PATIENT ACCESS TO MEDICAL INFORMATION: A MULTI-PERSPECITIVE STUDY

BY

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Dedication

To my mom and all the amazing women in my life:

Thank you for your unwavering comfort and support.

You have challenged me to know better and to be better.

I hope our daughters know such love.

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Abstract

Recent U.S health care policy emphasizes increased patient access to medical information to empower patients and improve quality of care. However, little is known about what access should consist of, how these systems will impact patients and physicians, and whether their use leads to better outcomes. Furthermore, the discrepancy between the 85 percent of Americans who use the internet and the 10 percent who access a patient portal is striking, suggesting a need to better understand barriers and facilitators concerning the use of patient portals. This three article dissertation builds upon existing research by: 1) providing a systematic review of the literature to determine the impact of patient-accessible records on quality of care; 2) identifying physician perceptions of patients' access to test results; and 3) exploring patients' experiences using portal-based test result notification. Despite a lack of evidence in the literature, psychological harm to patients is a major concern for both physicians and patients, especially as it relates to the release of sensitive test results. As portals continue to evolve, it is important to address both patient and physician concerns to facilitate acceptance and use, and to ensure that patients understand the medical information they are accessing. These findings suggest important considerations for health professionals, including medical social workers, who may be able to leverage this technology to engage patients in their care.

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Chapter 1: Introduction

Statement of the Problem

Failure to notify patients and follow up on abnormal test results has been found to be common and expensive in malpractice claims data (Gandhi et al., 2006a; Gale, Bissett-Siegel, Davidson, & Juran, 2011), leading to delays in diagnosis and treatment and, subsequently, patient harm (Matheny et al., 2007). Health care organizations are increasingly moving toward delivery of test results to patients via web portals as patients access to their test results may help mitigate delays in test result follow-up. However, portal adoption rates have remained low (Yamin, 2011). For many patients, managing health information online is a new task, and this new responsibility may not necessarily result in taking appropriate actions to decrease the risk of error or harm (Institute of Medicine, 1999; Buetow & Elwyn, 2007).

With the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, billions of dollars have been committed to facilitating the adoption and the "meaningful use" of health information technology (IT). The HITECH Act also highlights the importance of providing patients with electronic access to their clinical information (The American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5, 123 Stat 115, 2009) and incentivizes patient engagement in care as part of the "meaningful use" of electronic health records (Centers for Medicare and Medicaid services, 2010). Thus, the adoption of patient portals is an essential component of the national policy efforts to improve quality of care. Although patients are increasingly able to gain easy access to their medical information through patient portals and personal health records, good clinical practices and guidelines remain absent in this area.

Significance

Studies examining missed test results find that the rate of abnormal results lost to follow-up might be as high as 36%, resulting in a significant number of patients who fall through the cracks of the healthcare system (Wahls, Haugen, & Cram, 2007; Casalino et al., 2009; Elder, McEwen, Flach, Gallimore, & Pallerla, 2010). Both malpractice claims data (Gale, Bissett-Siegel, Davidson, & Juran, 2011; Gandhi et al., 2006b) and root cause analysis report data (Giardina et al., 2013) reveal missed test results to be a significant problem. A recent systematic review of outpatient test result follow-up found a wide range of rates for missed abnormal results, with 6.8% to 62% missed laboratory results and 1.0% to 35.7% missed radiology results (Callen, Westbrook, Georgiou, & Li, 2011). Despite increased use of health information technology, physicians have acknowledged that electronic systems used to inform patients of test results are far from satisfactory (Boohaker, Ward, Uman, & McCarthy, 1996; Poon et al., 2004). Inadequacy of current test result management systems may be a result of excluding physicians and patients from the design and implementation processes.

Increasingly, patients are encouraged to take an active role in their care and have expressed interest in having access to their health information (Cho et al., 2010; Pyper, Amery, Watson, & Crook, 2004). One potential method to mitigate delays in follow-up is to provide direct notification of test results to patients. Direct notification is the delivery of test results to patients through a patient portal, whether or not the ordering physician or another responsible physician has reviewed or taken follow-up action on the result. The patient portal is a secure website allowing patients to log on and access an assortment of functions connected to their electronic health record,

including scheduling, medication refill, secure messaging, and access to personal health records (PHR). Both physicians and patients believe that notifying patients of test results is important to maximize health care benefits (Murff et al., 2003; Baldwin, Quintela, Duclos, Staton, & Pace, 2005; Boohaker et al., 1996; Meza & Webster, 2000). However, physicians have expressed concern about the effects of new methods of communication (e.g., patient-physician email, electronic access to health records) on physician workload (Moyer, Stern, Dobias, Cox, & Katz, 2002) and patient anxiety and confusion (Zhou, Garrido, Chin, Wiesenthal, & Liang, 2007; Kittler et al., 2004; Johnson, Frankel, Williams, Glover, & Easterling, 2010). While these concerns have not been validated empirically (Zhou et al., 2007; Kittler et al., 2004; Wald et al., 2007; Hassol et al., 2004; Gravis et al., 2011), similar concerns may be raised for communication of abnormal test results through patient portals and may potentially thwart their benefits.

Currently, there is very little research regarding the effects of direct notification of test results. Despite physician concerns regarding electronic communication (Moyer et al., 2002; Zhou et al., 2007; Kittler et al., 2004; Johnson et al., 2010), it remains unclear how physicians and patients will perceive the risks and benefits of direct notification for abnormal test results, or how direct notification of these results will affect patient outcomes. Further, it is uncertain what factors will impact physician and patient acceptance of direct notification.

Meaningful Use. The HITECH Act established an incentive program for health care organizations and providers to demonstrate "meaningful use" of certified electronic health records (EHR).(Department of Health and Human Services, 2010) The definition of "meaningful use" (MU) includes a number of objectives to encourage the engagement

of patients and their families through increased electronic access to their clinical information (Department of Health and Human Services, 2010). For instance, Stage 2 of MU criteria includes providing patients with the ability to view online, download, and transmit their health information within four business days of the information being available to the provider (Centers for Medicare and Medicaid services, 2010). Measure 1 of Stage 2 requires that more than 50 percent of all unique patients are provided with timely online access to their health information. Measure 2 of Stage 2 requires that more than 5 percent of all unique patients view, download, or transmit their health information to a third party. While these initiatives to engage patients have received overwhelming support, it is unknown how best to maximize their benefits (Tenforde, Jain, & Hickner, 2011; Meyer, Atherton, Sawmynaden, & Car, 2012; Agarwal & Khuntia, 2009; Wilson & Peterson, 2010).

CLIA Program and HIPAA Privacy Rule. In 2011, the Department of Health and Human Services (HHS) jointly with the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Office for Civil Rights, proposed a rule allowing patients to access test results directly from the laboratory upon patient request (Department of Health and Human Services & Center for Medicare & Medicaid Services, 2011). The final rule was released in February 2014 and allows patients to request access to their test results directly from the laboratory without physicians' involvement (Department of Health and Human Services & Center for Medicare & Medicaid Services, 2014). The rule impacts 39 states and territories that either had no laws to regulate direct test result notification to patients, or where the practice was outright banned by state law (Giardina & Singh, 2011). It also ensures that

all CLIA (Clinical Laboratory Improvement Amendments) and CLIA-exempt clinical laboratories abide by HIPAA regulations, thus standardizing patients' rights to access protected health information. Finally, the rule does not allow the withholding of certain type of sensitive test (i.e.; genetic, cancer, pregnancy, sexually-transmitted disease, or mental health). The final rules states that the 30-day window will allow physicians to receive the results well before the patients and provide adequate time to follow-up on the result (Department of Health and Human Services & Center for Medicare & Medicaid Services, 2011).

This rule sets the groundwork for increasing patient access to test results, and much of this access could be expected to occur through the use of health IT. However, the impact to patients and physicians of test result notification via patient portals and PHRs are largely unknown, and it is unclear how patients' manage and act on the health information they receive. Furthermore, best practices concerning how health IT should be designed for optimal patient use have yet to be identified (Davis Giardina & Singh, 2011). Though there are not currently evidence-based practices for test result notification through the patient portal, the current health care policy climate heavily emphasizes greater patient-provider collaboration as a means of improving quality of care related to test results. These policy initiatives advocate for innovative methods to improve test result notification and underscore the importance of this project.

Innovation

So far, only a handful of institutions in the US have reported on their experiences with using a portal or PHRs to notify patients of laboratory results (e.g., Kaiser Permanente, Beth Israel Deaconess, Vanderbilt University Medical Center, and The

Department of Veteran Affairs) (Christensen & Oldenburg, 2009; Halamka, Mandl, & Tang, 2008; Osborn et al., 2011) but adoption of these systems is on the rise. Without a clear understanding of physician and patient preferences related to direct notification of test results, portal-based test result notification systems may not provide the innovation and benefit anticipated. There is a general lack of consensus in the literature about good clinical practices for patient notification of abnormal results and little empirical study of the outcomes of results notification via portals. The lack of evidence could hinder implementation and progress in the field of patient-facing health IT overall. This project is innovative because it will outline key issues for both physicians and patients concerning the use of patient portals and PHRs to convey health information. It explores the use of health IT as a method for test result notification and will lay the groundwork necessary to inform best practices related to abnormal test result notification to patients. In the era of "meaningful use" and increased adoption of EHRs and personal health records across a variety of healthcare systems, there is a growing need for evidence to inform beneficial practices and designs for delivery of test results via patient portals.

Overall Objective

The overall objective of this research is to: 1) review existing literature to identify the impact of providing patients access to their medical records on quality of care, as defined by measures of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity; 2) describe physician perspectives of direct patient notification systems, especially as they relate to abnormal test results; and 3) improve understanding of patients' experience and informational needs and of health

management practices regarding test result notification through the use of personal health records.

Chapter two will provide a more extensive review of the literature and the conceptual framework for this research. I review existing research on the technology acceptance model and the diffusion of innovation theory. Chapter Three presents my research as described in three separate studies. In Chapter Four, the concluding chapter, I revisit the significance of the findings and explore topics for further research.

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Chapter 2: Literature Review

This chapter presents the literature relevant to patient access to medical records. It includes a broad overview of patient access to medical records, the personal health record, and the patient portal, a method to facilitate access. The impact on the patient-physician relationship is also addressed, as it has been suggested that increased access may negatively impact the relationship. Finally, Article Two and Article Three will focus on access to test results through a personal health record and patient portal; therefore, a discussion of the problem of missed test results is included in the context of the role of direct patient notification.

Patient Access to Medical Records

Due in part to prioritization in Health Information Technology for Economic and Clinical Health (HITECH) Act, patient access to medical records is increasing (The American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111-5, 123 Stat 115, 2009). Evidence of the actual benefits and limitations of this access, however, is incomplete. It is unclear how patients, physicians, and the healthcare system at large will be impacted by this increased transparency. To date, patient-centered care has been shown to trend towards improved patient satisfaction, health behaviors, and health status (Lewin, Skea, Entwistle, Zwarenstein, & Dick, 2001; Dwamena et al., 2012).The emphasis on patient engagement should include patient access to timely and accurate information. For example, providing patients access to their medical records may be a powerful tool in creating a collaborative relationship between provider and patient by sharing access to knowledge (Tang, Ash, Bates, Overhage, & Sands, 2006) and providing patients the option to take active roles in their care. In fact, the Institute of

Medicine (IOM) advocates for the free flow of information between provider and patient and further asserts that patients should have unrestricted access to their medical information (Institute of Medicine, 2001).

Existing empirical literature suggests that patient-accessible records can improve patient-provider communication (Baldry, Cheal, Fisher, Gillett, & Huet, 1986; Cimino, Patel, & Kushniruk, 2002; Honeyman, Cox, & Fisher, 2005; Cimino, Patel, & Kushniruk, 2001), self-management (Fisher, Bhavnani, & Winfield, 2009; Honeyman et al., 2005), and patient satisfaction (Tang et al., 2006; Tang & Lansky, 2005; Matheny et al., 2007). Obstetric care in particular has been successful in utilizing patient-held medical records to improve patient participation and communication (Elbourne, Richardson, Chalmers, Waterhouse, & Holt, 1987; Lovell et al., 1987; Homer, Davis, & Everitt, 1999; Webster et al., 1996; Wackerle et al., 2010). A 2003 narrative review on the effects of patient access to their medical records found that access improves communication between provider and patient, adherence, and patient education (Ross & Lin, 2003). The review also found that patient-accessible records are unlikely to cause patient harm. However, providers may still be wary of allowing patients direct access to their records, fearing it may cause patient anxiety and increase provider workload (Ross et al., 2005; Ross, 1986; Johnson, Frankel, Williams, Glover, & Easterling, 2010; Siteman et al., 2006). To the contrary, a recent study granting patients electronic access to their doctors' notes found that patients reported an increased sense of control, better understanding of their medical issues, and improved recall of their care plans (Delbanco et al., 2012). Moreover, physician workload did not appear to increase, and in fact many of the physicians were unaware of whether their patients were even reading the notes.

Notwithstanding this promising evidence, there is little to substantiate the claims that access to a personal health record improves health outcomes that has been drawn from controlled studies (Archer, Fevrier-Thomas, Lokker, McKibbon, & Straus, 2011). The authors of this review concluded that a significant amount of the existing personal health record research is focused on satisfaction, adoption, and use rather than health outcomes. Additionally, a recent systematic review of controlled trials concluded that there is no evidence to support improvement of patient empowerment, the outcome most often touted as a value of the personal health record (Ammenwerth, Schnell-Inderst, & Hoerbst, 2011).

Personal Health Records and Patient Portal. The personal health record is a system whereby patients access, share, and update their medical information (Sittig, 2002). Patients typically own and manage this information themselves. There are two types of systems: tethered, integrated with the physician's electronic health record, and untethered or standalone health records (U.S.Department Of Health And Human Services, 2013). A tethered system is typically integrated with or populated by the patient's electronic health record, allowing the patient to view all or portions of their medical records. Untethered systems are more like vaults; patients input their information, maintaining their own health records (Greenhalgh, Hinder, Stramer, Bratan, & Russell, 2010). The American Medical Informatics Association's College of Medical Informatics concluded that tethered personal health records possess greater benefits than untethered systems (Tang et al., 2006). Though both systems offer a multitude of services, including health education and self- management capabilities, tethered PHR

systems typically include access to the medical record, prescription services, scheduling, secure messaging, and laboratory test results.

The patient portal is defined as “a secure online website that gives patients convenient 24-hour access to personal health information from anywhere with an internet connection” (National Learning Consortium, 2014, p. NA). The portal can be thought of as a tethered PHR (Ancker, Silver, & Kaushal, 2014; Osborn, Mayberry, Mulvaney, & Hess, 2010). Patients are able to access a variety of services, including secure messaging, medications, test results, appointment scheduling, and medical history. Because of the similarities between the two, they are often used interchangeably in the literature. The terms will similarly be used in this dissertation. Moving forward, PHR and patient portal will refer to secure, electronic access to personalized medical information.

Despite patient and physician interest (Health Industry Insights, 2006; Markle Foundation, 2006; Markle Foundation, 2008; Nazi, 2013; Markle Foundation, 2011), the personal health record continues to be an underutilized tool (Kaelber, Jha, Johnston, Middleton, & Bates, 2008; Nazi, 2013). Typically the digital divide, or the disparity in technology access, is referenced in underutilization (Kim & Kim, 2010). While racial and ethnic disparities exist in enrollment and use (Ancker et al., 2011; Goel et al., 2011; Sarkar et al., 2011; Yamin et al., 2011), there are additional barriers. A recent study examining enrollment barriers found that the majority of patients did not use the personal health record due to lack of information or motivation, while Internet and computer access was least likely to be cited as a barrier (Goel et al., 2011). Providers’ failure to promote the personal health record and patients’ lack of awareness of

availability and functions contribute to low adoption rates as well (DesRoches et al., 2008; Hassol et al., 2004; Winkelman, Leonard, & Rossos, 2005). A recent qualitative study with healthcare professionals at a Department of Veterans Affairs Medical Center found that they conceptualized the personal health record as a tool for patients not necessarily relevant to the clinical encounter (Nazi, 2013). Health care professionals also had very limited experience and education with the personal health record other than secure message training. Unfortunately, there is little evidence of best practices for encouraging patients to enroll and utilize personal health record programs (North et al., 2011).

Patient – Physician Relationship

As patient access to their medical records becomes more normalized, it has been suggested that the personal health record and patient portals may have an impact on the patient-physician relationship (Sung, Forman-Hoffman, Wilson, & Cram, 2006). A brief discussion of some of the main issues pertaining to this relationship is provided below.

Shared Decision Making. Organizations focused on patient rights, as well as the IOM and the Agency for Healthcare Research and Quality (AHRQ), encourage patients to participate in care and provide guidance on how to talk with physicians. Though there is no overall consensus on what shared decision-making is, it is generally thought of as a continuum between paternalism (where the physician makes the decision) and patient autonomy (where the patient makes the decision). In shared decision-making, the relationship between patient and physician is based on the idea

that each is working together to benefit the patient. haring information is a crucial part of this process (Karnieli-Miller & Eisikovits, 2009).

Patients are generally more satisfied with care, have a better understanding of their illnesses, and experience better outcomes when the physician provides more information and includes patient preferences in decision making (Street, Jr., Krupat, Bell, Kravitz, & Haidet, 2003). Recent literature has shown that physicians prefer patients to take a more active role in decision making (Murray, Pollack, White, & Lo, 2007; McGuire, McCullough, Weller, & Whitney, 2005). In fact, a national survey of U.S. physicians found that 75% preferred shared decision-making with patients (Murray et al., 2007). Those physicians were also more likely to encourage patients to look for medical information related to their health status.

Conversely, there is a trend in the decrease of positive attitudes towards patient-centered care among medical students as they move from the classroom into the clinic setting (Krupat et al., 2009; Haidet et al., 2001; Tsimtsiou et al., 2007; Haidet et al., 2002). This trend may suggest that the application of patient-centered care could become more complicated as students attempt to apply concepts learned in the classroom to the practice setting. Literature examining physician communication with patients has found that though physicians may hold shared decision-making values, they do not necessarily utilize them in communication with patients (Karnieli-Miller & Eisikovits, 2009; Pellerin et al., 2011). It may be that physicians are less likely to admit openly to a paternalist point of view now that the concept of patient-centered care has become the norm in the healthcare lexicon (Lynoe, Juth, & Helgesson, 2010). Despite the generally positive perceptions of shared decision-making, physicians who

encourage patient participation may become concerned about their patients' electronically accessing abnormal test results without evidence that such access may not cause psychological harm or anxiety to patients (Sung et al., 2006).

Power and Control in the Patient-Physician Relationship. Not surprisingly, physicians have shown significantly more interest in direct reporting of normal results than of abnormal results (Sung et al., 2006). They have expressed concern that direct notification would lack the level of explanation that a physician could provide. Physicians also may be concerned about transmitting abnormal test results without context and about the subsequent risk of psychological harm (Sung et al., 2006). The paradigm shift in the U.S. to patient-centered care raises questions of authority and responsibility in the patient-physician encounter. The proliferation of technology has offered patients access to medical knowledge that was once only available to health care providers and researchers. This access may create a better-informed patient, thereby allowing for the possibility of patient-physician partnership. However, direct notification of test results may challenge the traditional physician role and require a decentralization of power in the patient-physician relationship (Longtin et al., 2010). The reorganization of power will require behavior modification in the health care field and the promotion and acceptance of the patient partner role by individual practitioners. Additionally, as the IOM suggests, it will require full and unfettered access to personal health information by patients (Institute of Medicine, 2001).

In a systematic review of patient participation and patient safety, Longtin et al identified "desire to maintain control" (2010, p 55) as a barrier to providers' involvement in patient participation. As a result, some physicians may be hesitant to encourage more

egalitarian relationships with patients (including shared access to health information) for fear of identity loss (O'Flynn & Britten, 2006; Stevenson, 2003). One study found that older patients' enthusiasm to use email with physicians was related to their own physician's enthusiasm to use email with patients (Singh, Fox, Petersen, Shethia, & Street, Jr., 2009). If physicians are hesitant about web-based direct notification of certain types of results, patients may be hesitant as well. Thus, the study of physician beliefs and attitudes about patient participation and shared decision-making is essential because these beliefs may facilitate or hinder the use of web portal-based direct test result notification.

Test Results

Missed test results and patient safety. Diagnostic errors are major contributors to harmful outcomes in outpatient care (Singh, Naik, Rao R, & Petersen, 2008; Singh, Sethi, Raber, & Petersen, 2007; Singh et al., 2009a; Singh et al., 2009c; Singh, Petersen, & Thomas, 2006; Singh, Thomas, Khan, & Petersen, 2007; Singh et al., 2009b; Singh et al., 2010b; Singh et al., 2010a). Failure to follow-up abnormal test results is a common cause of diagnostic error (Schiff et al., 2009). A recent study of test result management in an urban community health organization found that 34% of abnormal test results did not have documentation of follow-up, and 49% of patients with follow-up did not receive care in a timely manner (Chen, Eder, Elder, & Hickner, 2010). Similarly, Boohaker et al. (1996) found that one-third of physicians do not always notify patients of abnormal test results.

In the VA outpatient setting, a study found that 18% and 10% of electronic imaging and laboratory result alerts, respectively, were not acknowledged by physicians

4 weeks after their initial transmission in an integrated electronic health record (EHR) (Singh et al., 2009c; Singh et al., 2010c). Furthermore, almost 8% of critical imaging results and 7% of abnormal laboratory result alerts lacked follow-up at 4 weeks, even when physicians acknowledged receipt of the results. Although physician access to EHRs and other technologies allows for faster access to test results, this access does not guarantee reliable, appropriately timed follow-up. There is a significant need for innovative methods, such as patient access to results through a personal health record, to reduce time to notification and trigger patient follow-up.

Test result reporting to patients is also relevant for the HITECH Act, which established an incentive program for demonstration of "meaningful use" of certified EHRs (Department of Health and Human Services & Centers for Medicare & Medicaid Services, 2010). Meaningful use greatly emphasizes timely patient access to their medical information. The three stages of meaningful use include a number of objectives to encourage patient engagement through increased electronic access (Centers for Medicare & Medicaid Services, 2012).

Direct patient notification of test results. Direct notification is the notification of test results to patients through a patient portal, whether or not the ordering physician has reviewed or taken action on the result. A handful of institutions around the U.S. use direct notification of laboratory results (Christensen & Oldenburg, 2009; Halamka, Mandl, & Tang, 2008), and others are likely to adopt this practice to meet the new "meaningful use" requirements. Further, patients want to be notified of all their test results, including normal and abnormal results (Baldwin, Quintela, Duclos, Staton, & Pace, 2005; Boohaker, Ward, Uman, & McCarthy, 1996; Meza & Webster, 2000; Peres

& Wellman, 2001; Grimes, Reis, Budati, Gupta, & Forjuoh, 2009), and in less time than is currently typical (Basu et al., 2011). High rates of notification of normal and abnormal test results are positively correlated with patient satisfaction (Leekha, Thomas, Chaudhry, & Thomas, 2009; Meza & Webster, 2000; Petrie et al., 2007), whereas increased time to notification is associated with patient dissatisfaction (Baldwin et al., 2005; Leekha et al., 2009; Schofield, Sanson-Fisher, Halpin, & Redman, 1994). Patients who receive direct notification of test results are more likely to perceive timely reporting (Cram, Schlechte, & Christensen, 2006) and be more satisfied with their care.

Although the effects of direct notification on patient outcomes are not known, early evidence suggests that other forms of direct patient notification can improve follow-up rates for clinical care. For example, one randomized trial examined the effects of direct patient notification (by mail) on follow-up of abnormal cervical screening results. None of the women who received abnormal results directly were lost to follow-up, compared to 23% of controls (Del Mar & Wright, 1995). A recent study examining patients' reactions to viewing laboratory test results online found that patients reported high levels of satisfaction, appreciation, calmness, happiness, and relief, while few patients experienced negative emotions (i.e., worry, fear ,anger) (Christensen, 2013). With increasing use of patient portals, direct notification of certain types of test results may enable patients to be more active in their care, ensure that patients are notified in a timely manner, and help decrease the number of test results lost to follow-up. However, concerns about the broad applicability of this practice remain (Gray, 2011; The Pennsylvania Medical Society, 2011). In particular, clinicians' perceptions of and willingness to implement automated patient e-notification are unclear.

