

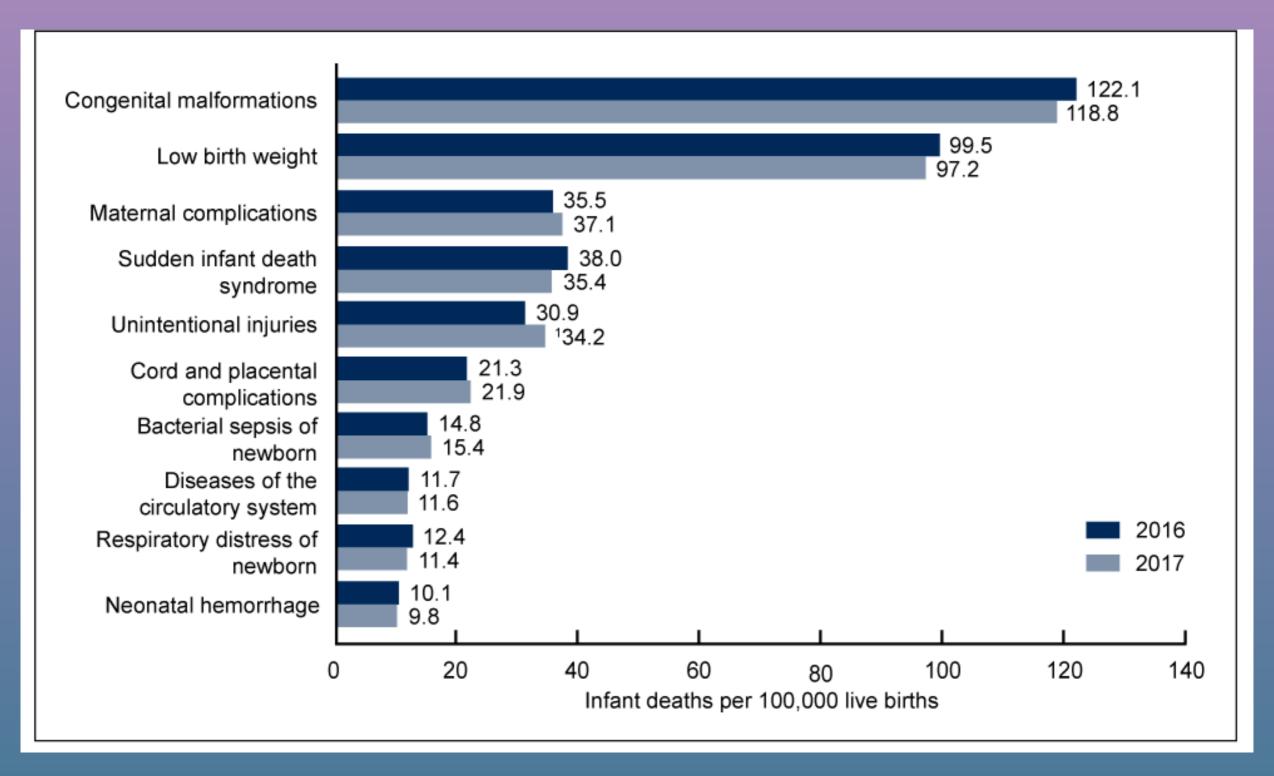
Infant Safety

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Infant Mortality in the US

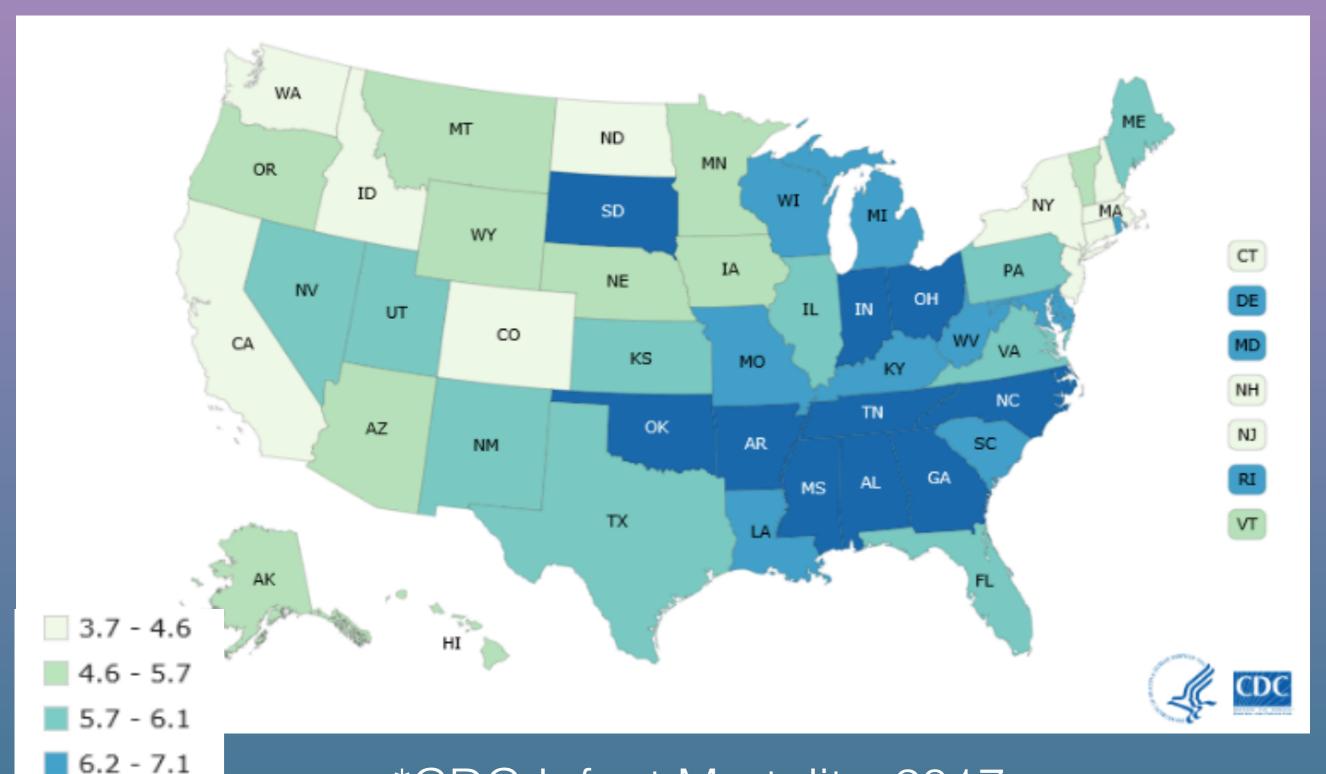
- 5.8 deaths per 1000 live births in 2017 (22,335 infants)
- Causes of infant deaths:
 - 1. birth defects
 - 2. prematurity and low birthweight
 - 3. maternal complications
 - 4. SUID
 - 5. Accidents / Injuries

