Effects of Meaningful Use (of Electronic Health Records) on Outcomes of (Quality and Patient Safety of Medical) Care

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Abstract

This paper presents the key findings of a cross-sectional study conducted to examine the effects of meeting the requirements of meaningful use of electronic health records (EHR) on the quality of care and patient safety in acute care hospitals in the United States. The study explored the difference in the quality of care and patient safety in acute care hospitals, which had met the requirements of meaningful use stage1, stage 2, and acute care hospitals which had not met any requirements of meaningful use (MU). The empirical results show that there is a positive association between acute care hospital meeting the requirements for meaningful use and it's clinical outcome measures when controlling for organizational characteristics (size, type, teaching status, and location) and case mix index (CMI). Two one-way ANOVA test was conducted to measure the difference between groups. The main effect, meeting the requirements for meaningful use was not significant indicating there were no significant differences in quality of care in acute care hospitals which had met the requirements for meaningful use. However, the results of one-way ANOVA for patient safety were significant, indicating there were significant differences in patient safety among the acute care hospitals which had met the requirements for meaningful use and those which had not met the requirements for meaningful use.

Keywords: Health information technology, electronic medical records, meaningful use, quality of care, patient safety.

Introduction

Donabedian defined the high quality of care as "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken into account of the balance of expected gains and losses that attend the process of care in all its parts" (Donabedian, 1984, p. 6). To measure the quality of care Donabedian proposed the structure, process, and outcome model. Electronic health records (EHR) are adopted by healthcare organizations to improve the structural aspect of the healthcare organization. Since adopting health information technology is included in the construct of structure, their potential influence on processes and outcomes of care is supported with this framework (Kazley & Ozcan, 2007). The criteria for meeting meaningful use requirements address the structural quality measures: using computerized provider order entry (CPOE), providing patients with an electronic copy of their health records upon request; providing patients with timely access to their medical records, and exchange essential clinical

information electronically with all the stakeholders involved in healthcare delivery (Dimick, 2010). The structural enhancement accorded by the adoption of the EHRs in acute care hospitals is predicted to have a profound impact on the practice of evidence-based medicine, delivering coordinated care by automating and standardizing the processes of care (Miller & Sim, 2004; Hillestad et al., 2005; Kazley & Ozcan, 2007). Structural enhancements and improved processes of care should then result in improved outcomes of care.

Although these two terms, electronic medical records (EMR) and EHRs, have been used interchangeably. EMRs are the building blocks for interoperable EHRs (Garret & Seidman, 2011). Dranove et al., (2012), stated, "an electronic medical record (EMR) is a catch-all expression used to characterize a wide range of technologies used by hospitals to keep track of utilization, costs, outcomes, and billings." Some of the components included in an EMR are clinical decision support systems (CDSS)[1]. computerized provider order entry (CPOE)[2], physician documentation, electronic prescribing (e Prescribing), and electronic medication administration (eMAR). If implemented and adopted by the frontline staff and providers, CPOE, CDSS, eMAR, and e-Prescribing have the potential of improving the outcomes of care and reduce the incidence of in-hospital medical errors (Dranove et al., 2012). EHR[3]s has been defined as a longitudinal patient health record with "access to evidence-based decision support tools that can be used to aid clinicians in decision-making…ensuring that all clinical information is communicated" (Jones et al., 2011).

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Based on the structure-process-outcome model, this study examined the outcomes of care delivered in acute care hospitals, which have implemented and adopted the capabilities of EHRs and thus improved the environment in which care is delivered. Several components of EHRs such as computerized provider order entry (CPOE), clinical decision support system (CDSS), electronic medication administration record (e-MAR), and e-prescribing provide the capabilities of improving the processes of care as all the appropriate patient-specific and medicine specific information is made available at the point of care to the providers involved in patient care. The capabilities of the EHRs are essential resources for reducing medical errors, adverse events and

[1] CDSS provides clinicians real-time feedback about wide-range of diagnostic and treatment-related information as they are entering electronic orders. Basic CDSS can check for errors and interactions: drug-drug interactions, routes, allergies, medications contraindications, and correct dosage.

