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Methods in Quality Improvement for Clinical and Academic Projects

Objectives

This session will prepare you for the QI workshop and address:

- What is QI (and what it isn't)
- How QI projects are organized
- Approaching project ethics
- Analyzing and presenting QI data
- Planning for publication

What is Quality Improvement?

- The science of using measurement to understand and improve the performance of a system
- In healthcare, quality improvement refers to systematic and continuous actions that lead to measurable improvement in care and outcomes for patients and populations

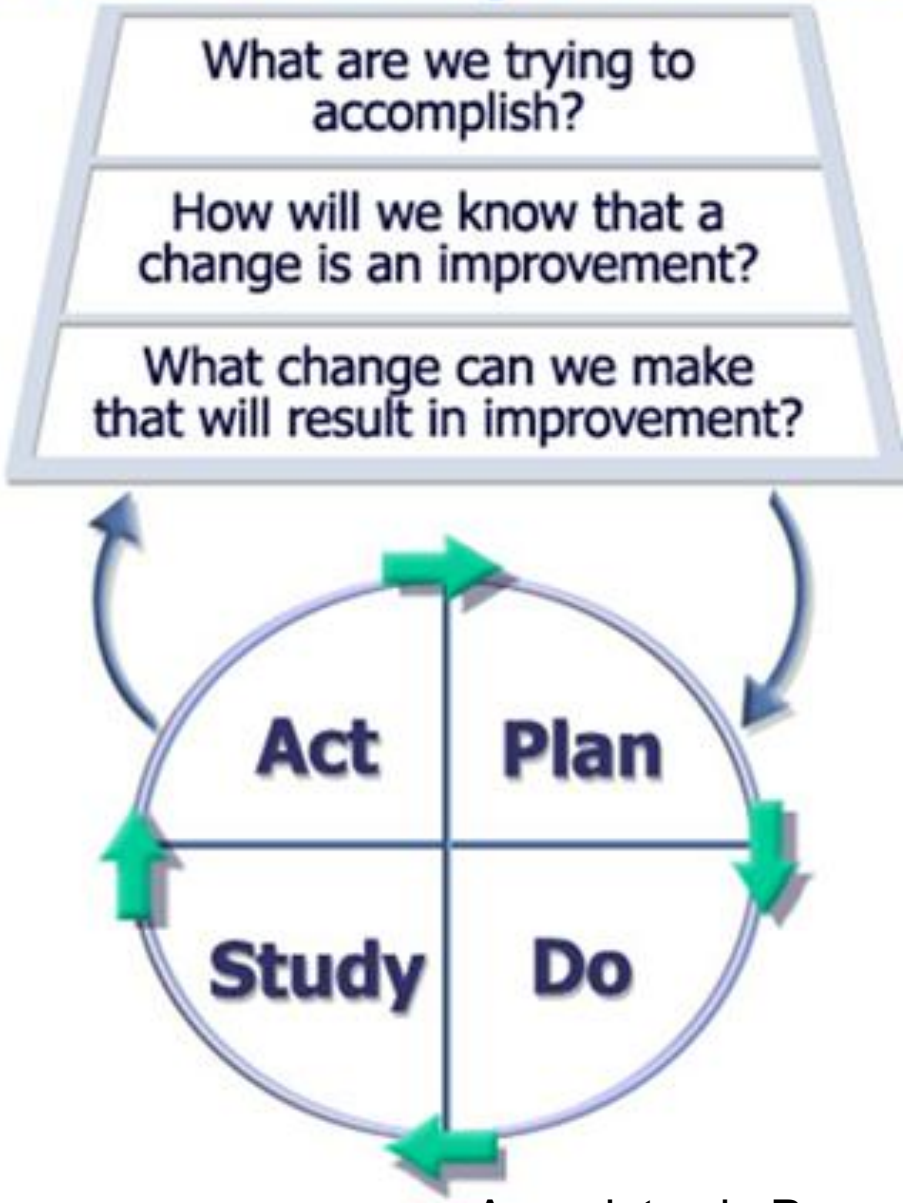
Adapted from Health Resources and Services Administration, 2011

What is Quality Improvement?

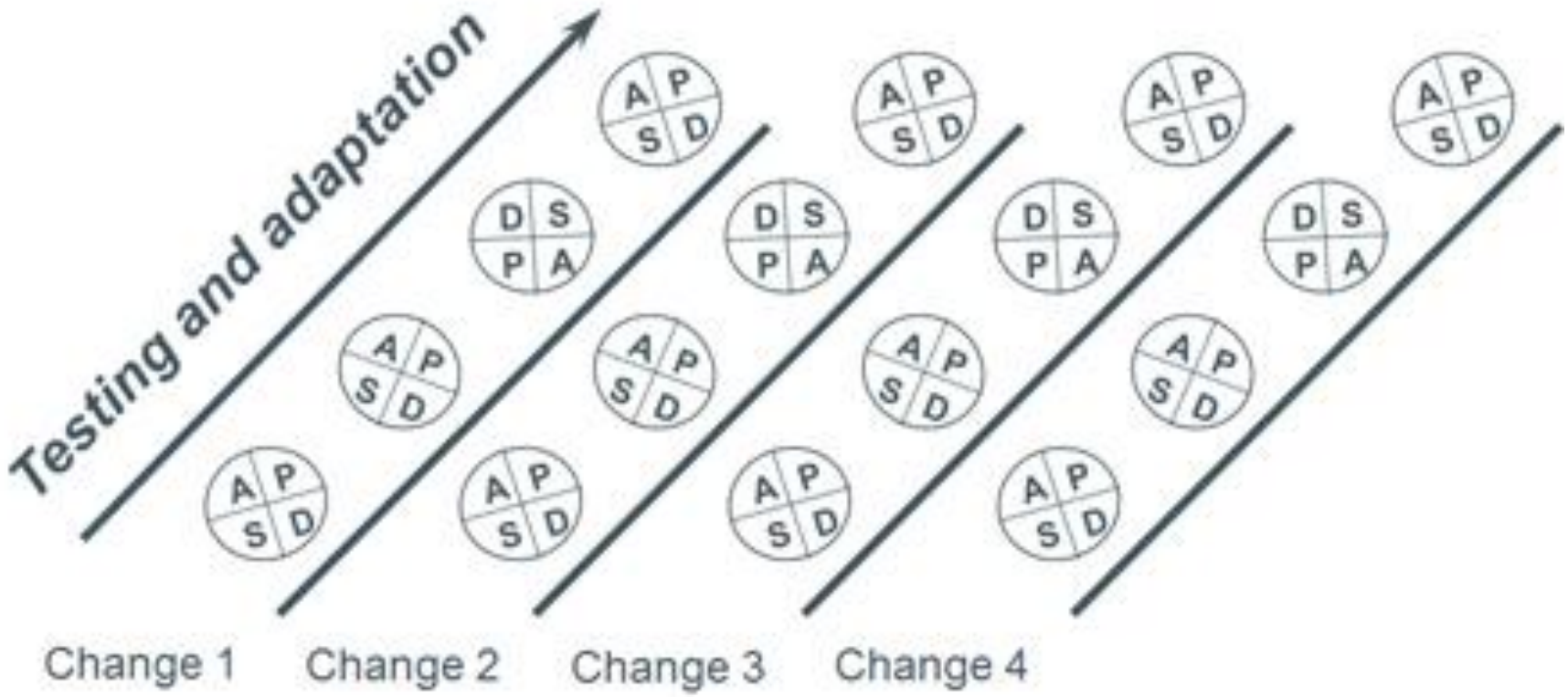
- Quality improvement is a process of identifying a problem, setting an aim, testing multiple changes, and continuously measuring progress toward better outcomes

- My own definition

Model for Improvement



Associates in Process Improvement, 1992


Testing and adaptation
A P S D
D S P A
Change 1
Change 2
Change 3
Change 4

www.ihi.org

QI Involves Systems

- "The System" = how things are done now

Resources (Inputs)	+	Activities (Processes)	=	Results (Outcomes)
People		What is done		Service delivery
Infrastructure		How it is done		Behaviour change
Materials				Health status change
Information				Patient experience
Technology				

Adapted from Donabedian, 1980

"Every system is perfectly designed to get the results it gets." *- Paul Batalden, IHI*

Terminology

- Quality Improvement is the process of using measurement and testing changes to improve outcomes
- Quality Assurance is the process of examining whether care meets an accepted standard
  - Alberta Evidence Act (Section 9) previously used the term "Quality Assurance" to describe legally protected activities that "study, assess or evaluate the provision of health services"
  - Now called "Quality Review"

How are QI and Research Different? Primary Purpose!

- **Quality Improvement (QI)**
- Purpose: *To improve a local process or outcome*
- Problem-based: “How can we make this better here?”
- Measures: Local performance *over time*
- Use of results: Directly applied to improve care
- **Research**
- Purpose: *To create new, generalizable knowledge*
- Question-based: “What is broadly true or effective?”
- Measures: Hypothesis testing, *statistical significance*
- Use of results: Shared to inform wider understanding

	Research	Quality Improvement
Purpose	Discover new knowledge	Use knowledge to fix a problem
Starting point	Hypothesis	Aim
Strategy	Interventions planned *a priori*	Tests of change inform next steps
Ethics Review	Performed by a research ethics board	Performed according to local guidelines (ARECCI in Alberta); REB exemption request if publishing
Variation and Bias	Reduced by using inclusion and exclusion criteria, randomization	Reduced by standardizing processes, so that change can be detected
Sample size	Calculated to ensure power to detect a meaningful difference; study ends when enrolment met	Focus on gathering enough information to reliably measure; project ends when aim is met
Analysis	After data collection complete or at a defined interim analysis; often uses hypothesis testing	Ongoing throughout tests of change; often uses run charts or control charts
Reporting standards	Determined by study type (e.g. CONSORT for clinical trials)	SQUIRE 2.0 guideline (Standards for QI Reporting Excellence)

Primary Purpose

You would like to reduce the median time to treatment of pain in your ED, currently 30 minutes, and decide to test if a nursing directive to provide analgesics at triage can produce a statistically significant change.

You compare time to analgesia before and after the order set change using a t-test.

Research or QI?

Primary Purpose

You would like to reduce the median time to treatment of pain for limb injury in your ED from 30 minutes to 15 minutes.

You work with your team to identify possible changes and decide to begin with a nursing directive for analgesia to be given in triage.

You create a chart to measure your progress toward the 15 minute aim.

Research or QI?

Your primary purpose is QI if:

- You are doing it to directly attempt to fix a local problem
- The work will be used locally regardless of whether it will be published
- Your team is willing to do more than one thing to address the problem
- You're not simply trying to conclude whether or not one thing worked

Reflection

- Think about your project for this course.
- What is your primary purpose?
- If it is to learn something new, what problem will the new knowledge help to solve?

What about Implementation Science?

- Implementation science is the study of methods to promote uptake of evidence into practice
- Both IS and QI share goal of improving quality
- QI has the purpose of *fixing a local quality gap* and may be shared so others can learn
- IS has the purpose of developing knowledge about *how to best implement evidence* across settings

Bauer et al. BMC Psych 2015. Intro to IS for the non-specialist.

What is “QI Research”?

- Often a term used by people unfamiliar with QI
- Misconception that anything measured = “research”
- Both QI and Research use measurement, but for different purposes
- “QI Research” could refer to studies that create knowledge about QI
  - What factors or strategies support improvement?

How is QI Organized?

A 10-Step Project Strategy

1. Identify the Problem
2. Form a Team
3. Consider Ethics
4. Understand the Problem
5. Set the Aim
6. Plan the Change
7. Measure the Change
8. Repeat Cycle as Needed
9. Sustain Success
10. Share

Defining the problem

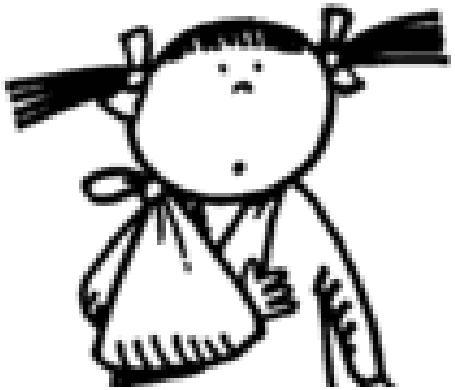
- Is there a quality gap?
  - Ideal conditions for QI success:
    - Solid evidence to inform a standard of care
    - Accessible data
    - Gap between current and desired practice
    - Motivation to change/improve
    - Resources to match scope of project

The problem statement

- Clear, specific description of the *gap between current and desired performance*
- Frames problem as measurable
- Creates urgency and shared understanding
- Doesn’t presume causes or solutions
- Structure: *For ___, current performance is [X], compared to desired performance [Y].*

ACH ED example

- Review of data on all children presenting with limb injury over a one-year period
  - 20% were given a pain score at triage
  - 32% received medication for pain during their visit



The problem statement: which is best?

- Pain in the emergency department is undertreated.
- Only 20% of children with limb injury receive a pain score upon ED arrival because the electronic record is cumbersome.
- For children presenting to the ED with acute limb injury, 20% receive a documented pain assessment at triage compared to the desired standard of 100%.

Imagine you have finished your research project. What problem can you address with this new knowledge?

Write a problem statement for the QI project you could design after finishing your research.

Forming a Team

- You need a team when…
- The task is complex, and no one person has the knowledge, skills, and experience to implement a solution.
- Change will require cooperation across units or disciplines and institutional alignment.

Consider Ethics

- Think again about your primary purpose
- If fixing a local problem, probably QI
- Proceed with ARECCI process
- If planning to share, contact REB to confirm exemption
  - Send protocol, ARECCI documents

ARECCI

- **A** p**R**oject **E**thics **C**ommunity **C**onsensus **I**nitiative
- Created in 2003 by Alberta REBs, health authorities, and Alberta Health and Wellness
- Recognition that all projects involving individuals and their health records can involve risk
- Standard process to review projects according to primary purpose (research or quality) and level of risk

Our impact

ARECCI helps project leads to address and mitigate ethical risks through decision support tools, training opportunities and project ethics consultation.

ARECCI decision support tools

ARECCI decision support tools consists of two complimentary tools to assist project sponsors.

1. The ARECCI Ethics Screening Tool and
2. ARECCI Guideline Tool.

These tools have been co-developed and validated. They help determine:

1. level of risk of your project,
2. types of ethical risks, and
3. appropriate type of ethics review.

Each tool aids in the identification of ethical areas of concern.

Legend

Provides more information about a question (if available).

