BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-015930
Article Type:	Protocol
Date Submitted by the Author:	12-Jan-2017
Complete List of Authors:	Chiou, Howard; Stanford University, Clinical Excellence Research Center; Emory University School of Medicine, Medical Scientist Training Program and Department of Anthropology Jopling, Jeffrey; Stanford University, Clinical Excellence Research Center; Gordon and Betty Moore Foundation Scott, Jennifer; Stanford University, Clinical Excellence Research Center Ramsey, Meghan; Stanford University, Clinical Excellence Research Center Vranas, Kelly; Stanford University, Clinical Excellence Research Center; Oregon Health & Science University Wagner, Todd; Stanford University, Clinical Excellence Research Center Milstein, Arnold; Stanford University, Clinical Excellence Research Center
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Intensive care, Qualitative research, Medical management
Keywords:	Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, INTENSIVE & CRITICAL CARE, QUALITATIVE RESEARCH

Title (50 words)

Detecting organizational innovations leading to improved ICU outcomes: a protocol for a double-blinded national positive deviance study of critical care delivery.

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Abstract (300 words)

Introduction: There is substantial variability in intensive care unit (ICU) utilization and quality of care. However, the factors that drive this variation are poorly understood. This study utilizes a novel adaptation of positive deviance approach— a methodology used in public health that assumes solutions to challenges already exist within the system to detect innovations that are likely to improve intensive care.

Methods and Analysis: We used the Philips eICU Research Institute database (eRI), containing 3.3 million patient records from over 50 health systems across the United States. Acute Physiology and Chronic Health Evaluation (APACHE) IVa scores were used to identify the study cohort, which included ICU patients whose outcomes were felt to be most sensitive to organizational innovations. The primary outcomes included mortality and length of stay. Outcome measurements were directly standardized, and bootstrapped confidence intervals calculated with adjustment for false discovery rate. Using purposive sampling, we then generated a blinded list of 5 positive outliers and 5 negative comparators.

Using rapid qualitative inquiry, blinded interdisciplinary site visit teams will conduct interviews and observations using a team ethnography approach. After data collection is completed, the data will be unblinded and analyzed using a cross-case method to

identify themes, patterns, and innovations using a constant comparative grounded theory approach. This process not only allows for the detection of innovations in intensive care, but also support an evaluation of how positive deviance and rapid qualitative inquiry methods can be adapted to healthcare.

Ethics and Dissemination: The study protocol was approved by the Stanford University Institutional Review Board (Reference: 39509). We plan on publishing study findings and methodological guidance in peer-reviewed academic journals, white papers, and presentations at conferences.

Strengths and Limitations

- This study is a methodologically innovative translation of the positive deviance approach to health services research, and incorporates both qualitative and quantitative rigor.
- A national database of ICU care in the United States is used, and the methodology is a mixed-methods approach that triangulates between qualitative and quantitative data sources.
- The project is likely to inform the organization of care delivery in ICUs, as well as both positive deviance and rapid qualitative methodologies in healthcare.
- The database is limited to ICUs with telemedicine capabilities, and case-mix adjustment using APACHE IVa is imperfect. Study participants and site visitors may also not be able to accurately ascertain which innovations drive performance.

Introduction

Critical illness represents an enormous burden in the United States, with more than 5 million patients admitted annually to ICUs. Caring for these patients consumes a disproportionate amount of resources: despite comprising less than 10% of all of the hospital beds, ICU care accounts for 13.4% of total hospital costs, and 0.66% of the national gross domestic product.[1] This burden will likely increase as populations age, as both utilization and the proportion of beds allocated to intensive care rise.[1–4]

Yet, the quality of care delivered varies dramatically between units and hospitals. ICUs differ widely in their rates of compliance with best practices and rates of avoidable complications (e.g., hospital acquired infections).[5] Risk-adjusted mortality also differs between ICUs, and the best ICUs in the country have 10-12 fewer deaths for every 100 patients than the lowest performing ICUs, even after controlling for factors like discharge practices and patient demographics.[6] These trends have been confirmed in more recent studies of ventilated patients.[7,8]

Rather than being driven by access to different technologies, these variations in performance are likely driven by differences in organization and practices.[9,10] Modern ICUs are more an *organizational innovation* than a technological one, matching a concentration of personnel and resources for any type of critically ill patient. Previous research has identified organizational factors like RN-to-patient ratios, daily care plans, and usage of care bundles as associated with improved risk-adjusted mortality.[11–13]

Unfortunately, innovations in organization and practice are not well described in the critical care literature. Hospitals do not typically share their innovative practices with one another, and data to compare ICU performance are not readily available. Although some practices may be published, context is frequently not reported in sufficient detail to ensure successful implementation.[14] All of these factors obscure our ability to identify which aspects of critical care organization and practices help drive performance.

Positive deviance is one methodology that may offer hope. This approach assumes that innovations that address problems common to many organizations have already been developed, and can be detected by studying positive outliers before being tested and disseminated.[15,16] Originating from global health, the approach has been used successfully in a wide variety of settings to improve healthcare quality, including diabetes management in primary care practices, and hospital door-to-balloon times in response to acute myocardial infarction.[17]

However, a systematic review of positive deviance studies in healthcare found research quality to be low, and there have been very few applications of the approach in the critical care setting.[15] Highlighting the need for increased rigor, a previous study utilizing qualitative site visits failed to identify differences between ICUs associated with performance.[10] The goal of this research protocol is to describe our methods for conducting a positive deviance study in critical care.

Methods and Analysis

Conducting a positive deviance study requires four steps: 1) identify outliers within an area of interest, 2) utilize qualitative approaches to generate hypotheses to explain their performance, 3) test hypotheses in a larger sample, and 4) disseminate evidence about best practices.[18,19] Our strategy utilizes a blinded, retrospective approach in two first steps. We will first analyze a national database of ICUs to develop a study cohort of five positive outliers and five comparator ICUs. This quantitative phase will be followed by in-depth qualitative work at these ten sites, where we will build comparative case studies on their innovations and themes.