Infant Mortality Causes in the United States



National Bureau of Vital Statistics, 2016 and 2017

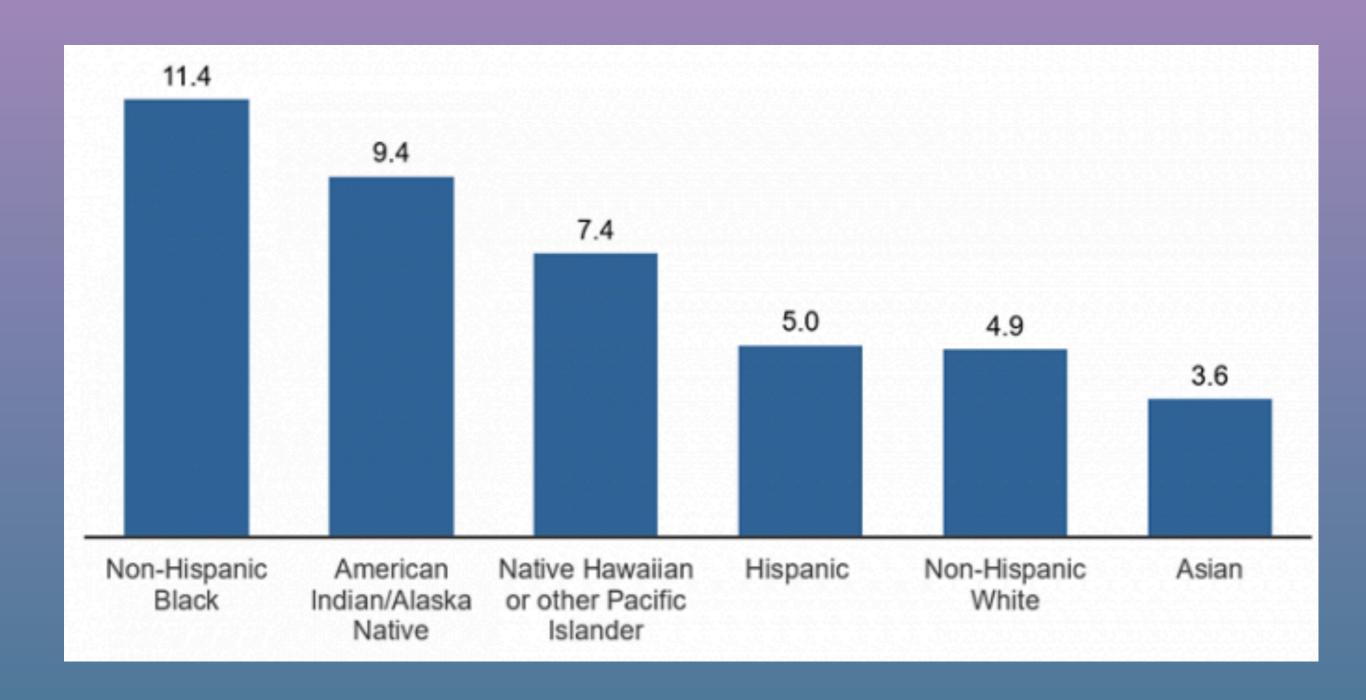
Infant Morbidity and Mortality in the United States



*CDC Infant Mortality, 2017

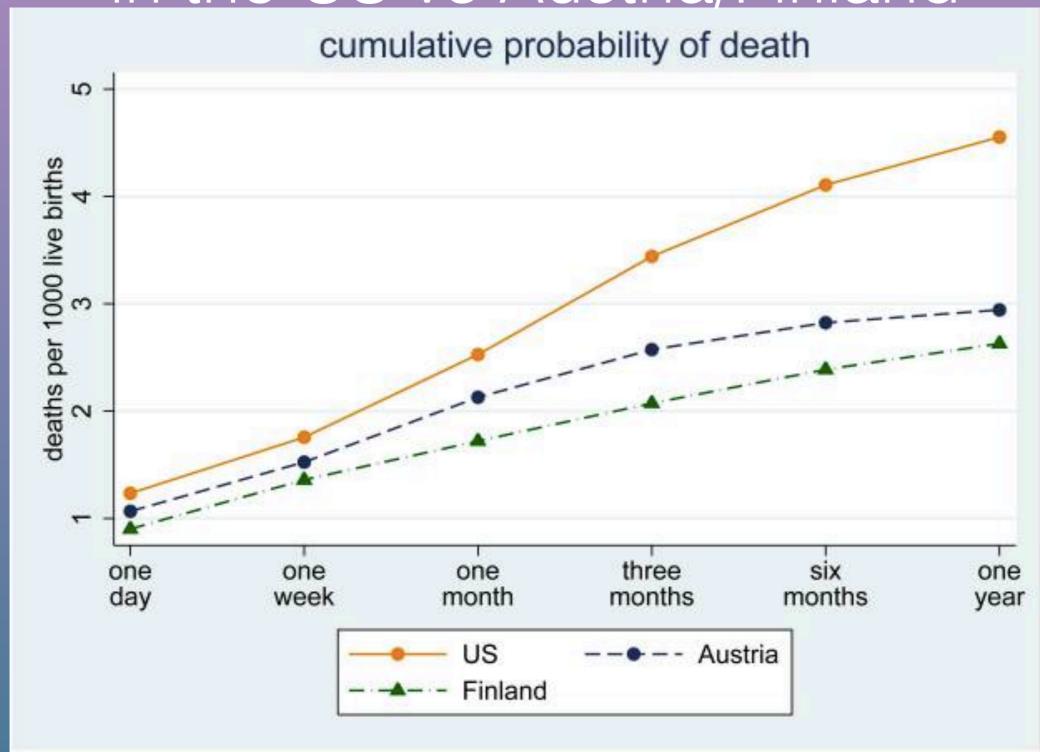
7.1 - 8.6

Infant Morbidity and Mortality in the United States



*CDC, Infant Mortality Statistics by Ethnicity, 2017

Infant Morbidity and Mortality in the US vs Austria/Finland



*Am Econ J Econ Policy. 2016 May; 8(2): 89-124.

