Pragmatic Science

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Uses of patient data

Health Care Operations

Direct patient care

QA (individual level)
- surgical case review
- infection control
- M&M conference
- credentialing/privileging
- etc.

QI (process mgmt; population level)
- planning
- evaluation

Population-level care delivery

Billing

System planning
- location, level, and organization of health services

Epidemiologic Research

(Observational; population-level)

Non-identifiable patient data

Identifiable patient data (usually for record linkage)

Direct patient contact

Experimental Research

Randomized treatments

Experimental treatments

Health care operations

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Population-level care delivery	**Billing**	**System planning** - location, level, and organization of health services

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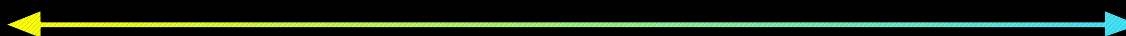
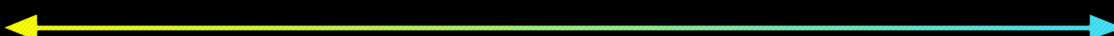
Oversight through enforceable policy



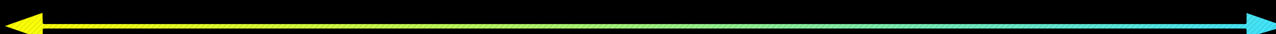
Oversight through IRBs

External validity



Internal validity

Performance



Publication

Pragmatic Science

Pragmatic: Relating to matters of fact or practical affairs often to the exclusion of intellectual or artistic matters.

Science: Knowledge covering general truths or the operation of general laws, especially as obtained and tested through the scientific method.

Scientific Method

Principles and procedures for the systematic pursuit of knowledge involving:

(1) the recognition and formulation of a problem;

(2) the collection of data through observation and experiment; and

(3) the formulation and testing of hypotheses.

Science has an implicit hope that the results obtained will lead to improvement, but "scientists" are not held accountable or evaluated by how far the results spread or the degree of improvement achieved.

Achieving interpretable comparisons

- ***Internal validity:*** *If measured outcomes changed, can that change be causally attributed to the intervention being tested?*
- ***External validity:*** *Within which external populations and settings do the measured results apply?*

Threats to internal validity

- ***Competing events / potential causes***
  (problems with establishing causality, not just association)
  -- use control group(s)
- ***Selection bias*** *-- randomize*
- ***Sentinel / Hawthorne effect*** *-- use blinding, placebo controls*
- ***Inconsistent intervention or measurement during the trial*** *-- use protocols*

The practice of medicine

- *Every physician commits:*
  - to track the treatments they give to their patients
  - and the outcomes they achieve
  - with an aim to improve treatments and outcomes for future patients

that is what it means to "practice" medicine

Quality of evidence

I. ***At least one randomized controlled trial***

II-1. ***Controlled trials without randomization***
(quasi-experimental designs)

II-2. ***Cohort or case-control studies***

II-3. ***Multiple time series** (observational studies)* ***or dramatic results***

III. ***Agreement among a group of respected authorities using formal consensus methods***

IV. ***Personal anecdote** ("in my experience")*

Lawrence RS, Mickalide AD. Preventive services in clinical practice: designing the periodic health examination. *JAMA* 1987; 257:2205-7.

What determines "truth?"

... how well the information convinces a group of knowledgable, critical peers ...

(the idea of a community standard of care -- what a group of physician peers agree upon)

What is the goal?

Ultimate scientific truth?

- or -

Something better than current practice?

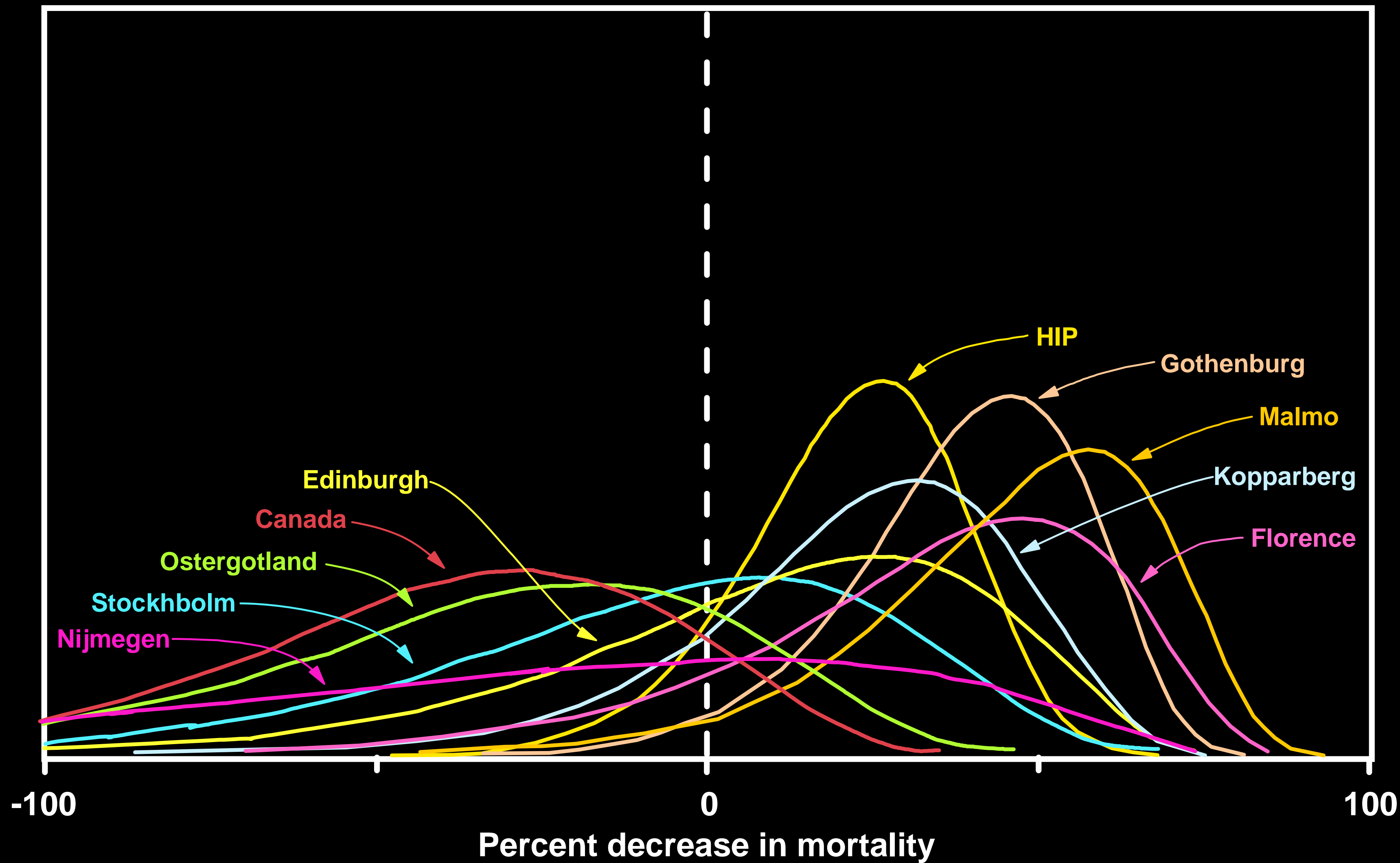
Burden of Proof: Either you prove (through an RCT) that the new way is better -- or I am free to do whatever I please (even though I have no valid scientific basis for my own chosen practice)

He uses statistics as a drunken man uses lamp posts ...

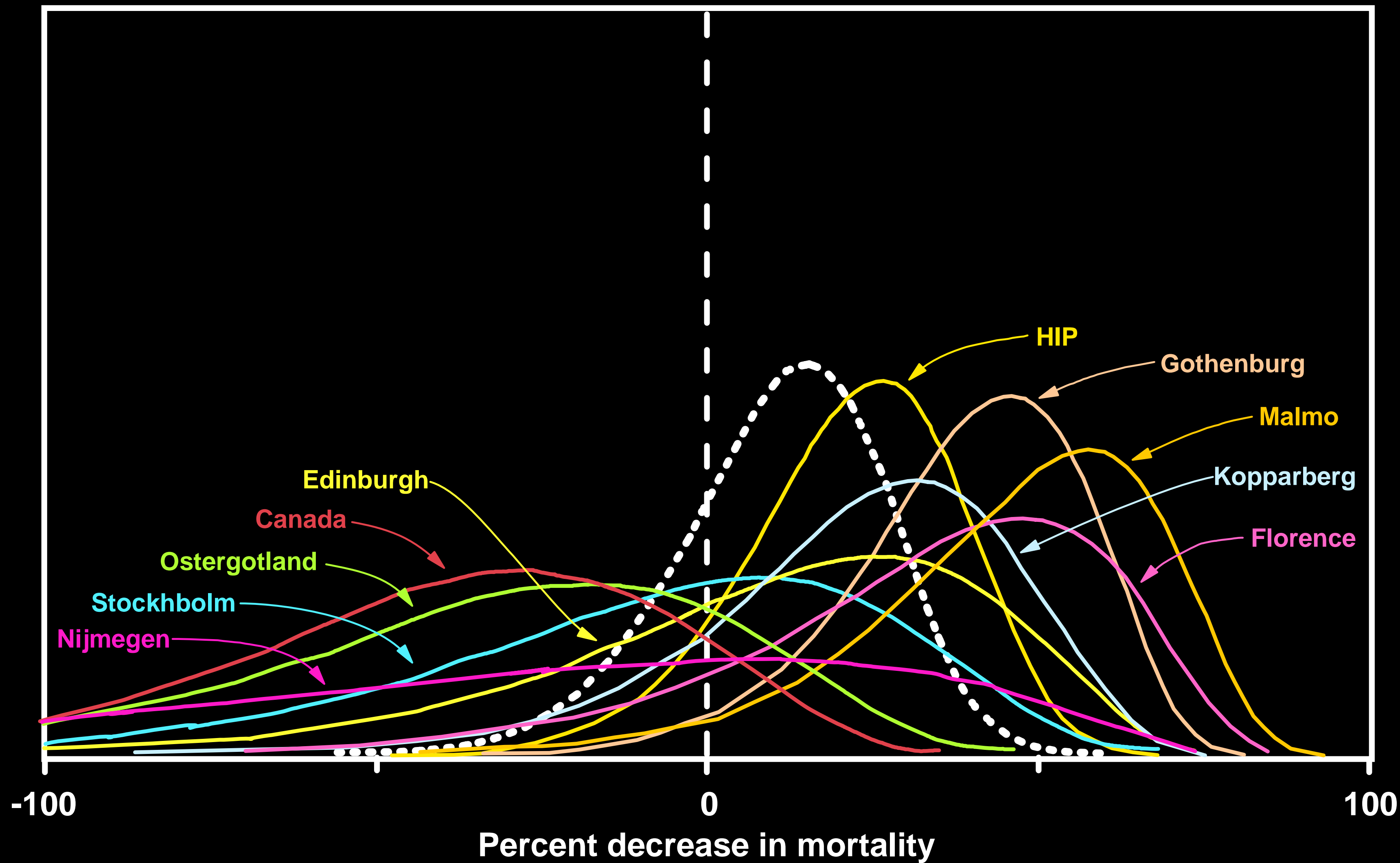
for support rather than for illumination

