Infant Safe Sleep: Importance, Challenges and Our Role as Physicians

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Disclosures

I have documented that I have no financial relationships to disclose or Conflicts of Interest (COIs) to resolve.

I have documented that my presentation will not involve discussion of unapproved or off-label, experimental use of a product, drug or device.
Objectives for Today’s Talk

By the end of this talk the learner will be able to:
• Understand the modifiable environmental risk factors that contribute to Sudden Unexpected Sleep deaths
• Counsel families on the American Academy of Pediatrics Safe Sleep recommendations
• Implement strategies to promote safe sleep practices in the clinical setting
• Better identify product dangers
Leading Causes of Infant Mortality
United States: 2016 and 2017

Fact:
3,400 babies in the US die suddenly and unexpectedly each year!
What is SUID or SUDI?

- **Sudden Unexpected Infant Death**
  - Occurs in a previously healthy infant
  - Can be explained or unexplained
    - Explained: trauma, drowning, suffocation
    - Unexplained: SIDS, undetermined
  - Most unobserved, during sleep/environment

- **Sleep-related deaths**
- **SIDS** represents a subcategory of SUID
Some causes of deaths that occur suddenly and unexpectedly during infancy

- SIDS
- Accidental suffocation
- Unknown
- Poisoning
- Metabolic disorders
- Hypothermia/Hyperthermia
- Neglect or homicide
What is SIDS?

**ICD-10 Definition:** The sudden death of an infant under one year of age which remains unexplained after the performance of a complete post-mortem investigation including:

- Performance of a complete autopsy
- Examination of the death scene
- Review of the case history
SIDS FACTS

• The leading cause of death in infants from one month to one year of age (post-neonatal infant mortality)
• A diagnosis of exclusion. The cause of death is assigned only after ruling out other causes
• Peak time of occurrence: 1-4 months
• Higher incidence in males
• No longer see a higher frequency in colder months

Percent distribution of SIDS by age at death: United States, 2004-2006

AAP Task Force on SIDS Policy Statement: Nov. 2011
SIDS FACTS

• Higher incidence in preterm and low birth weight infants

• Associated with:
  - Young maternal age
  - Maternal smoking with pregnancy
  - Late or no prenatal care

• 2-3 times more common in African-American, American Indian, Alaska Native children
Triple Risk Model to Explain SIDS

**Critical Developmental Period**

First 6 months

**Intrinsic risk factors**
- Smoking
- Prematurity
- Alcohol and illicit drugs
- Hypoxia
- Growth restriction

**Extrinsic risk factors**
- Prone/Side Sleep Position
- Soft Bedding
- Overbundling/Overheating
- Bed sharing
- Bed sharing + Smoking and/or Alcohol

**SIDS**

Vulnerable Infant
(e.g. brainstem dysfunction)

**Exogenous Stressors**

- Adapted from Filiano and Kinney, 1994

Modifiable Risk Factors
An example of SIDS pathogenesis

Adapted from Kinney and Thach, 2009
U.S. SUID Rate 1990-2020

AAP Task Force on SIDS

- Convened in 1992 because of initial data noting association between sleep position and SIDS
- Mission was to review the evidence and make recommendations about sleep position
- Comprised of experts in the field
  - Selected and approved by AAP Executive Board
Birth of a policy statement

- Create list of important topics
- Extensive literature review
  - Strength of quantitative data (randomized controlled trials > case control > observational studies)
  - Qualitative data: helps to inform quantitative data and to provide context and understanding
- Recommendations are based on epidemiological studies that include infants up to 1 year.
- A total of 159 new studies were included in review of evidence.
There are TWO Documents!

- Policy Statement: summary of recommendations
- Technical Report: background literature review and data analyses
Strength of Recommendation

- Scale based on the Strength of Recommendation Taxonomy (SORT)
  - A: There is good quality patient-oriented evidence
  - B: There is inconsistent or limited quality patient-oriented evidence
  - C: The recommendation is based on consensus, disease-oriented evidence, usual practice, expert opinion, or case series for studies of diagnosis, treatment, prevention or screening.
Correct Safe Sleep Environment
The More Things Change...

