The Tiniest Drug Endangered Child: Intrauterine Drug Exposure & Neonatal Abstinence Syndrome

Carla Saunders, NNP-BC
Advance Practice Coordinator
Pediatrix Medical Group
East TN Children’s Hospital
October 23rd, 2013

Addiction is a disease of the brain, NOT a moral failure

- Abuse
  - Intentional, Recreational, Unintentional
  - Use of a substance that does not conform to social norms
  - Can lead to addiction

Tolerance – Dependence – Addiction

**Tolerance**
- Our body develops tolerance to a drug’s effect so that an increased amount of drug is required to produce effect.

**Dependence**
- If the supply of the drug is removed then the person will exhibit "withdrawal symptoms".

**Addiction**
- The continuing, compulsive nature of the drug use despite physical and/or psychological harm to the user and society

*BEHAVIORAL*

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**DOPAMINE**
- Catecholamine
- Chemical neurotransmitter
- Sends signals to nerve cells
- Produced in several areas of the brain
- Responsible for reward-driven learning
- Allows body to sense pleasure


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**The Dopamine Pathway**
- The brain contains a natural reward system (limbic system)
- This increases temporary levels of dopamine

**Natural Triggers**
- Food
- Exercise
- Sex
- Nurturing children

Why is this important?

Drugs activate the same system activated by natural rewards

BUT…drugs activate the system stronger and longer

Drugs “hijack” the brains dopamine system and the brain becomes dependent on the drug

Natural rewards no longer produce the desired dopamine levels which result in a feeling of pleasure


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EVOLUTION OF ADDICTION

After a while, use of a drug leads to an adaptation in the brain

Brain expects higher levels of dopamine

The deficit in dopamine causes an inability to feel pleasure, except through drug use


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Effects of Drugs on Dopamine Release

![Graph showing effects of drugs on dopamine release](image)
Drug-induced deaths exceed MVA deaths

Epidemiology

NIDA estimates $600 billion is spent annually on costs associated with substance abuse in U.S.
- American Diabetes Association estimates annual costs associated with diabetes is $174 billion in 2007.
- National Cancer Institute estimates $125 billion in annual costs for cancer care in 2010.
- Projected $20 billion gym

- 2009 National Survey on Drug Use and Health:
  - 4.5 percent of pregnant women aged 15 to 44 have used illicit drugs in the past month.
  - In 2008 there were 9,430 babies born in Knox County according to Knox County hospitals birth records: Estimated 424 babies born annually in Knox County whose mother used illicit drugs in the past month.

- 2009 Key Birth Stats from CDC report 4,131,019 births in U.S.
  - Approximately 186,000 babies born to mothers who used illicit drugs in past month

Heroin

Cocaine

1999 Veterans Health Admin. Initiative: "Pain as the 5th Vital Sign"
JCAHO institute pain standards in 2001

Pain the 5th Vital Sign

1980s: Dr. Russell Portenoy lead drive to expand use of opioids
Risk of addiction felt to be less than 1%

1886 paper 38 cases supported safety of opioids outside end of life care

American Pain Society campaign "Pain as the 5th Vital Sign"

1998 Federation of State Medical Boards removes regulations on amount of narcotics physicians can prescribe

2004 Federation makes under treatment of pain "punishable"

Joint commission: is no evidence that addiction is a significant issue when persons are given opioids for pain control

Dr. Thomas Freiden
Director of the Centers for Disease Control

“When I was in medical school…. I was told…if you give opiates to a patient who's in pain, they will not get addicted. Completely wrong…. A generation of us grew up being trained that these drugs aren't risky. In fact, they are risky"
Prescription Nation: Addressing America's Prescription Drug Epidemic

Report from the National Safety Council, October 14, 2013

States with the largest sales of opioid painkillers also have the highest mortality rates.

