Our health care system is strained – doctors are doing their best to provide quality care for patients, but with the volume of their work,

²⁸ Code, *supra* note 26.

²⁹ PA Medical Practice Act, 63 P.S. § 422.41(8).

³⁰ *Koscielniak v. Bureau of Prof'l & Occupational Affairs*, 928 A.2d 402 (Pa. Commw. Ct. 2007).

³¹ *Koscielniak*, *supra* note 30.

³² HB 1358, The General Assembly of PA (2009).

**The General Assembly of Pennsylvania:
Patient Test Result and Information Act
House Bill 1358 (3)(b)**

An entity performing diagnostic imaging services shall send directly to the patient a written copy of the summary of the test results of diagnostic imaging services performed on the patient within ten days of sending the test results to the patient's prescribing physician.

increased patient cases and follow-up paperwork, it is possible that important results may get overlooked.”³³

The bill would require any entity performing one of fifteen diagnostic services “send directly to the patient a written copy of the summary of the test results of diagnostic imaging services performed on the patient within ten days of sending the test results to the patient’s prescribing physician.”³⁴

The bill attempts to establish mechanisms for ensuring compliance. It requires the PA Department of Health “conduct compliance reviews and investigate complaints filed” as a consequence of a testing entity failing to fulfill the requirements established by the bill.³⁵

This bill stands in contrast to current provisions of the PA Code. Currently, the Code states “Reports of clinical laboratory findings shall be made only to the person submitting the specimen or requesting the analysis, or his authorized agent.”³⁶ According to the PA Department of Health, this provision is understood to prohibit “Direct-to-Consumer” medical testing.³⁷ Were this law passed it is unclear what effect it would have on the requirements expressed in current provisions of the PA code.

33 Press release, Rep. Marguerite Quinn, Quinn Diagnostic Testing Bill Passes Health and Human Services Committee (Aug. 28, 2009)(on file with author).

34 HB 1358, note *supra* 32. (These tests include: “MRIs, Nuclear Medicine, Angiography, Arteriography, CAT scans, PET scans, Digital Vascular Imaging, Bronchoscopy, Lymphangiography, Splenography, Ultrasound, EEG, EKG, Nerve Conduction Studies, and Evoked Potentials.”)

35 *Commonwealth of Pa. House Committee on Appropriations Fiscal Note*, 2009-2010 Legislative Session. Note: while in the House Appropriations Committee, a fiscal study was commissioned to demonstrate the effect of this legislation on the PA Department of Health. The results demonstrated that even if complaints were made on 1% of covered diagnostic imaging tests, it would equate to over 40,000 actionable claims per year. It was suggested as a consequence of HB 1358 12 additional individuals should be hired by the department of health with a projected cost of \$975,000 per year.

36 28 Pa. Code. §5.47 (2007).

37 US. Dept. of Health and Human Services Centers for Medicare and Medicaid Services, *Direct Access Testing* (2004) Note: DTC Testing is understood to be where lay persons order medical testing for themselves. Available at <https://www.cms.gov/CLIA/Downloads/directaccesstesting.pdf>

**B. Outside the Commonwealth:
Legislative Approaches and Policies**

Legal approaches to a clinician's failure to inform outside Pennsylvania are also focused on addressing clinical standards of care or direct patient notification.

Under the ambit of legislation addressing standards of care, there are two distinct types of laws. Patient bill of rights statutes, and laws mandating specific duties and levels of interaction between physician and patient.

Patients' Bill of Rights are a potential solution to these problems. These vary from proposed federal legislation, to state law, to procedures adopted by private entities and organizations. For example, in 2001 the Bipartisan Patient Protection Act was introduced into Congress. This proposed federal law sought to establish a number specific patient rights including the right of individuals to have their medical decisions made by a doctor, the right to see a medical specialist, and the right go to the closest emergency room.³⁸ However, the bill was focused on regulation of insurance providers, and contained no specific provisions concerning patient notice requirements. Ultimately the bill did not pass the United States Senate. However, it does highlight the possibility that federal law establishing the rights and responsibilities of the patient doctor relationship is one means of addressing failure to inform.