Infant Mortality by Cause in US and Austria/Finland

Table 4
Postneonatal cause of death, by country

		(1)	(2)	(3)	(4)	(5)	(6)
	cause of	congenital abnormalities	respiratory	SIDS and other	accident	assault	other
	death:	and low birthweight		sudden deaths			
	US	0.380	0.068	0.699	0.208	0.064	0.613
	Finland	0.325	0.021	0.226	0.044	0.003	0.287
	Austria	0.377	0.007	0.185	0.030	0.013	0.175
US-							
Finland							
	raw	0.055	0.047	0.473	0.164	0.061	0.326
	difference						
	as share of	17%	224%	209%	373%	2033%	114%
	Finland						
US-							
Austria							
	raw	0.003	0.061	0.514	0.178	0.051	0.438
	difference						
	as share of	1%	871%	278%	593%	392%	250%
	Austria						

Am Econ J Econ Policy. 2016 May; 8(2): 89–124.

Topics in Infant Safety

- Amber Necklaces
- Alternative Formulas
- Vitamin K administration in the newborn
- Safe Sleeping/Co-sleeping
- Car Seat Safety

Themes for Each Topic

- Data / information
- Misconceptions (often anecdotal evidence)
- Risks
- Scientific evidence
- Recommendation, including alternatives

Overlying Principal

We, as providers of health care for infants have the responsibility to present information in a non-judgmental format to parents so that they may make informed decisions regarding their children's safety.

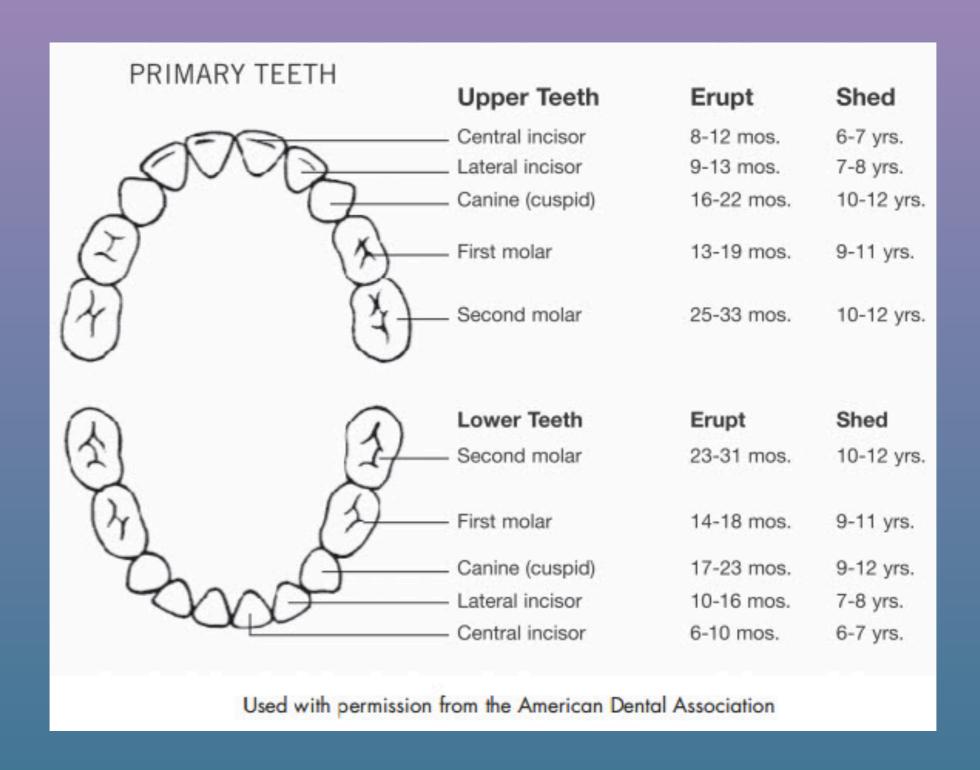
Amber Necklaces



Data / Information

- Increasing in use due to anecdotal evidence
- \$15-24 on online buying sites
- Marketed to be beneficial both mechanically and pharmacologically (succinic acid absorption)
- Teething is an issue that affects all infants and parents are reaching out for a "natural" alternative to help their babies.

