AHRQ Grant Final Progress Report

Title: The Value of Hospital-Related Patient-Saftey Interventions to Key Stakeholders

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Structured Abstract

Purpose: The U.S. healthcare system is encumbered by poor quality care and high costs. Claims are often made that improving quality and safety will save money, yet the cost implications of doing so are seldom rigorously evaluated. This Career Development Award (CDA) involved an educational and research program through which a physician investigator sought to achieve the following objectives: (1) to become expert in economic evaluations of healthcare interventions, (2) to develop a sophisticated understanding of the interplay between quality/safety and economic issues, and (3) to create a substantive research program examining the cost implications of implementing quality/safety interventions.

Scope: This CDA included educational activities and a research project conducted from April 2009 through December 2013.

Methods: To develop expertise in economics and cost analyses, the investigator audited graduate-level courses in microeconomics, financial accounting, cost-benefit and cost-effectiveness analysis, and cost and conducted extensive independent readings. To expand her knowledge of quality/safety and its relationship with costs, the investigator attended seminars and read extensively. Drawing on these experiences, she then developed a conceptual framework and applied it to the implementation of computerized provider order entry systems.

Results: Through this CDA, the investigator published the Quality-Cost Framework, a conceptual framework that describes how the quality of care influences healthcare costs and other cost types. The award has also resulted in several other publications. Finally, the investigator was awarded multiple grants addressing the cost implications of improving quality of care, including an AHRQ R01.

Key Words: quality of healthcare; medical error; economics; cost-benefit analysis; models, theoretical

Purpose

When Dr. Nuckols applied for this Career Development Award (CDA), she sought to become uniquely positioned at the intersection of the quality/safety field and the health economics field. She already had a strong motivation for and several years' experience in quality and safety research and had served as a Principal Investigator or key team member on several projects pertaining to quality and safety issues and their relationship to costs. Consequently, she designed the CDA educational and research components to develop her knowledge, skills, and experience in microeconomics and in the performance of economic evaluations of clinical interventions and to link these fields with quality of care. She planned to attain a sufficient understanding of microeconomic issues to be able to independently formulate novel hypotheses about important and emerging policy issues in this area, understand economic analyses and study methods, and lead studies testing economic hypotheses, where appropriate, in collaboration with health economists and econometricians. She also sought to become expert in performing economic evaluations, such as cost-effectiveness analyses, return-on-investment analyses, budget-impact analyses, and related studies. Performing economic evaluations often requires skills in examining clinical effectiveness, such as through systematic reviews and meta-analyses.

Because this was a CDA, Dr. Nuckols and her mentors had three types of objectives: career objectives, educational objectives, and research objectives. The three types were closely linked.

Career Objectives

This CDA was designed to enable Dr. Nuckols to achieve several career objectives over 5- and 10-year time horizons. For 10 years after the start of the CDA (2009), her objective remains to make substantive contributions to decision making in the fields of patient safety and quality of care by providing policymakers and other healthcare leaders with information regarding the potential effects of their decisions on quality/safety and costs.

Dr. Nuckols' career objectives over the first 5 years after the start of the CDA were to:

(1) Become expert in economic evaluations of patient-safety/quality-of-care interventions,

(2) Develop a highly sophisticated understanding of the interplay between quality/safety and economic issues,

(3) Create a substantive research program examining the cost implications of implementing quality and patient-safety interventions,

(4) Secure full funding as an independent investigator, and

(5) Achieve promotion to Associate Professor.

Educational Objectives

The educational objectives were to:

(1) Become expert in performing economic evaluations of healthcare interventions,

(2) Develop a broader and deeper understanding of current microeconomic theory for the healthcare sector; and

(3) Develop greater knowledge of the theory and practice of healthcare quality improvement.

Research Objectives

The research activities involved two specific aims:

(1) Aim One: To develop an approach to assessing the value of hospital-related patient-safety interventions to key stakeholders.