Andrew Lang (1844 - 1912)

Mammography



Mammography



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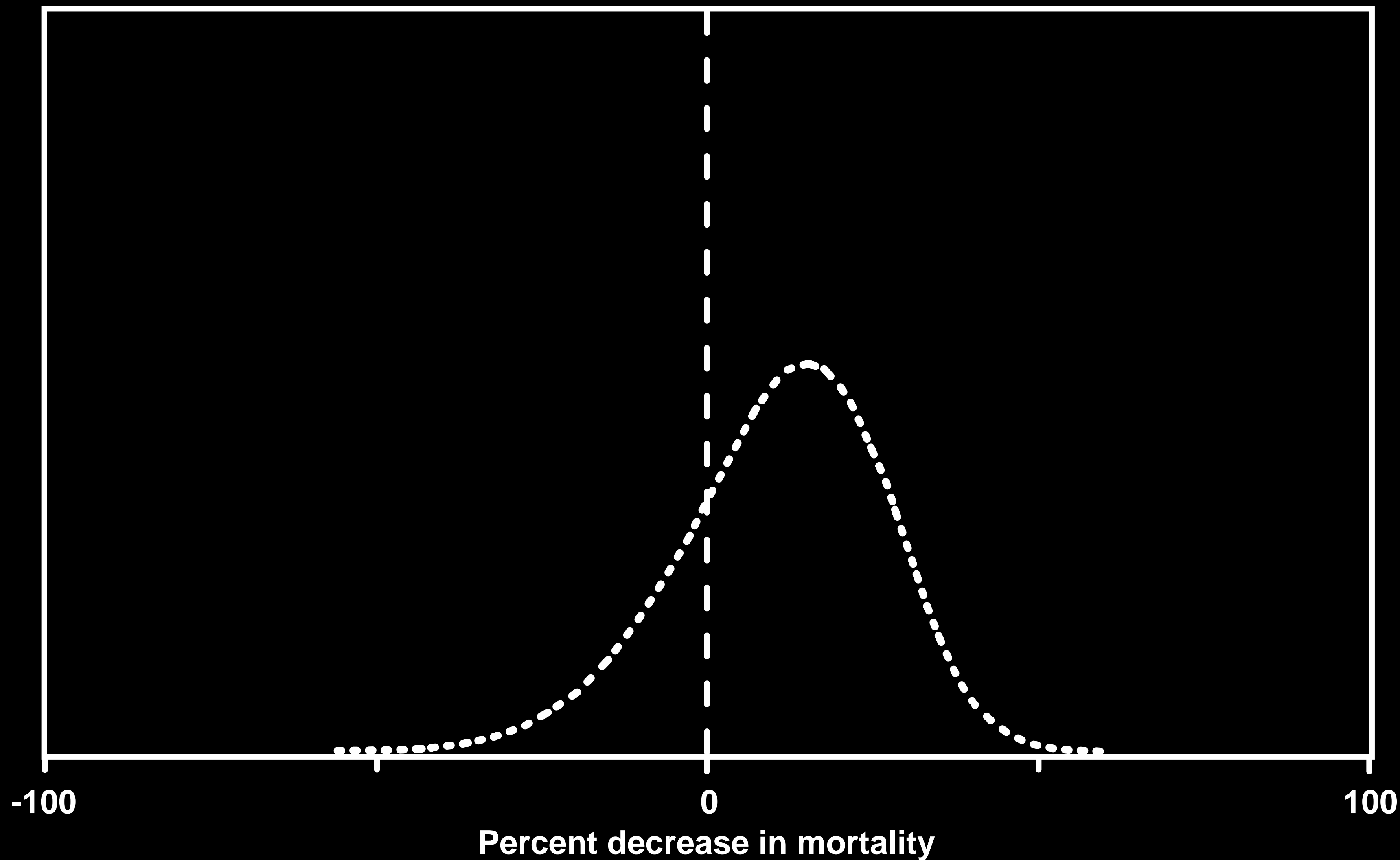

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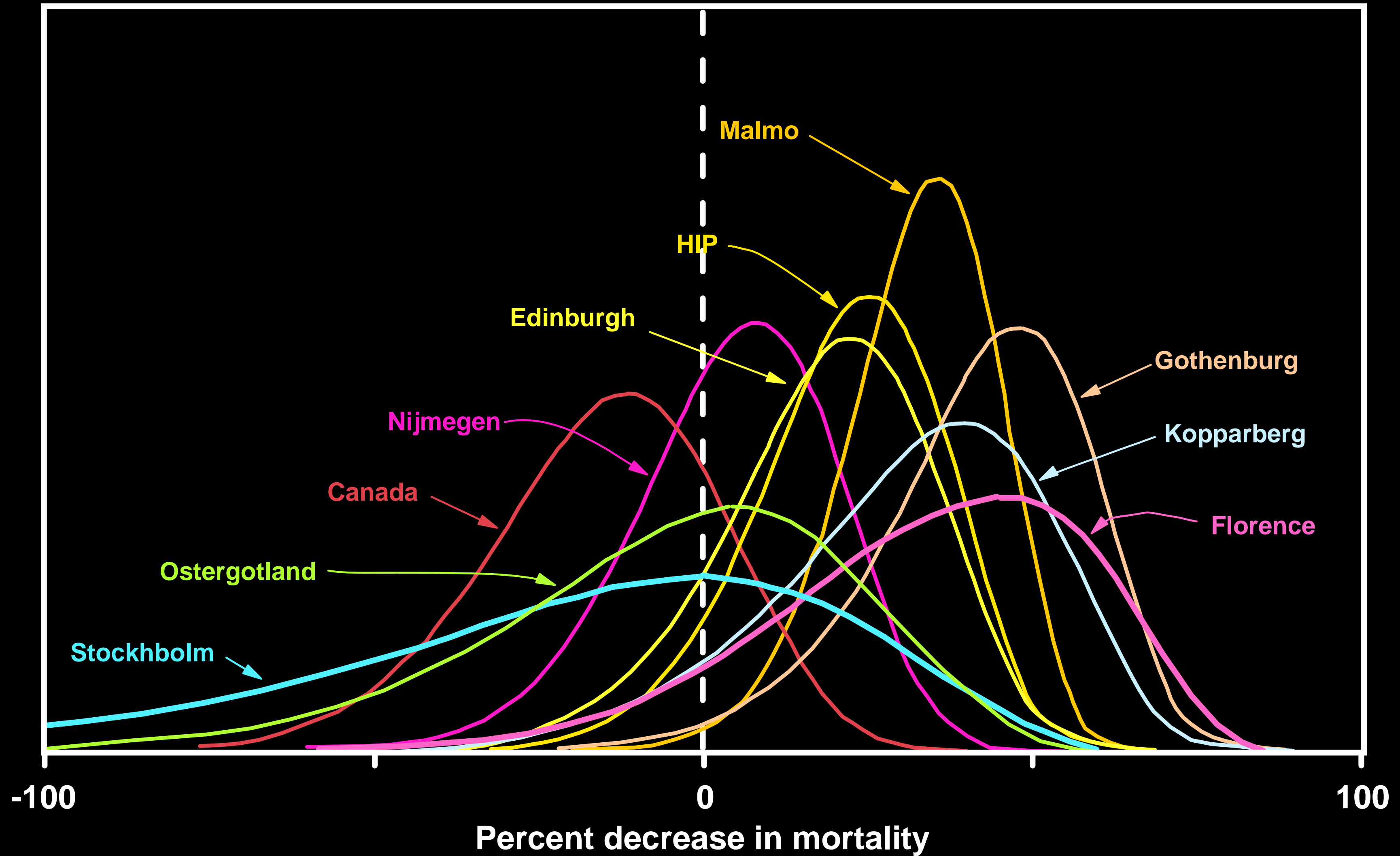

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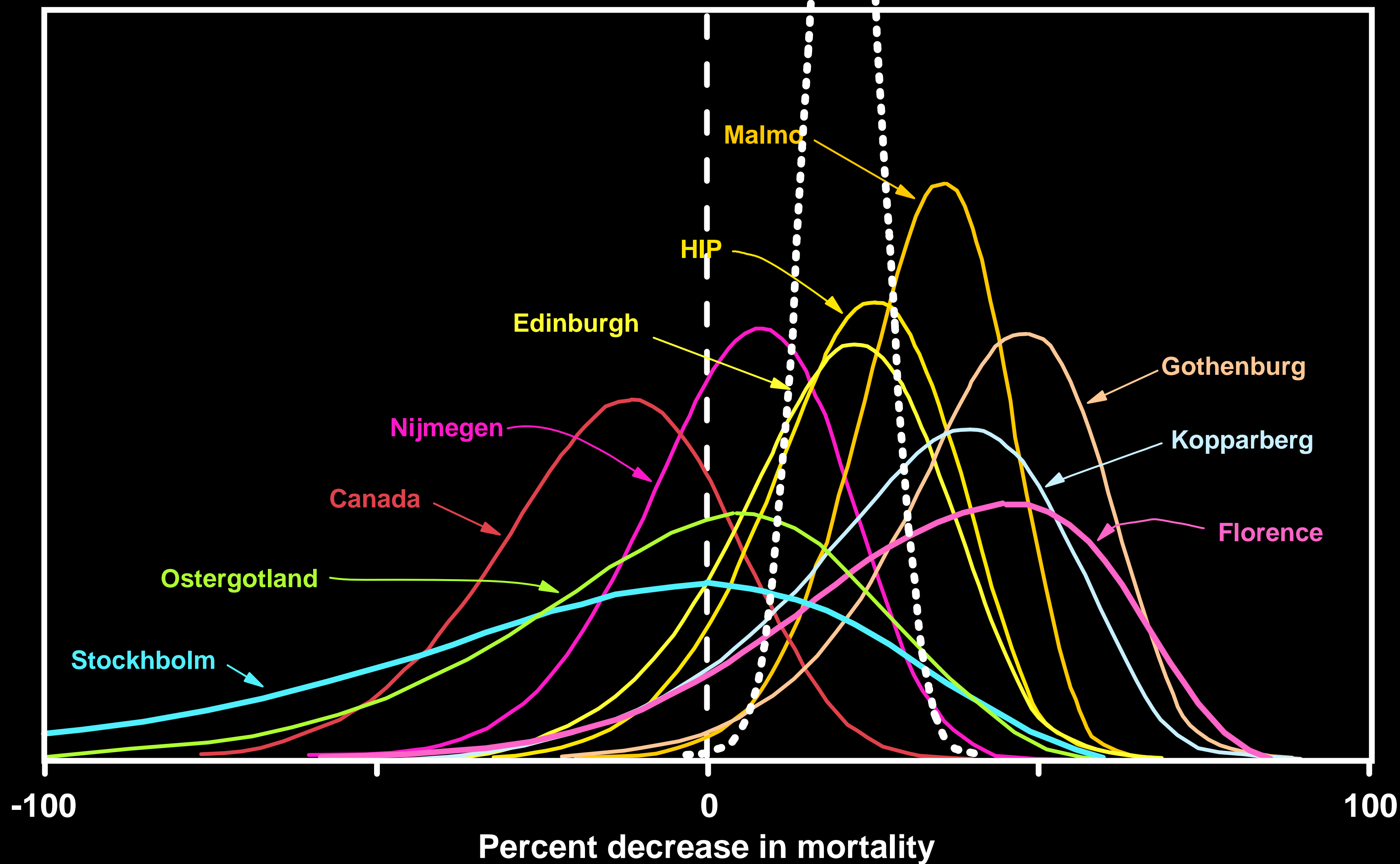

