The Golden Week Program® for Extremely Preterm Infants

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Golden Week Program®

GOLDEN WEEK

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Objectives

1. **Describe extremely preterm birth in the US**
2. Understand the impact of active care
3. Discuss potential treatments to improve outcomes
4. Learn about a quality improvement initiative to improve outcomes
5. Examine outcomes of the Golden Week Program

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Question 1

- Which of the following has the biggest impact on state differences in infant mortality rates

- A. SIDS
- B. Congenital anomalies
- C. Extremely preterm birth
- D. Neonatal encephalopathy

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Extremely Preterm Birth

- Defined as ≤ 27 6/7 weeks' gestation while periviable defined as 20 0/7 - 25 6/7 weeks' gestation
- Less than 0.5% of live births but they account for almost 50% of infant mortality in the US and 75% of the inter-state differences in infant mortality rates
- Characterized by the need to make complex ethical decisions both before and after birth

Raju et al. Obstet Gynecol 123:1083, 2014 Travers et al. J Perinatology. 2020

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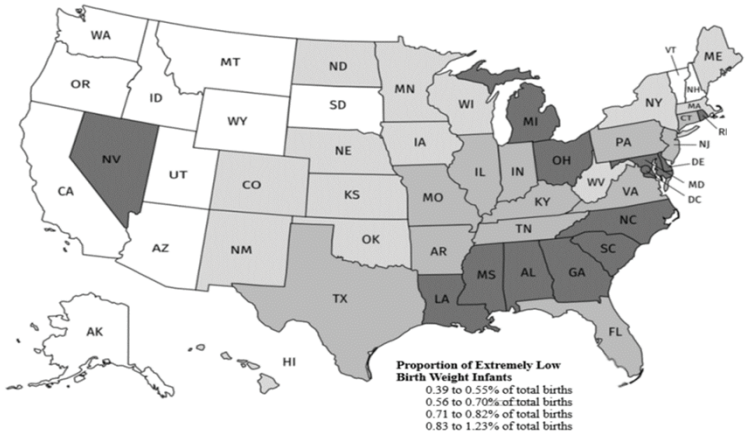

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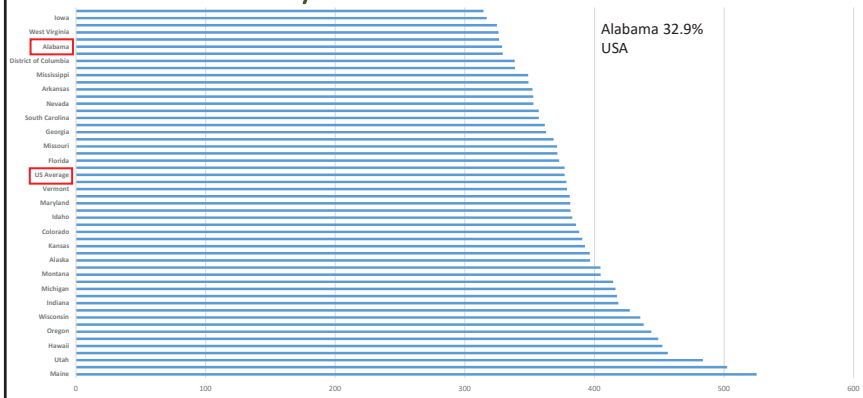
Infant Mortality Rate ELBWs in US 2017-2019



CDC Wonder database; accessed Jul 2022

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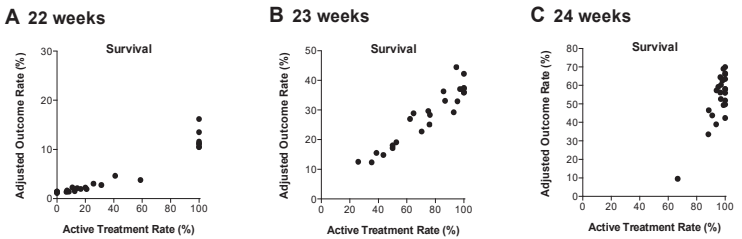
Active Treatment and Prognosis

- Increased hospital rates of active treatment associated with increased rates of survival and survival without NDI at 22, 23, and 24 weeks



Rysavy et al. N Engl J Med 372:1801, 2015

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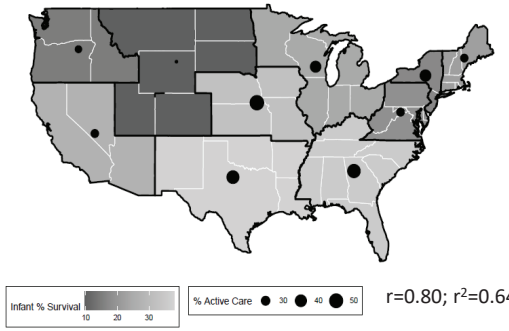
Regional Differences in Active Care and Survival



r=0.80; r^2=0.64; p=0.005

Travers et al. PAS. 2021. (unpublished)

