

The Period of *PURPLE* Crying<sup>®</sup>:  
Keeping Babies Safe in North  
Carolina



THE UNIVERSITY  
*of* NORTH CAROLINA  
*at* CHAPEL HILL

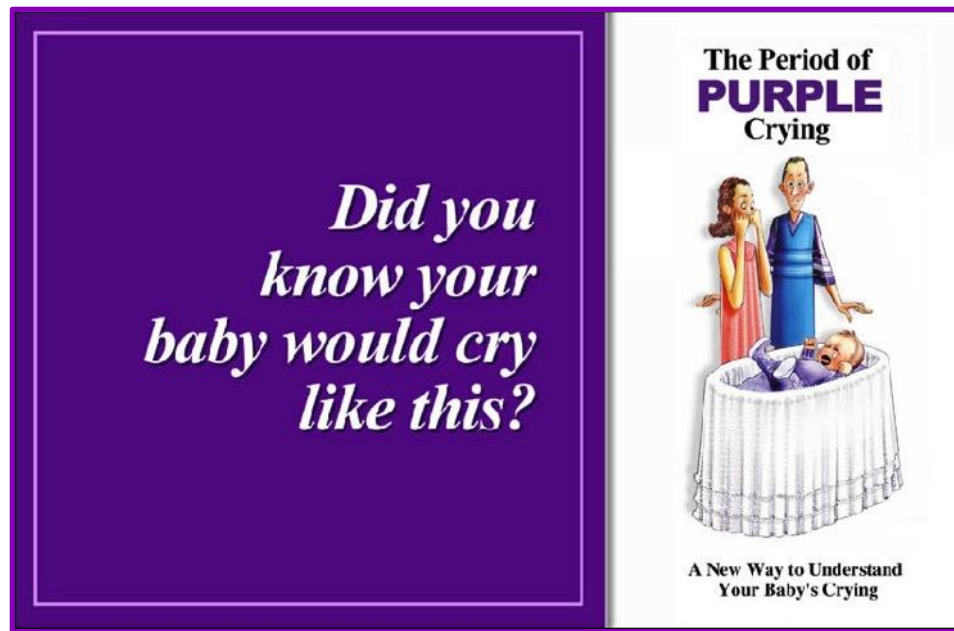


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# Context

- 17.9/100,000 children in first 2 years of life
- 30/100,000 births in first year of life

# The Period of *PURPLE* Crying<sup>®</sup>



Implemented statewide in every hospital and birthing center in NC early 2009

# NC version of the intervention

- Dose 1
  - Introduce the *Period of PURPLE Crying* to all parents in Nursery
  - Give program to parents to take home & use with other caregivers
- Dose 2
  - Reinforce at doctor's well child visit with posters, cards, and replacement materials
- Dose 3
  - Media dissemination of message to peers & public

# Collaborators

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# The Period of *PURPLE* Crying<sup>®</sup>: Keeping Babies Safe in North Carolina

- Statewide initiative to reduce incidence of abusive head trauma in young infants
- 3 'dose' campaign, multiple evaluation strategies
- Funding
  - Centers for Disease Control and Prevention
  - The Duke Endowment
  - Doris Duke Charitable Foundation

# Methods

- Participants
  - Nursing staff at 86 hospitals/birthing centers
- Procedures
  - Phone surveys at 6 mo, 18 mo and 30 mo following program implementation
  - Group interviews at 12 and 24 mo following program implementation
  - Paper and pencil surveys following training and at 12 and 24 months





# Methods

- Compliance to program protocols
  - Bedside teaching
  - Video viewing
  - Distribution of program materials
- Program adoption
  - Staff satisfaction
  - Integration of program