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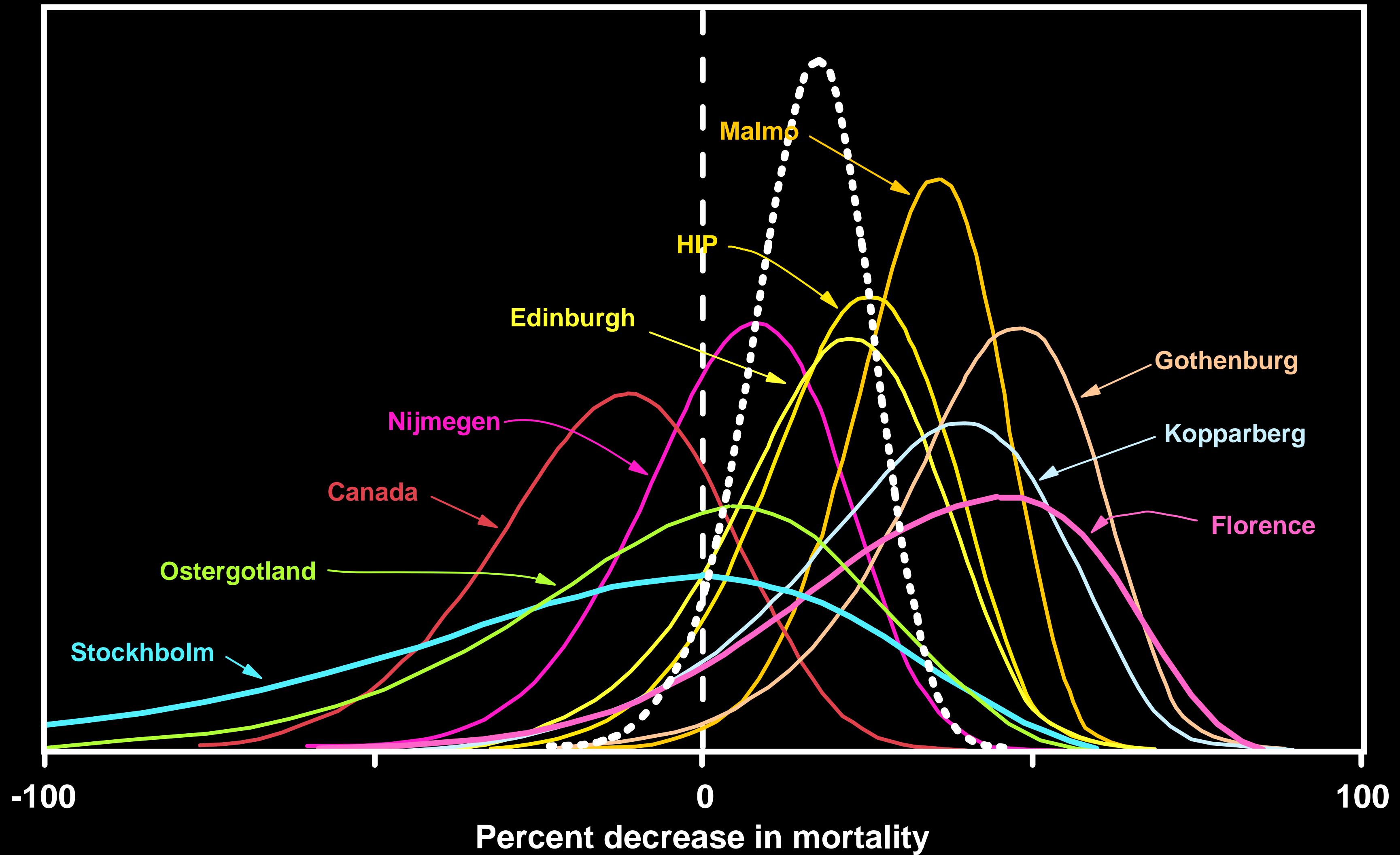


Improvement versus research

Performance/execution

Aim: *better practice*

Emphasizes *external validity*

Methods:

- *identify best known practice*
- *open loop (systems-level changes)*
- *tests observable (helps spread)*
- *stable bias (tolerates "dirty" data)*
- *just enough data*
- *changing hypotheses --*
- *sequential tests*
- *ongoing outcomes tracking*

Publishing research

Aim: *new knowledge*

Emphasizes *internal validity*

Methods:

- *establish clinical equipoise*
- *closed loop (patient-level changes)*
- *tests blinded*
- *no bias (demands "perfect" data)*
- *all possible data, just in case*
- *fixed hypotheses --*
- *one large test*
- *when study ends, data ends*

Plan-Do-Study-Act vs. *Plan-Do-Study-Publish*

Elements of Pragmatic Science

1. *Will and focus to change the system*
2. ***A practical, flexible improvement model*** *(based on, e.g., participants' level of readiness, availability of evidence, etc.)*
3. *A method to extract and package changes (start with a list of possible changes, not a brainstorm session)*
4. ***Efficient, effective use of data to direct and drive change***
5. ***Rapid testing of prototypes on a small scale, generating a sequential build-up of knowledge*** *(test then spread)*

Fundamental improvement questions

- ***What are we trying to accomplish?***

  A clear outcome target is essential to assign resources, garner collaboration, etc.

- ***How will we know that a change is an improvement?***

  Without this step, innovation is impossible ... "Truth is found more often from mistakes than from confusion" -- Francis Bacon, 1561-1626

- ***What changes can we make that will result in improvement?***

  A hypothesis generation step ...

modified from: ***The Foundation of Improvement*** by Thomas W. Nolan *et. al*

Writing aim statements

Initial aim statement *(from IHC ATP)*:

Our mission is to implement and determine compliance with a locally-developed clinical practice guideline for the management of immunocompetent adult patients with community-acquired pneumonia. We will also evaluate the impact of implementation on clinical and cost outcomes.

Improved statement *(from Dr. Tom Nolan)*:

Our mission is to improve the clinical outcomes and decrease the cost of caring for adult inpatients with pneumonia by integrating the use of a clinical practice guideline into the process of their care.

Sample aim statements:

Clinical Outcomes

- *Within the next 12 months 80% of our diabetic patients will have documented A1c levels $\leq$ 8.0%.*
- *Within 12 months we will reduce hospitalizations for our asthmatics to $\leq$ 1/1,000 per year for 0-14 year olds, $\leq$ 2/1,000 per year for 15-44 year olds, and $\leq$ 3/1,000 per year for 45-64 year olds.*

Patient Satisfaction

- *Within 9 months we will achieve a $>$ 90% "highly satisfied" rating on routinely monitored satisfaction surveys from our patients regarding (1) access to care, (2) waiting times, (3) service quality, (4) attention to personal needs, and (5) quality of our technical skills.*

Assignment

- ***List the attributes of a good aim statement***
- ***Prioritize the list***

Features of good aims statements

- ***Outcomes focused*** *-- linked directly to main run chart*
- ***Measurable***
- ***Stretch goals*** *(doable? Stage 1 vs Stage 2 change)*
- ***Specific target populations***
- ***Clear timelines***
- ***Terse, succinct, clear***
- ***Can identify general change strategy / approach***

Using data to improve

- *The minimum standard:* ***an annotated time series***

1. ***Start with a run chart*** *(80% of total value)*
   - *Run chart: a graph that tracks sequential instances of some measure*
2. ***Add center and goal lines*** *(anchors the eye - now 95% of total value)*
3. ***Add control limits*** *(in appropriate zones)*