[2] CPOE systems allow providers to electronically specify medication, procedures and laboratory orders. Patient safety issues attributed to illegible handwritten orders can be addressed with the use of CPOE.

[3] This definition is used to evaluate the effects of meaningful use requirements.

improving the quality of care. Several studies highlighted improved patient safety with the implementation and adoption of EHRs and the use of such components like the CPOE with an embedded CDSS in the delivery of care (Hillestad et al., 2005; Dixon & Zafar, 2009, p. 1; Bates et al., 1998; Bates et al., 1999; Kaushal,et al., 2003; Furukawa, Raghu, & Shao, 2010; Nuckols et al., 2014). In 2009, 11.9% of the U.S. hospitals had either a basic or a comprehensive EMR system. Urban and larger hospitals did better than small, rural, critical access and non-teaching hospitals in adopting EHRs.

Empirical evidence on the effects of MU requirements on quality of care is mixed. Buntin et al. (2011) reviewed the literature on the effects of health information technology from 2007-2010: most of the studies reviewed show significant benefits of health information technology (HIT). However, there were some studies, which highlighted the dissatisfaction with EHRs, in particular among some providers. The authors concluded, "…the expansion of health IT in the healthcare system is worthwhile" (Buntin et al., 2011). Jones et al., (2014), in a recent systematic review, examined the effects of MU on quality, efficiency, and safety of care in ambulatory and inpatient settings in the United States. The review included 236 studies; the researchers used MU functionalities to categorize the literature. The study concluded that although CDSS and CPOE were linked with "clinically and statistically significant benefits." The reduction in medication errors was attributed to CPOE. However the benefits associated with meaningful use were sometimes "not as large as the developers had expected, and there are also examples where the benefits were not realized"(Jones, Rudin, Perry, & Shekelle, 2014). Other systematic reviews conducted to examine the impact of HIT and MU on the quality of care had reported mixed results. However, some also have reported a more positive impact on the quality of care (Garg et al., 2005; Goldzweig, et al., 2009; Millery & Kufafka, 2010)

Samal and colleagues (2014), examined the relationship between meeting 15 core and 5 out of 10 MU objectives and improved quality of care for five chronic conditions at Brigham and Women's Hospital. The authors reported, "marginally better quality for two measures, worse quality for two measures, and not associated with better or worse quality for three measures" (Samal, Wright, Healy, Linder, & Bates, 2014). Appari et al. (2013) used national panel data to examine the impact of meeting MU Stage 1 requirements on hospital process quality measures. The authors concluded that hospitals, which improved their EHR capabilities to meet the requirements for MU Stage 1, reported improved process quality measures; this improvement in process quality measures was more evident in "lower quality hospitals." However, hospitals with advanced EHR systems saw "declines" in their process quality measures (Appari, et al., 2013). Encinosa and Bae (2015) assessed the effects of five MU core requirements on the incidence of adverse events in Florida area hospitals and concluded that MU core requirements were associated with a reduction in adverse events: 29% in low-quality hospitals and 27% in high-quality hospitals (Encinosa & Bae, 2015) (See appendix A-D for MU stage1 and MU stage 2 requirements).

Discussion and Hypotheses

These investments in health information technology were premised on compelling empirical evidence (Hillestad et al., 2005; Chaudhry et al., 2006), that EHRs have the potential of improving the quality and reducing the cost of healthcare. However, other studies showed mixed results on the effects of EHRs on the question of quality and cost of care (McCullough, Casey, Moscovice, & Prasad, 2010; DesRoches et al., 2010; Appari, Johnson, & Anthony, 2012). Meaningful use requirements are premised on aligning organizational and technological

capabilities to improve the delivery of healthcare. Meeting the requirements for meaningful use has been both expensive and complicated: and the evidence of these requirements on quality of care and patient safety is mixed.

