Has Quality Improvement Improved Outcomes in Neonatology?

Munish Gupta, MD MMSc

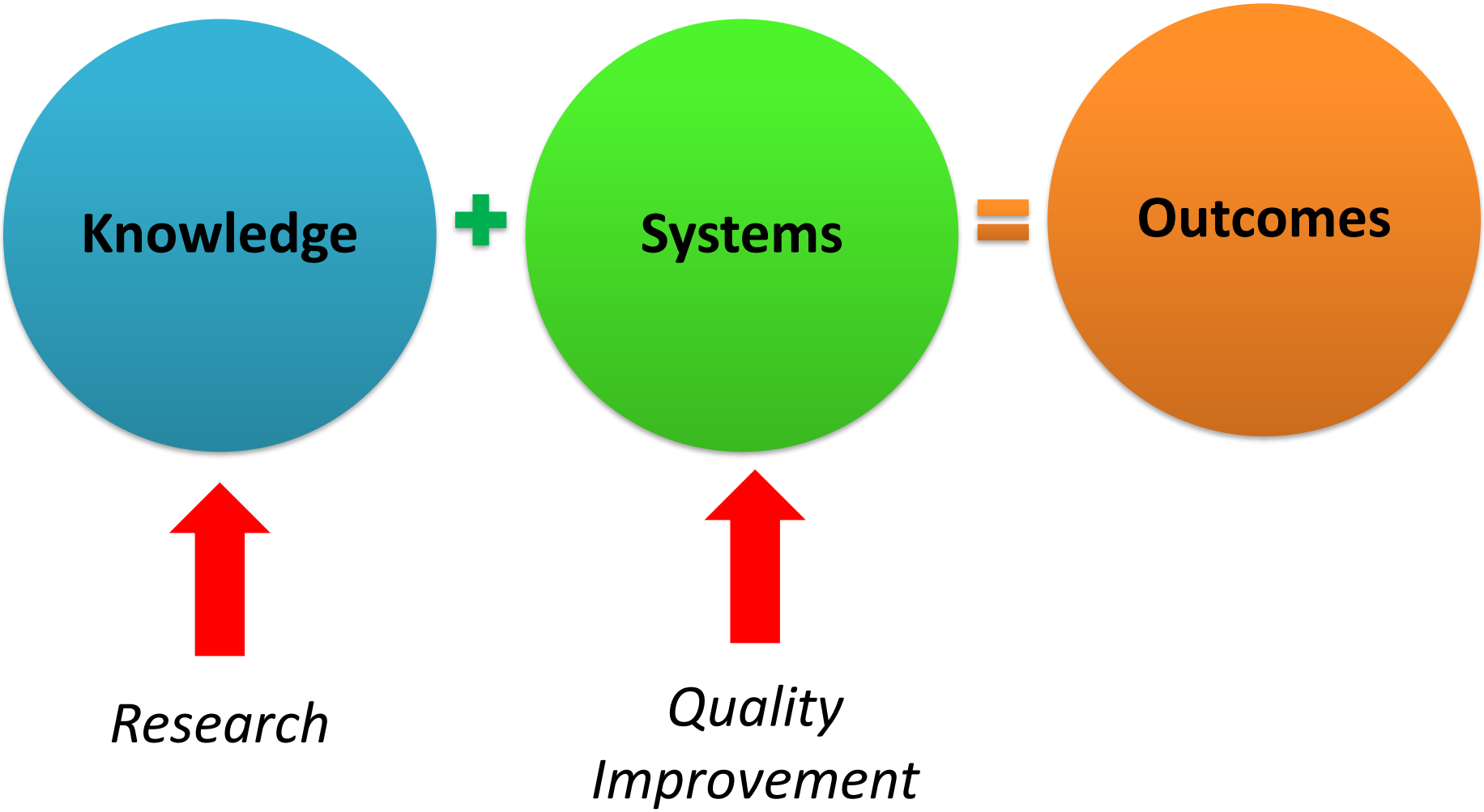
SHINE Conference

January 22, 2026


Duh
No duh
imgflip.com
JAKE-CLARK.TUMBLR

How do we improve outcomes in health care?

The Goal of Health Care



Adapted from Batalden, Qual Saf Health Care, 2007

Outline

1. Why isn't research enough?
2. How QI can help!
3. How QI may not help
4. Doing QI better

Definitions

- **Research**: a systematic investigation designed to develop or contribute to generalizable knowledge.
- **Quality Improvement**: systematic, data-guided activities aimed at improving care, processes, or outcomes in an organization.

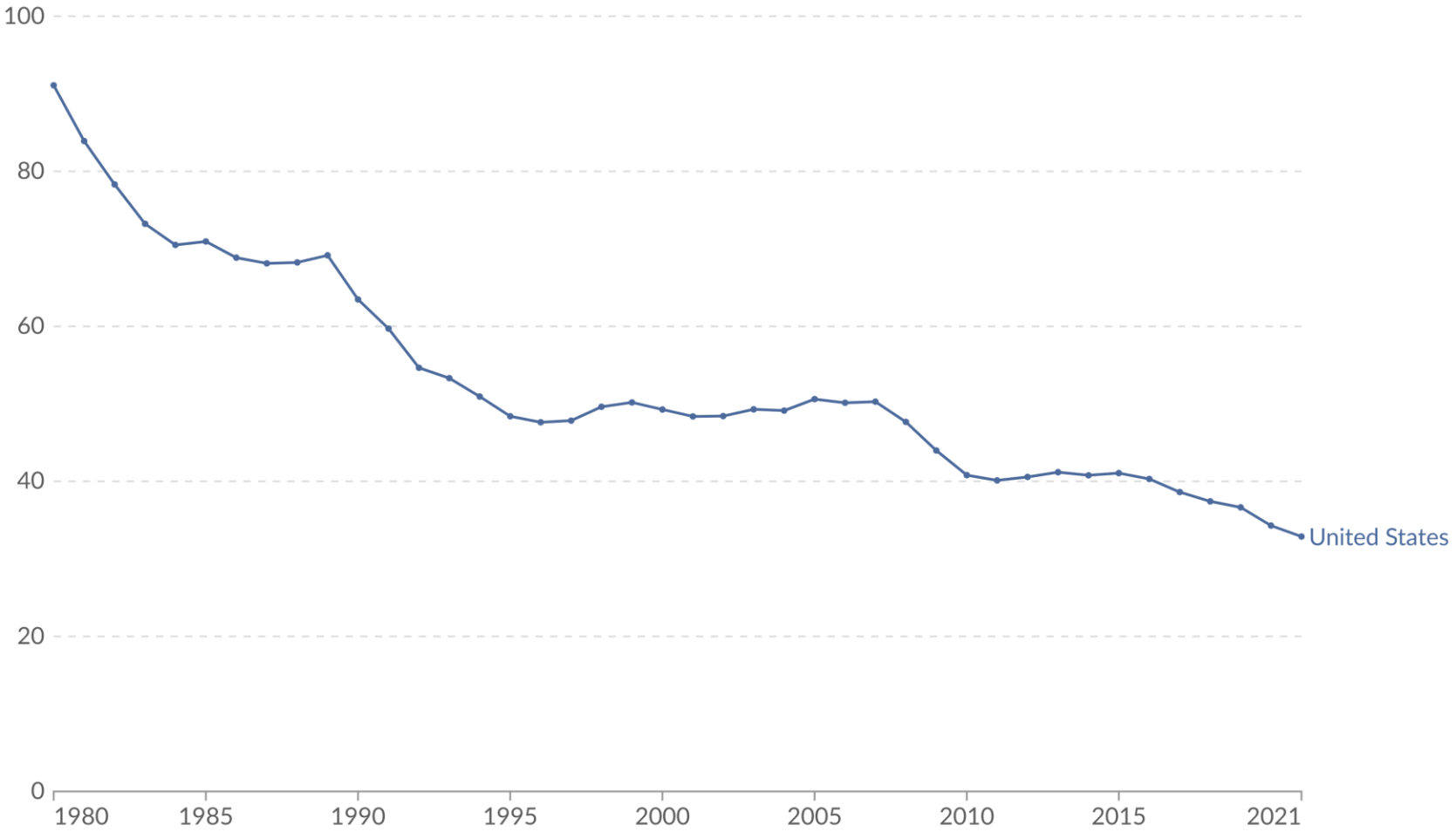
Levels of Evidence

Research has dramatically improved care and outcomes for newborns.

Death rate from neonatal preterm birth complications, 1980 to 2021

Our World in Data

The estimated death rate from neonatal[1] preterm birth complications[2] in children under five years old, per 100,000.



Data source: IHME, Global Burden of Disease (2024)

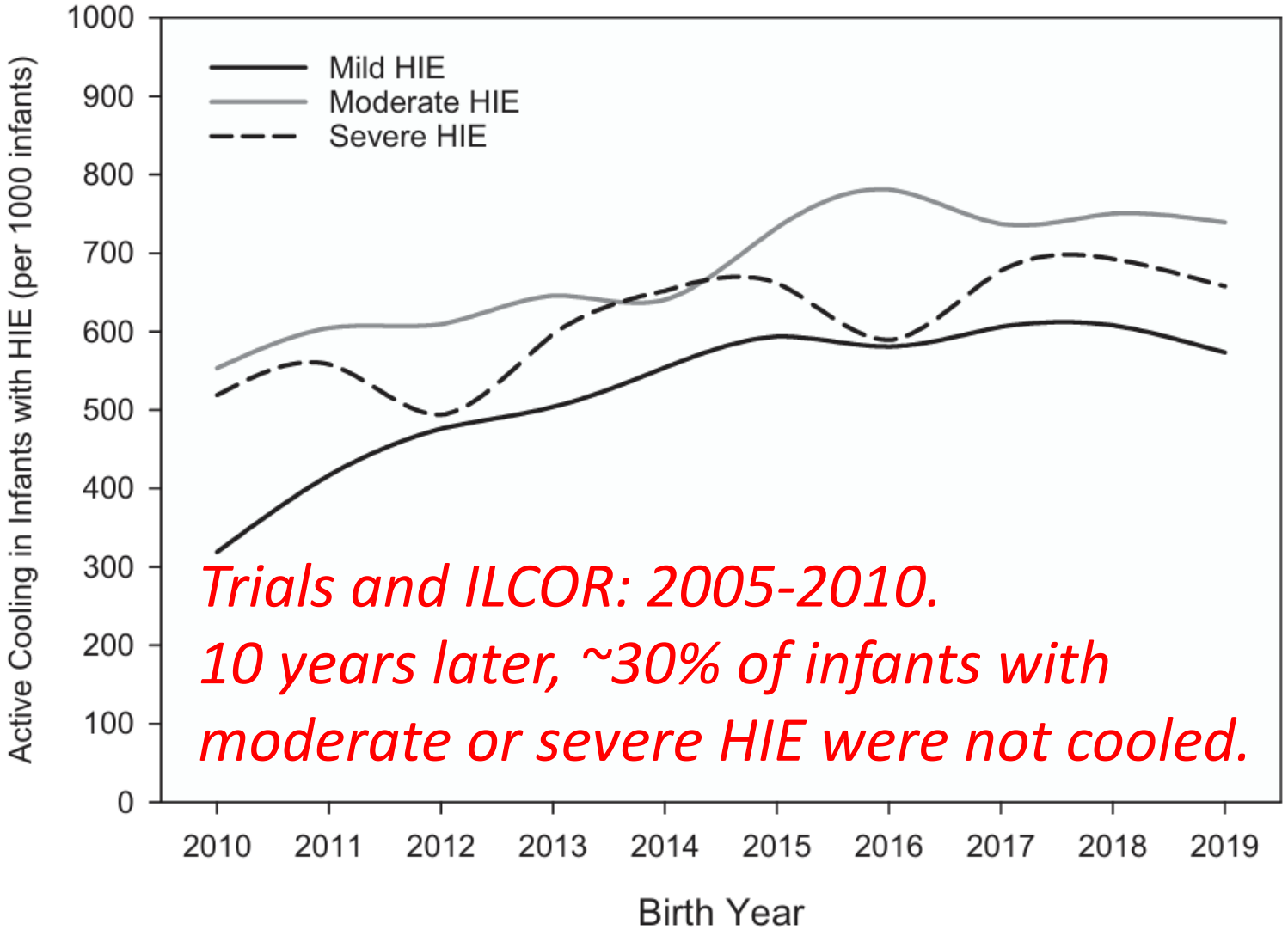
OurWorldinData.org/child-mortality | CC BY

Research has some limitations.