Quantitative Phase: Identifying Outliers

Data Source

This study will utilize data from the Philips eICU Research Institute database (eRI), containing over 3.3 million patient records from over 50 health systems from 2003 through 2015. All ICUs in the database have implemented the Philips eICU telemedicine system. Data for ICU admissions includes vital sign measurements, quality metrics, medication orders, and patient laboratory values. All of the ICUs in the study were offered an opportunity to opt-out of the study, and the protected health information of individual patients was not included. The database includes over 400 hospitals; as of 2014, there were 5,686 acute care hospitals in the United States, all of which had at least one ICU.[20]

ICU Cohort Selection

Inclusion criteria included all hospital units that contributed data to the Philips eRI database between 2013 and 2015. We then excluded hospital units who did not participate for all three years, as well as self-identified stepdown or intermediate care units. To minimize variation from small sample sizes, we also excluded low-volume ICUs, defined as ICUs with fewer than 300 discharges per year. The final cohort included 276 ICUs that cared for a total of 370,278 patients over three years. These ICUs form a geographically diverse sample of ICUs with eICU capabilities.

Outcome Measurements

Primary outcomes included mortality and length of stay for patients admitted to the ICU, since these parameters reflect both ICU quality and utilization. While mortality rates are generally low in critical care and thus too insensitive to use in comparisons,[21–23] rates of deaths are sufficiently high enough among ICU patients to be used as a quality indicator.[6] As patients may be transferred elsewhere in the hospital as death nears,[24] ICU patient mortality rates were calculated using deaths that occurred both in the ICU (in-ICU mortality), and including deaths after transfer elsewhere within the hospital (combined post-transfer mortality).

The eRI database does not include any cost estimates. We used length of stay used as a proxy for resource utilization, since up to 85% of ICU costs are explained by length of stay alone.[25] In this study, we calculated a mean residual for each ICU, utilizing the difference between observed and expected lengths of stay (OMELOS) as predicted by the APACHE IVa algorithm. Patients who died before discharge were excluded. As with mortality, we calculated length of stay including only ICU lengths of stay (in-ICU length of stay), and including days after transfer elsewhere within the hospital (combined post-transfer length of stay).

Patient Cohort Selection

The variation in outcomes between ICUs are mostly dominated by those who are very healthy or very sick. For example, ICU metrics are greatly skewed by low-risk patients

admitted to the ICU purely for monitoring purposes, and by high-risk patients for whom death may be a likely outcome. Consequently, this study included only patients who have a predicted risk of death between 2% and 20%, as predicted by the APACHE IVa algorithms. Patients without calculated APACHE IVa scores were excluded. These limits were based on expert consensus among clinicians familiar with the APACHE IVa scoring system.

Patients transferred between hospitals were also excluded from the study. Transfer status from another institution is an independent risk factor for mortality, even after controlling for case-mix.[26] Small numbers of transfer patients dramatically affect mortality rates,[27–29] and transfers are excluded from the APACHE IVa models.[30] In order to control for this "transfer bias", we excluded all patients who were transferred from another institution. We also excluded patients with extreme outlier unit lengths of stay above 300 days.

Direct Risk Standardization

In order to enable direct comparison of outcomes between each ICU, direct risk standardization was used to adjust for variations in case-mix.[31] In summary, we calculated a weighted average for each outcome variable using 2 percentage point increment risk groups based on APACHE IVa-predicted ICU mortality (e.g., 2-4%, …, and 18-20%). The weights were equal to the proportion of the number of patient records within each risk group. Weighted average mortality rates and lengths of stay were calculated for all patient records for each individual ICU. ICUs with less than 300 patient records for those within the 2-20% APACHE IVa-predicted mortality were excluded to eliminate extreme variations due to small sample sizes.

Bootstrapped Variance and Percentile Confidence Intervals

As risk adjustment was performed utilizing direct risk standardization, all adjusted outcome variables were weighted means. Unlike the arithmetic mean, no analytical analog of the standard error exists for weighted means.[32] Therefore, we estimated confidence intervals through bootstrapping.[33,34] All outcome variables were calculated for each ICU, utilizing 5000 resamples with replacement equal to the total number of patient records for each individual ICU. Variance and percentile confidence intervals were then calculated for each ICU.

Outlier Identification and False Discovery Rate Control

Outlier and comparator ICUs were defined as ICUs with confidence intervals that do not overlap with the population mean ($\alpha < 0.05$). P-values were generated for each ICU using a two-sided student's t test, and then adjusted for false discovery rate ($d < .05$) using the using the Benjamin-Hochberg procedure.[35] This process was repeated for each of the four outcome variables (i.e., in-ICU mortality, combined post-transfer mortality, in-ICU length of stay, and combined post-transfer length of stay), and visualized using caterpillar plots sorted by confidence interval limits. ICUs identified as

outliers on all four outcome variables were placed into positive outlier and negative comparator groups, respectively.

Qualitative Phase: Detecting Innovations

Site Selection

Two members of our study team (HC and MR) were provided with an unblinded list of ICUs identified as positive outliers and negative comparators. A purposive sample of 5 positive outliers and 5 negative comparators were selected, utilizing a maximum variation approach based on the following institutional characteristics: 1) ICU type, 2) patient volume, 3) academic affiliation, 4) presence of intermediate care units, 5) case-mix of ICU, 6) geographic locale, 7) urban or rural, and 8) health system.[17] The site visit teams were then provided with a blinded list of these ICUs for recruitment. The sample size of 10 sites is based on previous research establishing ten sites as likely to achieve thematic saturation for positive deviance studies in healthcare.[19]

Site Visits

We adapted the team-based Rapid Qualitative Inquiry (RQI) methodologies used in public health and applied anthropology, which rests on building rapport quickly, triangulating across multiple sources of data, and a multidisciplinary research team.[36] The blinded RQI team includes a surgeon and systems engineer (JJ), a registered ICU nurse and administrative fellow (DB), a healthcare researcher (RP)— all trained by two applied anthropologists (HC and HK). The research team will collect and analyze three key data sources: 1) semi-structured interviews, 2) unstructured observations, and 3) extant data.