45 out of 50 US States have adopted some type of specific Patient Right Law.³⁹ The majority of these laws permit individuals to obtain redress from insurance providers for discriminatory or improper conduct.⁴⁰ However several states have adopted provisions beyond creating causes of action against insurance providers, mandating specific patient rights in the receipt of care. For example, New York State has adopted a patients' bill of rights that provides that individuals must "receive complete information about your diagnosis, treatment and prognosis"⁴¹

38 S. 1052, 107th Cong. §1 (2001)

39 Genetics and Public Policy Center Berman Institute of Bioethics, Johns Hopkins University, Survey of Direct-to-Consumer Testing Statutes and Regulations (2007). Available at

<http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>

40 American Academy of Child and Adolescent Psychiatry, *AACAP State Patients' Bill of Rights Update* (2002).

41 10 NY Comp. Codes R. & Regs § 405.7 (2010).

Likewise states such as Minnesota, Florida, New Jersey and Texas have adopted patients' bill of rights with similar provisions. Pennsylvania likewise has enacted a Patient's Bill of rights.⁴²

Outside the realm of federal and state legislation, the Association of American Physicians and Surgeons adopted a Patient Bill of Rights in 1995 mandating that patients "be informed about their medical condition, the risks and benefits of treatment and appropriate alternatives."⁴³ Additionally, the American Hospital Association adopted a patients' bill of rights in 1973 stating "The patient has the right to and is encouraged to obtain from physicians and other direct caregivers relevant, current, and understandable information concerning diagnosis, treatment, and prognosis."⁴⁴ Moreover, many hospitals and practices have adopted similar patient bill of rights which establish similar protections for individuals receiving treatment.

Beyond patient bill of rights statutes, all states have medical licensing laws and licensing boards to administer these laws. A number of states have enacted specific standard of care laws, rather than leaving the exclusive regulation of this relationship to a state medical licensing board. These laws differ from Patient's Bill of Rights statutes, because they address the specific relationship between patients and physicians, and do not focus on individual rights with respect to insurance companies or medical care entities.

For example, New Hampshire maintains a state law governing the health care patient provider relationship. The law states "the patient has the right to receive information from the health care provider" and "the patient shall be fully informed by the health care provider of his or her medical condition, health care needs and diagnostic test results."⁴⁵ The law does not contain any specific provisions regarding the notice or form of diagnostic testing results.

42 28 Pa.Bull. 5011 (October 3, 1998). Note this is focused on insurance reform, and providing patient protections for individual enrolled in managed care plans. It does not specifically address clinical standards of care.

43 Association of American Physicians, Patient Bill of Rights (1995).

44 American Hospital Association, Patients' Bill of Rights (1973).

45 N.H. Rev. Stat. Ann. 30 § 332 (2010).

**New Hampshire
Title XXX § 332-I:2 (b), (c)
Medical Records and
Patient Information**

The patient has the right to receive information from the health care provider and to discuss the benefits, risks, and costs of appropriate treatment alternatives.

The patient shall be fully informed by the health care provider of his or her medical condition, health care needs and diagnostic test results, including the manner by which such results will be provided and the expected time interval between testing and receiving results, unless medically inadvisable and so documented in the medical record

Additionally, failure to inform litigation has increased in the last twenty years. For instance, in *Daly v United States of America*, it was held that a Washington State radiologist had a duty to directly inform a patient whose chest radiographs indicated sarcoidosis.⁴⁶ The court stated:

“The radiologist should have notified [the patient] of the abnormality. This duty is hardly burdensome and recognizes that those who place themselves in the hands of a person held out to the world as skilled in a medical profession...justifiably have the reasonable expectation that the expert will warn of [radiographic abnormalities] of which he is cognizant due to his peculiar knowledge of his specialization.”⁴⁷

Likewise, clinical risk management strategies have evolved to meet this trend. For example, in 1999 the American College of Radiology revised their standards for communication, introducing the idea of direct patient communication, stating:

“In those situations in which the interpreting physician feels that immediate patient treatment is indicated...the interpreting physician should communicate directly with the referring physician.... If that individual cannot be reached, the interpreting physician should directly communicate the need for emergent care to the patient [italics added] or responsible guardian, if possible.”⁴⁸

An alternative body of law exists that specifically requires direct patient notification of diagnostic testing results. In 1999 Congress passed the Mammography Quality Standards Act (MQSA) requiring radiology facilities to communicate directly with individuals on whom mammograms are performed, whether the results are normal or abnormal. The law was passed in response to growing concerns over the quality of diagnostic testing performed in these facilities.