Hypotheses

$H1_1$: Acute care hospital meeting the requirements for meaningful use is more likely to have better clinical outcome measures for common conditions (AMI, CHF, &PN) as measured by 30-day readmission and 30-day mortality rates than acute care hospital that is not meeting the requirements for meaningful use, when controlling for organizational characteristics (size, type, teaching status, and location) and case mix index (CMI).

$H2_1$: Acute care hospital meeting the requirements for meaningful use is more likely to have better patient safety as measured by PSI-90 and HAI than acute care hospital that is not meeting the requirements for meaningful use when controlling for organizational characteristics (size, type, teaching status, and location) and case mix index (CMI).

Data Collection

The unit of analysis for this study was acute care hospital. To study the effects of meeting the requirements for meaningful use on the quality and safety of patient care data was obtained from the 2014-2015 CMS Hospital Compare database, CMS EHR Incentive Program, CMS IPPS database, and AHA database. The CMS provides a unique ID to all U.S. hospitals; this identity was used to match the hospitals in these databases.

The AHA database was used to obtain hospital characteristics such as size measured by the number of staffed beds (small <= 99, medium =100-299, large = 300+), ownership (for-profit, not-for-profit, other), teaching status (teaching, nonteaching), and metropolitan status (rural, urban).

Method

A cross-sectional descriptive study was conducted to determine the effects of meeting the requirements for meaningful use on the quality and safety of patient care delivered in acute care hospitals in all fifty states and the District of Columbia. The CMS provides a unique ID to all U.S. hospitals; this identity was used to match the hospitals in these databases as done by previous researchers (Appari et al., 2013; Lin & Lin, 2014. For the study, a probabilistic stratified sample of acute care hospitals in the United States was included in the sampling frame of 3370 (N =3,370). The sample drawn from this frame included acute care hospitals, which have met the requirements for meaningful use stage 1 (MU1) in 2016 (N= 143),meaningful use stage 2(MU2)in 2016 (N=2195), and acute care hospitals which have not met the requirements for meaningful use (NOMU) in 2016 (N= 117) in 2016. The total sample included 2455 acute care hospitals (N =2455). The following acute care hospitals were included in the sample frame: for-profit hospitals, not-for-profit hospitals, state and local government hospitals. The following hospitals were not be included in the sampling frame: psychiatric hospitals, children's hospitals, long-term care facilities, prisons, university infirmaries.

Structural equation modeling was used in the study to analyze the association between the predictor meaningful use stage, and the dependent constructs: QUALITY, and SAFETY. Measurement models and a structural model were established to test the associations between the

predictor and the dependent variables. The statistical program, Mplus Version 7.2 was used (Muthen & Muthen, 1998).

The exogenous variable meaningful use stage (MUSTAGE) is measured by meaningful use stage 1(MU1), meaningful use stage 2(MU2), and not met requirements for meaningful use (NOMU). Hospital characteristics might influence the processes of care delivery, a variety of hospital characteristics such as teaching status, location, size, ownership type, and case mix index (CMI) were included as control variables.

The endogenous variables used in the study are QUALITY, and SAFETY (Figure 1& 2).