At this point in time, there are existing models for direct notification of test results. The Mammography Quality Standards Act (MQSA) provides a precedent for direct notification. MQSA was passed in October 1992 to establish national standards in mammography and improve timely notification to patients. In 1997, Congress issued the Mammography Quality Standards Act Final Rule, instituting mammography performance standards, including requiring mammography facilities to create notification procedures to ensure communication of test results (U.S.Department Of Health And Human Services, Food and Drug Administration, & Center for Devices and Radiological Health, 2002). In 1998, the Mammography Quality Standards Reauthorization Act amended the Mammography Quality Standards Act to include language that required mammography facilities to provide written patient notification of test results in lay terms within 30 days of the procedure (U.S.Department Of Health And Human Services & Food and Drug Administration, 1999; U.S.Department Of Health And Human Services et al., 2002). Providing a written report directly to the patient has become standard practice in mammography and has improved patient satisfaction (Priyanath, Feinglass, Dolan, Haviley, & Venta, 2002; Dolan et al., 2001). Patients prefer direct communication from the radiologist for both normal and abnormal results over waiting to meet with the ordering physician (Levin et al., 2000; Liu, Bassett, & Sayre, 1994).

Interestingly, states have attempted to pass legislation similar to MQSA to address malpractice concerns. In 2010, Pennsylvania introduced legislation that would require radiology reports to be sent directly to patients within 10 days of transmission to the ordering physician (Gray, 2011). The Pennsylvania Medical Society opposed this legislation due to confidentiality concerns and fear of causing patient anxiety and

confusion (The Pennsylvania Medical Society, 2011). The proposed legislation was not passed and similar legislation was never reintroduced. Therefore, this example illustrates that widespread use of direct test result notification will face several implementation and adoption challenges (Schiff, 2011).

Theoretical Background

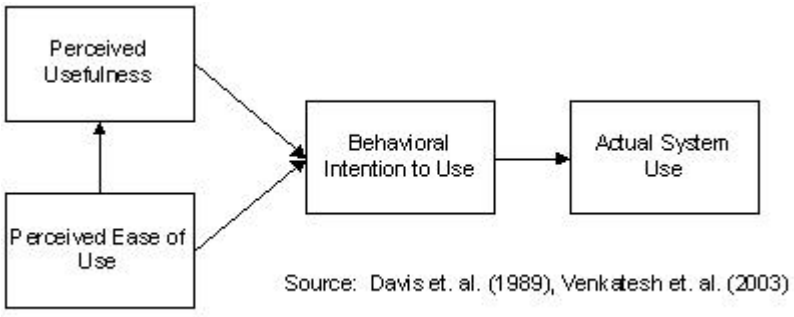
To better understand the acceptance and adoption of direct notification, two theoretical perspectives are discussed below. The Technology Acceptance Model (Davis, 1985) explains what factors influence system use and can be used to better understand the antecedents of physician and patient acceptance of direct notification. The Diffusion of Innovation (Rogers, 2003) explains how innovation spreads in a population. It can be used to guide this study in terms of the characteristics of adopters and the decision processes leading to adoption.

Acceptance of New Technology.

The theory of reasoned action states that a person's behavioral intention depends on the person's attitudes about the behavior and subjective norms (Fishbein & Ajzen, 1975). Attitude about the behavior is predicated on the individual's beliefs and evaluations, while subjective norms are predicated on normative beliefs and motivation to comply. The theory of reasoned action states that people are rational decision makers, consciously choosing their courses of action based on analysis of potential costs and benefits attached to each of the various behavior alternatives. This theory was adapted by Dr. Fred Davis, an informatician, to create the Technology Acceptance Model (Figure 1) (Davis, 1985). The Technology Acceptance Model posits that people

voluntarily tend to use or not use a system based on their attitudes, their belief of the system's usefulness, and their perception of ease of use of that system. Ease of use and perceived usefulness have a direct influence on intention to use; however, perceived usefulness is the stronger predictor (Venkatesh & Davis, 2000). Perceived usefulness is the degree to which an individual believes that using a particular system would enhance his or her job performance (Davis, 1989; Morton & Wiedenbeck, 2009). The easier a system is to use, the more useful the system. Over time, as people become more familiar with the system, ease of use becomes mediated by usefulness (Vankatesh, 1999; Winkelman, 2006).

Figure 1. The Technology Acceptance Model



The Technology Acceptance Model was originally developed to address issues of information technology (IT) underuse and is the most widely used theoretical model for explaining system usage (Davis, 1989; Davis, Bagozzi, & Warshaw, 1989; Holden & Ben-tzion, 2010; Koufaris, 2002). The Technology Acceptance Model is a general framework that allows for new variables to be added if they are theoretically relevant and based on empirical research. Previous studies indicate that Technology Acceptance Model variables can be successfully integrated with variables from other

theoretical approaches to better understand acceptance of new information technology (Ketikidis, Dimitrovski, Lazuras, & Bath, 2012).

Technology Acceptance Model and Physicians. In a literature review of adoption of electronic health records (Castillo, Martinez-Garcia, & Pulido, 2010), the authors found that user attitudes towards information systems, or "an individual's disposition to respond favorable or unfavorable to an object, person, institution, or event" (Ajzen, 2005) p 241) towards the system, is a critical factor for user adoption. The authors suggest that attitudes can be influenced in a more positive direction by highlighting and encouraging the usefulness and ease of use of the innovation. Barriers to EHR adoption include restricting physician autonomy and perceived overall risk (perception of negative consequences) (Archer & Cocosila, 2011; Sung et al., 2006). Additionally, perceived usefulness has been shown to be the strongest predictor of intention to use an EHR (Morton & Wiedenbeck, 2010; Morton & Wiedenbeck, 2009).

These barriers may also be relevant to physician acceptance of a personal health record or direct notification of patient test results. Physicians may inadvertently influence patient acceptance of these new technologies with their own attitudes and beliefs. Patient healthcare decisions and behaviors are often influenced by physician recommendations (Mazur & Hickam, 1990; Mazur & Hickam, 1994; Mazur & Hickam, 1997; Nawaz, Adams, & Katz, 2000; Kreuter, Chheda, & Bull, 2000; Stead, Bergson, & Lancaster, 2008). While patients may seek out and use health services, use of the personal health record may only be effective if both patients and physicians see its value (Ross et al., 2005; Morton, 2011).

Technology Acceptance Model and Patients. Since patients are not employees, patients may perceive the usefulness of the personal health record differently from physicians or healthcare institutions using EHRs (van't, Berg, Hiddema, & Sol, 2001). It is necessary first to evaluate if patients will actually use the system; intent to use can be determined by patients' perception of usefulness (Winkelman, 2006). According to a study utilizing the Technology Acceptance Model for patients, the model can be useful for conceptualizing patient personal health record use (Winkelman, 2006; Winkelman et al., 2005). The study found that for the personal health record to be perceived as useful, it should adhere to patients' priorities, be personalized, and be implemented in the context of a trust relationship (i.e., patient-physician relationship). Because patient acceptance and extended use have received little attention thus far, the parsimony of Technology Acceptance Model provides a good theoretical starting point for further understanding patient acceptance.

Limitations of the Technology Acceptance Model. An often cited limitation of Technology Acceptance Model is the exclusion of external variables and barriers to acceptance (Yarbrough Amy K, 2007). However, the Technology Acceptance Model has consistently explained about 40% of the variance in usage intention (Vankatest, 1999). The Technology Acceptance Model is also criticized for lacking variables associated with group, cultural, and social influences (Bagozzi, 2007). Despite these limitations, the Technology Acceptance Model aligns well with the exploratory nature of this research.

Diffusion of Innovations Theory.

Diffusion of Innovations theory is a tool for understanding how new ideas are spread through social groups. It provides an overview of how an innovation is communicated, the characteristics of innovations, the decision process leading to adoption, and the characteristics of adopters. Everett Rogers synthesized over 500 studies in multiple disciplines to develop the theory of Diffusion of Innovation. Diffusion is defined as the process through which an innovation is communicated through certain channels over time among the members of a social system (Rogers, 2003). Diffusion happens through four main concepts: 1) innovation, 2) communication channels, 3) time, and 4) social systems. To reach adoption, individuals progress through five stages: knowledge, persuasion, decision, implementation, and confirmation.

Diffusion of Innovation defines five characteristics of innovations: 1) Relative advantage, the extent to which an innovation is better than the idea before it; 2) Compatibility, the perception of an innovation as being consistent with adopters' needs; 3) Complexity/Simplicity, the level of difficulty in use; 4) Trialability, the ability to experiment before a commitment; and 5) Observability, the extent to which the innovation provides tangible results (Rogers, 2003). These five characteristics are positively related to the rate of adoption of an innovation.

Rogers (2003) also identified five types of adopters: innovators, early adopters, early majority, late majority, and laggards. Innovators are considered venturesome and are expected to be higher in socioeconomic status due to their ability to invest in the uncertainty of an innovation. Early adopters tend to be leaders, educated, younger and of a high socioeconomic status. This group holds the opinion leaders, or social leaders. They make judicious innovation decisions to maintain their positions as role models.

The early majority adopters tend to not be opinion leaders but have contact with early adopters. The late majority tends to be skeptical of innovation. And finally, the laggards are the last to adopt. Laggards tend to be the oldest and have lower socioeconomic status.

Extension of Diffusion of Innovations Theory for Information Technology Innovation. Moore and Benbasat (1991), drawing from Diffusion of Innovation and the Technology Acceptance Model, developed an instrument to measure the perceptions an individual may have concerning adoption of an IT innovation (Moore & Benbasat, 1991). Their instrument expanded Rogers' "five factors impacting adoption" to seven. The final instrument included relative advantage, compatibility, image, ease of use, results demonstrability, visibility, and trialability. The authors noted the similarities between Rogers' constructs "relative advantage" and "complexity" and Davis' constructs "perceived usefulness" and "ease of use." Additionally, they found that "observability" actually separated into two distinct constructs: results demonstrability (the actual use of the innovation), and visibility (the presence of the innovation in a setting). The authors also found that "image" was a construct within "relative advantage."

The Personal Health Record and Diffusion of Innovations Theory. A recent study testing the applicability of the Diffusion of Innovation model on patient perceptions found that non-adopters had lower innovativeness in information technology (Emani et al., 2012). As expected, the authors found that "ease of use" and "relative advantage" of the personal health record were the most important in predicting the value of the personal health record among patients. Interestingly, the study also did not find differences for education and income between innovators and laggards. The

authors speculate that this may be because the personal health record is not associated with a financial cost. They also acknowledge that it may be that their adopter category definitions were not appropriate and call for additional research addressing classification of personal health record adopters.

Since portals and personal health records continue to be underutilized, and it is unclear what factors impact acceptance and adoption, the Technology Acceptance Model and Diffusion of Innovation serve as useful theoretical models to inform the research proposed for this dissertation. As this research is exploratory, the purpose is not to test these models but to use their constructs as a framework for understanding patient and physician perceptions of patient-access medical records, specifically as they pertain to abnormal test results.

Empowerment.

Empowerment is typically advertised as one of the important functions of patient facing health information technology, such as PHRs and patient portals. In fact, the Meaningful Use requirements directed at increasing patient access to their health information appears to be based on the assumption that increased access will increase patient engagement in care. The concept of empowerment is not well defined in the medical literature (Anderson & Funnell, 2010; Samoocha, Bruinvels, Elbers, Anema, & Van Der Beek, 2010; Aujoulat, d'Hoore, & Deccache, 2007). In community psychology, empowerment has been defined as a process in which people achieve mastery over their lives (Rappaport, 1987). For patients, empowerment can be conceptualized as control over health behavior and health decisions (Schulz & Nakamoto, 2013; Schulz, 2014). For physicians, patient empowerment means a major shift in paradigm from

"feeling responsible *for* patients to feeling responsible *to* patients" (Anderson & Funnell, 2005).

Empowerment is particularly relevant to the profession of Social Work. Social Workers are committed to helping people manage their problems and providing the resources to do so (Edwards, 1995). The underlying assumption is that people deserve equal economic, political, and social rights. Social justice is a core social work value and Code of Ethics states, "Social workers strive to ensure access to needed information, services, and resources; equality of opportunity; and meaningful participation in decision making for all people" (National Association of Social Workers, 2014). Further the Code states that social workers should take part in activities that expand choice and opportunities for all people with emphasis on vulnerable populations. Whether patient access to their medical information results in patient empowerment, it is a step towards offering patients the option of collaborating in their care. For medical social workers, PHRs and portals may be useful tools in patient communication, education and coordination.

Summary

This literature review introduced the basic concepts of patient access to their medical information, the portal and personal health record and reasons and the concerns associated with increased patient access. It places patient access in context of a complex health care system where test results are missed. Additionally, policy priorities encouraging the adoption of patient portals to receive federal incentives offered through the HITECH act referred to most commonly as "Meaningful Use." The patient portal was introduced along with identifying the many features and capabilities

that it could offer to both providers and patients. Understanding common challenges, including the impact on the patient-physical relationship, should be an important consideration when implementing a patient portal. The remainder of the literature review provided an overview of relevant theoretical concepts explains the evaluation process of health information technology and provides a central framework for this work. Overall, this literature provides the context of patient portals and the elements to consider associated to adoption and use.

In this dissertation, I address the impact of patient accessible medical information through three distinct yet related research projects, 1) a systematic literature review to determine the effect of providing patients access to their medical records (electronic or paper-based) on healthcare quality; 2) a physician survey to determine physician perspectives about direct patient notification of *normal* and clinically *significant abnormal* test results; and 3) a qualitative study exploring patients' experiences receiving an abnormal test result through the portal.

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Chapter 3

Components of the Dissertation as Three Articles

Article One: Patient Access to Medical Records and Health Care Outcomes: A Systematic Review

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Contributorship Statement

Traber Davis Giardina, MA, MSW contributed to the conception and design of the project, acquisition of data, and the analysis and interpretation of the data. She drafted the article, worked with the team on revisions, and gave final approval of the version to be published.

Shailaja Menon, MPH, PhD contributed to the acquisition of data, analysis and interpretation of the data, provided critical revisions, and gave final approval of the version to be published.

Danielle Parrish, PhD, Dissertation Chair, contributed to the conception and design of the project and the analysis and interpretation of the data. She provided critical revisions and gave final approval of the version to be published.

Dean F. Sittig, PhD, Dissertation Committee Member, contributed to the conception and design of the project, provided critical revisions, and gave final approval of the version to be published.

Hardeep Singh, MD, MPH, Mentor, contributed to the conception and design of the project and the analysis and interpretation of the data. He provided critical revisions, and gave final approval of the version to be published.

Abstract

I conducted a systematic review to determine the effect of providing patients access to their medical records (electronic or paper-based) on healthcare quality, as defined by measures of safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. Articles indexed in PubMed from January 1970 through January 2012 were reviewed. Twenty-seven English-language controlled studies were included. Outcomes were categorized as measures of effectiveness (n = 19), patient-centeredness (n = 16), and efficiency (n = 2); no study addressed safety, timeliness, or equity. Outcomes were equivocal with respect to several aspects of effectiveness and patient-centeredness. Efficiency outcomes in terms of frequency of in-person and telephone encounters were mixed. Access to health records appeared to enhance patients' perceptions of control and reduced or had no effect on patient anxiety. Although few positive findings generally favored patient access, literature is unclear if providing patients access to their medical records improves quality.

Background

Engaging patients as partners in their own care has garnered growing interest as a method for improving the quality of healthcare delivery.(1-7) It is now widely acknowledged that a more patient-centered, collaborative approach is needed to foster patient engagement.(8) To date, research has shown a trend towards improved patient satisfaction, health behaviors, and health status in response to patient-centered practices.(9;10) One such practice is increasing patients' access to timely and accurate information. The Institute of Medicine (IOM)(11) advocates for unrestricted patient access to medical records. Further, patients have a legal right to access their medical records,(12) and multiple studies have documented their general interest in doing so.(13-19)

Providing patients access to their medical records may facilitate a more collaborative relationship between provider and patient.(20) Existing literature suggests that patient-accessible records can improve patient-provider communication,(21-25) self-management,(24;26) and patient satisfaction.(20;27;28) A 2003 narrative review on the effects of patient access to medical records found that access improves communication between provider and patient, patient adherence, and patients' knowledge about their own health and is unlikely to cause patient harm.(21) Despite these reassuring data, many providers are still wary of patient access to their records, fearing it may cause patient anxiety or increase provider workload.(14;21;29-31)

The IOM has recommended six major aims for improving the quality of health care delivery: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.(11) Using the six IOM aims as a framework for assessing potential benefits and patient outcomes, a systematic review was conducted to determine the effects of interventions that provide patients access to their medical records. The overall aim was to provide a timely synthesis of the growing body of literature on patient access to medical records in order to inform future policies and practices in this area.

Materials and Methods

Data Sources and Searches

English-language articles indexed in PubMed with publication dates between January 1970 and January 2013 were included. Potentially relevant studies were identified using a combination of MeSH headings and free text phrases (See Figure 1). Furthermore, the first and second author reviewed the bibliographies of each article to identify additional potentially relevant articles.

Study Selection

The first and second author divided the task of screening the titles and abstracts of all articles retrieved through the MeSH heading and key phrase search. We included quantitative studies that assessed the effect of patient-accessible records (electronic or paper-based) on quality-related outcomes in adult populations. We defined medical records as any patient-specific information held by the physician and/or healthcare system (see Figure 2). After the initial screening process, each investigator randomly

selected and reviewed 10% of the other's articles in order to ensure consistency in the selection process. All discrepancies were resolved through consensus.

Data Extraction and Quality Rating

One investigator extracted data from each article meeting the screening criteria and a second investigator extracted data for 10% of the articles in order to ensure reliability. Both reviewers scored each RCT using the Quality of Study Rating Form (QSRF).(32;33) The reviewer Kappa for the QSRF was 0.534 (95% CI, 0.411 to 0.674). Upon disagreement, the reviewers analyzed the paper together to reach consensus.

Results

The PubMed search resulted in 1247 citations, and bibliography review yielded 18 additional articles. The majority of citations were excluded based on abstract and title review (Figure 3). Twenty studies were RCTs and seven were uncontrolled observational studies (Appendix Tables 1 and 2 for study details). Almost half of the studies focused on patient populations with chronic diseases including diabetes, cancer, heart failure, and hypertension.

Scoring

Twenty RCTs were evaluated using the QSRF tool. The average score was 71 points (range 67-86).

Studies of Effectiveness

Physical health outcomes. Seven studies included variables measuring biological outcomes such as laboratory values, body mass index (BMI), and blood pressure. Of these, four studies included diabetes-specific quality measures.(34-37) Although glycated hemoglobin A_{1C} (HbA_{1C}) improved overall in 3 RCTs, the difference between intervention and control groups was significant only in one trial.(34-36) An observational study suggested an association between PHR use and improved laboratory values (HbA_{1C} and low-density lipoprotein cholesterol [LDL-C]), blood pressure, and health maintenance screening in diabetic patients;(37) however, blood pressure and LDL-C were not significantly different between intervention and control conditions in one of the aforementioned RCTs. (34) Two additional prospective studies examined the effect of PHR access on blood pressure control in patients with chronic disease and found no impact.(38;39)

Psychosocial health outcomes. Five studies addressed psychosocial variables including depression, anxiety, contentment, and quality of life. All 5 studies included an anxiety variable.(40-44) Three studies found no significant differences in anxiety between groups,(40;41;43) while two studies found that anxiety decreased with access to medical information.(42;44) Two studies evaluated self-reported depression and contentment in patients and found no significant differences between intervention and control groups.(40;43) Only one study measured quality of life and found that providing a paper copy of the medical record resulted in no significant improvement.(41)

Health behaviors and adherence outcomes. Four studies included measures of patient health behaviors and outcomes were mixed.(38;45-47) Two studies found no significant impact on adherence.(45;47) A third study found that patients who received only a computer-generated health summary were more likely to attend their next routine appointments than those in the other groups receiving only a written PHR with health promotion advice, both the computer-generated health summary and the written PHR, or neither.(38) This study also measured other health behavior; recipients of the written PHR were significantly more likely to report drinking less alcohol, whereas those who received only the summary were significantly more likely to say that they did not feel the need to change their alcohol use. In a follow-up RCT, use of medications, tobacco, and alcohol, and awareness of health maintenance did not appear to be influenced by access to a computer-generated health summary.(46)

Recall of medical information. Two studies addressed patient recall of medical information as an outcome of patient access to medical records and the results were mixed.(43;48)

Usage of PHR. Three RCTs compared usage of informational resources when given computer access to either personalized medical information or general health information and found that access to personalized information increased likelihood of usage.(49-51)

Accuracy of the medical record. One uncontrolled observational study evaluated the influence of a secure web-based patient portal on the accuracy of medication lists in the electronic health record and found no significant differences.(52)

Perceived usefulness of access to medical records. One trial randomized pregnant patients to use an Internet-based pregnancy resource either with or without additional access to personal antenatal health records.(51) Although both groups found the information easy to access and useful, there was no significant difference in perceived usefulness.

Studies of Patient-centeredness

Patient satisfaction. Eleven studies included primary outcomes related to satisfaction with various aspects of the patient experience, including care provided,(36;40;42;47;53;54) provider-patient communication,(18) information provided,(49;51) consultation,(55) and perceived quality of care.(39) In eight studies, no significant differences were found when patients were given access to their medical information via Internet, on a USB stick, or in paper form as compared to no access or access to general information only.(18;39-42;51;53;54) Only three found a moderate improvement in patient satisfaction when giving access to physician notes,(47;55) a copy of the letter sent from their specialist to their general practitioner, or a computerized medical record summary.(49)

"Informed" patient. Three studies measured pregnant women's perceptions of being informed when provided with access to their medical records,(40;54;56) of which two found a significant effect.(54;56)

Patient involvement in care. Seven studies measured various aspects of patients' involvement in their care. In two, there was no significant difference in self-efficacy between intervention and control groups(18;44) whereas in a third study, patients with type 1 diabetes reported greater diabetes-related self-efficacy when provided access to the entire health record compared to a web-based diabetes case management program only.(35) Studies of pregnant women found that patients who carried their full antenatal records endorsed greater perceptions of control of their pregnancies(40;56) and greater ease in talking to doctors and midwives than control group participants.(40) An RCT to study the effect of PHR access on patients undergoing in vitro fertilization (IVF) found no effect on measures of patient empowerment.(57) Another RCT evaluated the effect of PHR access found a statistically significant, though clinically negligible, difference in empowerment scores among patients with hypertension in the intervention group.(39)

Studies of Efficiency

Two observational studies included measures of efficiency, telephone and office visit rates, among PHR users and non-users. One measured the frequency of primary care office visits and documented telephone contacts after PHR adoption.(58) While both groups experienced a decrease in annual primary care office visit rates, the effect was significantly greater in the PHR user group. Telephone call rates significantly increased

in both groups, but more so among non-users. The second found that PHR users increased office visits and telephone contacts in the year following activation as compared to the year prior to activation, while non-users showed decreased office and telephone encounters during a similar 2-year time.(59) PHR users as a group had significantly more after-hours clinic visits, emergency department visits, and hospital visits.

Discussion

Our systematic review found that studies of interventions that provided patients access to their medical records have addressed three of six IOM's quality domains: effectiveness, patient-centeredness, and efficiency. Effects of patients' access to medical records on measures of safety, timeliness, and equity remain understudied.