Narcotics and Contraceptive Use: TennCare Women, CY2011

<table>
<thead>
<tr>
<th>Demographics</th>
<th>TennCare Women</th>
<th>Women Prescribed Narcotics (+30 days supplied)</th>
<th>Women Prescribed Contraceptives and Narcotics</th>
<th>Women Prescribed Narcotics without Contraceptives</th>
<th>% of Women on Narcotics and Contraceptives</th>
<th>% of Women on Narcotics without Contraceptives</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Women</td>
<td>293,962</td>
<td>45,774</td>
<td>122.0</td>
<td>6,402</td>
<td>37,374</td>
<td>82%</td>
</tr>
<tr>
<td>15 - 20</td>
<td>88,668</td>
<td>3,450</td>
<td>38.9</td>
<td>1,663</td>
<td>1,787</td>
<td>52%</td>
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<tr>
<td>21 - 24</td>
<td>52,677</td>
<td>5,244</td>
<td>176.9</td>
<td>1,756</td>
<td>3,486</td>
<td>66%</td>
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<tr>
<td>25 - 29</td>
<td>53,583</td>
<td>9,883</td>
<td>164.4</td>
<td>2,368</td>
<td>7,515</td>
<td>76%</td>
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<tr>
<td>30 - 34</td>
<td>48,173</td>
<td>10,504</td>
<td>218.0</td>
<td>1,501</td>
<td>9,003</td>
<td>86%</td>
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<tr>
<td>35 - 39</td>
<td>37,194</td>
<td>9,398</td>
<td>252.7</td>
<td>746</td>
<td>8,652</td>
<td>92%</td>
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<tr>
<td>40 - 44</td>
<td>27,944</td>
<td>7,235</td>
<td>265.3</td>
<td>364</td>
<td>6,831</td>
<td>95%</td>
</tr>
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</table>

DATA SOURCE: Division of Health Care Finance and Administration, Bureau of TennCare.

Unintended Pregnancy Among All Women & Opioid Abusers

![Graph showing unintended pregnancy rates among general population and opioid-abusing women.


Prenatal Care is Vital

“Adequate prenatal care often defines the difference between routine and high-risk pregnancy and between good and bad pregnancy outcomes.

- Timely initiation of prenatal care remains a problem nationwide, and it is overrepresented among women with substance use disorders. In part, the threat of legal consequences for using during pregnancy and limited substance abuse treatment facilities (only 14 percent) that offer special programs for pregnant women (SAMHSA 2007) are key obstacles to care.”

Early Intervention

Window of opportunity

- Brief interventions can provide an opening to engage women in a process that may lead toward treatment and wellness.

Pregnancy creates a sense of urgency to

- Enter treatment
- Become abstinent
- Eliminate high-risk behaviors


Is MAT cost-effective?

For every $1 spent on addiction treatment programs

- $4 to $7 saved in reduced drug-related crime, criminal justice, and theft
  - Including health-care costs, up to $12 saved.

- Other considerations
  - Neonatal abstinence syndrome might be reduced
  - More productive citizens

Neonatal Abstinence Syndrome (NAS)

- Constellation of withdrawal symptoms
  - CNS: Inconsolability, high-pitched crying, skin excoriation, hyperactive reflexes, tremors, seizures
  - GI: Poor feeding, excessive sucking, feeding intolerance, loose or watery stools
  - Autonomic/metabolic: Sweating, nasal stuffiness, sneezing, fever, tachypnea, mottling

Incidence of Maternal Opiate Use and NAS

Maternal Opiate Use increased x 5  
NAS Incidence tripled

Patrick, S. W. et al. JAMA 2012;307:1934-1940
NAS Incidence in the U.S.

Patrick, S. W. et al. JAMA 2012;307:1934-1940

Current TennCare Costs

- Healthy Newborn: $4,237
- NAS Newborn: $66,973

PREVENTABLE

Tennessee DOH Media Release October 7, 2013

American Academy of Pediatrics (AAP) Guidelines

- "Reported rates of illicit drug use... underestimate true rates..."
- 55 to 94% of neonates exposed to opioids in utero will develop withdrawal signs.
- Each nursery that cares for infants should develop protocol for screening for maternal substance abuse
- Screening is best accomplished by using multiple methods
  - Maternal history
  - Maternal urine testing
  - Testing of newborn urine/meconium
  - May consider umbilical cord samples

