Mechanics of Improvement

Evans Center for Implementation
& Improvement Sciences

Quality & Patient Safety,
Department of Medicine

4
Studying & Acting on Results

What Are We Talking About?

- Quality Improvement
  - A framework to systematically improve healthcare delivery[1]
- Improvement Science
  - Rigorous measurement of outcomes associated with efforts to improve care delivery
- Implementation Science
  - Scientific study of optimal strategies to promote the systematic uptake of research into practice to improve the quality or effectiveness of health services

Group Discussion

Improving Healthcare Delivery

1. AHRQ. Practice facilitation handbook. https://www.ahrq.gov/professionals/prevention-chronic-care/improve/system/pfhandbook/mod4.html

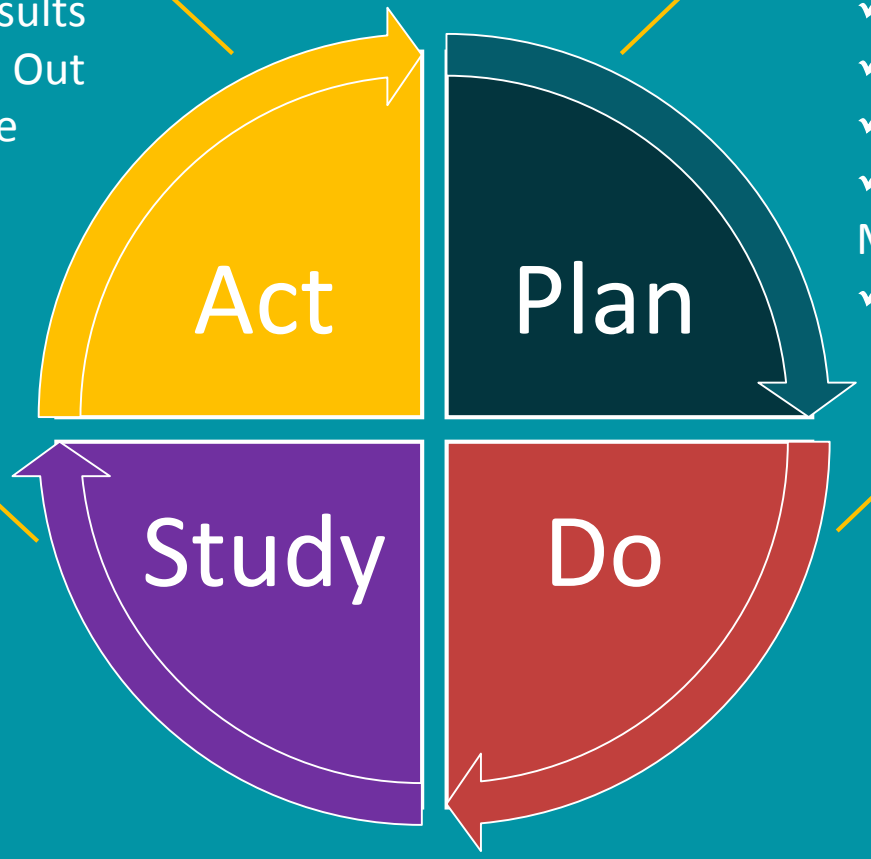
Past Sessions

Applying results

Iterative PDSA cycles – Disseminating Results
Planning for Spread – Scaling Up, Scaling Out
Planning for sustainability – Maintenance
Implications for Future Research

Identifying the potential for improvement

- ✓ Engaging Stakeholders
- ✓ Aims Statement – Research Objectives
- ✓ Identifying Best Practices
- ✓ Process Mapping – Conceptually Modeling
- ✓ Measuring Effectiveness & Processes



Measuring results

Study Design
Measuring Effectiveness, Implementation
Lessons Learned – Measuring Barriers/Facilitators

Effecting change

- ✓ Organizing Change – Implementation Strategies
- ✓ Data Collection
- ✓ Designing Small Scale Tests – Study Designs

Session 4 Objectives

1. Discuss trade-offs when selecting a study design
2. Consider different approaches to acting on measured results
3. Discuss planning for sustainability

Example: Implementing a new protocol for severe alcohol withdrawal in the MICU

Switching from
'Benzo + Phenobarb'
protocol

'Phenobarb+non-Benzo adjuvants'
protocol

Study Aims:

1. Determine whether new protocol is non-inferior to old protocol in rates of mechanical ventilator use, length of stay
2. Improve feasibility, acceptability, adoption of protocol use

