Quality Improvement in Healthcare: A Valuable Academic Pursuit

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So first things first…introductions. I am Sean Josephs.

Objectives

- Describe the UC / UCH Performance Improvement Way as a mental model for improving healthcare
- Translate important similarities and differences between Quality Improvement and Clinical Research
- Demonstrate the value of Healthcare Quality and Performance Improvement work as a scholarly activity

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Disclosures

- None

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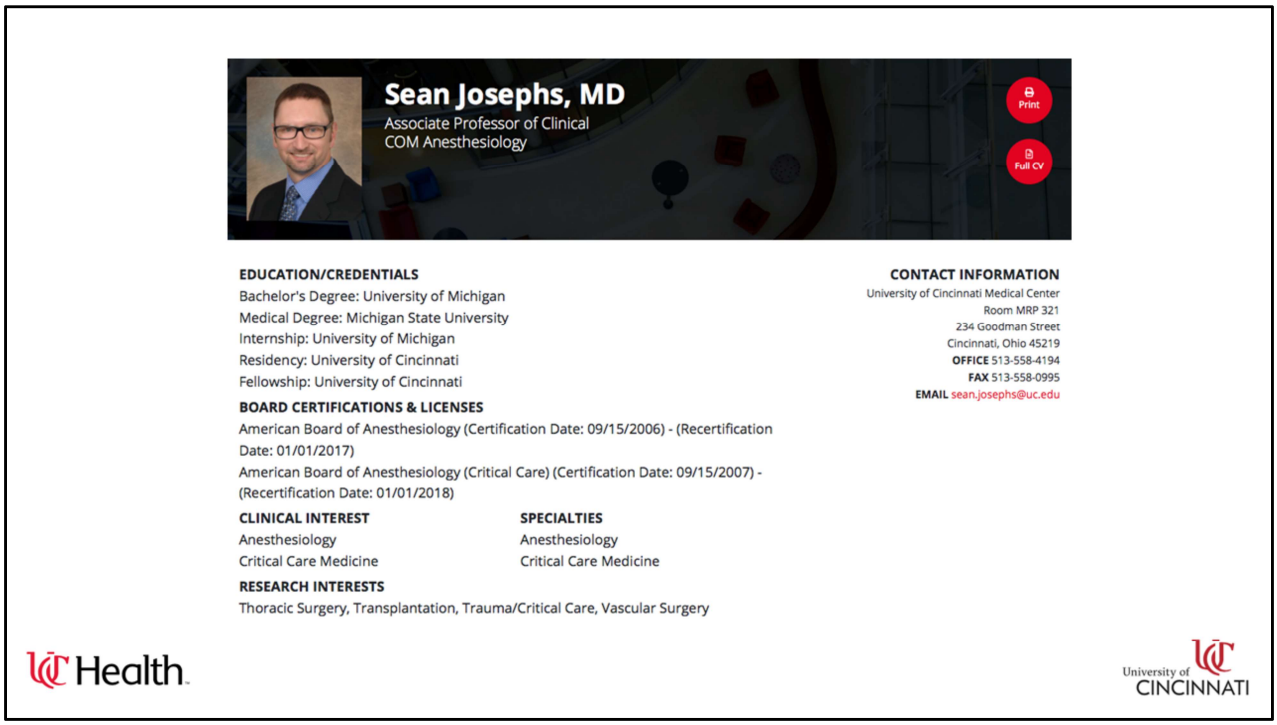
I have no disclosure.



Sean Josephs, MD
Associate Professor of Clinical
COM Anesthesiology

Print
Full CV

EDUCATION/CREDENTIALS
Bachelor's Degree: University of Michigan
Medical Degree: Michigan State University
Internship: University of Michigan
Residency: University of Cincinnati
Fellowship: University of Cincinnati

BOARD CERTIFICATIONS & LICENSES
American Board of Anesthesiology (Certification Date: 09/15/2006) - (Recertification Date: 01/01/2017)
American Board of Anesthesiology (Critical Care) (Certification Date: 09/15/2007) - (Recertification Date: 01/01/2018)

CLINICAL INTEREST
Anesthesiology
Critical Care Medicine

SPECIALTIES
Anesthesiology
Critical Care Medicine

RESEARCH INTERESTS
Thoracic Surgery, Transplantation, Trauma/Critical Care, Vascular Surgery

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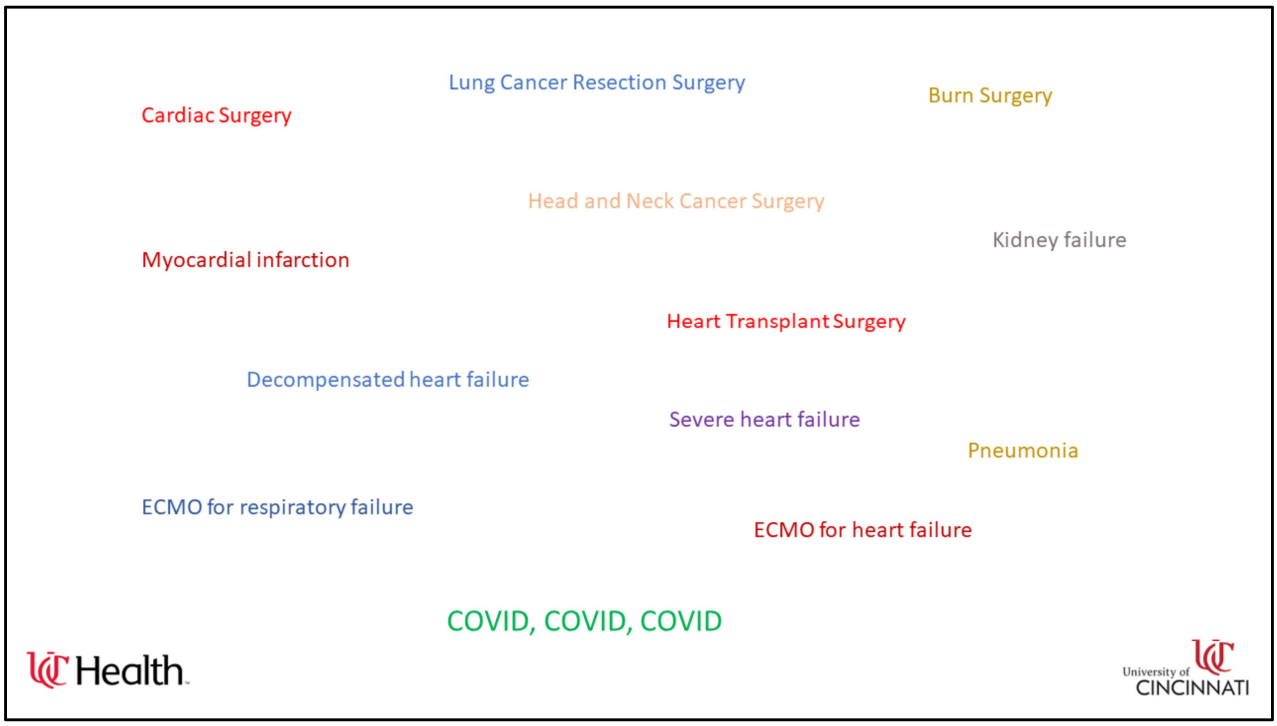
I am a board-certified anesthesiologist and intensivist (that means critical care doctor.) I trained at UM and MSU. I did my internship in Med/Peds at Michigan, residency and fellowship at UC.

I have led our departments efforts in Perioperative Medicine and Transplantation. I have since passed those responsibilities off. I have led our efforts in Quality and Safety for a number of years. I gained a lot of interest in improvement science starting in residency when I did a program here with Dr. Rouan that was funded by the Robert Wood Johnson Foundation called Achieving Competency Today (or ACT.) I later did some training at Children's across the street called I2S2 (their Intermediate Improvement Sciences curriculum) and AIM (their Advanced Improvement Methods Course.)

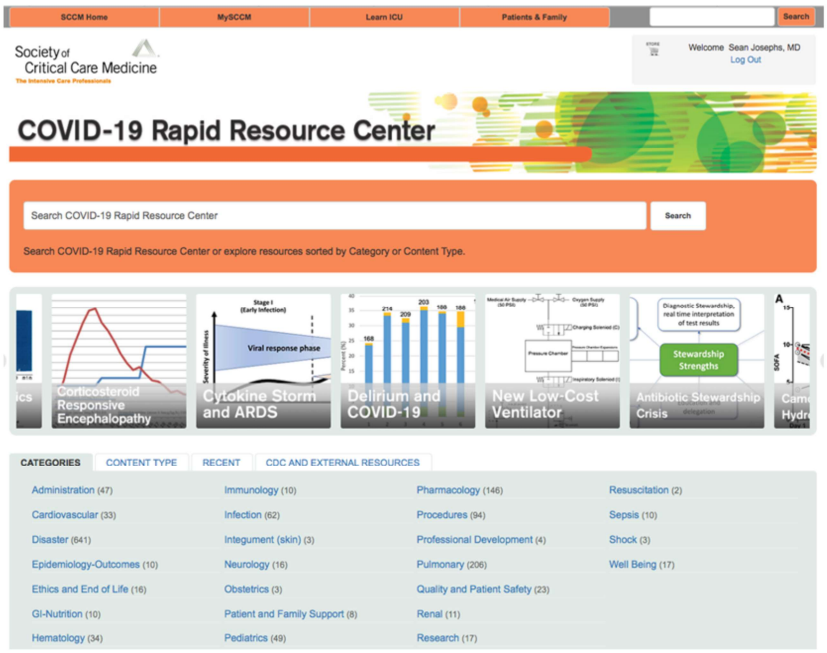
So it was a little hard to gauge the audience for this talk. I am not exactly sure what you think I am going to tell you today or what you are expecting to learn. I personally think that Quality Improvement in Healthcare is just as valuable if not more so than bench or clinical research. But many of you may disagree. Why do I feel this way?

Healthcare has become advanced. Very advanced. We know so much about diagnosing disease, treating disease, managing disease symptoms. We hope that physicians, advanced practice providers, nurses, respiratory therapists, physical therapist, pharmacists, etc know all of the stuff that we have discovered. We hope…

The bottom line is that we don't know the stuff that the world knows. It is too much to consume. Even when we break everybody up into specialists, subspecialists, and supersubspecialists it is very difficult to access and apply all of the information out there.



I am an Intensivist. I am a subspecialist but I function a lot like a generalist for doctors that put their patients in the ICU. I have to know a lot of different things. I have to be able to do a lot of different procedures. I care for patients after #cardiac bypass surgery, #lung resection surgery, and #major burns. I take care of patients who have had #myocardial infarctions, #massive head and neck cancer surgery, #new kidney failure, after #heart transplants, #decompensated and #severe heart failure, and #pneumonia. Because of these last few populations I make decisions about whether or not to put patients on ECMO. Because of these I have been involved quite a bit with the sickest of our COVID-19 patient this past year. Although I have been out of fellowship since 2006 and should have all of this down pat, I have learned something, I CAN'T KEEP UP!



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Just with COVID-19 there have been numerous studies, recommendations, retractions, and re-recommendations for things like dexamethasone, hydroxychloroquine, early vs late intubation, and whether or not to use ECMO. I have had to become familiar with sites like this one just in an attempt to keep up.

Many of you are familiar with this paper (slide with McGlynn *et al,* NEJM 2003 [1]). This was published in 2003. It was a retrospective study that randomly contacted some 6-7000 adults in 12 metropolitan areas of the United States and gained access to their medical records. They were attempting to determine if these adults were getting the care that they were supposed to be getting. They looked at 439 indicators of quality of care for 30 acute and chronic medical conditions as well as preventive care.

Do you know what they found?

A BIG PROBLEM!!!

According to this study they found that according to performance indicators adult Americans receive about 55% of the car that they should. They found significant variation in the care that was received based on the medical condition anywhere from 79% of cataract care to 10% of the appropriate care for alcohol dependence.

Table 3. Adherence to Quality Indicators, Overall and According to Type of Care and Function.

Variable	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)*
Overall care	439	6712	98,649	54.9 (54.3–55.5)
Type of care				
Preventive	38	6711	55,268	54.9 (54.2–55.6)
Acute	153	2318	19,815	53.5 (52.0–55.0)
Chronic	248	3387	23,566	56.1 (55.0–57.3)
Function				
Screening	41	6711	39,486	52.2 (51.3–53.2)
Diagnosis	178	6217	29,679	55.7 (54.5–56.8)
Treatment	173	6707	23,019	57.5 (56.5–58.4)
Follow-up	47	2413	6,465	58.5 (56.6–60.4)

Table 4. Adherence to Quality Indicators, According to Mode.

Mode	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)*
Encounter or other intervention	30	2843	4,329	73.4 (71.5–75.3)
Medication	95	2964	8,389	68.6 (67.0–70.3)
Immunization	8	6700	9,748	65.7 (64.3–67.0)
Physical examination	67	6217	19,428	62.9 (61.8–64.0)
Laboratory testing or radiography	131	5352	18,605	61.7 (60.4–63.0)
Surgery	21	244	312	56.9 (51.3–62.5)
History	64	6711	36,032	43.4 (42.4–44.3)
Counseling or education	23	2838	3,806	18.3 (16.7–20.0)

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N Engl J Med. 2003 Jun 26;348(26):2635-45

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Overall McGlynn found that people received about 55% of the recommended care. The held true for preventive, acute, or chronic care. It didn't matter if the care was related to screening, diagnostic care, treatment, or follow up—we miss 40 plus percent of the time. For some types of care that required history taking, counseling, or education we missed 60 to 80% of the time.

