Principles of Scientific Inquiry

Principles of Scientific Inquiry: How to do a QI Project

Thursday, November 9, 2023

Adewale Ajumobi, MD, MBA

Learning Objectives:

At the end of this presentation, participants should be better able to:

- Identify the principles of scientific inquiry
- Review the process to submit research protocols to IRB
- Recognize research and quality improvement methodologies
- Review the process to present and publish scholarly activities

Accreditation and Certification:

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Nurses

Provider is approved by the California Board of Registered Nursing, Provider #13664, for 1.0 contact hour.

Disclosure:

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Presenting Faculty:

Adewale Ajumobi, MD, MBA: No relevant financial relationships to disclose.

Principles of Scientific Inquiry: How to do a QI Project

Adewale Ajumobi, MD, MBA, FACP, FACG, AGAF, FASGE

Director of Scholarly Activities & Faculty Development

Associate Professor of Medicine

Definition of QI

"Systematic continuous approach that aims to solve problems in healthcare, improve service provision, and ultimately provide better outcomes for patients."

Backhouse A, Ogunlayi F. Quality improvement into practice. *BMJ*. 2020;368:m865

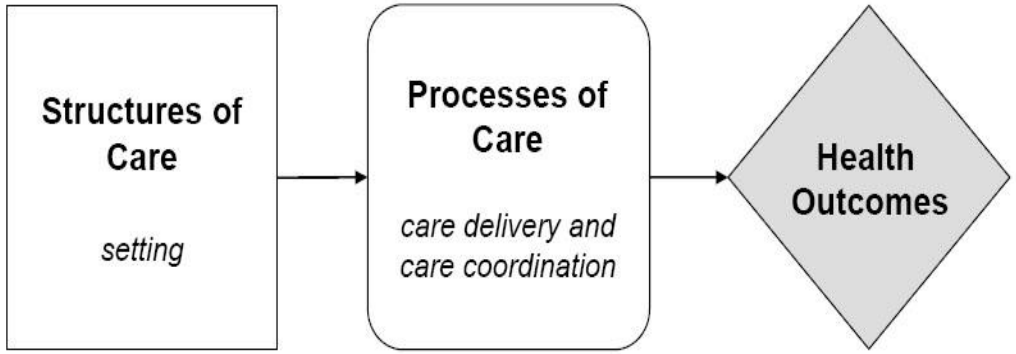
QI Focus (6 domains of healthcare quality)

1. Safe
2. Effective
3. Patient-centered
4. Timely
5. Efficient
6. Equitable

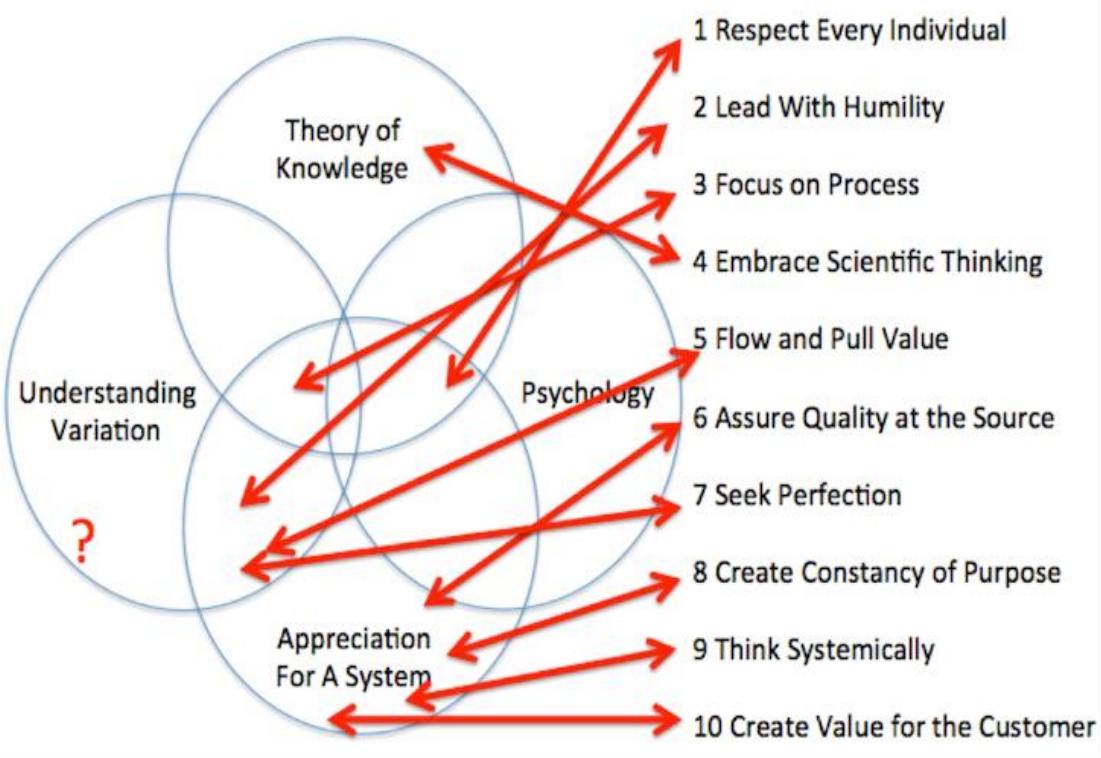
Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press; 2001.

