Opt-in consent policies: potential barriers to hospital health information exchange

Nate C. Apathy, BS,

Doctoral Candidate, Richard M. Fairbanks School of Public Health, Indiana University, Indianapolis, IN

Regenstrief Institute, Indianapolis, IN

A Jay Holmgren, MHI

Doctoral Candidate, Harvard Business School, Cambridge, MA

Abstract

Objectives: First, to assess whether hospitals in states requiring explicit patient consent ("opt-in") for health information exchange (HIE) are more likely to report regulatory barriers to HIE. Second, to analyze whether these policies correlate with hospital volume of HIE.

Study Design: Cross-sectional analysis of US non-federal acute care hospitals in 2016.

Methods: We combined legal scholarship surveying HIE-relevant state laws with the AHA Annual IT Supplement for regulatory barriers and hospital characteristics. Data from CMS reports for hospitals attesting to Meaningful Use Stage 2 in 2016 (MU2, renamed "Promoting Interoperability" in 2018) captured hospital HIE volume. We used multivariate logistic regression and linear regression to estimate the association between opt-in state consent policies and reported regulatory barriers and HIE volume, respectively.

Results: Hospitals in states with opt-in consent policies were 7.8 percentage points more likely than hospitals in opt-out states to report regulatory barriers to HIE (p=0.03). In subgroup analyses, this finding held among hospitals that did not attest to MU2 (7.7pp, p=0.02). Among hospitals attesting, we did not find a relationship between opt-in policies and regulatory barriers (8.0pp, p=0.13), nor evidence of a relationship between opt-in policies and HIE volume (ß=0.56, p=0.76).

Conclusions: Our findings suggest that opt-in consent laws may carry greater administrative burdens compared to opt-out policies. However, less technologically advanced hospitals may bear more of this burden. Furthermore, opt-in policies may not impact HIE volume for hospitals that have already achieved a degree of technological sophistication. Policymakers should carefully consider the incidence of administrative burdens when crafting laws pertaining to HIE.

Precis:

natea@iu.edu, 913-530-5741, 1050 Wishard Blvd, Indianapolis, IN 46202.

Opt-in patient consent requirements for health information exchange correlate with more reported regulatory barriers, especially among less technologically advanced hospitals.

Keywords

health information exchange; health information technology; patient consent policies; meaningful use; regulatory barriers

Introduction

Policymakers continue to advance interoperable health information exchange (HIE) as an important goal for the US health care system.[1,2] One of the anticipated benefits of HIE is reduced administrative burden of data sharing, which in turn can give providers more complete information at the point of care.[3–5] Digitization of the US health care system has brought us closer to realizing this goal through the HITECH Act's incentives for hospitals and physician practices to adopt increasingly sophisticated electronic health records (EHRs).[5,6] These incentives included supplementary Medicare reimbursements for hospitals that successfully demonstrated "meaningful use" of EHR functionality.[5] In the case of HIE, this consisted of sending electronic summaries of care during care transitions.[4] Despite these incentives, HIE capabilities among hospitals have continued to lag behind.[7,8] As patients struggle with a lack of infrastructure for exchange between providers,[9] hospitals have their own administrative burdens to enabling HIE, including the complex regulatory environment governing HIE across states;[10] which can create significant barriers for hospitals who already face uncertain incentives to share patient data.

Perhaps the biggest legal challenge to a robust national HIE infrastructure is the varied state policies regarding patient consent for data exchange.[10] State variation in consent policies comes from different approaches to default patient consent assumptions. States generally have either "opt-in" or "opt-out" patient consent requirements, although some have ambiguous or undefined patient consent policies.[11] Opt-in states like New York assume no patient consent and therefore require explicit consent from each patient to allow providers to share and access that patient's information via the HIE. (10 NY ADC § 300.5) Opt-out states like Kansas assume patient consent for exchange, but allow patients the opportunity to decline exchange. (KSA § 65–6832) Rates of non-participation in HIE have been found to vary by consent policy, with more than 95% of patients participating under opt-out scenarios and only 19% participating in opt-in settings,[10] consistent with the behavioral economics literature.[12–15] In the case that a patient chooses to not participate in HIE, that patient's information is not permitted to be shared or sent outside of the organization collecting the information. Disallowing this sharing would in turn depress the overall volume of HIE observed at the organization. Therefore, one would expect organizations under opt-in policies to engage in less exchange due to lower patient participation rates.

Despite this potential impact of opt-in consent policies on HIE, we are aware of no national studies of the impact of these laws on hospitals' barriers to and volume of HIE. Previous studies have examined patient decisions in the context of a single HIE and individual patient-level factors associated with opt-in to health information exchange data sharing.[16,17]

These studies provide important insight into the factors related to patients' HIE consent decisions, and imply that there is significant administrative cost to obtaining patient consent. Research at the organizational level has found that policies requiring explicit (i.e. opt-in) consent correlate with lower volume of clinical document exchange.[18] Finally, two nationwide studies have found the presence of consent laws to be associated with increased participation in HIE efforts.[19,20] Importantly, these studies compared the presence of explicit consent laws to the lack of consent laws, as unclear legal environments (i.e. when no consent laws exist) often require organizations to behave as conservatively as possible. To advance this literature, it is important to also study the nature of these laws. However, we are aware of no studies directly comparing opt-in and opt-out consent policies at the state level to determine if opt-in approaches lead to perceived regulatory barriers to HIE for hospitals and, in turn, reduced HIE volume.

The purpose of our study was two-fold. First, we aimed to estimate the relationship between state laws governing patient consent requirements and hospitals' probability of reporting regulatory and compliance barriers to HIE. Our second aim was to examine the extent to which these laws correlated with the level of hospital engagement in HIE. We anticipate our findings to be of interest to both state and federal policymakers and regulators currently crafting regulations for the future of health information exchange in the 21st Century Cures Act.[21] Understanding the impact of different regulatory approaches to health information exchange on creating barriers for hospital participation and volume of data sharing is critical to informing the construction of future HIE infrastructure.