Why isn’t research enough?

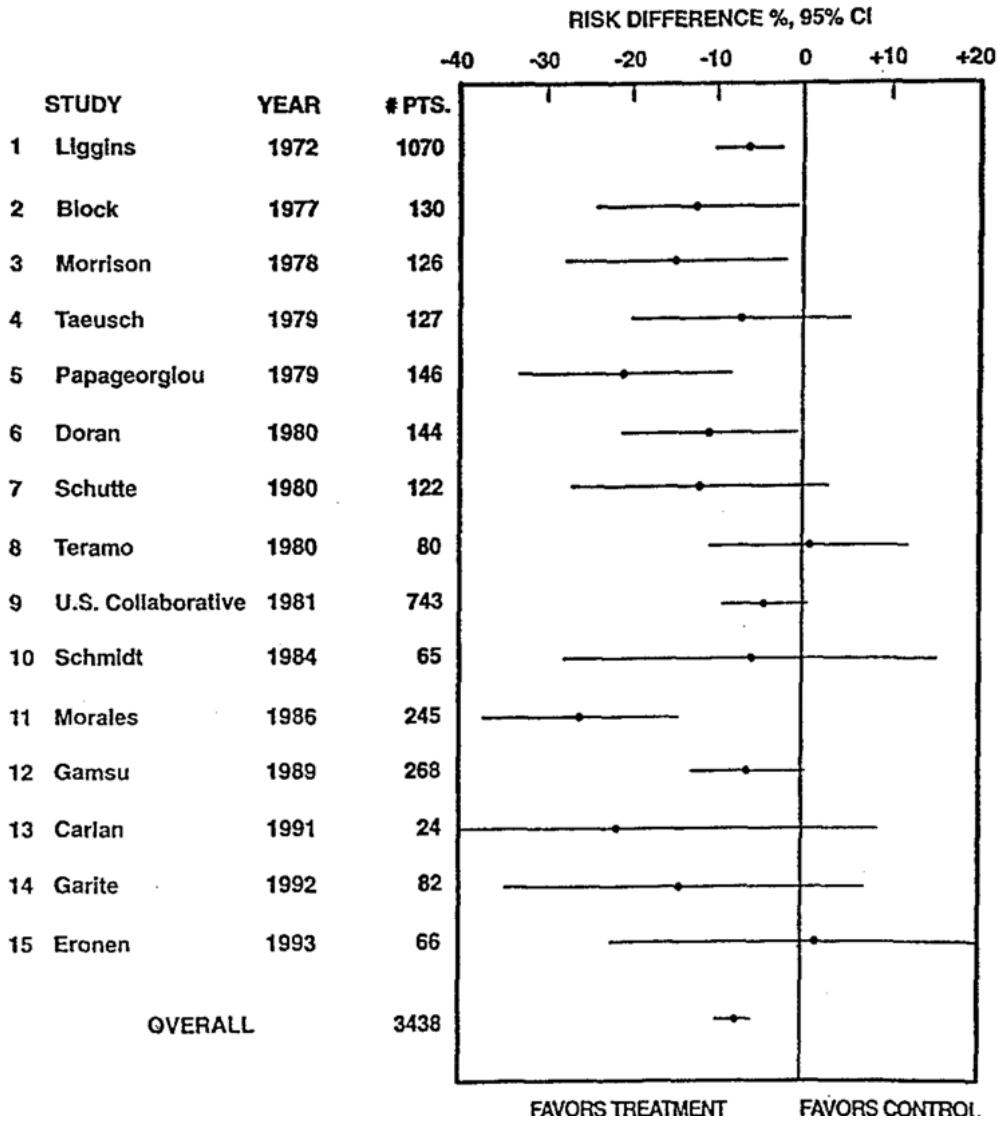
- Dissemination

Therapeutic Hypothermia for HIE, California



Bonifacio et al, Pediatrics, 2024

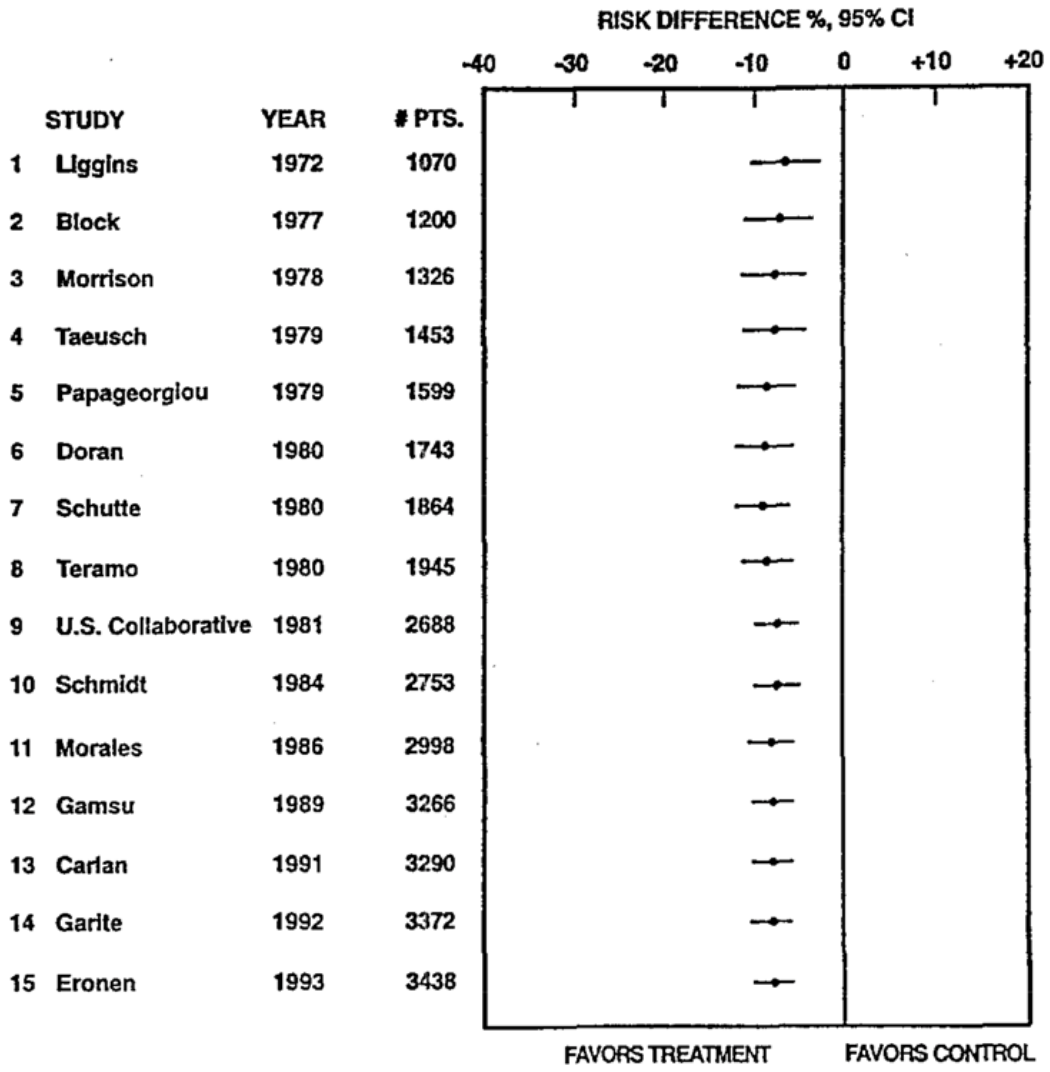
Antenatal Corticosteroids, Impact on RDS



15 RCTs of antenatal steroids over 20+ years

Sinclair J. Am J Obstet Gynecol. 1995; 173: 335

Antenatal Corticosteroids, Impact on RDS

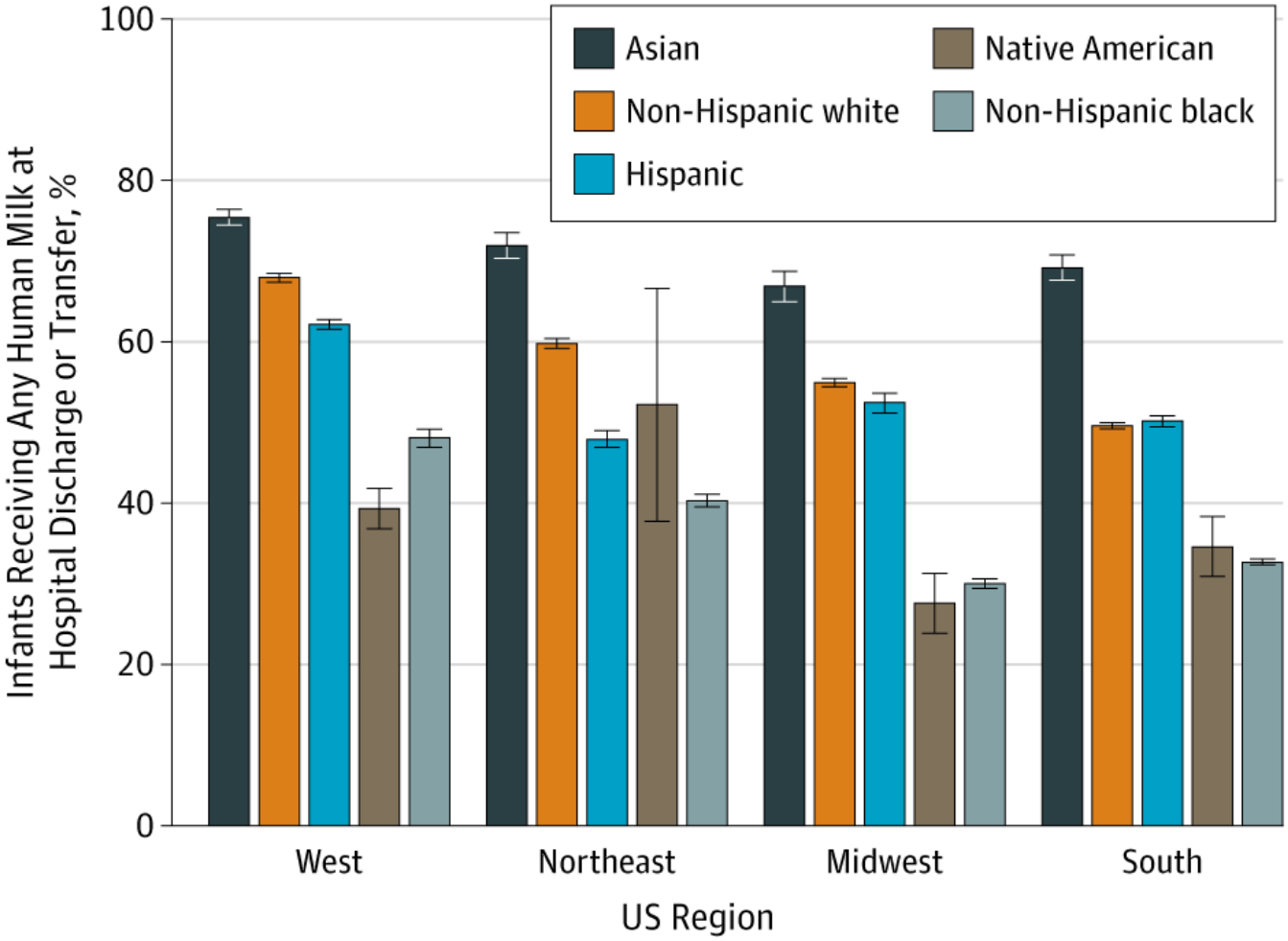


Effect size was basically known after FIRST trial

Sinclair J. Am J Obstet Gynecol. 1995; 173: 335

Variation in Any Human Milk at Discharge Among NICUs by Region and race/ethnicity

VLBW infants, 2008 to 2017



Parker et al, JAMA Pediatrics, 2019

Why isn’t research enough?