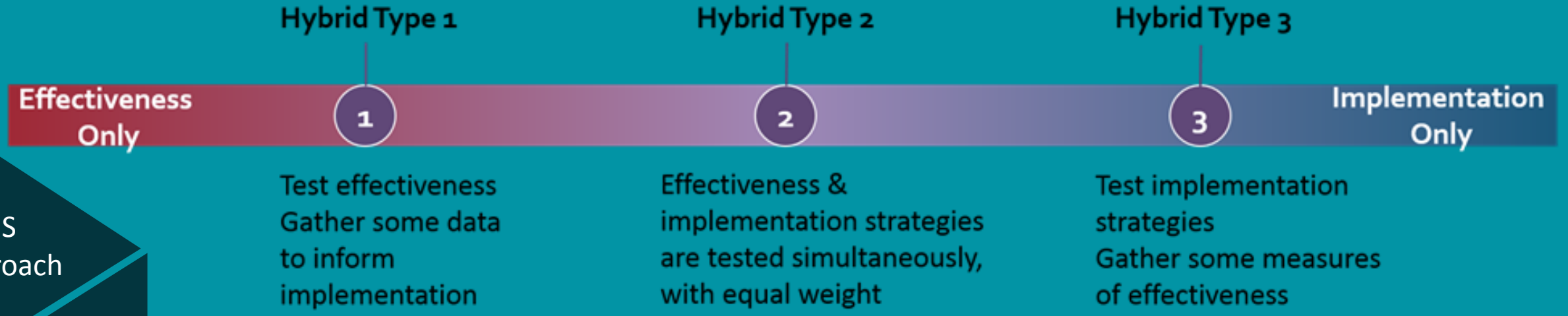
IIS Approach

Choosing a Conceptual Framework

Intervention	Implementation Strategies	Outcomes		
		Implementation	**Service**	**Client**
Evidence - Informed Practice: • 'Phenobarb + non-Benzo adjuvants' protocol	**BMC MICU Setting** • Multi-stakeholder group to redesign protocol • New order set • Trainings: 1:1, small group • Emails notifications of protocol change	• **Acceptability** of revised protocol format, clinical decision-making points, meds • **Adoption/**uptake of protocol • **Feasibility/**self-efficacy for completing protocol • **Fidelity**/adherence to protocol • **Sustainability**/ continued use of protocol	**Effectiveness** • Rates of mechanical intubation • Average length of stay	**Symptomology** • Average days in restraints • Average days 1:1 sitter was required • Seizure rates during MICU stay

Selecting a Study Design – *a few guiding questions*

1. Do you want to measure <u>effectiveness</u> of an intervention & evaluate implementation strategies?
   - ➢ No! OK, Which part are you interested in?
     - Intervention alone = efficacy or effectiveness, BUT NOT IMPLEMENTATION
     - Implementation strategy alone = Implementation, BUT not effectiveness
   - ➢ Yes! Consider a hybrid approach



IIS Approach

Tao of Study Design

More Effectiveness Outcomes

More Causal Inference

More Feasible

Individual patient RCT

Cluster randomization

Non-randomized, quasi-experimental

- Controlled pre/post (diff-in-diff)
- Regression discontinuity
- Interrupted time series

Retrospective observational effectiveness

Uncontrolled pre-post
Qualitative Case Study

More Implementation Outcomes

Selecting a Study Design – *a few guiding questions*

2. Quantitative &/or qualitative data collection, analysis?
   - Quantitative & qualitative are
     - — Methodological approaches for collecting, analyzing data
     - — NOT study designs
     - — Applicable to most study designs (some better than others)
     - — Most informative when combined as mixed methods to answer IIS questions

Ex. Sample outcomes from MICU study

Outcome	Data Source	Method	Outcome Type
Acceptability of protocol	Surveys, interviews	Mixed	Implementation
Rates of mechanical intubation	Medical records	Quantitative	Effectiveness
Average days in restraints	Medical records	Quantitative	Symptomology

Selecting a Study Design – *a few guiding questions*

3. Can I assign the exposure?
   - ➢ No: Observational study design (cohort, cross-sectional, case study, case-control)
   - ➢ Yes: Quasi-experimental or experimental study design

Ex. Implementing a new protocol for severe alcohol withdrawal in the MICU

- **Yes! Assigned MICU to be the only setting with this protocol change**
- **Picked a date that the protocols would switch in Epic**