(2) Aim Two: To apply this approach to one hospital-related patient-safety intervention, computerized physician order entry.

Scope

Researchers have extensively documented problems with the quality and safety of the medical care in the United States. Only half of basic care processes are provided as recommended, and injuries due to medical errors (preventable adverse events) in hospitals cause 44,000 to 98,000 deaths per year.(1, 2) To ameliorate these problems, many interventions have been designed, and some are being widely implemented. Others have yet to be widely adopted, despite being recommended by national policymaking organizations or judged effective by researchers.(3-6)

Even though the human toll from quality and safety problems is substantial, costs *should* be a major consideration in decisions about which improvement strategies to implement. Healthcare resources are not infinite, particularly with expenditures comprising a large percentage of the U.S. gross domestic product.(7) Other problems also limit length and quality of life. A few of relevance include lack of access to care due to underinsurance in many states, despite the Affordable Care Act; poor health literacy, which reduces patients' abilities to benefit from effective therapy; and diseases, such as cancer, for which more effective treatments would be highly valued. The existence of competing problems requires policymakers to prioritize—whether explicitly or implicitly—quality and safety interventions against alternative means of improving the health of the U.S. population and alternative uses for the same money. Consequently, it is important for stakeholders and policymakers to understand the full costs of these interventions and their value, meaning their costs relative to their benefits.

Effective patient-safety interventions benefit patients, but hospitals and physicians bear the costs of implementing them. Such costs are an important determinant of which interventions are adopted. For example, computerized physician order entry with clinical decision support (CPOE) is an oft-touted intervention designed to catch the errors that physicians make when ordering medications.(6) Evidence of CPOE's effectiveness has existed since at least 1994, yet, as of 2008, only 9% of general acute care hospitals had at least basic electronic health record systems including CPOE for medications. The Health Information Technology for Economic and Clinical Health (HITECH) Act, passed in 2009, provides substantial incentives for hospitals' adoption and "meaningful use" of health information technology, including CPOE(8) with clinical decision support (CPOE). By 2012, 44% had done so, specifically 38% of small, 47% of medium, and 62% of large hospitals.(9) Despite incentives that reach up to several million dollars per hospital, about half of small and medium hospitals and 40% of large hospitals had not adopted CPOE with CDSS by 2012.(9) The high cost of these systems to hospitals and the increased time burden on physicians have been identified as major barriers to adoption, in addition to technological hurdles.(4)

Cost considerations are also important, because CPOE is only one of several interventions designed to prevent harm from medical errors. When hospitals implement a multifaceted patient-safety program, the total cost can be substantial, particularly for small or safety net hospitals.(10) Thus, hospitals must also prioritize which interventions to implement. They generally do it on the basis of anticipated costs to the institution and perceived effectiveness.(3)

Despite the importance of cost considerations, few studies have quantified the value of patient safety interventions.(11) Researchers often describe patient safety problems or test interventions, but less attention has been paid to ensuring that the interventions themselves represent high-value healthcare.

State and national policies can influence the implementation of patient-safety interventions,(12, 13) and examining the interventions' effects on key stakeholders has important implications for developing these policies. Identifying market failures, such as a lack of a business case from the hospital perspective, or a lack of uptake by hospitals despite a business case, is important, because it suggests that additional incentives are needed. When payers or employers experience savings from the implementation of an intervention, subsidies are one logical option for resolving market failures. However, even when subsidies appear appropriate, there may be barriers to using them. Anti-trust laws restrict payments from hospitals to physicians, for example. Private entities may be reluctant to share information, particularly if it may hamper their ability to compete with other firms. Public payers may choose not to implement subsidies, even when there is a case for doing so from the societal perspective. Reasons can include budgetary constraints, a tendency to focus on short-term problems, and political opposition from stakeholder groups that may lose financially. Information about the effects of patient-safety interventions on stakeholders will make it easier to overcome these barriers and to identify policy levers that may promote implementation more effectively.