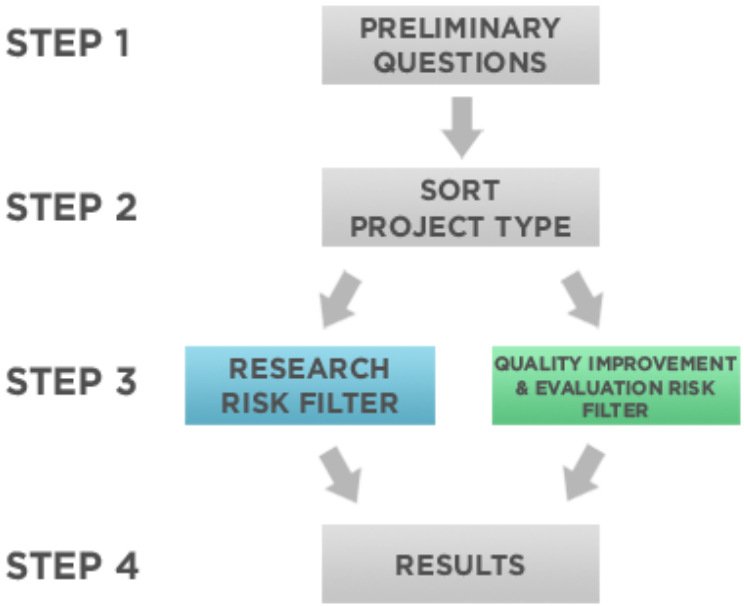
Save the current state of the tool and retrieve a URL for bookmarking.
Note: This is not the same as selecting File > Save As in your browser. Please use this save function instead.

E-mail the results of the tool.

Print the results of the tool.

Submit feedback regarding the tool.

Process



Project Title:

Date Completed: October 08, 2014

Step 1: Preliminary Questions

1. Is there an explicit requirement for review of this project by a Research Ethics Board as part of its funding arrangements? Yes No

2. Are there any local policies that require this project to undergo review by a Research Ethics Board? Yes No

13. Is the current project part of a continuous process of gathering or monitoring data within an organization? Yes No

Notes:

Next »

Your score indicates that the most probable purpose of your project is Quality Improvement or Program Evaluation.
Please proceed to determine the category of risk to your participants.

Does your project involve...

14. Likelihood that a breach of confidentiality could place participants at risk of legal liability, denial of insurance or other damage to financial standing, employability, or reputation? Yes No

15. A real or potential conflict of interest between an investigator and the sponsor of the investigation? Yes No

16. A power relationship between the investigator and participants (e.g., manager/employee, therapist/client, service provider/recipient, teacher/student)? Yes No

Next »

Save
Print
E-mail
Feedback

Your score is 19. The project involves Somewhat More Than Minimal Risk and should be reviewed by a Second Opinion Reviewer.

Questions that affected your final score:

19. Collection of data through technical procedures or diagnostic tools routinely employed in the setting?	1 pts
20. The use of tests, surveys, interviews, oral history, focus groups, or observation of public behaviour where the participants can be directly or indirectly identified through the information recorded?	2 pts
22. Personally identifiable data, documents, records or specimens originally collected solely for purposes not related to the current study?	2 pts
23. Special populations or any individuals or groups in a socially vulnerable position?	3 pts
26. A person who does not normally have access to participant records and whose use of records is for a secondary purpose?	11 pts

Ethics Screening Score Cutoff Points

Score

4. HOW WILL YOU MAXIMIZE BENEFITS AND MINIMIZE OR MITIGATE THE ETHICAL RISKS IN THE PROJECT?

POINTS TO CONSIDER

- How will your organization and participants benefit from the project?
- What are the risks identified by the *ARECCI Ethics Screening Tool* and how will you minimize and mitigate them?
- What are the risks of not doing this project?
- Will your organization tolerate the risks that remain in your project?

Describe the benefits to participants and to your organization.

Understanding the Problem

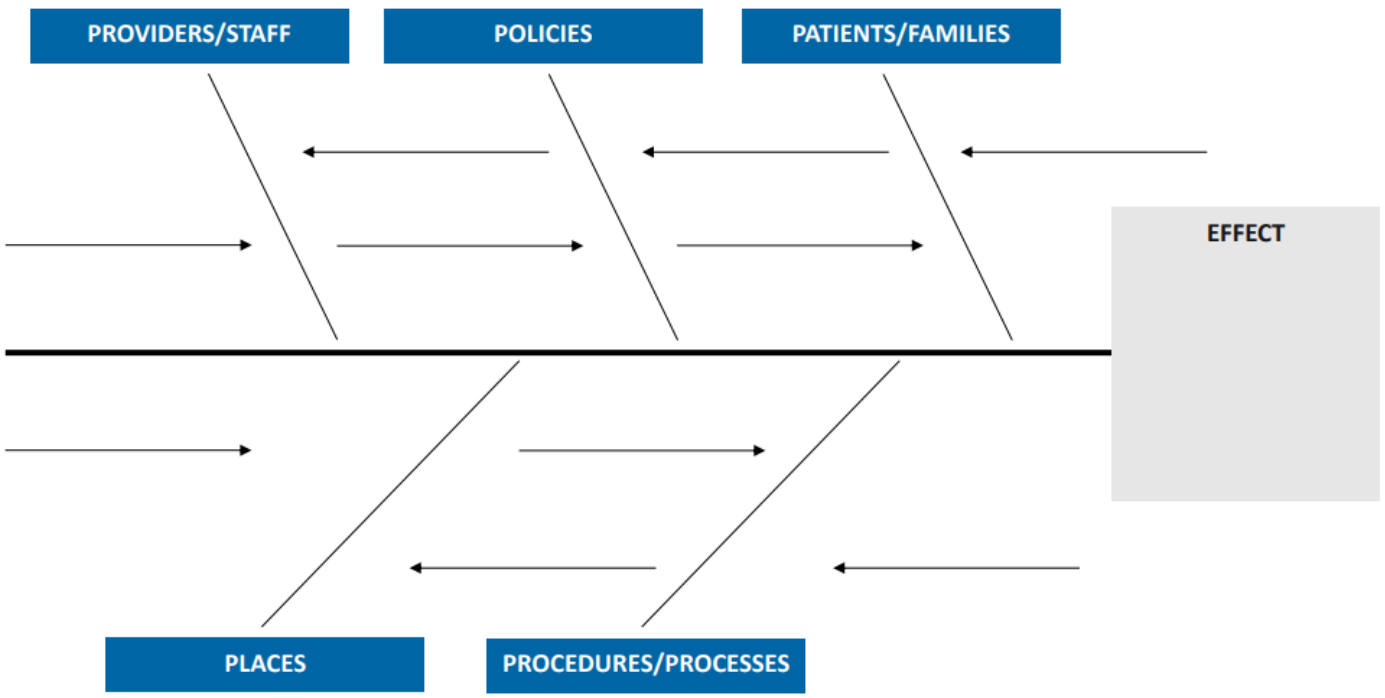
Understanding the Problem

- You will practice using tools for understanding the problem in the upcoming QI workshop
  - Fishbone Diagram
  - Process Mapping and Modified FMEA
- No single necessary or correct tool as long as you understand your problem before trying to solve it

Understanding the Problem

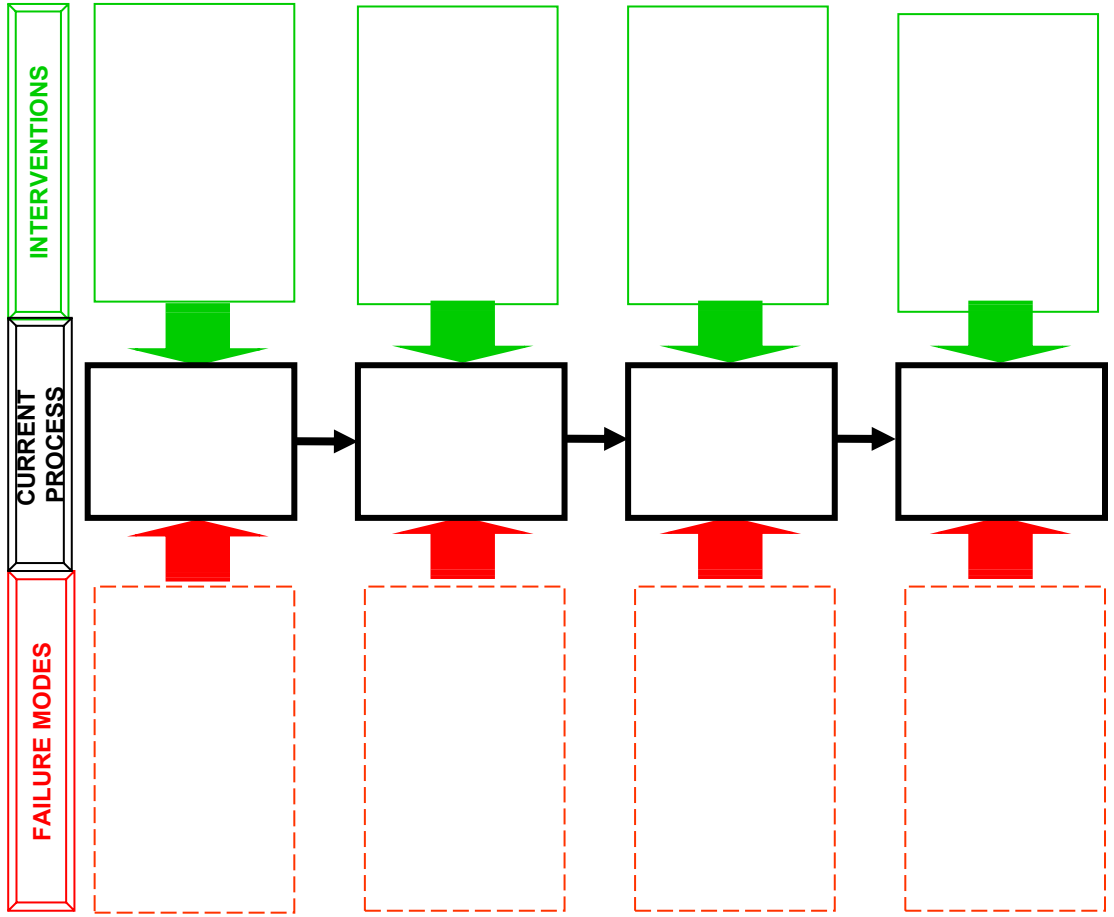
ALBERTA MEDICAL ASSOCIATION | ACTT Accelerating Change Transformation Team

Fishbone Diagram

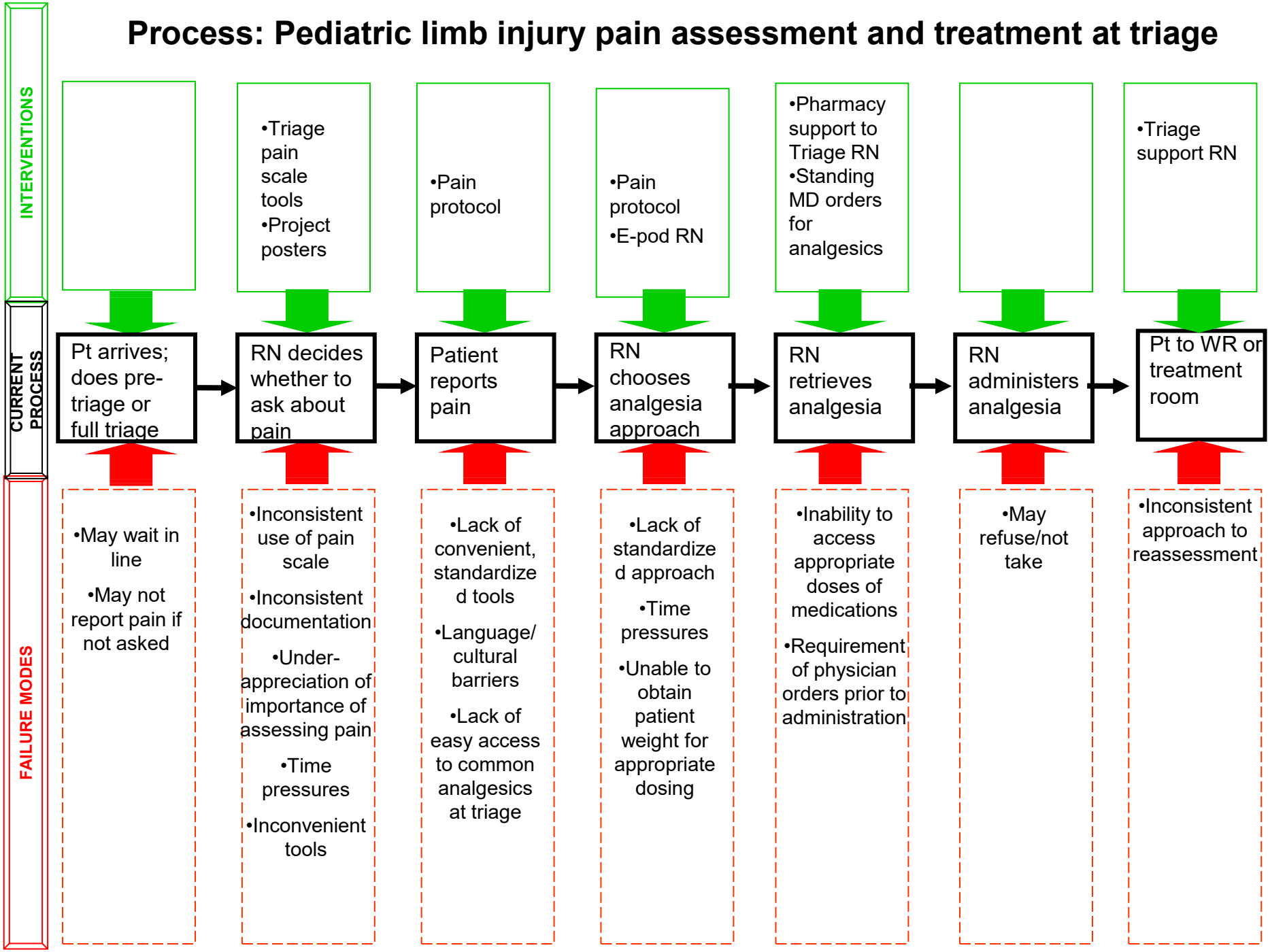


Simplified Process Map with FMEA

- Outlines steps in process
- Indicates potential failures
- Identifies potential solutions



Process: Pediatric limb injury pain assessment and treatment at triage



Setting Your Aim

Example:

We will increase the proportion of patients with limb injury who receive analgesic medication at triage from 32% to 40% within 6 months.