The MSQA creates a comprehensive set of quality

⁴⁶ *Daly v United States of America*, 946 F2d 1467 (9th Cir 1991).

⁴⁷ *Daly*, *supra* note 47.

⁴⁸ American College of Radiology. *ACR Standard for Communication: Diagnostic Radiology*. American College of Radiology (2001).

assurance requirements for facilities, and establishes a mechanism for enforcement and punishment of facilities that do not meet these established standards.

Providing patient notification is a requirement that mammography facilities must fulfill in order for accreditation by the FDA. The MSQA mandates that facilities send patients summaries of their test reports, written in “lay terms” within 30 days of their examination.⁴⁹ If results are deemed “suspicious” or “highly suggestive of malignancy”, facilities are required to notify the patients of this as soon as possible.⁵⁰

Additionally, several states have enacted laws requiring some level of patient notification of testing results. These laws are either limited to specific diseases and tests, or are contingent upon patient consent.

For example, the Florida state legislature passed a piece of legislation known as the “Omnibus AIDS Act” in 1988.⁵¹ This legislation covered a variety of issues related to the diagnosis and treatment of HIV/AIDs, and created requirements for state agencies and health care providers.

In 1998, the Act was amended to require that “all reasonable efforts be made to ensure the patient of his or her test results” and to relate specific information, particularly positive test results to subjects. It is left to the discretion of providers to determine how best to notify patients of the test results.⁵² The Florida law is exclusive to the notification of AIDS testing results. It does not extend to cover any additional conditions or types of tests.

California by contrast maintains a law that requires prescribing physicians to “provide or arrange for the provision of the results of a clinical laboratory test to the patient...if so

49 Mammography Quality Standards Act 21 C.F.R § 900.12(c)(2) (2010)

50 Mammography Quality Standards Act, *supra* note 50.

51 Department of Health, Division of Disease Control, Bureau of HIV/AIDS *Florida Omnibus AIDs Act: A Brief Legal Guide for Healthcare Professionals* (1999).

52 Florida Omnibus Healthcare, *supra* note 52.

requested by the patient.”⁵³ The law further requires that the results be conveyed in plain language to the recipient.

Additionally, in Virginia, a law was passed during the 2007 legislative term, that requires physicians to send laboratory test results directly to patients upon request of the patient.⁵⁴ This law included the provision that physicians have the discretion to determine when it would be appropriate to send these test results directly to the patient.⁵⁵

Many states have laws stating only the prescribing licensed medical professional or persons otherwise authorized under the law can receive direct test results. These statutes represent a potential legal roadblock to direct patient notification laws. State departments of health frequently interpret these statutes through administrative regulations. Consequently, there is a wide division in how an “individual authorized under the law” is defined. Some states empower patients to request lab results, while some states strictly limit this authority only to clinicians.⁵⁶ Currently, 34 states allow some form of direct disclosure to patients.

The California and Virginia laws typify the current trend in notification legislation. The distinguishing feature of these statutes is recognition of patient consent and request. They create a legal mandate for notice, but only upon affirmative patient or clinician approval. If a patient does not opt-in to notification, than the diagnostician is under no legal obligation provide direct notice.

**IV. Evidence for
the Effectiveness
of Various
Approaches**

The impact of legal solutions to failure to inform is difficult to assess. The first legal strategy is legislation designed to mandate a specific standard of care in the physician and patient relationship. By implication this form of legislation covers failure to inform by mandating open communication between clinician

53 Cal Health & Safety Code § 123148.

54 Va. Code Ann. § 54.1-2409.4 (2007)

55 Va. Code Ann., *supra* note 55.

56 Genetics and Public Policy Center Report, *supra* note 40.

and patient. This coverage is exemplified by patient's bill of rights and medical licensing laws. However, evidence and data specific to the impact of these legal approaches is lacking.