Methods

Setting and Data Sources

We used the American Hospital Association (AHA) Annual Survey and AHA Annual Survey - IT Supplement for 2016, as well as hospital-level Meaningful Use Stage 2 (MU2, renamed "Promoting Interoperability" in 2018) performance measures. The AHA Annual Survey is sent annually to the CEO of every hospital in the United States, with a request to complete it or designate completion to the most knowledgeable person in the organization. Respondents receive multiple mailings and follow-up phone calls. The 2016 survey was fielded in the period of November 2016 – April 2017, and the IT Supplement received a response rate of 58%. We limited our sample to non-federal, acute care hospitals in order to construct the largest sample of comparable hospitals in the data, especially those subject to similar market forces. This sample construction allows for comparison with the existing literature discussing hospital IT adoption and use.[6,22,23] Our analytic sample included 2,613 hospitals.

We merged this data with 2016 publicly reported MU2 health information exchange performance measures using the hospital's National Provider Identifier (NPI) to obtain the level of HIE usage for each hospital. MU2 performance measures are derived from the Medicare incentive program for hospitals and providers to adopt and use increasingly sophisticated health IT. Hospitals report performance measures annually, with successful attestation translating into increased reimbursements from Medicare. This data was available

only for hospitals that had attested to MU2 in 2016, limiting our sub-sample for this analysis to 1,135 hospitals.

Measures

Regulatory Barriers to Health Information Exchange—For our first aim examining the relationship between consent policy and hospitals experiencing regulatory barriers to HIE, our dependent variable was hospital-reported regulatory barriers to HIE. In the AHA survey, hospitals describe "barriers when trying to electronically (not eFax) send, receive, or find (query) patient health information to/from other care settings or organizations." We classified hospitals as experiencing regulatory barriers to HIE if they responded "Yes" to the following barrier: "The complexity of state and federal privacy and security regulations makes it difficult for us to determine whether it is permissible to electronically exchange patient health information."

Hospital Health Information Exchange Volume—For our second aim evaluating the relationship between state laws and the amount of HIE in which a hospital engaged, our primary dependent variable was hospital level of HIE usage, measured via MU2 public use files for eligible hospitals in 2016. As a requirement of attestation to MU2, hospitals report the percentage of patient transfers sent with electronic summaries of care (eSCR). To successfully attest, the hospital must send at least 10 percent of transfers with eSCR. This measure is calculated by dividing the number of patient transitions or referrals in which an eSCR was transmitted using certified EHR technology (CEHRT) or an HIE or health information organization (HIO) by the total number of transfers of care a hospital completes during the 90-day MU reporting period.[24] This measure has been used in previous work investigating how hospital factors and payment reform efforts relate to the level of HIE among hospitals.[7,23] It is worth noting that the nature of this measure introduces possible confounding via selection bias for this aim. We discuss the implications and empirical evaluations of this selection bias in the limitations section. Additionally, it may be that hospitals already using HIE and attesting to MU2 may be insensitive to regulatory barriers, having already achieved HIE in their state's regulatory environment. We investigate this specifically in aim one of our analysis.

State Health Information Exchange Consent Laws—The independent variables of interest capture state laws governing patient consent policies for the HIE that were in effect as of June 2016 and does not include the effective dates of each policy, thus precluding a longitudinal analysis. Schmit, et al. surveyed the HIE legal landscape as of 2016 and classified state laws that impacted HIE organizations and participants.[11] Our independent variable captures the state law regarding patient consent for HIE. These laws are classified as opt-in, opt-out, or other. (Figure 1) The "other" group consists of state laws that are ambiguous or describe patient HIE participation as "voluntary" without specifying a consent approach. For example, in Texas, the relevant legislation stipulates that HIE organizations may "implement, promote, and facilitate the voluntary exchange of secure electronic health information" (Texas Health & Safety Code § 182.101). Ambiguous state policies were those that could not be interpreted as strictly opt-in or opt-out. For example, Nevada stipulates that patient consent must be obtained upon retrieval of information from an HIE (NRS §

439.589), but does not explicitly dictate the nature of that consent, nor does it clarify rules for consent to patient participation in the HIE prior to information retrieval. We operationalized this variable with opt-out policies as the reference group, to estimate the effect of opt-in consent policies compared to opt-out policies. Our hypothesis was that opt-in consent policies would be associated with greater likelihood of reporting regulatory barriers to exchange. We matched policies via the state each hospital reported in the 2016 AHA survey.

Hospital Characteristics—Control variables were constructed from the AHA IT Supplement to control for a variety of organizational, technological, and market factors that have been shown to be related to the adoption of IT and health information exchange in existing literature.[8,25] We included the following control variables for organizational IT: hospital EHR adoption level (Less than Basic EHR, Basic EHR, or Comprehensive EHR);[26] primary EHR vendor (individual vendors for the top 90% of hospitals were listed individually, with all others classified as "other"). We also included a measure of whether or not the hospital used the dominant EHR in the hospital referral region (HRR), which has been found to be related to HIE capabilities.[27] For our second aim, we included hospital program year in the MU program as a proxy for experience with MU. We controlled for the following hospital factors: participation in a regional health information organization (RHIO); ownership (for-profit, local government, and non-profit); size (less than 100 beds, between 100 and 400 beds, and more than 400 beds); health system membership; teaching hospital status; critical access hospital status; medical home status; participation in CMS' bundled payments program and an Accountable Care Organization (ACO); percentage of total inpatient days for Medicare patients; and percentage of total inpatient days for Medicaid patients. Regional control variables included US Census Region where the hospital is located and urbanicity, defined by core-base statistical area codes (CBSA) of rural, micro, and metro. Finally, we included a measure of HRR market concentration using the Herfindahl-Hirschman Index (HHI). We used the total number of hospital beds per hospital in the HRR as the measure of hospital market share.[28] This was classified into Federal Trade Commission categories of unconcentrated, moderately, and highly concentrated.[29]

