Project Lazarus and the Chronic Pain Initiative: A Retrospective Review of a Successful Community-Based Overdose Prevention Initiative

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Outline/Objectives

- Discuss the impetus for an overdose prevention program in Wilkes County, NC
- Describe the content and process of Project Lazarus interventions
- Review outcomes data from 2009-2012
- Describe the NC statewide implementation of selected interventions from Project Lazarus (“CCNC Chronic Pain Initiative”)
- Review challenges and areas for future modification and growth
Prescription Medication Abuse: An Epidemic with Many Potential Causes

- Some inappropriate prescribing of controlled medications and much prescribing done without adequate screening or monitoring
- Dramatically increased rates of prescribing opioid analgesics
  - Expansion into chronic non-malignant pain
  - Past criticism of prescribers as “opioid-phobic”
  - Regulatory changes (e.g. Pain as the “5th vital sign”)
  - Aggressive marketing by pharmaceuticals
- Public expectations regarding treatment
  - Preference for “pill to get rid of pain” vs pain management
  - Perception that pain treatment=opioid treatment
  - Preference for quick fix rather than behavioral or situational change
  - Experience with complete resolution of acute pain syndromes
1990’s Regulatory and Ethical Climate

- JCAHO Standards for Pain Management
  - RI.1.2.8: “Patients have the right to appropriate assessment and management of pain.

- FSMB Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, April 1998 (updated 2004)
  - Endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities
  - “There is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated….The under treatment of pain is recognized as a serious public health problem that results in a decrease in patients’ functional status and quality of life”
  - “Appropriate pain management is the treating physician’s responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations.

- Renewed adherence to old definition of pain
  - “Pain is what the person says it is and exists whenever he or she says it does” [Margo McCaffrey, 1968].
US Therapeutic Opioid Use

<table>
<thead>
<tr>
<th>Year</th>
<th>Oxycodone</th>
<th>Hydrocodone</th>
<th>Morphine</th>
<th>Methadone</th>
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<tr>
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<tr>
<td>2006</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tr>
</tbody>
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Emergency department mentions and admissions to addiction treatment related to prescription opioids

Source: CDC, National Vital Statistics System, 2006
In 16 states, drug deaths overtake traffic fatalities - USA Today (Sept. 30th 09)
Fatal Unintentional Overdose Mortality Rates: NC (yellow) and US (blue), 1999-2008


Prepared by C. Sanford, 8/2009
In 2009, the average statewide rate for deaths due to unintentional poisonings was 11.0/100,000 persons and the statewide rate for dispensed prescriptions of controlled substances was 185,234.1/100,000 persons (Pearson's correlation coefficient was 0.64 [p was less than 0.0001]).

\(^1\)All rates are per 100,000 persons.

\(^1\)Source: North Carolina Division of Mental Health, Developmental Disabilities and Substance Abuse Services, Controlled Substances Reporting System

\(^1\)Source: North Carolina Division of Public Health, North Carolina State Center for Health Statistics, Vital Statistics

\(^1\)Analysis: North Carolina Division of Public Health, Injury Epidemiology and Surveillance Unit
Problem Acute in Wilkes County

Unintentional and undetermined intent poisoning mortality rates
Wilkes County, NC 2003-2009

Source: NC SCHS, August 2009
Wilkes County, NC

- Approximately 700 square miles in foothills of Appalachians
- Population 66,500
- Socioeconomically depressed: high unemployment, limited educational opportunities, poverty
- Primary industries: logging, textiles, farming
- High chronic pain burden due to physically demanding jobs
Wilkes County Overdoses
Diverse Problem, Broad-based solution

- Some medical use, some nonmedical use
  - Most had received Rx in months prior to OD
  - Per case reviews, mix of pseudoaddiction, abuse/addiction
- Fentanyl, hydrocodone, methadone (Rx for pain, not from methadone clinics), oxycodone, etc.
- Heroin rarely suspected
- Some combined with other CNS depressants
- Average age late 30’s
- County residents
- Frequent medical comorbidity
Project Lazarus, Overview