Table 5. Adherence to Quality Indicators, According to Condition.*

Condition	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)
Senile cataract	10	159	602	78.7 (73.3–84.2)
Breast cancer	9	192	202	75.7 (69.9–81.4)
Prenatal care	39	134	2920	73.0 (69.5–76.6)
Low back pain	6	489	3391	68.5 (66.4–70.5)
Coronary artery disease	37	410	2083	68.0 (64.2–71.8)
Hypertension	27	1973	6643	64.7 (62.6–66.7)
Congestive heart failure	36	104	1438	63.9 (55.4–72.4)
Cerebrovascular disease	10	101	210	59.1 (49.7–68.4)
Chronic obstructive pulmonary disease	20	169	1340	58.0 (51.7–64.4)
Depression	14	770	3011	57.7 (55.2–60.2)
Orthopedic conditions	10	302	590	57.2 (50.8–63.7)
Osteoarthritis	3	598	648	57.3 (53.9–60.7)
Colorectal cancer	12	231	329	53.9 (47.5–60.4)
Asthma	25	260	2332	53.5 (50.0–57.0)
Benign prostatic hyperplasia	5	138	147	53.0 (43.6–62.5)
Hyperlipidemia	7	519	643	48.6 (44.1–53.2)
Diabetes mellitus	13	488	2952	45.4 (42.7–48.3)
Headache	21	712	8125	45.2 (43.1–47.2)
Urinary tract infection	13	459	1216	40.7 (37.3–44.1)
Community-acquired pneumonia	5	144	291	39.0 (32.1–45.8)
Sexually transmitted diseases or vaginitis	26	410	2146	36.7 (33.8–39.6)
Dyspepsia and peptic ulcer disease	8	278	287	32.7 (26.4–39.1)
Atrial fibrillation	10	100	407	24.7 (18.4–30.9)
Hip fracture	9	110	167	22.8 (6.2–39.5)
Alcohol dependence	5	280	1036	10.5 (6.8–14.6)

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N Engl J Med. 2003 Jun 26;348(26):2635-45

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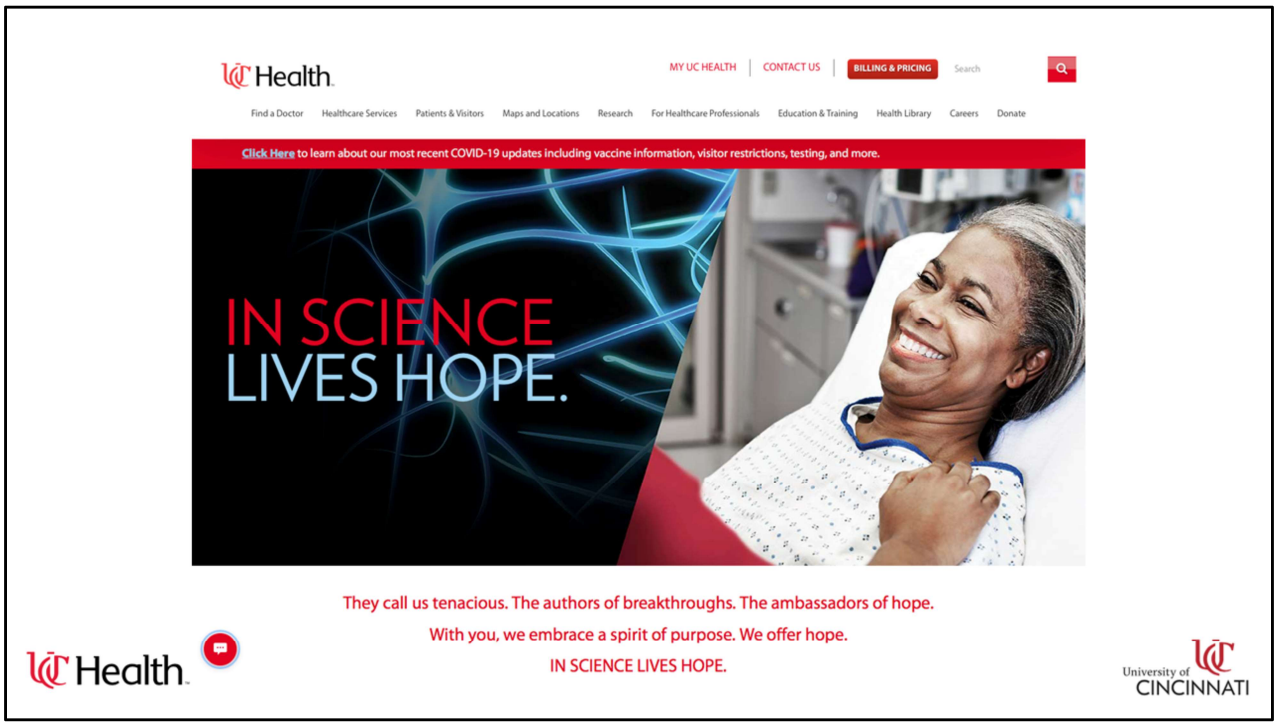
Although we were “okay” at treating cataracts and breast cancer (issues that often require surgery) we were much worse at dealing with other issues such as diabetes or alcohol dependence.

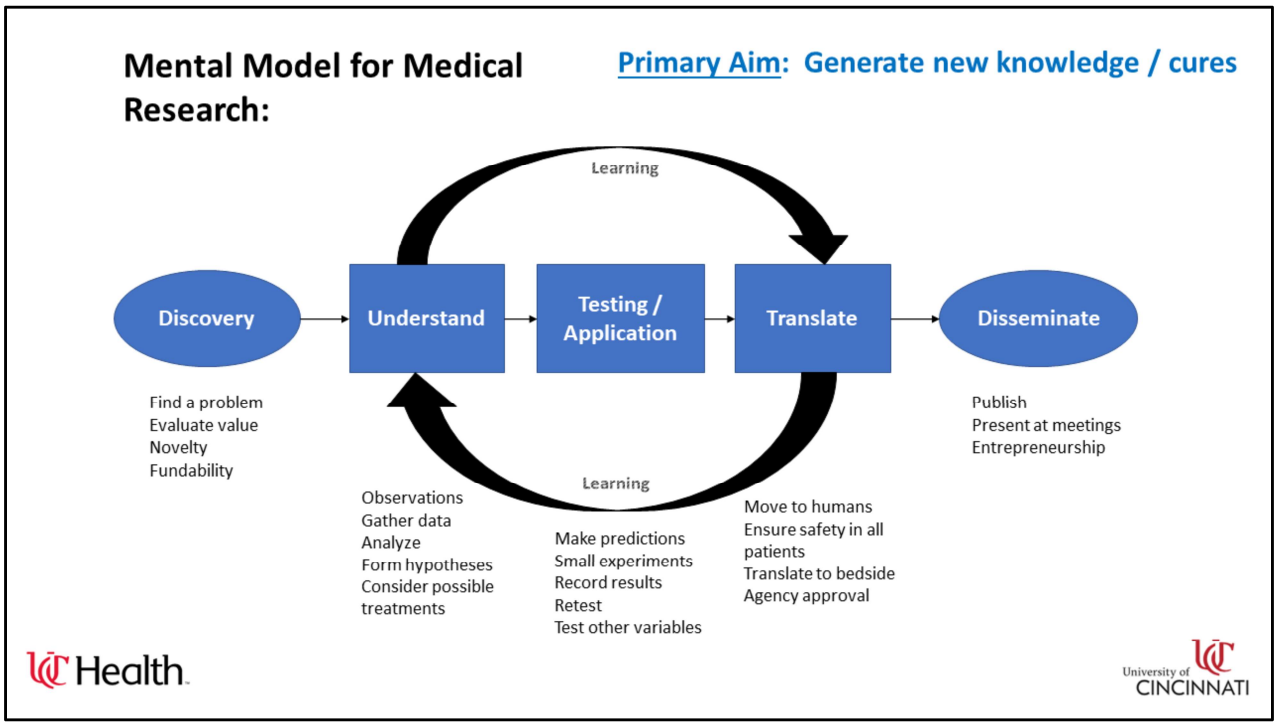
This study was published some 18 years ago.

How are we going to fix this?



Well, In Science, Lives Hope…

We are all living our careers in science.



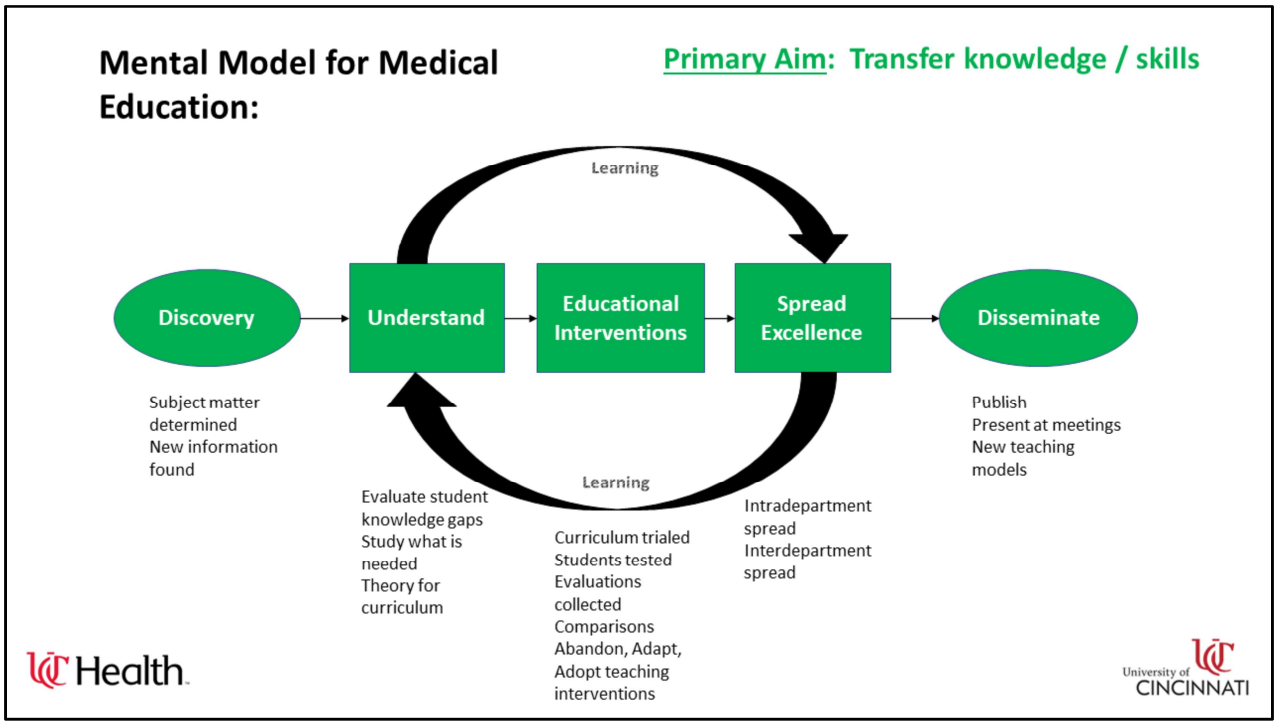
The researchers at UC and throughout the world have a scientific method, right. You look at your little segment of the world for problems to solve. Looking at your research area, your library of literature, your own laboratory experience you DISCOVER a problem.

After discovering a problem you seek to UNDERSTAND it. You observe the scenario, gather exploratory data, perform analyses. From this you start to generate hypotheses about the problem. You ask yourselves how you might FIX the problem or CURE the disease or make symptoms MORE TOLERABLE.

Once firm hypotheses are established you begin to TEST INTERVENTIONS on small scale. You make predictions, run experiments, record results, and plan for new or optimized interventions with new experiments.

Experiments eventually move from in vitro and in vivo studies to human trials. Studies move from Phase to Phase until there is adequate evidence of safety and a treatment effect that the intervention can be TRANSLATED from the bench to the bedside .

You DISSEMINATE your work through publication and presentations. The bigger the finding, the higher IMPACT of the journals and the bigger the national meeting presentation.



The educators have an analogous scientific method for imparting knowledge to our students.

At some point for instance medical educators DISCOVERED the subject matter and objectives that need to be learned to have a good grasp on let's say Microbiology, prior to internship. What bacteria do doctors need to know about? What is the spectrum of different antibiotics? What are the resistance mechanisms for which bacteria / antibiotic interactions?

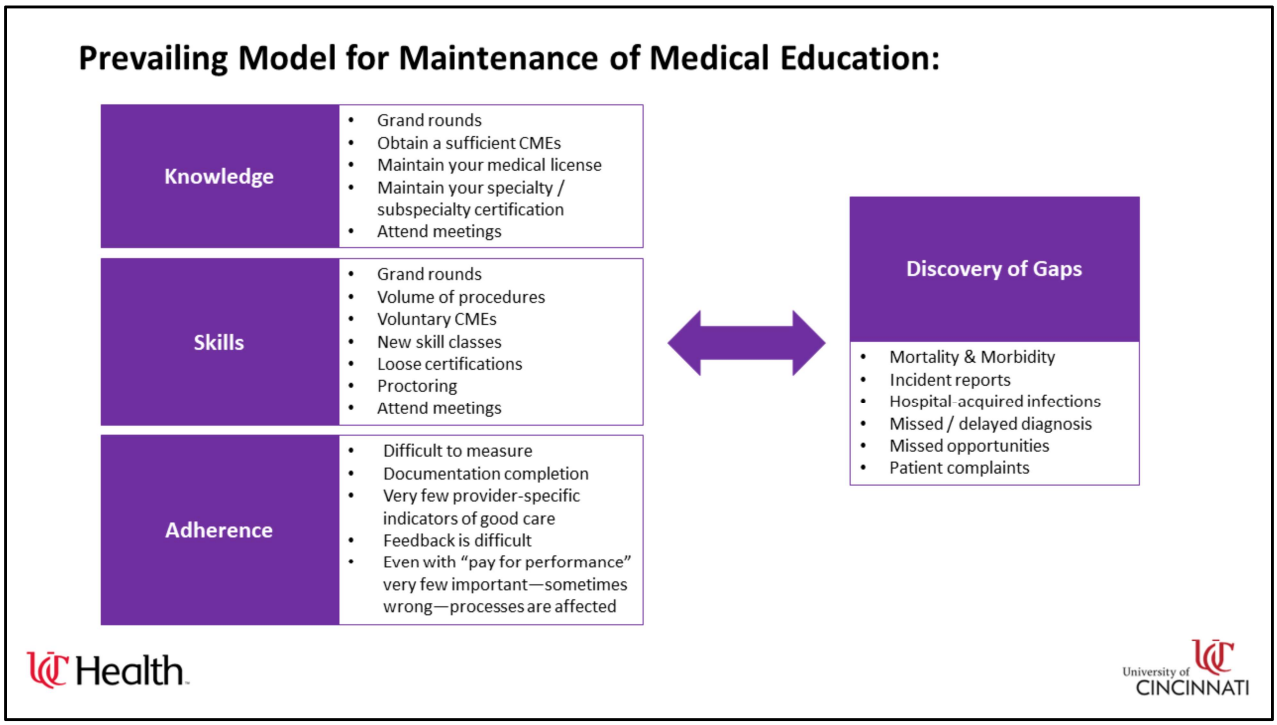
Time is spent UNDERSTANDING the knowledge gaps that must be filled. What topics are hard to understand? What lung infections are more difficult to remember? Why is it difficult to remember which bacteria develop extended beta lactamase resistance? Answering questions about such problems leads to a theory of what needs to be in the Microbiology curriculum to improve this knowledge transfer.

Over years EDUCATIONAL INTERVENTIONS get tested and employed. Although on a slower and larger scale than some bench experiments, some educational

interventions are found lacking and abandoned. Others are found to accelerate learning. Techniques like Problem-based learning discussions, priming students with questions before lecturing, having students teach the class, show success. Student test scores and class evaluations serve as metrics of improvement.

Best practices are implemented which increase EXCELLENCE in teaching and learning. News of new techniques move from class to class, department to department, school to school. Evaluations of programs enhance adoption in other departments.

Eventually very successful educators publish their techniques and DISSEMINATION is accelerated across the country. Interventions move from 1 center to many.



But let's stop there and ask ourselves "So what is the mental model for developing adherence to practice standards in postgraduate medicine? How do we ensure that the discoveries of our researchers actually move from bench to bedside? How do we ensure that the new information that is being taught to our current medicals students and residents is being learned by our faculty?

Let's evaluate our knowledge dissemination for non-trainees:

How about skills:

Where in any of these things do we ensure that the gaps in outcome-driving knowledge are filled?