- Dissemination
- Context

COMMENTARY

The Science of Improvement

Donald M. Berwick, MD, MPP, FRCP

IN THE EARLY 1890S, DR WILLIAM HALSTED DEVELOPED radical mastectomy for breast cancer. Surgeons performed the Halsted procedure for more than 80 years even though there was little systematic evidence for its

strained, progress may be the victim. For example, the RCT is a powerful, perhaps unequaled, research design to explore the efficacy of conceptually neat components of clinical practice—tests, drugs, and procedures. For other crucially important learning purposes, however, it serves less well.

Recent controversies about the evaluation of rapid re-

JAMA, March 12, 2008—Vol 299, No. 10 (Reprinted)

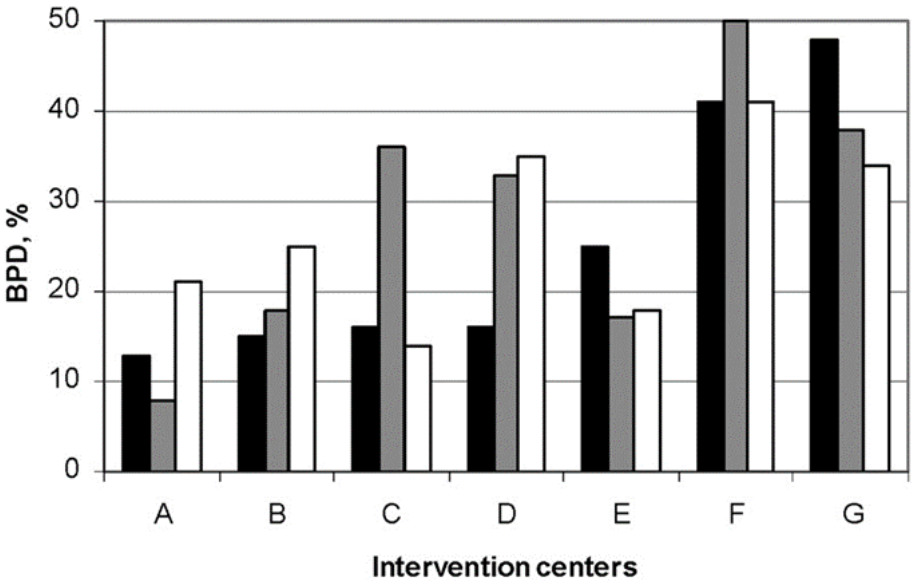
The Science of Improvement

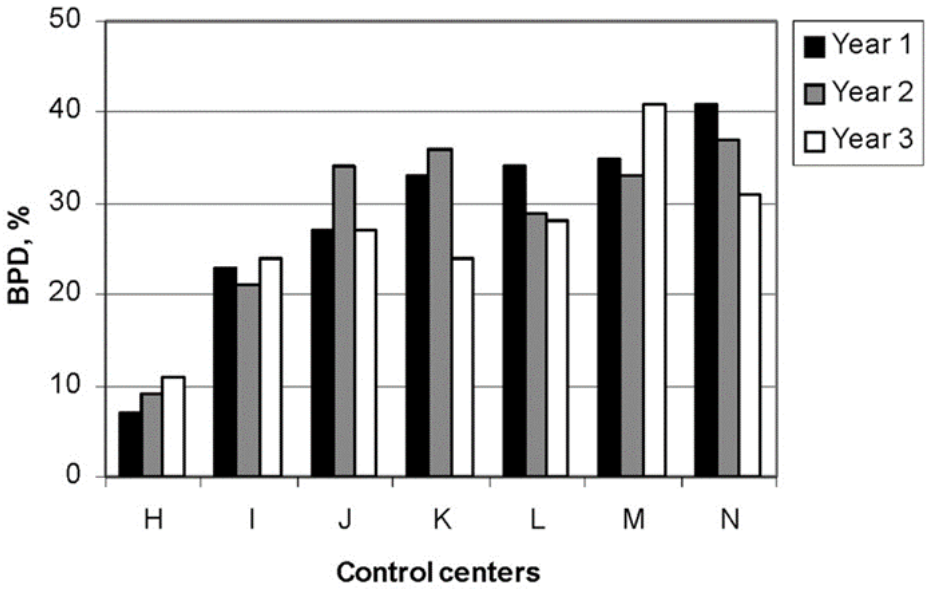
- In 1990s, wide spread of hospital-based rapid response teams based on numerous reports of beneficial impact
- In 2005, cluster randomized trial of rapid response teams (MERIT) found no benefit
- How to reconcile these?

Berwick, JAMA, 2008

Randomized trial of QI for BPD

14 centers: 7 randomized to QI package, 7 control





No impact on rates of BPD

Context

Context is external and internal factors and conditions that affect the delivery of health care. Traditional research models REMOVE context from analysis.

"In such complex terrain, the RCT is an impoverished way to learn."

-- D. Berwick

NIPPV: Evidence

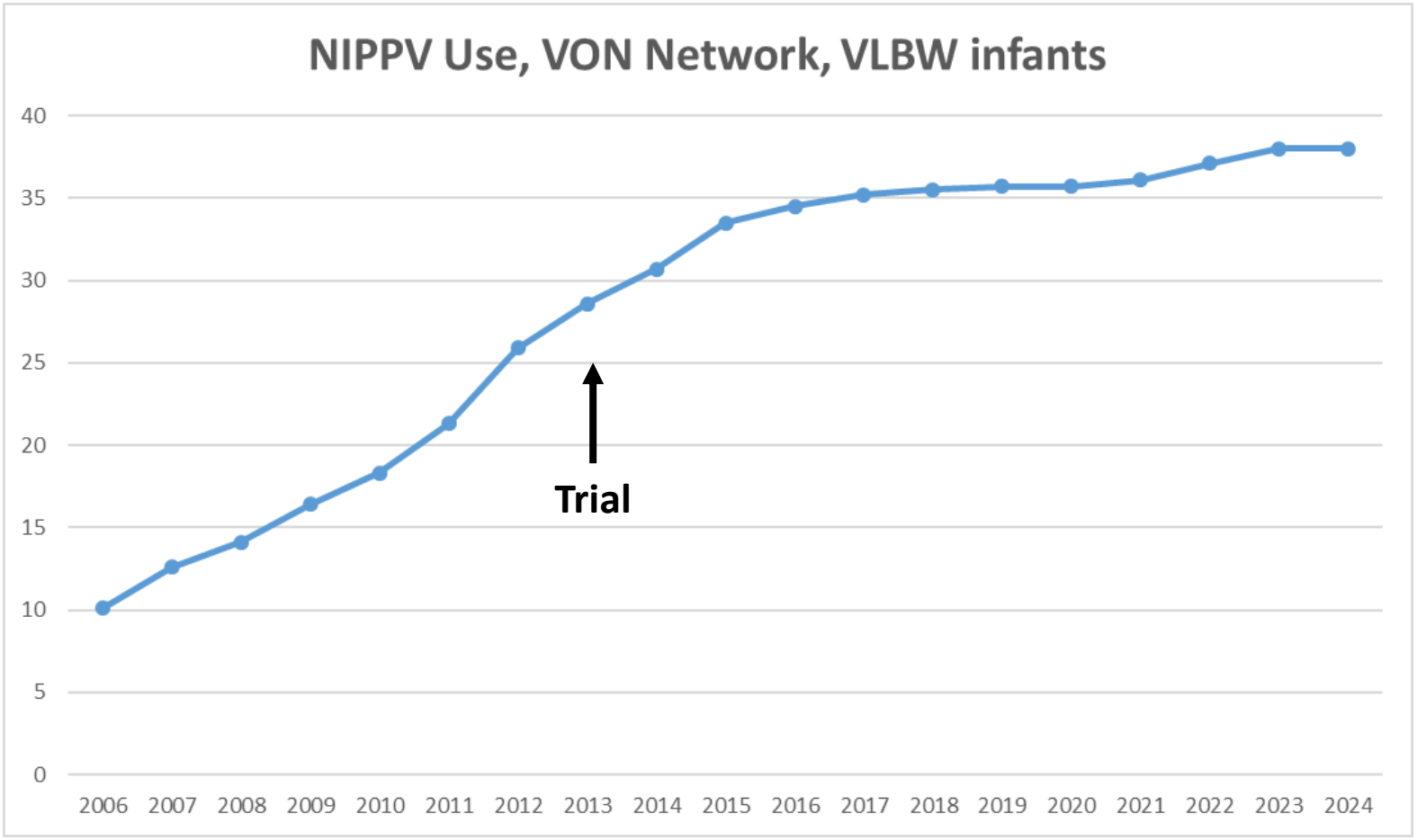
Table 2. Primary Outcome.*

Outcome	Nasal IPPV	Nasal CPAP	Odds Ratio	Odds Ratio Adjusted for Strata (95% CI)	P Value	Odds Ratio Adjusted for Strata and Baseline Covariates (95% CI)†
	no./total no. (%)					
Primary outcome: death at <36 wk of post-menstrual age or BPD	191/497 (38.4)	180/490 (36.7)	1.07	1.09 (0.83–1.43)‡	0.56	1.05 (0.80–1.39)
Components of primary outcome						
Death at <36 wk of postmenstrual age	34/504 (6.7)	41/503 (8.2)	0.82	0.81 (0.51–1.31)§	0.39	0.77 (0.48–1.24)
Survival with BPD	157/463 (33.9)	139/449 (31.0)	1.14	1.17 (0.86–1.57)‡	0.32	1.14 (0.84–1.54)
Death at <36 wk of postmenstrual age or BPD according to older NIH criteria in 20 infants	197/504 (39.1)	193/503 (38.4)	1.03	1.03 (0.79–1.35)‡	0.82	1.00 (0.76–1.31)

Large RCT (1000 infants) of NIPPV in preterm infants: no differences in any outcomes

Kirpalani et al, NEJM, 2013

NIPPV: Actual Use



Many centers find NIPPV works → LOCAL context

Adapting evidence to context

Medication

Respiratory Support

High Risk Follow Up Program

Less Context Sensitive

More Context Sensitive

Why isn't research enough?

- Dissemination → knowing what to do is not the same as doing it
- Context → complex systems may not fit research designs

How about QI?
Does it work?

Does quality improvement work in neonatology improve clinical outcomes?

Dan L. Ellsbury and Reese H. Clark

Current Opinion in Pediatrics, April 2017

Has Quality Improvement Really Improved Outcomes for Babies in the Neonatal Intensive Care Unit?