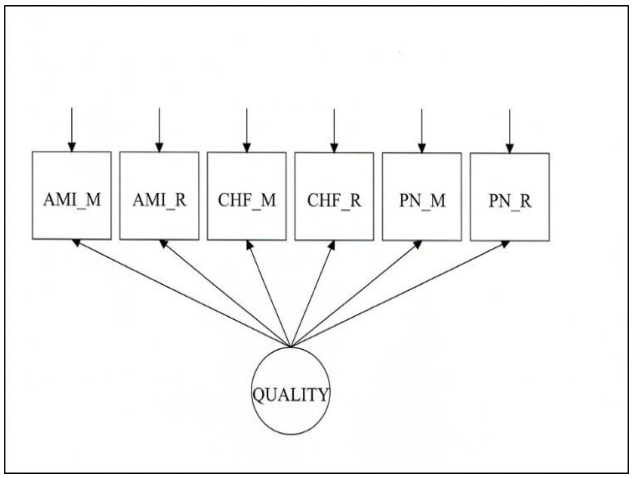

Figure 1 Measurement Model QUALITY

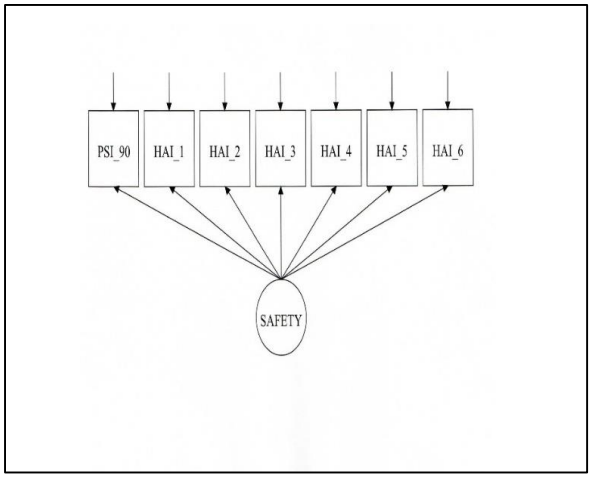

Figure 2 Measurement Model SAFETY

30-day readmission and 30-day mortality rates:
Acute myocardial infarction (AMI_R), (AMI_M)
Congestive heart failure (CHF_R), (CHF_M)
Pneumonia (PN_R), (PN_M)

PSI-90
Central line associated blood stream infection (HAI-1)
Catheter associated urinary tract infection (HAI-2)
Surgical site infection from colon surgery (HAI-3)
Surgical site infection from abdominal surgery (HAI_4)
Methicillin resistant Staphylococcus aureus (HAI-5)
Clostridium difficile (HAI_6)

Results

This section gives an overview of the empirical results of the study. Structural equation modeling (SEM) was used to analyze associations between meeting the requirements for meaningful use and the clinical outcomes of care when controlling for organizational characteristics such as

hospital size, type, teaching status, and location The recursive model used in the study reflects the view that meeting the requirements for meaningful use has a positive association with clinical