Benzo + Phenobarb Protocol

No Benzo Protocol

IIS Approach

Selecting a Study Design – *a few guiding questions*

4. Can I randomize how the exposure is assigned?
   - ➢ No: Quasi-experimental study design [(un)controlled pre/post, interrupted time series, regression discontinuity]
   - ➢ Yes: Experimental study design (individual randomized controlled trial, randomized stepped-wedge, cluster randomized trial)

Ex. Implementing a new protocol for severe alcohol withdrawal in the MICU

- Cluster randomization not ideal – single setting (campus consolidation)
- Interrupted Time Series design
  - Multiple observations before/after intervention (interruption)
  - Causal impact measured by change in intercept/slope in post-intervention observations
  - Pros: Good internal validity, rules out maturation, secular trend treats
  - Cons: Time intensive, sudden implementation, possible delayed effects

IIS Approach

Acting on Study Results

- Results of well-designed studies are informative
  - Sharing outcomes prevents re-inventing wheels
  - Informs program decisions
  - Rigorous studies promote generalizable lessons for other settings

IIS Approach

Source: Ilott I, Gerrish K, Pownall S, Eltringham S, Booth A. Exploring scale-up, spread, and sustainability: An instrumental case study tracing an innovation to enhance dysphagia care. Implementation Science. 2013.

What to do with Results After Implementation?

It worked!

- **Scale & Spread:** Disseminate EBP or implementation strategies

It Didn't work!

- Diagnose implementation challenges
- Modify approach using lessons, re-test

IIS Approach

Sustainability – *the frequently neglected, highly important implementation outcome*

- "The process through which new working methods, performance enhancements, and continuous improvements are maintained for a period appropriate to a given context" (Buchanan et al., 2007)

- Sustainability requires early planning, frequent maintenance
  - Design implementation strategies that aren't dependent on study funding
  - Schedule regular check-ins to brush-up on skills, train new hires
  - Continuously monitor key outcomes

IIS Approach

Implementation Success
Good Adoption, Acceptability, Fidelity

Implementation Decay
Dwindling Adoption, Acceptability, Fidelity

Source: Buchanan DA, Fitzgerald L, Ketley D. The sustainability and spread of organisational change. Modernising healthcare. Abingdon: Routledge Taylor & Francis Group; 2007.