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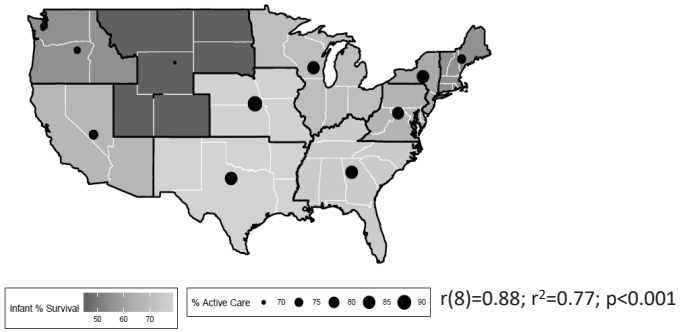
Regional Differences in Active Care and Survival



r(8)=0.88; r^2=0.77; p<0.001

Travers et al. PAS. 2021. (unpublished)

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Question 2

- What is the proportion of extremely preterm infant survivors with no or mild impairment at 10 years old?

- A. 47%
- B. 57%
- C. 67%
- D. 77%

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Intracranial Hemorrhage

- Extremely preterm infants are at high risk of intracranial hemorrhage
- The incidence increases with decreasing gestational age.
- Death and severe intracranial hemorrhage may be considered the most devastating outcomes in the first week after birth.
- Infants who die before a head ultrasound may not be diagnosed with intracranial hemorrhage.
- Severe intracranial hemorrhage is associated with high mortality and neurodevelopmental impairment.

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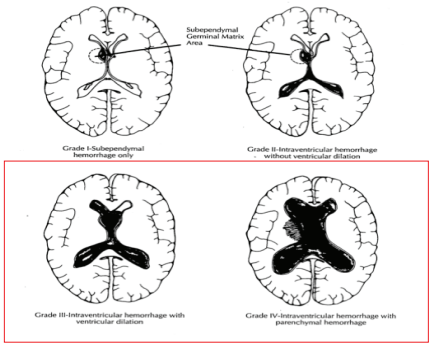
Grades of Intracranial Hemorrhage



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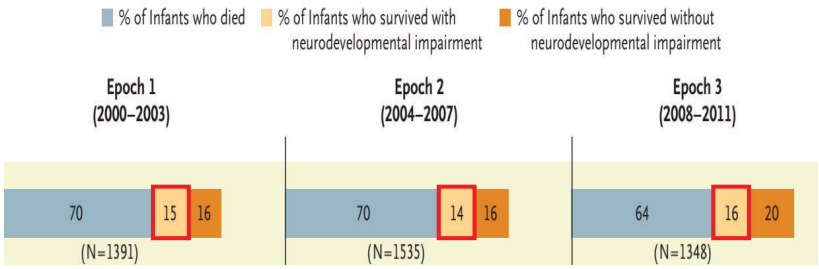
Periviable Survival and Neurodevelopment



Younge et al; NEJM; 2017. 376:617-628

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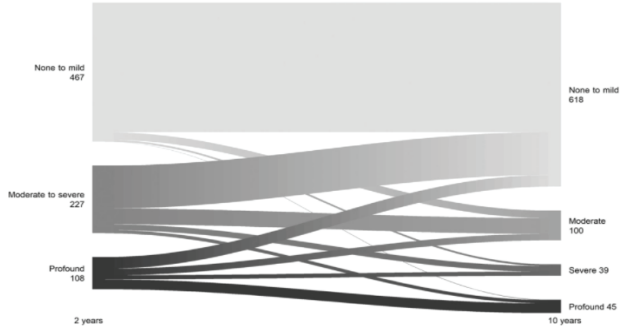
NDI Over Time in Extremely Preterm Infants



Taylor et al. Pediatrics. 2021.

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Summary

- Active postnatal care and survival differ by center and region in the US.
- Rates of active care and survival are strongly correlated at the lowest gestations.
- Survival rates at the lowest gestations are also correlated with survival at higher gestations.
- Increased survival is not correlated with an increase in infants with neurodevelopmental impairment.
- A proactive approach improves outcomes.