- Formalized in 2008
- Goal: Reduce overdose deaths (primary)
- “Reduce supply, reduce demand, mitigate harm”

**Funding**

- Purdue Pharma
- Drug Policy Alliance
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- National Association of Drug Diversion Investigators (NADDI)
- Personnel and materials through NC Harm Reduction Coalition and Northwest Community Care Network
The Project Lazarus model can be conceptualized as a wheel, with three core components (The Hub) that must always be present, and seven components (The Wheel) that can be initiated based on the specific needs of a community.
Project Lazarus, Interventions

Coalition building

- Project Lazarus staff “learning on the fly”
  - Grass-roots advocacy
  - Held twice per month meetings for the community
- Substance Abuse Task Force, Wilkes Healthy Carolinians Council
- NC Injury and Violence Prevention Unit
- Wilkes County Health Department
- Northwest Community Care Network
  - Regional network for Medicaid managed care with 70 practices serving 58,000 patients in 6 counties
- Sheriff’s department
  - Lazarus staff took sheriff to National Association of Drug Diversion Investigators (NADDI) conference
Project Lazarus, Interventions

Prescriber education and behavior

- CME Sessions on pain management at hospital
- Physician’s toolkit “Managing Chronic Pain”
  - Universal Precautions, Opioid Treatment Agreements (OTA), 4 A’s of pain medicine, Risk Stratification, Sample progress note, etc.
- “Academic detailing”: one-on-one prescriber education to >90% of prescribers
- Strongly encouraged use of OTA and insistence on single pharmacy
  - Flagged at other pharmacies (for Medicaid Rx)
  - Local hospital ED provided with copies of patients’ OTA
- Promotion of NC CSRS (2007); supplied notary to CME programs
NCCN placed care manager in ED for Medicaid and unfunded patients
- Develop better continuum of care for high utilizers
- Access pain/addiction/primary care treatment

- Vetted local pain clinics (out of county), facilitation of referrals

- Conducted chronic pain support groups (Lazarus staff)
Project Lazarus, Interventions

*Diversion control (supply reduction)*

- Local Hospital Emergency Department administration at the table
  - Enacted requirement to check NC CSRS prior to prescribing opioids
  - Reduced number of pills per prescription of opioids
  - Led to increase in ED visits in neighboring counties
- Police/sheriff (and DEA/SBI) sponsored “take-back” events and set up fixed disposal sites at police stations
- Drug diversion specialist law enforcement officer hired and trained (Funded by grant from NADDI)
- Assisted in licensing actions by NCMB; one provider sanctioned
  - Preexisting relationship with NCMB surrounding naloxone kits
Project Lazarus, Interventions

Addiction treatment (demand reduction)

- Worked with drug detox program, created educational materials
- Advocated to local mental health center to expand addiction treatment services including crisis counseling and walk-in clinics
- Facilitated buprenorphine and methadone availability
  - CME programs, lunch and learns, encouraged providers to become buprenorphine certified
  - Coaxed Mountain Health Solutions to open local clinic and assisted with Certificate of Need
  - Community education to dispel prejudice
Project Lazarus, Interventions

**Community education**

- Invited various community groups to coalition meetings (twice a month)
- School-based education and pledge cards
- Presentations at colleges, churches, civic organizations, health fairs, etc.
- Enhanced participation in Red Ribbon Campaign
  - Comprehensive educational program from National Family Partnership to promote awareness
- Billboard, radio, church bulletin, and newspaper ads warning against sharing and disposal
- Warning sticker attached to dispensed opioids: do not share, where to dispose, how to store
Project Lazarus, Interventions