Alan R. Spitzer, MD

Clinics in Perinatology, September 2017

REVIEW ARTICLE

Advancements in neonatology through quality improvement

Stephen A. Pearlman [1,2]✉

Journal of Perinatology, October 2022

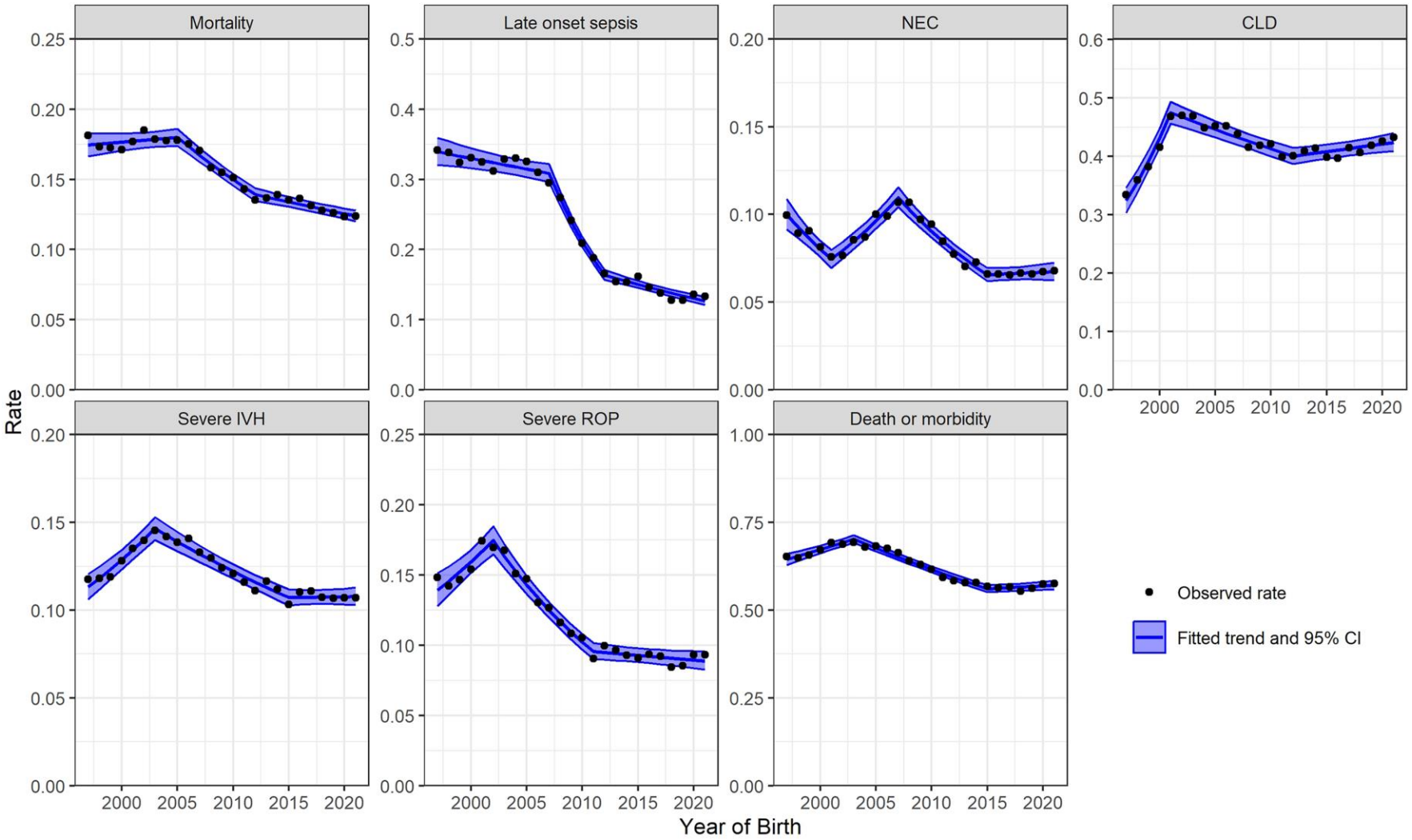
Cutting into the NICU: Improvements in Outcomes for Neonates with Surgical Conditions

Stephanie L. Bourque, MS, MSCS,* Karna Murthy, MD, MSc,† Theresa R. Grover, MD,* Loren Berman, MD, MHS,‡§ Stefanie Riddle, MD¶

NeoReviews, October 2024

Vermont-Oxford Network: 1997-2021

Infants born 24 to 28 weeks, 888 hospitals total



Horbar et al, Pediatrics, 2024

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Successful QI in neonatology

CLABSI	Unplanned extubations	Medication errors	Feeding, necrotizing enterocolitis
Retinopathy of prematurity	Perinatal opioid use	Bronchopulmonary dysplasia	Delivery room, golden hour
Intraventricular hemorrhage	Neonatal encephalopathy	Family-centered care	Parental mental health
Social determinants of health	Value and waste	Global improvement	Equity


50
1972
YEARS
2022
PHYSICIANS IN TRAINING
AND SCIENTIFIC ADVANCEMENTS
IN NEONATOLOGY
RECKITT/MEAD JOHNSON NUTRITION | AMERICAN ACADEMY OF PEDIATRICS

Key Scientific Milestone, by Decade

1970s	CPAP
1980s	Surfactant replacement
1990s	Nitric oxide
2000s	Therapeutic hypothermia
2010s	Benchmarking and collaborative QI

Let’s explore a couple of examples a little more closely.

Example 1: CLABSI
"the cost of doing business"

Is Bloodstream Infection Preventable Among Premature Infants? A Tale of Two Cities

Hany Aly, MD*; Victor Herson, MD‡; Anne Duncan, RN*; Jill Herr, MSN‡; Jean Bender, APRN‡; Kantilal Patel, PhD§; and Ayman A. E. El-Mohandes, MD, MPH*

PEDIATRICS Vol. 115 No. 6 June 2005

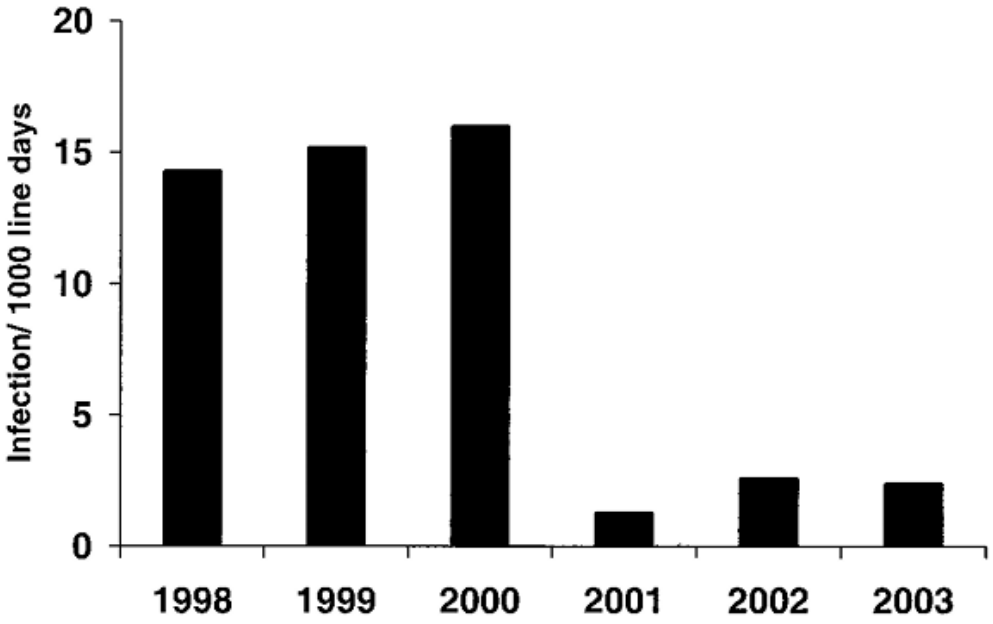


Fig 2. Annual rates of central line-related BSIs at George Washington University Hospital.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 28, 2006 VOL. 355 NO. 26

An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

Table 4. Incidence-Rate Ratios for Catheter-Related Bloodstream Infections.*

Variable	Incidence-Rate Ratio (95% CI)	P Value
Study period		
Baseline	1.00	
During implementation	0.76 (0.57–1.01)	0.063
After implementation		
0–3 mo	0.62 (0.47–0.81)	0.001
4–6 mo	0.56 (0.38–0.84)	0.005
7–9 mo	0.47 (0.34–0.65)	<0.001
10–12 mo	0.42 (0.28–0.63)	<0.001
13–15 mo	0.37 (0.20–0.68)	0.001
16–18 mo	0.34 (0.23–0.50)	<0.001
Teaching hospital	1.34 (0.73–2.46)	0.35
Bed size (per 100 beds)	1.03 (0.97–1.09)	0.33

* Incidence-rate ratios were calculated with the use of a generalized linear latent and mixed model (Rabe-Hesketh and Skrondal[18]), with robust variance estimation and random effects to account for clustering of catheter-related bloodstream infections within hospitals and clustering of hospitals within geographic regions. Rates of catheter-related bloodstream infection during and after implementation of the study intervention were compared with baseline (preimplementation) values, adjusted for the hospital's teaching status and number of beds.

Care bundles to reduce central line-associated bloodstream infections in the neonatal unit: a systematic review and meta-analysis

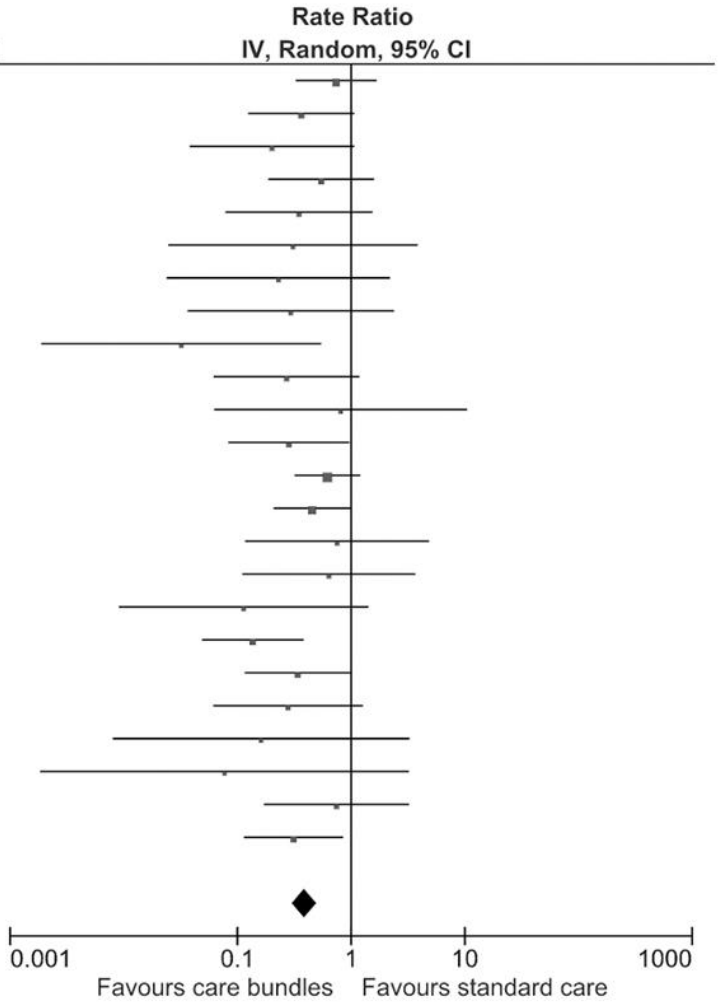
Victoria Payne,[1] Mike Hall,[2] Jacqui Prieto,[1] Mark Johnson[2,3]