Teething Facts



Misconceptions

- Amber necklaces contain succinic acid
- Succinic acid is an anti-inflammatory
- Break-away clasps break away
- Teething is a significant barrier to happiness and health in infants and toddlers

Risks

- infection
- choking
- strangulation
- death

Evidence

- Machet Study on bacterial count (N=27)
- Soudek Study on break away clasps (N=15)
- Death of 18m old by strangulation while napping
- 7m old who choked/aspirated a bead

Recommendations

- There is reasonable evidence to avoid amber necklaces for this benign process of teething.
 - French study that concludes that even when parents are informed of risks of strangulation, the perceived risk of pain from teething is what drives parents' decision to continue use of amber necklaces.
- Its up to us as practitioners to inform patients of the risks.
- Alternatives: Teething rings, cold washcloths, finger brushes; consider use of necklace on wrist or ankle
 - Avoid topical analgesics to avoid methemoglobinemia.



Alternative Formulas

Data / Information

- Sheep / Goat milk
- Homemade formulas
- European formulas
- All increasing in popularity helped along by celebrity blogs and influencers

Misconceptions / Goals about Alternative Formulas

- Raw milk from non-cow sources avoids allergies,
 GMO options and growth hormones/pesticides
- Homemade recipes provide appropriate fortification with iron, vitamins, minerals and carbohydrates
- Pasteurization kills "healthy bacteria" and causes deterioration of enzymes that aid digestion

Risks of Alternative Milks

- Low Iron, Folate, Vitamin B12
- Too much sodium, water
- Too many or too little calories
- Increased risk of bacteria: Listeria, Shigella, Salmonella, Botulinum toxin

Evidence

- Historical e/o iron deficiency anemia in babies prior to formula development
- Before 1870, 1/3 of all babies not breastfed died in the first year of life
- CDC Reports: regarding raw milk
 - 1993-2012: 127 outbreaks of infectious disease due to raw milk (1909 illnesses, 144 hospitalizations)
 - 59% of these were less than 5 years old

Recommendations

- Breast is Best!
- Donor Breastmilk, when pasteurized and vetted for infection is a suitable alternative.
- Commercial Formulas are safe. FDA does not approve formulas but regulates content and facilities.
- Raw milk is unsafe due to risk of infection.

Recommendations

- If you have a patient making/using homemade formulas or non-regulated formulas:
 - electrolytes, Vit B12, Fe, Folate levels q3m
 - weight check monthly
 - counsel on pasteurization and risks of infections, monitor for diarrhea, blood in stool, fevers and evaluate accordingly



Vitamin K

0.5 mL Single-dose Ampul R only 5/NDC 0409-9157-01

VITAMIN K₁ Injection

Phytonadione Injectable Emulsion, USP

1 mg/0.5 mL Neonatal Concentration

Protect from light. Keep ampuls in tray until time of use. For I.M., S.C., or I.V. (with caution).