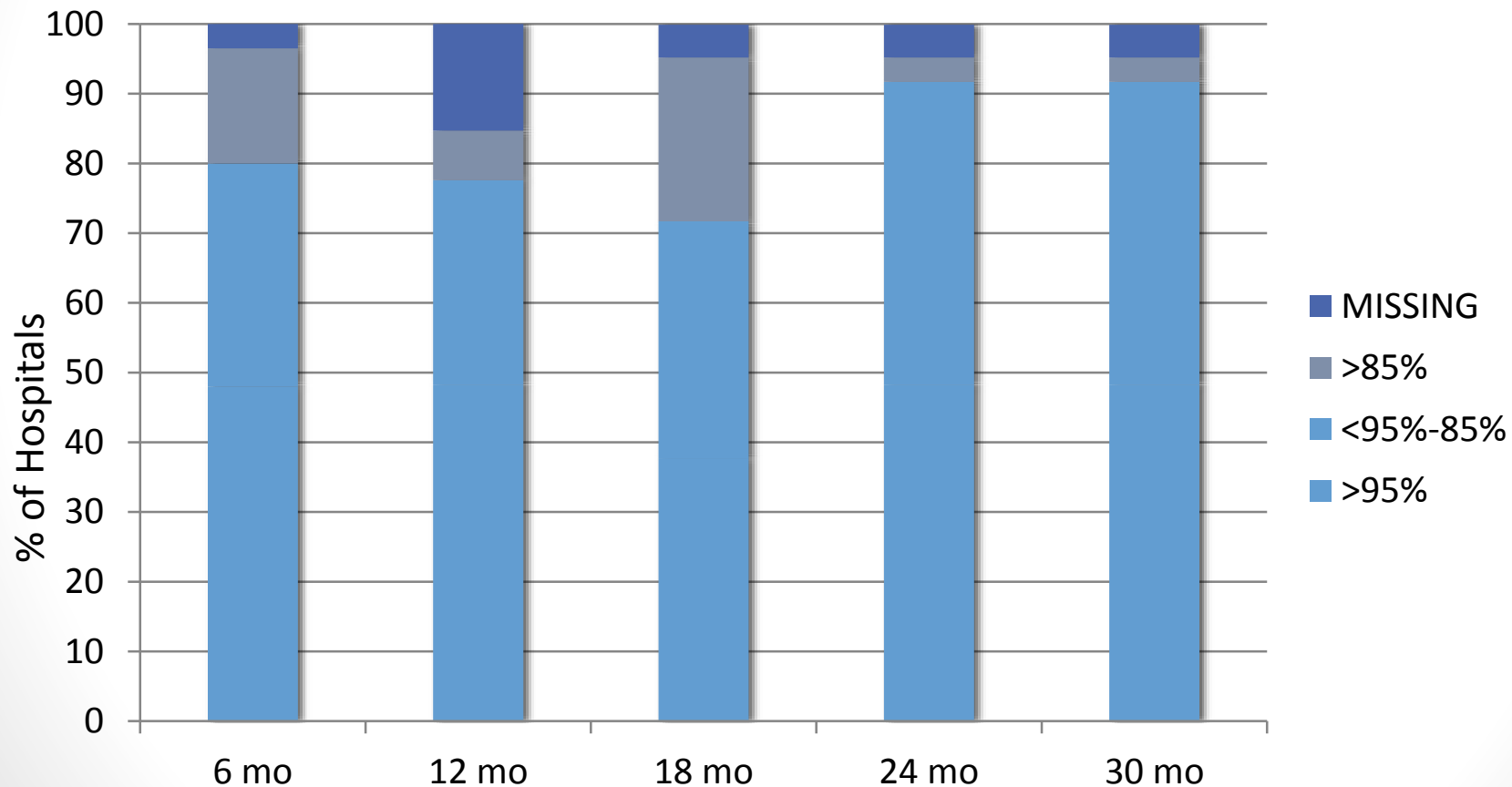
# Analysis

- Descriptive statistics for fidelity to program models and program adoption

# RESULTS

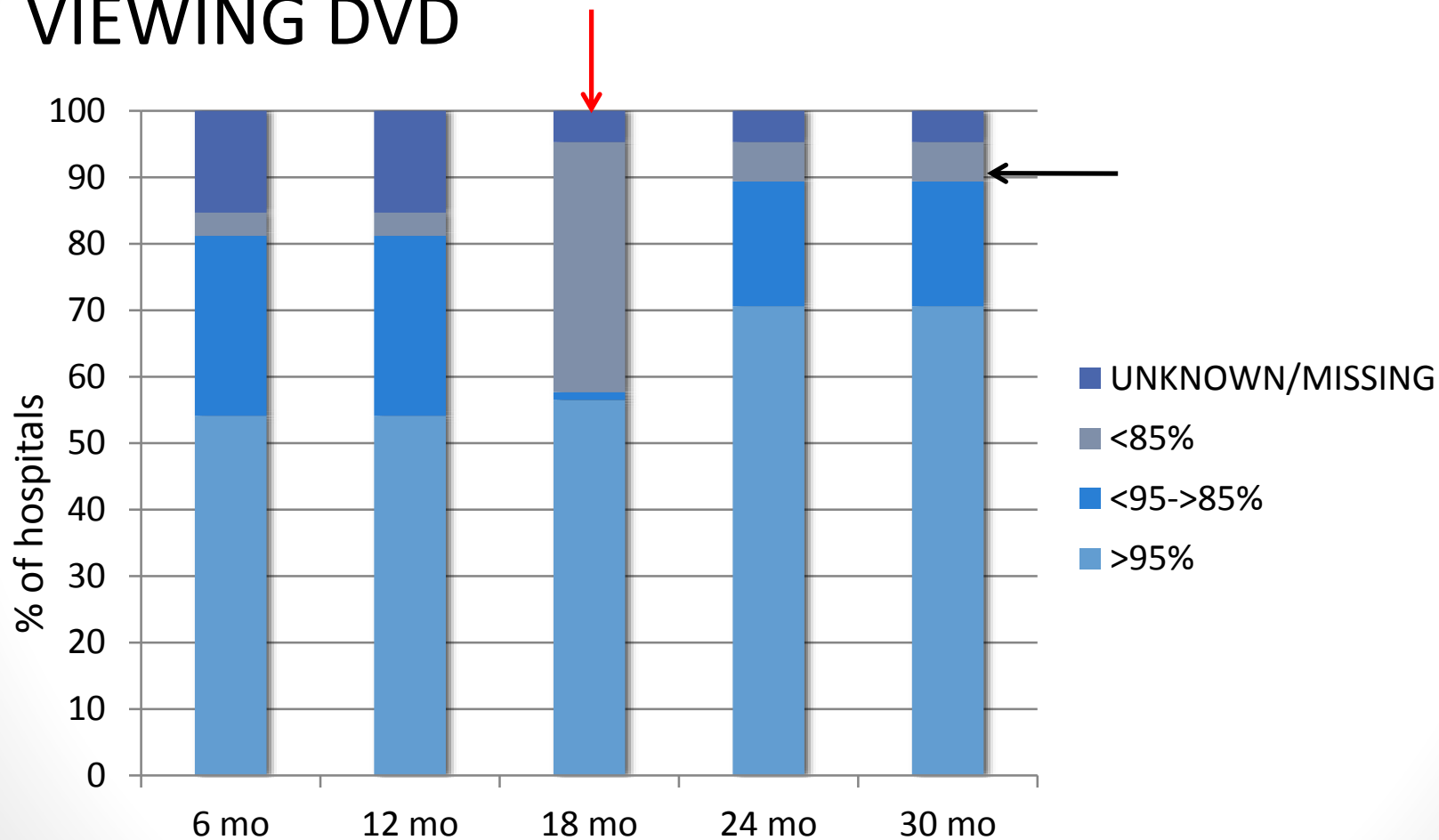
## Fidelity to program model

### BEDSIDE TEACHING



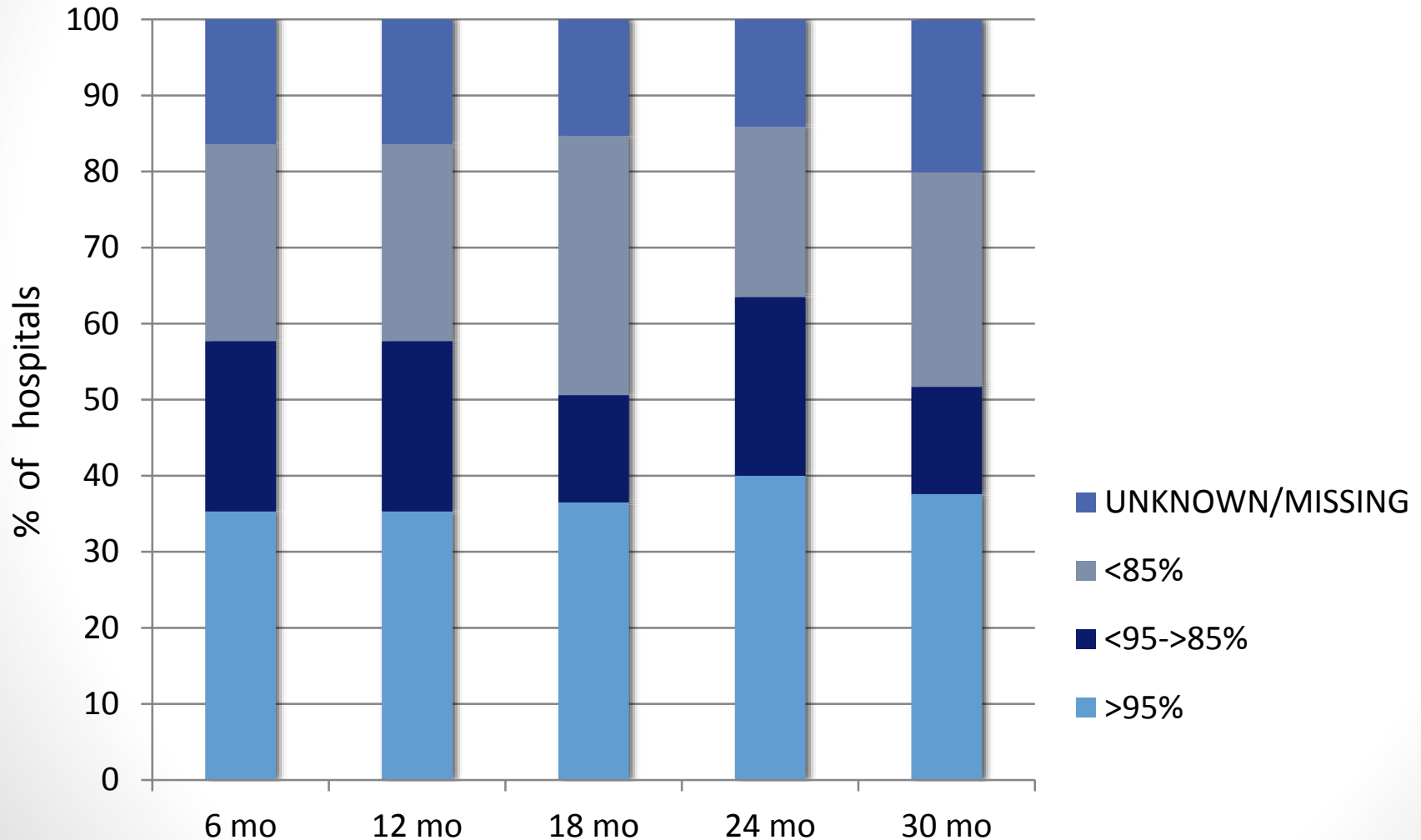
# Fidelity to program model

## VIEWING DVD



# Distribution of Program Materials

Program materials inventories



# Distribution of Program Materials

	<b>6 mo n= 75</b>	<b>12 mo n= 72</b>	<b>18 mo n= 73</b>	<b>24 mo n= 77</b>	<b>30 mo n=69</b>
Mean	91 %	87%	85%	88 %	86%
Median	96%	90%	90%	93%	92%
Range	(45-100)	(44 -100)	(41-100)	(38-100)	(28-100)

# Distribution of program materials

What percent of parents receive program materials?

	12 months N= 795 N(%)	24 months N=628 N(%)
>90%	740 (93)	586 (93.3)
50-89%	48 (6)	33 (5.3)
<50%	5 (0.7)	5 (0.8)
Missing	2 (0.3)	4 (0.6)

# PROGRAM ADOPTION

## Staff Satisfaction

	N=4235 Mean (SD) Range 1-5
How helpful do you think the information will be to your patients?	4.72 (.59)
How useful will this information be?	4.58 (.73)
How does <i>The Period of PURPLE Crying</i> <sup>®</sup> program compare to other information you may have received about preventing Shaken Baby Syndrome?	4.52 (.70)