Revisit Implementation Strategies to Sustain Effective Initiatives

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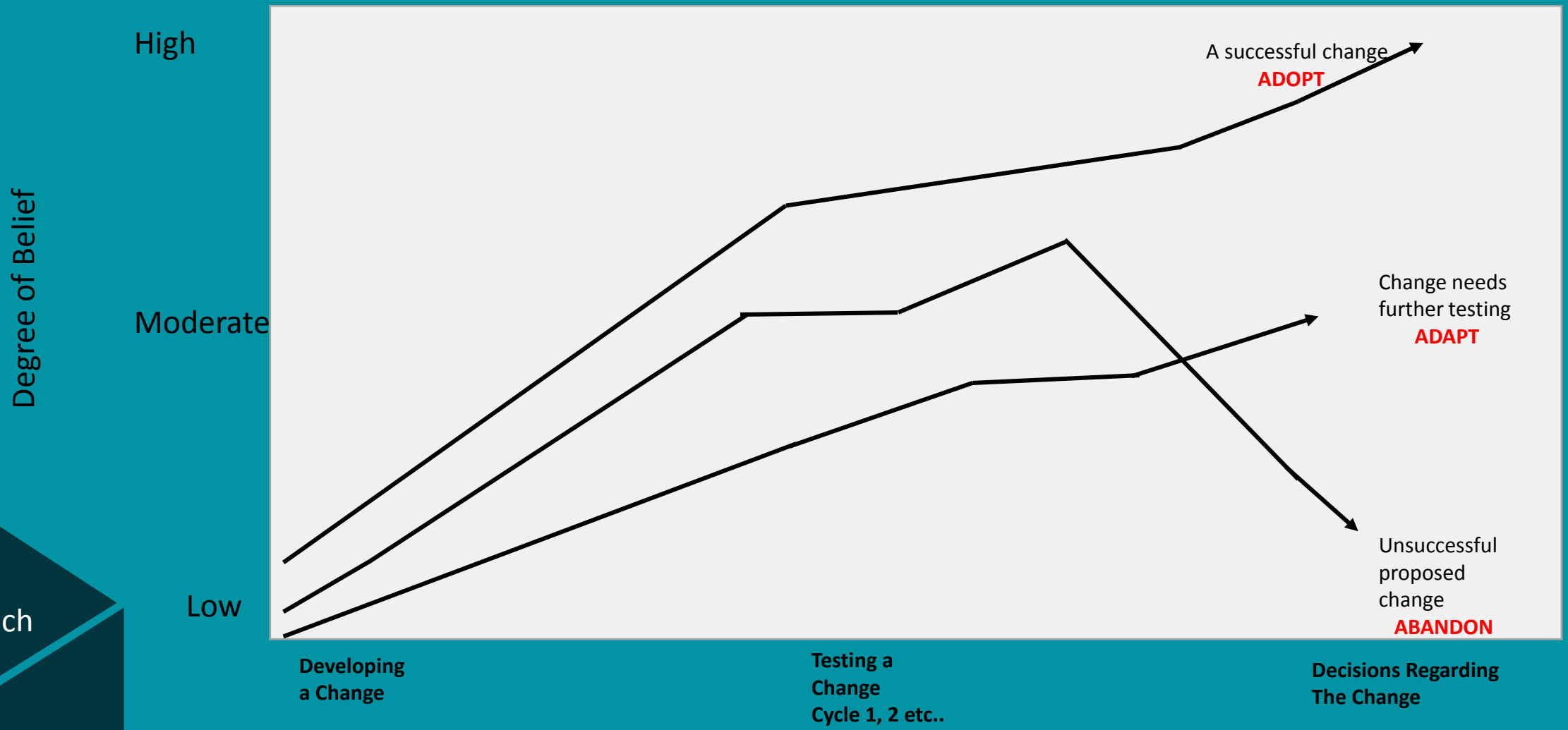
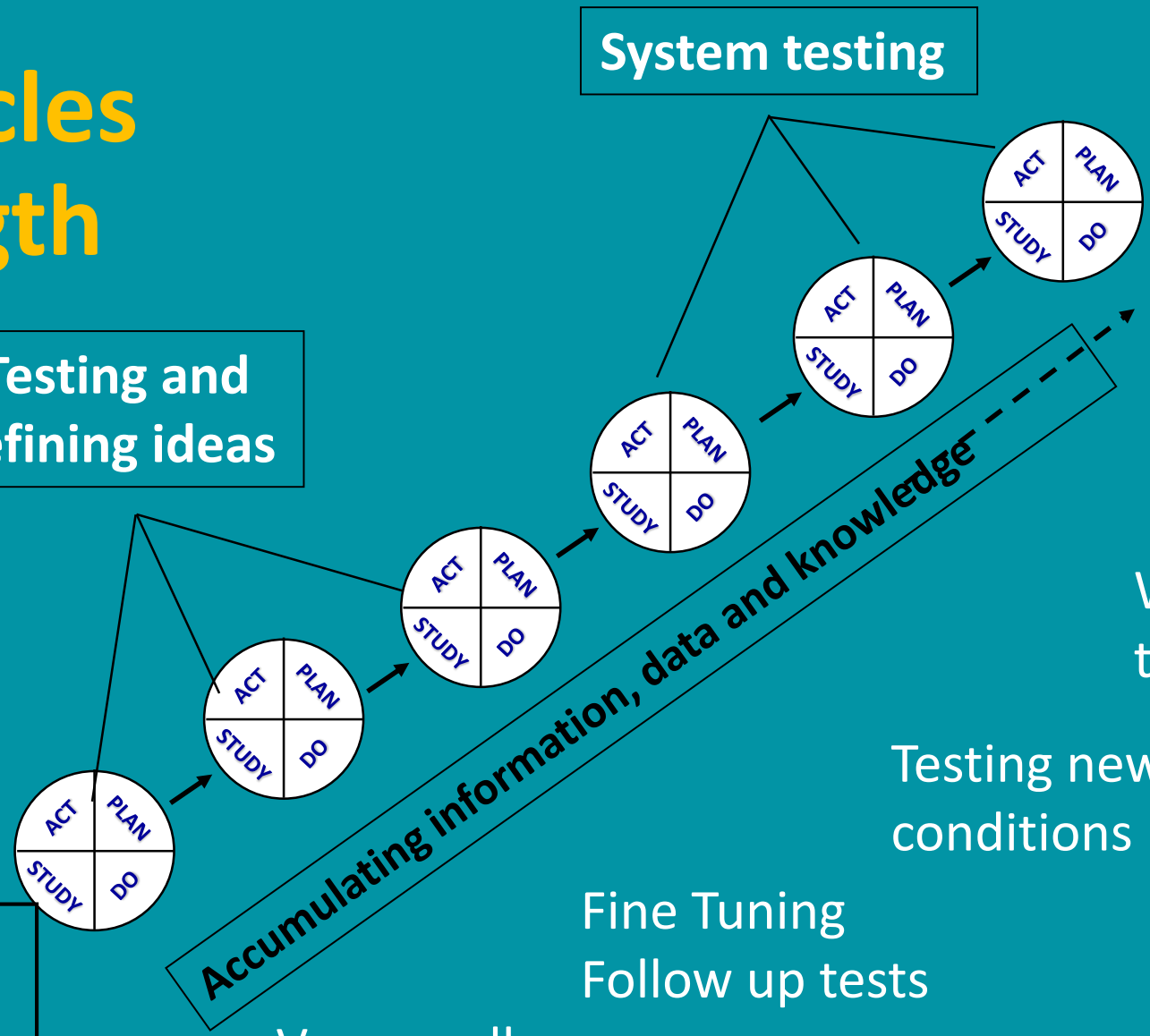
The QI Challenge
Creating Degree of Belief For Your Change