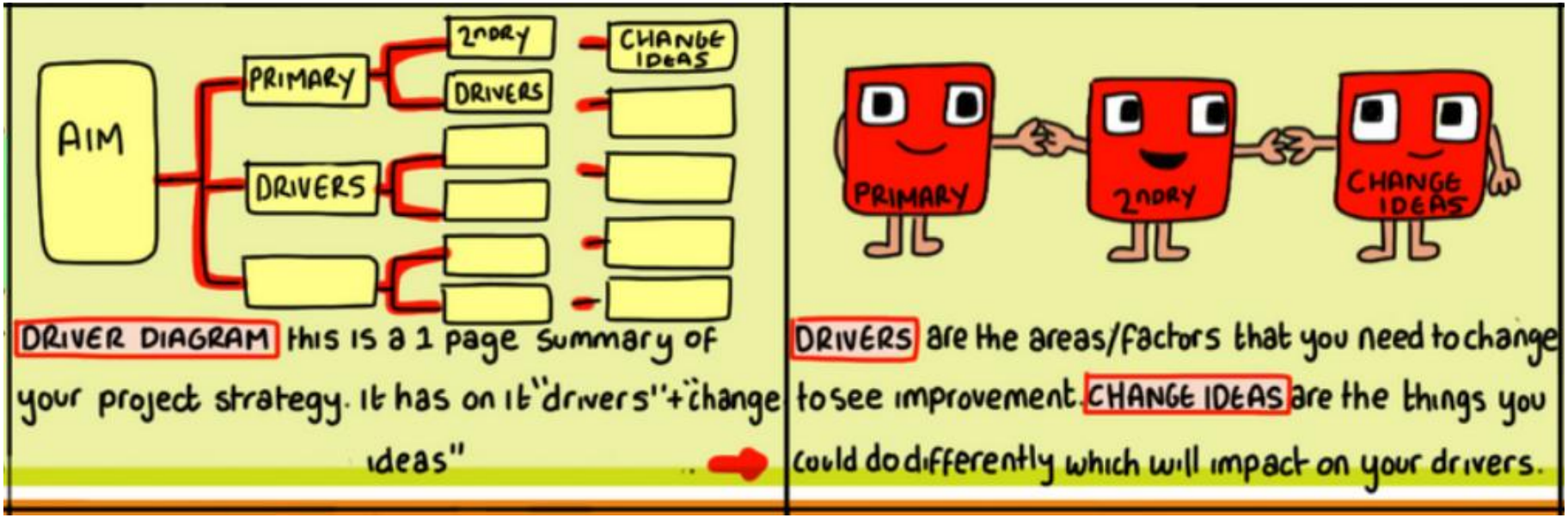
What is wrong with these aims?

- We will improve care of children with pain within 6 months.
- We will increase the proportion of patients with limb injury who receive analgesia by 50% within 6 months.

Return to your problem statement.

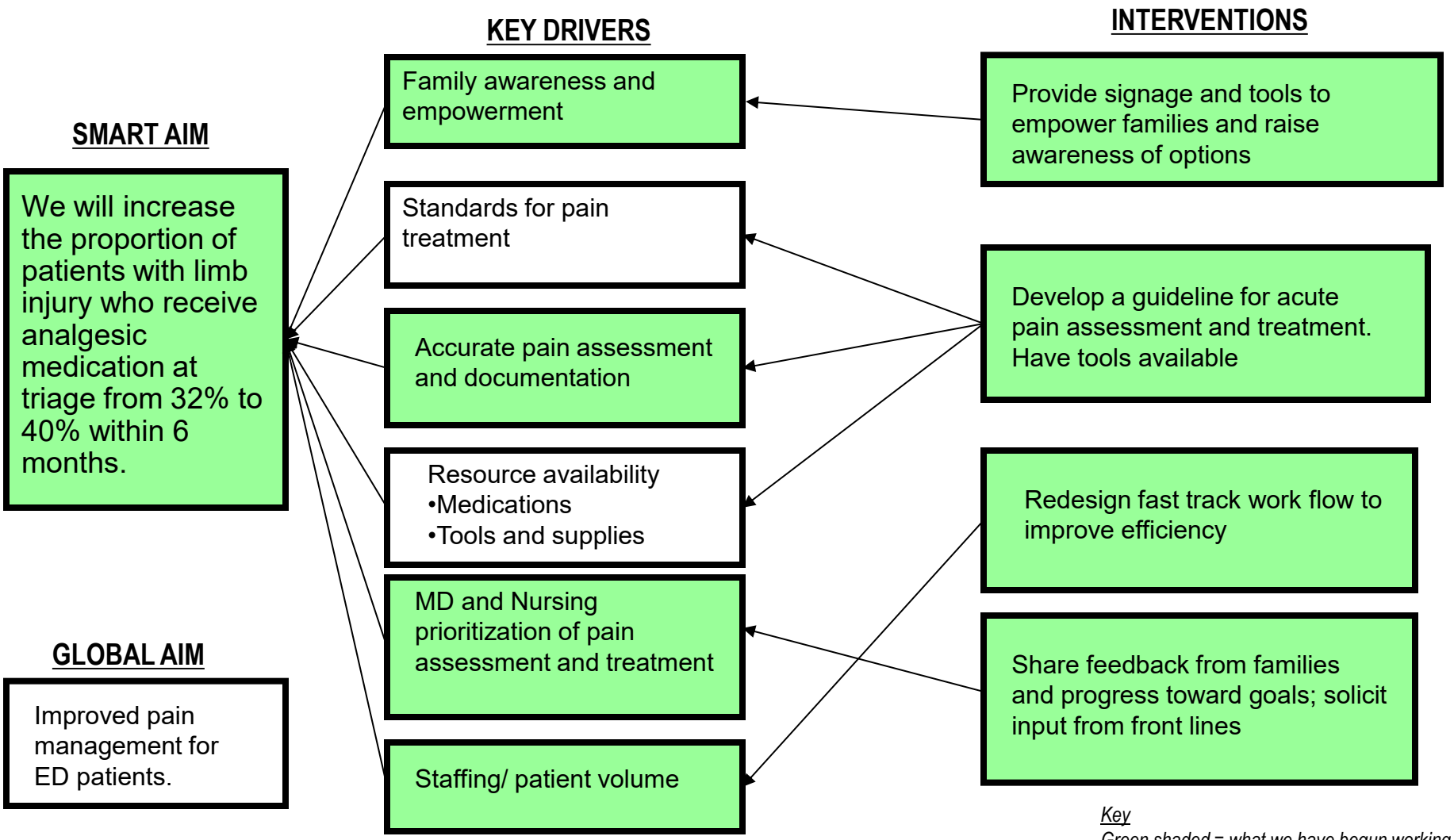
Write a SMART aim for your imaginary future QI project.

Planning the Change: Key Driver Diagrams



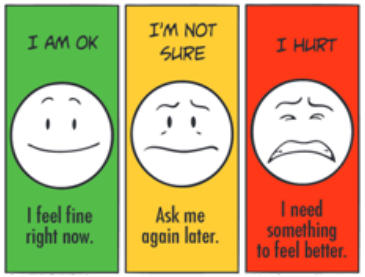
Source: The Illustrated Guide to Quality Improvement
by Sonia Sparkles, NHS Foundation Trust
https://qi.elft.nhs.uk/qi-illustrations/

KEY DRIVER DIAGRAM: Improving pain treatment



Key
Green shaded = what we have begun working on

How are you feeling?



Let's work together to reduce pain.

We can help by:

- helping kids rate their pain
- providing pain medicine
  - ask about no-needle options
- using comfort positions for procedures
- offering items on our comfort menu

Comfort Menu

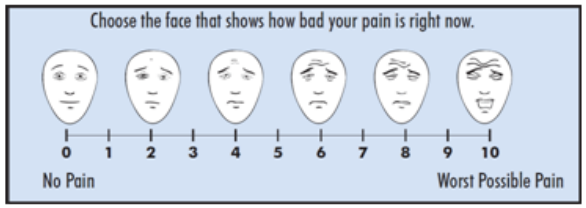
- ❑ Medicine for pain
- ❑ Numbing cream before needles
- ❑ Ice pack
- ❑ Warm blanket
- ❑ Wheelchair
- ❑ Splint
- ❑ Something to watch
- ❑ Something to play with

Kids can help by:

- talking to us - ask questions and let us know what we can do for you

Grown-ups can help by:

- letting us know if your child isn't comfortable
- providing distraction, reassurance, a soothing voice, or a loving touch
- ask about how to support your child during a procedure



Our commitment to comfort:

We'll do our best to promote comfort by helping to lessen pain and anxiety. Please let us know what we can do to help.

Alberta Children's Hospital

Alberta Health Services

Is your child having a needle?

Please ask if

Numbing Cream

(Maxilene® or Ametop®)

is right for your child.

Our goal is to use numbing cream

BEFORE ALL POKES

For IV starts & blood work

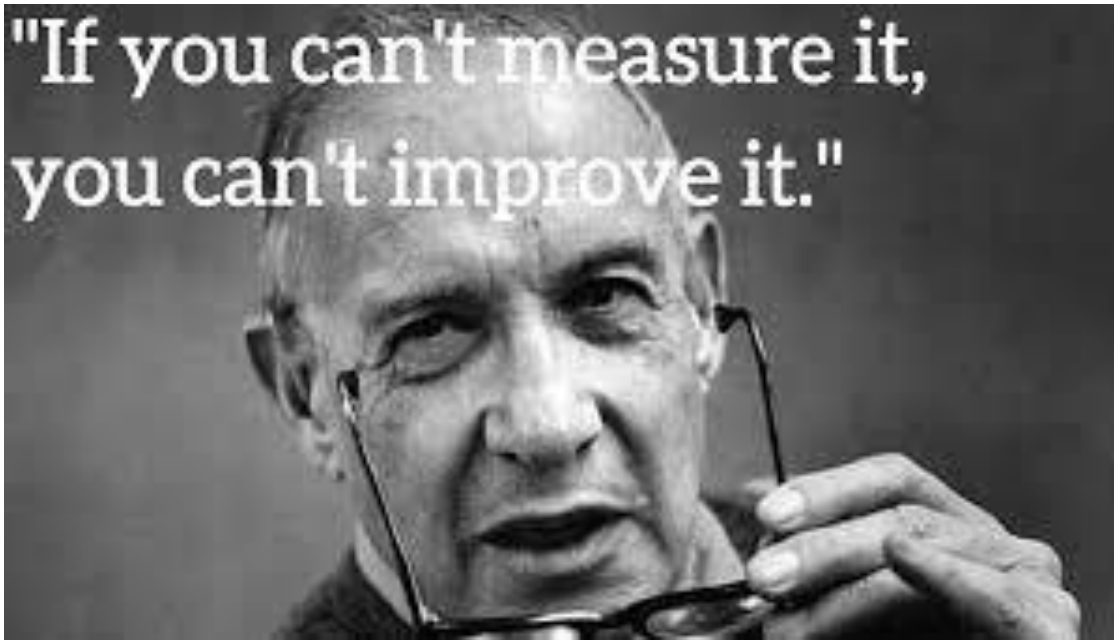
(as long as your child doesn't need their IV or blood work right away).

It takes **at least 30 minutes** to work.
If we forget, remind us early!

Alberta Health Services

AHS Commitment to Comfort©

Measuring Change



- *QI saying of uncertain attribution*

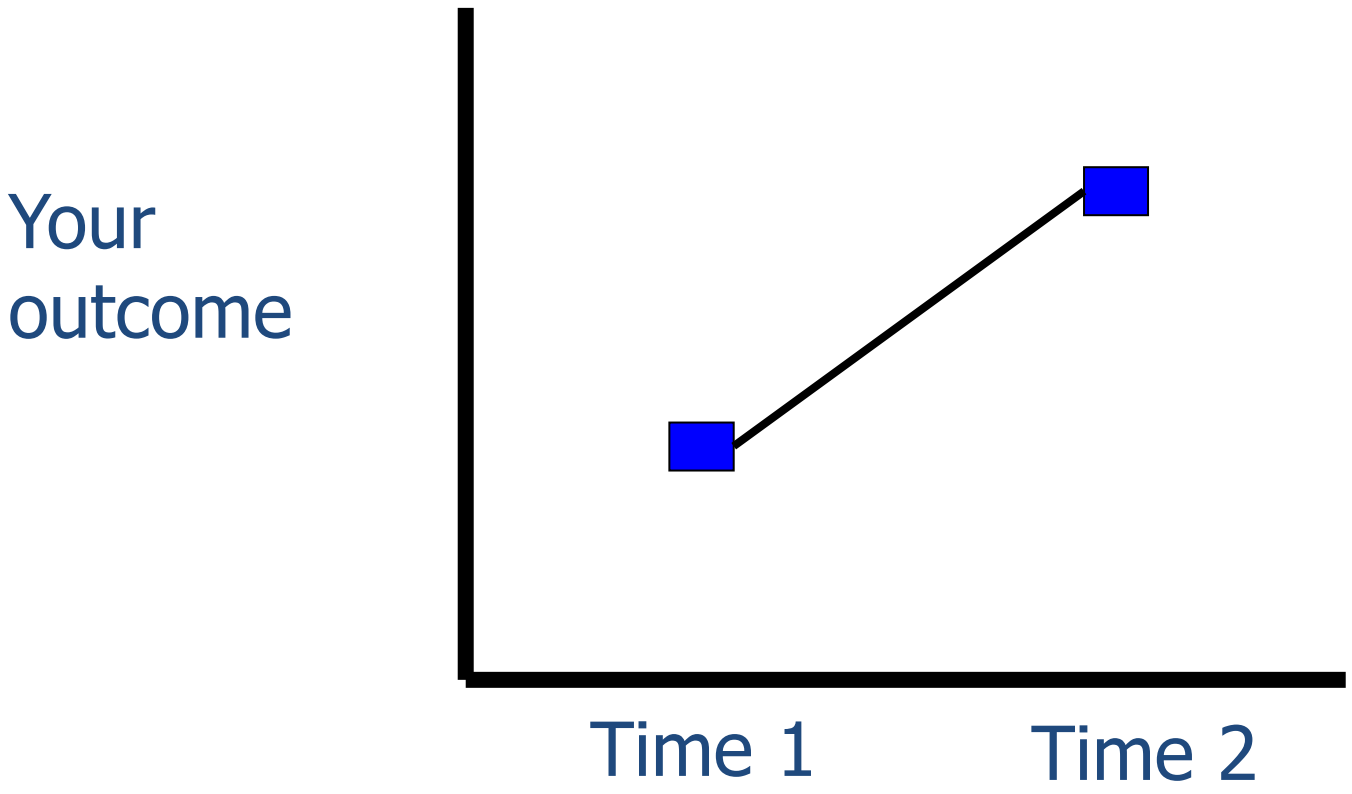
4 Types of Measures

- Outcome measures
  - Are changes leading to improvement of the end result?
  - Are we reducing pain with our pain management?
- Process measures
  - Are the parts and steps in the system functioning as planned?
  - Are we giving pain medication earlier?
- Structure measures
  - Do we have necessary structures in place?
  - Do we have an appropriate analgesia care guideline?

4 Types of Measures

- Balancing measures
  - Are changes designed to improve one part of the system causing new problems in other parts of the system
  - Can be structure, process, or outcome
  - *Are we increasing ED waiting time by adding pain treatment steps to the triage process?*

Before/After Studies



Did your project result in a change?