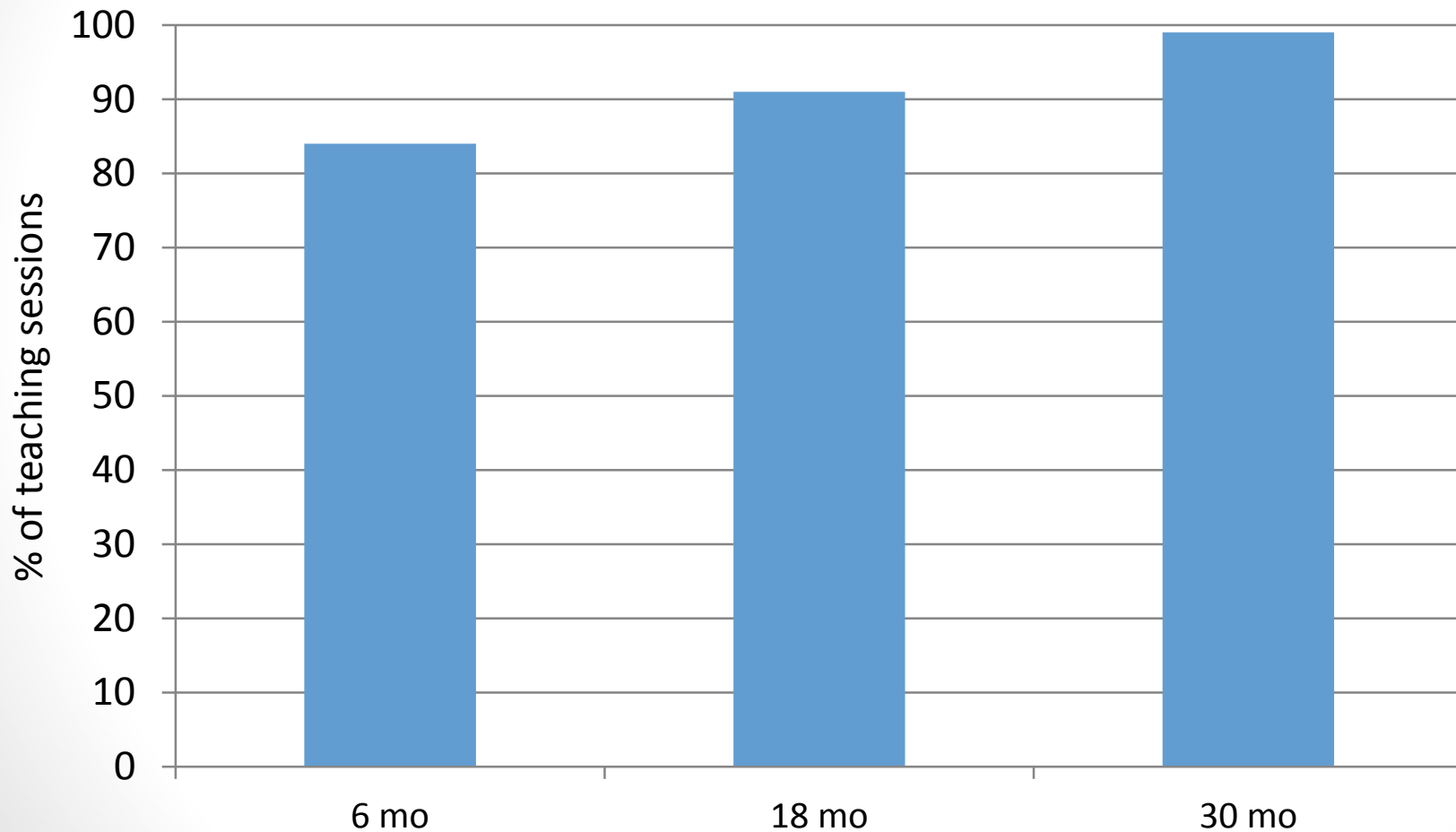
# PROGRAM ADOPTION

## Staff Satisfaction

	12 mo N(%)		24 mo N(%)	
How useful is this information for parents?	Very	651(82)	Very	398 (63)
	Useful	N/A	Useful	201 (32)
	Somewhat	134(17)	Somewhat	29 (5)
	Not Very	3(0.4)	Not Very	0
	Missing	7(1)	Missing	0

# PROGRAM ADOPTION

## Documentation in medical record



# Conclusions

- Hospitals demonstrate fidelity to program protocols across measurement strategies.
- Program material inventories suggest consistent distribution to parents.
- Hospital staff report satisfaction with program
- Systematic documentation in hospital medical record.

# Parent recall-Background

- Previous studies have shown higher retention of behavioral health messaging that spans more than one medium.
- One study showed that abusive head trauma prevention message was best retained when multiple medium were used (Russell BS 2008)
- We asked parents of infants in a state with a comprehensive near universal 3 dose AHT prevention program to report their recollection of The Period of Purple Crying

# Parent Recall Survey

- Telephone survey of parents of children less than 9 months of age
- Stratified random sample of birth certificates matched to phone numbers (landlines)
- Objective: to ascertain exposure to program and key messages
- N=1644
- Adjusted RR 52%
- Average age of infant = 3.3 months (range 1-8 months)

# Parent Recall Survey: Heard of the PURPLE Program

80.3% had heard of program (n=1314)

- 93% Hospital
- 9.7% Doctor's Office
- 8.4% Media
- 3.3% Health Department or Community Health Center
- 3.2% Friend/Relative
- 0.7% Home Visiting Nurse
- 9.4% Other
- 0.2% Don't Know

# Parent Recall Survey: Program Messages

Message	% (n)
Crying is normal	84.7 (1387)
Shaking a baby is dangerous	87.0 (1424)
Normal crying peaks at 2-3 months	59.9 (981)
Watch the DVD at home	83.1 (1360)
Read the booklet at home	73.8 (1208)
Share this information with others	80.3 (1315)
None of the above	4.2 (68)
Don't know	0.1 (1 )
Missing	0.2 (3)

# Parent Recall Survey: Materials About Normal Infant Crying

57.1% watched DVD in hospital (n=933)

- 73.7% watched with family/friends

84.3% received own copy of materials (n=1378)