The Consolidated Framework for Implementation Research (CFIR) will be used as a theoretical framework to guide both data collection and subsequent analysis.[37] CFIR is a determinant framework consisting of constructs known to be associated with effective implementation, and intended to guide evaluations and implementation strategy.[37,38] As the CFIR constructs include interventions, individuals, organizational context, and organizational processes, this framework provides both a typology and terminology to evaluate interventions and their context.

Semi-structured Team Interviews and Focus Groups

Bedside staff and unit managers will be recruited for interviews utilizing a combination of key informant, snowball, and opportunistic sampling.[39] Recruitment will occur using a maximum variation approach, aiming to capture a wide variety of perspectives at each site from across the hierarchy, including doctors, nurses, nursing technicians, and unit managers. Teams will recruit at least six to eight participants at each site, a sample size

found previously to be usually sufficient for thematic saturation in healthcare positive deviance.[19,40]

All interviews will be semi-structured, and utilize an interview guide that broadly addresses three key domains: unit-practices and communication, quality improvement, and relationships between management and frontline staff. The interviews will seek to identify innovations in these key domains and generate testable hypotheses that may explain variations in performance.[41] All interviews will be conducted in private settings, digitally recorded, and transcribed verbatim by professional transcriptionists.

Unstructured Observations

Observational data are particularly important for rapid qualitative approaches, as they provide a point of triangulation against data from interviews.[42] Our strategy requires observational data obtained using ethnographic methodologies, which are designed to access the typical routines and conditions of a field site.[43] Site visit teams will conduct at least two hours of direct observation in each ICU, including physician rounds, nursing shift changes, cardiopulmonary resuscitations, and fixed observation at nursing stations and eICU command centers. Each researcher will systematically generate descriptive field notes, including observed behaviors, processes, and environmental features.[39] These unstructured observations also provide opportunities to build rapport and conduct informal interviews with bedside staff.

Rapid Continuous Constant Comparative Analysis

This project will adapt a team-based, continuous analysis methodology commonly used in rapid qualitative approaches.[36] Considered critical to a team ethnographic approach, site visit teams will debrief as often as possible, reviewing field notes and interviews to generate potential hypotheses and innovations for each field site. The main purpose is to generate analytical field notes in a modified grounded theory approach, generating themes and causal explanations grounded in the data.[44,45]

All field notes, preliminary reports, and interview transcripts are then imported to Dedoose, a qualitative analysis software designed for teams.[46] All data will then be inductively coded using a combination of grounded theory and constant comparative methods, extending the formal codebook of themes identified during team debriefs. As site visit teams remain blinded to each site's outlier status, a constant comparative method will be used to generate causal models of factors and innovations, assessing the possibility that a field site is a positive outlier or negative comparator site in turn. Additional field notes are generated in this process ("memoing"), and a preliminary report for each site visit is generated.[36]

Cross-Case Analysis

All members of the study team will then be unblinded as to each sites' outlier status, and all data sources will be analyzed using a cross-case method.[47] Relevant

qualitative and quantitative data points will be entered into a matrix, organized by themes of interest identified during site visits, as well as the outlier status of each site. The data will then be interrogated for patterns, themes, similarities, and differences between the outlier and comparison sites. Causal models developed during the generation of preliminary reports will then be extended across multiple sites.

Ethics and Dissemination

The study protocol was reviewed and approved by the Stanford University Institutional Review Board (reference: 39509). Verbal informed consent will be obtained for all participants, and interviews will remain confidential and de-identified. Any study findings will only be reported in the aggregate, and individual ICUs will never be identified in publications. Participating ICUs will not be disclosed their outlier status, but all publications and reports will be shared with recruited sites. Potential innovations will also be disseminated to participants, as well as nationally through the work at the Stanford Clinical Excellence Research Center. We plan on publishing study findings and methodological guidance in peer-reviewed academic journals, white papers, and presentations at academic medical conferences.

Study Status

The quantitative portion of this study is complete. Qualitative data collection began in September 2016, and expected to complete by April 2017. Qualitative data analysis will be completed by June 2017.

Discussion and Limitations

We aim to extend positive deviance methods into a national study of intensive care. By focusing only on a subset of patients most likely to have lengths of stay and mortality rates affected by organizational processes and practices, this study aims to detect new innovations in the delivery of critical care. These innovations can then be tested in subsequent studies, and disseminated broadly if found to be efficacious.

There are several limitations to this study. First, the database includes only intensive care units that subscribed to the Philips eICU program. However, as the main objective of this study is to identify new organizational innovations that may drive ICU performance, the fact that all ICUs in this study have telemedicine capabilities ensures a similar level of technological access. In the United States, there are few other national databases of ICU quality, and the database is likely one of the most comprehensive data sources available.

Second, APACHE IVa is an imperfect measure of disease severity, although it remains one of the most widely used and best validated measures.[48,49] As the main purpose

of the quantitative portion of this project is to identify outlier ICUs likely to harbor organizational innovations, we believe the large sample sizes in this project will also protect against this limitation.

Finally, an intrinsic risk of the positive deviance approach is that success is dependent on the ability of either the researchers or the study participants to identify the innovations leading to variations in outcome. Although the double-blinded nature of this study maximizes our ability to correctly identify successful innovations, there is an unavoidable risk that no new innovations will be identified. Replication of positive deviance studies can also be challenging, as differing site visit teams may identify different innovations as worthwhile.

This protocol, however, also contains several novel features to further the translation of positive deviance methods to healthcare services research. First, we are conducting the study with both qualitative and quantitative rigor, responding to previous criticisms of the method. Second, this study is also one of the first to utilize a double-blinded strategy, as both study participants and site visit teams are not disclosed the outlier status of individual ICUs. These methodological innovations will allow us to evaluate not only the usage of positive deviance and rapid qualitative inquiry methods in healthcare, but also test rapid team ethnography as a research tool. Our hope is that our methodological evaluations will make as significant an impact as the new innovations we identify to help improve intensive care.