Analytic Approach: Design and Statistical Analyses

We examined differences in hospitals under different HIE consent policy regimes, using chi-squared analyses to test for bivariate relationships. We used logistic regression adjusting for hospital technology adoption levels and HIE participation as well as hospital and regional characteristics, with standard errors clustered at the state level to correct for correlation across hospitals in the same state. From these models, we computed marginal effects estimates and 95 percent confidence intervals for ease of interpretation. We also conducted subgroup analyses to disaggregate the findings from aim one across hospitals differing in their levels of technological sophistication. We divided our sample into hospitals attesting to MU (i.e. those with HIE volume performance data) and those not attesting to MU, and used the same logistic regression model. We compared these results to our main model including all hospitals to identify potential differences in the relationship between opt-in consent policies and reported regulatory barriers across these two groups of hospitals. This allowed

us to investigate the hypothesis that less technologically advanced hospitals were more likely to report regulatory barriers than relatively more technologically advanced hospitals.

For our second aim, we used multiple linear regression, controlling for hospital technology adoption and experience in the Meaningful Use program, organizational factors, and regional characteristics. We clustered standard errors at the state level. As a robustness check for both aims, we added controls for potential collider variables capturing hospital HIE capabilities that we excluded from our main regression models in separate regression models to validate that our primary estimates did not differ from those adjusting for these capabilities. All data preparation and analyses were performed in R using the RStudio development environment.[30,31]

Results

State Consent Laws

In the legal data collected by Schmit, et al., 34 states had HIE consent policies defined as either opt-in, opt-out, or other.[11] The remaining states and the District of Columbia are classified as missing in our dataset. In 2016, 7 states had opt-in HIE consent policies, 15 states had opt-out policies, and 12 were classified as having other approaches (Figure 1). In our primary regression model, there were 2,023 hospitals with complete data from these 34 states. Of these hospitals, 478 were from opt-in states, 783 from opt-out states, and 762 from states classified as other.

Barriers to Health Information Exchange

On average, 13 percent of hospitals reported regulatory barriers to health information exchange in 2016. In our bi-variate analysis, 20 percent of hospitals in states with opt-in consent policies reported regulatory barriers to HIE, compared to 13 percent of hospitals in states with opt-out, ambiguous, or voluntary policies (Figure 2), a statistically significant difference (p<0.001). Hospitals also differed across consent policy types with respect to their RHIO participation, ownership, size, region, medical home status, critical access status, participation in ACOs and bundled payment programs, and location in urban or rural areas (Table 1). A complete table of descriptive statistics across all covariates can be found in eAppendix Table 1.

In our logistic regression, hospitals in states with opt-in consent policies had an 7.8 percentage point higher probability of reporting regulatory barriers to health information exchange, compared to hospitals in states with opt-out policies (Average Marginal Effect (AME) = 0.087; p=0.034, Table 2). In a second model using other consent policies as the reference, neither opt-in nor opt-out policies illustrated a relationship with reporting regulatory barriers. Full regression results for our first aim, with both opt-out and other policies as the reference policy, are available in eAppendix Tables 2 and 3.

In our subgroup analyses stratifying hospitals by Meaningful Use attestation for health information exchange level, we found no evidence of a relationship between opt-in consent policies and reported regulatory barriers for hospitals that reported Stage 2 Meaningful Use attestation (AME=0.08; p=0.13, Table 2). However, finding that opt-in consent laws were

associated with perceived legal barriers to HIE held among the subsample of hospitals not attesting to Meaningful Use (AME=0.077; p=0.019, Table 2), which` may suggest that the burden of opt-in policies falls primarily on less technologically advanced hospitals. The full results of our subgroup analyses can be found in eAppendix Tables 4 and 5.

Finally, in our robustness check that included hospital HIE capabilities as potential collider variables, our primary aim one finding held in direction, magnitude, and significance (eAppendix Table 6). HIE capabilities of finding, sending, receiving, and using electronic patient health information were excluded from our main regression models examining consent policies and hospital-reported regulatory barriers to avoid collider bias, however these findings do not suggest that these variables constitute colliders in this analysis.

Volume of Health Information Exchange

Among hospitals reporting to MU2, on average, hospitals reported 43% of patient transfers were sent with an electronic summary of care record (Table 1). In bi-variate analyses of our second research aim, hospital HIE volume differed across state HIE consent policies, with hospitals in opt-in states reporting an average of 42 percent of transfers sent with eSCR compared to 45 percent and 41 percent of transfers in opt-out and other policy states, respectively (p=0.016). However, in multivariate linear regression adjusting for hospital EHR adoption, demographics and regional characteristics, we found no evidence of a relationship between opt-in state HIE consent policies and volume of HIE usage, compared to opt-out policies (ß=0.560; p=0.763, Table 2). Full regression results for the second aim can be found in eAppendix Table 7. Additionally, given the lower levels of HIE volume in opt-in states and the attenuation of that relationship in the adjusted model, we suspected that opt-in consent policies may be related to EHR adoption, which then would impact HIE volume. To test this, we conducted a multinomial logistic regression with consent policy type as the independent variable and EHR adoption level as the dependent variable. This test showed no significant relationship between these variables (eAppendix Figure 1).