Framework for QI

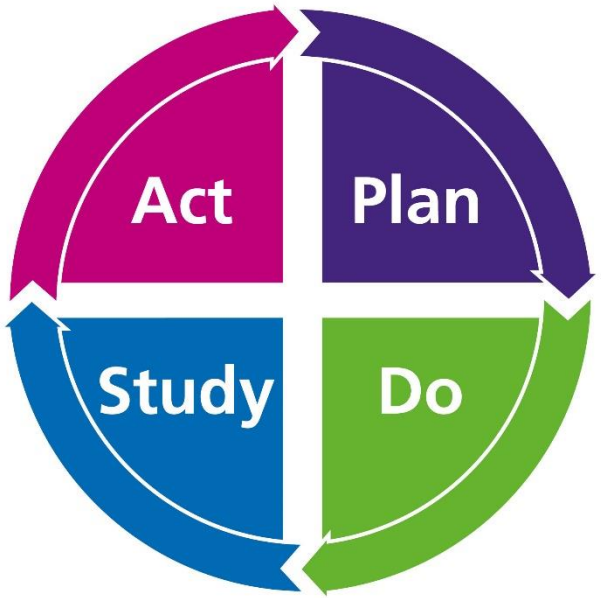
Avedis Donabedian



William Edwards Deming



QI Methodologies



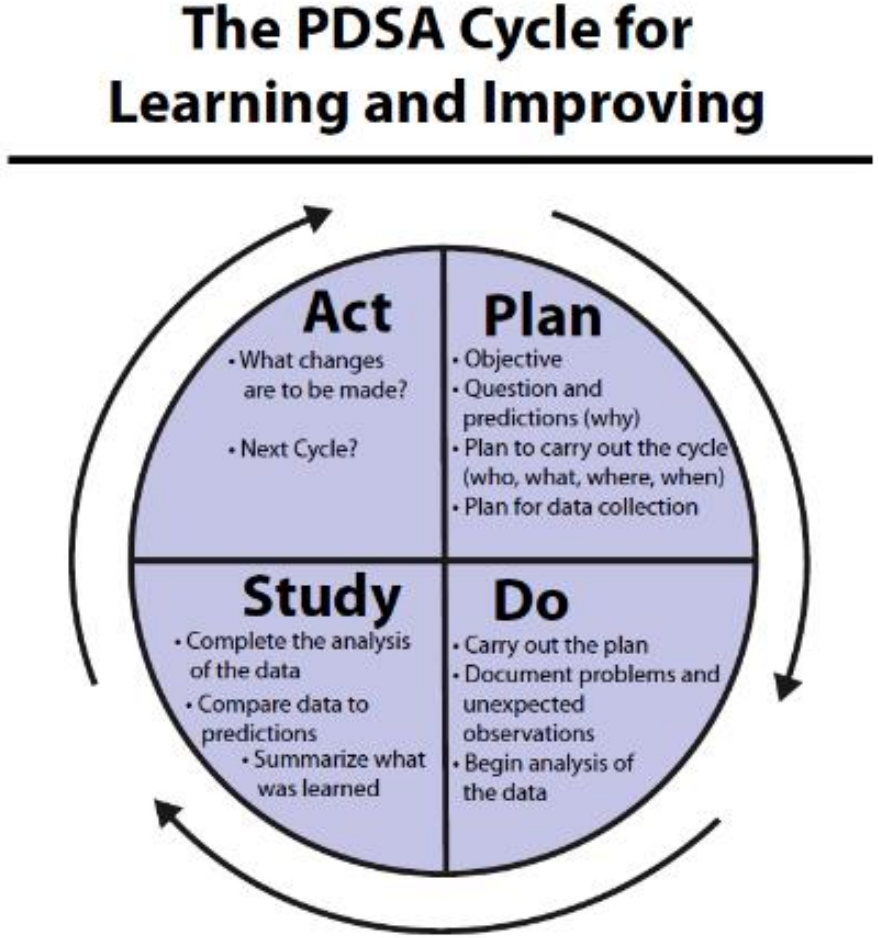
Optimal process improvement

Eliminate defects

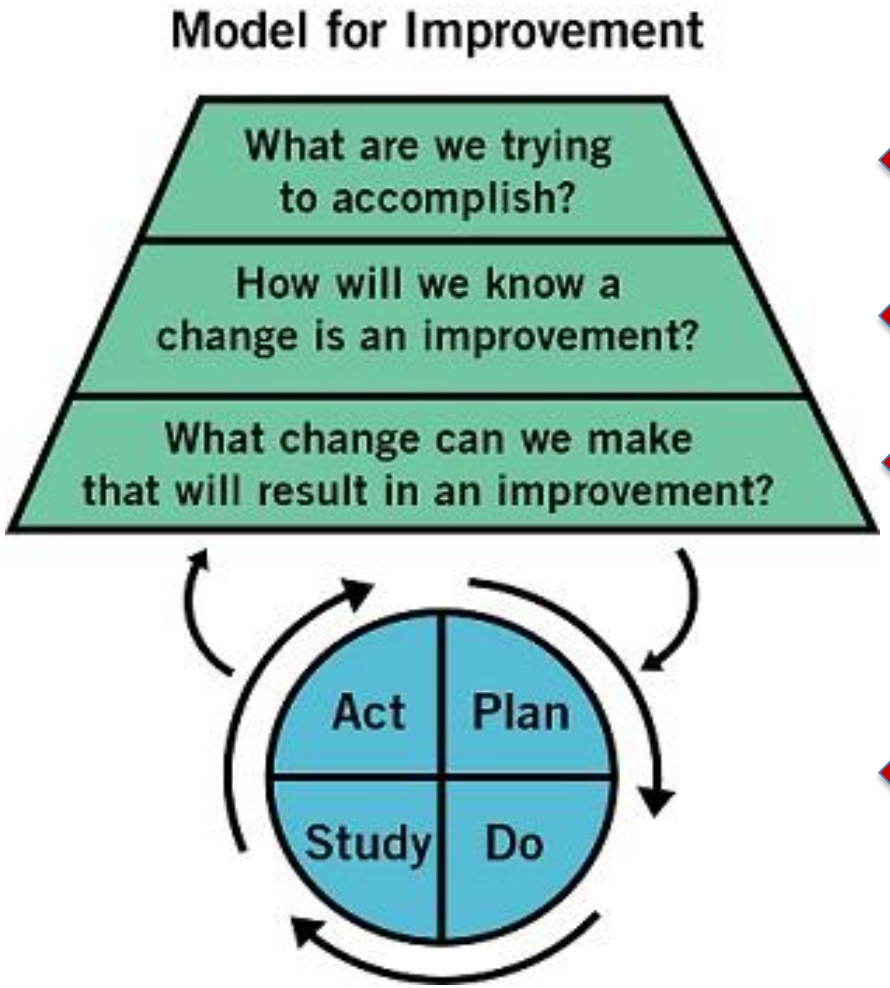
Improve efficiency

Phases of a Quality Improvement Project

- Innovation
- Pilot
- Implementation
- Spread



Model for Improvement



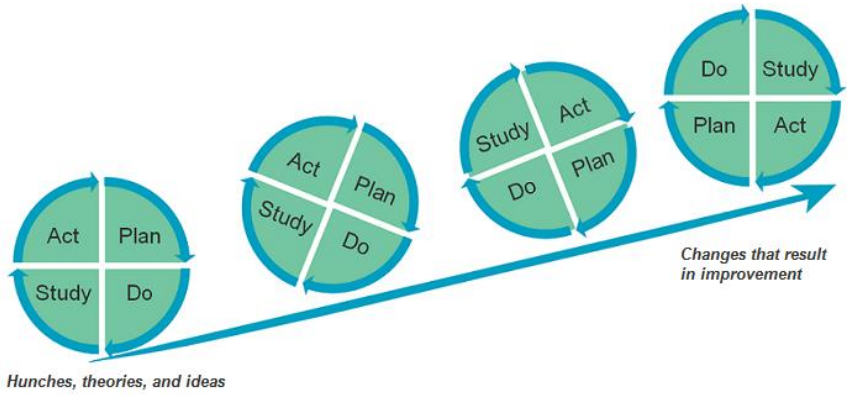
AIMS

MEASURES

CHANGES

TESTS OF CHANGE (PDSA)