Acknowledgments

The authors would like to thank Hilary King, Lloyd Provost, David Spiegelhalter, and Scott Halpern for providing thoughtful commentary and guidance towards the development of this protocol.

Authors' Contributions

JJ, HC, MR, KV, TW, and AM contributed significantly to the initial conceptualization of the project. JJ and HC were responsible for the study design. The quantitative analysis was conducted by JS, HC, and TW. The qualitative site visit team included JJ, RP, and DB. HC drafted the initial manuscript, and JJ, MR, KV, BR, TW, and AM provided substantial feedback for intellectual content on initial drafts. All authors approved the final copy.

Funding

This work was supported by The Gordon and Betty Moore Foundation grant number 4719 and the Stanford University Clinical Excellence Research Center. The following authors received salary support from this grant: HC, JS, AM, TW.

Competing Interests statement

None declared.

Data Sharing Statement

Due to the highly sensitive nature of the data collected, qualitative and quantitative databases will not be shared with others to protect study participants.

License Statements

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SUPPLEMENTARY FILE 1:

Interview Guide

INTERVIEWER INSTRUCTIONS

The questions below are not meant to be asked verbatim, nor asked necessarily in the order given here. Instead, they are meant to illustrate potential prompts that may be useful in eliciting participant responses within each domain. Your interview should be guided by the participant as much as the key domains below.

INTRO QUESTIONS

// Intended to probe unit culture and experiences of the interviewee in an open-ended manner. //

Tell us what it's like to work here.

Has working here changed over the time that you've been here? How?

What are some of the important working systems or practices that you have in place on the unit?

How are rounds done in your unit? Who participates? Are there particular practices that you think are unique to your unit in relation to rounds?

How do you know what the plan is for your patient(s)?

What are some of the biggest challenges to working here?

FRAMING FOR DOMAIN-BASED SECTIONS

We are particularly interested in how communication and work processes affect mortality rates and length of stay for patients. We've found that it is often useful to talk about these issues in the context of concrete examples, and so gear many questions toward patient progression and quality improvements on the unit. However, we invite you to think more broadly if other things come to mind related to these outcomes while we are asking these questions.

DOMAIN 1 – UNIT PRACTICES AND COMMUNICATION

// Intended to probe: Unit-level practices that help move patients toward discharge. How front line staff communicates about patient plans. //

I am going to move on to a few questions about communication around patient plans. In this section, we are focused on what we call "just right" patients. For us, these are patients "well-suited" for the ICU, i.e., not patients boarding in the ICU waiting for a lower level or care, or patients who are in the end of life/palliative category.

Think about a 'just right' patient who you currently have on your list. How do you get information about this patient's plan? Do you get the same plan from everyone? When there is a discrepancy, why is that?

How are you typically notified of a change in plans?

How do you make sure to progress that patient toward discharge in a safe and timely manner? What specific things do you do?

When complications arise, how is this handled? Does the plan change? How does the team communicate about this complication?

When you talk about complications with your team, is it a warm and welcome environment? Punitive?

(Normalize the fact that complications exist on the unit so staff can speak more openly.)

Are patient plans managed 24/7?

What role does the eICU play in the unit? What role does it play in patient progression?

DOMAIN 1.2 – EFFECTIVE PATIENT PROGRESSION EXAMPLE

Think of a recent time where you felt like you effectively managed a 'just right' patient in a safe and timely manner. Tell me what happened and why you felt like this was effective.

In your experience, how typical are these cases? What increases the likelihood of them happening?

DOMAIN 1.3 – INEFFECTIVE PATIENT PROGRESSION EXAMPLE

Think of a recent time where you felt like you did NOT effectively manage a 'just right' patient in a safe and timely manner. Tell me what happened and why you felt like it was ineffective.

In your experience, how typical are those types cases? What increases the likelihood of these cases happening?

DOMAIN 2 – QUALITY IMPROVEMENT

// Intended to probe opinions on quality improvement efforts and outcomes. //

Ask about the concrete improvements and initiatives that have been previously mentioned by the unit director or other staff. Use people's local languages and examples as much as possible to make the questions relevant to the interviewed population.

Are there specific initiatives that have been implemented to improve outcomes on the unit? If yes, give some examples.

We spoke with _____, who mentioned _____ changes that have been put in place. Can you talk about how these are have been implemented?

Are these _____ efforts "worth it"?

What are leadership factors that allow for continuous improvement of the unit?

How often are there discussions with all staff about quality improvement? What are those discussions typically like? Do you ever give feedback?

Important probe: Do you feel listened to?

Does your management share data on your unit's performance? Do you look at these data?

Can you think about a time when a unit level quality improvement effort/program was rolled out and worked well? Describe to me what occurred.

Probe: How was it rolled out? Was the staff involved in roll out?

Can you think about a time when a unit level quality improvement effort was rolled out and did NOT work well? Describe to me what occurred.

DOMAIN 3 – MANAGEMENT/FRONTLINE STAFF DISCONNECTS AND CONNECTIONS

// Intended to triangulate management perceptions with those of the frontline staff. //

// Intended to probe how/if there are any unit level factors that help frontline staff progress their patients in a safe and timely manner. //

In general, a unit should function well in order for individual patients to progress and the unit to function. How does your leadership enable your unit to function maximally? What challenges affect communication or alignment between frontline staff and unit management?

What are unit level factors that enable your frontline patient care processes regularly and efficiently?

CLOSING

// Intended to allow for additional observations. //

What else have we not talked about yet that you feel affects mortality rates or length of stay for patients?

Anything else that you would like for us to know about working on this unit, or your thoughts on the issues presented here?

Who else should we speak with?