How about our adherence to best practices:

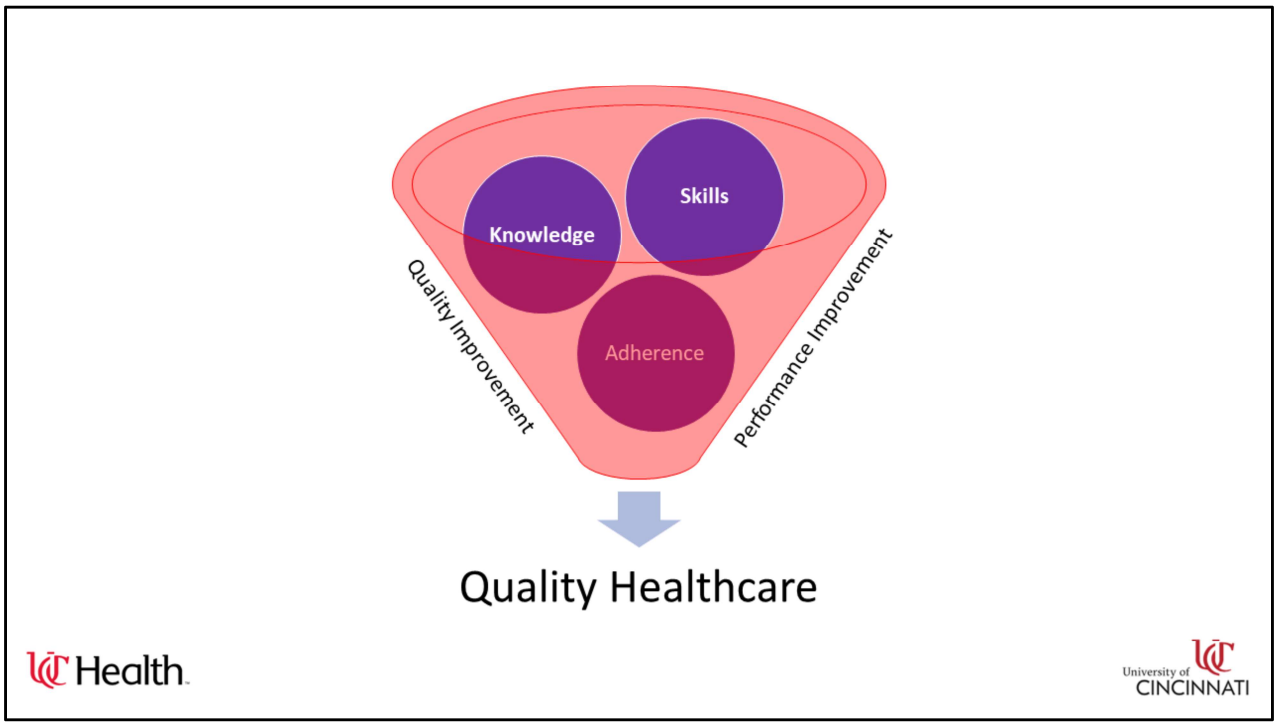
And how do we identify gaps in adherence?:
-Mortality and Morbidity conferences
-Incident reports
-Hospital-acquired complications
-Undesired outcomes
-Patient complaints

How do we drive adherence to the most important guidelines in each specialty?

All of these are retrospective. None are proactive.

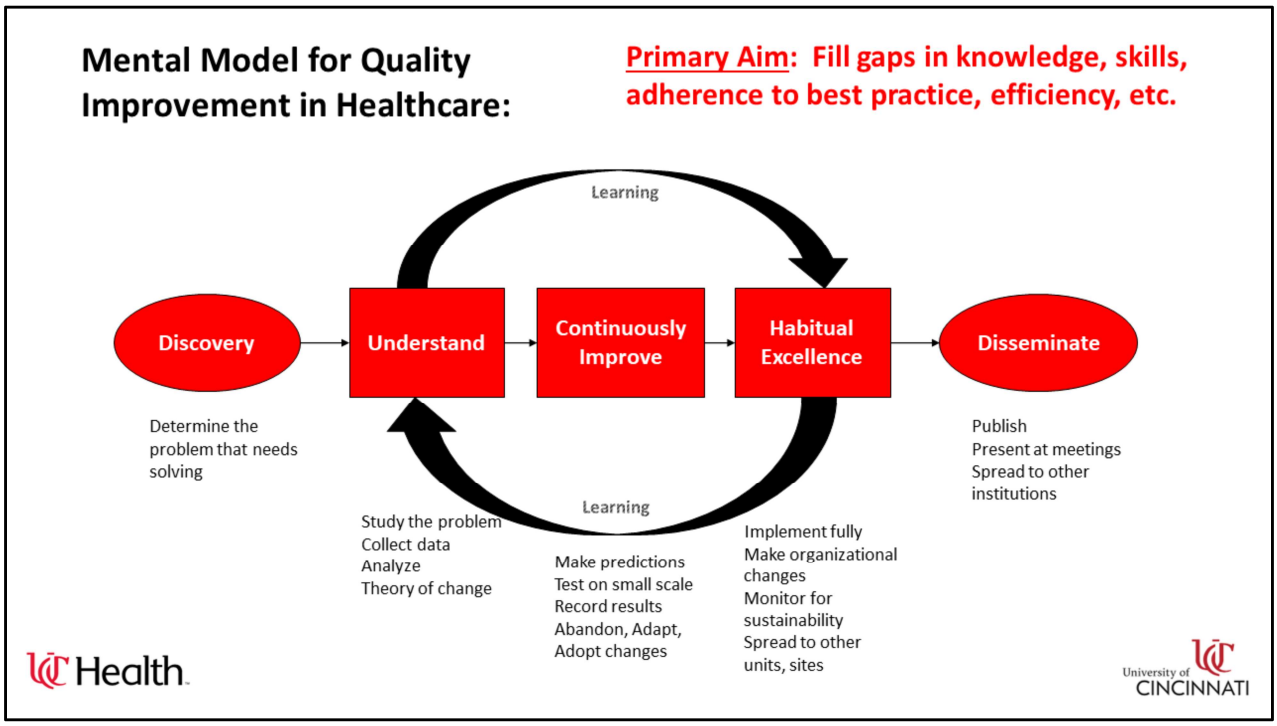
We rely heavily on the good nature and professionalism of providers to gain the knowledge and skill they need daily while they go through their working life.

I would argue that our prevailing mental model is much more vague and much less regimented than either our scientific models for medical research or education. WE KNOW WE HAVE A NON-STANDARD MODEL FOR MAINTAINING MEDICAL EDUCATION AFTER RESIDENCY / FELLOWSHIP TRAINING.



This is why QUALITY AND PERFORMANCE IMPROVEMENT IN HEALTHCARE is so important. Irrespective of the model you choose, it provides a method for finding and addressing problems that occur in the process of delivering the highly advanced research and knowledge of our healthcare system.

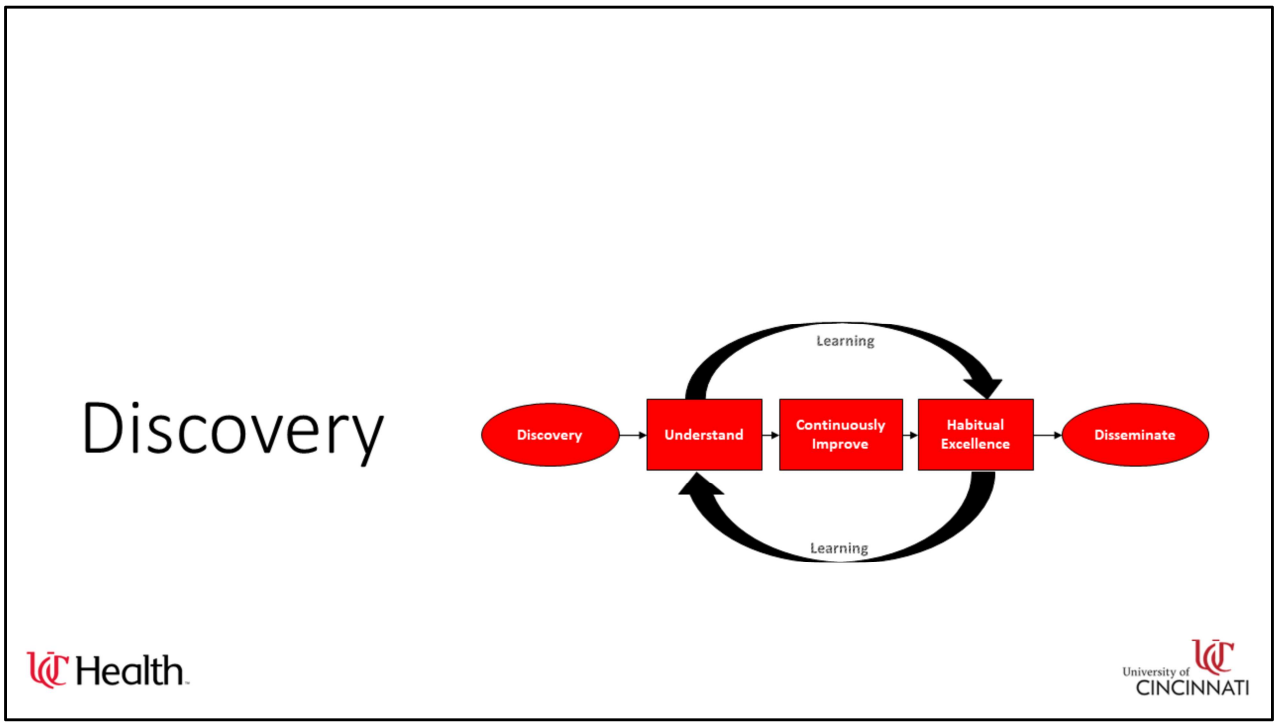
As it is our responsibility as an ACADEMIC MEDICAL SCHOOL to develop and discover new knowledge, it is our responsibility as an ACADEMIC HEALTH SYSTEM to ensure we have a method for finding performance gaps and eliminating them.



This is a lot of build up for this—but here is the MENTAL MODEL FOR QUALITY IMPROVEMENT that we have developed for UC Health. (Show UCH PI Way slide.) We are pushing a problem solving mental model that essentially goes through the same scientific methods that we would for either research or education with the primary aim of filling gaps in knowledge, skills, and adherence.

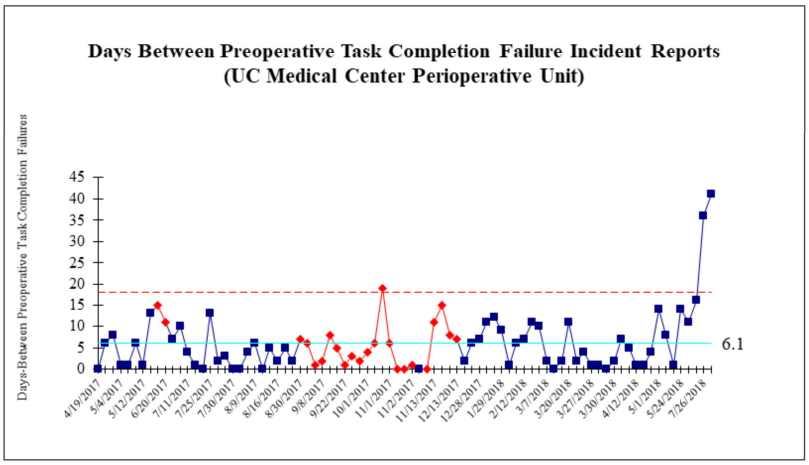
When assessing the quality of care provided in health care we need to have a system for #discovering problems, #systematically understanding them through observation and data, #making data driven changes with evidence of improvement, #sustaining the changes, and #spreading and disseminating the progress.

Now I would like to go through each step of these mental models as they pertain to some projects we have previously or are currently working on in the health system. I will try to provide analogies to highlight potential similarities and differences with respect to how our quality improvement model compares to research or educational models.



There are a lot of ways to do discovery in health care.

In CLINICAL RESEARCH we start with analyzing case reports, move to case series, perform retrospective and prospective observational studies



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In CLINICAL QUALITY IMPROVEMENT we might start with an incident report of a complication. If we see recurrent similar incidents we might look further. This slide here depicts a problem we identified at UCMC OR. I was the person that received notifications when patients would make it to the operating room prior to important tasks being completed. Some of these tasks might have been "still had their socks on" but some were much worse like "no consent" or "site not marked." For those of you not familiar with surgery this is a big deal. After reviewing the incident reports in succession we discovered that this was happening about every 6 days on average.

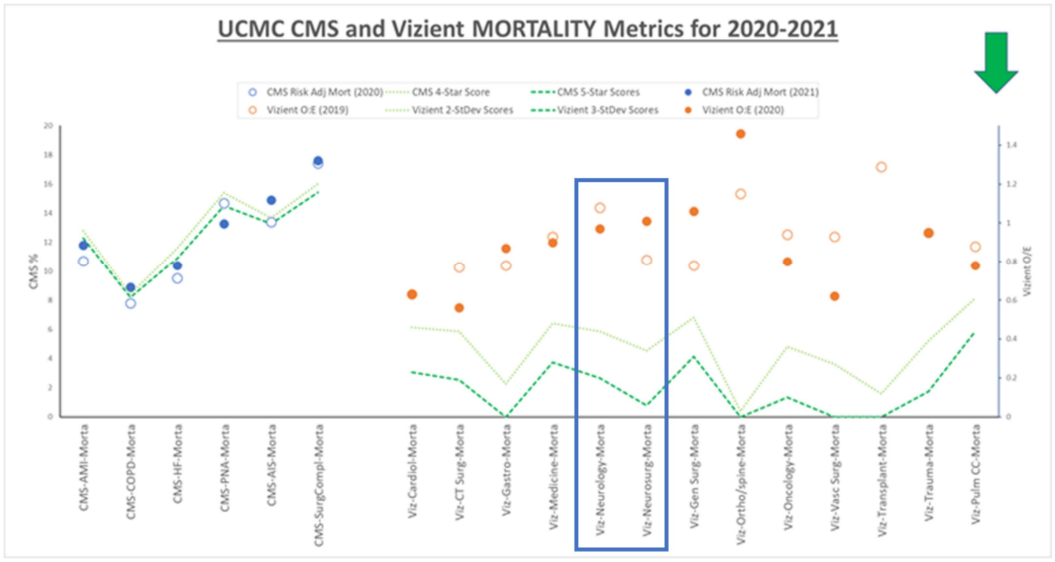
Some important things to note that are common to our discovery and analysis process in quality improvement.

-We like to see data over time. This allows us to see how the system has been functioning.

-We like to see the variation in the system and quantify it. Here you can see a mean and a control limit (above which would be considered statistically significant or non-random variation.)