PDSA Cycle



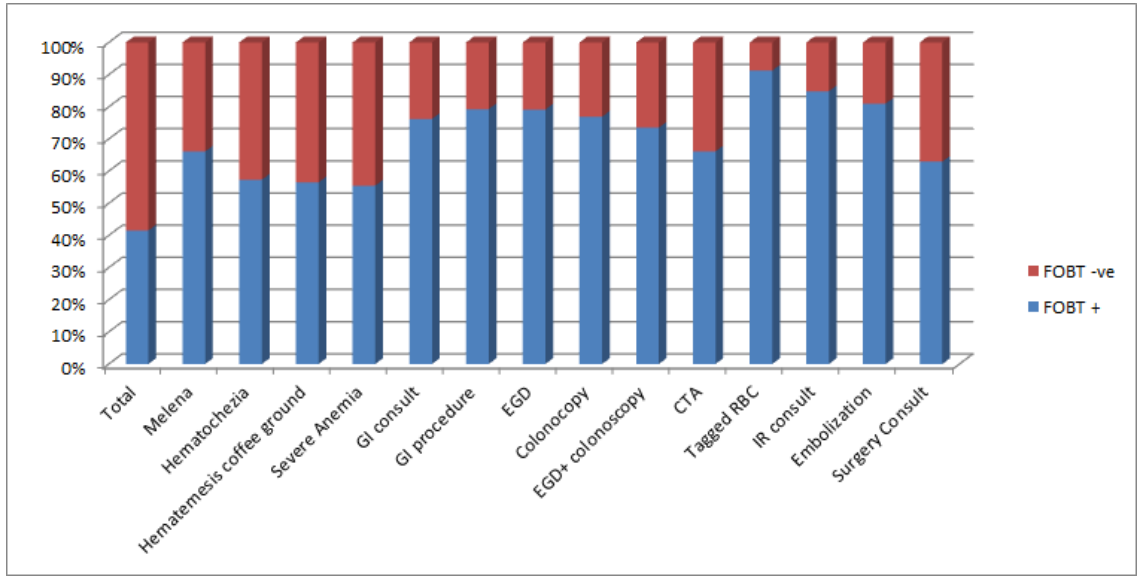
- Tests should be small and specific.
- Each test should influence the next one.
- Expand conditions if a test will work under different circumstances.
- Use the rule of 5s to expand testing.
- Results should evaluate if a test is promising.

STEP 1. Identify the problem

- What problem do you want to solve?

In 2019- 2.5% of all ED visits received FOBT
Close to 200/month
Gfobt, only 1 card, DRE, sometimes expired

- Why is it important to fix the problem?



STEP 2. Identify the solution

- How do you want to solve this problem?
- Who will benefit from this intervention? And how?
- Do you have any data that shows this intervention could benefit patient care?
- Make sure the intervention meets the following criteria:
- **Is it specific?**
- **Is it measurable?**
- **Is it achievable?**
- **Is it realistic/relevant?**
- **Is it timely?**

Aim Statement

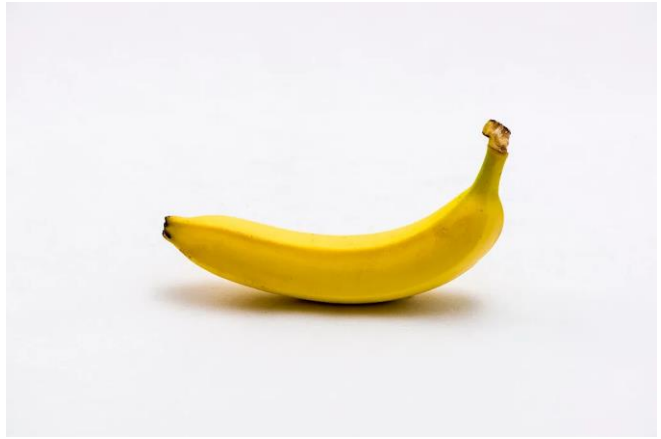
- What are you trying to accomplish?
- To increase / decrease: _____ (process/outcome)
- from: _____ (baseline %, rate, #, etc)
  to:_____
  (goal/target %, rate, #, etc)
- by: _____(date, 3-6 month timeframe)
- in: _____
  (population impacted)

STEP 3. Identify your team

Step 4. Identify the measures

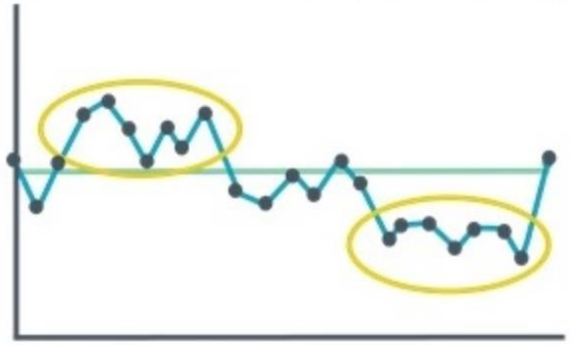
Outcome	Process	Balancing
% CRC screening rate at EH	% eligible pts w reminders for CRC SC	Time spent on vent vs re-intubation
Average HBA1C for pts w DM	% of pts with HBA1C check twice/yr.	LOS vs re-admission rates