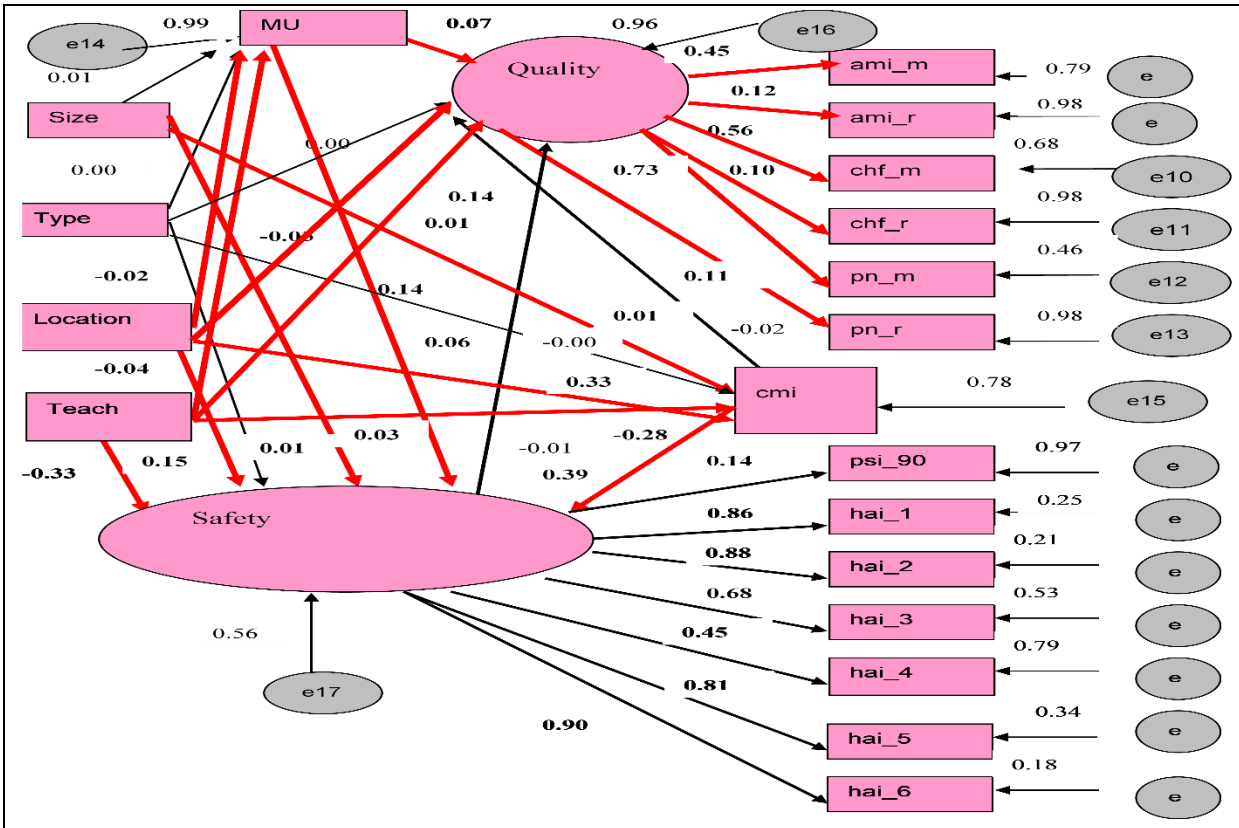

Figure 3 Path Diagram of Trimmed SEM Model

MU- Meaningful use stage
Size- hospital size
Type- Hospital ownership type
Location -Rural/ Urban
Teach- Teaching /Non -Teaching
CMI- Case mix index
Quality-(Figure 1)
Safety- (Figure 2)

outcomes of care in acute care hospitals. Certain organizational factors such as size, type, teaching status, and location, may affect the acute care hospitals ability to meet MU requirements; these were used as control variables. Case mix index (CMI) may affect the clinical outcomes of care, so CMI was used as a control for quality and safety.

The nested models were analyzed by examining if Model A fits the data well. The fit of the full model (Model A) was acceptable. CFI was 0.86 (i.e., >.80). TLI was 0.82 (i.e., >.80). SRMR was 0.06 (i.e., < .08). RMSEA was 0.07 (i.e., <.08). The fit of Model B (the trimmed model) was analyzed to examine if it might be better than the fit of Model A (the full model). Fit indices for each of the two models are shown (Table 3). The fit of Model B was acceptable (Table8). CFI was 0.86 (i.e., > .80). TLI was 0.82 (i.e., > .80). SRMR was 0.06 (i.e., < .08). RMSEA was 0.07 ((i.e., < .08). According to Kline (1998), the model with the lowest AIC is preferred. Model B with the lowest AIC was chosen as the best model of all the models (Byrne, 2016).

Table 1. Fit Indices for Each of the Single-level SEM Models

SEM	CFI	TLI	RMSEA	SRMR	AIC	BIC
Model A	0.86	0.82	0.07	0.06	1169180.72	1169666.97
Model B	0.86	0.82	0.07	0.06	1169178.77	1169657.42

Note. Model A=the full model. Model B=the Trimmed model. Model B is nested within Model A. CFI =comparative fit index; TLI =NNFI = non-normed fit index; RMSEA = root-mean-square error of approximation; SRMR = standardized root mean-square residual; AIC = Akaike information criterion; BIC =Bayesian information criterion; Model A was all free; Model B: One path (size -> quality) was fixed to zero.