-We gather data from an uncontrolled system often without the ability to

place controls.
-We sample in an effort to gather a representative picture of the data (although this study used a 100% sample of the Perioperative Incident Reports)



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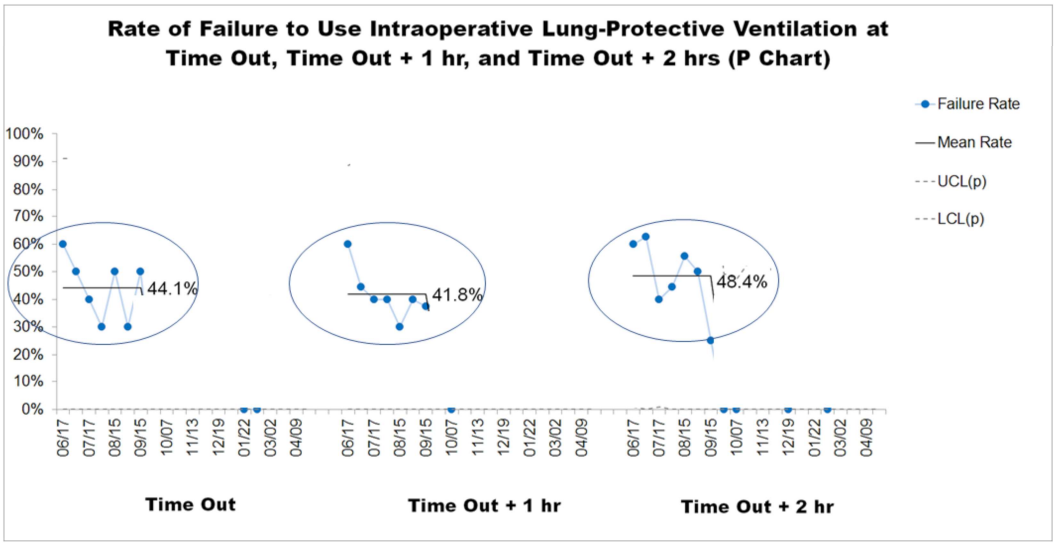
Another way to discover system opportunities for improvement is to look at our external rankings. As we are highly regulated by various agencies. Two of these are CMS (Center for Medicare Services) and Vizient (an organization that compiles administrative and billing data for numerous community and academic health systems.) We can gather data from both organizations to see how we are doing compared to other healthcare systems. CMS started assigning "star" ratings to hospitals a few years ago. This is based on a number of different categories of measures. Here I have displayed our current scores for CMS and Vizient in Mortality.

Some important points to be made from these data:
-Populations are different for each data set (e.g. Medicare recipients for the past year >65 vs Vizient all payors and ages). We don't get to define our own populations or those that would suit us best.
-Data are available at different cadences (e.g. CMS annual vs Vizient annually or monthly, depending). We don't get to control when we collect and receive our data.
-Subgrouping is different for each data set (CMS uses Principle Diagnoses vs Vizient DRG groupings by service line). We don't get to control the type of data used even if we don't like the method selected for metrics. We don't get to optimize it.
-Risk adjustment is different for each data set based on different logistic regression analyses specific to each of them. We have to trust "their" risk adjustments.
-They point you in a direction but require much further investigation. You can see that I have highlighted the Neurology and Neurosurgical mortality metrics. This is because we have started having some really good discussions between our UCH analysts, UC Departments of Neurology and Neurosurgery in an attempt to better understand why our mortality is where it is compared to other centers and where

any patient care gaps may be.

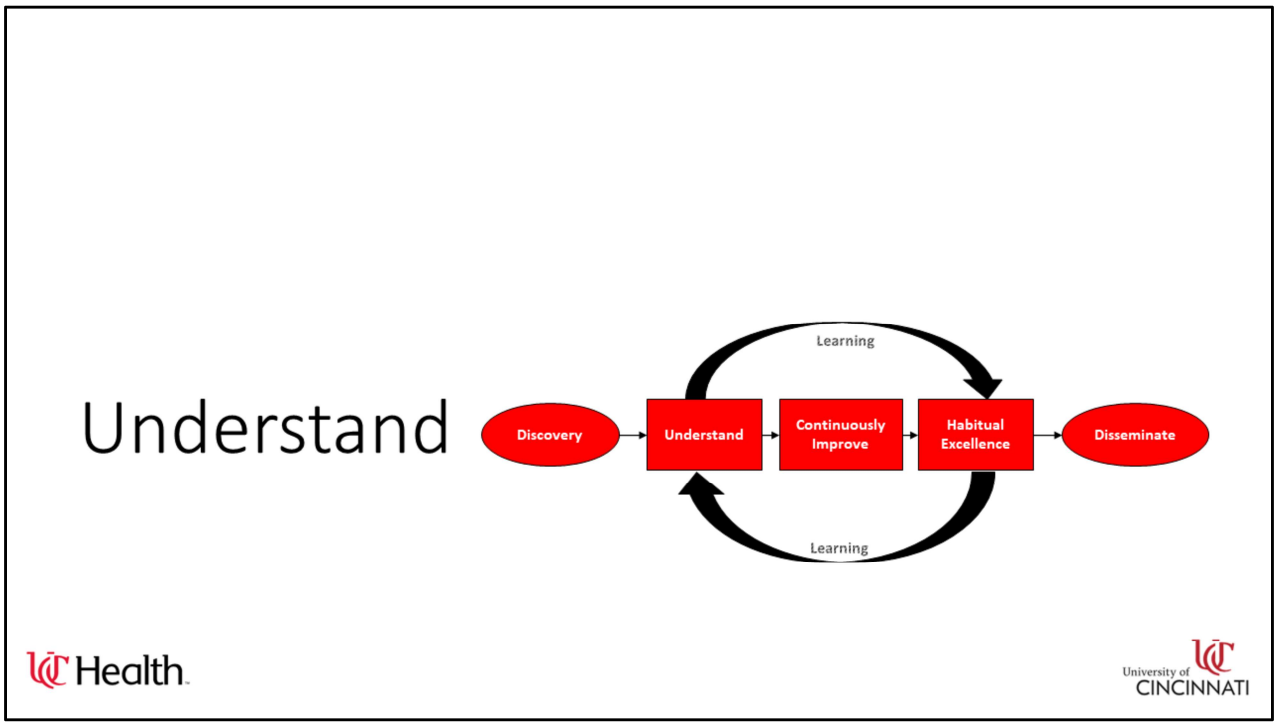


A third way to find areas for improvement is perform a gap analysis related to adherence to performance standards. This can be done by large data aggregation through the Epic EMR (which is relatively difficult to build and requires resources) or through manual processes at a provider level. I will give an example of a project that I worked on in Anesthesiology.

Several articles were published suggesting that using lower tidal volumes for mechanical ventilation (something known as Lung-Protective Ventilation) were not only protective for patients with lung injury, but that they were protective for normal patients undergoing surgery with general anesthesia.

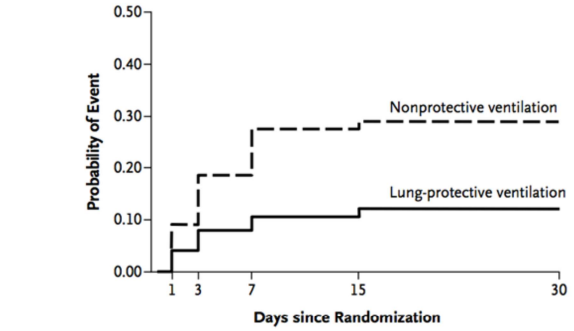
We weren't sure if our providers were doing this so we analyzed some charts. We did a very simple manual data extraction of charts (by we I mean our critical care resident/fellow Dr. Lemmink.) We found that sampling tidal volumes at the beginning of cases, 1 hour later, and 2 hours into cases our providers were failing to use protective tidal volumes about 45% of the time—INTERESTING GIVEN THE PREVIOUS NEJM STUDY I SHOWED YOU! This discovery led us to undertake a project to determine why this was and how to improve it.

From here on out I am going to focus on this project as it is one that I have the most understanding and experience with. Going through the rest of our mental model for improvement I will continue to highlight how a regimented approach to filling knowledge and adherence gaps can pay off.



##Before I go on to describe the remaining phases of our improvement model let me briefly frame the improvement project that we undertook in our department.

Improving adherence to intraoperative lung-protective ventilation



No. at Risk						
Nonprotective ventilation	200	182	163	145	142	142
Lung-protective ventilation	200	192	184	179	176	175

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N Engl J Med. 2013;369(5):428-437

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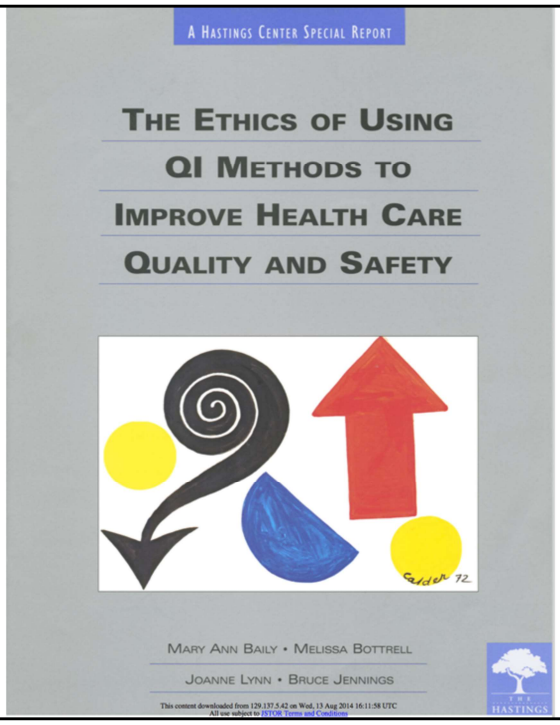
As we first sought to UNDERSTAND this problem we reviewed the literature.

WHAT TO DO: Intraoperative lung-protective ventilation has been shown to improve postoperative lung function in patients undergoing open abdominal surgery. [2-4] Although definitions differed slightly protective ventilation was broadly defined as tidal volumes <8 ml/kg of ideal body weight with non-zero positive end-expiratory pressure (PEEP.) [2-6]

HOW TO DO IT: Searching the literature at the time it appeared that patient size had been found to be associated with patterns of mechanical ventilation [7] and we found that education and feedback were noted to have improved provider adoption of lower tidal volume ventilation. [8,9].

So based on our literature search we had some ideas about how to approach the project.



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So Question #1: Is this best-practice or do we need another trial to determine this?

This is a very important question. If you know WHAT you are supposed to do for patients then you can focus on HOW you are going to get it done. You don't need patient consent or a randomized trial IRB protocol to improve the immediate care of patients. [10] If you are not sure if it is best practice you need to do a trial.

"QI is an *integral part of the ongoing management of the system for delivering clinical care*, not an independent knowledge seeking enterprise. QI practitioners design QI activities to bring about immediate improvements in care, relying on theory and evidence from research and practical experience to identify changes that are very likely to be beneficial. QI activities take place in a particular localized health care setting, their design is expected to incorporate the specific features of the setting, they are led by people who work in that setting, and they incorporate rapid feedback of results to bring about positive change for the patients in that setting."

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Baily *et al,* Hastings Center Report 2006 (Aug);36(4):s1-s40

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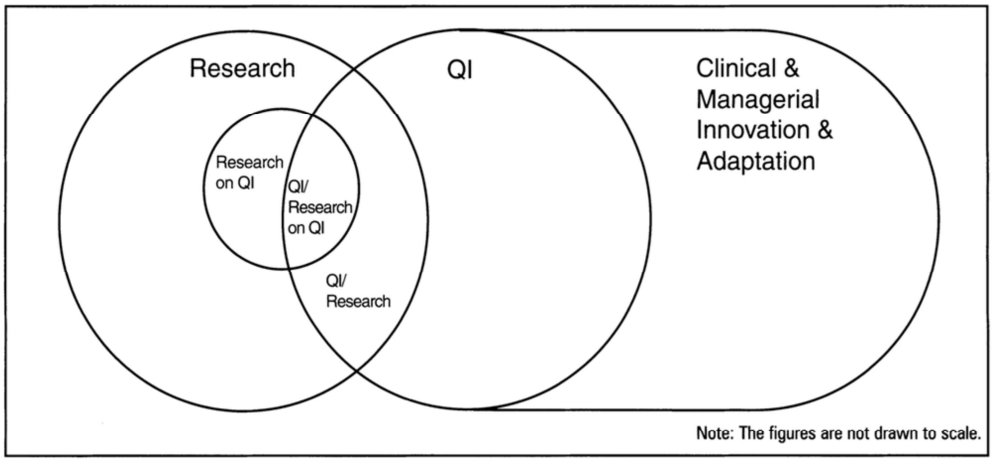
QI projects in general are not research. [Read quote from Hastings Center Report.] QI can and should be reported. This does not make it research.



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Baily *et al,* Hastings Center Report 2006 (Aug);36(4):s1-s40