Travers et al. PAS. 2021. (unpublished)

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Question 3

- Randomized controlled trials of antenatal steroids show a survival benefit for infants:

- A. Less than 24 weeks
- B. Less than 26 weeks
- C. Less than 28 weeks
- D. Less than 34 weeks

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Subgroup Meta-analysis of the Outcome Fetal and Neonatal Death at < 28 Weeks

Cochrane Library

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Test for overall effect: Z=0.64(P=0.52)					
1.6.4 In babies born < 28 weeks					
Doran 1980	3/11	8/16		22.91%	0.55[0.18,1.61]
Liggins 1972a	21/34	20/28		77.09%	0.86[0.61,1.23]
Subtotal (95% CI)	**45**	**44**		**100%**	**0.79[0.56,1.12]**
Total events: 24 (Treatment), 28 (Control)					
Heterogeneity: Tau^2=0; Chi^2=0.7, df=1(P=0.4); I^2=0%					
Test for overall effect: Z=1.3(P=0.19)					

Roberts et al. Cochrane. 2017.

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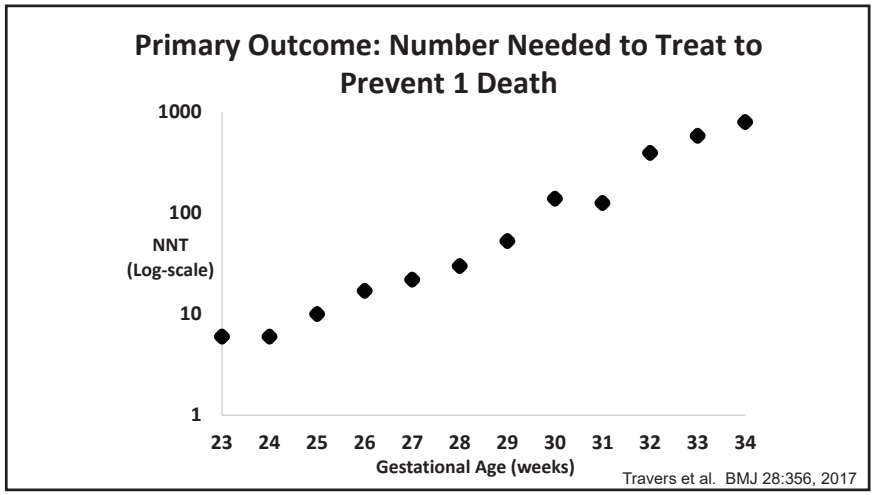

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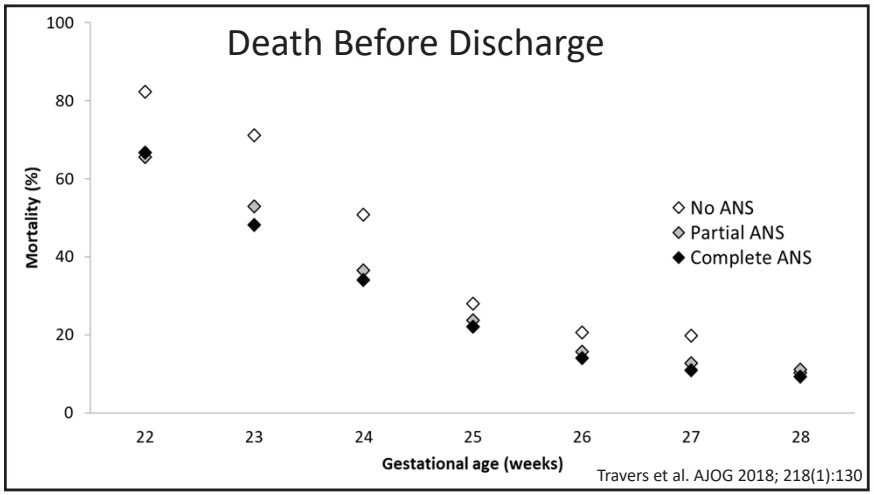

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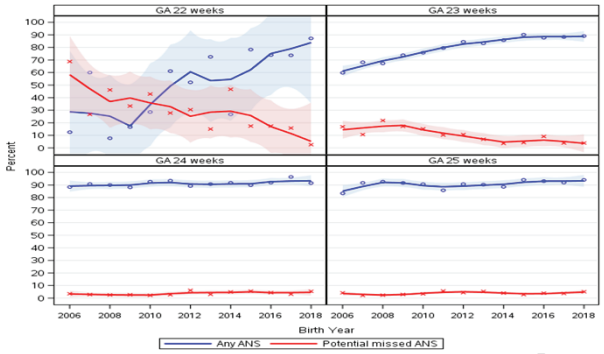
Missed Opportunities for Antenatal Steroids



Travers et al. BJOG. 2022.

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Missed Opportunities for Antenatal Steroids

- Mortality was 23% lower overall for infants exposed to antenatal corticosteroids than for those in the potential missed opportunities group (31.0% vs 54.8%, aRR [95% CI]: 0.77 [0.70-0.84], p<0.001, number needed to treat for benefit (NNTb) [95% CI]: 5 [4-6]).
- Severe ICH/PVL or death before discharge occurred in 44.7% of infants exposed to antenatal corticosteroids compared with 69.8% in the potential missed opportunities for antenatal corticosteroids (aRR [95% CI]: 0.78 [0.73-0.84], p<0.001, NNTb [95% CI]: 4 [4-5]).