**Harm reduction**

- Naloxone program: free kits (funded by Purdue Pharma) provided to physician offices, hospital, detox center, EMT and other first responders
  - Naloxone vials, atomizer for intranasal use, supplies for 2 doses
  - Instructional DVD for patients and loved ones
    - Patient responsibilities
      - Safe storage and disposal of opioids, need for honesty with physicians, pain contract
    - Signs and symptoms of opioid OD
    - Call 911, rescue breathing
    - How to use naloxone
    - Resources for substance abuse treatment
  - Each primary care office provided with portable DVD player
  - Target subpopulations identified
OPIOID OVERDOSE PREVENTION
NALOXONE RESCUE KIT
Store in Accessible Location at Room Temperature

P.O. Box 261 Moravian Falls, NC 28654 | (336) 667-8100
www.projectlazarus.org | info@projectlazarus.org
Project Lazarus Outcomes

1. Lower Risk in the Community

![Graph showing mortality rate reduction](image)

Start of Project Lazarus and Chronic Pain Initiative

69% ↓

2. Similar Benefit to Patients

![Graph showing percentage of patients receiving opioids](image)

Wilkes County vs. North Carolina vs. United States

3. Improved Risk : Benefit

![Graph showing hospital ED visits](image)

15% ↓

Number per Year

2008 2009 2010

![Graph showing prescriptions among OD deaths](image)

Percent (%)
Additional Outcomes (per discussion with Lazarus staff)

- Overdose deaths exclusively from abuse/addiction; no longer include pain patients
- ? No resurgence of heroin; too rare to detect in Wilkes County, but observed trend nationally
- Increase in methamphetamine-related arrests (highest in NC)
  - Law enforcement attributes this to reduced community tolerance for drug abuse and more referrals to police
- More than 70% of Wilkes County prescribers registered with NC CSRS compared to 26% statewide
- We believe the average dose (MED) of prescriptions was reduced
Overdose Risk Related to Dose and Number of Prescribers

- Low dose is defined as <100 morphine equivalent dose per day.
- Most patients (80%) are on low dose, prescribed by one doctor.
- 80% of overdoses are patients on high dose: half one doctor, half multiple doctors.
“Project Lazarus is an exceptional organization—not only because it saves lives in Wilkes County, but also because it sets a pioneering example in community-based public health for the rest of the country.”

White House Drug Control Strategy 2013 Congress
Chronic Pain Initiative and CCNC (Community Care of North Carolina)

- Background
  - Lazarus participants included administrators and care managers from Northwest Community Care Network (NCCN) which was a regional CCNC Network
    - NCCN provided funds and staff for Lazarus
  - CCNC had already been developing their own program to address opioid-related morbidity including chronic pain care managers
  - CCNC had experience with similar initiatives for other disease states, such as diabetes
  - CCNC administration was pleased with Lazarus and wanted to implement the model statewide
Localized “medical home” networks with emphasis on primary care

- 1,620 participating primary care practices
- 1.40 million Medicaid and 140,000 HealthChoice enrollees
  - 22,560 uninsured in HealthNet programs
  - 25,000 privately insured in pilot programs
Chronic Pain Initiative and CCNC (Community Care of North Carolina)

- **Goal**
  - Use the CCNC network with its team based approach to care to facilitate the statewide implementation of the community-based Project Lazarus model.

- **Strategies:**
  - Implement community coalition building process within selected counties and their associated CCNC networks.
  - Implement a clinical skills training component to improve the knowledge and skills of CCNC and other community clinicians.
    - Didactic seminars (CME and non-CME)
    - Case consultations
Chronic Pain Initiative: Funding

- CCNC submitted grant to Kate B. Reynolds (KBR) Health Care Trust for community coalition building and provider education statewide.
- KBR agreed to fund interventions in high need impoverished (“Tier 1”) counties ($1.3 million).
- NC Office of Rural Health matched the contribution for interventions in other counties (total support $2.6 million).
- Funds were short for the training seminars; Pfizer arranged to pay for half of them (20 seminars).
  - Brief chronic pain disease state talk incorporated at the beginning.
  - nonCME.
Coalition Building

- Similar to Lazarus process, ("it takes a village")
- Invite stakeholders to meeting
  - Public health
  - Law enforcement
  - School board/superintendent
  - Church leaders
- Show the local data regarding OD deaths
- Provide funding for grass roots campaigns ($6-10k)
- Frequent coalition meetings
Clinical Training Components