How to measure activity

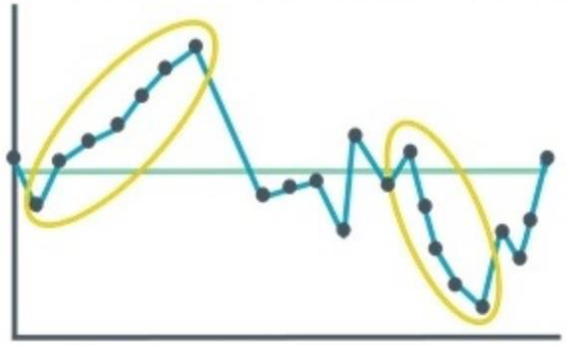


STEP 5. Project analysis and summary

1. A **shift** in the process is indicated by six or more consecutive points above or below the median.

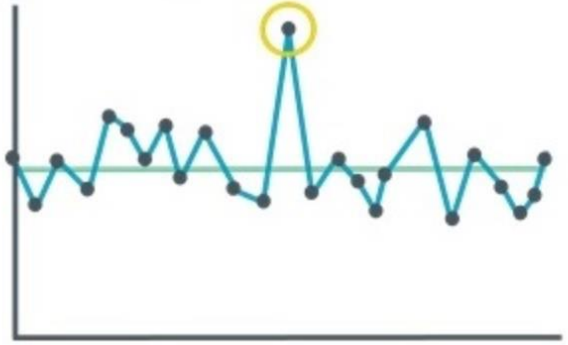


2. A **trend** is indicated by five or more consecutive points all increasing or decreasing.



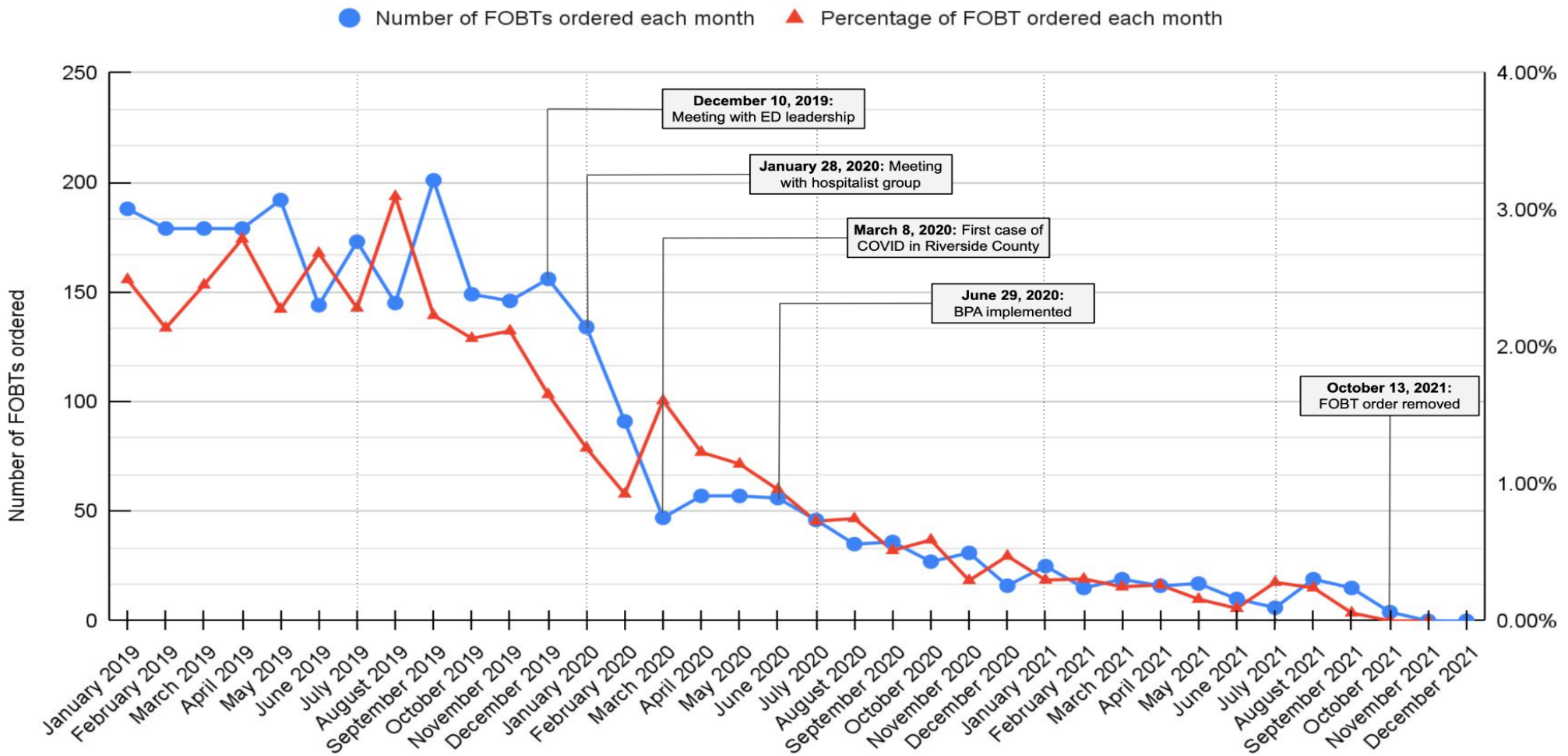
3. **Too many or too few runs** indicate a nonrandom pattern. (This one requires a table.)

4. An **astronomical data point** is a pretty good signal of a nonrandom pattern.



De-implementation of Fecal Occult Blood Testing in the Emergency Department and Hospital Units: A Quality Improvement Project

Trend of FOBTs ordered from January 2019 to December 2021



Key Steps for QI Projects

- Find a problem to solve.
- Find a mentor.
- Use EH QI worksheet.
- Write a protocol.
- Submit to IRB/Present at RQSC
- Start small & expand.
- Share your journey.

Alternatives to Quality Improvement

- **Research**

  -Generalizable new knowledge viz clearly defined ?? w systematic & rigorous MTD

- **Clinical Audit**

  -Find out if healthcare is being provided in line with standards

- **Service Evaluation**

-Investigate the effectiveness or efficiency of a service

- **Clinical Transformation**

-Deliberate, radical, irreversible change

- **Innovation**

 -New health policies, systems, products, technologies, services & delivery methods

ORIGINAL ARTICLE

Surveillance in Barrett's Esophagus: An Audit of Practice

Adewale Ajumobi · Khaled Bahjri · Christian Jackson · Ronald Griffin

CLINICAL GUIDELINE

ACP American College of Physicians *Best Practice Advice*

Upper Endoscopy for Gastroesophageal Reflux Disease: Best Practice Advice From the Clinical Guidelines Committee of the American College of Physicians

Nicholas J. Shaheen, MD, MPH; David S. Weinberg, MD, MSc; Thomas D. Denberg, MD, PhD; Roger Chou, MD; Amir Qaseem, MD, PhD, MHA; and Paul Shekelle, MD, PhD, for the Clinical Guidelines Committee of the American College of Physicians*

ESGE UNITED EUROPEAN GASTROENTEROLOGY ueg journal

Review Article

United European Gastroenterology Journal 2016, Vol. 4(5) 629–656
This article is published simultaneously in the journals Endoscopy and the United European Gastroenterology Journal.