QI Approach

Repetitive Cycles PDSA'S Strength



Sustainability Widely Tested / Degree of Belief Created

Wide scale test of change

Testing new conditions

Fine Tuning Follow up tests

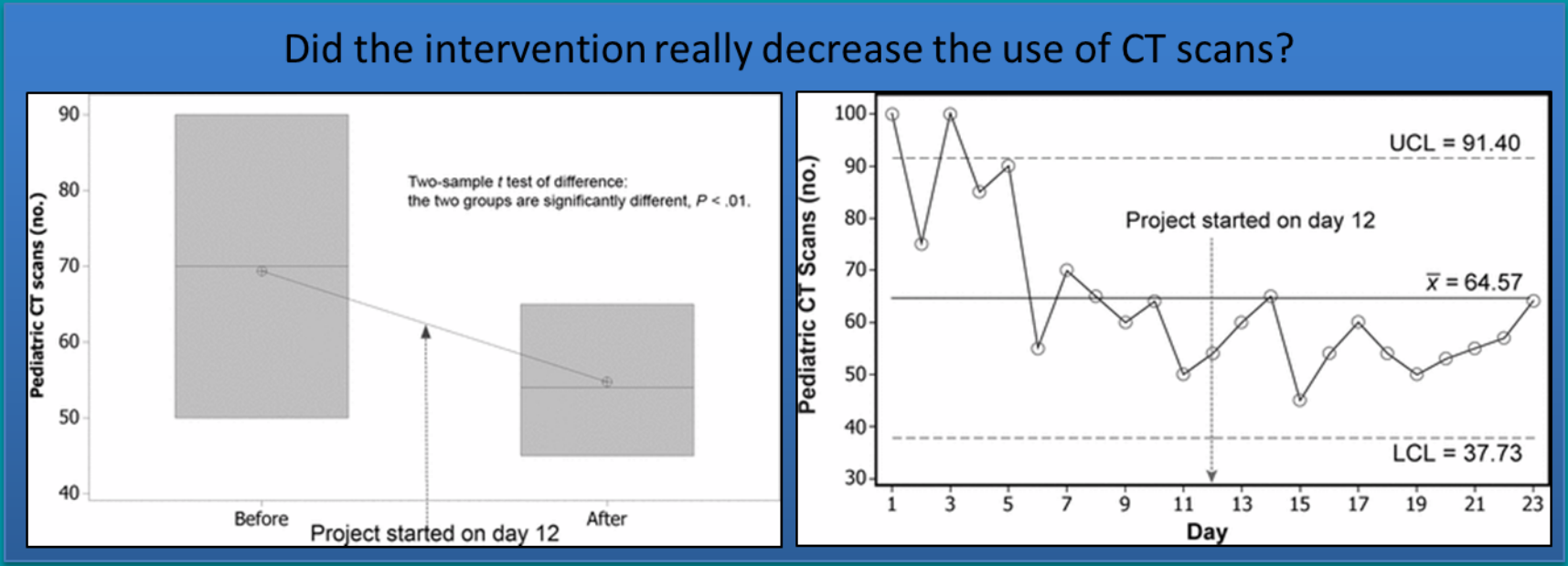
Very small scale test of change

QI Approach

Choosing Type of Design for Testing

	OBSERVATIONAL	BEFORE AND AFTER	TIME SERIES (Gold Standard)	FACTORIAL
TYPE OF DESIGN	A simple comparison of two processes without trying to effect outcome to see what might be better process	Comparison is made before and after the change introduced	***Before and After Time Series*** – Collects data over time ***Time Series with a Control group***- Adds a control group to design where no changes are made ***Time Series with Planned Grouping*** –Adds testing in wide range of conditions *systematically*	Includes tests where multiple changes are included Most often 2 Factor Design
ADVANTAGES	-Simplicity of design comparing your process to another's process where they might for example be using a new methodology to see if outcomes different	-Looking at effect of one change at a single