Arch Dis Child Fetal Neonatal Ed 2018

24 studies: five observational, 19 QI

Study or Subgroup	log[Rate Ratio]	SE	Weight	Rate Ratio IV, Random, 95% CI
Almeida 2016	-0.30436899	0.40874911	10.3%	0.74 [0.33, 1.64]
Arnts 2015	-1.0096648	0.53878134	5.9%	0.36 [0.13, 1.05]
Bizzarro 2010	-1.60235406	0.84066563	2.4%	0.20 [0.04, 1.05]
Bowen 2016	-0.6061358	0.53497223	6.0%	0.55 [0.19, 1.56]
Ceballos 2013a	-1.05605267	0.74939589	3.1%	0.35 [0.08, 1.51]
Chandonnet 2012	-1.178655	1.27852078	1.0%	0.31 [0.03, 3.77]
Erdei 2015	-1.47286238	1.1435612	1.3%	0.23 [0.02, 2.16]
Fisher 2013	-1.22276072	1.05635036	1.5%	0.29 [0.04, 2.33]
Kime 2011	-3.4404181	1.4366985	0.8%	0.03 [0.00, 0.54]
McMullan 2016	-1.30715704	0.74325612	3.1%	0.27 [0.06, 1.16]
Piazza 2016	-0.21192848	1.29662937	1.0%	0.81 [0.06, 10.27]
Rallis 2016	-1.26113122	0.61437039	4.5%	0.28 [0.08, 0.94]
Resende 2011	-0.48085063	0.32955708	15.8%	0.62 [0.32, 1.18]
Rosenthal 2013	-0.79126504	0.38706815	11.4%	0.45 [0.21, 0.97]
Salm 2016	-0.283887	0.94089247	1.9%	0.75 [0.12, 4.76]
Schulman 2012b (definition changed)	-0.45198512	0.88273483	2.2%	0.64 [0.11, 3.59]
Shepherd 2015	-2.17742195	1.27955262	1.0%	0.11 [0.01, 1.39]
Sinha 2016	-1.9945421	0.5140075	6.5%	0.14 [0.05, 0.37]
Steiner 2015	-1.08432633	0.53358074	6.0%	0.34 [0.12, 0.96]
Ting 2013	-1.2784054	0.76231734	2.9%	0.28 [0.06, 1.24]
Wang 2015	-1.82454929	1.52400152	0.7%	0.16 [0.01, 3.20]
Wilder 2016	-2.56494936	1.89466187	0.5%	0.08 [0.00, 3.15]
Wirstchafter 2010	-0.29546421	0.73828053	3.1%	0.74 [0.18, 3.16]
Zhou 2015	-1.16675009	0.50218317	6.8%	0.31 [0.12, 0.83]
Total (95% CI)			**100.0%**	**0.40 [0.31, 0.51]**

Heterogeneity: Tau² = 0.00; Chi² = 17.98, df = 23 (P = 0.76); I² = 0%
Test for overall effect: Z = 7.09 (P < 0.00001)



Payne et al, Arch Dis Child Fetal and Neonatal, 2018

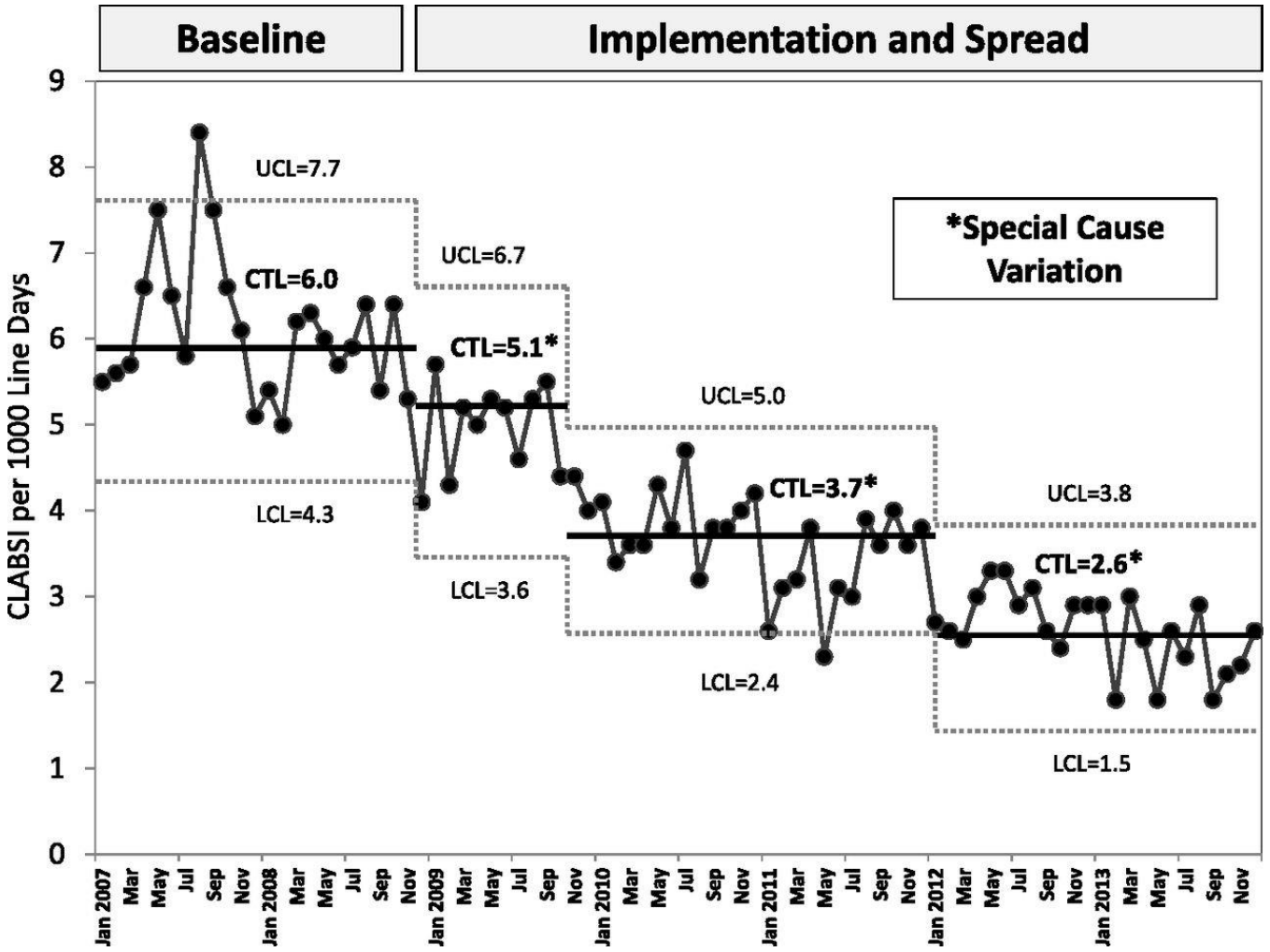
Interventions

- Skin preparation
- Maximum barriers
- Insertion checklists
- Daily line necessity
- Closed tubing systems
- Two-person tubing change
- PICC team

Are these interventions appropriate for QI?

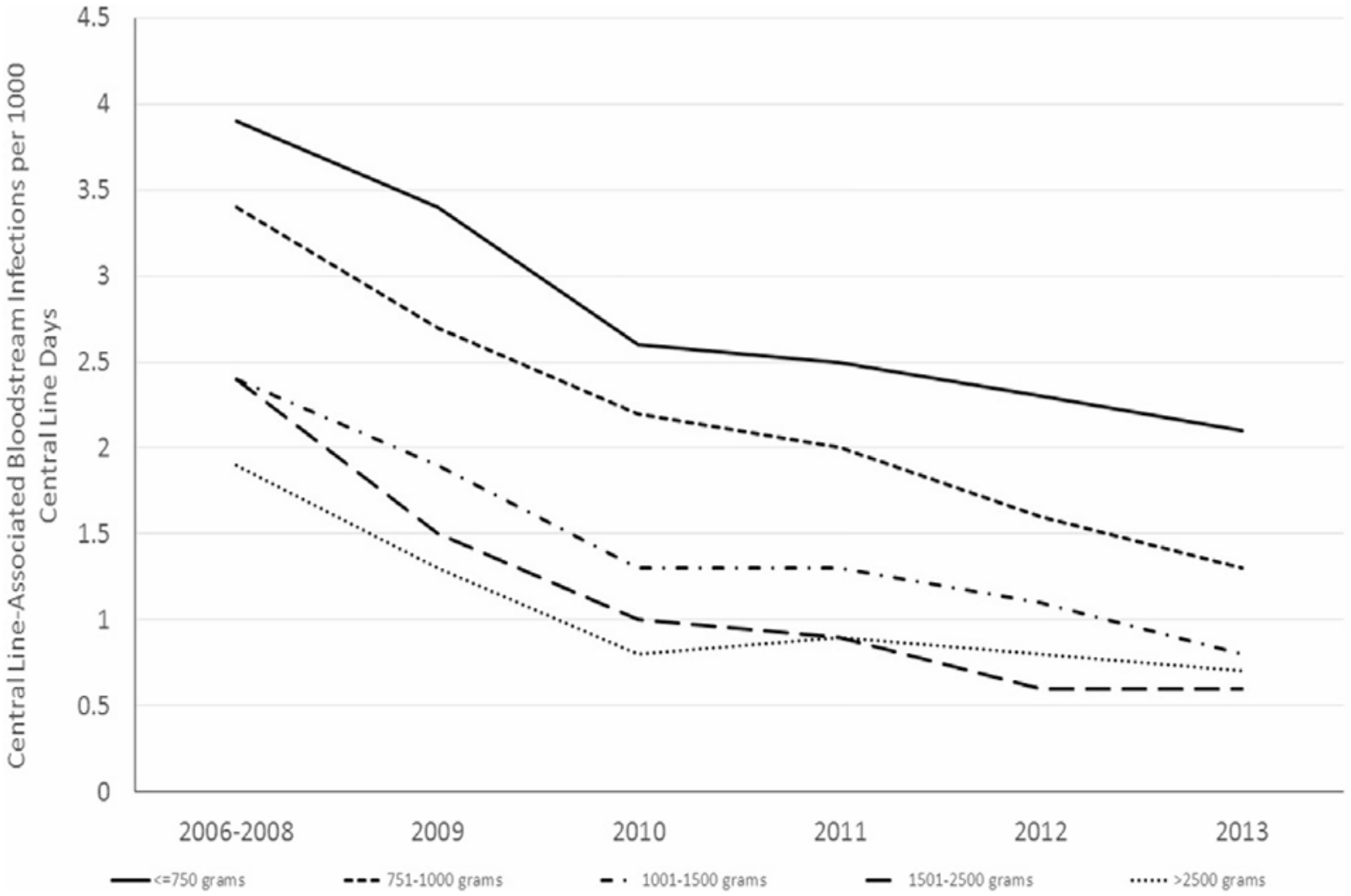
Pediatrix 100,000 Babies Campaign: CLABSI