BMJ Open

Detecting organizational innovations leading to improved ICU outcomes: a protocol for a double-blinded national positive deviance study of critical care delivery

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-015930.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Mar-2017
Complete List of Authors:	Chiou, Howard; Stanford University, Clinical Excellence Research Center; Emory University School of Medicine, Medical Scientist Training Program and Department of Anthropology Jopling, Jeffrey; Stanford University, Clinical Excellence Research Center; Gordon and Betty Moore Foundation Scott, Jennifer; Stanford University, Clinical Excellence Research Center Ramsey, Meghan; Stanford University, Clinical Excellence Research Center Vranas, Kelly; Stanford University, Clinical Excellence Research Center; Oregon Health & Science University Wagner, Todd; Stanford University, Clinical Excellence Research Center Milstein, Arnold; Stanford University, Clinical Excellence Research Center
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Intensive care, Qualitative research, Medical management
Keywords:	Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, INTENSIVE & CRITICAL CARE, QUALITATIVE RESEARCH

Title (50 words)

Detecting organizational innovations leading to improved ICU outcomes: a protocol for a double-blinded national positive deviance study of critical care delivery.

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Abstract (300 words)

Introduction: There is substantial variability in intensive care unit (ICU) utilization and quality of care. However, the factors that drive this variation are poorly understood. This study utilizes a novel adaptation of positive deviance approach— a methodology used in public health that assumes solutions to challenges already exist within the system to detect innovations that are likely to improve intensive care.

Methods and Analysis: We used the Philips eICU Research Institute database (eRI), containing 3.3 million patient records from over 50 health systems across the United States. Acute Physiology and Chronic Health Evaluation (APACHE) IVa scores were used to identify the study cohort, which included ICU patients whose outcomes were felt to be most sensitive to organizational innovations. The primary outcomes included mortality and length of stay. Outcome measurements were directly standardized, and bootstrapped confidence intervals calculated with adjustment for false discovery rate. Using purposive sampling, we then generated a blinded list of 5 positive outliers and 5 negative comparators.

Using rapid qualitative inquiry, blinded interdisciplinary site visit teams will conduct interviews and observations using a team ethnography approach. After data collection is completed, the data will be unblinded and analyzed using a cross-case method to

identify themes, patterns, and innovations using a constant comparative grounded theory approach. This process not only allows for the detection of innovations in intensive care, but also support an evaluation of how positive deviance and rapid qualitative inquiry methods can be adapted to healthcare.

Ethics and Dissemination: The study protocol was approved by the Stanford University Institutional Review Board (Reference: 39509). We plan on publishing study findings and methodological guidance in peer-reviewed academic journals, white papers, and presentations at conferences.

Strengths and Limitations

- This study is a methodologically innovative translation of the positive deviance approach to health services research, and incorporates both qualitative and quantitative rigor.
- A national database of ICU care in the United States is used, and the methodology is a mixed-methods approach that triangulates between qualitative and quantitative data sources.
- The project is likely to inform the organization of care delivery in ICUs, as well as both positive deviance and rapid qualitative methodologies in healthcare.
- The database is limited to ICUs with telemedicine capabilities, and case-mix adjustment using APACHE IVa is imperfect. Study participants and site visitors may also not be able to accurately ascertain which innovations drive performance.

Introduction

Critical illness represents an enormous burden in the United States, with more than 5 million patients admitted annually to ICUs [1]. Caring for these patients consumes a disproportionate amount of resources; despite comprising fewer than 10% of all hospital beds, ICUs accounts for 13.4% of total hospital costs and 0.66% of the national gross domestic product.[2] This burden will likely increase with the aging population, as both utilization rate and the proportion of beds allocated to intensive care rise.[2–5]

Yet, the quality of care delivered varies dramatically between units and hospitals. ICUs differ widely in their rates of compliance with best practices and rates of avoidable complications (e.g., hospital acquired infections).[6] Risk-adjusted mortality also differs among ICUs, with studies suggesting that high performing ICUs in the country have up to 10-12 fewer deaths for every 100 patients than the lowest performing ICUs, even after controlling for factors like discharge practices and patient demographics.[7] These trends have been confirmed in more recent studies of ventilated patients.[8,9]

Variations in performance are likely driven by differences in ICU organization and practices, rather than by access to technology.[10,11] Modern ICUs are more an *organizational innovation* than a technological one, matching a concentration of personnel and resources for any type of critically ill patient. Previous research has identified organizational factors like RN-to-patient ratios, daily care plans, and usage of care bundles as associated with improved risk-adjusted mortality.[12–14]

Unfortunately, innovations in organization and practice are not well described in the critical care literature. Hospitals do not typically share their innovative practices with one another, and data to compare ICU performance are not readily available. Although some practices may be published, context is frequently not reported in sufficient detail to ensure successful implementation.[15] All of these factors obscure our ability to identify which aspects of critical care organization and practices help drive performance.

Positive deviance is one methodology that may offer additional insights. This approach assumes that innovations that address problems common to many organizations have already been developed, and can be detected by studying positive outliers before being tested and disseminated.[16,17] Originating from global health, the approach has been used successfully in a wide variety of settings to improve healthcare quality, including diabetes management in primary care practices, and hospital door-to-balloon times in response to acute myocardial infarction.[18, 19]

However, a systematic review of positive deviance studies in healthcare found research quality to be low, and there have been very few applications of the approach in the critical care setting.[16] Highlighting the need for increased rigor, a previous study utilizing qualitative site visits failed to identify differences between ICUs associated with performance.[11] The goal of this research protocol is to describe our methods for conducting a positive deviance study in critical care. Specifically, we sought to identify organizational innovations in the delivery of critical care, adapting the first two steps of the positive deviance approach to generate hypotheses as to which innovations explain variation in ICU utilization and quality of care. A secondary objective was to identify potential organizational structures, processes, and contexts that may explain this variation. Through these aims, we hope to not only detect innovations in intensive care, but also support an evaluation of how positive deviance and rapid qualitative inquiry methods can be adapted to healthcare.

Methods and Analysis

Conducting a positive deviance study requires four steps: 1) identify outliers within an area of interest, 2) utilize qualitative approaches to generate hypotheses to explain their performance, 3) test hypotheses in a larger sample, and 4) disseminate evidence about best practices.[20,21] Our strategy utilizes a blinded, retrospective approach in the two first steps. We analyzed a national database of ICUs to develop a study cohort of five positive outliers and five comparator ICUs. This quantitative phase will be followed by

in-depth qualitative work at these ten sites, where we will build comparative case studies on their innovations and themes.