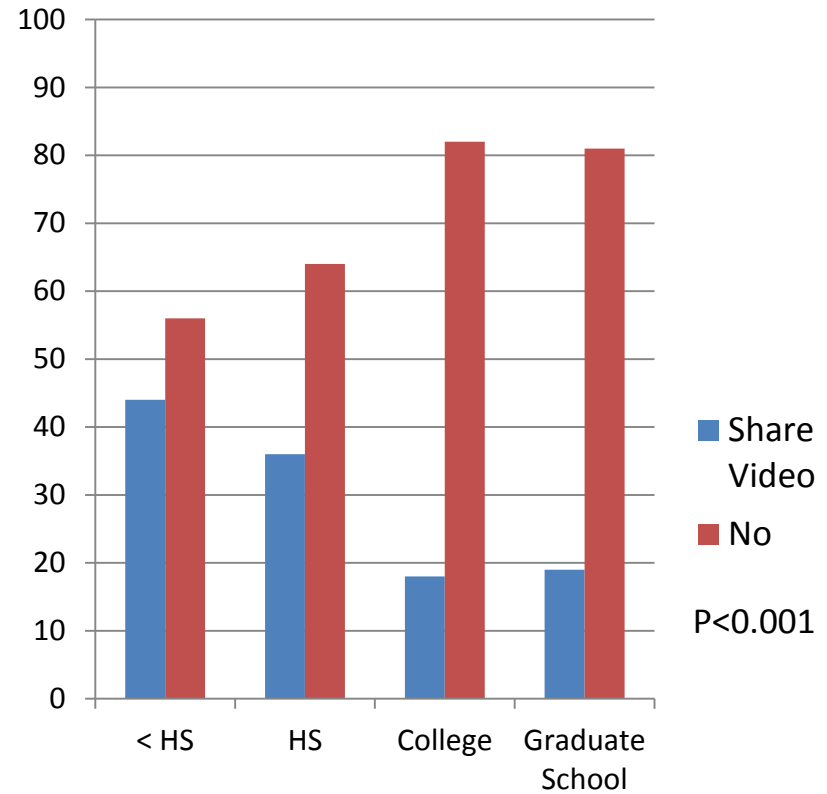
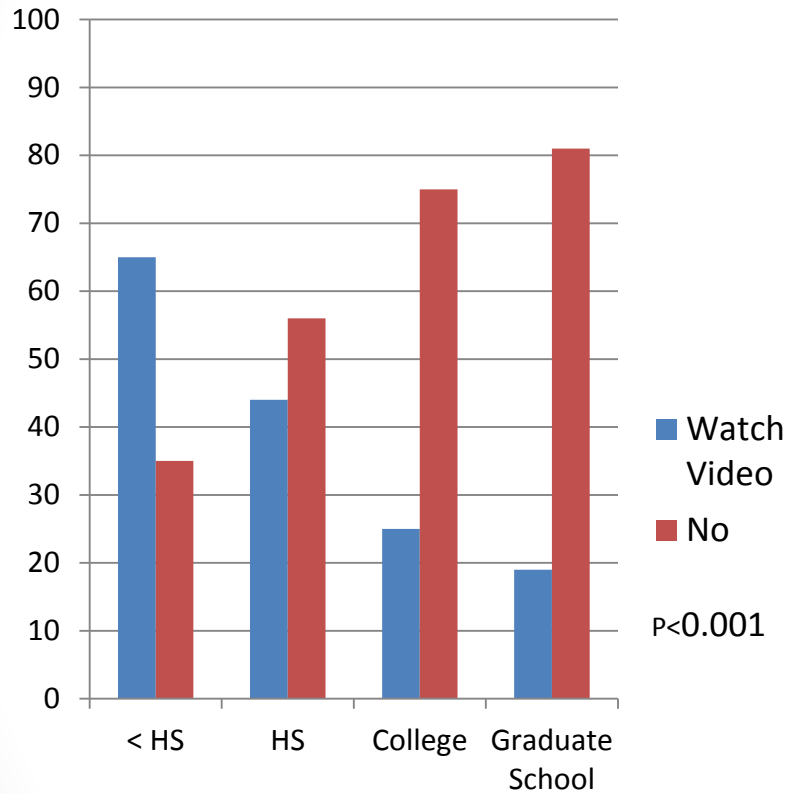
- 33.7% watched DVD at home
- 62.5 read booklet at home
- 25.5% showed DVD to others
- 30.7% showed booklet to others



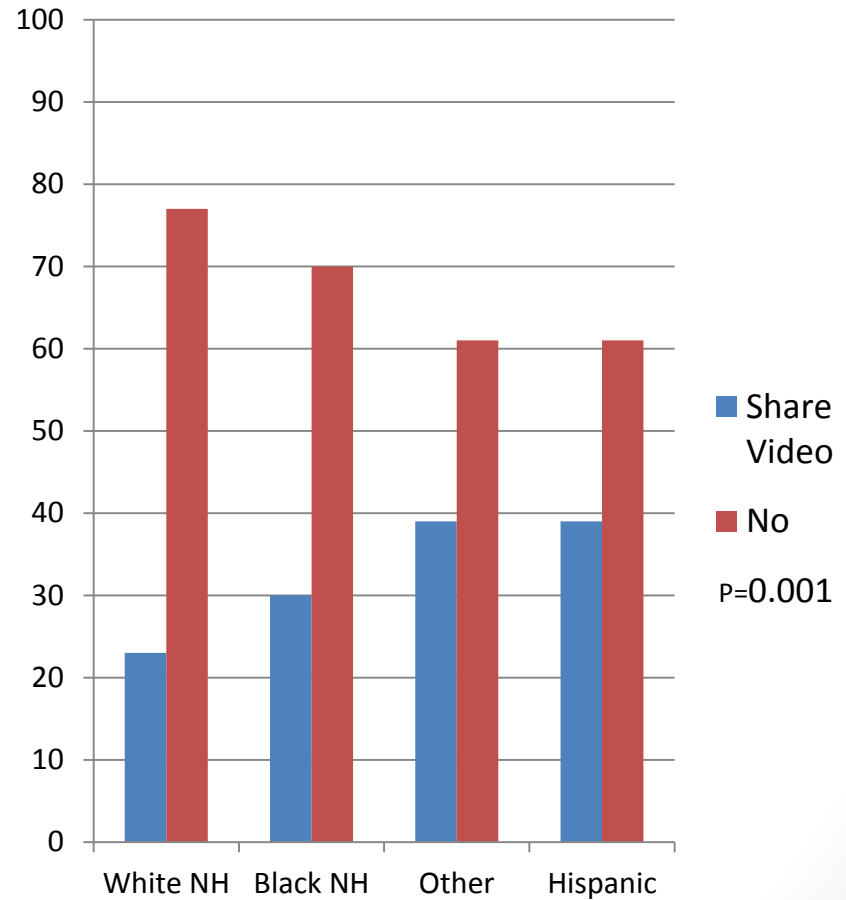
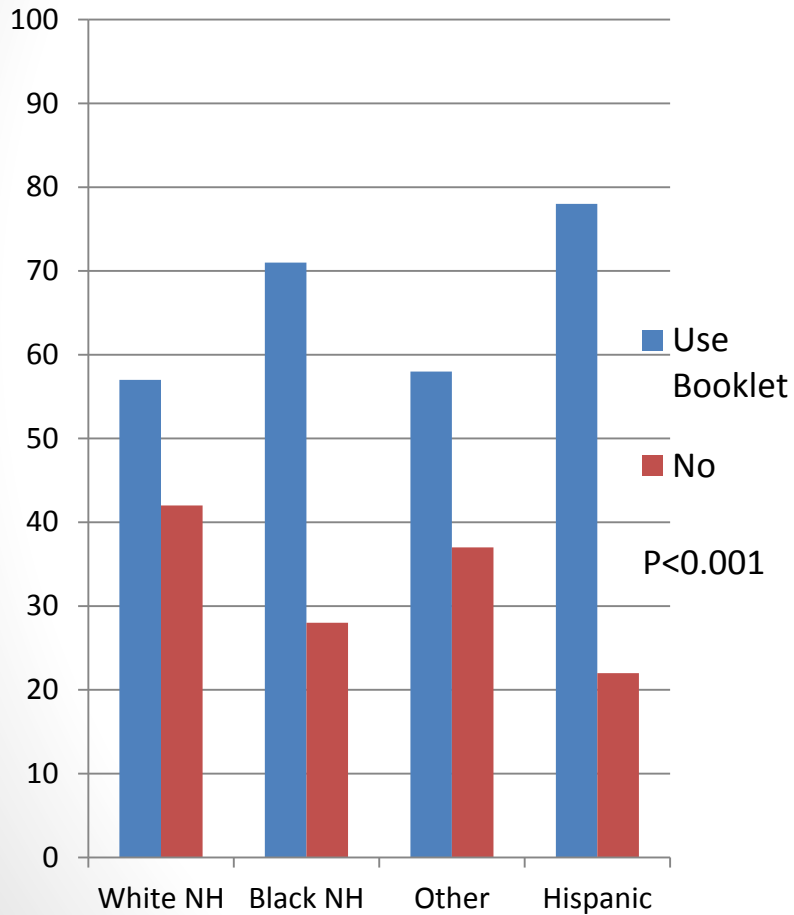
# Parent Recall Survey: Impact Measures