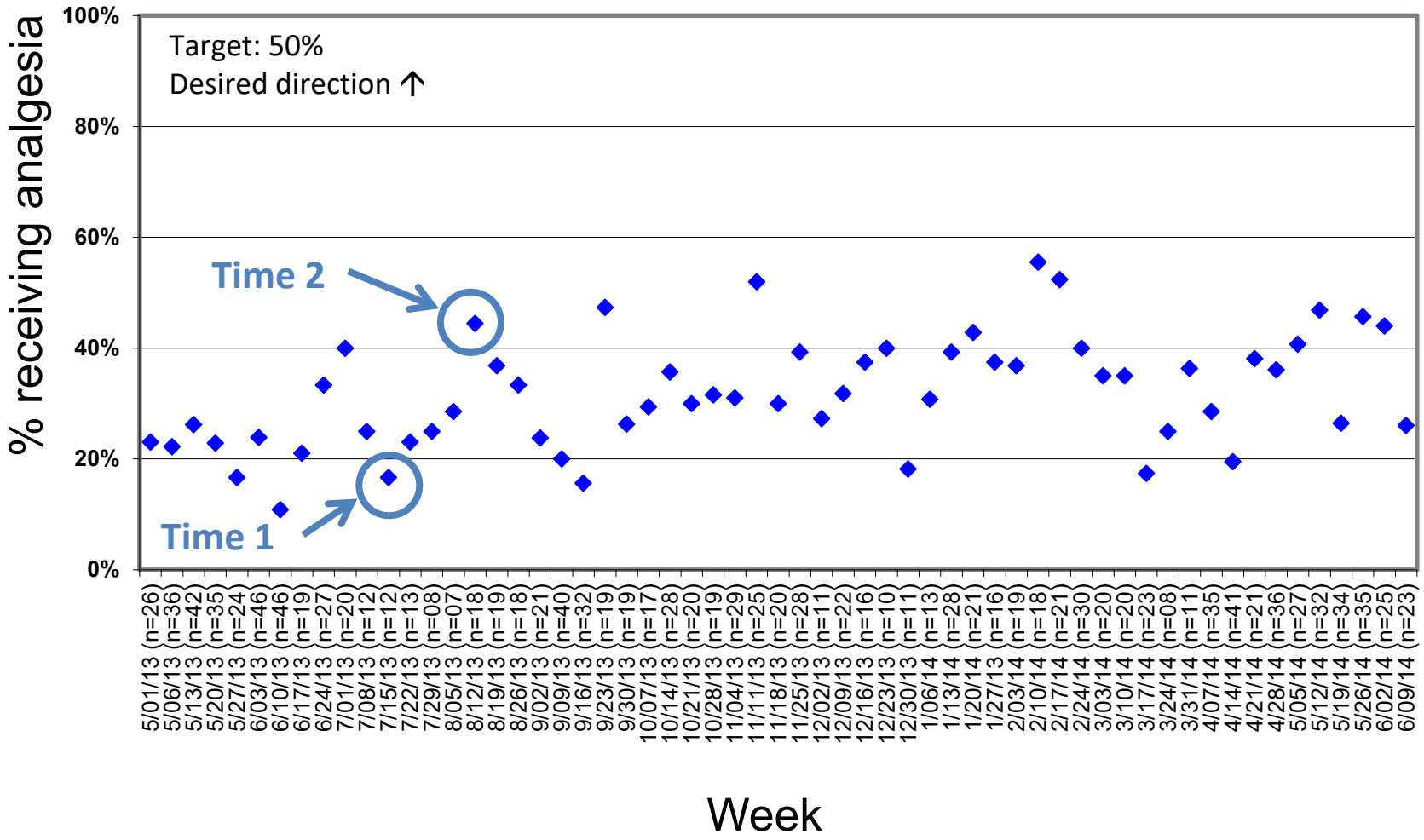
Pain study example

- Pain scale signs were created to determine whether this would result in more patients receiving analgesia during their ED visit
- In the week prior to the intervention, 16.6% met the target; one month after the intervention, 44.4% met the target
- Was the intervention a success?

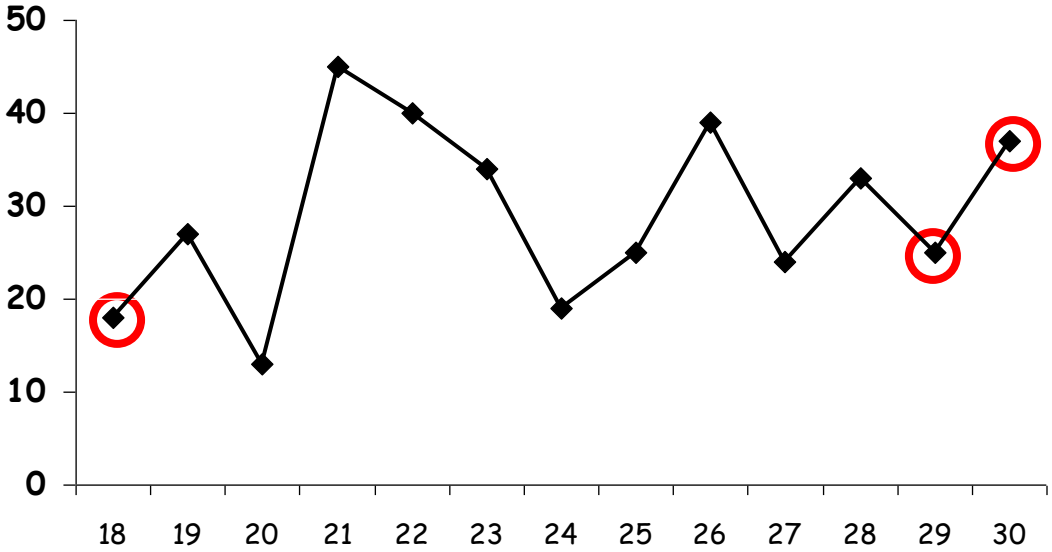
“Premature pizza party error”

- M. Siska, CCHMC

Proportion of patients receiving analgesia

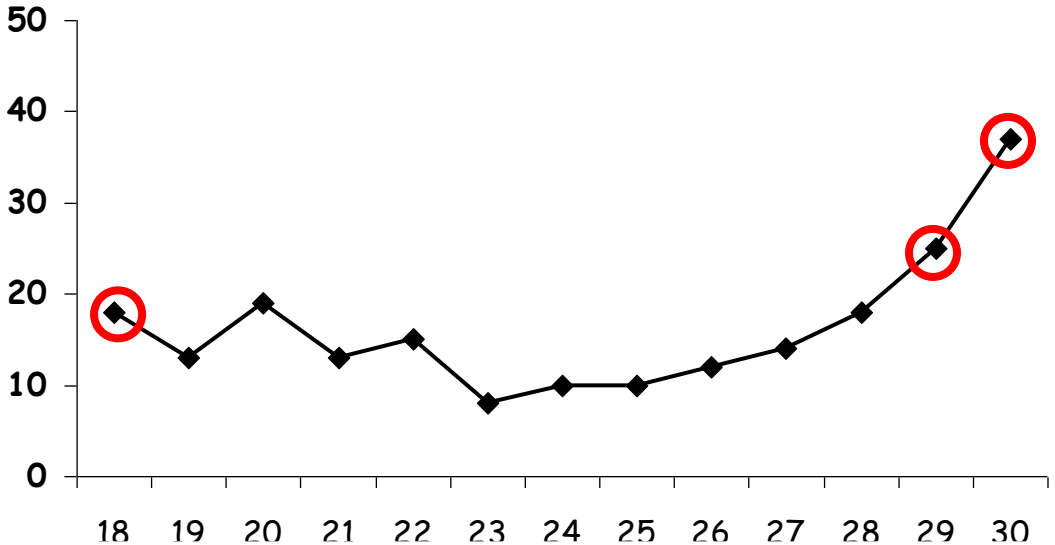


Data over time



What can you conclude here?

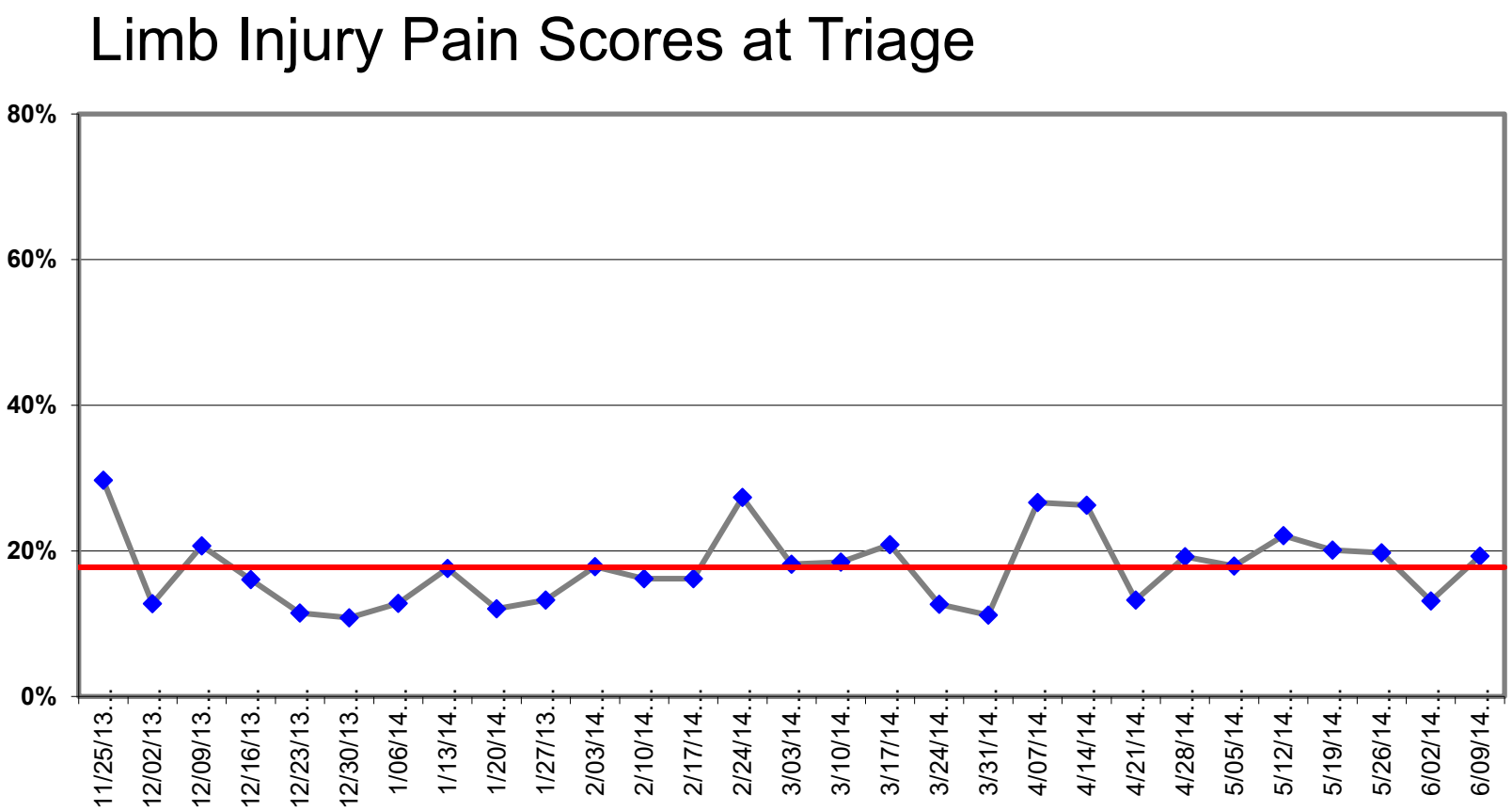
Or here?



Run Charts and Control Charts

- How do we know if variation is not random?
- How do we look at QI data and identify non-random changes, if monitoring in real time rather than using traditional statistical methods at the end of the project?

Run Chart


Limb Injury Pain Scores at Triage
80%
60%
40%
20%
0%
11/25/13...
12/02/13...
12/09/13...
12/16/13...
12/23/13...
12/30/13...
1/06/14...
1/13/14...
1/20/14...
1/27/13...
2/03/14...
2/10/14...
2/17/14...
2/24/14...
3/03/14...
3/10/14...
3/17/14...
3/24/14...
3/31/14...
4/07/14...
4/14/14...
4/21/14...
4/28/14...
5/05/14...
5/12/14...
5/19/14...
5/26/14...
6/02/14...
6/09/14...

Run Charts and Control Charts

- Statistical Process Control introduced by Walter Shewhart at Bell Labs in 1920's
- Described "common cause" and "special cause" variation
  - Common cause is variation due to chance
  - Special cause is variation beyond what is expected by chance
- Allows surveillance for non-random change

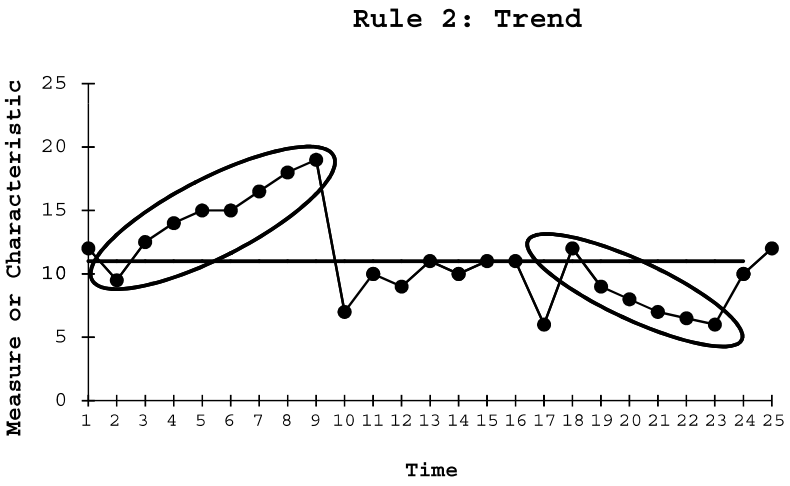
Types of variation

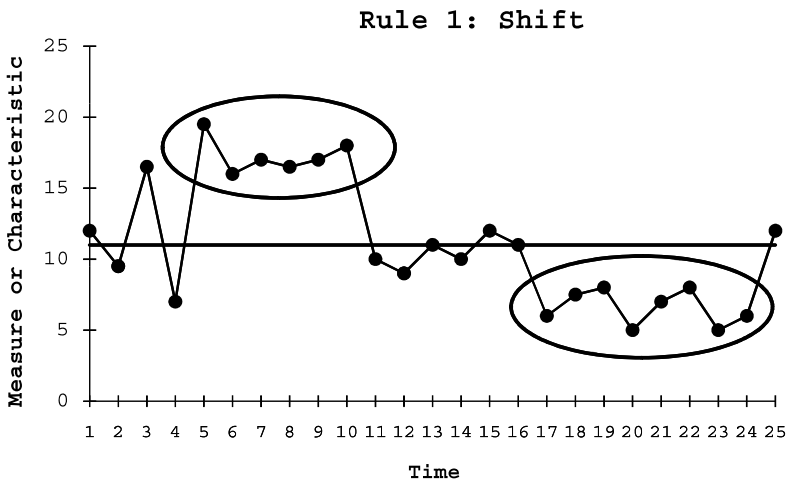
- Common Cause Variation
  - Random
  - Not explainable
  - Do not waste time investigating
- Special Cause Variation
  - Non-random
  - May be explained
  - Consider investigating