Methods

Dr. Nuckols' attainment of her 5- and 10-year objectives was, and is, contingent upon her attainment of the award's educational and research objectives; consequently, the Methods section addresses steps in the work that were related to the educational and research objectives.

Educational Objectives

To achieve her educational objectives, Dr. Nuckols audited graduate-level courses at UCLA and the Pardee RAND Graduate School, attended short courses at professional meetings and other venues, accessed seminars available through a variety of groups, and conducted independent readings on microeconomics with Dr. Escarce.

Formal Coursework: (1) Microeconomics II, UCLA School of Public Policy; (2) Cost-benefit and Cost-effectiveness Analysis, Pardee RAND Graduate School; (3) Advanced Topics in Decision Analysis and Cost Effectiveness, UCLA School of Public Health; and (4) Responsible Conduct of Research in Humans, UCLA Department of Biomathematics.

Short Courses: (1) Meta-analysis, Society for Medical Decision Making Annual Meeting, 2010; (2) Career Advancement for Scientists, Becoming Effective Leaders, UCLA NanoSystems Institute, April 2011; (3) Introduction to Behavioral Economics, Society for Medical Decision Making Annual Meeting, 2011; (4) Intuition and Deliberation in Medical Decision Making: A Psychological Perspective on Thought, Society for Medical Decision Making Annual Meeting, 2011.

Seminars (abbreviated list): (1) Cyber Seminars made available by the Veterans Affairs Health Services Research and Development Service: (a) Budget Impact Analysis; (b) How Can Cost Effectiveness Analysis Be Made More Relevant to U.S. Health Care?; (c) The Practice of Cost-Effectiveness Analysis: Designing, Conducting, and Interpreting CEA under Non-Ideal Circumstances; (d) Part 1 Implementation Research: PARiHS Framework, (e) Part 2 Applying Mutiple Frameworks and Theories to Implementation, (f) Health Systems Evidence – Evidence to Support Policymaking and Management (Part 1), (g) Research Design, (h) many others; (2) Seminars for RAND researchers: (a) Reliability and Misclassification in Provider Profiling; (b) Developing a Project Workplan.

Independent Reading (abbreviated list): (1) Health Economics (4th Edition), by Charles E. Phelps, Addison Wesley; (2) Hand Books in Economics: Health Economics, Volume 2, by Mark V. Pauly, Thomas G. McGuidre, and Pedro P. Barros, North-Holland; (3) Advances in Behavioral Economics, by Colin F. Camerer, George Lowenstein, and Matthew Rabin, Princeton Paperbacks; (4) several other books on behavioral economics; (5) a variety of materials on microcosting, return-on-investment analyses, budget-impact analyses, and other types of cost analyses used in healthcare.

Research Objective

Aim One: To develop an approach to assessing the value of hospital-related patient-safety interventions to key stakeholders.

Dr. Nuckols, with input from her mentors, developed a conceptual framework, the Quality-Cost Framework, that describes how quality of care influences healthcare costs and non-healthcare costs,

and the framework includes the consideration of different stakeholder perspectives. The objectives of the Quality-Cost Framework are to: (1) explain how variations in health-driven quality can create variations in healthcare and other economic costs and (2) facilitate the design and evaluation of empirical studies examining how quality influences costs. (See Figure.) The Framework builds on the work of Donabedian, RAND researchers, the Institute of Medicine, standard methods for cost-effectiveness analyses, and methods used in cost-benefit analyses outside the healthcare sector. It applies to a variety of analyses, including cost, cost-effectiveness, and econometric analyses. The quality and cost elements that are relevant to a particular analysis depend on its purpose, perspective, time horizon, patient population, target diseases or conditions, study design, and setting.

After developing the framework, we pilot tested it by conducting two directed literature searches and determining how often economic evaluations of quality improvement interventions included all the relevant aspects of quality that can be influenced by costs. This pilot test focused on two aspects of quality that have been targeted for improvement, achieving glycemic control for patients with type 2 diabetes mellitus and avoiding inappropriate imaging of the spine among individuals with back pain.