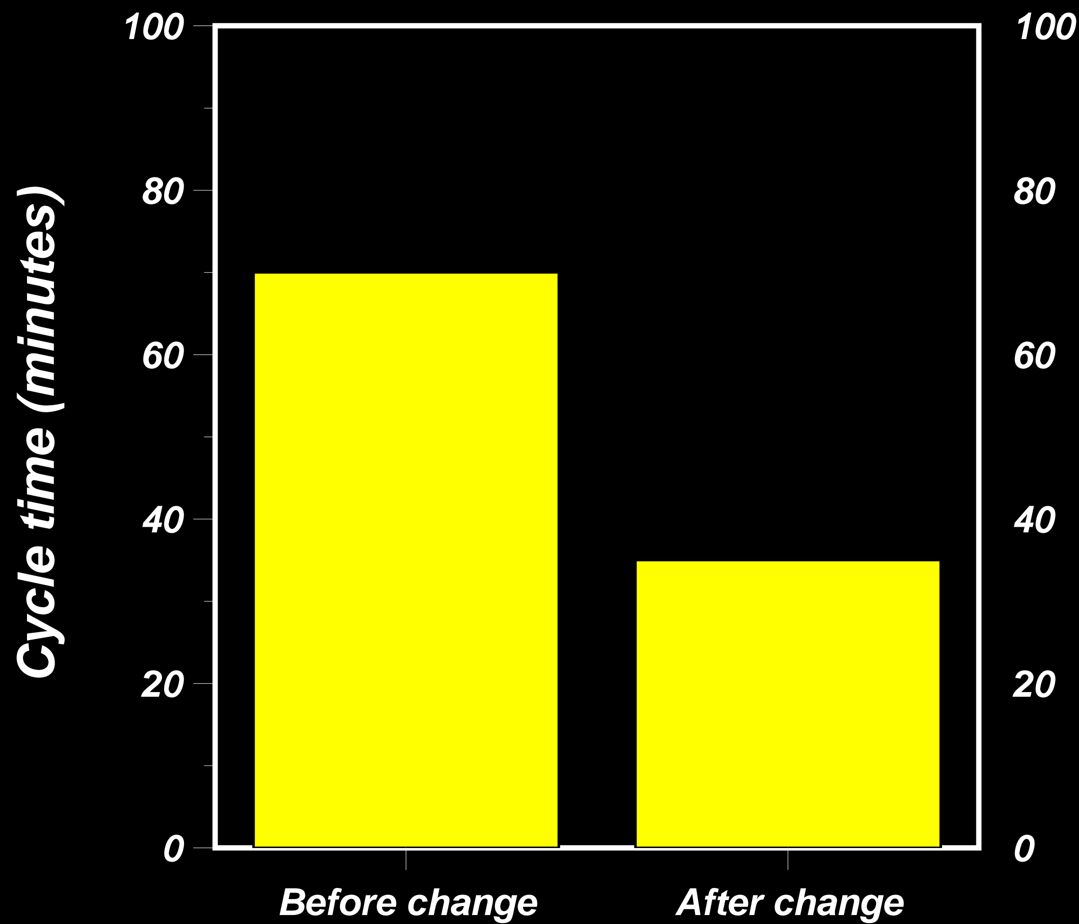
Graphical display

- ***Graphs are** (nearly) **always better than tables of numbers***
- ***Minimize chart junk***
  - *keep the graphic area clear (ticks on the outside)*
  - *avoid three dimensional figures*
  - *non-obtrusive grid lines (scales on both sides)*
- ***The human eye-brain can best interpret:***
  - *distance from a common origin (dot plots)*
  - *area (bar charts -- three dimensional figures can mislead)*
  - *absolute worst: visual angle (pie charts)*
  - *automatically calculates minimum distance between two lines, <u>not vertical distance</u>*

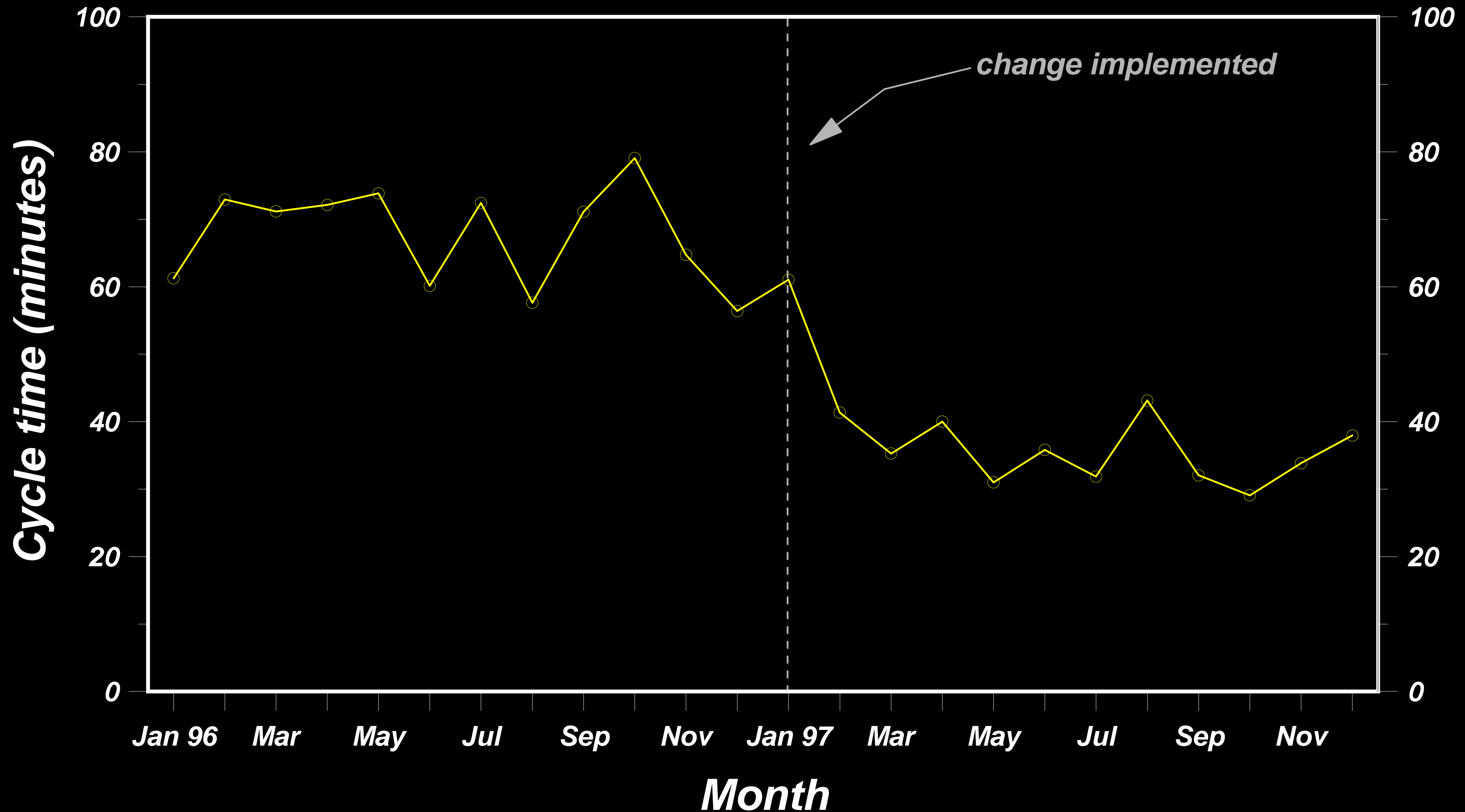
Cleveland, William S. *The Elements of Graphing Data*. Summit, NJ: Hobart Press, 1994 (AT&T).

Tufte, Edward R. *The Visual Display of Quantitative Information*. 1983.
Envisioning Information. 1990.
Visual Explanations: Images and Quantities, Evidence and Narration. 1997.
all from (Tufte): Graphics Press, P.O. Box 430, Cheshire, Connecticut 06410

Improvement in cycle time



Improvement in cycle time



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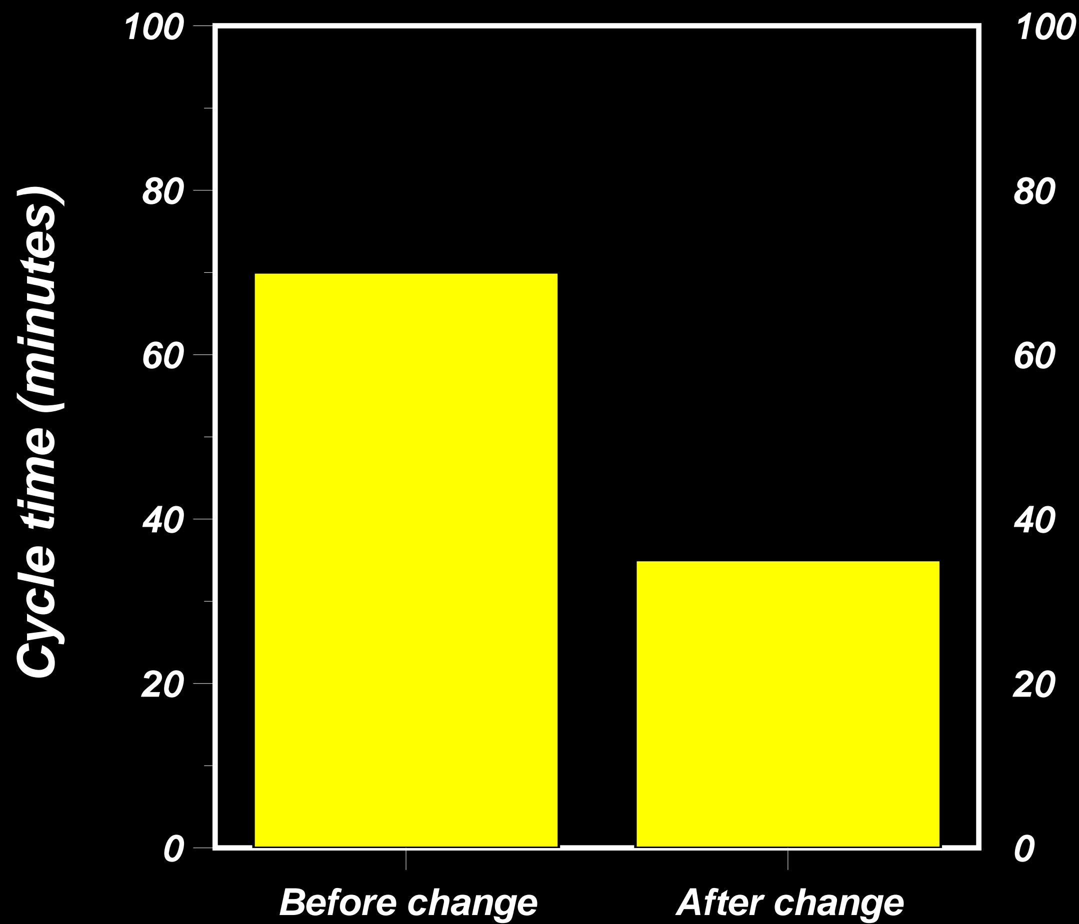

