The So What Outcome Factor in Research and EBP Projects: A Necessity to Speed the Translation of Research into Practice



Bernadette Mazurek Melnyk, PhD, RN, CPNP/PMHNP, FAAN

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The Current State of Healthcare

"Our health care system is in critical condition. Each year, fewer Americans can afford it, fewer businesses can provide it, and fewer government programs can promise it for future generations- A cure is needed."

The Innovator's Prescription:

A Disruptive Solution for Healthcare

Clayton M. Christensen



The "So What" Factor in Intervention Research & EBP Projects

- "So what" is the prevalence of the problem and is it modifiable through an intervention?
- "So what" will be the end outcome of the study or project be once it is completed?
- "So what" difference will the study make in improving health, education or healthcare quality, costs and, most importantly, patient, family or community outcomes?



The "So What" Factor in Intervention Research & EBP Projects

- "So what" will others do with the study's or project's outcomes?
- "So what" actions will you take to translate your study's findings or project's outcomes to real world settings?
- "So what" is the chance that others will adopt and implement your intervention based on its feasibility, reproducibility and cost?



Background/Significance of Preterm Birth

- Preterm birth costs the United States at least \$26.2 billion every year, or \$51,600 for every infant born preterm. The costs break down as follows:
 - \$16.9 billion (65%) for medical care
 - \$1.9 billion (7%) for maternal delivery
 - \$611 million (2%) for early intervention services
 - \$1.1 billion (4%) for special education services
 - \$5.7 billion (22%) for lost household and labor market productivity

(Preterm Birth: Causes, Consequences, and Prevention, a report published by the Institute of Medicine (2006) and partially funded by the March of Dimes, *March of Dimes, 2007,* http://www.marchofdimes.com/prematurity/21198_10734.asp)



Background/Significance

- Approximately 500,000 premature babies are born in the United States every year (about 1 in 8 babies are born premature)
- The preterm birth rate has risen more than 20% since 1990
- Premature infants experience a host of adverse physical and mental health/behavioral outcomes that persist well into the school-age and adolescent years, including learning disorders and developmental disabilities

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Background/Significance

 Parents of premature infants also experience a host of negative outcomes, including increased anxiety, depression, anxiety, PTSD, parent conflict, dysfunctional parent-child interactions and the vulnerable child syndrome





Background/Significance

 Parental stress, depression, anxiety, and quality of parent-infant interactions have been found to adversely impact infants' cognitive, behavioral, and neurological development



Study Design

A randomized controlled trial at two study sites in the Northeast involving 260 LBW premature infants, 258 mothers and 154 fathers with follow-up through 3 years corrected age





Theoretical Framework

Self-Regulation Theory (Leventhal & Johnson)

Control Theory (Carver & Scheier)

The Emotional Contagion Hypothesis (VanderVeer, Jimmerson)



Effects of the COPE Program on the Process and Outcomes of Parental and Infant Development/Adjustment



The Sample of Infants

- Mean gestational age = 31.3 weeks (range = 26 to 35 weeks)
- Mean birth-weight = 1650 grams, with 102 infants weighing less than 1500 grams
- Males = 126 (48.5%)
- Females = 134 (51.5%)



The COPE NICU Program

- 7 part series of audio tapes, driven by selfregulation theory and control theory, and a workbook that provided parents with infant behavior and parent role information and parent skills building activities that help parents implement the COPE information
 - 2-4 days after admission to NICU
 - 2-4 days after the first intervention
 - 1-4 days prior to discharge
 - 1 week after discharge
 - 2, 9 and 18 months after discharge



The COPE NICU Program

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The COPE Program Teaches Parents about the Behaviors and Physical Characteristics of Preterms







COPE also Teaches Parents How Best to Interact with and Parent their Preterm Infants







Parental Beliefs for Mothers



CopeComparison



Parent Stress Related to the NICU for Mothers



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Quality of Interaction with Infant in the NICU (Blinded Observer Rating)