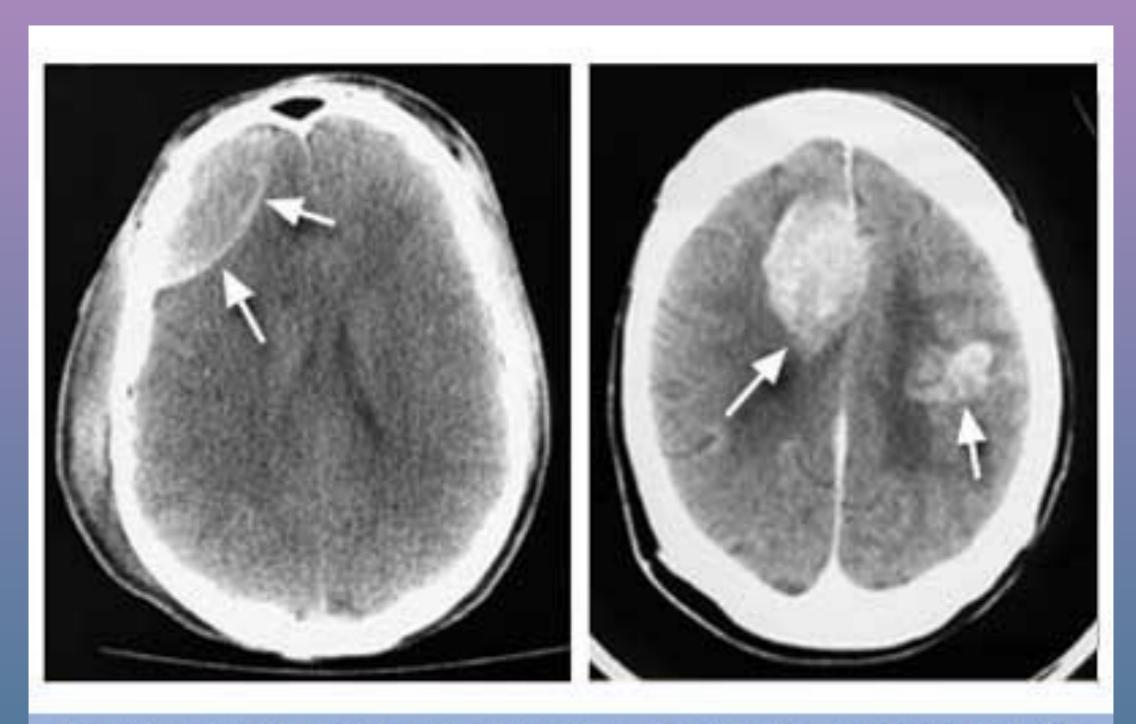
Each mL contains phytonadione 2 mg; polyoxyethylated fatty acid derivative 70 mg; dextrose, hydrous 37.5 mg; benzyl alcohol 9 mg added as preservative. May contain hydrochloric acid for pH adjustment. pH 6.3 (5.0 to 7.0). Usual dosage: See insert. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Physiology of Vit K

- Essential vitamin cofactor of Klotting factors II,
 VII, IX and X
- Vit K is in low supply in the newborn and infant due to immature liver, poor placental transport and low Vit K levels in breastmilk.
- Vit K levels are about 20% those of adults until 1 month of age.

Why give Vit K?

- To avoid VKDB (Vitamin K deficiency bleeding)
 - Early onset: within 24 hrs
 - Classic: 1-4 weeks of life
 - Late: 3 weeks to 8 months
- Risk of ICH increases with age of presentation



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Misconceptions about Vit K

- 1992 study suggesting a link between Vit K and leukemia/cancers
- traumatic event of the shot
- lack of awareness of risk
- "toxin" content in the injection

Evidence

- Prevalence: 4-7 cases / 100,000 births
- In EVERY case of ICH due to VKDB, there was parental injection refusal.
- 1992 leukemia study (N=800) debunked by all follow up studies and a 2002 metaanalysis including >1 million children

Evidence

- Nashville Study
 - 3.4% born in hospital with Vit K refusal
 - 28% born in birthing centers with refusal

Recommendations

- Intramuscular Vit K 0.5-1mg at birth
- Review birth history of all newborns in your practice
- Counsel Vit K refusers on risk, especially when associated with exclusive breastfeeding
- Oral Vit K dosing: 2mg at first feeding and again at 1, 4 and 8 weeks of age (STILL WITH RISK)