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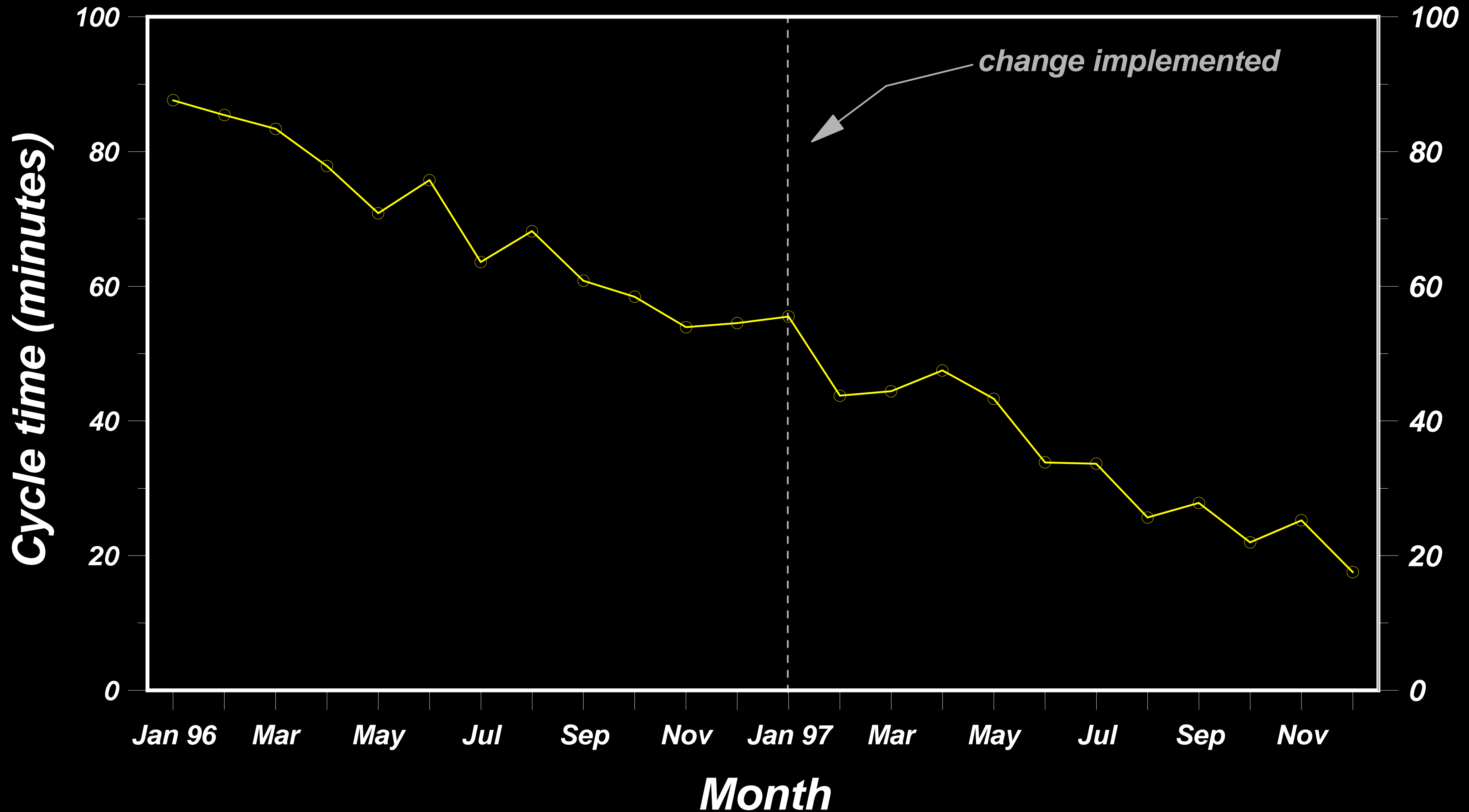
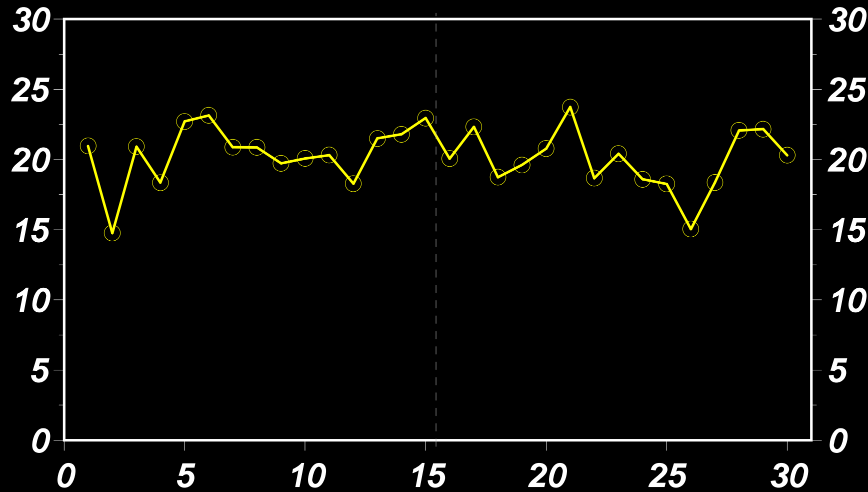
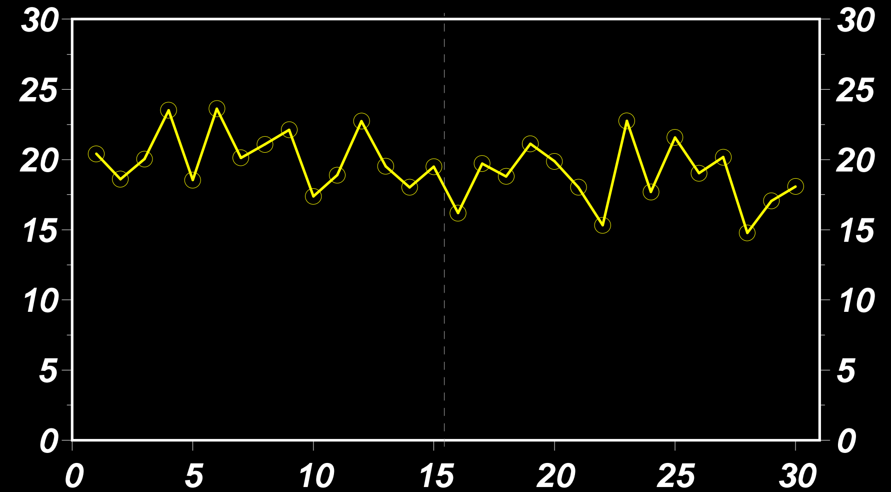
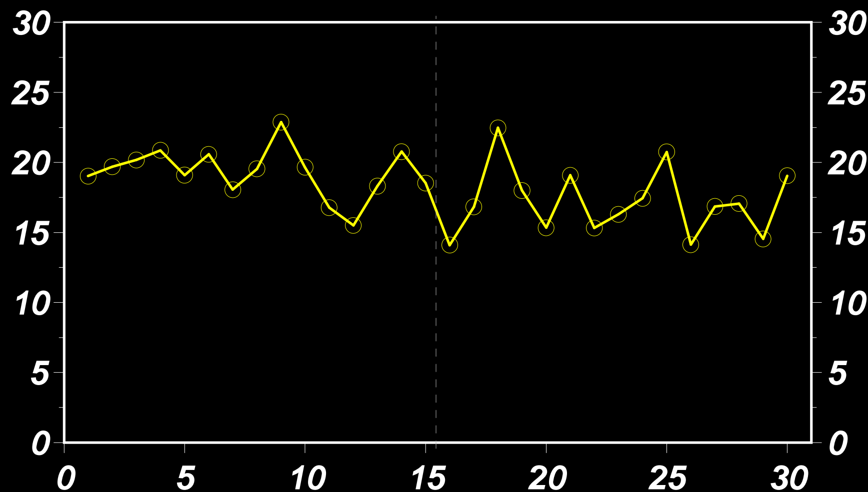
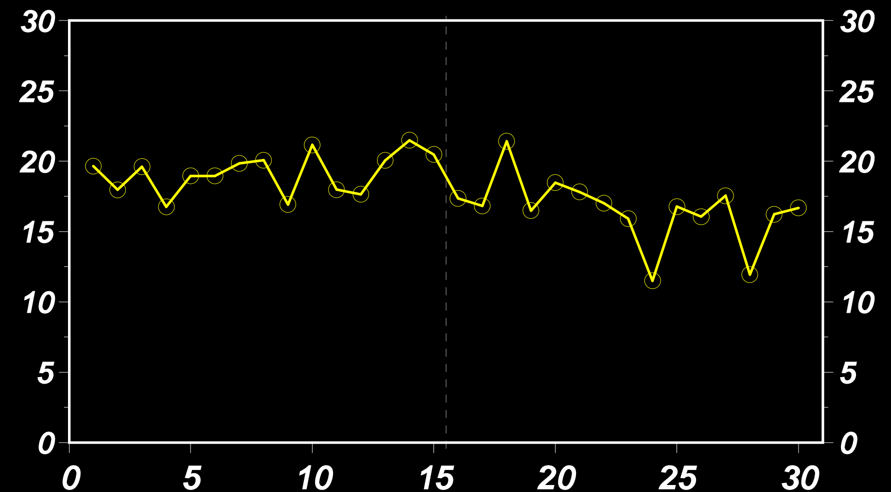


Statistically significant?