Despite concerns that might have been raised about patient access to medical records such as potential for patient anxiety and confusion, our review found no current evidence to substantiate any negative patient outcomes resulting from access to health information. Notably, access to medical information did not increase patient anxiety,(42;44) a common fear endorsed by physicians.(44;60;61) Conversely, the effects of PHR access on workload and system efficiency merit further evaluation. For instance, a better understanding of how PHRs and related technologies increase or decrease system burden can help with resource allocation decisions related to managing patients who use these tools.

Future research in this area should focus on interventions that target and measure actual health record usage and engagement in care. For example, some of the studies measured outcomes among patients who were already PHR users, primarily white, and with higher incomes and private insurance compared to PHR non-users.(37) Thus, PHR use may be a marker for characteristics related to better health outcomes, and providing access alone is unlikely to be sufficient to improve outcomes for all types of patients. For PHRs to be widely used for routine patient communication, or as "backup systems" to mitigate care delays,(62) issues of equity in PHR adoption and use need to be addressed.(63) Conversely, certain design features of PHRs may be able to influence patient engagement. For instance, patients given access to personalized information accessed electronic resources more frequently than those given only general educational information.(49-51) Whether carefully targeted PHR design can enhance equity and engagement among groups at higher risk for negative health outcomes remains to be seen.

Our review covered a relatively small group of studies in an emerging area of inquiry, and as such we erred in the direction of including smaller and less methodologically rigorous studies. The heterogeneity of study populations, intervention content, and measurement strategies varied, making it difficult to synthesize the evidence. The possibility of selective reporting and publication bias cannot be excluded. A fairly restrictive search criteria was used to address primary study aims, and thus we may have excluded papers not classified under our search terms. The first author attempted

to minimize this problem by reviewing bibliographies to locate additional articles not identified through database search.

In conclusion, our systematic review examined the effects of patients' medical record access and revealed few overarching trends. There was minimal evidence of psychological harm to patients. Limited evidence suggests that patients with access to medical records have improved levels of satisfaction, but evidence was less clear for other aspects of quality and absent for effects on patient safety, timeliness, and equity. Although few positive findings generally favored patient access, in light of mounting pressures to make medical records transparent to patients, more rigorous research is needed to evaluate this practice.

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Competing Interests Statement

The authors have no competing interests to declare.

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Figure 1: Study Search Terms

MeSH headings:

"patient access to records," "access to information," "patient participation," "medical records," and "health records, personal"

Free text phrases

"patient accessible," "patient access to medical record," and "patient portal"

Figure 2: Study Eligibility

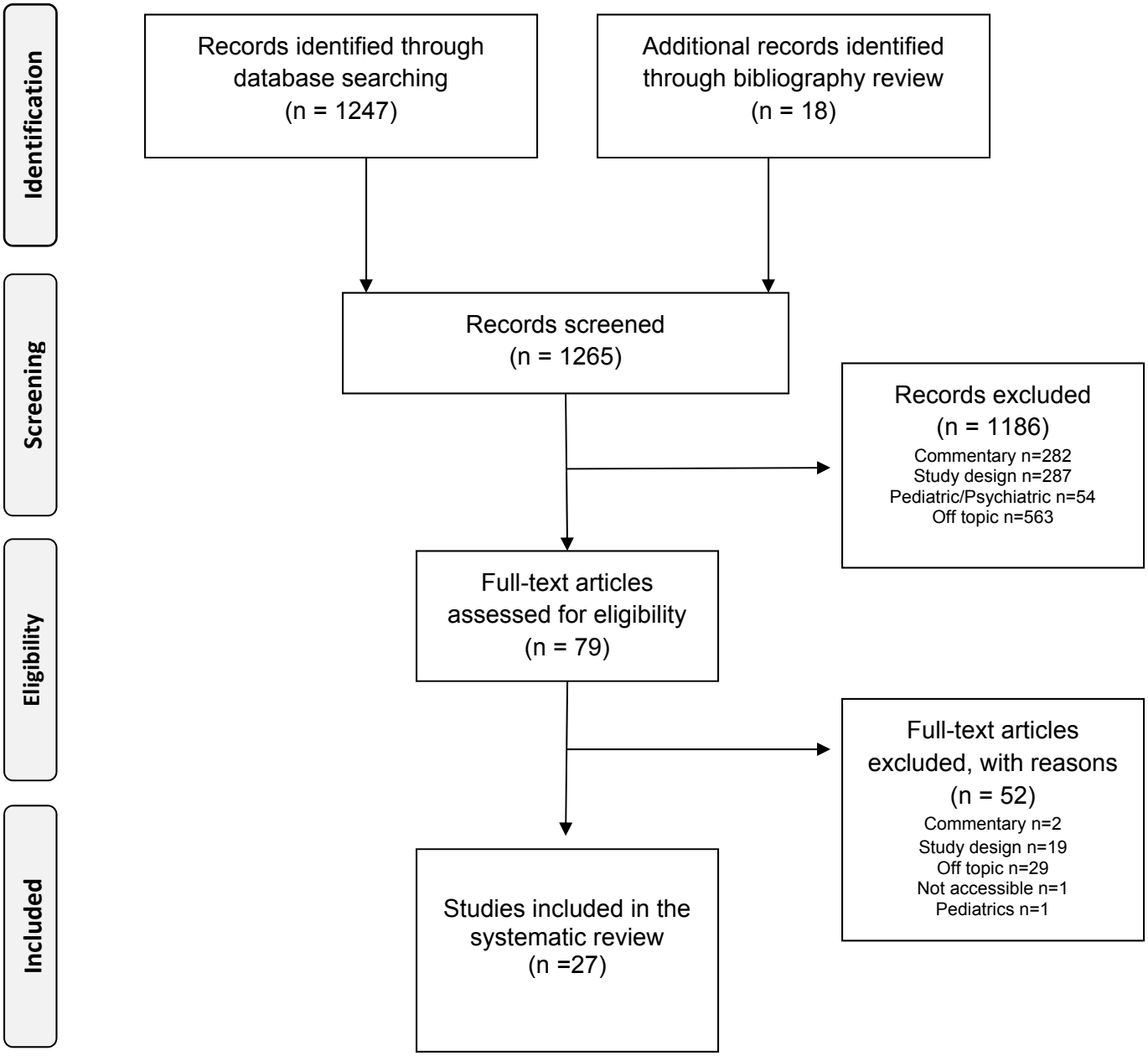
Inclusion:

Study reported comparative data between an intervention and comparison condition, including uncontrolled observational studies and randomized controlled trials (RCTs).

Exclusion:

1. studies without a comparison group,
2. studies of parental access to pediatric patient records,
3. studies focused exclusively on access to psychiatric records (due to distinct legal and ethical issues, and
4. papers which did not meet the following criteria on the basis of the title and abstract:
    a. human study population;
    b. adults age 18 and over; and
    c. published in a peer-reviewed journal, book, or monograph.

Figure 3: Flow Diagram of Study Report Selection



Appendix Table 1: Results of Randomized Controlled Trials

Study	Study Design	Intervention and patient population	Primary outcomes and IOM Dimension(s)	Main findings	Limitations	Score (total 95)
Grant et al[34]	RCT (N= 244)	**Intervention:** Access to integrated web portal-based personal health record and disease-specific health information **Patient population:** Patients diagnosed with diabetes.	Effectiveness 1. Hb A1c 2. Blood pressure 3. LDL-C	1. Modest improvement in HBA1c for both intervention and control patients, no significant difference at post-intervention (0.16% vs 0.26%, P=0.62); similar HbA1c levels and 1 year follow-up (7.1% vs 7.2%; P=0.45). 2. A statistically similar improvement over time in both study arms was also seen for blood pressure. 3. A statistically similar improvement over time in both study arms was also seen for LDL-C control.	• Low participation rates (7-14%) • Good control of health parameters at baseline • No indication of when the study took place • Non-random group assignment	73
Shaw et al.[51]	RCT (N=193)	**Intervention:** Intervention group given access to electronic antenatal record and personalized information through a condensed version of the clinical antenatal care planner and access to general pregnancy resource links **Patient population:** Pregnant women.	Effectiveness 1. Frequency of use 2. Perceived usefulness of the web-based information Patient-centeredness 3. Satisfaction with the web-based information	1. The mean number of log-ins was significantly different (P<0.001) for the personalized information group was 10.4 (SD 17.8) and the general information group was 1.8 (SD 1.4). 2. No significant difference. 3. No significant difference.	• High attrition rate • Single site study • Subjects not randomly selected for inclusion	66
Spodik et al.[42]	RCT (N=115)	**Intervention:** Intervention group provided with post procedure report after an outpatient endoscopy. **Patient population:** Patients undergoing an elective endoscopy.	Effectiveness 1. Post procedure anxiety Patient-centeredness 2. Satisfaction with endoscopy procedure	1. The intervention group had lower post procedure anxiety scores than the control group (P=0.001). 2. No significant differences.	• Single site study • Small sample size • 27.8% attrition rate • Subjects were not randomly selected for inclusion	76
Tuil et al.[57]	RCT (N=180)	**Intervention:** Intervention group given access to a personal health record with secure email. **Patient population:** IVF patients.	Patient-centeredness 1. Patient empowerment	1. No significant differences.	• Small sample • Limited power • Lack of a validated empowerment scale for this population • Subjects were not randomly selected for inclusion	80
Ross et al.[50]	RCT (N=328)	**Intervention:** Intervention group given access to a PHR. **Patient population:** Patients with type 2 diabetes.	Effectiveness 1. Usage	1. Usage was higher in the intervention group over the course of the study (772 vs. 319 days logged in, p=.001). Same proportion logged in at least once 83% intervention, 84% controls.	• Sample representativeness • Subjects were not randomly selected for inclusion	66

Ross et al.[18]	RCT (N=107)	**Intervention:** Intervention group given access to a PHR. **Patient population:** Patients diagnosed with heart failure.	Patient-centeredness 1. Self-efficacy 2. Patient satisfaction with doctor patient-communication	1. No significant differences. 2. No significant differences.	• Small sample size • 30% attrition rate in intervention group. • Subjects were not randomly selected for inclusion	66
Saunders et al.[55]	RCT (N=107)	**Intervention:** Intervention group given a copy of the letter sent from the specialist to general practitioner. **Patient population:** All patients under the care of the consultants.	Patient-centeredness 1. Overall satisfaction with consultation	1. Significant difference between the two groups (P=0.014).	• Small sample • Low response rate (58.8%) • Subjects were not randomly selected for inclusion	53
Maly et al.[47]	RCT (N=276)	**Intervention:** The experimental group received copies of their medical record progress note and completed question lists for physician review. The control group received health education sheets and completed suggestion lists for improving the clinic. **Patient population:** Patients seen in the study site clinic with a chronic medical condition.	Effectiveness 1. General health 2. Physical functional status 3. Patient adherence Patient-centeredness 4. Patient satisfaction with care	1. Significant improvement in the experimental group (P=0.001) but not controls (p=0.39). 2. Significant improvement in the experimental group means (p=0.001). 3. No significant differences. 4. Experimental group reported more satisfaction than the control group patients (P=0.045).	• Single site study • Small effect size • Subjects were not randomly selected for inclusion	77
Homer et al.[56]	RCT (N=150)	**Intervention:** Intervention group held their entire antenatal record through pregnancy versus standard practice (small, abbreviated card). **Patient population:** Women attending the hospital clinic for their first antenatal visit.	Patient-centeredness 1. Sense of control 2. Involvement in care	1. Intervention group patients were more likely to indicate they felt in control (P=0.013). a. Patients in the control group were more likely to indicate they felt anxious (P=0.025). 2. Intervention group more likely to indicate that the doctor/midwife explained everything in the record (p=0.006).	• Subjects were not randomly selected for inclusion	71
Banet and Felchlia[45]	RCT (N=58)	**Intervention:** Intervention patients received a copy of their medical history, clinical resumes, notes on outpatient visits, x-ray and scan reports, pertinent laboratory results and education packet on strokes. **Patient population:** First time stroke patients referred to the Stroke Team.	Effectiveness 1. Intention to modify health behaviors 2. Compliance with treatment	1. No significant differences. 2. No significant differences.	• Small sample • Limited measurement • Subjects were not randomly selected for inclusion	71

Liaw et al.[46]	RCT (N=364)	**Intervention:** Three intervention groups: 1) Patient given the Health Education Authority's written PHR, 2) Patient given a print out of the patient's computerized medical summary (CHR), 3) Patient given both the PHR and CHR. **Patient population:** Patients at five practices in Oxfordshire.	<u>Effectiveness</u> 1. Patient responses to receiving a personal health record a. Attend health check b. Kept and looked at record c. More aware of ways of staying healthy d. Reduced alcohol intake e. Felt no need to change	1. a. Patients receiving a CHR were more likely to attend a health check (p=.016). b. Having both records was associated with keeping and looking at the records (p=.014, p=.029, respectively). c. No significant differences. d. Patients receiving a PHR were more likely to report drinking less alcohol (P=0.026). e. Patients receiving a CHR were more likely to say that they felt not need to change (P=0.022).	• Low response rate for follow-up questionnaire (52%) • Used two recruitment methods – one sample was not randomly selected for inclusion	61
Elbourne et al.[40]	RCT (N=290)	**Intervention:** Intervention group was given full case notes to hold. Usual care group was given a co-operation card. **Patient population:** Women less than 34 weeks gestation who booked for antenatal care with one of the authors at the peripheral clinic at the Sandleford Hospital, Newbury.	<u>Effectiveness</u> 1. Anxiety 2. Depression <u>Patient-centeredness</u> 3. Satisfaction with maternity care 4. Feel better informed 5. Confidence 6. Control 7. Involvement of fathers 8. Communication	1. No significant differences. 2. No significant differences. 3. No significant differences. 4. No significant differences. 5. No significant differences. 6. Women carrying their own notes were nearly one and a half times more likely to say they felt more in control of their pregnancies (95% CI 1.08-1.95). 7. No significant differences. 8. Women carrying their own notes were more than one and a half times more likely to say they found in easier to talk to doctors and midwives antenatally (95% CI 1.16-2.59).	• Single site study • Subjects were not randomly selected for inclusion	66
Jones et al.[49]	RCT, three groups (N=525)	**Intervention:** Three intervention groups 1) General PHR giving patients general information about cancer. 2) Personal PHR giving patients a summary of their medical record and information about all the concepts and terms. 3) Booklet information - patients given printed booklets. **Patient population:** Patients diagnosed with breast, cervical, prostate, or laryngeal cancer.	<u>Effectiveness</u> 1. Compare patient use <u>Patient-centeredness</u> 2. Satisfaction	1. Usage: a. Personal versus general computer information: The personal computer information group were more likely to use the computer between the three week and three month follow-ups (P=.002). 3. Satisfaction: a. Personal versus general computer information: The personal computer information group had higher satisfaction score (p=.04). b. Computer versus booklet group: No significant difference.	• Single site study • Subjects were not randomly selected for inclusion	71
Lovell et al.[54]	RCT (N=235)	**Intervention:** Intervention group was given their maternity case notes to retain during the course of pregnancy. **Patient population:** All women seeking antenatal care at site.	<u>Patient-centeredness</u> 1. Satisfaction with the care given 2. Informed 3. Shared decision making	1. No significant differences. 2. Only 1.1% of mother's did not feel well informed during labor and delivery compared to 12.1% in the card group p<.01. 3. No significant differences.	• Single site study • Subjects were not randomly selected for inclusion	71

Rubin et al.[48]	RCT (N=78)	**Intervention:** Intervention group received the same verbal report and the standard computer-generated endoscopy report compared and the control group received usual care (verbal report alone). **Patient population:** Patients who presented to three endoscopists at the study site.	<u>Effectiveness</u> 1. Recall of endoscopic indications 2. Recall of endoscopic results 3. Recall of recommendations	1. Overall survey score for the intervention group were significantly higher (P=0.002). 2. No significant differences. 3. The intervention group were better able to recall the recommendations were made (P=0.003).	• Single site study • The intervention group could be reading their reports at the time of the survey • Subjects were not randomly selected for inclusion	86
Gravis et al.[41]	RCT (N=336)	**Intervention:** Patients provided with comprehensive cancer information through an organized medical record briefcase (OMR) and usual care (information and medical record delivered at the physician's initiative or upon the patient's request). **Patient population:** Patients newly diagnosed with breast cancer, colon cancer, Hodgkin lymphoma, and non-Hodgkin lymphoma that were to receive adjuvant chemotherapy in an outpatient setting.	<u>Effectiveness</u> 1. Anxiety levels, 2. Quality of life <u>Patient-centeredness</u> 3. Satisfaction with the care process	1. No significant differences 2. No significant differences 3. No significant differences	• Young women in early stages of cancer with a good prognosis • Single site study • Site already makes effort to help patients access information • Subjects were not randomly selected for inclusion.	71
Ralston et al.[36]	RCT (N=83)	**Intervention:** Intervention group met with care manager for 1 hour using a collaborative care approach to review online record together. This included an introduction to the web-based program and encouragement to review the online medical records, send weekly glucose readings, and secure emails as necessary. Control group received usual care alone. **Patient population:** Patients with type 2 diabetes.	<u>Effectiveness</u> 1. Change in GHb between baseline and end of the 12-month study period (adjusted for age, sex, and baseline GHb)	1. GHb declined significantly in the intervention group compared to the usual care (change -0.7%; P=0.01) at 12 months	• Cannot determine the impact of the care manager • Patients and providers were not blinded • Small sample • Subjects were not randomly selected for inclusion.	76
Wagner et al.[39]	RCT (N=443)	**Intervention:** Intervention patients were given access to a PHR. Control group did not have access to a PHR. **Patient population:** Patients with hypertension.	<u>Effectiveness</u> 1. Blood pressure <u>Patient-centeredness</u> 2. Patient empowerment 3. Patient perception of quality of care	1. No significant differences 2. Clinically insignificant difference in empowerment score 3. Clinically insignificant difference in patient perception of quality of care	• Sample representativeness • Subjects were not randomly selected for inclusion. • Relied on self-report of PHR use	71

McCarrier et al.[35]	RCT (N=77)	**Intervention: Intervention** Patients in the intervention group received usual care and were provided access to a nurse case manager and access to five websites: a PHR, diabetes diary, a planner, patient education, and a site to upload blood glucose readings. The control group received usual care. **Patient population:** Patients diagnosed with type 1 diabetes.	<u>Effectiveness</u> 1. HbA1c <u>Patient-centeredness</u> 2. Self-efficacy (Diabetes Empowerment Scale)	1. No significant differences 2. Significant difference between the control and intervention groups (p=0.044). The intervention group's mean score increased while the control group decreased.	• Cannot determine the impact of the care manager • Small sample size • Subjects were not randomly selected for inclusion.	71
Liaw et al.[46]	RCT (N=72)	**Intervention:** Intervention group was given access to computer generated, patient held record. **Patient population:** Patients with one or more chronic health problems.	<u>Effectiveness</u> 1. Functional status 2. Use of Medications 3. Health problems a. Systolic blood pressure b. Use of Alcohol c. Use of Tobacco	1. No significant differences. 2. No significant differences. 3. a. No significant differences. b. No significant differences. c. No significant differences.	• Small sample size. • Does not report p values for a number of the comparisons, these variables were not included. • The variable functional status is not defined.	67

RCT randomized control trial, HbA1c glycated hemoglobin A1C, LDL-C Low-density lipoprotein cholesterol**,** PHR personal health record, CHR computerized medical summary, BMI body mass index, ACEi Angiotensin converting enzyme inhibitor, IVF In vitro fertilization

Appendix Table 2: Uncontrolled Observational Studies with a comparison group

Study	Study Design	Intervention and patient population	Primary outcomes (with comparisons)	Main findings	Limitations
Zhou et al.[58]	Cohort with matched-controls (administrative data) (N=6402)	**Intervention:** Comparison of registered to PHR users and match-control group non-users. **Patient population:** Adult members of Kaiser Permanente Northwest	Efficiency 1. Annual adult primary care office visit rates, 2. Documented telephone contact rates	1. The intervention group office visit rates decreased by 10.3% (P<0.001) and controls decreased by 3.7 % (P<0.003). The difference between the change was significant (P<0.003). 2. The intervention group telephone rates significantly increased 16.2% (P<0.001) and the control significantly increased 29.9% (P<0.001). The difference between the increase was statistically significant at 13.7% (P<0.01).	• Subjects and controls were not matched by baseline office visit or telephone contact rates.
Staroselsky et al.[52]	cross-sectional survey (N=163)	**Intervention:** Comparison of the medication list accuracy PHR users and non-users **Patient population:** Primary care patients at the study site.	Effectiveness 1. Medication lists accuracy 2. If the patient had stopped taking it 3. If they had changed the regimen 4. Any new prescriptions and/or over the encounter drugs patients were currently taking	1. No significant differences. 2. No significant differences. 3. No significant differences. 4. No significant differences.	• Single site study. • Low response rate.
Wiljer et al.[44]	Quasi-experimental pre/post (N=250)	**Intervention: T**he intervention group was given access to a PHR. **Patient population:** Patients diagnosed with breast cancer.	Effectiveness 1. Anxiety levels Patient-centeredness 2. Self-perceptions of self-efficacy	1. Patients were less anxious at the post-test (p=.03). 2. No significant differences.	• 64% were active treatment, remainder were post treatment. • Almost half of the participants did not finish all the instruments.
Palen et al.[59]	Retrospective cohort with matched controls (n=158869)	**Intervention:** PHR users that had active access for at least 12 months and used at least 1 feature versus non-users enrolled in the health plan **Patient population:** Kaiser Permanente Colorado members.	Efficiency 1. Healthcare utilization a. Office visits b. Telephone c. After-hour clinic visits d. ER visits e. Hospitalizations	1. a. Significant increase in office visits (0.7 per member per year, 95%CI, 0.6-0.7,p<.001). b. Significant increase in telephone encounters (0.3 per member per year; 95%CI, 0.2-0.3, p<.001). c. Significant increase in after- hour clinic visits (18.7 per 1000 members per year, 95% CI, 12.8-24.3, p<.001). d. Significant increase in member rates of ER visits (11.2 per 1000 members per year, 95% CI, 2.6-19.7, p<.001). e. Significant increase in member rates of hospitalizations (19.9 per 1000 members per year, 95% CI, 14.6-25.3, p<.001)	• Single site study. • Were not able to access to the reasons why patients made contact with the health care system • Large sample size.

Tenforde et al.[37]	Retrospective cohort study (n=10,746)	**Intervention:** Patients using the PHR versus non-users. **Patient population:** Primary care patients diagnosed with diabetes.	Effectiveness 1. Diabetes quality measures a. HbA1c b. LDL-C c. Blood pressure d. BMI e. HbA1c testing f. ACEi/ARB use and/or micro albumin testing g. Pneumococcal vaccination h. Foot and dilated eye exam i. Smoking status	1. a. Users had lower HbA1c test values (p<.01). b. Users had lower mean LDL cholesterol (p<.01) c. Users had lower SBP and DBP values (p<.01) d. Users had higher BMI (p<.01) e. Users were more likely to have a HbA1c test completed during the study period (p<.01). f. No significant differences. g. No significant differences. h. No significant differences. i. Users were more likely to be non-smokers (p<.01).	• Representativeness of the sample
Wackerle et al.[53]	Cohort study (n=400)	**Intervention:** Intervention group received a USB stick containing their complete antenatal medical records to hold. The control group received usual care. **Patient population:** Intervention group-received care antenatal-to-postnatal at site. Controls received care elsewhere and only delivered at the site.	Patient-centeredness 1. Overall satisfaction with pregnancy 2. Overall satisfaction with delivery	1. No significant differences 2. No significant differences	• Single site study. • The control group did not receive care at the same institution as the intervention group.
Stevens et al.[43]	Cohort study (N=50)	**Intervention:** The intervention group was given free access to their hospital record. In the control group, the record was kept from the patient's view. **Patient population:** Patients admitted to the study site.	Effectiveness 1. Subjects' ability to list their diagnoses 2. Subjects' ability to list their medication, 3. Depression 4. Anxiety Patient-centeredness 5. Contentment	1. No significant differences 2. No significant differences 3. No significant differences 4. No significant differences 5. No significant differences	• Single site study • Small sample size

HbA1c glycated hemoglobin A1C, LDL-C Low-density lipoprotein cholesterol**,** PHR personal health record, CHR computerized medical summary, BMI body mass index, ACEi Angiotensin converting enzyme inhibitor, ARB angiotensin receptor blockers

Article Two: Releasing Test Results Directly to Patients: A Multisite Survey of Physician Perspectives

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Abstract

Objective: Failures to follow-up abnormal test results are common and may lead to care delays. Directly notifying patients about their test results has been proposed as a strategy to overcome this problem. We conducted a survey to determine physician perspectives about direct patient notification of *normal* and clinically *significant abnormal* test results.