330 U.S. NICUs, 2007 to 2013



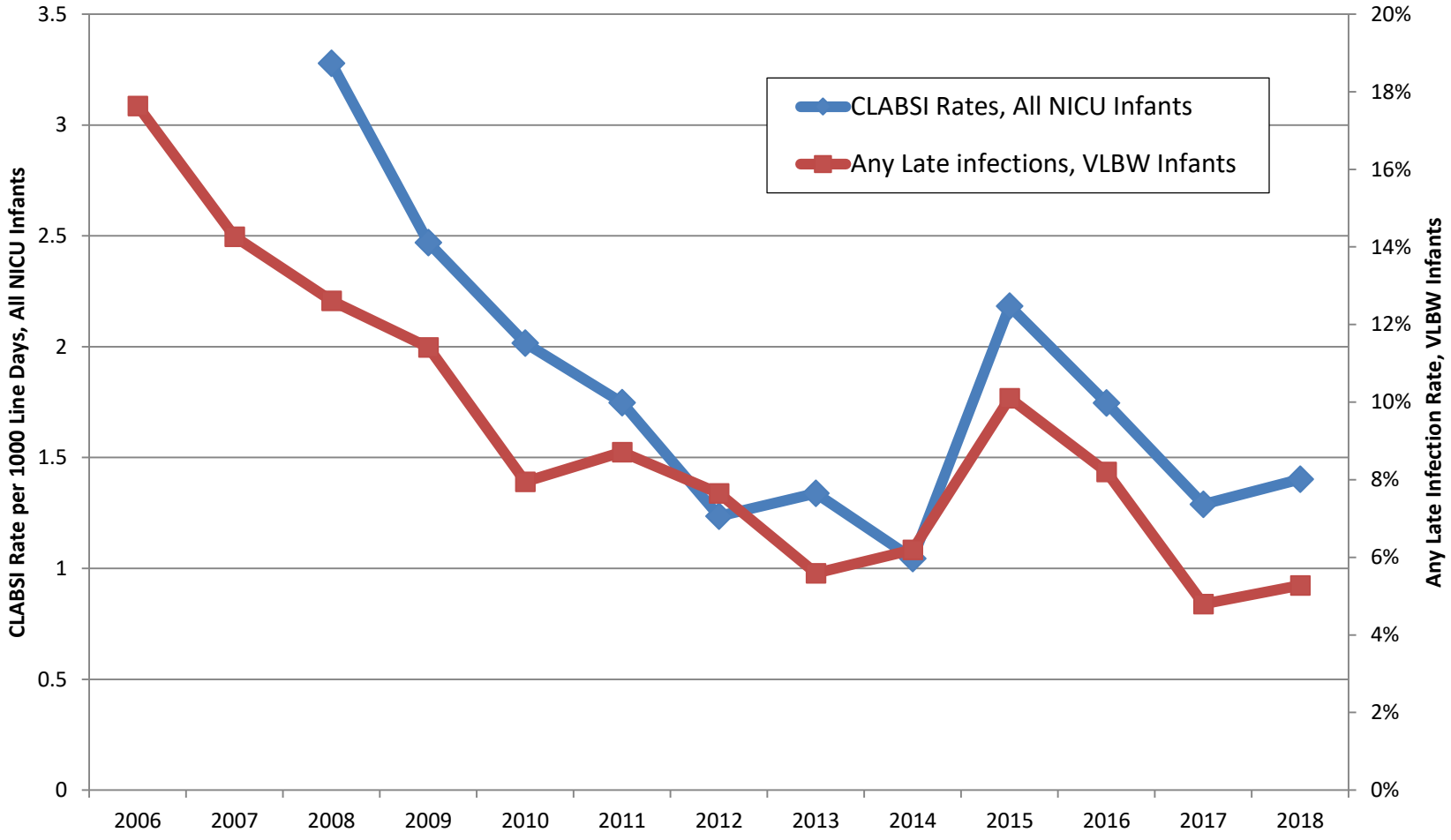
Ellsbury et al, Pediatrics, 2016

Pooled CLABSI rates by BW, Level III NICUs, NHSN



Mobley and Bizzarro, Seminars in Perinatology, 2017

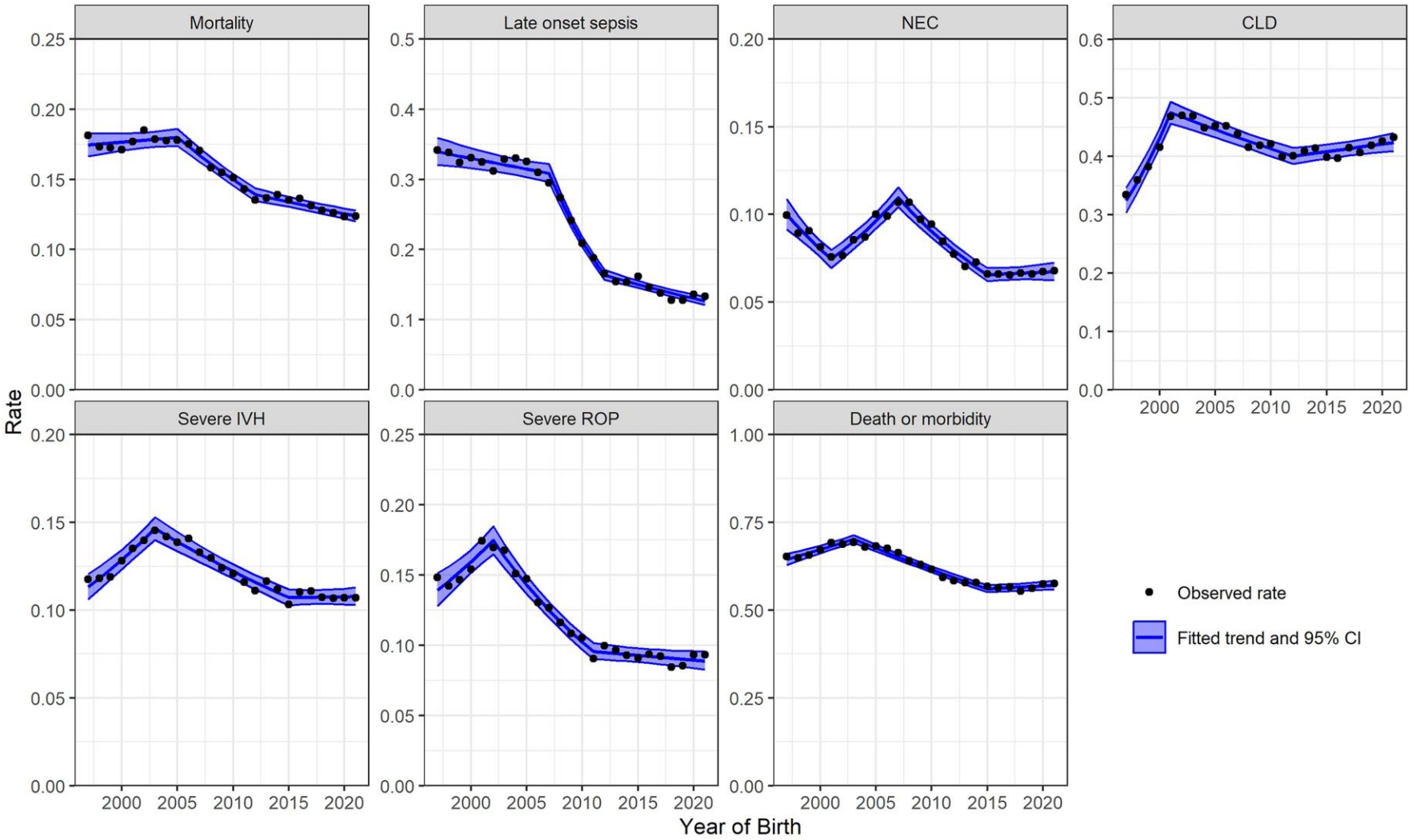
Any Late Infection and Central Line Associated Infections
Massachusetts NICUs, NeoQIC



Example 2: IVH

Vermont-Oxford Network: 1997-2021

Infants born 24 to 28 weeks, 888 hospitals total



Horbar et al, Pediatrics, 2024

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Quality Improvement Interventions to Prevent Intraventricular Hemorrhage: A Systematic Review

Erika M. Edwards, PhD, MPH,[a,b,c] Danielle E.Y. Ehret, MD, MPH,[a,b] Howard Cohen, MD, Denise Zayack, BSN, MPH,[a] Roger F. Soll, MD,[a,b] Jeffrey D. Horbar, MD[a,b]

PEDIATRICS Volume 154, number 2, August 2024:e2023064431

QI for IVH: Systematic Review

- 18 reports identified
- Many different interventions, spanning antenatal care, delivery room, and NICU
- Most widespread intervention:

Midline head positioning (15 reports)

Is midline positioning an appropriate intervention for IVH prevention?

QI reports suggest yes!
What does research show?

Cochrane Library
Trusted evidence.
Informed decisions.
Better health.

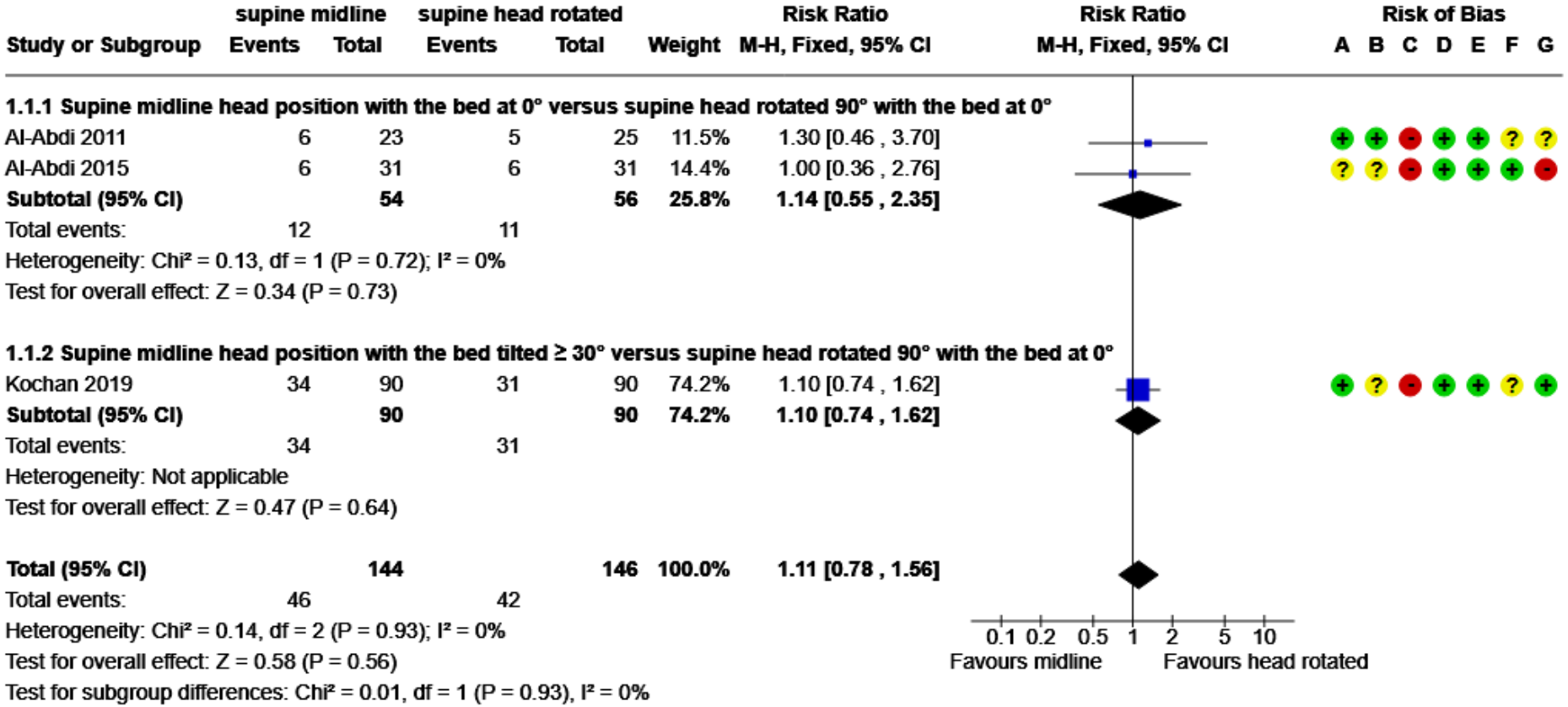
Cochrane Database of Systematic Reviews

[Intervention Review]