• Core messages are intact!
  - Back to Sleep
  - Room Sharing
  - No soft objects
  - Good prenatal care
  - Prenatal/Postnatal Exposures
  - Immunizations
Sleep Surface

• Use a firm, FLAT, non-inclined sleep surface
  – < 10-degree incline
  – Flex trunk to flip to side or prone
  – More abdominal muscles to maintain position
  – Muscle fatigue can contribute to suffocation

• Emergency use of alternative devices
2021 CPSC Safe Sleep for Babies Act

- Eliminate potentially dangerous sleep products (under 5 months)
- Products without standards must now meet crib/bassinet standard
- Hammocks, boxes, nests, in-bed sleepers
- NICHD suggests cradleboards as a culturally appropriate surface
2021 CPSC Safe Sleep for Babies Act

• Does not impact inclined products designed for play/awake time
• Car seats safest for travel
  – Transfer after travel/safe and practical
Safe Cribs Act (5/22)

- Illegal to sell crib bumpers or inclined sleepers!
  - Includes individual slat wraps
  - Does NOT include mesh bumpers
Breastfeeding

- Yes, it is still recommended!
- Follow recommendations from SOBr
- Extra focus on the NICU patient
- Culturally appropriate, respectful and non-judgmental communication
Bedsharing Still NOT Recommended

• Reasons for bedsharing:
  – Facilitate breastfeeding
  – Cultural preference
  – Belief better/safer for infant

• NOT recommended under any circumstances
  – Extensive review of all studies
  – Risk stratification
More than 10x Baseline Risk

- Person impaired in their alertness or ability to arouse because of fatigue or use of sedating medications
- Current smoker or smoked in pregnancy
- Bed sharing on a soft surface, such as a waterbed, old mattress, sofa, couch, or armchair.
5–10 x Baseline Risk

• Infant aged <4 months
• Anyone besides the parent
  – nonparental caregivers
  – other children
2-5 x Baseline Risk

- Preterm or low birth weight infant
- With soft bedding (pillows, blankets)
Overheating and Head Covering

• Added signs of overheating:
  – Sweating, flushed skin, core warm to touch

• Climate change /Extreme weather
  – Shift from cold weather increase to higher temperature.
    • Case-crossover design (peak temperature)
    • Montreal vs. Vienna
    • Cumulative temperature
    • Ecological data vs individual monitoring
Infant Products

• After birth transition, no need for hats
• Weighted blankets and swaddles not recommended
• Monitors do NOT prevent SIDS. Non-medical grade monitors should not be used for this purpose.
  – Can be used for parental peace of mind
  – Concern of leading to parental complacency
Pacifiers

• More specific recommendation for breast feeding infants:
  – Firmly established is defined as having sufficient milk supply; consistent, comfortable, and effective latch for milk transfer; and appropriate infant weight gain as defined by established normative growth curves.
  – The time required to establish breastfeeding is variable.
Tummy Time

• Changed from “a certain amount of prone positioning” to…

• “short periods of time beginning soon after hospital discharge, increasing incrementally to at least 15–30 min total daily by age 7 wk.”
Swaddling

- When an infant exhibits signs of attempting to roll, swaddling should no longer be used.
- Added: which usually occurs at 3–4 months but may occur earlier
- Why: it could increase the risk of suffocation if the swaddled infant rolls to the prone position
Education

• Culturally appropriate, respectful, and nonjudgmental communication between clinicians and parents

• Education campaigns:
  – innovative, socioculturally appropriate
  – Well-funded, strategically implemented and evaluated
Research

• Health Disparities:
  – Social determinants of health
  – Healthcare delivery system inequalities
  – Impact of structural racism and implicit bias

SUID rates increased significantly for non-Hispanic Black infants from 2019 to 2020, widening the disparities between these two groups during 2017 to 2019.
further increases the already existing disparities in these deaths, with the rate among infants born to non-Hispanic Black families now 2.3-fold higher than the general population and 2.8-fold higher than infants born to non-Hispanic white families.

In contrast to many middle- and high-income countries, the United States lacks large-scale support for families...

These data... reflect our societal failures... (and) sound the alarm about the need for interventions that look beyond individual counseling and toward community- and society-level solutions.
Healthcare Providers: Opportunities for Improvement
UNSAFE SLEEP PRACTICES WITH BABIES ARE COMMON.