The results of the structural equation model demonstrate a positive association ($p = 0.07$) between acute care hospital meeting the requirements for meaningful use and its clinical outcome measures for common conditions (AMI, CHF, &PN) as measured by 30-day readmission and 30-day mortality rates, when controlling for organizational characteristics (size, type, teaching status, and location) and CMI. There is a positive association ($p = 0.06$) between an acute care hospital meeting the requirements for MU and patient safety as measured by PSI-90 and HAI. Model fit decisions were based on four indices (a) comparative fit index(CFI), (b) Trucker Lewis index (TLI), and root mean square error of approximation (RMSEA). The literature for structural equation model suggests that model fit is excellent when the coefficient for CFI and TLI are greater than 0.95; the model fit is considered adequate if the coefficients are greater than 0.90, (Byrne, 2016). A coefficient of less than 0.05 is indicative of excellent fit and coefficient of 0.08 indicates an acceptable fit for RMSEA (Kline,2016).

Analyses of Variance Between Acute Care Hospitals Meeting MUSTAGE

As there were missing values in the original dataset, and multiple imputations were performed to replace missing data. To check the validity of SEM results and to compare the mean score of quality and patient safety in acute care hospital which have met the requirements for meaningful use and acute care hospitals which have not met the requirements for meaningful use the researcher conducted two one-way analysis of variance (ANOVA) with the original data. Before conducting ANOVA, two composite variable QUALITY, and SAFETY were created.

Table 2 - Summary Statistics Table for Interval and Ratio Variables

Variable	*M*	*SD*	*n*	Min.	Max.	Skewness	Kurtosis
QUALITY	16.43	0.83	1650	13.82	19.30	0.11	0.06
RSAFETY	1011.50	583.85	2022	1.00	2022.00	0.00	-1.20

Prior to the analysis, ANOVA assumptions were examined. This scatterplot is presented in Figure 4 &5. The result of Levene's test for QUALITY was not significant, F (2, 1647) = 0.17, p = .846, indicating that the assumptions of homogeneity of variance was met. SAFETY was non-normal the variable was transformed by rank transformation. The assumption of normality was assessed. The result of Levene's test was not significant, F (2, 2019) = 0.63, p = .534, indicating that the assumption of homogeneity of variance was met.