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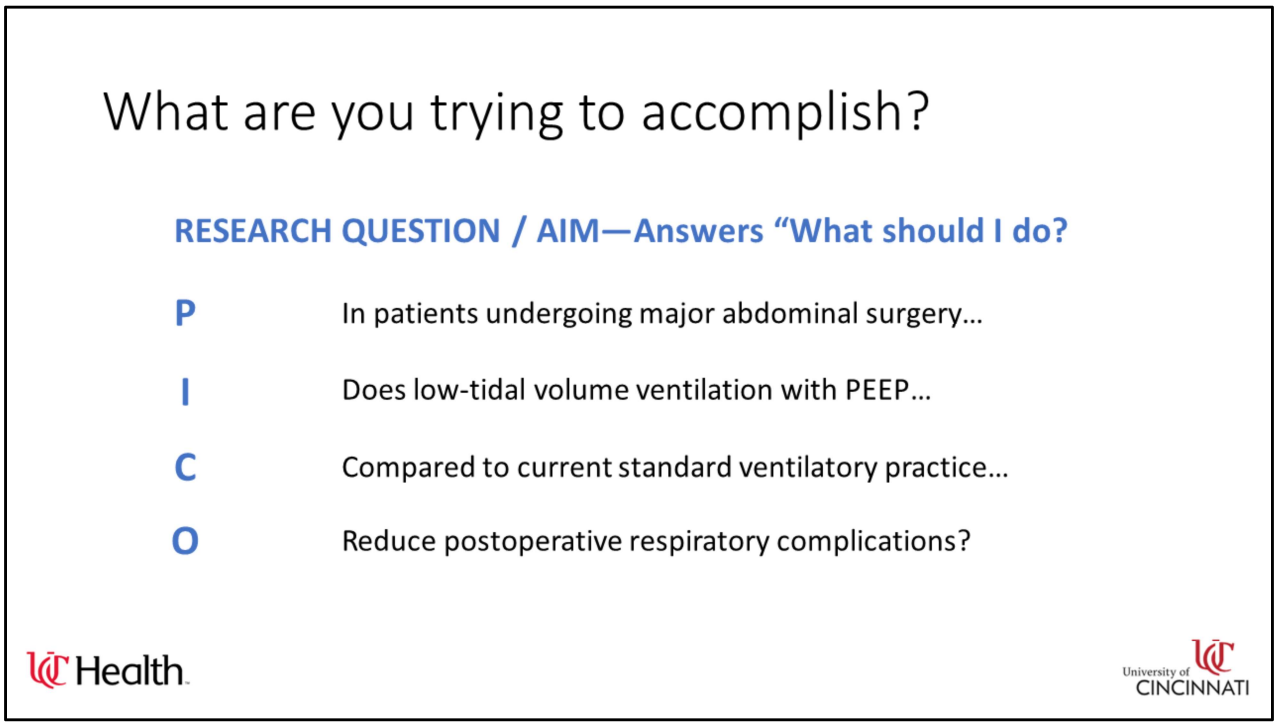
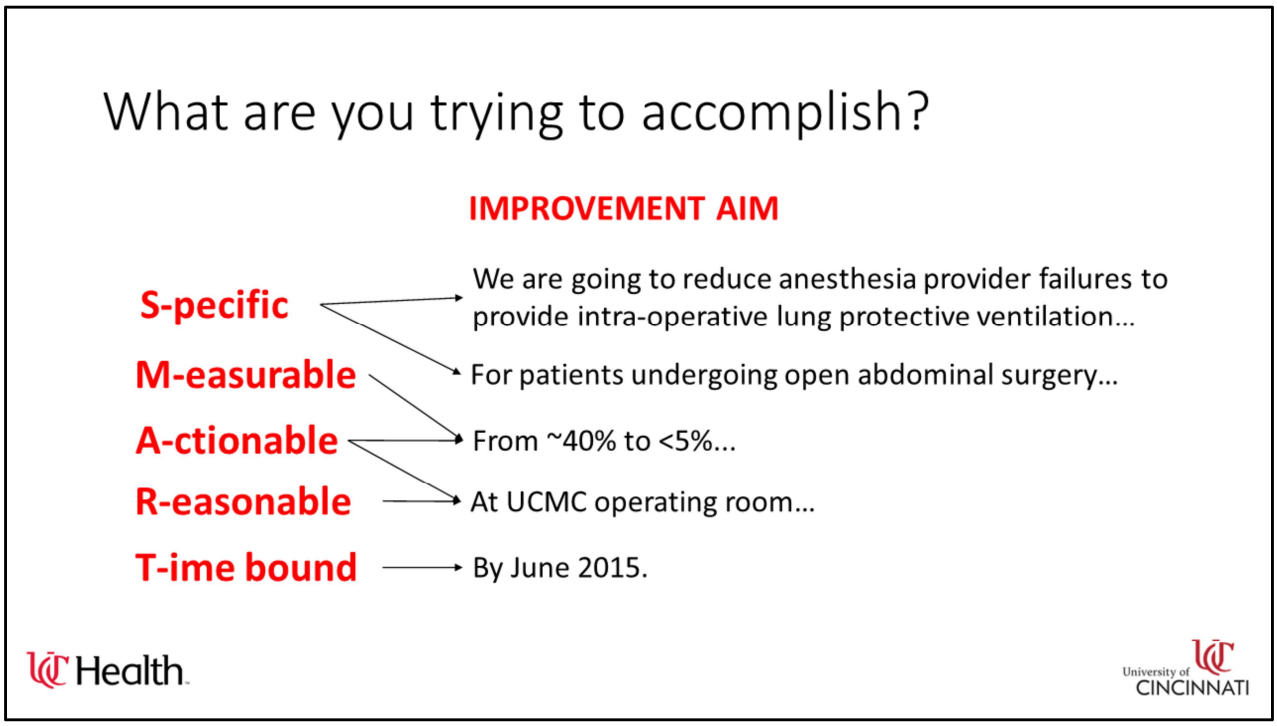
There are some QI projects which incorporate the purpose of producing generalizable new knowledge. These may be considered QI Research and as such require IRB review and consent from participants.

We did not feel this was research nor did the IRB.



Like in research we then developed an aim for the project. Aims should be as focused as possible. In research there is a general way we think about generating a research question. Some might use the PICO acronym (Population / problem, Intervention, Comparison group, Outcome)



In Improvement we use a different but regimented method for generating a specific, or SMART Aim. You can see this demonstrated here.

We try to make the aim as SPECIFIC as possible. We decided we would work on adherence by anesthesia providers…but specifically WHICH PATIENTS?

Although there is no real reason to assume this is harmful to a patient population the data in the literature suggested benefit in open abdominal surgery so we chose those patients.

In Improvement you need to make sure your problem is MEASURABLE…here we chose a categorical variable, percent of measured tidal volumes in the appropriate range.

We made sure it was ACTIONABLE (here it could be measured, it was at a site we had some control over, etc.) and REASONABLE (goal that could be achieved.)

What changes can you make to produce improvement?

Theory of change

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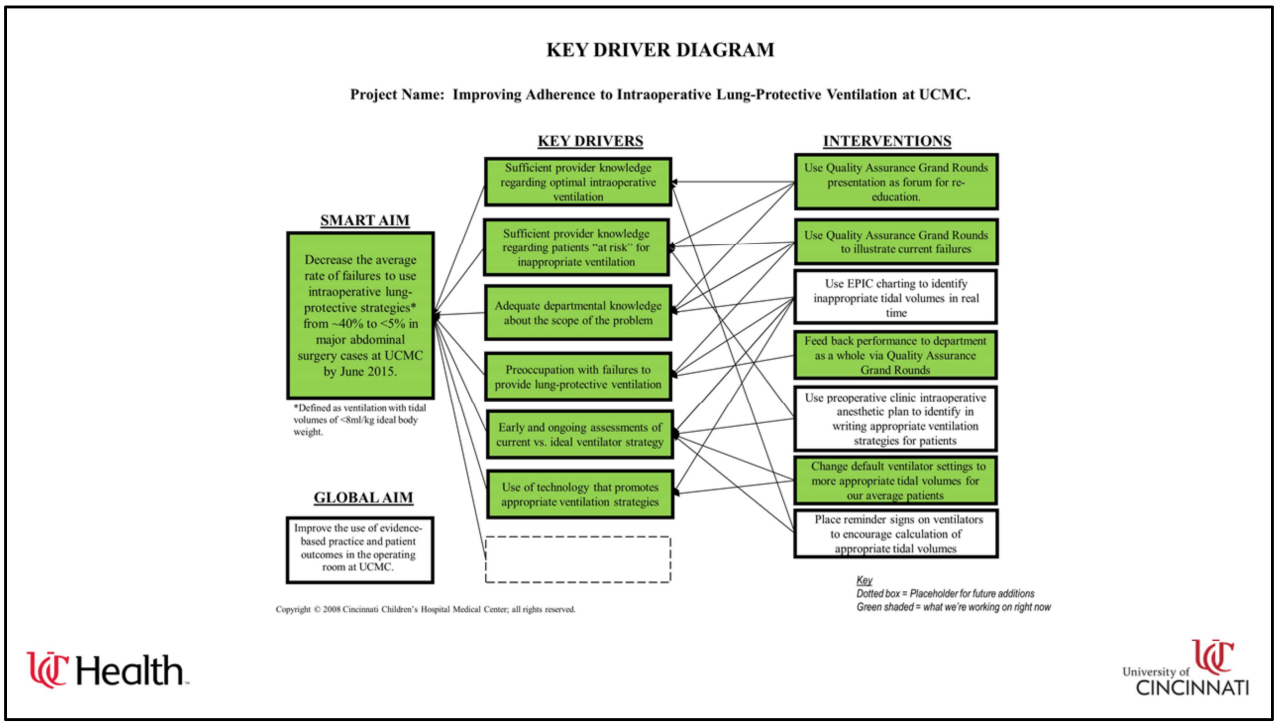


One thing you might notice about the difference in research and improvement is that, as I noted from the Hasting's Center paper I mentioned previously, research focuses on producing generalizable new knowledge. In medicine it often focuses on "WHAT TO DO" for a disease. It answers "WILL THIS WORK" to cure or alleviate symptoms.

Improvement focuses more on the "HOW." "HOW DO I GET PROVIDERS, UNITS, HOSPITALS TO DO WHAT HAS BEEN PROVEN TO WORK?"

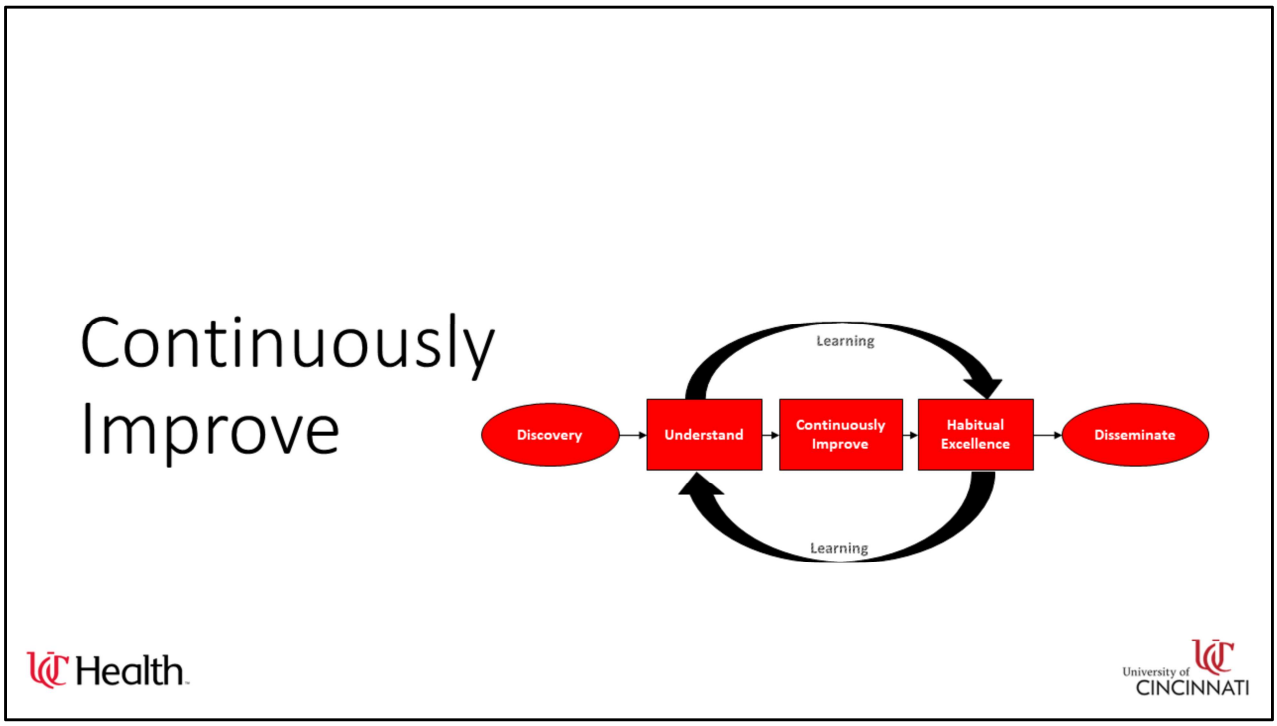
You will notice that a SMART aim doesn't say HOW one is going to make the improvement they are attempting. Once one knows what they are attempting to accomplish they need to develop a theory of what might make the system better.

This figure is a Key Driver Diagram for the project I was working on. It is a visual depiction of my theory for what I thought could Drive anesthesia providers toward better adherence. It states our SMART aim. Down the center are several "Key Drivers." By theory if all of these were present to the necessary extent then the SMART Aim would be accomplished. Some drivers I felt were important included

SUFFICIENT PROVIDER KNOWLEDGE, PREOCCUPATION WITH FAILURE, ADEQUATE KNOWLEDGE OF THE SCOPE OF THE PROBLEM, and USE OF TECHNOLOGY THAT PROMOTES APPROPRIATE VENTILATION.

On the far right of this figure are possible interventions that I thought might work to increase the presence of some of my drivers. For instance I thought that using our monthly QA Grand Rounds presentation for education and feedback could increase provider knowledge, raise awareness, and increase preoccupation with failure.

At the start of a project you don't know which of these interventions is going to work. You might have some evidence from the literature or from other institutions that one might have a high probability of success. Ultimately it takes testing to determine what changes will lead to improvement.



The third stage of our mental model for improvement is CONTINUOUSLY IMPROVE. Real improvement can only be achieved through testing and measurement of change. Just like the initial small scale experiments one might do to test a theory in a laboratory and yet preserve reagents and materials, in improvement you rarely are certain enough about a change eventually working that you should just implement it in large scale. (Not that some organizations, governments, etc don't lead like that.) To minimize wasting time or significant resources one should always test in small scale with a clear understanding of how they will know that a change is an improvement.

The kind of testing done in improvement work has some differences but many similarities to experimenting performed in basic science and clinical research.

How will you know that your change is an improvement?

Understanding variation and statistical difference for improvement

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Data consideration	Research	Quality Improvement
Aim	Generalizable new knowledge	Improve care process
Bias	Minimized	Accepted, consistent
Sample size	Prespecified N "Just in case"	Determined by start / length of project Sequential samples "Just enough"
Our project	All cases, 3 time points Before / After cohorts	All cases, 3 time points Time-series, no aggregation
Hypothesis	Fixed	Flexible
Testing strategy	One large test	Sequential tests
Timing of data analysis	After collection	Ongoing, real time
Type of analysis	Enumerative	Shewhart (SPC) charts
Categorical variables	Fisher exact test	P-charts
Continuous variables	Mann-Whitney U test	X_{bar} & S charts

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Adapted from Provost, Lloyd P., and Sandra Murray. The Health Care Data Guide : Learning from Data for Improvement, John Wiley & Sons, Incorporated, 2011. ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/uc/detail.action?docID=697964, Accessed 7/25/17.

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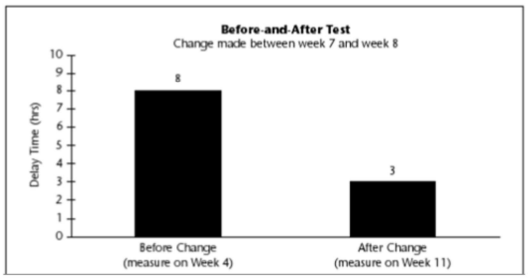
With each project whether research, education, or improvement you need to determine how to approach data and demonstrate comparative differences. A priori you should know how you are going to know whether to reject the null hypothesis in research, know that students have received the knowledge you have attempted to transfer to them in education, or KNOW THAT A CHANGE IS AN IMPROVEMENT.

Here is a table that summarizes some of the differences between how we use data in research and in quality improvement and eventually how we know that our change is an improvement.

FIGURE 1.5 Results of a Before-and-After Test: Case 1



Provost, Lloyd P., and Sandra Murray. The Health Care Data Guide : Learning from Data for Improvement, John Wiley & Sons, Incorporated, 2011. ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/uc/detail.action?docID=697964, Accessed 7/25/17.

Understanding variation over time is an important concept to comprehend in quality improvement in healthcare.