**Race/Ethnicity**

- **White**: Not Placing Baby on Back to Sleep - 16%
  - Any Bed Sharing - 53%
  - Any Soft Bedding - 33%
- **Black**: Not Placing Baby on Back to Sleep - 38%
  - Any Bed Sharing - 77%
  - Any Soft Bedding - 41%
- **Hispanic**: Not Placing Baby on Back to Sleep - 27%
  - Any Bed Sharing - 67%
  - Any Soft Bedding - 53%
- **Asian or Pacific Islander**: Not Placing Baby on Back to Sleep - 21%
  - Any Bed Sharing - 77%
  - Any Soft Bedding - 55%
- **American Indian or Alaska Native**: Not Placing Baby on Back to Sleep - 20%
  - Any Bed Sharing - 84%
  - Any Soft Bedding - 36%

**Age of Mother (years)**

- **19 or less**: Not Placing Baby on Back to Sleep - 30%
  - Any Bed Sharing - 69%
  - Any Soft Bedding - 49%
- **20-24**: Not Placing Baby on Back to Sleep - 28%
  - Any Bed Sharing - 58%
  - Any Soft Bedding - 46%
- **25-34**: Not Placing Baby on Back to Sleep - 19%
  - Any Bed Sharing - 57%
  - Any Soft Bedding - 36%
- **35+**: Not Placing Baby on Back to Sleep - 19%
  - Any Bed Sharing - 36%
  - Any Soft Bedding - 36%

Safe Sleep Nurse Modeling

- People trust nurses.
- Whatever the nurse does must be correct and it will be imitated in the home.
- Fact: supine positioning in the nursery can almost DOUBLE its use in the home!
TodaysBaby QI: Safe Sleep Teaching

• QI intervention median = 160 days
• Mothers reported receiving information 72% to 95%
  - increase of 24%-57%
• 94% babies observed supine (plus 24%)
• 88% infants in safe sleep environment
  - Increase of 33%
• Gains maintained up to 12 months

The Social Media and Risk-Reduction Training (SMART) study

- 4-group cluster randomized clinical trial
- 1600 mothers from 16 hospitals
- NQI breastmilk/safe sleep and videos breastmilk/safe sleep
- Daily messages x 11, then q 3-4 days to 2 months
- Safe sleep NQI plus M-health had highest compliance:
  - Supine sleep: 92.5%
  - Room sharing: 85.9%
  - No soft bedding: 81.9%
  - Pacifier use: 69.3%
- Largest effect from m-Health

Physician Advocacy is CRITICAL for reducing infant sleep-related deaths!!!
Missed Opportunities

Nearly half of caregivers did not receive correct advice on safe sleep practices from healthcare providers. Caregivers who received correct advice were less likely to place their babies to sleep on their stomach or side.

Physician Advocacy

- Srivatsa 1997: HCP education to new families...34% reduction in prone sleeping
- Colson 2009: Only 1/3 mothers advised by MD to use supine position...3 x more likely to position the baby properly
- Advice against bed-sharing by pediatrician associated with decreased bed sharing (OR = 0.66)
- A neutral attitude was associated with increased bed sharing (OR = 1.38)
Everybody wants the same thing: safe products
Who Oversees Product Safety?

- **Government**
  - Law
  - Regulators
- **Safety Certification Companies**
  - Nationally Recognized Testing Laboratories
- **Manufacturers**
- **Non-profit Safety Organizations**
Safety Standards Groups

- American Society for Testing and Materials (ASTM International)
- National Science Foundation (NSF) International
- Underwriters Laboratories (UL)
- Juvenile Products Manufacturer’s Association (JPMA)
Consumer Product Safety Act

- An Act to protect consumers against unreasonable risk of injury from hazardous products, and for other purposes.
- Enacted 10/27/72
- Effective 12/26/72
- CPSC: a permanent independent agency of the US government
The Consumer Product Safety Improvement Act (CPSIA, 2008)

- Amendment to CPSA (the Danny Keysar Child Product Safety Notification Act))
  - Lead and phthalates
  - Toy safety
  - Durable infant/toddler products
  - Third party testing and certification
  - Tracking labels
  - Imports
  - Civil and criminal penalties
  - SaferProducts.gov, a publicly-searchable database of reports of harm
  - Increased commissioners from 3 to 5
Durable Infant or Toddler Products