Materials and Methods: Physicians were surveyed at five diverse clinical sites in the US and Australia. The US-based study was conducted via a cross-sectional, web-based survey of primary care physicians and specialists between July 1, 2012 and October 1, 2012. An identical paper-based survey was self-administered between June 26, 2012 and September 3, 2012 with physician-specialists in Australia.

Results: Of 1417 physicians invited, 315 (22.2%) completed the survey. Two-thirds (65.3%) believed that patients should be directly notified of normal results, but only 21.3% were comfortable with direct notification of clinically significant abnormal results. Physicians were more likely to endorse direct notification of abnormal results if they believed it would reduce the number of patients lost to follow-up (OR=4.98, 95% CI=2.21-1.21) or if they had personally missed an abnormal test result (OR=2.95, 95% CI=1.44-6.02). Conversely, physicians were less likely to endorse it if they believed that direct notification interfered with the practice of medicine (OR=0.39, 95%CI=0.20-0.74).

Conclusions: Physicians surveyed generally favor direct notification of normal test results to patients but appear to have substantial concerns about direct notification of abnormal test results. Widespread use of direct notification should be accompanied by proactive strategies to help patients manage test result abnormalities they receive.

Background

Failure to follow up or notify patients of their abnormal test results (i.e., “missed” test results) can cause delays in diagnosis and treatment, potentially resulting in patient harm.(1) Abnormal test results receive delayed follow-up at an alarming frequency.(2-4) A recent systematic review of outpatient test result follow-up found a wide range of missed abnormal results, with 6.8% to 62% missed laboratory results and 1.0% to 35.7% missed radiology results.(5) Both malpractice claims(6;7) and root cause analysis reports(8) reveal the significance of this problem. Physicians have acknowledged that test result notification systems are less than satisfactory.(9;10) Although electronic health records are increasingly used to facilitate notification of abnormal test results to physicians,(11) follow-up failures continue to occur.(2;12)

One potential method to mitigate delays in test result follow-up could be to facilitate patients’ ability to access their test results. For instance, some institutions are providing patients with their test results immediately as they become available, without waiting for the ordering physician to release the results or initiate follow-up. This “direct notification” strategy has the potential advantage of engaging patients in their own care. On the other hand, test results often require interpretation and their significance might be unique to the patient, based on the type of test and specific health issue. Physicians have previously expressed greater willingness to release normal results directly to patients versus abnormal results that usually require further explanation and may be more likely to be misunderstood.(13;14) Although physicians acknowledge patient dissatisfaction with communication of test results, they express concerns with increased

patient anxiety and physician workload from providing patients direct access to imaging results.(15)

In the US, the Health Information Technology for Economic and Clinical Health (HITECH) Act highlights the importance of providing patients with electronic access to their clinical information(16) and incentivizes patient engagement in care as part of stage 2 “meaningful use” criteria.(17) To comply with meaningful use guidelines and foster transparency, many test results are being made available to patients through secure web-based portals within four days of being available. Australia is also implementing information technologies to improve health care,(18) including the use of patient-doctor communication tools.(19) While there is increasing movement towards direct notification in health care systems within the US and elsewhere,(20) there is little empirical evidence to guide its implementation and use.(21) In fact, there is emerging evidence that patients and physicians have discrepant views about direct notification timing strategies, patients favoring immediate versus physicians favoring a 7-day embargo.(22) Divergent perceptions about direct notification through patient portals(15) may potentially lead to inconsistent use, a lack of adoption of this new technology or other potential consequences bearing on patient care. Factors that might impact widespread implementation and use of direct notification need to be better understood in light of the recent meaningful use criteria.

We conducted a cross-sectional survey to explore physician perspectives about direct test result notification to patients in two countries, the US and Australia. The objectives

were to: 1) determine physicians' perceptions of direct notification of both normal and clinically significant abnormal test results; and 2) determine factors associated with physicians' comfort with direct notification of clinically significant abnormal test results to patients.

Methods

A cross-sectional international survey of physicians was conducted at five diverse clinical sites. Two sites were ambulatory clinics in two large public hospitals in Sydney, Australia, both of which were in the process of transitioning to electronic health records (EHRs). Three US settings were based in Texas; two were large private multispecialty practices using integrated, well-established EHRs and one was a network of multispecialty private physicians at varying levels of EHR adoption. The US-based study used an anonymous, web-based survey of primary care physicians (PCPs) and physician specialists between July 1, 2012 and October 1, 2012. An identical paper-based survey was self-administered by ambulatory clinic physician specialists at the two Australian clinical sites from June 26, 2012 to September 3, 2012. The study was approved by the local institutional review board at each site.

Questionnaire development

A psychometrician guided the questionnaire development process, which included a search of the relevant literature,(13;23;24) item writing and refinement, and iterative content review. After refining all survey items, the survey was pilot tested with 10 US PCPs and 2 Australian specialists for readability, clarity, and ease of completion in a

web-based format. Survey items were rated on a 7-point Likert-type scale with response options ranging from “strongly disagree” to “strongly agree.” Survey completion time was approximately 10-15 minutes.

Questionnaire Description

Survey items assessed physician demographics, practice characteristics, attitudes and beliefs towards the ethical principles involved in patient care and shared decision making, and preferences for direct notification of test results (discussed in detail below). Primary dependent variables included: 1) physician comfort with direct notification of *clinically significant abnormal* test results (defined as abnormal test results that are not immediately life threatening but require short-term follow-up); and 2) physicians’ opinions as to whether or not patients should receive direct notification of *normal* test results. The survey assessed the following types of potential predictors of these dependent variables:

Practices related to test result notification. Items assessed included the type of information system (paper and/or electronic) physicians used; the usual timing and methods for notifying patients of abnormal test results; responsibility issues related to test result notification; and existence of standardized policies and procedures for abnormal test result notification at the physician’s institution. Physicians were also asked whether they ever missed an abnormal test result.

Physician demographics. Items assessed physicians' gender, age range, race/ethnicity, job classification, type of employment, specialty type, and number of years in practice.

Physicians' attitudes and beliefs. The survey assessed physicians' perspectives regarding the effects of direct notification on both patients and physicians in terms of workload and reimbursement issues, improved patient follow-up, and patient anxiety and confusion(13) which might arise from direct test result access. To assess physicians' orientation towards paternalism,(25) physicians were asked about their attitudes regarding the relationship of two ethical principles to their healthcare decisions: 1) autonomy (respect for the decision making capability of an autonomous person) and 2) beneficence (providing benefits and balancing benefits against risk).(25;26) Paternalism was operationalized as physician orientation towards beneficence and away from autonomy. Physicians were also asked about their primary method of decision making from among five choices: exclusively doctor, mainly doctor with some patient input, shared decision making, mainly patient with some doctor input, and exclusively patient.

Direct notification preferences. These items focused on physicians' comfort with specific types of clinically significant abnormal test results that may be released to patients directly, as well as the time frames physicians would consider appropriate for direct notification.

Data collection

At the US sites, participants were invited to participate by an e-mail, which described the study and provided a link to the web-based questionnaire. Completion of the survey implied consent. Three follow-up reminders were sent by email at one, three, and five weeks after the initial survey invitation. Physicians were not offered incentives for participation. Due to low initial response rates, the survey remained open for three months. At the Australian sites, the research team contacted clinic administrators (secretaries and/or nurses) who then distributed the paper-based survey to the specialist physicians for completion using similar invitational content as the email. The researchers returned to collect the completed surveys at the end of each week and reminded clinic administrators of non-responders.

Data analysis

Once data collection was completed, it was downloaded US participant responses from the web and merged these records with those manually entered by the research team for the two Australian sites. Descriptive statistics were used to summarize the characteristics of respondents, and chi-square tests were used to compare US and Australian respondents on the dependent and independent variables described above. Fisher's exact test was used for categorical variables when the assumptions for the chi-square test were not met (two-tailed). For ease of interpretation, the first author recoded the dependent variable responses into dichotomous categories. Responses of "agree," "moderately agree," or "strongly agree" and "disagree," "moderately disagree," and "strongly disagree" were collapsed into two categories of "agree" and "disagree," respectively. The category of "neither agree nor disagree" was retained to compare US

and Australian respondents but was excluded in subsequent logistic regression analyses described below to avoid diluting either the agree or disagree category. Also "never," "sometimes," and "always" were collapsed into two categories, "never used" and "used."

Subsequently all responses were collapsed across sites and conducted logistic regression analyses using Hosmer and Lemesow's model building procedure(27) to determine predictors of physicians' comfort with direct notification of abnormal test results to patients. Univariable logistic regression analyses were used to assess potential relationships between each dependent variable and potential correlates for the baseline multivariable model. Independent variables significant at $P \leq 0.25$ were then entered into the baseline multivariable model and any variables not reaching a significance level of $P > 0.10$ were then excluded from the baseline multivariable model. To ensure the importance of predictor variables retained for the multivariable analysis and that relevant variables were not eliminated, each predictor variable was examined to ensure that estimated coefficients did not change markedly in magnitude from the baseline model to the preliminary multivariable model. Finally, the likelihood ration test was used to compare the baseline multivariable model to the new, revised model. Because there was no significant decrement in fit (LRT $X^2 = 9.21$, $df = 23$, $P = .995$), the more parsimonious model was retained. Odds ratios and their 95% confidence intervals were calculated for variables included in the final logistic regression model. All analyses were performed using SPSS Statistics 20 (IBM Corporation).

Results

Of the 1417 physicians invited, 315 (22.2%) completed the survey. Respondents included 245 US physicians (20.8% response rate) and 70 Australian physicians (29.5% response rate). Table 1 shows the characteristics of the respondents. The majority were male, over half were subspecialists, three-quarters worked full-time (75.2%, data not shown in tables), and over a third had 20 or more years of clinical experience. Compared to US physicians, Australian physicians were younger and had fewer years in practice. Australian physicians primarily reported using both electronic and manual test result management, while most US physicians used only an electronic system.

Table 2 shows physicians' attitudes towards direct notification of test results. Overall, most respondents did not agree that patients should receive direct notification of clinically significant abnormal test results, although nearly two-thirds agreed that patients should receive direct notification of *normal* test results. A greater proportion of US physicians (69%) agreed that patients should receive normal test results compared to Australian physicians (52%). These subsamples did not differ, however, with respect to views regarding abnormal test results.

The majority of physicians expressed concerns about direct notification of clinically significant abnormal test results, including patients' anxiety, confusion, lack of expertise to interpret the results, seeking of unreliable information to understand the results, and concerns that the patient would seek care without consulting their provider. Most respondents were not concerned with workload increase and over half did not believe a

direct notification system would reduce their workload. Only a small percentage of respondents were concerned with unreimbursed tasks and respondents were quite divided as to whether a direct notification system would reduce patients lost to follow-up as shown by the variable distribution of responses.

Table 3 lists physician practice characteristics and compares them across the two countries. More than half of physicians indicated that they typically notified patients of clinically significant abnormal test results within 24 hours; however, this was more frequently reported by US physicians (66%) than Australian physicians (47%). The majority of respondents agreed that the physician who ordered the test should be responsible for follow-up. However, responsibility issues surfaced quickly, with 28.3% of physicians endorsing the belief that the PCP should be solely responsible for notifying patients, regardless of who ordered the test and about a quarter indicating that it was not always clear who should notify patients of clinically significant abnormal test results.

Most respondents indicated that they telephoned the patient or scheduled an in-person follow-up appointment to discuss clinically significant abnormal test results with patients (99.7% and 89.2%, respectively; data not shown in tables). Most physicians had not yet adopted electronic communication methods to notify patients of clinically significant abnormal test results. Australian physicians were more likely at times to use the strategy of waiting until the next appointment to notify patients of clinically significant abnormal test results (75.9% vs. 43.1%, $P < .001$). Overall, 22.2% of physicians

indicated they had personally missed an abnormal laboratory or imaging test result, and 42.0% reported knowledge of a colleague who had missed an abnormal test result (data not shown in tables).

Table 4 lists physicians' attitudes toward direct release of specific types of clinically significant abnormal test results. Physicians were least comfortable with sensitive results, such as cancer screening and HIV. Although, more than half of participating physicians were not comfortable with the release of any of the tests listed, when asked to specify a time interval to direct notification they would be comfortable with, the majority endorsed 24 to 48 hours, with Australian physicians favoring the shorter interval.

More than two-thirds of respondents (68.4%) believed they shared responsibility for deciding treatment equally with patients and agreed that the ethical principle of patient autonomy and beneficence guided their healthcare decisions (74.9% and 89.5%, respectively; data not shown in tables). However, there were significant differences in endorsement of ethical principles by country. Australian physicians more often indicated that patient autonomy guided their healthcare decisions (87.1% vs. 71.1%, *P* = .014), whereas US physicians more often indicated that beneficence guided healthcare decisions (92.0% vs. 81.4%, *P* = .006).

Correlates of physician comfort with direct notification of abnormal test results

Physicians who agree that a direct notification system would reduce physician workload, reduce the number of patients lost to follow-up, and have missed a test an abnormal test result in the past year are more likely to be comfortable with direct notification of clinically significant abnormal test results (Table 5). Physicians who currently use the web portal to notify patients of test results are more comfortable with direct notification of abnormal test results. Physicians who agree that the ethical principal of patient autonomy guides my health care decisions are more likely to be comfortable with direct notification of abnormal test results. Conversely, physicians who had concerns about direct notification were less likely to be comfortable with direct notification of abnormal test results. Concerns included patient anxiety, patient confusion, patient lack of expertise to interpret results, patients seeking unreliable information, and concerns that direct notification interferes with the practice of medicine, and impacts physician workload.

Multivariable model

Our final multivariable logistic regression model predicting physician comfort with direct notification of abnormal test results revealed three predictors (Table 6). Physicians were significantly more likely to be comfortable with direct notification of abnormal results when they believed that direct notification will reduce the number of patients lost to follow-up or when they had personally missed an abnormal test result (OR = 4.98, 95%CI = 2.21 - 11.21 and OR = 2.95, 95%CI = 1.44 - 6.02, respectively). Conversely, physicians who indicated concern that direct notification of abnormal test results

interferes with the practice of medicine were significantly less likely to be comfortable with this practice (OR = 0.28, 95%CI = 0.11 - 0.77).

Discussion

We surveyed physicians about direct notification of test results to patients in two countries that are currently adopting health information technologies to improve patient access to medical information. While most respondents were in agreement with the practice of direct patient notification of normal test results, they had less favorable attitudes toward direct notification of clinically significant abnormal test results. Physicians who had personally missed an abnormal test result and believed that direct notification of abnormal results would reduce the number of patients lost to follow-up were more likely to be comfortable with direct notification of abnormal results. Our findings offer several considerations for institutions attempting to create a system that allows patients timely access to their test results.

To our knowledge, this is the first survey to specifically identify predictors of physician acceptance of direct notification of test results. Physicians' attitudes and beliefs about direct notification might play an integral role in patients' adoption of these new health communication strategies.(28;29) Given an increasing focus on transparency and patient engagement in health care,(30;31) it is essential to understand how direct notification will affect health care workflow. While physicians did not express concern that direct notification of abnormal test results would increase workload, they did indicate that it would interfere with the practice of medicine. Successful implementation

of direct notification systems might be somewhat dependent on how direct notification of various types of results fits within the health care workflow.

There was no evidence that physicians' approaches to medical decision-making or paternalism, the tension between beneficence and autonomy,(32) influenced their comfort with direct notification of abnormal results.(33-35) Prior studies also suggest that physicians largely prefer the shared decision-making model(36-38) and would like patients to take a more active role in decision-making.(38;39) Physicians were least comfortable with releasing sensitive test results, which may reflect a sense of professional responsibility to confirm patient notification and initiate follow-up. These results might not be candidates for direct notification.

Concerns that direct notification had potential to lead to patient misunderstanding, anxiety, and confusion remained prominent among survey respondents. Recent evidence shows that access to medical information (including test results) does not necessarily increase patient anxiety(40) and may in some cases decrease anxiety.(41;42) In view of this discrepancy between physicians' concerns, and the available evidence, effective strategies for implementing direct notification should provide patients access to tools to enhance context-based interpretation.(43;44) Few such tools exist at this time to improve patient comprehension of test results but our findings highlight the need for their development. In addition, current evidence generally indicates there is an absence of anxiety related to access to medical information (including test results)(40) and thus improving physician awareness of this

evidence is also warranted. Physicians were more likely to accept direct notification of clinically significant abnormal test results if they had personally missed a test result in the past and if they believed that direct notification would prevent patients being lost to follow-up. Thus, cognizance of system and personal vulnerabilities in test result management processes appeared to positively influence attitudes toward novel practices that might reduce these problems. If more physicians were aware of the potential of missed test results they may be more likely to accept direct notification of abnormal test results.

Finally, physicians' views of responsibility for test result follow-up were quite variable. This suggests that, especially between physicians, there is high potential for ambiguity as to who should ultimately be responsible for follow-up.(12) As direct notification becomes the norm, some of these ambiguities of responsibility have the risk of being transferred to patients. Therefore, institutional policies should be strengthened to clarify test result notification responsibilities for physicians as well as address responsibility aspects of direct notification.(21)

Our study has several limitations. Responses in this survey may reflect a social desirability bias; to minimize this concern, the survey was administered anonymously within the US sample. The response rate of 22% was low, but quite usual for physician surveys, (45-48) especially without monetary incentives.(49) Additionally, response rates to email surveys have declined over time,(50-52) which in this case may be due to the volume of emails physicians receive. We cannot identify reasons for possible

response bias as we did not collect any data on non-respondents. Finally, despite our effort to include a diverse sample, our generalizability is limited; our sample may differ from the larger national populations of U.S. and Australian physicians.

In conclusion, despite meaningful use initiatives to facilitate patient access to medical information on the horizon, we found that physicians have substantial concerns about direct notification of test results. Most concerns are about abnormal test results and more specifically about sensitive tests although physicians are generally in favor of direct notification of normal test results to patients. Health care institutions implementing direct patient notification systems will likely need to develop proactive strategies to both facilitate and evaluate this process. These strategies should consider providing patients with tools to enhance context-based test results interpretation of abnormalities, alleviating physician concerns of patient anxiety and confusion and addressing the potential impact on physician work.

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Table 1. Characteristics of Physician Respondents at United States (US) and Australian (AU) Sites	Total N (%)	US n (%)	AU n (%)	*P*
Gender				
Female	109 (36.7)	83 (36.4)	26 (37.1)	
Male	189 (63.4)	145 (63.6)	44 (62.9)	1
Age Group				
20-29	5 (1.7)	4 (1.8)	1 (1.4)	
30-39	72 (24.2)	44 (19.3)	28 (40.0)	
40-49	94 (31.5)	67 (29.4)	27 (38.6)	
50-59	79 (26.5)	69 (30.3)	10 (14.3)	
60-69	40 (13.4)	36 (15.8)	4 (5.7)	
70 and over	8 (2.7)	8 (3.5)	0	< .001
Race/Ethnicity*				
American Indian or Alaska Native		1 (0.4)	-	
Asian		43 (19.1)	-	
Black		10 (4.4)	-	
Hispanic or Latino		13 (5.8)	-	
Native Hawaiian or Other Pacific Islander		0	-	
White		135 (60.0)	-	
Prefer not to answer		23 (10.2)	-	
Position				
Academic physician		6 (2.7)	-	
Attending		103 (45.8)	-	
Attending and academic		18 (8.0)	-	
Nonacademic physician		93 (41.3)	-	
Resident		3 (1.3)	-	
Intern		2 (0.9)	-	
Visiting medical officer		-	1 (1.4)	
Staff Specialist		-	55 (78.6)	
Chief medical officer		-	1 (1.4)	
Registrar		-	12 (17.1)	
Other		-	1 (1.4)	
Number of years in practice				
< 5 years	40 (13.6)	29 (12.9)	11 (15.7)	
5-10 years	61 (20.7)	35 (15.6)	26 (37.1)	
11-15 years	50 (17.0)	41 (18.3)	9 (12.9)	
16-20 years	38 (12.9)	29 (12.9)	9 (12.9)	
20+ years	105 (35.7)	90 (40.2)	15 (21.4)	.001
Specialty				
Primary care	135 (45.3)	135 (59.0)	0	
Subspecialty	163 (54.7)	94 (41.0)	69 (100)	
Allergy	2	2	0	
Cardiology	15	4	11	
Critical Care	1	1	0	
Dermatology	8	5	3	
Emergency Medicine	2	2	0	

Endocrinology	2	2	0
ENT	1	1	0
Gastroenterology	5	5	0
General Surgery	4	4	0
Hematology/Oncology	25	3	22
Immunology	2	0	2
Infectious Diseases	8	2	6
Maternal-Fetal Medicine	1	1	0
Nephrology	4	4	0
Neurology	6	6	0
Nuclear Medicine	2	2	0
Obstetrics & Gynecology	13	12	1
Orthopedics	1	1	0
Plastic/Reconstructive surgery	2	0	2
Psychiatry	3	2	1
Pulmonary disease	6	6	0
Radiology	7	7	0
Renal Medicine	6	0	6
Respiratory Medicine	7	2	5
Rheumatology	11	1	10
Specialty Surgery	19	19	0

* Not collected for Australian physicians

Table 2. Comparison of US and Australian physicians' attitudes toward direct notification (N=315)				
	Total N (%)	US n (%)	AU n (%)	*P*
I am comfortable with patients receiving direct notification (i.e., without physician review) of clinically significant abnormal test results.				
Agree	64 (21.3)	48 (20.8)	16 (23.2)	
Disagree	227 (75.7)	176 (76.2)	51 (73.9)	
Neither agree nor disagree	9 (3.0)	7 (3.0)	2 (2.9)	.918
Do you agree that there should be direct patient notification of normal test results?				
Agree	194 (65.3)	158 (69.3)	36 (52.2)	
Disagree	76 (25.6)	48 (21.1)	28 (40.6)	
Neither agree nor disagree	27 (9.1)	22 (9.6)	5 (7.2)	.007
Overall, a direct notification system would reduce the number of patients lost to follow-up.				
Agree	112 (38.0)	89 (39.4)	23 (33.3)	
Disagree	123 (41.7)	93 (41.2)	30 (43.5)	
Neither agree nor disagree	60 (20.3)	44 (19.5)	16 (23.2)	.639
Overall, a direct notification system would reduce physician workload.				
Agree	86 (29.5)	75 (33.6)	11 (15.9)	
Disagree	170 (58.2)	119 (53.4)	51 (73.9)	
Neither agree nor disagree	36 (12.3)	29 (13.0)	7 (10.1)	.006
Concerns regarding direct notification of clinically significant abnormal test results				
Patient anxiety about test results				
Yes	267 (85.3)	205 (84.0)	62 (89.9)	
No	46 (14.7)	39 (16.0)	7 (10.1)	.254
Patient confusion about test results				
Yes	278 (88.8)	213 (87.3)	65 (94.2)	
No	35 (11.2)	31 (12.7)	4 (5.8)	.131
Patients lack expertise necessary to interpret the results[13]				
Yes	265 (84.7)	201 (82.4)	64 (92.8)	
No	48 (15.3)	43 (17.6)	5 (7.2)	.037
Patient may seek unreliable information to understand the results[13]				
Yes	235 (75.1)	184 (75.4)	51 (73.9)	
No	78 (24.9)	60 (24.6)	18 (26.1)	.875
Patient may seek care without consulting their provider[13]				
Yes	171 (54.6)	133 (54.4)	38 (55.1)	
No	142 (45.4)	111 (45.5)	31 (44.9)	1
Interferes with the practice of medicine[13]				
Yes	74 (23.6)	59 (24.2)	15 (21.7)	
No	239 (76.6)	185 (75.8)	54 (78.3)	.75
Physician workload increase				
Yes	86 (27.5)	68 (27.9)	18 (26.1)	
No	227 (72.5)	176 (72.1)	51 (73.9)	.879
Unreimbursed tasks				