Aim Two: To apply this approach to one hospital-related patient-safety intervention, computerized physician order entry (CPOE).

We applied to framework to CPOE in a different manner. We conducted an economic evaluation of this technology from the societal perspective, and the framework facilitated the consideration of the different types of costs that could be created by implementing CPOE. This analysis involved two major steps. First, we conducted a systematic review and meta-analysis to estimate the effects of CPOE on medication errors and preventable adverse drug events. Next, we created decision analytical models that incorporated the results of the meta-analysis and estimated the cost-effectiveness of CPOE systems over their useful life span.

Results

Dr. Nuckols achieved success with all three categories of objectives: career, education, and research. Because the educational objectives were largely achieved through the coursework and other activities described in the Methods section, that material is not reiterated here.

Career Objectives

Two of Dr. Nuckols' career objectives over the first 5 years after the start of the CDA related to creating a research program, being promoted to Associate Professor, and securing full funding as an investigator.

Educational Objectives

The coursework described above supports the stated educational objectives.

Research Objectives

Aim One: To develop an approach to assessing the value of hospital-related patient-safety interventions to key stakeholders.

The Milbank Quarterly published "The Effects of Quality of Care on Costs: A Conceptual Framework," and a manuscript describing how the framework was pilot tested using articles on diabetes and back pain is under development.(14) The Milbank article's abstract:

> *Context:* The quality of healthcare and the financial costs affected by receiving care represent two fundamental dimensions for judging healthcare performance. No existing conceptual framework appears to have described how quality influences costs.
> *Methods:* We developed the Quality-Cost Framework, drawing from the work of Donabedian, the RAND/UCLA Appropriateness Method, reports by the Institute of Medicine, and other sources.
> *Findings:* The Quality-Cost Framework describes how health-related quality of care (aspects of quality that influence health status) affects healthcare and other costs. Structure influences process, which, in turn, affects proximate and ultimate outcomes. Within structure, subdomains include general structural characteristics, circumstance-specific (e.g., disease-specific) structural characteristics, and quality improvement systems. Process subdomains include appropriateness of care and medical errors. Proximate outcomes consist of disease progression, disease complications, and care complications. Each of the preceding subdomains influences healthcare costs. For example, quality improvement systems often create costs associated with monitoring and feedback. Providing appropriate care frequently requires additional physician visits and medications. Care complications may result in costly hospitalizations or procedures. Ultimate outcomes include functional status as well as length and quality of life; the economic value of these outcomes can be measured in terms of health utility or health status-related costs. We illustrate our framework using examples related to glycemic control for type 2 diabetes mellitus or the appropriateness of care for low back pain.
> *Conclusions:* The Quality-Cost Framework describes the mechanisms by which health-related quality of care affects healthcare and health status-related costs. Additional work will need to validate the framework by applying it to multiple clinical conditions. Applicability could be assessed by using the framework to classify the measures of quality and cost reported in

published studies. Usefulness could be demonstrated by employing the framework to identify design flaws in published cost analyses, such as omitting the costs attributable to a relevant subdomain of quality.

Aim Two: To apply this approach to one hospital-related patient-safety intervention, computerized physician order entry.

So far, the CPOE work has yielded two papers. One is entitled "The Effectiveness of Computerized Order Entry at Reducing Preventable Adverse Drug Events and Medication Errors in Hospital Settings: A Systematic Review and Meta-Analysis is in press at the journal *Systematic Reviews.*

Background: The Health Information Technology for Economic and Clinical Health Act subsidizes hospitals' implementation of electronic health records with computerized provider order entry (CPOE), which may reduce patient injuries due to medication errors (preventable adverse drug events, pADEs). Effects on pADEs have not been rigorously quantified, but effects on medication errors, an intermediate outcome, have been variable. The objectives of this analysis were to assess computerized provider order entry's effectiveness at reducing pADEs in hospital-related settings and examine reasons for heterogeneity in effects on medication errors.