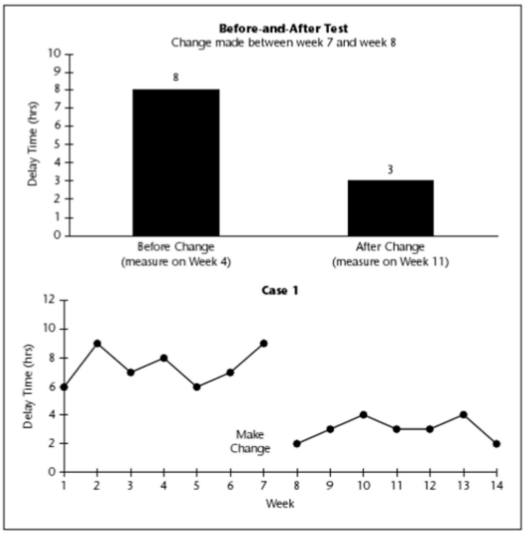
In research we often look at two relatively similar samples of patients with a single variable being different, the intervention. One aggregates the data and compares the two groups using some enumerative statistical test. A P value is produced and if there is less than a 5% of randomly finding a difference we say that the two groups are statistically different and reject the null hypothesis. Because of randomization and control of bias this is reasonable.

In quality improvement ruling out a random occurrence is more difficult. There are many uncontrolled background variables. There is potential for bias. To better understand the behavior of the system one is attempting to change and to determine whether change is occurring as soon as possible, the measure in question is best initially viewed over time. Consider these examples.

Example 1 is a typical before-and-after test of an intervention. [11] It shows the average delay time in a clinic for two time periods with a change made after the 7th

week. If you assume the statistics produce a $P<0.05$, you would confirm that your change produced an improvement.
Now consider the following cases.

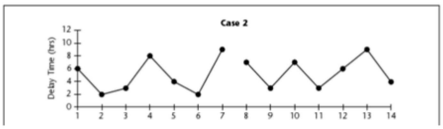
FIGURE 1.5 Results of a Before-and-After Test: Case 1



Provost, Lloyd P., and Sandra Murray. The Health Care Data Guide : Learning from Data for Improvement, John Wiley & Sons, Incorporated, 2011. ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/uc/detail.action?docID=697964, Accessed 7/25/17.

Case #1 shows a significant and stable change between the 2 time periods.

FIGURE 1.6 Other Possible Run Charts Associated with Before-and-After Graph



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Accessed 7/25/17.

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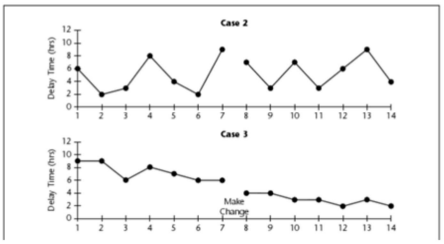
Case #2 shows a process with significant variation that did not improve.

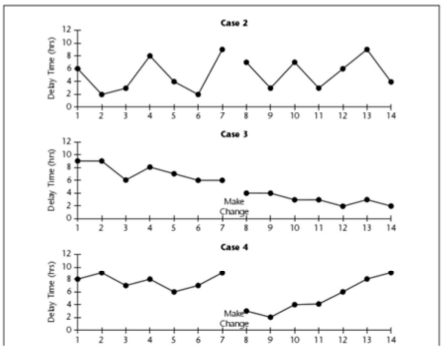
FIGURE 1.6 Other Possible Run Charts Associated with Before-and-After Graph



Provost, Lloyd P., and Sandra Murray. The Health Care Data Guide : Learning from Data for Improvement, John Wiley & Sons, Incorporated, 2011. ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/uc/detail.action?docID=697964
Accessed 7/25/17.

Case #3 shows a significant change that likely began much earlier than the intervention.

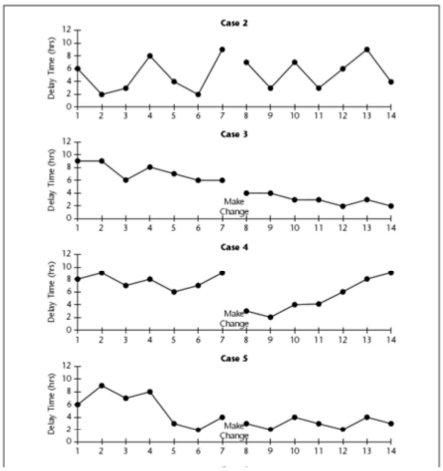
FIGURE 1.6 Other Possible Run Charts Associated with Before-and-After Graph



Provost, Lloyd P., and Sandra Murray. The Health Care Data Guide : Learning from Data for Improvement, John Wiley & Sons, Incorporated, 2011. ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/uc/detail.action?docID=697964
Accessed 7/25/17.

Case #4 shows a significant change initially occurring and then degrading over time.

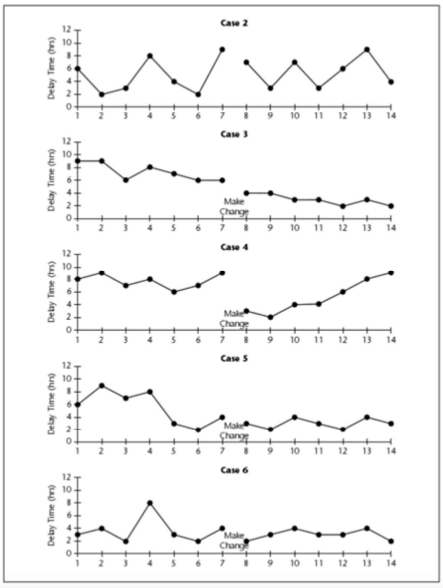
FIGURE 1.6 Other Possible Run Charts Associated with Before-and-After Graph



Provost, Lloyd P., and Sandra Murray. The Health Care Data Guide : Learning from Data for Improvement, John Wiley & Sons, Incorporated, 2011. ProQuest Ebook Central, http://ebookcentral.proquest.com/lib/uc/detail.action?docID=697964
Accessed 7/25/17.

Case #5 shows a significant change that likely started 3 weeks prior to the intervention.

FIGURE 1.6 Other Possible Run Charts Associated with Before-and-After Graph



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Case #6 shows no significant change but a single week outlier that could make the after period look better.

Simple visual inspection of data over time can change the degree of belief that an intervention either did or did not work. It can give insight into next steps to take to improve.

Improving Lung-Protective Ventilation…

- Created a "policy" or "expectation"
- Educated at grand rounds
- Fed back findings
- Defaulted ventilators to smaller tidal volumes

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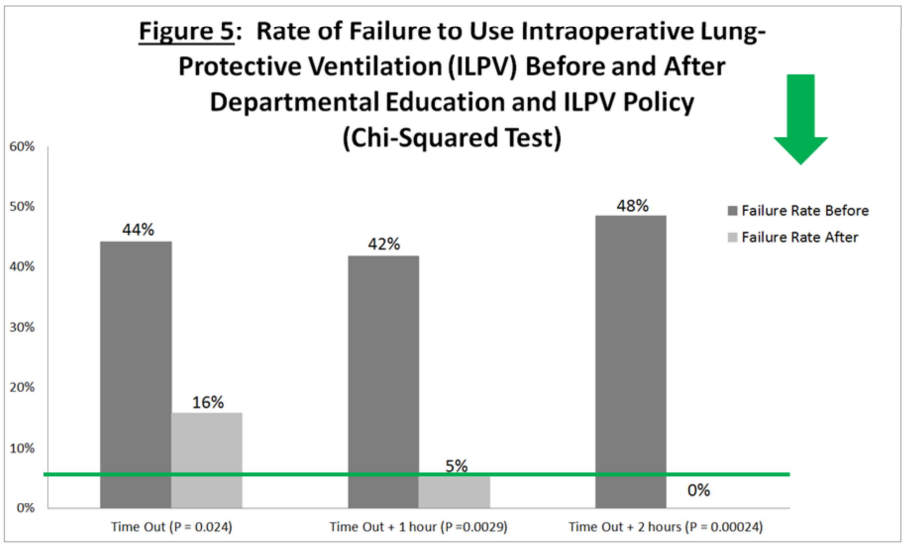
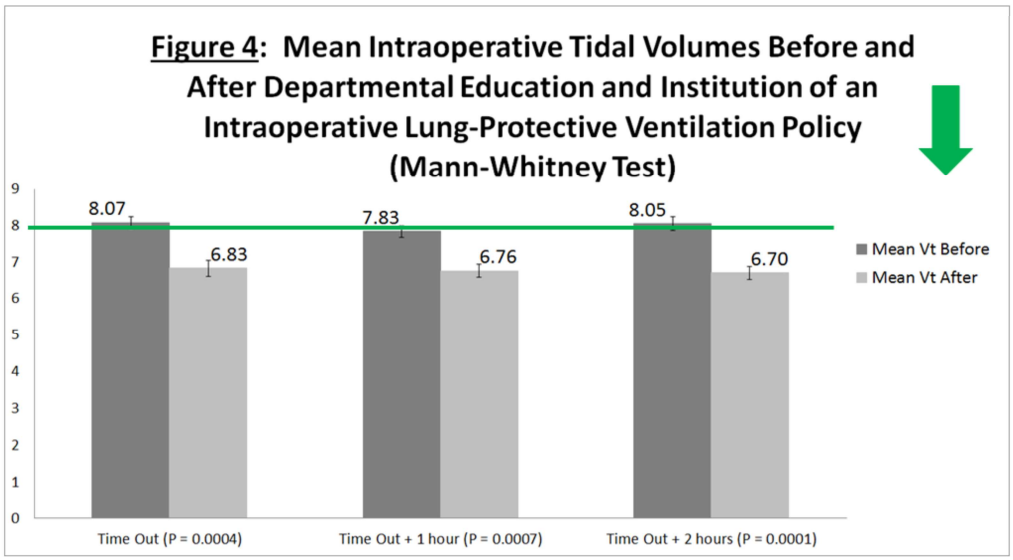
So let's get back to the improvement project we embarked on in the department of anesthesiology. If you remember we were trying to get providers to ventilate patients in the operating room with the proper tidal volumes. Our goal was to get them to use 6-8 ml/kg IBW throughout the entire case.

So here is what we did:
-We created a policy
-We educated
-We gave feedback about how people were doing
-Finally we changed the default settings on all of the ventilators to make it harder to fail

And here is what we found when we measured it…



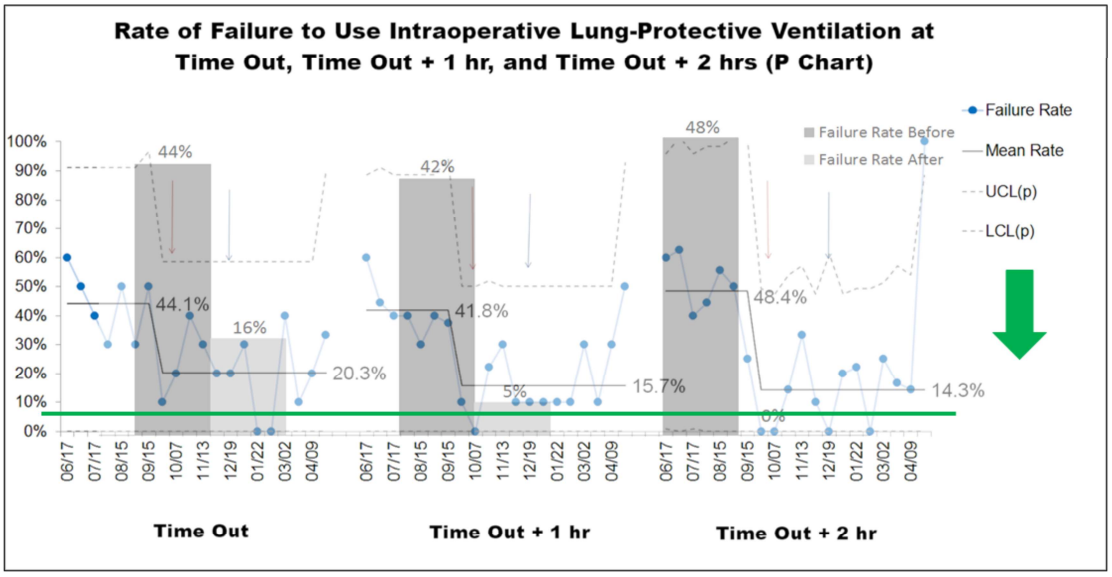
Here is our primary process metric, “rate of failure to provide intra-operative lung-protective ventilation” using a traditional Chi-squared test. You can see that there was a statistically different improvement in failure rates at all of the time points we measured after we implemented change. If you remember from our SMART Aim our goal was to reduce their failures to 5% or less.



Here is the continuous variable of tidal volumes per ideal body weight. Again here is a more traditional statistical approach using a Mann-Whitney U Test. One can see that there was a statistically significant decrease in tidal volumes that providers were using. Our goal was to get them to utilize tidal volumes less than 8 ml/kg IBW.

In actuality the AVERAGE that they were using at the beginning of the project was close to our goal. But AVERAGE means that a lot of the measurements could have been above this level. Our project was successful, right. See the P values.

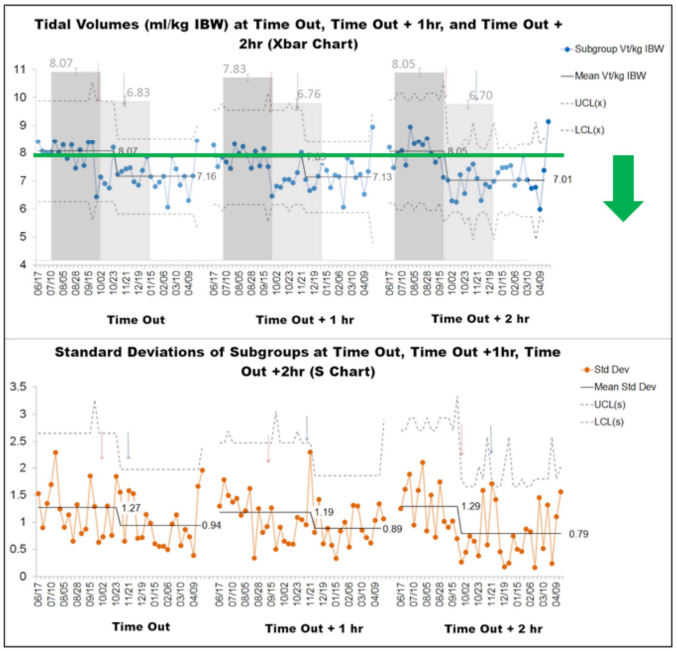
So let me ask you…if you needed 9 months to collect this data for comparison and you did several interventions over that period of time how would you know that your changes were working prior to finishing the study.



Here is how we actually reported our data. This is called a Shewhart chart, or statistical process control chart, or a process behavior chart depending on who you are reading. This is a way to follow metrics over time and it allows you to see change in real time as opposed to seeing it only after aggregation of data. This chart depicts the same data you saw aggregated above in our Chi Squared test. It shows the failure rate in subgroups of 10 sequential cases. In other words we determined the number of failures every ten cases chronologically.

Here are to additional Shewhart charts, these are for tidal volumes. In these charts you can see the average tidal volume of every 5 cases chronologically on the top chart and the standard deviation of those 5-case subgroups on the bottom chart.