Quantitative Phase: Identifying Outliers

Data Source

We used data from the Philips eICU Research Institute database (eRI), containing over 3.3 million patient records from over 50 health systems from 2003 through 2015. All ICUs in the database have implemented the Philips eICU telemedicine system. Data for ICU admissions includes vital sign measurements, quality metrics, medication orders, and patient laboratory values. All of the ICUs in the study were offered an opportunity to opt-out of the study, and the protected health information of individual patients was not included. The database includes over 400 hospitals; as of 2014, there were 5,686 acute care hospitals in the United States, all of which had at least one ICU.[22]

ICU Cohort Selection

Inclusion criteria included all hospital units that contributed data to the Philips eRI database between 2013 and 2015. We excluded hospital units who did not participate for all three years, as well as self-identified stepdown or intermediate care units. To minimize variation from small sample sizes, we also excluded low-volume ICUs, defined as ICUs with fewer than 300 discharges per year. The final cohort included 276 ICUs that cared for a total of 370,278 patients over three years. These ICUs form a geographically diverse sample of ICUs with eICU capabilities.

Outcome Measurements

Primary outcomes included mortality and length of stay for patients admitted to the ICU, since these parameters reflect both ICU quality and utilization. While mortality rates are generally low in critical care and thus insensitive to use in comparisons,[23–25] rates of deaths are sufficiently high enough among ICU patients to be used as a quality indicator.[7] As patients may be transferred elsewhere in the hospital as death nears,[26] ICU patient mortality rates were calculated using deaths that occurred both in the ICU (in-ICU mortality), and including deaths after transfer elsewhere within the hospital (combined post-transfer mortality).

The eRI database does not include any cost estimates. We used length of stay used as a proxy for resource utilization, since up to 85% of ICU costs are explained by length of stay alone.[27] In this study, we calculated a mean residual for each ICU, utilizing the difference between observed and expected lengths of stay (OMELOS) as predicted by the APACHE IVa algorithm. Patients who died before discharge were excluded. As with mortality, we calculated length of stay including only ICU lengths of stay (in-ICU length of stay), and including days after transfer elsewhere within the hospital (combined post-transfer length of stay).

Patient Cohort Selection

The variation in outcomes between ICUs are mostly dominated by those who are very healthy or very sick. For example, ICU metrics are greatly skewed by low-risk patients admitted to the ICU purely for monitoring purposes, and by high-risk patients for whom death may be a likely outcome. Consequently, included only patients who have a predicted risk of death between 2% and 20%, as predicted by the APACHE IVa algorithms. Patients without calculated APACHE IVa scores were excluded. These limits were based on expert consensus among clinicians familiar with the APACHE IVa scoring system.

Patients transferred between hospitals were also excluded from the study. Transfer status from another institution is an independent risk factor for mortality, even after controlling for case-mix.[28] Small numbers of transfer patients dramatically affect mortality rates,[29–31] and transfers are excluded from the APACHE IVa models.[30] In order to control for this “transfer bias”, we excluded all patients who were transferred from another institution. We also excluded patients with extreme outlier unit lengths of stay above 300 days.

Direct Risk Standardization

In order to enable direct comparison of outcomes between each ICU, direct risk standardization was used to adjust for variations in case-mix.[33] In summary, we calculated a weighted average for each outcome variable using 2 percentage point increment risk groups based on APACHE IVa-predicted ICU mortality (e.g., 2-4%, …, and 18-20%). The weights were equal to the proportion of the number of patient records within each risk group. Weighted average mortality rates and lengths of stay were calculated for all patient records for each individual ICU. ICUs with less than 300 patient records for those within the 2-20% APACHE IVa-predicted mortality were excluded to eliminate extreme variations due to small sample sizes.

Bootstrapped Variance and Percentile Confidence Intervals

As risk adjustment was performed utilizing direct risk standardization, all adjusted outcome variables were weighted means. Unlike the arithmetic mean, no analytical analog of the standard error exists for weighted means.[34] Therefore, we estimated confidence intervals through bootstrapping.[35,36] All outcome variables were calculated for each ICU, utilizing 5000 resamples with replacement equal to the total number of patient records for each individual ICU. Variance and percentile confidence intervals were then calculated for each ICU.

Outlier Identification and False Discovery Rate Control

Outlier and comparator ICUs were defined as ICUs with confidence intervals that do not overlap with the population mean ($\alpha \leq 0.05$). P-values were generated for each ICU using a two-sided student’s t test, and then adjusted for false discovery rate ($d < .05$)

using the Benjamin-Hochberg procedure.[37] This process was repeated for each of the four outcome variables (i.e., in-ICU mortality, combined post-transfer mortality, in-ICU length of stay, and combined post-transfer length of stay), and visualized using caterpillar plots sorted by confidence interval limits. ICUs identified as outliers on all four outcome variables were placed into positive outlier and negative comparator groups, respectively.

Qualitative Phase: Detecting Innovations

Site Selection

Two members of our study team (HC and MR) were provided with an unblinded list of ICUs identified as positive outliers and negative comparators. A purposive sample of 5 positive outliers and 5 negative comparators were selected, utilizing a maximum variation approach based on the following institutional characteristics: 1) ICU type, 2) patient volume, 3) academic affiliation, 4) presence of intermediate care units, 5) case-mix of ICU, 6) geographic locale, 7) urban or rural, and 8) health system.[18] The site visit teams were then provided with a blinded list of these ICUs for recruitment. The sample size of 10 sites is based on previous research establishing ten sites as likely to achieve thematic saturation for positive deviance studies in healthcare.[21]

Site Visits

We adapted the team-based Rapid Qualitative Inquiry (RQI) methodologies used in public health and applied anthropology, which rests on building rapport quickly, triangulating across multiple sources of data, and a multidisciplinary research team.[38] The blinded RQI team includes a surgeon and systems engineer (JJ), a registered ICU nurse and administrative fellow (DB), and a healthcare researcher (RP)— all trained by two applied anthropologists (HC and HK). The research team will collect and analyze three key data sources: 1) semi-structured interviews, 2) unstructured observations, and 3) extant data.