Yes	40 (12.8)	36 (14.8)	4 (5.8)	
No	273 (87.2)	208 (85.2)	65 (94.2)	.064
I have no concerns				
Yes	13 (4.2)	11 (4.5)	2 (2.9)	
No	300 (95.8)	233 (95.5)	67 (97.1)	.741

Table 3. Practices and Attitudes Related to Notification of Abnormal Test Results				
	Total N (%)	US n (%)	AU n (%)	*P*
As part of your usual practice when do you (or staff delegated by you) typically notify patients of clinically significant abnormal test results?				
< 24hrs	182 (61.5)	150 (65.8)	32 (47.1)	
24 hrs – 1 wk	99 (33.4)	72 (31.6)	27 (39.7)	
> 1 week	0	0	0	
Patient's next visit	15 (5.1)	6 (2.6)	9 (13.2)	.001
In my practice, there are written policies and procedures for notification of clinically significant abnormal test results.				
Agree	158 (52.7)	122 (53.0)	36 (51.4)	
Disagree	93 (31.0)	68 (29.6)	25 (35.7)	
Neither agree nor disagree	49 (16.3)	40 (17.4)	9 (12.9)	.508
The doctor who ordered the test or their assigned surrogate should be solely responsible for notifying patients of clinically significant abnormal test results.				
Agree	254 (84.1)	195 (84.1)	59 (84.3)	
Disagree	39 (12.9)	31 (13.4)	8 (11.4)	
Neither agree nor disagree	9 (3.0)	6 (2.6)	3 (4.3)	.635
The assigned primary care provider for the care of the patient should always be responsible for following up clinically significant abnormal test results regardless of who ordered the test.				
Agree	84 (28.3)	60 (26.4)	24 (34.3)	
Disagree	192 (64.6)	153 (67.4)	39 (55.7)	
Neither agree nor disagree	21 (7.1)	14 (6.2)	7 (10.0)	.182
It is not always clear who should notify patients of clinically significant abnormal test results.				
Agree	78 (26.4)	46 (20.4)	32 (45.7)	
Disagree	185 (62.5)	154 (68.1)	31 (44.3)	
Neither agree nor disagree	33 (11.1)	26 (11.5)	7 (10.0)	< .001

Table 4. Physician Comfort with Direct Notification of Abnormal Test Results by Test Type	Total N (%)	US n (%)	AU n (%)	*P*
If the direct notification of clinically significant abnormal test results became the norm, please select which test results you would be comfortable with releasing directly to patients.				
Complete blood count				
Yes	108 (34.5)	80 (32.8)	28 (40.6)	
No	205 (65.5)	164(67.2)	41 (59.4)	.229
Electrolyte panel				
Yes	101 (32.3)	74 (30.3)	27 (39.1)	
No	212 (67.7)	170 (69.7)	42 (60.9)	.167
Blood glucose				
Yes	154 (49.2)	117 (48.0)	37 (53.6)	
No	159 (50.8)	127 (52.0)	32 (46.4)	.405
Chest X-ray				
Yes	65 (20.8)	51 (20.9)	14 (20.3)	
No	248 (79.2)	193 (79.1)	55 (79.7)	.912
Lipid profile (TC, HDL, LDL, TG)				
Yes	154 (49.2)	119 (48.8)	35 (50.7)	
No	159 (50.8)	125 (51.2)	35 (50.7)	.774
Thyroid blood tests (TSH, T4, TPO)				
Yes	98 (31.3)	74 (30.3)	24 (34.8)	
No	215 (68.7)	170 (69.7)	45 (65.2)	.481
HIV				
Yes	44 (14.1)	39 (16.0)	5 (7.2)	
No	269 (85.9)	205 (84.0)	64 (92.8)	.065
Urinalysis				
Yes	106 (33.9)	82 (33.6)	24 (34.8)	
No	207 (66.1)	162 (66.4)	45 (65.2)	.855
Cancer screening tests (e.g., mammography, Pap smear)				
Yes	67 (21.4)	60 (24.6)	7 (10.1)	
No	246 (78.6)	184 (75.4)	62 (89.9)	.010
Please specify at what time interval, after the result became available, you would be comfortable with direct notification of clinically significant abnormal test results to patients				
24 hours	80 (29.4)	53 (26.0)	27 (39.7)	
48 hours	104 (38.2)	90 (44.1)	14 (20.6)	
7 days	51 (18.8)	44 (21.6)	7 (10.3)	
14 days	19 (7.0)	17 (8.3)	2 (2.9)	
30 days	1 (0.4)	0	1 (1.5)	
Other	17 (6.3)	0	17 (25.0)	< .001

Table 5. Univariable correlates of comfort with patients receiving direct notification of clinically significant abnormal test results

	Univariate Logistic Regression		
	OR	95% CI of OR	p-value
Overall, a direct notification system would reduce the number of patients lost to follow-up			
Disagree (Referent)			< .001
Agree	6.31	2.87-13.88	< .001
Neutral	5.43	2.24-13.16	< .001
Overall, a direct notification system would reduce physician workload			0.049
Disagree (Referent)			
Agree	2.11	1.13-3.92	0.018
Neutral	1.84	0.77-4.37	0.170
Concerns - Patient Anxiety			
No (Referent)			
Yes	0.38	0.18-0.81	0.013
Concerns - Patient Confusion			
No (Referent)			
Yes	0.22	0.09-0.53	0.001
Concerns - Patients Lack Expertise			
No (Referent)			
Yes	0.44	0.21-0.93	0.032
Concerns - Patient Seeks Unreliable Information			
No (Referent)			
Yes	0.43	0.23-0.80	0.008
Concerns - interferes with the practice of medicine.			
No (Referent)			
Yes	0.21	0.08-0.55	0.001
Concerns - Physician Workload			
No (Referent)			
Yes	0.58	0.30-1.14	0.116
Concerns - No Concerns			
No (Referent)			
Yes	9.12	2.71-30.72	< .001
Method of notification - Web Portal			
Never (Referent)			0.117
Sometimes	1.16	0.48-2.82	0.743

Always	4.64	1.09-19.82	0.038
In the past year, I have missed an abnormal laboratory or imaging result that led to delayed patient care.			
No (Referent)			< .001
Yes	3.89	1.20-7.56	< .001
Don't know	2.33	1.11-4.88	0.025
Age range			
20-29yrs (referent)			0.047
30-39yrs	0.11	0.02-0.74	0.023
40-49yrs	0.28	0.04-1.77	0.176
50-59yrs	0.17	0.3-1.10	0.063
60-69yrs	0.11	0.01-0.81	0.031
70+yrs	0.4	0.040-3.96	0.433
Patient autonomy			
No (Referent)			0.06
Yes	2.23	0.95-5.23	0.067
Don't know	0.64	0.12-3.37	0.601
Please specify at what time interval, after the result became available, you would be comfortable with direct notification of CS abnormal test results to patients			
24 hours (Referent)			0.085
48 hours	0.51	0.26-1.0	0.049
7 days	0.51	0.23-1.16	0.108
14 days	0.21	0.05-1.0	0.049
30 days	0	0	1
Other	0.11	0.01-0.90	0.040

Table 6. Logistic Multivariable Regression Exploring Predictors of Physician Comfort with Patient Direct Notification of Clinically Significant Abnormal Test Results and Agreement with Patient Notification of Normal Test Results

	Estimate	Std. error	Odds Ratio	95% CI	*P*
Comfort with patients receiving direct notification of clinically significant abnormal test results.					
Intercept	-2.65	0.34	0.07		< .001
Overall, a direct notification system would reduce the number of patients lost to follow-up					< .001
Disagree (Referent)					
Agree	1.61	0.41	4.98	2.21-11.21	< .001
Neutral	1.61	0.45	5.02	2.01-12.52	0.001
I am concerned that direct notification of clinically significant abnormal test results to patient interferes with the practice of medicine.					
No (Referent)					
Yes	-1.26	0.51	0.28	0.11-0.77	0.014
In the past year, I have missed an abnormal laboratory or imaging result that led to delayed patient care.					0.009
No (Referent)					
Yes	1.08	0.37	2.95	1.44-6.02	0.003
Don’t know	0.75	0.4	2.12	0.96-4.64	0.065

Article Three: The Patient Portal and Test Result Management: An Exploratory Study of Notification Preferences

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Traber Davis Giardina, MA, MSW is responsible for the conception and design of the project, acquisition of data, and the analysis and interpretation of the data. She drafted the article, worked with the team on revisions, and gave final approval of the version to be published.

Varsha Modi contributed to the data analysis, provided critical revisions, and gave final approval of the version to be published.

Danielle Parrish, PhD, Dissertation Chair, contributed to the conception and design of the project and the analysis and interpretation of the data. She provided critical revisions and gave final approval of the version to be published.

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Abstract

Many health institutions are implementing patient portals to allow patients to track and maintain their personal health information. While much of this is in response to Stage 2 of Meaningful Use for the HITECH Act, little is known about how patients engage and interact with these new electronic tools and what tools and strategies should be used to facilitate that interaction and maximize patient empowerment. The overall objective of this pilot study was to explore patients' experiences, informational needs, and preferences regarding abnormal test result notification through patient portals. . We conducted semi-structured interviews with 10 respondents between February 2014 and March 2014. Using thematic content analysis, four overarching themes were identified: health management practices, notification preferences, the physician's perspective, and other patients. Patients and caregivers strongly favored access to abnormal test results, but there were several concerns. This included concerns about time to notification, type of test results released, and patients with low health literacy and limited internet experience. To alleviate these concerns, best practices in portal-based test result notification should include, standardized type of tests released and time to notification, as well as strategies to help patients understand and manage the information they receive. These findings suggest important considerations for health professionals, including medical social workers.

Background

With the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act, nearly $30 billion dollars have been committed to facilitating the adoption of the meaningful use of health information technology. The HITECH Act emphasizes the importance of providing patients with electronic access to their medical information and incentivizes patient engagement in care as part of the meaningful use of electronic health records (Centers for Medicare and Medicaid services, 2010). The adoption of patient portals is an essential component of the national policy efforts to reduce costs and improve quality of care through increased patient engagement in care. Currently only about 28 percent of office-based physicians nationally are using electronic health records that provide patient access to records (Hogan & Kissam, 2010). While patients are encouraged to take active roles in their care and have expressed interest in having electronic access to their health information (Cho et al., 2010; Sanders et al., 2013), portal use is low nationally (Markle Foundation, 2011; California HealthCare Foundation (CHCF), 2010). Only 10 percent of American adults currently use a PHR (Markle Foundation, 2011).

Patient portals are increasingly being deployed with the underlying belief that they will engage and empower patients and improve health outcomes and efficiency. However, these claims have thus far been unsubstantiated in the literature (Davis Giardina, Menon, Parrish, Sittig, & Singh, 2013). The purpose of this study is to explore patients' experiences using to a portal to manage their care specifically as it relates to receiving abnormal medical test results. Medical social workers play an important role in supporting patients' management of chronic and acute conditions, and the use of such

records may provide an important resource to empower patients and caregivers to become informed partners in their care.

Patient Access to Information

The patient portal is a secure website that offers patients access to their personal health information. They are typically linked to the a physician's electronic health record (EHR) allowing patients to access some or all of the following medical information and health care functions: lab results, medication lists, secure messaging, appointment scheduling, and personal health records (Robert Wood Johnson Foundation, 2012).

Since 2001, the Institute of Medicine has advocated for the free flow of information between provider and patient, and further asserts that patients should have unrestricted access to their medical information (Institute of Medicine, 2001). Due in part to the HITECH Act incentives, the availability of patient-accessible medical records has recently increased. It may be that electronic access to medical records is a powerful tool in creating a collaborative relationship between provider and patient by sharing knowledge and providing patients the option to take an active role in their care (Tang, Ash, Bates, Overhage, & Sands, 2006; Ahern, Woods, Lightowler, Finley, & Houston, 2011). However, evidence of the benefits, limitations and challenges involved in implementing this approach is limited.

Existing empirical literature suggests that patient-accessible records can improve patient-provider communication, self-management, and patient satisfaction (Cimino, Patel, & Kushniruk, 2002; Fisher, 2009; Honeyman, 2005; Ross, 2003). A recent study granting patients electronic access to their doctors' notes found that patients reported an increased sense of control, better understanding of their medical issues, and

improved recall of their care plans (Delbanco et al., 2012). Nevertheless, there is little evidence drawn from controlled studies indicating that personal health record access improves health outcomes (Archer, Fevrier-Thomas, Lokker, McKibbon, & Straus, 2011). Additionally, there is no evidence in controlled trials to support improvement of patient empowerment, the outcome touted as most important for the provision of the personal health record (Ammenwerth, Schnell-Inderst, & Hoerbst, 2012).

Access to test results. Patient electronic access to test results is relatively new phenomena and very few studies have examined the benefits or risks associated with this access. A 2010 study of patients diagnosed with breast cancer found that, at post-intervention, 98.4 percent felt that online access to lab and imaging would be helpful in managing their care (Wiljer, 2010). Of the patients given access to their test results, 65 percent and 68 percent viewed their lab and imaging results, respectively. While patients expressed value in having online access to their test results and anxiety did not increase, feelings of self-efficacy related to PHR access also did not improve.

A 2013 survey of patients at Kaiser Permanente, an integrated health care organization, found that a large percentage of patients who had used their portal to access a laboratory result in the last year experienced primarily positive feelings when viewing laboratory results online (Christensen & Sue, 2013). Specifically, 68 percent were appreciative, 65 percent calm, 49 percent happy, 46 percent relieved, while only 7 percent were worried, 6 percent confused, 4 percent afraid and 1 percent angry. Kaiser Permanente patients have also increased use of their portal by 93 percent between 2008 and 2012. While these are promising results, it is unclear if these patients were viewing abnormal laboratory results. Additionally, the patients surveyed were a part of

Kaiser Permanente's "member research panel", a unique set of active patients that may not be generalizable to the Kaiser population or the U.S. population.

A UK survey published in 2014 looked at renal patients using a portal offering access test results (Woywodt, Vythelingum, Rayner, Anderton, & Ahmed, 2014). Most patients used the portal to monitor their kidney function. Specifically, 81 percent checked creatinine, 57 percent checked potassium, and 50 percent tracked their hemoglobin. Ninety-three percent indicated that, overall, the system helps them manage their condition; however, 32 percent of the patients reported experiencing worry after seeing their test results in the portal.

Policy Initiatives

Two national policies will have long-term impacts on patient test result notification, 1) the Meaningful Use requirements and 2) the CLIA Program and HIPAA Privacy Rule. The meaningful use (MU) provision of the HITECH Act was intended to encourage electronic health records adoption by providing financial incentives to hospitals and eligible professionals. Since the HITECH passage, EHR adoption by hospitals has increased with a significant proportion meeting the federal requirements for MU (Charles, King, Patel, & Furukawa, 2012). Meaningful use greatly emphasizes timely patient access to their medical information, making test result reporting to patients a major issue.

The MU requirements are being implemented in stages and include a number of objectives to encourage patient engagement through increased electronic access (Centers for Medicare & Medicaid Services, 2013b). While Stage 1 focuses on data capture and sharing, Stage 2 has a greater focus on rigorous health information

exchange and increased patient engagement by providing secure electronic access to personal health information (Centers for Medicare & Medicaid Services, 2013a). In fact, the 2014 stage 2 MU regulations require that 5 percent of patients download or view electronic health information and use secure electronic messages (e-mail) and that greater than 50 percent of patients are provided timely (within four business days of becoming available to the physician) electronic access to their health information (Centers for Medicare & Medicaid Services, 2013a).

The second policy, the CLIA Program and HIPAA Privacy Rule was finalized in 2014 by Department of Health and Human Services (HHS) (Department of Health and Human Services & Center for Medicare & Medicaid Services, 2014). The rule allows patients to request access to their test results directly from the laboratory without physicians' involvement. It requires that all clinical laboratories abide by HIPAA regulations, thus standardizing nationally patients' rights to access protected health information. Additionally, the rule does not allow labs to withhold sensitive test results (e.g.; genetic, cancer, pregnancy, sexually-transmitted disease, or mental health) but does grant a 30-window to report such results to patients, allowing physicians' adequate time to follow-up.

Together these policies set the foundation for increasing patient access to test results. Though there are not currently agreed upon best practices or standards for test result notification through the patient portal, the current health care policy climate emphasizes greater patient-provider collaboration as a means of improving quality of care related to test results. Ultimately these policy initiatives will support innovative methods to improve test result notification. However, before designing new methods

supporting these functions, it is essential to improve our understanding of how patients experience and use their online health records and perceive the electronic notification of their medical test results. As such, this study provides essential information regarding the views of patients using this technology. Specifically, this study aims to explore patients' experiences using their patient portal after receiving an abnormal test result.

Methods

Sample

Inclusion criteria included adults 18 years or older who have or had have access to a patient portal and have previously received any abnormal test result through their portal. Patients who received a phone call or any other method of communication about the abnormal test result prior to viewing it online were also eligible for inclusion. Due to the exploratory nature of this study, convenience sampling was used. We posted fliers at two local ambulatory clinics with established patient portals actively releasing abnormal test results. Additionally, we contacted patient advocates to share our study information with active patient email listservs. Study information was also shared through Facebook and LinkedIn accounts of the first author. This study was approved by the IRB committees at the University of Houston, Baylor College of Medicine and the Houston Veteran's Administration.

Data collection

Ten participants were interviewed from February 2014 to March 2014. Individual interviews were conducted over the telephone by the first author. The semi-structured interview guide included three sections: management of medical information, discussion of a specific abnormal test result, and test result notification preferences. The interview

length averaged 45 minutes, ranging between 15 minutes and 90 minutes. The shortest interview was a respondent without perceived health issues whose portal use was limited to annual physician visits. Verbal consent was obtained for all participants.

Data Analysis

All interviews were audio recorded and transcribed by the first author. After the interviews were transcribed, the transcripts were reviewed to cross check for accuracy. Researchers familiarized themselves with all data prior to coding. Using inductive qualitative content analysis (Patton MQ, 2002), the first and second author conducted independent analysis of the transcripts line by line to create an initial code book. Codes that conveyed similar meanings or ideas were combined to form new categories. To establish conformability, the authors met to discuss and refine codes and categories and identify emergent themes. Themes were shared with the research team for further discussion and disagreements were resolved by consensus.

Results

Our analysis resulted in four major themes, which included health management practices, notification preferences, the physician's perspective, and other patients.

Managing Health Information

All respondents indicated that they use their patient portal to manage their health information. However, this is depended on the presenting health problem. For example, patients and caregivers dealing with chronic conditions, such as diabetes, cancer, and kidney disease, also kept paper records of test results and imaging reports, and some kept copies of their imaging. Two respondents, who considered themselves to be

healthy except for slightly elevated cholesterol, did not think of themselves as managing their medical information so much as simply following up on their annual doctor's visit. "I don't know that I manage it except for when I actually go to the doctor for like a yearly checkup and then I look at the test results but I don't record anything myself. I just look at what they recorded in there [the portal]" (I8).

Redundancy. Interestingly, some respondents used their portal to avoid redundant testing. A respondent who had multiple blood transfusions while hospitalized was asked to take a hepatitis C test by her gastroenterologist. She assumed the test had been completed during her hospitalization, but upon checking the hospital portal she found the test had not been. "There were some questions about whether or not I was tested for hepatitis ever in the hospital, even with all of the blood transfusions. And it turned out I was not and that came in handy for that" (I2). Another respondent anticipates his physicians request for certain tests so he prints out copies from his portal to bring to his appointments. "Like so I'm gonna go over to my heart doctor at [clinic] and I'll take him a copy, if it's something I know he always [wants], I'll take him one" (I7). Another respondent, a caregiver to his wife, routinely requests copies of all her imaging. Having access to the imaging and the reports helped his wife avoid delays in care.

> We went to several appointments where they say 'well we'll call you in a few days when we're able to get those scans from [another clinic]' and I'm thinking wow, well this is fast growing, very serious cancer, you know, should we be waiting a few days? And you know it inevitably turned into over a week before they got what they needed. So by having these things at my hand and the doc says you know we haven't gotten anything from [the other clinic], I'll say, 'well, I

happen to have those reports right here' and then they'll just look at them then. (I6)

Finally, a respondent with multiple chronic conditions explained that having access to the portal at her neurologist's office allowed her to provide her medical history to other physicians.

> Try coming up as a teenager when, with 10 medical conditions and going to your doctor and the routine of questions they ask you over and over again. It's just easier to pull out the spreadsheet and hand it to them. Here you go. Like let's move on to the real questions. Here's all the numbers you want, here's all the this, the that. Well patient portal does that for me.

Notification Preferences

Sensitive tests. Overall, respondents felt that all test results should be available on the portal but that some abnormal results, those with high emotional impact or 'sensitivity', should be communicated verbally to the patient prior to being released on the portal. Some examples of sensitive tests given were any diagnosis that cannot be treated or cured, life threatening illnesses, cancer diagnosis, and genetic testing.

> So maybe, you know, we don't put the results of the cancer test that says you're going to die of cancer without the doctors interpreting it for you to the patient (laughs). But for those of us, you know, in my case I've got anemia and sodium and hyponatremia …that I need to monitor. (I3)

There were two exceptions. The first respondent preferences were heavily influenced by having recently experienced a delayed test result notification. When

asked directly about sensitive results, “if it’s something to do with the stuff that I’ve just been through [leukemia] or pap smear or some venereal disease, anything like that, I’d rather be able to get that online. If it was quicker, if I could get it them more quickly that way, I would do it.” (I2). When asked if she preferred receiving those types of results online as opposed to a telephone call, she conceded, “a telephone call would be alright but like I said if the doctor’s office is responsible and you’re gonna get it with in a, you know, two, three days then a telephone call would be fine. Especially if it’s abnormal” (I2). This respondent was unique in that the issue of timeliness outweighed perceived sensitivity.

The second exception, a respondent diagnosed with hepatitis C and vasculitis, felt that all her test results should be released at the same time they are available to the physician, regardless of sensitivity.

> I don’t really care to wait for the doctor to have me come in or waiting to release it until after they see me. I would rather the doctor get the result and me have it on my electronic [portal]. It’s my body, my result and despite what it is, it doesn’t matter what it is. I still want to see it. I’d like to see it when the doctor sees it and that isn’t always the case, you know…You know, I’m a grown up… (I9)

Delay and error. Half of the respondents experienced some type of error that appeared to have impacted their notification preferences. Two respondents received new cancer related results on the portal prior to physician communication. Both respondents perceived these results to be sensitive and not in the normal scope of abnormal test results. Additionally, both received the result on the portal going into the weekend and were unable to communicate with

their physician until Monday. One respondent with a past history of breast cancer received a suspicious mammogram report on a Saturday morning.

> The long and the short of it is um they said the results would be available to call the office on Monday that they might be able to post them on [the portal] over the weekend… I was a little shocked that they would post anything on [the portal] without talking to me and sure enough Saturday morning, woke up 6 o'clock, I went on [the portal] on my iPad and there it was, um, and the result was 'suspicious finding right breast. Possible problem' ah, the wording was something like that. 'Need a recheck.' You know, 'need to have patient come back in.' …You never tell a patient about something serious like that in either an email or a voicemail or on a portal, because you want to talk directly to the patient and let them know, um, and give them reassurance. (I1)

The other respondent who has been battling chronic illness since childhood received an abnormal blood test that she knew would initiate a leukemia/lymphoma work-up.