Head midline position for preventing the occurrence or extension of germinal matrix-intraventricular haemorrhage in preterm infants

Olga Romantsik[1], Maria Grazia Calevo[2], Matteo Bruschettini[1,3]

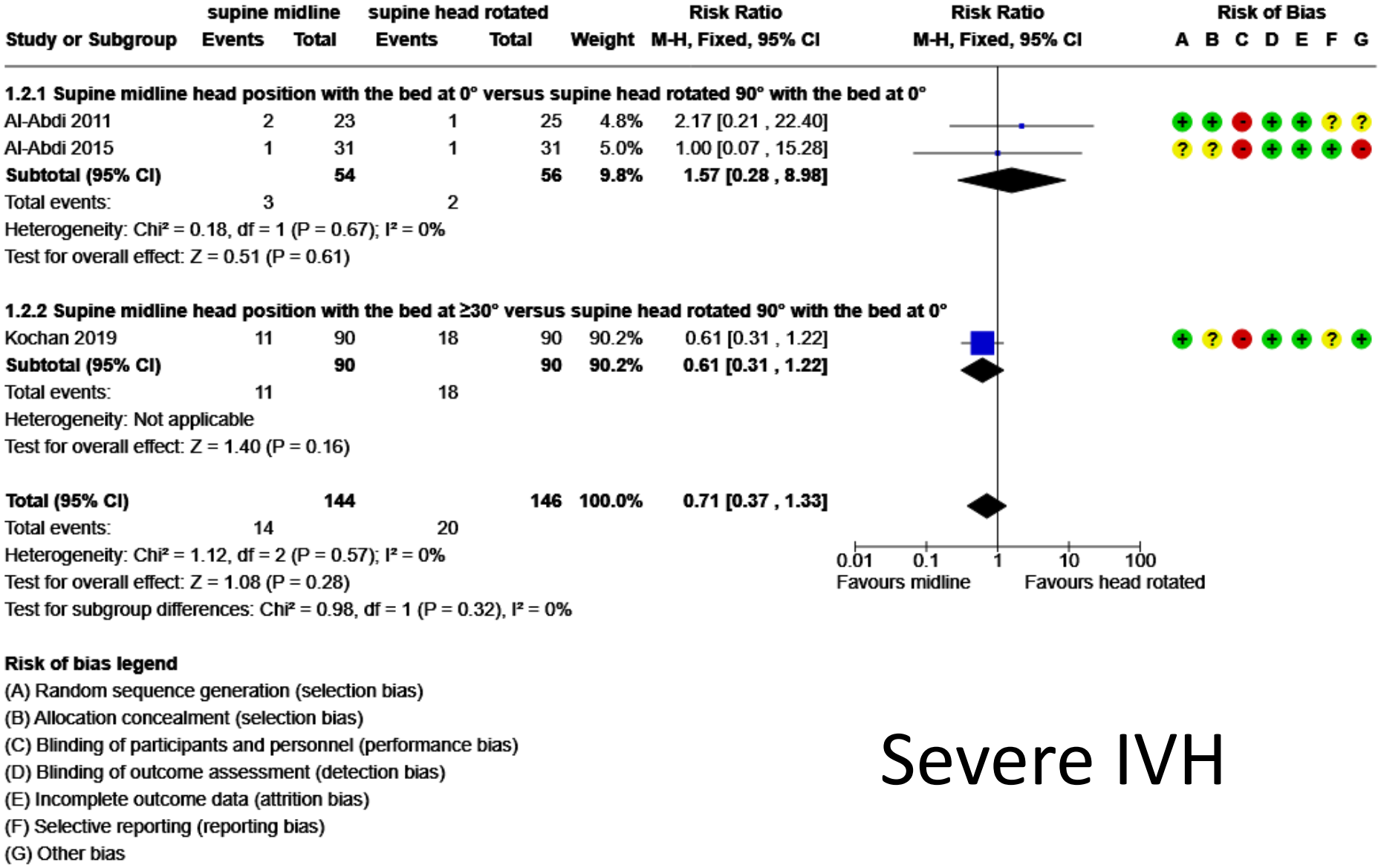
[1]Department of Clinical Sciences Lund, Paediatrics, Lund University, Skåne University Hospital, Lund, Sweden. [2]Epidemiology, Biostatistics Unit, IRCCS, Istituto Giannina Gaslini, Genoa, Italy. [3]Cochrane Sweden, Lund University, Skåne University Hospital, Lund, Sweden



Risk of bias legend

(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Any IVH



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(F) Selective reporting (reporting bias)
(G) Other bias

Severe IVH

Romantsik et al, Cochrane Reviews, 2020

Authors' conclusions

We found few trial data on the effects of head midline position on GM-IVH in very preterm infants. Although meta-analyses suggest that mortality might be reduced, the certainty of the evidence is very low and it is unclear whether any effect is due to cot tilting (a co-intervention in one trial). Further high-quality RCTs would be needed to resolve this uncertainty.

World Journal of Pediatrics (2025) 21:533–536
https://doi.org/10.1007/s12519-025-00922-6

EDITORIAL

Does midline head positioning decrease intraventricular hemorrhage or is it futile? Without a definitive trial, we will never know

Traci-Anne Goyen[1,2] · Pranav R. Jani[1,3] · Hannah Skelton[1,4] · Kylie Pussell[5] · Brett Manley[6,7,8] · William Tarnow-Mordi[9] · Positioning the preterm Infant for Neuroprotection (PIN) trial Investigator Collaborative Group

So where did this come from?

Evaluation and Development of Potentially Better Practices for the Prevention of Brain Hemorrhage and Ischemic Brain Injury in Very Low Birth Weight Infants

Patricia Carteaux, RN*; Howard Cohen, MD‡; Jennifer Check, BS§; Jeffrey George, DO‖; Pamela McKinley, RN¶; William Lewis, MD*; Patricia Hegwood, RN, MA‡; Jonathan M. Whitfield, MB ChB¶; Debra McLendon, RN, BSN§; Susan Okuno-Jones, RN, BSN, MA‖; Sharon Klein, RN, MS‡; Jim Moehring, RRT*; and Connie McConnell, RN‡

PEDIATRICS Vol. 111 No. 4 April 2003

Maintain Neutral Head Position When Turning and Positioning the Infant With the Head of the Bed Elevated 30 Degrees

The level of evidence is 4 or 6. Studies[29,30] have shown that turning the infant's head to the side affects jugular venous return and may affect intracranial pressure and cerebral blood flow. The benchmark site with the lowest rate of ICH used this practice.

Head position affects intracranial pressure in newborn infants

Journal of Pediatrics, 1983

14 infants, 6 with “asphyxia”, mean GA 35-36 weeks

Changes in Superior Sagittal Sinus Blood Velocities Due to Postural Alterations and Pressure on the Head of the Newborn Infant

Journal of Pediatrics, 1983

18 infants, healthy mean GA 39 weeks

Numerous examples demonstrate results of observational studies (including QI) may not match results of randomized trials.

While QI can convincingly show improvement in outcomes, we should be thoughtful about using QI to evaluate interventions that may have risks.

QI is not designed to show safety.

Another caution for QI. We need to do QI well to minimize risks of bias, chance, and confounding.

Unfortunately, we don't seem to do it that well.

SYSTEMATIC REVIEW

OPEN ACCESS

Systematic review of the application of the plan–do–study–act method to improve quality in healthcare

Michael J Taylor,[1,2] Chris McNicholas,[2] Chris Nicolay,[1] Ara Darzi,[1] Derek Bell,[2] Julie E Reed[2]

BMJ Quality and Safety, 2014

- 73 QI publications
- Less than 20% met criteria

RESEARCH ARTICLE Open Access

Can quality improvement improve the quality of care? A systematic review of reported effects and methodological rigor in plan-do-study-act projects

Søren Valgreen Knudsen[1,3*], Henrik Vitus Bering Laursen[3], Søren Paaske Johnsen[1], Paul Daniel Bartels[4], Lars Holger Ehlers[3] and Jan Mainz[1,2,5,6]

BMC Health Services Research, 2019

- 120 QI publications
- 3 met all four criteria

Quality Assessment of the Literature on Quality Improvement in PICUs: A Systematic Review

OBJECTIVES: To synthesize the literature describing quality improvement in PICUs and to appraise the quality of extant research.

DATA SOURCES: We searched the PubMed, Cumulative Index to Nursing and Allied Health Literature, and the Cochrane Central Register of Controlled Trials databases between May and June 2020.

STUDY SELECTION: Peer-reviewed articles in English that report quality

Yu Inata, MD[1,2]
Etsuko Nakagami-Yamaguchi, MD, PhD[1]
Yuko Ogawa, MD[2]
Takeshi Hatachi, MD, PhD[2]
Muneyuki Takeuchi, MD, PhD[2]

- 158 articles
- Rated with QI-MQCS
- Mean score: 11/16
- 17% “high quality”

Pediatric Critical Care Medicine, 2021

BMJ Open Quality

Completeness of reporting of quality improvement studies in neonatology is inadequate: a systematic literature survey

Zheng Jing Hu ,[1] Gerhard Fusch,[2] Catherine Hu,[3] Jie Yi Wang,[4] Zoe el Helou,[5] Muhammad Taaha Hassan,[5] Lawrence Mbuagbaw ,[1] Salhab el Helou,[2] Lehana Thabane[1]