Discussion

Our study is the first to directly compare opt-in and opt-out health information exchange consent policies across states. We found that, on average, hospitals in states with opt-in consent policies for HIE were more likely to report regulatory barriers to HIE compared to hospitals in states with opt-out consent policies, even when adjusting for a variety of hospital information technology, organizational, and market characteristics. This finding suggests that opt-in policies may uniquely contribute to hospital barriers to HIE compared to opt-out policies. Given the administrative burden that opt-in consent policies introduce,[17] our findings are consistent with a larger body of work supporting the claim that opt-in policies are more burdensome to implement. However, policies requiring explicit consent such as these may serve an important protective role in the use of patient health information.

Our sub-group analyses found that the relationship between opt-in consent policies and reported regulatory barriers only held for hospitals not attesting to MU2 in 2016. Hospitals subject to opt-in consent but having some degree of interoperable HIE capabilities were not more likely to report regulatory barriers. This finding supports the interpretation that

regulatory barriers may be borne primarily by hospitals that lag in technological sophistication and health information exchange capabilities in particular, or that opt-in consent policies discourage health information exchange on the extensive margin only. Opt-in consent policies may in turn further delay these hospitals in achieving interoperable health information exchange.

Despite hospitals' increased likelihood of reporting regulatory barriers to HIE in the presence of opt-in policies, we found no evidence of a relationship between opt-in consent policies and volume of HIE usage. This finding suggests that consent policy type does not directly influence the amount of HIE in which a hospital engages, though this analysis is limited only to the subgroup of hospitals attesting to MU2 and, as noted above, no more likely to report regulatory barriers to HIE. Additionally, given the cross-sectional nature of our data, we are unable to observe hospitals' reported regulatory barriers to HIE in prior years. Regulatory barriers to HIE, including opt-in consent policies, may have been more salient in previous years as hospitals were establishing HIE capabilities, and by 2016 these barriers may have been largely overcome.

Taken together, these findings illustrate that while opt-in consent regimes are related to barriers to HIE for hospitals, relatively technologically sophisticated hospitals use HIE at the same rate regardless of their state's consent policy. That is to say that while opt-in consent policies may contribute to a variety of administrative or technical barriers, organizations are able to overcome these barriers *if and when interoperable data exchange becomes an important institutional goal*. Our findings fit with other work finding that both incentives and hospital technical capabilities relate to HIE volume.[7,23]

While we find opt-in consent policies are related to higher reported rates of regulatory barriers to HIE among hospitals, opt-out policies may not be strictly superior. Opt-out policies raise concerns among patients of violating rights to informed choice.[32] While opt-out consent policies are generally less burdensome for clinicians and administrators, and are fully within the law under HIPAA, some evidence shows that patients may prefer opt-in systems for HIE consent.[33] Opt-in consent policies are often motivated by these twin forces that prioritize privacy and patient preference, despite the administrative burdens they may bring.[32] Policymakers should carefully consider these trade-offs going forward in deciding how laws pertaining to HIE should be crafted.

Future studies should consider directly examining variation in consent laws across jurisdictions or hospitals in different jurisdictions that share substantial numbers of patients, as the regulatory differences specific to patient consent in these settings are likely to be highly salient to hospitals. Furthermore, studies should examine the extent to which the volume of HIE is associated with the ultimate goals of interoperable HIE, namely improving efficiency, quality of care, and eventually health outcomes.

Limitations

Our study has several limitations. First, the analysis is cross-sectional in nature and only representative of hospitals and state policies in 2016. Furthermore, we can draw no causal conclusions given the cross-sectional data and lack of exogenous variation. Given that both

the database of state HIE laws and Meaningful Use performance reporting are as of 2016, we were limited in our ability to analyze the effects of laws over time. States passed HIE laws over a number of years, further limiting longitudinal analysis. For example, the effective dates of consent laws range from June 2008 to March 2016, with two-thirds going into effect after 2011. Second, some states in the legal database contained missing values for certain laws, in particular consent policies. Despite the listwise deletion of hospital observations in states with missing values for HIE policies, our sample sizes remained relatively robust from the states that were included in the analysis. However, this limits the generalizability of our findings outside of states included in the analysis, and prevents us from drawing conclusions at the national level. Third, in the analysis for our second research aim, it is possible that our estimates are impacted by selection bias. We only observe hospitals that successfully attested to Meaningful Use, a sample that may exclude hospitals with systematically lower levels of health IT sophistication from those analyses. This may be especially pronounced in analyses of HIE volume due to the volume threshold required for MU2 attestation. However, previous work has found limited evidence of selection bias in this sample of hospitals.[7] In this work, Lin, et al. used a Heckman selection model to identify if hospitals that did not attest to MU2 had lower predicted HIE volume compared to those that did. They found that the Heckman model estimates were essentially the same as multiple linear regression, indicating that using only MU2-attesting hospitals was unlikely to bias the findings. Furthermore, our measure of HIE usage – percentage of patient transfers sent with eSCR – has limitations in that it may not be perfectly sensitive to state consent policies, given that eSCR transitions have low administrative costs once exchange capabilities are in place. Nevertheless, we do find variation in this variable across hospitals, suggesting that rates of eSCR are not uniformly distributed.

Implications

Any policies states implement for health information exchange will have trade-offs. In the case of opt-in consent policies, states may choose to prioritize patient privacy, right to consent, and patient preferences at the cost of added administrative burden and regulatory hurdles for hospitals and providers. Policymakers should consider the existing legal structures related to health information exchange in their region and the technical capabilities of hospitals in their states to anticipate the burden that opt-in consent policies are likely to bring. Furthermore, federal policymakers tasked with reducing administrative burdens related to the use of EHRs – a specific provision of the 21st Century Cures Act – should consider that hospitals at varying levels of technological sophistication may experience different administrative burdens.