The Consolidated Framework for Implementation Research (CFIR) will be used as a theoretical framework to guide both data collection and subsequent analysis.[39] CFIR is a determinant framework consisting of constructs known to be associated with effective implementation, and intended to guide evaluations and implementation strategy.[39,40] As the CFIR constructs include interventions, individuals, organizational context, and organizational processes, this framework provides both a typology and terminology to evaluate interventions and their context.

Semi-structured Team Interviews and Focus Groups

Bedside staff and unit managers will be recruited for interviews utilizing a combination of key informant, snowball, and opportunistic sampling.[41] Recruitment will occur using a maximum variation approach, aiming to capture a wide variety of perspectives at each site from across the hierarchy, including doctors, nurses, nursing technicians, and unit managers. Teams will recruit at least six to eight participants at each site, a sample size found previously to be usually sufficient for thematic saturation in healthcare positive deviance.[21,42]

All interviews will be semi-structured, and utilize an interview guide that broadly addresses three key domains: unit-practices and communication, quality improvement, and relationships between management and frontline staff. The interviews will seek to identify innovations in these key domains and generate testable hypotheses that may explain variations in performance.[43] All interviews will be conducted in private settings, digitally recorded, and transcribed verbatim by professional transcriptionists.

Unstructured Observations

Observational data are particularly important for rapid qualitative approaches, as they provide a point of triangulation against data from interviews.[44] Our strategy requires observational data obtained using ethnographic methodologies, which are designed to access the typical routines and conditions of a field site.[45] Site visit teams will conduct at least two hours of direct observation in each ICU, including physician rounds, nursing shift changes, cardiopulmonary resuscitations, and fixed observation at nursing stations and eICU command centers. Each researcher will systematically generate descriptive field notes, including observed behaviors, processes, and environmental features.[41] These unstructured observations also provide opportunities to build rapport and conduct informal interviews with bedside staff.

Extant Data

Collection of contextual data is a critical component of RQI, and provides an additional basis from which hypotheses can be triangulated.[38] For example, site visit teams may encounter training documents, written policies, news reports, or locally collected data. With permission, these data will be digitized into the research database, and analyzed as described below.

Rapid Continuous Constant Comparative Analysis

This project will adapt a team-based, continuous analysis methodology commonly used in rapid qualitative approaches.[38] Considered critical to a team ethnographic approach, site visit teams will debrief as often as possible, reviewing field notes and interviews to generate potential hypotheses and innovations for each field site. The main purpose is to generate analytical field notes in a modified grounded theory approach, generating

themes and causal explanations grounded in the data.[46,47] While classic grounded theory emphasizes a primarily inductive approach, we will include a mixed grounded theory and content analysis as typical of rapid qualitative research[38, 47].

All field notes, preliminary reports, interview transcripts, and any extant data are then imported to Dedoose, a qualitative analysis software designed for teams.[48] All data will then be inductively coded using a combination of grounded theory and constant comparative methods, extending the formal codebook of themes identified during team debriefs. As site visit teams remain blinded to each site's outlier status, a constant comparative method will be used to generate causal models of factors and innovations, assessing the possibility that a field site is a positive outlier or negative comparator site in turn. Additional field notes are generated in this process ("memoing"), and a preliminary report for each site visit is generated.[38]

Cross-Case Analysis

All members of the study team will then be unblinded as to each sites' outlier status, and all data sources will be analyzed using a cross-case method.[49] Relevant qualitative and quantitative data points will be entered into a matrix, organized by themes of interest identified during site visits, as well as the outlier status of each site. The data will then be interrogated for patterns, themes, similarities, and differences between the outlier and comparison sites. Causal models developed during the generation of preliminary reports will then be extended across multiple sites.

Ethics and Dissemination

The study protocol was reviewed and approved by the Stanford University Institutional Review Board (reference: 39509). Verbal informed consent will be obtained for all participants, and interviews will remain confidential and de-identified. Any study findings will only be reported in the aggregate, and individual ICUs will never be identified in publications. Participating ICUs will not be disclosed their outlier status, but all publications and reports will be shared with recruited sites. Potential innovations will also be disseminated to participants, as well as nationally through the work at the Clinical Excellence Research Center at Stanford University. We plan on publishing study findings and methodological guidance in peer-reviewed academic journals, white papers, and presentations at academic medical conferences.

Study Status

The quantitative portion of this study is complete. Qualitative data collection began in September 2016, and expected to complete by April 2017. Qualitative data analysis will be completed by September 2017.

Discussion and Limitations

We aim to extend positive deviance methods into a national study of intensive care. By focusing only on a subset of patients most likely to have lengths of stay and mortality rates affected by organizational processes and practices, this study aims to detect new innovations in the delivery of critical care. These innovations can then be tested in subsequent studies, and disseminated broadly if found to be efficacious.

There are several limitations to this study. First, the database includes only intensive care units that subscribed to the Philips eICU program. However, as the main objective of this study is to identify new organizational innovations that may drive ICU performance, the fact that all ICUs in this study have telemedicine capabilities ensures a similar level of technological access. In the United States, there are few other national databases of ICU quality, and the database is likely one of the most comprehensive data sources available.

Second, APACHE IVa is an imperfect measure of disease severity, although it remains one of the most widely used and best validated measures.[50,51] As the main purpose of the quantitative portion of this project is to identify outlier ICUs likely to harbor organizational innovations, we believe the large sample sizes in this project will also protect against this limitation.

Finally, an intrinsic risk of the positive deviance approach is that success is dependent on the ability of either the researchers or the study participants to identify the innovations leading to variations in outcome. Although the double-blinded nature of this study maximizes our ability to correctly identify successful innovations, there is an unavoidable risk that no new innovations will be identified. Replication of positive deviance studies can also be challenging, as differing site visit teams may identify different innovations as worthwhile.