Drug Testing

<table>
<thead>
<tr>
<th>Types of UDTs</th>
<th>Results</th>
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<tr>
<td><strong>In-Office</strong></td>
<td>Immunoassays</td>
</tr>
<tr>
<td><strong>GC/MS</strong></td>
<td>Gas chromatography-mass spectrometry</td>
</tr>
<tr>
<td><strong>LC-MS/MS</strong></td>
<td>Liquid chromatography tandem mass spectrometry</td>
</tr>
</tbody>
</table>

- Meconium
- Umbilical Cord

AAP Guidelines - Newborn Observation

**Risk Factors**
- No prenatal care
- Limited prenatal care
- History of substance use or abuse
- Any positive screen during pregnancy
- Positive UDS on admission

**Recommendation**
- Observe in the hospital for 4 to 7 days
- Early outpatient followup
- Reinforce caregiver education about late withdrawal signs

American Academy of Pediatrics (AAP) Guidelines

Pharmacologic interventions include:
- Oral morphine solution, or methadone as primary therapy
- Increasing evidence for clonidine as primary or adjunctive therapy
- Buprenorphine use as primary or adjunctive therapy is also increasing
- Treatment for polysubstance exposure may include opioid, phenobarbital, and clonidine in combination.
NAS TREATMENT OPTIONS

INPATIENT
No standardized evidence based "Best Practice"
Lengthy
Unique challenges for staff and institution,
Physical and emotional challenges
Multidisciplinary needs
Staff education on Science of Addiction
Interacting with the substance abusing parent
Must be ORGANIZED STANDARDIZED and MULTIDISCIPLINARY

OUTPATIENT
Compliance
Physicians and pharmacies
Custodial changes
Caregiver bias

DIVERSION
Requires: contracts, incentives for compliance,
accountability for non-compliance

ETCH Haslam Neonatal Intensive Care Unit

152 beds / Level III NICU – 60 beds
- About 30 % of our NICU admissions
  primarily for NAS treatment
- 135 admissions for 2011
- 283 admissions for 2012
- Highest daily census: 37 in September, 2012

<table>
<thead>
<tr>
<th>Year</th>
<th>1st Quarter (JAN-MAR)</th>
<th>2nd Quarter (APR-JUN)</th>
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<tr>
<td>2011</td>
<td>8</td>
<td>13</td>
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<td>2012</td>
<td>29</td>
<td>24</td>
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<tr>
<td>2013</td>
<td>28</td>
<td>26</td>
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</tbody>
</table>
Typical course of treatment

- 70% of NAS babies
  - Wean in 20 days
  - No adjunctive meds
  - LOS 24 days

- 30% of NAS babies
  - Wean in 60 days
  - Require adjunctive meds
    - Phenobarbital (27%)
    - Phenobarbital + Clonidine (7%)
  - LOS 68 days
    - (longest LOS = 155 days)
Why do expectant mothers use drugs?

- Prior injury / chronic pain
- Medical need for pain management
  - Appropriately managed
  - Inappropriately managed
- In a substance abuse treatment program (MAT)
- Confusion between symptoms of withdrawal and early pregnancy.
- Family/social environment

Why do MDs continue to prescribe?

- ACOG Guidelines and SAMSHA Guidelines recommend to continue MRT (methadone or buprenorphine)
  - “Lesser of two evils”
    - Risky drug-seeking behaviors
    - Goals of quelling cravings
    - Prevent mini-withdrawals
    - Ceiling effect of being in treatment
      - Methadone, suboxone, subutex
        - Reveal danger of I.V. suboxone

"Standard of care for pregnant women with opioid dependence: referral for opioid-assisted therapy"

Abrupt d/c of opioids can result in preterm labor, fetal distress, or fetal demise

During intrapartum/postpartum period, special considerations are needed... ensure appropriate pain management, prevent postpartum relapse, prevent risk of overdose, ensure adequate contraception.
**Intrauterine Drug Exposure**

The presence or absence of NAS does not indicate the severity of intrauterine drug exposure or abuse.