- is a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years

<table>
<thead>
<tr>
<th>Baby changing products</th>
<th>Cribs (full and small)</th>
<th>Infant sleep products</th>
<th>Infant Bouncer Seats</th>
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<tr>
<td>Bassinets and Cradles</td>
<td>Gates and Enclosures</td>
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<td>Bedside Sleepers</td>
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<td>Folding chairs</td>
<td>Infant Bathtubs</td>
<td>Hook-on chairs</td>
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</table>
CPSIA: Beyond Basic Testing

- CPSC to develop “final regulations” for each category
  - Additional safety requirements
  - Physical and mechanical
- Until final regulations complete...
  - Manufacturers and importers are “encouraged” to comply with voluntary safety and performance standards
    - Mostly issued by ASTM International
American Society for Testing and Materials (ASTM) International

- 120 years
- 30,000 members, over 135 countries
- Develops voluntary consensus technical standards for materials, products
- Executive committee
- 150 technical committees- all product sectors... 62 subcommittees
- If product hazard identified: task group
ASTM

• Task groups:
  - all volunteer, anyone can participate
  - Manufacturers, importers, safety advocates, lobbyists, lawyers, trade associations, academia, general public
  - 10-20 individuals
  - Only ASTM members vote: all stakeholders have an equal voice
  - Review data: science driven
    • Include all points of view
2010 Inclined Sleeper Exemption

- CPSIA would eliminate inclined sleepers and hammocks
- SNPR: supplemental notice of proposed rulemaking
- Led to product exemption “new product”
- ASTM: creation of voluntary standards
  - Task group lead: engineer of the Rock n Play™
Rock ‘n Play Rejections

- Australian Regulators:
  - did not meet widely accepted best practices for infant sleep, and that a baby’s head could easily fall forward in a way that obstructs the airway

- Royal College of Midwives:
  - not endorse the product as a sleeper because it was only suitable for short periods of supervised wakefulness.

- Health Canada:
  - only allowed the product to be sold as a Rock ‘n Play Soothing Seat rather than a sleeper (warning stated “never leave child unattended” while in the product.)
Evolution of a Product Ban

- 2017 NPR... aware of 14 deaths (2005-16)
  - ASTM, voluntary
  - 10-30 degree seat angle

- 2019 Supplemental Proposed Rule (Supplemental NPR)
  - CPSC reports of 42 more deaths since 2017
  - Terminate the 2017 NPR
  - Mandatory rule more stringent
  - Limit angle to ≤ 10 degrees
CPSC Limitations

• CPSA Section 6(b)
  - CPSC cannot release product or company information without permission from manufacturer
    • Even for warnings about injuries or deaths
    • Companies have to consent to info disclosed and can negotiate language in CPSC press release

• 2018: CPSC website alert
  - “Caregivers Urged to Use Restraints with Inclined Sleep Products”
  - No products named
Evolution of a Product Ban

- CR publishes RNP sleeper investigation and calls for a recall
- AAP urges CPSC to issue recall
  - warns parents against use of inclined sleep products and states “warning issued by the CPSC and Fisher-Price on April 5 did not go far enough to ensure safety and protect infants.”
- Recalls followed...
JPMA: Still Supports Inclined Sleepers

• Seek decisions that do not result in the introduction of unintended consequences
• Creates more risk when we eliminate an entire product category without strong data to support that need
• parents may create makeshift solutions to solve for these issues
• introduce danger because an approved product does not exist
Gaps

- Recall Effectiveness
  - Voluntary
  - Communications
    • Outlets
    • Budget
    • Evaluation
- Sales on secondary markets
Product Recall Gaps

Product Recalls

**Belief**

92% of Americans say manufacturers should do all they can to get potentially dangerous recalled products out of homes.¹

**Reality**

6% of recalled products, on average, are returned or refunded.²

¹ Based on a July 2020 CR nationally representative survey of 2,031 American adults. Respondents were asked to focus on products that cost $75 or more. Percentage includes “agree” and “strongly agree” responses.

² CPSC, July 2017. Reflects portion of consumers whom the CPSC knows took part in a recall, including those who asked for a repair.
In the meantime.....

**Rocking sleeper recalls reissued following additional infant deaths**
At least 12 more infants have died since the products from Fisher-Price and Kids2 were recalled in April 2019. Some of the infants died after rolling from their back to their stomach or side while unrestrained.
And finally...