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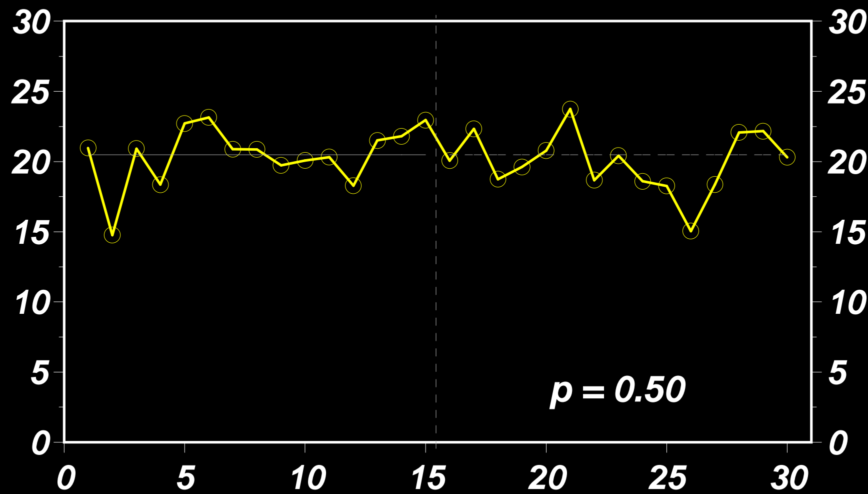
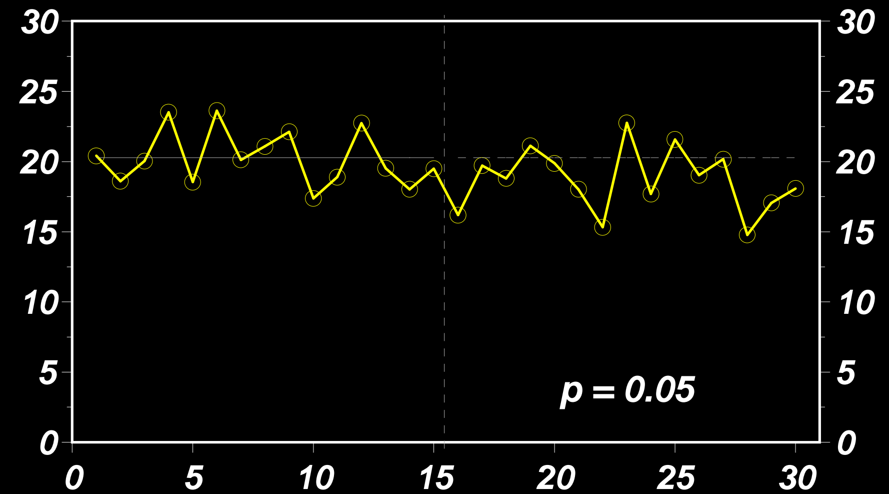
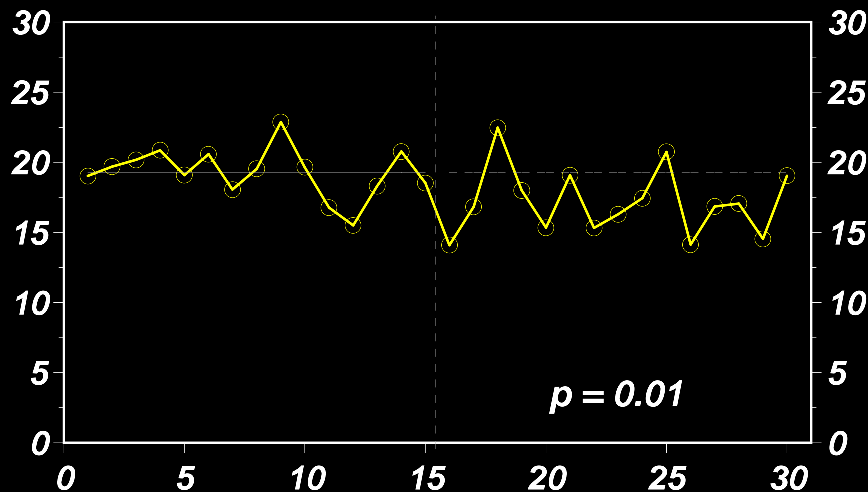
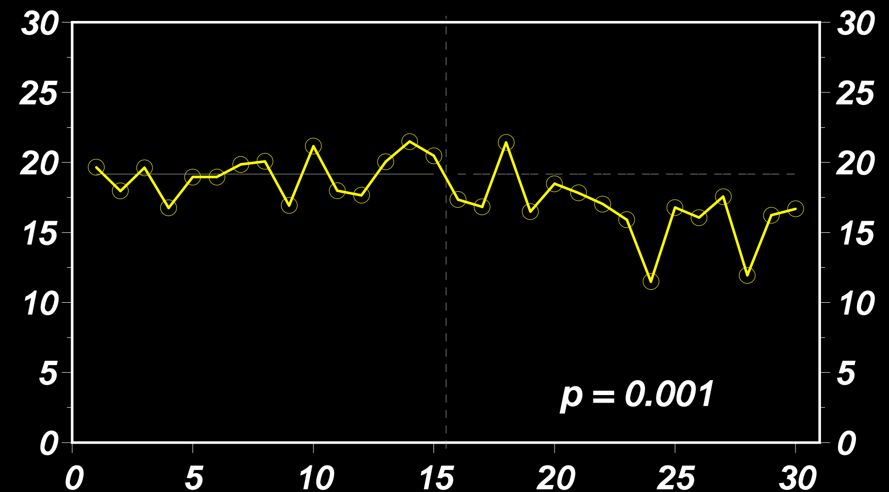








Why use level II-3 evidence?

- ***In many circumstances** (in fact, almost all current circumstances)**, level II-3 evidence is better than current practice***
- ***Level II-3 evidence can easily imbed in daily work***
  - *efficient data collection and analysis, without massive overhead*
  - *contributes to holding the gains*
- ***Change is a temporal phenomenon***

Use evidence higher than II-3 when:

- *Scant evidence supporting the change exists, and failure carries significant potential risk for patients*
- *The change will result in significant cost increases*
- *No theory supports the change*
- *The aim is to find causes of rare but important events*
- *Outcomes are separated by a substantial amount of time from the changes under study (high potential that extraneous, unrecognized causes will intrude)*
- *The change proposes enforced standardization, with widespread, compulsory compliance*
- *It is easy to generate better evidence (existing research infrastructure; natural experiments)*

The practice of medicine

- ***Every physician commits:***
  - **To track the treatments they give to their patients**
  - **and the outcomes they achieve**
  - **with an aim to improve treatments and outcomes for future patients**
- *Every physician also knows the necessity of objective data when assessing treatments and outcomes*
- ***So why do we all, in the actual practice of medicine, assess our treatments and outcomes subjectively -- in our heads?***

Change ideas: dystocia c-sections

- ***Inductions are done only for clear medical indications*** *(e.g., PIH or post dates at 42+ weeks)*
- ***The OB staff avoid c-sections for failure to progress before 3-4 cm dilation***
- ***Patients receive 1:1 labor support from nursing staff, doulas, or midwives***
- ***Physicians offer adequate pain relief to patients; nursing staff assess pain and provide a variety of pain-relieving techniques***

Change ideas: access to care

- *Traditional one-on-one visits to physicians are supplemented by other services*
- *Schedule contains fewer than 6 appointment types*
- *For primary care, 30-50% of appointments are reserved for same-day requests (10-20% for specialty care)*
- *Unnecessary return visits are minimized*
- *Monitoring system gets the ability to accurately predict need for increased capacity*
- *Protocols optimize the use of non-physicians*

Complete List of Change Concepts

A. Eliminate Waste
1. Eliminate Things That Are Not Used
2. Eliminate Multiple Entry
3. Reduce or Eliminate Overkill
4. Reduce Controls on the System
5. Recycle or Reuse
6. Use Substitution
7. Reduce Classifications
8. Remove Intermediaries
9. Match the Amount to the Need
10. Use Sampling
11. Change Targets or Set Point

B. Improve Work Flow
12. Synchronize
13. Schedule into Multiple Processes
14. Minimize Handoffs
15. Move Steps in the Process Close Together
16. Find and Remove Bottlenecks
17. Use Automation
18. Smooth Work Flow
19. Do Tasks in Parallel
20. Consider People as in the Same System
21. Use Multiple Processing Units
22. Adjust to Peak Demand

C. Optimize Inventory
23. Match Inventory to Predicted Demand
24. Use Pull Systems
25. Reduce Choice of Features
26. Reduce Multiple Brands of Same Item

D. Change the Work Environment
27. Give People Access to Information
28. Use Proper Measurements
29. Take Care of Basics
30. Reduce Demotivating Aspects of Pay System
31. Conduct Training
32. Implement Cross-Training
33. Invest More Resources in Improvement
34. Focus on Core Processes and Purpose
35. Share Risks
36. Emphasize Natural and Logical Consequences
37. Develop Alliance/Cooperative Relationships

E. Enhance the Producer/Customer Relationship
38. Listen to Customers
39. Coach Customers to Use Product/Service
40. Focus on the Outcome to a Customer
41. Use a Coordinator
42. Reach Agreement on Expectations
43. Outsource for "Free"
44. Optimize Level of Inspection
45. Work with Suppliers

F. Manage Time
46. Reduce Setup or Startup Time
47. Set Up Timing to Use Discounts
48. Optimize Maintenance
49. Extend Specialist's Time
50. Reduce Wait Time

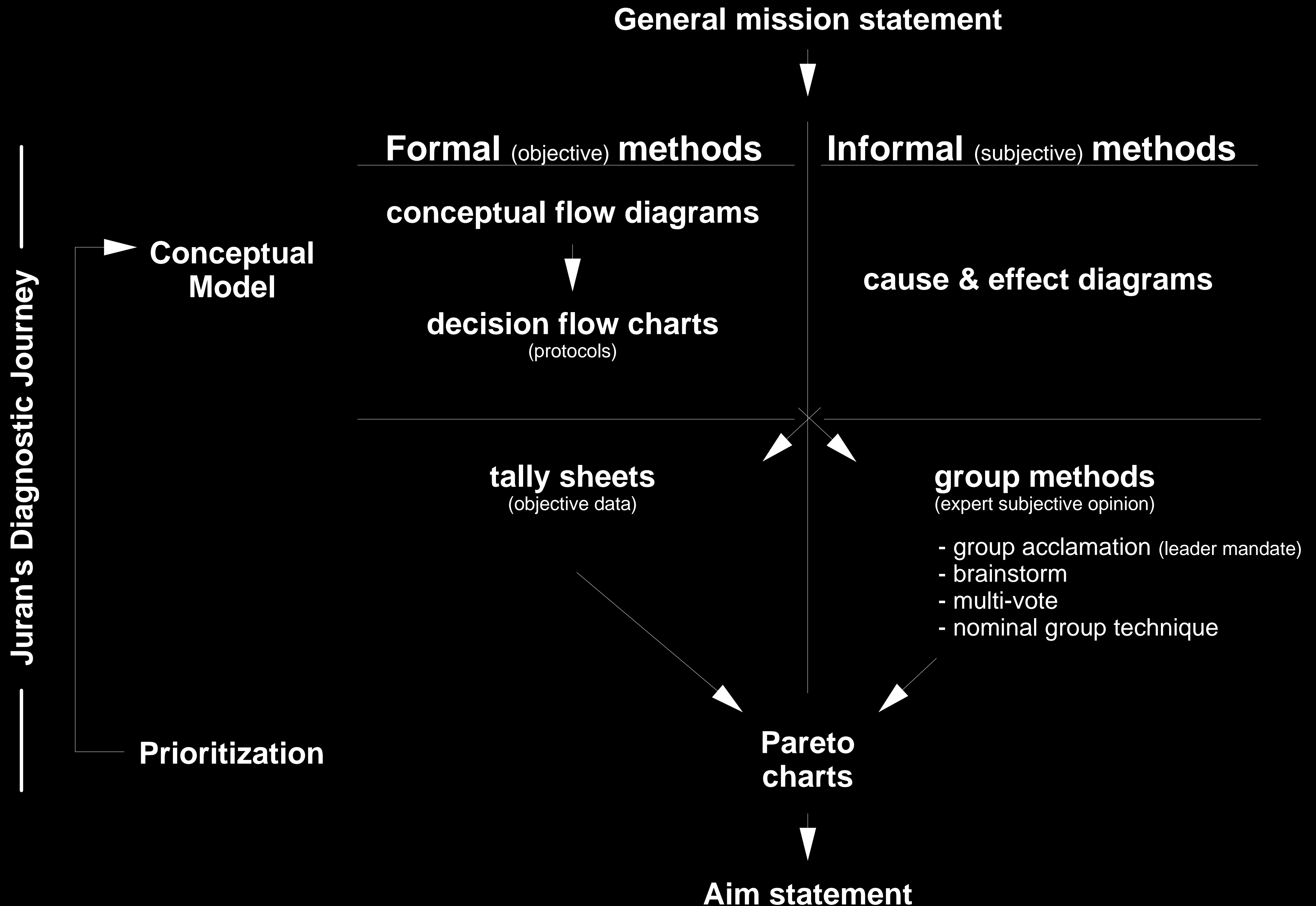
G. Manage Variation
51. Standardization (Create a Formal Process)
52. Stop Tampering
53. Develop Operational Definitions
54. Improve Predictions
55. Develop Contingency Plans
56. Sort Product into Grades
57. Desensitize
58. Exploit Variation