Special Causes

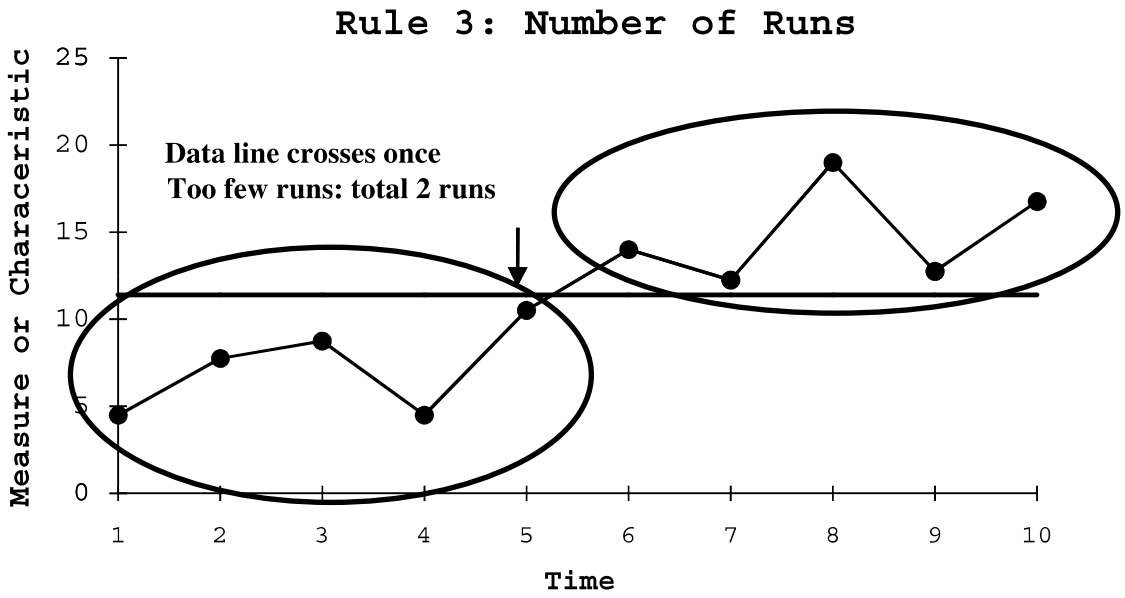
Shift	Trend	Run	Astronomical
• 6 or more consecutive points either *all* above or below the median	• 5 or more consecutive points all going up or all going down	• A series of points in a row on one side of the median • May have too many or too few for number of data points	• Not a statistical observation • Logically obvious that a data point is unlike any of the others

Run Charts


Rule 2: Trend
Measure or Characteristic
0
5
10
15
20
25
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Time

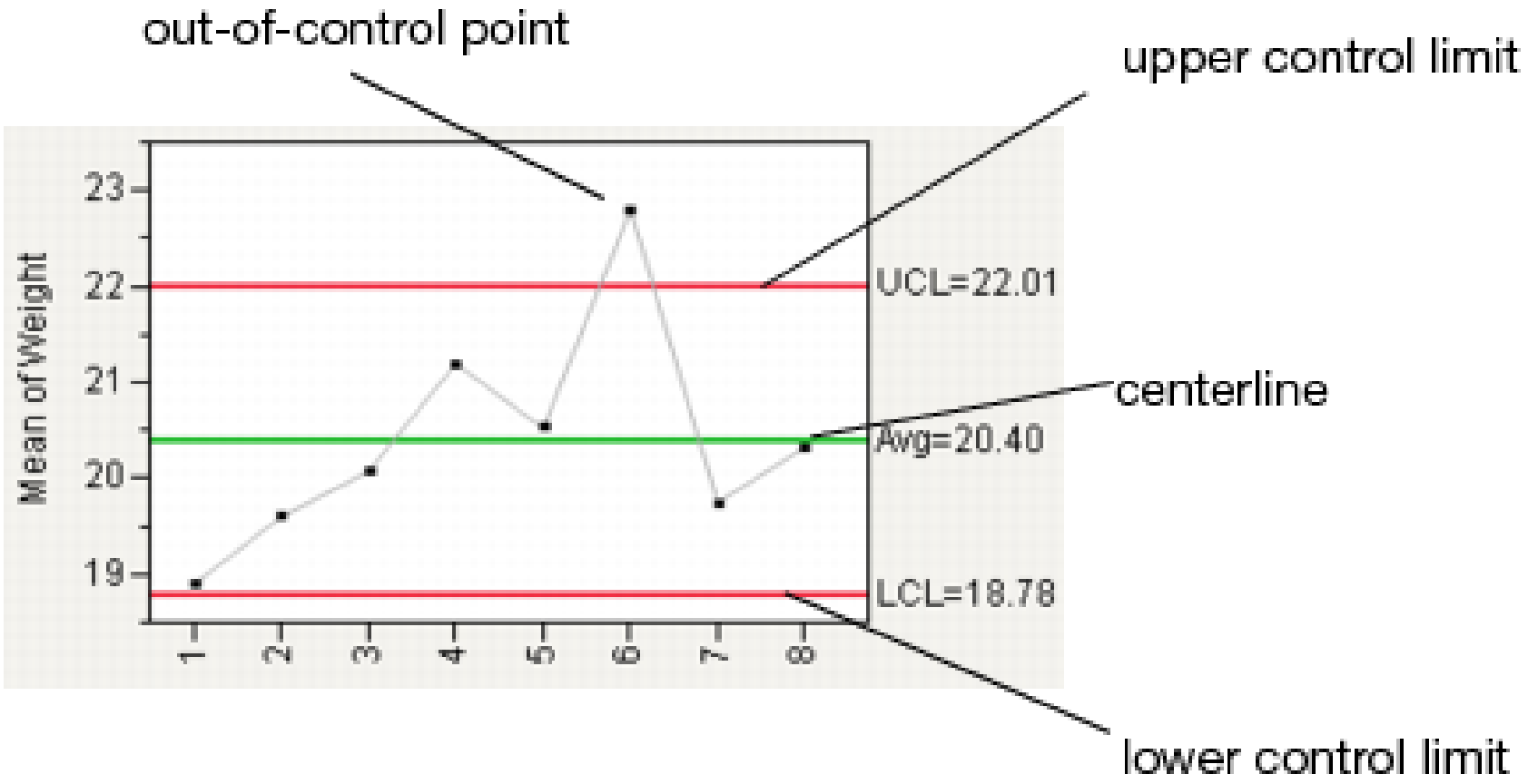

Rule 1: Shift
Measure or Characteristic
0
5
10
15
20
25
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Time