- Health care providers should have open, frank, nonjudgmental conversations with families about their sleep practices.
Communication

• Motivational Interviewing
  - Explore one’s reasons for change (barriers)
  - Patient generates own solutions

• Listen. Observe. Validate. Educate
  - Use a positive tone/No guilt
  - Allow the parent to ask most of the questions.
Culture Change: Know your audience!

- Cultural competence/Cultural barriers
  - What are the norms/expectations?
  - Why deviate from recommendations?
  - What are the barriers?

- Caregivers know the “message”, but are not changing behaviors

- Caregivers report a need to understand the reasons for safe sleep recommendations

- Gaining trust
  - Behavior change requires two-way communication!
MI Core Communication Skills

• Open-ended questions
  - Allows parent to tell their story

• Reflecting
  - Reflective listening shows parent you understand

• Affirming
  - Acknowledge parental strengths provides encouragement

• Summarizing
  - Reflections that tie together parent’s story
Open-Ended Questions

• Do you have a crib? vs Where do you put your baby down to sleep?
• Do you practice safe sleep? vs What plans do you have for safe sleep for your baby?
• What do you find most difficult in keeping a safe sleep environment?
• How often are you able to practice safe sleep?
Sometimes is an opportunity!

• Can you tell me more about that?
  - Problem recognition
  - Concern
  - Intent to change

• Help parents uncover their own motivation to change
  - Readiness
  - Willingness
  - Commitment
  - Plan
Guiding Parents Through Behavior Change

- Acknowledge: there may be different opinions
- Affirm: you have a lot of experience taking care of babies
- Educate about the dangers of unsafe sleep practice
- Summarize: what I hear you saying is safety is what is most important to you.
Stages of Change Model
(Transtheoretical)

• New knowledge/innovations pass through predictable stages:
  • Knowledge (exposure to its existence, and understanding of its functions);
  • Persuasion (the forming of a favorable attitude to it);
  • Decision (commitment to its adoption);
  • Implementation (putting it to use); and
  • Confirmation (reinforcement based on positive outcomes from it).
How Can I Improve My Practice?

- Do I listen more than I talk?
- Do I encourage the person to talk about their reasons for not changing?
- Do I keep myself open to the person’s issues?
- Do I invite the person to talk about and explore their own ideas for change?
- Do I ask permission to give my feedback?
Overcoming Barriers to Change: What parents are saying...

- Prone positioning: fear of choking
- Baby sleeps “better” on stomach
- Soft things are safer for the baby
- SIDS is “God’s will”
- Why bother? Recommendations keep changing anyway
- Vigilance: sleep with baby for protection
Things you can do in your practice...

- Give parents tools to cope with fussy babies
- Sleep-deprived parents may make poor judgments
- Make use of tools such as swaddling, side carrying, shushing, swinging, and sucking
Feeding the Baby at Night: “Safe Sleep Zone”

- Acknowledgment that parents may fall asleep while feeding baby
  - Safer to feed on bed than on sofa, couch, or armchair if you might fall asleep
  - No pillows, sheets, blankets, or other items that could obstruct infant breathing or cause overheating should be in bed
  - Return infant back to separate sleep surface as soon as parent awakens
Working Together

• Room not big enough for full crib
  - Portable crib or play yard
  - Non-traditional spaces
  - Save space when not in use

• Post C-section/difficult mobility
  - Move bassinet up to the edge of the bed

• Concern about legs getting stuck in crib slats
  - Use of sleep sack to contain the legs
Make Use of Your Assets

- A picture is worth a thousand words!
  - Educate through images
- All politics are local!
  - Know your numbers
  - Evidence-based Medicine
- It can’t happen to me!
  - Share real local stories
IT MIGHT NOT BE PRETTY.
BUT IT CAN BE PEACEFUL.
Should we use a safe sleep calculator??

SUDI Protection Plan for Test Baby

SUDI is sudden unexpected death in infancy, also known as SIDS or cot-death
Assessed SUDI risk is Medium (0.7 per 1000).
Make changes to reduce risk to Medium-Low (0.2 in 1000).