This protocol, however, also contains several novel features to further the translation of positive deviance methods to healthcare services research. First, we are conducting the study with both qualitative and quantitative rigor, responding to previous criticisms of the method. Second, this study is also one of the first to utilize a double-blinded strategy, as both study participants and site visit teams are not disclosed the outlier status of individual ICUs. These methodological innovations will allow us to evaluate not only the usage of positive deviance and rapid qualitative inquiry methods in healthcare, but also test rapid team ethnography as a research tool. Our hope is that these methodological innovations will make a significant impact in improving healthcare delivery and outcomes for critically ill patients.

Acknowledgments

The authors would like to thank Hilary King, Lloyd Provost, David Spiegelhalter, and Scott Halpern for providing thoughtful commentary and guidance towards the development of this protocol.

Authors' Contributions

JJ, HC, MR, KV, TW, and AM contributed significantly to the initial conceptualization of the project. JJ and HC were responsible for the study design. The quantitative analysis was conducted by JS, HC, and TW. The qualitative site visit team included JJ, RP, and DB. HC drafted the initial manuscript, and JJ, MR, KV, BR, TW, and AM provided substantial feedback for intellectual content on initial drafts. All authors approved the final copy.

Funding

This work was supported by The Gordon and Betty Moore Foundation grant number 4719 and the Stanford University Clinical Excellence Research Center. The following authors received salary support from this grant: HC, JS, AM, TW.

Competing Interests statement

None declared.

Data Sharing Statement

Due to the highly sensitive nature of the data collected, qualitative and quantitative databases will not be shared with others to protect study participants.

License Statements

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SUPPLEMENTARY FILE 1:

Interview Guide

INTERVIEWER INSTRUCTIONS

The questions below are not meant to be asked verbatim, nor asked necessarily in the order given here. Instead, they are meant to illustrate potential prompts that may be useful in eliciting participant responses within each domain. Your interview should be guided by the participant as much as the key domains below.

INTRO QUESTIONS

// Intended to probe unit culture and experiences of the interviewee in an open-ended manner. //

Tell us what it's like to work here.

Has working here changed over the time that you've been here? How?

What are some of the important working systems or practices that you have in place on the unit?

How are rounds done in your unit? Who participates? Are there particular practices that you think are unique to your unit in relation to rounds?

How do you know what the plan is for your patient(s)?

What are some of the biggest challenges to working here?

FRAMING FOR DOMAIN-BASED SECTIONS

We are particularly interested in how communication and work processes affect mortality rates and length of stay for patients. We've found that it is often useful to talk about these issues in the context of concrete examples, and so gear many questions toward patient progression and quality improvements on the unit. However, we invite you to think more broadly if other things come to mind related to these outcomes while we are asking these questions.

DOMAIN 1 – UNIT PRACTICES AND COMMUNICATION

// Intended to probe: Unit-level practices that help move patients toward discharge. How front line staff communicates about patient plans. //

I am going to move on to a few questions about communication around patient plans. In this section, we are focused on what we call "just right" patients. For us, these are patients "well-suited" for the ICU, i.e., not patients boarding in the ICU waiting for a lower level or care, or patients who are in the end of life/palliative category.

Think about a 'just right' patient who you currently have on your list. How do you get information about this patient's plan? Do you get the same plan from everyone? When there is a discrepancy, why is that?

How are you typically notified of a change in plans?

How do you make sure to progress that patient toward discharge in a safe and timely manner? What specific things do you do?

When complications arise, how is this handled? Does the plan change? How does the team communicate about this complication?

When you talk about complications with your team, is it a warm and welcome environment? Punitive?

(Normalize the fact that complications exist on the unit so staff can speak more openly.)

Are patient plans managed 24/7?

What role does the eICU play in the unit? What role does it play in patient progression?

DOMAIN 1.2 – EFFECTIVE PATIENT PROGRESSION EXAMPLE

Think of a recent time where you felt like you effectively managed a 'just right' patient in a safe and timely manner. Tell me what happened and why you felt like this was effective.

In your experience, how typical are these cases? What increases the likelihood of them happening?

DOMAIN 1.3 – INEFFECTIVE PATIENT PROGRESSION EXAMPLE

Think of a recent time where you felt like you did NOT effectively manage a 'just right' patient in a safe and timely manner. Tell me what happened and why you felt like it was ineffective.

In your experience, how typical are those types cases? What increases the likelihood of these cases happening?

DOMAIN 2 – QUALITY IMPROVEMENT

// Intended to probe opinions on quality improvement efforts and outcomes. //

Ask about the concrete improvements and initiatives that have been previously mentioned by the unit director or other staff. Use people's local languages and examples as much as possible to make the questions relevant to the interviewed population.

Are there specific initiatives that have been implemented to improve outcomes on the unit? If yes, give some examples.

We spoke with _____, who mentioned _____ changes that have been put in place. Can you talk about how these are have been implemented?

Are these _____ efforts "worth it"?

What are leadership factors that allow for continuous improvement of the unit?

How often are there discussions with all staff about quality improvement? What are those discussions typically like? Do you ever give feedback?

Important probe: Do you feel listened to?

Does your management share data on your unit's performance? Do you look at these data?

Can you think about a time when a unit level quality improvement effort/program was rolled out and worked well? Describe to me what occurred.

Probe: How was it rolled out? Was the staff involved in roll out?

Can you think about a time when a unit level quality improvement effort was rolled out and did NOT work well? Describe to me what occurred.

DOMAIN 3 – MANAGEMENT/FRONTLINE STAFF DISCONNECTS AND CONNECTIONS

// Intended to triangulate management perceptions with those of the frontline staff. //

// Intended to probe how/if there are any unit level factors that help frontline staff progress their patients in a safe and timely manner. //

In general, a unit should function well in order for individual patients to progress and the unit to function. How does your leadership enable your unit to function maximally? What challenges affect communication or alignment between frontline staff and unit management?

What are unit level factors that enable your frontline patient care processes regularly and efficiently?

CLOSING

// Intended to allow for additional observations. //

What else have we not talked about yet that you feel affects mortality rates or length of stay for patients?

Anything else that you would like for us to know about working on this unit, or your thoughts on the issues presented here?

Who else should we speak with?