DOI: 10.1177/2050640616664843
ueg.sagepub.com
SAGE

Performance measures for upper gastrointestinal endoscopy: A European Society of Gastrointestinal Endoscopy quality improvement initiative

Raf Bisschops[1], Miguel Areia[2,3], Emmanuel Coron[4], Daniela Dobru[5], Bernd Kaskas[6], Roman Kuvaev[7], Oliver Pech[8], Krish Ragunath[9], Bas Weusten[10], Pietro Familiari[11], Dirk Domagk[12], Roland Valori[13], Michal F Kaminski[14,15], Cristiano Spada[11], Michael Bretthauer[14,16], Cathy Bennett[17], Carlo Senore[18], Mário Dinis-Ribeiro[3,19] and Matthew D Rutter[20,21]

Editor's choice
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British Society of Gastroenterology guidelines on the diagnosis and management of Barrett's oesophagus

Rebecca C Fitzgerald,[1] Massimiliano di Pietro,[1] Krish Ragunath,[2] Yeng Ang,[3] Jin-Yong Kang,[4] Peter Watson,[5] Nigel Trudgill,[6] Praful Patel,[7] Philip V Kaye,[8] Scott Sanders,[9] Maria O'Donovan,[10] Elizabeth Bird-Lieberman,[11] Pradeep Bhandari,[12] Janusz A Jankowski,[13] Stephen Attwood,[14] Simon L Parsons,[15] Duncan Loft,[16] Jesper Lagergren,[17] Paul Moayyedi,[18] Georgios Lyratzopoulos,[19] John de Caestecker[20]

EISENHOWER QI EXPERIENCE

Karen D. Antwiler, MD
Addiction Medicine
Associate Faculty

Why Should You Do QIs?

- Expand knowledge on topic of interest
- Board certification requirement
- Fellowship goals
- Interdisciplinary collaboration
- Grants
- Hospital Recognition - Opioid Honor Roll

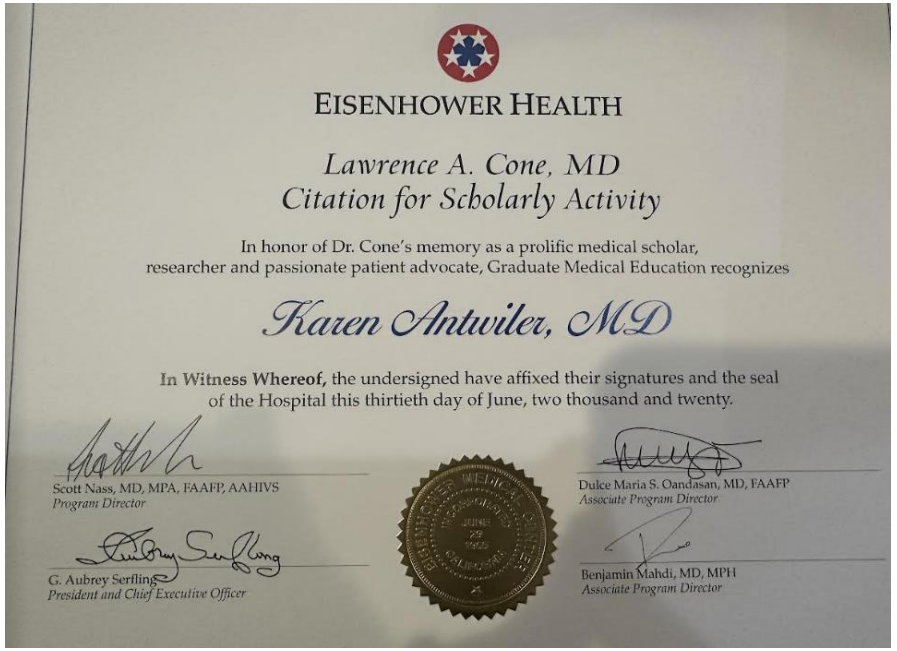
How QIs Have Helped Me

- Family Board Certification
- Fellowship Application
- Awards - Ruth Fox Scholarship, MERF, Program Director Research Award in Family Medicine, Lawrence Cone Award
- Present at conferences/publications - ASAM/CSAM/CHEST
- Interaction with hospital committees
- Knowledge of Informatics

What I Have Learned Through QIs

- Creating BPAs
- Working with IRB
- P&T
- Didactics for residents


The Association of Family Medicine Residency Directors and NAPCRG
are pleased to present
Karen Antwiler, MD
with the
Family Medicine Resident Award for Scholarship
2021
AFMRD
NAPCRG


EISENHOWER HEALTH
Lawrence A. Cone, MD
Citation for Scholarly Activity
In honor of Dr. Cone's memory as a prolific medical scholar, researcher and passionate patient advocate, Graduate Medical Education recognizes
Karen Antwiler, MD
In Witness Whereof, the undersigned have affixed their signatures and the seal of the Hospital this thirtieth day of June, two thousand and twenty.
Scott Nass, MD, MPA, FAAFP, AAHIVS
Program Director
Dulce Maria S. Oandasan, MD, FAAFP
Associate Program Director
G. Aubrey Serfling
President and Chief Executive Officer
Benjamin Mahdi, MD, MPH
Associate Program Director


CHHS
California Health & Human Services Agency
Hospital Quality Institute
Cal Hospital Compare
Eisenhower Health
2023 Honor Roll Award
for Sustained Improvement in Opioid Care
To receive this certificate, a California hospital scored ≥ 34 points on the 2023 Opioid Management Hospital Self-Assessment and scored at least one point in each of the following 4 domains of care: safe and effective opioid use, identifying and treating patients with opioid use disorder, overdose prevention, and applying cross-cutting opioid management best practices. This hospital achieved Sustained Improvement by holding Superior Performance for two years in a row.
Robert Imhoff
President
Hospital Quality Institute
Bruce Spurlock, MD
Executive Director
Cal Healthcare Compare

Tips For Your First QI

- Find an opportunity to improve
- Find a faculty lead
- Organize a team
  - Residents/fellows
- Establish principal/primary and secondary investigators
- Identify similar projects with design

INSTRUCTIONS FOR USE OF IRBNET FOR THOSE ASKING FOR RESEARCH DETERMINATION

1. **Complete Researcher Registration at www.IRBnet.org**
   IRBNet is Eisenhower's electronic IRB System (effective 9/26/19)
   - Use your Eisenhower e-mail address
   - Visit www.irbnet.org and complete a new user registration.
   - Affiliate with Eisenhower Medical Center

   All researchers and members of the research team must do this.
   IMPORTANT: You will receive an email from IRBNet with a link that you must click on to complete your registration
2. **Create a New Project in IRBNet to Submit your Project for Review**
   - Login to IRBNet.org
   - Download IRB form 15 under Forms & Templates on IRBNet.org.
   - Contact the IRB office at irb@emc.org if you have questions.
   - Complete the EMC IRB form15 on your hard drive
   - Upload your completed form 15, and either project description, proposed case report, or protocol, on IRBNet.
   - Share your project with any and all members of your research team.
   - Click on Submit

EISENHOWER MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

REQUEST FOR DETERMINATION
HUMAN SUBJECT'S RESEARCH OR QUALITY IMPROVEMENT

Instructions: Use this form when it is unclear whether the proposed activity requires review by the Institutional Review Board (IRB**).**

If the proposed study clearly is Human Research, do not complete this form. Instead please go into IRBNet and begin to create a new project. Once you are started, you will be able to access the Forms and Templates that you will need for your submission.