> When I got the message, I was like oh, ok I need to call back. I wonder if my labs were in. so I went ahead and checked the portal just in case they were there and they were there…I know that the differentials being that off pretty much meant that it was very abnormal and the protocol for that is usually a referral for leukemia and lymphoma so I was going to have to be referred to an oncologist. Um, and so I was pretty much in shock viewing my differentials on the portal without having spoken to my doctor yet and so I don't know if there was just a miscommunication on their part or um as far as like directly talking to the patient

> cause usually that's not their typical process. Once they've spoken to me, it gets posted… (I10)

In both cases, the respondents felt strongly that in the case of sensitive results, the portal should not replace verbal communication. However, both but still believed the portal was a useful patient tool.

> Nobody wants to find out that you're blood cell counts are off. You know and I was very angry and upset and I was like you know today is the day, you know, they're always talking about 'you're gonna more likely end up with leukemia or lymphoma. We're just waiting for that moment'… And I got that result and I thought wow, ok, this is what it looks like. And today is that day…I actually spoke with my doctor and they did apologize, you know, and it was an error in the way they followed that process, you know I see the value of it, in being able to go back in my records and not have to thumb through my records. It's there. It's in chronological order. It's sorted by appointment, by lab, by medication, by everything. You know I can go in there and access my entire medical history, all my diagnosis codes. Everything is in there and organized for me which is what I've been trying to do on my own... (I10)

Of note, only these two respondents, who received perceived sensitive results, indicated experiencing negative emotions, shock and anger, related to receiving their abnormal test results on the portal.

One respondent, a caregiver, was able to identify an error in his wife's portal and avoid an error in treatment. The oncologist recommended stopping his wife's treatment

plan based on a recent scan. Following the discussion, the respondent reviewed the radiologist's report in the portal and found the report was not his wife's.

> They had seen where I had been downloading all of her reports…and indeed this wasn't hers and they went back and looked at her other scans and looked at the raw scan instead of just the report…they rescanned her and found really good news that the cancer really hadn't spread at all and in fact it was stable and that we were gonna stay to the treatment regimen that we had. Had I not…actually looked at each one, we could have made a very tragic error in her care. (I6)

Similar to the respondents above, he felt that some abnormal test results should be communicated first via telephone, but was adamant that those results should be made available on the portal as well. If fact, he would like abnormal results released immediately to the portal to avoid delay.

> I would prefer them immediate and the reason is weekends and holidays. If there is a critical value, I'd sure like to see that if it's a Friday afternoon and all the doctors have left at noon… If it's a critical value, you know, that would be something good to know…you might need to take some action. (I6)

Finally, two respondents, a patient and a caregiver, both experienced delays. One patient undergoing chemotherapy for leukemia had a routine blood test to monitor her white blood cells. A few days later, she was admitted to the hospital through the emergency room due to a fever. At the time of admission, she was told she had "no white blood cells and no neutrophils". Later she learned these abnormal results had been available to the oncologist days a few days earlier, but he had failed to notify her. Unlike the three respondents above, she lost trust in her oncologist and felt that

abnormal test results should be given to patients in the fastest manner possible, even if that means getting them online without communication from the physician.

> But I didn't trust him. I'm sure he's a good physician, I mean a good doctor to treat chemo, I mean to treat leukemia but I never trusted him again after that for anything and I started getting everything on my own…So I'd rather get mine that way [online] because it's quicker than getting them from the physician's office. Because I've found that even if it's bad news, they don't call you quickly. (I2)

The last respondent, a caregiver for her parents, asked her mother's physician to place a standing monthly order for a sodium test so that should could monitor it to avoid falls. Her mother experienced a traumatic fall due to low sodium because the respondent was not able to monitor her sodium.

> Part of the problem I had was I didn't know for sure when the labs were ordered…I had a deal with the doctor to run the lab tests on a regular basis but I never knew if she was so I would email her, when, you know, when I didn't hear from her on a regular basis and you know, the last time mom was in the ICU for 4 days with low sodium. I had emailed her twice reminding her to order the labs and she hadn't done it. (I3)

Since then, the physician created a standing order and she has been able to monitor her mother's sodium on a monthly basis. This respondent indicated that she preferred to have normal and abnormal test result released immediately. However, she was comfortable with a very select set of results being embargoed for up to four days to give the physician time to call. Like the respondent above, she said, "To be honest, I don't trust my doctor" (I3).

Physician's Perspective

Eight of the respondents spontaneously indicated they understood the physician's perspective. Despite wanting immediate access to her results, one respondent said, "I know sometimes the doctor will wait till the visit and I can understand why because the doctor wants to tell me and check me over for whatever the negative test result." (I9) While a few of the respondents reported patronizing or condescending behavior from their physician in relation to explaining test results, they also seemed to sympathize with physicians. For instance, one respondent captured the tension,

> Most doctors when you ask them and even I, I'm well spoken with some education but even when I ask these questions, I will often get a literary [sic] equivalent of a pat on the head and 'oh run along little boy'. That's you know, 'we'll tell you if there's something bad'. And um very seldom do I find physicians that have the time or you know would even just pass out a written document that says 'here these could be things you ought to know'. And (sigh) I don't think there's an easy answer because I know from the other side of it that if they did that, they'd see two patients a day. (I6)

Another respondent felt frustrated by his physician's failure to trust his ability to read his test result. "But some doctors they won't give you nothing! You know over at [clinic] they won't give you nothing, you have to go over and ask. Not even the doctor. It's like, if there was something important on there, you know, I'd tell you about. It like, you're a dummy! You're a patient" (I7). Despite that frustration, this respondent also acknowledged the physicians' limited time. "I think they are pretty busy folks…You see

thousands of people and you're trying to budget them…like 5 to 10 minutes per person coming with a myriad of problems. You'll never get them out in 5 or 10 minutes" (I7).

"Other" patients

Without prompt, nine of the respondents expressed concern or acknowledged the complexity of patients receiving abnormal test results through the portal. Some respondents were concerned about patients' reactions to receiving abnormal test results through the portal, despite feeling that they were capable of receiving their results this way. Concerns ranged from patient anxiety and confusion to self-harm.

> Now personally, I have a great support system and I've been chronically ill since I was a child but to somebody that's newly diagnosed with a situation that might seem you know, um, horrendous or something that they might not be able to overcome, you know this is my third brain tumor but to somebody a brain tumor might seem detrimental and this is my third. You know, I could see somebody overreacting to an abnormal test result and thinking their life is over and taking a negative action to is and that's not a good thing. (110)

A few of the respondents also thought that some patients just don't want to know about their medical information or be involved in their care.

> I mean some people don't really want to know. I mean they really don't. I don't know. They really don't want to know the what? The gory details? I don't know what it is with people but they don't want to know. You know, you're supposed to make me better so I don't need to know. (I7)

Despite expressing concerns about other patients, they were unequivocal about receiving their own test results electronically. All the respondents indicated that

they should have access to their test results. “I don’t know that all people should do that. Especially elderly people or people that don’t even have a clue about what it means then I think they should wait to hear from the doctor but I would, I would like to have mine”(I2).

Discussion

This exploratory study examined patients’ experiences using their patient portal to access abnormal test result. Though patients and caregivers strongly favored access to abnormal test results, there were several concerns. This included concerns about time to notification, type of test results released, and patients with low health literacy and limited internet experience. Notification preferences appear to be influenced by past interactions with physicians and the health care system. Patients who have experienced a delay in notification advocated for immediate release of sensitive abnormal test results, but most patients suggested sensitive test results should verbally communicated by with a physician or health care professional. Finally, patients expressed mixed feelings about physicians not meeting their notification preferences. The findings from this study provide important considerations for physicians and other health professionals, including medical social workers, who are often looking for ways to empower patients and their families to become active partners in the management of their health.

To the best of our knowledge, this is the first study of its kind to qualitatively explore patient access to abnormal test results through their portal. Much of the current research has focused on patient portal use, but we know very little about patients’

experiences accessing test results through the portal. The passage of the HITECH Act and the Meaningful Use requirements has prioritized patient engagement in health care through the use of health information technology. While consumers generally want access to their health information, very few are currently taking advantage of this access. However, it is expected that the number of patients using health information technology will increase exponentially in the next decade (Markle Foundation, 2011). If the standard of care becomes to release results within four days to meet the MU requirements, the onus will be on physicians to contact patients with abnormal results before they are automatically released. To avoid release before verbal contact, some heath care systems are currently withholding certain test results through the portal or allowing physicians to release the result themselves.

Notification of abnormal test results via portals might face challenges from physicians. In our recent survey of U.S. and Australian primary care and specialist physicians, we found that 78.7 percent of physicians were not comfortable with direct patient notification of clinically significant abnormal test results (test results that are not immediately life threatening but require short-term follow-up) (Davis Giardina et al., 2014). Similar to the patients in the current study, physicians expressed concerns about patient anxiety and confusion when accessing abnormal test results online. To alleviate these concerns, best practices in portal-based test result notification should be accompanied by strategies to help patients understand and manage the information they receive. This may also reduce the amount of time physicians spend discussing non-problematic test results with their patients.

Though concerns about other patients tended toward confusion and anxiety, very few patients in this study experienced this themselves. Those who did experience anxiety received results they considered to be sensitive, or of high emotional impact, as they were related to suspicion of cancer. Most respondents believed that some sensitive tests should require a telephone call prior to release in the portal, this included, with some variation, new diagnoses, cancer related testing, and untreatable or deadly diseases. The sensitivity of test results was an issue of contention for The CLIA Program and HIPAA Privacy Rule (Department of Health and Human Services & Center for Medicare & Medicaid Services, 2014). The Rule addresses this issue directly, stating that patients have a right to their information under HIPPA and laboratories cannot withhold test results "based on the sensitive nature or potential for causing distress to the individual" (p. 7296). Further the rule states that laboratories categorizing tests into sensitive and non-sensitive is a subjective process and not in the best interest of patients. Interestingly, the rule does include a 30-day window for physicians to follow-up and even a 30-day extension. Moving forward, health care providers should consider both sensitivity and significance of the result when deciding which tests released and in what timeframe. Based on the preferences of the patients in this study, they may also want to include policy for avoiding release of test results during weekends or other off hours not staffed to answer questions.

While the theme of empowerment, an advertised advantage of the portal, did not emerge directly in the narratives, it was implicit in the patients' desire for access to their test results. If the underlying purpose of empowerment is increase patients' autonomy (Anderson & Funnell, 2010), providing access to test results allows patients to exert

control over their health in ways they find meaningful. For some patients, that means keeping track of their results to avoid error, delay, or testing redundancy. It can also mean the ability to closely monitor changes in health or simply to better understand a condition. Though a recent review of controlled trials found insufficient evidence to support increased empowerment(Ammenwerth et al., 2012), it may be an issue of how empowerment is conceptualized (i.e.; self-efficacy, control, activation). Despite patient empowerment being ubiquitous in the literature related to health information technology, there is no consensus on the definition (Anderson & Funnell, 2010; Samoocha, Bruinvels, Elbers, Anema, & Van Der Beek, 2010; Aujoulat, d'Hoore, & Deccache, 2007). Further work is needed to understand how patients can be empowered in relation to test results and use this information to improve health outcomes.

This study has several limitations. Our sample size is small due to difficulty in locating patients that have received abnormal result through their portal. However, we were able to obtain a diverse sample with regard to experience. The method of analysis may also be influenced by the researchers' own biases. Multiple interpretations of the data are possible. Additionally, we used convenience sampling, the least rigorous qualitative sampling technique and we did not collect demographic data. Despite these limitations, this study provides one of the first qualitative studies examining a new area of research – patients' experiences of patient portals and notification of abnormal test results. These findings have important implications for the future implementation of the use of patient portals for automatic notification of positive test results, and offer important insight to all health professionals that will interface with patients using this technology in medical settings.

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Chapter 4: Conclusion

The overall objective of this research was to better understand the impact of patient access to medical information and specifically physician and patient perceptions of patient access to abnormal test results. Test results notification continues to be problematic despite increased use of health information technology. A wide range of missed abnormal results has been found in the ambulatory setting: 6.8% to 62% missed laboratory results and 1.0% to 35.7% missed radiology results (Callen, Westbrook, Georgiou, & Li, 2011). Increasingly, patients are encouraged to take active roles in their care and have expressed interest in having access to their health information (Cho et al., 2010; Pyper, Amery, Watson, & Crook, 2004). One potential method to mitigate delays in follow-up is to provide patients access to their test results. It also aligns with the current national policies to facilitate patient engagement in care.

Two national policies will have long-term impact on test result notification to patients: Meaningful Use and the CLIA Program and HIPAA Privacy Rule. The HITECH Act established an incentive program for health care organizations and providers to demonstrate “meaningful use” (MU) of certified electronic health records (EHR) (Department of Health and Human Services, 2010). The definition of “meaningful use” includes a number of objectives to encourage the engagement of patients and their families through increased electronic access to their clinical information (Department of Health and Human Services, 2010). The CLIA Program and HIPAA Privacy Final Rule was released in 2014 by Department of Health and Human Services (HHS) jointly with the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Office for Civil Rights (Department of Health and Human Services &

Center for Medicare & Medicaid Services, 2014). The rule allows patients to request access to their test results directly from the laboratory without physicians' involvement.

These two policies set the foundation for increasing patient access to test results. Though there are not currently agreed upon best practices or standards for test result notification through the patient portal, the current health care policy climate emphasizes greater patient-provider collaboration as a means of improving quality of care related to test results. Ultimately these policy initiatives support innovative methods to improve test result notification, thus underscoring the importance of this project. This three-article dissertation contributes to the literature by answering the following important questions:

Study One: What are the effects of interventions that provide patients access to their medical records?

Study Two: What are physician perspectives of direct patient notification of normal and clinically significant abnormal test results?

Study Three: What are patients' experiences, informational needs, and preferences regarding test result notification through patient portals?

A description of each article and its impact on the field, as well as implications for social work research, practice and policy, are described below.

Article One: Patient Access to Medical Records and Health Care Outcomes: A Systematic Review

The first article is a systematic review of the literature to determine the effects of interventions that provide patients access to their medical records. The PubMed search resulted in 1247 citations, and bibliography review yielded 18 additional articles. Twenty

studies were RCTs and seven were uncontrolled observational studies. Almost half of the studies focused on patient populations with chronic diseases including diabetes, cancer, heart failure, and hypertension.

Our systematic review found that studies of interventions that provided patients access to their medical records have addressed three of six Institute of Medicine's quality domains: effectiveness, patient-centeredness, and efficiency. Effects of patients' access to medical records on measures of safety, timeliness, and equity remain understudied.

Most studies addressed effectiveness with variables measuring a diverse set of outcomes related to physical psychosocial health, patient health behavior and adherence, recall of medical information, personal health record (PHR) use, accuracy of the medical record, and perceived usefulness of access to medical records. Due to variability in outcome measures, it remains unclear if patient access to medical information improves physical health. Furthermore, interventions were not necessarily "pure" in that they may have contained elements other than simply providing access to PHRs. For example, one study conducted in a sample of patients with diabetes included a PHR training component and ongoing patient contact with a care manager, making the independent effect of PHR access uncertain (Ralston et al., 2009). Additionally, some studies measured outcomes among patients who were already users of PHRs. One study found that these existing users were younger, more likely to be white, had higher incomes, and more often had private insurance compared to PHR non-users; thus, use of a PHR may be a marker for characteristics more closely related to better health outcomes (Tenforde, Nowacki, Jain, & Hickner, 2012). Additional research is

clearly needed to establish whether access to medical records has an effect on physical health outcomes. This is especially relevant in light of the Stage 2 Meaningful Use requirement for patients to have timely online access to their health information (Centers for Medicare & Medicaid Services, 2013).

Our review found no current evidence to substantiate any negative patient outcomes resulting from access to health information. Access to medical information did not increase patient anxiety (Spodik et al., 2008; Wiljer et al., 2010), a common fear endorsed by physicians (Moyer, Stern, Dobias, Cox, & Katz, 2002; Sung, Forman-Hoffman, Wilson, & Cram, 2006; Wiljer et al., 2010). However, the effects of PHR access on workload and system efficiency merit further evaluation. Clarity about how patient portal and PHR use affect system burden can help with resource allocation decisions related to managing patients who use these tools.

Some of the studies found that while feelings of control were significant, feelings of confidence and empowerment were not. Although self-efficacy was found to be significant in only one of three studies, the study included a consultation with a nurse case manager that may have influenced outcomes. Although it might be premature to arrive at any definitive conclusion about patient engagement, it is possible that access to medical records alone may enhance patients' sense of control, but may not be potent enough to affect more deeply entrenched qualities such as self-efficacy, confidence, and empowerment.

Our review of studies examining the effects of granting patient access to their medical information revealed few overarching trends. There is no evidence of psychological harm to patients, one of the frequently cited physician concerns.

Moreover, while access to medical records appears to impact patient satisfaction, evidence was less clear for other aspects of quality and additional interventions might be needed to realize benefits of patient empowerment.

Article Two: Releasing Test Results Directly to Patients: A Multisite Survey of Physician Perspectives

The purpose of this survey was to determine physician perspectives about direct patient notification of *normal* and *clinically significant abnormal* test results. Physicians were surveyed at five clinical sites in the U.S. and Australia. The U.S.-based study was conducted via a cross-sectional, web-based survey of primary care physicians and specialists between July 1, 2012 and October 1, 2012. An identical paper-based survey was self-administered between June 26, 2012 and September 3, 2012 with physician-specialists in Australia.

Of 1417 physicians invited, 315 (22.2%) completed the survey. The majority were male, over half were subspecialists, three-quarters worked full-time (75.2%), and over a third had 20 or more years of clinical experience. Australian physicians were younger and had fewer years in practice. Two-thirds (65.3%) believed that patients should be directly notified of normal results, but only 21.3% were comfortable with direct notification of clinically significant abnormal results. The majority of physicians expressed concerns about direct notification of clinically significant abnormal test results, including patients' anxiety, confusion, lack of expertise to interpret the results, seeking of unreliable information to understand the results, and concerns that the patients would seek care without consulting their providers. Physicians were more likely to endorse direct notification of abnormal results if they believed it would reduce the

number of patients lost to follow-up (OR=4.98, 95% CI=2.21-1.21) or if they had personally missed an abnormal test result (OR=2.95, 95% CI=1.44-6.02). Conversely, physicians were less likely to endorse it if they believed that direct notification interfered with the practice of medicine (OR=0.39, 95% CI=0.20-0.74).

To our knowledge, this is the first survey to specifically identify predictors of physician acceptance of direct notification of test results. Physicians' attitudes and beliefs about direct notification might play an integral role in patients' adoption of these new health communication strategies (Kerns, Krist, Longo, Kuzel, & Woolf, 2013; Singh, Fox, Petersen, Shethia, & Street, Jr., 2009). Given an increasing focus on transparency and patient engagement in health care (Department of Health and Human Services, 2010), it is essential to understand how direct notification will affect health care workflow. While physicians did not express concern that direct notification of abnormal test results would increase workload, they did indicate that it would interfere with the practice of medicine. Successful implementation of direct notification systems might be somewhat dependent on how direct notification of various types of results fits within the health care workflow.

Concerns that direct notification had potential to lead to patient misunderstanding, anxiety, and confusion remained prominent among survey respondents. Recent evidence shows that access to medical information (including test results) does not necessarily increase patient anxiety (Giardina, Menon, Parrish, Sittig, & Singh, 2013) and may in some cases decrease anxiety (Spodik et al., 2008; Wiljer, 2010). In view of this discrepancy between physicians' concerns and the available evidence, effective strategies for implementing direct notification should provide patients

access to tools to enhance context-based interpretation (Krist et al., 2011; Krist & Woolf, 2011). Few such tools exist at this time to improve patient comprehension of test results, but our findings highlight the need for their development. In addition, current evidence generally indicates an absence of anxiety related to access to medical information (including test results)(Giardina et al., 2013); thus improving physician awareness of this evidence is also warranted.

Physicians have substantial concerns about direct notification of test results, despite policy initiatives to facilitate patient access to medical information. Physician concerns are about sensitive tests, they are generally in favor of direct notification of normal test results to patients. Health care institutions providing patient access to test results will need to develop strategies to provide patients with context-based tools to enhance interpretation of abnormalities. This may lessen physician concerns of patient anxiety and confusion and address the potential impact on physician work.

Article Three: The Patient Portal and Test Result Management: An Exploratory Study of Notification Preferences

Article Three is a qualitative study with the overall objective of exploring patients' experiences, informational needs, and preferences regarding test result notification through patient portals. I conducted semi-structured interviews with ten respondents between February 2014 and March 2014. Using thematic content analysis, we were able to identify four major themes: health management practices, notification preferences, patient research, and physician perspective.

All the respondents used their portals to manage their health information. Respondents who perceived themselves as healthy used their portal infrequently.

Respondents with chronic illness used their portal more regularly to keep track of test results and also kept paper records and imaging. Some respondents used their portal to avoid redundancy in testing and delay in treatment. Overall respondents felt that abnormal test results should be made available to them in the portal. Positive and negative past experiences with critical and sensitive results impacted notification preferences. Some examples of sensitive tests given by the respondents were any diagnoses that cannot be treated or cured, life- threatening illnesses, cancer diagnoses, and genetic testing. Respondents who received sensitive results or those which were cancer-related felt that these types of results should be communicated verbally prior to release, and not released during times (e.g., the weekend) when concerned patients cannot contact their doctors or other health professionals. Other respondents felt that they could trust their physicians to call when necessary. Respondents who had experienced delayed notification of abnormal test results insisted that abnormal results, with very limited exceptions, should be made available via the portal.

All of the respondents utilized the Internet to better understand their test results. However, they used Internet research in different ways. Some looked for additional information following a discussion with the physician, while for others, Internet research actually replaced a conversation with the doctor. In some cases, respondents use the Internet when the physician does not provide an interpretation. Context-based interpretation systems or information, such as those discussed in the second article, may also help improve the patients' interpretation of their results without having to rely on Internet resources, which may not always be up to date, consistent or reliable. Finally, while all the respondents indicated that they desire access to their test results,

they also expressed that some patients should not have direct access to their results if they have low health literacy or limited Internet experience.

In summary, respondents wanted access to their abnormal test results but felt that sensitive results should be communicated verbally. Health care systems and eligible professionals should consider identifying sensitive tests and build in a short-term embargo to allow for verbal communication prior to portal release. Patients also expressed a preference that their results not be released during hours when the reporting medical facility was not open to receive questions regarding the results. One limitation of this study is the inability to address differences in types of patient portal users, such as race/ethnicity. There is current research to suggest disparities in use (Sarkar et al., 2010; Sarkar, 2011; Yamin, 2011; Goel et al., 2011). For example, Sarkar et al. (2010) identified common similarities in those users who were less likely to log on to portals. This included ethnic and racial minorities, patients with limited health literacy, and patients with lower education. While the expectation is that access to health information technology, even among the groups mentioned above, will increase, it is unknown how these groups will prefer test result notification. It may be that some racial and ethnic minority groups do not perceive the usefulness of the portal and strategies to highlight this will be necessary (Goel, 2011). Guaranteeing that all patients, regardless of racial and ethnic background, utilize patient portals will be a difficult challenge.

Integrative Conclusions

This dissertation was designed to contribute to the growing body of literature on patient-accessible medical information. The three studies presented here form a cohesive body of work about patient access to medical information, specifically their

access to test results. The literature shows that patients do not experience harm when able to access their medical information. However, both physicians and patients are concerned about patient harm. Physicians are concerned that patients viewing clinically significant abnormal test results will cause anxiety and confusion, while patients are specifically concerned about issues of health literacy and interpretation and the notification of sensitive test results. As portals continue to evolve, it is important to provide patients with information they want and may benefit from and recognize that different patients have different informational and management needs. Overall, physicians need to be aware of the tools available to patients and the impact they have on patient outcomes. Further research with a diverse patient population is needed to determine how patients use health information technology to manage their medical information and their care. Additional research is also necessary to determine how to increase physician awareness of the benefits of patient-accessible medical records.