One must acknowledge that there is generally no specific requirement in these statutes that speaks directly to patient notification of diagnostic results. This absence makes these laws ill suited to addressing the specific harm caused by a clinician's failure to inform.

Even if these laws do have an impact on failure to inform, an additional difficulty is the lack of data to quantify their effect. These laws attempt to address the broad relationship between clinician and patient, so it is difficult to calculate their effectiveness in specifically reducing adverse outcomes arising from failure to inform. There are no studies addressing whether failure to inform rates were reduced after these laws were enacted.

Turning next to notification laws, these mandate proactive communication of results as a specific legal element of the treatment relationship. There are few studies on the effect of these laws. Even with the MSQA, the oldest and broadest type of this legislation, specific evidence of positive patient outcomes resulting from its requirements is minimal.

In 1998 the GAO issued a review of the MSQA in which they stated "Although the MQSA can be linked to improved quality of mammography images, it is difficult to say to what extent it has helped to improve mammography interpretation or increase the frequency of early detection of cancer which has been shown to save lives."⁵⁷ The study noted that data did not exist before the passage of the Act which could show the consequences of its requirements upon patient outcomes. Furthermore, the study did not even attempt to address the effect of the patient notification requirement of the MSQA.

57 Mammography Quality Standards Act: X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown: Hearing Before the Subcommittee on Health and the Environment, Committee on Commerce, House of Representatives, 106th Congr. (1998) (statement of Statement of Marsha Lillie-Blanton, Associate Director Health Services Quality and Public Health Issues Health, Education, and Human Services Division)

Alternatively, one could examine the volume of litigation based upon failure to communicate, and if the MSQA had any effect in reducing the frequency of these claims. In 1997 a Physician Insurers Association of America American College of Radiologist's survey claimed a substantial percentage of malpractice lawsuits filed against radiologists were based upon claims involving women who asserted that they had not been informed about abnormal mammogram results.⁵⁸ Accordingly, the MSQA was then amended in 1998 to include the patient notification provision.

Subsequent to these notification amendments, in a paper entitled *Communicating Findings of Radiologic Examinations*, Leonard Berlin states that "Implementation of the Mammography Quality Standards Act...virtually eliminated medical malpractice lawsuits alleging failure of communication of mammographic findings. It is intuitive to believe that direct reporting to patients of results of all radiographic examinations would similarly reduce, if not eliminate, all litigation alleging failure of communication."⁵⁹ However, Berlin provides no concrete data or studies reinforce these claims. Additionally, there are no independent studies examining this data.⁶⁰

Turning to state opt-in patient notification statutes, there are no studies indicating the number or percent of patient requests for direct communication of test results. Nor are there any studies indicating that there is a decrease in the number of adverse outcomes caused by the adoption of this legislation.

While no specific statistics exist assessing the effect of opt-in patient notification laws, in assessing the use of opt-in

58 Physician Insurers Association of American and American College of Radiology, Practice Standards Claims Survey. Physician Insurers Association of America, (1997).

59 Leonard Berlin, *Malpractice Issues in Radiology: Communicating Findings of Radiologic Examinations: Whither Goest the Radiologist's Duty?* American Journal of Radiology. 178; 809, 813(2002). Available at <http://www.ajronline.org/cgi/content/full/178/4/809>

60 Note; anecdotal evidence would suggest that litigation still arises from errors in mammography reporting, see: *Smith v. United States*, 119 F. Supp. 2d 561 (2000).

patient notice practices, one can look to the United States Department for Health and Human Services Agency for Healthcare Research and Quality study on patient safety practices published in 2001 for guidance.⁶¹ It was concluded when patients were given the ability to opt in to direct notification of test results, the rate of failure to inform was reduced.⁶² When patients had the ability to opt into direct notification of test results, the study found that 0% of individuals with abnormal results neglected a follow up visit with their treating physician. By contrast, 23% of individuals in the control group with abnormal results, who did not receive direct notification, failed to schedule a follow up visit.⁶³