Run Charts

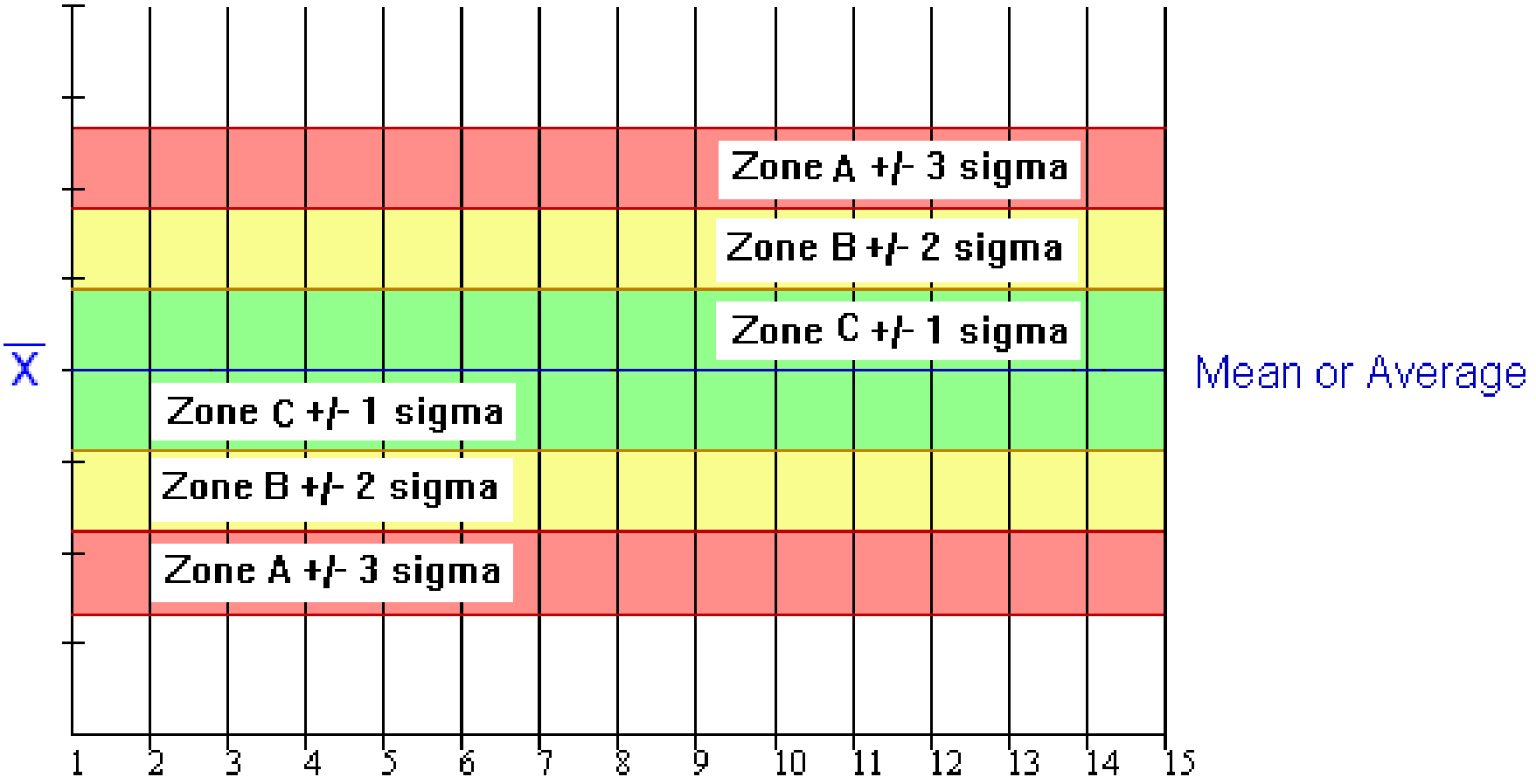


- Need to refer to a table for expected number of runs for number of data points

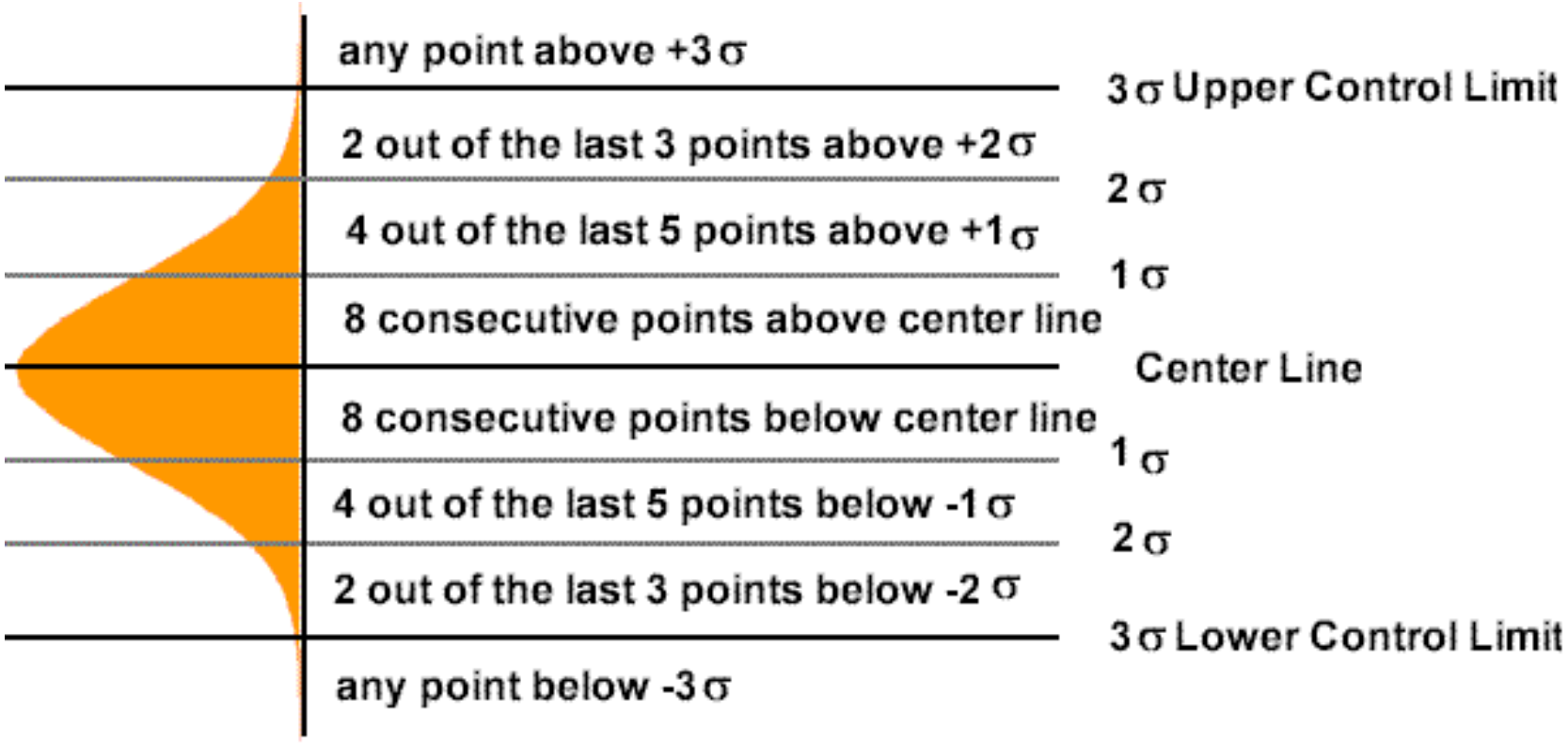
Control Charts



Control Chart Zones

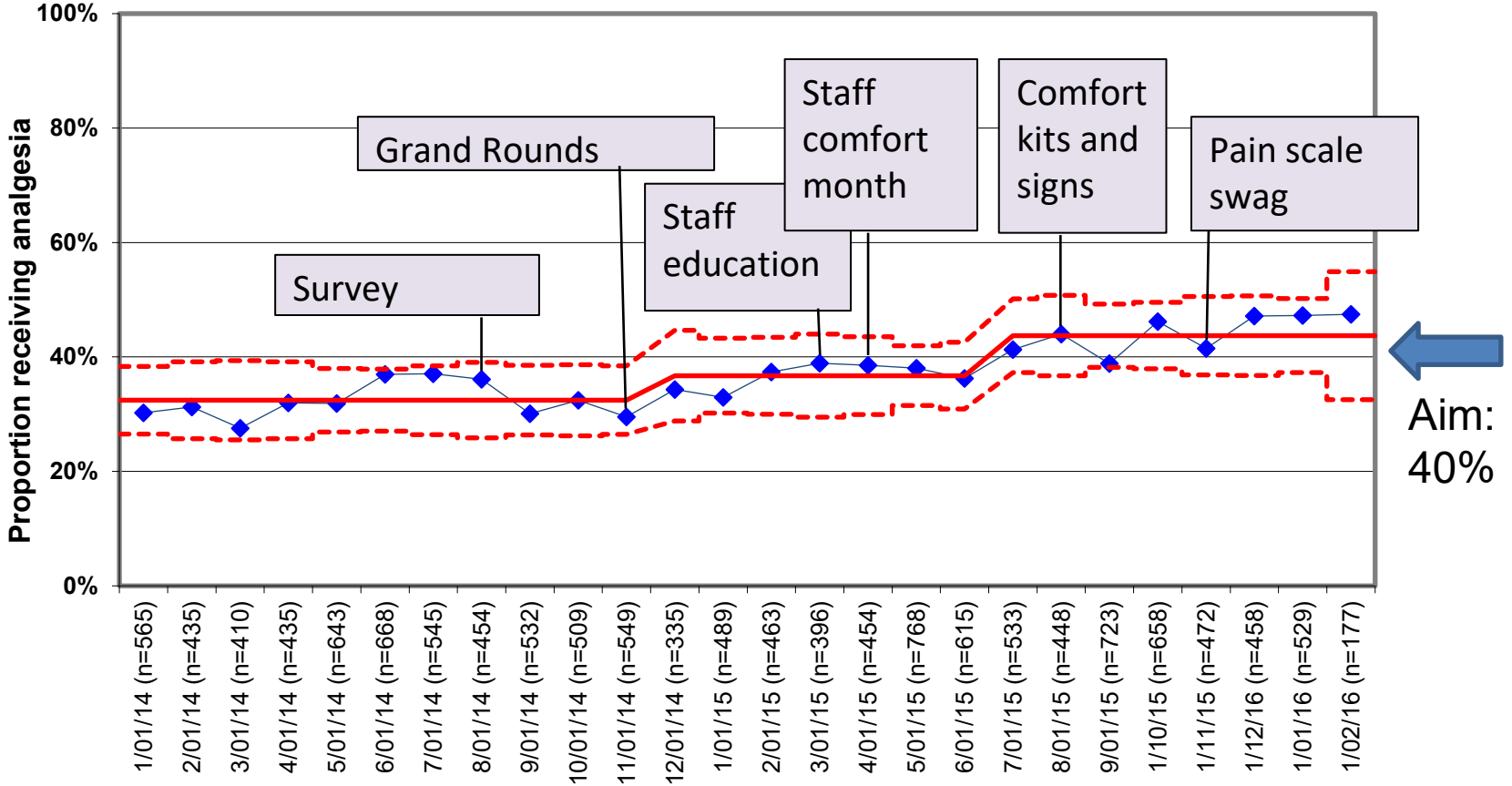


SPC: “Special Causes”



6 consecutive points trending up or down
14 consecutive points alternating up and down

Children 4-17 with limb injury receiving ≥1 dose analgesia



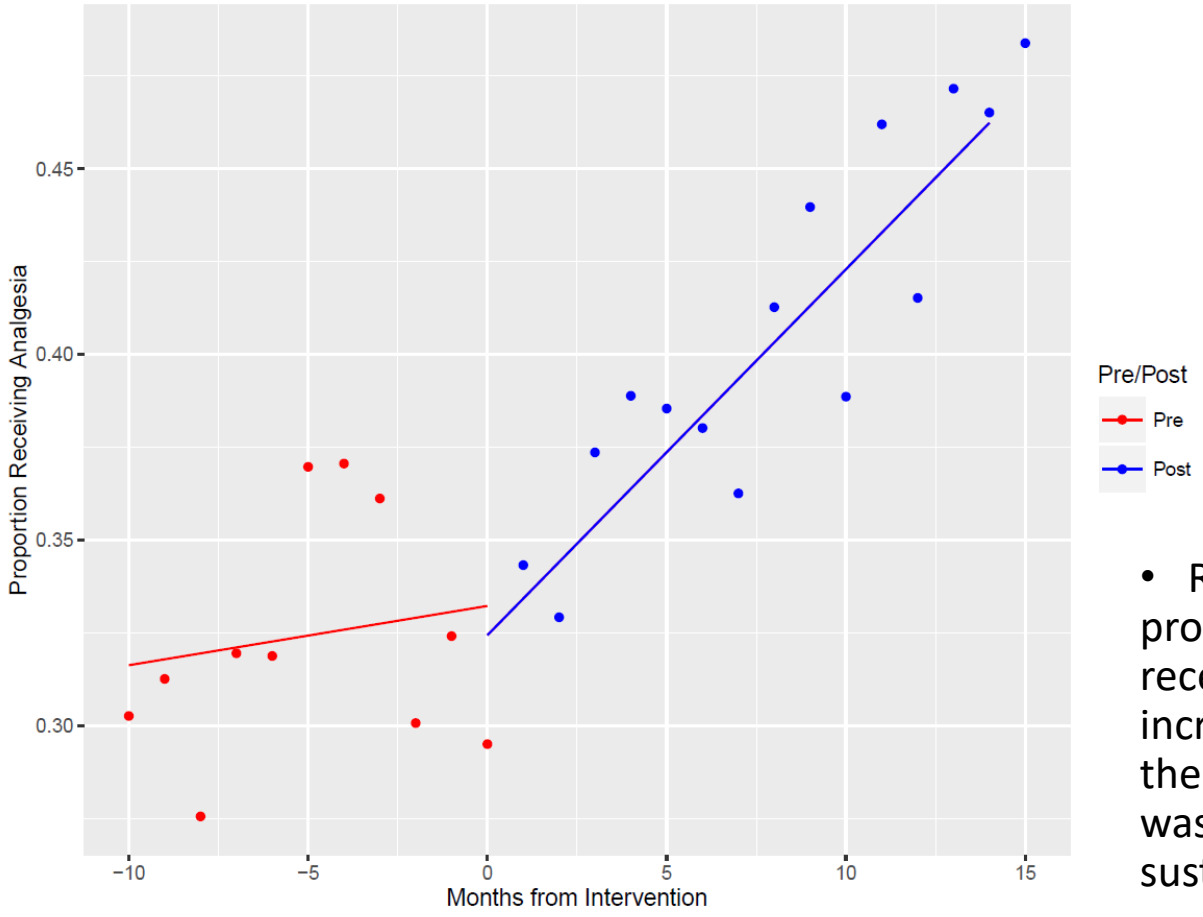
Increase from 32% to 44%

Combining Control Charts Analysis with Statistical Analysis

- Remember primary purpose is to reach the aim
- Significance of change is of secondary importance
  - May matter if deciding whether to sustain and spread
- Interrupted time series evaluates change over time
- Measures slope and intercept of line before and after designated time point
- Accounts for underlying trends

Kontopantelis E et al Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis *BMJ* 2015;350:h2750

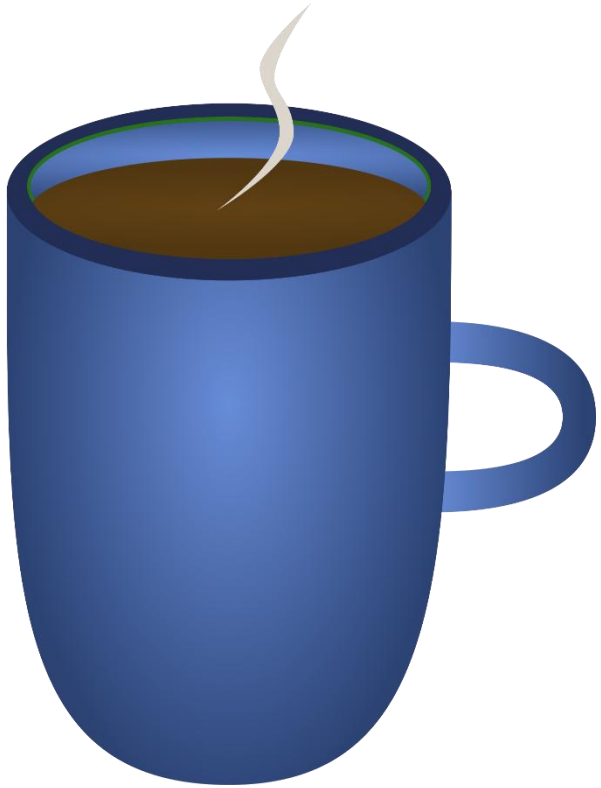
Interrupted Time Series



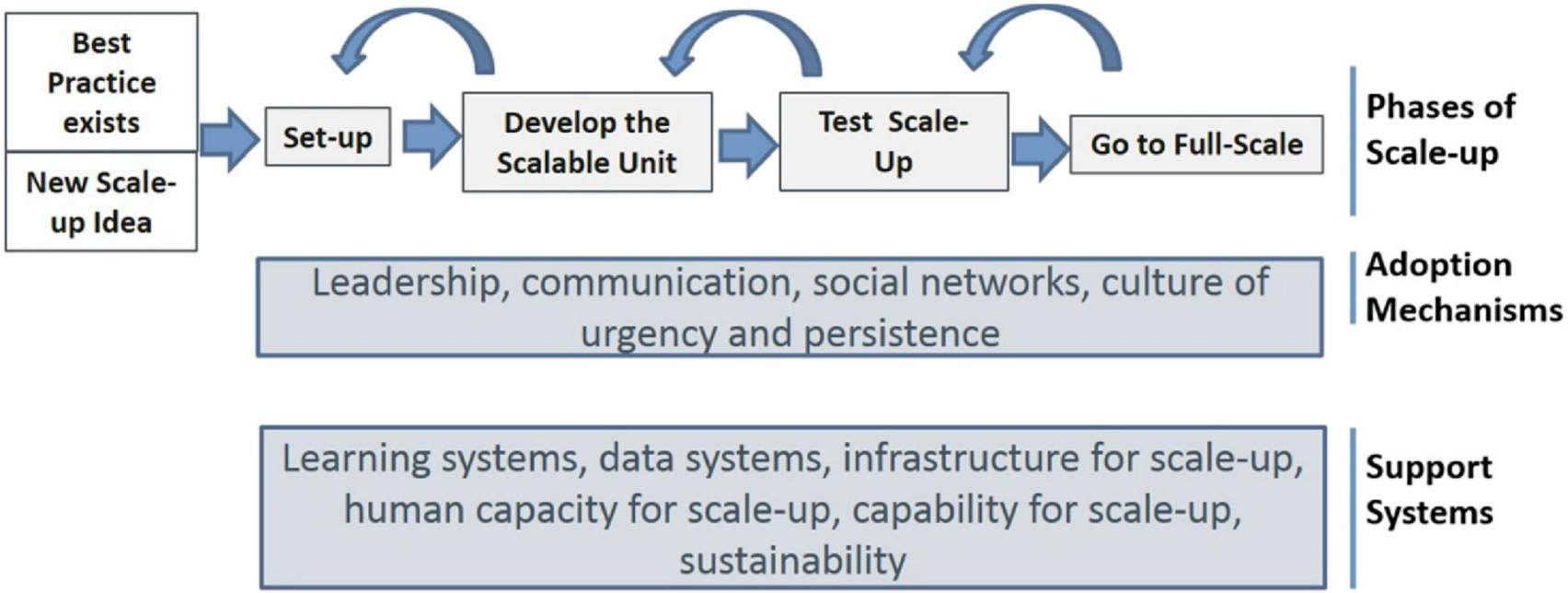
- Rate of change of the proportion of patents receiving analgesia in the ED increased at the beginning of the improvement phase and was sustained through the sustainability phase ($p < 0.05$).

Sustainability Planning

- **M**easurement
  - What measurement will continue?
- **O**wnership
  - Who will be in charge?
- **C**ommunication and Training
  - How will people be kept informed?
- **H**ardwiring Change
  - How can the right actions be made easy?
- **A**ssessment of Workload
  - How will impact on workload be managed?



A Framework for Spread



IHI, 2006

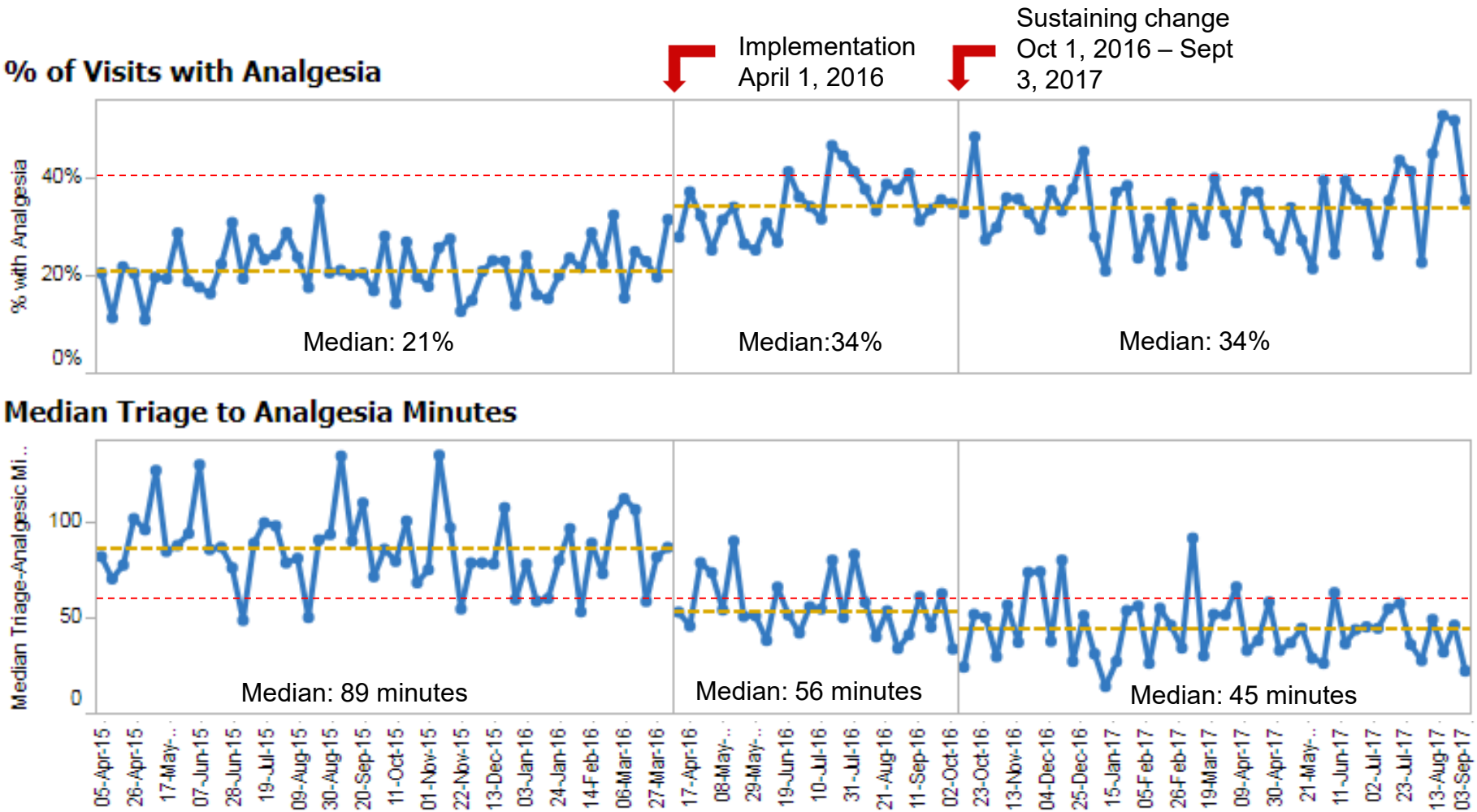
Test Scale-Up

- Aim: To form a quality improvement collaborative among the 3 Calgary general ED's to :
    1. Improve the proportion of children receiving analgesia for limb injuries from 23% to 40%
    2. Reduce the median time to analgesia from 89 minutes to < 60 minutes