Let me briefly discuss Shewhart charts.


Tidal Volumes (ml/kg IBW) at Time Out, Time Out + 1hr, and Time Out + 2hr (Xbar Chart)
Subgroup Vt/kg IBW
Mean Vt/kg IBW
UCL(x)
LCL(x)
8.07
6.83
7.83
6.76
8.05
6.70
8.07
7.16
7.13
8.05
7.01
Time Out
Time Out + 1 hr
Time Out + 2 hr
Standard Deviations of Subgroups at Time Out, Time Out +1hr, Time Out +2hr (S Chart)
Std Dev
Mean Std Dev
UCL(s)
LCL(s)
1.27
0.94
1.19
0.89
1.29
0.79
Time Out
Time Out + 1 hr
Time Out + 2 hr

Shewhart's Theory of Variation

- **Common Causes**—those causes inherent in the system over time, affect everyone working in the system, and affect all outcomes of the system
  - Chance cause
  - Stable process
  - Process in statistical control
- **Special Causes**—those causes ***not*** part of the system all the time or do not affect everyone, but arise because of specific circumstances
  - Assignable cause
  - Unstable process
  - Process not in statistical control

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Health Care Data Guide, p. 108

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In addition to visually inspecting data over time quantifying variation is important. This was initially done by Walter Shewhart. He was a statistician that published a book called The Economic Control of Quality of Manufacturing. [11] In it he laid out a theory to help improve systems of manufacturing. He wanted to make sure that companies worked on the correct issues when it came to improving defects.

He noted that some variation in quality was random and arose from causes inherent to the system. They affected everyone at all times. He called this type of variation COMMON CAUSE VARIATION.

He also described variation in quality that arose from causes that were not part of the system all of the time and did not affect everyone at all times. These arose due to special circumstances. He called this SPECIAL CAUSE VARIATION.

To Shewhart it was important to recognize these two types of variation because the interventions used to improve the quality of production were different depending on the type of cause. SPECIAL CAUSES required investigation to remove (or keep if desired) the cause. Seeing charts in real time was important to him because one

could investigate them immediately if non-random variation could be identified.

Poor quality arising from COMMON CAUSE VARIATION requires interventions that improve the system as a whole. They require studying the system, obtaining content knowledge about processes, and testing the changes that one theorizes will work.

Shewhart / Control Charts

A statistical tool used to distinguish between variation due to common causes and those due to special causes

1. Monitor variation in processes over time
2. Calculate a central tendency from the mean of the data
3. They help identify special cause signals by identifying non-random variation
4. Are a useful tool for process improvements efforts and maintaining sustainability

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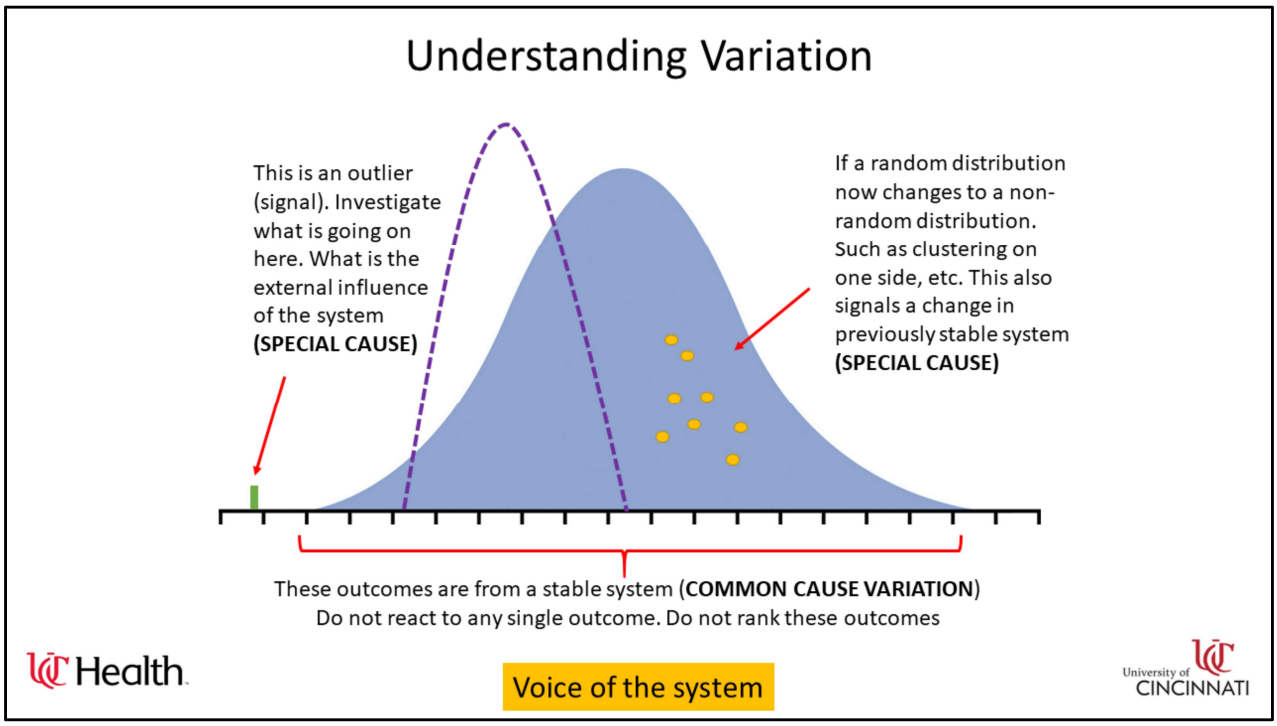


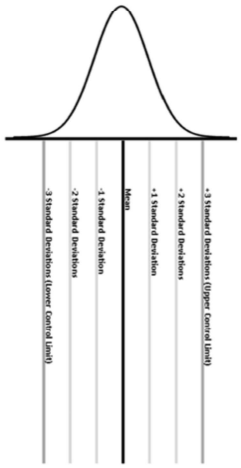
8 consecutive data points of one side of mean/ center line: 50, 25, 12.5, …. <0.5% (0,0039)

Basic Principles

Table 2
Control charts based on type of data and distribution

Type of Data	Distribution	Examples	Type of Control Chart
Continuous	Continuous (Gaussian)	Time to first skin to skin Admission temperature Birth weight Duration of stay[a]	X-bar and S charts
Discrete dichotomous	Binomial	Patient develops BPD (Y/N) Patient develops severe IVH (Y/N) Patient develops NEC (Y/N) Patient receives breast milk (Y/N)	P chart
Discrete count	Poisson	Number of CLABSIs Number of unplanned extubations Number of alarms Number of medication errors	U chart

Abbreviations: BPD, bronchopulmonary dysplasia; CLABSIs, central line–associated bloodstream infections; IVH, intraventricular hemorrhage; NEC, necrotizing enterocolitis.
[a] Often skewed distribution.



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Gupta M and Kaplan H, Clin Perinatol 2017;44:627-644

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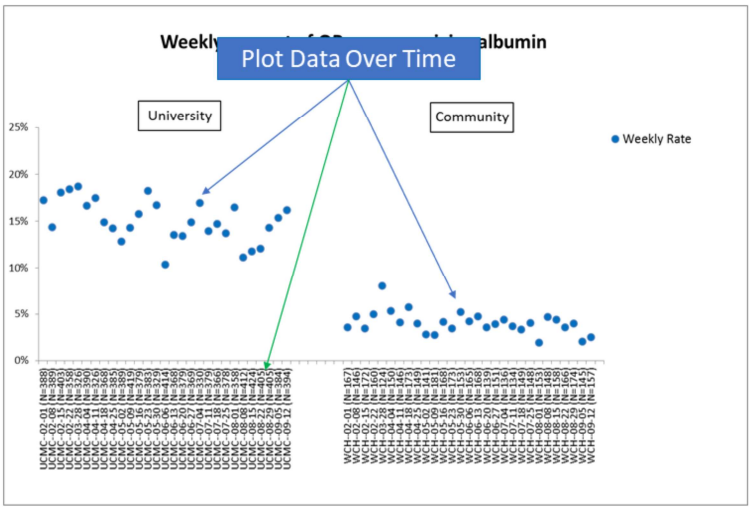
Anatomy of a Shewhart Charts
(Statistical Process Control / Behavior Charts)



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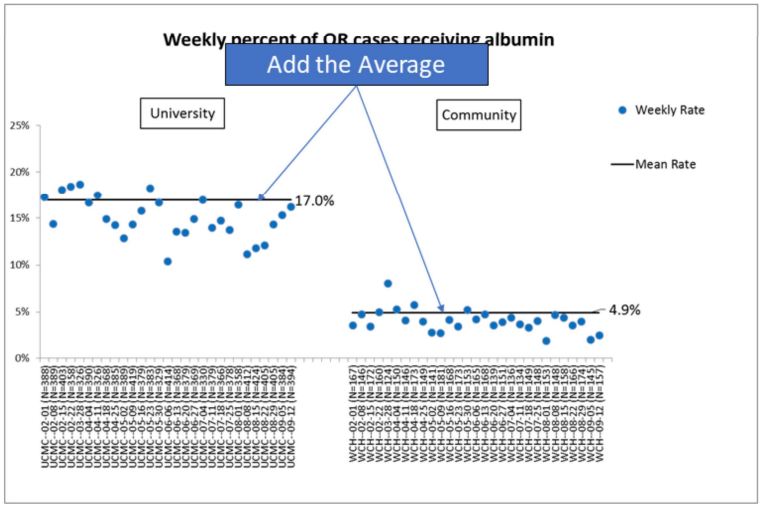

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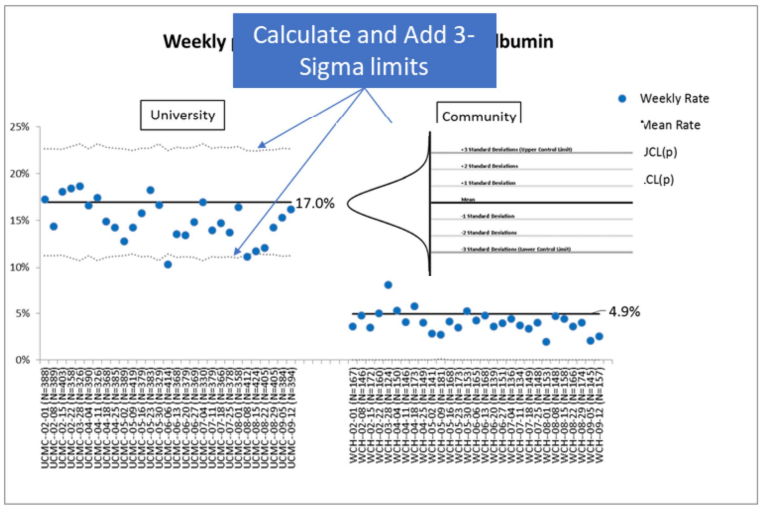

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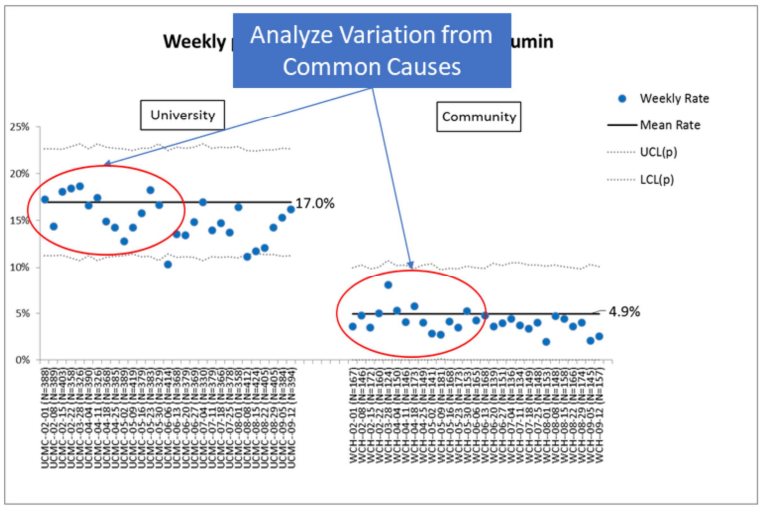

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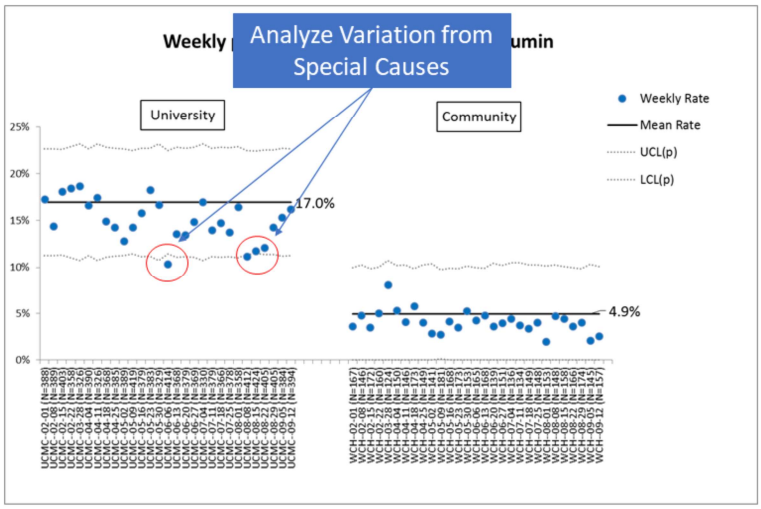

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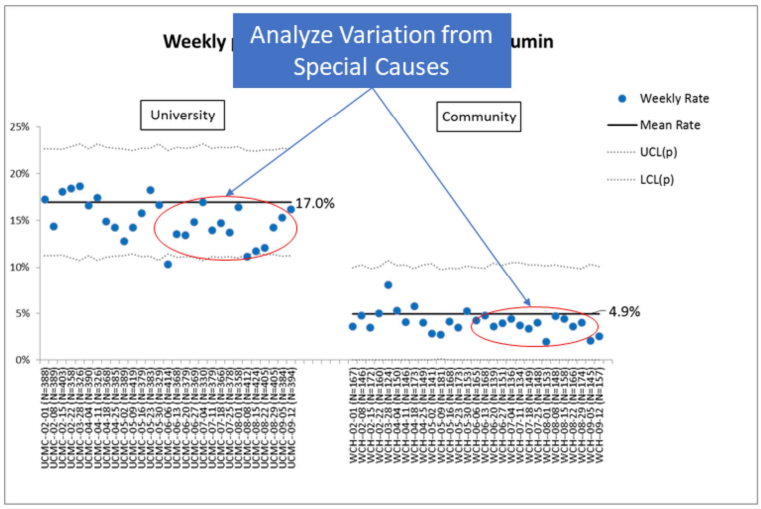