Travers CP et al. BJOG. 2022.

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Question 4

- The generally recommended umbilical cord management strategy for extremely preterm infants is the following:

- A. Delayed cord clamping 30-60 seconds
- B. Immediate cord clamping
- C. Milking/stripping before cord clamping
- D. Resuscitation before cord clamping

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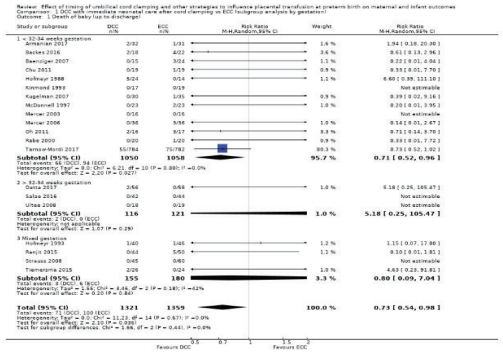
Delayed Cord Clamping - Mortality



Rabe et al. Cochrane. 2019.

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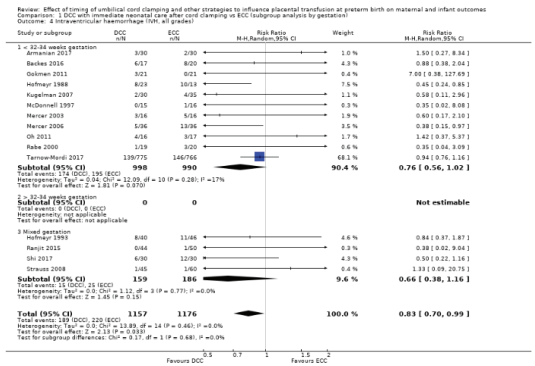
Delayed Cord Clamping – Any ICH



Rabe et al. Cochrane. 2019.

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DCC – Other Benefits

- Higher initial hematocrit
- Higher initial blood pressure
- Less need for inotropes

- NB: Cord milking not recommended for extremely preterm infants due to higher risk of ICH compared with DCC

Rabe et al. Cochrane. 2019.

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Starting FiO_2 for Resuscitation

- RCT of 21% versus 100% for neonatal resuscitation in 292 preterm infants <32 weeks
- Infants <28 weeks who received 21% had higher mortality (10 of 46 [22%]) versus 100% (3 of 54 [6%])
- Risk ratio: 3.9 [95% confidence interval: 1.1-13.4]; p=0.01).
- Respiratory failure was the most common cause of death.
- Other studies suggested no difference if targeting normal oxygen saturation goals per NRP guidelines.

Oei JL et al. Pediatrics. 2017.

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Question 5

- The best initial respiratory strategy for extremely preterm infants is

- A. Immediate intubation and delayed surfactant
- B. Immediate intubation and immediate surfactant
- C. Trial of CPAP with intubation and immediate surfactant if failing
- D. Trial of CPAP with intubation and delayed surfactant if failing

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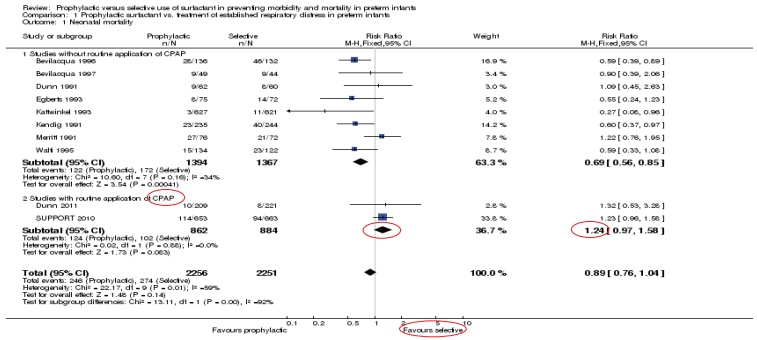
CPAP versus Prophylactic Surfactant



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Head Position

- Small studies suggesting a benefit or maintaining midline head position in terms of changes in cerebral blood flow.
- Emerging data that elevated head position may also help avoid swings in cerebral blood flow and cerebral oxygenation.

Pellicer et al. Pediatrics. 2002. Kochan et al. J Perinat. 2019.

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Carbon Dioxide Management

- Swings in carbon dioxide associated with severe brain injury in preterm infants.
- pH-controlled permissive hypercapnia may improve outcomes in preterm infants – no increased risk of death or ICH.

Fabres et al. Pediatrics. 2007.