- 100 randomly selected articles
- # of SQUIRE items reported: 22 out of 32

BMJ Open Quality, 2021

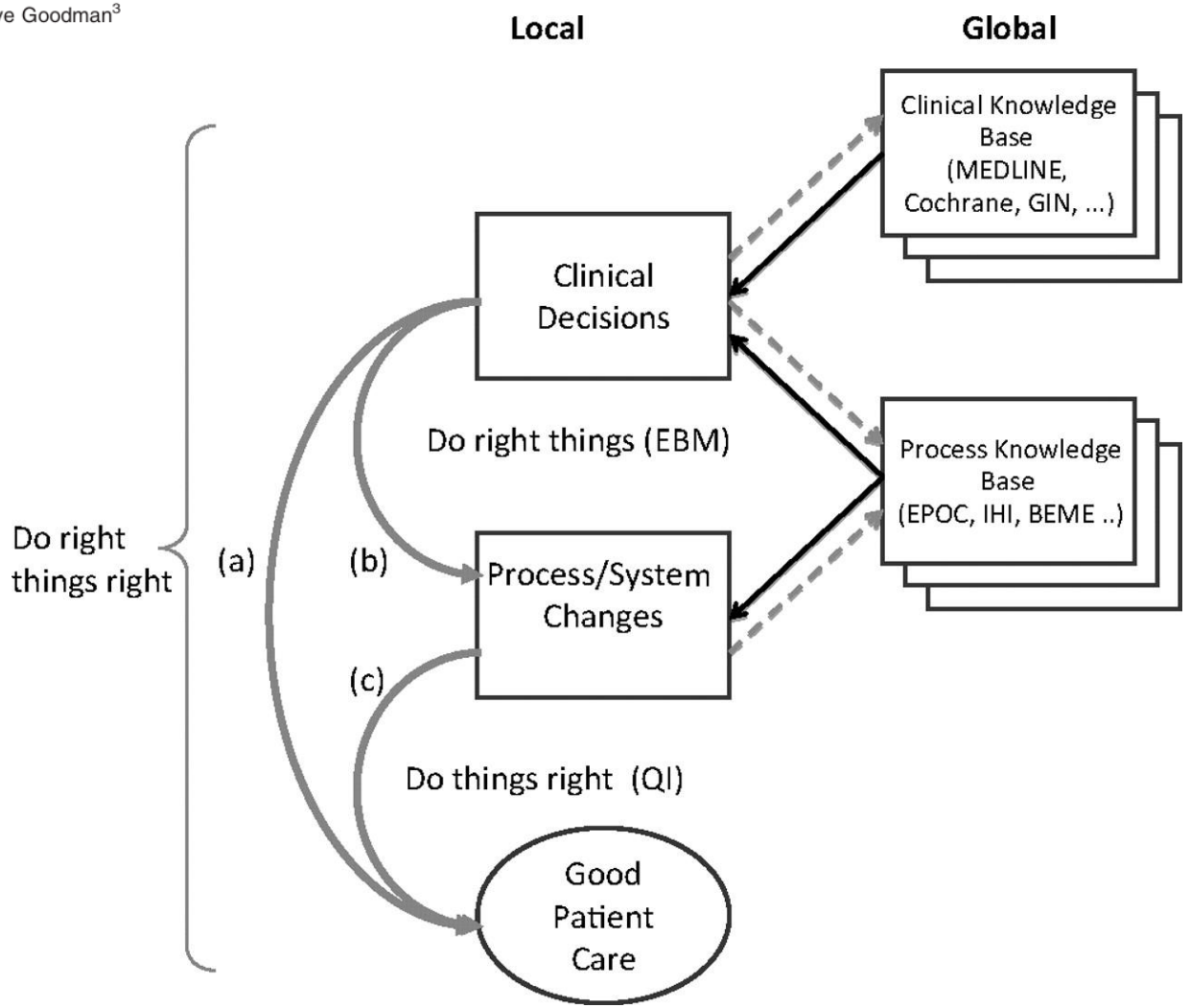
Doing QI Better

1. Define measures clearly
2. Use good process and structure measures
3. Do real PDSAs
4. **Use time-series data analysis well (SPC)**
5. Don’t use QI in place of research

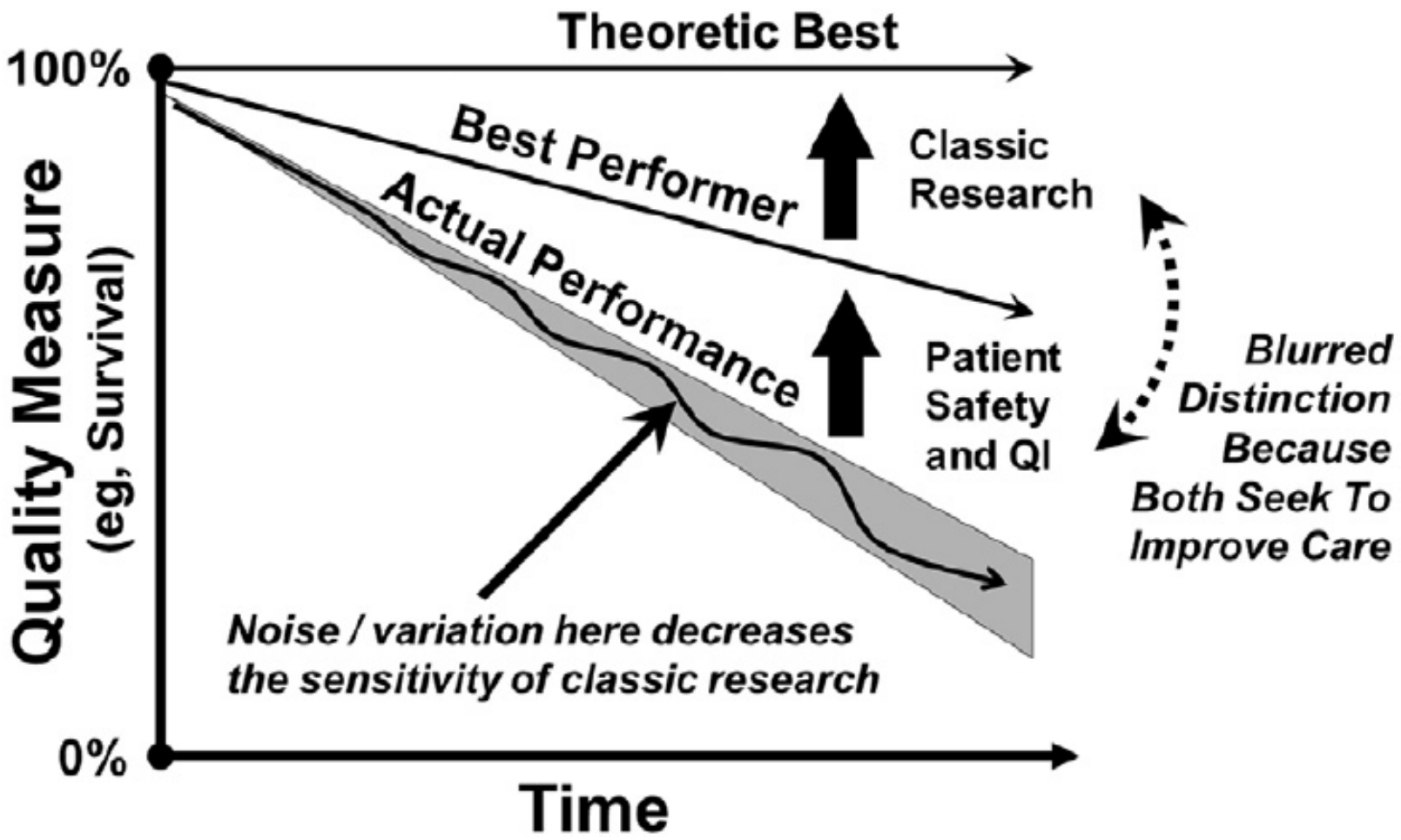
Research and QI should be complimentary.

Can evidence-based medicine and clinical quality improvement learn from each other?

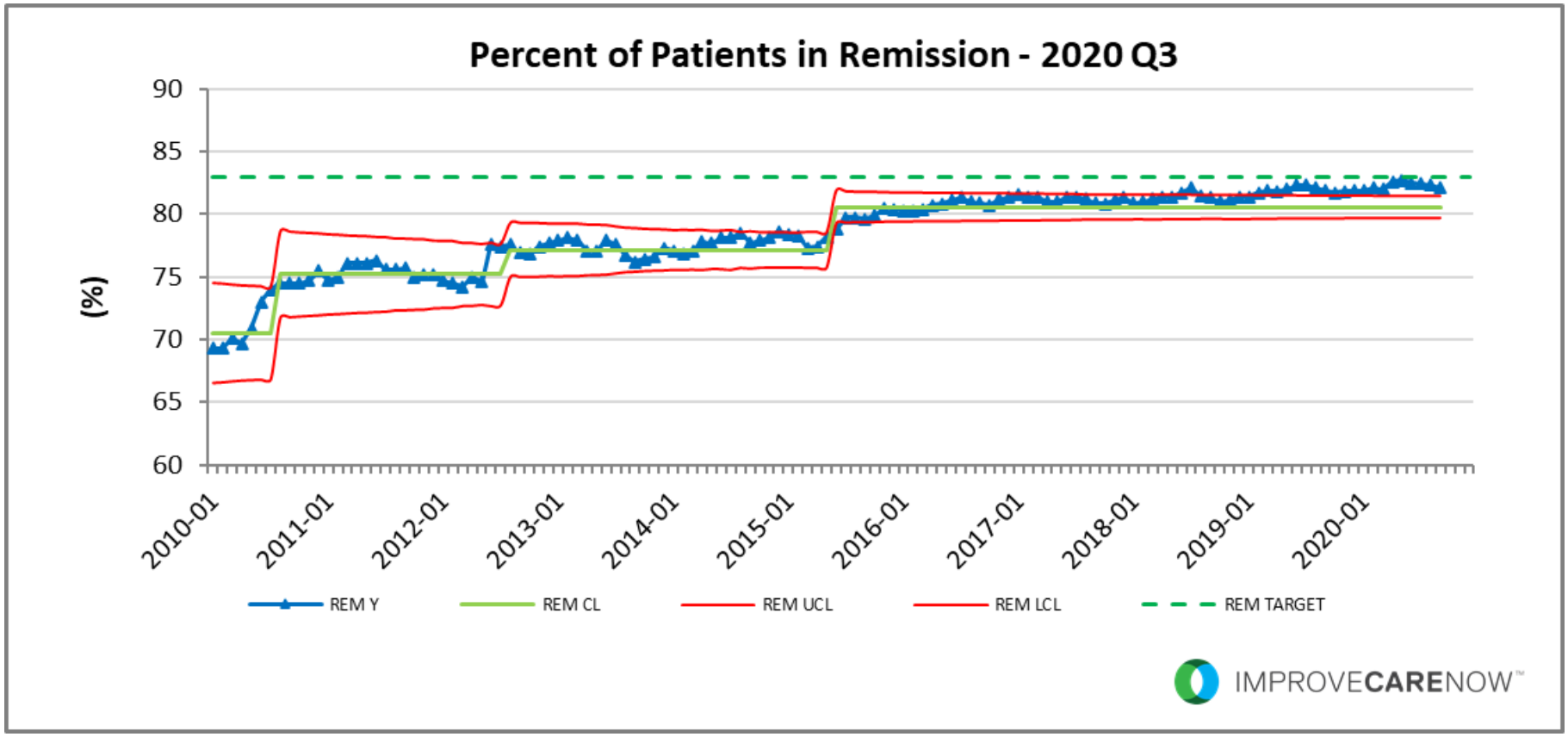
Paul Glasziou,[1] Greg Ogrinc,[2] Steve Goodman[3]



Glasziou P et al, BMJ Quality and Safety, 2011


Theoretic Best
100%
Best Performer
Actual Performance
Classic Research
Patient Safety and QI
Blurred Distinction Because Both Seek To Improve Care
Quality Measure (eg, Survival)
Noise / variation here decreases the sensitivity of classic research
0%
Time

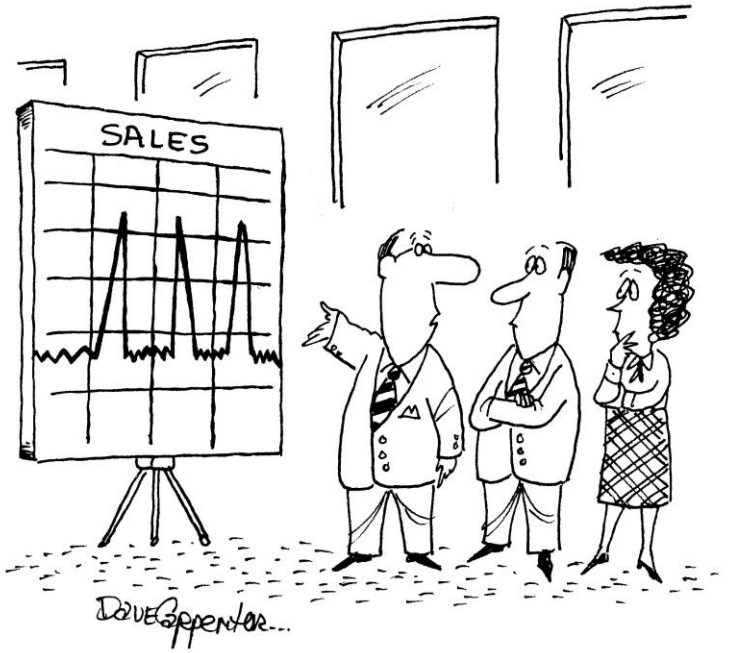
Steps to higher remission rates



Take home thoughts

- QI improves outcomes in neonatology.
- We need to be honest about what QI can and cannot do.
- We need to be careful about QI methods.
- Use QI with research, not in place of it.

Thank you



"I'm not superstitious either, but those were the three days Harris wore his lucky socks."