Maternal Depression Over Time

Cost Analysis

- The net direct health care cost savings per child through NICU discharge after deducting the cost of the COPE intervention was \$4,864
- Further subgroup analyses for LOS based on birthweight revealed that COPE infants <1500 grams had an even shorter NICU length of stay (n = 90, 8.3 days), which resulted in even greater savings

Results

Bayley MDI for High Parental Stress in the NICU

Results

FATHERS' PTSD FOR HIGH GRAVIDA

Other Key Outcomes

 COPE fathers made less ED visits at 6 months and less mental health visits at 2 years (4% compared to 14.8%) than attention control fathers

• COPE mothers missed fewer days of work at 2 years of age than attention-control mothers

 COPE fathers missed fewer days of work at 6 months compared to attention-control fathers

Results

- There was lower suicidal ideation for COPE mothers compared to control mothers with:
 - High parental stress
 - Low quality of mother-infant interaction
 - Greater length of NICU stay
 - Greater illness severity (high CRIB scores)

Longitudinal Effects of COPE Effects through 3 Years

Conclusions

 Routine administration of COPE in NICUs across the United States could not only improve infant and parent outcomes, but lead to substantial cost savings

• A decreased hospital cost of \$5,000 for 500,000 premature infants born every year in the U.S. would result in a 2.5 billion dollar cost-savings for the U.S. Healthcare System

From Evidence to Implementation

 Studies support that evidence-based practice can reduce patient morbidities, mortality and reduce costs

 It is estimated that there remains a large time gap between the generation of many research findings and their implementation into clinical practice to improve the quality of care and patient outcomes

Translating COPE into Clinical Practice: Lessons Learned

Funded by Phoenix Children's Hospital Competitive Grant Program

- The purposes of this disseminationimplementation study were to determine:
 - the impact of translating the evidence-based
 COPE program into clinical practice on
 nurses' EBP beliefs and implementation, and
 - the best strategy for disseminating COPE in the NICU so that all parents of preterms receive COPE

Subjects and Methods

- Subjects: 81 out of 180 nurses (45%) from a 55 bed NICU of a large children's hospital
- All participants completed the EBP Beliefs and EBP Implementation Scales (Melnyk & Fineout-Overholt) at baseline and six months after implementation of COPE in the NICU
- Nurses from two of the five pods in the NICU received an 8 hour workshop on EBP and the COPE program, and were then instructed to implement COPE

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Findings

• Very few parents received all phases of the COPE program in the first 12 weeks of the study

 A COPE Mentor was introduced after 12 weeks to assist the nurses with the implementation of COPE

Findings

 Nurses in the COPE pods had stronger beliefs about EBP and greater implementation of EBP than nurses in the non-COPE pods

 After the COPE Mentor was introduced, nearly all parents of preterm infants received all phases of the program

Barriers to Implementation

- Competing priorities because the physical care of the infants took higher priority than delivering the COPE program
- Time, due to the demands of caring for the infants
- Transfer of babies between the pods due to remodeling of the unit
- The nurses reported that the barriers were decreased with the introduction of the COPE mentor

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The ARCC Model

(Advancing Research & Clinical practice through close Collaboration)

The COPE Healthy Lifestyles TEEN Clinical Trial

- The aim of this clinical trial was to evaluate the efficacy of our COPE/Healthy Lifestyles TEEN (Thinking, Emotions, Exercise and Nutrition) Program on the healthy lifestyle behaviors, mental health and academic outcomes of 779 high school 14-16 year old adolescents
- Study outcomes included healthy lifestyle behaviors, depressive symptoms, anxiety, social skills, substance use, body mass index and academic performance
- Funded by NIH/NINR

Components of the 15-Session COPE Healthy Lifestyles TEEN Program

- 7 Sessions of cognitive-behavioral skills building
- Nutrition and physical activity education
- 20 minutes of physical activity in each session