point in time -Simple to conduct and easily understood	-***Before and After Time Series*** Possible to see patterns in improvement CONTINUING OVER TIME -***Time Series with Control and or Planned*** **Grouping** Significantly increase degree of belief if positive outcomes	-Allow for studying the effect of each change as well as their interactions -Good methodology for testing under different conditions and creating high degree of belief
DIS-ADVANTAGES	-Assumes that the two conditions under which processes were measured similar when in fact may have been important differences ----Individual biases may be present in interpreting results -Lowest degree of belief	-Vulnerable to misinterpretation if something unrelated to change occurs at same time the change is made that also effects outcome -More still needs to be added to increase degree of belief in applicability of change	-Takes a longer time -Increases complexity of testing design	-Adds further complexity to your design

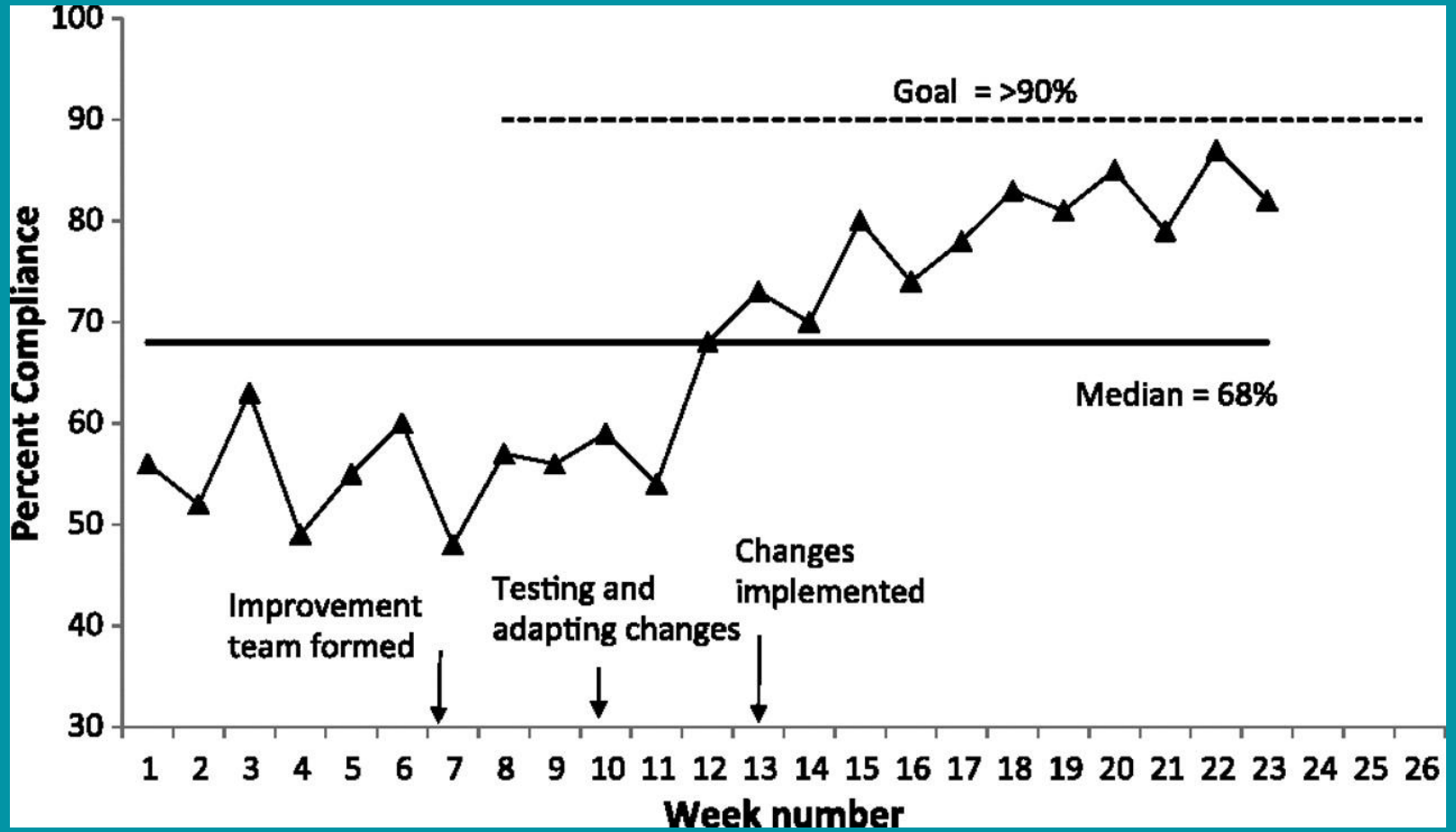
Creating Belief That It Was the Intervention That Created Result