- **Clinical Seminars** (40 over 2 years, 3.5 hr. each)
  - Led by pain doctors, psychiatrist, addictionologists
  - Local pain doctors to serve as adjunct faculty
    - Particularly helpful for community resources
  - Core didactic content (interactive) plus case
- **Recurring clinical case conferences and mentoring**
  - Facilitated by local experts and/or state-level mentors for site-specific application of clinical expertise.
  - Variable level of activity and involvement across the state
Seminar Content

- Role and limitations of opioids in the treatment of chronic pain including noncancer pain (second-line treatment)
  - Importance of NSAIDS/acetaminophen (nociceptive) and “antidepressants” and anticonvulsants (neuropathic and hypersensitivity)
- Importance of nonpharmacologic treatments (multidisciplinary)
- Risk stratification prior to Rx opioids and how it affects treatment plan
- Informed consent and Opioid Treatment Agreements
- Following the 4 A’s of pain medicine
- Classifying aberrant behaviors and intervening appropriately
  - Including stopping opioids or substitution with buprenorphine or methadone
- Use of the NC Controlled Substance Reporting System
- The role of naloxone rescue in reversing opioid overdose
Pushing Back the Pendulum?

Avoidance
Will not prescribe opioids:
• Fear of regulatory action
• Antiquated views of addiction
• Exaggerated perception of risk

Balance
Rational pharmacology: application of basic principles of medicine:
• Therapy tailored to risk stratification
• Tx adapted based on monitoring and outcome

Widespread Misuse
Prescribing without attention to dangers:
• Inadequate monitoring
• Excessive dosing
• Failure to respond to abuse

(Adapted from Passik, S.)
Risk Stratification Prior to Prescribing Opioids for Chronic Pain  
(A standard of care)

<table>
<thead>
<tr>
<th></th>
<th>Low Risk</th>
<th>Medium Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Etiology of Pain</strong></td>
<td>Clear/Identified</td>
<td></td>
<td>Vague/Non-specific</td>
</tr>
<tr>
<td><strong>Substance Abuse</strong></td>
<td>Negative family or personal hx.</td>
<td>Past history but stable recovery</td>
<td>Active abuse or addiction</td>
</tr>
<tr>
<td><strong>Psychiatric History</strong></td>
<td>None</td>
<td>Few/stable</td>
<td>Multiple/unstable</td>
</tr>
<tr>
<td><strong>Environment</strong></td>
<td>Stable/Supportive Resources</td>
<td></td>
<td>Unstable/ Few resources</td>
</tr>
<tr>
<td><strong>Activity Engagement</strong></td>
<td>Employed/Active/ Engaged in tx.</td>
<td></td>
<td>Unemployed/ Inactive/Med only</td>
</tr>
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</table>
Another Approach to Risk Stratification  
*Stay in Your Comfort Zone*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Low Risk</th>
<th>Moderate Risk</th>
<th>High Risk</th>
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<tbody>
<tr>
<td>Substance abuse</td>
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<td>Past</td>
<td>Current</td>
</tr>
<tr>
<td>Smoking (nicotine)</td>
<td>Never</td>
<td>Past</td>
<td>Current</td>
</tr>
<tr>
<td>Family history of addiction</td>
<td>None</td>
<td>Significant</td>
<td>Significant</td>
</tr>
<tr>
<td>Psychosocial factors</td>
<td>No major diagnoses; minor diagnoses treated or stable</td>
<td>Past major diagnoses; current issues with minor diagnoses</td>
<td>Current major diagnoses untreated or unstable</td>
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<tr>
<td>Age</td>
<td>Older</td>
<td>N/A</td>
<td>Younger</td>
</tr>
<tr>
<td>History of sexual abuse</td>
<td>No</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Controlled prescriptions lost or stolen</td>
<td>No</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Unauthorized substances in urine drug screens</td>
<td>Consistently negative</td>
<td>Initially positive</td>
<td>Consistently positive</td>
</tr>
</tbody>
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**Recommendations based on risk stratification**

| Healthcare setting | Primary care | Primary care with specialist support | Specialty pain management |