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Ventilation Strategies

Cochrane reviews comparing volume control and high frequency ventilation versus pressure control strategies

Volume Targeted Ventilation
Decreased severe ICH
(RR, 0.48; 95% CI, 0.28 to 0.84)
Decreased air leaks
Decreased death or BPD

High Frequency Ventilation
No difference in ICH
(RR, 1.10; 95% CI, 0.95 to 1.27)
Increased air leaks
Decreased death or BPD

Klingenberg et al. Cochrane. 2017.

Cools et al. Cochrane. 2015.

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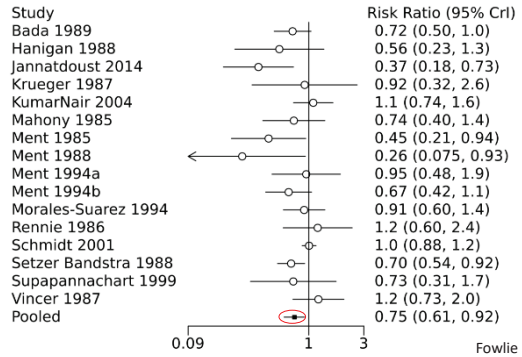
Indomethacin Prophylaxis for PDA



Fowlie et al. Cochrane. 2010.

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Fluid/Bolus/Transfusion Administration

- Liberal fluid administration associated with an increased risk of mortality and ICH in preterm infants.
- Normal saline bolus administration associated with a higher risk of developing ICH.
- Sodium bicarbonate administration associated with ICH.
- Sudden fluctuations in Na associated with ICH
- No benefit of more liberal use of blood and platelet transfusions in extremely preterm infants.

Bell EF et al. Cochrane. 2014.
Sankaran J et al. Pediatrics. 2018.
Lawn CJ et al. Cochrane. 2005.
Dalton et al. Am J Perinatol. 2015.

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Inotropes and Hypotension

- Absence of evidence from randomized controlled trials of inotropes in preterm infants.
- Limited data suggests that treatment of hypotension may be harmful if there are signs of good perfusion.

Sassano-Higgins et al. J Perinatol. 2011. Dempsey et al. Arch Dis Child Fetal Neonatal. 2009.

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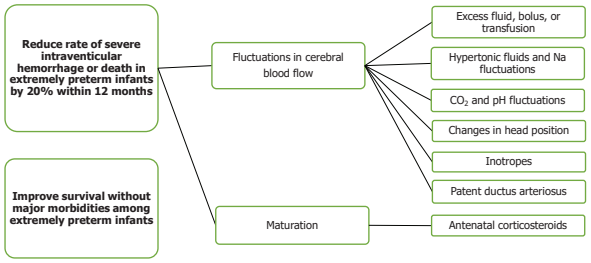
Golden Week Key Driver Diagram



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GOLDEN WEEK

The GOLDEN WEEK PROGRAM™ to Reduce Severe Intracranial Hemorrhage or Death among Extremely Preterm Infants

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Background and Rationale

- There are multiple evidence based potentially better practices that could be bundled to reduce death or severe intracranial hemorrhage.
- Non-adherence to evidence-based practices and lack of standardized guidelines may contribute to wide variability and adverse outcomes.
- Education alone may have a limited effect on adherence to evidence based practices.
- Standardized communication tools and checklists may improve communication, compliance with guidelines, and reduce variability.
- Electronic medical record order sets may provide a novel way to standardize treatment, reduce variability, and improve adherence.

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SMART Aim

- To reduce the rate of death or severe intracranial hemorrhage during the first week after birth among inborn extremely preterm infants by at least 20% (relative risk reduction) within 12 months.

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Preparing for Intervention

- Comprehensive literature review to develop evidence based GOLDEN WEEK PROGRAM ™ guidelines.
- A multidisciplinary core committee was created including a nursing, respiratory therapy and physicians.
- Consulted Obstetrics and Gynecology, Radiology, Pharmacy, and Health Informatics.
- Mapped perinatal care, delivery room care, admission processes, daily care, staff handovers, and patient rounds.

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GOLDEN WEEK PROGRAM ™ Launch

- Soft implementation phase April 2015
  - Physician education
  - New handover and rounding checklists
  - Monthly meetings and PDSA cycles
  - Monthly nursing and RT education
  - Preparation of order-sets
- Hard implementation phase April 2016
  - Electronic order-sets launched
  - Golden Week service
  - Golden Week nursing team

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Golden Week Program Interventions