Learning about normal infant crying...	% Agree (n)
Helped me to feel less frustrated when my baby was crying	91.2 (1472)
Helped me to understand that my otherwise healthy baby's crying can be very normal even if it goes on for hours	87.4 (1409)
Made me less stressed when my baby was crying	85.9 (1384)

# Education



# Race/Ethnicity



# Conclusions

- Recall of key messages is quite high.
- Use of materials at home is high (70% used, 45% shared)
- Reported using and sharing of materials is more common among women of lower education and Hispanic ethnicity

- The hospital is the most common place for parents to recall learning about The Period of PURPLE Crying.
- Doctor's office and media campaign represent small potential reinforcement areas.
- Despite the small cost, the distribution of materials seems important in AHT prevention education given the high rates of using materials post hospital discharge.

# Evaluation of outcome

- Prospective cohort analysis
- Nurse helpline calls for crying
- Difference in Difference

# Prospective Cohort Analysis

**Hypothesis:** Victims of AHT will be more likely to be born at a hospital with lower fidelity to the *Period of PURPLE Crying* program model.

- We measured fidelity of program implementation in our 86 hospitals based on 3 criteria (teaching, watching, and giving) and assigned hospitals as delivering the program with high, medium, or low fidelity.
- Using prospective surveillance in state PICUs and medical examiner records, we identified AHT cases over a 3 year period (n=138) and unintentional TBI cases (n=82) and assigned fidelity scores. We used the entire corresponding birth cohort and (n=663,038) and corresponding fidelity scores to maximize analytic power.
- Analysis conducted with Poisson Regression to calculate Incidence Rate Ratios (and 95% CI) for high, medium, and low fidelity to teaching, watching, and giving. Results compared for AHT and unintentional TBI.

# Cases/Rates (<24 months)

- AHT n= 138

Rate = 20.1/100,000 person-years

- Unintentional TBI n=82

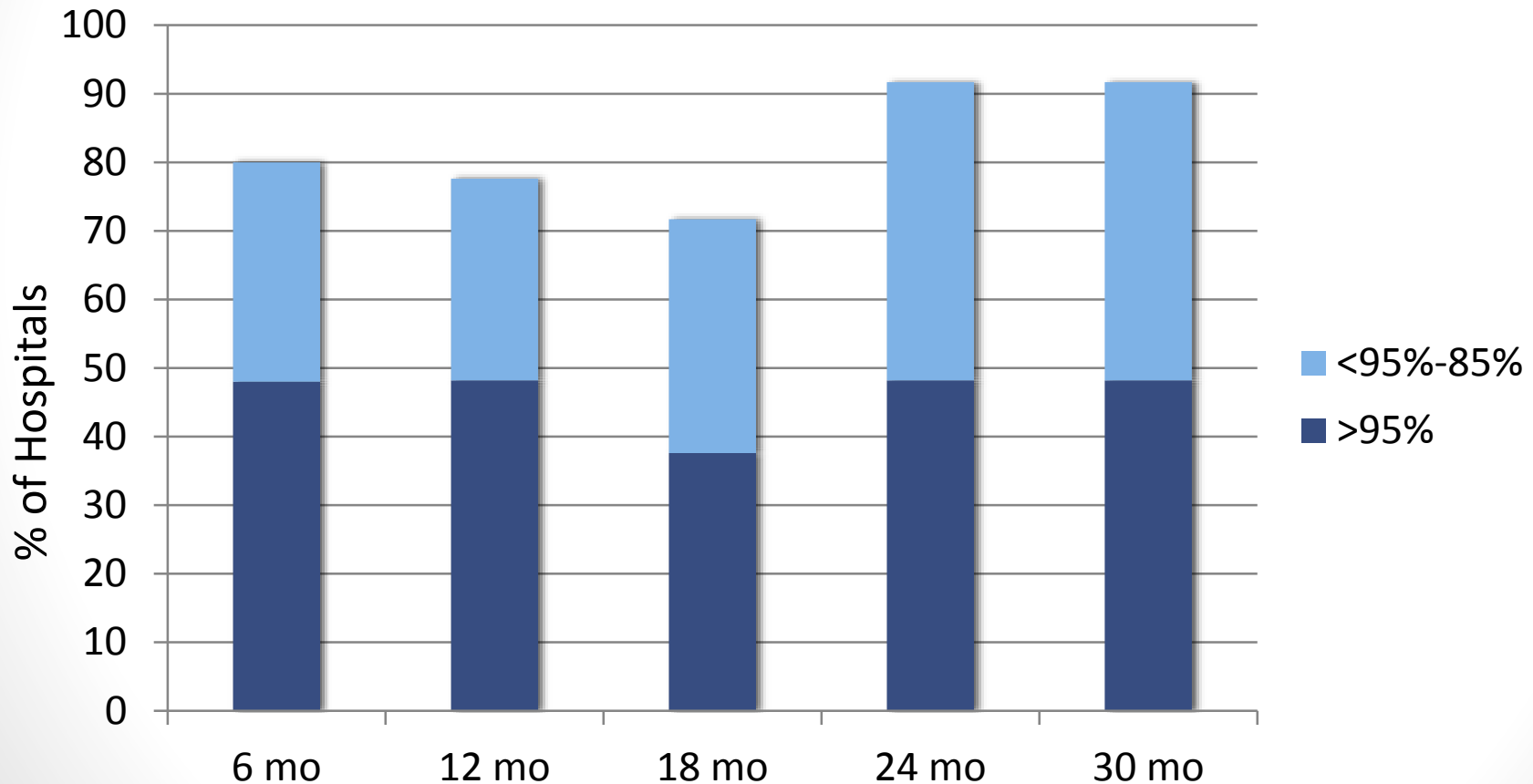
Rate = 12.4/100,000 person-years

These rates represent preliminary findings for April 1, 2009-March 31, 2012 and do not include all Medical Examiner cases.