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**The Newborn with Intrauterine Drug Exposure**

- Low birth weight
- Small Head Circumference
- Abnormal EEG pattern / Seizures
- Signs of physical dependency – withdrawal
- Signs of effects may last for months
  - Hypertonic
  - Tremors
  - Periods of irritability

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**Opioid Intra-Uterine Drug Exposure**

**OPIATES or OPIOIDS**
- Morphine
- Heroin
- Codeine

**Semi-synthetic and synthetic opioids**
- Oxycodone
- Hydrocodone
- Methadone
- Buprenorphine
- Tramadol
Drug source may be legal or illegal (diverted)
Used as directed, misused, or abused...

The baby doesn’t know the difference
They will affect brain development
Effects dependent on stage of gestation of the fetus had drug exposure

Fetal Brain Development

Majority of development occurs in first 12 weeks

- 2wks: Brain is first organ to develop
- 4wks: Cerebral hemispheres appear
- 5-6wks: Cranial nerves identifiable
- 6-7wks: Brain wave activity begins
- 7-8wks: Brain represents 43% of embryo
- 8-9wk: Begin to experience light sense of touch
- 13wks: Most of body has sensation to touch
- 19wks: Daily cycles of biological rhythms
- 26-38wks: Brain increases in weight by 400-500%

Brain Development

Neuroimaging showed physiological brain changes in drug-exposed infants vs. non-exposed infants

Temporal/frontal lobe changes

Permanent, can not be "fixed"

Nurturing and environment can mitigate damages
LONG-TERM EFFECTS

- BRAIN DEVELOPMENT
- SIDS
- SLEEP
- NEURODEVELOPMENTAL DELAYS
- BEHAVIOR REGULATION
- SENSORY PROCESSING
- COGNITIVE/LEARNING DELAYS
- PSYCHOSOCIAL IMPLICATIONS

Intra-Uterine Exposure to Other Drugs

Marijuana
- Decreased problem-solving skills
- Decreased attention
- Impulsivity
- Decreased memory, memory processing, even at 18 Y

Methamphetamine
- Memory
- Impulse control
- Decreased goal setting
- Decreased flexibility
- Increase in ADHD
“The focus has turned to the long-term developmental outcome of children with prenatal drug exposure, especially as they reach adolescence.”

-Henrietta Bada, MD, MPH

The Hidden Epidemic: Living with Neonatal Abstinence Syndrome (NAS) and What the Future Holds
September 13, 2013

Substance Use Disorders

“Addiction is a developmental disorder of adolescence”

Dr. Nora Volkow,
Director, National Institute on Drug Abuse
Public Health Issues

- NICU beds taken by infants whose only need is withdrawal treatment
- Behavioral issues in childhood
- Schools – teacher retraining
- Potential long-term public health issue
  - Generational addiction problems
  - 2nd and 3rd generational behaviors sustained
  - Genetic predisposition?
  - Does intrauterine exposure activate gene in utero?
  - Does NAS treatment complicate addictive tendencies?

The Levels of Prevention

<table>
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<tr>
<th>PRIMARY Prevention</th>
<th>SECONDARY Prevention</th>
<th>TERTIARY Prevention</th>
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<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>An intervention implemented before there is evidence of a disease or injury</td>
<td>An intervention implemented after a disease has begun, but before it is symptomatic.</td>
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<tr>
<td><strong>Intent</strong></td>
<td>Reduce or eliminate causative risk factors (risk reduction)</td>
<td>Early identification (through screening) and treatment</td>
</tr>
<tr>
<td><strong>NAS Example</strong></td>
<td>Prevent addiction from occurring</td>
<td>Prevent pregnancy</td>
</tr>
<tr>
<td></td>
<td>Prevent pregnancy</td>
<td>Screen pregnant women for substance use during prenatal visits and refer for treatment</td>
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Adapted from: Centers for Disease Control and Prevention. A Framework for Assessing the Effectiveness of Disease and Injury Prevention. MMWR. 1992; 41(RR-3); 001. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/00016403.htm