Conclusions

We compared opt-in state health information exchange consent policies to opt-out policies in 2016, and found that hospitals in states with opt-in consent policies were 7.8 percentage points more likely to report experiencing regulatory barriers to HIE. However, hospitals attesting to MU2 in these states did not systematically engage in less HIE, suggesting that these barriers are not borne by more technologically advanced hospitals. Our results fit with previous literature emphasizing the added administrative burden of opt-in consent policies

compared to opt-out policies, especially for less technologically advanced hospitals. Policymakers should consider the complexity of regional differences in consent policies and the incidence of regulatory burdens when crafting HIE consent policies or guidance to hospitals for policy compliance.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

References

1. Verma S. Remarks by CMS Administrator Seema Verma at the HIMSS18 Conference. Presented at the: Healthcare Information and Management Systems Society 2018 Conference; March 6, 2018; Las Vegas, NV https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-03-06-2.html. Accessed July 5, 2018.

2. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. Vol 84. Federal Register; 2019 https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf.

3. Walker J, Pan E, Johnston D, Adler-Milstein J, Bates DW, Middleton B. The value of health care information exchange and interoperability. Health Aff. 2005;Suppl Web Exclusives:W5-W10 - W5-W18. doi:10.1377/hlthaff.w5.10

4. Williams C, Mostashari F, Mertz K, Hogin E, Atwal P. From the Office of the National Coordinator: the strategy for advancing the exchange of health information. Health Aff. 2012;31(3):527–536. doi:10.1377/hlthaff.2011.1314

5. Washington V, DeSalvo K, Mostashari F, Blumenthal D. The HITECH Era and the Path Forward. N Engl J Med. 2017;377(10):904–906. doi:10.1056/NEJMp1703370 [PubMed: 28877013]

6. Adler-Milstein J, Jha AK. HITECH Act Drove Large Gains In Hospital Electronic Health Record Adoption. Health Aff. 9 2017 http://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1651. Accessed November 9, 2017.

7. Lin SC, Everson J, Adler-Milstein J. Technology, Incentives, or Both? Factors Related to Level of Hospital Health Information Exchange. Health Serv Res. 2 2018. doi:10.1111/1475-6773.12838

8. Holmgren AJ, Patel V, Adler-Milstein J. Progress In Interoperability: Measuring US Hospitals' Engagement In Sharing Patient Data. Health Aff. 2017;36(10):1820–1827. doi:10.1377/hlthaff.2017.0546

9. Ancker JS, Edwards AM, Miller MC, Kaushal R. Consumer perceptions of electronic health information exchange. Am J Prev Med. 2012;43(1):76–80. doi:10.1016/j.amepre.2012.02.027 [PubMed: 22704751]

10. Mello MM, Adler-Milstein J, Ding KL, Savage L. Legal Barriers to the Growth of Health Information Exchange-Boulders or Pebbles? Milbank Q. 2018;96(1):110–143. doi:10.1111/1468-0009.12313 [PubMed: 29504197]

11. Schmit CD, Wetter SA, Kash BA. Falling short: how state laws can address health information exchange barriers and enablers. J Am Med Inform Assoc. 2018;25(6):635–644. doi:10.1093/jamia/ocx122 [PubMed: 29106555]

12. Johnson EJ, Goldstein DG. Defaults and donation decisions. Transplantation. 2004;78(12):1713–1716. https://www.ncbi.nlm.nih.gov/pubmed/15614141. [PubMed: 15614141]

13. Benartzi S, Thaler R. Heuristics and Biases in Retirement Savings Behavior. J Econ Perspect 2007;21(3):81–104. doi:10.1257/jep.21.3.81

14. Junghans C, Feder G, Hemingway H, Timmis A, Jones M. Recruiting patients to medical research: double blind randomised trial of "opt-in" versus "opt-out" strategies. BMJ. 2005;331(7522):940. doi:10.1136/bmj.38583.625613.AE [PubMed: 16157604]

15. Patel MS, Volpp KG. Leveraging insights from behavioral economics to increase the value of health-care service provision. J Gen Intern Med. 2012;27(11):1544–1547. doi:10.1007/s11606-012-2050-4 [PubMed: 22549296]

16. Yaraghi N, Sharman R, Gopal R, Singh R, Ramesh R. Drivers of information disclosure on health information exchange platforms: insights from an exploratory empirical study. J Am Med Inform Assoc. 2015;22(6):1183–1186. doi:10.1093/jamia/ocv086 [PubMed: 26275625]

17. Yaraghi N, Gopal RD, Ramesh R. Doctors' Orders or Patients' Preferences? Examining the Role of Physicians in Patients' Privacy Decisions on Health Information Exchange Platforms. Journal of the Association for Information Systems. 2019;20(7):928–952. https://search.ebscohost.com/login.aspx?direct=true&db=bth&AN=137905802&site=eds-live.

18. Downing NL, Adler-Milstein J, Palma JP, et al. Health information exchange policies of 11 diverse health systems and the associated impact on volume of exchange. J Am Med Inform Assoc. 2017;24(1):113–122. doi:10.1093/jamia/ocw063 [PubMed: 27301748]

19. Adjerid I, Acquisti A, Telang R, Padman R, Adler-Milstein J. The Impact of Privacy Regulation and Technology Incentives: The Case of Health Information Exchanges. Manage Sci. 2016;62(4):1042–1063. doi:10.1287/mnsc.2015.2194

20. Brown-Podgorski BL, Hilts KE, Kash BA, Schmit CD, Vest JR. The Association Between State-Level Health Information Exchange Laws and Hospital Participation in Community Health Information Organizations. AMIA Annu Symp Proc. 2018;2018:313–320. https://www.ncbi.nlm.nih.gov/pubmed/30815070. [PubMed: 30815070]

21. Health Information Technology Advisory Committee (HITAC) | HealthIT.gov. https://www.healthit.gov/hitac/committees/health-information-technology-advisory-committee-hitac. Accessed April 20, 2018.