This form is required if it **is unclear** whether these activities require IRB review and the proposed project involves any of the following activities:
-Access to electronic medical records;
-Use or disclosure of Protected Health Information (PHI);
-The project is supported by federal funds;
-The project may be funded by an outside organization with a commercial interest
-The information will be used to support an application to the FDA or involves the use of a test article in a human subject;
-Patients or EMC staff will be interviewed;
-Patients or EMC staff will be asked to complete questionnaires
-Participants will be randomized into different intervention groups.

This form is part of a two part process:

The **first step** is for you to complete this form as best as you can at the early stage of project development. It is critical that you provide as much detail as possible. You can use this form or your protocol for your discussion with your Service Line Director in order to secure their support for the project. For nursing projects, this form can also be used to facilitate the Nursing Research Council's initial review. You can also send this form to the IRB office for guidance.

The **second step** will be to submit this form for an official determination. A determination as to whether this should be processed as a research project will be made by the IRB Co-Chair who will issue an official Determination Letter.

Principal Investigator/Project Leader:

Best Phone Number to Reach You:

Study/Project Title:

IRBNet ID#:

A. GENERAL INFORMATION

1. Thoughtfully provide a *concise and focused* description of **the research question** to be answered or tested.

2. Identify *your intent or purpose* in doing this project (is it to improve care on your unit or throughout EMC; is it to see if a new technique is successful and sharing the answer to your research question is novel enough that it can be applied broadly to similar groups, other institutions or other conditions; could the results be used to base a change in practice. etc.)

3. Has this question been answered already in the literature? If so explain why it needs to be tested again (e.g. need to test in a community hospital setting to see if there are differing results; need to see if this new approach will work on a specific population (e.g. geriatric patients, need to see if this new approach will work in a facility that must accommodate the fluctuating snowbird population; etc.)

4. Identify all proposed subjects (patients, family members, nurses, physicians, general staff)

5. Describe how data collection will occur and the type of information to be collected

B. YOUR ASSESSMENT OF WHETHER THIS MEETS OHRP DEFINITION OF RESEARCH

In your opinion and based upon your answers above, will this project meet the research definition in the Code of Federal Regulations, 45 CFR 46.102 (d) **as a systematic investigation designed to develop or contribute to generalizable knowledge.** Generalizable knowledge is defined as "Activities designed (with intent) to collect information about some individuals to draw general conclusions about other individuals that are predictive of future events and that can be widely applied as expressed in theories, principles, and statements and that enhance scientific or academic understanding."

For the project to be considered research, you must be able to answer yes to the following questions:

1. Is this a systematic investigation, including (but not limited to) a hypothesis, research development, testing, pilot work, and evaluation?
   ☐ Yes ☐ No

2. Is the activity primarily designed to develop NEW knowledge that can be applied broadly to similar groups or conditions?
   ☐ Yes ☐ No

C. YOUR ASSESSMENT OF WHETHER THIS MEETS THE OHRP DEFINITION OF HUMAN SUBJECTS RESEARCH

In your opinion and based upon your answers above, will this project meet the Human Subject definition in the Code of Federal Regulations, 45 CFR 46.102 (f) as involving a living individual about whom an investigator obtains data through intervention or interaction, or their identifiable private information. Your must be able to answer yes to the following

1 Does the study involve interaction or intervention with a living individual or group of individuals (whether identifiable or not)? (e.g. surveys, interviews, medical or education testing
   ☐ Yes ☐ No

2 Does the study involve access to identifiable private information?

D. ATTACHMENTS REQUIRED

1. Copy of your CV

2. Copy of a draft protocol or project plan.

_____ _____

Signature of Principal Investigator ***Date***

Pharmacy and Therapeutics Committee

- Know members of the P&T committee
  - -Tom H
- Request for project to be added to meeting
- Presentation of project via Zoom or in-person

Table 1. System-wide P&T Committee Responsibilities

Manage Formulary System
■ Formulary additions/deletions
■ Nonformulary drug use
■ Shortage/recall management
■ Therapeutic class reviews/therapeutic substitutions
Manage Medication Use
■ Antimicrobial stewardship
■ Guided (restricted-use) strategies
■ Medication-use evaluations
■ Medication-use policies, procedures, and protocols
■ Off-label drug use
■ Practice guidelines
Monitor Medication Safety
■ Black box warnings/REMS programs
■ Emerging medication safety information (eg, FDA alerts, ISMP)
■ Medication error and ADE trending

Results/Statistics

Epic Analyst

-Assist with data and statistical significance

EPIC IT/#5858

-Assist with BPA/EMR changes

Look through EPIC for other hospital designs

Example of Abstract/Protocol

EMC Optimization of Naloxone Co-Prescription
Lead: Karen D. Antwiler, MD (PGY-2, FM)
Faculty Advisor: Dr. Eduardo Javier, MD (Addiction Medicine)

Background:
Naloxone (Narcan) is a mu-opioid antagonist used in clinical settings to reverse the potentially lethal respiratory depression that occurs with opioid overdose. Cumulative deaths from drug overdoses in 2020 reached an all-time high of 81,000, with opioids involved in more than two-thirds of these cases.[1] The U.S. Centers for Disease Control and Prevention (CDC) issued guidelines which recommend co-prescription of Naloxone with opioids for a subset of patients as a risk reduction strategy to combat the opioid epidemic.[2]

Objective:
Increase access to Naloxone for patients at high risk of an opioid adverse event upon hospital discharge and in ambulatory visits.

Initial Planning:

1. Form interdisciplinary QI team.
2. Define project's scope and obtain support from respective departments.
3. Review other hospitals and academic centers protocol for Naloxone prescription.
4. Brainstorm potential screening criteria for patients at high risk for an opioid overdose.