Perinatal	Admission	Days 1-3	Days 1-7
Antenatal corticosteroids from 22 0/7 if resuscitating	Head position midline	Limit normal saline bolus	Formal physician handover every 12 hours
Delayed cord clamping 30-60 seconds	Transcutaneous CO_2 monitor	Limit bicarbonate bolus	Minimal handling
Higher (0.60) starting FiO_2 in delivery room	Line placement in 1st hour	Limit inotrope use	0.25% sodium chloride line flushes
Early CPAP and selective surfactant in delivery room	Evidence-based order-sets initiated	Limit transfusion of blood products	Slow flushing and withdrawal from CVLs
Heart rate electrodes in delivery room	Sodium acetate containing line fluids	Weight and serum Na Q12 and urine output Q6	Follow trends in clinical and laboratory values
Thermoregulation with bag and mattress	Single dose indomethacin prophylaxis	Careful total fluid intake changes ~ 10/kg/day	Volume control with target of 4/kg if on SIMV

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Analysis

- The primary outcome was death or severe intracranial hemorrhage in the first 7 days after birth among inborn extremely preterm infants.
- Balancing measures included the rate of spontaneous intestinal perforation and acute kidney injury.
- Data were analyzed using groups of 20 consecutive eligible infants and plotted on Statistical Process Control Charts
- Control chart rules for stability analysis were used to determine if and when special cause variation occurred in relation to PDSA cycles.

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Results

- 820 inborn extremely preterm infants were delivered during the study period.
- The mean (SD) gestational age of 25w 3d (11d) and median birth weight was 744 grams (211 grams)

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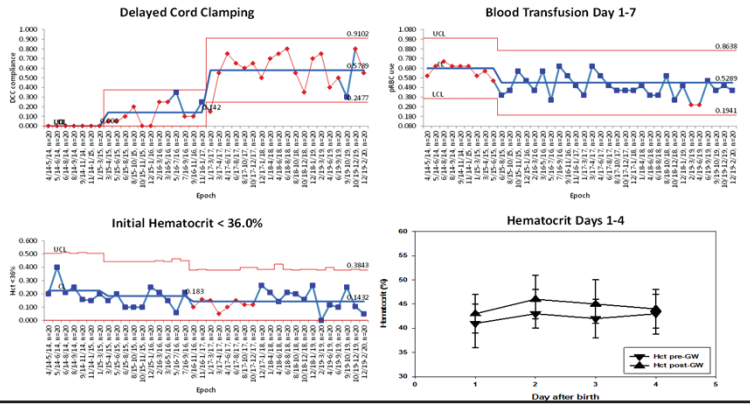
Delayed Cord Clamping, Hct, and pRBCs



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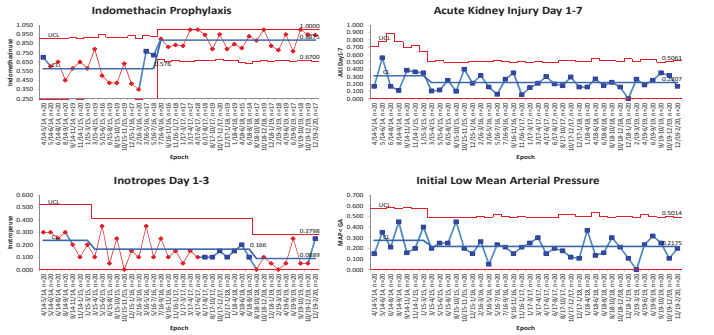
PDA and BP Management



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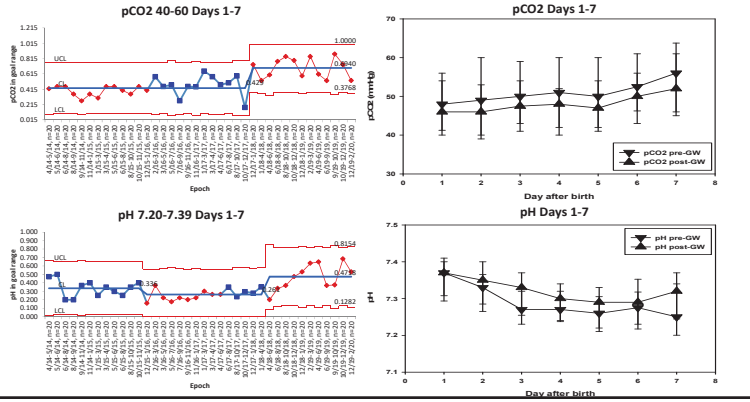
Golden Week pH and pCO2



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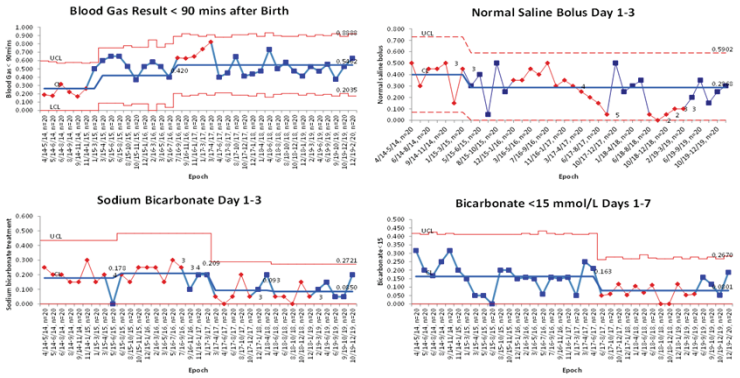
Blood Gas, NS Bolus, and Bicarbonate