CPI Tool Kit: Chronic Pain Management Progress Note

Chronic Pain Management Progress Note

Patient Name: __________________________
DOB: __________________________

Date of Visit: __________________________
Chart Number: __________________________

INTERIM HISTORY
Employment: __________________________

Social Support: __________________________

Mental Health: __________________________

Physical Activity: __________________________

Social Activity: __________________________

ASSESSMENT/PLAN

☐ FAQ performed
☐ Screened for depression
☐ Care Plan reviewed/updated
☐ Urine drug screen performed

Result:

☐ Continue regimen
☐ Changes made:

______________________________________

______________________________________

Chronic Pain Initiative Tool Kit: Pain Management Agreement

Pain Management Agreement

I understand that Dr. ___________________ is prescribing opioid medication to help me manage chronic pain that has not responded to other treatments. The goal of this medication is to lead to partial relief from pain, so that my physical, emotional, and social function will improve. If my activity level or general function gets worse, the opioid may be stopped or changed to something else. The risks, side effects and benefits of opioid treatment have been explained to me and I agree to the following instructions. Failure to follow these instructions may result in stopping the medication.

1. I will participate in any other treatments recommended by my provider. I will be ready to decrease or stop the opioid medication when other effective treatments become available.

2. I will take my medications exactly as prescribed and will not change the medication schedule or dosage without advance approval from my provider. I will provide my medication for pill counts at the provider’s request. I will not request early refills.

3. I will keep regular appointments with my provider.

4. All opioid and other controlled drugs for pain must be prescribed only by Dr. ___________________.

5. I will inform my provider within a week of discharge if I am hospitalized for any reason, or if I have another condition that requires the prescription of a controlled drug (like narcotics, tranquilizers, barbiturates, or stimulants).

6. I will choose one pharmacy where all of my prescriptions will be filled.

   Pharmacy Name: ____________________________
   Phone Number: ____________________________
   Fax Number: ______________________________
   Address: _________________________________

7. I understand that lost or stolen prescriptions will not be replaced, so I will keep my prescription and medication in a safe place. I will not under any circumstances sell, lend, or give my medication to others.

8. I agree to avoid all illegal and recreational drugs (including alcohol) and will provide urine or blood specimens at the doctor’s request to monitor my compliance.

9. I agree to follow my doctor’s recommendations regarding the operation of motor vehicles or heavy machinery while taking this medication.

10. Refills will be made only during regular office hours, which are ____________. Refills will not be made at night, on weekends or during holidays. I am responsible for keeping track of my remaining medication, so that I can call for refills in advance. This way, I will not run out of medication.

Patient Name (print): ________________________
Patient Signature: _________________________  Date: ______________
Provider Signature: ________________________  Date: ______________
Witness (optional): _________________________  Date: ______________

Source: Adapted from ICSI Assessment and Management of Chronic Pain, Second Edition, March 2007

CPI Toolkits may be accessed online at: https://www.communitycarenc.org/po
pulation-management/chronic-pain-project/
Aberrant Medication Taking Behaviors

Differential Diagnosis

- **Misuse**
  - Confusion, poor understanding or regimen or rules

- **Pseudoaddiction**¹
  - Behaviors that are similar to addiction stemming from desperate attempts to relieve pain
    - Opioid-induced hyperalgesia³
    - Opioid analgesic tolerance and escalating use³

- **Abuse/Addiction**

- **Chemical coping**
  - Self-medication of stress and psychiatric and physical symptoms other than pain

- **Diversion**
  - Opportunistic vs. professional

¹ Weissman DE, Haddox JD. 1989; ² Evers GC. 1997; ³ Chang C et al 2007
Local Pain Experts and Mentorship

- Local practitioners are identified and “vetted” through discussion with Core Faculty
- They are invited to participate in didactic trainings
- They are asked to be available for case discussions and meetings with local CCNC providers, including “lunch and learns”
Lessons Learned

- Successes
- Challenges and Opportunities
- Modifications
Preliminary Successes for Project Lazarus/CPI: Legislative Initiatives

- Influential in passage of Good Samaritan law and 911 law
  - Supports distribution and use of naloxone rescue
  - Supports physician prescribing
  - Protects 911 callers from drug-related arrest

- Disseminated/clarified Statute (NC122c) related to sharing clinical information
  - “Can share information without specific release for the purposes of case management.”