Project Design:

1. Identify patients at high risk of an opioid adverse event.
2. Create best practice advisory (BPA) within EPIC to order Naloxone when high-risk patient identified.
3. Establish baseline data for percentage of high-risk patients prescribed Naloxone at discharge.
4. Submit project and receive P&T approval.
5. Educate staff regarding prescribing Naloxone for high-risk patients.
6. Educate patients regarding using Naloxone to counteract opioid overdose.
7. Evaluate improvement in the rate of Naloxone prescriptions to high-risk patients after six months.

Measure:
Percentage of identified high-risk patients from Eisenhower Health prescribed Naloxone.

Goal:
20% increase in prescription of Naloxone for high-risk patients from Eisenhower Health.

Anticipated Issues:
1. Educating inpatient providers and clinical staff in an efficient manner without disrupting workflow
2. Classifying patients as high-risk by quantifiable data which can be pulled by EPIC
3. Implementing and creating new formulas and fields in EPIC to evaluate the criteria

Phase One: Identify High-Risk Patients
The first step is to identify patients who are at a high-risk of an opioid adverse event from Eisenhower Health in both inpatient and ambulatory settings. Numerous criteria or methods exist to identify these high-risk patients. Given the later phases of the project will rely upon this classification or identification to create a best practice advisory (BPA) within EPIC, it is important that patients be identified through quantifiable data and criteria. The United States Centers for Disease Control and Prevention (CDC) guidelines and criteria for high-risk patients were evaluated to be the foundation of identifying high-risk patients at Eisenhower. The following three criteria were selected: (1) patients prescribed opioids with a morphine milligram equivalent (MME) of greater than 50, (2) patients who suffered a prior overdose, and (3) patients concurrently taking benzodiazepines. If a patient prescribed opioids from Eisenhower Health meets *any* of these three (3) criteria, then the patient is identified as at a high-risk of an opioid adverse event.

In order to create a best practice advisory (BPA) within EPIC in phase two, these three criteria need to be interpreted and accessible within EPIC. This process is discussed in detail for each of the three criteria below.

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[1] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
[2] https://www.cdc.gov/drugoverdose/prescribing/guideline.html

1. Patients Prescribed Opioids with Morphine Milligram Equivalent of Greater than 50

Any patient who is prescribed opioids with a morphine milligram equivalent (MME) of greater than 50 is identified as at a high-risk of opioid adverse event upon discharge. To calculate the MME, each prescribed opioid needs to be converted to an MME. MDCalc[3] provides an MME calculator for the following 10 common prescribed opioids: codeine, FentaNYL buccal or sublingual tablets, FentaNYL patch (Duragesic), HYDROcodone (Vicodin, Norco, Lortab), HYDROmorphone (Dilaudid), Methadone, Morphine, OxyCODONE (OxyCONTIN, Roxicodone), OxyMORphone, Tapentadol, and TraMADol (Ultram). On MDCalc's website, for each of these 10 opioids, a user can input dosage (e.g. mg/dose) and doses per day to calculate MME/day. MDCalc also offers the formulas to calculate MME/day for each of the ten opioids. These formulas would be utilized to create a function which EPIC could use to calculate the MME/day based upon opioid prescriptions for Eisenhower Health patients. The MME value would then be stored in EPIC that could be utilized both by doctors and to create the BPA.

This formula[4] might look like the following:

$$MME = .15C + .13Ft + 2.4FD + HC + 4HM + 4M1 + 8M2 + 10M3 + 12M4 + 1MOR + 1.5OxC + 3OxM + 0.4T + .1TM$$

Where:
C = mg of Codeine per day
Ft = mcg of FentaNYL buccal or sublingual tablets per day
FD = mcg of FentaNYL patch (Duragesic) per day
HC = mg of HYDROcodone (Vicodin, Norco, Lortab) per day
HM = mg of HYDROmorphone (Dilaudid) per day
M1 = mg of Methadone where 1-20mg/day is prescribed
M2 = mg of Methadone where 21-40 mg/day is prescribed
M3 = mg of Methadone where 41-60 mg/day is prescribed
M4 = mg of Methadone where >60 mg/day is prescribed
MOR = mg of Morphine prescribed per day
OxC = mg of OxyCODONE (OxyCONTIN, Roxicodone) per day
OxM = my of OxyMORphone
T = mg of Tapentadol per day
TM = mg of TraMADol (Ultram) per day

2. Patients with Previous Opioid Overdose

Next, patients with previous opioid overdoses need to be identified. The method utilized for this project was to flag any patient with relevant ICD-10 coding. If a patient had any of the below ICD-10 codes then a patient would be identified as at a high risk of an opioid adverse event.

Phase Two: Create Best Practice Advisory within EPIC

Now that EPIC has quantifiable data by which to evaluate and identify patients who are at a high-risk of an opioid adverse event, a best practice advisory (BPA) can be created within EPIC. This BPA would trigger any time one of the three criteria was met to identify a high-risk patient. The BPA would identify the criteria by which the patient was classified as high-risk and instruct the doctor to prescribe Naloxone to the patient.

Phase Three: Baseline Data

Before the BPA is implemented and any training and education is given to staff and patients, the baseline data for current high-risk patients prescribed Naloxone needs to be gathered and established. The measure would be:

$$Baseline\ Data = \frac{\#\ of\ high\ risk\ patients\ prescribed\ Naloxone}{\#\ of\ high\ risk\ patients}$$

To gather the baseline data, a retrospective chart review would be done for all patients identified as high-risk under Phase One of the project who were discharged from Eisenhower Health in the previous six months.

Phase Four: P&T Approval

Project will be submitted to P&T to receive approval to implement the BPA and education of staff and patients.

Phase Five: Educate Staff on Naloxone

In order to maximize high-risk patients access to Naloxone, training and education of the inpatient and outpatient providers and clinical staff will be conducted. This training will be staggered to reduce any disruption of workflow. Training will be provided to family medicine residents and providers during one of the regularly scheduled didactics. Training for internal medicine residents and providers will be conducted during a noon report. Finally, training for clinical staff will be conducted through the nurse educators. This training and education will be developed around the CDC's guidelines for prescribing opioids for chronic pain and identifying patients at risk of opioid overdose.

Phase Six: Educate Patients on Naloxone

Patients who are prescribed Naloxone will also be provided education and instruction regarding the medication. A standardized instruction for Naloxone will be created and distributed as part of discharge instructions.[5] These instructions will be both in English and Spanish.