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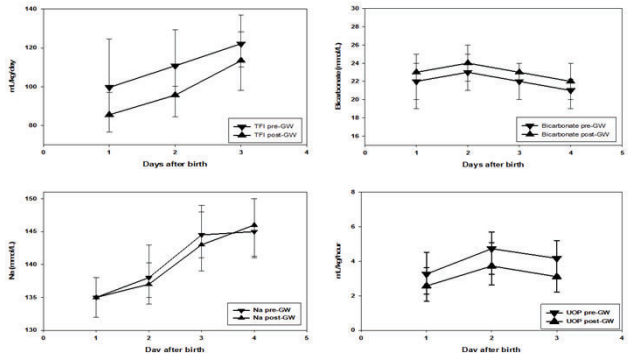
TFI, Bicarbonate, Sodium, and UOP



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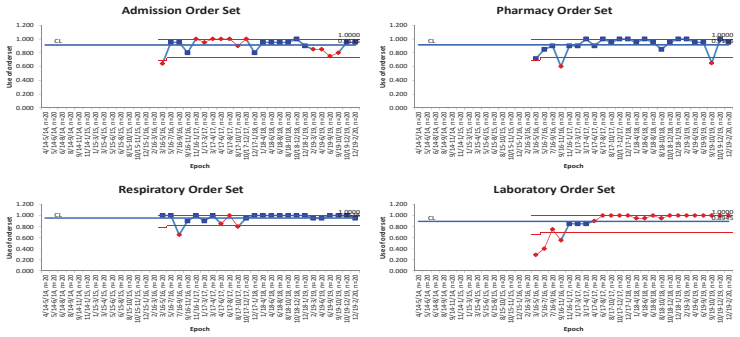
Order Sets



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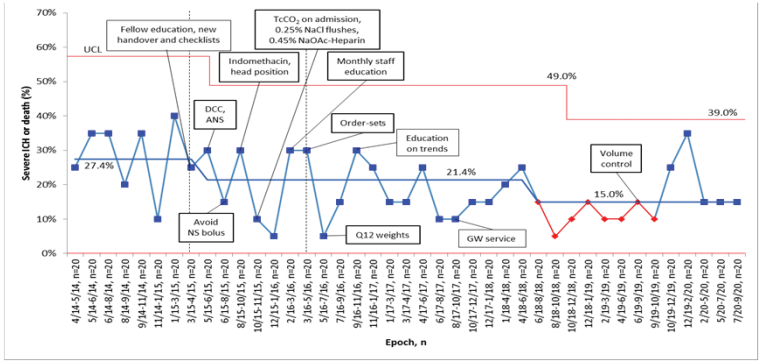
Severe IVH or Death



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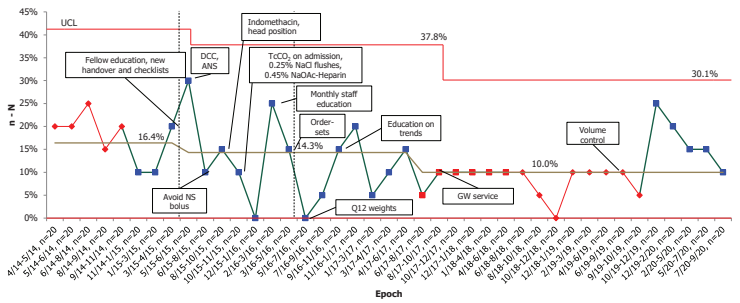
Severe IVH



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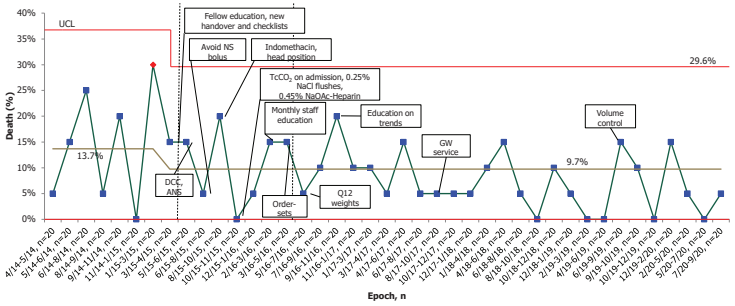
Death