Methods: Articles were identified using MEDLINE, Cochrane library, Econlit, web-based databases, and bibliographies of prior systematic reviews (September 2013). Eligible studies compared CPOE with paper-order entry; examined various types of pADEs or medication errors; and were set in acute-care hospitals. Studies on children or with limited event detection methods were excluded. Two investigators extracted data on pADEs, medication errors, and factors potentially associated with effectiveness. We used random effects models to pool data.

Results: Sixteen studies addressing medication errors met eligibility and pooling criteria; six also addressed pADEs. Thirteen studies used pre-post designs. Compared with paper-order entry, CPOE was associated with half as many pADEs (pooled risk ratio [RR] 0.47, 95%-CI 0.31-0.71) and medication errors (RR 0.46, 95%-CI 0.35-0.60). Regarding potential reasons for heterogeneity in effects on medication errors, five intervention factors and two contextual factors were sufficiently reported to support subgroup analyses or meta-regression. Differences between commercial vs. home-grown systems, type of clinical decision support (present vs. absent, and basic vs. moderate or advanced), hospital-wide vs. limited implementation, and U.S. vs. non-U.S. studies were not significant, nor was timing of publication. Higher baseline rates of medication errors predicted greater reductions ($p<0.001$). Other context and implementation variables were seldom reported.

Conclusions: In hospital-related settings, implementing CPOE is associated with >50% decline in patient injuries due to medication errors, although studies used weak designs. Decreases in medication errors are similar and robust to variations in several important aspects of intervention design and context. These findings suggest that CPOE implementation, as subsidized under the HITECH Act, may benefit public health. More detailed reporting of the context in which CPOE is implemented and how implementation is accomplished could shed light on factors associated with greater effectiveness.

The second paper addresses the cost implications to society of implementing this technology. It was presented as a poster at the Academy Health Annual Meeting. A manuscript entitled "A Cost-Utility Analysis of Computerized Provider Order Entry in U.S. Acute Care Hospitals" is under review at *Value in Health.*

Implications

Achieving these various objectives have enabled Dr. Nuckols to create a research program that focuses on the cost implications of improving quality and safety. She has led the development of three grants related to the effect of quality of care and costs. The last of these three grants specifically involves the Quality-Cost Framework.

The Value of High Quality Medical Care for Work-Associated Carpal Tunnel Syndrome, Agency for Healthcare Research and Quality, R01HS018982-01. 2010-2015. Principal Investigator: Steven M. Asch, Co-Principal Investigator: Teryl Nuckols, MD, MSHS. $2,500,000 (including indirect costs).

Individualizing Assessments of Risk to Reduce Falls in UC Hospitals. University of California Center for Health Quality & Innovation Program. 2011-2014. Co-Principal Investigators: Teryl Nuckols, MD, MSHS, and Catherine Walsh, RN, MSN. $375,000.

When Is Quality Improvement Cost Saving, Cost Effective, or Not a Good Value? Agency for Healthcare Research and Quality, 1R01 HS22644-01. 2013-2015. Principal Investigator: Teryl Nuckols, MD, MSHS; Principal Investigator for Subcontractor (RAND): Paul Shekelle, MD, PhD. $1,000,000 (including indirect costs).

Without the educational opportunities and experiences obtained through this Career Development Award, developing such a research program would have been far more challenging and may not have been attainable.

List of Publications and Products

Published during Award Period:

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11. Teryl K. Nuckols, MD, MSHS; Crystal Smith-Spangler, MD, MS; Sally C. Morton, PhD; Steven M. Asch, MD, MPH; Vaspaan M. Patel, MPH; Laura J. Anderson, MPH; Emily L. Deichsel, MPH; Paul G. Shekelle, MD, PhD. Factors Influencing the Effectiveness of

Computerized Order Entry at Reducing Medication Errors and Adverse Drug Events in Hospital Settings: A Systematic Review and Meta-Analysis. *Systematic Reviews.*

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