22. Office of the National Coordinator for Health Information Technology. Non-Federal Acute Care Hospital Electronic Health Record Adoption. Office of the National Coordinator for Health Information Technology; 2017 dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.

23. Lin SC, Hollingsworth JM, Adler-Milstein J. Alternative payment models and hospital engagement in health information exchange. Am J Manag Care. 2019;25(1):e1–e6. https://www.ncbi.nlm.nih.gov/pubmed/30667611. [PubMed: 30667611]

24. Office of the National Coordinator for Health IT. Transitions of Care Measure Requirements. https://www.healthit.gov/sites/default/files/transitions_of_care_toc.pdf.

25. Adler-Milstein J, Holmgren AJ, Kralovec P, Worzala C, Searcy T, Patel V. Electronic health record adoption in US hospitals: the emergence of a digital "advanced use" divide. J Am Med Inform Assoc. 2017;24(6):1142–1148. doi:10.1093/jamia/ocx080 [PubMed: 29016973]

26. Jha AK, DesRoches CM, Campbell EG, et al. Use of electronic health records in U.S. hospitals. N Engl J Med. 2009;360(16):1628–1638. doi:10.1056/NEJMsa0900592 [PubMed: 19321858]

27. Everson J, Adler-Milstein J. Engagement In Hospital Health Information Exchange Is Associated With Vendor Marketplace Dominance. Health Aff. 2016;35(7):1286–1293. doi:10.1377/hlthaff.2015.1215

28. Fulton BD. Health Care Market Concentration Trends In The United States: Evidence And Policy Responses. Health Aff. 2017;36(9):1530–1538. doi:10.1377/hlthaff.2017.0556

29. Index Herfindahl-Hirschman. United States Department of Justice. https://www.justice.gov/atr/herfindahl-hirschman-index. Published 6 25, 2015 Accessed May 17, 2019.

30. R Core Team. R: A Language and Environment for Statistical Computing. Vienna, Austria: R Foundation for Statistical Computing; 2018 https://www.R-project.org/.

31. Team RStudio. R Studio; 2015 http://www.rstudio.com/.

32. Esmaeilzadeh P, Sambasivan M. Patients' support for health information exchange: a literature review and classification of key factors. BMC Med Inform Decis Mak. 2017;17(1):33. doi:10.1186/s12911-017-0436-2 [PubMed: 28376785]

33. Simon SR, Evans JS, Benjamin A, Delano D, Bates DW. Patients' attitudes toward electronic health information exchange: qualitative study. J Med Internet Res. 2009;11(3):e30. doi:10.2196/jmir.1164

Take-Away Points:

Variation in consent policies for health information exchange pose a challenge to realizing the goal of interoperable HIE. In particular, opt-in policies require explicit patient consent and may impose administrative burdens on hospitals sharing data.

- Hospitals in states with opt-in patient consent requirements for HIE are more likely to report regulatory barriers to exchange, compared to those in states with opt-out policies that assume consent.

- This finding only holds for less technologically advanced hospitals, suggesting that these hospitals may bear more of this burden.

- Among more technologically advanced hospitals, opt-in consent policy was not related to level of HIE.
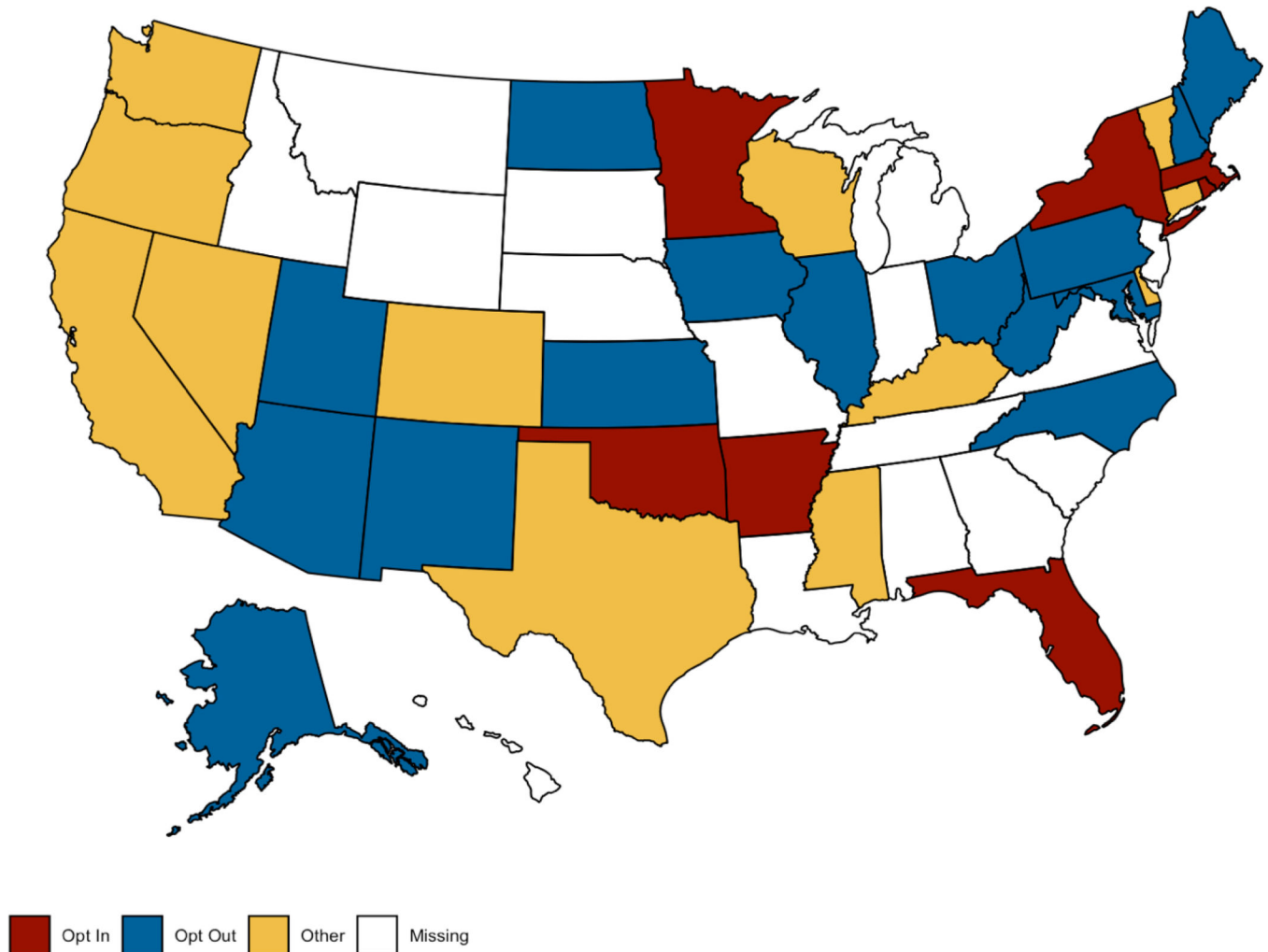
Figure 1. State HIE Consent Policies[a,b]