Implications for Practice, Policy and Research

This dissertation focused on capturing an overview of patient access to medical information and physician and patient perspectives of test result notification through the patient portal. Findings from these articles have important implications for practice, policy and research.

General access to medical information improves patient satisfaction but does not appear to impact other quality measures. Patient empowerment as currently measured in the medical literature did not improve in controlled interventions but feelings of control did. There is no evidence of patient harm in the literature. Physicians continue to be concerned about patient anxiety despite evidence to the contrary; however, the degree

to which they are aware of this evidence is unknown. Future efforts should focus on disseminating this information to physicians prior to and during the implementation of large patient portal systems. Continued research on physicians' adoption of these technologies is necessary, as their beliefs and attitudes about patient participation may impact patient use of portal-based notification systems (Kerns et al., 2013; Singh et al., 2009). Physicians' failure to promote electronic access can contribute to low adoption rates (DesRoches et al., 2008; Hassol et al., 2004; Winkelman, Leonard, & Rossos, 2005). Also, physician cognizance of system vulnerability appears to improve comfort with direct notification of abnormal test results. As such, making physicians and other health care providers aware of system weaknesses and potential risks to malpractice may also help facilitate buy-in and adoption. For instance, by making health care providers aware of system-wide missed and delayed test results.

Our qualitative work found that patients prefer access to their results as a way to manage and stay informed about their health conditions. Like physicians, past experiences with test result notification influenced their preferences regarding the notification of abnormal test results. When a patient experienced delayed notification, they were more likely to be concerned about receiving their abnormal test results in a timely manner. This suggests that a patient education component may also be necessary that provides information regarding how the patient portal can be used to enhance patient care. Specifically, patients in the third study shared how it helps them organize their medical information, keep more accurate records, and communicate more efficiently with their doctors.

The importance of patient notification of test results is well established in the literature (Singh, 2010). Because there is such variability in test result notification (Callen et al., 2011), it is important to explore innovative best practices for notification. Additionally, as the Stage 2 of Meaningful Use deadline approaches, eligible professionals must provide patients with the ability to access their health information electronically. More than 50 percent of all unique patients are required to have timely online access to their health information within four business days of its update in the electronic health record. Also, it requires that more than 5 percent of all unique patients view, download, or transmit their health information to a third party. Given the window of four days, it is worth considering whether it is preferable to release test results during active business hours to ensure that patients have access to medical personnel if questions arise. Likewise, context-based interpretation systems will likely also help reduce the frequency with which patients feel the need to call providers or look up potentially misleading information online concerning their test results.

The patient portal offers the possibility of timely access to test results to patients. It also allows patients and caregivers dealing with chronic illness to monitor their conditions. According to the Technology Acceptance Model, people voluntarily tend to use or not use a system based on their beliefs of the system's usefulness and their perceptions of ease of use of that system (Davis, 1985). In Article Three, patients told stories that attested to the usefulness of having access to their abnormal test results. This is also similar to the theory of diffusion concept of relative advantage, the extent to which an innovation is better than the idea before it (Rogers, 2003). Many of the patients interviewed found the portal to be superior to past methods of keeping paper

copies of test results. The patients interviewed did not speak of themselves as empowered or engaged, but having access to their electronic health records allowed them to act in ways that convey engagement in their care. They were able to avoid redundant testing and anticipate physician requests for documentation prior to their visits, resulting in more efficient medical experiences. As hospitals and health care professionals continue to implement the patient portal, a key component in increased portal adoption will be convincing patients of its usefulness through examples relevant to different types of patients.

Implications for Social work

Though empowerment had not yet been examined as an outcome variable in the literature at the time of this study, it appears that patients use their portals in ways that engage them in their care and that, consequently, may be empowering. This is particularly relevant to the profession of Social Work, and specifically, the goals of medical social workers and social workers working in health policy. Social workers are committed to helping people manage their own problems and ensuring the resources are available to do so (Edwards, 1995). Access to online medical information may provide a new way for patients to manage their illness. Patients that decide to access their medical information and test results are empowered, as they are responding to an invitation to increase their participation in their own medical care. For medical social workers, PHRs and portals may be useful tools in patient communication, education, and coordination.

Future Research

My research on patient access to their medical information - a priority of the federally mandated Meaningful Use requirements - suggests that, while portal users see themselves as capable consumers of medical information and the literature confirms that this access is not harmful, physicians remain skeptical. The portal is a powerful tool for patients, as it allows them (or their caregivers) to manage their own health information. These studies have provided essential information for my future research plans, which will focus on the development of interventions to educate physicians about the ways in which patients engage with the portal and with patients about the benefits of these systems. These interventions will help increase the adoption and use of this technology in a way that maximizes the benefits to both physicians and patients. Future research might examine whether providing access leads to increased patient empowerment, engagement, and collaboration. It would also be interesting to examine whether changes occur over time as a function of new generations' increased use of and comfort with technology.

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Appendices

Appendix A – Institutional Review Board

Article Two: Releasing Test Results Directly to Patients: A Multisite Survey of Physician Perspectives

December 08, 2011

BCM
Baylor College of Medicine

HARDEEP SINGH
BAYLOR COLLEGE OF MEDICINE
MEDICINE: HEALTH SRVCS RESEARCH

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H-28778 - PROVIDER PERCEPTIONS OF AUTOMATIC PATIENT NOTIFICATION OF ABNORMAL TEST RESULTS

APPROVAL VALID FROM 11/30/2011 TO 10/31/2012

Dear Dr. SINGH

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

Gabriel Habib

Association for the Accreditation of Human Research Protection Programs, Inc.
Full AAHRPP Accreditation

GABRIEL HABIB, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

KELSEY RESEARCH FOUNDATION

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Founded 1956

April 4, 2012

Hardeep Singh, M.D.
Houston VA HSR&D Center of Excellence
2002 Holcombe Blvd.
Houston, Texas 77030
Attn: Traber Giardina, MA

Dear Dr. Singh:

Your protocol entitled "Provider Perceptions of Automatic Patient Notification of Abnormal Test Results" was reviewed and approved at the Research and Education meeting on March 16, 2012.

If you have any questions about the procedures for conducting research at Kelsey-Seybold Clinic, please contact me at 713/442-1224.

Sincerely,

Sandra Johnson, CCRC
Research and Education Coordinator

5615 Kirby Drive • Suite 660 • Houston, Texas 77005 • 713/442-1214 • www.ksfnd.org

MICHAEL E. DeBAKEY VETERANS AFFAIRS MEDICAL CENTER

Memorandum

Date: December 21, 2011

From: Acting, Associate Chief of Staff/R&D (580/151)

Subj: Research Protocol Approval

Research Protocol Title: Provider Perceptions of Automatic Patient Notification of Abnormal Test Results

VA ID Number: 11L17.H **(Please use this VA ID number to identify the project when in contact with the VA Research Office)**

BCM IRB Number: H-28778 **BCM IACUC Number: N/A**

To: Hardeep Singh, MD, MPH

After successful review by:
The Information Security Officer on… 12/16/2011…,
The Privacy Officer on…….. 15/15/2011…,
The Subcommittee for Research Safety on …… N/A…..,
The BCM IRB on…….. 11/30/2011…..,
The BCM IACUC on…… N/A….

The above titled research protocol was **APPROVED** by the R&D Committee on 12/19/2011. Recruitment of patients and/or laboratory work and/or animal experiments can commence as soon as you, the principal investigator, and your Research Team have met with the Research Compliance Officer to review the most current rules for acquisition and retention of study records.

PLEASE MAKE NOTE OF THE FOLLOWING STIPULATIONS

1. **Documenting patient and other research subjects enrollment**
   When enrolling MEDVAMC patients in this project you:
   a) **MUST write a "Research Protocol Entry Note" in CPRS when the research involves treatment or some other clinical intervention.**
   b) **Should not write a "Research Protocol Entry Note" when the research does not involve a treatment or other clinical intervention.**
   c) **For Non-Veteran study enrollees, a CPRS Chart must be created and a Research Protocol Entry Note must be created ONLY when the research involves a clinical intervention.**

MEDVAMC Form 151-02
OCT 2007

   d) **In all cases, the original research records, including the original signed and dated informed consent document, the HIPAA authorization and the receipt of Privacy Notification, if applicable, must be kept in a study binder as specified by the Research Compliance Officer.**
   e) **A master list of all subjects from whom informed consent has been obtained must be maintained, unless this requirement has been waived by the IRB. This master list must be protected in compliance with all VA confidentiality and information security requirements.**

2. **For studies requiring informed consent**
   a) The most recent IRB-approved version of VA Form 10-1086 must be used for all VA-approved research, ***including,*** but not limited to, studies in which a VA principal investigator enrolls subjects at sites outside VA, such as affiliated hospitals, clinics, nursing homes or community centers. *Note:* The only exception to this requirement is a DOD study with active duty military personnel when no VA-specific language is necessary.
   b) The research subject must also sign a separate HIPAA authorization.
   c) Non – Veteran Research subjects must give written receipt of the VHA Notice of Privacy Practices.

3. **Pharmacy Service**
   If the research involves an investigational drug, please send a copy of the complete protocol, prepared for or by the study sponsor, to Nancy Hewitt in Pharmacy Service (mail code 119). **There is a charge for the use of Pharmacy Service. See the Research Share Point Folder for the full list of charges.**

4. **Reporting adverse events, deviations and exceptions**
   All adverse events, deviations from protocol, and exceptions to the human studies protocol must be reported to the IRB through BRAIN. Death or substantive events should also be reported directly to the MEDVAMC Research Office, the Privacy Officer, and the Facility Research Compliance Officer.

5. **People working on this project must be trained and credentialed.**
   All individuals involved in human research, whatever their role, must complete the Collaborative Institutional Training (CITI) "Basic Course in the Protection of Human Subjects". This training is required prior to approval to start research and is required every two years thereafter. The PI is responsible for verifying that all members of the research team are able to perform their assigned duties.

6. **National Clinical Trials Registry**
   Please ensure that your clinical trial project is registered with the National Library of Medicine's Clinical Trials Registry BEFORE the first patient is enrolled into the study. Remember, if you do not register your study, you risk not having the ability to publish your results in certain journals Registry information and guidelines are found at this website: http://clinicaltrials.gov/

7. **To keep this project active…Continuing Review**
   Renew the project in a timely manner when the renewal notification is sent to you. You are responsible for renewing the human studies protocols through BRAIN on an annual basis. The renewal of this protocol through BCM BRAIN System also serves to keep the project renewed and active with the MEDVAMC research program. **Failure to renew your protocol by the appropriate subcommittee prior to expiration will result in closure of your project by the R&D Committee.** Conducting research without R&D Committee approval will affect your standing in the VA.

8. **To make changes to the protocol**
   Changes to a protocol that involve humans, animals, biohazard materials, or radioactive materials must be approved before they are implemented. Changes in animal or human research should be submitted as an amendment to the relevant protocol through BRAIN. Changes in biohazard and/or radiation should be noted on the appropriate update application form and submitted to the Research Office, Bldg. 110, Room 306.

9. **Acknowledging VA Research Support and VA employment**
   Publications, presentations, media interviews, and similar activities must acknowledge the support of the Department of Veterans Affairs in this research. Acknowledgement is expected not only for direct research funding from the VA, but also for indirect support such as use of VA resources (patients, laboratories, and/or clinical facilities), and the investigator's full-time, part-time, or without compensation (WOC) appointment.

10. **You are responsible for any ethical breaches in the conduct of this research and these may affect your ability to do research with the VA in the future.**

LAURA A. PETERSEN, MD, MPH

The Michael E. DeBakey VA Medical Center Research & Development Program is accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. for the development and maintenance of an effective Human Research Protection Program.

Scott & White Institutional Review Board
Federalwide Assurance #FWA00003358
IRB Registration #IRB00000706

Notification of IRB Action

To:	Samuel Forjuoh, MD, Dr.PH
cc:	Dawn Begaye
Project ID:	120254
Title:	PROVIDER PERCEPTIONS OF AUTOMATIC PATIENT NOTIFICATION OF ABNORMAL TEST RESULTS
Level of Review:	Expedited Expedited Review Category: 45 CFR 46.110(b)(1)(7)
Date of Action:	5/30/2012
Type of Action:	Approval
Approval period:	5/30/2012 to 5/29/2013
Continuing review deadline:	4/29/2013*

***You are responsible for ensuring IRB approval is obtained for the continuation of your project by submitting the required progress report and supporting documentation by the continuing review deadline.**

Item(s) reviewed: Submission reference #: 033124

1. Initial Review Submission Form, Version 1.1
2. Application, Version 1.0
3. Study Proposal, Version 1.0
4. Data Spreadsheet 5/3/12, Version 1.0
5. Physician Survey
6. Baylor College of Medicine IRB Approval
7. Biosketch - Forjuoh

The IRB has waived the requirement for documentation informed consent based on 45 CFR 46.117 (c). Furthermore, federal regulations related to the protection of individually identifiable health information do not apply to the activity described.

Investigator Responsibilities:

- Conduct the study according to the currently approved protocol, institutional policies, and all applicable regulations
- Obtain approval from the IRB of any changes in the research prior to implementation except where necessary to eliminate apparent immediate hazards to human subjects. Such urgent changes must be reported to the IRB within five (5) working days.
- Personally supervise or conduct the research and ensure appropriate delegation of tasks
- Maintain complete and accurate study records and make them available for inspection
- Notify the IRB Office of any external inspections of the research
- Report unexpected adverse outcomes to the IRB within five (5) working days of knowledge of each occurrence
- Assume responsibility for initial and continuing review of the research by the IRB

IRB Responsibilities:

- Review and have authority to approve, require modifications in or disapprove all research activities
- Ensure all requirements for approval of research are satisfied in accordance with federal regulations
- Report any serious or continuing non-compliance by investigators to the appropriate institutional officials, the Office for Human Research Protections, the Food and Drug Administration and any other appropriate regulatory agencies
- Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects
- Determine that all criteria for IRB approval of research are met as stipulated in the federal regulations
- Require that information given to subjects as part of informed consent is in accordance with federal regulations
- Conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year, including the authority to observe or have a third party observe the research

Signature applied by Matt Ridley on 05/30/2012 11:31:28 AM CDT

Administrator and Authorized Representative of the Scott & White IRB

2401 S. 31st St., Temple, Texas 76508 Phone: 254-215-9030/9031 Fax: 254-215-9061

Department of Research
Telephone: 832-355-3710
Fax: 713-610-2272

ST. LUKE'S
Episcopal
Hospital

June 4, 2012

Hardeep Singh, M.D.
2450 Holcombe Blvd, Suite 01Y
Houston, TX 77021

RE: H-30648
PROVIDER PERCEPTIONS OF AUTOMATIC PATIENT NOTIFICATION OF ABNORMAL TEST RESULTS

Dear Dr. Singh:

Please accept this letter as notification that your protocol has received administrative approval from the Department of Research at St. Luke's Episcopal Hospital. We are looking forward to working with you in support of your research efforts.

For any questions, I can be reached at 832-355-3710. Thank you.

Sincerely,

Cheryl P. Fullmer RN, MBA
Director, Clinical Research
St. Luke's Episcopal Hospital

UNIVERSITY of HOUSTON

DIVISION OF RESEARCH

July 18, 2013

Traber Giardina
c/o Dr. Danielle Parrish
Dean, Social Work

Dear Traber Giardina,

Based upon your request for exempt status, an administrative review of your research proposal entitled "Physician Perceptions of Patient Access to Test Results" was conducted on May 15, 2013.

At that time, your request for exemption under **Category 4** was approved pending modification of your proposed procedures/documents.

The changes you have made adequately respond to the identified contingencies. As long as you continue using procedures described in this project, you do not have to reapply for review. * Any modification of this approved protocol will require review and further approval. Please contact me to ascertain the appropriate mechanism.

If you have any questions, please contact Alicia Vargas at (713) 743-9215.

Sincerely yours,

Kirstin Rochford, MPH, CIP, CPIA
Director, Research Compliance

*Approvals for exempt protocols will be valid for 5 years beyond the approval date. Approval for this project will expire **July 1, 2013**. If the project is completed prior to this date, a final report should be filed to close the protocol. If the project will continue after this date, you will need to reapply for approval if you wish to avoid an interruption of your data collection.

Protocol Number: 13464-EX

316 E. Cullen Building Houston, TX 77204-2015 (713) 743-9204 Fax: (713) 743-9577

COMMITTEES FOR THE PROTECTION OF HUMAN SUBJECTS

Article Three: The Patient Portal and Test Result Management: An Exploratory Study of Notification Preferences

UNIVERSITY of HOUSTON

DIVISION OF RESEARCH

December 10, 2013

Traber Giardina
c/o Dr. Danielle Parrish
Dean, Social Work

Dear Traber Giardina,

The University of Houston Committee for the Protection of Human Subjects (1) reviewed your research proposal entitled "PATIENT PERSPECTIVES OF DIRECT NOTIFICATION" on October 4, 2013, according to institutional guidelines.

At that time, your project was granted approval contingent upon your agreement to modify your protocol as stipulated by the Committee. The changes you have made adequately fulfill the requested contingencies, and your project is now **APPROVED**.

- **Approval Date: December 10, 2013**
- **Expiration Date: October 1, 2014**

As required by federal regulations governing research in human subjects, research procedures (including recruitment, informed consent, intervention, data collection or data analysis) may not be conducted after the expiration date.

To ensure that no lapse in approval or ongoing research occurs, please ensure that your protocol is resubmitted in RAMP for renewal by the **deadline for the September 2014** CPHS meeting. Deadlines for submission are located on the CPHS website.

During the course of the research, the following must also be submitted to the CPHS:

- Any proposed changes to the approved protocol, prior to initiation; AND
- Any unanticipated events (including adverse events, injuries, or outcomes) involving possible risk to subjects or others, within 10 working days.

If you have any questions, please contact Alicia Vargas at (713) 743-9215.

Sincerely yours,

Daniel O'Connor

Dr. Daniel O'Connor, Chair
Committee for the Protection of Human Subjects (1)

PLEASE NOTE: All subjects must receive a copy of the informed consent document, if one is approved for use. All research data, including signed consent documents, must be retained according to the University of Houston Data Retention Policy (found on the CPHS website) as well as requirements of the FDA and external sponsor(s), if applicable. Faculty sponsors are responsible for retaining data for student projects on the UH campus for the required period of record retention.

Protocol Number: 14043-01 Full Review: ____ Expedited Review: X

316 E. Cullen Building Houston, TX 77204-2015 (713) 743-9204 Fax: (713) 743-9577
COMMITTEES FOR THE PROTECTION OF HUMAN SUBJECTS

September 03, 2013

Baylor College of Medicine
Office of Research
One Baylor Plaza, 600D
Houston, Texas 77030
Phone: (713) 798-6970
Fax: (713) 798-6990
Email: irb@bcm.tmc.edu

HARDEEP SINGH
BAYLOR COLLEGE OF MEDICINE
MEDICINE: HEALTH SRVCS RESEARCH

H-33048 - PATIENT PERSPECTIVES OF DIRECT NOTIFICATION

APPROVAL VALID FROM 9/3/2013 TO 8/13/2014

Dear Dr. SINGH

The Institutional Review Board for Human Subject Research for Baylor College of Medicine and Affiliated Hospitals (BCM IRB) is pleased to inform you that the research protocol named above was approved.

The study may not continue after the approval period without additional IRB review and approval for continuation. You will receive an email renewal reminder notice prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedure must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of adverse events encountered during the study or of any new and significant information that may impact a research participants' safety or willingness to continue in your study.

The BCM IRB is organized, operates, and is registered with the United States Office for Human Research Protections according to the regulations codified in the United States Code of Federal Regulations at 45 CFR 46 and 21 CFR 56. The BCM IRB operates under the BCM Federal Wide Assurance No. 00000286, as well as those of hospitals and institutions affiliated with the College.

Sincerely yours,

Gabriel Habib

GABRIEL HABIB, M.D.
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

MICHAEL E. DEBAKEY VETERANS AFFAIRS MEDICAL CENTER

Memorandum

Date: September 16, 2013

From: Associate Chief of Staff/R&D (580/151)

Subj: Research Protocol Approval

Research Protocol Title: PATIENT PERSPECTIVES OF DIRECT NOTIFICATION

VA ID Number*: 13I08.H *(Please use this VA ID number to identify the project when in contact with the VA Research Office)

BCM IRB Number: H-33048 **BCM IACUC Number: N/A**

To: Hardeep Singh, MD

After successful review by the:
BCM IRB: 9/3/2013
Subcommittee on Research Safety: N/A
BCM IACUC: N/A

The above titled research protocol was **APPROVED** by the R&D Committee on 9/16/2013.

PLEASE MAKE NOTE OF THE FOLLOWING STIPULATIONS

1. **Documenting patient and other research subjects enrollment**
   When enrolling MEDVAMC patients in this project you:
   a) **MUST write a "Research Protocol Entry Note" in CPRS when the research involves treatment or some other clinical intervention.**
   b) **Should not write a "Research Protocol Entry Note" when the research does not involve a treatment or other clinical intervention.**
   c) **For Non-Veteran study enrollees, a CPRS Chart must be created and a Research Protocol Entry Note must be created ONLY when the research involves a clinical intervention.**
   d) **In all cases, the original research records, including the original signed and dated informed consent document, the HIPAA authorization and the receipt of Privacy Notification, if applicable, must be kept in a study binder as specified by the Research Compliance Officer.**
   e) **A master list of all subjects from whom informed consent has been obtained must be maintained, unless this requirement has been waived by the IRB. This master list must be protected in compliance with all VA confidentiality and information security requirements.**

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2. **For studies requiring informed consent**
   a) The most recent IRB-approved version of VA Form 10-1086 must be used for all VA-approved research, ***including***, but not limited to, studies in which a VA principal investigator enrolls subjects at sites outside VA, such as affiliated hospitals, clinics, nursing homes or community centers. *Note:* The only exception to this requirement is a DOD study with active duty military personnel when no VA-specific language is necessary.
   b) The research subject must also sign a separate HIPAA authorization.
   c) Non – Veteran Research subjects must give written receipt of the VHA Notice of Privacy Practices.

3. **Pharmacy Service**
   If the research involves an investigational drug, please send a copy of the complete protocol, prepared for or by the study sponsor, to Nancy Hewitt in Pharmacy Service (mail code 119). **There is a charge for the use of Pharmacy Service. See the Research Share Point Folder for the full list of charges.**

4. **Reporting adverse events, deviations and exceptions**
   All adverse events, deviations from protocol, and exceptions to the human studies protocol must be reported to the IRB through BRAIN. Death or substantive events should also be reported directly to the MEDVAMC Research Office, the Privacy Officer, and the Facility Research Compliance Officer.

5. **People working on this project must be trained and credentialed.**
   All individuals involved in human research, whatever their role, must complete the Collaborative Institutional Training (CITI) "Basic Course in the Protection of Human Subjects". This training is required prior to approval to start research and is required every two years thereafter. The PI is responsible for verifying that all members of the research team are able to perform their assigned duties.

6. **National Clinical Trials Registry**
   Please ensure that your clinical trial project is registered with the National Library of Medicine's Clinical Trials Registry BEFORE the first patient is enrolled into the study. Remember, if you do not register your study, you risk not having the ability to publish your results in certain journals Registry information and guidelines are found at this website: http://clinicaltrials.gov/

7. **To keep this project active…Continuing Review**
   Renew the project in a timely manner when the renewal notification is sent to you. You are responsible for renewing the human studies protocols through BRAIN on an annual basis. The renewal of this protocol through BCM BRAIN System also serves to keep the project renewed and active with the MEDVAMC research program. Failure to renew your protocol by the appropriate subcommittee **prior to expiration** will result in closure of your project by the R&D Committee. Conducting research without R&D Committee approval will affect your standing in the VA.