H. Design Systems to Avoid Mistakes
59. Use Reminders
60. Use Differentiation
61. Use Constraints
62. Use Affordances

I. Focus on the Product or Service
63. Mass Customize
64. Offer Product/Service Anytime
65. Offer Product/Service Anyplace
66. Emphasize Intangibles
67. Influence or Take Advantage of Fashion Trends
68. Reduce the Number of Components
69. Disguise Defects or Problems
70. Differentiate Product Using Quality Dimensions

The Improvement Guide. Langley GJ, Nolan KM, *et al.* San Francisco: Jossey-Bass, 1996; page 295.

Modeling processes



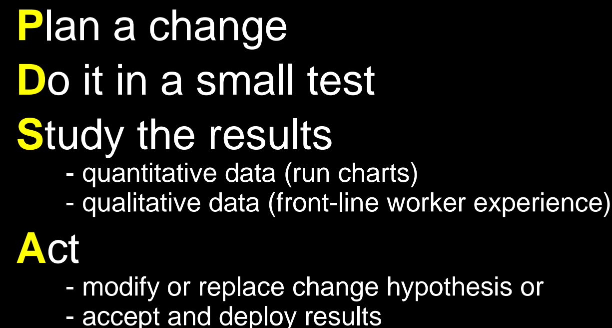
Modeling processes (cont'd)

Juran's Remedial Journey

Nolan's fundamental questions for improvement

1. What are we trying to accomplish?
   (focused **aim statement**)
2. How will we know that a change is an improvement?
   (measurement system - **run charts**, **balance measures**)
3. What changes could we make that might result in improvement?
   (list of **change hypotheses**)

Rapid Cycle Improvement



Plan a change
Do it in a small test
Study the results
- quantitative data (run charts)
- qualitative data (front-line worker experience)

Act
- modify or replace change hypothesis or
- accept and deploy results

Juran's Holding the Gains

Modeling Processes

General mission statement

Formal (objective) methods	Informal (subjective) methods
conceptual flow diagrams	cause & effect diagrams
decision flow charts (protocols)	
tally sheets (objective data)	group methods (expert subjective opinion) - group acclamation (leader mandate) - brainstorm - multivote - nominal group technique

Conceptual Model

Prioritization

Pareto charts

Aim statement

Nolan's fundamental questions for improvement

1. What are we trying to accomplish?
   (focused **aim statement**)
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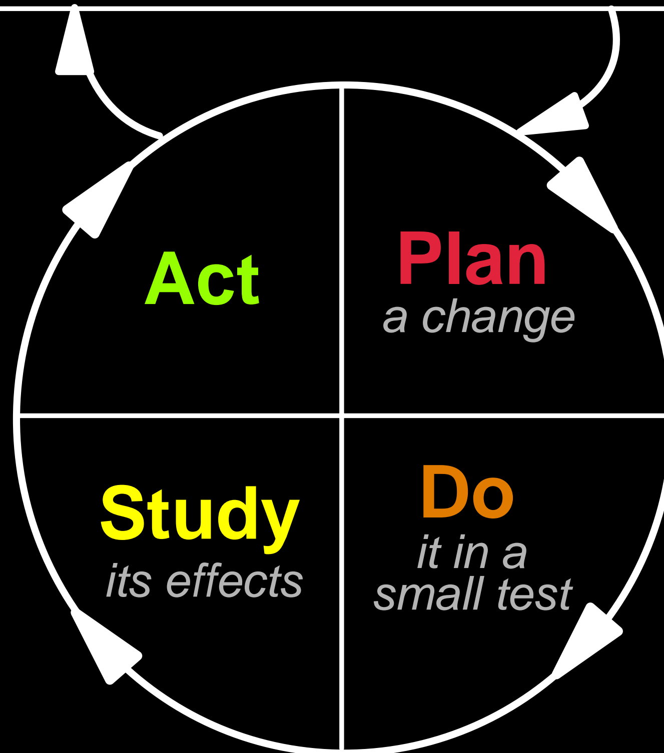
Juran's Diagnostic Journey

Juran's Remedial Journey

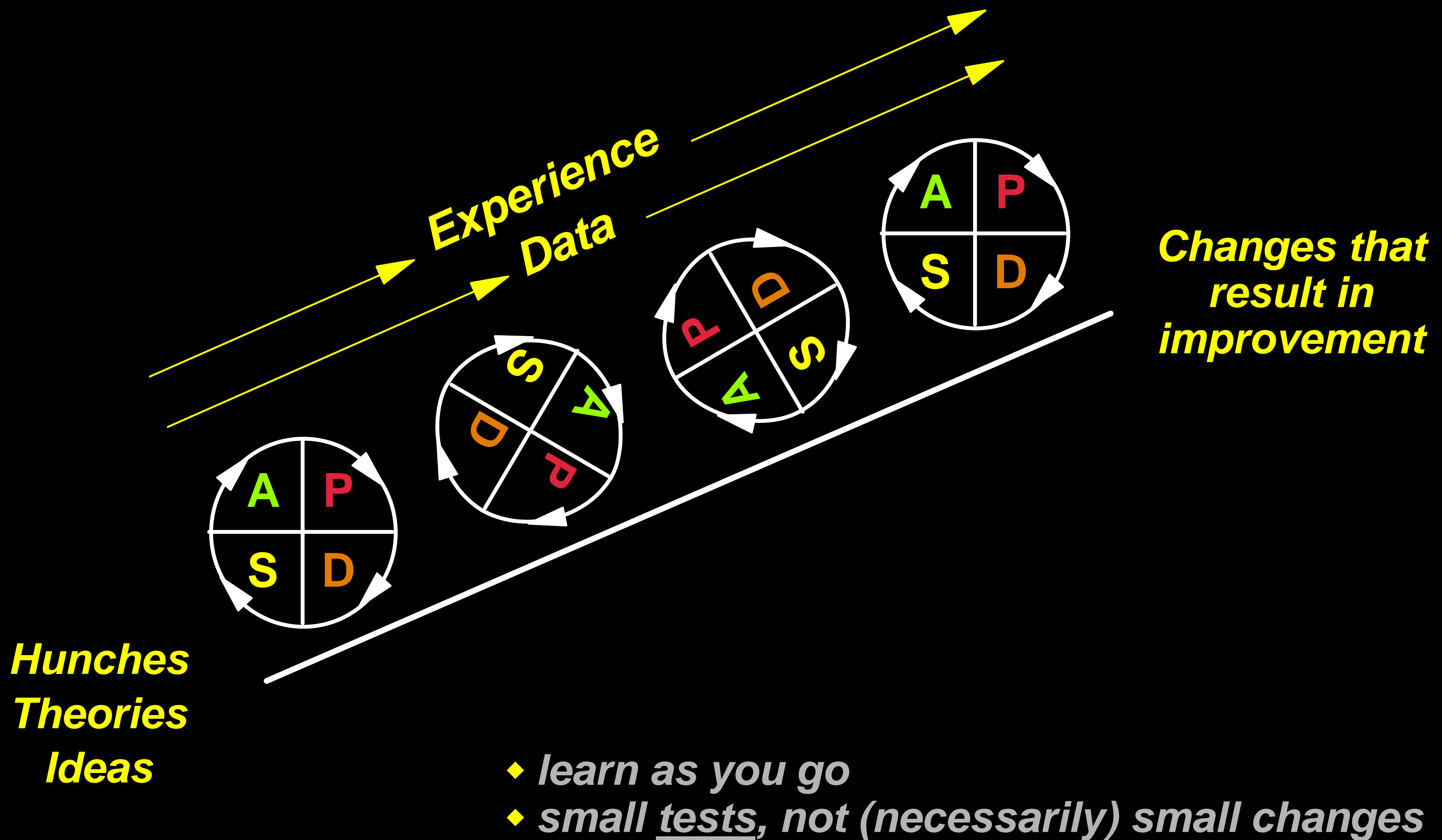
Juran's Holding the Gains

Model for improvement



- *guidelines may contain too many changes; therefore, select one or two to focus on at a time*

Repeated use of the cycle



- *learn as you go*
- *small <u>tests</u>, not (necessarily) small changes*

ATRIAL FIBRILLATION: FAST TRACK

St. Marys Hospital Medical Center, Madison, WI

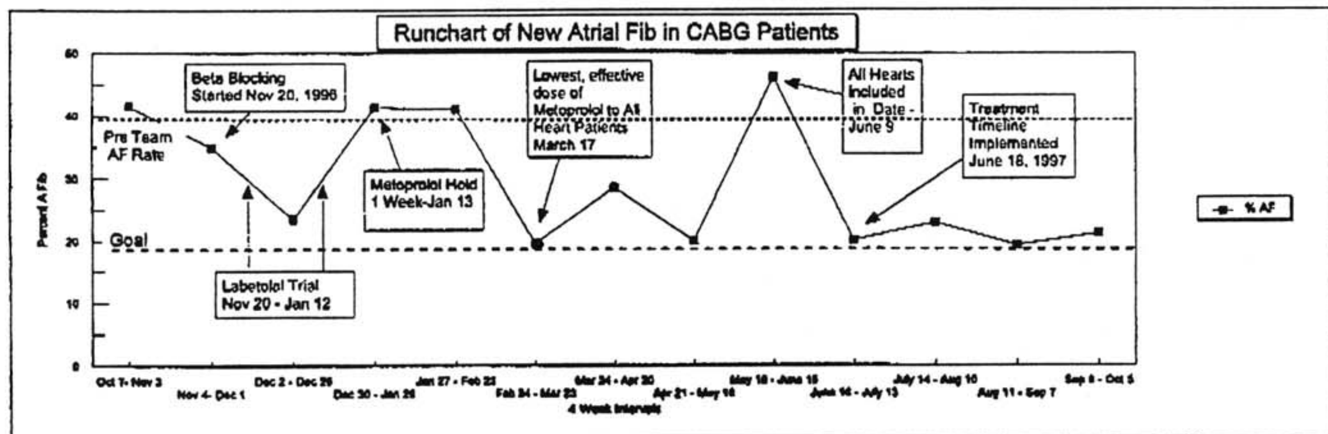
Aim To decrease new incidence of Atrial Fibrillation by 50% for CABG patients (DRG 106 & 107).
To limit the impact of new incidence of Atrial Fibrillation on LOS to be no more than 1 extra hospital day for same patient group (DRG 106 & 107).