QI Approach

Images: Radiographics. 2012 Nov-Dec;32(7):2113-26.

Time Series Data RUN CHARTS
Gold Standard for Demonstrating Effectiveness Change



QI Approach

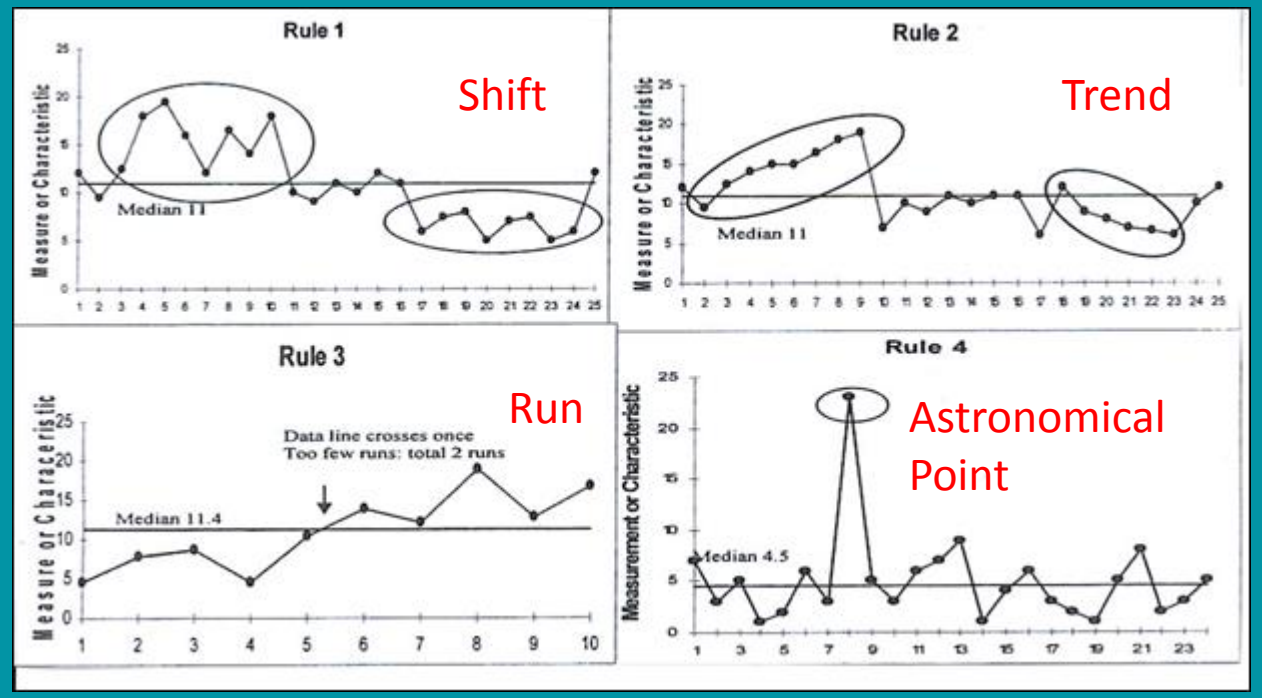
IN QI, DATA TELLS THE STORY

- Start with baseline data before change
- The signal of true change is found in when your data shows

SPECIAL CAUSE (NON-RANDOM VARIATION)