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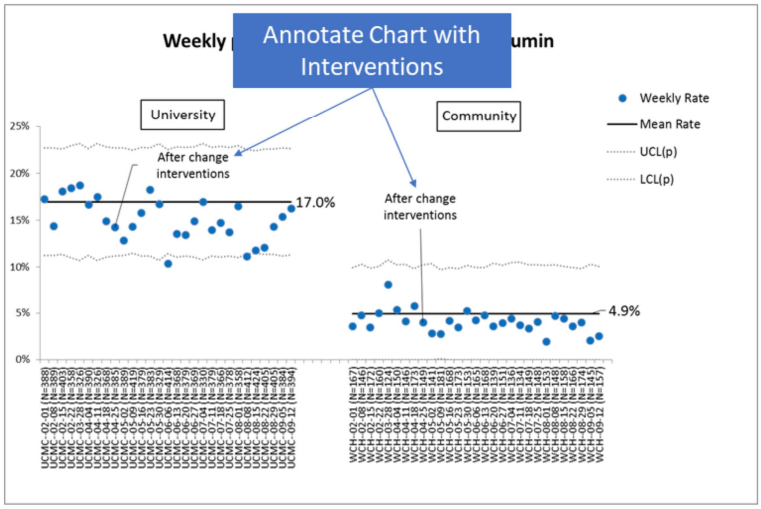

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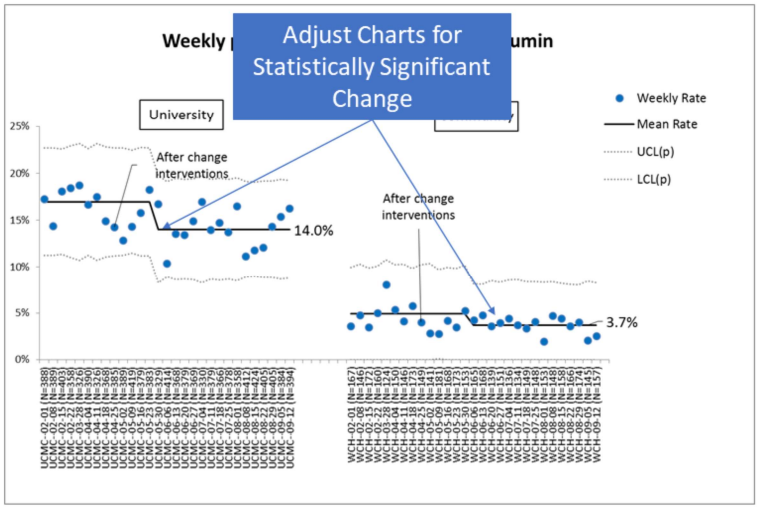

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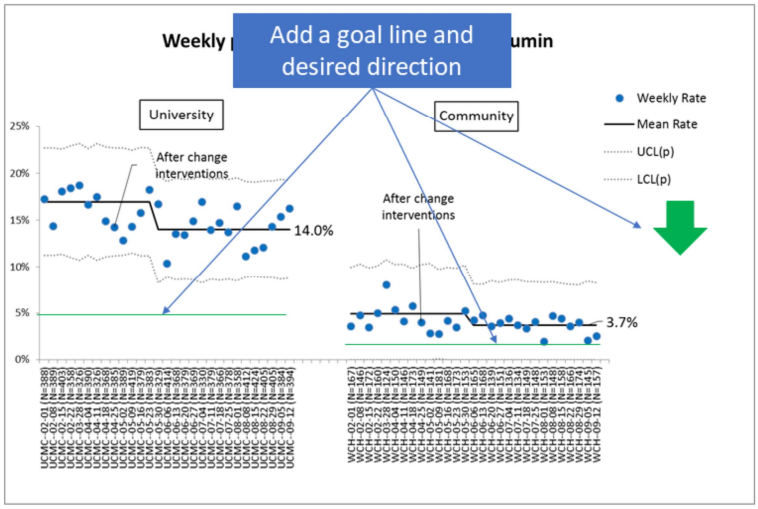
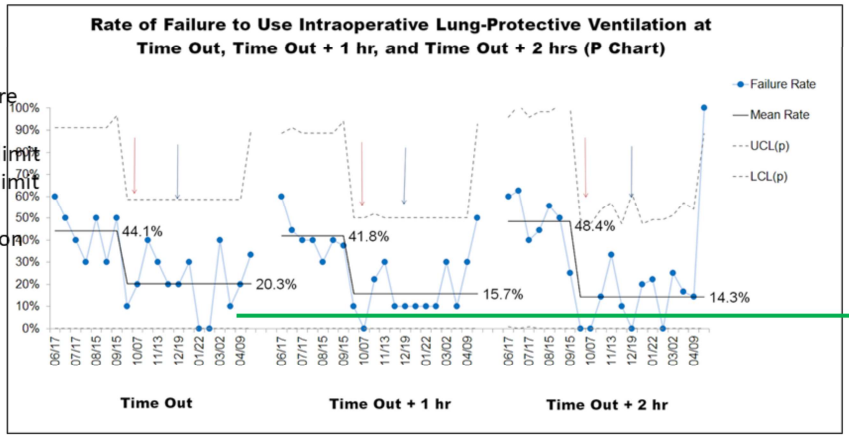


Using Shewhart Charts to Assess Adherence to Intra-operative Lung-Protective Ventilation

Title
X-axis = time
Y-axis = measure
Mean
Upper control limit
Lower control limit
Annotations
Desired direction
Goal line



Noted that failure rates decreased significantly after the interventions.
Red arrow = change #1; Blue arrow = change #2

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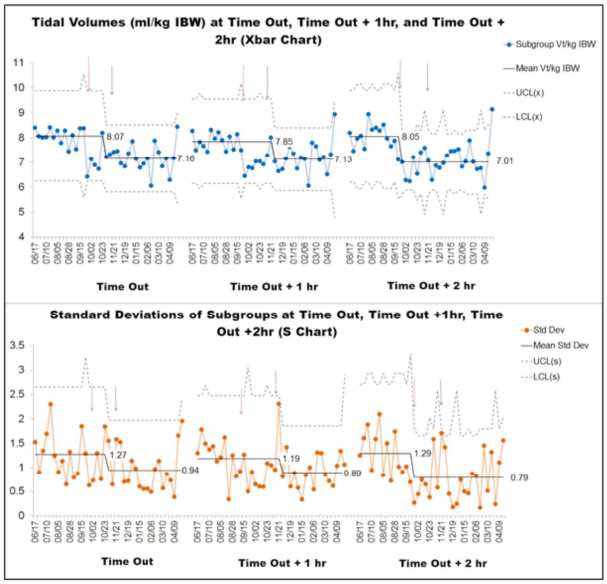
One of the primary ways that we followed our provider's adherence to protective ventilation techniques in the OR was with Shewhart charts. Here is an example. It depicts the percentage of cases where providers failed to use protective tidal volumes at three different OR time points. This is a P chart. The control limits are calculated assuming a binomial distribution.

Using Shewhart Charts to Assess Adherence to Intra-operative Lung-Protective Ventilation

Noted that Vt/kg IBW decreased significantly after the interventions.



Noted that variation in Vt/kg IBW decreased significantly after the interventions.

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We also looked at the continuous variable using a different Shewhart chart called an Xbar & S chart. This figure has two charts. The upper charts plots tidal volume averages for subgroups of 5 sequential cases for each time point. The lower chart plots the standard deviation of the data within each subgroup data point from the upper chart. This chart is somewhat analogous to a box & whisker plot.

On the chart you can see two major interventions as noted by the two arrows. You can see that the rate of failure decreased after the interventions. This is noted by the change in the mean. With Shewhart charts one starts collecting baseline data at the beginning of the project and freezes the mean after one begins making changes to the system. The likelihood of 8 or more points in a row appearing below or above the mean is 0.4%. It is very unlikely that this change occurred randomly.

You can see that if anything traditional enumerative data are more likely to show statistical significance since they lack the ability to critically analyze point-to-point variation. Shewhart charts utilize a lower P value if you will to demonstrate significance due to the significant lack of control and potential for bias inherent in working in uncontrolled systems and patient populations.

In our project there was not that much risk of performing interventions without solid evidence that they would work. It did cost my fellow and me time. It required my department to listen to my various lectures and read emails feeding back process measures of how we were doing. It required a little time from our anesthesia techs to reprogram some of our anesthesia machine ventilators. For a pretty low cost we gained a significant amount of adherence. More expensive and time-consuming interventions would certainly require a high degree of belief for a health system to implement. As you can see quality improvement work can be very rigorous and statistically sound and can produce the necessary evidence to support such efforts.

UCH PI Way--PART 2

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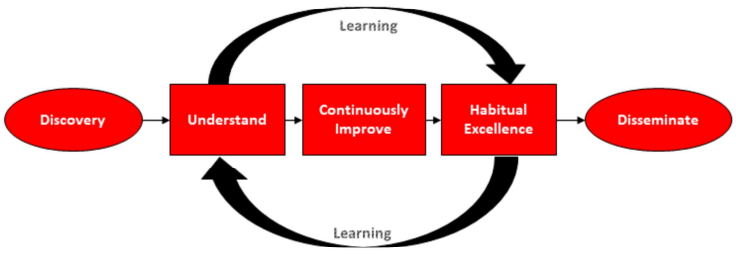
Habitual Excellence



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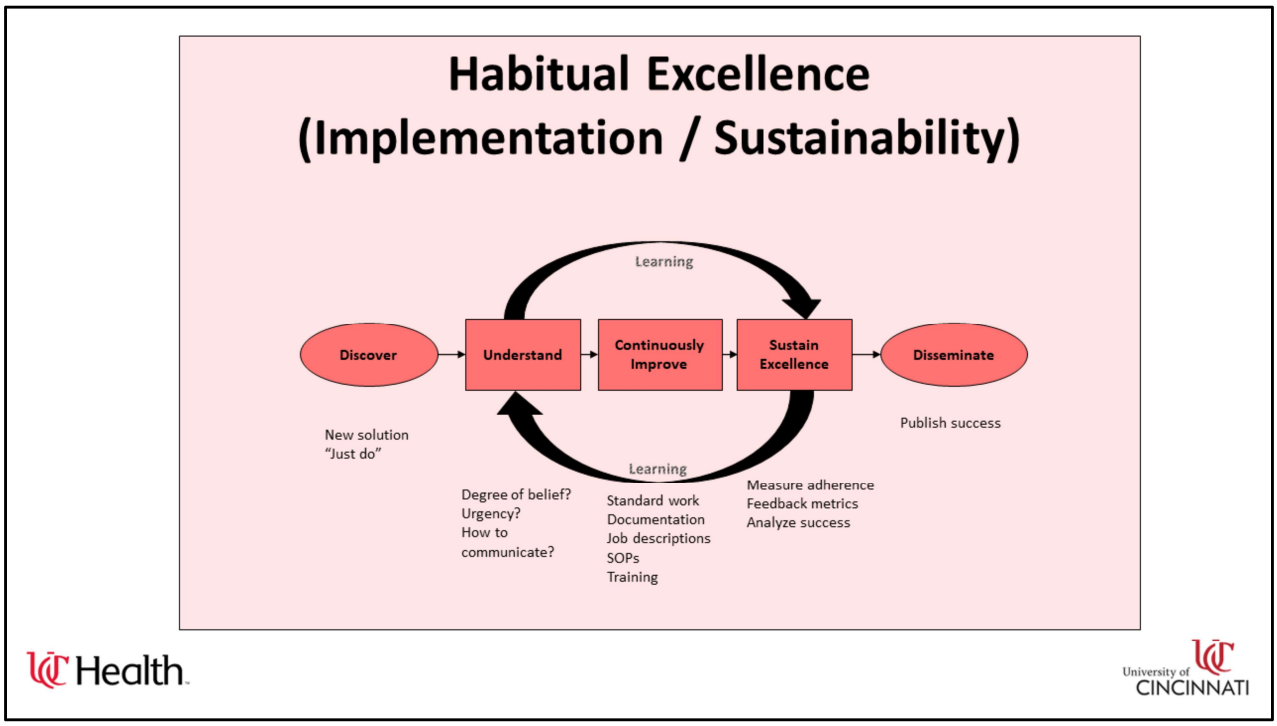
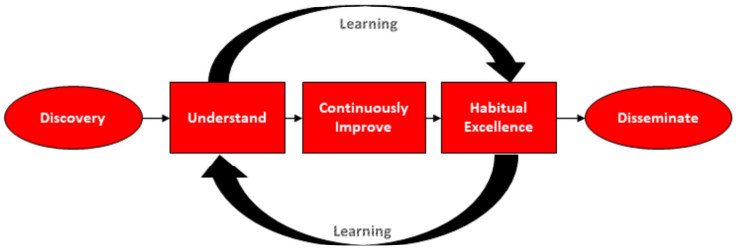


There is a whole additional science surrounding implementation.

Disseminate



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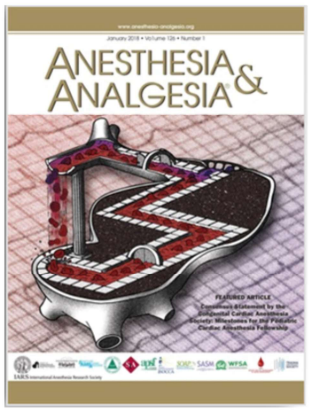
Improving Adherence to Intraoperative Lung-Protective Ventilation Strategies at a University Medical Center

Sean A. Josephs, MD, Gretchen A. Lemmink, MD, Judith A. Strong, PhD,
Cassandra L. Barry, MD, and William E. Hurford, MD



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Anesth Analg 2018;126:150-60

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ORIGINAL RESEARCH

Reliable adherence to a COPD care bundle mitigates system-level failures and reduces COPD readmissions: a system redesign using improvement science

Muhammad Ahsan Zafar,[1,2] Ralph J Panos,[1,3] Jonathan Ko,[4] Lisa C Otten,[4] Anthony Gentene,[5,6] Maria Guido,[5,6] Katherine Clark,[7] Caroline Lee,[7] Jamie Robertson,[8] Evaline A Alessandrini[2]

BMJ Qual Saf 2017;26:908-918

Pragmatic Challenge of Sustainability: Long-Term Adherence to COPD Care Bundle Maintains Lower Readmission Rate

Muhammad Ahsan Zafar, MD, MS; Brave Nguyen, DO; Anthony Gentene, PharmD; Jonathan Ko, RRT; Lisa Otten, RRT; Ralph J. Panos, MD; Evaline A. Alessandrini, MD, MSCE

The Joint Commission Journal of Quality & Safety 2019;45:639-45

QUALITY IMPROVEMENT REPORT

Sustained reductions in time to antibiotic delivery in febrile immunocompromised children: results of a quality improvement collaborative

Christopher E Dandoy,[1] Selena Hariharan,[2] Brian Weiss,[3] Kathy Demmel,[4] Nathan Timm,[2] Janis Chiarenzelli,[2] Mary Katherine Dewald,[2] Stephanie Kennebeck,[2] Shawna Langworthy,[4] Jennifer Pomales,[4] Sylvia Rineair,[5] Erin Sandfoss,[4] Pamela Volz-Noe,[2] Rajaram Nagarajan,[4] Evaline Alessandrini[2]

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BMJ Qual Saf 2016;25:100-109

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Questions?

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