Measures

Weekly rate of new incidence post op A Fib
LOS for all patients (with and without post op A Fib)
New incidence post op A Fib rate for different interventions

Sampling Methods

Data was collected on all CABG patients (DRG 106 & 107) Oct. 7 to June 8, 1997.
Starting June 9, data was collected on all heart surgery patients (valves, valve-revasc combo, myxoma removal)
Chronic A Fib patients were excluded
Atrial Fibrillation defined as - lasting 4 hours OR patient was treated



Key Changes

- Beta Blocker medication administered to medically appropriate patients
  * If patient was on a Beta Blocker pre op, gave a dose the morning of surgery
  * Assured that pre op Beta Blocker was resumed post op
  * Post operatively, prophylactic Beta Blockers were administered to patients not previously on Beta Blockers
    Trial of first dose given IV or po
    Trial of first dose given at 8 hours post op if stable or on POD #1
- Simplified the Beta Blocking process, giving lowest effective dose PO, Metoprolol 25 mg BID, or restarting patient's pre op medicine on POD #1
- Expanded Beta Blocker protocol to ALL heart surgery patients (not just CABGs)
- Implemented timeline for treatment of A Fib for entire care team

Contact Person - Helen Sheahan, RN, Team Leader
608-259-5585 hsheahan@ssmhc.com

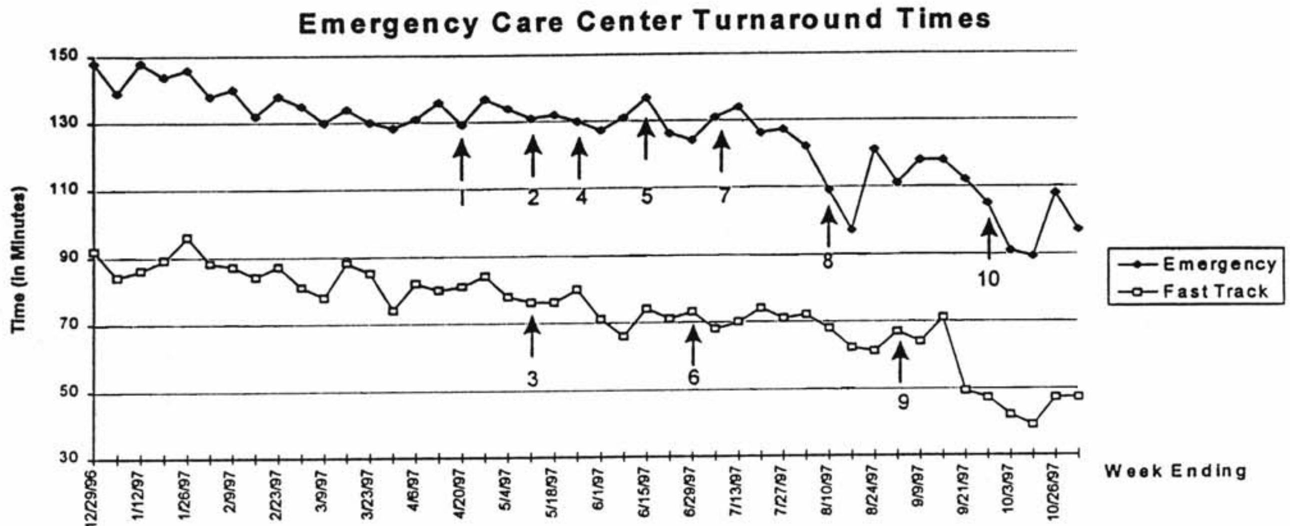
Nash Health Care Systems

Reducing Waiting Times in the ECC

Aim: To reduce throughput time in the Emergency Care Center for all types of patients (Fast Track, Emergency and Admissions) by 25%.

Key Outcome Measures: The duration of time from registration in the ECC to the discharge or admission time from the ECC.

Sampling Plan: 5 charts selected at 4 times per day (1000, 1900, 2200 and 0200) for 3 types of patients: Emergency, Fast Track and Admission.



Some Details on the Changes:

Fast Track

- Expanded hours of Fast Track from 12-16 hours/day (3)
- Reduced handoffs in Fast Track (3)
- Cross trained NAII's to do computer/secretarial duties (7)
- Rearranged NA coverage to cover the expanded hours in Fast Track (9)

Triage

- Changed triage nurse role, assisted with fast track when not busy (1)
- Triage/Registration done in room if empty (1)
- Used Protocol for extremity x-rays (6)

Other

- Developed system of cards to let physician know when x-rays, EKG's, etc. were complete (7)
- Respiratory Therapy in Emergency Saturday, Sunday and Monday 0900-2100, cross trained to do EKG's, draw blood (5)
- In house admitting physician to do workup upstairs (2)
- Additional Radiology tech added for weekend coverage (4)
- Contest held among the 4 teams of caregivers to determine the best ideas for decreasing delays (8)
- Contest among the 4 teams to determine best efficiency (10)

Results:

- Decreased wait time in Fast Track by more than 50%
- Decreased wait time in main Emergency by 40%
- Chartered inpatient admission process team to facilitate admission of ECC patients
- Decreased number of patients who leave without being seen by 50%
- These improvements made in spite of a 17% **increase** in patient volume since January 1997

IHC – Discharge Medications for Patients with Heart Disease

Aim: Improve to over 90% the proportion of CV patients, without specific contraindications, receiving appropriate discharge medications:

- Post MI — beta blocker
- CHF / LV systolic dysfunction — ACE inhibitor
- Ischemic heart disease — aspirin + HMG-CoA reductase inhibitor (statin)
- Chronic atrial fibrillation — warfarin

Outcomes measure(s): Among "ideal" patients (those who met indications, but had no drug-specific contraindications), proportion discharged on the indicated medication.

Sampling scheme: Baseline rates established through random sample chart review of all eligible patients, January – June, 1999. All eligible patients tracked and recorded using manual data sheets, completed by nurse at the time of discharge, from July 1999 on. Manual data collection sheets were compared to cases identified by examining ICD-9 diagnosis and procedure codes in hospital case-mix files, to insure that no eligible patients were missed.

Beta Blockers at discharge

Interventions:

1- Introduction of a standing order set, containing indication and contraindication check-off boxes for cardiac medications, placed in chart by nurses, with physician override. Tear-off copy for data collection.

2- Three additional hospitals added to original intervention site.

3- Repeat inservice of nurses, with introduction of regular performance feedback

Summary results:

	Baseline (Jan-Jun 99)	Intervention (Mar-Oct 00)
Beta blockers	57%	97%
ACE inhibitors	63%	95%
Aspirin	65%	98%
Statins	68%	91%
Warfarin	10%	92%

Use outside experience

Question posed on a listserve:

We are looking to reduce waiting time in the ED due to waiting for the Respiratory Therapists (RCPs). Three alternatives are under review:

1. *Transfer the RCPs' hours for ABGs and simple treatments to the ED, where they will be covered by the nursing staff.*
2. *Assign RCPs to the ED. Combine the job duties of the RCP with the ED technicians to fully utilize the position.*
3. *Assign RCPs to the ED. Combine the job duties of the RCP with the ED technicians and assign nursing duties (IV insertion, medication administration, etc.) to fully utilize the position.*

Has anyone attempted to institute any of the above alternatives? We are interested in hearing about your results and any difficulties in the implementation.

Improving time series evidence

Account for competing events

- ***Alternately add and remove the change*** *(ABAB design)*
- ***Stagger implementation in different units***
  (multiple time series, indexed back together for combined analysis)
- ***Identify and track potential competing events***
- ***Use non-randomized control groups***
  (quasi-experimental designs -- level II-1 evidence)

Account for selection bias

- ***Stagger implementation in different units, choosing units that cover a wide range of conditions***
- ***Identify and track potential sources of bias***
  (risk adjust inputs -- patients -- for known outcome predictors)

Effective use of data

- *Seek usefulness, not perfection*
- *Use a balanced set of measures*
- *Plot data over time*
- *Do not wait for the IS department*
- *Use sampling*
- *Use qualitative as well as quantitative data*
- *Choose summary statistics with caution*

A balanced set of measures

Consider:

- ***Medical results*** *(complications, achieving therapeutic goals, patient-assessed functional status; "quality" in traditional medical)*
- ***Patient / family satisfaction*** *(clinician-patient relationship, access / hassle / convenience issues; service quality)*
- ***Costs*** *(to complete the value equation)*
- ***Compliance with treatment indications*** *(appropriateness guidelines / utilization management)*
- ***Volume*** *(sometimes expressed as rates, as well as counts)*
- ***Cycle time*** *(for improvement as well as process function)*

(Thought) assignment

- ***Choose one or more improvement efforts in which you have been involved***
- ***What was the time, in days, between when the aim for the effort was established and when the first change was made, on a test or a permanent basis?***

Testing a change

- ***Assumptions about time***
  (Year-Quarter-Month-Week-Day-Hour- Minute)
- ***Minimum data requirement: before and after time series***
- ***Test on a small scale*** *(small tests, not small changes!)*
- ***Test under a variety of conditions***
- ***Build knowledge sequentially***

Promote and communicate change

- *Explain why a change is needed as soon as the aim is established*
- *Let people know who is on the team*
- *Assume the role of ambassador for change*
- *Leverage a prior successful change, using its attributes as an outline for your communication*
- *Keep the communications flowing as changes are developed and tested*
- *Widely publicize the results of your tests*
- *Utilize different media and forums*