- Supports the formation of CCNC Medicaid Provider Portal
  - Provider access to Opioid Treatment Agreements, claim data including pharmacy data
  - Utilized by ER staff and Care Managers
Preliminary Successes for Project Lazarus: CCNC

- **Care Managers (CM)**
  - Approximately 50 chronic pain CM
  - Involved by referral from PCP or from “high utilizer” list
  - Some embedded in clinics
  - Available for home visits, clinic visits, telephone interviews (similar to ACTT)
  - Perform mental health screens, refer to resources

- **ED policy shifts**
  - improved communication (Care Managers, Patient Portal)
  - Reduced Rx and numbers of pills prescribed
    - Don’t want to be the “low hanging fruit”

- **Engagement of Law Enforcement**
  - Pill take-back days
  - More drop boxes
Preliminary Successes for Project Lazarus and CPI

- Prescription Monitoring Program (NC CSRS)
  - Clarified that prescriber can contact another prescriber
  - Championed allowance to delegate authority/access
  - Simplified registration
  - Decreased reporting time from 7 to 3 days

- Naloxone reversal program
  - 4458 kits given out (including NC Harm Reduction Coalition) to patients, family members, first responders
  - 163 reported “reversals”

- Clinical seminar trainings
  - 26 programs statewide, 889 prescribers attended thus far
Specific content additions:

- Slides added to educate providers on prescribing naloxone rescue kits and the Good Samaritan Law
- Clinical information added about pregnancy and opioid dependence
- Content adapted as FSMB and NC Medical Board has revised its policies on prescription of controlled substances for chronic pain
- Discussions are ongoing regarding:
  - More detail on using prescription monitoring program (NC CSRS particularly but also access to SC, TN, and VA programs)
  - Specific recommendations for dentists
  - Specific recommendations for pharmacists
Challenges and Opportunities

- **Difficulty developing community coalitions**
  - Variability in local staff availability, turnover, and interest
  - Variability between CCNC networks (culture, infrastructure, community relationships, resources)
  - Modification: More direct communication with CPI coordinators to engage and problem-solve specific dynamics.
  - Overextension of central project staff
    - Modification: Additional staff hired, restructuring to allow for clearer responsibilities

- **Perceived and actual lack of community resources (pain, mental health, addiction)**
  - Recruit CCNC network providers for buprenorphine certification (goal of NC Governor’s Institute on Substance Abuse)
  - Enhance relationship with Pain Society of the Carolinas to identify providers and share areas of need throughout NC
  - Mobilize/incentivize local Pain Experts
Opportunities & Next Steps

- Increased attention to developing and possibly standardizing case conferences and mentoring
  - Case consultations with Local Experts from trainings
  - Phone consultations with Core Faculty members
  - Team conference calls discussing complex cases with pain expert
  - Pain specialist participation in on-site team treatment meetings
- Identify subpopulations in need (e.g. sickle cell, pregnancy)
- Increase participation in Clinical Seminars (and leverage “herd effect”)
  - As of summer 2014, CPI training is available online
  - Work with third party payers and medical malpractice providers within NC to incentivize participation in training.
- Continue with year 2 of CCNC network based trainings and mentoring per KBR/ORH grant
- Devise methods for determining which Lazarus/CPI interventions are most helpful
References and Resources


Acknowledgements

- Fred Brason
- Mike Lancaster
- Steve Kearney
- Jim Finch
- Jessica Eaddy
- Nidhi Sachdevi
The End