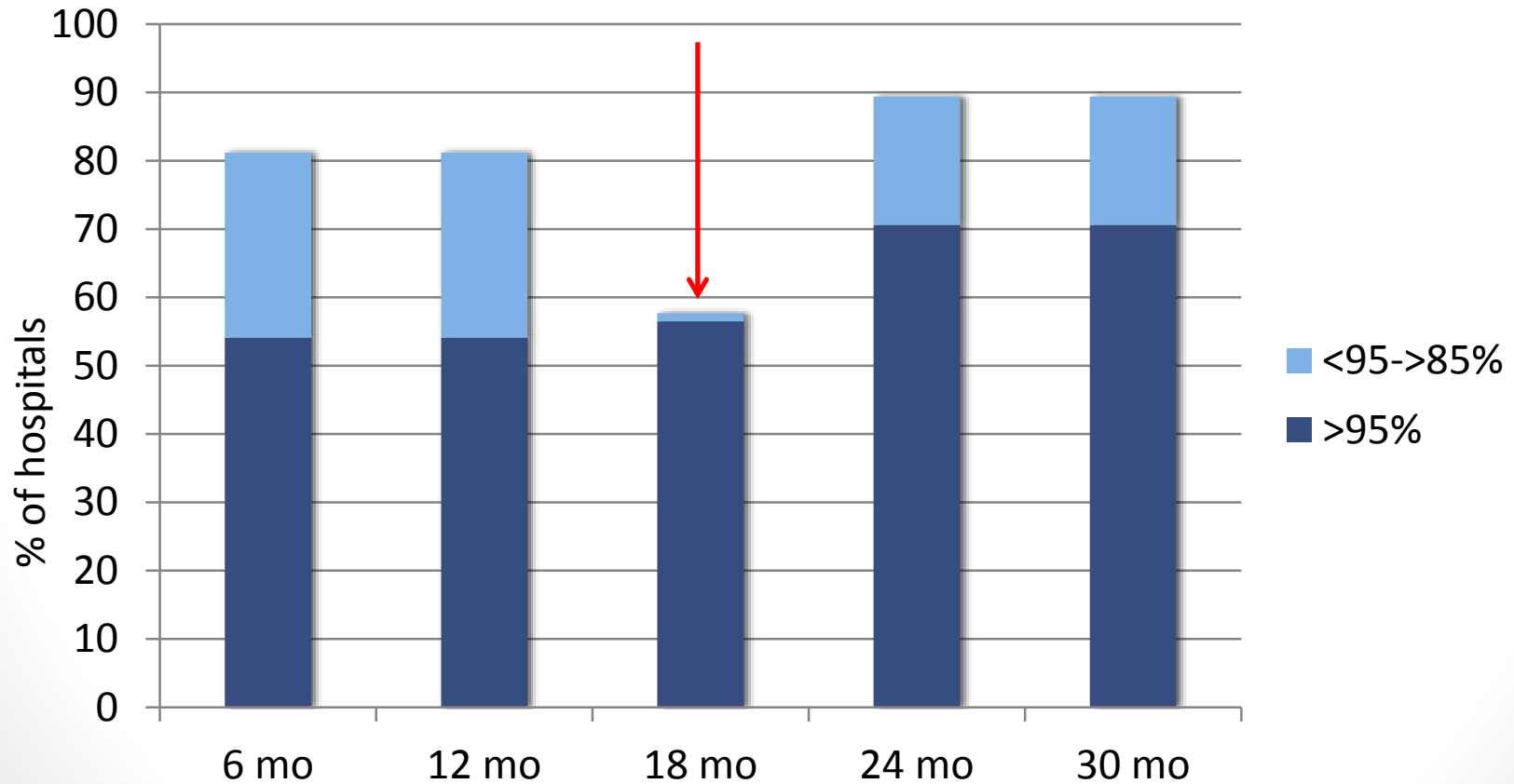
# Fidelity to program model

## BEDSIDE TEACHING

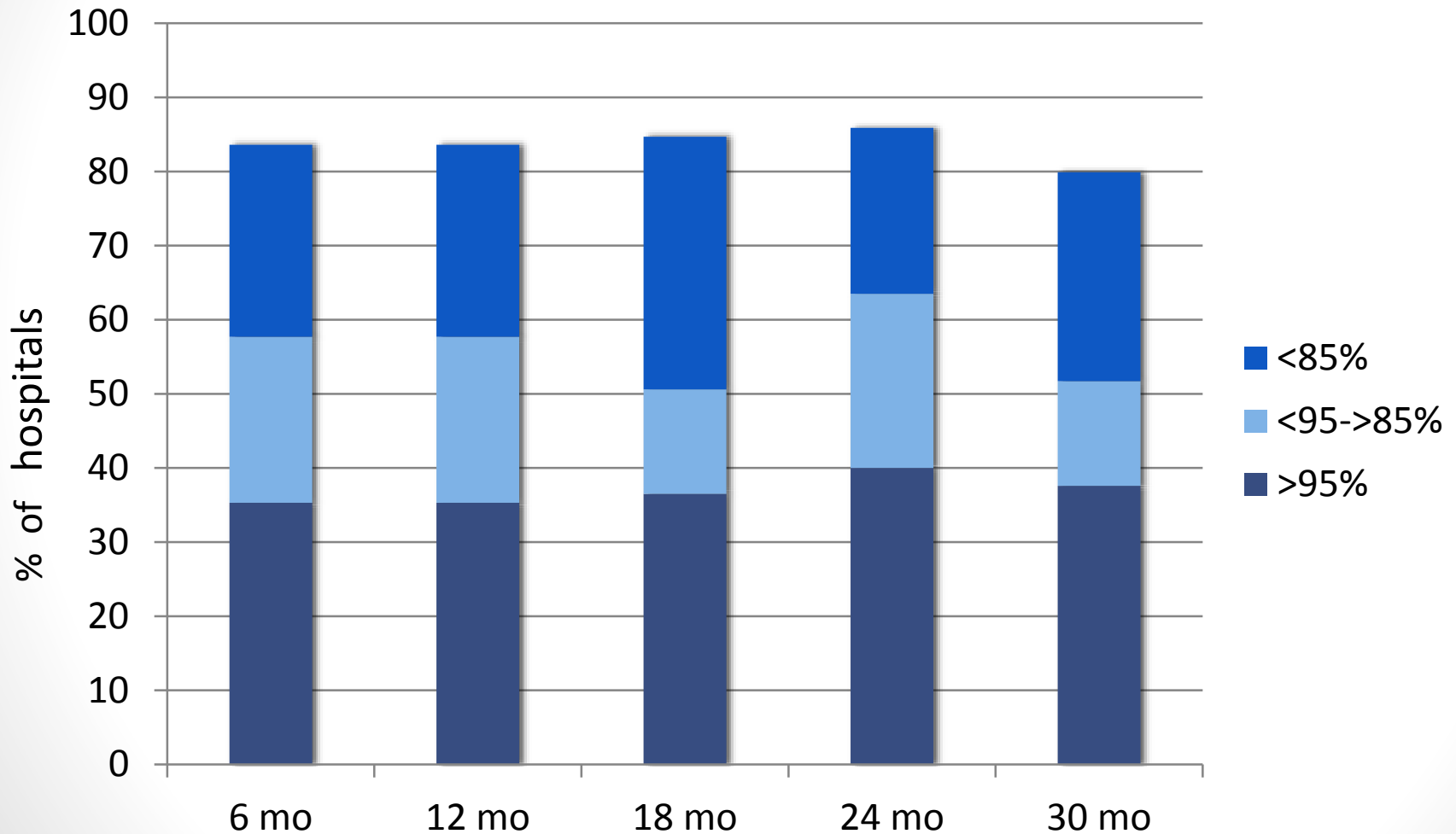


# Fidelity to program model

## VIEWING DVD



# Distribution of Program Materials



# Incidence Rate Ratios

Variable	IRR	(95% CI)
Abusive Head Trauma		
Teach	1.16	0.84-1.61
Watch	1.10	0.85-1.40
Give	0.96	0.73-1.27
Unintentional Traumatic Brain Injury		
Teach	0.66	0.42-1.05
Watch	0.78	0.55-1.10
Give	1.25	0.88-1.77

# Discussion

- Using a massive cohort (n=663,038) and a multi-method approach to measuring fidelity, there is no measured association with hospital fidelity and AHT

## Potential explanations:

- High rates of exposure and fidelity statewide (lack of variation)
- Indirect measurement of 'exposure' (using fidelity as a marker for probability of exposure)
- Systematic bias (hospitals/areas with more cases of AHT may work harder at implementation)
- The intervention may not work
- Success of intervention may not depend on fidelity to model as measured

# Calls to Nurse Helpline

- After hours advice from nurse (1/1/2006-12/31/2010, annual calls range from 12,868-21,200)
- Service covering 68 pediatric practices statewide
- Queried database pre and post intervention for proportion of calls related to crying for 0-3 month-olds and 3-12 months olds. Coded as 'crying only' if no other symptoms were coded.