TIPQC
Tennessee Initiative for Perinatal Quality Care

State wide recognition of NAS as a growing problem Spring 2011

Elected as statewide quality improvement initiative

Toolkit Development:
- Menu of Potentially Better Practices for the care of the NAS infant
- RedCap Data collection
- Grant for participation
Tennessee Department of Health

2012 “Prescription Safety Act” required prescribers to register with Controlled Substances Monitoring Database (CSMD)

NAS Subcabinet Working Group

Opioid Prescribing Guidelines Task Force

NAS Research Steering Committee

TN DOH Primary Prevention Strategies

Letter to FDA encouraging black box warning
Provider education
   Letter to providers to increase awareness
   Possibly add to “responsible prescribing”
   CME

TennCare limitations on opioid availability
   Requirement for counseling as part of prior authorization
   Limitations on available quantity

Request for Black Box Warning
TennCare Prior Authorization Form

Form available at: [https://tnm.providerportal.sxc.com/rxclaim/TNM/TC%20PA%20Request%20Form%20(Long%20Acting%20Narcotics).pdf](https://tnm.providerportal.sxc.com/rxclaim/TNM/TC%20PA%20Request%20Form%20(Long%20Acting%20Narcotics).pdf)

National Safety Council. Prescription Nation Addressing America's Prescription Drug Epidemic


NAS—Reportable Disease

- Health Commissioner has authority to add diseases to Reportable Disease list
  - **Reportable disease**—Any disease which is communicable, contagious, subject to isolation or quarantine, or epidemic...
  - **Event**—An occurrence of public health significance and required by the Commissioner to be reported in the List.
- Add NAS to state's Reportable Disease list
  - Effective January 1, 2013

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### Key Points

The impact of NAS does not end in the NICU.

Long-term impact to both the healthcare system and society is significant.

Prevention of unintended pregnancy is crucial.

Prenatal care with supervised replacement therapy is critical.

We must do all we can to promote prenatal care and substance abuse treatment/counseling in this high-risk population.

Incentives to seek help may allow more opportunities for the woman to receive successful treatment with lifelong benefits.

RX Substance abuse prevention and complete rehabilitation

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**Preventable**
Dr. Russell Portenoy, a New York City pain specialist decades ago was instrumental in the drive to expand use of opioid analgesics to treat chronic pain. Dr. Portenoy and others claimed that the risk of addiction to opioids use to treat chronic pain was less than 1%, this figure was based on virtually no scientific evidence.

In a frequently cited 1986 paper—based on just 38 cases—Portenoy and Foley concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse" = broader prescribing of the drugs for outside of use for terminal patient

That policy was drawn up with the help of several people with links to opioid makers, including David Haddox, a senior Purdue Pharma [manufacturer of OxyContin] executive then and now. The federation said it received nearly $2 million from opioid makers since 1997...

In 1998, the Federation of State Medical Boards released a recommended policy reassuring doctors that they wouldn't face regulatory action for prescribing even large amounts of narcotics, as long as it was in the course of medical treatment. In 2004 the group called on state medical boards to make under treatment of pain punishable for the first time.

The American Pain Society, of which he was president, campaigned to make pain what it called the "fifth vital sign" that doctors should monitor, alongside blood pressure, temperature, heartbeat and breathing.

A federation-published book outlining the opioid policy was funded by opioid makers including Purdue Pharma, Endo Health Solutions Inc. and others, with proceeds totaling $280,000 going to the federation.

The Joint Commission published a guide sponsored by Purdue Pharma. "Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death," the guide said. "This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control."
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The Joint Commission published a guide sponsored by Purdue Pharma. “Some clinicians have inaccurate and exaggerated concerns” about addiction, tolerance and risk of death, the guide said. “This attitude prevails despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control.”

Building consensus now is that there is little if any evidence that opioids provide safe and effective treatment for chronic non-cancer pain, and that paradoxical, under-appreciated conditions such as opioid-induced hyperalgesia and narcotic bowel syndrome can complicate long-term treatment.