Methods for the COPE Clinical Trial

- 11 Schools were randomly assigned to COPE or the Attention Control *Healthy Teens* Program
- Teachers attended a day of training on their intervention program and were supplied with all manualized materials, including power points, teen handbooks, and instructor manual
- Teachers integrated their intervention program into their health course curriculum once a week for 50 minute sessions over 15 weeks
- Observers rated the teachers on intervention fidelity four times during the course of the semester

Physical Activity Behavior Outcome

Teens who received the COPE curriculum had significantly greater steps per day than the teens who received the Healthy Teens curriculum

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* Statistically significant

BMI Immediately Post-Intervention

COPE participants had a lower average BMI than the Healthy Teens participants even though their BMI was higher at baseline

Depression Post-Intervention

Among teens with extremely elevated depression scores at baseline, those that received the COPE curriculum had on average, a lower depression score than those that received the Healthy Teens curriculum at the 15-Week follow-up

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Alcohol Use Post-Intervention

Alcohol use was significantly less in the COPE group than in the Healthy Teens group at the 15-week follow-up

*Data collected from Teen Questionnaires

Social/Academic Outcomes

The Social Skills Rating System showed that the COPE group had higher average scores on the Cooperation, Assertion, and Academic Competence subscales

* Teen Social Skills Rating System was completed by teacher at the end of the intervention (T1).

Percentage of overweight for the COPE and Healthy Teens groups across time COPE (COPE Healthy Lifestyles TEEN Program), Creating Opportunities for Personal Empowerment Healthy Lifestyles Thinking, Emotions, Exercise, Nutrition Program

12 Month Findings for Depression

	COPE			Healthy Teen			
Time Point	n	Estimated Mean ^a	Standard Error	n	Estimated Mean ^a	Standard Error	p- value
Baseline	12			12			
Post-Intervention	10	44.43	5.53	11	66.23	5.12	0.02
6-Month Follow-up	8	48.98	5.30	11	62.87	4.89	0.10
12-Month Follow-up	9	42.39	3.94	9	57.90	3.77	0.03
^a Adjusted for baseline differences							

Specific Teen Feedback

- Exercising when you are sad or angry helps you not get so stressed
- I learned how to control yourself when you're mad
- COPE helped me feel a little better about myself
- Exercise is fun and should be a part of everyday life
- I've actually started walking more and taking longer routes to increase my steps
- I look at food labels
- My motivation has drastically increased
- I learned how to set goals to be more active

Specific Parent Feedback

- She learned a lot about how to handle stressful situations
- The program has made my teenager more aware of the need for physical activity to safeguard her health
- It helped me take better care of myself
- It assisted in overall communication with my child
- It helps me to prevent diabetes and overweight
- It has helped me choose better foods for my family and motivate them to exercise regularly

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The Evidence from Implementation Science: Major Factors Influencing Adoption of EBPs

- Characteristics of the EBP (e.g., strength of the evidence, ease of administration, cost)
- Characteristics of the clinician (e.g., understanding, cognitive beliefs/confidence to implement)
- The environment and culture of the organization
- The process through which the change is implemented (e.g., building consensus, use of opinion leaders and EBP mentors)

We Must Make it Easy and Fun for Clinicians To Implement Best Practices

- Clinicians are overburdened with high patient loads and competing priorities
- Building EBPs into electronic records can help, but too many reminders may lead to clinicians beginning to ignore them

Conclusions

 We must accelerate the translation of research findings into clinical care in the form of evidencebased practice to improve healthcare quality and patient outcomes

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You Must Dream It Before You Can Do it!

Skeptics say "that will happen when pigs fly" Research & EBP Innovators say "Pigs can fly!"

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So What Now?

In the next 3-5 years, what will you do with the evidence that is generated to assure its translation into clinical practice to improve healthcare and patient outcomes?

There Is A Magic In Thinking Big!

The Dream, Passion and Persistence will get you through the "Character-Builders"

melnyk.15@osu.edu Slide Presentation Copyright, 2015

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