Golden Week Maintenance Phase

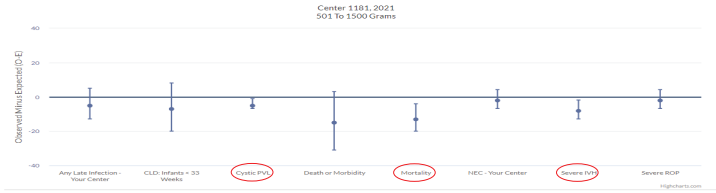
Golden Week – Year 2021

Month	Inborn Deliveries	# of Severe IVH	Deaths in 1st week of life
Jan	4	0	1
Feb	6	0	1
Mar	8	1	0
Apr	6	0	0
May	13	1	0
Jun	7	0	0
Jul	11	0	1
Aug	9	0	0
Sept	8	0	0
Oct	11	1	0
Nov	9	2	1
Dec	10	4	0
Totals	102	9 9%	4 4%

Golden Week Jan to Current 2022

Month	Inborn Deliveries	# of Severe IVH	Deaths in 1st week of life
Jan 22	11	1	0
Feb 22	11	0	1
Mar 22	9	3	2
Apr 22	6	1	1
May	18	3	0
Jun			
Jul			
Aug			
Sept			
Oct			
Nov			
Dec			
Totals	55	8 14.5%	4 7.2%

Outcomes - VON Data 2021



Center 1181, 2021, 501 To 1500 Grams

	N	O-E	O-E 95% Lower Bound	O-E 95% Upper Bound	SMR (Shrunken)	SMR 95% Lower Bound	SMR 95% Upper Bound
Any Late Infection - Your Center	230	-5	-13	5	0.8	0.5	1.2
CLD: Infants < 33 Weeks	206	-7	-20	8	0.9	0.7	1.1
Cystic PVL	220	-5	-7	-1	0.3	0.1	0.8
Death or Morbidity	230	-15	-31	3	0.9	0.7	1.0
Mortality	230	-13	-20	-4	0.6	0.4	0.9
NEC - Your Center	234	-2	-7	4	0.8	0.4	1.3
Severe IVH	195	-8	-13	-2	0.6	0.4	0.9
Severe ROP	192	-2	-7	4	0.8	0.4	1.3

Conclusion

- This comprehensive evidence-based quality improvement initiative was associated with improved outcomes in the first week after birth.
- A special cause variation in the rate of death or severe intracranial hemorrhage corresponded with lower use of inotropes and improved targeting of carbon dioxide and pH levels.
- A special cause variation in the rate of severe intracranial hemorrhage was associated with improved adherence to delayed cord clamping and avoidance of sodium bicarbonate administration in the first 3 days after birth.

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Future Directions

- Golden Week Program nurses training course expanding every year.
- Continue to track outcomes and enact changes to impact survival without major morbidity.
- Assess the outcomes of outborn infants.
- Assess the effect of our bundle of care on neurodevelopmental outcomes.

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Creating a Small Baby Program

- Include the whole team
- Use evidence-based medicine
- Check measures and data collection plan
- Agree time-frames
- Share data – care practices and outcomes
- Continue learning and expect change

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Quality Improvement in the NICU

- Agree standardized guidelines to reduce variability in care and outcomes
- Adhere to evidence-based potentially better practices
- Staff want to know why we do what we do – educate and ask questions
- Team based approach – respect and utilize
- Effort and attention to details

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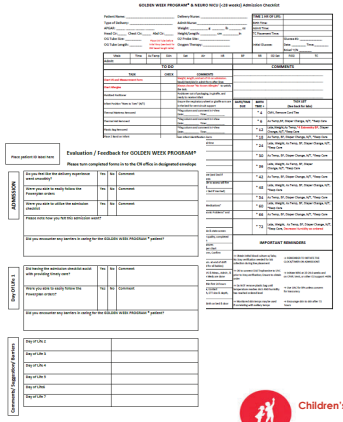
Solutions?

- Educate the whole team
- Standardized communication and checklists.
- Electronic medical record order-sets.
- Changing the culture?



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GOLDEN WEEK PROGRAM® ACCOMPLISHMENTS

2017 GAGE AWARD RECIPIENT "IMPROVING QUALITY"

https://www.youtube.com/watch?v=EEWLcEDAXho

CONFERENCE PRESENTATIONS

AMERICA'S ESSENTIAL HOSPITALS

National Association of Neonatal Nurses

VON Vermont Oxford NETWORK

2019 & 2022 UAB 5TH MAGNET REDESIGNATION "BEST PRACTICE"

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

MAGNET RECOGNIZED AMERICAN NURSES CREDENTIALING CENTER

2020 TRADEMARK DESIGNATION

2021 Golden Week Nursing Team

2022 Golden Week Publication

2022 GUINNESS WORLD RECORD "YOUNGEST SURVIVOR OF PREMATURITY"

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