Likewise, the Cornell Medical College study concluded that clinical risk management practices should involve some form of direct patient notification. The study further suggested clinicians should promote procedures where patients are told to call if after a certain time interval they have not been notified. This study indicates the threat of malpractice suits, coupled with adequate clinical risk management eliminates the need for specific legislation on this issue.⁶⁴

Finally, in determining the effectiveness of these legal approaches, one should acknowledge that these laws do not address the quality of the medical assessment or care. Even after the passage of the patient notification provisions of the MSQA, a 2002 study conducted by the Physician Insurers Association of America concluded eighty percent of claimants in breast cancer malpractice suits had received “either a negative or equivocal mammogram that led to a delayed diagnosis of their disease”.⁶⁵ If incorrect diagnoses are made in the first place, simply informing patients of these erroneous results will do nothing to improve their treatment outcomes.

When taken in sum, given the lack of information and the minimal effects upon the quality of patient care, it is unclear that

⁶¹ *Analysis, supra* note 19.

⁶² *Analysis, supra* note 19.

⁶³ *Analysis, supra* note 19.

⁶⁴ Casalino, *supra* note 1.

⁶⁵ Physician Insurers Association of America, Breast Cancer Study 3rd Edition 19 (2002).

these types of laws have any effect on improving patient outcomes.

**V. Proposals for
Pennsylvania
Policymakers**

Pennsylvania has two recognized courses of action. First, the Commonwealth could enact specific standard of care laws. However, there is little evidence to suggest these laws improve patient outcomes or reduce rates of clinician's failure to inform. Turning to patient notification laws, it is also impossible to determine if Pennsylvania citizens would benefit from a bill requiring direct patient notification. No data or assessments indicate patient notification laws reduce rates of failure to inform.

However, the Pennsylvania legislature could pass laws standardizing procedures in clinical facilities to conform to accepted risk management practices, or to align Commonwealth regulations with opt-in patient notification laws.⁶⁶ Rather than explicitly requiring test results to be sent to patients, the Commonwealth could require diagnostic testing entities provide patients with the option of having examination results directly sent to them. Limited studies have suggested this practice has a positive effect in reducing the rates of failure to inform when the option exists. Further, most medical diagnostic testing facilities already offer this as a choice to patients. Therefore, the proposed legislation would require what is already a widespread practice. Requiring direct notification only upon patient consent would also resolve privacy concerns voiced by organizations such as the Pennsylvania Medical Society in relation to this law.⁶⁷

The current legislation is limited to fifteen medical diagnostic tests, the majority of which are radiological. Some of the tests are dated and no longer frequently ordered by

⁶⁶ *Analysis, supra* note 19.

⁶⁷ Press release: *Bill Would Require Notifying Patients of Imaging Test Results*, PA Medical Society (1/20/2011) (On file with author). Note: the Pennsylvania Medical Society (PAMED) and others opposed House Bill 1358, believing that it could potentially cause patients to become confused about the meaning of the test results without a physician's explanation, and that it raised significant confidentiality concerns.

physicians. The bill should be modified to include all medical diagnostic testing. This eliminates the need to debate the inclusion of specific tests. Furthermore, any notification legislation should include a “lay term” requirement. As it stands now, medical diagnostic reports sent directly to individuals may result in the delivery of medical reports written in specialized language which would confuse and concern patients. A “lay term” provision would require that results be conveyed in a manner which patients can understand.

Ultimately, the unknown extent of this problem makes the impact of any proposed legislative action in Pennsylvania difficult to determine. There is no concrete evidence suggesting that Pennsylvania would benefit from legislation requiring direct patient notification. However, many diagnostic facilities have already adopted opt-in patient notification procedures as elements of their risk management protocols. Recognizing the acceptance of these practices, perhaps the best legislative strategy is a statute requiring all test providers provide patients with voluntary direct test result notification. This would align the medical law of the Commonwealth with protocols private industry has already identified as valid mechanisms for mitigating this type of harm.

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