1. Shift
2. Trend
3. Too few or too many runs
4. Astronomical point

SPECIAL CAUSE (Non Random Variation) validates intervention made

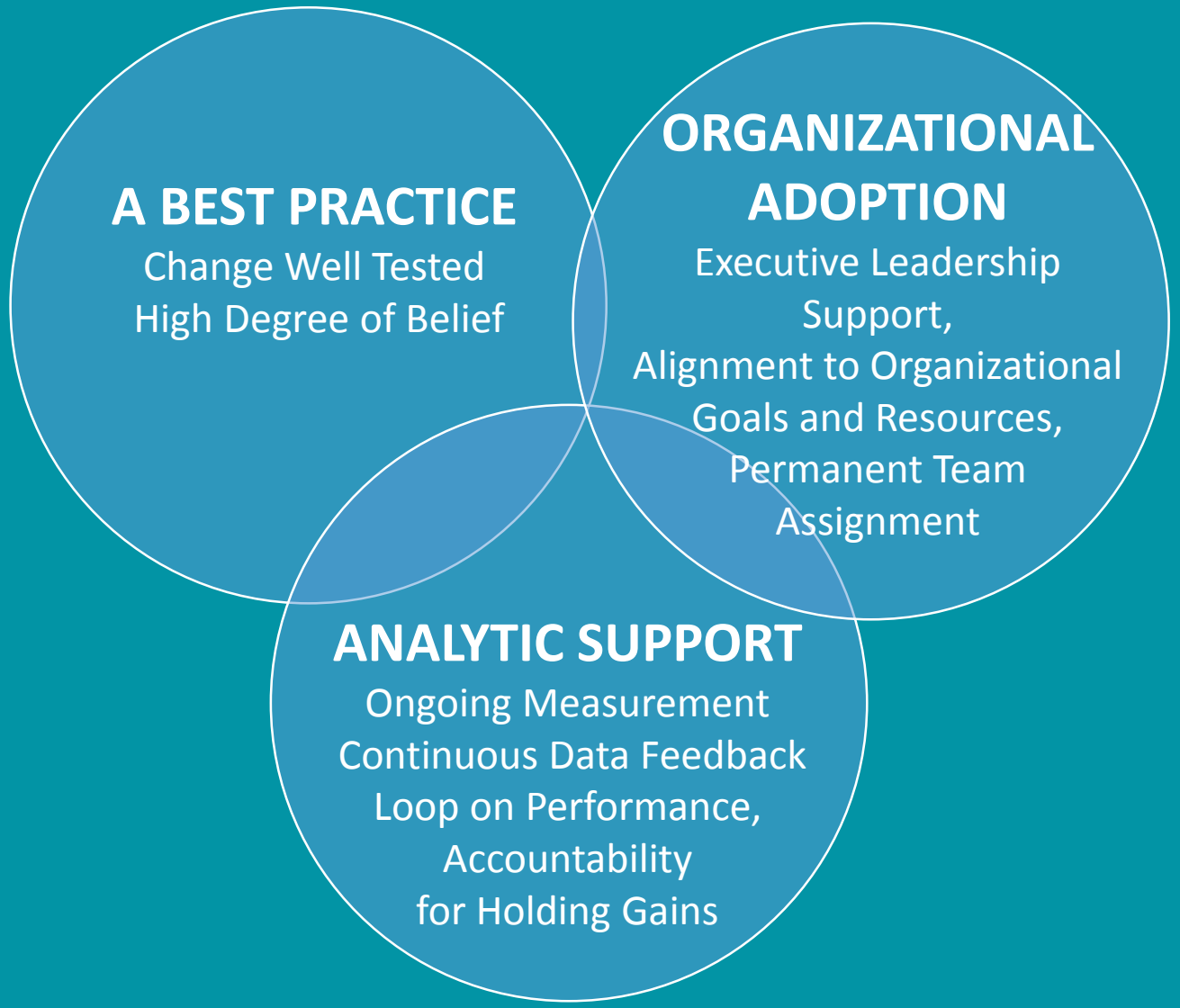


QI Approach

Planning for Sustainability
Part of the QI Framework From Beginning

QI Approach

Three Components For Sustainability



Sustainability Takes

QI Approach

Your Experience Study & Acting on Results

Think of a time you wanted to improve healthcare delivery…

- Do you lean toward using certain study designs?
  - Which ones, why?
- Biggest study design challenges?
- Experiences communicating or applying results?

Group Discussion