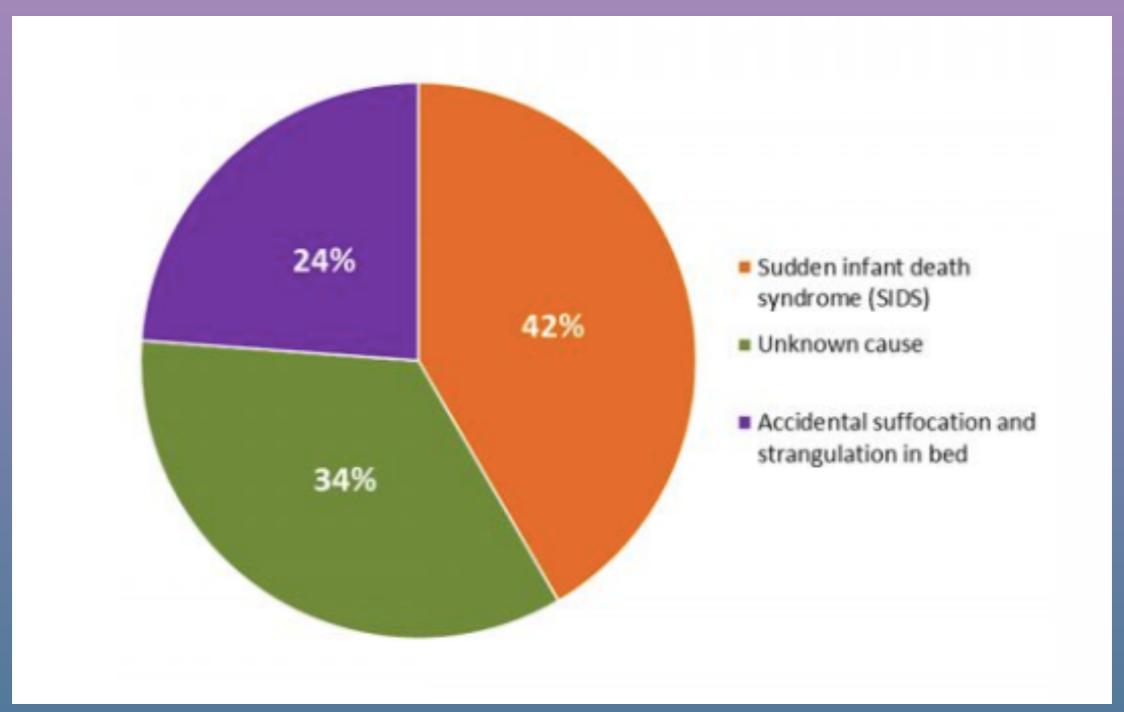


Safe Sleeping

Sudden Unexplained Infant Deaths (SUID)

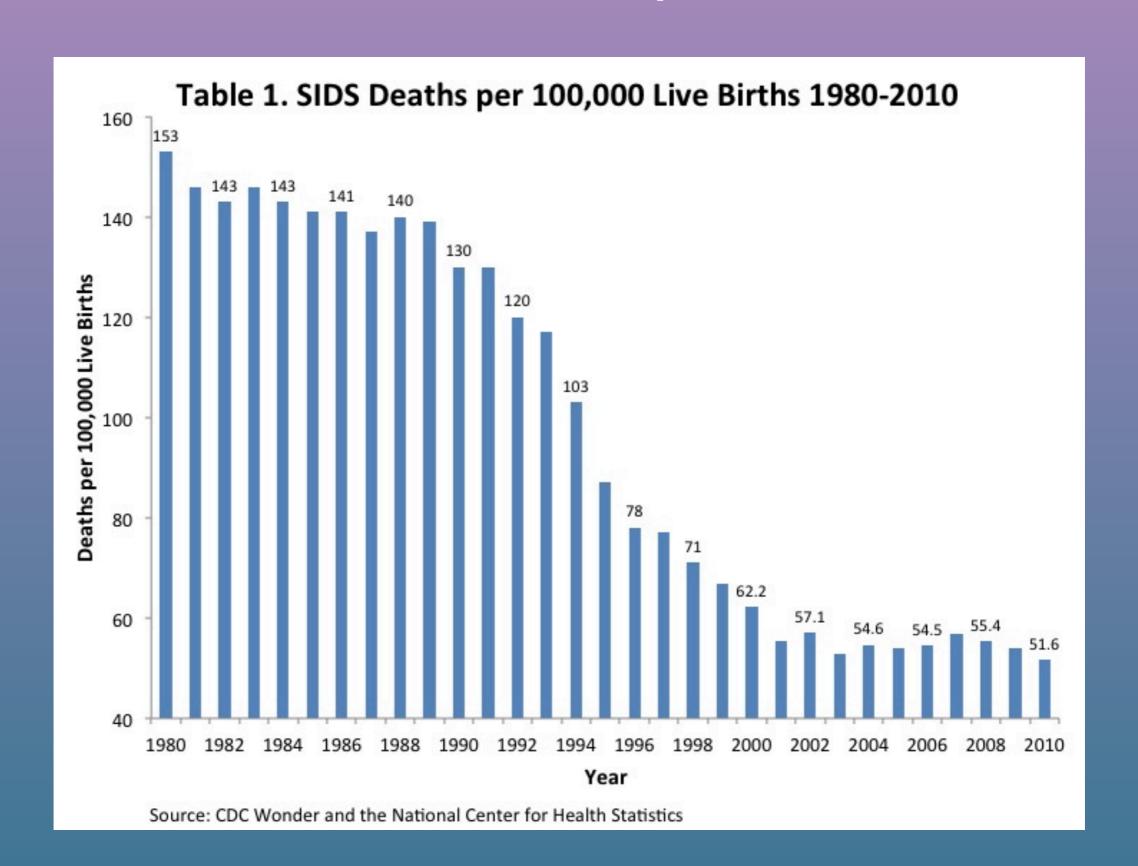
- 3500 sleeping deaths in 2016
- The leading cause of death in infants 1 month to 1 year of age is SIDS/SUID.