Test Scale-Up

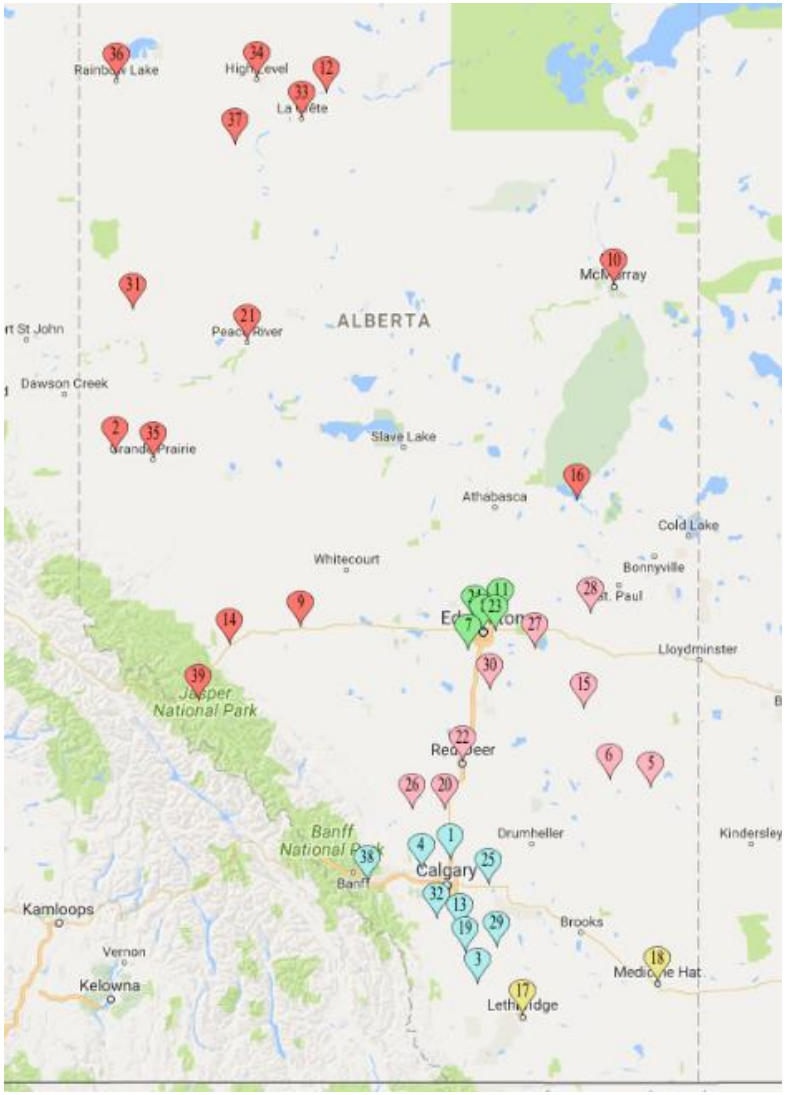
- Interventions
  - Quality improvement collaborative (QIC)
  - Project leads taught QI skills, shared resources
  - Interdisciplinary teams at each site
    - Physicians, nurses, orthopedic technicians
  - Each site developed key driver diagrams, set aims, planned tests of change (PDSA cycles)
  - Monthly QIC meetings to share learnings

Results


% of Visits with Analgesia
Implementation
April 1, 2016
Sustaining change
Oct 1, 2016 – Sept
3, 2017
% with Analgesia
40%
20%
0%
Median: 21%
Median:34%
Median: 34%
Median Triage to Analgesia Minutes
Median Triage-Analgesic Mi...
100
50
0
Median: 89 minutes
Median: 56 minutes
Median: 45 minutes
05-Apr-15
26-Apr-15
17-May-...
07-Jun-15
28-Jun-15
19-Jul-15
09-Aug-15
30-Aug-15
20-Sep-15
11-Oct-15
01-Nov-15
22-Nov-15
13-Dec-15
03-Jan-16
24-Jan-16
14-Feb-16
06-Mar-16
27-Mar-16
17-Apr-16
08-May-...
29-May-...
19-Jun-16
10-Jul-16
31-Jul-16
21-Aug-16
11-Sep-16
02-Oct-16
23-Oct-16
13-Nov-16
04-Dec-16
25-Dec-16
15-Jan-17
05-Feb-17
26-Feb-17
19-Mar-17
09-Apr-17
30-Apr-17
21-May-...
11-Jun-17
02-Jul-17
23-Jul-17
13-Aug-17
03-Sep-17

Full Scale

- 97 ED's invited, 36 accepted
  - All geographic zones
  - 40% of pediatric ED visits in Alberta



Full Scale

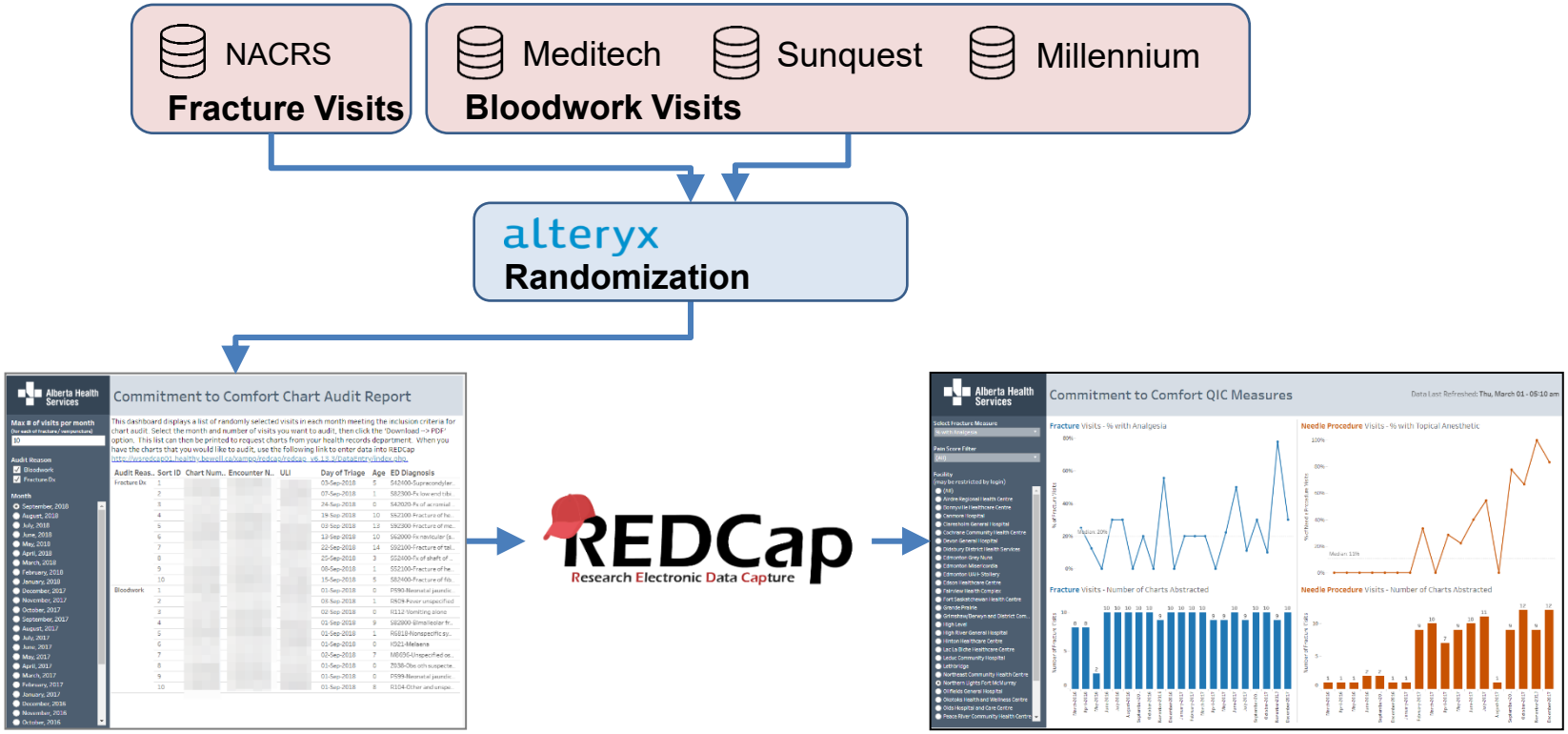
Process measures

- For patients 0-12 years of age undergoing phlebotomy
  - Proportion receiving topical anesthetic cream
- For patients 0-16 years of age with a fracture
  - Proportion with a documented pain score
  - Proportion who receive analgesic medication
  - Median time to analgesia