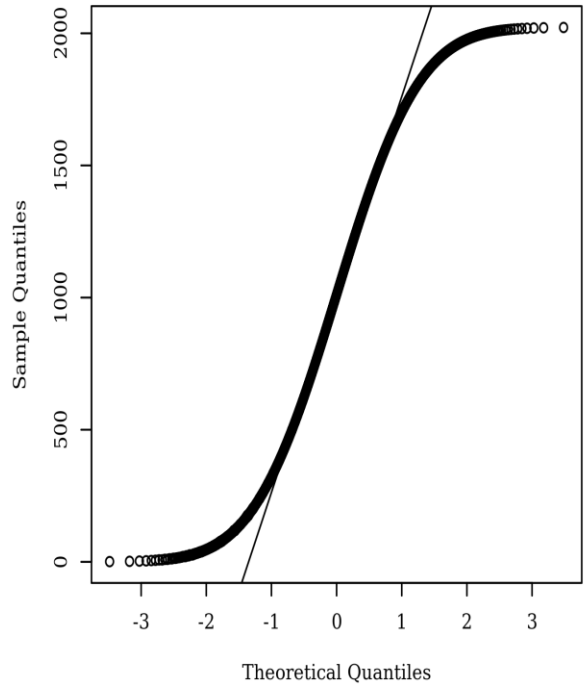

Figure 4 Q-Q Scatterplot for normality SAFETY

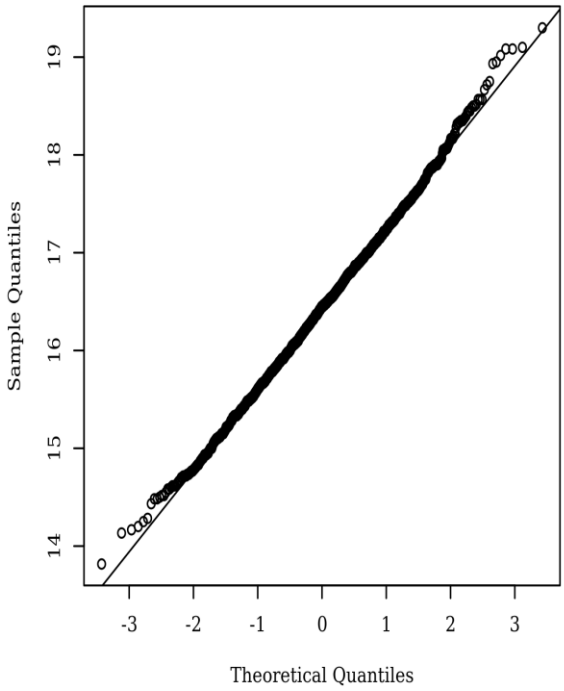

Figure 5 Q-Q normality plot for QUALITY

The results of the ANOVA were not significant, F(2, 1647) = 0.94, p = .389, indicating the differences in QUALITY among the levels of MUSTAGE were all similar. The main effect, MUSTAGE was not significant at the 95% confidence level, F(2, 1647) = 0.94, p = .389, indicating there were no significant differences in Quality by MUST levels. There were no significant effects in the model. As a result, posthoc comparisons were not conducted.

A second ANOVA was conducted to determine whether there were significant differences in RSAFETY by MUSTAGE. The results of the ANOVA were significant, F (2, 2019) = 5.24, p = .005, indicating there were significant differences in RSAFETY among the levels of MUSTAGE. The eta squared was 0.01 indicating MUSTAGE explains approximately 1% of the variance in RSAFETY. The means and standard deviations are presented in Table 1.

Table 1 - Analysis of Variance Table for RSAFETY by MUSTAGE

Term	*SS*	*df*	*F*	*p*	η^2_p
MUSTAGE	3558751.55	2	5.24	.005	0.01
RESIDUALS	685350228.95	2019			

Post-hoc. To further examine the differences among the variables, *t*-tests were calculated between each pair of measurements. Tukey pairwise comparisons were conducted for all significant effects. For the main effect of MUSTAGE, the mean of RSAFETYfor MU2 (M = 1023.72, SD = 581.02) was significantly smaller than for NOMU (M = 817.95, SD = 576.00). No other significant effects were found. Meeting the requirements for meaningful use explained 1% of the variance in patient safety

Conclusion and Implications

This study raises important questions. Are the tactics for achieving high-quality healthcare and patient safety based on the right assumptions? Is the national healthcare policy/strategy aligned with the rewards and incentives for the various agents of delivery of healthcare? The hospitals, on the other hand, have identified the other drivers of patient safety and healthcare delivery quality improvement. This may explain the lack of association of the MU and the quality outcomes data. In the future, healthcare policy will need to incorporate other measures of quality and value into the meaningful use parameters.

As with every study, there are certain limitations in the study. This study was designed as an observational study, cross-sectional study hence the results of this study cannot be interpreted as causal effects. Due to the sample size 2455 acute care hospitals, there were some disparate attributes. This poses a potential threat to the generalizability of the results. The results may be biased by unmeasured confounding variables such as reimbursement reforms and associated penalties for readmission and HAC; other innovative organizational changes instituted to address the issues of quality and safety. Hence, it is important to incorporate such organizational factors when examining the quality of care and patient safety. Future researchers should design a longitudinal study to examine the difference in the quality of care and patient safety as the hospitals progress from the early stages of meeting the requirements for MU Stage 1 and the changes in quality of care and patient safety as the hospital attests to meeting the requirements for MU Stage2.