Phase Seven: Evaluate Improvement

After six months of implementing the BPA and education of the staff and patients, a retrospective analysis will be conducted to determine the percentage of high-risk patients discharged from Eisenhower prescribed Naloxone.

$$\%\ of\ high\ risk\ patients\ prescribed\ Naloxone = \frac{\#\ of\ high\ risk\ patients\ prescribed\ Naloxone}{\#\ of\ high\ risk\ patients}$$

This rate will then be compared to the baseline data to determine the improvement rate over the course of the project.

$$Improvement\ Rate = \%\ of\ high\ risk\ patients\ prescribed\ Naloxone - Baseline\ Data$$

The goal for the improvement rate is 20%.

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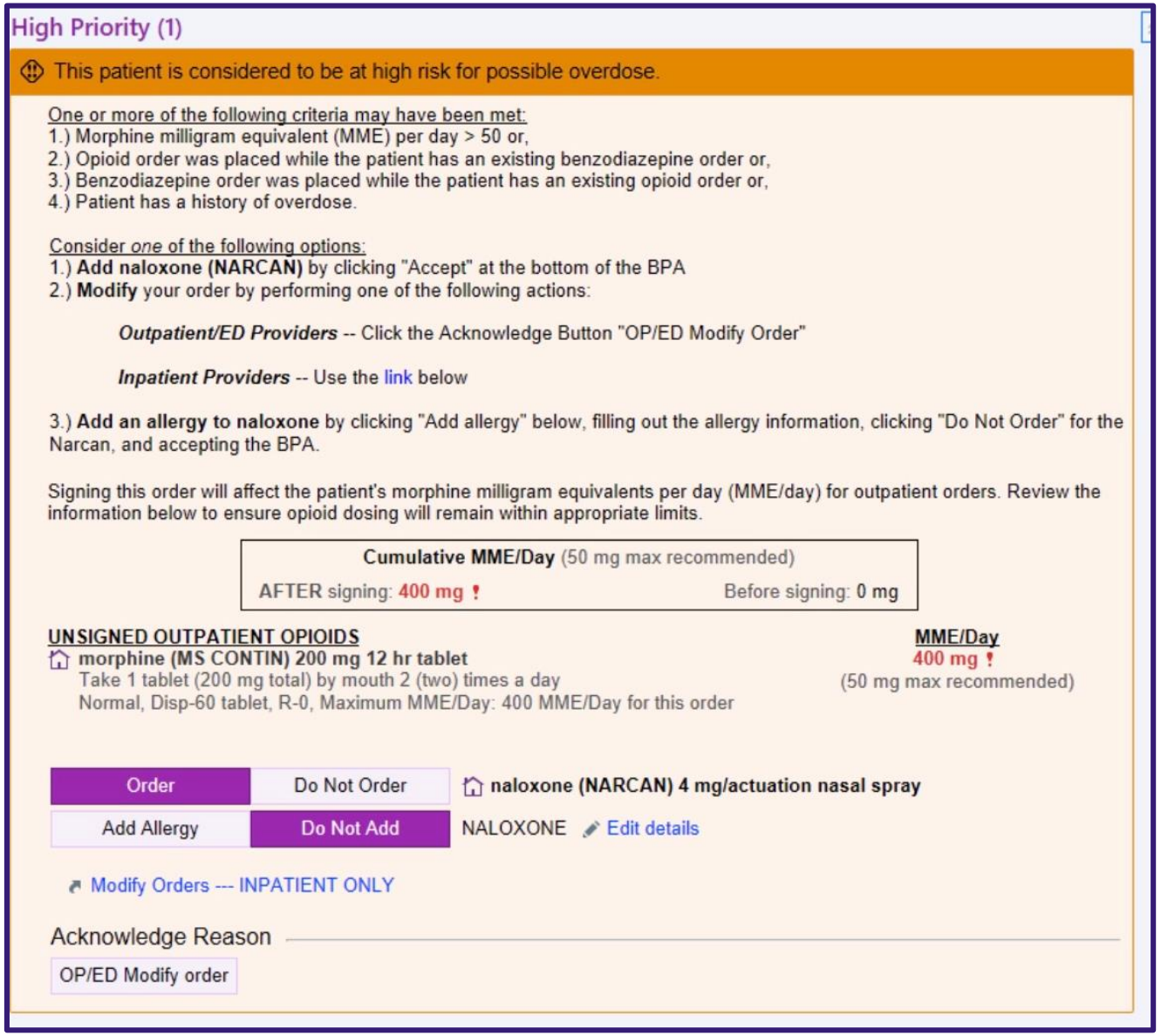
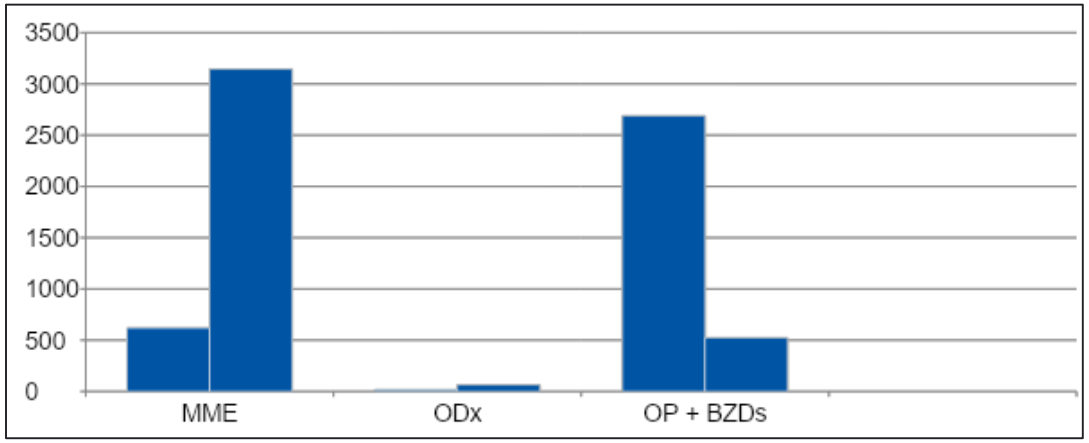
[5] e.g. http://www.prescribetoprevent.org/wp-content/uploads/2012/11/naloxone-one-pager-in-nov-2012.pdf





1. MME > than 50 (3145 patients)
618 Naloxone prescriptions (213 ambulatory and 405 inpatient) – 20% increase

2. Previous Opioid Overdose (63 patients)
15 Naloxone prescriptions – 20% increase

3.Opioids and benzodiazepine prescriptions (total of 2690 patients)
524 Naloxone prescriptions (226 ambulatory and 289 inpatient) – 20% increase

Take Homes

1. Retrospective Research
2. Early IRB Approval
3. P&T
4. Multiple PDSA Cycles
5. Confidentiality
6. Citations