See more at: http://www.thepoisonreview.com/2012/12/16/the-money-and-influence-behind-pain-as-a-fifth-vital-sign/#hash Shuttle.qbfK63s7.dpuf
Unintended Pregnancy Among All Women & Opioid Abusers

In TN, women with unintended pregnancy:
- More likely to have no preconception counseling (77.7% vs. 55.4%)
- More likely to have short interpregnancy interval (45.0% vs. 15.6%)
- More likely to have late or no prenatal care (28.1% vs. 10.9%)
- More likely to not take folic acid daily (82.6% vs. 64.7%)

National sample of opioid-abusing women
- Women with unintended pregnancy 60% more likely to have used cocaine within past 30 days compared to women with intended pregnancy


Potential Benefit of a Perinatal Substance Abuse Program (Early Start)

Purpose: cost-benefit analysis of an integrated prenatal intervention program for stopping substance abuse in pregnancy.
Retrospective study of 49,261 women
Kaiser Permanente Northern California
Completed questionnaires at OB clinics and had urine screening
Costs included: maternal health care (prenatal through 1 year postpartum), neonatal birth hospitalization care, and pediatric health care through 1 year
- Adjusted to 2009 dollars and mean costs adjusted for age, race, education, income, marital status, and amount of prenatal care.


Early Start

Mission:
- "to provide women with access to services and support to have an alcohol, tobacco, and drug-free pregnancy, allowing the delivery of a healthy baby."
Goal: Complete abstinence

Interventions
- Universal screening of all pregnant women
- Co-location of a licensed mental health professional in the Department of Obstetrics and Gynecology
- Linking Early Start appointments with routine prenatal care appointments
- Educating all women and clinicians

Potential Benefit of a Perinatal Substance Abuse Program (Early Start)

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<thead>
<tr>
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<th>SAF</th>
<th>SA</th>
<th>S</th>
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<tbody>
<tr>
<td>Maternal</td>
<td>$9,430</td>
<td>$9,230</td>
<td>$10,669</td>
<td>$8,382</td>
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<tr>
<td>Infant</td>
<td>$11,214</td>
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<td>$16,943</td>
<td>$10,416</td>
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<tr>
<td>Total</td>
<td>$20,644</td>
<td>$20,534</td>
<td>$27,812</td>
<td>$18,698</td>
</tr>
</tbody>
</table>

- Compared SAF and SA to S
- Net cost-benefit averaged $5,946,741 per year


DOH NAS Efforts in TN

- Spring 2012
  - “Prescription Safety Act” required prescribers to register with Controlled Substances Monitoring Database (CSMD)
  - Growing awareness of increasing NAS incidence among neonatal providers
  - Initial discussions between public health (TN Department of Health) and Medicaid (TennCare)
NAS Subcabinet Working Group

- Convened in late Spring 2012
- Committed to meeting every 3-4 weeks
- Cabinet-level representation from Departments:
  - Public Health (TDH)
  - Children’s Services (DCS)
  - Human Services (DHS)
  - Mental Health and Substance Abuse Services (DMHSAS)
  - Medicaid (TennCare)
  - Children’s Cabinet

NAS Subcabinet Working Group

- Working principles:
  - Multi-pronged approach
  - Best strategy is primary prevention but clearly must address secondary and tertiary prevention
  - Each department progresses independently, keep group informed of efforts
  - Supportive rather than punitive approach

Opiod Prescribing Guidelines Task Force

- Pain and addiction treatment specialists
- Primary care physicians
- Pharmacists
- Perinatal Specialists
- Midwifery
- Neonatology
- Legal
- State medicaid
- Charged by commissioner to "Be bold" in approach
- Implementation Goal: Jan 1st, 2014
NAS Research Steering Committee

Board identified Spring 2013
Monthly conference calls
Invitations sent to experts from across the state for September 25th 2013
Goal: Identify 3-5 potentially answerable research questions surrounding NAS
Identify groups to begin to look at developing research framework for each question

Innovation—any new idea—by definition will not be accepted at first. It takes repeated attempts, endless demonstrations, monotonous rehearsals before innovation can be accepted and internalized by an organization. This requires courageous patience.” — Warren Bennis