Breakdown of Sleep related deaths of infants by cause, 2016



CDC, National Vital Statistics Data

SIDS and Sleep Position



Risks: SUID (Sudden Unexpected Infant Death)

Maternal Factors	Infant Factors	Environmental Factors
young maternal age	preterm	prone sleeping position
tobacco/Etoh	low birth weight	soft surfaces, bedding accessories
late or no PNC		co-sleeping

Co-sleeping Data

- 13.5% of US families are co-sleeping
- Increased in Hispanic and African-American populations

Evidence

- Colson Study:
 - Co-sleeping and SUID: OR 2.89
 - If infant < 3m, OR 5.1
 - If other risk factors, OR 15

Recommendations



Recommendations

- Back to sleep!
- Room sharing, not bed sharing
- Firm surfaces, no accessories

Recommendations

- Consider pacifiers for reduced risk of SIDS
- Counsel on risks of tobacco and Etoh, couch/ sofa sleeping
- Consider co-sleeping in breast-feeding mothers without smoking/Etoh use with infants >3 months old on firm surfaces



Infant Car Seat Safety

Data / Information

- Traumatic infant deaths in the US in 2016:
 - 1. Unintentional suffocation (1023)
 - 2. MVA (88)
 - 3. Drowning (38)
- 59% of car seats are incorrectly used

Evidence

- Car seat use reduces risk of injury by 75% compared to seat belts alone.
- 500,000 kids each year ride without car seats or seat belts.
- Laws enforcing stricter car seat use are assoc'd with more use and less injury.

Data from NHTSA



Recommendations: Infants

- Rear facing, 5 point harness secured to the back passenger seat at a 45 degree angle
- NEVER in front seat
- Buckle at the nipple line and SNUG fit
- Watch length and weight limits on nonconvertible seats

Recommendations: Pre-term or LBW Infants

- Car Seat Trial:
 - <2500 grams
 - preterm
 - any risks for obstruction, As/Bs, heart defects or hypotonia

Recommendations: General Car Seat Safety

- Counsel on car seat safety at EVERY preventative visit. Consider TIPP sheets.
- REAR-FACING until at least 2 years old
- Booster seats for all kids <4'9" and 8 years old
- Back seat until age 13

Summary

- Communication is key.
- If you do not give your patient the information, then who will?
- Non-judgmental presentation of evidence is our best bet to help parents make an informed decision that will ensure their baby's safety.

Question 1:

The leading cause of death in infants 1 month to 1 year old is:

- A. Electrolyte abnormality
- B. SIDS/SUID
- C. Intracranial bleeding
- D. Acute lymphocytic leukemia

Question 2:

Which is true regarding Vitamin K deficiency bleeding (VKDB) and intracranial hemorrhage (ICH):

- A. Vitamin K administration does not affect the incidence of ICH in infants.
- B. As an infant ages, the risk of ICH in relation to VKDB is lower.
- C. The incidence of ICH in VKDB is 50% at any age.
- D. As an infant ages, the risk of ICH in relation to VKDB is higher.

Question 3:

Which recommendation regarding car seat safety is incorrect:

- A. Rear facing until age 1
- B. Back seat until age 13.
- C. Booster seat until age 8 and 4'9" in height.
- D. Rear facing as long as you can, but longer than age 2.