Strong baby
- Keep on doing these:
  - Breastfeeding
  - Drug-free pregnancy and caregiver
  - Back sleeping

Easy to Breathe - Safe to Sleep
- Keep on doing these:
  - Back sleeping
  - Same room as parent or caregiver
  - Own baby bed
  - Drug-free pregnancy and caregiver

Add more SUDI protection:
- Smokefree mother as soon as possible.
- Alcohol-free caregiver
- ALSO Immunise

Add more SUDI protection:
- Alcohol-free caregiver
- ALSO Sleep baby FLAT, NO PILLOWS, not overwrapped or too hot
- ALSO Bedsharing will increase risk to: 14 in 1000

Risk if changes not made –
- If alcohol free caregiver
- If smokefree mother
- If all changes are made
- If bed shared with baby

If bed shared with baby - 14
Counseling Strategies

Follow the Recommendations
• “Red Rules”
• Car seats: sometimes?
• Accepting deviations undermines the rules
• Better for establishing policies

Risk Reduction
• Some is better than none
• Decreasing barriers
• More reality based: parent-focused
• Partnership
• Better at individual level
Infant Sleep Safety: Lifetime Education

• A continuum starting in childhood
  – Secondary school, baby sitting classes
• Pre-pregnancy
• Pregnancy/prenatal education
  – Prior to baby shower…”wrong gifts”
• In hospital education and modeling
  – Include family, friends, baby sitters
• Re-enforcement in the doctor’s office
  – Especially between 1 to 4 months
• Grandparents: They hold great power!
• The General Public
Social Norms

- Unsafe sleep images!
  - In healthcare settings, advertising, stock images, internet, Facebook, Instagram
- Colson: prone positioning highly correlated with mother’s social norm (aOR 11.6)
- Kellams: high likelihood of bedsharing intent- perceived social norm favoring bedsharing (aOR 5.84)

Implications of Mothers' Social Networks for Risky Infant Sleep Practices

• Influence perceived normal or “acceptable” behavior
• Large networks = more variety
• Increased influence:
  - Stronger ties: family, frequency, long duration
  - Similar backgrounds
  - Dense networks (many know each other)
• Compared exclusive (kin, older, same race, strong ties, dense) vs expansive networks

Social Networks and Infant Sleep Practices

- Exclusive moms: younger, black, unmarried, less educated, lower socioeconomic status
- Both groups followed safe sleep but...
- Exposure to norms of unsafe sleep: more likely to practice it
Social Norms: The Petrified Wood Principle

• Petrified Forest National Park, AZ

• Which sign will most likely deter theft:
  - “Many past visitors have removed the petrified wood from the park, changing the state of the petrified forest”
  - “Please don’t remove the petrified wood chips,”

• First sign resulted in 4-fold increase is stolen wood chips!
  - Stealing chips is normal

Social Norms

• Injunctive norms = rules. Tell us how to behave
  - Assumes rational, information-based decisions
• Descriptive Norm: what’s normal in terms of what people are doing
• Do vs Should
Social Norms Influence Behavior

- Effect of feedback on electricity use in California
- If using more than average: reduced consumption
- If using less than average: increased consumption!
  - “boomerang effect”
- If using less than average + smiley face: No increase!
- If using more than average + sad face: No added benefit

### Infant Mortality Rates by Country

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<tr>
<th>Country</th>
<th>Infant mortality per 1,000 live births, 2017</th>
</tr>
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<tbody>
<tr>
<td>United States</td>
<td>5.8</td>
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<tr>
<td>Canada</td>
<td>4.5</td>
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<tr>
<td>France</td>
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<td>Switzerland</td>
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<td>Comparable Country Average</td>
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<td>Sweden</td>
<td>2.4</td>
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<tr>
<td>Japan</td>
<td>2.0</td>
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</tbody>
</table>
What is different in the US?

- No universal health care
- No paid family leave
- PA HB 181
Nocturnal Video Assessment of Infant Sleep Environments

• Video recordings at 1, 3 and 6 months (n = 160)
• Mostly older, white, college-educated
• First sleep: 79% crib/86% supine/9% safe sleep environment/58% room sharing
• Second sleep (28%): 9% safe surface/64% supine/67% shared a sleep surface

Impact of Eliminating Sleep-Related Deaths

Every week we lose 65 children which is equivalent to 3 kindergarten classrooms
Thank You!
Contact Information

• mgoodstein@wellspan.org