[a] Source for legal data: Schmit CD, Wetter SA, Kash BA. Falling short: how state laws can address health information exchange barriers and enablers. Journal of the American Medical Informatics Association. 2017 Nov 2;25(6):635–44. Available from: https://doi.org/10.1093/jamia/ocx122.

[b] Map illustrates differences in state laws pertaining to patient consent for health information exchange as of June 2016.
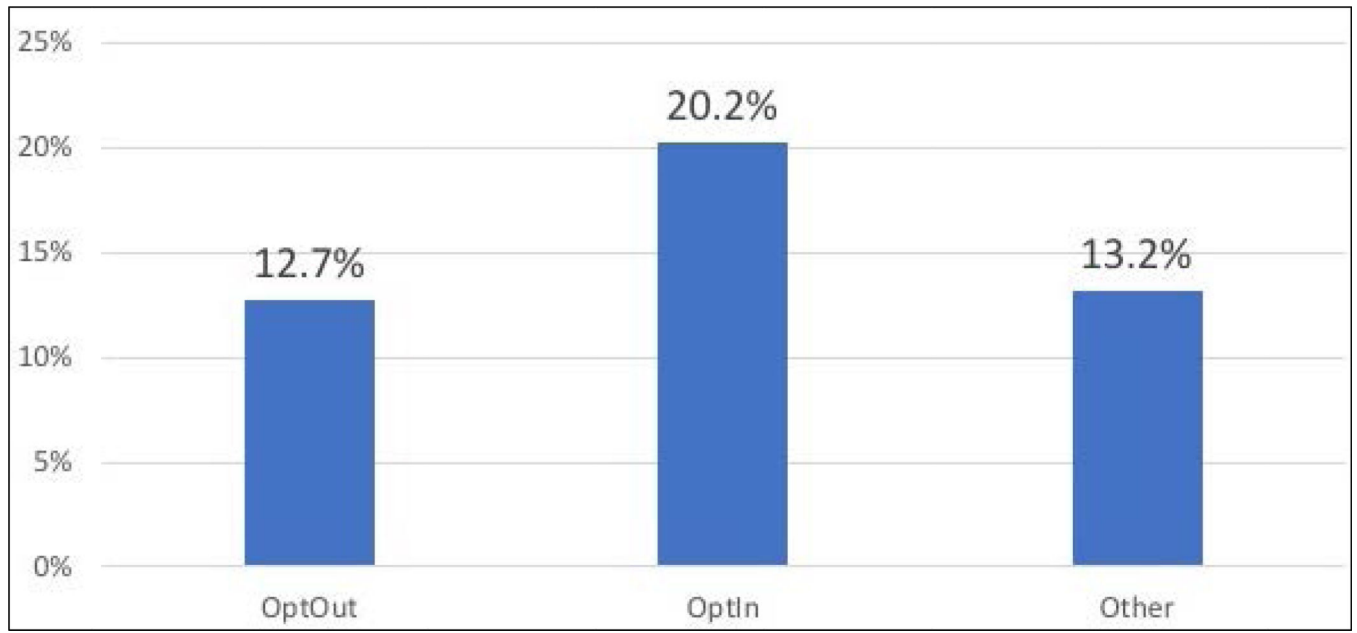
Figure 2. Percentage of hospitals reporting regulatory barriers to health information exchange across consent policy types[a,b]

[a] N=2,613

[b] Hospitals report "barriers when trying to electronically (not eFax) send, receive, or find (query) patient health information to/from other care settings or organizations." We classified hospitals as experiencing regulatory barriers to HIE if they responded "Yes" to the following barrier: "The complexity of state and federal privacy and security regulations makes it difficult for us to determine whether it is permissible to electronically exchange patient health information." Additional hospital statistics stratified by consent policy type are reported in Exhibit 3.

Table 1.