Balancing measures

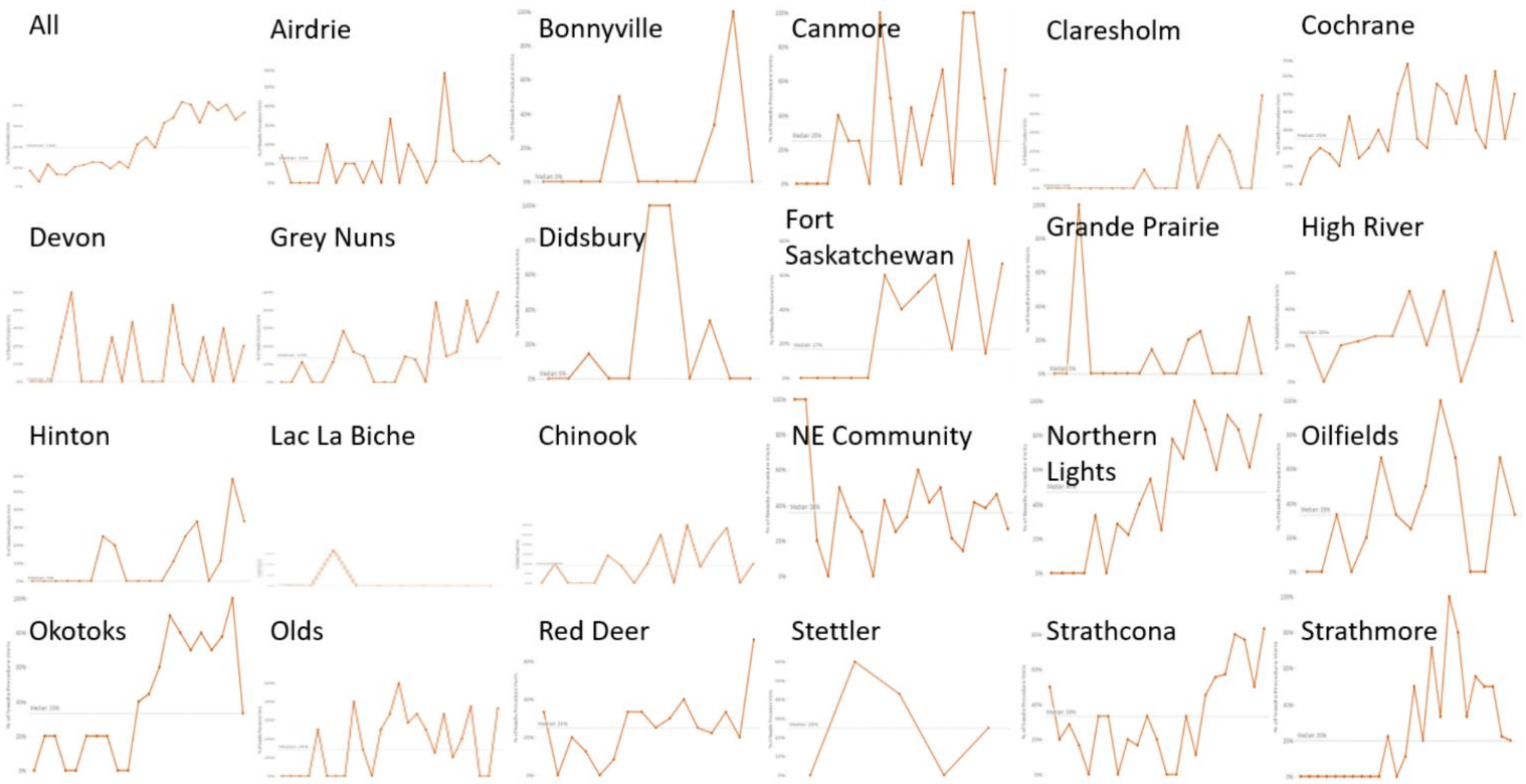
- Length of stay, opioid use

Methods

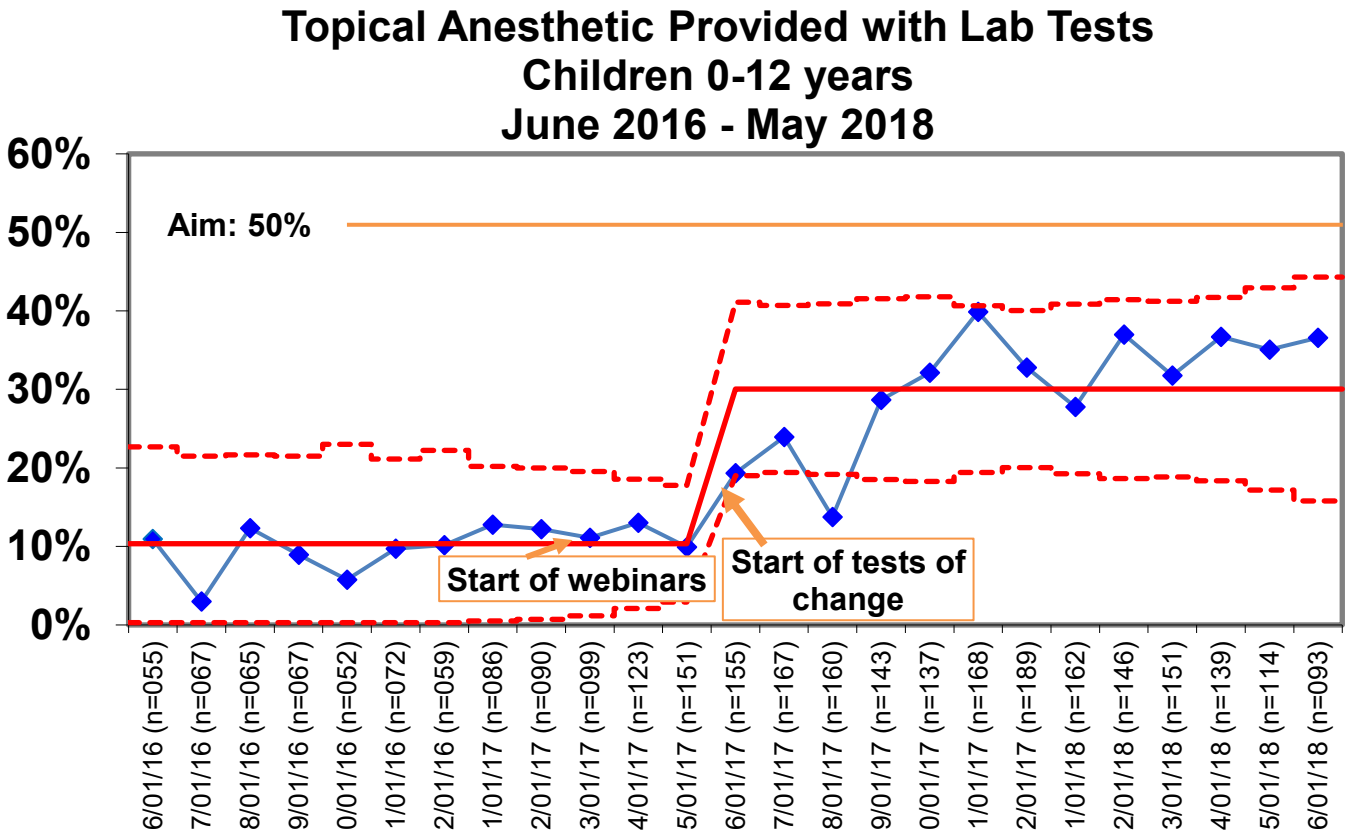

NACRS
Fracture Visits
Meditech
Sunquest
Millennium
Bloodwork Visits
alteryx
Randomization
Alberta Health Services
Commitment to Comfort Chart Audit Report
REDCap
Research Electronic Data Capture
Alberta Health Services
Commitment to Comfort QIC Measures

Results

Small Multiples: Topical Anesthetic



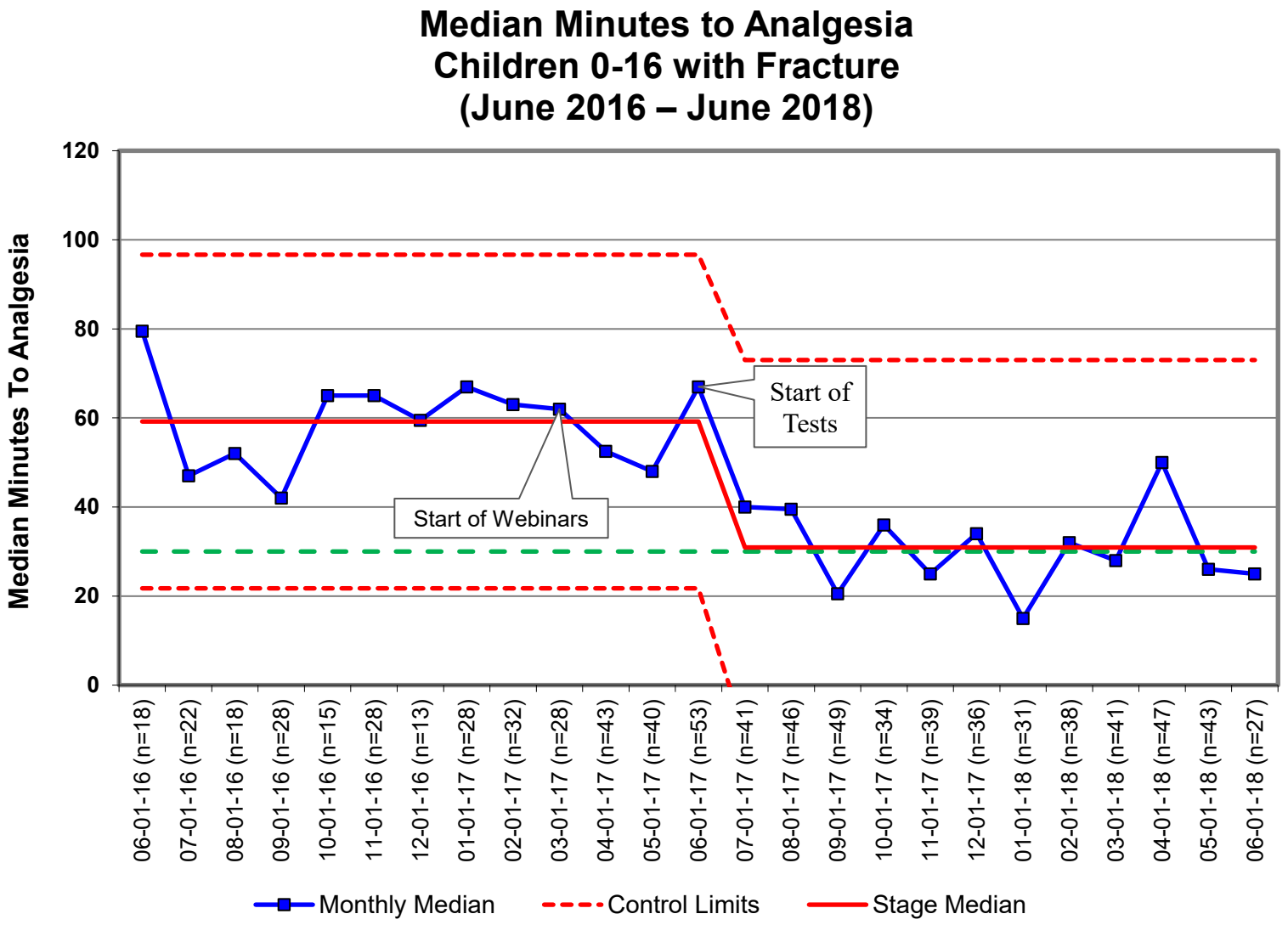
Results



↑ from 11% to 30%
Special cause+

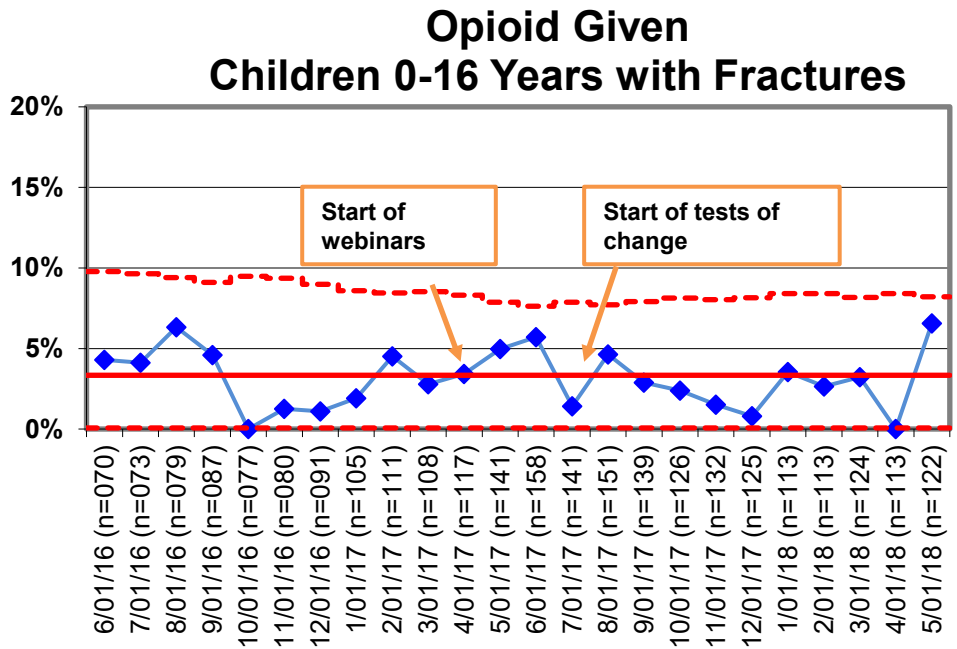
ITS $p < 0.001$ jump
$p < 0.05$ slope

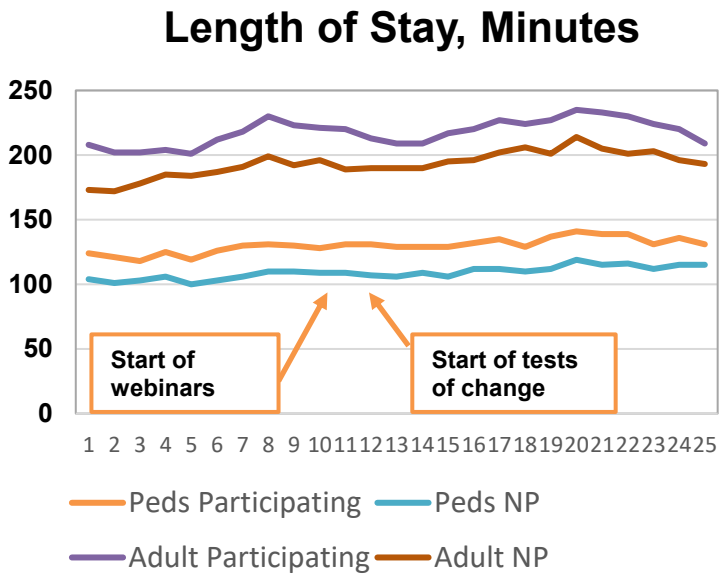
N = 2910


Median Minutes to Analgesia
Children 0-16 with Fracture
(June 2016 – June 2018)
Median Minutes To Analgesia
120
100
80
60
40
20
0
Start of Tests
Start of Webinars
06-01-16 (n=18)
07-01-16 (n=22)
08-01-16 (n=18)
09-01-16 (n=28)
10-01-16 (n=15)
11-01-16 (n=28)
12-01-16 (n=13)
01-01-17 (n=28)
02-01-17 (n=32)
03-01-17 (n=28)
04-01-17 (n=43)
05-01-17 (n=40)
06-01-17 (n=53)
07-01-17 (n=41)
08-01-17 (n=46)
09-01-17 (n=49)
10-01-17 (n=34)
11-01-17 (n=39)
12-01-17 (n=36)
01-01-18 (n=31)
02-01-18 (n=38)
03-01-18 (n=41)
04-01-18 (n=47)
05-01-18 (n=43)
06-01-18 (n=27)
Monthly Median
Control Limits
Stage Median

Results

Balancing Measures





SQUIRE 2.0 Guidelines

- Developed in 2008, updated in 2015, by a consensus panel of QI publication experts
- Gives authors a framework upon which to structure a QI manuscript
- The same framework can also be instrumental in project design
- Goal is to support high-quality writing about improvement efforts

http://squire-statement.org

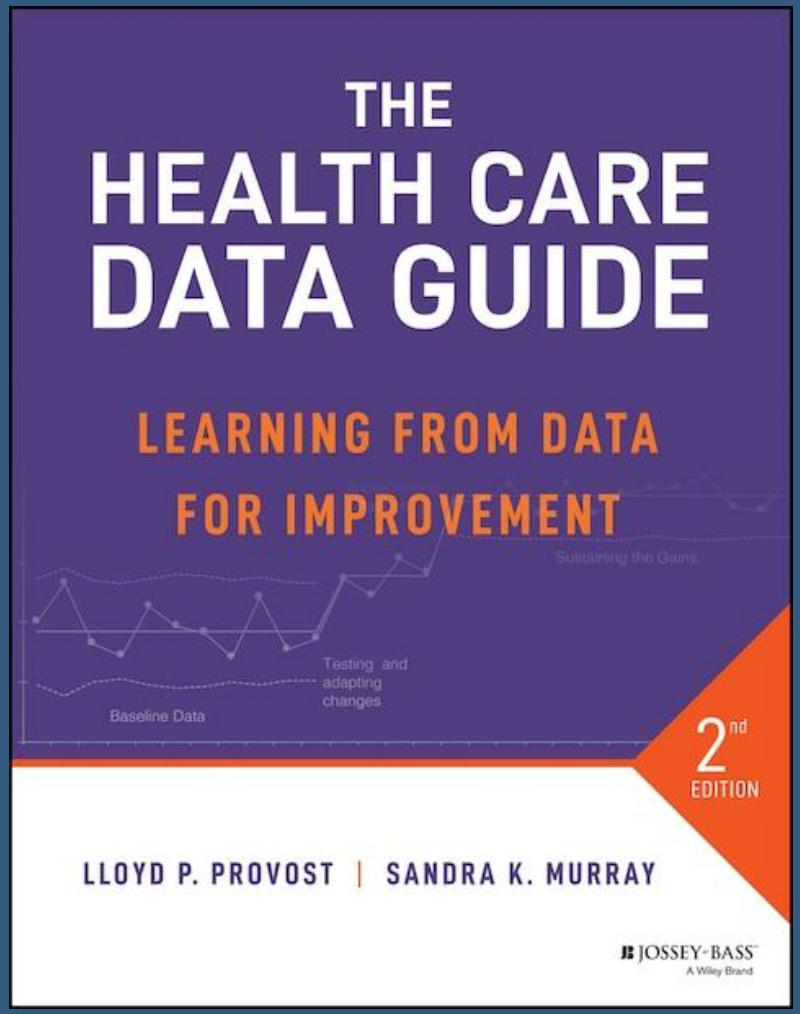
SQUIRE 2.0 Guidelines

Title and Abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
2. Abstract	a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions
Introduction	***Why did you start?***
3. Problem Description	Nature and significance of the local problem
4. Available Knowledge	Summary of what is currently known about the problem, including relevant previous studies
5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem, any reasons or assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work
6. Specific Aims	Purpose of the project and of this report
Methods	***What did you do?***
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work

Summary

- Quality improvement is a process of identifying and measuring a problem, setting an improvement aim, and testing and learning from multiple changes, knowing whether progress is being made, and striving to reach the aim
- Always be clear on your primary purpose
- QI projects measure progress over time
- Methods exist to guide project design, sustaining change, and share learnings

Questions?



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