- Post intervention, crying calls declined by 20% among 0-3 month olds (rate ratio 0.80, CI 0.73-0.87;  $p < 0.001$ ). Among 3-12 month olds, declined by 12% (0.88, CI 0.78-0.99,  $p = 0.03$ ).

# Difference in Difference Model

- Interrupted time-series analysis comparing rates of AHT (using hospital discharge data) for NC and 5 comparator states before and after implementation.
- Controlled for mortgage foreclose rates  
unemployment rates

From: **Effectiveness of a Statewide Abusive Head Trauma Prevention Program in North Carolina**

JAMA Pediatr. 2015;169(12):1126-1131. doi:10.1001/jamapediatrics.2015.2690

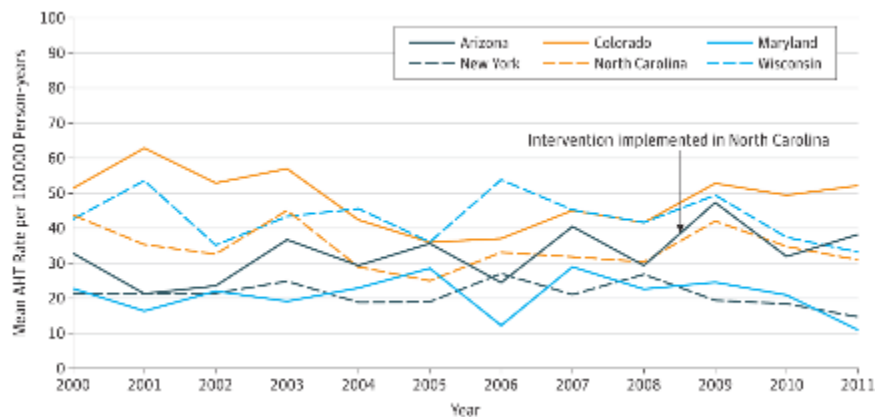


Figure Legend:

State-Level Abusive Head Trauma (AHT) Rates for Children Younger Than 1 Year in North Carolina and 5 Comparison States Based on hospital discharge data, January 1, 2000, to December 31, 2011.



# Results

- AHT rates in NC ranged from 25 to 45/100,000 from 2000-2011.
- Pre-intervention rate in NC 34.01/100,000
- Post-intervention rate in NC 36.04/100,000
- Comparison states 33.22/100,000 pre-intervention time period
- Comparison states 33.41/100,000 post intervention time period.
- Adjusting for mortgage foreclosure and unemployment reveals no significant difference ( $p=0.81$ )

# Conclusions

- Universal intervention implemented with high fidelity.
- Dose 2 and 3 extensive but less systematic and less comprehensive.
- Excellent parent recall.
- Some change in parent behavior (nurse advice line)
- No change in AHT demonstrated.