Descriptive statistics of hospital sample, stratified by state consent policy type[a,b]

		Overall	Stratified by Consent Policy Type		
			Opt Out	Opt In	Other
	n	3624	1015	648	950
Report Regulatory Barriers to HIE [***]		467 (12.9)	129 (12.7)	131 (20.2)	125 (13.2)
% of Transfers Sentw/ ESCR, mean (sd) [**]		43.0(24.3)	45.0(25.9)	41.7 (24.0)	41.2 (22.4)
EHR Adoption Level					
Less than Basic		779 (22.2)	190 (19.4)	128 (20.2)	199 (21.5)
Basic EHR		981 (27.9)	274 (28.0)	163 (25.7)	264 (28.5)
Comprehensive EHR		1756(49.9)	513 (52.5)	343 (54.1)	464 (50.1)
Hospital Uses Dominant EHR Vendor		1483 (42.3)	406 (41.3)	284 (44.9)	405 (43.5)
Ownership Type [***]					
Local Government		807 (22.3)	182 (17.9)	139 (21.5)	212 (22.3)
For Profit Hospital		720 (19.9)	140 (13.8)	116 (17.9)	244 (25.7)
Nonprofit Hospital		2097(57.9)	693 (68.3)	393 (60.6)	494 (52.0)
Size [**]					
Small (<100 beds)		1834(50.9)	529 (52.5)	292 (45.2)	482 (51.0)
Midsize (100–400beds)		1384(38.4)	385 (38.2)	268 (41.5)	369 (39.0)
Large (>400 beds)		382 (10.6)	93 (9.2)	86 (13.3)	94 (9.9)
Region [***]					
North Central		1158(32.0)	499 (49.2)	138 (21.3)	109 (11.5)
Northeast		508 (14.0)	196 (19.3)	212 (32.7)	30 (3.2)
South		1389(38.3)	208 (20.5)	298 (46.0)	437 (46.0)
West		569 (15.7)	112 (11.0)	0 (0.0)	374 (39.4)
RHIO Participation [***]		2155(60.9)	663 (67.1)	426 (66.9)	528 (56.7)
Medical Home [**]		817 (28.7)	231 (27.3)	163 (32.5)	185 (22.9)
Health System Member		2360(65.6)	659 (65.4)	439 (68.1)	622 (65.8)
Teaching Hospital		1164(32.4)	332 (32.9)	239 (37.1)	304 (32.2)
Critical Access Hospital [***]		831 (23.1)	283 (28.1)	134 (20.8)	181 (19.2)
ACO Member [***]		1064(36.2)	358 (41.7)	205 (40.0)	242 (29.8)
Bundled Payment Participant [*]		572 (19.6)	358 (42.3)	204 (40.4)	242 (30.0)
CBSA Type [***]					
Rural		680 (18.9)	220 (21.8)	106 (16.4)	138 (14.6)
Micro		541 (15.0)	173 (17.2)	86 (13.3)	127 (13.4)
Metro		2375(66.0)	615 (61.0)	453 (70.2)	680 (72.0)

[a]
Selected hospital characteristics. Numbers of hospitals are reported with percentages of the sample in parentheses. A full table with all characteristics used in multiple regression models can be found in the supplementary appendix.

[b]
Significance levels:

*
 $p < 0.05$

**
 $p < 0.01$

***
  $p < 0.001$

Table 2.

Regression estimates of the relationship between consent and placebo policies and hospital-reported regulatory barriers to exchange and level of HIE use [a,d,h,i]

	Aim One Main Analysis [b] All Hospitals Regulatory Barriers		Aim One: Subgroup Analysis [b] MU2-Attesting Hospitals [e] Regulatory Barriers		Non-MU Attesting Hospitals [f] Regulatory Barriers		Aim Two Main Analysis [c] MU2-Attesting Hospitals [e] HIE Level (MU eSCR%)	
State HIE Policy	AME [95%CI]	p-value	AME [95%CI]	p-value	AME [95%CI]	p-value	Beta [95%CI]	p-value
Patient Consent Policy	n=2,023 [g]		n=1,336		n=687		n=1,127	
Opt-Out (ref)	--	--	--	--	--	--	--	--
Opt-In	**0.078** * **[0.006, 0.151]**	0.034	0.08 [−0.024, 0.183]	0.131	**0.077 [0.013, 0.142]**	0.019	0.56 [−3.1, 4.23]	0.763
Other	0.024 [−0.054, 0.103]	0.539	0.025 [−0.093, 0.143]	0.677	**0.047 [0.004, 0.091]**	0.034	**−3.93 [−7.77, −0.1]**	0.045

[a] Estimates of key independent variables from four regression models.

[b] Multiple logistic regression was used to estimate the marginal effects for state policy variables with hospitals' reported regulatory barriers to HIE.

[c] Multiple linear regression was used to estimate the relationship between state policy variables and hospital reported HIE level, as measured by percentage of transfers sent with electronic summaries of care (eSCR) in 2016. This outcome variable is measured from 10–100 reflecting the hospital reported percentage.

[d] All regression models controlled for hospital EHR adoption level, EHR vendor, use of dominant EHR vendor in HRR, year in MU2 program (aim two only), RHIO participation, ownership type, size, system membership, specialty status, teaching status, critical access status, bundled payment participation, accountable care organization participation, Medicare percentage of inpatient days, Medicaid percentage of inpatient days, hospital referral region concentration classification (HHI), core-based statistical area (Metro, Micro, or Rural), and US Census region. All models used clustered standard errors at the state level.

[e] MU-attesting hospitals are those that reported a performance measure to CMS for percentage of transfers sent with electronic summaries of care in 2016

[f] Non-MU attesting hospitals were those that did not report this measure to CMS in 2016 but were in our sample of AHA IT Survey respondents.

[g] Sample sizes are reported for each regression model. For example, for our primary analysis of the relationship between opt-in consent policies and regulatory barriers to HIE, the sample size was 2,023 hospitals.

[h] Full regression results can be found in eAppendix Tables 2, 4, 5, & 6.

[i] Significance Levels:

*
p<0.05

**
p<0.01

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

***
p<0.001