8. **To make changes to the protocol**
   Changes to a protocol that involve humans, animals, biohazard materials, or radioactive materials must be approved before they are implemented. Changes in animal or human research should be submitted as an amendment to the relevant protocol through BRAIN. Changes in biohazard and/or radiation should be noted on the appropriate update application form and submitted to the Research Office, Bldg. 110, Room 306.

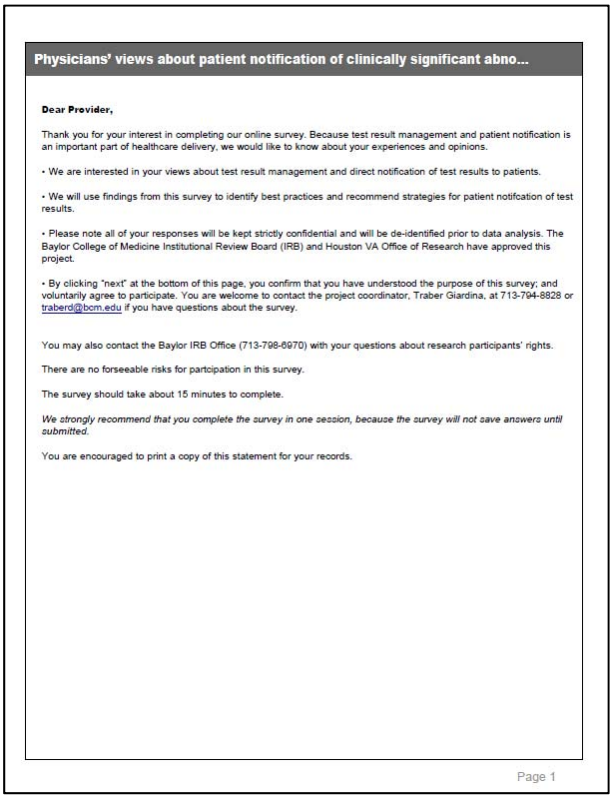
9. **Acknowledging VA Research Support and VA employment**
   Publications, presentations, media interviews, and similar activities must acknowledge the support of the Department of Veterans Affairs in this research. Acknowledgement is expected not only for direct research funding from the VA, but also for indirect support such as use of VA resources (patients, laboratories, and/or clinical facilities), and the investigator's full-time, part-time, or without compensation (WOC) appointment.

10. **You are responsible for any ethical breaches in the conduct of this research and these may affect your ability to do research with the VA in the future.**

LAURA A. PETERSEN, MD, MPH

The Michael E. DeBakey VA Medical Center Research & Development Program is accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. for the development and maintenance of an effective Human Research Protection Program.

Appendix B: Article Two Survey Instrument



Physicians' views about patient notification of clinically significant abno...

Dear Provider,

Thank you for your interest in completing our online survey. Because test result management and patient notification is an important part of healthcare delivery, we would like to know about your experiences and opinions.

- We are interested in your views about test result management and direct notification of test results to patients.
- We will use findings from this survey to identify best practices and recommend strategies for patient notifcation of test results.
- Please note all of your responses will be kept strictly confidential and will be de-identified prior to data analysis. The Baylor College of Medicine Institutional Review Board (IRB) and Houston VA Office of Research have approved this project.
- By clicking "next" at the bottom of this page, you confirm that you have understood the purpose of this survey; and voluntarily agree to participate. You are welcome to contact the project coordinator, Traber Giardina, at 713-794-8828 or traberd@bcm.edu if you have questions about the survey.

You may also contact the Baylor IRB Office (713-798-6970) with your questions about research participants' rights.

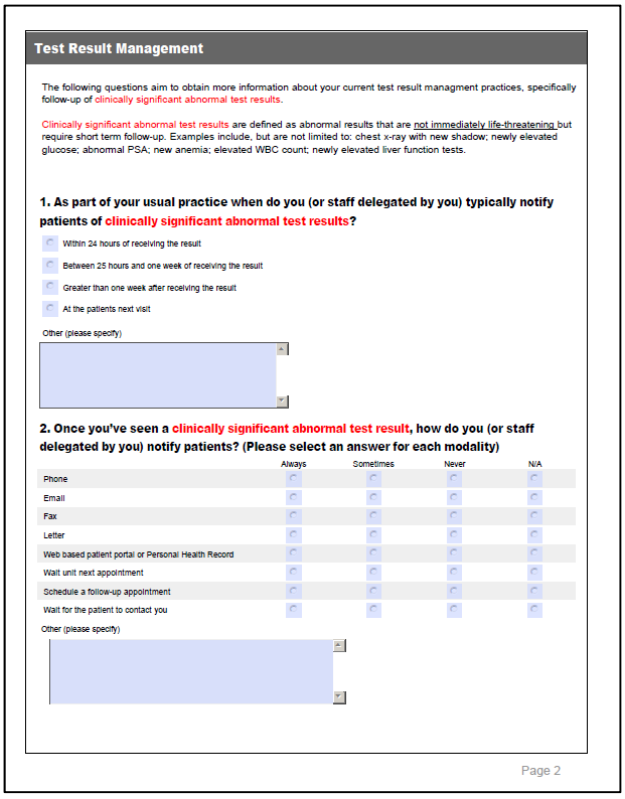
There are no forseeable risks for partcipation in this survey.

The survey should take about 15 minutes to complete.

We strongly recommend that you complete the survey in one session, because the survey will not save answers until submitted.

You are encouraged to print a copy of this statement for your records.

Page 1



Test Result Management

The following questions aim to obtain more information about your current test result managment practices, specifically follow-up of clinically significant abnormal test results.

Clinically significant abnormal test results are defined as abnormal results that are not immediately life-threatening but require short term follow-up. Examples include, but are not limited to: chest x-ray with new shadow; newly elevated glucose; abnormal PSA; new anemia; elevated WBC count; newly elevated liver function tests.

1. As part of your usual practice when do you (or staff delegated by you) typically notify patients of clinically significant abnormal test results?

- Within 24 hours of receiving the result
- Between 25 hours and one week of receiving the result
- Greater than one week after receiving the result
- At the patients next visit

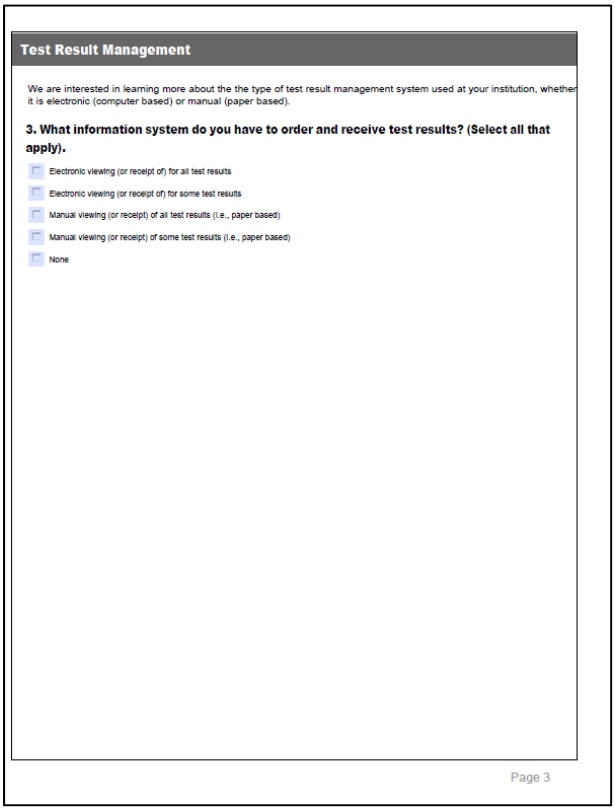
Other (please specify)

2. Once you've seen a clinically significant abnormal test result, how do you (or staff delegated by you) notify patients? (Please select an answer for each modality)

	Always	Sometimes	Never	N/A
Phone				
Email				
Fax				
Letter				
Web based patient portal or Personal Health Record				
Wait unit next appointment				
Schedule a follow-up appointment				
Wait for the patient to contact you				

Other (please specify)

Page 2



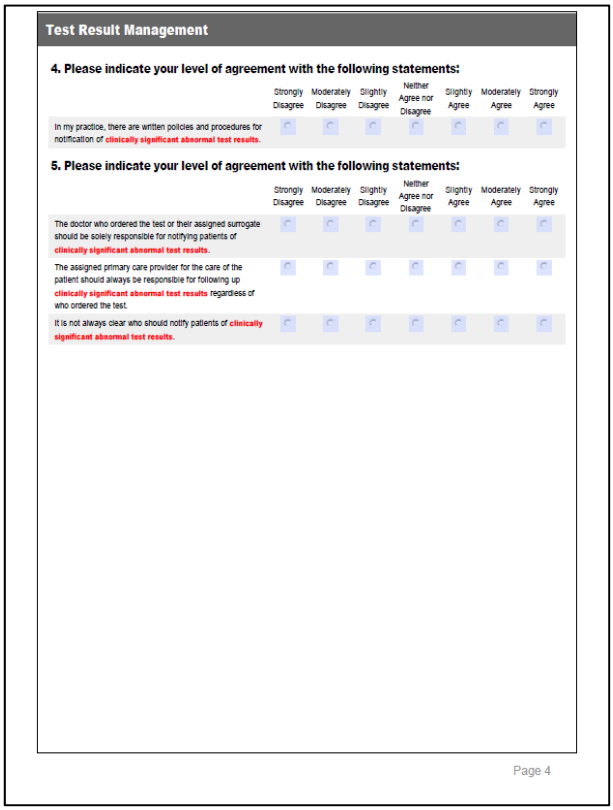
Test Result Management

We are interested in learning more about the the type of test result management system used at your institution, whether it is electronic (computer based) or manual (paper based).

3. What information system do you have to order and receive test results? (Select all that apply).

- Electronic viewing (or receipt of) for all test results
- Electronic viewing (or receipt of) for some test results
- Manual viewing (or receipt) of all test results (i.e., paper based)
- Manual viewing (or receipt) of some test results (i.e., paper based)
- None

Page 3



Test Result Management

4. Please indicate your level of agreement with the following statements:

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Neither Agree nor Disagree	Slightly Agree	Moderately Agree	Strongly Agree
In my practice, there are written policies and procedures for notification of clinically significant abnormal test results.							

5. Please indicate your level of agreement with the following statements:

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Neither Agree nor Disagree	Slightly Agree	Moderately Agree	Strongly Agree
The doctor who ordered the test or their assigned surrogate should be solely responsible for notifying patients of clinically significant abnormal test results.							
The assigned primary care provider for the care of the patient should always be responsible for following up clinically significant abnormal test results regardless of who ordered the test.							
It is not always clear who should notify patients of clinically significant abnormal test results.							

Page 4

Direct notification

The following questions aim to obtain your views about direct notification of clinically significant abnormal test results.

Direct notification is defined as the automatic release of test results directly to the patient regardless of whether the ordering physician has reviewed the results. Direct patient notification can be achieved via fax, mail, telephone, SMS message, email, or electronic patient portals.

Clinically significant abnormal test results are defined as abnormal results that are not immediately life-threatening but require short term follow-up. Examples include, but are not limited to: chest x-ray with new shadow; newly elevated glucose; abnormal PSA; new anemia; elevated WBC count; newly elevated liver function tests.

6. Please indicate your level of agreement with the following statements:

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Neither Agree nor Disagree	Slightly Agree	Moderately Agree	Strongly Agree
I am comfortable with patients receiving **direct notification** (i.e., without physician review) of **clinically significant abnormal test results**	○	○	○	○	○	○	○

Page 5

Direct notification

7. Please indicate any of your concerns regarding direct notification of clinically significant abnormal test results to patient. (Select all that apply)

- ☐ I have no concerns
- ☐ Interferes with the practice of medicine
- ☐ Patient anxiety about test results
- ☐ Patient confusion about test results
- ☐ Patient may seek care without consulting their provider
- ☐ Patient may seek unreliable information
- ☐ Patients lack expertise necessary to interpret the results
- ☐ Physician workload increase
- ☐ Un-reimbursed tasks

Other (please specify)

Page 6

Direct notification

8. If the direct notification of clinically significant abnormal test results became the norm, please select which test results you would be comfortable with releasing directly to patients. (Select all that apply)

- ☐ Complete blood count
- ☐ Electrolyte panel
- ☐ Blood Glucose
- ☐ Chest x-ray
- ☐ Lipid Profile (TC, HDL, LDL, TG)
- ☐ Thyroid blood tests (TSH, T4, TPO)
- ☐ HIV
- ☐ Urinalysis
- ☐ Cancer screening tests (e.g., Mammography, PAP smear)
- ☐ None of these

Other (please specify)

9. Please specify at what time interval, after the result became available, you would be comfortable with direct notification of clinically significant abnormal test results to patients.

- ○ 24 hours
- ○ 48 hours
- ○ 7 days
- ○ 14 days
- ○ 30 days

Other (please specify)

Page 7

10. Please indicate your level of agreement with the following statement

	Strongly Disagree	Moderately Disagree	Slightly	Neither agree nor disagree	Slightly Agree	Moderately Agree	Strongly Agree
Do you agree that there should be **direct patient notification** of normal test results?	○	○	○	○	○	○	○

Page 8

Direct notification

11. Please indicate your level of agreement with the following statements:

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Neither Agree nor Disagree	Slightly Agree	Moderately Agree	Strongly Agree
Overall, a direct notification system would reduce the number of patients lost to follow-up.	○	○	○	○	○	○	○
Overall, a direct notification system would reduce physician workload	○	○	○	○	○	○	○

***12. In the past year, I have missed an abnormal laboratory or imaging result that led to delayed patient care.**

- ○ Yes
- ○ No
- ○ Don't know

13. If you answered yes, please specify the type of result that was missed or for which follow-up was delayed. (Select all that apply)

- ☐ Chemistry
- ☐ Hematology
- ☐ Microbiology
- ☐ Pathology
- ☐ Radiology
- ☐ Cancer screening tests (e.g., Mammography, PAP smear)
- ☐ Don't know

Other (please specify)

***14. In the past year, colleagues I work with missed an abnormal laboratory or imaging test result that led to delayed patient care.**

- ○ Yes
- ○ No
- ○ Don't know

15. If you answered yes, please specify the type of result that was missed or for which follow-up was delayed. (Select all that apply)

- Chemistry
- Hematology
- Microbiology
- Pathology
- Radiology
- Cancer screening tests (e.g., Mammography, PAP smear)
- Don't know

Other (please specify)

Page 13

Demographics

16. Gender

- Male
- Female

17. Age range (years)

- 20-29
- 30-39
- 40-49
- 50-59
- 60-69
- 70+

Page 14

Demographics

18. What is your racial origin?

- White
- Black or African American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or Other Pacific Islander
- Prefer not to answer

Other (please specify)

19. What is your Ethnicity?

- Hispanic or Latino
- Not Hispanic or Latino
- Prefer not to answer

Page 15

Demographics

20. Job classification:

- Attending
- Non-academic physician
- Academic physician (Currently involved in academic activities as professor, instructor, etc.)
- Resident
- Intern

Other (please specify)

21. What is your speciality?

- Primary care (including internal medicine, hospitalist, general practice, and family medicine)
- Emergency Medicine
- Cardiology
- Endocrinology
- Gastroenterology
- Hematology/Oncology
- Nephrology
- Pulmonary Disease
- Radiology
- Rheumatology
- General Surgery
- Specialty Surgery

Other medical specialists (please specify) :

22. Please list the country where you completed medical school.

Page 16

Demographics

23. Type of Institution where you practice most of your care.

- Public
- Private

Other (please specify)

24. What is the average number of patients you see per week?

25. Employment at current institution?

- Part-time
- Full time

Other (please specify)

26. Number of years in practice?

- Less than 5 years
- 5-10 years
- 11-15 years
- 16-20 years
- More than 20 years

Demographics

27. Please indicate your level of agreement with the following statements:

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Neither Agree nor Disagree	Slightly Agree	Moderately Agree	Strongly Agree
The ethical principal of patient autonomy guides my healthcare decisions (e.g., What my patient wants)							
The ethical principal of beneficence guides my healthcare decisions (e.g., What I believe is best for the patient)							
The ethical principal of justice guides my healthcare decisions (e.g., Fair distribution of healthcare resources for all patients)							

28. When it comes to making decision about my patients' care, I am most comfortable when (select one):

- I make decision about treatment
- I make the final decision but consider the patient's opinion
- The patient and I share responsibility for deciding treatment
- The patient makes the final decision but considers my opinion
- The patient makes the final selection with little input from me

Additional comments

29. Would you like to include any additional comments?

Appendix C: Article Three Interview Guide

Interview Guide

Interview Guide – draft

Section 1 – General health information management

- Can you talk about how you currently manage your health information?
    - Probes
        - For instance, when your doctor suggests a test, a medication or makes a diagnosis, what do you do?
            - Examples: Ask the doctor for more information, Contact friends/family with medical expertise, internet searches
        - How do you keep track of your medical information?
            - Examples: Files at home, Online, doctor maintains them
- Do you typically use your portal to access your test results? (If clarification is needed – for instance, if you had a test done today, would do you look for it in your portal later that day or the next day or would you wait for a call?)
    - Probes –
        - If no, what are some of the reasons?
        - If yes, what are some of the reasons?
        - Tell me about the benefits of receiving test results through the portal?
        - Talk about any problems with receiving test results through the portal?

Section 2 - Test result specific

- Can you talk about a time you received an abnormal test result through your portal?
    - Probes-
        - What was the test?
        - Why was it ordered?
        - Did you know what the test was for at the time of the test (did your physician tell you why s/he was ordering it)?
        - How did you know it would be available on the portal?
- Talk about when you received the results – what happened?
    - Probes –
        - How did you find out about the result – did you receive it first from the portal or the physician's office?
        - Were you waiting to receive the test results?
        - How did you feel (emotionally)?
        - How long did you wait to log onto the portal?
- After your received the results, talk about what you did next?
    - Probe –

        - What was the first thing you remember doing?
        - Did you contact your physician about the test result?
        - Did you look up the result online?
        - Did you talk to friends/family about what the result means?
- Did the physician who ordered the test talk to you about the portal?
    - Did s/he tell you it would be available on the portal?
- **If applicable**: Talk about how you felt receiving a test result through the portal prior to being contacted by your health care provider.

Section 3 – PHR preferences

- How would you prefer to receive your test results? (Examples: physician, letter, email, secure message, PHR)
    - Normal
    - Abnormal
    - Sensitive tests (HIV, genetics, pathology)
- Some healthcare institutions make abnormal test results available through the PHR at the same time they are available to the physician.
    - Are you comfortable receiving test results through your portal prior to being contacted by your Physician/staff? ("It depends on the test" – talk about that, what kind of tests are you more or less comfortable with?)
    - Are you comfortable waiting for waiting for your doctor to review your test results and then providing them to you?
- Did your experience with the test result we discussed earlier influence your test result notification preferences?
- Have any of your physicians every spoken to you about your portal? If so, can you talk about that conversation?
    - Probes:
        - Did anyone (physician, nurse, staff) mention that you could log on to your portal to get your test results?
        - Did anyone encourage you to sign up?
        - Did your physician or nurse encourage you to use the secure message/email feature in your PHR to contact them?

Appendix E - Curriculum Vitae

TRABER DAVIS GIARDINA, MA, MSW

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EDUCATION

2010-2014	Ph.D. Candidate, Graduate College of Social Work, University of Houston
2005-2007	Master of Social Work, Graduate College of Social Work, University of Houston Concentration: Qualitative methodology
2002-2005	Master of Sociology, University of New Orleans Concentration: Qualitative methodology Thesis: *Meanings in Transition: Sexuality and Visibility for Partners of Transgender Men (FTM)* Chair: Pamela Jenkins, Ph.D., University of New Orleans
1997-2002	Bachelor of Liberal Arts, English and Sociology, University of New Orleans

PROFESSIONAL EXPERIENCE

2007-Present	Research Assistant, Houston Center for Quality of Care and Utilization Studies, Houston, TX
2007	Policy Analyst, Legislative Study Group, 81st Legislative Session, Austin, TX
2005-2007	Qualitative Data Analyst, Contract, New Orleans, LA

FELLOWSHIP

2003-2005	Graduate Research Assistant, Center for Hazards Assessment, Response and Technology, University of New Orleans, New Orleans, LA

PUBLICATIONS

Published in peer review journals

1. **Giardina, T.D.**, Menon, S., Parrish, D., Sittig, D.F., Singh, H. Patient access to medical records and health care outcomes: A systematic review. *J AM Inform Assoc.* 2013. doi: 10.1136/amiajnl-2013-002239. [Epub ahead of print].
2. **Giardina, T.D.**, King, B.J., Ignaczak, A., Paull, D.E., Hoeksema, L., Mills, P.D., Neily, J., Singh, H. (2013) Root Cause Analysis Reports Help Identify Common Factors in Delayed Diagnosis and Treatment of Outpatients. *Health Affair (Millwood).* 32(8);1368-75.

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3. Smith, M.W., **Giardina, T.D.**, Murphy, D.R., Laxmisan, A., Singh, H. (2013) Resilient Actions in the Diagnostic Process and System Performance. *BMJ Qual Saf.* Online. doi:10.1136/bmjqs-2012-001661

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2. **Giardina, T.D.,** Modi, V., Parrish, D., Singh, H. (2013). The patient portal and test result management: An exploratory study of notification preferences. Under Review.

PRESENTATIONS

1. **Giardina, T.D.**, Callen, J., Georgiou, A., Westbrook, J.I., Greisinger, A., Esquivel, A., Forjuoh, S.N., Parrish, D., Singh, H. Releasing Test Results Directly to Patients: A Multisite Survey of Physician Perspectives. 14th Annual Health Services and Outcome Research Conference, Kelsey Research Foundation, Houston, Texas, December 10, 2013.

2. **Davis Giardina, T.**, King, B., Ignaczak, A., Paull, D. Hoeksema, L., Mills, P., Neily, J., Singh, H. Understanding Diagnostic and Treatment Delays in Ambulatory Care: A Review of Root Cause Analyses Reports. VA HSR&D National Meeting, Washington, DC, July 16-19, 2012.

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6. Singh, H., **Davis Giardina, T.**, Forjuoh, S.N., Reis, M.D., Kosmach, S., Khan, M.M., Thomas, E.J. Use of Close Follow-Up as a Strategy to Mitigate Harm from Diagnostic Error in Primary Care. Society of General Internal Medicine, 34th Annual Meeting, Phoenix, AZ, May 7, 2011.

7. Casciani, H., Duron, J., **Davis Giardina, T**., McIngvale, E. Using Evidence-Based Practice for Effective Social Work. Invited Panel Discussion. PhD Student Symposium, University of Houston, Graduate College of Social Work. Houston, TX. March 3, 2011.

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11. Singh, H., **Davis, T.**, Khan, M.M., Thomas, E.J. Detection of diagnostic errors using electronic health records. Society of General Internal Medicine 32nd Annual Meeting, Miami Beach, FL, May 15, 2009.

12. Singh, H., Hirani, K., Kadiyala, H., Rudomiotov, O., **Davis, T.**, Khan, M.M., Wahls, T.L. Lung cancer diagnosis in the era of electronic medical records. Society of General Internal Medicine 32nd Annual Meeting, Miami Beach, FL, May 15, 2009.

13. Burley, D., **Davis, T.** Losing Ground in South Louisiana. Southern Sociological Society Annual meeting, Atlanta, GA, April 16, 2004.

TEACHING EXPERIENCE

2010	**Guest Lecturer.** Graduate College of Social Work, University of Houston. Lecture: The Affordable Care Act. Course: Affecting Social Policy
2011	**Teaching Assistant.** School of Social Work, University of Houston, Houston, TX Course: Program Evaluation

SERVICE

2012-2013 **Editorial Board**, *Perspectives of Social Work*, Graduate College of Social Work, University of Houston

2011-2012 **Editor**, *Perspectives of Social Work*, Graduate College of Social Work, University of Houston

2010-2011 **Associate Editor**, *Perspectives of Social Work*, Graduate College of Social Work, University of Houston

PROFESSIONAL MEMBERSHIP

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