Health information systems, and more specifically the EHRs, are not a panacea for all that ails the US healthcare sector. The effects of meeting the requirements for meaningful use on

clinical outcomes of care cannot be objectively examined in isolation. Although several control variables were used in the study, one important factor was the reimbursement changes which were instituted with the passage of the Patient Protection and Affordable Care Act (PPACA), future researchers should include reimbursement changes as a control variable in their study. Another important factor in examining the quality of care and patient safety in acute care hospitals is the effects of workflow changes and strategic interventions adopted at the organizational level to improve the quality of care and patient safety.

Care transitions are an essential aspect of continuity of care. Hence it is crucial to evaluate the effects of meeting the requirements for meaningful use in the ambulatory, long-term, sub-acute care, and rehabilitation settings. As the country moves towards integrated care delivery with accountable care organizations (ACO), and patient centeres medical homes (PCMH), it will be instructive to examine the effects of meaningful use requirements in integrated settings also.

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APPENDIX A

Requiremets for Meaningful Use Stage 1
Core Objectives

1.) Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines.
2.) Implement drug-drug and drug allergy interaction checks.
3.) Maintain an up-to-date list of current and active diagnoses.
4.) Generate and transmit permissible prescriptions electronically (eRx).
5.) Maintain active medication list
6.) Maintain active medication allergy list
7.) Record all of the following demographics:
    a. Preferred language
    b. Gender
    c. Race
    d. Ethnicity
    e. Data of birth
8.) Record and chart changes in the following vital signs:
    a. Height
    b. Weight
    c. Blood pressure
    d. Calculate and display body mass index (BMI)
    e. Plot and display growth charts for children 2-10 years, including BMI
9.) Record smoking status for patients 13 years old or older
10.) Report ambulatory clinical quality measures to CMS, or in the case of Medicaid EPs, the state(No longer core objective but still required)
11.) Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.
12.) Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies) upon request.
13.) Provide clinical summaries for patients for each office visit

APPENDIX B

Requirements for Meaningful Use
Menu Objectives

1.Implement drug formulary checks

2. Record advance directives for patients 65 years old or older

3. Incorporate clinical lab-test results into EHR as structured data

4. Generate list of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

5. Use certified EHR technology to identify patient- specific education resources and provide those resources to patients if appropriate.

6. The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

7. The eligible hospital or CAH that transitions their patients to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral.

8.Capablity to submit electronic data to immunization registries or immunization information systems and actual submission according to applicable law and practice.

9. Capability to submit electronic data on reportable lab results to public health agencies and actual submission according to applicable law.

10. Capability to submit electronic syndromic surveillance data to public health agencies and actual submission according to applicable law.

APPENDIX C

Requirements for Meaningful Use Stage 2
Core Objectives

(1) Use computerized provider order entry (CPOE) for medication, laboratory, and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines.

(2) Record all of the following demographics: preferred language, sex, race, ethnicity, date of birth, date and preliminary cause of death in the event of mortality in the eligible hospital or CAH.

(3) Record and chart changes in the following vital signs: height/length and weight (no age limit); blood pressure (ages 3 and over); calculate and display body mass index (BMI); and plot and display growth charts for patients 0-20 years, including BMI.

(4) Record smoking status for patients 13 years old or older.

(5) Use clinical decision support to improve performance on high-priority health conditions.

(6) Provide patients the ability to view online, download, and transmit information about a hospital admission.

(7) Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities.

(8) Incorporate clinical lab test results into Certified EHR Technology as structured data.

(9) Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.

(10) Use clinically relevant information from Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient.

(11) The eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.

(12) The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.

(13) Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice.

(14) Capability to submit electronic reportable laboratory results to public health agencies, where except where prohibited, and in accordance with applicable law and practice.

(15) Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice.

(16) Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR).

APPENDIX D

Requirements for Meaningful Use Stage2

Menu Objectives

(1) Record whether a patient 65 years old or older has an advance directive.

(2) Record electronic notes in patient records.

(3) Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT.

(4) Record patient family health history as structured data.

(5) Generate and transmit permissible discharge prescriptions electronically (eRx).

(6) Provide structured electronic lab results to ambulatory providers